CHAPTER 9: PRINCIPLES OF ETHICAL RESEARCH

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CHAPTER OVERVIEW

By definition, research seeks to explore something that is unknown. This uncertainty means there is always the possibility of harm arising from research. There are many examples in both near and distant history of serious harm to participants as a consequence of research, including permanent disability and death. This is why it is of great importance that research projects are informed by sound ethics, properly planned, approved by an independent ethical board and rigorously monitored throughout the duration of the study. This chapter will introduce four principles that govern the conduct of ethical research using relevant case examples to bring each principle to life. Topics explored in the chapter include:

- The importance of 'informed consent'
- Assessment of capacity to provide consent
- Measures to minimise and manage harm arising from planned research
- The importance of ensuring that possible benefits of the research outweigh the risks and costs to participants
- Ensuring that participants are treated fairly and equally throughout the study

LEARNING OBJECTIVES

By the end of this chapter you should be able to:

1. Explain why sound ethical procedures for the planning and conduct of research are important
2. Understand key principles that govern the conduct of ethical research
3. Illuminate each principle with case examples relevant to service-user-led research.

INTRODUCTION

Following the end of World War Two, sixteen Nazi doctors were tried and convicted of war crimes involving research on humans (Seidelman, 1996). During this research, people were forced to participate in 'medical' procedures that involved torture and often resulted in death (Weindling, 2005). During the trials, the doctors' defence lawyers argued that there were no existing laws that clearly defined the difference between legal and illegal research involving humans (Annas, 1992). Following the trials, the 'Nuremberg Code' and 'Declaration of Helsinki' established a set of ethical rules for research involving humans, designed to prevent similar atrocities from happening again. These rules related to four broad ethical principles that govern the conduct of medical research. These are:

- **Autonomy** – this means the right of people to make their own decisions
- **Non-maleficence** – this means doing no harm
- **Beneficence** – this means acting in people's best interests
- **Justice** – this means treating all people fairly and equally (Beauchamp and Childress, 2001).

Despite these principles, tragedies involving research continue to occur. You may recall the 'elephant man trial' (so-called because of the deformities caused by the trial medicine TGN1412) at Northwick Park Hospital in 2006. Six healthy volunteers ended up fighting for their lives in intensive care after being administered with the trial medicine. The researchers had failed to adequately consider, before trialling the medicine, what a safe dose for humans was likely to be (HMSO, 2006). This demonstrates how important it is that the process of approving and monitoring research studies is highly rigorous. This chapter will explain each of the four ethical principles above, using case examples to bring them to life.

Ethical principles

AUTONOMY – right to choose

Autonomy refers to the ethical duty of researchers to take active steps to ensure the person makes an independent decision about whether or not to take part in a research study. Anyone who takes part in a research study must provide informed consent. This means that people must give their permission to participate, with full understanding of what they are consenting to, free from pressure from others. A person cannot provide informed consent if they lack capacity. A person may be considered to have capacity if they can understand information provided about the study and the advantages and disadvantages of taking part. Importantly, they must also be able to form an independent decision on this and be able to communicate their decision to researchers.

Discussion point 1:

Considering the above, read **case example A** in **Figure 28**.

Figure 28 Case example A

You are a service user researcher doing an interview study on a mental health ward. You are recruiting in-patient service users to explore their experiences of physical restraint. A service user, Andrea, approaches you and says she is keen to take part. You speak to the nurse in charge and say that you would like to speak with Andrea and provide more information about the study. The nurse in charge informs you that, in her view, Andrea is not currently well enough to understand the risks and benefits of taking part and that, furthermore, the topic of the interviews is likely to cause significant distress to Andrea.

Would you:

- a) Ignore the nurse's advice. It's Andrea's decision whether or not to take part.
- b) Speak to Andrea, apologise, and say that it is not possible for her to take part.
- c) Leave the study information with Andrea, apologise and say that she is not able to take part at the present time because the nurses don't think she is well enough. Assure Andrea that you will continue to contact the ward to find out when the situation has changed.

The Mental Capacity Act (2005) requires that a person with a 'duty-of-care' (in this instance, the nurse in charge) should make a decision where a person may lack capacity. However, no assumptions should be made about the person's capacity based on factors not related to the specific task (i.e. in **case example A** this would be whether or not the service user had the ability to understand what the interview would involve and the risks and benefits of taking part).

Any decision must also acknowledge that capacity can change over time. It is also worth considering the potential vested interest the nurse has in preventing service users from reporting negative care experiences given the research topic in **case example A**. For these reasons, answer c is correct because the researcher has complied with the legal requirement to assess capacity but has also protected Andrea's right to participate in the study in the future.

To provide informed consent, a potential participant must have access to complete information about the study, including what their participation will involve. This information should include the aims, methods, risks and benefits of taking part and their right to withdraw from the study at any stage without penalty (Beauchamp and Childress, 2001). **Figure 29** provides a list of the key ingredients you should expect to find on a study information leaflet to ensure the potential participant is making a fully informed decision.

