Ethics, End-of-Life and Vulnerability

Rozemarijn Lidewij van Bruchem-Visser

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Ethiek, laatste levensfase en kwetsbaarheid

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Motto: leren is leven, leven is ontwikkeling (Atie Mol)

Colofon

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R.L. van Bruchem-Visser

Chapter 1: General introduction and outline of the thesis

Making treatment decisions in the vulnerable, often older patient.

Mr. A (82 years old) was brought to the Emergency Department (ED) with complaints of coughing and fever for four days. He had been inarticulate for months due to a progressive dementia and was showing signs of discomfort by grimacing and groaning. His wife said that her husband had choked on his food two days before the complaints had started. In the last month the general practitioner had twice treated him with oral antibiotics because of aspiration pneumonia. A third round of oral antibiotics was started two days prior to presentation on the ED, but the clinical condition of Mr. A had worsened. The evening of transfer to the ED, Mrs A had called the ambulance.

She told the ED staff that her husband had been bedridden for several months. He had stopped eating by himself, so she had started to feed him. Swallowing difficulties had been present for several weeks. Mrs. A requested the staff to "do all that can be done" to keep her husband alive. The staff is in doubt what to do. Should antibiotics be started?

In daily practice as internist geriatrician in a large university hospital I found myself regularly confronted with cases such as that of Mr. A, wondering about the "right way to act". I felt ill-equipped to deal with these issues, as ethics was not a topic that was systematically addressed during my medical training. I have, therefore, sought ways to enhance my knowledge on medical ethics, and carried out the research on medical ethical questions that resulted in this thesis. It is -of course- impossible to discuss all medical ethical problems that occur in vulnerable patients, so this thesis focuses on a selection of issues that I encountered in clinical practice. Empirical research as well as systematic literature reviews were used to address the issues under study regarding ethics in older, vulnerable patients.

The overall aim of this thesis is to map several ethical issues in the heterogeneous category of older, vulnerable patients, often dealing with end-of-life issues and to provide physicians with recommendations on how to handle complex medical ethical decisions.

Vulnerability

Vulnerability is to a certain extent present in all aspects of human existence. Vulnerability refers to a state of physical, emotional and cognitive stability that is in danger of being disturbed or destroyed due to being susceptible to destabilizing influences.(1, 2) Illness, disease and functional decline are visible signs of the vulnerability of a human body. For a person, illness and disease will most likely cause or increase physical, as well as emotional, vulnerability. In many cases, progressions of disease in the absence of treatment will cause further physical, emotional and cognitive decline. It is important to stress that a person can be

considered vulnerable in one setting, but at the same time non-vulnerable in another setting. It is rare for a person to be vulnerable in all aspects of being.(3)

Vulnerable groups were first mentioned in research in 1979 in the Belmont Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.(4, 5) Racial minorities, the economically disadvantaged, the very sick and the institutionalized were labelled as being vulnerable groups, described as considered to be worthy of protection. The aim of this report was to prevent the inclusion of these groups in research protocols while being unduly influenced in decision-making .(1) Examples are abundant, for instance of people at the lower end of hierarchically organized institutions, persons from lower social economical classes seeking monetary gratification or persons with impaired capacity to give informed consent. The latter category ranges from children to mentally impaired persons, as well as persons suffering from dementia. The notion of vulnerable groups has been criticized, however, as it suggests that all individuals in a certain subpopulation are alike and equally vulnerable.(5)

In acute care settings, the vulnerable patient is dependent on healthcare professionals. At such a moment the patient is weak, and the healthcare professional uses her strength (knowledge, interventions, medication) to protect the patient from further harm, or alleviate vulnerability.(1) However, in a chronic, less life-threatening situation, both patient and physician should aim to achieve an equal relationship. The physician can provide medical knowledge whereas the patient has a unique insight in the disease process and its effects on daily life.(1) The picture of an individual in need on one hand, and another individual capable of providing all the necessary help on the other does not do justice to real life, as healthcare professionals are not able to cure all disease, nor to alleviate all pain. Physicians, as well as other healthcare professionals, are vulnerable as well, both in their limited ability to cure and in being human themselves.

The vulnerability of geriatric patients

The group of so-called geriatric patients is growing rapidly. It is estimated that 88 million Europeans are 65 years or older (total 17%), increasing to 157 million people in 2060 (Eurostat Statistics). There is no such thing as ‘the older patient’. There is an enormous heterogeneity in older patients, as compared with younger, generally more healthy patients. The health condition of older patients is a combination of past and present illnesses and diseases, life events and medication use, whereas most younger people have no significant medical history. Some 70-year-olds are very active, others are totally dependent on other people. To consider all elderly persons as being vulnerable does not do justice to this group.

The biological age of a patient largely depends on their medical history, actual comorbidity, use of medication and physical capacity. In the elderly, besides the somatic axis, three more axes are used to describe the patient: psychiatric,

functional and social. In general, advanced age increases the possibility of suffering harm because of increased susceptibility to dysfunction and disability. People aged 65 years or older will more likely have multimorbidity, polypharmacy, cognitive decline and decreased physical activity. Studies show that 55-98% of older patients have multimorbidity, defined as two or more chronic diseases.(6) Interaction between different diseases makes it harder for the clinician to treat each singular, often in itself simple, condition. With declining physical and physiological functionality the elderly are more prone to frailty, psychological stress and social isolation.(3)

Frailty is a term used to identify vulnerable older patients from less vulnerable persons. Frailty is a syndrome, describing a patient with three or more of the following criteria present: unintentional weight loss, self-reported exhaustion, weakness, slow walking speed and low physical activity.(7) Although frailty is an important aspect in the holistic assessment of patients, frailty alone does not suffice in the triage of patients eligible for major treatments such as chemotherapy or surgery.(8) As there is no universal older patient, there also is no universal way of treating that patient. In general, guidelines have little to offer for the multimorbid patient.

In a 2018 study, patients with multiple chronic conditions were interviewed on their experiences with secondary care facilities.(9) It was concluded that a correct overview of patient care was essential to obtain an individualized approach to care. However, a patient with multiple chronic conditions does not seem to fit well in the current design of care, as it is predominantly designed to take care of single-disease-patients. As multimorbidity has shown a rising prevalence, this poses a challenge in providing the right care to this group of vulnerable patients.(10) Patients with multimorbidity experience a lower quality of life, report more mental problems and show an increased mortality.(11, 12)

With a patient using multiple medications and suffering from more than two chronic diseases, the clinician must be able to weigh all the different aspects to design the best plan of action for this particular patient with this particular combination of problems. The possibility of foregoing treatment, and for instance striving for quality of life instead of length of life should be considered. Tools are needed to identify the patient for whom forgoing treatment should at least be seriously considered, regardless of age.

