ENGENDERING HEALTH(Y) RESEARCH ETHICS IN EUROPE

Recommendations for a future instrument for the gender-sensitive assessment of health research protocols by research ethics committees (RECs)

Country Specific Report of Ireland

European Institute of Women's Health

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Funded by the European Commission, DG Research, Directorate E: Biotechnology, Agriculture and Food, under FP5, Programme 'Quality of Life and Management of Living Resources'.

Contract No. QLG6-CT-2002-30616

Published December 2003

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Background

The WHO Constitution states that: "The enjoyment of the highest attainable standard of health is one of the fundamental rights of every human being without distinction of race, gender, religion, political belief, economic or social condition". However, despite extensive investment in the prevention, screening and treatment of diseases in both men and women, global indicators of population health suggest significant and persistent inequalities in health status.

In every European country, women spend a greater proportion of their lives in a state of poor health and have lower disability-free life expectancy. Men have a lower life-expectancy and are more likely to die than women at almost all ages.

The proportion of the population receiving health screening for specific diseases and having access to effective treatment varies as a function of both gender and pathology. Further gender differences are also observed in biological vulnerability to specific diseases, clinical effectiveness of a variety of treatments, access to treatment and treatment compliance. Taking into account such gender differences in research and health policy will optimise health investments, reduce gender inequities and increase overall population health.

The differences in health between women and men have been documented extensively. In general, women live longer than men. Furthermore, diseases are distributed differently among women and men and men and women also differ in help-seeking behaviour and in access to and utilisation of health services. Evidence from clinical practice is growing that sex differences play a role in the distinct diseases as well: differences are observed in manifestation and natural course, in clinical presentation, symptom profile and underlying risk factors; in reaching a diagnosis and in optimal treatment. One of the diseases for which the differences are documented comprehensively is coronary artery disease (Orth-Gomér, 2000).

If health services are to meet the needs of both women and men, the differences between women and men need to be taken seriously in the provision of care. To realise the delivery of such care it is essential that the ones responsible for the care, the policy makers and health care providers, have access to the results of scientific research which addresses the differences between men and women adequately and ersensitive knowledge.

Sex differences refer in part to biological phenomena (called sex) and in part to socially constructed roles and relationships, personality traits, attitudes, behaviours and values that society ascribes to the two sexes on a differential basis (called gender) (Braithwhite, 2001). Gendersensitive knowledge means that differences in biological sex and cultural gender are addressed as well as the consequences of these differences for the provision of health care, for instance with respect to the diagnostic process, the choice of a treatment and the establishment of priorities in disease prevention and health promotion.

Among the first to consider gender as an important issue were psychologists (Stark-Adamec, 1984). In the field of physical health, cardiologists were the pioneers. It became clear that unless a woman with a heart attack presented herself in the way a man would do in such circumstances, she was not recognised as a heart patient, the so called Yentl syndrome (Healy, 1991). Because of the differences in clinical presentation, myocardial infarction was

underdiagnosed and undertreated in women. Even now, sex differences still exist in the sensitivity of the diagnostic tools and in the specificity of the clinical examinations, clinical presentation and symptom profile (Orth-Gomer, 2000). As a consequence, not all women with myocardial infarction receive optimal care and myocardial infarction is still more lethal in young women (Vaccarino, 1999).

In the member states, research ethic committees (RECs) play an important role in the actual performance of medical studies. Funding organisations often require the approval of a REC before deciding upon awarding a grant. A REC reviews a research protocol on ethical considerations. Such an assessment is guided by the three basic principles of ethics as worded in the Helsinki declaration: professionalism, informed consent and justice (WMO, 2000). A REC can ask for adjustments in the design and materials used before permission is given to carry out a research project.

To what extent the judgement of a REC affects the research practices, will depend on the juridical context in which a REC operates, but also on the interpretation of the basic principles. The latter will be influenced by the scientific backgrounds / discourses of the members of a REC. Since countries can vary considerably in the law considering medical human/animal studies and research ethic committees and in the composition of RECs, the impact of the assessment on the research practices can vary considerably by country.

