Palliative care research ethics

Lars Øystein Ursin
Associate professor
Department of public health and nursing
Department of philosophy and religious studies
NTNU

Plan for this lecture

- Research ethics approval case one
- Gatekeeping
- Basic research ethics
- Research ethics approval case two
- Reflections on palliative care research ethics

Purpose of this lecture

To show that *research ethics* is about

research and *ethics* - not just adherence to the law

research: doing good research

ethics: perception and assessments: to see what is at stake

Lokal komite mente tiltakene ME-forskerne gjorde var gode nok

– At alle skal ha tillit til en studie på et så omstridt felt er ønskelig, men ikke nødvendig, sier Lars Ursin i den regionale komiteen som godkjente søknaden om ME-studien.

- På hvert møte behandler vi saker der interessekonflikter er tema, sier Lars Øystein Ursin, som er førsteamanuensis ved NTNU, og sitter i den regionale etiske komiteen som vurderer studier. Foto: NTNU

The Norwegian health research ethics system

REK (Regional committees for medical and health research ethics)

NEM (National committee for medical and health research ethics)

§9.Requirements concerning prior approval

The research project must be approved in advance by the regional committee for medical and health research ethics.

When do you have to apply to REK?

Before you do medical and health research, defined as *making use of scientific methods to acquire new knowledge about health and disease*.

Project description

The purpose of the project is to gain knowledge about how nurses use the new standardized care plan "Livets siste dagar" at the end of life in Norwegian nursing homes.

A researcher will follow nurses in their everyday work, with a special focus on the relationship with the dying patient. Data will be collected through participatory observation, individual interviews with nurses.

Participants: as many nurses as possible in each ward (three palliative care wards), and 6-10 patients in the end-of-life phase.

REK's assessment

REK pointed out ambiguities in the project description, among other things related to its societal benefits, methods and consent.

Regarding consent: When should consent be obtained, how to safeguard the right to self-determination to exit the project; how to safeguard the right to self-determination when participants during the study lose their consent competence; who gives consent (patient only, or patient and relatives); who receives a response to a request to take part..

Feedback

The research group argued:

1. The study has a high societal benefit.

2. Researchers acknowledge that observation as a method in the dying person's room is very challenging, not least because the researcher's presence can be perceived as invasive and offensive, both by the dying person and their relatives. Researcher has relevant nursing experience to be able to exercise good ethical judgment in a way that is adapted to each individual, specific situation.

3. Ethical challenges related to ensuring continuous consent in the project, as the patient gradually weakens and eventually loses consent competence. Researchers state that it is not possible to conclude on the basis of general rules how the principle of informed consent can best be safeguarded for this group of patients; each case must be considered concretely through ethical judgment.

Decision

The majority in REK did not find grounds to approve the study. Based on a complaint from the research group, it was sent to NEM for a final decision.

NEM's assessment

NEM observe that the protocol and the ethical reflection have been significantly improved and simplified through the application process for REK. NEM agreed with REK's assessment that the purpose of the study is good, and that it is generally important with research projects that can contribute knowledge about the process around caring for people in the death phase.

NEM believes that an observational study at the end of life should only be carried out if the benefit of the research project is high. In this case, we can not see that the benefit is high enough to justify the challenging intervention.

It is also an important principle for research on vulnerable populations that the research cannot be done in other ways and that it benefits the participants or the group.

The main focus of the project is not the dying patient, but the nurse. This reduces the legitimacy of carrying out the project as applied for. The researcher himself is critical of the fact that the dying may not be seen with "the eyes of the heart", as Kari Martinsen puts it, but with a "registering eye".

In this project, NEM is paradoxically anxious that the research project in particular draws a "registering eye" into the dying person's room by a researcher observing the nurse's behavior on the deathbed.

NEM would also like to point out that the project does not address ethical issues related to the nurses who take part in the study to any great extent. Unlike patients and relatives, the nurses are not considered a vulnerable group in this research project.

However, they must be observed while practicing their profession in a vulnerable situation and to a vulnerable group of patients, which indicates that the project manager must to a greater extent reflect on ethical issues that may arise in relation to the nurses she wants to observe.

Decision

REK's decision to reject the application for prior approval is upheld.

