

Biostatistics.
v. 10, no. 3 (July 2009)
General Collection
WV1 B1916E
2009-08-27 07:54:00

Biostatistics

VOLUME 10 NUMBER 3 JULY 2009

www.biostatistics.oxfordjournals.org

Genome & Co. v. Univ. of Chicago
PGR2019-00002
UNIV. CHICAGO EX. 2074



PROPERTY OF THE
NATIONAL
LIBRARY OF
MEDICINE



**DOCKET
ALARM**

Find authenticated court documents without watermarks at docketalarm.com.

Biostatistics



Co-Editors

Peter J. Diggle
Scott L. Zeger

Advisory Board

Norman Breslow
David Cox
Sarah Darby
Peter Diggle
Mitchell Gail
Niels Keiding
Scott Zeger

Associate Editors

Rebecca Betensky
Adrian Bowman
Maria De Iorio
Paddy Farrington
Jason Fine
Joseph Hogan
Philip Hougaard
Hans van Houwelingen
Katja Ickstadt
Rafael Irizarry
Bani Mallick
Tom Nye
Roger Peng
Margaret Pepe
Louise M. Ryan
Naisyin Wang



OXFORD JOURNALS

VOLUME 10 • NUMBER 3 • JULY 2009

Biostatistics

- 405 **R. D. Peng**
Editorial: Reproducible research and *Biostatistics*
- 409 **D. Lee, C. Ferguson, R. Mitchell**
Air pollution and health in Scotland: a multicity study
- 424 **P. de Valpine, H.-M. Bitter, M. P. S. Brown, J. Heller**
A simulation–approximation approach to sample size planning for high-dimensional classification studies
- 436 **D. H. Y. Leung, Y.-G. Wang, M. Zhu**
Efficient parameter estimation in longitudinal data analysis using a hybrid GEE method
- 446 **J. Hardin, J. Wilson**
A note on oligonucleotide expression values not being normally distributed
- 451 **D. Y. Clement, R. L. Strawderman**
Conditional GEE for recurrent event gap times
- 468 **J. Hu, F. Hu**
Estimating equation–based causality analysis with application to microarray time series data
- 481 **J. E. Eckel-Passow, A. L. Oberg, T. M. Therneau, H. R. Bergen, III**
An insight into high-resolution mass-spectrometry data
- 501 **M. Haugen, F. Bray, T. Grotmol, S. Tretli, O. O. Aalen, T. A. Moger**
Frailty modeling of bimodal age-incidence curves of nasopharyngeal carcinoma in low-risk populations
- 515 **D. M. Witten, R. Tibshirani, T. Hastie**
A penalized matrix decomposition, with applications to sparse principal components and canonical correlation analysis
- 535 **C. Proust-Lima, J. M. G. Taylor**
Development and validation of a dynamic prognostic tool for prostate cancer recurrence using repeated measures of posttreatment PSA: a joint modeling approach
- 550 **M. A. van de Wiel, J. Berkhof, W. N. van Wieringen**
Testing the prediction error difference between 2 predictors
- 561 **P. S. Sanchez, G. F. V. Glonek**
Optimal designs for 2-color microarray experiments
- 575 **O. Saarela, S. Kulathinal, J. Karvanen**
Joint analysis of prevalence and incidence data using conditional likelihood
- 588 *Biostatistics* - Referees of Manuscripts Submitted Mid-2007 to Mid-2008

Subscriptions

A subscription to *Biostatistics* comprises 4 issues. Prices include postage by surface mail, or for subscribers in the USA and Canada by airfreight, or in India, Japan, Australia and New Zealand by Air Speeded Post.

Annual Subscription Rate (Volume 10, 4 issues, 2009)

Institutional

Print edition and site-wide online access:

£348/US\$696/€522

Print edition only: £331/US\$662/€497

Site-wide online access only: £317/US\$634/€476

Personal

Print edition: £167/US\$334/€251

Please note: US\$ rate applies to US & Canada, Euros applies to Europe, UK£ applies to UK and Rest of World.

