

Guidelines for Reporting Health Research

A USER'S MANUAL

Edited by David Moher, Douglas G. Altman,
Kenneth F. Schulz, Iveta Simera and Elizabeth Wager

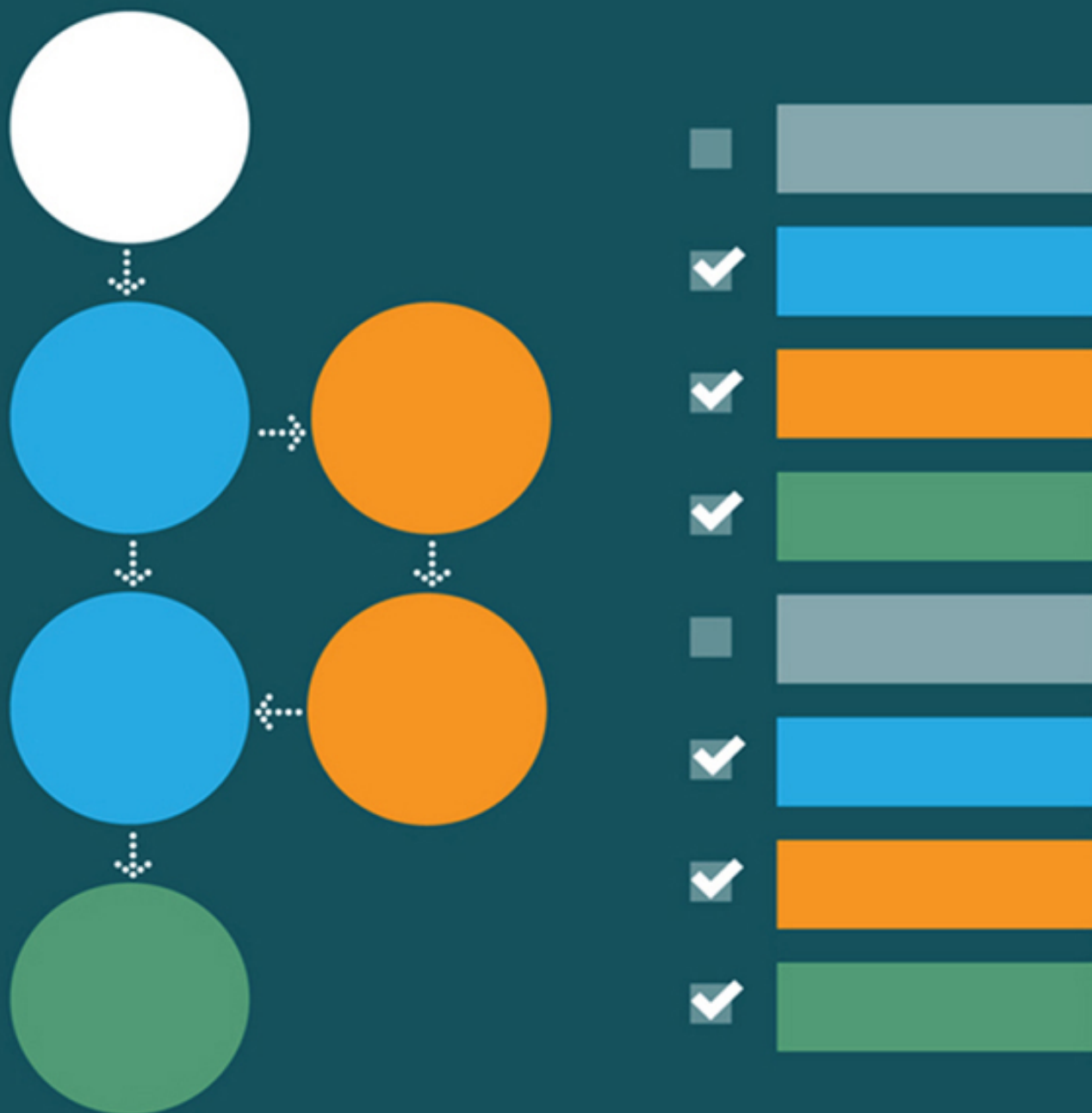


Table of Contents

[Title Page](#)

[Copyright](#)

[List of Contributors](#)