Equality in meeting the needs of both men and women is covered by the principle of justice. Equality can be looked for in all stages of the research protocol, from the choice of the health problem to be studied and the focus of study, to the study design and the report of the results.

Research practices have been male-oriented for a long time with a focus on health problems from a male perspective. In the sixties, the normal human being, studied in research projects, was male and mostly young (Science, 1995). Since then, more studies on women's health issues has been done. Yet, even now more men than women are included in medical studies of diseases that are common among both sexes.

With the studies on women's health issues, studies started to take the context of a health problem (role of gender) into account. Recently, a plea was made in favour of contextualising male health problems as well (Doyal, 2001). This will bring the wider perspective of gendersensitivity into medical research.

Introduction

This country specific report is part of an E.U. Project aiming to lay the groundwork for the development of a European instrument for the gender-sensitive assessment of biomedical research protocols (QLAM -2001- 00616; Qlg6-ct-2002-30161). Five member States took part in the project, and carried out research in their respective countries examining the opportunities to integrate the gender perspective into the ethical review processes.

The two main research questions of the project are;

1. What exists presently in terms of legislation and regulations in regards to Research Ethics Committees (REC's). The researchers were particularly interested in ascertaining what rules governed the functioning and the actual performance tasks in the five member states and whether the routines and the judicial embedding pay attention to the gender perspective.

2. Exploring if and how attention to gender can be implemented into the assessment procedures of RECs.

The complete report includes all five country specific reports, a comparison report and recommendations for the development of an instrument for a gender sensitive assessment for research protocols by RECs.

In the preparation and conduct of clinical research, not only the scientists and the sponsors (either private or public), but also the RECs play an important role. The latter hold a special because they explicitly operate independently from researchers and sponsors and are responsible to society at large. Their role is established in the World Medical Association Declaration on Helsinki on ethical principles for medical research involving human subjects (WMA, 2000). A REC is supposed to assess the design and performance of each

In modern medical practice, decisions regarding preventive measures, diagnostic tests and treatment possibilities are increasingly based on the results of clinical research and practice guidelines based on clinical research (evidence based medicine). Therefore, there is no question that the integration of a gender sensitive perspective within mainstream medical care could be greatly enhanced by clinical research that pays equal attention to women and men.

However, the scarcity of the scientific evidence on health problems in women is well documented. (America, 1996, Agenda, 1999) In the US this awareness has resulted in guidelines for the conduct of clinical studies by the National Institutes of Health in 1990 and 1994 (National Institutes of Health, 1994, accompanied by legislation directed by the National Institutes of Health to establish guidelines for the conduct of clinical studies by the National Institutes of Health to establish guidelines for the inclusion of women and minorities in clinical research. (NIH Revitalisation Act of 1993, Public Law 103-43; Freedman et al., 1995). The guidelines have been updated in 2000 (http//grants1.nih.gov/grants/guide/notice-files/NOT-od-00-.48.html). The implementation of these guidelines can be seen as a major reform in health research.

Although the European Union has made a clear commitment to gender equality in the Treaty of Amsterdam (European Union, 1999) there are no European guidelines that ensure equal attention to women and men in clinical research. A recent assessment of the Quality of life and management of living resources programme of the Fifth Framework has shown that attention for sex differences and gender issues is limited in the funded research projects. (LifeSciHealthPriority EU, 2003)

This led, among others, to the recommendation to develop European guidelines concerning the inclusion of women and minorities.

In the preparation and conduct of clinical research not only the scientists and the sponsors (either private or public) but also the research ethics committees (RECs) play an important role. The latter keep a special position because they explicitly operate independently from researchers and sponsors and hold a responsibility towards the society at large.

Their role is established in the World Medical Association Declaration of Helsinki on ethical principles for medical research involving human subjects.8 A REC is supposed to assess the design and performance of each experimental procedure involving humans or human materials on ethical grounds, setting quality criteria for doing research.