Mr. A is to be considered vulnerable on multiple aspects. He is unable to speak for himself, dependent on other parties for his basic needs and severely ill.

Decision-making regarding the vulnerable older patient
Quality of life and the harmful and beneficial aspects of medical interventions should play a larger role in the decision-making process regarding (major)

treatment options. The positive and negative effects for the patient should be carefully weighed, bearing in mind that most older patients have an increased risk of complications, and need more time for rehabilitation.(13) There is a risk of under- and overtreatment if the only criterion taken into account is age, with no regard for the status of a unique patient. Treating an older patient with the calendar age as the only criterion is likely to lead to overtreatment of the frail older patient and undertreatment of the biologically younger patient.

Evidence-based medicine (EBM) is necessary to ensure optimal treatment decisions. In older, vulnerable patients the basis for EBM may be limited due to various reasons. Older patients are frequently excluded from clinical trials and, therefore, scientific results in this category of patients are scarce.(14, 15) The results of research in younger, more healthy patients can not automatically be extrapolated to older patients. To generate more evidence in the treatment of vulnerable older patient, systematic acknowledgement of the patient situation and increasing doctors' experience and expertise on vulnerable older patients is essential.(16) In this thesis we have sought for measures that could aid in including more vulnerable patients in scientific research, thus generating more evidence on treatment decisions.

In chapter 2, dementia research was analysed to get a clearer picture of whether participants in clinical trials represent the general dementia population.

Apart from the need for more medical evidence for older, vulnerable patients, there is a growing acknowledgement of the need for tools on decision-making in treatment options for biologically ageing patients. Although it has been shown that cognitive as well as functional and psychosocial issues play a role in decision-making on major treatments options, systematic assessment of the above-mentioned three issues is not standard care.(17)

In vulnerable patients, it is particularly important that they benefit from an intervention. When a medical intervention seems to be in the best interest of the patient, it requires the process of shared-decision-making to be sure the intervention is what the patient really wants. At the same time, it is important to identify those patients, in whom forgoing treatment is the better choice. In a study including dialysis patients it was shown that patients who felt they had not made the decision themselves, but had followed the advice of their physician, more often showed regret. The same study showed that around 7% of patients regret their decision to start a major treatment and concludes that it is of importance that decision-making is attuned to values and preferences of individual patients.(18)

In the case of Mr. A, there is medical evidence to rely on. However, there is a vast difference between the research focusing on treating the pneumonia, with clear guidelines on which antibiotics to use, and the research on the long-term results of

treating a pneumonia in patients with severe dementia, advising to forego antibiotic treatment. (19) When treated with appropriate antibiotics, mortality from aspiration pneumonia is still high, with over 50% of patients dying within two weeks. With continuing swallowing difficulties, is it highly probable a subsequent aspiration pneumonia will develop in the foreseeable future.

Shared decision-making

Shared decision-making has become more common in the medical world. The professional provides the technical knowhow, explains the different options and allows the patient to decide which road to take. By making the decision, the patients must consider their own preferences. The physician should be able to inform a patient about the technical aspects of an intervention in a way that the patient fully understands, without influencing the patient. Still, in hindsight, doubts can be felt by the patient about a certain decision. However, nobody can predict what would have happened if that individual had decided against starting with this specific treatment. It could be argued that perhaps other doubts would have emerged. One of the challenges in shared decision-making is finding a way to inform the patient in the best way possible. As it is shown that relatively independent patients struggle to maintain an overview of their care, it is to be expected this problem will increase with the vulnerable patient because of cognitive, visual, auditory decline as well as lack of accompanying relatives.(9) Consultation recording is an easy to implement option to better inform patients and their relatives but is not yet used on a regular basis. In chapter 2.1 of this thesis, we investigated which categories of patients were included in scientific research on dementia with the aim to see if the research population was a reflection of the patients we see in daily clinical practice.

In chapter 2.2 we have explored literature to see if consultation recording could help this specific category of patients to benefit more from the doctor-patient communication and enable them to decide on a treatment in a well-informed way.

Mr. A is unable to participate in a shared decision-making conversation. However, his wife is speaking on his behalf. She should be informed of the different options, ranging from starting maximal treatment to providing palliative care.

Goals and preferences of the vulnerable patient

It is essential to make tailor-made medical decisions. The understanding of a patient's past and lived experiences will help determining what the goals and preferences are for this specific patient and how this reflects on treatment decisions.(20) A method of exploring lived experiences is not included in our standard of care, particularly not in the outpatient clinic of a hospital. Knowing the background of a patient, having shared their previous experiences in a hospital or nursing home and being made privy of their beliefs about life and death, enables a physician to understand their point of view. When a new disease appears, and

treatment decisions must be made, a patient must be informed about all the technically possible treatment options. But, at the same time, the well-informed physician should bear in mind the wishes and preferences of the patient. This can help in deciding what course of action to take. Advance Care Planning (ACP) is described as "a process that supports adults at any age or stage of health in understanding and sharing their personal values, life goals, and preferences regarding future medical care. The goal of ACP is to help ensure that people receive medical care that is consistent with their values, goals and preferences during serious and chronic illness".(21) Underlying goals of ACP are respecting individual patient autonomy, improving quality of care, strengthening relationships, preparing for end-of-life and reducing overtreatment.(22) With the use of ACP, end-of-life wishes were more likely to be known, but also followed more often.(23)

Another aspect to consider, is the location and time of initiation of the dialogue around values and preferences. A lot of questions arise when discussing this topic. Should we strive towards a dialogue regarding preferences and wishes concerning treatment decisions in its broadest sense, without addressing a specific treatment or intervention? Or is it more logical to connect such a conversation with a specific treatment decision? In the latter case, it is possible that multiple physicians will have similar conversations on different interventions. Perhaps such a conversation should be started before a life-threatening illness arises because, as Dutch saying goes: 'fear is a bad advisor'. A general practitioner's office could be considered a suitable environment to explore the wishes of an individual patient. However, even when the values and preferences of a patient are investigated and recorded, it is very likely that beliefs and convictions will vary with the progression of life and illness. The topic of wishes concerning treatments and/or interventions should be revisited regularly, especially when changes in general health are apparent.

Chapter 3 explores several different ethical issues and the relevant considerations in the vulnerable adult. In chapter 3.1, we investigated the challenges that physicians encounter when their opinions on medical decisions differ from those of the patient or relative(s). In chapter 3.2 we report a qualitative study as to what mechanisms play a role when requests for futile treatments are made. In chapter 3.3, we report an ethical dilemma: a case of organ donation following euthanasia. The required moral conditions are described in the last part of this chapter.