NON-MALEFICENCE – do no harm

Non-maleficence refers to the ethical responsibility not to harm the participant during the research. Obvious examples of potential harms from research include death, pain, injury, distress, offence or neglect. However, there is also a duty to avoid less obvious forms of harm such as to treat unfairly or act against participant interests, including wasting their time (Beauchamp and Childress, 2001).

Discussion point 2:

Consider **case example B** in **Figure 30**

– what harms have arisen from the research?

Figure 30 Case example B

You are a service user researcher doing an interview study on a mental health ward exploring in-patient service user experiences of physical restraint. You have recruited a service user, John, who has been assessed as having capacity, has had 48 hours to read the study information and has provided fully informed consent. Part way through discussing a restraint experience, John becomes extremely tearful and anxious and tells you he plans to harm himself after the interview.

Clearly the research topic in **case example B** had the potential to cause distress to participants. A study involving in-patient mental health service users is unlikely to receive ethical approval without a procedure for informing professionals if evidence they are at risk emerges during their participation. This means that John was also likely to be exposed to a second harm, having his confidentiality breached.

Any study that has the potential to cause distress should have an approved protocol to minimise and manage distress should it arise. This should include the nature of the support to be provided both during and after participation, emphasising that participants can end participation without penalty and have their data destroyed. Importantly, the wellbeing of the participant must be prioritised over the scientific benefit of their continued participation (Mental Capacity Act, 2005). Where there is a risk of breaking participant confidentiality, what participants say that could lead to their confidentiality being broken should be made clear to them verbally and in the written study information before participation.

BENEFICENCE – do good

For a research study to be considered ethical, it must prove it has enough potential benefit to warrant the time and other costs participants give up to take part. Importantly, the possible benefits to participants can be indirect (i.e. they can be of benefit to the participant through benefiting society or a wider social group). Crucially, the potential benefits must outweigh the potential costs to participants.

Discussion point 3: Consider **case examples A** and **B**. What are the potential benefits to service users and society of service user participation in this study? How do you think these weigh up against the possible harms identified in the previous section?

The study may have a number of benefits. Physical restraint can cause serious physical and mental harm to service users and staff (Bonner et al., 2002; Paterson et al., 2003; Renwick et al., 2016). Use of physical restraint is also expensive for the NHS (Flood et al., 2008). Research that draws focus on the issue and that may lead to policy changes reducing restraint use could therefore have possible benefits to both service users and society. When weighing up risks against benefits, it is important that the risks are not overstated and participants are not denied the benefits of making a contribution.

JUSTICE – treat fairly and equally

Researchers must treat participants and potential participants fairly and equally in order for a study to be considered ethical. This does not mean that all participants must be treated exactly the same way during a research study or a randomised controlled trial. [Chapter 3](#) provides a clear example of when this is not the case. However, sometimes researchers will be expected to provide an effective trial intervention to participants in the control group after a study has finished. This is because of the need to treat participants fairly and equally.

Researchers must consider fairness and equality when considering who to include in their study. Again, this does not mean it is ethically unacceptable to exclude people or groups on the basis of certain characteristics that would make their contribution to achieving the study's aims irrelevant. On the other hand, it does mean that every effort should be made to ensure those with a relevant contribution to make should be given fair opportunity to participate. Once participants have been recruited, the obligation to treat them fairly does not end. Researchers must consider how they are going to compensate participants for the time and other expenses they sacrifice to take part. Such payment should reflect the contribution they make. However, any payment should not represent such an incentive that the person feels unduly influenced to take part because they do not want to miss out on the payment. This would represent a violation of their right to choose (autonomy) free from the influence of others (Beauchamp and Childress, 2001).

This chapter has examined how issues of capacity and vested interest can potentially interfere with mental health service user participation in research. It provides a useful example of how and when the four ethical principles overlap and interact. Consider **case example A**: the nurse may have refused to allow the service user to participate out of a reasonable expectation that the research would harm the participant (Beauchamp and Childress, 2001).

If this assessment of potential harm was accurate, then this may have been an occasion where it was appropriate, in the short term, to deny the potential participant the right to choose (autonomy) and the benefits of participation (beneficence). However, if vested interest was at play, and the nurse was trying to silence critical views of care experiences, this would violate the participant's right to choose, the benefits of taking part, their right to be treated equally and fairly and, as such, would expose them to harm. This is why it is so important that, where a decision is taken to deny a participant the right to choose, this has been based on a sound, justifiable decision that has adequately balanced the potential risks of participation against the potential benefits. Furthermore, that a proper plan has been put in place to restore the potential participant's right to choose at the earliest stage possible (i.e. ensuring the person is able to participate when their circumstances have changed).

REFLECTIVE EXERCISE

- What are the four key features of ethical research?
- Give three examples of how a research project could do harm to a study participant.
- Describe three ways in which you can protect the confidentiality of research.

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