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Clinical and Epidemiological Aspects of End-of-Life Decision-Making

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Acknowledgements

This volume is the result of a conference held in the Trippenhuis in Amsterdam from 7 through 9 October 1999 under the auspices of the Royal Netherlands Academy of Arts and Sciences. The conference had 33 participants from all over the world. They all contributed to the conference by giving a lecture or presenting a poster, and by discussing each other's work and challenges for future research. This volume includes contributions of 17 speakers, which have all greatly benefited from these discussions.

The organizers of the conference, who are also the editors of this volume, are deeply grateful to the Royal Netherlands Academy of Arts and Sciences, for supporting the conference and generously providing financial and human support. Additional financial support was provided by the Netherlands Organization for Scientific Research, the Dutch Cancer Society, the Dutch Ministry of Health, the Foundation 'Vereniging Trustfonds Erasmus Universiteit Rotterdam', the Van Coeverden Adriani Foundation and the 'Dittmerfonds' of the Vrije Universiteit Amsterdam, the Department of Public Health of the Erasmus University Rotterdam, and the Faculty of Medicine of the Vrije Universiteit Amsterdam, all in the Netherlands, for which they are gratefully acknowledged.

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Introduction

Over the last decade or more, end-of-life care has been a focus of attention by the public, policy makers, and the health care professions in many developed countries. Many factors have contributed to this focus. Aging of the population, with growing proportions of people over 65, in all developed countries has emphasized geriatric care in general and end-of-life care because this group accounts for a significant majority of decedents. In addition, during this period there has been growing recognition in many countries that end-of-life care is less than optimal. Many dying patients experience pain and other physical symptoms. Much more could be done to provide better care for these patients. And yet there is a sense that health care systems have neither educated health care providers nor arranged services to ensure good care of the dying. In almost all Western countries, approximately 1% of the population dies each year. Including affected family members, this means that a significant proportion of the population confronts and is affected by death each year. Furthermore, from a policy perspective death and dying represent a significant proportion of health care costs. For instance in the United States, health care expenditures for decedents constitute about 27% of the Medicare program budget (the health care program for people 65 years of age and older); expenditures for decedents are five to six times those for average patients. It has been estimated that 10% or more of all health care spending in the United States goes to care for dying patients in the last year of their lives. While comparable data are not available for other countries, and the costs may not be quite as high as in the United States, expenditures on dying patients are still substantial and represent a large proportion of total health care spending. Finally, the extensive interest in and discussion of euthanasia and physician-assisted suicide have necessarily focused attention on the care of the dying and what factors might spur a dying patient to ask to have his or her life intentionally ended.

In various countries, researchers have been trying to understand end-of-life care. As with any research agenda, the particular questions they have addressed have depended upon a variety of factors including the researchers personal interests, priorities formed because of unique national concerns, and the structure of the nation's particular health care system. Some researchers have focused on euthanasia and physician-assisted suicide, others have examined the experience of cancer patients, others have examined practices in intensive care units, and still others the care of dying children. Yet many of the researchers have been working in isolation, and if

not isolated from researchers in their own countries then lacking interaction with end-of-life researchers in other countries. The benefits of sharing data and experiences, for instance, added insights that could be generated by comparing data from country to country and by seeing the effects of different practices, could not be realized.

In October 1999, a conference was organized with the overall objective of trying to create a worldwide community of researchers in end-of-life care who can create a shared pool of knowledge that can be used to improve care of the dying. Ultimately it was hoped that the researchers would share their research experiences, provide each other insights into what studies they have conducted, what data exist and what data needs to be collected. Beyond sharing and comparing current knowledge, the conference was intended to elicit commitments to:

1. develop common language, terms, and conceptual framework to guide future research;
2. develop common research methodologies and study designs;
3. develop common core sets of instruments and questions;
4. develop an organized and prioritized set of research objectives.

Achieving these four aims would permit direct comparisons of data between countries that would allow benchmarking of performance, comparisons of different end-of-life care practices and interventions, and even foster multi-national research projects. In these ways, research into end-of-life care would become a real scientific discipline with coherent objectives rather than an episodic and haphazard research interest of a few individuals.

Inevitably, the conference began with what exists. To begin sharing research experiences and data necessitates beginning with the available data. And to generate commonality requires looking for those specific topics in which researchers from various countries have conducted studies. Consequently, the conference focused on four major topic areas in which researchers from diverse countries have assembled rigorous data:

1. the withdrawal or withholding of potentially life-prolonging medical interventions;
2. euthanasia and physician-assisted suicide;
3. end-of-life decision-making for neonates;
4. end-of-life decision-making for the demented.

Obviously, these are not the only topics in which there is important research related to end-of-life care. Data exist on the experience of pain and other symptoms, burdens on caregivers, and use of hospice, just to name a few. Nevertheless, these represent key topics that are of interest to the public and policy makers, in which researchers from a variety of countries have conducted studies that could be profitably shared and compared. This accounts for the organization of these proceedings.

The organizers hoped to identify individuals who have conducted empirical research on each one of these topics. The emphasis was on researchers who have

conducted rigorous and valid studies generating reliable and comparable data. It was not possible to realize this hope. While in some countries a large number of groups have been conducting rigorous end-of-life research for a decade or more, in other countries the organizers failed to find substantial research, even as yet unpublished research, on end-of-life care. Representatives from as many countries as possible were invited to participate and present their research findings. Researchers from eight Western European countries, Canada, Australia and the United States with data from even more countries participated.

These proceedings represent a collection what we believe to be the best available data on end-of-life care in the developed world. And yet, we acknowledge there are many glaring deficiencies. There are many countries with advanced health care systems from which we have no data and in which there does not appear to be substantial on-going research. Furthermore, there are many topics on which there are only a handful of data that lack comparable studies in other countries or for which comparisons cannot be made because of differing methodologies. For instance, the burdens placed on family members of caring for dying patients. Finally, there are many topics that simply have not been rigorously studied in any country. For instance, the role of spirituality for dying patients, or quality of dying patients' experiences in various sites of death, need serious examination in all countries. The organizers hope that by collecting existing data, assembling an international cohort of empirical researchers, and, most importantly, developing common research objectives, instruments, and methodologies, research will be spurred. It is hoped that the shared research resources will encourage individuals in countries that have not studied end-of-life care to begin research, studies in various countries that use common measures permitting multi-national comparisons, and multi-national collaborative research projects on end-of-life care. To this end we have established a Web site (www.emgo.nl/endoflife) for the sharing of research instruments and questionnaires and developing of collaborative projects.

The Editors

Gerrit van der Wal

Clinical and Epidemiological Aspects of End-of-Life Decision-Making: a Conceptual Framework[1]

Developments in Death and Dying

At the turn of the century it is good to realize that only 100 years ago most deaths concerned young people who died from infectious diseases, such as tuberculosis. Members of the family sat at the bedside. Physicians had almost nothing to offer, at least from our current point of view. Increased welfare, improved sanitation, vaccination programs – and later on also antibiotics, and other health care achievements – have changed this picture dramatically.[1]

Nowadays, industrial nations have an aging society, supported and sustained by flourishing technology. And the role of medicine with respect to death and dying has become an important topic of scientific and societal debate. Until recently, death was regarded as the ultimate defeat of medicine. Curing disease, preventing death, and rehabilitation have traditionally been the main goals of health care, but doctors have now become aware of their responsibility beyond the stage at which death is inevitable, and recognize adequate care for the terminally ill as another important goal of medicine.

Several cultural, medical, epidemiological and demographical factors may explain this current interest in death and dying. In modern society there seems to be an increasing emphasis on patient autonomy. People want to control their own life, including the end of it, and they want to have a voice in how and when they die. Advances in medical technology have strongly increased the ability of medicine to prolong the life of seriously ill patients, which inevitably yields questions about the appropriateness of applying such technology in all cases. Technology has two faces: for some it is life saving, but for others it prolongs the dying process and results in great suffering for both patient and family. Cancer is an increasingly important cause of death, because of decreasing death rates from cardiovascular disease. Finally, death now mainly occurs at old age, and the aging of society causes increasing death rates.[2-4]

Not surprisingly, also in the domain of research there is a growing interest in death and dying. However, most empirical research into palliative care and

[1] I thank Dick Willems, Agnes van der Heide, Paul van der Maas, and Bregje Onwuteaka-Philipsen for their comments on this paper.

end-of-life decision-making is in its infancy. In particular, there is a need for more international collaboration in the field of epidemiological and clinical research.

Area and Definitions

When formulating a research agenda on end-of-life decision-making it is important to be sure that one is working in one and the same field, with some recognizable actors and factors in it. Furthermore, in collaborative research it is important to speak the same language and to use the same wording and phrasing. Therefore, some remarks are made on area and definitions.

Medical care at the end of life includes palliative care and may involve decisions on medical interventions that, intendedly or unintendedly, may hasten the moment of dying. Curative care, provided for a patient with a potentially fatal illness, is aimed at curing or prolonging life (including the symptomatic treatment of complaints and symptoms). Palliative care, however, is no longer aimed at curing or prolonging life, but at alleviating pain and other symptoms (while much attention is paid to the psychosocial, emotional and spiritual needs of the patient).[5]

Medical end-of-life decisions are decisions made by physicians with regard to actions which are aimed at hastening the patient's death, or in which is taken into account the possibility that death will be hastened.[6] Such end-of-life decisions include:

1. decisions about whether or not to *withdraw* or *withhold* potentially life-prolonging treatment, for instance, mechanical ventilation, tube-feeding, dialysis;
2. *alleviation of pain or other symptoms* with, for instance, opioids, or *terminal sedation* with benzodiazepines or barbiturates in dosages which are large enough to include the hastening of death as a possible or certain side-effect;
3. *physician-assisted death*, defined as the prescription, supply or administration of drugs with the explicit intention (of enabling the patient) to end the patient's life (i.e., *euthanasia* and *assisted suicide*, respectively, when at the patient's explicit request).

Curative Care, Palliative Care and End-of-Life Decisions

The relationship between curative care, palliative care and medical end-of-life decisions differs for each type of decision. This is visualized in Figure 1.

Some people die an unexpected and sudden death, for instance, from a stroke, a heart attack or a car-accident. With regard to these deaths there is, by definition, no question of terminal or palliative care, neither there is the possibility of, or the need for, end-of-life decision-making. There is another group of deaths, which is not preceded by an end-of-life decision, but in which, until the end, curative or life-prolonging care is provided. In most non-sudden deaths (at least in the

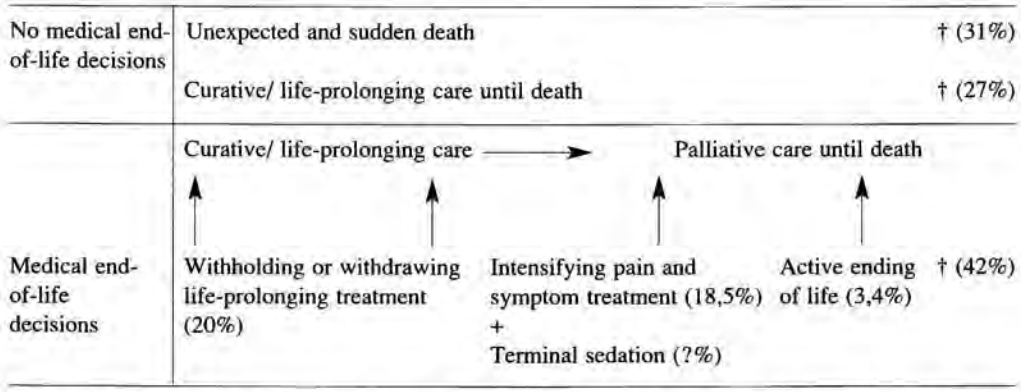
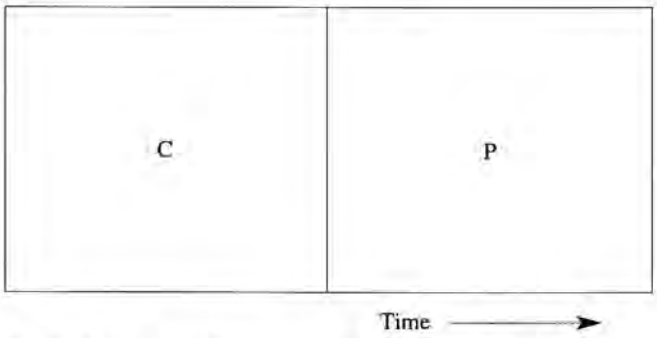


Figure 1. The relation between curative care, palliative care and medical end-of-life decisions (illustrated with death percentages for the Netherlands).

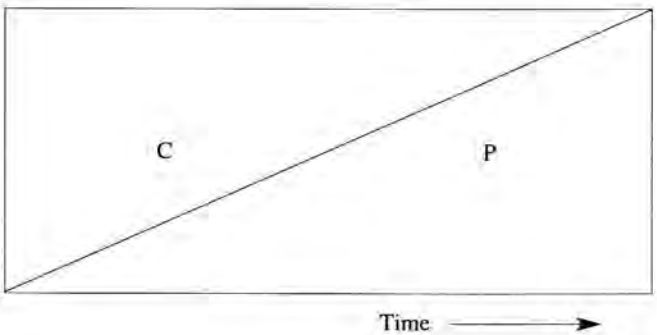
Netherlands) one or more end-of-life decisions have been made. By definition, palliative care only begins after it has been decided that curing disease or prolongation of life are no longer among the aims of medical care. Intensifying the alleviation of pain and symptoms can take place throughout the entire terminal phase and/or mark the end of this phase if it unintentionally results in hastening death. This also applies to terminal sedation, be it that the hastening of death in this case is much more likely. Intentional, active life-termination, whether or not at the explicit request of the patient, definitely concludes the terminal phase.[7]

The definitions suggest a clear division between curative/life-prolonging care and palliative care (Figure 2.a). In practice, however, the transition is often much smoother. In the literature (and by the WHO) the transition is also presented as a gradual one (Figure 2.b).[5] The explanation for this paradox is twofold. Firstly, some types of potentially curative/life-prolonging treatments, for instance, antibiotics or radiation, are also used for palliative purposes only; that can be confusing. Secondly, and more important, in practice the decision-making usually concerns no single type of curative/life-prolonging treatment, but often a sequence of different methods of treatments, which can be withheld or withdrawn at different times. For instance, when chemotherapy has been stopped, antibiotics can be started; or when it has been decided not to carry out surgery, artificial administration of fluids can be continued. Figure 2.c shows that for each separate non-treatment decision there is a clear-cut line between curative/life-prolonging care and palliative care, but also that the transition, as a whole, remains smooth. In fact, Figure 2.c. shows only half of the picture, because the transition (dotted line) only concerns withdrawing, and not withholding. Actually, decision-making concerning the withholding of treatment makes the scheme even more complicated. Like withdrawal, decisions on whether or not to withhold a specific treatment are usually not made simultaneously. (Besides, not every possible type of treatment is always

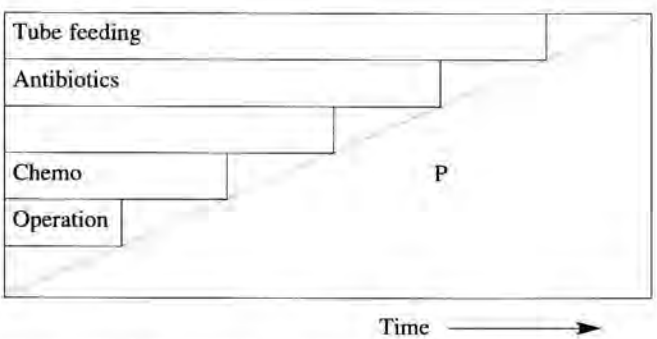
Figure 2. The relation between curative(c) and palliative(p) care on a time-axis.



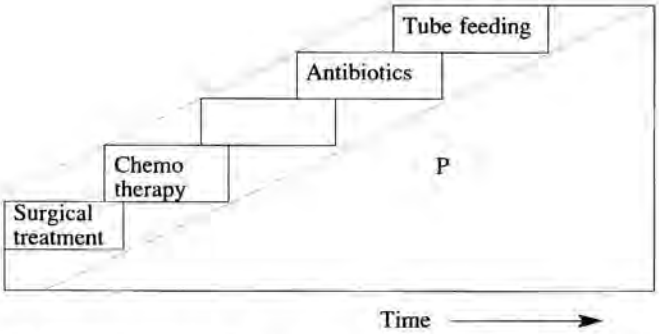
2a. By definition palliative care starts after curative/life-prolonging care has forgone.



2b. The sharp conceptual demarcation seems in contrast to practice, where the transition is often felt as smooth. Also the WHO uses this model.



2c. In more detail there is for each separate non-treatment decision a clear-cut line between C + P, but the transition as a whole remains smooth.



2d. In reality not every possible curative or life-prolonging treatment is at stake or starts at the same moment; that holds not only for withdrawing but also for withholding.

at stake). Thus, there is a second, comparable transition-line with respect to withholding treatment. This results in an apparently diffuse overall-transition between medical care aimed at curing disease or prolonging life and care aimed at palliation, but a clear-cut line for separate decisions on specific types of treatment (Figure 2.d).

Dimensions of End-of-Life Decisions

Although medical end-of-life decisions all share the characteristic that they potentially hasten death, they should otherwise not all be grouped into one category. For instance, withholding artificial administration of fluids to a patient who, in the terminal phase of dementia, apparently no longer wishes or needs to eat or drink is a completely different decision to granting the explicit request of a young woman with terminal breast cancer for a lethal intravenous injection.

Therefore, in developing a research program, the use of a conceptual framework of end-of-life decisions may be helpful. Medical end-of-life decisions could be categorized on the basis of the following dimensions.

1. The physician's action or omission.
2. The physician's reason for acting or omitting.
3. The physician's intention with regard to hastening death.
4. The preference of the patient.
5. The competence of the patient to express that specific preference.
6. The prognosis of the patient.
7. The effect on the patient of the action or omission.

This order of dimensions is not hierarchic per se. The specific combination of dimensions in the physician-system (1-3), including colleagues, nurses, et cetera, and in the patient-system (4-7), including family and authorized representatives, determines which type of end-of-life decision is at stake.

Table 1. A conceptual framework for medical end-of-life decisions.

	Physician[1]		Patient[2]			
Action or omission	**Reason for end-of-life decision[3]**	**Intention to hasten death**	**Preference[4]**	**Competence**	**Prognosis[5] death**	**Effect on hastening**
Withholding treatment	Medical futility and/or Patient's refusal	Primarily Or Secondarily Or None	Refusal +/- Informed consent +/-	Currently competent or Incompetent – Temporarily or – Not always been or – Always been	Life expectancy + Quality of life	Possible or Probable or Certain
Withdrawing treatment	Medical futility and/or Patient's refusal	Primarily Or Secondarily Or None	Refusal +/- Informed consent +/-	Currently competent Or Incompetent – Temporarily or – Not always been or – Always been	Life expectancy + Quality of life	Possible or Probable or Certain
Pain/symptom treatment	Suffering	Secondarily Or None	Informed consent +/- Request +/-	Currently competent or Incompetent – Temporarily or – Not always been or – Always been	Quality of life + Life expectancy	Possible or Probable
Terminal sedation[6]	Suffering And/or Patient's request	Secondarily Or None	Informed consent +/- Request +/- Refusal +/-	Currently competent or Incompetent – Temporarily or – Not always been or – Always been	Quality of life + Life expectancy	Certain
Administration lethal drugs	Suffering And/or Patient's request	Primarily	Request +/-	Currently competent or Incompetent – Not always been or – Always been	Quality of life + Life expectancy	Certain
Prescription lethal drugs	Suffering And/or Patient's request	Primarily	Request +	Currently competent	Quality of life + Life expectancy	Probable or Certain

[1] Other actors in the physician's system are colleagues, nurses and other caregivers.
[2] Other actors in the patient system are family (incl. other next of kin) and authorized representatives.
[3] Reason for end-of-life decision. Compassion is presupposed and other possible underlying motives as enjoyment of power, saving costs etc. are not included in the framework.
[4] Under preferences complex motives as self-sacrificing disposition, not wanting to be dependent, saving costs etc. can be hidden. Preferences can be articulated orally or written.
[5] Especially with regard to treatment alternatives for prolonging life or optimal quality of life.
[6] Including forgoing tube feeding.

A Conceptual Framework of End-of-Life Decisions

Table 1 presents a conceptual framework of medical end-of-life decisions. It is not the intention to discuss the whole model here; only the different dimensions will be discussed briefly, occasionally related to a specific medical end-of-life decision.

In the first column, the most relevant categories of *acting or omitting* by the physician are presented. They form the core of the different medical end-of-life decisions mentioned above. The physician's *reason* for an end-of-life decision can be that she feels obliged to comply with a patient's refusal to be given life-prolonging treatment, or is of the opinion that (further) treatment is medically futile. Other reasons might be that the physician wants to reduce or end the suffering of the patient, whether or not complying with a request from the patient at the same time. The physician can make an end-of-life decision with the primary or secondary *intention* to hasten death, or only take into account the possibility that death will be hastened. *Preferences* of the patient may be articulated orally or in writing (sometimes also in advance). The patient can refuse treatment or give informed consent to a proposal from the physician to withhold or withdraw treatment. A physician can also make an end-of-life decision without taking into account the wishes of the patient, for instance, because the patient cannot express his preference or because the physician has a paternalistic approach. Only in the case of assisted suicide, that is, prescribing lethal drugs at the patient's request, this is impossible. *Competency* refers to the patient's ability to assess the situation and make an appropriate decision. If the patient is currently competent, then his wishes do count. If the patient is temporarily incompetent, for instance, because of a depression or some other psychiatric disease, treatment may be initiated. If the patient will remain, but has not always been, incompetent (for instance, because of terminal (sub-)coma, dementia, persistent vegetative state), then an advance directive and/or representatives are involved. When the patient has always been incompetent (for instance, in case of neonates or severely mentally handicapped people), representatives may play an important role in articulating the best interest of the patient. The *prognosis* of the patient may be the starting point for end-of-life decision-making. The assessment of the remaining quantity and quality of life influences the perspective of the patient as well as the physician. The prognosis is especially important with regard to the question of whether there are any other better and/or less far-reaching or less harmful treatment alternatives. What counts here are the underlying disease (will the patient inevitably die?; is the disease treatable?; is the treatment futile?), the life expectancy (is death imminent?) and the suffering (is it unbearable and/or hopeless, and to what extent is palliation possible?). Finally, the *effect* of the action or omission co-determines the order of medical end-of-life decisions. This does not concern the intended effect, nor the believed effect, but the actual effect or at least the effect that can reasonably be expected (preferably evidence-based). The key question is whether the end-of-life decision will result possibly (for instance, a decision to administer high dosages of opioids), probably (for instance, a decision to withdraw mechanical ventilation) or certainly (for instance, a decision to administer a

high dosage of intravenous potassium-chloride) in the hastening of death. This depends on the clinical condition of the patient (for instance, an adult patient with cancer metastases versus a very premature neonate), the type of omission (for instance, chemotherapy versus dialysis) and the type, dosage and method of administration of drugs (for instance, 100 versus 1000 milligrams of opioids given orally or intravenously).

The presented framework is mainly descriptive. Which dimensions are most important in classifying and weighting the end-of-life decisions depends on the scope: clinically, psychologically, morally or judicially. The most decisive factors seem to be: action or omission, the intention of the physician and the preference of the patient. There are, however, a number of important modifying factors: the reason(s) (including motive(s)) of the physician, the competence of the patient (including the representatives' role if a patient is incompetent), the prognosis, and the effect of the action or omission on the patient.

State of Affairs in Research

Science-based end-of-life medical care can contribute to transparent and rational decision-making, which may result in a better quality of care and in an improved quality of the last stage in life, including the dying process. Epidemiological and clinical research is a prerequisite. Empirical research of good quality concerning patients in the terminal phase of a disease is relatively scarce. This applies to clinical research, as well as to research into the prevalence, incidence and course of symptoms, and also the risk factors for symptoms that are difficult to treat; it also applies to health services research. The research is mainly restricted to patients with cancer and has mainly been carried out in hospitals and hospices, and not in home care settings or nursing homes. Problems encountered in this field of research concern the recruitment of patients, their difficulty in filling in questionnaires or answering interview questions, and the high rate of attrition, due to worsening of their condition or death. Outcome measurement of the quality of care involves a number of largely unsolved problems: measurement instruments must impose very little burden on the patient, attention must be paid to existential problems, and bottom-effects and bias due to response-shift must be taken into account.

In patient-related research into end-of-life decision-making the same problems are encountered. Most empirical research in this field has an epidemiological character, consists mainly of retrospective studies, and is mainly based on the physician's perspective. Comprehensive studies have, as yet, only been carried out in the Netherlands, Australia and Belgium. Non-treatment decisions and treatment intensifying the alleviation of pain and other symptoms were, in these countries, found to precede death rather frequently, whereas the prevalence of euthanasia, physician-assisted suicide and life-ending without an explicit request from the patient was much lower. Non-treatment decisions have also been quite frequently studied in the United States. Studies on the attitudes of physicians (and nurses) towards end-of-life

decision-making have been carried out in Australia, Canada, the United States and also in many European countries.

Cross-National Research

Most of the empirical end-of-life research has taken place in the past decade. Unfortunately, it is often difficult to compare the results of studies carried out in different countries, because of differences in the study-designs and differences in the underlying concepts and definitions. Working to achieve consensus on these issues and using a common framework may help to bridge these differences.

Otherwise, in collaborative research into end-of-life decision-making, cross-national differences are very relevant. They may influence the dimensions as presented in the framework of end-of-life decisions, and the weighting procedure. For example: limited insurance against a long-standing illness can determine a patient's wishes with regard to the hastening of death, and euthanasia regulation, whether or not subject to the penal code, can lead to differences in practice. Possible cross-national factors that could function as determinants in end-of-life decision-making are, for instance, differences in ethnicity, prosperity, religion, quality of palliative care and current law (Table 2).

Table 2. Possible cross-national differences and determinants of end-of-life decision-making.

Demographic	– age / sex structure, esp. aging – ethnic groups
Economic	– unemployment – poverty – health care budget
Socio-cultural	– history – tradition – religion – education – autonomy-appreciation
Health care	– accessibility – insurance – doctor-patient relationship – palliative care
Legal	– current law – principle of expediency – interaction medical and legal system

Research and Practice

Research and practice involving end-of-life decision-making has to be linked. This also applies to primarily science-driven epidemiologists searching for new evidence and primarily practice-driven clinicians looking for evidence-based guidelines. Two sides of the same picture are at stake here. Epidemiological research is necessary, for example, to investigate the determinants, characteristics and cross-national differences involved in end-of-life decision-making. The results of such research can be beneficial, for instance, in setting up intervention studies which, in turn, can contribute to the improvement of practice (guidelines). Eventually, the quality of medical care at the end of life will be enhanced (Figure 3).

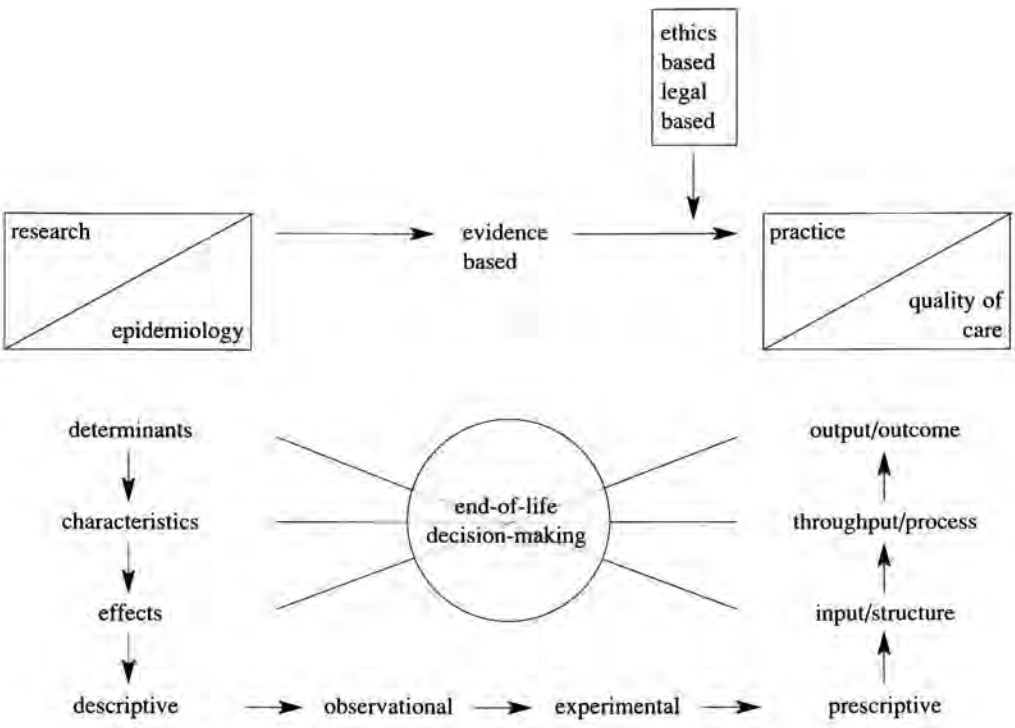


Figure 3. Research and practice involving end-of-life decision-making.

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Part I Decisions to Withhold or Withdraw Life-Prolonging Therapy

Agnes van der Heide

Non-Treatment Decisions in Dutch Medical Practice[1]

Abstract

Recent developments in the field of medicine and the increased interest in palliative care have resulted in a growing awareness that medical decision-making in the terminal stage of life not only concerns choosing which interventions are appropriate, but also which interventions are inappropriate. This paper gives an overview of Dutch research on decision-making with regard to whether or not to apply life-prolonging treatment. In 1990, the *Remmelink study* was the first to indicate that non-treatment decisions frequently precede death in the Netherlands: 28% (95% confidence interval [CI], 26%-29%) of all deaths were preceded by such a decision. In 1995, a second study showed that this percentage was 30% (95% CI, 28%-31%) and may be on the increase. Non-treatment decisions quite frequently concern elderly patients who die in nursing homes. The majority (67%) of non-treatment decisions concern patients who are not (fully) competent and cannot decide for themselves at the time of the decision-making. Non-treatment decisions not only involve technologically advanced interventions but also, and most frequently, the withdrawal or withholding of antibiotics (25%) and artificial nutrition or hydration (25%). End-of-life decision-making seems to be at least as common for the mentally handicapped as for competent patients. It is concluded that the increasing importance of end-of-life decision-making warrants further research into its clinical and epidemiological aspects, and that such research should also address ethical, societal and internationally comparative issues.

Advances in the field of medicine have greatly improved the possibilities to treat seriously ill patients and to prolong life or postpone death. However, these advances also increasingly urge physicians and patients to decide on which interventions are appropriate and which are not. Although it is obvious that many patients greatly benefit from modern medical technology, it is also clear that these developments have their disadvantages. This may hold even more strongly for patients who are in the terminal stage of their lives, when the traditional medical

[1] This paper is largely based on research work carried out by Johanna H. Groenewoud, MD, Agnes van der Heide, MD, PhD, Loes Pijnenborg, MD, PhD, Johannes J.M. van Delden, MD, PhD, Paul J. van der Maas, MD, PhD, and Gerrit van der Wal, MD, PhD.

goals of sustaining and prolonging life are no longer self-evident. One of the main challenges of medical decision-making at the end of life is to determine which interventions are appropriate at what time, while taking into account the shift in aims from cure and prolongation of life to contributing to a high-quality terminal stage of life. One of the resulting issues is decision-making with regard to whether and when to refrain from applying potentially life-prolonging medical interventions. Such medical interventions may range from technologically advanced methods of treatments, such as surgery, mechanical ventilation and renal dialysis, to relatively simple interventions, such as giving antibiotics or the artificial administration of nutrition and fluids. The right of competent patients to refuse such interventions, even if this may entail a 'premature' death, is nowadays widely accepted in many countries. When end-of-life decision-making concerns patients who are no longer able to adequately speak and decide for themselves, the decision-making is more complicated. There is a broad consensus among physicians that they will not at the request of patients or family apply treatment that is, according to scientific or professional standards, 'medically futile'. However, the definition of medical futility is often not clear, due to scientific and probabilistic uncertainty and differences in underlying concepts among the parties involved. Furthermore, when the decision-making is considered to be guided by the patient's best interest, opinions may vary on how this best interest is defined, which decision serves the interests of the patient best, and whether physicians, relatives or others are best able to determine the interests of the patient.

Overview of Dutch research

The increasing awareness that high-quality palliative care for patients in the terminal stage of life includes appropriate decision-making on whether and when to apply or refrain from life-prolonging interventions, has yielded a need for empirical research. Medical practice at the end of life may, just like other areas of medical decision-making, benefit from a solid base of evidence. In this paper, an overview is given of Dutch research in this field in the last decade of the 20th century. This research has mainly focused on assessing epidemiological characteristics of non-treatment decisions, that is, decisions to withhold or withdraw potentially life-prolonging treatment, in terms of frequency and main backgrounds.

1990 Remmelink study and 1995 replication study

In 1990, the Dutch government commissioned a committee to investigate medical practices concerning the end of life. The committee, named after its Chairman Professor Jan Remmelink, who was attorney general of the Supreme Court at that time, was asked to explore the incidence and backgrounds of euthanasia, together with other end-of-life decisions. As a result, not only euthanasia and assisted suicide were studied, but also decisions to administer potentially life-shortening drugs to alleviate pain or other symptoms, and decisions to forgo potentially life-prolonging treatment. The study was performed at the Department of Public Health of the Erasmus

University Rotterdam, by a research group headed by Professor Paul J. van der Maas.[1,2] The study consisted of three parts. Firstly, face-to-face interviews were held with a randomized sample of 405 physicians, including general practitioners, nursing home physicians and physicians from 5 clinical specialties that are frequently confronted with the death of patients. The response rate for this part of the study (study I, interview study) was 91%. The second study consisted of postal questionnaires that were sent to physicians who had reported a stratified sample of 5197 deaths to Statistics Netherlands, from August through November 1990. The response rate for this part of the study (study II, death certificate study) was 73%. In the third part of the study, physicians who were interviewed for part I were asked to complete the questionnaire used in part II for each patient in their care who died during a period of 6 months after the interview. Of the 405 physicians interviewed, 322 (80%) agreed to participate in this third part of the study (study III, prospective study).

In 1995, the Dutch government commissioned an evaluation of the recently established public notification procedure for physician-assisted death. This evaluation study included a replication of the 1990 Remmelink study, so that any possible developments or changes in the incidence and backgrounds of end-of-life decision-making could be studied, resulting in an informed discussion of the benefits and drawbacks of the notification procedure. This notification procedure did not include the reporting of non-treatment decisions, and will be further described elsewhere in this volume. The 1995 study was performed at the Department of Public Health of the Erasmus University Rotterdam and the Department of Social Medicine of the Vrije Universiteit Amsterdam. The research groups were headed by Professor Paul J. van der Maas and Professor Gerrit van der Wal, respectively.[3] The 1995 study replicated study I (interview study) and study II (death certificate study) of the Remmelink study. Study I was, however, limited to end-of-life decisions that included the administration of life-shortening medication. Study II also addressed non-treatment decisions, and was based on 5146 deaths (response rate, 77%). Details of the design of both the 1990 Remmelink study and the 1995 replication study are described in detail in the paper by Onwuteaka-Philipsen in this volume.

Incidence of non-treatment decisions, 1990-1995

Both the 1990 and the 1995 study showed that, in the Netherlands, death is frequently preceded by a decision to withhold or withdraw potentially life-sustaining treatment (see Table 1). In 1990, 28% (95% confidence interval [CI], 26%-29%) of all deaths and 39% (95% CI, 38%-41%) of all non-sudden deaths were preceded by such a decision.[4] In 1995, these percentages were 30% (95% CI, 28%-31%) and 43% (95% CI, 42%-45%), respectively. Approximately 30% of all non-treatment decisions were followed by the administration of (potentially) life-shortening drugs, and this had a more decisive life-shortening effect. Therefore, non-treatment decisions were the most important end-of-life decision in 18% (95% CI, 17%-19%) of all deaths in 1990, and in 20% (95% CI, 19%-21%) of all deaths in 1995.[6,7]

Table 1. Non-treatment decisions in the Netherlands, 1990 and 1995.

	1990 (n=5197)	1995 (n=5146)
Death was	%	%
Sudden and unexpected	30	31
Non-sudden, not preceded by non-treatment decision	43	39
Non-sudden, preceded by non-treatment decision	28	30
Non-treatment decision was most important end-of-life decision	18	20

The relative number of non-treatment decisions seems to be on the increase between 1990 and 1995, which also holds for euthanasia but not for other end-of-life decisions, such as physician-assisted suicide, ending of life without the patient's request or the administration of opioids in potentially life-shortening doses.[7] Non-treatment decisions are the most frequent medical end-of-life decisions, together with decisions to administer potentially life-shortening doses of opioids. Non-treatment decisions quite frequently concern elderly patients: in 1990, 33% of all deaths among patients aged 80 years or over were preceded by a non-treatment decision, and in 1995 this percentage was 36% (Table 2). Furthermore, non-treatment decisions are made relatively often for female patients.

Table 2. Frequency of non-treatment decisions according to patient characteristics and specialism of the physician.

	1990		1995	
	total n	%	total n	%
Age, years				
0-64	1160	21	1313	23
65-79	1999	26	1792	26
80 and over	2038	33	2041	36
Sex				
Male	2665	24	2611	26
Female	2532	31	2535	34
Cause of death				
Cancer	2174	34	2119	31
Cardiovascular disease	1103	15	910	15
Neurological disease	572	37	466	43
Pulmonary disease	379	30	306	41
Other	969	30	1345	36
Specialism of the reporting physician				
General practitioner	2356	29	2493	17
Clinical specialist	1766	20	1560	35
Nursing home physician	986	46	929	52

Decision-making process

In the Netherlands, just over 40% of all deaths are reported to the central death register by general practitioners and most of these deaths occur at home.[8] Approximately 40% of all deaths occur in hospitals and approximately 18% occur in nursing homes. Non-treatment decisions quite frequently concern patients who die in nursing homes. Of all non-treatment decisions, 42% were made by clinical specialists, 32% by nursing home physicians, and 23% by general practioners.[5] This over-representation of nursing home physicians is partly explained by the fact that they are less often than other specialists confronted with the unexpected death of their patients, but even when the denominator is restricted to non-sudden deaths, nursing home physicians appear to make non-treatment decisions more frequently (in 59% of all non-sudden deaths, 1995 study) than clinical specialists (48%) or general practitioners (28%). This difference is to some extent related to differences in the age of the patients and the underlying diseases.

Table 3. Characteristics of non-treatment decision-making for patients for whom a non-treatment decision had been the most important end-of-life decision.

	1990 (n=991) %	1995 (n=1097) %
Estimated shortening of life*		
< 24 hours	41	42
1-7 days	28	28
1-4 weeks	15	15
> 1 month	7	8
Unknown	9	7
Competent patients#	23	26
Decision was discussed with patient	100	93
Not (fully) competent patients#	62	67
Decision was discussed with patient	11	14
Patient's wish was known from previous discussions	12	12
Decision was discussed with relatives	71	71
Decision was discussed with		
Colleagues	48	52
Nursing staff	55	47
Decision was not discussed with anyone	7	5

* Estimated amount of time by which life was shortened as a result of the non-treatment decision.
\# Competency was unknown for 15% of all patients in 2990, and for 7% of all patients in 1995.

Non-treatment decisions mostly concern patients who are in the very last stage of their disease: over two thirds of all non-treatment decisions in 1995 involved an estimated shortening of life of one week or less (see Table 3). One of the most important issues in making non-treatment decisions is the involvement of the patient in the decision-making. Such involvement is largely determined by the competence of the patient, that is, the degree to which the patient is able to adequately evaluate his situation and make the necessary decisions about it. In both the 1990 and the 1995 study, details of the decision-making process were assessed for all cases in which an end-of-life decision had been made, and for the most decisive one in case of multiple decisions. It was found that of all cases in which a non-treatment decision had been the most decisive end-of-life decision, approximately 25% concerned competent patients (see Table 3).

The patient had been involved in making the decision to withdraw or to withhold potentially life-prolonging treatment in virtually all those cases. Thus, the majority of non-treatment decisions concern patients who are not (fully) competent and cannot decide for themselves at the time of the decision-making. This obviously complicates the decision-making process. In such cases, non-treatment decisions are virtually always made after discussions between the attending physician and one or more other persons involved. Only a small minority of all non-treatment decisions were made solely by the attending physician. When a patient is completely or partially incompetent, physicians either try to find out about the opinion of the patient (11% in 1990, 14% in 1995), or they take into consideration information from previous discussions with the patient (12% in both years) or the opinion of relatives (71% in both years). Furthermore, approximately half of all non-treatment decisions were made after the attending physician had consulted one or more colleagues or the nursing staff.

Types of treatment

Whereas the growing capacity of medicine to postpone death seems to be one of the causes of the increasing importance of non-treatment decisions at the end of life, this does not imply that such decisions only or predominantly concern technologically advanced interventions. Of all non-treatment decisions that were studied in 1995, 25% involved the withdrawal or withholding of antibiotics, and 25% involved forgoing artificial nutrition or hydration.[5] Other types of treatment that were relatively frequently forgone were vasopressor medication (11%), other types of medication (18%), mechanical ventilation (10%), surgery (9%) and hospital admission or diagnostic procedures (8%). Nursing home physicians and general practitioners predominantly forewent artificial nutrition or hydration, antibiotics, other medication and diagnostic interventions, while decisions not to apply mechanical ventilation or surgery were mostly made by clinical specialists.

Whether or not patients should receive artificial nutrition or hydration in the terminal stage of their life is a subject that frequently arises in discussions concerning non-treatment decision-making. Here again, decision-making is especially difficult when it is related to incompetent patients. In the terminal stage of dementia, for instance, a patient's refusal to take food or fluids may be the result of practical

problems, such as difficulties in choosing what to take, bringing a spoon to the mouth or chewing, but it may also be an inherent part of the concluding disease process which results in the death of the patient. Opinions vary on whether the fact that nutrition and hydration are basic requirements for all human life has any relevance to the decision-making. It is obvious that total withholding of food and fluids results in the short-term death of the person involved, but the palliative or life-prolonging effects of artificial administration of food and fluids remain unclear. Research in this field is difficult, but the few observational studies that have been carried out do not seem to provide any evidence for the beneficial effects of administering nutrition and hydration to terminal patients.[9,10] In the 1995 study, it was found that 8% of all deaths and 23% of all deaths occurring in nursing homes were preceded by the decision to withhold or withdraw artificial nutrition or hydration.[11] Such decisions most frequently concerned elderly female patients who were no longer able to decide for themselves. Relatives were involved in the decision-making process in most cases (89%).

Non-treatment decisions in the mentally handicapped

In 1997, Van Thiel et al. reported in the *British Medical Journal* on the results of a study on end-of-life decisions for mentally handicapped people living in institutions in the Netherlands.[12] In this study, 89 physicians caring for mentally handicapped people were retrospectively questioned about the most recent case of death that had been preceded by an end-of-life decision. It was found that the death of mentally handicapped people had been preceded by the decision to withhold or withdraw treatment (as the most important end-of-life decision) in 30% of all cases, compared to the 20% of cases found in the 1995 national survey. Physicians had discussed such decisions with the patient in 5% of all cases, whereas the patient's relatives or representative had been involved in 80% of all cases. The authors conclude that end-of-life decision-making is at least as common for the mentally handicapped as it is for competent patients. However, the debate on these aspects of terminal care is not as open as one may wish, even in the Netherlands, which may have its consequences for the quality of the empirical knowledge in this field.

Conclusions

It may be expected that non-treatment decisions will become even more important in medical care at the end of life in future decades. Technological developments are evolving, resulting in a growing ability to fine-tune medical interventions to individual characteristics, which inevitably yields an increasing need for establishing treatment goals, balancing the benefits and drawbacks of interventions and making adequate and evidence-based decisions. One of the most important requirements for high quality end-of-life decision-making is that physicians are aware that choosing and making decisions are inevitable ingredients of end-of-life care. Adequate and appropriate decisions can only be made when it is clear which alternatives are available

and which interests may or should be served. As a result, high quality decision-making is above all shared decision-making, that is, decision-making that involves patients, physicians, other professional care-givers, and relatives.

Important research questions

Further research in the following areas may contribute to high quality end-of-life care and non-treatment decision-making:

1. Knowledge about how, and in which circumstances, people actually die is limited and should be improved, including knowledge about the determinants of why patients and relatives experience a dying process as positive or negative, and the role of decisions about the provision of life-prolonging treatment.
2. In clinical practice, the focus of medical care is often not just a question of either prolonging life or providing palliative care, but some subtle combination of the two. Clarification of the concept of non-treatment decision-making may contribute to the rationality and basis of decision-making.
3. The relationship between the need for, and the use and evaluation of palliative care services and non-treatment decision-making should be studied. At this moment it is not clear why in some patient groups non-treatment decisions in themselves are sufficient to allow patients to die peacefully, whereas in other groups the administration of life-shortening medication seems to be needed much more frequently.
4. Further exploration is needed of the attitudes among the general population, and in various professional groups, towards decision-making with regard to life-prolonging treatment for various patient groups and the motives that may lead to such decisions, for example in situations which involve allocation problems.
5. International collaborative research is very important to determine the universal versus country- and culture-specific characteristics and determinants of end-of-life care, so that measures to improve quality in health care and in public health policies can be suited to the various different circumstances.

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David A. Asch and Kathy Faber-Langendoen

Sequencing the Withdrawal of Life-Sustaining Treatments[1]

Abstract

Previous studies have demonstrated that when patients are withdrawn from life-sustaining treatments, these treatments are often withdrawn sequentially, rather than all at once. We observed the sequence of withdrawing life support among 211 consecutive patients dying in four Midwestern United States hospitals from whom at least one of eight specific life-sustaining treatments was or could have been withdrawn. We used a parametric statistical technique to explain the order in which these forms of life support were withdrawn in terms of a set of previously determined characteristics of the forms of life support including, among other characteristics, their cost, scarcity, and discomfort. We found a distinct sequence in which the eight forms of life support were withdrawn in this clinical sample. The observed order was, from earliest to latest: blood products, hemodialysis, vasopressors, mechanical ventilation, total parenteral nutrition, antibiotics, intravenous fluids, tube feedings ($p < 0.0001$). This sequence is almost identical to that observed in a previous study based on hypothetical scenarios. Those forms of life support perceived as more artificial, scarce, or expensive were withdrawn earlier than those with less of these characteristics. We conclude that the preference for withdrawing some forms of life-sustaining treatments over others is associated with intrinsic characteristics of the forms of life-sustaining treatments themselves. Once the decision has been made to forgo life-sustaining treatment, the process used remains complex and appears to target many different goals simultaneously.

In the United States, there is an established ethical consensus that patients may forgo unwanted life-sustaining treatments.[2-6] Although physicians generally accept these choices,[7-15] an enlarging body of empirical evidence suggests that both physicians' attitudes and practices vary greatly in this area, and this variation may be explained by differences in physicians' rank or experience,[6,9,16] specialty,[12,15,17] preferences for risk,[11] religion,[15] or specific biases in the way they make their decisions.[10]

[1] Much of this paper is drawn from: Asch DA, Faber-Langendoen K, Shea JA, Christakis NA. The sequence of withdrawing life-sustaining treatments from patients. Am J Med 1999;107:153-156. The help and contributions of Drs. Shea and Christakis are gratefully acknowledged.

Most patients who require one form of life-sustaining treatment also require others. A patient receiving mechanical ventilation, for example, may also be receiving antibiotics, intravenous fluids, vasopressors, or hemodialysis. The withdrawal of any one of these interventions might result in the patient's death. For this reason, a decision to withhold or withdraw life support often involves decisions about multiple interventions. Figure 1 shows schematically that patients or their proxies typically participate actively in the decision to withdraw life-sustaining treatment, but that once this decision has been made, there remains a subsequent decision about which forms of life support to withdraw or how to withdraw them. The second decision, about the specific process by which life support is withdrawn, is usually entrusted to physicians.

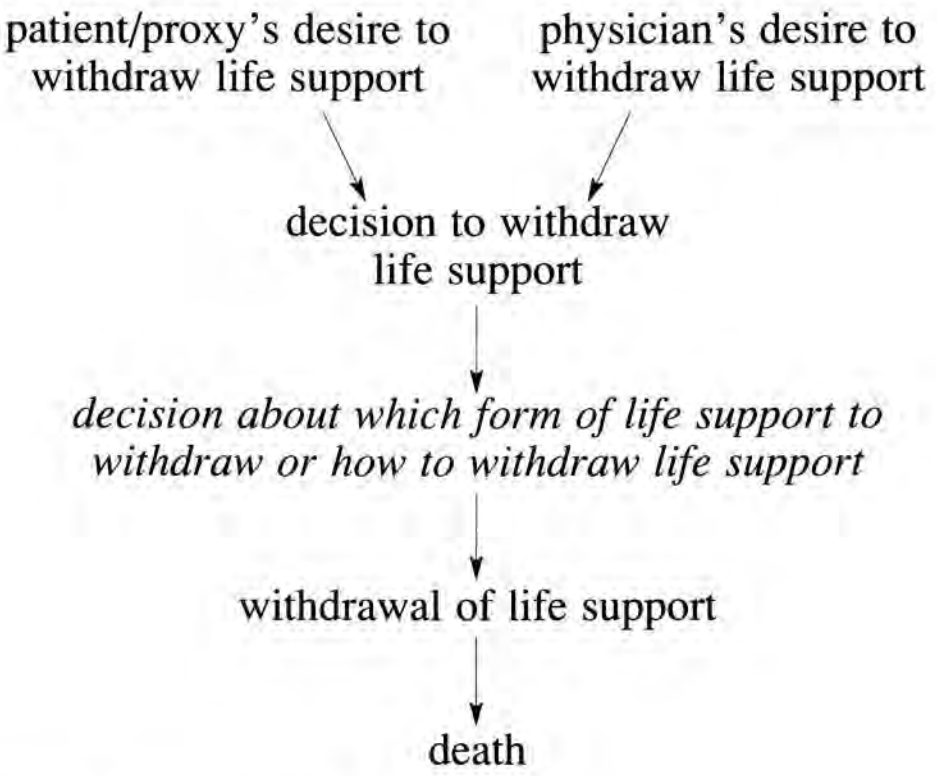

Figure 1. Schematic steps in the withdrawal of life support.

There has been considerably more research and comment about the first of these decisions than the second. Nevertheless, the second decision is important for at least two reasons: first, there are choices to be made. How life support is withdrawn can determine the rapidity of death, the comfort of the patient, the perceptions

of the family, the use and availability of scarce resources and many other considerations that may represent clinical or social goals. Understanding how these decisions are made may help identify problems in those processes and perhaps ways to improve them so that these goals can be met more effectively. Second, decisions about how life support is withdrawn may be a particularly sensitive indicator of the factors that are important to physicians in this setting. Physicians' participation in dichotomous decisions about whether to withdraw life support in general are relatively blunt, at least when compared to subtler decisions about how to do so or which specific forms of life support should be withdrawn and in what order. Understanding physicians' decision processes at this subtle level may provide additional insight into the factors that motivate them. Several decades of research in decision psychology demonstrates that factors that are strongly persuasive and motivate human decisions are not necessarily normatively justifiable. Physicians, like other humans, are often motivated by factors that are psychologically compelling on first glance, but lack normative power when examined more deeply. Examining how physicians decide how to withdraw life support may provide a window on these factors and, ultimately, lead to improvements in their decisions.

One might imagine that once the decision has been made to withdraw a patient from life-sustaining treatment, then all of that treatment would be withdrawn simultaneously and promptly. After all, a decision to withdraw life-sustaining treatment typically signals a substantial shift of goals from prolonging life to a concern for comfort or dignity, or the acceptance of death. Nevertheless, several observations—either of actual clinical practices or of physicians' responses to hypothetical clinical vignettes—suggest that all forms of life support are typically not withdrawn simultaneously and promptly. Instead, there is often a stepwise retreat as various forms of life support are withdrawn (and in some studies withheld), and often this retreat occurs in a systematic order. On the whole, these findings suggest that when life support is withdrawn, physicians are doing more than just shifting the goal away from the prolongation of life, and at least appear to be targeting other goals as well. The main purpose of studying these decisions is to uncover these hidden motivations.

Indeed, there is evidence that rather than forgo all forms of life support at once, physicians often withdraw or withhold life support in sequence, or forgo some forms of life support while retaining others. For example, in a study of 115 patients who had life support forgone in two San Francisco intensive care units between 1988 and 1989, Smedira and colleagues found that mechanical ventilation and intravenous vasopressors were the interventions most often withdrawn first.[18] In a study of 70 patients dying consecutively in a Midwestern United States hospital in 1989, Faber-Langendoen and Bartels found that 74% died after some intervention was withheld or withdrawn, that on average 5.4 interventions were forgone per patient, and that although resuscitation and intubation were often the first interventions to be withheld, mechanical ventilation tended to be withdrawn later than other interventions.[19] Faber-Langendoen followed up this study with an expanded examination of three additional Midwestern hospitals, with nearly identical results: in a sample of 274

consecutive dying patients, 229 deaths were preceded by decisions to withdraw or withhold some form of life-sustaining treatment, and these patients had an average of 3.8 potentially life-sustaining interventions forgone before death, often not simultaneously.[20] This study also revealed that some forms of life support were forgone more often than others. For example, dialysis was forgone in 25 of 33 possible instances (76%), mechanical ventilation was withdrawn in 31 of 74 possible instances (42%), but intravenous fluids were forgone in only 36 of 157 possible instances (23%).

In a series of related studies, Christakis and Asch explored the decisions made by 481 of 862 Pennsylvania internists responding to a mail survey containing a variety of hypothetical clinical vignettes. All together, these studies revealed that some physicians have strong preferences when given a choice among different forms of life support to withdraw. For example, in one study, they found that physicians prefer to withdraw forms of life support required because of an underlying disease process over those required because of an iatrogenic complication, regardless of the form of life support involved.[10] Similarly, they found that physicians prefer to withdraw recently instituted rather than longstanding interventions, and to withdraw forms of life support that will result in immediate death rather than delayed death.

In a companion study, they found that medical specialists prefer to withdraw familiar technologies when withdrawing life support, so that, for instance, pulmonologists preferred to withdraw mechanical ventilation; nephrologists preferred to withdraw hemodialysis; gastroenterologists preferred to withdraw tube feedings; hematologists preferred to withdraw blood products and cardiologists preferred to withdraw intravenous vasopressors, all relative to otherwise matched comparison internists.[16] In addition, they found that preferences for withdrawing certain forms of life support are associated with the characteristics of the forms of life support themselves, for example, their scarcity, invasiveness, or expense.[21] In general, physicians prefer to withdraw blood products and prefer not to withdraw intravenous fluids, and these preferences are associated with the perceived scarcity of blood products, among other factors.

Because these studies were based on responses to hypothetical clinical situations or from the expressed preferences of physicians responding in the abstract, the studies could be constructed with experimental designs not usually possible in actual clinical practice. As a result, these studies reach deeply into possible decision processes. For the same reason, however, an important limitation of these studies is that they do not reflect decisions made in real clinical situations.

To address these limitations in part, we combined data from disparate studies to address novel questions: what is the sequence of the withdrawal of life-sustaining treatments from real patients dying in United States hospitals and how does this sequence compare to that derived from earlier work with hypothetical situations? An important goal of this work was to test whether the insights learned through experimental manipulation in hypothetical situations reflect observations from real clinical practice.

