

NICE

**A CONTEMPORARY HISTORY OF THE NATIONAL
INSTITUTE FOR HEALTH AND CARE EXCELLENCE**

Paul Atkinson and Sally Sheard



“This book is a thoroughly researched history of NICE which tells its story in the words of many of those who were in the room where it happened. It is an indispensable account of an institutional innovation which largely achieved its objectives. The book will be of interest to readers who wish to understand the economics and politics of priority setting in health care in the real world.”

—**Professor Sir Chris Ham**

“Any organisation that attracts admiration, criticism, world-wide interest and controversy deserves an authoritative historical record. Whilst British health-care organisations all too often get abolished or reformed in their early years, this remarkable and fascinating book explores NICE’s evolution and survival, and honestly explores both its successes and the many challenges it has faced.”

—**Sir David Haslam**, *Chair of NICE, 2013–2019, Dorset, UK*

“Atkinson and Sheard skilfully illuminate the history and evolution of NICE, one of the UK’s most important health regulatory institutions, interweaving oral testimony with archival research and policy theory. The book is a powerful account of the persistent challenges faced by modern health systems of balancing finite resources against new therapeutic possibilities and health gains for individuals and populations.”

—**Stephanie Snow**, *Professor of Health, History and Policy;
Director: NHS at 70, University of Manchester, UK*

“Few organisations have had as much impact on translating evidence-based medicine into practice as NICE has had in the UK. From the appraisal of drugs to the production of guidelines, the organisation has had to navigate one of the most challenging policy areas. Based on extensive archival research and interviews with those involved, this groundbreaking book will be essential reading for historians of recent medicine and health policy makers.”

—**Carsten Timmermann**, *Professor of History of Science,
Technology & Medicine, University of Manchester*



Taylor & Francis

Taylor & Francis Group

<http://taylorandfrancis.com>

NICE

It may seem as if the National Institute of Health and Care Excellence (NICE) has always been part of the UK's health and social care landscape. But this fascinating book charts the evolution of NICE from its origins 25 years ago, as well as how this development illustrates many of the key themes effecting health care today.

In a period of rapid medical and technological advance, NICE has been both a gatekeeper to ensure that health care resources are spent where they are needed most, and a promoter of patient access to the best new technologies. Through a detailed history, the authors show how NICE's remit grew from health care to public health to social care, advancing the use of evidence-based policy making and health economics as it did so. Playing a key role in ethical debates which often made the news, NICE also re-aligned the relationship between patients, politicians and the pharmaceutical industry.

Written by two of the leading scholars in the field, this fascinating history also situates NICE in an international context, where it is often seen as a model to follow. It will be key reading for students and researchers in the fields of health and social care and health policy, as well as professionals and interested general readers.

Paul Atkinson is Senior Research Fellow in the Department of Public Health, Policy and Systems at the University of Liverpool. He is a historian with an interest in health policy and the use of evidence for policy.

Sally Sheard is Executive Dean of the Institute of Population Health, and Andrew Geddes and John Rankin Professor of Modern History, at the University of Liverpool. She is a health policy historian and analyst with an interest in the interface between expert advisers and policymakers.



Taylor & Francis

Taylor & Francis Group

<http://taylorandfrancis.com>

NICE

A Contemporary History of the National
Institute for Health and Care Excellence

Paul Atkinson and Sally Sheard

First published 2025
by Routledge
4 Park Square, Milton Park, Abingdon, Oxon OX14 4RN

and by Routledge
605 Third Avenue, New York, NY 10158

Routledge is an imprint of the Taylor & Francis Group, an informa business

© 2025 Paul Atkinson and Sally Sheard

The right of Paul Atkinson and Sally Sheard to be identified as authors of this work has been asserted in accordance with sections 77 and 78 of the Copyright, Designs and Patents Act 1988.

All rights reserved. No part of this book may be reprinted or reproduced or utilised in any form or by any electronic, mechanical, or other means, now known or hereafter invented, including photocopying and recording, or in any information storage or retrieval system, without permission in writing from the publishers.

Trademark notice: Product or corporate names may be trademarks or registered trademarks, and are used only for identification and explanation without intent to infringe.

British Library Cataloguing-in-Publication Data

A catalogue record for this book is available from the British Library

ISBN: 978-1-032-21492-4 (hbk)

ISBN: 978-1-032-81772-9 (pbk)

ISBN: 978-1-003-50127-5 (ebk)

DOI: 10.4324/9781003501275

Typeset in Times New Roman
by codeMantra

Contents

<i>Acknowledgements</i>	<i>ix</i>
<i>List of Figures</i>	<i>xi</i>
<i>List of Abbreviations and Glossary</i>	<i>xiii</i>
Introduction	1
1 Origins	7
2 A policy window opens (May 1997–Autumn 1999)	39
3 The ‘boost phase’: NICE at work, 1999–2006	75
4 The public and patients	108
5 Health technology appraisal, 1999–2007	134
6 NICE guidelines	170
7 Public health and social care	211
8 From gatekeeper to access and innovation champion? NICE and appraisal since 2007	238
9 Conclusions	279
<i>Appendix 1: List of persons quoted and their connection with NICE</i>	<i>287</i>
<i>Appendix 2: Comprehensive list of NICE guidelines up to 6 March 2024</i>	<i>289</i>
<i>Index</i>	<i>299</i>



Taylor & Francis

Taylor & Francis Group

<http://taylorandfrancis.com>

Acknowledgements

We are grateful above all to all the people listed in Appendix 1 who talked to us about their experiences of NICE and its work: this book would have been impossible to write without their involvement. Peder Clark made a substantial contribution to the researching and writing of Chapter 4 while working in our Governance of Health research group. We are grateful to NICE for providing opportunities to discuss the research findings at board meetings, for arranging access to archive materials and for permission to use the data in Appendix 2. We also thank the King's Fund for permission to use the data in Figure 1.1, and Lateef Akanni for input to Figure 1.1. The research leading to this book was supported by a Wellcome Trust Senior Investigator Award held by Sally Sheard for the Governance of Health project. Wellcome provided a Costed Extension to make the work on NICE possible, which we acknowledge with thanks.



Taylor & Francis

Taylor & Francis Group

<http://taylorandfrancis.com>

Figures

I.1	Timeline of NICE's history and its policy and political context	5
1.1	Annual real terms growth in NHS spending by government term and party, 1955–2022	9
6.1	The Key Stages of NICE Guideline Development (2006)	187



Taylor & Francis

Taylor & Francis Group

<http://taylorandfrancis.com>

Abbreviations and Glossary

ABPI:	Association of the British Pharmaceutical Industry
BBC:	British Broadcasting Corporation
BMJ:	British Medical Journal
CDF:	Cancer Drugs Fund
CMO:	Chief Medical Officer
DEC:	Drug Evaluation Committee <i>or</i> Development and Evaluation Committee
DH:	Department of Health, renamed Department of Health and Social Care (DHSC) in 2018
DHSS:	Department of Health and Social Security (predecessor of DH 1968–88)
EBM:	Evidence-Based Medicine
ERG:	Evidence Review Group: expert input to a NICE Technology Appraisal
GDG:	Guideline Development Group
GP:	General Practitioner
HDA:	Health Development Agency: public body for evidence, standards and capacity in public health, 2000–05.
HTA:	Health Technology Assessment <i>or</i> Appraisal
ICER:	Incremental Cost-Effectiveness Ratio
IPPR:	Institute of Public Policy Research
ITV:	Independent Television (UK TV channel)
NCC:	NICE National Co-ordinating Centre for guidelines (several for different topics)
NHS:	National Health Service
NHS England:	DH body providing some HQ functions for the NHS since 2013
NHS Executive:	DH body providing some HQ functions for the NHS in the 1990s
NICE appraisal:	see TA

NICE appraisal method:	NICE's preferred analytical techniques for HTA (set out in the NICE Reference Case)
NICE appraisal process:	NICE's standard operating procedure for carrying out a Technology Appraisal, setting out e.g. points at which to consult
NICE guidance:	recommendations from any NICE programme (HTA, guidelines, etc.)
NICE guideline:	document describing the appropriate NHS treatment and care of people with specific diseases and conditions
NICE:	National Institute for Clinical Excellence (later renamed National Institute for Health and Clinical Excellence/ National Institute for Health and Care Excellence)
OFT:	Office of Fair Trading: UK competition authority
PCT:	Primary Care Trust: local NHS body responsible in the 2000s for commissioning health care. Previously Primary Care Group
PPI:	Patient and Public Involvement
PPRS:	Pharmaceutical Price Regulation Scheme, since 2019 the Voluntary Scheme for Branded Medicines Pricing and Access
QALY:	Quality-Adjusted Life Year
SCIE:	Social Care Institute for Excellence
SIGN:	Scottish Intercollegiate Guidelines Network
SVJs:	Social Value Judgements published by NICE's Citizens Council
TA:	Technology Appraisal: NICE guidance document based on HTA and other evidence
TNA:	The National Archives
WHO:	World Health Organization

Introduction

Consider two short vignettes. In February 2005, Barbara Clark was diagnosed with an aggressive form of breast cancer and told she had a 14% chance of survival. A private consultant advised her of a promising new drug, Herceptin, only available on the National Health Service (NHS) to people with late-stage cancers. As he explained to her, ‘interim trial results are looking very positive, but it is likely to be a long time before the drug is available on the NHS for women [with early-stage breast cancer]’. By May he was advising her ‘this is a wonder drug. But ... it is exceptionally expensive ... NICE will have to consider it for ... approval. But that could take years, and without their go-ahead, the NHS won’t prescribe it to you’. Faced with a likely cost of £50,000 per year, Clark began to consider selling her house. She also began a high-profile campaign in which her local MP, Ian Liddell-Grainger, called in Parliament for the government to order NICE to fast-track its approval of Herceptin. Clark commented in her 2007 book: ‘Fast-tracking, of course, isn’t what NICE does. The longer they delay approval for a new drug, the more money the NHS can save’.¹ NICE approved Herceptin for early-stage treatment in August 2006.

In December 2023, NICE published a Technology Appraisal about devices to help manage blood glucose levels in type 1 diabetes.² It details who will be offered hybrid closed loop (HCL) technology, in which a body-worn monitor talks to an insulin pump. Writing for Diabetes UK’s website, one of the charity’s young volunteers for its peer-to-peer support programme praised the new guidance:

After living with type 1 diabetes for 21 years now, I can confidently say that using a HCL has undoubtedly changed my life. ... I now sleep through the night and feel so much more rested. It also takes away a lot of the mental burden for me, particularly the minute-by-minute decision making. ... The HCL system allows me to show up better in many areas of my life; in my relationships, my physical health and at work. I feel so incredibly lucky to have this technology and welcome the latest guidance from NICE.³

1 Clark (2007), 61, 84, 112. We discuss the Herceptin case in Chapter 5.

2 NICE (2023).

3 Diabetes UK (2013).

2 NICE

This book examines the policymaking behind personal stories like these. NICE, the National Institute for Health and Care Excellence, is the British public body charged with producing guidance on the effectiveness and cost-effectiveness of interventions for the NHS and the wider health and care system.⁴ It influences critical, and sometimes tragically fraught, ethical choices in British healthcare, and affects over £100 billion of expenditure each year. This book examines NICE's origins in 1990s debates about rationing and cost containment, and charts the way that, almost alone among public bodies established under Tony Blair, it has stood the test of time. In a period of rapid medical and scientific advance, and significant health service change in Britain, NICE has been entrusted with the responsibility for deciding which technologies the NHS should fund. It has played a key role in making the application of economic concepts such as cost-effectiveness and opportunity cost acceptable in decision-making. Once surrounded by critics, NICE is now widely respected by patient organisations, the pharmaceutical industry and the health professions, both in the UK and internationally.

Looking at NICE's technology appraisal activities, we consider how it has struck a balance between controlling the rising costs of healthcare and promoting access for all to the best new technologies (generally, but not only, medicines). NICE is more than a technology appraisal organisation, important though this role is, and we also describe its contribution to evidence-based decision-making in healthcare through its output of guidelines. Arguably, these influence the patient experience even more than NICE's technology appraisals. We also document and assess NICE's major contribution to patient and public involvement in healthcare decision-making. Its Citizens Council set out social value judgements to underpin NICE's work, such as valuing the lives of people of all ages equally.

NICE's 25th anniversary is a good opportunity for retrospection and for debate. This book is the work of historians, and complements accounts of NICE by social scientists, economists, ethicists and others.⁵ Its methods are those of the historian: to identify the widest possible range of sources, weigh their reliability and compare the accounts they give. Central to this have been 65 oral history interviews with people present at the events described: those working at NICE, politicians and their civil servants, representatives of patients, lay members of NICE's Citizens Council, doctors, the staff of pharmaceutical manufacturers, health economists and others. Full particulars are given in Appendix 1. While there are legitimate questions about the reliability of witness testimony (just as with any other kind of source), there is reason to see it as a trustworthy source for, in particular, participants' feelings and motivations – and of course, human memory being what it is, rather less so for dates and names.⁶ Each interview was transcribed. While the recordings and

4 NICE has changed its name, but not its acronym, reflecting its growing range of responsibilities. It was the National Institute for Clinical Excellence (1999–2005) and the National Institute for Health and Clinical Excellence (2005–2013) before acquiring its present name.

5 A recent collection of some of these other perspectives is Littlejohns and Syrett (2024).

6 The case for witness testimony is well put by Thompson (2000).

transcripts have been stored, it was a condition of some interviewees' participation that these raw materials remain private: a price we were prepared to pay for privileged access to people at the heart of events.

As we have in previous research, we also organised a 'witness seminar' modelled on the work of Tansey and the History of Twentieth Century Medicine Group.⁷ A witness seminar has the benefit of bringing participants together to discuss, debate, agree or disagree about their reminiscences and their significance. Ours concentrated on the origins and establishment of NICE.⁸

We also worked from written materials. As normal in modern history, the problem was not too little material but too much. NICE itself has published more than 2,000 pieces of guidance. This prodigious output was neither written nor curated with historians' convenience in mind, however: NICE carefully removes outdated guidance from its website for good medical reasons, requiring us to locate older material in libraries. Other useful published sources have included government reports, Parliamentary debates, and newspapers. The Government Web Archive, while difficult to search, has furnished, for example, all NICE's Annual Reports, a rich source for NICE's public presentation of its work.⁹

Among unpublished papers, a set of Department of Health documents newly released by the National Archives provided some valuable insights into policymaking just before and after NICE's establishment, illustrating for example the politics of Blair's efforts to keep the pharmaceutical industry onside while simultaneously giving NICE its head. We were also pleased to be given access to small collections of personal papers held by Mike Rawlins, Trevor Jones and Tony Culyer. Reassuringly, this previously unseen material very largely confirmed the picture emerging from the interviews and published sources.

Our interpretation of our sources has been informed, but not, we hope, unduly constrained, by political theory such as the work of Moreira and of Cairney, on evidence and policy, and Kingdon on agenda-setting.¹⁰ We have done our best to avoid taking received wisdoms at face value. Working mainly from official papers and the recollections of office holders, for instance, it was important to question and historicise government's (and NICE's) framings of the issues under discussion. We have tried to follow Rose and Valverde's advice to ask: what do those who wield power think it is their business to sort out? What qualifies as a 'problem'? And who gets to say?¹¹

Another received wisdom to handle carefully was the hagiographic view of NICE's history, held by many participants, which attributed NICE's successes almost exclusively to the exceptional qualities of Rawlins, its first chair, and Andrew Dillon, its first Chief Executive. The 'great men' view of history apparently remains

7 Tansey (2006).

8 Atkinson and Sheard (2020).

9 <https://www.nationalarchives.gov.uk/webarchive/>.

10 Moreira (2012); Cairney (2016); Kingdon (2003).

11 Rose and Valverde (1998).

appealing. Rawlins, NICE's Chair from its establishment until 2013, who gave us an interview and took part in the witness seminar, died in January 2023. The scale of his impact on health and medicine in the UK merits a whole biography to itself: here we can at least assess that part of his legacy relating to NICE. We discuss in Chapter 3 how closely the 'great men' view of history approaches the truth in NICE's case.

This book is organised thematically rather than chronologically, although we do introduce our themes in approximately the chronological order in which they became important. This approach allows us to discuss the big issues of interpretation in a much more coherent way. This risks losing the chronological thread for some readers, so we offer here a timeline which may be convenient (Figure I.1).

Chapter 1 is NICE's prehistory, dealing with mounting concerns about the cost of healthcare and policy options for dealing with this. We note especially the rise of evidence-based medicine, health economics, which at this time was driving the growing role of the Quality Adjusted Life Year (QALY) in decision-making, and health technology assessment. In Chapter 2, we account for the arrival of NICE at the end of the 1990s and the details of the shape it took. Chapter 3 presents an analytical look at the young organisation at work: its interactions with other health policy actors and the 'feel' of the organisation itself. We then single out in Chapter 4 the important cross-cutting theme of NICE's pioneering commitment to patient and public involvement.

The next four chapters survey the major areas of NICE's activity. In Chapter 5, we tell the story of its technology appraisal up to 2007, before leaving this field to discuss NICE's treatment guidelines in Chapter 6. Chapter 7 examines the less well-known, but intriguing, field of NICE's work on public health and on social care. Chapter 8 then returns for the second half of the technology appraisal story, beginning in 2008. Chapter 9 offers some concluding thoughts and a little reflection about possible futures.

Works of history need to justify their choice of start and end dates. This book begins with the announcement of NICE in 1997 and a look at the streams of thought and activity leading up to that. A closing date was less obvious: NICE is a continuing story. Some history is too recent to weigh up the significance of particular events (and some sources have yet to come to light). We have taken the pragmatic decision to end our account around the start of 2020. This leaves to future scholars such events as NICE's contribution to the British response to the COVID-19 pandemic. NICE gained a new Chair, Sharmila Nebhrajani, in May 2020 and a new Chief Executive, Samantha Roberts, in February 2022, so this choice also leaves their terms of office for others to examine.

The research for this book was funded by a Wellcome Trust Senior Investigator Award to research the 'Governance of Health', looking at the key groups in UK health policy in recent decades: doctors, health economists and managers (including management consultants).¹² The history of NICE sheds a good deal of light on

¹² Transcripts of our witness seminars in the wider project are at: <https://www.liverpool.ac.uk/population-health/research/groups/governance-of-health/witness-seminars/>.

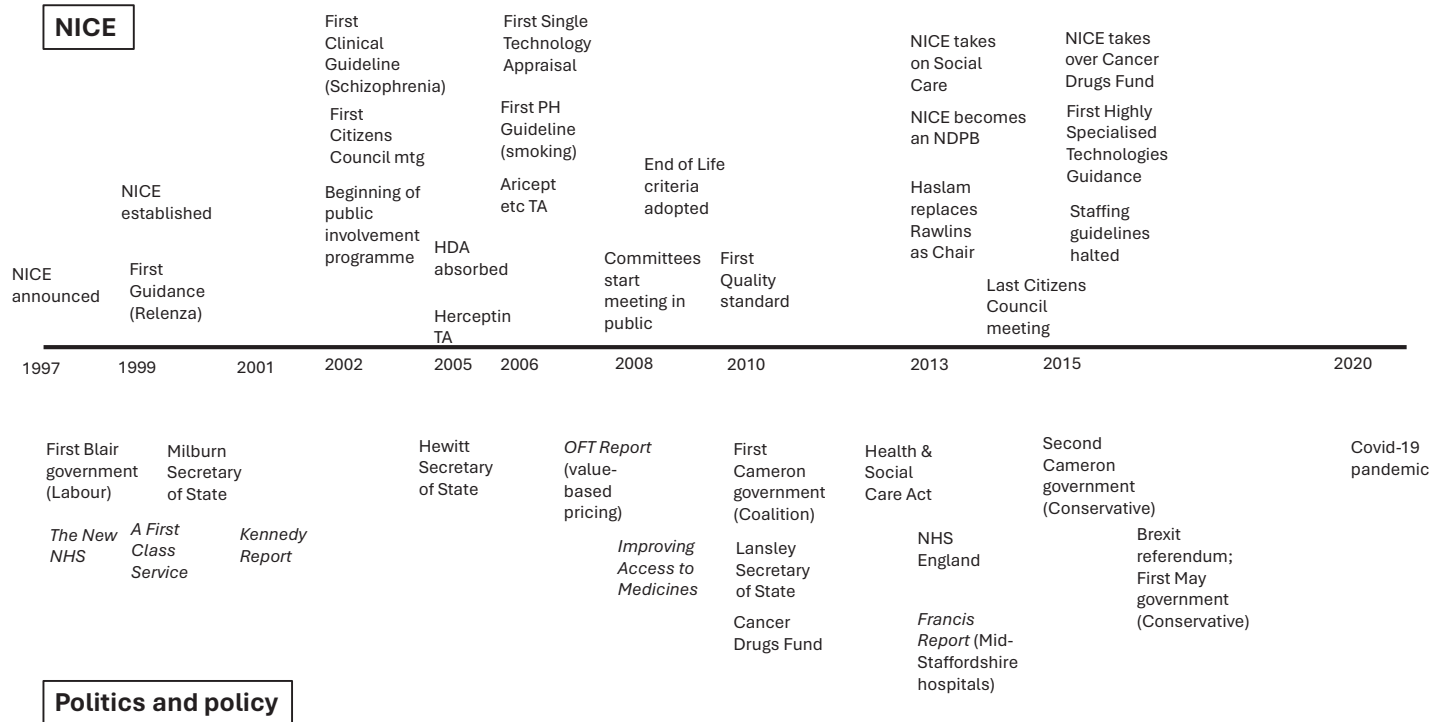


Figure 1.1 Timeline of NICE's history and its policy and political context.

the changing influence exercised by these groups. While senior people at NICE, past and present, have given us every assistance in our research, this is not an official history and the interpretations we put forward here are our own.

Bibliography

- Atkinson P & Sheard S (eds) (2020) *Origins and Establishment of NICE (c. 1997–2002)*, witness seminar held online on 18 June 2020 (Liverpool: Department of Public Health and Policy, University of Liverpool).
- Cairney P (2016) *The Politics of Evidence-Based Policy Making* (Basingstoke: Palgrave MacMillan).
- Clark B (2007) *The Fight of my Life* (London: Hodder and Stoughton).
- Diabetes UK (2013) Diabetes tech: Young Leader shares her views on updated NICE guidance (Last accessed 18 September 2024).
- Kingdon J (2003) *Agendas, Alternatives and Public Policies*, second edition (New York: Longman).
- Littlejohns P & Syrett K (eds) (2024) *NICE at 25: A Quarter-Century of Evidence, Values, and Innovation in Health* (London: Routledge).
- Moreira T (2012) *The Transformation of Contemporary Health Care: The Market, the Laboratory, and the Forum* (Oxford: Taylor & Francis).
- NICE (2023) *TA943 Hybrid Closed Loop Systems for Managing Blood Glucose Levels in Type 1 Diabetes* (London: NICE). (Last accessed 18 September 2024).
- Rose N & Valverde M (1998) Governed by law? *Social and Legal Studies* 7(4), 541–551.
- Tansey E (2006) Witnessing the witnesses: potentials and pitfalls of the witness seminar in the history of twentieth-century medicine, in Doel R & Söderqvist T (eds) *The Historiography of Contemporary Science, Technology, and Medicine* (London: Routledge), 260–278.
- Thompson P (2000) Introduction, in Bornat J, Perks R, Thompson P & Walmsley J (eds) *Oral History, Health and Welfare* (London: Routledge), 1–20.

1 Origins

The establishment of NICE in 1997 was part of a long-term change, becoming visible from the mid-1970s, in the governance of health in the UK.¹ Many politicians and media commentators have presented this process as a transition from a top-down ‘command and control’ model dominated by central government since the 1940s, to a market (or simulated market) model of delivery since the 1980s. It is wiser to see the process as a development of the National Health Service’s (NHS) underlying tensions (e.g., between the health care citizens want and the amount they are willing to pay, and between clinical autonomy and cost control – both central topics to our discussion). Greener and Powell, for example, suggest a transition from an older system in which doctors dominated local decisions but the Ministry of Health was accountable centrally, to one where ministers decide much more, but aim to diffuse accountability, when policy fails, onto local managers: ‘from local paternalism with national accountability to its opposite, national paternalism with local accountability’.² We will explore how NICE itself can be used as an example of ministers (for better or worse) diffusing responsibility away from themselves.

The political and economic context in recent decades has been one of mounting concern about cost. However, hard choices about how to control costs were politically unpalatable, and therefore avoided. Health policy was shaped by changing power relationships between senior doctors, managers (including management consultants), politicians and the profession of health economics, with its emphasis on the consideration of opportunity cost. Doctors were gradually losing some of their previous discretion over treatment choices, and legitimacy, in the face of growing consumerism and the probing enquiries of evidence-based medicine about which medical interventions actually worked.

This chapter examines the ways these tendencies shaped the emergence of NICE. It first describes the problem – or complex of problems – which health

1 NICE’s remit covers only England. But it was a response to pressures felt throughout the UK (and much more widely). We do not attempt in this book to describe the responses of Scotland, Wales or Northern Ireland, but will touch on NICE’s interactions with these UK countries where necessary.

2 Greener and Powell (2008). On diffusing responsibility, see particularly Klein R (2013), 202 and 292–295, and Hammond et al. (2018).

polymakers felt they were facing. Then it surveys some key policy responses that were advocated with increasing impact. We consider some political reasons why these policies were not taken up more quickly, and conclude with a brief look at what was, nevertheless, done to put them into practice before 1997.

Analysing policy through this threefold identification of problems, policies and politics is an application of Kingdon's well-known 'multiple streams analysis'. This political science research proposes that policymaking incorporates three 'streams': problems (the things that capture the attention of those in and around government); policies (the things the 'policy community of specialists' advocate) and politics (mood, opinion, election results and the things politicians do to influence these).³ Kingdon's key insights are, first, that these streams each develop under their own internal dynamic, but, second, that what determines events is how they connect: change happens in a 'policy window', when a problem is recognised, a solution available and the political climate allows this choice to be selected. (This stress on the mingling of streams uses the same metaphor as Woolcock, Szreter and Rao, who describe history not as a simple, steady flow of causes and consequences, but as 'a river of fluid and swirling potential, with many eddies and back currents in it'⁴).

In this chapter, we will have least to say about the 'politics' part, since it remained unfavourable to major initiatives, and these were delayed until after 1997 (which in itself suggests Kingdon's framework has some explanatory value here). We argue in Chapter 2 that the election of a new government in 1997 opened one of Kingdon's 'policy windows'.

The problem: getting more population health gain from constrained budgets

The 'problem' which we want to use to frame the origins of NICE is this: how could British governments use constrained public resources to get as much health gain as possible for the population? 'Health gain' is not a straightforward term, and the goals of health policy had not always been expressed in this way.⁵ It is instructive that a problem began to be framed in this 'economising' way from about the 1970s.⁶ We will touch on why this might have been when we discuss the rise of health economics later in this chapter. The two core ideas are simple enough: that the goal of health spending should be better outcomes (more health, however measured), not simply more activity (outputs, such as numbers of operations or drugs dispensed); and that policy should aim for greater efficiency in securing more health per pound spent.

3 Kingdon (2003).

4 Woolcock et al. (2011).

5 Some of the foundational literature includes Fanshel and Bush J (1970); Sackett and Torrance (1978); Rosser and Kind (1978), and Hunt et al. (1986).

6 We use 'economising' to refer to an approach that stresses economic concepts, above all efficiency: see below.

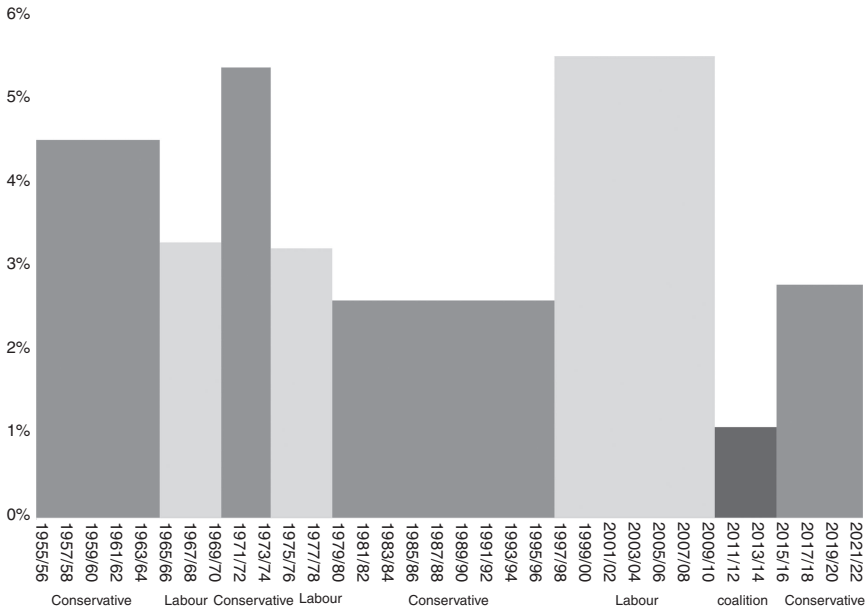


Figure 1.1 Annual real terms growth in NHS spending by government term and party, 1955–2022.

At the root of the problem was the collision between rising public expectations of the health sector (fuelled by an ageing population, medical advances, and to some degree by growing consumerism), and constraints on the resources available. For British governments, that meant the amount they felt they could afford to allocate to the NHS. From the 1970s, the growth in expectations accelerated while the availability of resources failed to keep pace.⁷ Figure 1.1 illustrates the changing pace of NHS spending growth: while this is positive in relation to retail prices in every year but one, it often dipped below the pace needed to cope with a growing and ageing population, technological change and rising expectations.

Debates about the role of NICE have often emphasised getting best value for money from drugs, although (as we shall see) NICE's role is much wider. Drugs have historically made up about a sixth of NHS spending.⁸ We should therefore avoid discussing NICE overwhelmingly in terms of its drug appraisal activity. For example, another of its programmes, the production of treatment guidelines, examined in Chapter 6, affects a much larger area of NHS expenditure. The drugs bill

7 Klein (2013) has a particularly clear account of how these policy choices have been handled, for example Chapter 3 on the 1960–1975 period. On the scarcity of resources for health care, see especially Klein et al. (1996). This contains a particularly good discussion of how the word 'rationing' should be, and was, used. New (1996), and Coulter and Ham (eds) (2000) are also valuable.

8 Office of Fair Trading (2007), 12–13.

has risen somewhat faster than overall NHS spending however: the King's Fund reports that the drugs bill grew from £13 billion in 2010/11 to £17.4 billion in 2016/17 –around 5% a year, and 12% in the hospital sector.⁹

British governments have been concerned for decades about the rising cost of drugs to the NHS, introducing the Pharmaceutical Price Regulation Scheme (PPRS) in 1957. We shall have cause to discuss the interaction of the PPRS with NICE's work in Chapters 5 and 8: it can very briefly be summarised as a voluntary agreement between government and industry, which has tried, with some success, to reconcile the restraint of price growth with the survival of a thriving UK pharmaceutical industry by capping, first, prices, and later, profits.¹⁰

One other facet of the problem of getting more health gain for our money is important: the relationship between the local and the national. In the absence of national policy before 1997, local health authorities adopted their own approaches to priority-setting. A health technology might be funded in one place but not another. In England this was strongly criticised by patient groups (and drug manufacturers) as a 'postcode lottery'. This had existed throughout the history of the NHS, but Margaret Thatcher's 1991 internal market reforms made the variations explicit for the first time, in contracts for care services between NHS purchasers and providers.¹¹ The Labour Party, in opposition during the early 1990s, made the postcode lottery a key part of their criticism of Conservative health policy. So part of the wider problem about maximising health gain was how to choose the solutions at a national level instead of locally.

We should note here some particularly British features of the much more general problem of expectations running ahead of health care resources. The British system of health care, with (even looking only at England) the world's largest single-payer national health system, has been much more centralised than most other countries. This has put greater political weight on finding a solution at the centre. Policies, to which we turn next, have been framed in terms of what the centre, rather than other actors, should organise. This has, for example, put national resources behind health technology assessment (HTA), as we shall see. The urgency of resolving the problem has been greater because accountability for it has been clearer than in many other states.

Related to this but separate, British political values have emphasised the (often ill-defined) concept of 'fairness'.¹² Solutions to the problem of making resources go further have been ruled out if they have been perceived as inequitable: local

9 King's Fund (2018).

10 A short treatment of the first three decades of the PPRS is Luce (1987). Raftery (2013) covers more recent years. As the Guillebaud Committee on the Cost of the NHS said in 1956, 'The whole problem [of pharmaceutical price regulation] is obviously one of great complexity and difficulty'. In 2019 the PPRS became the Voluntary Scheme for Branded Medicines Pricing and Access (see Chapter 5).

11 Ham (2000) discusses the making of these policies.

12 For a discussion of English and Scottish approaches to fairness in health care resource allocation, see Carr-Hill and Sheldon (1992).

prioritisation and the postcode lottery in particular. All of this shaped the discussion from which NICE would emerge.

Policy proposals: new ways to use evidence in health policy

In this section we will make use of Kingdon's framing of policies as potential courses of action with their own champions and developers, which exist with some independence from the debate about 'problems' (and from the field of politics). His view that the owners of policies go looking for problems for which they could be used seems relevant to the present case. This section reviews a series of policies which were under active debate in the UK in the 1980s and 1990s, examining how they were relevant to the later emergence of NICE. A common thread is that each 'policy' involved a new approach to what counted as evidence for policymaking, and how evidence ought to be used.

What do we mean by a policy? The everyday usage – that it is a decision by some authority about what should be done, or not done – obscures some important things. Cairney, more helpfully, defines policy as 'the sum total of government action, from signals of intent to the final outcomes'.¹³ This draws attention, among other things, to the difference between intentions and actions, and to the way policy involves people at many levels, some with no formal role. Actors make policy continuously: policymaking is not a set-piece event forming a specific moment for using evidence.¹⁴

Evidence-based medicine

One policy option was the use of 'evidence-based medicine' in the NHS. If some health care interventions had only a poor evidence base to suggest they were effective, then measures to discourage their use might save money. Failing that, then at least a requirement to show evidence of effectiveness – and, critically, cost-effectiveness – before new interventions were taken up could ensure that new spending produced as much health gain as possible. By discouraging the least cost-effective interventions, this policy might be hoped to at least exert some downward pressure on the growth in health expenditure.

The evidence-based medicine movement grew from concerns among some doctors to improve the quality of clinical decision-making. In North America from the late 1960s, clinical academics such as David Sackett began to harness the methods of epidemiology (such as finding reliable statistical associations between health states and other variables), and of health state measurement, to problems of diagnosis and treatment, creating what they called clinical epidemiology. Walter Holland, who took up clinical epidemiology in the UK in the 1960s, stressed the focus on whole populations more than his North American counterparts, who often studied

¹³ Cairney (2016).

¹⁴ A similar approach is taken by Ham (2009), 131–133.

populations of hospital patients.¹⁵ This was partly because a national health service made the whole population a suitable level of analysis and decision-making. Holland saw his major role as supporting the health service: he recalled regular meetings of research directors at the Nuffield Trust about identifying the issues and how to influence government. He told us in 2017 that he ‘never really saw any distinction’ between health services research and public health research’.¹⁶

In the UK in the 1970s, Archie Cochrane was among the most influential advocates of randomised controlled trials and of identifying ineffective procedures which might be discontinued so that the resources saved could be better spent.¹⁷ Later, the Cochrane Collaboration emphasised the weighing of evidence about treatments to establish their reliability, and the synthesis of evidence using data from many trials (meta-analysis) by applying statistical methods to allow more reliable conclusions by using larger numbers of cases. Iain Chalmers was prominent in this activity: he was also a major advocate of ‘systematic reviews’ of existing research evidence to reduce bias.¹⁸ All of this amounts to a major intellectual project to use research evidence in a more rigorous way.

In both groups, particularly in America, the initial emphasis was very much on better clinical treatment decisions: better care for the individual patient. On both sides of the Atlantic, a focus on creating better policies soon came to be added.¹⁹ A distinction between different ‘levels’ of policy will be helpful as we consider the work of NICE. The most helpful expression of this was provided by Klein as long ago as 1990, when he wrote of ‘governance’ policies (on the organisation and financing of health care), service policies (on resource allocation and service configuration) and practice policies (on the delivery of care to the patient).²⁰

Most of what NICE has done has addressed the third of these. However, health care organisations such as hospitals increasingly find a need for ‘service policies’. NICE has also done some work at this level, for example, with its ‘service standards’ and the special case of its Cancer Service Guidance.²¹ Chapter 6 examines the way NICE guidelines have sometimes had a foot in each camp: treating individuals and planning services. Klein later elided these two fields into what he called ‘clinical policy-making’, to distinguish them from ‘governance policies’ or ‘national policymaking’.²² This was not entirely helpful, since in principle service and even practice policies might be laid down nationally – as some have since been by NICE.

A long tradition in the UK – as elsewhere – had emphasised the professional autonomy of the doctor, and, before 1997 government had been reluctant to stir

15 Daly (2005), 150–153.

16 Walter Holland, interview 12 June 2017. See also Holland (2002). The Nuffield [Provincial Hospitals] Trust is a think tank which aims to improve the quality of health care in the UK.

17 Cochrane (1972).

18 Daly (2005), 157–162.

19 See e.g. Daly (2005), 74.

20 Klein (1990).

21 Mark Baker interview, 18 May 2022.

22 Klein and Williams (2000), 24.

up controversy with doctors by seeming to curtail this autonomy by setting any ‘practice policies’ at all. As the Department of Health (DH) civil servant responsible for policy on clinical effectiveness guidelines in the mid-1990s recalls, government ‘was willing to support doctors themselves improving best care, but not to be an actual player itself’.²³ Chapter 3 will discuss how NICE reflected, and furthered, a radical change in this after 1997.

Who was advocating evidence-based medicine and why? Hunter, in 1997, described its rise as ‘a political power struggle between clinicians on the one hand and a newly empowered breed of health-services researchers on the other embracing a range of disciplines, but principally epidemiology, statistics and health economics’.²⁴ This puts the right stress on these quantitative disciplines, but Hunter’s account understates the contribution of doctors themselves to the rise of evidence-based medicine. The new tools it offered seem to have had a strong attraction for a subset of the medical profession, first visible in medical academia and later among some of the profession’s leaders. Practising clinicians were slower to embrace evidence-based medicine, and some scepticism remains, for example the concern that it is ‘cookbook medicine’ and diminishes the individual clinician’s scope to use judgement in matching treatment decisions to each patient’s needs. We will return to this critique in Chapter 3.

The reason that evidence-based medicine seems to have gained some traction with the leaders of the medical profession in the UK may be their belief that embracing it might stave off worse forms of interference.²⁵ In the climate we have discussed, where governments have become more interventionist, some leaders at (in particular) the UK’s medical Royal Colleges may have reasoned that treatment guidelines produced under their own guidance would be less harmful to the profession’s autonomy and perhaps to patients’ interests.²⁶ David Pink, who worked on the development of NICE at DH in 1997–99, comments that:

in those days most Royal College clinical guidelines were rather aspirational, they didn’t concern themselves with the cost of healthcare whatsoever, the technology appraisal, the rationing of drugs issue, the Royal Colleges didn’t want anything to do with.²⁷

The mention of cost is a reminder that the evidence-based medicine movement is concerned with the effectiveness of treatments: their cost-effectiveness has not been an intrinsic part of the project, and some evidence-based medicine advocates have avoided it for fear of raising more resistance among clinicians.²⁸ However, when governments and health organisations were already on the search for more

23 David Pink, interview 28 May 2020.

24 Hunter (1997).

25 Weisz et al. (2007).

26 For background on England’s medical Royal Colleges, and their relevance to NICE, see Chapter 3.

27 Pink interview.

28 Daly (2005), 115–118.

cost-effective care, it is unsurprising that they would latch onto evidence-based medicine. Health economists (as we shall see shortly) were looking for ways to measure the health gain from different interventions, which could (in principle) be costed, allowing a prioritisation of those producing most gain for each pound spent. Evidence-based medicine seemed to promise information about health gain which doctors themselves might accept as rigorous. The attraction, for government, of harnessing evidence-based medicine to the cost-effectiveness agenda was clear.

Bolt, who studied evidence-based medicine in the Netherlands, shares the view that it did not remain solely a critical thinking tool for individual physicians – its products came to be used too by governments and other authorities.²⁹ The medical sociologist David Armstrong was well-placed to notice the phenomenon in the UK in the 1980s and 1990s. He told us that evidence-based medicine was useful to a much broader tendency in government to want to measure, and hence better control, what was happening in health care:

in a way, the [English] individuals and organisations [funding and organising medical research] were all part of this more general influence ... evidence-based medicine, the move towards deliverables and managerialism, impact ... any organisation that got onto that bandwagon was going to succeed.³⁰

Evidence-based medicine, then, was attractive to government. There were at least two reasons for this. As we have seen, it might contribute to saving money by identifying interventions which were ineffective and should no longer be funded. A cynic might even expect government to welcome those cases where inadequate evidence of effectiveness could be found: perhaps government might remove funding there too.³¹ And at the least, evidence-based medicine might help get the most health gain for each pound spent on new interventions, by directing it to the most effective ones.

A second reason for the attractiveness of evidence-based medicine to government was that it might take some of the hard choices out of the political arena. Some politicians have hoped that invoking science would give extra legitimacy to policy decisions such as excluding particular medical procedures from funding.³² Thus, in the US, Belkin identified an ‘expectation and hope that contentious issues in public life can be resolved by appeal to scientific measures and procedures rather than by the wise judgment of selected individuals’, an approach he found unlikely to succeed.³³ Similarly, Rodwin argued that ‘It is not possible to purge issues of value, purpose, or politics from public policy. Nevertheless, when faced

29 Bolt (2015).

30 David Armstrong, interview 2 May 2017.

31 Klein et al. (1996), 104.

32 See for example Jasanoff (1990).

33 Belkin (1997).

with contentious health policy issues, Americans often try to do just that'.³⁴ Writing a little later, Syrett felt this was exactly what the UK government was attempting with NICE (see Chapter 5).³⁵

The purely technocratic approach to using evidence-based medicine in government rapidly attracted criticism. The famous 'Oregon experiment' of 1987, in which the US state rationed Medicaid benefits on the basis of a cost-effectiveness analysis that initially used little or no lay input, was rapidly modified in the light of public reaction.³⁶ Similarly, Hunter reviews a range of cases from the Netherlands to New Zealand where there was also a rapid departure from the early enthusiasm to make a list of exclusions from health care funding on a technocratic basis.³⁷ Coulter and Ham add the interesting comment that this failure to restrict the scope of health care through political decisions at the 'macro' level has given more impetus to ensuring resources are used efficiently at 'micro' level by writing treatment guidelines which do this, for example in the Netherlands and the UK.³⁸ This should remind us that evidence-based medicine has been as much (or more) about producing guidelines as about producing HTAs. NICE's guidelines activities, which we describe in Chapter 6, are, then, perhaps its purest use of evidence-based medicine. They may also be, on the argument presented here, a pragmatic response to the difficulty of pursuing cost-effectiveness more directly.

Today, failing to rely on evidence-based medicine as one of the sources of policy would be regarded as heresy in government circles. This can obscure the fact that some pointed out its possible weaknesses from the beginning. Their criticisms still deserve attention. Klein speaks of evidence-based medicine as 'the new scientism', describing it as a claim that the use of scientific knowledge would solve the NHS' problems.³⁹ Subsequent experience supports Klein's 1996 claim that science was unlikely to dispose of the need for painful choices in the allocation of health care resources. Similarly, David Armstrong regards clinical epidemiology as a shoring up of the old 'scientific medicine' paradigm that 'we could have evidence and facts, that it would come down to numbers and concrete evidence'.⁴⁰ Privileging randomised controlled trial evidence above all other kinds can exclude much evidence that is highly valuable, above all in looking at public health interventions, as Greenhalgh recently reminded us in a different context.⁴¹ But Klein was also right to think that evidence-based guidelines could inform treatment choices, promote better clinical practice and make the criteria applied in resource allocation more transparent.⁴²

34 Rodwin (2001).

35 Syrett (2003).

36 Dixon and Welch (1991).

37 Hunter (1997), 97–114.

38 Coulter and Ham (2000), 9.

39 Klein (1996). A similar view is given by Harrison (1998).

40 Daly (2005), 116.

41 Greenhalgh (2020).

42 Klein et al. (1996), 102–108.

We claimed earlier that, by producing appraisals and guidelines, NICE was engaged in a form of policymaking. It was also clearly making use of, and contributing to, evidence-based medicine. This prompts some reflection on the discussions that have taken place about ‘evidence-based policymaking’. Cairney has discussed the relationship between this and evidence-based medicine.⁴³ He is a firm sceptic, from a political science standpoint, about the possibility or desirability of ‘evidence-based’ policy (and prefers the goal of ‘evidence-informed’ policy). It appears to us that a number of commentators, noting how policymakers press the use of evidence-based medicine on doctors, have felt that it was only reasonable to make the same demands on policymakers themselves: what’s sauce for the goose is sauce for the gander.⁴⁴ Cairney’s view, which we share, is that evidence-based policy is not possible because, first, even if ‘the evidence’ exists, it doesn’t tell you what to do; second, the evidence policymakers demand does not match the evidence science could ever supply; and third, policymakers make choices in a complex policymaking system in which the role of evidence is often unclear. NICE has made ‘clinical policy’ (in Klein’s phrase above) and has found that the rigorous use of evidence is essential but not sufficient, adding important elements of judgement, about which we will have much to say in later chapters.

Health economics

While evidence-based medicine has been one stream of policy which ultimately shaped NICE, health economics has been a second one. Much of the relevant thinking about priority setting and selection of treatments would have been impossible without concurrent developments in health economics, particularly in the measurement of health benefits. This provided one of the two components needed to assess cost-effectiveness. In so doing, it also gave an incentive to health systems like the NHS to develop the other necessary component: information on costs at the level of individual interventions, which a system like the NHS, not needing to bill patients for items of service, had not previously needed. We therefore now examine this second stream of policy developing since the 1960s: the use of health economics (and economic concepts generally) in policymaking. Health economics has contributed essential techniques, but also, as we noted at the start of the chapter, a very broad framing (indeed, so broad as just to be ‘economics’, not health economics): that policy should have a goal of maximising some measurable definition of utility (health gain) within available resources.

This broad conception of the ‘economising’ goal of health policy stems in part from health policymakers’ growing focus on, and capacity for, planning since the 1970s. As Ron Brown pointed out in his study of the 1974 reorganisation of NHS administration, one of the four stated goals of that major exercise was ‘to provide effective central control over the money spent on the service and to ensure

43 Cairney (2016).

44 A good example is Ham et al. (1995).

that maximum value is obtained for it'.⁴⁵ So, for example, a planning cycle was introduced, and steps were begun (including a formula for resource allocation) to even out differences in standards between regions. In the 1980s, Haywood and Alaszewski noted 'the managerialist strategy adopted by successive governments', including 'the considerable development of ... work study, operational research ... cost-benefit analysis'.⁴⁶ Rathwell (1987) charts the development of NHS planning and some of its problems, attesting to vigorous debate about how to plan.⁴⁷

This brings us to the new receptiveness for economic advice. Some of our earlier work has examined the interface between expert advisers and policymakers, especially in the domain of health policy.⁴⁸ It has led us to speculate that, as the costs of health care increased in the second half of the twentieth century, policymakers sought different types of advice from new sources which have supplemented and increasingly competed with that traditionally provided by the medical profession. Where to look, then, for new advice? Since the Second World War there has been a worldwide professionalisation of government in which 'science' became recognised as the ultimate source of authority.⁴⁹

As a result, health policy has turned more than previously to the biomedical sciences for input, but it is economics which has benefited most. Globally and across a vast range of policy, economics' self-presentation as a science has been outstandingly successful. Economists of all specialities by the late 1960s had a degree of expert authority across many domains of public policy, notably in the US.⁵⁰ In the US by the mid-1970s, three-quarters of the social scientists at high level civil service posts were economists.⁵¹ In the UK, Clive Smee, who was the Chief Economic Adviser at the Department of Health and Social Security (DHSS) from 1984 to 2002, describes patient long-term efforts to improve the quality of decision-making:

[we] were vaguely aware of how many resource allocation decisions were made in ad-hoc ways, often with little or no relevant evidence of benefits or costs. No grand strategy was developed for correcting this situation. Instead [we looked for] opportunities to show that systematic appraisal methodologies, particularly those that pushed out the boundaries of quantification, could lead to different, better or more defensible solutions.⁵²

45 Brown (1979), 41.

46 Haywood and Alaszewski (1980), 11.

47 Rathwell (1987).

48 Sheard (2014); Sheard and Donaldson (2005).

49 Bledstein (1976); Majone (1989); Rose (1989). See also Shapin (1995); Freeman and Sturdy (2014).

50 Markoff and Montecinos (1993); Nelson (1987).

51 Rhoads (1978). See also Wildavsky (1985); Anderson (1996); Aaron (1978) for discussion on the impact of social scientists.

52 Smee (2005), 81.

Health economics did not initially develop as a separate sub-discipline: this was to come in the 1960s, so far as the US and the UK were concerned. The sub-discipline was not far developed in 1963 when Kenneth Arrow published ‘the most widely cited health economics paper of all time’: ‘Uncertainty and the Welfare Economics of Medical Care’.⁵³ This provided a framework for thinking about the economics of the market for medical care using the language and tools of modern microeconomics. It argued that in health care there are market failures because consumers are exposed to risks that are not fully insurable (in part due to problems of moral hazard), and because they lack the information and expertise required to assess risks and treatments.⁵⁴ With hindsight, it can be seen as the leading edge of the emergence of the new ‘economising model’ of health care, focused on improving efficiency, minimising risks for third-party payers, cost containment, and improving the working of the market, that eventually coalesced around a policy prescription of income-graduated cost-sharing.

This model of health care is closely linked to the rise of the so-called New Public Management, ably dissected by Ferlie as a mix of ‘demand for public sector performance, efficiency and productivity, ... proliferation of efficiency targets, market testing, performance indicators and ever more elaborated audit systems’.⁵⁵ For Ferlie and other commentators, this meant public bodies were to be ‘run on more business like lines’, encouraged by two crucial mechanisms: ‘quasi markets and managers’. In this policy context the ‘economising’ strand in health economics has had more influence than other possible concerns such as the distribution of welfare.⁵⁶ Perhaps this has been because economising has been more useful to the policymakers. (In a notable contrast between policy in Scotland and England, the former country has been more influenced in establishing an HTA body by Scandinavian approaches to HTA, which treat clinical effectiveness, cost-effectiveness, organisational issues and patient issues as equivalent).⁵⁷

Health economics took off in the UK in the 1960s, only slightly behind developments in the US.⁵⁸ The University of York, founded in 1963, was one of the first to gather a cluster of economists working on health economics. This was due in part to the recruitment strategy of Alan Peacock, first head of the economics department. One key economist recruited to York in 1964 was Alan Williams. During the secondment he undertook after his arrival at York to the Civil Service (based in

53 Arrow (1963).

54 Arrow et al. (2011). Arrow’s paper is the only one of the authors’ chosen top 20 articles to focus on healthcare. See also Hammer et al. (2001).

55 Ferlie (2001).

56 Fox (1990); Melhado (2000), 244, 247.

57 Karen Facey, former head of the Scottish Medicines Consortium, interview 26 November 2019. See Facey (2017).

58 For a more detailed discussion, see Mackillop and Sheard (2019). We have also published the transcript of a witness seminar: Mackillop et al. (2018). Discussions of this history by UK health economists include Culyer (1981); Croxson (1998); Lee and Mills (1979); Blaug (1998); Hurst (1998); and Forget (2004).

the Treasury) between 1966 and 1968, he met Cochrane (see above), and Rachel Rosser (who stimulated him to develop his Quality Adjusted Life Year (QALY) measure, as discussed below).

Tony Culyer, later to be NICE's vice-chairman, arrived at York in 1969 from the University of Exeter. He had already begun to take an interest in the concept of need as applied to health care, which he developed with Mike Cooper into a paper commissioned in 1967 as part of a British Medical Association (BMA) report on Health Care Financing.⁵⁹ As discussed below, Culyer was the main organiser of the UK Health Economics Study Group, formed in 1972, and through the next 20 years he and his York colleagues Jack Wiseman, Williams and Alan Maynard became senior figures in UK health economics.

Maynard arrived at York in 1971. He set up the Graduate Course in Health Economics and in 1983 was the founding director for the Centre for Health Economics (CHE). Like his colleagues, he developed a high-profile reputation as a health economist, which helped him to attract significant government funding to York from the DHSS (parent government department for the NHS) and the Economic and Social Research Council (ESRC). The DHSS employed its first two full-time economists in 1970 (David Pole and Jeremy Hurst). From 1970 the advisory role of the York department was formalised through an annual grant from the DHSS, and there was additional funding through the Nuffield Provincial Hospitals Trust.

By the mid-1980s the work of the York CHE economists regularly attracted media attention. This was in part because the NHS was of increasing concern to the public and, as discussed below, there was now a distinct, discussable health economics term, the QALY, that the public could comprehend. *The Times Higher Education Supplement* featured the York centre in 1987, noting that it had more than 40 staff working on 20 research projects. Maynard, in particular, was a regular 'talking head' – and along with his colleagues was subjected to scrutiny by the sociologists Ashmore, Mulkay and Pinch in their 1989 book, *Health and Efficiency. A Sociology of Health Economics*.⁶⁰ Their media analysis found comments such as these:

Professor Alan Maynard of York University has been making rather a lot of appearances on the goggle box recently. But we had no idea that he was also becoming a pin up. [*Health Service Journal*, 20 Feb 1987]

The Man who has become the scourge of GPs. [*General Practitioner* 17 October 1986]

Media references to Williams included:

A health boffin [*Northern Echo* 3 Sept 1986]

QALY-Wallies like Prof Alan Williams and his associates at York University [*Doctor* 28 May 1987].

59 Cooper and Culyer (1970).

60 Ashmore et al. (1989).

Other academic hotspots for health economics did emerge, notably Aberdeen and Brunel Universities, where the Health Economics Research Group (HERG) was set up in the early 1980s, when it worked on the DHSS-funded study of heart transplant programmes (discussed later in the chapter).⁶¹ Its founder, Martin Buxton, also attracted policy and media attention, but not to the extent of the York group.

The Nuffield Provincial Hospitals Trust, under the direction of its Secretary Gordon McLachlan between 1956 and 1986, was a key player – regularly bringing together government ministers, civil servants and academics to discuss directions in NHS policy.⁶² Such was Nuffield’s involvement in the evolution of health economics that it can be traced through its series of books under the general title *Problems and Progress in Medical Care*. Culyer’s contribution to the seventh series in 1972 is typical: in it he demonstrated his ambivalence on roles of the market and the state in medical care.⁶³ Nuffield gave the small group of UK health economists a larger platform on which to showcase their work. McLachlan’s role was critical: he actively developed connections with US organisations – leading study tours and inviting key US health economists to come to the Nuffield Trust as visiting fellows, such as Alain Enthoven. Another, more specialist, thinktank, the Office of Health Economics, was established in 1962 with funding from the pharmaceutical industry. It has regularly published research papers, most of which have a clear industry interest.

The UK-focused Health Economists Study Group (HESG) was formed in 1972, and initially hosted by its founding members Culyer (the main organiser), Williams and Bob Lavers at the University of York. Bronwyn Croxson, herself an economist, who wrote a history of HESG for its 25th anniversary in 1997, claims that in 1972 ‘its time had come’, as there was ‘an increasing supply of and demand for’ economists working in the area.⁶⁴ She also suggests that HESG consciously supported health economists in developing strategies to cope with critical members of the medical profession.⁶⁵

Turning to the specific need for measuring health benefits of interventions, which we noted earlier, the most influential contribution of health economics here has been the QALY. By the 1960s, some US health economists had begun attempting to use cost effectiveness analysis. In 1976, the Harvard economists Zeckhauser and Shephard applied the term QALY to the technique.⁶⁶

They considered how individual attitudes to health-risking behaviour changed over lifetimes; and posited a protocol for ‘saving’ the cheapest lives first, adding: ‘we would continue purchasing QALYs until the last unit purchased just cost us the

61 Martin Buxton, personal communication.

62 McLachlan (1992).

63 Culyer (1972).

64 Croxson (1998).

65 Note that Klein viewed the appointment of economists in the DHSS in the early 1970s as an attempt by the civil servants to inject a new source of expertise to balance that of the medical profession: Klein (1976).

66 Zeckhauser and Shepard (1976).

amount we were willing to pay for it'. Their simulated case studies on road traffic accidents and heart attack victims demonstrated the lack of information on costs and benefits that was required to implement a QALY technique. One of the main reasons for their interest was the enormous increase in expensive technologies such as renal dialysis. It also reflected concerns that not all years of life could be valued equally, which had implications for the costs of end-of-life care, as well as for the survival chances and return to work of those left with disabilities, for example, after heart attacks. Shephard went on to work with his Harvard colleagues J S. Pliskin and Milton Weinstein to refine the concept and its application in the US.⁶⁷

In the UK the QALY had a different birth, with little direct acknowledgement of the parallel US activities.⁶⁸ It also prompted a very strong public reaction, which peaked in 1987 with three prime-time television programmes discussing its potential implications for NHS care.⁶⁹ *The Scotsman* newspaper did, pithily, attribute the term correctly: 'The idea is originally American – inevitably'.⁷⁰ On the ITV programme 'This Week' on 9 October 1986 Maynard debated with Jonathan Dimbleby:

Maynard: If we're trying to produce just one year of life with no disability or distress, hips to put it crudely are a much better buy than heart transplants.

Dimbleby: The Centre at York would have the funds diverted from new hearts to new hips.

Although it appeared to have been Maynard who took the spotlight for the QALY discussions, it was his colleague Williams who had given the US term a UK presence. His classic paper on the economics of coronary artery bypass grafting (CABG), published in the *British Medical Journal* in 1985 ended a long gestation.⁷¹ Williams was stimulated by his contact with economists working in Whitehall during his secondment in the late 1960s. When he returned to York he tried to devise a measure of NHS effectiveness 'that focused on the intrinsic value of health as a good in its own right', motivated in part by the work on evaluating care of the elderly by one of his students, Ken Wright.⁷² Wright was working on Activities of Daily Living (ADLs), trying to give weights to subjective issues such as pain and physical disability. Williams' crucial step was to devise a way to combine valuations of both mortality and morbidity into one measure, so that the QALY could be used to compare interventions for different diseases by considering both of these dimensions.

67 Pliskin et al. (1980).

68 For more detail, see Mackillop and Sheard (2018).

69 ITV *This Week*, 9 October 1986; ITV *This Week* 16 October 1986; BBC1 *The Heart of the Matter* 7 October 1986; BBC *The Life and Death Game* 10 June 1987.

70 *Scotsman*, 5 January 1987.

71 Williams (1985).

72 Williams (2005).

This triggered for Williams memories of an index of crime seriousness that he had come across in the Home Office. A serendipitous encounter brought him to the work of Rachel Rosser, a psychiatrist who had been developing a similar measure for use in the evaluation of medical treatments, with a classification system based on disability and distress which generated 29 different health states to which she and her husband Vincent Watts (a Home Office operational research analyst) had attached a set of relative social values to act as weights in a scoring system.⁷³ Williams, in a personal history written in 2005, acknowledged that through Rosser, who was

linked into an international network of health status index developers... I discovered key actors such as Bush in the USA and Torrance in Canada... In the UK, some early pioneers were Grogano and Woodgate (1971), but they were not making much impact amongst clinicians and were totally unknown to social scientists involved in the evaluation of health and social care.⁷⁴

Williams modified the non-UK scales, and asked Rosser and her colleague Paul Kind to re-work their data.⁷⁵ His work chimed with funding priorities from the Social Science Research Council on social indicators, which he developed through projects with his York colleagues Culyer and Lavers. He also later recruited Kind to his York team. From the mid-1970s onwards Williams refined his model, creating a cost per QALY for specific medical interventions to be applied to setting priorities in health care budgets. He solicited support from Douglas Black, Chief Scientist at the DHSS, who gave him several opportunities to increase his policy profile through appointments to committees, and he directed Michael Drummond, another York colleague (and former graduate student) to produce a couple of resource books on economic appraisal in 1981.⁷⁶ Drummond recalls how some of this activity led to NICE:

the gestation of NICE was that there were some people in the economists section of the Department of Health and I was on a committee that developed a set of ... guidelines that were pre NICE and so a number of us I think had a record of working, at least for the Ministry.⁷⁷

This attribution of NICE's origins to a few DH economists is more than just the partial perspective of one who exaggerates their own role: how much more, we shall examine later in the chapter.

73 Rosser and Watts (1974).

74 Williams (2005); Grogano and Woodgate (1971); Berg (1973).

75 Kind et al. (1982).

76 Drummond (1981a, 1981b).

77 Milke Drummond, interview 12 March 2020.

It is worth quoting Williams' account of how he 'launched' the UK QALY at a Consensus Development Conference on the role of CABG in 1984: 'This was an opportunity to roll out the cost per QALY approach in all its glory... Much to my surprise, I did not get annihilated by the critics, and my findings proved to be quite influential...' ⁷⁸ This work was published in the *British Medical Journal* the following year. ⁷⁹

In 1987, supported by further work with Rosser and Kind, a new Measurement and Valuation of Health Group at York, and a European consortium to identify a 'common core' of three or four elements that most health status indexes contained, Williams developed the EQ5D descriptive measure of health-related quality of life, which has become the most commonly used measure in QALY calculations in the UK. Reflecting on this period, Williams recalled it as 'the most important period in my entire life as an empirical researcher, since it required a very high level of commitment to carry it through in the face of a great deal of scepticism and even of outright hostility... What carried us through was a shared vision about the importance of what we were doing.' ⁸⁰

This was the beginning, not the culmination, of the development of the QALY. Important later issues included how best to base its measurement of the quality of life in patient and public perceptions, involving the use of patient reported outcomes measures (PROM), rather than the older approach of measuring a drug's efficacy by looking at a variable based in the science, which sometimes lacked much meaning for quality of life. Williams also took a leading role, in the 1990s, in securing a growing place for the QALY in decision-making on questions of equity. ⁸¹ As Maynard reports,

'Williams dedicated his life to persuading reformers, clinical and political, to the cause of ... PROM. Whilst he had some success in getting such quantification into health technology assessment, in particular the use of QALYs in ... NICE, one of his final papers (Kind and Williams, 2004) again emphasised the absence of routine PROM measurement and management in the NHS.' ⁸²

Health Technology Assessment

HTA has conveniently been defined as research about the clinical and cost-effectiveness, and broader impact, of health care treatments and tests. ⁸³ The technologies under consideration need not be drugs (as we shall see), but most have

78 Williams (2005), 197.

79 Williams (1985).

80 Williams (2005), 198.

81 See especially Harris (1985); Williams (1997). Harris would later be a severe critic of NICE and QALYs.

82 Maynard (2008).

83 The definition adopted by England's National Institute for Health Research (n.d.).

been. In the case of drugs, HTA is an additional form of assessment which may be added to the existing statutory tests of safety, quality and efficacy, long required in medicines licensing legislation, hence its description at times as a ‘fourth hurdle’ which any new drug must clear. HTA examines effectiveness, which differs from the licensing authorities’ focus on efficacy by asking how well the technology will work *in everyday use* as opposed to in a trial. The additional focus on cost-effectiveness and the cost implications of adoption is a further difference. The rise of the QALY provided a powerful new tool for looking at cost-effectiveness.

HTA is a convincing example of Jasanoff’s ‘co-production of science and the social order’, in which, while science shapes society, society also shapes science.⁸⁴ Scientific knowledge creates power, for drug companies and also for the state, but at the same time it is the drug companies and the state (and – far from independently of either – the research sector) which create that scientific knowledge. The causal relationship between knowledge and power is contingent and negotiable, and controlling the discourse can matter more than controlling the means of pharmaceutical production.

We should regard HTA as a ‘technology of governance’.⁸⁵ We saw earlier in the chapter how evidence-based medicine and economics were attractive to the state for reasons including their potential for cost control and the extra legitimacy which the deployment of science could provide for painful policy decisions, such as not funding a new health care technology or de-funding an existing one. HTA is a further strong example of this. Simons and Schniedemann, writing about evidence-based policymaking, remind us that ‘technologies’ (or ‘instruments’) like HTA are themselves constituencies, and not neutral tools to be deployed by more powerful actors. They speak of evidence-based policy as a ‘meta-instrument’ aiming to establish a particular role for research, which co-evolves with an ‘instrument constituency’ motivated in part by the prospect of securing an occupational niche for itself. Chapter 8 discusses the case of modelling as an example of the experts creating a role for themselves. Of course to relativise in this way the claims which HTA has made for itself is by no means to dismiss its value.

UK developments in HTA did not, of course, take place in a vacuum: indeed they were informed by examples which were already developing elsewhere. Experiments with HTA as a possible or partial solution to the mounting costs of health technologies took place in several countries, starting approximately in the 1980s and 1990s. Some of the more prominent initiatives include the following. Australia’s Pharmaceutical Benefits Scheme and New Zealand’s Pharmac were early adopters of HTA within publicly funded health care: we shall note their influence on NICE. Germany’s Institute for Quality and Efficiency in Health Care (IQWiG) was another early actor, but without the same influence on the UK.⁸⁶

⁸⁴ Jasanoff (2004).

⁸⁵ Simons and Schniedemann (2021).

⁸⁶ IQWiG, the Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (Institute for Quality and Efficiency in Health Care), Germany’s health technology assessment agency.

Thailand's Health Intervention and Technology Assessment Program (HITAP) has been a notably ambitious example from a middle-income country, a component of Thailand's policy to achieve Universal Health Coverage (UHC). Practitioners of HTA have assembled in groups such as the International Society of Technology Assessment in Health Care (ISTAHC), 1984–early 2000s; HTA International, since 2003, and the International Decision Support Initiative, since 2013.⁸⁷ HTA has been praised more widely than it has been adopted by governments. All states face the challenges in using HTA which we will see NICE navigating: their responses vary with their political contexts and priorities.

In this section we have seen an emerging set of policy options with some strong advocates. Responding particularly to growing resource pressures on the health care sector, they said that action was urgent, especially from the early 1990s. Timmins' description of this atmosphere as 'febrile' characterises it well.⁸⁸ What needs explaining is why it took until autumn 1997 to produce significant policy response.

Politics: why was there no major initiative before 1997?

Kingdon's 'multiple streams' approach to understanding policymaking seems helpful in suggesting that policy decisions are not taken until problems, policies and politics align. We have seen the 'problem' develop from at least the 1970s, and discussed policies gradually being put forward from about the same era. It does seem to have been politics which prevented major steps from being taken before the 1997 move to set up NICE. For example, the debate about priority setting became more intense from the 1980s, but led only to very tentative measures, as we will show next. This was despite a ferment of publications, debate and private initiatives like the 'Healthcare 2000' commission, led by a former head of the NHS Management Executive, Duncan Nichol. Patricia Hewitt, whom we will meet as a Labour Health Secretary in Chapter 5, was the deputy chair of Healthcare 2000: at this time, she had moved from a think tank, the Labour-friendly Institute for Public Policy Research, to the management consultants Accenture.⁸⁹ Other think tanks prominent in these debates included the Nuffield Trust, the King's Fund and the Office for Health Economics. This latter was funded by the pharmaceutical industry: it was energetic in getting health economic thinking noticed in the policy world.

None of these interventions, high-powered or otherwise, got much purchase on government policy in the short term. Why not? The first part of the answer lies in the context of politics at the time. John Major's two 1990–97 administrations were weak governments which lacked the political capital necessary to do something potentially unpopular. Major was constantly being undermined from the Right by the so-called 'Euro-sceptic' wing of his party, while a succession of

⁸⁷ HTAi, *Historical Information*; NICE International, *Review 2014*.

⁸⁸ Timmins (2016), 27.

⁸⁹ Patricia Hewitt, interview 18 December 2019; Nicholas Timmins: personal communication.

high-profile allegations of corruption against Conservative MPs further weakened the government's political standing. Busy fighting these distractions, Major and his Health Secretaries, William Waldegrave, Virginia Bottomley and Steven Dorrell, were not looking for trouble in new policy areas.

Further political considerations also stood in the way of setting up a new organisation for HTA. The quasi-market approach to managing health care that the 1991 reforms had brought in would, to some in the Conservative Party, have ruled out creating a quasi-government body. Major was dismantling and reshaping NHS structures, not creating new ones. And his government was under attack from Labour for having too many unaccountable quangos.⁹⁰ All this made it unlikely that a Conservative government would create a new one.

Closer to home for the Health Secretaries, the Government's health policy agenda was already over-full. Implementing the 1991 internal market reforms of the NHS was the biggest, most challenging set of changes in NHS history. It left little space for ministers to think about other tasks. By the time that they had, nonetheless, carved out space for a major public health White Paper and a programme of primary care improvements, there was no room left for thinking about priority-setting in a radical way.⁹¹ It was one of the problems marked 'too difficult'. All governments have preferred rearranging the governance of the NHS to engaging with any of the hardest problems (for instance tackling the social determinants of poor health and inequalities, reconciling demand with willingness to fund, building a satisfactory and sustainable social care system, or ensuring a sufficient workforce is available).

But it is also difficult to think that radical steps would have been taken even without the distractions. An approach to priority setting which even appeared to question the fundamentals of a universal NHS offering (free at the point of use) would have cost the Conservatives more political capital than it would to other parties. Part of the political legacy of the Thatcher NHS reforms was a vulnerability to attacks from the Left questioning the Conservatives' commitment to the NHS. The former Conservative Chancellor Nigel Lawson illustrated the political problem when he famously complained in 1992 that the NHS was the closest thing the British had to a national religion.⁹² Priority setting in health care in 1990s England is a good case of the old argument that a party seen as an institution's 'friend' gets more political licence from voters to reform it radically than one seen as its 'enemy'. New Labour benefited from this in 1997, as we shall see in Chapter 2.

The absence of a faster political response to this combination of problem with available policy options would not greatly surprise many political scientists. Those who adopt the 'advocacy coalition' framework have suggested that major policy

90 Blair was promising to consign the quango state 'to the dustbin of history' Leader's speech, Blackpool, 1996: British Political Speech. Nicholas Timmins, personal communication.

91 On the content of this policy agenda, see for example Ham (2009).

92 Delamothe (2008).

change is rare, because ‘policy core beliefs’ are usually rigidly held.⁹³ Policy-oriented learning, while possible, usually happens over the long term. Policy advocates should often expect it to take a decade to make the political breakthrough they seek.⁹⁴ The best application of political theory to understanding the absence of policy initiatives on priority-setting in England in the 1990s may be in the political framing of the problem. The theory stresses that the way the problem is framed is important and contested. We suggest that, perceiving that activism over priority setting would only ever lose them votes, 1990s Conservatives took pains to frame the resource pressures on the NHS as something that internal market reforms would deal with by increasing efficiency. A secondary strategy was diverting attention to other topics and (rightly or wrongly) downplaying the importance of the priority-setting challenge.

As testimony to the slowness of the policy learning process, we close this section with a reminiscence by Mike Rawlins of a conversation with one of Dorrell’s junior ministers from 1994 to 1997, Gerry Malone:

[He] did say to me once, some years after NICE had been established, that he never had the idea of NICE but he did recognise when he was a minister that something needed to be done, and it couldn’t go on as it was, but they didn’t really have anything to offer on it.⁹⁵

Some first English steps (1977–97)

Here we look at the policy initiatives which did get under way. Many were tentative and committed government to no more than funding a piece of research. Some had larger implications. Enthusiasts had published sporadically on the cost-effectiveness of interventions since at least the 1940s: their recommendations were not often taken up in policy.⁹⁶ The establishment of a Government Economic Service and the arrival of economists at the health ministry began to alter this from the 1970s. For example the DHSS economist Hurst (whom we shall meet again in Chapter 2) published an estimate in 1977 that the NHS could save £100 million by reducing average length of stay.⁹⁷ Work of this type typically identified variation between hospitals and showed the benefits achievable if all were to reach the performance of the best.

Terri Banks, one of DHSS’ top finance officials from the mid-1970s to about 1990, recalls a long-running effort on her part to introduce programme budgeting there – Hurst was a key member of her team.⁹⁸ This would use routinely collected

93 Jenkins-Smith et al. (2017).

94 Cairney (2016).

95 Mike Rawlins, in Atkinson and Sheard (2020). For Gerry Malone’s career, see <https://members.parliament.uk/member/1272/career>.

96 Sheard (2013).

97 Hurst (1977).

98 Terri Banks, interview, September 2017.

information to generate an understanding of what different programmes (e.g., services for the elderly) cost, and what level of activity spending could buy. It was useful for planning, accountability and, most particularly, for strengthening the DHSS case in Public Expenditure Survey negotiations with Treasury. Although Banks was frustrated that the results being measured were often intermediate outputs, not health benefits, this work set the culture for later attempts to link costs and benefits in greater detail than programme level. There were, for example, experiments with applying HTA to CABGs, hip replacement, heart transplants (in 1985) and breast cancer screening (in the Forrest Report of 1986).⁹⁹

The heart transplant and breast cancer screening studies were, in Smee's words, 'seminal' to the systematic use of HTA in DHSS' work, a transition that took place at the end of the 1980s.¹⁰⁰ The Department set up a Standing Group on HTA in 1993, for example, under the leadership of Miles Irving. The increasing amount of HTA being commissioned through the 1990s fed directly into the NICE HTA model, which we will discuss in Chapter 5. DH economists, led by Smee, took a central role in advising on methods, selecting the academic health economists for advisory committees and developing the capacity to carry out the new work.

Not all the initiatives came from the centre, however. One initiative that is widely praised by those involved, for its role in pushing HTA forward in the NHS, was the opening of Drug Evaluation Committees by NHS Regional Health Authorities (RHAs). About four were established in different regions: the Wessex one has become best-known and went by the name of the Development and Evaluation Committee (DEC).¹⁰¹ Its work was well summarised at the time by Andrew Stevens (who went on to play a significant part in NICE's drug appraisal committees).¹⁰² NHS purchasers and providers identified locally important topics, which were evaluated by a team working to a well-defined format in 'a service-led academic institute', the Wessex Institute of Public Health.

Several of these features are direct forerunners of NICE's HTA model. The Wessex DEC was the idea of Dr Graham Winyard, an innovative public health doctor who later moved to DH and was eventually a Deputy Chief Medical Officer there. He describes the DEC as a response to the internal market, which in his view created a need to provide information for purchasers (all the clinical knowledge being with the providers at that stage). The DEC won backing of the RHA and of 'real medical heavy hitters' in the region.¹⁰³ So when Winyard went to DH, he knew this model worked. We will take up the story of his input to the birth of NICE in Chapter 2.

The establishment of the NHS R&D programme in 1991, on which we have already published, was an expression of DH's growing interest in using evidence

99 Smee (2005), 79–99; Buxton (1985); DHSS (1986).

100 Smee (2005), 82. Note here that the DHSS split in 1987, into the Department of Health (DH) and the Department of Social Security.

101 Bruce Campbell, interview.

102 Stevens et al. (1995).

103 Graham Winyard, personal communication.

to inform the delivery of health care.¹⁰⁴ The programme's charismatic first Director, Michael Peckham, thoroughly embraced the 'economising' health economic perspective discussed here: 'the [1991 NHS] reforms in a way began to introduce the notion of, "should we buy that rather than that?" which was knowing about cost-effectiveness and evidence'.¹⁰⁵ There was strong support for the recently-established HTA programme, allowing it, unlike many HTA initiatives worldwide, to commission new research on effectiveness as well as reviewing existing findings. Indeed, HTA was close to the centre of the new R&D programme's attention. Tom Walley, the HTA's Director in the early 2000s, comments that 'people at the time often referred to the HTA Programme as the "jewel in the crown" of the R&D Programme, basically because it was the only jewel'.¹⁰⁶

DH's NHS R&D programme began to create other important resources for evidence-based medicine. In 1992, responding to a proposal from Iain Chalmers, it funded the establishment of the Cochrane Centre, which built on Chalmers' development of an evidence base at his National Perinatal Epidemiology Unit. The centre became an international collaboration producing a growing number of regularly updated systematic reviews of evidence.¹⁰⁷ An NHS Centre for Reviews and Dissemination was opened at the York CHE in 1993, charged with publishing 'Effective Healthcare Bulletins'.¹⁰⁸ All of this amounted to a new place in the sun for evidence-based medicine. It began giving a new intellectual authority to guidelines produced in the new ways. At this stage, though, their purchase on NHS decisions about what services to provide was tentative. Evidence-based medicine's advocates had convinced government that it was a good idea: the easy part. The harder challenge remained, to convince enough doctors and medical leaders. Without that, a government short of political capital, such as those of 1990–97, would do little to back this policy agenda with firmer action.

As well as developments in the world of evidence-based medicine and HTA, the policy debate about using cost-effectiveness in decisions about the NHS' use of drugs began to have an impact on government decisions by the mid-1990s. This impact was slow to begin: our earlier examples show a lack of impact. For example, in 1994, the House of Commons Health Committee produced a report giving support in principle to the idea of making cost-effectiveness a 'fourth hurdle' which new drugs must cross (in addition to safety, quality and efficacy).¹⁰⁹ This was one of many Parliamentary recommendations not taken up by Government, and there was nothing remarkable in this, but in the right circumstances it could have triggered a programme of work. Similarly the famous 1995 'Child B' case, in which Cambridge Health Authority had to defend in court a decision not to provide a second

104 Atkinson et al. (2019). For Peckham's approach, see Peckham and Smith (1996).

105 Michael Peckham, interview 23 August 2017.

106 Tom Walley, interview 23 February 2017.

107 Daly (2005), 166–168.

108 Timmins (2016), 21.

109 Timmins (2016), 22; House of Commons Health Committee (1994).

bone marrow transplant or chemotherapy, although it prompted much reflection in the policy world, did not lead to any government intervention or policy change.¹¹⁰

In the same year, DH managed the controversy over whether the NHS would fund the use of beta interferon for multiple sclerosis by adopting delaying tactics. Timmins quotes his interview with Malone on this, with Malone saying:

I told ... the great and the good ... I really don't want to ban this but we are going to have to go fairly slowly to prove it, and to discover whether it is in fact effective.¹¹¹

A DH Executive Letter told health authorities the use of beta interferon was up to them: a prolongation of the postcode lottery approach which satisfied no-one. Looking to the future, however, Malone reports that he asked officials to 'devise some scheme where ministers do not have to take these decisions', seeing himself – very reasonably in one sense – as the least qualified person in the room to take the decision.¹¹² This is a clear illustration of the desire among ministers to diffuse responsibility, discussed at the start of this chapter. This episode was also the trigger for DH beginning its horizon-scanning operation to spot emerging expensive technologies which would pose problems, a mechanism later used in deciding on referrals to NICE (see Chapter 5).

There were also public political commitments to evidence-based medicine. When Dorrell, Conservative Secretary of State for Health, wanted to emphasise his party's commitment to the NHS in 1996, he chose evidence-based medicine as one of the main pledges to include in that curious manifesto in the form of a White Paper, *The NHS: A service with ambitions*.¹¹³ And in the same year, the NHS Executive nailed its colours to the mast with the statement:

The overall purpose of the NHS is to secure, through the resources available, the greatest possible improvement in the physical and mental health of the people ... In order to achieve this, we need to ensure that decisions about the provision and delivery of clinical services are driven increasingly by evidence of clinical and cost-effectiveness, coupled with the systematic assessment of actual health outcomes.¹¹⁴

Here was a very clear commitment to maximising health gain per pound spent, and to the use of evidence-based medicine ('clinical effectiveness') and HTA ('cost-effectiveness') to secure this. The influence these linked ideas had by now was powerful enough to survive the 1997 change of government, as we shall see in Chapter 2.

110 Ham (1999).

111 Timmins (2016), 32.

112 Timmins (2016), 32.

113 Secretary of State for Health (1996).

114 NHS Executive (1996).

We close this survey of policy developments before 1997 with a short look at the influence of Smee, who filled the DH Chief Economic Adviser role at this time. In his long tenure (1984–2002), he played an important part in raising the profile of economics in health policy. Good examples include the growing frequency of his contacts with Secretaries of State. While once a year may have been:

...par for the course when I first went into the Economic Adviser's Office ... by the time I'd left, I would feel neglected if I hadn't seen him or her probably once a week, sometimes every day of the week, depending on what we were working on.¹¹⁵

The Special Adviser Simon Stevens' testimony about Smee is that he was:

a very effective synthesiser of sensible wisdom from the health economics world. ... Alan Maynard and lots of other good people contributed [but] Clive was able to bring it together. And [there] was his personal stature ... which meant that he was trusted, ... politicians listened to Clive.¹¹⁶

Smee's importance to the question of priority-setting, pre-eminently one in which to call on economic advice, is suggested too by memberships of working groups of officials, something in which Smee excelled at putting himself and his economist colleagues forward. Intriguingly (as there is no more information on this group),

I found that I would be asked to join working groups or whatever to look at things which were hush hush. ... So we did at one point [before 1997] have a working party on rationing. How we might start rationing health services and what criteria we would use for that?¹¹⁷

He also played a long-term role in encouraging the academic economists to develop the QALY. Williams had been his mentor in his early days in government, showing Smee (who had no specialised training in health economics) what the important issues in health policy were.¹¹⁸ This linked Smee with York, which DHSS partly funded. At times, Smee shielded work developing the QALY from ministerial attention, fearing that they would misunderstand and oppose it:

I was amazed at how quickly the Department accepted cost per QALY and for a long time, we actually kept partly hidden from ministers what we were doing in that area. ... we thought Dobson would not understand cost per QALY and yet we were by then commissioning evaluations all over the

115 Clive Smee, interview 1 March 2016.

116 Simon Stevens, interview.

117 Smee interview, May/June 2016.

118 Smee, interview 1 March 2016.

place, looking at breast cancer screening or whatever it was and coming up with... I don't think he read the reports. But subsequently I don't think he was as big a fool as we thought he was. ... I can certainly remember times when I thought 'my God, I hope this report is not going near Dobson he will say stop all this nonsense.'¹¹⁹

Smee's 1996 sabbatical to North America, Australia and New Zealand, as he reported, told him 'we were off the pace in the use of cost-effectiveness criteria in evaluating new drugs'.¹²⁰ It is likely that this encouraged him in his next step in this area. (The Department's willingness to release its chief economist for 12 weeks may, though, also suggest the degree of drift it was in by 1996.)

In early 1997 Smee set up an Expert Workshop on DH Guidelines for Pharmaco-Economic Studies, of which we have seen the unpublished papers. They devised guidelines for evaluating the cost-effectiveness of drugs, reporting early in 1998. Charles Dobson tells us this document, unsurprisingly, fed directly into DH's preliminary work on how NICE appraisal should be organised (see Chapter 2).¹²¹ York health economists were prominent, Culyer (later vice-chair of NICE) taking the chair. Other main commentators on the papers were Buxton (above) and Adrian Towse, the Director of the Office for Health Economics.

In this account of a disparate range of government initiatives, and decisions *not* to intervene, we can see a pattern in which officials often made the running, putting proposals to ministers. They engaged with the 'policy stream', as one would expect: this engagement led them to advocate taking up some of its proposals. Ministers showed an understandable reluctance. We single out Smee as the pre-eminent example of this activism, though Peckham's role in the broader process of making evidence-based medicine part of policy was also important. (In Towse's words, 'without Michael Peckham and without Clive Smee it wouldn't have been possible to set up NICE when it was set up'.)¹²² To a large degree Smee fits the picture Kingdon has painted of the 'policy entrepreneur', a person who provides the necessary agency to bring together the problem, policy and politics streams, leading to action. This reading of Smee's influence is informed by Cairney's comment that policy entrepreneurs 'tend to be the people who know when to act, rather than people who can manipulate policy processes to make things happen'.¹²³ The examples given here of Smee's patience and sense of timing suggest that he fits this interpretation.

119 Smee, interview, May/June 2016. 'Dobson' is Frank Dobson (1940–2019), Secretary of State for Health 1997–99.

120 Timmins (2016), 33.

121 Charles Dobson interview.

122 Adrian Towse, interview.

123 Cairney (2016).

Conclusion

In this chapter we have explored the intellectual origins of NICE in new ideas about using evidence to make health policy. Most important of these, because it shaped the application of the others, was the economising approach to shaping health policy goals. Essentially neoliberal and rooted in the thinking of US economists like Arrow, this way of thinking stressed improving efficiency, minimising risks for third party payers, cost containment, and improving the working of the market. Other forms of health economic thinking existed: UK governments found them less useful and largely left them aside.

To speak of new ideas about using evidence in health policy in this way reveals how the story of NICE's origins fits into the pattern described by Moreira.¹²⁴ His thesis is that knowledge production has been at the heart of recent transformations of health care: via the market, embedding economic rationality; the laboratory, through the use of scientific evidence in policy; and the 'forum', applying deliberative procedures in decision-making. It is clear from his work that NICE is among the examples leading Moreira to these conclusions, and we shall see that it is a good exemplar of all three cases.

What we have seen so far in this chapter are beginnings, with methodologies emerging and winning credibility. Sometimes, this was an uphill intellectual struggle, for example in medical academia at times, or when a wider range of people criticised the thinking behind the QALY. There was some movement, but not yet in the direction of a separate body like NICE. As long as the methodologies which were developing were in the hands of academic researchers, dependent on a DH R&D Directorate for funds, their purchase on what happened in the NHS would always be indirect and precarious.

Going further, even handing these tools to an arm's-length body like NICE was in itself no guarantee that the NHS would start to change. That would require the body to be one with the self-confidence, and the political backing, to operate in radical ways. We will see in the next chapter how a new political scene opened a policy window for establishing a new organisation: Chapter 3 will examine how NICE was able to press this agenda well beyond the 1997 government's initial hopes and expectations.

Bibliography

Primary sources

BBC1 *The Heart of the Matter* 7 October 1986 (TV programme).

BBC *The Life and Death Game* 10 June 1987 (TV programme).

Blair T Leader's speech, Blackpool, 1996: British Political Speech (Last accessed 27 September 2024).

124 Moreira (2012).

- Department of Health and Social Security (1986) *Breast Cancer Screening (Forrest Report)* (London: HMSO).
- House of Commons Health Committee (1994) *Priority Setting in the NHS: The NHS Drugs Budget*. Second Report, Session 1993–94 (London: HMSO).
- ITV *This Week* 9 October 1986 (TV programme).
- ITV *This Week* 16 October 1986 (TV programme).
- National Institute for Health Research (n.d.) HTA programme (Last accessed 7 January 2022).
- NHS Executive (1996) *Clinical Guidelines: Using Clinical Guidelines to Improve Patient Care within the NHS* (London: Department of Health).
- NICE International (2014) *Review 2014* (Last accessed 6 April 2023).
- Office of Fair Trading (2007) *The Pharmaceutical Price Regulation Scheme: An OFT Market Study* (London: Office of Fair Trading).
- Scotsman* 5 January 1987.
- Secretary of State for Health (1996) *The NHS: A Service with Ambitions* Cm 3425 (London: TSO).

Secondary sources

- Aaron H (1978) *Politics and the Professors: The Great Society in Perspective* (Washington DC: Brookings Institution).
- Anderson O (1996) Influence of social and economic research on public policy in the health field: a review. *Milbank Memorial Fund Quarterly/Health and Society* 44(3), 11–51.
- Arrow K (1963) Uncertainty and the welfare economics of medical care. *American Economic Review* 53(5), 941–973.
- Arrow K, Bernheim B, Feldstein M, McFadden D, Poterba J & Solow R (2011) 100 years of the American economic review: the top 20 articles. *American Economic Review* 101, 1–8.
- Ashmore M, Mulkay M & Pinch T (1989) *Health and Efficiency. A Sociology of Health Economics* (Buckingham: Open University Press).
- Atkinson P, Sheard S & Walley T (2019) “All the stars were aligned”? The origins of England’s National Institute for Health Research. *Health Research Policy and Systems*, 17(1).
- Atkinson P & Sheard S (eds) (2020) *Origins and Establishment of NICE (c. 1997 – 2002)*, witness seminar held online on 18 June 2020 (Liverpool: Department of Public Health and Policy, University of Liverpool).
- Belkin G (1997) The technocratic wish: making sense and finding power in the managed medical market place. *Journal of Health Politics, Policy and Law* 22, 509–532.
- Berg R (ed) (1973) *Health Status Indexes* (Chicago: Hospital Research and Educational Trust).
- Blaug M (1998) Where are we now in British Health Economics? *Health Economics* (7), S63–S78.
- Bledstein B (1976) *The Culture of Professionalism. The Middle Class and the Development of Higher Education in America* (New York: Norton).
- Bolt T (2015) *A Doctor’s Order. The Dutch Case of Evidence-based Medicine (1970–2015)* (Antwerp: Garant).
- Brown R (1979) *Reorganising the National Health Service* (Oxford: Blackwell).
- Buxton M (1985) *Measurement of the costs and benefits of heart transplant programmes at harefield and papworth hospitals* (London: HMSO).
- Cairney P (2016) *The politics of evidence-based policy making* (Basingstoke: Palgrave MacMillan).