[Foreword: Guides to guidelines](#)

[Introduction](#)

[How did it start? How did we get here?](#)

[What to do about it?](#)

[Are we there yet?](#)

[References](#)

[Preface](#)

[Part I: General Issues](#)

[Chapter 1: Importance of Transparent Reporting of Health Research](#)

[Introduction](#)

[What do we mean by inadequate reporting of research?](#)

[Consequences of nonpublication and inadequate reporting](#)

[Principles of reporting research](#)

[What can be done to improve the quality of reporting of research?](#)

[References](#)

[Chapter 2: How to Develop a Reporting Guideline](#)

[Deficiencies in reporting health research studies](#)

[The role of reporting guidelines in promoting clear and transparent reporting](#)

[How to develop a guideline for reporting health research articles](#)

[Closing comments](#)

[References](#)

[Chapter 3: Characteristics of Available Reporting Guidelines](#)

[Methods](#)

[Results](#)

[Descriptive information](#)

[Background of reporting guidelines](#)

[Consensus process](#)

[Guideline development process](#)

[Postconsensus activities](#)

[How reporting guidelines were developed](#)

[Comment](#)

[References](#)

[Chapter 4: Using Reporting Guidelines Effectively to Ensure Good Reporting of Health Research](#)

[Reporting guidelines](#)

[Who benefits from the use of reporting guidelines?](#)

[Using reporting guidelines](#)

[Whose responsibility is good reporting of research?](#)

[References](#)

[Chapter 5: Ambiguities and Confusions Between Reporting and Conduct](#)

[Examples of item-specific scenarios](#)

[Allocation concealment from the CONSORT 2010 statement](#)

[Sequence generation from the CONSORT 2010 statement](#)

[Discussion](#)

[References](#)

[Chapter 6: The EQUATOR Network: Helping to Achieve High Standards in the Reporting of Health Research Studies](#)

[EQUATOR Network](#)

[Funding](#)

[References](#)

[Part II: Specific Reporting Guidelines](#)

[Chapter 7: SPIRIT \(Standard Protocol Items: Recommendations for Interventional Trials\)](#)

[Name of guideline](#)

[When to use this guideline \(what types of studies it covers\)](#)

[Current version](#)

[Extensions or implementations](#)

[Related activities](#)

[How best to use the guideline](#)

[Development process](#)

[Evidence of effectiveness of guideline](#)

[Endorsement and adherence](#)

[Cautions and limitations \(including scope\)](#)

[Creators' preferred bits](#)

[Future plans](#)

[References](#)

[Chapter 8: CONSORT for Abstracts](#)

[Name of guideline](#)

[History](#)

When to use this guideline (what types of studies it covers)

Development process

Current version compared with the previous versions

Extensions and/or implementations

How best to use the guideline

Evidence of effectiveness of guideline

Endorsement and adherence

Cautions and limitations (including scope)

Mistakes and/or misconceptions

Creators' preferred bits

State how participants were allocated to interventions

For the primary outcome, a result for each group and the estimated effect size and its precision should be stated

Include the registration number and name of trial register

Future plans

Acknowledgments

References

Chapter 9: CONSORT

Name of guideline

When to use CONSORT

Current version compared with previous versions

Extensions and implementations of CONSORT

How best to use the guideline

Development process

Evidence of effectiveness of guideline

Endorsement and adherence

Cautions and limitations

Creators' preferred bits

Future plans

References

Chapter 10: CONSORT Extension for Better Reporting of Harms

Name of guideline

History/development

When to use this guideline (what types of studies it covers)

Previous version

Current version

Extensions and/or implementations

Related activities

How best to use the guideline

Development process

Evidence of effectiveness of guideline

Endorsement and adherence

Cautions and limitations (including scope)

Creators' preferred bits

Future plans

References

Chapter 11: CONSORT for Nonpharmacologic Treatments

Name of guideline

When to use the extension of the CONSORT Statement for nonpharmacologic treatments

Development process

[Extension compared with the CONSORT checklist](#)

[How best to use the extension guidelines](#)

[Evidence of effectiveness of the extension guidelines](#)

[Endorsement and adherence](#)

[Cautions and limitations](#)

[Creators' preferred items](#)

[Future plans](#)

[References](#)

[Chapter 12: CONSORT for Pragmatic Trials](#)