Methods

Patients

A university and a community hospital in Minnesota, and a university and a community hospital in Missouri were selected to provide diversity of reimbursement, socioeconomic and political settings, physician characteristics, and cultural background. Patients were recruited sequentially. The charts of all acute-care patients dying in these institutions during the study period were reviewed. The study period for the university hospital in Minnesota was May 1 – June 30, 1989, during which time there were 73 deaths. The study period for the other hospitals was June 30, 1992 until 75 deaths were recorded at each of those institutions. Of the 298 requested charts, 291 (98%) were available for review. Of these, seventeen patients were admitted directly to hospice or extended care beds and were excluded; 229 of the remaining 274 patients died following a decision to forgo life-sustaining treatment. Nursing and physician chart notes, order sheets, medication records, and ventilator flow charts were reviewed to determine the time at which each decision to forgo treatment was made. Ties were allowed. Further details about patient recruitment have been reported elsewhere.[19] For the present analysis, in order to make the data as similar as possible to those collected in the studies using hypothetical situations, we consider only decisions to withdraw eight potentially life-sustaining treatments (listed in Table 2). Our sample is restricted to 211 patients who were on one or more of the eight specific forms of treatment and thus could have had a treatment withdrawn. For each patient, each of the eight forms of life support could have been withdrawn, continued until death, or not received. Forms of life support that were withdrawn were ranked in the order in which they were withdrawn. Forms of life support that were continued until death were given a rank that put them at the end of the rank list because these treatments could have been withdrawn, but were not. Forms of life support that were not received contribute no information to our statistical models.

Attributes of forms of life support

In previous work,[20] we had empanelled seven internists who, through a modified Delphi technique, developed a list of thirteen attributes that could characterize the eight forms of life support, such as 'cost,' 'pain upon withdrawal,' 'scarcity,' 'invasiveness,' and the like. There are no objective standards by which forms of life support can be rated as scarce, painful, or the like. Therefore, using the responses of an expert panel of 23 critical care physicians, we developed numerical ratings for each of the eight forms of life support along each of the thirteen attributes using a 1-10 scale, anchoring the form of life support scoring highest at ten and the form of life support scoring lowest at one. For example, critical care physicians feeling that a certain form of life support is the most painful to withdraw were asked to give that form of life support a ten along the attribute 'pain on withdrawal.' We refer to these items as ratings along attributes. Table 1 reports the thirteen attributes, and the mean rating of each of the eight forms of life support along these attributes, provided by the 23 critical care physicians. We used these ratings to help explain the choices physicians were observed to make in the clinical data set.

Table 1. Mean ratings of each of eight forms of life support along thirteen attributes*

	Antibiotics	Blood products	Intravenous fluids	Intravenous vasopressors	Mechanical ventilation	Renal dialysis	Total parenteral nutrition	Tube feedings and fluids
Invasive	2.3	3.2	1.8	4.7	9.6	8.7	4.9	4.5
Scarce	2.0	8.0	1.0	3.0	6.1	6.6	3.5	1.9
Unnatural	4.7	5.5	4.0	6.7	8.9	8.6	6.1	4.3
Artificial	5.0	5.4	4.3	7.7	9.6	9.1	6.3	4.7
Expensive	5.8	6.6	2.0	5.9	9.1	9.4	6.8	4.3
Uncomfortable when withdrawn	2.0	2.4	2.9	2.0	8.5	3.7	1.6	2.9
Causes death rapidly when withdrawn	2.8	4.2	2.9	8.7	9.6	5.1	2.3	1.8
High technology	3.1	3.1	1.2	5.0	9.3	9.0	5.3	2.7
Requires an ICU	1.2	1.8	1.5	8.7	9.4	3.5	1.5	1.1
Requires an active intervention to withdraw	4.6	4.5	4.7	7.2	9.8	6.6	5.2	5.0
Requires continuous administration	2.7	2.6	7.0	8.8	9.6	3.6	6.0	5.0
Causes patient discomfort	1.5	2.3	1.4	2.5	9.5	7.6	2.5	3.5
Emotionally taxing for patients	1.7	4.0	1.5	4.5	9.3	7.8	3.6	4.7

* Modified from Asch DA, Christakis NA. Why do physicians prefer to withdraw some forms of life support over others? Intrinsic attributes of life sustaining treatments are associated with physicians' preferences. Medical Care 1996; 34:103-111.

Statistical analysis

We analyzed the rank ordered data using a new parametric statistical model, called the 'exploded logit model,' developed for this purpose.[22] This method takes advantage of the fact that when subjects rank a series of items, they provide more information about their preferences than when they simply select the most preferred item from the list. They provide information about many different possible pair-wise comparisons of items on the list. The purpose of specifying models with this method is to uncover influences, or determinants, of the rankings. Parameter estimates provided by these models represent the differences in the log odds of preferring to withdraw one form of life support compared to an omitted category (we used antibiotics) and so provide an estimate of the size of differences along a ranked list. Using this technique, we first examined the observed sequence of withdrawal over the eight forms of life support. We compared the sequence observed from the actual clinical cases derived from the chart review in Minnesota and Missouri to the sequence observed from the hypothetical cases presented to the internists in Pennsylvania. We then incorporated the attribute ratings into the model to help explain the observed sequence on the basis of the intrinsic characteristics of the forms of life support. Statistical analyses were performed using SAS version 6.11.

Results

Demographic and clinical characteristics of the 211 patients included in this analysis are shown in Table 2. As expected, most patients receiving one form of life support were also receiving others.

Table 2. Characteristics of the 211 patients.

Characteristic	
Mean age (s.d.)	65.7 (23)
Female sex, n (%)	101 (48)
Race, n (%)*	
African-American	45 (28)
Caucasian	115 (71)
Native American	1 (0.6)
Mean length of stay, days (s.d.)	18.0 (22.0)
Primary diagnosis, n (%)	
Cancer	49 (23)
Cardiovascular disease	50 (24)
Sepsis	43 (19)
Gastrointestinal disease	19 (9)
AIDS	8 (4)
Other	43 (20)
Number of life-sustaining therapies, n (%)	
1	55 (26.1)
2	68 (32.2)
3	60 (28.4)
4	18 (8.5)
5	7 (3.3)
6	2 (1.0)
7	1 (0.5)

* Data are missing for 50 patients from one hospital that does not characterize patients by race.

Table 3 reports a multivariable model reflecting the observed sequence of withdrawing the eight forms of life support. The numbers of patients receiving each treatment are shown in the second column. These clinically derived ranks are very similar to those found using hypothetical questions using either exploded logistic regression[20] or mean rank ordering.[10] The only differences are that mechanical ventilation has moved up in rank from seven to four, and intravenous fluids and tube feedings, which are now adjacent, have reversed. The odds ratios provided by the exploded logit model permit an assessment of the magnitude of physician preferences among the items. For example, the odds of withdrawing hemodialysis before antibiotics was about twice as great as the odds of withdrawing total parenteral nutrition before antibiotics and six times as great as the odds of withdrawing intravenous fluids before antibiotics. The confidence intervals around the odds ratios of adjacent and near adjacent forms of life support often overlap, reflecting sparse data for some comparisons as well as similar effect sizes. Nevertheless, for the entire rank list, $X^2 = 44.53$ (df = 7), suggesting that the observed sequence is non-random ($p < 0.0001$). The column on the far right reports, for comparison, the ranking of hypothetical situations reported previously.[20]

Table 3. Observed sequence of withdrawing eight forms of life support.

Form of life support	From clinical study				Rank from study of hypothetical scenarios[20]
	Number receiving treatment (%)	Rank	Odds ratio	95% Confidence interval*	
Blood products	32 (15)	1	13.9	2.8-70.4	1
Hemodialysis	18 (9)	2	3.0	1.1-7.9	2
Vasopressors	60 (28)	3	2.1	1.0-4.6	3
Mechanical ventilation	30 (14)	4	2.0	0.9-4.5	7
Total parenteral nutrition	33 (15)	5	1.4	0.6-3.5	4
Antibiotics	140 (66)	6	1		5
Intravenous fluids	156 (73)	7	0.5	0.3 – 1.0	8
Tube feedings	28 (13)	8	0.2	0.1-0.6	6

* Confidence intervals that include one imply the lack of a statistically significant difference between the revealed preference for the withdrawal of a form of life support and the revealed preference for the withdrawal of antibiotics, the omitted category.

Table 4 reports bivariable odds ratios for each of the thirteen attributes as predictors of the sequence of withdrawing the eight forms of life support. These odds ratios reflect the ability of individual attributes to predict the observed sequence of withdrawing the eight forms of life support. In general, forms of life support with more of each of these characteristics are withdrawn sooner than forms of life support with less of each of these characteristics. For example, the more 'artificial' a form of life support was perceived by our panel of critical care physicians, the more likely it was to be withdrawn from patients in our sample; each one-point increase in this

characteristic increased by 30% the odds that the form of life support would be withdrawn. The sequence of withdrawal appears to be uninfluenced by whether a form of life support is uncomfortable when withdrawn or requires continuous administration. Multivariable models designed to control for effects of the multiple attributes produced unstable parameter estimates, most likely because of sparse data.

Table 4. Bivariable odds ratios for each of thirteen attributes.

Attribute	Odds ratio	95% Confidence interval	
Artificial	1.3	1.2-1.5	
Causes death rapidly when withdrawn	1.2	1.1-1.3	
Causes patient discomfort	1.1	1.0-1.2	
Emotionally taxing for patients	1.2	1.1-1.3	
Expensive	1.3	1.1-1.4	
High technology	1.2	1.1-1.3	
Invasive	1.2	1.1-1.3	
Requires an active intervention to withdraw	1.2	1.1-1.4	
Requires an ICU	1.1	1.1-1.2	
Requires continuous administration	1.0	0.9-1.1	NS
Scarce	1.3	1.2-1.5	
Uncomfortable when withdrawn	1.1	1.0-1.2	NS
Unnatural	1.4	1.2-1.6	

NS = Not significant. Confidence intervals that include 1.0 are not significant at the 0.05 level.

Discussion

These results identify a distinct and consistent sequence in which various forms of life support are withdrawn. This finding is evident from the analysis of the clinical data presented here, and it gains additional support from the similarity of these findings to those reported previously using data derived from hypothetical questions of internists. The distinct and consistent sequence observed is surprising given its context. If withdrawing life-sustaining treatment signals a major shift in goals, for instance, from the goal of cure or prolonging life to a primary concern for comfort or an acceptance of death, one might expect life-sustaining treatments to be withdrawn simultaneously. In contrast, the observed stepwise retreat reveals a complexity of decision-making that may be influenced by patient, surrogate, or physician ambivalence, or the desire to affect the timing of death or in other ways exhibit control over the process. To our knowledge, this is the first study that has sought to explain the clinically observed sequencing of the withdrawal of life support by examining the underlying characteristics of the forms of life support themselves. This study suggests that even when decisions to withdraw life support have been made, the process used reflects other moral, social, and clinical goals. These goals include a desire to withdraw forms of treatment physicians perceive as expensive, scarce, or artificial.

This study has several limitations. First, although our goal was to evaluate the sequence of withdrawing life-sustaining treatment in clinical settings, no patient received all eight forms of life support we studied, and most received only two or three. The many missing data elements limit the statistical power of our analyses and widen the confidence intervals reported in Table 3; nevertheless, these missing data elements reflect the clinical reality that escapes hypothetical scenarios. Indeed, the striking similarity between our results here and those derived from our previous study of hypothetical choices (from which no data were missing) supports the validity of both sets of findings. Second, the patients in this study were drawn from four university and community hospitals in Minnesota and Missouri during the period from 1989-1992, and the practice patterns we observed may not reflect practice patterns more generally or more currently. Again, however, the similarity of the results between this clinical study and the study of Pennsylvania internists suggest that these observed activities reflect general decision making processes; in the study based on hypothetical scenarios, we found that only the age of the physician had a significant effect on preferences of alternative forms of life support to withdraw. Third, in this study we have reported only on activities related to withdrawing life support. Although decisions to withdraw or withhold life-sustaining treatment often co-exist, the ranking observed in Table 3 differs from the ranking observed when decisions to withhold life-sustaining treatment are included and combined with decisions to withdraw life-sustaining treatment.[19] Such differences suggest that decisions to withhold or to withdraw life-sustaining treatments are not made the same way, even though they may target similar goals.

Conclusions

These findings provide a compelling reminder of the complexity of end-of-life decisions. The care dying patients receive in United States hospitals has recently come under harsh criticism. One way to view these results is to see them as providing additional evidence of non-clinical and potentially irrelevant factors that influence decisions at the end of life. Seen from this perspective, the results presented here add to the enlarging body of research that identifies an agenda for reform of the care of the dying. An alternative way to view the results of this study is to see them as reflections of the multiple goals clinicians and patients apparently target simultaneously at the end of life.

Important research questions

Early research in almost any field is descriptive, and the research presented here fits that category. The presented findings are empirical, which may represent an advance over, or at least a complement to, the purely theoretical scholarship that characterizes much of bioethics. Even so, the findings presented here are based on observations of everyday clinical practice in their natural settings, rather than observations

of behavior and outcomes in response to experimental manipulations, as in a clinical trial. These findings are more meaningful as a result.

Is there a next level in this research? As discussed in the introduction, the overall purpose of these descriptive investigations is to uncover clinical practices that could stand improvement against normative standards of behavior, or at least against well endorsed standards. For example, if pulmonary physicians are indeed relatively uncomfortable withdrawing dialysis even from patients for whom life support is to be withdrawn, then their professional characteristics are somehow getting in the way of achieving patient goals. If, when physicians make decisions about how to withdraw life support, they are influenced by the intrinsic characteristics of those forms of life support, they might be motivated by factors that the patients themselves would find irrelevant. Do these decision processes represent errors or biases? They might not given a broad view that recognizes the physicians themselves as moral participants in these activities. With that view, the decisions physicians need to make for their own peace of mind may be relevant. But these decision processes are certainly faulty when viewed from a narrower perspective that considers as valuable only the achievement of patient goals.

The next step in research of this kind is 'de-biasing.' If one learns that physicians systematically make one kind of decision when they ought to make another, fail to consider a factor that ought to be relevant, or tend to consider a factor that generally is not, then one has an agenda for reforming physician practices. However, getting physicians to change their practices or think or make decisions in different ways is difficult. Even if one can find fault with the decisions expressed or revealed in these studies, the physicians who made them are not bad or evil: they are just human. Getting the human out of their decision making may not be such a good idea, even if it were possible.

In a series of studies, decision psychologists have learned that some parents avoid vaccinating their children against some contagious illnesses because they fear the adverse consequences of the vaccine, even if they understand that the risks imposed by not vaccinating their child are greater than the risks imposed by failing to vaccinate their child.[23,24] This decision making process, which has been called 'omission bias,' is clearly a bias in that it leads to the expectation of worse outcomes as judged by a plausible and common standard, and it seems to result when parents feel they will be held more responsible for the consequences of their actions than the consequences of their omissions.[25,26] Baron has shown, however, that parents who exhibit this bias can be corrected by appealing to something like the 'Golden Rule,' and asked which outcomes their child would prefer (the outcome with the lowest risk) and whether their child would care whether that outcome was reached through vaccination or non-vaccination.[27]

Results like these would seem encouraging in the end-of-life setting where physicians, like parents, serve as agents to the goals of another party. Nevertheless, decisions surrounding end-of-life care are considerably more complex than vaccination decisions, and in practice the history of interventions to improve these processes is considerably less encouraging than what might be thought at first. In the United States, for example, the SUPPORT study[28] involved a monumental nurse-based effort to

educate physicians about patient goals in the critical care setting, yet resulted in no difference in decision making and no difference in clinical outcomes. Aronowitz and Asch have argued that improving end-of-life care confronts what may be impassible obstacles because the situation is one in which there are often no good outcomes, and so patients and their clinicians are fundamentally ambivalent about their goals; the goals are often inconsistent over time or at the same time; and therefore these goals are inherently difficult to pin down or satisfy.[29]

International collaboration in these areas is likely to be challenging, given that so many of the important issues that underlie these decisions reflect social values, professional norms, and legal and regulatory structures that differ substantially across cultures. If all ethics are local, cross-cultural observations may have little practical value. At the same time, these differences allow for the development of alternative models that may be adaptable in different nations.

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Integrating Preferences for Life-Sustaining Treatments and Health States Ratings into Meaningful Advance Care Discussions[1]

Abstract

Advance care planning tries to ensure that decision-making for decisionally incapacitated patients is patient-centered. This has particular relevance for end-of-life decisions. Although many people in the United States favor advance care planning, only a minority prepares advance directives. One impediment to clinician encouragement and involvement is not knowing how to discuss these issues.

To help frame advance care planning discussions, we studied the interrelationships between treatment preferences and health state ratings of patients and well adults. The study population included a diverse sample of well adults and patients (n=342). Six treatment preferences were elicited in current health and two hypothetical states describing permanent coma and severe dementia. The six treatments were antibiotics, long-term hemodialysis, short-term mechanical ventilation, cardiopulmonary resuscitation (CPR), long-term jejunal feeding tube, and long-term mechanical ventilation.

When participants declined noninvasive treatments, they usually declined more invasive treatments, and when they wanted to receive invasive treatments, they usually accepted less invasive ones. The data suggest an empirically derived, organizing sequence of treatments that represent increasing degrees of 'aggressiveness' that is influenced by invasiveness and treatment duration. CPR was in the mid-range of aggressiveness, and preferences for CPR were poor predictors of other treatment preferences.

These results suggest that eliciting preferences for only CPR is not sufficient information to infer a patient's preferences for more invasive or long-term life-sustaining treatments. In addition, knowing that patients want treatment in their current health does not generalize well to wanting treatment in more impaired functional health states. Lastly, refusing treatment in severely impaired states of health, such as severe dementia or permanent coma, does not generalize well to refusing treatment in less impaired states of health.

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In this chapter the rationale for the role of advance care planning in end-of-life decision-making is reviewed. We also review our research in this area, complementing previously published data with new analyses and discuss how these data help frame advance care planning discussions. Finally, an outline is given for a research agenda on advance care planning.

Advance care planning has received attention as an important means to enhance end-of-life care.[1,2] The major goal of advance care planning is to extend a patient's right to self-determination into the period when he or she becomes decisionally incapacitated. This is supposed to occur by ensuring that medical decisions made on behalf of patients without decisional capacity are based on either their previous wishes or their best interests. Advance care planning aims to accomplish this by having (1) the patient's wishes, expressed during a period of prior decisional capacity, serve as an action guide, and/or (2) the patient specify a surrogate decision-maker who will represent him or her in making decisions.

It is important to differentiate advance care planning from advance directives. Advance care planning is a process that involves four steps: (1) thinking about one's values and preferences for medical care if one is unable to communicate, (2) communicating these values and preferences to loved ones and health care providers, (3) documenting values and preferences, and (4) ensuring that these documents are accessible and up-to-date. Advance directives represent only one part of this process: they are the mechanisms used to document patients' wishes or appoint surrogate decision-makers.

It is hoped that advance care planning will serve several additional functions: (1) reduce the risk of over-treatment and under-treatment, (2) minimize the conflicts among family members and between clinicians and family members, and (3) reduce the burden of surrogate decision-making that is placed on family members. Unfortunately, there are limited data that support the effectiveness of advance directives.[3-5] Before indicting the use of advance directives, it is prudent to recognize the barriers to effective advance care planning. These are outlined below.

- Reimbursement mechanisms for advance care planning discussions are uncertain.[6]
- Efforts to promote efficiency in the outpatient setting have reduced the length of provider-patient visits.
- In spite of patient interest, physicians often wait too long or never initiate advance care planning discussions.[7-9]
- When discussions occur, they are often superficial (for instance, cardiopulmonary resuscitation (CPR) is often discussed without reference to the need for mechanical ventilation or likelihood of failure).[10-12]
- Advance directives often are written using vague language or are restricted to terminal illness or permanent vegetative states. This inhibits clinical applicability.[5,12-14]
- Clinicians frequently are inadequately educated and trained to conduct advance care planning discussions.[11,15]
- Clinicians and surrogates lack good understanding of patients' wishes.[16-19]

These barriers led us to investigate preferences for life-sustaining treatment and attitudes about health states with a diverse sample of volunteers. Participants were

provided with detailed descriptions of health states and treatments to facilitate more informed decision-making. Once informed choices were elicited, the relationships between assessments of health states and treatment preferences were characterized, as well as the relationships between different treatment preferences within a health state and across health states. These data provide a valid profile of attitudes and preferences that could form the basis for meaningful advance care planning discussions. This in turn could result in better discussions, more meaningful advance directives, and increased utility in clinical settings. The specific study questions addressed in this research are as follows:

1. When people consider life in a particular circumstance as 'worse than death,' what is the likelihood that they will refuse life-sustaining treatments in that circumstance?
2. How well does a person's preference for one treatment in a specific health state predict that person's preferences for other treatments in the same health state?
3. How well does a person's preference for one treatment in a specific health state predict that person's preferences for the same treatment in other health states?
4. If an advance care planning discussion is organized based on the results from this data set, how would it be structured, and why?

Methods

Overview

The research findings reviewed in this chapter are derived from a longitudinal study conducted between 1991 and 1995 in which preferences for life-sustaining treatments were elicited under a variety of conditions. Participants also rated their current health state and two hypothetical states depicting severe dementia and permanent coma. Some of the results from this study have been published elsewhere.[20-21] In this chapter, these results are reviewed and additional analyses are presented.

Patient population

The study participants were volunteers from seven groups in the Seattle area: younger well adults age 21 to 65 (n = 50), older well adults over age 65 (n = 49), older adults (over 65 years of age) with at least one chronic illness (n = 49), persons with cancer and a physician-estimated life expectancy of 6-24 months (n = 49), persons with AIDS or class IV HIV infection (n = 50), survivors of a stroke that occurred within the last ten years and resulted in residual impairment (n = 45), and nursing home residents who were expected to remain in the nursing home for at least six months (n = 50). Participants had to be at least 21 years of age, have no major vision or hearing impairments, show cognitive ability according to the Telephone Interview for Cognitive Status, and speak English.[22] Well adults could not have any health condition that had lasted longer than one year, be receiving regular treatment by a health care provider or be taking medications more than twice monthly.

Table 1. Participant characteristics at baseline

	Younger well adults (n=50)	Older well adults (n=49)	Persons with chronic illness (n=49)	Persons with terminal cancer (n=48)	Persons with AIDS (n=50)	Stroke survivors (n=45)	Nursing home residents (n=51)	Total sample (n=342)
Characteristic								
Mean age, years (s.d.)	41 (12)	72 (6)	76 (7)	60 (11)	37 (7)	63 (13)	80 (12)	61 (19)
Female sex, %	58	67	59	44	6	38	80	50
Education, % some college	96	76	47	56	70	58	28	62
Married/living with partner, %	54	49	31	60	16	71	12	41
Self rating of health, % fair or poor	0	6	31	42	54	31	32	28
Functional status, %*								
No to little dysfunction	98	88	35	27	0	0	0	36
Mild to moderate dysfunction	2	10	47	50	54	58	14	33
Severe dysfunction	0	2	18	23	46	42	86	31
Have depressive symptoms, %†	8	6	12	17	46	27	28	21
Low satisfaction with health and quality of life, %‡	10	8	35	48	72	67	60	43

* Functional status measured by the Sickness Impact Profile.[23] Total Sickness Impact Profile scores < 3 represent no to little dysfunction, scores ranging from 3 to 19.99 represent mild to moderate dysfunction, and scores ≥ 20 represent severe dysfunction or the need for assistance with three or more activities of daily living.

† Depressive symptoms measured by the Center for Epidemiologic Studies-Depression scale.[24] A score of ≥ 16 on the Center for Epidemiologic Studies-Depression scale indicates probable depression.

‡ Satisfaction measured by the Perceived Quality of Life scale.[25] Low satisfaction is defined as a score less than the sample mean of 7.3.

All variables differ across participant groups, $p < 0.0001$.

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Well adults were recruited by sending letters to addresses that were randomly selected from the telephone directory. Eligible patients were identified with the help of community and university-affiliated physicians and social service intermediaries. Potential participants were sent or given information statements about the project. If an individual was interested in learning more about the study, he or she could contact the study office. All persons who contacted the study office were screened. Informed consent occurred at the time of the interview. A total of 342 persons participated in the study. The characteristics of the participants are presented in Table 1.

Questionnaire description

Treatment preferences, health state ratings, and health status data were collected during in-person interviews. Preferences for antibiotics, long-term mechanical ventilation (with tracheostomy), long-term hemodialysis, long-term jejunal tube feeding, short-term mechanical ventilation, and CPR were elicited in each participant's current health and two hypothetical states representing severe dementia and permanent coma. Two versions of a visual aid to facilitate decision-making were used. Figure 1 shows the visual aid used to elicit preferences for CPR. A similar visual aid used for the other five treatments has been previously published.[20] That visual aid showed that the outcome of choosing treatment would result in a 100% chance of returning to the baseline state. Treatment preferences were elicited after reviewing the visual aid with the simple question, 'Do you want to receive treatment?'

The health states were characterized in four domains: (1) thinking, remembering and talking; (2) walking and mobility; (3) self care; and (4) pain and discomfort. For each domain, three to four levels were described with examples. For the current health situation, the participant selected the appropriate level of function for each domain.[20] The dementia state was characterized as 'think, remember, and talk with great difficulty; get around with great difficulty; perform self care with some difficulty; and are in no physical pain or discomfort.' The permanent coma situation was described as 'do not think, remember, or communicate in any way; are confined to a bed; do not perform self care activities; and are in no physical pain or discomfort.' These descriptions were complemented by examples written in everyday language. For example, 'get around with great difficulty' was further characterized with 'walk or use a cane, walker, or wheelchair but are limited to the house.' The descriptions of the levels and common language examples are presented elsewhere.[20] Health state ratings were elicited after reviewing the four domain descriptions with their corresponding examples. The ratings were elicited with the simple question, 'How would you rate this health state?'

Measurement

Treatment preferences were indicated on a five-point scale: 'definitely no', 'probably no', 'not sure', 'probably yes', and 'definitely yes'. Health states were rated on a seven-point scale: 'much worse than death', 'somewhat worse than death', 'a little worse than death', 'neither better nor worse than death', 'a little better than death', 'somewhat better than death', and 'much better than death'.

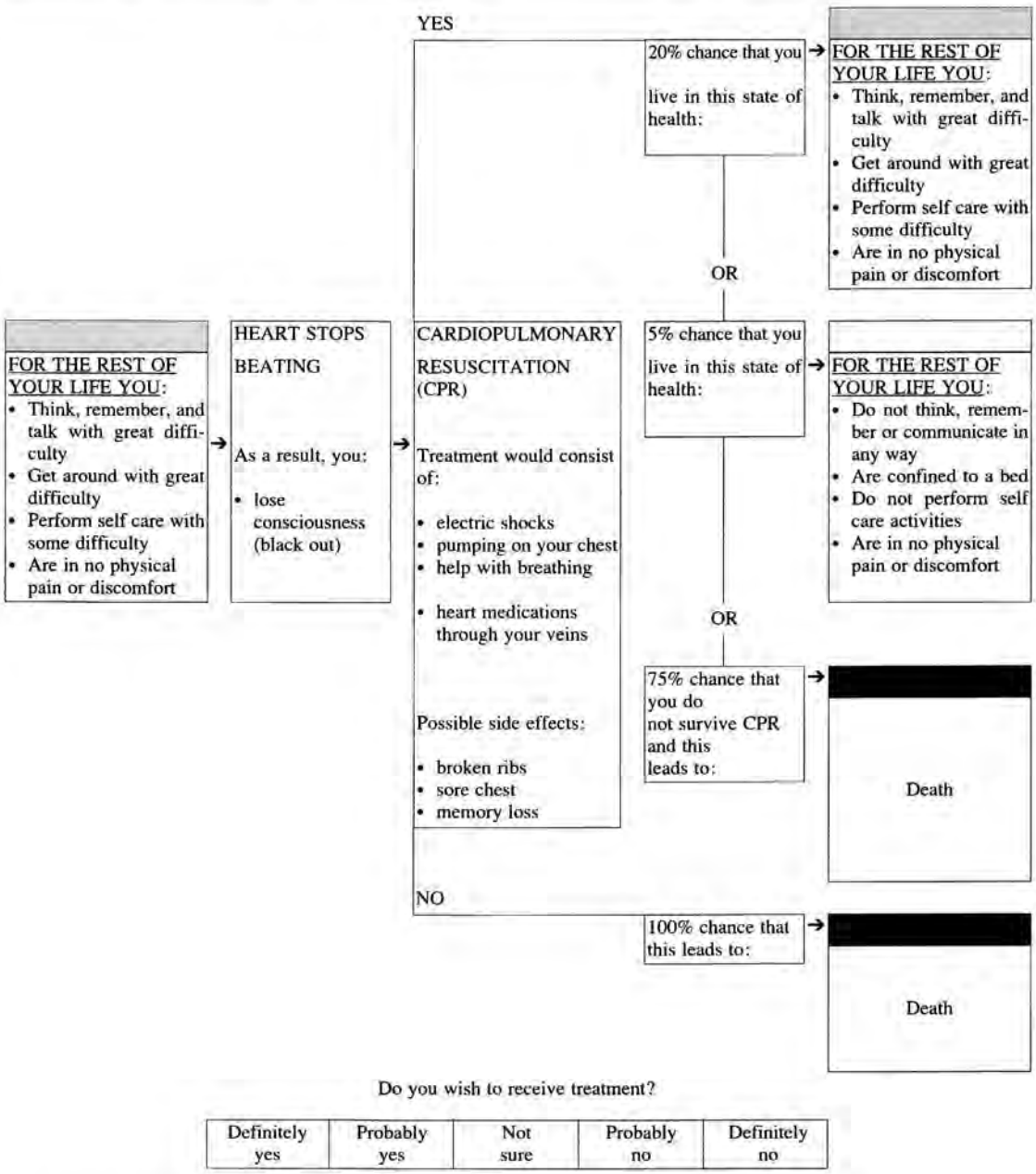

Figure 1. Sample of the visual aid to elicit preferences for CPR in the dementia health state.
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Analytic strategies

To facilitate analyses, the five-point treatment preference scale was collapsed into three clinically-based categories: forego treatment (representing 'definitely no' and 'probably no'), accept treatment (including 'definitely yes' and 'probably yes'), and not sure. The health state rating scale also was collapsed into three categories: worse than death, neither better nor worse, and better than death. To address the first study question, the percentage of treatment decisions that were refused when the health states were rated as 'worse than death' was calculated. To address the second and third study questions, positive and negative predictive values were used to assess the relationship between treatment preferences. Positive predictive value is the conditional probability that a person will want one treatment given a preference in favor of a different treatment. Negative predictive value is the conditional probability that a person will forego one treatment given a preference to forego a different treatment.

Results (previously reported)

Distribution of health state ratings and treatment preferences

Nearly all participants rated their current health as better than death. In contrast, 52% rated permanent coma as worse than death and 27% rated severe dementia as worse than death. Table 2 shows the distribution of treatment refusals in the three health states.

Table 2. Percentage of treatment refusals* in each of the three health states.

Treatment	Current health	Dementia	Coma
Antibiotics	5	20	62
Short-term mechanical ventilation	12	44	71
Cardiopulmonary resuscitation	23	60	85
Long-term dialysis	25	56	86
Long-term feeding tube	41	64	86
Long-term mechanical ventilation	58	77	86

* Includes 'probably no' and 'definitely no' treatment preference ratings.
Preferences for treatments differed across health states for every treatment ($p < 0.0001$) and across treatments for every health state ($p < 0.0001$).

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Relationship between 'worse than death' health state ratings and treatment preferences

When health states were rated as worse than death, participants chose to forego life-sustaining treatments 85% of the time. The 15% of decisions in which participants accepted treatment in health states rated as 'worse than death' had several explanations.

First, many people wanted antibiotic treatment, viewing it as relatively simple and short-term. Second, some people used the 'worse than death' language to connote an undesirable state, rather than a literal interpretation in which death would be preferred to continued existence in that situation. Another reason given was that people wanted to respect the wishes of family members that they continue living.[20]

Predictive values between treatment preferences in current health

In general, the preference to receive more invasive treatments had high positive predictive value for less invasive treatments in current health (range, 0.86-1.0). For example, if a participant was willing to accept long-term treatment with a feeding tube, there was a greater than an 88% probability that s/he also would accept CPR, short-term mechanical ventilation, or intravenous antibiotics. In addition, preferences to forego less invasive treatments had moderately high negative predictive value for more invasive treatments (range, 0.61-0.94). For example, saying 'no' to intravenous antibiotics generalized to saying 'no' to all other life-sustaining treatments with greater than a 77% probability.[21]

Predictive values of treatment preferences between health states

The positive predictive values of treatments in permanent coma for the same treatment in severe dementia were high (range, 0.8-1.0). In contrast, wanting a treatment in current health did not generalize well to wanting the same treatment in the dementia situation (range, 0.44-0.77). Weak positive predictive values also were seen when trying to generalize treatment preferences from the dementia situation to the permanent coma situation (range 0.27-0.51).[21]

The negative predictive values of treatment preferences from current health to severe dementia were high (range, 0.88-0.97), excluding antibiotics which had a negative predictive value of 0.72. There were high negative predictive values when generalizing treatment preferences from the severe dementia situation to the permanent coma situation (range, 0.92-0.99). In contrast, weak negative predictive values were found generalizing from the permanent coma situation to the severe dementia situation (range, 0.20-0.77).[21]

Results (not previously reported)

Predictive values between treatments within hypothetical health states

As shown in Table 3a, the preference to receive more invasive treatments in the severe dementia situation had moderate to high positive predictive values for less invasive treatments, especially for intravenous antibiotics. For example, if a participant wanted long-term mechanical ventilation, there was a greater than a 78% probability that s/he also would want all other treatments. However, the converse was not true: no preference for any other life-sustaining treatment generalized well to long-term mechanical ventilation. Preferences for CPR did generalize well to antibiotics,

but only moderately well to short-term mechanical ventilation, long-term dialysis and long-term feeding tubes, and rather poorly to long-term mechanical ventilation.

Table 3a. Positive predictive value of treatments in dementia for each other.

		Then, the probability of saying 'yes' to this treatment is:					
If a person said 'yes' to:	n*	ABX	SMV	CPR	DYL	LFT	LMV
Antibiotics (ABX)	249	- -	.51	.41	.37	.33	.18
Short-term mechanical ventilation (SMV)	134	.96	- -	.60	.58	.49	.33
Cardiopulmonary resuscitation (CPR)	106	.97	.75	- -	.64	.59	.37
Long-term dialysis (DYL)	100	.92	.78	.68	- -	.63	.41
Long-term feeding tube (LFT)	82	.99	.79	.77	.77	- -	.45
Long-term mechanical ventilation (LMV)	47	.96	.94	.83	.87	.79	- -
Overall rate = yes†	342	.73	.39	.31	.29	.24	.14

Table 3b. Negative predictive value of treatments in dementia for each other.

		Then, the probability of saying 'no' to this treatment is:					
If a person said 'no' to:	n*	ABX	SMV	CPR	DYL	LFT	LMV
Antibiotics (ABX)	67	- -	.91	.99	.90	.96	1.00
Short-term mechanical ventilation (SMV)	150	.41	- -	.85	.83	.91	.95
Cardiopulmonary resuscitation (CPR)	206	.32	.62	- -	.76	.85	.93
Long-term dialysis (DYL)	192	.31	.65	.82	- -	.89	.96
Long-term feeding tube (LFT)	219	.29	.63	.80	.78	- -	.93
Long-term mechanical ventilation (LMV)	262	.26	.54	.73	.70	.77	- -
Overall rate = no†	342	.20	.44	.60	.56	.64	.77

* The n refers to the number of respondents who said 'yes' (Table 3a) or 'no' (Table 3b) to the treatments in the rows.

† The overall rates indicate how often participants wanted (Table 3a) or did not want (Table 3b) each of the treatments shown in the columns. All predictive values are significantly different from the overall rates ($p < 0.001$).

Table 3b shows that preferences to forego less invasive treatments in the severe dementia situation had moderate to high negative predictive values for more invasive treatments. For example, if a participant wanted to forego antibiotics, there was greater than an 89% probability that s/he would want to forego all other treatments. Preferences to forego most treatments generalized well to foregoing long-term feeding tubes and long-term mechanical ventilation. However, saying 'no' to long-term mechanical ventilation had moderate to poor negative predictive value for other treatments.

Tables 4a and 4b show results for predictive values between treatments in the permanent coma situation. There are similar patterns as with the dementia situation, but with lower positive predictive values and higher negative predictive values.

Table 4a. Positive predictive value of treatments in coma for each other.

		Then, the probability of saying 'yes' to this treatment is:					
If a person said 'yes' to:	n*	ABX	SMV	CPR	DYL	LFT	LMV
Antibiotics (ABX)	89	- -	.52	.36	.26	.20	.28
Short-term mechanical ventilation (SMV)	68	.68	- -	.44	.37	.34	.35
Cardiopulmonary resuscitation (CPR)	36	.89	.83	- -	.61	.50	.58
Long-term dialysis (DYL)	33	.70	.76	.67	- -	.61	.58
Long-term feeding tube (LFT)	26	.69	.88	.69	.77	- -	.62
Long-term mechanical ventilation (LMV)	30	.83	.80	.70	.63	.53	- -
Overall rate = yes†	342	.26	.20	.11	.10	.08	.09

Table 4b. Negative predictive value of treatments in coma for each other.

		Then, the probability of saying 'no' to this treatment is:					
If a person said 'no' to:	n*	ABX	SMV	CPR	DYL	LFT	LMV
Antibiotics (ABX)	210	- -	.91	.97	.95	.96	.98
Short-term mechanical ventilation (SMV)	243	.79	- -	.98	.98	.99	.98
Cardiopulmonary resuscitation (CPR)	288	.70	.82	- -	.95	.95	.95
Long-term dialysis (DYL)	293	.68	.81	.93	- -	.97	.95
Long-term feeding tube (LFT)	294	.68	.82	.93	.97	- -	.94
Long-term mechanical ventilation (LMV)	295	.70	.80	.93	.94	.94	- -
Overall rate = no†	342	.61	.71	.84	.86	.86	.86

* The n refers to the number of respondents who said 'yes' (Table 4a) or 'no' (Table 4b) to the treatments in the rows.

† The overall rates indicate how often participants wanted (Table 4a) or did not want (Table 4b) each of the treatments shown in the columns. All predictive values are significantly different from the overall rates ($p < 0.001$).

Predictive values of treatment preferences between health states

The predictive values of treatments in one state of health (index state) for the same treatment in another state of health (outcome state) varied widely, but several patterns can be seen (Tables 5a and 5b). First, high positive predictive values were seen for treatment preferences from either coma or dementia to current health. Second, the negative predictive values of treatment preferences from current health to permanent coma are moderately high.

Additionally, the data in the tables show that both positive and negative predictive values, within and across scenarios, are consistently more accurate (predictive) than the overall preference rates derived from all the participants. This indicates that for a given person, knowing some of his or her treatment preferences in one health state will more accurately predict preferences for another treatment in that health state or the same treatment in another health state than simply knowing, in general terms, what other people would want in similar circumstances.

Table 5a. Positive predictive values (PPV) for treatment preferences in one health state to another.

	Current health → Coma			Coma → Current health			Dementia → Current health		
Treatments:	n*	PPV	Rate†	n*	PPV	Rate†	n*	PPV	Rate†
Antibiotics	319	.27	.26††	89	.97	.93††	249	.99	.93
Short-term mechanical ventilation	287	.23	.20	68	.99	.84	134	.99	.84
Cardiopulmonary resuscitation	244	.14	.11	36	.97	.71	106	.99	.71
Long-term dialysis	217	.15	.10	33	.97	.63	100	.98	.63
Long-term feeding tube	166	.15	.08	26	.96	.49	82	.87	.49
Long-term mechanical ventilation	102	.24	.09	30	.80	.30	47	.96	.30

Table 5b. Negative predictive values (NPV) for treatment preferences in one health state to another.

	Current health → Coma			Coma → Current health			Dementia → Current health		
Treatments:	n*	NPV	Rate†	n*	NPV	Rate†	n*	NPV	Rate†
Antibiotics	18	.78	.61††	210	.07	.05††	67	.19	.05
Short-term mechanical ventilation	40	.87	.71††	243	.14	.12††	150	.23	.12
Cardiopulmonary resuscitation	77	1.00	.84	288	.27	.23	206	.36	.23
Long-term dialysis	87	1.00	.86	293	.30	.25	192	.43	.25
Long-term feeding tube	140	.97	.86	294	.46	.41	219	.58	.41
Long-term mechanical ventilation	200	.95	.86	295	.64	.58	262	.74	.58

* The n refers to the number of respondents who said 'yes' (Table 5a) or 'no' (Table 5b) to the treatments in the rows, considering the predicting health state to the left of the arrows.

† The rates reflect the fraction of participants who wanted (Table 5a) or did not want (Table 5b) the treatments in the rows, considering the second health state to the right of the arrows.

†† These predictive values do not differ significantly at the $p = 0.01$ level. All other values of PPV and NPV are significantly different from the rates ($p < 0.001$).

Discussion

In this research, the relationship between treatment preferences and ratings of health states as well as the predictive values of life-sustaining treatment preferences were examined. The data further support earlier research indicating that quality of life and perceptions of states worse than death motivate the desire to forego life-sustaining treatment.[26-27] The relationships between treatment preferences affirm earlier findings showing that (1) when patients decline noninvasive treatments, they usually decline more invasive treatments, and (2) when they want to receive invasive treatments they usually accept less invasive ones.[28]

The data also suggest an empirically-derived, organizing sequence in which to order treatments. The treatments as listed in Tables 3 and 4 (antibiotics, short-term mechanical ventilation, CPR, long-term dialysis, long-term feeding tube, and long-term mechanical ventilation) represent degrees of 'aggressiveness' that incorporate invasiveness and duration of treatment. This ordering of treatments is validated by the consistent patterns of predictive values along each row and down each column. Positive predictive values are always higher for less aggressive treatments and negative predictive values are always higher for more aggressive treatments.

Advance care planning discussions that pertain to treatment preferences and health state ratings can be organized by systematically reviewing the results from these analyses. Practice would suggest that a good place to begin a discussion of advance care planning is to inquire about who would be the best person to speak on the patient's behalf. Following this, the clinician can ask about life-sustaining treatment preferences in current health. If the patient says she 'wants nothing' in current health, the clinician should probe for an explanation that provides the context for these preferences. Patients who 'want nothing' in their current health are very likely not to want treatment under any circumstances. This interpretation can and should be verified directly with the patient.

If, however, a patient is interested in receiving life-sustaining treatment in current health, the next set of questions should determine whether the patient is interested in receiving life-sustaining treatment in all circumstances (including long-term coma and/or terminal illness). Since only a small minority of individuals desire life-sustaining treatment in all circumstances, identifying them quickly may streamline the discussion. The most common situation, however, is that patients have a mix of preferences. Thus, the next set of questions should have two goals: (1) to characterize two thresholds of unacceptability: one for health states and the other for treatments, and (2) to understand why the person would not want treatments under certain circumstances.

To achieve the first goal, a clinician should inquire about whether living under specified situations, such as severe dementia or permanent coma, would be considered a 'fate worse than death.'[27-29] A question that introduces this topic is, 'What kinds of situations do you fear the most?' If the patient identifies one or more of these situations, the clinician should explore the patient's reasons. Afterwards, the clinician should confirm that the patient would not want life-sustaining treatment if faced with a life-threatening illness in the situation(s). Asking about a few specific treatments should verify the inference that life-sustaining treatments should be withheld or withdrawn under these unacceptable circumstances. Occasionally a patient will indicate that a health state would be unacceptable and yet she would want one or more life-sustaining treatments. In these circumstances, asking the 'why' question should illuminate other important and clinically-relevant values or concerns that have bearing on advance care planning.

When a patient indicates that a situation is acceptable, follow-up questions about preferences for a few treatments should illuminate the patient's threshold for treatment acceptability. For example, if the patient is asked about long-term use of a mechanical ventilator and would desire such treatment, then the chances are good that she will want all other treatments in a particular state of health. Conversely, if a patient is asked and says no to treatment with antibiotics, she would likely not want other treatments.

There are three important clinical caveats that derive from these results. First, eliciting preferences only for CPR, as is often done, is not enough to understand a patient's overall preferences for life-sustaining treatment. CPR generalizes poorly to other life-sustaining treatments that are perceived to be more invasive or long-term. Second, wanting treatment in one's current health does not generalize well to wanting

treatment in more impaired functional health states. Third, refusing treatment in a severely impaired state of health (severe dementia or long-term coma) does not generalize well to refusing treatment in less impaired states of health (for instance, current health).

It is known that at present, physicians spend a very limited amount of time discussing advance care planning with their patients and often do not develop a shared understanding of their patients' values or preferences.[12,16-18] The extrapolation of these data into an approach to advance care planning discussions may help clinicians, as it is organized, balanced, and straight-forward. Moreover, by asking the 'why' questions after eliciting preferences and listening to the responses, the discussion will stay patient-focused. In addition, many patients have diagnoses with predictable prognoses. In these situations, the advance care planning discussions can be streamlined further by focusing on the anticipated circumstances for the particular patient.

The proposed advance care planning questions do not address the important challenge that patients need to understand the health states and treatments that are raised in any discussion. Without rich descriptions, patients may be unable to visualize the treatments and health states, and therefore may be poorly prepared to formulate preferences that reflect their values and interests. This barrier to effective advance care planning suggests the need for a patient-centered workbook. A workbook that is sensitive to the data presented herein is called *Your Life Your Choices*.[30] It is aimed to motivate patients and facilitate deliberation in advance care planning. It also describes in detail the health states and treatments that are often addressed in advance care planning discussions.

Some patients may prefer to discuss general values or goals of care rather than specific treatment preferences.[13,31] Unfortunately, reliance on general values has shown limited generalizability to treatment preferences. Similarly, treatment goals that rely on general statements, such as 'attempt cure' or 'consider quality of life,' appear to have limited ability to translate consistently into treatment preferences. Other patients may prefer to have family members decide what is best when the situation arises.[32-33] Reliance on the family may prevent over-interpretation of directives and is supported by social custom. However, relying on the family to make decisions for decisionally-incapacitated patients does not lessen the value of explicit discussions between patients and their family members before the need arises.

A major study limitation is that the people who agreed to participate differ from the general population in the United States because (1) they were predominantly white and well educated, and (2) they were willing to think about these issues. Another limitation is that participants were asked to assume three things that make the decisions less realistic than they would be in actual practice when formulating their treatment preferences. These included considering the hypothetical health states to be permanent, accepting the stated probabilities of treatment success, and that the decisions would not have economic implications.

Despite these reservations, we believe these data and the resultant approach to advance care planning discussions may help clinicians, patients, and their family members. Prior to asking the recommended questions however, clinicians should decide how they plan to (1) introduce the topic, (2) address the emotional content of

the discussions, (3) facilitate communication between the patient and family or surrogate decision-maker, (4) ensure that patients understand what they are talking about, and (5) follow-up either with regard to further deliberation or developing an advance directive.

Important research questions

Future research should take several paths. With comparable populations, research should evaluate the effect of these guidelines on discussions, proxy preparedness, and decision-making under conditions of decisional incapacity. Before generalizing these data and guidelines to different populations, other research should validate the correlates and predictive value of preferences in other populations within and across national boundaries and include a more diverse ethnic mix. The barriers to thinking about and discussing end-of-life care, as well as the role of the family and community in decision-making, may vary widely across societies. Moreover, many of the issues that frame the approach to decision-making at the end of life and/or under circumstances of decisional incapacity may vary across nationalities and cultures. These include, but are not limited to the following: physician culture as it relates to involving patients (and families) in medical decisions, the use of advanced medical technologies to prolong life, lay fears about over-treatment and loss of dignity, societal pressure to control health care costs, and the legal climate that surrounds advance care planning and medical behaviors that shorten life. These potentially influential factors suggest the need for collaborative international research.

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Joan M. Teno

End-of-Life Decision-Making: From Whether to When

Abstract

In the United States three decades ago, Luis Kuntner created the 'living will' in response to a tragic court case. At the time, the debate focused on the morality and legality of forgoing and withdrawing life-sustaining treatment. The United States, in contrast to other countries, fully embraced and promoted to the use of advance directives. The Study to Understand Prognosis and Preferences for Outcomes and Risks of Treatment (SUPPORT), a randomized controlled trial, provided physicians with patient-specific information on the patients' prognosis and preferences, as well as a nurse to facilitate communication and decision-making. This study however, did not enhance communication or physician understanding of patient preferences. In this paper, findings from the qualitative and quantitative data from this project will be used to support the assertion that the key question now is *when* (not whether) life-sustaining treatment or change in treatment goals should occur for those with progressive, serious chronic illnesses. Moreover, such decisions are key to the quality of care. Research is needed to support this change in decision-making, including studies that focus on (1) developing further the scientific evidence base for palliative care, (2) understanding the role of public policy on the quality of end-of-life care, (3) examining the process of communication and negotiation to arrive at such transitions in the goals of care, and 4) developing and validating conceptual models and measurement tools.

Death at the turn of century, as depicted by Munth, was a young person dying of infectious disease while the family members sat at the bedside. Physicians had little to offer. Now, a century later, industrial nations have an aging society of persons dying of chronic, progressive, and eventually fatal illnesses. This has led to many older persons fearing that they will be shackled to unwanted technology. Such fear drove Grandma Layton to draw the following picture: a self-portrait of her shackled to an unwanted respirator, helpless, with a cockroach walking across her face. Improved sanitation, penicillin, mechanical ventilators, and other advances have played a role in those persons aged 85 and older being the fastest growing segment of the United States population. However, technology such as Cardio-Pulmonary Resuscitation (CPR), mechanical ventilation and even nasal-gastric feeding tubes are a double edge sword. For some, these technologies are life saving; for others, they prolong dying and can result in great suffering for patients and their families.

In the United States, the widespread use of CPR and ventilators was followed by a moral and ethical debate over forgoing and withholding potential life-sustaining treatment. Court cases such as Quinlan, Cruzan, and two recent United States Supreme court cases on physician assisted suicide have helped to resolve some of the legal issues over a person's right to control the timing of his or her death. The United States has fully embraced an 'Advance Directive movement' with the United States Congress ratifying formal written advance directives in the passage of the Patient Self-Determination Act. In 1969, this movement was launched by Luis Kuntner's coining of the term 'living will,' a document with the intent of allowing a competent person to state preferences prior to a period of decision-making incapacity. The living will usually includes a vaguely worded statement that if a person is irreversibly ill without hope, then medical care should focus on comfort and not employ heroic treatments. Many in the United States embraced advance directives as the means to solve the public fear of dying shackled to unwanted technology, in pain, alone and isolated from family members.

The Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment (SUPPORT), a 28 million dollar study of 9105 seriously ill persons, provides insights about decision-making and patient outcomes during the time period immediately prior to and after the implementation of the Patient Self-Determination Act.[1] This study, which examined decision-making in its Phase I from 1989 to 1991, found important opportunities for improvement in communication and the use of advance directives. However, phase II of SUPPORT, a block randomized controlled trial, did not improve end-of-life decision-making. As I have written, important lessons have been learned and not learned from this study.[2] In this essay, I will expand upon two previous efforts to draw further insights based on analysis of the quantitative and qualitative database. There are two fundamental claims that I will make.

1. In the United States, we struggled with the question of the morality of withholding and withdrawing life-sustaining treatment. For the most part, we have resolved those moral questions. A much more difficult decision faced by health care providers, patients, and their families is at what point a person should make a transition in medical goals from pursuing aggressive care at all costs to utilizing a mixture of aggressive and palliative care or, finally to focusing on comfort even if this hastens death. Simply stated, the fundamental question now is when, not whether, life-sustaining treatment is stopped or not begun.
2. The management of such transitions is essential to high-quality medical care. Errors in the timing of transitions can be made in both directions. Fundamental to exemplary medical care is that a care plan is formulated with an understanding of the patient's disease trajectory, the patient's goals of care, and the equitable constraints imposed by society.

Results of SUPPORT will be utilized to provide the evidence for each of these assertions. We are still in our infancy in describing and understanding what is so fundamental to the human state: dying. SUPPORT provides early, yet important descriptive studies of decision-making for seriously ill adults. A brief overview of the SUPPORT study will be presented prior to providing the justification for these two claims.

Overview – SUPPORT Study

The genesis of the SUPPORT study was the increasing public fear that medical technology was trumping patient preferences. The perception was that physicians were unilaterally disregarding patient's informed preferences to forgo life-sustaining treatment. Indeed, the research to support this was based on case reports[3] and two published studies.[4,5] Solomon and colleagues found that more than one in two health care providers reported that they provided overly burdensome treatment to a dying person. In addition, Teno and researchers at Brown University found that 21% of patients with symptomatic HIV disease reported that their current treatments were contrary to their preferred treatment approach of focusing on comfort. The overall goal of the SUPPORT project was to improve decision-making for seriously ill adults with the guiding principle that decisions regarding life-sustaining treatment ought to reflect a competent individual's informed preferences. A fundamental premise of the study was that patient specific information on prognoses would be an important aide for physicians, patients, and family members in making decisions about the use of life-sustaining treatments.

The study was designed with two distinct phases. Phase I was an observational study with enough patients enrolled in 9 disease categories to allow adequate development of prognostic models to provide patient specific information as part of the planned Phase II intervention study. The study enrolled patients who met entry criteria at five geographically diverse locations across the United States. Each center was an academic medical center. These centers were located in Boston, MA; Durham, NC; Los Angeles, CA; Cleveland, OH; and Marshfield, WI. Two of these centers were in major metropolitan cities, while one city was in a rural area of the central United States. To be eligible, patients had to meet criteria for one or more of the following nine disease categories: metastatic colon cancer, non-small cell lung cancer (stage III or IV), severe congestive heart failure, severe chronic obstructive pulmonary disease, end stage liver disease, non-traumatic coma, acute respiratory failure, multiple organ system failure with sepsis or a malignant condition. Patients were eligible for the study if they had survived 48 hours since admission, had a planned admission longer than 72 hours, were at least eighteen years old, and spoke English.

Data collection

Both a review of the medical record and interviews were conducted with the patient, his or her surrogate (a person who would make medical decisions if the patient was unable to do so), and the most senior physician who was responsible for the patient's medical care. The medical records were reviewed both prospectively for measures of patients' disease severity and resource utilization and retrospectively for decision-making processes and outcomes of medical care. Interviews with the patient and/or the surrogate were conducted during the first week, the second week, the second month and the sixth month after study entry. For those patients who died during the six months of follow-up, the surrogate was interviewed about the circumstances of his or her family member's death. Interviews focused on patient preferences, communication, perceived prognosis, pain and other symptoms, and the functional status

of the patient. Physicians were interviewed only during the first and second of week of hospitalization with a focus on prognosis communication with the patient, and understanding of the patient's preferences.

In the first phase of the study, a total of 4301 seriously ill persons were enrolled.[1] The median age was 65 years, with 27% of the patients dying on that hospital admission and nearly one in two persons dying in the six months of follow-up. The first phase of the study revealed that too often these seriously ill persons had not discussed their preferences for resuscitation with their physicians, and as a result physicians often misperceived patient preferences for resuscitation. It was found that nearly one in two physicians misperceived a patient's preference to forgo resuscitation[6] and that misperception was associated with an increase in resource use. While communication was lacking, there was only a small number of patients who potentially had CPR attempted against their wishes. Rather, it was found that do-not-resuscitate (DNR) orders were written late, often within days of death. Such a pattern of late decision-making when medical treatment was futile resulted in prolonged stays in the intensive care unit (ICU), with 38% of dying persons spending more than ten days in the ICU.

An intervention was designed that mainly provided physicians with information about a patient's preferences, advance directive status, symptom reports, the objective prognosis based on statistical models, and the patients' subjective prognosis. Furthermore, a nurse was provided who, at the request of the physician, could council patients on advance directives, pain management, and other aspects of decision-making. A total of 4804 seriously ill persons were enrolled in the intervention phase of the study. Based on the phase I data, five outcome variables were selected: (1) timing of DNR orders, (2) pain, (3) physician understanding of patient preferences for resuscitation, (4) time spent in undesirable states prior to death, and (5) resource use. Several of these outcome variables assumed that patients, once informed of their prognoses, would opt for less care and that physicians would understand and/or agree with those preferences, resulting in reduced resource utilization. It was never the goal of the intervention to reduce resource utilization; rather, it was hypothesized that many patients desired less care than they were currently getting.