The assessment procedure is guided by the four generally adopted principles of ethics: safeguarding the well-being of potential participants (non-maleficience), promoting scientific validity (beneficence), enhancing the rights of potential participants (autonomy), and equal rights in the treatment of potential participants (justice).9 The recently adopted EU-Directive on the conduct of good clinical research10 strengthens a REC's role in the review of clinical research. This makes RECs suitable actors for a European-wide integration of the gender perspective in biomedical research.

The aim of the E.U. project (QLAM -2001- 00616; Qlg6-ct-2002-30161) is to lay the groundwork for the development of a European instrument for the gender sensitive assessment of biomedical research protocols. For that purpose the possibilities are investigated for the integration of the gender perspective in the ethical review in five Member States: Austria, Germany, Ireland, Sweden and The Netherlands.

In this country specific report the following research questions and sub questions are addressed for Ireland:

i. What are the decisive moments during the ethical review procedure which can be used for integrating the gender perspective.

1. How is the procedure actually performed?
2. What are the formal rules with respect to the procedure performed
3. Which tools are available to do so?
4. How is the quality of reviewing set and maintained?

ii. In what judicial and scientific context do RECs operate, including the national policy on ethical review? How can new issues be brought into the ethical review?

iii. How are political decisions about research ethics (at the EU level, at the national/regional level) implemented at the level of research ethics committees?

iv. What is the attention paid to gender aspects in the actual practices of RECs and the corresponding formal rules guiding the ethical assessment?

Methods

The study is explorative in nature. The data collection covers a broad field. The information was mainly obtained through structured interviews with two key informants and two REC members. Special criteria were set for selecting the informants to take care of a good coverage of the different levels in the system of ethical review.

Key informant 1 was consulted on organizational aspects and the embedding structure of RECs and had to be a person, with an influential position and insight in the functioning of a REC, e.g. a current or former REC member with a considerable number of years of experience- KI-1.

Key informant 2 provided information on policy involving RECs - KI-2. He or she had to be well-informed about the system of ethical review (from an organization in the top of the ethical review structure, e.g. from a national committee on research ethics or from the government who is involved in the implementation of the EU guideline on Good Clinical Practice).

The two REC members, preferably one male and one female, were the consultants on the review procedures. They were from two separate RECs with a considerable work load and contrasting backgrounds with respect to affiliation (yes/no university-related) or level (national/regional versus local). Both members were required to have many years of experience, preferably the chair or secretary.

The interviews with each of the key informants and with the REC members had their own focus and the set of questions used was adapted accordingly. The actual data collection started with the identification of the two key informants and interviewing them, using a set of questions which slightly differed, depending upon the informant and the corresponding focus of the interview.

They were asked for a description of the role and functioning of RECs, the system of ethical review they operate in, the role of policy-making and the implementation of the EU-Directive of Good Clinical Practice in the Conduct of Clinical Trial and for references to corresponding documents. Their descriptions were back-upped by a close reading of the written material they referred to on direct and indirect clues supporting a gender sensitive approach in the ethical review.

For each of these documents a description is given of the main purposes and the way they are implemented, completed with the discovered clues on the attention for gender aspects. Thereafter, the current routines of a REC were mapped by interviewing two REC-members, a male and a female, each from a different REC. As the key informants did, the REC members were also asked for to relevant documents.

Likewise, their descriptions were matched with clues on attention for gender aspects derived from the written material.

Research already conducted on the routines, roles or functioning of RECs, in particular in relation to gender

issues, was listed and summarized on the directions of the informants interviewed and/or through a literature search. Furthermore, the number of RECs and their workload (in terms of number of proposals reviewed per year) was documented.

In total four persons were interviewed. All interviews were audio-taped.

Three of the four informants were male, one female, covering a variety of backgrounds such as physician, ethicist, lawyer and philosopher. Originally, we had hoped to interview two female informants, however with one female informant, it proved too difficult to arrange a suitable time due to pressure on her work time. Criteria were set for two key informants and two REC members.

