



International Society for Clinical Biostatistics

Number 1 July 1985

Editor: J. Seldrup

What!

At the 2nd Meeting of the Executive of the International Society for Clinical Biostatistics held in connection with ISCB-4 in Paris in September 1983, it was decided to try to launch a newsletter. Following a re-affirmation at the 3rd Meeting of the Executive in connection with ISCB-5 in San Marino in 1984, I was careless enough to be persuaded to be the editor. So this is the birth of the ISCB Newsletter.

We intend to publish two newsletters a year, and will rely on your help to fill our columns. In this

first issue we thought it would be right and proper to introduce you to the history of the Society. Over the page you will find a leader on Adverse Drug Reactions, a report on the latest Executive in San Marino, and the list of executive members for 1984/85. In this first newsletter you will also find a profile on our Chairman, a "letter home from San Marino", a call to come to Düsseldorf, and a meetings calendar.

Hope you like the concoction.
Happy reading.

History of ISCB Part 1

There has always been a need for interaction between statistician and practitioner, and in no field of application of statistics has this been more vital than in medicine. Not only are the consequences of clinical situations so potentially and immediately beneficial to the human race, but also the problems and issues involved are stimulatingly complex. Throughout this Century there have been splendid examples such interaction. In early 1978 this was the topic of conversation around a dinner table in Brussels. A small group of biostatisticians had gathered to discuss the results of some clinical trials, and, that work done, their conversation turned to the clinician's view of the statistician and vice versa. It was agreed that in order to encourage more interaction between clinician and statistician there was a need for an international forum, and the idea of a meeting to 'test the water' was agreed.

The organisation of such a meeting was undertaken by EORTC in Brussels, and hosted by Dr. Maurice Staquet over a two-day period in May 1979. It was the first advertised meeting of the International Society for Clinical Biostatistics and got the Society off to a flying start

with keynote talks from, amongst others, David Cox, Ed Gehan and Nathan Mantel - all biostatisticians of international repute who work closely with clinical colleagues. It was agreed by most of those present at this meeting (ISCB-1) that a start had been made. It was also agreed that the Society should be brought into formal existence and further meetings planned.

The development of the Society was being somewhat paralleled in North America by the Society for Controlled Clinical Trials and links were maintained through a representative of ISCB sitting on their Council.

It is clear from the subsequent development of ISCB that it owes a great debt to Maurice Staquet for his organisation of ISCB-1 following that dinner conversation, and to EORTC for hosting the first meeting.

The next meeting, ISCB-2 took place at the University of Exeter, United Kingdom, in September 1980, and was again a two-day meeting.

It was organised by Dr. Ray Harris, and continued the process of involving clinicians and statisticians. An exciting event for the Society was

the joint presentation of a paper by a clinician and a statistician on work following discussions initiated during ISCB-1. The Exeter Meeting used parallel sessions to discuss various themes, and the idea was born of the possible integration into the meeting of a symposium dedicated to a particular clinical topic - this was first done at ISCB-3 in Rotterdam. The meeting made a small profit and the existence of the Society was formalised with the acceptance of a statement of the objectives, and with the election of a small Acting Committee to draw up a constitution to put to the General Meeting of the Society during ISCB-3.

The Acting Committee consisted of Drs. R.R. Harris, Exeter, (Chairman), R.A. Dixon, Sheffield, (Secretary), and D.W. Wilson, Cardiff, (Treasurer). In the time between ISCB-2 and ISCB-3 this Committee met on numerous occasions to draw up the draft constitution, liaise with the Organising Committee for ISCB-3, and generally put the Society on a sound basis in preparation for an Executive Committee to take over in Rotterdam.

To be continued in the next newsletter.

Adverse drug reactions

There is a growing appreciation in professional as well as lay circles that a drug which is capable of preventing, relieving or even curing a disease is potentially dangerous; in the process of favourably influencing our bodies the drug may in fact also be harmful. The evaluation of risks and benefits is an all important part of the doctor's considerations when he prescribes.

How does he know the risk/benefit ratio? The truth is probably that he does not. If it is an old drug, albeit a well-established drug, medical opinion, if not knowledge, may demand a certain relationship, but it is not likely that this has been achieved by careful study. If it is a new drug the pharmaceutical company will have studied its benefits as well as its unwanted effects intensively during its research programme, but in a number infinitely small in comparison with the potential number of patients who may receive it after marketing.

There is much debate about the monitoring of adverse drug reactions, of the pros and cons of cohort studies, case-control studies, monitored release studies, prescription-event-monitoring etc. A debate where epidemiologists and statisticians would have much to contribute over and above calculating the numbers of patients needed for various kinds of studies. A debate where together with clinicians and regulatory authorities much useful research must result.

