

Hans-Holger Bleß
Miriam Kip *Eds.*

White Paper on Joint Replacement

Status of Hip and Knee
Arthroplasty Care in Germany

OPEN

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H.-H. Bleß
M. Kip
(Eds.)

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Status of Hip and Knee Arthroplasty Care in Germany

With 46 Figures

Editors

Hans-Holger Bleß
IGES Institut GmbH
Berlin, Germany

Dr. med. Miriam Kip
IGES Institut GmbH
Berlin, Germany

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Foreword

This White Paper on Joint Replacements aims to present an impartial review and a comprehensive overview of the current healthcare situation for hip and knee arthroplasty patients in Germany.

White Papers present independent information on topics that are relevant to society. This White Paper is based on comprehensive literature reviews and data research which have been evaluated in collaboration with experts in the field of endoprosthetics to give a sound summary of the current situation. In addition, it identifies needs for action to improve care. It also identifies various needs for action towards the improvement of care. White Papers on health-related topics can therefore contribute to shaping medical care and healthcare policies. The IGES Institute has presented White Papers on multiple sclerosis, stroke prevention in atrial fibrillation, acute coronary syndrome and diabetes mellitus.

Hip and knee arthroplasty are amongst the most frequently performed procedures in German hospitals. Common reasons for performing this surgery are joint wear or fractures which occur considerably more frequently in old age. Surgical procedures are continuously being refined and treatment pathways have to be adapted to increasing demands.

How successful are current surgical treatments? How have case numbers for hip and knee surgery developed over the past few years? Which healthcare structures do we need in order to meet the rising demands of an increasingly aging population in the future? What do renowned experts call for with regard to future arthroplasty care?

The authors and experts investigate these questions and further issues in the following chapters.

As the editors of this book, we would like to thank the authors of the individual chapters and the participants of the expert panel workshop. We would especially like to thank Prof. Karsten Dreinhöfer, Medical Director and Head of the Department of Orthopaedics and Traumatology, Medical Park Berlin and Prof. Klaus-Peter Günther, Executive Director of the University Center of Orthopaedics and Traumatology at the University Hospital Carl Gustav Carus of the Technical University Dresden for the editorial revision of the manuscript.

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Dr. Miriam Kip, Hans-Holger Bleß

IGES Institut

Berlin, June 2016

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List of Authors and Participants of the Expert Panel Workshop for the White Paper on Joint Replacements

Authors

Dr. Hubertus Rosery

Florian Rothbauer

Michael Weißer

Ute Zerwes

AiM GmbH

Assessment in Medicine, Research and Consulting

Marie-Curie-Straße 8

79539 Lörrach

Hans-Holger Bleß

Dr. med. Miriam Kip

Dr. rer. medic. Silvia Klein

Simon Krupka

Dr. rer. medic. Tonio Schönfelder

Cornelia Seidlitz

IGES Institut GmbH

Friedrichstr. 180

10117 Berlin

Editorial revision

Univ.-Prof. Dr. med. Karsten Dreinhöfer

Charité – Universitätsmedizin Berlin and Medical

Park Berlin (Charité Universitätsmedizin und

Medical Park Berlin Humboldtmühle)

Berlin Humboldtmühle

An der Mühle 2–9

13507 Berlin

Prof. Dr. med. Klaus-Peter Günther

University Hospital Carl Gustav Carus of the

Technical University Dresden (Universitäts-

klinikum Carl Gustav Carus an der Technischen

Universität Dresden)

Fetscherstraße 74

01307 Dresden

Expert workshop participants

Univ.-Prof. Dr. med. Karsten Dreinhöfer

Vice-President of the Professional Association
of Orthopaedic Surgeons

(Berufsverband der Fachärzte für Orthopädie
und Unfallchirurgie e. V. (BVOU))

Professor of Musculoskeletal Rehabilitation,

Prevention and Health Services Research at the

center for musculoskeletal surgery »Centrum für

Muskuloskeletale Chirurgie (CMSC)«

Charité – Universitätsmedizin Berlin

Medical Director and Head of the Department

for Orthopaedics and Traumatology

Medical Park Berlin Humboldtmühle

An der Mühle 2–9

13507 Berlin

Prof. Dr. med. Klaus-Peter Günther

Past President of the German endoprosthesis

society »Deutsche Gesellschaft für Endoprothetik

(AE)«

Past President of the German Society of Ortho-

pedics and Orthopedic Surgery (Deutsche

Gesellschaft für Orthopädie und Orthopädische

Chirurgie (DGOOC))

Executive Director of the University Center of

Orthopedics and Traumatology at the University

Hospital Carl Gustav Carus of the Technical Uni-

versity Dresden (Universitätsklinikum Carl Gustav

Carus an der Technischen Universität Dresden)

Fetscherstraße 74

01307 Dresden

Dr. med. Dipl.-Ing. Hans Haindl

Publicly appointed expert in medical devices

Georgsplatz 1

30974 Wennigsen

Prof. Dr. med. Karl-Dieter Heller

Secretary General of the German arthroplasty association »Deutsche Gesellschaft für Endoprothetik (AE)«

First Chairman of the German association of senior orthopedists and trauma surgeons »Verband leitender Orthopäden und Unfallchirurgen (VLOU)«

Vice-President of the Professional Association of Orthopaedic Surgeons (Berufsverband für Orthopädie und Unfallchirurgie e. V. (BVOU))

Board member of the German Society of Orthopedics and Orthopedic Surgery (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC))

Vice President of the German hip society »Deutsche Hüftgesellschaft (DHG)«

Head of the Orthopedic Department Herzogin Elisabeth Hospital

Leipziger Straße 24
38124 Braunschweig

Dr. med. Andreas Hey

Managing Director of the German arthroplasty registry

»Deutsche Endoprothesenregister gGmbH (EPRD)«

Straße des 17. Juni 106–108
10623 Berlin

Prof. Dr. Dr. Reinhard Hoffmann

Secretary General of the German Trauma Society (Deutsche Gesellschaft für Unfallchirurgie (DGU))

Secretary General of the German Society for Trauma Surgery (Deutsche Gesellschaft für Orthopädie und Unfallchirurgie (DGOU))

Medical Director of the BG Hospital Frankfurt am Main (Unfallklinik Frankfurt am Main gGmbH)
Friedberger Landstraße 430
60389 Frankfurt am Main

Univ.-Prof. Dr. med. Rüdiger Krauspe

President of the German Society of Orthopedics and Orthopedic Surgery (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC)) in 2015

Director of the Department of Orthopaedics
Düsseldorf University Hospital
Moorenstraße 5
40225 Düsseldorf

Univ.-Prof. Dr. med. Georg Matziolis

Professor of Orthopedics at the Jena University Hospital, Campus Eisenberg
Medical Director of the Clinic for Orthopaedics and Accident Surgery at the Waldkrankenhaus Eisenberg (Waldkrankenhaus »Rudolf Elle« GmbH)
Klosterlausnitzer Straße 81
07607 Eisenberg

Univ.-Prof. Dr. med. Henning Windhagen

Medical Director of the Orthopaedic Clinic of the Hannover Medical School in the DIAKOVERE Annastift Hospital
Anna-von-Borries-Straße 1–7
30625 Hannover

Past President of the German Society of Orthopedics and Orthopedic Surgery (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC)), and the German Society for Orthopaedics and Trauma (Deutsche Gesellschaft für Orthopädie und Unfallchirurgie (DGOU))

List of abbreviations

ACCP	American College of Chest Physicians	DGUV	German Social Accident Insurance Deutsche (Gesetzliche Unfallversicherung)
ADL	Activities of Daily Living	DIMDI	German Institute of Medical Documentation and Information (Deutsches Institut für Medizinische Dokumentation und Information)
AE	German arthroplasty association »Deutsche Gesellschaft für Endoprothetik e. V.«	DRG	Diagnosis Related Groups
AHB	Subsequent rehabilitation (Anschlussheilbehandlung)	DRV	German Statutory Pension Insurance (Deutsche Rentenversicherung)
AOK	Statutory health insurance (Allgemeine Ortskrankenkasse)	DVT	Deep vein thrombosis
AQUA-Institut	AQUA Institute for Applied Quality Improvement and Research in Health Care (Institut für angewandte Qualitätsförderung und Forschung im Gesundheitswesen Institut GmbH)	EBM	Uniform Value Scale (Einheitlicher Bewertungsmaßstab)
AR	Additional remuneration	EPRD	German joint replacement registry »Endoprothesenregister Deutschland (EPRD)«
ARCO	Association Research Circulation Osseous	ESC	European Society of Cardiology
ASA	American Society of Anesthesiology	ETM	Evidence-based treatment modules (Evidenzbasierte Therapiemodule)
AWMF	Association of the Scientific Medical Societies in Germany (Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften e. V.)	EULAR	European League Against Rheumatism
BÄK	German Medical Association (Bundesärztekammer)	FEISA	Research and development institute for social affairs and the healthcare system in Saxony-Anhalt »Forschungs- und Entwicklungsinstitut für das Sozial- und Gesundheitswesen Sachsen-Anhalt«
BfArM	Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte)	G-BA	Federal Joint Committee (Gemeinsamer Bundesausschuss)
BMG	Federal Ministry of Health (Bundesministerium für Gesundheit)	G-DRG	German Diagnosis Related Groups
BMI	Body Mass Index	GKV	Statutory health insurance (Gesetzliche Krankenversicherung)
BMWi	Federal Ministry for Economic Affairs and Energy (Bundesministerium für Wirtschaft und Energie)	GOÄ	Physicians' fee catalog (Gebührenordnung für Ärzte)
BQS	Institute for Quality and Patient Safety (Institut für Qualität und Patientensicherheit GmbH)	HIV	Human immunodeficiency virus
BVMed	The German Medical Technology Association (Bundesverband Medizintechnologie e. V.)	HKK	Statutory health insurance »Handelskrankenkasse«
BVOU	Professional Association of Orthopaedic Surgeons (Berufsverband der Fachärzte für Orthopädie und Unfallchirurgie e. V.)	HV	Curative procedure (Heilverfahren)
CC	Complications or comorbidities	IC	Integrated care
DAH	German association for osteoarthritis support »Deutsche Arthrose-Hilfe e.V.«	ICD	International Statistical Classification of Diseases and Related Health Problems
DALY	Disability Adjusted Life Years	IgeL	Individual health services paid for privately by the patient »Individuelle Gesundheitsleistungen«
DGOOC	German Society of Orthopedics and Orthopedic Surgery (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie e. V.)	InEK	German Institute for Hospital Reimbursement »Institut für das Entgeltsystem im Krankenhaus (InEK)«
DGOU	German Society for Orthopaedics and Trauma (Deutsche Gesellschaft für Orthopädie und Unfallchirurgie e. V.)	IQTiG	Institute for Quality Assurance and Transparency in Healthcare (Institut für Qualitätssicherung und Transparenz im Gesundheitswesen)
DGU	German Society for Trauma Surgery (Deutsche Gesellschaft für Unfallchirurgie e. V.)	IQWiG	Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen)
		IRENA	Intensified post-rehabilitation care (Intensivierte Rehabilitations-Nachsorge)

IV	Integrated care (Integrierte Versorgung)	VKA	Vitamin K antagonist
FJC	Federal Joint Committee	VTE	Venous thromboembolism
KHEntgG	Hospital Remuneration Act (Krankenhausentgeltgesetz)	WHO	World Health Organization
KHG	Hospital Financing Act (Gesetz zur wirtschaftlichen Sicherung der Krankenhäuser und zur Regelung der Krankenhauspflegesätze)	WidO	Research Institute of the statutory health insurance AOK »Wissenschaftliches Institut der AOK«
KSS Score	Knee Society Score	WIP	Scientific institute of the private health insurances »Wissenschaftliches Institut der Privaten Krankenversicherungen«
KTL	Classification of therapeutic services (Klassifikation therapeutischer Leistungen)	WOMAC	Western Ontario and McMaster Universities Arthritis Index
LMWH	Low-molecular-weight heparin	YLD	Years Lived with a Disability
MDD	Medical Device Directive	ZE	Additional remuneration
Morbi-RSA	Morbidity oriented risk adjustment scheme (Morbidityorientierter Risikostrukturausgleich)	ZLG	Central Authority of the Länder for Health Protection regarding Medicinal Products and Medical Devices (Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten)
MPG	Medical Devices Act (Medizinproduktegesetz)		
MTPS	Mechanical thromboprophylaxis stockings (compression stockings)		
NICE	National Institute for Health and Care Excellence		
NIH	National Institutes of Health		
NHP	Nottingham Health Profile		
NSA	Non-steroidal antiphlogistic drugs		
NUB	New examination and treatment methods »Neue Untersuchungs- und Behandlungsmethoden«		
OECD	Organisation for Economic Cooperation and Development		
OPS	German procedure classification »Operationen- und Prozedurenschlüssel«		
OTA	Surgical technician (Operationstechnischer Assistent)		
PE	Pulmonary embolism		
PROM	Patient-Reported Outcome Measures		
QALY	Quality-Adjusted Life Year		
QSR	Quality assurance using routine data (Qualitätssicherung mit Routinedaten)		
REDIA	Rehabilitation and diagnosis-related groups study (Rehabilitation und Diagnosis Related Groups-Studie)		
RKI	Robert Koch Institute		
SGB	Social Security Code (Sozialgesetzbuch)		
SHI	Statutory health insurance		
ST	Surgical Technicians		
SVR	Advisory Council on the Assessment of Developments in the Healthcare System (Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen)		
THA	Total hip arthroplasty		
TKA	Total knee arthroplasty		
TK	Statutory health insurance (Techniker Krankenkasse)		
vdek	Association of Substitute Health Insurance Funds (Verband der Ersatzkassen e. V.)		

Introduction to the Indications and Procedures

Cornelia Seidlitz, Miriam Kip

- 1.1 Definition – 2**
- 1.2 Etiology, Indications and Treatment Goals – 2**
 - 1.2.1 Etiology – 2
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 - 1.2.3 Surgery Goals and Objectives – 8
- 1.3 Materials, Surgical Procedures and Risks – 8**
 - 1.3.1 Material Requirements – 8
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 - 1.3.3 Factors Influencing Treatment Success and Complications – 10
- References – 13**

Summary

Arthroplasty is defined as the surgical replacement of a joint with artificially produced material. Total arthroplasty refers to the replacement of all joint surfaces concerned, while partial replacement involves the replacement of only one or some of the surfaces but not the entire joint. Hip and knee joints are those that are most frequently replaced. The most common indications for hip or knee arthroplasty are symptomatic osteoarthritis and femoral neck fractures (hip). When patients undergo hip or knee replacement for the first time (due to osteoarthritis) they are usually between 60 and 70 years of age. More than two thirds of patients who undergo arthroplasty due to femoral neck fractures are over 85 years of age. Primary arthroplasty refers to the first hip or knee replacement and revision arthroplasty refers to follow-up surgery on the same joint. The period of time (without complications) between primary arthroplasty and revision arthroplasty is termed as »service life«. In symptomatic osteoarthritis, arthroplasty is performed after all conservative and joint preserving therapy options have been exhausted. With regard to femoral neck fractures, joint replacement is usually the primary treatment option. Surgery aims to improve the quality of life, to restore the greatest possible functionality, mobility and freedom from pain, to assure a long service life with good weight-bearing capacity and to avoid secondary complications. These constitute important prerequisites for leading an independent life in old age.

1.1 Definition

Arthroplasty is defined as the essential surgical replacement of a joint with artificially produced material which is fixated in the bone (joint replacement, endoprosthetic surgery, alloarthroplasty) (Claes et al. 2012; Wirtz 2011). Total replacement refers to the replacement of all the joint surfaces concerned while partial replacement involves the replacement of only one or some of the surfaces but not the entire joint. Hip and knee joints are the most frequently replaced, but endoprosthetic implants are also used to replace other joint functions, such as shoulder or elbow joints (Claes et al. 2012; Wirtz 2011).

The most common reason for joint replacements is joint surface destruction from wear of the cartilage lining due to degenerative diseases such as osteoarthritis, fractures and other changes in bone and connective tissue structures. Under certain circumstances, these can lead to permanent loss of function, permanent pain and impaired mobility of the affected joint, as well as a decrease in quality of life. If these symptoms cannot be treated otherwise, replacement with an artificial joint becomes necessary in order to avoid secondary complications and to restore the patient's ability to participate adequately in everyday life.

The causes and consequently also the risk of requiring joint replacements are largely dependent on age. On average, patients are aged between 60 and 70 years when they receive an artificial hip or knee joint replacement for the first time.

1.2 Etiology, Indications and Treatment Goals

1.2.1 Etiology

Symptomatic osteoarthritis constitutes the most common reason for requiring hip joint replacement (Claes et al. 2012; Wirtz 2011). Over 80 % of all primary hip surgery is due to osteoarthritis-related symptomatic degenerative changes in the articular surfaces (osteoarthritis of the hip) (Barmer GEK 2010). Other reasons include periarticular fractures, such as femoral neck fractures (Strohm et al. 2015), chronic inflammatory rheumatic diseases, misalignments and pathological changes of the bone substance, due to tumors for example, metastases or osteoporosis, which increase the risk of periarticular fractures (Claes et al. 2012).

In the majority of cases, osteoarthritis also constitutes the main reason for requiring knee joint replacement (osteoarthritis of the knee). Osteoarthritis is responsible for 96 % of all primary endoprosthetic procedures on the knee (Barmer GEK 2010). Other reasons for knee joint replacements are much less frequent (Wirtz 2011).

■ **Tab. 1.1** Osteoarthritis classification and risk factors (selection)

Classification	Risk factors	Description
Primary (idiopathic)		localized (hip, knee) or generalized (polyosteoarthritis, more than three joint regions affected)
Secondary	congenital and acquired joint defects	e.g. hip dysplasia, malalignments of the knee
	endocrine diseases	e.g. diabetes mellitus
	metabolic disorders	e.g. hemochromatosis, hypercholesterolemia, hyperuricemia
	posttraumatic	e.g. following joint fractures, fractures near the hip, cruciate ligament injury in the knee
	other causes	e.g. sepsis, inflammatory rheumatic disease, circulatory disorders of the bone near the joint in avascular necrosis of the femoral head and femoral condyle

Source: IGES – Günther et al. 2013

■ Osteoarthritis

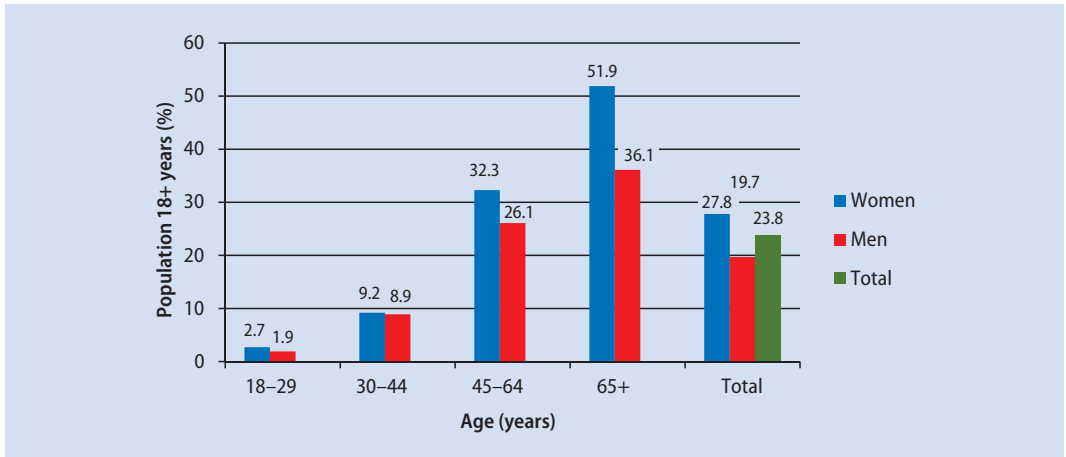
Numerous potential risk factors for osteoarthritis-related joint changes exist (■ Tab. 1.1). If these risk factors cannot be clearly ascertained, the osteoarthritis is classified as primary or idiopathic. In contrast, secondary osteoarthritis has one or more identifiable risk factors that may contribute to the advancement of the disease. General risk factors include age, sex as well as genetic, biomechanical and inflammatory factors. In addition body weight, osteoporosis, cardiovascular and metabolic diseases can also negatively affect cartilage metabolism. Risk factors resulting in local effects include injuries, circulatory disorders, congenital or acquired malformations and too much strain on only one side of the joint. As a result, multicausal rather than monocausal explanatory models are therefore generally favored nowadays (Günther et al. 2013).

The main symptoms of osteoarthritis are pain and increased restriction in mobility of the affected joints. In most cases, the disease usually progresses chronically, initially with symptoms such as joint stiffness which at first only occur after a longer period of strain on the affected joint. At first, pain only occurs following certain movements or after longer periods of rest (pain on initial movement). At a later stage, the pain is not associated with strain and becomes continuous (resting pain, nocturnal pain) (Claes et al. 2012).

Osteoarthritis is characterized by an imbalance in the cartilage metabolism in which catabolic processes prevail. Cartilage degeneration initially leads to the formation of new less resistant cartilage tissue. Therefore, joint function is restored but the joint is less resistant to strain. Over time, the cartilage tissue can be completely destroyed and the exposed bone underneath becomes deformed and the joint thickens (Claes et al. 2012).

In the advanced stage (active osteoarthritis) the increasing destruction of cartilage tissue and consequent inflammation of the synovial membrane lead to acute episodes of pain, movement restriction, swelling, joint warmth and sensations of tension. Sensitivity to weather, heat and cold are also typical symptoms during this phase. Generally, this stage of the disease can last several years and can include phases with and without symptoms (Claes et al. 2012) (■ Fig 1.1).

During the late stage of the disease (decompensated osteoarthritis), the progressive destruction of the joint is accompanied by permanent pain and functional restrictions. This leads to diminished quality of life in patients as daily life activities (e.g. washing, getting dressed) and mobility are affected. Pain then occurs during minor movements or even at rest. Chronic pain can also develop, caused by cartilage destruction, sclerosis and the formation of bone projections (osteophytes) as well as damage to



■ Fig. 1.1 Lifetime prevalence of osteoarthritis in Germany in 2012. (IGES – RKI 2014)

adjacent structures such as bones, muscles, capsules and ligaments. Osteoarthritis can ultimately lead to stiffness and instability of the affected joints resulting in immobility of the patient and consequently in the development of severe secondary diseases (Claes et al. 2012).

According to the Robert Koch Institute (RKI), the lifetime prevalence of osteoarthritis in Germany in 2012 was 27.8 % in women and 19.7 % in men. There was a noticeable rise in the prevalence of the disease in older age groups: In the 30 to 44 years age group, 9.2 % of the women surveyed and 8.9 % of men reported to have osteoarthritis, in the 45 to 64 years age group, 32.3 % and 26.1 % respectively reported to have osteoarthritis as did approximately 50 % all women and 36 % of men who were older than 65 years of age (■ Fig. 1.1). Previous studies have shown that the prevalence of symptomatic osteoarthritis in the population is estimated to be around 10 % in people over 60 years of age (Sun et al. 1997).

Due to the expected future demographic trends in Germany, a significant rise in degenerative joint diseases and therefore in hip and knee osteoarthritis requiring treatment can be expected (RKI 2009). Corresponding estimates for the increased needs of endoprosthetic care for other countries (Culliford et al. 2015; Kurtz et al. 2007) cannot be directly applied to Germany. However, prognoses published in relation to the development in musculoskeletal diseases

(Ewerbeck and Dreinhofer 2009) together with estimates from the German Society for Orthopaedics and Trauma (Deutsche Gesellschaft für Orthopädie und Unfallchirurgie e. V.) (DGOU) (Schmitt 2014) based on demographic trends and disease burdens give reason to expect an increase in these age-related diseases the future. An increase in the number of heavily overweight people in the population constitutes another influencing factor that will play an important role with regard to knee joint replacements (Derman et al. 2014).

■ Femoral neck fracture

Besides osteoarthritis, another important risk factor for hip joint replacement is the femoral neck fracture. It gains growing importance with increasing patient age (Claes et al. 2012; Strohm et al. 2015). Femoral neck fractures are close to the joint and require surgical treatment in most cases. Conservative therapy is only possible in cases of stable, non-impacted fractures. The surgical procedures available include procedures that preserve the joint and endoprosthetic procedures. The procedure selected will depend on the type of fracture and the age of the patient, amongst other factors. Usually, an endoprosthesis is implanted in patients over 65 years of age and in patients already suffering from joint osteoarthritis (Pfeifer et al. 2001). Osteosynthetic procedures aim to preserve the joint with the help of locking nails, cannulated screws or dynamic

hip screws consisting of extramedullary plates and antirotation screws (Claes et al. 2012).

The most common causes of femoral neck fractures are falls that occur at home which in turn can be ascribed to underlying diseases, for instance neurological or heart diseases.

A femoral neck fracture is one of the most common late-stage complications of osteoporosis (Stöckle et al. 2005). The prevalence of osteoporosis amongst the over 50 age group is approximately 14 % (women: 24 %; men: 6 %) (Hadji et al. 2013).

Factors which contribute to femoral neck fractures include age-related reduced bone mineral density and a higher risk of falling. Risk factors for falls include vitamin D deficiency (which affects the muscles), coordination disorders (for example due to medication), dizziness, defective vision, weakness, multimorbidity or existing diseases of the musculoskeletal system. The average age of patients with femoral neck fractures is relatively high and hence rapid mobilization is particularly important in order to avoid further complications. Preservation of the femoral head is given primary importance solely in younger patients (Claes et al. 2012).

Femoral neck fractures in younger patients are rare and are usually the result of so-called high-energy traumas, i.e. road traffic accidents and falls from great heights. Additionally, malignant diseases that are accompanied by bone destruction can also lead to femoral neck fractures (pathological fractures).

Femoral neck fractures are associated with severe pain in the hip region, restricted mobility of the hip joint and on walking. Often, the affected leg is noticeably shorter and rotated outwards. External signs of injury include hematomas or swelling above the hip joint. In cases of impacted fractures, clinical signs can be very discrete in that patients may still be able to walk for several days despite the fracture (Claes et al. 2012).

The risk of femoral neck fractures in one's lifetime is indicated to be between 11 % to 23 % in women and 5 % to 11 % in men (Stöckle et al. 2005).

This incidence rises with increasing age with a marked increase from the age of 74 years in particular (RKI 2009). Consequently, with a steadily increasing proportion of older people in the population, it can be assumed that the absolute number of

femoral neck fractures will also rise (Berufsverband der Fachärzte für Orthopädie e. V. 2004, Pfeifer et al. 2001). Given the current demographic trends in Europe, it is assumed that the incidence of femoral fractures will increase by at least fourfold over the next 60 years.

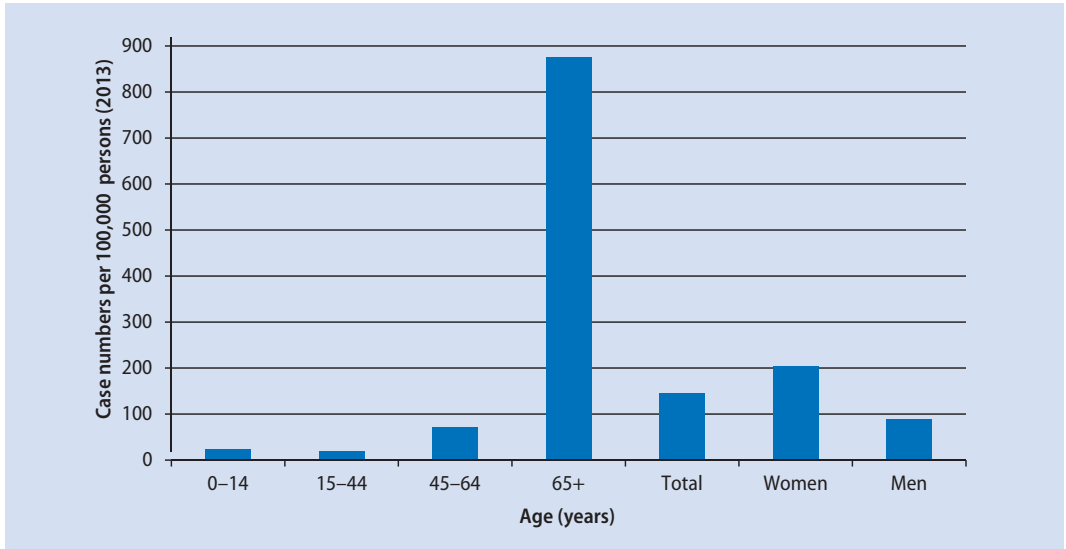
To date, only limited data from studies on the incidence of femoral neck fractures in Germany is available. An epidemiological investigation based on hospital statistics from 2004 found an incidence of 140.9 per 100,000 inhabitants. In correlation with the age-dependency, the incidence in older population groups (over 65 years) was significantly higher (662 per 100,000 inhabitants as opposed to 21.7 per 100,000 inhabitants in groups aged below 65 years) and was also significantly higher in women than in men (Icks et al. 2008).

According to the latest hospital diagnoses data, the number of inpatient cases in 2013 was 144 per 100,000 inhabitants (age standardized). The number of cases in the over 65 years of age group was at 875 cases per 100,000 inhabitants and as expected, women were affected more than twice as often as men (■ Fig. 1.2).

■ Femoral head necrosis

In femoral head necrosis the bone tissue of the femoral head dies (osteonecrosis). This is a result of ischemia (circulatory disorder) of the affected area (Meizer et al. 2007).

Inadequate blood supply can result from traumatic factors (posttraumatic osteonecrosis), such as tearing or overstretching following a femoral neck fracture, or various different risk factors and underlying diseases (nontraumatic osteonecrosis). There are several different risk factors and underlying diseases which can lead to nontraumatic osteonecrosis. Identifiable risk factors which are observed in 50 % to 80 % of cases include alcohol and nicotine abuse, dyslipidemia, pregnancy and hereditary coagulation disorders such as thrombophilia. In addition, high-dose corticosteroid intake (for example, for chronic inflammatory diseases) is associated with a high risk of disease development. Diseases that have been observed to result in higher rates of femoral head necrosis include systemic lupus erythematosus, HIV, malignancies, and inflammatory bowel diseases, amongst others.



■ **Fig. 1.2** Inpatient case numbers per 100,000 inhabitants with a femoral fracture (S72) by age group and by sex (age-standardized) (2013). (IGES – Federal Statistical Office 2014)

Symptoms associated with femoral head necrosis vary greatly between individuals and are non-specific (Hofmann et al. 2002). Particularly at the start of the disease, which advances bilaterally in 30 % to 70 % of cases, there may initially be no symptoms such as pain on weight bearing or difficulty walking. During the later stage, femoral head necrosis leads to movement restrictions and strong recurrent hip pain radiating into the thigh and knee. With the progression of the disease, pain at rest may also occur and in the final stages of the disease osteoarthritis of the hip with complete destruction of the joint may occur (AWMF 2009b).

Early diagnosis of femoral head necrosis is crucial to joint-preserving treatment and improved long-term prognosis. In 85 % of patients, the disease will progress within two years if the initial diagnosis is left untreated and results in femoral head collapse with complete destruction of the joint in over half of the patients (Hofmann et al. 2002). Based on the criteria developed by the Association Research Circulation Osseous (ARCO), idiopathic femoral head necrosis (without any known cause) is categorized into five different stages (0 to IV). The progression of each stage varies greatly between individuals and the duration can also vary from a period of several

days to several years (ARCO classification) (AWMF 2014).

In German-speaking countries, the incidence of femoral head necrosis is estimated at 0.01 %, which corresponds to approximately 5,000 to 7,000 patients a year (Hofmann et al. 2002). The disease occurs mainly between the ages of 25 and 55 years with a peak at 35 years of age. Men are affected four times as often as women. According to a routine data analysis conducted by the Barmer GEK, bone necrosis was indicated as the relevant main diagnosis upon discharge in approximately 3 % of primary total hip arthroplasty (THA) cases (Barmer GEK 2010).

1.2.2 Indications

■ Primary arthroplasty

The indication for a hip or knee replacement is based on patient-relevant clinical and radiological criteria together with a thorough examination of the patient's medical history (Claes et al. 2012, Wirtz 2011).

The clinical diagnosis includes an examination of the affected joint as well as of the structures and

tissue surrounding the joint. It also includes functional tests and pain assessments, for example, determining how far the patient can walk free of pain. The mobility of the joint can only be assessed by clinical examination. In addition, pain and other complaints can be evaluated by means of standardized patient surveys (AWMF 2009a, 2008; Claes et al. 2012; Wirtz 2011).

Besides objective criteria, a patient's degree of suffering and his or her requirements at the time of the examination play a substantial role in the decision for or against replacement of the affected joint. For instance, a replacement should not be recommended if the radiological findings show a joint affected by osteoarthritis but the patient does not have osteoarthritis-related symptoms or does not have many complaints (AWMF 2009a, 2008; Claes et al. 2012; Wirtz 2011).

According to Claes et al. (2012), an indication for a hip joint replacement exists if a patient's quality of life is severely affected by pain or functional impairment. Additional factors include conservative therapies that are insufficiently effective (medication, avoiding strain on the affected joint, physiotherapy, physical therapy, etc.) as well as visible causative radiological changes such as morphological joint damage, which cannot be treated conservatively (Claes et al. 2012). Furthermore, indications for hip joint replacements exist for patients over the age of 60 years who have femoral neck fractures and in patients with femoral fractures due to pathological bone diseases (for example metastases, osteoporosis) (Claes et al. 2012).

According to Wirtz (2011), an indication for total knee arthroplasty (TKA) in primary and secondary osteoarthritis of the knee exists if the conditions are associated with severe pain and movement impairments which can be confirmed radiologically (Wirtz 2011). Both the European League Against Rheumatism (EULAR) and the US National Institutes of Health (NIH) consider the indication for a knee joint replacement to exist if, alongside the radiological evidence of osteoarthritis, a patient has continuous pain that is not manageable with drugs, or if the disease is accompanied by substantial functional impairments (EULAR 2002, NIH 2004).

■ Revision arthroplasty

Revision arthroplasty entails the removal and replacement of one or more components of the hip or knee endoprosthesis. It is therefore a follow-up surgical procedure for primary hip or knee arthroplasty that is performed on the same joint.

Follow-up surgery without replacement or removal of the (entire) artificial joint can also be performed if the endoprosthesis is not functioning entirely correctly (EPRD 2015), for example to remove a hematoma (revision without replacement). The time between primary replacement and revision is termed as »service life« (EPRD 2015).

Usually, revision arthroplasty is performed after the »natural« service life of the endoprosthesis has come to an end. In some cases, however, earlier revision replacement might become necessary. Reasons for revision arthroplasty include loosening of the implant, instability of the artificial joint, extensive bacterial infections and progressive degeneration of parts of the joint that have not yet been replaced. Revision can also become necessary if functional impairments of the artificial joint severely restrict a patient's activities and are often accompanied by pronounced pain. Additionally, acute or chronic infections as well as traumatic fractures close to the joint or the endoprosthesis as well as problems with the implant and the primary replacement procedure may make revision replacement necessary. Other reasons include local inflammatory tissue reactions, wear (micro-abrasive particles) of the endoprosthetic material and the quality of the endoprosthesis fixation. Patient compliance and characteristics such as age or weight also have a significant impact on the endoprosthetic service life (Section 1.3.3). Documented arthroplasty in the German joint replacement registry »Endoprothesenregister Deutschland (EPRD)« will enable a reliable determination of the service life in future, which can be related to the different levels of care such as to the surgeon, the hospital performing endoprosthetic surgery, the individual endoprosthesis and the type of endoprosthesis depending on the initial documentation.

1.2.3 Surgery Goals and Objectives

Primary arthroplasty aims to restore joint function as much as possible, to reduce pain caused by osteoarthritis (hip or knee) and by other diseases. It also aims to rapidly mobilize patients after femoral neck fractures. A further goal is to achieve a long service life with good weight-bearing capacity and to avoid (secondary) complications. On the whole, a patient's quality of life should be improved and their mobility enhanced (Claes et al. 2012; Wirtz 2011). Mobility is a basic prerequisite for leading an independent life and preserving patients from social isolation, especially in older age groups (Moon 2014).

1.3 Materials, Surgical Procedures and Risks

1.3.1 Material Requirements

Ideally, the primary endoprosthesis should be retained over a lifetime. Despite tremendous technical advances and the availability of high-quality materials, this cannot be achieved for all patients. In general, both hip and knee endoprostheses are weight bearing body parts and must be designed accordingly, also with regard to the material selected (Claes et al. 2012, Wirtz 2011).

The implants undergo extensive testing with regard to functionality, quality, reliability and safety which constitutes a prerequisite for statutory product requirements. Corresponding requirements can be found in international standards which are reviewed every five years (BVMed 2014).

Regardless of the field of application, implants must have the longest possible durability which why is hard-wearing materials with minimal wear even when used in combination with other materials are employed. In addition, the materials must be accepted by the body as there is risk of potential rejection. It is recommended that metals (such as cobalt-chromium and titanium alloys) be used which are connected to the bone and tribologically paired with synthetic materials (polyethylene) or ceramics (NICE 2014).

Meanwhile, many different variations of these artificial joints exist. Therefore, a short overview of how they function and the most important features is provided in the following paragraphs.

Nowadays, hip endoprostheses usually consist of an acetabular cup and a femoral stem onto which a modular endoprosthesis head is attached. The cup may consist of one piece (usually polyethylene) or of a metal cup with an inlay (modular cup). Frequently, fractures in elderly people are treated by solely replacing the femoral head with a so-called hemiendoprosthesis without replacing the cup. In this case, a (usually modular) head which has the size of the natural femoral head is attached to the endoprosthetic stem. Special procedures such as surface replacements are of minor relevance for hip joints (Claes et al. 2012).

Parts of the knee joint or the joint surface are replaced by bowl-shaped implants on the femoral side and a tibial baseplate, which can be fixated into the medullary cavity with or without a stem. The bearing surface between the femur and the tibia can be connected with the baseplate or be mobile and gliding. The back of the patella may be replaced with an implant (Wirtz 2011).

The contact surface between the bone and implant is of great importance for weight bearing on the joint after surgery. This connection technique is generally referred to as fixation. An implant can be fixated with or without bone cement – combined solutions are termed hybrid fixation or partial cementation. The applied bone cement is a special artificial cement (polymethylmethacrylate). Uncemented endoprosthesis components can have a special surface design or coating (e.g. titanium specifications or hydroxylapatite) in order to support secondary bone ingrowth. Primary stable fixation is achieved by fixing the endoprosthesis to the bone (so-called press-fit) (Claes et al. 2012; Wirtz 2011) with the aim of permanently attaching the endoprosthesis to the bone bed. Opinions on the advantages and disadvantages of cemented and uncemented fixation vary and the choice of procedure depends on different factors (such as age and bone quality) (see Section 1.3.3) (Claes et al. 2012, Wirtz 2011).

1.3.2 Surgery

Prior to surgery the physician informs the patient of any possible complications and risks. Specific treatment planning includes selecting the appropriate endoprosthesis based on clinical and radiological criteria as well as deciding on the surgical access route (■ Fig. 1.3).

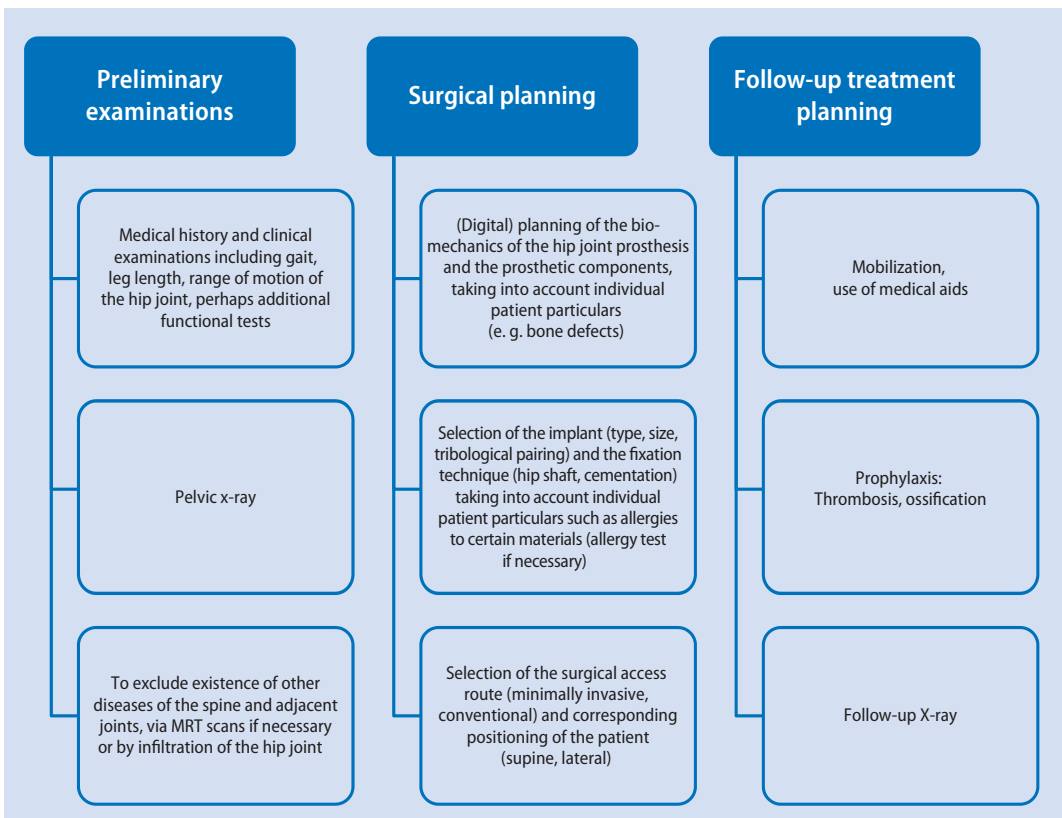
In hip arthroplasty, the natural structures of the pelvis and the upper leg are usually replaced, i.e. the acetabulum in the pelvis and part of the femoral shaft as well as the femoral head in the upper leg. When all these structures are replaced, the procedure is referred to as total replacement or total arthroplasty. Total arthroplasty also includes short stem femoral head prostheses, which are usually used in younger patients, as well as surface replacement prostheses.

If the acetabular cup does not need replacing, the procedure is termed as partial replacement,

hemiarthroplasty or partial arthroplasty. An example of this is the dual head prosthesis, which is particularly used in cases of femoral neck fractures in elderly patients (Claes et al. 2012).

The accuracy of the endoprosthetic fit is tested regularly by means of a trial prosthesis while the joint is being surgically prepared. The surgeon must ensure that there is enough tension on the ligaments and the soft tissue for the artificial joint to glide and to avoid dislocation. The implantation of the actual endoprosthesis is performed either with or without bone cement. Subsequently, the surgical access route is closed. The position of the endoprosthesis is checked by x-ray immediately after surgery (Claes et al. 2012).

Special care must be taken when positioning the patient during arthroplasty. Cushioning materials are used to prevent pressure points on the patient and warming systems are used to prevent hypother-



■ Fig. 1.3 Elements of treatment planning based on hip arthroplasty. (IGES – Wilken et al. 2014)

1 mia. The patient can be placed in a lateral or supine position. It is important to accurately secure the patient in the selected position with the help of props and straps in order to avoid any changes in position during the surgery (Claes et al. 2012).

In knee arthroplasty, parts of the upper leg (distal femur) and the lower leg (proximal tibia) are replaced with artificial material. Different types of implants are used depending on the nature and severity of the underlying disease. Structures that are usually replaced include portions of the femoral bone (femoral component) to substitute the defective condyle as well as parts of the lower leg around the tibial plateau (tibial component) and the menisci. The patella may or may not be replaced. A synthetic component is placed on the tibial component in order to minimize friction between the tibial and femoral components (»inlay«) (Wirtz 2011).

Unicondylar surface replacement, i.e. on one side of the joint only, is possible if knee function is not yet severely impaired by cartilage abrasion and the bone is affected on only one side of the knee joint. Usually, the medial (inner) side is replaced. Besides the structure of the cartilage and bone, the condition of the ligaments is also crucial to decision making. Unilateral surface replacement is often termed unicompartamental knee replacement using a unicondylar sled prosthesis that may also be referred to as sled prosthesis or mono-sled (Wirtz 2012).

Bicondylar and hinge prostheses are used for total knee arthroplasty. Here, the degree of coupling is an important distinguishing factor. Hinge prostheses are axially supported. Usually, this type of prosthesis is selected if the ligamentous apparatus is severely impaired because the hinge significantly restricts mobility. However, surface replacement prostheses without coupling or with partial coupling are used more frequently. A prerequisite for using these types of endoprosthesis is sufficient functionality of the patient's ligamentous apparatus. The artificial knee is often fixated with bone cement, but uncemented or hybrid fixation is also feasible (Wirtz 2011).

Positioning during knee arthroplasty is designed to allow frequent changes in position of the leg as specific steps during treatment require the extremities to be mobile. Therefore, rolls and special leg

holders are used allowing the leg to be positioned in an upright 90 degree position (Wirtz 2011).

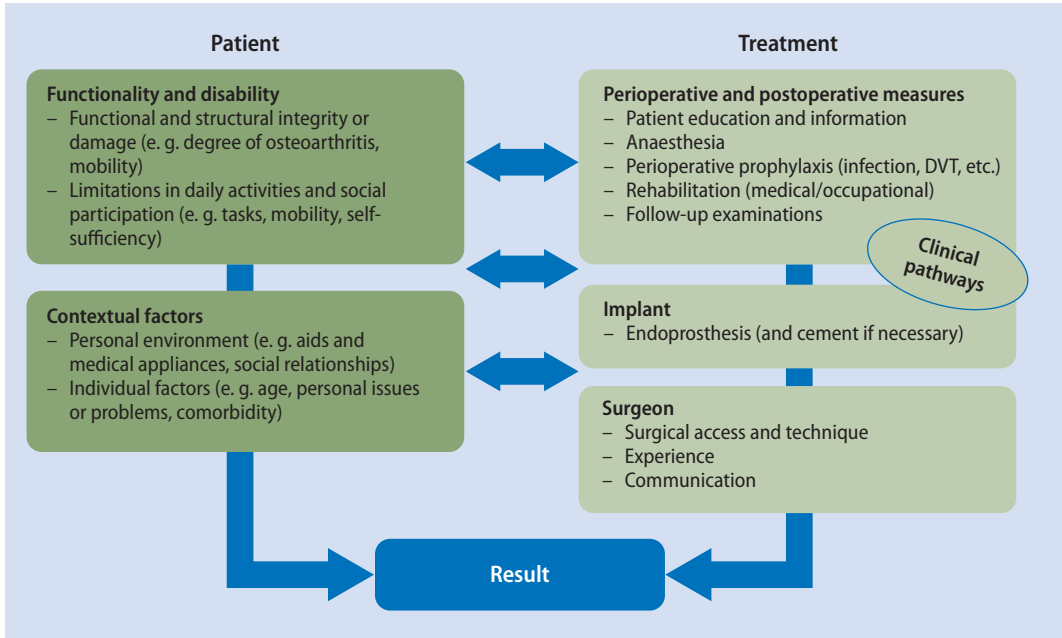
Numerous studies on various surgical access routes for both the hip and the knee joint exist. However, no significant advantage in any one of the particular procedures has been shown. Less invasive access routes have been advocated in recent years, as they reduce the extent of tissue incision. However, actual clinical effectiveness is a matter of debate and they may also bear a higher risk of complications. In hip revision surgery, for instance, the initial access route used during primary surgery is often used again. Additionally, these procedures require more extensive imaging of tissue and bone structures (Claes et al. 2012; Wirtz 2011).