- Carr-Hill R & Sheldon T (1992) Rationality and the use of formulae in the allocation of resources to health care. *Journal of Public Health Medicine* 14(2), 117–126.
- Cochrane A (1972) *Effectiveness and Efficiency: Random Reflections on Health Services* (London: Nuffield Provincial Hospitals Trust).
- Cooper M & Culyer A (1970) *An economic assessment of some aspects of the organisation of the National Health Service*. Appendix A of the BMA report Health Services Financing (London: BMA).
- Coulter A & Ham C (eds) (2000) *The Global Challenge of Health Care Rationing* (Buckingham: Open University Press).
- Croxson B (1998) From private club to professional network: an economic history of the Health Economists' Study Group, 1972–1997. *Health Economics* 7(S1), S9–S45.
- Culyer A (1972) The “market” versus the “state” in medical care, in McLachlan G (ed) *Problems and Progress in Medical Care* Vol. 3 (London: Nuffield Provincial Hospitals Trust), 1–32.
- Culyer A (1981) Health, economics and health economics, in Van der Gaag J & Perlman M (eds) *Health, Economics and Health Economics* (Amsterdam: North Holland Publishing Company), 3–14.
- Daly J (2005) *Evidence Based Medicine and the Search for a Science of Clinical Care* (Berkeley: University of California Press).
- Delamothe T (2008) A fairly happy birthday. *BMJ* 337(7660), a524.
- Dixon J & Welch H (1991) Priority setting: lessons from Oregon. *Lancet* 337(8746), 891–894.
- Drummond M (1981a) *Principles of Economic Appraisal in Health Care* (Oxford: Oxford University Press).
- Drummond M (1981b) *Studies in Economic Appraisal in Health Care* (Oxford: Oxford University Press).
- Facey K (2017) Health technology assessment, in Facey K, Single A & Hansen H (eds) *Patient Involvement in Health Technology Assessment* (Singapore: Springer Nature).
- Fanshel S & Bush J (1970) A health status index and its application to health services outcomes. *Operations Research* 18(6), 1021–1066.
- Ferlie E (2001) Public management in the United Kingdom: efficiency and accountability. *Politiques et Management Public* 19(3), 121–138.
- Forget E (2004) Contested histories of an applied field: the case of health economics. *Journal of Political Economy* 36(4), 617–637.
- Fox D (1990) Health policy and the politics of research in the United States. *Journal of Health Politics, Policy and Law* 15(3), 481–499.
- Freeman R & Sturdy S (2014) Knowledge in policy: embodied, inscribed, enacted, in Freeman R & Sturdy S (eds) *Knowledge in Policy* (Bristol: Policy Press), 1–17.
- Greener I & Powell M (2008) The changing governance of the NHS: reform in a post-Keynesian health service. *Human Relations* 61(5), 617–636.
- Greenhalgh T (2020) Will COVID-19 be evidence-based medicine's nemesis? *PLoS Medicine* 17(6), e1003266.
- Grogano A & Woodgate D (1971) Index for measuring health. *Lancet* II, 1024–1026.
- Ham C, Hunter D & Robinson R (1995) Evidence based policymaking. *BMJ* 310(6972), 71.
- Ham C (1999) Tragic choices in health care: lessons from the Child B case. *BMJ* 319(7219), 1258–1261.
- Ham C (2000) *The Politics of NHS Reform, 1988–97: Metaphor or Reality?* (London: King's Fund).
- Ham C (2009) *Health Policy in Britain*, sixth edition (Basingstoke: Palgrave MacMillan).

- Hammer P, Haas-Wilson D & Sage W (2001) Kenneth arrow and the changing economics of health care: “Why arrow? Why now? *Journal of Health Politics, Policy and Law* 26(5), 8365–8849.
- Hammond J, Speed E, Allen P, McDermott I, Coleman A & Checkland K (2018) Autonomy, accountability and ambiguity in arm’s length meta-governance: the case of NHS England. *Public Management Review* 21(8), 1148–1169.
- Harris J (1985) *The Value of Life* (London: Routledge and Keegan Paul).
- Harrison S (1998) The politics of evidence-based medicine in the United Kingdom. *Policy & Politics* 26(1), 15–31.
- Haywood S & Alaszewski A (1980) *Crisis in the Health Service: The Politics of Management* (London: Croom Helm).
- Holland W (2002) *Foundations for Health Improvement: Productive Epidemiological Public Health Research 1919–1998* (London: The Stationery Office).
- HTAi (n.d.) HTAi, *Historical Information* (Last accessed 14 December 2021).
- Hunt S, McEwen J & McKenna S (1986) *Measuring Health Status* (London: Croom Helm).
- Hunter D (1997) *Desperately Seeking Solutions: Rationing Health Care* (London: Longman).
- Hurst J (1977) *Saving Hospital Expenditure by Reducing in-Patient Stay* (London: Government Economic Service Series No. 14: HMSO).
- Hurst J (1998) The impact of health economics on health policy in England, and the impact of health policy on health economics. *Health Economics* 7(S1), S47–S62.
- Jasanoff S (1990) *The Fifth Branch: Science Advisers as Policymakers* (Cambridge, MA: Harvard University Press).
- Jasanoff S (ed) (2004) *States of Knowledge: The Co-Production of Science and the Social Order* (London: Routledge).
- Jenkins-Smith H, Nohrstedt D, Weible C & Ingold K (2017) The advocacy coalition framework: an overview of the research program, in Weible C & Sabatier P (eds) *Theories of the Policy Process* (Boulder, CO: Routledge), 135–171.
- Kind P, Rosser R & Williams A (1982) Valuation of quality of life: some psychometric evidence, in Jones-Lee M (ed) *The Value of Life and Safety* (Amsterdam: North Holland), 159–170.
- Kingdon J (2003) *Agendas, Alternatives and Public Policies*, second edition (New York: Longman).
- King’s Fund (2018) The rising cost of medicines to the NHS: what’s the story? (Last accessed 18 September 2024).
- Klein R (1976) The rise and decline of policy analysis: the strange case of health policymaking in Britain. *Policy Analysis* 2(3), 459–475.
- Klein R (1990) Research, policy and the national health service. *Journal of Health Politics, Policy and Law* 15(3), 501–523.
- Klein R (1996) The NHS and the new scientism: solution or delusion? *Quarterly Journal of Medicine* 89(1), 85–87.
- Klein R, Day P & Redmayne S (1996) *Managing Scarcity: Priority Setting and Rationing in the National Health Service* (Buckingham: Open University Press).
- Klein R & Williams A (2000) Setting priorities: what is holding us back – inadequate information or inadequate institutions? in Coulter A & Ham C (eds) *The Global Challenge of Health Care Rationing* (Buckingham: Open University Press), 15–26.
- Klein R (2013) *The new politics of the NHS*, seventh edition (Boca Raton, FL: CRC Press).
- Lee K & Mills A (1979) The contribution of economics to health service planning. *Health and Social Service Journal* 89(4627), C35–C40.

- Luce T (1987) Thirty years of pharmaceutical price regulation: developments in the National Health Service Price Regulation Scheme since 1957, in Teeling Smith G (ed) *Costs and Benefits of Pharmaceutical Research* (London: Office of Health Economics), 28–31.
- Mackillop E & Sheard S (2018) Quantifying life: understanding the history of Quality-Adjusted Life Years (QALYs). *Social Science and Medicine* (211), 359–366.
- Mackillop E, Sheard S & Lambert M (eds) (2018) *The Development of Health Economics and the Role of the University of York* (Liverpool: Department of Public Health and Policy, University of Liverpool).
- Mackillop E & Sheard S (2019) The politics of health policy knowledge transfer: the evolution of the role of British health economics academic units. *Evidence and Policy* 4(15), 489–507.
- Majone G (1989) *Evidence, Argument and Persuasion in the Policy Process* (New Haven, CT: Yale University Press).
- Markoff J & Montecinos V (1993) The ubiquitous rise of economists. *Journal of Public Policy* 13(1), 37–68.
- Maynard A (2008) The public-private challenge in health care, in Mason A & Towse A (eds) *The Ideas and Influence of Alan Williams: Be Reasonable – Do It My Way* (London: Office of Health Economics) 27–46.
- McLachlan G (1992) *A History of the Nuffield Provincial Hospitals Trust* (London: Nuffield Trust).
- Melhado E (2000) Economic theory, economists, and the formulation of health policy. *Journal of Health Politics, Policy and Law* 25(1), 244, 247.
- Moreira T (2012) *The Transformation of Contemporary Health Care: The Market, the Laboratory, and the Forum* (Oxford: Taylor & Francis).
- Nelson R (1987) The economics profession and the making of public policy. *Journal of Economic Literature* 25, 49–91.
- New B (1996) The rationing agenda in the NHS. *BMJ* 312(7046), 1593–1601.
- Peckham M & Smith R (1996) *Scientific Basis of Health Services* (London: BMJ Publishing Group).
- Pliskin J, Shepard D & Weinstein M (1980) Utility functions for life years and health status. *Operations Research* 1(28), 206–224.
- Raftery J (2013) Value based pricing: can it work? *BMJ* 347, 18–19.
- Rathwell T (1987) *Strategic Planning in the Health Sector* (London: Croom Helm).
- Rhoads S (1978) Economists and policy analysis. *Public Administration Review* 38, 112–120.
- Rodwin M (2001) The politics of evidence-based medicine. *Journal of Health Politics, Policy and Law* 26(2), 439–446.
- Rose R (1989) Political economy and public policy: the problems of joint appraisal, in Samuels W (ed) *Fundamentals of the Economic Role of Government* (New York: Greenwood Press), 147–156.
- Rosser R & Watts V (1974) The development of a classification of the symptoms of sickness and its use to measure the output of a hospital, in Lees D & Shaw S (eds) *Impairment Disability and Handicap* (London: Heinemann Educational Books for the SSRC), 157–170.
- Rosser R & Kind P (1978) A scale of valuations of states of illness: is there a social consensus? *International Journal of Epidemiology*, 7, 247–358
- Sackett D & Torrance G (1978) The utility of different health states as perceived by the general public. *Journal of Chronic Diseases*, 31, 697–704.
- Shapin S (1995) Here and everywhere: sociology of scientific knowledge. *Annual Review of Sociology* 21, 289–321.

- Sheard S & Donaldson L (2005) *The Nation's Doctor. The Role of the Chief Medical Officer, 1855–1998* (Oxford: Radcliffe Medical Press).
- Sheard S (2013) Getting better faster: convalescence and length of stay in British and US Hospitals, in Abreu L & Sheard S (eds) *Hospital Life: Theory and Practice from the Medieval to the Modern* (Bern: Peter Lang), 299–330.
- Sheard S (2014) *The Passionate Economist. How Brian Abel-Smith Shaped Global Health and Social Welfare* (Bristol: Policy Press).
- Simons A & Schniedermann A (2021) The neglected politics behind evidence-based policy: shedding light on instrument constituency dynamics. *Policy & Politics* 49(4), 513–529.
- Smee C (2005) *Speaking Truth to Power: Two Decades of Analysis in the Department of Health* (Oxford: Radcliffe).
- Stevens A, Colin-Jones D & Gabbay J (1995) Quick and clean: authoritative health technology assessment for local health care contracting. *Health Trends* 27, 37–42.
- Syrett K (2003) A technocratic fix to the “legitimacy problem”? The Blair government and health care rationing in the United Kingdom. *Journal of Health Politics, Policy and Law* 28(4), 715–746.
- Timmins N (2016) *A Terrible Beauty: A Short History of NICE* (Nonthaburi: Health Intervention and Technology Assessment Program HITAP).
- Weisz G, Cambrosio A, Keating P, Knaapen L, Schlich T & Tournay V (2007) The emergence of clinical practice guidelines. *Milbank Quarterly* 4, 691.
- Wildavsky A (1985) The once and future school of public policy. *Public Interest* 79, 25–41.
- Williams A (1985) The economics of coronary artery bypass grafting. *British Medical Journal* (291), 326–329.
- Williams A (1997) All cost-effective treatments should be free... OR how Archie Cochrane changed my life!, The Cochrane Lecture. *Journal of Epidemiology and Community Health* 51(2), 116–120.
- Williams A (2005) Discovering the QALY OR how Rachel Rosser changed my life, in Oliver A (ed) *Personal Histories in Health Research* (London: Nuffield Trust), 191–206.
- Woolcock M, Szreter S & Rao V (2011) How and why does history matter for development policy? *Journal of Development Studies* 47(1), 70–96.
- Zeckhauser R & Shepard D (1976) Where now for saving lives? *Law and Contemporary Problems* 40(4), 5–45.

2 A policy window opens (May 1997–Autumn 1999)

This chapter describes the short-term opportunity that allowed the establishment of NICE in 1997–99, and asks why the arrival of a New Labour government was the catalyst for NICE’s emergence.¹ It makes use of the political science concept of a ‘policy window’. Though older than Kingdon’s multiple streams analysis, this concept was important for Kingdon and reached a wider audience through his work. The theory proposes that decisions are taken only when there is a ‘coupling’ of problem, policy and politics. Such a window may be opened by a change in the ‘problem’ stream (e.g., a problem becoming acute) or in the ‘politics’ stream (e.g., a change of administration or other event bringing new participants with different views to the fore). (As the ‘policy’ stream develops more slowly, it’s less likely that a new policy would open a ‘window’.) This coupling is made by ‘policy entrepreneurs’, a concept we encountered in Chapter 1. Policy windows can also close rapidly, for example when (as in the case of British health policy in the 1990s) a new administration starts making decisions, which invariably please some but disappoint others, bringing an end to the honeymoon period in which people look to the newcomers with a degree of anticipation.²

1997: the early New Labour policy decisions

The May 1997 change of administration, the election of a New Labour government under Tony Blair with a large Parliamentary majority, certainly seems to have provided the policy window in which a national body could be set up, charged with using the tools of Health Technology Assessment (HTA) and evidence-based medicine to promote effectiveness and cost-effectiveness in the National Health Service (NHS). We saw at the end of Chapter 1 how the previous administration was either unwilling or felt itself unable to press forward with this, although potentially sympathetic to the idea.

1 Regarding the usage ‘New Labour’, the Labour Party never changed its name, but in this era its leaders took pains to present it as ‘New Labour’.

2 Kingdon (2003), 169.

Labour's public position before the election had largely been opposition to the Conservative internal market reforms of 1991. There was very little detail about what New Labour would do differently: probably good politics but not promising in terms of policy. Alan Milburn, who was appointed to the number 2 position in Department of Health (DH), admitted that when Blair appointed him, he gave him the job of coming up with a health policy, 'because when you're in opposition you don't really have one you have a sort of ... skeletal framework'.³ This goal very rapidly became a project to produce a White Paper (policy statement) on the reform of the NHS, a task for which Milburn was made the lead minister, and in which he was ably assisted by the Special Adviser Simon Stevens.

It was Milburn and Stevens who made the main political contribution to setting up NICE. Milburn was widely seen by colleagues as energetic and ambitious (he was later, briefly, to be tipped as a future Prime Minister): politically and personally he was close to Blair.⁴ Stevens was a gifted and ambitious Labour activist and NHS manager whose later career has included being a Vice President at the US United Healthcare Group, Chief Executive of NHS England (2014–21) and subsequently a member of the House of Lords.⁵ In overall charge of DH was Frank Dobson, a figure firmly identified with old rather than 'New' Labour. Dobson took a back seat in the policy work of 1997 discussed here, but was to demonstrate his interest in NICE and grasp of the policy and politics involved a little later, as we shall see.

Establishing NICE was, then, one strand of a larger set of policies about the NHS. The logic (or at least the White Paper narrative) binding these together was slow to emerge. In Milburn's recollection:

the big picture was how did you ... overcome the anarchy that had become the architecture of the NHS. GP fund holders here, GP non-fund holders there, some national standards but no overall national architecture, none of the drivers that you would see in comparable sectors of the economy around regulation and national standards and so on. So it was quite a big thing that I was trying to trying to grapple with and NICE was absolutely central to that.⁶

In what sense, central? It turns out this was more than rhetoric: Milburn went on to explain:

the three big pieces of the jigsaw that were put in place were the new architecture of commissioning ... the Commission for Health Improvement [CHI] that eventually became the CQC, and then NICE.⁷

3 Alan Milburn, interview 27 July 2021.

4 See, for example, BBC News (website) (2004) Profile: Alan Milburn, 7 September 2004.

5 Stevens of Birmingham, *Who's Who & Who Was Who* (2023).

6 Milburn interview.

7 Milburn interview. CQC: the Care Quality Commission, a 2009 rebranding of CHI, or rather of its successor, the Healthcare Commission. Compared to NICE, CHI led a troubled existence.

The recollection of Andy McKeon, the DH Under-Secretary who was at the centre of the White Paper team, confirms this view about ministers’ concern to give the NHS a modernised and coherent national architecture:

Labour ministers ... were going to put the N back into the NHS so it would be genuinely a national service with national standards and the things that followed from that. ... [I don’t know if they used it publicly but] that was certainly a phrase they used in private.⁸

For McKeon, it was Baroness Margaret Jay, a Minister of State in DH, who best captured how the three elements fitted together: she ...

pitched this hardest ... she said “What we’re looking for, is when you go shopping to Marks & Spencer’s, you come out with a bag ... you know three things from that: one is, it’s a brand ... And in that bag would be a product which was of high quality and guaranteed to be of high quality” ... NICE – the names were kicked around a bit – was effectively the guarantee of quality: that was the spec[ification] for quality, and ... the care regulator ... was the guarantee – and what you had was ... NICE, which set the quality standard in clinical terms and somebody came round and inspected it: CHI. It was clear ministers wanted an inspectorate in CHI and a quality standards setter [in] NICE.⁹

Focussing, then, on the NICE strand of this thinking, three issues were at the heart of the emerging policy. The first was cost-effectiveness. Dobson and, especially, Milburn saw the value of Clive Smee’s arguments (which we saw in Chapter 1) for using HTA to get more health gain from the same finite resources. Smee later said that Milburn ‘from the start was very interested in cost-effectiveness’.¹⁰ Milburn confirmed this to us:

Clive is also absolutely right to say that ... who wouldn’t be because here we were having made a rather foolish commitment in opposition to freeze public expenditure, we come in with also a commitment to cut waiting lists and

8 Andy McKeon, interview 3 October 2019.

9 McKeon interview. The same emphasis on NICE setting quality standards against which CHI would inspect care providers is evident in TNA JA53/946 Milburn to Winyard, 2/3/98 – this had become settled policy. (Officials’ correspondence with ministers was at this time formally with their private secretaries. We have adopted the convention of naming the ministers.) Note in passing that Jay’s thinking here is the origin of the NHS’ now-ubiquitous blue and white logo. The ‘care regulator’ was CHI (see above). Ministers of State in the UK are the second tier of minister, one below members of the Cabinet. Giving this role, unusually for the time, to a member of the House of Lords rather than the Commons suggests the importance Prime Minister Blair attached to the role being given to Jay (ministers in the Lords usually have more junior functions).

10 Timmins (2016), 38.

there's no money? ... the barometer of politics around the NHS i.e. waiting lists were only going ... up when we promised that they were going down. So therefore ensuring that you literally got every penny that you could to work to its maximum benefit was a really important thing. You bet your bottom dollar I was very concerned about cost effectiveness.¹¹

Like Milburn, NICE's chair Mike Rawlins recalled clearly that the New Labour commitment not to increase spending in its first two years had sharpened the need to spend limited money cost-effectively:

also remember that when Labour came to power in 1997, they promised to use the same sort of budgets that had been previously set by Ken Clarke, they weren't increasing expenditure, so they had a problem.¹²

The second of the three issues which proposals for NICE had to address was the so-called 'postcode lottery'. Talking about cost-effectiveness was politically very unattractive. The political background (Chapter 1) had made cost control, let alone the word 'rationing', too toxic to address openly. 1997 was hardly the moment for a candid public debate about whether to restrict access to treatments. Joe McCrea, the Special Adviser in Dobson's team with responsibility for policy communications, is particularly revealing about this:

Of course NICE was rationing and it is rationing, yes? But that would have been absolutely politically toxic, for a Labour government to say we are rationing access to health care. I always remember this: when Anne Widdecombe took over as Health [spokesperson], asking a question to Tessa Jowell, and she said, 'is rationing being ended in the NHS?' and Tessa just got up and says, 'Yes', and sat down, and that was it.¹³ ... Our thing on that was, shut it down, close it down ... is there rationing in the NHS? No. End of. And not get into the debate.

Interestingly, NICE did introduce rationing, quite properly. "What we're doing is, we're making sure that everybody gets access to the same drugs, it's all done on a fair basis, and it saves the NHS money, but we're not rationing."¹⁴

McCrea's recollections show how cost-effectiveness and geographical equity both mattered to Dobson's team, though only the latter was suitable for public consumption at the time. 'Ending the postcode lottery' was the slogan: 'Why is it that in

11 Milburn interview.

12 Rawlins, in Atkinson and Sheard (2020), 16. Kenneth Clarke had been Chancellor of the Exchequer 1993–97 (previously Secretary of State for Health, 1988–90).

13 Anne Widdecombe MP was Shadow Health Secretary, 1998–99: Tessa Jowell MP was the first Minister of State for Public Health, 1997–99.

14 Joe McCrea, interview 6 December 2019.

Amber Valley I can get access to this drug, but in Erewash I can't?'¹⁵ NICE's role, said the public line, was to support equal access to drugs everywhere by ensuring that there was one national decision about which drugs were cost-effective. The attractiveness of this to politicians at the time is not to be underestimated. As McCrea told us,

I said 'what's the bloody political significance of this then?' and Frank said 'it gets rid of the postcode lottery.' ... That's all my appreciation was at that point, NICE is a thing that gets rid of the postcode lottery, end of.¹⁶

Milburn, notwithstanding his statement quoted earlier about cost-effectiveness, also told us, similarly, that:

although people now think that the origins of NICE were about cost effectiveness, actually the origins lay much more in fairness. Because the really big debate at the time was about the fairness lottery in care. I was really about ensuring that there were common approaches to the adoption of new drugs and therapies into the NHS and that the lottery ... was tackled, and obviously NICE was one mechanism to do so.¹⁷

One important question here is whether those involved believed NICE was going to save money by its application of HTA to the NHS. Big claims about this had been made for HTA for some time. Michael Peckham, the first Director of NHS R&D, who established the first NHS HTA programme in 1993, claimed in 1996 that stopping the use of technologies found to be ineffective was going to save £1 billion.¹⁸ DH's own economists were, unsurprisingly, more guarded about their expectations, as was the head of DH's Public Expenditure Survey team, Bill McCarthy.¹⁹ Smee's 2005 memoir contains no claims about global savings.²⁰ And Rawlins told the *Times* soon after his appointment to NICE in 1999: 'anyone who believes that NICE will reduce NHS expenditure is whistling in the wind'.²¹ In this he was of course following the government line: avoiding the idea that NICE was there to save money. No doubt he also spoke from conviction (and was to be proved right). The other justifications for NICE's existence – geographical equity and more access for NHS patients to the most cost-effective medicines – were increasingly deployed instead.

In contrast to Milburn, Stevens is clear that for him cost-effectiveness came first. As a Special Adviser, while Stevens was very much a Labour politician at this time,

15 McCrea interview. The reference is to two adjacent districts in Derbyshire.

16 McCrea interview.

17 Milburn interview 27 July 2021.

18 *Independent* 2 January 1996, NHS 'wastes £1 bn on ineffective treatments'.

19 TNA, JA53/946 CSR6: Machinery for Cost and Clinical Effectiveness. 4 December 1997. For the relevance of CSR Project 6, see below.

20 Smee (2005).

21 *Times* 27 May 1999, Viagra now: the Government cannot escape the reality of rationing.

he was expected to think more about policy and less about politics, and so could afford to be more technocratic, less anxious about any electoral consequences:

until [1996 or 1997], I think it's fair to say, that there had been plenty of people willing to talk about clinical effectiveness, but cost effectiveness was regarded as a bit of a dirty word. I took the view that it was essential to the rational allocation of resources in a publicly funded system and so it would be highly desirable to cross that bridge and call a spade a spade. And in fairness I think that Chris Smith did too.²²

The third issue involved in setting up NICE was how to diffuse the blame for unpopular decisions to exclude certain drugs from NHS services. We touched on this in Chapter 1: two of our interviewees link it specifically with the establishment of NICE. David Pink, the civil servant who led the team setting up NICE's organisation, recalls that:

in 1997 you had ... the prospect that the NHS was going to continue to be a painful headache for ministers and politicians, [because of rising costs] ... evidence-based medicine was not actually making the politicians' job any easier, it was making it worse, because decisions were being made in the NHS to not provide treatments, and ... people were trying to hold ministers accountable for what was going on. So I think the political reasons were in some ways quite negative, issues of clinical cost-effectiveness and evidence-based medicine ... could stop at NICE, and not go up to the minister's desk.²³

Adrian Towse, the Director of the Office of Health Economics, was similarly conscious of the politics:

you certainly get, I mean, for most of NICE's existence you have had a situation in which backbench MP after MP would stand up and say 'this is a terrible decision' in public, and in private they would say 'thank goodness they made that decision!' [laughs]. So that political cover was extremely important.²⁴

In our interviews with participants, we probed the question of external influences on the drafting of the White Paper. All were clear that ministers and officials kept external involvement to a minimum, taking – at the most – informal soundings of one or two outside players. This was not abnormal for the preparation of a White

22 Simon Stevens, interview 27 January 2022. Smith was the Labour Opposition Health spokesman, 1996–97.

23 David Pink, in Atkinson and Sheard (2020), 15.

24 Adrian Towse, interview 1 March 2021.

Paper. Stevens recalls that one contribution to designing a new NICE-like body was a private dinner with members of the Rationing Agenda Group, which had convened in 1996 to ‘deepen the British debate on rationing health care’.²⁵ The RAG comprised influential people from many parts of health care. At this dinner:

we were discussing what form NICE should take and they convened a dinner at the home of Nick Ross of *Crimewatch* fame. Richard Smith, Editor of the *BMJ* was there, various others, and we had a wide discussion on how this thing should run. There were by then lots of people with an interest, which is part of the reason why it was the right institutional innovation at the right time. The table was set.²⁶

At this point in the chronology, it may be helpful to introduce DH’s developing work stream on the quality of health care, whose impact on NICE became stronger the following year (1998): we take that strand up in a later section of this chapter.²⁷ Long before landmark events such as the Bristol paediatric heart surgery scandal and Harold Shipman’s conviction for murder, medical civil servants at DH were working on policy ideas for the linked fields of quality of care and patient safety, a project which came to be identified above all with Professor Liam Donaldson. In 1997 Donaldson was the Regional Director and Director of Public Health for the NHS’ Northern and Yorkshire region, and was to become the government’s Chief Medical Officer the following year. Donaldson’s background, like that of others in this team, was in public health medicine. Their work fitted into a public health tradition of looking at health care from a whole population perspective, and trying to organise it to maximise population health.²⁸ (If this sounds very similar to the ‘economising’ approach we discussed in Chapter 1, this is because it is. Readers might also note a debt to the clinical epidemiology approach we also discussed there.)

Significantly for NICE, the consequence was that DH placed the development of policies and plans for NICE within this stream of work. As Alan Langlands, Chief Executive of the NHS Executive, noted in a minute to ministers of September 1997, the new branch he was establishing to lead NHS quality work (soon to be headed by Dr Felicity Harvey) was tasked among other things with work on the ‘quality

25 New (1996) sets out the RAG’s position and lists its members.

26 Stevens interview. For the RAG see New (1997), and Atkinson and Sheard (2020), 35. The broadcaster Nick Ross was a founder and is President of HealthWatch, an independent body that promotes evidence-based medicine. Richard Smith of the British Medical Journal was to be an incisive and at first very critical commentator on NICE’s work.

27 For a survey, see Leatherman and Sutherland (2003).

28 The way public health thinking should affect health care has been a long-term theme in the history of the Chief Medical Officer, a role which has combined leadership of the public health profession with medical advice to government on all topics, including health care. Different individuals have navigated this differently, often keeping health care at arm’s length. See Sheard and Donaldson (2005).

chapter’ of the White Paper.²⁹ In the 1997 White Paper, the brief announcement of NICE (see Box 2.1) is folded into a discussion of plans ‘to give national drive to improved quality’ (and improved performance). In Milburn’s recollection, this section of the White Paper was even drafted by Donaldson.³⁰ In this way, a large dose of ‘public health’ style thinking was added to the more single-minded focus on cost-effectiveness which characterised the approach to NICE of economists like Smee. While, as we have just argued, the two approaches had much in common, the ‘public health’ orientation concentrated on how to secure the greatest benefits from health care, while the economising perspective laid more stress on how to control or reduce its costs.

It is possible, then, to divide policymakers into ‘pessimists’ who viewed NICE, and HTA in particular, as one measure to help slow the NHS’ drift towards long-term unaffordability, and ‘optimists’, whose agendas included geographical equity and better access for NHS patients to the most (cost-) effective technologies. A lot of writing about HTA demonstrates this optimism that its use will make the world better and not just more affordable. It feels unlikely that the people working at NICE in its first years could have daily summoned up the enthusiasm and dedication which many report (Chapter 3) if they had only been rationing, as NICE Director of Corporate Affairs Anne-Toni Rodgers reports:

I didn’t see NICE as a rationing body: people who worked there didn’t see it as such, we saw it as an organisation to provide access to new medicines, equitable access ... The more I talked to Mike [Rawlins] as well, the more it was about how we standardised clinical guidelines.³¹

The optimists and their aspirations have shaped NICE’s work, and made it much easier to present positively to a sceptical world.

An important member of DH’s talented public health team in 1997 was Graham Winyard, whom we met in Chapter 1 as the founder of the Wessex Development and Evaluation Committee (DEC). Winyard has told us he regards NICE as ‘my baby’.³² His work in Wessex certainly showed the feasibility of what NICE would later do, but his claim rests on more than this, notably on policy work at DH in the autumn of 1997 which he has described in an interview with Nicholas Timmins:

ministers wanted a strategy on quality, and of course quality sprawled into everyone’s domain in the Department ... it was all a bit shambolic ... I decided, with some temerity, to try to grip it. ... I built up a schema ... a story of what government could do about quality down one side and what the professions could do about it on the other ... with the suggestion

29 TNA JA53/946 Langlands to ministers, Developing Quality in the NHS, 16 September 1997. The addressees were Dobson, Jay, Milburn and Jowell.

30 Milburn interview.

31 Anne-Toni Rodgers, interview 8 October 2019.

32 Graham Winyard, personal communication.

of an organisation outside the Department that would produce audit tools and guidelines on clinical and cost-effectiveness. [After presenting this to Milburn and his colleagues] I turned the projector off. And Milburn said, “no, keep it on” and the rest of the discussion was about this big schema ... as far as I am concerned, that was where NICE was born.³³

No copy of Winyard’s schema has so far been tracked down in the archives: Winyard himself referred us to the 1998 White Paper *A First Class Service* (discussed later in this chapter), one of whose figures apparently draws on its content.³⁴ Given the networked, or collegiate, nature of most policymaking, the search for an individual who first had the idea of NICE may be fruitless. More pertinently, we can see that NICE is a body for which people wish to take the credit. In the words of the proverb, ‘success has many fathers but failure is an orphan’.

Prominent by their absence in the 1997 pre-White Paper policy discussions were the leaders of the medical profession. DH had recently (1994) unified its old parallel medical and administrative hierarchies, but any dialogue with medical leaders would still have taken place through DH’s medical officers.³⁵ This group took the lead in preparing the section of the White Paper on the quality of health care, and we assume that they had at least some conversations with the profession about this. The key discussion that apparently did not take place, however, was about the nature of NICE’s relationship with the medical Royal Colleges in producing treatment guidelines. There was to be a further missed opportunity for College input on this in 1999 (below).

Another voice largely absent from policy discussions was that of NHS managers or services. It is true that the DH White Paper team was led by NHS Executive Director of Planning Alasdair Liddell, a career NHS manager but an unrepresentative, cerebral and policy-minded one.³⁶ Liddell does appear in the DH papers in 1999, chairing DH’s Medicines Policy Oversight Group, but they contain no evidence of this shadowy group’s impact (if any) on NICE.³⁷ If ministers and leading officials paid little attention to this NHS manager in their midst, they were similarly incurious about what might be learned from NHS managers at local or regional level. Symptomatic of this lack of curiosity was their failure to make use of the proposal in a letter of November 1997 from four HTA leaders to Jay and Scottish health minister Sam Galbraith.³⁸ They announced that their drug evaluation

33 Timmins (2016), 39–40.

34 Graham Winyard, personal communication. See Department of Health (1998), paragraphs 1.13–1.15 and Figure 1.

35 Sheard (2010).

36 *Guardian*, 11 January 2013, Alasdair Liddell (1949–2012).

37 TNA JA 765/15 NICE (April 1999–July 2000).

38 TNA, JA53/946 Milne and others to Jay, Galbraith and others, Creation of InterDEC, 18 November 1997. The authors were Ruairaidh Milne (Wessex Institute of Public Health), Andrew Stevens (University of Birmingham), Ron Akehurst (Trent Institute for Health Services Research/School of Health and Related Research–SchARR, Sheffield) and Norman Waugh (Scottish Health Purchasing Information Centre).

centres – DECs (Chapter 1) – had combined to form ‘InterDEC’, and now made an (abortive) bid to become the body providing HTA to the NHS. The rejection of this intriguing proposal was a symptom of the new government’s centralising mindset, a feature of Whitehall noted so often both before and since.³⁹

It is not clear where the name NICE came from. One apocryphal story, which we do not believe, says it came to Derek Wanless, the banker and public policy adviser, in the back of a taxi. Early discussions inside DH about the body’s name used the phrase ‘clinical effectiveness’. Someone, more likely than not Dobson, noticed that this could make the appealing acronym ‘NICE’ when combined with ‘National Institute’, and at the same time the ‘effectiveness’ was somehow transmuted into ‘excellence’, which does not fit the brief of the organisation as well. The ‘institute’ part, which likewise does not match the actual nature of NICE very well, may have been aimed at conveying academic detachment and political neutrality, or just been needed to make a good acronym. It did not escape DH officials or the media that two new bodies set up in the White Paper, NICE and CHI, could easily be seen as ‘good cop’ and ‘bad cop’ and labelled NICE and ‘Nasty’.⁴⁰ Stevens adds a comical, yet revealing, angle on the name, with an account of Treasury’s view about it:

Treasury came back a day or two before the white paper was published saying “we don’t like the word National, because if NICE comes up with things that are too expensive, then that would drive a lot of costs into the system which we couldn’t block, so you must drop the word National”. We went back and said, “okay just to be clear, this body that is going to be doing rationing, you don’t want it to be called NICE, you want it to be called ICE” – which was sufficient to win the argument.⁴¹

a vignette that says something about Treasury’s obsessive quest to stifle all new public spending, and about the constant fencing between it and spending departments.

1997: the announcement of NICE – White Paper The new NHS: modern. dependable

The White Paper saw the light of day on 8 December 1997. In this section we interpret what it said about NICE, and then describe policy developments between then and the next White Paper, of July 1998, which we pick up in the following section. The White Paper committed the government to open an institution called NICE. There was little detail: essentially a paragraph (Box 2.1), which said the goal was to further clinical and cost-effectiveness, drawing up new guidelines, and bringing together existing DH-funded guidelines programmes. NICE, it was

³⁹ For example by us, in Atkinson and Sheard (2022).

⁴⁰ Paul Atkinson, personal recollection.

⁴¹ Stevens interview.

claimed, would promote consistency and equity in access to services: Labour politicians emphasised how NICE would put an end to the ‘postcode lottery’. But there was no mention of Health Technology Assessment or reference to the appraisal of drugs. This was to be fleshed out in publications over the next two years.

It was very much a Milburn project. As he told Edwards and Fall, ‘When you come into government having been out for so long, you want to put it right ... get your hands dirty and get your sleeves rolled up’.⁴² Milburn said to us, ‘I physically wrote [the White Paper] on my computer ... much to the horror of officials’.⁴³ As one of those officials (PA), I ought to report that this is true in a deep rather than a literal sense. Milburn, fairly late in the drafting process, broke with Civil Service convention by getting involved in directly drafting the text (as opposed to writing comments in the margins of a draft, for a Private Secretary to relay back to the policy team). He did not in practice write most of the final words, but key ideas and passages are indeed his handiwork, and his intervention crystallised the main messages of the document. By doing this, Milburn underlined his personal investment in the project (and probably signalled some continuing distrust that officials were invested enough). As officials, we were indeed horrified at first: mainly that he would add new proposals which we had not had time to sufficiently prepare that did not happen.

The 1997 White Paper *the new NHS: modern. dependable* did not mention HTA by name. It described NICE’s role as to ‘give a strong lead on clinical and cost-effectiveness, drawing up new guidelines and ensuring they reach all parts of the health service’, and to ‘give new coherence and prominence to information about clinical and cost-effectiveness’.⁴⁴ NICE was one element in a much larger story, in a document carefully calibrated to secure good publicity. (Its drafting was even informed by the use of focus groups, convened by New Labour’s strategy and polling adviser, Philip Gould, a very unusual approach at the time.⁴⁵) The idea of cost-effectiveness shelters, in this text, behind ‘clinical effectiveness’, a conveniently undefined concept to which few would take exception. The equity argument for HTA is to the fore: NICE ‘guidelines ... will help ensure greater local consistency’, ending the postcode lottery so that ‘two-tierism becomes a thing of the past’.⁴⁶ The document is a masterpiece of political triangulation, carefully weighing the possible reactions not only of the media and the voting public, but also, for example, of clinicians, an issue explored further in Chapter 3. HTA is presented here with one eye on the risk of it being perceived as an attack on clinical freedom.

42 Edwards and Fall (2005).

43 Milburn interview.

44 DH (1997), 24, 68.

45 Paul Atkinson, personal recollection: I did the paperwork commissioning Gould’s work.

46 DH (1997), 49.

Box 2.1 The government's first announcement of plans for NICE

National Institute for Clinical Excellence

7.11 A new National Institute for Clinical Excellence will be established to give new coherence and prominence to information about clinical and cost-effectiveness. It will produce and disseminate:

- clinical guidelines based on relevant evidence of clinical and cost-effectiveness
- associated clinical audit methodologies and information on good practice in clinical audit
- in doing so it will bring together work currently undertaken by the many professional organisations in receipt of Department of Health funding for this purpose
- it will work to a programme agreed with and funded from current resources by the Department of Health.

7.12 The National Institute's membership will be drawn from the health professions, the NHS, academics, health economists and patient interests. It will need to have access to an appropriate range of skills, including economic and managerial expertise as well as specialist input on specific issues. The Government will consider developing the role and function of the National Institute as it gathers momentum and experience.

Source: DH (1997). *The new NHS modern. dependable* (London: HMSO), pp. 68–69.

Shortly after the publication of *The new NHS*, in early 1998, there was a meeting between Jay and Rawlins (who was not yet even under consideration as a chair for NICE), which sheds further light on government thinking about HTA. According to Rawlins' recollection, Jay said to him:

we are thinking of introducing an element of cost-effectiveness into whether or not we should fund drugs. Could the Committee on Safety of Medicines [CSM – which Rawlins then chaired] do that? Could it give advice to the licensing authority on whether a drug was cost effective?⁴⁷

47 Timmins (2016), 41. The drug licensing authority at that point was the Medicines Control Agency (now the Medicines and Healthcare Products Regulatory Agency, the MHRA). The CSM was established under the Medicines Act (1968) to advise the licensing authority on safety, quality and efficacy. It was replaced in 2005 by the Commission on Human Medicines.

Rawlins told her a new body to give such advice would be a better idea, because if the CSM had to do this job, in the frequent cases where the cost-effectiveness judgement was difficult or marginal, the temptation would be too great for the CSM to fudge the issue by turning the drug down on safety, quality or efficacy grounds instead:

I know committee behaviour, and if they knew that in 20 or 30 minutes they would have to make a rotten decision on cost-effectiveness, they would fudge the first [decision].⁴⁸

This meeting shows that Chris Smith's February 1997 enthusiasm to use cost-effectiveness as a policy yardstick had been carried into government despite the change of spokesman.⁴⁹ But at the same time it indicates that the policy developed in opposition by Smith and Stevens remained at a high level of abstraction. As McKeon puts it, Dobson and Stevens:

had a set view of what they wanted to do but not necessarily in detail, and how it worked out ... they had a view what they wanted to do about rationing, and NICE was part of the response to that ... [their] way to address rationing, I think ... was the national standards and NICE was a way of addressing rationing ... their thought was we don't want this done locally, but we do need to do something ...⁵⁰

McKeon feels that it was Stevens who had done most of the prior thinking about the 'rationing' question, and contributed such components of the final NICE mix as the setting of national standards and the use of QALYs to estimate the health gain from different technologies.

This chapter has already reported how the Government's commitment to avoid spending increases in its first two years put DH budgets under extra pressure, and concentrated Milburn's and other's minds on cost control. Chancellor of the Exchequer Gordon Brown's 1997 innovation of a three-year Comprehensive Spending Review (CSR), reporting in 1998, increased this focus. Departments were expected to examine their plans and budgets with all the usual economising rigour. Part of DH's input to this was a project ('CSR Project 6') chaired by Smee, which provides some clues as to how his part of the Department was viewing NICE. The project's

48 Rawlins, interview 18 September 2019. Similarly, Rawlins later told the House of Commons Select Committee on Health:

[at] the Committee on the Safety of Medicines, I spent my life vigorously avoiding a fourth hurdle and any time any member even opened their mouth and mentioned money, I had to tell them to wash it out with soap.

House of Commons Select Committee on Health (1999)

49 Timmins (2016) cites a February 1997 speech by Smith on this, 34.

50 McKeon interview.

overall remit was ‘Machinery for Cost and Clinical Effectiveness’.⁵¹ Smee noted in a comment on a paper commissioned for the CSR6 project from the Centre for Health Economics at the University of York, that:

it may be premature to conclude that HTAs are likely on balance to imply reductions in NHS expenditure ... [it was] very difficult to achieve savings once technologies have been diffused in inappropriate ways. ... focus [should be] on controlling [their] introduction. How might this be more effectively achieved?⁵²

Naturally this emphasis on cost control was even stronger at the centre of Government than in DH. The note of a ministerial meeting in 1998 about how NICE would operate has Robert Hill (the Prime Minister’s adviser on health policy) relaying Treasury concerns that appraisal delegated to NICE would not be ‘rigorous enough if the body appraising was at arm’s-length from the Department’.⁵³ Put this alongside Treasury’s anxieties over even NICE’s name (above) and a picture of doubt about NICE’s impact on expenditure begins to emerge. Would it be the dutiful servant in the cause of cost control for which the centre clearly hoped? Smee aligns himself with this view in his book, where he writes that:

Departmental economists provided some early support to the establishment of NICE, but their role is now [2005] primarily of warning of any tendency for the analysis to neglect economic principles,

for example when NICE guidelines paid too little attention to their expenditure impact or when NICE appraisals took too ‘lenient’ an approach to evaluation.⁵⁴

What emerges from a close reading of the sources about this period, published and unpublished, is that Dobson, Milburn and Stevens saw NICE as a solution to a political as much as a policy problem: that of how to exert downward pressure on the growing cost of the NHS without allowing opposition language about rationing to gain political traction. (‘Exerting downward pressure’ allows for the possibility that costs will continue to rise – however it makes them rise less rapidly.) The history of NICE plays out against the global, decades-old problem that the costs of health care are rising faster than citizens’ willingness to pay for them.⁵⁵ It is possible to see the HTA role given to NICE mainly as a response to this: not one, perhaps, that many saw as a magic bullet to actually cut costs, but at least to exert downward pressure on their growth. This thinking is evident in the 1998 CSR report and in Smee’s wariness about ensuring NICE stuck to ‘economic

51 TNA, JA53/946, CSR6: Machinery for Cost and Clinical Effectiveness. 4 December 1997.

52 TNA, JA53/946, Setting the expenditure implications for a sample of Health Technology Assessments, 11 November 1997.

53 TNA, JA53/946, National Institute for Clinical Effectiveness, 2 March 1998.

54 Smee (2005), 83–84.

55 Klein et al. (1996).

principles’, such as ‘assess[ing] the expenditure impact on the NHS’.⁵⁶ It might be characterised as the agenda of the Treasury. We are about to see, however, that cost control was not DH’s only goal.

The quality of health care: the White Paper *A First Class Service* (1998)

NICE was a small piece of a very ambitious programme of health system reform. *The new NHS* was followed by a hectic stream of policymaking. One of the most important parts was the work Donaldson led on the quality of health services. The July 1998 White Paper *A first class service: Quality in the new NHS* should be seen partly as an exercise to rebalance DH’s public priorities in the direction of Donaldson’s key concerns including evidence-based medicine and patient safety.⁵⁷ Of the ‘three continuing objectives’ that it set out:

- to improve continually the overall standards of clinical care
- to reduce unacceptable variations in clinical practice
- to ensure the best use of resources so that patients receive the greatest benefit,

the last clearly covers HTA (while the first and second cover, among other things, the production of NICE guidelines). In other words, while health economics on its own provided enough inspiration for the NICE HTA programme, and had powerful advocates including Smee, policy about NICE, including its HTA activity, was also being shaped by another powerful agenda, that of quality improvement. This was just as well for NICE’s acceptability to the medical profession and the public, as we shall see in Chapters 3 and 4.

A First Class Service was DH’s first public statement that NICE was going to conduct HTA. While not using the phrase, it said the new body would ‘appraise new health interventions, and advise the NHS on how they can be implemented’. The White Paper also set out for the first time a detailed outline of the appraisal process which the Department expected NICE would follow (see Box 2.2).

The expectation was of ‘annually 30–50 appraisals of the most significant new and existing interventions’, an estimate that dropped to 20–30 in DH’s 1999 discussion paper *Faster Access to Modern Treatment: How NICE Appraisal will Work*, a document whose place in the preparations for NICE’s opening we will discuss later in the chapter.⁵⁸ By way of comparison, NICE has now been given the responsibility of appraising *all* new active substances in drugs authorised for the UK market, and published 56 appraisals in 2018–19, a typical recent year.⁵⁹ To a reader in the 2020s the most striking thing about the 1998 proposal is the leisurely pace of appraisal it envisaged. While some early appraisals were of drugs already in use,

56 Smee (2005), 84.

57 DH (1998).

58 NHS Executive (1999).

59 NICE (2019). On implementation of this policy, see Chapter 5.

Box 2.2 DH's proposed NICE appraisal process, 1998

Appraisal of new interventions: outline of proposed process

- Department of Health 'scans horizon' for new interventions (technologies) in development and assesses potential impact on the NHS
- Well in advance of expected launch on NHS, the most significant interventions are selected for probable appraisal
- Discussion with sponsoring companies on likely information requirements
- One year before expected launch: Department of Health formally asks NICE to carry out the appraisal and asks sponsoring company to submit evidence
- Four to six months before: sponsoring company submits evidence
- NICE secretariat will critically review the submitted evidence and add commentary including further analysis of the likely impact on the NHS. Sponsoring company has opportunity to see and add any further comments
- Multi-professional appraisal group, under the oversight of NICE, reviews all the evidence, draws up recommendations and information for patients. Sponsoring company/Department of Health have opportunity to comment on recommendations
- Appraisal group finalise recommendations and information. NICE issues to NHS summary of evidence considered in time for launch of the product
- NICE may require further research after the initial launch, if evidence is insufficient to reach a clear judgement
- Recommendations can be reviewed in the light of new information, for example on improved forms of new technology

Source: DH (1997). *The new NHS modern, dependable* (London: HMSO), pp. 68–69.

for a new product it is hard to imagine that patients or pharmaceutical manufacturers reading this took a relaxed view of a process lasting a year, and the 1999 paper revised this estimate downwards. Indeed, Trevor Jones of the Association of the British Pharmaceutical Industry (ABPI) recalls a 'fear we had ... that there would be a further delay to us of a year or more, that's not good for the patients or the industry ... the concern was delay – of access, delay of return on investment'.⁶⁰ The issue of pace has remained important, as we shall see in Chapters 5 and 8. Charles Dobson, the DH civil servant in charge of work on the NICE appraisal process, recalls:

... a number of not entirely happy discussions with the ABPI ... who, of course, were absolutely opposed to anything of the kind. ... as we wanted

60 Trevor Jones, in Atkinson and Sheard (2020), 19.

to minimise noise from the pharmaceutical industry, we tried to make the process as smooth and fast as we possibly could.⁶¹

Another theme of lasting importance which surfaces for the first time in *A First Class Service* is how to manage new technologies which are launched with a dearth of cost-effectiveness evidence. NICE might simply bat these away if it felt such evidence was not likely to emerge, but in 1998 DH was already envisaging a need, in more doubtful cases, to undertake ‘further research after the initial launch if evidence is insufficient to reach a clear judgement’. We will see shortly how NICE’s very first technology appraisal raised this issue, and how it has been handled more recently.

The first step of all in Box 2.2, horizon scanning, is another long-term issue for HTA. DH picked technologies for HTA which it felt likely to make a significant difference, at first in a very ad hoc way, but with rapidly increasing professionalism after the appointment of the new government. In October 1997, for example, Dr Sheila Adam, Deputy Director of DH’s Health Services Directorate, informed ministers that the NHS Executive Board had

decided that a more systematic approach should be taken to scanning the clinical horizon for innovations, to consulting the NHS and the professions on these, and to deciding how best to respond.⁶²

Accordingly, they established a Managing Clinical Innovations Group, which made use of the National Horizon Scanning Centre which they commissioned from the University of Birmingham.⁶³ Cost control was the dominant DH criterion:

Two criteria ... sort of went together: whether it affected a significant sub-population, and the financial impact, which is the product of the potential number of treatments times the additional cost over and above current best care. ... [the] horizon scanning [unit] ... would make an estimate on the number of the population that would potentially benefit, and they would often have an idea of the sort of price at which it was likely to be on the market ...

I developed ... a gigantic spreadsheet ... with a possible forecast of the net expenditure on the NHS in the years relevant to the current public expenditure review. There was a lot of guesswork involved, ... how fast the NHS would actually take up an innovation ... I would typically assume ... you wouldn’t reach the saturation point until at least year three after the initial appraisal ... We [aimed at a] best guess at the aggregate financial impact

61 Charles Dobson, interview 16 March 2020.

62 TNA JA53/946, Sheila Adam to Milburn: Managing Clinical Innovations Group, October 1997.

63 NHS Executive (1999).

on the NHS. I think we ... almost always forecast a more rapid uptake than actually happened.⁶⁴

This internal DH appraisal guided its referrals to NICE (and for many years every NICE technology appraisal began with a referral from DH: a very hands-on process compared with later developments).

The 13 pages which *A First Class Service* devoted to NICE provided an unusually detailed blueprint for a new public body. They show, in more detail than *The new NHS*, how NICE fitted into the bigger policy picture. They enlarge considerably on the story presented there about what NICE would do and how. They set out the makeup of the NICE Board and commit it to setting up a Partners' Council, hinting at an important role for the representatives of patients, themes we will take up in the next two chapters. Mercy Jeyasingham, then working at the National Eczema Society, a patient organisation (and later to serve on NICE's Board and Partners' Council), recalls that:

as I read *A First Class Service*, we had a lot of questions about what was the patient involvement? It did mention the patients, but ... obviously it was a White Paper, there was no detail.⁶⁵

The pages of *A First Class Service* also convey how NICE was to take over a range of existing activities: those listed in the White Paper include National Prescribing Centre appraisals and bulletins, the clinical guidance contained in PRODIGY (a computer aided prescribing decision-support system for GPs), the DH-funded National Guidelines Programme and Effectiveness Bulletins. Also bundled into NICE's activities were the four existing 'Confidential Enquiries', systems for blame-free reporting of serious adverse clinical events with a view to drawing lessons for improved practice.⁶⁶ This roll-call of previous activities now to be combined with NICE should serve to counter any impression that the form NICE took in April 1999 was designed on a blank sheet of paper as a pure, evidence-based response to a policy problem. It also had this complicated and slightly messy hinterland – which brought with it significant existing funding streams over which the infant NICE gradually secured control (Chapter 3).

Enter Mike Rawlins and Tony Culyer (1998)

After one brief earlier appearance, in his role as the Chairman of the CSM (above), Professor Sir Mike Rawlins (knighted in 1999) made his main entrance in September 1998. Given his central role in the story of NICE, a pen picture

⁶⁴ Dobson interview.

⁶⁵ Mercy Jeyasingham in Atkinson and Sheard (2020), 14.

⁶⁶ The four Confidential Enquiries dealt with Perioperative Deaths, Stillbirths and Deaths in Infancy, Maternal Deaths, and Suicide and Homicide by People with Mental Illness.

is in order. Rawlins was a brilliant clinical pharmacologist (a professor at 32) and, more importantly, someone with the confidence to engage in public affairs without the least awe for the other participants. As Una O’Brien (Permanent Secretary at DH 2010–16) put it,

Mike Rawlins was just outstanding ... he just had the confidence of the politicians and I think that’s really, really important. And experienced enough to sit around the table and tell it how it is, ... he had all of the authority that Chris Whitty has today, and the eminence.⁶⁷

Andrew Dillon recalls that:

when I was being interviewed by the headhunters, they told me that DH had indicated that the chair would need ‘managing’ occasionally, and did I think I could do that? I seem to remember getting the impression that they were a bit worried about Mike’s independence and outspokenness.⁶⁸

A later (post-NICE) measure of Rawlins’ eminence is that when he stood for President of the Royal College of Physicians in 2014 he came second with more votes than the eight other unsuccessful candidates combined.⁶⁹ As far as his lack of awe is concerned, this was a man who could say what others were only thinking, for example, about the greed of some of the pharmaceutical companies, and who publicly debated with as formidable an adversary as Newt Gingrich on the rights and wrongs of excluding treatments on cost-effectiveness grounds.⁷⁰ Frank Dobson told Timmins, ‘I knew the industry was wary of him. But they were also respectful. And I thought that combination was no bad thing. He was clever, charming and tough as old boots’.⁷¹

Another point in his favour was that Rawlins had, by 1998, a good deal of experience of how the NHS and public bodies generally were run, which was valuable at NICE. He served on the Committee on the Safety of Medicines from 1980 to 1998 (chairing it from 1993), which was plainly the perfect vantage point from which to understand the central issues and participants in medicines policy. On top of a clinical career, he had been vice-chairman of the Northern Regional Health

67 Una O’Brien, interview 2 February 2022 (Chris Whitty, the government’s Chief Medical Officer since 2019, will be familiar to British readers for his media appearances as an official spokesman on Covid-19).

68 Andrew Dillon, personal communication.

69 Royal College of Physicians (2015); Rawlins, personal communication.

70 For Rawlins’ sometimes combative approach to big pharma, see for example the verdict of Trevor Jones of the ABPI, quoted by Timmins (2016): ‘he used to lambast the industry from time to time over its prices ... many people within it saw him as the enemy’ (51). Gingrich was Speaker of the US House of Representatives, 1995–99. The clash with him took place in an online debate organised by the *Economist* magazine in October 2009 (*Economist* 2009).

71 Timmins (2016), 52.

Authority from 1990 to 1994, while Donaldson was one of its Directors. He must have made a favourable impression on Donaldson, who suggested his name to Frank Dobson as a candidate for the Chair of NICE.⁷² And three further things made Rawlins an attractive candidate and gave him a general interest in NICE's work: in his words, firstly:

I'd always felt – I wasn't a health economist in any sense – but up in Newcastle I made sure that we didn't pay more for medicines than we ought to. ... For example, ... I persuaded my colleagues [that] if they prescribed a brand name, the pharmacist could substitute a generic. Things like that – so I was sort of conscious of it. The [second] thing was, I also recognised that guidelines could be very helpful, but the trouble was they were incredibly variable in quality and nobody knew which was a good quality guideline and which was not. So I was supportive of the general direction of travel. ... [thirdly] postcode prescribing ... particularly with Beta Interferon. I was aware that if you lived one side of Newcastle you got it, and if you lived the other you didn't. And that seemed wrong: ... either everybody has it or nobody has it.⁷³

Historians are generally curious about the relative importance of individuals and structures in shaping events. 'What would have been different without Mike Rawlins?' is one of the imponderable counterfactual questions that participants in these events have nevertheless asked. All those who expressed an opinion regarded him as indispensable: there is a general view that Rawlins and Andrew Dillon (who are usually spoken of in the same sentence) were the authors of NICE's success during the long period when Rawlins was Chairman and Dillon Chief Executive.⁷⁴ There will be more to say about this in Chapter 3. A better question at this point would be whether there was anything inevitable about Rawlins getting the job. The answer is no. First of all (unless his account is to be dismissed as false modesty) Rawlins did not at first consider applying:

Towards the end of 1998 I had done two terms as Chairman of the Committee on the Safety of Medicines. ... I had no special idea about what I was really going to do: I didn't have a plan. ... I had a vague idea I would try and follow up on all the surviving UK thalidomide people: find out how their physical health was, their social ... Then I sort of vaguely knew about this idea of NICE, but I hadn't really gone into it: I hadn't thought about it very much.⁷⁵

Another reason why NICE could easily have had a different chairman is that Rawlins was the government's second choice: Frank Dobson was (in typical style)

⁷² Liam Donaldson, personal communication.

⁷³ Rawlins interview.

⁷⁴ Respectively, 1999–2013 and 1999–2020.

⁷⁵ Rawlins interview.

candid enough to tell him so.⁷⁶ The post was first offered to the President of the Royal College of Obstetricians and Gynaecologists, and Chairman of the Academy of Medical Royal Colleges, Sir Naren (now Lord) Patel, who declined it because he had just accepted another post, from which he felt he could not withdraw.⁷⁷ Timmins' account of events emphasises how Dobson relished a role in appointments which he should not rightfully have exercised: Timmins sees Dobson (doubtless rightly) as a sort of kingmaker.

Rawlins' name may have come into the frame at the initiative of Professor Sir George Alberti (the University of Newcastle's Dean of Medicine, 1995–97, and then President of the Royal College of Physicians, 1997–2002) or of Donaldson – all three of them nationally eminent doctors then based in Newcastle. Our interview with Alberti usefully reveals some of this 'hidden wiring' of government, as Peter Hennessy has described it: for example that the three met and talked medical politics.⁷⁸ Much is sometimes made of a so-called 'Geordie Mafia' when talking about the networks of health policymakers around the new government in 1997. This is overdone, and partly represents a metropolitan underestimation of the amount of talent and influence present in any major regional centre (no-one uses the phrase 'London mafia' in this way!) Milburn – whose Darlington constituency was in any case a county away from Newcastle – had contacts in many different cities: those based in Newcastle did not demonstrably have exceptional access to him.⁷⁹ If anything the York connection is more interesting – Frank Dobson (raised in the city), the University's Centre for Health Economics and its head Tony Culyer, and Dobson's Parliamentary Private Secretary Hugh Bayley, MP for York (who trained in health economics there).

While Dobson's 'pre-interviewing' of leading candidates undeniably illustrates the power of the hidden wiring, public appointments – in 1997 as now – operated under a visible official process independent of politicians, which claims to make its selection on objective, published criteria. In the words of the civil servant responsible:

This had to be done in a demonstrably objective and open process, not least because the institute we were setting up was about objectivity and openness in taking decisions. ... I had an ex-police officer who acted as a sort of invigilator/observer, he was being paid by some ... national body dealing with public appointments, to, if you like, be a fly on the wall.⁸⁰

76 Timmins (2016), 49.

77 Timmins (2016), 49.

78 George Alberti, interview 10 November 2016. On 'hidden wiring', see Hennessy (1995).

79 When Alberti himself refers in the interview to a Geordie Mafia, this is one entirely composed of senior doctors: no Milburn.

80 David Pink, interview 28 May 2020. The regulating body was most likely the Civil Service Commission (this role now belongs to the Commissioner for Public Appointments).

There were thousands of applicants. In a sign of changing times, the process apparently weeded out another President or ex-President (not Lord Patel, in other words) of one of the medical Royal Colleges:

his heritage from the royal colleges, ... was deemed as his entire qualification for the job. He had no inclination or willingness to fill in an application form addressing explicit points, he told me that he hadn't done such a thing since he was a senior house officer. That one fell by the wayside because he just couldn't engage with a conventional recruitment process.⁸¹

NICE's second recruit, a key one for its policymaking, was Professor Tony Culyer of the Centre for Health Economics at the University of York. Culyer's influence on NICE was above all personal, the fruit of his individual qualities such as his attitude to the interplay of economics and ethics. (As Timmins, then public policy editor of the *Financial Times*, puts it, Culyer was: 'a health economist but he's also a philosopher'.⁸²) Culyer is an unusual economist for his engagement with the broader, more philosophical aspects of 'values', and he transmitted to NICE a significant strand in health economic thinking, as we saw in Chapter 1. His recruitment was Rawlins' idea. Rawlins had got to know Culyer through the latter's leadership of DH's Research and Development Task Force in 1993–94.⁸³ In Rawlins' words,

I had sort of got to know, slightly, Tony Culyer, ... he was extraordinarily helpful: he sort of educated me into health economics. He was the mastermind behind the approach we took. ...I was sort of impressed with him because he was a sort of sensible economist: he wasn't a hard-line, ... he was an economist with a sensible approach.⁸⁴

Notoriously, we all tend to label as 'sensible' those experts whose advice confirms what we already wanted to do. Weible et al. write that 'one of the fundamental purposes of scientific and technical information is to inform and legitimise governments' choices – especially in high-stake situations'.⁸⁵ (Another NICE example concerning an economist labelled 'sensible' would be Stevens' verdict on Smee's 'sensible wisdom'.⁸⁶) 'Sensible' experts are usually contrasted with those giving inconvenient advice by the use of a label such as 'hard-line', 'doctrinaire', 'academic' or 'unrealistic'. Economic, like other expert, advice, is subject to contestation between different policy actors about how it should be framed. Another

81 Pink interview.

82 Nicholas Timmins, interview 17 December 2019.

83 For the background and text of what the NHS universally calls the 'Culyer Report', see DH (1994); we discuss this in Atkinson et al. (2019).

84 Rawlins interview.

85 Weible et al. (2020).

86 Stevens interview.

property it shares with other expert advice is the difficulty the advisor frequently has engaging with the mental world, presuppositions and vocabulary of the policy-maker, and Rawlins may well be thinking of this too here: Culyer is an economist who speaks empathetically and persuasively with policymakers.⁸⁷

For his part, Culyer jumped at the chance being offered to him:

I saw NICE as a great opportunity for rational decisions favouring population health... I had also been very much influenced by Archie Cochrane and subsequently by the Canadians at McMaster, with the what was then called, some people still call it, the evidence-based medicine movement. It seemed to me that if you do accept the basic premise of those epidemiologists and clinicians, that the object of health services is to improve the health of the population then it seems to me that... that leads very quickly to some notion of cost-effectiveness, criterion for deciding what in general is going to be made available for that population, and I admit that it immediately struck me that NICE could be developed into an instrument that was fit for that purpose.⁸⁸

To return to the narrative of events, once it had announced its plans for NICE in two White Papers (1997 and 1998) DH began moving rapidly to establish the organisation, not only recruiting for a Chair but also settling the organisational details. Indeed, officials realised that NICE could provide ministers with one of the ‘quick wins’ which were politically desirable, given that much of the policy agenda in *The new NHS* required time-consuming primary legislation: ‘Frank [Dobson], and indeed Alan [Milburn], probably, were very keen on doing things before the legislation, which is why NICE got established as a Special Health Authority’.⁸⁹ That could be done under existing legal powers. This gave NICE a stronger NHS flavour than it would have otherwise have had, but also made it (in law) a creature of the Secretary of State, instead of a ‘Non-Departmental Public Body’ with the appearance of greater independence from government. Both these signals had to be altered in 2013 when Andrew Lansley wanted not only to give it responsibilities beyond the NHS in social care (Chapter 7) but also to take as much health governance as possible out of the political sphere and away from the daily control of Secretaries of State (Chapter 8).⁹⁰

This process, as one would expect with the construction of any new public body in the UK, took place mostly in Whitehall offices, away from ministers, who had other concerns, and away from the public sphere. In contrast to the deliberately consultative, transparent approach which NICE took with its work subsequently,

87 A large literature discusses scientific advice to policy makers. We would single out Kogan’s work on ‘boundary spanners’: Kogan et al. (2006), and also Cairney (2017).

88 Tony Culyer, in Atkinson and Sheard (2020), 7–8. On McMaster, see Chapter 1. McMaster University, Montreal, Canada, was the base of David Sackett and Brian Haynes, important figures in evidence-based medicine.

89 McKeon interview.

90 Timmins (2012).

Pink, DH's project manager for the establishment of NICE, recalls that 'the actual creation of NICE itself was ... a "head down charge towards the finish line"'.⁹¹ Pink told our witness seminar that:

the actual detailed work to do the creation was very technocratically driven by key civil servants, Clive Smee in particular and through Clive to his network of contacts. The political advisors were active, and from time to time Alan Milburn and the secretary of state was to a degree, but not in the design work really. They were not really [involved] in the boundary definitions of [NICE's] work.⁹²

We were wanting to get Frank Dobson to weigh in on our side, but he showed a real reluctance to get drawn into any of the detail. He was a nice guy, I liked him, I would have loved to see him in the pub on a Friday night, but he wasn't into the administration of public policy.⁹³

For much of the time from Rawlins' appointment in September 1998 to NICE's launch the following April, deciding how it should operate was a two-man show between him and Pink, involving the usual potentially edgy relationship between civil service project manager and chair-elect ('shadow chair'):

Well Mike is Mike, I worked very closely with Mike ... Interesting and peculiar relationship because I considered I was in charge of the project on the part of [DH], but of course ... he was chair elect I remember it being quite comfortable most of the time, but Mike was never going to become a sort of tame frontman for Whitehall ... He wasn't overly interfering ... I saw this as my project and wanted to get on with it, I didn't want ministers involved except when I wanted them involved, because I knew I had got my deadline, and Mike I wanted involved in the way that I wanted him involved, in a specific role ... he didn't get involved in the programme of work, as such. But he was involved and interested, obviously, in things like the rest of the appointments to the board ... having meetings at senior levels in the department.⁹⁴

Of course not all of this preparatory work was about the minutiae of 'pay and rations'. Elements of what we would regard as policy had to be teased out too, and Rawlins and Pink felt a considerable freedom to get on with that (in Pink's case, constrained at times by the need for approval from Smee and other senior colleagues):

Pink: There was huge debate about the technology appraisal programme and the rationing questions, and the cost effectiveness questions, and there

91 Pink interview.

92 David Pink, in Atkinson and Sheard (2020), 22.

93 Pink interview.

94 Pink interview.

was political endorsement that that debate should happen, but not necessarily ... saying “and ... the answer should be such and such”.

Rawlins: That’s about right, I mean one of the great things was when we were setting up NICE was that really they let us get on with the job and didn’t interfere.⁹⁵

1999: NICE opens its doors: enter Andrew Dillon

DH policy documents such as those we have been discussing provided a skeleton for the necessary policy: we have seen how Rawlins worked with Culyer and DH officials from his appointment in September 1998 to put the flesh on it. This is an obvious example of the way in which, according to political scientists, ‘some policy is made within a “core executive” but most in “policy communities” out of the public spotlight’.⁹⁶ Rawlins could not assemble his own team until NICE came into being on 1 April 1999, as public spending rules on this were very strict. In this section, we take the narrative from the start of 1999 to the point in August of that year where NICE was operational, had received all its initial ‘marching orders’ from DH, and was about to conduct its first, famous, appraisal (of Relenza: Chapter 5).

This section makes use of a valuable tranche of DH papers recently opened in the National Archives, which together show an activist Department setting NICE’s direction of travel in considerable detail, and with great care to prepare the ground for it politically, for example by briefing the pharmaceutical industry about the intended form of NICE appraisal. Senior officials, in keeping with Whitehall practice, discussed ‘detailed proposals for handling the various interest groups’, for example ‘off-the-record briefing by officials for the specialist (professional) press and presentations ... to key professional, industry and patient groups’. Resistance was anticipated and plans to counter it prepared:

there will be considerable noise from the pharmaceutical industry and possibly from some patient groups; indeed the ABPI appear already to have launched a pre-emptive strike with a booklet (to be launched tomorrow) on “NHS rationing by cost”. We are preparing detailed defensive briefing...⁹⁷

In 1999, then, the ‘core executive’ kept hold of the policy decisions it considered important in NICE’s case. The DH papers also capture some of Rawlins’ influence over DH’s preparatory work, and Pink was another source for Rawlins ‘having meetings at senior levels in the department’ during these months.⁹⁸

95 Pink and Rawlins, in Atkinson and Sheard (2020), 22.

96 Dunlop et al. (2018); Cairney (2016). The quotation is from Cairney (2021).

97 TNA JA53/947 National Institute for Clinical Effectiveness (NICE), Gina Radford (PH Development Unit) and Charles Dobson to Milburn, 19 January 1999, ‘National Appraisal of New Technologies’.

98 For example TNA JA53/947 National Institute for Clinical Effectiveness (NICE), ‘NICE Project Team Meeting With Professor Michael Rawlins: Agenda (21/12/98); Pink interview.

One essential piece of preparatory work was to build up a working HTA process, at least in shadow form. This ran the risk of pre-empting NICE's own decision-making, but DH were sufficiently self-confident not to lose sleep over that. To meet the requirements of good governance, and establish the new organisation's ownership, the NICE Board, once appointed, approved the 'live' version, after NICE officers, particularly Rod Taylor, had developed it in some significant ways (Chapter 5). DH's consent to the results of this further work was registered in a Memorandum of Understanding on Appraisal of Health Interventions between DH and NICE in August 1999, which appears to have been published or at least circulated to interested parties such as manufacturers.⁹⁹

But to return to January of that year, DH's first step in 1999 on developing the HTA process was to publish the discussion paper *Faster Access to Modern Treatment: How NICE Appraisal will Work*, largely the work of Charles Dobson.¹⁰⁰ This built on the work of the DH expert group on Guidelines for Pharmaco-Economic Studies in 1997–98 (Chapter 1).¹⁰¹ Further ingredients came from learning which Dobson took from the experiences of Australia and the Canadian provinces, while, according to Dobson, Chris Henshall, a branch head in DH's R&D Directorate, contributed:

one of the conceptual breakthroughs ... the distinction between assessment and appraisal, that you needed a group of academics to look at the evidence base ... summarise that, but on top of that you needed a process which applied the judgements, which was the appraisal proper. That was the value-added of having NICE itself.¹⁰²

We discuss in Chapter 5 how important this layering of judgement over initial technical analysis was to become.

Next came a curious episode which represents a second missed opportunity for the leaders of the medical profession to have more influence over the nature of NICE's work. We saw earlier in this chapter how the profession had relatively little input to the 1997 White Paper. Now, just as NICE was on the point of coming into existence, came a belated attempt to exercise the kind of influence on a major health policy which might have been expected. In Pink's words,

the [medical Royal] Colleges were a bit taken aback ... by the fact that the new Labour government had jumped onto a piece of turf that they might have considered theirs before. ... there were some discussions that they would set

99 Buxton papers, DH (1999).

100 NHS Executive (1999). TNA JA53/947 National Institute for Clinical Effectiveness (NICE), has detail on the preparation of *Faster Access*, consultation responses and DH discussions on next steps.

101 The 1997–98 work (in the Buxton papers), confusingly, was sometimes titled 'Guidelines on Cost-Effectiveness Analyses'.

102 Dobson interview.

up NICE themselves and it would be truly at arms-length ... it wouldn't be a government institution. But I don't think that proposal came forward until ... regulations ... were about to be laid before parliament, it was far too late.¹⁰³

even after ... the White Paper, the relevant professional bodies just couldn't get their act together. They did at the last moment. ... it petered out very quickly ... an approach was made at a very senior level ... I think it was the president of the Academy of Medical Royal Colleges. ... it was ... [not] even a suggestion that they would buy in to ... what was going to be created, it was a suggestion that they were going to take away the issue, as it were, and that was never going to work with the politicians, by that stage.¹⁰⁴

After that, claims Pink, 'the stakeholder who should have been on board is the Royal Colleges, or the medical and nursing professions, but they had dropped the ball and were sulking'.¹⁰⁵ We take up the story of NICE's early relations with the Colleges and professions in Chapter 3.

When the secondary legislation was laid before Parliament to bring NICE into being, the Conservative Opposition used the opportunity to attack the new body as primarily an instrument for cost control, and the government for seeking to conceal this. In Committee, Philip Hammond MP led for the Conservatives, and said 'This NICE will be nasty'.¹⁰⁶ NICE was in fact about cost-effectiveness, he maintained, rather than clinical excellence. NICE's 'prime purpose will be seen as providing a fig leaf for Government in rationing health care, while continuing to deny that such rationing exists'.

Michael Rawlins had (Hammond continued) said 'It's no good us recommending a therapy if there isn't any money available', and that if the Department of Health advised NICE that a treatment could not be afforded, NICE would 'say that it is clinically effective, but that we are unable to recommend it as there are insufficient resources to make it available to the patients'. 'What price clinical excellence?', concluded Hammond. Later in the debate the Conservative David Amess described these remarks from Rawlins as 'letting the Labour rationing cat out of the bag'. Responding for the government, John Denham ducked the charge of rationing (in the manner advocated by McCrea – see above), claiming instead that 'NICE will promote innovation and quality ... NICE is essential for our plans for fair and equal treatment of patients within a health service that is truly national'.¹⁰⁷ With the government's large majority, the outcome of the debate was never in doubt.

On 1 April 1999, accordingly, NICE came into being. For the scholar, the legal acts bringing this about (Establishment Order, Framework Document and the like) are, in the main, poor sources for policy, dealing instead with 'pay

103 Pink, in Atkinson and Sheard (2020), 21.

104 Pink interview.

105 Pink interview.

106 House of Commons: Third Standing Committee on Delegated Legislation (1999).

107 House of Commons: Third Standing Committee on Delegated Legislation (1999).

and rations' type governance matters, and done to a Whitehall template. The one important exception is the Secretary of State's Directions to NICE, which are considerably more interesting.¹⁰⁸ As these were made in August 1999, we will turn to them in a moment. Meanwhile, the second key actor in NICE's history, Andrew Dillon, has to make his entrance. Appointing the chief officer of a new public body is an intricate project management problem: (s)he can only be appointed by the Board, which has to come into being first, and the person can only be paid once the body has a legal existence and a budget. With flexibility and goodwill, all this can be made to work despite the public sector's bureaucratic constraints.

These legal niceties explain why someone so central to NICE's early success was only appointed at this late moment (and did not appear on the payroll until July). Dillon went through a kind of pre-selection by Rawlins and was approved by Frank Dobson (as provided for in the legal framework, in contrast to Rawlins' own 'vetting' by Dobson), leading to a rubber-stamping at NICE's first Board meeting, the day before NICE opened its doors. In Rawlins' words:

It was one of those times when you just throw yourself on the mercy of the board. So I said "look, I am really sorry to say this, but we have got to appoint a chief executive and I've got Andrew Dillon sitting outside. He's been agreed by the Secretary of State, so give me a break and say you agree to appoint him."¹⁰⁹

While Rawlins had been identified and encouraged to apply for his post at NICE, Dillon simply replied to the job advertisement. He had not heard of NICE until that moment, or picked up on 'the debate about the need for a national body, or approaches to more forensic and objective ways of making decisions about new treatments and services'.¹¹⁰ So, like Rawlins, there was nothing inevitable about his applying for, let alone getting, the job. Of his motives, Dillon says:

it just seemed really interesting. ... I do remember being intrigued by the idea, not so much about the drugs side of it, but just the general notion that this would be a national point of reference on decisions that, as a hospital chief executive, you would get embroiled in all the time. So much of that debate ... [then] took place in the almost total absence of objective information ... The idea that there could be some national point of reference on new [treatments and services] just felt good.¹¹¹

108 All these documents are most easily accessible as drafts in TNA, mainly in JA53/947 National Institute for Clinical Excellence (NICE) and JA 765/15 NICE. The usual databases of legislation have poor to non-existent coverage of these types of document.

109 Timmins (2016), 55.

110 Andrew Dillon, in Atkinson and Sheard (2020), 19.

111 Andrew Dillon, in in Atkinson and Sheard (2020), 19.

As with Rawlins earlier in the chapter, a pen picture of Dillon will be useful here. Rona McCandlish, who began to work with NICE in 2001 and later served on its Board, had the following penetrating insights. For her, Dillon has:

A kind of unflinching tenacity, and a steeliness, some people would say. In private he's a very warm and fun-loving guy, but both around the shop and in public he's kind of, not easy to engage: I've heard some people feeling he was flippant and supercilious, in the way he so lightly goes along these big issues... But actually ... he's very courteous, deeply caring, deeply committed to public sector values and incredibly astute politically, but not someone who emotes in public. Which is what you need when you're going to be a chief exec for 20 years.¹¹²

Dillon's account of his application for the NICE job suggests a powerful intellectual curiosity. Added to that, he was, in common with Rawlins (in the words of Jones at the ABPI) 'tremendously enthusiastic, highly intelligent, ... listened to people's views and ... [was] not [a] puppet of the system'.¹¹³ This is evident in the published transcript of a witness seminar which the authors held in 2020.¹¹⁴

A career NHS manager and graduate entrant to what was then known as the National Administrative Training Scheme, Dillon had been Unit Administrator and Unit General Manager for a succession of well-known London hospitals (such as the Royal London and the Royal Free) since 1981 (when he was 27 years old).¹¹⁵ He became chief executive of the St George's Hospital Group, a major London teaching hospital in 1991.¹¹⁶ This CV marked him out as one of the 'high fliers' among NHS managers, and it must have caused surprise among his peers when he took the NICE job instead of continuing to climb the recognised hospital management career ladder.

As an outstanding public sector manager, Dillon soon demonstrated at NICE his adeptness in managing people, both within and beyond the organisation itself. We will discuss in Chapter 3 how Dillon, Rawlins and their team shaped the culture of the new organisation. Here it is worth noting that, as in any good leader, this was not accidental:

one of the opportunities was that you could create the culture you wanted for NICE. Over time, as Chief Executive, I appointed people and the organisation's behaviour was shaped by those individuals, who helped form its DNA.¹¹⁷

112 Rona McCandlish, interview 3 December 2019.

113 Quoted by Timmins (2016), 51.

114 Atkinson and Sheard (2020).

115 Dillon, Sir Andrew. *Who's Who & Who Was Who* (2023).

116 Not long afterwards this became the St George's Healthcare NHS Trust.

117 Andrew Dillon, interview 2 July 2020.

Jane Gizbert, one of NICE's Directors, made a similar point. Even making allowances for loyalty, there is enough light and shade in her interview to suggest we are being given some real insights into how Dillon worked with his executive team:

Thanks to Andrew, we had a very stable, very well-run and collegiate senior management team. I've been here 11 years, there's not a lot of turnover. We all respect each other, we get along professionally, and it works. Andrew is amazing; he will not put up with any nonsense and the way that he leads is very clear. I think the senior management has provided stability and a sense of calm. Andrew has made this into an organisation that feels friendly, and that things are going to be OK.¹¹⁸

The longevity of so many of NICE's senior figures (Rawlins and Dillon themselves being prime examples) is so unusual in the contemporary English public sector that it deserves to be noticed in this way. Again, it was something Dillon aimed for, not accidental. As he put it:

make [staff] feel that this is a place where they can enjoy working, in which they are respected and supported and admired ... it occurred to me that that was the way you got the best out of people, that was the way you could recruit and keep people. There are lots of organizations that shed people constantly because the environment is unpleasant, and wearing, and not sufficiently rewarding, it's very important. I really didn't want NICE to be like that.¹¹⁹

One of Dillon's important early roles was as spokesman to the media. He wanted to set a style:

that we were going to be proactive, and in particular that we were going to stand up and account for what we had done, wouldn't just hide behind a statement ... we were going to stand up, and that meant me, because there wasn't really anybody else around, I felt a real personal responsibility that somebody would go in front of a microphone or camera and explain how our decision was taken.¹²⁰

Taking personal responsibility for communication was one thing, but how effectively did he do it? One prominent journalist regarded him as:

not very good with the lay public, who need things explained very simply. That's where you need a politician figure, someone who understands how to talk to people. ... I did think that he was not very helpful to the cause at all.¹²¹

118 Jane Gizbert, interview 14 November 2019.

119 Dillon interview.

120 Dillon interview.

121 Journalist, unattributable interview.

Other journalists tend to agree. One, who recalled Dillon as ‘a rather cold fish’, did acknowledge that in its first years NICE was:

under siege, it was a very, very different situation for them, so they were very closed, and difficult ... [often] the best thing was just to keep their heads down, put their helmets on, take the flak. So I don’t altogether blame them.¹²²

In most senses, far from not being the required ‘politician figure’, Dillon adeptly read and navigated the political environment in which NICE had to function. (Richard Sykes, the Chairman of GlaxoWellcome, regarded him as *too much* of a politician, as we shall see in Chapter 5.) Dillon’s own account treats his own ‘political’ operations and those of Rawlins as more or less inseparable, and gives a vivid picture of the close relationship with New Labour Whitehall:

‘we had pretty close engagement with ministers and their special advisers ... we were frequent visitors to ministers’ offices, we had meetings with Tony Blair ...

[Q:] you would pick up the phone to these people?

[A:] Yes’.¹²³

Dillon’s enthusiasm, curiosity and energy meant he could get more involved in a subject than the colleague responsible for it might wish. At least one former Director at NICE certainly found his management style too ‘hands-on’. This was by no means a universal view. One member of the original Board does offer some corroboration when they claim that Dillon did not, a few years on, want a ‘hard-headed’ expert on the Board who might have been a threat to his own intellectual authority.¹²⁴ What is not in doubt is Dillon’s commitment to taking the initiative and providing decisive leadership. The chief executives of many other public bodies aspired to do this: since the introduction of general management in the NHS in the 1980s it had been the preferred style. Dillon succeeded in living up to the aspiration. The large majority of those commenting on him as a manager see him as an exceptionally good one, whose skills served NICE well.

Returning to the events of mid-1999, the final piece of this chapter’s narrative is DH’s completion of the statutory process of launching NICE. What remained to be done after the April launch was the making of Directions by the Secretary of State instructing NICE on its functions. This document and NICE’s Framework Document, a piece of standard Whitehall governance practice for arm’s-length bodies, both available in the National Archives, set out formally what DH wanted NICE for, and so represent key sources for its establishment.¹²⁵ NICE is given three

122 Different journalist, unattributable interview.

123 Dillon interview.

124 Unattributable interview.

125 TNA, JA 765/15 NICE, Nick Clarke to ministers, ‘Secretary of State Directions to NICE’, 27 July 1999.

principal tasks: firstly to undertake HTA on ‘the clinical benefits and the costs of ... health care interventions ... and to make recommendations’; secondly, develop guidelines on ‘best practice in the management of ... disease and conditions’ and, thirdly, ‘develop methods of clinical audit for the review of clinical care’. This reference to clinical audit harks back to the 1997 White Paper (see Box 2.1). Unlike HTA and guidelines, the language of ‘clinical audit’ has faded from use – though the practice lives on – and we shall revisit this third function, on which the early NICE expended significant effort, in Chapter 3 when we look at NICE’s relationship with the medical profession.

Another feature which strikes the present-day reader of the Directions is the liberal peppering of phrases preserving the Secretary of State’s control over, for example, topic selection and the approval of each NICE recommendation and guideline before its dissemination (a right of approval not exercised in practice). NICE has since become considerably more independent of government control, as we shall see in later chapters. One matter which caused Parliamentary controversy was the list of matters to which NICE had to ‘have regard’ in the exercise of its functions.¹²⁶ The controversial one was ‘any guidance from the Secretary of State ... on the resources likely to be available’. When the Directions were published, DH officials drew ministers’ attention to lobbying by the ABPI for the removal of this criterion. The pharmaceutical industry wanted NICE to be free to make its recommendations, unconstrained by any view of what funds were likely to be available to fund them. The advice to ministers, which they accepted, was to retain this affordability criterion, since ‘NICE will have to have regard to the broad resource prospects for the NHS if its guidance is to be credible’.¹²⁷

With the August Statutory Instruments mentioned earlier, the act of creation was complete, and NICE could make its own way in the world, not – of course – leaving these tramlines of policy, which also included publication of an initial work programme, but nevertheless exercising a wide discretion in how it followed them.¹²⁸

The launch window of 1997–99: concluding reflections

This chapter has shown how the 1997 change of government opened a window in which the establishment of an arm’s-length body to provide the NHS with HTA and treatment guidelines, bringing together both effectiveness and cost-effectiveness, became possible. A little political science, especially about the nature of ‘policy windows’, has helped shed light on why events unfolded as they did. We have shown how the incoming government took this opportunity, moving rapidly while it still enjoyed a political honeymoon with important actors, including large

126 House of Commons (1999).

127 TNA, JA 765/15 NICE, Nick Clarke to ministers, ‘Secretary of State Directions to NICE’, 27 July 1999.

128 TNA JA 614/331 The new NHS: N.I.C.E. Press Release: ‘NICE programme to target killer diseases’, 4 November 1999.

sections of the health professions. The chapter also demonstrates that NICE was given political permission, indeed encouragement, to develop its roles ambitiously from the start. There was nothing tentative about either the government's policies for NICE (except perhaps in the first public statement, the 1997 White Paper), or the preparatory work on their implementation undertaken by Rawlins, his gradually assembling cast, and DH.

In concluding, how should we interpret these busy years? Two observations seem justified. First, the two points of view circulating in policy communities about HTA, optimistic and pessimistic, which were discussed in the first section of the chapter, were both influential. Neither became dominant. NICE did not become the tool of the pessimistic, economising, persuasion and devote itself to exerting downward pressure on NHS spending. In Rawlins' comment of 1999, already cited, 'anyone who believes that NICE will reduce NHS expenditure is whistling in the wind'.¹²⁹ Nor did NICE confine itself to the wider economising agenda of helping the NHS to spend whatever was available as effectively as possible ('allocative efficiency'). On the contrary, NICE's goals, right from the start, extended beyond this and into the territory of the 'optimists', which included geographical equity – ending the 'postcode lottery' by introducing national assessment for new technologies – and better access for NHS patients to new medicines. And sometimes the dedication to more effective health care – by producing high quality evidence-based guidelines – was an end in itself, not one qualified by the need to look at cost-effectiveness (to the chagrin of Smee and others).

Coming to the history of NICE with a preconceived idea that NICE was an HTA organisation may be unhelpful, then, as we shall see in later chapters. Rawlins himself, after all, often declared that NICE's guidelines – which frequently confined themselves to effectiveness, rather than cost-effectiveness – were more important: he told us 'the guidelines have been the thing that's really made the big difference for NICE'.¹³⁰ Indeed it would be misleading even to assume that producing health technology appraisals (Chapters 5 and 8) and treatment guidelines (Chapter 6) were always conceptually distinct activities for those planning and directing NICE's work, notwithstanding the way these have become separate programmes with separate teams within NICE.

The second observation to be made is that the new government re-framed the policy problem so that setting up an arm's-length body became conceivable. As Frank Dobson told Timmins,

there was no national body advising on whether things were worthwhile. There were lots of bodies producing guidance ... but none of it had any authority. It was a perfect shambles. And if we were going to get a rational approach something like NICE was needed.¹³¹

129 *Times* 27 May 1999, Viagra now: the Government cannot escape the reality of rationing.

130 Rawlins interview. NICE make this point in print, for example NICE (2000).

131 Timmins (2016), 43.

And in the words of Pink, which bear out our arguments in Chapter 1:

NICE benefitted from programs that were funded by the previous government ... But under the previous administration, the notion that that should all come together in a national body was a complete non-starter, I say that as someone who was working for the previous administration and would have liked NICE to be created a lot earlier. But there was just no way a government body such as NICE was going to come into being, perhaps the government would have smiled on a professional body [doing the work of] NICE coming into being, but that wasn't going to happen either, because the professional leaders were never going to set up such a body.¹³²

NICE, then, emerged as an amalgam of optimistic project to improve access and equity, and pessimistic project to wring the most out of every last pound of scarce health spending and turn away new technologies when this philosophy required that. A second legacy of these two years of preparation was that NICE began life as independent-minded body given free rein by government in a quite new way. With these understandings in mind, Chapter 3 will take an analytical look at the young organisation at work.

