



# International Society for Clinical Biostatistics

# News

Number 28

December 1999

Editor: David W. Warne

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## Editorial

After seven years, I can finally complain I've got too much to include in the News ! As we approach the New Year, the Society is thriving with many more people involved in Subcommittees than ever before. Moreover, after the highly successful meeting in Heidelberg, plans are well under way for our next meetings in Trento, Stockholm, Dijon and London. And the Society is intending to be active between Meetings too... read on !

We've set up a new offer with Arnolds for ISCB members to subscribe to Statistical Methods in Medical Research at a reduced rate. If interested, please send the enclosed form to the ISCB Office.

Between Newsletters, you can check the ISCB home page for updated information. We are also in the process of setting up an emailing list, both for informing members of books for review and future events, and for discussing topics of interest to ISCB members. I do hope many of you will take part in this new venture.

Thanks to the many contributors to this News: Paul Johnson, Anna Bartkowiak, Rainer Muche & Friederike Rohlmann, Berthold Lausen, Stefan Hantel, Ralph Kodell, Emmanuel Lesaffre, Maria Grazia Valsecchi, Bjarne Nielsen, Rita Schou and the ISCB Office, Simon Day, John Whitehead, Mike Campbell, Jorgen Seldrup and Nancy Geller.

In 2000, it is expected that the News will come out as usual in May/June and December, and the deadlines for contributions are early April and early November.

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## ISCB Membership

After the huge success of the Heidelberg meeting, the largest in ISCB's history, the numbers of members and countries stand at an all time high. A special welcome to the 245 new members.

		end	end	Dec	Dec	Dec	Dec	Dec	Dec	Jun	Dec
		89	92	93	94	95	96	97	98	99	99
	<b>Total</b>	<b>261</b>	<b>596</b>	<b>715</b>	<b>698</b>	<b>725</b>	<b>702</b>	<b>685</b>	<b>729</b>	<b>480</b>	<b>818</b>
	<b># Countries</b>	<b>23</b>	<b>32</b>	<b>32</b>	<b>31</b>	<b>33</b>	<b>34</b>	<b>37</b>	<b>37</b>	<b>33</b>	<b>41</b>
#	Country										
1	Germany	30	67	75	84	71	78	72	70	51	186
2	UK	50	90	176	120	144	121	128	169	90	135
3	USA	18	45	40	39	41	40	79	66	49	76
4	France	30	52	62	50	73	67	52	52	26	49
5	Denmark	4	58	38	31	30	32	26	35	25	38
6	Sweden	23	51	53	54	58	64	51	45	29	38
7	Netherlands	14	30	38	33	36	29	31	39	23	35
8	Hungary	1	21	17	18	19	25	27	29	29	29
9	Italy	16	33	37	32	32	33	26	33	20	26
10	Poland		11	11	24	24	30	21	19	25	26
11	Belgium	13	22	27	30	30	32	35	29	19	25
12	Switzerland	14	25	22	80	33	29	24	25	14	23
13	Japan	2	6	7	5	7	4	10	13	8	20
14	Austria	4	9	11	13	11	16	13	11	8	15
15	Spain	10	12	18	12	46	23	14	16	7	12
16	Norway	13	18	25	22	12	18	10	10	10	11
17	Australia	6	9	11	6	9	8	11	9	9	10
18	Finland	2	7	7	9	9	9	7	5	5	10
19	Canada	6	12	14	14	11	13	15	14	8	9
20	Portugal	1	3	5	2	2	2	2	5	2	5
21	Israel	1	3	4	4	4	4	3	3	3	4
22	Romania						2				4
23	Singapore							3	6	3	4
24	Hong Kong		1	1	2	3	3	3	3	3	3
25	Ireland	1	2	3	4	3	4	4	2	2	3
26	Cuba								2	2	2
27	Czech. Rep.			1	1	1	1	1	1		2
28	New Zealand		1		1		2	1	2		2
29	Russia					1	3	3	3	2	2
30	Slovenia		1	2	3	2	1	1	3	1	2
31	South Africa		1	4	1	3	2	2	2	2	2
32	Greece		1	1	1				1		1
33	Croatia										1
34	India		1	1	1	1	1	1	1	1	1
35	Malaysia					2	1	2	2	1	1
36	Mexico						1	1	1	1	1
37	Pakistan								1	1	1
38	Philippines									1	1
39	Thailand		1	1		1	1	2	1		1
40	Turkey		1	1							1
41	Ukraine										1
42	Brazil					2					
43	China		1	1	1	1	1	1			
44	Colombia							1	1		
45	Indonesia						1				
46	Iran						1	1			
47	Kenya		1	1							
48	Kuwait	1									
49	Oman	1									
50	South Korea					3		1			
51	Zimbabwe				1						

## Presidential Annual Report for 1999 and Wishes for the New Year

The ISCB constitution (section 5.04f) states, "The President ... shall present an Annual Report describing the activities of The Society during the previous calendar year ...; the Report shall be distributed to the Membership or published in the Newsletter."

During the early part of 1999, the final plans for the annual meeting in Heidelberg were made. Karsten Schmidt and I were in frequent communication with Norbert Victor and many members of the organising committee concerning various details. The Programme Committee, chaired by Martin Schumacher, arranged an exciting and stimulating programme and the Local Organising Committee took great care in making sure we had a very active social programme. Not only did this meeting have a World Wide Web site, but it was updated frequently and for the first time, the programme was put on the site and on-line registration and hotel reservations were introduced. Also, this meeting introduced the first ISCB presidential lecture, which was given by Professor Juni Palmgren (University of Stockholm). The organisers should be recognized for doing a very fine job and paying so much attention to detail.

Most ISCB business during the year was conducted by email, with occasional telephone calls and face-to-face meetings. The officers have had extensive email with one another. I introduced occasional communication with the ExCom via memo sent by email; there were five sent this year, two progress reports; the meeting agendas and related documents, to enable careful reading prior to coming to Heidelberg, where a face-to-face meeting took place; and the last two, votes on establishing a programme of Conference Awards for biostatisticians from ISCB target countries and establishing a Subcommittee on Operations.

Much of the work of ISCB is done by its subcommittees. The four subcommittees continued to be active in the past year. The subcommittees have presented separate reports which are included in this issue of the Newsletter and I outline their achievements briefly. The student conference awards subcommittee (John Whitehead, chair) organised, judged and granted five awards for the 1999 meeting and will grant three in 2000. The Education subcommittee (Michael Campbell, chair) held a very successful Cluster Trials Course and Workshop in Sheffield. In addition, to facilitate future ISCB course organisation, Michael Schemper prepared terms of reference for organising ISCB courses in statistically developing countries. The subcommittee has received permission to plan two courses under the guidelines. The subcommittee on Fraud (Marc Buyse, chair) submitted and got accepted in Statistics in Medicine a position paper on the role of biostatistics in the prevention, detection and treatment of fraud in clinical trials. The subcommittee members also wrote a manuscript summarising the results of the survey conducted in 1998 of the membership's experience with fraud. This paper has been submitted for publication. The subcommittee on

regulatory affairs (Helmut Schäfer, chair) commented on the European Agency for the Evaluation of Medicinal Products (EMA) proposed guideline on Bioavailability and Bioequivalence.

Two new subcommittees were established at the Heidelberg meeting. The Subcommittee on Communication (David Warne, chair) has as its terms of reference 1) To consider the future of the ISCB News, including a) the possibility of establishing an editorial board with specified responsibilities; b) procedures for transition of editorship; 2) To maintain the ISCB homepage on the World Wide Web and facilitate placement of annual meeting information on the homepage; 3) To consider other communications with members, such as through email or the World Wide Web. This subcommittee has just established an email list which can be used by members to make comments and inquiries (statistical or otherwise). The ISCB homepage is found at [www.iscb-homepage.org](http://www.iscb-homepage.org).

The Subcommittee on National Groups (Michael Schemper, chair) has as its terms of reference 1) To help those who are interested in forming a National Group through the approval process; 2) To review the arrangements with the current National Groups, specifically regarding financial matters; 3) To set rules and standards for funding of ISCB members of National Groups and others from countries with exchange control restrictions or barriers to receive waivers from the annual meeting registration fee and other financial assistance. This subcommittee has already put together a programme of conference awards for biostatisticians from ISCB target countries (in particular the formerly communist countries of central and eastern Europe) for the Trento meeting. Details are also found in this Newsletter.

At the end of the year, a third new subcommittee was established. We have been operating under the present constitution since August, 1996 and the ExCom thought it was time to review and possibly update some of the provisions. The Subcommittee on Operations, chaired by Karsten Schmidt, has as its terms of reference 1) To review operations under the constitution and make recommendations (if necessary) for clarifications and amendments; 2) To collate, prepare or initiate preparation of the society's operating procedures.

You will see on the last page of this Newsletter that we have our annual meetings planned in advance for several years now. In 2000 we will meet in Trento, Italy and in 2001 we will meet in Stockholm, Sweden. In Heidelberg, we approved a proposal for the year 2002 for a meeting in Dijon, France. In addition, we have agreed to hold a joint meeting in 2003 with the Society for Clinical Trials in London, England.

Overall, 1999 has been a busy and fruitful year for ISCB. I thank the officers, the ExCom and all of the members for their contributions and encourage the continuation of activities in 2000.

## Statistical Methodology in Clinical R&D

From Jorgen Seldrup

On April 10-12, 2000 the Drug Information Association (DIA) will hold what will become its 11<sup>th</sup> Annual European Workshop on Statistical Methodology in Clinical R&D.

From a modest beginning in 1990 in Vienna, this workshop has grown as an annual event to become an attractive meeting ground for not just statisticians but anyone with a keen interest in the application of statistics to drug development. It thus attracts attendees not only from the pharmaceutical industry but also from contract research organisations, academia and regulatory bodies. The DIA is advised by a European Statistics Advisory Committee of senior statisticians as to the yearly venue and the outline/content of the scientific programme.

The year 2000 Workshop will take place in Barcelona, Spain. Erik Cobo chairs the Scientific Programme Committee (SPC) with co-chairs Albert Cobos and Mariano Sust. Together with a six person SPC, the programme has been designed to cover sessions on simulation methods, randomisation and compliance measurements in clinical trials as well as special populations and the application of composite endpoints in cardiology. Full details of the programme may be found in the loose-leaf insert in the Newsletter. If you want to discuss important statistical issues of current interest in drug development, Barcelona is the place to meet in 2000.

For further information contact the DIA European Office at Postfach 4012 – Basel, Switzerland. Tel.: +41 61 386 9393, Fax: +41 61 386 9390 or e-mail: [diaeurope@stepnet.de](mailto:diaeurope@stepnet.de)

**MP  
S** Medical and Pharmaceutical  
Statistics Research Unit

**PROFESSIONAL DEVELOPMENT COURSES 2000**

at  
Reading, UK  
Düsseldorf, Germany  
Cary, North Carolina, USA

**FOR CLINICAL PERSONNEL**

**21 FEBRUARY 2000, READING**

**Data and Safety Monitoring Board  
Workshop**

*Presenters: John Whitehead, Sue Todd*

*Guest Presenter: Julian Bion*

*Reader in Intensive Care Medicine  
Queen Elizabeth Hospital, Birmingham*

**FOR MEDICAL STATISTICIANS**

**22-23 FEBRUARY 2000, READING**

**Sample Size Determination in Efficacy  
and Equivalence Trials**

*Presenter: Anne Whitehead*

**24 FEBRUARY 2000, READING**

**Use of PEST 4**

*Presenter: John Whitehead*

**6-7 JUNE 2000, READING**

**Introduction to Sequential  
Clinical Trials**

*Presenters: John Whitehead, Kim Bolland*

**8-9 JUNE 2000, READING**

**Further Topics in Sequential  
Clinical Trials**

*Presenters: Nigel Stallard, Sue Todd*

**19-20 JUNE 2000, DÜSSELDORF**

**Introduction to Sequential  
Clinical Trials**

*Presenters: John Whitehead, Nigel Stallard*

**21-23 JUNE 2000, DÜSSELDORF**

**From Theory to SAS®: Likelihood-  
based Statistical Inference**

*Presenters: John Whitehead, Nigel Stallard*

**DATE TO BE ANNOUNCED, NORTH CAROLINA**

**Introduction to Sequential  
Clinical Trials**

*Presenter: John Whitehead*

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## Photos and Review of ISCB-GMDS-99 in Heidelberg

Mostly Snapped by the Editor

Tony Johnson receives his presentation from John Wiley for editing *Statistics in Medicine* for so many years:



Sing Bach at the Old University:



Juni Palmgren delivers the first Presidential lecture.



