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Research ethics and the problem how to teach it

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European researchers and members of ethics committees feel the need to improve *Good Scientific Practice*, to ensure *the protection of human subjects* in clinical trials and to evaluate *consequences of research.* To enhance the current situation, a focus on the process of training and training materials in research ethics is desirable. Since the complicated moral issues of research, often divergent, cannot be addressed solely by an individual judgement based on a mere natural intuition. If the moral consciousness of the researcher is supposed to enable him to perceive and evaluate his actions adequately, special training is required to attain the perceptive sensitivity for possible conflicts and the conceptual clarity for possible solutions. Based on the reflection on the structure and items of research, ethics results of a European study are introduced and elements of a European core curriculum for teaching research ethics are proposed.

The paper aims at reviewing and comparing the existing training materials on research ethics in Europe, the USA and Canada. It also proposes different modules of research ethics training for the members and secretariat of Research Ethics Committees. The paper emphasises the urgent need to establish a European curriculum in research ethics reflecting a common understanding of the field in Europe.

Key words: research ethics, misconduct, informed consent, training materials, core curriculum research ethics, conflict of interests, conflict of principles, ethos of research

INTRODUCTION

As an expression of human reason, research as a necessary condition for the advancement of science must be assessed for its intrinsic value as well as for the individual and societal merits of its application. Both the actual research itself and the application of its results can be linked with morally problematic aspects. This was most clearly revealed by historical experiences with serious violations of the rights of research subjects and the undesired side effects of some technical inventions. Both representatives from political circles and the scientific community itself have reacted to these experiences with a number of official regulations and internal codes, recommendations, etc. More recently it has become obvious, however, that the problem can only be partly addressed by regulations of this kind with a more or less binding character.

Looking at science and research in general, the institutional goal of science and research is the extension of certified knowledge. The normative professional standards derive from the goal and the methods of science and research. The entire structure of technical and moral norms implements the final objective. Sets of institutional imperatives comprise the 'ethos' of modern science. In coming to terms with the ethical and legal problems associated with modern scientific research and its application, scientists themselves play an important role: they bear the responsibility for observing internal scientific standards, they have to think about the aims and consequences of their research measured against the yardstick of the relevant ethical and legal criteria, etc. Only when the scientists fulfil these tasks competently and responsibly, will research be able to count on the necessary trust in the long run and public acceptance of research will be engendered. The fulfilment of the ethical responsibility of researchers takes place in broad areas in the form of the scientists themselves voluntarily observing professional commitments (codes) and standards. For this self-observance, the scientists and researchers have to reflect their ethos.

Therefore, the individual researcher himself must be aware of the moral dimensions of his actions. Four main reasons can be identified: firstly, it is the best way to implement at least part of the necessary ethical evaluation within the research process itself and thus to ensure that this evaluation takes place "in time", i.e. at an early stage rather than having to deal retrospectively with emerging problems that should have been prevented at an earlier stage. Secondly, it is the best way to

identify new problems and, by extension, to initiate their necessary reflection by the public and by political actors as well as by experts from the fields of ethics, law, sociology and other areas. Thirdly, it helps to prevent research ethics from becoming a one-sided control system in which the researcher will eventually feel that he / she was under permanent external surveillance and maybe even suspicion. Fourthly, it reflects in a most adequate way that a moral and ethical judgement is by its nature an internal element of practical judgements in general and in the area of research in particular.

Yet, the often divergent and complicated moral issues of research cannot be addressed solely by an individual judgement based on a mere natural intuition. If the moral consciousness of the researcher is supposed to enable him to perceive and evaluate his actions adequately, special training is required to attain the perceptive sensitivity for possible conflicts and the conceptual clarity for possible solutions. The need for training in research ethics has been clearly acknowledged both by political bodies and by the scientific community. Workshops and projects supported by the European Commission, the Council of Europe, UNESCO and others recognise this need. In the 2001 *Science and Society Action Plan* (Action 31) of the European Commission it is explicitly stated, "Model courses and training modules will be developed in order to raise the awareness of researchers in the field of ethics".