However, we must not forget, and we should never cease to emphasise, that drugs will always remain potentially dangerous chemical substances, and no amount of drug monitoring will ever prevent this. What we must debate is a practical solution, which will limit the potential suffering of our patients.

Report of 3rd Executive Committee Meeting

On the occasion of ISCB-5 in San Marino, the Executive Committee held its third meeting, the chair being taken by Prof. Dr. Med. H.J. Jesdinsky of the University of Düsseldorf.

Following the "usual" apologies for absence and matters arising, the minutes of the 2nd Executive Committee Meeting held in Paris were signed. It was then resolved that Barclays Bank Ltd. be appointed the Bankers of ISCB. The Secretary reported that the Editor of *Revue d'Epidemiologie* was about to make available to members of ISCB free copies of the Autumn issue of the Journal, containing papers from ISCB-4.

Professor Marubini of the University of Milan on behalf of the Local Organising Committee reported on the trials and tribulations of organising ISCB-5. A paper on 'Information for Invited Speakers' and the adjudication of contributed papers were discussed at length amidst the arrival of the best San Marinense sandwiches the Grand Hotel could muster. This was just as well, as a session on the next ISCB meeting in Düsseldorf ensued, appropriately helped along with a variety of beers.

Various ideas for venues and organisers for ISCB-7 in 1986 were brought up, as were future meetings plans in general, but it proved not possible to fix a venue for 1986. Subsequent to the meeting, however, it is now hoped to hold ISCB-7 in Cardiff, United Kingdom.

Under the heading of 'ISCB Journal' a general discussion took place on incentives to becoming, and advantages of being, members of the Society. On a proposal to attempt to produce a journal it was agreed that the Society currently had inadequate funds to underwrite such a launch, and that it would await the effect of the newsletter in generating an increase in membership. It was also agreed that members would receive one free issue of 'Statistics in Medicine' in 1985, containing some

of the papers from the San Marino meeting. A further incentive to membership was proposed and agreed: a £15 reduction in registration fees for the Düsseldorf meeting.

To spread the information about ISCB the Society relies on a series of National Representatives. It was proposed to extend the list to include members in Eastern Europe. It is hoped that representatives would also make a contribution to future newsletters through a column "From our local representative".

The final items on the agenda dealt with the soliciting of sponsorship, expenses for travel and accommodation, the mailing list and honorary auditors. It was resolved to invite Mr. A. Kramer (France) and Dr. C.G. Pierpoint (France) to audit the 1984 account and Dr. H.J. Trampisch (Germany), and Dr. D. Machin (UK) the 1985 accounts.

Finally, Professor Gehan proposed a vote of thanks to Professor Marubini, Professor Gallus, and their colleagues and staff for their efforts in putting on the San Marino meeting. The next Executive Committee meeting will be held in Düsseldorf on 20th September, 1985.

Executive Committee 1984/85

President

Professor H.J. Jesdinsky (Düsseldorf)

Vice-President

Dr. D.W. Wilson (Cardiff)

Secretary

Dr. R.A. Dixon (Sheffield)

Treasurer

Dr. W. Koepcke (Munich)

Committee Members

Professor R. van Strik (Rotterdam)

Dr. J. Seldrup (Horsham)

Professor E. Gehan (Houston)

Professor G. Gallus (Milan)

Profile

Hans J. Jesdinsky was born on 27th January, 1931 in Düsseldorf. He studied medicine in Cologne, Bonn and Innsbruck, and qualified as MD in 1956.

Until 1963 he was at the University Hospital, Bonn, where his main interest was psychosomatic medicine (bodily changes induced by emotion in patients with hyperthyroidism, hypertension or obesity).

He then spent two years in the pharmaceutical industry (E. Merck, Darmstadt) designing pharmacological experiments, planning and documenting clinical trials.

In 1965 he joined the Department of Medical Statistics at the University of Freiburg/Breisgau and studied mathematics, probability theory,

statistics and computer science. In 1969 he became Reader in Medical Statistics and Documentation, and in 1973, Associate Professor. He then moved to the newly founded Department of Medical Statistics and Biomathematics at the University of Düsseldorf, to become Professor and Head of Department in 1975.

His main interests are in design and analysis of clinical trials, design and analysis of epidemiological studies, quality control in medical laboratories and health care.

He is a member of the Biometric Society, the American Statistical Association, the Society for Epidemiological Research, the Society for Clinical Trials, the International Society for Clinical Biostatistics and various national scientific bodies.