The Communications Subcommittee (Bjarne, David, Elisabeth and Ted):



From Ralph Kodell:

ISCB99 Wine-Country Tour  
Wine-Tasting Session at  
Bad Dürkheim



We were promised 15-20°C for the Meeting but there was a typo and we got 15+20°C (= 35°C) !

What a beautiful city to hold our meeting – so much culture to learn about. The week started off with the 'organised sight-seeing tour' which unfortunately failed to turn up. The entertainment at the Conference Dinner was also lacking but otherwise things at the Conference went very smoothly, astonishing when you realise this was the largest ISCB meeting ever.

Were the Organisers stressed ? Certainly not: everything was superbly organised by delegating responsibilities to a large, enthusiastic team who all deserve to be thanked. Lutz Edler's emailing list was also a good idea, though I hear maintaining such a list can be time-consuming and painstaking. Despite this, we'll be setting up one for ISCB soon...

Congratulations too to the webmaster Axel Brenner for providing a new source of detailed information which will be a model for future Meetings. However, beware of web bookings – not everything may turn out as you requested as I found out – perhaps tourist offices and hotels haven't yet reached the information age.

The Scientific Programme was very well put together, with the concept of streaming lectures of similar topics being properly understood by Jürgen Windeler and his team, resulting in fewer moves between lecture rooms during the day, much appreciated in a large meeting.

Overall, well done – it was a great meeting ! We look forward to Norbert Victor's continuing contributions to ISCB, now he's joined the ExCom.

## ISCB Subcommittees

Please contact the chairmen of these subcommittees for further information.

Title	Terms of Reference	Members
<b>Fraud</b>	<ol style="list-style-type: none"> <li>To promote the role of appropriate biostatistical contributions in the assessment of misconduct.</li> <li>To develop statistical tools for assessment of data fabrication and falsification.</li> </ol>	<b>Chair:</b> Prof. Emmanuel Lesaffre (B), <b>Secretary:</b> Dr Jane L. Hutton (UK), <b>Members:</b> Dr Marc Buyse (B), Dr Lutz Edler (D), Prof. Stephan Evans (UK), Dr Nancy Geller (USA), Prof. Stephen L. George (USA), Prof. Gordon Murray (UK), Dr Jonas Ranstam (S), Dr Bruno Scherrer (F) <i>Supported by: Dr Harbajan Chadha-Boreham (F), Prof. Theodore Colton (USA), Dr Peter Lachenbruch (USA).</i>
<b>Statistics in Regulatory Affairs</b>	The subcommittee on Regulatory Affairs will review, comment upon and seek to influence the development of regulatory requirements, guidelines and other documents concerning the scientific aspects of data generation, collection, management, analysis, and reporting. In general, the subcommittee will seek out and handle all regulatory issues in the name of the Society with the approval of the President or in his absence, the Vice-President.	<b>Chair:</b> Dr Jørgen Seldrup (F), <b>Secretary:</b> Prof. Stephen Senn (UK), <b>Members:</b> Prof. Helmut Schäfer (D), Dr Karsten Schmidt (DK).  <a href="http://www.ucl.ac.uk/~ucaksjs/Guidance.html">http://www.ucl.ac.uk/~ucaksjs/Guidance.html</a>
<b>Education</b>	To organise one or two day courses on contemporary methods in clinical biostatistics which will involve one or several members as lecturers which will be presented in locations represented by the Society. Guidelines and plans of previous courses are available.	<b>Chair:</b> Prof. Mike Campbell (UK), <b>Members:</b> Dr Nancy Geller (USA), Prof. Michael Schemper (A), Dr Albert Cobos (E), Carol Redmond (USA), Shai Linn (ISR)
<b>Student Conference Awards</b>	Student conference awards are available for registered postgraduate students to attend the annual meeting and present a paper. The Subcommittee shall receive submissions, judge them, and administer the awards. The rules are announced in a timely issue of the Newsletter.	<b>Chair:</b> Prof. John Whitehead (UK), <b>Secretary:</b> Dr Bjarne Nielsen (DK), <b>Members:</b> Dr Marc Buyse (B), Dr Bruno Cesana (I)
<b>Communications</b>	<ol style="list-style-type: none"> <li>To consider the future of the Newsletter, including ways to support the Editor, procedures for transition of editorship.</li> <li>To maintain the ISCB homepage on the World Wide Web and facilitate placement of annual meeting information on the homepage.</li> <li>To consider other communications with members, such as through email or the World Wide Web.</li> </ol>	<b>Chair:</b> Dr David Warne (CH), <b>Secretary:</b> Dr Bjarne Nielsen (DK), <b>Members:</b> Dr Nancy Geller (USA), Dr Elisabeth Svensson (S) Prof. Ted Colton (USA)
<b>National Groups and other countries with exchange control restrictions or barriers</b>	<ol style="list-style-type: none"> <li>To help those who are interested in forming a National Group through the approval process.</li> <li>To review the arrangements with the current National Groups, specifically regarding financial matters.</li> <li>To set rules and standards for funding of ISCB members of National Groups and others from countries with exchange control restrictions or barriers to receive waivers from the annual meeting registration fee and other financial assistance.</li> </ol>	<b>Chair:</b> Prof. Michael Schemper (A), <b>Members:</b> Prof. John Whitehead (UK), Dr Jorgen Seldrup (F), Dr Siem Heisterkamp (NL), Dr Julia Singer (H)
<b>Operations</b>	<ol style="list-style-type: none"> <li>To review operations under the constitution and make recommendations (if necessary) for clarifications and amendments.</li> <li>To collate, prepare or initiate preparation of the society's operating procedures.</li> </ol>	<b>Chair:</b> Dr Karsten Schmidt (DK), <b>Members:</b> Mr Simon Day (UK), Dr Tony Johnson (UK), Dr Nancy Geller (USA)

## Book Review by Paul Johnson (USA)

Peter Armitage and Theodore Colton (Eds.): Encyclopedia of Biostatistics, Volume 1, John Wiley

Armitage and Colton edit a volume of work that will be of interest to statisticians/biostatisticians, epidemiologists, health science researchers, public health scientists, medical researchers, pharmaceutical scientists and many more. It is a large-scale reference work. The editors remark that the Encyclopedia of Biostatistics should be regarded as complimentary to the Encyclopedia of Statistical Sciences, edited by S. Kotz and N. L. Johnson, published in 9 volumes by John Wiley & Sons (1982-1988).

The Encyclopedia of Biostatistics, published in 6 volumes, contains 1208 articles. This is a review of Volume 1. I am certain that this volume is representative of all other volumes. The book brings together material and ideas from many contributors, and makes an important contribution to the field of biostatistics. This is an excellent book.

The more I read, the more there was to like about this encyclopedia. The articles have been written by different contributors but all are consistent in their excellent presentation of the material. The articles clearly explain the key concepts. The articles are extremely thorough in their descriptions of these concepts, ideas and referenced research material. The beginning of the book starts with a very useful list of acronyms and abbreviations. Next the contents are listed in alphabetical order for ease of reference. There then follows a list of contributors containing many very well known and distinguished people in the area of biostatistics. They have all contributed to make this such a first class and excellent book. The book contains many entries and the articles have been written so that a reader can obtain a great deal of accurate and useful information. They can obtain this information quickly and efficiently. I will mention three examples, that are representative of this volume of work. The 'Analysis of Variance' section starts with an overview followed by a description of the model. The general linear model is written and its matrix form given. The parameters are estimated and an analysis of variance table produced. The total sum of squares is broken down into its components and also shown in matrix form.

The section is complete, clear and could very well be used for class-room teaching. It flows with such an easy style that makes it very enjoyable to read. The 'Bootstrap Method' is quite a simple concept, but at times difficult to explain in writing.

The author of this section has made it simple to follow. This section contains several useful examples that aid in describing the method. The formulae and graphs are clear and complete. This section is concise, extremely informative and is representative of all other sections and entries. There follows a separate section for bootstrapping in survival analysis. The entry for 'ARMA and ARIMA Models' could not have been more clearly written. There is so much information contained within this article. The introduction is followed by a description of the ARMA model with clearly understandable formulae. The non-seasonal and seasonal ARIMA model are next described. The article continues with a description of the autocorrelation function, model identification and the transfer function model (including identification). These concepts are fully described with complete pertinent information. An interesting example is given and plots produced. References are provided.

The whole book is filled with this level of excellence. The graphs are clear and precise. All mathematical formulae, equations and models are complete, clear and readable. Cross-referencing is done in bold, for ease of reference. There is only one very minor point I did not like with this book.

The editors include biographical memoirs of statisticians and others. It is important to recognise these people who have contributed so much to the field of biostatistics, but at the same time I am not sure if this is the place. If this is the place then it may have been better to have collected all of these memoirs and section them off from the more important reference material. It is a minor point and certainly does not distract from the encyclopedia as being an excellent piece of work. The editors remark how much they enjoyed their role in this remarkable enterprise. I would like to add how much I enjoyed reading the final version of this 'remarkable enterprise'. I highly recommend the Encyclopedia of Biostatistics.

## Subcommittee Report: Communications

David Warne <100557.2260@compuserve.com>  
Bjarne Nielsen <BN@spadille.dk>  
Ted Colton <tcolson@bu.edu>  
Elisabeth Svensson <eliss@math.chalmers.se>  
Nancy L. Geller <ng@helix.nih.gov>

Inaugural Meeting: Heidelberg, Wed 15 Sep 1999, 1300-1345  
Present: DWW, BN, ES, TC Apologies: NG

The members introduced themselves over a working lunch and informally and rapidly discussed various ideas on communications:

0) Terms of Reference: It was decided to accept these, but that currently no editorial board is necessary: the Subcom will act as DWW's 'support team'.

1) ISCB www homepage will be updated regularly, especially on the new Subcommittee's membership and terms of reference.

2) We should try to gather info from the Heidelberg meeting to help future meetings, especially email lists, webpages etc.

3) Books for review could be announced on the webpage or by email (how many members have access to these ?)

4) An email list for rapid mailing could be set up to announce books, courses, reminding about subscriptions, advertising jobs etc.

5) New printing proposals. Already we had 1 colour page in the June News for the overhead photo of the Heidelberg site.

6) Postage: Some members felt their News arrived very late, perhaps reducing the chance of getting a book to review. This has been reviewed and the current system seems OK.

7) Coordination of mailings by the ISCB Office, especially mailshots between Newses, could be improved by better communication between Editor and Office.