MATERIALS AND METHODS

The paper provides a very detailed description and interpretation of training programs in research ethics using the data of the EC-Study on European Training Materials and other world-wide relevant resources. A comparative analysis of different European and American training programs in research ethics as well as an analysis of the concept of research ethics is presented in the paper. The author also proposes a different core research ethics training for the members and secretariat of Research Ethics Committees.

RESULTS AND DISCUSSION

1. What is *Research Ethics* about?

Research ethics can be considered to be an area of applied ethics in which a) research in general, b) research in individual research areas or c) specific problem constellations spanning several research areas are addressed from the ethical perspective.

a) Research ethics as ethics of research in general

Research ethics as the ethics of research in general encompasses above all the question about the appropriate ethos of the scientist or the formal preconditions for ethical research (duty of care, honesty when handling data, exclusion of fraud and misconduct, etc.) but also the question about the appropriate position and importance of science in research in the overall system of a pluralist society.

b) Research ethics and the ethics of individual research areas

Reflection on research ethics has emerged above all in the field of medical and, more particularly, clinical research. Furthermore, special attention is given to research in animals which is taken into account in the framework of research ethics. Finally, research ethical concepts are developed in conjunction with research in the life sciences, engineering sciences and technology development (biotechnology, information technology and information sciences).

Research ethics in the area of human medical/ clinical research. Research is an integral part of modern medicine whether it be with respect to problems as yet unsolved in prevention, diagnosis or therapy or with respect to the necessary quality assurance for preventative, diagnostic or therapeutic methods already in use. Ethical questions are raised above all when this research involves humans. The questions raised with regard to suitable protection of test persons are very diverse. They concern above all problems of risk assessment, informed and voluntary consent of the test person as well as privacy and data protection. Some of these problems are even more acute when the test persons belong to so-called vulnerable groups (children, psychiatric patients, prisoners, etc.) or when research in humans is conducted in so-called developing countries.

Research ethics in the field of research with animals. Another wide area of the debate on research ethics touches on animal welfare in conjunction with experimental research in medicine, pharmacology and the life sciences. Against this backdrop, it is mainly the key words "respect for the animal's ability to suffer", "animal rights", "dignity of the creature" and "risk-benefit analysis" which are discussed in conjunction with the various moral philosophical approaches in the field of animal ethics like anthropocentrism, pathocentrism, biocentrism, physiocentrism or holism.

Research ethics in the field of the environmental sciences. The research ethical debate in the field of environmental sciences focuses less on environmental research itself and more on research in different areas of science which are of ecological relevance because of the use of corresponding techniques in research or applications. This applies in particular to the engineering areas of energy and construction, but also to biotechnological and genetic engineering applications and research. Whereas in the field of construction discussion focuses primarily on applications, when it comes to energy issues or questions about fundamental research in the field of biotechnology and genetic engineering it is the research orientation as a whole which is up for discussion. Should there be any research at all in the field of nuclear energy when the research reactor may already constitute a potential threat to man and environment? Which ecological or health risks are linked, for instance, to genetically modified organisms in the research laboratory or field experiments?

Research ethics in the field of the engineering sciences. A series of engineering schools in the USA offers courses in ethics. In these courses the focus of discussion is less on research than on the (possibly ambivalent) application of its results and the general life world and anthropological importance of technology. The situation here reflects the fact that application-related disciplines like the engineering sciences (above all those with safety risks and the potential for abuse) were quick to develop specific professional ethical attitudes and standards. However, in the debates the question which is playing a repeated and an increasing role is whether and, if so, to what extent fundamental research does not already bear responsibility for the research results and their application. After all, fundamental research is a basis on which application-oriented research builds. Furthermore, it is increasingly being undertaken in close co-operation with potential application areas.