Bibliography

Primary sources

- BBC News (website) (2004) Profile: Alan Milburn, 7 September 2004.
- Buxton papers DH (1999) Memorandum of Understanding on Appraisal of Health Interventions between DH and NICE in August 1999, typescript.
- DH (1994) *Supporting Research and Development in the NHS. A Report to the Minister for Health by a Research and Development Task Force Chaired by Professor Anthony Culyer* (London: HMSO).
- DH (1997) *The New NHS Modern. Dependable* (London: HMSO).
- DH (1998) *A First Class Service* (London: HMSO).
- House of Commons Select Committee on Health (1999) Minutes of Evidence. Examination of witnesses (Questions 20–39), 4 February 1999.
- House of Commons: Third Standing Committee on Delegated Legislation (1999) Wednesday 10 March 1999: National Institute for Clinical Excellence (Establishment and Constitution) Order 1999 4.30 pm.
- Economist*, In sickness and in health, Vol 393, Issue: 8652, 10 October 2009.
- Guardian*, 11 January 2013, Alasdair Liddell (1949–2012).
- House of Commons, 10 November 1999: National Institute for Clinical Excellence (Vol 337, Col. 1066).
- Independent* 2 January 1996, NHS 'wastes' 1bn on ineffective treatments.
- NICE (2000) *Corporate Plan 2000–2003* (London: NICE).
- NICE (2019) *Report and Accounts 2018–19* (London: NICE).

132 David Pink, in Atkinson and Sheard (2020), 12.

- NHS Executive (1999) *Faster Access to Modern Treatment: How NICE Appraisal will Work: a discussion paper* (Leeds: NHS Executive, typescript).
- Royal College of Physicians (2015) Professor Jane Dacre is elected president of the Royal College of Physicians (Last accessed 23 September 2024).
- Times* 27 May 1999, Viagra now: the Government cannot escape the reality of rationing.
- TNA, JA53/946, CSR6, Machinery for Cost and Clinical Effectiveness.
- TNA JA53/946, Langlands to ministers, Developing Quality in the NHS, 16 September 1997.
- TNA JA53/946, Sheila Adam to Milburn: Managing Clinical Innovations Group, October 1997.
- TNA, JA53/946, CSR6: Machinery for Cost and Clinical Effectiveness. 4 December 1997.
- TNA, JA53/946, Milne and others to Jay, Galbraith and others, Creation of InterDEC, 18 November 1997.
- TNA, JA53/946, Setting the expenditure implications for a sample of Health Technology Assessments, 11 November 1997.
- TNA, JA53/946, National Institute for Clinical Effectiveness, 2 March 1998.
- TNA JA53/947, National Institute for Clinical Effectiveness (NICE), ‘NICE Project Team Meeting With Professor Michael Rawlins: Agenda 21/12/98’.
- TNA JA53/947, National Institute for Clinical Effectiveness (NICE), Gina Radford (PH Development Unit) and Charles Dobson to Milburn, ‘National Appraisal of New Technologies’, 19 January 1999.
- TNA JA 614/331 The new NHS: N.I.C.E., Press Release: ‘NICE programme to target killer diseases’, 4 November 1999.
- TNA JA 765/15, NICE, April 1999–July 2000.
- TNA, JA 765/15 NICE, Nick Clarke to ministers, ‘Secretary of State Directions to NICE’, 27 July 1999.

Secondary sources

- Atkinson P, Sheard S & Walley T (2019) “All the stars were aligned”? The origins of England’s National Institute for Health Research. *Health Research Policy and Systems* 17(1), 1–14.
- Atkinson P & Sheard S (eds) (2020) *Origins and Establishment of NICE (c. 1997–2002)*, witness seminar held online on 18 June 2020 (Liverpool: Department of Public Health and Policy, University of Liverpool).
- Atkinson P & Sheard S (2022) Designing effective central-local co-operation: lessons from Liverpool’s Covid-19 response. *Policy Design and Practice* 5(3), 346–361.
- Cairney P (2016) *The Politics of Evidence-Based Policy Making* (Basingstoke: Palgrave MacMillan).
- Cairney P (2017) Evidence-based best practice is more political than it looks: a case study of the “Scottish approach”. *Evidence & Policy* 13(3), 499–515.
- Cairney P (2021) The UK Government’s COVID-19 policy: what does “guided by the science” mean in practice? *Frontiers in Political Science* 3, 1–14.
- Dunlop C, Radaelli C & Trein P (eds) (2018) *Learning in Public Policy* (London: Palgrave, 2018).
- Edwards B & Fall M (2005) *The Executive Years of the NHS* (Oxford: Radcliffe).
- Hennessy P (1995) *The Hidden Wiring: Unearthing the British Constitution* (London: Gollancz).
- Kingdon J (2003) *Agendas, Alternatives and Public Policies*, second edition (New York: Longman).

- Klein R, Day P & Redmayne S (1996) *Managing Scarcity: Priority Setting and Rationing in the National Health Service* (Buckingham: Open University Press).
- Kogan M, Henkel M & Hanney S (2006) *Government and Research: Thirty Years of Evolution* (Dordrecht: Springer).
- Leatherman S & Sutherland K (2003) *The Quest for Quality in the NHS A Mid-term Evaluation of the Ten-year Quality Agenda* (London: Nuffield Trust/The Stationery Office).
- New B (1996) The rationing agenda in the NHS, *BMJ* 312(7046), 1593–1601.
- New B (ed) (1997) *Rationing: Talk and Action in Health Care* (London: Wiley/King's Fund).
- Sheard S & Donaldson L (2005) *The Nation's Doctor: The Role of the Chief Medical Officer, 1855–1998* (Oxford: Radcliffe Medical Press).
- Sheard S (2010) Quacks and clerks: historical and contemporary perspectives on the structure and function of the British Medical Civil Service. *Social Policy & Administration* 44, 193–207.
- Smee C (2005) *Speaking Truth to Power: Two Decades of Analysis in the Department of Health* (Oxford: Radcliffe).
- Timmins N (2012) *Never Again? The Story of the Health and Social Care Act 2012: A Study in Coalition Government and Policy Making* (London: King's Fund and Institute for Government).
- Timmins N (2016) *A Terrible Beauty: A Short History of NICE* (Nonhaburi: Health Intervention and Technology Assessment Program HITAP).
- Weible C, Nohrstedt D, Cairney P, Carter D, Crow D, Durnová A, Heikkilä T, Ingold K, McConnell A & Stone D (2020) COVID-19 and the policy sciences: initial reactions and perspectives. *Policy Sciences* 53, 225–241.
- Who's Who & Who Was Who* (2023) *Dillon, Sir Andrew* (Oxford: Oxford University Press).
- Who's Who & Who Was Who* (2023) *Stevens of Birmingham, Baron (Simon Laurence Stevens)* (Oxford: Oxford University Press).

3 The ‘boost phase’

NICE at work, 1999–2006

This chapter looks at NICE during its formative early years. During this time NICE rapidly took on new functions including the evaluation of medical devices, surgical interventions and public health interventions. (Later, in 2013, as we will discuss in Chapter 7, NICE’s remit was extended even more ambitiously, into social care.) Working at NICE in its earliest years had all the excitement of a start-up company, plus challenging scientific and ethical problems, and (often unwelcome) media attention. Tension points like NICE evaluations of drugs such as Relenza and Herceptin, and the publication of guidelines on myalgic encephalopathy or Parkinson’s disease, show an organisation designing its processes under fire, and negotiating its role in the health care world.¹

It is not very unusual for a new body to be seen as having a ‘heroic period’ at the start of its existence, setting patterns for its subsequent behaviour. Staying true to the (real or supposed) ideals of founders, for example, is part of the ‘usable past’ of many entities, from nations to businesses.² Some of NICE’s staff see it in this way, referring, for example, to the need to remain true to the organisation’s ‘revolutionary roots’.³ NICE seems to exemplify particularly strongly this phenomenon of a powerful influence exerted by an organisation’s original culture over all that it subsequently does. As Andrew Dillon expressed it:

so much of the culture that NICE developed and indeed many of the principles that still endure ... were formed in those very early days. They are a product of the people who were around then, the way they thought, and you can trace some of the ways in which NICE sets up new programmes now back to decisions that were taken in the early days about the right way to go about bringing evidence together, interpreting it and producing something useful from it.⁴

1 On the ME guideline (NICE 2007), see Chapter 6.

2 The valuable concept of a usable past was popularised by the US historian Henry Steele Commager (1967).

3 Kendall Jamieson Gilmore, NICE Associate Director of Strategy, personal communication.

4 Andrew Dillon, in Atkinson and Sheard (2020), 54.

This setting of the culture in NICE's early days was mostly deliberate. Dillon (a critic might say, with the benefit of hindsight) said in 2020 that he regarded his most important legacy to NICE as:

the culture of the organisation ... I think ... I knew right at the start ... that it was an extraordinary opportunity to be appointed right at the beginning ... it brought with it some great opportunities ... one of the opportunities was that you can create the culture you would like to work at NICE.

[Dillon and his earliest colleagues] hope[d] that it would be a ... place ... where people really looked forward to coming in to work, partly because it was a job they wanted to do, the organisation was doing something they felt excited about and committed to, but partly because the atmosphere in the place would be fun, so that coming to work was more than just a way of paying the mortgage. ... the interaction with people, and the kind of people who had been appointed ... made you look forward to work, that was what I really hoped for.⁵

Of course how a Chief Executive recalls his original aspirations, and what his staff felt about it at the time, could be different: however, independent corroboration that this vision really was achieved includes this verdict from consultants who conducted a staff survey in about 2004: 'the overall conclusion was, we don't usually see staff who are so committed to what they do, outside the charitable sector'.⁶ Similarly, Jean Gaffin, who served on NICE committees and had a wide experience of the voluntary sector, recalls that:

the quality of the NICE staff has always been amazingly high. They recruit well, they must treat people well because they retain staff. ... The standard of paperwork and attention to detail is really phenomenal, and I think that is a sign of a well-run organisation. The committees matter ... but the material that you're fed, and the way it is dealt with after the discussions, is crucial.⁷

NICE at work: working at NICE

Three things distinguish NICE in its early years from the majority of government bodies. The first was the intellectual excitement of carrying out a task which was at once difficult and important. We saw in Chapter 2 how this was Dillon's feeling: colleagues who joined him felt similarly. Several report that it was the intellectual challenge which drew them to NICE more than anything else, for example Bruce Campbell, a surgeon who chaired the advisory committee for NICE's Interventional Procedures Programme, who referred to the 'fun' of his early work at

5 Andrew Dillon, interview 2 July 2020.

6 Gillian Leng, interview 26 November 2019.

7 Jean Gaffin, interview 25 November 2019.

NICE (and how this was later crowded out by procedural inflexibility and ‘political correctness’). He describes himself as:

attracted ... [to] topics that no-one else had tackled because they were too difficult, or aspects of practice that were controversial and there was really very little evidence. ... I liked saying “what is there here to inform us, how can we best make a judgement, what’s the best thing we can do, based on the evidence we have?” And that, I suppose, is what NICE does. So it was an intrinsic interest I suppose.⁸

For Dillon, Campbell and many others, it was precisely these questions about evidence-based (or evidence-informed) decision-making that provided the buzz. Gillian Leng (NICE’s Guidelines Programme Director from 2001, Deputy Chief Executive 2007–2020 and Chief Executive, 2020–2022), to add one more example: ‘was really interested to see NICE being set up, and thought, that’s where I’d like to work’.⁹ For others, it was more specifically the novel use of health economics, or the question (which we discuss in Chapter 4) of how to elicit and use social value judgements. This work had a high political, or policy, profile too, a relatively unusual combination which attracted a good field of applicants when posts were advertised, and contributed to existing staff’s motivation to stay on.

The second unusual aspect of NICE in this period was the improvisatory, problem-solving excitement of working in a start-up. This had some unexpected similarities with private business. In Dillon’s words, ‘in those days nobody talked about “start-ups” in the way they do now, but I guess it had the feel of a start-up’.¹⁰ David Barnett, who was in at the start as the first chair of the Appraisal Committee, says of his time at NICE: ‘that ten years of my career is probably the most engaging, exciting, and at times stressful, of the whole time’.¹¹ While the first Blair administration created a good number of new public bodies, it is fair to say that NICE approached the challenge of getting started with more flair and freedom than most.

This emerges vividly in the recollections of, among others who were on the initial staff, Anne-Toni Rodgers, who was NICE’s second employee, joining as Director of Corporate Affairs. Rodgers, whose career up to 1999 had been in the pharmaceutical industry, had a background of launching new teams in what would now be called the ‘market access’ operations of drug companies. Dillon actively encouraged her to apply.¹² Since this section uses her testimony a good deal, it is worth considering its reliability. It is not immune from the pitfalls of much ‘elite oral history’ – such as using stock phrases and ideas rather than eyewitness testimony, and post hoc burnishing of the speaker’s reputation – but the important factual details are well

⁸ Bruce Campbell, interview 13 January 2020.

⁹ Leng interview.

¹⁰ Dillon, in Atkinson and Sheard (2020), 19.

¹¹ David Barnett, interview 15 November 2019.

¹² Anne-Toni Rodgers, interview 8 October 2019.

corroborated with the recollections of others.¹³ Where other sources contradict her, we have quoted them, as in the section on the media below. Rodgers' background seems to have made her especially useful for the start-up phase:

NICE had a lot of academics and NHS managers, but they didn't have somebody who was commercially savvy and thought about the customer's perspective ... we quickly developed a customer focussed approach, it was very clear in how we operated and it was very different for an NHS body at the time.¹⁴

(Pressed on who the 'customer' was, Rodgers clarified that this meant, in order of importance, 'patients, NHS, professionals, public, because for us to succeed we had to have that, and then the industry'.)

One or two examples of this 'start-up' atmosphere must suffice. David Pink, joining NICE on loan from Department of Health (DH) on day one, recalls that, at the launch event itself:

the website ... supposedly launched by Frank Dobson ... wasn't a real website ... rather than risk the vagaries of the internet, I recorded a session of someone actually interacting with the website, but I recorded it as a DVD and then Frank Dobson had to act out as if he was showing the gathered press the website of the new organisation ... he was showing a film but pretending it was real.¹⁵

He adds that 'we had signed a lease, but the floor had only been installed in a couple of the rooms, the rest of the floor was up', while Rodgers recalls that before office furniture and machines could be purchased:

We (Andrew Dillon and I) sat stuffing envelopes on the floor ... we wanted to catch ... the last post, so I carried all these envelopes home in carrier bags to get into the post at Ascot. That's how much of a start-up it was, it was hilarious.¹⁶

Tony Culyer recalls how Board meetings, too, would be full of innovation and novelty:

Part of the excitement was that every meeting had consequences. In those days we were establishing the thing for the beginning, and then we got new

13 A good account of doing elite oral history is Seldon and Pappworth (1983). See also Berridge (2010) for a similar discussion, focussed on health policy.

14 Rodgers interview.

15 David Pink, interview 28 May 2020.

16 Rodgers interview.

things to consider, and we were inventing new institutions like the Citizens' Council.¹⁷

It certainly made it easier for NICE to innovate in this way that its relationship with government – which we examine later in the chapter – allowed it, at the same time, considerable freedom and yet also good access to ministers and special advisers. Of the various arm's-length bodies created by health ministers under the first Blair administration (1997–2001), NICE was a – perhaps the – favourite child.

The last of our three exceptional features of NICE in its early years was simply the managerial skill of the chief executive. We saw in Chapter 2 that Dillon was one of the NHS' high fliers, a group of hospital managers whose skills are rarely understood by those outside health care. A small public body (as NICE then was) was very lucky to attract a manager of this calibre, who would more usually have planned out a career running progressively larger acute hospitals. In year one at NICE, Dillon knew that delivery was what counted most for NICE's credibility. More importantly, he had the skills to make a telling personal contribution to this. As he wrote in NICE's first annual report:

What matters most is that we do what we say we are going to do and that we do it to a consistently high standard. This is critical to gaining and holding onto the trust and confidence we are working for.¹⁸

NICE and its health care partners

NICE survived, then thrived, by keeping a complex group of stakeholders sufficiently happy, taking account of their views, and where necessary working on changing their behaviour. Stakeholders included doctors and their medical Royal Colleges, other health care workers, the pharmaceutical industry and the NHS. In the words of Leng:

over the years I've mapped out all the key bodies with influence, who either work with us directly or might support implementation of our products, or might commission us: ... a whole range of different roles that external organisations might have ... [and] they've changed over the years.¹⁹

This section focuses on one part of NICE's policy environment: people and organisations that were active in health care, with whom NICE consequently had to engage in order to achieve impact. One key constituency, however – patients, patient organisations and the general public – has been given a chapter of its own (Chapter 4), in view of its special importance in NICE's history, and the wider

¹⁷ Tony Culyer, interview 2 March 2020. The Citizen's Council is discussed in Chapter 4.

¹⁸ NICE (2000).

¹⁹ Leng interview.

relevance of its interactions with NICE for health policy in the UK. Accordingly, it is not discussed further in this chapter. After looking at the health care sector, this chapter turns to three other parts of NICE's policy environment: its relations with central government, the media and interested organisations in other countries. Operating as it does in such a complex policy environment, it is perhaps obvious that a major source of NICE's impact has been the quantity and quality of attention it devotes to managing these relationships.

An important factor in NICE's relations with all these different constituencies has been its approach to transparency. The word is now used so frequently in public life that it can become a nearly meaningless cliché, but from the outset NICE's Directors decided that it was in the infant organisation's interests to do as much business as possible publicly and with the maximum of consultation. NICE practices such as question and answer sessions in public Board meetings, then uncommon, have since been more widely adopted. Rodgers reports advocating this transparency when NICE's original Technology Appraisal process was being designed. She apparently said of one draft:

"the minute you send that out ... people are going to complain about it, so we'll call it an interim appraisal process." ... [we said] "we will use it for the first sets of appraisals, and during this time we'll ... take feedback on how it works from you." Which meant we shifted the debate from ... "this is idiotic, why are you doing this?" to "Ah, they're actually asking us for input." That defined how we ran our business. Transparency was key.²⁰

The professions

Every profession has its leaders and its rank and file. Relationships with both mattered for NICE, and the two categories required very different strategies. To start at the top, the medical, nursing and other health care professions in the UK each have a complicated ecology of leaders, some devoted more to education, others to professional standards, some passionately interested in health policy of every type others in conditions of service, politics and so on. Bulking largest in NICE's policy environment were the medical Royal Colleges.²¹

The Colleges are a central part of medicine's existence as a profession in England.²² In this period most of them resembled Oxbridge colleges, in the eminence of their heads, their status as thought leaders, their (sometimes ancient) wealth, strong institutional traditions and strong networks into the policy world. A regular meeting between the Chief Medical Officer and their assembled Presidents was one

²⁰ Rodgers interview.

²¹ In 1997 there were ten Royal Colleges, the best known being those of Physicians, Surgeons and General Practitioners. Although these two paragraphs are written in the past tense, change since 1997 in the features described has been slow.

²² The Scottish position is similar.

example of such networks. Phone calls from College Presidents to health ministers would be put through, not transferred to an official.²³ The Colleges commanded great respect from rank-and-file doctors, who had been socialised into professional attitudes which the Colleges themselves moulded, above all by their control of higher specialist training.²⁴ While intellectual and institutional conservatism were not universal, they were a frequent feature, and this was not promising ground for an innovation like NICE. As Pink remarked:

I remember ... a president of a Royal College pointing out to me that his College had existed since ... [the year] fifteen something or other – and that the NHS was a relatively recent phenomenon from their point of view, and [he] intended, in all seriousness, not to humour [it].²⁵

On standards of specialist practice, Chapter 1 has shown how the consensus, shared in government even after Thatcher's attack on the power of the medical profession in the 1980s, was that the Colleges' word was law. We saw there, too, how the Colleges took an immediate interest in clinical guidelines, even if only a defensive one seeking to control their content for fear of external interference. Governments in the 1980s and 1990s had drawn the line at challenging clinical autonomy: guidelines were acceptable so long as they did not purport to instruct a doctor what to do. The choice of verbs about the role of guidelines mattered (and still matters). Of the position in 1999, Pink recalled that:

I had been trying to get the medical royal colleges, and the nurses, and midwives ... to set up such an institute for a number of years, and I would have had access to government money to support it ... what they had to do was agree to it ... [so] that their members would see they had bought into it, and that was where they forever balked.²⁶

All in all, the starting point for NICE's relationship with the Colleges was not terribly promising in 1999: Dr Peter Littlejohns, NICE's founding Clinical and Public Health Director, recalled that:

at the beginning the Colleges were polite to Mike Rawlins because they knew him, but on paper they were very critical, actually quite derogatory. I mean George Alberti did an article talking about 'Bill and Ben, the Flowerpot Men at NICE', I mean Mike and Andrew. I'm not sure ... obviously that was very flippant.²⁷

23 On the declining status of medical advice to government, however, see Sheard S (2010).

24 That is, the process of becoming a consultant physician, surgeon or GP etc.

25 Pink interview.

26 Pink interview.

27 Peter Littlejohns, interview 18 September 2019.

This history of the Colleges' involvement in guidelines led NICE directly to their doors. As so often, money worries risked souring the relationship. NICE had next to no money in its first years, but civil servants had ingeniously decided to repurpose some substantial DH grants to the Colleges as NICE money for guideline production. Getting away with this without gravely offending the Colleges required deft footwork, partly from DH but mainly from Rawlins. In the words of Rona McCandlish, a midwife and researcher who had an honorary position on the Royal College of Obstetricians and Gynaecologists' guidelines board at the time, the history of DH funding of 'clinical effectiveness' work at the Colleges:

...didn't mean to say that NICE was well-received because, perhaps, there had been a, not cosy, but a way of doing things that the Colleges had with...

Q: I've heard that it was quite a hands-off thing, that the Colleges ended up doing what they thought was best with the money?

A: That's right. Best with the money and inconsistent and what would be likely to go down well with their members. So it wasn't a straightforward transition'.²⁸

The solution spared the Colleges' feelings and saved face: NICE took control of how the funds were allocated, but they were spent with the Colleges at first. That left NICE in a position to bring in, gradually and diplomatically, a different agenda, about topic selection, and the processes and standards of guideline production.²⁹ This was classic Whitehall politics: it had worked before when DH had taken control of NHS hospitals' research budgets in the 1990s – following a review by none other than Culyer, by now NICE's deputy chairman.

Rawlins' own recollections of this add a human dimension:

when we started off, Frank Dobson said "I'm afraid I've not got much money for you, you're going to have to use the clinical effectiveness money" ... When I told [George Alberti, as President of the Royal College of Physicians], 'the bad news is that you're going to lose that clinical effectiveness money: the good news is that you're going to get it back again, but you're going to use it to produce guidelines,' [he was] fine. I knew the President of the College of Surgeons pretty well too – Barry Jackson – he'd been with me at St Thomas'.³⁰

28 Rona McCandlish, interview 3 December 2019.

29 Chapter 6 will show that it was DH which made the topic selection.

30 Mike Rawlins, interview 18 September 2019. George Alberti (interview 17 January 2023) bears out this account. Sir Barry Jackson was President, Royal College of Surgeons, 1998–2001. Rawlins and Jackson knew each other at St Thomas' Hospital, London, in the late 1960s or early 1970s. Rawlins' mention of personal ties hints at the way medical networks allow doctors to draw on early acquaintance as capital long afterwards, a feature of many professions but particularly strong in medicine. On ways of reading social networks, see Morrissey R (2015) and Berridge (2005).

NICE's task of winning its stakeholders' support for its work was pursued by means of an untiring charm offensive. Where this was directed at the medical profession, Rawlins was its spearhead and Leng described how, 'often, ... Mike Rawlins, would go along to those meetings [with Colleges], senior medics, just important relationships'.³¹ He quickly showed his mettle as an advocate. For example, on the important topic of clinical autonomy and the possible effect of NICE guidelines in limiting it, in 1999 the chairman of the Health Select Committee, during an evidence session with Rawlins, reported that doctors had told him:

there are some threats to their clinical freedom in respect of what is being proposed by NICE, ... [NICE] will be looking over their shoulders and possibly interfering in an area that has been left to their discretion?³²

Rawlins' response was that of a doctor trying to use gentle persuasion on his medical colleagues:

As a practising doctor myself I have some sympathy with that, but ... when you are confronted, as wise old George Godber said many years ago, with the patient in front of you, you also have to remember the rest of the patients in the waiting room. You cannot allocate resources to the one individual without taking into account those others ... We have finite resources in the health service, we always have had. Every health care system has that sort of problem.³³

This was the principle of opportunity cost expressed in the language of the doctor.

Doctors were by no means, however, the only health care profession with whom NICE needed a good relationship. The nursing and midwifery professions, taken together, ranked second to medicine in terms of influence over policy and politics, and thus also needed NICE's assiduous attention. By the 1990s, government attitudes had progressed from treating these and other health care professions as 'handmaids' to medicine, via a phase of political correctness in which the phrase 'and nursing' was sprinkled over every document, to one which looked at the roles and policy relevance of these professions and their clinical activities in a more case-by-case, evidence-informed, way. NICE's behaviour reflected this newer perspective.

The NICE Board generally had at least one nurse or midwife. While both Rawlins and Rodgers took pains to get Board members to think corporately rather

³¹ Leng interview.

³² House of Commons, Health Committee (1999), Q. 99. The committee chairman was David Hinchliffe MP.

³³ House of Commons, Health Committee (1999), Q. 9. George Godber was Chief Medical Officer 1960–1973: *Who's Who & Who Was Who*, 'Godber, Sir George' (2007).

than as representatives of any profession, this composition was a careful choice, intended, besides recruiting talented people, to send a signal:

the nursing community was so pleased that a nurse had been appointed to the board, because there had been lots of discussion about whether a nurse would be or would not be, when NICE was established.³⁴

McCandlish played a big role in guideline development in NICE's earliest years, joining the Board in 2008: we will see more of her work in Chapter 6, where we shall also note that, of NICE's six collaborating centres for guideline production, one was the Royal College of Nursing (RCN). One interviewee told us that the RCN was 'much happier to follow instruction than, say, the College of Surgeons'.³⁵ This may come as a surprise to those familiar with the vigour with which nursing bodies have generally represented the profession to government in recent decades: our interviewee was discussing guideline production rather than speaking more generally.

Mary McClarey, another research nurse, served on the Board from the beginning. She had been the RCN's clinical effectiveness lead during the 1990s, when the non-medical health professions had been hard at work establishing the validity of their own contributions to the clinical effectiveness and clinical audit agendas. McClarey felt a strong sense of representing nursing, for all Rawlins' and Rodgers' reservations about professional advocacy on the Board, which she fully understood: 'Mike was quite clear always to say, "you're a board member"'.³⁶ During her time on the Board, she seems to have been a significant channel of communication with the nursing profession; she was often contacted by colleagues who wanted something passed on:

They overstated my power ... [but I could] take that suggestion to the Board to say, "look, from a nursing perspective there is an urgent need for x to be considered", ... or I could simply email Carole, or Gillian, or whoever, and say, "I've just had this request from the RCN ... the CPHVA", or whatever, and pass it on with a paragraph of why I think this is worth passing on.³⁷

Some of NICE's relations with professional leaders – and others groups to whom we will shortly turn – were conducted through its Partners Council, a stakeholder

34 Mary McClarey, interview 7 January 2020. The original Board had eight non-executive members: including Rawlins, these comprised three doctors; McClarey was the sole nurse, Culyer a health economist and the others lay people (NICE 2001). While Board appointments are made by the Secretary of State, after due process, skilled Chairs like Rawlins are more than capable of encouraging their preferred candidates to apply, often successfully.

35 Unattributable interview.

36 McClarey interview.

37 McClarey interview. Carole (Longson) was NICE's co-ordinator of Technology Appraisals, Gillian Leng the deputy chief executive; CPHVA is the Community Practitioners' and Health Visitors' Association.

body which DH had decided NICE must have. Interviewees tended to refer diplomatically to its *early* usefulness: be that as it may, it did not endure for the long term. It is hard not to conclude that it was a civil servant's bright idea about how to do 'stakeholder engagement': one which those with more personal experience of the activity did not greatly appreciate. In Rawlins' words,

there was something called the Partners' Council which was set up, we were mandated to have the Partners' Council, which was really a sort of stakeholders' council, so there was patients and the professions and the industry and so on. It gradually withered on the vine and attendance got less and less and less, and that was when Andrew and I decided to ask [the] Secretary of State ... to remove it from our Statutory instruments. ... Basically because we were interacting in other ways. ... through the Colleges, patient organizations.³⁸

Turning from NICE's relations with professional leaders to its interactions with rank and file clinicians, NICE has had a substantial impact on professional practice. How do we know? To begin with, the paper trail of NICE publications with this goal is very large indeed. First and foremost were the guidelines. We have already noted that the choice of verbs about guidelines mattered, in the context of wider controversy about the limits of clinical freedom: what did a guideline *do*? No one in DH or NICE wanted guidelines to compel, producing the kind of 'cookbook medicine' which would deskill the clinician. There was always a distinct difference between what NICE sought to do in guidelines and the "protocols" that were widely introduced in the US in the 1980s and 1990s by Health Maintenance Organisations. The latter had to be followed for health insurance claims to be paid: something a lot closer to 'cookbook medicine'.

Even if 'binding guidelines' (an oxymoron) had been shown to be good for effectiveness or cost-effectiveness, they would have been terrible politics. Giving evidence to a Parliamentary committee at the time of NICE's establishment, Rawlins said:

clinical guidelines never can encompass one hundred per cent of patients, people vary and some people, some patients, do not fit into guidelines so there needs to be a lot of professional judgment in determining which people are appropriate to follow the guidelines and which patients are not.³⁹

This is a line which NICE has reproduced frequently: 'Guidelines help health professionals in their work, but they do not replace their knowledge and skills'.⁴⁰

38 Rawlins interview.

39 House of Commons, Health Committee (1999).

40 WHO Regional Office for Europe (2007), 21, quoting NICE.

Currently, the landing page for each online NICE guideline negotiates the questions of professional – and patient – autonomy in this way:

When exercising their judgement, professionals and practitioners are expected to take this guideline fully into account, alongside the individual needs, preferences and values of their patients or the people using their service. It is not mandatory to apply the recommendations, and the guideline does not override the responsibility to make decisions appropriate to the circumstances of the individual, in consultation with them.⁴¹

Mark Baker, in charge of guidelines for several years, recalled that: ‘Guidance was aimed at the typical doctor’.⁴² This applied not only to NICE guidelines and technology appraisals, which were often rather dry and detailed for everyday professional use, but also to more tailored products such as Clinical Knowledge Summaries, which ‘provid[e] primary care practitioners with a readily accessible summary of the current evidence base and practical advice on best practice’, or NICE Quality Standards, which ‘set out priority areas for quality improvement’.⁴³

The range of NICE publishing activity to influence clinician behaviour also included, over time, distribution (though not editorial control) of the British National Formulary (the medicines formulary carried and consulted daily by large numbers of British health care professionals).⁴⁴

A second kind of evidence about NICE’s impact on professional practice comes from our interviewees. For example McClarey:

... used to do a monthly column with one of the nursing journals: that was quite fun. You had to do it again and again, and each time you think of something new to say. That was quite good, because you could write about what the latest guidance was coming, ... key points of what it would mean for nursing. That went down pretty well, I think, I did that for several years.⁴⁵

Leng, herself a doctor, recalled noticing that NICE was gradually winning over most doctors:

we do have general support from the medical profession now. Early days I think we probably didn’t ... They don’t always agree, they might pick holes in various bits of recommendations, but generally they trust what we do.

41 For example, NICE (2014) CG178 Psychosis and schizophrenia in adults: prevention and management (Last accessed 27 October 2023).

42 Mark Baker, interview 18 May 2022.

43 NICE (n.d.) ME/CFS (web page); NICE (n.d.) How to use quality standards (web page).

44 As a formulary, the BNF ‘details all medicines that are generally prescribed in the UK, with information about: indications and dosages, contraindications’ and so on. The editorial process used by BNF Publications to produce its resources has been NICE accredited.

45 McClarey interview.

... I have taught medical students ever since I've been here ... You used to talk to them about NICE and you'd get comments like, "there should just be more money for the NHS and you shouldn't have NICE", and "my consultant doesn't agree with what NICE has said", but now ... medical students see NICE as essential and use NICE guidelines to pass their exams. It's kind of bread and butter, whereas it used to be ...⁴⁶

A telling example provided by Campbell, who chaired the NICE committee on interventional procedures, illustrates the process by which guidance could gain influence among clinicians:

NICE produced this guideline saying you should use ultrasound to visualise the veins [when inserting central venous lines] ... many anaesthetists ... were just vitriolic about how unnecessary this was ... A few years later, nobody would have considered putting a central line in without an ultrasound machine.

Q: What would have brought them round?

A: clearly what the guidelines actually [said], a lot of the forward-thinking people were already doing: ... the guideline prompted hospitals to get an ultrasound machine ... a couple of anaesthetists started using it and said, "it's much easier," and gradually it crept through the profession.⁴⁷

Professional regulators in the UK such as the General Medical Council (GMC) have accepted that they should direct their registrants to pay heed to NICE guidelines. The GMC, for instance, directs doctors that:

When making decisions about using resources, you must ... Be familiar with any local and national policies that set out agreed criteria for access to a particular treatment ... For example ... NICE ... guidelines.⁴⁸

here the verb is a fairly undemanding 'be familiar with'. NICE also had an indirect impact on practice via its influence on the content of the widely-read journals – not those read only by academics, but high-circulation ones like the *British Medical Journal*. NICE staff, from Rawlins to those at more junior level, published in the *BMJ*, and NICE's growing stature has been reflected in the frequency with which its work is cited. In the professions, journals matter: adherence to professional standards is understood to include keeping one's relevant knowledge up to date.⁴⁹

46 Leng interview.

47 Campbell interview. See NICE (2002).

48 GMC, Leadership and management for all doctors. While the Nursing and Midwifery Council website refers readers to NICE guidance, it does not appear to carry a similar statement.

49 For example the GMC instructs doctors to 'Keep your professional knowledge and skills up to date' (GMC, The duties of a doctor registered with the General Medical Council).

Documenting NICE's efforts to influence clinical practice in this way is one thing. How far were these successful? One of the big themes in public policy is the so-called 'implementation gap', and it is unsurprising that NICE itself should have devoted energy to measuring its own impact, and seeking to maximise this.⁵⁰ The question of how far to go was not a simple one (we encountered the same issue in our earlier work on the NHS R&D Programme).⁵¹ Leng took a particular interest, but began by observing:

Mike Rawlins was known for saying, in the early days, 'NICE isn't in the implementation business'. He was quite clear ... NICE's role was to produce the guidance ... the [NHS] Modernisation Agency and other[s] ... would do the job, but after a few years it became clear that nobody else was actually taking any interest in the implementation of our guidance, and we needed to.⁵²

Leng's concern to secure as much impact as possible triggered a substantial programme of work, including a strategy comprising clear communication of guidance, work to motivate uptake (e.g., through the Colleges), practical support such as educational tools and evaluation. NICE secured the preparation of 'impact reports', which would go to its Board meetings, distilling as much as could be discovered about what different guidance in a particular field had made.⁵³ Martin Eccles, the founding chairman of NICE's Guidelines Advisory Committee (see Chapter 6), would in 2006 become one of the founding editors of the journal *Implementation Science*, an indication that NICE had access to rigorous scholarship to help in its approach to implementation.

One 'pathway to impact', as some of the modern jargon would describe it, which was identified while NICE was still in embryonic form, was the use of 'clinical audit' or 'clinical governance'. These were terms coined by DH during the 1990s for a process to ensure that consultants would be properly accountable for the consequences of their decisions.⁵⁴ We noted in Chapter 2 how the 'blueprint' for the 'new NHS' proposed by Baroness Jay involved NICE setting standards, and bodies such as the Commission for Health Improvement (CHI) checking that they were being met. The government expected that processes of clinical audit would ensure that staff were working towards NICE guidance from day to day. Accordingly, the Secretary of State's Directions to NICE which we noted in Chapter 2 gave NICE three tasks – not only HTA and guidelines as we might have assumed but also to 'develop methods of clinical audit for the review of clinical care'.⁵⁵ Enlarging

50 See for example Pressman and Wildavsky (1984) and Marsh and Rhodes (1992).

51 Atkinson and Sheard (2019).

52 Leng interview.

53 Leng interview.

54 Pollitt (1993).

55 For these Directions, see TNA, JA 765/15 NICE, Nick Clarke to ministers, 'Secretary of State Directions to NICE', 27 July 1999.

slightly on this, Rawlins told the Health Select Committee in 1999 that NICE would do three things: HTA, guidelines and, thirdly, 'to develop and promote clinical audit particularly in the areas in which the Institute has produced appraisals and produced clinical guidelines for'.⁵⁶ NICE commissioned clinical audit materials from the University of Leicester to accompany individual guidelines.⁵⁷

In effect, then, NICE guidance was to shape clinical practice in the NHS as a result of clinical audit: effectively, peer pressure. This project was substantially successful: a revealing indication of NICE's ability to get enough of the health care professions onside. Twenty years on, few now dispute NICE's right to publish guidance (guidelines & HTA) which, in practice, constrain health care professionals' clinical freedom a good deal. Rawlins and his colleagues must have done a good job on the medical Royal Colleges, and the professions more widely: their views have moved a long way.

The pharmaceutical industry

NICE's initial relations with the pharmaceutical industry were unsurprisingly frosty. Pharmaceutical executives had a range of fears, some well-founded, that government policy could leave their industry with reduced revenues. To some degree they had been caught napping by the announcement of NICE and the new policy emphasis on cost-effectiveness and population health. Julia Earnshaw, who worked in this under-regarded sphere of health outcomes at Glaxo at the time, explains this in terms of drug companies' cognitive world.⁵⁸ The influential figures in drug development were scientifically and clinically oriented, and the people to whom they spoke in the NHS were senior clinicians. Evidence was all about the clinical trial, and a drug's safety and efficacy, not about these wider issues. Earnshaw recalls giving internal briefings about HTA and cost-effectiveness to R&D clinicians who were:

outraged ... it was "what about the patients?" They're so absorbed in the science and the clinical thing and they can see this medicine's going to really help people, and those people have very little involvement in selling it, they were horrified. ... it's just it wasn't their world. Remember the people they were interfacing with at that point in the NHS, it wasn't their world either. ... they were gobsmacked, shocked, no idea.⁵⁹

Industry leaders felt, with some justice, that government policy was bolting on new innovations rather than taking a coherent overall view of what it wanted from the pharmaceutical sector. Government papers show the British Pharmaceutical Group

56 House of Commons, Health Committee (1999).

57 Littlejohns interview.

58 Julia Earnshaw, interview 15 November 2019.

59 Earnshaw interview.

putting this to the Prime Minister in March 1999. Their note raises a spectrum of issues, from pricing to R&D, but NICE is the new and unsettling factor.⁶⁰ The BPG feared that ‘under current proposals industry would be excluded to a significant extent from the operations of NICE’. This was a high-powered group of chief executives, including Tom McKillop (AstraZeneca), Richard Sykes (Glaxo Wellcome) and Jan Leschley (SmithKline Beecham). The BPG returned to the charge later in the year, after NICE’s rejection of Relenza, discussed in Chapter 5.⁶¹

Adrian Towse, from the vantage point of director of the Office of Health Economics (funded by, but enjoying an interestingly semi-independent relationship with, the Association of the British Pharmaceutical Industry [ABPI]), now thinks the industry misjudged the politics:

in my view the industry’s initial handling of the appearance of NICE was politically disastrous...

it suddenly becomes a ‘well are you going to stand up to these guys? Are you going to let them walk all over you?’ and at that point the government’s position is obvious, so the consequence of going down that route was to reinforce Number Ten’s commitment to Frank Dobson and to NICE.⁶²

Behind the scenes, however, others were taking a longer view. At Glaxo, the decision was taken (see Chapter 5) to submit Relenza to NICE again with more evidence, but only for those at greatest risk from flu, a strategy that was rewarded with approval. More broadly, Trevor Jones, Director-General of the ABPI, seems to have decided early, probably as soon as he was called in for a briefing by Dobson, that NICE mattered a lot to the government and that his goal should be to reach a satisfactory way of living with it:

[Dobson] said “Trevor, I am going to introduce something which you won’t like, which is called NICE” ... I said ... you have been very clear with the nation that people should get medicines, well healthcare, free at the point of access, Aneurin Bevan stuff, and equally there shouldn’t be a postcode lottery, and there clearly is. ... Very socialist view of life, and a good one. So, that was my main concern, to say how would we deal with that?⁶³

The picture we have given so far in this chapter of NICE working out relationships with its stakeholders has been one of NICE taking the initiative, working out solutions to differences, achieving success by painstaking persuasion and focusing on doing its work well. Jones’ recollections suggest that the path was not as smooth as this:

[when] it started off, it was just total chaos, frankly. They just arbitrarily picked topics to review, more, in my opinion, guided by the politics of the

60 TNA: JA 614/331 The new NHS: N.I.C.E.

61 TNA: JA765/6 Hip prostheses appraisal (sic).

62 Adrian Towse, interview 1 March 2021.

63 Trevor Jones, interview 22 April 2020.

product than the need for patient access, and then the systems of review were very obtuse and we didn't know what kind of data we were going to provide and they were going to get, and then there started to be leaks, and that is the last thing you want, uncertainty ... so I think the first year was a really difficult time for us.⁶⁴

Jones' irritation comes across clearly in the text of various briefings he gave to industry bodies, which he has shared with us. But the overall story he tells is that over the first two years or so, NICE learnt what it had to do differently, and the parts of the industry with most insight into UK politics began to think in terms of adapting to NICE's existence and looking for opportunities in it. Others, such as some of the American companies, continued for longer to think that approaching NICE as a negotiation, and a trial of strength, would bring them the desired outcomes. Rodgers recalls, for example, the head of Novartis telling a conference that: 'NICE is just this body that you can influence ... how we [got our drug approved] is we lobbied, we influenced, we got the patients to write letters' – a claim which she rebutted.⁶⁵

This process of mutual adaptation is also described by Earnshaw, who recalls Glaxo starting a project about 'what do we need to do as a business in response to the development of evidence-based medicine?'⁶⁶ Later, she worked intensively with NICE on the development of appraisal methods. She describes this as at least partly a process of encouraging NICE not to follow all the enthusiasms of HTA academics, but rather to get some 'realism' into how assessment was done. One change was to allow the company's representatives to answer questions at Appraisal Committee meetings: this saved time as they were usually the ones with the necessary data. Summing up, Earnshaw speaks of NICE's first few years as a time of:

dawning recognition this wasn't going to go away. Your environment's changed: in any business if your customers change you have to learn about your customers and change as well, you can't expect to just carry on. So ... initially it was the R&D machine and [then] the whole drug development machine became much more aware and began to think about [HTA] as part of drug development.⁶⁷

Jones, meanwhile, was keeping a close eye on NICE, setting up what he called a NICE monitoring programme:

we had all that information in the companies whose products were being reviewed, and that meant that we could create scoreboards... when I went to see the minister or Secretary of State, I could actually say, look this is what is happening folks, and it is your organisation so can you sort it out?

64 Jones interview.

65 Rodgers interview.

66 Earnshaw interview.

67 Earnshaw interview.

As it happened, my relationship with Andrew Dillon and Michael Rawlins was very close, that meant that I could communicate with them and they did listen, which is great.⁶⁸

Over these first few years, most of the pharmaceutical industry came to share Jones' view of NICE. The industry began to see potential benefits from NICE's existence. Its appraisals, viewed by much of the world as a gold standard, could be used to promote a product:

because Britain had a good reputation internationally in terms of understanding medicines, that if you did get a positive approval from them you could go around the world and say "look, what's wrong with you folks?"⁶⁹

Or, in the words of NICE's second Chair, David Haslam:

I met a lot of industry chiefs, and their biggest complaint, to my amazement, wasn't about our methods or anything, it was about the fact that we didn't look at all their drugs, we only looked at a few. Which I found completely extraordinary, that they found a 'yes' from NICE to be so valuable on an international market, that they wanted us to do more.⁷⁰

What applied internationally also applied within England. NICE put paid to the industry's fear that every NHS purchasing body might make its own cost-effectiveness decisions, or that every region might follow the view of its own Drug Evaluation Committee:

the smarter execs realised that this was potentially a huge strategic gain for the industry, because if NICE said the drug was cost effective ... there is a huge political weapon, why on Earth are patients not getting it? And ... when the funding mandate was introduced [2002], so that if NICE recommended something then the clinical commissioners were duty bound to make sure that resources were available should clinicians want to prescribe it. That was a huge win for the industry.⁷¹

This also saved the industry some costs in sales representatives:

what really mattered was whether you were selling evidence that your product represents value. If you sell that evidence to the NHS, centrally, then the

68 Jones interview.

69 Jones interview.

70 David Haslam, interview 24 April 2020.

71 Towse interview.

NHS is supposed to start using your product, you don't need to knock on the door of every individual prescriber and tell them about this evidence.⁷²

NHS organisations

NHS organisations, in contrast to individual clinicians working in the NHS, were not very visible in NICE's deliberations in its early years. This can be explained partly by the absence of a national HQ to speak for the NHS to NICE or to government.⁷³ How much of a problem was this in practice? So far as allowing the NHS to influence NICE decision-making was concerned, some have suggested this was not too serious. Rodgers, Director of Corporate Affairs in these years, presented the relationship like this:

We felt we were part of the NHS, and wanted to be easy to do business with, so we held our public Board meetings around the country in hospitals. We had this phrase, "the guidance is created by the NHS for the NHS": we're just managing the process. Because it was NHS doctors and nurses and pharmacists who sat on the committees, the clinical guidelines were written by [NHS] professionals.⁷⁴

While true, this did not give a voice to NHS organisations or managers, who might, for example, have had a view on whether NICE's technology appraisal decisions were leading to new technologies crowding out older ones that delivered more health gain.

Another perspective on this question comes from Ken Jarrold, the NHS Executive's Deputy Chief Executive in the mid-1990s, and then a Strategic Health Authority leader. He shares the view that the relative lack of NHS management input was not problematic.⁷⁵ In his view, leading managers including Directors at the NHS Executive were very positive about NICE's work, welcoming the creation of a national policy on which technologies to employ. With many other challenges to deal with, this group had no appetite to spend time on a topic like NICE, which was developing in ways they welcomed. In Jarrold's recollection, the leading managers regarded Dillon as one of their own, who could be trusted. Jarrold does not recall the NHS Executive ever taking a collective decision on any approach to NICE, being content to treat it as one of the 'givens' of their working environment.

In addition to the question of NHS organisations' ability to influence NICE, we should ask how well NICE could influence those organisations. In particular,

72 Towse interview.

73 While various bodies from 1985 onwards with titles like 'NHS Executive' looked like a national HQ, none had such a role in law and none was a good mechanism to transmit most kinds of information from local NHS managers to the centre. This complex area is explored in Edwards and Fall (2005), and, for the years after 2012, in Timmins (2018).

74 Rodgers interview.

75 Ken Jarrold, personal communication.

this raises the issue of how quickly or fully NICE guidance was implemented, one which we addressed earlier in this chapter when looking at the health care professions. In this section we will add a few reflections on how this played out at the level of organisations, as opposed to clinicians.

Baker, who had seen guidelines from the standpoint of both producer and user (see Chapter 6), was optimistic about the degree of take-up in hospitals (but less so in primary care):

most decent hospitals had set up fairly competent systems for receiving, disseminating and monitoring the implementation of guidance. When I went to Leeds as the Medical Director I was impressed with the system that was in operation there. It was pragmatic, it was sensible, it was comprehensive so every piece of guidance had a sponsor in the organisation.⁷⁶

At NICE, people were well aware that their guidance ran the risk of not getting enough traction. Patient groups and pharmaceutical companies would often press them on this. For example, Trevor Jones recalled that:

At the first NICE Conference I said to [Rawlins] on stage “Michael, if you approve all of these products and it is not being picked up by the NHS to end postcode prescribing, what will you do?” He said “I’ll hound the Secretary of State to the end of the islands.”⁷⁷

A picturesque turn of phrase which perhaps tried to make up in rhetoric what NICE lacked in power. The Secretary of State would have to do something: a reasonable enough attitude. What the Secretary of State did do, in 2002, was to put in place the Direction that the NHS had to fund the technologies which NICE recommended in HTAs.⁷⁸ This represents the most effective lever so far created to ensure the uptake of NICE guidance, and it has dealt with implementing HTAs quite effectively. Guidelines have never been given similar legal backing, and it is hard to see how they could have been without creating worse problems, already discussed. However, the succession of further initiatives by DH and NICE such as NHS Evidence and Quality Standards can be read as indicating that securing the implementation of NICE guidelines continues to be challenging.

We discussed earlier what impact a NICE guideline has on clinicians. When it comes to NHS organisations and their managers, the NICE guidelines web pages tell them:

Local commissioners and providers of healthcare have a responsibility to enable the guideline to be applied when individual professionals and people

⁷⁶ Baker interview.

⁷⁷ Jones interview.

⁷⁸ Department of Health (2003). See Chapter 5.

using services wish to use it. They should do so in the context of local and national priorities for funding and developing services.⁷⁹

An NHS manager, needing to navigate the challenges of delivering a service – notably the challenge of constrained resources – is not likely to find these words terribly informative. Lacking the authority to tell NHS organisations what to do about a guideline (in contrast to a HTA), NICE has come up with a text which says more about the delicate politics of positioning NICE in relation to NHS England (or DH) than anything else. Its caveat about funding priorities robs the previous sentence of most of its force, emphasising the weaker grip that guidelines, compared to TAs, have on the NHS, and the weaker grip that guidelines have on the NHS compared to their grip on clinicians. This is a licence for service managers to ignore the guidelines they feel they lack the resources to implement, a state of affairs with which we must assume DH is content since they allow it to persist.

The question of central government's ability to influence what happens in the NHS is of course much more general than just that of whether NICE guidelines are implemented. Paul Corrigan, who was a Special Adviser at DH from 2001 to 2005 (and a 10 Downing Street Special Adviser on health in the following two years), told us candidly that, for all New Labour's focus on this, they failed to crack the problem of ensuring NICE guidelines were implemented:

the idea of spreading good practice across the health service was a much harder thing than simply having NICE guidance ... the notion of just saying to NICE ... you issue guidance on X and Y and Z and it will happen was naïve ... one of the problems of the rationalism of New Labour is the belief that rationality worked ... simply [saying] "this is the right thing to do" as an argument for change is inadequate.⁸⁰

Intriguingly, Corrigan recalls that when DH set up the NHS Modernisation Agency in 2001, he had a discussion with its Director David Fillingham, and made the connection between its role in ensuring the implementation of key service policies (such as shorter waiting lists and times) and the challenge of implementing NICE guidelines.⁸¹ But Corrigan believes that he missed an opportunity by not acting on this realisation.⁸² This is not to say that doing so would have stood a high chance of success. The well-worn metaphor of the NHS as a supertanker requiring a long delay to change course retains its relevance, and, as we have seen, making guidelines in some way binding ran the risk of rejection by the professions as a form of 'cookbook medicine'.

79 This is standard text in all online NICE guidelines, for example NICE (2004).

80 Paul Corrigan, interview 16 November 2022.

81 For Fillingham's role at the agency see <https://www.england.nhs.uk/author/david-fillingham/> (last accessed 2 April 2024).

82 Corrigan interview.

NICE and health economics

NICE's relationship with the discipline of health economics, while not strictly part of health care, merits a short discussion here. We saw in Chapter 1 how the developments in policy thinking which led to NICE were themselves only possible because of the influence of health economics. Once established, NICE's existence became a major stimulus to the discipline. NICE contracted for large volumes of health economic advice, initially mainly from higher education, and pharmaceutical companies had to make extensive use of health economists to produce evidence for NICE, whether as contractors or direct employees.

In judging how much health economic analysis was necessary, NICE had to strike a balance. Over-complex analysis could delay the results of appraisals, as drug companies pointed out, while not enough analysis might mean decisions that rested on too little evidence to carry conviction. And of course all the expert work had a cost of its own. The design of appraisal, as Culyer recalled, involved 'health economists who were not part of NICE ... academic health economists and the health economists in industry ... with working parties, short reports or minutes of meetings which were ... built into policy statements'.⁸³ In Earnshaw's recollection, when appraisal methods were designed:

they'd got this big committee made up of the great and the good of the academic world with a few people from patient groups, me the nominal person from the pharmaceutical industry ... the bulk of these people were from the HTA, health economics, academic community and NICE staff. What used to concern me was they would always want ... more and more complex and sophisticated methods. I was never sure that [there was] enough balance, although the NICE staff did do their best...

everyone was very clear there were conflicts of interest for pharmaceutical companies, but there wasn't quite so much focus on [whether] academic groups working with NICE ha[d] any conflicts in terms of the methods that they were proposing.⁸⁴

NICE and the government

This section is about NICE and the government in London. Health care is a 'devolved matter' in the UK, meaning that the governments of Scotland, Wales and Northern Ireland can make their own decisions about how to engage with NICE.⁸⁵ Currently Wales and Northern Ireland use NICE guidance as a matter of course, while Scotland, which has HTA and guidelines bodies of its own, does so more selectively.

83 Culyer interview.

84 Earnshaw interview.

85 At first, Wales had a statutory relationship with NICE more like that of England: see for example the funding Direction referred to earlier in this chapter, in which certain functions of the Secretary of State were, when applicable to Wales, transferred to what was then called the National Assembly for Wales.

NICE, like any arm's-length body, had (and still has) a published framework document with government, setting out its mandate. At the all-important political level, though, NICE enjoyed a good deal of freedom. This was partly because ministers understood the political benefits of giving NICE the freedom, and with it the responsibility, to make individual appraisal decisions, but it went further. Ministers trusted NICE's leaders to make most of the running in designing the new organisation's procedures: in particular, how guidelines and appraisals would be conducted. As Rawlins recalled:

Andrew and I were pretty well given a free hand by Frank Dobson ... apart from some of the officials wanted ... we had to get their approval before we did a guideline on a particular subject. That's all gone now, but it was slightly irritating ... But we got a pretty free hand and very little interference really.⁸⁶

This did not mean that government was indifferent to NICE during these years. On the contrary, despite giving themselves a demanding agenda of changes to the NHS, ministers and their special advisers appear to have made themselves surprisingly available for policy discussions with NICE. In Dillon's words,

in those very early few years ... we had pretty close engagement with ministers and their special advisers, Simon Stevens, and Chris Ham, and Robert Hill. We were ... frequent visitors to ministers' offices, we had meetings with Tony Blair, so a kind of relationship that just doesn't exist now ... a very close and very supportive relationship ... extremely helpful ... to be able to quickly get access to the Secretary of State, to have conversations about what we were doing, to test out ideas

Q: So you would pick up the phone to these people?

A: Yes ... as NICE was evolving ... quickly ... it was really good to be able to go and have a conversation ... Not to seek permission, particularly, but just to get ... a sense of how we were approaching the mandate that we got was consistent with what the people who had written the mandate expected us to do.⁸⁷

NICE was not content with cultivating effective relationships with the government of the day, but also, like any prudent public body, set out to convince the Opposition of their usefulness. Rodgers notes that this could have been challenging, given NICE's high political profile at the time it was established:

Mike, we, went and talked to the Tories, Labour and the Lib Dems and we made sure they understood our values. We were one of the few organisations that all sides, understood why we were there, what we had to achieve, which

⁸⁶ Rawlins interview.

⁸⁷ Dillon interview. Chris Ham was director of the DH strategy unit, 2000–04; Robert Hill was the Prime Minister's special adviser on health and other subjects, 1997–2002.

was quite an important position. We were high-profile, we could easily have been closed down when political views changed.⁸⁸

Culyer also remembers this as important:

How do we make sure that this isn't seen as Tony Blair's baby? And therefore got a political bias that with a change of government could be very prejudicial...

... the main thing was talking to Opposition members. Mike did a lot of that. ... I know he went to a lot of trouble, and I think was very persuasive. They realised this was something *they* could use, it wasn't intrinsically biased against the private sector or against Tory principles. I think that's something that worked really quite well. And the evidence is that we survived a change of government. Indeed one of the first things the Tories did was to give NICE additional jobs.⁸⁹

In Chapter 8 we do note how in 2008–10 there were some in the pharmaceutical industry who tried to persuade the Conservative Party to clip NICE's wings. The interesting point is how little impact this had.

NICE and the media

In NICE's earliest years, relations between the organisation and the media were often wary. Leaders at NICE knew that the stakes were high: they had a difficult argument to make and the mass media might make or break their public reputation. In the words of one senior journalist:

The problem for NICE was, they were under siege, it was a very, very different situation for them, so they were very closed, and difficult. I had a few run-ins with them; I said, 'this is not helpful, you've got to tell us what's going on, be more transparent, you'll get better press.' I think they just didn't believe that. And then they'd be right. This is one they weren't going to win, and the best thing was just to keep their heads down, put their helmets on, take the flak. So I don't altogether blame them.⁹⁰

This frustration in the liberal parts of the media, who supported NICE's mission and wanted NICE to fight more openly for it, was voiced more strongly by Sarah Boseley, health correspondent of the *Guardian*:

[NICE] was obtuse and obstructive and difficult and really poor with the press: really bad. I've told Andrew Dillon and Mike Rawlins that, and said,

88 Rodgers interview.

89 Culyer interview.

90 Unattributable interview.

‘for heaven’s sake get out there and talk to people properly in a way that the general public will understand, because you’re not fighting your corner...

They even denied that it was about cost-effectiveness ... it was silly to pretend that money wasn’t an issue. Just because the tabloids were baying that people were going to die because the NHS wouldn’t spend money ... NICE should have taken it on the chin and said, this is what we’re about, this is what we have to do.⁹¹

Nicholas Timmins, who was the social affairs editor of the *Financial Times* at this moment, praised Rodgers, NICE’s first Director of Corporate Affairs, as a well-informed professional, and, unlike other journalists quoted here, he compared NICE’s media operation favourably with some other public bodies.⁹² Rodgers’ own account stressed being fearless in insisting on accuracy, and claims to have had a rapport with leading journalists:

We recognised the power of the press. I would phone journalists back and say, “you do that and I’m going to the Press Complaints [Commission]. I’ve just factually told you that’s not true, you print that I’m going to phone your editor.” We were quite a non-traditional public body in that way ... I think it was just youth and balls, ... There was an anti-NICE lobby in parts of the media, but ... we had really good relationships with the media including the BBC, the [Financial Times], Times, Guardian: we also had good relations with Jenny Hope [of the Daily Mail] – which was anti at the time. We were just open.⁹³

Plainly there is a difference of opinion here. Boseley and others wanted to fight NICE’s corner, in her phrase, which explains their frustration when NICE did not take the pugnacious line they wanted. But NICE was working at not making enemies, and a liberal journalist could attack right-wing media in ways which Dillon and Rodgers rightly judged that a public body should not, especially one hoping to be acceptable to Conservative as well as Labour governments. Nor could NICE have criticised the pharmaceutical industry in some of the ways Boseley wished while trying to build the working relationships it needed there. NICE’s buttoned-down approach to the media in its first years was the least risky strategy.

Preeminent among media critics on the right was the *Daily Mail*. One could see this entirely as party politics. The *Daily Mail* was, at this time, a largely uncomplicated supporter of the Conservative Party. Corrigan, Special Adviser first to Tony Blair and later to Alan Milburn, saw it this way. As a Labour politician in a Special Adviser role about communications, he felt it was a matter of:

going to [NICE] and saying “we’ve got your back ... you’re safe. You do what you want,” and because at the time ... the New Labour comms and

91 Sarah Boseley, interview 13 January 2020.

92 Nicholas Timmins, interview 17 December 2019.

93 Rodgers interview.

policy machine was pretty good ... you could ... say, “OK the *Daily Mail*’s going to take lumps out of you but we will organise your defence” ... I don’t remember having those conversations with many organisations. ... it would be, the Secretary of State would say “this organisation has 100% my confidence and we asked them to do a job, they’re doing that job, ... the particular thing they’re under attack [for] is not to do with me it’s to do with them.”⁹⁴

The *Daily Mail*’s hostile line towards NICE can be read in a broader way though. As one senior journalist put it:

the *Daily Mail* always saw itself as the paper of Middle England, and Paul Dacre’s genius was to be able to have a sense of what would move Middle England. Of course if you go and ask someone, ‘look, we’ve got this treatment but really it’s too expensive, we can’t give it to everyone’, of course people will react in horror ... There were many dinner tables I sat round, defending NICE, saying, “we’ve got to do this” ... But people don’t like that, not when it comes to medicine. So ... that was a natural knee-jerk reaction which the *Mail* latched onto and defended. Fair enough.⁹⁵

This insight supports the view that NICE was easier to attack than to defend in the media. Human interest stories, and ‘miracle drug breakthrough’ stories, were and are easier to write, and more popular among readers, than the kinds of defence, necessarily more abstract and analytical, which journalists like Boseley wanted to write.

It is fitting to give a final word here on NICE and the media to Barbara Clark, who successfully fought to receive Herceptin for her breast cancer. Her published account complicates any straightforward reading of the media’s behaviour and influence. She was an actor in her own right, rather than someone manipulated by the media or the drugs industry. While we do read of *Mail* and *Express* photographers telling her to look sad ‘which didn’t reflect my state of mind: I was full of fight’, the other side of the picture emerges too. She contacted Herceptin’s manufacturers, Roche, before going on national radio, not the other way round: ‘I do not want to make a fool of myself ... I need to know this drug inside out. I need to understand the results of the trials’. And Clark could use the media as well as them using her: when GMTV asked her to come to London for an interview: ‘I was exhausted, but GMTV had helped me win this fight and I owed them a favour or three. And a day and night in London ... would be a great adventure for [her son]’.⁹⁶

94 Corrigan interview.

95 Unattributable interview. Paul Dacre was Editor-in-Chief of the *Daily Mail*, 1998–2021.

96 Clark (2007), 99, 101, 139.

NICE on the global stage

NICE's work also took on international dimensions. We noted in Chapter 1 how NICE came into being at the same time as several other countries began taking an interest in health technology assessment: guidelines were also a global topic of interest. Several people working at NICE were eager that the benefits of its work should be felt beyond the UK. For example, Kalipso Chalkidou joined NICE in 2004 to work on methods development. She recalled 'Francoise [Cluseau, who had worked on the NICE guidelines manual] saying, "we're doing all this work but we should really help other countries"''.⁹⁷

There was growing interest around the world in what NICE was doing. In the course of work unrelated to NICE, Chalkidou went to:

Siberia ... in the middle of nowhere, a place called Khanty-Mansiysk, the governor said, "Wow, I love NICE, I'm looking at the website, it's wonderful!" I thought "Wow!" It became apparent that lots of people, not just individuals, bureaucrats here and there, a movement, people thinking how can we get our money to take us further, and here's a model of an institution that brings all this [together].⁹⁸

There was, then, interest both within NICE and from other countries in sharing some of what NICE did. The question of how to organise and resource this international work has never been fully resolved. In a time of government funding cuts, leaders at NICE felt constrained to push for this work to be separately funded, perhaps by the UK's then Department for International Development, or by international organisations. The picture has mostly been one of enthusiasts for HTA and guidelines in different countries approaching NICE for help, followed by efforts to secure project funding. Funders have included the Bill & Melinda Gates Foundation, the Rockefeller Foundation and the World Bank.⁹⁹

Chalkidou and others, with some encouragement from Rawlins and Dillon, put a proposal to the NICE board in 2008 for an operation to be called NICE International, which was accepted. But the problem of funding persisted (e.g., many funders would not contribute to overheads as NICE demanded, operating on a cost recovery basis).¹⁰⁰ There was a parting of the ways and Chalkidou, with about a dozen colleagues, left to continue the same kind of work externally.¹⁰¹ This developed into the International Decision Support Initiative (IDSI), which has been chaired by Culyer, and aims to help governments manage the use of health care technologies. It is especially active in Africa and southeast Asia. In Culyer's words,

97 Kalipso Chalkidou, interview 26 November 2019.

98 Chalkidou interview.

99 NICE International (2014), Kalipso Chalkidou, interview 26 November 2019.

100 NICE sets out its cost recovery requirements on its website in the *International Strategy for NICE 2022–25*.

101 Chalkidou interview.

reflecting his dedication to using health economics both rigorously and thoughtfully, IDSI:

is quite uncompromising in its views on how decisions should be made, advocates very much a NICE style, or at least an idealised style from the early days.¹⁰²

NICE now reports that over its lifetime it has undertaken over 200 engagements in 50 countries.¹⁰³ A few examples will illustrate the kind of international activity that was involved. Thailand featured prominently from early on. The Thai government had become interested in HTA as part of its push for universal health coverage, and made a link with NICE's work. Dr Yot Teerawattananon, Program Leader of Thailand's Health Intervention and Technology Assessment Program (HITAP), invited Chalkidou and a colleague to evaluate their work.¹⁰⁴ This blossomed into a longer-term connection, and the establishment of HTA Asia Link, a capacity building initiative to encourage early career HTA professionals.¹⁰⁵ Chalkidou comments that 'The Thais have been critical in NICE International being set up, and then the broader network surviving'.¹⁰⁶ Elsewhere, people from NICE worked with the health system in China from 2008, discussing pathways of care and guidelines, for example for respiratory conditions and stroke, and encouraged the creation of a Chinese HTA organisation – something which the Chinese health ministry did in its own time, about ten years later.¹⁰⁷ Meanwhile, IDSI have worked with people in Ghana and Kenya to try and set up an African hub of technical expertise that would be able to support governments in decision-making, a little like HTA Asia Link.¹⁰⁸

NICE International is now a branding used by NICE, for example in its web presence, and the organisation has a team that goes by that name.¹⁰⁹ The diplomatic drafting of NICE's current *International Strategy*, where it covers co-operation with outside groups such as IDSI, hints at ongoing sensitivities about past disagreements, while signalling NICE's commitment to continue international work – if its costs can be recovered in each case. Under more favourable fiscal policies, governments could have developed NICE's international work into a significant example of international development co-operation and British 'soft power'.

A 'dream team'?

Having discussed how NICE operated in its first few years, we are now in a position to offer the commentary which we promised in Chapter 2 on the general view

102 Culyer interview.

103 NICE International (web page).

104 Chalkidou interview.

105 For more on HITAP, see Culyer et al. (2016).

106 Chalkidou interview.

107 Chalkidou interview.

108 Culyer interview.

109 NICE International (web page).

that Rawlins and Dillon were the authors of NICE's success. Discussing the NICE leaders he has known, Timmins recalled of Rawlins that:

as Dobson famously said of him, [he] was "clever, charming and tough as old boots." ... And he was. ... Andrew ... had the intellectual capacity to cope with the ethical and other arguments ... not all NHS managers would have that, so they were lucky they appointed him. ... Culyer's a health economist but he's also a philosopher, so when they had to ... all three of them could engage with ... difficult ethical questions ... the intellectual firepower was very impressive...¹¹⁰

To pick out one more individual, Rawlins said of Barnett, first chair of NICE's Technology Appraisal Committee:

I was particularly impressed that he was willing to forego being a Censor at the College of Physicians, which is sometimes a stepping stone to becoming president, to join us at NICE. I was impressed by that, and Frank Dobson agreed, and so we appointed him at the same board meeting that we appointed Andrew.¹¹¹

Every organisation has a 'usable past' which shapes its self-image. Part of NICE's is a warm admiration for Rawlins and Dillon. Nearly all of those interviewed for this book describe them in the most glowing terms possible. But doing oral history involves looking out for moments when an interviewee is repeating a received wisdom rather than giving a testimony drawn purely from their lived experience: it can take the form of clichés like 'we weren't worried about crime in those days, we all left our front doors unlocked', or a conviction that history has been shaped by certain 'great men' (usually men).¹¹² The latter, hagiographic, kind of memory is not unusual in the medical field, for example. (Almost all past Presidents and Deans were apparently paragons.)

A judicious historian will therefore want to check any account of past leaders that stresses their virtues and the scale of their personal contribution – not from any prior assumption that this is wrong, but simply from an awareness that hagiographic memory is a real phenomenon. In this section we have qualified the received wisdom about Rawlins' and Dillon's contribution, not radically, but to the extent that we now identify half a dozen people – and not just two – who all made essential contributions in NICE's first years. (It would be invidious to claim that we have found everyone whose work was this important, and others have good claims too.) Those mentioned in this section did make up a team of exceptional

110 Timmins interview.

111 Mike Rawlins, in Atkinson and Sheard (2020), 25.

112 See for example, Abrams (2010), 114–118 on the impact of the 'narrative turn' on the practice of oral history.

abilities, energy and dedication. Leaders set an organisation's culture (not least by the appointments they make, and by retaining the good people – something NICE did notably well – and keeping them motivated and empowered). In these ways the people at the top of NICE in these years not only made major personal contributions but also did much to build NICE into a highly effective organisation.

To continue in the judicious fact-checking spirit, have we merely progressed from one hagiographic account, of two 'great men', to another, about a 'dream team'? A former DH health economist commented ironically on Timmins' history of NICE, *A Terrible Beauty*, how that work had suggested that 'the very best chaps were chosen and they did the best of all possible jobs'.¹¹³ Is there in fact more nuance than this? Looking at the quality of the team and the teamwork, the unusual longevity of most people's service at NICE does suggest a team who worked together well. In any such group of highly motivated and intellectually curious people, there will have been vigorous discussion, and at times disagreement, about policy, but a natural reticence to let the outside world see that, for example by committing it to paper (or telling an interviewer), means we have found little evidence of it. Vigorous debate is a strength not a weakness in any case, up to the point where the disagreements surface publicly in ways that harm, for example, an organisation's credibility. We found no evidence of that.

Conclusions

Turning from our anonymous health economist's 'best chaps' to the question of whether they 'did the best of all possible jobs', we conclude by attempting an assessment of NICE's early success. By any measure, what NICE achieved between its birth and our somewhat arbitrary chapter end of 2006 was very considerable (and ending this survey in a different year would not alter this verdict). To begin with, NICE, unlike most public bodies born under the first Blair administration of 1997–2003, has survived as an organisation, despite successive governments' eagerness for structural reform. This demonstrates that NICE succeeded in persuading governments, at least, that it was carrying out a valuable task effectively.

NICE's greatest success in these first years was to build its reputation and win widespread acceptance as an organisation that used evidence rigorously and acted fairly. In a hotly contested policy area, this was an impressive achievement. Later chapters look in more detail at how NICE achieved this in its health technology appraisals and guidelines programmes. We have suggested in this chapter that the key reason for NICE's success was the quality of the people it was able to attract and retain. We refer here to large numbers of staff, and the volunteers who worked on appraisal and guideline groups. The motivation, excitement and engagement were exceptional. NICE addressed what a large number of capable people in these years viewed as one of society's big challenges, and these people showed themselves willing to get involved. The particular contribution of Rawlins, Dillon and

113 Timmins (2016), 186.

their colleagues in the executive team was a special case of the impact NICE's people had.

There were also factors in NICE's policy environment in these years giving it a favourable wind. At the beginning, New Labour enjoyed a political honeymoon period, in which bolder choices went without effective challenge. This in turn made it easier for Ministers to give NICE its head. Delegating hard choices about treatments to an arm's-length body remained attractive long afterwards too, to all parties, but in these early years the combination of freedom and political cover which Whitehall gave to NICE left it with unusual scope to set its own policies. NICE created a virtuous circle in which, by delivering the mandate given to it, the organisation earned the autonomy to innovate so as to further improve the quality of its work.

On the negative side of any balance sheet, concerns remained about whether NICE guidance was having as much influence on NHS behaviour as intended. Governments throughout the 2000s struggled to find ways to promote change in the NHS: in the view of Corrigan, one of the Special Advisers at DH at the time, more should have been done on NHS mechanisms to promote the uptake of NICE guidance in particular.¹¹⁴

For the views of some external commentators on NICE's achievements in these years, we turn to a pair of reports from the European office of the World Health Organization. In 2003, an international team looked at NICE's technology appraisal programme. They saw it as 'an important model for technology appraisals internationally'. The authors felt that appraisal could be made more transparent and faster, but:

Overall, the Review Team was impressed by the commitment to using rigorous methodology throughout the process of technology assessment ... Published technology appraisals are already being used as international benchmarks - an obvious recognition of their credibility.¹¹⁵

When they reviewed NICE's guidelines programme in 2006, the verdict was also very positive. The authors did find the guideline development process 'expensive and slow', and feared the current approach might not be sustainable. Their overall conclusion, though, was that:

NICE is one of the largest, most productive and best organized developers of clinical guidelines in the world ... [it] has a large number of highly motivated and enthusiastic staff and contributors with a wealth of diverse competencies. It is a well resourced, well managed and, justifiably, proud organization without arrogance. It is also highly innovative, continually evolving and, in many areas, ahead of comparable organizations around the world...

114 Corrigan interview.

115 WHO Regional Office for Europe (2003).

It would appear that the methods used in the NICE Clinical Guidelines Programme are widely respected and are increasingly being taken into consideration. Perceptions of their usefulness vary, however, as does the extent to which their recommendations are being implemented.¹¹⁶

We close this chapter with the reflection that NICE's first years were a remarkable achievement, which left NICE so strong that it could weather all the challenges of the following years, such as value-based pricing and the Cancer Drugs Fund, which we examine in Chapter 8: challenges which would have taken down a weaker organisation.

Bibliography

Primary sources

- British National Formulary
Department of Health (2003) Directions to Primary Care Trusts and NHS trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE) (Last accessed 2 February 2022).
General Medical Council, The duties of a doctor registered with the General Medical Council (Last accessed 12 January 2023).
General Medical Council, Leadership and management for all doctors (Last accessed 2 April 2024).
House of Commons, Health Committee (1999) Session 1998–99, Minutes of Evidence, 4 February 1999.
NHS England website <https://www.england.nhs.uk/author/david-fillingham/> (Last accessed 2 April 2024).
NICE (2000) Annual Report and Accounts 1999–2000, Introduction, Andrew Dillon (Last accessed 14 February 2024).
NICE (2001) *Annual Report 2000–2001* (London: NICE).
NICE (2002) TA49 Guidance on the use of ultrasound locating devices for placing central venous catheters.
NICE (2004) *CG19 Dental Checks: Intervals between Oral Health Reviews* (London: NICE).
NICE (2007) *CG53 Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (or Encephalopathy): Diagnosis and Management* (London: NICE).
NICE (2014) CG178 Psychosis and schizophrenia in adults: prevention and management (Last accessed 27 October 2023).
NICE International (2014) *Review 2014* (London: NICE).
NICE (n.d.) How to use quality standards (web page) (Last accessed 13 April 2023).
NICE (n.d.) *International Strategy for NICE 2022–25*
NICE (n.d.) NICE International (web page) (Last accessed 12 April 2023).
Nursing and Midwifery Council website.
TNA, JA 614/331 The new NHS: N.I.C.E.

116 WHO Regional Office for Europe (2007).

TNA, JA765/6 Hip prostheses appraisal.

TNA, JA 765/15 NICE, Nick Clarke to ministers, 'Secretary of State Directions to NICE', 27 July 1999.

WHO Regional Office for Europe (2003) *Technology Appraisal Programme of the National Institute for Clinical Excellence A review by WHO* (Copenhagen, WHO Regional Office for Europe) (Last accessed 13 April 2023).

WHO Regional Office for Europe (2007) *The Clinical Guideline Programme of the National Institute for Health and Clinical Excellence (NICE) A review by the World Health Organization* (Copenhagen: WHO Regional Office for Europe) (Last accessed 13 April 2023).

Secondary sources

Abrams L (2010) *Oral History Theory* (London: Routledge).

Atkinson P, Sheard S & Walley T (2019) "All the stars were aligned"? The origins of England's national institute for health research. *Health Research Policy and Systems*, 17(1).

Berridge V (ed) (2005) *Making Health Policy: Networks in Research and Policy after 1945* (Amsterdam and New York: Rodopi).

Berridge V (2010) Hidden from history?: oral history and the history of health policy, *Oral History* 38(1), 91–100.

Clark B (2007) *The Fight of my Life* (London: Hodder and Stoughton).

Commager HS (1967) *The Search for a Usable Past, and Other Essays in Historiography* (New York: Alfred A. Knopf).

Culyer A, Podhisita C & Santatiwongchai B (2016) *A Star in the East: A Short History of HITAP* (Nonthaburi, Thailand: HITAP).

Edwards B & Fall M (2005) *The Executive Years of the NHS: The England Account 1985–2003* (London: Nuffield Trust).

Marsh D & Rhodes R (1992) *Implementing Thatcherite Policies: Audit of an Era* (Milton Keynes: Open University Press).

Morrissey R (2015) Archives of connection: "whole network" analysis and social history, *Historical Methods* 48(2), 67–79.

Pollitt C (1993) Audit and accountability: the missing dimension? *Journal of the Royal Society of Medicine* 86(4): 209–211.

Pressman A & Wildavsky J (1984) *Implementation: How Great Expectations in Washington Are Dashed in Oakland* (Oakland: University of California Press).

Seldon A & Pappworth J (1983) *By Word of Mouth: 'Elite' Oral History* (London: Methuen).

Sheard S (2010) Quacks and clerks: historical and contemporary perspectives on the structure and function of the British medical civil service, *Social Policy & Administration* 44, 193–207.

Timmins N (2016) *A Terrible Beauty: a Short History of NICE* (Nonthaburi: Health Intervention and Technology Assessment Program HITAP).

Timmins N (2018) *'The World's Biggest Quango' The First Five Years of NHS England* (London: King's Fund and Institute for Government).

Who's Who & Who Was Who: 'Godber, Sir George' (2007) (Oxford: Oxford University Press).

4 The public and patients

We promised in Chapter 3 to devote a separate chapter to NICE's interactions with the public and patients, in view of their special importance in NICE's history, and their wider relevance for health policy in the UK. This chapter examines the topic, looking first at patient and public participation in decision-making, through membership of structures such as advisory committees, and then at the way NICE gathered and used evidence from patients and their organisations.

There was more to NICE's dedication to patient and public involvement (PPI) than a belief in this as a general principle. Two more specific motives also emerge from the evidence. One was the view, promoted particularly by Tony Culyer, that NICE's work could never be purely technical, would always express a set of values, and that these ought to be those of wider society (see Chapter 5).¹ Accordingly, deep and genuine PPI was part of NICE's secret for earning society's trust, something that was essential if it was to have permission to exercise its own judgement rather than mechanically following a formula for technology appraisal. This approach follows the thinking of American writers Daniels and Sabin, who speak of 'accountability for reasonableness'.² Their influence on NICE is clear: Daniels contributed a chapter 'Accountability for Reasonableness and the Citizens Council' to a book about NICE, patients and the public by Peter Littlejohns, NICE's medical director, and Mike Rawlins.³

The other specific motive which NICE had for its approach was a belief that involving patients at every step would draw them into the process of ensuring that the NHS took up NICE's guidance. Well-informed patients would be stronger advocates for access to the new technologies that NICE recommended. Anne-Toni Rodgers recalls:

the internet was new, we weren't afraid of it, we used it ... NICE was an organisation that said to patients, 'you go online, take our patient information to the doctor ... We wanted the public to go and demand care because

1 Tony Culyer, interview 2 March 2020.

2 Daniels and Sabin (1997).

3 Littlejohns and Rawlins (2009, 2018). Littlejohns confirmed Daniels' influence in his interview, 18 September 2019.

that would drive access. ... We wanted to become the single core source of information for patients and the public in the NHS

In her words, the intention was that: ‘Anyone can see what their path of care should be, what the treatment should be and what they should be asking for, and physicians can see it, there’s consistency and equity of care’.⁴

This intention of building a constituency is clearer still in Andrew Dillon’s recollections:

even in those very early days when we didn’t know that much about how you got guidance implemented, we knew immediately that part of that was engaging with and getting the support of the organised patient advocacy movement, because they had their memberships, networks, they had influence, and so getting them signed up ... just seemed, apart from just an important thing to do in its own right, a good way of giving the implementation of the recommendations we were going to make a bit of extra oomph.⁵

Involving the public and patients in decision-making

The need for social value judgements

Leaders at NICE, then, felt from the start that the technical rigour of appraisal had to feed into a process of judgement, and that this judgement should apply a set of social values which were uncovered by a form of deliberation. This is discussed further in the ‘using judgement’ section in Chapter 5. Participants agree that Culyer was central to this realisation. In his account:

I think HE [health economics] probably influenced us in other ways. For example the whole question of values was not an exclusively HE issue, plainly, a set of fundamentally philosophical issues arises. I think it was NICE that ... coined the phrase ‘social value judgments’. ... I remember doing a slide presentation to either the board or the senior management team ... in the early days in Covent Garden, where I said, ‘you do realise that this isn’t just all about medical science, there are a lot of values,’ and I just led them through all the kinds of value judgments that were involved, and how we were really an agent to interpret what was the public good here. That’s normally a Parliamentary function but it had been delegated to us. That was when the idea of there being a social value judgement, that is to say, value judgments being made by a committee on behalf of society as a whole. That’s where that idea first came’.⁶

4 Anne-Toni Rodgers, interview 8 October 2019.

5 Andrew Dillon, interview 2 July 2020.

6 Culyer interview.

Nor were people at NICE alone in seeing values as an essential part of NICE's process. We will see in Chapter 5 how Clive Smee, DH's Chief Economic Adviser, divided economists into those who thought cost-effectiveness calculations should *determine* policy and those, like him, who thought they should only *inform* it. And Chris Ham, director of the DH strategy unit, 2000–04, similarly wrote that:

Of course, evidence from clinical trials and cost-effectiveness studies, and the views of clinicians and economists, play an important part in informing decision making. Priority setting, however, often involves making value judgements about the use of resources and their allocation between competing claims. These value judgements may apply both to individual technologies and to decisions about the relative priority to be given to different technologies or treatment programmes.⁷

With DH and NICE's leaders in agreement, the requirement for a Citizens Council was included in government's mandate to NICE when it was established. It is interesting that, within NICE as well as elsewhere, the technical experts pushed back against the application of judgement and social values to their results. Littlejohns recalls arguing that technical analysis:

was a significant input into the decision-making process but it wasn't the end-all, that's why we had committees deliberating on that. That led to an internal debate within NICE between those of us who felt that cost-effectiveness was important but was one of the values that NICE took into account, with those who felt that cost-effectiveness *was* the value, and the only [reason] we have all these other social values was to see whether they would impinge or affect the overall cost-effectiveness analysis. Though it's a subtle difference it was a huge debate, and it continued for a long time, because when you've produced the social values, they were supposed to influence the whole of NICE. Appraisals felt they'd developed their own processes, they were up and running, and they weren't going to take woolly social values into account.⁸

We might observe that this resistance to a role for social values, and an insistence on the purity of health technology appraisal (HTA) techniques, ignores or denies the socially produced nature of HTA itself, a point raised in Chapter 1 where we argued that the 'economising' approach was only one of the possible ways of using economics.

Discussion of some of the philosophical underpinnings of social value judgements, such as the work of Daniels and Sabin, prompts the question whether NICE also made use of work being done in bio-ethics. Initially, it did not. Culyer and Littlejohns were

⁷ Davies et al. (2005), 41.

⁸ Peter Littlejohns, interview 14 January 2020.

both sceptical of its usefulness.⁹ When NICE decided in 2007 to update its approach to social value judgements in view of its new responsibility for public health, NICE did convene a group of bio-ethicists, but it is revealing that Littlejohns regarded the most useful contributor as Professor Albert Weale, a former chairman of the Nuffield Council on Bioethics, and himself not a bio-ethicist but a political scientist, because he ‘really understood the practical aspects of taking complex bioethical concepts but making them plausible and understandable to the general public’.¹⁰ It appears that NICE were looking above all for pragmatism here.

Citizens’ juries, deliberative democracy, and the birth of the Citizens Council

In August 2002, adverts started appearing in 8 national and over 70 regional newspapers, offering the general public the exciting opportunity to ‘have [their] say in the NHS’ by contributing to how NICE ‘decide[s] what the NHS should provide’.¹¹ These advertisements elicited a warm response; ‘[a]pproximately 35,000 people expressed an initial interest in being considered for membership, with 4,437 returned completed application forms’.¹² NICE was seeking a group of 30 individuals, statistically weighted to be broadly representative of the wider population, in terms of ‘gender, age, socioeconomic status, ethnicity, disability and geography’.¹³ This select group of ‘ordinary but extraordinary citizens’ and its subsequent iterations would become NICE’s Citizens Council, a fascinating experiment in public involvement in healthcare decision-making.¹⁴

What NICE wanted was, as the Council’s project manager Ela Pathak-Sen put it, ‘people of all ages and backgrounds who are prepared to listen and have their say ... people who have an inquiring mind and some good old-fashioned common sense’.¹⁵ While this might seem an uncontroversial objective, opposition health spokespeople were having none of it. Conservative Liam Fox claimed that the then Labour ‘government is already hiding behind the figleaf of NICE, and NICE is now hiding behind the second figleaf of a citizens’ council’. His Liberal Democrat counterpart Evan Harris was happy to echo such sentiments, arguing that the ‘government forces the scientists in NICE to make political rationing decisions and to take the blame for them. NICE are now simply trying to take shelter behind an unaccountable group of unelected public frontmen’.¹⁶

9 Littlejohns interview, 14 January 2020.

10 Littlejohns interview, 14 January 2020. The Nuffield Council on Bioethics is an independent body that examines and advises on ethical issues arising from developments in bioscience and health. Its own use of deliberation with a wide range of people will have given Weale some of the insight Littlejohns refers to.

11 Davies et al. (2006), 78–79; NICE (2002a).

12 Rawlins (2009, 2018), 78.

13 Rawlins (2009, 2018), 77.

14 Ela Pathak-Sen, interview, 11 March 2021.

15 Pathak-Sen interview.

16 *Guardian* 20 August 2002, Public invited to advise medicines watchdog.

What was a Citizens Council or even a citizens' council?¹⁷ NICE's 12-year experiment in deliberative democracy started in 2002, and called together 30 'ordinary' people biannually to consider some of the knotty questions around health and healthcare that NICE dealt with. It was derived from a much longer conversation about how the general public might influence day-to-day decision-making by policy elites. This section outlines the genesis of the Citizens Council, from its intellectual roots in Rawlsian philosophy through to the more immediate healthcare 'rationing' debates of the 1990s.¹⁸ The roots of the Citizens Council lay among newly influential thinktanks advocating citizens' juries to democratically address problems of public policy, and growing interest in public and patient involvement in healthcare. But it was also catalysed by high profile news stories debating the need to make the kind of 'tragic choices' in healthcare discussed in Chapter 5.

What then, was a citizens' jury? 'A citizens' jury', according to an important paper written in 1999, 'brings together a group of randomly chosen citizens to deliberate on a particular issue, whether it is the setting of a policy agenda or the choice of particular policy options'.¹⁹ The allusion to its legal counterpart is instructive; as Coote and Mattinson explained for the Fabian Society in 1997, 'in common with the legal jury, the citizens' jury assumes that a small group of ordinary people, without special training, is willing and able to take important decisions in the public interest'.²⁰ Indeed, in its simplicity and appeal to responsible citizenship, this 'idea of "twelve men [sic], good and true"' became particularly attractive to centre-left thinkers and policymakers during the 1990s.²¹ Pamphlets by think-tanks such as the Fabian Society, and particularly the Institute of Public Policy Research (IPPR), brought this model of deliberative democracy not only to those who would form the incoming New Labour government but also to the wider public with, for example, a citizens' jury in Luton filmed and broadcast on the BBC's current affairs programme *Newsnight* on 10 January 1997.²²

The origins of these public experiments were some three decades earlier, in the (unconnected) work of American philanthropist Ned Crosby and German sociologist Professor Peter Dienel.²³ Both developed their similar ideas of deliberative democracy by extending the work of American philosopher John Rawls, and his contention that citizens acquire a sense of societal justice by political engagement. Crosby and Dienel's ideas developed this further by suggesting that such 'moral learning' could develop through participation not just in wider democratic processes but specifically through deliberative and discursive environments such as

17 We have adopted NICE's practice of writing 'Citizens Council' without an apostrophe.

18 Rawls J (1971) sets out Rawls' influential theory of *justice as fairness*, describing a society of free citizens holding equal basic rights and cooperating within an egalitarian economic system.

19 Smith and Wales (1999).

20 Coote and Mattinson (1997), 4.

21 Jo Lenaghan, interview 19 May 2021.

22 Coote and Lenaghan (1998), 25.

23 Coote and Lenaghan (1998), 13; Stewart et al. (1994), 1.

citizens' juries.²⁴ It is clear from one of his publications that Rawlins, too, was persuaded of this educational value of deliberation, even quoting Thomas Jefferson on the subject.²⁵ One problem with this aspiration is the large amount of deliberation which would have to go on to educate an appreciable portion of the public.