■ Anesthesia

Two anesthetic techniques can be used for both endoprosthesis hip and knee surgery: general anesthesia and regional anesthesia. General anesthesia requires artificial ventilation and is based on anxiolysis, analgesia, muscle relaxation and sedation. Under certain circumstances, regional anesthesia, in which the patient is conscious, may also be used in the form of spinal anesthesia or by blocking peripheral nerves or regions with a single injection or by continuous application by means of a catheter. General and regional anesthesia can be used alone or in combination. Anesthesia aims to allow for pain-free surgery, rapid mobilization after surgery and as much pain reduction as possible in the early rehabilitation phase (Claes et al. 2012, Wirtz 2011).

1.3.3 Factors Influencing Treatment Success and Complications

A number of factors can influence the success of joint replacement treatment (■ Fig. 1.4). Besides the design of the implant and surgical procedure, a patient's individual characteristics can impact total hip and knee arthroplasty outcomes. These characteristics include age, sex, degree of preoperative osteoarthritis and functional status of the joint in question. Additionally, concomitant diseases (particularly obesity, cardiovascular diseases, diabetes mellitus and immune system disorders) can lead to perioperative and postoperative complications.



■ Fig. 1.4 Factors influencing treatment success. (IGES – Günther et al. 2015)

Social deprivation, personality traits and patient expectations with regard to the surgery also play an influencing role (Günther et al. 2015; Schäfer et al. 2010). Patient compliance, i.e. the degree to which a patient correctly follows medical advice with regard to daily care of the joint, constitutes a further important factor in the success of joint replacement.

Optimal presurgical planning is important, including investigation into risk factors of a patient that are potentially modifiable. Well-planned post-operative rehabilitation treatment (ambulatory or inpatient rehabilitation) contributes to treatment success (Claes et al. 2012; Wirtz 2011) and plays an important role in attaining longer service life of an implant, high patient satisfaction and cost-effectiveness (Krummenauer et al. 2008; Krummenauer et al. 2006).

Arthroplasty procedures are associated with potential risks caused by surgical and anesthetic procedures in general or with the insertion of the implant itself. Joint replacement can involve the following major risks (Anonymous, Günther et al. 2015):

- Inflammation and suppuration (periprosthetic infection): Artificial joint replacements are always associated with an increased risk of in-

flammation (infection) because pathogens (bacteria) that enter the body or that already exist therein tend to accumulate on the surface of foreign bodies. Once a certain number of bacteria have accumulated, pus may begin to develop around the implant. These infections can occur shortly after the operation («early infection») or later («late infection»). The risk of infection can vary between different patient groups. Patients with diseases associated with a weakened immune system in particular bear a higher risk of infection. These diseases include diabetes mellitus and rheumatic diseases. Moreover, patients who have a focus of infection in other parts of the body or who suffer from obesity have a higher risk of infection. The risk of infection is reduced through the administration of antibiotics during surgery.

- Blood clots (thrombosis and embolism): The formation of blood clots constitutes a general risk in surgery of the knee and hip joints. Antithrombotic drugs are recommended for the prevention of thrombosis.
- Nerve damage: During surgery, inadvertent damage to the nerves may occur through phy-

sical manipulation such as pressure or tension in the regions concerned. Regional anesthesia may also cause nerve damage. Congenital hip dislocation also constitutes a risk factor as the leg may become over extended during hip joint surgery.

- Injury of blood vessels and postoperative bleeding: Surgery on the hip or knee joint is generally associated with the risk of injury to blood vessels close to the joint. Moreover, despite adequate hemostasis, postoperative bleeding may occur due to antithrombotic therapy.
- Leg length inequality and dislocations constitute specific risks during hip joint replacement: When hip joints are replaced, the aim is to achieve equal leg lengths. However, the operation may lead to a lengthening and sometimes even a shortening of the affected leg. In addition, there is a risk of dislocation subsequent to surgery as on the one hand, the implant is not an identical copy of the joint and on the other hand, the surgical procedure involves opening and partially removing the stabilizing joint capsule.
- Fractures: Necessary pressure exerted during the course of this type of surgery may cause fractures in rare occasions. The risk of fractures is higher for in uncemented fixation as this requires higher pressure during insertion.
- Calcification in the tissue near the prosthesis: During the first few months following surgery, calcification may occur within the surgical wounds which can lead to reduced mobility and pain. Administration of anti-inflammatory drugs for two weeks after surgery is recommended in order to prevent this. Alternatively, irradiation of the affected region is possible.
- Loosening of the prosthesis and material wear: It is rare for the prosthesis not to have successful bone ingrowth. If the case should arise,

early replacement of the prosthesis becomes necessary due to loose fit. Particulate wear debris may be released during the course of prosthesis use, which can contribute to loosening of the implant. However, given the quality of materials currently in use there is only a slight risk of such an abrasion occurring and hence individual prosthesis components rarely break for this reason. However, if they do break, it is usually due to loosening of the prosthesis.

- Allergies: Even though it is still currently unclear if allergies to parts of the prosthesis increase the risk of complications, specific materials in the prosthesis should be avoided should a patient be allergic to them. About 10 % of the population is allergic to nickel, for example.
- Persisting complaints: Besides the complications described, bursitis or tendonitis, for example, may cause persisting complaints following surgery. This, however, has been observed in comparatively few patients.

Repeat surgery or revision replacement may become necessary due to complications. Replacing an implant is considerably more complicated than the primary replacement (primary arthroplasty) as the surgeon has to deal with less bone substance therefore increasing the likelihood of fractures and other complications. A patient may also have to undergo revision surgery in which the prosthesis is not replaced or in which only a component is added to the existing endoprosthesis (renewed operation with addition). These revisions are usually performed on the hip and knee to replace the bearing surfaces and to manage recurring hip dislocations. However, dislocations may also necessitate the replacement of an implant should this occur repeatedly (Claes et al. 2012; Wirtz 2011).

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Prevalence of Hip and Knee Arthroplasty

Florian Rothbauer, Ute Zerwes, Hans-Holger Bleß, Miriam Kip

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Summary

The annual rate of primary hip and knee arthroplasty has not increased since 2007. In the 70 years plus age group, the rate of primary hip arthroplasty was 1.1 % (in both 2007 and 2014) and the rate of primary knee arthroplasty was 0.7 % in 2007 and 0.6 % in 2014.

In 2014, the prevalence of surgery in relation to the entire population was 0.26 % for the hip and 0.19 % for the knee. Approximately 219,000 primary hip replacements and 149,000 primary knee replacements were documented in Germany in 2014. The most common procedure performed on a joint was total replacement. Approximately 40 % of all primary hip or knee replacements are performed in patients in the 70 to 79 year age group; women are more frequently affected than men (ratio 2:1). In 2014, the absolute number of revisions (including revisions without replacements) amounted to approximately 30,000 for the hip and 20,000 for the knee. The number of revisions performed in any given year is not necessarily directly related to the number of primary replacements performed in the same year. Instead, the number of revisions should be considered in relation to the cumulative number of primary replacements performed over the past years and decades. As with primary arthroplasty, approximately 40 % of the revisions are performed on patients in the 70 to 79 years age group. However, the difference between men and women is less pronounced.

Between 2007 and 2014, the rate of hip and knee revision replacements (including revision without replacements) also remained stable. In 2014, in the 70 years plus age group, the rate of revision replacements (including revision without replacements) was 0.19 % for the hip and 0.10 % for the knee. The annual utilization rate of primary hip and knee arthroplasty varies internationally. Regional differences also exist within Germany itself, as evaluations conducted by the statutory health insurances for the period from 2005 to 2011 have shown. A comparatively low utilization rate was associated in particular with low incidences of osteoarthritis, low social status, a high number of regional specialist physicians (orthopedists) and patients living in urban areas.

Hip and knee arthroplasty constitute effective treatments for patients with substantial (or impending) permanently restricted joint function due to joint

destruction or pain which can no longer be treated otherwise. They are also used to treat fractures near the joint. The different types of arthroplasty procedures aim to restore good joint function, weight-bearing capacity and quality of life. The prevalence (utilization) of arthroplasty is an important aspect for planning ambulatory and inpatient care, as well as for estimating demands and subsequent demands such as rehabilitation measures and questions with regard to resource allocation. The following chapter presents the utilization hip and knee arthroplasty services in Germany and differentiates these according to age and gender, type of procedure and fixation technique. The presentation distinguishes between primary and revision arthroplasty. Furthermore, this chapter investigates regional differences in distribution of these medical care services and in temporal developments with regard to their utilization in Germany and compares these internationally.

2.1 Database

The German procedure classification »Operationen- und Prozedurenschlüssel (OPS)« enables detailed observations of the annual inpatient primary and revision hip and knee replacements performed in Germany. In the German healthcare system, the OPS is primarily used for administrative purposes to identify the services rendered to inpatients.

Bone and joint replacements are classified in Section 5-82 of the OPS (■ Tab. 2.1). The coding system allows for reliable distinctions to be made between primary arthroplasty, revision, revision total arthroplasty and the removal of hip joints (5-820/5-821) and knee joints (5-822/5-823). In addition, age and sex of patients are specified. OPS 5-820 and 5-822 document primary endoprosthetic care (primary arthroplasty) for hip and knee joints respectively. OPS 5-821 and 5-823 and further differentiated sub-codes refer to revision surgery, i.e. revision total arthroplasty and revisions (follow-up surgery and re-revisions) on joints that have already undergone previous endoprosthetic surgery.

■ Tab. 2.1 OPS classification

OPS	description	OPS	description
Hip: Primary arthroplasty			
5-820.0	Total arthroplasty	5-820.2	Total arthroplasty, custom-made prosthesis
5-820.3	Femoral head prosthesis	5-820.4	Dual head prosthesis
5-820.5	Acetabular support cup	5-820.7	Acetabular liner locking cup
5-820.8	Surface replacement	5-820.9	Short-stem femoral head prosthesis
5-820.x	Other	5-820.y	Unspecified
Hip: Revision total arthroplasty and revision			
5-821.0	Revision (without replacement)	5-821.1	Femoral head prosthesis replacement
5-821.2	Acetabular cup replacement	5-821.3	Revision cemented total arthroplasty
5-821.4	Revision uncemented total arthroplasty	5-821.5	Revision total arthroplasty, hybrid endo-prosthesis
5-821.6	Revision total arthroplasty, custom-made prosthesis	5-821.7	Total endoprosthesis removal
5-821.8	Femoral head prosthesis removal	5-821.9	Dual head prosthesis removal
5-821.a	Femoral head cap removal	5-821.b	Acetabular cup removal
5-821.c	Acetabular support cup removal	5-821.d	Acetabular liner locking cup removal
5-821.e	Total endoprosthesis removal, custom-made prosthesis	5-821.f	Dual head prosthesis replacement
5-821.g	Surface prosthesis replacement	5-821.h	Surface prosthesis removal
5-821.j	Femoral neck preserving femoral head prosthesis (short-stem femoral head prosthesis) replacement	5-821.k	Femoral neck preserving femoral head prosthesis (short-stem femoral head prosthesis) removal
5-821.x	Other	5-821.y	Unspecified
Knee: Primary arthroplasty			
5-822.0	Unicondylar sledge prosthesis	5-822.1	Bicondylar surface prosthesis, unconstrained, without patella replacement
5-822.2	Bicondylar surface prosthesis, unconstrained, with patella replacement	5-822.3	Bicondylar surface replacement prosthesis, partially constrained, with patella replacement
5-822.4	Bicondylar surface prosthesis, partially constrained, without patella replacement	5-822.6	Hinged endoprosthesis, without patella replacement
5-822.7	Hinged endoprosthesis, with patella replacement	5-822.8	Patella replacement
5-822.9	Custom-made prosthesis	5-822.a	Endoprosthesis with enhanced flexion, without patella replacement
5-822.b	Endoprosthesis with enhanced flexion, with patella replacement	5-822.c	Interpositional non-anchored implant
5-822.d	Bicompartmental replacement, without patella replacement	5-822.e	Bicompartmental replacement, with patella replacement

Tab. 2.1 OPS classification

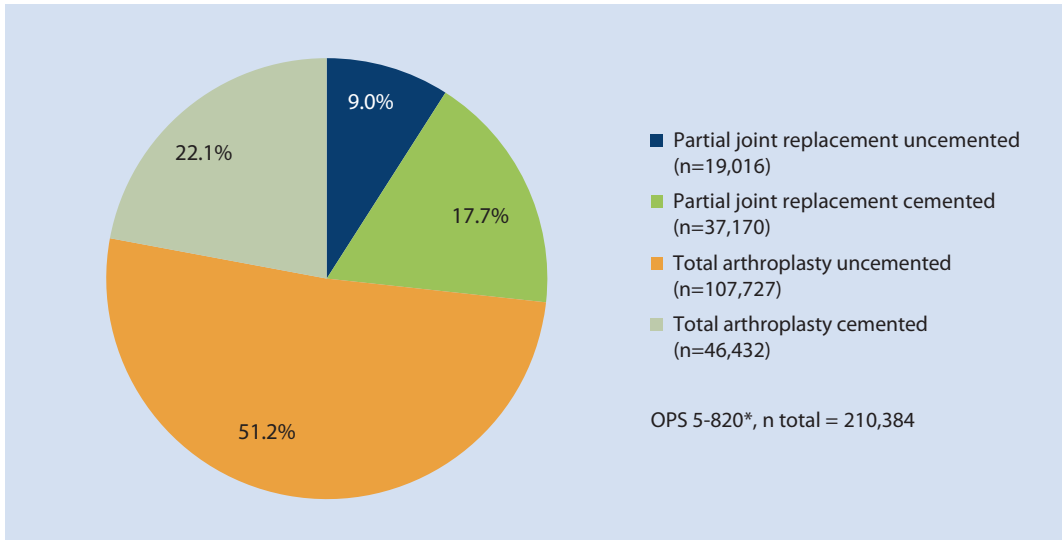
OPS	description	OPS	description
5-822.f	Implantation of an endoprosthesis joint without movement function 5-822.x	5-822.x	Other
5-822.y	Unspecified		
Knee: Revision and replacement operation			
5-823.0	Revision (without replacement)	5-832.1	Unicondylar sledge prosthesis replacement
5-823.2	Bicondylar sledge prosthesis replacement	5-823.3	Hinged endoprosthesis replacement
5-823.4	Custom-made prosthesis replacement	5-823.5	Patella prosthesis replacement
5-823.6	Unicondylar sledge prosthesis removal	5-823.7	Bicondylar surface prosthesis removal
5-823.8	Hinged endoprosthesis removal	5-823.9	Patella prosthesis replacement
5-823.a	Custom-made prosthesis removal	5-823.b	Replacement of an endoprosthesis with enhanced flexion
5-823.c	Replacement of an interpositional non-anchored implant	5-823.d	Removal of an endoprosthesis with enhanced flexion
5-823.e	Removal of an interpositional non-anchored implant	5-823.f	Bicompartmental prosthesis replacement
5-823.g	Bicompartmental prosthesis removal	5-823.h	Replacement of endoprosthesis joint without movement function
5-823.j	Removal of an endoprosthesis joint without movement function	5-823.x	Other
5-823.y	Unspecified		

Source: IGES – DIMDI (2015)

The German Federal Statistical Office (Statistisches Bundesamt) makes OPS data publicly available as is stipulated by § 21 of the German Hospital Remuneration Act. Only case-based and not patient-based data can be accessed. Consequently, the number of cases does not (necessarily) correspond to the number of patients. Two-stage surgery is documented as two separate cases and subsequently individual patients may be counted multiple times.

The Federal Statistical Office dataset does not permit statistical evaluations of the surgical access, endoprosthesis material or of whether the surgery was planned or had to be performed as an emergency. Determining the durability of the endoprostheses (service life) is also not possible as no connection can be made between the actual implantation and prosthesis removal for individual pa-

tients. The Federal Statistical Office dataset also does not portray connections to underlying indications (osteoarthritis, fractures and other causes). Although hospitals report connections between diagnoses and procedures to the respective health insurances and the German Institute for Hospital Reimbursement (InEK), combining this data publicly is not possible. Moreover, further clinical parameters required for describing indications such as pain, joint function or quality of life are not depicted. Connections with indications and procedures, for example, will be made possible in the future through the German joint replacement registry »Endoprothesenregister Deutschland (EPRD)« (► Chapter 4). As the risk of having to undergo joint replacement is not uniformly spread across all population and age groups, reliable statements about



■ Fig. 2.1 Distribution of hip joint arthroplasty utilization (n = 210,384) (OPS 5-820.*) by total and partial replacement and fixation technique (2013). (IGES – Federal Statistical Office 2014)

the differences in prevalence (for example, in regional and international comparisons) can only be made after adjusting or standardising the respective databases for influencing characteristics such as age or sex. Regional evaluations of health insurance data (for example by Schäfer et al. 2013; Lüring et al. 2013) usually report prevalence rates that are standardized to population structures. Furthermore, consistent survey methods should be employed to ensure good reliability for making comparisons. Presentations of patient-related OECD data that internationally compare prevalences of endoprosthetic hip and knee surgery usually do not take these aspects into sufficient consideration (► Chapter 6).

2.2 Utilization of Primary Arthroplasty

According to data from the Federal Statistical Office, a total of 219,325 primary hip arthroplasties were performed in 2014 and 210,384 in 2013 (absolute numbers). Out of the 210,384 primary hip arthroplasties performed in 2013, 154,159 (73.3 %) were total arthroplasties (THA) and 56,225 (26.7 %) were partial arthroplasties. 60.2 % (126,743 cases) of all hip endoprostheses were implanted without ce-

ment (Federal Statistical Office 2014) (■ Fig. 2.1). In 2014, the rate of surgery in the general population (as determined on 31 December 2014) was 0.26 % (own calculation, Federal Statistical Office 2014, Federal Statistical Office 2015).

The absolute number of primary knee arthroplasties was 149,126 in 2014 and 143,024 in 2013. 84 % of the 143,024 primary knee arthroplasties performed in 2013 were bicondylar replacements (■ Fig. 2.2). The rate of knee replacement surgery in the total population (as determined on 31 December 2014) was 0.19 % in 2014 (own calculation, Federal Statistical Office 2014, Federal Statistical Office 2015). In contrast to primary hip arthroplasty, the majority of primary knee arthroplasties (79.6 %) were fixated with cement. Entirely uncemented fixation was documented in 10.5 % of all operations and hybrid/partially cemented fixation was documented in 9.6 % of the primary replacements (Federal Statistical Office 2014).

In the age group of over 60-year-olds, well over 65 % of primary hip or knee replacements were performed in women (Federal Statistical Office 2014). A higher proportion of female hip and knee arthroplasty patients has also been well documented elsewhere (Braun 2013; Lüring et al. 2013). The higher percentage of female patients is due to the higher

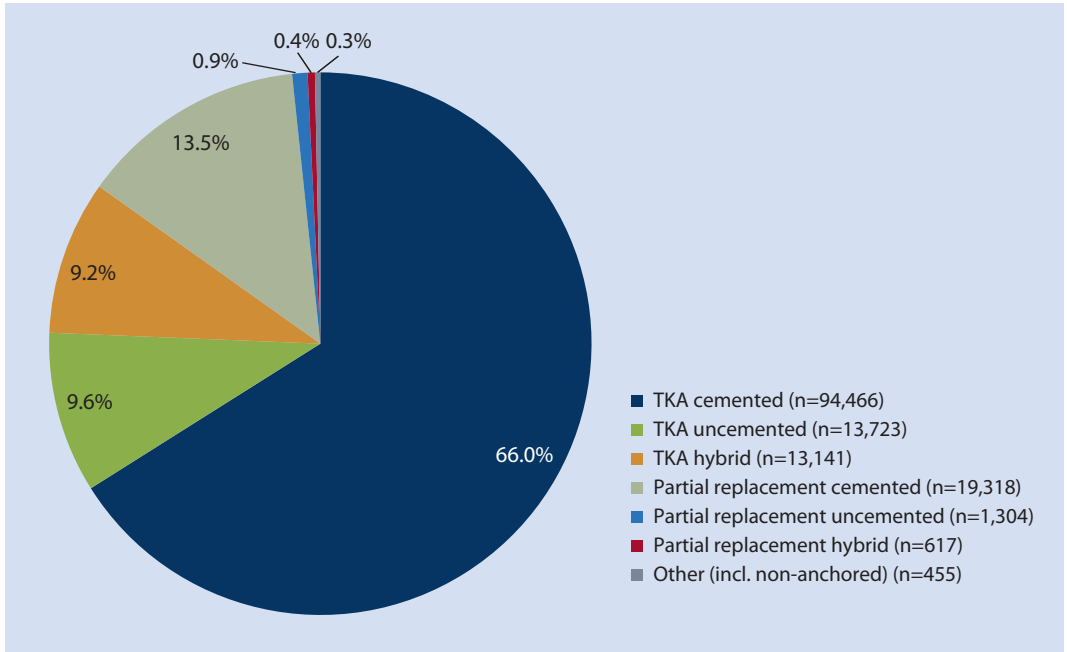


Fig. 2.2 Distribution of primary knee arthroplasty utilization (absolute number, n = 143,024) (OPS 5-822.*) by total and partial replacement and fixation technique (2013). (IGES – Federal Statistical Office 2014)

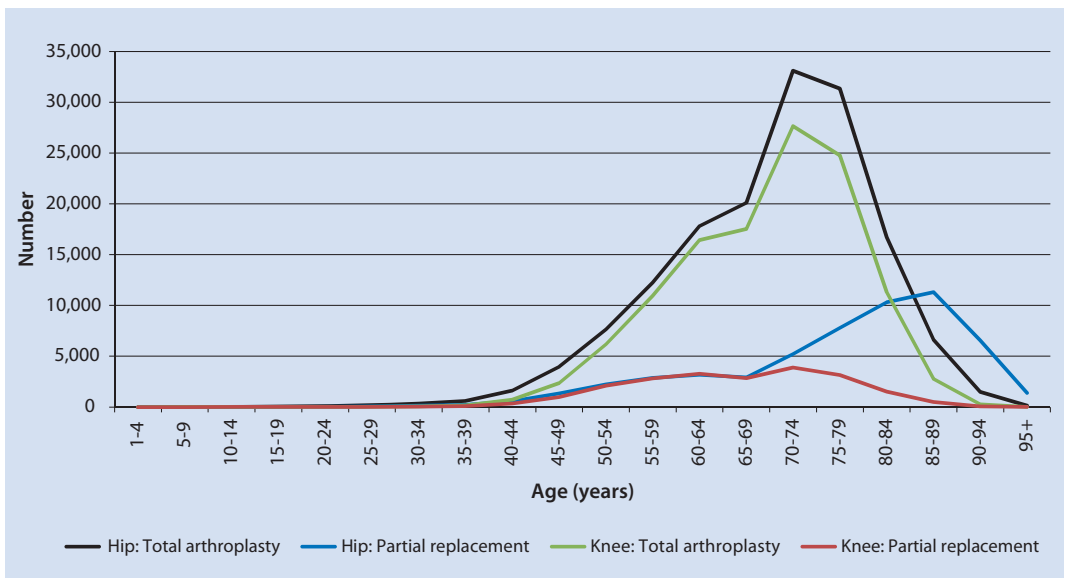


Fig. 2.3 Utilization (absolute number) of primary hip and knee arthroplasty by total and partial replacement and age group (2013). (IGES – Federal Statistical Office 2014)

2.3 · Utilization of Revision Total Arthroplasty and Revision Surgery

prevalence of osteoarthritis in women (most common indication for hip or knee arthroplasty) in addition to a significantly longer life expectancy for women (Rabenberg 2013).

Primary surgery is clearly associated with patient age: Approximately 40 % of all primary hip or knee replacements documented in Germany are performed in the 70 to 79 year age group (■ Fig. 2.3). In 2013, the average age at the time of the primary total hip or knee arthroplasty was 69.7 and 69.2 years respectively. Patients who underwent partial knee replacement were slightly younger on average (mean age 65.8 years). In contrast, the highest number of patients who underwent partial hip replacement was observed in the 85 to 89 year age group. This age group has more documented cases of primary partial hip replacements than of total hip replacements. This is primarily due to the high prevalence of femoral neck fractures which occur particularly often in this age group and are predominantly treated with partial replacements (Section 1.2.1 and Section 1.2.2) (■ Fig. 2.3) (Federal Statistical Office 2014).

There is also a link between patient age and the employed fixation technique: The proportion of cemented total hip arthroplasties (THA) increases with age in comparison to uncemented THA (Federal Statistical Office 2014).

2.3 Utilization of Revision Total Arthroplasty and Revision Surgery

According to the Federal Statistical Office, a total of 35,133 revision hip arthroplasties were performed in 2014 and a total of 31,067 revision hip arthroplasties and 21,678 revision knee arthroplasties were performed in 2013 (including revisions without replacements) (absolute numbers). In 2014, this corresponded to a prevalence of surgery of 0.04 % (hip) and 0.06 % (knee) respectively in the general population (as determined on 31 December 2014) (own calculation, Federal Statistical Office 2014, Federal Statistical Office 2015). 3,784 cases and 3,213 cases were revisions without component replacements on the hip and the knee respectively. Accordingly, revisions without replacements accounted for approximately 12 % and 16 % of all documented hip and

■ **Tab. 2.2** Utilization (absolute number) of revision total replacements and revisions on the hip and knee (2013)

Description	Prevalence	
	n	%
Hip joint		
Total arthroplasty		
Revision total arthroplasty (uncemented)	4,537	14.6
Revision total arthroplasty (cemented)	2,325	7.5
Revision total arthroplasty (partially cemented)	871	2.8
Custom-made prosthesis replacement	837	2.7
Partial replacement		
Acetabular cup component replacement	12,473	40.1
Femoral head prosthesis replacement	4,859	15.6
Dual head prosthesis replacement	941	3.0
Surface prosthesis replacement	221	0.7
Femoral neck preserving femoral head prosthesis replacement	219	0.7
Revision (without replacement)	3,784	12.2
Revision total arthroplasty and revisions, total	31,067	100
Knee	n	%
Bicondylar surface prosthesis	11,290	55.4
Unicondylar sledge prosthesis replacement	2,317	11.4
Hinged endoprosthesis replacement	1,222	6.0
Endoprosthesis with enhanced flexion replacement	699	3.4
Custom-made prosthesis replacement	533	2.6
Bicompartmental prosthesis replacement	459	2.3
Patella replacement	439	2.2
Other	212	1.0
Revision (without replacement)	3,213	15.8
Total	20,384	100

Source: IGES – Federal Statistical Office (2014)

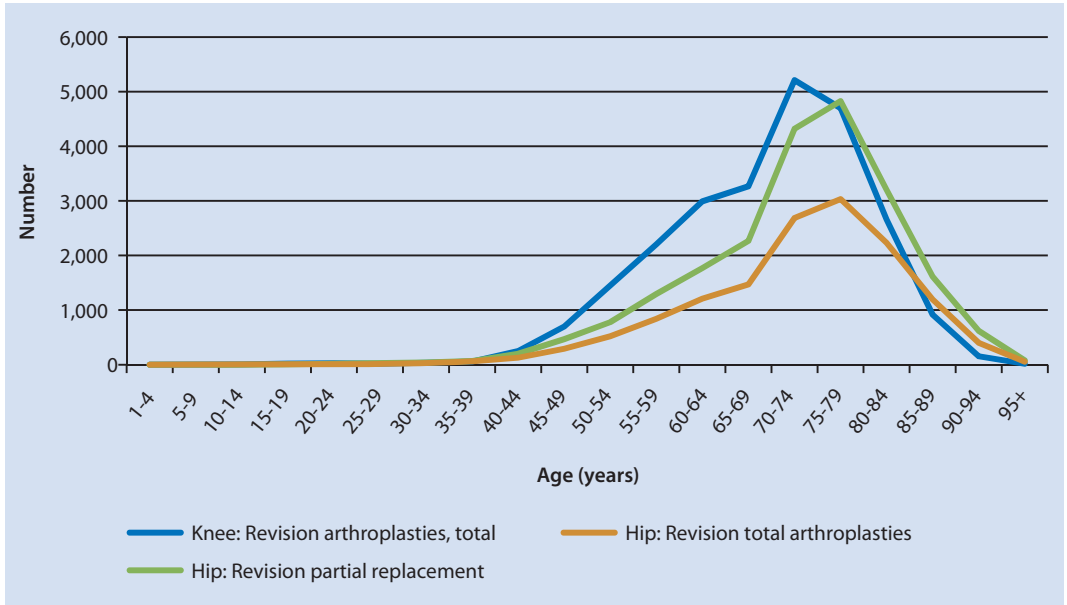


Fig. 2.4 Utilization of revision arthroplasty (absolute number) including revisions without replacements by type and age group (2013). (Source: IGES – Federal Statistical Office 2014)

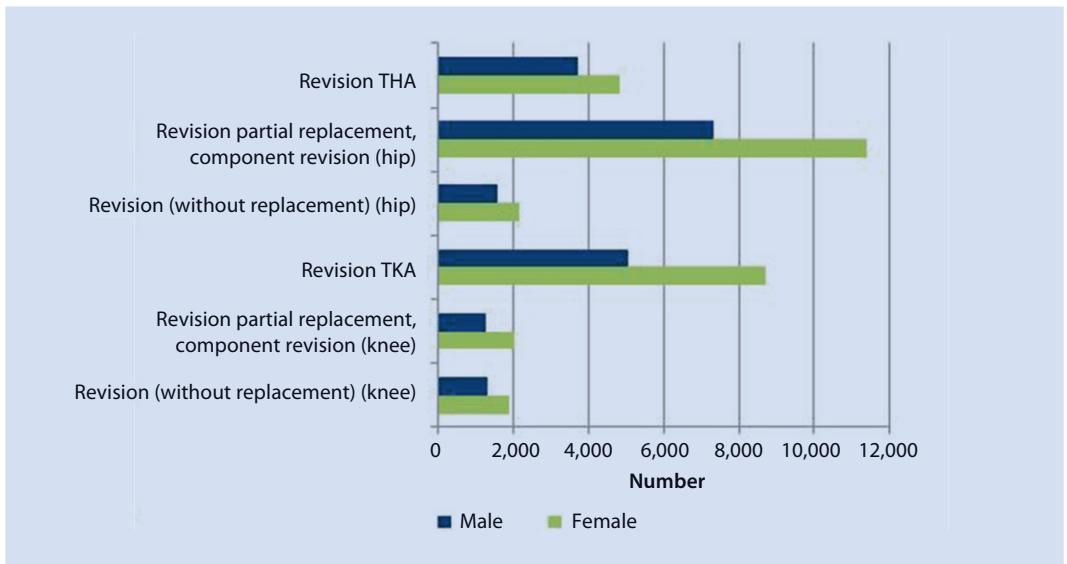


Fig. 2.5 Utilization (absolute number) of joint replacement procedures on the hip and knee by type of revision replacement (including revisions without replacements) and by sex (2013). (Source: IGES – Federal Statistical Office 2014)

knee replacements respectively which were conducted in one year (2013). Replacements of acetabular cup components (partial replacement) or of bicondylar surface prostheses were the most common revision replacements performed on the hip and the knee respectively (■ Tab. 2.2) (Federal Statistical Office 2014).

In 2013, the highest number of revision total arthroplasties and revisions (partial replacements) were performed in the 75 to 79 year age group. 40 % of all revision total arthroplasties and revisions on the hip and knee were performed in the 70 to 79 year age group. In 2013, the average age of patients who underwent revision total arthroplasty and other revision surgery on the hip was 72.5 years and 69 years for those who underwent revision total arthroplasty and other revision surgery on the knee. These average ages are slightly higher than the average ages of patients who undergo primary surgery (■ Fig. 2.4) (Federal Statistical Office 2014).

As with primary arthroplasty, the absolute number of revision total arthroplasties and revisions is higher in women than in men. Considering that the absolute number of primary replacements in men is markedly lower than in women, men undergo comparatively more revisions and revision total replacements (■ Fig. 2.5).

However, a direct link between the number of revision total replacements and primary replacements in a certain year cannot be ascertained. The number of revision total replacements should be considered in relation to the cumulative number of primary replacements performed over the past years and decades because endoprostheses have long mean service lives. ► Chapter 6 presents expert opinions on the different aspects of evaluating the prevalence of revision replacements (including revisions without replacements).

2.4 Regional Distribution

The regional distribution of hip and knee arthroplasty across the German federal states and districts was evaluated by Schäfer et al. based on accounting data (secondary data) of patients insured with the statutory health insurance AOK. This included 24 million insurees from the years 2005 to 2009. The

authors calculated age-standardized surgery rates (primary hip or knee arthroplasty per 100,000 insurees per year). Only total arthroplasties were taken into account. Age-standardized rates (European standard) were calculated in order to minimize distortions arising from demographic differences between the regions and to enable comparisons between regions and other studies (Schäfer et al. 2013).

In 2009, a total of 148 primary hip replacements and 132 primary knee replacements per 100,000 AOK insurees was performed. Marked differences were observed at federal state levels: The lowest rate of hip replacements was documented in Berlin with 120 operations and the highest in Lower Saxony with 168, corresponding to a difference of approximately 40 % (■ Fig. 2.6). The rate of knee replacements showed equally distinct regional variations at federal state level (78.4 %): The lowest rate of replacement was again observed in Berlin (90) and the highest number of primary TKAs in the study population was observed in Bavaria (160). Upon solely evaluating federal area states and excluding federal city states, the lowest rates of hip replacements can be observed in Saxony-Anhalt (143) and the lowest rate of knee replacements in Mecklenburg-Western Pomerania (109). The highest are observed in Bavaria, Lower-Saxony and Schleswig-Holstein and Thuringia (Schäfer et al. 2013).

The AOK evaluation also demonstrated major differences at district levels. The lowest hip arthroplasty rate (average value for the period between 2005 and 2009) was 106 cases (in the district Neustadt an der Weinstraße) and the highest rate was 216 cases per 100,000 insurees (in the district Neustadt an der Aisch). The regional differences for TKA were also higher than for hip procedures at district levels (Schäfer et al. 2013).

The German Society for Orthopaedics and Trauma (DGOU) published a report on behalf of the foundation »Bertelsmann Stiftung« describing the regional differences and influencing factors on knee arthroplasty. This report also describes distinct regional differences for knee arthroplasty procedures (■ Fig. 2.7). The evaluation was also based on accounting data from AOK insurees but these were obtained from the period between 2005 and 2011. This investigation also found that in 2011, age-standardized utilization of knee replacement

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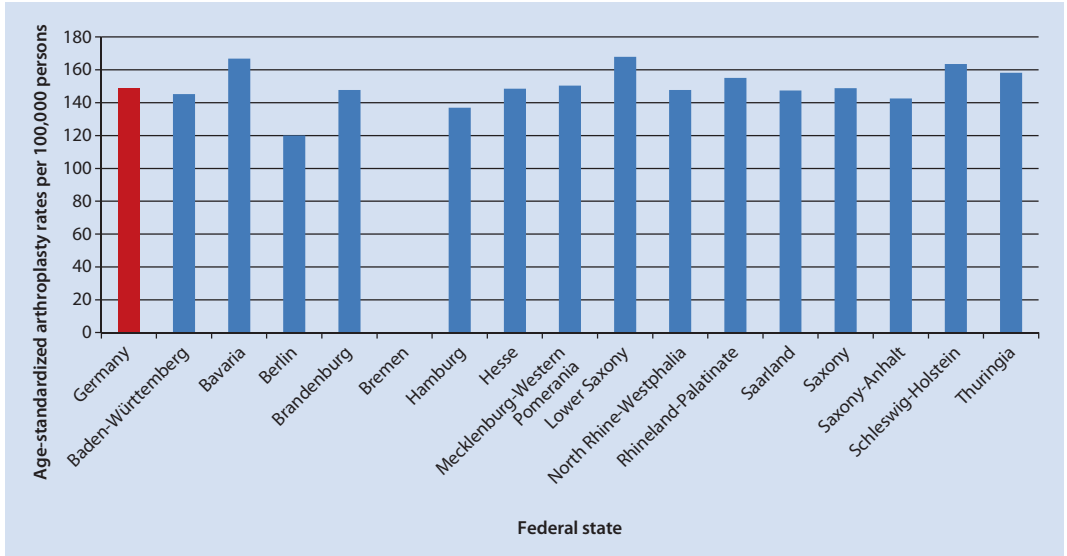


Fig. 2.6 Age-standardized primary hip arthroplasty rates per 100,000 AOK insurees in 2009. (Source: IGES – Schäfer et al. 2013)

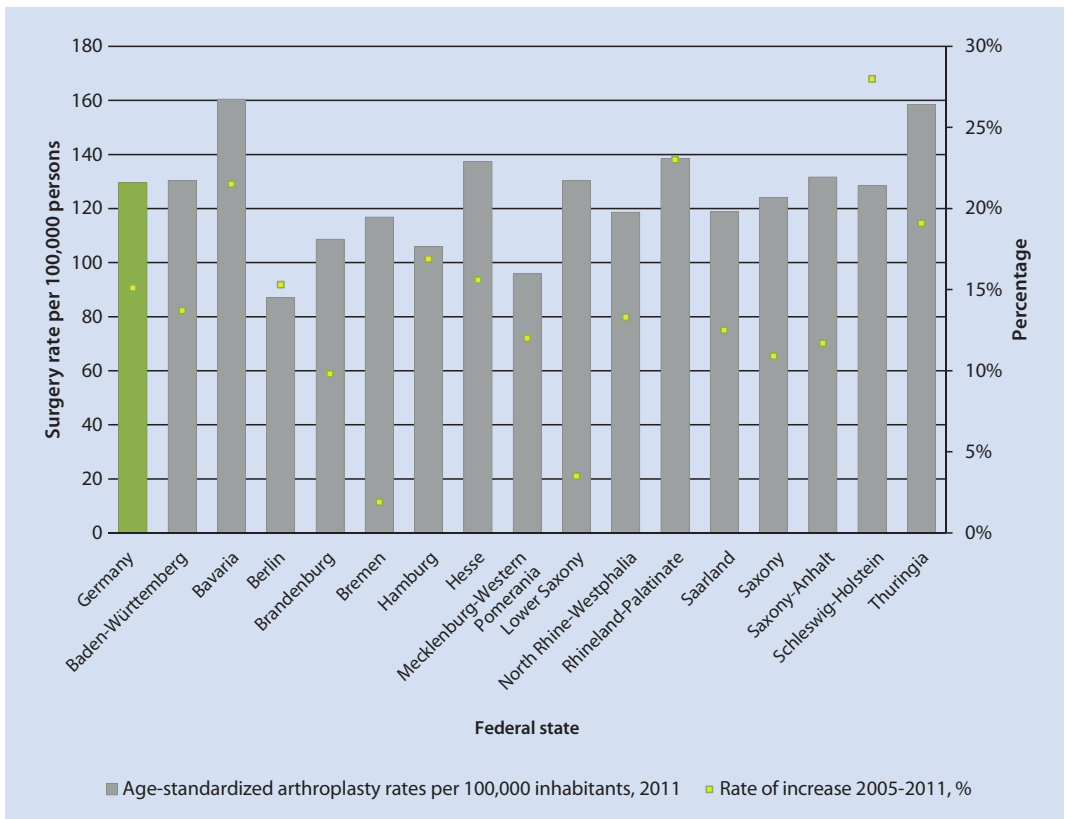
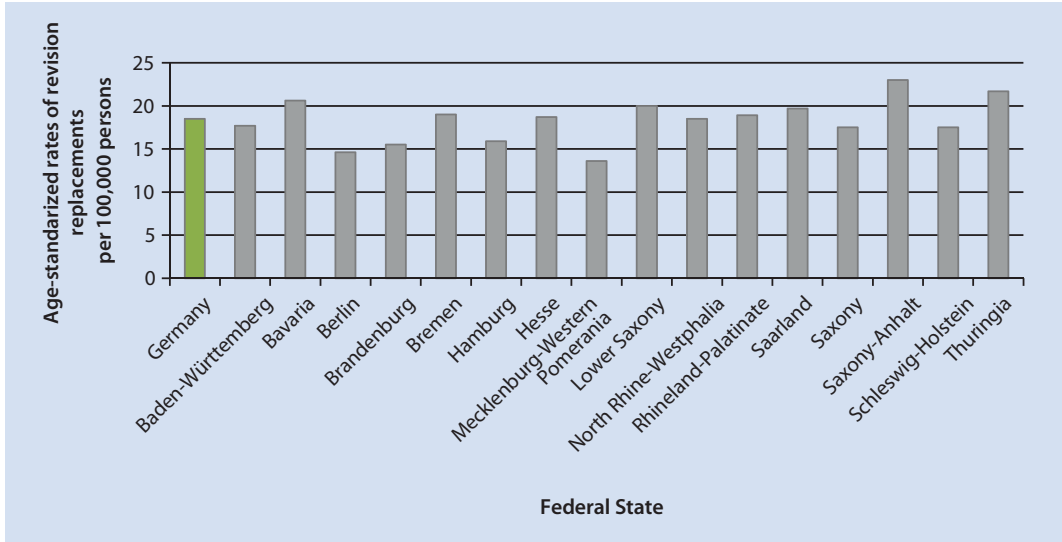


Fig. 2.7 Age-standardized primary knee arthroplasty rates per 100,000 AOK insurees in 2011, by federal state (patient domicile) and as a national average in Germany, with increases of arthroplasty rates, 2005-2011. (Source: IGES – Lüring et al. 2013)



■ Fig. 2.8 Age-standardized revision knee arthroplasty rates per 100,000 inhabitants, by federal state (patient domicile) and as the national average in Germany (2011). (Source: IGES – Lüring et al. 2013)

procedures was highest in Bavaria and lowest in Berlin. According to the calculations, above-average increases in rates in the years 2005 to 2011 can be observed for patients in the federal states of Schleswig-Holstein, Rhineland-Palatinate, Bavaria, Thuringia, Hamburg, Hesse and Berlin (Lüring et al. 2013).

In the East German regions, the numbers of both types of joint replacement procedures were generally below the average value (except Thuringia) (Schäfer et al. 2013).

The numbers correlated with the osteoarthritis incidence (prevalence) whereby regions with high incidences had comparatively higher rates of THAs and TKAs. Further variables that could explain the regional differences in utilization were local numbers of specialist physicians (orthopedists), regional socioeconomic status and patients living in urban areas. The lower the regional number of orthopedists and the higher the socioeconomic status of the population were in a region, the higher the rate of total arthroplasty procedures amongst insurees living in that region. Total arthroplasties were performed considerably less frequently in urban areas than in rural areas (Schäfer et al. 2013).

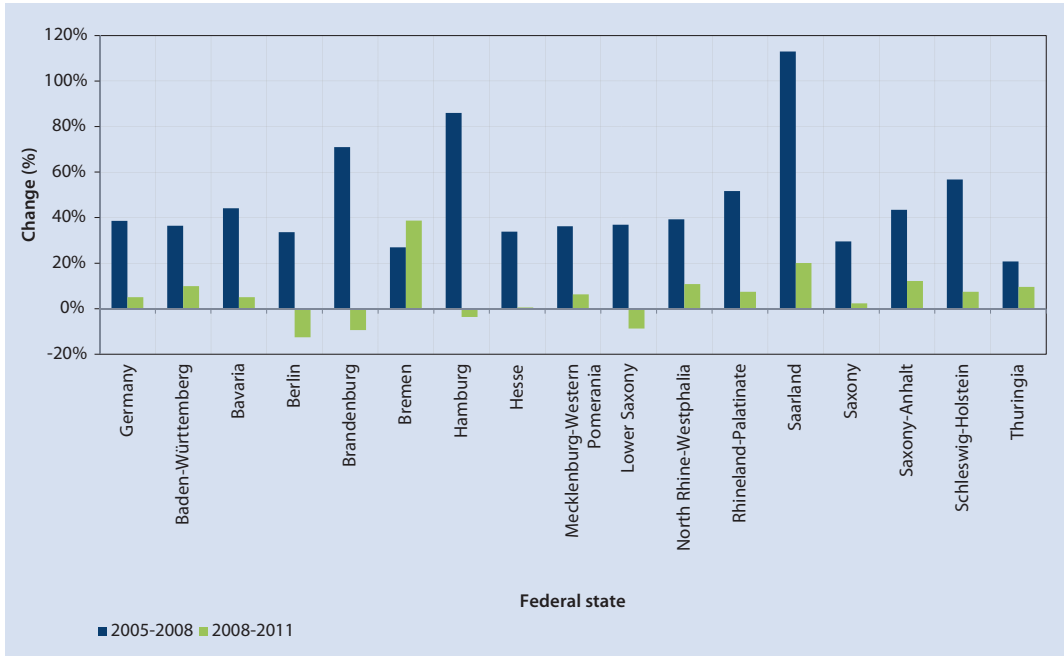
■ Fig. 2.8 shows Lüring et al.'s calculations for age-standardized surgery rates for revision replace-

ments on the knee per 100,000 inhabitants in 2011, according to federal states of patient domiciles and using the national average as a comparison. Revision replacements were defined as »any renewed surgery on the same knee joint«.

The analysis shows that in 2011, the highest numbers of revision knee replacements in relation to the number of inhabitants were performed in Saxony-Anhalt, Thuringia, Bavaria and Lower-Saxony. Patients in Mecklenburg-Western Pomerania had the lowest rates of revision.

■ Fig. 2.9 clearly demonstrates that surgery rates in the federal states have in part increased considerably over the past ten years. However, the graph differentiates between the rates of increase for the periods between 2005 and 2008 and between 2008 and 2011, illustrating that the rise in surgery rates was considerably higher in the earlier period than in the later period (with the exception of Bremen). From 2008, the rates of increase generally tend to be lower and even show declines in some federal states (Lüring et al. 2013).

With this, federal states in the southeast had almost consistently higher rates of surgery than in the northeast. At district level, the differences are even more pronounced. With regard to primary replacements, the district with the highest rate of replace-



■ Fig. 2.9 Rates of change in age-standardized revision knee replacement rates, 2005-2008 and 2008-2011. (Source: IGES – Lüring et al. 2013)

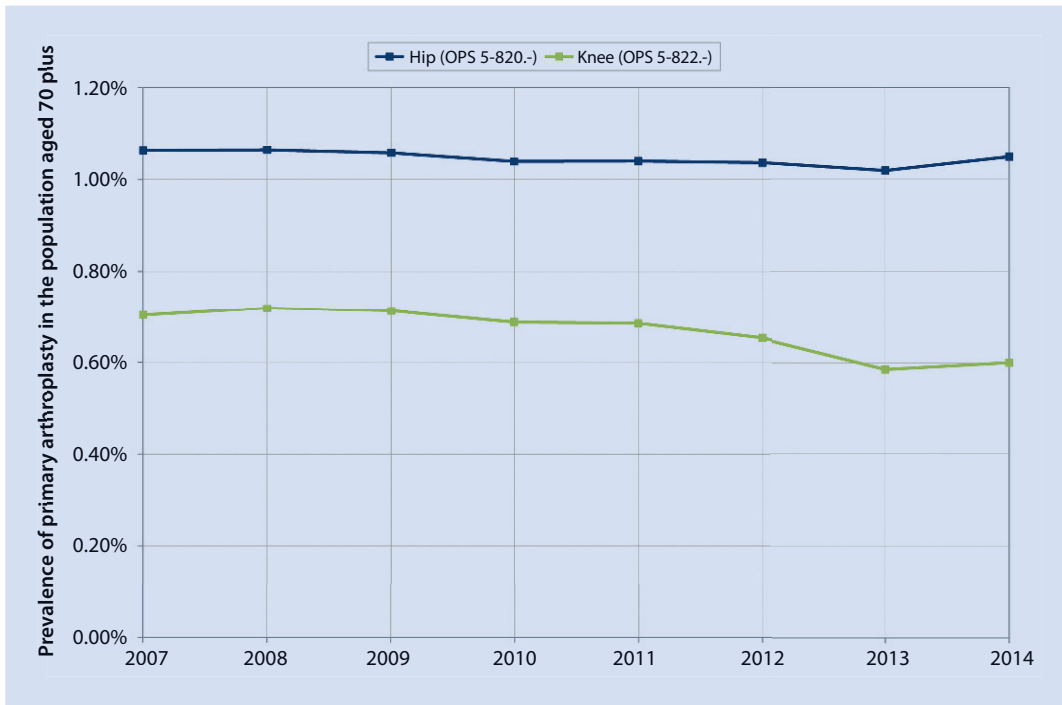
ments had a 2.9-fold higher rate of knee arthroplasty than the district with the lowest rate. With regard to revisions, the greatest difference between two districts was 4.9-fold (Lüring et al. 2013).

