



World Health Organization
Geneva

Emergency and Humanitarian Action (EHA)

Advisory Group on Research in Emergencies

Report from the informal meeting of Paris
16 December 1999

The third meeting of the Advisory Group on Research in Emergencies (AGRE) was held at the Confédération des Syndicats médicaux français, 60 Boulevard de Latour-Maubourg, Paris, on 16 December 1999. A sub-group meeting to discuss the ethics framework took place on 15 December at WHO Geneva.

1. ETHICS FRAMEWORK

The Group noted that, since the previous meeting, the ethics template had not been modified. The restrictive tone of the draft framework was not conducive to promote research in emergencies.

Function, scope and potential use

The function of the framework should be clarified. The present draft focussed on controlled trials, which constitute a small part of all research, particularly in emergencies. Ethics guidelines should be developed to cover the entire range of research, including surveys and evaluations. They should be presented so as to encourage investigation, in order to increase evidence for yet perfunctory emergency public health practice.

The ethics framework should therefore move away from the stable situation and find degrees of freedom instead of restrictions to enable research to be conducted. Under these conditions, the aim is to obtain evidence that can be used to improve current practice. To do this, new research methods will have to be generated. An example would be the sequential replication of therapeutic feeding centres using an alternative approach, known to be safe from trials in a non-emergency setting. The research unit would then be the feeding centre, thus avoiding the selection of a control group. The outcome of such studies would provide an evidence base for good practice, albeit less strong than from an RCT. Regardless the design, research in emergencies should be conducted with scientific rigour. Data collection and analysis should follow agreed standard procedures.

Criteria are wanted to judge if research is exploitative and to assess its quality. The objectives of a study are to be considered first. If the aim is to improve public health practice in emergencies, the subjects will potentially benefit. If there are other objectives, possible exploitation of a vulnerable population should be excluded. Classification of research in other terms than descriptive or analytical might be helpful.

It was agreed that the preamble needed to be more positive oriented and should state parameters for application (type of trial, type of emergency). Four major issues should be addressed:

1. Separate standards for controlled trials
2. Define the type(s) of research to be promoted e.g. observational studies
3. Review and enlarge the “risk-benefit” concept. The point was made that benefits do not always go to the study subject. For example, health education may target the mother while aiming to improve the health of the child. Public health interventions often result in externalities (gratuitous surplus effects on the community) that can be either positive or negative.

4. Formulate the specific problems regarding informed consent in emergency settings to see how they differ from traditional research settings.

The analogy between prisoners and refugees (see previous meeting report) is misleading and should be deleted.

Dr Perrin volunteered to prepare a short text on the application of ethics criteria at different levels of research (i.e. from purely descriptive to RCT).

The group noted that ethics guidelines are under discussion at the international level. Many national governments have regulated medical research in their country. The Advisory Group cannot overrule negative decisions taken by a national government. The national political context and examples of country Institutional Review Boards (IRB) and their standards are to be included. But research criteria vary widely between countries and in some cases may not be stringent enough for emergency situations. In complex emergencies, the protection of hostile populations may not be in the interest of the government in power. Potential security issues around the disclosure of information should also be addressed.

The World Health Organization has no overarching review board. The Advisory Committee on Health Research (ACHR) provides policy advice to the Director General. Individual Departments have produced their own specific systems for support of and involvement in research.

The question was raised if the Group could resort to any sanctioning mechanism against research that would violate a future ethics framework. In countries with a functioning government, it might be possible to take violations to court. In the case of refugees, UNHCR could take responsibility for its constituents. However, UNHCR would see an advantage in the existence of an independent body such as the Advisory Group. Other emergency situations can occur where the affected population is internally displaced and civil society has broken down. The Group should respond to the need for universal guidelines and jurisdiction, a subject the draft template does not deal with. The legal frame can only follow onto the ethics frame, which should be completed first.

Risk-benefit

The notion that benefits should accrue directly and temporally to the subjects of the study applied to the actual study participants and not to the entire population from which the study sample was taken. The next version of the ethics framework will take care to clarify this point.

Informed consent

Analogy was made between the ethics of research in mental health and in emergency settings, with a high need for investigation being countered by difficulties in obtaining informed consent. The question was raised if we should look at emergency affected populations as a homogenous group, since living conditions can be quite different. Taxonomy of situations (e.g. IDPs, besieged cities, camps) is required to deal with the key issue of implied coercion and define the conditions that change the level of coercion. Defining extreme situations of dependency is more important for studies that involve randomisation than for descriptive studies.