Crosby's and Dienel's ideas caught the eye of Professor John Stewart in the mid-1980s, a researcher of local government at the University of Birmingham, and from there found its way to the world of centre-left think-tanks that were making their presence felt on the British political landscape.²⁶ Foremost amongst these was IPPR, and after a degree of persuasion by Stewart and consultation with Dienel, the think-tank began to seriously investigate how the model might be applied to a British context. IPPR recruited a researcher (future Labour MP Liz Kendall) specifically to work on the issue, and over a series of pamphlets sketched out their ideas.²⁷ These in turn led to a series of pilot citizens' juries, in Luton, London, Cambridge and Walsall. All addressed different aspects of health policy. From IPPR's point of view, the reasons for this focus were twofold:

First, there was already a strong interest from health authorities in developing new models for public involvement and consultation. Second, questions about rationing were high on the health policy agenda: as unelected bodies, health authorities were facing a crisis of legitimacy as they ... [took] increasingly controversial decisions about setting priorities and allocating resources ... [health authorities] needed input from the wider public.²⁸

This first reason reflected a longer history of public and patient involvement in the NHS and healthcare matters. As Mold has written, by this point in the late twentieth century, 'the notion of patient "voice" acquired increased attention from the government and health policy maker, following on from the emergence of the "patient-consumer" in the British NHS'.²⁹ But these developments in turn chimed with broader shifts in post-war British history. A valorisation of 'ordinariness' and appeals to various types of 'citizenship' (which found particular purchase with New Labour) all contributed to the attractiveness of citizens' juries as a way of involving the public in health policy decisions.³⁰

IPPR researcher Jo Lenaghan had been hired alongside Kendall to work on healthcare priority-setting, and for Lenaghan, 'the two [projects – citizens' juries and priority-setting] ended up cross-fertilising each other'.³¹ Through the pair's

24 Doheny and O'Neill (2010).

25 Littlejohns and Rawlins (2009, 2018), 75.

26 Crosby (n.d.).

27 Lenaghan interview. These publications were Stewart et al. (1994), Coote and Lenaghan (1998) and Delap (1998).

28 Coote and Lenaghan (1998), 14.

29 Mold (2015), 142.

30 Langhamer (2018); Grant (2016); Clarke (2005).

31 Lenaghan interview.

work, alongside colleagues such as Coote and researchers at the health policy think-tank The King's Fund, citizens' juries came to be seen as a way of approaching this contentious issue, and addressing the perceived 'democratic deficit' of the health service.³² This phrase described the observation that important decisions about resource allocation and healthcare funding were being made by unelected bodies, some of whom were perceived to be very far removed from public accountability.

The question of rationing and 'tragic choices' exercised the King's Fund very much at this time. The Fund devoted an entire publication to the 'Child B' case, and the lessons that might be learnt from it.³³ One of the smaller, but nonetheless significant recommendations that Ham and Pickard made in their report was that 'innovations in democratic practice, such as citizens' juries' should be investigated, 'as a way of promoting effective public deliberation on priority-setting'.³⁴ Indeed, it had been no coincidence that one of IPPR's pilots had been conducted with Cambridge and Huntingdon Health Authority, under whose purview the Child B case had played out.³⁵ Nor that The King's Fund themselves provided £240,000 to run three further pilots of citizens' juries.³⁶ The apparent success of these influenced NICE to investigate how they might incorporate the public into their deliberations.

Ham brought this interest in citizens' juries with him when he became the Director of DH's Strategy Unit in 2000. He soon brought it into his dealings with NICE. It appears that it found expression as an outlet for government nervousness that NICE might lose credibility with the public. In Littlejohns' account:

We'd said 'no' to Relenza, we were saying 'no' to Beta Interferon, we were saying 'no' to the Alzheimers drugs, the Government was getting nervous. Chris Ham ... said, 'are we sure how the public (not the patient) understand what's going on and why we need NICE and whatever?'³⁷

It does not look as though Ham was trying to dictate the details however. Littlejohns continued:

'So we said "we'll look into it: what do you want?"' – "Don't know." At that time obviously focus groups were a very dominant approach. We looked at it: there was focus groups, obviously surveys, the conclusion was – by that time we were certainly aware of Norman Daniels' approach: we certainly felt deliberation was important.³⁸

32 A relatively early discussion of these issues is Coote (1993). See also Fabian Society (1996).

33 For the 'Child B' case, concerning whether to fund an expensive treatment, see Chapter 1.

34 Ham and Pickard (1998), 92.

35 Lenaghan interview.

36 Davies et al. (1998), 1. These pilots were evaluated in McIver (1998).

37 Littlejohns interview, 18 September 2019.

38 Littlejohns interview, 18 September 2019.

But deliberation might take many different forms:

So we explored citizens' juries, but we felt, well, what we couldn't have was people second-guessing what our Appraisal Committees and guidelines were doing, and we already had patients on those groups. What we did was we set up – Mike [Rawlins] was the driver for this, and Tony Culyer – Citizens Council, that was deliberative, and look at key issues that would inform the day-to-day appraisals, as opposed to looking at individual interventions, appraisals. That's when Norman Daniels got a bit uppity with us, because he'd think unless you actually get down to getting the public involved in individual questions it wasn't a true deliberation.³⁹

So NICE's solution to this problem was a Citizens Council which deliberated to establish the underlying social values, and then patient participation in individual appraisal and guidelines committees which deliberated on individual decisions but included 'experts' as well as lay people (see below). Dillon's recollections of the discussions with Ham very much bear out Littlejohns' version:

conversations that Mike Rawlins and I had with Chris Ham ... He was really keen on the idea of a Patients' Council, and I think that had been informed by experiences he had had elsewhere, of engaging in that very focused and structured way with members of the public.⁴⁰

The Citizens Council at work

The Citizens Council was announced in the NHS Plan of 2000, after discussions between researchers at IPPR, the King's Fund, NICE and civil servants.⁴¹ Indeed, Lenaghan, who had been researching healthcare priority-setting and citizens' juries, had moved to the DH Strategy Unit, which was responsible for producing the Plan.⁴² The plans for the Council were produced three months later, shaped by discussions between NICE, the CMO Liam Donaldson and the Strategy Unit.⁴³ Although people who had written extensively on citizen's juries such as Coote were briefly consulted, it was also clear that the Council would be distinct from the models already piloted.⁴⁴

A document by Ham, addressed to the CMO, set out the Council's future shape.⁴⁵ It would be substantially larger than the previous citizen's juries (30 members rather than the 12–15 that had been the most common amount in the pilots),

39 Littlejohns interview, 18 September 2019.

40 Dillon interview.

41 DH (2000).

42 Lenaghan interview.

43 Davies et al. (2005), 40.

44 Anna Coote, interview, 17 May 2021.

45 Davies et al. (2005), 41.

and that they would meet regularly, being appointed on a fixed-term, with up to a third of members regularly retiring to ‘combin[e] a degree of consistency with an element of freshness’. The idea of recruiting members by random selection from electoral registers – as with legal juries – was considered, but rejected in favour of public advertisements. Members should have no formal or professional stake in healthcare: the disinterested ordinariness of the Council was seen as essential to success.

The model evolved further the following year, amongst mild teething problems, such as a failure to recruit a project manager through secondment from the NHS. The decision was taken to outsource the running of the Council, in liaison with a small internal team. Apart from fitting the current ‘contracting-out’ ethos, this was also ‘a useful device for distancing NICE from the Council and avoiding the “contamination” or “capture” problem’.⁴⁶ This referred to the concern that members of the Council would merely parrot back what NICE wanted them to say, if the working relationship became too close, a point which received a lot of attention.

Vision 21, a ‘Manchester-based research and consultation agency specialising in research for the not-for-profit sector’, was therefore contracted after a tendering process. Run by future Labour MP Simon Danczuk and Ruth Turner, Vision 21 was well-connected and had achieved some acclaim for their work with homeless and other disadvantaged communities.⁴⁷ They ran the recruitment campaign that would result in such great public interest and press coverage. They were also responsible for the conspicuously ‘ordinary’ line-up of the first Citizens Council, the result, as Turner would wryly reflect of Vision 21 operating ‘like some bizarre casting agency’ as they attempted to secure a membership that was representative of the wider population of England and Wales.⁴⁸ The success of their efforts was made clear in the first press release announcing the membership of the Citizens Council, which tabulated the expected number of participants for various identifiable characteristics against what was achieved.⁴⁹

The Citizens Council was a well-funded and supported endeavour at its outset; slickly run, and with enthusiastic buy-in from NICE leaders.⁵⁰ The fact that it paid its participants (fairly but not extravagantly) for their time set the Council apart from many other public and patient involvement projects.⁵¹ Furthermore, NICE was determined that the deliberations of the Citizens Council should be as transparent and accessible as possible. Meetings were held in public, and reports summarising the Councils’ discussions were made available on the NICE website. While the initial reports of the Council were written up by facilitators, later ones were drafted by a journalist of some standing – Geoff Watts – to ensure that the prose

46 Davies et al. (2005), 43.

47 *Guardian* 27 March 2002, The real deal.

48 Ruth Turner, interview 11 May 2021.

49 NICE (2002b).

50 Many interviewees commented on how much of a personal interest Rawlins took in the workings of the Citizens Council.

51 Pathak-Sen interview.

was accessible to a wide audience.⁵² Finally, NICE was at pains to ensure that the Citizens Council's activities were properly evaluated, bringing in a team from the Open University to conduct an ethnographic study of the project. In short, if, as Liam Fox claimed, the Citizens Council was indeed a 'figleaf', it was certainly a well maintained one.⁵³

The Open University team spent approximately two years (2002–2004) closely observing the Citizens Council by attending four Council meetings, observing the methods of both NICE and Vision 21, and conducting interviews with Citizen Council members.⁵⁴ Their account provides the most detailed description of the early years of the Citizens Council, beneath the surface of NICE's official reports. In presenting this warts-and-all picture, their research occasionally ruffled feathers as their version of events clashed with the perhaps idealised view of proceedings that was held internally.⁵⁵

Certainly, the early meetings of the Citizens Council were not plain sailing, and two incidents described by the Open University researchers provide insight into some of the broader tensions of the deliberative democracy approach. The first of these occurred in the very first meeting held in Salford on a November weekend in 2002, and illustrated the difficulties of an exercise that involved engaging people with no previous knowledge or experience of complex healthcare decision-making. At the start of the second day, the facilitators were thrown out, and a 'quiet revolt' instigated, as the councillors took matters into their own hands to work out what exactly they were there for, and what they were being asked to do.⁵⁶ This illustrated the confusion and disorientation that the group felt, and a lack of clarity that they initially felt about both the process and objectives of the Council. In contrast to previous citizens' juries, NICE did not ask questions that related directly to specific circumstances, but much broader, what might be described as meta-questions. For example, the topic under discussion for the first Council was 'clinical need', with the question: 'What should NICE take into account when making decisions about clinical need?'⁵⁷

Certainly a challenging and open-ended question for any group of 30 strangers from deliberately disparate backgrounds to consider, and agree upon a collective answer. But the episode also achieved significance afterwards, both for the facilitators from Vision 21 and for NICE more generally. Vision 21 regarded such situations as 'business as usual' for citizens' juries, considering almost that the incident demonstrated both a readiness for robust discussion and skilled facilitation on their part in firstly acquiescing to and then successively quelling the revolt. NICE too

52 Littlejohns (2009, 2018), 90.

53 The Open University team calculated that the Citizens Council cost just under £470k between 2002 and 2004. Davies et al. (2006), 178.

54 For a detailed description of the Open University team's methods, see Davies et al. (2006), 247–254.

55 Sarah Seymour-Smith, interview, 5 July 2021.

56 Davies et al. (2006), 173.

57 NICE (2002c), 5.

was able to put a positive spin on the episode; for the executive, it became ‘an iconic anecdote which presented the Citizens Council as strong and independent-minded people, who were not under anyone’s sway: vindication, that is, of “no capture, no contamination”’.⁵⁸

If this first incident was indicative of a procedural problem that could relatively easily dealt with and ironed over, the second raised more ethical questions about the meaning of representativeness, and the status and voice of minorities in such groups. In what became known as the ‘clapping incident’, one of the councillors suggested:

I don’t mean any offence to anyone in the room or anything like that. It’s not fair that people use ethnic minorities, disabilities when it suits them. Don’t use it when it doesn’t suit them [the majority of the group claps loudly].⁵⁹

This incident was awkwardly defused initially by simply deferring discussion of its implications, but clearly it left minority members of the group feeling troubled. Pathak-Sen recalls the ‘uncomfortable’ atmosphere, and subsequently having ‘lots of toilet conversations with people who were upset’.⁶⁰ The issue reared its head in later discussions at subsequent Council meetings, when members were discussing the issue of racism; one voiced the opinion that ‘I believe we’ve been spending time here discussing political correctness when we’re here to discuss the NHS’.⁶¹ Of course, this idea of ‘political correctness’ alluded to much broader cleavages in British society at the turn of the millennium, as ethnic minorities and especially immigrant communities became the scapegoat in the tabloid imaginary for the perceived disenfranchisement of white British people. The issue of race and racism has been part of discourse about the health service since its inception.⁶²

Within the Citizens Council this went largely unaddressed, as group cohesion was maintained by ‘letting sleeping dogs lie’ and ‘the concern that some issues and differences were too dangerous or threatening to discuss’.⁶³ Against this interpretation, Pathak-Sen, as NICE’s project manager, felt that ‘difficult conversation’ and ‘uncomfortable moments’ were all part of the process, and that

if we are going to have what we termed at the time “politically correct” conversations, we are not going to understand how people are thinking. Of course these conversations were bounded by the ground rules set by the Council at the start.⁶⁴

58 Davies et al. (2006), 173.

59 Davies et al. (2006), 138.

60 Pathak-Sen interview.

61 Davies et al. (2006), 142.

62 Bryan et al. (2018), 89–140; Bivins (2017); Redhead (2021).

63 Davies et al. (2006), 145.

64 Pathak-Sen interview.

Nonetheless, the Open University team concluded from their quantitative research into participation in meetings that:

participation levels for the four black and minority ethnic (BME) members of the Council were compared with the average participation level for the Council as a whole. The contributions of the BME members were muted and significantly lower overall.⁶⁵

In other words, although the ambitions of the Citizens Council were admirable in terms of achieving statistical representativeness of the wider population, the reality of intergroup dynamics and broader structural racism meant that some groups were able to put their views across more readily than others.

What did the participants themselves think of the experience? One testimony was provided by Brian Brown, a member of the Council between 2002 and 2006, and a veteran of six meetings. Brown's account, included in a book edited by Littlejohns and Rawlins, clings closely to NICE's own narrative of the 'extraordinary wisdom' of 'ordinary' people.⁶⁶ Brown contrasted his own 'ordinariness' as a plumber with the knowledge and expertise of the specialists that NICE used as witnesses at meetings. Some of his comments were subtly telling. For example, Brown noted that:

The Citizens Council is I think, largely a means of demonstrating that NICE is taking public perspectives into account. It provides some extra validation of NICE decisions and is a part of the transparent way NICE works ... Even now I think NICE is wrestling with exactly what to do with the output from the Citizens Council.⁶⁷

While not entirely reinforcing the 'fig-leaf' view of the Citizens Council, Brown's ambivalence does suggest that even or perhaps especially its participants were cognisant of the cover that they provided from political fire. Furthermore, Brown questioned what the function of the Citizens Council was, and whether its deliberations were having any tangible impact on decision-making.

An interview with another, much later, member of the Citizens Council suggests a different function of participation in the project. Rupe Chand, who served a three-year term until what might be termed the Council's managed decline in 2014, was enthusiastic about his involvement, not because he thought it had had any decisive impact on decision- or policy-making, but, as he put it:

I felt my benefit was actually learning more about something, and opening my eyes to think, "there is a lot of stuff behind the couch that we don't know

65 Davies et al. (2006), 123.

66 Pathak-Sen (2009, 2018), 81.

67 Brown (2009, 2018), 127.

about”, not hidden agendas and stuff, cloak and dagger stuff, but there is a lot of stuff that goes on that we don’t appreciate. And I think it is a shame that everyone doesn’t have the opportunity to listen to professionals.⁶⁸

Chand’s experience had provided an insight into how healthcare prioritisation was conducted, and the factors that experts had to weigh up when coming to a decision. This illustrates the ‘student’ dynamic that the Open University team had identified when looking at the engagement between the members of the Council and the witnesses who presented on particular issues.⁶⁹ It also highlights the tension between the lay and the expert perspective, and the power imbalances inherent in that. But, bringing us back to Rawls and the educational effect of participation, it also presents the Citizens Council as in some way being comparable to jury service; a duty that contributes to wider society in some small way, but for the individual, may be transformative in their understanding of the deeper workings of the justice system and others’ views of right and wrong.

The legacy and influence of the Citizens Council

The Council operated for 12 years, and while never officially disbanded, stopped meeting in 2014, before being quietly removed from the NICE website around 2019. The reason for this is not entirely clear, but some observers felt that the format and the questions asked of the Council had run their course. Littlejohns, for instance, commented that ‘there’s only so many general issues you can explore’, though Culyer disagreed, believing that there remained ‘a whole host of really interesting things that would have mattered’.⁷⁰

Key staff members had left to pursue other projects, and perhaps the wider political landscape had changed. Many of those who had been involved in championing citizens’ juries had done so within the receptive years of the New Labour administration. While Gordon Brown had in 2007 described citizens’ juries as Labour’s ‘big idea’, in the meantime David Cameron’s ‘Big Society’ had come and gone.⁷¹ What, then, was the legacy of this experiment in deliberative democracy?

The influence of the Citizens Council can be understood in two areas. Firstly, its impact on NICE internally, and the executive’s decision-making and wider culture during its establishment, as well as its legacy in terms of successor initiatives. Secondly, the wider impact of what was almost certainly the longest and largest trial of the citizens’ jury model of deliberative democracy in Britain.

As perhaps has been implicit up until this point, the influence of the Council on NICE’s decision-making, for all the money and resource that was put into it, was arguably diffuse. While the Council’s reports disseminated what the consensus

68 Rupe Chand, interview, 4 August 2021.

69 Davies et al. (2006), 98.

70 Littlejohns interview, 18 September 2019; Culyer interview.

71 *Guardian* 30 September 2007, ‘Sham’ citizens’ juries face controls.

views of the meeting were, they were often mild-mannered summaries of differing points of view that would always remain unresolved. As such, they perhaps did not give the NICE executive much more than the gentlest of steers on issues. Perhaps it could not have been otherwise: both the vastness and the vagueness of what the Citizens Council were being asked to do in a short period of time with a rotating cast of (by design) very different people mitigated against precise, focussed and easily implementable recommendations. Indeed, there was a sense that the Citizens Council might be the wrong tool for the job. The Open University team described the situation thus:

It was not perhaps that [NICE] did not know what it wanted to know. It was more that whether what it wanted to know was knowable and could be successfully elicited by means of a jury approach.⁷²

However, this equivocal judgement does not necessarily mean that the Citizens Council was entirely a talking shop. The NICE executive could point to the development of their Social Value Judgements, and Rawlins and Culyer were keen to highlight that the Citizens Council had directly influenced thinking about, for example, how ‘NICE might take account of age in its considerations of clinical and cost effectiveness’.⁷³ In producing its report on the relevance of age, the Citizens Council, as on other occasions, had presentations from thinkers representing the main opposing views. Alan Williams presented his QALY-based arguments that ‘in order to reduce inequalities in people’s lifetime experience of health, it is necessary to discriminate against the old’, adding ruefully that ‘I only convinced about one-third of them’.⁷⁴

Culyer has also described the existence of social value judgements as a valuable reality check for decision-makers who might otherwise not always have their feet on the ground:

the main way that the Citizens Council had success was [to] reassure the board that it had the right approach to something. I don’t think we ever changed very much, if anything, as a consequence of any decisions reached by the Citizens Council regarding the Board’s decisions. When they could agree with us it was tremendously heartening. I thought, and I’m sure everybody on the board felt the same way, when the Citizens Council said, “no, this is what we think is the ethically correct thing to do”, and if it happened to be the way we were already doing it, great: it was confirmatory. But it was very expensive.⁷⁵

72 Davies et al. (2006), 83.

73 Rawlins and Culyer (2004).

74 Williams (2005). See NICE (2003).

75 Culyer interview.

Nicholas Timmins, then public policy editor at the *Financial Times*, saw its value in a similar way:

the Citizens [Council] they constructed clearly did help in the early years, because they put questions to it such as should we value older people more or less than young people... that gave a kind of legitimacy to the decisions they were, in practice, taking ... I do think that Citizens bit was probably quite important early on. You'd sit in a room with all these clever people and come to a view about it, but does it wash? It was a way of testing whether what they thought they should do washed. So I think that was quite useful.⁷⁶

Timmins says here that the Citizens Council strengthened the legitimacy of NICE by providing a test of whether the principles it wanted to follow would 'wash' with the public. (It's easy to see why this gave rise to the criticism that NICE used the Citizens Council as a 'fig-leaf'.) We have noted earlier how NICE wanted to add an element of judgement to the health economic rigour of its appraisals. It now becomes clearer that establishing the Citizens Council was a significant component of this, one which sought, with some success, to position NICE's exercise of judgement as something done on behalf of society as a whole and in accordance with society's values, one of Culyer's founding principles.

The quiet demise of the Citizens Council did not mean the end of searching for social value judgements at NICE. In 2019, NICE initiated a new public engagement programme, under the banner of NICE Listens. Described as having been devised to 'give NICE an understanding of public opinion on moral, ethical and social value issues', it promised to:

invite members of the public to take part in a "citizen's jury" style event. This will give those involved time to learn and become familiar with the topic area, before discussing it in detail. An independent organisation will facilitate the process, to make sure it's fair and transparent. They'll produce a final report, which will be presented to our executive team and public board.⁷⁷

This superficially appears as old wine in new bottles, particularly when the first topic was announced as 'health inequalities', an issue that the old Citizens Council had last addressed in 2006.⁷⁸ But it also suggests a resilience to the idea of the citizens' jury after a time out of fashion, a trend witnessed more broadly over the last few years.

Indeed, perhaps this could be the wider legacy of NICE's Citizens Council, as political interest in the model of a citizens' jury has begun to revive. Citizens' juries have continued to be highly popular modes of engagement in Canada, while NHS England, the Scottish Executive and the social enterprises Our Life and Shared

⁷⁶ Nicholas Timmins, interview 17 December 2019.

⁷⁷ NICE (n.d.) Our projects and partners.

⁷⁸ NICE (2006).

Future have organised some 20 health-related citizens juries in disadvantaged communities.⁷⁹ Furthermore, in June 2019 perhaps the most high profile iteration of the model was convened by six Select Committees of the House of Commons, who called for a citizens' assembly to consider 'how the UK can meet the Government's legally binding target to reduce greenhouse gas emissions to net zero by 2050'.⁸⁰ NICE's Citizens Council offers an intriguing blueprint for these developments, and the lessons that might be learnt. Perhaps the Climate Assembly has already successfully learnt one of these; it asks a direct and answerable question on an issue of immediate and tangible relevance to its participants.

Beyond the Citizens Council: patient representation on committees

NICE was, as we have seen, clear from the start that, in addition to having a Citizens Council, there should be representatives of patients on each individual advisory committee. There were also lay (rather than patient) members on NICE's Board: in 2001, for example, three of the six non-executive directors represented the public: Fred George, Roy Luff and Mercy Jeyasingham.⁸¹ NICE's Partners Council, the stakeholder body discussed in Chapter 3, was made up of 25% patient representatives.⁸² Jeyasingham began her NICE career on this body before joining the Board. She had previously worked at the National Eczema Society and the Black Health Forum, and served on the King's Fund's grants committee: an experienced patient advocate. Her recollection of the Partners' Council included:

the fact that we were equally represented: I think 25% of the council were patient care representatives ... more of an equal voice and being listened to and acted on, so that was very clear from the early days, that Andrew [Dillon] and Mike [Rawlins] were interested in our views, and it wasn't just ... the professionals that were being listened to. That gave us courage to demand even more.⁸³

Lay membership of the Boards of public bodies was the norm by 1999: NICE was not doing something unusual. In contrast, having patient representatives on the key working committees was not yet taken for granted. Rodgers recalls:

the first Appraisal Committee meeting: the academics and the industry physicians said, "we don't need patients here, because we see patients all the time, we know what they think." We disagreed and they listened ... clinical data is not enough: the way people live, how care is delivered, can impact effectiveness. A single mum of three on benefits can't drive to hospital three times a week, it's important to understand all aspects.⁸⁴

79 Bryant and Hall (2017), 10.

80 Climate Assembly UK, (web page).

81 NICE (2001).

82 Mercy Jeyasingham, interview 18 December 2019.

83 Jeyasingham interview.

84 Rodgers interview.

Rodgers explains the need for patient participation partly in terms of raising the quality of the decisions, rather than of a moral right to representation. This attitude is an echo of the changes in the evidence demanded from drug trials by the 1990s, from ‘clinical markers’ of efficacy to a greater interest in the impact on patients’ activities of daily living.⁸⁵ According to Rodgers, some clinicians:

saw the disease on the other side [of their desk] but not the patient, and the world was changing: we needed to see the patient and [clinicians] needed to understand the impact of what they were doing on people’s lives, not just on the disease. So it really did shift.⁸⁶

One example of patient organisations pressing for this emphasis on real-world effectiveness as opposed to technical efficacy is the work of Eric Low from Myeloma UK, who often had contact with NICE. As Dillon recollects, Low was:

interested in the whole question of how both ... research into, and decision-making about, health technologies ... takes advantage of the perspective of people who are living with particular diseases and conditions, or organizations that can speak on their behalf, and especially interested in how clinical trials are constructed in ways that ... concentrate on data and endpoints that are relevant to patients, instead of just “of interest” to researchers or companies.⁸⁷

This pragmatic value of having patients around was acknowledged by Rawlins:

When we started I was being told that we were just being politically correct [about] patients. But actually they were very valuable ... We were interested in the views of patients right from the very start. There was a slight problem, in that sometimes patients were lobbied by the industry. In fact sometimes patients were organised on the basis of them being given money by pharmaceutical companies, then they tend to lobby, so we had to be rather careful about patients, or at least the patient organisations – not patients themselves really.⁸⁸

The industry practice alluded to here by Rawlins, of funding patient groups with a shared interest in the take-up of a new drug, has often been commented on.⁸⁹ To take an example described to us by a former lobbyist, in 2008 Roche provided financial support for the Rarer Cancers Foundation (later the Rarer Cancers Forum) to

85 See for example Epstein S (1996), 208–228.

86 Rodgers interview.

87 Dillon interview.

88 Mike Rawlins, interview 18 September 2019.

89 The practice was raised with us by Mercy Jeyasingham, who had seen it happening at the National Eczema Society (interview) and Sarah Boseley (interview 13 January 2020).

commission a report from the lobbying company Health Mandate on access to cancer drugs in the UK.⁹⁰ Later, in this chapter, we will note how a participant in patient advocacy like Alastair Kent was conscious of the need to guard against losing credibility by being drawn into this kind of lobbying.

NICE took the decision at the beginning to have patient representatives on committees. This made a good impression on patient groups: Jean Gaffin, for example, had been the Chief Executive of Arthritis Care, and felt that in the late 1990s:

There was less lay representation on stuff: now everywhere you look, every or most committees or stuff in the NHS has got lay representation. It was progressive of NICE to start off with two lay representatives on Appraisal Committees.⁹¹

For this to be valuable and not tokenistic, quality as well as quantity of the representatives mattered. As Culyer describes it, NICE's PPI:

was a very well supported activity, it wasn't just a "let's involve patients" it was a "where do we get the advice in order to identify people who would be really good in the various roles that we want for patients to be involved in?"⁹²

NICE's first four patient representatives on technology appraisal committees, a 'gang of four' as Gaffin described them, were chief executives of patient groups. Along with Gaffin herself, formerly of Arthritis Care, were Peter Cardy, then the chief executive of the Multiple Sclerosis Society and formerly of the Motor Neurone Disease Association; Ruth Lesirge, who was then running Cottage Homes (now the Retail Trust, a charity which provides advice and support and housing to pensioners of the retail trade); and James Partridge, founder of Changing Faces, the UK charity for people with a scar, mark or condition on their face or body.⁹³

Operating as a patient representative, as many others have found in other contexts, could be challenging. Their status and authority for contributing was not as straightforward as that of others in the room. As Gaffin put it:

you're in a room, you're a lay person, you haven't got scientific background and you're sitting with some top doctors, top scientists, top health economists, and it could be ... I didn't want to be daunted by it, I just wanted to make sure I had my say. I thought I had a fairly narrow role, just to ask what would it be like for patients.⁹⁴

90 Bill Morgan interview, 20 April 2022.

91 Jean Gaffin, interview 25 November 2019.

92 Culyer interview.

93 David Barnett, interview 15 November 2019; Dillon interview.

94 Gaffin interview.

As Jeyasingham commented, to get the most out of patient representatives (and even more from patients giving evidence, whom we will consider next), things like pay, training and support were essential:

from my own background I knew you can't just plonk people on boards and things, you need to give them support and training, to understand what their role is on these places. ... So training was important. But also to have the kind of people that were confident enough to speak up, especially when you got what I would call the great and the good, or the world's leading experts in X around the table, just to have the confidence of questioning or to raise issues was quite important.⁹⁵

To provide this kind of support, NICE set up the National Guidelines and Audit Patient Involvement Unit in December 2001.⁹⁶ It was based at the College of Health, a national charity that promotes patient interests in the NHS, and benefited from the existing PPI experience of Marcia Kelson (soon to be the Director of NICE's Patient Involvement Unit, where she would remain influential). NICE later took the work of supporting patient input in-house under the long-term leadership of Barbara Meredith.⁹⁷

There is a connection between PPI in decisions and the apparently separate issue of meeting in public. In accordance with expectations about transparency, NICE's Board meetings, and papers, have always been public. Meetings of appraisal committees were not, initially, but this changed in the first few years. Members of the public observing meetings could not participate in them, but their visibility and the effort to make them feel welcome could be influential. As Jeyasingham recalls in relation to Board meetings:

Even from the beginning our public board meetings were public, we obviously had the people with MS [multiple sclerosis], kidney cancer and all sorts of people: we always as board members would individually go and speak to them, even if they were lobbying outside, and invite them in. Mike [Rawlins] made sure that he was at the forefront of that. I have to say that made [a] huge difference to the whole ethos of NICE around PPI.⁹⁸

Using evidence from patients and their organisations

We have seen how NICE valued the presence of patient and public representatives in deliberation, both on the Citizens Council and in committees. The picture now needs to be completed by examining the role of patients in giving evidence to NICE's advisory committees, both for guidelines and for technology appraisals.

95 Jeyasingham interview. A similar point was made by Rawlins (interview).

96 National Guidelines and Audit Patient Involvement Unit (n.d.) (web page) (accessed 1 October 2019). The College of Health has a national reputation for promoting patient involvement, specifically in relation to clinical audit and clinical guidelines.

97 Gaffin, interview.

98 Jeyasingham interview.

The exact issues on which patients' evidence was valued, how best to obtain it, and – perhaps conceptually hardest of all – how to weight it alongside the rest of the evidence on a technology, were all questions which had to be grappled with.

To begin with the obvious, using patient evidence was a choice, and one which not all HTA organisations made. Kent had become the director of the Genetic Interest Group, a charity promoting the policy interests of people with rare genetic conditions, in 1990. With the gradual emergence of treatments for more of these conditions, NICE has increasingly made decisions affecting very small groups of patients. In Kent's view,

the thing about NICE has been, since its start it has recognised that it is important to take some account of the end user, the patient, the family perspective. Unlike a lot of HTA type agencies at that time ... who saw HTA as a kind of a semi scientific process, you know you feed the data in at one end, you turn the handle and the answer comes out at the other.⁹⁹

Taking evidence from patients themselves seems to have been the result of pressure from the patient and public representatives on the advisory committees, rather than a feature designed in from the beginning. Gaffin claims this was the work of the 'gang of four' original patient representatives already mentioned. The four of them put their concerns to Rawlins and Dillon:

Initially [patients] didn't come in person, and that was the issue we wanted to take up, because it meant that the weight of evidence, both written and oral, from the health professionals, was not balanced if you only had written evidence from a patient group. That was not exactly, initially, popular, because people feared that people would come along and talk about 'me, me, me,' rather than this condition and its effect. ... We wanted patients to be able to come, and usually it was somebody representing the kind of organisations we all belonged to. There was some good data often, because people were running helplines, stuff like that. So we did that, there was a little bit of unease, but once it got through a couple of months it was taken as a norm.

It was a big responsibility for us, you were talking about a different ... condition every meeting. That's quite hard. It's much better if someone comes who has personal experience, or professional experience of running an organisation.¹⁰⁰

A process was soon devised. David Barnett, chair of the first Technology Appraisal Committee, recalls how contributors:

were selected by the patient care organisations, and then they came along, and we usually had two, maybe three, patient advocates, patient experts we

⁹⁹ Alastair Kent, interview 8 July 2022.

¹⁰⁰ Gaffin, interview.

called them, and two or three clinical experts. They would sit around with the committee. I would explain what was going to happen and we would ask. During the process I would often refer to them, say ‘what do you think about what’s just been said?’ The committee members would ask them directly questions and they would do them. Then we would file out of the room and have our discussion and come to our final decision. They were very helpful, and very grateful I think to be involved. I found it helpful.¹⁰¹

As Gaffin remembers:

sometimes you would have a chief executive of an organisation and a member of it. Occasionally you just would get a particular patient coming along. They began to be really well-briefed, and it worked well. It was an integral part of the committee once it got going.¹⁰²

Barnett and Gaffin’s account was the view from NICE’s side of the table. For the patient (or carer) participants themselves, this could be a stressful, high-stakes experience, seen as a one-off opportunity to tell someone with influence about life-changing issues affecting them or a relative. For a rare condition, as Kent explains, it was particularly likely that the patients or carers with the relevant experience of the condition belonged to a very small group with no background in this kind of work, and so providing emotional support and practical coaching was essential. He would:

steer them clear of saying “this drug is wonderful, we must have it” and more [like saying:] “if the change that is claimed for this particular drug is brought about then this is the impact it will have on our lives, these are the sorts of things we will hopefully be able to do that we can’t do now. These are the changes that will ... enhance the quality of our life”¹⁰³

This was an emotionally charged experience for all involved. The next chapter records examples of public demonstrations and newspaper campaigns aiming to influence specific appraisal decisions. Notable cases included Herceptin and Beta Interferon, and later the kidney cancer drugs discussed in Chapter 8. Barnett, who chaired the Beta Interferon appraisal, remembers how:

We were also faced with the public involvement, and particularly the MS Society’s strong beliefs in the importance of this. ...They were very, very intense and passionate about it, and we had a lot of meetings – they weren’t public meetings then, but the patient representatives, many of them in

101 Barnett interview.

102 Gaffin, interview.

103 Kent interview.

wheelchairs and so on. I was faced with considerable media interest in that. It was trial by fire.¹⁰⁴

Rodgers, responsible for managing NICE's media relations over Beta Interferon, adds a further dimension:

for every letter we got supporting the MS Society's position, we got many more from people with MS (the type not impacted by the drugs) who said, "please don't approve these drugs, they will only work for a certain patients, we don't think they're an innovation, if you do, money for drugs will come from our physiotherapy" etc. They understood budgets, people with chronic and lifelong conditions understood how the money moved, and what they could see was, if you do this, we're going to lose access to our support services and our facilities'.¹⁰⁵

This encapsulates the concern about the trade-off between funding new and existing treatments in a cash-limited NHS, which is discussed in Chapter 8. Reflecting on his range of experiences with patient organisations, Dillon commented:

at one end of the spectrum where Eric [Low of Myeloma UK] is very much sitting, [the approach] was 'actually, this organisation [NICE] is genuinely committed to improving the quality of care, so we should be working with it, and supporting it, and helping it deliver on that mandate'. At the other end of the spectrum: 'this is an organisation whose purpose is just to delay or frustrate, or otherwise prevent access to stuff that we, as patients, have a right to get'.¹⁰⁶

This brings us to the difficult questions of identifying the issues on which NICE wanted evidence from patients, and how to weigh this evidence alongside the clinical and health economic evidence, which claimed a very different sort of authority, rooted in science and professional knowledge. One straightforward answer was to steer away from 'emotion' and look for things which were countable, lending them a sort of objectivity. Rodgers recalls that the organisation Patients Involved in NICE said NICE: 'don't really listen to the emotions, but they listen to your reviews of your members where you say, "nine out of ten people think this is a good idea"'.¹⁰⁷

NICE's approach to these questions is well illustrated by an early debate involving patient members of the committees and the rest of the NICE team. James

104 Barnett interview. Dillon, too, recalls Peter Cardy, then the MS Society's Director, as 'a really determined and active participant' (interview).

105 Rodgers interview.

106 Dillon interview.

107 Rodgers interview.

Partridge, one of the ‘gang of four’ patient members on appraisal committees, was particularly interested in thinking through what contribution a patient organisation could make, and, in Dillon’s recollection, asking:

just how does the advisory committee then take into account that input ... He developed the idea of ... a patient impact statement, he wanted ... NICE to formally develop ... a standardised model ... for a patient impact statement. And was really keen for the organisation to do that.¹⁰⁸

Gaffin, also part of this initiative, called this:

trying to commission the kind of evidence that you got from the scientist, from the patient.¹⁰⁹

As Barnett, from the committee chairman’s perspective, points out:

there was an absence of a presentation dossier from the patient/carer point of view. We had a NICE appraisal committee document for the committee to look at, we had the manufacturer’s submission, we had an ERG [independent Evidence Review Group] viewpoint, but we didn’t have an equivalent from the patient and carers. [the patient members] wanted to set up a similar kind of independent group who would produce that kind of distillation of the patients’ views on this technology.¹¹⁰

But Barnett continues:

And it didn’t work. It didn’t work because it was very difficult to produce something which was seen to be non-partisan, and [the patient members] were very disappointed about that.¹¹¹

NICE did commission a feasibility study, but its results were disappointing.¹¹² Gaffin and Barnett put a brave face on this. In principle one might weigh the more subjective-seeming patient evidence alongside the other material in any of three ways: devising some mechanistic calculus; devising processes which at least gave patients confidence they had been heard; and leaving the balancing of evidence solely to the judgement of the committee. The first of these is implausible, and any objectivity it might seem to deliver probably spurious. NICE’s solution on this occasion – relying a good deal on judgement but also placing a lot of process and around it – is of a piece with its wider approach to HTA decision-making, to which we turn in the next chapter.

108 Dillon interview.

109 Gaffin interview.

110 Barnett interview.

111 Barnett interview.

112 Gaffin interview.

In conclusion, NICE's engagement with the public and patients was nothing if not energetic. The organisation saw, even before its opening day, its own specific need to be open to public and patient input as well as the more general one, and did more than the average NHS body (as it then was) about this. The Citizens Council was notably innovative, again because NICE could see that deliberation about values was pragmatically useful as well as desirable in principle.

We would look in vain for signs that NICE had found the philosopher's stone of citizen input, solving the problem of how to identify and express social value judgements for all time. But it would be unreasonable to expect this to exist, social values presumably being a matter of negotiation, interpretation, disagreement and change. A lot of what NICE did aim for, and achieve, can be summarised under the heading of Sabin and Daniels' 'accountability for reasonableness', a body of work which clearly interested Culyer, Littlejohns and others.¹¹³ As such, NICE's solutions to the problem were rightly provisional, and, as part of the policy process, they invite and depend on continued public scrutiny.

Bibliography

Primary sources

- Climate Assembly UK (web page) (Last accessed 22 September 2021).
DH (2000) *The NHS Plan* (London: DH).
Guardian 27 March 2002, The real deal.
Guardian 20 August 2002, Public invited to advise medicines watchdog.
Guardian 30 September 2007, 'Sham' citizens' juries face controls.
National Guidelines and Audit Patient Involvement Unit (n.d.) (web page) (Last accessed 1 October 2019).
NICE (2001) *Annual Report 2000–2001 and Summary Financial Statement* (London: NICE).
NICE (2002a) Have Your Say in Health Press Release 2002/044B, 19 August 2002 (Last accessed 17 August 2021).
NICE (2002b) NICE announces members of first UK Citizens Council Press Release 2002/056, 8 November 2002 (Last accessed 17 August 2021).
NICE (2002c) Citizens Council, *Report of the first meeting of the NICE Citizens Council: Determining 'Clinical Need* (London: NICE).
NICE (2003) *Citizens Council Report on Age* (London: NICE).
NICE (2006) Citizens Council, *Report on NICE Citizens Council Meeting, 8–10 June 2006: Inequalities in Health* (London: NICE).
NICE (n.d.) Our projects and partners (web page) (Last accessed 4 October 2024).

Secondary sources

- Bivins R (2017) Picturing race in the British National Health Service, 1948–1988, *Twentieth Century British History* 28(1), 83–109.

113 Daniels and Sabin (1997).

- Brown B (2009, 2018) The view of a Citizens Council member, in Littlejohns P & Rawlins M (eds) *Patients, the Public and Priorities in Healthcare* (Abingdon: Radcliffe), 125–128.
- Bryan B, Dadzie S & Scafe S (2018 [1985]) *The Heart of the Race: Black Women's Lives in Britain* (London: Verso).
- Bryant P & Hall J (2017) *Citizens Jury Literature Review* (Manchester: Shared Future).
- Clarke J (2005) New Labour's citizens: activated, empowered, responsabilized, abandoned?" *Critical Social Policy* 25(4), 447–463.
- Coote A (1993) Public participation in decisions about health care. *Critical Public Health* 4(1), 36–49.
- Coote A & Mattinson D (1997) *Twelve Good Neighbours: The Citizen as Juror* (London: The Fabian Society).
- Coote A & Lenaghan J (1998) *Citizens' Juries: Theory into Practice* (London: Institute for Public Policy Research), 25.
- Crosby N (n.d.) Intellectual background of the citizens jury process (Last accessed 8 September 2021).
- Daniels N & Sabin J (1997) Limits to health care: fair procedures, democratic deliberation, and the legitimacy problem for insurers. *Philosophy & Public Affairs* 26(4), 303.
- Davies C, Bennett E, Wetherell M & Seymour-Smith S (2005) *Opening The Box Evaluating the Citizens Council of NICE* (Milton Keynes: The Open University)
- Davies C, Wetherell M & Barnett E (2006) *Citizens at the Centre: Deliberative Participation in Healthcare Decisions* (Bristol: Policy Press).
- Davies S, Hanley B, New B, Sang B & Elizabeth S (1998) *Ordinary Wisdom: Reflections on an Experiment in Health and Citizenship* (London: The King's Fund).
- Delap C (1998) *Making Better Decisions. Report of an IPPR Symposium on Citizens' Juries and Other Methods of Public Involvement* (London: Institute for Public Policy Research).
- Doheny S & O'Neill C (2010) Becoming deliberative citizens: the moral learning process of the citizen juror. *Political Studies* 58(4): 630–648.
- Epstein S (1996) *Impure Science: AIDS, Activism and the Politics of Knowledge* (Berkeley: University of California Press).
- Fabian Society (1996) *Health Crisis – What Crisis?: Proceedings of the Fabian / Socialist Health Association New Year Conference 1996* (London: Fabian Society).
- Grant M (2016) Historicizing citizenship in post-war Britain. *Historical Journal* 59(4), 1187–1206.
- Ham C & Pickard S (1998) *Child B: Tragic Choices in Healthcare* (London: The King's Fund).
- Langhamer C (2018) 'Who the hell are ordinary people?' Ordinarity as a category of historical analysis. *Transactions of the Royal Historical Society* 28, 175–195.
- Littlejohns P (2009, 2018) The citizens council reports, in Littlejohns P & Rawlins M (eds) *Patients, the Public and Priorities in Healthcare* (Abingdon: Radcliffe), 89–108.
- Littlejohns P & Rawlins M (eds) (2009, 2018) *Patients, the Public and Priorities in Healthcare* (Abingdon: Radcliffe).
- McIver S (1998) *Healthy Debate?: An Independent Evaluation of Citizens' Juries in Health Settings* (London: The King's Fund).
- Mold A (2015) *Making the Patient-consumer: Patient Organisations and Health Consumerism in Britain* (Manchester: Manchester University Press).
- Pathak-Sen E (2009, 2018) Ordinary people, extraordinary wisdom, in Littlejohns P & Rawlins M (eds) *Patients, the Public and Priorities in Healthcare* (Abingdon: Radcliffe), 81–88.

- Rawlins M & Culyer A (2004) National institute for clinical excellence and its value judgments. *British Medical Journal* 329, 224–227.
- Rawlins M (2009, 2018) Background to NICE’s citizens council, in Littlejohns P & Rawlins M (eds) *Patients, the Public and Priorities in Healthcare* (Abingdon: Radcliffe), 75–80.
- Rawls J (1971) *A Theory of Justice* (Cambridge, MA: Harvard University Press).
- Redhead G (2021) ‘A British problem affecting British people’: sickle cell anaemia, medical activism and race in the national health service, 1975–93. *Twentieth Century British History* 32(2), 189–211.
- Smith G & Wales C (1999) The theory and practice of citizens’ juries. *Policy & Politics*, 27(3), 296.
- Stewart J, Kendall E & Coote A (eds) (1994) *Citizens’ Juries* (London: Institute for Public Policy Research).
- Williams A (2005) Discovering the QALY OR how Rachel Rosser changed my life, in Oliver A (ed) *Personal Histories in Health Research* (London: Nuffield Trust), 191–206.

5 Health technology appraisal, 1999–2007

We saw in Chapter 1 how the Department of Health (DH) began to test the water with Health Technology Appraisal (HTA) in the late 1980s and 1990s. We also noted there how HTA is a ‘technology of governance’, useful to the state for reasons including its potential for cost control, and the extra legitimacy which the deployment of science could provide for painful policy decisions. In Chapter 2 we observed DH under its incoming New Labour ministers making policy decisions about how NICE would operate, including some quite detailed ones about the initial form of NICE’s HTA activities. We have seen how HTA was an actor in the contingent and negotiable relationship between science and society. This chapter attempts to map some of the main areas of negotiation. It begins with the start of NICE’s operations in 1999, and ends immediately before a far-reaching controversy broke out over expensive cancer drugs in 2008: Chapter 8 takes up the story there and brings it up to 2020.

The development of NICE’s HTA appraisal system, 1999–2007

This section, rather than aiming for a blow-by-blow account of the immense amount of technology appraisal which NICE has done, or even a summary of the key events, draws out some big themes and tries to interpret critically what was going on: we present them in, broadly the chronological order in which they became important. The reader who requires chapter and verse on (for example) what was appraised and when is referred to the NICE website, which retains a wealth of detail.

We saw in Chapter 1 how DH discussed the appraisal process and method with the pharmaceutical industry’s health economists in its Expert Workshop on DH Guidelines for Pharmaco-Economic Studies.¹ DH initially expected that NICE would carry

¹ NICE uses ‘process’ to describe the sequence of events a technology has to pass through during appraisal, and ‘method’ for the technical approach to assessment. Note that ‘appraisal’ refers to the whole process, and ‘assessment’ is often used for the earlier part, where the rigorous analytical method is applied before the papers go to the appraisal committee for them to exercise their judgement.

out at least 20 appraisals every year, which soon proved to be an underestimate. To get started, NICE now had to operationalise both its process and its method, very rapidly. When Rod Taylor was appointed NICE's first Director of Technology Appraisal, he recalls being the organisation's fourth member of staff. Then,

After I'd been in the job a month, Frank Dobson requested that NICE evaluate Zanamivir/Relenza, and publicly announced that. It became clear – through the *Evening Standard!* – what our task was. ... I think he gave us three months, to effectively embed a procedure. We had to do two things: set up a technical assessment, and then set up a committee who were going to evaluate both the clinical effectiveness and the cost-effectiveness and then make a decision.²

Designing the first appraisal process

We look first, then, at how the appraisal process was designed and why it took the form it did. The dilemma in designing an appraisal process was whether to have a quick process before the drug was placed on the UK market, with the likelihood that effectiveness data would be thin at times, and perhaps need revision later, or a more thorough process with much better effectiveness data, only completed after the drug had been brought into use. (DH's original 1998 proposal, of a slow process before the drug came to market, combined the worst of both worlds.) The point here is, as Richard Sykes of Glaxo Wellcome told us, that little meaningful data about effectiveness may be available from the clinical trial alone: a period of real-world use is valuable (at the least) for assessing a drug's true effectiveness, and thus its cost-effectiveness:

how do you know whether it's value for money ... You do a [clinical trial] phase III study, you might have 2000 people: ... How the hell can you decide whether something's value for money, treating 2000 people? ... You've got to put the drug on the market, let people use it, and then after three years, five years, you say, 'is this value for money?' ... you can't decide whether it's value for money or not, without the data: look at ACE inhibitors.³ ACE inhibitors were developed for renin hypertension [but were then found to be] absolutely amazing drugs for congestive heart failure. How the hell would you know that until you've been in 10,000 people, 50,000, 200,000 people? ... And that's true of many, many drugs.⁴

2 Rod Taylor, interview 16 October 2019. The newspaper report of the referral of Relenza to NICE was: *Evening Standard* 7 July 1999, NHS catches cold.

3 Angiotensin-converting enzyme (ACE) inhibitors help relax veins and arteries to lower blood pressure. In the 1950s and 1960s the renin-angiotensin system was thought to play a role only in the most serious hypertension: this understanding changed from the 1970s.

4 Richard Sykes, interview 19 September 2019.

It might be objected that postponing appraisal so long would have tied the National Health Service (NHS) into buying new drugs for (say) five years without knowing if they were cost-effective. This was certainly a problem with Sykes' suggestion, and one not wholly overcome by his claim that the PPRS cap on each company's UK profits (until it was revised in 2019) provided the fiscal safeguard which the NHS needed. DH and NICE resolved the dilemma by choosing the first option, appraisal as soon as possible after UK market authorisation. The pharmaceutical industry preferred this: Sykes remained something of a lone voice in calling for the other option (although Virginia Bottomley MP took up his argument in the 1999 debate about NICE already mentioned). NICE has since operated two schemes quite like the Sykes approach, however: Patient Access Schemes with risk-sharing for the uncertainty about the drug's effectiveness (such as beta interferon, discussed later in this chapter) and the remodelled version of the Cancer Drugs Fund (see Chapter 8).⁵

NICE's appraisal process had many sources. Charles Dobson, who largely drafted *Faster Access to Modern Treatment: How NICE Appraisal will Work* at DH in 1999 (Chapter 2), modestly suggests that once NICE took over responsibility for designing the process, they 'made some refinements, built in some more checks and balances'.⁶ Taylor, who was in charge of the design by then, credits DH somewhat less and other sources more. He mentions learning from other countries, unusually for the civil service (though Clive Smee's sabbatical is a relevant precedent): in this case existing HTA agencies in Australia – apparently particularly influential – and Canada.⁷ Andrew Dillon comments that the main international influences on NICE's development were from related initiatives in Australia, New Zealand, Canada, Sweden and the Netherlands.⁸

More unusually, the centre (in the form of Taylor and NICE) was willing to learn from the periphery:

[I] borrowed a lot from the Drug Evaluation Committees [DECs] which some [NHS] regions had ... One thing I borrowed was this important split between the technical appraisal and the committee's analysis – the very technical, analytical work done by experts, and the final decision taken in a committee meeting. Some people wanted NICE to do the whole thing, but I was very insistent that we should farm out the technical appraisal to independent units. We got a lot of useful ideas for technique from the South Western DEC.⁹

5 For Bottomley's intervention, which quotes Sykes, see House of Commons: Third Standing Committee on Delegated Legislation (1999). Bottomley had been the Secretary of State for Health, 1992–94.

6 NHS Executive 1999; Charles Dobson, interview 16 March 2020.

7 Taylor interview: there is more detail on both visits in the interview with David Barnett, 15 November 2019, who also took part. Tom Walley, Professor of Clinical Pharmacology, University of Liverpool, stresses the importance of Australia in particular (personal communication).

8 Andrew Dillon, personal communication.

9 Taylor interview. South Western Regional Health Authority is not to be confused with Wessex RHA, which also had a role in NICE's origins (Chapter 2); Bruce Campbell (interview, 13 January

The contracting out of technical appraisal to independent (usually academic) units, felt to Taylor like an afterthought or serendipity. In his account, the government's new policy of national guidance meant 'by definition, the DEC's became redundant overnight. I saw there was potential to utilise their academic, statistical capacity, and realign it to serve ... NICE'.¹⁰ It can also be viewed, though, as an example of the contracting-out culture promoted by the New Public Management in the UK since the 1980s and as DH's (and the rest of Whitehall's) default method of obtaining a new service for government use.¹¹

Making appraisal robust was NICE's most important challenge of 1999. NICE met the challenge very effectively. Although the 1999 model has developed significantly since then (as we shall discuss), all its most important features were in place by the time NICE published a summary of its appraisal system in November 1999.¹² The scale of this rapid achievement is noteworthy: it was a task of considerable political as well as technical complexity. David Barnett, Professor of Clinical Pharmacology in the Department of Cardiovascular Sciences at the University of Leicester and the first chair of the Appraisal Committee, recalls:

All the early appraisals were a major learning curve, not just for me but for everybody. The amount of workload, the processes, the way the methods were established at that time were quite skeletal. So there was a lot of work to be done in committee, and in the parallel Development committee, to try and understand how we would apply the rules and how they were developed. So it was intense ... it was a small team, establishing new things.¹³

Before the appraisal system had been operating for long, it was given extra teeth. In 2002, as noted in Chapter 3, DH ministers issued a Direction under which NHS bodies had to make funding available for the treatment of patients whose clinicians recommend treatments in line with NICE appraisals.¹⁴

Evidence-based appraisal

The new appraisal system had five enduring features which contributed to its success.¹⁵ To begin with, it was evidence-based. The evidence-based medicine approach we discussed in Chapter 1 was deployed with thoroughness and

2020) chaired the South Western DEC and recalls a formal handover of responsibility to David Barnett on the establishment of NICE. Adrian Towse (Director of the Office for Health Economics) adds another element which Taylor borrowed from the DEC's: an Incremental Cost-Effectiveness Ratio (ICER) threshold of £20,000 per QALY (interview 1 March 2021).

10 Taylor interview.

11 On the New Public Management see Ferlie (2001).

12 NICE (2000).

13 Barnett interview.

14 Department of Health (2003).

15 A good short account of NICE's HTA processes and methods is Barnett et al. (2009).

enthusiasm, for example, its hierarchy of the different types of evidence, putting systematic reviews at the top.¹⁶ Andrew Stevens, former Professor of Public Health at the University of Birmingham and a member of the first Relenza appraisal committee, recalls how, in that appraisal, the choice of patient population used in the analysis was central to the rejection of Relenza:

Glaxo [Wellcome] had put forward three big trials, all of which specifically excluded anybody at risk [of developing complications from influenza], and the appraisal was about the at-risk groups, it seemed almost sort of bizarre to the committee that anybody should have thought [Relenza would be approved], as we in effect had no data on the question in front of us.¹⁷

And cost-effectiveness was examined with the same rigour as effectiveness. The basic approach was handed to NICE by DH (Chapter 2). The approach to cost-effectiveness analysis was ambitious: the form of analysis to be used must allow ‘all the different uses of health care resources to be comparably appraised, not simply different treatments for a given disease or different uses of pharmaceutical spending’.¹⁸ That meant analysts must compare health gain with cost, measuring health gain in terms of ‘health related quality of life and life expectancy’. The QALY, which we met in Chapter 1, was recommended for this purpose since it combines these two dimensions in a single scale. Analysts were directed, as a logical consequence of this approach, to report ‘the additional cost per unit of health gain’, that is, the Incremental Cost-Effectiveness Ratio (ICER), which has ever since formed the heart of the NICE appraisal methodology. Having established the ICER for the technology under evaluation, comparison with an ICER threshold could indicate whether the technology was sufficiently cost-effective to recommend. In 2004 an updated *Guide to the Methods of Technology Appraisal* set out these requirements as a default method for cost-effectiveness analysis, which it called the Reference Case. Departures from using the Reference Case approach were permitted, but had to be justified.

Using judgement

In NICE’s opinion, technical rigour would never have been enough. It chose not to simply apply the result of a comparison between a technology’s ICER and a threshold value. Instead, it added a second enduring feature of the appraisal system: the exercise of judgement, or in other words the inclusion of a deliberative stage in the process.¹⁹ The deliberative approach has been central to NICE’s methods and to

16 For the hierarchy of evidence, see for example Murad et al. (2016).

17 Andrew Stevens, in Atkinson and Sheard (2020), 30.

18 Buxton papers, Evaluation of Health technology for use in the NHS (1999), typescript.

19 For a technical discussion of deliberative processes and a view that NICE’s processes do what is required from them, see Culyer (2006).

their success. We have already seen the stress which Taylor laid on this and noted how he copied this approach – of separating technical ‘assessment’ by a specialist ‘Assessment Group’ from the final ‘appraisal’ decision of a committee – from the work of NHS regional DECs. Subjecting expert findings to a deliberative process for approval in this way may seem unremarkable – there are many other examples from public life around the world – but it was not the inevitable choice. As Smee comments,

Economists tend to split between those who believe cost-effectiveness calculations should *make* or determine policy decisions and those who believe they should *inform* such decisions. DH economists generally took the latter view, accepting that there is bound to be a role for social value judgements.²⁰

This dichotomy is a good example of the wider one between ‘evidence-based policymaking’ and ‘evidence-informed policymaking’. NICE has chosen the latter. Its use of a threshold ICER is a case in point. Barnett describes the appraisal committee’s use of the threshold like this:

it [the threshold] wasn’t set, it was case law. It just came about, it became either obvious or rule-of-thumb that it was the way to do it, that £20,000 or £30,000 per QALY was considered to be the range, anything less than £20,000 per QALY would be probably be acceptable, and anything over £30,000 per QALY would have to have extenuating circumstances, and in the middle there was a lot of argy-bargy.²¹

Though this could convey an impression of merely ‘muddling through’, this is not what was happening. Syrett has written of the ‘disjuncture between the ostensibly neutral technocratic methodology employed by NICE and the value-laden ethical and political nature of many of the decisions which it must reach’.²² It follows from this ‘disjuncture’ that allowing the ICER calculation to *make* the appraisal decision rather than *inform* it would not have been politically acceptable. Rather than seeing Barnett, and by extension, NICE, as failing to use health economics rigorously enough, it seems he was aiming to use a deliberative process sensitively to arrive at the conclusions most acceptable to the public, with the ICER threshold serving as scaffolding rather than straitjacket.²³ Barnett’s use of the phrase ‘case law’, simultaneously suggesting a level of discretion and a clear obligation to follow what has been laid down, hints that he was influenced, consciously or otherwise, by the common law approach to jurisprudence.

20 Smee (2005), 84.

21 Barnett interview.

22 Syrett (2003).

23 This is the picture of Barnett’s work at NICE that emerges in Adam Wishart’s 2009 documentary film *The Price of Life*, described by the *Mail on Sunday* as ‘unsettling but vital and grimly fascinating’ (Last accessed 28 February 2022).

Some of the extensive literature about NICE's processes, for example by Syrett, painted them in these early years as 'attempting to solve the difficult questions inherent in health care priority-setting by technocratic means', as we saw in Chapter 1.²⁴ That misrepresents what NICE was trying to do in technology appraisal. As the economist John Appleby has pointed out,

NICE was faced with many fundamental technical and social value issues over how it would go about its work. ... how was it to make a judgement about whether a health care intervention was cost effective enough to merit inclusion in the NHS 'package' of care? And indeed, to what extent was the pure issue of cost-effectiveness to be qualified or amended by other criteria? ... NICE not only [needed] a practical solution but one which [was] acceptable to the public.²⁵

In Tiago Moreira's terms, it was:

a question not only of ensuring the production and dissemination of scientifically robust research, but also of taking into account the various perspectives and concerns different groups have about knowledgemaking in society. It is a question of ensuring, as Nowotny, Scott and Gibbons suggested (2001), that socially robust knowledge is produced.²⁶

NICE's first vice-chair, the York health economist Tony Culyer, was central to its decisions about how to produce 'socially robust knowledge'. He brought to NICE, and the challenge which it faced (of designing an HTA system acceptable to the public), an analytic focus on getting the philosophical basis right. Here, that meant distinguishing between normative 'value' judgements and positive (in the sense of objective) economic techniques – the same distinction we cited Smee making earlier in this section.²⁷ Since NICE had to use society's values, reasoned Culyer, it needed the best method it could devise for discovering what these were. As he and Mike Rawlins wrote, 'advice from NICE to the NHS should embody values that are generally held by the population that the NHS serves'.²⁸ This need was the genesis of NICE's Citizens Council, which we examined in Chapter 4. And as Taylor commented, for committees to have access to a published set of 'Social Value Judgements' also simply saved them time and trouble:

That helped protect the committee members, for instance when it was very clear that things like baseline severity didn't matter, or ... patient income. It

24 Syrett (2003).

25 Appleby (2016). See also Culyer et al. (2007).

26 Moreira (2012); Nowotny et al. (2001).

27 Some of Culyer's key work on this is collected in Culyer (2013).

28 Rawlins and Culyer (2004).

meant that we could get on with our business ... it presented a very helpful [way] in which to operate in a technical sense. ... it was a very smart move.²⁹

Giving stakeholders a voice in the process

A third enduring feature of the appraisal system has been the striking extent to which stakeholders have the opportunity to comment during the process. As Box 5.1 shows, NICE's appraisal process built in opportunities for comment at every stage. The very preliminary version used for the rapid evaluation of Relenza was agreed with Glaxo Wellcome. As Taylor recalls, 'There was an iterative process where we could consult with the company where we could say, "are we missing something, are you missing something? Why are we getting different results?"'³⁰ Anybody could comment after going through a simple process of registering their interest with NICE: in practice, the manufacturer had the most to say. NICE's process differed in this respect from the Scottish approach, in which SIGN uses less consultation and arrives at quicker conclusions.³¹

Patient and public involvement

The next feature of NICE's process to note is the way that patient and public involvement was built in from the start. Chapter 4 is the proper place to discuss the prominent place which patients and the public have had in NICE's activities, a feature not confined to technology appraisal. What we should note here is that appraisals, from the start, involved both evidence from patients with an interest in the technology and also the presence of two standing lay members on each appraisal committee. The submissions by patients (often by patient organisations) meant that a committee hearing would nearly always have to weigh up very different kinds of evidence: clinical trial results, health economics, but also personal testimony about the real-world impact of an appraisal decision. Just how this was negotiated could be complex:

David [Barnett] would often begin the closed part of the meeting by saying, 'look, folks, that was a very moving scenario, but remember why we're here: our role is a technical one, it's not to be emotional'.³²

In Taylor's (and Tom Walley's) view, Barnett's background as a doctor gave him a greater ability to manage this mixture of the human and the scientific. Walley adds

29 Taylor interview.

30 Taylor interview.

31 SIGN is the Scottish Intercollegiate Guidelines Network, now part of Healthcare Improvement Scotland.

32 Taylor interview. The aspiration to be technical, not emotional was not always achieved: Tom Walley recalls attending an appraisal committee which 'did exactly the opposite, with no discussion – Andrew Stevens was chairing and tearing his hair out at the inconsistency of it' (personal communication).

that ‘it would never have worked had NICE or its appraisal committees been led by health economists’.³³ Another appraisal committee provides a powerful example of this problem of how to weigh different types of evidence against each other:

a patient advocate ... a deaf young woman ... gave a brilliant presentation, [about] ... the value of having hearing in two ears rather than one ... at the end of the presentation I think most normal folk would have said they are completely convinced that this is worth doing ... but once the patient advocate left the room, the ... health economist chair of the committee said ‘well, she was a sweet girl but there was no data in what she gave us’, and you got that clash between healthcare as a caring act of a society to support the unfortunate, and the hard-edged science of the health economists saying that no numbers had been provided and they couldn’t do anything with her testimony. I think patients found that quite difficult.³⁴

Surviving legal challenge

The last of the five enduring qualities of NICE’s appraisal process, which were put in place from the beginning, was the conscious effort to design a system that was lawyer-proof.³⁵ NICE was taking decisions whose impact on drug manufacturers’ revenues could be substantial. Manufacturers would be certain to use the administrative law tests of reasonableness to mount legal challenges (‘judicial reviews’) against adverse decisions where they saw a prospect of success – the more so because UK regulators’ influence on the global pharmaceutical market was out of proportion to the UK’s market share, thanks in part to other governments’ confidence in the quality of the UK’s regulatory processes, with the result that, while the UK was only 3% of the global pharmaceutical market, the NHS price had an influence on about a quarter of the world, as other countries used the NHS price to help negotiate their price.³⁶ Having a drug blocked in the UK mattered more than the UK’s market share implied.

The design of NICE’s appraisal processes was always intended to pass the tests of reasonableness, and all other relevant law. Of course, the features of appraisal already discussed – rigour in the use of evidence, consultation, attention to the views of patients and the public – contributed to a lawyer-proof process. NICE’s leaders were also clear from the beginning that the greatest possible transparency about their work would be essential. NICE was set up at the beginning of the digital age, and used the still new and unfamiliar World Wide Web to publish key papers, including NICE’s preliminary finding, for each appraisal. On some early occasions, NICE’s disclosures contained price-sensitive information which

33 Tom Walley, personal communication.

34 David Pink, interview 28 May 2020.

35 Rawlins (2016), 138; Mike Rawlins, interview 18 September 2019.

36 Ruggeri and Nolte (2013).

manufacturers thought they had provided in confidence, an oversight requiring some rapid correction.³⁷

Transparency was central to making the process robust. As Catherine Law (who chaired the Public Health Interventions Advisory Committee rather than a Technology Appraisal Committee) recalls, this radical openness:

was proposed by, I think Mike Rawlins, there was all this ‘men in grey suits turning down cancer drugs’ and things, and when it was opened up there was nothing to hide, and I think [that goes] for a lot of things. That’s [something] I think NIHR have in common, this spirit of openness. Put everything on the web, share all the materials, share all the methods, let people and come and see you operate, and mostly, the process protects you.³⁸

A further element of transparency, on top of its application to individual appraisals, has been NICE’s regular, open and consultative updating of its processes and methods.

NICE’s appraisal processes turned out to have been designed so prudently that no legal challenge was even mounted, let alone upheld, against its first 119 appraisal decisions, spanning the period to 2007.³⁹ In the following two years, three appraisal cases did reach court, of which one was dismissed. While NICE leaders such as Rawlins are understandably proud of this record, it can also be interpreted as overshooting the target, in the sense that a legally riskier approach would probably have been cheaper and produced quicker decisions. Against that, one must weigh the political and presentational need to win the respect of NICE’s stakeholders by avoiding high-profile errors.

NICE’s independence: the politics of technology appraisal

‘The creation of NICE represents part of a continuing strategy of blame avoidance and blame diffusion within the NHS’, according to Keith Syrett.⁴⁰ Klein, similarly, presents NICE as a fresh chapter in central government’s ‘strategy of blame diffusion’:

If in the past politicians had sheltered behind the doctrine of clinical autonomy – i.e. leaving it to clinicians to determine how to use resources – in future they would shelter behind the dictates of evidence-based medicine. It would be NICE which would be responsible for laying down standards and determining the criteria for the use of new drugs.⁴¹

37 Mercy Jeyasingham, interview 18 December 2019; Trevor Jones, interview, 22 April 2020.

38 Catherine Law, interview 2 October 2019.

39 Rawlins (2016), 139.

40 Syrett (2003).

41 Klein (2013), 202.

Box 5.1 'NICE's approach to appraisal c. 1999–2004

- 1 DH selects drugs for appraisal
- 2 Scope
- 3 Consultation on scope (scoping workshop)
- 4 DH decision on referral
- 5 Invitations to consultees (e.g., patient groups, professional bodies, manufacturers) and commentators (e.g., comparator manufacturers, researchers, Scotland) to submit evidence
- 6 Academic centre commissioned to review the evidence
- 7 Consultees and commentators comment
- 8 Evaluation report
- 9 Appraisal Committee considers the Evaluation Report and verbal evidence from nominated clinical experts and patients/carers
- 10 Preliminary recommendations published in Appraisal Consultation Document (ACD)
- 11 Committee meets again to consider comments on the ACD
- 12 Committee sends Final Appraisal Determination (FAD) to NICE for approval
- 13 FAD sent to consultees and commentators
- 14 Consultees may appeal
- 15 If no appeal, FAD is basis of guidance issued to NHS. No further right of appeal, but guidance is reviewed in the light of new evidence.

Source: NICE (2004) *A guide to NICE*.

This section looks at the politics of technology appraisal, examining the official story of NICE's relationship with DH and the cases where this has been put in question. NICE's independence certainly had advantages for policymakers. David Pink, who led DH's work to set up the organisation, and moved to NICE as soon as it opened, recalls:

one of the great advantages of setting up NICE for almost all the other political and organisational players is that hot potato topics could be given to NICE, and the fact that a drug was or wasn't available on the NHS ... the Department of Health ... could offload it onto NICE. But the other side of that coin was that NICE would have to be independent, would have to not be a creature of the Department of Health, and I don't think the department was comfortable.⁴²

42 Pink interview.

In other words, despite the attractiveness in principle of giving NICE its head, in day-to-day operations DH sometimes found this hard, certainly in NICE's early years. On one hand, interviewees in both DH and NICE have assured us that DH did not want to sway NICE's appraisal decisions. On the other, DH was a consultee, and did occasionally make observations on some appraisals. Charles Dobson recalls that, although it was routine to report NICE's preliminary finding to ministers, officials' advice to them was nearly always not to comment, and this was taken.⁴³ Some at NICE, such as Anne-Toni Rodgers, its first Director of Corporate Affairs, were very firm about policing NICE's independence. Discovering a DH policy lead telephoning a NICE colleague with the Secretary of State's feedback on a particular appraisal, for which the period for comments had closed three days earlier, Rodgers took the phone and said:

“you're not doing this, no! ... we have a process: you're outside the process, ... unless it comes in on time, it's not counted.” And I hung up on him. He went to Andrew [Dillon] and Mike [Rawlins] and [they] just said to him, “we cannot have it”, because that is political influence. It comes in written form, on time, or we don't consider it.⁴⁴

Unlike such tensions over individual appraisals, the issue of whether DH or NICE should control the selection of technologies for appraisal was, in Pink's words, ‘a longer fight over a longer period of time’.⁴⁵

Relenza (1999)

As is well known, NICE's first technology appraisal, of the influenza drug Relenza, immediately became a touchstone for its independence. Everyone following the world of pharmaceuticals knew the weight of expectation that NICE would endorse a drug marketed by the largest British manufacturer to reduce the duration of a major disease. NICE's refusal to recommend its use was a shock (except to those who studied the evidence more closely), and a powerful signal of independence. Especially significant was the refusal of Frank Dobson and Tony Blair to reopen the decision in the face of vigorous lobbying by Sykes, then chairman of Relenza's manufacturer, Glaxo Wellcome. This included a public threat to take Glaxo Wellcome's operations overseas, which, though not carried out, did underline the importance of the Relenza decision.⁴⁶ We understand that Frank Dobson commented to

43 Dobson interview.

44 Anne-Toni Rodgers, interview 8 October 2019.

45 Pink interview.

46 For Sykes' threat, see e.g. Timmins (2016), 10, and for a wry comment, the satirical journal *Private Eye*, 987, 15 October 1999.

Rawlins: ‘we’d have had to back you regardless, whether you were right or wrong. Fortunately, you were right!’⁴⁷ Rawlins’ conclusion was:

It showed we were an evidence based organisation, and that we would make decisions on the available evidence, not on a wing and a prayer or a promise. ... the industry learnt that there would be no political interference with our decisions, even when they involved a major UK company threatening to leave the UK. It was a tough few weeks. But we could not have had a better start.⁴⁸

Sykes is convinced that NICE rejected Relenza for the wrong reasons and did so under political pressure:

In my opinion the whole thing was politically driven and that’s why people got really annoyed with it. From square one it was nothing to do with “we’ll look at drugs, we’ll decide if they’re effective, not effective”, it was purely to save money and it was political, it was driven by politics. Frank was totally under control, Frank had agreed that Relenza was a great drug... Frank had intimated that there would be no problem with this ... and I went to his office and he was surrounded by two sixteen-year-olds who were telling him, “Frank, you can’t do this,” and poor Frank was shaking because he hadn’t a clue what to do.

I don’t think Mike [Rawlins] was political at all ... It was Andrew Dillon that had all the power, and he was a political beast.

it was a test case, wasn’t it, so, again, perfect for them to make political spin.⁴⁹

While we could not positively identify the ‘two sixteen-year-olds’, it is likely they were Simon Stevens (then a young-looking 31) and a Private Secretary.⁵⁰ Trevor Jones, then Director-General of the Association of the British Pharmaceutical Industry, was another voice suggesting that the selection of drugs for evaluation was political: ‘They just arbitrarily picked topics to review, more, in my opinion, guided by the politics of the product than the need for patient access’.⁵¹

We interviewed Dillon, Rawlins, and Simon Stevens, and ultimately find Sykes’ account of these politics implausible. It is not unthinkable that politicians, including Stevens, let NICE understand that they hoped its existence would exert downward pressure on NHS drug costs, as we have seen. And there is no reason to doubt that DH’s selection of drugs to refer to NICE was partly a result of political choices,

47 Timmins, 10.

48 Timmins, 14–15.

49 Sykes interview.

50 Simon Stevens interview, 27 January 2022.

51 Jones interview.

though we have not found strong evidence. But Sykes' pictures of Frank Dobson and of Rawlins are a long way out of line with how most other contemporaries saw them. Rawlins, for example, far from not being 'political at all', seemed to one interviewee to have had the confidence of the politicians, and to be 'big enough to sit round a table and tell them how it was'.⁵² If there had been a political plan to use Relenza to make a demonstration of intent, he would have been in on it – but there was not. NICE was not fully prepared for Relenza and could have declined to deal with it. Rawlins told us that:

Frank Dobson said to me, "do you mind doing the appraisal of Relenza, because if you feel it's too early...", and I thought, "what the hell, this is what we've been set up to do, let's get on with it."⁵³

In favour of the interpretation that ministers held their hands and did not seek to sway NICE's judgement, we may also cite Taylor's account, as one member of the appraisal committee as well as Director of Technology Appraisal, that the outcome of the Relenza appraisal was no foregone conclusion:

nobody predicted that at that time, we didn't know what the decision was going to be until we got to the appraisal ... when I did ... cost per QALY, I kept going back and checking it because I thought, "this just doesn't look right, this is too different to what the company has provided, this is too high." ... so I'm sure that, like all of these things there's [no truth to the] conspiracy theories.⁵⁴

Herceptin (2005)

Subsequent technology appraisals – with the arguable exception of beta interferon in 2000–02 (below) – did not bring NICE's independence into question until May 2005, when Roche and Genentech, the manufacturers of the breast cancer drug Herceptin, announced impressive trial results for its use in early stage cancers.⁵⁵ Mike Richards, DH's National Cancer Director, was very impressed indeed. The issue this time was not about whether NICE would approve it, but about how long this would take. NICE appraisals took more than a year at this point, and did not begin until DH referred the drug to them, which never occurred before it had been licensed for use. With a course of treatment costing £44,000 or more, the delay left some patients with the prospect of selling their homes to fund private treatment or dying before the NHS would supply the drug.⁵⁶ Sections of the media, with the

52 Unattributable interview.

53 Rawlins interview.

54 Taylor interview.

55 NICE had earlier approved Herceptin for late-stage cancers.

56 Clark (2007).

Daily Mail prominent, ran high-profile campaigns for Herceptin to be made rapidly available on the NHS.

In October 2005, Patricia Hewitt, the then Secretary of State for Health, encouraged by the strength of Richards' advice, instructed the NHS to test new patients for the HER2 gene, which indicated that they would benefit from Herceptin. She also announced that she wanted Herceptin to be licenced 'as quickly as possible' and the treatment 'to be available within weeks of the licence being given'.⁵⁷ The same month, she told NHS commissioning groups that they 'should not refuse to fund Herceptin solely on the grounds of its cost'. Herceptin was licensed for early stage use in May 2006 and the cost-effectiveness of this use case was approved by NICE two weeks later. Richards, based on the clinical evidence he saw at the time, was in no doubt this was the best choice:

when Patricia Hewitt actually made the decision that it should be used [people said:] "Oh, she can't do that, she can't do that, terrible thing, politicians interfering!" She was bloody well right. I don't always say that about politicians by the way.⁵⁸

Richards took the initiative in two ways: advising DH ministers of the validity of the claims for Herceptin and pressing for solutions to the problem of delay in NICE appraisal. We will see him again in Chapter 8 in an equally activist guise. Hewitt's actions brought relief to the Herceptin patients and defused the media campaigns, but caused dismay to those who valued NICE's independence. Her intervention was attacked by health services organisations, some medical journals and some of the broadsheet media.⁵⁹ Explaining her decision to speak publicly about Herceptin, Hewitt recalls that it was motivated by:

two things. Mike Richards, our brilliant cancer tsar. And feminism. I've always been a feminist, it's a crucial part of my politics. Obviously breast cancer is a huge issue for women, with an exceptionally well-organised campaign. So this was politically very salient. ... it didn't cross my mind to leave it to a junior minister, it was just too big, too sensitive.

Mike Richards was clear about the clinical case for Herceptin. What I had to do was to be seen standing shoulder to shoulder with women with breast cancer, without dictating to NICE. That was the challenge.⁶⁰

Hewitt, in short, managed the situation as an elected politician, not as a technocrat. This illustrates the difficulty identified by Belkin and Syrett in turning decisions

57 There are more details of these events in Timmins (2016), 75–85.

58 Mike Richards, interview 3 October 2019.

59 For an example see Alvarez-Rosete and Mays (2008).

60 Patricia Hewitt, interview 18 December 2019.

such as the approval of drugs into purely technocratic ones. She makes this clearer with her comment that:

we knew Herceptin was going to be licenced ... we were also sure that NICE was going to approve it, because from what Mike Richards told me about the clinical trials, they simply couldn't reject it for the ... patients for whom it was relevant. And in any case, I was going to bet on that. I was completely clear in my own mind that you could not have the Secretary of State saying "this drug must be approved": that would have made a nonsense of the institution we ourselves had created. But getting NICE to start its own appraisal, in parallel with the safety authorities, rather than waiting until the drug had been licensed – I thought that was a brilliant solution, because it met completely legitimate demands for Herceptin but didn't compromise NICE.

We were expecting Herceptin to be licensed in July 2006, with NICE making its decision shortly afterwards. So I also agreed with officials that women diagnosed with early stage breast cancer from early October 2005 would all be tested for HER2 receptors since, typically, diagnosis, surgery and chemotherapy would take 9–12 months before a woman could be treated with Herceptin. That was a very important announcement, backed by a £100million funding commitment.⁶¹

It is clear that Hewitt and her political colleagues valued NICE's independence, and that they knew their actions nevertheless came close to crossing the line beyond which they were endangering it. Dillon recalls that Hewitt tried to get Rawlins to support her publicly but he refused.⁶² Paul Corrigan, in the Prime Minister's office, was apparently thinking of intervening to defend NICE's independence if he felt Hewitt had gone too far, though in the event he did not.⁶³ As Hewitt told us,

you can only really do these things once... you can't be a Health Secretary who believes in NICE and ally yourself with those who want NICE to make a particular decision more than once. I may not have said that explicitly to anyone; that was simply my own very strong political instinct. I would never have done it without Mike Richards' absolute clinical support for Herceptin.

it was a really difficult one because the publicity was building and I knew I could not say "NICE must approve Herceptin" or "the NHS must pay for Herceptin". On the other hand, of course that was exactly what they needed to do. So I had a very clear position along the lines of: When Herceptin is

61 Hewitt interview. For her announcement, see for example *Independent*, New breast cancer drug to be available for all, Hewitt rules, 6 October 2005.

62 Dillon, personal communication.

63 Hewitt interview; Paul Corrigan, interview 16 November 2022. Corrigan was the PM's Special Adviser on Health at this point.

ready for the NHS [ie both licensed by the safety regulator and approved by NICE], the NHS will be ready for women who need Herceptin.

The short-term challenge was that, even before Herceptin had been licensed – let alone approved by NICE – PCTs had the discretion to pay for it. At least one did [for Barbara Clark, one of the women with HER2 breast cancer who was leading the campaign]. Another didn't. Again, I needed to show my sympathy for the women without instructing PCTs to fund an off-label drug; so I asked for a meeting with at least one PCT to discuss the issues. I was treading a very careful line although there was one quote of mine, I think in a local newspaper, that did go over the line. But I never instructed PCTs to fund Herceptin; that would clearly have been wrong.⁶⁴

Hewitt avoided crossing the line again, and her successors have done likewise. All of them have seen the political value of diffusing responsibility for decisions about which drugs the NHS will use.

Speeding up appraisal

The benefits of faster appraisal are clear: beneficial cost-effective drugs reach the patients who need them sooner, while manufacturers enjoy a longer period of sales to the NHS before the patents on their drugs expire and cheaper competitors are placed on the market.⁶⁵ Every day after licensing that NICE approval is delayed, and the NHS remains under no obligation to buy, is a day of lost revenue. Faster appraisal also has disadvantages: it may cost NICE more (since more staff and committees are necessary), and increases the risk of handling mistakes, while *earlier* appraisal, by using less real-world data, increases the risk of incorrectly assessing effectiveness and costs.

One thing which eased Hewitt's dilemma over Herceptin a little was that some work between DH officials and NICE was already under way to see how appraisal could be accelerated. Each party seems to have felt the other was the main source of delay, and progress towards a resolution was not rapid. Herceptin was the catalyst. Hewitt takes personal credit for the move to 'parallel processing', in which drugs are referred to NICE's appraisal process before they receive a market licence – the approach which let Herceptin receive its NICE approval within a fortnight of licensing. (NICE had been working towards this already.) Meindert Boysen, NICE's former deputy chief executive and director of its Centre for Health Technology Evaluation, who joined NICE in 2004, recalls the push from the Herceptin case:

the Herceptin rumblings, that's when I think everybody suddenly saw a chance to change the dynamic from ... an academically-informed exercise ...

⁶⁴ Hewitt interview.

⁶⁵ English law gives a drug up to 20 years of patent protection, though according to the ABPI 12 of these are often used up in the R&D phase before it is placed on the market: ABPI (n.d.).

we were very much facing a battle against time, these things were taking ages, and we were ... relying heavily on the academic input and interpretation of the HTA. ... They had a view about how things were supposed to be done, and ... it took a long time to connect that into what industry were hoping for and what our committees were trying to achieve, so that ... was perhaps the biggest issue ...

rather than sitting down with a blank sheet of paper and developing the most amazing model of diabetes, or whatever ... take stuff you already have, make something out of it, get on with it quicker so the committee can come to an informed decision, albeit with risk, but I think some academic units just couldn't quite live with that idea.⁶⁶

One reason for that was the lower academic status of the new form of assessment, causing academic units some problems in peer review exercises such as the government's Research Assessment Exercise (since 2014 the Research Excellence Framework).⁶⁷ There were two big changes to the NICE process which gave effect to this switch from an academic to a service delivery ethos. First, many of the early technology appraisals had carefully compared a new technology with a number of competitors in a 'Multi-Technology Appraisal' (MTA). NICE now abandoned this in favour of Single Technology Appraisal (STA). Barnett explains that MTA was 'destroying the good for the achievement of perfection', and adds:

I had my reservations about [STA], because it was quick and ... [not] nasty, but quick and not necessarily robust. But it developed ... There was a lot of issues about MTA versus STA. ... getting the single question right, of a STA, was often quite difficult because there were many competitors. For example if you have drugs for the treatment of psoriasis, particularly biologics, there were so many of them. A MTA would look at a hierarchy and a process of which you'd use first, and second, and juggle about which was the most cost-effective way to do it if one failed, whereas a STA tried to simplify that. I think it worked.⁶⁸

The other major change was that, from 2006 onwards, instead of the (usually academic) Assessment Group engaged by NICE writing an assessment on which the manufacturer then commented, manufacturers now wrote an initial submission on which similar teams, called Evidence Review Groups (ERGs) in the case of an

66 Meindert Boysen, interview 23 April 2020. His interpretation is shared by Julia Earnshaw (formerly of GlaxoWellcome), interview 15 November 2019.

67 Since these informed the allocation of government research funds, the incentive was to spend academic time in novel research, publishable in scholarly journals: not in routine work for e.g. NICE.

68 Barnett interview. Casson et al. (2013) report that STAs took a median time of 48 weeks compared to 74 for MTAs.

STA, commented.⁶⁹ Like the switch from MTA to STA, this moved the appraisal process from a more academic ethos to a more ‘service delivery’ one, where reaching an adequately rigorous decision quickly was more important than reaching the methodologically best possible decision. This change was driven by the political need for speed which the Herceptin case so well demonstrated. Amanda Adler, an appraisal committee member from 2004 (and later Chair), thinks this change brought both benefits and problems, and was certainly on the lookout for any exploitation of it by companies. It cannot be maintained, though, that this switch simply made approvals more likely. Apart from speculating that company submissions might try to hide the bad news by making the volume of text larger, she comments that ‘the advantage is that [the company] really know the stuff’, while the disadvantage is that the company submission is necessarily one-sided.⁷⁰

Boysen, who was in charge of the process from 2009, goes further, acknowledging that NICE is:

taking the risk that ... we won’t be finding the truth, we will be finding out whether the company is trying to tell us a story that really isn’t ... based on the evidence, so scrutinising and reviewing it, but we wouldn’t know whether there was another story to tell, because we were not asking the ERGs ... to do their own thing ... it went well to the extent that industry considered this to be a very attractive scenario, and ... now this is the basis under which we are surviving, because without this we couldn’t have charged, and now we are charging for ... going through NICE, and that is because they can make a submission.⁷¹

Charging for appraisal, which began in 2019, is discussed in Chapter 8, along with further moves to speed up appraisal: the 2006 changes did not fully satisfy either manufacturers or patient groups.

Negotiating the ethics of opportunity cost

We referred earlier in the chapter to NICE’s success in squaring the circle of applying rigorous, rational, decision processes to HTA while simultaneously retaining sufficient support from politicians, media and the public. This could of course be both intellectually and politically challenging. The need to keep sufficiently in line with public opinion was an important motive for NICE’s patient and public involvement and engagement, which we discuss in Chapter 4. And retaining sufficient societal consent for its work also obliged NICE to engage unceasingly with a sometimes hostile media, as we describe in Chapter 3. Here, we note some examples of the way that NICE and DH defended the ‘ethics of opportunity cost’

69 Kaltenthaler et al. (2011).

70 Amanda Adler interview, 14 January 2020.

71 Boysen interview.

approach (i.e., applying an ICER threshold), while at times bending to the wind of political, public and media opinion.

Beta interferon (2002)

The most celebrated example is probably the case of beta interferon, an expensive multiple sclerosis drug manufactured by the US company Biogen, whose effectiveness varied for different forms of the disease, and whose long-term benefits for patients were at first (not unexpectedly) unclear. When beta interferon was first marketed in the UK in the early 1990s, DH had declined to take a central decision on its use when pressed to do so.⁷² In 2000 DH asked NICE for an appraisal: NICE found against the drug, upholding this view on appeal in 2002. What stood out about this case was principally the strength of the opposition to it from the Multiple Sclerosis Society, many individual patients and the media. Andrew Stevens also regards beta interferon as an early example of the very expensive drugs which are now seen more frequently: at a lower price, beta interferon would have passed NICE's cost-effectiveness test.⁷³ In a similar way to the Relenza case, in which the government had backed NICE in a judgement challenged by a powerful manufacturer, Prime Minister Tony Blair now supported NICE against a broader-based challenge including demonstrations by patients and newspaper advertisements.

Blair wanted something more politically palatable than outright resistance to this pressure, however. The obvious solution was a lower price. As Andy McKeon, then DH's lead official on medicines policy, recalls:

the brutal truth was, Tony Blair couldn't stand the heat, there was a lot of aggravation ... it was quite brutal and stark, and so I was asked, ordered, to find a way through, which essentially allowed Beta Interferon but didn't undermine NICE, so we did. ... We invented, with Charles [Dobson]'s help, the very first risk-sharing scheme. ... the companies, although they wanted to sell their drug, they were actually a bit affronted about patients not getting medicine that they might need. There was actually a moral aspect – I hope I'm not being too naïve – to the people in the room about 'how can we help to do this?' ... So they reduced the price and put money into nurses and ancillary services, which was a good thing for MS generally, and we would take the data, over five years or whatever ... and see if the benefits justified the cost and reached the necessary QALY count. It was carefully judged that when, they [NICE] went through what we did on this and said, 'we don't feel we've been undermined', very kind of Andrew [Dillon] to say so.⁷⁴

72 Timmins (2016), 32.

73 Andrew Stevens, in Atkinson and Sheard (2020) 14.

74 Andy McKeon, interview 3 October 2019.

The deal involved starting with an assumption that the expected benefits would materialise over the long term, with the companies agreeing to pay back some of the price if they did not.⁷⁵ We have also been told, unattributably, that NICE thought the risk-sharing scheme was unnecessarily complex, and that Dillon told DH: ‘we only wanted you to get some money off them, not this ten-year scheme!’⁷⁶ This would help explain why later risk-sharing schemes (Patient Access Schemes) were much simpler, generally involving just a confidential NHS discount, and were not in fact modelled on the beta interferon example.⁷⁷ Expert comment generally views the Risk Sharing Scheme unfavourably.⁷⁸ One assessment of it was that, at £50–100 million, it was a costly failure.⁷⁹

Simon Stevens, by now at 10 Downing Street as the Prime Minister’s health adviser, confirms the PM’s role in the beta interferon case:

I went with Blair to a TV interview with a live audience at St Thomas’ Hospital ... it had been deliberately set up by the producers to try and snooker the Prime Minister on NICE and rationing. The camera panned to an audience member who said “I’m a patient with multiple sclerosis and I can’t get beta-interferon – what are you going to do about it?” Tony sort of gave his prepared answer that these were decisions for clinicians, and then the guy sat next to her chimed in with “well I’m her neurologist and I think she should have it”. Ultimately once again a deal was done on the discounts on that product, and the CEA [cost-effectiveness analysis] process lived to fight another day.⁸⁰

Age-related macular degeneration (Visudyne: 2002)

Another example of the ethics of opportunity cost at work illustrates how hard it is to explain the health economic reasoning behind a decision which just ‘looks wrong’ to the many outside observers who are applying a different logic. In June 2002 NICE published its Final Appraisal Determination (FAD) on photodynamic therapy (PDT) for age-related macular degeneration (an eye disease) using Novartis’ drug Visudyne (verteporfin).⁸¹ Picking its way through a complex set of sub-groups of patients with different presentations of the disease, the

75 Dobson interview.

76 Unattributable: DH official.

77 Carole Longson (interview, 27 November 2019) regards bortezomib (Velcade), as the forerunner of NICE Patient Access Schemes. This drug, co-developed by Millennium/Takeda and Janssen, for the treatment of multiple myeloma, was approved by NICE in October 2007 on the basis that the manufacturer would return the NHS’ money for any patient who did not show a defined response to treatment. See NICE (2007).