The report discusses manifold reasons for the differences in prevalence. One aspect is that regional differences in access to hospital care exist. Additionally, a bias is created in that patient domiciles and the place of surgery are not in the same region. Additional matters of discussion are revenue structure and that the remuneration system may set wrong incentives and consequently also contribute to the regional differences. The authors, however, emphasize that the observed increasing case numbers which are not caused by demographic changes should not solely be attributed to wrong financial incentives (Lüring et al. 2013). On the whole, however, the data is insufficient for establishing causal relationships (Lüring et al. 2013).

2.5 Case Number Developments

2.5.1 Primary Arthroplasty

Since 2007, the absolute number of primary hip and knee arthroplasties has been increasing, which is in line with the growing number of older people (risk population) in the population. From 2007 to 2014, the prevalence of primary hip and knee replacements amongst patients over the age of 70 years (as determined on 31 December in the respective year) did not increase and remained stable at 1.1 % for primary hip replacements (2007 and 2014) and between 0.7 % and 0.6 % (2007 and 2014 respectively) for primary knee replacements (■ Fig. 2.10) (own calculation, Federal Statistical Office 2014, Federal Statistical Office 2015). After an increase in the absolute number of primary replacements from 2007 to 2011, the number of hip replacements showed a slight decline from 213,935 cases in 2011 to 210,384 cases in 2013, followed by an increase to 219,325 cases in 2014. In 2009, the number of primary knee replacements was 159,137, which remained almost



■ Fig. 2.10 Prevalence of primary hip and knee replacements in the population aged 70 plus (2007 to 2014). (Source: IGES – own calculation, Federal Statistical Office 2014, Federal Statistical Office 2015)

unchanged in 2010 and 2011 and subsequently declined. In 2013, 7.6 % fewer primary knee replacements were performed than in 2008 and 10.1 % fewer primary replacements (absolute number) than during the peak year 2009.

Changes in case numbers over time can be observed when examining the utilization of THA with regard to the fixation technique selected. During the six-year observational period, the number of uncemented total arthroplasties (not including custom-made prostheses) rose by 5 % in absolute numbers. The utilization of cemented procedures decreased in the same period: Cemented and partially cemented total replacements declined by 33 % and 9 % respectively from 2008 to 2013. Custom-made prostheses only played a marginal role (■ Fig. 2.11).

Case numbers for the four most common types of primary knee arthroplasty have been declining over the past few years (■ Fig. 2.12). The decline in the number of primary arthroplasties is primarily due to a reduced utilization of cemented total replacements.

An evaluation of the case number developments for primary hip and knee replacements in Germany from 2005 to 2011 showed that the increase in the number of primary hip replacements can largely be ascribed to demographic developments. In contrast, non-demographic factors prevailed with regard to the increase in primary knee replacements (Wengler et al. 2014).

If case number developments cannot be sufficiently explained by the demographic developments, this may be an indication of an existing over-supply or shortage of care (Barmer GEK 2010). Besides demographics, other factors and their respective changes (medical, economic, systemic, Section 2.4) influence the prevalence of utilization of medical services over time. Often, these effects cannot be sufficiently quantified (► Chapter 6).

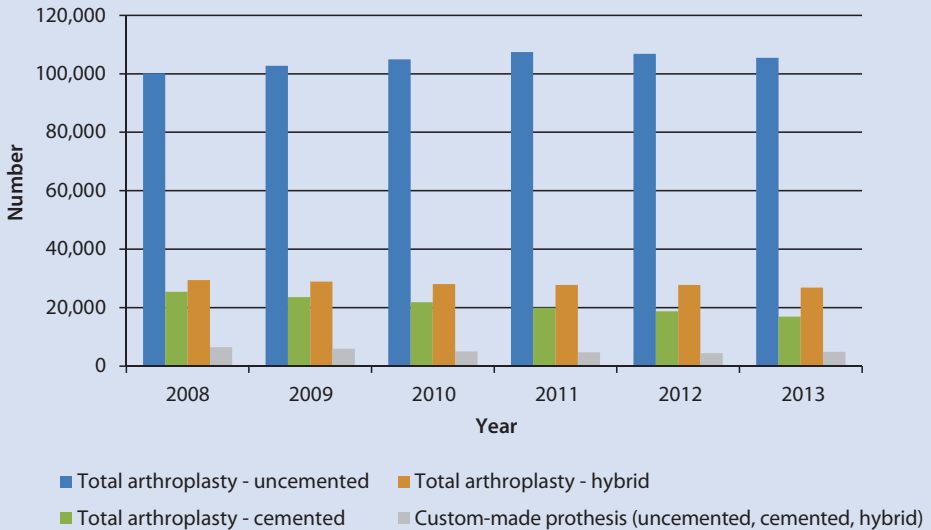


Fig. 2.11 Absolute number of primary THAs performed, by fixation technique, over time (2008 to 2013). (Source: IGES – Federal Statistical Office 2014)

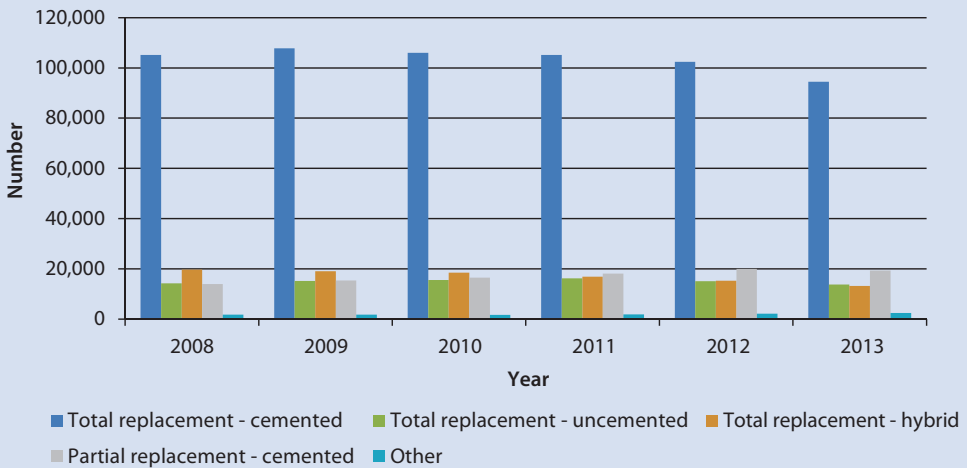
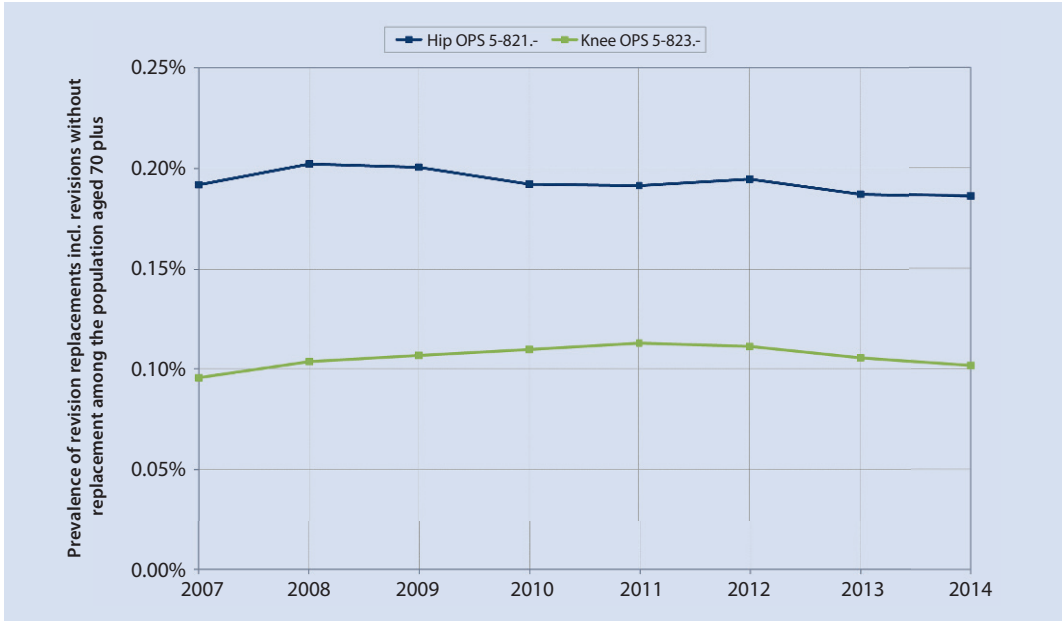


Fig. 2.12 Absolute number of primary knee replacements performed, by fixation technique (2008 to 2013). (Source: IGES – Federal Statistical Office 2014)



■ Fig. 2.13 Prevalence of revision total hip and knee replacements and revisions (without replacements) in the population aged 70 plus over time (2007 to 2014). (Source: IGES – own calculation, Federal Statistical Office 2014, Federal Statistical Office 2015)

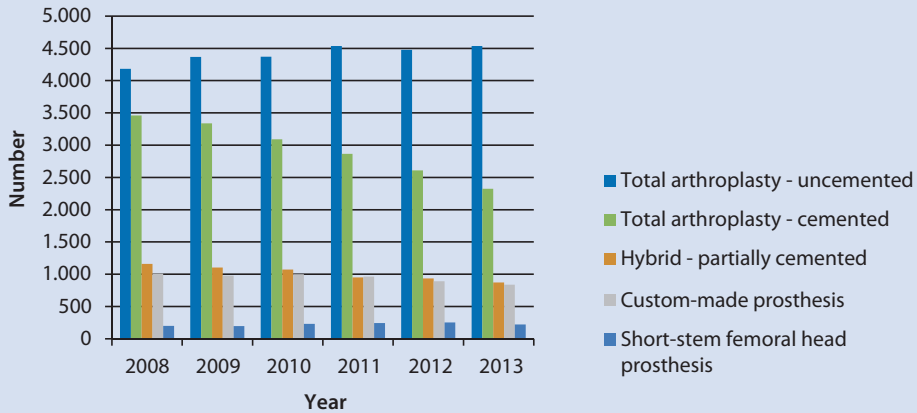
2.5.2 Revision Total Arthroplasty and Revision Surgery

The absolute number of all revision total arthroplasties and revisions without replacement performed on the hip and knee increased in the period between 2007 and 2014. Since 2007, the prevalence of hip and knee revision replacement surgery (including revisions without replacements) amongst people in the population aged 70 plus (population as determined on 31 December of the respective year) has remained stable at 0.19 % (2007 and 2014) for hip replacement surgery and at 0.10 % for knee replacement surgery (■ Fig. 2.13) (own calculation, Federal Statistical Office 2014, Federal Statistical Office 2015). During the observational period from 2008 to 2013, the absolute number of revision total hip replacements in relation to total replacements decreased by 12.2 %. This is predominantly due to a decrease in the number of cemented THAs which declined steadily by altogether 32.8 % from 2008 to 2013. In contrast, the number of DRG-coded revision replacements of uncemented total replace-

ments increased by 8.5 % during the same period. This increase can presumably also be ascribed to the higher number of uncemented arthroplasties. Partially cemented total arthroplasties and custom-made prostheses were also revised less frequently in 2013 than in 2008, with a decrease of 24.9 % and 17.0 % respectively. When an uncemented total arthroplasty is revised, it is usually replaced with another uncemented total arthroplasty (33.2 % of uncemented total replacements) or with a custom-made prosthesis (38.7 %) (■ Fig. 2.14).

From 2008 to 2013, the most frequent revision knee replacement performed by far was bicondylar surface replacement, followed by revisions without replacements and unicondylar sledge prosthesis replacements (■ Tab. 2.3).

37.5 % of all the observed bicondylar surface prosthesis replacements are recorded with the synthetic inlay replacements. This procedure is easier to perform and associated with fewer complications than replacements of other implant components with bone fixation (Lüiring et al. 2013). Inlay replacement was the most common type of revision



■ **Fig. 2.14** Absolute number of revision hip replacements performed, by fixation technique, over time (2008 to 2013). (Source: IGES – Federal Statistical Office 2014)

■ **Tab. 2.3** Absolute number of revision replacements and revisions (without replacements) performed on the knee over time (2008 to 2013)

OPS	name	2008	2009	2010	2011	2012	2013
5-823.0	Revision (without replacement)	3,497	3,421	3,444	3,518	3,291	3,213
5-823.1	Unicondylar sledge prosthesis replacement	1,971	1,974	2,057	2,297	2,443	2,317
5-823.2	Bicondylar surface prosthesis replacement	10,590	11,049	11,821	11,916	11,614	11,290
5-823.3	Hinged endoprosthesis replacement	1,011	1,068	1,127	1,245	1,255	1,222
5-823.4	Custom-made prosthesis replacement	480	535	529	585	563	533
5-823.5	Patella prosthesis replacement	450	446	535	516	528	439
5-823.b	Replacement of an endoprosthesis with enhanced flexion	866	811	824	774	840	699
5-823.c	Replacement of an interpositional non-anchored implant	184	178	174	132	119	100
5-823.f	Replacement of a bicompartamental prosthesis	0	480	512	461	516	459
5-823.h	Replacement of an endoprosthetic joint without movement function	0	0	0	63	84	112
5-823.x	Other	242	225	241	202	194	188
5-823.y	Unspecified	31	41	25	19	32	16

Source: IGES – Federal Statistical Office (2014)

■ **Tab. 2.4** Absolute number of revision bicondylar surface prosthesis replacements, over time (2008 to 2013)

OPS	Description	2008	2009	2010	2011	2012	2013
5-823.20	Same prosthesis type	305	247	255	228	241	247
5-823.21	With a different surface prosthesis, uncemented	47	53	50	31	32	38
5-823.22	With a different surface prosthesis, (partially) cemented	1,212	1224	1210	1167	1116	1101
5-823.23	With a hinged endoprosthesis, uncemented	39	58	56	59	67	68
5-823.24	With a hinged endoprosthesis, (partially) cemented	2,093	2275	2474	2557	2494	2362
5-823.25	With a custom-made prosthesis, uncemented	68	71	87	80	84	91
5-823.26	With a custom-made prosthesis, (partially) cemented	1,765	1938	2126	2110	1927	1763
5-823.27	Inlay replacement	3,796	3961	4240	4507	4539	4534
5-823.28	Partial replacement of femoral component	287	255	311	257	284	262
5-823.29	Partial replacement of tibial component	887	875	934	843	774	738
5-823.x	Other	91	92	78	77	56	86

Source: IGES – Federal Statistical Office (2014)

performed in 2008. By 2013, the number of inlay replacements had increased by 19.4 % whereas other commonly performed types of surgery showed lower rates of increase. In a revision procedure, the entire surface prosthesis is usually removed and replaced with cemented hinged or custom-made prostheses unless solely the inlay is being replaced. Other procedures only play a minor role. Only 3.2 % of all revision total replacements (i.e. not including partial replacement) are performed without using cement (■ Tab. 2.4).

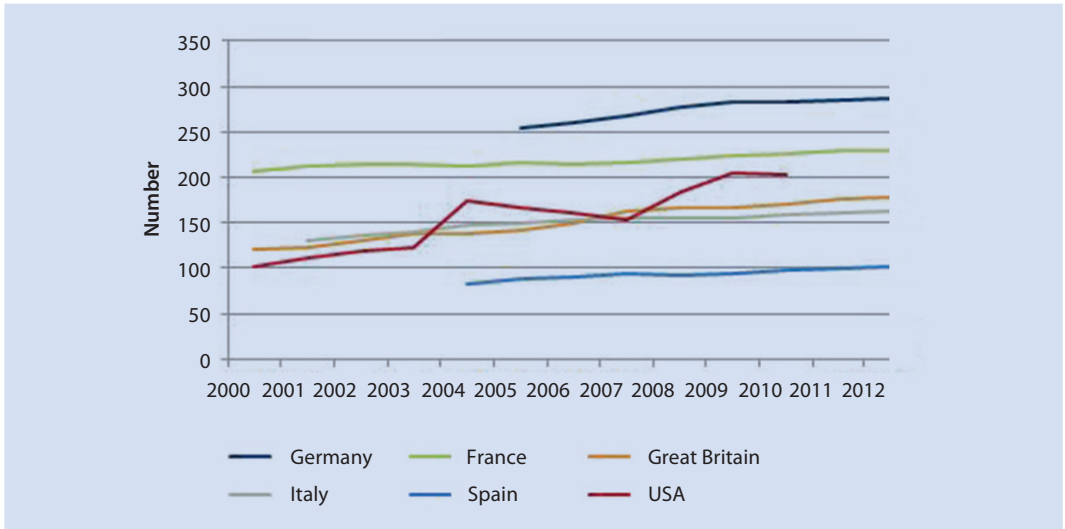
Due to the described increase in primary knee replacements up until 2009, Lüring et al. (2013) predicted a corresponding increase in revision knee replacements. According to Federal Statistical Office OPS data, the predicted continuing increase of knee replacements (Haas et al. 2013; Lüring et al. 2013) has not been observed to date (Federal Statistical Office 2014).

Pabinger et al. evaluated the utilization of hip joint replacements in connection with economic data from OECD countries from 1990 to 2011. They

found that the rates of increase in surgery are particularly pronounced in the under 65 years age group and therefore expect a strong increase in revision total replacements and revision surgery due to this demographic change (Pabinger and Geissler 2014).

2.6 International Comparison

Over the last decades, the absolute number of hip and knee arthroplasties has increased in Germany as well as in other European countries and in the USA (Finkenstädt and Niehaus 2015; Merx et al. 2003; Wengler et al. 2014). The demand for joint replacements has increased with the increasing prevalence of age-related underlying diseases and other risk factors, such as osteoarthritis and osteoporosis, which are associated with a higher risk of femoral neck fractures (■ Fig. 2.15, OECD 2014). Reasons for this are related to demographic changes which are accompanied by an increase of people at



■ Fig. 2.15 International numbers of hip replacements per 100,000 inhabitants based on OECD data over time (2002 to 2012) (presentation of prevalence rates without age adjustments). (Source: IGES – OECD 2014)

risk for joint replacements, amongst other things (Wengler et al. 2014).

Analyses have demonstrated that after a bias correction of demographic factors, endoprosthetic surgery only increased by 3 % between 2005 and 2011; without this correction it increased by 11 % (Wengler et al. 2014) (Section 2.5.1).

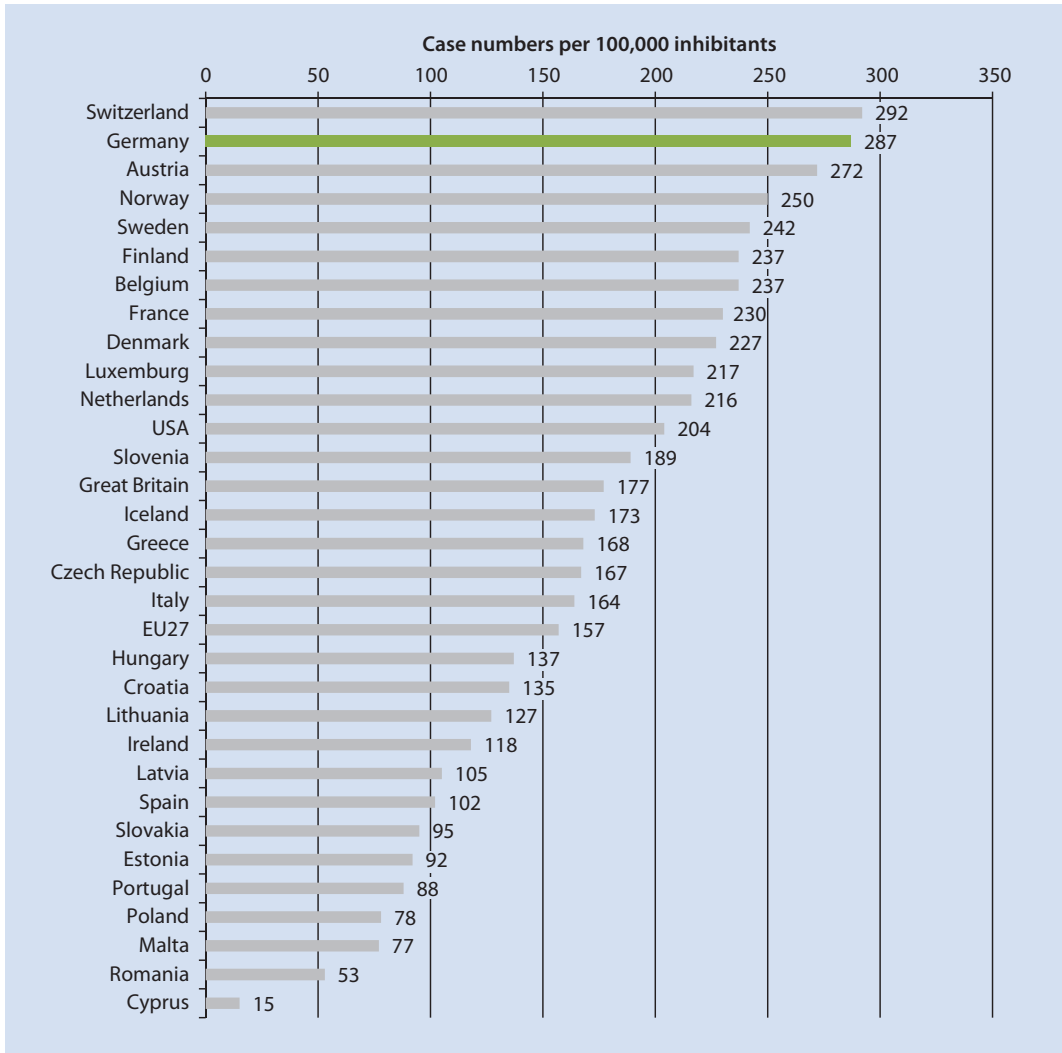
In an international comparison based on OECD data, Germany ranks amongst the top positions for the number of joint replacements performed (■ Fig. 2.16 and ■ Fig. 2.17; OECD 2014). However, the OECD database does not take into account demographic change, current population age structures and other factors influencing the utilization of surgery. As hip and knee replacements are strongly age-dependent, statements about country-specific healthcare situations for these procedures derived from this data (oversupply or shortage of care) are not particularly reliable, even solely because country-specific age structures have not been taken into consideration.

Age and age structures differ significantly internationally (■ Fig. 2.18). In 2012, around half the German population was 45.53 years or older (median age), making it the country with the second oldest population amongst the OECD countries following Japan. Within Europe, Germany and Italy

have the oldest populations (United Nations 2013). A populations« age distribution is relevant with regard to healthcare when the risk of a disease markedly increases with age as this is accompanied by a higher likelihood of requiring certain therapeutic measures such as joint replacements.

A study conducted by the Scientific Institute of the Private Health Insurances (Wissenschaftliches Institut der Privaten Krankenversicherung (WIP)), evaluated the impact of different ages in populations of different countries on the prevalence of 15 different types of surgery including hip and knee arthroplasty. The study was based on data published in the OECD health statistics (Finkenstädt and Niehaus 2015). In the study, Germany, with a median age of 44.3 years, was the country with the oldest population amongst the countries observed, following Japan (44.6) (■ Fig. 2.19).

Finkenstädt et al. demonstrated that including age structures of the German population in evaluations has an impact on its international ranking (hip: 32 countries, knee: 21 countries). When age structure is taken into account for hip joint replacements, Germany ranks 2nd instead of 5th following Switzerland, Norway, Austria and Luxemburg. For knee joint replacements, Germany's position shifts from 5th to 8th (■ Fig. 2.20 and ■ Fig. 2.21; Finken-

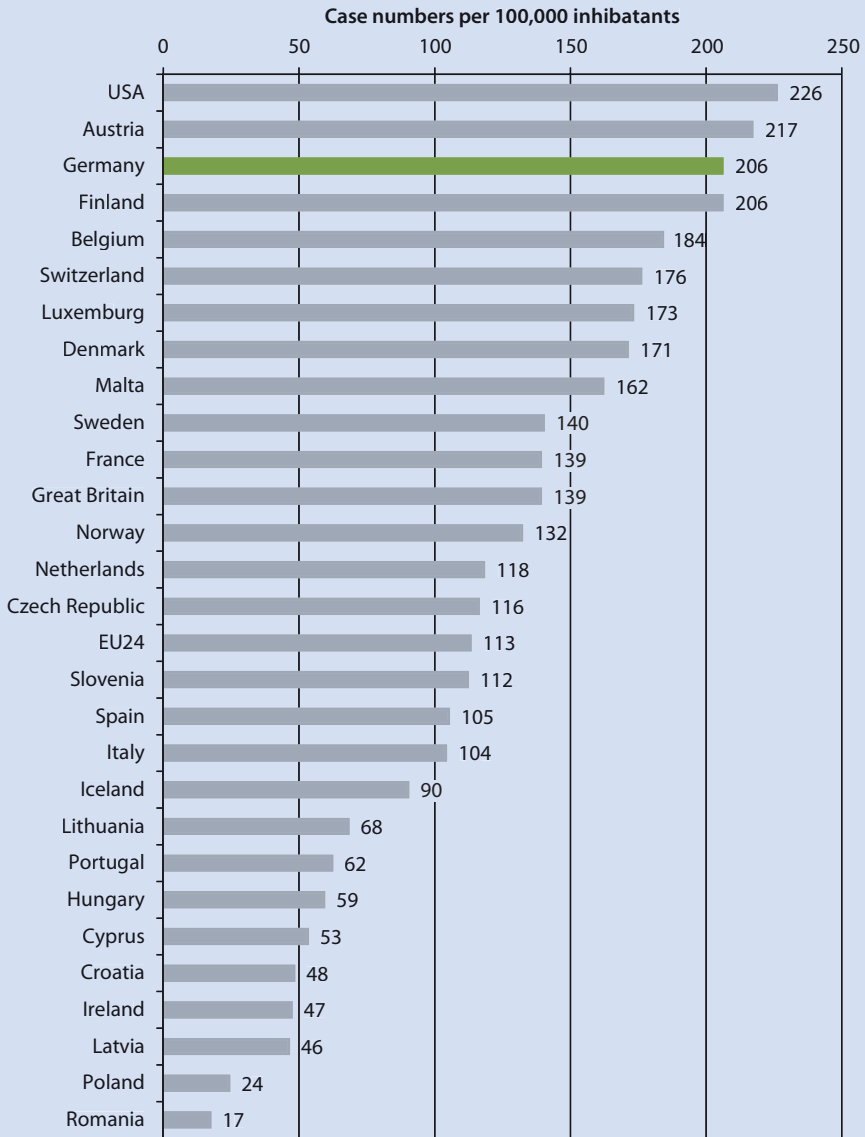


■ Fig. 2.16 Numbers of hip joint replacements per 100,000 inhabitants in OECD countries and the USA, 2012 (or latest data) (rates without age adjustments). (Source: IGES – OECD 2014)

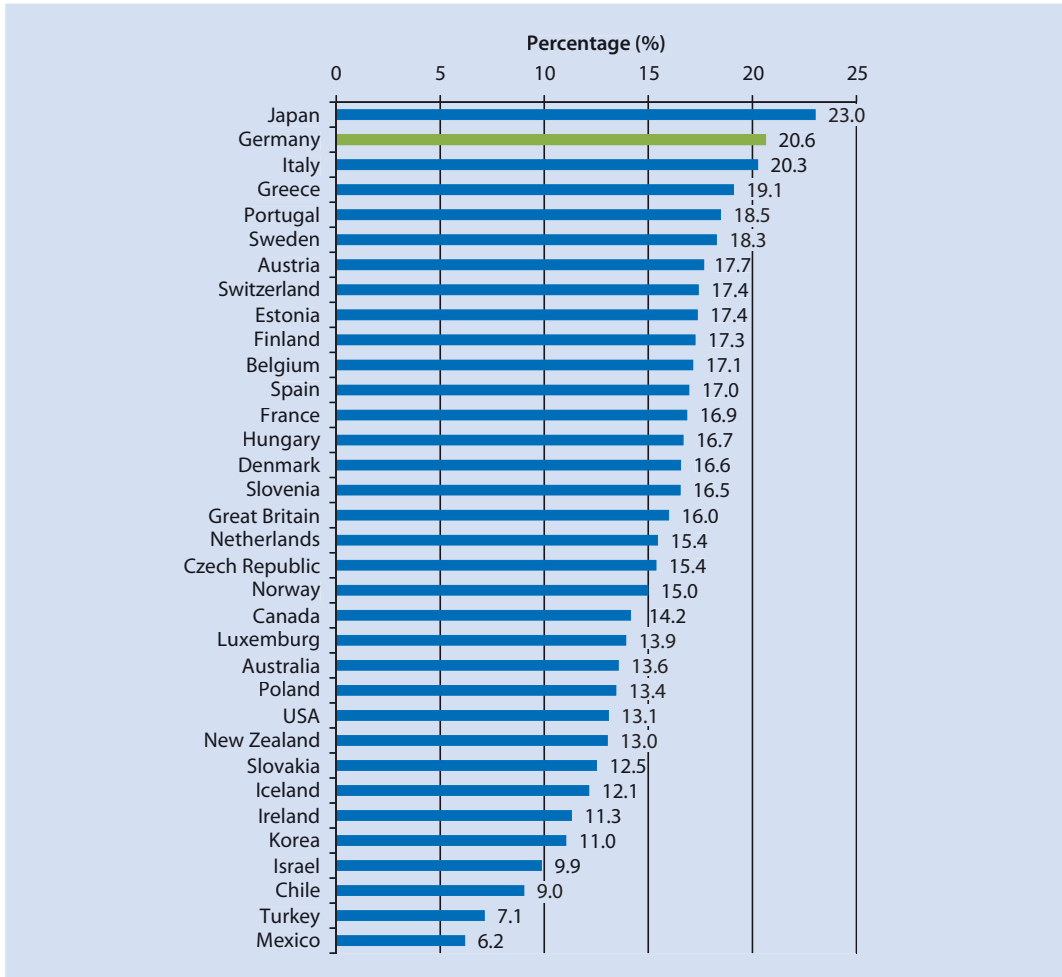
stätt and Niehaus 2015, 2013). A potential indicator of the status of healthcare that is currently subject to discussion is a factor derived from the lowest and the highest rates of surgery (Niethard et al. 2013). Based on the OECD data, this factor is 2 for hip arthroplasty in Germany (Finkenstädt and Niehaus 2015) and 4 for hip arthroplasty in the USA (Fisher et al. 2010). Knee arthroplasties in Germany differ regionally by a factor of 3.2 (Finkenstädt and Niehaus 2015) and in the USA by a factor of 3.8 (Fisher et al. 2010). For hip operations in particular, a high

rate of surgery with a comparatively low level of regional variance permits the assumption that the surgery indications and the standard of care have generally been accepted (Niethard et al. 2015).

Besides demographic factors, social, economic, structural and medical aspects (Merx et al. 2003; Pabinger and Geissler 2014) as well as specific characteristics of the individual national healthcare systems, such as different coding systems and differences in data recording, have an impact on the utilization of medical services and/or how they are



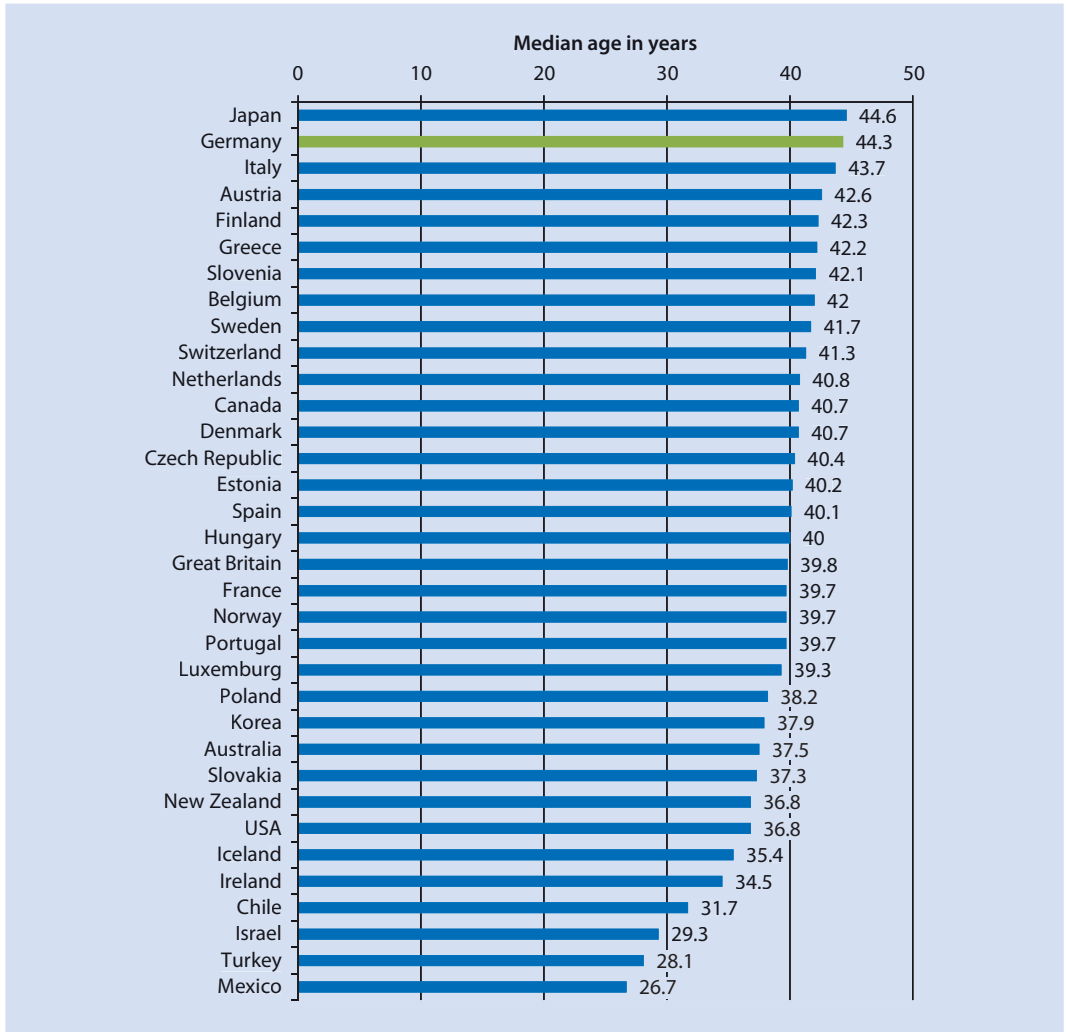
■ Fig. 2.17 Numbers of knee joint replacements per 100,000 inhabitants in the OECD countries and the USA, 2012 (or latest data) (presentation of prevalence rates without age adjustment). (Source: IGES – OECD 2014)



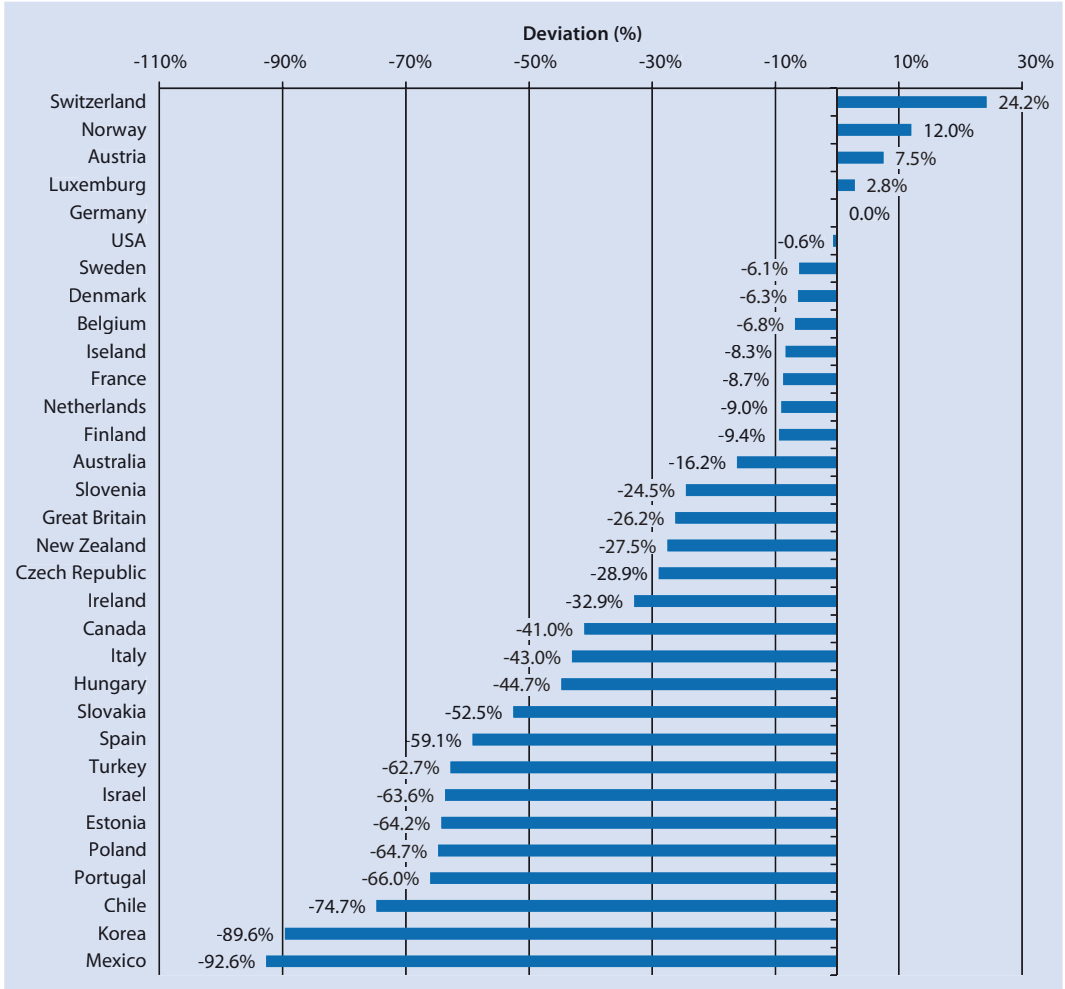
■ Fig. 2.18 Percentage of people aged ≥ 65 years in the total population, 2010. (Source: IGES – OECD 2014)

depicted. Some countries, for example, only report total hip arthroplasty (e.g. Estonia) and others include partial hip replacements (OECD 2014). In some countries, data from private hospitals are not included in the statistics (for example, Ireland) or only partially included (for example, Spain) (Finkenstädt and Niehaus 2015; OECD 2014). The utilization of joint replacement procedures is also related to the economic performance and the per capita healthcare expenditure of a country (Pabinger and Geissler 2014).

This clearly illustrates that data from international comparisons should be interpreted with caution. Evaluations of national healthcare statuses based on international comparisons or OECD data rankings are not reliable without making appropriate adjustments.



■ Fig. 2.19 Median ages in OECD countries, 2010. (Source: IGES – OECD 2014, Finkenstädt and Niehaus 2015)



■ **Fig. 2.20** Case number deviations for hip replacements in Germany following age-standardization. (Source: IGES – OECD 2014, Finkenstädt and Niehaus 2015)

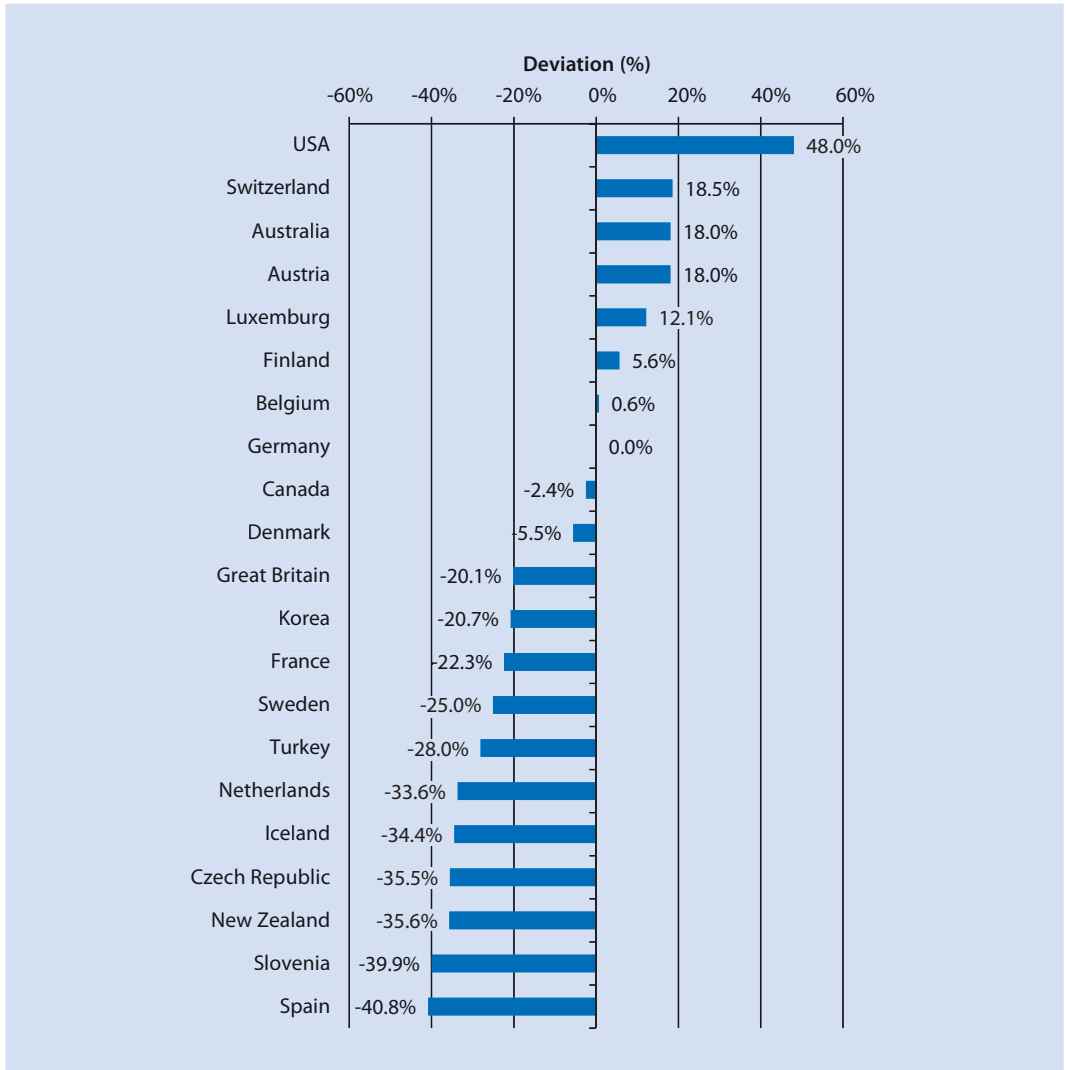


Fig. 2.21 Case number deviations for knee replacements in Germany following age-standardization. (Source: IGES – OECD 2014, Finkenstädt and Niehaus 2015)

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Status of Healthcare

*Michael Weißer, Ute Zerwes, Simon Krupka, Tonio Schönfelder, Silvia Klein,
Hans-Holger Bleß*

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Summary

Approximately half of all hospitals in Germany perform primary hip and knee arthroplasty. Symptomatic osteoarthritis is the cause of 80 % of primary hip replacements and 96 % of primary knee replacements. In accordance with mandatory external quality assurance measures for hospitals, an increase in the documentation of appropriate indications has been observed for a growing proportion of patients over the last few years and reached 96 % for both types of surgery in 2014. A limiting factor, however, is that some of the relevant indication criteria do not yet exist in a standardized or evidence-based format. Hip and knee replacements are amongst the most commonly performed inpatient procedures. Patients who undergo primary hip or knee replacement account for approximately 2 % of all full-time inpatients. Over the past years, the length of hospital stay for arthroplasty patients has been declining continuously with a greater decline relative to the average length of stay for all other types of hospital treatments. In 2014, the average length of stay was approximately 11.8 days and 10.6 days for total hip and for total knee arthroplasty respectively. Surgical complications during inpatient stays for primary arthroplasty have been declining for years and are now in the lower single-digit percentage range. Routine statutory health insurance data between 2005 and 2006 show that that 3.5 % of primary hip arthroplasty patients and 3.8 % of primary knee arthroplasty patients underwent premature revision total replacement within the first 2 years after surgery. The risk of complications from endoprosthetic surgery depends on numerous factors. Influencing factors include the implant itself and the type surgery performed (including the surgeon's experience, surgical techniques, the duration of surgery, etc.), the patient's medical characteristics (concomitant diseases, compliance, etc.) as well as the type of rehabilitation care and ambulatory follow-up care. To date, no relevant data on service lives and influencing factors have been systematically collected in Germany. However, this is expected to change thanks to the German arthroplasty registry »Endoprothesenregister Deutschland« which was established in 2011. Rehabilitation treatment should start soon after surgery and in the majority of cases this is commenced a few days after discharge from hospital. However, due to

shorter lengths of hospital stays, patients in rehabilitation clinics have greater care requirements. Older multimorbid patients in particular, require targeted geriatric, interdisciplinary care. Surveys carried out on statutory health insurees have indicated that most patients show a significant reduction in symptoms after surgery and that this is still the case even 5 years after surgery. In addition, a large majority of patients are satisfied with the procedure. These effects are more pronounced in hip surgery patients than in patients who have undergone knee replacements. The vast majority of patients return to work following the procedure.

Quality of care cannot be ascribed to an implant alone as a number of other factors need to be taken into consideration. To a greater degree, the entire ambulatory medical care chain, including medical care before admission into hospital, acute care, follow-up care and rehabilitation, are crucial to the quality of care. Nationwide quality initiatives in Germany aim at improving the transparency and analysis of medical services as well as improving the quality in the provision of care. The following chapter describes the chain of care and quality aspects of care.

3.1 Basis of the Study

Illustrations of the use and quality aspects of replacement surgery in Germany are founded on numerous expert reviews and reports, as well as on different data sources. The expert reviews refer to three data sources:

1. Data based on § 21 of the German Hospital Remuneration Law.
2. Routine data from individual statutory health insurances.
3. Routine data on the prevalence of all reported procedures according to the German procedure classification »Operationen- und Prozedurenschlüssel (OPS)« compiled by the Federal Statistical Office of Germany.

On the whole, different primary and secondary data studies based on the volume and quality of care exist (■ Tab. 3.1).

