

Association for Improvements
In the Maternity Services

The National Childbirth Trust

A Charter for Ethical Research in Maternity Care

Research should be undertaken
with women, not on women...

Introduction

Special consideration should be given by researchers and ethics committees to research on pregnant, labouring and newly delivered women

This charter was drawn up after extensive discussion between three national maternity organisations: The Association for Improvements in the Maternity Services (AIMS), the National Childbirth Trust and the Maternity Alliance. Ethical issues in research on human subjects have been covered by a number of organizations.¹⁻⁷

It is widely accepted that there may be particular ethical difficulties in conducting research on certain groups of people such as children, people with mental illness, and those with learning difficulties. However, until now, the issues which make childbearing women a group requiring consideration have not been fully addressed.

The issues

When a woman who is pregnant, in labour, or breastfeeding, agrees to take part in research, she is consenting for two people, herself and her child. The full effects of such treatment may not be known for many years. For example, it is now known that stilboestrol, taken in the false hope of preventing miscarriage, is associated with an increased incidence of malignancy and other problems in the children many years later.^{8,9}

We know from published studies that women are often asked to consent to take part in research while they are actually in labour. At such a time women will usually be unable to give their full attention to the details of a research project. They are likely to be coping with painful contractions, they may have been given drugs and they may be anxious about possible complications.

Women in labour feel particularly vulnerable, not only for themselves but for their babies, and may be afraid of antagonizing their carers by not doing what the carers suggest. Even women who are not yet in labour, but have entered hospital for other reasons, for example induction, may feel powerless.

This has led us to conclude that there should be an extended, two-stage information and consent process:

- ✓ **Wherever possible, women should be given information well in advance of being asked for their consent to participate.**
- ✓ **Informed consent should be sought as close to randomisation/treatment as possible.**

1 Prior information

1.1 *Consent should not normally be sought unless the woman has had prior information*

A woman who is about to be induced, have a caesarean section, is in labour, or is newly delivered should not be asked to consent to research unless she has been given prior information during her pregnancy. This gives women an opportunity to learn about randomised controlled trials and the research issues involved, and to consider the physical and emotional implications of possible effects for them.

By having information in advance, women will have the opportunity to think about the detail, ask any questions and talk matters over with their partners or others.

- ◆ Wherever possible, women should be informed about research being undertaken before they enter the hospital for treatment and before they go into labour.
- ◆ Written information should be given out at antenatal clinics, including those run by hospitals, GPs and midwives, so that women and their partners can think matters over.
- ◆ The information should be in a language and format comprehensible to each woman, as suggested by Consumers for Ethics in Research (CERES).¹⁰
- ◆ Special provision should be made for those who have different languages and cultural backgrounds.
- ◆ In addition to providing written information, researchers should consider using videos to explain research to women and there should always be opportunities for discussion with a midwife, doctor or researcher.
- ◆ Special provision should be made for the needs of women who have disabilities or reading difficulties.

1.2 *Exceptional circumstances*

There are some exceptional circumstances, where it may not be possible to give information well in advance, for example when the condition occurs early in pregnancy. An example might be ectopic pregnancy. These exceptions need to be considered carefully by ethics committees.

2 Informed consent or refusal

Women who have been provided with adequate information beforehand are in a better position to give valid consent to participate in research when asked.

However, they will need an explanation, an opportunity to read the leaflet again, to ask questions and, wherever possible, time to consider their decision.

Consent should be sought at the time of the proposed randomisation/treatment, since only then may the woman finally know how she feels about participating. Women should neither feel under pressure to join the study, nor be asked to decide without time to consider. Their decisions should be voluntary. It should be made clear that further information can be requested at any time and that consent can be confirmed or withdrawn at any time.

Those requesting consent should be particularly sensitive to the reluctance of some women in labour, or newly delivered, to offend their carers.

3 Written information to keep

Written information about the study must be given to every woman to keep – not just shown and taken away.

4 Whom to contact

All information should state clearly whom the woman can contact to discuss the study if she so wishes, and how to do this.

5 What is being studied and why?

In the leaflet, women should be told the purpose of the research, how the results will be used and that they may see the full protocol if they wish.

6 What is being measured?

Information should always make clear what outcomes are being measured. Women may not wish to enter a study if the outcomes which are important to them are not included.

7 Effects of treatment

The information should include any known or suspected physical and emotional effects of the treatment or procedure on both mother and child.

8 Will the baby be treated differently?

If research involves any change in observations, examinations, separation from the mother, investigations,

follow-up, or treatment of the baby after birth, this must be explained fully in the leaflet.

9 The right to see the results

All participants should be told in the information leaflets that they may see results, published or unpublished, including conference paper. It may be necessary to ask them to supply a stamped addressed envelope and possible photocopying costs. If this is not practical (e.g. lengthy PhD thesis) they must be given information on how to obtain them. It is equally important for subjects to be able to find out if the research was never completed.

10 The right to know what treatment was given

Women and children involved in blind randomised studies have a right to know which treatment they were given after the trial has been completed, or if a trial is stopped for any reason, and this 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 should already be standard practice.