8) Thinking to the eventual transition to a new News Editor, DWW suggested that he write a job description of what the editor's job currently entails.

9) Publish articles on what's going on statistically in various countries.

AGM Question:

Can ISCB publish stats. courses on web ? Any ideas on this, anyone ? It's something to discuss and will come up more and more in the future.



**The Ares-Serono Group** is a leading multinational company engaged in research, development and marketing of products in the biotechnology field. With Executive Headquarters in Geneva (Switzerland), Ares-Serono ranks among the world's leading biopharmaceutical companies.

The **Reproductive Health Biometrics Department** is looking for

### **DATABASE MONITOR(S)**

#### **Responsible for:**

- The creation and maintenance of clinical data capture packages using a variety of programs.
- Preparing data entry screens and data validation procedures to ensure that clinical trial data are entered and stored to a high quality standard.

#### **The positions require:**

- Diploma in Computer Sciences or Biology.
- Fluent English. French would be an asset.
- Minimum 2 years experience in data management with ORACLE.
- Experience in Pharmaceutical industry, in SAS and UNIX a plus.
- Accurate, flexible and able to work in a team.

### **BIOSTATISTICIANS**

#### **Responsible for:**

- bringing statistical expertise and input for clinical studies;
- for analysing results and for
- supporting R&D on various statistical issues.

#### **The positions require:**

- PhD in Biostatistics, Statistics or Mathematics;
- SAS expertise;
- excellent command of English;
- ideally, experience in statistical issues for clinical studies, preferably in the field of biotechnology;
- strong organisational, communication and interpersonal skills

In addition to a challenging career in a high-technology and creative environment, we offer continued training and personal development along with an excellent remuneration and benefits package, including, if needed, assistance with relocation to Geneva.

If interested, please send your CV to:

**ARES SERONO INTERNATIONAL S.A.**  
**Human Resources Department**  
**Chemin des Mines 15bis**  
**CH-1202 Geneva**  
**Switzerland**



D.W. Hosmer & S. Lemeshow: Applied Survival Analysis: Regression Modeling of Time to Event Data, John Wiley, 1999

The authors of the classical book 'Applied Logistic Regression' (1989) published a second applied textbook: 'Applied Survival Analysis'. It covers an up-to-date description of the methods used in analysing time to event data. The book focuses on practical applications and not on mathematical theory and proofs. Beyond descriptive methods and parametric models, 80% of the book deals with the proportional hazards model, which is probably the most applied model in modern survival analysis.

Hosmer and Lemeshow assume that the reader has a basic knowledge in methods of linear and/or logistic regression analysis. The idea is, not to show all basics of regression analysis but the application of the proportional hazards model based on this knowledge. In doing so, the authors can direct to analogies in other models and do not have to introduce the theory of estimating and testing in regression analysis. Thus, the book is an ideal textbook for people with knowledge in regression analysis who want to make themselves acquainted with the methods of survival analysis.

The authors put great emphasis on the interpretation of each step of the calculation and their consequences on the analysis. Though, the book is a helpful guide and advisor in analysing datasets. A further advantage is the detailed interpretation of the results of the models. This makes the book also understandable for people, who want to get into survival analysis without deep knowledge of other regression methods. The authors give an excellent presentation of the main points one has to pay attention to when analysing a regression model. Those who are interested in principal and mathematical basics of survival analysis have to look for other sources of information. Thus the word 'applied' in the title of the book is very well chosen by the authors although the reader should be willing to understand the basic formulas.

Every presented method in the book is completed with a real-world example for supporting the learning process. The datasets used in the examples can be downloaded from a FTP-server and analysed for a better understanding of the computational steps. In addition, Hosmer and Lemeshow give some advice of how to use the statistical software packages STATA, BMDP, SAS, S-Plus. Each chapter ends with some tests to check the acquired knowledge. However, the test solutions are missing. Giving the results of the tests would probably have gone beyond the scope of this book but could have been implemented on the FTP-server. A good source of getting further into the field of survival analysis is the bibliography which gives a good overview of the recent literature.

After a short preface and an introduction to censoring mechanisms, the univariate analysis like Kaplan-Meier method is described. The proportional hazards model and the estimation of the regression coefficients is introduced in Chapter 3. Chapter 4 shows possibilities of how to interpret such a fitted regression model. Different strategies and difficulties of interpretation are illustrated by examples.

Chapter 5 is addressed to variable selection. The basic idea and the problems of variable selection - how to identify the most suitable regression model - are presented. First, Hosmer and Lemeshow describe a technique, which is based on the conventional meaning of the variables, bivariate and multiple models. The authors dedicate a large part of this chapter to the question of how to include variables into the model. Among others, the fractional polynomials from Royston and Altman are described. In a second step the inclusion of interactions in the model is examined. This chapter is rounded off by mentioning the stepwise selection and the best subset selection, which probably are the most commonly used automatic methods for variable selection.

The calculation of the model should not be realised without examining the adequacy of the model. In Chapter 6, the authors describe methods for checking the conditions of the model, especially the proportionality of hazards and the goodness of fit, before they present and interpret the final model.

Extending methods are presented in the next three chapters. In Chapter 7, methods based on the proportional hazard model are described. Hosmer and Lemeshow cover considerations of time dependant covariates - covariates with changing influence on survival probabilities in time - and they give hints on more extensive literature. In Chapter 8, parametric regression models are presented alternatively to the proportional hazard model. A great advantage in using such models is the complete specification of the model. It leads to a better prediction of survival times. However, more specific assumptions of the underlying survival process have to be made. Chapter 9 introduces further developments in the field of survival analysis in recent times. In each of these 3 chapters Hosmer and Lemeshow give a brief introduction and then refer to more far-reaching literature. Since new aspects in survival analysis are more frequently presented in the scientific literature, the reader of this book gets a good overview of these new aspects going beyond the proportional hazard model.

In summary it may be said that this book is extremely readable. Because of the above mentioned detailed interpretation of the analysing steps and the description of corresponding pitfalls it can be recommended to all those who are about to use such models as well as to those who already worked with them but want to revise their procedures.

### REMINDER

Dues for 2000 are now due. (See p.27)

## **Letter home from Heidelberg**

From Jorgen Seldrup

I Heidelberg der tabte jeg mit hjerte.

What on earth is he talking about, I hear you saying, unless you are Danish... I lost my heart in Heidelberg. I almost lost myself too, trying to find my hotel Am Schloss which turned out to be on top of a car park. This only became evident after having been close several times, driving down one-way streets and through an assortment of tunnels. It was always going to be just under the castle, wasn't it? It looked so easy on the map.

Well, I arrived here (finally) on Sunday afternoon just in time to only miss a quarter of the tutorial I had booked. I am namely at the ISCB. My apologies for not writing home from last year's ISCB annual venue, Dundee. I had planned to write on the Wednesday, but then I went whisky tasting instead...

Heidelberg in September, in 30°C, beer on Rathaus Platz, artists competing for your attention not far away, the sound of an operetta in the distance, a walk in the sunshine on Philosophenweg. And if that was not enough there was always the ISCB meeting to go to.

Do you know in how many ways you can project a slide - including the right way up? Have you ever enjoyed the 'travelling' laser pointer's red dot? Did you know that some speakers' control panel will let you make the curtains go up and down when you want the next slide? We had it all, including a conference dinner am Schloss (not my hotel, but the real thing – and isn't it half up a hill!) with speeches ... and speeches ... and speeches ... However, the wine was good; it would have been much nicer with the food though!

Do you know? We had gatecrashers at our regulatory sub-committee meeting on Monday. Nice to be popular, but it was a bit of a fraud (Get it? It was a few people loose from the fraud subcommittee – could someone have tinkered with their agenda?).

But when all is said and done, I will be quite happy to lose my heart again in Heidelberg.

## **Subcommittee Report: Regulatory Affairs**

**Chairman: Helmut Schäfer (until 13 September 1999), Jørgen Seldrup (13 Sep. 1999-)**

The subcommittee has commented on behalf of ISCB on the draft note for guidance on the investigation of bioavailability and bioequivalence proposed by the European Agency for the Evaluation of Medicinal Products (EMA).

The subcommittee has also prepared a letter to the EMA offering our cooperation in the development of guidelines and asking about the plans at the European level concerning the participation of scientific societies. This letter is related to the activity started by the chairman of the subcommittee via the German Federal Council with the objective of achieving a formal basis for an official participation of scientific societies in the consultation process for guidelines.

A meeting of the subcommittee took place on September 13<sup>th</sup> 1999.

Helmut Schäfer has served as chairman for three years. Due to new responsibilities in his faculty, he asked the president to nominate a new chairman. Jørgen Seldrup was proposed as the new chairman and confirmed by the executive committee.

## ISCB Student Conference Awards, 2000

Student Conference Awards are available for registered postgraduate students to attend and present a paper at ISCB21 in Trento, Italy, 4-8 September 2000. It is intended that 3 Awards will be made. Selection will be on the basis of a summary (3-5 pages) of the paper to be presented. For full details of the scheme, which should be studied prior to preparing an application, please write to:

Professor John Whitehead  
Chairman, ISCB Student Conference Awards Subcommittee  
MPS Research Unit, The University of Reading  
PO Box 240, Earley Gate  
Reading, RG6 6FN, UK  
Tel: +44 118 931 8027, Fax: +44 118 975 3169  
Email: [j.r.whitehead@reading.ac.uk](mailto:j.r.whitehead@reading.ac.uk)

The closing date for applications will be Friday, 11 February 2000.

## Subcommittee Report: Student Conference Awards

1. The awards for 1999, and their talks were  
Michael Branson, University of Reading, UK.  
*Clinical comparisons of immediate versus delayed therapy: issues of analysis.*  
Tom Loeys, University of Ghent, Belgium.  
*Estimating the effect of treatment receipt with covariate-specific exponential baseline survival and randomized assignment.*  
Didier Renard, Limburgs University, Belgium.  
*Validation of surrogate endpoints in multiple randomized clinical trials with discrete outcomes.*  
Stijn Vansteelandt, University of Ghent, Belgium.  
*Regression models for disease prevalence with diagnostic tests on pooled serum samples.*  
Karen Williams, University of Wales, Cardiff, UK.  
*Effect of prediction rule and parameter values on patient specific risk estimates and hence classification in Down syndrome screening.*

2. For 1999, the scheme was funded jointly by ISCB and ZMBT. The total cost to ISCB was £1061.83.
3. A total of seven applications were made. The subcommittee felt that the standard of the winning entries was high, but more entries would have been welcome. The scheme will be advertised earlier and more widely for 2000.
4. The subcommittee is grateful to Jørgen Seldrup for his service to the Awards Scheme over the past two years. He is now leaving the subcommittee, and his place has been taken by Bruno Cesana.

## Advert: Statistical Solutions

## Subcommittee Report: Education

The ISCB Sub-committee has had a busy year. Michael Schemper has contacted a large number of people in target countries interested in hosting courses run by the ISCB. He has also compiled a list of potential course givers. He has also compiled a Terms of Reference document to describe the procedures that should be followed when an ISCB sponsored course is run. This is presented below.