Mr. A has not discussed any treatment preferences or goals with his wife or general practitioner (GP). In the conversation with his wife the physician should try to explore what Mr. A's goals and preferences were when he was still able to communicate. Mrs A told the physician that her husband had always been very independent. He had tried to avoid hospitals and physicians as much as possible. Her wish to "do all that could be done" was based on her sense of duty to fight for her husband. Although she found it hard to hear, she agreed with the physician and

the GP that the situation her husband had been in for the last months was lacking any quality of life.

Futility
Certain interventions, diagnostic procedures or treatments are considered futile. A futile medical treatment is described as "serving no useful purpose, completely ineffective", although multiple descriptions of the term have been debated.(24) According to the code of medical ethics as well as Dutch law, a physician may not initiate or continue diagnostic procedures, interventions or treatments that are considered futile, even when the patient or relatives request or demand them. Chapter 4 of this thesis elaborates on the placement of a percutaneous endoscopic gastrostomy (PEG-tube) for artificial nutrition in older patients with severe dementia, as an example of an intervention that is deemed medically futile. In multiple current guidelines the advice is given to forego that intervention in this category of patients. In chapter 4.1, we describe a case in which a conflict arose because relatives demanded the insertion of a PEG-tube, against the advice of the physician. Next to a description of the case, considerations and recommendations for the physician involved are provided. Chapter 4.2 is an introduction to why we should not tube-feed patients with severe Alzheimer dementia. In chapter 4.3, we investigate how often a PEG-tube is inserted in patients with and without severe dementia. Survival and ethical considerations that play a role are explored.

Dealing with an aspiration pneumonia in a patient with severe dementia is challenging. A decision has to be made to either start curative or palliative treatment. Although treatment of an aspiration pneumonia in patients with severe dementia is not considered completely futile, the consensus is to advice starting palliative, symptomatic treatment.

Ethical framework for decision-making in the vulnerable patient
There is a need for an ethical framework as guidance for the physician through ethical dilemmas. In chapter 5, we review which ethical frameworks, specifically designed for the older patient, have been described in current literature.

An ethical framework guiding the treating physicians of Mr. A was not present. A decision was made in the multidisciplinary treatment team, after consulting Mr. A's wife and GP. Symptomatic treatment was started, Mr. A was transferred to the geriatric ward and died several hours later in the presence of his wife. She was very sad he had died, but grateful he had not suffered any discomfort in his last hours and relieved he was spared from further harm.

In the general discussion in chapter 6, the main findings of this thesis, including clinical implications and future directions, are discussed. Chapter 7 provides a summary in English and Dutch.

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Chapter 2: Scientific research in vulnerable patients

Chapter 2.1: Has dementia research lost sense of reality? A descriptive analysis of eligibility criteria of Dutch dementia research protocols.

Rozemarijn L van Bruchem-Visser, Karin R Jongsma, Suzanne van de Vathorst, Francesco US Mattace Raso

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ABSTRACT

BACKGROUND/OBJECTIVES
A substantial proportion of dementia patients are excluded from research participation, while for extrapolation of the research findings it is important that the research population represents the patient population. The aim of this study is to provide an analysis of dementia research and its exclusion criteria in order to get a clearer picture whether the research participants represent the general dementia population.

METHODS
Dementia studies registered at toetsingonline.nl between 2006-2015 were analysed. Study characteristics, funding and eligibility criteria were described and analysed using a standardized scoresheet.

RESULTS
The search yielded 103 usable study protocols. The number of trials has increased over the years, and 35% of the studies were industry-financed. Alzheimer's disease was the most researched type of dementia (84%). In observational studies the most frequently observed exclusion criterion is a neurological condition, in drug studies and other intervention studies the most frequently used exclusion criterion is a somatic condition. 86% of all protocols had at least one exclusion criterion concerning comorbidity. Most studies focused on mild or moderate dementia (78%).

CONCLUSION
Our study has shown that the distribution of dementia research over the different subtypes of dementia does not correspond with the prevalence of these subtypes in clinical practice. The research population in the protocols is not representative of the larger patient population. A greater number of dementia patients could derive benefit from the conducted research, if the research agenda were more closely aligned with the disease prevalence. A better representation of all dementia patients in research will help to meet the needs of these patients.

INTRODUCTION

Research with dementia patients brings about some unique challenges that may hamper the generalizability of the research findings. In research with elderly patients age, comorbidities and sensory impairment are often used exclusion criteria.(1-3) Regarding multimorbidity, it is estimated that 55-98% of the patients older than 65, live with 2 or more chronic conditions.(4) Most people suffering from dementia are over 70 years of age. Thus, a substantial proportion of the patients with dementia are excluded from research participation. As a consequence, the participants in dementia research may not represent the general dementia population. If the validity and generalizability of the findings from biomedical research are weak, patients cannot benefit from the findings of these studies.

The population of patients with dementia is challenging: the group is heterogeneous with regard to the type of dementia, the severity of disease and the presence of comorbidities. It also means that adjusted research methods, such as sub-group analysis are required, and extrapolation of the findings remains uncertain.(2)

The aim of this study is to analyse study and population characteristics of dementia research protocols in the Netherlands between 2006 and 2015. Particularly, we analysed eligibility criteria in order to get a clearer picture whether the general population and the research population are concordant.

MATERIALS AND METHODS

Search strategy

We searched for dementia research protocols on toetsingonline.nl, the Dutch online assessment portal of the Central Committee on Research Involving Human Subjects and of the accredited Medical Research Ethics Committees. The Toetsingonline database contains all biomedical studies conducted in the Netherlands that are reviewed by a Research Ethics Board. The trial data are self-reported by trial sponsors or investigators. Each record contains a set of data elements describing the study's purpose, design, eligibility criteria, location, sponsor and other protocol information, although not all fields are mandatory and publicly accessible. In March 2015, we searched for all approved protocols regarding dementia between 2006-2015 including the term dementia, cognitive decline, Alzheimer disease (AD), Parkinson dementia (PD), Lewy body dementia (LBD), familial dementia, frontotemporal dementia (FTD), vascular dementia (VD).

Data extraction

Data extraction was conducted by using a data extraction form (See supplemental file 1). This form was developed in order to standardize data extraction, on the

basis of a pilot assessment by the two investigators together (KJ and RB) of a random selection of 30 protocols. All remaining protocols were scored by two researchers (KJ and RB) independent of each other. Disagreements that arose were solved by discussing the protocol together. The main outcome measures were: type of dementia (AD, VD, PD, familial dementia, FTD, LBD, MCI), type of study (observation, drug intervention, other interventions), expected number of participants, and their age, comorbidities (somatic, psychiatric, neurological), competence, drug use and living situation.

