

Special Article

Ethics and Deontology in Nursing Research: A Discussion Paper

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Abstract

Introduction: In considering the importance of research in the development of nursing, this paper examines and describes the ethical principles governing the novice nurse-researcher's activities. It also defines codes regulating biomedical research but also some practical ways in which the novice researcher can contemplate and reflect on key questions when planning a study.

Aim: To provide an inclusive and practical guide for the novice nurse researcher concerning some ethical dimensions when planning, executing or assessing nursing research.

Discussion: Fundamental ethical issues in international nursing research are identified and extended in an effort to offer a brief, yet practical and consensus of ethical behaviour in research for the novice nurse. Also, procedural considerations are examined. Finally, broad guiding principles for designing and reviewing research are offered as follows: Respect for Autonomy; Self-determination; Full disclosure; Withdraw at any time with no consequences; Beneficence and Non-maleficence; Justice; Veracity; Fidelity; **Confidentiality**; Human dignity; Privacy; Post-research appreciation. Examples and debate on the above mentioned ethical principles are presented.

Conclusions: The ethical principles guiding health care studies are presented with respect to patients, society and the profession. Certain references are made to key ethical aspects to be considered from the conception of the research idea to the study aftermath.

Key words: ethics, ethical principles, deontology, nursing research

Introduction

Ethical limitations exist throughout the research process, starting from the research idea, the choice of subjects, and the method to be used, data collection and processing, writing a report, up to the publication and dissemination of the results. Even the decision of whether to investigate something or not has moral dimensions. On the other hand, if the nursing profession continues to base much of its practice on traditions, habits and 'practice as

usual', as it happens in many countries under austerity, health consumers may lose the opportunity for the best possible care (Theofanidis, 2015). Therefore, it can be said that it is unethical *not* to investigate clinical issues of concern.

One of the biggest problems faced by researchers is to decide when to continue their research and when to stop it when the study has surpassed the ethically acceptable boundaries. For this reason, the researcher

needs a mentor, i.e. someone who has the appropriate knowledge and experience to be able to give an objective view. In the academic field, the researcher has de facto the appropriate guidance through the supervisor who oversees his/her study (Muthuswamy, 2013).

In hospitals, approval to conduct an investigation is given by the Ethics Committee, which has to examine the usefulness of the research, the suitability of its methodology and whether the research protocol submitted covers all ethical issues. Apart from the initial approval, however, there is no direct mechanism to oversee the researcher when collecting data (Nardini, 2014; Rid et al., 2010).

Yet, there are grey areas when tackling ethical concerns especially for the student nurse or the inexperienced researcher and therefore concise guides are needed.

Aim

The aim of the present paper is to provide an inclusive and practical guide for the novice nurse researcher concerning some ethical dimensions when planning, executing or assessing nursing research.

Discussion

The basic ethical principles in nursing research

The initial six basic ethical principles as set in 2007 by the Nursing and Midwifery Board of Ireland (NMBI) and re-launched in 2015, aimed at protecting patients or participants from possible side effects or other adverse implications when partaking in a research study. These are further expanded from other critical referencing to include topics from contemporary debates on research ethics providing a 'Dozen Ethical Principles' as follows:

1) Respect for Autonomy

Respect for autonomy acknowledges the individual as an independent person who is able to make choices for him/herself (Ursin, 2009; Rogero-Anaya 1994). Within the

research context, the researcher is required to make certain that the principle of autonomy is adhered to for those participating in healthcare research by ensuring the right to retain his/her ability to make their own decisions without being controlled by anyone else.

2) Self-determination

A person has the right to choose freely without duress whether or not to participate in a research study. In this light, to enroll people in research without their free will and consent is to treat them merely as 'a means' (Wertheimer, 2014). For example, one might argue that the researcher is 'using' his/her subjects as a means to get to some valid results and conclusions but the subject per se is not (or should not) get any direct/indirect benefits (e.g. financial rewards) from partaking. Yet, no sensible moral principle could justify using people as a means for health research.

3) Full disclosure

This principle ensures that a person has received adequate information outlining the nature of the study, including the likely risks and benefits, thus enabling them to make an informed choice. The right to self-determination and the right to full disclosure are major components on which informed consent is based (Iedema et al., 2011; Polit & Beck, 2004).

4) Withdraw at any time with no consequences

For some groups in society, it may not always be possible to assure the principle of respect for autonomy (Delmar et al, 2011). Some may have diminished levels of autonomy and need additional protection regarding participation in research studies, because of their inability to give true informed consent.