Research ethics in the field of the information sciences. In the field of technical information research, the emphasis is primarily on data security and protection of the private sphere and also on the consequences of technical innovations against the backdrop of the structures and functions of social and cultural communication. Here, too, it is the applications which are discussed and less research itself. The questions debated here about data protection and data security also touch on other questions in areas like, for instance, medical research.

c) Problem constellations which span several research areas

Conflict of interest. As a rule, research is borne and accompanied by a large number of different, possibly conflicting, interests be they scientific, economic or social, be it the interest of individuals or groups. In medical / clinical research, for instance, and by extension in the area of responsibility of clinical ethics committees, a distinction can be made among the following types of conflicts of interest:

• trials may improve the health of the society but might damage the health of the individual subject who is involved in the trial

• trials may have scientific results – especially in the case of drug trials – but could damage the health of the human subject

• trials may have economic results – especially in the case of drug trials – but could damage the health of the human subject

• several institutions with different interests (industry, associations, different clinical departments) might be involved in the same trial, triggering a fundamental clash among concerns.

• Solving of conflicts of interest of this kind is a central problem of research ethics.

Conflict of principles. Research ethics reflect on scientific research from an ethical angle. Since ethical principles of a different kind are brought into play here – individual ethical principles like autonomy, psychophysical integrity and confidentiality, socio-ethical principles like distributive justice, promotion of the *bonum commune* and protection of minorities as well as ethical principles of factuality and truthfulness, transparency and efficiency – principles of relevance in the individual case may come into conflict with each other. One of the most cited examples for such conflict in the area of medical / clinical research is the conflict between the ethical principles which govern scientific research as a methodological pattern (in which the participant is an 'object' of investigation) and the principles involved in an individual physician–patient relationship or have to be respected as individual rights. How has, for instance, the "right to know" and the "right not to know" to be respected if one result of a study could be the accidental investigation of a disease which the subject in trial was not aware of befores. Is there a right or even a duty to inform the "subject" as a "patient", although he has not given his prior consent? The problem of a possible conflict of principles is, therefore, one of the central problems of research ethics.

Problems and conflicts of multinational / multicentre research. In many ways research is not a national matter, but is undertaken on an international level. Research results are internationally received and may be applied in countries other than those in which they were generated. This leads to problems when it comes to different ethical, legal and scientific standards, for instance, when research is financed from EU funds which, however, is not legally permitted in the country of a member of the research consortium. Questions of multinational / multicentre clinical trials are particularly intensively discussed when they touch the problem of which ethics commission's vote is to be valid and according to which standards decisions are to be taken. The different standards raise important questions: Is there one "Ethics all over the world?" Are there shared ethical principles? How large is the gap between the different moral and legal traditions on the one hand and shared basic ethical objectives on the other? What are the criteria for the decision-making process and how are the guidelines used as references? Where is the standardised overall methodology for an ethical review?

Responsibility and multidisciplinarity of ethics committees. The ethical reflection on research enjoys growing support from ethics committees. This development can be observed above all in the area of medical or clinical research but also in other areas of research. In this context, it is not only the researcher himself who is responsible for the "moral quality" of his research but, at the same time, each member of the ethics committee who is responsible for monitoring the "moral quality" of this research. The exact nature of this type of responsibility is another important question for research ethics. Another issue has to be considered: Members of ethics committees often come from diffe-

rent scientific disciplines like medicine, environmental science etc, others are lawyers, philosophers, theologians or are educated in the social sciences. What kind of education do the members of ethics committees really need regarding the ethical questions they have to decide upon? Do physicians need an education in ethics and philosophers in medicine? These questions are also being increasingly discussed in research ethics.

2. *Training Material* for Ethics in Research: A European Study (1)

To educate and train students and researchers, training material for research ethics is necessary for teachers. The German Reference Centre of Ethics in the Life Sciences reviewed different kinds of training material for research ethics in Europe in a EC-Study on European training materials. The main training material for ethics in research compiled within the framework of this study is material which, in terms of its objectives and / or didactic form, *explicitly* appears as training material for ethics in research for non-philosophers (but not as a general investigation on the subject of research ethics). It can cover research ethics in general or a special kind of research ethics within fields of application like medicine, engineering, biotechnology, etc. Furthermore, material was also taken into account which is not training material either in the above sense, but which contains important reflections of the sociological, psychological, curricular or didactic nature with respect to the teaching of research ethics and could be of use in particular for lecturers. These published materials present experiences with teaching and didactical concepts to help teachers to teach research ethics.