[Practihc \(Pragmatic Randomized Controlled Trials in Health Care\)](#)

[History/development](#)

[When to use this guideline \(what types of studies it covers\)](#)

[Previous version](#)

[Current version](#)

[Extensions and/or implementations](#)

[Related activities](#)

[How best to use the guideline](#)

[Development process](#)

[Evidence of effectiveness of guideline](#)

[Endorsement and adherence](#)

[Cautions and limitations \(including scope\)](#)

[Creators' preferred bits](#)

[Future plans](#)

[References](#)

[Chapter 13: CONSORT for Cluster Randomized Trials](#)

[Name of guideline](#)

[History/development](#)

[When to use this guideline \(what types of studies it covers\)](#)

[Current version/previous versions](#)

[Extensions and/or implementations](#)

[Related activities](#)

[How best to use the guideline](#)

[Evidence of effectiveness of guideline](#)

[Endorsement and adherence](#)

[Cautions and limitations \(including scope\)](#)

[Mistakes and misconceptions](#)

[Creators' preferred bits](#)

[Future plans](#)

[References](#)

[Chapter 14: CONSORT for Noninferiority and Equivalence Trials](#)

[Name of guideline](#)

[History/development](#)

[When to use this guideline \(what types of studies it covers\)](#)

[Current version/previous versions](#)

[Extensions and/or implementations](#)

[Related activities](#)

[How best to use the guideline](#)

[Development process](#)

[Evidence of effectiveness of guideline](#)

[Endorsement and adherence](#)

[Cautions and limitations \(including scope\)](#)

[Mistakes and misconceptions](#)

[Creators' preferred bits](#)

Future plans

References

Chapter 15: STRICTA (STandards for Reporting Interventions in Clinical Trials of Acupuncture).

Name of guideline: STRICTA

When to use STRICTA?

Development process

Current version

Evidence of effectiveness of guideline

Endorsement

Misconceptions

Creator's preferred bits

Future plans

References

Chapter 16: TREND (Transparent Reporting of Evaluations with Nonrandomized Designs).

Name of guideline

History/development

When to use this guideline (what types of studies it covers)

Current versions

Previous versions

Extensions to be aware of

Related activities

How best to use the guideline

Development process

Evidence of effectiveness of guideline

Endorsement and adherence

[Cautions and limitations \(including scope\) Mistakes and/or misconceptions](#)

[Creators' preferred bits](#)

[Future plans](#)

[References](#)

[Chapter 17: STROBE \(STrengthening the Reporting of Observational studies in Epidemiology\).](#)

[STROBE Statement](#)

[History/development](#)

[When to use this guideline \(what types of studies it covers\)](#)

[Current versions](#)

[Previous versions](#)

[Extensions to be aware of](#)

[Translations](#)

[Related activities](#)

[How best to use the guideline](#)

[Development process](#)

[Evidence of effectiveness of guideline](#)

[Endorsement and adherence](#)

[Cautions and limitations \(including scope\)](#)

[Creators' preferred bits](#)

[Future plans](#)

[References](#)

[Chapter 18: STREGA \(Strengthening the Reporting of Genetic Associations\).](#)

[Strengthening the Reporting of Genetic Associations](#)

[When to use STREGA](#)

[Current version](#)

[Extensions](#)

[Related activities](#)

[How best to use the guideline](#)

[Development process](#)

[Evidence of effectiveness of guideline](#)

[Endorsement and adherence](#)

[Cautions and limitations](#)

[Creators' preferred bits](#)

[Future plans](#)

[References](#)

[Chapter 19: STARD \(STAndards for Reporting of Diagnostic Accuracy Studies\).](#)

[History/development](#)

[When to use this guideline \(what types of studies it covers\)](#)

[Current versions](#)

[Previous versions](#)

[Extensions be aware of](#)

[Related activities](#)

[How best to use the guideline](#)

[Evidence of effectiveness of guideline](#)

[Endorsement and adherence](#)

[Cautions and limitations \(including scope\) Mistakes and/or misconceptions](#)

[Creators' preferred bits](#)

[Future plans](#)

[References](#)

[Chapter 20: SURGE \(The SURvey Reporting GuidelinE\).](#)

[Name of proposed guideline](#)