Data synthesis
The eligibility criteria used in the study protocols were grouped into themes. For classifying data, we made the following choices: we have included protocols that (also) studied Mild Cognitive Impairment (MCI) in the group of dementia protocols. In most cases, there was no distinction made between MCI and mild dementia, therefore we assumed that these protocols included a combination of MCI patients as well as patients with dementia. Furthermore, we considered use of medication an exclusion criterion if any medication use was mentioned as an exclusion criterion in the protocol. The same way of reasoning was used for any sensory impairment, any somatic, any neurologic and any psychiatric comorbidity. We have not scored substance abuse [34 in total] as a psychiatric exclusion criterion, Alzheimer in Down-syndrome patients is scored as Alzheimer research [2 studies in total], the living environment criterion was divided in dependent (institutionalized patient, being taken care of by care-professionals 24/7) and independent (either living at home or at an assisted-living facility, care by a proxy and under supervision of a GP).

Descriptive analysis
We excluded studies that investigated interventions for proxies, studies that not primarily focused on dementia, or prolongations of an earlier study (because the eligibility criteria were not described in the prolongation-protocol).
In the analysis we focused on the description of the type of studies and on the eligibility criteria for participants. Descriptive statistics were used to describe the study- and participant characteristics. Categorical variables were reported as proportions and continuous variables as ranges or absolute numbers. Due to the descriptive nature of the study, formal statistical comparisons were not made.

RESULTS

Search results
The combination of search terms yielded 150 protocols. The duplicates were removed and 135 distinctive research protocols remained. From these 135 protocols, 20 studies were excluded. Thus, 115 studies remained of which 12 were drug studies with healthy volunteers and 103 with dementia or MCI (Mild Cognitive Impairment) patients (see Figure 1).

Characteristics of the protocols

Dementia protocols

The total number of participants between 2006 and 2015 (excluding healthy volunteers) was n= 26422, ranging from 12 to 2400. In comparison, in the year 2014 alone, 427.500 research participants were included in any study to any disease in the Netherlands.(5) A substantial proportion of the dementia protocols (36%), concerned relatively small studies, enrolling 100 subjects or less. Almost half the studies are mono-centre studies, a third of the studies include participants from at least one country outside of the Netherlands (See table 1). Of the 103 studies with dementia patients, 30 were drug trials, 29 other intervention studies and 44 observational studies. In total 35% of the studies were financed by the industry (see table 1). Of the studies sponsored by the industry, 62% concerned drug-intervention studies.

Healthy volunteers

The studies with healthy volunteers were 11 drug-intervention studies and 1 observational study. The number of participants ranged from 4 to 74, with a total of 422 participants. All of these studies, but one, were financed by the industry and focused on Alzheimer's disease. These protocols with healthy volunteers are not further described or analysed in this paper.

Number and type of studies over the years

A notable trend is that the total number of research protocols seems to be increasing, in total 11 protocols were reviewed in 2006-2007, compared to 34 in 2014-2015; especially drug trial research has grown tremendously over the past years (See Table 1). The industry has initiated more research trials in the last few years, 18 trials in 2014-2015 compared to 1 in 2006-2007. In all publication years, AD was the most researched specified type of dementia.

Type of Dementia

Remarkable is that a substantial proportion of studies (32%) do not specify the type of studied dementia (in figures and tables labelled as all dementias), while the types of dementia vary tremendously in terms of severity, symptoms and needed care. MCI/prodromal dementia composes 12% of the studies. Nine per cent studied two or more types of dementia, all of these included AD. Of the studies focusing specifically on one type of dementia, AD is the type of dementia most often studied in terms of number of trials (84%) and in expected number of participants (13011). By contrast, only a small number of studies focused on vascular and Lewy body dementia; familial dementia is not studied in any of the protocols (see figure 3 and 4). Most drug trials and observational studies concerned Alzheimer's disease, and most non-drug interventions were aimed at an unspecified group of dementia patients (see table 1).

Eligibility criteria used in the Dementia study protocols

Age

Regarding age, we found that 60% of the studies use age as an eligibility criterion, either an upper limit alone (7 protocols), a lower limit alone (28 protocols) or an age range (27 protocols). The range of the upper limit is 60-100 years, with an average of 83.7 years. The lower age limit is ranged 18-65 with an average range of 49.1 years.

Competence

24% of the studies noted competence of the research participant in their inclusion criteria, while 49% demanded the consent of the patient (implying participant's competence). The consent of a proxy was required in 24% of the protocols, 23% asked both proxy and informed consent. In approximately half of the studies (51%), having a proxy was required to be included in the research, even if their consent was not necessary.

Living situation

Dementia patients living in nursing homes were explicitly excluded from 22% of the studies. Only a small proportion of the studies (13%) focused explicitly on patients living in nursing homes due to dementia. All other studies either recruited independently living people or did not mention living situation as an eligibility criterion. Due to other recruitment demands, patients living in nursing homes were nevertheless excluded from these studies. For instance, in 23 studies cognitive screening tools were used with scores implying mild or moderate dementia.

Dementia screening instrument

A dementia-screening instrument, such as the Mini Mental State Examination (MMSE) and Clinical Dementia Rating (CDR) was used in 62% of the protocols. MMSE is most often used, and there is a large variety in the range set for eligibility, ranging between 10-30. Some studies set no lower limit at all for the MMSE score, but these studies require that the patient should live independently, thereby implicating a MMSE score of at least 10. Most studies consider patients with a MMSE score of 10 or less as severely demented. (6)

Severity of the dementia

Severely demented patients were excluded from most protocols: 16 protocols focused on MCI or mild dementia and 52 protocols excluded patients with a CDR score >2 or MMSE<10. Of the remaining 35 protocols, 5 required competence of the research participant and 7 required that the participant was independently living, which are unlikely conditions for severely demented patients. In the remaining 23 protocols (22%), severely demented patients may be enrolled, unless they have non-eligible comorbidities.

Comorbidity and medication use
Concerning comorbidities, 22% of the studies noted a visual or hearing impairment as an exclusion criterion. Medication use was stated as an exclusion criterion in 38% of the protocols. In 54% of the studies, patients with a psychiatric disorder were excluded. Somatic comorbidities were indicated as an exclusion criterion in 54% studies. 56% excluded patients with neurological conditions. In 9% of the protocols all these 5 exclusion criteria were noted and 14% noted none of these exclusion criteria. The most often mentioned exclusion criterion in observational studies is a neurological condition other than dementia, in both drug studies and other intervention studies the most often used exclusion criterion is a somatic condition.