Mike Campbell organised a Course and Workshop on the design and analysis of cluster randomised trials. The course was held on 5th July and was attended by 75 people. It was given by Allan Donner of the University of Western Ontario and Neil Klar of the Biostatistics Unit of the Dana-Farber Cancer Institute, Boston, USA. The Workshop was held on the 6th and 7th of July. A total of 69 people attended the Workshop of whom 8 came for the Workshop only. Invited speakers were Patrick Heagerty of the University of Seattle who spoke on the analysis of cluster trials using generalised estimating equations, David Spiegelhalter of the MRC Biostatistics Unit in Cambridge UK who spoke on Bayesian analysis of cluster trials and Jane Hutton of the University of Newcastle UK, who spoke on ethics and cluster trials. Twenty one people gave contributed 20 minute papers on a variety of aspects of cluster

trials, from the design and analysis to applications in primary care. There was also discussion about a CONSORT statement for the reporting of cluster trials. Min Yang from the Multilevel Project at the Institute for Education, London gave a demonstration of MIWin and Gilda Piaggio from the World Health Organization in Geneva demonstrated the program Acluster. The papers will form a special issue of Statistics in Medicine. As would be expected, the majority of people were from the UK, but (including invited speakers) there were 3 from the USA and Holland, 2 from Finland, Denmark and Australia, and one each from Norway, France, Spain, Thailand, Canada and Switzerland.

In general the feedback was very positive, and both the course and workshop were felt to be very successful.

Two additional members for the committee, Carol Redmond from the US and Shai Linn from Israel have been proposed.

Next year we hope to deliver two courses in target countries and possibly organise a course for statisticians who have to referee clinical papers for their statistical content.

## Terms Of Reference For Organising ISCB Courses

### IN ISCB 'TARGET' COUNTRIES

1. It is assumed that contact has been established between a possible local organiser (LO) and a member of the Educational Subcommittee of ISCB (ES).
2. The LO prepares a plan of 1-2 pages giving the likely location, the likely number assumed attending and topic and speaker. The plan should also contain information on the expected costs of the course for the LO (without costs for speaker) and whether a course fee (and at which amount) will be considered. There may also be alternatives suggested by the LO which are to be chosen by the ES (all members agreeing). The ES may also suggest corrections (all members agreeing) to this draft by the LO. The officers should be kept informed of such negotiations through the president.
3. The full ExCom is informed by the ES about the draft by the LO and can comment. The officers give final approval through the president. Not more than 2 courses of this type will be approved per year.
4. Payment by ISCB for speaker: 2 nights accommodation for 1 day course and 3 nights accommodation for 2 days course; local \*\*\*hotel basis (prices differ much between countries). The LO selects a suitable hotel and makes reservations. Air fares: lowest possible non weekend fares. If speaker wishes to stay the Saturday/Sunday night extra hotel nights can be covered if the final sum of travel and accommodation costs is not increased. The same applies also to any other means of transport. The speaker is also entitled to a honorarium of GBP 50/hour of course. If the above principles are violated in a course the Society will not pay for the excess expenses. In case of uncertainty (special circumstances) the LO should seek direct financial approval from the treasurer as early as possible.
5. If items 1-3 are successfully completed the LO and the speaker can decide on any further details. To ensure high quality of the courses printed notes (transparencies) should be sent to the LO for duplication for the course. Exercises should be encouraged. Reading lists could be given to those who register early.
6. If one month before course is to begin the number pre-registered is below 12 the course should be cancelled. At least it will not be supported by ISCB. Only charges already incurred (e.g. low cost airfares) will be paid by ISCB in this case.
7. Announcements should indicate that ISCB is supporting the course and mention that the number of course participants is limited and so early booking is recommended. It should also be mentioned that course will be cancelled (with 1 month notice) in case of insufficient pre-booking. This local and regional announcement should be checked and approved by a member of the ES who further sends it to the News editor of ISCB for publishing in the Newsletter and in the ISCB Homepage.
8. The courses are non-profit. Either the costs for advertising, course room etc. are covered by the LO or the fee is such that it covers only such expenses. If there is a surplus by the LO it would have to be given to ISCB for reducing ISCB's expenses for the speaker.
9. There will be advertisement material on ISCB available at the course registration.
10. At the end of the course all participants are requested to fill out an anonymous standard questionnaire (which will be designed by ES) on their satisfaction with the course. After the course the LO gives a final short report to ES and encloses completed questionnaires. Names and addresses of participants are also sent for future mailing by ISCB. The reimbursement for the speaker is then done by the treasurer, based on the bills for travel and accommodation.

The meeting started at 5.00 p.m., 15 September 1999

The agenda of the meeting was:

1. President's Report
2. Treasurer's Report
3. Subcommittee Reports and motions for continuation of subcommittees
4. Newsletter Report
5. Future meetings
6. Other business

## 1. President's report (NLG)

The president introduced the meeting, briefly describing the agenda.

The president expressed gratitude to the Heidelberg ISCB Programme and Local Organising Committees for arranging an exciting meeting and stimulating programme. This meeting in Heidelberg had a World Wide Web site, which was updated frequently, and included the programme and on-line registration and hotel reservation for the first time. The meeting also introduced the first ISCB presidential lecture.

The president reported that, during the year, the officers had many email contacts and a conference call, and various problems were discussed. Part of the discussion between officers concerned the proposal of new subcommittees forwarded at last summer's meeting (Communication, Long Range Financial Planning and Operations). Also a new proposal of a Subcommittee on National Groups and other countries with exchange control restrictions or barriers arose during the year. The genesis of this subcommittee was both an inquiry from Cuba about forming a National Group and a number of requests for financial assistance for attendance at this meeting by statisticians in statistically developing countries. The Education Subcommittee has proposed presenting short courses in 'statistically developing countries', and it became apparent that this may lead to formation of other national groups and additional requests for support to attend annual meetings.

According to the decisions reached by the Executive Committee, two new subcommittees were presented to the AGM for approval.

## 2. Treasurer's report (JW)

JW expressed gratitude to Karsten Schmidt, Bernhard Huitfeldt and Rita Schou who produced the budget figures and helped him through his first period as treasurer.

*Comments on the balance as of 31 Dec. 1998:*

a) The active balance is approximately £(UK pounds)112,000. This is £6,000 less than last year, but this does not seem to be a problem, given that the current balance would be sufficient to cover the failure of a future annual meeting. The financial status of the Society is considered healthy by the ExCom.

b) The £6,000 loss includes a £3,600 loss for the 1998 meeting in Dundee (JW reminded that the ExCom had told the organisers of the Dundee meeting that ISCB was ready to take the risk of a loss, in order to keep the meeting fee low). The remainder of the loss was due to general running expenses of ISCB.

*General comments and related decisions.*

c) For the future, the treasurer suggested tracking:

- the costs related to the student conference awards;
- support for ISCB ExCom members to attend the meeting;
- support for members of the National Groups to attend the meeting.

These costs should become separate figures in the future balance description, so that the Society members can see more clearly how money is spent.

d) JW requested that subcommittees provide estimates for expenses related to their proposals for their future activities.

e) It was announced that the membership fee for year 2000 would be unchanged.

The balance and report from the treasurer was approved unanimously.

## 3. Subcommittee Reports and motions for continuation of subcommittees

The four Subcommittee Chairs reported on the activity of their subcommittee, and their reports are included below, with revised terms of reference and list of members. Namely, reports were from:

*Steven Senn (for Helmut Schäfer) on Regulatory Affairs*

*Emmanuel Lesaffre (for Mark Buyse) on Fraud*

*John Whitehead on ISCB Student Awards*

*Mike Campbell on Education (in particular, Michael Schemper on short ISCB courses in statistically developing countries)*

The motion for continuation of these subcommittees was approved unanimously.

The president reported that the ExCom approved two new subcommittees: Subcommittee on Communication (Chair: David Warne) and the Subcommittee on National Groups (Chair: Michael Schemper). The terms of reference and list of members are reported below.

## 4. Report on newsletter

D. Warne gave a brief report on the ISCB News. Two large issues are produced annually and the plan is to continue this pattern next year. Future activities will also be decided on by the new subcommittee on Communications.

## 5. Future ISCB meetings

Maria Grazia Valsecchi reported on the 21st ISCB meeting, which will be held in Trento (Italy) on September 4-8, 2000. A brochure was included in the Conference bag. A Web site is available for information ([www.gelso.unitn.it/~iscb2000](http://www.gelso.unitn.it/~iscb2000)).

Juni Palmgren reported on Stockholm, 2001. The dates of this meeting have been changed to 19-23 August.

These two meetings had been reported before. Two new proposals were presented and approved by the AGM:

Harbajan Chadha-Boreham for a meeting in Dijon in 2002.

Simon Day (for Diana Elbourne) for a joint meeting with the Society for Clinical Trials in London, year 2003. Diana Elbourne will serve as the LOC.

The meeting closed at 6.00 p.m.

The meeting was attended by about 60 ISCB members:

Biganzoli, Elia, Campbell, Mike, Cesana, Bruno, Chada-Boreham, Harbajan, Cole, Tim, Colton, Ted, Day, Simon, Decarli, Adriano, Demezuk, Marek, Freedman, Laurence, Gehan, Edmund, Geller, Nancy, Gurney, Elaine, Hakulinen, Tino, Harrell, Frank, Heisterkamp, Simon, Hinke, Axel, Huitfeldt, Bernhard, Johnson, Tony, Julia, Singer, Kawalec, Ewa, Kim, Kyungmann, Klersy, Catherine, Krusinska, Eva, Kupis, Wiheld, Lausen, Berdhold, Lesaffre, Emmanuel, Lörstad, Mats, Machin, David, Mesbah, Mouner, Mowery, Richard, Mulder, Paul, Nehwiz, Gerhard, Nielsen, Bjarne, Palmer, Chris, Redmond, Carol, Reiczigel, Ienö, Schemper, Michael, Schmidt, Karsten, Schumacher, Martin, Seldrup, Jørgen, Senn, Stephen, Shai, Linn, Shchenbatyy, Mykhalo, Starnich, Helena, Suci, Stefan, Thalabard, Jean-Christophe, Titelx, Laurence, Valsecchi, Maria Grazia, Van der Holt, Ron, Van Houwelingen, Hans, van Putten, Wim, van Strik, Roel, Victor, Norbert, Warne, David, Whitehead, John.



## Book Review by Paul Johnson (USA)

Filomena Pereira-Maxwell: A-Z of Medical Statistics: A Companion for Critical Appraisal, Arnold

Pereira-Maxwell writes a medical statistics dictionary. It is compactly written but at the same time contains much useful information. The author mentions the book is for non-statisticians. The book provides for a collection of statistical terms, definitions, formulae and concepts often encountered in medical journals. It is a useful guide and contains many references that are very recent. The book contains many different concepts. The author shows the inter-dependency between these various concepts by highlighting in bold those independent entries. This is useful but at time can be distracting when a page contains so many bold links for various other entries. A picture paints a 1000 words and it is nice to see that the author uses graphs and illustrations to describe certain concepts. However I found the graphs and plots within the book to be very drab and average looking. Some graphs were close to a full page whereas others were too small to view (e.g., the area under the curve plots).

There were times when a simple formula would have been a much better tool to use rather than describing the concept with lines of text. The definition for the coefficient of variation provides a good example of this oversight. The author's definition of 'p-value' is long winded, confusing and is in fact misleading. The author writes 'The p-value may also be thought of as the probability that a Type I error has occurred'. This will certainly mislead the reader. The analysis of variance (ANOVA) concept is one that is seen widely through out the medical literature. It is an extremely important one that forms the basis for comparing more than two treatment groups. The author explains this concept poorly, and does not even provide for the always seen ANOVA table.

This missing table shows clearly the detailed structure of the ANOVA and its components. The author in fact gives more space describing the concept of skewness than the analysis of variance. There are only 5 lines in total used to describe the multivariate equivalent to the analysis of variance (MANOVA).

