

Suhail A.R. Doi Gail M. Williams Editors

Methods of Clinical Epidemiology



Springer Series on Epidemiology and Public Health

Suhail A.R. Doi Gail M. Williams *Editors*

Methods of Clinical Epidemiology



Springer Series on Epidemiology and Public Health

Series Editors Wolfgang Ahrens Iris Pigeot

For further volumes: http://www.springer.com/series/7251

Suhail A.R. Doi • Gail M. Williams Editors

Methods of Clinical Epidemiology



Editors Suhail A.R. Doi Clinical Epidemiology Unit School of Population Health University of Queensland Herston, Queensland Australia

Gail M. Williams Department of Epidemiology & Biostatistics School of Population Health University of Queensland Herston, Queensland Australia

 ISSN 1869-7933
 ISSN 1869-7941 (electronic)

 ISBN 978-3-642-37130-1
 ISBN 978-3-642-37131-8 (eBook)

 DOI 10.1007/978-3-642-37131-8
 Springer Heidelberg New York Dordrecht London

Library of Congress Control Number: 2013940612

© Springer-Verlag Berlin Heidelberg 2013

This work is subject to copyright. All rights are reserved by the Publisher, whether the whole or part of the material is concerned, specifically the rights of translation, reprinting, reuse of illustrations, recitation, broadcasting, reproduction on microfilms or in any other physical way, and transmission or information storage and retrieval, electronic adaptation, computer software, or by similar or dissimilar methodology now known or hereafter developed. Exempted from this legal reservation are brief excerpts in connection with reviews or scholarly analysis or material supplied specifically for the purpose of being entered and executed on a computer system, for exclusive use by the purchaser of the work. Duplication of this publication or parts thereof is permitted only under the provisions of the Copyright Law of the Publisher's location, in its current version, and permission for use must always be obtained from Springer. Permissions for use may be obtained through RightsLink at the Copyright Clearance Center. Violations are liable to prosecution under the respective Copyright Law.

The use of general descriptive names, registered names, trademarks, service marks, etc. in this publication does not imply, even in the absence of a specific statement, that such names are exempt from the relevant protective laws and regulations and therefore free for general use.

While the advice and information in this book are believed to be true and accurate at the date of publication, neither the authors nor the editors nor the publisher can accept any legal responsibility for any errors or omissions that may be made. The publisher makes no warranty, express or implied, with respect to the material contained herein.

Printed on acid-free paper

Springer is part of Springer Science+Business Media (www.springer.com)

Preface

This book was written to fill the gap that exists in the methods of epidemiology of interest to clinical researchers. It will enable a reader who is currently undertaking research to get key information regarding methodology. It will also help health care personnel from all fields (doctors, nurses, allied health, dentists, pharmacists, etc.) to obtain an effective understanding of methodology useful to research in their field as we cover the unique methods not covered properly in current research methods texts. The classic theoretical focus is avoided because we believe that research must be based on understanding guided by the reader's knowledge of the methodology.

Part I begins by introducing readers to the methods used in clinical agreement studies. It is written to suit beginners but without turning off intermediate users. Qualitative and quantitative agreement are presented, and this section explains how we can utilize these methods and their strengths and weaknesses. Part II shows readers how they can interpret and conceptualize diagnostic test methodologies and ends with an introduction to diagnostic meta-analyses. Part III takes the reader through methods of regression for the binomial family as well as survival analysis and Cox regression. Here, the focus is on methods of use to clinical researchers. These methods have different names and multiple interpretations, which are explained. It is important to know what associations you are interested in and know what data are available and in what form they can be used. An in-depth discussion of the use of these methods is presented with a view to giving the reader a clear understanding of their utility and interpretation. Part IV deals with systematic reviews and meta-analyses. A stepby-step approach is used to guide readers through the key principles that must be understood before undertaking a meta-analysis, with particular emphasis on newer methods for bias adjustment in meta-analysis, an area in which we have considerable expertise.