Tab. 3.1 Overview of selected publications, focusing on case numbers and database analysis of hip and knee arthroplasty

Author	Publication	Analysis topic	Sample	Period	Focus
AQUA Institute	Bundesauswertungen	Hip and knee endoprostheses	Accounting data acc. to § 301 Volume V of the German Social Security Code	2009–2014	Quality indicators
AQUA Institute	Hüftendoprosthesenversorgung Abschlussbericht	Hip endoprostheses	Settlement data acc. to § 301 Volume V German Social Security Code	2004–2010	Development of quality indicators
AQUA Institute	Knieendoprothesenversorgung Abschlussbericht	Knee endoprostheses	Accounting data acc. to § 301 Volume V German Social Security Code	2004–2010	Development of quality indicators
Barmer GEK	Barmer GEK Krankenhaus-Report 2010	Hip and knee endoprostheses	SHI routine data, patient survey approx. 8 million patients	2003–2009	Case number development
Braun	hkk-Gesundheitsreport 2013	Hip and knee endoprostheses	hkk routine data; Federal Statistical Office data	2008–2012/ 2006–2011	Development of revision surgery over time; services associated with joint replacements
Haas et al.	EndoCert®-Zertifizierung von endoprothetischen Zentren in Deutschland 2013	Hip and knee endoprostheses	Federal Statistical Office data	2004–2010	Factors influencing the quality of care
Lüring et al.	Report der DGOOC/Bertelsmann Stiftung 2013	Knee endoprostheses	AOK routine data; approx. 25 million insurees	2005–2011	Regional differences
Rabenberg	Robert Koch Institut, Arthrose 2013	Hip and knee endoprostheses	Federal Statistical Office data (in addition to GEK and AOK)	2010	Endoprostheses prevalence (case number development)
Schäfer et al.	Krankenhaus Report 2012	Hip and knee endoprostheses	AOK routine data; approx. 25 million insurees	2005–2009	Regional differences

Source: IGES – own presentation

3.2 Ambulatory Care

Different groups of specialist physicians are involved in the ambulatory care of patients who have undergone hip and knee replacements. The chain of care comprises primary care physicians (general practitioners and internists working as primary care physicians), orthopedic and trauma surgery specialists in as well as radiologists. Physio-

therapists and occupational therapists are also involved.

The indication for joint replacement surgery is made by specialists in orthopedics and trauma surgery, based on clinical and radiological criteria that take into consideration the related benefits and risks (Section 1.2).

Usually, patients suffering from arthrosis have been in ambulatory medical care for years before a

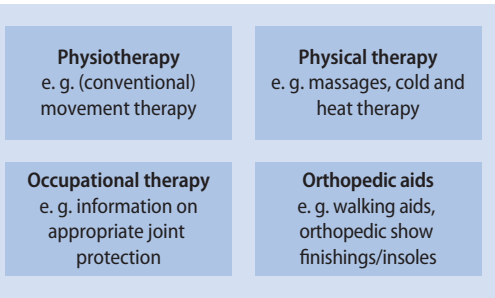


Fig. 3.1 Factors of conservative, non-drug treatment of osteoarthritis. (Source: IGES – Claes et al. 2012 and Wirtz 2011)

hip or knee replacement becomes necessary. Conservative arthrosis therapy comprises the use of therapeutic products and medical aids (Fig. 3.1) as well as pain management drugs (AWMF 2009a, b).

In many cases, joint replacement constitutes the primary treatment of femoral neck fractures. In contrast to the case of osteoarthritis, surgical care here is urgent (acute), i.e. should take place shortly after the event as otherwise an imminent and considerable deterioration of the patient’s state of health is to be expected (Claes et al. 2012).

Tab. 3.2 shows the use of ambulatory treatment of statutory health insurance patients prior to joint replacement for the period 2003 to 2009. According to patient reports, e.g. 74 to 85 % of patients who received a hip or knee joint replacement had taken medication for joint pain prior to surgery (Barmer GEK 2010).

An analysis of routine data from the SHI Handelskrankenkasse (hkk) found that ambulatory services prior to joint replacement surgery accounted for around two thirds of all ambulatory services (i.e. pre- and postoperative, for 6 months each). This was the case for both total hip and total knee arthroplasty (Braun 2013).

Owing to the remuneration and visiting consultant system, the orthopedic specialist who treated the patient in ambulatory care and who made the recommendation for surgical inpatient care has the option of performing the surgery.

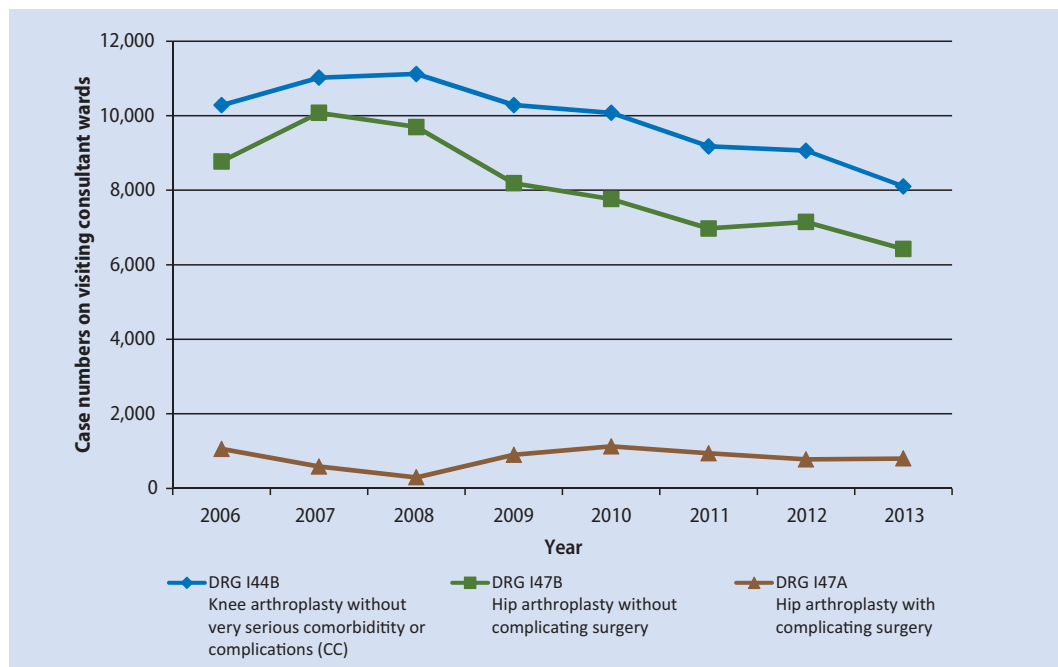
Visiting consultants with admission privileges are »(...) statutory health insurance physicians who are not employed by the hospital and are entitled to treat their patients in hospital as inpatients or day-care patients using the services, facilities and materials available without receiving any remuneration from the hospital (§ 121 [2] Volume V German Social Security Code). Fee-based physicians are also not employed by the hospital but make their services available to the hospital for a fee.

The number of cases of hip joint replacements and revisions (including partial replacements) and knee joint replacements in visiting consultant wards are declining (Fig. 3.2).

Tab. 3.2 Annual patient use of ambulatory treatment services prior to joint replacement (questionnaire survey)

Joint	Hip		Knee	
Population	Barmer GEK insurees			
Evaluation period	2003 (n = 555)	2009 (n = 1,080)	2003 (n = 301)	2009 (n = 940)
Pain management with drugs	76.4%	74.1%	82.4%	85.0%
Physiotherapy	50.6%	46.4%	39.5%	40.2%
Massage	19.8%	14.3%	14.6%	12.3%
Physical therapy	20.0%	13.4%	17.6%	9.3%

Source: IGES – Barmer GEK 2010



■ Fig. 3.2 Number of cases of the most common DRGs for hip and knee joint replacements in visiting consultant wards, patients with normal length of stays, 2006–2013. (Source: IGES – InEK 2015)

3.3 Inpatient Care

3.3.1 Primary Arthroplasty

Capacity of care, proximity to domicile and waiting times

Hip and knee joint replacements rank amongst the most common procedures performed in the inpatient care sector. According to 2013 DRG statistics, out of a total of 18,531,819 patients in inpatient care, approximately 2% of these underwent primary hip and knee joint replacements (Destatis 2014).

The AQUA Institute conducted a national »External Quality Assurance for Inpatient Care« assessment for elective primary total hip arthroplasty (THA), recorded 1,075 hospitals performing primary THA (AQUA-Institut 2013a). 1,031 hospitals performed primary total knee arthroplasty (TKA) (AQUA-Institut 2013c). In total, more than half of all German hospitals performed primary hip or knee joint replacement surgery in 2013 (Destatis 2015a). Between 2009 and 2013, there was a decline in the number of hospitals that performed total hip

arthroplasty. It must be noted, however, that there was a decline in the overall number of hospitals as well (■ Tab. 3.3).

Between 2009 and 2010, the number of hospitals that performed primary TKA increased slightly, after which it remained relatively steady until 2013 (AQUA-Institut 2012c, 2013c, 2014c, 2015d, 2010c, 2014c). The percentage of centers performing endoprosthesis surgery in relation to the total number of hospitals increased from 49.0 % to 51.7 %.

In 2014, the method used to count hospitals for inpatient quality care assurance purposes changed, whereby additional locations of each hospital were also included in the count. Hence, as of 2014, the number of recorded hospitals performing THA replacement surgery increased to 1,229 hospitals (AQUA-Institut 2015b) and to 1,160 hospitals performing TKA (AQUA-Institut 2015d).

A study evaluated the distance patients traveled to hospitals for hip joint replacements (OPS 5-820, including partial prostheses), for both elective surgery and emergency treatment, based on data from hospital cases of 71,870 AOK insureds in 2006 (Fried-

Tab. 3.3 Total number of hospitals in Germany, centers that performed hip and knee joint replacements, and percentage of hospitals performing endoprosthetic surgery 2009–2014

	2009	2010	2011	2012	2013
Number of hospitals in Germany ¹⁾	2,084	2,064	2,045	2,017	1,996
Number of hospitals that performed primary THA ²⁾	1,156	1,149	1,112	1,091	1,075
Proportion of hospitals that perform THA out of all hospitals in Germany ^{1), 2)}	55.5%	55.7%	54.4%	54.1%	53.9%
Number of hospitals that performed primary TKA ³⁾	1,022	1,036	1,030	1,033	1,031
Proportion of hospitals that perform TKA out of all hospitals in Germany ^{1), 3)}	49.0%	50.2%	50.4%	51.2%	51.7%

Source: IGES calculations – 1) Destatis 2015a, 2) AQUA-Institut 2010b, 2011b, 2012a, 2013a, 2014a, 3) 2010c, 2011c, 2012c, 2013c, 2014c

rich and Beivers 2009). The average distance to the service-providing hospitals was 17.6 kilometers (elective surgery 19.7 km, emergency procedures 12.4 km). A total of 41% of the patients had the procedure performed in the hospital closest to their domicile (elective surgery 34.3 %, emergency procedures 56.8 %). Older patients in particular were treated close to their homes and had the lowest average travel distances. For elective surgery, the patient travel distances in rural areas were the longest. Moreover, patients in urban areas often did not choose the nearest hospital. On the whole, the study results indicate that hospital care close to the domicile of the patient becomes more important with increasing age. Hospitals located further away are particularly chosen for specific elective surgery. These are usually smaller establishments specialized in performing specific procedures (Friedrich and Beivers 2009).

Waiting times for surgery are not systematically recorded in Germany (Finkenstädt and Niehaus 2013). A telephone survey conducted in 2010 by the American foundation »Commonwealth Fund« found that patients in Germany have a waiting time of 4 months at most for elective surgery (of any kind). 78 % of those surveyed had this surgery performed within one month (The Commonwealth Fund 2010).

Overviews of health economic data show broad spans of waiting times for hip joint replacements. In 2008, the waiting time in Germany and Austria was

between 1 month and 12 months. In Switzerland, the waiting period was between less than 1 month and 6 months, and in Great Britain approximately 8 months (Effenberger et al. 2008).

More up-to-date data on waiting times, provision of care close to the patient's domicile and waiting times specifically for patients with indications for knee replacements could not be sourced. Overall, the decision with regard to waiting times for hip or knee joint replacements must take into consideration minimizing the time the patient has to live with diminished quality of life and avoiding revision surgery over their lifetime and/or an as long as possible service life of the endoprosthesis. Additionally, study results suggest that a realistic waiting period as well as regular and transparent communication during the waiting period have a positive influence on patient satisfaction with regard to waiting times (Conner-Spady 2011).

■ Indication (underlying disease)

Symptomatic osteoarthritis constitutes the most common underlying disease in patients who are admitted to hospital for hip or knee joint replacements. A study based on routine data from a statutory health insurance fund found that osteoarthritis of the hip joint accounted for 80.1% of all procedures and osteoarthritis of the knee joint accounted for 96 % (■ Tab. 3.4). Femoral neck fractures constituted 12.5 % of all indications for hip joint replacements (Barmer GEK 2010).

Tab. 3.4 Frequency of treatment diagnosis for hip or knee joint replacements (primary replacement) amongst statutory health insurances (Barmer GEK, 2007–2009)

Diagnosis	Description	Percentage
Hip		
M16	Osteoarthritis of hip	80.1%
S72	Fracture of femur	12.5%
M87	Osteonecrosis	3.1%
T84	Complications of internal orthopedic prosthetic devices	2.1%
M	Other diseases of the musculoskeletal system	1.0%
C	Malignant neoplasms	0.5%
	Other diagnoses 0.6%	
Knee		
M17	Osteoarthritis of knee	96.0%
T84	Complications of internal orthopedic prosthetic devices	2.0%
M	Other diseases of the musculoskeletal system	1.6%
	Other diagnoses	0.3%

Source: IGES – Barmer GEK 2010

However, with the patients' increasing age, an increase in the percentage of hip joint replacements due to fractures can be observed. In the 65 to 74 years age group, femoral neck fractures were the surgical indication for hip joint replacement in 8.6% of cases and in the 75 to 84 years age group femoral neck fractures accounted for 26.8%. In addition, it was found that 66.1% of those receiving hip joint replacements due to femoral neck fractures were over the age of 85 (Barmer GEK 2010) (■ Fig. 3.3).

■ Comorbidity and perioperative risk

The most common concomitant diseases of patients undergoing hip or knee joint replacement were determined by several studies based on administrative data from statutory health insurances (■ Tab. 3.5).

Tab. 3.5 Examples of common concomitant diseases of hip and knee joint replacement patients (n = 149,717)

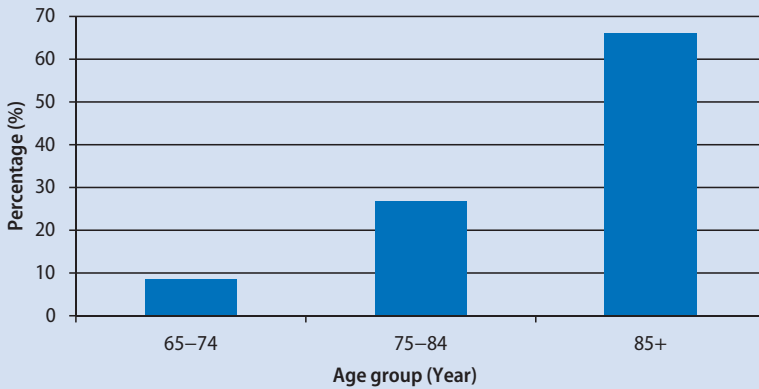
Concomitant disease	Prevalence	
Diabetes mellitus	16.0%	
Heart failure	7.7%	
Chronic renal failure	5.9%	
COPD	5.2%	
Asthma	1.9%	
Arteriosclerosis	1.7%	
Malignant neoplasms	1.0%	
Acute renal failure	0.4%	
Barmer GEK (2010), Initial survey 2009	Hip (n = 1,120)	Knee (n = 1,033)
Diabetes mellitus	10%	12.7%
Cancer excluding leukemia	9%	8.6%
COPD	7.7%	8.7%
Stomach ulcer	7.6%	9.9%
Heart failure	7.1%	10.2%

Source: IGES – Barmer GEK 2010; Jeschke and Günster 2014

The studies showed that patients with hip or knee replacements suffered from diseases such as diabetes mellitus and heart failure, which are particularly common at an older age (RKE 2015).

In the survey for TKA care documented in the »2010 Barmer GEK Hospital Report« (Barmer GEK Krankenhaus-Report 2010), 46.5% (initial survey 2009) and 56.6% (follow-up survey 2009) of patients reported suffering from at least one concomitant disease. Amongst the patients with THA, 39.8% (initial survey 2009) and 50.2% (follow-up survey 2009) suffered from at least one concomitant disease. The prevalence of individual concomitant diseases was comparable for patients with THA and TKA (Barmer GEK 2010).

Each surgical procedure involves certain risks that are not only related to the operation itself but also the required anesthesia. These added risks prevail for the duration of the surgery as well as for a certain period subsequent to the surgery (perioperative com-



■ **Fig. 3.3** Age distribution of femoral neck fractures (572) treated with hip joint replacements (Source: IGES – Barmer GEK 2010)

plication risk). Amongst other things, surgical risk depends on the extent of the surgery, the expected duration, anatomical conditions, blood loss and patient positioning. Anesthetic risk is described as the risk associated with the anesthetic method applied. For elective surgery in particular, the benefits must be carefully weighed against the risks of the surgery and anesthesia (Claes et al. 2012; Wirtz 2011).

Furthermore, the comorbidity of patients who undergo endoprosthetic surgery constitutes a significant influencing factor for the overall risk associated with the procedure (Singh 2013, Lau 2016). The American Society of Anesthesiology classifica-

tion (ASA classification system) has been used to estimate patients' perioperative risks for a long time. The treating anesthetist documents the ASA classification during premedication, based on the American Society of Anesthesiology (ASA) classification requirements. The ASA classification groups patients into up to six classes (► Chapter 1). Patients' ASA classifications were also included in the external quality assurance conducted by the AQUA Institute (AQUA-Institut 2015d). The majority of patients were assigned to ASA class 2 (with mild systemic disease) or class 3 (with severe systemic disease and functional limitations) (■ Tab. 3.6).

■ **Tab. 3.6** ASA classification for primary THA (n = 160,559) and TKA (n = 130,802) (2014) documented for External Quality Assurance for Inpatient Care

ASA	Description	THA classification [%]	TKA classification [%]
ASA 1	A normal, healthy patient	8.4	5.5
ASA 2	A patient with mild systemic disease	61.3	61.1
ASA 3	A patient with severe systemic disease and functional limitations	29.8	33.0
ASA 4	A patient with severe systemic disease that is a constant threat to life	0.5	0.4
ASA 5	A moribund patient	0.01	0.01

ASA = American Society of Anesthesiology

Source: IGES – AQUA-Institut 2015b and AQUA-Institut 2015d

This seems plausible in view of the fact that only healthy patients are classified into ASA 1 and patients who undergo hip or knee joint replacement already have an underlying symptomatic disease. Over the period 2009 to 2014, the distribution of the documented patient population within the ASA classifications remained almost constant (AQUA-Institut 2010b, c, 2011b, c, 2012a, c, 2013a, c, 2014a, c, 2015b, d).

A limiting factor, however, is that the ASA classification has been subject to strong criticism for several decades. One particular point of criticism is the lack of distinct criteria for classifying patients into the ASA categories. This especially affects ASA classes 2 and 3, to which most patients are assigned. Study results suggest that the allocation to a given ASA class is often undertaken subjectively and physicians' evaluations often differ in this respect (Shah et al. 2013). In addition, the ASA classification is hardly relevant to later patient pathways.

In contrast, specific comorbidities or clinical parameters, such as blood sugar values, tachypnea and lack of sinus rhythm, are of much higher importance for clinical decision-making and perioperative risk assessment. With regard to the long-term complication risks and/or the long-term success of treatment following endoprosthetic surgery, other specific concomitant diseases seem to have a significant influence. For example, it was demonstrated that obesity, diabetes mellitus and hyperglycemia are associated with an increased risk of joint inflammation during the first post-operative year (Jämsen et al. 2012).

On the whole, studies suggest that using scores which enable differentiated and objective assessments of a patient's general comorbidity, such as the Charlson Comorbidity Score (Charlson et al. 1987), enable good predictions of postoperative mortality and morbidity (Singh et al. 2013, Lau et al. 2016).

In addition, analyses of mortality after endoprosthetic surgery do exist. Based on Barmer GEK routine data, patients who received primary joint replacements were identified and analyzed with regard to cases of death (Barmer GEK 2010). The study shows that 1.0 % of patients who underwent a hip joint replacement died during the inpatient stay. 4.3 % of the patients died within 365 days after discharge from hospital, but distinct differences in the

underlying diseases were observed. 21.4% of patients with a femoral fracture died within one year after discharge from hospital. In contrast, only 0.7 % of the patients with osteoarthritis of the hip died within one year after discharge from hospital (Barmer GEK 2010).

An inpatient mortality of 0.1% was observed in patients who had undergone knee joint replacements. 1.3 % of the patients died within one year after discharge from hospital. In individual sub populations, hardly any differences could be identified with regard to mortality (Barmer GEK 2010).

■ Surgical procedures

Jaschinski et al. (2014) conducted a nationwide survey in Germany on elective total hip and knee arthroplasty based on data from hospitals that recorded a minimum of 100 primary operations in their 2010 quality reports. Chief physicians from 694 orthopedics/trauma surgery departments and the respective anesthetists were contacted in writing with the aim of gaining insight into treatment processes and medical approaches as well as obtaining suggestions for optimizing care. 31.8 % of the hospitals contacted responded. 303 questionnaires from 221 hospitals were statistically evaluated, based on which the authors concluded that the study was representative (Jaschinski et al. 2014).

50% of the surgery was performed by the chief physicians, 40% by senior physicians and approximately 10% by other physicians in senior positions (heads of division, lead physicians, assistant physicians) on the day of admission or no later than one day after admission (Jaschinski et al. 2014). Other study results show that the duration of surgery was on average 75 minutes (hip) or 85 minutes (knee) (AQUA-Institut 2012a, c, 2013a, c, 2014a, c, 2010b, c, 2011b, c). Postoperative pain management and perioperative antibiotic prophylaxis were documented for almost all patients (■ Tab. 3.7; Jaschinski et al. 2014; AQUA-Institut 2012a, c, 2013a, c, 2014a, c, 2010b, c, 2011b, c).

■ Length of stay

According to a nationwide analysis conducted in Germany by the AQUA Institute, the length of stay and the length of postoperative stay for primary THA and TKA surgery have been declining for

Tab. 3.7 Description of inpatient care for THA and TKA

Description	THA (percentage of patients)	TKA (percentage of patients)
Jaschinski et al. (2014)		
Surgery on day of admission	16%	17%
Surgery one day after admission	84%	83%
Drainage of the surgical site	93%	94%
Removal of drain on the second postoperative day	80%	83%
Pain management:		
- Opiates	97%	91%
- NSA	85%	85%
- COX-2 inhibitors	60%	58%
- Paracetamol	20%	19%
- Epidural catheter	10%	12%
- Peripheral nerve blocks	30%	91%
- Cooling	0%	37%
AQUA-Institut 2014		
Medium duration of surgery	74.5 min	85.2 min
Use of special navigation systems	1.3%	10%
Perioperative antibiotic prophylaxis	99.7%	99.7%
Application of minimally invasive surgical techniques	13.9%	1.8%
Application of surgery robots	1 case	4 cases
Source: IGES – AQUA-Institut (2012c, 2013c, 2014c, 2015d, 2010c, 2014c)		

years. In Germany, the average length of stay for a patient who has undergone a hip or knee replacement is about 5 days longer than that of a patient admitted to hospital for other reasons. From 2009 to

2013, the length of stay for THA and TKA showed a greater decline than the average length of stay for all other types of hospital treatment in Germany (Fig. 3.4 and Fig. 3.5).

Discharge from hospital

The AQUA Institute's External Quality Assurance for Inpatient Care assessment examines quality indicators for treatment (nationwide). One of the predetermined quality goals for at the time of hospital discharge is that 80% of the primary TKA patients are able to bend the knee joint by $>90^\circ$ in addition to being able to fully stretch it. In addition, two parameters for patient independence were examined: independent walking and autonomous daily hygiene (AQUA-Institut 2015d).

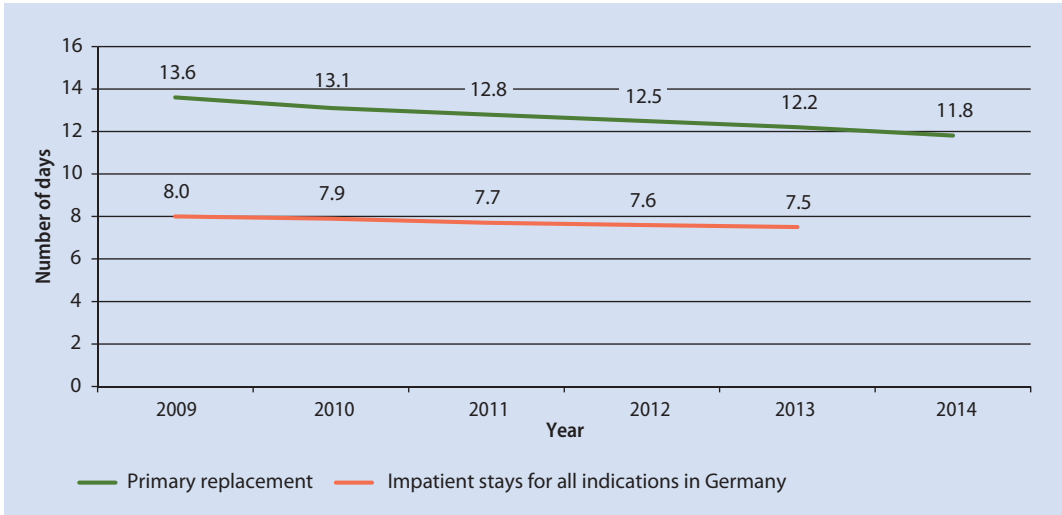
With regard to the ability to walk, it was observed in 2014 that after TKA 99.5 % of the patients were able to walk independently upon discharge (AQUA-Institut 2015d). Of the 0.4 % of patients who were unable to walk independently upon discharge, 56.6 % had been able to walk independently prior to the surgery.

In addition, the data shows that 99.4 % of patients were able to perform their daily hygiene routine independently upon discharge. Of the 0.5 % of patients who were unable to carry out their daily hygiene routine independently upon discharge, 48.8 % had been able to do so prior to surgery (AQUA-Institut 2015d).

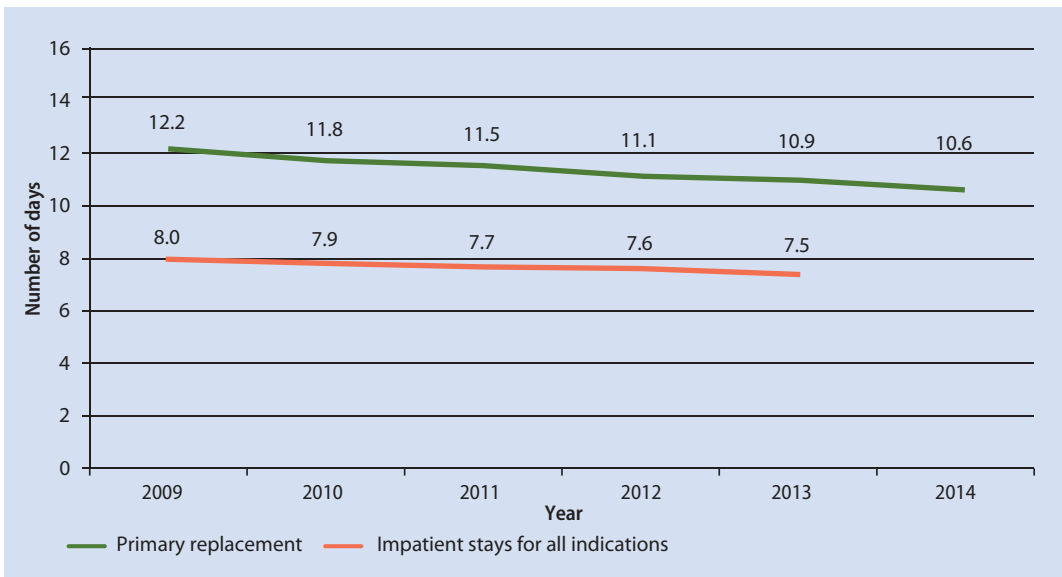
The reported ability to walk independently and to perform a daily hygiene routine upon discharge only fluctuated slightly over the past few years (AQUA-Institut 2012a, 2013a, 2014a, b, 2010b, 2011b).

A current survey of rehabilitation hospitals in North Rhine-Westphalia found that the percentage of patients who were unable to care for themselves independently was significantly higher: Only 20.4 % of the patients who had undergone TKA were able to walk on admission (> 50 m), 17 % were able to bend the operated knee by $> 90^\circ$ and a further 63 % of the patients by between 70° to 90° (Quack 2015).

The specific location into which a patient is discharged following his/her inpatient stay for primary THA can be identified based on the »Reason for discharge« documented in the External Quality Assurance for Inpatient Care assessment. Two main



■ Fig. 3.4 Length of stay for THA and in general in Germany, in days (2009–2014). (Source: IGES – AQUA-Institut 2012a, 2013a, 2014a, 2014b, 2010b, 2011b and Destatis 2015a)



■ Fig. 3.5 Length of stay for TKA and in general in Germany (2009–2014). (Source: IGES – AQUA-Institut 2012c, 2013c, 2014c, 2015d, 2010c, 2011c and Destatis 2015a)

discharge scenarios exist. In 2014, »Normal termination of treatment« was the reason provided for 47.3 % of patients and »Discharge into a rehabilitation establishment for follow-up care« for 48.3 % of the patients. This shows that about half the patients are transferred directly into rehabilitation follow-up care and almost the same number of pa-

tients is initially discharged into their home environment. This distribution of figures had been similar in the previous years (AQUA-Institut 2012a, 2013a, 2014a, b, 2010b, 2011b).

The AQUA evaluation results are in accordance with the 2010 Barmer GEK Hospital Report survey results. Amongst the patients who received a new

hip joint in 2008/2009 and who were interviewed in 2009, 48.5 % were transferred directly into a rehabilitation establishment upon discharge. 11.5 % were discharged into a home environment and 39.1 % initially went home and subsequently into a rehabilitation hospital (Barmer GEK 2010).

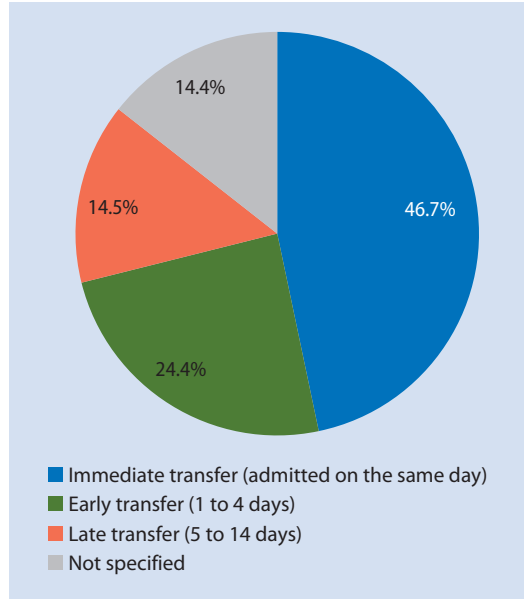
According to AQUA Institute data based on discharge after primary TKA in 2014, treatment of 50.2 % of patients was terminated normally, i.e. they were discharged to return home. 45.8 % of the patients were discharged directly into a rehabilitation facility. Further reasons for discharge were the normal termination of treatment with planned follow-up care (2.2 %), transfer to another hospital (1.1 %) and discharge to a care establishment (0.2 %) (AQUA-Institut 2015d).

The AQUA evaluation results are also confirmed by the 2010 Barmer GEK Hospital Report study results (Barmer GEK 2010). 48.2 % of the patients who underwent TKA in 2008/2009 were transferred directly into a rehabilitation hospital upon discharge. 41.7 % of the patients initially went home and were admitted into a rehabilitation hospital later. The remaining patients were discharged to return home or into another establishment.

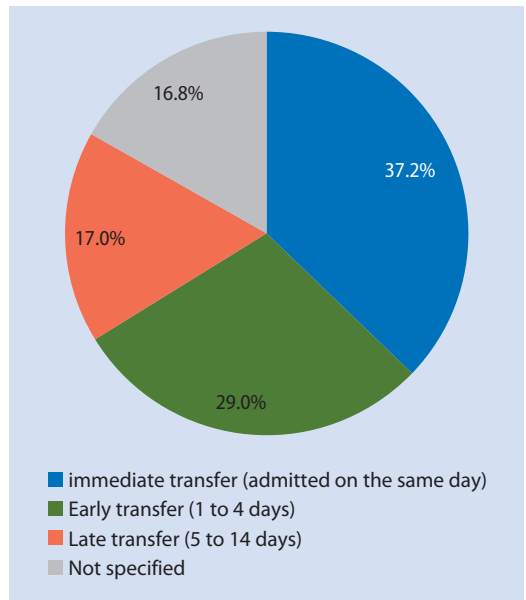
An analysis conducted by the statutory pension insurance DRV Bund elucidates that about half of THA patients and over a third of all TKA patients were transferred straight into a rehabilitation hospital after surgery (■ Fig. 3.6 and ■ Fig. 3.7).

In the 2010 Barmer GEK Hospital Report, patient surveys from 2004 and 2009 also provide data on the frequency of follow-up rehabilitation care. In the initial interview in 2009, 88.6 % of all primary hip or knee arthroplasty patients reported having undergone rehabilitation treatment. Amongst patients who had received revision surgery, the percentage was 75.6 %. In the initial 2004 survey, the values were markedly closer together (88.9 % vs. 85.7 % respectively). This report also does not provide information on whether all the surveyed patients were capable of undergoing rehabilitation and required it, so it is not apparent as to why post-operative rehabilitation did not take place.

From these different datasets, it can be concluded that not all patients actually receive follow-up rehabilitation, and not all patients are transferred from acute hospital treatment to a rehabilitation



■ Fig. 3.6 Time between hospital discharge and admission to a rehabilitation hospital following THA (2007). (Source: IGES – Deutsche Rentenversicherung Bund 2010)



■ Fig. 3.7 Time between hospital discharge and admission to a rehabilitation hospital following TKA (2007). (Source: IGES – Deutsche Rentenversicherung Bund 2010)

Tab. 3.8 Percentage of hospitals that performed primary replacement surgery and percentage of hospitals that performed revision surgery

Description	2009	2010	2011	2012	2013
Number of hospitals in Germany	2,084	2,064	2,045	2,017	1,996
Hip					
Percentage [%] of hospitals that performed primary replacements out of the total number of hospitals	55.5	55.7	54.4	54.1	53.9
Percentage [%] of hospitals that performed revision surgery out of the total number of hospitals	51.8	52.4	51.1	52.0	51.4
Knee					
Percentage [%] of hospitals that performed primary replacements of the total number of hospitals	49.0	50.2	50.4	51.2	51.7
Percentage [%] of hospitals that performed follow-up surgery of the total number of hospitals	44.6	45.6	46.0	48.0	48.7
Source: IGES – Destatis 2015a, AQUA-Institut 2011a, 2012a, 2012b, 2013a, 2013b, 2014a, 2014b, 2010b, 2011b, AQUA-Institut 2013d, 2014d, 2010d, 2011d, 2012d					

hospital »As soon as possible after achieving early mobilization« (Deutsche Rentenversicherung Bund 2009).

After the introduction of DRGs in 2003, the length of stay in acute-care hospitals reduced significantly. The »REhabilitation und DIagnosis Related Groups« study (REDIA-Studie), a prospective, multi-center, randomized, long-term study, investigated the effects of introducing DRGs into acute care on the medical service requirements and rehabilitation costs. During the observational period from 2003 to 2009, the average length of stay for THA patients, for instance, decreased by 3.6 days from 17.7 days to 13.3 days. Furthermore, during the period of study, it was observed that the patients' condition at the start of the rehabilitation phase deteriorated with regard to postoperative general condition and pain levels (van Eiff 2011).

3.3.2 Revision Total Arthroplasty

■ Capacity for provision of care

The number of hospitals in Germany that perform hip joint revision surgery based on standards set by the External Quality Assurance for Inpatient Care procedures is lower than the number of hospitals

that perform primary THA (Tab. 3.8). The absolute number of these hospitals is also decreasing, in line with trends seen in the number of hospitals in general. The percentage of hospitals that perform revision surgery after TKA shows a slight upwards trend.

The reasons why not all hospitals that perform primary replacement surgery do perform revision total arthroplasty are largely unclear. Nonetheless, endoprosthetic implant and implant component replacements are significantly more demanding technically and more complicated than primary replacements (AQUA-Institut 2014d, 2012f). Perhaps not all hospitals are capable of performing this surgery.

■ Reasons for revision total arthroplasty

Both primary replacements and/or the replacement of endoprosthetic hip implants and implant components are recorded for the External Quality Assurance for Inpatient Care procedures in Germany. Replacing an endoprosthesis may become necessary if the individual prosthesis components loosen due to wear and tear, amongst other things. In the External Quality Assurance for Inpatient Care procedures, the reasons for these replacements are documented in the form of preoperative radiological findings. The prevalence of each particular reason is

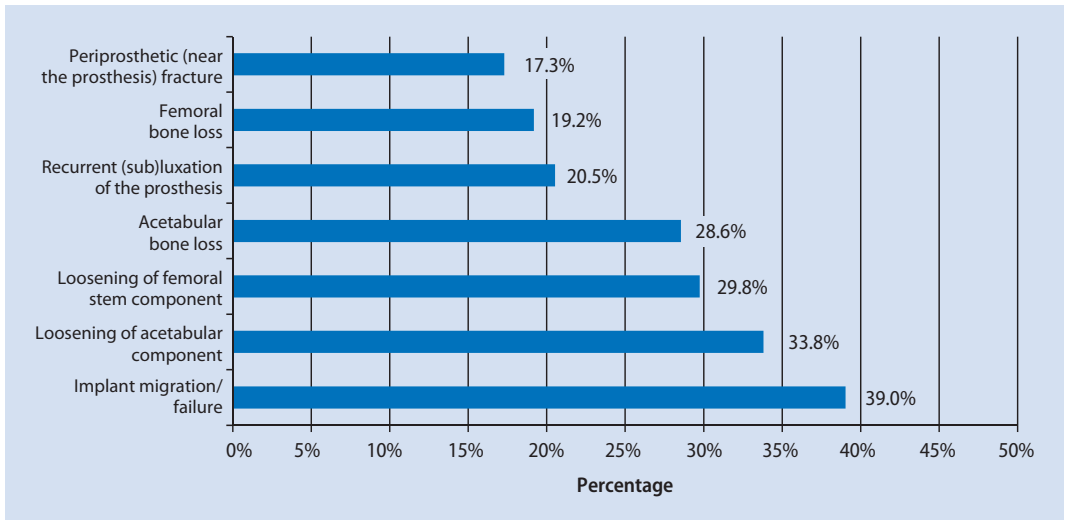


Fig. 3.8 Preoperative, radiological findings for revision THA (2014). *Multiple answers possible. (Source: IGES – AQUA-Institut 2014b)

illustrated in Figure 3.8. Based on this, significant reasons include (recurring) (sub)luxation of the endoprosthesis, implant migration, implant failure, implant or joint wear, pain, bacterial infections and inflammation of the joint (AQUA-Institut 2014b).

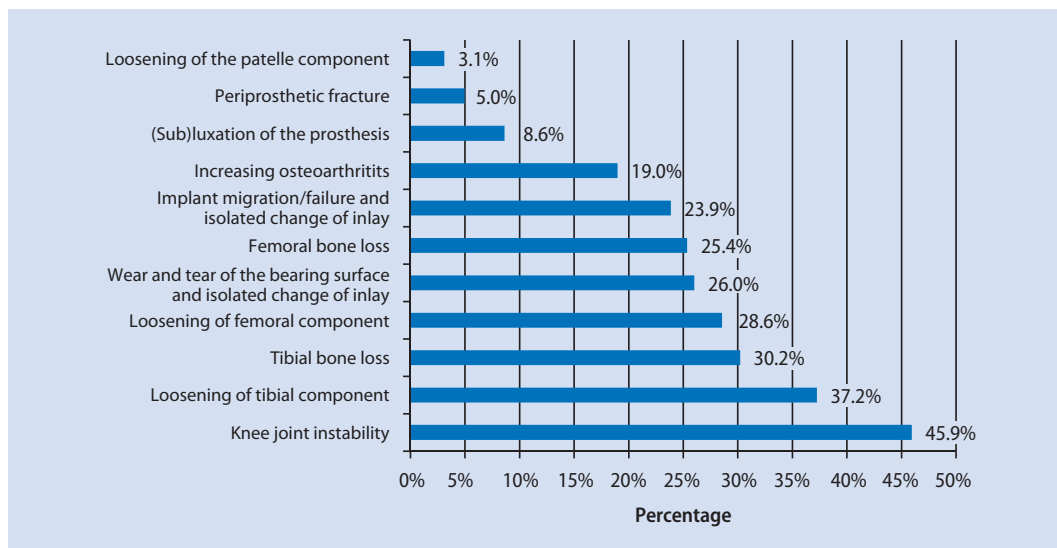
From a data interpretation perspective, it must be noted that multiple responses are possible. Loss of the femoral bone, for example, may be accompanied by a loosened femoral stem component and implant migration while a periprosthetic fracture or luxation is frequently cited as the sole indication for revision hip replacement.

A systematic review conducted by Prokopetz et al. (2012) investigated the risk factors for revision total arthroplasty after primary THA. The risk factors identified, which were consistent and statistically significant across the studies evaluated, included younger patient ages at the time of primary replacement, increased comorbidity, the presence of bone necrosis (rather than osteoarthritis) and the surgeon's experience (number of joint operations carried out) and larger femoral heads. The review does not state the size of the femoral head from which point the level of risk increases. In two of the three studies examined, the maximum femoral head size of the implanted femoral component was 28 mm (Prokopetz et al. 2012). The review conducted by Prokopetz et al. (2012) shows that alongside wear

and tear, other factors such as the surgeons' experience constitute a significant risk of revision surgery. Likewise, the revision surgery itself and the service life constitute important quality indicators for primary replacement, as well as for the overall long-term success of the treatment.

Men are at a higher risk of requiring revision total arthroplasty due to aseptic implant loosening or infection. Longer operation times constitute another risk factor for revision surgery due to infection. The results also show that smaller femoral heads (≤ 28 mm) of the femoral component constitute a risk factor for revision surgery due to dislocations (Prokopetz et al. 2012).

In the External Quality Assurance for Inpatient Care in Germany, conducted by the AQUA Institute, the replacement of knee endoprostheses and/or prosthesis components are also evaluated. All surgeries performed on patients from the age of 20 are recorded. At least one of the indication criteria in the following overview must be present for the operation to be included in the quality assurance evaluation (AQUA-Institut 2015a).



■ Fig. 3.9 Radiological findings for revision TKA in the External Quality Assurance for Inpatient Care evaluation (2014). (Source: IGES – AQUA-Institut 2015a)

Indication criteria for including cases in the quality assurance evaluation conducted by the AQUA Institute

- (Sub)luxation of the prosthesis
- Implant migration, implant failure and isolated change of inlay (OPS: 5-823.19, 5-823.27, 5-823.b0, 5-823.f0)
- Wear and tear of the bearing surface and isolated change of inlay (OPS: 5-823.19, 5-823.27, 5-823.b0, 5-823.f0)
- At least one pain criterion and at least one radiological criterion
- At least one pain criterion and at least one positive pathogen detection
- Laboratory signs of inflammation and one positive pathogen detection

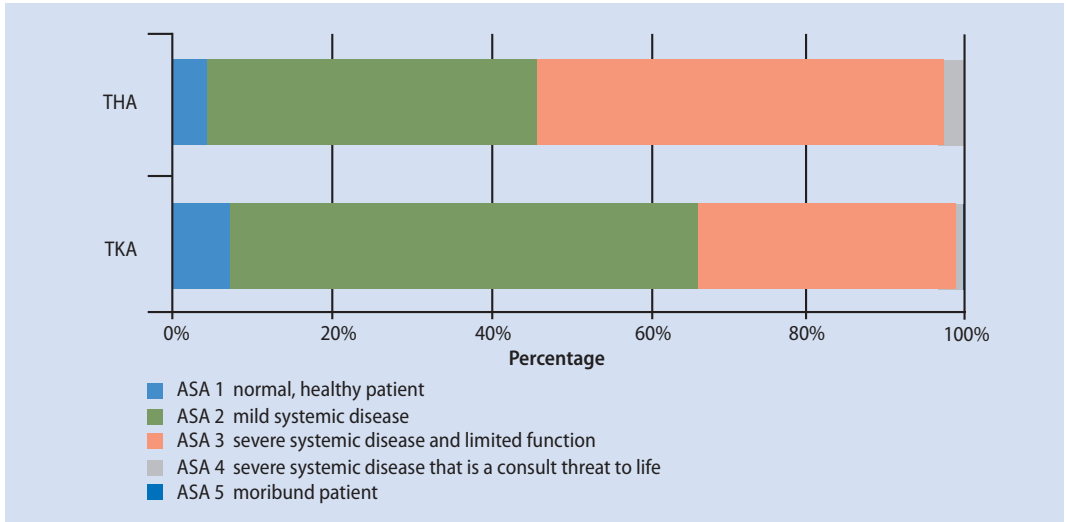
(Source: IGES – AQUA-Institut 2015a)

The common reasons for revision TKA in 2014, determined by the AQUA Institute's external quality assurance using objective radiological criteria, are shown in Figure 3.9.

The 2010 Barmer GEK Hospital Report evaluated revision hip and knee joint surgery data recorded

until the end of 2009, based on patients who had undergone THA and TKA between 2006 and 2008. Within 90 days after discharge from hospital, 1.0 % of THA patients and 0.6% of TKA patients consequently had to undergo surgery on the same side, i.e. revision surgery including revisions without replacements. Within one year following primary replacements, 2.0% of THA patients and 3.7% of patients with osteoarthritis who were being followed up underwent another operation on the same joint. In a small group of patients with atypical diagnoses, the revision rate was 6% (Barmer GEK 2010). A survey based on routine data from the SHI Techniker Krankenkasse found that 3.5% of patients after primary THA and 3.8% of patients after primary TKA underwent revision total arthroplasty within the first two years (Linder et al. 2012).

The correlation between the time of revision surgery and the quality of the resulting outcome was investigated in a further study (Hardeman et al. 2012). Early revision total arthroplasty taking place less than two years after primary replacement had higher failure rates than revision total arthroplasty carried out later. Better results were observed in older patients (> 65 years) and in partial revision surgery. Patients with low KSS scores (Knee Society Score) before revision total arthroplasty also had



■ **Fig. 3.10** ASA classification of revision THA and TKA recorded for the External Quality Assurance for Inpatient Care evaluation (2014). ASA = American Society of Anesthesiology. (Source: IGES – AQUA 2015c, e)

lower scores after the revision. However, the improvement in score in this group was significantly higher than for patients who had had higher values at the start of the study (Hardeman et al. 2012).

■ Perioperative risk

The 2014 quality assurance of inpatient care analyses recorded ASA classifications, which are aimed at giving a point of reference in the assessment of perioperative risk. Here, the analyses indicated that the majority of patients who underwent revision THA were allocated to ASA class 3 (patients with severe systemic disease and functional limitations) (50.5%). Patients who underwent revision TKA were proportionately more frequently grouped into class 2 (mild systemic disease) (52.7%) (■ Fig. 3.10). Compared to primary replacement (hip and knee), patients undergoing hip or knee revision surgery often have a higher ASA score (AQUA-Institut 2015c). Differences in ASA scores between primary and revision surgery patients are particularly due to the higher average age of hip replacement patients and hence also associated with a higher age-related comorbidity.