Ambiguous criteria
A remarkable finding is that 15% of the dementia studies explicitly state very ambiguous exclusion criteria, such as 'Any other condition that in the opinion of the investigator would complicate or compromise the study', or 'investigator's uncertainty about willingness, ability, or medical status of patient to comply with protocol requirements' which leaves much room for interpretation to the researcher without the further intervention of a Research Ethics Board. Most of these studies were drug trials initiated by the industry.

DISCUSSION

This analysis provides a first snapshot of the landscape of dementia research and of dementia research participants as listed on Toetsingonline in the Netherlands. The results of these research studies provide the basis for treatment and prevention for Dutch dementia patients. From this report of research trials in dementia patients, several noteworthy observations emerge.

Study characteristics
There is a discrepancy between the focus of the research trials and the prevalence rate of the different types of dementia. The estimated prevalence of AD, as reported in the literature, varies between 30 and 75% of all dementia patients.(7-9) The WHO estimates that AD accounts for approximately 41% of all dementias and VD for 32%.(8) Stevens et al. reported a prevalence of 31% AD, 22% VD, 3% PD, 8% FTD and 11% LBD.(9) As our data have shown, a disproportionate number of research trials, which specified the subtype of dementia, focus on AD (Figure 4).

Mixed pathologies are common in practice, and it is not always easy to distinguish clinically between the types of dementia. This is especially true for AD and VD, and AD and LBD.(7, 10) The 9 study protocols that studied two or three types of dementia, did aim to differentiate between subtypes of dementia. The 33 studies that enrolled patients with all types of dementia did not make that distinction, disregarding the necessity of an appropriate diagnosis of type of dementia to tailor

future cure and care. Although different types of dementia are described in literature, it is not always possible to distinguish the specific types of dementia in a single patient. In the studied protocols, it was not always described on which ground a dementia subtype was diagnosed., since the goal of our study is to sketch the landscape of scientific research regarding dementia, we have followed the assumptions made regarding subtypes of dementia.

In addition, our study suggests that the number of industry-sponsored trials increased over the past years. These mostly focused on drug trials concerning AD and MCI. Not many trials focused on VD, PD, LBD and none on familial dementia. The number of participants in these few studies was also fairly low, implying these types of dementia are comparatively understudied in the Netherlands. The LBD and VD studies were conducted as mono-centre studies in the Netherlands, thus for each of this subtype of dementia, only one single institute studied these in the past 10 years. Although small trials are necessary in some cases (eg, early-phase drug studies, trials of rare/orphan diseases), obtaining clinically meaningful and generalizable information from small studies may be difficult.

Clinical research is reported to undergo the same globalization process as other industries and sciences, especially in the realm of clinical trials.(11, 12) Our data showed that 32% of the studies enrolled patients in (at least) one country outside of the Netherlands. Cooperation between centres (multicentre research) is considered beneficial, because it contributes to the generalizability of the patient population. Multicentre research can also contribute to the inclusion of sufficient participants, which might be a challenge in a population as heterogeneous as dementia patients. However, the living and care conditions vary tremendously in different (European) countries, which can complicate multicentre international research in patients suffering from dementia.

Representation of dementia patients

The discovery of effective interventions to prevent or delay disability in older persons is a public health priority. In order to let the growing number of dementia patients benefit from the findings in research, it is necessary that the results of the research trials can be extrapolated to the general population of dementia patients.

In the Netherlands, most people with advanced stages of dementia live in nursing homes, which is approximately 25% of all dementia patients.(13) We have seen that the dementia research protocols mainly focus on mild/moderate dementia, as can be concluded from the MMSE/CDR scores used in the analysed protocols as well as by the requirement that people should still live at home. To be living independently at home, one would expect a MMSE score of approximately 15 or more. Most patients suffering from advanced dementia will not be living at home independently. When a patient is only eligible for enrolment in studies if living independently at home, it is safe to assume that he or she will not be suffering

from advanced dementia. Dementia patients living in nursing homes differ in relevant aspects from patients living at home, concerning the severity of the dementia and the care needed.
Many of the findings obtained in independent living patients cannot be extrapolated to severely demented patients. Since the severely demented patient-group requires and receives the most intense care, one would expect a large proportion of the observational or care research to be conducted in this group. The need for assistance with daily living, impaired cognition and incontinence can affect both the efficacy and the risks of a particular intervention and also the ability of a patient to implement a treatment or successfully complete self-management tasks.(2)

Elderly patients typically have concomitance of multiple illnesses, as a result of two processes: the association between age and incidence of degenerative diseases and the development over time of complications of the existing diseases. Comorbidity is considered one of the hallmarks of geriatric patients, and a fundamental component of their complexity. Sensory impairment is prevalent among the elderly; in people aged 70 years or older, approximately 24% to 36% suffer from visual impairment or blindness and one third of all 65+ people experience disabling hearing loss.(14-16) Somatic multimorbidity is prevalent in 55-98 patients aged 65 years or older.(4) As shown in the results, most research protocols incorporate exclusion criteria regarding somatic comorbidities or sensory impairment. The research participants are generally required to be healthy and not sensory deprived, whereas the average dementia patient has several comorbidities, including sensory deficits.

Therefore, dementia patients included in research protocols do not seem to represent the average patient population suffering from dementia. Excluding patients with comorbidities limits the external validity and might not truly represent the wider spectrum of patients seen in clinical practice. To the degree that it is clinically feasible, studies should include multimorbid individuals of all ages reflective of the general dementia population. A possible solution to the limited external validity of RCTs is the implementation of pragmatic studies (or real-life studies), which are gaining widespread recognition and support among clinicians and are of particular interest for policy-makers.(17-19) Pragmatic studies are designed to evaluate the effectiveness of interventions in the full spectrum of real-life settings in order to maximize applicability and generalizability, as opposed to the optimal situations created in RCTs. Therefore, these studies are suitable to include a large number of participants, have a small number of eligibility criteria to allow a variety of patients in the trial, have patient-centred outcomes, and use clinical interventions similar to those used in routine care.(18, 19)
A surprising finding that deserves attention is the frequent mentioning of ambiguous exclusion criteria. These criteria offer researchers too much freedom to selectively exclude potential research participants without the intervention of a

Research Ethics Board. The selective exclusion of eligible research participants is, however, problematic for both scientific and ethical reasons. It results in an arbitrary selection of participants and limits both the internal and external validity of the study. Preventing eligible patients to participate in research is also known as gate keeping, and withholds the choice to participate from research participants.(20)

Limitations

A limitation inherent to the use of the research registry includes missing data; for example the phase of the drug trial, information regarding the informed consent process and the competence of the research participant were not included in the publicly accessible part of the registry. Therefore we could not provide a further analysis of the mismatch between the necessity for informed consent and the apparent lack of attention for the research participant's competence. Furthermore, the registration of biomedical research trials in the web portal Toetsingonline is compelled since the end of 2011, while before this time it was voluntary; it is thus unclear how many data are missing from the years before 2011. Finally, since Toetsingonline is a prospective register, the number of participants is based on an anticipation of the researchers; and does not necessarily correspond with the actual number of enrolled participants.