Review Article

PALLIATIVE MEDICINE

A systematic review of reasons for gatekeeping in palliative care research

Palliative Medicine
2016, Vol. 30(6) 533–548

DOI: 10.1177/0269216315616759
pmj.sagepub.com
SAGE

Marijke C Kars[1], Ghislaine JMW van Thiel[1], Rieke van der Graaf[1], Marleen Moors[1], Alexander de Graeff[2] and Johannes JM van Delden[1]

Abstract

Background: When healthcare professionals or other involved parties prevent eligible patients from entering a trial as a research subject, they are *gatekeeping*. This phenomenon is a persistent problem in palliative care research and thought to be responsible for the failure of many studies.

Aim: To identify potential gatekeepers and explore their reasons for gatekeeping in palliative care research.

Design: A 'Review of Reasons' based on the systematic Preferred Reporting Items for Systematic Reviews and Meta-Analyses approach and a thematic synthesis.

Gatekeeping in palliative care research

Palliative care is a young discipline, and the need to strengthen its evidence base is currently widely acknowledged. However, conducting such studies is problematic.

Gatekeeping defined: ‘the process whereby actors involved in the research process prevent participation of eligible patients in clinical research’

Gatekeepers

1. HCPs (physicians, nurses and allied healthcare workers): “The recruitment problems are often ascribed to the reluctance of healthcare professionals (HCPs) to include patients in palliative care research.”
2. Research ethics committees (RECs)
3. Management
4. Relatives
5. Researchers: “A remarkable finding is that gatekeeping was even observed among researchers who felt uncomfortable approaching potentially vulnerable patients”

Reasons for gatekeeping

1. Fear of burdening the patient
2. Difficulty with disclosure of health status
3. Fear of burdening the patient's relatives
4. Doubts about the importance or quality of the proposed study
5. Attitude towards research and (research) expertise

Gatekeeping – negative by definition?

What's lacking is the *patient perspective*:

"It is striking that although gatekeeping is touched upon in many studies, the phenomenon has not been studied in depth. To better understand gatekeeping, the experiences and views of palliative care patients regarding PCR participation should be explored to complement the views of gatekeepers."

Review Article

PALLIATIVE MEDICINE

A systematic review of reasons for gatekeeping in palliative care research

Palliative Medicine
2016, Vol. 30(6) 533–548

DOI: 10.1177/0269216315616759
pmj.sagepub.com
SAGE

Marijke C Kars[1], Ghislaine JMW van Thiel[1], Rieke van der Graaf[1], Marleen Moors[1], Alexander de Graeff[2] and Johannes JM van Delden[1]

Abstract

Background: When healthcare professionals or other involved parties prevent eligible patients from entering a trial as a research subject, they are *gatekeeping*. This phenomenon is a persistent problem in palliative care research and thought to be responsible for the failure of many studies.

Aim: To identify potential gatekeepers and explore their reasons for gatekeeping in palliative care research.

Design: A 'Review of Reasons' based on the systematic Preferred Reporting Items for Systematic Reviews and Meta-Analyses approach and a thematic synthesis.

A major concern is that gatekeepers prevent the patients from making their own decisions regarding research participation, thereby overriding their autonomy.

To preserve the patients' right to decide for themselves, patients should at least be informed about the opportunity to participate in medical research.

Review Article

PALLIATIVE MEDICINE

A systematic review of reasons for gatekeeping in palliative care research

Palliative Medicine
2016, Vol. 30(6) 533–548

DOI: 10.1177/0269216315616759
pmj.sagepub.com
SAGE

Marijke C Kars[1], Ghislaine JMW van Thiel[1], Rieke van der Graaf[1], Marleen Moors[1], Alexander de Graeff[2] and Johannes JM van Delden[1]

Abstract

Background: When healthcare professionals or other involved parties prevent eligible patients from entering a trial as a research subject, they are *gatekeeping*. This phenomenon is a persistent problem in palliative care research and thought to be responsible for the failure of many studies.

Aim: To identify potential gatekeepers and explore their reasons for gatekeeping in palliative care research.

Design: A 'Review of Reasons' based on the systematic Preferred Reporting Items for Systematic Reviews and Meta-Analyses approach and a thematic synthesis.

Review Article

PALLIATIVE MEDICINE

Palliative Medicine
2018, Vol. 32(4) 851–860


Reprints and permissions:
sagepub.co.uk/journalsPermissions.nav
DOI: 10.1177/0269216317744503
journals.sagepub.com/home/pmj

Dying persons' perspectives on, or experiences of, participating in research: An integrative review

What is already known about the topic?