There are only 6 lines of text to describe the concept of maximum likelihood and yet this concept is found repeatedly when examining medical literature with a statistical component. The author correctly mentions that bootstrapping is done by taking a large number of repeated samples from a single data set usually using a computer. The author forgets to mention the key component that the resampling is done with replacement. I am not sure why the author would write 'usually using a computer'. For a bootstrap test at the 5% level of significance a minimum of 1000 simulated sets of data from the original are often desirable. How else would you perform a reliable bootstrap? The author correctly mentions the fact that the identification of outliers is important.

The author continues that this can be done by simple graphical methods. For the multivariate situation this is simply not the case. The book may be useful to those looking for a dictionary of statistical terms used in medical research. After reading the back of the book, the foreword, acknowledgements and the introduction I expected a better book. I was disappointed. If you take away the appendix, reference and index sections the book is 86 pages long. I find it hard to recommend purchase of this book by individuals.

## ISCB Aims

*The Society* is organised and shall be operated for educational and scientific purposes with the following Aims:

- to stimulate research on the biostatistical principles and methodology used in clinical research;
- to increase the relevance of statistical theory to clinical medicine;
- to promote high and harmonised standards of statistical practice;
- to work with other societies and organisations in the advancement of biostatistics;
- to promote better understanding of the use and interpretation of biostatistics by the general public, and by national and international organisations and agencies within the public and commercial sectors with an interest in, and/or responsibilities for, public health; and
- to provide a common forum for clinicians and statisticians through meetings, seminars and publications.

## Book Review by Anna Bartkowiak (Poland)

W.J. Krzanowski, *An Introduction to Statistical Modelling*, Arnold

W.J. Krzanowski, professor of statistics at the University of Exeter, UK, is well known for his authorship of some excellent books on multivariate statistics with an emphasis on the user's perspective; also for original contributions in applied statistics.

The reviewed book is in principle addressed to a general user of statistical methods who might wish to have in one place (one book) a presentation of basic models and the mathematical reasoning connected with them. This book does it. Reading the book one feels the master's hand.

According to the author's introductory statement, statistical treatment of data can be roughly categorised as either description or analysis:

**Description** is primarily interested with exploration, summaries and finding important patterns and trends.

**Analysis** has the wider scope of using the information available in the data to make general statements on the mechanism that was operating to produce the data. In order to make statements of that kind we need firstly to abstract the essence of the data-producing mechanism to a kind of statistical model. Fitting the model to a given set of data will then provide a framework within which we can try either to provide an explanation of the system or to predict future outcomes.

The book is concerned with formulating typical statistical models for univariate data. We may find in the book a clear concise mathematical formulation of most frequently used statistical models.

First two chapters ('Introduction' and 'Distribution and Inference') define basic concepts used in subsequent chapters.

The next three chapters ('Normal response and quantitative explanatory variables: regression' in 66 pages, 'Normal response and qualitative explanatory variables: analysis of variance' - in 43 pages, and 'Non-normality: the theory of generalised linear

models' in 26 pages) are the core of the book. They describe the basic linear model specified for regression and analysis of variance with emphasis on fitting and assessing the models to given data and specifying tested hypotheses.

Apart from the mathematical description of the classical linear model with its to day standard topics like model building and validation we find here also a section on non-linear models (Mitscherlich's equation and logistic growth curve for sigmoidal relationships). The chapter on generalised linear models explains also, how to assess the fit of that kind of models, and how to compare them - by using the deviance.

The next two chapters are devoted to model building for categorical data. These are: 'Binomial response variables: logistic regression and related methods' in 21 pages and 'Tables of counts and log-linear models' in 23 pages.

The last chapter: 'Further topics', in 10 pages, contains a kind of author's remarks and comments, which topics were included in previous chapters, and which were not.

The author expresses the opinion that the preceding sections of the book have set out what is hopefully a fairly complete account of models that are most useful in practical data analysis and, therefore, are most likely to be included in degree courses whose major components include statistics. Therefore, almost inevitably, the book might be used as a catalogue of various statistical models.

Subsequently the author expresses the view that model building is an iterative process and that model building is as much an art as a science. I particularly favor the last point.

Generally speaking, the book is written in a very clear and precise manner. It is easy to read and understand. It explains the basic mathematical concepts of the presented models with some illustrative examples. It is advisable especially for non-mathematicians like researchers in science, engineering, computer science, and others who have some mathematical background and want to understand the principles of statistical reasoning underlying real data analysis.

## Announcement

From Begoña Campos Bonilla, Barcelona

I would like to announce that the University of Barcelona is going to offer a new PhD programme entitled 'Biometry and Statistics', whose purpose is to prepare students to face different careers in the statistics field, either assessment or research.

Enrolment is for two academic years. During the first one, students have to attend selected courses drawn from a list in order to achieve the required number of credits. None of them is compulsory, all are optional. Topics range from mathematical statistics to applied statistics to the health sciences. During the second year, students have to join a research project supervised by a tutor. In this way, each student may design his/her academic curriculum.

Three departments of the University of Barcelona will participate in the programme: Dep't of Statistics, Dep't of Public Health and Dep't of

Methods for the Behavioural Sciences. Options to take courses from other linked programmes are open. Please visit the following web site for more information:

<http://www.bio.ub.es/estad/docencia/Biometria/Programa.html>

(Sorry, at present it is only in Catalan)

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The second edition of Hollander and Wolfe's *Nonparametric Statistical Methods* covers many aspects. The authors see one major improvement of the new edition in the expanded coverage of nonparametric methods for experimental design (Chapters 6 and 7). Moreover, the inclusion of a bootstrap approach to derive a confidence interval of the Kendall population correlation coefficient (Chapter 8.4.), expanded coverage of nonparametric regression methods (Chapter 10) and new coverage of life distributions and survival analysis (Chapter 11). The whole book benefits from many data examples and typical use of Minitab and StatExact packages.

Assuming that the majority of the readers of the ISCB newsletter are interested in the handbook character, i.e. coverage of the field, I decided to review the content of the book by stating the section titles and afterwards giving my - of course personal - assessment of the book.

**Chapter 2: The Dichotomous Data Problem.** The authors start with a binomial test problem (2.1.) and the estimation of the probability of success (2.2.).

**Chapter 3: The One-Sample Location Problem.** The distribution-free signed rank test (Wilcoxon) (3.1.), an estimator associated with Wilcoxon's signed rank statistic (Hodges-Lehmann) (3.2.), a distribution-free confidence interval based on Wilcoxon's signed rank test (Tukey) (3.3.), a distribution-free sign test (Fisher) (3.4.), an estimator associated with the sign statistic (Hodges-Lehmann) (3.5.), a distribution-free confidence interval based on the sign test (Thompson, Savur) (3.6.), *one-sample data*: procedures based on the signed rank statistic (3.7.), procedures based on the sign statistic (3.8.), an asymptotically distribution-free test of symmetry (Randles-Fligner-Policello-Wolfe, Davis-Quade) (3.9.), *bivariate data*: a distribution-free test for bivariate symmetry (Hollander) (3.10.) and efficiencies of paired replicates and one-sample location procedure (3.11.).

**Chapter 4: The Two-Sample Location Problem.** A distribution-free rank sum test (Wilcoxon, Mann and Whitney) (4.1.), an estimator associated with Wilcoxon's rank sum statistic (Hodges-Lehmann) (4.2.), a distribution-free confidence interval based on Wilcoxon's rank sum test (Moses) (4.3.), a robust rank test for the Behrens-Fisher problem (Fligner-Policello) (4.4.), Efficiencies of two-sample location procedures (4.5.).

**Chapter 5: The Two-Sample Dispersion Problem and Other Two-Sample Problems.** A distribution-free rank test for dispersion - Medians equal (Ansari-Bradley) (5.1.), an asymptotically distribution-free test for dispersion based on the Jackknife - Medians not necessarily equal (Miller) (5.2.), a distribution-free rank test for either location or dispersion (LePage) (5.3.), a distribution-free test for general differences in two populations (Kolmogorov-Smirnov) (5.4.) efficiencies of two-sample dispersion and broad alternatives procedures (5.5.).

**Chapter 6: The One-Way Layout.** A distribution-free test for general alternatives (Kruskal-Wallis) (6.1.), a distribution-free test for ordered alternatives (Jonckheere, Terpstra) (6.2.), a distribution-free test for umbrella alternatives (Mack-Wolfe) (6.3.), a distribution-free test for umbrella alternatives, peak known (Mack-Wolfe) (6.3.a.), a distribution-free test for umbrella alternatives, peak unknown (Mack-Wolfe) (6.3.b.), a distribution-free test for treatments versus a control (Fligner-Wolfe) (6.4.), distribution-free two-sided all-treatments multiple comparisons based on pairwise rankings - general configuration (Dwass, Steel, Critchlow-Fligner) (6.5.), distribution-free one-sided all-treatments multiple comparisons based on pairwise rankings - ordered treatment effects (Hayter-Stone) (6.6.), distribution-free one-sided treatments multiple comparisons based on joint rankings (Nemenyi, Daminco-Wolfe) (6.7.), contrast estimation based on Hodges-Lehmann two-sample estimators (SPØTVOLL) (6.8.), simultaneous confidence intervals for all simple contrasts (Critchlow-Fligner) (6.9.) and efficiencies of one-way layout procedures (6.10.).

**Chapter 7: The Two-Way Layout.** A distribution-free test for general alternatives in a randomized complete block design (Friedman, Kendall-Babington Smith) (7.1.), a distribution-free test for ordered alternatives in a randomized complete block design (Page) (7.2.), distribution-free two-sided all-treatments multiple comparisons based on Friedman rank sums - general configuration (Wilcoxon, Nemenyi, McDonald-Thompson) (7.3.), distribution-free one-sided treatments versus control multiple comparisons based on Friedman rank sums (Nemenyi, Wilcoxon-Wilcox, Miller) (7.4.), Contrast estimation based on one-sample median estimators (Doksum) (7.5.), a distribution-free

test for general alternatives in a randomized balanced incomplete block design (BIBD) (Durbin, Skillings-Mack) (7.6.), asymptotically distribution-free two-sided all-treatments multiple comparisons for balanced incomplete block designs (Skillings-Mack) (7.6.), a distribution-free test for general alternatives for data from arbitrary incomplete block design (Skillings-Mack) (7.7.), *replications - two-way layout with at least one observation for every treatment-block combination*: A distribution-free test for general alternatives in a randomized block design with an equal number  $c(> 1)$  of replications per treatment-block combination (Mack-Skillings) (7.9.), asymptotically distribution-free two-sided all-treatments multiple comparisons for a two-way layout with an equal number of replications in each treatment-block combination (Mack Skillings) (7.10.), *analyses associated with signed ranks*: a test based on Wilcoxon signed ranks for general alternatives in a randomized complete block design (Doksum) (7.11.), a test based on Wilcoxon signed ranks for ordered alternatives in a randomized complete block design (Hollander) (7.12.), approximate two-sided all-treatments multiple comparisons based on signed ranks (Nemenyi) (7.13.), approximate one-sided treatments versus control multiple comparisons based on signed ranks (Hollander) (7.14.), contrast estimation based on one-sample Hodges-Lehmann estimators (Lehmann) (7.15.) and efficiencies of two layout procedures.