In this context, training material can take on many different forms, for instance:

- Book (textbook, handbook, conference proceedings, etc.)
- Article (taken from journal, taken from book, etc.)
- Online material
- Collection of slides, transparencies, PowerPoint files, etc.
- CD-ROM, or
- Web tour.

a) European Training Material for Ethics in Research

Material which, irrespective of its origin, is used *de facto* in Europe could be deemed to be "European" training material. This, however, would mean that the spectrum of potential material would be too broad, because it would potentially include any material used in Europe; at the same time the term "European" would lose any differentiating function.

Secondly, material could be classified as "European" if in terms of context it reflects a possibly specific "European" approach, a specifically "European perspective" or specifically "European principles". Even if it is not easy, for instance, to distinguish between an "American approach on research ethics" in contrast to a "European approach on research ethics", typical differentiations of this kind are occasionally used in the expert literature. For instance, when it comes to the ethics of medical research, a distinction is seen between the "American" and the "European approach". The former followed more the so-called "four principle way" concept – respect for autonomy, non-maleficence, beneficence, justice (cf. Beauchamp / Childress) (2) – whereas the latter was based more on the concept of "human dignity" as a very central and crucial concept and on principles like "integrity" and "solidarity". This can be found, for instance, in the Convention of Human Rights of the Council of Europe (3) and the Charter of the EU. Furthermore, it is pointed out that these studies play a more crucial role within the Anglo-American approach where ethics and law are closer together and the legal system is a case law system. However, these distinctions are rather a tendentious classification which would require closer examination in individual cases. On the other hand, the American or Anglo-American approach is acknowledged in continental Europe as is the European approach in the Anglo-American area. Furthermore, concepts like "autonomy" or "person" tend to be interpreted differently even within Europe itself, or to be more precise, between Great Britain and Continental Europe. Europe is home to a great diversity of variant cultures, traditions and languages. They are the foundation for a similar diversity of moral (unofficial) and legal (officially binding) regulations which make up the set of different legal systems. For these reasons a pragmatic solution has been chosen and the term "European" is defined with regard to the authors and their distinct affiliation to institutions in the target countries.

b) USA / Europe Divide

Compared to the situation in the USA, the volume of *European* training material ("Training Material for Research Ethics") found within the framework of the mentioned study is considerably smaller (especially when it comes to easily accessible resources like the World Wide Web). Apart from the generally different nature of the scientific and university culture, other reasons for this difference could be

- the well advanced tradition in the USA of including elements of professional ethics in the curricula of various disciplines (*e.g.*, business ethics, clinical ethics); as a consequence, there is a long established development of corresponding manuals and materials;
- bioethics, which has developed intensively since the late 1960s and has led to the establishment of regular professorships for medical or clinical ethics at almost all medical schools in the USA and to the anchoring of this discipline as a compulsory element in the curricula of medical schools (and also in the curricula in courses like nursing and related areas);
- the liability law practiced in the USA prompts professionals to adjust their actions strictly to applicable rules and regulations.

c) West / East Divide

Within the European training material identified, the western European far outweighed the eastern European. Among the western European training material, the British, Scandinavian and German material forms the biggest group. The reason for the greater number of western European material is probably due to the fact that research ethics is far less developed as a discipline in its own right in eastern European countries and is often restricted to the local initiatives of individual researchers. Where research ethics is taught, reference is frequently made to US-American or to western European material.

d) Prevalence of Specific Research Ethical Issues

No training material could be found that covers all subjects of research ethics. Instead, there are often individual areas (medical ethics, environmental ethics, etc.) or individual aspects (informed consent, privacy, minimal risk, etc.) which form the focus. This result is not surprising since research ethics is usually taught within a teaching framework concerning a special application like medicine or biotechnology.