One key informant (KI -1) was selected to provide information on policy. They held the following positions: Member of Cork University Hospital REC(K1); Member of the Dublin City University Research Ethic Committee and the Irish Council of Bioethics (K2); Member of the Health Research Board Ethics Committee and the Irish Council of Bioethics, M1); and Member of Irish College of General Practitioners M2). All four interviewees had extensive experience of assessing protocols. K2 was interviewed in her office at work, M1 was interviewed at his office and the other two interviewees, K1 and M2 were interviewed at our own office.

In the further report of the findings the informants are indicated by the corresponding abbreviation.

1. Law and regulations.

In Ireland, the only national legal underpinning to the ethical review of research protocols involving humans is the statutory document the Control of Clinical Trials Acts, 1987 and 1990. The Scope of the Acts includes persons who may conduct trials, definition of clinical trials, categories of trials and exemptions, ethics committees. There is also Guidelines on the Implementation of the Act, which do not constitute a legal document. However they do offer guidelines on the role, membership and mode of working of Ethics Committees.

There is however no structural framework in place to implement these guidelines or oversee regulation, monitoring of the Acts. Some individual RECS do not refer to the Acts in their policy and procedures manual but rather refer to the International Commission on Harmonisation guidelines on Good Clinical Practice (ICH/GCP) or United States legislation from the FDA or NIH.

Therefore, the REC's in Ireland are operating a regulatory vacuum and often adhere to U.S. based regulations or international declarations such as the Declaration of Helsinki. The tendency to look to the United States stems from the fact that many sponsors are from the United States. In early 2002, the Royal Irish Academy established the Irish Council of Bioethics as an independent body to consider the ethical issues raised by developments in biotechnology in an informed manner.

The establishment of the Council was recommended by the Government Report of the Inter-Departmental Group on Modern Technology published in 2000. One of the sub groups which has been established by the Irish Council of Bioethics, has as it's terms of reference to review in depth the existing practices of Ethical Committees in Ireland, the aim of the group is to produce the guidance on the composition structure and operations of Ethical Committee's in Ireland. Each Research Ethics Committee in Ireland, shares information through the Association of Research Ethics Committees and the Irish Medicines Board (IMB).

The use of medicines for clinical research purposes in Ireland falls within the remit of the Irish Medicines Board. All and any adverse events from a trial, even if felt not to be due to the trial medications, are notified to the trial sponsor and The Irish Medicines Board

and the Committee must also be notified. The IMB only becomes involved if there are adverse effects from the trial, and is not involved in the assessment process. A REC committee may also approve a protocol on condition it is approved by the IMB, but this is not mandatory.

i. Embedding structure

According to recent research conducted by the Irish Council of Bioethics there are currently around 50 local research ethics committees in Ireland, most of them attached to hospitals. They range from committees which meet infrequently to consider one or two projects to the research ethics committees in the major hospitals which usually meet monthly to consider perhaps 6-12 proposed projects. Each committee is independent but they share information through the Association of Research Ethics Committees of Ireland and the Irish Medicines Board.

It is usual for a committee to have a comprehensive questionnaire style form often containing 30-40 questions, many based on the major points of the ICH/GCP and the Control of Clinical Trials Acts guidelines. Members of the board will represent a certain view or expertise (medico-legal, philosophical, medical etc)

In most hospitals, the term 'ethics committee' refers to the local committee composed of medical and lay members which meets to discuss proposed protocols. Some health boards and health care institutions have similar committees. The Committee usually consists of a 'reasonable' number of members (at least five) who collectively have the qualifications and expertise to review and evaluate the science, medical aspects and ethics of a proposed trial.' (ICH-GCP)

3. Composition of REC's

Formal Rules

The Control of Clinical Trials Acts, 1987 and 1990 states that in determining the memberships of Ethics Committees it is recommended that the membership should, as far as possible, include both sexes and comprise both lay and medical members.

The Acts propose as a minimum membership for an Ethics Committee, three medical practitioners, at least one of whom is independent of the institution in which the study is to conducted and on e , at least, who should be personally familiar with the conduct of clinical trials generally, one paramedical (defined as a person actively involved in patient care). One professional non medical person, one person with legal competence, one member of the lay public whose competence and integrity the public could be expected to respect.

