

Research ethical challenges in cross-disciplinary and cross-cultural health research: the diversity of codes

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ABSTRACT

The scope of health research has increased considerably during the last three to four decades, both geographically and regarding the range of disciplines participating in biomedical research. In other words cross-cultural and cross-disciplinary projects are much more common in the World's biomedical research of today. For the large part that involves human research subjects, ethics based on fundamental human values is still an integrated part of project planning and management. However, in the light of the increasing complexity of research, the controlling codes (i.e. laws, declarations, conventions and guidelines) have undergone important changes and have increased considerably in numbers. Hence, groups from different disciplines and cultures need to adjust their projects' research ethical policies and implementations in accordance with the various codes' common denominators. Sometimes research ethical codes are even incompatible at certain points.

The article describes key ethical aspects of cross-cultural and cross-disciplinary projects, with special emphasis on acquiring consent, avoiding harm, attending to needs, and describing the obligations when a project is over.

On this background the authors conclude that researchers in the planning phase of a project should: 1) seek knowledge and professional advice related to the transgression of cultural and disciplinary borders, 2) introduce a long-term perspective for a project's activities and consequences, and 3) select the appropriate among the existing many ethical codes. These suggestions apply to several stakeholders: researchers, scientific societies, agencies for scientific support, information and ethical control, as well as research political agencies.

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INTRODUCTION

For nearly 40 years the Declaration of Helsinki has been the backbone in ethical standards for biomedical research involving humans. Although the Declaration is still very central, a large number of codes (i.e. laws, conventions, declarations and guidelines) have been published to further guide researchers, donors, sponsors and research policy agencies. However, the number and the diversity of ethical codes and the increasing amount of dilemmas appearing, especially in cross-disciplinary and cross-cultural projects, warrant some clarification. The general trend is that no code is capable of covering all ethical aspects. Consequently it is necessary for the scientific community to discuss how to rank the existing codes, when the ethics of cross-disciplinary and cross-cultural projects are planned or evaluated. The present article aims to give an overview of the relevant ethical codes and raise some key questions.

RESEARCH ETHICS

Ethics in research has two main components – research ethics and the researcher's ethics (i.e. the scientist's personal honesty). Only the former will be dealt with here. An analytical discussion necessitates a contemporary, semantic definition of ethics instead of still frequently appearing etymological pseudo-definitions of ethics as "being derived from Greek 'ethos', meaning the good life". The semantic

definition applied here is: "Ethics is an overall term for the immaterial values, norms and attitudes, which are prevalent in a country or a culture and which lie behind the country's or culture's concepts of main ideals, the derived laws and other codes, and which ideally determine citizens' personal lives, their relationships to each other and the legal and private institutions of their society" (1).

In a global perspective, ethics also includes a responsibility for the ecological balance of the planet Earth, its soil, water and air, and the diversity of its flora and fauna (1). Most important constituents of this definition and its use for comparative, definitory purposes are the immaterial values (e.g. solidarity with fellow men, equality, justice, truth, responsibility, freedom and professionalism). The weighting of these and other immaterial values can differ between countries and cultures. But as reflected in the Convention of Human Rights, several are so fundamental that they are not negotiable. Other values reflect a less fundamental cultural diversity and consequently it will be easier to find a common denominator on such issues. The basic principle for transnational, ethical negotiations is the demand that the participating countries must agree, and consequently, that each of them has a right to veto. In a longer perspective it is still the aim to promote ethical convergence between different cultures' and countries' notions on the values behind research ethics, for instance on such complicated matters as right to autonomy and related gender differences.

CROSS-DISCIPLINARITY

Though most research is still mono-disciplinary, research involving more than one discipline has become more frequent during the last few decades, and has widened the spectrum of innovative research. Cross-disciplinarity defined as research comprising different, formalized specialities has posed a number of challenges for the researchers themselves. Those who ventured into cross-disciplinary research have had to find compromises regarding study designs and methods for data collection and analyses as well as divergent emphases on theoretical frameworks (often based on different paradigms) – challenges which have been overcome with varying degree of success. However, the systems that serve as infrastructure for cross-disciplinary research activities have developed in mono-disciplinary environments. Thus, there are some additional constraints for cross-disciplinarity: 1) The career structures of most disciplines are basically based on mono-disciplinary advancements; 2) funding is mainly provided by research agencies that are if not mono-disciplinary then confined within traditional delimitations of for example natural or social sciences; 3) evaluation is mostly based on mono-disciplinary criteria; 4) the choice of journal for publication (preferably in prestigious journals many of which are mono-disciplinary) and the different publication preferences (e.g. whether a discipline favours monographs with one author or smaller articles with many co-authors) constrain cross-disciplinary publishing (2, 3).