**Chapter 8: The Independence Problem.** A distribution-free test for independence based on signs (Kendall) (8.1.), an estimation associated with the Kendall statistic (Kendall) (8.2.), an asymptotically distribution-free confidence interval based on the Kendall statistic (Samara-Randles, Fligner-Rust, Noether) (8.3.), an asymptotically distribution-free confidence interval based on Efron's bootstrap (8.4.), a distribution free test for independence based on ranks (Spearman) (8.5.), a distribution free test for independence against broad alternatives (Hoeffding) (8.6.) and efficiencies of independence procedures (8.7.).

**Chapter 9: Regression Problems. One regression line:** A distribution-free test for the slope of the regression line (Theil) (9.1.), a slope estimator associated with the Theil statistic (Theil) (9.2.), a distribution-free confidence interval associated with the Theil test (Theil) (9.3.), an intercept estimator associated with Theil statistic and use of the estimated linear relationship for prediction (Hettmansperger-McKean-Sheather) (9.4.), *k* ( $\geq 2$ ) **Regression lines:** An asymptotically distribution-free test for the parallelism of several regression lines (Sen, Adichie) (9.5.), *general multiple regression:* Asymptotically distribution-free rank-based tests for general multiple linear regression (Jaekel, Hettmansperger-McKean) (9.6.), *Nonparametric regression analysis:* An introduction to non-rank-based approaches to nonparametric regression analysis (9.7.) and efficiencies of regression procedures (9.8.).

**Chapter 10: Comparing Two Success Probabilities.** Approximate tests and confidence intervals for the difference between two success probabilities (Pearson) (10.1.), an exact test for the difference between two success probabilities (Fisher) (10.2.), inference for the odds ratio (Fisher, Cornfield) (10.3.), Inference for  $k$  strata of  $2 \times 2$  tables (Mantel and Haenszel) (10.4.) and efficiencies (10.5.).

**Chapter 11: Life Distribution and Survival Analysis.** A test of exponentiality versus IFR alternatives (Epstein) (11.1.), a test of exponentiality versus NBU alternatives (Hollander-Proschan) (11.2.), a test of exponentiality versus DMRL alternatives (Hollander-Proschan) (11.3.), a test of exponentiality versus a trend change in mean residual life (Guess-Hollander-Proschan) (11.4.), a confidence band for the distribution function (Kolmogorov) (11.5.), an estimator of the distribution function when the data are censored (Kaplan-Meier) (11.6.), a two-sample test for censored data (Mantel) (11.7.) and efficiencies (11.8.).

The appendix includes 180 pages distribution tables and answers to selected problems.

The book is an impressive handbook for nonparametric methods.

I miss a more general view of linear rank statistics along the terminology of Hajek & Sidak (1967). Such a general terminology should allow to reduce the length of some sections. The coverage of bootstrap is via a special case and could be more general.

## **Introduction**

*'Conference Awards for Scientists' are available for biostatisticians from ISCB target countries (in particular the formerly communist countries of central and eastern Europe) to attend and give a presentation at ISCB21 in Trento, Italy, 4-8 September 2000. Up to eight such awards will be granted. Award winners will have their registration fee waived and also their accommodation will be paid by ISCB. Selection will be made on the basis of a one-page summary of the paper to be presented and on an application form. Further details of the award scheme are given below. Applications should be sent to*

Professor Michael Schemper  
Chairman, ISCB Subcommittee on 'National Groups'  
***Department of Medical Computer Science, Section of Clinical Biometrics***  
Vienna University  
Spitalgasse 23  
A-1090 Vienna, AUSTRIA

Tel: +43 1 40400 6689

Fax: +43 1 40400 6687

email: [Michael.Schemper@AKH-Wien.ac.at](mailto:Michael.Schemper@AKH-Wien.ac.at)

The closing date for application will be Friday, 11 February 2000

### *Rules*

1. The ISCB Conference Awards for Scientists Scheme is administered by the Subcommittee on 'National Groups' established by the Executive Committee of ISCB. The purpose of the scheme is to support and encourage biostatisticians working under financial constraints, and to enable them to participate in international dialogue.
2. Who can apply?  
Scientists from 'ISCB target countries' (in particular the formerly communist countries of central and eastern Europe) whose work will be benefited by attending an ISCB conference.
3. What is covered by the award?  
The registration fee is waived and an inexpensive accommodation is paid and organised by ISCB.
4. What are the conditions for application?  
(a) Submission of a one-page summary of an intended oral presentation or poster which must concern the application of statistical methodology to clinical or epidemiological research. Applicants who do not have a specialist topic to present are invited to prepare a more general paper with a title such as 'The need for biostatistical development in my country/region/department'.  
(b) Submission of a completed application form (item 6).  
The application has to be received by the Chairman, ISCB Subcommittee on 'National Groups' by 11 February 2000.
5. Who will decide on an application?  
The 'National Groups' Subcommittee will decide as soon as possible, usually within six weeks of the closing date for applications, based on the following criteria: Quality of summary, financial need, value of attendance at meeting to region (to National Groups), preference to those not supported by ISCB for the previous meeting, possible set-up of future National Groups. In selecting award winners, each member of the Subcommittee will independently grade each application. In the case of ties in total grades, the Subcommittee will make the final selection through discussion. The Chairman of the Subcommittee will inform each applicant on the Subcommittee's decision.
6. Application form:

# Application: Conference Awards for Scientists

21st Annual Meeting of the International Society for Clinical Biostatistics,  
Trento, Italy, 4-8 September 2000

First Name	
Surname	
Title	
Country of residence	
Current affiliation (complete address)	
Current position	
Research interests	
Language skills	
I have submitted an abstract (give title)	
Two most relevant publications	
Give details why ISCB should support you to attend this conference	

I would prefer to give an oral presentation / a poster.

I agree to become a member of the ISCB for the year 2000 if I am granted the award. There will be no charge for this.

Date:

Signature:

Brian S. Everitt & Graham Dunn (Eds.): *Statistical Analysis of Medical Data*, Arnold (1998)

Everitt and Dunn compiled a number of articles from different authors covering four areas of current interest in biostatistical research. The editors selected the following four topics:

- Survival Analysis
- Longitudinal Data Analysis
- Bayesian Methods
- Statistics in Imaging

The first chapter, written by the editors (Statistics in medical research) provides an historical overview about medical statistics using four famous scientists, followed by an introduction to the four topics of this book.

#### **Survival Analysis**

*Keith R. Abrams: Regression models for survival data.* Abrams uses an example of survival data in end-stage of renal diseases (ESRD) to explain survival models. The ESRD study followed up 252 patients who entered a renal dialysis program. Baseline covariates as well as time dependent covariates were recorded. Abrams explains classical survival analysis techniques like Kaplan-Meier estimates and the log-rank test, but also proportional hazards models including time-dependent covariates or stratified models. Furthermore, Bayesian models are introduced. Sections discussing model-comparisons and discussing the applications of the models to the data are included.

*Odd O. Aalen: Frailty models.* Aalen discusses proportional frailty models, the effect of frailty models on relative risks and multivariate models. An example of duration of amalgam filling in teeth is used to explain the multivariate situation.

*Ørnulf Borgan & Bryan Langholz: Risk set sampling designs for proportional hazards models.* This chapter discusses sampling designs for proportional hazards models applied to cohort studies. These designs include nested case-control sampling and counter matching. The designs are illustrated by lung cancer data among uranium miners and by data from an epidemiological study investigating the possibility that electromagnetic fields generated by power lines are associated with childhood cancer.

*Mark R. Segal: Tree-structured survival analysis in medical research.* Segal describes the application of the Classification and Regression Tree (CART) technique in the context of survival analysis. He also provides references to available software. This technique is illustrated with a breast cancer cohort study and with an HIV cohort study.

#### **Longitudinal Data Analysis**

*Alan Taylor, Kevin Pickering, Catherine Lord & Andrew Pickles: Mixed and multi-level models for longitudinal data: growth curve models of language development.* This chapter describes the growth curve modelling using random effect models for unbalanced data, which require neither the number of observations nor the intervals of time between observations to be the same for all subjects. These models are applied to the analysis of the development of language in young children.

*Charles S. Davis: The analysis of longitudinal studies having non-normal responses.* This chapter focuses on distribution-free methods for the analysis of longitudinal studies having non-normal responses. These methods are applied to complete and incomplete data. Three examples are used to demonstrate the application of the models.

*Garrett M. Fitzmaurice: Regression models for discrete longitudinal data.* This chapter explains the application of marginal regression models (the focus is on the regression parameters for the marginal expectation of each response separately) and conditional regression models (the mean response being modelled is conditional not only on covariates, but also on values of previous responses or on

unobserved random effects) to discrete longitudinal data. Several examples illustrate the application of these techniques.

*Peter J. Diggle: Dealing with missing values in longitudinal studies.* This chapter describes several imputation methods for missing data. It is assumed that the data are continuously distributed. The methods range from simple techniques like last observation carried forward to more advanced methods modelling the missing value process like selection models or pattern mixing models. The methods are explained with a schizophrenia trial.

#### **Bayesian Methods**

*E. Clare Marshall & David J. Spiegelhalter: Comparing institutional performance using Markov chain Monte Carlo methods.* This chapter describes the application of Markov chain Monte Carlo methods (MCMC) to data of the second audit of renal transplantation performed by the United Kingdom Transplant Support Service Authority. The basic ideas of the MCMC as well as conventional fixed or mixed effect models are discussed. The software BUGS is also addressed in this chapter.

*Larry V. Hedges: Bayesian meta-analysis.* This chapter describes the basics of Bayesian meta-analysis. The application of this method is presented for studies of the effects of environmental tobacco smoke on lung cancer. The United States Environmental Protection Agency published a meta-analysis of these studies.

#### **Statistics in Imaging**

*Ian Ford & Andrew P. Holmes: Functional neuroimaging and statistics.* This chapter provides an introduction to the statistics used in the construction and the analysis of neuroimages. The areas of application discussed in this chapter include autoradiography, single-proton emission computed tomography (SPECT), positron emission tomography (PET), functional magnetic resonance imaging (fMRI), and electroencephalography (EEG).

*S. Rabe-Hesketh, M.J. Brammer & E.T. Bullmore: Localizing brain activation in a single subject using functional magnetic resonance imaging.* The authors present their methodology to handle several issues that need to be considered when attempting to localise activation imaged through BOLD (Blood Oxygen Level Dependent) contrasts.

This book is written 'for graduate students working in medical statistics' and also 'for medical researchers who want an applications-based introduction to current statistical methods'. The book provides an interesting lead-in to the four topics. The chapters are understandable without detailed knowledge of the addressed topics. The reference lists of each chapter are very comprehensive and provide an overview about the current literature. Nevertheless, it requires sound statistical knowledge and further readings to apply the addressed methodologies to data. It is not the aim of this book to present the statistical methodology like a monograph or a textbook, but it aims to invite the reader to look into these areas of biostatistical research. Therefore, this book can be recommended for all students and all medical researchers looking for an introduction in one of the addressed topics or looking for an overview about currently active research in biostatistics.

## **Subcommittee Report: Fraud**

The general position paper 'The role of biostatistics in the prevention, detection and treatment of fraud in clinical trials' has been accepted in *Statistics in Medicine*.

The paper on the ISCB questionnaire 'The biostatistician's view on fraud in medical research' has been submitted for publication.

The project also aims at developing software to detect fabricated data. Up to date only one data set (from Bruno Scherrer) has been received to test the software to be developed. Emmanuel Lesaffre has started some experiments to examine which multivariate methods can detect simple fabricated data and how fabricated data differ from real data. At least two more data sets are expected from Prof. Heisterkamp.

At the Executive Meeting in Heidelberg (September 13, 1999) Emmanuel Lesaffre has been appointed the new chairman for the subcommittee. We thank the former chairman, Marc Buyse, for his excellent work.