11 Who is undertaking the study?

The names, positions, and qualifications of the researchers should be given. If the research is part of a multi-centre study, this should be explained and the name and address of the central co-ordinator should be included on the information leaflet. If the study is for a thesis or student assignment, this should also be explained.

12 Who is funding the research?

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

13 How to contact the ethics committee

The leaflet should carry the name, address, and telephone number of the relevant ethics committee(s) which approved the study, and the committee's reference number for the project.

14 Confidentiality

Women should be informed that any information on themselves or their babies will be treated confidentially.

15 How to withdraw

People who take part in research are routinely told that they may withdraw at any time, but are not told how to do this or if it might cause any difficulties.

Apart from exceptional circumstances, women should be told that they can withdraw themselves and their babies at any time, and how to do this. For example, it can be suggested that the women could say to the doctor, *"I've decided I don't want to be in this study now."*

Researchers should explain if withdrawing from treatment after entry is likely to be hazardous or impossible. This must be explained at an early stage of providing information and before the women decide to enter the study. For example, in a trial on prostaglandin gel, the woman should be made aware that once inserted into the vagina, it is not possible for the gel to be removed.

16 Recording involvement

The fact that a mother and baby were involved in a study, and the study's reference number, should be recorded in the clinical records of both.

17 Keeping long-term records

Ethics committees should require researchers to make provision for the retention of details of all mothers and babies involved in clinical research (with their consent) so that longer-term effects can be studied if problems are suspected in the future.

18 Evaluation of parents' views and experiences

Since maternity care can have long-term effects on bonding, mental and physical health and family relationships, the measurement of clinical outcomes alone is inadequate.

Social science research on patients should be submitted to ethics committees for approval. As with other research, the committee has to consider both the quality of the design and the usual ethical issues such as possible distress or breaching confidentiality.

Well designed social science research should be an integral part of clinical research, not an after-thought. Parents' views and experiences should be explored systematically as part of clinical studies involving new drugs, equipment, surgery or other treatments.

Parents' views and experiences should also be sought when changes are introduced in procedures or the delivery of care.

19 Monitoring quality

Social science research should be judged by standards which are just as rigorous as those used to judge clinical research. It is unethical to do poorly designed research which will not produce reliable results.

Research interviews, questionnaires or tests are not necessarily harmless. They can cause long-term anxiety and distress, as well as providing misleading information if done poorly.

Research ethics committees should include members with social science qualifications, able to comment on methodology and judge whether the qualifications and experiences of the researchers are appropriate and adequate.

20 Is it research?

Market research and audits which include parents' views can cover sensitive issues. Poor design and analysis can produce misleading results which might have harmful consequences. When there is any doubt, studies should be submitted to ethics committees for advice on both quality and ethical acceptability.

21 Informed consent or refusal to social science research

Women should be given reasonable time to think about participating in social science research and should not be expected to give an immediate response to a request to answer an interviewer's questions.

They should be fully informed of the methods to be used, and what is being measured. Whenever possible, they

should be given advance notice of the topics to be covered in interviews and they should be offered a copy of the questionnaire to keep.

Before participating in surveys or interviews, parents should be informed in writing that if they participate, they can opt out of any questions they do not want to answer.

22 Transfer of research

Parents should be informed if there is any chance that entries about their personality or state of mind could be made in their, or their children's, medical records as a result of being in a research study. Such comments could affect their future medical care.

23 Confidentiality in research

People participating in sociological, psychological or epidemiological research should be given the same assurance of confidentiality as those in clinical trials.

Parents should be told who will know they were involved in the study and who will have access to information which might be recognized as relating to them.

In conclusion

Research should be undertaken with women, not on women.

Researchers should involve women in the planning of studies and should include user representatives early in this process.

We believe this Charter will benefit parents, their children, and researchers. Greater openness and more time to think will help to develop trust between childbearing women and researchers. We believe it will also raise awareness about the importance of well-designed research.

We would be happy to be involved with discussions with consumers, researchers, ethics committees or professional bodies about this Charter.

References:

- 1 World Medical Association Declaration of Helsinki, *Recommendations guiding physicians in biomedical research involving human subjects*; Adopted 1964 and revised in 1975, 1983 and 1989; World Medical Handbook of Declarations.
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- 4 The Royal College of Physicians of London, August 1996, *Guidelines on the practice of Ethics Committees in medical research involving human subjects, (Third Edition).*
- 5 Department of Health, *Local Research Committees*, OHSG 91(5), London.
- 6 Leigh & Baron Consulting Ltd and Christie Associates, 1994; *Standards for Local Research Ethics Committees. A framework for ethical review.* McKenna, NHS Department of Health Training Committee, Bristol.
- 7 European Commission, 1991; *Updated standards for the testing of medicines for human use, 91/507/EEC.*
- 8 Vassey, MP, et al, 1983; *A randomized double-blind controlled trial of the value of stilboestrol therapy in pregnancy: long-term follow up of mothers and their offspring*, British Journal of Obstetrics and Gynaecology, 90:1007-17.
- 9 Herbst, AL and Bern, HA, 1981; *Developmental effects of diethylstilbestrol (DES) in pregnancy*, New York: Thieme Stratton Inc.
- 10 CERES, *ibid.*

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