CROSS-CULTURAL ASPECTS

Culture as a term has been encircled in countless definitions. Here only its immaterial constituents are considered leading to the following definition: Culture is the sum of immaterial values, beliefs and conceptual patterns which influence the spiritual and practical life of a group of people or a dominant part of a whole nation. Cross-cultural relationships can be found within multi-ethnic nations or between countries each with their dominant culture, as for example in collaboration between researchers from developing and developed countries. Ethical standards vary significantly between cultures as a result of differences for instance in history, religion, ethnicity, economical situation and traditions.

RESEARCH ETHICS AS PART OF RESEARCH PLANNING AND EVALUATION

The visibility of the main components of research ethical standards in projects is necessary both as a framework for the planning of a

project and as a checklist for the evaluation of a project's results in manuscript form, for instance for editors, peer reviewers, readers and board members of scientific committees. Irrespectively of disciplines, the main components applying to projects are:

1. The originality of the scientific idea. In some cases (e.g. drug trials) projects repeating published information do not add to the global sum of knowledge or to professional standards. However, repetitive research may be warranted in situations where a set of new, paradigm transgressing results needs a few confirmatory studies in order to avoid a type 1 error in the first study or in order to study the same topic within a different socio-cultural or ecological context at different points in time. Expressed in ethical terms: unoriginal research involving humans is not ethically acceptable, even when it is without risks for the participants, because the results do not yield new, generalizable knowledge in return for the participants' altruism or hopes.
2. The appropriateness of the chosen methodology and the researchers' competence to conduct the research. Inappropriate methodology and/or researchers' incompetence make projects involving humans unethical.
3. The consideration of the potential benefit for the participants, for instance in controlled trials based on comparisons between two groups. In cases of studies involving only healthy volunteers which are primarily based on altruism, special security measures must be applied to balance the scientific benefit.
4. The presence of measurable and controllable risks related to the intervention needs to be judged against risks related to spontaneous courses of diseases or circumstances of daily life.
5. The perspectives for implementing results to larger groups of patients or whole populations, after the research is over.

If these scientific and potential health policy questions are answered satisfactorily, the planning and evaluation proceed to the following ethical points:

1. The respect for participants as individuals should be expressed in the form of true and understandable information, right to autonomy, freedom to reply positively or negatively without any direct or indirect reprisals, right to leave the project at any time, right to be offered information about the results when the research is over and to be advised on the importance of project results for the individual participants.
2. The respect for members of a community must be shown as respect for immaterial values in the participants' society.

For cross-disciplinary and cross-cultural projects the ethical challenge for collaboration between researchers consists in respecting each other's expertise and knowledge in a non-hierarchical way and to include all discipline related ethical codes in the overall ethical judgement.

The cross-cultural challenges are obviously most important for researchers working outside their own cultures. They will be addressed here though not in a form accompanied by detailed solutions. They comprise:

1. Consent as a special issue in relation to gender. In countries or cultures with male dominance in families and society, obtaining informed consent from women needs cultural knowledge. The aim should be to find a balance that represents a step towards equality without trying to introduce drastic changes over night. Familiarity with the codes covering this aspect is very important (4). The same applies to getting consent from children in cultural setting where adults (including the children's guardians) hold strong authority. Also here existing codes or advisory guidelines might be of help (4).
2. Avoiding harm, and comparing risks to potential benefits, is cen-

tral for all kinds of research ethical codes. The challenges for researchers working outside their own cultures differ from cases where all parties belong to the same culture. In addition, asymmetrical power relations may play a major role. Ways of dealing with vulnerability and avoiding exploitation is also dealt with in existing codes and advisory guidelines (4-8).