Concluding remarks

In our study we found that the distribution of dementia research over the different types of dementia does not correspond with the prevalence of these dementia types in clinical practice. Furthermore, we found that the research population is not representative of the larger population of people suffering from dementia. Therefore, the possibility to extrapolate research findings of drug, intervention and observational studies to the patient population is limited Furthermore, the exclusion of dementia patients in the more advanced stages of dementia in research studies, means that this group of patients cannot benefit from possible therapeutic effects of the studies and may not profit developed interventions and new insights, because this group differs significantly from the group of research participants. Moreover, ambiguously formulated exclusion criteria should always be avoided and should not be accepted by Research Ethics Boards, because these criteria limit the internal and external validity of the research.

A greater number of dementia patients could derive benefit from research, if the research agenda were more closely aligned with the disease prevalence. Lewy body dementia, familial dementia and vascular dementia are understudied compared to their disease prevalence and require more attention. In order to improve the generalizability of the research findings to the broader dementia population, it is important that the research participants reflect the population of patients. This is important for both intervention as well as observational studies. Regarding the extrapolation of research results of intervention studies we encourage the conduct

of 'pragmatic studies' in order to extend the applicability of RCTs results to real-life settings.
Our study may be useful to stakeholders, including policy makers, academic centres, industry, and investigators, and aid future decision-making regarding the conduct of trials in dementia patients. A better understanding of which conditions and populations are insufficiently addressed in the current research practice should provide guidance to organizations on how to allocate and prioritize available resources.

FIGURE 1: Flowchart of search results

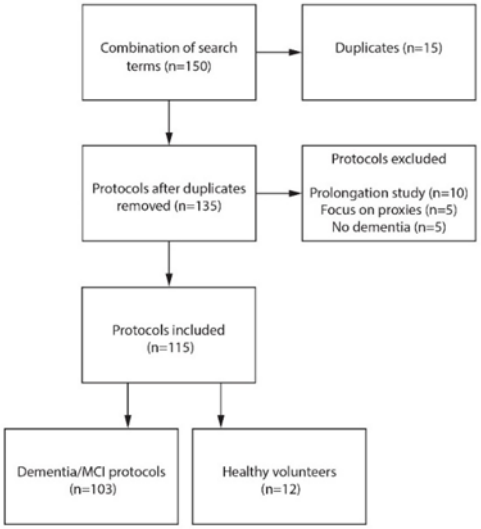
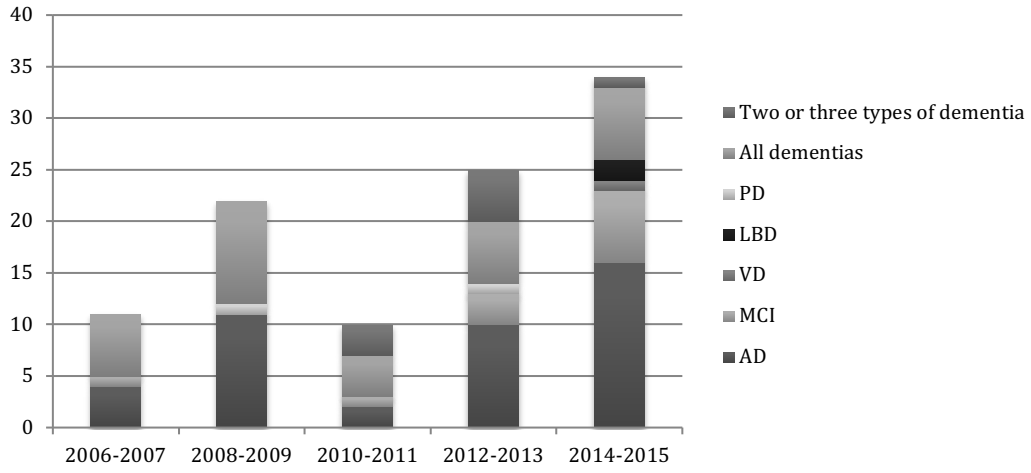


TABLE 1: Overview of study and eligibility criteria

Type of dementia	AD	MCI	VaD	FTD	LBD	PD	All types	2 or 3 types	Total
No of studies	43	12	1	2	1	2	33	9	103
Study characteristics	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)	N (%)
Observational	21 (49)	4 (33)	0 (0)	0 (0)	1 (100)	1 (50)	11 (36)	5 (56)	44 (43)
Drug trial	17 (37)	5 (42)	1 (100)	2 (100)	0 (0)	1 (50)	1 (3)	3 (33)	27 (26)
Other intervention	5 (14)	3 (25)	0 (0)	0 (0)	0 (0)	0 (0)	219 (58)	1 (11)	29 (28)
Industry financed	23 (53)	7 (58)	0 (0)	2 (100)	0 (0)	1 (50)	1 (3)	0 (0)	34 (33)
Not financed by industry	20 (47)	5 (42)	1 (100)	0 (0)	1 (100)	1 (50)	32 (97)	9 (100)	69 (67)
Participants	13011	5170	30	210	60	700	6306	935	26422
Mono	17 (40)	4 (33)	1 (100)	0 (0)	1 (100)	0 (0)	18 (55)	6 (67)	47 (46)
Multicentre	7 (16)	1 (8)	0 (0)	0 (0)	0 (0)	0 (0)	13 (39)	2 (22)	23 (22)
International multicentre	19 (44)	7 (58)	0 (0)	2 (100)	0 (0)	2 (100)	2 (6)	1 (11)	33 (32)
Elegibility criteria									
Sensory deficit	12 (28)	1 (8)	0 (0)	0 (0)	1 (100)	1 (50)	8 (24)	0 (0)	23 (22)
Medication use	20 (37)	6 (50)	1 (100)	1 (50)	0 (0)	1 (50)	5 (15)	5 (56)	39 (38)
Psychiatric	29 (67)	9 (75)	1 (100)	2 (100)	1 (100)	1 (50)	9 (27)	5 (56)	57 (55)
Somatic	27 (63)	9 (75)	1 (100)	2 (100)	1 (100)	1 (50)	12 (36)	5 (56)	58 (56)
Neurological	32 (74)	9 (75)	0 (0)	2 (100)	1 (100)	2 (100)	8 (24)	4 (44)	61 (60)
Age criterion	32 (74)	10 (83)	0 (0)	2 (100)	1 (100)	2 (100)	12 (36)	3 (33)	32 (60)
Living situation	8 (19)	1 (8)	1 (100)	2 (100)	0 (0)	0 (0)	22 (67)	0 (0)	34 (33)
Competence	12 (28)	2 (17)	1 (100)	2 (100)	0 (0)	1 (50)	5 (15)	3 (33)	26 (25)
Informed consent	24 (56)	6 (50)	1 (100)	2 (100)	0 (0)	2 (100)	9 (27)	6 (67)	50 (49)
Proxy consent	10 (23)	3 (25)	0 (0)	2 (100)	0 (0)	1 (50)	6 (18)	3 (33)	23 (22)
Caretaker required	24 (56)	5 (42)	1 (100)	2 (100)	0 (0)	1 (50)	14 (42)	5 (56)	50 (49)
Use of diagnostic tests	34 (79)	6 (50)	1 (100)	2 (100)	0 (0)	1 (50)	13 (39)	8 (89)	65 (63)