Daily Practice - REC 1. – Health Research Body National

The Role of the REC 1 is to carry out initial and continuing review of intramural research projects to assure that; it assesses protocols mostly for drug research but also on ethical issues. REC 1 reviews protocols in accordance with the requirements of

i. Title 45 CFR Part 46 - Protection of Human Subjects - Department of Health and Human Subjects, National Institutes of Health and the Office for Protection from Research Risks and

ii. the Council for International Organisations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects.

It also applies the ethical principles for medical research set out in the declaration of Helsinki 1964.

In 2003, there were six members (one female, five male) Four had a clinical medical background,

one medico legal and one was an ethicist. The Committee meets four times a year.

Daily practice in REC 2 – Medical Practitioners Membership Body

The role of REC-2 is to ensure that the content of the clinical trial documentation is relevant and accurate, the submissions are prepared and progressed in a consistent manner, and are subject to appropriate ethical review and approval procedures. REC 2 ensures that clinical trials are conducted in accordance with the ethical principles 'that have their origin in the Declaration of Helsinki and are consistent with GCP and Clinical Trials Act 1987/ 1990

The composition rules in the Standard Operating Procedures of the REC state that there should be a minimum of 7 and a maximum of 20 members. In September 2002 there were 12 members, four of whom were female. The maximum number of meetings a year is 5 and no more than 8 protocols can be assessed per meeting.

Attention for gender issues in written material

In the policy procedure manual of REC 1, consideration is given to the number of male and female on the ethics committee. The standardised application form, which researchers submit to the REC is written in the he/she form and under the heading "Recruitment of Participants", it is asked whether participants will be recruited from any of 9 listed special, vulnerable populations including pregnant women/women of childbearing potential. There is no attention for gender issues in the policy and procedure manual of REC 2. However, the application form requires applicants to state whether women of childbearing potential are included. If they are it is required that the protocol sheet address the 8 points in the committee's check list for studies involving women of childbearing potential.

Below is the 8 points

i. scientific justification
ii. negative teratogenic studies
iii. warning subject that foetus may be damaged
iv. initial negative pregnancy test
v. forms of contraception defined
vi. duration of use to exceed drug metabolism
vii. exclude those unlikely to follow contraceptive advise
viii. notify investigator if pregnancy suspected.

4 Assessment procedure.

The main purpose of the ethical review is to assure that the rights and welfare of human subjects involved in the research are adequately protected and that the rights pertaining to confidentiality and privacy of human subjects are protected and the risks to the human subjects are reasonable in relation to the potential benefits, if any, to the subjects, and the importance of the knowledge to be gained, and informed consent is obtained by methods that are adequate and appropriate.

Formal laws for the procedure.

The Clinical Trials Acts describes basic requirements for persons performing an assessment. The Acts deal with aspects of financial inducement and selection, the criteria to be used for the recruitment and the selection of participants and procedures used for the purpose of obtaining the appropriate consent and other issues regarding consent.

Daily practice in the REC 1 Health Research Institution National.

Protocols submitted for review will be included on the agenda of the next meeting of the REC.

Submission forms and associated documentation will be circulated to members of the REC one week in advance of the meeting.
Each Protocol submission will be assigned to one primary reviewer who will present the protocol to the REC for discussion. The members of the REC will discuss the protocol, where necessary the principal investigator will be invited to join the meeting to elaborate further on the submission and respond to questions. The REC will reach a consensus on the status to assign to the protocol.

The decisions of the REC are classified as follows;

Approval
Conditional Approval
Deferral
Rejection

There are also procedures regarding amendments to protocols which requires written documents. There are also procedures for transferring a protocol to another investigator.

Daily Practice in REC 2 – Medical Practitioners Membership Body

1. The first step when an inquiry is sent to the Ethics office re submission procedures is that the REC forward proposal form and submission check list.

2. Submissions must be received by Ethics Office at least three weeks prior to next review meeting.

3. The Committee require

Proposal form
Patient consent
Patient information leaflets
Questionnaires
Protocol
Investigator brochure where applicable processed by ethics office

4. When all above requirements are processed, the proposal is logged on database and is included on agenda for next committee meeting.

