

Section 11

Clinical trials and informatics support

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INTRODUCTION

The Clinical Trials and Informatics Support group provides technical support in statistics and data processing to the rest of the Department.

Technical support to research activities includes statistical advice in the review and development of research projects, and responsibility for the management and analysis of some single-centre and nearly all multicentre studies carried out by the Programme. The group also coordinates the implementation of Good Clinical Practice (GCP) guidelines in all of the Programme's research activities. In the area of technical support to countries, the group assists in the formulation, execution and review of institution-strengthening policies in statistics and data processing, and in the organization and conduct of workshops and training courses in these areas for scientists from collaborating institutions. Staff of the Clinical Trials and Informatics Support group provide on-the-project training in research data management and statistical analysis to staff of centres participating in some multicentre studies or carrying out their own single-centre trials. They also contribute to the development of appropriate techniques for the conduct, management and analysis of multicentre research projects in reproductive health in developing countries. Staff members of the group also provide local informatics support to the administrative management of the Department.

The group's strategy is to coordinate international multicentre studies from Geneva while continuing to enhance the ability of individual centres to handle their own single-centre and national multicentre studies.

SUPPORT TO RESEARCH ACTIVITIES

Specific objectives

The objectives are to provide high-quality and efficient statistical and data-processing support to all research conducted by the Programme, and to ensure statistical and methodological rigour, including adherence to GCP guidelines.

Progress

Support to research projects

Activities carried out by the group in 2001 in support of research projects included:

- technical advice in their development and review;
- statistical design;
- assistance with project organization;
- data processing, monitoring and management;
- data analysis and preparation of statistical reports; and
- participation in the writing of scientific papers resulting from the projects.

A total of 63 research projects were supported by the group. The distribution of these projects by their stage of support at the end of 2001 is shown in Table 11.1.

Table 11.1. Number of studies by stage of support (December 2001)

In the planning stage or just starting: protocol preparation, forms design, data management systems design, supplies distribution	20
Ongoing studies: data validation, data quality control, study monitoring, interim analysis	12
Final analysis: final data cleaning, preparation of final analysis	9
Statistical report drafted, manuscript in preparation, revisions and/or additions to final analysis	13
Final analysis completed	9
TOTAL	63

In addition to the technical support given to these specific projects, all of which are being coordinated in Geneva, support was given to Programme staff with the technical review of projects submitted to them for funding and arrangements for logistic support to projects before launching. The technical review focused mainly on the biostatistical and data processing aspects of the protocol while logistic support arrangements included site-visits to the proposed study and coordinating centres to review facilities and data collection mechanisms.

Implementation of GCP guidelines in research

During 2001, efforts continued to formally implement WHO GCP research guidelines throughout the Programme's research activities. Scientific staff of the Department were organized into groups to edit the 69 Standard Operating Procedures (SOPs) drafted during the previous year. The editing procedure is still in progress and will be completed during the first half of 2002.

SUPPORT TO INSTITUTION-STRENGTHENING ACTIVITIES

Objective

The objective of these activities is to strengthen the statistical and data-processing capabilities of selected developing country institutions to support their own research work.

Activities

The following are the highlights of activities during 2001:

Training courses, seminars and workshops

A staff member of the group gave lectures on strategies for data analysis of observational studies and randomized con-

trolled trials at the 11th Postgraduate Course for Training in Reproductive Medicine and Reproductive Biology at the WHO Collaborating Centre of the Cantonal Hospital, University of Geneva, Geneva, Switzerland. It was attended by 28 participants.

Site-visits

Staff of the group visited the Centre de Recherche en Reproduction Humaine et Démographie (CERRHUD) and the WHO Institut Régional de Santé Publique (IRSP) both in Cotonou, Benin to discuss the possibility of establishing training courses in biostatistics and data processing for French-speaking African countries. Staff of the Department visited the National Research Institute for Family Planning (NRIFP), Beijing, China, to help assess its capabilities to coordinate three research projects of the Rockefeller Foundation Initiative in China. In another visit to Beijing and Shanghai, assistance was provided in the preparation of the Conference on Quality Care in the Chinese family planning programme. Issues related to data management in the context of the collaboration between the State Family Planning Commission (SFPC) and the Department were also discussed.

Annex 1

CONSULTANTS AND TEMPORARY ADVISERS DURING 2001

Name	Nationality	Place of assignment
Virgile Capo-chichi	Benin	Geneva
Sihem Landoulsi	Tunisia	Geneva
David Machin	United Kingdom	Geneva
Alain Pinol	France	Geneva

Annex2**PUBLICATIONS IN 2001**

Donner A, Piaggio G, Villar J. Statistical methods for the meta-analyses of cluster randomization trials. *Statistical Methods in Medical Research*, 2001, **10**:325–328.

Gülmezoglu AM, Villar J, Nhu Ngoc N, Piaggio G, Carroli G, Adetoro L, et al. for the WHO Collaborative Group to Evaluate Misoprostol in the Management of the Third Stage of Labour. WHO multicentre randomized trial of misoprostol in the management of the third stage of labour. *The Lancet*, 2001, **358**:689–695.

Piaggio G, Elbourne D, Villar J, Pinol A, Schulz KF and Gülmezoglu AM, for the WHO Collaborative Group To Evaluate Misoprostol in the Management of the Third Stage of Labour. Reporting of methods for randomisation, concealment and blinding: the example of the WHO misoprostol third stage of labour trial. *Controlled Clinical Trials* (submitted).

Piaggio G, Pinol A. Use of the equivalence approach in reproductive health trials. *Statistics in Medicine*, 2001, **20**:3571–3587.

Piaggio G, Carroli G, Villar J, Pinol A, Bakketeig L, Lumbiganon P, et al. Methodological considerations on the design and analysis of an equivalence stratified cluster randomization trial. *Statistics in Medicine*, 2001, **20**:401–416.

Piaggio G, d’Arcangues C, Machin D, eds. Statistical methods in reproductive health. Special issue. *Statistics in Medicine*, 2001, **20**:3487–3648.

Piaggio G, d’Arcangues C, Machin D. Preface to the Special issue on statistical methods in reproductive health. *Statistics in Medicine*, 2001, **20**:3487–3488.

von Hertzen H, Honkanen H, Piaggio G, Bartfai G, Erdenetungalag , Gemzell-Danielsson K, et al. for the WHO Research Group on Post-Ovulatory Methods for Fertility Regulation. WHO multinational study of three misoprostol regimens after mifepristone for early medical abortion: I. Efficacy. *British Medical Journal* (submitted).