Unfortunately, the intervention did not impact on any of the five chosen outcome variables. The low rates of communication persisted. Physicians still did not discuss prognoses or patient preferences. Thus, it is not surprising that the intervention did not impact resource utilization or time spent in undesirable states prior to death. During phase II of the study, intervention nurses wrote a narrative about decision-making shortly after the patient's death or discharge from the hospital. A narrative was done for every tenth study patient and commented on decision-making, patient clinical status, situation of the family and any financial concerns, course of pain, and outcomes of the intervention. These narrative data have been analyzed by triangulating the qualitative (that is, the nurse narratives) and quantitative data sources (that is, the chart review and interviews with patient, surrogate, and the attending physician).

In summary, the SUPPORT study was a complex effort with multiple data collection methods that provided snapshots of decision-making and patient outcomes for nearly 9000 seriously ill people between 1989 and 1994. The results of the study demonstrate

that complex issues such as medical decision-making can be examined through interviews and abstraction from medical records. An intervention consisting mainly of information did not impact physician, patient, or family member behavior.

Assertion No 1 – The fundamental question has changed from whether to when

While the Advance Directive and Right to Die movement in the United States has helped resolve fundamental moral questions about withholding or withdrawing life-sustaining treatment, one of the main implications of the SUPPORT study findings is that we are struggling with a more difficult question of *when*, not whether, life-sustaining treatment is withdrawn. A mistake of the Advance Directive movement has been to focus exclusively on cases that are troublesome. This focus has helped to resolve ethical dilemmas, but it has not addressed the concerns of using advance directives for the majority of dying persons.

The SUPPORT study provided us with the opportunity to examine the impact of advance directives on decision-making at a time prior to and after the implementation of the Patient Self-Determination Act (PSDA). This federal Act mandated that all segments of the health care system inform patients about their rights to participate in medical decision-making and formulate written advance directives. Likewise, health care institutions must have formal policies about written advance directives and document them in medical records, and institutions must educate health care providers and the community about advance directives. Despite the intense focus on the use of written advance directives, the SUPPORT found that there was no substantial increase in the use of advance directives or change in their role in medical decision-making.[7-10]

Prior to the PSDA, one in five seriously ill adults had a written advance directive. This rate remained similar in the two years after the implementation of the PSDA. Thus, the majority of decisions in the seriously ill must be made without the use of advance directives. SUPPORT examined the impact of written advance directives on resuscitation decision-making. It was assumed that written advance directives would facilitate communication leading to clarification of patient preferences to forgo resuscitation. Thus, written advance directives were hypothesized to increase discussion about resuscitation between the patient and health care provider and to result in a DNR order when the patient reported a preference to forgo resuscitation. Prior to and after the PSDA, nearly one in two persons with an advance directive and preference to forgo CPR did not have a DNR order, and nearly 60% of seriously ill people had not discussed their preferences for resuscitation with a physician.[8]

In order to understand the limited effectiveness of advance directives, Teno and colleagues examined nurse narratives for those persons with an impaired mental status, patients with a poor two month objective statistical model estimate of prognosis, or patients who had died during the enrollment hospitalization.[11] These criteria were formulated to ensure that selected persons had a sustained period of mental incapacity when the advance directive ought to have played a role in decision-making.

Of the 58 narratives reviewed, there was only one case in which a patient preference written as an advance directive was trumped, and this was at the request of the patient's wife in order to allow a daughter to come to terms with her father dying. Despite the concern that physicians were unilaterally trumping patient preferences, no physician knowingly trumped or disregarded a patient's preference. Rather, advance directives were not prospectively discussed and written advance directives were only considered when the patient was hopelessly ill. The words of one surrogate struggling to make decisions for her 75 year-old husband with acute respiratory distress syndrome from viral pneumonia framed the struggle that health care providers and surrogates go through in making decisions: *'I know that he has a living will.. he has a durable power of attorney.. what I don't know is when are the terms hopelessly ill meant to apply in his circumstances..'*

This narrative illustrates the fundamental question now facing seriously ill persons with chronic illness: when do we stop life-sustaining treatment? For the most part, these decisions are not about continued futile care. Instead, health care providers, patients, and their families are faced with decisions involving the tradeoffs between quality versus quantity of life.

This has been the fundamental error in bio-ethics: the assumption that there is a clear dividing line between those who are among the living and those who are among the dying and that a written document stating preferences for those who are 'hopelessly ill' would improve decision-making and outcomes. Rather, a written advance directive is one tool in a process of advance care planning.

Advance care planning is a process of communication and negotiation that helps patients formulate preferences and goals for medical care both presently and at a future time when the patient is unable to participate in decision-making. I am arguing for a much broader view of advance care planning, one that realizes that advance care planning needs to be tailored to the patient's disease course and circumstances. Advance care planning is an ongoing process which must recognize when the patient is ready to make a transition in the goals of care and formulate a set of plans to ensure those preferences will be honored. The critical decision for the majority of patients is not whether a final resuscitation attempt is undertaken; instead, different diagnoses require a variety of decisions. For example, the essential decision for a cancer patient is whether to pursue an additional round of chemotherapy. Often, this is the sentinel decision that leads to formulating a plan of care that focuses on patient comfort, no further hospitalization, and forgoing resuscitation. A central focus of advance care planning and palliative care should be on helping the patient make choices regarding transitions in the goals of care. These choices are likely to be necessary when current medical treatment offers the patient little benefit or when the patient perceives that his or her quality of life has reached a self-defined sub-optimal level.

The first step of advance care planning is formulating preferences for the present and for a future period of diminished mental capacity. The crucial second step is that the health care providers formulate a plan of care (including contingency plans) that will ensure that those goals are achieved. Contingency plans can range from an emergency home kit for the management of terminal dyspnea to clear instructions on whom to call in the middle of night rather than dialing '911'.

Assertion No 2 – Key to quality medical care at the end of life is the management of transitions in goals of care.

The decision to stop active treatment is crucial to defining quality medical care for dying persons and their families. Errors can be made in both directions. Plans must be formulated in light of the disease trajectory, the patient's preferences, and equitable constraints imposed by society. An analysis from the SUPPORT project illustrates the importance of patient preferences and their impact on costs and longevity. Physicians often misperceived patient preferences to forgo resuscitation. When the patient preferred to forgo resuscitation, 31% of the physicians believed that the patient wanted CPR and 22% stated that they did not know the patient's preferences. When a physician believed that the patient wanted CPR contrary to the patient preferences, health care costs were higher and patient's survival was longer.[6] The SUPPORT results suggest that the accord between patient and physician preferences impacts longevity and resource utilization.

Analysis of the SUPPORT data illustrates that there are important tradeoffs between costs and longevity. SUPPORT examined decision-making at a time when the majority of persons were paying by care for fee for service, not by managed care. Physicians play a key role in counseling patients regarding these decisions, as illustrated by the following quotation from a SUPPORT intervention nurse's narrative.

'[The attending physician] asked if she wanted the breathing tube out, and she said that she did. The [attending physician] said, 'Well, let me state that if the breathing tube comes out, then you will die.' There was a pregnant pause, and then she, after a while, shook her head feebly. The attending quoted and documented that she had a 25% chance of recovery. When he said that to the patient with the husband near the bed, the husband held out four fingers and said, 'Twenty-five percent, honey, that is just one of those four fingers. Grab it. Grab it'.'[11]

The patient died on that hospital admission after two more weeks in the ICU. The physician's strong words influenced decision-making, potentially convincing a patient to continue treatment only to die after two more weeks in an ICU on a respirator. The conversation could have ended with the comment, 'your right, there is little hope. We are going to place you on a morphine drip and stop the mechanical ventilator.' A reasonable person may differ on the decision that should be made: what constitutes acceptable quality of life differs. Thus, shared decision-making that aims to ensure a patient's role in decision-making is important to defining quality of end-of-life care.

Important research questions

For the next several decades, industrialized nations are going to be faced with an aging population in which persons die of progressive, chronic illnesses. International research that examines how different cultures approach this problem and the impact of policy on the quality of care will be important. Potential areas of research include the following:

1. Qualitatively examine how health care providers speak with dying persons about their preferences and goals of care. Does a model promoting patient autonomy lead to improved outcomes? What is the role of patient preferences in longevity? Do physician preferences impact longevity? How does this vary among diverse cultures?
2. Examine the determinants of hospice length of stay in regard to public policy across industrialized nations (for instance, resource measures such as the per capita number of hospital beds).
3. Develop, refine, and validate conceptual models of the quality of care with an emphasis on the perspectives of the dying person and his or her family. How do the views of dying persons and their families vary among different cultures? Can a single measurement tool be developed that will collect valid information across different cultures? If yes, how does the patient and family perspective on quality of care vary among different cultures?
4. Grow of the scientific evidence base of palliative care medicine. Key areas of investigation include: (a) treatment of dyspnea with an emphasis on the role of opiates and anxiolitics, (b) diagnosis and treatment of acute change in mental status, (c) palliation of fatigue, (d) recognition and management of opiate toxicity, (e) the role of chemotherapy as palliation for patients for whom scientific evidence suggests that treatment will not prolong survival, and (f) the appropriate use of terminal sedation.

At the turn of the twentieth century, physicians were often faced with watching a young person dying of an infectious disease at home. Now, in this new millenium, health care providers are faced with an aging population. The majority of persons will now die of progressive, chronic, and eventually fatal illnesses. The essential question now is *when*, whether, life-sustaining treatment should be stopped or forgone. The 'when question' has profound implications for resource utilization. Public policy will differ in industrialized nations on the role of patient autonomy and access to technological care. Research that understands the impact of different public policies on end-of-life decision-making will be important to quality of end-of-life care.

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Forgoing Life-Prolonging Treatment in Sweden: Attitudes, Practices and Methodological Issues

Abstract

The international discussion on forgoing potentially life-prolonging treatment is extensive. The Swedish contribution to this discussion is modest. However, when the focus is on withholding and withdrawing life-prolonging treatment in Sweden, the contribution is more significant. The purpose of this chapter is to give an overview of Swedish research in this field, and to identify and discuss some issues for further research.

Disagreeing with professional guidelines, a majority of health care professionals are of the opinion that there is an ethically relevant distinction between withholding and withdrawing life-support. Swedish health care professionals believe that they should inform patients about their do-not-resuscitate decisions. These attitudes are in harmony with national recommendations. However, less than half of competent patients are actually informed. The general public, compared to intensive care physicians, want more patient and family influence on decisions to withdraw life support. The Swedish Priority Commission categorically prohibits the use of chronological age as a criterion for denial of medical care, but many professionals consider such denial acceptable.

Thus, a great deal is known about attitudes and practices in Sweden. In the opinion of the authors, the main methodological problems are related to the justification of practical conclusions. We argue that value premises (that is, conceptions of what is right or wrong), in combination with results from surveys on attitudes, experience and behaviour, are required to justify such conclusions. With reference to end-of-life situations, an important task is therefore to identify value premises by means of various different methods and to discuss these value premises openly in medical decision making, research and societal debate.

'Potentially life-prolonging treatment' can be defined as 'any medical intervention, technology, procedure, or medication that is administered to a patient in order to forestall the moment of death, whether or not the treatment is intended to affect the underlying life-threatening disease(s) or biological processes'.[1] Many articles have been written on forgoing such treatment. For instance, a search in Medline in June 2000 for articles published during the past ten years (keywords: [life-prolong or life-sustain] and [withhold or withdraw or forgo]) identified 217 articles. The Swedish contribution to the international discussion is modest. However, when the focus is on

withholding and withdrawing life-prolonging treatment in Sweden, the results are more significant.

The purpose of this chapter is twofold. The first part presents an overview of the research on forgoing potentially life-prolonging treatment in Sweden. The results of such research are often used to support recommendations for clinical practice or public health policy, but, as is well known, recommendations do not follow from facts alone. Empirical data are important, but not sufficient; value premises are also needed. These are usually not mentioned, and almost never formulated in medical articles, at least in Sweden. In the second part, it is argued that the research methods used to identify such value premises need to be improved.

Data on attitudes and practices

There are, of course, many different ways in which the Swedish research on forgoing life-prolonging treatment can be presented. Four subsections have been chosen: (1) withholding and withdrawing treatment, (2) communication, (3) decision making, and (4) documentation of the decision making. These are not only the most frequently discussed topics in the Swedish debate; they also comprehensively describe this research. For each topic, whenever data are available, both attitudes and practices will be discussed.

Withholding and withdrawing treatment

Is there an ethically relevant difference between withholding potentially life-prolonging treatment and withdrawing such treatment? Guidelines on forgoing treatment state that there is no such difference,[1,2] and this is also the opinion of most ethicists[4-6], but many health care professionals do not agree.[1,7-16] They believe that there is an ethically relevant difference between withholding and withdrawing such treatment. Most often, withdrawing is seen as ethically more problematic than withholding. A study carried out by Melltorp and Nilstun in 1992 supports the conclusion that many health care professionals believe that there is such a difference.[17] A questionnaire was distributed to 148 physicians and nurses at the Intensive Care Unit (ICU) of the University Hospital MAS in Malmö. One set of questions referred explicitly to possible differences between withholding and withdrawing life-prolonging treatment. Not less than 50% of the respondents were of the opinion that there is an ethically relevant difference.

The question of whether or not there is an inherent distinction between withholding and withdrawing life-prolonging treatment is still controversial. None of the participants in the debate have succeeded in their attempt to convince their opponents. It is therefore proposed that a change should be made in the emphasis in professional guidelines. They should avoid the controversial issue. What should be underlined is that the particular *situation* and the *consequences* of withholding and withdrawing life-prolonging treatment should always be taken into account. Thus, from a pluralistic perspective, whether or not there is an inherent ethical difference between withholding and withdrawing life-sustaining treatment is not decisive.

Communication

In Sweden, the do-not-resuscitate (DNR) decision is usually made without the participation of the patient, but if the patient asks, he or she will be informed. For instance, Asplund and Britton found that only 7% of physicians, 'always' or 'in the majority of cases' discussed DNR decisions with the patient, and 33% discussed them with the relatives.[18] Eighteen percent of the physicians stated that the question of withholding resuscitation treatment was discussed with the patient only if the patient raised the issue. In a study by Löfmark and Nilstun, a random sample of 104 Swedish cardiologists and 196 cardiology nurses were asked about their experience and opinion concerning DNR decisions.[19,20] Of the 220 respondents, 179 had been involved in a DNR decision. The prognosis was discussed with all patients who were considered to be competent, while the DNR decision was only discussed with about one third. Half of the respondents were of the opinion that DNR decisions should be discussed with all competent patients (see Table 1 and Table 2).

Table 1. Experience of physicians and nurses with regard to the most recent DNR decision in which they were involved.

Questions	Physicians (N = 39-57)			Nurses (N = 81-122)		
	Yes %	No %	Doubt %	Yes %	No %	Doubt %
Was the decision discussed with the patient?	9	87	4	5	83	12
Was the decision discussed with the relatives?	60	36	4	60	17	24
Was the prognosis discussed with the patient?	22	74	4	17	66	17
Was the patient able to take part in the discussion?	20	64	16	17	64	19
Did the patient take the initiative for the discussion?	9	87	4	8	81	11

Table 2. Physicians' and nurses' opinion about involving the patient in a DNR decision.

Questions	Physicians (n = 39-57)			Nurses (n = 81-122)		
	Yes %	No %	Doubt %	Yes %	No %	Doubt %
Should the patient be consulted?	50	13	37	55	7	39
Should the relatives be consulted?	74	10	16	78	1	21
Should the patient decide?	48	27	25	60	11	29
Should the relatives decide?	22	62	16	36	32	32

In a study by Sjökvist, Nilstun, Svantesson and Berggren, a questionnaire was distributed to a random sample of 1200 persons in the general public, and all 339 nurses and 121 physicians from a random sample of 29 of 61 the ICUs in Sweden.[21] The majority of the general public, and of the nurses and physicians (87%, 81% and 77%, respectively) were of the opinion that the physicians should raise the question about continued ventilator support with either the patient or the family, or both. However, the number of respondents who were of the opinion that the question should not be raised was significantly larger ($p<0.001$) among the nurses and physicians than among the general public (14%, 16% and 8%, respectively).

In a study by Valverius, Nilstun and Nilsson, a questionnaire was sent to 952 randomly selected registered specialists from sixteen different disciplines who were responsible for the care of terminally ill adult patients.[22] The questionnaire was also sent to 122 physicians working in palliative care units and 130 registered members of the Swedish Association for the Study of Pain. Of the responding physicians, 63%, 95% and 46% respectively, had more than occasionally during the previous year been medically responsible for the treatment of adult patients in the terminal stage of some type of incurable disease. The respondents were asked to answer each question by estimating a score for all their dying patients during the previous year. This score was indicated on an 11-point scale. For instance, if none of their patients expressed a desire to withhold treatment, they should score '0'; if all their patients expressed such a wish, they should score '10'. The relevant answers indicate that it is twice as common for patients to express a wish to withhold treatment than a wish to withdraw treatment (see Table 3).

Table 3. Wishes expressed by patients and actions performed by physicians.*

	Randomly selected physicians (n=952)		**Palliative care physicians (n=122)**		**Members of the Association for Study of Pain (n=130)**	
	mean	**s.d.**	**mean**	**s.d.**	**mean**	**s.d.**
Try to estimate the proportion of patients who *expressed a wish*						
• to withhold treatment	2.7	2.4	3.7	2.9	2.0	2.4
• to withdraw treatment	1.5	1.7	1.8	1.7	0.8	1.2
Try to estimate the proportion of patients for whom you *decided*						
• to withhold treatment	5.6	3.2	6.0	3.6	4.4	3.5
• to withdraw treatment	3.0	2.5	3.3	2.5	2.5	2.6

* Figures represent mean and standard deviation on an 11-point scale: 0 = 'none'; ... 10 = 'all'.

Professional guidelines in Sweden and in Europe recommend that physicians should inform patients about their diagnosis, prognosis and treatment options.[23,24] However, as indicated above, less than 50% of competent patients were informed of the DNR decision, despite the fact that they were able to communicate and competent enough to understand. In a study by Löfmark and Nilstun, 21 patients who were consecutively admitted to a department of internal medicine in a secondary hospital were interviewed.[25] The diagnoses were known and the patients were fully able to communicate. Only three were subject to a DNR decision, but all of them fulfilled the criteria of serious illness, as indicated by an instrument called 'prognosis-after-resuscitation' (PAR).[26] An interview method similar to clinical conversation – first perception of the situation, and then thoughts about the diagnosis, the prognosis and possible methods of treatments – was used in order to adhere to clinical praxis. Following the structure of this method proved to be very successful. Within twenty minutes of conversation most patients seemed to be ready to talk about the fundamental questions of life and death. It was quite easy to get an idea of both the patient's values and his understanding of medical issues. For example, the patients' knowledge about cardio-pulmonary-resuscitation was very poor. When asked at the end of the interview, none of the patients said that they were troubled by the conversation itself, and many patients approved. They also emphasized that it is the doctors' duty to give such information to their patients. Most of the patients welcomed the participation of a relative and a nurse, but a few did not.

Decision making

In Sweden, the official policy is that life-prolonging treatment should not be denied because of chronological age.[27] This policy is also emphasized in a recent official report on priority-setting in health care, which states that 'chronological age-limits, ..., should not be applied in medical decision making'.[28] With regard to the attitudes of health care professionals, surveys which have been carried out show somewhat conflicting results. In a study by Melltorp and Nilstun, one set of questions referred explicitly to chronological age.[29] As an introduction to the questions, two vignettes were presented. The first described a man who was 75 years old, and the other a man who was 25 years old. Both men had diabetes, were blind and had previously attempted suicide. Due to cerebral stroke they were at present in coma and in need of mechanical ventilation. For both patients the prognosis was very poor. In each question the respondents were asked first about withholding, and then about withdrawing life-sustaining treatment. The answers indicate that the use of chronological age in end-of-life decisions is very controversial (see Table 4).

Sjökvist, Berggren, Svantesson and Nilstun found similar results in their study.[30] The answers from the general public, nurses and physicians in this nation wide study also indicate that age as a determinant of life-support is very controversial. Approximately 50% of respondents in the three groups answered that age should influence the decision on whether or not to withhold ventilator treatment in an ICU.

Table 4. The relevance of chronological age for decisions concerning forgoing life-sustaining treatment according to health care professionals (n=114).

	Age per se is *de facto* considered relevant in the ICU		Whether the patient is 25 or 75 influences own judgement	
	withhold	withdraw	withhold	withdraw
	n	n	n	n
Yes, certainly	25	15	13	10
Yes, probably	53	51	37	39
Feel very uncertain	8	9	16	15
No, probably not	19	28	26	27
No, certainly not	8	9	21	22
Missing data	1	2	1	1

In a questionnaire survey of physicians (n=352) and nurses (n=498) in 12 ICUS, carried out by Sjökvist, Berggren and Cook, the respondents were asked to rate the importance of the patient's age in the decision to withdraw life-support.[31] On a scale from 7 (extremely important) to 1 (completely irrelevant), physicians as well as nurses indicated that the patient's age was important (4.9 and 5.2, respectively).

The Swedish Priority Commission categorically prohibits the use of chronological age as a criterion for denial of medical care.[32] Nevertheless, a little over 40% of the health care professionals participating in the study by Melltorp and Nilstun were inclined to accept chronological age *per se* as a criterion when decisions to forgo life-sustaining treatment are to be made.[29] The majority were of the opinion that chronological age as a matter of fact is used as a criterion. In the study by Sjökvist et al. the percentage of physicians and nurses who accepted the use of age as a criterion was even higher.[31]

There is reason for concern about this discrepancy. When chronological age as a criterion is denied in official documents but used by many health care professionals, there is an overwhelming risk of double standards of morality. If the arguments against all forms of age-based rationing are convincing, attitudes ought to be influenced and changed. If not, the exceptions should be clearly identified and regulations sanctioning such cases should be stipulated in official documents.

In the study by Valverius, Nilstun and Nilsson, the participating physicians were also asked about their actions with regard to withholding and withdrawing possible life-prolonging treatment.[22] The physicians decided to forgo such treatment more often than twas requested by the patients, implying that such decisions are often taken without prior consultation with the patient. Decisions to withdraw treatment were less common than decisions to withhold treatment (see Table 3).

The Swedish official guidelines acknowledge that the family should always be informed about the diagnosis and the treatment options in the case of an unconscious or in other ways incompetent patient. However, the guidelines also emphasize that it is the physicians who should decide about the withdrawal or withholding of life-support.[33]

One purpose of the study by Sjökvist, Nilstun, Svantesson and Berggren, was to investigate whether the official guidelines have the support of the general public and ICU professionals in Sweden.[21] In the questionnaire the following scenario was presented: 'A 60 year-old married woman had a serious accident in which she received injuries to her head. One month later she is still unconscious and needs the assistance of a ventilator to breathe. The woman will die within 24 hours if the ventilator is withdrawn. The physician is completely convinced that she will not regain consciousness, but she might live for a short time if the ventilator is kept in place. The physician is considering withdrawal of the treatment and allowing her to die.' The respondents were told that the physician had raised the subject of ventilator treatment in a discussion with the family. The respondents were then asked: 'Who do you believe should decide whether or not the ventilator treatment should be continued?' Of the physicians, 61% answered that they alone should make the decision, a view held by only 5% of the public and 20% of the nurses. None of the physicians thought that the family alone should make the decision, compared to 19% of the public and 6% of the nurses (see Table 5).

Table 5. Opinions on decision making concerning the continuation of ventilator treatment.

	Public n=763	**Nurses n=291**	**Physicians n=107**
Assuming that the physician has raised the question of ventilator treatment for discussion with the family, who do you believe should decide whether or not the ventilator treatment should be continued?			
	%	%	%
Family only	19	6	0
Physician only	5	20	61
Family and physician together	73	70	36
Uncertain	3	4	4

These answers show that the public and the physicians disagree as to their respective discretionary power, while the nurses hold a central position. Furthermore, twice as many members of the public and nurses, compared with physicians, preferred a joint decision made by the family and the physician (73%, 70% and 36%, respectively). In the questionnaire, the respondents were, as one alternative, told that a year ago this patient had said that she did not want to be put on a ventilator if she became hopelessly ill. They were then asked whether they thought that the ventilator treatment should be continued. Over 90% of the ICU professionals and over 80% of the Swedish general public thought that ventilator treatment should be withdrawn in this situation.[30]

Documentation of decisions

According to the Swedish Medical Record Act of 1986, medical records should contain information about all the planned and implemented interventions essential to the

care of a patient and about the reasons for all major interventions.[34] All decisions to withhold or withdraw life-prolonging treatment should therefore be documented. Melltorp and Nilstun found that in 6% of medical records from the ICU in Malmö, Sweden, there were notes indicating that decisions to withhold or withdraw life-prolonging treatment had been made.[35] The decisions were often recorded in rather vague ways. The most frequently made and documented decisions were those to withhold resuscitation and to withhold mechanical ventilation. This is not surprising, since such treatment, to be successful, must be initiated immediately if a patient has a cardiac or respiratory arrest. The reasons given for not providing life-prolonging treatment were related to both to quantitative questions (how long will the patient live with or without treatment?) and to qualitative questions (what is the patient's quality of life?). The expression 'futile care' is often applied to such reasons.

The purpose of another study by Nilstun and Löfmark was to investigate whether DNR decisions were documented with symbols or other 'secret' signs in the patient records.[36] Almost 50% of the respondents (physicians and nurses) stated that symbols were used, for instance a zero (with or without a cross), a sad face, a cross, a dot (often green) or a combination of letters or numbers which were difficult, if not impossible, for outsiders to understand. One third of the physicians and one fourth of the nurses defended this practice, but more than one third of the respondents stated that they were uncertain about it.

Sjökvist, Sundin and Berggren describe various experiences with a special protocol for documenting decisions to limit life-support in an ICU.[37] The results of their one-year prospective study showed that decisions to limit life-support were documented in this protocol for 61/1008 (6%) of the patients and for 39/79 (49%) of all patients who died in the ICU. Of the 61 patients with a special protocol, seven survived for more than three months. The decision was altered for five patients in favour of additional limitations and for four patients in favour of fewer or no limitations. Local protocols of this type make it easier to implement the decision made, to improve the care provided and to initiate the palliative phase of intensive care.

Important research questions

During the 1990s, an increasing number of studies on medical ethics have used the methods of epidemiology and ethnology to collect and analyze empirical data on attitudes and practices. One rationale for carrying out such studies is that they can 'identify issues that actually arise and processes actually used for dealing with them, and thereby suggesting where normative analysis is most needed'.[38] However, the authors of articles on these studies do not limit themselves to suggesting issues for normative analysis. They also use their results to support recommendations. For instance, both Waller[39] and Kenis[40] assume that the fact that surveys indicate that the majority of the general public are in favour of euthanasia is a good reason to legalize such acts.

However, to progress from facts to recommendations may be problematic, and the second part of this chapter will deal with the need for further research related to the methodological issues involved. First, the authors argue that recommendations do not

follow from facts alone, but require value premises. Secondly, two different ways to choose such value premises are discussed; they may be based on preferences, or reflect more basic values underlying such preferences. To avoid misunderstanding, it is emphasized that this tendency to formulate or imply recommendations based on empirical results, is a general problem. It applies to most of the Swedish studies on forgoing life-prolonging treatment – as should be clear from the summaries above.

The 'is-ought' problem

How are facts related to recommendations, that is, how is 'what is the case' related to 'what ought to be the case'? The standard interpretation of the Scottish philosopher David Hume (1711-1776) is that no set of non-moral premises (that is, premises that contain only descriptive terms) can entail a moral conclusion.[41,42] The move from 'is' to 'ought' is often covered by an appeal to the supposed authority of our ideas, for instance, about what we need.[43] But words, such as 'need', combine a certain natural description with a certain moral evaluation. The implication of the moral evaluation is a value premise to the effect that needs *ought* to be satisfied. Arguments of this sort are often made plausible by such ambiguous words.

Precise formal statement often helps in the detection of incomplete arguments. When reasoning is stated formally it becomes evident that value premises (that is, conceptions of what is right or wrong, good or bad, just or unjust) are required. [44] Only in combination with acceptable value premises can results from empirical studies on attitudes and practices regarding end-of-life decisions support normative conclusions. If this approach is made explicit, the normative conclusions (drawn or suggested) may be rationally discussed, not only by questioning some scientific aspect of the study,[45] but also by critically assessing the value premises used or presupposed[5] and the logic of the argument.[46]

Value premises based on preferences or underlying values

It is relatively easy to collect and analyze data on preferences to find out whether a majority of people in the community agree on a particular issue. Furthermore, the respondents' answers, in combination with value premises based on such preferences, indicate possible health care policies, and may sometimes be translated directly into such policies. However, there are also some troublesome disadvantages, the most important of which is that the preferences expressed by the respondents are based on both values and beliefs, and people sometimes believe what is not true. To exclude answers based on such false beliefs, it would be necessary to ascertain which respondents are reasonably well informed, for instance, about the consequences of providing life-prolonging treatment, compared to withholding or withdrawing such treatment. To avoid this problem, one may try to identify the underlying values. However, as has been pointed out by Ubel, this is also problematic because values expressed by the respondents may be subconsciously influenced by factors that cannot be discovered by common survey methods. [47] Thus, the respondents may understand the questions, and answer honestly, but still not express their values.

One way to reveal such factors is, according to Ubel, to use experimental survey designs. The descriptions of clinical situations (or abstract categories and principles) are 'manipulated' so that different respondents receive different descriptions. For instance, in a vignette the patient may be 40 years old for one group of respondents, and 80 years old for another. Through such methods, it is possible to see how the values people express are influenced by different descriptions.

Using questionnaires to collect different types of data has been the dominant empirical method in studies on end-of-life decision making. In contrast to such methods, Singer, Martin and Kelner have performed in-depth, open-ended, face-to-face interviews to identify and describe elements of quality end-of-life care from the patient's perspective.[48] They maintain that such methods are needed to complement the more traditional survey methods. The authors agree, but also believe that such interviews can lead to a better understanding of the underlying values influencing decisions to forgo life-prolonging treatment.

Concluding remark

Value premises, in combination with results from surveys, may be used to justify normative conclusions. However, preferences alone do not provide an adequate basis for such premises. They ought, as far as possible, to reflect the values underlying these preferences. The ideal is a set of value premises that are intellectually and emotionally satisfying to the persons involved or affected.[49] This requires 'stability against correct information, old and new, and stability against emotional adjustment'.[50] An important task is to develop better methods to identify such values. Different types of questionnaires, interviews and experimental studies are useful tools, but adequate formulation of the value premises also requires philosophical analysis.

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Qualitative Research on End-of-Life Care: Unrealized Potential

Abstract

Care for dying patients falls distressingly short of what people need and expect. According to patients, the most pressing issues in end-of-life care are adequate pain and symptom control, appropriate use of life sustaining treatments, and support of patients and families. These three foci are the 'basic science' of end-of-life care. The subjective experiences of patients and their families, and the organizations and culture that provide end-of-life care, are complex social phenomena that are best examined using the approaches and methods of qualitative research.

However, general medicine journals, the main vehicles for communication between researchers and health care providers, seem to undervalue the potential contributions of qualitative research. This underrepresentation is at least partly because reviewers used by general medicine journals often hold misconceptions about the purpose, methods and assumptions of qualitative research that almost always result in papers, even good ones, being rejected for publication.

In this paper a very brief overview will be provided of qualitative research methods, illustrations from our own research of misconceptions held by general medicine journal reviewers about qualitative research, and describe how empirical research using qualitative methods can contribute to improving end-of-life care.

Care for dying patients falls distressingly short of what people need and expect,[1-6] and improving the quality of care delivered at the end of life is one of the principal obligations of 21st century medicine. As research agendas are forged to improve care for the dying,[7] we are confronted with two important questions: What do we need to know? How do we acquire this knowledge?

According to patients, the most pressing issues in end-of-life care are adequate pain and symptom control, appropriate use of life sustaining treatments, and support of patients and families.[8-10] When formulating research that will help understand and improve the quality of end-of-life care, these three areas of investigation, which have the experiences of patients at their core, are obvious foci with which to begin. The patient's experience of pain and other symptoms, decision-making regarding life-sustaining treatments, and the experiences of patients and families are the 'basic science' of end-of-life care. Additional research priorities include the organization and culture of end-of-life care delivery. These foci, the subjective experiences of patients and their families, and the organizations and culture that provide end-of-life care, are complex

social phenomena. What is the best way to explore and understand organizations, cultures and experiences?

It has long been recognized in the social sciences, such as sociology and anthropology, that these issues are best examined using the approaches and methods of qualitative research. This is increasingly being appreciated by investigators in health care[11-13] and health services[14] research. However, despite these advances, general medicine journals, the main vehicles for communication between researchers and health care providers, seem to undervalue the potential contributions of qualitative research. General medicine journals, some of which allow considerable space for end-of-life issues, predominantly contain research reports from scientists who employ the methods of quantitative research (for instance, epidemiology and clinical trials). In other words, there is silence where there should be a rich discussion of the issues (that is, the 'basic science') crucial to improving the quality of care provided for the dying.

The purpose of this paper is to examine the potential usefulness of qualitative research on end-of-life care and demonstrate that this potential has not been fulfilled. We hope this paper will sensitize researchers, editors and reviewers to the potential contributions of qualitative research to improving end-of-life care. In the spirit of constructive criticism, we will provide what might be termed 'audit and feedback' regarding qualitative research in end-of-life issues. The paper is organized into four sections. First, we will provide evidence that qualitative research is underrepresented in general medicine publications of empirical research in end-of-life care. Second, we will provide a very brief overview of qualitative research methods. Third, we will provide some illustrations from our own research of misconceptions held by general medicine journal reviewers about qualitative research that lead to these manuscripts being rejected. Fourth, we will describe how empirical research using qualitative methods can contribute to improving end-of-life care.

Qualitative research is underrepresented in publications of empirical research on end-of-life issues

Table 1 shows the results of a MEDLINE search of articles describing original empirical research in the area of end-of-life care by journal. The study involved an English-only keyword search using 'end-of-life', 'palliative care', and 'euthanasia', between January 1999 and July 2000. Excluded from this study were commentaries, research review articles, book reviews, and letters to the editor. The journals were selected to represent different journal types. In the study period, the six general medicine journals published 23 articles of empirical research on end-of-life care, of which only three used qualitative methods. These journals published many more articles on end-of-life issues, but these were mostly commentaries.

We also examined the two most influential science journals, a journal that specializes in end-of-life care, and a journal that specializes in social science research in health care. The two science journals published no empirical research on end-of-life care. The end-of-life specialty journal published ten empirical studies of end-of-life issues, none using qualitative methods. By contrast, the social science journal, which

Table 1. Empirical research in end-of-life articles by journal (January 1999 – July 2000).

Journal	No of articles: empirical research in end-of-life issues	No of articles: empirical research using qualitative methods in end-of-life issues
General medicine journals		
New England Journal of Medicine	2	0
Lancet	2	0
JAMA	10	1
Annals of Internal Medicine	1	0
British Medical Journal	6	1
Canadian Medical Association Journal	2	1
Science journals		
Science	0	0
Nature	0	0
End-of-life journal		
Journal of Palliative Care	10	0
Social science journal		
Social Science & Medicine	6	4

specializes is multi-method research, published six empirical studies on end-of-life, four using qualitative methods. These findings suggest that few empirical studies on end-of-life are published given the size of the problem and the overwhelming evidence that the quality of end-of-life care needs improvement.

Before we discuss why we think qualitative research in end-of-life issues is underrepresented in general medicine journals, we will provide a brief overview of qualitative approaches and methods.

Overview of qualitative research methods

Qualitative research is an interdisciplinary, interpretive field of inquiry. It has existed for as long as people have asked questions about social phenomena. Modern qualitative research consists of analytic procedures that facilitate the interpretation of data collected using a variety of techniques including field observations, personal interviews, focus groups, case studies, document analysis and other sources that describe routine and problematic moments in organizations and individual lives. The goal of qualitative research is to understand the meaning of social phenomena in their natural settings, particularly for the people and organizations involved. Qualitative research methods may be used to develop basic descriptive knowledge, evaluate programs and develop theory. The resulting knowledge can be used to guide the interpretation of quantitative findings, develop research instruments (for instance, surveys), guide practice and research, and influence policy.

Qualitative research methods are often contrasted with quantitative research methods which seek to quantify, or count, phenomena under various conditions, and test defined

hypotheses about causality or relatedness, based on numerical data. Quantitative research strives for generalizability and controls intervening or confounding variables using sampling and statistical methods. Qualitative research seeks to understand the particular characteristics of the phenomena under study and admits the influence of all intervening variables as data to be described and analyzed. Qualitative researchers accept that research interventions, including researchers themselves, may influence the phenomenon under study, and try to be honest and transparent about personal biases that inevitably shape research interests, questions, data collection, analysis, interpretation, writing and the dissemination of results. In recent years, qualitative researchers holding a post-modern conceptual framework contend that both the investigator and research participant hold perspectives that are filtered by language, profession, gender, class, and ethnicity, that participants are often unable to fully explain what they think or feel, and that investigators can never fully understand the people and phenomena they study. Consequently, these researchers do not feel a need to impersonate the aloof, objective 'other', but can freely include emotion, multi-voiced text, and responsibility, often with political overtones, in their arsenal of interpretive and expressive tools.

A fundamental tenet of research is that the purpose of the research will influence the approach and shape the research question, and it should be the research question that determines the appropriate research method.[15] This facilitates innovation because all questions are in play rather than forcing investigators to choose from a limit range of questions predetermined by their limited knowledge of only a few methods (for instance, clinical epidemiology, randomized controlled trials). For example, Table 2 shows four research questions about the same issue: two amenable to a quantitative study and two amenable to a qualitative study.

Table 2. Quantitative and qualitative research questions.

Quantitative research question	Qualitative research question
How many dialysis patients think completing an advance directive is a good idea?	Why do so many dialysis patients think that advance directives are good thing, but so few actually complete one?
How many dialysis patents have completed an advance directive?	What is the role of an advance directive in people's advance care planning?

Table 3. Research questions, research strategies and data sources.

Research question	Research strategy	Data sources
What does it mean? Why is it meaningful?	Phenomenology[28,29]	Interviews, written anecdotes
What is it (system, institution) like? What are they (people, group) like?	Ethnography[30,31]	Interviews, observations
What is happening? How/why is it happening?	Grounded theory[32,33]	Interviews, observations, document analysis
How do they communicate? What are they communicating?	Discourse analysis[34,35]	Interviews, dialogues, document analysis

Qualitative research consists of a wide range of heterogeneous methods and approaches. Table 3 provides examples of four types of research questions and relevant qualitative methods. Since a characteristic of good research is the appropriateness of the method, investigators that can use both quantitative and qualitative research methods, sometimes in combination, will be able to explore many important questions that are not amenable to single-method investigators. Later in this paper we will describe a few of these different qualitative research methods and their contributions to end-of-life care.

In the next section we will discuss misconceptions held by general medicine journal reviewers that will relate to aspects of this overview of qualitative methods.

Qualitative research is often misunderstood by journal reviewers

Why are qualitative studies in end-of-life care underrepresented in general medicine journals? One reason may be that some qualitative studies and corresponding manuscripts are inferior in quality. We believe, however, that another reason is that reviewers used by general medicine journals are biased against qualitative studies because they often hold misconceptions about the purpose, methods and assumptions of qualitative research. This is not surprising given that most physicians, who serve as reviewers for these journals, are trained exclusively in quantitative research methods. These misconceptions on the part of general medicine journal reviewers almost always result in papers, even good ones, being rejected for publication. In this section, we have reproduced some actual comments from general medicine journal reviewers that illustrate these misconceptions. These reviews pertained to five papers reporting qualitative studies on end-of-life care that were rejected by at least one general medicine journal, three of which have been published in other general medicine or specialty journals, two are being reviewed elsewhere.

Each of the reviewers' statements included in this section was received in response to a submission of a manuscript to a general medicine journal, illustrates an important misconception about qualitative research, and formed part of the grounds for the paper being rejected by the journal. The reviews are organized by methodological category and accompanied by a brief rebuttal.

Sampling

> (1) *Two other problems have to do with failure to provide demographic data of the non-participants in order to determine the representativeness of the participant study sample.*

Sampling strategies in qualitative research generally reflect the fact that the phenomenon under investigation is not known or understood clearly in advance. Sampling strategies purposefully target individuals or circumstances that are thought to be most likely to illuminate these phenomena. Qualitative researchers do not attempt, or claim, to produce findings that are generalizable to populations. Their interest is in the experiences of the particular people involved. Review (1) implies that the participants of this study have nothing of interest to contribute to our understanding of end-of-life

issues. A basic assumption of qualitative methods is that the perceptions and experiences of each individual are important and should be, at least, recognized.

> (2) *Also no correlations were attempted involving participant characteristics and outcome measures.*

Review (2) raises the question: how would a researcher know what characteristics to correlate? Without a conceptual framework, grounded in a more detailed knowledge of the phenomenon under study, statistical correlations based on the standard battery of demographics are often fishing expeditions. Moreover, the outcome of this study was a description of the perspectives and experiences of the participants. What 'outcome measures' should be singled out for correlation?

> (3) *The study group was confined to patients with esophageal cancer. My guess is that a significant percentage of younger women with breast cancer would insist on more information and more control over treatment decisions. The authors should discuss this possibility.*

Perhaps patients with esophageal cancer would have perspectives that are different than patients with breast cancer, but the former were being studied. To describe the perspective of breast cancer patients, one would need to ask them in another study. The reviewers' comments suggest an unrealistic expectation about the generalizability of qualitative research findings.

> (4) *The study group focused on a relatively uncommon devastating malignancy with a poor prognosis requiring major life-threatening surgery. The informed consent process might be quite different for cosmetic surgery, low risk function restoration surgery, et cetera. The authors should speculate in the discussion about the applicability of their findings to these other conditions.*

The purpose of the study in question was to describe the perspectives of a particular group of patients. To discuss the applicability of this description to patients with other conditions would indeed be speculation (that is, guesswork, not research).

> (5) *Generalizability – this paper seems to describe in-depth interviews with 32 people. What can be meaningfully said based on the comments of 32 people? For most researchers 32 is a pilot study that is then pursued in a larger study.*

Whereas comments (3) and (4) posed questions about the generalizability of the findings across different research contexts, or under significantly different circumstances, comment (5) poses a more fundamental challenge about epistemology and evidence, namely whether it is even possible to gain knowledge about a phenomenon of interest based on a limited number of cases. Since the journals that rejected the manuscript each present case studies on individual patients as part of their regular content, this question is particularly salient. Although the epistemological foundations of qualitative research are beyond the scope of this chapter, where qualitative research elucidates aspects of phenomena that are recognizable and reconcilable with the experience of those involved, it is as valid a source of knowledge as any other.[16] This reviewer would have been accurate in writing, 'For most quantitative researchers 32 is a pilot study.'

Analysis and interpretation of data

> (6) *One observation is novel and perhaps important: 'Of the 10 participants who discussed advance care planning with others and received a negative response, none completed an AD form.' This simple observation on a small number of subjects is provocative and well worthy of a prospective trial.*

Because this reviewer is focused primarily on the generalizability of the findings, she has failed to recognize that the finding in question, which was not described in any previous literature, already provides reasonable grounds for physicians to attend to this particular aspect of advance care planning in practice. The key message here is that this particular feature of the phenomenon does happen, and may happen to readers' patients.

> (7) *A lot of anecdotal data are presented, but it is hard to identify trends clearly. The researchers did not explore other significant variables that would affect planning, such as religion.*

Qualitative research findings are often labeled 'anecdotal'. However, qualitative data are collected and analyzed systematically, that is, the opposite of anecdotally. In addition, it is often difficult for qualitative researchers to distill extensive amounts of textual data and analysis into the very limited space and format provided in general medical journals. This is another systematic bias against qualitative research that, to be fair, is beyond the control of reviewers.

Writing and presentation

> (8) *The six elements of the study explored would be better presented without the verbatim quotes.*

> (9) *I am uncertain whether this paper is appropriate for* [journal name]. *If so deemed, I would recommend that it be rewritten as a letter to the editor (with all the quotations omitted and with sufficient space dedicated to the study's limitations).*

The verbatim quotes are data selected to perform two important functions. First, they reveal the genuine voice of the participants, which is a key strength of qualitative methods. Second, they provide evidence that the analytic interpretations were not merely fabricated, but reasonably reflect the data on which they were based.

General comments

> (10) *The authors have tackled a very difficult area to study and are to be commended; however, I believe this article would have more impact if published in a journal that includes more quasi-experimental/qualitative research. Biases apparent in this article make it unsuitable, in my opinion, for publication in* [journal name].

This reviewer has perfectly underscored the focus of this section. She is not convinced that qualitative studies can produce knowledge that would be of interest to

physicians who are the principal readers of a general medicine journal, yet she has failed to offer appropriate and meaningful criticisms of the qualitative methods themselves. The reviewer's judgement is unrelated to the appropriateness of the method to the question, rigor of the actual investigation, or quality of the manuscript. We believe it is based on fundamental misconceptions about the purpose and methods of qualitative research.

Contributions of qualitative research on end-of-life issues

Qualitative research can contribute to our understanding of end-of-life issues and to improvement of care for the dying. As mentioned above, some of the fundamental issues in end-of-life care involve complex social phenomena that are best explored using qualitative research methods. Moreover, different qualitative methods or approaches can contribute different types of knowledge pertaining to end-of-life issues. At the University of Toronto Joint Center for Bioethics we have a strong emphasis on qualitative methods in end-of-life research. In this section we will use examples from our own work to illustrate four qualitative research methods and a specific contribution each has made to understanding and improving end-of-life care. There are, in addition, other fine examples of qualitative research on end-of-life issues in the research literature.

Content analysis

Content analysis is a quasi-qualitative method whereby text is coded and then reduced to a unit-by-variable matrix that may be quantified. It assumes that the meaning people assign to words or experiences are common sense, or taken for granted. The limitation to content analysis is that meaning is not always so transparent or simple. Singer, Martin and Kelner developed a taxonomy of quality end-of-life care using a modified content analysis of interviews with three groups of people: dialysis patients, people with HIV, and residents of a long-term care facility.[8] This study was the first to describe quality end-of-life care from the perspective of patients. The taxonomy of end-of-life care from the patient's perspective highlights the needs of dying patients and so can shape the care that should be provided.

Ethnography

Ethnography 'combines research design, fieldwork, and various methods of inquiry to produce historically, politically, and personally situated accounts, descriptions, interpretations, and representations of human lives', and can help researchers to better understand the beliefs, motivations, and behaviors of participants or groups of participants.[17] Ethnography is often used in cultural studies. Bowman used ethnography to develop a description of Chinese-Canadian seniors' perceptions of end-of-life issues.[18] These perceptions had not previously been described in detail. Although there is tremendous diversity in any cultural or religious group, Bowman's findings

provide assistance to health care providers and policy makers to better understand the cultural perspectives of some Chinese patients.

Grounded theory

Grounded theory is 'a general methodology for developing theory from data that are systematically gathered and analyzed' and is appropriate for exploring phenomena that are conceptually dense and involve social processes.[19,20] It is particularly useful for developing a theory or a conceptual framework in contexts where none exists, or where the existing frameworks appear flawed. Singer, Martin, and others, have used grounded theory to develop a new conceptual model of advance care planning from the perspectives of dialysis patients[21] and people with HIV.[22] Before this work, the prevailing conceptual framework for advance care planning was based on the perspectives of 'experts', and all advance care planning intervention studies based on the expert-derived framework had failed to achieve their desired outcomes. The new model of advance care planning is grounded in the experiences of patients and, therefore, is more suitable for framing research interventions and guiding education and practice.

Phenomenology

Phenomenology is a qualitative method based in phenomenological philosophy that helps to develop a description of 'what it feels like to...'.[23,24] Phenomenology as a research method helps investigators understand the experience and perspective of individuals, particularly within the context under study. Workman used phenomenology to describe the problems and conflicts related to 'futile' treatment in the Intensive Care Unit (ICU) from the perspective of twelve ICU nurses and physicians.[25] This study provided a forum for the voices of ICU providers who anguish over conflicts regarding treatment decisions. It provides policy and practice recommendations that seek to prevent and lessen the conflict that creates so much moral anguish among providers, patients and families.

There are also other qualitative methods that may make a useful contribution to the end-of-life literature but which, to our knowledge, have not yet done so. Two such methods are case study and participatory action research. A *case study* is 'an empirical inquiry that investigates a contemporary phenomenon within its real-life context, especially when the boundaries between phenomenon and context are not clearly evident'.[26] The focus of case study research is the system or institution that serves as the context for the phenomenon under study. *Participatory action research* is a method for the study of practice, language and organization with a commitment to action that reforms or improves.[27] It has its philosophical roots in theories associated with liberation theology and human rights activism which are oriented toward social, economic and political development to improve the lives of vulnerable people. It has also been used to improve a variety of systems and institutions such as classrooms and schools, community groups, corporations, and industries.

Conclusion

Qualitative research can make significant contributions to understanding and improving end-of-life care. At the center of end-of-life care are the experiences of patients and their families. Other core issues include the organization and culture of end-of-life care delivery. Qualitative research methods are well suited to provide insight into these fundamental issues, the 'basic science' of end-of-life care. Lamentably, qualitative research in end-of-life is underrepresented in general medicine journals, at least partly because of bias among its reviewers who hold misconceptions about the approaches and methods of qualitative research.

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Part II Administration of Potentially Life-Shortening Drugs

Ezekiel J. Emanuel

Euthanasia and Physician-Assisted Suicide in the United States at the Turn of the 21st Century

Abstract

For more than a decade, the ethics and legality of euthanasia and physician-assisted suicide have been actively debated in the United States. This debate has fairly clearly settled the legal questions and added significant empirical data to inform the debate. This chapter gives a review of both the legal decisions and legislative initiatives regarding euthanasia and physician-assisted suicide and the many empirical studies of the American public, physicians, and patients related to their attitudes and experiences regarding euthanasia and physician-assisted suicide.

In 1997, the United States Supreme Court definitively ruled 9-0 that there is no constitutional right to either euthanasia or physician-assisted suicide. But it also made clear that there is no constitutional barrier for states to legalize euthanasia or physician-assisted suicide. Only Oregon has legalized physician-assisted suicide; many other states have passed laws to ensure euthanasia and physician-assisted suicide are illegal. The most recent referendum, in 1998 in Michigan, voted overwhelmingly to oppose legalizing physician-assisted suicide. Data on the public's attitudes shows that support for euthanasia and/or physician-assisted suicide is variable with a majority supporting these interventions for patients in extreme pain but not for other reasons. The elderly, African-Americans, Catholics, and religious individuals are much more likely to oppose euthanasia and physician-assisted suicide. Most surveys of physicians show a majority oppose euthanasia or physician-assisted suicide, with considerable variation among specialties. Support for these interventions among physicians appears to have declined in recent years. About a quarter of physicians, and as many as half of oncologists, have received requests for euthanasia or physician-assisted suicide, but a small minority, less than 10% of all physicians and fewer than 20% of oncologists, have performed euthanasia or physician-assisted suicide. And the physicians who have performed these interventions do them very rarely: most only once in a career. Data from cancer, HIV/AIDS, amyotrophic lateral sclerosis (ALS), and terminally ill patients suggest that depression, hopelessness, and psychological distress are the primary factors associated with personal interest in euthanasia or physician-assisted suicide. Pain, which is the reason most Americans find euthanasia and physician-assisted suicide acceptable—does not appear to be a main motivating factor behind patients' personal desire for euthanasia or physician-assisted sui-

cide. It appears that considerably less than 1% of all Americans die from euthanasia or physician-assisted suicide.

Over the last decade the legality of euthanasia and physician-assisted suicide in the United States has been resolved. Empirical research has contributed significantly to our understanding of the attitudes and practices regarding euthanasia and physician-assisted suicide, especially the depth of public support, the factors associated with patient interest, and physician practices regarding euthanasia and physician-assisted suicide. However, several important questions remain unanswered.

Euthanasia and physician-assisted suicide burst onto the United States public arena in 1988 with publication of 'It's over, Debbie' in JAMA.[1] This article stirred a debate with many people criticizing the anonymous case.[2,3] The sentiment became more favorable toward euthanasia and physician-assisted suicide with publication of Timothy Quill's article on his patient Diane.[4] Since that time there have been numerous papers debating the ethics and legality of these interventions as well as empirical studies examining the practices.[5] In the past decade we have gained significant understanding about attitudes towards euthanasia and physician-assisted suicide in the United States as well as the practices themselves. This review of the current level of understanding about euthanasia and physician-assisted suicide in the United States will be divided into 5 parts: (1) review of the current legal circumstances; (2) review of the public's attitudes; (3) review of physicians' attitudes; (4) review of physicians' practices and experiences; and (5) review of patients' attitudes and experiences. It will conclude with a summary of the most important questions that need further empirical inquiry.

Legal status of euthanasia and physician-assisted suicide in the United States

On June 26, 1997, the United States Supreme Court definitively ruled, 9-0, that there is no constitutional right to euthanasia or physician-assisted suicide.[6,7] While the written opinions are diverse, and some even consider them bizarre, and while many have tried to discern possibilities for endorsement of a right to euthanasia or physician-assisted suicide, this ruling seems quite definitive.[8,9] There does not seem a basis on which five justices would endorse a constitutional right to euthanasia or physician-assisted suicide. But the Supreme Court did rule that there is no constitutional prohibition to legalizing these interventions, thereby permitting the states, like Oregon, to enact statutes legalizing them.

A few weeks after the United States Supreme Court ruling, the Supreme Court of Florida, a state with a strong constitutional guarantee of privacy, also ruled that there is no state constitutional right to physician-assisted suicide.[10] Indeed, the trend in state legislatures has decidedly been against legalizing euthanasia and physician-assisted suicide. Since the early 1990s, seven state legislatures have voted explicitly to prohibit euthanasia and physician-assisted suicide.[11] In only one state has a bill to legalize euthanasia and/or physician-assisted suicide even been considered by a full chamber of a state legislature and the legislature defeated that bill 99 to 42.[12] Further, only one committee of one state legislative body has ever voted to endorse legalizing

euthanasia and/or physician-assisted suicide. In the one state that put legalization of euthanasia or physician-assisted suicide before the voters in a referendum in the last three years, the proposal was resoundingly defeated. In November 1998, 70% of Michigan voters opposed legalizing physician-assisted suicide.[13]

Thus, Oregon remains the only jurisdiction in the world in which physician-assisted suicide or euthanasia is legal. For reasons, that may become clear when we consider public attitudes toward euthanasia or physician-assisted suicide, it seems unlikely that any state legislature will endorse legalization in the near future. Indeed, it appears that interest in legalization has gone through a cycle and is currently on the decline with more attention focused on improving end-of-life care and many people recognizing that euthanasia and physician-assisted suicide cannot achieve this end since they influence the dying process of only a handful of decedents.

Table 1. Framing effects: variations in the public's attitudes toward euthanasia and physician-assisted suicide depending upon the questions asked.

Survey question	Year	Proportion of public supporting euthanasia or physician-assisted suicide (%)
When a person has a disease that cannot be cured, do you think doctors should be allowed to end the patient's life if the patient and his or her family request it?*	1950	34
	1982	61
	1991	63
	1998	59
A patient develops metastatic cancer, which invades the bones and and causes excruciating pain. Current levels of morphine, nerve blocks, and other treatments are failing to control the pain completely. In this case would it be alright, upon request from the patient, for the doctor to administer intravenous drugs, such as potassium, to intentionally end the patient's life?#	1993	65.6
As you may know, physician-assisted suicide involves a doctor giving a terminally ill patient the means to end his or her life. Do you think it should be legal for a doctor to help a terminally ill patient commit suicide?†	1997	45
If a person has a disease that will ultimately destroy their mind or body and they want to take their own life but cannot do it by themselves, should a doctor be allowed to administer lethal drugs to end the person's life?‡	1998	47
Sometimes, terminally ill patients want to die and ask a doctor to help them commit suicide. Should it be legal for doctors to give a lethal dose of drugs to terminally ill patients who ask for it?§	1999	54

* Reference 15 and Gallup Poll June 1998.
\# Reference 16.
† Princeton Survey Research Associated for Kaiser Family Foundation and Harvard University, November 5, 1997.
‡ CBS News Poll, November 23-24, 1998.
§ Rasmussen Research, March 30, 1999.