■ Surgical procedures

Compared to primary replacements, revision total arthroplasty is described as technically more demanding and more complicated (Claes et al. 2012;

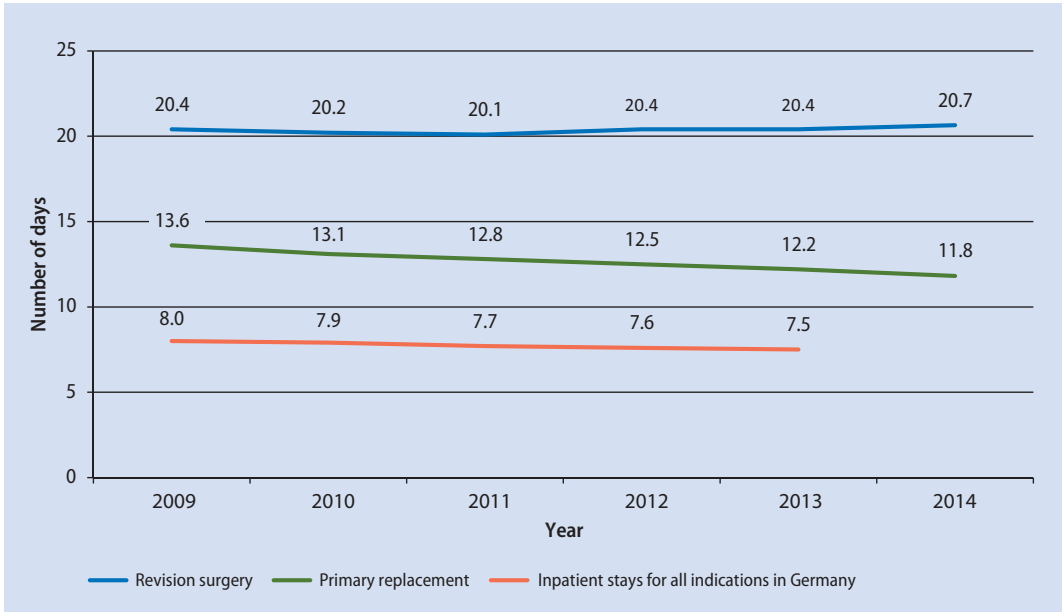
Wirtz 2011). The surgeon performing the procedure has to take into account primary replacement surgery, the procedure and materials used. The current status of the patient, in particular with regard to the periarticular status (bone structure, soft tissue) must also be taken into account. If an infection is suspected, additional laboratory tests must be conducted. In contrast to primary replacements, the entire joint may not need replacing but potentially only the defective parts. Both cemented and uncemented fixation of the new endoprosthesis are possible (AQUA-Institut 2012f).

According to information from the External Quality Assurance for Inpatient Care assessments, the average duration of both revision THA and TKA has been about 2 hours for several years, which is considerably longer than the time taken for primary replacements (75 or 85 minutes) (AQUA-Institut 2010a, 2011a, 2012b, 2013b, 2014b, 2015d).

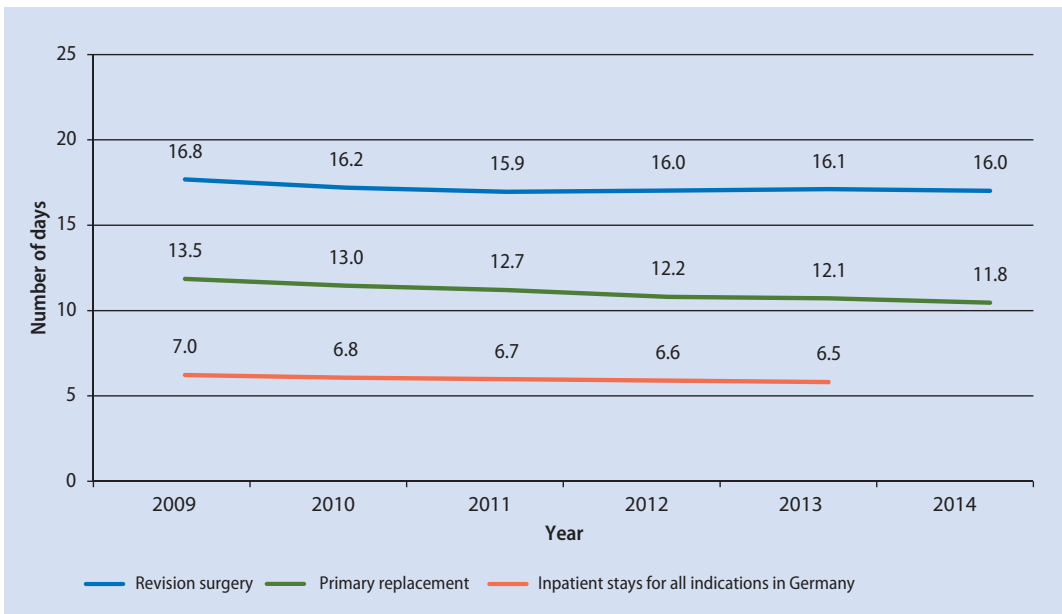
■ Length of stay

Patients undergoing revision total arthroplasty usually have a considerably longer length of hospital stay than for primary replacements.

Just as is the case for primary TKA, the length of stay in hospital after revision TKA is longer (by approximately 8 days) than the general average length of stay in German hospitals. After revision surgery,



■ Fig. 3.11 Length of stay of patients undergoing revision surgery, primary THA, and the average length of stay in Germany, in days. Note: At the time of writing, the average length of stay in Germany for 2014 was not yet available. (Source: IGES – AQUA-Institut 2010a, 2011a, 2012b, 2013b, 2014b and Destatis 2015a)



■ Fig. 3.12 Mean length of stay in days for revision surgery after TKA, 2009 to 2014. Note: At the time of writing, the average length of stay in Germany for 2014 was not yet available. (Source: IGES – AQUA-Institut 2013d, 2014d, 2015e, 2010d, 2011d, 2012d and Destatis 2015c)

patients remained in hospital for 3 to 4 days longer than after primary replacement surgery (■ Fig. 3.11 and ■ Fig. 3.12).

■ **Discharge from hospital**

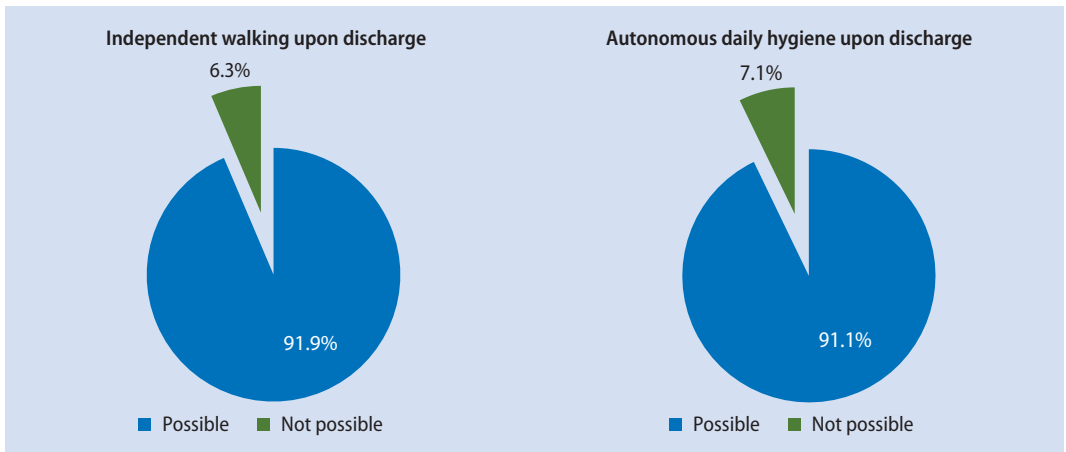
In Germany, patient independence upon discharge after revision total arthroplasty differed from patient independence after primary total arthroplasty.

With regard to THA, more patients were unable to walk independently or perform daily hygiene independently upon discharge after revision THA than after the primary replacement (6.3 % vs. 0.4 %

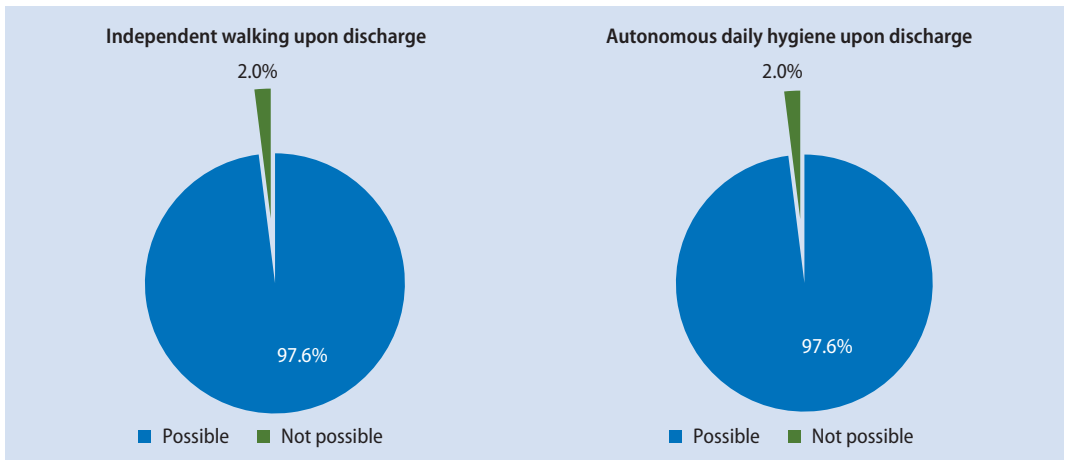
and 7.1 % vs. 0.5 % respectively) (■ Fig. 3.13 and Section 3.3.1).

As with primary arthroplasty, the results showed only minor variations over the previous years (AQUA-Institut 2010a, 2011a, 2012b, 2013b, 2014b, 2015c).

97.6% of patients who had undergone revision TKA were able to walk independently upon discharge (99.5% after primary arthroplasty) (AQUA-Institut 2015e). 97.6% of the patients were able to perform their daily hygiene themselves upon discharge (primary arthroplasty: 99.4%) (■ Fig. 3.14).



■ Fig. 3.13 Ability to walk independently and carry out autonomous daily hygiene after revision THA at the time of discharge in 2014. (Source: IGES – AQUA-Institut 2015c)



■ Fig. 3.14 Ability to walk independently and to carry out autonomous daily hygiene after revision TKA at the time of discharge in 2014. (Source: IGES – AQUA-Institut 2015e)

■ **Tab. 3.9** Reasons for discharge following primary and revision total arthroplasty (2014)

Reasons for discharge in 2014 (acc.to § 301 Volume V German Social Security Code)	Primary THA	Revision THA	Primary TKA	Revision TKA
Discharge into a rehabilitation establishment (%)	48.3	32.1	45.8	32.9
Treatment ended normally (%)	47.3	52.6	50.2	59.0
Transfer to another hospital (%)	1.4	5.6	1.1	2.6
Discharge into nursing care (%)	0.3	3.7	0.2	0.9
Death (%)	0.2	1.8	0.1	0.4

Source: IGES – AQUA-Institut 2015b, 2015c, 2015d, 2015e

The External Quality Assurance for Inpatient Care assessment shows that as with primary replacement, only a small number of patients are transferred straight into a rehabilitation facility after revision surgery (■ Tab. 3.9).

3.3.3 Accompanying Measures during Inpatient Stay

■ Pain management

Regardless of the surgical access route, endoprosthetic surgery for osteoarthritis of the hip (THA) and osteoarthritis of the knee (TKA) is associated with a high intensity of pain (Laubenthal and Neugebauer 2009). Effective pain management contributes to improved convalescence, rapid mobilization and a reduced rate of complications such as deep vein thrombosis (DVT) (Simanski 2008). Pain management comprises pre-, intra- and postoperative phases and also plays an important role for the patients« in long-term ambulatory care (Laubenthal and Neugebauer 2009).

Particularly after TKA, individually tailored and continuous pain management is considered crucial in the success of treatment. Various studies show that continuous postoperative pain management is better relative to single injections or to the administration of medication as required. Moreover, it has been demonstrated that continuous analgesia by means of peripheral catheter procedures reduces the use of postoperative morphine and contributes to quicker rehabilitation compared to single injections.

In addition, evidence shows that peripheral catheter procedures can lead to early mobilization and better functionality compared to the general administration of systemic opioids (Cappelleri et al. 2011).

The S3 guideline »Treatment of acute perioperative and posttraumatic pain«¹ recommends the use of non-opioid analgesics after both THA and TKA for pain management after discharge from hospital (Laubenthal and Neugebauer 2009). Randomized studies have demonstrated the effectiveness of conventional, non-steroidal antiphlogistics and non-opioid analgesics, such as paracetamol for postoperative pain control (Lohom et al. 2002; Peduto et al. 1998; Silvanto et al. 2002). For high intensity pain these can be combined with strong opioids in multimodal analgesic therapy (Simanski 2008).

■ Thromboprophylaxis

Besides appropriate pain management and mobilization, thromboprophylaxis plays an important role in THA and TKA procedures. Hip and knee joint replacements are amongst the primary causes of venous thromboembolism (VTE) (European Society of Cardiology 2014). VTE includes deep vein thrombosis (DVT) and pulmonary embolism (PE), which are the most serious complications of DVT. The PE mortality rate within the first few weeks following THA is between 0.09 % and 0.19 % (Fender

1 The implementation of the S3 guideline on the »Treatment of acute perioperative and posttraumatic pain« is currently under review.

et al. 1997; Howie et al. 2005; Khan et al. 2007; Shepherd and Mills 2006).

Thrombosis is a vascular disease that occurs when a blood vessel is narrowed or occluded by a blood clot. Causes include damage to the vascular walls through surgery (Perka 2011). In order to avoid such complications, blood coagulability is reduced through medication (anticoagulation) (AWMF 2015). Anticoagulants are used to inhibit the growth of the thrombus and constitute a prerequisite for physiological fibrinolysis which dissolves the thrombus. The period of risk period associated with VTE begins with surgery. Several days or weeks can elapse before a thrombus develops and as a result most cases of symptomatic vein thrombosis occur after the inpatient stay. As a result, thromboembolism prophylaxis is also necessary after discharge (AWMF 2015).

Although in principle VTE is associated with all types of surgery, orthopedic patients are at a higher risk owing to the activation of coagulation due to tissue and bone injuries, vein damage, immobilization and heat generation from the use of bone cement (Perka 2011). Further distinctive factors include advanced age (above 60 years), weight (BMI > 30), tumor diseases and previous venous thromboembolism in the patient or the patient's family history (AWMF 2015, Cionac Florescu et al. 2013; Falck-Ytter et al. 2012).

Without thromboprophylaxis, approximately 40 %–60 % of all patients who undergo elective THA and TKA develop VTE (Perka 2011). With thromboprophylaxis, this is reduced to 1.09 % in patients who undergo knee replacement surgery and 0.53 % of patients who undergo hip replacement surgery (Januel et al. 2012).

■ ■ Pharmacological VTE prophylaxis

The rate of VTE complications can be reduced significantly through medication (AWMF 2015) (European Society of Cardiology 2014; Falck-Ytter et al. 2012). Pharmacological prophylaxis can also be accompanied by physical and mobilization measures to further reduce the risk of VTE. The same approach should be taken for VTE prophylaxis for both inpatient and ambulatory care. Certain guidelines recommend pharmacological prophylaxis for hip joint surgery over a period of 28 to 35 days and

for at least 10 to 14 days after knee joint surgery (AWMF 2015; Falck-Ytter et al. 2012). For TKA, the current American College of Chest Physicians (ACCP) guidelines recommend extending pharmacological prophylaxis for a period of up to 35 days after the inpatient stay (Falck-Ytter et al. 2012). If the VTE risk is increased, especially due to additional concomitant diseases, VTE prophylaxis should be continued for as long as the disease persists (AWMF 2015).

A recent prospective study by Jorgensen et al. indicates that thromboprophylaxis for the duration of inpatient stay is sufficient for patients who are treated according to a »fast track« THA and TKA treatment concept, and that there are no additional benefits exist in continuing the treatment during ambulatory care (Jorgensen et al. 2013). In this study, approximately 4,700 patients with a length of stay of ≤ 5 days received VTE prophylaxis. During the 90 day follow-up period, thromboembolic events occurred in 0.84 % of the patients and VTE was found in 0.41 %. These complication rates correspond to those observed in other studies in which VTE prophylaxis was conducted over a longer period. However, due the study design, it cannot be ultimately concluded that conducting VTE prophylaxis solely during the period of inpatient stay is sufficient. The study by Jorgensen et al. did not compare its findings with an internal control group but with data from different studies in which the patient populations might have differed with regard to relevant risk factors (e.g. comorbidity, immobilization, length of stay).

Currently recommended, effective VTE pharmacoprophylaxis after joint replacement includes factor Xa inhibitors, (low-molecular-weight) heparins (LMWH), thrombin inhibitors, vitamin K antagonists (VKA) and other anticoagulants (AWMF 2015; European Society of Cardiology 2014).

Acetylsalicylic acid should not be used as a monotherapy due its low prophylactic effect against VTE compared to the other medications mentioned above (AWMF 2015; Falck-Ytter et al. 2012). The Association of the Scientific Medical Societies in Germany (AWMF) does not recommend the use of VKA such as warfarin and phenprocoumon, after taking into consideration the effectiveness and the risk of bleeding compared to the heparins (Encke et

al. 2015). The AWMF refers to a study conducted by Samana et al., amongst others, which demonstrated that there was no difference between VTE prophylaxis with warfarin or LMWH in patients with hip surgery with regard to DVT rates, but that the patients treated with warfarin showed a much higher prevalence of bleeding complications (5.5 % versus 1.4 %) (Samana et al. 2002). In contrast, the ACCP and European Society of Cardiology (ESC) guidelines advocate the use of VKA for VTE prophylaxis (European Society of Cardiology 2014; Falck-Ytter et al. 2012).

Contraindications for thromboprophylaxis are: the known risk of bleeding, hemorrhagic and ischemic strokes within the previous six months and gastrointestinal bleeding within the previous month (European Society of Cardiology 2014). If contraindications exist, intermittent pneumatic compression (e.g. foot, calf and thigh) should instead be used for patients who have had THA and physical measures (e.g. medical compression stockings) for patients after TKA (AWMF 2015).

■ ■ Bleeding risk in patients on anticoagulant therapy

The primary risk of anticoagulant therapy for VTE prophylaxis is bleeding, which accounts for 2 % to 3 % over a period of 3 months (Scherz et al. 2013). Specific patient characteristics that are associated with an increased bleeding risk during anticoagulant therapy are renal failure, a history of bleeding and a simultaneous intake of platelet aggregation inhibitors (Decousus et al. 2011; Falck-Ytter et al. 2012). The level of risk doubles in older patients (≥ 65 years) compared to younger patients (Spencer et al. 2008).

Different scoring methods have been developed to assess an individual patient's risk of bleeding (Beyth et al. 1998; Kearon 2003; Kuijjer et al. 1999; Ruíz-Giménez et al. 2008). These scores stratify the patients according to their bleeding risk. However, these risk scores have not been sufficiently tested in patients in orthopedic surgery (Falck-Ytter et al. 2012), and do not differentiate between low and high bleeding risks precisely enough, particularly in older patients (≥ 65 years) (Scherz et al. 2013). Hence, there is a need to develop and validate tools to stratify risks in patient populations after THA and TKA.

■ Physiotherapeutic measures and mobility

In general, physiotherapeutic and physical therapies such as balneotherapy, massage, gait training and cooling should be carried out after joint surgery. According to the S3 guideline »Prophylaxis of venous thromboembolism (VTE)« further physical measures for the preventing VTE include medical compression stockings, e.g. thigh-length and knee-length stockings that increase venous blood velocity and consequently prevent thrombus formation. Such measures are particularly prudent when a contraindication for pharmacological VTE prophylaxis exists, e.g. due to an increased bleeding risk (AWMF 2015).

Physiotherapy aims to assist mobilization and in the prevention of functional impairments, as well as in pain relief, and therefore an integral part of comprehensive pain management regimes (Laubenthal and Neugebauer 2009). A recent review showed that particularly early mobilization (defined as »getting out of bed« and »walking« as soon as possible after hip or knee replacement surgery) can result in shortening the length of stay by approximately 2 days (Guerra et al. 2015; Tayrose et al. 2013). Moreover, improvements were noted with regard to free movement, muscle power and health-related quality of life. Undesired events caused by early mobilization, such as hemodynamic instability or the increased risk of falling, did not occur significantly more frequently when compared to control groups without early mobilization (Guerra et al. 2015). Other studies were able to demonstrate lower risks of DTV, PE, chest infections and urinary retention during early mobilization (Renkawitz et al. 2010).

3.3.4 Complications

Intra- and postoperative surgical complications during inpatient stays are recorded for the External Quality Assurance for Inpatient Care assessments in Germany. The case rates for primary total arthroplasty in 2014 are summarized in ■ Tab. 3.10.

The documented rate of operations that involved at least one complication during the inpatient stay lies in the single-digit percentage range. Over the last few years, this rate has been declining, as has the rate of all cases, except for fractures. How-

Tab. 3.10 Intra-/postoperative surgical complications requiring treatment after primary and revision total arthroplasty during hospital stays in Germany in 2014

Intra-/postoperative surgical complications requiring treatment	Primary THA	Revision hip	Primary TKA	Revision knee
Number of operations with at least one complication (%)	2.76	9.00	1.91	4.29
Malposition of the implant (%)	0.05	0.19	0.03	0.12
Dislocation of the implant (%)	0.10	0.40	0.03	0.06
Luxation of the endoprosthesis (%)	0.27	1.94	–	0.09
Misalignment of the patella (%)			0.02	0.1
Wound hematoma/postoperative bleeding (%)	0.86	2.95	0.86	2.17
Vascular lesion (%)	0.03	0.16	0.02	0.07
Nerve damage (%)	0.25	0.56	0.1	0.09
Fracture (%)	0.82	1.73	0.15	0.39
Other (%)	0.54	2.09	0.8	1.69

Source: IGES – AQUA-Institut 2015b, 2015c, 2015d, 2015e

ever, a change in the counting method since 2013 (number of operations rather than of patients) only permits a limited comparison with the case rates in previous years.

The percentage of patients with at least one general postoperative complication that required treatment following joint replacement (primary and revision surgery) is in the single digit range, as with the rates for the other cases (Tab. 3.11).

Compared to 2009, a decline in the rate of postoperative wound infections can be observed, although the overall case rates (other wound infections) stagnated or rose during the same period (Tab. 3.12).

In addition, for primary arthroplasty, it is important to note the rate of registered, revision surgery required resulting from complications related to hip endoprostheses during the inpatient stay. This also showed a decrease from 2009 (1.7 %) to 2014 (1.4 %). The rate of revision surgery required due to complications with the knee endoprostheses ranged between 1.4 % of patients in 2009 and 0.87 % of patients in 2012. In 2013 and 2014, revision surgery due to complications was at 1.3 % and/or 1.15 % for hip and knee surgery respectively.

Tab. 3.13 and Tab. 3.14 show that the rate of complications in revision total arthroplasty is several times higher than the rate of complications in primary replacements. The same applies to the rate of registered, revision surgery required due to complications. For revision total arthroplasty, these varied between 5.6 % and 7.5 % between 2009 and 2014. In contrast to primary replacements, a noticeable declining trend in case rates is not apparent. It should be noted that the rate of complications mentioned so far refer to the period during which the patient is treated in an acute-care hospital.

Up to a third of the complications following hip joint replacements occur after an inpatient stay, as shown by an analysis conducted by the AOK Research Institute (Wissenschaftliches Institut der AOK, WiDO) (Jeschke and Günster 2014). The analysis used AOK routine data while conducting »Quality Assurance with Routine Data« procedures (Section 3.3.4)

The evaluation included 154,470 patients from 930 hospitals who had undergone primary hip joint replacements (THA and partial replacements) between 2007 and 2009 whose treatment diagnosis

3.3 · Inpatient Care

Tab. 3.11 General postoperative complications requiring treatment following primary and revision total arthroplasty during hospital stays in Germany in 2014

General postoperative complications requiring treatment	Primary hip replacement	Revision hip	Primary knee replacement	Revision knee
Number of patients with at least one complication (%)	2.92	7.98	3.02	4.91
Pneumonia (%)	0.16	0.86	0.17	0.38
Cardiovascular complications (%)	0.67	2.44	0.62	1.22
Deep vein thrombosis in leg/pelvis (%)	0.09	0.16	0.40	0.26
Pulmonary embolism (%)	0.08	0.28	0.17	0.24
Other (%)	2.11	5.40	1.89	3.31

Source: IGES – AQUA-Institut 2015b, 2015c, 2015d, 2015e

Tab. 3.12 Postoperative wound infection after primary and revision total arthroplasty during inpatient stays in Germany in 2014

Postoperative wound infection	Primary hip replacement	Revision hip	Primary knee replacement	Revision knee
Surgery with wound infections (%)	0.42	4.18	0.26	1.8
Of which according to CDC classification:				
A1 (superficial infection) (%)	39.47	22.56	53.22	24.92
A2 (deep infection) (%)	53.02	66.61	38.01	60.57
A3 (cavities/organs) (%)	7.51	10.83	8.77	14.51

Source: IGES – AQUA-Institut 2015b, 2015c, 2015d, 2015e

Tab. 3.13 Rate of complications after acute-inpatient treatment following hip joint replacement

Quality indicator	Total number of cases (n)	Follow-up observation period (%)	Inpatient phase primary replacement (%)	Overall period (%)
Revision surgery within 365 days	149,637	1.88	1.65	3.53
Surgical complications within 90 days	152,567	1.96	5.29	7.25
Thrombosis/pulmonary embolism within 90 days	152,354	0.43	0.69	1.12
Femoral fracture within 90 days	152,885	0.25	1.74	1.99
Mortality within 90 days	154,220	0.48	0.43	0.91
Complication index*	154,240	3.36	7.73	11.09

* Sum of individual quality indicators, cases in which a patient had several complications were counted as a single event.

Source: IGES – Jeschke and Günster 2014

■ Tab. 3.14 Postoperative complications of AOK patients after TKA

Description	Patients	Percentage [%]
Total	40,483	100
Pneumonia	149	0.4
Pulmonary embolism	215	0.5
Thrombotic events	828	2.0
Bleeding complications	5,267	13.0
Ventilation for over 24 h	69	0.2
Postoperative infection	143	0.4
Other postoperative complications	514	1.3
Complications through orthopedic endoprotheses, implants or transplants	689	1.7
Luxation, sprain and strain of the knee joint and knee joint ligaments	67	0.2

Source: IGES – WiDO 2007

was documented as »osteoarthritis of the hip« (97 % of patients). Patients who had already undergone a hip joint replacement two years prior to the index surgery were excluded, as well as hospitals with fewer than 30 cases in the above-mentioned period (■ Tab. 3.13).

With regard to primary replacements, the study shows that complications caused by the surgery can especially develop in the period of up to 90 days following discharge from hospital. The »Surgical complications« quality indicator was defined by the ICD-10 diagnosis codes »Luxation« (ICD-10: S73), »Complications of internal orthopedic prosthetic devices« (ICD-10: T84.0/5/8/9) and »Complications of procedures« (ICD-10: T81.2/3/5/8/9). The evaluation primarily investigated the connection between complications occurring during inpatient stays and during the follow-up period of observation. The publication makes the following general statement: »With regard to hospital-related complications, barely any links can be observed between the events during the initial inpatient stay and during the follow-up period for any of the indicators investigated [...]« (Jeschke and Günster 2014).

Similar analyses are available for knee endoprotheses. The Federal Association of the AOK's final 2007 report on the Quality Assurance of Hos-

pital Care using Routine Data (QSR) analyzed 2003 routine data of postoperative complications of AOK insureds who had undergone knee replacements (bicondylar surface replacement prosthesis or hinged endoprosthesis) (WiDO 2007). In total, data from 40,483 patients who had undergone knee joint replacements in 2003 were analyzed (73.8 % women, average age of 70.1 years). Patients of 30 years of age or younger were excluded. The most frequently documented complications were general surgical risks, such as bleeding or a thrombotic event (■ Tab. 3.14).

During the inpatient stay, revision TKA with replacement or removal was performed in 0.3 % of the patients (WiDO 2007).

An analysis based on pre-defined reasons for readmission to hospital showed that in the first year after TKA, 1.8 % of patients were readmitted for revision with replacement or removal of the prosthesis. Revisions without replacement or removal were performed on an inpatient basis in 0.6 % of patients within the period of one year (WiDO 2007).

3.4 Rehabilitation

According to § 26 of the German Social Security Code Volume IX, the overall goals of medical rehabilitation services are:

1. To prevent, overcome, minimize, stabilize and inhibit the deterioration of a disability, including chronic disease.
2. To avoid, overcome and minimize restrictions in the ability to work, reduce nursing care requirements, prevent deterioration of the disability and thwart a premature need for continuous social security benefits and/or reduce the amount of ongoing social security benefits.

Medical rehabilitation comprises treatment by the physician, drugs and wound dressings, therapeutic products, orthopedic devices and other medical technical aids and if necessary, endurance tests. The major medical rehabilitation payers are statutory health insurances (SHI), the German Statutory Pension Insurance (Deutsche Rentenversicherung (DRV)) and the German Statutory Social Accident Insurance (Deutsche Gesetzliche Unfallversicherung (DGUV)). According to the German Social Security Code Book policy »Rehabilitation before Nursing Care«, statutory health insurances are obliged to fund rehabilitation treatment for patients who are no longer of working age. The DRV funds treatment for patients of working age according to the »Rehabilitation Before Pension« policy (Kladny 2013).

Rehabilitation measures that are initiated without prior hospital treatment are termed »Heilverfahren (HV)« (curative procedure) in German. Rehabilitation after surgery is termed »Anschlussrehabilitation« or »Anschlussheilbehandlung (AHB)« (subsequent rehabilitation). Socio-medical prerequisites for subsequent rehabilitation (AHB) are that the diagnosis is included in the AHB indication group list, that there is an existing need of rehabilitation, that the patient is able to undergo rehabilitation and a has positive rehabilitation prognosis. »Status post endoprosthetic surgery of the hip joint, knee joint, shoulder joint and the ankle joint« is considered to be a diagnosis eligible for subsequent rehabilitation (AHB). Further prerequisites for subsequent rehabilitation (AHB) are that rehabilitation

is to be conducted »Subsequent to postoperative care« and that »Persistent postoperative functional restrictions« exist (Deutsche Rentenversicherung 2005).

The German Statutory Pension Insurance considers patients to be in need of rehabilitation if the ability to work is severely jeopardized or already impaired. Statutory health insurances consider patients to be in need of rehabilitation if everyday functions are impaired for a longer period of time than normal. If there is solely residual muscle weakness and restriction of movement, ambulatory therapeutic products and functional training are deemed sufficient (Maier-Börries and Jäckel 2013). An indication for postoperative rehabilitation should therefore be made if patients have restrictions in performing activities of daily living and participating in daily life, which require medically led and supervised interdisciplinary multimodal treatment.

A patient's ability to undergo rehabilitation encompasses both the physical and psychological ability to use all of the therapeutic services offered as well as a willingness to do so. A patient undergoing rehabilitation treatment must

- have undergone early mobilization and be able to eat without assistance, wash themselves and to move about in the ward;
- be strong enough to endure effective rehabilitation treatment;
- be motivated and have the mental capacity and necessary physical strength to actively participate in rehabilitation treatment (DRV-Indikationsliste AHB).

Overall basic prerequisites for inpatient rehabilitation treatment after hip and knee replacement surgery usually include:

- non-irritated wound without any indication of local infection,
- being predominantly independent with regard to the most important activities of daily living (Barthel ADL index score of at least 65),
- having sufficient and safe mobility, at least for short walking distances in the ward (with the help of walking aids),
- having already attained minimum satisfactory functionality of the operated joint:

- hip: extension/flexion 0/0/80°
- knee: extension/flexion 0/5/80–90°,
- having sufficient personal motivation to undergo rehabilitation and
- being in a sufficient cognitive state (no severe dementia).

The aim of subsequent rehabilitation (AHB) is to prepare the patients for the demands of their everyday and working lives. An important focus is the regain of lost functions and/or learning to compensate for them as much as possible. Rehabilitation prognosis is an assessment of the likelihood of a patient reaching set rehabilitation goals. Reaching of these goals must be highly likely, and should take into consideration both the type as well as the duration of the treatments required in order to enable the patient to participate in daily life.

Ambulatory rehabilitation services have received special funding with the range of services having been expanded over the past few years (Deutsche Rentenversicherung Bund 2009) which are based on certain legal requirements (cf. § 19, section 2, Volume IX of the German Social Security Code). Prerequisites for participation in ambulatory rehabilitation are that patients are physically and emotionally capable and have a degree of mobility that is higher than the degree required for inpatient rehabilitation. Patients must be able to reach the facility by means of public transport within a reasonable amount of time. The following aspects support the case for inpatient rehabilitation (Heisel and Jerosch 2007):

- walking distance under 100 m,
- use of public transport and use of a private vehicle not possible,
- danger of falling due to insecure gait,
- unable to climb stairs,
- increased need of nursing care,
- provision of care at home not guaranteed,
- comorbidities in need of treatment,
- driving distance to an ambulatory rehabilitation center of longer than 30 minutes.

Applications for subsequent rehabilitation (AHB) are made by the treating physician on behalf of the patient. Consequently, the applicant is the person undergoing rehabilitation. The physician is respon-

sible for assessing the necessary prerequisites and for making recommendations for the need for subsequent rehabilitation (AHB) to the relevant social insurance institution.

Existing data with regard to (medical) rehabilitation is generally considered to be very limited, fragmented and in need of improvement (Augurzky et al. 2011; SVR Gesundheit 2014). The following chapters aim to portray the circumstances for patients who have undergone total arthroplasty.

3.4.1 Therapy Recommendations and Standards

In general, hardly any guidelines exist with recommendations for specific rehabilitation therapy for individual diseases (SVR Gesundheit 2014). However, extensive textbooks (Heisel and Jerosch 2007; Imhoff et al. 2015; Stein and Greitemann 2015) and specific scientific publications (Heisel 2012; Kladny 2007; Rupp and Wydra 2012) exist which describe the basics in detail.

The German Statutory Pension Insurance (DRV) has developed standards for subsequent rehabilitation (AHB) therapy following THA and TKA. These standards constitute part of the DRV's quality assurance. They differ from the general guidelines in that they do not include any therapy algorithms. They aim to put forward »Evidence-based care provision of therapeutic rehabilitation services«. The standards are predominantly based on scientific guidelines, literature reviews, expert surveys as well as on an analysis of rehabilitation services that have actually been covered in Germany by the pension insurance (Deutsche Rentenversicherung Bund 2010). The standards apply to both THA and TKA indication fields. Evidence-based treatment modules (ETM) were derived from this. These individual modules include a list of services in accordance with the standardized classification of therapeutic services (KTL) with a minimum of specific ETM (Deutsche Rentenversicherung Bund 2011). Fields of major significance include movement therapy, training in activities of daily living, as well as educating patients in matters related to total arthroplasty and health (▣ Tab. 3.15).

Tab. 3.15 Evidence-based rehabilitation therapy standards for THA and TKA developed by the German Statutory Pension Insurance

ETM	Description	Minimum percentage of patients to be treated accordingly (%)
01	Movement therapy	90
02	Activities of daily living training	90
03	Physical therapy	50
04	THA/TKA patient education	80
05	Health education	80
06	Nutritional education	20
07	Psychological counseling and therapy	10
08	Relaxation training	10
09	Social and social security law counseling	30
10	Job integration support	20
11	Follow-up care and social integration	50

ETM = Evidence-based therapy modules

Source: IGES – Deutsche Rentenversicherung Bund (2011)

3.4.2 Provision of Care

In 2014, almost 2 million patients underwent inpatient rehabilitation. No explicit data is available for the indications and case numbers for hip and knee joint replacements. In 2014, there were 399 rehabilitation hospitals with specialist orthopedic departments in Germany which treated approximately 650,000 patients in total (Destatis 2014).

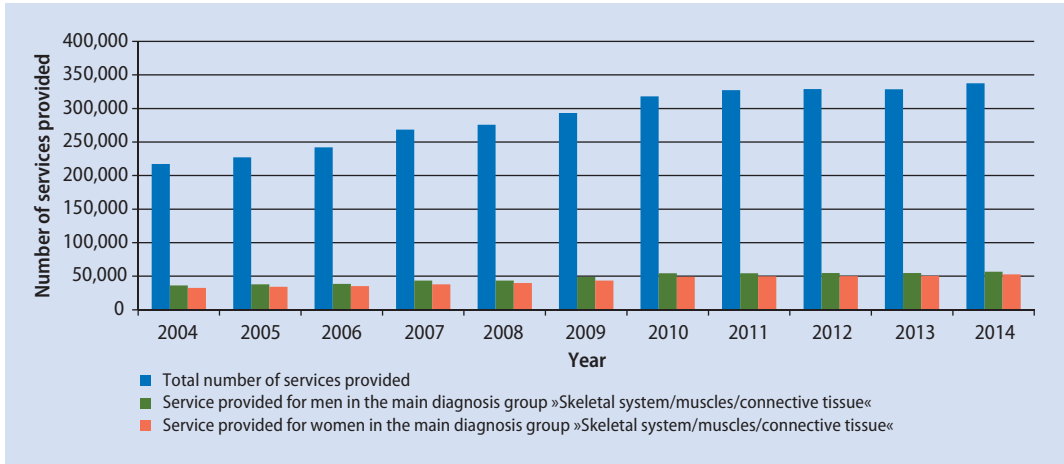
For some indications, particular emphasis is placed on the importance of having access to rehabilitation services close to the patient's domicile, as this allows for incorporating family and social environments into the treatment. However, rehabilitation does not necessarily take place close to a patient's home. The German Statutory Pension Insurance figures for 2014 demonstrate that, within the country, a patient's domicile and the rehabilitation hospital are not always in the same region. For example, many patients living in Berlin, Hamburg or Bremen undergo inpatient rehabilitation treatment in other federal states, while, on the other hand for example, more patients undergo rehabilitation treatment in Hessen, Mecklenburg-Western Pomer-

ania and Schleswig-Holstein than are residents of those federal states (GBE-Bund 2015).

According to the Integrated Care Policy (§ 140, Volume V German Social Security Code), contracts are concluded between statutory health insurance funds and service providers of acute and rehabilitation care. The contracts aim to better interlink acute inpatient treatment and the subsequent hospital or ambulatory rehabilitation measures. A study on improving care demonstrated that integrated care concepts, which ensure a seamless connection between the acute phase and inpatient rehabilitation for hip and knee joint replacement patients, had positive effects on patient satisfaction and outcome quality (Bethge et al. 2011).

3.4.3 Utilization of Services

The Federal Statistical Office publishes the number of full-time inpatients in preventive medicine facilities and rehabilitation establishments with over 100 beds, classified according to the main diagnoses groups (Destatis 2015b). In 2014, a total of 1.66 mil-



■ Fig. 3.15 Services provided in subsequent rehabilitation treatment (AHB) in the DRV (2004 to 2014) (Source: IGES – Deutsche Rentenversicherung Bund 2014b)

lion patients were treated, of which 606,000 were treated in orthopedic departments. 518,000 patients had diseases of the musculoskeletal system, a further 102,000 suffered from injuries. The most common main diagnosis in 2014 was osteoarthritis of the hip (coarthrosis), followed by osteoarthritis of the knee (gonarthrosis). Approximately 104,500 patients with an indication of osteoarthritis of the hip (ICD-10 M17) were treated in these facilities. The highest patient numbers were recorded for the age group between 70 and 75 years (21,099) and between 75 and 80 years (20,808). With further increasing age, patient numbers decreased significantly. In total, significantly more women than men with osteoarthritis of the hip (approx. 63,000 vs approx. 41,000 respectively) underwent rehabilitation treatment. This ratio was even more pronounced for osteoarthritis of the knee (66,000 vs. 38,000) (Destatis 2015b). These figures take into account all payers, but no distinction is made between curative procedures for osteoarthritis and subsequent rehabilitation (AHB) after replacement surgery.

DRV statistics show that in 2014 over 1 million medical rehabilitation services were provided for people in employment, of which 350,655 (36 %) were related to »Skeletal system/muscles/connective tissue« disorders. Follow-up services for rehabilitation constituted about one third of all medical rehabilitation services (337,618). One in three of the

procedures are performed for musculoskeletal indications (Deutsche Rentenversicherung Bund 2014b). Figure 3.15 illustrates the developments since 2004 as well as the number of services performed for indications in the main diagnosis group for »Skeletal system/muscles/connective tissue« disorders according to gender. Besides hip and knee replacements, the 56,603 procedures recorded for men and 52,652 for women in 2014 also include further procedures on the spine and other extremities.

Ambulatory rehabilitation services account for 13 % of the entire range of medical rehabilitation services funded by the DRV, of which around two thirds of the indications are in the musculoskeletal domain. In the main diagnosis group »Skeletal system/muscles/connective tissue«, the percentage of ambulatory services out of the entire volume of medical rehabilitation services is under 25 %. This accounts for about 76,000 measures (Deutsche Rentenversicherung Bund 2014a).

According to the Federal Statistical Office, in 2014 patients within the main diagnosis group »Musculoskeletal system and connective tissue«, had an average length of stay of 22.1 days in (inpatient) preventive medicine and rehabilitation facilities with over 100 beds. The length of stay was 21.1 days for cases within the more specific main diagnosis group »Polyosteoarthritis and osteoarthritis« (ICD-10 M05-06 and M15-19) (Statistisches Bundesamt 2013).

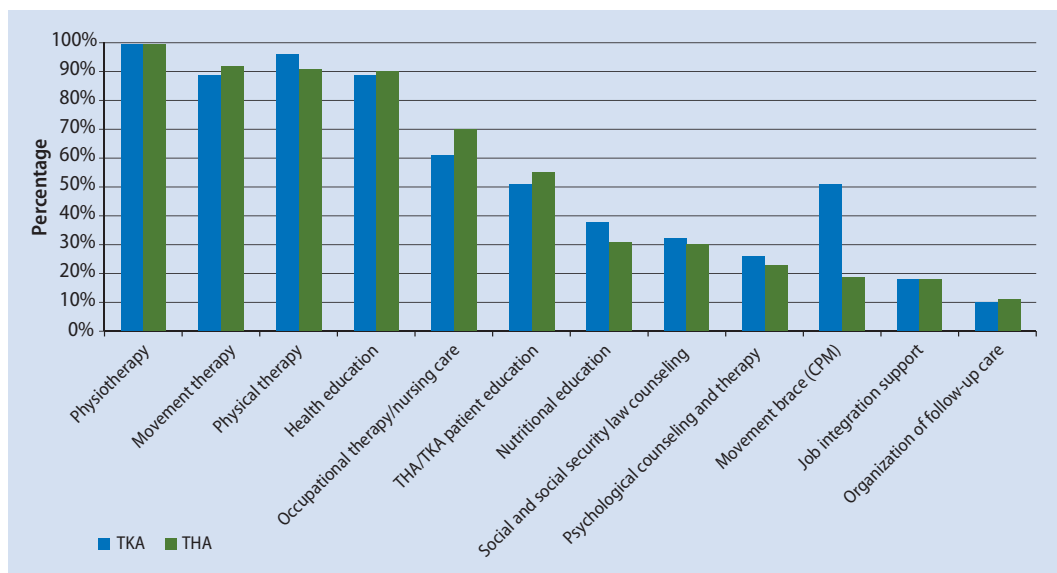


Fig. 3.16 KTL analysis: Percentage of patients undergoing rehabilitation with at least one therapy unit/ rehabilitation. (Source: IGES – Deutsche Rentenversicherung Bund 2010). Note: KTL = classification of therapeutic services (Klassifikation therapeutischer Leistungen); the data presented is derived from the commonly used German Statutory Pension Insurance classification system for therapeutic services. The system uncodes all the services rendered with the help of four-figure codes. The data is collected routinely every year and serves the purpose of documentation and quality control within the German Statutory Pension Insurance.

3.4.4 Implementation of Therapeutic Measures

The »Therapy standards for medical rehabilitation following THA and TKA« developed by the German Statutory Pension Insurance provides an overview of therapeutic measures performed during subsequent rehabilitation (AHB) (Section 3.4.1) (Deutsche Rentenversicherung Bund 2011). The standards were developed based on an analysis of all rehabilitation measures funded by DRV Bund which were completed between 1 January 2007 and the cut-off date of November 10, 2007 (Deutsche Rentenversicherung Bund 2010).

This analysis included patients in subsequent rehabilitation (AHB) who received therapy and who had a primary or secondary diagnosis of »osteoarthritis of the hip« (ICD-10 M16) or »osteoarthritis of the knee« (ICD-10 M17) recorded in their discharge summary and who had had a joint implant (Z96.6 or Z98.8). Under these criteria, 66,842 KTL datasets from 3,652 patients after hip replacement

and 41,459 KTL datasets from 2,186 patients after knee replacement were recorded (Deutsche Rentenversicherung Bund 2010).

The KTL data analysis contains information on the percentages of patients who received treatment with the evidence-based therapy modules in question and the average number of therapy units that were performed in one week (Gülich et al. 2010). The results are summarized in Figure 3.16 and Figure 3.17.

According to this table, the majority of patients received physiotherapy (99.5 %), physical therapy (96.0 %), movement therapy (89.0 %) and health education (89.0 %). Over half the patients received occupational therapy/nursing care (61.0 %), THA/TKA education (51.0 %) and therapy with a movement brace (CPM) (51.0 %). It is important to note that the DRV therapy standards were revised in 2011 and in part include some reworded evidence-based therapy module titles and different KTL code allocations. However, the titles of some modules remain the same and the core contents

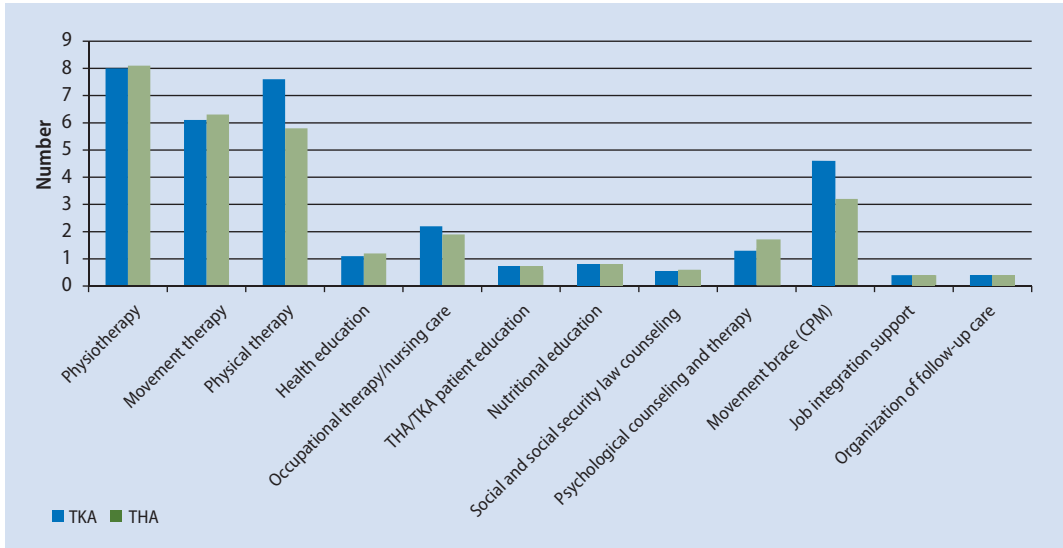


Fig. 3.17 KTL analysis: Therapy units per week (mean values). (Source: IGES – Deutsche Rentenversicherung Bund 2010). Note: KTL = classification of therapeutic services (Klassifikation therapeutischer Leistungen); the data presented is derived from the commonly used German Statutory Pension Insurance classification system for therapeutic services. The system un-codes all the services rendered with the help of four-figure codes. The data is collected routinely every year and serves the purpose of documentation and quality control within the German Statutory Pension Insurance.

are comparable (cf. Deutsche Rentenversicherung Bund 2011, 2010). This means that the current provision of care, if provided according to the revised therapy standards, may differ slightly from the results presented.

It should be noted that the analyses only include working people. Accordingly, the patients' ages are comparatively low (THA: 54.1; TKA: 55.7) and cannot be considered representative of all patients undergoing rehabilitation after endoprosthetic surgery (Gülich et al. 2010).