e) Areas and Issues Touched upon

The dominant subjects in the training material are those which refer to an ethical assessment within the framework of human medical and / or clinical research. What is particularly noticeable here is the subject of human experimentation and the extensive treatment of issues in conjunction with autonomy, respect, informed consent, subjects unable to consent, the role of representatives and reference to the national and international laws and codices which are also binding for clinical research. This is not surprising, because medical ethics is the most developed of the professional ethics and can look back on a long tradition which began with Hippocrates. This is also due to the fact that clinical research is very highly regulated, because of the high risk potential for the test persons. Even those European countries in which there are no or only few regulations in this area are bound by European or international regulations. Hence, training for students and researchers in the areas of the life sciences and medicine and for members of clinical ethical committees is of great practical importance.

All other areas of research ethics are touched upon far less frequently. The most frequent of these is the ethical assessment of animal experimentation. Ethical questions with respect to the information sciences were very rarely touched upon in the material evaluated. In the case of environmental sciences and the new nanotechnology listed in the Call of the European Commission, no training material could be identified concerning the area of research ethics.

In the literature, increasing attention is paid to the subject of ‘good clinical practice’ and ‘good scientific practice’. Experiences with unethical research activities, falsification of data or risky experiments have led to pick up the issues of research ethics in general (ethos of the researcher) and also to the elaboration of regulations. This is equally reflected in the training material, some of which deals in a very general way with research ethics and only touches on disciplines in an exemplary manner. This also applies to the subject of the very position of the sub-system science in society.

What is noticeable, particularly in comparison with US-American training material, is that in European training material the theories of ethics (metaethics, different ethical approaches, etc.) are dealt with in a very comprehensive manner in order to facilitate their discussion in class. Emphasis is frequently given to highlighting the differences, for instance, between utilitarian and deontological approaches.

f) Target Groups

The target groups could only be identified when they were explicitly mentioned in the material. In this study, no examinations could be made of the question as to who were the target groups if there was no explicit mention of them in the material. The vast majority of the identified training material is intended for students in the later stages of their university studies, particularly in the areas of medicine and the life sciences. Apart from students in the individual disciplines, the main target group consists of members of ethics committees who are to be attracted to the training material and for whom training material is provided. What should not be underestimated is the material which is provided for teachers and which is classified in the study as Material on Teaching Research Ethics. This type material indicates a wealth of teaching experience which is already available.

g) National Background

The identification of the national background proved particularly difficult within the framework of this study. For instance, English-language training material cannot simply be classified as “British training material” or German-language training material as “German training material”, because English-language training material is also developed by Dutch or Swedish and German-language training material by Austrians or Swiss nationals. The origin of the author does not necessarily lead to conclusions about the national character of the training material either. Authors of South African or Danish origin work, for instance, in the United Kingdom or Austrians in Germany. Furthermore, the language indicator is particularly poorly suited to establish a national reference, because there are many translations into other national languages.

3. Comparison with the US Training Material for Ethics in Research

a) Dominance of American material

When comparing the availability of US and European training material in research ethics, there is a striking dominance of US-American material. Not only are most of the basic and standard books (also used in Europe) of US-American origin, US-American universities and

specialised institutions, in particular medical and engineering schools, also run an impressive array of courses for students and professionals in the field, many of them web-based using state-of-the-art technology.

One of the best examples of excellent training material in research ethics is the Research Ethics Training Curriculum for international scientists, prepared by Family Health International (FHI) with most of the material available for interactive training on-line. The material is available in English, French and Spanish. As indicated by the authors, there is a need to fill the gap in European developments of material of this kind. The material covers very high standard didactic criteria (5).