- Conducting research with dying persons can be controversial and challenging due to concerns for the vulnerability of dying persons and the potential burden that research might impose.
- Access to dying persons for research purposes is limited due to perceived gatekeeping by treating clinicians, managers and policy-makers.

What this paper adds?

- Dying persons value the opportunity to choose to participate in research, even when there is no hope of cure or life prolongation.
- Vulnerability should not be assumed in the dying person.
- Research participation can be beneficial to the dying person by providing an opportunity to help others, contribute to society, science and future patient care.

A systematic review of the experiences of vulnerable people participating in research on sensitive topics

What is already known about the topic?

- Gaining ethics approval to conduct research on sensitive topics with populations considered to be vulnerable is often a challenging process.
- If appropriate treatment is to be designed for specific groups of people, research needs to be conducted to identify those needs.

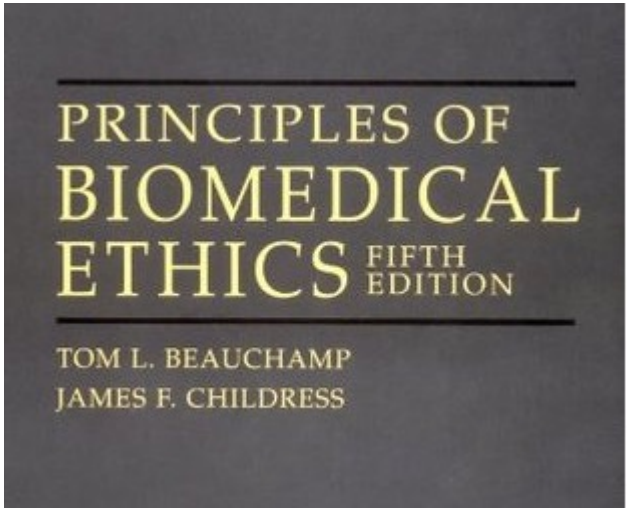
What this paper adds

- Evidence of benefits from participating in research significantly outweighs the potential for harm.
- In those instances where harm occurs, it is typically not long-lasting or severe and the majority of participants are pleased they have participated and would do so again.
- Identification of strategies that can be adopted to safeguard the wellbeing of vulnerable populations participating in research.

The basics..

The four principles:

1. *Respecting autonomy*
2. *Avoiding harm*
3. *Doing good*
4. *Ensuring justice*



Act on medical and health research (the Health Research Act)

§5.Responsible conduct

Medical and health research must be organized and carried out in a responsible manner.

Research must be based on respect for the research participants' human rights and dignity. The participants' welfare and integrity shall have priority over scientific and social interests.

Informed consent

Research participants should not be forced to take part in research, and exploited in the research project.

So, the participant should give *informed consent*, which means: *voluntary* enrolment based on *understanding*..

Act on medical and health research

§13.Consent

Consent must be obtained from participants in medical and health research, unless otherwise laid down in law. Consent must be informed, voluntary, express and documented.

If the research participant can be regarded as being in a relationship of dependency with the person requesting consent, meaning that the research participant might feel pressured to give their consent, informed consent must be obtained by another person whom the research participant does not have this kind of relationship with.

So, what about vulnerable persons, the young and the frail and..

..is it OK that we invite them to take part in research?

After WWII, Nuremberg code: NO, we have to protect vulnerable groups

Nowadays: YES, to exclude vulnerable persons is to increase their vulnerability, by excluding these groups from the benefits of research

CIOMS 2016, Guideline 16

Adults who are not capable of giving informed consent must be included in health-related research unless a good scientific reason justifies their exclusion.

Act on medical and health research

§18. Research that includes minors and people who lack competence to give consent may only be done if the potential risks or disadvantages for the person are insignificant.

For people who lack competence to give their consent, it is a requirement that there is no reason to believe that the person concerned would have been averse to participating in the research project if they had had the capacity to give their consent, and that similar research cannot be done on people who have the capacity to give consent.

Consent is neither a *necessary*, nor a *sufficient*, condition for legitimate research participation

Project description

The purpose of the project is to provide knowledge about the consequences of giving patients with severe mental illness an increased right to decide their own follow-up and treatment. The background for the study is an amendment to the Mental Health Care Act (PHVL) that patients with severe mental illness can no longer be subject to coercive mental health care, if they have consent competence.

It is desirable to use medical records data from two periods of two years before and two years after the change in the law, respectively, and compare these two periods. Participants will be approx. 100 patients with a psychosis diagnosis who have been subject to coercive mental health care without a 24-hour stay.