FIGURE 2: Type of study over the years



AD = Alzheimer's dementia; VD = vascular dementia; MCI = mild cognitive impairment; LBD = Lewy body dementia; FTD = frontotemporal dementia; PD = Parkinson's dementia

FIGURE 3: Pie-chart of the studied single subtypes of dementia

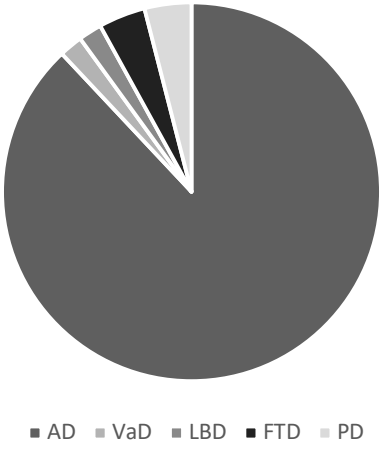
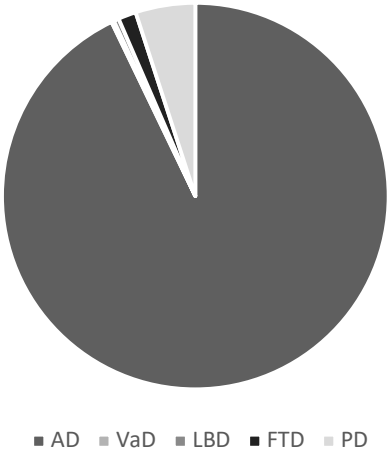


FIGURE 4: Pie chart number of participants per specified subtype



AD = Alzheimer's dementia; VaD = vascular dementia; LBD = Lewy body dementia;

FTD = frontotemporal dementia; PD = Parkinson's dementia

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Chapter 2.2: Consultation recording: What is the added value for patients aged 50 years and over? A systematic review

Lisanne J Dommershuijsen, Christine WM Dedding, Rozemarijn L van Bruchem-Visser

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ABSTRACT

BACKGROUND/OBJECTIVES
This systematic review aimed to provide medical professionals with insight into beneficial and harmful effects of consultation recording for patients aged 50 years and over. This insight could enable medical professionals to decide on whether or not to promote consultation recording in their practice.

METHODS
The systematic literature search was performed in six databases; additional relevant articles were sought using the snowball method. Studies were included that investigated the value of consultation recording for patients aged 50 years and over. The selected studies were analysed on affective cognitive outcomes, behavioural outcomes, and health outcomes.

RESULTS
Twenty-five studies of both qualitative and quantitative design were included. Consultation recordings mainly improved patient satisfaction, recall, fulfilment of information needs, and decision-making. Both positive and negative effects were reported on anxiety. The recordings did not distinctly affect functional outcomes or quality of life.

CONCLUSION
Consultation recording positively influenced patients' affective cognitive and behavioural outcomes, and the negative effects of consultation recording were minor. Because of the positive effects of consultation replay, we recommend that doctors promote consultation recording among their patients of 50 years and over. However, more studies are necessary among older patients because this patient population is underrepresented in the current literature.

INTRODUCTION

Doctor-patient communication is an essential element of good clinical practice.(1) Adequate communication can positively affect patient satisfaction and can even improve health outcomes.(2) Despite the importance of effective communication, doctor-patient communication is often sub-optimal.

It has been shown that patients experience many difficulties in remembering the information given during their medical consultation.(3) Kessels showed in his 2003 review that patients immediately forget between 40% and 80% of the medical information conveyed by their doctor.(3) Recall and understanding of medical information is particularly poor among older people which could be attributed to declining cognitive abilities and difficulties experienced in structuring information.(3-5).

A commonly used tool to improve recall and understanding is consultation recording.(6) A survey in the United States has shown that more than one in four physicians ever recorded a consultation for patients' personal use and about one in five of the general public ever recorded a consultation.(6, 7) Most consultations are recorded in oncology settings, presumably because of the emotional nature of these consultations.(7)

Many physicians recognise the importance of consultation recording, but there are also concerns. Doctors worry that patients may encounter interpretation difficulties and express medico-legal concern.(8) In addition, between 3% and 15% of patients report to have ever covertly recorded their consultation, which can undermine the doctor-patient relationship.(9)

In order for doctors to embrace consultation recording, the value of recording for patients needs to be evaluated. Several previous reviews have investigated the effects of consultation recording and have shown that recordings increase patient satisfaction, recall, and understanding, and are useful to inform relatives.(10-12) However, it is unclear whether consultation recording has similar effects on the patient group that experiences most difficulties in recalling and understanding information: older patients. This literature review aimed to provide medical professionals with insight into older patients' reported beneficial and harmful effects of consultation recording.

METHODS

Inclusion and exclusion criteria

The inclusion and exclusion criteria of this review are listed in Table 1. To be included, studies needed to evaluate the value of audio or video recording a doctor-patient interaction for patients aged 50 years and over. Only original studies

published in peer-reviewed journals were included. For practical reasons, studies in languages other than English were excluded.