5) Beneficence and Non-maleficence

The research should not harm any participant. The direct physical complications of any investigation may be obvious on most occasions, but long-term complications are not always predictable or measurable. Also, the psychological effects are much more difficult to detect and quantify. The research process

should benefit both participants and society in general. Benefits can arise from participating in an experimental therapy that is not yet available to the public. Also, participants in a survey are likely to receive more attention and human contact than other patients. But when this relationship ends with the end of the research work, feelings can be reversed and ex-participants may experience the isolation and lack of attention in a very negative way (Bhanji, 2013).

As far as general good is concerned, the benefit of research is clear when it produces new, documented knowledge and when it supplies society and future generations with solutions such as effective therapies or answers to theoretical issues.

6) *Justice*

The investigator should be fair to all participants. This presupposes that everyone enjoys the same level of services and everyone is treated equally. Moreover, these parameters reinforce the credibility and validity of the research itself and its results. The golden rule is to remember that any needs and interests of the participants are preceded by the needs and objectives of the research. Finally, the researcher must realize that between him/her and the research subjects, a relationship of power is always created, which de facto puts the researcher in the position of power. It is therefore the responsibility of the researcher to balance this relationship and to avoid exploiting his/her position. Finally, it is important not to focus solely on the research process or the data collection phase per se, but to recognize the obligation to treat participants equitably before, during and after the research study (Wheat, 2009).

7) *Veracity*

Veracity involves the concepts of truth about the research study and the absence of deception. Individuals have the right to be told the truth and not to be deceived about any aspect or stage of the research process. All aspects of a research project require explanations by the researcher, who must make every effort to ensure the participants

understand the implications throughout the study. The principle of veracity is linked with respect for autonomy (Gillon, 1994).

8) *Fidelity*

This principle represents the relationship of trust that has to be built between the researcher and the participant. Participants essentially entrust themselves to the researcher who has a strong moral obligation to protect them throughout the research process. For example, if the researcher discovers that participants are at risk, they should not go beyond the point where their patients are actually entering that risk zone. However, there is still some ambiguity as to the limits of this risk in terms of its type and effect and its temporary or permanent impact. Therefore stringent criteria are needed to guide researchers about the moral aspects of their decisions. Thus, in order to build trust between researcher and participants, it is necessary for researchers first to tell the truth even if this results in subjects refusing to participate in the research (Breitenstein et al., 2012).

Thus, the researcher should also be scrupulously honest because when considering information about a research study, a 'half truth' is a 'covert lie'.

9) *Confidentiality*

The information received and that relating to the participants should be treated with full confidentiality. This means that data should be used solely for the specific research purposes as formally formulated in the information protocol signed by the participant. Patients' personal information should be secured in all stages of the research process and measures should be taken for them not being accidentally disclosed. For this purpose, identification numbers or codes should be used as even initials that have been used in the past, have proven to bridge confidentiality (Kaiser, 2009; Orb et al., 2000).

Although research methodologies vary, i.e. some are more 'personal' or intrusive than others; basic ethical principles apply to all. Some practical examples of ethical dimensions

of some research methodologies or data collection types are provided below.

10) Human dignity

Health research must be based on the paramount premise of respect for human dignity. The protection of human dignity and personal integrity is clearly set out on both national and international legislation. However, in research ethics terms, this principle ascertains that people hold interests and personal integrity, which cannot be dismissed for the greater societal benefit via research. In this light, researchers have a moral obligation to protect personal integrity, individual freedom, self-determination, respect privacy, family life, and safeguard against harm or unreasonable stress (Winter & Winter, 2018; Jones, 2015).

11) Privacy

From a legal perspective the ethical issue of privacy is an extension of confidentiality, but the protection of privacy is increasingly linked to the processing of personal data. Thus, contemporary health research must be conducted in line with careful considerations for data protection, such as responsible use and storage of personal data. However, privacy also has a wider scope in research ethics especially under the light of the risk of data hacking. Thus, researchers must ensure robust gate keeping and double caution in storing, processing and handling information on their subjects (Knoppers, 2012).

12) Post-research appreciation

There have been numerous reports of research subjects feeling used or been taken advantage of, when a study is concluded. Thus, it is important for the researcher to act with care when the study is concluded and there is no 'after sale care' as one would expect in marketing. Out of respect for the subjects' time, researchers should treat them with appreciation at the study's end point. Archives and documents retained by the researchers may also contain sensitive personal data, and therefore subjects need information and reassurance that their data will remain safe and treated with care and respect. In this light, the

return of partial or full findings to participants has been recognized as a moral obligation of researchers based on the principle of reciprocal respect for individuals for their time and effort to partake. Furthermore, showing appreciation for a subject's participation establishes a sense of good will and enhances the feeling of being acknowledged for one's contribution to science (Fernandez et al., 2005).