Statutory health insurances are responsible for funding subsequent rehabilitation (AHB) of a majority of patients who are not working. However, to date, only little data on rehabilitation for SHI insurees has been published.

The Barmer GEK reports that in 2009 almost 90 % of approximately 2,200 insurees who had undergone THA or TKA underwent inpatient rehabilitation. Their average age was 65 years, two thirds were over the age of 60 (Barmer GEK 2010).

The AOK Rheinland conducted a pilot project with the intention of establishing rehabilitation timelines and investigated 120 THA and 110 TKA

patients. The average ages were 75 and 74 years respectively. The final quality outcome of rehabilitation outcome quality was measured based on the Staffelstein-score which takes into account both objective clinical findings and subjective aspects. »Pain«, »Activities of daily living« and »Range of movement« are each weighted one third. A total score of 120 points can be achieved. The evaluation was conducted with reference to an achievable rehabilitation potential. It is suitable for both THA and TKA. The Staffelstein-score improved from 64 to 92 in the group of investigated THA patients and from 57 to 87 in the group of TKA patients. On average, the greatest progress in rehabilitation determined by this score was observed in the first 2 weeks of therapy. The rehabilitation goal for both groups was set at a score of 86, which was achieved by 76 % of THA patients and by 57 % of TKA patients. The average length of stay was 19.1 and 19.8 days respectively. However, in both groups almost 10 % of the patients needed significantly more than 21 days (Tuncel et al. 2015b).

An investigation conducted by the Techniker Krankenkasse as part of the »TK EVA« rehabilita-

tion project investigated over 8,600 THA and 8,100 TKA patients in 9 rehabilitation hospitals in Rhineland-Palatinate between 2007 and 2009. The average patient age was just under 75 years. By means of a modified Staffelstein-score, the measured THA outcomes improved from 53 % to 78 % and the TKA outcomes from 50 % to 76 % (Baulig et al. 2015).

3.4.5 Effectiveness of Subsequent Rehabilitation

Rehabilitation is generally regarded as a multi-dimensional intervention and is consequently difficult to evaluate. Literature reviews have described that numerous small-scale controlled studies illustrate the positive effects of subsequent rehabilitation treatment (AHB) after total hip and knee replacement (Aliyev 2010; Baulig et al. 2015; Kladny et al. 2002, 2001; Middeldorf and Caaer 2010; Müller et al. 2015; Tuncel et al. 2015a, 2015b). Clear indications of improved pain reduction, improved joint mobility, increased mobility and independence, reduced falls, self-management as well as improvements in performing activities of daily living and participation in daily life have been observed.

A systematic literature review on the effectiveness of different rehabilitation therapies in patients who have undergone hip and knee joint replacements have shown that the studies conducted are vastly heterogeneous, and do not contain enough significant data. Up to now, it has been demonstrated that individual therapy measures, such as sports and movement therapy as well as physiotherapy, are effective. However, the data did not allow for conclusions about the required frequency and duration of the measures (Müller et al. 2009). In 2014, the Advisory Council on the Assessment of Developments in the Healthcare System (Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen (SVR)) established that »the lack of an evidence base common to many cases does not automatically prove that rehabilitation is ineffective«. Even though there is predominantly no proof of efficacy under controlled conditions, it can indeed be assumed that benefits exist. However, it is often questionable as to whether they have an added benefit over alternative treatments (SVR Gesundheit 2014).

3.4.6 Post-Rehabilitation Care

Post-rehabilitation care aims to guarantee the long-term outcome and presents an ongoing challenge. Most patients require further treatment after their rehabilitation treatment is completed. To this end, the German Statutory Pension Insurance has initiated a post-rehabilitation care system called »IRE-NA« (Intensivierte REhabilitations NACHsorge) which, however, has not yet been adopted by other payers. The system permits the patient to continue with movement therapy measures after completion of the DRV-funded rehabilitation. These measures usually take place in groups in rehabilitation facilities close to the patient's domicile. Alternatively, the practice-based treating physician prescribes 3 to 8 weeks of physiotherapy or device-based physiotherapy. However, not all patients need this therapeutic prescription in which case continuing with the training program learned during rehabilitation for a period of about 6 weeks sufficiently compensates for any remaining deficits. Patients can also be integrated into functional training which, for example, is organized by the German league against rheumatism (Rheumaliga).

3.4.7 Challenges

After the introduction of DRGs in 2003, the length of acute-care hospital stays reduced significantly. The »REhabilitation und DIAgnosis Related Groups« study (REDIA-Studie) is a prospective, multi-center, randomized long-term study on the effects of DRG introduction into acute care on medical service requirements and the costs of rehabilitation (von Eiff et al. 2011). 10 years later, admission to rehabilitation hospitals after hip or knee replacement is, on average, one week earlier. Due to this premature start of rehabilitation, a significant deterioration in the patients' condition at the start of the rehabilitation was observed. This, in turn, led significantly higher costs for the rehabilitation hospitals, i.e. for more staff to assist with the therapy, changing dressings and wound treatment as well as for more pain medication, antibiotics, thromboprophylaxis and laboratory tests. Patient resilience was affected owing to the reduced overall condition

after surgery. The Staffelstein-score decreased from 78 to 70. The number of complications also increased steadily. Therefore, between 2003 and 2009, the number of wound healing complications increased from 1.6 to 6.5 %, the number of hematomas from 4 to 10.8 % and mobility impairments due to complications from 1.6 to 12.3 %. A consequent increase in the number of patient transfers back into acute care constituted a significant cost factor for the rehabilitation institutions involved, as the transport costs are usually included in the rehabilitation case fees.

While these figures undoubtedly demonstrate a higher financial burden on the rehabilitation institutions, no increase of the remuneration rates for subsequent rehabilitation treatment (AHB) can be seen in practice, not even for the nursing rates paid by the statutory health insurance funds.

Process changes could potentially lead to improvements: The immediate start of so-called »fast-track rehabilitation« in the acute-care hospital could become an interesting option. A recent literature review found that this can reduce the length of hospital stays. In addition, there were indications that early intervention can improve the patient's physical state at the start of rehabilitation treatment (Quack et al. 2015).

3.4.8 Outlook

The demographic change with its increasingly aging population and simultaneous improved care has led to a marked rise in the number of patients who undergo elective joint replacement surgery and in endoprosthetic treatment of femoral neck fractures (Dreinhofer and Schwarzkopf 2010). Evidently, this has a significant impact on acute-care hospitals and particularly also on the rehabilitation hospitals: An increasing number of multimorbid patients with significant mobility restrictions and who are in need of nursing care need to be looked after.

This demands a structural change: The development of geriatric traumatology centers can be understood as a response to the increasing number of fragility fractures and is characterized by the interdisciplinary treatment through surgical departments and geriatric institutions. However, given the

expected patient numbers in orthopedics and trauma surgery, covering this demand through geriatric departments will be very challenging. In addition, not all elderly patients benefit from geriatric treatment because they do not require it (Kladny 2015). More often, specialist rehabilitation by a multidisciplinary team with competency in geriatric medical care will be required. Specialist rehabilitation treatment will have to adapt to the specific requirements of a patient group which is growing increasingly older (Dreinhofer and Schwarzkopf 2010).

This urgently requires structural and financial adaptations. At present, there is only one so-called rehabilitation phase in orthopedic treatment, which, as described earlier, has prerequisites such as the ability to undergo rehabilitation and is largely based on patients who are mobile and can look after themselves. Meanwhile, however, this is undoubtedly no longer the case. A multi-phase care system with several levels of care, as has already been introduced in neurology, also seems worthwhile for orthopedics. The patient is assigned to a specific rehabilitation phase depending on the intensity of the required assistance and nursing care. With increasing independence, the rehabilitation phase may be changed to the next phase. Naturally, the required resources for phases that require a high intensity of nursing care are significantly higher and are consequently accompanied by higher nursing care fee rates.

From a scientific perspective, the data situation for assessing the effectiveness and cost-effectiveness for rehabilitation measures, including their duration and intensity, is limited for subsequent rehabilitation (AHB) following replacement surgery as well as for most other procedures. Moreover, no clear criteria for allocating patients to ambulatory or inpatient rehabilitation exist. In 2014, the Advisory Council on the Assessment of Developments in the Healthcare System found: »There is a lack of high-quality, multi-armed, prospective studies which could be conducted in a rehabilitation setting despite some methodological challenges. In order to realize such studies, more rehabilitation research funding is needed so that appropriate high-quality study designs can be applied to large patient cohorts. To this end, rehabilitation research should be organized across the payer institutions in future« (SVR Gesundheit 2014).

3.5 Quality Aspects of Care

Quality of care can be considered from different perspectives. From the angle of attaining treatment outcomes which are relevant to the patient, factors such as avoiding complications and improving quality of life are in the foreground. From a statutory health insurée perspective, maintaining high average treatment outcomes throughout Germany, avoiding unnecessary primary replacements and premature revision surgery are important for making efficient use of financial resources. On the other hand, the providers of core medical services (replacements/ revision surgery) and rehabilitation establishments are interested in avoiding complications in patients and attaining optimal results with limited funds. In doing so, they aim to fulfill their medical responsibility, successfully acquire patients in competition with other establishments and, beyond this, fulfil statutory quality assurance standards. The following section will discuss factors that could have an influence on the quality of care.

3.5.1 Materials

The materials used in replacement surgery have been subject to continuous step-by-step innovation for a long time. All materials used in endoprosthetics are subject to mechanical strain, especially the articular joint surfaces, i.e. the bearing, high-friction surfaces. Over time, friction will inevitably lead to wear and tear of the material, through which particles can also be released into the surrounding tissue. This can lead to tissue reactions and bone loss which, in turn, lead to loosening and failure of the joint implant. Materials are advanced with the help of tribology research, as has been the case, for instance, with more wear-resistant materials (Mittelmeier et al. 2012).

Joint replacement registries can contribute to the early detection of undesired features or anomalies in certain product types and devices, even though validation through direct comparison is not possible and despite the fact that international registries have neither consistent nor uniform early warning concepts (Liebs et al. 2014).

The meanwhile established German joint replacement registry »Endoprothesenregister Deutschland (EPRD)« (Section 4.3) aims to inform manufacturers »through an early warning system that provides early feedback on potential problems, innovation risks and outcome shortfalls« as well as longer-term results for the implants used (Hassenpflug and Liebs 2014). For example, for hip and knee prostheses, the Australian National Joint Replacement Registry separately details specific, concrete products with higher than anticipated rates of revision (AOA 2014). As different registries use different systems, detailed knowledge of the registry's methodology is necessary for evaluating and comparing the results.

3.5.2 Surgery and Perioperative Management

There are no conclusive study results which permit definite comparisons and demonstrate a specific procedure to be fundamentally superior. For hip joint replacements, less invasive access routes with techniques that are sparing with the soft tissue (no detachment of the muscle insertions) are considered advantageous. There are some studies which suggest that using such techniques subsequently result in less pain, shorter lengths of stay and fewer blood transfusions. However, a higher learning curve must be taken into account on introducing less invasive access techniques and their overall significance is ultimately still unclear (Ibrahim et al. 2013). To date, for knee joint replacements, it has not been shown that less invasive access techniques with reduced muscular trauma and less impact on the tissues surrounding the joint are advantageous compared to conventional access techniques (Ibrahim et al. 2013). Precise implant alignment plays a major role in knee replacement. A wrong alignment and incorrect rotation can result in an abnormally high degree of implant abrasion, early loosening and patellofemoral problems (Ibrahim et al. 2013).

A retrospective analysis of over 1,100 cases of primary hip replacements in a German university hospital suggests that a longer duration of surgery significantly increases the probability of postoperative complications, particularly if the surgery takes

longer than 90 minutes (6.4-fold increased risk of complication). Therefore, a shorter duration of surgery is more favorable for the treatment outcome (Zenk et al. 2014).

In addition, Prokopetz et al. (2012) report a link between longer surgery duration and revision surgery and the occurrence of infections. In Germany, performing a TKA takes an average of 74.5 minutes. In contrast, average revision surgery, as defined by External Quality Assurance for Inpatient Care standards, takes over 2 hours and has higher complication rates during the inpatient stay compared with inpatient stays for primary replacement.

Hip revision can be performed in one-stage or two-stage (i.e. in two steps over time) procedures. According to the report on External Quality Assurance for Inpatient Care in Germany, 9.4 % of all revision surgery in 2014 was reported to have been performed in a two-stage procedure (AQUA-Institut 2015b).

In cases of aseptic loosening, one-stage surgery is generally accepted, whereas revision surgery for infected endoprostheses (septic endoprosthesis) is usually performed in a two-stage procedure. At any rate, early and radical wound debridement with removal of the infected implant is considered important in the treatment of septic endoprostheses. The two-stage procedure permits identifying the pathogen and potential resistance between removing the endoprosthesis and the actual revision. A disadvantage here is a higher morbidity and lower quality of life during the time when the patient is without an endoprosthesis (Gravius et al. 2011).

Preoperative patient information ranks highly amongst the non-surgical quality assurance measures. This not only involves providing information about risks, advantages, the procedure and follow-up care for the respective surgery, which alone can lead to reduced pain and less anxiety for the patient. Matching the surgeon's and the patient's expectations for the treatment outcome is of greater importance as these often diverge and, additionally, there is a link between patient satisfaction and fulfilled expectations.

The anesthetic method is individually selected for the patient and takes into account the perioperative risk, the surgical procedure and the expected (postoperative) pain and mobility, amongst other

things. In studies and meta-analyses, regional anesthesia for hip replacements is considered superior to general anesthesia with regard to the duration of surgery, blood loss, the need for transfusions, the risk of thromboembolic events, postoperative nausea and vomiting. A positive effect on functional outcomes 3, 6 and 12 months after surgery is unclear (Atchabahian et al. 2015). The intraoperative injection of local anesthetics into the area surrounding the joint can have a positive effect on the postoperative pain (Andersen and Kehlet 2014; Kerr and Kohan 2008).

Antibiotic prophylaxis, which is also performed in the majority of cases in Germany, is deemed necessary and reduces the risk of postoperative wound infections, particularly when administered as a single shot, regardless of whether this is done locally (in the cement) or systemically (Gollwitzer et al. 2011). Multimodal (interdisciplinary) care concepts (such as »fast track« or »enhanced recovery«) encompass the inpatient treatment period from admission to discharge. The concepts aim to shorten the time required for functional recovery and increase patient satisfaction by reaching functional goals more rapidly during inpatient treatment and consequently shortening the length of stay. Moreover, they aim at reducing the overall patient mortality and morbidity. Additionally, avoiding complications while accelerating convalescence can contribute to improved cost efficiency (Husted 2012). The multimodal care concepts implement clinical elements such as pain management, thromboembolism prophylaxis and mobilization. They also integrate individual patient characteristics and aspects of their home life into structured interdisciplinary treatment pathways with clearly defined and documented outcome parameters (therapy goals) (Husted 2012).

In a meta-analysis (n = 22 studies), Barbieri et al. (2009) investigated the effect of structured treatment pathways for hip and knee joint replacements. For the observed treatment pathways the rate of inpatient complications was significantly lower and the length of stay shorter compared to the normal care pathway (Barbieri et al. 2009).

A retrospective cohort study conducted in the Netherlands demonstrated a clear reduction in the length of stay for hip joint replacements after the

Tab. 3.16 Surgeons and anesthetists' assessments and prognosis of the degree of influence of individual factors on length of stay reduction for hip and knee joint replacement

Area	Evaluation for the period			
	2010–2012	Prognosis (2013–2015)		2010–2012
Hip				
	Surgeon		Anesthetist	
Anesthetic method	Low	Low	Medium	Low
Treatment pathways	High	High	High	High
Fixed discharge criteria	Medium	Medium	Medium	Medium
Reduction of complications	Medium	Medium	Medium	Medium
Surgical technique	Medium	Medium	High	Medium
Economic factors	High	Medium	Medium	High
Patient education	Medium	High	Low	Low
Patient selection	Low	Low	Low	Medium
Pain management	High	High	High	High
Knee				
	Surgeon		Anesthetist	
Anesthetic method	Medium	Medium	Medium	Low
Treatment pathways	High	High	High	High
Fixed discharge criteria	High	High	Medium	Medium
Reduction of complications	Medium	Medium	Medium	Medium
Surgical technique	Medium	Medium	High	Medium
Economic factors	Medium	Medium	Medium	High
Patient education	Medium	Medium	Low	Low
Patient selection	Low	Low	Low	Medium
Pain management	High	High	High	High

Source: IGES – Jaschinski et al. 2014

implementation of an enhanced recovery treatment pathway compared to before or after the implementation phase (den Hartog et al. 2015).

A registry study showed that in Norway, a fast track treatment concept was also associated with low rates of complication and revision and high patient satisfaction after primary and revision hip and knee surgery, even in the 1 year follow-up (Winther et al. 2015).

In 2014, Jaschinski et al. published a nationwide survey of hospital physicians in Germany, asking which factors the physicians considered relevant for reducing the length of stay (in the past and in future). The assessments of surgeons performing hip and knee replacements and those of the anesthetists are presented in [Tab. 3.16](#), grouped into three degrees of impact (high, medium, low) for each potential influencing factor.

This shows that especially treatment pathways and pain management are considered to be factors that significantly influence the reduction of the length of stay. Patient selection (i.e. the careful selection of patients for surgery) and the anesthetic method chosen, on the other hand, are considered to have the lowest level of influence according to those surveyed (Jaschinski et al. 2014).

3.5.3 Surgeon

The surgeon plays a major role. He/she is responsible for planning treatment and performing the surgery, through which he/she substantially influences all aspects specific to the procedure which are reflected in the treatment outcome.

In their systematic review, Prokopetz et al. demonstrated that surgeons who have conducted low numbers of operations constitute a risk factor for revision total arthroplasty after primary THA. Conversely, this signifies a lower risk of revision total arthroplasty when the surgeon has more experience. The surgeon's (practical) experience therefore seems to be of significant importance. Regardless of the precise anchoring technique for hip replacements (hybrid, cemented, cementless), the most experienced surgeons only took an average of 53.2 (± 17.4) minutes, surgeons with medium-level experience took on average 74.5 (± 25.5) minutes and surgeons with the least experience took an average of 80.8 (± 21.9) minutes.

The rate of postoperative complications was highest for the least experienced surgeons with 5.0 %, as opposed to 3.0 % for the more experienced and 2.7 % for the most experienced surgeons. The analysis shows that for surgeons with the least experience, the risk of complications is always fundamentally higher, regardless of the actual duration of the surgery (Zenk et al. 2014).

Overviews of studies on surgeons performing knee and hip replacements demonstrate a predominantly positive correlation between the case numbers of performed operations performed by a surgeon and the outcome with regard to complications or revision (Haas et al. 2013). Experienced (specialist) surgeons who have performed a higher number of operations have a positive effect on the treatment outcome.

3.5.4 Hospital

Given the major role surgeons play and the importance of their degree of experience for treatment outcomes gives rise to the question of whether a minimum number of replacement surgery cases should be made a requirement in hospitals as well. Studies demonstrate a link between a surgeon's number of performed cases and postoperative mortality, and suggest that the mortality associated with hip replacements is related to the number of patients treated in the hospital (Haas et al. 2013).

In Germany, a minimum number of cases per hospital has been set as a requirement for total knee arthroplasty (► Chapter 4), but not yet for hip replacements.

Regardless of minimum case number regulations, the hospital structures are of significant importance for setting discharge criteria. Discharge criteria can contribute to shorter length of stays when used in multidisciplinary settings but they have only been established in 40 % of hospitals in Germany (► Chapter 4).

Meanwhile, many hospitals have been certified, with which they aim to validate and improve their quality assurance measures and to inform their patients about their good quality of care. Particularly the EndoCert system described in ► Chapter 4 is particularly worth mentioning here.

3.5.5 Patient

Fulfilled patient expectations with regard to the surgery have a significant impact on treatment outcome satisfaction. Therefore, it is important that the surgeon and the patient discuss expectations prior to surgery. Patient and surgeon surveys suggest that patients with total hip replacements have particularly higher expectations of being able to do sports after the operation than their surgeons. In general, patients with more physical restrictions and those with lower incomes tend to be more optimistic than their surgeons with regard to the treatment outcomes (Jourdan et al. 2012).

A study involving more than 1,300 patients who underwent primary total hip replacement across a total of twelve European countries demonstrated

that patients with higher expectations prior to surgery are more likely to have improvements after the operation (measured by means of functionality scores). Especially joint function and/or joint stiffness as well as pain perception correlated positively with the expectations (Judge et al. 2011). ■ Tab. 3.17 shows the different expectations of the patients surveyed in the study in the order of frequency of response.

Further patient-related factors that can influence treatment outcomes can evidently be found in the patient prerequisites (Günther et al. 2015). In the past, for instance, a patient's body mass index (BMI) was often discussed, i.e. how far being overweight has an impact on the treatment outcome. A review, which included a quantitative analysis, concluded that obese THA patients more frequently have dislocations, aseptic loosening, infections and venous thromboembolism (Haverkamp et al. 2011). A higher body mass index (BMI) in knee joint replacement patients can cause higher rates of postoperative complications and a lower prosthesis service life. Additionally, this has a negative impact on the (subjective) patient satisfaction (Lüring et al. 2013). Therefore, obesity seems to tend to have a negative effect on the treatment outcome with regard to complications. In individual studies, obesity was also observed to have a negative effect on hip revisions (Lübbecke et al. 2007).

Other investigations, which included several thousand THA patients from different studies, show that even with a high BMI, there were significant improvements in patient-reported treatment outcomes and from this point of view, a high BMI should not be an obstacle for total arthroplasty (Judge et al. 2014).

Concomitant diseases are discussed as frequently as patient-related influencing factors. They are considered to be cofactors for the THA implant survival period and have a direct impact on the rate of complications. Especially diabetes mellitus and other diseases that negatively influence the patient's immune response increase the rate of postoperative infections (Günther et al. 2015; Zhu et al. 2015). This is confirmed by calculations conducted by the Barmer GEK based on surveys and routine data. They identified that a higher patient age and the presence of concomitant diseases constitute negative factors for successful surgery (Barmer GEK 2010).

■ Tab. 3.17 Range of patient expectations related to THA

Subject and related patient expectation	percentage [%] (n = 1,035)
Long walking distance	46.0
Housework	26.7
Activities of daily living	25.7
Sport and leisure activities	25.1
Feeling less pain	23.6
Being pain-free	23.0
Gardening	19.1
Shopping	10.9
Work	8.2
Leading an independent life	8.0
Returning to normal activities as far as possible	7.3
Driving	5.4
Holidays	3.5
Looking after others	3.4
Sleeping	1.9
Sexual activity	0.5
No expectations	1.0

Source: IGES – Judge et al. 2011

It is unclear whether exercise has a positive or negative impact on the (medium to long-term) treatment outcome. Patient surveys indicate that THA patients who do sports have a higher overall satisfaction with the surgery (Simmel et al. 2008). Regardless of the types of exercise »permitted« by international guidelines, literature recommends advising patients individually on the possibilities and risks of specific sport activities after THA, also with regard to specific rehabilitation measures that can help prepare the patient for a specific sport activity (Jacobs et al. 2009). Early revision total arthroplasty for younger patients is discussed, as they exercise a comparably higher strain on the endoprosthesis (Claes et al. 2012, Wirtz 2011).

Smokers are advised to refrain from smoking for at least 4 weeks before and after the surgery, as this has shown advantages for hip and knee joint surgery complication risks (Gollwitzer et al. 2011). Beyond this, alcohol abuse is considered a patient-related risk factor, i.e. a behavior that is entirely within the patient's responsibility, for aseptic loosening (AQUA-Institut 2012e). The prescribed postoperative medication, e.g. for pain management, should be taken consistently so that the patient is as symptom-free as possible (Section 3.3.3).

Furthermore, there seems to be a link between high ASA scores and the frequency of postoperative complications. Being over the age of 70, male and having a concomitant disease also lead to a higher complication profile for knee joint replacements (Lüring et al. 2013).

There also seems to be a connection between the preoperative stage of the disease and postoperative patient satisfaction with knee replacements in that patients who suffer from only mild osteoarthritis are less satisfied (excluding mechanical reasons). Additionally, existing osteoporosis could be a negative factor for treatment outcome. Other factors that have a negative influence, at least in the short term, could be the patient's life circumstances (being single, separated, widowed, unemployed, pensioned) or suffering from depression (Schäfer et al. 2010). Ultimately, however, these connections have not been validated, as individual studies have reported the opposite and the complex interconnections have not yet been fully elucidated (Lüring et al. 2013).

Providing good preoperative patient information not only enables discussion of expectations, advantages and risks of the surgery, but also informs the patient about the demands of postoperative rehabilitation and the necessity of his or her active participation in the recovery process. The patient's compliance and motivation are of major importance, particularly for complex rehabilitation measures (AQUA-Institut 2012f).

3.5.6 Post-Discharge Treatment Outcomes

In general, about 6 to 7 weeks following (primary) hip or knee joint replacement patients should largely be able to move the affected leg free of pain and bear full weight on it. Walking without any support at all is usually possible after 10 to 12 weeks. However, annual medical follow-ups should be conducted to examine the patient's gait, any residual symptoms as well as to assess the need for medical technical aids, amongst other things (Heisel 2008). Whether sporting activities outside of medical rehabilitation (e.g. fitness workouts, cycling, swimming) can be undertaken after a total replacement, particularly after THA, mostly depends on individual patient characteristics such as age, concomitant diseases, bone quality and condition of the muscles. Psychological factors, including risk awareness and ambition, should also be taken into account when making any recommendations. As a rule, patients are recommended to abstain from undertaking medically unsupervised (leisure) sports activities for 3 to 6 months (Schmitt-Sody et al. 2011). In addition, a recent meta-analysis found evidence that the behavioral and movement restrictions which are, in part, still frequently prescribed for the first few weeks or months following hip replacements (e.g. supine lying position, using walking aids, avoiding bending the hip joint by over 90 degrees) do not lead to lower rates of luxation. On the contrary, patients who were given more lenient behavioral restriction recommendations (»not sitting with crossed legs«) or none at all resumed activities earlier and showed a greater level of satisfaction (van der Weegen et al. 2015).

The 2010 Barmer GEK Hospital Report investigated the quality of life of selected insured patients and their level of outcome satisfaction following THA or TKA treatment by means of a written, retrospective and multidimensional survey.

The results show that the quality of life for THA patients who were operated in 2003 was comparable to that of patients who had surgery later in 2008/2009 (determined at an average of 9.2 and 9.3 months after the index surgery respectively). This demonstrates that the quality of surgery remained consistent over a period of several years. The report uses scores based on the so-called Nottingham

■ **Tab. 3.18** Patient satisfaction results after hip surgery, survey on behalf of Barmer GEK

	Hip		Knee	
	Initial survey 2004	Initial survey 2009	Initial survey 2004	Initial survey 2009
Satisfaction with the artificial hip joint:	n = 556	n = 1,106	n = 334	n = 1,016
- (entirely) satisfied	58.3%	63.4%	44.9%	43.2%
- partially satisfied	33.3%	28.7%	38.0%	38.5%
- not satisfied	8.5%	8.0%	17.1%	18.3%
Willing to undergo another total arthroplasty if required:	n = 559	n = 1,109	n = 335	n = 1,020
- fully	76.9%	75.4%	62.7%	60.7%
- with limitations	18.2%	20.9%	29.6%	27.6%
- no	4.8%	3.7%	7.8%	11.7%
Willing to recommend total arthroplasty:	n = 552	n = 1,102	n = 332	n = 1,020
- fully	80.3%	81.1%	68.7%	65.5%
- with limitations	15.9%	15.5%	20.8%	21.8%
- no	3.8%	3.4%	10.5%	12.7%

Source: IGES – Barmer GEK 2010

Health Profile (NHP), a tool for collecting subjective patient reports (patient-reported outcome measures, PROM) for the domains energy, pain, emotional reaction, sleep, social isolation and physical mobility. The highest scores and hence the most marked limitations, were assessed for the domains energy, pain, sleep and physical mobility (highest score, i.e. worst result: 20.4 out of a maximum of 100 for sleep in the initial 2004 survey) (Barmer GEK 2010).

Three aspects were surveyed for outcome satisfaction: satisfaction with the artificial hip joint, willingness to undergo another total arthroplasty if required, and willingness to recommend total arthroplasty. The results of the initial 2004 and 2009 surveys are presented in ■ Tab. 3.18. According to these results, the majority of patients who had undergone surgery in 2003 and in 2008/2009 were satisfied with the joint replacement and were willing to undergo another total arthroplasty or to recom-

mend the procedure. However, a small number of the interviewees had undergone revision surgery and not primary surgery.

Additionally, response results from patients who had been interviewed for the first time in 2004 and who were again interviewed in 2009 (n = 424, n = 425, n = 421) differed only slightly to the previous results, showing that the overall level of symptoms remained distinctly low, even 5 years after primary surgery (Lequesne index). Results for patient satisfaction were also comparable to the first survey (Barmer GEK 2010).

A similar analysis is available for TKA patients. In initial surveys conducted in 2004 and in 2009, health-related quality of life and satisfaction of the selected patients were recorded approximately 9 months after surgery (Barmer GEK 2010). To this effect, the Nottingham Health Profile was used, enabling the patients to self-rate their subjective health in six domains: energy, pain, emotional reaction,

Tab. 3.19 Mean values and standard deviations as percentages of satisfied/dissatisfied patients after TKA

	Satisfaction (%)	Dissatisfaction (%)
1990–1999	81.2 (±9.5)	16.9 (±10.5)
2000–2012	85.0 (±7.9)	8.5 (±5.6)
Europe (13 publications)	83.8 (±8.0)	8.9 (±6.6)
North America (10 publications)	85.2 (±6.9)	12.5 (±4.2)

Source: IGES – Schulze and Scharf 2013

sleep, social isolation and physical mobility. The highest scores, and hence the greatest limitations were rated for pain, sleep, physical mobility and energy. The health-related quality of life scores in 2004 and 2009 remained almost unchanged. The overall highest score (31.8 out of a maximum of 100 points) was observed for pain in the initial 2004 survey. Six and a half years after the index surgery, minor to moderate declines were observed in all domains compared to the survey conducted 9 months after surgery. Noticeable deteriorations were observed in the domains of energy (+5.9) and physical mobility (+4.0), which are not, however, statistically significant. The scores for pain remained at a higher level and relatively stable.

The results also show that almost half of the patients with artificial knee joints were entirely satisfied and that the majority of patients were prepared to undergo another total arthroplasty and were willing to recommend the procedure to others. These levels of satisfaction, however, tended to be lower than those for THA.

The results of the follow-up survey in 2009 are also available. The responses of the patients who were followed-up in 2009 and had been interviewed for the first time in 2004 differed only slightly from the earlier results (n = 261 for satisfaction with the artificial knee joint, n = 260 for willingness to undergo another total arthroplasty, n = 206 for willingness to recommend total arthroplasty). Consequently, the reduction of symptoms and the satisfaction 5 years after surgery were comparable to the values obtained 9 months after surgery (Barmer GEK).

A systematic review based on existing studies investigated postoperative patient satisfaction

after TKA for periods from 1990 to 1999 and from 2001 to 2012. **Tab. 3.19** shows the most significant results and illustrates the patients' overall higher level of satisfaction and lower level of dissatisfaction following surgery compared to the previous decade. The main influencing factors with regard to postoperative satisfaction were body mass index, postoperative joint function, expectations, pain, mental function and employment status (Schulze and Scharf 2013). In addition, pre-operative expectations, particularly with regard to functional improvement, influenced treatment outcomes and consequently patient satisfaction (Judge et al. 2011). Improved outcome quality is linked to providing patients with realistic information, patients' attitudes towards the procedure as well as the careful selection of patients. (Halawi et al. 2015).

Additionally, the success of joint replacement surgery can be measured based on whether a patient reintegrates into working life. An analysis of routine data from the German Statutory Pension Insurance shows that 85 % of patients aged between 18 to 60 years, who had undergone hip joint replacements and subsequent rehabilitation (AHB), were able to resume work within 2 years after rehabilitation treatment. Particular risk factors for failing to return to working life were older age and having a manual occupation. The analysis also shows that after rehabilitation approximately 37 % of the patients observed earned a lower salary and hence had lower social security contributions. Moreover, the authors demonstrated that 17 % of the patients observed changed jobs after hip joint replacement (Krischak et al. 2013).

Tab. 3.20 Surgery with documented, fulfilled indication criteria, primary arthroplasty and revision total arthroplasty. Nationwide results based on operations performed in Germany (2014)

Quality indicator	Result 2014	Trend
Primary hip replacement with fulfilled indication criteria	95.84 %	↗
Revision hip replacement with fulfilled indication criteria	93.10 %	→
Primary knee replacement with fulfilled indication criteria	96.86 %	↗
Revision knee replacement with fulfilled indication criteria	92.31 %	→

Note: The arrows in the »Trend« column describe »whether progress in quality of care in 2014 compared to 2013 is positive (upward pointing arrow), negative (downward pointing arrow) or unchanged (horizontal arrow)«.

Source: IGES – AQUA-Institut 2015b, c, d, e

3.5.7 Indications

A German federal group of experts defines the indicator used for external quality assurance for inpatient care purposes, for both primary THA and TKA. This is standard procedure for defining quality indicators in general. The defined quality goal is that »an appropriate indication be used frequently«, which is why the indicator selection is based on equivalent features found in literature and in international guidelines. For primary hip replacements, data is recorded in patients with at least one pain criterion or at least one movement restriction criterion as well as one specific documented value for the degree of severity of osteoarthritis. For primary knee replacements, data is recorded in patients who have at least one pain criterion and a specific documented value for the degree of severity of osteoarthritis. The number of operations that meet these documented criteria are assessed in relation to the total number of recorded operations (AQUA-Institut 2015b, d).

According to in a national survey on primary hip and knee replacements, the overall results have been within the target range and have been improving continuously for several years. The increase in documentation of appropriate indications for the national survey shows that surgery with documented, previously undefined indication criteria was performed in individual cases only (2014: < 5 %). A limiting factor, however, is that the fundamental criteria such as the degree of pain or the time of the

surgery, do not yet exist in standardized or evidence-based forms (Claes et al. 2012, Wirtz 2011, Günther et al. 2013). In addition, cases with defined standardized indications such as trauma cases, amongst others, are not represented in the external quality assurance (► Chapter 6).

For revision total arthroplasty, the rate of appropriate indications documented is lower than for primary surgery and shows a consistent trend. The indicator is defined differently than in primary surgery. The quality goal for hip and knee arthroplasty here is »a frequently used appropriate indication based on clinical symptoms, radiological criteria or signs of inflammation«. Operations in patients with the defined criteria are assessed in relation to the total number of recorded operations (► Tab. 3.20; AQUA-Institut 2015c, e).

3.5.8 Regional Differences

Studies suggest that there are regional differences in quality of care. Figure 3.18 shows the rates for each federal state of unfulfilled indication criteria developed by the AQUA Institute based on THA patients. For comparison purposes, the average rates in Germany are also presented. This shows that in Lower-Saxony, the number of unfulfilled (or not recorded) indication criteria is almost twice as high as the German average of 4.8 % or 3.4 % for THA and TKA respectively. Besides Lower-Saxony, Bavaria, Saxony-Anhalt and Rhineland-Palatinate

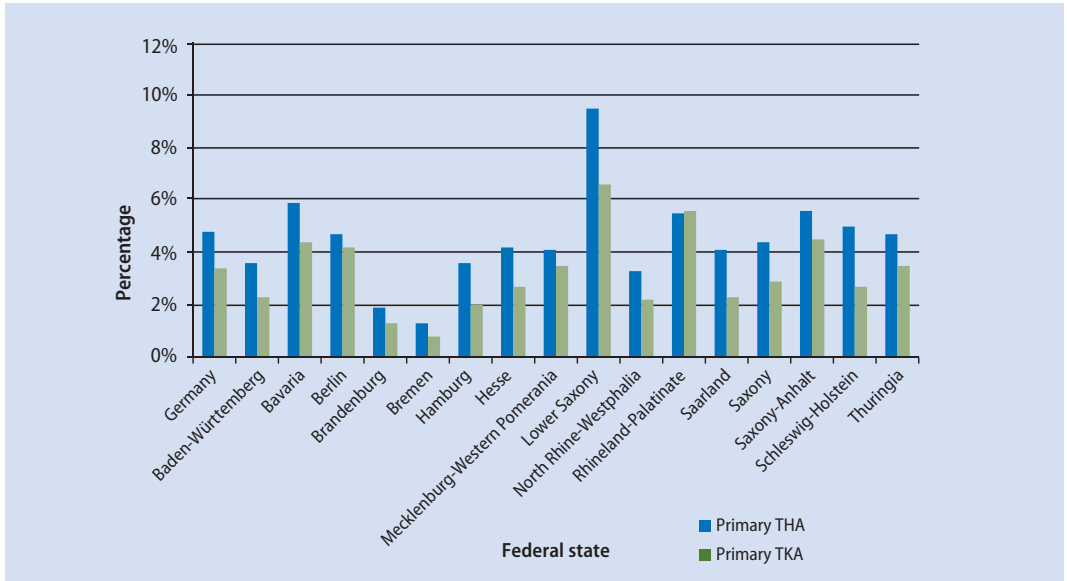


Fig. 3.18 Percentage of unfulfilled indication criteria used for external quality assurance for inpatient care for primary THA and TKA in German federal states (2013). (Source: IGES – AQUA-Institut 2014a, 2014c)

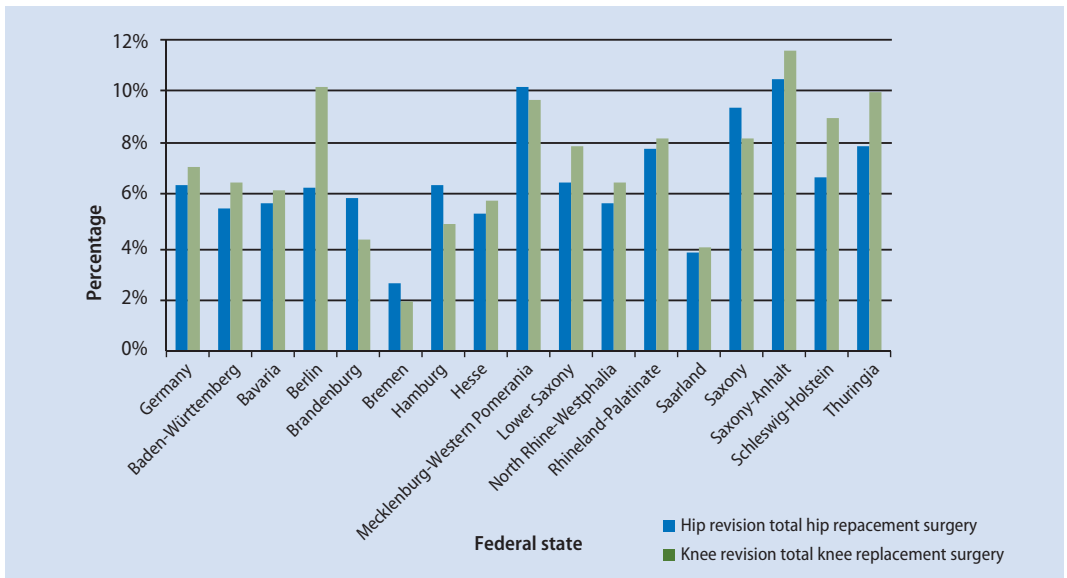


Fig. 3.19 Percentage of unfulfilled indication criteria used for external quality assurance of inpatient care for revision THA and TKA in German federal states. (Source: IGES – AQUA-Institut 2014b, 2014d)

are above the national average with regard to the rate of unfulfilled of indication criteria for both hip and knee replacement surgery. These rates have shown relatively constant trends in most of the federal states. The results for entire Germany, Baden-Württemberg, Bavaria and Schleswig-Holstein improved relative to the previous year (AQUA-Institut 2013a).

The same analysis with regard to revision total arthroplasty shows a different regional distribution (■ Fig. 3.19). Saxony-Anhalt, Mecklenburg-Western Pomerania, Saxony, Thuringia, Rhineland-Palatinate, Schleswig-Holstein as well as Lower-Saxony

are above the nationwide average of 6.4 % and 7.1 % with regard to unfulfilled indication criteria for the hip and knee respectively.

The general trend of these rates has remained relatively constant in most federal states. The results for entire Germany, Baden-Württemberg, Bavaria and Schleswig-Holstein improved relative to the previous year (AQUA-Institut 2014a).

While the trends for individual federal states do not show any significant changes compared to the previous year, a decrease by 0.7 percentage points was documented in the average for Germany (AQUA-Institut 2014b).

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Healthcare System Stakeholders

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Summary

In order for a medical device to be marketable in Europe it must bear the CE mark. CE certification is granted if the device conforms to specific safety and performance requirements. Monitoring is conducted by so-called »Notified Bodies«. Manufacturers can select any one of these certification bodies to certify a medical device. In Germany, the certification procedure for endoprostheses is regulated in the Medical Device Directive 93/42/EEC and is implemented through the Medical Devices Act and further decrees. Up to now, the AQUA Institute for Quality Improvement and Research in the Healthcare System (AQUA-Institut für angewandte Qualitätsförderung und Forschung im Gesundheitswesen) has been responsible for external inpatient quality assurance which is mandatory in Germany. The institute publishes detailed reports concerning the quality outcomes of patient care, which both hospitals and patients can use for comparisons with other establishments. As of 2016, the Institute for Quality Assurance and Transparency in the Healthcare System (Institut für Qualitätssicherung und Transparenz im Gesundheitswesen (IQTIG)), which was founded by the Federal Joint Committee, has assumed this responsibility. The German arthroplasty registry »Endoprosthenregister Deutschland« was initiated in 2013 and aims to document quality outcomes of knee and hip arthroplasty across Germany. The purpose of the registry is to enable the tracking of typical service lives of implants used and to investigate reasons for undesired treatment outcomes. The validity of the registry is still limited as about only half of the hospitals that perform arthroplasty currently contribute to it and only a limited number of primary hip and knee arthroplasties are recorded.

EndoCert is a certification system that was established by the German Society of Orthopedics and Orthopedic Surgery (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC)) and the German arthroplasty association »Deutsche Gesellschaft für Endoprothetik (AE)« and the Professional Association of Orthopaedic Surgeons (Berufsverband der Fachärzte für Orthopädie und Unfallchirurgie e. V. (BVOU)).

Initial results show a decline in complication rates and an improvement in outcome quality amongst a few certified institutions.

Alongside representing the interests of their members and offering basic and specialty training, medical societies also assume an important role with regard to research and towards improving the quality of healthcare. The trauma registry »TraumaRegister of the German Society for Trauma Surgery (Deutsche Gesellschaft für Unfallchirurgie (DGU))« is affiliated with hospitals specializing in trauma surgery and aims to evaluate the effectiveness of methods used in medical treatment. The German arthroplasty association »Deutsche Gesellschaft für Endoprothetik (AE)« is a division of the German Society for Orthopaedics and Trauma (Deutsche Gesellschaft für Orthopädie und Unfallchirurgie (DGOU)) and is involved in quality assurance of endoprosthetic care and in the development of new technologies.

4.1 State Actors

In order for a medical device to be marketable in Europe it must bear the CE mark. CE mark certification can be obtained if the device conforms to specific safety and performance requirements. Medical devices are categorized into four classes (I, IIa, IIb, III) in addition to active implants. The classification is based on the potential safety risk that the medical device bears when it is used. A walking aid (class I) is categorized in a lower class than a dental implant (class IIb) or a hip implant (class III). The medical device's class determines the types of conformity assessments that are to be conducted. Hip and knee endoprostheses are class III devices and are therefore subject to stringent testing (BMG 2010).

Conformity assessment procedures are conducted by so-called »Notified Bodies«. As of November 2015, 62 Notified Bodies have been operating in Europe of which 13 are based in Germany (European Commission 2015). Endoprosthesis manufacturers are free to choose any Notified Body that has been notified to certify their products in a particular device category. Notified Bodies are state-accredited and state-monitored. An expert group for certification bodies from the Central Authority of the Länder for Health Protection with regard to Medicinal Products and Medical Devices (Zentralstelle der Länder für Gesundheitsschutz bei

Arzneimitteln und Medizinprodukten (ZLG)) is responsible for notifying and monitoring the certification bodies as stipulated by the Medical Devices Act.

Devices bearing the CE mark are available on the market for a limited period only. After five years at most the quality management systems of both the manufacturer and the devices must be recertified according to § 11 section 11 of the Medical Device Directive (MDD). Following an initial certification, annual audits are conducted by the Notified Bodies. In addition, the Notified Bodies conduct spontaneous audits of the manufacturers and their major suppliers (European Union 2013).

The certification procedure for endoprostheses is standardized and regulated by the Medical Device Directive 93/42/EEC which is implemented in Germany through the Medical Devices Act and other decrees. Endoprostheses that have been granted the CE mark according to the Medical Devices Act are marketable across the 31 member states of the European Economic Area.

According to § 15 of the Medical Devices Act, the Federal Ministry of Health (Bundesministerium für Gesundheit (BMG)) must inform the Federal Ministry for Economic Affairs and Energy (Bundesministerium für Wirtschaft und Energie (BMWi)) of which bodies have been notified by the ZLG and what their assigned responsibilities are. Subsequently, the BMWi informs the European Commission. Beyond this, the BMG has various responsibilities which directly and indirectly affect the field of arthroplasty. These include establishing regulations for medical rehabilitation and developing frameworks for monitoring medical devices.

The Federal Institute for Drugs and Medical Devices (Bundesinstitut für Arzneimittel und Medizinprodukte (BfArM)) is an independent federal authority within the Federal Ministry of Health portfolio and is both directly and indirectly involved in the field of arthroplasty. Responsibilities of the BfArM with regard to medical devices include centralizing recording, evaluating and assessing risks and coordinating relevant corrective measures that subsequently need to be taken (BfArM 2013).

The BMG also assumes a supervisory role in the healthcare system's joint self-governing structure. The Federal Joint Committee (Gemeinsamer Bun-

desausschuss (G-BA)) is the highest decision-making body for this structure.

4.2 Federal Joint Committee

The Federal Joint Committee (G-BA) is the highest decision-making body of the joint self-government consisting of healthcare providers and payers in Germany. The G-BA decides which services are covered by statutory health insurance (SHI) as well as which quality assurance measures are employed in patient care (G-BA 2015a).

External quality assurance within hospitals is regulated by § 137 Volume V of the German Social Security Code. The G-BA has commissioned the AQUA Institute for Applied Quality Improvement and Research in Health Care (AQUA-Institut für angewandte Qualitätsförderung und Forschung im Gesundheitswesen GmbH) for the supervision and implementation of external inpatient quality assurance (Section 4.3.1). Annual publications on external quality assurance for the years from 2009 to 2015, which also exist for THA and TKA amongst other procedures, are available on the AQUA Institute website (<http://www.sqg.de>, accessed: 24 February 2016). According to § 137a Volume V of the German Social Security Code, the G-BA is responsible for the founding of the Institute for Quality Assurance and Transparency in Healthcare (Institut für Qualitätssicherung und Transparenz im Gesundheitswesen (IQTiG)) as an independent scientific institute. Since 2016, the IQTiG has assumed the role of the AQUA Institute's quality assurance tasks with regard to endoprosthetics (Section 4.3.2).