There are currently no “best practice” guidelines on obtaining informed consent. The non-acceptance rate for participation could be used as an indicator of potential bias. Candidate participants should be given ample time to decide. A measure of freedom and independence is hard to establish, but there is a link between stress and dependency. The basic rule is to ascertain that a subject is able to say yes or no without fearing the consequences of her/his choice. For some operational research (e.g. the introduction of a new type of cooking pot), community or family consent might be preferred.

Getting informed consent to study mental health problems, directly related to an emergency situation, can be especially problematic. As an example, the sub-group discussed the need for more evidence on the routine practice of making children draw their war experience. While drawing is an accepted intervention in an individual therapeutic environment, the (possibly harmful) effects of the same approach in a different context are unknown. Since drawing is already a routine intervention, programme evaluation or retrospective studies were recommended.

The management of sexual violence and its consequences poses similar problems. The standard counselling used in non-conflict settings may be insufficient or inappropriate in emergency situations. The different programmes set up by voluntary agencies need to be evaluated.

Choice of controls

The design of controlled trials hinges on the choice of a commensurate baseline for the population under study. When investigating a refugee population, the baseline could be an internationally accepted level of care, a local standard or that from the home country. When the treatment in a refugee setting is at a higher level than in the surrounding environment, the refugee standard should be adopted as the baseline. According to the sub-group, no research should be carried out before baseline conditions had reached the currently recommended standards for best practice. Not all group members shared this opinion.

The management of severe malnutrition was cited as an example. Though it was argued that the timing of a study depended on the chosen outcomes, participants noted that increased mortality could not be considered a valid outcome, since there is no place for phase I trials in emergency settings. Interventions for phase IV clinical trials should already have proven safety.

Confidentiality

Confidentiality should be adhered to. If a study can cause distress to the participants, institutions are needed to provide long-term support without singling them out. This is of prime importance for studies concerning human rights abuses. The Kosovo experience taught researchers that such studies should seek approval of an IRB. Participants in the study should have been told that they might feel worse by recalling events and psychosocial support should have been in place. Longer-term follow-up was also needed at various times to assess both individual and community outcomes.

The sub-group suggested that the SPHERE project could assist to develop and disseminate standards for research in emergencies. A consultation of experts was felt to be the first step needed. Action on this proposition should be taken by the Secretariat, subject to a decision on the future of the Group.

2. RESEARCH INVENTORY

The first edition of the inventory only included published research. Since publishing papers is time-consuming, it can be expected that the majority of research remains grey literature. Often, these studies have not gone through a rigorous peer review. Including grey literature would involve finding and accessing the information, triage for relevance and evaluation of quality. Although this is a complex process, systematic exclusion results in loss of information, as well as an increase in the time lapse for applying new findings.

Because of the cost of printing and distribution, the Group recommended to place an electronic version of the inventory on the EHA Web site and publicise the site map. The electronic version could then be indexed, adapted for easy searching and regularly updated. A separate section for grey literature could be added at a later stage and might include a space for readers' comments. It would also be possible to link the database to other sites providing access to full papers. However, the primary objective of the Group is to encourage more applied research.

An inventory of ongoing research should be set up, as this relates closest to the remit of the Group. Since relatively few people are active in emergency research, they could be contacted and brought together into a research fraternity. Development of common protocols would generate comparable data, providing added value to researchers. There was some discussion around the potential sensitivity of research results and possible reluctance to share data. The concern appeared to apply more to evaluation than to the bulk of emergency research. In fact, a lot of research information is already publicly available and only has to be gathered. Identifying focal points in different areas (nutrition, mental health, communicable diseases etc.) would be the first step.

3. RELATIONSHIP OF THE GROUP WITH WHO

The Group felt that WHO (EHA) should take an official role as Secretariat of the Group and transform it into an Advisory Committee. That would imply a commitment to provide human and financial resources. The committee should retain an inter-agency character though. The Group wished to remind EHA that it had been established as an attempt to strengthen the role of WHO in emergencies. The mutual role, expectations and relationship between WHO and the Group needed to be clarified, an issue to be explored before the next meeting could be held.

As for expanding the membership of the Group, proposed new members should be elected for their personal merit in the field of emergency research. At the same time they should represent a relevant institution. Links with WHO Collaborating Centres for Emergency and Humanitarian Action can be considered, provided they fit in with the specifications above.

It was resolved that Dr R. Waldman should write a letter to Dr X. Leus, Director EHA, regarding the continuation of the Group and its eventual funding.

