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Review Article

PALLIATIVE MEDICINE

A systematic review of reasons for gatekeeping in palliative care research

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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.

The recruitment problems are often ascribed to the reluctance of healthcare professionals (HCPs) to include patients in palliative care research.

Researchers have sought practical solutions to overcome gatekeeping, such as obtaining data from relatives instead of patients, adapting informed consent procedures or bypassing HCPs in the process of identifying and soliciting eligible patients.

Gatekeepers

1. HCPs (physicians, nurses and allied healthcare workers)
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 defined: 'the process whereby actors involved in the research process prevent participation of eligible patients in clinical research'

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.

The basics..

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 (the Health Research Act)

§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 is to increase their vulnerability, by excluding these groups from the benefits of research

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

A systematic review of reasons for gatekeeping in palliative care research

Marijke C Kars[1], Ghislaine JMW van Thiel[1], Rieke van der Graaf[1], Marleen Moors[2], Alexander de Graeff[3] and Johannes JM van Delden[1]

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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

Act on medical and health research

§5.Responsible conduct

Medical and health research must be organised 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.

Medical and health research must take into account ethical, medical, health, scientific and privacy factors.

The tricky issue of decision-making capacity

Not everyone has the capacity to consent – but everyone has the capacity to refuse and withdraw

Still, «Ulysses contracts» should be avoided…

…and: in some situations (coercion) it is a matter of well-being versus liberty, while in others (indifference) it is a matter of well-being versus dignity

Are Severely Depressed Patients Competent to Consent to Research?

Carl Elliott, MD, PhD

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Arch Gen Psychiatry. 1997;54(2):113-116. doi:10.1001/archpsyc.1997.01830140021003

Abstract

Depressed patients are often asked to take part in clinical research studies that carry risk. These patients are generally assumed to be mentally competent to consent to research, since depression often leaves a patient's cognitive abilities intact. In this article, it is argued that many severely depressed patients may not be competent to consent because they cannot be considered accountable for their decisions. The article presents 2 arguments: first, that it is unclear whether the decisions of some severely depressed patients are authentically theirs, and second, that some severely depressed patients may not have the appropriate minimal degree of concern for their own well-being. It is argued that assessments of competence must take account of emotional factors, and that, if severely depressed patients are incompetent to consent, research studies involving a poor risk-benefit ratio will

Most accounts of competence focus on intellectual capacity and abilities to reason, and depression is primarily a disorder of mood.

To put the matter simply, if a person is depressed, he or she may be *aware* that a protocol carries risks, but simply not *care* about those risks.

What we really want to know when we ask if a patient is competent is whether that individual is able to make a decision *for which he or she can be considered accountable.*

Some patients, as a result of their depression, may even *want* to take risks.

We might wonder about the competence of one such patient, a 49-year-old woman capable of fully understanding the electroconvulsive therapy for which she was being asked to consent, but who, when told that electroconvulsive therapy carried a 1 in 3000 chance of death, replied, “I hope I am the one”.

Assessing decision-making capacity – distinct from the decision made?

First, we establish the person's decision-making capacity, and *then* we act according to the person's authoritative statement/ask the proxy

Or: *First* we listen to the person's assessment, and *then* decide whether it is authoritative or not

Increased risk demands increased decision-making capacity..

..or increased decision-making assessment?

Michigan: parents who choose not to vaccinate their children must attend vaccine education sessions at local public health offices

Palliative care researcher: Explain the study again if the potential participant declines?