Since 2005, hospitals in Germany which have been approved to treat statutory health insurance patients are obliged to publish structured quality reports online. Amongst other details, these reports include case numbers for individual indications and operations that a hospital has performed. In addition, the hospitals are obliged to publish some of the outcomes of the surveyed indicators for external inpatient quality assurance purposes. Patients can therefore obtain information about the procedures a hospital is specialized in and check the measurable quality outcomes (quality indicators) before undergoing treatment. However, as these reports only con-

tain past outcomes, they can only give a reference and do not cover all potential quality indicators (G-BA 2014b). Since 2013, a G-BA reference database provides access to overall German hospital quality reports. Information from these reports can be accessed with hospital search engines providing further details on individual quality aspects that have not been included in the above mentioned reports. The database can be accessed through the following website: <http://www.g-ba-qualitaets-berichte.de/> (accessed: 22/12/2015) (G-BA 2015b). The G-BA introduced a regulation with regard to the annual number of total knee arthroplasties which is set at a minimum of 50 procedures per hospital (site) per year. This means that hospitals may only provide these services on behalf of the SHI if they expect to perform at least 50 TKAs per year (G-BA 2014a). This regulation is based on study data for hip and knee endoprosthetics which show a predominantly positive connection between case numbers and treatment outcomes (Haas et al. 2013, Lau et al. 2012, Schröder and Ewerbeck 2007, Zenk et al. 2014).

The minimum volume regulation includes the following procedures (G-BA 2014a):

- 5-822.9** custom-made prosthesis,
- 5-822.g** bicondylar surface prosthesis,
- 5-822.h** femoral and tibial stem prosthesis,
- 5-822.j** endoprosthesis with enhanced flexion,
- 5-822.k** bicompartamental partial joint prosthesis.

However, there are exceptional budgets which allow a hospital to perform TKAs and be reimbursed by the SHI even if it has not reached the limit of 50 operations per year. An example of this is emergency surgery (G-BA 2014a). An analysis of data from German hospital quality reports from 2004 to 2010 concluded that despite the introduction of minimum volumes, case numbers which were previously below the specified limit have not been in decline. This also applies to TKA. According to the evaluation, this was the case for approximately 8 % of hospitals performing primary TKA (n=81) and 1 % of all cases (n=2,048) in 2010. 19 hospitals did not indicate any relevant exceptional budgets in their quality reports. In contrast, the analysis shows a sharp increase in the number of hospitals that were just below the minimum volume threshold and that

had increased their case number to precisely the threshold value (de Cruppé et al. 2014). According to the so-called »TKA transparency list of the federal associations of the health insurance funds and the Federation of Private Health Insurance Funds«, 808 German hospitals met the minimum number requirement for TKA in 2011 (vdek 2011). This is markedly lower than the number of hospitals that performed primary TKA in 2011.

It should be noted that the minimum volume regulation applies to primary total arthroplasty. Unicondylar prostheses replacement and revision total arthroplasty which are technically more demanding are not governed by this regulation. This can lead to distortions in service provision as hospitals increasingly perform total arthroplasty in order to meet the minimum number requirements. Consequently, fewer unicondylar sledge prostheses are implanted, even though this procedure is less harsh on the bones.

4.3 Quality Assurance Initiatives

4.3.1 AQUA Institute

The AQUA Institute was commissioned to supervise and implement external quality assurance for inpatient care. For distinct medical procedures such as THA and TKA (primary and revision surgery), treatments in all hospitals in Germany are documented according to certain quality indicators. The data are recorded, prepared and evaluated by quality offices at state level (LQS) and by the AQUA Institute (up until 2015). Comparative feedback on the outcomes is provided to the hospitals. If individual hospitals show irregular outcomes, the LQS conduct a so-called »structured dialogue« with the hospitals in order to initiate measures towards improving quality.

The AQUA Institute has made comprehensive and detailed quality reports available concerning the outcomes of patient care in hip and knee endoprosthetics, which is an important aspect in the debate regarding quality of care in this particular field of healthcare.

External hospital quality assurance publications for endoprosthetics are available on the internet at: www.sqg.de in the following areas:

4.3 · Quality Assurance Initiatives

- primary total hip arthroplasty,
- revision total hip arthroplasty and component revision,
- primary total knee arthroplasty,
- revision total knee arthroplasty and component revision.

The web page lists the national evaluations and descriptions of quality indicators for the period from 2009 to 2014. As of 2016, the newly founded IQTiG has assumed the AQUA Institute's role in the field of endoprosthetics.

4.3.2 Institute for Quality Assurance and Transparency in Healthcare

The Institute for Quality Assurance and Transparency in Healthcare (IQTiG) was founded in early 2015 by partners in the joint self-governing structure of the healthcare system and the BMG (IQTiG 2015). On behalf of the G-BA, it is to develop measures for quality assurance and present quality of care criteria in the healthcare system and take part in their implementation (IQTiG 2015). The IQTiG focuses mainly on cross-sectoral quality assurance and developing evaluation criteria for certificates and quality seals. The IQTiG evaluation results are to be published transparently and presented in a manner that is understandable by the general public (IQTiG 2015).

4.3.3 German Arthroplasty Registry »Endoprothesenregister Deutschland«

The German arthroplasty registry »Endoprothesenregister Deutschland (EPRD)« (EPRD 2015a) aims to document quality outcomes of knee and hip arthroplasty across Germany (EPRD 2015b). To this end, routine hospital accounting data and pseudonymized patient data from the health insurances (for example, underlying diseases) are analyzed together with the manufacturers' data of the implanted prosthesis components. A product database was established in order to identify prostheses components. It currently lists approximately 45,000 items

and is continuously being updated. The data are stored for over a period of 30 years (EPRD 2015b).

The aim of the registry is to enable tracking of individual implant components, to determine typical service lives of a product and to investigate reasons for undesired treatment outcomes which are not always due to the implant. Patients can therefore be kept informed if they are potentially affected by outcome abnormalities. In addition, the registry enables the analyses of data at a hospital level, taking into account not only information about the implant itself but also aspects of inpatient care and patient-related factors. Physicians, hospitals, endoprosthesis manufacturers and health insurance funds are informed of the results serving as a basis for the further development of quality assurance measures (EPRD 2015b, Hassenpflug and Liebs 2014).

Establishment of the registry was initiated by the German Association for Orthopaedics and Orthopaedic Surgery (DGOOC), the AOK Federal Association, the Association of Substitute Health Insurance Funds (vdek), the BQS Institute for Quality and Patient Safety (BQS) and the prostheses manufacturers represented by The German Medical Technology Association (BVMed) (EPRD 2015a, b). The registry is managed by »Deutsche Endoprothesenregister EPRD gGmbH«, a DGOOC subsidiary (EPRD 2015a). It is financed by participating health insurance funds, hospitals and by the industry. According to its own statements, the registry is exclusively committed to scientific principles and guarantees the independent and neutral evaluation of documented data (EPRD 2015b).

The EPRD was initiated in Germany in 2011 and following a probation phase was introduced nationally in 2013. Hospitals that perform arthroplasty can contribute to the EPRD (EPRD 2015b). Arthroplasty registries were introduced in other countries much earlier than in Germany. In Sweden, for instance, knee arthroplasty registries were introduced in 1975 and hip arthroplasty registries in 1979 (Kärrholm 2010, Knutson and Robertsson 2010). Various studies have demonstrated significant decreases in the rates of complications and in the necessity of revision replacements following the introduction of these registries (Herberts and Malchau 2000, Malchau et al. 2005, Swedish Knee Arthroplasty Register (Hrsg.) 2014). Other arthro-

plasty registries exist in Norway, Finland, Denmark, England, Canada, Australia and New Zealand (Hassenpflug and Liebs 2014).

The EPRD's 2015 status report largely presents descriptive data on primary hip and knee arthroplasty and revision arthroplasty according to patient age and gender. The most common reason for revision total hip and knee replacement is implant loosening (hip: 46.7 %, knee: 39.4 %) followed by infections (hip: 10 %, knee: 13.9 %). Implant component failure accounted for of 3.3 % of all revision total hip arthroplasties and 2.9 % of revision total knee arthroplasties. Determining implant service life based on the data is not yet possible as the majority of patients undergoing revisions underwent primary surgery before they were recorded in the EPRD (EPRD 2015b).

Significant and reliable results can only be achieved through high rates of participation in the registry (Hassenpflug and Liebs 2014). According to February 2016 figures, 684 out of 1,200 hospitals that performed arthroplasty participated in the registry. In 2015, over 140,000 endoprosthetic hip and knee replacements were documented (EPRD 2016).

Participation in the registry and the quantity of data submitted therein is voluntary. Data on implants and surgery are only recorded after a patient has given his/her consent in writing following which participating hospitals can decide whether they document the data for all affected patients or not (EPRD 2015b). Given that the recording of such data is not mandatory, there is the risk of considerable data loss or having only partially documented data in the registry. This may lead to data biases in that the actual quality of treatment may not be fully depicted through the registry. When interpreting the registry evaluations, one must take into account the fact that the represented population consists of patients insured by the statutory health insurance AOK and the Association of Substitute Health Insurance Funds »vdek« (EPRD 2015b). The source population consequently represents approximately two thirds of the insurees from statutory and private health insurances in Germany (BMG 2015). Potential differences amongst those insured by the health insurance funds and insurance companies can influence the validity of the outcomes of the analysis of the registry.

4.3.4 endoCert

endoCert is an initiative and a certification system for centers that perform knee and hip arthroplasty. The initiative was started by the DGOOC with the support of the German association for arthroplasty »Deutsche Gesellschaft für Endoprothetik (AE)« of the German Society for Orthopaedics and Trauma (DGOU) and the Professional Association of Orthopaedic Surgeons (BVOU) (► Section 4.4).

endoCert aims to develop and assure quality of treatment through the certification of medical centers based on up-to-date scientific insights and on its experience through the establishment of medical centers in other fields. At present, this certification concept is limited to elective arthroplasty (Haas et al. 2013). General criteria for the certification process are presented in ■ Fig. 4.1.

Medical centers are required to provide documentation that cover structural quality (e.g. equipment, staff qualification), process quality (e.g. standardized treatment pathways) and outcome quality (patient-reported results, e.g. satisfaction and objective outcomes).



■ Fig. 4.1 General criteria for the endoCert certification process. (Source: IGES – Haas et al. 2013)

4.3 · Quality Assurance Initiatives

The minimum case volume thresholds for arthroplasty for different centers are listed below. However, the initiative emphasizes that these are not recommendations for legal minimum volume regulations:

- Arthroplasty center: At least two main surgeons who each perform at least 50 THAs and/or TKAs per year (on their own or as responsible assistants)
- Arthroplasty center providing comprehensive care: At least two main senior surgeons who each perform at least 100 THAs and/or TKAs per year, including revision total arthroplasty surgery

This results in a link between minimum case numbers for surgeons and minimum case numbers for arthroplasty centers (at least 100 per year) and arthroplasty centers providing comprehensive care (at least 200 per year).

Centers that would like to attain certification must provide evidence showing that they conform to the quality requirements at all levels (establishment, structures, processes, outcomes). After an application has been submitted, assessed and any further questions and outstanding issues have been clarified an on-site audit is conducted. The center is subsequently granted a period of time in order to rectify any shortfalls. Certifications are limited to a duration of 3.5 years. Besides the initial audit, additional supervisory audits are conducted and the center is audited again once the certification has expired. If the center no longer fulfills the given requirements at this time, the certification can be suspended or, in the worst case, revoked (Haas et al. 2013).

The endoCert website (www.endocert.de) lists 471 certified treatment centers in Germany (as determined on 24 February 2016). Some endoprosthetics centers (comprehensive care) have reported a reduction in complication rates and improvements in quality of outcomes after implementation of the certification (Lewinski et al. 2015). Attaining certification works as an incentive for the centers as they can demonstrate a high level of quality of care to the general public and their (potential) patients and also improve treatment outcomes allowing them to attain good benchmarking levels and external inpatient quality assurance results.

However, at present it is expected that the long-term effects of endoCert on treatment outcomes (complications, service lives) can only be evaluated in combination with the EPRD (Section 4.3.3). Hospitals that participate in endoCert are also obliged to participate in the EPRD (Haas u. Mittelmeier 2014).

4.3.5 Project on Quality Assurance of Inpatient Care using Routine Data

In 2002, the quality assurance initiative for inpatient care using routine data »Qualitätssicherung der stationären Versorgung mit Routinedaten (QSR)« was started as a joint research project between the AOK Federal Association, HELIOS Kliniken, the research and development institute for social affairs and the healthcare system in Saxony-Anhalt »Forschungs- und Entwicklungsinstitut für das Sozial- und Gesundheitswesen Sachsen-Anhalt (FEISA)« and the AOK Research Institute (Wissenschaftliches Institut der AOK (WiDO)). The project aimed to »review the possibilities of measuring quality on the basis of SHI routine data« and specific quality indicators were developed to this end (WiDO 2007).

Information on hospital stays is obtained from routine data, in the same way as for statutory external hospital quality assurance data collection. The main difference with regard to statutory quality assurance measures and an advantage of the project is that several episodes within the chain of a patient's treatment can be combined to obtain longer-term treatment outcomes. This is made possible through data from AOK insurees. The major limitations of this approach are that the data pool is restricted to AOK insuree data only, the characteristics of which differ to those of the general population, in addition to the fact that the data used for the quality analysis were collected for other purposes and hence only permit limited observations concerning the quality of treatment (Jeschke et al. 2013).

4.3.6 Quality Assurance Measures in Rehabilitation

Quality assurance measures are also conducted for rehabilitation treatment. Ambulatory and inpatient rehabilitation institutions with care contracts (according to § 111, 111a or 111c section 1 Volume V of the German Social Security Code) are to conduct external quality assurance measures according to § 137d Volume V of the German Social Security Code. In addition, legal regulations exist for establishing internal quality measures within the institutions according to § 135a section 2 Volume V of the German Social Security Code. The Federal Association of the Statutory Health Insurance Funds (GKV-Spitzenverband) agrees upon the external quality measures with »the major care provider organizations« according to § 137d Volume V of the German Social Security Code. The agreement specifies that the QSReha[®] procedure be the measure (GKV Spitzenverband (Hrsg.) 2008).

QS-Reha[®] takes into account structural quality, process and outcome qualities as well as patient satisfaction. According to data currently available, approximately 300 specialist institutions participate in QS-Reha[®]. They are listed on the website (<http://www.qs-reha.de/>; accessed: 24 February 2016). The group of »musculoskeletal diseases« is included as an indicator. In 2011, the BQS Institute won the tender to evaluate quality assurance measures. Outcomes from individual institutions are compared with those in the same indication area in order to obtain comparative quality outcomes and average outcomes. The procedure has not yet been fully established. Ambulatory rehabilitation facilities for musculoskeletal diseases (and other areas) have only been included in the procedure during the currently ongoing three-year data collection period from 2015 to 2017 (QS-Reha 2015).

The German Statutory Pension Insurance also conducts comprehensive quality assurance measures in the fields of structural quality as well as process and outcome quality. The procedures include (Deutsche Rentenversicherung 2015):

- surveys of the structural quality of rehabilitation institutions,
- patient interviews to determine patient satisfaction with rehabilitation measures and to

obtain patient evaluations on the success of treatment,

- assessments of individual rehabilitation processes by experienced rehabilitation staff,
- documentation of the range of therapeutic services provided by the rehabilitation institutions,
- developing rehabilitation guidelines for the structuring of rehabilitation measures.

These measures also cover THA and TKA. Rehabilitation establishments are issued so-called »Reports on the quality assurance of rehabilitation« which provide feedback about how they conform to the above-mentioned rehabilitation therapy standards and to enable comparisons with other institutions. Therapy standards are divided into modules that enable targeted improvements if any shortfalls are identified (Deutsche Rentenversicherung Bund 2011). Systematic publications of quality assurance outcomes do not exist but overall results, for example with regard to patient satisfaction, may be included in other publications (Deutsche Rentenversicherung Bund 2013). In addition, assessments of patient discharge reports are conducted by experienced physicians in so-called peer reviews. Checklists for rehabilitation procedures, processes and indication-specific requirements are used for these reviews (Baumgarten and Klosterhuis 2007).

4.3.7 Review of Orthopedics and Trauma Surgery Research

Diseases of the musculoskeletal system are amongst the most common diseases in Germany. In 2013, these diseases accounted for 313 days of incapacity to work per 100 insuree years with which diseases of the musculoskeletal system were more frequent than any other type of disease (DAK 2014). Osteoarthritis is one of the most common joint diseases in adults worldwide. It is characterized by degenerative diseases of the joints caused by wear and tear of the articular cartilage. Large joints such as the hip (osteoarthritis of the hip) and knees (osteoarthritis of the knee) are most commonly affected. In Germany, arthrosis of the hip or knee joint affects approximately 28 % of women and approximately 20 % of

men (lifetime prevalence) (► Chapter 1). Arthroplasty has become an established procedure for treating these joint diseases (Mittelmeier et al. 2012).

The DGOU surveyed the increasing prevalence of musculoskeletal diseases in relation to demographic trends, current therapeutic measures and the need for further research. The results of this survey were published in a 2012 White Paper: »Research in Orthopedics and Trauma Surgery – Review and Outlook (Weißbuch »Forschung in Orthopädie und Unfallchirurgie – Bestandsaufnahme und Ausblick«)«. The White Paper contains detailed information about fundamental research, current research activities and future perspectives with regard to musculoskeletal research (Mittelmeier et al. 2012).

Due to demographic trends and the increasing number of younger patients being treated, it can be expected that the numbers of hip and knee arthroplasties will rise in the future (Ewerbeck et al. 2012). External quality assurance in the field of endoprosthetics in Germany focuses on short-term outcome quality documented up to the point of patient discharge (Liebs and Hassenpflug 2012). Long-term outcome quality is currently not being systematically measured and the effects of different determinants on outcome quality are unknown. It is still currently unclear how long-term outcome quality could be measured precisely (service life, health-related quality of life, patient satisfaction) and how it is affected by surgical procedures, implants, follow-up care and individual patient characteristics (Liebs and Hassenpflug 2012). According to the authors of the White Paper, maintaining an endoprostheses registry could be one way of measuring and evaluating patient data with regard to long-term quality as this has been shown to contribute to significant improvements in the quality of care in other countries (Liebs and Hassenpflug 2012). Such a registry was introduced into German hospitals in 2013 (Section 4.3.3).

Comparative sustainability testing for safe and low-risk medical devices is another objective that has been identified for future research (Mittelmeier et al. 2012). Simulations are to play a greater role in the testing of implants in the future. New implants are to undergo endurance testing by means of

modern computer simulations and robot tests before they are approved (Mittelmeier et al. 2012).

Further research in the future is to focus on physiological, biological, biomechanical mechanisms of action and their interactions with the aim of developing new materials and bioactive coatings. Past research has contributed to developing specific types of synthetic materials that reduce implant abrasion and consequently improve patient care (Ewerbeck et al. 2012).

4.4 Medical Societies and Professional Associations

The **German Society of Orthopedics and Orthopedic Surgery (DGOOC, Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie)** is dedicated to promoting orthopedics and represents the interests of approximately 3,000 members (DGOU 2013). Besides providing continuing education and specialty training programs in orthopedics, the DGOOC is involved in developing evidence-based guidelines in collaboration with other medical societies. Various DGOOC divisions are responsible for the improvement in different orthopedic sub-specialties. Each division may found its own non-profit association as, for example, the rheumatic orthopedics division has done with the creation of the association »Deutsche Gesellschaft für orthopädische Rheumatologie e.V.« (DGORh 2015, DGOU 2013). Working groups within the DGOOC deal with specific scientific subject areas. Currently, there are 17 working groups, including the German joint registry (EPRD) working group (DGOOC 2015). The DGOOC established the EPRD (Section 4.3.3) as a non-profit limited liability company under German law as a wholly-owned subsidiary.

The **German Society for Trauma Surgery (DGU, Deutsche Gesellschaft für Unfallchirurgie)** was founded in 1922 and includes approximately 4,600 members. The DGU is committed to providing basic and specialty training as well as continuing education in orthopedics and trauma surgery. It publishes guidelines for trauma surgery diagnostics and therapy and plays a major role in quality assurance and improvement of treatment for severely injured

patients (DGU 2015b). The DGU trauma registry »TraumaRegister DGU« is an organization made up of trauma surgery specialist hospitals which aims to assess the quality of care and evaluate medical treatment methods with regard to their effectiveness. Over 100,000 datasets from severely injured patients are currently documented in the Trauma Register DGU (DGU 2015a). The DGU trauma network »TraumaNetzwerk DGU« aims to establish nationwide networks for interdisciplinary care of severely injured patients and consequently optimize treatment (DGU 2015a).

The **German Society for Orthopaedics and Trauma (DGOU, Deutsche Gesellschaft für Orthopädie und Unfallchirurgie)** represents the interests of its two funding bodies, the DGOOC and DGU in orthopedics and trauma surgery. The DGOU was founded in 2008 as a non-profit association and currently includes approximately 10,000 members. Responsibilities of the DGOU include basic and specialty training, continuing education, promotion of research in orthopedics and trauma surgery, making networks and platforms available for scientific exchange and enabling the communication of research results through different scientific journals (DGU 2015b).

The German arthroplasty association »**Deutsche Gesellschaft für Endoprothetik e. V. (AE)**« is a division of the DGOU dealing with endoprosthetics (DGOU 2015). It was founded in 1996 as a non-profit association with the aim of improving the quality of life of patients with joint diseases and injuries (Deutsche Gesellschaft für Endoprothetik 2014). The AE's main responsibilities include quality assurance and quality control of endoprosthetic care as well as the further development of existing and novel technologies for movement recovery. To this end, the association works closely together with the medical technology industry (Deutsche Gesellschaft für Endoprothetik 2014).

The **Professional Association of Orthopaedic Surgeons (BVOU, Berufsverband für Orthopädie und Unfallchirurgie)** represents the professional interests of orthopedic and trauma surgery specialists in medical associations and political institutions. The association currently includes approximately 7,000 members (BVOU 2015a). In addition, the BVOU organizes certified advanced and further

training in orthopedics, trauma surgery and related subjects in collaboration with the orthopedic academy »Akademie Deutscher Orthopäden« (BVOU 2015b).

Together with the AE and the BVOU, the DGOOC has developed an initiative for certifying medical institutions that offer joint replacement services (endoCert, section 4.3.4).

4.5 Patient Support and Advice

The German association for osteoarthritis support »**Deutsche Arthrose-Hilfe e.V.**« is a registered non-profit association which aims to inform people suffering from osteoarthritis about the causes, prevention and treatment of osteoarthritis. It also provides support and counseling in individual cases. The association regularly publishes the »Arthrose-Info« magazine which provides information about the different types of osteoarthritis, their diagnoses and treatment as well as prevention and early detection methods (DAH 2015c).

A further goal is to support scientific and clinical osteoarthritis research (DAH 2015b) for example, by funding research projects and providing grants to young scientists. The association funded the establishment of the EPRD, for example (Section 4.3.3), in addition to a study to measure patient preferences with regard to TKA as well as the in-vivo evaluation of hip implant fixation in THA (DAH 2015a).

The German league against rheumatism »**Deutsche Rheuma-Liga**« includes 290,000 members and describes itself as the largest self-help organization in the field of healthcare. Its responsibilities include offering support and self-help services to patients, representing the interests of those suffering from rheumatism in politics, healthcare and the public as well as promoting research (Deutsche Rheuma-Liga 2015a). To this end, the Rheuma-Liga collaborates closely with other associations and organizations such as the DGOOC (Deutsche Rheuma-Liga 2015b). It makes comprehensive information available regarding endoprosthetics and facilitates decision-making processes with regard to replacement surgery. Amongst other things, it provides reports on patient experiences, a fact sheet on arthroplasty and information about treatment

options if an implant is defective (Deutsche Rheuma-Liga 2015c).

The pain forum »Forum Schmerz« is a division of the German Green Cross (Deutsches Grünes Kreuz e. V.) which keeps patients informed on pain therapy options and makes recommendations for various approaches to treatment in collaboration with a scientific advisory board. The forum provides information online (<http://www.forum-schmerz.de/schmerz-infos/arthrose.html>, last accessed: 22 December 2015) regarding osteoarthritis, its causes, diagnosis, therapies and self-help options (Forum Schmerz 2015).

4.6 The German Medical Technology Association (BVMed)

As a trade association, The German Medical Technology Association (BVMed) promotes and represents the interests of the medical technology industry and trade companies in public and informs political decisions (BVMed 2014b). The BVMed currently includes 227 member companies (BVMed 2015a).

The BVMed represents the interests of its members with regard to hip, knee, shoulder and spinal implants, heart valves and defibrillators as well as medical dressings, incontinence products, synthetic disposable items such as catheters and cannulas, homecare services and nanotechnology applications (BVMed 2014a).

The BVMed provides its members with information and advice on legal matters and regulations and establishes platforms for dialogue and exchange through project groups, working groups and sector interest groups. The »Endoprosthetics – Implants« sector interest group is involved in public discussions and works towards informing political decision-makers about the benefits of endoprosthetic care (BVMed 2015a).

4.7 Training and Further Education of Healthcare Staff

The outcome of joint replacement surgery is not only determined by factors relating to an individual

patient and accompanying diseases but also to medical staff involved in the operation. Studies on hip and knee replacements demonstrate that a surgeon's professional capabilities can influence the rate of complications (Lau et al. 2012, Zenk et al. 2014).

4.7.1 Basic and Specialty Training of physicians

As registered organizations under public law in Germany, all State Chambers of Physicians (Landesärztekammer) are responsible for offering further specialist training. The German Medical Association (Bundesärztekammer) develops (model) regulations on specialty training which serve as a recommendation for the State Chambers of Physicians (BÄK 2015). In addition to (model) specialty training regulations, (model) guidelines are also given for further training. These guidelines are developed in collaboration with the State Chambers of Physicians and are also based on feedback from medical societies and professional associations. The (model) guidelines stipulate requirements for training in terms of the number of examinations and treatments that must be performed to attain a specific qualification. They also take into account average performance of hospitals and medical practices (BÄK 2011).

Specialty training for orthopedics and the sub-specialty trauma surgery were merged in 2005 (BÄK 2015). The goal upon completion of this six-year specialty training for orthopedics and trauma surgery is for physicians to attain basic and subsequent specialist competence in orthopedics and trauma surgery upon completion of the required training period.

According to the German Medical Association's 2013 model code of continuing professional development, physicians must undergo continuing education in order to maintain and develop their professional expertise. Physicians are required to attain a minimum of 250 additional training credit points within a period of five years. According to Volume V of the German Social Security Code, statutory health insurance physicians and consultants in working in hospitals are required to provide further evidence of participation in continuing medical education.

Professional associations (e.g. DGOOC, DGOU) and institutional centers provide part of the further training required. In addition, workshops and seminars held by manufacturers of medical devices also constitute part of the further training (BVMed 2015b). Further training programs have not been systematically evaluated.

Further training and continuing education for physicians and nursing staff plays an important role in establishing integrated comprehensive risk and quality management under endoCert (Haas et al. 2013).

4.7.2 Training and Continuing Education for Nursing Staff

Nursing training is regulated by the Nursing Act (Krankenpflegegesetz). Surgical nursing staff firstly work in a surgical unit for at least six months and subsequently complete a two-year vocational training program. Surgical technicians (Operationstechnischer Assistent (OTA)) undergo a three-year training program. OTAs support the surgical team and the patient before, during and after surgery (DOSV 2016). Training content and examination regulations for nursing staff are developed in parallel to those of physicians. Further training events, workshops and seminars held by manufacturers of medical devices manufacturers also constitute part of the training and continuing education for nurses.

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Health Economic Aspects

Michael Weißer, Hubertus Rosery, Tonio Schönfelder

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Summary

The costs incurred for knee and hip arthroplasty depend on the different type of treatments provided within the chain of medical care. Indirect costs of the disease, such as the incapacity to work resulting from the underlying diseases and intangible costs which cannot be evaluated in monetary terms, must also be taken into account. Patient care is financed through established remuneration systems. According to different publications, data extrapolations have shown that German statutory health insurances spent approximately 1.4 to 1.6 billion euros per year on hospital treatments for hip arthroplasty between 2003 and 2009. With regard to knee arthroplasty, expenditure for the same period was estimated at 1.0 to 1.3 billion euros per year. The direct costs for the associated inpatient stays are financed through case-based fees, which are in turn based on the actual average hospital costs. The most commonly remunerated case fees (hip arthroplasty/knee arthroplasty) have shown cost increases of a few percentage points over the last few years which are mainly due to the rising costs of personnel. In the two case-fee groups, implant costs constitute 21 % of the total cost for hip treatments and 25 % of the total cost for knee treatments. Particularly complicated cases such as infected hip endoprostheses are relatively more costly. With regard to indirect costs, the diagnosis »Osteoarthritis of hip« (ICD-10 M16) resulted in 2,585,157 days of incapacity to work amongst compulsory statutory health insurances (excluding pensioners) in 2011. For »Osteoarthritis of knee« (ICD-10 M17) the figure was almost double at 4,971,052. Some patients who are in employment are unable to return to work despite having undergone a joint replacement and either have to change profession or accept a loss of income that includes social security contributions. Osteoarthritis, which is the most common reason for hip or knee replacements, is associated with a significant, increasing and in part immeasurable disease burden. International studies have demonstrated that the disease is accompanied by a high degree of suffering on the part of the patient as the large majority (70 % or more) would be personally willing to finance the hip or knee arthroplasty at their own cost if the procedures were not included amongst those reimbursed by health insurance systems. Hospitals in Germany finance the costs of arthroplasty with one of several

possible arthroplasty case fees selected according to the specific service provided and the circumstances of each case. The case fees are based on the average costs of a given treatment. The case fee figures in 2015, which were based on certain benchmarks, ranged between approximately 6,400 euros and 17,300 euros. However, case fees do not always seem to cover the hospital costs, particularly in the treatment of more complicated cases.

5.1 Costs

5.1.1 Direct Costs

Direct costs of treatment for patients who undergo knee or hip arthroplasty include those incurred prior to surgery, during inpatient stay and over the course of postoperative treatment.

The typical ideal treatment pathway for patients with osteoarthritis of the knee and the hip starts in an ambulatory setting with a consultation with a primary-care physician and continues with the referral to a practice-based specialist who subsequently refers the patient to hospital for surgery. After surgery, the patients undergo (subsequent) rehabilitation procedures and, if necessary, follow-up ambulatory care by the specialist physician (AQUA-Institut 2012).

Therefore, healthcare providers who are directly involved in the patient treatment, i.e. primary-care physicians, practice-based specialists, hospitals and rehabilitation establishments consequently incur healthcare expenses. Beyond this, physicians prescribing medication, therapeutic products or medical technical aids also add to further healthcare expenditure as do prescriptions for other care providers (for example, physiotherapists) in addition to material costs for equipment and consumables.

In 2008, the disease costs cited for the entire spectrum of osteoarthritis (ICD-10 M15M16) in Germany amounted to 7.62 billion euros. This total cost is distributed across various establishments within the chain of care (Rabenberg 2013) as presented in [Tab. 5.1](#).

Malzahn (2014) made various observations from an economic perspective with regard to the conservative and surgical treatment of patients who

■ **Tab. 5.1** Osteoarthritis-related disease costs in Germany in 2008, by type of medical institution

Type of institution	Total expenditure in million €
Ambulatory institutions	2,547
Doctors' practices	978
Pharmacies	939
Ambulatory care	515
Others	660
Inpatient/day-care facilities	4,284
Hospitals	2,705
Preventive/rehabilitation facilities	873
Inpatient care/day-care	706
Other institutions	790
Institutions in total	7,620

Source: IGES – Destatis (2015)

are of working age (20–59 years) who were suffering from osteoarthritis of the knee. His observations were based on the individual one-year periods before and after arthroplasty to treat osteoarthritis of the knee«. The data were obtained from services provided to male AOK insurees who were of working age. ■ Tab. 5.2 presents total expenditures for individual patients in the periods 12 months before to 12 months after surgery, divided into two age groups and according to conservative or surgical

treatment. The data shows that the group of older patients constitutes the absolute majority of patients observed, but that individual patient expenditures are lower for the older age group than for the younger age group. This applies to both conservative and surgical treatment (Malzahn 2014).

The largest single expenditure item for individual patients, outside of expenses incurred in hospital, was expenditure on therapeutic products. It remains the largest single expenditure as long as the expenditure for medication is divided into costs that are strictly related to osteoarthritis only and costs that are potentially connected to osteoarthritis in a broader sense, as was done in the publication. These expenditures are presented in ■ Tab. 5.3.

■ Tab. 5.4 presents expenditures for hospital services provided to the patient cohort observed. The implantation of the actual prosthesis is included in the 12 months after surgery expenditure period which is why preoperative hospital expenditure is the same for both considerations (with/without endoprosthetic replacement).

Endoprosthetic surgery costs have been estimated at 7,105.50 euros. This accounts for the difference observed between hospital expenditure with and without endoprosthetic replacements (costs per patient 12 months after surgery). The costs for the replacement itself are to be considered as an estimate based on the lowest determined value. This value is higher than the average expenditure for knee arthroplasty as it includes treatment costs related to osteoarthritis of the knee (main diagnosis M17) over a period of three months after surgery (Malzahn 2014).

■ **Tab. 5.2** Total individual patient expenditures for total knee arthroplasty (TKA) due to osteoarthritis of the knee

Patient age (years)	Case number	Expenditure (€)		
		12 months before surgery		12 months after surgery
		Conservative treatment	Surgery	
			Including TKA expenditure	Excluding TKA expenditure
20-49	452	1,249.34	9,638.71	2,533.21
50-59	3,895	988.26	8,145.07	1,039.57

Source: IGES – Malzahn (2014)

Tab. 5.3 Expenditures for therapeutic products, contractual physician care and drugs for patients with osteoarthritis of the knee who undergo total knee arthroplasty (TKA)

Patient age (years)	Expenditure 12 months before surgery (€)	Expenditure 12 months after surgery (€)
Expenditure for therapeutic products		
20–49	125.25	378.97
50–59	133.38	395.57
Expenditure for contractual physician care		
20–49	75.19	87.55
50–59	95.55	106.81
Expenditure for drugs I: strictly for osteoarthritis only		
20–49	55.13	58.19
50–59	65.91	65.09
Expenditure for drugs II: potentially related to osteoarthritis		
20–49	196.52	313.14
50–59	114.39	100.45
Source: IGES – Mahlzahl (2014)		

Tab. 5.4 Hospital expenditure for patients with osteoarthritis of the knee who undergo total knee arthroplasty (TKA)

Patient age (years)	Expenditure 12 months before surgery (€) per patient	Expenditure 12 months after surgery (€) per patient
Hospital expenditure		
20–49	797.28	8,800.86
50–59	579.03	7,477.15
Hospital expenditure excluding endoprosthesis replacement		
20–49	797.28	1,695.36
50–59	579.03	371.65
Source: IGES – Mahlzahl (2014)		

According to the SHI Barmer GEK (2010), extrapolations from the period between 2003 and 2009 showed that statutory health insurance funds in Germany spent approximately 1.4 to 1.6 billion euros per year on hospital treatment for hip arthroplasty. For knee arthroplasty, the amounts for the same period were estimated at 1.0 to 1.3 billion euros per year (Barmer GEK 2010).

The remuneration that a hospital receives for inpatient treatment cases constitutes the direct health insurance fund costs for the treatment case. The hospitals receive fees on a case-per-case basis (case fees) for individual inpatient stays for primary total arthroplasty and revision total arthroplasty/revisions (the case fees are also labelled Diagnosis Related Groups (DRGs)). The case fees reflect the

average costs of treatment during a patient's stay in hospital.

The most commonly remunerated endoprosthetic procedure on the hip is DRG I47B (revision or replacement of a hip joint without complicating diagnosis/without complicating surgery). With regard to knee arthroplasty, the most common DRG is I44B (implantation of a bicondylar endoprosthesis or other endoprosthesis implantation/revision on the knee joint) (InEK 2009), cf. ■ Tab. 5.5 and ■ Tab. 5.6.

As can be seen from the terms used to describe the DRGs, the fees usually cover several different types of interventions. Consequently, calculating the average costs of primary arthroplasty, revisions and/or revision hip or knee replacements separately is not possible. This is because the DRG system remunerates similar cases and treatments based on the average costs of different interventions.

The cost composition of an individual DRG is presented in ■ Tab. 5.5 and ■ Tab. 5.6 using DRG I47B (endoprosthetics hip joint) and DRG I44B (endoprosthetics knee joint) as examples. The German institute for hospital reimbursement »Institut für das Entgeltsystem im Krankenhaus (InEK)« collects the relevant cost data from several hundred German hospitals on an annual basis (§17b German Hospital Remuneration Act KHG (InEK 2014)). The calculations are defined by actual average cost data for specific cases in a particular year. The tables contain data from 2008 to 2013 illustrating changes in proportions of the different costs.

■ Tab. 5.5 shows that medical personnel (cost type 1–3) account for the largest proportion of costs related to DRG I47B cases, i.e. the average hip replacement or revision case (2,750.33 euros in 2013, or just under 44 % of the total amount). In contrast, implants show lower proportions of medical personnel costs at 1,329.94 euros or approximately 21 % of the total amount. From 2009 to 2013, the costs for an average treatment case rose by approximately 325 euros, which was due to increasing staff costs in particular. Implant costs, however, have hardly changed.

A similar trend is presented in ■ Tab. 5.6. In 2013, the staff costs related to hospital treatment cases under DRG I44B (implantation of a bicondylar endoprosthesis or other endoprosthesis implan-

■ Tab. 5.5 Simplified calculation matrix, exemplified with G-DRG I47B (revision or replacement of a hip joint)

Personnel and material costs, data for the year	Personnel costs [€]			Material costs [€]			Material costs [€]			Personnel/material costs			Total
	1	2	3	4a	4b*	5*	Other medical requirements		Medical infrastructure	Non-medical infrastructure	7	8	
							6a*	6b*					
2013	1,152.4	938.6	659.3	84.3	42.7	1,329.9	305.1	158.0	430.2	1,191.1			6,291.7
2012	1,113.4	938.5	639.3	88.2	50.8	1,303.4	297.1	166.9	419.4	1,147.8			6,164.7
2011	1,070.7	920.4	610.5	90.6	57.0	1,320.9	305.2	159.9	411.2	1,151.4			6,097.8
2010	1,020.0	884.0	587.1	100.4	52.3	1,331.8	303.5	145.4	395.5	1,127.4			5,947.4
2009	973.6	891.3	602.1	108.5	45.9	1,360.3	326.5	140.0	385.4	1,132.8			5,966.3

Note: *Individual costs/actual expenditures; source: IGES – InEK (2015c)

Tab. 5.6 Simplified calculation matrix based on G-DRG I44B (implantation of a bicondylar endoprosthesis or other endoprosthesis implantation/revision on the knee joint)

Personnel and material costs, data for the year	Personnel costs [€]			Material costs [€]				Personnel/material costs		Total	
	1	2	3	4a	4b*	5*	6a*	6b*	7		8
2013	1,203.6	935.6	748.3	87.4	30.9	1,504.8	313.8	214.7	446.4	1,263.4	6,749.1
2012	1,133.8	916.2	711.3	91.4	36.9	1,527.4	309.4	211.9	429.3	1,203.3	6,571.0
2011	1,060.2	912.2	662.2	93.5	40.2	1,508.4	316.4	187.7	420.9	187.4	6,389.0
2010	1,032.6	869.1	644.6	103.9	43.1	1,566.1	320.0	163.1	410.4	1,163.9	6,316.9
2009	995.0	892.1	666.3	112.8	37.9	1,632.0	344.1	164.9	401.6	1,189.9	6,436.6

Note: *Individual costs/actual expenditures; source: IGES – InEK (2015c)

Tab. 5.7 Costs of infected hip endoprostheses in the DRG system

Group	Patient number	Costs per patient (€)
Infected hip endoprosthesis	49	29,331.36
Primary THA	21	6,263.59

Source: IGES – Haenle et al. (2012)

tation/revision on the knee joint) amounted to 2,887.37 euros (cost types 1-3), approximately 43 % of the total amount. Implant costs amounted to 1,504.78 euros or approximately 22 % of the total amount. In these DRG cases, the costs also increased by approximately 315 euros from 2009 to 2013. Although implant costs decreased during this period, staff costs in particular increased, as was the case for DRG I47B. Haenle et al. (2012) conducted a retrospective study on the costs of revision surgery due to periprosthetic infection after primary total hip arthroplasty. The study assessed a group of 49 patients who underwent revision (with different kinds of revision procedures) the different costs of which were compared to the costs and remuneration for 21 patients with primary total hip arthroplasty. All the patients were treated in the Rostock University Medical Center. The 49 patients with infected endoprostheses had an average length of stay of 52.7 days, of which 4.4 days were in intensive care. The average costs for both groups are shown in **Tab. 5.7** (Haenle et al. 2012).

This shows that revision total replacements with periprosthetic infection lead to costs that are several times higher than primary arthroplasty costs. The highest cost items of the surgery are presented in **Tab. 5.8** (Haenle et al. 2012).

The analysis is not representative for Germany as it was based on a small group of patients who were treated in a single center. However, the calculation does demonstrate the additional expenses for treating infected endoprostheses.

An additional German study including 114 patients assessed the surgery costs of hip revisions due to aseptic loosening of the endoprosthesis (one of

■ **Tab. 5.8** Costs of primary THA and infected hip prosthesis

Costs of	Primary THA	Infected hip prosthesis
Implant	€2,111.66 (33.7 %)	€5,133.12 (17.5 %)
Medical requirements	€1,165.27 (18.6 %)	€6,254.99 (21.3 %)
Normal hospital ward	€1,713.76 (27.4 %)	€7,134.91 (27.4 %)
Anesthesia	€710.27 (11.3 %)	€5,395.61 (18.4 %)

Source: IGES – Haenle et al. (2012)

the most common reasons for revisions, ► Chapter 3.3) (Assmann et al. 2014). The study focused on the direct costs of the intervention and compared these with the respective DRG calculations. DRG calculations are maintained by the German Institute for Hospital Reimbursement »Institut für das Entgeltssystem im Krankenhaus (InEK)« using cost data from several hundred German hospitals (► Chapter 5.2). An analysis published by Assmann et al. (2014) grouped the cost components into two cost items: the hospital ward costs and the actual surgery costs. ■ Tab. 5.9 illustrates a comparison between the average treatment costs of the study population and the calculated costs of the most common DRGs. It should be noted that the DRG characteristics and calculations are based on 2011 figures and specifications (Assmann et al. 2014).

The majority of revision replacements (98 of a total of 114 patients) were allocated to DRGs I46A (referred to in 2011 as »Change of prosthesis of the hip joint with very severe CC or with allogenic bone transplant«) and I46B (referred to in 2011 as »Change of prosthesis of the hip joint without very severe CC, without allogenic bone transplant«). The direct average costs in the study population were 4,380 euros which were below the calculated costs for the corresponding DRGs. The authors attribute this difference to indirect hospital costs (administrative costs, buildings, energy, etc.) (Assmann et al. 2014). As this study solely illustrates the cost structure of one individual hospital it cannot be considered representative for Germany as a whole.

A randomized controlled study conducted in Finland of patients who underwent TKA to determine whether delayed or untimely treatment leads

to (additional) costs presents the following results (Tuominen et al. 2010). Over 400 osteoarthritis patients were randomly allocated either to a waiting list for surgery to take place within three months or, as is common in normal hospital routine, to a waiting list with a waiting period of longer than three months. The average waiting times were 94 days in one group and 239 days in the other. Statistically significant differences between the groups were identified for two aspects. In the group that had to wait longer for surgery, the health-related quality of life one year post-surgery was higher than in the other group. In contrast, the weekly cost of medication at the time of hospital admission was higher in the group that had shorter waiting periods. The authors discuss that the latter result could be due to the fact that patients within the shorter waiting period group had more severe pain at the time of inclusion in the study. No statistically significant differences with regard to the weekly cost of medication could be found at the time of the three month follow-up and one year after surgery (Tuominen et al. 2010).

In most cases of hip and knee arthroplasty patients undergo subsequent rehabilitation treatment (AHB) and some patients even receive medical rehabilitation care prior to surgery (► Chapter 3.4). The direct costs of rehabilitation should be added to the costs of additional ambulatory care and inpatient stays. However, as mentioned in Section 3.4., the data regarding rehabilitation are fragmented and limited.

Tab. 5.9 Average costs of patient cases in a study population and average costs of respective DRG calculations for hip joint revisions due to aseptic loosening of the endoprosthesis

	I46A (n=55)		I46B (n=43)		Other DRGs (n=16)		All patients included in the study (n=114)
	Study	DRG calculation	Difference	Study	DRG calculation	Difference	
Ward costs	1,847.3	2,554.8	-707.5 (72.3 %)	1,351.0	1,897.8	-546.8 (71.2 %)	1,655.1
Surgery costs	2,627.7	3,517.4	-889.7 (74.7 %)	2,520.1	2,645.4	-125.3 (95.3 %)	2,724.9
Total costs	4,475.0	6,072.2	-1,597.2 (73.7 %)	3,871.1	4,543.2	-672.1 (85.2 %)	4,380.0

Source: IGES – Assmann (2014)

5.1.2 Indirect Costs

From a societal perspective, indirect costs arise as patients with osteoarthritis of the knee or hip are unable to work and hence lose years of employment.

In 2011, the diagnosis »Osteoarthritis of the hip« (ICD-10 M16) resulted in 2,585,157 days of incapacity to work amongst the compulsory statutory health insurances (excluding pensioners). For »Osteoarthritis of the knee« (ICD-10 M17), the number of days of incapacity to work was almost double at 4,971,052 days. In the same year, approximately 1,600 working people went into retirement due to a reduced capacity to work as a result of osteoarthritis of the hip and approximately 3,100 due to osteoarthritis of the knee. In 2011, these accounted for almost 80 % of all people going into retirement because of osteoarthritis. The average age at the time of retirement was approximately 55 years for women and 56 years for men. The diseases osteoarthritis of the knee and osteoarthritis of the hip are therefore of great economic importance with regard to indirect costs (Rabenberg 2013).

This is further highlighted by an analysis of routine data by the German Statutory Pension Insurance. Even if patients can be reintegrated back into work after undergoing a joint replacement, it may result in their having to change profession or in a loss of income that includes social security contributions. The analysis shows that this is the case in 36.5 % of all patients following total hip arthroplasty (Krischak et al. 2013).

5.1.3 Intangible Costs and Health Burden

Besides direct and indirect costs, patients are also subject to intangible costs.

- » Intangible costs arise from incidents such as pain and anxiety and cannot be directly calculated in terms of resource requirements or evaluated in monetary terms (IQWiG 2015).

Intangible costs are difficult to quantify and hence only very few studies on the subject exist. With regard to the underlying diagnosis (► Chapter 2) high

intangible costs due to pain and anxiety before surgery can be expected on the part of patients. A number of international studies based on data collected on a patient's willingness to pay for treatment have been conducted. However, their validity for Germany is limited. Approaches that use the willingness to pay aim to assess intangible costs for avoiding disease, pain and anxiety in monetary measures.

An Australian study surveyed patients who had to undergo THA or TKA and their willingness to pay for treatment two to three years after the surgery. The patients were asked how much and whether they were willing to pay out of their own pocket for arthroplasty if the procedure was not included in the services provided by the healthcare system. 71 % of THA patients were prepared to pay for the operation but 11 % reported that they were not willing to do so. 25 % of the patients stated they were willing to pay more than 15,000 Australian dollars, which was equivalent to the hospital costs for joint replacements at the time. With regard to TKA patients, 70 % reported that they were willing to pay for the surgery, but 16 % said they were not. 18 % of the patients said they were willing to pay over 15,000 Australian dollars. Amongst the patients who were willing to pay for surgery in both groups (THA and TKA), the relative majority in each group were willing to pay up to 4,999 Australian dollars. The author's calculations illustrated that those patients who were more willing to pay achieved better outcomes after surgery with regard to both their general and disease-specific conditions (including pain, joint stiffness and physical function). According to the authors, other aspects besides the state of health also played a role in the willingness to pay for treatment. For TKA patients, the most important aspects included the patients' willingness to recommend the treatment, having private health insurance and lower WOMAC pain scores. For THA patients, the strongest predictor for the willingness to pay was income, followed by the pain classification in the WOMAC score (Cross et al. 2000).