4. FORMAT OUTLINE OF PROJECT PROPOSALS

The group aims to give technical advice, not formal approval. For example, a letter of endorsement could be provided, to be attached to a proposal. While the Group would not be able to resort to legal sanctions, it could play an advocacy role by informing sponsors or donors. Prospective researchers should get the approval of the local IRB. In situations where no IRB is functioning, WHO guidelines on how to conduct research in emergencies would be useful. Professor Golden will share with the Group the guidelines he published on how to write a research proposal. It would be worthwhile to distil some earlier Group discussions and submit them for publication.

The Group briefly discussed the required content of proposals for review. The following information was considered essential:

- Title of study; name, function and background of investigators; institutions.
- Background to the study; objective(s) or hypothesis; literature research.
- Study design and justification for the research in the proposed setting.
- Description of subjects (population, location).
- Procedure for informed consent.
- Expected or potential benefits (individual, community, science).
- Possibility to extrapolate results.
- Hazards, risks (political, psychological, other) and adverse effects.
- Anticipated cost; proposed source(s) of funding.
- Sample size; recruitment methods.
- Specimens and their management.
- Proposed statistical analysis.
- Implementing partners.
- Time frame.
- Explanatory note on definitions employed.
- Ownership of data generated, academic freedom to publish.
- Plan for publication and dissemination.

Professor Golden will prepare a draft proposal outline, with questions added under each heading and circulate it to the group members.

5. GENERAL FOLLOW-UP

The proposed initiatives would benefit from a research Web site. The main constraint remains shortage of resources. Dr Deboutte will contact Dr Nuyens at the Council on Health Research for Development (COHRED) to enquire about materials for researchers in low-income countries.

The Group proposed the week of 19-23 June 2000 as a suitable date for the next meeting.

LIST OF PARTICIPANTS

Professor M. Golden

Department Medicine and Therapeutics
University of Aberdeen
Foresthill AB9 2ZD, United Kingdom
Tel. (0044) 1224 681 818
Fax (0044) 1224 699 884
e-mail m.golden@abdn.ac.uk

Dr Etsuko Kita

Bureau of Medical Center of Japan
International Medical Center of Japan
Ministry of Health
1-21-1 Toyama, Shin-juku, Japan
Tel. 00
Fax 00
E-mail etkita@it.imej.go.jp

Dr J. Leaning

Senior Research Fellow
Harvard Center for Population
and Development Studies
9 Bow Street
Cambridge MA 02138, USA
Tel : (001) 617 495 3699
Fax: (001) 617 495 5418
e-mail jleaning@tiac.net

Dr S. Malé (Represented by Ms K. Burns)

Senior Epidemiologist
Office of the United Nations
High Commissioner for Refugees
P.O. Box 2500
1211 Geneva, Switzerland
Tel (0041) 22 739 8407
Fax (0041) 22 739 7371
e-mail male@unhcr.ch

Dr C. Paquet

Chargé de mission
Institut de Veille Sanitaire (INVS)
12 rue du Val d'Osne
94415 Saint Maurice, France
Tel (0033) 1 4179 6847
Fax (0033) 1 4179 6790
e-mail c.paquet@invs.sante.fr

Dr P. Perrin

Chief Medical Officer
International Committee of the Red Cross (ICRC)
19 avenue de la Paix
1202 Geneva, Switzerland
Tel (0041) 22 730 28 10
Fax (0041) 22 733 20 57
e-mail pperrin@icrc.org

Dr J.-P. Revel

Senior Officer, Relief Health
International Federation of Red Cross
and Red Crescent Societies (IFRC)

P.O. Box 372

1211 Geneva 19, Switzerland

Tel (0041) 22 733 03 95

Fax (0041) 22 730 44 38

e-mail revel@ifrc.org

Dr M. Toole

Medical Epidemiologist

International health Unit

Macfarlane Burnet Centre for Medical Research

Yarra Bend Road

PO Box 254, Fairfield, Victoria

Australia 3078

Tel (0061) 3 9282 22 16

Fax (0061) 3 9482 31 23

e-mail toole@burnet.edu.au

Dr R. Waldman

Director, Program on Health Consequences
of Forced Migration

Columbia School of Public Health

60 Haven Avenue-B2

New-York NY 10032, USA

Tel (001) 212 304 52 19

Fax (001) 212 305 70 24

e-mail rw178@columbia.edu

WHO participants :

Department of Emergency and Humanitarian Action (EHA)

Dr D. Deboutte

Tel (0041) 22 791 2546

Fax (0041) 22 791 4844

e-mail deboutted@who.int

Ms A. Shah

Tel (0041) 22 791 2740

Fax (0041) 22 791 4844

e-mail shaha@who.int

Dr M. Thieren

Tel (0041) 22 791 4626

Fax (0041) 22 791 4844

e-mail thierenm@who.int