There are other subscription rates available; for a complete listing please visit

www.biostatistics.oxfordjournals.org/subinfo.

Full pre-payment in the correct currency is required for all orders. Payment should be in US dollars for orders being delivered to the USA or Canada; Euros for orders being delivered within Europe (excluding the UK); GBP sterling for orders being delivered elsewhere (i.e. not being delivered to USA, Canada, or Europe). All orders should be accompanied by full payment and sent to your nearest Oxford Journals office. Subscriptions are accepted for complete volumes only. Orders are regarded as firm, and payments are not refundable. Our prices include Standard Air as postage outside of the UK. Claims must be notified within four months of despatch/order date (whichever is later). Subscriptions in the EEC may be subject to European VAT. If registered, please supply details to avoid unnecessary charges. For subscriptions that include online versions, a proportion of the subscription price may be subject to UK VAT. Subscribers in Canada, please add GST to the prices quoted. Personal rate subscriptions are only available if payment is made by personal cheque or credit card, delivery is to a private address, and is for personal use only.

The current year and two previous years' issues are available from Oxford University Press. Previous volumes can be obtained online at <http://www.periodicals.com/oxford.html> or from the Periodicals Service Company, 11 Main Street, Germantown, NY 12526, USA. Email: psc@periodicals.com. Tel: +1 (518) 537 4700. Fax: +1 (518) 537 5899.

For further information, please contact: Journals Customer Service Department, Oxford University Press, Great Clarendon Street, Oxford OX2 6DP, UK. Email: jnl.cust.serv@oxfordjournals.org. Tel (and answerphone outside normal working hours): +44 (0)1865 353907. Fax: +44 (0)1865 353485. **In the US, please contact:** Journals Customer Service Department, Oxford University Press, 2001 Evans Road, Cary, NC 27513, USA. Email: jnlorders@oxfordjournals.org. Tel (and answerphone outside normal working hours): 800 852 7323 (toll-free in USA/Canada). Fax: 919 677 1714. **In Japan, please contact:** Journals Customer Services, Oxford University Press, 4-5-10-8F, Shiba, Minato-ku, Tokyo, 108-8386, Japan. Email: custserv.jp@oxfordjournals.org. Tel: +81 3 5444 5858. Fax: +81 3 3454 2929.

Methods of payment. (i) Check (payable to Oxford University Press, to Oxford University Press, Cashiers Office, Great Clarendon Street, Oxford OX2 6DP, UK) in GBE Sterling (drawn on a UK bank), US\$ Dollars (drawn on a US bank), or EU€ Euros. (ii) Bank transfer to Barclays Bank Plc, Oxford Group Office, Oxford (bank sort code 20 65 18) UK

overseas only Swift code BARC GB 22 (GBE Sterling to account no. 70299332, IBAN GB89BARC20651870299332; US\$ Dollars to account no. 66014600, IBAN GB27BARC20651866014600; EU€ Euros to account no. 78923655, IBAN GB16BARC20651878923655). (iii) Credit card (Mastercard, Visa, Switch or American Express).

Biostatistics (ISSN 1465-4644) is published quarterly in January, April, July, and October by Oxford University Press, Cary, NC. *Biostatistics* is distributed by DHL, Mills Road, Quarry Wood Industrial Estate, Aylesford, Kent ME20 7WZ, UK. Periodicals postage paid at Rahway, NJ, and at additional entry points.

US Postmaster: send address changes to *Biostatistics*, c/o Mercury International, 365 Blair Road, Avenel, NJ 07001.

Oxford Journals Environmental and Ethical Policies

Oxford Journals is committed to working with the global community to bring the highest quality research to the widest possible audience. Oxford Journals will protect the environment by implementing environmentally friendly policies and practices wherever possible. Please see <http://www.oxfordjournals.org/ethicalpolicies.html> for further information on Oxford Journals' environmental and ethical policies.

