AIMS For a better birth...

Ethics Watch

AIMS Journal 2005, Vol 17, No 2

Jean Robinson reports on the difficult ethical area of "consent" and "informed choice", and calls for an update on the Charter for Ethical Research in Maternity Care.

We get a constant rich stream of information from women about 'consent' in maternity care. There are problems with treatment they agreed to, but felt they were not fully informed about, and often there are hostile reactions or they are overridden (or even assaulted) in labour when they refuse interventions they do not want. These are not occasional comments; they are a standard part of the postbag. So we are ever-watchful on ethical issues. The daily education we have from our callers has been invaluable when we read research, and it helps enormously when we are asked by researchers to comment on research they plan to do, or to write information leaflets for patients.

Updating the Charter

We need to update the Charter for Ethical Research in Maternity Care we produced with the National Childbirth Trust in 1997. This was a great success and was praised by the Department of Health, and the Royal Colleges, and has been translated into French and German. We wanted to highlight the fact that pregnant women who consent to research before or during labour and birth, are agreeing to exposure to drugs, procedures, or new technology for two people, not one - the mother and the unborn, or newborn, child, so ethical standards for consent must be high. One of the things we have learned from women's birth stories, is that the new mother is likely to become more protective and critical after she has seen and held the baby. Some who had happily consented during labour to try a new, untested drug, dosing the fetus as well as themselves, protested if the doctor then wanted to take the new baby out of their sight for harmless observations and tests for the research. This was now a separate human being they were responsible for, and 'consent' had a different meaning. We insisted, for example, that whenever possible women should be given advance information while they were pregnant about research that was being done in labour, or on newborn babies, knowing how difficult it is to refuse. We also wanted parents who would later be approached for consent to have time to think it over before agreeing, although we accepted that some procedures are so urgent that delay may not be possible.

Who Understands Randomisation?

But we are all a bit wiser nowadays. It is not enough for consumer groups to look at a trial design and work with researchers to produce an honest, understandable patient information leaflet. We now know that even leaflets we, and the NCT, had helped to write still weren't good enough - as studies have shown.

Parents had agreed to randomisation, but they didn't know what it was[1] or they had not fully understood what the researchers were measuring[2]. Giving written information - however good - is not enough. We now know that the Informed Choice leaflets about maternity care preparewomen as we all hoped, because of the culture of the professions who controlled their distribution, and of the institutions in which they were used (see the splendid book I reviewed in our last issue[3]

Research comparing different treatments almost always randomly allocates patients to one or the other (often done by computer) - because that is the best way to get a reliable result, and reduce bias. Social science studies have now shown that one of the main problems for most people being asked to take part in a trial is that they cannot quickly understand the concept of randomisation at such a time. An important example came with the ECMO trial (Extra Corporeal Membrane Oxygenation). This was a new treatment - virtually a lung bypass - to help newborn babies dangerously ill with breathing problems. They were to be randomly allocated to the new, or conventional, treatment, and parents would have to make a quick decision to enter the trial when they were very stressed. We helped to write the leaflet. Parents who had consented, were later asked by social scientists by questionnaire and in depth interviews what they had understood[1]. It was clear that most parents hoped their babies would get ECMO - but entry into the trial was the only way of getting the new treatment (a crucial ethical issue in itself). Many had misunderstood what randomisation was, how it was done, and why it was used. Some thought it was a way of selecting babies for treatment with scarce resources. Parents whose babies had got ECMO treatment and survived, realised that those without it had died, and felt it was unfair.

Another example of misunderstandings comes from the ORACLE trial, where women in premature labour were randomly allocated to have antibiotics or a placebo (pills that looked the same, but contained no drugs) to see if this would delay labour till the baby was bigger, and also reduce the number of babies who died or were handicapped. Both AIMS and the NCT helped to design the information leaflet. Later, women from the trial were sent a simple questionnaire.[2] Forty three percent of the women said it was the leaflet which had helped them most to understand the trial, compared with 30% who said it was talking to the midwife and 19% who said it was the doctor - so that suggests our work was helpful. Fourteen percent of women said they felt under pressure to take part, though this was mostly from time, and worry, rather than pressure from staff. It was clear that many had not fully understood the purpose of the trial (eg though they knew one of the aims was to see if the drugs prolonged pregnancy, many had not realised it was also to compare deaths and damage in babies) We do not have their views on randomisation.

Another recent study asked healthy adults at adult education classes about their views on research[4] .about half those questioned could not believe that doctors genuinely didn't know if one treatment was better than another when they did research. The fact that individual doctors may feel sure they know, but the profession as a whole is uncertain, makes it more complicated. Many adults were unhappy about randomising patients. Nor did they believe that it was necessary to use randomisation to compare treatments. No wonder many people entering trialsdon't fully understand what they are told!

A list of problems

These are some of the issues we need to talk over with the NCT, the Maternity Alliance and Consumers for Ethics in Research. We are particularly keen to explore:

- (a) consent under difficult conditions (eg while recovering from a caesarean under general anaesthetic, or after being woken up in the night after being given a sleeping pill, as in the ECMO trial).
- (b) consent when the only way of getting a new treatment is to enter the trial.
- (c) Although the in-depth follow up to the ECMO trial showed important problems with understanding randomisation, and the more simple ORACLE follow up showed women did not fully understand outcomes being measured, these alone did not raise major issues with consent in the context of these trials. Comments from patients and the public which show what they thought randomisation was about can teach us useful lessons. And we must take on board the fact that some people think the whole idea of randomisation is wrong - it is ethically unacceptable.
- (d) even being asked to enter a trial can carry a price. In a blind trial (like ORACLE) the woman does not know which treatment she is getting. But for other trials it is impossible to do that: patients agree to be randomised and then are bound to know the difference (eg social support in pregnancy compared with none). A number of studies have shown that some of those who were not allocated the treatment they really wanted and get the "wrong" one may feel disadvantaged, depressed or resentful. This could affect outcomes. And those who get the "successful" treatment - like ECMO parents, may feel guilty when other people's children die without it.
- (e) Should we take another look at the method proposed by Dr. Zelen: the researcher randomly allocates patients to either the standard or new treatment, then approaches those allocated to the new treatment for consent. They then have only a simple decision - do they want to try the new treatment or stick with the old one. This method has been used by some researchers, but has been criticised because people are initially randomised without their consent. However, they can all be asked first at the beginning to agree to have the results of their treatment followed up[5].
- (f) Only the mother can consent to treatment for herself, but after the birth researchers speak of "parental" consent for the child - and possible differences between parents are not mentioned. There can be, as we know from one family, an aftermath when one parent consented to research the other was unhappy about.
- (g) exclusions from research. Too often women with bad outcomes (eg stillbirths and neonatal deaths) are excluded from research on opinions of care users. We think they should be given the chance to take part. Women who do not speak English are also left out, for reasons of convenience and cost (unless researchers are studying Asian groups, etc.) Perhaps consumer views would help grant-givers to be more generous.

Please send us any comments you have to help our discussion, especially if you have been asked to take part in research, or if you are a professional or lay representative who has been involved in it. - Jean

Robinson

References

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