

Ethical aspects of research

KEY WORDS

- ▶ Autonomy
- ▶ Capacity
- ▶ Consent
- ▶ Equipoise
- ▶ Ethics
- ▶ Uncertainty principle

Anyone undertaking research, be it quantitative or qualitative, needs to consider the ethicality of what they are doing. Undertaking research is in many ways similar to other activities in health and social care in that it requires the people undertaking it to gain the consent of those involved. Research also requires some element of altruism on the part of the people being involved and so requires that the researcher is careful about not exploiting their relationship with the potential research subjects.

Most interestingly, and perhaps again in common with much health and social care practice, research involves a degree of uncertainty. That is we do not know what any piece of research will show — that is the point of doing the research.

Being an ethical researcher, or indeed when considering the ethicality of a research paper you are reading requires so much more than the researcher just gaining the approbation of an ethics committee. Ethicality and ethical questions pervade the whole of the research process and are a necessary element of the planning and execution of any worthwhile study.

UNCERTAINTY

The guiding principle that underpins all research is that if uncertainty. We are uncertain as to what the research will find, we are uncertain as to how the people involved in the research will experience the research, we are uncertain as to the side effects (or unintended consequences) arising from the research, we are uncertain as to whether what is being researched will work in this group of individuals. The list of uncertainties is endless.

That said uncertainty is the driving force in research because if we knew the answer to the research question, there would be no purpose undertaking the research. Research for research's sake may pose an ethical problem; that is if we know the answer as to how well a new dressing works on an infected ulcer, then why would we submit people to the rigours and uncertainties of a research study only to show what we already know?

The use of people's time and exposing people to

unnecessary procedures is in itself an ethical issue. Failing to treat people as an end in themselves — as opposed to treating them as a means to an end — shows a great deal of disrespect for them as people (or as the philosophical texts say as persons) and fails to recognise their autonomy (Eby, 2000).

The uncertainty principle is in nature very similar to the notion of equipoise, which poses the concept that research study participants (participating in a randomised controlled trial for ease of definition) would be neither “advantaged nor disadvantaged” should they receive any of the treatments under study (in as far as what we already know about the study area) (Djulbegovic et al, 2000).

Simply put the primary ethical questions concerning research involving human subjects are: “do we already know the answer to this question” and “is this research necessary?” If the answer the first question is yes, and to the second no, then don't do it.

RESPECTING AUTONOMY

It is easy to think that if we lack any certainty about the outcome of a study then it would be hard to justify doing it and incredibly hard ethically to ask people to become involved. How can a healthcare professional justify exposing people to such unknowns?

The answers lies in the proper exercise of gaining informed consent. In everyday clinical practice we use consent as a means of gaining the permissions to undertake task both simple and more complex. So we ask permission of people to take their blood pressure as well as to undertake complex brain surgery. In the one case there is little potential for harm to befall the person, in the other there is a great potential for harm; but, and this is an important but, what allows healthcare professionals to engage in both activities is that they have gained consent.

Like clinical activity, respect for autonomy (and for persons) through the exercise of gaining consent demonstrates that caring professionals recognise that most people have the capacity most of the time to make decisions about what they want to happen to them. As with the brain surgery example above when entering in to the gaining of consent for research the researcher will lay out the potential risks and benefits

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insofar as they are known and empower the potential participant to make a decision about whether to participate for themselves.

This suggests strongly that no matter how important the research question is for humanity as a whole, it is the supremacy of the individual which should always be the researcher's primary concern. Such a notion is also seen in the Declaration of Helsinki (World Medical Association, 2008) (which provides the blueprint for the ethical considerations in all medical research) where it states "In medical research involving human subjects, the well-being of the individual research subject must take precedence over all other interests."

ELEMENTS OF CONSENT

Consent is one of the worst understood ideas in health care and consequently it is often not gained in a satisfactory manner. Perhaps in the research setting, more so that the clinical, it is hugely important not only to understand the nature and purpose of consent, but also to gain it properly.

Notably, consent does not have to be gained for something that is known. That is to say when consent is gained for surgery, we cannot know with certainty what the outcome will be in every case. Consent covers as many eventualities as are known and respects the individual enough for them to weigh up the information given in order to make a choice about what will happen to them. That is consent recognises that people can weigh up and make decisions about what level of risk, or uncertainty, they are happy to live with. Secondly, before we lay out the elements of consent needed in the research, and indeed clinical, context it is worth noting that consent is a process and not an event. That is to say that people have the right to change their mind. This means the best studies are clear that people who consent to take part may withdraw from a study at any time.

There are five interlinked elements to consent:

- ▶▶ Capacity (the individual's ability to understand information and make decisions)
- ▶▶ Information (the giving of information such that the person receiving it has the data they need to

make a choice)

- ▶▶ Understanding (whether the person has understood the information they have been given – i.e. is it in accessible language and has the person taking consent checked that the potential participant has understood what they have been told?)
- ▶▶ Freedom from coercion (is the person making the choice to consent or not free from pressure from others while making their own choice?)
- ▶▶ Freedom of choice (is there a real choice for the person; perhaps to take part or not to take part in the study and receive the usual treatment?)

The failure of the researcher to ensure that each of these elements of consent is met will mean that the consent they gain is invalid. For example it is questionable as to whether one can give true consent to be involved in a trial of a new intervention for a life threatening illness when there is no existing treatment as this would mean there was arguably no choice (other than death).

Likewise where the potential research subject is in a relationship with the researcher, for example the researcher is their clinic nurse, it is questionable as to whether there is a degree of coercion for them to be involved in the research.

When designing, reading or critiquing research these are simple, but ultimately important that as a health or social care practitioner you are reassured that any research you use has been undertaken with the informed consent of all those involved.

CONCLUSION

For research to be ethical, it has to ask questions the answers to which are not already known; that is questions where there is a degree of uncertainty as to the answer. The guiding principle for undertaking research is that the researcher needs to respect the autonomy (the personhood) of the potential participant and gain meaningful consent to participate. Consent is not always about what is definite, rather it is truthful about what is known and what is not and empowers the potential research participant to make an informed choice about participation.



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