ICMR draft ethical guidelines: a critique

Saheli Women's Resource Centre

Women's groups in India have grappled with ethics in medical research since the early '80s when blatant ethical violations during clinical trials came to light. From injectable contraceptives being tested on women unaware that they were part of a trial; inadequate follow-up and downplaying side-effects in trials on Norplant and anti-fertility vaccines, to illegal trials on quinacrine by NGOs, we have contended with non-implementation of existing ethical norms. We have also attempted to redefine the very norms themselves. Violations by scientific bodies such as the Indian Council of Medical Research (ICMR) in contraceptive research and epidemiological research such as the study on cervical cancer, demonstrate the need for public debate and intervention.

In 1997, Draft guidelines were issued by the ICMR seeking input from health professionals and activists. The 'Consultative Document on Ethical Guidelines on Biomedical Research Involving Human Subjects' includes many areas not covered by the sketchy 1980 ICMR Policy Statement on Ethical Considerations Involved in Research on Human Subjects, such as human genetics research, organ transplantation, epidemiological research and Assisted Reproductive Technologies (ARTs). Widening the scope of the document is an encouraging sign of the attempt to keep pace with the challenges posed by scientific and technological developments.

However, the Draft fails to acknowledge changing social trends, especially in the context of gender and class inequalities in Indian society. Ethical guidelines should go beyond technicalities and build effective safeguards so that the unequal power relationship between researchers and subjects is neutralised and no new avenues of exploitation of research subjects are opened up. It is crucial that the basic principles be stated clearly and unambiguously. The current document falls short of these objectives.

Contentious issues remain relating to newer technologies like genetic research which need to be publicly debated with groups working in these areas. As a women's organisation, we shall address the shortcomings in the Draft in areas in which we have been directly engaged:

Informed consent

Informed consent is central to ethical biomedical research, but has not received adequate attention. The Draft undermines the cardinal principle of informed consent in the interest of "the overall purpose and importance of research". Issues which need consideration are:

- The prejudice that adequate information cannot be imparted to illiterate people should be dispensed with.
- Information about potential risks and benefits should be provided verbally and in writing in simple, comprehensible language without technical jargon, and in vernacular whenever necessary.
- A social worker (not the doctor alone) should be involved in counselling. During written informed consent, the signature should be witnessed by a person not related with the trial.
- For research involving the whole community/ large group, the consent of the village elder and/or community leader should not be considered adequate. Proxy consent (as is being proposed) should not be permitted.
- Where a new study proposes to use samples collected for a previous study, consent for the earlier study cannot be deemed to apply to the new study.
- Even when the research design involves minimal risk (e.g. only collecting data from subjects' records) the Ethical Committee should make a case-by-case judgement about waiving informed consent.
- Researchers should not be allowed to disclose the identity of the participants to those not associated with the trial, without seeking permission from the Ethical Committee.
- Health insurance should be mandatory for trial participants, and should be communicated while obtaining informed consent.

Assisted reproductive technologies

Instead of guidelines for research, this section reads like promotional literature for such technologies. There is a lop-sided and unnecessary emphasis on equipment and descriptions of technical procedures.

The Draft reveals biases which could work against the interests of certain sections who are not within the narrowly defined confines of the family such as single parents and non-heterosexuals. Persons should not be denied ARTs on grounds of sexual preference or marital status. The notion of "legitimacy" of children needs to be redefined keeping in minds the custodial rights of mothers.

Ethical guidelines should not accept social stigma attached to infertility as a norm. Societies have evolved social ways for childless couples to deal with infertility, such as adoption.

The Draft reinforces conservative attitudes by recommending matching of religious and ethnic background for donor insemination. Issues like religion and educational level have no bearing on genetic inheritance and should not be considered during donor selection.

The Draft focuses only on risks to the subject and does not touch upon other ethical issues involved with ARTs which arise out of changes in family structures. Who gets custody of frozen embryos after a divorce? Can a woman be inseminated with her partner's sperm after his death? Should the identity of a sperm or egg donor be revealed? What are the legal aspects of these situations, relating to inheritance and custody? Though it is difficult to envisage changes in laws right away, dilemmas and conflicts are bound to arise and a document on ethical considerations

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should take into account the changing societal trends.