History/overview

When to use this guideline (what types of studies it will cover)

Development process

Future plans/next steps

Evidence of effectiveness of guideline

References

Chapter 21: COREQ (Consolidated Criteria for Reporting Qualitative Studies)

Name of guideline

History/development

When to use this guideline (what types of studies it covers)

Current version

Extensions and/or implementations

Related activities

How best to use the guideline

Development process

Evidence of the effectiveness of guideline

Endorsement and adherence

Cautions and limitations (including scope)

Key features

Future plans

References

Chapter 22: SQUIRE (Standards for Quality Improvement Reporting Excellence)

Name of guideline

History/development

[When to use this guideline \(what types of studies it covers\)](#)

[Previous versions](#)

[Current version](#)

[Extensions and/or implementations](#)

[Related activities](#)

[How best to use the guideline](#)

[Development process](#)

[Evidence of effectiveness of guideline](#)

[Endorsement and adherence](#)

[Cautions and limitations \(including scope\)](#)

[Mistakes and misconceptions](#)

[Creators' preferred bits](#)

[Future plans](#)

[Acknowledgments](#)

[References](#)

[Chapter 23: REMARK \(REporting Recommendations for Tumor MARKer Prognostic Studies\)](#)

[Name of guideline](#)

[History/development](#)

[When to use this guideline \(what types of studies it covers\)](#)

[Current version](#)

[Previous versions](#)

[Extensions and/or implementations to be aware of](#)

[Related activities](#)

[How best to use the guideline](#)

[Development process](#)

[Evidence of effectiveness of guideline](#)

[Endorsement and adherence](#)

[Cautions and limitations \(including scope\)](#)

[Creators' preferred bits](#)

[Future plans](#)

[References](#)

[Chapter 24: PRISMA \(Preferred Reporting Items for Systematic Reviews and Meta-Analyses\)](#)

[Name of guideline](#)

[History/development](#)

[When to use this guideline \(what types of studies it covers\)](#)

[Previous version](#)

[Current version](#)

[Extensions and/or implementations](#)

[Related activities](#)

[How best to use the guideline](#)

[Development process](#)

[Evidence of effectiveness of guideline](#)

[Endorsement and adherence](#)

[Cautions and limitations \(including scope\)](#)

[Creators' preferred bits](#)

[Future plans](#)

[References](#)

[Part III](#)

[Chapter 25: Statistical Analyses and Methods in the Published Literature: The SAMPL Guidelines](#)

[Introduction](#)

[Guiding principles for reporting statistical methods and results](#)

[General principles for reporting statistical methods](#)

[General principles for reporting statistical results](#)

[References](#)

[Chapter 26: Guidelines for Presenting Tables and Figures in Scientific Manuscripts](#)

[Introduction](#)

[What to present?](#)

[What format to use: figure, table, or text?](#)

[General principles for tables and figures](#)

[General principles for tables](#)

[General principles for figures](#)

[Suggestions for specific situations](#)

[Survival curves \[19\]](#)

[Box plots \[20\]](#)

[Bar graphs](#)

[Paired data \[9, 21\]](#)

[Stratified data \[1, 9\]](#)

[Table 1 \(participant baseline characteristics\) \[22\]](#)

[References](#)

[Chapter 27: Documenting Clinical and Laboratory Images in Publications: The CLIP Principles](#)

[Introduction](#)

[Components of documentation](#)

[Placement of information in the text](#)

[Further development](#)

[Acknowledgments](#)

[References](#)

[Appendix](#)

[An excerpt from an example documenting magnetic resonance images: reporting information on the hardware and software used in image acquisition](#)

[Chapter 28: Reporting Guidelines for Health Economic Evaluations: BMJ Guidelines for Authors and Peer Reviewers of Economic Submissions](#)

[Name of guideline](#)

[When to use the guidelines](#)

[Development process](#)

[Current version compared to previous versions](#)

[How best to use the guideline](#)

[Evidence of effectiveness of guideline](#)

[Endorsement and adherence](#)

[Cautions and limitations](#)

[Creators' preferred bits](#)

[Future plans](#)

[References](#)

[Part IV](#)

[Chapter 29: Establishing a Coherent Reporting Guidelines Policy in Health Journals](#)

[Introduction](#)