He is also a Consultant to the Federal Health Office, the German Research



Professor H.J. Jesdinsky

Association, the Federal Ministry of Research and Technology, and the Commission on Medicines of the Medical Profession.

Letter home from San Marino

Dear All,

We are just sitting at Venice Airport waiting for a flight home. If Marco Polo had ever had half the problems we have just had getting from the airport to Piazza San Marco, he would not have been so famous for his travels. If ever there was a 'flying' visit to Venice, if you can say that about a bus ride having failed to negotiate favourable terms with the water taxis, this must be it.

"See Venice and die", they say; well, we almost did. In two hours, with all our luggage, as, would you believe it, there is nowhere at the airport to leave luggage (we even tried hiring a car just to leave our stuff in, but the pretty girl at Hertz looked at us in disbelief, and suddenly there were no cars free) we made it. And we were glad we did. Such a strange and mysterious place, sombre and yet so full of colour and sound and life. I kept seeing images of 'Death in Venice', and Mahler's music is still haunting me. I want to go back there.

But what am I doing in Venice, I hear you say. Well, I have been to a conference in San Marino for the last five days. We flew out to Venice a week ago, and went on a coach along the Adriatic to Rimini - about 200 km - and then inland about another 25km. As we approached Rimini out of the sunshine there, suddenly, was Mount Titano, on which is perched the capital of San Marino. A strange place in many ways, or maybe it was only because it was out of season. There was certainly a lot of souvenirs still left - the same souvenirs, in fact, in most shops. Where else could you buy the same lighter or the same leather covered fancy bottle in so many shops? Where else could you see so many generic gins or cognac copies?

We stayed at La Grotta (and no, it was not that bad). The conference was held a short walk away, in Palazzo dei Congressi, very well equipped for the purpose apart from the coffee machine. It took a lot of persuasion from the organisers to convince the barman, that his pride coffee espresso could not be prepared individually for 200 people in the course of half an hour.

I almost stayed at the conference all week; but one afternoon I did go down onto the beach with a friend, expecting to stroll in the sand and enjoy the sundrenched bodies on view. But what a sad day to have chosen - no sun, no deckchairs, and all the other bodies were fully dressed as well. We abolished our disappointment with some local vino in a little cafe, whilst solving most of the world's problems, topped up with a few statistical ones.

Well, I must go now, the plane back to London is being called - Gate numero due. I will write again after the next meeting in Düsseldorf.

Kind Regards. J.S.

SIRMCE ANNOUNCEMENT

The International Society for Research on Civilization Diseases and Environment (SIRMCE) was founded in Luxembourg in 1973, and has expanded rapidly during recent years. The activities of this multi-disciplinary Society, expressed in the form of National Workshops and International Meetings, have been addressed to problems relating, for example, to non-communicable diseases, health and the environment, occupation-related medicine and mental health. Examples of our current activities include problems related to cancer research, depression and suicide, nutrition, chronobiology and ecotoxicology.

For further information on membership to SIRMCE and its planned activities, please contact Dr. D.W. Wilson, Tenovus Institute for Cancer Research, Heath Park, Cardiff, CF4 4XX. UK.

ISCB-6 Düsseldorf 16-20 September 1985

The Institute of Medical Statistics and Biomathematics at the University of Düsseldorf will play host to the Sixth International Meeting on Clinical Biostatistics, 16-20 September, 1985, in Düsseldorf, the regional capital of North Rhine-Westphalia, FRG.

The main themes of the Conference will be:

- 1 The Role of Biostatistics in Long Term Clinical Studies
- 2 Quality Control in Clinical Medicine
- 3 Clinical Biostatistics as an Aid to Medical Decision Making
- 4 Clinical Oncology
- 5 Cancer Morbidity and Mortality
- 6 Methodology of Clinical Trials

Following a get-together on Monday evening, the scientific programme will commence on Tuesday morning. Wednesday sees a joint session with the Deutsche Gesellschaft für Medizinische Dokumentation, Informatik und Statistik (GMDS) on 'Biostatistics as an Aid to Medical Decision Making'. At ISCB-4 and 5 mini-symposia on Diabetes and Gastroenterology, respectively, were held. This tradition will be maintained at ISCB-6, where Thursday's proceedings will be devoted particularly, but not exclusively, to a symposium on Clinical Oncology. The meeting will finish on Friday.

And if all this is not enough, a brief glance at the brochures for 'Düsseldorf - for convention visitors' would suggest that there is a useful correlation between city pleasures and delegates' leisure time.