Also worth mentioning is the "Institutional Review Board Guidebook" (6), which was prepared after the President's Commission for the Study of Ethical Problems in Medicine, and Biomedical and Behavioural Research expressed the need to provide training for members of IRBs. In its 1981 report, "*Protecting Human Subjects: The Adequacy and Uniformity of Federal Rules and Their Implementation*", (7) the Commission stated that it "is clear that researchers and IRB members desire help both in understanding the policies and principles that underlie the regulations governing research with human subjects, and in identifying the issues to which one should be sensitive in designing or reviewing research proposals". The Guidebook is not designed to tell IRBs whether or not specific protocols should be approved (unless the regulations specifically prohibit the proposed activity or method). It does point out issues to which IRBs should pay attention and presents, wherever possible, areas where ethicists and others concerned with these issues have arrived at a consensus on the ethical acceptability of a particular activity or method (*e.g.*, in clinical trials, the use of placebos where a standard therapy is available). The Guidebook is also intended as a tool that will serve as the focal point for the human subjects work of IRB administrators and members. In loose-leaf format, the Guidebook includes the regulations, relevant institutional documents (*e.g.*, the institution's assurance and operating policies and procedures), and relevant forms. In addition to the text dealing with specific topics, the Guidebook contains a glossary of terms and a bibliography of sources. The loose-leaf format permits the Office for Protection from Research Risks (OPRR) to distribute updated chapters as new areas of research emerge that have implications for research on human subjects or as regulations are revised. The first edition of the Guidebook was produced in the early 1980s under the contract with the President's Commission by Public Responsibility in Medicine and Research (PRIM&R). PRIM&R is a Boston-based, non-profit organisation that sponsors annual conferences on topics related to the protection of human subjects. The present Guidebook is a revised, updated and extended second edition prepared under contract by Robin Levin Penslar, Research Associate at the Poynter Center for the Study of Ethics and American Institutions, in consultation with the Office for Protection from Research Risks and its numerous advisors. The Poynter Center is an independent ethics centre attached to Indiana University. The recent edition of the Guidebook was last updated in 2001. The Poynter Center organises an annual 'Teaching Research Ethics Workshop' (8). Several other Programmes can be found at US Universities.

A Canadian on-line training programme for REB members and support staff is another initiative that should be noted. Initiated by the Quebec Ministry of Health and Social Services and created with the contribution of REB members and experts, the training program integrates theory with practice in the broad field of research ethics. Designed to promote better learning with respect to applying theoretical knowledge to practical demands, the training program is founded on two pedagogical strategies. On-line tutorial: enhancement of theoretical knowledge and application of principles by means of questions and dynamic simulation exercises inspired by REB daily activities. Training workshops: deepening of theoretical knowledge by means of practical activities, the application of the knowledge acquired through web-based training, and the exchange of knowledge and experiences among the participants. The on-line tutorial provides preliminary preparation for those attending the training workshops. While the on-line tutorial deals with numerous pertinent national- and international-level issues and texts in the regulation of ethical research, it focuses on those issues and texts that are of particular concern in the Québec context. (9)

b) Is there a European deficit in developing training materials?

It would, however, be misleading to conclude that there is a major need for similar material in Europe. What has to be borne in mind is the already mentioned fundamental differences between the US-American and the European teaching traditions at university level:

- the US university system is characterised by a much stronger organisation on the course module level, and
- there is a clear tendency to teach research ethics almost exclusively in the practical context of its application in the various fields rather than in the greater context of applied ethics as part of ethics courses.

This approach of integrating the study of research ethics as teaching modules into other courses leads to a greater demand for basic or standardised material.

Furthermore, it is very frequently the case in the medical or engineering schools that

- the lecturers come from the life sciences, medicine or engineering sciences and not from normative disciplines in terms of their training;
- frequently there are only limited links to faculties with normative disciplines like philosophy, theology or law.

This means that this type of lecturer has very different requirements when it comes to the existence and quality of training materials from those of a lecturer

who was actually trained in a normative science. The latter prefers to collect material for his lessons himself and makes more use of material collections than didactically prepared material. This second type of lecturer in his affiliation to various faculties and disciplines is encountered far more frequently in European universities.