Attitudes of the American public towards euthanasia and physician-assisted suicide

There have been innumerable surveys of the American public on euthanasia and physician-assisted suicide.[14,15,16] Most surveys are a few questions added to other general surveys and do not probe very deeply; only a few have been in depth analyses. In general, three conclusions can be drawn from these data that both opponents and proponents of euthanasia or physician-assisted suicide endorse.

First, there are significant framing effects in the public's response to questions. Depending on how questions are worded and the types of choices offered, public support for euthanasia or physician-assisted suicide can vary quite widely from under 50% to nearly 70% (Table 1). However, very few surveys find public support in excess of 70% no matter how the questions are crafted. This leads to what might be called the 'Rule of Thirds.' Roughly, one third of Americans support euthanasia or physician-assisted suicide no matter what the circumstances. For instance, 29.3% of Americans support euthanasia or physician-assisted suicide for terminally ill patients who are not in pain but desire these interventions because they view life as meaningless. Similarly, 36.2% support euthanasia or physician-assisted suicide for terminally ill patients who give as their reason not wanting to be a burden on their family.[17] These are the roughly one third who support euthanasia or physician-assisted suicide almost no matter the reasons; their attitudes are not affected by the interventions or the circumstances.

Conversely, approximately one third of Americans oppose euthanasia or physician-assisted suicide no matter what the circumstances, even for terminally ill competent patients with unremitting pain. Almost all the surveys that report the highest levels of support for euthanasia or physician-assisted suicide utilize questions probing the use of such interventions for patients with extreme pain. For instance, 65.6% of the public supports euthanasia or physician-assisted suicide for patients who request these interventions because of extreme pain (Tables 1 and 2).[16] Similarly, among caregivers of terminally ill patients, 58.7% support euthanasia for a terminally ill cancer patient with unremitting pain.[17] These data mean that roughly one-third of Americans—the difference between 100% of the public and the 65% who support euthanasia for patients in pain—oppose euthanasia or physician-assisted suicide even for terminally ill patients who are experiencing unremitting pain despite optimal management.

The remaining one-third of Americans constitutes the volatile public. They support euthanasia or physician-assisted suicide in some circumstances, usually involving extreme pain, but oppose it in other circumstances, such as for reasons of indignity, or meaninglessness, or because the patient feels he is a burden (Table 2).

The framing effects and this 'Rule of Thirds' means that support for euthanasia or physician-assisted suicide is not as extensive as the reports that two-thirds of Americans support these interventions make it appear. Furthermore, for very few of these people, members of the Hemlock society and a few others, is legalizing euthanasia or physician-assisted suicide a leading issue, the primary issue that will determine their vote. In this sense, euthanasia and physician-assisted suicide are not

Table 2. Variations in the public's support for euthanasia and physician-assisted suicide by scenario and intervention.*

Scenario Terminally ill patient with:	Support for euthanasia (%) (%)	Support for physician-assisted suicide (%)
Unremitting pain despite narcotics, nerve blocks and other pain treatments.	65.6	66.5
Functional debility—no pain but cannot get out of bed or provide self-care.	49.2	48.1
Burden on family—has no pain but concerned about the burden that deterioration might place on the family.	36.2	36.2
View life as meaningless—has no pain but finds waiting for death meaningless and purposeless	29.3	32.8

* From reference 16.

like abortion is for the Christian right, the environment for environmentalists, or lower capital gains taxes for the rich: the issue that determines their vote. In other words, support for euthanasia and physician-assisted suicide is not a litmus test issue; it is not an issue many people will vote on alone. Politicians know that support for euthanasia or physician-assisted suicide is neither firm nor deep and hence are unwilling and unlikely to take chances in voting to legalize them. This is one reason state legislation legalizing euthanasia or physician-assisted suicide is unlikely.

Second, the American public does not distinguish between euthanasia and physician-assisted suicide. While medical ethicists, philosophers, lawyers, and others have spent much time debating whether euthanasia is fundamentally different from physician-assisted suicide and elucidating potential distinctions, the American public does not seem to make much of the distinction. Polls show that Americans support euthanasia at the same rate that they support physician-assisted suicide (Table 2). For instance, 65.6% of the public supports euthanasia for a terminally ill patient with unremitting pain while 66.5% support physician-assisted suicide in the same scenario; 29.3% support euthanasia because a terminally ill patient feels life is meaningless while 32.8% support physician-assisted suicide in the same circumstances.[16]

Third, there are certain socio-demographic characteristics associated with support and opposition to euthanasia or physician-assisted suicide. Consistently, people who are Catholics and those who report themselves to be more religious are significantly more opposed to euthanasia or physician-assisted suicide. Similarly, African-Americans

Table 3. Comparing attitudes of the american public and patients on euthanasia and physician-assisted suicide.*

Scenario	Public (%)	Terminally ill patients (%)	Caregivers of terminally ill patients (%)
When a person has a disease that cannot be cured, do you think doctors should be allowed to end the patient's life if the patient and his or her family request it?	63	60.2	NA
Unremitting pain despite narcotics, nerve blocks and other pain treatments.	65.6	54.8	58.7
Burden on family—has no pain but concerned about the burden that deterioration might place on the family.	36.2	32.7	29.1

* From references 16 and 17.

and older individuals are significantly more opposed to euthanasia or physician-assisted suicide (Figure 1). Finally, some, but not all, surveys suggest that women are significantly more opposed to euthanasia or physician-assisted suicide. Interestingly, patients with physician determined terminal illnesses, such as cancer and COPD, have attitudes that are almost identical with the public's (Table 3). In other words, having a serious, even life-threatening illness itself does not seem to affect attitudes toward the permissibility or opposition to euthanasia or physician-assisted suicide. Similarly, being a caregiver for a terminally ill patient or a recently bereaved caregiver does not seem to affect attitudes toward euthanasia or physician-assisted suicide (Table 3).

Attitudes of American physicians regarding euthanasia and physician-assisted suicide

Over the last decade, American physicians have been extensively surveyed about euthanasia and physician-assisted suicide.[18-37] Many of the surveys, especially the early ones, are methodologically problematic.[5] The surveyed cohorts are narrow or biased, the response rates are low, the questions are either poorly worded, conflating terminating medical treatments with euthanasia, emotionally laden, or biased, or the questions do not probe very deeply. In recent years, the surveys have solved most if not all of these problems and the data are more reliable. By critically examining the overall data, certain conclusions can be drawn about physicians' attitudes regarding euthanasia or physician-assisted suicide.

In all but a few of the surveys, only a minority of American physicians supports euthanasia or physician-assisted suicide.[18-37] In other words, most surveys find that the majority of American physicians oppose euthanasia or physician-assisted suicide. For instance, in a survey of Michigan physicians, Bachman and colleagues could

demonstrate a majority of physicians (56.6%) supporting physician-assisted suicide only when they were forced to choose either legalization or an explicit ban; without being forced into this choice only 38.9% supported permitting physician-assisted suicide.[29] In a survey of Oregon physicians, Lee and colleagues reported that 66% said that physician-assisted suicide would be ethical in some cases.[30] More typical are surveys that report a small proportion of physicians who support euthanasia or physician-assisted suicide.[20,27,34,36,37] For instance, among oncologists 45.5% supported physician-assisted suicide for a terminally ill cancer patient with unremitting pain while 22.7% supported euthanasia in the same situation.[16]

These data demonstrate another important factor: unlike the American public, American physicians do distinguish between euthanasia and physician-assisted suicide. They are much more likely to support providing physician-assisted suicide than providing euthanasia (Figure 2).[16,24,29,36,37] No study has found a majority of physicians supporting euthanasia. The only surveys getting close to support by a majority of American physicians ask about physician-assisted suicide. Thus, unlike the American public, support for euthanasia or physician-assisted suicide among American physicians crucially depends upon the intervention being asked about.[16]

There are important predictors of support for euthanasia or physician-assisted suicide. As with the American public, American physicians who are Catholic and religious are significantly less likely to support euthanasia or physician-assisted suicide.[16,24,27,29,34,37] Similarly, surveys have reported certain specialties as more supportive of euthanasia or physician-assisted suicide than others. Surgical oncologists support euthanasia or physician-assisted suicide more than medical oncologists.[37] Others have reported psychiatrists and obstetricians and gynecologists as more supportive of euthanasia or physician-assisted suicide with internists, especially oncologists, less supportive.[27,29,30,34] Still others have found family or general practitioners as more supportive than internists.

Finally, at least among American oncologists, there appears to be a significant decline in support for euthanasia or physician-assisted suicide between the early and late 1990s.[16,37] Between 1994 and 1998, support for both euthanasia and physician-assisted suicide in the scenario of a terminally ill cancer patient who had unremitting pain significantly declined among oncologists. Support declined by 50% for physician-assisted suicide and by 75% for euthanasia (Figure 1).[16,37]

Practices of American physicians regarding euthanasia and physician-assisted suicide

Many American physicians have reported receiving requests for euthanasia or physician-assisted suicide. The precise proportion of physicians who have received such requests is unclear, as there is significant variation in the reported frequencies (Table 4). For instance, Fried and colleagues (1993) reported that 18.9% of Rhode Island physicians received requests for physician-assisted suicide while 13.2% received requests for euthanasia.[24] Among Michigan oncologists, Doukas and colleagues (1995) reported that 38% received requests for physician-assisted suicide while 43%

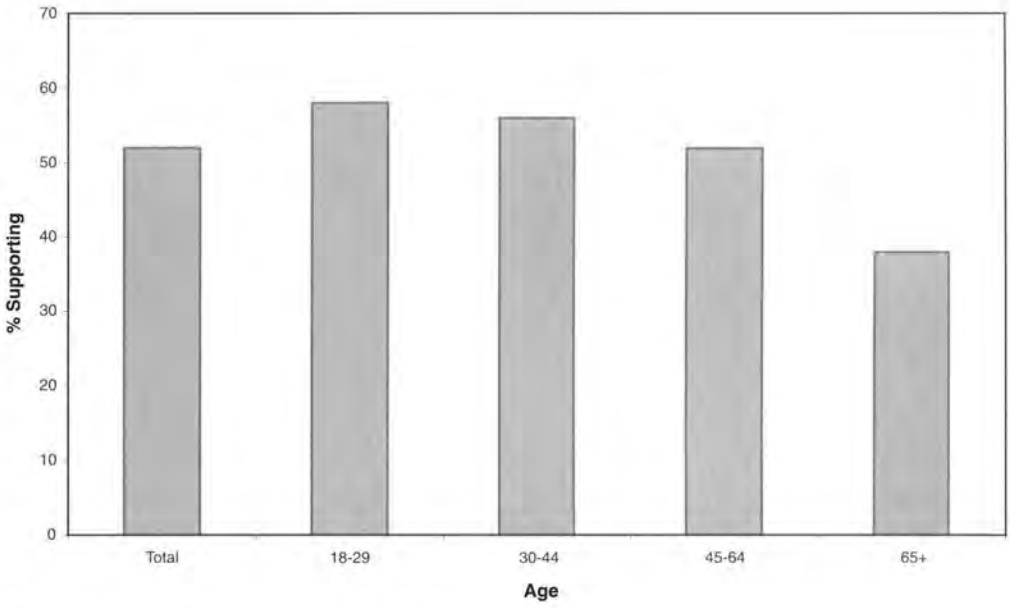

Figure 1. Support for euthanasia by Americans.

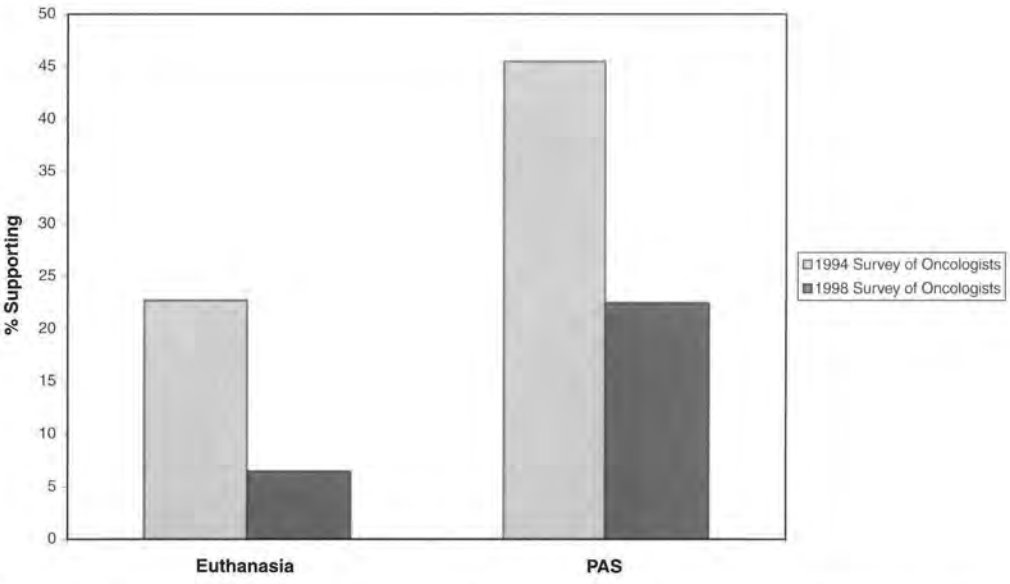

Figure 2. Decline in support for euthanasia and physician-assisted suicide among American physicians.

received requests for euthanasia.[28] Lee and colleagues (1996) reported that among Oregon physicians 21% have received requests for physician-assisted suicide.[30] Back and colleagues (1996) reported that 26% of Washington state physicians had been asked to hasten death, with 18% of oncologists having received requests for physician-assisted suicide and 9% having been asked for euthanasia within the previous year.[31] Emanuel and colleagues (1996) reported that among American oncologists 50.6% had received requests for physician-assisted suicide and 37.6% had received requests for euthanasia.[16] Meier and colleagues (1998) reported that 18.3% had reported receiving requests for physician-assisted suicide while 11.1% had received requests for euthanasia; in this survey 25% of oncologists received physician-assisted suicide requests with 13% receiving a request for euthanasia.[34] A survey of 3299 American oncologists by the American Society of Clinical Oncologists (ASCO) revealed that 38.2% had received requests for euthanasia and 56.2% had received requests for physician-assisted suicide.[37]

Table 4. Requests for euthanasia and physician-assisted suicide among American physicians.

Study	Publication date	Type of survey	Response rate (%)	Types of physicians surveyed (n)	Euthanasia (%)	Physician-assisted suicide (%)
Fried et al.[24]	1993	Mail	65	265 Rhode Island physicians	13.2	18.9
Doukas et al.[28]	1995	Mail	61.6	154 Michigan oncologists	43	38
Lee et al.[30]	1996	Mail	70	2761 Oregon physicians	NA	21
Back et al.[31]	1996	Mail	57	828 Washington state physicians	26*	
			56	107 Washington state oncologists	9#	18#
Emanuel et al.[16]	1996	Telephone	73	355 United States oncologists	37.6	50.6
Meier et al.[34]	1998	Mail	61	1902 United States physicians	11.1	18.3
			71	275 United States oncologists	13	25
Willems et al.[36]	2000	Telephone	80	152 Oregon oncologists, internists, and family practitioners	48†	
ASCO[37]	2000	Mail	41.7‡	3299 United States oncologists	56.2	38.2

* The question did not distinguish euthanasia from physician-assisted suicide; it asked 'Has a patient ever requested help to hasten death?'

\# These are data on requests in the last year.

† This represents the pooled responses to requests for euthanasia and physician-assisted suicide.

‡ There were two cohorts of oncologists with 39.8% response rate and 51.5% response rate. The answers to these questions did not differ and their results were pooled for reporting. This response rate is the average of the two cohorts.

NA, not availabe

These different reported rates of requests for euthanasia and physician-assisted suicide may reflect methodological issues, such as: (1) the differences between mailed and telephone surveys; (2) the different dates, with physicians being more willing to acknowledge performing these interventions in later years, as the debate becomes more public and accepted; (3) the different regions of the country with those in the West performing these interventions more frequently than the New England or North Central region[34]; and (4) the different investigators, with physicians more willing to acknowledge performing these interventions when the survey comes from investigators from the same state or a colleague in the same specialty.[16,28-31,37] However, differences in specialty may play the most important role. Oncologists are more likely to care for dying patients than internists, surgeons or any general list of physicians. Consequently, surveys of oncologists are more likely to report higher proportions of requests. Nevertheless, even among oncologists, the survey results vary considerably suggesting residual methodological issues.

In general, physicians who have received requests have received few requests.[31,32,37] For instance, Meier and colleagues report that overall physicians who received requests for physician-assisted suicide received a median of three requests in their careers (range 1-100) and a median of four requests for euthanasia (range 1-50).[34] Surveys have not thoroughly illuminated physicians' responses to requests for euthanasia or physician-assisted suicide. Back and colleagues reported that initially 76% of physicians increased treatment of physical symptoms, 65% treated depression and anxiety, and 24% referred the patient for a psychiatric evaluation.[31] Similarly, Meier and colleagues reported that 71% of physicians responded to requests for euthanasia or physician-assisted suicide by increasing analgesic treatment, while 30% used fewer life-prolonging therapies, and 25% prescribed anti-depressants.[34]

Despite being illegal, many studies indicate that a small but definite proportion of American physicians has performed euthanasia and/or physician-assisted suicide.[32,36] However, the data provide conflicting evidence on the precise frequency of such interventions. Reported frequencies of performing euthanasia and physician-assisted suicide vary more than 6-fold among even the best of studies (Table 5). For instance, Fried and colleagues (1993) reported that 2.5% of Rhode Island physicians performed physician-assisted suicide while 1.3% reported performing euthanasia.[24] Among Michigan oncologists, Doukas and colleagues (1995) reported that 18% participated in physician-assisted suicide while 4% received requests for euthanasia.[28] Lee and colleagues (1996) reported that 7% of Oregon physicians had performed physician-assisted suicide.[30] Back and colleagues (1996) reported that 4.6% of Washington state physicians performed physician-assisted suicide while 1.7% had performed euthanasia.[31] Emanuel and colleagues (1996) reported that among American oncologists 13.5% had participated in physician-assisted suicide and 1.8% had performed euthanasia.[16] Meier and colleagues (1998) reported that 3.3% had reported performing physician-assisted suicide while 4.7% had committed euthanasia; in this survey 3% of oncologists participated in physician-assisted suicide and 2% committed euthanasia.[34] The ASCO survey of American oncologists revealed that 10.8% had performed physician-assisted suicide while 3.7% had performed euthanasia.[37]

Table 5. Performance of euthanasia and physician-assisted suicide among American physicians

Study	Publication date	Type of survey	Response rate (%)	Types of physicians surveyed (n)	Euthanasia (%)	Physician-assisted suicide (%)
Fried et al.[24]	1993	Mail	65	265 Rhode Island physicians	1.3	2.5
Doukas et al.[28]	1995	Mail	61.6	154 Michigan oncologists	4	18
Lee et al.[30]	1996	Mail	70	2761 Oregon physicians	NA	7
Back et al.[31]	1996	Mail	57	828 Washington state physicians	1.7	4.6
Emanuel et al.[16]	1996	Telephone	73	355 U.S. oncologists	1.8	13.5
Slome et al.[32]	1997	Mail	60	137 San Francisco AIDS physicians	NA	53
Meier et al.[34]	1998	Mail	61	1902 U.S. physicians	4.7	3.3
			71	275 U.S. oncologists	2	3
Willems et al.[36]	2000	Telephone	80	152 Oregon oncologists, internists, and family practitioners	0	7
ASCO[37]	2000	Mail	41.7*	3299 U.S. oncologists	3.7	10.8

* There were two cohorts of oncologists with 39.8% response rate and 51.5% response rate. The answers to these questions did not differ and their results were pooled for reporting. This response rate is the average of the two cohorts.

NA, not availabe

Much of this variation may be attributable to the reasons cited above, especially the differences in specialties. However, there is another methodological concern. The study by Meier and colleagues is the only study to have ever reported that more American physicians perform euthanasia than physician-assisted suicide.[34] This finding contrasts with the extant data on American physicians' attitudes and practices regarding euthanasia and physician-assisted suicide. The data on physicians' attitudes demonstrates that physicians are significantly more willing to perform physician-assisted suicide than euthanasia.[24,26,28,37] Further the other studies of performing euthanasia and physician-assisted suicide demonstrate physicians performing physician-assisted suicide more frequently than euthanasia (Table 5). Thus in the study by Meier and colleagues it appears that physicians were not all reporting cases of euthanasia. As reported by Emanuel and colleagues[38], despite careful wording physician frequently confound euthanasia and terminating life-sustaining treatments, and this may be more common and harder to control for in mailed rather than telephone surveys because there is no opportunity to clarify responses. Thus, the study by Meier and colleagues may classify many cases as euthanasia that are in fact not euthanasia.

When American physicians have performed euthanasia or physician-assisted suicide they have done so very rarely. Meier and colleagues reported that the median number of physician-assisted suicide cases was two (range 1-25) while the median

number of euthanasia cases was two (range 1-150).[34] A recent survey by ASCO of oncologists reported that of those who had performed physician-assisted suicide, 37% had done so only once in their careers while 18% had done so five or more times.[37] Similarly, among the American oncologists who had performed euthanasia, over half had done so only once and just 12% had done so five or more times.[37]

Two studies have examined the impact of performing euthanasia or physician-assisted suicide on physicians. Meier and colleagues and Emanuel and colleagues reported that the majority of physicians were comfortable having performed euthanasia or physician-assisted suicide.[34,38] However, according to Meier and colleagues, 19% of physicians were uncomfortable after performing physician-assisted suicide and 12% were uncomfortable after performing euthanasia. (This lower proportion of feeling uncomfortable after performing euthanasia may reflect that many of these so-called 'euthanasia' cases were actually cases of terminating life-sustaining treatments.) They also found that in similar circumstances only 1% would not comply with physician-assisted suicide and 7% would not comply with euthanasia. Emanuel and colleagues reported that 25% regretted performing euthanasia or physician-assisted suicide and that 15% had adverse emotional reactions to performing euthanasia or physician-assisted suicide. At least in the cases reported by Emanuel and colleagues, these reactions did not seem related to fear of prosecution.

Finally, there is some disagreement about failed physician-assisted suicide attempts. Emanuel and colleagues reported that in 15% of cases, physician-assisted suicide failed; that is, patients were given a prescription, attempted suicide but did not die.[38] Ganzini and colleagues recently reported that there were no failed attempts in Oregon.[39] And the reports from the first two year's experience by the Oregon Health Division report no 'failed' physician-assisted suicide attempts.[40] As Nuland points out, the lack of problems with physician-assisted suicide in these reports from Oregon contrasts with the recently reported Dutch experience.[41] In the Netherlands, 7% of physician-assisted suicide cases had complications and in 16% it was taking 'longer than expected.' Ultimately, in 18.4% of physician-assisted suicide cases, Dutch physicians intervened to administer lethal medications, converting physician-assisted suicide cases into euthanasia.[42] The importance of this for the United States relates to the possibility of legalizing physician-assisted suicide without legalizing euthanasia, and what is to be done in the cases of 'failed' physician-assisted suicide. As the data demonstrate, in the Netherlands the accepted norm is to administer lethal medications, that is, perform euthanasia, in cases of failed physician-assisted suicide. This would not be permitted in the United States if euthanasia remains illegal. If the data from Emanuel and colleagues and the Dutch investigators is correct, there may be serious dilemmas for physicians if physician-assisted suicide is permitted but euthanasia is not.

Attitudes and practices of American patients regarding euthanasia and physician-assisted suicide

A few studies have examined the attitudes and experiences of American patients regarding euthanasia and physician-assisted suicide (Table 6).[43,44,45] Breitbart and

Table 6. Patients attitudes toward and experiences with euthanasia and physician-assisted suicide.

Study	Publication date	Type of survey	Response rate (%)	Types of physicians surveyed (n)	Personally considered euthanasia or physician-assisted suicide (%)	Factors associated with considering euthanasia or physician-assisted suicide	Factors NOT associated with considering euthanasia or physician-assisted suicide
Emanuel et al.[16]	1996	Telephone	61	155 New England cancer patients	27.3*	Depressive symptoms Poor physical functioning Less religious Higher incomes	Pain
Breitbart et al.[43]	1996	Mail	NA	378 New York City HIV patients	55#	Depression Hopelessness Fewer social supports	Pain Pain intensity Pain related functional impairment
Ganzini et al.[44]	1998	In-person	71	140 Oregon ALS patients	56†	Male More education Hopelessness Less religious	Depression Pain Perceived effect on family Use of hospice
Emanuel et al.[17]	Submitted	In-person	87.4	988 U.S. terminally ill patients	10.5‡	Lack of appreciation Depressive symptoms Care needs	Pain

* Considering euthanasia or physician-assisted suicide pooled patients who had positive responses to questions about considering euthanasia or physician-assisted suicide for themselves, hoarding drugs for the purposed of suicide, and reading the Hemlock Society's book, *Final Exit*.

\# The question stated: 'Would you consider physician-assisted suicide if it were legal?'

† Question phrasing: 'Under some circumstances I would consider taking a prescription for a medicine whose sole purpose was to end my life.'

‡ Question phrasing: 'Have you seriously thought about taking you life or asking your doctor to end your life?'

colleagues examined HIV/AIDS patients in New York City[43]; Ganzini and colleagues interviewed ALS patients in Oregon[44]; and Emanuel and colleagues surveyed oncology patients in Massachusetts.[16] In addition, there are data reporting on the first two years of experience of legalized physician-assisted suicide in Oregon encompassing some 43 cases.[40,45] There are additional data on the practices of euthanasia and physician-assisted suicide among patients in six different United States cities determined to be terminally ill by their physicians.[17] At least four major conclusions can be drawn from these data.

First, mainly oncology patients utilize euthanasia and physician-assisted suicide. Among the first 43 cases of physician-assisted suicide in Oregon 72% of the patients had cancer.[40] Meier and colleagues report that among patients receiving physician-assisted suicide 70% had cancer while among those receiving euthanasia only 23% had cancer.[34] (This is another indication that the euthanasia data reported by Meier and colleagues are not really euthanasia cases but include many cases of terminating life-sustaining treatments.) These data are comparable to the data from the Netherlands where 80% of euthanasia and 78% of physician-assisted suicide cases involved patients with cancer[46] and from the Northern Territory, Australia where all seven patients who received euthanasia had cancer.[47]

Second, it appears that pain is not a major determinant of interest in or use of euthanasia or physician-assisted suicide (Table 6). Almost all of these studies as well as the interviews with physicians who have administered euthanasia and physician-assisted suicide[31,34,38,46,47] have shown that pain is not a predictor of patients' interest in euthanasia or physician-assisted suicide. For instance, among the patients receiving physician-assisted suicide in Oregon only one of fifteen had uncontrolled pain.[45] Breitbart and colleagues reported that pain, pain intensity and pain related functional impairment were not associated with interest in physician-assisted suicide among HIV/AIDS patients.[43] Emanuel and colleagues reported that for oncology patients pain was not associated with personal interest in euthanasia or physician-assisted suicide. [16] However, they did find that for terminally ill patients pain was among the factors associated with personally considering euthanasia or physician-assisted suicide.[17]

Third, depression, hopelessness, and general psychological distress are consistently associated with interest in physician-assisted suicide and euthanasia (Table 6). Breitbart and colleagues reported that depression and hopelessness were strongly related to interest in physician-assisted suicide for HIV/AIDS patients.[43] Emanuel and colleagues reported that both for oncology patients and terminally ill patients more generally depressive symptoms were associated with personal interest in euthanasia or physician-assisted suicide such as discussing these interventions and hoarding drugs for the purpose of physician-assisted suicide.[16] Ganzini and colleagues reported that hopelessness, but not depression, was associated with 'considering taking a prescription for a medicine whose sole purpose was to end my life.'[44]

Fourth, Emanuel and colleagues reported that among terminally ill patients the extent of caregiving needs was associated with interest in euthanasia or physician-assisted suicide.[17] Ganzini and colleagues, however, reported that there was not an association between the burden of caring for the patients and whether caregiver's supported or opposed a patient's request for physician-assisted suicide.[44]

What is not known for sure is the frequency of use of physician-assisted suicide and euthanasia in the United States. In the Netherlands, 3.4% of all deaths are by euthanasia or physician-assisted suicide including involuntary euthanasia.[46] In Oregon, the proportion of all deaths by physician-assisted suicide reported to the Oregon Health Division is 0.09%.[40] Such a low rate raises skepticism that not all cases of physician-assisted death are reported.[40] Emanuel and colleagues have found a rate of 0.4% among competent terminally ill patients.[17]

Future empirical research regarding euthanasia and physician-assisted suicide

There are six major areas in need of additional research in the United States. First, there are little data on the relationship between euthanasia and physician-assisted suicide and the provision of optimal end-of-life care. Are euthanasia and physician-assisted suicide used as truly 'last ditch' interventions for patients refractory to appropriate end-of-life interventions? Or are they used as substitutes for optimal end-of-life care? The ASCO survey suggested that there was a relationship between not being able to get dying patients all the care they needed and utilization of euthanasia and physician-assisted suicide. This result needs confirmation. Further we need to understand what are the predictors of physicians who come to use euthanasia and physician-assisted suicide only after trying optimal care versus those who use these interventions as a substitute. Is this the result of structural and financial barriers to optimal end-of-life care or is it the result of problems, such as lack of training in end-of-life care, on the part of physicians?

Second, there are widely divergent data on how frequently physician-assisted suicide fails and no data on what is done when it does fail. If in the United States only physician-assisted suicide will be permitted, what do physicians do when it fails?

Third, there is no information on the short and long-term impact of euthanasia and physician-assisted suicide on the surviving family members of the patients. Immediately after the interventions, families may have the psychological need to be supportive of the decision and believe that the right thing was done. However, with the passage of time, they may have different views. We have no data on the long-term impact of euthanasia and physician-assisted suicide on surviving family members.

Fourth, there are conflicting data on the actual frequency of euthanasia and physician-assisted suicide. These interventions occur, but how frequently? It may be that conducting a death certificate follow-back study modeled on the Dutch study[46] will be the best way to obtain accurate data on the frequency of these interventions as well as the reasons for the interventions, the palliative measures taken, and the effects on the family.

Fifth, there are no data on the frequency of non-voluntary euthanasia in the United States. In the Netherlands, non-voluntary euthanasia occurs in 0.7% of deaths. The rate may be higher in the United States given the expense and financial problems associated with end-of-life care.[48,49] Issues of coercion and of performing euthanasia on patients who are not competent are serious and there are inadequate data on these events in the United States.

Finally, we also have no data on euthanasia and physician-assisted suicide among children. While death is rare among children, there are several thousand deaths among children with cancer and HIV/AIDS. These deaths tend to occur after significant and prolonged illnesses and symptom management is less than optimal.[50] There may be cases of pediatric euthanasia or physician-assisted suicide. Why these occur and how they are handled is also important.

Unfortunately each of these issues is very difficult to study because euthanasia and physician-assisted suicide are relatively rare events requiring screening by many physicians to identify just a few cases. Thus, such studies will be very large and very expensive.

Conclusion

Over the last decade there has been a substantial amount of empirical research conducted on euthanasia and physician-assisted suicide in the United States. This empirical research has revealed many unexpected findings that have significantly influenced the public debate. Such findings include:

1. Public support for euthanasia and physician-assisted suicide is closely linked with the reasons patients want these interventions; the public supports the interventions only for patients in excruciating pain.
2. Yet, pain does not appear to be the primary factor motivating patients to request euthanasia and physician-assisted suicide; depressive symptoms, hopelessness, and other psychological factors appear to motivate patient requests for euthanasia and physician-assisted suicide.
3. Euthanasia and physician-assisted suicide occur, albeit at a very low rate. Indeed, over 99% of all dying Americans do not have these interventions and even in the Netherlands more than 96% of all decedents do not have these interventions. This last factor has emphasized that euthanasia and physician-assisted suicide are not the way to improve end-of-life care for the vast majority of decedents.

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Physicians' Experiences with Legalized Physician-Assisted Suicide in Oregon[1]

Abstract

The Oregon Death with Dignity Act (ODDA) was enacted in November 1997, legalizing physician-assisted suicide for competent, terminally ill Oregonians. There are no data on patients who request, but do not receive, a lethal prescription and physicians' experiences with such requests.

In 1999, we mailed a questionnaire to physicians who were eligible to prescribe under the ODDA. Of 4053 eligible physicians, 2649 (65%) returned the survey. One hundred forty-four respondents received 221 requests for lethal prescriptions since enactment of the law and reported outcomes of 165 patients: 29 patients received a lethal prescription and seventeen died from self-administering it. The mean age of requesting patients was 68 years, 52% were male, 67% had a malignancy and 20% had symptoms of depression. The most common reasons for the request were loss of independence, poor quality of life, readiness to die, and desire to control the circumstances of death.

Seventy-one percent of responding physicians had cared for six or more terminally ill patients in the previous 12 months. Overall, these physicians were confident in their abilities, had positive attitudes about, and had attempted to improve their skills in caring for terminally ill patients. There were no differences between physicians who did and did not prescribe on either these measures or type of physician reimbursement. In two thirds of patients the physician recommended at least one substantive palliative intervention; patients who received a palliative intervention were more likely to change their mind about wanting a lethal prescription than those who did not.

The Oregon Death with Dignity Act (ODDA) legalized physician-assisted suicide for competent, terminally ill Oregonians in October 1997.[1] This law allows a physician who has primary responsibility for managing a patient's terminal illness to prescribe a

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dose of a lethal medication, which the patient may self-administer. The Act specifies that a second physician must confirm that the patient's prognosis is terminal (less than six months to live), the patient has decision-making capacity, and the decision is voluntary. The patient must make one written and two oral requests over fifteen days. Referral to a mental health professional is required if either the attending or consultant physician is concerned that the patient's judgment may be impaired by a mental disorder. The physician must ask the patient to inform his family of the request, but the patient is not required to comply. Physicians are required to report to the Oregon Health Division that they have prescribed the medication and complied with the safeguards.

There has been a great deal of speculation both in the medical and lay press about the effect of legalized physician-assisted suicide on care of the dying and the characteristics of Oregon patients requesting physician-assisted suicide and their physicians. Experts have hypothesized that patients who pursue physician-assisted death are depressed, have pain, lack social support, and are motivated by financial concerns or a desire to not burden their families.[2-11] Commentators have insisted that requests for physician-assisted suicide would not occur if patients received adequate palliative care. Many have claimed that women, minorities, and the poor, all of whom may have less access to health care, including palliative alternatives, would disproportionately choose legalized physician-assisted suicide.[12-13] Others have suggested that physicians who agree to participate in physician-assisted suicides would be less likely to do so if they had greater knowledge, skills, and comfort in caring for dying patients.[12] Some experts have expressed concern that willingness to accede to requests occurs because of exhaustion or a sense of failure by the treating physicians.[14-16] Others have suggested that with increased cost concerns and the rise of managed care, physician-assisted suicide would be encouraged as a less expensive alternative to palliative care.[10,12,14] Because Oregon is the only state in the United States that allows physician-assisted suicide and Oregon residency requirements are poorly defined, there were predictions that the state would become a mecca for non-Oregonians seeking physician-assisted suicide, and that 'euthanasia clinics' would be set up to meet this need, such that most prescriptions for a lethal medication would come from a small number of physicians.[3,12]

Research results to date do not entirely substantiate these concerns; however, few researchers have studied persons with legal access to physician-assisted suicide. Several studies of seriously ill and dying patients indicate that depression and hopelessness are more common in persons with an interest in physician-assisted suicide or hastened death, and other studies indicate that patients interested in hastened death or physician-assisted suicide perceive less social support.[2,17-19] There is less evidence for the role of pain in requests for physician-assisted suicide, and one study even found that increased pain was associated with less interest in physician-assisted suicide.[2,18] Authors of one survey reported that willingness to endorse physician-assisted suicide was correlated with decreased knowledge of symptom management.[20] In general, studies find that minorities and poorly-educated persons are less supportive of legalizing physician-assisted suicide.[21] One study reported that health care professionals who supported physician-assisted suicide had higher

'burnout levels'.[20] This paper examines these concerns in light of a survey of Oregon physicians about patients who requested physician-assisted suicide in 1998 and early 1999.

Methods

The study was a self-administered, mailed survey. Details of the methods used in this study have been published elsewhere.[22] A list was purchased of all licensed physicians from the Oregon Board of Medical Examiners. Physicians allowed to prescribe under the ODDA are those primarily responsible for the health care of a patient with a terminal illness. Physicians included were actively practicing in the fields of internal medicine and its subspecialties, family practice, general practice, gynecology, surgery and its subspecialties, therapeutic radiology and neurology. We excluded physicians in training, retired physicians, and physicians not practicing.

A questionnaire was developed based on previous surveys on this issue, discussions with physicians in Oregon who had received requests or participated in the ODDA, and discussions with experts in the field of end-of-life care. The survey was refined after pretesting with a convenience sample of fourteen physicians and, with the assistance of Compassion in Dying, an advocacy organization, and six physicians who had prescribed under the ODDA. These physicians were not excluded from the final sample.

Physicians were asked to complete information on patients who requested a lethal prescription under the ODDA only if the patient was terminally ill, the request was explicitly for a lethal prescription, and it occurred after November 1997. 'Explicit request' was defined as a 'request from a patient for a lethal dose of medication to be used to end life as set forth in the ODDA.' 'Terminally ill' was defined as 'within reasonable medical judgment the patient will die within six months.' The ODDA requires that a consultant evaluate the patient to determine if the patient meets the criteria of the law. We asked that only attending physicians, not consultants, complete the information in order to minimize duplicate information.

Most answers were forced choice responses. The survey probed the physicians' attitudes toward the ODDA, their willingness to prescribe under the Act, their attitudes toward caring for dying patients and attempts to improve their ability to care for dying patients. Physicians provided demographic and medical information on requesting patients, their outcomes, and indicated whether, based on conversations with the patient, a particular value, condition, or symptom was present and important in the decision to request a lethal prescription. The physicians specified interventions other than a lethal prescription that they had addressed before the request or recommended or implemented after the request. In an open-ended question, the physician specified interventions that altered the patients' desire for a lethal prescription.

In order to identify when two or more physicians potentially reported on the same patient, cases were matched for age within one year, gender, marital status, disease, and size of community. Only information from the second physician's encounter is reported unless this physician did not fully complete the survey.

The survey was mailed in February 1999, a reminder post-card two weeks later, and a second copy of the survey in March 1999 that was coordinated with a fax or phone call. In May 1999, after 47% of the sample had responded, a third copy of the survey was sent with a check for $25, a letter of endorsement from the Governor of Oregon, John Kitzhaber, MD, and a simultaneous fax. Several subspecialist leaders in the medical field in Oregon were asked to write personal letters to colleagues. Of these, the Chair of the Department of Neurology at Oregon Health Sciences University wrote a letter to all Oregon neurologists encouraging them to answer the survey. Surveys were accepted through August 1999. To allow tracking of the questionnaires, return envelopes were coded with an identifying number. The survey was separated from the identifying envelope upon receipt, then recoded to render it anonymous. Surveys were scanned into an electronic database.

Summary statistics included proportions for categorical variables and means and standard deviations for continuous variables. Pearson Chi-square was used to test for associations in levels of responses.

Results

Of 4053 eligible physicians, 2649 (65%) returned the questionnaire. One hundred forty-four respondents (5%) received 221 requests for lethal prescriptions since November 1997. Nine patients appeared to be reported by more than one physician. Information was incomplete for six others, who were excluded because it could not be determined if the data was duplicated. Of the remaining 206 requests, we received complete information on 143 patients and partial information on 22 patients. Twenty-seven physicians indicated they received 41 requests, but gave no information on the patients. In 87% of cases where the physician supported the ODDA, we received complete or partial information regarding patients, compared to 71% of cases where the physician opposed or neither supported nor opposed the ODDA ($p = 0.007$).

Physician characteristics

Of the 144 respondents who received a request, 55% supported the ODDA, 17% neither supported nor opposed, and 28% opposed the ODDA. Fifty-one percent were willing to prescribe a lethal medication, 12% were uncertain, and 37% were unwilling to prescribe. In the previous twelve months, 71% of these physicians had cared for six or more terminally ill patients, and 58% had referred six or more patients to hospice. Seventy-eight percent of these physicians received only one request for a lethal prescription since enactment of the law, 18% had received two or three requests, and 4% had received four or more requests. Overall, these physicians were confident in their abilities to care for dying patients and, since passage of the ODDA, had attempted to improve their skills in recognizing and treating pain and depression in terminally ill patients. The majority of physicians, whether or not they prescribed, had positive feelings about care of the dying. There were no differences between the sixteen physicians who prescribed and the 128 who did not prescribe on these factors, or their attitudes toward terminally ill patients (Table 1).

Table 1. Physicians characteristics.

	All respondents (n=144)	Prescribed a lethal medication* (n=16)	Did not prescribe (n=116)
	n (%)	n (%)	n (%)
Number of terminally ill persons cared for in last 12 months			
< 6	42 (29)	4 (25)	34 (29)
≥ 6	102 (71)	12 (75)	82 (71)
Sought to improve knowledge of pain medications in terminally ill in last four years			
Not at all/only a little	17 (12)	3 (19)	13 (11)
Somewhat	66 (46)	5 (31)	56 (48)
A great deal	61 (42)	8 (50)	47 (41)
Confidence in use of pain medication in terminally ill improved in last four years			
Not at all/only a little	19 (14)	1 (6)	18 (16)
Somewhat	58 (40)	10 (63)	44 (38)
A great deal	66 (46)	5 (31)	54 (47)
Respondent attempted to improve knowledge of depression in terminally ill in last four years			
Not at all/only a little	34 (24)	5 (31)	25 (22)
Somewhat	70 (49)	6 (38)	60 (52)
A great deal	40 (28)	5 (31)	31 (27)
Respondent prefers to avoid contact with dying patients			
Not at all	115 (80)	13 (81)	92 (80)
Only a little/somewhat	28 (20)	3 (19)	23 (20)
Respondent finds care of dying patients emotionally satisfying			
Not at all/only a little	29 (20)	1 (6)	26 (22)
Somewhat	52 (36)	8 (50)	39 (34)
A great deal	62 (43)	7 (44)	51 (44)
Respondent feels competent in communicating with dying patients			
Not at all/only a little	4 (3)	1 (6)	3 (3)
Somewhat	46 (32)	5 (31)	39 (34)
A great deal	94 (65)	10 (63)	74 (64)
Respondent feels confident in caring for dying			
Not at all/only a little	6 (4)	1 (6)	5 (4)
Somewhat	52 (36)	6 (38)	43 (37)
A great deal	86 (60)	9 (56)	68 (59)
Respondent finds care of dying intellectually satisfying			
Not at all/only a little	33 (23)	27 (23)	2 (13)
Somewhat	56 (39)	44 (38)	8 (50)
A great deal	55 (38)	45 (39)	6 (38)

* Twelve respondents received requests, but the respondent did not indicate whether he/she prescribed or not.

$p > 0.05$, in all comparisons between physicians who did and did not prescribe lethal medications.

Patient characteristics

The mean age of the requesting patients was 68 years, 97% were Caucasian, 52% were male, 46% were married, and 95% had at least a high school education. Thirty-four percent lived in a rural area or town of less than 25,000. Malignancy was the most common terminal diagnosis, but one in six had cardiopulmonary disease, and one in ten had a neurologic disease. AIDS was very uncommon (Table 2). Physicians noted depressive symptoms in 20% of requesting patients. In 17% (n = 24), depression or another psychiatric disorder impaired the patient's judgment. In thirteen cases (9%), the physician was uncertain if a mental disorder was impairing the patient's judgment: this included three patients who changed their mind about physician-assisted suicide before completing the law's requirements, one patient who died before completing the law's requirements, four who did not meet the law's requirements for other reasons, two patients cared for by physicians who were unwilling to prescribe in any case, and three patients for whom the physician had not completed the evaluation. No depressed patient received a lethal prescription.

At the time of the request, pain was experienced by 49% of patients, fatigue by 59%, and dyspnea by 31%. These symptoms were important in the decision to request a lethal prescription either because the patient had the symptom at the time of the request or feared it in the future. For instance, pain was important for 43%, fatigue for 31%, and dyspnea for 27%. The most common conditions and values important in the patients' decisions to request a lethal prescription were loss of independence (57%), poor quality of life (55%), readiness to die (54%), desire to control the circumstances of death (53%), seeing existence as pointless (47%), and loss of dignity (42%).

Perceiving oneself as a financial drain (11%) and lack of social support (6%) were uncommon reasons for requests. On the other hand, a desire not to burden one's family was an important reason for the requests of 38% of patients. Physicians were more likely to honor the prescription if the patient wanted to control the circumstances of his death (83% for those who received a lethal prescription and 45% for those who did not) ($p < 0.001$) and less likely if the patient viewed himself/herself as a burden (10% for those who received a lethal prescription, 47% for those who did not, $p = 0.001$). Four of 143 patients had lived in Oregon for less than six months, but only one patient had moved to Oregon specifically because of the ODDA.

Physician interventions

Physicians provided information about interventions they recommended or implemented in 142 requesting patients. The most common interventions recommended by the physician after the request were pain control (30%), addressing other physical symptoms (30%), hospice referral (27%), seeking the advice of another colleague (28%), mental health consultation (20%), trial of antidepressants (18%), stopping food and hydration as a means of hastening death (16%), palliative care consultation (13%), social work consultation (11%), chaplain consultation (10%), and transfer to a new physician (9%). When asked in an open-ended question if one or more interventions altered the patient's desire for a lethal prescription, in 42 of 140 cases physi-

Table 2. Characteristics of patients who requested a lethal prescription.

	n	n(%)
Terminal diagnosis*	158	
Malignancy		106 (67)
End-stage cardiopulmonary disease		29 (18)
Neurologic disease		15 (9)
AIDS		4 (3)
Other		13 (8)
Size of community in which patient resides	158	
Rural or small town (< 25,000)		54 (34)
Medium-sized town (25,000-250,000)		53 (34)
Large city or suburb		51 (32)
Type of health coverage[1]	143	
Medicare		63 (44)
Health maintenance organization		23 (16)
Managed care insurance plan		20 (14)
Fee for service insurance plan		17 (12)
Oregon Health Plan/Medicaid		11 (8)
Military, VA/Champus		4 (3)
No insurance		3 (2)
Unknown		18 (13)
Enrolled in hospice at time of request	141	
Yes		45 (32)
No		96 (68)

* Total percentage > 100 as physicians could mark more than one category.

cians agreed. These physicians indicated that successful interventions included pain and symptom management in 11 patients; hospice services, reassurance, and reassurance that the prescription would be available (eight patients each); treatment of depression, services to the family, and alternative means to hasten death (three patients each); and palliative care consultation in one patient.

In 67% of patients, the physician recommended at least one substantive intervention (pain or symptom control; hospice referral; mental health, social work, chaplain or palliative care consultation; or a trial of antidepressants) or sought the advice of a colleague. In 48% the physician implemented the intervention. Patients who received a substantive intervention were more likely to change their mind about wanting a lethal prescription (31/67) compared to those who did not receive a substantive intervention (11/73) ($p < 0.001$). Of the 29 patients who received a lethal prescription, nineteen received hospice services before or after the request. Of the ten who did not receive hospice services, six received pain management before or after the request.

Of the eighteen patients who received a lethal prescription but not a substantive intervention after the request, sixteen were either already enrolled in hospice (eleven) or had no pain (five). Thirteen of sixteen who died by lethal prescription were enrolled in hospice (data missing on one patient).

Patient outcomes

Physicians reported the outcomes of 165 patients. Twenty-nine patients received lethal prescriptions. Seventeen died from self-administering them, eleven died of their underlying disease, and one was still alive at the time the physician completed the survey. Of the 136 patients who did not receive a lethal prescription, 15% did not meet the ODDA criteria, 15% changed their mind, and 20% died before completing the requirements. In 29% of cases the physician was not willing to provide in any case, in 22% the physician was not willing in the particular case, in 5% of cases the physician had not completed the evaluation, and in 7% the patient had completed the law's requirements and was eligible but did not receive a prescription (physician could mark more than one category; therefore, percentages sum to greater than 100%).

Health care characteristics

Thirty-percent of requesting patients were covered by a managed care health plan or health maintenance organization. In contrast, 49% of all Oregonians receive health care coverage from a managed care health plan or a health maintenance organization.[23] Fifty percent of requesting patients who had a managed care health plan received a palliative care intervention compared to 47% with other types of insurance ($p > 0.05$). There was no difference in proportions who received a lethal prescription or died by lethal prescription between these two groups. Three patients had no insurance; one died by lethal prescription.

Barriers to receiving a prescription

Twenty-four of forty-one responding physicians who lived in small towns supported the ODDA, but small town physicians were unlikely to prescribe lethal medication: only 3% of small town physicians who received requests prescribed a lethal medication compared to 28% of physicians in towns with populations over 25,000. This did not result in a clear limitation of access for persons in small towns and rural areas. Thirteen percent of requesting patients living in small towns or rural areas received a lethal prescription from the responding physician compared to 21% of patients in larger communities ($p = 0.20$). Thirty-five percent of patients requested a lethal prescription from at least one other physician. Reflecting this referral process, 27% (38/143) of the survey physicians had known the patient for less than one month at the time of the request.

Discussion

We surveyed Oregon physicians eligible to prescribe under the ODDA in order to obtain information about their experiences with requests for lethal prescriptions from terminally ill patients. One hundred forty-four physicians received 221 requests and gave information on the outcomes of 165 patients of whom 29 received a lethal prescription from sixteen physicians. The results lend support to some but not all of the speculations about legalization of physician-assisted suicide.

Concern has been raised that if physician-assisted suicide were legal, women, poor, and ethnic minority patients might request it because of less social support and lack of health care access.[12] Demographics of requesting patients, however, were almost identical to all Oregon decedents. In 1998, 2% of all decedents in Oregon lacked health insurance for hospice, and in 1996, 97% of Oregon decedents were Caucasian and 51% were men.[24-25] Patient concerns about finances and lack of social support were rarely the stated reason for the request. More than one third of patients requested physician-assisted suicide because they perceived themselves as a burden to others, but Oregon physicians were very reluctant to accede to requests from these patients.

Physical concerns, primarily pain, fatigue, and shortness of breath, were commonly reported and should continue to be a focus of palliation in requests for physician-assisted suicide. Palliative interventions, especially referral to hospice, appear to be effective alternatives for some patients. Oregon physicians appeared to be cautious about proceeding with physician-assisted suicide and focused instead on palliative care alternatives: two thirds recommended a palliative intervention and almost half implemented one. In 76% of those who received a lethal prescription (22 of 29), the patient was either in hospice or the physician responded to the request with a palliative intervention. Further research is needed to understand which interventions are most effective and why not all recommended interventions are implemented.

Concerns have been raised that physicians may accede to requests for physician-assisted suicide because they lack knowledge, skills or comfort in care of the dying or are exhausted and discouraged by the patient's course.[14-16] Of the 144 physicians who received requests, most reported making substantial efforts to improve their knowledge and skills in care of the dying, and most had positive attitudes toward working with this population. There were no differences between the physicians who honored a request and those who did not on any of these measures. Physicians in managed care and health maintenance organizations, which are perceived as reducing financial risk by minimizing expensive services, may lack time and resources to deliver palliative services or perceive financial benefits to supporting physician-assisted suicide over more expensive palliative care. We found, however, that there was no difference in comparing managed care/health maintenance organization patients to other patients, in proportion who requested physician-assisted suicide, received a lethal prescription, or received other palliative care interventions. The small number of prescribing physicians may have limited our ability to compare these two groups and further work is needed in understanding their skills and attitudes.

One in five requesters were perceived by the physicians as depressed. In other studies, depression was found in 59 to 100% of persons interested in physician-assisted suicide or hastened death, and cancer patients who have committed suicide.[2,26-27] Whether depression is less common in persons who request a lethal prescription, or Oregon primary care physicians failed to detect it could not be determined. Most respondents had made efforts to improve their ability to recognize depression in terminally ill patients. In 1995, 28% of Oregon primary care physicians indicated they were uncertain if they could recognize depression in a patient

requesting physician-assisted suicide.[28] In contrast we found that 9% of the responding clinicians were uncertain whether depression or another psychiatric disorder was influencing the patient's judgment.

There are several sources of bias and potential error in our study. Although the response rate was high, the experiences of 35% of Oregon physicians who did not answer the survey are unknown. We may have underestimated duplicate patient information if physicians erred in recording patient demographics. Physicians opposed or uncertain about the ODDA were significantly less likely to complete patient information and this response bias leaves less confidence and knowledge about the perceptions of these physicians and the interventions that they recommended or implemented with patients. Finally, although physicians were directed to base information about patients' reasons for the request only on conversations with the patients, this is not as reliable as surveying patients directly.

Our findings are similar to the Oregon Health Division report on physician-assisted suicide completers in 1998-1999. The Oregon Health Division report on 43 patients who died by physician-assisted suicide documents that 98% were white race, 56% male, and patients who completed suicide were more likely to have completed college compared to other Oregon decedents. Concern about finances was rare: 76% were enrolled in hospice and 2% lacked insurance. However, 47% of families of these patients reported patient concerns about being a burden. Concerns about loss of autonomy occurred in over two thirds of patients and loss of bodily functions occurred in 58% of patients. Over half of these patients had physical suffering.[29]

Important research questions

Legalization of physician-assisted suicide in Oregon makes it possible to design studies which can empirically test many beliefs articulated by both proponents and critics of this practice and to develop conceptual models of why patients request physician-assisted suicide and how physicians negotiate these requests. Our study represents a broad overview of legalized physician-assisted suicide, but more focused, well-designed studies are needed in order to more rigorously test hypotheses.

Our survey was designed based on experts' concerns and beliefs about legalized physician-assisted suicide. Qualitative studies may reveal concerns by health care providers and patients that have not been previously considered. The patient's own experience and process of decision-making about physician-assisted suicide should be studied prospectively. Many current studies are based on physician surveys and interviews, which may not accurately reflect the patient experience. Case-control studies would help determine the excess risk contributed by depression, financial concerns, and fear of burdening others. The degree to which surveys of ill persons' attitudes about physician-assisted suicide reflect the attitudes of persons actually requesting physician-assisted suicide must be explored.

Physicians in our study reported interventions implemented, but the quality and comprehensiveness of these interventions are unknown. Barriers to palliative inter-

ventions must be explored. Does a patient's desire for independence and control influence his/her acceptance of palliative interventions? How well has physical suffering been addressed? Although our study showed that hospice referral is an effective alternative for physician-assisted suicide, it is unclear which components of hospice are most helpful.

Once the prescription has been written, there are many unanswered questions. How do patients decide, once the prescription is available, whether or not, or when to take it? What is their mental status just before ingestion? Finally, the psychological effects of participation or failing to participate in physician-assisted suicide on physicians, the effect of legalization on other health professionals, and the emotional sequelae for families and loved ones of those who die from physician-assisted suicide or who desire physician-assisted suicide and are unable to obtain it remain important questions for active study.

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Luc Deliens and Freddy Mortier

Empirical Research on End-of-Life Decisions in Medical Practice in Belgium (Flanders)[1]

Abstract

Belgium is a country with no formal registration or authorization procedure for end-of-life decisions. Acts of euthanasia ('the administration of drugs with the explicit intention of ending the patient's life at the patient's request') are treated as murder under criminal law. In 1996, a study of euthanasia and other medical practices concerning the end of life was conducted in Hasselt, a city in the Flemish part of Belgium. All physicians who signed a death certificate in 1996 received an anonymous self-administered mail questionnaire. The response rate was 55% (75% among family physicians and 44% among clinical specialists).

