Ethical principles underpin decision making in the research process. This article considers the seven ethical principles that are most frequently highlighted in the literature. Although the principles will be considered individually, they are not mutually exclusive, and the article demonstrates that they are closely linked.

Introduction

Ethical principles form the foundations for decision making within the many stages of the research process. This article will consider the seven ethical principles that are most frequently highlighted in the literature:

- Beneficence
- Non-maleficence
- Fidelity
- Justice
- Veracity
- Confidentiality
- Respect for autonomy

Although these principles will be considered individually, they are not mutually exclusive. This article will demonstrate that these principles are closely linked, and that a simple question or a complex dilemma may involve more than one ethical principle.

Beneficence

Beneficence is the requirement to benefit the patient. It is the underlying principle in all medicine, health care and research (Faden and Beauchamp 1986). Physicians are primarily guided by the Hippocratic Oath, which states: ‘I will use the treatment to help the sick according to my ability and judgement, but never with a view to injury and wrongdoing.’

Nurses must adhere to the Code of Professional Conduct (UKCC 1992), which states that the nurse must:

‘...act always in such a manner as to promote and safeguard the interests and well-being of patients and clients’ (UKCC 1992).

Both codes emphasise the necessity to benefit the patient and not to do harm. The aim of benefiting the patient applies as much to research activities as it does to clinical care.

Elements The principle of beneficence can be further divided into four distinct and independent elements (Box 1) (Faden and Beauchamp 1986). Beneficence is characterised as an active state as opposed to non-maleficence which is a passive state. This suggests that non-maleficence is an extension of beneficence. However, it is necessary to separate these two ethical principles because they may conflict (Faden and Beauchamp 1986).

Beneficence obliges the researcher to weigh or balance the potential benefits against the potential risks (Faden and Beauchamp 1986, Garity 1995). The potential to cause harm is unavoidable – when anyone tries to help someone, he or she risks causing harm to that person (Gillon 1994). Researchers should ensure that projects demonstrate the potential for net benefit over harm. The potential benefits should always outweigh the risks and the research participant should always be considered more important than the research protocol, even if this means invalidating data (Tarling and Crofts 1998).

Research should benefit the individual and society in general (Parahoo 1997), but the benefits to society should not take precedence over the safety of the patient. The beneficence of any action is extremely personal and may differ between individuals (Gillon 1985a). This highlights the link between the principles of beneficence and autonomy.

Beneficence is the most important principle for nurses involved in clinical research. It is unethical to involve patients and research participants in any research if no benefit is expected either to the patient or to society. The researcher should always place more emphasis on the safety of the research participant than any other factor.

Box 1. The elements of beneficence

- One ought not to inflict evil or harm
- One ought to prevent evil or harm
- One ought to remove evil or harm
- One ought to promote good
Non-maleficence

Non-maleficence assumes that no harm should come to the patient or research participant as a result of taking part in a study (Faden and Beauchamp 1986, Garity 1995). This principle is closely linked to beneficence, but it is difficult to estimate or monitor the harm to which research participants may be exposed. This harm may be physical, emotional, social or economic (Burns and Grove 1995). A physical harm may be easily identified and, therefore, avoided or minimised. Emotional, social and economic factors may be less obvious and the participant may be harmed without the researcher being aware.

All research studies have the potential to cause harm to research participants (Tarling and Crofts 1998) and there are five categories into which studies can be placed according to the level of harm or discomfort to which they may be subjected (Reynolds 1972):

- No anticipated effects.
- Temporary discomfort.
- Unusual levels of temporary discomfort.
- Risk of permanent damage.
- Certainty of permanent damage.

**No anticipated effects** These studies usually do not involve any contact with the research participant and frequently entail the review of medical notes or documentation. However, researchers should be aware that they are invading the person’s privacy. It is important to consider the need to acquire informed consent even though there may be no further contact with the participant.