[Eight steps toward implementing a reporting standards policy](#)

[Conclusion](#)

[Reference](#)

[Index](#)

[End User License Agreement](#)

List of Illustrations

[Figure 6.1](#)

[Figure 9.1](#)

[Figure 9.2](#)

[Figure 11.1](#)

[Figure 13.1](#)

[Figure 14.1](#)

[Figure 19.1](#)

[Figure 26.1](#)

[Figure 26.2](#)

[Figure 26.3](#)

[Figure 28.1](#)

List of Tables

[Table 2.1](#)

[Table 3.1](#)

[Table 9.1](#)

[Table 11.1](#)

[Table 13.1](#)

[Table 13.2](#)

[Table 14.1](#)

[Table 14.2](#)

[Table 15.1](#)

[Table 19.1](#)

[Table 20.1](#)

[Table 20.2](#)

[Table 21.1](#)

[Table 22.1](#)

[Table 22.2](#)

[Table 23.1](#)

[Table 23.2](#)

[Table 28.1](#)

[Table 29.1](#)

[Table 29.2](#)

[Table 29.3](#)

Guidelines for Reporting Health Research: A User's Manual

EDITED BY

David Moher

Ottawa Hospital Research Institute and University of
Ottawa, Ottawa, Canada

Douglas G. Altman

Centre for Statistics in Medicine, University of Oxford and
EQUATOR Network, Oxford, UK

Kenneth F. Schulz

FHI360, Durham, and UNC School of Medicine, Chapel
Hill, North Carolina, USA

Iveta Simera

Centre for Statistics in Medicine, University of Oxford and
EQUATOR Network Oxford, UK

Elizabeth Wager

Sideview, Princes Risborough, UK



WILEY Blackwell

BMJ|Books

This edition first published 2014 © 2014 by John Wiley & Sons, Ltd.

Registered office: John Wiley & Sons, Ltd, The Atrium, Southern Gate, Chichester, West Sussex, PO19 8SQ, UK

Editorial offices: 9600 Garsington Road, Oxford, OX4 2DQ, UK

The Atrium, Southern Gate, Chichester, West Sussex, PO19 8SQ, UK

111 River Street, Hoboken, NJ 07030-5774, USA

For details of our global editorial offices, for customer services and for information about how to apply for permission to reuse the copyright material in this book please see our website at www.wiley.com/wiley-blackwell

The right of the author to be identified as the author of this work has been asserted in accordance with the UK Copyright, Designs and Patents Act 1988.

All rights reserved. No part of this publication may be reproduced, stored in a retrieval system, or transmitted, in any form or by any means, electronic, mechanical, photocopying, recording or otherwise, except as permitted by the UK Copyright, Designs and Patents Act 1988, without the prior permission of the publisher.

Designations used by companies to distinguish their products are often claimed as trademarks. All brand names and product names used in this book are trade names, service marks, trademarks or registered trademarks of their respective owners. The publisher is not associated with any product or vendor mentioned in this book. It is sold on the understanding that the publisher is not engaged in rendering professional services. If professional advice or other expert assistance is required, the services of a competent professional should be sought.

The contents of this work are intended to further general scientific research, understanding, and discussion only and are not intended and should not be relied upon as recommending or promoting a specific method, diagnosis, or treatment by health science practitioners for any particular patient. The publisher and the author make no representations or warranties with respect to the accuracy or completeness of the contents of this work and specifically disclaim all warranties, including without limitation any implied warranties of fitness for a particular purpose. In view of ongoing research, equipment modifications, changes in governmental regulations, and the constant flow of information relating to the use of medicines, equipment, and devices, the reader is urged to review and evaluate the information provided in the package insert or instructions for each medicine, equipment, or device for, among other things, any changes in the instructions or indication of usage and for added warnings and precautions. Readers should consult with a specialist where appropriate. The fact that an organization or Website is referred to in this work as a citation and/or a potential source of further information does not mean that the author or the publisher endorses the information the organization or Website may provide or recommendations it may make. Further, readers should be aware that Internet Websites listed in this work may have changed or

disappeared between when this work was written and when it is read. No warranty may be created or extended by any promotional statements for this work. Neither the publisher nor the author shall be liable for any damages arising herefrom.