The applicant requested an exemption from the consent requirement because the research participants may at times have reduced consent competence or have had negative experiences with coercive use and therefore will not wish to consent to their health information being used in research.

REK's assessment

REK emphasized that the patient group are people who have experienced that their autonomy has previously been violated. Nevertheless, it is desired to research the patients' health information without the patients' permission. REK points out that exemption from the consent requirement must be anchored in an assumption that the patients would have consented, if they had been asked. In this case, it appears that a proportion of patients would probably say no.

The committee was of the opinion that such an arrangement would deprive the participants of the right to self-determination, and that in the worst case it would be perceived as a breach of integrity. Furthermore, it could lead to a significant weakening of the participants' confidence in research. REK was also concerned about general trust in research if it becomes known that research is being done on patients who do not want it.

Decision

The justification from the applicant for exemption from the consent requirement is not considered good enough. REK approved the project, but made it a condition that consent was obtained.

NEM's assessment

NEM believes it is important that the element of violation in the coercive use in treatment is not highlighted alone - the element of care is also important to mention. The same care element is also relevant for research that obviously aims to contribute knowledge that is helpful to the patient group.

NEM agrees with REK that presumed consent is generally important for research ethics assessment, but a premise for this assumption is that one is dealing with people who can rationally assess the risk, discomfort and disadvantage of participating in the project against the benefit. In this project, the participants' consent competence and rational judgment will vary.

NEM's assessment is that research without consent in very special contexts such as this must be acceptable, even though it cannot be assumed that consent would have been given if the participants had been asked. Gaining more knowledge about the effects of coercion and voluntariness is of great value and when it can be done gently and with little risk for the participants, NEM believes that society's trust in research will remain - even if the consent requirement is deviated from.

However, NEM finds that the research protocol has weaknesses and ambiguities that raise doubts about the benefits to society. Large amounts of highly sensitive data will be collected in a study with limited human resources.

Decision

The project is not approved.

Journal of Pain and Symptom Management
Volume 48, Issue 6, December 2014, Pages 1211-1221

Special Series on Research Methodology

Ethical Conduct of Palliative Care Research: Enhancing Communication Between Investigators and Institutional Review Boards

Amy P. Abernethy MD, PhD [a, b], Warren H. Capell MD [c], Noreen M. Aziz MD, PhD,

The palliative care field is deeply committed to

1) building its evidence base to reduce suffering and improve quality of life through thoughtful investigation
2) upholding its focus on humane and compassionate care for patients and caregivers
3) identifying and resolving issues that could impede conduct of ethical research.

For these purposes, palliative care investigators must develop strategies for proactively addressing—with efficiency, integrity, and rigor—ethical concerns that pertain to conduct of research in this population.

Reasons for caution, because the palliative care population

- is especially fragile and *vulnerable*, thus warranting extra protection from potential exploitation
- is more likely than other potential study participants to be incapable of *understanding* research and/or accurately interpreting its conditions
- and, that the end of life is a *sacrosanct time*, into which research activity may present an unwelcome and/or inappropriate intrusion

…in several studies, most palliative care patients *welcome the opportunity* to participate in research, reporting benefits that include a sense of contribution to greater community good, a sense of *meaning to life*, a *feeling of pride*, and the *opportunity to reflect* on life and the illness experience. Many people see participation in research as an opportunity to engage in an *altruistic endeavor* in the limited time they have remaining…

…IRBs reviewing palliative care protocols have been described as “powerful gatekeepers,” at times imposing an unjustly paternalistic attitude that denies palliative care patients the opportunity to participate in research…

Investigators may practice *IRB avoidance*, in which they deliberately design their protocols to minimize IRB scrutiny.

Anticipated ethical concerns may influence study design, potentially decreasing generalizability of study findings.

For example, concern about certain patients being too sick to participate in research may lead to exclusion of those patients—who may be the ones most representative of the population that stands to benefit from the evidence generated.

What can palliative care investigators do today to ensure clear communications with IRBs and expedient conduct of ethically sound palliative care research?