This chapter explores the incidence of end-of-life decisions in Belgium (Flanders). Based on the corrected data obtained from the study in Hasselt, incidence estimates are presented for euthanasia and physician-assisted suicide, ending of life without the patient's explicit request, alleviation of pain and symptoms with a potential life-shortening effect, and withholding or withdrawing of a potential life-prolonging treatment. Furthermore, the circumstances of these end-of-life decisions that are relevant to legislation and to ethical acceptability are discussed. Based on our research experience in the domain of end-of-life decisions, we are of the opinion that the following topics deserve more attention in future research: assessment of the criteria used by physicians to define and establish the '(in)competence' of patients; patient-physician communication about the end of life under conditions of secrecy and prohibition (versus regulated conditions); research into the role of paramedical personnel, and, in particular, nurses; development and testing of causal models to explain why end-of-life decisions happen; the design of comparative international research.

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In Belgium, euthanasia is illegal and treated as intentionally causing death under criminal law. Belgian physicians could also be prosecuted for physician-assisted suicide, if the act is interpreted by the Prosecutor as the 'deliberate refusal to help a person in need'. Although euthanasia and probably also physician-assisted suicide are illegal under criminal law, actual prosecutions are exceptional and the potential legalization of these medical practices is the subject of increasing debate in Belgium, both in the official Advisory Committee on Bioethics and in the Federal Parliament. In Belgium the discussion focuses on euthanasia, strictly defined as 'a deliberate life-ending act performed by a physician at the patient's explicit request'.[1] In 1998, on the bases of a report issued by the Advisory Committee on Bioethics, the Senate spent about two days debating the desirability of the legalization of euthanasia. Representatives of the majority parties of the Parliament (newly formed after the general elections of June 1999) declared that a formal registration and authorization procedure for euthanasia would be put to the vote in the coming year. Yet, Belgium still has no formal registration or authorization procedure for end-of-life decisions in medical practice, and the hospitals and nursing homes have no written policy concerning euthanasia and physician-assisted suicide.

Since most of the deaths involving euthanasia or physician-assisted suicide are reported in the death certificates as deaths from natural causes, the incidence of euthanasia or Physician-assisted suicide cannot be deduced from official mortality statistics. Empirical research on end-of-life decisions in Belgium is rather scarce, and (prior to the study presented here) no study has ever investigated the number of deaths involving end-of-life decisions in medical practice. In 1997, a research project on end-of-life decisions was commissioned by the Fund for Scientific Research, to be carried out by an inter-university and inter-disciplinary group of researchers. Since then, some theoretical and empirical publications have been based on this research project.[2-8] The results of the pilot study in the city of Hasselt were published in 1998.[3-5] As it was the first study to generate empirical data on the incidence of euthanasia, physician-assisted suicide and other end-of-life decisions in Belgium, this pilot study attracted a great deal of attention in both the medical and the public press in Belgium. In 1998-1999 a nationwide study was conducted in Flanders (the Dutch-speaking region of Belgium, inhabited by approximately 60% of the Belgian population). The first results of this study have recently been submitted for publication in an international journal.[7] This chapter focuses on the main results of the pilot study in the city of Hasselt.

The main objective of this study on end-of-life decisions is to estimate the incidence of euthanasia, physician-assisted suicide and other end-of-life decisions in medical practice in Hasselt. In this research project, physician-assisted death was defined as 'the administration of drugs with the explicit intention of shortening the patient's life', and can be divided into three sub-categories (Box 1).[6] Euthanasia was defined as 'the administration of drugs with the explicit intention of shortening the patient's life, at the patient's explicit request'. Physician-assisted suicide was defined as 'the prescription or supply of drugs with the explicit intention of enabling the patient to shorten his life'. This study also addressed other medical end-of-life decisions. These involved life-terminating acts other than acts performed at the explicit

BOX 1 End-of-life decisions in medical practice studied

1. **Physician-assisted death:**
   a. *Euthanasia*:
      the administration of drugs with the explicit intention of shortening the patient's life, at the patient's explicit request
   b. *Physician-assisted suicide*:
      the prescription or supply of drugs with the explicit intention of enabling the patient to shorten his or her life
   c. *Ending of life without the patient's explicit request*:
      the administration of drugs with the explicit intention of shortening the patients life without an explicit request by the patient

2. **Alleviation of pain and symptoms:**
   a. *life-shortening not intended*:
      alleviation of pain and symptoms with opioids in doses with a potential life shortening effect, but shortening the patient's life was not intended
   b. *life-shortening co-intended*:
      alleviation of pain and symptoms with opioids in doses with a potential life shortening effect, and shortening the patient's life was co-intended

3. **Non-treatment decisions:**
   a. *life-shortening not intended*:
      withholding or withdrawing of a potential life prolonging treatment, but shortening the patient's life was not intended
   b. *life-shortening co-intended*:
      withholding or withdrawing of a potential life prolonging treatment, with the co-intention of shortening the patient's life
   c. *life-shortening explicitly intended*:
      withholding or withdrawing of a potential life prolonging treatment, with the explicit intention of shortening the patient's life

request of the patient, and also the alleviation of pain and symptoms with the side effect of shortening of life (the 'double effect'), as well as non-treatment decisions. The ending of life without the patient's explicit request was defined as 'the administration of drugs with the explicit intention of shortening the patient's life without an explicit request from the patient'. Related to the life-shortening intention of the physician, 'alleviation of pain and symptoms with opioids in doses with a potential life-shortening effect' was divided in the sub-categories of 'not intended' and 'co-intended' by the physician. Related to the life-shortening intention of the physician, 'non-treatment decisions' were divided into three sub-categories: 'not intended', 'co-intended' and 'explicitly intended' by the physician. Box 1 shows a schematic representation of all end-of-life decision categories studied.

The Belgian research on end-of-life decisions, presented here, is the first replica of the studies, which have been carried out in the Netherlands.[9,10] This is a neighboring country, with comparable language, culture and history, but with a somewhat different health care system and with a totally different legal arrangement for euthanasia and physician-assisted suicide. Therefore, comparisons are interesting and some criticisms of the Dutch official notification procedure for euthanasia can be addressed.

Methods

The research design and questionnaire used for the Belgian study on end-of-life decisions were almost identical to those used in the Dutch studies. The core of the mail questionnaires was based on the Dutch questionnaires used in 1990 and 1995 studies.[9,10] Since the Dutch language is spoken both in Flanders and in the Netherlands, only a few questions had to be slightly rephrased in order to clarify certain subtle linguistic differences. Some questions were added, based on the preliminary results of the pilot study.[3,4] In the Netherlands the death-certificate studies were conducted under legal protection of the participating physicians by the Public Prosecution and the Minister of Justice. In Belgium there was no such additional protection, so the feasibility of the research design and methods was therefore first tested in a pilot study in Hasselt.

The death-certificate study in the city of Hasselt

Hasselt is a city with 78 registered family physicians and 200 specialists, a population of 67,398 inhabitants and an annual mortality rate of 1.2 %. The study population in the study comprised all deaths which occurred in Hasselt in 1996 (n = 970). For each death certificate, the physician who signed it was identified and was sent one anonymous self-administered mail questionnaire per death (with a maximum of five per physician). Using the total design method, 489 questionnaires were distributed and 269 questionnaires were received back.[13]

Questionnaire

The questionnaire consisted of three parts. Part 1 described the different medical practices at the end of the life of a patient, divided into three basic categories: administration or supply of lethal drugs, alleviation of pain and symptoms, and non-treatment decisions (Box 1). The structure of the questionnaire made it possible to identify the last end-of-life decision that preceded the death of the patient. Respondents were also asked to describe their intention, with regard to the end-of-life decision: whether they took into account the possibility of life-shortening, whether shortening the patient's life was co-intended, and, finally, whether shortening the patient's life was explicitly intended. Part 2 made it possible to investigate the decision-making process that preceded the most recent end-of-life decision, and assessed a number of requirements for prudent practice (for instance, whether there had been a previously discussed and explicit request by the patient, an explicit request from relatives, whether the physician

had consulted colleagues). Part 3 provided some background characteristics of the physician. Upon receipt of the completed questionnaire, mortality data and patient characteristics were linked anonymously to the data from the questionnaire.

Response and weighting of the data

The response rate was 55% (n = 269). The response rates were 74.6% for the family physicians and 44.4% for the specialists. The results presented in this paper have been corrected for the over-representation of specialists in the non-response group.

Results

Incidence estimates

Based on the corrected data from the pilot study in Hasselt, the estimates of end-of-life decisions in Belgium (Flanders) were made. Table 1 presents the observed incidence of end-of-life decisions, as well as the estimates for 1996, based on all deaths registered during the year (n = 55,795).

Among all deaths studied in Hasselt, death occurred suddenly and unexpectedly in 35.1%; an end-of-life decision was possible, but did not occur in 27.6%, and death was preceded by at least one end-of-life decision in 37.3% (Table 1). Of all deaths, 4.8% resulted from physician-assistance (administration, prescription or supply of

Table 1. Euthanasia and other end-of-life decisions in medical practice in Belgium (Flanders), 1996.

	n	%*	Estimates for whole nation, 1996
Total number of deaths (studied) in Belgium (Flanders)	269	100	55,795
No end-of-life decision made	169	62.7	34,983
All sudden and unexpected deaths	95	35.1	19,584
All deaths without end-of-life decision in all non-sudden death situations	74	27.6	15,399
Physician-assisted death	13	4.8	2678
Euthanasia (incl. physician-assisted suicide)	4	1.5	837
Ending of life without the patient's explicit request	9	3.3	1841
Alleviation of pain and symptoms with a potentially life-shortening effect	43	16.0	8927
Shortening the patient's life was not intended	18	6.8	3794
Shortening the patient's life was co-intended	25	9.2	5133
Withholding or withdrawing of a potentially life-prolonging treatment	44	16.5	9206
Shortening the patient's life was not intended	22	8.4	4687
Shortening the patient's life was co-intended	8	2.9	1618
Shortening the patient's life was the explicit intention	14	5.1	2846

* Percentages are based on the total number of deaths studied in the city of Hasselt (n = 269) and corrected for non-response bias.

lethal drugs), among which 1.5 % from euthanasia or physician-assisted suicide, and 3.3 % from the ending of life without the patient's explicit request.
The incidence of the alleviation of pain and symptoms with opioids in doses with a potential life-shortening effect was 16.0%. In 6.8% of all cases the possibility of shortening the patient's life was taken into account, but was not intended. In 9.2% of all cases shortening the patient's life was co-intended (Table 1). Non-treatment decisions occurred in 16.5% of all deaths; in 8.4% of cases the possibility of shortening the patient's life was taken into account, but was not intended; in 2.9 % of cases shortening the patient's life was co-intended; in 5.1 % of cases shortening the patient's life was the explicit intention.

Circumstances relevant to legality and to ethical acceptability

In Table 2 the intentions are related to the different types of end-of-life decisions. When an end-of-life decision was made (n = 101), in 40.6% of the cases the physicians were merely aware of the probable life-shortening effects of their acts. In 32.7% of the cases, the intention to shorten the patient's life was present, together with other considerations (alleviation of pain, treatment of anxiety or respiratory problems, et cetera). In 26.8% of the cases, ending the patient's life was the explicit objective of the end-of-life decision. Thus, in approximately 60% of the cases there was an intention to hasten the patient's death.

Table 2. End-of-life decisions and the physician's intention to shorten the patient's life (n = 269).

	n	%	% of all deaths*
KNOWING that the end of life might be hastened, of which:	41	40.6	15.2
Withholding or withdrawing of a potentially life-prolonging treatment	23	18	22.8
Alleviation of pain and symptoms with a potentially life shortening effect	17.8	8.5	6.7
Life-shortening was CO-INTENTED, of which:	33	32.7	12.3
Withholding or withdrawing of a potentially life-prolonging treatment	8	25	7.9
Alleviation of pain and symptoms with a potentially life-shortening effect	24.7	3.0	9.3
Life- shortening was PRIMARILY INTENTED, of which:	27	26.7	10.0
Withholding or withdrawing of a potential life prolonging treatment	14	13	13.9
Physician-assisted death	12.9	5.2	4.8
TOTAL	101	100	37.3

Chi^2: $p < 0.001$ for end-of-life decision, that is, withholding or withdrawing of treatment or the administration of drugs, versus intention, that is, knowing that the end of life might be hastened, life-shortening was co-intended, or life-shortening was primarily intended.

* Percentages are based on the total number of deaths studied in the city of Hasselt (n = 269) and corrected for non-response bias.

In 71.3% of the cases in which an end-of-life decision was made (n = 96, 5 missing) the physician had neither informed the patient about the intended act, nor discussed it with the patient beforehand. The explicit consent of the patient was obtained in 8.1% of the cases. In 14.0% of cases the intended act was discussed with the patient but no explicit consent for the end-of-life decision was obtained (and perhaps not sought). There was no significant relationship between obtaining the explicit consent of the patient and the type of end-of-life decision.

The reason why the patient was not consulted (n = 74) in 73.5% of such cases was that, in the opinion of the physician, this was not possible. In the remaining 26.5% of the cases, the patient was not consulted or informed, although the physicians thought that it would have been possible. The reasons the physicians most frequently gave for not consulting the patient were: 'because this was clearly the best for the patient' (28.2%), 'diminished consciousness' (26.5%), 'the patient was unconscious' (18.5%), and 'the patient was suffering from dementia' (13.6%). There was no relationship between either consulting or informing the patient or not doing so and the type of end-of-life decision. In 9.8% of the cases in which the patient had not been consulted, there had been an indirect request from the patient at some time. In 15.9% of these cases there was only a request from the patient's family. In the remainder of the cases, there had not even been an indirect request. The frequency of indirect requests was not related to the type of end-of-life decision.

Finally, in about half of the cases in which an end-of-life decision had been made (n = 101) the physician had consulted colleagues before acting (51.0%). The percentage of end-of-life decisions preceded by the consultation of a second physician differs with the type of end-of-life decision, but the relationship was not significant (withholding or withdrawing of a potential life-prolonging treatment: 57.8%; alleviation of pain and symptoms with a potential life-shortening effect: 48.8%; physician-assisted death: 35.7%; Chi^2: $p > 0.33$).

Discussion

From our results we can conclude that end-of-life decisions are predominant in medical practice in the city of Hasselt in Belgium. The preliminary results of the nationwide study in Belgium (Flanders) seem to be similar to the results of the pilot study in Hasselt. In 37.3% of all deaths in Hasselt an end-of-life decision was involved. The strict Belgian law has not prevented physicians from performing euthanasia or making other end-of-life decisions explicitly intended to shorten a patient's life. The estimated incidence of all medical end-of-life decisions 'explicitly' intended to shorten the life of the patient was 10% of all deaths.

Prior to this study, nationwide estimates on the incidence of end-of-life decisions have been made only for the Netherlands, Australia and the United States.[9,10,15,16] Reliable comparisons can only be made between our study and the Dutch studies

because of the shared methodology of the death certificate study (Table 3). Table 3 shows the incidence figures for the Netherlands, Australia and Belgium (Hasselt). However, the Australian data on end-of-life decisions were collected by means of a survey among physicians. Thus, in Table 3 the Australian figures are mainly presented to indicate the (possible) importance of methodological issues. The percentage of deaths preceded by an end-of-life decision in our study is very comparable with the results of the Dutch studies of 1990 and 1995. Furthermore, the estimated incidence of all end-of-life decisions where the physician intended life-shortening was also comparable with the Dutch results. Nevertheless, compared with this neighboring country, in which euthanasia and physician-assisted suicide are tolerated under certain conditions, in Belgium (Flanders) the incidence of euthanasia is lower, but the incidence of ending a patient's life without an explicit request from the patient is much higher (Table 3).

Table 3. End-of-life decisions in medical practice in the Netherlands, Australia and Belgium.

	The Netherlands (%)		Australia (%)	Belgium (Hasselt) (%)
End-of-life decisions	1990*	1995#	1996†	1996
Physician-assisted death:	**2.7**	**3.3**	**5.3**	**4.8**
Euthanasia (incl. physician-assisted suicide)	1.9	2.6	1.8	1.5
Ending of life without the patient's explicit request	0.8	0.7	3.5	3.3
Alleviation of pain and symptoms with a potentially life-shortening effect:	**18.8**	**19.1**	**30.9**	**16.0**
Shortening the patient's life not intended	15.0	16.3	24.4	6.8
Shortening the patient's life co-intended	3.8	2.8	6.5	9.2
Withholding or withdrawing of a potentially life-prolonging treatment:	**17.9**	**20.2**	**28.6**	**16.5**
Shortening the patient's life not intended	9.2	6.9	3.9	8.4
Shortening the patient's life intended	8.7	13.3	24.7	8.0
All deaths with an end-of-life decision	**39.4**	**42.6**	**64.8**	**37.3**

* The percentages are based on the total number of deaths in the Netherlands in 1990 (n = 128,786)[9]
\# The percentages are based on the total number of deaths in the Netherlands in 1995 (n = 135,546)[10]
† The percentages are based on the total number of deaths in Australia between July 1994 and June 1995 (n = 125,771)[15]

Furthermore, comparative data on the competence of the patient, previous consultation of another physician, previous discussion of the decision with relatives or others, and the amount of time by which life was shortened, consistently support the assumption that end-of-life decisions are made with more prudence in the Netherlands than in Belgium.

Important research questions

Based on our research experience in the domain of end-of-life decisions, we think that the following topics deserve more attention in future research.

1. *Assessment of the criteria that physicians apply to define and establish the 'competence' or 'incompetence' of a patient.*

Some studies directly or indirectly address the question of the attitude of patients towards euthanasia or physician-assisted suicide and their competence to face end-of-life decisions. [17-20] Little is known, however, about the ways in which physicians assess 'competence'. According to the Belgian study, most of the end-of-life decisions reported by the physicians did, indeed, concern 'incompetent' patients. However, comparison of the results of the Flemish incidence study with the Dutch studies shows that Flemish physicians have both a certain reluctance to comment on the 'competence' of a patient and a certain bias toward diagnosing patients as 'incompetent'.[7,10] In order to explain these differences, it is necessary to address the question of what standards of capacity the physicians use to define 'incompetence', how they assess patients on the basis of these standards, and how this assessment influences the end-of-life decision-making process. In other words, research on end-of-life decisions should address the 'clinical aspects of competency' more directly.

2. *Patient-physician communication about the end of life under conditions of secrecy and prohibition (versus regulated conditions)*

In Belgium the relative rarity of 'direct' explicit and repeated requests from the patient for life-shortening is frequently related to 'indirect' requests or previous requests made by the patient. Some physicians argue that such requests are valid. Previous verbal requests, it may be argued, closely resemble advance directives.[21] Moreover, indirect requests have the advantage of protecting the physician from the risks of discussing possible illegal intentions. If we want to understand what is going on in exchanges in which indirect and previous requests play a role, and if we want to know whether such requests are valid, it is necessary to study more closely the dynamics of patient-physician communication under conditions of secrecy and legal prohibition. Since most of the data we have on this subject are Dutch, they mainly concern exchanges in – extremely rare – contexts of openness and may under-estimate (as some would say) the ethical quality of decisions made under the veil of legal prohibition.

3. *Research into the role of paramedical personnel and, in particular, nurses.*

In the Belgian study on end-of-life decisions it was found that there was a great involvement of nurses in end-of-life decision-making and practice. For instance, in 35% of all cases of administration of lethal drugs, the actual administration was carried out by nurses, and a further 16% of all cases the nurses assisted the physician and/or the patient with the administration of lethal drugs. Although several studies

have addressed this issue, more comprehensive information is needed about the role of nurses as independent informers of patients and their families, as intermediaries between physicians, patients and their families, and as executors of end-of-life decisions.[22-24]

4. More causal models could be developed

Although advances have been made in the knowledge of what happens at the bed of the dying, less is known about why it happens (the determinants of end-of-life decisions). More complex causal models, integrating several levels of determinants, are needed to explain why a certain type of end-of-life decision is made.[22-24] It may be assumed that decisions in clinical settings are dependent on higher-order arrangements. End-of-life decision-making could be considered to comprise three broad domains of provision and of interlocking regulation, namely the non-treatment area, palliative care, and active life-termination. To explain the epidemiological patterns of end-of-life decision-making, closer attention must be paid to the relationships between the domains of regulation and provision involved in end-of-life decisions. For instance, Belgium and France are increasingly focusing on the provision and regulation of palliative care, preferring to leave the domain of active life-termination uncontrolled yet prohibited, while the medical profession itself is formulating non-treatment regulation. The Netherlands is focusing on legally tolerating, yet administratively controlling active life- termination, relying on a well-established framework of non-treatment regulation, mainly formulated by the medical profession, but perhaps paying less attention to the field of palliative care. The United States, on the other hand, has mainly regulated the area of non-treatment decisions. The explanatory role of these and other higher-level arrangements should be closely examined. In developing causal models, different variables are considered to be important potential determinants of end-of-life decisions: at the personal level (for instance, the opinions and attitudes of physicians); at the organizational level (for instance, the health care organization; the access to health care; the role of professional organizations, such as medical associations, the role of ethics committees and thus of advance directives and deontological codes); at the societal level (for instance, the role of medical training and the role of public opinion). It is clear that many of these challenging aspects of research require an international comparative approach.

5. Comparative international research is needed

Because the Belgian study applied a research design and a study questionnaire which were almost identical to those used in the Dutch studies, valid comparisons can be made. This provides certain opportunities for collaborative research and for comparative analyses, based on the Dutch and the Flemish data. By doing so, some assumptions underlying public health policies can be addressed, for instance, wether a restrictive public policy approach (Belgium) which prohibits euthanasia and physician-assisted suicide, but allows other medical end-of-life decisions, may be justified on the grounds that it is more protective of the rights or interests of patients than a liberal approach (the Netherlands). Nevertheless, only a limited number of studies

have estimated the incidence of various different types of end-of-life decisions and have established the medical and ethical circumstances of these decisions.[7,9,10,15,16] It is clear that more of these studies are needed, especially at the level of states or nations, are needed. The debates on public policy with regard to end-of-life decisions still suffer from the lack of reliable empirical evidence about the actual incidences of end-of-life decisions, as well as about the ways in which health care workers (primarily physicians and nurses) justify these decisions to themselves and to others.

Furthermore, to make valid and reliable comparisons between countries or nations, a co-ordination of the various research designs and questionnaires is needed. Due to disparate research designs, it remains unclear wether the substantial differences in the incidence of end-of-life decisions in Australia and Belgium (or the Netherlands) can be explained by real differences in medical practice in these countries or by the different research designs that have been applied ('survey among physicians' versus 'death-certificate study') (Table 3).

The importance of end-of-life research in society

The finalities of end-of-life research, whether or not epidemiological or clinical, reside in protection of terminal patients' rights or interests, improvement of the quality of life of these patients, and improvement of the quality of the medical care provided at the end of life. Changes in disease patterns in the population, in the nature of the dying process, in medical technology, and in the ways in which society handles death and dying, inevitably induced new, and forcibly experimental, ways of dealing with terminal illness. Although medical institutions and settings are the main theatre for the non-sudden dying process, the issues involved raise intricate questions about the values of life and death and the ways in which society as a whole, including health care workers, should handle them. Hence, end-of-life research is concerned with the professional, institutional, moral and legal regulation of the care provided for the dying, and also the criteria which should be applied to assess the medical, ethical and legal soundness of the guidelines which are formulated for decision-making and conduct. Clinical and epidemiological research on end-of-life decisions, in particular, has a special supportive role in this process of designing and testing both traditional and new guidelines. It focuses, unlike other disciplines, on the empirical reality of end-of-life medical practice. It may study, for instance, the incidence of different end-of-life decisions, the acceptability of the way in which a combination of drugs shortens the dying process of a patient, and the question of whether palliative care which conforms with optimal professional standards is guaranteed to make pain tolerable, et cetera.

However, it should be noted that research of this kind, although focusing on medical practice, is not limited to the establishment of 'medical' facts, but goes even further. It is partly guided by, but also generates results that may be interpreted within ethical, legal, sociological and psychological frameworks. For instance, the fact that a physician discusses a life-shortening decision with a competent patient is not only based on medical considerations, but also on 'ethical' aspects of the physician-patient

exchange. Similarly, the finding that the active termination of a patient's life is burdensome for the physician is based on a psychological fact, and the finding that the majority of the general public (or medical professionals) is in favor of a regulated legalization of euthanasia and physician-assisted suicide refers to an important sociological fact. Hence, strictly medical matters pertain to the domain of clinical and epidemiological research on end-of-life decisions, but ethical and legal reasoning, and the formulation of public policy concerning the end of life are also closely involved.

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Colleen M. Cartwright

Attitudes of Australian Doctors, Nurses and Community Members Towards Physician-Assisted Suicide and Euthanasia[1] [2]

Abstract

Debate about euthanasia and physician-assisted suicide has been increasing in many countries over recent years, including Australia. Recent Australian studies found support for euthanasia ranging from 33 to 60% for doctors, 38 to 77% for nurses, and 65 to 75% for community members. This paper reports on three large postal surveys, which investigated attitudes of doctors, nurses and community members to a range of end-of-life issues. Results are reported for those questions directly related to medical decisions at the end of life, including physician-assisted suicide and euthanasia. Across the three studies responses to the 38-page questionnaire were received from almost 3000 participants. Response rates ranged from 76% for health professionals in the first study to 50% for community members in the third study. A majority of respondents said that, if asked by a competent patient, doctors or nurses should (a) give additional pain relief even if they believe that this will hasten the patient's death; and (b) turn off a life-support machine. There was strong support from community members for the legalization of physician-assisted suicide/euthanasia, moderate support from nurses, but much less support from doctors. Qualitative data indicated that these are complex issues, requiring further discussion and investigation.

Debate about euthanasia and physician-assisted suicide has been increasing over recent years and include arguments for and against legalization of these actions. An aging population in many countries, increasing health care costs and use of technology to sustain life/prolong dying has added urgency to these debates. Australia, although geographically distant to the United States and Europe where much of the discussion has taken place, has not been isolated from the debates. Australia is a federation of six states and two territories. Health law is the responsibility of each state or territory. However, the territories do not enjoy the same degree of autonomy accorded to the states and their laws are subject to veto by the Federal government. In recent years bills which would

[1] Funding: Study 1 – National Health and Medical Research Council; Study 2: General Practice Evaluation Programme, Commonwealth Government. Co-researchers in these studies were: MA Steinberg and GM Williams (all studies); J Najman (Qld 1 and NT); R Hoffenberg and MJ Clarke (Qld 1); MH Parker and C Del Mar (Qld 2); G Robinson and WB Tyler (NT).

legalize physician-assisted suicide and/or active voluntary euthanasia have been presented to several state and territory parliaments, but have either been rejected by the parliament or have lapsed when an election was called. On 1 July 1996, the Northern Territory of Australia became the first place in the world to enact legislation which allowed both physician-assisted suicide and euthanasia (the *Rights of the Terminally Ill Act (1995)* (ROTI)). The legislation was subsequently overturned by the Federal Government in March 1997, with the *Euthanasia Laws Act*. (Note: Had the legislation been passed by one of the states, the Federal government could not have overturned it).

Studies on attitudes and practices

A number of studies undertaken in Australia during the past decade assessed attitudes to physician-assisted suicide and/or euthanasia.[1-13] (Table 1). Support for euthanasia ranged from 33 to 60% for doctors,[1,4,6-12] and 38 to 77% for nurses.[3,5,6,12,13] Support from patients or community members for legislation allowing physician-assisted suicide and euthanasia ranged from 65 to 75%.[6,9,12] In 1991, Owen, Tennant and colleagues found that, of 105 oncology patients interviewed at a major teaching hospital, 'one third ... anticipated some role for taking active steps to end their own lives'. In addition to these studies, Morgan Gallop Polls, repeated regularly in Australia since 1962, have shown increasing community support for legalizing euthanasia (from 47% in 1962 to 76% in 1996).[14]

In their 1987 study of Victorian doctors, Kuhse and Singer[1] found that 40% had been asked to hasten death, 29% had taken active steps to bring about the death of a patient who had asked them to do so (the majority on more than one occasion), and 93% of doctors who had been asked for assistance to die considered that such requests are sometimes rational. In their study of Victorian nurses in 1991,[3] it was found that 55% of respondents had been asked by patients for assistance to end their lives either by permitting the patient to forego life-sustaining measures or by active assistance to end life. Only 5% said that they had complied with the request without having been asked by a medical practitioner to do so.

In both studies the main reasons for such requests were persistent and unrelievable pain and terminal illness and infirmities of old age, with terminal cancer being the medical condition most often mentioned. Fifty nine percent of the doctors and 75% of the nurses thought that it would be a good thing if Australia had a system such as exists in the Netherlands; 60% of doctors and 78% of nurses thought that the law should be changed to allow doctors to take active steps to bring about a patient's death under some circumstances, and 40% of doctors and 65% of nurses said that they would be willing to be involved in active voluntary euthanasia if it were legal.

When Baume and O'Malley repeated the Kuhse and Singer study with doctors in New South Wales in 1993[4] they found that almost half of the 1268 respondents had been asked to perform euthanasia, of whom 28% had complied, and there was majority support for changes to the law.

The use of specific scenarios to determine doctors' practices was the method employed by Waddell and colleagues in 1996.[8] They requested doctors to select from a range of treatment options for specific patients and conditions; for instance, one scenario described a 56-year old man with motor neurone disease who requested

Table 1. Australian research on attitudes to physician-assisted suicide and euthanasia.

Year	Researchers	Subjects (n)	Response rates (%)	Support for change of law (%)	Other positive responses (%)
1987	Kuhse and Singer	2000 Victorian doctors	46	60	
1991	Owen, Tennant and colleagues	105 New South Wales oncology patients	63		34
1991	Kuhse and Singer	1942 Victorian nurses	49	78	
1993	Baume and O'Malley	1945 New South Wales doctors	65	58	
1994	Aranda and O'Connor	380 Victorian palliative care and oncology nurses	45	50	
1994	Steinberg, Cartwright and colleagues	1092 Queensland public;	53	65	
		277 Queensland doctors,	76	43	
		569 Queensland nurses and 14 other palliative care staff			
1995	Hassan	494 South Australian doctors	60	44	
1995	Waddell, Clarnette and colleagues	2172 doctors across Australia	73	NA	15
1996	Steinberg, Parker, Cartwright and colleagues	581 Queensland patients;	67	65	
		287 Queensland family physicians	60	33	
1996	Wilson, Kay and Steven	1108 family physicians across Australia	80	56	
1996	Kuhse, Singer and colleagues	3000 doctors across Australia	64	NA	30
1997	Cartwright, Robinson and colleagues	1069 Northern Territory public;	50	75	
		343 Northern Territory doctors	51	35	
		415 Northern Territory nurses	59	66	
1997	Kitchener and Jorm (Scenarios)	2000 Australian Capital Territory nurses	61	38-71	

NA, not asked

physician-assisted suicide. Only 14% of respondents indicated that they would provide physician-assisted suicide or euthanasia for this patient, while 84% would provide palliative care only. Scenarios presented to nurses in the Australian Capital Territory by Kitchener and Jorm in 1997[13] found that, among approximately 1200 nurses who responded, 38% supported a change in the law to allow active voluntary euthanasia for a young man with AIDS, 39% for an elderly man with early stage Alzheimer's disease, 44% for a young woman who had become quadriplegic, and 71% for a middle-aged woman with metastases from breast cancer.

In 1996, Kuhse and colleagues[11] found that 800 of 1918 responding doctors had made end-of-life decisions for patients, that 26 said that they had performed euthanasia, and that 51 reported ending the patient's life without the patient's explicit request. The proportion of all Australian deaths that involved a medical end-of-life decision were: euthanasia, 1.8% (including physician-assisted suicide, 0.1%); ending of a patient's life without this patient's concurrent explicit request, 3.5%; withholding or withdrawing of potentially life-prolonging treatment, 28.6%; alleviation of pain with opioids in doses large enough that there was a probable life-shortening effect, 30.9%. In 30% of all Australian deaths, a medical end-of-life decision was made with the explicit intention of ending the patient's life, of which 4% were in response to a direct request from the patient. Overall, Australia had a higher rate of intentional ending of life without the patient's explicit request than the Netherlands.

The Queensland and Northern Territory Studies

Between 1994 and 1997 three studies were undertaken by researchers from the University of Queensland to assess the attitudes of doctors, nurses and the general community to a range of issues relating to end-of-life decision making. Two of the studies were conducted in Queensland[6,9] and one in the adjoining Northern Territory.[12] Two researchers from the Northern Territory University joined the research team for the latter study. Throughout this paper the studies will be referred to as Qld 1, Qld 2 and NT. The NT study was conducted while the ROTI Act was still in force.

Questionnaire development

Using data from focus groups and key informant interviews with representatives of medical, nursing, ethics, legal, general and older community groups and additional information from the relevant literature, three base-line questionnaires were developed (medical, nursing and community) (Qld 1). To ensure that questions were not biased, each question had to pass an advisory committee in which members' attitudes towards physician-assisted suicide and euthanasia were widely disparate. Emotive terms such as 'intolerable pain' or 'unbearable suffering' were avoided. The questionnaires were piloted, and slight amendments made for specific professional or age groups.

Additional interviews were held with family physicians and patients for Qld 2 study and with Northern Territory health professionals and community members for the NT study. Questionnaires from Qld 1 were amended as necessary for the subsequent studies. Topics covered in the questionnaires included advance directives, enduring power of attorney for health matters, doctor-patient communication, pain management, palliative care, physician-assisted suicide, euthanasia, legal and administrative matters and demographics (34-40 page questionnaires).

Sample Selection

Qld 1 study

- The health professional sample included the Director of Nursing of every nursing home in Queensland, two groups of community nurses, all members of the Queensland Critical Care Nurses Association, all members of the Queensland Palliative Care Association, two groups of family physicians, all Brisbane-based members of the Australian Society for Geriatric Medicine, and 10% each of the Brisbane membership of the Colleges of Physicians, Surgeons, Anesthetists and Psychiatrists, randomly sampled from lists provided by the Colleges (total n = 1184). After deleting those who were overseas, had left the profession or were included in more than one database, the final eligible sample was 1129.
- For the community, a stratified random sample of 1100 was drawn from the 1995 Queensland Electoral Role. As these issues are considered to be of greater concern to older people, 700 of the sample were aged 60 and above, stratified by age and sex to match the Queensland 1991 Census. Eight of the 1100 were in a nursing home, leaving a final eligible sample of 1092.

Qld 2 study

- 305 family physicians from Brisbane (n = 241) and Toowoomba, a large rural city (n = 64), were randomly sampled from all family physicians in those areas who had a consultation rate of 3000 or more in the previous year. Of these, eighteen were overseas, deceased, interstate or no longer practicing, leaving a final eligible sample of 287.
- From a random sample of 31 of the 172 family physicians who returned questionnaires, 626 patients who had been seen in the previous twelve months were randomly sampled from appointment records. Of these 45 were non-contactable, too ill or frail, deceased or under eighteen, leaving an eligible sample of 581 patients (Brisbane, n = 348; Toowoomba, n = 233).

NT study

- All medical practitioners registered in the Northern Territory, with the exception of those known to be radiologists or pathologists, were included in the sample (n = 480). Of these, 137 were no longer in the Northern Territory, not at the address given, overseas, interstate or had left the profession, leaving an eligible sample of 343. (Note: in the Northern Territory living conditions are sometimes quite difficult and the population is particularly mobile. It also tends to have a more transient health professional population).
- From the approximately 2000 nurses registered in the Northern Territory at 1 July 1996, 448 were randomly sampled. Of these, 33 were no longer living in the Northern Territory or not at the address given, or were no longer nursing, leaving an eligible sample of 415.
- The Commonwealth Electoral role for the Northern Territory was used as the sampling frame for the community sample. As the use of questionnaires was consid-

ered an inappropriate method for data-collection with the Aboriginal community, remote areas of the Northern Territory were not included in the study. A random sample, stratified by area and age, resulted in the selection of 1298 community members. Of these, 229 were not contactable, too ill or frail, spoke insufficiently English or were deceased, giving a final eligible sample of 1069. (Note: the mobility of the population made it impossible to accurately determine how many of the remaining sample actually received their questionnaires, but they remained in the base-line total).

Definitions

The following definitions were used in the 3 studies:

Palliative care does not aim to cure patients but aims to care for them, physically keeping them as comfortable and pain-free as possible, while also attending to their emotional, mental, social and spiritual needs. Palliative care also includes caring for the patient's family and/or significant others, including during the time following the death of the patient.

Persistent vegetative state: a person will be considered to be in a persistent vegetative state (PVS) if, over a period of not less than twelve months there has been no return of cognitive, behavioral or verbal responses, no purposive motor responses or other evidence of voluntary motor activity; appropriate clinical and investigative diagnosis has been undertaken, and the diagnosis of PVS is based on repeated observation by the physician responsible for the care of the patient.

Physician-assisted suicide refers to such things as the physician giving a person advice about how to commit suicide, giving the person a prescription for medication to use for suicide, preparing a mixture for the person to take to commit suicide and/or setting up equipment for the person to use to commit suicide. It does *not* include performing the action, such as giving the person an injection of the drugs.

Euthanasia means taking active steps to end the life of another person, at that person's request, for what they see as their best interests. Active euthanasia refers to an action such as giving the person an injection of medication sufficient to cause the death of that person.

Response rates

Across the three studies responses to the 38-page questionnaire were received from almost 3000 participants. Response rates [6(b), 9, 12(b)] ranged from 76% for health professionals in Qld 1 to 50% for community members in the NT study (Table 1). The age distribution of community members was similar in Qld 2 and NT; Qld 1 had more older respondents because of the sampling process.

Results

The studies asked questions about a range of end-of-life issues, from advance health directives and enduring power of attorney, through pain management and palliative

care to physician-assisted suicide and euthanasia. Results are reported in this paper only for those questions directly related to medical decisions at the end of life, including physician-assisted suicide and euthanasia.

Pain relief in terminal illness

Participants in all three studies were asked the following question: *'It is recognized that using large doses of morphine may hasten a person's death. If a terminally ill patient requests extra medication to control pain should the doctor give the medication, even if they know that this will hasten the patient's death?'* Participants were also asked if the nurse should give the medication if it has been ordered p.r.n. A majority of respondents in all three studies said 'yes' to these questions (Table 2).

Stopping life support for a competent patient

Participants in all three studies were asked: *'If a competent person is being kept alive by a life support system (such as a respirator) and that person asks for the machine to be turned off, do you think the doctor should comply with that request?'* A majority of respondents in all studies said that doctors should turn off the machine when asked to do so by a competent person. Those who did not say 'yes' to this question were more likely to say 'not sure' than to say 'no' (Table 2). Nurses were more likely than doctors to say 'yes' to this question.

Table 2. Should a doctor or nurse give extra morphine, or should a doctor switch off the machine, at the request of a competent terminally ill patient?

	QLD 1		QLD 2		NT	
	Health professionals (n = 821) % replying 'yes'	Community members (n = 475) % replying 'yes'	Family physicians (n = 168) % replying 'yes'	Patients (n = 379) % replying 'yes'	Health professionals (n = 407) % replying 'yes'	Community members (n = 522) % replying 'yes'
Doctor should give morphine	96	85*	94	91	95	87
Nurse should give morphine	91	*	80	74	88	71
Doctor should switch off machine	(n = 847) %	(n = 475) %	(n = 167) %	(n = 382) %	(n = 406) %	(n = 529) %
Yes	65	72	56	72	58	71
No	9	10	14	11	12	13
Not sure	26	18	30	17	30	16

* Combined question: 'should doctor/nurse give the medication?'

Persistent vegetative state

Health professionals in Qld 1 and the NT study and community members in the NT study were asked: '*If a patient has been in a persistent vegetative state for more than twelve months, should (a) artificial respiration be stopped?; (b) artificial nutrition be discontinued?; and (c) artificial hydration be discontinued?*' There was very strong agreement from all three groups that artificial respiration should be discontinued (Qld 1 health professionals, 93%; NT health professionals, 89%; NT community members, 87%). For artificial nutrition the agreement was 75%, 72% and 75%, respectively. Although 76% of the NT community members also said that artificial hydration should be discontinued, there was less agreement about this among the health professionals with 61% for Qld 1 and 59% for the NT study. In both Qld 1 and the NT, nurses were less likely than doctors to say that these options should be discontinued, and in Qld 1 this difference was significant.

Physician-assisted suicide

There is often confusion, particularly in the general community, about the difference between physician-assisted suicide and euthanasia. In these studies the terms were clearly defined and participants in all three studies were then asked: '*If a terminally ill person has decided that his life is of such poor quality that he would rather not continue living, do you think a doctor should be allowed by law to assist such a person to die?*' The majority of respondents in the three studies said 'yes' to this question. In Qld 1 and the NT study, health professionals were more likely to say 'yes' than 'no'; however, these two groups included nurses who were more likely than doctors in both studies to say 'yes'. In the Qld 2 study, family physicians were much more likely to say 'no' than 'yes' (Table 3).

Active voluntary euthanasia

In the two Queensland studies participants were asked '*Do you think the law should be changed to allow active voluntary euthanasia for terminally ill people who decide that they no longer wish to live?*' (Note: this question made no mention of pain or suffering). Community members' and patients' responses were very similar in both studies (Table 3) with 65% in both cases supporting a change in the law. Again family physicians (Qld 2) were the least supportive of this option, with more family physicians saying 'no' than 'yes'. In the Qld 1 study, more health professionals said 'yes' than 'no' to the option of changing the law. However, this study included nurses, and for this question critical care nurses were much more likely to support a change in the law, with 61% in favor of doing so; 50% of the Directors of Nursing of nursing homes also supported a change in the law.

As the *Rights of the Terminally Ill Act* was still in operation in the Northern Territory at the time the study was conducted there, the question asked in the Queensland studies did not apply. Participants were therefore asked: '*To what extent do you approve of the law that was recently passed in the Northern Territory which allows a terminally ill person to request physician-assisted suicide or euthanasia?*'.

Table 3. Should a doctor be allowed by law to assist a terminally ill patient to die, and should the law be changed to allow active voluntary euthanasia for terminally ill people?

	QLD 1		QLD 2		NT	
	Health professionals (n = 844) %	Community members (n = 487) %	Family physicians (n = 166) %	Patients (n = 384) %	Health professionals (n = 414) %	Community members (n = 531) %
Should doctor assist patient to die?						
Yes	43	60	30	62	59	73
No	34	23	49	21	27	18
Not sure	23	17	21	17	14	9
Should law be changed to allow euthanasia?	(n= 848) %	(n = 481) %	(n = 168) %	(n = 384) %	(Not applicable – law had been changed in NT)	
Yes	43	65	33	65		
No	36	19	48	21		
Not sure	21	16	19	14		

Responses were on a five-point scale from 'strongly approve' to 'strongly disapprove'.

Of the community members, 75% either strongly approved or approved of the new legislation, 18% disapproved or strongly disapproved and 7% neither approved nor disapproved; for health professionals 53% either strongly approved or approved, 31% disapproved or strongly disapproved and 16% neither approved nor disapproved. However, once again it was the responses of nurses that impacted on these figures, with 66% strongly approving or approving of the legislation, compared with only 35% of the doctors.

Qualitative data from the studies illustrated the complexity of professional and community responses. For instance, two doctors in the NT study who marked the 'strongly disapprove' option for attitude to the ROTI law, wrote: (1) 'I'm not opposed to euthanasia. I just don't think we should hand such a can of worms to lawyers and bureaucrats'; and (2) 'I've been helping my patients with this for years but we don't need a law about it'. They *strongly disapproved* of the legislation, but not necessarily of euthanasia per se. One Northern Territory community member who *strongly approved* of the ROTI law said: 'Tell the Federal Government to keep out of our business', adding further uncertainty to the analyses, as it was unclear whether Northern Territory community respondents approved of a law allowing euthanasia, or simply supported their right to pass such a law.

Younger community members in the Qld studies were the most likely to support physician-assisted suicide and euthanasia. As the Qld 1 study had been over-sampled for older people, community responses in this study were weighted to reflect the actual age composition of the population, resulting in an increase in support for

physician-assisted suicide from 60 to 65% after weighting, and from 65 to 70% for euthanasia. In the NT study, respondents over 60 were somewhat less likely than those under 60 to support both options, but responses were not age-linear: in both cases those aged 30 to 39 were the most likely to support both physician-assisted suicide and euthanasia.

Palliative care and pain management

As opponents of physician-assisted suicide and euthanasia frequently claim that good palliative care and pain management would obviate the need for these options, optimal palliative care was defined and participants were asked two questions: in the two Queensland studies they were asked (1) '*If good palliative care were freely available to everyone who needed it, do you think anyone would ever ask for assistance to end their lives?*', and (2) '*If it were always possible to control a person's pain, in a terminal care situation, do you think anyone would ever ask for euthanasia?*'.

Respondents in both studies said that people would still ask for assistance to end their lives, even if good palliative care were freely available and that people would still ask for euthanasia even if pain could be controlled (Table 4). Health professionals and family physicians were more likely to say 'yes' to these questions than community members and patients were.

Table 4. If good palliative care were freely available would anyone ever ask for assistance to die, and if pain were controlled would anyone ever ask for euthanasia?

	QLD 1		QLD 2	
	Health professionals (n = 840) %	Community members (n = 471) %	Family physicians (n = 170) %	Patients (n = 378) %
With good palliative care, would anyone ask for assistance to die?				
Yes	70	68	72	62
No	30	32	28	38
If pain were controlled would anyone ask for euthanasia?	(n = 849) %	(n = 479) %	(n = 170) %	(n = 386) %
Yes	61	45	65	46
No	20	30	22	29
Not sure	19	25	13	25

These two questions received some criticism, particularly from health professionals, because of the 'do you think *anyone* would *ever*...' wording and were therefore amended in the NT study, as follows: (1) '*If good palliative care were freely available to everyone who needed it, approximately what percentage of patients do you*

think would still ask for assistance to end their lives?', and (2) *'If it were always possible to control a person's pain, in a terminal care situation, approximately what percentage of patients do you think would request euthanasia?'*.

Only 8% of both health professionals and community members said that no-one would ask for assistance to end their lives and only 9% of health professionals and 13% of community members thought that no-one would ask for euthanasia. However, community members were significantly more likely than health professionals to believe that more than 20% of patients in each case would ask (Table 5).

Table 5. Palliative care and pain control (NT study only).

	n	None	1-5	6-10	11-20	21-50	>50
With good palliative care what percentage of patients would ask for assistance to die?							
Health professionals	389	8	43	16	13	13	7
Community members	411	8	16	13	12	22	29
With good pain controle what percentage of patients would ask for euthanasia?							
Health professionals	394	9	48	17	14	7	5
Community members	491	13	20	16	16	19	16

Religion and religiosity

Religion is thought to significantly impact on attitudes towards physician-assisted suicide and euthanasia. In these studies, health professionals who were Catholic were most likely to disapprove of euthanasia and physician-assisted suicide; those who said they had no affiliation were most likely to approve of these options. For community members, extent of religious beliefs rather than religious affiliation predicted their responses, with those who said that their religious beliefs influenced them a great deal most likely to disapprove of physician-assisted suicide and euthanasia, and those whose religious beliefs influenced them not at all most likely to approve of these options.

Doctor-patient relationship

Concern is also sometimes expressed that if euthanasia becomes a legal option it would negatively impact on doctor-patient relationships: most respondents in these studies did not think that laws allowing physician-assisted suicide and euthanasia would harm the trust between doctors and patients; most thought that such laws would open up discussion of end-of-life issues between doctors and patients.

Conclusion

In Australia there is broad health professional and community support for some medical decisions at the end of life, that is, providing adequate pain relief to patients even if that subsequently hastens the patient's death; withdrawing life-support systems when a competent patient requests this; withdrawing artificial ventilation and nutrition from a patient who has been in a persistent vegetative state for at least twelve months. There was slightly less support, although still majority support, for withdrawing artificial hydration.

There is strong support among community members for legislative change to allow physician-assisted suicide and active voluntary euthanasia. However, health professionals were divided on the matter; nurses are more likely to favor such change while the majority of doctors are opposed to it. The qualitative data highlighted the fact that simple 'yes' or 'no' responses to questions on such complex issues may be misleading. Those who oppose euthanasia legislation may not be anti-euthanasia. Similarly, some who support such legislative change may be following other agendas. It would also be too easy to portray doctors who oppose such actions as paternalistic or not wanting to relinquish control of end-of-life decisions to patients; or to portray nurses as more compassionate, with better understanding of patient and family needs. However, further analysis of the qualitative data in these studies suggested that many doctors have deep concern for the well-being of patients, and of the wider community, and believe that legislation allowing physician-assisted suicide and euthanasia is fraught with difficulties, especially for older people who may be seen (or see themselves) as a burden.

Important research questions

Further in-depth research is required to understand 'the attitudes behind the attitudes' expressed in these studies. The research team has secured funding to carry out such research. Questions to be addressed include:

1. What factors, other than religious beliefs, influence attitudes to euthanasia and physician-assisted suicide?
2. What do health professionals and the general community understand the terms 'euthanasia' and physician-assisted suicide' to mean?
3. Would legalizing physician-assisted suicide and euthanasia lead to more, or fewer instances of these actions?
4. What are the attitudes and concerns of indigenous Australians? There is a serious lack of data in this area.

More research is required in Australia with terminally ill people. Although a small amount has been done,[2] there are major practical and ethical constraints on discussing such matters with those who are terminally ill. To address concerns that allowing active voluntary euthanasia will create a 'slippery slope' leading to non-voluntary or involuntary euthanasia, accurate figures are required about the current rate

of physician-assisted suicide and euthanasia in Australia and the number of patients who currently want these options but are unable to access them. There are two barriers to obtaining such information: firstly, as these actions are illegal many health professionals and community members will be reluctant to acknowledge their involvement in them, even where confidentiality is assured; secondly, confusion exists in the minds of many people about what is, or is not, euthanasia. Some respondents in our studies said that they had been involved in euthanasia but their description of the event made it clear that what they thought was euthanasia was not.

International collaboration in such research will help to ensure that terminology and methods are consistent, and will also avoid duplication of research efforts. The National Health and Medical Research Council in Australia encourages researchers to collaborate across disciplines and locations.

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Bregje D. Onwuteaka-Philipsen

Euthanasia in the Netherlands: Incidence, Circumstances and Quality Assurance[1]

Abstract

In the Netherlands, euthanasia and physician-assisted suicide are still subject to the penal code, but if the requirements for prudent practice are met, a physician can expect not to be prosecuted. This chapter will present data on the incidence of euthanasia and physician-assisted suicide, the circumstances under which it takes place and the quality assurance of its practice. In both 1990 and in 1995, nationwide studies were carried out to address these topics. They consisted of a death certificate study, in which the attending physicians of a stratified sample of deaths received a questionnaire, and interview study, in which a stratified sample of physicians were interviewed about their experiences with end-of-life decisions. Furthermore, the results of the evaluation of the project 'Support and Consultation on Euthanasia in Amsterdam' (SCEA), a project aimed at professionalizing consultation of another physician in cases of euthanasia, are described.

In the Netherlands, in 1995 approximately 9700 explicit request for euthanasia were made, resulting in some 3600 cases of euthanasia or physician-assisted suicide. This is a slight increase compared to 1990, but there are no indicators to suggest that there is an increase in the practice of euthanasia and physician-assisted suicide among vulnerable patient groups. In 1990, 18% of all cases were reported to the Public Prosecutor, whereas in 1995, 41% of all cases were reported. The SCEA project supported family physicians and increased the quality of consultations. Therefore networks like SCEA are being set up all over the country.

In the Netherlands, euthanasia and physician-assisted suicide are still subject to the penal code, but if the requirements for prudent practice are met, a physician can expect not to be prosecuted.[1] These requirements include:

- the patient's request should be well-considered, voluntary and persistent
- the patient's suffering should be unbearable and hopeless
- there should be no acceptable alternatives for (palliative or curative) treatment

[1] This paper is largely based on research work carried out by Jacqueline Cuperus-Bosma, MD, PhD, Ilinka Haverkate, PhD, Agnes van der Heide, MD, PhD, Paul J. van der Maas, MD, PhD, Gerrit van der Wal, MD, PhD, and Dick Willems, MD, PhD.

- the physician should consult another physician
- the physician should report the case as described in the notification procedure.

To establish a mechanism for public oversight, a notification procedure has been in use since 1991 and was enacted legally by the Dutch legislature in June 1994. According to this procedure, a physician who has assisted in a patient's death does not issue a certificate of natural death, but instead informs the coroner that it was a physician-assisted death. The coroner conducts a postmortem examination, collects the relevant data, informs the Public Prosecutor of the death, and submits all the relevant documents. The Public Prosecutor presents the case, together with his or her own opinion, to the Assembly of Prosecutors General. The assembly provisionally decides whether or not to prosecute. The Minister of Justice makes the final decision with regard to prosecution.

Several studies on euthanasia and physician-assisted suicide have been conducted in the Netherlands in the last decade. During the period 1990-1991, a nationwide research project commissioned by the Remmelink Committee studied the incidence and circumstances of euthanasia and other medical end-of-life decisions.[2,3] During the same period, other studies were carried out among large numbers of family physicians and nursing home physicians.[4-7] During the period 1995-1996, a second nationwide study took place, not only focusing on the incidence and circumstances of euthanasia and other medical end-of-life decisions, but also on changes that took place between 1990 and 1995, and on the evaluation of the notification procedure.[8,9] Various international publications have been based on these studies.[10-35] In this context some qualitative research projects also have to be mentioned.[36,37] Finally, in 1997, a research project started, in which a new way of organizing the consultation of another physician, the project Support and Consultation on Euthanasia in Amsterdam (SCEA), was evaluated.[38,39]

This chapter will present data on the incidence of euthanasia and physician-assisted suicide, the circumstances in which it takes place and the quality assurance of its practice. It will mainly be based on data from the 1995 nation-wide study, where useful compared to the data obtained in 1990, but will also include data from the SCEA project when discussing quality assurance.

Methods of the 1995 study

Definitions

Euthanasia is defined as 'the administration of drugs with the explicit intention of ending a patient's life, at the patient's explicit request'. Physician-assisted suicide was defied as 'the prescription or supply of drugs with the explicit intention of enabling a patient to end his or her own life'.

Study design

For the 1995 study, data were collected in two sub-studies. In the 'death certificate study' questionnaires were sent to a stratified random sample of physicians attending

deaths, identified from death certificates. In the 'interview study' a stratified random sample of physicians was interviewed. The two studies were designed to generate complementary information, with the interviews producing more detailed background information and the death certificates study providing a strong quantitative framework. The study design of the 1990 Remmelink study was similar to that of the 1995 study and is described in more detail in this volume by Van der Heide.

Study population

The death certificate study consisted of a stratified sample taken from all approximately 43,000 deaths that occurred from 1 August through 1 December, 1995. Each death was assigned to one of five strata on the basis of the likelihood that an end-of-life decision was involved. This likelihood was based on the cause of death (for instance, no end-of-life decision could have been made if a person had died instantly in a car accident). The sample consisted of 50% of the cases in stratum 4 (greatest likelihood), 25% of the cases in stratum 3, 12.5% of the cases in stratum 2, 8.3% of the cases in stratum 1 and 8.3% of the cases in stratum 0. The response rate was 77% with 5146 questionnaires being returned.

In the random sample included in the interview study, physicians were stratified according to their specialty: 124 family physicians, 74 nursing home physicians and 207 physicians from five specialist fields of medicine (cardiology, surgery, internal medicine, pulmonology and neurology). In order to achieve the desired number of 405 interviews, a sample of 559 physicians was taken: 83 did not meet the selection criteria, and 21 either had a chronic illness or could not be located. Of the remaining 455 physicians, 50 were unwilling to participate (11%). The main reason for non-response was lack of time.