Library of Congress Cataloging-in-Publication Data

Guidelines for reporting health research : a users manual / editors, David Moher, Douglas G. Altman, Kenneth F. Schulz, Iveta Simera, Elizabeth Wager. p. ; cm.

Includes bibliographical references and index.

ISBN 978-0-470-67044-6 (pbk.)

I. Moher, David, 1957- editor of compilation. II. Altman, Douglas G., editor of compilation.

III. Schulz, Kenneth F., editor of compilation. IV. Simera, Iveta, editor of compilation.

V. Wager, Elizabeth, editor of compilation.

[DNLM: 1. Biomedical Research—methods.

2. Research Report—standards. 3. Peer Review, Research—standards. W 20.5] R850

610.72'4—dc23

2014000621

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

Wiley also publishes its books in a variety of electronic formats. Some content that appears in print may not be available in electronic books.

Cover design by Rob Sawkins a Opta Design Ltd.

List of Contributors

Douglas G. Altman Centre for Statistics in Medicine,
University of Oxford, Oxford, UK

Andrew Booth Cochrane Collaboration Qualitative
Research Methods Group

Andrew H. Briggs Health Economics and Health
Technology Assessment, Institute of Health & Wellbeing,
University of Glasgow, Glasgow, UK

Patrick M.M. Bossuyt Department of Clinical
Epidemiology & Biostatistics, Academic Medical Center,
University of Amsterdam, Amsterdam, the Netherlands

Isabelle Boutron Centre d'Epidémiologie Clinique,
Assistance Publique-Hôpitaux de Paris, Paris, France
Centre Cochrane Français, INSERM U738, Université
Paris Descartes, Paris, France

Marion K. Campbell Health Services Research Unit,
University of Aberdeen, Aberdeen, UK

Margaret M. Cavenagh Cancer Diagnosis Program,
Division of Cancer Treatment and Diagnosis, National
Cancer Institute, Bethesda, MD, USA

Myriam Cevallos CTU Bern and Institute of Social and
Preventative Medicine, University of Bern, Bern,
Switzerland

An-Wen Chan Women's College Research Institute,
Toronto, ON, Canada

ICES@UofT, Toronto, ON, Canada

Department of Medicine, Women's College Hospital,
University of Toronto, Toronto, ON, Canada

Mike Clarke All-Ireland Hub for Trials Methodology
Research, Centre for Public Health, Queens University
Belfast, Belfast, Northern Ireland

Frank Davidoff Annals of Internal Medicine,
Philadelphia, PA, USA

Don C. Des Jarlais Baron Edmond de Rothschild
Chemical Dependency Institute, Beth Israel Medical
Center, New York, NY, USA

Michael F. Drummond University of York, York, UK

Matthias Egger Institute of Social and Preventive
Medicine (ISPM), University of Bern, Bern, Switzerland

Diana R. Elbourne London School of Hygiene and
Tropical Medicine, London, UK

Jeremy Grimshaw Ottawa Hospital Research Institute
and University of Ottawa, Ottawa, ON, Canada

Karin Hannes Cochrane Collaboration Qualitative
Research Methods Group

Angela Harden Cochrane Collaboration Qualitative
Research Methods Group

Janet Harris Cochrane Collaboration Qualitative
Research Methods Group

Allison Hirst Nuffield Department of Surgical Sciences,
University of Oxford, Oxford, UK

John Hoey Queen's University, Kingston, ON, Canada

Sally Hopewell Centre for Statistics in Medicine,
University of Oxford, Oxford, UK

INSERM, U738, Paris, France

AP-HP (Assistance Publique des Hôpitaux de Paris),
Hôpital Hôtel Dieu, Centre d'Epidémiologie Clinique,
Paris, France

Univ. Paris Descartes, Sorbonne Paris Cité, Paris, France

Timothy T. Houle Department of Anesthesiology, Wake Forest University School of Medicine, Winston-Salem, NC, USA

Samuel J. Huber University of Rochester School of Medicine and Dentistry, Rochester, NY, USA

John P.A. Ioannidis Stanford Prevention Research Center, Department of Medicine and Division of Epidemiology, Department of Health Research and Policy, Stanford University School of Medicine, and Department of Statistics, Stanford University School of Humanities and Sciences, Stanford, CA, USA