Ethical dimensions in observational research

The observation method is a research technique where the researcher closely observes a situation, phenomenon, or practice as it happens, that is, in real space and time. Observation can be done with or without actual researcher involvement or direct participation (which is the usual case), and the researchers cover one or more full days to get a real picture of the situation they are studying. Typical examples of such studies are the recording of practices (observation of clinical practice, drug delivery etc.) or habits (division of labor, existence of team spirit, degree of hierarchy) of a particular ward (Hamric, 2002).

Ethical dilemmas arise when the researcher also activates his professional role. For example, the investigator records a situation, but at the same time observes bad practices, mistakes or omissions that make up or pose a risk to patients (Perlman, 2000). The researcher who may be a physician or nurse automatically acquires two conflicting roles. Should he remain a mere observer or intervene for the benefit of the patient? Of course, this attitude would modify the final results and weaken the research in general, but how moral is it not to interfere only to protect the aims of the research study?

Ethics of experiments

The experimental research method carries most of the organizational and psychological risks for participants by any other research method per se. The barbaric and unreasonable experiments of the Nazi doctors, where prisoners were used as consumables (equal to experimental animals), made some philosophical sociologists, lawyers, and

representatives of religious bodies in the 1950s, to strongly question the ethics of this method by suggesting banning experiments in humans all together (Annas & Gordin, 1992). Nevertheless, experiments with humans continued, although more emphasis was placed on preliminary animal studies (Heale & Shorten, 2017).

A few years later, the critics of the experiments reverted to the case of thalidomide that had been inadequately tested in pregnant women and resulted in the birth of children either without or with deformed limbs. Experiments in medicine continued since that tragic event, but the thalidomide shock was the second stage in the development of experimental methodology where exhaustive testing in experimental animals was established before testing a new drug in healthy volunteers (Fowler-Dixon, 2002).

In parallel, some ecologists, biologists and activists begun to make the first strong protests on animal experiments. The development of experimental methods and the parallel criticism have led the scientific community to create some sound commonly accepted principles for conducting a clinical study, which are:

- Volunteers who are lured by a direct or indirect payment are excluded from drug tests. Cruel examples are the financial reward or the reduction of sentencing to prisoners.
- A non-consideration is an essential requirement since the human body must neither be sold nor rented. The fundamental principle of each experiment is the statistical preparation to ensure statistically significant results, whether or not it is in favor of or against the studied study variable. This means that the researcher must have pre-selected adequate sample size and appropriate measurement methods to make it almost certain that the study will produce statistically valid results.
- The primary responsibility of the researcher is to maximize impartiality and minimize bias before, design, execute, and then report the experiment. Practically this is ensured by use of a random sample and a

double blind study methodology. However, the rapid evolution of experimental methods now suggests the use of a triple blind study where the identity of the two experimental groups (active and placebo) is unknown to the participants, the investigator and the research analyst.

However, the experimental method should be used only when absolutely necessary. Newell (1992) argues that simply because patients are an available and convenient population does not mean that they should be used by anyone trying to prove something.

Ethics of questioning

Questionnaires are used to collect information such as facts, knowledge, attitudes, aspirations, experiences, and behaviors of individuals. The questionnaire can be completed by the researcher himself (survey plans), or by the participant (in his / her own place and time). The latter case is one of the few methods of collecting data where the moral problem of sample anonymity can be overcome as the participant can return the questionnaire anonymously.

Yet, ethical dilemmas may emerge when the researcher encodes the questionnaires he sends out by numbering the 'sending list' so that he knows when they are picked up who returned them and who did not. Many researchers using a "self-completed" data collection questionnaire believe they do not need the patient's informed consent because the questionnaire is viewed as more discreet than the face-to-face interview or observational study and certainly less intrusive than the experimental one.

Nevertheless, the questionnaire interferes with one's privacy and the very nature of the questions may cause a cruel violation of the person's personal life. Questions (even if not answered) can "scrape" old wounds and trigger unpredictable situations. For example, three consecutive questions from a real questionnaire for mass cervical cancer

screening are listed below and illustrate this point.