78 For example, McCabe et al. (2010).

79 Raftery (2010).

80 Stevens interview.

81 NICE (2002a).

appraisal committee recommended the treatment be used, but only in a patient's 'better-seeing eye, or only functioning eye'. The response of patient groups was highly critical: quoted in the *Daily Mail* under the headline 'You must go blind in one eye before NHS will treat you', Robin Hill of the Macular Disease Society, said:

Despite the fact that we have an effective treatment, NICE ... is recommending that PDT should only be offered to those patients who have already lost the sight of one eye. Patients whose circumstances compel them to rely upon the NHS will be condemned by NICE to Russian roulette for their one good eye. An accident or a sudden haemorrhage, or failure to get a clinic appointment within a matter of days, may take away at a stroke life's quality as they know it.⁸²

The Royal National Institute of Blind People (RNIB) was similarly critical. While the FAD could have been clearer about its reasoning, it is likely the committee reasoned that the cost per QALY was substantially lower if this expensive procedure was only carried out in one eye. Novartis and the RNIB/Macular Disease Society appealed the decision and it was revised: the 2003 final guidance does not refer to treating only one eye.⁸³ Hewitt (who was not a health minister at the time of these events) found this case particularly unsettling:

The one that just made me ill, was people with age-related macular degeneration. I had a colleague who had it. The NICE guideline was, you will only get this drug if you are going to go blind in your second eye ... If you went private I think you could get it for your first eye ... I just found that unbearable, indefensible. I remember having to answer some questions about it, and I had to fall back on ... "we have an independent body and that's the right thing to have."⁸⁴

What is interesting about the case, for our present purposes, is the way that the rigorous use of cost-effectiveness analysis in isolation appears to have produced a result which a range of people found unacceptable – and that NICE's appraisal committee (chaired in this case by Barnett, whom we have already described as a thoughtful pragmatist) found a way to modify its original finding in the light of this reaction. This was how NICE's consultation process was designed to work: when the RNIB described the process as a 'saga of changing views and moveable goal-posts', NICE's corporate affairs director Rodgers was quick to defend the process, telling the media: 'It is very disappointing that when the independent committee

82 *Daily Mail*, 13 June 2002, You must go blind in one eye before NHS will treat you.

83 NICE (2003).

84 Hewitt interview.

that advises us listens to, and acts on, consultation feedback, it is accused of “moving the goalposts” or “developing a saga”.⁸⁵

Alzheimer’s disease drugs (Aricept and others: 2006)

In our final example of the ethics of opportunity cost clashing with other ethical standpoints, the controversy arose partly from NICE’s rejection of a fairly inexpensive drug: many did not make the distinction between cost-effectiveness and affordability. In January 2006 NICE reported on a review of its earlier approval for three Alzheimer’s disease drugs, stating that new evidence now showed that several were not cost-effective in the early stages of the disease, only the later.⁸⁶ This was a difficult message to put across: why let a disease become more serious before starting to treat it? The cost-effectiveness answer was that the impact of the drugs on patients’ need for care seemed mild but broadly equal across mild, moderate and severe dementia: taking them early seemed not to enhance their impact but did add significantly to the cost.⁸⁷

The low cost per patient was an easier concept to engage with, and this was what dominated public debate. As Boysen recalls,

people suddenly saw that by making noise about what we do, and have banners on Parliament saying “£2.50 a day: how come that is not good enough? ...” [they might affect the outcome of the appraisal].⁸⁸

According to the *Daily Mail*, one person with Alzheimer’s said:

the drugs have made a big difference. They have vastly improved the quality of my life. They talk about money, but these drugs only cost £2.50 a day. It seems madness to take away things that help people.⁸⁹

The 2006–07 story of the Alzheimer’s drugs illustrates, then, how, in trying to be guided by the ethics of opportunity cost, NICE ran into major political difficulties which often stemmed from the public’s unawareness of how it worked as well as public disagreement with this approach. NICE’s decisions stood, even after judicial review, but left many unconvinced.

The widening scope of NICE’s HTA

This chapter has so far dealt entirely with drugs. Before closing, it is important to note NICE was charged from the beginning with assessing health technologies in

85 Eaton (2002).

86 The drugs were Aricept, Exelon and Reminyl.

87 Timmins (2016), 86.

88 Boysen interview.

89 *Daily Mail*, 18 July 2007, Alzheimer’s sufferers demand drugs ban is lifted.

general and not just drugs in particular. Furthermore, new fields have been added since NICE's establishment. It will come as no surprise to learn, too, that NICE's HTA has grown immensely in volume as well as this growth in scope. Osipenko et al. report that NICE's productivity in HTA has grown steadily: on their definitions, 27 TAs were completed between 2001 and 2005, 57 between 2006 and 2010, 102 between 2011 and 2015 and 223 between 2016 and 2019.⁹⁰ The NICE website lists 615 current pieces of technology appraisal guidance which had been published by the end of 2019.

In 2019, the new Voluntary Scheme for Branded Medicines Pricing and Access, agreed between government and the pharmaceutical industry, set out the ambition of 'delivering faster adoption of the most clinically and cost effective medicines', and to this end:

All New Active Substances in their first indication, and extensions to their Marketing Authorisation to add a significant new therapeutic indication, will undergo an appropriate NICE appraisal, except where there is a clear rationale not to do so. NICE expects to achieve this by April 2020.⁹¹

In the event, lack of capacity, and the COVID-19 pandemic, delayed the implementation of these plans, but they are now part of the statutory duties laid on NICE and affect its workload from now on.

Interventional procedures

Beyond drug evaluation, NICE began planning in 2001–02 for a new interventional procedures evaluation programme, which was to involve 'taking responsibility for assessing the safety and efficacy of new interventional procedures'.⁹² In the world of medicines, safety and efficacy are the business of the regulator (in the UK, the MHRA): surgical procedures were not subject to any such regulation. As the first chair of NICE's Interventional Procedures Advisory Committee (IPAC), the surgeon Bruce Campbell, recalls, this NICE programme had its origin in a voluntary initiative of the medical Royal Colleges (as it would have had to, in order to secure the level of consent from practising clinicians which it did):

hardly anyone in the world had been looking at new procedures. The problem with procedures was that any surgeon could decide he/she was going to do something innovative and just do it. That's what used to happen: it was one of the reasons laparoscopic cholecystectomy created a whole lot of disasters in the early '90s: people would just invent procedures and do them, or hear

90 Osipenko et al. (2024).

91 DHSC and ABPI (2018). The Voluntary Scheme is the successor of the PPRS mentioned earlier in the chapter.

92 NICE (2002b).

about a procedure and do it. In order to try and make some sense of this, a group of people from the Royal College of Surgeons, the Royal College of [Obstetricians and] Gynaecologists, and the cardiologists .. set up an initiative in 1996 called SERNIP, the Safety and Efficacy Register for New Interventional Procedures.⁹³

The Bristol children's heart surgery scandal and Professor Sir Ian Kennedy's far-reaching 2001 report on it led to a government mandate for NICE to take over this work 'with a remit altogether more comprehensive and demanding'.⁹⁴ Campbell recalls a certain amount of informality in the way he was told about this:

I was doing an operating list in 2001 and I was suddenly told Sir Michael Rawlins wanted to talk to me. ... Mike began with the words, 'Bruce, your country needs you,' and explained to me that SERNIP had been told it shouldn't continue, NICE had been asked to take over its function and develop something: could I do it?⁹⁵

As Campbell and an Australian colleague reported in 2003, NICE was aiming for:

a database of all new procedures, cooperation of all surgeons and other doctors undertaking new procedures, and recommendations that will be observed throughout the health service—all in a process that is public and transparent. Success, therefore, requires a balance between the primary aim of protecting patients and the need to encourage and foster innovation. Doctors will need to be engaged by clear assurances that their own protection from clinical and medicolegal risk is a central theme.⁹⁶

The IPAC operates a good deal like a Technology Appraisal Committee for a drug, though since a procedure has no manufacturer, the case for it was presented by some of the expert witnesses. It is noteworthy that IPAC looks at safety and efficacy but not, as the rest of NICE does, at cost-effectiveness. Campbell explains this by saying there is much less evidence available about the effectiveness of a new interventional procedure, which does not have to be trialled before introduction, than of a drug, which does (though we have seen the dissatisfaction of some commentators on the amount of effectiveness evidence available even for new drugs). IPAC's origin in a voluntary endeavour run by Royal Colleges, who perhaps had some reluctance to rank cost-effectiveness as high as clinical effectiveness, in common with many clinicians, could have been a further factor. Campbell reports that the IPAC encourages patient input, as in a TAC, but when examining a new

93 Campbell interview.

94 Campbell and Madder (2003). The Kennedy Report is: Bristol Royal Infirmary Inquiry (2001).

95 Campbell interview.

96 Campbell and Madder (2003).

procedure that very few had yet experienced, patients could be difficult to track down. He sought out differing expert opinions, requiring three witnesses, always including one not using the new procedure:

Often you'd have ... one who didn't do the procedure [who] said, "these people are crackers, this is a completely bonkers procedure, they shouldn't be doing it, they shouldn't be allowed, for these reasons..." This was very informative.

The IPAC could make one of four recommendations:

if the evidence is [sufficiently good] the recommendation was for ... "standard arrangements" [for clinical governance, consent and audit]; if the evidence isn't really quite good enough – and this applies to a lot of procedures – you should tell your hospital what you plan to do, tell your patients in detail, and be involved in research and/or thorough audit: these measures were called "special arrangements" for governance, for consent, and for audit or research. Number three: a recommendation for use in research only, and number four: do not use.⁹⁷

Today the process and range of possible outcomes is essentially the same. 'Use in research only' was the committee's 2017 recommendation on the use of mesh for vaginal wall prolapse, a case examined further in Chapter 6.⁹⁸ By the end of 2019 NICE had published 665 pieces of interventional procedures guidance.

Diagnostics and other appraisals

In recent years the distinctions between pharmaceuticals and some elements of medical devices technology ('medtech') are starting to blur, which has threatened to make NICE's work more challenging. Evaluating an interventional procedure can also, at times, be inseparable from evaluating the device which the procedure inserts into a patient. Even without this convergence of technologies, the growing importance of diagnostics and devices in health care would have drawn NICE into new areas of HTA since 2009. The COVID-19 pandemic has given the non-specialist a new insight into the importance of diagnostics: the response to the pandemic would have been far more difficult without effective COVID tests. The experience has also illustrated how expensive sophisticated tests can be. A 2020 NHS England paper reported that diagnostic activity formed part of over 85% of clinical pathways, adding that the NHS spent over £6bn a year on over 100 diagnostic services and carried out an estimated 1.5 billion diagnostic tests.⁹⁹

97 Campbell interview.

98 NICE (2017).

99 NHS England (2020).

NICE began to enter the field of diagnostics in 2009/10, when it brought forward its new Medical Technologies Evaluation Programme (MTEP), on the effectiveness of new devices and diagnostics, with the aspiration to lead to ‘a more uniform and joined-up approach to their use in the NHS’.¹⁰⁰ The diagnostics assessment programme (in which technologies are examined by a dedicated Diagnostics Advisory Committee, first chaired by Professor Adrian Newland) published its first three sets of recommendations in 2011–12, including a positive recommendation for the use of four new-generation cardiac computed tomography (CT) scanners to help diagnose and manage patients with coronary artery disease who are difficult to image.¹⁰¹ One of NICE’s contributions to the COVID-19 response was to waive the usual fee to companies using its Scientific Advice Programme for technologies including diagnostics.¹⁰² NICE had produced 20 Diagnostics Guidance documents by the close of 2019.

Linked to diagnostics in NICE’s MTEP are medical devices. These were part of the appraisal picture as soon as Campbell’s work on interventional procedures began: some procedures require the implantation of a device, and some devices (such as a pacemaker) can only be used as part of a surgical procedure. MTEP came into being in response to a decision by DH ministers, published in Lord Darzi’s 2008 *High Quality Care For All NHS Next Stage Review Final Report*. In a section praising NICE while requiring it to speed up appraisal (of which more in Chapter 8), this promised that:

For new clinical technologies, we will simplify the way in which they pass from development into wider use by creating a single evaluation pathway, and will develop ways to benchmark and monitor their successful uptake.¹⁰³

NICE’s Medical Technologies Advisory Committee (which was initially also chaired by Campbell) operates in very much the same fashion as the other advisory committees in HTA, already discussed in this chapter. Manufacturers notify the MTEP about new devices, and some are selected for appraisal. Unlike drugs, there is no mandate to the NHS that those approved by NICE must be funded. This has at times caused problems: a manufacturer’s incentive to submit a new device to appraisal is correspondingly less than for a drug, given the risk to its market prospects if NICE should fail to recommend it. The economic analysis here is more limited than for drugs, taking the form of cost-effectiveness analysis (which examines the cost of a unit of a specified kind of benefit), rather than NICE’s standard approach to drugs, the more far-reaching cost-utility analysis (which measures benefit in the generic form of gain in health-related quality of life, allowing very

100 NICE (2010).

101 NICE (2012).

102 NICE (2020).

103 Department of Health (2008).

different interventions to be compared). NICE had published 46 pieces of Medical Technologies Guidance by the end of 2019.

While listing the extensions of NICE's HTA role beyond drugs, we should briefly (since this is covered in Chapter 7) mention the establishment of a Public Health Interventions Advisory Committee in 2005. And most recently, appraisal of digital interventions has begun, for example of digital therapies for anxiety and depression. Guided self-help, which can track people's mood or advise on breathing exercises, for example, is recommended by NICE guidance to help treat mild to moderate anxiety and depression.¹⁰⁴ In 2019 NICE began a pilot programme evaluating five digital technologies, referred to by NHS England and NHS Improvement.¹⁰⁵ A new framework has been published setting out the somewhat different evidence standards needed in digital technologies, including artificial intelligence, compared to previous ones. Digital technologies are appraised, however, by one of four existing advisory committees.¹⁰⁶

Health technology appraisal: 'tough decisions', 'tragic choices'

The HTA decisions described in this chapter were rarely easy.

What NICE does is make tough decisions about priorities. We've got to set priorities. There's no argument about that. The only argument is about how you determine those priorities.¹⁰⁷

Coronavirus: Doctors given new guidelines on choosing which patients to treat in critical care: NHS staff face tragic choices if hospitals run out of intensive care beds or ventilators. ... The advice from the National Institute for Health and Care Excellence (NICE) was produced amid concerns that the NHS would be overwhelmed.¹⁰⁸

Some were indeed 'tough', in Alan Milburn's phrase, and 'tragic', as the *Independent* put it. Here we report a few of the perspectives on what it was like to be 'in the room' making such choices.¹⁰⁹ We also reflect on the history of how NICE has approached this task.

Several of our interviewees told us, in effect, that sitting on an appraisal committee was a matter of duty, that public life requires groups of experts and lay people to undertake demanding (and unpaid) roles such as reaching these choices on access to health technologies. Taking part in an appraisal decision is certainly intellectually demanding, with some hundreds of pages of submissions to read on

104 NICE (2018a).

105 NICE (2020); NICE (2018b).

106 NICE (2022).

107 Alan Milburn, *Sunday Express* June 25 2000. Quoted in NICE (2000).

108 *Independent*, 21 March 2020, Coronavirus: Doctors given new guidelines on choosing which patients to treat in critical care.

109 See also Wishart (2009).

each drug and frequently three appraisal hearings completed in a day.¹¹⁰ Expert participants sometimes speculate on how thorough the lay members' understanding of the finer points may be, something that any such deliberative process has in common with jury service in the criminal justice system. At NICE as in the courts, those designing the process have judged that the benefits of lay participation outweigh these potential difficulties.

What do lay members themselves think? Jean Gaffin, a founding member of the Appraisal Committee who had joined NICE from a patient organisation, recalled:

It was a really interesting and challenging time ... the most challenging thing I ... did. Because I had to get my head round the health economics. ... the clinical effectiveness stuff was sometimes difficult, because I haven't got a scientific background: health economics I struggled with for five years really.¹¹¹

Mercy Jeyasingham, a member of NICE's Board and of its appeals panels from the beginning, is a particularly informative witness on the lay member perspective:

We knew it was pretty serious. I took all appeals really, really, seriously, because ... most of them were about getting very expensive medicines to people. I always felt that because I was the patient rep in those days I had to be fair to all patients, and so the cost-effective issue was really, really important to me. Because my background was patient advocacy, I didn't want those who shout loudest to get more. So with my equalities background and my patient advocacy background, I wanted an even playing field, that it should always be on the evidence. But of course NICE only does stuff where the evidence is controversial: if it was clear-cut you wouldn't need NICE. ... I was aware of the tricks of the trade. First of all, have your voice put in the papers. "these poor people that are being denied ... treatment."

Which is why I understood Aricept and Herceptin, but I looked at the evidence as well. On the other side I thought, yes, it's really great when we're doing our campaigns. But I also knew that most of those campaigns were being paid for by the pharmaceutical industry, [as] when I was at the National Eczema Society.¹¹²

Drug manufacturers have also been accused of coaching the clinical experts who attend, which is not declared as a conflict of interest. One insider told us:

in the past I used to work alongside pharma companies and help with their NICE submissions. Before the appraisal committee the company

110 James Mahon interview 3 November 2021.

111 Jean Gaffin, interview 25 November 2019.

112 Jeyasingham interview.

representatives at the committee would go through a practice with other staff playing the roles of the ERG, the NICE chair, committee members ... there were times when the clinician who would be attending the meeting as an independent clinical advisor would also be at that practice ... and they would be advised “if the committee ask this, then say this”.¹¹³

Mary McClarey, a nurse and NICE Board member who sat on the Appeals Committee, recalls that the hardest thing was:

Refusing a drug, knowing it would deliver benefit but ... not effective enough to meet the criteria. Heartbreaking, to face patients and their families. ... Those were the hardest decisions. Sometimes knowing before the public did what the outcome was going to be, and not wanting it to be ... that’s different to not agreeing with it. ... [Everyone] will think something is a priority, and I don’t think you can ever ask people – for example I couldn’t say to you, how would you feel if it was your son? ... If it was your son, heaven and earth would have to be moved ... so those kind of subjective views and comments aren’t really helpful, you’ve got to make it with an objectivity that’s not always easy.¹¹⁴

Given the high stakes of these decisions for the technologies’ manufacturers, one might reasonably imagine that proceedings could be adversarial. We need to remember, though, that manufacturers did not attend committee meetings at first, then being admitted first as, effectively, observers, and later allowed to answer questions. A pharmaceutical manufacturer has, since then, typically been represented by a specialist in regulatory affairs and market access, and by expert(s) in the pharmacology and health economics of the submission. Also frequently present have been patient organisations (evidence being given by their staff, and often by patients themselves). The input of the Evidence Review Group (ERG), set up in the 2005 changes, is essential, as is that of expert witnesses such as specialist doctors. Members of the public are allowed to attend as observers.

Some hearings have indeed felt adversarial to their participants. They have tended to become more so. Jeyasingham recalls that even appeals:

used to be quite informal, it never used to be so adversarial. I remember the end of one on digital hearing aids, we were having a good chat with the person who ran the charity for it, who was one of the appellants ... The appeals process then became more formalised, it became very adversarial, whereas it was always supposed to be an enquiry. ... I remember Beta Interferon ...: very adversarial, huge amount of information to get through.¹¹⁵

113 Unattributable interview.

114 Mary McClarey, interview 7 January 2020.

115 Jeyasingham interview.

Dillon likewise recalls a kind of honeymoon period when a ‘rather collegiate, friendly, respectful atmosphere’ prevailed: this changed, in his recollection, with beta interferon, which saw a degree of hostility creep into relations with both the patient organisation and one of the manufacturers: ‘we realised that these were extraordinarily important decisions with big impacts, and that the nature of those impacts could generate a rather different atmosphere and response to what we had been used to’.¹¹⁶

The evidence of ERG health economists attending appraisal committees suggests an adversarial climate, in which they were targets of pharmaceutical company hostility: while they saw themselves as part of the ‘NICE team’, helping the committee to ask the right questions, the manufacturers – and sometimes NICE too – seem prone to have viewed them more as one of two competing parties presenting rival cases.¹¹⁷ As one observer has commented, ‘the resources all sit with the industry and it’s an unequal fight’.¹¹⁸ Of course there was hostility towards, as well as from, pharmaceutical manufacturers at times. Julia Earnshaw, who attended NICE appraisals for GlaxoWellcome, recalls a meeting where:

one of our very senior clinical people ... was astounded, he said he had never been treated so rudely in his life. ... in a regulatory situation you would always be treated with a degree of respect, but [at NICE hearings] it didn’t always happen. I have one example, when ... the woman who was sitting next to me ... a GP, just said, without any prompting, “can I tell you I never see pharmaceutical company representatives, I consider it the worst form of professional prostitution.” Nice to meet you!¹¹⁹

We turn, finally, to reflect on the meaning of NICE’s history of making its tragic choices. We noted earlier that this was a thread that runs throughout NICE’s existence. The nature of their choices was not lost on the protagonists, as their words make clear. The phrase ‘tragic choices’ was popularised by Calabresi and Bobbitt, in their seminal book of the same title, which examined the methods that societies could use to make choices about the allocation of scarce resources and the diverse ways in which the United States, England, and Italy did so.¹²⁰ We have not found evidence that NICE’s leaders referred to previous thinking on the subject, such as Calabresi and Bobbitt’s, which is interesting since they often did this in other areas of policymaking. None of our interviewees used the phrase with us, though a number, such as McClarey called the committee hearings ‘difficult ... terrible ... really hard’.¹²¹

116 Andrew Dillon, in Atkinson and Sheard (2020), 43.

117 Mahon interview.

118 Tom Walley, personal communication.

119 Earnshaw interview.

120 Calabresi and Bobbitt (1978).

121 McClarey interview.

Hoffmaster and Hooker, discussing the ethics of allocating kidneys for transplantation, describe tragic choices as those which flow from ‘conflicts between fundamental moral values, none of which can be renounced’.¹²² In NICE’s case, this is often a conflict between two competing calls on the same health care resources. Chris Ham, a frequently cited health policy and management academic, and Director of DH’s Strategy Unit from 2000 to 2004, wrote of the 1995–96 Child B case, under the title ‘Tragic choices in health care’, that it:

demonstrates the tension between a concern to use resources for the benefit of the population as a whole and the urge to respond to the needs of individuals faced with the prospect of death.¹²³

This might better be expressed as having to choose between the health (sometimes the survival) of one set of patients or of another set: the ethics of opportunity cost. NICE began by maintaining that in doing this, ‘a QALY is a QALY is a QALY’: a given quantity of change in any person’s health status was worth the same whoever it happened to and in whatever the circumstances.¹²⁴ Twenty years of experience of making tragic choices has modified this to some extent. It has been hard for policy-makers at NICE not to feel that the QALYs secured by extending a life are worth more than other QALYs. They gave expression to this view by adopting the End of Life criteria in 2009 (discussed in Chapter 8).

Furthermore, it would have been very uncomfortable to place complete reliance on the techniques of health economics in determining the valuation of life and of different health states: it would have put the chosen methods under extreme and repeated pressure. We have seen how NICE opted, not for that technocratic approach, in which the ‘right’ answer is read off from the calculation of a technology’s ICER, but, instead, to modify the rigorous use of such methods by using a deliberative process to keep the results compatible with the values of society. Such an approach matches that of Calabresi and Bobbitt, who argue that compromise is inevitable when making tragic choices, because only compromise honours the fundamental nature of such choices: that even though none of the important conflicting values can be abandoned, a choice must be made. NICE, then, has selected a particular way of making these compromises.

Hoffmaster and Hooker argue that, to be acceptable, a policy for making tragic choices:

‘has to ... be regarded [as] necessary, effective, fair, and responsible. There are, however, various notions of effectiveness and multiple forms of fairness ... all of which inevitably conflict. Consequently, the moral burden of

122 Hoffmaster and Hooker (2013).

123 Ham (1999).

124 This view was advanced in, for example, Rawlins and Culyer (2004).

legitimacy and responsibility falls not just on the tragic choice itself but also on how the tragic choice is made.

choices [must] emanate from a rational decision-making process, and the operation of compromise in that process [must] retain fidelity to all the conflicting fundamental values. [the best choice] minimizes the tragic outcome of not being able to satisfy all the conflicting fundamental values by satisfying each proportionately to its importance in the current circumstances.¹²⁵

This would account for the considerable effort which NICE has invested in designing processes which command support, and speaking up for them in public debate.

Faced with such tragic choices, one's first instinct may well be to seek a way not to make them: should someone else be making them? Could more resources be found? But since resources are finite, either policymakers select one option or another, or else the market makes the choice blindly. That is, of course, one policy option. In 2006, US Deputy Secretary of Health Alex Azar argued that attempts to keep drug costs down, such as NICE, would stifle innovation.¹²⁶ Stronger moral arguments have also been advanced: North American readers may recall Sarah Palin's use of the language of 'death panels' to attack technocratic decision-making about the allocation of health care resources. NICE, or rather Rawlins, became involved in the debate in the US, where Rawlins debated the question with Newt Gingrich in October 2009 with his usual gusto:

You may dislike the introduction of a cost effectiveness component; but if your antagonism to comparisons of the efficacy, effectiveness and safety of two or more interventions were shared by my (and your) medical colleagues in the US, I would despair for the future of American medicine. In fact I know they rely on Comparative Effectiveness Research, as much as we do in Europe, in providing clinically appropriate care for all their patients.¹²⁷

We agree with Rawlins that, whether or not policymakers face up to tragic choices, finite resources are still allocated to one group and not another: the question is then whether it is better to take the decision consciously and transparently.

This chapter brings the story of HTA at NICE up to, broadly, 2007. Most of its present-day features are perceptible even in this early period. And the biggest dilemmas, for example how to reconcile speed and robustness, were also visible early on. HTA would, nevertheless, develop much further. Chapter 8 will take up the story, and lead us through such topics as the 'End of Life' criteria, the growing problems posed by cancer drugs, the growing stress on fostering innovation in the

125 Hoffmaster and Hooker (2013).

126 Kmietowicz (2006).

127 Rawlins Papers, 'Closing statement'. The motion debated was 'This house believes that the widespread use of comparative effectiveness reviews and cost/benefit analyses will stifle innovation and lead to unacceptable rationing of health care'. Reported in *Economist*, 10 October 2009, In sickness and in health.

life sciences industries and the problems raised by trying to build in affordability alongside effectiveness and cost-effectiveness.

Bibliography

Primary sources

- Bristol Royal Infirmary Inquiry (2001) *Learning from Bristol: The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984–1995*. Command Paper: CM 5207 (London: HMSO).
- Buxton papers Evaluation of Health technology for use in the NHS (1999) typescript.
- Daily Mail*, 13 June 2002, You must go blind in one eye before NHS will treat you.
- Daily Mail*, 18 July 2007, Alzheimer's sufferers demand drugs ban is lifted.
- Department of Health (2003) Directions to Primary Care Trusts and NHS trusts in England concerning Arrangements for the Funding of Technology Appraisal Guidance from the National Institute for Clinical Excellence (NICE) (Last accessed 2 February 2022).
- Department of Health (2008) *High Quality Care for All: NHS Next Stage Review Final Report* CM7432, 44 (Last accessed 22 February 2022).
- Department of Health and Social Care and ABPI (2018) The 2019 Voluntary Scheme for Branded Medicines Pricing and Access (Last accessed 4 September 2024).
- Economist*, 10 October 2009, In sickness and in health, Vol 393, Issue 8652.
- Evening Standard* 7 July 1999, NHS catches cold.
- House of Commons: Third Standing Committee on Delegated Legislation (1999) Wednesday 10 March 1999: National Institute for Clinical Excellence (Establishment and Constitution) Order 1999 4.30 pm.
- Independent*, 6 October 2005, New breast cancer drug to be available for all, Hewitt rules.
- Independent*, 21 March 2020, Coronavirus: Doctors given new guidelines on choosing which patients to treat in critical care.
- NHS England (2020) Diagnostics: Recovery and Renewal (Last accessed 31 July 2024).
- NHS Executive (1999) *Faster Access to Modern Treatment: How NICE Appraisal will Work: a discussion paper* (Leeds: NHS Executive, typescript).
- NICE (2000) *Annual Report 1999–2000* (London: NICE).
- NICE (2002a) Final Appraisal Determination: Photodynamic therapy for age-related macular degeneration (Last accessed 20 February 2022).
- NICE (2002b) *Annual Report, 2001–2002* (London: NICE).
- NICE (2003) TA068 Macular degeneration (age related) - photodynamic therapy (Last accessed 20 February 2022).
- NICE (2004) *A guide to NICE* (NICE: London).
- NICE (2007) TA129 Bortezomib monotherapy for relapsed multiple myeloma (Last accessed 20 February 2022).
- NICE (2010) *Annual Report and Accounts 2009/10* (NICE: London).
- NICE (2012) *Annual Report and Accounts 2011/12* (NICE: London).
- NICE (2017) Mesh for vaginal wall prolapse should only be used in the context of research, says NICE (Last accessed 21 February 2022).
- NICE (2018a) *Annual Report and Accounts 2017/18* (NICE: London).
- NICE (2018b) Board meeting papers 18 July 2018 (Last accessed 4 October 2024).
- NICE (2020) *Annual Report and Accounts 2019/20* (NICE: London).
- NICE (2022) Digital Health (Last accessed 22 February 2022).

Private Eye, 987, 15 October 1999.
Rawlins Papers, ‘Closing statement’.

Secondary sources

- Atkinson P & Sheard S (eds) (2020) *Origins and Establishment of NICE (c. 1997 – 2002)*, witness seminar held online on 18 June 2020 (Liverpool: Department of Public Health and Policy, University of Liverpool).
- Alvarez-Rosete A & Mays (2008) Reconciling two conflicting tales of the English health policy process Since 1997, *British Politics*, 183.
- Appleby J (2016) What’s in and what’s out? The thorny issue of the threshold, in Timmins N (ed) *A Terrible Beauty: A Short History of NICE* (Nonhaburi: Health Intervention and Technology Assessment Program HITAP), 155.
- Association of the British Pharmaceutical Industry (ABPI) (n.d.) Unpacking the UK’s pharmaceutical IP incentives (Last accessed 31 July 2024).
- Barnett D, Stevens A, Boysen M & Longson C (2009) Developing evidence-based guidance for health technologies: the NICE experience, in Killoran A and Kelly M (eds) *Evidence-based Public Health: Effectiveness and efficiency* (Oxford: Oxford University Press), 400–421.
- Calabresi G & Bobbitt P (1978) *Tragic Choices* (New York: Norton).
- Campbell B & Maddern G (2003) Safety and efficacy of interventional procedures. *BMJ* 326(7385): 347–348.
- Casson S, Ruiz F & Miners (2013) How long has NICE taken to produce technology appraisal guidance? A retrospective study to estimate predictors of time to guidance. *BMJ Open* 3(1), e001870.
- Clark B (2007) *The Fight of my Life* (London: Hodder and Stoughton).
- Culyer A (2006) NICE’s use of cost effectiveness as an exemplar of a deliberative process. *Health Economics, Policy and Law* 1(3), 299–318.
- Culyer A, McCabe C, Briggs A, Claxton K, Buxton M, Akehurst R, Sculpher M & Brazier J (2007) Searching for a threshold, not setting one: the role of the National Institute for Health and Clinical Excellence. *J Health Serv Res Policy* 12(1), 56–58.
- Culyer A (2013) *The Humble Economist* (London: Office of Health Economics).
- Eaton (2002) NICE accused of restricting treatment for eye patients. *BMJ* 325, 852.
- Ferlie E (2001) Public management in the United Kingdom: efficiency and accountability. *Politiques et Management Public* 19(3), 121–138.
- Ham C (1999) Tragic choices in health care: lessons from the Child B case. *BMJ* 319(7219), 1258–1261.
- Hoffmaster B & Hooker C (2013) Tragic choices and moral compromise: the ethics of allocating kidneys for transplantation. *Milbank Quarterly* 91(3), 528–557.
- Kaltenthaler E, Boland A, Carroll C, Dickson R, Fitzgerald P & Papaioannou D (2011) Evidence Review Group approaches to the critical appraisal of manufacturer submissions for the NICE STA process: a mapping study and thematic analysis. *Health Technology Assessment* 15(22), 1–82.
- Klein R (2013) *The new politics of the NHS*, seventh edition (Boca Raton, FL: CRC Press).
- Kmietowicz Z (2006) Experts defend NICE against attack by US politician. *BMJ* 333, 1087.
- McCabe C, Chilcott J, Claxton K, Tappenden P, Cooper C, Roberts J, Cooper N & Abrams K (2010) Continuing the multiple sclerosis risk sharing scheme is unjustified. *BMJ* 340, c1786.

- Moreira T (2012) *The Transformation of Contemporary Health Care: The Market, the Laboratory, and the Forum* (Oxford: Taylor & Francis), 7.
- Murad M, Asi N, Alsawas M & Alahdab F (2016) New evidence pyramid *BMJ Evidence-Based Medicine* 21, 125–127.
- Nowotny H, Scott P & Gibbons M (2001) *Re-thinking Science: Knowledge and the Public in an Age of Uncertainty* (London: Polity Press/Blackwell).
- Osipenko L, Ul-Hasan S, Winberg D, Prudyus K, Kousta M, Rizoglou A, Rustignoli I & van der Maas L (2024) Assessment of quality of data submitted for NICE technology appraisals over two decades. *BMJ Open* 14, e074341.
- Raftery J (2010) Multiple sclerosis risk sharing scheme: a costly failure. *BMJ*, 340, 1672.
- Rawlins M & Culyer A (2004) National institute for clinical excellence and its value judgments. *BMJ* 329(7459), 224.
- Rawlins M (2016) NICE, the law, its social values and its stakeholders, in N Timmins (ed) *A Terrible Beauty: A Short History of NICE* (Nonhaburi: Health Intervention and Technology Assessment Program HITAP), 136–153.
- Ruggeri K & Nolte E (2013) Pharmaceutical pricing the use of external reference pricing (Rand Corporation), 17 (Last accessed 30 August 2024).
- Smee C (2005) *Speaking Truth to Power: Two Decades of Analysis in the Department of Health* (Oxford: Radcliffe).
- Syrett K (2003) A technocratic fix to the “legitimacy problem”? The Blair government and health care rationing in the United Kingdom. *Journal of Health Politics, Policy and Law* 28(4), 715–746.
- Timmins N (2016) *A Terrible Beauty: a Short History of NICE* (Nonhaburi: Health Intervention and Technology Assessment Program HITAP).
- Wishart A (2009) *The Price of Life* (documentary film).

6 NICE guidelines

In this chapter we examine the development of NICE's guidelines work. Drawing on interviews with those at the heart of this activity, we show the importance of guidelines production and of the methods NICE developed, both for health and social care and for the wider practice of policymaking in the UK. Much of what is said about NICE, in the media and among health professionals and policymakers, refers in fact only to its Technology Appraisals (TAs). This is unsurprising given the orientation of early communications by government and NICE itself. Even a member of NICE's original Board recalls not being aware at first that there were to be guidelines as well as TAs.

It was partly that, in NICE's first years, guidelines were simply less visible, because high-profile TAs such as Relenza had first call on everyone's attention, including NICE's leaders. Then there was the lead time to produce NICE's first clinical guidelines: this was much longer than for TAs. Professor Mike Drummond, the York health economist (and Director of York's Centre for Health Economics, 1995–2005) who served on NICE's Guidelines Advisory Committee, recalls: 'when we started off, an average guideline was taking two years, so what do you do in the first two years?'.¹

In truth, however, treatment guidelines have been central. Those closest to NICE, including Mike Rawlins, saw NICE's guidelines as its most important activity. In a 2009 interview with Nicholas Timmins, Rawlins justified this in several ways: guidelines dealt with 'the whole [patient] pathway' from diagnosis to treatment, and every aspect of care.² NICE's guidelines, for example the one on the management of hypertension, could prevent large numbers of premature deaths and save a lot of treatment costs. Rawlins also pointed proudly to the adoption of NICE's schizophrenia pathway in Spain, Italy, Australia and California, while Adrian Towse at the Office of Health Economics draws attention to NICE guidelines' usefulness to middle-income countries.³ Guidelines are, indeed, the most

1 Mike Drummond, interview, 12 March 2020.

2 Timmins (2016), 115–119.

3 For the schizophrenia pathway, see NICE's first clinical guideline: NICE (2002a); Adrian Towse, interview 1 March 2021.

straightforward NICE product for other countries to re-use: while all its guidance is specific to the English setting, guidelines do not suffer from the same close link with drug prices in different markets as TAs do – those do not translate as easily. One could add a further argument that guidelines focus on improving forms of care already in use, whereas TAs deal with potential new therapies.

For all these reasons, ‘Mike [Rawlins] ... did always maintain that ... it’s guidelines that NICE will be known for’, according to the founding chairman of the Guidelines Advisory Committee, Professor Martin Eccles.⁴ Appointed in 2000, Eccles was at that point professor of primary care research at Newcastle: one of several early recruits personally head-hunted by Rawlins. (In an illustration of the way Rawlins used his personal networks for this, Eccles had studied medicine under both Rawlins and George Alberti.)

By 2014–15, when both programmes had thoroughly got into their stride, NICE was spending £13m on the Centre for Clinical Practice (producing guidelines), compared to only £10.6m on the Centre for HTA (covering medical technologies and diagnostic guidance as well as HTA).⁵ These investment choices give the lie to the usual assumption that technology appraisal dominates NICE’s work. Another indication of the relative importance of the two activities is that NICE guidelines affect a larger group of patients than TAs, which are increasingly likely to address expensive drugs with small potential patient populations. An interesting comment from Andrew Dillon offers a further reason to see guidelines as more important than TAs. In his view, clinical guidelines have become the scene of the significant controversies, rather than the TA programme as in NICE’s first decade.⁶ For him, NICE guidelines had upset patients over myalgic encephalopathy/chronic fatigue syndrome (ME/CFS), the National Health Service (NHS) over *in vitro* fertilisation and clinicians over the repair of abdominal aortic aneurysms: ‘We have managed to annoy just about everybody’.

What is a guideline, and what is the difference between a guideline and a TA? For NICE,

Clinical guidelines are recommendations on the appropriate treatment and care of people with specific diseases and conditions within the NHS in England and Wales. They are based on the best available evidence. Guidelines help health professionals in their work, but they do not replace their knowledge and skills.⁷

The subject of a guideline, then, is how to deal with a medical condition, whereas the subject of a TA is the suitability of a technology. This water was muddied just a little by NICE’s initial preference for multi-technology appraisals (MTAs),

4 Martin Eccles, interview 20 September 2019.

5 Timmins (2016), 125.

6 Andrew Dillon, interview 2 July 2020.

7 NICE (2003a).

comparing (if possible) all the current technologies addressing one condition. (For example, the TA on asthma inhalers for young children evaluated devices from eight manufacturers.⁸) We saw in Chapter 5, however, that since 2005 NICE has largely moved away from MTAs to single TAs.

NICE's inheritance: UK clinical guidelines before 1999

We saw in Chapter 1 how there were clinical practice guidelines in the UK before NICE, one of the main outputs of the evidence-based medicine (EBM) movement. Weisz et al. offer a thorough account of the genesis of guidelines, tracing them back to the 1930s in the US, but with growing interest after 1945.⁹ While some have thought guidelines stemmed largely from administrators wanting to control costs, and others, more subtly, think they were the doctors' response to such pressures, ensuring that they retained control of practice, Weisz et al. paint a broader picture. They regard guidelines as the product of a whole set of circumstances, including the needs of research, the growth of ever larger health care organisations, as well as the preoccupations of funders. Concern at what came to be euphemistically called 'health care variations' played a part, for example variations in the type or rate of treatment. Guidelines came to serve the new priorities of quality and safety rather than cost-cutting.

US government interest in guidelines was reflected in the establishment in 1990 of a National Guidelines Clearing House.¹⁰ By 1995, however, some were pushing back against the (Federal) Agency for Healthcare Policy and Research taking too prominent a role: not everyone was happy that a government body should do this. It became necessary for the AHCPR to morph into the Agency for Healthcare Research and Quality, a formulation leaving 'policy' out of the picture. Such controversy illustrates the way that guidelines *are* policy and so are always at least liable to be political.

In the UK, the Thatcher NHS reforms, separating purchasers and providers, 'made the control of costs and quality the direct responsibility of the government, thereby creating the need for national standards of evaluation and leading to a proliferation of guidelines'.¹¹ This mirrors the boost which the same NHS reforms gave to HTA, which we noted in Chapter 1, encouraging purchasers to ask "should we buy that rather than that?" which was knowing about cost-effectiveness and evidence'.¹²

This proliferation of guidelines meant that their quality was variable. A pressure group which was not able to persuade the NHS that a particular service or procedure was essential could at least publish a guideline recommending it. Government could deflect pressure for service developments by agreeing that a guideline could

8 NICE (2000a).

9 Weisz et al. (2007).

10 Eisenberg (1998).

11 Weisz et al. (2007), 712.

12 Michael Peckham, interview 23 August 2017.

be produced. Eccles describes his scepticism about many of the guidelines of the 1990s:

one of the best-known examples would at that point have been the British Thoracic Society asthma guidelines. There were a number of attributes of the BTS guidelines that one might have wished to change: there was a very close link with the pharmaceutical industry, it was a pretty good example of – in the nicest possible way – consultants telling GPs how to do things. That is not to suggest consultants don't have specialist knowledge – they clearly do – but it wasn't at all clear how the BTS, who I think are a very good organisation, had taken account of a range of things.¹³

Specifically, Eccles was critical about the absence of 'an explicit process about how you located, interpreted, synthesised the best evidence', such as was by then being seen in the AHCPR's guidelines work, for example in publications for them by Kathleen Lohr. Also unexamined, by Eccles' account, was the justification for selecting a particular scope for a guideline. Indeed, rather than being of variable quality, Eccles felt that existing guidelines, 'mostly ... were of uniformly poor quality'.¹⁴

There were efforts to address this. The Royal College of General Practitioners ran a Guidelines Skills Course, which Eccles led for a number of years. His own work at Newcastle produced evidence-based guidelines, under the banner of the North of England Evidence-Based Guideline Development Group (GDG): they were published in the *British Medical Journal*.¹⁵ Elsewhere, Peter Littlejohns, soon to become NICE's first Clinical and Public Health Director, received NHS R&D funding for his work at St George's Hospital with Professor Joe Collier. They developed the 'St George's Instrument' for assessing guidelines and used it to assess guidelines on behalf of Department of Health (DH), an activity commissioned by Graham Winyard, the DH medical adviser we have already encountered in connection with HTA in Chapter 1.¹⁶ This work was later extended to develop the EU-funded AGREE instrument.¹⁷

1999: laying the foundations

A 'policy window' for guidelines

We saw in Chapter 2 how, in Kingdon's terms, a 'policy window' opened in the UK in 1997 for the establishment of NICE. Here we explore in a little more detail how the

13 Eccles interview.

14 Eccles interview.

15 Eccles et al. (1996). The same edition of the *BMJ* also has short summaries of the group's angina and asthma guidelines.

16 Peter Littlejohns, interview 18 September 2019.

17 AGREE (Appraising Guidelines, Research and Evaluation), endorsed by the EU and WHO as the standard approach to assessing the quality of clinical guidelines. See Cluzeau (2003).

window opened for the production of government-backed and evidence-informed treatment guidelines. Kingdon's policy windows, it will be recalled, were created by the simultaneous existence of problem, policy and politics which enabled the adoption of the policy. In this case, the widely acknowledged problem was the existence of 'health care variations' and a lack of evidence on which to base treatment decisions across a wide range of health care. To policymakers with the 'economising' approach to health care which we described in Chapter 1, this was certainly a problem. By the 1990s, thanks to the developments we have described here, the large-scale production of evidence-informed (or evidence-based) guidelines was emerging as a viable policy solution.

The politics of government sponsorship for such an activity were difficult, however: it seemed at first irreconcilable with the clinical freedom to select the best treatment for each patient. We have just seen how in the US this produced major difficulties for the AHCPR. Political difficulties about government sponsorship of treatment guidelines were, of course, a subset of the broader problem about government interference with clinical freedom, which we described in Chapter 1.

The 1997 Labour government's willingness to be more interventionist, and its political freedom of action to do so, opened the window. The Minister of State for Health, John Denham, made this clear in the Parliamentary committee debate on 10 March 1999 on the Order setting up NICE.¹⁸ Denham said:

NICE will promote innovation and quality in the NHS ... NICE is essential for our plans for fair and equal treatment of patients within a health service that is truly national ... NICE guidelines will provide a common effectiveness foundation for the NHS.

This was a statement of New Labour's three-part approach to reforming NHS governance: NICE would communicate, via guidelines (and other guidance including TAs), which treatments were effective, bodies such as Primary Care Groups would commission them from hospital trusts, and an inspectorate, initially called the Commission for Health Improvement, would ensure that NICE's guidelines had been followed.

A different kind of openness to NICE guidelines among the policy community was demonstrated in the Kennedy Report, published in July 2001.¹⁹ Commissioned to examine unexpected death rates in paediatric heart surgery at Bristol, Ian Kennedy's voluminous and wide-ranging report was very influential for the whole field of health care quality in England. NICE did not escape Kennedy's gaze, and he concluded that it should have the 'overarching responsibility for the setting of standards'.²⁰ All Kennedy's references to NICE are about the importance

18 House of Commons: Third Standing Committee on Delegated Legislation (1999).

19 Bristol Royal Infirmary Inquiry (2001).

20 Bristol Royal Infirmary Inquiry (2001), 387.

of its work and ensuring its independence. This level of endorsement in such an important document helped cement the place of NICE guidelines.

Taking over the driving seat

In 1999, NICE inherited a DH budget for guideline production, which was being spent with the medical Royal Colleges, as we saw in Chapter 3: a pipeline of guidelines was already in production. (Over its first three years, NICE published six from this inherited series, a notably low rate of output from the pre-NICE production arrangements.²¹ The final legacy guidelines came out in 2002–03.²²) We saw in Chapter 2 how the Colleges had made a late, and unsuccessful, bid in 1999 to take control of government-sponsored guidelines production themselves. This must have left the impression that the question of responsibilities (and funding) would be a sensitive one. This section will add a little more detail about how NICE achieved the transition from this pre-1999 world to the current one, in which NICE is in the driving seat, setting the scope of each guideline and approving it before publication.

At first, leaders at NICE do not seem to have been clear about the best way to work with the Colleges and produce guidelines of the desired kind. According to Littlejohns, both Rawlins and Dillon were thinking of quality assuring and kitemarking guidelines being produced by the Colleges. In this account, Littlejohns was the one who persuaded NICE into a more hands-on approach:

I said ‘it won’t happen, because we want guidance to look at cost-effectiveness, which we’re doing with drugs. We need to attempt to do the same with guidelines around cost-effectiveness.’ Never been done before; Colleges won’t be able to do it, we’ll have to do it ourselves ... [Guidelines] have to be based on these criteria, so they’re not a College guideline: the College co-ordinates a professional group, including patient groups, and they need to quality-assure the process according to our guidelines, our criteria.²³

This account of the importance of cost-effectiveness as an issue to resolve with the Colleges is corroborated by Drummond, the health economist on the Guidelines Advisory Committee:

NICE would lay down the template for what they had to do but, for example would include economics which wouldn’t have been a natural thing for the colleges to do, which I think [was] probably one of the major reasons for any success because it was the idea that you work through the professionals, not try to foist something on them.²⁴

21 NICE (2002b).

22 NICE (2003b).

23 Littlejohns interview.

24 Drummond interview.

The outcomes of this search for a cost-effectiveness element in guidelines are considered later in this chapter.

The Colleges were, naturally, all different. In Drummond's recollection:

the psychiatrists had had a tradition of working with evidence based medicine and with economists because the Royal College of Psychiatrists had a link with Martin Knapp who was at Kent and the Institute of Psychiatry in London, ..., but surgeons didn't even want it to be evidence based particularly, they are surgeons as well – why bother with all that literature? The General Practice people were pretty good, but they did vary, I think the Maternity Care people were pretty good as well.²⁵

Gillian Leng was recruited to NICE in 2001 to be the Director of its Guidelines programme. She interprets the challenge of working with the Colleges as one of gaining the degree of control NICE wanted over a programme which had previously been given a lot of latitude. She reports that the relationship with the Colleges:

was a really positive one, on one level, because they were actively engaged in this work, and they wanted things to be a success. But it was a bit tense on another, because our management of contracts was different from the DH. DH treated the funding more as a grant, whereas we were treating it as formal contract management with timelines and regular accounting.²⁶

This increased formality took the form of setting up National Co-ordinating Centres (NCCs) for different topics, largely based within the different Colleges. In 2006 there were NCCs for acute care, cancer, chronic conditions, mental health, nursing and supportive care, primary care, and women's and children's health.²⁷ (This approach of contracting out the programme management as well as content delivery would later be adopted by the National Institute for Health Research, established by DH in 2005 to run the NHS R&D programme.²⁸) A good example of an NCC is the one for Women's and Children's Health (the NCCWCH). Rona McCandlish, who joined its Board and later became its chair, recalls that 'it wasn't a straightforward transition, and of course each College still has an enormously different culture and different professions'.²⁹ In the previous system of DH funding the Colleges to write guidelines, McCandlish recalls that there had not been:

this expectation of delivery, it took years to fire that up. I think it is now well fired up, but it wasn't in the past. It had been much more artisanal, much

25 Drummond interview. Professor Martin Knapp has been Professor of Social Policy and Director of the Personal Social Services Research Unit at the LSE, and Director of the NIHR School for Social Care Research.

26 Gillian Leng, interview 26 November 2019.

27 WHO Regional Office for Europe (2007), 21.

28 Atkinson and Sheard (2019).

29 Rona McCandlish, interview 3 December 2019.

more guys getting round the table, having a chat and somebody writing it, that kind of thing. It's very different now.³⁰

The arrival of 'formal contract management' and an 'expectation of delivery' described by Leng and McCandlish illustrate the part played by NICE in the arrival of the New Public Management into this area of health policy. By 2006, NCCs were reappointed by open tender.³¹ These developments represent a thoroughly commercial approach to getting business done, which was a departure from older ways of working. There were teething troubles, including some difficulties in finding agreement on how different groups with professional interests would work together. In the case of NCCWCH, there were the Royal College of Obstetricians and Gynaecologists, which hosted the centre, the Royal College of Paediatrics and Child Health, who were 'not entirely enchanted that [it] was called the Women's and Children's Centre', and the Royal College of Midwives, who had also bid to be the host. In this field there were also 'very knowledgeable and vocal experts' from the users of services, as we shall see later in this chapter.³²

As we have seen, NICE has never accredited/'kite-marked' other organisations' guidelines, as some must have wished, though it seems to have considered the possibility, perhaps in response to one of the recommendations of the WHO review in 2006.³³ Around 2011, it did adopt an 'accreditation programme' which accredited guideline development methods, rather than particular guidelines themselves. Mark Baker, who was the director of NICE's Centre for Clinical Practice from 2012 to 2018, recalls that:

lots of organisations that thought themselves to be distinguished failed to get accreditation including the British National Formulary ... it became a badge of honour for almost all developers and did massively improve the quality of guideline production across the UK and internationally.³⁴

David Haslam, who went on to chair the Board of NICE from 2013 to 2019, was the first chair of this accreditation programme. He recalls how:

'we started looking at major national guidelines, and actually felt an awful lot of them were of poor quality. I know in the early days [we] turned down a lot of very, up until then, well-respected guidelines, who were deeply upset by this, but then went away and looked at their processes, and realised that actually we were right, there were holes in their methodology. Particularly in addressing things like conflict of interest, addressing things like patient and public engagement and process. Which is, of course, absolutely critical.'³⁵

Haslam adds, however, that the programme was later the victim of budget cuts.³⁶

30 McCandlish interview.

31 WHO Regional Office for Europe (2007), 22.

32 McCandlish interview.

33 WHO Regional Office for Europe (2007), 35.

34 Mark Baker, interview 18 May 2022.

35 David Haslam, interview 24 April 2020.

36 Haslam, interview 15 February 2021.

What should NICE guidelines be? Setting the philosophy and methodology

This section describes what NICE was trying to do in its guidelines work. The starting point, in terms of governance, therefore, has to be what DH mandated it to do. We saw in Chapter 2 that in its first public announcement of NICE, the White Paper *the new NHS modern. dependable*, DH said that NICE:

will be established to give new coherence and prominence to information about clinical and cost-effectiveness. It will produce and disseminate:

- clinical guidelines based on relevant evidence of clinical and cost-effectiveness.³⁷

The most striking thing about the wording of the whole announcement is that nowhere does it say NICE will produce TAs: it is *all* about guidelines. We suggested in Chapter 2 that this was a presentational gambit to try and please as many of the White Paper's readers as possible by ducking the issue of rationing. But, whatever the private motivations for this choice, its result was a public message that NICE was all about guidelines. Other messages included the clear commitment quoted here to EBM. The establishment of NICE and the institution of NICE guidelines would demonstrate the arrival of EBM practitioners – examples of whom we shall meet in this chapter, such as Eccles, Leng and Littlejohns – at the heart of policy, a development we noted in Chapter 2. The concern with cost-effectiveness as well as clinical effectiveness is also evident, as is the goal of reducing geographical variations in treatment.³⁸

By the time it came to DH giving NICE its Secretary of State's Directions and Framework Document in the summer of 1999, TA had become the first item on the list of three core functions it was directed to carry out. Guidelines come second: of these, the Directions say:

develop guidelines providing advice on best practice in the management of such diseases and conditions as may be notified by the Secretary of State.³⁹

In carrying out these functions, NICE was to have regard to the Secretary of State's 'broad clinical priorities (as set out for instance in National Priorities Guidance and in National Service Frameworks)', clinical need, the 'broad balance of benefits and costs', 'any guidance from the Secretary of State ... on the resources likely to be available' – the controversial one – and, lastly, 'the effective use of available

³⁷ DH (1997), 68–69.

³⁸ DH (1997), 49.

³⁹ TNA, JA 765/15 NICE, Nick Clarke to ministers, 'Secretary of State Directions to NICE', 27 July 1999.

resources'.⁴⁰ The message that guidelines were to take cost-effectiveness into account was unmistakable, and NICE duly did. In NICE's first Annual Report, for example, Dillon commented that:

we had two guiding principles: - firstly our advice must be based on a rigorous analysis and assessment of all the available evidence and secondly, it must encompass both clinical and cost effectiveness. We also wanted to ensure that the Institute's guidance whilst being robust and authoritative was directly relevant to contemporary clinical practice.⁴¹

This neatly summarises a good deal of NICE's philosophy: not only the evidence-based approach and the importance of cost-effectiveness but also the search for robustness (as in capacity to survive challenge, including legal challenge – see Chapter 5), and, not least, the search for real-world relevance. Guidelines that did not address the most important clinical areas, or did so in an overly academic way, were to be avoided. In the event, getting the right balance between academic rigour, speed and usefulness in clinical practice had to be negotiated over a considerable period. (We have seen in Chapter 5 how the same issue played out in the field of TAs, when Meindert Boysen referred to wanting a quicker decision rather than waiting for academics to 'develop ... the most amazing model of diabetes, or whatever'.⁴²)

The importance of reporting on cost-effectiveness was further underlined in 2008 when the Citizens Council declared in its Social Value Judgements that:

Those developing clinical guidelines, technology appraisals or public health guidance must take into account the relative costs and benefits of interventions (their 'cost effectiveness') when deciding whether or not to recommend them.

[Although] Decisions about whether to recommend interventions should not be based on evidence of their relative costs and benefits alone.⁴³

Making guidelines

This section describes how NICE produced its guidelines. Though it may sound a dry topic, it is important because, to have an impact, NICE guidelines had to be better than existing ones. Producing a good-quality evidence-based guideline

40 DH, Directions to the National Institute for Clinical Excellence.

41 NICE (2000b).

42 Meindert Boysen, interview 23 April 2020.

43 NICE (2008).

called for much more than reaching a consensus of experts around a table over a few hours or a few meetings. In Baker's words:

the big thing for all NICE programmes was to maintain the quality of the brand. The whole point of NICE ... was that it was better at doing this work than anybody else. As guideline developers go it was phenomenally expensive to be the best and the pressure was always to do more for less ... while maintain[ing] world leadership ... unless they're world class in terms of methods and process no-one's going to take any notice.⁴⁴

NICE began with big ambitions, as Mercy Jeyasingham, a lay member of the original board, recalls:

one of the first things I asked Andrew Dillon was, "where do you think this organisation will be in ten years' time?" Andrew said, "I think we'll probably have done most of our work by then, because we will have covered all the major diseases and we will have produced all the guidelines" ... his prediction obviously didn't come true.⁴⁵

Similarly, NICE's annual report for 2002–03 said that the guidelines programme 'will, eventually, provide guidance on the management of all the major causes of morbidity and preventable early mortality'.⁴⁶ While Jeyasingham was of course right that NICE did not produce guidelines on everything in ten years, a look at the list of guidelines in Appendix 1 suggests that it was reasonable for NICE to claim, after just five years, that:

we have produced guidance on aspects of most of the commonly occurring diseases and conditions. Hundreds of thousands of patients are now getting access to effective treatments more quickly than would otherwise have been the case, and some are being treated in ways that would simply not have been available to them without NICE guidance.⁴⁷

A severe critic might raise an eyebrow at that 'aspects of', the hedging language of the typical press release. At the end of the ten years to which Dillon had referred, NICE had published 83 clinical guidelines covering major conditions such as hypertension, lung and breast cancers, dementia, stroke and type 2 diabetes.⁴⁸

44 Baker interview.

45 Mercy Jeyasingham, NICE Board member, interview 18 December 2019.

46 NICE (2003b).

47 NICE (2004).

48 See the chronological list in Appendix 2.

Topic selection

How, then, were the topics for guidelines set, and by whom? DH had, at first, every intention of calling the shots. We saw in Chapter 1 that, having been caught napping by the beta interferon controversy in 1995, DH began an in-house exercise in horizon-scanning: this was pessimistic and ‘economising’ in spirit, asking what expensive new drugs might soon be calling for hard policy choices: it focussed initially, in other words, on deciding what HTAs, rather than what guidelines, were going to be needed.⁴⁹ However, DH also had a keen interest in which guidelines should be produced. The topic selection committee which it ran, with an external chair and membership from the medical Royal Colleges and academia, moved from an exclusive focus on HTA to one which also covered guidelines. In the words of the civil servant who serviced the group, Charles Dobson:

we tried to get a sort of coherence between the topics going to the guidelines and the topics going to NICE appraisals. Very often ... one of the questions for the advisory [topic selection] committee was ‘would it be better just to do an appraisal of one treatment, or ... go straight to a clinical guideline where that would be one of a number of potentially complementary treatments?’⁵⁰

DH also invited, at some point (we have not found documentation about when) proposals from the general public. NICE, too, was able to suggest topics.

David Pink, the civil servant who project-managed the establishment of NICE, moved to that role from being the lead official on clinical guidelines before 1997. On secondment to NICE in its first couple of years, as Head of Guidelines, Pink recalls some jockeying for position between NICE and DH over topic selection – understandably, as this was clearly a crucial issue for both HTA and guidelines. The first couple of years:

was the awkward phase ... the department asserted [that topic selection] wasn’t something that was within the powers and independence granted to NICE. That the topics NICE was to work on were to be determined by a process the department would own.⁵¹

Which, in law, was absolutely true (unsurprisingly, as DH was the author of the relevant law, the Directions already quoted in this chapter). But just because those Directions gave the Secretary of State power to select the ‘diseases and conditions’ to be covered, it did not follow that NICE had to be a passive recipient of such direction, refraining from offering advice and suggestions. This had to be worked through. Pink added that while some areas of contention were rapidly resolved,

49 See Chapter 2.

50 Charles Dobson, interview 16 March 2020.

51 David Pink, interview 28 May 2020.

‘topic selection ... was ... a longer fight over a longer period of time. With a set of perfectly valid arguments on both sides’.⁵²

These arguments exemplify a point well made by Kogan et al. in their work on the use of science in policy at the DHSS (DH’s forerunner).⁵³ These authors argued that government could not commission research well so long as it viewed the process in transactional, customer and contractor, terms, since policymakers and scientists worked in different epistemic communities. Eccles illustrated this when he told us that policymakers were ‘interested in things that couldn’t necessarily be answered by going to the evidence’.⁵⁴ He added that there could be topics where:

NICE would have to say, “OK, we can see the area, can we ... go away and work on it to see if we can turn it into something [about which] we think a guideline could be developed, so that the questions are ... something a guideline process could actually answer.”

There would be a clash, for example, when DH wanted a guideline to resolve a policy problem whilst NICE regarded the question as un-researchable in the current state of evidence (one example being the use of pedometers: Chapter 7). We discuss Kogan’s insights further at the end of the chapter.

With the passage of time, attitudes at DH about who should select the topics changed: officials came to favour an arm’s-length relationship which gave this responsibility to NICE. The 2006 WHO review states that topic selection,

which at the time of the review [May 2006] was the responsibility of the Department of Health, was described in particular [by their broad range of interviewees] as not being fully transparent and not obviously consistent with health care priorities.⁵⁵

By the time of publication in 2007, DH had relinquished this responsibility. Contradicting this account, Baker reports that, even after 2012, although ‘theoretically [DH chose the topics for the guidelines,] we told them what to refer and they referred’.⁵⁶ While both versions cannot be right (at least in the black and white of the Secretary of State’s Directions at any given time), in practice, control of topic selection was a grey area, remaining a potential conflict zone.

52 Pink interview.

53 Kogan et al. (2006).

54 Eccles interview.

55 WHO Regional Office for Europe (2007), 34.

56 Baker interview.

Methodology and evidence

NICE's early recruits were critical to shaping its guidelines programme. Not only did their selection demonstrate the philosophy Rawlins wanted to apply: these people had strong influences on how it was implemented. The track record of Eccles, the obvious example, as chair of the programme, has already been mentioned. He gave NICE guidelines a richly methodologically – for example sociologically – informed grounding, often absent from earlier guidelines programmes, as we have seen. Eccles attended to such things as the nature of patient and public input, and the dynamics of how people with different forms of expertise (patient experience as well as professional knowledge) could actually work together on a guideline, even commissioning research from Tiago Moreira on how well NICE did that. This research:

was an attempt to get around the fact that experts are never short of ... opinions ... and if you ... want to hear from all [the participants] you need to ensure you have put in place a process that allows you to.⁵⁷

Eccles paid attention, too, to the nature of evidence itself: what counted, and how to weigh one kind of evidence against another. NICE drew here on earlier scholarly work. The Cochrane Collaboration, in particular, had been (in the words of Moreira), 'responsible for the codification of the procedures of systematic reviewing and meta-analysis as well as for the articulation of the role of such procedures in the governance of health care'.⁵⁸ The products of this work of codification included a 'hierarchy of evidence', in which systematic reviews were accorded top billing, above, for example, descriptive studies or expert consensus. In preparing its own guidelines methodology, NICE expressly drew on this hierarchy of evidence.

This is spelt out in early NICE clinical guidelines, for example the one on schizophrenia discussed below.⁵⁹ In acknowledging this hierarchy of evidence, that guideline cites two sources: a classification by the US Agency for Healthcare Policy and Research, mentioned earlier in this chapter, and a scheme formulated by the Clinical Outcomes Group of the NHS Executive in 1996. In this way we see the insertion of a fairly rigid view about evidence into UK policymaking.⁶⁰ While we would not question the technical rigour of the Cochrane-led approach, we agree with Klein and colleagues that it – necessarily, and like all previous attempts to replace judgement with technical knowledge – falls into the trap of 'scientism': the idea that more scientific knowledge, or its fuller application to policy, would solve all problems.⁶¹

57 Eccles interview. For the results of this study, see Moreira et al. (2006).

58 Moreira (2012), 93.

59 NICE (2002a).

60 See Eccles and Mason (2001).

61 Klein et al. (1996), 102–107. See also Klein (1996).

There have, in practice, been ‘evidence wars’, ably described by, for example, Prasad and Ioannidis, and by Montini and Graham.⁶² It turns out that rather than evidence resolving each policy difficulty, the admissibility and interpretation of evidence can easily become the turf on which policy disagreements are conducted. NICE GDGs had to negotiate the battlefields of some of these evidence wars, using their deliberative processes to reach their own verdicts on which evidence to rate most highly. We shall examine in a moment how this became especially difficult when there was qualitative evidence from patients about their experiences to weigh against biomedical, statistical or economic evidence. Furthermore, Chapter 7 will report some of the controversies affecting how NICE weighed up different types of evidence to reach recommendations on public health interventions – a particularly thorny field as far as evidence wars are concerned. Meanwhile, the topic of multimorbidity offers an instructive case study in NICE’s use of evidence in guidelines.

The challenge of multimorbidity

As early as 2006, the eminent team who produced the WHO review cited earlier commented that ‘some types of topics were not being considered for guideline development. Almost all guidelines are disease-focused rather than symptom-focused or including co-morbidities’.⁶³ How could guideline production hope to address the fact that most patients had more than one condition, and avoid dealing with each in potentially misleading or even dangerous isolation? It was no accident that NICE’s attention was focussed onto this problem by its first general practitioner chairman, Haslam – GPs being specialists in managing multimorbidity. He felt that as the incoming chairman in 2013:

the big [issue] for me was ... NICE being very academic, very focused on, for me, the diseases rather than the patients, very focused on conditions rather than usability in the real world ...

if you recruit an organisation full of world-class scientists, with a very precise way of looking at the world, who are uncomfortable with uncertainty, who are uncomfortable when the evidence fizzles away because the research hasn’t been done, it is almost, as with all of us, our strengths are our weaknesses, the great strength of the organisation was its methodology and the way it saw the world, and that then became its weakness, which was that the world ain’t like that ...

I had absolutely no kick back in these areas at all, ... I was immensely encouraged by the response of [NICE] ... as an organisation it had recognised that there was an issue and didn’t quite know what to do about it.⁶⁴

62 Prasad and Ioannidis (2014); Montini and Graham (2015).

63 WHO Regional Office for Europe (2007), 34.

64 Haslam, interview 24 April 2020.

Writing useable guidelines about multimorbidity remains a mostly unresolved problem. NICE did respond to Haslam's urging by publishing guideline NG56, Multimorbidity: clinical assessment and management, in 2016, but the right answer to the underlying problem remained a thorny issue, debated, for example at the 2023 NICE Conference, without much sign of a methodological breakthrough.⁶⁵

Baker was at the helm of the Centre for Clinical Practice for the production of NG56, and his thought process regarding the use of evidence shows him setting off from a purely biomedical conception of it but arriving at a quite different one. For Baker, 'evidence' continued to be something from the biomedical episteme, but for guidelines to work it now required qualification by something else, about patients:

what the multi morbidity guideline introduced ... was the concept of frailty ... [a] new [DH] clinical director ... a former colleague of mine from Leeds ... John Young ... started to talk to me about frailty. The degeneration of DNA ... an irreversible process and so on and suddenly everything started to fall into place. So when we set up the multi morbidity guideline I steered it towards this understanding of frailty and how people reach a certain point in their clinical history where there is no return to health and the imposition of system specific guidance ceases to be relevant. ... I suppose the multi morbidity guideline was a recognition by NICE and its teams that there came a point when things other than the evidence came into play rather more importantly at the patient level.⁶⁶

Eccles had been thinking particularly about evidence when he insisted on the transparency of the guideline production process:

I always maintained with any guideline that I wrote: 'I don't mind if you disagree with me: I would be very upset if we don't know why we disagreed.' It would either be around interpretation of evidence, application of evidence, or scope of the guideline, so you should be able to set out what the various elements were that were important in any subsequent debate.⁶⁷

Other recruits to NICE's guidelines programme

Another influential figure for the guidelines programme was Littlejohns. He described his own recruitment interview like this:

I said, "well, if I had the opportunity to design a job that was the culmination of all my interests in guidelines, quality improvement, health service

65 NICE (2016).

66 Baker interview.

67 Eccles interview.

research, prioritisation, equity in health care – this would be it.” Mike Rawlins said: “great, you start on Monday!”⁶⁸

Littlejohns was to write the first NICE guideline production process, capturing the design work undertaken by the original Guidelines Advisory Committee.⁶⁹ Other arrivals at NICE also made a big impact. Mary McClarey had been working on a clinical guidelines programme at the Royal College of Nursing, and ‘really felt quite passionate about the use of guidelines. The nursing community were very keen’.⁷⁰ This was her motivation to apply, successfully, to be one of NICE’s first Board members. McCandlish was a key figure in the cutting-edge National Perinatal Epidemiology Unit in Oxford, a significant element of Iain Chalmers’ work on EBM at the time.⁷¹ She lost no time in joining the board of the NICE-funded co-ordinating centre for guidelines in this field.

Pink was succeeded as head of the guidelines programme by Leng in 2001. Her story could represent a number of health professionals who became enthusiasts for EBM and took up academic, government or health service positions to advance this agenda:

I got interested in evidence-based practice as a junior doctor, because consultants I worked for had varying approaches to standardisation of care, so I became interested in what the evidence said ... [got] involved in the Cochrane Collaboration when it was being set up ... [and then] in some of the Scottish guidelines, the SIGN guidelines.⁷²

Leng saw the job advertisement and applied:

because of the opportunity it gave to do something about best practice, based on the evidence. I’d worked with Cochrane for almost ten years by that point, and Cochrane reviews are great at pulling together randomised controlled trials, but they don’t give recommendations for practice: there was [a] gap between ... the reviews [and] clinical practice, and that’s the space that guidelines can fill: ... NICE as a national organisation was so well-placed at that interface ... I wanted to use the evidence to make a difference.⁷³

The production process

Turning to the process of guideline production itself, this is perhaps best described by reference to an official NICE flow chart (Figure 6.1). The importance of – once

68 Littlejohns interview.

69 Eccles interview.

70 Mary McClarey, interview 7 January 2020.

71 McCandlish interview.

72 Leng interview.

73 Leng interview.

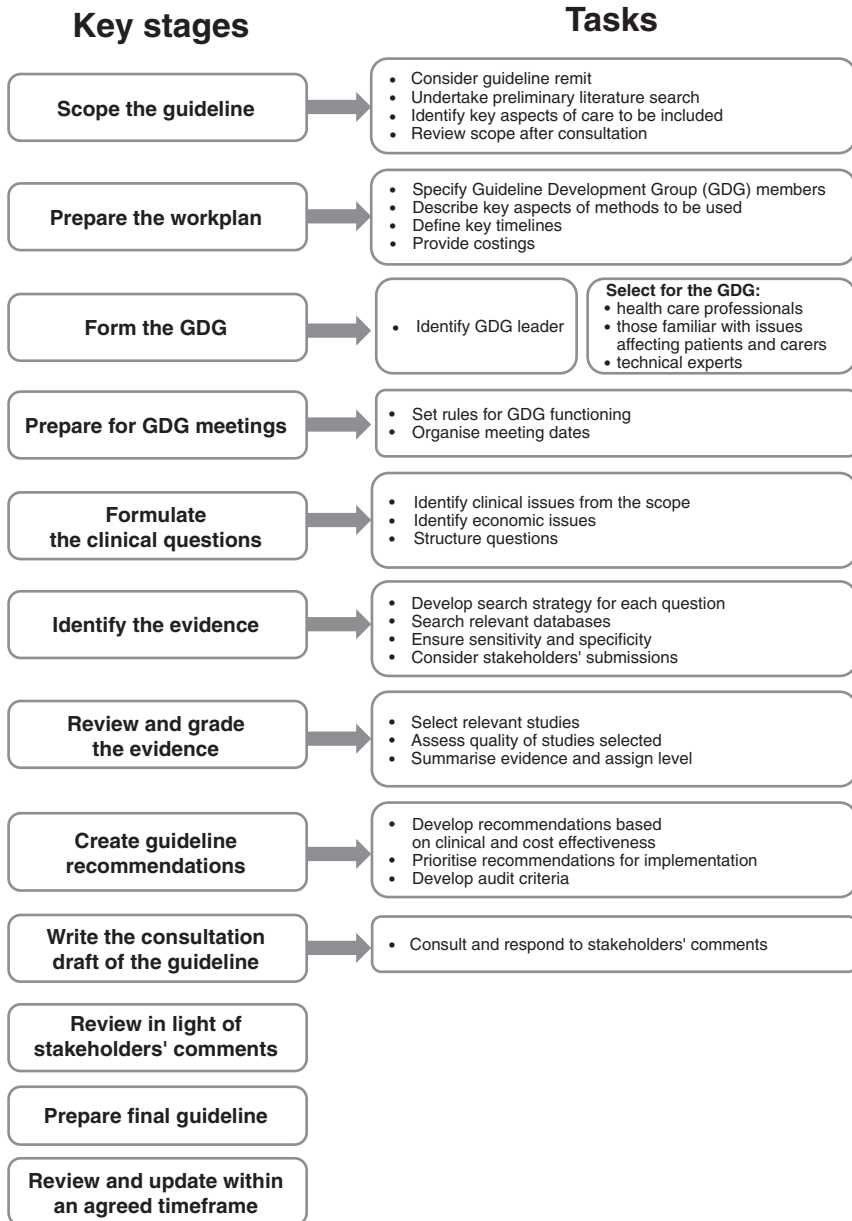


Figure 6.1 The key stages of NICE guideline development (2006).

Source: NICE (2006) Guidelines Manual.

again – apparently dry issues such as the scoping of a guideline quickly becomes visible. As Eccles put it:

this would now look perfectly straightforward, but it wasn't necessarily ... [the] question about the scope of the guideline ... was really important ... [scoping was] ... usually ... a lot more straightforward for technology assessments, because there's a technology, what does it do? Whereas guidelines were usually developed around an area of clinical practice. ... The technical bit was "how you get the evidence." The social bit was "how you define the scope." So the definition of the scope of a guideline was ... a social process.⁷⁴

Eccles' 'areas of clinical practice' lack the carefully defined boundaries provided, for example, by the licensed indications for the use of a drug, hence the 'social process' of working the boundaries out: each scope is a social object, not one supplied by biomedical science (begging the question of the social element in the scoping of even a TA). For an example of how much scope matters, when NICE decided to produce its first guideline, on schizophrenia, it made a great difference to patients, relatives, health care professionals and drug manufacturers whether this should cover diagnosis, include management in primary care, or be confined to treatment in acute secondary care.⁷⁵

In a fashion somewhat similar to NICE's preparation of TAs, highly technical preliminary work was assigned to evidence specialists, normally employed by the relevant NCC. Their expertise included analysing the quality of clinical trial reports and systematic reviews: economic analyses were also conducted. These specialists prepared an analysis of the available evidence, to be pored over by the GDG, consisting principally of clinicians but also containing a methodologist, a health economist and about three patient representatives. The presence of plenty of clinicians did not always guarantee a favourable reception from the rest of their professions: meetings with wider groups of clinicians could produce robust reactions.⁷⁶

The clinicians were appointed on the basis of applying to NICE, and had to satisfy NICE about any conflicts of interest. In Baker's words: 'sometimes we have to lose good people because they're unable or unwilling to give up their work for pharma'.⁷⁷ They would more likely be working in a general hospital than a teaching hospital:

we generally took the view that super specialists should bloody well know what they're doing so our guidance tended to be targeted at general hospitals rather than teaching centres ... so we felt it was important to have people typical of the audience ... we wouldn't stack a committee with teaching

⁷⁴ Eccles interview.

⁷⁵ NICE (2002a).

⁷⁶ Unattributable interview with NICE Board member.

⁷⁷ Baker interview.

hospital academics, or major trialists ... the importance of their work was the evidence, not their interpretation of it. Researchers are notoriously bad at understanding their own evidence.⁷⁸

It is informative to see how much this wish to select typical (consultant) clinicians for GDGs differs from the older approach to choosing who should write guidance, which had been a kind of cult of the super-expert. No longer were the nation's brightest and best from the world of science to be automatically recruited to government advisory committees on their academic credentials, as earlier in the twentieth century. Baker's rationale for departing from this, a mistrust of experts' capacity to translate their own research findings into recommendations for routine clinical practice, illuminates his approach to making guidelines. As the former Medical Director of a large teaching hospital, Baker wanted to combine scientific rigour with managerial pragmatism in order to produce guidelines which not only recommended 'the right thing' but also won credibility among those who would have to implement them. This fitted well with NICE's often-professed concern to make guidelines that people would find usable, and would use.⁷⁹

Writing guidelines was a very resource-intensive as well as a lengthy process. Guidelines would try to address about 20–25 questions, rather than every aspect of a topic, but since each meeting might only get through three of these, the process was lengthy. The group distilled its recommendations from the evidence presented to it, and with the analysts' help compiled a justification of the decisions reached.⁸⁰ Drummond, perhaps particularly sensitive to their opportunity cost, as an economist, recalls that:

there was quite a lot of antagonism out in the service about this because I think an average guideline was costing about a quarter of a million and people would say, "well you could have five epilepsy nurses for that".⁸¹

In an unsurprising echo of the situation with HTA, there was continuous pressure on NICE to make the guideline production process faster and cheaper. It is doubtful, though, whether this pressure was quite as acute, in the absence of commercial pressures on drug companies to press for speed which we saw in Chapter 5.

In another similarity with HTA (which we discuss in chapters five and eight), it turned out to be necessary to review and regularly update the methods guide. A good example was the publication in 2004 of two documents.⁸² The first, '*The Guideline development process – an overview for stakeholders, the public and the NHS*', described how to register an interest as a stakeholder and comment on

⁷⁸ Baker interview.

⁷⁹ See for example Dillon's comments on this, above.

⁸⁰ Drummond interview; Baker interview.

⁸¹ Drummond interview.

⁸² NICE (2004), 11–12.

emerging guidelines before they were finalised. With guidelines as with TAs, the NICE process was designed to incorporate a great deal of transparency, with the goals of producing guidance that was both more reliable and better able to withstand subsequent challenge.

The second 2004 publication, *‘Guideline development methods – information for national collaborating centres and guideline developers’*, was much more technical, and set out the guideline development process in detail. Its approach was based on the international AGREE guideline development instrument, whose development Littlejohns had led before joining NICE, as noted earlier in this chapter. NICE benefited here from the cross-fertilisation of talent with the UK Cochrane Centre and Cochrane Collaboration: we have already seen how Leng was one example of this. The recruitment in 2005 of Phil Alderson to work on methodologies was another, bringing, in Baker’s words, ‘the discipline and structure that Cochrane had developed world-wide’.⁸³

One final observation about the process of guideline production is how, faced with funding reductions and the need to make savings, NICE has progressively amalgamated several streams of guidelines work which were originally distinct: most importantly, bringing together the production of public health guidelines (which we will discuss in the next chapter) and clinical guidelines. One achievement in his term as Director of which Baker was proud was to integrate this work in NICE’s Centre for Guidelines in 2017, using the same processes and methods for all the varied work streams. He reports that this allowed NICE to produce the same volume of work as previously despite a 25% budget cut.⁸⁴ We shall consider in Chapter 7 how far this was beneficial for the quality of NICE’s public health work.⁸⁵

Handling cost-effectiveness in guidelines

Drummond, who has probably had the most influence on the use of economics in NICE guidelines, considers that:

the impact on the guidelines of economics was just to say ... hang on, there’s a resource issue here and you can’t just ... make that recommendation without thinking about the cost implications. ... trying to pick on things where you knew there was a big cost issue to ... get people thinking about that.⁸⁶

We have already seen testimony in this chapter from Littlejohns and Drummond that it was unusual to want guidelines to include cost-effectiveness. Leng, similarly, was quite right to observe that ‘most guideline developers around the world don’t put health economics into their guidelines’.⁸⁷ However the government had

83 Baker interview. For Cochrane, see Chapter 1.

84 Baker interview.

85 NICE’s search for an integrated approach to all its guidance continues. At the time of writing NICE is consulting on introducing an integrated Prioritisation Board: NICE (2024).

86 Drummond interview.

87 Leng interview.

mandated NICE to do so, as we saw. In responding to that commission, NICE were far from completely in the dark about how best to proceed. In the immediately preceding years, the NHS HTA programme had pointed to the need for a carefully considered approach to effectiveness and cost-effectiveness in guidelines. This work partly came from Eccles' North of England Guidelines Group, which we have already met. A 1998 discussion paper from the University of York Centre for Health Economics reported on this project, which developed evidence-based guidelines for use in primary care that explicitly considered the economic aspects of their recommendations.⁸⁸ With an excellent sense of timing, the authors (Eccles and Drummond among them) framed the paper as advice that NICE would imminently need.

It is worthwhile to consider this group's conclusions about the problems to be solved before guidelines could take account of cost-effectiveness. Drummond described this work as follows: 'we developed some clinical guidelines and then had various strategies to see whether people would adopt them': the emphasis was on clinician behaviour.⁸⁹ The main problems the authors identified were making valid and generalisable cost estimates, grading the quality of evidence about costs, and making recommendations to clinicians in a form likely to promote adoption. The proposed solution was a radical move away from estimating cost-effectiveness ratios, with a focus instead on seeing cost-effectiveness from the GPs' standpoint.

Thus the researchers looked first at the effectiveness of the intervention and then whether it was 'worthwhile': 'for the benefits involved, what was the net requirement in health resource costs, and where did the costs and savings occur?'⁹⁰ Discouraging adoption of a technology might take the form, as Drummond put it, of saying: 'well that doesn't do very much and by the way it's quite expensive'.⁹¹ Even if their GP colleagues had been likely to use cost per QALY estimates, the authors did not, in any case they examined, find enough data to derive these.

Although this work showed the challenges of using a cost-effectiveness test that was as rigorous as the use in HTA of a cost per QALY threshold, some argued that this should be the goal. In a *British Medical Journal* editorial in 2004, for example, the Sheffield health economists Allan Wailoo et al. argued that the NICE guidelines programme confused the two approaches of effectiveness for the individual and cost-effectiveness analysis.⁹² The diplomatic response, in a letter to the editor from Littlejohns and NICE colleagues including Drummond, was that NICE was doing its best and more help from health economists would be welcome.⁹³ They felt that health economists found TAs much easier to engage with than guidelines: it is easy to see that – in view of the extra complexity discussed here – they were right.

88 Mason et al. (1998).

89 Drummond interview.

90 Mason et al. (1998), 23.

91 Drummond interview.

92 Wailoo et al. (2004).

93 Littlejohns et al. (2004).

The prompt recruitment of Eccles and Drummond to NICE ensured that the thinking of their research group quickly shaped NICE's use of economic analysis in guidelines. They brought with them their emphasis on speaking a language to which clinicians would relate. Drummond was one of the committee members who were invited rather than responded to an advert. His previous work had recommended him to Eccles, just as his contributions to DH work, for example on 'Pharmaco-Economic Studies', described in Chapter 1, had commended him to government. (NICE's deputy chair, Tony Culyer, had been his head of department at York – an example of how closely York's Centre for Health Economics was knitted into health policymaking at this time. As Drummond put it, 'health economists have naturally been willing to mix it with the decision makers, in a way that some other disciplines didn't fancy'.⁹⁴) Drummond's research interests made him a good economist to choose:

I was always and still am probably an economist who's more connected with the clinical people and never been a mainstream economist, did a lot of work with clinicians ... I was probably a better fit for the Guidelines Committee than a number of the other people.⁹⁵

A significant difference between TAs and guidelines was that, while the former all considered whether a *new* technology should be adopted or not, the latter also had the scope to examine whether *existing* technologies were cost-effective and should continue to be used. An important strand of policy discussion in the 1990s had revolved around how much could be saved by dropping particular procedures from the NHS: the results have generally been disappointing in terms of savings.⁹⁶ Early on, NICE addressed one of the examples regularly mentioned in the 1990s: in March 2000 the first TA advised that 'prophylactic removal of pathology-free impacted third molars [wisdom teeth] should be discontinued'.⁹⁷ Drummond reports that, at NICE:

we weren't necessarily dealing with whether the NHS would have to spend more money ... guidelines [contained] ... quite a lot of disinvestment or discontinuation ... the needs of the NHS were as much about trying to stop spending some of the money – and in the guidelines you had a balance I think of ... adopt some sort of new thing ... but also can we cut waste, can we be more efficient? ... now NICE have developed these lists of do not do's ... [although] my own family doctor ... he's never read it.⁹⁸

94 Drummond interview.

95 Drummond interview.

96 Coulter and Ham (2000).

97 NICE (2000c).

98 Drummond interview. A recent such list can be found at the NICE (n.d.) 'Cost saving guidance' web page. The list has just 14 entries and the largest saving, use of a superior foot ulcer dressing allowing less frequent clinical review, amounts to £22,000 per 100,000 population: using the list does not have a dramatic impact on NHS budgets.

Drummond hints here, of course, at the familiar ‘implementation problem’, suggesting the importance of making guidelines palatable to clinicians, and possibly indicating one reason why more benefit has not come from NICE’s guidance to discontinue certain therapies.

Economic analysis has certainly made a difference to NICE guidelines. For example, all but one of the guidelines published in eight months of 2015 used *de novo* economic analyses (and not just reviews of the economic literature) to help answer at least one of their key clinical questions.⁹⁹ Examples from 2015 alone include a study comparing the cost-effectiveness of surgery alone with surgery plus chemotherapy in bladder cancer (recommending the latter), and a number of studies (each) to support the guidelines on Gastro-oesophageal reflux disease: children and young people (NG1) and on Diabetes in pregnancy (NG3).

One important example of the use of cost-effectiveness analysis was Drummond’s work for NICE in 2014 ‘checking the economics was right in the big statins guideline’, as he put it.¹⁰⁰ This guideline supported the clinically controversial view that everyone with a 10% or greater ten-year risk of developing cardiovascular disease should be prescribed statins as prophylaxis. Faced with concerns that the high number of patients thus drawn in would have a significant budget impact, cost-effectiveness analysis was an obvious choice. Its results in this case strongly supported the NICE recommendation.¹⁰¹ NICE has since revised this guideline and currently advises supporting patients to attempt lifestyle changes before prescribing statins.¹⁰²

A picture emerges of both the benefits and the challenges of attempting to build cost-effectiveness into guidelines. For Drummond, a health economist at the centre of events, the benefits of extending cost-effectiveness analysis from HTA into guidelines included a much greater opportunity to present it in ways that fostered co-operation with clinicians and promoted their compliance with the advice offered.¹⁰³ It was also valuable to look at a whole patient pathway, not just a single technology: guidelines thus opened up more areas to economic analysis. Drummond also valued the opportunity to look at disinvestment from ineffective technologies as well as investment in new ones – something which spares patients from procedures of doubtful value as well as potentially saving money (the actual savings not being very impressive). Challenges, however, included the tension between emphasising the quality of individual care, and equity, fairness or efficiency. Unlike TAs, the recommendations of guidelines were not binding for the NHS and so might be expected to have less impact.

99 Drummond (2016).

100 Drummond interview. For the guideline itself see NICE (2014a).

101 Drummond (2016).

102 NICE (2023).

103 Drummond (2016).

Guidelines for whole services

Like TAs, guidelines are ‘policy’. In Klein’s terms, discussed in Chapter 1, they may be ‘service policies’ (how a service should be designed) or ‘practice policies’ (how to treat an individual). NICE’s position statement quoted at the start of this chapter addresses only the latter, but, as we shall see, guidelines have, from NICE’s earliest days, often addressed the former too.¹⁰⁴ Guidelines about whole services have the potential to raise politically difficult issues about affordability (although practice guidelines can too, as we saw in the case of statins).

