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Smith PG, Morrow RH, Ross DA, editors. *Field Trials of Health Interventions: A Toolbox*. 3rd edition. Oxford (UK): OUP Oxford; 2015 Jun 1.

## Preface to the third edition

Field trials of interventions against disease in LMICs may be complex and expensive undertakings, requiring the follow-up of hundreds, or thousands, of individuals for long periods. The conduct of such trials requires careful planning, in order to assure their timely and successful completion. Over the last several decades, an increasing number of large field trials have been conducted successfully in LMICs and have provided information critical to the assessment of the likely health impact of potential interventions. With a few exceptions, descriptions of the detailed procedures and methods that were essential for the conduct of successful trials are not published. A consequence of this is that those planning field trials have few practical guidelines available to them, and investigators have to design a study, often with little access to the knowledge and experience that has been accumulated previously. Personal experience is a good teacher, but, all too often, investigators have learned by repeating the mistakes of previous field researchers, at considerable cost and inconvenience.

Problems arise in the design, conduct, or analysis of many trials that may be unique to the particular study, but most potential problems have been faced by many investigators previously, some of whom devised good solutions and some not so good ones. Few publications exist which document this wealth of experience, and it is very difficult for potential field investigators to learn the practical issues in trial design and conduct.

The intention of this manual is to go some way towards filling this gap in the literature. It builds on the first two editions and has been comprehensively revised to take account of the evolution of methods that has taken place since the first edition in 1990. It has been compiled by contributors with extensive direct experience in the design, conduct, and analysis of field trials, and it attempts to document their accumulated experience for the guidance of those who might undertake **field trials of health interventions** in LMICs. It can be read in its entirety as an introduction to the field and/or can serve as a reference volume during each of the different stages of planning, conducting, and analysing a field trial.

The first edition had the title *Methods for field trials of interventions against tropical diseases: a toolbox*. We changed the title for the second edition to ***Field trials of health interventions in developing countries: a toolbox***, recognizing that many issues discussed in the manual will be relevant to the conduct of field epidemiological studies on diseases that would not necessarily be classed as 'tropical'. For the third edition, we have changed the title again to ***Field trials of health interventions: a toolbox***, as the 'developing country' terminology has been generally replaced by 'LMICs', but this would have made for a rather tortuous title! The focus of the book nonetheless is on field research in LMICs. Though some sections have wider relevance, we have preserved trials in the title because they are the main orientation of the book.

For the third edition, we have comprehensively reviewed the content of all the chapters that were included in the second edition. In addition, we have added chapters on topics or issues that were incompletely covered previously. Specifically, there are new chapters on conducting systematic literature reviews, trial governance, preliminary studies and pilot testing, budgeting and accounting, intervention costing and economic analysis, and Phase IV studies. Most of the other chapters have been rewritten, taking into account the substantial developments in trial methodology that have taken place since the second edition was published in 1996.

The *Toolbox* will always be a work in progress, and our intention is to continue to refine and improve it, as experience is gained with its practical use. We encourage those who use the manual to write to the editors if there are aspects of the manual that they think are in need of improvement.

Responsibility for producing initial drafts of the different chapters of the manual was assigned among the participants listed at the front of the book. The editors reviewed each of the contributions, and input was also sought from contributors other than those who had drafted the specific chapter. In this way, many different persons contributed to each chapter, and it seemed inappropriate therefore to attribute responsibility for any one chapter to individuals, as each chapter owes its final form to the collective contributions of those listed.

The text was discussed extensively and edited by the three of us to try to maintain a uniform style. The manual was also circulated to other field research scientists for their suggestions for any changes. We gratefully acknowledge

valuable contributions from: Salim Abdulla, Martin Adjuik, Chris Grundy, Claudia Hanson, Adnan Hyder, Maria Merritt, Honorati Masanja, Luke Mullany, Hassan Mshinda, Annabelle South, and Susanne Wedner.

We are also very grateful to those who authored the first and second editions of the book, upon whose contributions the third edition is built. These are: Jackie Cattani, John Cleland, Nick Day, Joel Gittelsohn, Andy Hall, Birthe Høgh, Betty Kirkwood, Lindlwe Makubalo, Tom Marshall, Louis Molineaux, Jorg Pönnighaus, S. Radhakrishna, Ian Riley, Bob Snow, Harrison Spencer, Marcel Tanner, Carol Vlassoff, and Fred Wurapa. In addition, we are grateful to the following field research scientists who commented on chapters in the first two editions: Astier Almedon, Steve Bennett, Boachie Boatin, Loretta Brabin, David Brandling-Bennett, Gilbert Burnham, Peter Byass, Andreas de Francisco, Tony Degrement, Aime de Muynck, Isabelle de Zoysa, Anne Dick, Nicola Dollimore, Herbert Gillies, Brian Greenwood, Hazel Inskip, Japhet Killewo, Sarah Macfarlane, Bruce Macleod, Gilly Maude, Daan Mulder, Andrzej Radalowicz, Brian Southgate, Malcolm Pike, Roger Webber, Jimmy Whitworth, and Andrew Wilkins.

From the above, it is apparent that the *Toolbox* benefited from the wisdom of a large number of field research scientists. We apologize to those whose suggestions we have incorporated, but whose contribution we have inadvertently omitted to acknowledge!

We have been very keen to ensure that the *Toolbox* is made available as widely as possible, especially to those in LMICs. We are delighted therefore that, in addition to a paperback version, it has been possible to make the book available online and in open access through generous financial support from the UNDP/World Bank/WHO Special Programme for Research and Training in Tropical Diseases and from the Wellcome Trust.

*London and Baltimore*

2015

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Bookshelf ID: NBK305503