- *Do you have a history of sexually transmitted disease?*
- *Have you been sexually abused?*
- *Do you have a family history of cervical cancer?*

These questions besides being highly personal can trigger and restore traumatic memories or experiences and create unpleasant feelings especially for the examinee and ultimately for the researcher too. The second question of the example above would hurt a woman who has had similar experiences. She may be annoyed and even ask the researcher why such issues are brought up and why should she discuss such personal issues. In this context, misplaced questions can raise suspicions about their usefulness to the subject matter, the aim of the questionnaire and the process itself. Therefore, it should be remembered that a question or questionnaire that may potentially "abuse" the participants is in itself an instrument of abuse. Questionnaires can also lead to feelings of guilt about living styles, for example by asking crude questions about nutrition to parents, on child obesity. Others may cause feelings of threat, such as the questionnaires they evaluate ones abilities or capabilities.

Practical instructions for research conduct

In summary, the novice researcher can contemplate and reflect on the following brief questions when planning a study:

1. *Why?* : Is the research to be done for merely learning how to execute a study? Is it to pass a class? Is it for adding a strong point to your resume? Or are you trying to add new knowledge?
2. *Will anyone be hurt?* : Is any participant at risk, directly or indirectly, physically, psychologically, mentally or otherwise?
3. *Is it worth it?* : Does the intended study have a good chance of having something new to add? Is it likely to reach reliable and useful conclusions?

4. *How will anonymity and confidentiality be assured?* : Will you be holding sensitive data or the identity of the participants? How will you encode them? What will you do if the data falls into the wrong hands? Are you capable of respecting confidential information?

5. *How is informed consent going to be secured?* : Will you be giving adequate written and oral explanations to future participants about your study? Will you be telling the truth at all stages? Will you be providing sufficient time and opportunity to be asked questions?

6. *How are you going to be dealing with your findings?* How will the results be publicized to make the most of the study? Will you be presenting them regardless of positive or negative outcomes? Will you avoid the temptation to 'massage' your results? Will you avoid concealing some of the results that may affect people or situations in favor you, i.e. be tempted to side-profit from your findings?

Informed consent

Informed consent is the process by which researchers try to ensure that potential participants understand the potential risks and benefits of their involvement in a research study. The consent of the prospective participant needs to be assured in more than one way. Researchers focus on the written consent form as the main assurance. Thus, an informed consent is essentially a written statement of agreed participation with several variations. In the simplest form it consists of a small text indicating the desire to participate. This form is an attempt legally to secure the researcher in particular in the event of future claims on the part of the participants. However, this kind of "contract" has no particular moral or scientific weight (Hardicre, 2014).

A better form is one that describes clearly the purposes of the study, its methodology, its timetable and highlights the potential risks for the participants. Essentially, this form is a miniature of the research protocol, where at the end the invitation to partake to the study is clearly stated and provisions are made that the text has been read, understood and signed by

the participant. The date and signature of witnesses are elements that provide legal protection, especially in experimental - pharmaceutical studies where the risk of harm is increased. There is no specific guide to the size of the text and the details it contains as it needs to be read and explained under no time pressure. Generally, however, the consent form should contain all the information that ensures that all relevant information concerning the procedures of the study is included, with the avoidance of legal or complex language and 'small print' (Kho et al., 2009).

Moreover, the consent form should contain the perspective participant's rights including the right to withdraw without any repercussions at any stage of the research process and contact details of either the main researcher or a contact person are provided. It should also state clearly, the potential risks and benefits of participation, expected duration of study and extent of confidentiality. Finally, a copy of the form should be given to the participant. It should be stressed that potential subjects must participate willingly and only after consent forms are completed and checked (Fouka & Mantzorou, 2011; Albala et al., 2010).

Conclusions

Distinctive issues that face nurse researchers are confronted by the scientific paradigm, as well as the other issues analyzed in this review, testify that the ethics of health care studies become increasingly complex to design and execute in an ethically correct manner. Research context is becoming more sophisticated but key ethical principles remain a bulwark to protect key actors, namely the subjects, the researchers, the institutions involved and the process itself.

Yet, bad science is not only a poorly designed or ill executed study but research that was not needed to begin with. In these lines, it has been argued that poorly designed research is by definition non-ethical and should not be done because at best it will waste patients' time and in the worst it will cause psychological and physical harm.

Overall, solid ethical guidance needs to keep abreast of contemporary changes, such as technological innovations or advanced research techniques, in order to provide a moral compass for nursing research in the future.