Rather than warning NICE off this turf, however, DH has at times specifically called on it to provide service guidelines. The reasons for this stem – at least in part – from the 1997 New Labour philosophy we saw Margaret Jay set out in Chapter 2: a three-part architecture of standard-setting, service commissioning and inspection. The setting of standards was not reserved to NICE: the 1997 White Paper set out how National Service Frameworks [NSFs] would also play a role.¹⁰⁵

What remained much less clear was who would set which standards: NICE or the writers of NSFs (DH itself). Cancer is the most intriguing case, having a NSF *avant la lettre*, in that Mike Richards, appointed the first DH ‘Cancer Czar’ (officially ‘National Clinical Director’) in 1999, describes the 1995 Calman-Hine Report on cancer services as the NSF for cancer.¹⁰⁶ In Richards’ words, this report:

gave a very broad framework for what should happen with cancer ... what was needed was more detailed guidance on individual cancer types ... Where does that differ from a clinical guideline? In that it really tries to set out what the shape of services should be, and the case for a multi-disciplinary team, the case for reconfiguring surgical services...¹⁰⁷

This was the genesis of the Improving Outcomes Guidance for cancer services, produced in a methodology apparently designed by Richards himself and one which would certainly have failed Eccles’ tests: it began with expert consensus on the desirable components of any town’s service, and subjected the emerging themes to ‘evidence-based reviews ... so it ended up being evidence-based, wherever there was evidence’. Richards and his colleagues worked through the different kinds of cancer in this way,

and once NICE had been established, it was somewhat thrust upon them, taking this programme on – because it made no sense for it to sit in isolation

104 For example NICE (2002a) says that it covers ‘how best to organise mental health *services* in order to help people with schizophrenia’ (p. 35, emphasis added) and, for instance, calls on ‘local health communities [to] review their existing service provision ... against this guideline’, proceeding to give further advice on how (p. 26).

105 DH (1997), 49.

106 Mike Richards, interview, 3 October 2019. See DH (1995).

107 Richards interview.

once there was a national institute. If I'm being frank, they hated it because it wasn't their own methodology. ... I would say it was really important in terms of driving change in cancer.¹⁰⁸

Baker, working as the Director of a cancer network at this point and advising on the cancer service guidelines, endorses this account: '[NICE] criticised our document for saying it wasn't a clinical guideline and we said "no it isn't, it's an entirely different beast designed to improve the organisation of care"'.¹⁰⁹ Richards, clearly an enthusiast for service guidance, wishes it had been the norm across the board, not just in cancer:

if you haven't got the basic shape of the service right in the first place, [implementing the clinical guidelines is] less likely to happen. So I think the combination of having service guidance and a clinical guideline, that's optimal to me.¹¹⁰

However, although coronary heart disease and mental health acquired their own NSFs and Czars soon after cancer, they were not to follow it down this road of service guidelines. NICE published a series of 'cancer service guidance' documents but never one for another medical condition.¹¹¹

NICE does publish 'Quality Standards', short distillations of the key messages in NICE guidelines: 198 of these are current and posted on the NICE website.¹¹² While the majority of the content is practice guidance, service guidance is also included (or implied – the boundary between the two is inevitably fuzzy), for example that 'Adults with suspected heart failure have specialist assessment and transthoracic echocardiography within 2 weeks of referral' if certain clinical signs are present.¹¹³ In an echo of Richards' view (above) that service guidelines create the context in which practice guidelines can be (more easily) followed, NICE Quality Standards prompt commissioners to include specific things in the services they specify, and providers to put 'systems' in place for the standard to be achieved. NICE clearly aims to influence the shape of services by this route. Government sensitivity about the implications is suggested by the section of the Health and Social Care Act 2012 devoted to NICE Quality Standards, which provides that they only have effect, and may be published, if endorsed by NHS England.¹¹⁴

108 Richards interview.

109 Baker interview.

110 Richards interview.

111 Baker interview. Archival traces of the cancer service guidance remain, for example in NICE (2016), which describes itself as 'an update of the NICE cancer service guidance on improving outcomes in haematological cancers (published October 2003)'.

112 Andrew Lansley, then the Secretary of State for Health, committed NICE to produce Quality Standards in a White Paper: DH (2010): see Klein R (2013), 281, 296.

113 NICE (2011).

114 Health and Social Care Act 2012, s. 234. In the case of Quality Standards on public health, the power to approve lies with the Secretary of State.

The most famous, or notorious, NICE guidelines for whole services were the ‘staffing guidelines’ prepared in 2013–15. Their notoriety revolves around the government’s suppression of NICE guidance. Thanks in part to the *Health Services Journal*, there is a fair amount in the public domain and only a brief summary will be given here, drawing on our interviews with some of the participants.¹¹⁵

NICE had discussed staffing before, notably in its cancer services guidance going back at least to 2003.¹¹⁶ To illustrate the form a typical reference to staffing might take, the 2016 guideline on haematological cancers spoke of the need for multidisciplinary teams, listed the essential professions these should comprise, and, most prescriptively, specified that units should ‘have consultant-level specialist medical staff available 24 hours a day ... the equivalent of at least 3 whole-time consultants’.¹¹⁷ (That the only minimum staffing number given is one for consultants might tell us something important about the dominance of the hospital doctor’s perspective in the research NICE examined, or in the relevant GDG. Anyone who works in health policy will have been struck by how frequently a medical committee’s proposed policy solution – rightly or wrongly – is ‘more consultants’.)

The short-lived NICE staffing guidelines series went beyond this, however. In 2013 DH commissioned NICE to prepare ‘guidance on safe staffing levels’ in response to a recommendation in the Francis Report on the care provided by the Mid-Staffordshire NHS Foundation Trust.¹¹⁸ NICE undertook £1M of work, and two documents were published, before government began to get cold feet in the summer of 2015.¹¹⁹ Despite official denials by both DH and NICE, it is clear that Simon Stevens (then Chief Executive of NHS England) pressed NICE not to publish its A&E staffing guidance: this led to a decision to transfer the preparation of safe staffing guidance to a new agency, NHS Improvement (under the closer control of DH), announced by Jeremy Hunt (then Secretary of State for Health and Social Care) shortly afterwards. It is clear too that Hunt overruled NICE’s fallback position of publishing the work on A&E without the status of guidance.

What new light did our interviewees shed on these events? Baker forthrightly condemned the staffing guidance programme as a ‘ludicrous programme, no evidence, seriously compromised the NICE brand’, a product of Francis not being properly critical of the evidence given to his Inquiry, and Hunt finding it politically necessary to agree to Francis’ recommendations in full. Baker’s main objection

115 See *Health Services Journal* (2015) for the government emails secured by the *HSSJ*’s Freedom of Information (FOI) request.

116 NICE (2016) gives an example.

117 NICE (2016).

118 NICE (2014b); Mid-Staffordshire NHS Foundation Trust Inquiry (2013). The impression that the Mid-Staffordshire scandal and the Francis Report made on public opinion was second only to the impact of the 1997 Bristol scandal and Kennedy Report, discussed earlier: see Klein (2013), 295–298.

119 For the £1M, see *Health Services Journal*, 14 October 2015, Exclusive: NICE safe staffing U-turn followed meeting with Hunt’s office. The publications were NICE (2014c) and NICE (2015). NICE (2014c) was the first and apparently last NICE publication in the ‘staffing guidance’ series.

was that the science to make this an evidence-based activity did not exist: there was ‘no attempt to suggest actually how on earth are we going to know what [safe staffing guidance] is since no-one in the world has ever done it’.¹²⁰ Dillon comments that: ‘DH were perfectly entitled to ask us to stop, but I wanted it in writing, so that it would be clear where responsibility for cancelling lay’.¹²¹

Stevens, Una O’Brien (Permanent Secretary at DH at the time) and Jean Gaffin (a non-executive member of NICE committees) largely confirmed the existing narrative. O’Brien explained how the then Chief Nursing Officer, Jane Cummings, had been instrumental in persuading Hunt and other ministers that staffing guidance had to be evidence-based and that, accordingly, the job should be given to NICE: ‘... this would give the guidance rigour. That was a difficult time with lots of edgy conversations as I recall they were tempted to set the standards themselves’.¹²²

Gaffin adds the perspective of a member of NICE’s staffing guidance committee, emphasising the politically charged nature of the task and the (linked) need for speed:

that was highly political. ... the Francis report came out, criticising the NHS, and the Department had a lot of very fast reactions to it, and one of them was to say, “we are going to solve the staffing issue by developing guidelines for safer staffing.” And it was all going to be done the day before yesterday, so I [was told] ‘we’re forming this committee very quickly, we’re not going through the usual application procedures because it’s got to start soon ... It was very, very difficult to get the evidence’.¹²³

What is the long-term relevance of the staffing guidance episode? It highlights the longstanding issues of the affordability of NICE guidance for the NHS, NICE’s independence from government, and the scope for conflict between these. Insiders like Baker and Gaffin, with the greatest insight into the guideline production process, draw our attention, too, to the challenges of finding evidence.

Despite the highly charged political atmosphere following the Francis Report and its disturbing findings about the Mid-Staffordshire Trust, the staffing guidance episode did not develop into a crisis, a turning point in NICE’s history, for example in its relations with NHS England or DH. All the key players (Hunt, Stevens and Dillon) wanted it not to and successfully finessed this conflict away. One thing did change: its 2013–15 staffing guidelines activity represents the high-water mark of NICE’s influence on NHS service organisation. Thereafter, there was a return to a more exclusive focus on practice guidelines, with any implications for service design handled discreetly within these. The question of whether, as Richards

120 Baker interview.

121 Andrew Dillon, personal communication.

122 Una O’Brien, interview 2 February 2022.

123 Jean Gaffin, interview 25 November 2019, where she also notes the use of evidence from Australia.

believes, the publication of service guidelines would add something valuable, would repay further investigation.

Guidelines and patients

The relationship of NICE guidelines to the patients whom they were supposed to benefit had various components. We have seen in this chapter how patients would be incorporated in each GDG – and that the dynamics of making sure they were heard were not straightforward. In the words of McCandlish:

there were organisations such as the NCT or BLISS ... SANDS, and similarly the children’s charities ... The model was to find people ... from those communities to come to be part of the group. It was really hard though, because there ... was lip-service really to how it would be to be the non-professional member on the group, and it would be very determined by who your chair was, how much you would get to say, I think. It was much smaller, the P[atient and] P[ublic] I[nvolvement] support from NICE ... at that time.¹²⁴

Fiona Loud, who was Director of the Kidney Alliance from 2007, also recalls a lot of variability in the amount of attention paid to the patient voice, again mentioning how critical the attitude of the GDG chair was.¹²⁵ Despite this variable experience in GDGs, McCandlish was optimistic, at least for her sector, that patient or service user representatives were making an impact:

... in maternity care we have very knowledgeable and vocal experts. In terms of who would come on these groups from NCT, or MumsNet now and places like that, these people are probably more knowledgeable scientifically than many of the health professions are, so it’s not a pushover.¹²⁶

Moreira et al., called in by NICE to study these group dynamics in 2006, shed light on how much different kinds of participant contributed to each of four ‘domains’ they identified (science, practice, politics and process), reporting that the ‘patient role was one of being called in to “ground” and mediate disputes between primary care doctors, secondary care specialists and methodologists about “practice”’.¹²⁷ To illustrate this kind of dispute, Rawlins mentioned that:

when we did a guideline on Parkinson’s disease, there were too many neurologists on it. One of the things was before your patients were started on

124 McCandlish interview. NCT is the National Childbirth Trust; BLISS the leading UK charity for babies born premature or sick, and SANDS the Stillbirth and Neonatal Death Society.

125 Fiona Loud, interview 24 August 2022.

126 McCandlish interview. mumsnet.com describes itself as ‘the UK’s biggest network for parents’.

127 Moreira et al. (2006).

[the drug] they should be seen by a neurologist. The GPs were up in arms and said, “Why? There’s an eight-month waiting list in my area!”¹²⁸

A second component of patient involvement was the input of patient groups at the consultation stage of each guideline. And a final one is that guidelines have, with increasing emphasis, been seen at NICE as documents written for patients as well as professionals to use. Whether or not intended to be read primarily by patients, the aspiration from the start was that guidelines should be patient-centred, focussing on what mattered to them rather than any more abstract measure of, for example, health or recovery. Thus McClarey’s justification for wanting ‘the nursing perspective’ to find a place in NICE’s recommendations was that she saw this perspective as concentrating on ‘how it was for the patient in the frontline, which of course doctors, physios, all the others knew as well’.¹²⁹ The claim – quickly qualified, presumably out of inter-professional diplomacy – that nurses knew this best of all is worth noting in passing.

A concentration on patients’ needs could be expressed in various ways. For example McClarey recalled how:

A friend of mine had a cancer and ... said to me, “the best thing for me is ... I’ve got a [phone] number [of] a cancer nurse, and she will tell me what the next stage is, what this thing means.” That’s part of the NICE guidelines, I wouldn’t say I was responsible for that, but ... I felt really chuffed.¹³⁰

In another example, Loud points to Clinical Guideline 169 on acute kidney injury, for which she served on the GDG, describing how they led to improvement in the detection of this frequently undiagnosed condition: ‘changes there which have [been] perpetuated to this day’.¹³¹

NICE was not always so successful. To concentrate too much on failures or controversies would risk leaving a misleading impression, but some episodes which have left an effect on the public’s picture of NICE are worth briefly recounting. First, implants of vaginal mesh or tape for the treatment of pelvic organ prolapse or urinary incontinence have, for some patients (about 1 in 15 by some estimates), had debilitating complications causing intense pain and recurrent infections. NICE entered this territory early, with a TA on tension-free vaginal tape for stress incontinence published in 2003. This was replaced by a succession of guidelines, most recently, in 2019.¹³² The accumulation of evidence about complications has resulted in growing caution at NICE: the 2019 text calls for surgery to be used only when non-surgical approaches have failed or been

128 Rawlins interview, 18 September 2019.

129 McClarey interview.

130 McClarey interview.

131 Loud interview. The reference is to NICE (2013).

132 The current guideline is NICE (2019): the trail of earlier guidance can be followed in Appendix 2.

rejected, for counselling about the possible complications, and for the recording of outcomes in a national registry (a regular recourse for treatments about which doubt persists).

Not all patient groups found the 2019 guideline acceptable. Speaking to the *Guardian*, Kath Sansom, of the campaign group Sling the Mesh, said:

We are appalled that despite ... the obvious suffering of many women, these guidelines are no different from what was published in 2003. They ... clear the way for the next generation of women to be harmed. We told our stories and NICE ignored us.¹³³

There was similar disappointment from the All-Party Parliamentary Group on Surgical Mesh, and from Baroness Julia Cumberledge in her capacity as chair of the Independent Medicines and Medical Devices Safety Review – a government initiative set up in 2018 partly in response to patient-led campaigns on the use of surgical mesh.¹³⁴

A second guideline which did not land well with some of the patients affected was the 2007 one on ‘chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy)’ – even the name of the condition being controversial.¹³⁵ Baker’s account suggests NICE had ‘allowed the psychiatrists on the committee to subvert it between draft and final publication’. Apparently all reference to severe illness was dropped and the only treatments that remained were those involving cognitive behaviour therapy (CBT), with the result that the patient members of the Committee resigned.¹³⁶

‘Graded exercise therapy’ (GET) was also advocated, but the problem with CBT and GET was the underlying ‘biopsychosocial’ model of what ME/CFS was. The guideline produced strong protest in some parts of the ME/CFS patient community, and apparently even some hate mail. As a subsequent Director of the guidelines work, Baker has an interest in comparing the 2007 guideline unfavourably with the one produced under his management, but on the published evidence the shortcomings of the earlier guideline are clear. Dillon recalls that:

In the case of Chronic Fatigue Syndrome it was very definitely the patient community that were angry that NICE simply hadn’t understood the nature of the condition or were recommending things [patients] didn’t think were appropriate.¹³⁷

133 *Guardian*, 2 April 2019, Vaginal mesh: new guidelines insufficient, say campaigners.

134 Independent Medicines and Medical Devices Safety Review (n.d.).

135 NICE (2007).

136 Baker interview.

137 Dillon interview.

In November 2020 NICE published for consultation a 356-page ‘evidence review’ discussing 55 randomised trials, and patient experience, comparing the effectiveness of non-pharmacological interventions for adults, children and young people diagnosed as having ME/CFS.¹³⁸ This report acknowledged that NICE’s previous recommendations had been controversial. It advised that CBT could not be regarded as a curative intervention, though it might help some patients with managing symptoms. GET fared worse still, the report concluding that it should not be offered to people with ME/CFS. These findings were repeated in NICE’s published guideline after the consultation.¹³⁹ An editorial critique of the guideline’s methodology in a scholarly journal brought a firm response from scientists involved in its production.¹⁴⁰

This example shows NICE updating a guideline (something that happens regularly, as the list in Appendix 2 shows). Looking at this with the lens of Morerira et al.’s four fields, the case of ME/CFS looks like one where the grounds for review were not only – perhaps not even principally – science (the availability of new data or the emergence of new therapies), but more to do with practice (a growth in the use of the problematic therapies, and the basing of welfare benefits policy on a biopsychosocial model, to the detriment of people with ME/CFS) – but above all, because of politics: the groundswell of patient opposition.¹⁴¹ There is an echo of this ‘biopsychosocial’ versus physiological controversy with long Covid, though on this occasion the medical experts appear much more open to the physiological model. As long as the impulse to dismiss conditions of complex or obscure aetiology as ‘all in the mind’, or society’s propensity for victim-blaming, persist, similar cases will crop up.

Finally and more briefly, the case of Lyme disease is another where a NICE guideline has gone down badly with some patients affected.¹⁴² Lyme, a rare tick-borne infection, leaves a minority of patients with long-term tiredness, aches and loss of energy.¹⁴³ Stella Huyshe-Shires at Lyme Disease Action, someone who personifies McCandlish’s description of the patient advocate who is ‘probably more knowledgeable scientifically than many of the health professions’, served on the GDG and reported that the guideline has helped ensure that patients get the best treatment at first diagnosis. Nevertheless:

I know a lot of patients didn’t like it because they thought that ... “in the US doctors say they have cured lots of patients by giving them months and months of antibiotics. But there isn’t the evidence. Some patients did feel

138 NICE (2020).

139 NICE (2021).

140 For the critique see White et al. (2023), and for the response, Barry et al. (2024).

141 For the welfare benefits implications see for example the ministerial statement in House of Commons, Parliamentary Debates 17 January 2012.

142 NICE (2018).

143 NHS website (n.d.) ‘Lyme Disease’.

that private clinics have got evidence but the NICE process doesn't use it. But the private clinics don't produce the information.¹⁴⁴

A common thread here, and perhaps in other cases such as back pain, is how – especially when the aetiology of the condition is complex or obscure and the evidence for effectiveness of interventions is poor – NICE can be caught between inflexible positions taken up by groups of doctors and of patients. These battles would have happened anyway, but the existence of NICE means its guidance becomes part of the battlefield. On our evidence, NICE's approach to guidelines makes the areas of controversy more explicit (Eccles' point above) and maps out a systematic approach to resolving them. It does not in itself, of course, remove the disagreement.

How guidelines have changed

Comparison between NICE's very early and more recent guidelines calls for some library research, as NICE removes withdrawn guidelines from its online presence.¹⁴⁵ Here we briefly compare the oldest guideline, on schizophrenia (hereafter CG1), with NICE's most recent schizophrenia guideline, from 2014 (hereafter CG178).¹⁴⁶ The style and content of CG1 have a certain air of special care being taken, as though it had been important to make the first product a success and an exemplar. While the guideline was commissioned from NICE's National Collaborating Centre for Mental Health (whose co-director, Dr Tim Kendall, chaired the schizophrenia GDG), CG1 spells out how (at this period of NICE's history) members of its Guidelines Advisory Committee 'oversee the development of the guideline and take responsibility for monitoring its quality'.¹⁴⁷ On this first guideline, those selected for this included the leading figures in the Committee: Eccles, Drummond, and the Director of NICE's Patient Involvement Unit, Marcia Kelson, whom we met in Chapter 4: nothing was being left to chance.¹⁴⁸

As further evidence of CG1's special status, we have already referred to the way it set out the justification for the choice of grading scheme applied to evidence, quoting the intellectual authorities (such as the American AHCPR and DH's Clinical Outcomes Group) for the approach selected.¹⁴⁹ Arguably very few people involved in schizophrenia as a patient, carer or health care professional would be interested: the inclusion of this material reads more like NICE setting out its claim for all its future guidance to be taken seriously.

144 Stella Huyshe-Shires, interview 29 June 2023.

145 All published and subsequently withdrawn guidelines are included in Appendix 2 to this volume.

146 NICE (2002a, 2014d).

147 NICE (2002a), 33. The following month (January 2003), the GAC was replaced by Guidelines Review Panels for each subject area.

148 Drummond's interview describes his input to NICE (2002a) and some of the arrangements for its production.

149 NICE (2002a), 29–30.

Justifiably describing 2002–03 as their ‘busiest and most productive year so far’, NICE’s 2002–03 Annual Report, like CG1 itself, demonstrates the pride taken in publishing the first guideline for which it had been wholly responsible:

This year was marked particularly by the publication of the first NICE clinical guideline. ...The guideline on schizophrenia ... resulted from a collaboration between health professionals, patients and academics, each of whom brought their individual knowledge and experience to bear. The resulting recommendations, put into practice by the NHS, will make a very real difference to people who have too often been poorly served...¹⁵⁰

Twelve years later, the publication of CG178 was understandably a much more routine matter than CG1 had been. The new document was essentially a scheduled update to the previous schizophrenia guideline of 2009, itself of course an update of CG1.¹⁵¹ The update involved going back to the evidence, leading to changed recommendations on, for example, peer support and self-management, preventing psychosis, and service-level interventions. A comparison with the 2002 text shows that, while new clinical evidence had emerged (e.g., about new drugs or use cases for existing drugs), more of the changes were more addressed at examining the evidence for interventions which had become common since 2002, in some cases following government policy initiatives. These included assessment for PTSD at first presentation, a greater emphasis on psychological interventions such as CBT, and the monitoring of physical health by the secondary care team for the first twelve months.

Illustrating the development of guidance from 2002 to 2014, the section of CG1 on treatment of the acute episode has nothing to say on CBT beyond recommending its availability as a treatment option (a recommendation getting an ‘A’ grading for being based on a RCT). By 2014 (in fact, by the 2009 document, which was not further updated in 2014 on this), CBT merits 14 lines discussing how a patient should receive at least 16 one-to-one sessions, with detailed recommendations about its content. Here, the updating of guidance reflected new research and its dissemination, for example adding that CBT should ‘follow a treatment manual (with evidence of efficacy from a clinical trial, if possible)’.¹⁵²

It is beyond the scope of this volume to comment on the clinical validity of any NICE guideline. We do note, nevertheless, that a review of CG1 by an eminent international group of academic psychiatrists found that it had the highest ‘methodological validity’ of 24 guidelines studied, referring to its ‘rigour of development and applicability ... its recommendations were evidence-based with a clear description of how evidence was synthesised’.¹⁵³ British medical academic comment on

150 NICE (2003b).

151 NICE (2009).

152 NICE (2014d), 22.

153 Gaebel et al. (2005).

CG178 disagreed about whether NICE was right, or ‘biased’, to accept a ‘lower’ standard of evidence in support of CBT than for drug treatments, an example of the form taken by some of the ‘evidence wars’ mentioned earlier.¹⁵⁴

In conclusion, there were no radical changes between 2002 and 2014 in the general approach of guidelines. CG178 was somewhat shorter and simpler, partly because it could refer to other documents for amplification in a way not possible in 2002. The two documents, however, tackled the same task using very similar approaches. Guidelines, a key area of NICE’s work, are a strong example of the phenomenon noted in Chapter 3 of NICE laying down ways of working very early in its existence which continue to set the pattern of activity long afterwards.

Conclusions: NICE guidelines as an episode in UK science policy

What is the relevance of NICE guidelines for the study of policymaking in the UK? They represent the use of science for policymaking. Simultaneously, the development of NICE’s methods for doing guidelines represents the making of policy for science. Accordingly, this concluding section discusses two sets of questions, the first about how and why NICE’s use of science for guidelines has developed as it has, and the second about what the production of NICE guidelines tells us about the UK’s science policy. (We take that phrase to mean UK government policies about how much research it should fund, of what kinds, through what relationships with the world of research, to solve what problems, and similar matters.¹⁵⁵)

How has NICE used science in its guidelines and why?

NICE has taken EBM (and evidence-based policymaking, as already discussed) further, and spent more on it, than almost anyone else. Its guidelines programme (and its HTA programme) is one of the world’s most extensive, and NICE has succeeded in winning a global reputation for the quality of this work. NICE has, unusually, also tried to build cost-effectiveness into its guidelines. This has been a major intellectual investment. The production of NICE guidelines also involves elements of deliberation and public involvement. These three elements – evidence of effectiveness, evidence of cost-effectiveness and public deliberation – correspond to the three forms of knowledge identified by Moreira (2012) under the labels of ‘laboratory’, ‘market’ and ‘forum’.¹⁵⁶ His contention that such ‘knowledge – and the collective negotiation of what counts as such – has become central to the governance of health care’ is surely very true in the case of NICE, and exemplified in the way it produces guidelines.

Our biggest concern in this chapter has been with the knowledge created by Moreira’s ‘laboratory’ – shorthand for ‘controlled, mechanism-based procedures

154 See Taylor and Perera (2015), and the response by Kendall et al. (2016).

155 British Academy (2019), 4.

156 Moreira (2012).

of knowledge making', in particular, as we observed earlier in this chapter, the randomised controlled trial and the systematic review. It is important analytically not to follow the policymakers' tendency to reify these procedures into something neutral and objective. Rather, their adoption represents a choice involving political assumptions about whose evidence is most valid, and having political implications for the decisions that are taken. For example, as Will and Moreira have argued, this approach to using evidence tends to 'skew policy towards well-documented and funded health care problems to the detriment of less visible, singular conditions'.¹⁵⁷

This way of looking at the world is, for Porter, the product of 'a particular imaginary of "good governance" that is attached to impersonal judgement based on the systematic documentation of the population's lives'.¹⁵⁸ It is a way of thinking rooted in, and contributing to, the particular type of democratic, pluralistic society existing in Britain in the 1960s and 1970s, with its own view of the moral and political functions of science, of 'the laboratory'.¹⁵⁹ Drawing on our earlier work on the origins of NHS R&D, we see Holland's 'social epidemiology' as a particularly clear example of this world view.¹⁶⁰

The three forms of knowledge can pull in contradictory directions. NICE has invested heavily in ways to combine the 'effectiveness' and 'cost-effectiveness' strands in guidelines, and codified this in procedure manuals: it is not intellectually easy but it is possible, and documented. The tension really begins in earnest when the third strand, deliberation, comes into play. For guidelines, this is when evidence such as a systematic review arrives at a GDG. We have, in this chapter and earlier, seen participants commenting on the difficulty of reconciling all the different inputs at this point.

One of Moreira's arguments about this tension is that it arises because the outputs of the 'laboratory' become 'entangled' here with political calculation: that the GDG has to think about 'the devices and procedures that enable [evidence] to be translated into health care policy'.¹⁶¹ His own ethnographic observation of a NICE GDG at work shows them discussing how, since one of the relevant clinical trials was 'politically important', they ought to say why they had not given it more weight. This observation about translation into policy is true enough, but tensions between the evidence of effectiveness and cost-effectiveness and everything which the deliberators in the 'forum' bring to the discussion can in fact arise for any number of reasons. NICE guidelines have provoked controversy with: patients (ME/CFS; Lyme disease), practitioners (low back pain; repair of abdominal aortic aneurysms), the NHS (number of IVF cycles) and ministers (staffing guidelines). As Dillon put it, 'We have managed to annoy just about everybody'.¹⁶²

157 Will and Moreira (2010).

158 Porter (1995).

159 See Moreira (2012), 88.

160 Atkinson et al. (2019); Holland et al. (2007).

161 Moreira (2012), 109.

162 Dillon interview.

What do NICE guidelines show us about UK science policy

NICE guidelines, although this is not immediately obvious, are a good field from which to learn about UK science policy: their subject matter – health and health care – is closer to citizens’ daily concerns than some other policy areas where science is important, like energy or national security. It is easier when looking at NICE guidelines than at some more arcane field to see some of the issues. Firstly, how science and policy frame issues differently, as we observed earlier in the chapter when looking at topic selection. It is necessary to understand the implications of this if we are to understand the limits of evidence-based policymaking. Most importantly, as Claire Craig put it in a recent British Academy report on science policy in the UK, there are frequently situations:

where the stock of accessible scientific knowledge ... doesn’t match the immediate policy question ... [presenting a] choice between a reasonably certain answer to a partial question and a very uncertain answer to a ‘better’ ... question. Scientists may have the luxury of being able to define the [issue] in a way they believe may be most tractable to science; while policy-makers have to fight very hard to frame the issues ... in a way that makes them tractable to policy, and sometimes simply cannot achieve it.¹⁶³

This is a very good description of the problem of having to make a decision in conditions of uncertainty, which is so common in the preparation of NICE guidelines. Following from this first point are some considerations about how the producers of evidence and its consumers in the policy world can bridge this gap in order to engage productively. It now seems common ground among those working on the nexus between evidence and policy that the best solutions involve:

mechanisms for brokerage and ‘glue’ ... forms of connective tissue through which various institutional bodies can articulate evidence, problems, needs, goals and ideas about the future to one another. These connective tissues are vitally important ... Therefore, a central challenge for government is to [ensure] that policymakers can democratically manage shared ideals and potential tensions that might exist between them.¹⁶⁴

NICE guideline production is an important instance of such a brokerage mechanism. It has to manage and compare evidence of varying kinds – as we discussed earlier in the chapter – and reconcile competing problems and goals. Which aspects of the treatment of schizophrenia are most important to patients and their carers? Which to the psychiatrists? And which are tractable to current science?

163 Craig (2019), 41. See also Cairney (2016).

164 British Academy (2019), 4.

It had been DH itself, or rather its predecessor the DHSS, that had commissioned the Kogan research referenced earlier in this chapter into this problem of bridging the gap between evidence and policy, as long ago as the 1970s.¹⁶⁵ Against the managerialist, market-oriented approach to the use of research in policy adopted by the Rothschild Report, or the pure interest-led focus of the Medical Research Council at the time, Kogan et al. were pioneers of this more deliberative, interactive approach.¹⁶⁶ While scholars such as Davies are mainly pessimistic about DHSS and its successor's capacity to take Kogan's insights on board, at least some elements of this more interactive view of research and policy can be seen in the way NICE has used evidence in guidelines.¹⁶⁷ To have methodologists, medical academics and patients and carers sitting at the same table in a GDG is a significant step in this direction. Less promisingly, NICE has not always managed to improve much on the DHSS in its inability to let the NHS find a voice in the discourse between policy and research.¹⁶⁸

In conclusion, the 22 years of NICE guidelines form an excellent source in which to study some of the sharpest questions of health politics: the interplay of different powerful stakeholders including government and the medical profession; the growing influence of knowledge about effectiveness, cost-effectiveness and deliberation; and the tensions between these sources of authority. Since guideline production is a devolved form of policymaking, guidelines place NICE in a central position in the present-day governance of health. They also form the heart of NICE, revealing most of its core ideas.

Bibliography

Primary sources

- Bristol Royal Infirmary Inquiry (2001) *Learning from Bristol: The Report of the Public Inquiry into Children's Heart Surgery at the Bristol Royal Infirmary 1984–1995*. Command Paper: CM 5207 (London: HMSO).
- DH (1995) *A Report by the Expert Advisory Group on Cancer to the Chief Medical Officers of England and Wales. A Policy Framework for Commissioning Cancer Services – The Calman–Hine Report* (London: Department of Health).
- DH (1997) *The New NHS Modern. Dependable* (London: HMSO).
- DH (2010) *Equity and Excellence: Liberating the NHS* (London: HMSO).
- Guardian*, 2 April 2019, Vaginal mesh: new guidelines insufficient, say campaigners.
- Health and Social Care Act 2012.
- Health Services Journal*, 14 October 2015, Exclusive: NICE safe staffing U-turn followed meeting with Hunt's office.
- Health Services Journal 'NICE email bundle' (2015) (Last accessed 7 October 2024).

165 Kogan et al. (2006).

166 The Rothschild Report of 1973 set a new framework for British government science funding, in a purchaser-provider model. See Davies (2019).

167 Davies (2017) discusses these three approaches to the science/policy issue and their historiography.

168 Davies (2017), 285.

- House of Commons: Third Standing Committee on Delegated Legislation (1999) Wednesday 10 March 1999: National Institute for Clinical Excellence (Establishment and Constitution) Order 1999 4.30 pm.
- House of Commons, Parliamentary Debates 17 January 2012 (Last accessed 22 March 2024).
- Independent Medicines and Medical Devices Safety Review (n.d.) (Last accessed 21 March 2024).
- Mid-Staffordshire NHS Foundation Trust Inquiry (2013) *Report of the Mid Staffordshire NHS Foundation Trust Public Inquiry* (London: TSO) (Last accessed 7 October 2024).
- NHS website (n.d.) 'Lyme Disease' (last accessed 22 March 2024).
- NICE (2000a) *TA10 Guidance on the Use of Inhaler Systems (devices) in Children under the Age of 5 Years with Chronic Asthma* (London: NICE).
- NICE (2000b) *Annual Report 1999–2000* (London: NICE).
- NICE (2000c) TA1 Guidance on the extraction of wisdom teeth.
- NICE (2002a) *CG1 Schizophrenia: Core Interventions in the Treatment and Management of Schizophrenia in Primary and Secondary Care* (London: NICE).
- NICE (2002b) *Annual Report 2001/2002 and Summary Financial Statement* (London: NICE).
- NICE (2003a) A Guide to NICE (Last accessed 2 August 2024).
- NICE (2003b) *Annual Report 2002/2003 and Summary Financial Statement* (London: NICE).
- NICE (2004) *Annual Report 2003–2004* (London: NICE).
- NICE (2006) *Guidelines Development Methods Manual* (London: NICE).
- NICE (2007) *CG53 Chronic Fatigue Syndrome/Myalgic Encephalomyelitis (or Encephalopathy): Diagnosis and Management* (London: NICE).
- NICE (2008) *Social value Judgements: Principles for the Development of NICE Guidance*, second edition (London: NICE).
- NICE (2009) *CG82 Psychosis and Schizophrenia: Management* (London: NICE).
- NICE (2011) *QS9 Chronic Heart Failure in Adults* (London: NICE).
- NICE (2013) *CG169 Acute Kidney Injury: Prevention, Detection and Management* (London: NICE).
- NICE (2014a) *CG181 Cardiovascular Disease: Risk Assessment and Reduction, Including Lipid Modification* (London: NICE).
- NICE (2014b) *Annual Report and Accounts 2013–14* (London: NICE).
- NICE (2014c) SG1 Safe staffing for nursing in adult inpatient wards in acute hospitals: Safe staffing guideline (Last accessed 26 March 2024)
- NICE (2014d) *CG178 Psychosis and Schizophrenia in Adults: Prevention and Management* (London: NICE).
- NICE (2015) *NG4 Safe Midwifery Staffing for Maternity Settings* (London: NICE).
- NICE (2016) *NG47 Haematological Cancers: Improving Outcomes* (London: NICE).
- NICE (2016) *NG56 Multimorbidity: Clinical Assessment and Management* (London: NICE).
- NICE (2018) *NG95 Lyme Disease* (London: NICE).
- NICE (2019) *NG123 Urinary Incontinence and Pelvic Organ Prolapse in Women: Management* (London: NICE).
- NICE (2020) *Myalgic Encephalomyelitis (or Encephalopathy)/Chronic Fatigue Syndrome: Diagnosis and Management. [G] Evidence Reviews for the Nonpharmacological Management of ME/CFS* (London: NICE).
- NICE (2021) *NG206 Myalgic Encephalomyelitis (or Encephalopathy)/Chronic Fatigue Syndrome: Diagnosis and Management* (London: NICE).

- NICE (2023) *NG238 Cardiovascular Disease: Risk Assessment and Reduction, Including Lipid Modification* (London: NICE).
- NICE (2024) Public consultation on our new approach to prioritising guidance (Last accessed 7 March 2024).
- NICE (n.d.) 'Cost saving guidance' web page (Last accessed 15 March 2024).
- TNA, JA 765/15 NICE, Nick Clarke to ministers, 'Secretary of State Directions to NICE', 27 July 1999.
- WHO Regional Office for Europe (2007) *The Clinical Guideline Programme of the National Institute for Health and Clinical Excellence (NICE) A Review by the World Health Organization* (Copenhagen: WHO Regional Office for Europe) (Last accessed 13 April 2023).

Secondary sources

- Atkinson P, Sheard S & Walley T (2019) "All the stars were aligned"? The origins of England's national institute for health research. *Health Research Policy and Systems* 17(1), 1–14.
- Barry P, Kelley K, Tan T & Finlay I (2024) NICE guideline on ME/CFS: robust advice based on a thorough review of the evidence. *Journal of Neurology, Neurosurgery, and Psychiatry* 95(7), 671–674.
- British Academy (2019) *Lessons from the History of UK Science Policy* (London: British Academy).
- Cairney P (2016) *The Politics of Evidence-Based Policy Making* (Basingstoke: Palgrave MacMillan).
- Cluzeau F (2003) Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. *BMJ Quality & Safety* 12, 18–23.
- Coulter A & Ham C (2000) Introduction: international experiences of rationing, in Coulter A & Ham C (eds) (2000) *The Global Challenge of Health Care Rationing* (Buckingham: Open University Press).
- Craig C (2019) Policy towards science and science in policy: questions and answers? in British Academy (ed) *Lessons from the History of UK Science Policy* (London: British Academy), 40–47.
- Davies S (2017) Organisation and policy for research and development: the health Department for England and Wales, 1961–1986. PhD Thesis, London School of Hygiene & Tropical Medicine.
- Davies S (2019) Rothschild reversed: explaining the exceptionalism of biomedical research, 1971–1981. *British Journal for the History of Science* 52(1)(192), 143–163.
- Drummond M (2016) Clinical guidelines: a NICE way to introduce Cost-Effectiveness Considerations? *Value In Health* 19, 525–530.
- Eccles M, Clapp Z, Grimshaw J, Adams P, Higgins B, Purves I & Russell I (1996) North of England evidence based guidelines development project: methods of guideline development. *BMJ* 312(7033), 760–762.
- Eccles M & Mason J (2001) How to develop cost-conscious guidelines. *HTA* 5, 8.
- Eisenberg J (1998) AHCPR focuses on information for health care decision makers. *Health Services Research* 33(4 Pt 1), 767–781.
- Gaebel W, Weinmann S, Sartorius N, Rutz W & McIntyre J (2005) Schizophrenia practice guidelines: international survey and comparison. *British Journal of Psychiatry* 187(3), 248–255.

- Holland W, Olsen J & Florey C (2007) *The Development of Modern Epidemiology. Personal Reports from Those Who Were There* (Oxford: Oxford University Press).
- Kendall T, Whittington CJ, Kuipers E, Johnson S, Birchwood M, Marshall M, Morrison A & NICE guideline development group for CG178 (2016) NICE v. SIGN on psychosis and schizophrenia: same roots, similar guidelines, different interpretations. *British Journal of Psychiatry* 208(4), 316–319.
- Klein R (1996) The NHS and the new scientism: solution or delusion? *Quarterly Journal of Medicine* (89), 85–87.
- Klein R, Day P & Redmayne S (1996) *Managing Scarcity: Priority Setting and Rationing in the National Health Service* (Buckingham: Open University Press).
- Klein R (2013) *The New Politics of the NHS*, seventh edition (Boca Raton: CRC Press).
- Kogan M, Henkel M & Hanney S (2006) *Government and Research: Thirty Years of Evolution* (Dordrecht: Springer).
- Littlejohns P, Leng G, Culyer A & Drummond M (2004) Maybe health economists should participate in guideline development. *BMJ* 329, 571.
- Mason J, Eccles M, Freemantle N & Drummond M. (1998) *NICEly Does it: Economic Analysis Within Evidence-Based Clinical Practice Guidelines*, University of York Centre for Health Economics CHE Discussion Paper 164.
- Montini T & Graham I (2015) “Entrenched practices and other biases”: unpacking the historical, economic, professional, and social resistance to de-implementation. *Implementation Science* 10, 24.
- Moreira T, May C, Mason J & Eccles M (2006) A new method of analysis enabled a better understanding of clinical practice guideline development processes. *Journal of Clinical Epidemiology* 59(11), 1199–1206.
- Moreira T (2012) *The Transformation of Contemporary Health Care: The Market, the Laboratory, and the Forum* (London: Routledge).
- Porter T (1995) *Trust in Numbers: The Pursuit of Objectivity in Science and Public Life* (Princeton: Princeton University Press).
- Prasad V & Ioannidis J (2014) Evidence-based de-implementation for contradicted, unproven, and aspiring healthcare practices. *Implementation Science* 9, 1.
- Taylor M & Perera U (2015) NICE CG178 psychosis and schizophrenia in adults: treatment and management – an evidence-based guideline? *British Journal of Psychiatry* 206(5), 357–359.
- Timmins N (2016) *A Terrible Beauty: A Short History of NICE* (Nonthaburi: Health Intervention and Technology Assessment Program HITAP).
- Wailoo A, Roberts J, Brazier J & McCabe C (2004) Efficiency, equity and NICE clinical guidelines. *BMJ* 328, 536–537.
- Weisz G, Cambrosio A, Keating P, Knaapen L, Schlich T & Tournay V (2007) The emergence of clinical practice guidelines. *Milbank Quarterly*, 4, 691.
- White P, Abbey S, Angus B, Ball H, Buchwald D, Burness C, Carson A, Chalder T, Clauw D, Coebergh J, David A, Dworetzky B, Edwards M, Espay A, Etherington J, Fink P, Flottorp S, Garcin B, Garner P ... Zeman A (2023) Anomalies in the review process and interpretation of the evidence in the NICE guideline for chronic fatigue syndrome and myalgic encephalomyelitis, *Journal of Neurology, Neurosurgery, and Psychiatry* 2023(94), 1056–1063.
- Will C & Moreira T (eds) (2010) *Medical Proofs, Social Experiments: Clinical Trials in Shifting Contexts* (Farnham: Ashgate).

7 Public health and social care

In 2005 NICE took on the responsibility for public health interventions, transferring responsibilities and staff from the Health Development Agency (HDA). Public health brought with it big debates about, in particular, the evidence for focussing on the ‘upstream’ prevention of illness: whether it is best to concentrate on the social determinants of health, for example through taxes on sugary drinks, or on individual responsibility, with dietary advice. NICE became both battleground and participant in ‘evidence wars’ about what worked, how that was demonstrated, and what standard of proof was needed for action.

The addition of responsibility for social care interventions in 2013 necessitated NICE ‘leaving the NHS’, at least in legal terms, changing from an NHS body to a ‘Non-Departmental Public Body’. The social care sector is larger than, and markedly different from, the NHS, calling on NICE to develop new approaches to evidence, relationships with new delivery organisations and different kinds of service users.

In common with the health care guidelines discussed in Chapter 6, and in contrast to the Health Technology Assessments (HTAs; Chapters 5 and 8), the NICE guidance discussed in this chapter was advisory: no-one was mandated to implement it.

Government policy on public health in 2004–05

The extension of NICE’s responsibilities into the field of public health in 2005 took place against a backdrop of changing government attitudes towards public health. By the 1990s, the Conservative suspicion of public health itself (evident under Thatcher, for example in the sidelining of the Black report in 1979) as probably a kind of socialism, had receded. By 1988 the then CMO Sir Donald Acheson was permitted to publish the milestone report *Public Health in England* (generally called the Acheson Report), which set out ambitions for the future role and development of public health.¹ Secretary of State Virginia Bottomley’s 1992 White Paper *The Health of the Nation* acknowledged a debt to the WHO’s *Health for*

1 DH (1988).

All by the Year 2000 and took a strategic approach to population health improvement, identifying the impact on health of wider government policies, though it soft-pedalled the issue of inequality and other socioeconomic problems.²

After the election of a Labour government in 1997, this circumspection was no longer necessary. There was a new focus on the ‘social determinants of health’, acknowledging the link between health and such factors as income, housing and education, and the ways in which these shaped diet, exercise, smoking and alcohol use.³ Labour’s increased ambitions had been set out in their 1999 White Paper *Saving Lives: Our Healthier Nation*.⁴ By 2004, ministerial thinking had developed into a ‘Third Way’ philosophy which rejected both a ‘paternalistic state’ which ‘constrain[s] personal decisions’ and also ‘stand[ing] back, leaving people’s health to whatever the hidden hand of the market and freedom of choice produces’. In their place, a White Paper of 2004 proposed letting citizens take responsibility for their own health while providing them with sound information giving them more power to do so. There would be public communications campaigns on sexual health, obesity, smoking and alcohol consumption, better food labelling and a push for smoke-free environments.⁵

This emphasis on providing good information to the public linked easily with the role of NICE. Published in November 2004, four months after NICE’s absorption of the HDA had been announced (see below), the White Paper set out, in warm, reassuring words, how this merger was good for public health and its practitioners, while retaining the strength of the NICE ‘brand’. Extra resources were promised, and NICE experienced its first name change, becoming the National Institute for Health and Clinical Excellence.⁶ There was an emphasis on how NICE would bring expertise in the appraisal of cost effectiveness to bear on public health questions. Most significantly, the White Paper expressed the ambition that NICE would:

integrate upstream (prevention) and downstream (treatment) knowledge and guidance on effective practice and intervention ... identifying which actions will have the greatest impact on health. It will become possible to compare evidence for the cost effectiveness of early ill health prevention programmes with the evidence of the cost effectiveness of treatment later. The NHS and its partner organisations, including local government, will benefit from this stronger evidence base both as to what works within the field of public health, inequalities and ill-health prevention and on the case for investment upstream.⁷

2 Health Foundation (n.d.).

3 Begley and Sheard (2023), 33.

4 DH (1999).

5 DH (2004a). In fairness to its authors, the White Paper did acknowledge how health inequalities made healthy choices harder for some than others.

6 In 2013 it became the National Institute for Health and Care Excellence (see below).

7 DH (2004a), 190.

The story of Government policy on public health in 2004 does not make complete sense, however, without a recognition that, alongside the Blair-supporting Secretary of State for Health John Reid, health policy was also being made by Blair's rival Gordon Brown at the Treasury. Brown had already commissioned banker Derek Wanless in 2002 to advise on the desirable scale of health care expenditure, and Wanless had perceptively noted that the answer would (in the long run) depend in part on how far the population adopted healthier lifestyles.⁸ In February 2004, he delivered a second report, *Securing Good Health for the Whole Population*, which enlarged on this theme. Here, Wanless noted that the major constraint to further progress on the implementation of public health interventions was the weakness of the evidence base, noting particularly the lack of information about cost-effectiveness.⁹

Further support for the idea that people were looking to strengthen the public health evidence base in 2004 comes from the Wellcome Trust's decision, in the light of the second Wanless Report, to convene a Public Health Sciences Working Group whose terms of reference were 'to consider the current state of the public health sciences in the UK and make recommendations on measures that will enhance their impact upon the public health'.¹⁰ This group of no less than 14 professors, which included DH's Director of R&D (John Pattison), the President of the Faculty of Public Health (Sian Griffiths) and other opinion leaders, concluded somewhat predictably that 'far greater investment' was needed in this work, along with recommendations on research data, the translation of discoveries into policy, and public understanding.

At NICE, Peter Littlejohns and Mike Kelly were quite clear, writing a *Lancet* editorial in September 2005, that the motivation for making NICE responsible for public health guidance was indeed the Wanless agenda of using evidence-based preventive interventions to improve health and so reduce the need for health care. Both were important leaders of NICE's public health activity: Kelly will be introduced later in this chapter, while Littlejohns was NICE's first Clinical Director and Public Health Director. They wrote:

Wanless considered that there was no reason why the cost-effectiveness of prevention interventions should not be assessed in the same way as disease-management strategies. The analysis would allow commissioners of services (usually primary-care trusts) to compare the relative merits of prevention and treatment strategies, and would allow commissioners to develop a business case for purchasing a balanced portfolio of interventions.¹¹

8 Wanless (2002).

9 Wanless D (2004).

10 Wellcome Trust Public Health Sciences Working Group (2004).

11 Littlejohns and Kelly (2005).

Littlejohns should take some of the credit for the inclusion of this view in the Wanless report: NICE had submitted evidence to Wanless, and Littlejohns had attended Treasury meetings during the drafting.¹² In similar vein, Andrew Dillon recalled that ‘we really liked the idea of bringing our ability to advise on clinical practice, with treatment, together with advice on prevention’.¹³ However, this ambitious hope of integrated commissioning decisions across prevention and treatment has largely not been achieved.

NICE absorbs the Health Development Agency (2005)

Rather than looking to the broader philosophical goals of the Wanless reports or the 2004 White Paper, however, explanations for NICE’s 2005 absorption of the HDA should be sought mainly in government’s short-term fiscal problems: the 2004 White Paper’s case for comparative analysis of the cost-effectiveness of prevention and treatment reads like an intellectually elegant post-hoc justification. Funding pressures in the NHS had made a reduction in management costs politically necessary, and one element of this was a radical reduction in money retained at the centre for arm’s-length bodies (ALBs). DH’s review of its (many) ALBs reported in July 2004.¹⁴ Surprisingly, it did not set out specific arguments in favour of its recommendations for each body. Lord (Norman) Warner, the health minister whose portfolio included NICE at this time (as well as the ALBs Review), recalled that:

one of the bodies that under-whelmed me was the [HDA] ... I thought it would benefit from NICE’s more structured and evidence-based approach.¹⁵

Similarly Paul Corrigan, a Special Adviser in DH at this point, regarded the HDA as ‘underpowered. So what you do is link that with a powerful organisation’.¹⁶ Corrigan added:

beware of being successful because that means people come along and say “here, you were good at this why don’t you have a go at this” ... I don’t think the things we asked [NICE] to do were mad but they were pretty difficult implementation challenges [such as] ... an obesity strategy.¹⁷

Kelly, who was in charge of research at the HDA from 2000, bears out this account of events. While convinced that the HDA was producing valued work reviewing

12 Peter Littlejohns, interview 14 January 2020.

13 Andrew Dillon, interview 2 July 2020.

14 DH (2004b), 16.

15 Warner (2021), 297–298.

16 Paul Corrigan, interview 16 November 2022.

17 Corrigan interview. Former CMO Sally Davies, referring to the NIHR, called this civil service tendency to give more jobs to successful bodies the ‘Christmas tree’ principle.

the evidence for interventions (discussed below), he recalls that the organisation was:

running into trouble, ... partly because there were colleagues within the Department of Health who were not convinced the HDA were really delivering on the broader [tasks].¹⁸

When the government lost confidence in the HDA, amalgamation with NICE was not the only possible solution. In Kelly's recollection, HDA staff were expecting a merger, but with the Health Protection Agency – so much so that the two bodies had held joint board and management meetings in preparation.¹⁹ The ministerial decision to merge the HDA into NICE has, like the rest of the ALBs Review, an improvisatory feel about it. Corrigan's predilection for giving the work to a visibly successful body, on the 'Christmas tree' principle, appears to have carried the day.

Dillon's recollection of events and Mike Rawlins' papers also show that the merger came out of the ALBs Review, rather than some grander strategy:

[like] all organizations we were wondering 'have we done enough to survive this?' I seem to remember a process where each organisation had to set out a case for its continued existence, if you were lucky enough to have big names out there in the system who could write in support of you obviously that was very helpful. So we knew that there might be a potential change, but we were very surprised when the decision was made to merge us with the Health Development Agency, we hadn't anticipated that.²⁰

Another example, then, of the relative importance of contingency compared with deep-laid plans. Dillon adds that NICE was not anxious about surviving the ALB Review, feeling that its work was understood to be valuable. The question was more what might be added to its functions. Correspondence in the Rawlins Papers shows NICE's leaders speculating about (but not angling for) the HDA and the Social Care Institute for Excellence (SCIE, see below), along with some DH medical advisory committees which could also be seen as producing guidance for the NHS:

[John Bacon, the responsible DH Director], in effect, invited us to put forward our views on what should happen. ... So, we need to decide what we want. Options include:

1 everything (N[atational] P[atient] S[afety] A[gency], HDA, ... and any others we fancy. A huge 'quality and standards' body. This will mean disestablishment and merger ...

18 Mike Kelly, interview 6 July 2022.

19 Kelly interview.

20 Dillon interview; Rawlins Papers, 'ALB'.

3 ... integration of small advisory groups on the list that Liam [Donaldson] is looking at.

However we approach this, if we want to avoid merger, we should be clear about why the NHS needs NICE, as NICE, that what we do is to set standards in clinical practice and that therefore, the only bodies that should be considered as candidates for the ‘NICE family’ are those that clearly do that.²¹

Once a systematic look like the ALB Review was taken at the crowded field of advisory bodies which had grown up around DH over the years, it was not hard to make a logical case for NICE to absorb, say, the Joint Committee on Vaccination and Immunisation or the Scientific Advisory Committee on Nutrition, though in the event both survived.²²

Absorbing the HDA involved a decision to wind up its regional teams, which was more than simply about saving money:

We didn’t feel they fitted the NICE model, as a diffuse public health resource, so we went round and talked to them all, and then we took a decision to replace the regional teams with implementation consultants, which wasn’t universally popular.²³

First steps

Kelly became the head of NICE’s new Centre for Public Health. NICE’s strong reputation by 2005 made him see the merger as ‘a real opportunity’; he recalls that NICE’s:

clinical guidelines were really ... admired and we’d obviously taken some notice of this.

In particular, Kelly’s HDA team had been taking the NICE approach to guidelines on board already:

the HDA and NICE had received the commission to develop what were called [independent] clinical guidelines on the prevention of obesity. So ... some of my team at the HDA had been working closely with colleagues at NICE and we’d learnt a lot about the way they worked, how guidelines were developed and we joined their methods, as it were, prior to any talk of amalgamation.

21 Rawlins Papers, ‘ALB’; Rawlins Papers, ‘RE ALB Review J[ohn] B[acon] postscript’.

22 Catherine Law, interview 2 October 2019.

23 Gillian Leng, interview 26 November 2019.

Following the merger,

all the things we'd done on developing the evidence base could be moved into this a step up so to speak ... it can go up a gear and we'll start producing public health guidelines. Which I suppose was the logical next step.²⁴

NICE's first public health guideline was on the use of brief anti-smoking interventions in the course of interactions between health care workers and patients. It was agreed with DH that it made good sense to do the first guidelines on areas where the existing evidence base was strong. This had the twin attractions of producing the first product more quickly – as it turned out, within 12 months – and starting gently with a topic where there would not be much methodological controversy:

we didn't choose some ... obscure [field], we did smoking and physical activity because ... we'd got all that material and it was readily available. ... they were areas, particularly smoking, where the evidence looks a lot more traditional ... than in say something like social [and] emotional wellbeing of children, say. In other words there are trials relating to smoking cessation, there are RCTs.²⁵

This was a topic, then, on which the established community of evidence specialists, used to drug trials above all, would not be likely to attack public health guidance as over-ambitious or scientifically unjustified.

The first set of DH commissions to NICE for PH guidance was informed by the 2004 public health White Paper, a logical choice for ministers and officials. This way, they hoped NICE would assist the implementation of their public health plans by developing the evidence about which interventions would serve these best. The list was in two parts: a set of very specific 'interventions', including methods to increase physical activity, reduce transmission of chlamydia and promote smoking cessation, and, secondly, a set of broader 'programmes', including, again, smoking cessation, but also improving nutrition for low-income mothers and children, and, broadest of all, ways to support behaviour change.²⁶ This distinction between specific and more general did not last, and probably owed most to the tactical consideration just mentioned of starting with the simpler problems. There is a hint of an eagerness to progress beyond those in the comment by the advisory committee's first chair that 'once we'd done all the little tiny things we started doing much bigger things anyway, so it didn't make much difference'.²⁷

24 Kelly interview.

25 Randomised controlled trials. Kelly interview.

26 Littlejohns and Kelly (2005).

27 Law interview.

This was Professor Catherine Law, appointed first chair of the Public Health Interventions Advisory Committee in 2005, serving until 2015. She was one of the new breed of evidence specialists whose arrival in policymaking we have noted in earlier chapters:

I'm quite interested in synthesising evidence, in using research for public policy, I'd done quite a bit of research ... both commissioning research and using research ... I thought [turning it into guidance] was a good way of testing, using research, it was what I was committed to.²⁸

Law's background in evidence synthesis and related research included being recruited by Graham Winyard to the Wessex Institute of Public Health, one of NICE's intellectual sources for its approach to HTA, as we saw in Chapter 1. With a special interest in child health, she had been seconded to DH in 1997 to work on Acheson's Inquiry on Inequalities in Health.

Asked how to ensure that research was made most relevant to society, Law's answer was the process of public engagement for which NICE had by then become known: 'Engagement of lay people, lay expertise, and patients, and transparency of business and methods'.²⁹ In public health, there were times when, for reasons of equity, extra effort went into engagement with specific social groups, for example public consultation events with black African populations about HIV testing.³⁰ Ann Williams, who joined a public health committee as a lay member (working at the time with Citizens' Advice Bureaux) recalled wanting above all that 'whatever the policy came out it was realistic and going to be practicable and of use'.³¹ Sometimes this meant searching questioning of the draft produced by the Evidence Review Group.

Since all NICE public health work flowed from a DH commission on a specific topic, the quality of commissioning, a subject we examined in Chapter 6, was important. In public health, there seems to have been less effective organisation of the DH input than the longer-established operation on medicines and health care guidelines. DH's NICE liaison team was located in its Medicines Division for obvious historical reasons, and in Law's view did not look after the public health dimension as effectively as medicines: 'You'd get a referral with smoking and children, it would be from the smoking team, they hadn't seen the children team, so they hadn't added the bits that they needed to know from their perspective'.³²

28 Law interview.

29 Law interview.

30 Law interview.

31 Ann Williams, interview 29 April 2020.

32 Law interview.

Questions about evidence

NICE was called upon to bring independence, rigour and transparency to the examination of the evidence. There are specific challenges about using evidence to produce guidance in public health, above and beyond the wider issues discussed in Chapter 6.³³ There is more research on the nature of problems than on the effectiveness of interventions. Among the intervention studies that do exist, it has been easier to study focussed small-scale interventions than wide programmes, where it is harder to exclude confounding factors affecting the assessment of outcomes. This risks favouring downstream interventions merely because the evidence is simpler. Interventions are often much more effective for some groups than others, but in the 2000s, few intervention studies had been large enough to distinguish effectiveness in sub-groups, for example more disadvantaged ones, confidently. Qualitative research findings, which shed most light on the factors affecting – for example – behaviour change, are not easy to integrate with quantitative evidence.

Law and Kelly were central to NICE's early work on this. Law summed the challenges up by saying 'it's about all sorts of things, how you come to judgements, what you know and what you don't know, the nature of knowledge, politics and social science'.³⁴ By the end of her ten-year term chairing the public health committee, Law felt that NICE had come a long way towards addressing the 'upstream' issues in public health:

NICE was extremely NHS-focussed, originally, and it broadened its outlook and that's to its credit. ... to embrace and understand a 'social determinants' approach, that public health is not simply about screening programmes and vaccinating people, but saying why they might become unwell and how you might prevent that. So thinking about the wider efforts of society.³⁵

One aspect of rigour which was important in public health was for the NICE team to push back when they felt there was insufficient evidence to support guidance – the same phenomenon which Martin Eccles saw in relation to treatment guidelines, discussed in Chapter 6. Law's experience was that:

Sometimes we had such poor evidence, they weren't very well-conceptualised referrals, you really thought, what's the point in ... writing a 60-page document on this, and in one case the committee declined to make guidance ... all we would have been using would have been our common sense. We weren't really constituted to be a common sense committee ... if all you need is common sense then there are plenty of other groups around the world, or in your local council, who'd have lots.³⁶

33 For what follows, a good summary is Law (2010).

34 Law interview.

35 Law interview.

36 Law interview.

Apparently the example in question concerned promoting physical activity in leisure centres and the design of play equipment.

When Kelly moved from academia to the HDA in about 2000, he recalls that there was no:

systematic notion of public health evidence synthesis review and dissemination. ... my job was to try to develop the methods and processes for doing evidence based public health and obviously you couldn't just take the manuals from Sackett and company in Canada or Muir Gray and so on in the UK or the evidence-based medicine people in Oxford because you were dealing with a much broader evidence base.³⁷

Kelly reports that at the HDA he had to contend with the views of some public health academics who were sceptical that it was possible to evaluate the outcomes of interventions, as opposed to the proximate outputs they achieved, something he was keen to do:

we had quite a battle really with the scientists who said it wasn't possible, with those who said it shouldn't be done as well as those who said it couldn't be done. But the R&D people in the Department of Health were very keen for it to happen, they'd also already established the Centre for Reviews and Dissemination in York.³⁸

At the HDA, Kelly and his team were producing what they called evidence reviews, not guidelines. The distinction is important: this was a more tentative framing of the content, not as prescriptive as a guideline. HDA produced about 25–30 of these in all, which, as far as Kelly is concerned, were well received:

people working in the NHS with public health roles and responsibilities found them really useful and so ... within a year we'd begun to establish a bit of a reputation³⁹

When this operation became part of NICE in 2005, Kelly and his team, as we have seen, had become familiar with the NICE method of producing guidelines from their joint work on the prevention of obesity. They knew that public health evidence was somewhat different to health care evidence, but Kelly realised that his

37 Kelly interview.

38 Kelly interview. The Centre for Reviews and Dissemination had been established in 1994, part of the new NHS R&D programme: see Atkinson et al. (2019).

39 Kelly interview.

HDA team had already worked out the hardest part of the methodology needed to produce guidelines in public health:

we'd already done the evidence synthesis bit which is always is the most difficult with public health because you're pulling together disparate disciplines, methods, [for example] social anthropology ... what we brought to the table was the techniques for doing the evidence synthesis and review, and then we married it to the system of the advisory committees, appraising and analysing it and my team acted as the technical support, in the way that the NICE [Evidence Review Groups did in health care].⁴⁰

In the end, against expectation, 'it wasn't a very tricky thing to do actually once I realised it's not very tricky'.⁴¹

There were other differences from treatment guidelines. In public health, the NICE team found the context of the intervention made more difference: public, and staff, reactions to interventions, and how the intervention in question interacted with other programmes – most obviously in complex areas like diet and physical activity. NICE began to commission 'barriers and facilitators' reviews, examining the qualitative literature for evidence on this.⁴²

NICE's new Centre for Public Health also needed to overcome suspicions from the health care guidelines specialists about the possibility of producing public health guidelines with the same rigour as their own. Mark Baker, the director of NICE's Centre for Clinical Practice from 2012 to 2018, whom we met in Chapter 6, provided an example of this potentially hostile perspective:

all Public Health professionals are political ... there were real challenges [to draft guidelines from NICE's] guidance executive ... it happened to Public Health almost invariably. ... The analysis was generally ... subcontracted for each guideline. [That] ... made it quick but not necessarily good, now the committees were all almost invariably political in their approach because they were composed of Public Health professionals and NICE was very careful not to be political in its approach if the evidence didn't support recommendations.⁴³

NICE's guidance executive was a small committee of its directors. Kelly confirms that it made a searching examination of each draft:

the Guidance Executive [would] go over it with a fine toothcomb and any mistakes in it they would pick up at that point. ... I had to sit there and

40 Kelly interview.

41 Kelly interview.

42 Law interview.

43 Mark Baker, interview, 18 May 2022.

defend every line and comma and full stop in those documents' ... if you could stand that test you know that the Adam Smith Institute weren't going to get you.⁴⁴

One of the things which Baker's criticism of public health as 'political' (compared to health care) exemplifies is a point of view about what counts as evidence. If the hierarchy of evidence with randomised controlled trials at the top had been the whole story, NICE would not have been able to say nearly as much about public health interventions (where RCTs are often simply not possible). In public health, the 'evidence wars' discussed in Chapter 6 often took the form of debate about what other evidence could be admitted, and how to treat it rigorously. Public health specialists such as Law argued that there was more than one route to rigour:

What I was most proud of is that we were able to adapt the NICE methods to be suitable for public health, but NICE still recognised them and the public health community still recognised them. There was a lot of concern that, [if] we could only look at trials, wouldn't work for public health. There was a concern from NICE that their public health people were "wishy-washy, sandal-wearing, they don't really understand the cut and thrust of scientific debate." We dealt with that.⁴⁵

They dealt with this by reassuring the evidence specialists that they were applying the same method in public health, just adapting it to different challenges:

we all debated and interpreted the evidence. So the way you do that in public health might be different, but it's still fundamentally you still start off with what's known, and what is known about the costs and benefits. So that fundamental thing, we didn't change. I think that was what people thought we might change, and we didn't.⁴⁶

We noted earlier that it was easier to study focussed small-scale interventions than wide programmes, where it is harder to exclude confounding factors affecting the assessment of outcomes. This difference in the strength of evidence made NICE more likely to recommend downstream interventions. It also meant that friction with government, to which we will shortly turn, was more likely when NICE addressed broader programmes of upstream disease prevention.

44 Kelly interview. The Adam Smith Institute is a UK think tank which describes itself as 'promot[ing] free market, neoliberal ideas'. It has criticised public health interventions from this perspective on various occasions.

45 Law interview.

46 Law interview.

Economic evidence

We have already noted Wanless' 2004 observation that evidence on the cost-effectiveness of public health interventions was particularly thin. How did NICE address this challenge? Kelly describes the merger with NICE as the beginning of attention to cost-effectiveness:

the other big difference of course when we moved into NICE [was] we had to do health economics ... at the HDA we hadn't done any kind of economic appraisal ... so we had to ... devise ways of putting the public health evidence base through the same ... health economic scrutiny that NICE were doing on drugs and pharmaceuticals and so on. ... conceptually that was really tricky.⁴⁷

Kelly had taken some persuasion at first: he was not an instinctive believer in this. It seems to have been Tony Culyer who changed his mind:

I was deeply sceptical and I'd even written at least one paper outlining my scepticism about the application of cost utility analysis and the QALY to public health

Tony Culyer ... came to see me and he said "look that paper you did ... put the cat among the pigeons but of course you're right but ... if you want to build the case for public health you've really got to do cost utility analysis and use QALYs because it will build the case in a way that the policy makers and the nay sayers can't argue with."⁴⁸

This is another example of the reach of York's Centre for Health Economics, one of many in this book. It exemplifies their staff's interventionist, pragmatic attitude to policymaking. Culyer had taught economics to Kelly when he had been an undergraduate. CHE staff including Mark Sculpher, Richard Cookson, Brian Ferguson and Karl Claxton would regularly work with NICE's public health team, and for example sit on committees. Economists from Brunel University were also visible in this work.

Kelly was understandably apprehensive about how the application of cost-utility analysis (QALYs) in public health was going to turn out. He believed, of course, that the effective interventions would also be cost-effective: after all, they were cheap, and most reached large numbers of people. But would using QALYs capture this and help win over policymakers as Culyer predicted? Kelly vividly recalls his astonishment at the strength of the results. NICE's threshold cost per QALY was then £20,000–30,000 (see Chapter 5). Kelly's economists reported to the meeting

47 Kelly interview.

48 Kelly interview.

on the smoking cessation guidelines that the figure for one intervention was £150, for another, £700. Kelly said:

“can we stop there because I think you must have the decimal point in the wrong place?” and they said “well we thought that too but we’ve run this calculation again and again and again and them’s the results.” ... in terms of that economic methodology, anyway, they’re absolutely cost effective and in fact that’s probably the most original finding of the lot.⁴⁹

QALYs for the interventions in the physical activity guideline, which the public health committee considered the same afternoon, were similarly striking. While these costs per QALY have turned out to be lower than those for most public health interventions considered by NICE later, the newer ones are also typically far lower than for the drugs NICE evaluates. A recent examination of 71 NICE public health guidelines found that 27 used QALYs: of these 75% had a cost per QALY below £20,000 and the median was only £1986.⁵⁰

Bringing in QALYs was the hardest methodological challenge: Littlejohns and Kelly said in the 2005 *Lancet* article that NICE’s biggest challenge in taking on public health was ‘agreeing a health-economic methodology that can accommodate incremental cost-effectiveness ratios, in a health context, with the broader benefits of social interventions’.⁵¹ Paying attention to those broader benefits (e.g., gains accruing to others beyond an individual receiving the intervention) was important. Accordingly, NICE continued to use measures including Return on Investment (ROI), knowing it would help the guidelines achieve more impact. Culyer’s reasoning that QALYs impressed ministers was sound, but the other measures could have more impact on decision makers in, for example, local authorities, where key decisions on public health activity were most likely to be made, following the transfer of public health responsibilities to them in 2013.

The power dynamics of implementing public health (and, as we shall see, social care) interventions differ from those in health care, and this shapes how NICE has to approach the presentation of evidence. Major LA spending decisions are often signed off by a local authority’s whole team of Directors, and by elected members holding all the different policy portfolios, not only public health. As a generic, rather than health-specific, measure, ROI is a more familiar concept than the QALY and starts from an advantage in carrying these wider debates. This is particularly important if an authority is contemplating action on the wider determinants of health (say, housing), which falls beyond the responsibility of the public health department. A measure which sets out to capture benefits to the

49 Kelly interview.

50 Owen and Fischer (2019).

51 Littlejohns and Kelly (2005).

whole community, or the LA's overall running costs, has more impact.⁵² As Kelly confirms:

sometimes we would also do an addition to the cost utility analysis, we would also use cost consequence analysis which is many ways is much more intuitive from a decision maker's point of view especially in, say, a local authority than a QALY.⁵³

When it came to public health topics, NICE was, in other words, able to bypass Alan Milburn's early insistence that costs and benefits be evaluated only in relation to the NHS (see Chapter 3). As Law observed, most addiction interventions are only cost-effective when the costs to the criminal justice system are included, as they are much larger than the health service costs, of, say, alcohol or cannabis use. Law notes that:

when we did transport interventions, the Department of Transport routinely uses cost-benefit analyses. So we felt we wanted to be able to do an analysis which they would recognise. So we did a cost-benefit analysis, having checked in the [NICE] methods manual that was allowed, which indeed it was. I think we were quite flexible, thinking about that. It was a challenge getting other sectors to invest for health service benefit.⁵⁴

This purposeful approach to selecting the type of economic analysis with a view to the intended audience bears out Moreira's view, discussed in Chapter 6, that the outputs of the 'laboratory' can become 'entangled' with political calculation.⁵⁵

Tensions with government

Public health guidelines, although always produced on topics agreed with government, were bound to produce tensions from time to time. A minister might want a stronger endorsement of something in which they were already invested, or conversely for NICE to give less support to an intervention that was politically unattractive to them.

An example of the former came early on, when the Minister for Public Health, Yvette Cooper, let it be known that she would like NICE to give its support to the use of pedometers for measuring physical activity. NICE resisted on the basis that the available evidence was weak: a situation more likely to arise in public health than in HTA – the temptation for a minister to feel there was a 'common

52 For a clear exposition of benefit measurement in public health, see Edwards and McIntosh (2019).

53 Kelly interview.

54 Law interview.

55 Moreira (2012), 109.

sense' argument for an intervention being stronger in everyday matters like physical activity than abstruse ones such as a new cancer drug. In Kelly's recollection:

DH had already invested heavily in buying [pedometers], a warehouse full of them ... there was some pressure put on us, you know "can't you say a bit more about how good these things are?" But you know you have to stand firm, now that was gentle pressure ... [Cooper] wasn't best pleased with this but she didn't push it and so off we went with our guidance ... the golden rule at NICE [was] you could only go with what the evidence said, you couldn't go with what you wished the evidence said ... because once you start doing that your reputation is going to get shot to pieces.⁵⁶

The 2010 coalition government seems to have wanted NICE to do more public health work. Una O'Brien, then Permanent Secretary at DH, recalled that in 2010:

we asked [NICE] to take on more of the public health guidelines and initially I sensed a bit of reluctance, even resistance: as much as to say "can we really do this and will we find the evidence?" and all that sort of thing...

I did get a bit of a push to do more when Andrew Lansley came in [as Secretary of State for Health] with his big focus on public health; he felt, and he was right, that it wasn't getting the attention that it needed.⁵⁷

Nick Seddon, who was one of David Cameron's Special Advisors, confirms the interest in public health, adding that a childhood obesity strategy was a particular goal.⁵⁸ However, there were tensions. NICE's work on alcohol was the sticking point. Unluckily, guidance on preventing alcohol-related harm had been commissioned by a Labour government in 2008, but delivered to a Conservative-led coalition after the 2010 general election. Some of the recommendations dealt with focussed interventions and were uncontroversial, but one wider recommendation in particular attracted the criticism of business, Conservative politicians and the right-wing media. Kelly recalls that:

once we got into things like alcohol and some of the things that were ideologically particularly after 2010 not aligned really with the Government policy ... it became fantastic material for the newspapers, the *Daily Mail* ... I spent a lot of time being interviewed on the *Today* programme.⁵⁹

the guideline covered all aspects really of public health prevention on alcohol including brief interventions in primary care, brief interventions in places like police station cells where people have been locked up for drunkenness.

56 Kelly interview.

57 Una O'Brien, interview 2 February 2022.

58 Nick Seddon, interview 30 March 2022.

59 Kelly interview. *Today* is BBC Radio 4's morning news and current affairs programme.

Through education, through messaging, availability, licensing and so on. But the absolute sticking point was minimum unit pricing.⁶⁰

Minimum unit pricing (MUP) is the policy (adopted with some success in Scotland) of a legal lower limit on the price of products per unit of alcohol they contain. Its advocates claim that it is effective in reducing the alcohol consumption of problem drinkers, and the (in any case illegal) alcohol purchases of children. At the levels set in Scotland, a MUP delivers this without a significant impact on the budgets of ordinary drinkers, whose purchases are higher priced already, or the incomes of manufacturers (which may in fact rise), or of pubs. The main losers from MUP are supermarkets which lose the opportunity to sell alcohol products as loss leaders. The political right viewed all of this as an example of the ‘nanny state’, however. In Kelly’s account:

Andrew [Lansley] was very, very unhappy with this and the following day they, DH put out a briefing which essentially claimed that NICE had got the evidence wrong. That was a bad move because one thing NICE didn’t get wrong was evidence. It may have been politically inept but the evidence wasn’t wrong

Lansley would have been a lot more astute (in Kelly’s view) to have said:

“sorry NICE we’re not going to go with that because we don’t think presently the electorate will support [us] on that” and of course it would have died a death pretty quickly after that.⁶¹

Law took a similar view to Kelly. The producers of evidence are prone to take a linear view of policy impact: good evidence should lead to policy change.⁶² In public health, this can mean that advocates for interventions expect NICE to lobby for them (because their evidence is reliable). As Law put it: ‘Some academics think, “absolutely this works, and therefore ...” Some academics do see themselves as advocates’. The Kelly and Law view of NICE’s own role, however, reflects the real nature of policymaking:

policy makers have a lot of things to consider, and politics being the art of the possible, they’re not going to consider things that they consider politically impossible ... if NICE recommend something and government ignore it, that’s their prerogative, they were voted in and NICE wasn’t. I see myself much more as a knowledge broker than an advocate.⁶³

60 Kelly interview.

61 Kelly interview.

62 Atkinson (2022); Cairney (2016).

63 Law interview.

The alcohol MUP guidance coloured Lansley's view of NICE's public health work. It led to a review of NICE's public health work programme, with the dropping of some sensitive topics:

the NICE ... public health programme was reviewed and we were told to drop certain things ... where they seemed to impact on policy rather than on more simple interventions and we kind of in the end reached a sort of *modus operandi* where we would in future steer away from things that were obviously policy. Now ... in public health terms sometimes policy is your biggest lever so to steer away from it is to deny the effectiveness of, let's say, all the things that were done on tobacco control over the years, or sanitation.⁶⁴

Law confirms this change of focus in the government's commissions from NICE:

the referrals became much more downstream, so we had less, to my mind, impactful interventions to assess, because it was much more clinical type interventions in public health practice, ... the more important ones were not asked for ... I felt we got rather boring referrals. ... for about a year we didn't have any referrals at all.⁶⁵

There have been other examples besides MUP. Herrick describes how the 2010 coalition government opposed the NICE guidelines on cardiovascular disease prevention, which called for regulations on fat and trans fat content in food, restrictions on advertising and specific health-orientated labelling.⁶⁶ In general, under Conservative or Conservative-led governments from 2010 to 2024 NICE has found public health guidelines that focus on interventions to change individual behaviour politically safer. It has run into difficulty with, or been warned off pursuing, broader programmes such as those affecting food regulation or advertising, which are more politically charged, and raise issues about whether public health should be about individual or collective decisions.

Social Care

The social care sector, for which NICE took on the responsibility to provide guidance in 2013, differs substantially from health care in the UK. Some of these differences were challenging for NICE to navigate in preparing useful guidance. For example, social care services in England have been means-tested, while health care has been free at the point of use.⁶⁷ That has meant that service users, funding a large share of activity, make many of the decisions about what services to use. This

64 Kelly interview.

65 Law interview.

66 Herrick (2011).

67 Timmins (2017), 605.

makes them, rather than public bodies, potentially the key audience for guidelines about what works. Looked at from a care provider's point of view, this 'personalisation' agenda in social care can mean that service users' satisfaction with a service is a more powerful influence on delivery choices than anyone's advice about its effectiveness.

The difficult policy environment which social care has inhabited, while arguably making guidelines more valuable, has also made them harder to frame in ways likely to be useable. Perhaps most basically, organising social care has steadily become more problematic as demand for it has risen just as supply has decreased.⁶⁸ Writing in 2000, Daly and Lewis could argue that changes in social care have been more complex than simply spending cuts: there had certainly been cuts to some (not all) cash benefits but also (in the 1990s) more spending on services. Since 2010 the picture has been dominated more by declining resources.

There has been a long-term ambition to deliver more health and care services in the community, and less in institutional settings (stretching back at least to the 1960s). Arguably this thinking reached its culmination in the health and social care White Paper *Our health, our care, our say* (2006).⁶⁹ This policy direction has sometimes – whatever its intrinsic merits – been dominated by an NHS agenda of seeking earlier discharge of hospital in-patients, and the challenge of doing this safely. But austerity after 2010 has meant a much harder financial environment, at a time when there has also been more policy pressure for service change to improve cost-effectiveness, with a strong belief that preventative and 'care in the community' approaches would deliver this. The pace of change since the 1990s has been 'frenetic'.⁷⁰ We might reasonably think this made service commissioners more receptive to the kind of guidance on effectiveness and cost-effectiveness which NICE has tried to provide.

The Coalition government of 2010 lost no time in setting out plans for structural change in health and social care. The story of the collision between Secretary of State Lansley's blueprint, developed before the election, with the complexities of delivery (and coalition politics) has been told elsewhere.⁷¹ The addition of social care guidance to NICE's responsibilities was a small facet of this root and branch programme of structural change. The White Paper *Equity and excellence: Liberating the NHS* was published less than three months after the general election.⁷² In a section devoted to expanding NICE's role in publishing Quality Standards for the NHS, the White Paper stated:

With the increasing importance of coherent joint arrangements between health and social care, the standards will cover areas that span health and

68 Daly and Lewis (2000).

69 DH (2006).

70 Glasby (2012), 13.

71 Timmins (2012).

72 DH (2010).

social care. We will expand the role of NICE to develop quality standards for social care. The Health Bill will put NICE on a firmer statutory footing, securing its independence and core functions and extending its remit to social care.⁷³

The goal of better coherence between the health and care sectors was widely shared: however, the announcement of these details as a decision already taken came as a surprise to many. The Health and Social Care Act 2012 (as it became), made the changes the White Paper had promised. On the details of NICE's governance, taking on a role in social care meant that it could hardly remain a Special Health Authority and part of the NHS. So with effect from 2013 it was technically a Non-Departmental Public Body (NDPB).

Most actors involved with NICE feel this gave it more independence. The small print, for any NDPB, leaves government in charge of appointments to the Board, and still agreeing a work programme through a framework document. Ultimately, how independent an NDPB is depends more on politics than law. The politics favoured more independence for NICE under the Coalition, since Lansley's broader programme was to set up a structure (across health and social care) which distanced ministers from operations, and which could only be amended in future by legislation. This merely underlined the existing attractiveness for health ministers (discussed in Chapter 3) of giving NICE a large measure of freedom.

This section examines how NICE engaged with the unique challenges of producing guidance for the social care sector. First, it may be helpful to gain a picture of what this NICE guidance looks like. Seventy-one current guidelines are listed under the 'social care guidelines' heading on the NICE website.⁷⁴ The first dealt with the reassuringly 'medical' topic of how medicines in care homes should be managed. As with public health, the first foray into a new field took on a topic within NICE's comfort zone where existing medical approaches to evidence could be followed.

There is no separate guidelines series for social care: NICE social care guidelines belong to existing series, mainly 'NICE Guidelines' (NGs) and its predecessor 'Clinical Guidelines' (CGs) – examples can be found in Appendix 2.⁷⁵ Many, for example 'looked-after children and young people' (NG205) or 'safeguarding adults in care homes' (NG189), deal with topics mainly of interest to the social care sector alone, but a significant group cover medical conditions where people are likely to have social care needs, and social care forms only part of these guidelines' content. Examples include 'epilepsies in children, young people and adults' (NG217).

Of the 71 current guidelines, 19 were originally published before NICE took on responsibility for social care, and, of these, 13 were also last updated before

73 DH (2010), 23.

74 NICE (n.d.-a) social care.

75 'Managing medicines in care homes' was given the reference SC1 but this series was not continued.

then. This, and the absence of a separate social care series, suggests that ‘social care guidelines’ should be interpreted as a search term rather than a self-contained programme of work, something which reflects the desire to approach health and social care as one coherent whole. Since April 2013, about five times as many guidelines on health (counting only the CG and NG series) as on social care have been produced. This is perhaps best explained by the wide-ranging nature of social care guidelines, such as the examples already given. NICE has split social care into fewer, larger, topics for guidance purposes, compared to its treatment guidelines. This reflects the outlook of social care professionals, more frequently viewing clients’ needs in categories like advocacy, carers or safeguarding than in relation to detailed ‘diagnoses’.

NICE took responsibility for social care guidance in April 2013. In preparation, it had appointed Jane Silvester, from a background in local government and the voluntary sector, as its first Associate Director for Social Care in October 2012. NICE was not entering a virgin field. An SCIE had already existed since 2003, with a mission of ‘developing and promoting knowledge about good practice in social care’.⁷⁶ This was a relationship to be worked through, as Mercy Jeyasingham recalls. What was the relationship to be, for example between publishing guidance and promoting good practice?

how do we work with SCIE, what’s appropriate, what are the boundaries here, most of the board didn’t feel confident about social services: I felt quite excited about it, obviously, because I was involved in it. We talked about health-social care boundaries as well. There were quite a lot of debates about that, and being sensitive to SCIE, which had been a partner for the guidelines stuff.⁷⁷

While this was organisationally quite different from the case of the HDA, as SCIE remained in existence whereas the HDA was absorbed, some of the same issues about what was meant by evidence, and how it was used, had to be addressed (as discussed below). SCIE’s Chief Executive in 2012–13 was Andrea Sutcliffe, who had been NICE’s Planning and Resources Director until 2007.⁷⁸ Law, who was interested in developments because of her public health responsibilities at NICE, had this observation:

aspects of clinical guidance and aspects of public health guidance intersected so much with social care that as long as the social care community could accept NICE being part of it, then I think it was an obvious thing to do. It’s very difficult but it’s gone well really.⁷⁹

76 Social Care Institute for Excellence (2004).

77 Mercy Jeyasingham, interview 18 December 2019.

78 Leng interview. Andrea Sutcliffe is now Chief Executive and Registrar of the Nursing and Midwifery Council.

79 Law interview.

SCIE has since developed into a registered charity, whose income from government, no doubt a victim of austerity, has fallen from over 90% to about two-thirds.⁸⁰ Immediately after 2013, NICE commissioned work from it in much the same way as from its Collaborating Centres for guidelines: later, as Gillian Leng recalls, ‘we have now brought it in-house. Once we got enough experience it felt inefficient to do it through SCIE, although they contributed a lot of support for implementation’.⁸¹ Presumably this lay behind SCIE’s reduced income from government sources. Since 2016 NICE and SCIE have, nevertheless, jointly commissioned more than 30 short and accessible ‘social care quick guides’.⁸²

Different ideas about evidence have been challenging at times. As Deputy Chief Executive at NICE, and as a doctor firmly situated in the world of evidence-based medicine, Leng found the different outlook of local government problematic at times:

evidence isn’t really what [social care] talk about. The focus in social care is personalisation, and it’s about what the individual receiver of care or their carers feels is right, and the research evidence doesn’t generally come into it, it’s personalisation.⁸³

Leng felt that the view of elected local authority members was: ‘their evidence base comes from the views of the local population, because they’re there – rightly – to respond to the wants of their local population.’⁸⁴ This is of course an example of the political process using more kinds of evidence than that generated by scientific and technical experts, as discussed earlier in the chapter. At times leaders at NICE hoped that the world of local government might be persuaded to see evidence in a more similar way to NICE – influenced perhaps by the arrival of evidence-minded public health staff in local authorities as a result of the structural changes of 2013.⁸⁵ It is not easy to see why local government leaders would be persuaded, on a philosophical level. They would be more likely to respond that scientific evidence should inform, not determine, their local political choices. In all of this, there is a nagging feeling that central government, and NICE on its behalf, has found local political decision-making and accountability inconvenient. But since the governance of social care, quite unlike the NHS, runs through local democracy, NICE has had more impact here when it has talked a pragmatic language of ‘what works’, as SCIE does, rather than hoping to make converts to a more wide-ranging philosophy of evidence-based policymaking.

80 Social Care Institute for Excellence (2022); Social Care Institute for Excellence (n.d.).

81 Leng interview.

82 Leng interview; NICE (n.d.-b).

83 Leng interview.

84 Leng interview.

85 Leng interview.

One example where this appears to have worked would be the local authority commissioning of social care services. Williams (as Commissioning and Contracts Manager in Adult Social Services for Liverpool) commented that:

as somebody who looks at research studies to inform practice, I would say yes, they do get used, ... I certainly make sure that the other commissioning and contract managers are aware, and I will say when we are having discussions, I always say “well what does the NICE guidance say?”

Q: do they need much persuading?

A: No, I think it comes back, again, to “is it practicable?”⁸⁶

Another issue which NICE found difficult in social care was implementation, or getting traction for the guidance it published. We saw in Chapter 3 how NICE’s leaders had found this a challenge in the NHS, and developed responses such as working through regulators and professional structures such as the Colleges, and producing audit tools. Many of these avenues were harder to use in social care. The workforce was larger, and its organisation and training much more diffuse (e.g., with far more employers, most in the private sector). Training in social care, with less science content than in health care, did not predispose staff to think about evidence in the same ways.⁸⁷

One area of successful work for NICE has been finding and publicising good practice at the interface of health and social care. Leng mentioned the example of:

encouraging assessment of people’s hydration in care homes, [this] came from a group of pharmacists and their knowledge of what NICE had done, ... working with the people in the care homes to get some change.⁸⁸

This has been supported by an annual award for these ‘shared learning examples’, an illustration of what an organisation like NICE can try when more direct pathways to impact are not available. But the limits to NICE’s guidance are suggested by the question from local government officers, ‘is it mandatory?’⁸⁹ There is mandatory guidance from government on some subjects, but NICE social care guidance is not in that category. When local authorities’ resources are as tightly constrained as since 2010, non-mandatory guidance will receive a low priority unless it also demonstrates some gain in cost-effectiveness.

Methods and processes for producing guidance: like health care or different?

This chapter has dealt with two areas, public health and social care, with rather different characteristics to NICE’s original core interest of health care. The question

86 Williams interview.

87 Leng interview.

88 Leng interview.

89 Leng interview.

naturally arose, whether the same methods and processes originally developed to produce health care guidelines would be applicable in the new areas. (Recall that in NICE terminology, methods are the analytical techniques for evidence review, while processes are the administrative ways, such as consultation requirements, in which decisions are reached.)

Against the idea of a unified approach, it could be argued that the characteristics discussed in this chapter made different processes necessary, for example the use of extra types of economic analysis in public health. There were also considerations of audience: as we have seen, a style which landed well with NHS readers might not be welcomed in local government:

what we wanted to do was to integrate health and social care, to support the implementation agenda. So we wanted to use a similar format across health and social care, to bring it all together. But the social care audience didn't really like that format, it was too dry, it was too medically-orientated, too long and didn't work.⁹⁰

This was the consideration that led NICE to produce the social care quick guides. But these arguments did not deter NICE from opting, all the same, for a unified approach to producing guidelines: the 'quick guides' were an extra.