## **Book Review by Stefan Hantel (Germany)**

Gareth A. Lewis, Didier Mathieu & Roger Phan-Tan-Luu: *Pharmaceutical Experimental Design*, Marcel Dekker (1999)

The authors present an integrated approach to statistical experimental design for scientists developing pharmaceutical dosage forms. They address this book primarily to pharmacists and pharmaceutical scientists. Therefore, they did not present the mathematical theory in detail. Nevertheless, statisticians also may find the application of the theory of experimental design in the area of pharmaceutical application interesting.

The authors are using examples either from the literature or from unpublished studies. Particular topics are:

- drug excipient compatibility study
- dissolution testing
- granulation
- tablet formulation and process study
- formulation of sustained release tablets
- dry coating for delayed release dosage forms
- extrusion-spheronization
- solubility
- nanoparticle synthesis
- microcapsule synthesis
- oral solution formulation
- transdermal drug delivery.

Chapter 1 introduces experimental design, describes the focus of this book and provides necessary basic definitions and concepts.

Chapter 2 describes screening designs for qualitative factors at different levels. This includes single factor designs, multiple factor designs with equal levels and multiple factor designs with unequal levels.

Chapter 3 deals with the qualitative analysis of the influence of selected factors. The primary focus of this chapter is on the two-level factorial design with some generalisations.

Chapter 4 provides some mathematical tools. This includes multi-linear regression techniques and analysis of variance models. These tools are required for the subsequent chapters. Some methods for model selection are also addressed without theoretical justification, which would be far beyond the scope of this book.

Chapter 5 describes the response surface methodology. Several mathematical models are introduced and the selection of an appropriate model is discussed.

Chapter 6 deals with pharmaceutical process optimisation and validation. The authors focus primarily on graphical methods. Other methods such as steepest ascent or optimum path are also covered.

The issue of chapter 7 is analysing and minimising variability. Methods for analysing variability and strategies for reducing variability are addressed. The problem of non-constant variances is also discussed. Furthermore, the 'Taguchi' method for quality assurance and approaches in scaling-up and process transfer are discussed.

Chapter 8 covers the application of exchange algorithm as non-standard designs.

In chapter 9, the standard mixture designs and models are described. This chapter addresses models without constraints as well as constraint mixtures. Alternative models are also discussed.

Chapter 10 discusses constrained models in pharmaceutical formulation in more detail.

The text focuses primarily on the design and planning of experiments and not on the analysis of the experiment. The statistical methods are mostly parametric models (e.g., regression technique and analysis of variance). The text is clearly written and understandable without detailed statistical knowledge. Nevertheless, some knowledge in basic matrix algebra (also provided in an appendix) is necessary. In some situations, the issue of sample size determination would be helpful. Each chapter includes a reference list and some literature for further reading, which are very helpful to collect more detailed information, which cannot be covered by the scope of this book. This book can be recommended for all scientists concerned with the design of pharmaceutical experiments as an introduction to this important issue.

## ISCB21: Trento 2000 – 4-8 September 2000

From Maria Grazia Valsecchi

The CALL FOR ABSTRACTS for the meeting have been sent around at the beginning of December '99 and they should be by now available to all ISCB members.

The CALL FOR ABSTRACTS contains:

- information on abstract submission : abstract should be sent to the Scientific Secretariat (see below), and **deadline for submission is March 1st, 2000.**
- details on the Scientific Programme, on ISCB initiatives and on the social events during the meeting;
- the REGISTRATION FORM and information on hotels and travel modalities. Early registration, **before June 18th, 2000**, with a reduced fee of **450,000 Italian Lira** (approximately 150 UK pounds) is strongly recommended.

You are welcome to find this information and subsequent updates in the Web page:

**[www.gelso.unitn.it/~iscb2000](http://www.gelso.unitn.it/~iscb2000)**

or contacting the conference secretariat:

### **ISCB-2000 Conference Secretariat**

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The scientific secretariat, **for abstract submission**, is:

### **ISCB-2000 Scientific Secretariat**

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## Announcement: German BUGS User Group

Literature database on BUGS and MCMC methods in Internet

The German BUGS User Group (DEBUG) offers the interested public a database containing literature references on the program BUGS, on Gibbs Sampling and generally on Markov chain Monte Carlo methods. The database is accessible through the Internet, the site is

<http://userpage.ukbf.fu-berlin.de/~debug/>.

At the moment (end 10/1999) the database contains approximately 600 references to journal articles, books, book chapters and programs. Continuous update is foreseen. The following items can be searched for: Authors, titles, journals, years. The database does not yet contain keywords.

For further information please contact:

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The next meeting of DEBUG is intended to be in Rostock, 03/2000, at the congress of the German Region of the Biometric Society.

## ISCB Course and Workshop on Cluster Randomised Trials

From Mike Campbell

The Cluster Trials course was held on 5th July. A total of 75 people attended the course given by Allan Donner of the University of Western Ontario and Neil Klar of the Biostatistics Unit of the Dana-Farber Cancer Institute, Boston, USA. In the evening a walk was arranged through the grounds of nearby Chatsworth House and a meal at a country hotel.

The Cluster Trials Workshop was held on the 6th and 7th of July. A total of 69 people attended the Workshop of whom 8 came for the Workshop only. Invited speakers were Patrick Heagerty of the University of Seattle who spoke on the analysis of cluster trials using generalised estimating equations, David Spiegelhalter of the MRC Biostatistics Unit in Cambridge UK who spoke on Bayesian analysis of cluster trials and Jane Hutton of the University of Newcastle UK, who spoke on ethics and cluster trials.

Twenty one people gave contributed 20 minute papers on a variety of aspects of cluster trials, from the design and analysis to applications in primary care. There was also discussion about a CONSORT statement for the reporting of cluster trials. Min Yang from the Multilevel Project at the Institute for Education, London gave a demonstration of MIWin and Gilda Piaggio from the World Health Organization in Geneva demonstrated the program Acluster.

There is a possibility that the papers will form a special issue of Statistics in Medicine. As would be expected, the majority of people were from the UK, but (including invited speakers) there were 3 from the USA and Holland, 2 from Finland, Denmark and Australia, and one each from Norway, France, Spain, Thailand, Canada and Switzerland.

Organiser's Comments Unofficial evaluation was very positive. An official evaluation form was given out, and there were a few minor complaints: the lecture room did not have tables for writing on, the title 'Workshop' was misleading- it was more like a conference. Some of the medical people complained about the number of formulas in the course and lack of hands-on experience. However, the course was very cheap (£90) and included a full set of photocopied overheads. A commercial course could cost 4-5

times as much, but would have far fewer participants and would include individual tuition. Neil Klar only produced his overheads on the morning of the course, which involved a lot of extra work for the organisers. In future, if they were to give the course again, the notes should be obtained well in advance. Hopefully Donner and Klar's book will have been published before any future course and could be bundled into the materials. There was too much material for a one day course. I would suggest that if we ran a course again on this topic, we do it in mainland Europe or the US, we do it over two days, and we include hands-on computing.

It was very gratifying to run such a successful course. The local organisation was done entirely by myself and my personal assistant, Alison McGowan. This was not too arduous in the run up to the event. However, during the event we seconded an assistant for a day but she was only able to come for a few hours, and so Alison and I were kept very busy. It was very helpful to have the virtual committee of eight at the end of an email, to bounce ideas and suggestions off. I waived the registration fee for the course and workshop for them, which ensured their presence, but might have been rather generous. Detailed accounts will be submitted in time for the ISCB meeting, but a minor profit is likely, which will be shared between the three guarantors, the ISCB, the Institute for Primary Care Sheffield, and the Health Services Research Collaboration, Bristol.

In retrospect, nine months was rather short time to set up the conference. I started in October, after the ISCB meeting in Dundee and I felt I had to get the invited speakers sorted before advertising. The venue was arranged just after Christmas and electronic adverts were out by January. However, due to the time to arrange speakers and delay in printing, the printed advert did not appear in RSS News until May. This meant that Abstracts were accepted until the end of May, which only left a month for acceptance of Abstracts, and details of the programme to be sorted. Alison was off sick for a few days around then and as a consequence, final details were not posted until one week before conference. However, this did not appear to have affected recruitment and only one person mentioned it in the evaluation.

From Simon Day

As Mike Campbell has written, 75 of us attended the one day course on cluster randomised trials given by Allan Donner and Neil Klar. The participants came from a variety of backgrounds, possibly achieving one of the aims of ISCB that we never manage particularly well at annual conferences. I got chatting with a couple of general practitioners, someone from a health authority responsible for assessment of primary care needs as well as the traditional crowd of beer swilling statisticians.

So to the style and content of the course.... Well one of the GPs I was talking to was quite relieved to find out he was sitting next to a statistician (that must be a first!); he said he would get me to explain all the formulae that he anticipated would be flying across the screen. 'Oh, don't worry' I boldly replied, 'there are many more issues to think about than just the formulae. I'm sure I'll want some opinion from you on practicalities of randomisation, informed consent, blinding, etc.' In general, I think his concerns were more necessary than mine. Allan Donner started gently, rose to a mathematical crescendo which left my friend looking worried but then brought us quickly back down to earth with plenty of words, references and thought provoking examples. A few more equations here and there but not so many that it left anyone struggling too much. And, after all, we got to take a full set of notes home with us so we can have a look in more detail at our leisure

(leisure *lezh'ur*, noun. time free from employment; time not spent at work; time not spent doing house work, home maintenance or helping children with their school work.

Usually exists between about 11pm and 7am.) Sorry, I digress.

The afternoon session given by Neil Klar was certainly aimed more at the statistical cluster than the medical cluster. But these are important and often difficult issues so it would be wrong just to leave them out because some of the audience might not understand them. Neil took us from simple analyses at the cluster level with completely randomised and balanced designs through to mixed effects models, multilevel models, generalised estimating equations and sandwich estimators (well, this was the afternoon session).

My thanks — and our thanks — go to Mike, his virtual committee and, of course, to Alan and Niel. I certainly benefited from attending the course. I was not able to attend the follow-on workshop due to too many calls on my leisure- (see above) time. I was sorry to miss it. There are claims that ISCB has helped to bring together the largest ever meeting of experts and others interested in cluster randomisation. That is probably true. So what can the Education Subcommittee do next?

