Ethical aspects of research (part 2)

KEY WORDS
- Choice
- Coercion
- Consent
- Ethics
- Sampling
- Voluntariness

PETER ELLIS
Registered Manager at The Whitepost Health Care Company; Independent Nursing and Health Care Consultant, Writer and Educator

The first paper in this subseries about the ethics of research identified how uncertainty is an important guiding principle in demonstrating research is necessary into a particular health-related issue — that is because the answer to an important question is not known. It also discussed how research needs to be respectful of the people who are potential participants and that one of the main ways of demonstrating respect for participants is to ensure consent is gained for the research process. We also saw how equipoise was important in suggesting that participating in the research would, probably, neither "advantage nor disadvantage" those taking part.

In this paper, we will continue to explore some of the issues readers of research should ask of the papers they read and use to inform practice. In particular, we will look at voluntariness and how this should be protected during the research process; we also explore how freedom from coercion and the promotion of freedom of choice both serve to protect this important principle.

FREEDOM FROM COERCION

In the last paper, we said that gaining consent from potential research participants allowed the researchers to involve people in research. This is important in tort law (which includes all negligence cases as well as intentional wrongs which result in harm), where the principle is stated as volenti non fit injuria (to one who consents no wrong is done (Miller and Wertheimer, 2010). In essence this means that those volunteering to take part in research accept the risk that, if we accept the uncertainty principle, it is possible that the research process may cause them some harm. Consent for research is, therefore slightly, different to that in clinical practice, where we might be more certain of the outcomes we explain to patients.

But where does voluntariness start and end in the research process and what does it mean to consent? Voluntariness is recognised by many to be a complex issue and one which is hard to measure, especially where it comes to research participation (Mamotte and Wassenaar, 2015). Even the most single minded among us know that when we are faced with illness or the need for surgery, we may tend to look to the attending professionals for advice, which we feel we should follow. We identified voluntariness as freedom from coercion in the last paper, but what does this look like in practice?

A good example of how the patient-professional relationship might interfere with true voluntariness, and perhaps become coercive, is when researchers use people for the research who are already in a dependent relationship with them or the service within which they work. Sampling in this way is often called convenience sampling, because it relates to approaching people for a study who are convenient to find perhaps because they are coming to a particular clinic or use a general practice surgery.

One of the ethical difficulties with such samples is that the person attending the clinic may feel under an obligation to participate in the research because the nurse treating them asked them to. Similarly undertaking research using students, colleagues or friends throws up a whole raft of questions about how voluntary the consent might actually be (Brewis, 2014).

We said in the previous paper that freedom from coercion is a feature of gaining informed consent, and while there is no suggestion that any researcher would actively coerce potential participants, patients might feel that they have to take part in research to 'please' their nurse — this in turn raises questions as to whether the consent is truly voluntary. Because of this, such sampling requires that the researcher makes extra effort to reassure potential participants that they do not have to take part and they can withdraw from any research and this will not have an impact on their ongoing care. Such reassurance must happen regularly throughout the course of the research, as consent is an ongoing process and not a one-off event (Usher and Arthur, 1998).

Freedom from coercion also means that the researcher must not make promises that they cannot keep and that they do not say things about the research which are misleading or designed to induce the person to take part. Again this

undermines the voluntary nature of the consent as the potential participant would be under the impression they are volunteering for something which is in fact not the case.

Is is difficult to be objective since patients will naturally want to believe that taking part in a research project will be beneficial for them; above all where a new drug is being trialled. This takes us back to the issue of equipoise, identified in the last paper, where researchers, applying the principle of balance of interests, should explain that they are not sure if taking part in the research will benefit the individual or not, but will probably neither advantage nor disadvantage the individual.

True freedom from coercion is, therefore, hard to achieve for any research process. At its best, people may want to take part in a study because they feel altruistic, they want to help others, and this sentiment drives their decision to participate. At its worst, people feel they should participate to please their doctor or nurse, or because it might impact their care in some way.

FREEDOM OF CHOICE

Promoting choice is the bedrock of good health and social care. We can see this in all clinical scenarios, which includes the simple question "may I take your blood pressure?". There are a number of potential answers, presenting the patient with the choice to say: "yes", "no" or "if you explain to me what you are going to do and why" for example.

Asking questions in this way, rather than perhaps just saying "stick your arm out I want to take your blood pressure", quite simply promotes choice and makes it clear to patients that they are in charge of what will happen to them.

In the research setting, the promotion of choice requires that potential participants understand that they have a number of options open to them:

- Take part in the research and see it through to the end
- Take part in the research and see it through to the end but then withdraw their data
- Start the research and withdraw part way allowing the data collected so far to be used
- Start the research and withdraw part way not allowing the data collected so far to be used
- Do not take part in the research at all.

What this illustrative rather than exhaustive list demonstrates again is that consent and, therefore, the opportunity to exercise choice is a process. Good research, especially longitudinal research (that taking place over a period of time) will ensure that participants are asked if they want to continue at regular intervals and their options made clear to them.

Choice is inextricably linked to having information available and both engaging with the information as well as understanding what the information means. Real-life healthcare research demonstrates that many people fail to take account of the information they are given about their healthcare, for example, in relation to screening; drawing significant question marks as to whether people truly consent to what is done to them (Whelehan et al, 2015).

Ethical research, therefore, highlights the choices people have at all stages of the process and reassures them that whatever their choice will not affect the care they otherwise receive. Such undertaking is an important element of the information given to potential participants at the start of the study and provides some reassurance to the ethics committees that the research will be conducted in an ethical manner.

CONCLUSION

This paper has identified that consent is the cornerstone of ethical research and that voluntariness is one of the fundamental elements of consent. We have seen there are a number of circumstances and reasons that voluntariness is hard to achieve, but that the ethical researcher will look for ways to promote voluntary participation in research through ongoing support and reassurance of participants.

We have seen choice is a fundamental part of the consent process and that it is the role of the researcher to ensure that potential and actual participants are aware of the choices open to them at all stages of the research process. WUK

REFERENCES

Brewis J (2014) The Ethics of researching friends. *Brit J Manage* 25: 849–62

Mamotte N, Wassenaar D (2015) Measuring voluntariness of consent to research: an instrument review. *J Empirical Res Human Res Ethics* 10 (2): 121–31

Miller F, Wertheimer A (2010) *The Ethics of Consent: Theory and Practice.* Oxford University Press, Oxford

Usher KJ, Arthur D (1998) Process consent: a model for enhancing informed consent in mental health nursing. *J Adv Nurs* 27: 692–7

Whelehan P, Evans A, Ozakinci G (2015) Informed choice and consent among women attending for breast screening in the UK: data from a qualitative study. *Breast Cancer Research* 17(1): 06