3. Attending to needs, either related to the project or independent of it has to be considered already in the planning and budgeting phase. Needs related to the project will have to be covered by the research team. This obligation constitutes a common ideal irrespectively of discipline (natural science, social science or biomedicine). Needs occurring to members of the study population which are unrelated to the project (e.g. incidental events such as diseases, 'disasters' or strong social needs) must be taken seriously and, as far as resources suffice, referred to relevant authorities in the study area if they cannot be dealt with and covered by a budget allocation for such unpredicted events. Such provision for 'emergencies' has to be decided upon during the planning phase and must be part of the information to participants.
4. The ethical obligations when the project is over are a part of project planning that are often left out. This may lead to local disappointments, researchers' frustrations and may become a burden for granting bodies. The challenges have to be met in the planning phase, answering such questions as: Will any participants directly or indirectly be informed about the results and the consequences for themselves? Will participants be offered the best of the two interventions tested against each other, and if so when and for how long time? Which are the perspectives for the scientific community or the various stakeholder groups in the recipient country? Will equipment be left for future use in the recipient country; and will technical competence and possibilities for maintenance be present?

THE DIVERSITY OF CODES AND THEIR APPROPRIATENESS FOR CROSS-DISCIPLINARITY AND CROSS-CULTURAL PROJECTS

The number of ethical codes (here applied as an inclusive term for legislation, conventions, guidelines and declarations) comprising basic ethical principles and types of public control is rapidly increasing. This development can be considered a positive trend judged from its effect as eye-openers for the ethical aspects of all research involving humans. But on the other hand the many existing, uncoordinated codes which are either national or international, legally based or advisory by nature, and which link to either specific disciplines or are generally applicable, have created a confusing picture for researchers. This is the case in national, mono-disciplinary projects, but the complexity becomes much greater when diversity of cultures and disciplines is added. As a point of reference for active researchers dealing with cross-disciplinary health research, the most important codes will be commented below, with emphasis on their general relevance and the pros and cons for their dealing with cross-disciplinarity and cultural diversities.

The World Medical Association's so-called Helsinki Declaration (9) has had a strong impact on biomedical scientists' concepts of and respect for research ethics. But in spite of the profound changes of the disciplines involved in biomedical research during the past 25 years, the methods and the levels of variables applied in the latest version from the year 2000 still have medical doctors as the main target group and do not sufficiently deal with cross-disciplinarity. Neither does it adequately address the geographical globalization of biomedical research. On the contrary its paragraphs 29 and 30 can be read in a way that might exclude research in developing countries with the aim of testing less expensive interventions than those accessible in the World's most affluent societies. Likewise, the Declaration's demand can also have a negative effect as participants after a trial are assumed to get access to the best proven intervention, irrespectively of time perspectives, economy and necessary local infra-

structure (10). Accepting the Declaration's shortcomings, the principles involved can still be inspiring for biomedical research involving humans.

UNESCO has issued a Universal Declaration on the Human Genome and Human Rights (11) comprising the research aspect of human genetics. The Declaration is very relevant to genetic research in developing countries, involving scientists from developed countries, and has a wide disciplinary perspective.

In 1999, the World Health Organisation published its International Guidelines on Bioethics (12), which contain a comprehensive list of selected international codes, declarations and guidelines on issues such as medical ethics, bioethics, health care ethics and human rights aspects of health – issues which are also reflected in WHO's own ongoing work with research ethics.

For HIV preventive vaccine research, UNAIDS has published a guidance document (13).

Turning to the European scene, up to now the initiatives of the Council of Europe/European Union have had an increasing impact on the World's scientific communities. Central is the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine: Convention on Human Rights and Biomedicine (5, 6). The Convention is in accordance with today's globalised biomedical research and is not restricted to medicine as such, but centred on patients. Furthermore, it is not restricted to the European member states, but comprises in principle also European states' cooperation with countries outside Europe, whether signatory states or not. A supplement to the Convention is a so-called Protocol (a judicial term for an additional legal document) entitled: Draft Additional Protocol to the Convention on Human Rights and Biomedicine on Biomedical Research. This new Council of Europe document (7) and its Explanatory Report (8) which are to be published in 2003 describe in detail the implementation of basic ethical principles of the Convention to today's biomedical research. Like the Convention it comprises all disciplines, which work scientifically with patients, and it specifically mentions research in countries not party to the Protocol (§ 31). When dealing with clinical trials on drugs for human use, scientists from member countries of the European Union are obliged to follow Directive 2001/EC (14) also under conditions including 'third countries'.