## Books and Software for Review

### New and recent books

Author	Title	Publisher	Reviewer
Peter Armitage (ed)	Encyclopedia of Biostatistics: Vol. 4: Med-Pre	John Wiley (1998)	Aurelio Tobias
Alan Stuart, Keith Ord & Steven Arnold	Classical Inference & the Linear Model (Kendall's Library of Statistics 2a)	Arnold (1998)	Anna Bartkowiak
Donald C Monkhouse & CT Rhodes (Eds.)	Drug Products for Clinical Trials	Marcel Dekker (1998)	
Chi-Lun Cheng & John W Van Ness	Statistical Regression with Measurement Error (Kendall's Library of Statistics 6)	Arnold (1999)	
A Lawson, A Biggeri, D Böhning, E Lesaffre, JF Viel, R Bertollini (eds.)	Disease mapping and risk assessment for public health	John Wiley (1999)	
S Ghosh (ed)	Asymptotics, Nonparametrics and Time Series	Marcel Dekker (1999)	
Adrian Bowman & John McColl (eds)	Statistics and Problem Solving: Computer-based case studies from the STEPS project	Arnold (1999)	
Michael J Campbell & David Machin	Medical Statistics: A Commonsense Approach (3 <sup>rd</sup> ed.)	John Wiley (1999)	
GM Clarke & D Cooke	A Basic Course in Statistics (4 <sup>th</sup> ed.)	Arnold (1997)	
JK Lindsey	Models for Repeated Measurements (2 <sup>nd</sup> ed.)	Oxford (1999)	
JM Bernardo, JO Berger, AP Dawid & AFM Smith	Bayesian Statistics 6	Oxford (1999)	
Brian D Hahn	Essential MATLAB for Scientists and Engineers	Arnold (1997)	
Helio S Migon & Dani Gamerman	Statistical inference: An Integrated Approach	Arnold (1999)	
Daniel Zelterman	Models for Discrete Data	Oxford (1999)	
Edward L Korn & Barry I Graubard	Analysis of Health Surveys	John Wiley (1999)	
BLS Prakasa Rao	Statistical Inference for Diffusion Type Processes	Arnold (1999)	
David J Bartholomew & Martin Knott	Latent Variable Models & Factor Analysis	Arnold (1999)	
Graham Dunn	Statistics in Psychiatry	Arnold (2000)	
M. Elizabeth Halloran & Seymour Geisser (eds.)	Statistics in Genetics	Springer (1999)	
MM Shoukri & CA Pause	Statistical Methods for Health Sciences	CRC (1999)	

Arnold:	<a href="http://www.arnoldpublishers.com">http://www.arnoldpublishers.com</a>
Oxford:	<a href="http://www4.oup.co.uk/">http://www4.oup.co.uk/</a>
John Wiley:	<a href="http://catalog.wiley.com/index.cgi?">http://catalog.wiley.com/index.cgi?</a>
Marcel Dekker:	<a href="http://www.dekker.com/catalog/catalog_top.htm">http://www.dekker.com/catalog/catalog_top.htm</a>
Springer:	<a href="http://www.springer.de/statistic/books/newbooks.html">http://www.springer.de/statistic/books/newbooks.html</a>
Chapman & Hall:	<a href="http://www.crcpress.com/www/chaphall.htm#ms">http://www.crcpress.com/www/chaphall.htm#ms</a>

#### Important note to potential reviewers:

We regularly receive books from publishers for review in the Newsletter. We are most grateful for these 'donations', the reviews of which we regard as a service to you, our members. Regretfully, some individuals, despite repeated reminders, neither return a review, nor the book to ISCB... When requesting a book, please remember that you're making a commitment to the Society to do a little work in return for keeping the book. Please be aware that reviewers who fail to comply with the principles will have their names published in the News.

## Information on Submitting Articles

Articles sent via email or on diskette (Word, WordPerfect or text) on almost any topic are most welcome. This is an informal newsletter for you the readers, so please join in and make ISCB News a magazine that's even more interesting and fun to read.

## Advertising Rates

<p><b>The prices are:</b></p> <p><b>Full</b>            <b>A4 page:</b>        <b>£ 200</b></p> <p><b>Half</b>             <b>A4 page:</b>        <b>£ 150</b></p> <p><b>Quarter</b>        <b>A4 page:</b>        <b>£ 100</b></p>	<p><b>Additionally, we will include loose flyers with the distribution of the newsletter at an initial handling cost of £ 150. However, if the addition of the flyers increases the postal charges, the advertiser will also be charged the difference in distribution costs. For further information, please contact the Editor.</b></p>
<p><b>Publishing dates</b> <b>(and deadlines)</b></p>	<p><b>2000:</b></p> <p style="text-align: center;"><b>(early April)</b></p> <p style="text-align: center;"><b>(early November)</b></p> <p style="text-align: right;"><b>May/June,</b> <b>December.</b></p>



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### ISCB: Changes of Address or Email

Please inform the Permanent Office that looks after the membership and mailing list databases.

## ISCB Membership Information

The **International Society for Clinical Biostatistics (ISCB)** was founded in 1978 to stimulate research into the principles and methodology used in the design and analysis of clinical research and to increase the relevance of statistical theory to the real world of clinical medicine.

The ISCB organises an annual scientific meeting which members and non-members are able to attend. The main objective of the annual scientific meetings is to create an opportunity for the exchange of knowledge, experience and ideas among clinicians, statisticians and members of other disciplines, such as epidemiologists, clinical chemists and clinical pharmacologists, working or interested in, the field of clinical biostatistics.

The scientific meetings cover a broad spectrum of biostatistical interests and regularly include sessions on the design and analysis of clinical trials, epidemiology and statistical methodology, as well as from time to time considering more specialist issues such as, for example, education of biometricians and biometrics users, pharmacokinetics, medical data-bases and pharmacopidemiology. Each meeting includes a mini-symposium devoted to a particular medical or statistical field.

Previous meetings in recent years have been held in Budapest (1996), Boston (1997), Dundee (1998), and Heidelberg (1999). A selection of talks at the meetings, for which papers are submitted for review and which are eventually accepted, are published in *Statistics in Medicine*. The ISCB benefits from a special journal concession from John Wiley & Sons Limited, the publishers of *Statistics in Medicine*, so that members are able to subscribe to the journal at a preferential rate.

The ISCB also organises courses to cover particular statistical topics. These are run to precede or follow on from the annual scientific meeting and are given by the foremost researchers in the field. Recent courses have included Analysis of Ordered Categorical Data, Cross-over Trials in Clinical Research, Analysis of Repeated Measures, Survival Analysis, Extending the Cox Model, and Statistical Methods for Genetic Epidemiology.



Vice-President, Mr Simon Day (UK),  
Secretary, Prof. Maria Grazia Valsecchi (I),  
Treasurer, Prof. John Whitehead (UK), and

### Members:

Newsletter Editor, Dr David Warne (CH),  
Webmaster: Dr Bjarne Nielsen (DK), and  
Prof. Mike Campbell (UK), Dr Bruno Cesana (I), Prof. Ted Colton (USA), Dr Siem Heisterkamp (NL), Dr Emmanuel Lesaffre (B), Prof. Michael Schemper (A), Dr Jørgen Selstrup (F) and Prof. Norbert Victor (D).

The annual general meeting of the ISCB is organised to coincide with the scientific meeting. Membership of the Society is drawn from more than 40 countries worldwide and the number of members is nearly 800.



The ISCB also has special **Subcommittees** dealing with particular aspects of biostatistics. These are listed on p.6 along with their Terms of Reference.



The Society publishes a **Newsletter** 2 or 3 times a year. The editor is Dr David Warne, Chemin Frank-Thomas 40, CH-1208 Geneva, Switzerland. Items for inclusion in the Newsletter should be sent to him (if possible on a 3.5' disk, Word format or text, or email to: [100557.2260@compuserve.com](mailto:100557.2260@compuserve.com) [david.w.warne@serono.com](mailto:david.w.warne@serono.com)

**Membership** of the Society is open to all with an interest in biostatistics. The current annual (to 31 December 2000) Ordinary membership fee is £15. The Full-time Student Membership fee is £7.50. Members can also choose to receive *Statistics in Medicine* at a reduced cost (see above), and benefit from the reduced conference fee, at least £15 less than for non-members. **Applications** for membership should be sent to:

ISCB Permanent Office, PO Box 25,  
DK-3480 Fredensborg, DENMARK  
Tel: +45 48 484 100,  
Fax: +45 48 484 200,  
email: [iscb@post3.tele.dk](mailto:iscb@post3.tele.dk)  
[Office@iscb-homepage.org](mailto:Office@iscb-homepage.org)

**WWW:** <http://WWW.ISCB-HOMEPAGE.ORG>

### REMINDER

Dues for 2000 are now due. (See p.27)

Have you checked the ISCB Homepage? <http://www.iscb-homepage.org>

Check often for updated information between issues of the ISCB News!

The current composition of the **Executive Committee** (ExCom) is as follows:

### Officers:

President, Dr Nancy Geller (USA),

## Membership Subscription

### INTERNATIONAL SOCIETY FOR CLINICAL BIOSTATISTICS 2000 Membership Subscription

Surname \_\_\_\_\_ Initials/Name \_\_\_\_\_ Occupation (please tick):

Title (Prof./Dr/etc.) \_\_\_\_\_ Post held \_\_\_\_\_  Statistician

Business address \_\_\_\_\_  Medical Doctor

\_\_\_\_\_  Both

Post code and country \_\_\_\_\_  Neither

Phone No. and Fax No. \_\_\_\_\_ email: \_\_\_\_\_ www: \_\_\_\_\_

SUBSCRIPTION:  £ 15.00 Ordinary membership of ISCB (to 31 December 2000).  
(please tick one only)  £ 7.50 Full-time Student Membership of ISCB (to 31 Dec. 2000).  
 £ 210.00 Ordinary Membership of ISCB (to 31 December 2000) +  
subscription to *Statistics in Medicine* 2000.  
(including access to SiM website where the journal contents, abstracts  
and references can be searched)

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**ISCB Permanent Office**

**P.O. Box 25**

**DK-3480 Fredensborg**

**Denmark**

**Tel: +45 48 48 41 00, Fax: +45 48 48 42 00**



## Calendar

**11-13 June 2000**

**Edmonton, CANADA**

Statistics and Health

Info: <http://www.stat.ualberta.ca/~brg/conf.html>  
email: [brg@stat.ualberta.ca](mailto:brg@stat.ualberta.ca), fax: +1 780 492 6826, tel: +1 780-492-4230

**2-7 July 2000**

**California, USA**

International Biometric Conference

Info: <http://www.biostat.ucst.edu/IBC2000/>

**21-25 August 2000**

**Utrecht, NETHERLANDS**

Compstat 2000 organised jointly by Statistics Netherlands and Utrecht University

Info: Professor Peter van der Heijden, Department of Methodology and Statistics,  
Faculty of Social Sciences, Utrecht University, PO Box 3508 TC, Utrecht, Netherlands.  
Fax: +31 30 2535797, email: [compstat@fbu.uu.nl](mailto:compstat@fbu.uu.nl),  
www: <http://neon.vb.cbs.nl/rsm/compstat>

**4-8 September 2000**

**Trento, ITALY**

ISCB21

Info: Centro Servizi Culturali Santa Chiara, Via S. Croce 67, I-38100 Trento, ITALY

Tel: +39 0461 986488, Fax: +39 0461 231044,  
email: [iscb2000@gelso.unitn.it](mailto:iscb2000@gelso.unitn.it) or [cscsctn@tin.it](mailto:cscsctn@tin.it)

<http://www.gelso.unitn.it/~iscb2000/>

**11-15 September 2000**

**Reading, ENGLAND-UK**

RSS 2000 Conference

Info: Dave Collett  
email: [d.collett@reading.ac.uk](mailto:d.collett@reading.ac.uk)

**19-23 August 2001**

**Stockholm, SWEDEN**

ISCB22

Info: Clinical Data Care, Warfvinges Väg 16, S-11251 Stockholm, SWEDEN

Tel: +46 8 618 2280, Fax: +46 8 618 2281,  
email: [theresa.westerstrom@ISCB.stockholm2001.org](mailto:theresa.westerstrom@ISCB.stockholm2001.org)

**9-13 September 2002**

**Dijon, FRANCE**

ISCB23

Info: Harbajan Chadha-Boreham  
email: [h.chadha-boreham@fournier.fr](mailto:h.chadha-boreham@fournier.fr)

**20-24 July 2003**

**London, ENGLAND**

ISCB24 joint with Society for Clinical Trials

Info: Diana Elbourne  
email: [diana.elbourne@lshtm.ac.uk](mailto:diana.elbourne@lshtm.ac.uk)