Two arguments led to this decision. The first was economy: under growing budgetary pressure, NICE wanted to reduce its costs, which, as we have seen, were not trivial. As Leng put it:

The public health team came into NICE and set out their own guideline development manual, and then the social care team came along, and they set their own manual too. ... We eventually decided this was inefficient, and we should have one manual for guidelines ... that would work right across all topics. If there were any particular reasons why it had to be different for either clinical, social care or public health, then the manual should reference it, rather than having three separate documents. You wouldn't believe what a job it is to keep guidelines up to date and regularly consult on any changes!⁹¹

The second argument for a single NICE process and methods manual was the strength of the NICE brand by 2005. Its work on health care guidance by then had gained a strong reputation for independence, rigour and transparency. Presented with the task of devising ways to produce public health guidance in 2005, Kelly calculated that hitching public health to this vehicle would get NICE's outputs more respect than inventing a whole guideline production system afresh. And as we have seen, there was still room at the margins for recognition in the methods manual that a different approach – for example, to economic evaluation – could be justified and adopted.

90 Leng interview.

91 Leng interview.

Conclusions

Former Chief Medical Officer Sally Davies warned in another context of the danger that a successful public body, like a Christmas tree, would gradually have more and more things attached to it. NICE has not entirely avoided this. We saw in Chapter 2 how, before its birth in 1999, NICE already had several of these extras added to its core functions, for example National Prescribing Centre appraisals and bulletins, PRODIGY, and the four ‘Confidential Enquiries’, systems for blame-free reporting of serious adverse clinical events. In this chapter, it has become clear that guidance on public health and social care were added to NICE’s role, not from some inescapable business logic, but because a minister needed to find a new home for a function. NICE became the destination because it appeared to do its existing work well. None of the individual choices looks perverse, but neither were any of them inescapable or necessarily the best option. The Whitehall logic of reducing administrative costs by having fewer organisations, needing fewer overheads like Boards or headquarters buildings, played an important part.

It is clear that NICE itself did not lobby government for any of the extra responsibilities.⁹² Its leaders felt with reason that they had enough to do already. Rather, NICE and the partner bodies merged or brought into contact with it, like the HDA or SCIE, have had to retrospectively make a logic out of the structural changes. This is not unusual for government, and it is one of the skills of the senior official to find the opportunities in this kind of change in their policy environment. This is a matter of securing the best available outcome and not only of presenting the decision in the most favourable light.

Some high hopes were riding on the decisions to add public health and social care to NICE’s remit. The second Wanless Report, in 2004, argued the benefits of comparing the cost-effectiveness of prevention and treatment, enabling rational choices between the two. Lansley’s 2010 White Paper hoped that a social care role for NICE would smooth the way for closer integration of health and social care. In each case, it was rash to think that better co-ordination of the production of guidance could deal with a more deep-seated problem of service delivery. In each case, NICE has been able to make a positive impact, particularly because of the extra force which the strength of its ‘brand’ and its processes lent to guidance. This has been more demonstrable in public health, where there was a readier audience for NICE’s approach to the use of evidence, than in social care.

Bibliography

Primary sources

Adam Smith Institute (website) (Last accessed 8 August 2024).

DH (1988) *Public Health in England: Report of the Committee of Inquiry into the Future Development of the Public Health Function*. Cm 289 (London: TSO).

92 Rawlins papers, ‘ALB’.

- DH (1999) *Saving Lives: Our Healthier Nation* (London: HMSO) (Last accessed 8 August 2024).
- DH (2004a) *Choosing Health: Making Healthier Choices Easier* (London: HMSO) (Last accessed 9 August 2024).
- DH (2004b) *Reconfiguring the Department of Health's Arm's Length Bodies* (London: Department of Health), 16 (Last accessed 9 August 2024).
- DH (2006) *Our Health, Our Care, Our Say* (London: TSO).
- DH (2010) *Equity and Excellence: Liberating the NHS*. Cm7881 (London: TSO).
- Health Foundation (n.d.) Policy Navigator website (Last accessed 8 August 2024).
- NICE (n.d.-a) Social care: quick guides (web page) (Last accessed 27 June 2024).
- NICE (n.d.-b) Social care: quick guides (web page) (Last accessed 27 June 2024).
- Rawlins Papers, 'ALB' [Arm's-Length Bodies].
- Rawlins Papers, 'RE ALB Review J[ohn] B[acon] postscript' (email Andrew Dillon to colleagues 7 January 2004).
- Social Care Institute for Excellence (2004) *Annual Report and Financial Statements, 2003–04* (London: SCIE).
- Social Care Institute for Excellence (2022) *Annual Report and Financial Statements 2021/22* (London: SCIE).
- Social Care Institute for Excellence (n.d.) Web site (Last accessed 27 June 2024).
- Wanless D (2002) *Securing our Future Health: Taking A Long-term View* (London: HM Treasury) (Last accessed 9 August 2024).
- Wanless D (2004) *Securing Good Health for the Whole Population: Final Report* (London: HM Treasury) (Last accessed 9 August 2024).
- Wellcome Trust Public Health Sciences Working Group (2004) *Public Health Sciences: Challenges and Opportunities* (London: Wellcome Trust) (Last accessed 27 August 2024).

Secondary sources

- Atkinson P, Sheard S & Walley T (2019) "All the stars were aligned"? The origins of England's national institute for health research. *Health Research Policy and Systems* 17(1).
- Atkinson P (2022) What the Covid-19 experience has taught us about the limits of evidence-informed policy making (blog).
- Begley P & Sheard S (2023) *Making Genetics and Genomics Policy in Britain: From Personal to Population Health* (Abingdon, Oxon: Routledge).
- Cairney P (2016) *The Politics of Evidence-Based Policy Making* (Basingstoke: Palgrave MacMillan).
- Daly M & Lewis J (2000) The concept of social care and the analysis of contemporary welfare states. *British Journal of Sociology* 51(2), 281–298.
- Edwards R & McIntosh E (eds) (2019) *Applied Health Economics for Public Health Practice and Research* (Oxford: Oxford University Press).
- Glasby J (2012) *Understanding Health and Social Care*, second edition (Bristol: Policy Press).
- Herrick C (2011) *Governing Health and Consumption: Sensible Citizens, Behaviour and the City* (Bristol: Policy Press).
- Law C (2010) Policy and evidence-based public health, in Killoran A & Kelly M (eds) *Evidence-Based Public Health: Effectiveness and Efficiency* (Oxford: Oxford University Press), 1997–2008.
- Littlejohns P & Kelly M (2005) The changing face of NICE: the same but different. *Lancet* 366(September 3), 791–794.

- Owen L & Fischer A (2019) The cost-effectiveness of public health interventions examined by the National Institute for Health and Care Excellence from 2005 to 2018. *Public Health* 169, 151–162.
- Timmins N (2012) *Never Again? The Story of the Health and Social Care Act 2012* (London: King's Fund and the Institute for Government).
- Timmins N (2017) *The Five Giants: A Biography of the Welfare State*, third edition (London: William Collins).
- Warner N (2021) *In Pursuit of Competence: Life as a Westminster Nomad* (Tolworth: Grosvenor House).

8 From gatekeeper to access and innovation champion? NICE and appraisal since 2007

Chapter 5 described the evolution of NICE's health technology appraisal (TA) activities from its establishment in 1999 up to 2007. We saw NICE build a sophisticated set of processes for the appraisal of technologies ranging from drugs to surgical procedures, struggle to reconcile speed of appraisal with robustness against challenge, and begin to move from an academic flavour of HTA to a 'service delivery' model, with an apparatus of governance, standards and service levels more suited to that. This chapter takes the story up to the present. As in Chapter 5, we avoid a detailed narrative of events in favour of a broadly chronological survey of some important themes.

In this chapter we will argue that, after around 2007, NICE moved more decisively than before towards championing access to new medicines for the NHS and its patients. This potentially threatened NICE's integrity (and reputation) as a rigorous evaluator of cost-effectiveness: was it going soft on expensive new drugs? NICE's growing enthusiasm for access to the best new medicines also posed a risk for the NHS' financial sustainability: all of this had to be delicately negotiated. NICE was challenged to decide whether its role was to hold back a pharmaceutical industry greedy for profits (described by one interviewee as 'the forces of darkness'), or to champion wider access to effective (and cost-effective) technologies. We, therefore, examine here NICE's appraisal of new cancer drugs and its difficult relationship with central government over NHS access to these. This leads to discussion of the changing relationship between NICE and NHS England. Still on the subject of access, we then chart the way NICE has developed a role in support of innovation in the UK's life sciences industries. Before any of these, however, we must briefly consider the value-based pricing episode of 2007–11.

Value-based pricing

History is not, as Henry Ford supposedly said, 'just one damn thing after another', a random sequence of events. But nor is it a straightforward, easily-read flow of causes and consequences. It is more like 'a river of fluid and swirling potential, with many eddies and back currents in it'.¹ The value-based pricing episode threatened

1 Woolcock et al. (2011).

NICE's existence, but ultimately changed little. It is one of the 'back currents'. The story of why NICE survived illustrates both the contingent nature of policymaking and NICE's usefulness to all its key stakeholders by 2007: seeing it threatened, they rallied to its support.

The Office of Fair Trading Report, 2007

On 13 September 2005, the Office of Fair Trading (OFT), then a non-ministerial government department with a mission to 'make markets work well for consumers', launched a market study on the Pharmaceutical Price Regulation Scheme (PPRS).² The PPRS was the government-industry voluntary agreement for reconciling price restraint with a thriving pharmaceutical sector, mentioned in Chapter 1. John Vickers, the OFT's chairman, said:

we want to examine whether the PPRS works well to ensure that pharmaceutical markets meet the needs of patients by offering adequate rewards to pharmaceutical companies for developing new and useful drugs, while providing the taxpayer with value for money.³

The OFT selected the PPRS for examination on its own initiative, as was normal for its market studies. According to the *Financial Times* report just quoted, this review was part of the OFT's 'drive to examine the quality of public procurement', and followed a study noting growing market concentration and high barriers to entry. In other words, the OFT was applying its general economic mandate to promote healthy competition to the NHS market for drugs.

Its grasp of economics was sounder than its insight into the NHS. The resulting OFT report, in February 2007, called for the introduction of a value-based pricing scheme, by which it meant:

reviews of the cost effectiveness of individual drugs ... would set a maximum price ... in accordance with the clinical benefits it delivers relative to an appropriate comparator ... [this would] ensure the price of drugs reflect their clinical and therapeutic value to patients and the broader NHS.⁴

The authors felt NICE ought to play a central role, and discussed different options for that. All retained NICE's role as the trusted body for assessing a drug's effectiveness: a pricing unit within Department of Health (DH) was to be tasked with

2 Office of Fair Trading (n.d.); gov.uk (government web site) (n.d.) 'OFT'. The OFT was wound up, with most of its responsibilities passing to the Competition and Markets Authority, in 2014. Typically, market studies are examinations into the causes of why particular markets are not working well for consumers, leading to proposals as to how they might be made to work better: OFT (2010).

3 *Financial Times*, 14 September 2005, OFT to investigate pricing scheme for medicines.

4 Office of Fair Trading (2007), 1, 5. For an excellent early reaction to the OFT report, see Walley (2007).

negotiating the new prices on the basis of NICE's analysis.⁵ A *Financial Times* editorial welcomed the report as 'sensible in its aims. Somewhat undercooked and perhaps a little naive in some of its conclusions'.⁶

More than three years of debate ensued. No one was opposed to basing the price which the NHS, on its patients' behalf, paid for a drug on its 'value' to them – the first big challenge, however, was reconciling the views of the many groups affected about how to define and calculate that value. Both the industry and patient groups feared that any change might leave them worse off.⁷ And implementation, it soon became clear, would be challenging: even the naively optimistic OFT report suggested the scheme could not start before 2010. There was also a major presentational problem: the decision whether to exclude a drug on cost-effectiveness grounds seemed to land back where it had been before NICE, with the doctor (or the hospital), dispensing with the NICE guidance behind which doctors could shelter. The logical difference between the existing situation and the proposal might not, in fact, have been large, but doctors were nevertheless alarmed that they would be pushed into a highly visible rationing role.⁸

NICE, the Conservative Party and the pharmaceutical industry: 2008–10

It is in the light of the ongoing value-based pricing debate that we must interpret a November 2008 Conservative plan to 'renew' NICE.⁹ This intriguing 33-page document affirms that 'Conservatives have supported NICE since its inception'. We have seen in Chapter 2 that, in fact, they did not, in NICE's earliest years, so rewriting history in this way in 2008 is a powerful sign of NICE's growing acceptance across the world of politics. Indeed, the authors go so far as to endorse a then-current policy idea that NICE should expand by absorbing the Joint Committee on Vaccination and Immunisation.¹⁰ The document calls for NICE to work with the pharmaceutical industry and avoid an adversarial relationship. The small print would effectively gut NICE by making it advisory, while 'transfer[ring] responsibility for "recommending" or "not recommending" medicines to the NHS Board'. This, as we have just seen, was also the gist of the OFT's recommendation.

The document's author was Stuart Carroll, though the foreword was signed by Mark Simmonds MP, Shadow Minister for Health – number two to Andrew Lansley in the Conservative shadow health team. Carroll, the more interesting figure, holds an MSc in Health Economics from the University of York (the Department

5 Office of Fair Trading (2007), 105, 107.

6 *Financial Times*, 21 February 2007, Editorial. In search of a perfect price for medicines.

7 Adrian Towse, interview 1 March 2021.

8 Timmins (2016), 111–112; BBC News web page 20 November 2010, NHS reform warning from Royal College of GPs; Raftery (2013) comments: 'Value based pricing ... was presented as a way of avoiding NICE refusals. How this might happen was left unclear'.

9 Rawlins papers, Conservative Party (2008) *Improving access to new drugs: a plan to renew The National Institute for Health and Clinical Excellence (NICE)*; Carroll (2009).

10 The JCVI is an independent Departmental Expert Committee and an influential statutory body.

funded with DH seed money), and worked for the pharmaceutical industry from 2005, while also serving as ‘Health Adviser’ to the Conservatives in 2008–10. In this capacity he chaired the Bow Group’s Health & Education Policy Committee, later working at Sanofi, the ABPI, the government’s COVID-19 Vaccines Task Force, and recently as Director of Market Access and Policy Affairs for the UK and Ireland at vaccine manufacturer Moderna.¹¹ These allegiances could explain the document’s emphasis on championing access to new drugs, rather than on assessing their cost-effectiveness. The Bow Group’s interest in NICE persisted in 2009, when they sent it a questionnaire about its work and future plans, of a rather anodyne nature, which Mike Rawlins and Andrew Dillon duly completed.¹²

Carroll’s career trajectory (health economics, industry, politics, think tanks, PM Theresa May’s ‘Chief of Staff’ for her re-election campaign in 2019, and six years’ service on NICE’s appeals panel) illustrates more than just the ‘revolving door’ between government and its stakeholders.¹³ Of more interest here is the example it provides of the workings of what is variously labelled a ‘policy community’, ‘policy network’ or a ‘policy ecosystem’.¹⁴ Here is a beautifully clear case in support of the theory that complex states operate more by ‘governance’ than by ‘government’: that since there are too many tasks for any government, many are delegated to unaccountable groups such as experts, think tanks, and stakeholder groups like industry associations.¹⁵ For Carroll to write a Conservative Party medicines policy document while an employee of the US pharmaceuticals company UBC makes an unanswerable case that this kind of delegated governance exists. The question remains of how influential the document was: the most important recommendations of *Improving access to new drugs: a plan to renew NICE* were not adopted despite being the policy of the dominant party of the 2010 Coalition government.

In the political climate of 2008 and 2009, the various actors in the UK medicines policy community were well aware that the Conservatives were likely to form the next government. When they did so in 2010, in coalition with the Liberal Democrats, the Coalition Programme for Government contained a commitment to include value based pricing in the next PPRS, due in 2013, and framed its proposed cancer drugs fund (discussed in the next section) as a ‘bridge to value based pricing’.¹⁶ Its policy statements followed the line of the OFT report by proposing that NICE would no longer make a formal recommendation for or against the use of a drug.¹⁷

11 *Pharmaceutical Journal* (n.d.). The Bow Group describes itself as a conservative think tank which ‘represents all strands of conservative opinion’. Bow Group (n.d.); Carroll S (n.d.).

12 Rawlins papers, *Bow Group Research Questionnaire August 2009*.

13 Carroll S (n.d.).

14 Oliver and Faul (2018).

15 Cairney et al. (2019).

16 Raftery (2013).

17 *Financial Times*, 13 December 2010, NHS puts onus on doctors over costly drugs; DH (2010a).

In 2010–11, NICE, then, still had plenty to be concerned about, as its Annual Report makes clear.¹⁸ In an elegant piece of organisational politics, NICE positions itself as an essential part of whatever new framework might emerge, while avoiding criticism of the government's new plaything:

We believe that the aims of value-based pricing can be achieved by adapting the current NICE technology appraisal process and by building on the best of a system that is widely regarded as the world leader in evaluating the cost and clinical effectiveness of new drugs.¹⁹

Value-based pricing: much ado about nothing?

Three years later, the government, having struggled to specify the detail of what value based pricing was supposed to be, and increasingly preoccupied with the problematic details of all its other health reforms, completed its retreat from the OFT model and opted, more or less, for the *status quo ante*, leaving assessment of value with NICE and price negotiation with the Department of Health.²⁰ Or, in the words of Adrian Towse, Director of the Office for Health Economics, 'we already had a type of value based pricing before the Office of Fair Trading came up with the term, and we still have it'.²¹ We endorse Towse's explanation for the 2013 closing of the 'policy window' to the OFT proposals: it was largely about changes in the world of politics itself, rather than in the nature of the problem or the policy. Specifically:

by that time the Secretary of State had a lot of other things to worry about [laughs]. So the fact that this part of his great reform agenda had been consigned to the dustbin was not his greatest worry! ... it could have worked, but ... some ... obvious issues ... needed political nuancing, which, well the Secretary of State didn't seem to be famous for ..., his view was that he could ram this down the industry's throat, I don't think it ever occurred to him that patients' groups would ever object to it.²²

A further consideration, not to be underestimated, is the intrinsic difficulty of making the superficially simple idea of value-based pricing work in the complex environment of the drugs market. David Haslam, NICE's second chair, summarised it in this way:

there was a real logic behind it ... but the more you looked at the practicalities and the legalities, for instance, if you could take into account the fact that if

18 NICE (2011a).

19 NICE (2011a).

20 Raftery (2013). For the Lansley reforms, see Klein (2013) and Timmins (2012).

21 Towse interview.

22 Towse interview.

[a treatment] could get someone back to work ... there would be an effective saving ... That makes ... perfect sense, doesn't it? Apart from the fact that because men earn more than women you would prioritise male illnesses over female, you would de-prioritise anyone over retirement age, that's illegal. ... the moment you go into these things you realise 'yes, but', so we could understand the drive behind it, [but this] is why it all hit the buffers.²³

Summing up the value-based pricing episode, we have noted it as an illustration of the contingent way in which medicines policy has emerged. This is true in three ways. Firstly, the OFT report was produced for reasons unconnected with NICE. Secondly, the episode shows the impact of personalities: medicines policy has not always been driven by impersonal forces such as scientific advance or economic need. Lansley's character, his conviction that he could work out the technical detail and the politics would then fall into place, was a determining, not an incidental, factor. The OFT report led to the outcome which it did – little change to the PPRS, DH medicines policies or NICE's ways of working – because Lansley found value-based pricing intellectually attractive, and pursued it without thinking through the politics or the implementation well enough to overcome the obstacles they posed. And thirdly, the value-based pricing proposal became – by chance – stuck in the processes of policy and politics at the same time as Lansley's immense NHS reform and legislative agenda, which took precedence when Government did not have the bandwidth to manage both at once.

The affair also showed how much its stakeholders valued NICE. We have seen how GPs, patient groups, and pharmaceutical manufacturers all rallied to the defence of the status quo. Whether or not they had previously welcomed NICE's HTA activities – and, as we have seen, it varied – they all recoiled from the uncertain future of a new kind of PPRS with value-based pricing, and the fresh investment of analytical effort for which this called.

One final observation may be made on the value-based pricing episode. The OFT report's authors had stumbled into a minefield when they lighted on the concept of 'value' in health. The idea had long been familiar to health economists, who had developed sophisticated ways of defining and measuring it, often under other names such as 'health gain'. In the 2000s, however, public discourse began to entangle this rigorous kind of thinking about 'value' with the much looser usages familiar to business writers, including those with an interest in pharmaceuticals. These ranged from the academic, like Michael Porter at Harvard Business School, to the promoters of each new drug and company, good or bad.²⁴ Everyone was in favour of value and everyone meant something different. The discourse about 'value in health' became meaningless once no-one could speak about value without defining it, adding more transparent language – which removed the need to use the word. This discourse nonetheless continues unabated.

23 David Haslam, interview 24 April 2020.

24 Porter's influential ideas about value in health are most accessible in Porter and Teisbert (2006).

Access to the new cancer drugs

From around 2008, new cancer drugs became a test case for the claim that NICE was swinging away from the ‘gatekeeper’ role of keeping out poor-value drugs, and towards a role of access champion for new medicines. NICE’s appraisals of new cancer drugs did not take place in a vacuum: to return to Jasanoff’s ‘idiom’ of co-production, which we introduced in Chapter 1, the cancer drugs story is a prime example of the ways in which the production of medicines, ostensibly a matter purely of science and technology, becomes entangled with the unfolding story of the social world of politics, business, the media and more.²⁵ This section tries to chart these processes and at least partly uncover their dynamics.

Rising prices, harder choices

One of the entangled strands of the cancer drugs problem was that those being placed on the global market were becoming more expensive. This hardly explains why it was in 2008 that cancer drugs became problematic – the trend had become visible in the late 1980s, and we have seen in Chapter 5 that Herceptin had been a strikingly expensive new cancer drug back in 2005. But in any case, pharmaceutical manufacturers who had enjoyed buoyant revenues from older ‘blockbuster’ drugs wanted a new income stream as those came out of patent protection and were undercut by low-priced competitor products. Drugs for chronic diseases were attractive: each patient might need them for a long time, producing a long steady stream of income. Alternatively, even if a cancer drug only prolonged life by a few months, as was often the case, public fear of cancer was strong enough to create a strong demand, allowing high prices to be charged.²⁶

At least partly in consequence of this, much impressive science was undertaken to produce new generations of chemical entities and formulate new drugs from them, often using novel biotechnologies such as the manufacture of monoclonal antibodies – not only as treatments for cancer, though many were. NICE’s job has become more difficult as these new therapies are brought to market, with their eye-watering prices, and dependence for evidence of their effectiveness, almost always, on modelling which extrapolates from tiny numbers of patients. This makes them extra hard to assess.

In a no-holds-barred statement to the *Observer* in August 2008, in which he maintained that kidney cancer drugs could be produced for about a tenth of their current price, Rawlins gave his view of what was happening, a critical line which he and Dillon took publicly on various occasions around this time:

‘Part of the problem is that the pharmaceutical industry is looking at a very bad period in the future because a lot of their big earners are going off patent,

²⁵ Jasanoff (2004).

²⁶ Timmins (2016), 96–97.

and many companies are looking at a 30 or 40 per cent [revenue] reduction in the next five years unless they come up with new drugs,' he said. 'And so part of the cost is cushioning against that'.²⁷

How did these expensive new drugs affect NICE's HTA work? They would often come in above the cost per QALY threshold: that made it likely NICE would reject them. This would then trigger a round of appeals, public controversy and the intervention of patient groups, normally with a straightforward message that their members needed the new product regardless of cost.²⁸ Not surprisingly then, this was a period when, according to Bill Morgan (then a researcher on health policy for the Conservative Party), there was 'a lot of pharmaceutical company investment in lobbying for reforms to NICE in cancer medicines'.²⁹

The trouble with kidney cancer drugs (2008)

One might say that this – at first imperceptibly gradual – process began with drugs for kidney (renal) cancer. Certainly that was where the re-ignition of public controversy about NICE appraisals began, after a quieter spell following the rapid succession of storms over Herceptin and the Alzheimer drugs Aricept, Exelon and Reminyl during 2005–07. The new media storm centred on kidney cancer drugs like Sutent (sunitinib – manufactured by Pfizer and the first to market), Avastin (bevacizumab), Nexavar (sorafenib) and Torisel (temsirolimus). NICE's draft guidance on these, with a negative finding, came out in August 2008.³⁰ The debate played out slightly differently from previous occasions such as the Herceptin controversy: argument came to focus this time on the NHS's rules concerning a patient's right to 'top up' the funding of their treatment with their own funds, allowing the most expensive drugs to be used when the NHS would not pay for them (i.e., in the absence of a NICE recommendation).³¹

A question like this, which went to the heart of the kind of NHS people wanted, was bound to rise up the political agenda. Think tanks such as the King's Fund and Reform joined the debate.³² Should all patients with the same health needs get the same service? Did 'topping up' undermine that? The (Labour) Secretary of State for Health, Alan Johnson, had to intervene. His position was against topping up, but he also saw that the political pressure had to be managed away somehow. NHS

27 *Observer*, 17 August 2008, Health chief attacks drug giants over huge profits.

28 An argument which the manufacturers themselves might fund a patient group to put forward more effectively: see Chapter 4.

29 Bill Morgan interview, 20 April 2022.

30 *Guardian*, 7 August 2008, *Kidney cancer drugs judged too costly for 3,000 NHS patients*.

31 See for example *Daily Mail*, 12 September 2008, 'Patients could turn to black market to buy cancer drugs if they can't pay to top up NHS treatment', warn experts.

32 The King's Fund is 'an independent charitable organisation working to improve health and care in England' - King's Fund (n.d.); Reform is a 'think tank [set up] to challenge the idea that increasing public spending ... was the only way to improve public services' - Reform (n.d.).

cancer services were always a high-profile topic, given public attitudes to cancer, and Labour had made improving them a flagship policy in the 2000s. The oncologist Professor Sir Mike Richards had been appointed DH's National Cancer Director (popularly, the 'Cancer Czar') in 1999 (and, as such, had been a key adviser on the adoption of Herceptin in 2005). Richards was now tasked with sorting out 'topping-up':

I was asked by Alan Johnson. First of all [he] tried very firmly to keep his head in the sand on this, but it ... was the most contentious issue of that year in the NHS. The wonderful thing is it's completely dropped off the radar since. ... he felt he had to get an independent review ... and I was asked to do that. One of the more challenging tasks in my career.³³

His report in November 2008 had important implications for NICE.³⁴ One intriguing feature of the report is that it dealt even-handedly with drugs in general, rather than demanding preferential treatment for cancer drugs – a position Richards was to maintain in later policy debates, as we shall see.³⁵ Missing from the report, however, was any discussion of the extent to which the UK spent less on drugs for cancer (and other conditions) than comparable countries, a topic he had investigated. This evidence was grist to Richards' mill in pressing for higher spending, but Johnson persuaded him that he should examine it in more detail and publish later, so as not to distract attention from the resolution of the top-up issue.³⁶ Of more immediate impact for NICE, the Richards 'Improving Access' report noted how the:

increasing numbers of drugs that are targeted to treat often relatively small groups of patients for a short period of time near the end of their life will challenge existing processes. There is a strong case ... for introducing new arrangements for assessing these drugs ... [DH] should work with NICE to assess urgently what affordable measures could be taken to make available drugs used near the end of life that do not meet the cost-effectiveness criteria currently applied.³⁷

This work did proceed urgently: NICE unveiled its new 'end of life' criteria in January 2009.³⁸ We shall discuss these new criteria in context, in the next section of this chapter. NICE's Final Appraisal Determination on the four kidney cancer drugs in the following month adopted the new 'end of life' approach. Only Sutent got through.

33 Mike Richards, interview 3 October 2019.

34 Richards (2008).

35 Richards interview.

36 Richards interview. The report, discussed below, is: Richards (2010).

37 Richards (2010), 42–43.

38 NICE (2009a).

The Cancer Drugs Fund: a politician's medicines policy (2010–16)

Sutent, although approved, was to have a sting in the tail for NICE. In 2007, the NHS refused to provide it to a kidney cancer patient called Clive Stone, who responded by establishing the Justice for Kidney Cancer Patients campaign.³⁹ Stone, an ex-bank manager living in the Parliamentary constituency of the Conservative Party leader David Cameron, is credited with persuading Cameron to set up the Cancer Drugs Fund (CDF), to which we now turn.⁴⁰ Every policy expert to whom we have spoken regards the CDF as a disastrous policy error, discriminating unfairly between patients on the basis of their diagnosis and wasting very large sums of money. Even the government's own published impact assessment said before the CDF opened its doors that annual costs would outweigh benefits by £169m.⁴¹ But is the expert perspective the whole story? And if the experts are right, then why was policy made this way?

Cameron, then Leader of the Opposition, announced his intention to establish the CDF on 3 April 2010, in mid-election campaign.⁴² His proposal was simply to buy cancer drugs without reference to NICE's appraisal guidance, in other words without consideration of their cost-effectiveness. In praise of this approach, the *Telegraph*, a Conservative-supporting newspaper, said patients were 'currently subject to a national system of rationing which means they are routinely refused treatments ...' The effect of the policy would be to dispense with NICE, so far as cancer drugs were concerned at least.

Nicholas Timmins describes Cameron's announcement as 'out of the blue'.⁴³ It came as a complete surprise to the policy community, within which the problem of unequal access to cancer drugs, and a number of solutions, but not this one, were under discussion. What Cameron had done was bypass the usual channels of policy debate and gone for a policy on very largely political grounds. This explains the hostility of the policy specialists. A lot of the unfavourable comment draws attention to the policy's emergence during an election campaign, which emphasised its political nature.

Cameron, though bypassing government officials, had done some homework, such as a fairly rudimentary look at the cost. The headline announcement of £200 million seems to have been selected because this was the amount which the NHS would save under the Conservative policy of cancelling a planned Labour increase in national insurance.⁴⁴ Timmins and *Guardian* journalist Sarah Boseley have reported how Cameron's aides examined whether this sum would be

39 *Oxford Mail*, 4 June 2016, David Cameron leads tributes to inspirational medical campaigner Clive Stone.

40 *Oxford Mail*, 29 April 2017, Family of Oxfordshire cancer campaigner Clive Stone defend the Cancer Drugs Fund he fought for.

41 DH (2010b).

42 *Daily Telegraph*, 3 April 2010, Cameron pledges to lift restrictions on cancer drugs available on NHS.

43 Timmins (2016), 106.

44 Timmins (2016), 106. National insurance is (effectively) a payroll tax in the UK.

sufficient by phoning Bill Morgan, the former Conservative researcher, by then working for the lobbying company MHP Health Mandate – an account confirmed to us by Morgan.⁴⁵

It is worth pursuing the Health Mandate thread a little further as it sheds light on pharmaceutical industry lobbying. The company, and Morgan's colleague there, Mike Birtwistle, are credited in Richards' 'international variations' report for assistance with drafting. The report was, in Richards' words, the work of 'a group ... I co-chaired ... with the Chief Executive of Roche UK, John Melville. So we looked across, really worked very closely with industry, looking at all the drugs ...'⁴⁶ Birtwistle told the *Guardian* his input was 'supported by Roche as part of MHP's ongoing consultancy work for them and was part of John Melville's contribution to delivering the project'.⁴⁷ Previously (in 2008) Roche had paid for the Rarer Cancers Foundation (or Forum, the name varied) to commission a report from Health Mandate on access to cancer drugs in the UK, a common industry lobbying practice.⁴⁸

In fairness to Roche, they did tell the *Guardian* that editorial control of Richards' 'international variations' report rested ultimately with the Department of Health, and, having interviewed Richards, we cannot imagine him submitting any report that he regarded as biased in Roche's favour. The facts remain that: Roche manufactured some of the most expensive cancer drugs such as Kadcyla and Avastin; both were rejected by NICE; Roche paid for reports showing (correctly) that access to cancer drugs was more difficult in the UK than some comparable countries; this information was used in the Conservative press release about the CDF in April 2010; and the CDF went on to spend large sums on Roche drugs including Kadcyla and Avastin. Melville would be a saint if he did not allow himself some satisfaction with this outcome.

Following the election, the establishment of the CDF was announced in the Coalition Programme for Government in May 2010.⁴⁹ In July 2010 Lansley signalled that the CDF would open the following April after a consultation on the details, at the same time releasing Richards' delayed 'international variations' report and linking it to £50m of immediate new money for cancer drugs.⁵⁰ In Rawlins' recollection, he and others tried to talk Lansley out of it, but to no avail:

I remember two [NICE Board] members sitting with ... Lansley when he became Secretary of State, trying to persuade him to ditch the idea. I can still remember meeting with him, Mike Richards and Bruce Keogh. ... But

45 Timmins (2016), 106; *Guardian*, 8 August 2014, Cancer Drugs Fund seems to help pharmaceuticals giant Roche most; Morgan interview.

46 Richards interview.

47 *Guardian*, 8 August 2014.

48 Morgan interview.

49 DH (2011).

50 DH (2010c); Richards (2010).

anyway ... Lansley was under strict instructions from his boss to make sure it happened, ... it was a stupid policy and could have undermined us.⁵¹

Richards recalls discussing the implementation:

Lansley wanted to give the money to PCTs, while I wanted it held centrally.. I was fairly sure that PCTs would try to divert the funds to other purposes and would have widely varying criteria for which cancer patients should benefit, introducing a new postcode lottery. I clearly remember telling Lansley that he would 'scupper' the CDF if he gave the money to PCTs. (He looked shocked!). We compromised on giving it to Regions, but ultimately brought it back to national level through specialised commissioning.⁵²

So Lansley set up the CDF. From April 2011 £200m per year was provided for three years, divided between England's ten Strategic Health Authorities (SHAs): each was to devise their own plan to fund cancer treatments. Individual doctors applied to the SHA's clinically-led panel to fund their patient's treatment in a case where they had been unable to access a drug recommended by their oncologist, typically because NICE had not recommended NHS use and the local NHS had not decided to fund it. It quickly became clear that this rapidly-sketched operating procedure was unsustainable – and the details of how the CDF worked did change quite quickly, with, for example, NHS England taking over its operation in 2013.

The DH impact assessment had made the tongue-in-cheek assumption that 'pharmaceutical companies will not increase the prices of their products in the expectation that the NHS will pay more for cancer drugs'.⁵³ However they did just that: the CDF was an easy target. Since there was no cost-effectiveness test, when it approved a treatment it would pay the prices they asked. The budget was exceeded and then substantially increased on more than one occasion, and the CDF's annual cost reached £416m in 2014/15.⁵⁴ Picking up on growing unease about the CDF, in September 2015 the National Audit Office, the UK Parliament's value for money watchdog, published an Investigation into it, following up on concerns raised by earlier work it had done on cancer services.⁵⁵ The NAO reported that since October 2010 the CDF had spent £968m, and its overspend in the most recent year had been 48% of its allocated budget – an eye-watering number rarely seen in UK government spending programmes. 51% of patients supported by the CDF had received drugs which NICE had previously appraised but not recommended. Change was clearly on the way.

51 Mike Rawlins, interview 18 September 2019. At the time Professor Sir Bruce Keogh was the NHS Medical Director at DH (later National Medical Director at NHS England – the same job in a new organisation) – Keogh, Prof Sir Bruce, *Who's Who & Who Was Who* (2023).

52 Richards interview. See next section.

53 DH (2010b).

54 National Audit Office (2015).

55 National Audit Office (2015).

Living with the Cancer Drugs Fund since 2015

In July 2015, NHS England proposed that the CDF should become a ‘managed access’ fund that would pay for promising new drugs while NICE put them through its usual appraisal procedure. This change meant the CDF would no longer pay for drugs that NICE had appraised and found wanting. These changes represent a compromise between the political need to retain a scheme highly valued by the Prime Minister (who had just been re-elected, this time with a majority), and the demands of affordability and cost-effectiveness. Everyone, by this stage, agreed that the cost (-effectiveness) dimension had made the CDF unsustainable in its existing form.⁵⁶

The 2015 proposals for reforming the CDF, based on drafts by Dillon and Carole Longson and agreed with NHS England, DH and Downing Street, set out to bring it more in line with the approach to drugs taken by NICE. NHS England officials responsible for overseeing the CDF (and trying to contain its costs within the budget envelope the government had set) concluded there was a need to incentivise drug companies to apply some ‘pricing discipline’ by creating a new set of economic incentives replacing those of the CDF in its original form. Simon Stevens recalls that:

‘David [Cameron] was understandably proud of the fact that through the Cancer Drugs Fund the concerns that cancer patients weren’t getting the most modern cancer medicines had initially been taken off the table’ – nevertheless the open-ended drug pricing meant that the fund was unsurprisingly soon significantly overspent.⁵⁷

NICE and NHS England consulted jointly on how to operate the reformed CDF. Their plan benefited from the backing of a recently published independent Cancer Taskforce report, which also ‘proposed that the new CDF should operate with NHS England and NICE’.⁵⁸ Administration passed from NHS England to NICE, ironically in view of the hostility of Rawlins and other NICE leaders to the CDF’s original manifestation. After protracted consultation and political negotiation (often with Cameron on one side, and Stevens and Hunt on the other), the CDF was therefore reformed. It became in Stevens’ words, a “‘maybe” fund for promising but initially unproven new drugs’: one which paid for a medicine – or, more precisely, its use in a particular ‘indication’ (the diagnosis, kind of patient and stage of disease) – where it seemed plausible it might turn out to be cost-effective but which needed more real-world evidence before NICE could be sure.⁵⁹ This kind of ‘managed access’ was considerably more sophisticated than Richard Sykes’ 1999 proposal (discussed in Chapter 5): there was now a rebate (or risk-sharing) mechanism

56 National Audit Office (2015).

57 Simon Stevens, interview 27 January 2022.

58 NICE (2015a).

59 Stevens interview.

under which a company would pay back some of the cost of the drug to the NHS if its benefits turned out to be disappointing.

The perspective from NICE, specifically from Meindert Boysen, who in 2015 was its Programme Director for TAs, is interesting because it places the emphasis, not on cost-effectiveness, but on access:

we had to create a scenario in which NHS England would accept higher risk as long as we could plausibly say that [these drugs] are cost effective. That was the quid pro quo and I think we managed to get that done.⁶⁰

In other words, Boysen is saying that once NICE thought a new cancer drug was a good prospect, it wanted NHS England to overcome its concern that the drug's cost-effectiveness might not be as good as first thought. Later sections of this chapter will look further into the debate over the competing priorities of access (getting effective drugs to NHS patients) and cost-effectiveness. But, to conclude our account of the CDF, Cameron's acceptance of the changes which took effect in April 2016 was one of his last interventions in medicines policy: three months later he was out of office, succeeded by a Prime Minister (Theresa May) who took no special interest in the CDF.

Interpreting cancer drugs policy since 2008

The experience of the CDF illustrates the complexity and uncertainty of NICE's policy environment, and the growing importance of NICE's relationship with NHS England, especially about the affordability and cost-effectiveness of new drugs. We will turn to this relationship in a later section of this chapter. We should also highlight the unusual salience of politics in the cancer drugs story. Kingdon's 'multiple streams analysis', which we encountered in Chapter 1, helps us understand the politics of the CDF. Kingdon proposes that policymaking incorporates three 'streams': problems, policies, and politics.⁶¹

In Kingdon's terms, access to cancer drugs was acknowledged to be a problem in the UK, and rose up the agenda because, in part, of the unfavourable comparisons which Richards and Melville made between the UK's spending per head and other countries'. As political scientists have observed, a key area of political contestation is the framing of a problem. The distinctive thing about the CDF is that the problem was framed by actors in the 'politics' stream rather than the 'policy' stream. (Although, against this view, Nick Seddon reminded us that 'most Prime Ministers ... attach themselves, from time to time, to agendas which ... may not be purely based on the work of policy experts and health economists'.⁶²) Either way, the CDF delivered a solution to the political problem (in Morgan's

60 Meindert Boysen, interview 23 April 2020.

61 Kingdon (2003).

62 Nick Seddon, interview 30 March 2022.

words, ‘paying ... 200 million to make sure that you don’t get a nasty Daily Mail front page’).⁶³ It fell far short, however, of solving the ‘policy’ problem (of making a ‘tragic choice’ – see Chapter 5 – about balancing access, affordability, cost-effectiveness and scientific uncertainty about effectiveness). After five years (2010–15) of framing the cancer drugs problem as a political problem, the Cameron government decided to accept the advice of officials and revert to framing it as a policy problem.

One consequence was to move much of the accountability for access to cancer drugs back from government to NICE. We saw in Chapter 5 how ministers often sought to distance themselves from the more tragic (and controversial) choices in health care. Where to place this accountability remains a perennial issue in health policy. In 2005, in relation to Herceptin, Patricia Hewitt had strayed close to (or over) the line between leaving access decisions to NICE and taking responsibility for them, motivated by her political judgement that patients and voters would find it intolerable for her to do otherwise. Cameron’s 2010 decision was not entirely dissimilar. Both are reminders of the limits to society’s willingness for tragic high-profile choices about access to medicines to be delegated to experts: at some point, we appear to want a politician to make the decision and be accountable for it.

Changes to appraisal since 2008: easier access for new drugs

In this section we look at the sequence of changes to appraisal since 2008, summarised in Box 8.1. NICE’s philosophy, since its establishment, has been to create a technically rigorous method of assessment, which forms only the first part of the overall appraisal process, and generates material on which, in the second part of the process, the appraisal committee exercises its judgement. NICE uses ‘*process*’ to describe the sequence of events a technology has to pass through during appraisal, and ‘*method*’ for the technical approach to assessment.⁶⁴

The story of why these changes took place when and as they did is surely of more interest to the general reader than any of the technical detail (which can be found in the references provided in Box 8.1). As before, we find ‘co-production’ a helpful lens for examining this history. Thus, on the one hand it is true that developments within the world of science and technology (such as the marketing of digital health care technologies from the mid-2010s) compelled NICE to bring forward new forms of appraisal in order to accommodate the different spectrum of evidence the new technologies were able supply to HTA. For example, while randomised controlled trials are still treated as the gold standard for drug appraisal, they are not feasible or ethical for every technology.

On the other hand, it was by no means the case that every change in the appraisal method flowed from technical development in the technologies being

⁶³ Morgan interview.

⁶⁴ It is confusing of NICE to use ‘appraisal’ as a label for the initial assessment, as it sometimes does, for example in ‘Guide to the methods of technology appraisal’ in Box 8.1.

appraised, or the invention of better appraisal methods. Many of them are best understood as NICE's responses to changing social value judgements about what appraisal ought to deliver. As we observed in Chapter 5, following Hoffmaster and Hooker, there are many conflicting notions of effectiveness and fairness, and policy makers – such as NICE – need to maintain the legitimacy, not only of their individual choices, but also of the method by which choices are made.⁶⁵ To a critic, this can look like amoral trimming to the latest fashionable point of view, but the alternative, taking a stand against society's current values, would become self-defeating if pressed so far that NICE and its decisions lost their legitimacy in the public eye. One critical question is therefore: whose value judgements does NICE reflect: government's, society's, or those in society with the loudest voices?⁶⁶

Box 8.1 Main changes to NICE appraisal processes and methods

April 2004: *Guide to the technology appraisal process**

- First consolidation of NICE's earliest *process* guides. A companion volume (also 2004) describes the *method*.

2005/06: *Guide to the single technology appraisal (STA) process*

- Sets out the newly introduced STA process (see Chapter 5)

June 2008: *Guide to the methods of technology appraisal*

- Renewal of version published in 2004, in the light of: progress in HTA methodology, growing experience of managing ambiguity and uncertainty in the evidence, and the production of the first NICE Social Value Judgements.

January 2009: *Supplementary Advice: Appraising life-extending, end of life treatments*

- Additional flexibility if life expectancy less than 2 years, innovative drug extends it more than 3 months. Primarily for rare conditions

65 Hoffmaster and Hooker (2013).

66 Chapter 4 discusses NICE's approach to discovering what society's value judgements were, above all using its Citizens Council.

April 2013: *Guide to the methods of technology appraisal*

September 2014: *Guide to the processes of technology appraisal*

May 2018: *Guide to the processes of technology appraisal*

- the single technology appraisal and fast track appraisal processes
- processes for the Cancer Drugs Fund and assessing budget impact.

2019: *Charging for technology appraisals and highly specialised technologies*

- a STA cost £142,800 in 2022/23, with 75% discount for smaller companies

1 February 2022: *Guidance Development Manual; Topic Selection Manual*

- more weight to health benefits in the most severe conditions
- Generic manuals aligning NICE HTA approaches for all kinds of technologies

(NICE's online 'contents page' for its current technology appraisal guidance is <https://www.nice.org.uk/About/What-we-do/Our-Programmes/NICE-guidance/NICE-technology-appraisal-guidance>.)

*For definitions of 'process' and 'method' see text.

Modifying the appraisal method: responding to pressures

In Chapter 5 we saw NICE changing its appraisal processes in the years up to 2006, making them start earlier and operate faster, for the benefit of both patients needing the new drugs and manufacturers. Permission was granted for appraisal to run in parallel with market authorisation, so that a newly licensed drug might receive NICE approval almost immediately; Single Technology Assessment was introduced alongside the slower and more wide-ranging Multi-Technology Assessment; and manufacturers took over the writing of the initial case for a drug's approval. We concluded that these changes did not obviously tip the balance towards NICE approving rather than rejecting new drugs, but did produce faster decisions. The post-2008 changes brought in some 'modifiers', in the official jargon, to the NICE Reference Case (the default appraisal method, which relies mainly on calculating the ICER using QALYs). We now test these post-2008 changes against the same two questions we used in Chapter 5: did they move the dial towards 'yes', and did they speed up appraisal? We will take a chronological approach.

The 2005–06 changes had demonstrably made appraisal faster, but it could never be fast enough for seriously ill patients wanting a new drug, or manufacturers seeking to recover their investment before the end of patent protection (see Chapter 5).⁶⁷

67 Evidence of faster appraisal comes from Casson et al. (2013).

Pressure continued, for example in the Conservative Party paper *Improving access to new drugs: a plan to renew NICE*, which we encountered earlier in this chapter. This included proposals for faster appraisal (one of which, starting appraisal at the time of licensing, had, in fact, already been adopted – as long ago as 2005). In reality, NICE had grasped the importance of speed, and was working on it diligently throughout these years, mainly within its existing structures. Speed again became a major policy issue for NICE with the launch of the joint government-industry Accelerated Access Collaborative in 2018: we return to this initiative in a later section of the chapter.

The first initiative we consider, the June 2008 *Guide to the methods of technology appraisal*, is best interpreted as NICE itself presented it: a renewal of the 2004 edition in the light of two main developments: technical progress in HTA, and NICE's adoption of its first set of Social Value Judgements (SVJs, discussed in Chapter 4).⁶⁸ The 2008 SVJs gave force to the advice NICE received from its Citizens Council. Their incorporation into the updated methods guide signalled the Board's seriousness about using SVJs. More mundane, though important for the work of practitioners of drug appraisal, the 2008 *Guide* and its companion volumes codified important changes since the 2004 edition such as STA and ERGs.

The 2008 *Guide* was never an exercise in trimming towards the drugs industry. Two of pharma's most experienced commentators – Julia Earnshaw (of Glaxo-SmithKline) and Gavin Lewis (Roche) – gave the *Guide*'s consultation draft a cautious welcome which welcomed NICE's continuing commitment to the use of judgement and the balancing of competing goals, while expressing concern about how strong NICE's commitment was to look beyond the ICER and consider extra factors when reaching a recommendation.⁶⁹ These extra factors, which the industry's critics have been apt to view as 'fixes' or 'fiddles', have since come to the fore, as we shall soon see.⁷⁰ NICE's 'rules of the game' have been one of the stakes in a long-term contest between access and cost-effectiveness: an enduring theme in the story of HTA in the UK.

A final observation linked to the 2008 *Guide* concerns the use of modelling to estimate a new technology's clinical and cost effectiveness. Such modelling had often been used from NICE's earliest days, but its impact had grown, and this probably prompted the inclusion in the *Guide* of a significant section on the subject. Modelling takes the results of a clinical trial and extrapolates from them where the available trial data fails to give a full picture of likely costs and benefits. For example trial patients might not be typical NHS patients, or data might have been gathered only on intermediate outcomes rather than survival or the 'health-related

68 For NICE's account of the changes marked by the 2008 methods guide, see Barnett et al. (2009).

69 Earnshaw, and Lewis (2008).

70 Examples of such criticism include Collins and Latimer (2013), O'Mahony and Paulden (2014) and Charlton (2020).

quality of life' (HRQL) which underlies the QALY and thus the NICE method.⁷¹ Permitting modelling is a deliberate decision to peer into an uncertain future of a drug's use and make informed guesses. Refusing to do so is another option, adopted in Germany, a position attacked by Towse of the Office of Health Economics, who told us this policy lay behind Germany's inability to approve the use of the Astra-Zeneca vaccine against Covid-19.⁷²

What we should note at this point, though, is that NICE has permitted a great expansion in the modelling of costs and benefits, while also laying down rules about its use, as in the 2008 *Guide*. This is one of the most important examples of NICE's willingness to accept uncertainty and risk, described by Boysen (who was, let us recall, in charge of NICE Single Technology Appraisals from 2006, and HTA as a whole from 2009):

when I started we [said] 'this is the threshold, can't go above it. We are going to have to say no.' We said no to quite a number of things for a time. It has moved to having a much larger toolbox, and various ways of managing uncertainty and risk and actually allowing us to attend to the access needs, and supporting life sciences. As well as making sure we are not asking the NHS to spend money that they shouldn't be. But it's a combination, and it has changed over time, but it is still very much on my mind.

... the real question we are asking is 'what do you people find acceptable?' With COVID in mind I am thinking that people will find a lot more acceptable, are willing to accept much more risk, in order for NICE to be ... quicker.⁷³

To paraphrase these important comments, NICE's tolerance of modelling is one situation where it tries to act on its understanding of a social value judgement: in this case, that a level of risk and uncertainty are acceptable in order to secure earlier appraisal and approve more new drugs. As economists from one ERG told us, drugs are now approved on:

weaker and more immature data ... 95% of your QALY claim ... is beyond the time period for which you have data. So ... the majority of it is just speculation and when you look at the curves they're all over the place. ... in the past, I think, NICE wouldn't have looked at these things.⁷⁴

71 There are clinical reasons why trials may avoid enrolling, for example, more vulnerable patients.

The literature on trial design, its shortcomings and their politics is extensive. For an accessible and critical view, see Goldacre (2012).

72 Towse interview.

73 Meindert Boysen, interview 23 April 2020.

74 James Mahon, interview 3 November 2021.

Modelling can pose a risk to the transparency of NICE decision-making. It has become so complex that few apart from its practitioners could understand its methods and assumptions.⁷⁵ Against this, however, a health economist (for example) could reasonably object that clinical medicine, too, can be opaque to the uninitiated.

The last days of 2008 saw the first of the ‘fixes’ we mentioned earlier, when NICE issued the ‘End of Life’ guidance already mentioned, for implementation from January 2009.⁷⁶ The pace and other details of publication make clear that it was an urgent response to a pressing problem: Richards’ report on access to drugs, describing the issue and proposing this solution, only came out in November.⁷⁷ Also in November, NICE held a Citizens Council meeting on the topic of Departing from the Threshold, which gave support to such departures where, among other things, the treatment was life-saving, the illness was extremely severe or there were no alternative therapies.⁷⁸ The ensuing NICE guidance prays the findings of this meeting in aid, though the brief meeting report make no specific reference to end of life situations.

Giving extra weight to the final months of life was a conscious departure from the previous line that ‘a QALY is a QALY is a QALY’, something Richards characterised as the ‘equity’ line.⁷⁹ It drew criticism from the equity line’s defenders.⁸⁰ NICE’s next annual report observed, without giving the context of Richards’ report, that:

‘we know that people value any extra time at the end of their life, so we have asked our independent advisory bodies to take this into account’. ‘The first technology to be approved using this new criteria was sunitinib for the first-line treatment of advanced and/or metastatic renal cell carcinoma’.⁸¹

Richards characterises this guidance as a compromise he worked out with Rawlins and Dillon – rapid problem solving in a small group of officials behind closed doors (in much the same way as the reform of the Cancer Drugs Fund in 2015 – see earlier section of this chapter):

NICE were quite reluctant to have different criteria, I understood that, but they actually had a citizens’ panel of some description, which, roughly speaking, said they should. I remember discussions [with Mike Rawlins and Andrew Dillon], we came up with this answer.⁸²

75 Tom Walley, personal communication.

76 NICE (2009a).

77 Richards (2008).

78 NICE (2008).

79 For an example of NICE saying ‘a QALY is a QALY’ see for example Rawlins and Culyer (2004).

80 Collins and Latimer (2013).

81 NICE (2009b). Sunitinib is the generic name for Sutent.

82 Richards interview.

NICE prides itself on transparent decision-making and careful consultation on draft guidance of all kinds, and does deserve this reputation, but, in a crisis, Whitehall's older ways of working have at times taken over and NICE has gone along with them, recognising where the power lies when ministers or their top officials are seriously engaged with a problem. Arm's-length governance has been the default mode, and a valuable one – as we have seen in Chapter 3 – but not the only way of making medicines policy.

The next of the 'fixes' to modify the use of the ICER – of the kind Earnshaw and Lewis and the drugs industry (see above) had been hoping for – came in 2011.⁸³ It affected drugs likely to have substantial long-term benefits for children. As with the 'end of life' guidance, by making it easier for NICE to approve new drugs, this benefited specific groups of seriously ill patients, and also the pharmaceutical industry, and by crowding out existing NHS treatments with better ICERs, it worked against the interests of some existing patients and the overall cost-effectiveness of NHS spending.

Making sense of what changed in 2011 requires a short excursion into the economics underlying the NICE method. Adopting a health care technology brings changes in the costs and benefits which patients and the NHS experience. The timing of these costs and benefits matters, because people are observed to value them less, the further into the future they occur ('time preference'). This concept is used in economic appraisal worldwide, for all fields, not just health care. Economists apply a discount rate to reflect this social preference, reducing the value of future sums by – in the UK public sector in 2011 – 3.5% per year, to arrive at a 'net present value' of the whole flow of costs and benefits over the time period selected for analysis. Now consider two hypothetical drugs costing the same amount and producing the same number of extra QALYs: one delivers them all over three years and nothing thereafter, the other provides the benefit over thirty. This discounting approach (which was already included in the NICE Reference Case) clearly declares the second drug to be less valuable than the first.

How does society react when this approach is applied? This was the kind of social value judgement which NICE set up the Citizens Council to identify (see Chapter 4). Many people disagree with one of the results of the discounting strategy explained here: that, other things being equal, a cancer drug giving adults benefit over (say) the next three years is more valuable than one benefiting children during (say) the next 30. This situation can easily arise, because children who survive the disease have more years ahead of them in which they could experience a drug's benefits.

This was the case with Mepact (mifamurtide), a drug marketed by Takeda for the treatment of osteosarcoma, a rare and often fatal bone cancer affecting children

83 Earnshaw and Lewis (2008).

and young adults. NICE initially rejected mifamurtide, mainly because its ICER, at £57,000, was much too high. According to NICE's published account:

The Appraisal Committee looked to the Methods Guide to see if another discount rate could be used but the committee had to stick within the rules. The issue was then taken up by the NICE Board who issued an amendment.⁸⁴

That was in July 2011. The Board's decision was that the standard 3.5% discount rate supplied by the government discounted the distant-future benefits of saving children's lives by too much. A lower discount rate of 1.5% was to apply (to benefits, though not costs) where 'treatment effects are both substantial in restoring health and sustained over a very long period (normally at least 30 years)'.⁸⁵ On these revised criteria, the Appraisal Committee then recommended mifamurtide, its ICER having dropped to £36,000.⁸⁶

In a critical commentary from a health policy and health economics perspective, O'Mahony and Paulden commented that NICE's 'apparent motivation for recommending differential discounting was to ensure a favorable cost-effectiveness ratio for a [specific] drug'.⁸⁷ They accepted the use of judgement and the making of exceptions to hard and fast rules such as the use of the ICER, but criticised NICE for 'selective adjustment of appraisal methods' and argued that NICE had provided no evidence for the selection of a 1.5% rate – in short, that this was a 'fiddle' to get Mepact over the line, by altering the rules rather than by making it an overt exception. We agree with O'Mahony and Paulden that the 'ambiguities, difficulties, and inconsistencies, [of NICE's new guidance on the topic] ha[d] the potential to undermine the scientific rigor of NICE's economic evaluation process'. This was a rare mis-step: it went against NICE's usual practice of maintaining a rigorous, evidence-based method and then allowing judgement to be exercised on its outputs: it is unclear why NICE did this, and it brought expert criticism which could easily have been avoided.⁸⁸

In 2013, NICE began to develop its Highly Specialised Technologies (HSTs) evaluation programme, to provide guidance to the NHS on new and existing highly specialised medicines and treatments, which we consider further in a later part of this chapter. Boysen described to us how it operates:

things like orphan drugs, for us to say there is a threshold for rare diseases, say higher than the one we currently have for standard TAs, or indeed an end of life threshold, that can only work if the stewards of the healthcare in England are supporting it. We have turned that into not talking about thresholds

84 NICE (2011b).

85 NICE (2011c).

86 NICE (2011c).

87 O'Mahony and Paulden (2014).

88 Some of this is discussed in Charlton (2020).

but in terms of QALY weight, so what we think are reflections of the weighting of the benefits by society, so an end of life benefit weighs 1.6 times higher than one achieved not at the end of life, and highly specialised benefits count for five times what you would otherwise get, between three and five times, but those, we could never have done those things on our own, is my reflection. We would have to have some mandate for those things to change.⁸⁹

As an example of the subject matter handled by the HSTs programme, its first guidance, in January 2015, concerned the use of eculizumab for treating atypical haemolytic uraemic syndrome.⁹⁰ This was an expensive treatment which would not have been approved without the ‘five times’ QALY weighting.

NICE’s appraisal activities continue to develop. In 2017 a programme was added to deal with digital technologies.⁹¹ This covered such things as mobile phone apps that guided self-help in anxiety and depression. If these are to be appraised, new methods are needed: it is hard to see how a randomised controlled trial could be done. The appraisal of such technologies, though they are perhaps not often as expensive as drugs, might, depending on future innovations and NHS policies on digital services, become important. April 2018 saw further changes to appraisal:

that are designed to support earlier engagement between companies and NICE, and to resolve as many as possible of the technical uncertainties in the companies’ submissions before it is seen by the appraisal committee. The intention is to reduce the need for a second appraisal committee meeting at which negative draft guidance is changed following further engagement with the company. This currently happens in approximately 60% of appraisals, and adds time and effort to the processes of the NICE and the companies involved.⁹²

Most recently of all, NICE brought out a new Guidance Development Manual & Topic Selection Manual in February 2022, which give more weight to health benefits in the most severe conditions. They are also innovative in moving from separate manuals for each programme to generic manuals aligning NICE’s HTA approaches for all kinds of technologies.

A dose of the New Public Management: charging for appraisal

We have kept back one element from this chronological account, for separate discussion here, because it was a development of a different kind from the changes to the NICE method just discussed. From 1 April 2019, NICE began charging

⁸⁹ Boysen interview.

⁹⁰ NICE (2015b).

⁹¹ NICE (2018).

⁹² NICE (2019).

manufacturers a fee for its TA and HSTs assessments. A single TA now costs £142,800 (with some concessions for smaller companies).⁹³ The implications – for NICE, the pharmaceutical industry and society – merit examination.

One of the objectives which DH had set for NICE in the Business Plan for 2016–17 was to ‘put in place arrangements to charge the cost of the TA programme to industry users, from April 2017’.⁹⁴ This should be seen as part of DH’s contribution to the post-2008 cross-government austerity programme, rather than as a DH initiative. Austerity meant that NICE had to manage a 15% reduction in its running costs between 2009/10 and 2019/20.⁹⁵ Starting to charge manufacturers and making major reductions in its running costs were NICE’s main ways of coping. Of course the austerity programme itself was a political choice reflecting the neoliberal agenda of its authors, however much they protested that it was fiscally essential. Our argument is that a neoliberal political programme drove the introduction of charging at NICE, but that the political motivation was located at the centre of government rather than with DH or NICE’s leadership.

Dillon told NICE’s Board in 2017 that charging had ‘financial, operational and reputational risks’, and reported that ‘following discussion with the Department of Health, it has been decided that NICE’s cost recovery proposals will be considered in the context of the emerging life sciences strategy’.⁹⁶ We will examine the impact of the government’s Life Sciences Strategy later in the chapter. Dillon seems to have realised early that some delay to the beginning of charging for appraisal would be inevitable. It looks as if in 2017 he was managing DH’s reaction to delay by placing the charging issue in a bigger context. Using the Life Sciences Strategy for this was a shrewd choice: the life sciences industry was certain to have views about the principle of charging, and some expectations about what NICE should deliver in return, so a period of debate and reflection was good policymaking as well as buying time.

Some of the participants see NICE’s introduction of charging as no more than NICE’s forced response to funding cuts: a matter of living from hand to mouth (and of simply following DH’s orders). But Dillon’s mention of the ‘reputational risks’ of charging demonstrates his awareness that some would see neoliberal ideology at work. True, DH gave NICE no choice in the matter, and when the relevant documents are opened at the National Archives we may see whether or not the Treasury, in turn, gave DH any choice.⁹⁷ Either way, the introduction of charging was a political choice made *somewhere* in Whitehall.

This choice was not made in an ideological vacuum: it adopted a pre-existing policy solution with its own advocates, in search of suitable problems to which it might be applied – a classic case of Kingdon’s general description of policies.⁹⁸

93 NICE (2019); NICE (n.d.-a).

94 NICE (2017a).

95 A cut in cash terms from £55.2M to £47M: NICE (2010); NICE (2020).

96 NICE (2017a).

97 The confidentiality of UK Government documents is currently protected by a 20-year rule.

98 Kingdon (2003).

Viewing government services (in this case TA) like commodities, which could be bought and sold in a market by ‘purchasers’ and ‘providers’, was – long before 2016 – a quintessential part of the so-called New Public Management. From the 1980s, this neoliberal philosophy set out to reform public sector management using private sector templates including privatisation, managerialisation, marketisation, top-down reform, the search for value for money, the use of performance indicators and an emphasis on the management of change.⁹⁹ Since the Thatcher government this philosophy has become increasingly dominant in English public administration, and DH was no stranger to it, as we have shown elsewhere using the example of the NHS R&D programme.¹⁰⁰ Natural, then, that DH should reach for this particular ‘technology of governance’ (charging) when faced with the problem of cutting spending on NICE but sparing the still-valued TA programme.

Further, the introduction of charging was another step down the neoliberal road of hollowing out the state, moving from a model of ‘government’, where elected politicians are viewed as the policy makers, to one of ‘governance’, in which the state leaves some of its policymaking role to others. For example, rather than the Department of Health running medicines policy (however defined), parts of it have progressively fallen under the control of HTA units, health economics units, and even the pharmaceutical industry itself (e.g., writing the first draft of the case for a drug’s cost-effectiveness, as we have seen since 2005). The disturbing question about charging for drug appraisal is whether ‘he who pays the piper, calls the tune’: does charging a fee make regulatory capture more likely? Moving from the original position of ‘government funds the TA programme out of taxes because it is a public good’ to funding it from industry charges might involve ceding more influence over the process to industry itself, with worrying implications for the integrity of NICE appraisals of cost-effectiveness.

But how far has this happened in practice? First of all, it is clear that those at NICE have not wanted it to. Dillon, for instance, emphasised the more general principle to the NICE Board in 2017 that:

We cannot favour products simply to enhance their commercial prospects, because that would destroy our reputation for objectivity and undermine the trust we must earn from health professionals and patients.¹⁰¹

Has charging compromised the integrity of NICE appraisal more gradually and insidiously, however? Perhaps those in charge have been reluctant to see the signs? British officials pride themselves on objectivity, and may consequently find it harder to recognise the march of neoliberal values inside their own institutions. (One Permanent Secretary has denied to us, in another context, that any such description

⁹⁹ Ferlie et al. (1996); Hood (2007).

¹⁰⁰ Atkinson et al. (2019).

¹⁰¹ NICE (2017a).

was appropriate for developments in their Department since the 1980s.¹⁰²) For a follower of Foucault, of course, giving more power to companies by creating a more ‘market’-like relationship between them and public bodies would simply be one of those ‘technologies of governance’ which gain strength from concealing their operations.¹⁰³

Boysen, from NICE, argues that, rather than charging changing NICE’s appraisal behaviour, the earlier changes to appraisal had made it attractive enough to industry for the introduction of charging to be acceptable.¹⁰⁴ And Tim Irish, a non-executive member of the NICE Board, similarly felt that, from the time he arrived in 2015:

it was how do we evolve technology assessment to be, in my words, as good and as robust as it had always been, but a bit quicker, and could we do it more efficiently, and frankly could we charge for it?¹⁰⁵

Irish, like our other NICE interviewees, stresses that NICE carefully considered how to ensure that charging would not influence appraisal decisions. He maintains firmly that comparison of approval rates before and after charging bear this out, and the data – insofar as they can be used for this, since approval is no longer a yes/no decision – seem to bear him out.¹⁰⁶ Looking beyond NICE insiders like Irish, the evidence that charging *has* made NICE more accommodating to the industry is – perhaps inevitably – more circumstantial. Economists from an Evidence Review Group working for NICE told us, for example:

‘it always feels to us ... that NICE bend over backwards for the company ... I can’t help feeling that if the company wasn’t paying for this maybe [NICE would] have a different approach.’¹⁰⁷

Summing up, the lengthy process of introducing charging illustrates how NICE has engaged with the wider policy context within which it has to carry out its tasks. NICE had no choice about introducing charges for appraisals: there was a direct instruction to do so from ministers, and without the revenue, NICE’s operations would have had to be radically curtailed given the reductions in government funding. NICE’s leaders were keen to avoid letting the charging regime diminish the rigour of the appraisal process, and were well aware that this would be scrutinised. There is no clear evidence that it has changed the nature of appraisal. All that is clear is that charging is harmful, at some level, to NICE’s reputation: reasonable observers wonder whether it must inevitably colour an appraisal committee’s proceedings in the manner just suggested, and this doubt is harmful in itself.

102 Personal communication: unattributable.

103 Foucault (2003), 239–264.

104 Boysen interview.

105 Tim Irish, interview 17 March 2021.

106 Barham (2019).

107 Mahon interview.

NHS England: a new relationship with the NHS

NICE was set up to advise the NHS: in one – perhaps overly legalistic – sense, NHS organisations making decisions about commissioning health care have always been NICE’s most important stakeholder. But the NHS and its governance have been far from static in the years since NICE’s establishment, and NICE’s relationship with the NHS has had to develop to keep up with far-reaching changes. The question, ‘who speaks for the NHS?’ has been particularly important. At its inception in 1999, NICE had a national NHS partner, making policies about how clinical services should be delivered, in the form of the NHS Executive. As we saw in Chapter 3, in other circumstances this body might have had more influence on NICE, speaking for commissioners (or providers) of services, but in practice its top managers’ attention was always elsewhere. In 2003 the Executive was wound up, some of its powers returning to DH and the rest devolved to local NHS bodies: the voice of NHS management in NICE’s debates, always weak, was now divided and became still more diluted.

Then, on 1 April 2013, as part of the Lansley reforms of the NHS, DH brought to an end its increasingly uncomfortable in-house operation to provide some central decision-making functions for the English NHS. These roles were transferred to a new arm’s-length body, NHS England. Lansley’s goal, endorsed by his successor Jeremy Hunt, was to take central government out of the picture as far as possible.¹⁰⁸ This left NHS England’s Chief Executives considerable scope for exercising their own initiative: first David Nicholson and, from April 2014 to July 2021, Simon Stevens. This shift in the location of policy responsibility spelt major change for NICE, as Dillon recalls:

The creation of NHS England changed NICE’s external relationships really quite fundamentally. Before NHS England the proxy for our understanding of what the NHS wanted from [us] and its ability to action it was ... mainly ... the Department of Health. With the creation of NHS England ... not only did we have a new source for the NHS view on everything, but NHS England became the primary ..., or ... single customer for the majority of the appraisal programme.¹⁰⁹

This section explores the implications for NICE of this sharper focussing of NHS policy interests in its work. While the arrival of NHS England would in itself have brought important changes for NICE, personalities added to its impact. In Stevens (whom we met in chapters two and five), one of the main protagonists of the establishment of NICE had taken charge at the NHS. Although the cost-effectiveness agenda he had pursued as a Special Adviser in the 1990s was far from the only

108 Klein (2013); Hammond et al. (2018). For a somewhat different interpretation, see Timmins (2018).

109 Dillon, in Atkinson and Sheard (2020), 43.

topic demanding his attention, Stevens emphasised to us its importance in his new role:

[Q:] NICE was a fairly small part of your whole landscape from [2014] on ...?

[A:] I wouldn't say it was too small a part because there were several problem sets I inherited where these questions were live, including driving better value from specialised commissioning, and choices on the adoption of several new high profile therapies.¹¹⁰

Stevens' examples of these 'problem sets' included overspending in 2014/15 on specialised commissioning (to which we will shortly turn) and the 'festering problem of what to do about the Cancer Drugs Fund'. These topics exemplify the importance, for NHS England, of living within its budget. Its relationship with NICE has always been coloured by this imperative, and it is now time to look more closely at it.

Affordability

We saw earlier in the chapter, in the context of NICE needing to introduce charges for appraisals, that the central government austerity programme from 2010 onwards posed severe challenges across the public sector. NHS England's annual real terms funding growth fell from over 3.5% in the previous three years fell to less than 1% for each of the three years from 2010/11.¹¹¹ In relation to medicines, this led to a challenging search for a way to build in safeguards for affordability, in competition with other politically important goals including access to the most effective medicines. Crude cost control measures bypassing NICE were politically unacceptable – much better for NICE to be the one accountable for saying 'no', when it did so – so any solution needed to be built around NICE. Of course affordability was not a wholly new challenge: the issue had been debated when NICE was established, as we saw in Chapter 2. But the scale of the fiscal challenge after 2008 made the sums much more difficult, and NICE's increasing orientation towards saying 'yes' to expensive new drugs when possible did not make them easier.¹¹²

The main public manifestation of the affordability problem has been NHS England's desire to operate a kind of 'affordability test' in addition to the NICE cost-effectiveness test. The intention has been that, although a new drug might be cost-effective, NHS England should have a route to avoid introducing it if its

110 Simon Stevens interview.

111 Stiebahl S (2024).

112 Boysen (personal communication) has argued that the 2019 Voluntary Scheme for Branded Medicines Pricing and Access (see Chapter 5) already provides some 'guard rails' to protect the NHS budget, as it and its predecessors have always been supposed to. Under the Scheme, any growth in sales above an agreed level results in manufacturers making payments to DH. However, if NHS England had seen this as sufficient protection, they would not have felt they had an affordability problem: clearly not the case in practice. DHSC and ABPI (2018).

impact on costs was unsustainable. This required some political finesse if it was to avoid creating major difficulties with patient groups and manufacturers. Conversations between NHS England and NICE began not long after Stevens' arrival in 2014, and in 2015 NHS England delayed the introduction of costly new treatments for hepatitis C on the grounds of affordability'.¹¹³ Morgan comments that:

the decision to introduce a budget impact test on the Hepatitis C medicines ... really began taking an axe to how NICE worked. Because what you should do is, NICE should have said these are cost-effective medicines and NHS England should have [persuaded the Treasury to pay]¹¹⁴

This confuses the chronology a little by talking about the formal Budget Impact Test a couple of years early, and shows too much faith in the Treasury's flexibility, but neatly encapsulates the hopes of the pharmaceutical industry. It was in 2017 that the Budget Impact Test was formalised. Provision was made that if a technology being appraised by NICE would have an NHS budget impact exceeding £20 million, in any of the first three years, NHS England may begin commercial discussions with the manufacturer about a possible discount. If no agreement is reached, NHS England may ask DHSC for a variation to the statutory funding requirement for technologies which NICE approves.¹¹⁵

The Budget Impact Test places a financial incentive on manufacturers to reach agreement on a discount – a good example of the 'discipline' Stevens has sought to impose to ensure value for money from pharmaceutical expenditure. As he put it to us, this test has had a 'demonstrably disciplining effect on the willingness of companies to negotiate on price, volume and patient outcomes'.¹¹⁶ The initiative for the Budget Impact Test came from NHS England as the national body charged in law with managing value from the medicines bill: its precise form was a matter of careful discussion between NICE and NHS England. As Dillon recalls:

The budget impact cap was the result of a conversation I had with Stevens in the margins of a meeting, where we talked about the need for it and had an initial discussion about what the amount should be.¹¹⁷

NICE and NHS England had competing goals here, and agreement was reached because both saw the need for a mechanism and acted pragmatically to agree on one. We heard both points of view in our interviews: Nick Seddon reported that, while everyone was pleased about NICE's independent status, 'NHS England ... started to raise questions about whether or not you could have a body that had

113 Timmins (2016), 127.

114 Morgan interview.

115 NICE (n.d.-b).

116 Stevens interview.

117 Dillon, in Atkinson and Sheard (2020), 45.

such independence but no budgetary responsibility'.¹¹⁸ For NICE, Boysen had a clear understanding of the NHS England position but regretted how much it had to respond to short-term financial pressures when he wanted to take the longer view on which medicines should be in use: 'They ... have a much shorter ... timeframe ..., so it is difficult to make a strategic conversation, though we are now in a much better place with NHS England ...'.¹¹⁹

Highly specialised commissioning

To understand the relationship between NICE and NHS England, it is necessary to know that the drug treatments most likely to be covered by a NICE appraisal, most likely to have a high unit cost, and most likely to have a high cost per QALY, are funded centrally by NHS England, in an exception to the norm in which local NHS bodies are funded to commission services. As NHS England's own in-house commissioning activity, this service has a prominence for NHS England's senior managers which it would not otherwise have. The tendency for its costs to rise faster than the NHS average accentuated this.¹²⁰ The closeness of the collaboration between NHS England and NICE is exemplified by joint policy consultations the two bodies have held on how NICE should evaluate new products.¹²¹

In the NHS England Highly Specialised Commissioning programme, there has been a sustained effort to become a more professional purchaser of drugs. This has had implications for NICE. In particular, NHS England as a large purchaser expects to be able to negotiate a confidential discount on many drugs' list prices.¹²² It is the manufacturers who insist on confidentiality: if the world knew the NHS price, it would strengthen every purchaser's hand in negotiating their own discount. NICE becomes involved, not in a price negotiation (which all sides agree would cause confusion about its role), but by estimating a cost per QALY on the basis of the discounted price. A prominent recent example involved the cystic fibrosis drug Orkambi, manufactured by Vertex, which offered it for sale in 2018–19 at a price representing £100,000 per patient per year.¹²³ Stevens commented to us:

frankly, we hunted together as a pack, NHS England and NICE, on things such as the Vertex dispute, and because politicians were ultimately willing to hold their nerve, in the end we reached a very satisfactory conclusion both for patients and for taxpayers.¹²⁴

118 Nick Seddon, interview.

119 Boysen interview.

120 *Health Services Journal*, 18 December 2015, Simon Stevens interview, "Substantial risk" to specialised care budget, NHS England warns.

121 NICE (2017b).

122 The Rawlins interview discussed early cases of this.

123 *Pharma News* 31 January 2019, Vertex an "extreme outlier" in pricing and behaviour, says NHS England.

124 Simon Stevens interview.

We saw in the previous section how Morgan (who has since worked as a lobbyist for the pharmaceutical industry, co-founded the PR and lobbying firm Evoke Incisive Health, and became a health policy adviser to a Prime Minister), regretted the growing role of NHS England and longed for a return to the time when a drug was placed on the market and evaluated by NICE at the company's price.¹²⁵ This is a fair reflection of many drug companies' views: NICE has established credibility with them as an arbiter of cost-effectiveness, a role whose necessity they no longer dispute. With NHS England, the relationship can be more adversarial, though Vertex is an extreme case of that.

NHS England's confidential negotiations have beaten down some of the very high list prices to levels at which NICE judges the drug to be cost effective. The benefit for individual patients is clear, but the confidential nature of these deals means that no-one other than those doing them can judge whether they are value for money. That did not matter as much when it affected only a few medicines, but the number of deals seems to be growing, and the difficulty of holding NHS England accountable to Parliament or the public for the value for money which they represent is troubling.

Summing up NICE's relations with NHS England since the latter's establishment in 2012, the new organisation has provided NICE with a co-ordinated NHS view. We have seen how this was dominated by affordability, and sometimes by a concomitant short-termism: the goal (understandably) was not always more than to live within the current year's budget. The relationship has been close, but the politics of the NHS have meant that NHS England cannot always signal its priorities as clearly as NICE would want. In Boysen's words:

the budget impact test, fast track and highly specialised [technologies], ... new part of those things is ... that these are joint consultations with NHS England. So we are, for good or for bad, very close to them, and Andrew [Dillon] has very often said part of the reason for NICE's existence and success is that we carefully listen to what the stewards of healthcare want us to do. It is not really for us to tell the health service what they should be investing in, necessarily, they should tell us what they value. And that has been a difficult conversation...¹²⁶

Championing access to medicines: supporting innovation in the life sciences industries

The last part of this chapter attempts some conclusions about the development of NICE's relationship with the life sciences industries since its establishment in 1999. For some critical scholars, NICE has moved away from the purity of appraising technologies solely by looking at their ICERs and applying a threshold. These

125 *Guardian*, 22 August 2023, Private firm linked to No 10 adviser handed NHS waiting lists contract.

126 Boysen interview.

writers say NICE's emphasis is now too much on supporting innovation. For example Charlton and Rid argue that NICE's approach to appraisal 'curtails its goals to promote health and health equity'.¹²⁷ They criticise 'a lack of transparency and accountability regarding NICE's treatment of innovative technologies', and raise concerns about equity based on departures from the strict use of thresholds. NICE has, it must be said, been conscientious about the publication of decisions and their reasoning: no lack of transparency there. However, Charlton and Rid may be right that the justification of particular appraisal decisions now involves more judgement and rests less on pure calculation. Transparency is also diminished by the growth in patient access schemes and confidential NHS discounts, which obscure the true price and thus the true cost-effectiveness of the drugs affected.

Another way of looking at innovation is provided in a 1987 paper by Jeremy Hurst, the influential DH health economist.¹²⁸ He summarises what he believes to be the goals of government medicines policy as:

- improve the health of the current population (safety and efficacy of drugs);
- develop better medicines (innovation); and
- limit the burden on those who pay for current medicines and research – ultimately, the consumer and the tax-payer.

This approach stresses the competing pressures on a body like NICE and indicates that policy will always be a trade-off between them.

To promote innovation, the second of Hurst's goals, government policy has several possible levers. NICE is only one element. Government, and NICE's leaders, see its role as ensuring that new technologies are appraised quickly as well as competently, so that NHS patients gain access to cost-effective new technologies. This is how the industry buzzword, 'access', is linked to the goal of promoting innovation. We examine this theme by looking briefly at the wider canvas of government medicines policy, and then at NICE's evolution within it. We need to recall that NICE, as a government body, responds to government policy and has, for example, a published Framework Document in which ministers instruct it how to do this (though these are legalistic documents which do not mention 'innovation' or 'access' as policy goals).¹²⁹

The climate of government medicines policy

The incoming Labour government of 1997 espoused the idea that investment in R&D was critical to productivity which in turn was the main driver of growth. The pharmaceutical sector attracted their attention due to its prominence in the British economy.

¹²⁷ Charlton and Rid (2019).

¹²⁸ Hurst (1987).

¹²⁹ A recent example is DHSC and NICE (2018). TNA, JA 765/15 NICE contains the 1999 Framework Document.

The idea that successful research-led innovation would benefit the economy as well as patients came to be labelled ‘Health & Wealth’.¹³⁰ This led to a new activism in smoothing the path for innovation in the pharmaceutical industry. An early example relevant to NICE was the establishment in 2000 of the Pharmaceutical Industry Competitiveness Task Force (PICTF), a government-industry forum permitting the latter to lobby the former more effectively for policies more supportive of innovation. Our research in the National Archives has confirmed previous speculation that Prime minister Tony Blair proposed this body as consolation to the industry in the aftermath of NICE’s rejection of Relenza (see Chapter 5).¹³¹

‘Health and wealth’ thinking continued to play an important role in the later 2000s. In 2003 a report from the government Biosciences Innovation and Growth Team (BIGT) was candidly titled *Bioscience 2015: Improving National Health, Increasing National Wealth*, and particularly advocated more spending on NHS R&D and better collaboration between the NHS and industry.¹³² This outlook was central to the way Sally Davies, later Chief Medical Officer, approached her responsibilities for NHS R&D, setting up the National Institute for Health Research and, for instance, streamlining drug trials in NHS settings.¹³³ Doors in Whitehall were open to advocates of ‘health and wealth’ policies to get new drugs more quickly to the NHS. Prominent examples were the venture capitalist Sir David Cooksey and Oxford’s Regius Professor of Medicine, Sir John Bell. This all contributed to a policy climate in which DH would encourage NICE to be helpful, above all by getting new products through appraisal quickly.

This climate did not change with the election of a coalition government in 2010 and Conservative governments from 2015. George Freeman, who filled the new ministerial post of Parliamentary Under Secretary of State for Life Sciences from 2014 to 2016, is a good example of the political enthusiasm for encouraging disruptive new manufacturers, especially in genomics. He worked closely with John Bell: their collaboration produced the Life Sciences Industrial Strategy in August 2017, to which the government responded with a Life Sciences Sector Deal whose ambition was ‘to make the UK a top tier global hub for biomedical and clinical research and medical innovation’.¹³⁴ A government-NHS-industry Accelerated Access Collaborative (AAC) was launched in April 2018, whose goal was to establish ‘a new fast-track route into the NHS for “breakthrough” medicines and technologies’.¹³⁵ NICE supports the AAC in several ways, for instance supporting pre-appraisal activities on products the AAC has endorsed, and hosts the AAC secretariat.¹³⁶ (The

130 Atkinson et al. (2019).

131 TNA, JA765/6, Owen Barder, Private Secretary to the PM, to Janet Grauberg, Principal Private Secretary to the Secretary of State for Health: ‘Meeting with the British Pharma Group, 4 November [1999]’.

132 Bioscience Innovation and Growth Team (2003).

133 Atkinson et al. (2019).

134 Department for Business, Energy and Industrial Strategy (2018).

135 DH (2017).

136 NHS England (n.d.).

AAC's first chief executive, Dr Sam Roberts, became chief executive of NICE in February 2022.) This policy background shows the government's medicines policy priorities and will have set the tone for its relations with NICE.

How has NICE changed?

Alongside this look at government's expectations, it is also worthwhile to examine what NICE has done in the field of access and innovation. We examined changes to appraisal earlier in this chapter. Viewed in the round, these changes show NICE seeking to expand access to new medicines. NICE has always worked hard to reconcile this with maintaining the rigour of its appraisal method. NICE has explained the logic of its changes in each case, though the complexity of more recent ones, particularly for HSTs, has made the process less transparent to outside observers.

One good way of summing up the way NICE's thinking has changed about access to medicines is provided by Carole Longson. Longson was one of Boyesen's predecessors as NICE's head of technology evaluation. She describes NICE developing its position because of the logic of a dedication to access which it had all along, rather than in response to external pressure. In her account, NICE recognised that all products coming to market were likely to have some value for some patient: the thing was to find it for the right patient. The development of NICE appraisal by the mid-2000s meant that:

you've got this really sophisticated machinery that could actually tease that out for you, ... so why don't you apply it with that kind of perspective?¹³⁷

This meant that the NICE response to some technologies could change from 'no' to 'yes, if ...' Longson also described a related shift from using only the best quality information, for a yes/no judgement, to 'embrac[ing] all information and then find[ing] out how to best use that information for the decision at hand'. Longson thinks of appraisal first of all as a scientific problem, and perhaps this is why she emphasises this intellectual kind of explanation for NICE's growing stress on access to medicines. This explanation and the political one we have suggested in this chapter – that NICE needed to reflect social values – are not mutually exclusive. In this case, both pushed NICE in the same direction.

There was a moment in 2009 where NICE engaged more formally with the question of the relation between appraisal and innovation. Cooksey wrote, in a report for the BIGT, mentioned earlier, that 'the perceived problem for UK industry is that NICE appraisals do not operate in a way that is supportive of innovation, or uptake and access to medicines'.¹³⁸ NICE's response was to commission a report from Professor Sir Ian Kennedy QC (the chair of the Bristol child heart surgery Inquiry in 2001 and a very prominent figure in the world of UK health care

137 Carole Longson, interview 27 November 2019.

138 Bioscience Innovation and Growth Team (2009).

by then).¹³⁹ His report *Appraising the Value of Innovation and Other Benefits* is notably cool about adding a specific mechanism to the appraisal method to reflect innovation, saying that innovation should be handled by judgement, not a spurious quantitative approach.¹⁴⁰ Unpublished papers shown to us by Rawlins show that the NICE Board felt that the pharmaceutical industry were pushing it too hard here, and did not want a special ‘fix’ for innovative technologies.¹⁴¹ The episode is best interpreted as NICE manoeuvring to head off an unwelcome proposal while minimising open disagreement with industry or government.

Beyond the appraisal system, NICE has been active in other ways to promote innovation. It is reasonable to see these initiatives as NICE’s way of supporting (and being seen to support) innovation and access without compromising the rigour of appraisal. In its earliest days, NICE had to begin an appraisal with data which a manufacturer had collected, in clinical trials, primarily to establish a drug’s safety and efficacy: often this was less than ideal as a source for estimating its benefits. NICE responded by setting up a Scientific Advice service in about 2009, which helps manufacturers understand in advance how to assemble the evidence NICE needs. This is a good example of the Longson approach of finding access opportunities rather than passively adjudicating what companies present. NICE followed this up in 2015 with its Office for Market Access, also provided on a fee for service basis. It helps companies understand the NHS medicines landscape and who to engage with, and facilitates contacts, a service presumably most valuable to the many smaller manufacturers. NICE’s 2016–17 annual report described these, in language clearly aimed at a business audience, as:

provid[ing] important ... opportunities for life sciences companies to develop compelling value propositions and to navigate the sometimes complex pathways into the NHS for their products.¹⁴²

Conclusion: ‘fighting the forces of darkness’, or promoting access to medicines?

One of the debates this chapter has considered is whether NICE has approached its role in appraisal as that of a gatekeeper, shutting out poor value technologies, or an enabler, seeking ways for NHS patients to have access to new medicines where they are cost-effective. Our answer has been that NICE chose the latter. NICE’s policies, like those of the government and NHS England, reflect the ‘health and wealth’ philosophy we have discussed. While admitting new products to the NHS is good for the pharmaceutical industry and its stakeholders, NICE regards access to new medicines as good for health as well as wealth.

139 Andy McKeon, interview 3 October 2019.

140 Kennedy (2009).

141 Rawlins papers, Kennedy Response v6 MDR’s crits.

142 NICE (2017c).

The case for NICE to act only as a gatekeeper is linked with a negative view of the industry. Graham Winyard described pharma to us, semi-seriously, as ‘the forces of darkness’, reflecting a powerful strand of commentary such as Ben Goldacre’s *Bad Pharma* and much investigative journalism.¹⁴³ When we report that NICE has opted for the enabling rather than the gatekeeping role, we do not suggest that NICE has been naïve, or unduly influenced by pharma’s lobbying. (Nor is it our purpose to dispute the critiques of the industry.) Rather, we interpret NICE’s relationship with pharma as a grown-up one in which each party understands and partly distrusts the motives of the other. This applies equally to NHS England’s relationship with pharma, which makes sense of Stevens’ comment about NICE and NHS England ‘hunting together’ in situations like the controversy over the pricing of Orkambi.

So NICE promotes access to new medicines believing this is good for health. This does leave the question of whose health: the problem of opportunity cost. We should recall here that if NICE is approving new medicines whose ICER (cost per QALY) is higher than existing NHS treatments, then new treatments which are less cost-effective than existing ones are crowding them out, with an overall loss of welfare for patients. This point was forcibly made by Karl Claxton and colleagues in 2013–15, when they estimated that existing treatments had an ICER of about £13,000 (while NICE’s indicative threshold is £30,000).¹⁴⁴ Claxton, another of the York health economists, had made important contributions to NICE’s HTA in its early days: David Barnett, chair of the first Appraisal Committee, describes him as “the Johnny Cash of health economics, I mean he’s a star, cool guy”.¹⁴⁵

Assuming Claxton’s sums were right, a ‘welfare-maximising’ NICE would have set the threshold at about £13,000 and rejected nearly all recent drugs. In a public response at the time, Dillon defended the QALY threshold as a product of social values, and not something NICE could alter on its own, adding that decisions on new drugs were not made on the basis of QALYs alone, thus emphasising the role of judgement alongside quantitative assessment.¹⁴⁶ The issue is not so much, for Dillon, whether the threshold is set too high as that the exercise of judgement one case at a time produces an implied threshold which is open to continuing debate.¹⁴⁷

Boysen told us that NICE appreciates the problem:

in committee we say, “be careful what you wish for, if you say yes to a new drug, because there is a whole group of patients you don’t see”. So we are feeding this notion of the risk-averse, “don’t do it if it might displace health that you can’t really control”. At the same time, over the years we have been

143 Goldacre (2012).

144 Claxton et al. (2013). See also Maynard and Bloor (2015). Claxton and colleagues return to the charge in Claxton et al. (2024).