**Temporary discomfort** In these studies, the discomfort to the participant is temporary and is similar to that which he or she would encounter in his or her daily life. It ceases when their involvement in the study ceases. These projects usually involve questionnaires and interviews that involve minimal risk. However, risks do exist and may include fatigue, headaches, muscle tension, anxiety, embarrassment and time commitment. The researcher should be aware that these risks may occur and have strategies for managing them.

**Unusual levels of temporary discomfort** The research participant may experience discomfort during and after completion of the study. These studies may include interviews about psychologically stressful experiences that may continue to distress participants for some time after their contact with the researcher has ended. The researcher should be aware of the potential risks and be prepared, if necessary and appropriate, to refer participants to a trained counsellor.

**Risk of permanent damage** This research is most common in biomedical research involving drug studies, where some of the adverse effects of the active substance may be unknown. Such substances undergo an extensive period of research, sometimes lasting many years, before they are administered to humans. However some uncertainty remains, so the researcher should have strategies in place to manage adverse events.

**Certainty of permanent damage** This type of research is highly questionable regardless of the benefits that may be gained. The experiments performed by Nazi doctors would fall into this category. These studies violate the fifth principle of the Nuremberg Code, the Hippocratic Oath and the Code of Professional Conduct. No studies that fall into this category should be allowed to proceed.

The ethical principle of non-maleficence should go a long way to protecting research participants from harm as a result of research. Equipoise should exist between the potential risks and benefits. The risks should never outweigh the benefits and the researcher should be aware that there are potential risks with all research.

Fidelity

Fidelity is the research principle concerned with the building of trust between the researcher and the participant (Parahoo 1997). The research participant will entrust him- or herself to the researcher, who subsequently has an obligation to safeguard the participants and their welfare in the research situation (Garity 1995). It is important to gain the participant’s trust by being open and honest (Alderson 1995). There are some risks associated with all research and there may be some risks that are still unknown (Tarling and Crofts 1998). To build a trusting relationship, the researcher must make sure that the research participant knows about the risks. The provision of this information should occur during the process of gaining informed consent.

Hospital patients will often agree to anything a nurse or medical researcher suggests. A potential participant may view an invitation to take part as a recommendation rather than a request (Hewlett 1996). The trust that research participants place in researchers obliges them to be faithful to their commitment for protection.

Justice

This research principle requires the researcher to be fair to participants (Parahoo 1997). The needs of the research participants should always come before the objectives of the study. The main problem with this ethical principle is the selection of populations (Garity 1995). Vulnerable groups such as older people, those who are mentally ill, the military or prisoners, should not be used merely for their convenience. Questions may also be raised if there is a financial reward for researchers, or their organisation, to undertake the research.

If any researcher is to use a vulnerable population, he or she should justify this decision. This is usually done by applying for ethical approval. All potential research participants in the healthcare setting are vulnerable by the nature of their compromised health status.

Veracity

The research principle of veracity highlights the obligation of the researcher to tell the truth about
the research study (Garity 1995). The researcher should tell the truth even if it deters potential participants from entering the study (Parahoo 1997). A researcher who is not completely open and truthful may withhold information from the participant or raise false hopes about the potential benefits of the study intervention.

Veracity is closely linked with the principle of respect for autonomy (Gillon 1994). People organise their lives on the assumption that others will not deceive them. Their autonomy is infringed if they are deceived because information is withheld that may contribute to their decision making. Not telling the truth undermines the principle of respect for autonomy (Gillon 1985c). In clinical care there are instances when deception may be justified, based on three arguments (Gillon 1985c):

- The Hippocratic Oath states that doctors have an obligation to benefit the patients under their care. It could be argued that this obligation overrides any obligation not to deceive.
- Truth cannot always be communicated. Doctors are not always in a position to know the truth and patients will not understand what they are told.
- The patient may not wish to know the truth. These instances are unlikely to occur in research, making the need for veracity even more important.

The researcher should ensure that all potential research participants have all the information they require to make an informed decision about their involvement in the research study. Research ethics committees stress the need to provide accurate and comprehensive information. However, the obligation to adhere to the principle of veracity exists throughout the participation in the research study.