References

- Albala I., Doyle M., Appelbaum P. (2010) The evolution of consent forms for research: A quarter century of changes. *IRB: Ethics and Human Research*, 32(3):7-11.
- Annas G., Gordin M. (1992) *The Nazi doctors and the Nuremberg Code*. New York:Oxford University Press.
- Bhanji S. (2013) Health care ethics. *Journal of Clinical Research Bioethics*, 4(1): 141-142.
- Breitenstein S., Robbins L., Cowell J. (2012) Attention to Fidelity: Why Is It Important? *The Journal of School Nursing*, 28(6) 407-408.
- Delmar C., Alenius-Karlsson N., Højer Mikkelsen A. (2011) The implications of autonomy: Viewed in the light of efforts to uphold patients' dignity and integrity, *International Journal of Qualitative Studies on Health and Well-being*, 6:2-9.
- Fernandez C., Taweel S., Kodish E., Weijer C. (2005) Disclosure of research results to research participants: A pilot study of the needs and attitudes of adolescents and parents. *Paediatr Child Health*. 10(6): 332-334.
- Fouka G., Mantzorou M. (2011) What are the major ethical issues in conducting research? Is there a conflict between the research ethics and the nature of nursing? *Health Science Journal* 5(1): 3-14.
- Fowler-Dixon, S (2002) Ethical issues confronting clinical research: How did we get here? *Human Research Protection Program (HRPP) Education*. Paper 5. <http://digitalcommons.wustl.edu/hrpoed/5>.
- Gillon R. (1994) Medical ethics: four principles plus attention to scope. *BMJ*. 16; 309(6948):184-188.
- Hamric A. (2002) Bridging the gap between ethics and clinical practice. *Nursing Outlook*, 50(5):176-178.
- Hardicre J. (2014) Valid informed consent in research: an introduction. *British Journal of Nursing*, 23(11):564-567.
- Heale R., Shorten A. (2017) Ethical context of nursing research. *Evidence-Based Nursing*, 20:7-14.

- Iedema R., Allen S., Britton K., Piper D., Baker A., Grbich C., Allan A., Jones L., Tuckett A., Williams A., Elizabeth Manias E., Thomas H Gallagher T. (2011) Patients' and family members' views on how clinicians enact and how they should enact incident disclosure: the "100 patient stories" qualitative study. *BMJ*; 343:d4423.
- Jones D. (2015) Human Dignity in Healthcare: A Virtue Ethics Approach. *The New Bioethics*, 21(1):87-97.
- Kaiser K. (2009) Protecting Respondent Confidentiality in Qualitative Research. *Qual Health Res.* 19(11):1632–1641.
- Kho M., Duffett M., Willison D., Cook D., Brouwers M. (2009) Written informed consent and selection bias in observational studies using medical records: systematic review. *BMJ*. 2009 12;338:b866. doi: 10.1136/bmj.b866.
- Knoppers M. (2012) Privacy, Confidentiality, and Health Research. *International Journal of Epidemiology*, 42(1):359-363.
- Muthuswamy V. (2013) Ethical issues in clinical research. *Perspect Clin Res.* 4(1): 9–13.
- Nardini C. (2014) The ethics of clinical trials. *Ecancermedicalscience.* 8:387.
- Newell D. (1992) Intention-to-treat analysis: implications for quantitative and qualitative research. *Int J Epidemiol.* 21(5):837-41.
- Nursing and Midwifery Board of Ireland (2015) Ethical Conduct in Research: The Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives. Department of Health. www.NMBI.ie/What-We-Do
- Orb A., Eisenhauer L., Wynaden D. (2000) Ethics in Qualitative Research. *Journal of Nursing Scholarship*, 33:1:93-96.
- Perlman M. (2000) Ethical issues in 'observational research. *Paediatr Child Health.* 5(2): 89–90.
- Polit D., Beck C. (2004) *Nursing Research, Principles and Methods.* Lippincott Williams & Wilkins, Philadelphia PA:147-156.
- Rid A., Emanuel E., Wendler D. (2010) Evaluating the risks of clinical research. *JAMA.* 304:1472–1479.
- Rogero-Anaya P., Carpintero-Avellaneda J., Vila-Blasco B. (1994) Ethics and Research in Nursing. *Nursing Ethics*, 1(4):216-223.
- Theofanidis D. (2015) Nursing stroke patients in Greece in austerity times. *Int. Journal of Caring Sciences*, 8(2):238-240.
- Ursin L. (2009) Personal autonomy and informed consent. *Medicine, Health Care and Philosophy*, 12(1):17-24.
- Wertheimer A. (2014) (Why) should we require consent to participation in research? *J Law Biosci.* 1(2):137–182.
- Wheat K. (2009) Applying ethical principles in healthcare practice. *British Journal of Nursing.* 18(17):1062-1063.
- Winter S., Winter S. (2018) Human Dignity as Leading Principle in Public Health Ethics: A Multi-Case Analysis of 21st Century German Health Policy Decisions. *Int J Health Policy Manag.* 7(3): 210-224