5. Pre meeting procedure includes that the meeting will be fully constituted under the Clinical Trials Act and is ensured that each protocol be allocated to a relevant committee member for detailed review.

6. A quorum of at least 5 members must be present Hon. Sec. may act as Chair in absence

7. Previous minutes and matters are discussed, each submission is discussed in detail and a list of queries is compiled

8. Each Company/Investigator in turn answers any queries the committee may have.

9. A vote on each submission is taken and recorded on the minutes of the meeting. If any of the members are participating in a trial that is under review by the Committee, he/she will not participate in the discussion on that submission and must absent himself/herself from vote.

10. All investigators of protocols submitted for review are informed of the committees de

11. Investigators who submitted Amendments or adverse events for review will be notified of the committee's decision in writing.

12. All correspondence must be signed by either the Secretary or Chairman.

Attention for gender in the written material

The policy and procedure manuals of the REC 1 and REC 2 do not refer to gender, only in regards to women of childbearing potential, which constitutes a vulnerable group for REC 1.

i. Training and quality assurance

In Ireland, a coherent policy on quality assurance does not exist. There is no provision of a nation wide training system.

According to the Clinical Trials Acts 1989 and 1991, the Research Ethics Committees must monitor the health of participants during and after the clinical trial, details of recruitment are also to be maintained. The Acts also state that the REC satisfy itself that the qualifications of each person who would conduct the clinical trial and, where appropriate, the resources available to him.

There is no provision of a nation wide training system, and individual REC's do not train potential members either.

If a submitted protocol is rejected by one REC the applicant has the option to submit it to a separate REC although it must be noted that it has already failed a prior assessment of a REC.

5. Policy Making.

At present, the Irish Council of Bioethics is attempting to prepare Irish RECs for the implementation of the EU Directive. The working group on Ethical Committees which has been established by Prof. Cecily Kelleher to review in depth, the existing practices of Ethical Committees in Ireland. The aim of the group is to produce guidance on the composition, structure and operation of Ethical committees in Ireland. This working group however is very much at a preliminary stage and has so far made no reports. While this working group is comprised of Council members, external expertise is also co opted and submissions are sought from relevant groups.

There is no attention to the gender aspect referred to in any documentation from the Irish Council of Bioethics.

i. The implementation of the EU- Directive on Good Clinical Practice in Clinical Trials.

The implementation of the EU- Directive has faced many obstacles in Ireland. In Ireland, the responsibility for funding and managing trials is usually shared among various people – a funding body (could be a charity, government, industry, etc) a principal investigator and a coordinating/statistical center. However, under the new regulations, one sponsor would have to assume responsibility for all this, and assume financial liability for indemnification.

This approach will not suit the collaborative approach to shared responsibilities in mult-centre, non-commercial trials. It is modeled on the pharmaceutical industry where a single corportate entity takes on the role and the associated responsibilities. (HRB, 2003) Establishing a national ethics committee has not materialised yet.

The Irish Council of Bioethics has no supervisory or monitoring role. The Health Research Body in Ireland have also raised concerns that that public's and patients' interests are vest served if the only clinical trials that are likely to proceed are those that may give rise to clinical improvements for patients whose condition or quantity makes them economically attractive to the pharmaceutical sector. (HRB, 2003)

Attention to gender issues in the Directive

No reference is made to 'female', 'male', 'woman' or 'man', 'sex' or 'gender'. The Directive addresses minors and incapacitated adults as specific groups. In the paragraph on incapacitated adults the patient population is mentioned;

"The Ethics Committee with expertise in the relevant disease and patient population concerned or after taking advice in clinical, ethical and psychological

questions in the field of the relevant disease and patient population concerned, has endorsed the protocol."

Making conclusive or general remarks regarding procedures and processes of research ethics committees for the Irish case is difficult as Races work independently of one another. The Irish Council of Bioethics is currently undertaking the significant task of creating a database to collate the procedure and work of RECs.

