AIMS For a better birth...

A Charter for Ethical Research in Maternity Care

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Everyone realises that there may be particular ethical difficulties in conducting research on children, the mentally ill or those with learning difficulties.

Such patients may be capable of giving valid consent. Pregnant, labouring and newly delivered women have not been usually been considered as a group with special needs.

We would like to change this, and we would like all Ethics Committees to be rigorous in their consideration of research protocols.

WHAT ARE THE PROBLEMS?

Firstly, when a woman who is pregnant, in labour or breastfeeding, agrees to take part in research, she is consenting for two people not one – for herself, and her unbom child. As we know from the stilboestrol saga, treatment given to a pregnant woman can damage her child 20 years later. It is a heavy responsibility. We sometimes find that women who consented to experimental treatment when the baby was still in the womb, refuse extra, even minor, examinations which are part of the research after the baby is bom; with a visible baby in their arms, they have become much more protective.

Secondly, women are often asked whether they will be part of a study when they are in labour and having painful contractions - and possibly anxious about complications which have arisen. They may have already have been given drugs which prevent them from thinking clearly. This is no time to ask a woman if she is willing to try a new form of epidural.

Thirdly, we know that a woman in labour feels exceptionally vunerable, not only for herself but for her baby, and may be afraid of antagonizing her carers by refusing to do what they suggest. Even women who are not yet in labour, but have entered hospital for monitoring or induction often feel they have to comply.

We receive far too many complaints from women who were given unwanted treatment in labour to have confidence in consent procedures for research. We think that the way much research has been conducted on pregnant women in the past has often been unacceptable.[1] There is no real "informed consent" because women are in no position to take in information, and do not feel they can refuse.

AIMS believes that special consideration should be given by researchers and ethics committees to research on pregnant, labouring and newly delivered women, and therefore we propose the following Charter for Research. In preparing this we have worked closely with the National Childbirth Trust, and

representatives of both groups support the principles involved. The safeguards we propose for the families we represent could, of course, well be extended to many other research subjects.

PRIOR INFORMATION

Women who are in labour or newly delivered, should not be asked to take part in research unless they have been given information beforehand.

It is common for Ethics Committees to insist on a period of delay after patients have been given information (e.g. 24 hours) before they consent to taking part in research, so that they have a chance to think things over and consult others, and there is less chance of their being pressurised. Of course with some types of research patients are in no position to think things over, and urgent action may be required, so Committees do sometimes approve such studies. However, whereas patients and their doctors do not know that they are going to have a road accident hence, women do know a baby is on the way, so there is time for consultation.

What we suggest for pregnant women is an extended two-stage information and consent process. Whenever possible, women should be informed about research proposals before they go into labour, or enter hospital for induction or treatment. Written information should be given out at ante-natal clinics,

so that women and their partners can think it over. Those who are interested in joining can say so, and this will be indicated on their notes. Final consent – or refusal – can be obtained at the time of proposed treatment, since only then will the woman know how she feels, but at least she will have had a chance to look at the information beforehand and talk it over with her partner.

We recognise that there may be exceptions where the condition is uncommon, occurs early in pregnancy, or presents only as an acute state, where it may not always be possible to give infomiation beforehand and those should be carefully considered, by Ethics Committees. However, we do not consider research on premature labour, for example, is in itself an exception.

Prior information gives all women an opportunity to learn about randomized trials - and why it is important to randomize whenever possible – and research issues involved.

WHO IS DOING THE STUDY?

The name and qualifications of the chief local researcher should be given. If the research is part of a multi-centre study, this should be explained and the name, address and telephone number of the central co-ordinator should also be included on the information leaflet. If the study is for a thesis, this should be explained.

WHO IS FUNDING THE RESEARCH?

Women have a right to know who is contributing to the cost of the study, and this infomiation should be included in the leaflet.

WHAT IS BEING MEASURED?

Written information (in all appropriate languages), videos, etc. should always make clear what outcomes are being measured to all the women being asked. It may be that women and babies are undergoing risk or discomfort in a clinical trial, but the outcomes which are important to them or future generations are not being measured.

HOW AND WHY IS IT BEING STUDIED?

All subjects should be told in the leaflet they may see the full protocol if they wish.

INFORMATION TO KEEP

Written information about the trial must be given to every subject to keep (not shown and taken away).

HOW TO CONTACT THE ETHICS COMMITTEE

The leaflet must carry the name and address of the Ethics Committee(s) which approved it, and the Committee's reference number for the study.

HOW TO WITHDRAW

Women should be told not only that they can withdraw themselves and their babies at any time, but HOW to do this (e.g. *'just say to the doctor or midwife. "I have decided I no longer wish to be in this study. Please stop the treatment immediately. Please write this in my case notes now."*)

Researchers routinely say: "You can withdraw at any time. "but do not always explain that stopping treatment might in fact be hazardous or impossible. This information must be given at the earlier information stage, and before women decide to enter. (e.g. some women have wanted prostaglandin gel removed after it was inserted into the vagina, and were told it was impossible, whereas an oxytocin drip can be removed – though we have not yet heard of a woman who succeeded in getting it done.)