It may be appropriate to inform participants of new knowledge that emerges during the progress of a study; this may influence his or her decision to withdraw from the study. Withdrawals are an integral part of research and although researchers are often keen to recruit and retain participants, they should also be equally keen to produce results that comply with high ethical standards. This can only be achieved if sufficient emphasis is placed on the need for veracity.

Confidentiality

To create the ethical principle of confidentiality two conditions must exist:

- One person must undertake not to disclose information considered to be secret.
- A different person must disclose to the first person information that he or she considers to be secret (Burns and Grove 1995, Gillon 1985b).

If the first person does not divulge the information, confidentiality is maintained. Within research, this confidentiality of information must be respected (Parahoo 1997).

Unlike the code of confidentiality adopted by the Catholic church, confidentiality within health care is not so absolute (Gillon 1985b). However, it is an important element in the relationship – reinforced by the professional codes – between the health professional and the patient (Tarling and Crofts 1998). If patients fear that their confidentiality will be broken, they may be unwilling to divulge important information. This could result in misdiagnosis and the wrong treatment. Confidentiality is also essential to the relationship between researcher and participant. If the participant is unwilling to provide all the required information to the researcher, the results may be invalid.

There may be circumstances when maintaining confidentiality could cause more harm than divulging information (Gillon 1985b). The Hippocratic Oath qualifies its statement about confidentiality with the line ‘which ought not to be spoken abroad.’ This is ambiguous and may be taken to imply that the oath envisaged circumstances when it was permissible for information obtained to be ‘spoken abroad.’ There may be rare instances when the researcher gains information which might be detrimental if kept confidential. Such instances would require careful consideration, while considering the other ethical principles.

Respect for autonomy

Respect for autonomy is a principle frequently associated with a number of different concepts, including:

- Privacy.
- Voluntariness.
- Self-mastery.
- Free choice.
- Choosing one’s own moral position.
- Accepting responsibility for one’s own choices.

These ideas contribute to a definition of respect for autonomy that describes the concept as the ‘...personal rule of self by adequate understanding while remaining free from controlling influences by others and from personal limitations that prevent choice’ (Faden and Beauchamp 1986).

This is not as straightforward as it may seem because there are three types of autonomy (Box 2) (Gillon 1985c). Most people will accept the principle of autonomy and believe that their own autonomy should be respected.

Box 2. Three types of autonomy

- Autonomy of thought – this includes a wide range of intellectual activities that are described as thinking for oneself

- Autonomy of will – this involves the freedom of the individual to do something based on one’s own deliberations

- Autonomy of action – when the decision has been made the individual making the decision should be able to act as he or she wishes
It is not always possible to adhere to this principle. Some groups in society are considered to have diminished levels of autonomy (Burns and Grove 1995). These may include children, the terminally ill and some hospitalised patients. Many of these individuals may not be in a position to make choices about what is in their best interests. There is much debate about who – if anyone – should have the right to take the right to autonomy away from a person.

Researchers must respect the autonomy of potential research participants to decide about their involvement in any research study. The researcher may contribute to the process by providing information that will help the individual with his or her autonomy of thought. However, there is a risk that the researcher may be inclined to offer information that will coerce the potential participant to enter the study. This clearly links autonomy very closely with veracity and fidelity. The researcher may overemphasise the potential benefits and not highlight the potential risks. A researcher who does this is not adhering to the principle of respect for autonomy.

When an individual has made an autonomous decision, the researcher should respect that decision – even if it is not the response the researcher hoped for. Only the patient, or his or her next of kin, can possibly know what is best for the potential participant in a particular situation. There may be many intrinsic factors at work which the researcher is not aware of (Faden and Beauchamp 1986).

Conclusion

This article has briefly explored the seven ethical principles that underpin ethical thinking in healthcare research. Any research project will raise ethical questions that the researcher must answer. These principles can be used as a framework to guide the researcher through the research process. The seven ethical principles are closely linked and any ethical question may require the researcher to consider more than one principle. A researcher who complies with these principles will produce research of a high ethical standard.

REFERENCES