Thomas A. Lang Tom Lang Communications and Training International, Kirkland, WA, USA

Julian Little Department of Epidemiology and Community Medicine, Canada Research Chair in Human Genome Epidemiology, University of Ottawa, Ottawa, ON, Canada

Elizabeth W. Loder British Medical Journal, London, UK

Division of Headache and Pain, Department of Neurology, Brigham and Women's Hospital, Boston, MA, USA

Harvard Medical School, Boston, MA, USA

Hugh MacPherson Department of Health Studies, University of York, York, UK

Lisa M. McShane Biometric Research Branch, National Cancer Institute, Bethesda, MD, USA

Donald Miller Department of Anesthesia, The Ottawa Hospital, Ottawa Hospital Research Institute and University of Ottawa, Ottawa, ON, Canada

David Moher Clinical Epidemiology Program, Ottawa
Hospital Research Institute, Ottawa, ON, Canada

Jane Noyes Centre for Health-Related Research, School
for Healthcare Sciences, College of Health &
Behavioural Sciences, Bangor University, Bangor, UK

Mary Ocampo Ottawa Hospital Research Institute,
Ottawa, ON, Canada

Greg Ogrinc Dartmouth Medical School, Hanover, NH,
USA

Donald B. Penzien Department of Psychiatry, Wake
Forest University School of Medicine, Winston-Salem,
NC, USA

Gilda Piaggio Statistika Consultoria Ltd, São Paulo,
Brazil

Jason L. Roberts Headache Editorial Office, Plymouth,
MA, USA

Philippe Ravaud Centre d'Epidémiologie Clinique,
Assistance Publique-Hôpitaux de Paris, Paris, France
Centre Cochrane Français, INSERM U738, Université
Paris Descartes, Paris, France

John F. Rothrock Department of Neurology, University
of Alabama at Birmingham, Birmingham, AL, USA

Margaret Sampson Children's Hospital of Eastern
Ontario, Ottawa, ON, Canada

Willi Sauerbrei Department of Medical Biometry and
Medical Informatics, University Medical Centre,
Freiburg, Germany

David L. Schrager UCLA Emergency Medicine Center,
Los Angeles, CA, USA

Kenneth F. Schulz FHI 360, Durham, and UNC School of Medicine, Chapel Hill, NC, USA

Dugald Seely Ottawa Integrative Cancer Centre, Ottawa, ON, Canada

Iveta Simera Centre for Statistics in Medicine, University of Oxford, Oxford, UK

George C. M. Siontis Clinical Trials and Evidence-Based Medicine Unit, Department of Hygiene and Epidemiology, University of Ioannina School of Medicine, Ioannina, Greece

Cassandra Talerico Neurological Institute Research and Development Office, Cleveland Clinic, Cleveland, OH, USA

Sheila E. Taube ST Consulting, Bethesda, MD, USA

Jennifer Tetzlaff Ottawa Methods Centre, Clinical Epidemiology Program, Ottawa Hospital Research Institute, Ottawa, ON, Canada

Allison Tong Sydney School of Public Health, University of Sydney, Sydney, Australia

Dana P. Turner Department of Anesthesiology, Wake Forest University School of Medicine, Winston-Salem, NC, USA

Elizabeth Wager Sideview, Princes Risborough, UK

Laura Weeks Ottawa Integrative Cancer Centre, Ottawa, ON, Canada

Merrick Zwarenstein Schulich School of Medicine and Dentistry, Western University, London, ON, Canada

Foreword

Guides to guidelines

Drummond Rennie, MD

University of California, San Francisco, USA

Introduction

Good patient care must be based on treatments that have been shown by good research to be effective. An intrinsic part of good research is a published paper that closely reflects the work done and the conclusions drawn. This book is about preventing, even curing, a widespread endemic disease: biased and inadequate reporting. This bias and poor reporting threatens to overwhelm the credibility of research and to ensure that our treatments are based on fiction, not fact.

Over the past two decades, there has been a spate of published guidelines on reporting, ostensibly to help authors improve the quality of their manuscripts. Following the guidelines, manuscripts will include all the information necessary for an informed reader to be fully persuaded by the paper. At the same time, the articles will be well organized, easy to read, well argued, and self-critical. From the design phase of the research, when they may serve as an intervention to remind investigators, editors, and reviewers who find it easy to get the facts, and to note what facts are missing, all the way through to the reader of the published article who finds it easy to access the facts, all of them in context.