Measurement instruments

The questionnaire used in the death certificate study consisted of 24 structured questions. Four types of questions were asked: (1) what did the physician do (or not do)?, (2) what was his or her intention in doing so?, (3) was the physician's decision made at the request of the patient or after discussions with the patient?, and (4) was the patient competent? By classifying the responses it was possible to determine whether, and if so, which, medical decision(s) concerning the end of life were taken. Furthermore, questions were also asked about other topics, such as discussions with colleagues and other people involved. Approximately 30 experienced and specifically trained physicians conducted the interviews. The questionnaire, which mainly consisted of open-ended questions, contained approximately 120 pages, and the interviews lasted for 2,5 hours on average. Because of the controversial nature of the subject, anonymity was emphasized. The death certificate study was completely anonymous. In the interview study, the interviewers signed a declaration with regard to confidentiality, which was given to the respondents. Moreover an arrangement was made with the Minister of Justice, which guaranteed that the research data would never be made available to the Public Prosecutor for judicial purposes.

Analysis

Because of the stratified samples, proportions and 95% confidence intervals for these proportions were obtained by using the method of direct standardization in order to adjust for marked variation among the different types of physicians (interview study) and the probability of the various types of decisions in each stratum (death certificate study).

Methods of the evaluation of the SCEA project

SCEA

The project was based on two services that SCEA offered to family physicians in Amsterdam: providing information and advice on all possible aspects of euthanasia and physician-assisted suicide, and providing specifically trained physicians for formal consultation. The SCEA physicians (all family physicians) followed a three-day training program in which not only the necessary skills, but also knowledge about the requirements for prudent practice, palliative care and medico-technical aspects of euthanasia and physician-assisted suicide were addressed. During consultations the SCEA physicians worked according to a protocol that was specifically developed for this project. If necessary, they could contact a member of a team of experts (for instance, an oncologist, a psychiatrist, a lawyer, an ethicist, a pastor) for extra information. Each week, two of the twenty SCEA physicians were on call, and could be reached 24 hours a day through a special telephone number. Both before and during the study period the project was brought to the attention of the family physicians by special mailings and short notices in the newsletter issued by the Amsterdam Association of Family Physicians. The project started with a test period on 1 April 1997, was officially implemented on 1June 1997 and ended on 1 June 1998. The goals of SCEA were supporting family physicians and improving the quality of consultation, improving the quality of medical-professional decision-making and performance of euthanasia and physician-assisted suicide, and increasing the willingness to report cases of euthanasia and physician-assisted suicide. The questions of the evaluation study were wether the implementation had been successful and whether the goals of SCEA were met.

Design

The design of the study was observational. All family physicians in Amsterdam received a written questionnaire at the end of the study period. During the study period, registration took place in various ways: SCEA physicians filled in a registration form for every contact they had, and family physicians who contacted SCEA for a consultation received a questionnaire. The number of reported cases of euthanasia and physician-assisted suicide performed by family physicians in Amsterdam were derived from the records of the Public Prosecutor.

Population

All family physicians registered in Amsterdam (who were not SCEA physicians and who had been registered for at least one year, n = 376) received a questionnaire. Subsequently, sixteen were excluded because of retirement or prolonged illness; 260 family physicians returned the questionnaire (72%). Of the 84 questionnaires given by SCEA physicians to family physicians who contacted them for consultation, 71 were returned (85%).

Measurement instruments

An anonymous postal questionnaire, mainly consisting of pre-structured questions, was sent to the family physicians in the summer of 1998. The questionnaire contained questions about background characteristics, the family physician's experience in performing euthanasia and physician-assisted suicide, the last time the family physician had granted a request for euthanasia and physician-assisted suicide during the study period, if any, the last time the family physician had refused a request for euthanasia and physician-assisted suicide during the study period, if any, the family physician's experience of acting as a consultant, opinions on consultation, and experiences with and opinions about SCEA

Analysis

To investigate the association between the use of SCEA and the quality of consultation and medical-professional decision-making and performance, consultations by SCEA physicians (questionnaire given to family physicians who consulted a SCEA physicians and who performed euthanasia or physician-assisted suicide, n = 54) were compared with consultations by other consultants (most recent case of euthanasia and physician-assisted suicide during the intervention period, n = 43).

Results

Incidence

Table 1 shows the incidence of euthanasia, physician-assisted suicide and, to put these figures in perspective, other end-of-life decisions in the Netherlands. In 1995, in 42% of all deaths an end-of-life decision was taken; in 2.4% of all deaths this was euthanasia and in 0.3% this was physician-assisted suicide. The corresponding figures for 1990 were 38%, 1.8% and 0.3%, respectively.

Not all requests for euthanasia result in the actual performance of euthanasia or physician-assisted suicide. In 1995, approximately 34,500 requests were made for euthanasia or physician-assisted suicide 'at a later time' (about 25,100 in 1990) and 9700 explicit requests for euthanasia or physician-assisted suicide (8900 in 1990) were made, whereas euthanasia was performed approximately 3200 (2300 in 1990) and physician-assisted suicide occurred approximately about 400 times (400 in 1990). When euthanasia or physician-assisted suicide was explicitly requested but

not performed, in about half of the cases it was because the physician refused the request, and in about half of the cases it was because the patient had already died.

Table 1. Euthanasia and other end-of-life decisions in the Netherlands, 1990-1995.

	1995		1990	
	n	%	n	%
Total number of deaths in the Netherlands	135,500	100	128,800	100
No end-of-life decisions made	78,600	58	79,800	62
Sudden and unexpected death	42,000	31	38,600	30
Other deaths without end-of-life decision	36,600	27	41,200	32
Physician-assisted death	4500	3.4	3700	2.9
Euthanasia	3200	2.4	2300	1.8
Physician-assisted suicide	400	0.3	400	0.3
Ending of life without the patient's explicit request	900	0.7	1000	0.8
Alleviation of pain and symptoms with possible life-shortening effect	25,100	18.5	22,500	17.5
Partly with the intention of hastening death	4100	3	4,500	3.5
Taking into account the probability or certainty that death will be hastened	21,000	15.5	18,000	14
Withholding or withdrawing life-prolonging treatment	27,100	20	22,500	17,5
With the explicit intention of hastening death	17,600	13	11,000	8,5
Taking into account the probability or certainty that death will be hastened	9500	7	11,500	9

Of the interviewed physicians, 77% had at some time received an explicit request for euthanasia or physician-assisted suicide, 53% of physicians had ever performed euthanasia and 29% and done so during the past year (Table 2). Family physicians had ever performed euthanasia more often than medical specialists and, especially, nursing home physicians. Of the respondents, 35% had never performed euthanasia but could conceive of situations in which they would be prepared to do so. Of the remaining 12%, the majority said that they would not perform euthanasia, but would be prepared to refer patients requesting euthanasia or assistance in suicide to a colleague. These percentages are almost identical to those found in 1990.

Circumstances

Table 3 shows that in cases of euthanasia and physician-assisted suicide the patients tend to be relatively young compared to all deaths. The greatest difference between euthanasia cases and all deaths lies in the cause of death: it occurs relatively frequently in patients with cancer (80% of euthanasia cases versus 27% of all deaths) and it is relatively rare in patients with cardiovascular diseases (3% of euthanasia cases versus 29% of all deaths). In over half of the cases the estimated time by which life was shortened was one week or less. In 9% it was more than one month. There were no apparent differences in patient characteristics between euthanasia cases in 1990 and 1995.

Table 2. Physicians' practices and attitudes with regard to euthanasia or assisted suicide (weighted percentages, 1995 interview study).

Euthanasia or physician-assisted suicide	Family physicians 1995 (n=124) %	Clinical specialists 1995 (n=207) %	Nursing home physicians 1995 (n=74) %	Total 1995 (n=405) %	Total 1990 (n=405) %
Ever performed	63	37	21	53	54
(Had performed during the previous 24 months)	(38)	(16)	(3)	(29)	(24)
Never performed, but would be willing under certain conditions	28	43	64	35	34
Never would, but would refer to another physician	7	15	10	9	8
Never would perform or refer	2	4	5	3	4
Total	100	100	100	100	100

The most frequently mentioned reasons for the patients to request for euthanasia or physician-assisted suicide were unbearable and hopeless suffering (74%), preventing deterioration (56%), preventing further suffering (47%) and pointless suffering (47%). Pain was mentioned in 32% of the cases, but it was never the only reason mentioned. The patient's request was almost always explicit (97%), fully voluntary (98%) and repeated several times (93%). In 87% of cases there were no other alternatives for treatment, and in 12% of cases there still were alternatives, but these were refused by the patient.

Quality assurance

Consultation of another physician took place in approximately 63% of all cases of euthanasia. It is related to notification: it occurred almost always in cases that were reported to the Public Prosecutor (99%) and in an estimated 37% of unreported cases. The reason that physicians most frequently mention for not consulting another physician was that it was not their intention to report the case.

In order to investigate the quality of consultation, eight criteria for good consultation were derived from discussions in the medical profession, jurisprudence and the notification procedure. Four of these criteria concern the independence of the consultant: the consultant should not work in the same practice as the attending physician, should not be a co-attending physician, should not be a medical trainee and should not know the patient. The other four criteria concern the consultant's activities: the consultant should see the patient, discuss the request of the patient, discuss alternative methods of treatment and make a written report of the consultation. In the 1995 study it was found that in most cases of euthanasia and physician-assisted suicide the majority of these eight criteria were met; percentages varied from 75% for 'did not know the patient' to 100% for 'was not a medical trainee'. For family physicians it was possible to compare data from this period with data from the years before 1990, using data from an earlier study among family physicians.[4,5] Most of the eight criteria

Table 3. Patient characteristics of people to whom euthanasia was performed and of all deaths (weighted percentages, 1995 interview study).

	Euthanasia 1990 (n = 141) %	Euthanasia 1995 (n = 257) %	All deaths 1995 (n = 135,675) %
Patient's age, years			
0-49	9	9	8
50-64	25	28	12
65-79	45	43	36
≥ 80	21	19	44
Patient's sex			
Male	59	43	50
Female	41	57	50
Cause of death			
Cancer	70	80	27
Cardiovasculair disease	9	3	29
Disease of the nervous system	3	4	11
Pulmonary disease	6	2	9
Other	12	11	24
Amount of time by which life was shortened			
<24 hours	21	18	NA
1 day to 1 week	39	44	
>1 week to 1 month	26	31	
>1 month	13	7	
Unknown	1	-	

NA, not applicable

were less frequently met before 1990. The most evident improvement concerned the following criteria: making a written report (from 32% to 88%), not knowing the patient (from 39% to 77%), seeing the patient (from 55% to 91%). All eight criteria were met in 7% before 1990 and 61% in 1995.

The notification rate increased from 18% in 1990 to 41% in 1995. The most important reasons given for reporting a case of euthanasia or physician-assisted suicide were that the physician always reported cases of euthanasia or physician-assisted suicide (75%), that reporting is obligatory (17%), that it is the official policy of the physician's institution (13%) and that it is important to give an account to society (13%). Reasons given for not reporting a case of euthanasia or physician-assisted suicide were the wish to avoid the fuss of a judicial inquiry (51%), the wish to protect the patient's relatives from a judicial inquiry (24%), a request from the patient's relatives to be protected from a judicial inquiry (20%), fear of prosecution (20%), failure to fulfil the requirements for prudent practice (16%), and the belief that assistance with death should be a private matter between doctor and patient (12%). There were no major differences between reported and unreported cases in terms of patient characteristics or the material requirements for prudent practice. However, the

procedural requirements (consultation, a written request, a written report) were met less often in the unreported cases.

Support and consultation for euthanasia in Amsterdam

All but two physicians (99%) knew of the existence of SCEA a year after its start and almost all had positive attitudes towards it. Of the family physicians who had performed euthanasia or physician-assisted suicide in the year after the start of SCEA, 53% had contacted SCEA at least once and 91% of all family physicians intended to contact SCEA in the future in applicable situations. The majority of family physicians in Amsterdam felt to some (32%) or a large (58%) extent supported by the availability of SCEA for consultation. This was also the case looking at the group of family physicians who had not contacted SCEA but did receive an explicit request in the year after the start of SCEA: 41% felt to some and 44% felt to a large extent supported by the availability of SCEA. The most frequently mentioned advantages of consultation through SCEA were that SCEA physicians are knowledgeable (50%), that they are independent (44%), that they are easily available (18%), that the physician does not have to burden another colleague for the consultation (17%), and that SCEA physicians are experienced (15%). The most frequently mentioned disadvantages of consultation through SCEA were that they do not know who the SCEA-physician will be (51%), that they fear institutionalization of a select group (18%), that a SCEA judgement should not get too weighty (9%), and that it is a burden for SCEA-physicians (9%).

Most of the eight criteria for good consultation were met in almost all consultations both by SCEA-physicians and by other consultants. SCEA-physicians only significantly more frequently did not know the patient than other consultants (98% versus 84%). Considering all criteria together there was a clear difference: while in consultations with SCEA physicians seven or eight of the criteria were met in 92% of the cases, seven or eight criteria were met in 67% of consultations with other consultants. Table 4 shows that, in general, physicians who had consulted SCEA physicians were even more positive about most statements on the quality of consultation than physicians who consulted other consultants. No differences were found in the extent to which the requirements for prudent practice were met in cases of euthanasia or physician-assisted suicide between cases in which there had been a SCEA-consultation or another consultation. In 1996, the year prior to the start of SCEA, family physicians in Amsterdam performed approximately 190 cases of euthanasia and physician-assisted suicide, and reported 136 (72%). Between 1 June 1997 and 1 June 1998, the first year of SCEA, family physicians in Amsterdam performed approximately 200 cases of euthanasia and physician-assisted suicide and reported 144 of these (72%).

Conclusion

In view of the high response rates and the fact that on almost all aspects the results of the interview study and the death certificate study were comparable, the results of this study can be considered to give a reliable overview of the incidence and the

background of euthanasia and physician-assisted suicide in the Netherlands, the functioning of the euthanasia notification procedure and the developments in these fields until 1995.

Table 4. Extent to which family physicians who consulted a SCEA physician (n = 54)* or another physician (n = 43) agreed with statements on different aspects of the quality of the consultation.

	totally agree %	agree %	agree more than disagree %	neither agree nor disagree %	disagree %	p†
The consultant was able to give an independent judgement						
- Consultant was SCEA physician	94	4	2	-	-	0.002
- Consultant was other physician	67	30	2	-	-	
The consultant had sufficient knowledge about palliative care						
- Consultant was SCEA physician	74	6	20	-	-	< 0.001
- Consultant was other physician	58	40	2	-	-	
The consultant was able to assess the patient's competence						
- Consultant was SCEA physician	93	8	-	-	-	0.007
- Consultant was other physician	67	30	2	-	-	
The consultant had sufficient knowledge about the patient's disease						
- Consultant was SCEA physician	89	9	2	-	-	> 0.05
- Consultant was other physician	74	23	-	2	-	
The consultant had sufficient knowledge about the judicial procedure						
- Consultant was SCEA physician	86	6	8	-	-	< 0.001
- Consultant was other physician	47	40	7	7	-	
The consultant had adequate social skills in his or her contact with me						
- Consultant was SCEA physician	89	8	4	-	-	0.005
- Consultant was other physician	67	33	-	-	-	
The consultant had adequate social skills in his or her contact with the patient (and family)						
- Consultant was SCEA physician	83	4	14	-	-	0.001
- Consultant was other physician	65	30	5	-	-	
The consultants activities were adequate to obtain insight into the situation						
- Consultant was SCEA physician	85	9	6	-	-	> 0.05
- Consultant was other physician	67	26	3	-	-	
The quality of the consultation was generally good						
- Consultant was SCEA physician	89	11	-	-	-	0.003
- Consultant was other physician	63	37	-	-	-	

* one to three missing observations per statement
† Chi^2-test

There appears to have been an increase in the practice of euthanasia and physician-assisted suicide. There are no indications to suggest that there has been a change in patient characteristics of patients who have received euthanasia or physician-assisted suicide: it continues to be a rare occurrence in nursing home patients, the number of cases of suicide assisted by psychiatrists appears to be very few, and there are no indications of an increase in the practice of life-termination among chronically ill patients.

There has been an increase in the quality assurance of euthanasia and physician-assisted suicide. In most cases the attending physicians have consulted another physician before performing euthanasia or assisting with suicide and the quality of consultation has increased between 1990 and 1995. Moreover, there has been a considerable increase in the percentage of all cases that is reported. However, the majority of cases of euthanasia and physician-assisted suicide are not reported. Therefore, although there have been improvements, public control of the practice of physician-assisted death was still far from adequate. After the 1995 study, the notification procedure was changed with the purpose of increasing the notification percentage by involving the medical profession in the review of cases and by shortening the whole procedure. After notification, the cases are now reviewed in regional committees in which not only a lawyer, but also a physician and an ethicist participate. These committees advise the Public Prosecution on whether or not the physician should be prosecuted. This advice is not binding, but will, in general, be followed. Whether this new procedure is, indeed, an improvement is yet to be evaluated.

The SCEA project was the first project in the Netherlands that attempted to improve the quality of care in the field of euthanasia and physician-assisted suicide. In general, the implementation of the project has been successful, both in terms of the process and in the perception and the use made of SCEA by family physicians in Amsterdam. SCEA has been particularly successful in giving the family physicians a feeling of support, but also in increasing the quality of consultations (that was already high). However, it seems to have had no influence on the quality of the medical-professional decision-making and performance of the attending family physicians or on their willingness to report cases of euthanasia and physician-assisted suicide to the Public Prosecutor. It is possible that this finding is influenced by the limitations of the study: it was not possible to find a matching control group and the study had a relatively short follow-up of one year. The results of SCEA have stimulated the Dutch minister of Health to finance a new project in which similar networks like SCEA will be established in all regions of the Netherlands. This new project 'Support and Consultation on Euthanasia in the Netherlands' (SCEN) has started in September 1999. Within one year similar consultation networks have become operative in eight of the 27 districts of associations of family physicians in the Netherlands and plans to establish a network have been made in the majority of the other districts.

Important research questions

The following issues are important for future (international) research on euthanasia and physician-assisted suicide:

1. In order to answer questions concerning a possible slippery slope (undesirable increase of cases, that is, to frequent or with undue care) or an uncontrolled (avoiding public observation) increase in the number of cases of physician-assisted death, it is important to assess the incidence and circumstances of the practice of physician-assisted death periodically (using similar methods).
2. Critics of the Dutch approach claim that the practice of euthanasia and physician-assisted suicide is the result of bad palliative care. Others think that euthanasia and physician-assisted suicide may, in exceptional cases, be the final stage of good palliative care. However, the relationship between palliative care and the practice of euthanasia and physician-assisted suicide has never been studied.
3. Looking for sharper quality indicators of the quality of decision-making. This could be done by looking more closely at the decision-making process of attending physicians. For instance, how do they assess whether or not the patient suffers from depression, the request is really voluntary and the suffering is unbearable and hopeless?
4. Looking for ways of quality improvement of the decision-making process, for instance, by developing and implementing a protocol that can help attending physicians through the decision-making process that commences after they receive an explicit request for euthanasia.
5. Getting insight into the effectiveness of new notification procedures (disclosure of cases, adherence to requirements of prudent practice).
6. Investigating the role of nurses in the decision-making process and the performance of euthanasia and physician-assisted suicide.
7. Investigating the emotions, expectations and opinions of patients and their family. Most research until now has been focused on the physician (mostly for practical reasons), while the patient perspective is very important. This is especially the case when a physician refuses a patient's request.
8. The emotions of attending physicians performing euthanasia or physician-assisted suicide. Deciding on granting or refusing a request for euthanasia and physician-assisted suicide is a far reaching decision and performing euthanasia or assisting in suicide is irreversible. How do physicians cope with this? Do they need support and is this support available? Do these things change when physicians have applied euthanasia more frequently?
9. International comparison is interesting for most of the issues mentioned. This can provide invaluable insight if it is combined with a comparison of health care systems, and cultural, socio-economic and other characteristics.

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Giving Opioids with a Potentially Life-Shortening Effect: Experiences and Perceptions of Dutch Physicians[1]

Abstract

In the palliative care provided for patients with a terminal disease, physicians sometimes prescribe opioids in dosages that may be considered to have a life-shortening effect by physicians. Empirical information on the experiences and perceptions of such actions is lacking. The objective of this study is to report the frequency, intentions, patient characteristics, and other aspects of decisions made by Dutch physicians to give or increase opioids, taking into account or (partly) with the intention of a possible life-shortening effect. Method was a nationwide survey of physicians with written questionnaires (1) and face-to-face interviews (2) that was conducted in 1995-1996. Participants were (1) attending physicians of a random sample of 6060 patients who died in 1995; (2) random sample of 405 physicians. In 17% of the deaths, physicians had given dosages of opioids they regarded as possibly life-shortening. In 13%, they had only taken the shortening of life into account, in 3% they had partially intended to shorten life, and in 1% this was the explicit intention. Physicians estimated the amount of time by which life had been shortened as 'probably none' in 48% of the cases, less than 24 hours in 72%, and less than a week in 94%. The dosages of opioids used were less than 50 milligram in 39%, 51-100 milligram in 30%, 101-200 milligram in 21%, 201-500 milligram in 8%, and above 500 milligram in 3% of the cases. Physicians often take a life-shortening effect of opioids into account and sometimes partly or explicitly intend it. Indications were found that physicians attribute stronger lethal effects to opioids than can be warranted. The double effect rule is rarely relevant and has several shortcomings.

Palliative care provided for patients in the terminal stage of disease often necessitates giving increasing dosages of opioids, which physicians and patients may associate with shortening life. The rule or doctrine of the double effect states that life-shortening effects of opioids would be morally wrong if caused intentionally but permissible if foreseen but unintended.[1] The double effect rule has recently been subject to

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renewed debate[2-6] and it is explicitly condoned in the United States in the pending Pain Relief Promotion Act.[7] However, in an extensive literature search we found only one publication reporting empirical data.[8]

In this paper, the frequency is reported with which Dutch physicians reported to have given or increased dosages of opioids, taking into account or (partly) with the intention of hastening death. Furthermore, data are presented about their intentions, the characteristics of the patients, the estimated amount of time by which life had been shortened, the extent to which giving opioids is discussed with the patient, the family and colleagues, the opioid dosages used, and the opinions of physicians. The results are based on a nationwide study on euthanasia and other medical decisions concerning the end of life, which was conducted in 1995 and 1996.[9,10]

Methods

During the period 1995-1996 a nationwide study took place in the Netherlands focusing on the incidence and circumstances of euthanasia and other end-of-life decisions. The study consisted of two main parts: a death certificate study to provide reliable quantitative information, and an interview study to provide more in-depth case-related information.

1995 death certificate study

Questionnaires were sent to the physicians who had attended a stratified random sample drawn from all approximately 43,000 deaths that occurred in the Netherlands from 1 August through 1 December, 1995. For this purpose all cause-of-death forms regarding this period were examined by two physicians and assigned on clinical grounds to one of five strata with an increasing probability that a medical decision concerning the end of life could have been made. A case was assigned to stratum 0 if no such decision had been possible (for instance, sudden death). These cases were retained in the sample, but no questionnaires were sent to the physicians. When the likelihood was deemed high that there had been a medical decision that might have hastened death, the case was assigned to stratum 4. The final sample contained 50% of the cases in stratum 4, 25% of the cases in stratum 3, 12.5 % of those in stratum 2, and 8.3 % of the cases in each of strata 1 and 0. A procedure was devised to ensure that both the physician and the deceased person would remain completely anonymous. Of the 6060 questionnaires mailed, 77% were returned.

The questionnaire contained 24 questions about medical decisions concerning the end of life, patients' and decision-making characteristics, and drug dosages. Three questions concerned opioids and their (presumed) life-shortening effects (see Box).

1995 interview study

We interviewed a stratified random sample of 405 physicians, which included 124 general practitioners, 74 nursing home physicians, and 207 physicians from five clinical specialties (cardiology, surgery, internal medicine, pulmonology, and neu-

BOX 1 Questions concerning the use of opioids

4. Did you or a colleague take one or more of the following actions (or ensure that one of them was taken), taking into account the probability or certainty that this action would hasten the end of the patient's life:
   4a. withholding a treatment*?
   4b. withdrawing a treatment*?
   4c. intensifying the alleviation of pain and/or other symptoms using morphine or a comparable drug?

* In this study, 'treatment' includes tube-feeding.

5. Was hastening the end of life partly the intention of the action indicated in 4c?

6. Was death caused by one or more of the following actions, which you or a colleague decided to take with the explicit intention of hastening the end of life*?
   6a. Withholding a treatment**?
   6b. Withdrawing a treatment**?

* 'Hastening the end of life' may also be understood as 'not prolonging life'.
** In this study, 'treatment' includes tube feeding.

7. Was death caused by the use of a drug* prescribed, supplied or administered by you or a colleague with the explicit intention of hastening the end of life (or of enabling the patient to end his or her own life)?

* This may mean one or more drugs; morphine is also sometimes used for this purpose.

rology). Such physicians attend 87% of all deaths in the Netherlands occurring in hospitals and almost all deaths occurring elsewhere. In order to achieve the desired number of 405 interviews, 559 physicians were sampled. Eighty-three did not meet the criteria for selection, and a further 21 were ill or could not be located. Fifty physicians (11% of those who met the selection criteria) declined to take part in the study. Approximately 30 experienced physicians, who were trained intensively for this purpose, conducted the interviews from November 1995 through February 1996. During the interviews, detailed questions were asked about the most recent case in which a physician had been involved in any medical decision that he or she thought could have hastened the death of the patient, and also about opinions and attitudes concerning such decisions and their legal status.

For this article, we selected cases in which physicians reported having given opioids in a dosage that might have shortened life. We excluded cases in which death had been the consequence of either withholding or withdrawing a treatment or in which opioids were given in combination with more potent lethal drugs, for instance, barbiturates or neuromuscular relaxants. To extrapolate the findings to all deaths in

the Netherlands, we calculated weights. For the death certificate study, the weights were based on the stratification procedure. For the interview study, they were based on the percentage of physicians from the various specialties who were represented in the sample. Interview data were corrected for the 13% of in-hospital deaths that are attended by clinicians from other specialties than the five sampled. Univariate and multivariate logistic regression analyses were performed to calculate odds ratios and their 95% confidence intervals (95% CI). P-values less than 0.05 were considered to indicate statistical significance. We calculated dosages as milligrams of oral morphine by using an equianalgesic table.[10]

Results

The death certificate study showed that physicians reported that they had given dosages of opioids which they considered to be (possibly) life-shortening preceding 17% of all deaths; they no more than took into account the possibility of shortening life in 13%, while shortening life was partly their intention in 3%, and explicitly their intention in 1% of all deaths. Table 1 shows that, independent of the intention, decisions to give opioids that in the perception of the physician possibly hastened the end of life concerned cancer patients in more than half of the cases. Physicians estimated the amount of time by which life had been shortened as 'probably none' in almost half of all cases, but almost never when life-shortening had been their explicit intention. They estimated the shortening of life to be less than 24 hours in 72% of all cases, and less than a week in 94% of all cases; these percentages did not significantly differ according to the intention. Univariate logistic regression showed that an explicit intention more frequently (65%) involved an estimated shortening of life by more than a day, compared to cases in which life-shortening was only taken into account (21%) (odds ratio, 6.0; 95% CI 3.7-9.8). Multivariate logistic regression analysis with the patient's age and diagnosis and the physician's specialty as independent variables, showed that an explicit intention was significantly associated with specialty: compared to clinical specialists, nursing-home physicians administered opioids less frequently with the explicit intention of shortening life (43% versus 10%) (odds ratio, 0.24; 95% CI: 0.10-0.57). There was no statistically significant relationship with the patient's diagnosis ($p = 0.20$) or age ($p = 0.99$).

Table 1 also shows that discussion of the decision with colleagues, family and nursing staff occurred most often in cases in which there had been an explicit intention to shorten life. General practitioners and nursing home physicians were less likely to consult their colleagues than clinical specialists (odds ratio, 0.1, with 95% CI, 0.01-0.2; and odds ratio, 0.4, with 95% CI, 0.2,-,0.7, respectively).

Data on the extent to which giving opioids in a dosage that the physician considered possibly life-shortening, had been discussed with the patient are presented in Table 2. Discussion with the patient had taken place in 78% of the cases when shortening life was the explicit intention; in 77% of these cases, the physicians reported that they had received an explicit request from the patient for shortening life. When shortening life was partly intended discussion had taken place with 54% of the

Table 1. Characteristics of giving opioids with the possible effect of shortening life, related to the physician's intention (1995 death certificate study, weighted percentages).

Hastening of death was	Only taken into account (n = 765) %	Partly intended (n = 169) %	Explicitly intended (n = 94) %	Total (n = 1028) %
Diagnosis				
Cancer	52	64	71	55
Circulatory disease	12	15	32	11
Respiratory disease	8	4	6	7
Infections (incl. AIDS)	1	3	-	1
Neurological disease	8	6	7	7
Other	20	8	13	18
Age of patient (years)				
20-49	6	8	9	7
50-64	15	21	22	16
65-79	38	37	38	38
≥ 80	41	34	32	39
Sex of patient				
Male	51	48	40	50
Female	49	52	60	50
Estimated shortening of life				
> 6 months	-	1	-	0
1-6 months	1	1	2	1
1-4 weeks	4	8	5	4
1-7 days	16	33	58	22
< 24 hours	22	34	32	24
Probably no shortening	58	24	2	48
Specialty				
General practitioner	36	50	48	39
Clinical specialist	32	37	43	34
Nursing home physician	29	13	10	25
Other	3	-	-	2
Discussed with*				
One or more colleagues	34	36	59	36
Nursing staff	32	35	54	35
Family	54	66	74	57
Other	2	3	-	2
Nobody	20	15	6	19

* More than one answer could be given

patients (69% of those who had made an explicit request), and with 40% when it was only taken into account (42% explicit request). Patients with whom the decision had not been discussed had (clearly or less clearly) expressed a previous wish for their death to be hastened in most cases (34%) when the physician explicitly intended to

Table 2. Giving opioids with the possible effect of shortening life and discussion with patient, competence, request (death certificate study, weighted percentages).

Hastening of death was	Only taken into account (n = 765) %	Partly intended (n = 169) %	Explicitly intended (n = 94) %	Total (n = 1028) %
Discussed with patient*				
Shortly before giving opioids	18	21	30	20
Some time before	21	33	48	25
Not discussed	60	46	22	55
When discussed with the patient (shortly or some time before):				
	(n = 305)	(n = 93)	(n = 74)	(n = 472)
Explicit request from patient	42	69	77	52
No explicit request from patient	58	31	23	48
When not discussed with the patient:				
	(n = 427)	(n = 71)	(n = 20)	(n = 518)
Had patient ever expressed a wish for hastening of death?				
Yes, clearly	6	14	20	8
Yes, not very clearly	7	10	14	7
No	87	76	66	85
Was patient competent at the time of giving opioids?				
Yes	20	7	4	18
Not fully	19	20	22	20
No	61	72	72	63
Reason for not discussing decision with patient†				
Patient unconscious	31	58	50	35
Dementia	29	17	33	28
Clearly the best for patient	22	19	33	22
Would do more harm than good	7	7	6	7
Mental disorder	3	4	11	4
Mentally handicapped	1	-	-	0
Other reasons	23	11	11	21
Explicit request from family	4	15	29	6

* Data on discussion with the patient were missing in 38 cases (4%).
† More than one answer could be given.

shorten life. Of the patients with whom giving or increasing opioids had not been discussed, 83% were not (fully) competent at that time; the percentage of competent patients, among those with whom the decision had not been discussed, was highest (20%) when the physician had only taken the shortening of life into account. When

Table 3. Dosages of opioids given in the last 24 hrs (calculated as milligram of oral morphine*), related to estimated shortening of life and to request, discussion with patient and intention of physician† (1995 death certificate study, weighted percentage).

	Intention				Estimated shortening of life			Request from the patient	Total
Dosage	Only taken into account	Partly intended	Explicitly intended	Probably none	< 24 hours	1-7 days	> 7 days		
0 -50 milligram (n = 306), %	86	12	2	62	21	13	4	14	39
51-100 milligram (n = 252), %	79	14	7	43	32	22	4	19	29
101-200 milligram (n = 174), %	66	24	10	39	27	27	7	36	21
201-500 milligram (n = 70), %	60	21	19	24	31	34	10	44	8
> 500 milligram (n = 24), %	43	24	33	9	9	73	9	48	3

* Parenteral opioids are considered to be twice as strong as oral opioids.[22] To calculate equivalent dosages from other opioids to morphine, an equianalgesic table has been used.[10]

† Data on dosages or method of administration are missing for 196 cases (24%); they could not be calculated as equivalent of morphine in six cases (1%).

life-shortening had been explicitly intended this was 4%. The most frequently mentioned reasons for not discussing the decision with the patient were that the patient was unconscious (35%) or had dementia (28%), or that the physician thought that the decision was clearly the best for the patient (22%). The latter reason was mentioned as the only one in 7% of all cases in which the decision had not been discussed with the patient.

In 95% of the cases in which the physician considered the dosage of opioids to be possibly lethal, they were the only drugs given; in 2% a benzodiazepine was the second drug. In the remaining 3%, various secondary drugs were used. Opioid dosages in the last 24 hours varied between 0.83 and 8000 milligram as an equivalent of oral morphine (24% missing data on dosages or method of administration; dosages could not be calculated as an equivalent of morphine in 1%). Table 3 shows that the reported dosages of opioids were 50 milligram or less in 39% of all cases, between 50 and 100 milligram in 29%, between 100 and 200 milligram in 21%, between 200 and 500 milligram in 8%, and over 500 milligram in 3%. When the dosage was 50 milligram or less, the shortening of life had only been taken into account in 86% and had been the explicit intention in 2%; when the dosage had been over 500 milligram these percentages were 43% and 33%, respectively. In the lowest dosages (50 milligram or less), physicians estimated life-shortening as 'probably none' in 62%, and less than one week in 13%, but when the dosage was over 500 milligram these percentages were 9% and 73%, respectively. In a univariate logistic regression analysis with the dosage as independent variable, an estimated life-shortening of more than a day was more likely in dosages of over 500 milligram compared to a dosage of 50 milligram or less (odds ratio, 20.3; 95% CI 6.6-62.1). There was an explicit request in more cases when a high dosage was given than when a low dosage was given.

The interview study provided information about previous opioid use and more details about the motives and attitudes of physicians. Table 4 shows that 80% of the patients who had received opioid dosages that the physician thought might shorten their life had already been taking opioids before. Of the 20% opioid-naive patients, 42% received 50 milligram or less in the 24 hours preceding death, 24% received between 50 and 100 milligram, 30% between 100 and 200 milligram, and 4% between 200 and 500 milligram (not shown in table). When asked to specify what they meant by 'partly intending to hasten the end of life', physicians in 15% of the cases said that another intention, usually the alleviation of pain, had been equally important, and that in 48% of the cases life-shortening was a secondary intention. In the remaining 37% of cases, physicians said that life-shortening was more their hope than their intention, or that, after all, it was not intended. The majority of the physicians stated that they would act in a similar way with a similar patient in similar circumstances (93%) and that their decision had improved the quality of the dying process (95%).

Table 5 shows that those physicians who had ever given opioids in dosages that they thought could hasten death could more often conceive of situations in which they would be willing to perform euthanasia or assist with suicide (90% versus 77%) or had already done so (56% versus 30%), than those who had never given opioids in

Table 4. Other aspects of giving opioids with the possible effect of shortening life (1995 interview study, weighted percentages).

Hastening of death was	Only taken into account (n = 117) %	Partly intended (n = 130) %	Explicitly intended (n = 73) %	Total (n = 320) %
Was patient treated with opioids before giving opioids in a possibly life-shortening dosage?	82	89	73	80
Would physician act in a similar way with a similar patient in similar circumstances?*	95	93	92	93
Has action improved quality of dying process?				
Considerably	68	63	64	67
Somewhat	28	31	27	28
Not	4	6	8	5

* Percentage that answered "yes".

Table 5. Opinions of physicians (1995 interview study, weighted percentages).

	Physicians who had ever given opioids with the possible effect of hastening death (n = 362) %	Physicians who had never given opioids with the possible effect of hastening death (n = 72) %
Could conceive of situations in which she would perform euthanasia or assist in suicide	90	77
Ever performed euthanasia or physician-assisted suicide	56	30
Considers herself religious	45	62
Agrees with following statement:		
'everybody has a right to decide about his own life and death'	65	53
'adequate pain treatment and terminal care make euthanasia avoidable'	31	38

such dosages. Physicians who had never given opioids with a possible life-shortening effect more frequently stated that they belonged to a religious denomination or adhered to a specific philosophy of life.

Discussion

Dutch physicians gave opioids thinking that this might have hastened death in approximately one sixth of all deaths. The 1990 Remmelink Study found almost the same.[12] In approximately one fifth of these cases, there was a partial or explicit intention to hasten death. In an American study of hospitalized pancreatic cancer patients, this percentage was estimated to be considerably higher: out of a total of 118 comatose patients, 54 (46%) were given narcotics (three of them in combination with major sedatives) in the last four hours of their life, which, according to the authors, has a 'recognized life-shortening potential'.[6]

The diagnoses of patients receiving opioids with a possible life-shortening effect differ from those in euthanasia: 55% had cancer, compared with 80% in cases of euthanasia.[7] Decisions to give opioids with an alleged possible life-shortening effect often involved incompetent patients. The more explicit the intention to shorten life, the more likely it was that the physician had discussed the decision with the patient. However, an explicit intention was occasionally not discussed with a competent patient. A few physicians mentioned as the only reason for not discussing their decision that it was 'clearly the best for the patient'. Giving an assumedly potentially lethal dosage of opioids was discussed with colleagues in less than half of the cases, even if life-shortening was the explicit intention. We conclude that decision-making should be improved, both in order to prevent unjustified attributions of lethality and to increase transparency for the patient and others involved.

An important question is whether physicians are right in attributing a life-shortening effect to the opioids they gave. Opioids can be taken in large dosages for long periods,[10,13] and it is unclear whether an increase in opioid dosage really hastens death (and if so, to what extent), especially in patients who are already taking opioids,[14,15] as was the case in 80% of the patients in our interview study. The role of the patient's clinical condition is another uncertain factor. Physicians are not very accurate in estimating the length of survival of patients, with a tendency to overestimate it in terminal patients.[16,17] Therefore, the estimated life-shortening effects in our study (less than a day in 24% of cases, less than a week in 22%, and more than a week in 5%) are more likely to be overestimations than underestimations. Moreover, physicians thought that there had been no life-shortening in 48% of the cases. Thus, they took hastening the end of life into account about twice as often as they (with hindsight) thought that such an effect had actually occurred. The reported opioid dosages were generally not high (less than 100 milligram in 70% of the patients in the death certificate study), an explicit intention to shorten life was not always reflected in high dosages, and the highest dosages did not always result in the largest estimated effects in terms of shortening life. From this, we infer that there probably was a considerable overrating of the lethal effect of opioids. Therefore, the results of

our study could be yet another indication that physicians have a lack of knowledge about opioids that needs to be addressed in their professional education.[18-21]

If it is true that physicians over-estimate the lethal effects of opioids, the rule of the double effect, that is based on a distinction between foreseen and intended effects, loses part of its relevance. However, a life-shortening effect of opioids cannot be totally excluded. Various authors have pointed out that the distinction between foreseen and intended is vague and malleable.[1,3] Our data indicate a number of additional shortcomings of the double effect rule. Firstly, intentions of physicians are more differentiated than the 'yes' or 'no' that the double effect rule allows for. We distinguished three types of intentions, but even that is probably too crude a classification. Secondly, the ethical focus has been almost exclusively on allowability issues and not on the moral quality of 'double effect' actions. As a consequence, questions such as whether physicians should discuss possible life-shortening effects (if these are probable) with patients and families, or whether living wills or advance directives have significance for actions with a double effect, are left unanalyzed. Moreover, possible safeguards that are needed to prevent both abuse and unjustified attributions of lethality are not addressed in the double effect theory. Thirdly, in addition to their intentions, the reasons and motives physicians have for giving possibly or presumably lethal dosages of opioids (for instance, unbearable suffering, respect for autonomy) are important aspects which are not accounted for in the double effect rule.

One limitation of our study is that the data are retrospective and are derived from the self-reports of physicians. Moreover, there were 25% missing data on dosages. It is unclear whether this has biased our results, but if so, it seems likely that the physicians tended to forget the lower dosages. More detailed prospective clinical studies are needed to address additional questions, such as the role of the patients' clinical condition and previous opioid use, and also studies among physicians about these decisions that are very closely related to palliative care and occur much more frequently than euthanasia. Those studies should, in particular, address the uncertainty of the lethal effects of opioids. Knowledge about these types of decisions would profit from international comparisons, because it is probable that the frequencies and circumstances of these decisions are dependent on the predominant religion, the culture and the juridical situation in various countries. In a country in which termination of a human life is forbidden under all circumstances, physicians might be more likely to increase dosages of opioid, taking into account or even intending to shorten life. The legal and cultural climate might also influence the extent to which the decision is discussed with the patient and the family, and the extent to which physicians consider it ethical to discuss or not to discuss such decisions. On the other hand, it would also be important to relate the decision-making to national regulations concerning the prescription of opioids, and to the views and attitudes of physicians and lay people with regard to these drugs. Research should, for instance, address the relationship between the fear of addiction, the idea that opioids are 'drugs of last resort' and that their prescription is an indication of imminent death, views about maximum dosages, and the frequency with which physicians prescribe or increase opioids with a perceived life-shortening effect. One final important aspect of international comparison would be the extent of the education physicians receive concerning opioids and their

experience with prescribing them in relation to the frequency of attributing lethal effects to opioids. Do well-educated physicians with extensive experience in prescribing opioids less often consider an increase in the dosage of opioids to be lethal than those who are less informed about opioids, or less experienced in prescribing them?

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Part III End-of-Life Decisions for Neonates

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Epidemiology and Ethics in the NICU

Abstract

No medical professional is obliged to provide futile care. To be useful, however, futility determinations must be prospective and accurate. We wondered how accurately the professionals who work in the neonatal intensive care unit (NICU) recognized futile medical care as they were providing it, day-to-day, infant-to-infant. To estimate the accuracy of futility prognostications, we prospectively surveyed doctors and nurses in a NICU on their assessment of whether babies would survive or die. We then determined the number of times professionals predicted that a baby would die, and noted the accuracy of these predictions.

Overall, 802 infants were admitted to the NICU during this time period. We studied the 254 patients who received mechanical ventilation on at least one hospital day. Of the 254 ventilated patients, 55 (22%) died and 199 (78%) survived. Twentysix (13%) of the surviving infants survived after at least one day characterized by at least one estimate of 'death'. Indeed, eight infants survived despite having at least one hospital day in which ALL respondents predicted death. Whereas all respondents predicted survival in 78% of all patient days, these predictions were correct in 92%. On the other hand, all respondents predicted death at three consecutive days in 3% of all patient days and they were right in 82%. The percentages of correct predictions were considerably lower for the remaining cases in which the predictions were less uniform.

It is concluded that many futility assessments in the NICU are inaccurate. If certainty about futility were the only criterion that can justify a decision to withhold or withdraw life-sustaining treatment in the NICU, these data would make such decisions virtually impossible. These data also suggest caution in legitimizing policies that allow physicians to unilaterally determine that treatment will be futile. There is no quick and easy technical solution to the problems of prognostication.

Many people have an idea of what might be considered a 'good death.' For most people, a 'good death' is <u>not</u> one that takes place alone in an intensive care unit, tethered to high-tech life-support equipment, cared for by professionals who are unsuccessfully trying to prolong one's life. Instead, the good death takes place peacefully, surrounded by friends and loved ones, with careful attention to palliation of pain and suffering. By this view, each death in the Intensive Care Unit (ICU) can be interpreted as a failure of prognostication because if we knew the patient was dying, we would

have moved him or her out of the ICU. Nevertheless, most Americans who die today die in ICUs or other inpatient hospital settings. In one study, only 16% of deaths occurred at home, while 51% occurred in hospitals.[1] Less than 10% of Medicare beneficiaries who die ever get referred to a hospice and most of those are referred within a month of their death.[2]

From the perspective of the critical care doctor, the problem is not straightforward. Many patients die in ICUs, but many others, who are at great risk to die, are successfully treated and survive. If doctors could accurately distinguish those who are going to die from those who are going to survive, they could provide life-sustaining treatments to those who would survive and palliative care to those whose death was inevitable. Consequently, physicians, ethicists, economists and policy makers all recognize an urgent need to refine prognostic ability and accuracy.

Questions about prognosis and clinical decision making can be addressed under two broad moral frameworks. The first focuses on patient autonomy and the belief that patients (or, in the case of children, their parents) are in the best position to determine what type of health care they want. The goal for doctors, under this framework, is to empower patients by giving them the information and the authority that they need in order to determine the course of their treatment. With regard to end-of-life care, the central article of faith underlying this approach is the belief that, since patients *want* 'good deaths' as outlined above, and since they are not getting them, the problem must be that they do not have the knowledge or the power to make the choices that would give them what they want. The other broad moral framework focuses on medical futility. By this view, the problem is not that patients are disempowered. Instead, it is that both doctors and patients generally want and choose continued life-sustaining medical treatment unless the treatment is futile. Therefore, the challenge is not one of procedural empowerment but of prognostic refinement. If we can learn better how to determine whether a treatment is futile then doctors and patients will both be willing to forego it.

It has been difficult to develop refined prognostic techniques. In general, the problems hover around two related but separable questions. First, *how certain* do we have to be that treatment will be futile in order to treat it as such. Any quantitative assessment of prognosis will always have some uncertainty, some statistically definable 'confidence interval' around a point estimate. However, determining the sufficient degree of precision of the estimate will always require a value judgment. The second question concerns the *particular outcomes* that 'count' in the calculation of futility. Death is the easy one. The harder ones are whether any particularly dismal quality of life should also count as a treatment failure.

There are many ethical dilemmas in the Neonatal Intensive Care Unit (NICU), and almost as many solutions as dilemmas. Religion, philosophy, natural law, civil law, criminal law, to name but a few disciplines, have each been invoked as a source of authority to resolve the inevitable conflicts arising at the confluence of uncertain outcome, physical pain, and financial expenditure. This chapter primarily focuses upon an epidemiological research agenda for such dilemmas. The discussion will be divided into three parts: first, conclusions derived from retrospective studies of NICU mortality; next, conclusions derived from prospective

studies of NICU mortality; and finally, proposals for prospective studies of NICU morbidity.

Retrospective insights into futility

Who dies in the NICU and when do they die? Two different populations of NICU babies raise very different moral issues. One sub-population at high risk of mortality is the group of babies with severe congenital anomalies. The other high-risk population consists of extremely premature or low birthweight babies. Our studies have focused on the second populations: very premature, extremely low birthweight (ELBW) babies. The ethical dilemmas raised by these two populations are quite distinct. For babies with congenital anomalies, the prognosis is usually fairly well defined and understood. For complex congenital heart disease, for example, the mortality rates with surgery are well defined.[3] For myelomeningocele, the long-term morbidity has not changed much in twenty years.[4] Because the prognosis for these babies is relatively clear, the dilemmas focus on whether the burdens of treatment outweigh the benefits.

The dilemmas for ELBW babies are different. For them, the range of outcomes is enormous, from death or neurologic devastation to completely intact survival. Furthermore, outcomes have changed so dramatically over the past twenty years that predicting long term outcomes today is tenuous. These ELBW infants account for the vast majority of deaths in the NICU.

The majority of larger infants who die succumb to congenital anomalies. Many of these deaths are post-neonatal. At present, in industrialized countries, babies of less than 500 gram birthweight rarely survive. Above 1000 gram, survival rates are higher than 90%. Consequently, virtually all of the ethical controversy in the NICU focuses on babies between 500 and 1000 gram birthweight. This corresponds roughly to between 24 and 28 weeks of gestational age.

More interesting than which patients die is when they die. The vast majority of doomed infants die quickly. The median day of death in this NICU population is roughly the third day after admission. Across many NICUs with many varied practice styles, this phenomenon is remarkably robust. In almost all reports, the large majority of doomed NICU infants die early, and the smallest babies, who are at the greatest risk of dying, die the soonest.[5]

Two conclusions follow directly from these observations: one with profound implications for individual infants, the second with implications for public policy. Consider a group of infants born at 500 to 600 gram on their first day of life (DOL). Overall, only one infant in four in this group will survive. However, consider the same population three days later. Most of the doomed infants have now died, leaving a markedly different prognosis for the residual population of DOL 4 survivors. Even the tiniest infants who survive to DOL 4 have a very reasonable (over 70%) likelihood of surviving to discharge. Thus, although birthweight is a powerful predictor of survival on DOL 1, birthweight carries much less prognostic significance only a few days later.

The second, perhaps less obvious, conclusion that derives from these observations is that the relative proportion of medical resources expended on doomed ELBW infants does *not* depend either on birthweight or mortality risk. Rather resources expended on doomed infants remain consistently low across all birth weight groups. This is true because, although smaller babies are more likely to die, they also tend to die after far shorter hospital stays. Consequently, although more 600 gram infants die than 900 gram infants, they die earlier and consume fewer medical resources during their brief lives. Furthermore, the few 600 gram birth weight infants who do survive stay in the NICU a long time before discharge (approximately 100 days). Consequently, considering the 600 gram cohort as a whole, many more bed days are allocated to surviving infants than doomed ones, despite the fact that there are many more doomed infants than survivors, precisely because the doomed babies stay so much shorter than the survivors. Regardless of birthweight, roughly 85% of bed-days (equivalent to 85 cents of every NICU dollar) are allocated to infants who will be discharged alive.[6]

Prospective insights into mortality

No medical professional is obliged to provide futile care. To be useful, however, futility determinations must be prospective and accurate. Physicians and other medical caretakers often have intuitions about the likelihood of survival for patients in their care. Previous studies suggest that intuitions of survival garnered on the day of admission to an ICU or NICU correlate significantly (in a statistical sense) with patient outcomes.[7,8] There are, however, two problems with these observations. First, the correlations are not strong; that is, there is a lot of slippage between predictions of non-survival and actual death. Second, predictions on the day of admission do not take into account the 'trial of therapy' that is inherent in ICU care. No one is admitted to an ICU for 'hospice' care. Rather, ICU patients get aggressive, high-tech care in an attempt to prolong their lives. Patients, it is often said, 'declare themselves' in response to their therapy, but these declarations may take time before they are interpretable. Consequently, instead of analyzing one-time predictions on the day of admission for ICU patients, a more ethically relevant approach might be to analyze serial assessments made daily for the same ICU patient.

We wondered how accurately the professionals who work in the NICU recognized futile medical care as they were providing it, day-to-day, infant-to-infant. To find out, we asked doctors and nurses in our NICU one single question every day about patients in their care: do you think this child will die before hospital discharge, or live to go home to his family? We obtained responses from multiple caretakers for each infant for each day.

Overall, 802 infants were admitted to the NICU during this time period. We studied the 254 patients who received mechanical ventilation on at least one hospital day (infants treated with nasopharyngeal continuous positive airway pressure were excluded from this analysis). For each ventilated patient, on each day, nurses (both primary nurse and other nurses 'covering' the patient in the NICU), residents, fellows,

and attendings were approached and asked 'Do you think this child is going to live to go home to his family, or die before hospital discharge?' In addition to 'live' or 'die', each respondent was allowed to answer 'uncertain' if she could not comfortably predict either survival or non-survival for that infant, on that day.

Of the 254 ventilated patients, 55 (22%) died and 199 (78%) survived. Not surprisingly, the non-survivors were on average smaller and had shorter gestations than the surviving infants. Almost half of the non-survivors (27/55) were less than 750 gram at birth. In contrast, nearly three-fourths (148/199) of the survivors weighed over 1000 gram at birth.

Prediction profiles were obtained for 230 of the 254 (91%) infants who received mechanical ventilation during the study period: 192/199 (96%) surviving infants and 38/55 (69%) non-surviving infants. All of the non-survivors who were not profiled died in the first 72 hours of life, except two infants who were born and died during a one-week scheduling interruption. The 230 patient profiles contain predictions obtained on 2867 patient days. The average number of daily predictions for each ventilated infant was four. Consequently, approximately 11,000 predictions of patient outcomes were compiled during the 48 weeks of this study. There was no significant difference in the number of daily predictions obtained for non-survivors versus survivors.

Prediction profiles for non-survivors

Death between DOL 1-3: 21 of the 55 (38%) non-survivors died in the first three days of life. The median day of death for these infants was DOL 2. Six of these infants received prediction profiles, all of which reflected uniform prediction of death by every health care provider on every day. Each of the other infants in this category died before any outcome predictions were obtained.

Death between DOL 4-10: 12 of the 55 (22%) non-survivors died between DOL 4 and 10. Ten of these doomed infants received prediction profiles. As a group, these profiles were also homogeneously both dismal and accurate. Seven of the ten infants in this category had 100% prediction of death on every DOL from birth to the day of death. For two other patients in this group the profile differed only slightly: on at least one day during the first 72 hours of life survival was thought likely by at least one respondent. However, by DOL 4 non-survival was uniformly and accurately predicted. Thus for nine of the ten non-surviving infants in this group, on each day between DOL 4 and DOL 10, no respondent thought that the child would survive (that is, the prediction of survival to discharge was 0% for each hospital day).

Death after DOL 10: 22 of the 55 (40%) non-survivors died after DOL 10. All of these infants received prediction profiles. In contrast to the homogeneity that characterized profiles of infants who died before DOL 10, the 22 later-dying infants were a heterogeneous group. Only five (22%) of these 22 late-dying infants had the uniform prediction of death that categorized predictions for infants who died prior to DOL 10. Each of the other seventeen late-dying infants was predicted to live by many (if not all) observers on many (if not all) hospital days. Eleven (50%) of these late-dying infants suffered, with little warning, a fatal medical catastrophe (NEC, sepsis, pneu-

monia, et cetera). The rapid and unexpected nature of their demise is emphasized by the observation that for seven of these late-dying infants, not even one day of their hospital stay was marked by 0% prediction of survival. Six (27%) of 22 late-dying infants had prediction profiles categorized by considerable uncertainty, both within respondents and across days. That is, several hospital days were characterized by 'pessimism' (that is, low predictions of survival), alternating with periods of 'optimism', characterized at times by up to 100% prediction of survival. These infants often survived for many weeks prior to their death.

Prediction profiles for survivors

Prediction profiles for survivors reflected two distinct hospital courses. The vast majority of surviving infants were predicted by all (or almost all) observers to survive on all (or almost all) days of mechanical ventilation. One hundred fiftyseven (81%) of the 193 survivors had this consistent, accurate prediction profile and for 136 (70%) of 193 surviving infants, every NICU ventilator-day was characterized by 100% prediction of survival. Twentyone other survivors had profiles nearly as positive: for these infants, a brief period of uncertainty was followed by increasing confidence in the likelihood of survival, but at least 90% of their hospital ventilator-days were characterized by 100% prediction of survival. At the other end of the continuum, 26 (13%) of 193 surviving infants survived somewhat unexpectedly; that is, after at least one day characterized by at least one estimate of 'death'. Indeed, eight infants survived despite having at least one hospital day in which *all* respondents predicted death.

Accuracy of predictions of survival and non-survival

Predictions of survival for ventilated infants were very common and very accurate. Over three quarters of NICU days occupied by ventilated patients were characterized by uniform prediction of survival. Of these predictions, 92% were correct. Non-survival predictions were much less common and much less accurate. The more people who consistently predicted non-survival, the more accurate the predictions were. However, even when every health care professional predicted that a baby would die for three days in a row, they were wrong 18% of the time. The percentage of accurate prognostications is shown in the Table.

Table. Percentage of positive and negative prognostications.