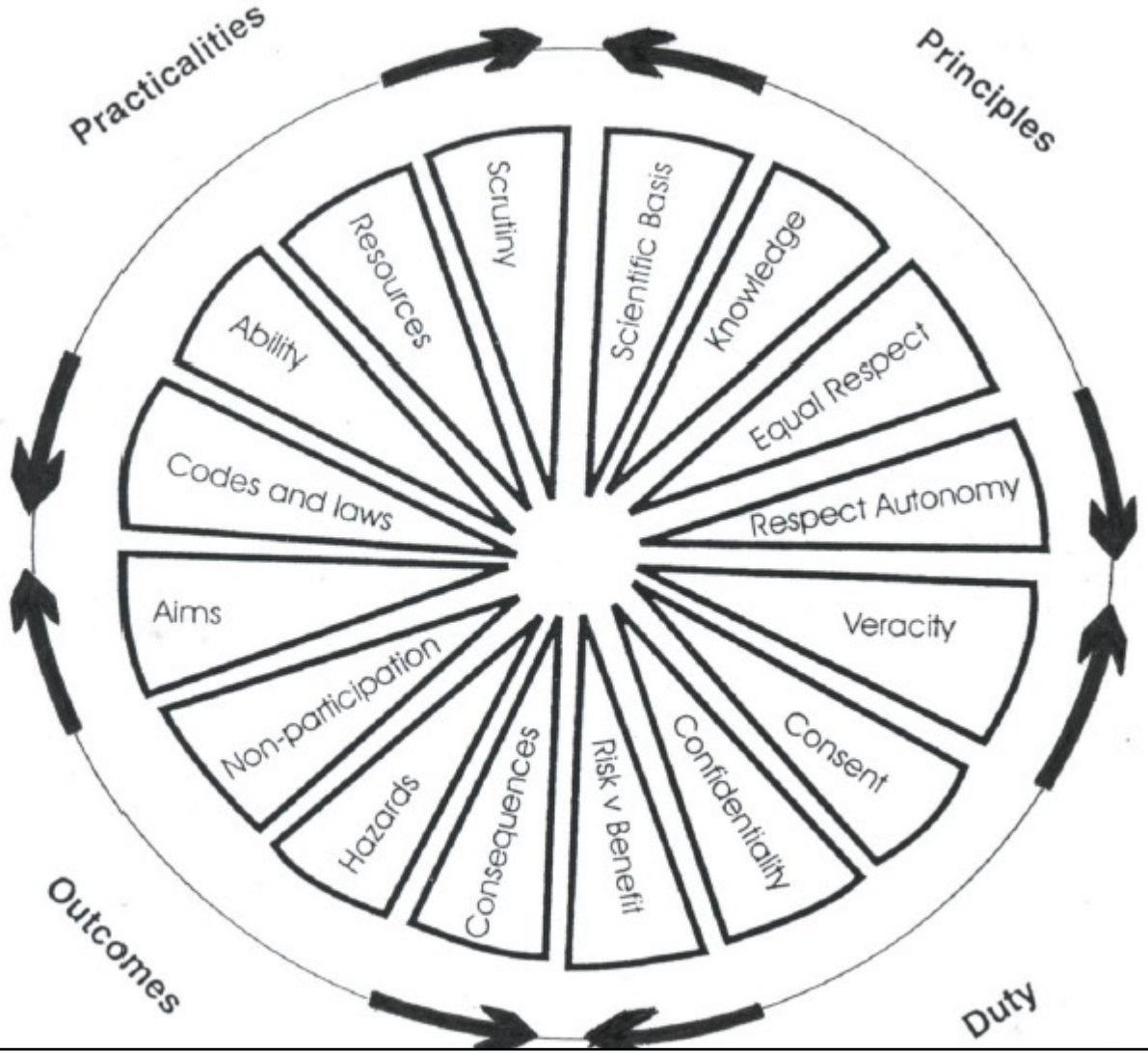
- Palliative care investigators may need to pay particular attention to potential sources of coercion or undue influence, and provide a detailed description of the planned processes for working with, and protecting participants.
- The patient's voice also may be strengthened by embedding, in the protocol of interventional studies, an inquiry into how participation in the current research impacts the patient and caregiver experience.
- Above all, palliative care investigators must maintain integrity in their research methods, including the use of approaches that minimize bias and maximize generalizability of results.

…and:

More sensitive research demands more experienced and well-reflected researchers

It's not just about *what* you are going to do, but *how* you are going to do it

Conducting qualitative research with palliative care patients: applying Hammick's research ethics wheel



Tools Share

nt when attempting to
ancer. It focuses on the
rch study undertaken by
incorporate the ethical
vel. Ethical reasons for

..AND/OR IN FILLING OUT THE REC/IRB FORM