With an average population of 600,000 and a 'reputation for natural gaiety, relaxation and hospitality' as the 'number one on the German "live and let live" list', statisticians, as well as clinicians, will agree on the significance of holding ISCB-6 in Düsseldorf.

For "eine gemütliche Stunde" see you in Düsseldorf in September.

International Conference on Foundations of Statistical Inference - Applications in Medicine, Social Sciences and Industry.

An international conference on foundations of statistical inference and its application to medicine, social sciences and industry, initiated by the Department of Statistics, the Hebrew University of Jerusalem and organised by the Israeli National Council for Research and Development will be held in Jerusalem, Israel, from December 15-18, 1985. (Dates are subject to change to December 9-12).

The interdisciplinary aspect of the conference will provide a forum for collaborative efforts among researchers in different fields of application. The Advisory Board of the conference consists of Professors Lawrence Brown (Cornell University and Hebrew University), David R. Cox (Imperial College), M.H. DeGroot (Carnegie-Mellon University), A. Dvoretzky (Hebrew University), Ingram Olkin (Stanford University) and Marvin Zelen (Harvard University).

For further information, contact Professor Yoel Haitovsky, Chairman of the Scientific Organising Committee, Department of Statistics, Hebrew University, Jerusalem, Israel 91905.

Other enquiries, for instance about membership should be sent to Dr. R.A. Dixon, University of Sheffield Medical School, Beech Hill Road, Sheffield, S10 2RX United Kingdom.

Correspondence for, or about, the newsletter should be sent to Dr. J. Seldrup, Ciba-Geigy Pharmaceuticals, Wimblehurst Road, Horsham, West Sussex. RH12 4AB United Kingdom.

1985 Calendar

July 29-31

Fifth International Conference on Mathematical Modelling

University of California, Berkeley, CA.
Contact: Xavier J.R. Avula, Institute for Applied Sciences - Office Branch, PO Box 1488, Rolla, MO 65401.

August 7-9

III International Meeting of Statistics in the Basque Country

Bilbao, Spain
Contact: The Secretariat, III International Meeting of Statistics in the Basque Country, PO Box 32, Lejona (Biscay), Spain.

August 12-22

International Statistical Institute - 45th Biennial Session

Amsterdam, The Netherlands.
Contact: I.S.I., 428 Prinses Beatrix Laan, 2270 AZ Voorburg, The Netherlands.

August 29-30

Mason Conference in Medical Statistics

University of Strathclyde, Glasgow.
Contact: Dr. G.D. Murray, Dept. of Statistics, University of Glasgow, University Gardens, Glasgow, G12 8QW, UK.

September 2-5

Nordic Symposium on Biometric Methods in Epidemiology and Environmental Research

Ristiina, Finland.
Contact: Dr. T. Hakulinen, Finnish Cancer Registry, Liisankatu 21B, 00170 Helsinki 17, Finland.

September 16-19

GLIM 85 Conference

Lancaster, UK.
Contact: Dr. R. Gilchrist, Dept. of Mathematics, Statistics and Computing, Polytechnic of North London, Holloway Road, London, N7 8DB, UK.

September 16-20

ISCB-6

International Society for Clinical Biostatistics

Düsseldorf, FRG.
Contact: Dr. R.A. Dixon, University of Sheffield Medical School, Beech Hill Road, Sheffield, S10 2RX, UK.

October 1-2

Evaluation of the Benefit/Risk Profile of Drug Strategies of Post-Marketing Surveillance

Bergamo, Italy.
Contact: IPR International, 12 Rue des Halles, 75001 Paris, France.

October 13-16

Clinical Data Management Techniques

Cavalieri Hilton, Rome, Italy.
Contact: Ms. L. Kaufman, Merck & Co, PO Box 2000, Rahway, NJ 07065, USA.

December 3-5

Third Annual Conference of the Indian Society for Medical Statistics

Calcutta, India.
Contact: Dr. T. Krishan, Organising Secretary, Third Annual Conference of ISMS, Indian Statistical Institute, 203 BT Road, Calcutta 700 035, India.

December 4-6

41st Annual Conference on Applied Statistics

Newark Airport Holiday Inn, Newark, NJ, USA.
Contact: Walter R. Young, Medical Research Div., Cyanamid Co., Bldg. 60, Room 203, Pearl River, NY 10965, USA.

December 15-18

International Conference on Foundations of Statistical Inference: Applications in Medicine, Social Sciences and Industry

Jerusalem, Israel.
Contact: Professor Yoel Haitovsky, Chairman of the Scientific Organising Committee, Dept of Statistics, Hebrew University, Jerusalem Israel 91905.