Prognostication	% of patient days	% correct
Uniform prediction of survival	78	92
One prediction of death	18	40
50% prediction of death	11	51
100% prediction of death during one day	5	69
100% prediction of death during three days	3	82

Conclusions and future research questions

The study has methodologic limitations. First, our data may reflect a self-fulfilling prophecy; that is, once 'non-survival' is predicted is the balance of NICU care 'tilted' to produce the demise of the infant? We saw no evidence of such behavior during the study period. In fact, the overwhelming majority of non-survivors in our study did not have DNR orders. Second, our predictions may reflect a 'herd' phenomenon; that is, once the opinion of 'non-survival' was articulated (particularly by the attending physician), did others 'jump on the bandwagon'? This possibility is difficult to evaluate, as the opinions may equally have reflected shifts in the bodies of the infants as in the minds of the evaluators. Nevertheless, we explored this possibility in a pilot study by comparing predictions of our respondents to predictions of experienced NICU nurses who did not participate in rounds or provide direct patient care during the study period. There was substantial agreement between our 'blinded' respondents and our study respondents.

These data carry a number of important implications for discussions about prognostications of medical futility and the withholding and withdrawing of life-sustaining treatment in the NICU. First, they suggest that very little recognizably 'futile' care is being provided. That is, there were very few circumstances in which every professional agreed that the baby would not survive, treatment was extended, and the baby eventually died. To the extent that prolonged treatment was provided to babies who ultimately died, almost all of their deaths were unpredictable. Second, our data raise the disturbing possibility that many futility assessments are inaccurate. This raises some interesting problems. If medicine, like meteorology, is an inexact science, long-range predictions of death, at least in the NICU, may be as imperfect and as useless as long range weather forecasts. Furthermore, if certainty about futility were the only criterion that can justify a decision to withhold or withdraw life-sustaining treatment in the NICU, these data would make such decisions virtually impossible. We would suggest that there are situations in which withdrawal of care is appropriate, that such decisions are always based on probabilistic information about outcomes, and that certainty is therefore an impossible threshold and an illusory criterion for such decisions.

Finally, we have demonstrated that the 'distributive justice' argument strongly favors continued NICU care. The vast majority of NICU resources are directed to infants who ultimately survive to go home to their families, tenfold more than ICU resources directed toward sick adults.

We have only begun to explore the implications of predictions of morbidity. Future research should focus on the relationship between predictions of mortality and ultimate outcomes for patients who survive. A great deal of population-based literature recounts the likelihood of morbid outcomes (almost always a combination of motor spasticity and cognitive impairment) as a function of risk factors for NICU patients. In brief, this work shows that the higher the risk of death, the higher the risk of survival with impairment.[9]

However, just as with mortality, morbidity is more importantly described from a prospective viewpoint. Clinicians are not faced with 'a population' (although public

policy makers are). Rather doctors and nurses deal with patients one at a time. What do we know about the accuracy of predictions of impairment in survivors of NICU care while the infants require life-support in the NICU, as opposed to at their two-year check-up? The answer, in short, is very little. Although some physiologic events in the NICU have clearly been correlated with subsequent impairment, very little attention has been paid to caretaker intuitions (either serial or 'one-time') about morbid outcomes.

One could design a prospective morbidity study closely paralleling the prospective mortality study described in the section above. One could ask caretakers on a daily basis whether the infant in their care was going to 'live but be impaired', with various degrees of impairment specified or not. Correlation of these intuitions with subsequent outcomes would provide at least a first-cut answer to the predictive value of intuitions of morbidity. It may turn out that the predictions of outcome by doctors are not that bad, but that mortality is not the only bad outcome to be avoided. Survival with severe neurological deficits may be as bad or worse in the minds of some parents.

Parental perception of the goals of NICU care is a second important area for future research. Do parents feel that they are adequately involved in decision-making now? For parents of babies who died, do they feel that they achieved a 'good death?' If not, what mechanisms might facilitate more truly shared decision-making? The goal should be to combine the best epidemiological data with the best methods of sharing that data to insure that parents understand, and then seek the best decision for each infant within the inevitable constraints of prognostic uncertainty.

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Current Concepts and Future Research on End-of-Life Decision Making in Neonatology in the Netherlands[1]

Abstract

In 1995 in the Netherlands, neonatal death was preceded by the decision to forego life-sustaining treatment in 57% of all cases. Almost 70% of pediatricians said they had withheld treatment because of no chance of survival, and 43% because of poor prognosis. For treatment withdrawal, these figures were 84% and 68%, respectively. Parents almost always participated in the decision making and had explicitly asked for it in approximately one third of cases. Some 30% of the pediatricians had at some time abandoned a decision because parents did not agree, and 30% had at some time refused a parental request for an end-of-life decision that they considered unjustified. In over 80% of the decisions, colleagues were consulted. Most pediatricians believed that end-of-life decisions should be reviewed for public control, but preferably not by the Public Prosecutor, who plays a key role in the current judicial notification procedure.

In 1998, a discussion group formed by the government concluded that deliberate ending of life should be subject to special scrutiny, since it is not inherent to normal medical practice. The group advised to design a retrospective assessment by a committee of independent doctors and judicial and ethical experts, and provided a listing of requirements for prudent medical practice relevant for end-of-life decisions in neonatal care.

Since previous research on end-of-life decisions in neonatology was retrospective in design, many questions with respect to the characteristics of the decision making process, team meetings, and communication with the parents remain unanswered. Which medical, nursing, social, religious, ethical and judicial aspects are determinant factors, and what happens to the families afterwards? The open debate on ethical issues in the Netherlands promotes future collaborative multidisciplinary and prospective research to answer these questions.

Advances in perinatal medicine have resulted not only in the survival of many more extremely sick and pre-term babies, but also in an increased risk for an adverse

[1] This paper is largely based on research work carried out by Carmen L.M. de Graaff, Agnes van der Heide, Louis A.A. Kollée, John G.C. Kester, Richard de Leeuw, Paul J. van der Maas and Gerrit van der Wal.

subsequent outcome. In some cases, life-sustaining treatment may not be in the child's best interest. In those cases, physicians have to make difficult decisions. In this review, the history of ethical discussions on neonatal intensive care in the Netherlands is briefly reviewed, and data obtained from studies on end-of-life decision making are presented. Questions arising from these empirical data will be discussed and future research topics will be addressed. Parts of this paper have been published elsewhere.[1]

History

During the rapid development of neonatal medicine in the 1970s and 1980s, Dutch pediatricians became aware of the drawbacks involved in neonatal intensive care. From 1986 onwards, a working group from the Pediatric Association of the Netherlands has been discussing the various types of end-of-life decisions. In 1989, a preliminary report was presented to the members of the Association in a special meeting. A minority of members did not accept the proposal of the working group to allow the withdrawal of life-sustaining treatment for patients who might be able to survive with continuation of treatment. The preliminary report focused on the withholding and withdrawal of treatment. Intentional ending of life was discussed extensively in the working group, but no consensus was reached at that time. In following years, the working group continued to discuss the subject, both within the group and with external experts. Finally, the definitive report *'Doen of laten? Grenzen van het medisch handelen in de neonatologie' [To do or not to do? Boundaries of medical action in neonatology]* was approved by the general assembly of the Pediatric Association of the Netherlands in November 1992.

The report 'Doen of Laten?' [*'To do or not to do?'*][2]

In the report, end-of-life decisions in neonates were categorized into three types: withholding life-sustaining treatment, withdrawing life-sustaining treatment, and intentional ending of life in exceptional cases. These decisions can be made if there is a lack of chances of survival or if there is an extremely poor prognosis for later life if the infant survives. According to the report, there is no ethical problem involved in the decision to withhold or withdraw life-sustaining treatment in cases of inevitable short-term death. This is considered to be a medical decision. If the baby has a chance of survival, the prognosis for later life must be made very carefully and should be based on medical facts. In the report, some important points were described to determine the future quality of life: the mental and physical burden of the infant's life, the infant's capability to interact with his or her environment, the self-sufficiency or dependency of the infant on caregivers and the health care system, and the expected life-span. As these points cannot be evaluated in a simple scoring system, the assessment has to be made on the basis of the overall picture of the quality of the future existence of the individual patient.

The working group was of the opinion that parents and physicians share the responsibility. The doctor takes the final decision, but the parents' wishes should be taken into account. When parents want treatment to be continued this will be done, unless it will cause the child unbearable suffering. Before taking end-of-life decisions, consultation of a team of at least two other physicians and nurses is regarded as mandatory. A minority of cases in which end-of-life decisions are considered concerns newborns who are not dependent on life-sustaining treatment, but have an extremely poor prognosis for future quality of life. Examples are newborns with very severe spina bifida and hydrocephalus, who do not meet the criteria for surgery, or newborns who have survived severe hypoxic-ischemic encephalopathy. Pediatricians in the Netherlands have different opinions on the acceptability of active termination of life in such cases. Some pediatricians feel that it may be acceptable in rare cases, but others are of the opinion that active termination of life in such babies would never be justified, because they are not receiving intensive life-sustaining treatment (any more). The working group stated that in cases in which life-sustaining treatment was withheld or withdrawn because death was inevitable, or because of very poor quality of life in case of survival, a certificate of natural death can be signed by the physician, since the disease was the natural cause of the baby's death. The working group stated that this is in accordance with the law, in contrast with the situation in a case of active termination of life, in which the doctor should not sign a certificate of natural death, since this is illegal. At the time when the working group prepared its report, no empirical research data on the practices and attitudes with respect to end-of-life decisions in the Netherlands were available, but in the 1990s the incidence of end-of-life decisions in Dutch neonatal intensive care units (NICUs) was studied.

The incidence of end-of life decisions

Early studies published articles on the frequency of end-of-life decisions taken in NICUs, which show that in the 1970s and the 1980s life-sustaining treatment had been withdrawn or withheld in between 10% and 30% of all fatal cases. [3-5] In the 1990s, the percentages found in Canada and the United States were higher; between 73% and 90%.[6-8] In 1990, in four Dutch NICUs, life-sustaining treatment was forgone in 59% of infant deaths. [9] In a similar study over the year 1993 in the same units, it was found that this figure had increased to 81%.[10] In a single NICU, from 1990 to 1994, 80 % of all deaths in that unit occurred after the withdrawal of artificial ventilation. [11] In these three Dutch studies, two-thirds of the end-of-life decisions were made because there was no chance of survival. The data published show that in the 1990s approximately 80% of deaths in neonatal intensive care units were preceded by an end-of-life decision in the Netherlands, and also in the United States and Canada.

In the Netherlands, intentional ending of life should be reported to the Coroner for judicial examination. The Coroner will discuss the case with the Public Prosecutor who decides whether or not the physician will be prosecuted. If physicians act according to the requirements for prudent medical practice, they will not be prosecuted. However, much uncertainty exists with respect to the judicial consequences of reporting the intentional ending of a newborn baby's life, and therefore cases are almost never

reported. In 1995, only three cases were reported. In 1996, two cases in which doctors were prosecuted finally resulted in acquittal, because the acts were deemed medically unavoidable. A nationwide study, commissioned by the Ministers of Health and Justice, was performed a few years ago to evaluate the current judicial notification procedure for euthanasia. [12] Parallel to this study, another nationwide study was performed to provide an overview of both practices and attitudes concerning end-of-life decisions in neonates. [13,14] The main results of this study are described below.

Study on practices and attitudes in the Netherlands

A national study on practices and attitudes in the Netherlands was performed in 1995. The study consisted of two parts. The first part was a retrospective study of all 338 consecutive deaths of infants under one year of age from August through November 1995, derived from the death certificates registered by the national statistics. A questionnaire was sent to the attending physicians. Physicians and patients remained completely anonymous to the investigators. Of the questionnaires sent, 88% were returned. Key-questions were whether life-sustaining treatment had been withheld or withdrawn, whether drugs with potentially life-shortening effects had been administered and, if so, whether there had been the explicit intention to hasten death. The second part of the study was an interview study. A random and stratified sample of 67 pediatricians was invited to participate. Only one pediatrician refused, so 66 were interviewed, of whom 31 were neonatologists or intensive care pediatricians and 35 were general pediatricians. They were asked if they had ever forgone life-sustaining treatment, and if they ever administered a drug with the explicit intention of ending a patient's life. For each of these decisions the most recent case, if any, was comprehensively discussed. At the end of the interview, personal opinions were asked on end-of-life decision-making in neonates and on the review procedures for these decisions. To obtain valid estimates for the Netherlands, weights were calculated, based on the percentage of neonatologists and intensive care pediatricians who were represented in the sample, and on the distribution of all deaths of infants under one year of age in the Netherlands per general pediatrician interviewed.

Results of the death certificate study

The incidence of end-of-life decisions in the death certificate study is shown in Table 1. In 38% of the cases no end-of-life decision was made at all, in 24% death occurred suddenly and unexpectedly, and in 14% treatment was continued until death. In the remaining 62%, an end-of-life decision preceded the death. In 57%, death was preceded by the withdrawal or withholding of life-sustaining treatment. Most of these decisions were made because there was no chance of survival; an extremely poor prognosis for later life was the main reason in 18%. In 23% of all deaths, withholding or withdrawing treatment was followed by the administration of drugs (mostly opioids) to alleviate pain and discomfort, in doses that may have shortened life. Pain relief is generally regarded as being inherent to appropriate medical care, even if it results in shortening of life. In 8% of all deaths, forgoing life-sustaining treatment was followed

Table 1. Incidence of end-of-life decisions in infants under one year of age in the Netherlands (death certificate study).

	(n = 299) %
Death was not preceded by an end-of-life decision	
death sudden and unexpected	24
treatment continued until death	14
Death was preceded by an end-of-life decision	
life-sustaining treatment withheld/withdrawn	57
no drugs administered	26
drugs administered to alleviate pain and symptoms in doses that may have shortened life	23
drugs administered explicitly to hasten death	8
life-sustaining treatment not forgone, but	5
drugs administered to alleviate pain and symptoms in doses that may have shortened life	4
drugs administered explicitly to hasten death	1

by the administration of drugs with the explicit intention of hastening death because of severe and intolerable suffering. In 4% of all deaths, the only end-of-life decision that was made was the decision to administer potentially life-shortening drugs as palliative care to alleviate pain and symptoms. One percent of all deaths was preceded by a decision to administer a drug with the explicit intention of hastening death in infants who were not dependent on life-sustaining treatment. This percentage represents a total number of 10 to 15 such end-of-life decisions per year in the Netherlands.

Table 2. Statements of pediatricians about their practices concerning end-of-life decisions (interview study).

	Neonatologists/ intensive care pediatricians (n = 31) %	General pediatricians (n = 35) %	All %
Had at some time withheld life-sustaining treatment			
no chance of survival	67	66	67
poor prognosis for later life	55	30	43
Had at some time withdrawn life-sustaining treatment			
no chance of survival	100	68	84
poor prognosis for later life	97	40	68
Had at some time administered drug with explicit intention to hasten death[*]			
yes	45	31	37
no, but could conceive of situations in which they would	29	49	39
would never administer, but would refer to another physician	21	20	20
would never administer or refer patient	4	-	2

[*] Whether or not after a preceding decision to forgo life sustaining treatment.

Results of the interview study

The experiences of pediatricians with end-of-life decisions in neonates are shown in Table 2. Of all pediatricians interviewed, 67% had withheld treatment because of no chance of survival, and 43% because of a poor prognosis for later life. Withdrawal of treatment at least once had been practiced by 84% because of no chance of survival, and by 68% because of a poor prognosis for later life. Neonatologists had withdrawn treatment much more often than general pediatricians. This is explained by the fact that neonatal intensive care in the Netherlands is concentrated in ten NICUs. 45% of the neonatologists and intensive care pediatricians and 31% of the general pediatricians had at some time administered drugs with the intention to hasten death, whether or not following a decision to forgo life-sustaining treatment. Furthermore, 29% of the neonatologists and intensive care pediatricians and 49% of the general pediatricians could conceive of situations in which they would, although they had never actually done so; 22% stated that they would never do so.

Congenital anomalies were the most frequently mentioned underlying diagnoses. Pre-term birth occurred in 30%, and perinatal asphyxia in approximately 25% of the cases. Congenital anomalies of the central nervous system, multiple congenital anomalies, and perinatal asphyxia were the most frequent diagnoses when drugs had been administered to hasten death.

Table 3. Practices and attitudes of pediatricians with regard to the role of parents in end-of-life decisions (interview study)

	Neonatologists/ intensive care pediatricians (n = 31) %	General pediatricians (n = 35) %	All (n = 66) %
Most recent end-of-life decision because of no chance of survival			
discussed with parents	93	92	92
parents requested decision	23	43	38
parents agreed with decision	93	92	92
parents disagreed with decision	-	-	-
Most recent end-of-life decision based on quality-of-life aspects			
discussed with parents	97	67	74
parents requested decision	28	33	32
parents agreed from the beginning	69	35	44
parents agreed after a while	28	32	30
parents disagreed with decision	-	-	-
Did not make an end-of-life decision because parents did not consent			
ever	45	26	29
never, would be willing to do so under certain conditions	36	59	55
never, would never be willing to do so	19	15	15
Did not make an end-of-life decision despite the request of parents to do so			
ever	37	21	24
never, would be willing to do so under certain conditions	53	58	57
never, would never be willing to do so	10	21	19

Pediatricians considered the involvement and approval of parents to be an important requirement for prudent decision-making (Table 3). Parents participated in the end-of-life decision making process in almost all cases attended by neonatologists, but only 67% of the cases attended by general pediatricians were discussed with the parents. End-of-life decisions were never taken against the explicit wish of parents. Parents had explicitly asked for the decision in approximately one third of all end-of-life decisions. Approximately one third of the respondents had at some time in their medical career abandoned an end-of-life decision because parents could not agree with such a decision. Most respondents were willing to refuse a parental request for an end-of-life decision if they did not consider it to be justified. Of the neonatologists, 37% had refused a parental request to end life, compared with 21% of the general pediatricians.

Table 4. Statements of pediatricians concerning review of end-of-life decisions (% replying 'yes', interview study).

	Neonatologists/ intensive care pediatricians (n = 31) %3	General pediatricians (n = 35) %
Forgoing life-sustaining treatment is a medical decision that should be reviewed in		
all cases	52	51
some cases	36	34
no cases	13	14
Administration of a drug to end life is a medical decision that should be reviewed in		
all cases	94	91
some cases	7	9
*Administration of a drug to end life is a medical decision that should be reviewed by**		
caregivers involved	20	32
independent medical professionals	55	59
committee not restricted to medical professionals	75	59
Public Prosecutor	10	5
others	10	18

* More than one answer possible.

Consultation of colleagues before making an end-of-life decision occurred in over 80% of all cases. Table 4 shows the personal opinions of the pediatricians with regard to review of end-of-life-decisions. Of the pediatricians, 52% believed that all end-of-life decisions should be reviewed in some way, and 94% believed cases of intentional ending of an infant's life with drugs should always be reviewed. Opinions varied on who should perform the review. The majority of the pediatricians thought that a committee of independent physicians, together with judicial and ethical experts, would be best qualified to perform this review. The Public Prosecutor was thought to be the appropriate reviewing authority by only 10% of the respondents,

although this is the core of the current judicial notification procedure in the Netherlands.

Review of end-of-life decisions

In 1996, the Dutch Minister of Health and the Minister of Justice established a discussion group, commissioned to make proposals for an adapted notification procedure and an assessment procedure for cases in which the life of a newborn baby with a serious medical condition is deliberately ended. It is apparent that such (rare) decisions are nearly always preceded by decisions to forgo treatment and/or decisions regarding palliative care. The group's report was issued in 1997. [15] A comprehensive survey of the requirements for prudent medical practice was given. The discussion group took the view that decisions to forgo life-sustaining treatment should, in principle, be inherent to normal medical practice, which is not subject to any special form of statutory assessment. Deliberate ending of life, however, is fundamentally different, and should accordingly be subject to special scrutiny. The group concluded that the best approach would be to design a retrospective assessment procedure in which a multidisciplinary committee plays a central role, but the law has not yet been changed. The main requirements for prudent medical practice which are relevant in the context of end-of-life decisions, derived from the report issued by the discussion group,[15] are listed below.

General requirements concerning all types of end-of-life decisions

It should be clear which doctor is primary responsible for the case. All the necessary diagnostic procedures should be performed. The prognosis should be based not only on the doctor's personal knowledge and experience, but also on published data. The team members (including the nursing staff) who are caring for the patient should discuss the diagnosis and prognosis of the patient, and there should be consensus on the diagnosis and prognosis. Parents should, from the beginning, be properly guided and fully informed about all developments in their infant's condition.

Specific requirements concerning decisions to forgo life sustaining treatment

Such a decision can only be taken if, according to the relevant medical standard, treatment is considered to be futile or to have no prospect of success. The doctor should consider the patient's overall present and future medical condition, and should not forgo life-sustaining treatment on the grounds of quality-of-life aspects without the agreement of both parents.

Specific requirements concerning palliative care

When deciding to forgo life-sustaining treatment, the patient should receive all the palliative care necessary to alleviate or prevent suffering. Other experts, such as nursing staff, home care providers and social workers, should be involved in palliative care, if necessary. Parents' needs for psychosocial care and spiritual support should

be considered. Administration of analgesic drugs that may shorten the patient's life because of the side effects must always be discussed with the parents.

Specific requirements concerning the deliberate ending of life

Before deciding to deliberately end the life of a newborn baby, the doctor must ascertain that the patient is suffering intolerably, that no alternative treatment to avoid unnecessary suffering is available, and that the parents explicitly agree with the decision. Advice should be requested from an independent and qualified doctor at another hospital. Any proposal to deliberately end the life of a patient should be discussed with the team caring for the patient, including the nursing staff, and the views expressed should be taken into account when the final decision is made.

General requirements concerning the doctor-parent relationship

Parents should be properly informed and should be stimulated to discuss the matter with other people, such as like social workers and spiritual advisors. The doctor should allow them to seek a second opinion. If the parents wish a particular type of treatment to be continued, despite the fact that the doctor believes it should be discontinued, this wish should be respected, unless continuation would lead to unacceptable suffering. If the parents wish an end-of-life decision to be taken, which is inconsistent with the doctor's personal professional responsibility, the doctor will not respect this wish. If agreement cannot be reached, the doctor should consider asking another doctor to take over the case or transferring the patient to another hospital. It is self-evident that, in addition to the medical history, diagnosis and prognosis, other details should be recorded. A record should also be made of the views of the parents and the medical and nursing staff, the advice of other doctors consulted, the decision taken, the palliative care provided, dosages of any medication given and differences of opinion within the team or between the doctor and the parents. After the life of a patient has been deliberately ended, the doctor should notify the Coroner and not complete a certificate of (natural) death.

Conclusions

In the present neonatal intensive care environment it is impossible to neglect the ethical dilemmas which caregivers face from time-to-time. Doctors are morally and legally entitled to forgo life-sustaining treatment if there is no chance of survival. However, opinions on the right of doctors to take quality-of-life aspects into account differ between cultures and within populations, based on different religious traditions and other characteristics. The majority of pediatricians in the Netherlands are of the opinion that quality-of-life considerations must be taken into consideration in the decision making. They, just as the majority of the population, accept a very poor quality of (future) life as motive to forgo life-sustaining treatment in critically ill newborn babies. The frequency with which death in a neonate in the Netherlands is preceded by a decision to forgo treatment was found to be 57%, and in NICUs as high

as 80%, which is in line with data from other countries. The administration of potentially life-shortening drugs, which are given in palliative care to alleviate pain and suffering, whether or not after forgoing life-sustaining treatment, is considered to be accepted as good clinical practice in terminal care, even if death is hastened. This probably explains the relatively large percentage of pediatricians in this study who admitted that they had administered life-shortening drugs. However, in the Netherlands the intentional ending of life of patients who are not in terminal care is very rare. Parents participate in the decision-making process in most cases. Pediatricians in the Netherlands are of the opinion that some form of public control on end-of-life decision-making in newborns is necessary. However, most pediatricians reject the current notification procedure, in which the Public Prosecutor is almost directly involved. Review by a multidisciplinary committee of independent physicians, together with judicial and ethical experts, of cases of intentional ending of life in neonates, preceding the judgement of the Public Prosecutor, is considered to be probably more effective as public control.

It is important that difficult ethical problems in neonatal care are openly discussed within both the medical profession and society. In 1997, the Royal College of Paediatrics and Child Health in the United Kingdom published a document as a framework for the practice of forgoing life-sustaining treatment in children. [16] In this document it was stressed that it is fundamental that the child's interests are served. Another important statement in this document was that 'it is unrealistic to expect complete consensus'. One should 'seek as much ethical common grounds as possible, while acknowledging sincerely held differences of opinion'.

We should maintain high standards of quality, not only with regard to the medical treatment itself, but also the way in which we handle the ethical aspects of the treatment. More research on end-of-life decision making will help to further improve these standards of quality.

Important research questions

Since previous research on end-of-life decisions in neonatology was retrospective in design, knowledge is incomplete and many questions remain unanswered. One of the key issues in establishing the prognosis for later life in critically ill infants is the predictability of poor outcome. Probably the predictability is less good than we would like it to be. Establishing the prognosis for later life includes subjective elements that should be minimized. Prospective studies on predictability of the outcome after survival might be of value for improvement of the quality of the decisions taken.The procedures of team meetings that result in end-of-life decisions may vary a lot, depending on the local structure of meetings between the various professional groups involved in neonatal care, the personal characteristics of the people involved, and the way in which such meetings are chaired. Decisions should not only be based on scientific and medical data, but also be placed in the context of moral considerations. Moral aspects should be discussed in balance with medical aspects. The author is not aware of any specific training programs for multidisciplinary meetings to discuss ethical

issues concerning individual patients. However, in the St. Radboud University Hospital neonatal intensive care unit in Nijmegen, the Netherlands, the multidisciplinary meetings on end-of-life decision making have recently been structured and formalized. Meetings are chaired by a medical ethicist and the discussion takes place according to a checklist of relevant aspects. It starts with defining the individual moral problem, followed by a discussion of the relevant medical and nursing aspects. Subsequently, social and religious aspects, consequences of the disease and treatment for the well-being of the patient, opinions and feelings of the parents, and a number of aspects concerning the responsibilities of the doctors and other caregivers is discussed. Finally, the decision is made, based on the conclusions derived from the items discussed. The chairperson makes sure that all relevant aspects are discussed in time-balance with each other. This method of 'moral deliberation' will be evaluated to determine whether or not it contributes to the quality of decision making.

Another subject for future research concerns the medical, nursing, social, religious, ethical and judicial aspects that determine the outcome of individual decision making processes. Since many of the characteristics may remain hidden if studied retrospectively, a prospective multi-center study, in which individual neonatal intensive care patients are monitored, could provide in-depth information about the decision processes. In such a study, the interaction among caregivers, and between caregivers and parents, should be monitored by independent researchers The implementation of the end-of-life decisions taken, and a follow-up of the families involved, could be included in such a study. If similar multi-center studies are performed in different countries, the differences between individual institutions and between countries can be analyzed and explained.

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Marina Cuttini and the EURONIC Study Group

End-of-Life Decisions in Neonatal Intensive Care: Results from a Multicenter European Study[1]

Abstract

A European Concerted Action project (EURONIC) was carried out to explore the end-of-life decision-making process in a large, representative sample of Neonatal Intensive Care Units (NICUs) in several countries: France, Germany, Great Britain, Italy, Luxembourg, the Netherlands, Spain, and Sweden.

Structured questionnaires were used to record data on the organization and policies of the NICUs, and to survey the views and practices of the staff with regard to ethical decision-making.

In all countries most physicians reported having been involved at least once in setting limits to intensive care because of incurable conditions; less so because of a baby's poor neurological prognosis. Adopted strategies varied between countries. Practices such as continuation of current treatment without intensifying it and withholding of emergency measures appeared to be widespread. In contrast, the frequency of doctors reporting withdrawal of mechanical ventilation was highest in Sweden (90%), the Netherlands (89%) and Great Britain (83%), intermediate in France and Germany, and lowest in Spain and Italy (36 and 28%, respectively). Only in two countries was the administration of drugs with the purpose of ending the patient's life reported with substantial frequency: France (73%) and the Netherlands (47%). When a decision to limit treatment for a baby is under consideration, most NICUs reported a policy of taking into account the parents' opinion. However, the percentage of NICUs where parental involvement is explicit ranged from 19% in Italy to

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89% in Great Britain. Clearly, similar problems are approached in different ways in the various countries. The findings of this study may provide an opportunity for physicians to review their practices critically, in the light of what is done by other colleagues, and foster an open discussion about these difficult decisions.

In the past two decades, neonatal mortality in industrialized societies has dramatically decreased among progressively smaller and less mature babies.[2-5] However, despite an increased use of aggressive treatment, the outcome for some categories of infants is still very poor,[3] and some authors suggest that, in selected circumstances, options of non-intervention or withdrawal of treatment should be available.[6,7] While the right of the adult, competent patient to refuse medical care and, in some countries, even to be supported in his decision to obtain a dignified and painless death is generally recognized,[8] the situation is much more complex when the patient is a child or a neonate. Neonates cannot decide for themselves, and cannot express their views on issues such as 'quality of life' and life with disabilities. They cannot make a 'living will', nor have they any previous life experience, which the surrogate decision-maker can draw upon in order to make choices on their behalf. Who should speak for them? Traditionally, parents are entitled to make decisions on behalf of their minor children; given their bond of affection with the babies, and because they are the ones to whom the consequences matter most, they are often regarded as the best possible decision-makers.[9] On the other hand, pediatricians have often ascribed to themselves the role of 'child's advocate', and the growing acceptance of the patient's 'best interest' standard leaves little consideration for the interests of family members.[10]

And how should the decisions be made? Some call for a probabilistic approach and propose to withhold treatment from the very start for babies known to be at greatest risk of an adverse outcome. Others criticize this policy on the grounds that it is difficult to predict at birth whether an individual child will survive or not, and what the extent of handicap will be. The prognosis will become clearer later, when treatment may be discontinued if it appears to be futile or likely to impose too heavy a burden on the child. Whatever strategy is chosen, the potential of a long life lying ahead of a surviving neonate, either healthy and productive or doomed to pain and limitations, makes the stakes of decision-making particularly high.

These issues have been extensively discussed in the literature by ethicists, philosophers, medical law experts, and policy-makers. In contrast, studies reporting empirical data on decisions to forego intensive care are relatively few.[11] Most concern the English-speaking countries[12-18] or the Netherlands, where non-prosecution of euthanasia for the competent adult appears also to influence neonatal decision-making.[19,20] Data collected in a comparable way across different cultures and countries are particularly scarce.[21]

The EURONIC Project

Objectives

EURONIC is an international research project aimed at exploring the views, attitudes, and self-reported practices of physicians and nurses with regard to ethical decision-

making in neonatal care, in relation to the cultural, legal and religious backgrounds of the various countries.[22] Eight countries took part in the study (France, Germany, Great Britain, Luxembourg, the Netherlands, Spain, Sweden and, with co-ordinating tasks, Italy), which was later extended to Estonia, Lithuania and Hungary.Ethical decisions were defined as decisions regarding the use of diagnostic and/or treatment procedures when the balance between the benefits and the burdens of intensive care, both for the patient and for his family, is not known or is even clearly unfavorable. Examples are situations where intensive care can merely prolong the dying process, as in the case of fatal conditions (for instance, anencephaly), or where it may achieve survival, but only with severe physical and/or mental disability.In order to meet the objective of the study, it was necessary to describe:

1. the Units where issues of ethical decision-making arise, and where decisions are made;
2. the opinions, views and practices of the health care personnel;
3. the legal and ethical backgrounds of the countries involved.

Sample

In each participating country all the Neonatal Intensive Care Units (NICUs) satisfying four inclusion criteria were identified: care of very low birthweight infants (less than 1500 gram) on a routine basis (at least twenty admissions per year); capacity for prolonged mechanical ventilation; pediatrician or neonatologist (in Sweden, a nurse neonatologist) on duty in the hospital on a 24-hour basis; no transfers to other Units for medical reasons. In Luxembourg, the Netherlands, Sweden and Central and Eastern European countries all such Units were invited to take part in the study. In France, Great Britain and Spain a random sample was selected after stratification according to geographical area, and in Italy and Germany according to area and Unit level. The latter was defined by the number of intensive care cots in Italy (less than five, five or more) and by university affiliation (yes or no) in Germany. Only Units with more than five cots were sampled in Great Britain; Northern Ireland and Wales were not included. All the physicians and nurses regularly employed, either part or full time, in the selected Units at the time of the study were invited to participate. Absence from the Unit on a long-term basis (that is, sabbatical leave, maternity leave, serious health problems) was the only exclusion criterion applied.

Materials

Structured questionnaires were used to record data on the organization and policies of the NICUs, and to survey the views and practices of the staff with regard to ethical decision-making.

The staff questionnaire was anonymous and self-administered to protect confidentiality. It was originally prepared in English and subsequently translated into the national languages. The accuracy of the translation was checked by back-translation

into English and simultaneous review of the national versions by a panel of translators to ensure identical semantic content in each language.

Two pilot studies were carried out. First, the staff questionnaire was administered through a personal interview with ten doctors and ten nurses in each country to probe the overall performance and suitability to the different national contexts. After extensive amendments, a second pilot study tested in one randomly selected Unit in five countries (France, Germany, Italy, Spain and Great Britain) the staff response to the questionnaire presented in the final anonymous and self-administered form.

For the legislation survey, a list of topics, rather than a questionnaire, was prepared to guide the collection of comparable data on the legal and ethical background of each country.[23] For each topic, information was sought in three areas: the law governing medical practice; guidelines issued by official bodies, such as professional organizations and national ethics committees; any recognized authoritative sources of additional guidance (for instance, textbooks).

Data-collection and statistical analysis

The actual study took place in 1996-1997 and 144 NICUs were recruited in the eleven countries, with an overall response rate of 86%. In each NICU the staff questionnaires were distributed only to staff who were willing to participate in the project. A total of 1401 acceptable questionnaires were returned by doctors, and 3425 by nurses. Response rates, computed as the number of completed questionnaires over that of distributed questionnaires plus the number of staff who were unwilling to participate were 89% for doctors and 86% for nurses. Questionnaire coding and computer-storage were carried out at the co-ordinating center in Trieste, Italy. Comments made by respondents and answers to the few open questions were integrally transcribed and translated. Data-analysis was performed with the Stata statistical package, version 6.0. The sampling strategy used in the selection of the NICUs was taken into account by applying each observation (that is, variable from Unit or staff questionnaire) a weight equal to the inverse of the probability to select, within a given country and stratum, the NICU to which the questionnaire belonged.[24] Weighted national results can therefore be considered representative of the whole country.

The results are presented as weighted proportions and 95% confidence intervals (CI). In the calculation of the latter, standard errors were adjusted to take into account the cluster sampling study design, that is, the non-independence of observations within the same Unit. Logistic modeling was used to control international differences for the effect of confounding variables, and to explore additional factors, which might be related to decision-making. Variables related to the individual physician (age, gender, having had children, religion and religiousness, length of professional experience, daily work in neonatal intensive care, involvement in follow-up of graduates from intensive care, and in research) and to the NICU (belonging to a teaching hospital; number of very low birth-weight admissions per year; presence of a clinical Ethics Committee in the hospital) were selected for inclusion in the multivariate models.

Selected results

For the purpose of this paper, selected results from the physician survey[25] and from the NICU policies study[26] will be presented. Findings from the legislation project will be included in the discussion. Only Western European countries will be included; results from Luxembourg are omitted for confidentiality reasons, the participating Unit being the only existing Unit in the country.

Characteristics of the sample

The number of responding physicians, response rates, and socio-demographic and professional characteristics are presented in Table 1. Male gender was predominant among Swedish and German neonatologists, while the opposite was true in the Netherlands; distributions in the other countries were close to 50%. The distributions of age and length of experience in neonatal intensive care were correlated, and differed across countries: in Italy and Sweden physicians tended to be older than in the rest of Europe. When asked 'what religious background were you brought up in', the most frequent answer given in Spain, Italy and France was 'Catholic', while in Sweden, Germany and Great Britain it was 'Protestant'. The majority of respondents in Italy, Germany and Spain considered religion 'extremely' or 'fairly' important.

End-of-life decision-making: self-reported practices throughout professional life

In every country the majority of doctors reported that hey had decided at least once during their professional life, by themselves or together with others, 'to set limits to intensive interventions, and let nature take its course even if the patient died' in the case of fatal or terminal conditions (Table 2). The percentages of physicians reporting a similar decision because of poor neurological prognosis were lower in most countries, particularly in Italy, Spain and Germany.

When controlled for the effect of potential confounders in a multivariate logistic model (Table 3) differences between countries did not disappear. Female physicians were slightly more likely than their male colleagues to report decisions to limit care in the case of incurable conditions. Both age and length of professional experience were found to have an effect, with older and more experienced doctors being more likely than junior doctors to have ever made end-of-life decisions. The importance a physician attributes to religion in her life was also consistently associated with decision-making: physicians rating religion as 'extremely' or 'fairly' important were less likely to have ever limited treatment both in the case of fatal or terminal conditions (odds ratio, 0.5; 95% confidence interval [95% CI], 0.3-0.8) and because of poor neurological prognosis (odds ratio, 0.6; 95% CI, 0.4-0.9). Type of religious background had a less clear-cut effect. Daily work in the Unit (as opposed to rotating for night/day shifts or supervision only) was associated with an increased probability of reporting a non-treatment decision in the case of incurable conditions, and experience in the follow-up of babies after discharge was associated with similar decisions because of poor prognosis.

Table 1. Number, response rate and characteristics of physicians*.

	Italy	Spain	France	Germany	Netherlands	Great Britain	Sweden
Number (response rate)	271 (95)	206 (94)	206 (90)	226 (87)	134 (88)	89 (69)	93 (91)
	%	%	%	%	%	%	%
Male gender	54	54	53	67	43	55	75
Age-categories							
Under 30 years	3	22	23	11	24	27	1
30-39 years	36	33	46	64	53	51	18
40 years and over	61	45	31	25	23	22	81
Religious background							
None	3	-	13	7	20	12	23
Catholic	96	100	68	43	46	22	5
Protestant	1	-	5	49	31	45	70
Other	-	-	14	1	2	20	2
Importance of religion							
Important (extremely/fairly)	69	51	40	57	28	43	27
Years of experience in neonatal IC, median	11	7	5	2	2	3	9
Dpercentage of physicians with daily duties in the Unit	80	33	47	38	44	35	52

* Adapted and reprinted with permission from The Lancet [24]

Table 2. Proportion of physicians having ever decided (by themselves or together with others) to set limits to intensive interventions*.

	Italy % (95% CI)	Spain % (95% CI)	France % (95% CI)	Germany % (95% CI)	Netherlands % (95% CI)	Great Britain % (95% CI)	Sweden % (95% CI)
In case of fatal or terminal conditions	61 (55-67)	76 (69-83)	85 (77-91)	86 (79-91)	81 (77-84)	77 (69-84)	96 (85-99)
In case of poor neurological prognosis	46 (39-54)	61 (50-70)	85 (77-90)	69 (56-79)	78 (71-83)	74 (60-85)	90 (82-95)

* Reprinted with permission from The Lancet [24]

Table 3 Results of multivariate logistic regression for having ever set limits to intensive inteventions*.

	In case of fatal or terminal conditions			In case of poor neurological prognosis		
	Adjusted odds ratio	(95% CI)	p-value†	Adjusted odds ratio	(95% CI)	p-value†
Country			< 0.001			< 0.001
Italy	1			1		
Spain	9.4	(4.3–20.9)		4.1	(2.2-7.8)	
France	17.3	(7.1–42.3)		19.2	(9.2-40.0)	
Germany	10.7	(5.0-22.8)		5.0	(2.4-10.7)	
Netherlands	10.6	(5.3-21.4)		9.6	(4.6-20.1)	
Great Britain	11.2	(4.2-30.3)		9.2	(3.5-24.1)	
Sweden	11.0	(2.2-54.1)		9.8	(3.3-29.3)	
Gender			0.05 > p > 0.01			> 0.05
Male	1			1		
Female	1.5	(1.1-2.1)		1.1	(0.8-1.7)	
Age (years)			< 0.001			0.01 > p > 0.001
under 30	1			1		
30-39	5.7	(2.5-12.8)		2.9	(1.5-5.6)	
40 or over	8.2	(2.6-25.4)		2.3	(0.9-6.0)	
Years of experience			< 0.001			< 0.001
< 6	1			1		
6-15	3.6	(1.7-7.4)		3.0	(1.8-4.9)	
> 15	5.3	(2.1-13.4)		2.7	(1.0-7.2)	
Religious background			< 0.001			0.05 > p > 0.01
Catholic	1			1		
Protestant	2.8	(1.6-4.8)		1.3	(0.6-2.7)	
Other	0.5	(0.2-1.6)		0.4	(0.2-0.9)	
None	0.8	(0.4-1.8)		0.8	(0.3-1.8)	
Importance of religion			0.01 > p > 0.001			0.01 > p > 0.001
Not important	1			1		
Important	0.5	(0.3-0.8)		0.6	(0.4-0.9)	
Daily duties in the Unit			< 0.001			
No	1			1		
Yes	2.3	(1.6-3.4)		1.4	(1.0-2.1)	
Involvement in follow-up			> 0.05			0.05 > p > 0.01
No	1			1		
Yes	1.1	(0.7-1.7)		1.5	(1.0-2.2)	

* Adjusted odds ratios are odds ratios adjusted for all the variables listed in the table and having had children, working in a teaching hospital, involvement in research, number of very low birth weight infants treated in the Unit per year, and presence of a clinical Ethics Committee in the hospital.

† P-value represents the overall statistical significance of the variable.

Table 4. Proportion of physicians having ever made end-of-life decisions for newborn infants (by themselves or together with others)*.

	Italy % (95% CI)	Spain % (95% CI)	France % (95% CI)	Germany % (95% CI)	Netherlands % (95% CI)	Great Britain % (95% CI)	Sweden % (95% CI)
Withhold intensive care (for instance, resuscitation at birth, mechanical ventilation)	45 (36-54)	75 (67-81)	63 (55-71)	69 (59-78)	85 (78-91)	81 (73-87)	88 (78-94)
Withhold emergency treatment/manoeuvres (for instance, resuscitation for cardiac arrest)	52 (46-59)	65 (59-71)	75 (68-81)	74 (62-83)	83 (78-87)	80 (71-86)	90 (80-95)
Continue current treatment without adding others	78 (74-81)	92 (86-95)	76 (65-84)	86 (78-92)	75 (66-83)	71 (62-79)	97 (90-99)
Withdraw life-saving drugs (for instance, cardiotonics)	34 (26-42)	48 (38-59)	50 (41-60)	79 (70-86)	71 (60-80)	64 (59-68)	53 (39-66)
Withdraw mechanical ventilation	28 (18-41)	36 (26-47)	66 (55-75)	61 (48-73)	89 (84-93)	83 (75-89)	90 (82-95)
Administer sedatives and/or analgesics to suppress pain even if this might cause respiratory depression and death	32 (24-43)	64 (56-72)	87 (81-91)	67 (56-76)	89 (80-94)	70 (59-79)	86 (74-93)
Administer drugs with the purpose of ending the patient's life	2 (1-5)	2 (1-6)	73 (63-81)	4 (1-14)	47 (33-60)	4 (2-9)	2 (1-8)

* Reprinted with permission from The Lancet [24]

Table 4 presents the details of the non-treatment decisions ever made by physicians during their professional life. The vast majority of physicians in every country reported continuation of 'current treatment without additional treatment'. Also withholding intensive care, either at birth or subsequently (for instance, by refraining from mechanical ventilation), and withholding emergency treatment appeared to be widely reported practices, although less frequently in Italy. In contrast, the frequency of doctors reporting withdrawal of mechanical ventilation showed wider variability between countries, being highest in the Netherlands, Great Britain and Sweden, intermediate in France and Germany, and lowest in Spain and Italy. In case of a newborn's pain not balanced by a real chance of recovery, most physicians in every country but Italy appeared to accept the risk of death as a side effect of analgesia. Again, adjusting for length of professional experience and other potential confounders did not blur the differences among countries (results not shown in tables).

Only two countries reported with substantial frequency decisions to administer drugs 'with the purpose of ending the patient's life': France (73% of respondents) and the Netherlands (47%). This finding was supported by the replies to questions on the most recent observed case involving an ethically problematic choice (data not shown in tables): only in France and the Netherlands was the ethical dilemma leading to decision-making framed by a substantial fraction of respondents as deciding 'whether to administer drugs with the purpose of ending the life of a baby not dependent on intensive care but with a very poor prognosis' (26% in France and 14% in the Netherlands), and was the administration of drugs to end life reported as the final decision made (48% in France and 14% in the Netherlands).[24]

The role of parents in decision-making: policies of Neonatal Intensive Care Units

Results from the NICUS survey[25] offer an opportunity to understand the role of parents in decision-making by comparing the policies prevailing in different countries (Table 5). Most Units in each country report a policy of taking into account the parents' views, either by directly involving them in the decision, or indirectly 'sounding out' their opinion. Great Britain is evidently the country where parents are more often explicitly involved in decision-making, by openly participating (78% of Units) or even by assuming full responsibility for the choice (11%). In contrast, none of the French Units reported open involvement of parents in the decision-making, although parental views are always 'indirectly sounded out and taken into account'. Ten percent of the Italian and 6% of the Spanish Units have no policy regarding this issue.

Discussion

In a paper that has become classical,[27] the American lawyer Nancy Rhoden delineated three approaches to making decisions for neonates in the face of uncertainty. The first involves withholding intensive care from the very start in neonates with a poor prognosis, based on birthweight, gestational age, and other factors known to be

Table 5. NICUs' policies regarding parental participation in decision-making.

	Italy % (95% CI)	Spain % (95% CI)	France % (95% CI)	Germany % (95% CI)	Netherlands % (95% CI)	Great Britain % (95% CI)	Sweden % (95% CI)
They may choose the course of action for their baby	0	0	0	0	0	11 (2-47)	0
They may take part in the decision	19 (8-39)	35 (20-55)	0	54 (30-76)	50 (50-50)	78 (44-94)	26 (18-35)
Their wishes are indirectly sounded out and taken into account	48 (31-66)	47 (29-66)	100	44 (23-68)	50 (50-50)	11 (2-47)	68 (59-76)
They do not take part in the decision but are informed about it	22 (10-42)	12 (4-30)	0	2 (0.4-0.9)	0	0	6 (6-6)
There is no policy about this issue	10 (3-29)	6 (1-24)	0	0	0	0	0

* Adapted and reprinted from the Archives of Disease in Childhood Fetal Neonatal Ed.[25]

predictive of an adverse outcome. This 'statistical approach' which, according to Rhoden, was applied in Sweden, sacrifices a number of infants which might have responded favorably to treatment despite their initial poor start. Moreover, should some babies survive despite the withholding of treatment, their final outcome may be much worse than it should have been after intensive care. In contrast, the 'wait until certainty' strategy prescribes aggressive treatment for every infant until there is a virtual certainty of death or irreversible coma. Some years ago, a paper reviewing outcome among surviving very low birthweight infants[28] raised the hypothesis that the higher disability rates found in studies carried out in the United States might be attributed precisely to this policy. The third approach is the British 'individualized prognostic strategy', requiring initial treatment of every infant, followed by regular re-evaluation of its benefits and burdens and by withdrawal if the prognosis is confirmed to be poor.

The present study reveals today a more complex scenario, with practices of withholding and withdrawing treatment co-existing in the same country, although with different frequencies. 'Continuing current treatment without additional treatment' is in most countries, including Spain and Italy, the most frequently reported way to limit care. In France, Great Britain, the Netherlands and Sweden more clear-cut decisions, such as withdrawal of mechanical ventilation, were also frequently reported, while only two countries mentioned with significant frequency decisions to 'administer drugs with the purpose of ending the patient's life': France and the Netherlands.

Documenting the occurrence of euthanasia is difficult, both because of the illegal status of the act, and the ambiguities in its definition.[29] Withdrawal of mechanical ventilation is often accompanied by sedation to control symptoms and prevent suffering,[30] and sometimes even by the administration of paralyzing agents:[16] a certain degree of misclassification might therefore have occurred in this study between such a practice (as carried out, for instance, in Great Britain or Sweden) and intentional killing. On the other hand, in the description of the most recent observed clinical case only French and Dutch physicians chose to frame the ethical dilemma leading to decision-making as 'whether to administer drugs with the purpose of ending the life of a baby not dependent on intensive care but with a very poor prognosis'. This kind of situation, which leaves no room for ambiguity, corresponds to the French definition of active euthanasia as was found in a qualitative study carried out, within this same project, in two Units in France.[31] In one of these Units, some of the interviewed physicians clearly mentioned the possibility of 'active euthanasia, that is interruption of the life of a baby already autonomous in terms of vital functions'.

In the Netherlands, euthanasia, being by definition at the request of the patient, concerns only the autonomous adult. However, end-of-life decisions on behalf of incompetent patients, and even newborns, are known to take place. In a recent study,[19] carried out among a sample of 31 neonatologists, 14 (45%) reported having at least once administered drugs with the explicit intention of ending life, a figure strikingly close to the findings of our study.

NICU policies concerning parental involvement in decision-making should be evaluated in the light of the practice of physicians concerning end-of-life decisions discussed

above. Most Units in every country reported a policy of taking into account the views of the parents in the case of non-treatment decisions. There are, however, degrees in such involvement, which may range from explicit participation, to 'indirect' sounding out of parents' wishes to merely informing the parents about the decision taken. Great Britain, on the one hand, and France, on the other, offer the best representation of these different attitudes.

In 89% of the British Units, parents are given the opportunity to take part in the decision, and this finding is consistent with the Anglo-Saxon tradition of respect for personal autonomy, and with the evidence from other published studies. In contrast, in France, 100% of the NICUs report a policy of indirectly sounding out parental opinions which are 'taken into account' by the members of the staff who make the decision. The staff therefore take upon themselves not only the full responsibility of the decision and the consequent action, but also that of interpreting the parents' views, and decide both about the 'best interest' of the patient and the limits of the burden which may be imposed on the family.

The desire to protect parents from the burden of these difficult choices appears to be the major factor underlying this very uniform approach, as shown by some of the comments made by physicians on the staff questionnaires:

'(...) I personally believe that parents must be informed of the state of health and the prognosis of the baby, but that they should not take part in the decision concerning limitation or withdrawal of treatment. They must in no way feel guilty for having wished for the death of their baby.'

'(...) parents (...) must at no stage be able to take part in the decision so that they may never have the remorse of having wanted and decided the death of their child.'

However, the few studies carried out to investigate the preferences of parents do not support the hypothesis of a harmful effect of participation in decision-making. Benfield found no difference in grief reactions between parents of children for whom respiratory support was withdrawn, and parents whose infants died despite uninterrupted care.[32] In fact, parents having a role in decision-making reported less subsequent problems, such as anger, depression, sleeping difficulties, loss of appetite and wanting to be left alone. The authors conclude that '(...) informed parents can participate as partners with their physician in difficult infant-care decisions, even when death results, and subsequently adjust to their loss in a healthy manner'.

Walwork and Ellison studied the grieving patterns and psychosocial functioning of the parents of 20 newborns from whom life support was withdrawn after a decision-making process in which the parents had participated.[33] One year after the event, these parents did not, as a group, give evidence of any unusual, prolonged or pathological grieving process, nor did they carry a burden of guilt for their participation in the decision. On the contrary, they tended to accept the responsibility for their choice and felt that it was the right one.

Conclusion

The results of this study show firstly, that collaborative international research on these delicate issues is feasible and worthwhile; and secondly, that analysis of ethical issues on a cross-cultural basis can provide insights, which would not be achievable with research, carried out within a single country. A key result of this survey is that differences between countries can neither be explained by the characteristics of the physicians involved, nor those of the NICUs. National legislation certainly plays a role. Italian law is strongly protective towards human life, especially when children are involved.[22] In contrast, in Great Britain and the Netherlands a series of court cases have tested the appropriateness of withholding and withdrawing treatment in selected circumstances, both in the case of a dying patient and because of severe handicap. Yet, the relationship between clinical practices and legislation is far from absolute, as is forcefully illustrated by the example of France, where legislation is similar to that in Italy. Clearly, the values and cultural beliefs of society, which are wider than those strictly embedded in legislation, are at stake.[34] Professional guidelines, where they exist,[35,36] and the position of influential individuals[37] or groups may represent, at the same time, the product of such cultural values, and contribute to their reinforcement. Lastly, the effect of individual physician characteristics, such as religiousness, shows that clinical circumstances, culture and law are not the only factors which govern ethical decisions; as it was already suggested,[38] the opportunity of revealing such personal values to parents should be seriously discussed.

Important research questions

Future research should focus on the parents, their needs regarding information, and the demand of being involved in decision-making. The best possible strategies to inform parents about their baby's health status, and especially about the long-term prognosis, should be developed and tested. Their views regarding end-of-life decisions on behalf of their children should be explored, and the long-term consequences of their participation in decision-making should be carefully monitored. Again, an international approach may prove fruitful not only to explore the relationship between cultural values and expectations, but also to develop policies which are targeted to the specific needs of the families within a certain country and culture.

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Part IV End-of-Life Decisions for Patients with Dementia

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Impact of Palliative Interventions and Mortality Rate in Hospitalized Patients with Advanced Dementia

Abstract

By the year 2040 the prevalence of dementia in the United States alone is estimated to rise to over nine million affected individuals, with an age-specific prevalence that is similar in virtually all nations in which it has been studied. Costs of care increase with severity of dementia, with an annual United States estimate of over 200 billion dollars by the year 2040. Dementia causes a myriad of suffering, for the patients themselves as well as for their family and paid caregivers. Despite the inevitably progressive, incurable, and terminal nature of dementing illnesses, programs providing palliative approaches focused on relief of suffering, maximizing comfort and quality of life, and support for family caregivers are remarkably sparse. This evolves in part from the highly variable survival time of patients with advanced dementia, making accurate prognostication impossible and leading to uncertainty about the proper goals of medical care: is the purpose of health care to maximize the length of life or is the primary focus the promotion of best possible quality of life?

A series of studies aimed at characterizing the care of persons with advanced dementia in the hospital setting found: (1) a substantial proportion on perwons with advanced dementia are lacking functional surrogate decision-makers; (2) painful and uncomfortable hospital procedures are commonly employed in this patient population; and (3) palliative care consultation had little impact on the type of care received. These findings have implications for establishing new models of medical care for this growing patient population.

Alzheimer disease and related dementing illnesses are incurable, progressive disorders leading gradually to complete loss of cognitive function and subsequent death. There are presently over four million Americans with diagnosed dementia, approximately half of whom are in the late stages of disease: bed- or chair-bound, unable to comprehend or recognize their surroundings or caregivers, incontinent, and completely dependent on others for all activities of daily living. The prevalence of dementia increases exponentially between ages 65 and 85, doubling with every five years of age, and has risen ten-fold since 1900 in association with the increase in life expectancy occurring in the last century. The age-specific prevalence is similar in virtually all nations in which it has been studied, including France, Italy, Great Britain, Japan, China, and the United

States.[1] By the year 2040 the prevalence of dementia in the United States is estimated to rise to over nine million affected individuals.[2] Costs of care increase with severity of the dementing illness with an annual United States estimate of over 100 billion dollars in 1993 alone, a figure that is expected to double by 2040.[2]

Site of care during the advanced stages of dementia has not been well studied, in part because of the unreliable nature of death certificate data in identifying dementia as a cause of death.[3] In one study in an academic teaching nursing home, 25% of long-term nursing home residents were hospitalized at least once during the second six months of their nursing home stay, a group characterized by a higher risk of severe functional decline, recent deterioration, heart or respiratory failure, feeding tubes, and decubitus ulcers.[4] Another study of dementia patients with involved family caregivers found that the majority of care in the last six years of life was provided at home, with death occurring at home in 42%, in a nursing home in 32%, and in the hospital for 26%.[5] For patients without closely involved family caregivers, as well as for those spending their last months to years in a nursing home, the frequency of hospitalization and of death in hospital is presumably higher.