Digital Object Identifiers

For information on dois and to resolve them, please visit www.doi.org.

Permissions

For information on how to request permissions to reproduce articles/information from this journal, please visit www.oxfordjournals.org/jnl/permissions.

Advertising

Advertising, inserts, and artwork enquiries should be addressed to Advertising and Special Sales, Oxford Journals, Oxford University Press, Great Clarendon Street, Oxford, OX2 6DP, UK. Tel: +44 (0)1865 354767; Fax: +44 (0)1865 353774; E-mail: jnladvertising@oxfordjournals.org.

Submissions

For instructions on submitting a manuscript to *Biostatistics*, Please see the Instructions to Authors at www.biostatistics.oxfordjournals.org.

Disclaimer

Statements of fact and opinion in the articles in *Biostatistics* are those of the respective authors and contributors and not of *Biostatistics* or Oxford University Press. Neither Oxford University Press nor *Biostatistics* make any representation, express or implied, in respect of the accuracy of the material in this journal and cannot accept any legal responsibility or liability for any errors or omissions that may be made. The reader should make his/her own evaluation as to the appropriateness or otherwise of any experimental technique described.

© 2009 Oxford University Press; all rights reserved.

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 without prior written permission of the Publishers, or a licence permitting restricted copying issued in the UK by the Copyright Licensing Agency Ltd, 90 Tottenham Court Road, London W1P 9HE, or in the USA by the Copyright Clearance Center, 222 Rosewood Drive, Danvers, MA 01923.

Biostatistics (2009), **10**, 3, pp. 405–408
doi:10.1093/biostatistics/kxp014

Editorial

As coeditors of *Biostatistics*, we wish to encourage the practice of making research published in the journal reproducible by others. The following invited piece by Roger Peng sets out our policy on this; Roger will be assuming the role of Associate Editor for reproducibility as set out in his piece.

While we consider reproducibility to be a desirable goal, we wish to emphasise that our policy is to encourage our authors to consider this as an opportunity that they may wish to take, rather than as a requirement that we impose upon them. All submissions to the journal will continue to be reviewed using our established system; the issue of reproducibility will be considered only when a paper had been accepted for publication on the basis of its scientific merit as judged by our peer-review process.

PETER J. DIGGLE, SCOTT L. ZEGER

Reproducible research and *Biostatistics*

ROGER D. PENG

Johns Hopkins University

1. INTRODUCTION AND MOTIVATION

The replication of scientific findings using independent investigators, methods, data, equipment, and protocols has long been, and will continue to be, the standard by which scientific claims are evaluated. However, in many fields of study there are examples of scientific investigations that cannot be fully replicated because of a lack of time or resources. In such a situation, there is a need for a minimum standard that can fill the void between full replication and nothing. One candidate for this minimum standard is “reproducible research”, which requires that data sets and computer code be made available to others for verifying published results and conducting alternative analyses.

The need for publishing reproducible research is increasing for a number of reasons. Investigators are more frequently examining weak associations and complex interactions for which the data contain a low signal-to-noise ratio. New technologies allow scientists in all areas to compile complex high-dimensional databases. The ubiquity of powerful statistical and computing capabilities allows investigators to explore those databases and identify associations of potential interest. However, with the increase in data and computing power comes a greater potential for identifying spurious associations. In addition to these developments, recent reports of fraudulent research being published in the biomedical literature have highlighted the need for reproducibility in biomedical studies and have invited the attention of the major medical journals (Laine *and others*, 2007). Even without the presence of deliberate fraud, it should be noted that as analyses become more complicated, the possibility of inadvertent errors resulting in misleading findings looms large. In the examples of Baggerly *and others* (2005) and Coombes *and others* (2007), the errors discovered were not necessarily simple or obvious and the examination of the problem itself required

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.