The differences revealed by the comparison of the curricular teaching of research ethics between Europe and the USA and within European countries go beyond the actual circumstances described here and can be attributed to underlying specificities in the culture of the various countries. This has to do above all with

- differences in the specificity of university teaching,
- the different nature of the links between teaching and research and academic teaching and occupational practice,
- the links between research and application which have developed and are assessed differently,
- the different way in which ethics are implemented in behaviour and teaching,
- the different form of state and non-state regulation in the areas of relevance for the study,
- the underlying differences in the legal systems and political cultures.

A separate study would be required in order to determine how the different nature of the situations with respect to the subject of study in Europe compared with those in the USA and the different nature of the situation in European countries depends on such underlying factors. This would also be necessary with respect to the qualification of a specifically European approach in research ethics and its application.

There are various indications that the differences between the Anglo-American university and scientific culture and the continental European university and scientific culture and the corresponding differences in the role and nature of ethics in law play a special role. Nevertheless, the globalisation of research in the sciences has already led to a growing levelling of these differences or has created opportunities in order to develop research ethics spanning these differences.

On the whole, it will have to be said that the way ethics was implemented in the scientific, research and university culture which is typical of the countries of western Europe – characterised by freedom of value judgements in basic research in connection with professional virtue ethics in the fields of application; a dominant role of law; a strong influence of professional organisations; a dominance of traditional moral attitudes concerning teachable and conveyable rules and norms, etc. – was not quite as equal to the new challenges of research as the Anglo-American culture. Roughly speaking, in the face of new fields of action in research, rule- and norm-based ethics seem to be more practical and adequate than ethics based on attitudes and traditions. This may also be an explanation for the described possible backlog in the countries of continental Europe. However, in the meantime it has become obvious that apart from the initially identified deficits, there are also specifically continental potentials, such as the approach to developing new regulations, which are made necessary under the pressure of expanding research, on the basis of a codification of human rights which is commonly acceptable. These potentials, though, are not yet adequately developed (cf., for example, the new Protocol on Biomedical Research of the Council of Europe) (10) and need to be implemented into curricula.

4. Elements of a European Core Curriculum to Teach Research Ethics in Biomedical Science

In several European workshops in Brussels, Strasbourg, Vilnius, Montpellier, Tours, Moscow the author could discuss together with European researchers and specialists in research ethics topics which have to be touched in a European Core Curriculum for Research Ethics in biomedical sciences. The following list of topics illustrates a compilation of this workflow and the discussions.

Topic 1: General Bioethics and Research Ethics

- History of bioethics and research ethics (Nuremberg Code, Tuskegee Syphilis Experiment, Milgram Experiment, Belmont Report, Helsinki Declaration, etc.)
- current approaches of bioethics and research ethics
- concept, scope and ethos of science and research
- bioethics as an integrated discipline with contributions from moral philosophy / ethics, law, theology, social sciences, medicine and life sciences
- emphasizing the interdisciplinary aspects and the hermeneutic problem of different discipline related languages.

Topic 2: Distinction between clinical practice and research

- Goals of medicine versus goals of science
- patient versus test-persons
- physicians versus investigators.

Topics 3: Methodological problems of science and research

- Risk management
- placebo control
- research equipoise
- emergency research
- withholding proven treatment
- problems of using social science methodologies (data collection methods like interviews, observation, statistics; non-random sampling and research validity; feed-back to research participants, etc.).

Topic 4: Legal Documents

- Identifying relevant legal documents (national and international laws, professional guidelines etc)
- distribution of documents

• translation of documents into national language
• training how to read national and international legal documents.

Topic 5: Conflicts
• Conflict of interests
– health of the society / health of the individual
– scientific results / health related results / economic results
– role of institutions (lobbies, politics, sponsors etc.)
– allocation of scarce resources,
etc.
• Conflict of principles
– right to know / right not to know
– autonomy / protection, etc.

Topic 6: Informed Consent
• Free and informed consent
– adequate information and well formulated information sheets
– importance of the lay persons in the committees
– withdrawing of consent and safe exit
• well-being of the persons involved, with special attention to vulnerable groups (minors, incapacitated persons, prisoners, indigenous populations etc.)
• practically expressed autonomous decision (how autonomously decide people in different societies at different level of education, etc.)
• data protection
• emergency research.