To which, given the ignorance, ineptitude, inattention, and bias of so many investigators, reviewers, and journal editors, I would add a decisive “Maybe!”

How did it start? How did we get here?

In 1966, 47 years ago, Dr Stanley Schor, a biostatistician in the Department of Biostatistics at the American Medical Association, in Chicago, and Irving Karten, then a medical student, published in *JAMA* the results of a careful examination of a random sample of published reports taken from the 10 most prominent medical journals. Schor and Karten focused their attention on half of the reports that they considered to be “analytical studies,” 149 in number, as opposed to reports of cases. They identified 12 types of statistical errors, and they found that the conclusions were invalid in 73%. “None of the ten journals had more than 40% of its analytical studies considered acceptable; two of the ten had no acceptable reports.” Schor and Karten speculated on the implications for medical practice, given that these defects occurred in the most widely read and respected journals, and they ended presciently: “since, with the introduction of computers, much work is being done to make the results of studies appearing in medical journals more accessible to physicians, a considerable amount of misinformation could be disseminated rapidly.” Boy, did they get that one right!

Better yet, this extraordinary paper also included the results of an experiment: 514 manuscripts submitted to one journal were reviewed by a statistician. Only 26% were “acceptable” statistically. However, the intervention of a statistical review raised the “acceptable” rate to 74%. Schor and Karten's recommendation was that a statistician be made part of the investigator's team and of the editors'

team as well [1]. Their findings were confirmed by many others, for example, Gardner and Bond [2].

I got my first taste of editing in 1977 at the *New England Journal of Medicine*, and first there and then at *JAMA the Journal of the American Medical Association*, my daily job has been to try to select the best reports of the most innovative, important, and relevant research submitted to a large-circulation general medical journal. Although the best papers were exciting and solid, they seemed like islands floating in a swamp of paper rubbish. So from the start, the Schor/Karten paper was a beacon. Not only did the authors identify a major problem in the literature, and did so using scientific methods, but they tested a solution and then made recommendations based on good evidence.

This became a major motivation for establishing the Peer Review Congresses. Exasperatedly, in 1986, I wrote:

One trouble is that despite this system (of peer review), anyone who reads journals widely and critically is forced to realize that there are scarcely any bars to eventual publication [3].

Was the broad literature so bad despite peer review or because of it? What sort of product, clinical research reports, was the public funding and we journals disseminating? Only research could find out, and so from the start the Congresses were limited strictly to reports of research.

At the same time, Iain Chalmers and his group in Oxford were struggling to make sense of the entire literature on interventions in health care, using and refining the science of meta-analysis to apply it to clinical reports. This meant that, with Chalmers' inspired creation of the Cochrane Collaboration, a great many bright individuals such as Altman, Moher, Dickersin, Chalmers, Schulz, Gøtzsche, and

others were bringing intense skepticism and systematic scrutiny to assess the completeness and quality of reporting of clinical research and to identify those essential items, the inadequate reporting of which was associated with bias. The actual extent of biases, say, because of financial conflicts or failure to publish, could be measured, and from that came changes in the practices of journals, research institutions, and individual researchers. Eventually, there even came changes in the law (e.g., requirements to register clinical trials and then to post their results). Much of this research was presented at the Congresses [4-6]. The evidence was overwhelming that poor reporting biased conclusions – usually about recommended therapies [7]. The principles of randomized controlled trials, the bedrock of evidence about therapies, had been established 40 years before and none of it was rocket science. But time and again investigators had been shown to be making numerous simple but crucial mistakes in the reporting of such trials.

What to do about it?

In the early 1990s, two groups came up with recommendations for reporting randomized trials [8, 9]. These were published but produced no discernible effect. In discussions with David Moher, he suggested to me that *JAMA* should publish a clinical trial according to the SORT recommendation, which we did [10], calling for comments – which we got in large numbers. It was obvious that one of the reasons that the SORT recommendations never caught on was that while they were the product of a great deal of effort by distinguished experts, no one had actually tried them out in practice. When this was done, the resultant paper was unreadable, as the guidelines allowed no