Dementia as a disease in need of palliation

Dementing illness causes a myriad of suffering, for the patients themselves as well as for their family and paid caregivers. In the early stages, awareness of loss of memory and capacity is commonly associated with severe depression, anxiety, and a progressive sense of helplessness, existential dread, and loss of meaning in life. In later stages, dementia patients frequently suffer from agitation, paranoia, hallucinations, fear, and anxiety. The inability to recognize or remember caregivers who are attempting to help with dressing or bathing or feeding is often terrifying and may lead to hostile physical or verbal outbursts. Restlessness and wandering with associated risk of getting lost are common. Standard forms of medical care such as a physical examination, routine wound care, or a blood test may be experienced as incomprehensible and frightening bodily assaults. The inability to articulate or ask for relief from common causes of pain, such as arthritis, headache, or skin breakdown may also be contributors to agitation and restlessness, and are often unrecognized.

Serious and life-threatening medical illnesses common among the elderly population are also major contributors to suffering in the dementia patient. For instance, pneumonia is associated with dyspnea, tachypnea, cough, and pain, causing symptom distress that is typically undetected and untreated in the cognitively impaired. The leading causes of death for persons with end-stage dementing illness are infectious diseases, primarily pneumonia, urosepsis, and infectious complications of pressure ulcers and skin breakdown. Suffering results both from the endogenous effects of the acute illness itself, as well as the distress associated with its treatments (for instance, venipuncture, blood gas determinations, and other needle sticks, restraints, nasogastric tubes, and endotracheal suctioning).[6,7]

Because of the progressive dependency predictably associated with even the earlier stages of dementing illnesses, the burden on family caregivers is enormous. The vast

majority of the personal care as well as the financial resources needed for paid assistance required by dementia patients, comes not from the health care system but primarily from family members, with an associated toll in terms of fiscal, emotional, physical, and existential and spiritual suffering.[8,9] The SUPPORT study, focusing on hospitalized adults with a broad range of life-threatening illnesses found that over half of the families suffered one or more serious adverse effects (for instance, loss of most of the family's savings) during the course of the patient's terminal illness.[10] Long-term family caregivers of patients with chronic illnesses such as dementia typically face much longer periods, often a decade or more, of intensive responsibility for the needs of their loved one. Family caregivers perform tasks ranging from negotiating the intricacies of the health care system, to the provision of skilled (injections, tube feedings) and so-called unskilled (bathing, toileting, diaper changing) care to their demented relatives whose needs progressively increase just as their ability to interact or express affection continues to decline.[11] The suffering and needs of families of dementia patients is therefore a major focus of palliative care for this population.

Barriers to palliative care in dementia

Despite the inevitably progressive, incurable, and terminal nature of dementing illnesses, programs providing palliative approaches focused on relief of suffering, maximizing comfort and quality of life, and support for family caregivers are remarkably scarce. Even the Medicare Hospice program, whose sole focus is the palliation of terminal illness, serves almost no patients with a primary diagnosis of dementia. In a national survey of over 1000 United States hospices in 1995, fewer than 1% of hospice patients had a primary diagnosis of dementia and only 7% had dementia as a secondary diagnosis with another terminal illness.[12] Reasons reported by these hospices to account for low enrollment of dementia patients include the difficulty of accurately prognosticating survival time and the high (and costly) respite needs of dementia family caregivers.[12] The basis for these concerns lies in the Medicare hospice reimbursement system, originally developed to be responsive to the short-term and more predictable needs of cancer patients and their family caregivers: United States' hospices are reimbursed under a capitated per-diem rate, and are subject to retroactive denials of payment for patients who survive longer than the six month prognosis eligibility criterion required for admission to hospice. Thus, patients who live longer than six months, as well as those with costly custodial care and respite service needs, pose unacceptable financial risks to most hospice programs in the United States. Other studies have reported that hospice staff are unaccustomed to and uncomfortable with patients who cannot express their own wishes and with whom they cannot establish any kind of a relationship.[13] Furthermore, the long-term and experienced family care giver is sometimes perceived by hospice staff as overly controlling of the patient's care and not as accepting of the skilled services and advice provided by hospice professionals, in contrast to patients and families with shorter illness experience and more traditional hospice diagnoses, such as cancer.

In part because of the variable survival time of patients with advanced dementia, uncertainty about the proper goals of medical care is common: is the purpose of health care to maximize length of life or is the primary focus the promotion of best possible quality of life? Family and professional caregivers vary in their endorsement of palliation and comfort measures as the primary goal of medical care for persons with advanced dementia. In a study of active family caregivers and MD and non-MD members of the Gerontological Society of America, a majority of all groups chose palliation as the most appropriate level of care for end-stage dementia patients.[14] Such a choice was associated with increasing age of the respondent and prior experience with a terminal care situation. In contrast, another study of family members (mostly adult daughters) of severely demented nursing home residents found that a majority favored hospitalization and intensive care under hypothetical scenarios of pneumonia and worsening sepsis, although most rejected tube feeding and cardiopulmonary resuscitation under the same circumstances.[15] Ambiguity about the goals of medical care typically surfaces when decisions about treatment of acute or intercurrent illnesses, such as infections, arise: should the pneumonia patient be treated with antibiotics, transferred to the hospital, or intubated, or should they be treated symptomatically with analgesics, antipyretics and oxygen? Should a dementia patient who is refusing food or having difficulty swallowing be nourished via a feeding tube? The answers to these questions depend critically upon the goals of care and since each of these medical interventions may prolong life, a family member's decision to forego any one of them becomes an active decision to let the patient die of their underlying disease. Particularly when the patient has not previously articulated his wishes for care under such circumstances (through the process of advance care planning), family decision-makers typically find such decisions wrenching, and often feel as if they are holding the power of life and death for their loved one in their own hands, a responsibility they are neither prepared for nor anxious to assume. Even the process of balancing the burden of suffering against the value of continued life is difficult for surrogate decision-makers since dementia patients can neither express their preferences nor describe what they are feeling to their professional and family caregivers. In the absence of reliable evidence of the patient's wishes and degree of physical suffering necessary to assess what would constitute the patient's best interests, the family decision-maker must base their decision on what seems to manifest the proper expression of a loving fiduciary role, that is, 'what would a good wife do for her husband under these circumstances?' rather than 'would my husband want this quality of life if he were able to communicate?' or 'is my husband suffering as a result of his disease and its' treatment?'.[16]

More accurate prognostication of survival time in advanced dementia would help both professional and family decision-makers to negotiate these choices. If it were possible to predict with reliability which dementia patients were likely to die within a six-month period regardless of medical treatment, the focus on palliation as the most appropriate goal of medical care would be clearer. Several investigators have attempted to define measurable clinical characteristics that place persons with advanced dementia at predictably high risk of death. Though Volicer and colleagues found that following a fever episode older age, more advanced dementia, a palliative

care plan, and recent (within six months) nursing home admission were predictive of six month mortality, a substantial fraction of patients meeting these criteria survived for longer periods.[17] Another study of mildly demented subjects followed over seven years found that male sex, shorter duration of illness, presence of extrapyramidal signs, and a lower mental status score were associated with a higher risk of mortality, but again the time ranges were broad and the individual variability high, limiting the utility of such algorithms for individual decisions about use of life-sustaining treatments.[18] Multiple descriptive studies of mortality rates after percutaneous endoscopic gastrostomy tube placement in cognitively impaired individuals found a median of survival of only six to seven months.[19-21] Although these high mortality rates suggest that need for a feeding tube is a marker of serious underlying illness, precise estimates of survival time for individual patients are impossible. Thus, to a degree typical of other chronic illnesses such as heart or respiratory failure, substantial prognostic uncertainty is probably an irreducible feature of Alzheimer's dementia.[22] This suggests that other bases for decision-making, involving knowledge of patient's prior wishes and values, surrogate assessments of patient quality of life, and forging a consensus based on shared narratives about the patient as a person will continue to be key variables in the process of determining the goals of medical care for persons suffering from advanced stages of dementing illness.[23,24]

Research in hospitalized dementia patients

In a series of studies aimed at characterizing the care of persons hospitalized with advanced dementia, Mount Sinai researchers have evaluated the capability of surrogates of patients with advanced dementia to participate in medical decision-making on their behalf; the burden of suffering associated with common hospital procedures and experiences for acutely ill adult in-patients; and the impact of hospital-based palliative care consultation on the care received by older persons with acute medical illness superimposed on advanced dementia.

Barriers to obtaining consent in dementia research: implications for surrogate decision-making.[25]

As part of a randomized controlled clinical trial of palliative care consultation in acutely ill hospitalized persons with advanced dementia, nearly 50% (68/145) of otherwise eligible subjects could not be randomized because they either had no functional surrogate to make decisions on their behalf, or their surrogate was incapable of participating in the decision-making process. The absence of a functional surrogate appears to be more common among hospitalized dementia patients than among similar patients in long-term care or home settings, and may explain in part how the patient came to be transferred to a hospital (that is, there was no functional surrogate to make the decision to keep the patient at home or in the nursing home in the context of an acute illness). The prevalence of dementia patients without functional surrogates is unknown, although several other studies also suggest that the problem is not rare, and is likely to increase with the growth in the population at risk.[26-28] These

data suggest that mechanisms of decision-making for advanced dementia patients will require attention to those without functional surrogates, and studies of how best to protect the interests of this uniquely vulnerable population of patients are badly needed.[29]

Suffering associated with routine hospital procedures and experiences[30]

Hospitalized patients are routinely subjected to multiple needle sticks, difficult invasive procedures, and so-called 'transfer trauma' associated with change in physical environment and caregivers. Dread of hospitalization is common among older or seriously ill patient populations familiar with what the experience is like. For cognitively impaired populations who can neither consent to nor understand the reasons for such experiences, iatrogenic suffering associated with hospitalization is likely to be at least as great as it is for the cognitively intact patient. If family members and other surrogates are to balance the potential benefits of hospitalization in terms of longer life and relief of acute illness against the burden of suffering imposed by hospitalization, some quantitative measure of these burdens would be helpful. To this end, Mount Sinai researchers interviewed 130 cognitively intact hospitalized patients for their ranking of the pain and discomfort associated with sixteen common procedures (for instance, arterial blood gas determination) and experiences (for instance, waiting for a procedure in radiology).[30] Subjects rated arterial blood gas determinations, nasogastric tube placement, central line placement, peripheral intravenous catheter insertion, and mechanical ventilation as the top five most painful procedures (in descending order). The five procedures associated with highest discomfort were nasogastric tube placement, mechanical ventilation, mechanical restraints, central line placement, and indwelling urethral catheters. The study showed that a five-point numeric rating scale was able to produce valid and reliable rankings of pain and discomfort. Subjects were able to accurately discriminate pain from discomfort, and although these measures were correlated, they differed across the procedures studied. These data should be used to help identify and reduce the iatrogenic suffering associated with hospitalization for acute illness, and, in patients unable to speak for themselves, can serve as surrogate measures of the pain and discomfort dementia patients may experience in the hospital.

A randomized controlled clinical trial of palliative care consultation for hospitalized patients with advanced dementia[35]

Although exact numbers are not available, substantial numbers of advanced dementia patients spend time in acute care hospitals when they are nearing death. In a multi-institutional study, 30.6% of nursing home patients with pneumonia were transferred to hospitals, comparable to figures reported in several other studies (see cites below).[31] One study of 3782 long-term care residents found that 25% were hospitalized at least once, with higher risk associated with heart or respiratory failure, recent functional decline, decubitus ulcer, and presence of a feeding tube.[32] Another study of 312 long-term care patients who developed pneumonia found lower two-month mortality overall in the 79% of patients treated in the nursing home as com-

pared to the 21% transferred to hospital.[33] However, patients with only moderate dependency at baseline (that is, the least functionally impaired) and evidence of less severe pneumonia (normal respiratory rate) had the greatest risk of functional decline or death after hospitalization for pneumonia. Finally, in a Veterans Affairs long-term care setting, a study of 108 consecutive pneumonia patients found a 19% two week, 59% one year, and 75% two year mortality rate, with risk of death highest in the most functionally impaired.[34] In this study 29% of patients were transferred to an acute care hospital, a factor which had no influence on mortality.

Because of the frequency of and distress associated with hospitalization in persons with advanced dementia, a study of the impact of palliative care consultation focused on comfort-oriented goals of care was undertaken in a sample of acutely ill hospitalized dementia patients. Mount Sinai investigators conducted a prospective randomized controlled trial of palliative care consultation (intended to enhance comfort and reduce distressing interventions) versus usual care in 100 consecutive severely demented patients studied over a three-year period in a large New York City teaching hospital.[35] The intervention and control group were comparable on major baseline characteristics, including age, sex, dementia stage, ethnicity, existence of advance directives, site of residence, diagnosis at admission, and presence of a feeding tube at time of admission. There were no differences in number of rehospitalizations, mean length of stay post-randomization, or mortality. Few patients in either group received invasive or complex diagnostic tests but overall 40% received daily phlebotomy, 74% intravenous therapy, 75% systemic antibiotics, 44% new feeding tubes, and 69% of the subjects received long-term enteral feeding. There were no differences between intervention and control groups with respect to any of these outcomes. Intervention patients were more likely than control patients to be discharged with an explicit palliative care plan but otherwise there were no other outcome differences between control and intervention groups. Mortality rates were high and were similar in both intervention and control groups. Median survival was 175 days (50% of the subjects were dead within six months of study entry).

The palliative care consultation failed to effect the care of hospitalized patients with advanced dementia. Patients hospitalized with end-stage dementia have a high mortality rate equivalent to that seen in metastatic solid tumor malignancies and end-stage congestive heart failure. Awareness of the terminal nature of the illness should guide establishment of appropriate goals of care for this population including measures directed at maximizing comfort and avoidance of unduly burdensome medical interventions.[35] For unclear reasons, the palliative care consultation had minimal impact upon the care received by the intervention patients, an observation with important implications for research priorities on palliative care in end-stage dementia. Reasons advanced by the investigators to account for the absence of effect of the intervention included:

1. Low numbers of subjects (as noted above, nearly half of eligible patients could not be entered in the study because they had no functional surrogate) may have resulted in a type 2 error.

2. The consultative and investigational nature of the intervention (that is, the primary doctor did not request the consult but instead agreed to have his or her patient entered into the study) may have been too weak to influence care decisions made by primary doctors and family decision-makers.
3. It is likely that selection bias plays an important role in that patients with advanced dementia who are hospitalized in the context of acute illness are probably predisposed to receive invasive acute care as opposed to comfort oriented measures that might have resulted in a decision not to transfer to hospital in the first place. This possibility gains support from the observation that surrogates of study subjects were often difficult to reach, rarely visited the hospital, and had variable levels of engagement with the day-to-day decision-making about their relative's care.
4. Most of the dementia patients were strangers to the attending physician responsible for their hospital care- this lack of primary care continuity may have encouraged the use of life-prolonging technologies since the responsible physician typically had no insight into the patient's values or prior stated preferences.
5. New York State requires a high evidentiary standard of clear and convincing evidence of a patient's wishes before a surrogate is empowered to decide to forego life-sustaining treatments. This legal context inhibits decisions to choose palliative care plans in the absence of formal advance directives (present in only 15 % of these subjects).
6. Finally, the primary physicians and family decision-makers may not have considered advanced dementia to be a terminal illness and may have assumed that comfort as the primary goal of medical care only becomes appropriate in the last weeks or months of life. In fact the variability in survival time even in the most severe dementing illnesses and the associated uncertainty about prognosis inhibits the application of palliative care plans as long as prolonging life remains the highest priority goal of medical care.

Important research questions

Clinical research in palliative care is difficult in virtually all patient and family groups because of the intensity of illness and the difficulties inherent in asking such vulnerable populations to give time and energy to the aims of clinical research. These challenges are magnified many times in the late stages of dementia, a group of patients who can neither understand nor consent to participation in research, and who cannot report or express their symptoms and other sources of distress. Reliance on surrogates for consent to participate depends both upon the availability of surrogates and upon their capacity to understand and give informed consent on behalf of their loved-one, both major barriers to the conduct of the study described above. Similarly the reliability of surrogate reports of patient symptoms is poor and surrogate responses have repeatedly been shown to demonstrate poor agreement with the reports of cognitively intact patients.[37] In view of these observations research is needed on means of enhancing patient participation in establishing their wishes about

the goals of medical care in early stages of illness, both by assessing capacity of early dementia patients to participate in such a decision-making process, and then by assessing the impact of such decisions on the care ultimately received. Thus the main research priorities in palliation of late stage dementing illness are:

1. Studies of the capacity of early stage dementia patients to articulate their wishes and goals for their future medical care.
2. Longitudinal studies of the long-term impact of such a decision-making process on actual care received years later.
3. Given that much, but not all, data suggests that advance care planning has minimal impact on ultimate care decisions, studies of the reasons for this failure and efforts to address them are also needed.[38-40]
4. Studies are needed to evaluate sources of suffering in dementia, their frequency and intensity, and how these vary by ethnicity, care setting, and dementia stage. Application of surrogate measures such as quantification of distress due to procedures and diseases in the cognitively intact can be used to estimate burden of suffering in dementia patients. Further study of observational measures of distress intensity in different settings and clinical circumstances is also needed.
5. Larger studies of palliative approaches to care of end-stage dementia are urgently needed. Though randomization is difficult because surrogates may have strong preferences for types of care, it should be attempted to diminish the chance that outcomes attributed to the palliative care intervention are in fact due to other variables. These studies of new models of care for advanced dementia must be conducted in diverse clinical settings, but especially in acute care hospitals, and in the nursing homes and home care settings where most dementia patients reside.
6. Randomized trials of care of acute illness superimposed on chronic dementia in different settings are needed to identify optimal approaches, both in terms of burden of illness, burden of diagnostic and treatment interventions, family and professional caregiver satisfaction, mortality, and costs.
7. Finally, studies of new models of care focusing on real support for family caregivers at home (personal care aides, housekeeping support, support groups, respite care), long-term care settings characterized by home-like as opposed to institutional settings with training support for the difficult work of aides and other paid caregivers, and models aimed at safety, reassurance, and patient centered activities (as opposed to the traditional institutional medical model) are also necessary.[41-43]

The major methodological challenge in research on palliation in late stage dementing illness is the lack of direct evidence (by patient report) of what the patient is feeling. This lack of reliable patient-centered measures of suffering drives the use of surrogate measures based either upon the observations of others (family or other caregiving staff) or upon extrapolation from the reports of cognitively intact persons with similar clinical experiences. In a related manner, surrogate consent for participation in research, or even for the process of basic medical decision-making depends critically upon the ability of the surrogate to engage with and understand the issues as well as their willingness to take responsibility for decisions on their relatives behalf.

A substantial minority of persons suffering from advanced dementia has no functional surrogate, a major barrier both to research and to rational clinical decision-making.

The prognostic uncertainty inherent in chronic degenerative disorders such as dementia poses challenges to consensus on the goals of medical care, which also inhibit conduct of research and development of new models of palliation for dementia. While most, but not all, family members and health professionals endorse comfort care as the primary goal of medical care in end-stage dementia, these theoretical beliefs are severely challenged when immediate decisions about life-sustaining treatments are faced in the context of sudden or acute medical deterioration. Lack of valid predictors of mortality for individual patients will require that professionals and the public develop a moral and relational framework that will allow a shift in the priorities of medical care away from the current predominant focus on maximal possible life-prolongation, to an alternative focus on compassionate care and a maximal sense of security and comfort, given the progressive and hopeless nature of the disease. In combination with serious efforts to determine patient's wishes for care in earlier stages of disease, such public and professional education will improve awareness of the progressive and irreversible nature of dementia, creating expectation and demand for the excellent compassionate care that should become the standard for advanced disease.

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End-of-Life Decisions Concerning Patients with Dementia: a Challenge for Future Research

Abstract

End-of-life decisions concerning demented patients are complicated, not only because these decisions are difficult in itself, but also because of limited or no involvement of the patient in the decision-making process. In addition, there is uncertainty about the prognosis of patients with a dementia, and about his reactions to diagnostic and therapeutic procedures. Hence, caregivers are faced with ethical dilemma's of over- and undertreatment of the patients, and also with the question whether it is acceptable to further expose the patient to the definite deteriorating clinical course of the dementia syndrome. Although this is all well recognized in health care, physicians and nurses find little empirical research results to facilitate discussions in this area and thus improve quality of care. End-of-life decisions for these patients range from (not) starting or stopping artificial nutrition and hydration, and forgoing antibiotics and other medications, to questions whether or not to hospitalize a patient in case of life-threatening disease. Forgoing such therapeutic measures usually result in questions and decisions about how to properly control pain and other symptoms, and how to provide comfortable end-of-life care. Although some empirical studies give a first insight in this field of health care, many questions remain unsolved and need to be studied to help physicians and nurses to improve their daily practice of end-of-life care. We suggest a research agenda on end-of-life decisions for demented patients that is structured according to four main topics:

1. The types and frequencies of these decisions, the various motives and considerations (including ethical dilemma's) for certain decisions and the participation in the decision-making process.
2. Patient's former health condition and problems related to the chosen end-of-life decision and the further clinical course after an end-of-life decision is made.
3. Implementation and evaluation studies of guidelines for proper clinical practice of end-of-life decisions and care in these patients.
4. Instrument development in relation to end-of-life decision-making for demented patients.

As these decisions are not related to one country or one culture alone, all involved are challenged to develop this important and relatively new area of research in an international context.

In medical as well as in nursing care, many different decisions have to be made especially when patients reach the end of their life. For patients with a chronic disease, such as dementia, many of these end-of-life decisions are not isolated, but emerge in the context of a person suffering from a long-lasting disabling disease with inevitable, progressive physical and cognitive deterioration, and the loss of personality and identity.[1] The appropriate care for these patients, which is in fact comprehensive palliative care, consists of careful medical treatments for intercurrent illnesses, treatments of pain and burdening symptoms, and of complications arising in connection with the dementia syndrome, taking into account the patient's personal views, wishes and life-expectancy. But, should all possible types of care and interventions be used in every patient, and to what extent? How do we achieve acceptable end-of-life dementia care, that is well adjusted to the individual patient, and what kind of end-of-life decisions are relevant in this respect?[2]

Concepts

The most important end-of-life decisions concerning patients with dementia are withholding or withdrawing artificial nutrition and hydration, withdrawing or withholding treatment with antibiotics, decisions with regard to medication for the alleviation of pain and symptoms (for instance, overall pain management, opioids in large doses, levels of sedation) and decisions to stop long-lasting medication regimes (for instance, vitamins, anti-hypertensives, thyroxine, Parkinson medication, et cetera). Another dominant issue concerning end-of-life decisions is the question of hospitalization of demented patients in case of life-threatening disease or acute medical conditions with a significant burden of disease. This raises questions, such as: should every demented patient with a rapid progression of physical and cognitive impairments, and further deterioration due to comorbidity, be hospitalized after a hip fracture? And, is hospitalization of a demented patient with a mechanical ileus a matter of routine, or are there circumstances in which a physician can forgo hospitalization of the patient? And, with regard to research, do we know which reasons are being taken into consideration when thinking about hospitalization, and what circumstances to forgo hospitalization are acceptable for caregivers, the patient and the family in such cases of life-threatening disease?

From a nursing perspective, caregivers are also faced with a wide range of decisions, such as the level of support for the activities of daily life and care routines related to the discomfort caused by these routines (for instance, how long in and out of bed, with or without day-cloth, when to stop preventive measures such as the prevention of pressure sores, the use of catheters, et cetera). End-of-life decisions include euthanasia and physician-assistance with suicide.[3] However, according to the Dutch definitions, full competency of the patient and his ability to make an explicit request are two of the most important conditions that have to be met before a request for euthanasia or physician-assisted suicide can be honored. As these conditions cannot be met for many, if not all, demented patients, they can, by definition, not receive these interventions. If life-ending medication is administered to

demented patients, this is called 'ending of life without the patient's explicit request'.[4]

The degree of difficulty of all the above mentioned decisions, as experienced by the professionals and family involved, is related to several factors, such as lack of adequate knowledge about the prognosis of the dementia syndrome, the uncertain outcome of medical interventions, problems with the reconstruction of the patient's wish, and serious ethical dilemmas, such as the acceptability of further suffering and deterioration from the dementia process while being sure of a definite negative prognosis for these patients.[1] Usually, there is uncertainty about the extent to which demented elderly people can tolerate the burden of diagnostic and therapeutic procedures, as well as uncertainty with regard to the incidence of negative side-effects from these procedures, such as delirium, depression, pressure sores, et cetera. Even the introduction of necessary interventions, such as intravenous infusions, can be a serious problem. In addition, the success of many interventions is speculative in very frail demented elderly people, and raises questions about the contribution of diagnostic and therapeutic potentials to the patient's quality of life against the background of his limited life- expectancy.

All becomes even more complicated with the gradually decreasing ability of the patient to be involved in the decision-making process. Although the patient's participation in care-planning is a fundamental prerequisite in health care, most patients in the category under study have impaired competency, which limits their ability to express their wishes and preferences when important and complicated decisions have to be made. Furthermore, incompetence in itself is not an all-or-nothing phenomenon, and a patient might be incompetent to participate in a decision on whether or not to be hospitalized or to undergo certain diagnostic procedures, while being very well capable of indicating which dress she prefers, when held up by a nurse. Although the reconstruction of the patient's wish through consultation with the family, caregivers and physicians is a common answer to this problem, the interpretation of the patient's current behavior and signals and preferences from the past implies that the opinions and conclusions of all people involved are highly subjective. Are we really acting according to the patient's preferences and wishes? This 'best we can do' approach is understandable, but, at the same time, the caregivers and others involved are faced with difficult ethical dilemmas with regard to the best type of care and treatments that should be given to the patient. With regard to these aspects of care for demented patients, one can expect to find many different decisions and thus many different solutions for the same problem, not only between countries, but also within countries in our world of Western medicine and its technological orientation. So, the many ethical problems and differences in care solutions are not only a national, but also an international issue, and not tied to the legal system or ethical concepts of any one country.[1] Another important, and even further complicating aspect is the tendency in Western societies to negotiate health care; some would like caregivers to be very restrictive in care and interventions for demented patients, while others fear that doctors might undertreat these patients.

Hence, end-of-life decisions are not only complicated by their mere nature, but also by their context in terms of the patient's health status, the various prognostic

considerations, and the lack of adequate involvement of the patient in the individual decision-making process. This results in difficult ethical dilemmas, while little or no support is found from research related to all these aspects.

Empirical studies

Almost no empirical data can be found in the international literature on end-of-life decisions concerning patients with dementia. For all deceased patients (demented and non-demented), data from the Dutch evaluation study of the notification procedure for euthanasia indicate that the estimated incidence of medical decisions concerning the end of life is 42.6%: 20.2% of all deaths involved a decision to forgo (withdrawing or withholding) treatments, 19.1% involved a decision to administer opioids in large doses and 3.3% involved a decision to apply direct life-ending medication, such as euthanasia.[3] In 8% (just over 10,000 persons) of all deaths in the Netherlands (n = 135,500; the death certificate study of the Dutch evaluation study, 1995) a decision to forgo artificial nutrition and hydration was taken, with striking differences among categories of physicians (family physicians, 4%; clinical specialists, 4%; and nursing home physicians, 23%). In approximately two-thirds of these cases there were also other end-of-life decisions, such as forgoing other types of life-sustaining treatments (45%) and/or decisions to alleviate pain- and symptoms (40%).[3,5]

When only focusing on non-sudden deaths, non-treatment decisions (withholding or withdrawing potentially life-prolonging treatment) are made more frequently for the older age-groups (36% in patients aged 80 years and over) than for younger age-groups (23% of patients under 65 years of age), and more frequently for patients who died of a mental disorder (including Alzheimer's disease) (52%) than for, for instance, patients who died of a neurological disease (including cerebrovascular accidents) (43%), cancer (31%) or a cardiovascular disease (15%).[5] In all deaths (sudden and non-sudden) involving one or more non-treatment decisions, the most important decisions were forgoing artificial nutrition or hydration (in 25% of all deaths with non-treatment decision(s)), antibiotics (25%), medication other than vasopressors (18%) (vasopressors 11%), mechanical ventilation (10%), surgery (9%) and hospital admission or diagnostics (8%).[5] Nevertheless, not much is known about the reasons and motives underlying these decisions, or about the clinical course after a non-treatment decision has been made. For demented patients, apart from the patient's reconstructed wish, it can be expected that unbearable suffering and continuous deterioration, no chance of improvement, recurrence of problems even after several treatment attempts, and the futility of further treatment are among the motives for non-treatment decisions.[5,6]

The relative frequency of all non-treatment decisions is highest among nursing home physicians: in half of all deaths (52%) in nursing homes a decision to forgo one or more types of treatment was made, compared to a third of all deaths (35%) attended by clinical specialists and a fifth of all deaths (17%) attended by family physicians. Also, in all cases in which a non-treatment decision was involved, the decision to forgo artificial nutrition and hydration was made much more frequently

by nursing home physician (in 44% of non-treatment cases) than by family physicians (22%) and clinical specialists (12%). The trend of this finding was the same for antibiotics with (almost) twice the frequency or higher for nursing home physicians compared to other physicians (nursing home physicians, 36% of cases; family physicians, 15% of cases; clinical specialists, 21% of cases). Forgoing hospitalization of a patient occurred with more or less the same frequency for nursing homes physicians and family physicians (11% and 13%, respectively).[5]

It is likely that many of the deaths attended by nursing home physicians concerned demented patients, since nursing homes in the Netherlands play an important role in caring for the demented. Just over half of all 57,000 nursing home beds are occupied by demented patients, and it is estimated that approximately 50% of all demented patients in the Netherlands finally die in a nursing home.[7,8] Hence, this is an important setting in which to study and teach end-of-life decisions concerning demented patients.[9]

A number of specific Dutch studies have focused on end-of-life decisions in demented patients in nursing homes.[4,6] Results from a prospective observational study on pneumonia showed that a quarter of demented nursing home patients with pneumonia were not treated with antibiotics. These patients were in a later stage of the dementia process, but not older, than the group that was treated with antibiotics, and had lower levels of well-being both two weeks before the pneumonia and at the time the treatment decision was made. In addition, their food intake was more often insufficient, and they were more often dehydrated.

In an interview study among nursing home physicians in the Netherlands, the participants were asked about their most recent case in which an end-of-life decision was made. It was found that forgoing artificial nutrition and hydration and/or not withholding or withdrawing treatment with antibiotics were the most important end-of-life decisions. Forgoing artificial nutrition and hydration occurred in 60% of incompetent patients (in the incompetent category, 46% dementia, 22% stroke, 10% pneumonia, 6% cancer and 16% some other main diagnosis) and in 42% of competent patients. Similar data were found for not withholding or withdrawing antibiotics: 55% in incompetent and 44% in competent nursing home patients. Forgoing planned hospitalization (a decision made for one fifth of incompetent and one third of competent patients) was also a distinctive end-of-life decision. Based on the method of interviewing participants about their most recent cases, almost all data in this study are somewhat higher than the data found by Groenewoud and colleagues.[5]

As end-of-life decisions are made relatively frequently in nursing homes, the interview study also focused on policies with regard to forgoing life-prolonging treatment in the group of patients for whom a non-treatment decision concerning artificial nutrition and hydration was finally made. For both competent and incompetent patients in this group, in approximately 50% of the cases nursing home physicians had, in a very early stage after the patient's admission to the nursing home formulated medical policy agreements (advanced care planning) about forgoing possible curative or life-prolonging treatment (for 44% of competent and 48% of incompetent patients). In the case of competent patients, the decision was usually discussed with the patient involved (nine out of ten times) and in the case of incompetent patients

with one or more of the patient's children (also nine out of ten times). Of all these incompetent patients, six out of ten had never previously expressed the wish to forgo treatment in the future, according to the knowledge of the physician, other caregivers and family. These earlier agreements were adhered to for all competent patients, but for only 60% of the incompetent patients, because of unexpected changes in patient's condition, earlier agreements not being suitable for the present situation and the fact that the earlier agreements would be medically futile in the patient's present situation. If a nursing home physician decided to forgo artificial nutrition and hydration, in 90% of cases the health status of the patient was the dominant reason, because of unconsciousness (one third of patients), breathlessness (one quarter of patients), overall deterioration (one fifth of patients), problems with eating, drinking and swallowing (one fifth of patients) and pain (one tenth of patients). Fever (one in ten cases) and pressure ulcers (one in twenty cases) were also mentioned as reasons. Important considerations in relation to these reasons were: poor quality of life (58% of cases), not unnecessarily prolonging life (58%), no chance of improvement (50%) and the futility of further treatment (38%).

Hence, distinct end-of-life decisions concerning artificial nutrition and hydration, antibiotics, medication and hospitalization are frequently made in medical practice in nursing homes, more often for incompetent than for competent patients. On the other hand, forgoing hospitalization was a more frequent decision for competent patients. The patient's health status and related prognosis, and a variety of considerations reflecting quality of life and futility of treatment, are important contextual aspects of the decision-making process. The date presented above represent a first step in exploring this important aspect of care for (in general) vulnerable demented patients. Therefore, much more research is needed to improve end-of-life decision-making concerning demented patients and subsequently enhance the quality of the care provided for these patients.

Research agenda and methodological issues

End-of-life decisions concerning demented patients are inherent to the more comprehensive concept of the palliative care that is needed for these patients. Some of the important domains in this type of care are: the patient's health status, levels of (dis)comfort, autonomic functioning, participation in decision making, psychosocial well-being (including personal convictions and spirituality), safety and support, attention for and consultation with family and friends, and continuity of care. Thus, whenever possible, these domains should be taken into consideration when designing research projects on end-of-life decisions. Together with the issues and determinants discussed in the first two paragraphs of this Chapter, a whole new field of research emerges which should address many issues that have not been studied so far. When developing this field of research, one should also focus on methodological issues, such as standardization of terminology, specific study designs, levels of analyses, the development of measurement instruments and the psychometric testing of these instruments.

Hence, when formulating a research agenda on end-of-life decisions concerning demented patients, it is recommended that this field of research should be divided into domains that are recognizable from both practical and scientific points of view. Although various different divisions can be made, we suggest the following main areas for research, in the realization that some research questions are closely related to one another or might even overlap to a certain extent.

1. *Types of end-of-life decisions and the decision making process concerning demented patients*

What are the types and frequencies of end-of-life decisions concerning demented patients, in relation to attending physicians in the same and in different health care settings, and what are the characteristics, health status and problems of the patients? This range of questions not only refers to the differences that are likely to be found between physicians, but also to the different ways in which physicians might decide, given the same type of problem. For example, hospitalization policies for similar demented patients with a hip fracture will definitely vary among physicians for various reasons and considerations (see next question), but also because of differences in the structure and organization of the health care system between specific areas, or even between countries.[8]

What are the types and relative weight of the various reasons, motives and considerations (including ethical considerations), which underlie end-of-life decisions concerning demented patients, in relation to physicians characteristics, patient characteristics, health status et cetera? This question relates to why and on what grounds certain decisions are made, and to the predictors for certain end-of-life decisions.

What is the level of participation of the patient in the decision-making process, and what is done by the various caregivers to reconstruct the patient's wish? Continuing on this theme, it is relevant to study how professionals interpret behavior and reactions as signals of a certain direction of the wish of a patient, preferably starting with qualitative research. In this respect it is also important to study the relationship between (levels of) incompetence, participation in decision making and the type of decision that is made.

What diagnostic procedures (in the broad sense) are used to support and legitimize end-of-life decisions concerning demented patients, and how are these procedures evaluated (with regard to burdens, complications, benefits, et cetera) by physicians, other caregivers and families? In other words, what is done from a more medical point of view to formulate (additional) arguments to support the decision that is being made?

How, and in what way do both professionals and non-professionals participate in the decision-making process, what is their relative influence on the outcome of the decisions and how do they evaluate their participation, both during the decision-making process and after the decision is made? In other words, to what extent did consultation of professionals and families take place, and what is their influence and what is the level of satisfaction with regard to their involvement in the final end-of-life decision(s)?

2. *Clinical practice and clinical course of health and disease in relation to end-of-life decisions*

What are the health and disease problems that precede a specific end-of-life decision, and what is the clinical course after the end-of-life decision is made? This question refers to the patient's health status, levels of impairments and disabilities, burdening symptoms, and progression of all these problems over the previous weeks, and to the specific end-of-life decision made, such as, for example, forgoing antibiotic treatment for demented patients with pneumonia. And, what changes are observed in the patient's health status, (dis)comfort, survival, et cetera, after the decision is made?

What are the policies and practices of physicians with regard to pain treatment (under-treatment, over-treatment, intentions such as 'double effect', et cetera) for demented patients for whom an end-of-life decision is made?

Does the type and quality of previous and current alleviation of pain and symptoms predicts certain end-of-life decisions concerning demented patients? Or, in more general terms: what previous medical and non-medical care strategies predict specific end-of-life decisions, such as increasing doses of opioids, prescribing sedatives, hastening death, et cetera? This question is also important because some people believe that certain end-of-life decisions (euthanasia, hastening death) in countries like the Netherlands are the result of poor palliative care and, in particular, insufficient alleviation of pain and symptoms. In this context, the role and place of terminal sedation for demented patients, after specific end-of-life decisions have been made, should also be studied.

What are the effects of life-sustaining treatment and interventions, such as intravenous hydration, hospitalization, resuscitation, et cetera on symptoms, survival and (dis)comfort after such an end-of-life decision is made for patients with dementia? Or, formulated in a more general way: what are the levels of (dis)comfort and (presumed) quality of life after a decision for life-sustaining interventions is made for a demented patient?

3. *Implementation and evaluation studies of guidelines developed for end-of-life decision-making concerning demented patients*

When guidelines (most likely as checklists with relevant points that should be considered in the decision-making process) are formulated for end-of-life decisions concerning demented patients, research questions should focus on the appreciation of these guidelines by physicians and other professionals, and on the determinants of adherence or non-adherence to these guidelines. For example, there might be a tendency to use a guideline only marginally, if the patient's care policy was clear and adequately discussed in the early stage after admission to a nursing home. At least, that is what was found in a recently finished study on pneumonia in demented patients.[6]

Does protocolled palliative care result in different questions concerning end-of-life decision-making and in different decisions, compared to usual end-of-life care for demented patients? (See also the related question in section 2).

4. *Development of measurement instruments in relation to end-of-life decision making concerning demented patients*

What type and content of measurement instrument is needed to assess the level of (in)competency of demented patients?

How should pain be measured in demented patients for whom an end-of-life decision has to be taken?

How should the types and quality of care be measured when comparing health care settings in end-of-life research and guideline evaluation studies?

How should a patient's quality of life (levels of (dis)comfort) be measured before and after an end-of-life decision is made for a demented patient?

What types and content of instruments are needed to evaluate the appreciation of the different participants in the decision-making process?

Research on end-of-life decisions concerning demented patients faces numerous medical, ethical, judicial and methodological problems, which are often also interrelated. We lack sufficient insight into the (medical) prognostic factors of the dementia process to enable us to choose the appropriate decision from the variety of different end-of-life decisions. If the decision is to provide life-sustaining treatment, we are confronted with the ethical question of whether or not we do good and avoid harm by further exposing the patient to the inevitable deterioration of the dementia process.[1] And, how often are we supposed to treat patients with successive and recurrent pneumonia, other recurrent infections and a fever? How should we interpret the reactions of patients when they obstruct attempts that are made to feed them, or when they repeatedly remove naso-gastric tubes? And from a more judicial point of view, what is the place and role of advanced directives in the decision-making process and how do we know if surrogates act in the line of the patient's wish?

Methodological problems include (apart from the lack or insufficiency of measurement instruments and problems concerning informed consent and low consent rates) the question of which outcome parameters best reflect the clinical course and effects of interventions such as life-sustaining treatment, guideline implementation, et cetera. In addition, randomization or recruiting comparable (control and intervention) groups can be difficult, due to reasons such as comorbidity, but definitely also because of ethical problems with randomization. Differences in dropout numbers and (selected) survival further endanger the validity of the results found in research on demented patients. Also, levels of care might vary considerably, even within the same type of health care setting, making comparisons of the results complicated.[8] Assuring, for example, that terminal care is provided in the same way (standardized) in different settings, may demand considerable efforts at high costs. And, last but not least, how do we obtain representative samples of physicians from the different health care settings within a country, and even more difficult, within different countries. Hence, international collaboration should not only focus on individual research projects, but also on the development of standardized instruments and appropriate methods that can be used for research in the field of end-of-life decisions concerning demented patients.

Opportunities for international collaborative research

A challenge for international research are, for instance, studies on the differences in types and frequencies of end-of-life decisions concerning demented patients among the various physicians and clinical practices in participating countries, and relating the data obtained from these studies to cross-cultural views on dementia care, the views and motives of physicians underlying specific end-of-life decisions for demented patients, the standpoints and level of consensus with regard to the acceptability of specific end-of-life decisions among professional associations (for instance, medical associations), the structure of the health care system (health insurance schemes, the availability of services and staff, fee for services versus capitation, et cetera)[7,8] and the judicial context in each country. Other aspects that are also likely to show much variation within and between countries are differences in the place and role of advanced directives, the role of the families in end-of-life decisions, the prescription of medication after an end-of-life decision is made, et cetera. International collaboration should also focus on the development and validation of measurement instruments, as well as the formulation of guidelines for end-of-life decisions. For instance, positive and encouraging experiences were gained from the international input in the development of a new guideline (checklist of points for consideration) on the question of whether or not to treat pneumonia in demented nursing home patients with antibiotics.[6] When discussing international research and developing instruments to evaluate end-of-life decisions in demented patients, a first step is to form a group of international researchers and clinicians in participating countries, who can contribute from both the university (academic) settings and the health care settings that are relevant for the above-mentioned areas of research. When such a group is formed, a first initiative should be to prioritize the many questions contained in the research agenda and to explore the feasibility within each country of selected projects.

We continue to have, for instance, positive experiences in this regard with the interRAI group, an international research and development group which is involved in the design of instruments to assess the care provided for elderly people.[10] The assessment instruments for nursing homes and for home care, that were developed by this group, have been translated, and are now being validated and implemented in more than twelve different countries around the world. Although these internationally standardized instruments are primarily developed with the aim of improving care-planning, the data obtained are being used for many national and international comparative studies.[11] This model is also worth considering for end-of-life decision-making concerning demented patients. On the other hand, collaboration could also start with one limited and well-defined study that is feasible in a few countries, focusing, for instance, on one or two research questions.

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Part v Epilogue

Medical Decision-Making at the End of Life: the Research Agenda

A new research domain

In the past decade many textbooks have been issued on the subject of death and dying and on medical care at the end of life. Influential medical journals have published large numbers of commentaries and editorials on the merits and shortcomings of modern medical care for patients who are in the terminal stage of life. Somewhat more recently this discussion is being influenced by support from empirical studies on health care at the end of life. The papers in this volume show that end-of-life decision-making is a rich and promising research domain. A wide variety of researchers, including physicians, epidemiologists and ethicists, have presented data from studies on many different topics within this domain of medical decision-making. As such, this volume presents an overview of topics that are currently being studied. This overview is obviously far from complete, and lacks the contributions of many other important researchers. It is considered to be new in its focus on empirical research concerning the clinical and epidemiological aspects of end-of-life decision-making. Other types of research, for instance research from disciplines such as bioethics or sociology, are not dealt with here, although their importance for clinical practice and public policy-making is beyond any doubt. However, whereas the most important aim of end-of-life medical care is to improve the quality of the terminal stage in life for patients and relatives, including the dying process, it is felt that valid and reliable data on current practices and attitudes can make a highly important contribution to providing opportunities for such improvement.

Research in medical end-of-life care

When medical end-of-life care is directed at contributing to the quality of dying for the patient and the family and friends, the related research domain can be defined as all research aimed at identifying conditions for a 'good' death and developing and evaluating medical interventions, including decisions to forgo interventions, aimed at realizing those conditions. This delineates a very broad and multidisciplinary research domain, that can be structured along various different dimensions, of which the most important are determinants, interventions and participants. The possible determinants of a 'good' death are listed in Table 1, and demonstrate that the modi-

fiable dimensions of the patient's experience are especially important. They act as a guide to the appropriate medical and health care interventions.

Table 1. Determinants of and interventions towards a good death.*

Modifiable dimensions of the patient's experience
– Physical symptoms
– Psychological and cognitive symptoms
– Social relationships and support
– Economic demands and care giving needs
– Hopes and expectations
– Spiritual and existential beliefs
Fixed patient characteristics
– Clinical status (disease/prognosis)
– Socio-demographic characteristics
Care-system interventions
– Professional interventions
– Health-care institutional interventions
– Family and friends interventions
– Socio-economic policy interventions
– Social, judicial interventions

* Based on Emanuel EJ, Emanuel LL. The promise of a good death. Lancet 1998;351(Suppl 2):21-29.

The relevant participants are primarily the patient, the family and friends, and the health care professionals, especially physicians and nurses. Because some of the possible interventions may have a life-shortening effect, they have a special status in the public, professional and political debate. The decisions involved are listed in Table 2. For these types of decisions the public, medical professionals and policy-makers may also be considered to be relevant participants in the sense that in some countries some decisions cannot be made, or are at least illegal.

Table 2. Medical decisions concerning the end of life.

Forgoing life-prolonging treatment, that is,
– decisions about whether or not to withdraw or withhold potentially life-prolonging treatment
Intensifying symptom management, that is,
– alleviation of pain or other symptoms with, for instance, opioids, or terminal sedation with benzodiazepines or barbiturates, in doses large enough to invoke hastening of death as a possible or certain side effect
Physician-assisted death, that is,
– euthanasia: the administration of drugs with the explicit intention of ending the patient's life at the patient's explicit request
– assisted suicide: the prescription or supplying of drugs with the explicit intention of enabling the patient to end his or her own life
– life-ending without explicit request of the patient by administration of drugs

A conceptual framework for medical decisions that possibly involve a life-shortening effect has been developed in the first paper of this Volume by Van der Wal. Further combining determinants, interventions and participants will result in a large three-dimensional matrix, that could be filled with only a very limited amount of empirical information, but that may form a useful framework for a research agenda on end-of-life research.

Decisions to withdraw or withhold life-prolonging therapy

Part I of this volume presents a broad overview of current research efforts concerning medical decision-making with respect to whether or not to initiate or continue (potentially) life-prolonging treatment. Dutch epidemiological studies have shown that non-treatment decisions, that is, decisions to withhold or withdraw life-prolonging treatment, are very common in current end-of-life care, and that the relevant decision-making involves technologically advanced, as well as more basic medical interventions. Although non-treatment decision-making is undoubtedly a less controversial issue than end-of-life decisions in which life-shortening medication is involved, a large number of Swedish studies demonstrate that non-treatment practices and general opinions often do not coincide, and vary between different societal groups. This may (partly) be explained by the fact that non-treatment decision-making appears to be a rather complicated process, both from the physician's perspective, as is shown by Asch and Faber-Langendoen, and from the patient's perspective, which is demonstrated in the work of Pearlman and others. Whereas it is often argued that the patient's preferences and goals should be the focus of end-of-life health care, correct interpretation of such preferences and goals and adequate inclusion of them in the decision-making process appears to be difficult. Qualitative research may provide important clues in this respect, as is argued by Martin and colleagues.

Administration of (potentially) life-shortening drugs

Most research in this field focuses on the attitudes of physicians, nurses, patients and the general public towards (the legal status of) euthanasia and physician-assisted suicide. It shows, for instance, that in the United States between approximately 30% and 100% of physicians, patients and the general public, depending on the exact question posed, had positive attitudes towards euthanasia and physician-assisted suicide. In Australia this percentage was the same for physicians, but in surveys among patients and the general public positive attitudes ranged between 65% and 75%. Somewhat more recently, research has been carried out to examine the practice of administrating (potentially) life-shortening drugs. Although there are differences between the countries with regard to the frequency with which euthanasia and physician-assisted suicide are performed, it is important to realize that these interventions occur in a very limited number of deaths. Comparison between Australia, Belgium and the Netherlands showed no evidence of large differences in incidence between countries with more or less restricting

legislations. Studies in the Netherlands and in Oregon, the only two places in the world where there is a 'liberal policy' in combination with policy guidelines to control the practice of physician-assisted death, are consistent in their conclusion that such regulatory systems do not seem to increase the incidence of physician-assistance with death, or have a negative effect on the prudence of the decision-making. It is noticeable that much more research has focused on euthanasia and physician-assisted suicide than on the administration of potentially life-shortening drugs to alleviate pain and symptoms, a practice that occurs much more frequently.

End-of-life decisions for neonates

A field of particular interest in end-of-life decision-making is neonatology. Whereas rapid advances in neonatal care during the past three decades have made survival for severely affected newborns much more likely, almost all clinicians caring for infants have to deal with questions about the appropriateness of life-sustaining treatment for extremely pre-term infants or infants with very serious congenital anomalies. In their paper, Meadow and Lantos point out that decision-makers in neonatal intensive care cannot avoid the probabilistic aspects of disease and illness. Reliable prognostication is, they argue, a very important aspect of adequate decision-making, and especially studies on the (predictors of) long-term morbidity of affected newborns should be part of the research agenda. This also applies to searching for pathways to achieve the greatest possible common ethical grounds in the decision-making, as is stated by Kollée. Insight into other than the purely medical aspects of end-of-life decision-making, such as ethical, cultural, legal, historical and many other aspects, can be gained from international comparative studies, such as the landmark project presented in this volume by Marina Cuttini on behalf of the EURONIC Study Group.

End-of-life decisions for patients with dementia

Meier's paper shows that patients with dementia are a specific group with specific problems concerning end-of-life care and research methodology in this field. Important characteristics are that dementia causes a myriad of suffering, not only for patients but also for family and care-givers, and that patients are incompetent, especially in the later stages of the disease, and cannot express their symptoms. This can result in insufficient palliative care. Finally, the prognosis of patients with dementia is often uncertain, which may lead to doubts about the appropriate goals of medical care. In his contribution, Ribbe focuses on end-of-life decisions for patients with dementia. Although there has been limited research on this topic, the withdrawing or withholding of treatment, such as antibiotics for pneumonia and the artificial administration of food or fluids, seems to be relatively common in this patient group. End-of-life care for demented patients could benefit from research on determination of the important sources of suffering for these patients, their prognosis and the methods of decision-making. Other important issues that need to be studied are medical interventions,

such as the implementation of specific palliative care approaches, and the development and implementation of guidelines for decision-making.

Framework for future research

Descriptive and explanatory studies

Most studies on palliative care and medical end-of-life decision-making focus on the very terminal stage of the disease. However, in many diseases this terminal stage is preceded by a period during which the physician and, usually somewhat later, the patient are already certain that the disease will be fatal in the foreseeable future. This results in a process in which patients gradually disengage from their routine daily responsibilities and gradually redefine their goals. Medicine and health care can naturally follow and support this process, as is illustrated in the Figure.

Often there is no single moment of transition between life-prolonging treatment and palliative care. For instance, doctor and patient may decide against chemotherapy or surgery, but agree about the use of antibiotics in case of pneumonia, or continued

Time	Patient perspective	Treatment goals and choices
Birth		
↓	full life	All medical interventions aim at prolonging life or improving quality of life.
Transition 1		
↓	incurable disease, quality of life fair-good	Some options to prolong life are not used, for instance, early detection of new diseases, chemotherapy. Chronic disease and life threatening complications are treated.
Transition 2		
↓	incurable disease, quality of life poor	Burdensome treatment will be worse than current life. Life-threatening complications may not be treated (antibiotics, treatment at ICU), tube feeding may be withheld or withdrawn.
Transition 3		
↓	death better than life	Decision that death is better than current life. Withholding or withdrawing life-prolonging treatment, increasing opioids, physician-assisted death.
Death		
↓		Care for relatives and friends
Bereavement		

Figure.

mechanical ventilation. There is very little empirical information about these transitions from the perspective of the patient and the physician, or their practical consequences. This means that there is an urgent need for follow-up studies that document these processes in an early stage, when death may still seem far away, but inevitable. These studies should focus on the determinants of the patient's experiences of the quality of the dying process, the contribution of health care and the determinants of the medical decisions taken during that period, often combining quantitative and qualitative approaches. In addition to these patient-oriented studies, there is a need for more large scale epidemiological studies, describing where and how patients die, what kind of health care they receive at the end of life and what kind of medical end-of-life decisions may have been involved. More basic biomedical research could also have important contributions by improving our understanding of dying and death as a biological process.

Intervention research

There is already a certain tradition in clinical intervention research aimed at relieving specific symptoms, such as pain, bowel obstruction and anorexia. However, there is certainly room for more research in this area, and priorities may be guided by better knowledge of the frequency of specific symptoms and complaints during the terminal phase of life. In addition to cancer, AIDS and neuromuscular diseases, many other diseases, such as COPD, chronic heart failure and dementia, deserve attention. Another type of intervention research focuses on the decision processes described earlier. Medical decision-making at the end of life differs in many respects from standard clinical decision-making, because prolonging life will loose its paramount importance as outcome criterion, leaving even more room for patient preferences with respect to quality of life. This shift of perspective in an already emotional period demands specific skills of the physician and nursing staff, to enable them to arrive at decisions that serve the best interest of the patient and the family and friends. Especially decisions to refrain from further life-prolonging treatment, but also the other decisions mentioned in Table 2, deserve more research. Interventions to improve the physician-patient communication and the decision-making process might include specific training of physicians, developing guidelines, creating consultation possibilities, et cetera. Finally, interventions in the health care system, such as terminal care units in nursing homes, outreaching consultation teams, paid care leave for a member of the family, should be evaluated.

International comparisons

Opinions and practices with respect to death and dying may vary between societies, due to cultural, political, legal and health care differences. This probably also applies to medical practice during the terminal phase of life. Despite the overwhelming similarity in clinical approaches throughout the western world, due to universally applicable technologies and research methods, there is much less consensus about the role of medical care in the terminal phase of life. There probably is consensus that medical

care has a role in alleviating suffering, and that patients may refuse life prolonging treatment, but the resulting practice may differ from country to country. The prevalences of decisions to withhold or withdraw life-prolonging treatment and decisions to alleviate pain with a possible life-shortening effect may differ. Physician-assistance with suicide and euthanasia, although illegal, are probably practiced in every country, but the frequencies and reasons for doing so may differ. Health care provisions for terminally ill patients, as well as the availability of other means to create the best conditions for a 'good' death may also differ. Therefore, there is considerable opportunity for international comparative studies in all areas in which variations may be expected. International comparative studies can be important to determine which approaches provide a better quality in the dying process. This will range from the perception of a 'good' death and the prerequisite conditions, the availability of different types of health care provisions for terminally ill patients, such as palliative services and professional home care, and the frequency of the different types of medical decisions that are made during the terminal stage of life. This requires the development and the use of standardized questionnaires and measurement instruments, as well as uniform study designs, in order to identify differences in experiences, opinions and practices and the possible cultural, social, judicial, political and health care determinants.

Priorities in the research agenda

Research on end-of-life health care includes end-of-life decision-making as well as the evaluation of specific clinical palliative interventions. The latter is an already more or less established research domain. In end-of-life decision-making, information about the effectiveness of palliative interventions is one of the elements in the clinical decision process. In summary, three main priorities for research on end-of-life decision-making can be identified. The first is to study the natural history of dying and the determinants of a 'good' death as perceived by patient and relatives. Such studies would include the variables mentioned in Table 1, and should preferably be follow-up studies, monitoring at least the last six months of life and taking into account the sequence of events and the transitions that take place, not only in patient experiences and attitudes, but also in the medical decisions, as illustrated in the Figure. The second priority is to perform international comparative studies using uniform designs and measurement instruments, in order to identify possible differences in the frequencies of end-of-life decisions and to relate these differences to patient and physician characteristics, and especially to relevant characteristics of the health care system, attitudes of the medical professionals and the public, the legal system, et cetera. This will form a starting point for more in-depth studies. For patient follow-up studies and for epidemiological studies, a core set of research instruments and outcome measures is indispensable. For both types of studies instruments have already been developed, but for many aspects of study these instruments may have to be refined or new ones developed. This issue could be defined as the third research priority.

It is obvious that much effort is still required to establish a firm body of scientific knowledge that will contribute to the quality of medical care in the terminal stage of life for many people in many countries. This volume and the work of the conference might represent a small step towards that ultimate goal.

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