However it is beyond doubt that even with the lack of overall structure the RECs ensure that protocols comply with the prevailing ethical and scientific standards and rules. The control of Clinical Trials Acts 1989 and 1991, is an excellent source of document and reference for Research Ethics Committees. However, there is no regulatory or monitoring body to ensure that each REC's complies with its' guidelines.

Nevertheless, even without this monitoring checks are in place to ensure that highest ethical standards are maintained. Such checks and balance may derive from sponsors criteria, the professional and independent make up of the committee, the prestige and reputations of the governing institution, as well of course as the REC's reviews procedures and the thoroughness of their work.

A regulatory or monitoring body however is necessary, if training, be it general or specific, (In this case gender awareness training) is to become a serious aim for Research Ethics Committees.

It would appear from the interviews at least, that there is little adamant opposition to the implementation of a gender sensitive instrument to ensure that gender awareness is included in the work of RECs . However, from our research it would appear that , it is not on the current Research Ethics agenda.

Organisational embedding of REC's in Ireland; regulations regarding procedures, assessment procedures and financial affairs.

Statutory Acts and Guidelines – Ministry of Health. Control of Clinical Trials Acts 1987 1990

European and International Legislation that the REC's refer to.

Irish Council of Bioethics. Advisory Panel to oversee implementation of EU Directive.

Irish Medicines Board (IMB) Overall responsibility of all medicines used in clinical trials. Individual REC's share information through IMB also.

Hospital REC's

Academic Hospital REC's Governing Institution - University

Heath Institutions REC's

Membership Bodies REC's

Regional Health Board REC's

Conclusions

In Ireland, Research Ethic Committees operate at a national level in a structural and regulatory vacuum. The Irish Council of Bioethics sub committee on Ethics Committees are preparing for the implementation of the EU Directive, and are at a preliminary stage. They are looking to other European countries to find models of best practice and are particularly impressed with the systems in the Netherlands and Sweden.

The fact that presently international multicentre clinical trials require local research ethics committee approval from each site participating in a trial is unnecessarily cumbersome and tedious. A single ethics committee in each member state of the E.U. (as is proposed by the E.U. Directive) will act as the opinion for all sites in that state, with the local ethics committee being reduced to a simple "yes or no" decision for that study.

This will certainly shorten the long process of approval and ensure greater regulatory control and standardise procedures and practices. As O'Briain writes regarding Ireland's preparations for the implementation of the E.U. Directive;

"efforts are being made to find a compromise which maintains a meaningful role for local research ethics committees while increasing the efficiency of testing and introducing new medications."

If the gender perspective is to be mainstreamed and implemented into the policies and procedures of the Research Ethics Committee, the most immediate and potentially viable method of introduction would be as part of a training module. However, as the implementation of the Directive will be very challenging for Ireland, it is unlikely that resources and time will be used to introduce a gender perspective that lacks legislative back up.

If a gender perspective is to be implemented successfully, it must be a two track approach. Firstly academics, scientists and all vested interest must acknowledge that a gender perspective is necessary and in the interest of best practice and legislation must be introduced at a European level that ensures that scientific policies and procedures that effect human beings well being, are gender proved.

Effective therapeutic intervention depends on accurate determination of groups likely to be at risk, availability of effective screening programmes, willingness and ability to undertake protective measures, existence of appropriate treatment and access to treatment. Significant gender differences exist in relation to each of these factors.
There is a need to create more awareness of the need for gendersensitive research, producing evidence, which can inform policy makers in the development of effective public health programmes for the future .

Guidelines for both researchers , and RECs need to be available to ensure that gender is part of the criteria in the development of research protocols, the funding of research and the monitoring and evaluation of the research process.

.All research ethics committees, working for both academic organisations and the industry sector need

to be made aware of the need to include the gender perspective in all their research activities. This will require gendersensitive training programmes to be delivered to the various RECs at both national and regional level ,and the preparation of gender guidelines, these are some of the tasks which could be developed by the newly formed Irish Council of Bioethics.

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