The relation between beneficence and autonomy

Discrete and conflicting values: Competent vs incompetent persons

Semi-discrete supporting values: Soft and hard paternalism

Non-discrete converging values: Decision-making competence assessments


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SCIENTIFIC CONTRIBUTION

The logic of the interaction between beneficence and respect for autonomy

Shlomo Cohen[1]

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Abstract
Beneficence and respect for autonomy are two of the most fundamental moral duties in general and in bioethics in particular. Beyond the usual questions of how to resolve conflicts between these duties in particular cases, there are more general questions about the possible forms of the interactions between them. Only recognition of the full spectrum of possible interactions will ensure optimal moral deliberation when duties potentially conflict. This paper has two simultaneous objectives. The first is to suggest a typological scheme of all possible modes of interaction; these will be classified under the "discrete," "semi-discrete," and "non-discrete" categories, according to whether the meaning and/or forms of expression of each duty are treated as independent from or rather as constrained by the other. The second objective is to show that all logical possibilities of interaction indeed have real expressions in medical ethics, to provide clear illustrations of each, and in particular to stress those that have usually escaped recognition.

The relation between beneficence and autonomy

Shlomo Cohen: «determination of competence (and hence autonomy) is not made solely by a neutral assessment of whether decision-making ability passes some minimal threshold, but is (also) a function of a beneficent cost-benefit analysis of the potential consequences to the patient of our recognizing her decision-making authority in a given context of choice. In such cases autonomy depends conceptually on beneficence, since the diagnosis of autonomy rests (partially) on a beneficence-guided assessment"

Which of these does or does not go together with competence – and exploitation?

Voluntariness

Autonomy

Paternalism

Moralism

Why should potential research participants decide?

Because of respect for persons?
Because it is a legal right?
Because the consumer is always right?
Because it empowers the person?
Because it makes the person happy?

..or because: then we do not have to decide?

§9.Requirements concerning prior approval

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

ELSEVIER

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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.

The "Statin Study"

Eligible participants were adults, diagnosed with advanced life-limiting illness, with an estimated prognosis of one to six months who were taking statins for primary or secondary prevention.

The primary objective was to determine whether discontinuation of statins affects 60-day survival.

Secondary objectives were to determine the impact of discontinuing vs. continuing statins on incidence of clinically significant cardiovascular events as well as quality of life, performance status, anxiety and depression, symptoms, polypharmacy, satisfaction with care, and costs.

Data were collected in person at baseline, and thereafter by telephone weekly through Week 4, every other week from Week 5 until death or six months (24 weeks), and monthly from Week 25 until death.

Ethical Issues Raised by the IRB for the Statin Study and Their Resolution

Issue	Resolution
Consent-related issues, in the setting of anticipated cognitive/physical decline	
Assurance of ongoing informed consent (repeated consent at all data collection time points to ensure continued willingness vs. consenting at baseline only)	Discussed the relative burden vs. benefit of repeating full consent process (which is what was requested) at each data collection point. Explained that the study design required following patients over time to capture the effects of the intervention on patient outcomes throughout their illness trajectory, including the primary study outcome, survival, necessarily spanning a time when the participant would be unable to make decisions, and act as his or her own advocate. Clarified that the primary treating physician would continue to act as the study participant's advocate throughout the course of the study and would have the ability to override study randomization. Modified consent form to include language stating that a family member of the study participant should approach the treating physician and/or study team with *any* concerns about the study participant's involvement in the study. Emphasized that all participants are followed closely for safety through the adverse event monitoring and reporting process.
Impaired functional status, cognition intact (cannot sign form but able to give consent)	Clarified that the CRC, as part of obtaining informed consent, would assess for cognitive deficits or confusion. If the participant who is unable to physically sign the consent form provides his or her verbal consent, then the CRC and a witness would sign the consent form, and an explanation at the bottom of the consent form would indicate that compromised functional status (not cognitive status) made it impossible for the patient to sign the consent form, and that verbal consent was obtained and witnessed
Identification of an appropriate advocate for study participants to make study discontinuation decisions once study participants are no longer able to make decisions for themselves	Assured the IRB that, at each study visit, participants would be briefly assessed for their ongoing understanding of and interest in continuing to participate in the study. In the consent form, and during the informed consent process, it was made explicit that • Participants may withdraw from the study at any time, and family members, treating clinicians, and other patient

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. The quality of the evidence base in palliative care is at stake. Rigor and ethical considerations cannot be compromised for the sake of expediency.

…and:

More sensitive research demands more experienced and well-reflected researchers