Topic 7: Misconduct and Fraud in Research
• Fabrication, falsification, or plagiarism in proposing, performing, or reviewing research, or in reporting research results
• problem of plagiarism
• good scientific practice in research and scholarship as essence for the integrity of science and research
– self-binding in science and research
– guidelines of science organisations.

Topic 8: Special Issues of Disciplines
• Disciplines related to the approach to cover problems of special areas (paediatrics, surgery, pharmacology, genetics, pharmacogenetics, ethnogenetics, psychiatry, etc.)
• disciplines related to case studies.

Topic 9: Special Applications
• Embryo and fetal research
• stem cell research
• tissue collection and biobanks
• genetic data
• animal research,
etc.

Topic 10: Multinational / Multicentre Trials
• Discussion of different standards, different experience (different cultural traditions versus basic common ethical objectives in Europe)
• overall methodology of ethical reviews
• importance of the "local knowledge" (relationship between investigators and reviewers)
• facing the problem of no developed philosophy or social science in some of the countries involved.

Topic 11: Communication and Responsibility
• Communication between investigator and human subjects involved in a trial
– to ensure informed consent
– to provide well developed information sheets
– to train the hermeneutic competence of the investigators (translation) apart from scientific competence
• responsibility of the REC members (not only of the investigator).

Topic 12: Regulation, Authorities and Policy
• Impact of phase IV studies (scientific?, marketing?, access to health care? etc.)
• orphan drugs, forgotten diseases (cannot be regulated by market rules but by politics / policy).

Topic 13: Methodology of Review Process
• Reporting and peer reviews
• learning how to integrate different disciplines / views
• identifying types of arguments and lines of argumentation / clarifying arguments
• protocol design: understanding the design means understanding the ethical problems of the design
• special attention on administration / paper work.

Topic 14: Role of Sponsors
• Definitions of sponsors
• time factor – cost factor
• problems of markets: (cf. no markets in developmental countries)
• orphan drugs / forgotten diseases
• liability (internationally different)
• sharing costs / co-sponsoring: Universities / Industries / public (like EC) (win / win but different approach: Knowledge / Products)
• multicentre trials
• transfer of technology
• avoiding over-regulation.

In summary, it can be hold that lay people and experts of different disciplines face different needs concerning training programmes and training materials. Therefore, programmes should be developed in a flexible manner. Especially extra modules for chairperson and secretary members have been discussed as very reasonable. A modular system can include different lengths of training courses and different methods (day training, series of workshops, long distance learning, etc.). One of the most considered points is the improvement of the connection between local committees to exchange

experiences, training programs and materials and to build up a network which should include an Internet platform and forum.

CONCLUSIONS

1. Research ethics can be considered to be an area of applied ethics in which a) research in general, b) research in individual research areas or c) specific problem constellations spanning several research areas are addressed from the ethical perspective.

2. The need for training in research ethics has been clearly acknowledged both by political bodies and by the scientific community. Combined efforts should be undertaken to improve the general conditions.

3. Compared to the situation in the USA, the volume of *European* training material ("Training Material for Research Ethics") found within the framework of the mentioned study is considerably smaller (especially when it comes to easily accessible resources like the World Wide Web).

4. Within the European training material identified, the western European far outweighed the eastern European. Among the western European training material, the British, Scandinavian and German material forms the greatest group.

5. The dominant subjects in the training material are those which refer to an ethical assessment within the framework of human medical and / or clinical research. What is particularly noticeable here is the subject of human experimentation and the extensive treatment of issues in conjunction with autonomy, respect, informed consent, subject unable to consent, the role of representatives and reference to the national and international laws and codices which are also binding for clinical research.

The paper suggests a European Core Curriculum for Research Ethics in biomedical sciences. Extra modules for chairperson and secretary members could be a very useful component of such a curriculum.

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