Contraceptive research

Lack of separate attention to this area of research is a serious lacuna.

The bulk of contraceptive research is targeted towards women, a section of society that already has lower nutritional levels and poor access to health facilities. Secondly, most of the emerging contraceptive technologies have multi-systemic effects, and require more careful studies in order to ensure their long term safety vis-à-vis women's health and their future progeny.

All aspects of contraceptive research must respect the diverse knowledge and needs of women, as defined by women. Further, fertility and pregnancy are not diseases, but a normal part of a woman's life and must be understood as such. Since contraceptives are used by healthy women and men in the prime of their lives, the risks-benefit evaluation has to be different from that used on drugs/procedures for treatment of diseases. We suggest the following broad guidelines within which contraceptive research must be conducted:

Contraceptive research and development

- Hazardous contraceptives, and contraceptives with potential for abuse should not be promoted. Instead, such methods should be promoted which: enhance women's health and well-being; are user-controlled; are reversible in the case of spacing methods; meet women's needs at various points in their life cycle; and exhibit demonstrable advantages over existing contraceptives
- Research must assess the degree of risk to children conceived as a result of contraceptive failure.
- More resources must be allocated to the development of safer methods of contraception, such as barrier methods, that offer protection from sexually transmitted diseases, especially HIV; and also to the development of male contraceptives.
- As part of formal research processes, mechanisms must be introduced which facilitate equal participation of women's health activists and potential contraceptive users in decision-making and advisory bodies involved in: setting research priorities; monitoring ongoing research; defining the criteria for safety; reviewing research findings and assessing the acceptability of a method to proceed from one research stage to another.
- Contraceptive research must be subject to review by multidisciplinary ethics committees.
- There should be transparency in contraceptive research, including: criteria for determining research priorities, information on research protocols, process and findings; criteria for determining safety; funding and patent information.

Testing, evaluation, approval and monitoring

- Written informed consent must be obtained from all the participants of research trials.
- Researchers, government and funding institutions are responsible for ensuring the safety of trial participants, and are liable in case of damage to the health or life of trial participants or their future progeny.
- Participants must be informed of their right to withdraw from trials at any time. Voluntary withdrawals must get due weightage during trial evaluations.
- To determine whether a contraceptive is appropriate for a particular country, trials must take place within that country. Participants in these trials must reflect the make-up of women who will be using the contraceptives
- Long-term monitoring and follow-up of trial participants and children born to them during or after trials must be undertaken to determine the effects of the contraceptive technologies over time.
- Contraceptive trials should immediately cease if the potential arises for serious risk to trial participants. Users' responses to and assessment of the contraceptive method under review must be recognised as valid research findings and incorporated into the evaluation process.
- Independent mechanisms must be established to monitor research trials to ensure compliance with international ethical standards.

Post marketing surveillance

In this age of liberalisation, it is surprising that the Draft makes only a passing mention of Post Marketing Surveillance (PMS). Our experience with PMS of contraceptives demonstrates the problems inherent in the concept. PMS being conducted by the pharmaceutical company which stands to gain directly, defies scientific objectivity. There is an urgent need to provide stringent guidelines to govern PMS. Some recommendations:

- Monitoring mechanisms should be an integral part of the licensing agreement.
- PMS should be time-bound.
- Information should be provided on the package of the drug/device clearly stating that it is undergoing PMS
- Adequate information must include all potential side-effects, however rare.
- Treatment plan for side effects/ complications must be part of the ethical clearance prior to commencement of marketing/PMS
- Mechanisms to award damages in case of complications, serious side-effects, long term problems, etc. must be set into motion.
- License/registration should be provisional until results of PMS are available.
- Results of PMS should be subject to independent expert analysis.

New ethical guidelines, in addition to keeping pace with scientific developments, must prioritise safeguarding the rights, health and well-being of research subjects. The manner in which political ideology permeates medical research makes it imperative to develop a pro-people, pro-woman definition of "overall purpose" of research.

References:

1. Indian Council of Medical Research: Draft Consultative Document on Biomedical Research Involving Human Subjects, 1997.

2. Canadian Women's Committee on Population and Development: Bill of Rights for Contraceptive Research, Development and Use, 1993