THE RIGHT TO SEE THE RESULTS

All subjects should be told in the leaflet they may see all results, published or unpublished, including conference papers, if they supply a stamped addressed envelope and if necessary pay photocopying charges. If this is not practical (e.g. lengthy Ph.D. theses) they must be given references as to how to obtain them. It is equally important for subjects to be able to find out if research was never completed.

REPORTING INVOLEMENT

The fact that mother and baby were involved in a study, and its reference number, should be entered in

the clinical notes of both.

KEEPING RECORDS LONGTERM

Young researchers move on, but the good - or ill - they do lives after them. Ethics committees should require them to make provision for retention of details of all mothers and babies involved in clinical research (with consent), so that longer term effects can be studied if problems - or additional benefits - are suspected in future. Most parents will gladly consent to this, once they realise the implications. We deplore the Department of Health suggestion to Ethics Committees that in order to preserve confidentiality, records should be destroyed after research is completed. All parents are concerned about long term effects. Longer term follow up studies can provide reassurance, as well as warnings on what should be avoided, and adequate provision should be made for confidential storage.

THE RIGHT TO KNOW WHAT TREATMENT WAS GIVEN

Where women and/or babies were involved in a blind randomised study, they have a right to know eventually which treatment they were given. This knowledge could be important for their own future health or that of their child. How they obtain this information should be explained in the information leaflet. Where giving early information might bias follow-up studies, this should be explained beforehand. (Breaking the code where medical problems arise is of course, already standard practice)

THE RIGHT TO PROTECTION IN SOCIAL SCIENCE RESEARCH

AIMS has constantly criticised the failure of obstetricians to find out what women thought of care (e.g. induction, active management of labour, rupturing membranes). However, now that obtaining mothers' (and fathers) views is accepted, we are seeing a number of superficial, biased, badly designed and amateurish studies. Some seem to have been intended from the outset to prove that women liked the care they got. Poor quality research is per se unethical, yet Ethics Committees have apparently approved studies of a standard which would have been unacceptable in clinical research.

Many committees do not include social scientists and they are unused to dealing with ethical issues in this kind of research, and they may be unable to judge quality or know whether the submission comes from someone with appropriate training.

They may assume that simply giving a questionnaire or carrying out psychological or sociological research is fairly harmless. This is not necessarily so.[2] Administering questionnaires or tests can cause long term anxiety and distress, as well as providing dangerously misleading information if it is done badly. Bias - intentional or unintentional – can enter the analysis. Some patients have described their involvement in psychological studies as "mind rape". Others have discovered that damaging comments about their personality or problems now appear on their case notes or have found they were identifiable from published studies.

As well as the rights above (e.g. the right to see the research results), there are additional needs in social

science research:

THE RIGHT T0 QUALITY CONTROL

Woman should have the assurance that a protocol has been examined by an ethics committee which includes members with appropriate research expertise.

IS IT RESEARCH?

There is a blurring of boundaries between management “market research" or “audit” studies and sociological studies. Often audit or management questionnaires cover sensitive issues or client groups yet these are not submitted to ethics committees and are designed and analysed by staff with no social science expertise. If there is any doubt, the studies should have ethical approval.

THE RIGHT TO INFORMATION

Women must be given full and truthful information about aims and methods to be used in any social science research. Wherever possible they should see questionnaires before they decide to take part, and should be given a copy to keep.

THE RIGHT T0 OPT OUT

Those who agree to answer questionnaires (oral or written) should be told not only that they can opt out at anytime, but that they do not have to answer every question.

WHAT HAPPENS T0 RECORDS?

Women may not realise that entries about their personality or state of mind could be made in their medical records as a result of their involvement in psychological research. They should have a right to control this.

WHAT HAPPENS T0 TAPES?

Women should have control over the use and disposal of sound recordings or videotapes, even if anonymised'

Research should be done WITH women not ON women. Fostering such an attitude can only increase goodwill towards research. Some researchers may object to the Charter, and say we are making their job too difficult, but we believe it will benefit both researchers and parents and their children. Greater openness and time to think will help to educate all pregnant women about the importance of well-designed studies. Their access to the results of the studies they co-operated in will also be a safeguard against research fraud.

AIMS would like to continue discussions on these issues with parents, consumer groups and researchers.

Jean Robinson

REFERENCES

1. Robinson, J. *Informed Refusal.* BRITISH JOURNAL OF MIDWIFERY, November 1995.
2. Robinson, J. It's only a questionnaire - a consumers view of ethics in social science research. BRITISH JOURNAL OF MIDWIFERY, December 1995.

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