A study of 105 patients with osteoarthritis of the knee conducted in a center in Singapore investigated the amounts participants were willing to pay for a hypothetical, complete cure of osteoarthritis without any side effects. The willingness to pay depended not only on the patients' income and employ-

ment status but also on their general condition. A higher perceived state of health led to a lower willingness to pay (Xie et al. 2008).

Health-related factors that have a significant influence on the (hypothetical) willingness to pay for treatment of osteoarthritis of the knee, or for THA and TKA as alternative intangible cost variables, seem in particular to be pain and the patients' general state of health. In addition, (socio)economic factors also seem to play a role in the amount patients were willing to pay.

The quality-adjusted life year (QALY) concept is an approach that takes into account a patient's quality of life for cost evaluations. It measures the benefit of medical interventions or surgery in relation to the resulting prolongation of life and the quality of life gained by the patient (Schulenburg and Greiner 2007). To calculate this, the effect of surgery on the quality of life as well as on the prolongation of life must be identifiable. In this concept, one year of full health corresponds to a value of 1 (= optimum state of health) and death corresponds to a value of 0 (= worst state of health) (Phillips and Thompson 2009, Schulenburg and Greiner 2007). For example, surgery that prolongs the remaining lifetime of a patient by 10 years with impaired health of 0.75 would result in 7.5 (10×0.75) quality-adjusted life years or QALYs.

A study carried out from the perspective of the German SHI system by Mujica-Mota et al., analyzed both the average and incremental costs per QALY of patients who were either treated conservatively (without surgery) or who underwent THA (Mujica-Mota et al. 2015). The analysis demonstrated that the costs for both forms of treatment were comparable. For 55-year-old patients, non-surgical treatment leads to costs of approximately 27,300 euros for their remaining lifetime. With regard to THA, timely and delayed surgeries were analyzed separately. The median period between both operations was 11 years. Delayed THA resulted in costs of 26,800 euros and timely THA resulted in costs of 28,600 euros. However, marked differences were found between the treatment procedures with regard to QALYs. Non-surgical treatment amounted to 10.3 QALYs, and significantly higher values of 18.8 QALYs were established for delayed THA and 20.7 QALYs for timely THA. When the incremental

costs per QALY (discounted at 5 %) were investigated for both types of surgical treatment, timely THA was shown to be more cost-effective than delayed THA by approximately 1,000 euros for women treated at the age of 55 and 1,250 euros for women treated at the age of 65 and 1,100 euros or 1,900 euros respectively for men (Mujica-Mota et al. 2015).

Chronic joint diseases are considered to be the most frequent cause of disability in the USA. According to WHO calculations, they are the fourth most common cause of years lived with a disability (YLD) worldwide (Merx et al. 2007).

The Global Burden of Disease study compared 291 diseases based on the causes of disabilities measured in YLD and ranked hip and knee osteoarthritis 11th amongst diseases assessed worldwide in 2010. Following diabetes and falls, hip and knee osteoarthritis are therefore amongst the most common diseases that lead to disability. In 1990, osteoarthritis was ranked 15th amongst diseases assessed. According to calculations in this study, the YLDs for osteoarthritis of the hip and knee have risen globally from 10.5 million in 1990 to 17.1 million in 2010 (Cross et al. 2014).

For the entire disease burden, calculated as disability-adjusted life years (DALY), osteoarthritis of the hip and the knee ranked 38th in 2010, following cardiovascular diseases and epilepsy, amongst others. Since 1990, the number of DALYs has been increasing with osteoarthritis of the hip and the knee ranking 48th, resulting in an increase in their disease burden as was also observed for YALYs. In 1990, they accounted for 0.42 % of the total DALYs calculated. In 2010, this proportion rose to 0.69 % (Cross et al. 2014).

Joint diseases, particularly osteoarthritis which is the most common reason for requiring a joint replacement, are therefore accompanied by a significant, increasing and sometimes immeasurable disease burden.

5.2 Financing, Remuneration and Regulations

Statutory health insurance funds in Germany cover ambulatory services provided by physicians who are

members of statutory health insurance physicians' associations. These services are remunerated based on the uniform value scale »Einheitlicher Bewertungsmaßstab (EBM)«. The physician is remunerated directly for services that are listed in the EBM without the patient having to pay for the services themselves.

Regarding private health insurance, the physician invoices the patient based on the physicians' fee catalog »Gebührenordnung für Ärzte (GOÄ)«. The patient pays for the service and the costs are subsequently reimbursed by the private health insurance fund.

The costs of medication, therapeutic products and medical technical aids prescribed by the physician are covered by the payers, provided they are approved for reimbursement.

For both statutory and private health insurances there may be services that have not been approved by the payers and which patients consequently have to cover themselves without being reimbursed. Under the statutory health insurance system, individual health services that are paid for privately by the patient are termed »Individuelle Gesundheitsleistungen (IGeL)«.

Immediate and running costs of medically required hospital services are covered by statutory and private health insurances and remunerated according to the German case-based payment system »German Diagnosis Related Groups, (G-DRG)«. The G-DRG system is developed further every year by the InEK. Chapter 5.1.1 presents typical DRGs for hip and knee replacements and the corresponding benchmarks for 2015. It also illustrates how a DRG is calculated. The most common case rates related to hip arthroplasty, according to the available relevant data (data publication according to § 21 Hospital Remuneration Act), are listed in ■ Tab. 5.10 and those related to knee arthroplasty are listed in ■ Tab. 5.11. The tables illustrate the levels of remuneration for each flat rate as a monetary benchmark for patients with normal lengths of stays in 2015. They also show the case numbers of patients with normal lengths of stay recorded in 2013. In some federal states, the amount reimbursed may deviate from the benchmarks presented.

An additional DRG which is not listed in the tables as it is attributable to both hip and knee ar-

■ **Tab. 5.10** Hospital case fees for hip arthroplasty, main department (2015)

DRG	Text	Case fee (benchmark, €)*	Registered patients with normal lengths of stay main department 2013
I03A	Revision or replacement of the hip joint with complicating diagnosis or arthrodesis or age < 16 years or bilateral surgery or several major procedures on the joints of the lower extremities with complicated procedure, with major CC or multi-stage replacement or surgery in several regions	17,280.46	1,835
I03B	Revision or replacement of the hip joint with complicating diagnosis or arthrodesis or age < 16 years or bilateral surgery or several major procedures on the joints of the lower extremities with complicated procedure, without major CC, without multi-stage replacement, without surgery in several regions	12,049.15	4,919
I05A	Revision or replacement of the hip joint without complicating diagnosis, without arthrodesis, without complex surgery, with major CC	10,129.81	6,773
I46A	Revision replacement hip joint prosthesis with major CC or surgery in several regions	17,089.82	1,247
I46B	Revision replacement hip joint prosthesis without major CC, without surgery in several regions	9,105.52	14,188
I47A	Revision or replacement of the hip joint without complicating diagnosis, without arthrodesis, without major CC, age > 15 years, with complicating surgery or implantation/revision replacement of a radial head prosthesis or change of inlay of the hip	7,861.51	10,317
I47B	Revision or replacement of the hip joint without complicating diagnosis, without arthrodesis, without major CC, age > 15 years, without complicating surgery	7,237.9	147,861

* Assuming a nationwide base rate of 3231.20 euros in 2015; abbreviation: CC = complications or comorbidities, source: IGES calculations based on InEK data (2015a)

throplasty is DRG I36Z (bilateral implantation or revision hip or knee replacement). In 2013, approximately 800 patients with normal lengths of stay in Germany were allocated to this DRG. Similar to the calculations in ■ Tab. 5.10 and ■ Tab. 5.11, the benchmark value for this was 11,978.06 euros in 2015 (InEK 2015a).

Usually, the hospitals are required to cover their own costs based on these case rates. For the health insurance funds these constitute the direct costs of the relevant treatment cases.

Two main further remuneration pathways exist for costly treatments, which can be applied in addition to the relevant DRG case rate. Both options are

defined by the InEK, as are the case rates themselves.

Additional funding for innovations is available under new examination and treatment methods »Neue Untersuchungs- und Behandlungsmethoden (NUB): Hospitals can submit NUB applications to the InEK DRG institute once a year. The InEK subsequently determines whether the prerequisites for temporary additional remuneration (NUB) for the individual hospital are fulfilled. If the NUB application is approved, the hospital enters into negotiations with the payers during the course of its overall budget negotiations. Negotiations are based on the number of treatments and the remuneration

■ **Tab. 5.11** Hospital case fees for knee arthroplasty, main department (2015). IGES calculations based on InEK data (2015a)

DRG	Text	Case rate (benchmark, €)*	Registered patients with normal lengths of stay main department 2013
I04Z	Implantation, replacement or removal of a knee endoprosthesis with complicating diagnosis or arthrodesis	11,451.37	4,111
I43A	Implantation or replacement of specific knee or elbow endoprostheses or replacement of shoulder or ankle prostheses, with major CC	15,836.11	1,014
I43B	Implantation or replacement of specific knee or elbow endoprostheses or replacement of shoulder or ankle prostheses without major CC	10,297.83	11,075
I44A	Implantation of a bicondylar endoprosthesis or other endoprosthesis implantation/revision on the knee joint, with major CC or correction of a rib cage deformity	11,121.79	1,314
I44B	Implantation of a bicondylar endoprosthesis or other endoprosthesis implantation/revision on the knee joint, without major CC or without correction of a rib cage deformity	7,764.57	103,628
I44C	Various types of endoprosthetic surgery on the knee joint	6,407.47	17,875

* Assuming a nationwide base rate of 3231.20 euros in 2015; abbreviation: CC = complications or comorbidities, source: IGES calculations according to InEK data (2015a)

amounts (§ 6 Section 2 Hospital Remuneration Act (SVR Gesundheit 2014)). Individual hospital negotiations regarding implantable endoprostheses for »(total) temporomandibular joint replacements« and »expandable endoprostheses« were granted by the InEK for the year 2015 (InEK 2015b).

Besides the NUB process, there is also the option of negotiating so-called additional remunerations (Zusatzentgelte (ZE)) in addition to the DRG case rate (cf. § 7 Hospital Remuneration Act (KHG)). These additional remunerations are not restricted to innovations (SVR Gesundheit 2014). In 2015, there were a total of 170 additional remunerations which are partly negotiable by individual hospitals. Regarding replacement surgery, additional remunerations for modular endoprostheses (ZE 2015-25, OPS 5-829.k, OPS 5-829.m) for individual hospitals can be agreed upon between the hospitals and the health insurance funds (InEK 2015a).

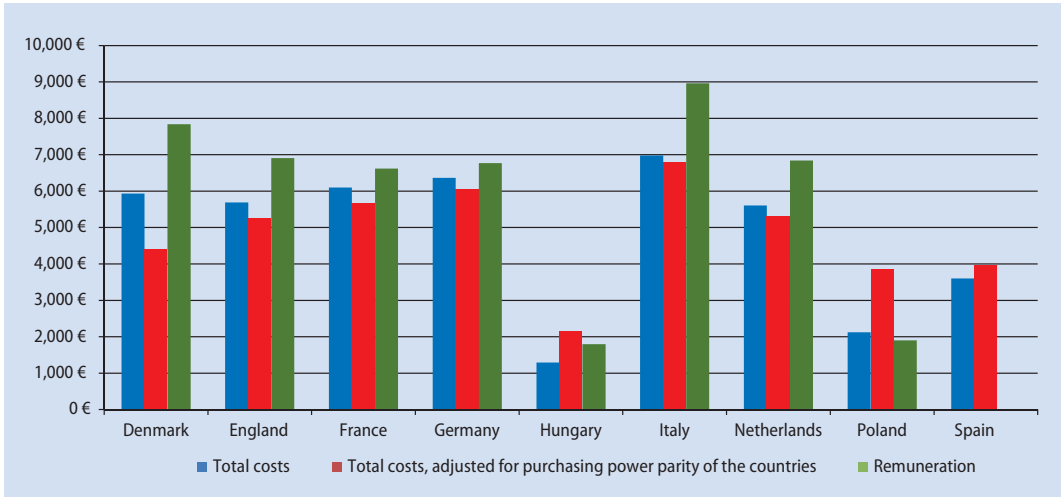
Figure 5.1 illustrates a total cost comparison of unilateral primary hip replacement in nine European countries and shows that the remuneration

was higher than the calculated costs for all countries except for Poland. The remuneration for Spain could not be determined due to the specifics of the healthcare system. It can also be observed that the level of remuneration in Germany was not the highest amongst the countries listed (Stargardt 2008).

Although the analysis for Germany indicates a financial gain for hospitals performing the surgery, the actual situation can differ significantly depending on the treatment case.

Haenle et al. 2012 reviewed not only the costs of revision procedures in comparison to primary THA but also the corresponding excesses or shortfalls in payments in the DRG remuneration system. The average costs, DRG remuneration and the excess or shortfalls in payments for both groups are presented in ■ Tab. 5.12 (Haenle et al. 2012).

It becomes apparent that the treatment of infected hip endoprostheses resulted in costs of almost 30,000 euros and a deficit of approximately 12,700 euros. Consequently, cases in treating hospitals were underfinanced. This demonstrates the



■ Fig. 5.1 Costs and remuneration of primary hip arthroplasty in nine European countries in 2005. (Source: IGES – Stargardt 2008)

■ Tab. 5.12 Deficit/surplus in the DRG system with regard to infected hip endoprostheses

Group	Number of patients	Costs per patient (€)	DRG remuneration (€)	Excess payment or shortfalls (€)
Infected hip prosthesis	49	29,331.36	16,645.76	-12,685.60
Primary total hip arthroplasty	21	6,263.59	7,045.00	781.41

Source: IGES – Haenle et al. (2012)

economic challenge hospitals are faced with in such treatment cases, and they have to compensate the losses through gains made via other types of treatment.

A distinctive situation exists related to SHI financing. The so-called health fund »Gesundheitsfonds« was introduced on 1 January, 2009. Statutory health insurance funds receive the same amount (basic rate) for every insuree and additional or reduced amounts adjusted according to age, sex and risk (KV Berlin 2007). The morbidity oriented risk structure adjustment scheme (Morbi-RSA) takes into account the health status of insurees with regard to funding (Jahn et al. 2012). The additional remuneration for morbidity is based on 80 costly, chronic and severe diseases. »Osteoarthritis of the large joints« is included amongst the diseases listed by the German Federal Insurance Office (Bundes-

versicherungsamt) which also covers osteoarthritis of the knee and the hip (Bundesversicherungsamt 2014).

Through the Morbi-RSA, health insurance funds that include older and more sickly insurees receive higher funds than those that include many healthier or young insurees. This assures compensation in accordance with the SHI's solidarity code, and consequently health insurance funds do not have the economic incentive to specifically acquire young and healthy patients as members (Bundesversicherungsamt 2008). As a result, standardized additional remunerations can be claimed for every insuree suffering from one of the 80 diseases. If during a patient's stay in hospital any of the relevant diseases are diagnosed, the additional remuneration is immediately paid to the patient's health insurance fund. If the diagnosis is made during ambulatory

treatment, the additional remuneration is only paid in the following quarter once the diagnosis has been confirmed (DIMDI 2015).

Remuneration for rehabilitation services, which play a particular role following acute-care in hospital, is paid based on a per diem rate or case fee rate. Per diem rates tend to be applied for remuneration by the German Statutory Pension Insurance funding bodies and case rates by the statutory health in-

surance. The degrees of severity of the cases are not differentiated in the case rates. Consequently, the financial risk of treating patients with severe cases lies with the care providers and not the payers. The case fees cover all costs, including investment costs. There is »hardly any representative data« with regard to the case rate amounts (SVR Gesundheit 2014).

5

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Requirements for Adequate Arthroplasty Care (Expert Opinions)

Hans-Holger Bleß

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Summary

The previous chapters reviewed the status of knee and hip arthroplasty care based on existing literature. This chapter assesses the current situation from an expert perspective through the examination and analysis of available data. In August 2015, a workshop was conducted in preparation for this chapter, which was attended by a renowned panel of experts and stakeholders who play an important role in shaping the provision of healthcare services in Germany. This chapter presents the results following this workshop, the content of which has been approved by the relevant participants.

The panel of experts (■ Tab. 6.1) represented the following areas of care:

- Research and Training
- Specialized Clinical Care
- Medical Rehabilitation
- Professional Medical Societies
- Registry
- Statutory Health Insurances
- Medical Technology

Relevant statements regarding hip and knee arthroplasty in the following areas were selected:

- Prevalence of primary and revision arthroplasty
- Healthcare situation for primary and revision arthroplasty
- Health economics

The experts were requested to give their interpretation of the data and discuss the requirements, aims and challenges of joint replacement care as well as potential solutions and future needs for action.

6.1 Prevalence of Hip and Knee Arthroplasty

According to the German Federal Statistical Office, approximately 210,000 primary hip arthroplasty (partial or total replacement) inpatient cases were registered in Germany in 2013. In the same year, approximately 143,000 primary knee arthroplasty (partial or total replacement) inpatient cases (► Chapter 2) were recorded. Patients in the 70 to 80

years age group constitute the largest proportion of all hip and knee arthroplasty cases (hip: 41.8 %, knee: 41.0 %). The average patient age for primary total hip arthroplasty (THA) was 69.7 years in 2013 and for primary total knee arthroplasty (TKA) 69.2 years.

Primary hip arthroplasty case numbers recorded by the Federal Statistical Office for the period from 2008 to 2013 show a plateau from 2009 to 2011 with approximately 213,000 operations each year. After a peak in 2011 at 213,935 cases, the case numbers decreased slightly in 2012 and 2013 (► Chapter 2). A similar trend is observed in primary knee arthroplasty: A plateau phase can be observed from 2009 and 2011 with a subsequent marked decline in case numbers in 2012 and 2013. While approximately 159,000 cases of knee arthroplasty were recorded in 2009, approximately 143,000 cases of primary knee arthroplasty were recorded in 2013 (► Chapter 2).

According to the panel of experts, data published by the Federal Statistical Office was originally collected solely for accounting purposes and is consequently only of limited use in making reliable evaluations in relation to hip and knee arthroplasty case number progressions. Consequently, the data do not permit evaluations of the degree to which government policy or patient-related causes, for example, influence the rate of joint replacements. For reliable assessments of both the prevalence of arthroplasty and potential influencing factors, further data should be used in the future (for example, from the German joint replacement registry »Endoprothesenregister« or the EndoCert initiative). This would enable a comprehensive, quality-assured and cross-sectoral collation of data which would allow reliable and verifiable interpretations.

In previous years, frequent comparisons have been made to international data (for example, OECD comparisons) to evaluate case number development trends for hip and knee arthroplasty. These trends confirmed Germany's alleged top ranking position in this field. However, according to the panel of experts, these comparisons are unfounded owing to several factors such as different patient cohorts, the means by which surveys were carried out, inclusion criteria and, in part, a lack of age standardization. Meanwhile, however, this has

■ **Tab. 6.1** Expert panel workshop participants

Name	Occupation
Univ.-Prof. Dr. Karsten Dreinhöfer	<p>Professor of Musculoskeletal Rehabilitation, Prevention and Health Services Research at the center for musculoskeletal surgery »Centrum für Muskuloskeletale Chirurgie (CMSC)«, Charité – Universitätsmedizin Berlin</p> <p>Medical Director and Head of the Department for Orthopaedics and Traumatology Medical Park Berlin Humboldtmühle</p> <p>Vice-President of the Professional Association of Orthopaedic Surgeons (Berufsverband der Fachärzte für Orthopädie und Unfallchirurgie e. V. (BVOU))</p>
Prof. Dr. med. Klaus-Peter Günther	<p>Executive Director of the University Center of Orthopedics and Traumatology at the University Hospital Carl Gustav Carus of the Technical University Dresden (Universitätsklinikum Carl Gustav Carus an der Technischen Universität Dresden)</p> <p>Past President of the German endoprosthesis society »Deutsche Gesellschaft für Endoprothetik (AE)«</p> <p>Past President of the German Society of Orthopedics and Orthopedic Surgery (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC))</p>
Dr. med. Dipl.-Ing. Hans Haindl	Publicly appointed expert in medical technology
Prof. Dr. Karl-Dieter Heller	<p>Head of the Orthopedic Department Herzogin Elisabeth Hospital Braunschweig</p> <p>Secretary General of the German arthroplasty association »Deutsche Gesellschaft für Endoprothetik (AE)«</p> <p>First Chairman of the German association of senior orthopedists and trauma surgeons »Verband leitender Orthopäden und Unfallchirurgen (VLOU)«</p> <p>Vice-President of the Professional Association of Orthopaedic Surgeons (Berufsverband für Orthopädie und Unfallchirurgie e. V. (BVOU))</p> <p>Board member of the German Society of Orthopedics and Orthopedic Surgery (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC))</p> <p>Vice President of the German hip society »Deutsche Hüftgesellschaft (DHG)«</p>
Dr. med. Andreas Hey	Managing Director of the German arthroplasty registry »Deutsche Endoprothesenregister gGmbH (EPRD)«
Prof. Dr. Dr. Reinhard Hoffmann	<p>Medical Director of the BG Hospital Frankfurt am Main (Unfallklinik Frankfurt am Main gGmbH)</p> <p>Secretary General of the German Trauma Society (Deutsche Gesellschaft für Unfallchirurgie (DGU))</p> <p>Secretary General of the German Society for Trauma Surgery (Deutsche Gesellschaft für Orthopädie und Unfallchirurgie (DGOU))</p>
Univ.-Prof. Dr. med. Rüdiger Krauspe	<p>Director of the Department of Orthopaedics Düsseldorf University Hospital</p> <p>President of the German Society of Orthopedics and Orthopedic Surgery (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC))</p>
N. N.	Statutory health insurance representative
Univ.-Prof. Dr. med. Georg Matziolis	<p>Professor of Orthopedics at the Jena University Hospital, Campus Eisenberg, Department of Orthopaedics and Trauma Surgery</p> <p>Medical Director of the Clinic for Orthopaedics and Accident Surgery at the Waldkrankenhaus Eisenberg (Waldkrankenhaus »Rudolf Elle« GmbH)</p>
Univ.-Prof. Dr. med. Henning Windhagen	<p>Medical Director of the Orthopaedic Clinic of the Hannover Medical School in the DIAKOVERE Annastift Hospital</p> <p>Past President of the German Society of Orthopedics and Orthopedic Surgery (Deutsche Gesellschaft für Orthopädie und Orthopädische Chirurgie (DGOOC)), and the German Society for Orthopaedics and Trauma (Deutsche Gesellschaft für Orthopädie und Unfallchirurgie (DGOU))</p>

also been amended in relevant publications (► Section 2.6).

Nonetheless, despite limitations in the reliability and validity of the data available so far, the panel of experts has observed some obvious connections. In the period from 2009 to 2011, during which a plateau in the number of arthroplasty cases was observed, the necessity of arthroplasty was being critically discussed in the media which consequently led to uncertainty amongst patients. The incorrect assessment, consequently rectified, that Germany was ranked in the top position with regards to arthroplasty rates, led to verifiable confusion and mistrust towards treating doctors. The panel of experts deemed knee arthroplasty to have been affected in an over proportionate manner by these discussions. At the same time, however, the panel of experts indicated that before having to resort to surgery, more conservative treatment alternatives were available for the knee than for the hip and consequently, knee patients have a broader range of treatments to choose from. Additionally, fractures constitute a more frequent indication for hip arthroplasty which could explain the greater decline in knee arthroplasty. In addition, the decline in arthroplasty rates could also be related to an improvement in conservative treatment over the past few years.

However, the panel of experts expects a renewed increase in the number of hip and knee replacements in the future based on current demographic trends and the related increases in degenerative joint diseases. Another factor that could lead to a rise in knee arthroplasty is the fact that joint preserving arthroscopic surgery for osteoarthritis of the knee has been subject to criticism and may no longer be reimbursed as it is not considered a curative procedure. Consequently, joint preserving surgery may be performed less frequently in the future. Softer criteria such as access to care, who makes the indication and the institution in which it is made (primary care physician, specialist physician, hospital) as well as changes in the public perception of joint replacements will influence the development. However the impacts cannot be predicted at present.

6.1.1 Fixation Techniques and Revision Total Replacement

Federal Statistical Office data on the types of implanted prostheses and the fixation techniques used show that the majority of hip procedures (51 % in 2013) are total hip arthroplasties (THA) without the use of bone cement (► Section 2.2). In contrast, for the knee, total knee arthroplasty (TKA) with the use of bone cement for fixation constitutes the largest proportion of surgery cases (66 % in 2013) (► Section 2.2).

Revisions and revision total replacements over the past few years (2008 to 2013, also based on Federal Statistical Office data) show a marked increase following primary uncemented THA. In addition, there was also a distinct decrease in the number of revision procedures following cemented primary THAs in the period from 2008 to 2013 (► Section 2.3). With regard to knee arthroplasty, the rates of revision total replacement and revision remained predominantly stable. Solely bicondylar surface replacements showed an increase in rates up until 2011 and a subsequent decrease in revision replacements over time.

According to the panel of experts, interpreting the data published for case number trends for revision and revision total replacements is also limited as it involves raw data that were reported to the Federal Statistical Office by the payer institutions. The data included numerous different types of revision and revision total replacement procedures, including surgery without or with only partial replacements of prosthetic components through to revision total replacements. It is unclear to what extent the current documentation, information transfer and analysis routines in hospitals and external institutions (payers, AQUA, Statistical Office) correctly depict the numbers and types of operations actually performed. This could result in misleading estimations of the number of operations performed.

Determining correlations between primary implantation and replacement and/or revision is not possible as existing data do not link cases. Development trends in replacement and revision surgery rates are typically characterized by two peaks. Shortly after primary replacement, renewed surgery may become necessary mainly due to infections and

complications and in rarer cases due to implant-related issues. A second peak occurs after ten years or more and is due in particular to the loosening of the implant. These two peaks overlap in the Federal Statistical Office's cumulative presentation hence making a connection between primary surgery and the need for revision total replacement or revision indeterminable. This will only be possible through future evaluations of data from the German joint replacement registry »Endoprothesenregister«.

6.1.2 Regional Distribution and International Comparison

Analyses of AOK insuree data show that there are regional differences in the rates of primary hip and knee arthroplasty per 100,000 inhabitants (► Section 2.4). When observing data within an area from the southeast to the northwest of Germany, it can be seen that in 2013, there was an upward trend in the number of surgeries performed.

The panel of experts considers that the regional distribution shown by AOK insuree data is not entirely representative as varying patients in the cohorts may potentially differ from the patients of other payer institutions. Moreover, in order to make conclusive assessments, other factors that could potentially have an impact on the regional rates must also be taken into consideration. These include potential differences in patient demands and socio-economic factors (for example, lifestyle habits) as well as differences between urban and rural areas. International statistics also show that social deprivation considerably influences the rate of knee and hip arthroplasty. Lower rates of surgery in areas with high social deprivation can also be observed in Germany. Some of the experts also consider that supply-driven or economic reasons may play a role: Practice-based physicians are also permitted to perform endoprosthetic surgery as visiting consultants with admission privileges or through other contractual agreements with hospitals (for example, as so-called fee-based physicians). According to the panel of experts, an indication of potentially influencing monetary factors could be the considerable differences in the rates of care observed at administrative levels, particularly at the individual federal state borders.

Regional variations in remuneration for surgery performed by fee-based surgeons could be deduced from this observation. Conversely, surprisingly higher rates of surgery were observed particularly in areas with lower numbers of specialist physicians. This might suggest more intensive conservative treatment being performed as an alternative to surgery in regions with higher numbers of practice-based orthopedists. However, from the panel of experts' point of view, regional differences in Germany cannot be conclusively assessed as numerous concurrent influencing factors with largely unclear causal relationships are still a matter of ongoing discussion. Therefore, more funding towards improving healthcare research is necessary.

Contradictory data exist when comparing international surgery rates to those in Germany based on publications using data from other OECD countries. Two years ago, a comparison of endoprosthetic procedures conducted in five EU countries (UK, France, Germany, Italy, Spain) and the USA, based on raw, non-age-standardized data was published and showed there were similar increases in surgery rates in both hip and knee replacements per 100,000 inhabitants in the period from 2000 to 2012. The original database which was published by the OECD at the time, ranked the OECD countries according to surgery rates. In this case, Germany had the highest rate of hip arthroplasty (287 procedures per 100,000 inhabitants in 2012) (► Section 2.6) and ranked third for knee arthroplasty following Austria (highest rate) and Finland (second highest rate) (► Section 2.6).

However, when age-standardized data are used for the OECD country ranking, which take into account specific demographic factors per country, Germany's ranking shifts from a top position to 5th for hip arthroplasty. For knee arthroplasty, Germany drops from 3rd to 8th position (► Section 2.6).

The panel of experts emphasize that there are serious methodological shortfalls in the OECD's ranking of international surgery rates. The data used are derived from data sources that differ in so many ways that making comparisons is questionable.

International coding systems differ, which therefore do not allow for any direct comparability. The case numbers in the OECD database, for example, are based on ICD codes and do not permit

clear differentiations to be made between elective (osteoarthritis-related) arthroplasty and emergency arthroplasty which is performed to treat fractures. They also partly contain both primary and revision procedures. The lack of age-adjusted data, in at least the first publications, has already been pointed out. This is an important point as absolute numbers without appropriate adjustments for demographic criteria lead to significant biases, particularly with regard to the increasing rates of osteoarthritis in older age groups. According to the panel of experts, these biases lead to surgery rates in regions with older populations being over estimated as has been the case in Germany, for example. Finally, virtually no further information exists regarding population groups used for the OECD assessment, i.e. whether the total population or only inpatient cohorts were taken into account or whether the data included information from private payer institutions or not. Major differences in the healthcare systems also do not favor the comparison of figures. Individual countries, for example, may have long waiting lists for the surgical procedures in question.

According to the panel of experts, if all the influencing factors discussed were taken into account, the actual ranking of the rates of care would be considerably different. In addition, there are clear indications to suggest that case numbers correlate with individual gross national products. Consequently, the panel of experts agrees that it can be assumed that financially weaker countries do not meet their care needs.

Need for action and solution approaches

- Fact-based open discussions about the benefits and risks of arthroplasty, drawing on comprehensive quality-assured and cross-sectoral data.
- Revision and harmonization of definitions and coding guidelines for revision total replacement and revision surgery in order to achieve reliable coding for the services provided in hospitals.
- Improving healthcare research in order to gain reliable insights into care needs and care provision at regional and national levels.

6.2 Status of Hip and Knee Arthroplasty Care

Germany seems to offer arthroplasty care nationwide (► Chapter 3). This is the case for both knee and hip arthroplasty as indicated by the fact that more than half of all German hospitals perform these procedures, amongst other things (► Section 3.3). Primary hip arthroplasty is performed due to osteoarthritis of the hip in 80 % of cases (► Section 3.3) and in approximately 12,5 % of cases due to femoral neck fractures. With regard to knee arthroplasty, approximately 96 % of primary surgery is performed due to osteoarthritis of the knee (► Section 3.3). Approximately one third of the patients who undergo either THA or TKA also suffer from serious systemic diseases and substantial functional limitations (ASA score 3) (► Section 3.3).

For THA patients, the length of stay in hospital is about 4.5 days longer than the average length of stay in a German hospital. Shorter lengths of stay have been observed in the past few years. While the length of stay was in the region of 14 days in 2012, it decreased to 12 days in 2014. A similar trend can be observed for TKA patients.

Treatment begins with the treatment plan before the actual surgery. This includes preliminary examinations, surgery planning and follow-up treatment planning. Numerous aspects therefore have an influence on the treatment and its outcome.

According to external inpatient quality assurance data, nearly all THA and TKA patients are able to walk independently and perform a daily hygiene routine themselves upon discharge from hospital.

The panel of experts confirms that nationwide care coverage exists for hip and knee arthroplasty in Germany. Consequently, travel times for patients are not problematic. In the opinion of some of the experts, there is even a surplus of hospitals providing arthroplasty services which, however, cannot be confirmed merely based on the number of hospitals offering joint replacement services. Instead, the panel of experts suggests that status of care evaluations should be based on differentiated analyses of certified arthroplasty centers. Only in this way would it be possible to qualitatively evaluate the number of hospitals performing endoprosthetic surgery based on defined quality criteria.

The panel of experts pointed out that patient demands with regard to arthroplasty have noticeably changed in recent years. Patients demand faster recovery for early weight-bearing and mobility as well as being able to resume sporting activities more rapidly. This does not imply that more surgery is being performed but that the expectations of the surgery itself and the outcomes have increased. At the same time, changes in patient expectations have also led to behavioral changes with regard to activities of daily life after joint replacement. This has resulted in implants being subjected to more stress and strain.

The panel of experts has observed marked improvements in the quality of devices used over the past few years. For example, they considered the developments in so-called tribological pairing positive, especially with regard to the different technologies used in the manufacturing of ultra-highly cross-linked polyethylene and new ceramic materials with significantly reduced risks of breakage. These implants are more expensive than implants using conventional materials, but they lead to significantly reduced wear and therefore fewer late stage complications. Other aspects, such as the impact of different implant stem lengths on the treatment outcomes cannot be fully evaluated at present. On the whole, the panel of experts considers the overall situation confusing due to the wide range of devices being used and the data situation unclear with regard to surgery outcomes for the different types of prostheses.

In addition, the panel of experts believes that any modifications in a hospital's administration with regards to purchasing processes could be problematic in practice in that they can lead to changes in implant procurement. For hospital administrations economic factors play a more important role than quality. Repeated changes in the type of implant being used necessitate regular training on behalf of both surgeons and the surgical teams which could increase the risk of complications. According to the panel of experts, it would make more sense if a hospital agreed on a defined set of products containing a few high-quality devices that are quality-assured based on scientific data and for which relevant know-how exists within the hospital.

6.2.1 Medical Rehabilitation

Usually, patients undergo subsequent rehabilitation (AHB) after the acute inpatient stay for the replacement surgery. This rehabilitation aims to generally strengthen and mobilize patients while taking into account their personal and individual rehabilitation goals particularly with regard to the required activities of daily living (ADL) (► Section 3.4).

These rehabilitation procedures are financed by different payer institutions which include the German Statutory Pension Insurance (Deutsche Rentenversicherung, DRV), statutory and private health insurances as well as the German employers' liability insurance associations. To date, only limited and unstructured data are available on subsequent rehabilitation (AHB) treatment and a general overview of all the measures provided does not exist.

Furthermore, the depth and quality of the data in most fields is so restricted that only limited differentiated evaluations and interpretations are possible.

According to the panel of experts, the data published by the German Statutory Pension Insurance (DRV) on the number and types of procedures conducted during subsequent rehabilitation (AHB) for TKA and THA is limited in terms of representation as it predominantly refers to rehabilitation patients in general and not in particular to total arthroplasty patients. In addition, data publications by some health insurance funds are only very rudimentary and of limited applicability.

The Advisory Council on the Assessment of Developments in the Healthcare System (Sachverständigenrat zur Begutachtung der Entwicklung im Gesundheitswesen (SVR)) found that »Even though hardly any evidence pertaining to the effectiveness of rehabilitation under controlled conditions can be confirmed, it may still be assumed that benefits do exist«.

The panel of experts agrees that rehabilitation subsequent to acute inpatient care is necessary for the large majority of patients. Younger and otherwise healthy patients in particular may benefit from ambulatory rehabilitation close to their domiciles and for the growing number of older patients treatment in a rehabilitation clinic is appropriate in most cases.

The panel of experts stated that over the last few years, significantly shorter lengths of stay in acute care hospitals together with the higher number of older people undergoing surgery and the number of patients with concomitant diseases have led to patients being more unwell and in greater need of care when they are transferred to rehabilitation establishments. These patients have considerably higher nursing care needs and medical requirements, which, however, are currently not reflected in the remuneration for subsequent rehabilitation (AHB) in orthopedics. Consequently, patients who require higher nursing care are often transferred into geriatric care which does not always warrant specialist rehabilitation care.

The panel of experts sees a need for closer collaboration across all sectors and medical institutions including payers. There is also a need for a graded remuneration system in order to maintain adequate care for the patients.

According to the panel of experts, the fact that subsequent rehabilitation (AHB) does not always take place immediately after discharge from hospital does not imply a lack of care. Many patients request to be discharged to return home to be in their familiar environment after their inpatient stay. In addition, the German Statutory Pension Insurance recommendation stating that that subsequent rehabilitation (AHB) should start within 14 days after discharge from hospital is not evidence-based. Different regulations for this exist when making comparisons at an international level. For example, some countries provide home care without subsequent rehabilitation or provide subsequent rehabilitation at home. Nevertheless, subsequent rehabilitation (AHB) should take place as soon as possible after treatment in hospital. Advantages of this would be that patients recover sooner and gain their ability to work quicker while avoiding complications. Avoidable delays include procedures such as complicated application processes for different payer institutions or arduous transfer processes and arranging for subsequent rehabilitation (AHB). Speeding up these processes would be advantageous.

6.2.2 Service Lives and Revision

To date, the service lives of hip and knee endoprostheses in Germany have not been investigated or any reports on the subject published outside of studies. The German joint replacement registry »Endoprothesenregister Deutschland (EPRD)« is still in the process of being established and it is therefore not yet possible to analyze any registry data. International registries such as the National Joint Registry for England, Wales, Northern Ireland and the Isle of Man, the Scandinavian registries and the Australian National Joint Replacement Registry have been collecting comprehensive data on endoprosthesis service lives for several years (► Section 4.3). However, particularly in the field of hip arthroplasty, insights from these data cannot be directly applied to Germany due to the differing healthcare systems, amongst other things. For example, Scandinavia and England have higher rates of cemented hip arthroplasty.

Conversely, uncemented hip arthroplasty is relatively common in Norway, Finland and Australia, as is the case in Germany, while the implants and surgical techniques differ to those used in other countries.

In addition, the different international registries are very heterogeneous with regard to their data collection. Also, specific outcomes are defined differently, in the case of revision, for example (► Section 4.3). For this reason, considerable efforts are being made in support of standardizing arthroplasty registries worldwide while the German joint replacement registry (EPRD) is being established.

According to the panel of experts, different reasons for revision exist, the most common currently being revision and revision total replacement due to infection. The prevalences of knee and hip arthroplasty differ and are influenced considerably by risk factors such as body weight, diabetes mellitus and other diseases with impaired immune systems. Other reasons for revision and revision total replacements, particularly during early postoperative stages, are luxation and/or instability. In the long term, conditions such as aseptic loosening and particulate wear of a stable fixated prosthesis may deem revision and replacement surgery necessary. Contrary to public perception, revision due to prosthesis

fractures owing to material failure is very rare. Investigations into these occasional ceramic prostheses fractures (less than 0.01 % of all implantations) have shown that they could not be solely attributed to material failure but that the implantation technique may also play a role. For this reason, medical societies collaborate with the manufacturers to conduct intensive training, for example. Prosthesis failure can also be provoked by strain due to excess weight or activity. As is often the case, according to the panel of experts, not enough data exist to conclusively evaluate the situation.

Revision total hip or knee replacement or component replacements lead to longer average lengths of hospital stay than primary arthroplasty (► Section 3.3). THA patients who undergo revision total replacement have inpatient stays of almost nine days longer compared to primary surgery. The length of stay for revision total knee replacement patients is four days longer on average than for primary TKA patients. In general, replacement surgery is considered to be technically more demanding and more challenging to perform.

6.2.3 Adherence to Indication Criteria

In Germany, the rates of adherence to medical indication criteria for both primary and revision THA and TKA are recorded during external inpatient quality assurance procedures. The indication criteria are defined by a federal expert group (► Section 3.5). From this quality assurance data, the adherence to indication criteria for primary THA showed an increasing trend nationally over the past few years with 95.8 % in 2014. For individual federal states, the data published showed significant differences in adherence to indication criteria. Revision total replacements had an adherence to indication criteria of 93.1 % on a national level in 2014. At federal state levels, the differences observed are similar to those observed for primary arthroplasty.

The results are comparable for TKA. In 2014, the adherence to indication criteria at a national level was 96.9 % for primary TKA and 92.3 % for revision TKA. Here again, federal state levels show marked differences between individual states (► Section 3.5).

From the panel of experts« point of view, adherence to indications is generally poorly documented. At present, there are no guidelines on the time points for when arthroplasty should be performed and the data collected for external quality assurance (stage of osteoarthritis visible in x-ray, pain and mobility indicators) is only questionably suitable for determining »appropriate indications«. According to the panel of experts, some indications cannot be portrayed on the basis of the AQUA data as they do not necessarily correlate with arthritic changes as observed in x-rays (for example, aseptic necrosis or tumor near the joint). Particularly necrosis of the femoral head which is relatively common accounting for approximately 3 % of endoprosthetic surgery is generally assessed incorrectly as it is not coded separately. With regard to this indication and others, the data generated do not correspond to the actual healthcare situation and incorrectly suggest that indications are not being adequately adhered to. In addition, current data collection procedures do not include other factors that have been shown to influence indications, such as prior treatment, comorbidity, problems with other joints, quality of life and expectations prior to surgery. Consequently, a group of experts is currently working together with professional associations to develop indication guidelines for joint replacements. Regardless of these contentual issues, service providers« reliability with regard to the use of the actual coding has also not been assessed, therefore indicating that data quality on the whole is not reliable.

However, the panel of experts say, it should not be assumed that regional differences in the prevalence of the provision of care are generally due to the issue of documentation of »appropriate indications«.

Registry data would provide a suitable approach for improving quality assurance. Registries contribute to the collection of information and data according to standardized criteria. A prerequisite for this is that all patients are recorded in the registry. This is why the panel of experts believes that private payer institutions should also submit their patient data to the registry. Private payer institutions are currently not participating in the reporting process. In addition, reporting should not only be made mandatory but should also be remunerated. Making

reporting mandatory would be a prerequisite for improving care especially for multimorbid patients. In addition, sufficient funding should be made available to subsequently enable evaluations of the registry data.

6.2.4 Minimum Volume Regulations and Increasing Case Numbers

Minimum volume regulations for primary TKA were introduced at a hospital level in 2006. According to this regulation, a hospital may only be reimbursed for TKAs by the SHI if it performs at least 50 TKAs per year. Analyses conducted by the Institute for Quality and Efficiency in Health Care (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen (IQWiG)) show that the introduction of minimum volumes has led to increases in case numbers (► Section 3.5).

According to the panel of experts, the minimum volume regulation could lead to an increase in case numbers during the transition period as some of the care providers operating below the thresholds may still perhaps attempt to meet the requirements. However, after the introduction of the regulation, no further increase in case numbers can be expected for to this reason as larger centers with higher case numbers are not affected and hospitals that had had case numbers below the threshold are subsequently no longer included.

However, other factors may also play a role in increasing case numbers. For example, when the minimum volume regulation was introduced, the remuneration for conservative therapies was simultaneously reduced, which may have influenced the decision for joint replacement therapy.

Meanwhile a positive correlation between case numbers and the quality of service provision has been shown in many fields, for which reason the panel of experts consider the minimum volume regulation to be a positive step on the whole. However, there are certain issues with regard to the actual implementation of such regulations in endoprosthetic care. On the one hand, there is sufficient evidence to show that hospitals operating as centers have low rates of morbidity and/or mortality in addition to a decline in complication rates alongside

the increasing experience of the surgeons. On the other hand, no reliable data-based thresholds exist for individual surgeons or for hospitals in which several surgeons perform arthroplasty. Consequently, the thresholds which were determined in the Endocert® procedure are subject to further modification. Some experts consider the current threshold of 50 arthroplasties per year per surgeon to be too low. The panel of experts state that there is no danger of the minimum volume regulation jeopardizing nationwide coverage of endoprosthetic care. However, the aim of healthcare policies to provide care close to patients' domiciles will always be in conflict with the desire to establish specialized treatment centers that are located further apart.

Need for action and potential solutions

- Optimizing cross-sectoral care concepts.
- Systematic establishment and development of a relevant database, i.e. the German joint replacement registry »EPRD«, which includes all patients. This entails mandatory registry participation including patients with private health insurance. At the same time adequate funding for data collection and evaluation is required.
- Developing appropriate indication criteria and improving data collection in order to gain reliable information for developing relevant needs-based care.
- Developing suitable criteria for determining ambulatory and inpatient rehabilitation needs. Correlating these criteria to future new phases in orthopedic rehabilitation to determine the degree of comorbidity and nursing care assistance required.
- Emphasis on requirements for and the importance of specialist rehabilitation for older patients.
- Accelerated application processes and arrangements for subsequent rehabilitation (AHB).
- Developing and recording suitable quality criteria to appropriately depict the complex influence that physicians, patients and the implants have on quality.

- Improving knowledge regarding patient preferences and expectations paired with higher patient involvement in the decision-making process.
- Concentrating on providing care through experienced surgeons in certified arthroplasty care centers.
- Intensifying care research to gain reliable information about care requirements at regional and national levels.
- Supporting rehabilitation research independent of care providers in order to develop needs-oriented and optimized care.

6.3 Health Economic Aspects of Arthroplasty

From a health economic perspective, the direct costs arising from endoprosthetic care need to be taken into particular consideration. Results from AOK data were published with regard to patients suffering from osteoarthritis of the knee who underwent TKA in Germany. Not taking into account the costs for the TKA surgery itself, the data analysis showed that the costs for the period of 12 months after surgery (for example, for therapeutic products, drugs, contract physician care) are higher than those for the period of 12 months prior to surgery. The costs for younger patients were considerably higher than for older patients (► Chapter 5). Nonetheless, several studies have demonstrated the definitive cost efficiency of endoprosthetic care and of different rehabilitation procedures in Germany (► Chapter 5).

A cost and remuneration comparison of inpatient primary THA cases (i. e. hospital cases) in nine EU countries conducted in 2005 showed that even after adjustments for purchasing power parity, Italy has the highest costs followed by Germany. Cost comparisons become difficult when an individual country's purchasing-power parity has not been adjusted for. This can be demonstrated by using non-adjusted average costs of hip and knee joint replacements in Switzerland as an example. In this case, after simple currency conversion, the costs of

the most common DRGs are more than double than those in Germany (► Section 5.2).

The overall costs have risen over the past few years as becomes apparent when considering the most common DRG case fee calculations for hip and knee arthroplasty. Costs for physician treatment make up the largest proportion. The average costs for implants have either remained the same (hip) or decreased (knee).

Meanwhile, the relative proportion of overall costs per case is markedly below 25 %.

Treatment of infected hip endoprostheses in particular presents an economic challenge for hospitals. According to certain publications, deficits (higher costs versus remuneration) caused by this are on average over 12,000 euros per case per hospital.

Osteoarthritis is of particular economic importance. In 2011, osteoarthritis of the hip or knee resulted in approximately 7.6 million days of incapacity to work (osteoarthritis of the knee: approximately 5 million days, osteoarthritis of the hip: approximately 2.6 million days) (► Section 5.1). In addition, in 2011, almost 80 % of all retirements due to osteoarthritis were due to osteoarthritis of the hip or knee.

The panel of experts clarified that the higher costs for younger patients can be explained by the different indications related to this age group. »Normal« patients within this age group with osteoarthritis of the knee are unusual. Instead, patients usually suffer from more complex and cost-intensive general diseases (for example, joint damage due to hemophilia).

Need for action and potential solutions

- Fact-based discussions on the costs of diseases from a social perspective, irrespective of payers, type of service or individual aspects of care provision.
- Potentially involving patients financially, for example with fixed, diagnosis-dependent additional surcharges that guarantee basic care. This issue should be the subject of further open and straightforward discussions. This would also necessitate improving patient information and getting patients more involved in their treatment.

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