We thank Lorna O'Brien from authorserv.com for her dedicated help with the editing of this book and Federica Corradi Dell'Acqua, Editorial Manager for Biomathematics & Statistics at Springer for continuous advice throughout the publication process. Finally, we realize that this first edition may include inconsistencies and mistakes, and we welcome any suggestion from readers to improve its content.

30 June 2012 Brisbane Suhail A.R. Doi Gail M. Williams

Acknowledgments

Every effort has been made to trace rights holders, but if any have been inadvertently overlooked the publishers would be pleased to make the necessary arrangements at the first opportunity.

List of Abbreviations

ADA	Adenosine deaminase activity
AGME	Accreditation Council for Graduate Medical Education
ANA	Antinuclear antibodies
ANOVA	Analysis of variance
AUC	Area under the curve
BAK	Bias-adjusted kappa
BF	Body fat
BMI	Body mass index
BP	Blood pressure
CADTH	Canadian Agency for Drugs and Technology in Health
CASP	Critical Appraisal Skills Programme
CEBM	Centre for Evidence Based Medicine
CF	Correction factor
CHF	Congestive heart failure
CI	Confidence interval
CL	Confidence limits
CT	Computed tomography
CV	Coefficient of variation
DOR	Diagnostic odds ratio
DXA	Dual-energy X-ray absorptiometry
ECT	Electroconvulsive therapy
ELISA	Enzyme-linked immunosorbent assay
EPHPP	Effective Public Health Practice Project
ES	Effect size
ESR	Erythrocyte sedimentation rate
ESS	Effective sample size
FN	False-negative
FP	False-positive
FPR	False-positive rate

CLM	Generalized Linear Model
GLM	
HIV	Human immunodeficiency virus
HSROC	Hierarchical summary receiver operator characteristic
HTA	Health technology assessment
ICC	Intraclass correlation coefficient
ICC	Intraclass correlation coefficient
IID	Independent and identically distributed
ITT	Intention-to-treat
LAG	Lymphangiography
LCL	Lower confidence limit
LR	Likelihood ratio
MERGE	Method for Evaluating Research and Guideline Evidence
MeSH	Medical Subject Heading
MI	Myocardial infarction
MRI	Magnetic resonance imaging
MSE	Mean squared error
NLM	National Library of Medicine
NOS	Newcastle-Ottawa Scale
NPV	Negative predictive value
NSS	Numerical sum score
NTP	Negative test probability
OCLC	Online Computer Library Center
OFIA	Operational financial impact assessment
PABAK	Prevalence-adjusted-bias-adjusted kappa
PICO	Population, intervention or exposure, comparison, outcome
PPV	Positive predictive value
PT	Pertussis toxin
QCR	Qualitative rating on level of components
QE	Quality effect
QOR	Qualitative overall rating
QUADAS	Quality Assessment of Diagnostic Accuracy Studies
RCT	Randomized controlled trial
RE	Random effect
REVC	Random effects variance component
RLR	Ratio of the likelihood ratio
ROC	Receiver operating characteristic
ROM	Range of motion
RR	Relative risks
SD	Standard deviation
SE	Standard error
SEM	Standard error of the measurement
SLE	Systemic lupus erythematosus
SMD	Standardized mean difference
TcB	Transcutaneous bilirubin
-	

TN	True-negative
TP	True-positive
TPR	True-positive rate
TSB	Total serum bilirubin
UCL	Upper confidence limit
WHO	World Health Organization

Contents

Part I Clinical Agreement

1	Clinical Agreement in Qualitative Measurements	3
2	Clinical Agreement in Quantitative Measurements	17
3	Disagreement Plots and the Intraclass Correlation in Agreement Studies Suhail A.R. Doi	29
4	The Coefficient of Variation as an Index of MeasurementReliabilityOrit Shechtman	39
Par	t II Diagnostic Tests	
5	Using and Interpreting Diagnostic Tests with Dichotomous or Polychotomous Results	53
6	Using and Interpreting Diagnostic Tests with Quantitative Results	67
7	Sample Size Considerations for Diagnostic Tests	79
8	An Introduction to Diagnostic Meta-analysis	103
9	Health Technology Assessments of Diagnostic Tests	121