145 David Barnett, interview.

146 Dillon (2015).

147 This is also the view of Culyer et al. (2007).

very much saying that we are here to provide access; to support life sciences, so it's a bit of a difficult story.¹⁴⁸

In closing, this brings us back to Clive Smee's observation (Chapter 5) about the need to temper economic analysis with judgement. As an appraisal committee does that on one drug, so, it seems, NICE does on its overall policy approach. The pure economics alternative was never politically feasible. Such a 'radical NICE' would have set its face firmly against all new drugs whose ICER was worse than that of existing technologies. That would have led to NHS patients not getting any of the expensive new drugs – a situation similar to that apparently experienced by Cuba. This would have been politically unacceptable because of its effects on manufacturing, on the UK's international trade, and on groups of patients in need of new treatments. No UK government would have allowed NICE to operate in this way. That leaves the question of how far to go towards favouring innovation firmly in the political arena where it belongs: NICE's answers to this will be credible only if they are in step with society's judgements.

Bibliography

Primary sources

- Atkinson P & Sheard S (eds) (2020) *Origins and Establishment of NICE (c. 1997–2002)*, witness seminar held online on 18 June 2020 (Liverpool: Department of Public Health and Policy, University of Liverpool).
- BBC News web page, 20 November 2010, NHS reform warning from Royal College of GPs.
- Bioscience Innovation and Growth Team (2003) *Bioscience 2015: Improving National Health, Increasing National Wealth* (London: Department of Trade and Industry).
- Bioscience Innovation and Growth Team (2009) *Review and Refresh of Bioscience 2015: A Report to Government by the Bioscience Innovation and Growth Team* (London: Department for Business, Enterprise and Regulatory Reform).
- Bow Group (n.d.). (Last accessed 14 March 2022).
- Carroll S (n. d.) LinkedIn page (Last accessed 19 July 2023).
- Daily Mail*, 12 September 2008, Patients could turn to black market to buy cancer drugs if they can't pay to top up NHS treatment, warn experts.
- Daily Telegraph*, 3 April 2010, Cameron pledges to lift restrictions on cancer drugs available on NHS.
- Department for Business, Energy and Industrial Strategy (2018) *Life Sciences Sector Deal 1* (Last accessed 21 June 2022).
- DH (2010a) A new value-based approach to the pricing of branded medicines: government response to consultation (Last accessed 22 July 2022).
- DH (2010b) Impact assessment of proposal for a cancer drug fund (Last accessed 30 March 2022).

148 Boysen interview.

- DH (2010c) £50m additional funding for cancer drugs. *Press Release* 27 July 2010 (Last accessed 30 March 2022).
- DH (2011) The Cancer Drugs Fund: Guidance to support operation of the Cancer Drugs Fund in 2011–12 (Last accessed 30 March 2022).
- DH (2017) Accelerated access scheme means patients will get new treatments faster. *Press Release*: 3 November 2017 (Last accessed 21 June 2022).
- DHSC & ABPI (2018) The 2019 Voluntary Scheme for Branded Medicines Pricing and Access (Last accessed 4 September 2024).
- DHSC & NICE (2018) Framework agreement (Last accessed 11 October 2024).
- Dillon A (2015) Carrying NICE over the Threshold, NICE Blog, 19 February 2015 (Last accessed 23 June 2022).
- Financial Times*, 14 September 2005, OFT to investigate pricing scheme for medicines.
- Financial Times*, 21 February 2007, Editorial. In search of a perfect price for medicines.
- Financial Times*, 13 December 2010, NHS puts onus on doctors over costly drugs.
- gov.uk (government web site) (n.d.) ‘OFT’ (Last accessed 21 August 2024).
- Guardian*, 7 August 2008, Kidney cancer drugs judged too costly for 3,000 NHS patients.
- Guardian*, 8 August 2014, Cancer Drugs Fund seems to help pharmaceuticals giant Roche most.
- Guardian*, 22 August 2023, Private firm linked to No 10 adviser handed NHS waiting lists contract.
- Health Services Journal*, 18 December 2015, Simon Stevens interview, “Substantial risk” to specialised care budget, NHS England warns.
- Kennedy I (2009) *Appraising the Value of Innovation and Other Benefits* (London: NICE).
- King’s Fund (n.d.) About us (web page).
- National Audit Office (2015) *Investigation into the Cancer Drugs Fund*. (London: NAO).
- NHS England (n.d.) Accelerated Access Collaborative (web page) (Last accessed 21 June 2022).
- NICE (2008) Citizens Council Report No 11, Departing from the Threshold (Last accessed 10 October 2024).
- NICE (2009a) *Appraising Life-extending, End of life Treatments* (London: NICE).
- NICE (2009b) *Annual Report and Accounts 2008/09* (London: NICE).
- NICE (2010) *Annual Report and Accounts 2009/10*. (London: NICE).
- NICE (2011a) *Report and Accounts, 2010–11* (London: NICE).
- NICE (2011b) *How should NICE Assess Future Costs and Health Benefits?* (Last accessed 13 April 2022).
- NICE (2011c) *Discounting of Health Benefits in Special Circumstances* (London: NICE).
- NICE (2015a) Consultation now open on plans to reform Cancer Drugs Fund. *Press Release* (Last accessed 4 April 2022).
- NICE (2015b) *Annual Report and Accounts 2014/15* (London: NICE).
- NICE (2017a) Public Board Meeting 18 January 2017 (Last accessed 11 October 2024).
- NICE (2017b) NICE and NHS England consultation on changes to the arrangements for evaluating and funding drugs... NICE Board Paper 15 March 2017.
- NICE (2017c) *Annual Report and Accounts for 2016–17* (London: NICE).
- NICE (2018) *Annual Report and Accounts 2017/18* (London: NICE).
- NICE (2019) *Annual Report and Accounts 2018/19*. (London: NICE).
- NICE (2020) *Annual Report and Accounts 2019/20*. (London: NICE).
- NICE (n.d. a) *Charging for Technology Appraisals and Highly Specialised Technologies* (Last accessed 21 April 2022).
- NICE (n.d. b) Budget Impact Test (web page) (Last accessed 7 February 2022).

- Observer*, 17 August 2008, Health chief attacks drug giants over huge profits.
- Office of Fair Trading (2007) *The Pharmaceutical Price Regulation Scheme: An OFT Market Study* (last accessed 21 August 2024).
- Office of Fair Trading (2010) OFT519: *Market Studies* (web page).
- Office of Fair Trading (n.d.) archived home page (Last accessed 21 August 2024).
- Oxford Mail*, 4 June 2016, David Cameron leads tributes to inspirational medical campaigner Clive Stone.
- Oxford Mail*, 29 April 2017, Family of Oxfordshire cancer campaigner Clive Stone defend the Cancer Drugs Fund he fought for.
- Pharma News*, 31 January 2019, Vertex an “extreme outlier” in pricing and behaviour, says NHS England.
- Rawlins papers, Conservative Party (2008) *Improving access to new drugs: a plan to renew The National Institute for Health and Clinical Excellence* (NICE).
- Rawlins papers, *Bow Group Research Questionnaire August 2009*.
- Rawlins papers, ‘Kennedy Response v6 MDR’s crits’.
- Reform (n.d.) Our history (web page) last accessed 23 March 2022).
- TNA, JA765/6 NICE, Owen Barder, Private Secretary to the PM, to Janet Grauberg, Principal Private Secretary to the Secretary of State for Health: ‘Meeting with the British Pharma Group, 4 November [1999]’.
- TNA, JA 765/15 NICE, 1999 Framework Document.

Secondary sources

- Atkinson P, Sheard S & Walley T (2019) “All the stars were aligned”? The origins of England’s national institute for health research. *Health Research Policy and Systems* 17(1), 1–14.
- Barham L (2019) NICE numbers at 20, Pharmaphorum (Last accessed 24 September 2024).
- Barnett D, Stevens A, Boysen M & Longson C (2009) Developing evidence-based guidance for health technologies: the NICE experience, in Killoran A & Kelly M (eds) *Evidence-Based Public Health* (Oxford: Oxford University Press), 398–410.
- Cairney P, Heikkila T & Wood M (2019) *Making Policy in a Complex World* (Cambridge: Cambridge University Press).
- Carroll S (2009) Is there anything nicer than NICE? A question the conservative shadow health team is right to ask. *Value in Health* 12(5), 631–633.
- Casson SG, Ruiz J & Miners A (2013) How long has NICE taken to produce technology appraisal guidance? A retrospective study to estimate predictors of time to guidance. *BMJ Open* 3(1), e001870.
- Charlton V & Rid A (2019) Innovation as a value in healthcare priority-setting: the UK experience. *Social Justice Research* 32(2), 208–238.
- Charlton V (2020) NICE and fair? Health technology assessment policy under the UK’s national institute for health and care excellence, 1999–2018. *Health Care Analysis* 28(3), 193–227.
- Claxton K, Martin S, Soares M, Rice N, Spackman E, Hinde S, Devlin N, Smith P & Sculpher M (2013) Methods for the Estimation of the NICE Cost Effectiveness Threshold, CHE Research Paper 81, Centre for Health Economics, University of York.
- Claxton K, Sculpher M & Culyer A (2024) NICE and resource allocation in the NHS: Paradise lost? in Littlejohns P & Syrett K (eds) *NICE at 25: A quarter-century of evidence, values, and innovation in health* (London: Routledge), 16–32.

- Collins M & Latimer N (2013) NICE's end of life decision making scheme: impact on population health. *BMJ* 346, f1363.
- Culyer A, McCabe C, Briggs A, Caxton K, Buxton M, Akehurst R, Sculpher M, Brazier J (2007) Searching for a threshold, not setting one: the role of the National Institute for Health and Clinical Excellence. *Journal of Health Services Research & Policy* 12(1), 56–58.
- Earnshaw & Lewis (2008) NICE guide to the methods of technology appraisal. *Pharmacoeconomics* 26, 725–727.
- Ferlie E, Ashburner L, Fitzgerald L & Pettigrew A (1996) Characterizing the 'new public management', in Ferlie E, Ashburner L, Fitzgerald L & Pettigrew A (eds) *The New Public Management in Action* (Oxford: Oxford University Press), 204–227.
- Foucault M (2003) *Society Must be Defended: Lectures at the Collège de France, 1975–76* (Harmondsworth: Penguin).
- Goldacre B (2012) *Bad Pharma: How Drug Companies Mislead Doctors and Harm Patients* (London: Fourth Estate).
- Hammond J, Speed E, Allen P, McDermott I, Coleman A & Checkland K (2018) Autonomy, accountability and ambiguity in arm's length meta-governance: the case of NHS England. *Public Management Review* 21(8), 1148–1169.
- Hoffmaster B & Hooker C (2013) Tragic choices and moral compromise: the ethics of allocating kidneys for transplantation. *Milbank Quarterly* 91(3), 528–557.
- Hood C (2007) Public service management by numbers: why does it vary? Where has it come from? What are the gaps and the puzzles? *Public Money & Management* 27(2), 95–102.
- Hurst J (1987) New attitudes in assessing benefits, in Teeling Smith G (ed) *Costs and Benefits of Pharmaceutical Research* (London: Office of Health Economics), 18–24.
- Jasanoff S (ed) (2004) *States of Knowledge: The Co-Production of Science and the Social Order* (London: Routledge).
- Kingdon J (2003) *Agendas, Alternatives and Public Policies*, second edition (New York: Longman).
- Klein R (2013) *The New Politics of the NHS*, seventh edition (Boca Raton: CRC Press).
- Maynard A & Bloor K (2015) Regulation of the pharmaceutical industry: promoting health or protecting wealth? *Journal of the Royal Society of Medicine* 108(6): 220–222.
- Oliver & Faul V (2018) Networks and network analysis in evidence, policy and practice. *Evidence and Policy* 14(3), 369–379.
- O'Mahony J & Paulden M (2014) NICE's selective application of differential discounting: ambiguous, inconsistent, and unjustified. *Value in Health* 17(5), 493–496.
- Pharmaceutical Journal* (n.d.) Stuart Carroll, author details <https://pharmaceutical-journal.com/author/stuart-carroll> (Last accessed 10 October 2024).
- Porter M & Teisbert E (2006) *Redefining Health Care. Creating Value Based Competition on Results* (Cambridge, MA: Harvard Business School).
- Raftery J (2013) Value based pricing: can it work? *BMJ* 2013(347), f5941.
- Rawlins M & Culyer A (2004) National institute for clinical excellence and its value judgments. *BMJ* 329(7459), 224.
- Richards M (2008) *Improving Access to Medicines for NHS Patients* (London: DH).
- Richards M (2010) *Extent and Causes of International Variations in Drug Usage* (London: COI). <https://assets.publishing.service.gov.uk/> (Last accessed 29 March 2022).
- Stiebahl S (2024) NHS funding and expenditure, House of Commons Library Research Briefing (Last accessed 24 September 2024).

- Timmins N (2012) *Never Again? The Story of the Health and Social Care Act 2012* (London: King's Fund and the Institute for Government).
- Timmins N (2016) *A Terrible Beauty: A Short History of NICE* (Nonthaburi: Health Intervention and Technology Assessment Program HITAP).
- Timmins N (2018) 'The World's Biggest Quango' *The First Five Years of NHS England* (London: King's Fund and Institute for Government).
- Walley T (2007) Fair pricing for medicines in the UK. *Expert Review of Pharmacoeconomics & Outcomes Research* 7(3), 207–209.
- Woolcock M, Szreter S & Rao V (2011) How and why does history matter for development policy? *Journal of Development Studies* 47(1), 70–96.

9 Conclusions

The intellectual origins of NICE's work lie in new ideas about using evidence to make health policy, which grew in importance in the 1970s and particularly the 1980s. We have come to the same conclusions about these as Moreira.¹ He describes three new forms of knowledge: 'market', 'laboratory' and 'forum' – economic rationality, the use of scientific evidence and deliberation. For our account of NICE, the first of these has been the most important, because it shaped the way government policy makers applied the other two. We refer to it here as the 'economising' approach, so as to stress the conscious decision to apply economics to new fields. We also want to emphasise that in government minds, it was motivated above all by fear about rising health care costs and the desire to gain control over them. This was what we label the 'pessimistic' outlook: there was also an 'optimistic' approach to using these new ways of thinking which we will discuss in a moment.

The development of these ideas, and their use to set up NICE and carry on its work, illustrates wider relationships between science and society. These relationships should not be viewed deterministically. Many episodes described here show how contingency and negotiation played an important role in determining the end result, for example the contributions of individuals and the importance of their networks.

When applied to the making of health policy, health economics and evidence-based medicine can be seen as 'technologies of governance'. That is, ways of making policy which were useful and attractive to the state. Apart from their potential for cost control, they could give the extra political legitimacy for painful policy decisions which the deployment of expert knowledge could provide. Health Technology Assessment (HTA) was a highly effective marriage of these two new ways of thinking.

By the 1997 General Election, all the necessary intellectual groundwork was in place. But this did not mean that the Conservative administration of 1992–97 was about to set up an independent body for HTA or guidelines, let alone a confident one willing and able to shape the policy environment. On the contrary, although

1 Moreira (2012).

troubled by challenging choices about new health technologies, this government sought to avoid the friction with the medical profession which it expected from a move in that direction.

The replacement of a Conservative by a Labour administration in 1997 opened this policy window. Innovation in this area, including setting up an arm's-length body, became suddenly conceivable and indeed desirable. There were two reasons. The first was the context of new policy goals for the NHS in general. We have seen how NICE fitted into the so-called 'new NHS' being designed by Labour ministers. The three-part structure they sketched out in 1997 called for national standards, which would support the commissioning of services, that were then inspected to check the standards were being met. NICE was integral to setting the standards. A second factor setting innovation free in 1997 was simply the change of government in itself: the sense among policymakers of optimism and possibility.

The period between the announcement of NICE in 1997 and its establishment in 1999 was therefore one of ambitious innovation (as in other areas of health policy). Mike Rawlins, quickly nominated as chair-elect, had a central role in this thinking. So too did his deputy, Tony Culyer. Within the Department of Health (DH), the Chief Economic Advisor Clive Smee made a major contribution, acting as a kind of policy entrepreneur, to the development of the economic approaches which NICE would adopt in HTA. At the same time, though, DH medical civil servants in public health, notably Graham Winyard, became influential in shaping the new body.

Crudely (since both took a more nuanced view than this), the DH economists developed the 'pessimistic' approach in which NICE was primarily about cost control, while the public health specialists advocated an 'optimistic' approach where HTA and guidelines were there to ensure that patients had access to the best care affordable. Rawlins was temperamentally in the second group. Policy ended up balancing the two, since both had attractions. NICE would have been severely weakened, especially in the eyes of patient groups and doctors, if it had been dedicated to cost control alone.

Once established in 1999, NICE enjoyed an unusual degree of freedom, and encouragement, to develop policy. It benefited from government's wish for it to be seen as independent, a lightning-conductor for unpopular decisions about which medicines the NHS could use. But more than this, Rawlins in particular managed to persuade ministers such as Alan Milburn (at first Minister of State and in 1999–2003 Secretary of State) that he could deliver their policies. This was partly a matter of personality, but also, of course, that NICE as a whole was beginning to build a record of success and reliability.

One of the more striking things about NICE in its early years was the air of excitement which surrounded it. More than just the clean sheet of paper of any 'start-up', this was also the sense that it had permission to tackle the important intellectual and moral challenges of priority setting in health care. This contributed to the willingness of a large group of gifted people to work for or with the new body. The names of Mike Rawlins and Andrew Dillon are well-known but the capacity and dedication of many others was important too. Less frequently mentioned but still important were, for example, Carole Longson in HTA, Ruth

Turner, whose organisation set up and supported the Citizens Council and Rona McCandlish, one of the leaders of the collaborating centres who took charge of guideline production.

There was no particular moment when this founding period came to an end. By 2008, some of the issues in HTA had become more challenging, the answers more technical, and in 2010 a change of government brought new health ministers for whom NICE was someone else's idea, not their own. (NICE had nevertheless succeeded in establishing enough credibility with Conservatives as well as Labour by this point.) Austerity and shrinking budgets after 2010 meant that more of NICE's managerial focus had to go on doing more with less, reducing the scope for more ambitious innovation. People involved with NICE, whether as staff or more widely, continue to look back to its early years, which have shaped it more strongly than is perhaps the case in many other organisations. NICE's current leaders speak of anchoring NICE in these roots as it faces new and harsher challenges, and holding onto the reputation built then for rigour, independence and transparency.

The early construction of the NICE organisation was done exceptionally well, which partly explains why it has been NICE, almost alone among the Blair administration's new public bodies, which is still going strong. (Another reason is that delegating hard choices about priorities in health care to an outside body continues to be attractive to all political parties.) DH's 2004 *Arm's-Length Bodies Review* demonstrates that, by then, NICE had already made itself indispensable. It had built its reputation and won widespread acceptance as an organisation that used evidence rigorously and acted fairly. People were already speaking of a NICE 'brand' in this positive sense, something rare among public bodies. NICE secured these early achievements through diligent leadership (e.g., careful and transparent system design) and, for example, by attention to recruiting and keeping the best people. The longevity of many NICE staff members is striking. Andrew Dillon's role as chief executive was critical to this: Rawlins could have led a good organisation with many another good chief executive, but with Dillon he could lead an outstanding one.

It is important, of course, not to get carried away with this story of success. How much difference was NICE making? Never quite as much as it hoped – its continuing internal debates about impact, about whether its guidance was being implemented, demonstrate this. A range of commentators (such as groups convened by the World Health Organization) praised NICE for the quality of its processes and outputs, but the link from these to health outcomes was not as clear. We saw in Chapter 3 that this had a lot to do with the wider NHS context. The NHS' capability to change and develop services has never been as strong as policymakers would wish. Ultimately NICE should be judged against the mandate given to it by DH, which was to produce guidance: this it did extremely well.

The involvement and engagement of the public and patients have been an important strand of NICE's story. Its leaders knew from the beginning that this was not just an ethical obligation but also pragmatically useful. It was, for example, a way to make guidance more likely to get implemented by building coalitions in favour of adoption. NICE's work could never be purely technical, it would always express a set of values, and these ought to be those of wider society. Accordingly,

deep and genuine patient and public involvement was part of NICE's secret for earning society's trust, something that was essential if it was to have permission to exercise its own judgement rather than mechanically following a formula for technology appraisal.

The Citizens Council, which gave form to Tony Culyer's ideas about being led by social value judgements, was genuinely innovative, and getting it off the ground was a major exercise. Its reports did not produce obvious changes in policy direction, more likely indicating that NICE had read the public mood reasonably well. Since it was genuinely independent, this was valuable, not just window-dressing. NICE decided in 2014 that it had got all it could from the Citizens Council, and effectively replaced it. Its next initiative, NICE Listens, has not achieved the same profile. Partly driven by the need to cut costs and a sense that the Citizens Council had answered the big questions, the end of the Citizens Council has had some ill effects. As NICE's work has become more complicated (e.g., modelling the effects of expensive cancer drugs on small populations or evaluating new kinds of technologies), it has become harder for the public to relate to. Giving up the Citizens Council has made it a little harder to show that NICE's work continues to rest on social value judgements.

Patient and public involvement has been integral to producing guidance. This has only been possible because of a prior decision: that guidance required deliberation, not just scientific rigour. NICE opted, in other words, to produce evidence-*informed* policy rather than evidence-*based* policy. NICE's success offers good reasons why this should be preferred in policy making more generally. Rod Taylor and David Barnett (in HTA), along with Martin Eccles (in the guidelines programme), were critical figures in setting up the processes that made this work. NICE has chosen to use a deliberative process to arrive at the conclusions most acceptable to the public, with the use of QALYs and the ICER threshold serving as scaffolding rather than straitjacket. Deliberating could be mentally and, at times, emotionally taxing, but many participants saw it as a civic duty like jury service. HTA in particular has involved 'tragic choices' in which compromise is both inevitable and right. The choice to be made is between the health (or even survival) of one set of patients and that of another set: the ethics of opportunity cost.

There has constantly been a tension in NICE appraisal between speed, rigour and transaction cost. NICE's first instinct was to prioritise rigour: this served it well in building up the reputation for doing the job properly. Over time, speed has become a growing priority, as cases as early as Herceptin (2005) demonstrate. With the onset of government austerity policies, cost reduction has also become prominent. Reconciling all three is an optimisation problem of thankless complexity, at which NICE has done better than we could reasonably have expected.

With the development of NICE's HTA role in more recent years, especially after 2008, HTA choices have become more challenging. NICE has had to make the best decisions it could by attempting to apply the approach it chose at the start. Occasionally, policy choices which were fully defensible such as introducing the End of Life criteria in 2009 have looked like a rushed reaction to political pressures. At other times, as with changing the discount rate for the benefits of children's

drugs, they have looked like a political fudging of a painful issue. These have been problems more of handling than of substance. Faced with the growing difficulty of giving access to the best drugs, NICE has confronted questions such as how much uncertainty society will tolerate, and also what weight to place on encouraging the development and deployment of innovative treatments. Most of its changes in appraisal method, when examined carefully enough, have commanded a good measure of approval.

We agree with Rawlins that, whether or not policymakers face up to tragic choices, finite resources are still allocated to one group and not another: the question is then whether it is better to take the decision consciously and transparently. NICE represents the most serious attempt so far to do this.

NICE guidelines exemplify how Moreira's three new forms of knowledge – laboratory, market and forum – have come to dominate health care decisions. Here, the category of 'laboratory' stands for 'controlled, mechanism-based procedures of knowledge making', in particular, as we observed earlier in Chapter 6, the randomised controlled trial and the systematic review.² It is important not to follow the policymakers' tendency to reify these procedures into something neutral and objective. This way of looking at the world is based on 'a particular imaginary of "good governance" that is attached to impersonal judgment'.³ It is a way of thinking rooted in, and contributing to, the particular type of democratic, pluralistic society that existed in Britain in the 1960s and 1970s, with its own view of the moral and political functions of science – of 'the laboratory'.⁴ We see Walter Holland's 'social epidemiology' as a good example.⁵ With NICE, the presence of the 'forum' – deliberation – helps reduce the danger that the laboratory (and the 'market' – economic rationality) will dictate health care decisions in a technocratic way.

NICE's current statutory functions are not so much the logical results of a clear set of policy goals as the outcome of various contingencies over the years. This is, of course, normal. It is clearly true in the case of NICE's roles in public health and social care: not that giving NICE responsibility for them was irrational, but in practice it happened for contingent reasons. The second Wanless Report, in 2004, argued the benefits of comparing the cost-effectiveness of prevention and treatment, enabling rational choices between the two. Andrew Lansley's 2013 White Paper hoped that a social care role for NICE would smooth the way for closer integration of health and social care. In each case, it was rash to think that better co-ordination of the production of guidance could deal with a more deep-seated problem of service delivery. But in each case, NICE has been able to make a positive impact, particularly because of the extra force which the strength of its 'brand' and its processes lent to guidance.

2 Moreira (2012).

3 Porter (1995).

4 For some of this, see Moreira (2012), 88.

5 Holland et al. (2007).

Summing up, NICE applies some powerful technologies of governance (health economics, evidence-based medicine, HTA and clinical guidelines) to the search for the best ways to make the tragic choices posed by opportunity cost in health and health care. It combines these technologies with a fundamental dedication to deliberation rather than the untrammelled application of science or economics. NICE's processes and methods are the field on which issues (such as whether drug x is sufficiently cost-effective) are contested, rather than magic tools for resolving them. NICE meets a widely felt need to remove individual decisions about technologies and treatments from the political arena: the processes and methods by which it does this will permanently and rightly be the subject of political debate.

While some countries have too few resources to have many realistic choices about the health technologies they will use, all countries above a certain income level face the kind of decisions NICE is there to make. In this book, we have shown that governments in England opted for NICE because it fitted a group of long-lived social value judgements about how priorities in health care ought to be decided: social values which differ from country to country (and may change over time). These ideas cover such concepts as evidence, rationality, independence, transparency and deliberation. Although structured by them, NICE and the details of its form and function were not inevitable: historical contingency, for example in the personalities involved, has played a considerable part.

Though created by government, NICE did not remain its creature, which would have likely led to failure. Instead, it has successfully developed a 'brand' which is trusted by most of the people and organisations with which it works. It is striking that no one calls for its abolition anymore. By basing its decisions in deliberation, informed by social values, NICE preserves both its relevance to society's wishes, and a degree of responsiveness as these change. The context in which it works, and the tasks it is given, will only become harder, but so far it offers the best way of negotiating them.

Where next?

It is unwise to attempt to predict the future. It is particularly unwise for historians to believe they are better at this than others. Instead, we ask here what parts of NICE's past it is most important to use in the future. We spoke in Chapter 3 of a useable past, and now try to identify the elements which may be most useable.

Obscure as the future is, many agree that one major challenge will be the rising cost of new treatments, for example because rapid technological progress in genetics is leading towards 'personalised' or 'precision' medicine based on each patient's genes. How will this affect NICE? So far, the line has been held that NICE determines cost-effectiveness, while government (directly or by delegation to NHS England) decides which cost-effective treatments are affordable.

Making affordability NICE's problem would seriously weaken it. It may be tempting to a future government to do that: this would be harmful. If NICE came to be identified primarily with keeping down NHS costs, this would greatly reduce the trust it could expect from patients and their clinicians. It would make the *Daily*

Mail type of media reporting of NICE as a ‘rationing body’ easier to write and easier to believe. NICE’s credibility depends on the public believing that it serves the common good. So far, there still seems to be a good deal of consent to the idea that not all technologies can be funded regardless of price, and that the NHS should prefer cost-effective ones to less cost-effective ones.⁶ It is also clear that public opinion wants there to be qualifications to this rule, such as a preference for end of life care, and for children with life-threatening illness. (We largely have NICE and its Citizens Council to thank for the clarity with which we know this.) Making such compromises is the right answer to tragic choices, as Hoffmaster and Hooker pointed out (Chapter 5), provided it gives the right weight to each of the conflicting values.⁷ The choice of weights, as Tony Culyer pointed out, is a social value judgement. This emphasises the importance of NICE continuing to uncover what society’s value judgements are.

We should recall that this is not only a point about HTA and new treatments but also about guidelines. Guidelines are at least as important, and the goal which they have always had of incorporating cost-effectiveness will only become more important, given the pressure on resources for health and social care.

NICE has weathered the challenges it has faced so far principally through the strength of its ‘brand’. Enough people have had enough confidence that NICE would make the right decisions. The reasons for this are characteristics and behaviours which are worth holding onto. People have accepted NICE guidance because they have seen it as based on rigour and independence. Rigour is difficult and expensive: it involves securing the best available expert input but also two other things. There is a rigour about securing full engagement and involvement of the public and patients. Exercising deliberation in a rational and even-handed way is also part of rigour. The ability to reach decisions in a rigorous way cannot be wished into existence: NICE has built it up by retaining in its staff, committee members and leadership an intellectual curiosity about how best to use evidence and a dedication to doing it well. NICE has had a culture which has attracted and retained the most able and committed people. An organisation without this orientation would end up in box-ticking.

It has also been essential to NICE’s brand that it has worked transparently. This too is expensive. NICE has been known as an organisation that works in the open and consults about its decisions and its methods. As some of the subject matter becomes more scientifically complex, the communication task involved gets harder, but remains just as important. The expectation has been that everything is consulted on, workings are visible. If people, for example the editor of the *British Medical Journal*, think NICE falls short of that, they comment:

NICE faces ever greater challenges and needs our continuing support. But to deserve that support it has to keep close to its radical roots. Relying on

6 Timmins N (2019).

7 Hoffmaster and Hooker (2013).

a surrogate outcome for its approval of the new cholesterol lowering drug inclisiran, and hiding its cost analysis, are worrying signs that it has lost its rebellious heart. These things are not right and must be challenged.⁸

This brings us to independence. NICE's credibility depends on this too. As a government body (even though enjoying the degree of distance from government which a Non-Departmental Public Body does), it cannot manifest its independence in all the ways that campaigning journalists may advocate (though their scrutiny, like that of academics, is a welcome safeguard). We saw in Chapters 3 and 5 how NICE's independence depends in reality on its leaders reading the political environment and judging how best to win the debates that matter. So far, NICE's leaders, and perhaps DH's civil servants, have successfully reminded health ministers that an independent NICE is much more valuable to them.

NICE has also drawn strength from the public perception that it is independent of industry: the growing government emphasis since the late 2000s on supporting innovative new treatments has made demonstrating this more challenging. We have argued that there is some public appetite for innovation, above all where it benefits patients with life-threatening conditions. NICE has, as we have seen, found ways of assisting innovation which do not alter its HTA process, such as its Scientific Advice Service and Office for Market Access. However, modifiers to the HTA method which increase access for new drugs need to find their justification in social values: future governments need to understand that bending the HTA rules on industrial policy grounds alone would undermine NICE's credibility and do more harm than good.

In the uncertain future that health and social care face worldwide, NICE is an asset, commanding considerable respect for the way it handles one of the most difficult sets of policies. It will remain an asset for as long as it can show that, through all the new complexities it will face, it remains true to its roots.

Bibliography

- Godlee F (2021) Why healthcare needs rebels. *BMJ* 375, n2559.
- Hoffmaster B & Hooker C (2013) Tragic choices and moral compromise: the ethics of allocating kidneys for transplantation. *Milbank Quarterly* 91(3), 528–557.
- Holland W, Olsen J & Florey C (2007) *The Development of Modern Epidemiology. Personal Reports from Those Who Were There* (Oxford: Oxford University Press).
- Moreira T (2012) *The Transformation of Contemporary Health Care: The Market, the Laboratory, and the Forum* (Oxford: Taylor & Francis).
- Porter T (1995) *Trust in Numbers: The Pursuit of Objectivity in Science and Public Life* (Princeton: Princeton University Press).
- Timmins N (2019) *NICE at 20: A Cause for Celebration* (London: King's Fund).

8 Godlee (2021).

Appendix 1

List of persons quoted and their connection with NICE

Amanda Adler	Chair, Technology Appraisal Committee, NICE
George Alberti	President, Royal College of Physicians
Mark Baker	Director, Centre for Clinical Practice, NICE
David Barnett	Chair, Technology Appraisal Committee, NICE
Sarah Boseley	Health correspondent, <i>Guardian</i>
Meindert Boysen	Director, Centre for Health Technology Evaluation, NICE
Bruce Campbell	Chair, Interventional Procedures Advisory Cttee, NICE
Kalipso Chalkidou	NICE International
Rupe Chand	Citizens Council, NICE
Anna Coote	Institute of Public Policy Research
Paul Corrigan	Special Adviser to Alan Milburn (DH) & Tony Blair
Tony Culyer	Deputy Chair, NICE
Andrew Dillon	Chief Executive, NICE
Charles Dobson	Medicines Division, DH
Liam Donaldson	Chief Medical Officer for England
Michael Drummond	Director, Centre for Health Economics, University of York
Julia Earnshaw	VP, Health Outcomes & Regulatory Affairs, Glaxo Wellcome
Martin Eccles	Chair, Guidelines Advisory Committee, NICE
Karen Facey	Head, Scottish Medicines Consortium
Jean Gaffin	Member, NICE Technology Appraisal Committee
Kendall Jamieson Gilmore	Associate Director of Strategy, NICE
Jane Gizbert	Director of Communications, NICE
David Haslam	Chair, NICE
Patricia Hewitt	Secretary of State for Health
Stella Huyshe-Shires	Lyme Disease Action
Tim Irish	Board member/acting Chair, NICE
Mercy Jeyasingham	Board member, NICE

Trevor Jones	Director, Association of the British Pharmaceutical Industry
Mike Kelly	Director, Centre for Public Health, NICE
Alastair Kent	Genetic Interest Group
Catherine Law	Chair, Public Health Interventions Advisory Cttee, NICE
Jo Lenaghan	Institute of Public Policy Research
Gillian Leng	Deputy Chief Executive, NICE
Peter Littlejohns	Clinical and Public Health Director, NICE
Carole Longson	Director, Technology Evaluation Centre, NICE
Fiona Loud	Policy Director, Kidney Care UK
James Mahon	Economist in a NICE Evidence Review Group
Rona McCandlish	Chair, National Co-ordinating Centre for Women's & Child Health
Mary McClarey	Board member, NICE
Joe Mccrea	Special Adviser to Frank Dobson (DH)
Andrew Mckee	Director General of Policy and Planning, DH
Alan Milburn	Secretary of State for Health
Bill Morgan	Special Adviser to Andrew Lansley (DH)
Una O'Brien	Permanent Secretary, DH
Ela Pathak-Sen	Project Manager, Citizens Council, NICE
Michael Peckham	Director of NHS Research and Development
David Pink	Medicines Division, DH
Mike Rawlins	Chair, NICE
Mike Richards	National Cancer Director, DH
Anne-Toni Rodgers	Director of Corporate Affairs, NICE
Nick Seddon	Special Adviser to David Cameron
Sarah Seymour-Smith	Open University researcher, Citizens Council
Simon Stevens	Special Adviser to Frank Dobson/ Chief Executive, NHS England
Richard Sykes	Chair, GlaxoWellcome
Rod Taylor	Director, Technology Evaluation Centre, NICE
Nicholas Timmins	Public Policy Editor, <i>Financial Times</i>
Adrian Towse	Director, Office of Health Economics
Ruth Turner	Vision 21 (development of Citizens Council)
Tom Walley	Director, NHS R&D HTA Programme
Ann Williams	Adult Social Services, Liverpool City Council
Graham Winyard	Deputy Chief Medical Officer, DH
A small number of other interviewees who chose to remain unattributable.	

Appendix 2

Comprehensive list of NICE guidelines up to 6 March 2024

<i>Reference</i>	<i>Title</i>	<i>Published</i>
CG1	Schizophrenia	01/12/2002
CG2	Infection control: prevention of healthcare-associated infection in primary and community care	25/06/2003
CG3	Preoperative tests for elective surgery	25/06/2003
CG4	Head injury	23/06/2003
CG5	Chronic heart failure: Management of chronic heart failure in adults in primary and secondary care	23/07/2003
CG6	Antenatal care	23/10/2003
CG7	Pressure ulcer prevention: pressure ulcer risk assessment and prevention, including the use of pressure-relieving devices (beds, mattresses and overlays) for the prevention of pressure ulcers in primary and secondary care	22/10/2003
CG8	Multiple sclerosis: Management of multiple sclerosis in primary and secondary care	26/11/2003
CG9	Eating disorders in over 8s: management	28/01/2004
CG10	Type 2 diabetes foot problems: Prevention and management of foot problems	28/01/2004
CG11	Fertility: assessment and treatment for people with fertility problems	25/02/2004
CG12	Chronic obstructive pulmonary disease: Management of chronic obstructive pulmonary disease in adults in primary and secondary care	25/02/2004
CG13	Caesarean section	28/04/2004
CG14	Familial breast cancer	23/05/2004
CG15	Diagnosis and management of type 1 diabetes in children, young people and adults	23/07/2004
CG16	Self-harm in over 8s: short-term management and prevention of recurrence	28/07/2004
CG17	Dyspepsia: Management of dyspepsia in adults in primary care	25/08/2004
CG18	Hypertension	23/08/2004
CG19	Dental checks: intervals between oral health reviews	27/10/2004
CG20	The epilepsies: The diagnosis and management of the epilepsies in adults and children in primary and secondary care	27/10/2004
CG21	Falls: the assessment and prevention of falls in older people	24/11/2004

(Continued)

(Continued)

<i>Reference</i>	<i>Title</i>	<i>Published</i>
CG22	Anxiety: Management of anxiety (panic disorder, with or without agoraphobia, and generalised anxiety disorder) in adults in primary, secondary and community care	06/12/2004
CG23	Depression: management of depression in primary and secondary care	06/12/2004
CG24	Lung cancer: diagnosis and treatment	23/02/2005
CG25	Violence: short-term management for over 16s in psychiatric and emergency departments	23/02/2005
CG26	Post-traumatic stress disorder: management	23/03/2005
CG27	Referral guidelines for suspected cancer	26/06/2005
CG28	Depression in children and young people: identification and management	26/09/2005
CG29	Pressure ulcers: the management of pressure ulcers in primary and secondary care	28/09/2005
CG30	Long-acting reversible contraception	26/10/2005
CG31	Obsessive-compulsive disorder and body dysmorphic disorder: treatment	29/11/2005
CG32	Nutrition support for adults: oral nutrition support, enteral tube feeding and parenteral nutrition	22/02/2006
CG33	Tuberculosis: Clinical diagnosis and management of tuberculosis, and measures for its prevention and control	22/03/2006
CG34	Hypertension: management of hypertension in adults in primary care	28/06/2006
CG35	Parkinson's disease in over 20s: diagnosis and management	28/06/2006
CG36	Atrial fibrillation: The management of atrial fibrillation	28/06/2006
CG37	Postnatal care up to eight weeks after birth	23/07/2006
CG38	Bipolar disorder: The management of bipolar disorder in adults, children and adolescents, in primary and secondary care	26/07/2006
CG39	Anaemia management in people with chronic kidney disease	27/09/2006
CG40	Urinary incontinence: the management of urinary incontinence in women	25/10/2006
CG41	Familial breast cancer	25/10/2006
CG42	Dementia: supporting people with dementia and their carers in health and social care	22/11/2006
CG43	Obesity prevention	13/12/2006
CG44	Heavy menstrual bleeding: assessment and management	24/01/2007
CG45	Antenatal and postnatal mental health: Clinical management and service guidance	28/02/2007
CG46	Venous thromboembolism (surgical)	23/04/2007
CG47	Feverish illness in children: assessment and initial management in children younger than five years	23/05/2007
CG48	MI – secondary prevention: Secondary prevention in primary and secondary care for patients following a myocardial infarction	23/05/2007
CG49	Faecal incontinence in adults: management	27/06/2007
CG50	Acutely ill adults in hospital: recognising and responding to deterioration	25/07/2007
CG51	Drug misuse in over 16s: psychosocial interventions	25/07/2007
CG52	Drug misuse in over 16s: opioid detoxification	25/07/2007

(Continued)

(Continued)

<i>Reference</i>	<i>Title</i>	<i>Published</i>
CG53	Chronic fatigue syndrome/myalgic encephalomyelitis (or encephalopathy): diagnosis and management	22/08/2007
CG54	Urinary tract infection in under 16s: diagnosis and management	22/08/2007
CG55	Intrapartum care: Care of healthy women and their babies during childbirth	26/09/2007
CG56	Head injury: Triage, assessment, investigation and early management of head injury in infants, children and adults	26/09/2007
CG57	Atopic eczema in under 12s: diagnosis and management	12/12/2007
CG58	Prostate cancer: diagnosis and treatment	27/02/2008
CG59	Osteoarthritis: the care and management of osteoarthritis in adults	27/02/2008
CG60	Otitis media with effusion in under 12s: surgery	27/02/2008
CG61	Irritable bowel syndrome in adults: diagnosis and management	23/02/2008
CG62	Antenatal care for uncomplicated pregnancies	26/03/2008
CG63	Diabetes in pregnancy: Management of diabetes and its complications from pre-conception to the postnatal period	26/03/2008
CG64	Prophylaxis against infective endocarditis: antimicrobial prophylaxis against infective endocarditis in adults and children undergoing interventional procedures	17/03/2008
CG65	Hypothermia: prevention and management in adults having surgery	23/04/2008
CG66	Type 2 diabetes	28/05/2008
CG67	Lipid modification: Cardiovascular risk assessment and the modification of blood lipids for the primary and secondary prevention of cardiovascular disease	28/05/2008
CG68	Stroke and transient ischaemic attack in over 16s: diagnosis and initial management	23/07/2008
CG69	Respiratory tract infections (self-limiting): prescribing antibiotics	23/07/2008
CG70	Inducing labour	23/07/2008
CG71	Familial hypercholesterolaemia: identification and management	27/08/2008
CG72	Attention deficit hyperactivity disorder: diagnosis and management	24/09/2008
CG73	Chronic kidney disease: early identification and management of chronic kidney disease in adults in primary and secondary care	24/09/2008
CG74	Surgical site infections: prevention and treatment	22/10/2008
CG75	Metastatic spinal cord compression in adults: risk assessment, diagnosis and management	26/11/2008
CG76	Medicines adherence: involving patients in decisions about prescribed medicines and supporting adherence	28/01/2009
CG77	Antisocial personality disorder: prevention and management	28/01/2009
CG78	Borderline personality disorder: recognition and management	28/01/2009
CG79	Rheumatoid arthritis in adults: management	25/02/2009
CG80	Early and locally advanced breast cancer: diagnosis and treatment	25/02/2009
CG81	Advanced breast cancer: diagnosis and treatment	23/02/2009
CG82	Psychosis and schizophrenia: management	25/03/2009

(Continued)

(Continued)

<i>Reference</i>	<i>Title</i>	<i>Published</i>
CG83	Rehabilitation after critical illness in adults	25/03/2009
CG84	Diarrhoea and vomiting caused by gastroenteritis in under 5s: diagnosis and management	22/04/2009
CG85	Glaucoma: diagnosis and management	22/04/2009
CG86	Coeliac disease: recognition and assessment	27/05/2009
CG87	Type 2 diabetes: The management of type 2 diabetes	27/05/2009
CG88	Low back pain in adults: early management	27/05/2009
CG89	Child maltreatment: when to suspect maltreatment in under 18s	22/07/2009
CG90	Depression in adults: recognition and management	28/10/2009
CG91	Depression in adults with a chronic physical health problem: recognition and management	28/10/2009
CG92	Venous thromboembolism: reducing the risk for patients in hospital	27/01/2010
CG93	Donor milk banks: service operation	24/02/2010
CG94	Unstable angina and NSTEMI: early management	24/03/2010
CG95	Recent-onset chest pain of suspected cardiac origin: assessment and diagnosis	24/03/2010
CG96	Neuropathic pain in adults: pharmacological management in non-specialist settings	24/03/2010
CG97	Lower urinary tract symptoms in men: management	23/05/2010
CG98	Jaundice in newborn babies under 28 days	19/05/2010
CG99	Constipation in children and young people: diagnosis and management	26/05/2010
CG100	Alcohol-use disorders: diagnosis and management of physical complications	02/06/2010
CG101	Chronic obstructive pulmonary disease in over 16s: diagnosis and management	23/06/2010
CG102	Meningitis (bacterial) and meningococcal septicaemia in under 16s: recognition, diagnosis and management	23/06/2010
CG103	Delirium: prevention, diagnosis and management in hospital and long-term care	28/07/2010
CG104	Metastatic malignant disease of unknown primary origin in adults: diagnosis and management	26/07/2010
CG105	Motor neurone disease: non-invasive ventilation	28/07/2010
CG106	Barrett's oesophagus: ablative therapy	11/08/2010
CG107	Hypertension in pregnancy: diagnosis and management	25/08/2010
CG108	Chronic heart failure in adults: management	25/08/2010
CG109	Transient loss of consciousness ('blackouts') in over 16s	25/08/2010
CG110	Pregnancy and complex social factors: a model for service provision for pregnant women with complex social factors	22/09/2010
CG111	Bedwetting in under 19s	27/10/2010
CG112	Sedation in under 19s: using sedation for diagnostic and therapeutic procedures	15/12/2010
CG113	Generalised anxiety disorder and panic disorder in adults: management	26/01/2011
CG114	Anaemia management in people with chronic kidney disease	09/02/2011
CG115	Alcohol-use disorders: diagnosis, assessment and management of harmful drinking (high-risk drinking) and alcohol dependence	23/02/2011

(Continued)

(Continued)

<i>Reference</i>	<i>Title</i>	<i>Published</i>
CG116	Food allergy in under 19s: assessment and diagnosis	23/02/2011
CG117	Tuberculosis: clinical diagnosis and management of tuberculosis, and measures for its prevention and control	23/03/2011
CG118	Colorectal cancer prevention: colonoscopic surveillance in adults with ulcerative colitis, Crohn's disease or adenomas	23/03/2011
CG119	Diabetic foot problems: Inpatient management of diabetic foot problems	23/03/2011
CG120	Coexisting severe mental illness (psychosis) and substance misuse: assessment and management in healthcare settings	23/03/2011
CG121	Lung cancer: diagnosis and management	21/04/2011
CG122	Ovarian cancer: recognition and initial management	27/04/2011
CG123	Common mental health problems: identification and pathways to care	25/05/2011
CG124	Hip fracture: management	22/06/2011
CG125	Chronic kidney disease (stage 5): peritoneal dialysis	27/07/2011
CG126	Stable angina: management	23/07/2011
CG127	Hypertension in adults: diagnosis and management	24/08/2011
CG128	Autism spectrum disorder in under 19s: recognition, referral and diagnosis	28/09/2011
CG129	Multiple pregnancy: antenatal care for twin and triplet pregnancies	26/09/2011
CG130	Hyperglycaemia in acute coronary syndromes: management	26/10/2011
CG131	Colorectal cancer: diagnosis and management	01/11/2011
CG132	Caesarean section	23/11/2011
CG133	Self-harm in over 8s: long-term management	23/11/2011
CG134	Anaphylaxis: assessment and referral after emergency treatment	14/12/2011
CG135	Organ donation for transplantation: improving donor identification and consent rates for deceased organ donation	12/12/2011
CG136	Service user experience in adult mental health: improving the experience of care for people using adult NHS mental health services	14/12/2011
CG137	Epilepsies: diagnosis and management	11/01/2012
CG138	Patient experience in adult NHS services: improving the experience of care for people using adult NHS services	24/02/2012
CG139	Healthcare-associated infections: prevention and control in primary and community care	28/03/2012
CG140	Palliative care for adults: strong opioids for pain relief	23/05/2012
CG141	Acute upper gastrointestinal bleeding in over 16s: management	13/06/2012
CG142	Autism spectrum disorder in adults: diagnosis and management	27/06/2012
CG143	Sickle cell disease: managing acute painful episodes in hospital	27/06/2012
CG144	Venous thromboembolic diseases: diagnosis, management and thrombophilia testing	27/06/2012
CG145	Spasticity in under 19s: management	25/07/2012
CG146	Osteoporosis: assessing the risk of fragility fracture	08/08/2012
CG147	Peripheral arterial disease: diagnosis and management	08/08/2012
CG148	Urinary incontinence in neurological disease: assessment and management	08/08/2012

(Continued)

(Continued)

<i>Reference</i>	<i>Title</i>	<i>Published</i>
CG149	Neonatal infection (early onset): antibiotics for prevention and treatment	22/08/2012
CG150	Headaches in over 12s: diagnosis and management	19/09/2012
CG151	Neutropenic sepsis: prevention and management in people with cancer	19/09/2012
CG152	Crohn's disease: management	10/10/2012
CG153	Psoriasis: assessment and management	24/10/2012
CG154	Ectopic pregnancy and miscarriage: diagnosis and initial management	12/12/2012
CG155	Psychosis and schizophrenia in children and young people: recognition and management	23/01/2013
CG156	Fertility problems: assessment and treatment	20/02/2013
CG157	Chronic kidney disease (stage 4 or 5): management of hyperphosphataemia	13/03/2013
CG158	Antisocial behaviour and conduct disorders in children and young people: recognition and management	27/03/2013
CG159	Social anxiety disorder: recognition, assessment and treatment	22/05/2013
CG160	Fever in under 5s: assessment and initial management	22/05/2013
CG161	Falls in older people: assessing risk and prevention	12/06/2013
CG162	Stroke rehabilitation in adults	12/06/2013
CG163	Idiopathic pulmonary fibrosis in adults: diagnosis and management	12/06/2013
CG164	Familial breast cancer: classification, care and managing breast cancer and related risks in people with a family history of breast cancer	25/06/2013
CG165	Hepatitis B (chronic): diagnosis and management	26/06/2013
CG166	Ulcerative colitis: management	26/06/2013
CG167	Myocardial infarction with ST-segment elevation: acute management	10/07/2013
CG168	Varicose veins: diagnosis and management	24/07/2013
CG169	Acute kidney injury: prevention, detection and management	28/08/2013
CG170	Autism spectrum disorder in under 19s: support and management	28/08/2013
CG171	Urinary incontinence in women: management	11/09/2013
CG172	Myocardial infarction: cardiac rehabilitation and prevention of further cardiovascular disease	13/11/2013
CG173	Neuropathic pain in adults: pharmacological management in non-specialist settings	20/11/2013
CG174	Intravenous fluid therapy in adults in hospital	10/12/2013
CG175	Prostate cancer: diagnosis and management	08/01/2014
CG176	Head injury: assessment and early management	22/01/2014
CG177	Osteoarthritis: care and management	12/02/2014
CG178	Psychosis and schizophrenia in adults: prevention and management	12/02/2014
CG179	Pressure ulcers: prevention and management	23/04/2014
CG180	Atrial fibrillation: management	18/06/2014
CG181	Cardiovascular disease: risk assessment and reduction, including lipid modification	18/07/2014
CG182	Chronic kidney disease in adults: assessment and management	23/07/2014
CG183	Drug allergy: diagnosis and management	03/09/2014

(Continued)

(Continued)

<i>Reference</i>	<i>Title</i>	<i>Published</i>
CG184	Gastro-oesophageal reflux disease and dyspepsia in adults: investigation and management	03/09/2014
CG185	Bipolar disorder: assessment and management	24/09/2014
CG186	Multiple sclerosis in adults: management	08/10/2014
CG187	Acute heart failure: diagnosis and management	08/10/2014
CG188	Gallstone disease: diagnosis and management	29/10/2014
CG189	Obesity: identification, assessment and management	27/11/2014
CG190	Intrapartum care for healthy women and babies	03/12/2014
CG191	Pneumonia in adults: diagnosis and management	03/12/2014
CG192	Antenatal and postnatal mental health: clinical management and service guidance	17/12/2014
NG1	Gastro-oesophageal reflux disease in children and young people: diagnosis and management	14/01/2015
NG2	Bladder cancer: diagnosis and management	25/02/2015
NG3	Diabetes in pregnancy: management from preconception to the postnatal period	25/02/2015
NG5	Medicines optimisation: the safe and effective use of medicines to enable the best possible outcomes	04/03/2015
NG8	Chronic kidney disease: managing anaemia	03/06/2015
NG9	Bronchiolitis in children: diagnosis and management	01/06/2015
NG10	Violence and aggression: short-term management in mental health, health and community settings	28/05/2015
NG11	Challenging behaviour and learning disabilities: prevention and interventions for people with learning disabilities whose behaviour challenges	29/05/2015
NG12	Suspected cancer: recognition and referral	23/06/2015
NG14	Melanoma: assessment and management	29/07/2015
NG17	Type 1 diabetes in adults: diagnosis and management	26/08/2015
NG18	Diabetes (type 1 and type 2) in children and young people: diagnosis and management	01/08/2015
NG19	Diabetic foot problems: prevention and management	26/08/2015
NG20	Coeliac disease: recognition, assessment and management	02/09/2015
NG23	Menopause: diagnosis and management	12/11/2015
NG24	Blood transfusion	18/11/2015
NG25	Preterm labour and birth	20/11/2015
NG26	Children's attachment: attachment in children and young people who are adopted from care, in care or at high risk of going into care	25/11/2015
NG28	Type 2 diabetes in adults: management	02/12/2015
NG29	Intravenous fluid therapy in children and young people in hospital	09/12/2015
NG31	Care of dying adults in the last days of life	16/12/2015
NG33	Tuberculosis	13/01/2016
NG35	Myeloma: diagnosis and management	10/02/2016
NG36	Cancer of the upper aerodigestive tract: assessment and management in people aged 16 and over	10/02/2016
NG37	Fractures (complex): assessment and management	17/02/2016
NG38	Fractures (non-complex): assessment and management	17/02/2016
NG39	Major trauma: assessment and initial management	17/02/2016
NG40	Major trauma: service delivery	17/02/2016
NG41	Spinal injury: assessment and initial management	17/02/2016

(Continued)

(Continued)

<i>Reference</i>	<i>Title</i>	<i>Published</i>
NG42	Motor neurone disease: assessment and management	24/02/2016
NG45	Routine preoperative tests for elective surgery	05/04/2016
NG47	Haematological cancers: improving outcomes	25/05/2016
NG49	Non-alcoholic fatty liver disease (NAFLD): assessment and management	06/07/2016
NG50	Cirrhosis in over 16s: assessment and management	06/07/2016
NG51	Suspected sepsis: recognition, diagnosis and early management	13/07/2016
NG52	Non-Hodgkin's lymphoma: diagnosis and management	20/07/2016
NG54	Mental health problems in people with learning disabilities: prevention, assessment and management	14/09/2016
NG56	Multimorbidity: clinical assessment and management	21/09/2016
NG57	Physical health of people in prison	02/11/2016
NG59	Low back pain and sciatica in over 16s: assessment and management	30/11/2016
NG61	End of life care for infants, children and young people with life-limiting conditions: planning and management	07/12/2016
NG62	Cerebral palsy in under 25s: assessment and management	25/01/2017
NG65	Spondyloarthritis in over 16s: diagnosis and management	28/02/2017
NG66	Mental health of adults in contact with the criminal justice system	21/03/2017
NG69	Eating disorders: recognition and treatment	23/05/2017
NG71	Parkinson's disease in adults	19/07/2017
NG72	Developmental follow-up of children and young people born preterm	09/08/2017
NG73	Endometriosis: diagnosis and management	06/09/2017
NG75	Faltering growth: recognition and management of faltering growth in children	27/09/2017
NG77	Cataracts in adults: management	26/10/2017
NG78	Cystic fibrosis: diagnosis and management	25/10/2017
NG80	Asthma: diagnosis, monitoring and chronic asthma management	29/11/2017
NG81	Glaucoma: diagnosis and management	01/11/2017
NG82	Age-related macular degeneration	23/01/2018
NG83	Oesophago-gastric cancer: assessment and management in adults	24/01/2018
NG85	Pancreatic cancer in adults: diagnosis and management	07/02/2018
NG87	Attention deficit hyperactivity disorder: diagnosis and management	14/03/2018
NG88	Heavy menstrual bleeding: assessment and management	14/03/2018
NG89	Venous thromboembolism in over 16s: reducing the risk of hospital-acquired deep vein thrombosis or pulmonary embolism	21/03/2018
NG94	Emergency and acute medical care in over 16s: service delivery and organisation	28/03/2018
NG95	Lyme disease	11/04/2018
NG97	Dementia: assessment, management and support for people living with dementia and their carers	20/06/2018
NG98	Hearing loss in adults: assessment and management	21/06/2018
NG99	Brain tumours (primary) and brain metastases in over 16s	11/07/2018
NG100	Rheumatoid arthritis in adults: management	11/07/2018

(Continued)

(Continued)

<i>Reference</i>	<i>Title</i>	<i>Published</i>
NG101	Early and locally advanced breast cancer: diagnosis and management	18/07/2018
NG104	Pancreatitis	05/09/2018
NG106	Chronic heart failure in adults: diagnosis and management	12/09/2018
NG107	Renal replacement therapy and conservative management	03/10/2018
NG115	Chronic obstructive pulmonary disease in over 16s: diagnosis and management	05/12/2018
NG116	Post-traumatic stress disorder	05/12/2018
NG118	Renal and ureteric stones: assessment and management	08/01/2019
NG119	Cerebral palsy in adults	15/01/2019
NG121	Intrapartum care for women with existing medical conditions or obstetric complications and their babies	06/03/2019
NG122	Lung cancer: diagnosis and management	28/03/2019
NG123	Urinary incontinence and pelvic organ prolapse in women: management	02/04/2019
NG124	Specialist neonatal respiratory care for babies born preterm	03/04/2019
NG125	Surgical site infections: prevention and treatment	11/04/2019
NG126	Ectopic pregnancy and miscarriage: diagnosis and initial management	17/04/2019
NG127	Suspected neurological conditions: recognition and referral	01/05/2019
NG128	Stroke and transient ischaemic attack in over 16s: diagnosis and initial management	01/05/2019
NG129	Crohn's disease: management	03/05/2019
NG130	Ulcerative colitis: management	03/05/2019
NG131	Prostate cancer: diagnosis and management	09/05/2019
NG132	Hyperparathyroidism (primary): diagnosis, assessment and initial management	23/05/2019
NG133	Hypertension in pregnancy: diagnosis and management	25/06/2019
NG134	Depression in children and young people: identification and management	25/06/2019
NG136	Hypertension in adults: diagnosis and management	28/08/2019
NG137	Twin and triplet pregnancy	04/09/2019
NG140	Abortion care	25/09/2019
NG142	End of life care for adults: service delivery	16/10/2019
NG143	Fever in under 5s: assessment and initial management	07/11/2019
NG144	Cannabis-based medicinal products	11/11/2019
NG145	Thyroid disease: assessment and management	20/11/2019
NG147	Diverticular disease: diagnosis and management	27/11/2019
NG148	Acute kidney injury: prevention, detection and management	18/12/2019
NG151	Colorectal cancer	29/01/2020
NG154	Neonatal parenteral nutrition	26/02/2020
NG155	Tinnitus: assessment and management	11/03/2020
NG156	Abdominal aortic aneurysm: diagnosis and management	19/03/2020
NG157	Joint replacement (primary): hip, knee and shoulder	04/06/2020
NG158	Venous thromboembolic diseases: diagnosis, management and thrombophilia testing	26/03/2020
NG180	Perioperative care in adults	19/08/2020
NG181	Rehabilitation for adults with complex psychosis	19/08/2020
NG185	Acute coronary syndromes	18/11/2020
NG192	Caesarean birth	31/03/2021

(Continued)

(Continued)

<i>Reference</i>	<i>Title</i>	<i>Published</i>
NG193	Chronic pain (primary and secondary) in over 16s: assessment of all chronic pain and management of chronic primary pain	07/04/2021
NG194	Postnatal care	20/04/2021
NG195	Neonatal infection: antibiotics for prevention and treatment	20/04/2021
NG196	Atrial fibrillation: diagnosis and management	27/04/2021
NG197	Shared decision making	17/06/2021
NG198	Acne vulgaris: management	25/06/2021
NG201	Antenatal care	19/08/2021
NG202	Obstructive sleep apnoea/hypopnoea syndrome and obesity hypoventilation syndrome in over 16s	20/08/2021
NG203	Chronic kidney disease: assessment and management	25/08/2021
NG204	Babies, children and young people's experience of healthcare	25/08/2021
NG206	Myalgic encephalomyelitis (or encephalopathy)/chronic fatigue syndrome: diagnosis and management	29/10/2021
NG207	Inducing labour	04/11/2021
NG208	Heart valve disease presenting in adults: investigation and management	17/11/2021
NG210	Pelvic floor dysfunction: prevention and non-surgical management	09/12/2021
NG211	Rehabilitation after traumatic injury	18/01/2022
NG215	Medicines associated with dependence or withdrawal symptoms: safe prescribing and withdrawal management for adults	20/04/2022
NG217	Epilepsies in children, young people and adults	27/04/2022
NG219	Gout: diagnosis and management	09/06/2022
NG220	Multiple sclerosis in adults: management	22/06/2022
NG222	Depression in adults: treatment and management	29/06/2022
NG224	Urinary tract infection in under 16s: diagnosis and management	27/07/2022
NG225	Self-harm: assessment, management and preventing recurrence	07/09/2022
NG226	Osteoarthritis in over 16s: diagnosis and management	19/10/2022
NG228	Subarachnoid haemorrhage caused by a ruptured aneurysm: diagnosis and management	23/11/2022
NG229	Foetal monitoring in labour	14/12/2022
NG230	Thyroid cancer: assessment and management	19/12/2022
NG231	Barrett's oesophagus and stage 1 oesophageal adenocarcinoma: monitoring and management	08/02/2023
NG232	Head injury: assessment and early management	18/05/2023
NG233	Otitis media with effusion in under 12s	30/08/2023
NG234	Spinal metastases and metastatic spinal cord compression	06/09/2023
NG235	Intrapartum care	29/09/2023
NG236	Stroke rehabilitation in adults	18/10/2023
NG237	Suspected acute respiratory infection in over 16s: assessment at first presentation and initial management	31/10/2023
NG238	Cardiovascular disease: risk assessment and reduction, including lipid modification	14/12/2023
NG239	Vitamin B12 deficiency in over 16s: diagnosis and management	06/03/2024

Index

Note: *Italic* page numbers refer to figures and page numbers followed by “n” denote endnotes.

- Accelerated Access Collaborative (AAC) 270–271
accreditation programme 177
Acheson, Donald 211
Adam, Sheila 55
Adler, Amanda 152
affordability test 265
Alaszewski, A. 17
Alberti, George 59, 81
Alderson, Phil 190
Alzheimer’s disease drugs 114, 156, 245
Amess, David 65
Appleby, J. 140
Appraising the Value of Innovation and Other Benefits (Kennedy) 272
arm’s-length bodies (ALBs) 214–216
Armstrong, David 14, 15
Arrow, K. 18, 33
Ashmore, M. 19
Azar, Alex 166
- Baker, Mark 86, 94, 177, 180, 182, 185, 188–190, 196, 197, 200, 221, 222
Banks, Terri 27
Barnett, D. 77, 103, 127, 128, 130, 137, 139, 141, 151, 155, 273, 282
Bayley, Hugh 59
Belkin, G. 14, 148
Bell, John 270
beta interferon, case of 30, 58, 114, 128–129, 136, 147, 153–154, 163–164, 181
Bevan, Aneurin 90
Bioscience 2015: Improving National Health, Increasing National Wealth 270
Biosciences Innovation and Growth Team (BIGT) 270, 271
- Birtwistle, Mike 248
Black, Douglas 22
Blair, Tony 2, 3, 39, 40, 69, 77, 79, 97–99, 104, 145, 153, 154, 213, 270, 281
Bobbitt, P. 164, 165
Bolt, T. 14
bortezomib 154n77
Boseley, Sarah 98–100, 247
Bottomley, Virginia 26, 211
Boysen, Meindert 150, 152, 156, 179, 251, 256, 259, 263, 267, 268, 271, 273
Brown, B. 119
Brown, Gordon 51, 120, 213
Brown, R. 16
Budget Impact Test 266
Buxton, Martin 20, 32
- Cairney, P. 3, 11, 16, 32
Calabresi, G. 164, 165
Cameron, David 120, 247, 250–252
Campbell, Bruce 76, 77, 87, 157, 158, 160
cancer drugs 147, 244–252
Cancer Drugs Fund (CDF): cancer drugs policy since 2008 251–252; politician’s medicines policy (2010–16) 247–249; since 2015 250–251
Cardy, Peter 125
Carroll, Stuart 240–241
Chalkidou, Kalipso 101, 102
Chalmers, Iain 12, 29, 186
Chand, Rupe 119, 120
Charlton, V. 266
chronic fatigue syndrome/myalgic encephalomyelitis (encephalopathy) 200
Citizens Council 79, 131, 140, 281–282, 285; ambitions of 119; birth of 111–112;

- Council meetings 117, 257; ‘fig-leaf’ view of 119; group cohesion 118; jury service 120; legacy and influence of 120–123; membership of 116; in NHS Plan of 2000 115; patient representation on committees 123–126; requirement for 110; social value judgements 2, 115, 179, 255, 258
- Clark, B. 1, 100
- Clarke, Kenneth 42
- Claxton, K. 223, 273
- clinical audit/clinical governance 50, 70, 84, 88–89, 159
- clinical decision-making 11, 12
- clinical effectiveness 13, 18, 30, 44, 48–49, 82, 84, 135, 158, 162, 178, 242
- Clinical Guidelines 13, 81, 172–173, 191; Clinical Guidelines by NICE *see* NICE Guidelines
- clinical policy-making 12, 16
- Cochrane, Archie 12, 19, 61, 183, 186, 190
- cognitive behaviour therapy (CBT) 200, 201, 203, 204
- Collier, Joe 173
- Comprehensive Spending Review (CSR) 51
- Cooper, M. 19
- Cooper, Yvette 225
- Coote, Anna 112, 114, 115
- coronary artery bypass grafting (CABG) 21, 23, 28
- Corrigan, Paul 95, 99, 105, 149, 214, 215
- cost-effectiveness 175–176, 190–193, 205; EBM movement 13–15, 39, 44; health technology appraisal 30, 89; NHS 39, 43, 46; NICE appraisal of 262; in NICE Guidelines 175–176, 190–193, 205
- cost-utility analysis 223, 225
- Coulter, A. 15
- COVID-19 pandemic 4, 157, 159–160, 201, 241, 256
- Craig, C. 206
- Crosby, N. 112, 113
- Croxson, B. 20
- Culyer, Tony 3, 19, 20, 22, 56–57, 59–61, 63, 78, 82, 96, 98, 101, 103, 108–110, 115, 120–122, 125, 131, 140, 192, 223, 224, 280, 282, 285
- Cummings, Jane 197
- Dacre, Paul 100
- Danczuk, Simon 116
- Daniels, N. 108, 110, 114, 115, 131
- Darzi, Ara, Lord: *High Quality Care For All NHS Next Stage Review Final Report* 160
- Davies, S. 207, 235, 270
- Denham, John 65, 174
- Department of Health (DH), from 2018
- Department of Health and Social Care (DHSC) 69–71, 144; appraisal process and method 56, 134, 153; budgets 51, 175; civil servants 13, 45, 54, 280; ‘clinical audit’ or ‘clinical governance’ 88; clinical effectiveness 48; cost control 55; documents 3, 63, 178, 181; economists 22, 28, 104, 139, 269; funding 50, 82, 176; Guidelines for Pharmaco-Economic Studies 32; ‘international variations’ report 248; medical and administrative hierarchies 47; NICE’s relationship with 144–145, 150, 152; and NICE service guidelines 194, 217; policy developments 31, 45, 46; pricing unit 239–240, 242; R&D Directorate 33, 220; risk-sharing scheme 154; ‘scans horizon’ 54; Strategy Unit 115
- Department of Health and Social Security (DHSS) 17, 19, 22, 27–28, 31, 182, 207
- Dienel, P. 112, 113
- Dillon, Andrew 3, 57, 58, 63–70, 75–79, 92, 93, 97–99, 101, 103, 104, 109, 115, 124, 127, 129, 130, 136, 145, 146, 149, 153, 154, 164, 171, 175, 179, 180, 197, 200, 214, 215, 241, 244, 250, 257, 261, 262, 264, 266, 273, 280, 281
- Dimbleby, Jonathan 21
- Dobson, Charles 32, 54, 64, 136, 145, 181
- Dobson, Frank 40, 57–59, 62, 66, 71, 78, 82, 90, 97, 103, 135, 145, 147
- Donaldson, Liam 45, 46, 53, 58, 115, 216
- Dorrell, Steven 26, 27, 30
- Drummond, Michael 22, 170, 175, 176, 189–193, 202
- Earnshaw, Julia 89, 91, 96, 164, 255, 258
- Eccles, Martin 88, 171, 173, 178, 182, 183, 185, 188, 191, 192, 194, 202, 219, 282
- economics: health *see* health economics; NICE method 258–259, 274; use of 190
- Edwards, B. 49
- Enthoven, Alain 20
- epidemiology 11, 13, 15, 29, 45, 205, 283
- evidence-based appraisal 137–138

- evidence-based medicine (EBM)
 movement: attractiveness of 14–15, 24;
 clinical decision-making 11, 12; clinical
 effectiveness 30; clinical policy-making
 12; cost-effectiveness 13–15, 39, 44;
 development of NICE at DH 13, 91,
 178, 204, 232, 284; governance policies
 or national policymaking 12; medical
 interventions 7; ‘the new scientism’
 15; in NHS 11–12, 29; NHS Executive
 commitment to 30; ‘Oregon experiment’
 15; practice policies 12; public political
 commitments to 30; rise of 4, 13;
 service policies 12
- evidence-based policymaking 16, 24, 139,
 206, 232
- evidence-informed policymaking 139
- Evidence Review Group (ERG) 163–164
- evidence wars 184, 204, 211, 222
- ‘expectation of delivery’ 176, 177
- fairness, concept of 10, 253
- Fall, M. 49
- Faster Access to Modern Treatment: How
 NICE Appraisal will Work* 53, 64, 136
- Ferlie, E. 18
- Fillingham, David 95
- Final Appraisal Determination (FAD) 144,
 154–155
- ‘formal contract management’ 176–177
- Fox, Liam 117
- Freeman, George 270
- Gaffin, Jean 76, 125, 127, 130, 162, 197
- Galbraith, Sam 47
- General Medical Council (GMC) 87
- George, Fred 123
- Gibbons, M. 140
- Gizbert, Jane 68
- Glaxo (Glaxo Wellcome) 90, 91; *see also*
 Relenza
- Goldacre, B. 273
- graded exercise therapy (GET) 200, 201
- Graham, I. 184
- Greener, I. 7
- Grogano, A. 22
- Guide to the methods of technology
 appraisal* 138, 253–255
- Ham, Chris 15, 97
- Hammond, Philip 65
- Haslam, David 92, 177, 184, 185, 242
- Haywood, S. 17
- Health and Social Care Act (2012) 230
- health care partners of NICE: health
 professions 80–89; NHS organisations
 93–95; NICE and health economics 95;
 pharmaceutical industry 89–93
- Health Development Agency (HDA) 211,
 214–218
- health economics 13, 16–23, 59–60, 102,
 109, 139, 141, 162, 163, 190, 241, 279;
 ‘economising’ goal of health policy
 16–18; evolution of 20; media analysis
 19–20; NICE HTA programme 53;
 NICE’s relationship with 96, 223, 284;
 profession of 7; quasi markets and
 managers 18; rise of 4, 8; use of 16, 77;
 valuation of life and health states 165;
see also economics
- Health Economists Study Group (HESG)
 20
- health gain 16, 30, 41, 93, 243;
 evidence-based medicine 14; population
 8–11; problem of 8–11; use of QALYs
 51, 138
- health policy 7–15, 26, 33, 39–40, 113–114,
 213, 252, 279–280
- health technology appraisal (HTA)
 71; agencies in Australia 136; and
 cost-effectiveness 30; development of
 29; establishment of HTA Asia Link
 102; NICE’s Technology Appraisal
 machinery and its publications *see* NICE
 Technology Appraisal; Scandinavian
 approaches to 18; *see also* health
 technology assessment
- health technology assessment (HTA)
 4, 10, 211, 279; defined 23–24; and
 guidelines 101; political considerations
 26; practitioners 25; as technology
 of governance 24; tools of 39; UK
 developments in 24; *see also* health
 technology appraisal; NICE Technology
 Appraisal
- Hennessy, P. 59
- Henshall, Chris 64
- Herceptin (2005) 1, 75, 100, 128, 147–150,
 152, 162, 244–246, 252, 282
- Herrick, C. 228
- Hewitt, Patricia 25, 148–150, 155, 252
- Highly Specialised Technologies (HSTs)
 259
- High Quality Care For All NHS Next Stage
 Review Final Report* (Darzi) 160
- Hill, Robert 52, 97

- Hoffmaster, B. 165, 253, 285
 Holland, W. 11, 12, 205, 283
 Hooker, C. 165, 253, 285
 Hunter, D. 13, 15
 Hurst, Jeremy 27, 269
 Huyshe-Shires, Stella 201
- Incremental Cost-Effectiveness Ratio (ICER) 138–139, 153, 165, 224, 254–255, 258–259, 268, 273–274, 282
- Institute for Quality and Efficiency in Health Care (IQWiG: German organisation) 24
- International Decision Support Initiative (IDSI) 101–102
- ‘international variations’ report 248
- Irish, Tim 263
- Irving, Miles 28
- Janoff, S. 24, 244
- Jeyasingham, Mercy 56, 123, 126, 162, 163, 180, 231
- Johnson, Alan 245, 246
- Jones, Trevor 3, 54, 90–92, 94, 146
- Kelly, Mike 213–216, 219–221, 223–227, 234
- Kelson, Marcia 126, 202
- Kennedy, I. 158, 174, 271; *Appraising the Value of Innovation and Other Benefits* 272
- Kent, Alastair 125, 127, 128, 176
- Keogh, Bruce 248
- Kind, P. 22, 23
- Kingdon, J. 3, 8, 11, 25, 32, 39, 173, 174, 251, 261
- Klein, R. 12, 15, 143, 183, 194
- Knapp, Martin 176
- Kogan, M. 182, 207
- Langlands, Alan 45
- Lansley, Andrew 61, 226–230, 235, 240, 243, 248, 249, 264, 283
- Law, Catherine 143, 218, 219, 222, 225, 227, 228, 231
- Lawson, Nigel 26
- Lenaghan, Jo 113, 115
- Leng, Gillian 77, 79, 83, 86, 88, 176–178, 186, 190, 232–234
- Leschley, Jan 90
- Lesirge, Ruth 125
- Liddell, Alasdair 47
- life sciences industries 268–269; *see also* pharmaceutical industry
- Littlejohns, Peter 81, 110, 111, 114, 115, 119, 129, 131, 173, 175, 178, 185, 186, 190, 191, 213, 214, 224
- Longson, Carole 250, 271, 272, 280
- Loud, Fiona 198, 199
- Luff, Roy 123
- Lyme disease 201
- Major, John 25, 26
- Malone, Gerry 27, 30
- Margaret Jay, Baroness 41, 47, 50, 88, 194
- Mattinson, D. 112
- Maynard, A. 19, 21, 23, 31
- McCandlish, Rona 67, 82, 84, 176, 177, 186, 198, 201, 281
- McCarthy, Bill 43
- McClarey, Mary 84, 163, 164, 186, 199
- McCrea, Joe 42, 43
- McKeon, Andy 41, 51, 153
- McKillop, Tom 90
- McLachlan, G. 20
- Medical Technologies Evaluation Programme (MTEP) 160
- medicines policy 57, 153, 241, 243, 247–249, 251, 258, 262, 269; climate of government 269–271; Conservative Party 241; DH 243, 262; goals of government 269; politician’s 247
- Melville, John 248, 251
- Mepact (mifamurtide) 258
- Meredith, Barbara 126
- Milburn, Alan 40–43, 46, 47, 49, 51, 52, 59, 61, 62, 99, 161, 225, 280
- minimum unit pricing, alcohol (MUP) 227–228
- Mold, A. 113
- Montini, T. 184
- Moreira, T. 3, 33, 140, 183, 198, 204, 205, 225, 279, 283
- Morgan, Bill 245, 248, 266, 268
- Mulkay, M. 19
- multimorbidity 184–185
- ‘multiple streams analysis’ 8, 39, 251
- multi-technology appraisal (MTA) 151–152, 171–172
- National Co-ordinating Centres (NCCs) 176, 177, 188
- National Health Service (NHS) 78, 79; development of 7; drug costs 146; effectiveness and cost-effectiveness in 39, 43, 46; evidence-based medicine 11–16; financial sustainability 238;

- hospitals' research budgets 82; HTA programme 191; influence on 105; 1991 internal market reforms 26; market for drugs 239; medicines landscape 272; 'new NHS' 280; NHS Plan of 2000 115; 1997 White Paper *the new NHS: modern. dependable* 40, 48–53; organisations 93–95; public and patient involvement 109, 113, 255; purchasers and providers 10, 28; purchasing body 92; R&D programme, establishment of 28–29, 88, 176, 205, 262; regional DECs 139; rising cost of drugs 10; rules 245; 2010 White Paper *Equity and excellence: Liberating the NHS* 229; in social care 61; spending growth 9, 9–10; use of drugs 29; for women 1
- National Institute for Clinical Excellence (NICE) 50; approval of Herceptin 1; at DH *see* Department of Health (DH); economic evidence 223–225; establishment 3–4, 7, 39–40, 44; on global stage 101–102; and government 96–98; guidelines *see* NICE Guidelines; Health Development Agency 214–218; health policy 11–25; history of 3–4, 5; HTA *see* health technology appraisal (HTA); and its health care partners 79–96; launch window of 1997–99 70–72; and media 98–100; origins 2–3, 7–33, 39, 43, 279; patient and public involvement 282; policy initiatives 27–32; politics 25–27; problem of 8–11, 9; questions about evidence 219–222; public health 211–228; responsibilities 211; social care sector 228–233; statutory functions 283; TAs *see* NICE technology appraisal; Technology Appraisal Committee 103; tensions with government 225–228; 1998 White Paper *A first class service: Quality in the new NHS* 53–56; 1997 White Paper *the new NHS: modern. dependable* 48–53; working at 76–79
- National Service Frameworks (NSFs) 194
- Nebhrajani, Sharmila 4
- New Labour 39–41
- 'new NHS' 88, 280
- New Public Management 18, 137, 177, 260–263
- NHS England 40, 95, 122, 159, 161, 195–197; affordability test 265; Budget Impact Test 266; and CDF 250; creation of 264; and NICE, relationship between 238, 250, 251, 266–268; operation in 2013 249; relationship with pharma 273
- NHS Evidence and Quality Standards 94
- NHS Executive 30, 45, 47, 55, 93, 183, 264
- NHS Improvement 196
- NHS Modernisation Agency 95
- NHS Plan (2000) 115
- NHS Regional Health Authorities (RHAs) 28
- NICE guidance 95–96, 211, 230, 233, 240, 257, 285; clinical audit 88–89; government's suppression of 196; issue of 94, 105, 197; to treat mild to moderate anxiety and depression 161
- NICE Guidelines 230; 'accreditation programme' 177; arrival of 'formal contract management' and 'expectation of delivery' 177; Clinical Guidelines series (CGs) 230, 289–295; cost-effectiveness, importance of 175–176, 190–193, 205; DH budget for guideline production 175; on Diabetes in pregnancy (NG3) 193; 'epilepsies in children, young people and adults' (NG217) 230; on gastro-oesophageal reflux disease: children and young people (NG1) 193; guidelines for whole services 194–198; 'looked-after children and young people' (NG205) 230; methodology and evidence 183–184; multimorbidity: clinical assessment and management in 2016 184–185; and patients 198–202; philosophy and methodology 178–179; 'policy window' in UK in 1997 173–175; production process 179–180, 186, 188–190, 204; recruitment interviews 185–186; 'safeguarding adults in care homes' (NG189) 230; on schizophrenia, 2002 (CG1) 202; on schizophrenia, 2014 (CG178) 203–204; stages of 186, 187; topic selection 181–182; UK clinical guidelines before 1999 172–173; UK science policy 206–207
- NICE Technology Appraisal 2, 15, 28, 32, 52, 63, 91, 94, 104, 110, 137, 147, 148, 156–157, 161, 164, 181, 238, 243, 245, 267; age-related macular degeneration (TA068) 154–156; Alzheimer's disease drugs 156; benefits of faster appraisal 150–152; case of beta interferon 153–154; cost-effectiveness 89, 262; decisions 130, 152, 161–167; designing

- appraisal process 135–137; development of 134–143, 271, 282; diagnostics and other appraisals 159–161; equity argument for 49; ethics of opportunity cost 152–156; evidence-based appraisal 137–138; evolution of 238; and guidelines 96, 101, 181, 193, 280; Herceptin (2005) 147–150; integrity of 262; interventional procedures 157–159; issues in 281; method 138, 253–254; patient and public involvement 129–130, 141–142; policy debate 62; political considerations 89, 143–145; problem of delay 148; process 54, 253–254; purity of 110; Relenza (1999) 145–147; ‘service delivery’ model 238; speed, rigour and transaction cost 282; spending on 171; stakeholders 141; surviving legal challenge 142–143; technical progress in 255; tragic choices 282; using judgement 138–141
- Nichol, Duncan 25
 Nicholson, David 264
 Non-Departmental Public Body (NDPB) 61, 211, 230
 Nowotny, H. 140
 Nuffield Provincial Hospitals Trust 19, 20
- O’Brien, Una 57, 197, 226
 Office of Fair Trading (OFT) 239–243
 O’Mahony, J. 259
 optimistic approach to using health economics 71, 279, 280
 ‘Oregon experiment’ 15
 Orkambi 267
- Palin, Sarah 166
 Parkinson’s disease 198–199
 Partners Council 84–85
 Partridge, James 125, 129–130
 Pathak-Sen, Ela 111, 118
 patient and public involvement (PPI) 2, 4, 108, 125–126, 141–142, 152, 282; Citizens Council *see* Citizens Council; citizens’ jury 112, 114; in decision-making 109; history of 113; rationing and tragic choices 114
 patient reported outcomes measures (PROM) 23
 Paulden, M. 259
 Peacock, Alan 18
 Peckham, Michael 29, 32, 43
 personalisation agenda, in social care 229, 232
- pessimistic approach to using health economics 71, 279, 280
 pharmaceutical industry 89–93
 Pharmaceutical Industry Competitiveness Task Force (PICTF) 270
 Pharmaceutical Price Regulation Scheme (PPRS) 10, 239
 photodynamic therapy (PDT) 154, 155
 Pickard, S. 114
 Pinch, T. 19
 Pink, David 13, 44, 62–65, 72, 78, 81, 144, 145, 181, 186
 Pliskin, J. S. 21
 policy community 8, 174, 241, 247
 policy ecosystem 241
 ‘policy window’ in UK (1997) 173–175
 population health 8, 45, 61, 89, 212
 Porter, M. 243
 Porter, T. 205
 postcode lottery 10–11, 30, 42–43, 49, 71, 90, 249
 Powell, M. 7
 priorities in health care 22, 281, 284
 public health: challenges 222; economic analysis 234; evidence wars 222; government policy on 211–214; guidance 178, 179, 213, 217, 219, 234; guidelines 190, 217, 221, 225, 226, 228; interventions 15, 75, 143, 184, 213, 222–224; issues in 219; medicine 45; NICE’s work on 4, 211–212, 223, 228, 231; orientation 46; as political 222; research 12; style thinking 46
Public Health in England (Acheson Report) 211
- Quality-Adjusted Life Year (QALY) 4, 19; cost-utility analysis 223; in decision-making 4, 23; development of 23; in health technology assessment 4; influential contribution of health economics 20; in physical activity guideline 224; rise of 24; for specific medical interventions 22; use of 51, 191, 223, 282; weighting 260
- Rao, V. 8
 Rathwell, T. 17
 rationing (of health care) 2, 9, 31, 46; ABPI attack on 63; politics of 42, 51–52, 65, 111, 247, 285; Rationing Agenda Group 45
 Rawlins, Michael 3, 4, 27, 42, 43, 50, 51, 56–63, 65–69, 71, 81–85, 87–89, 92, 97,

- 98, 101, 103, 104, 108, 113, 115, 119, 121, 124, 126, 127, 140, 143, 146, 147, 149, 158, 166, 170, 171, 175, 183, 186, 198, 215, 241, 244, 248, 250, 257, 272, 280, 281, 283
- Rawls, J. 112, 120
- Relenza (1999) 75, 90, 114, 135, 138, 141, 145–147, 153, 170, 270
- Richards, Mike 147–149, 194, 195, 197, 246, 249, 251, 257
- Rid, A. 266
- Risk Sharing Scheme 154
- Roberts, Samantha 4, 271
- Roche 124; cancer drugs 248; Herceptin 147
- Rodgers, Anne-Toni 46, 77, 78, 80, 83, 85, 91, 93, 97, 99, 108, 123, 124, 129, 145, 155
- Rodwin, M. 14
- Rose, N. 3
- Ross, Nick 45
- Rosser, R. 19, 22, 23
- Royal Colleges (medical) 13; and NICE 79–83; role in guidelines 64–65, 175–176
- Royal College of Nursing (RCN) 84, 186
- Royal National Institute of Blind People (RNIB) 155
- Sabin, J. 108, 110, 131
- Sackett, D. 11
- Safety and Efficacy Register for New Interventional Procedures (SERNIP) 158
- Sansom, Kath 200
- schizophrenia 202, 203, 206
- Schniedermann, A. 24
- science policy (UK) 206–207
- Scott, P. 140
- Securing Good Health for the Whole Population* (Wanless) 213
- Seddon, Nick 226, 266
- ‘service delivery’ model of guidance production 151–152, 238
- Shepard, D. 20
- Silvester, Jane 231
- Simons, A. 24
- single technology appraisal (STA) 151–152, 253–255
- Smee, C. 17, 28, 31, 32, 41, 43, 46, 51–53, 60, 62, 71, 110, 139, 140, 274, 280
- Smith, Chris 44, 51
- Smith, Richard 45
- social care: guidance for 230–231, 233; guidelines 230–231; NHS in 61; NICE’s work on 4, 170, 228–230, 233, 283; ‘personalisation’ agenda in 229; quick guides 232, 234; satisfactory and sustainable 26; training in 233
- social epidemiology 205, 283
- Social Value Judgements (SVJ): Citizens Council 2, 122, 179, 258; development of 121; existence of 121; need for 109–111; NICE’s responses 253, 255, 282; use of 77
- Stevens, Andrew 28, 138, 153
- Stevens, Simon 31, 40, 43, 45, 48, 51, 52, 60, 97, 146, 154, 196, 197, 250, 264–267, 273
- Stewart, J. 113
- ‘St George’s Instrument’ for assessing guidelines 173
- Sutcliffe, Andrea 231
- Sykes, Richard 90, 135, 136, 145–147, 250
- Syrett, K. 15, 139, 140, 143, 148
- Szreter, S. 8
- Taylor, Rod 64, 135, 136, 140, 141, 282
- technologies of governance 24, 134, 262–263, 279, 284
- Thailand’s Health Intervention and Technology Assessment Program (HITAP) 25, 102
- Thatcher, Margaret 10, 26, 81, 172, 211, 262
- Timmins, Nicholas 25, 30, 46, 57, 59, 71, 99, 103, 104, 122, 170, 247
- Towse, Adrian 32, 90, 170, 242, 256
- tragic choices 112, 114, 161, 164–166, 282–285
- Turner, Ruth 116, 280–281
- Universal Health Coverage (UHC) 25
- values 10, 22, 110, 122, 273, 281, 284; based pricing 241–243; Culyer and 60, 108–109, 140; in health 243; for money 135, 239, 249, 262, 266, 268; and tragic choices 165–166; *see also* Social Value Judgements (SVJ); tragic choices
- Valverde, M. 3
- Vickers, John 239
- Vision 21 116, 117
- Visudyne (verteporfin) 154
- Wailoo, A. 191
- Waldegrave, William 26

- Walley, T. 29, 141
Wanless, Derek 48, 214, 223, 235; *Securing Good Health for the Whole Population* 213
Watts, Geoff 116
Watts, V. 22
Weale, Albert 111
Weinstein, M. 21
Weisz, G. 172
Wessex Development and Evaluation Committee (DEC) 46
White Paper: *Equity and excellence: Liberating the NHS* 229; *A first class service: Quality in the new NHS* 47, 53–56; *The Health of the Nation* 211; *the new NHS: modern. dependable* 48–53, 56, 61, 178; *The NHS: A service with ambitions* 30; *Our health, our care, our say* (2006) 229; *Saving Lives: Our Healthier Nation* 212
WHO: *Health for All by the Year 2000* 211–212
Widdecombe, Anne 42
Will, Catherine 205
Williams, A. 18–23, 31, 121
Winyard, Graham 28, 46, 47, 173, 218, 273, 280
Woodgate, D. 22
Woolcock, M. 8
Wright, Ken 21
Zeckhauser, R. 20