The attitudes and rules applied by the USA are reflected in the National Institute for Health's (NIH) guidelines for the Conduct of Research Involving Human Subjects at the NIH (15) covering all research sponsored by the USA, even when carried out elsewhere. Other American guidelines are expressed in the US National Bioethics Advisory Commission's Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries (16). The latter report draws attention to situations where such research creates dilemmas: "Such controversies are perhaps most likely to occur when the nations involved do not share the same cultural, economic, political and ethical perspectives or when they are at different stages of development".

The Council for International Organisations of Medical Sciences (CIOMS) has just published its revised version of International Ethical Guidelines for Biomedical Research Involving Human Subjects (17) which also deals rather extensively with research in developing countries.

Probably the most relevant, advisory document on ethics of transnational, cross-cultural and often cross-disciplinary research with focus on developing countries is the comprehensive report and the derived recommendations of the Nuffield Council of Bioethics Working Party (4). The cross-cultural perspectives point especially to the importance of early and later peri-project involvement of relevant social scientists (e.g. anthropologists or sociologists) taking into consideration such topics as: religion, family structures, societal and political diversities and especially conceptual differences in donor and recipient countries' views on autonomy, use of placebos and methodological 'blinding'. The imbalance between developing and

developed countries' economic resources and health infrastructures is mentioned with an emphasis on non-exploitation, and the moral necessity of including some degree of capacity building in the recipient country. Furthermore, the question is raised as to what is done when the research is over, and a case is made to accept the principle that control groups sometimes can be treated with the best attainable standards of the national health service of the developing country, and not the best anywhere in the World.

As an example of important, internal, ethical guidelines for non-medical disciplines, with a projective perspective for transnational applications, codes for anthropologists are very illustrative. Such an example is the Code of Ethics of the American Anthropological Association from 1998 (18, 19). This very comprehensive code deals with all aspects of anthropology, including animal and archaeological research. Research with human beings is comprised meticulously in the Code's chapter three, ranging from fieldwork to responsibility for both scholarship and the public. It also includes a reference list of other, global, primarily US codes of relevance for anthropological research.

CONCLUSION AND RECOMMENDATIONS FOR THE STAKEHOLDERS

The four relevant categories of stakeholders involved in research planning and evaluation are: A) researchers, B) scientific societies, C) agencies for scientific support, information and ethical control, and D) research policy agencies. The recommendations of the present article for these relevant groups are (with relevant target groups marked in parentheses):

1. Mutual knowledge and respect are a necessary basis for cross-disciplinary research cooperation. Avoid a hierarchy of cooperating disciplines' importance (A, B).
2. In cross-cultural projects seek professional advice from relevant social scientists (e.g. anthropologists or sociologists), if these disciplines are not represented in the project group itself (A, B, C, D).
3. It is an integrated part of the planning process to consider issues that might occur during and after the project period and to consider the potential consequences of the scientific results (A, C, D).
4. Include the aspect of capacity building in cross-cultural and transnational projects (A, C, D).
5. Rank and select the codes to be considered and respected in the planning phase of a project and which can be referred to while the study is running (A, B, C, D).

At a more general level, the following principles can guide:

1. Respect laws and guidelines of both the recipient and the donor country, especially when fulfilling the demand for acceptance of a project in research ethical control agencies on both donor and recipient side.
2. Confer with international, authoritative codes comprising all represented scientific disciplines (4- 8, 11, 13).
3. Seek inspiration for research ethical analyses and decisions in international, high quality guidelines and recommendations (9, 15, 16, 18, 19).
4. State the codes applied in the research project and in resulting publications.
5. Remember that ethical codes do not always give clear answers to ethical dilemmas. Rather do they serve as points of reference based on which the researchers have to make sometimes difficult, individual choices.

In this paper we have given an overview of the multitude of ethical codes which are relevant to health research. With focus on cross-disciplinarity and cross-cultural aspects we have furthermore outlined

some of the pertinent questions relating to project planning and evaluation. We hope that this overview will lead to continued dialogue among relevant stakeholders and that more research teams will venture into the field of cross-disciplinarity and cross-cultural research.

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