Search strategy
The literature search included the terms “recording” and “elderly” along with “consultation” or synonyms for these terms. The full search strategy can be found in Appendix A. The following databases were searched: Excerpta Medica Database (Embase), Medical Literature Analysis and Retrieval System Online (MEDLINE), Psychological Information Database (PsycINFO), Web of Science, Cumulative Index to Nursing and Allied Health Literature (CINAHL), and Google Scholar. In addition to the systematic search, the references of all relevant studies and reviews were checked for potential articles to include. Articles of all dates were included until November 2018.

Selection and quality assessment
Endnote was used to structure references. First, the titles and abstracts of all articles were scanned. Potentially relevant titles and abstracts were then compared by two researchers. Second, the full text of relevant articles was assessed using the inclusion and exclusion criteria. If the full text of an article was not available, the corresponding author was emailed whenever possible; the full text was assessed for eligibility if the author responded within three weeks. After full-text screening, articles included by both researchers were compared again and potential disagreement was resolved by discussion.

We used the Cochrane Collaboration’s tool for assessing risk of bias for randomised studies and the Methodological Index for Non-Randomised Studies for non-randomised studies.(13, 14). The Critical Appraisal Skills Programme qualitative checklist was used to assess qualitative studies.(15) The quality of each study was assessed by two researchers independently, after which the results were discussed. All studies were scored as being of either high or low quality. We did not use a predefined cut-off for the number of items to be scored as positive for a study to be of high quality, as this was not recommended by the quality-assessment tools. A high-quality study needed to have no significant methodological flaws. If too little information on the methodology was present in the article to determine the quality, a low-quality score was given.

Data extraction and synthesis
The data were synthesized using a recently published framework by Lafata (see Figure 1).(16) This framework describes how doctor-patient communication can affect patients. Communication affects patient outcomes in three ways. The first indirect path leads to affective cognitive outcomes, including for instance patient satisfaction, and then to health outcomes. The second leads to health outcomes through behavioural outcomes, which entail for example treatment adherence. The final path leads directly to health outcomes, including for instance quality of life.

Several sub-outcomes were considered within the three outcome measures, which all emerged from the included articles. These sub-outcomes were satisfaction, mood state, and recall and understanding for affective cognitive outcomes; sharing recording, future contacts and consultations, decision-making, and effect on recorded consultation for behaviour outcomes; and symptoms, need for emergency help, sick leave, and quality of life for health-outcomes.

RESULTS

Included studies

The literature search yielded 2208 unique references. After screening for titles and abstracts, 58 studies remained. For these records, the full text was assessed leaving 25 articles for the analysis of the literature review. The flow diagram and reasons for exclusion can be found in Figure 2. The most common reason for exclusion was that the value of a general information tape was assessed rather than the value of a consultation tape.

Table 2 provides an overview of the studies included in this review. The included studies were undertaken in Australia, Canada, Denmark, the Netherlands, Norway, Sweden, the United Kingdom, and the United States. Fourteen studies were randomised controlled trials (RCTs) and the other eleven were cohort or qualitative studies. Nineteen of the 25 studies were performed among cancer patients. Some studies investigated additional interventions besides consultation recording, including written information, general information tapes and question prompt lists. All studies used either a questionnaire or a (semi-)structured interview as an outcome measure. The timing of the outcome measurement ranged from a couple of days to a year after the intervention.

The results of the included studies will be described on the basis of the three outcomes of the conceptual framework: affective cognitive outcomes, behavioural outcomes, and health outcome.(16) An overview of the results of the RCTs and comparative cohort studies is provided in Table 3 for affective cognitive outcomes, Table 4 for behavioural outcomes and Table 5 for health outcomes.

Affective cognitive outcomes

Satisfaction

In general, patients were highly satisfied with the consultation recording. Participants of three studies rated the recording intervention between 83 and 94 out of a maximum of 100.(17-19) Four studies reported that most participants would recommend the interventions to others or would want future consultations to be recorded.(20-23) In addition, two studies indicated that participants who did not receive a consultation tape felt disappointed.(24, 25)

Besides the studies that described patient feedback, a number of RCTs also analysed the effect of consultation recording on patient satisfaction. Four large RCTs found significant effects of the recording on different aspects of patient satisfaction. The RCT of Dunn and Bruera showed that satisfaction with the consultation was higher in the consultation recording group compared to the control group or a general tape group.(26, 27) Dunn also showed that satisfaction with the tape itself was higher in the consultation tape group than the generic tape group.(26) Moreover, Ong found a significantly higher general satisfaction and satisfaction with interpersonal aspects in the intervention group compared to the control group after a week, but not after a three months.(20) In their study, satisfaction with the communication did not differ between the groups and satisfaction with the consultation only increased significantly in patients under 55 years of age. Finally, the study by Wolderslund showed that patients who received a consultation tape rated their satisfaction with the treatment and confidence in and relationship with the physician higher than the control group.(28) Despite the effects on satisfaction shown in these RCTs, the RCTs by Hack and Hack did not show a significant difference in satisfaction with the communication.(17, 18)

Consultation tapes were considered complementary to summary letters from the treating physician.(22, 29, 30) Most patients preferred receiving both a consultation tape and a summary letter. Reasons for preferring a tape were that it was more reassuring and personal, and not restricted to what the doctor thought was important. On the other hand, reasons for preferring a letter were that it was easier to share, because it was less personal, and easier to file.

Mood state

Mood state was defined as depression, anxiety, adjustment to illness and perceived control in the studies included in this review. Four studies reported on the effect of recordings on depression. None of these studies found a difference in depression scores in the intervention group compared to the control group.(30-33) Interestingly, the RCT by Mishra showed that the consultation tape group scored significantly better on depression than the general tape group.(33)

Studies have described different effects of consultation recording on anxiety; it has been hypothesised that a consultation tape is comforting for some, while distressing for others. Four RCTs did not find a significant difference in anxiety levels between the consultation tape and control group.(30-33) Similar to the findings for depression, the RCT by Mishra found significantly improved anxiety scores in the audiotape group compared to the general tape group.(33) Patient-feedback showed that not listening to the consultation recording was often anxiety-related. Nevertheless, the listening itself was not distressing for most, but even was encouraging.

Other relevant aspects considering the patient's mood state are adjustment to illness and perceived control. Three RCTs of Dunn, Hack and Hack reported that psychological adjustment was not significantly better in the intervention group than in the control group.(17, 18, 26) On the contrary, a qualitative study by Ah-Fat indicated that the consultation tape helped patients to adjust emotionally and psychologically to their illness.(34) Additionally, the RCT conducted by Mishra showed that the consultation tape group experienced significantly more control over their health than the group that received a generic tape or no tape.(33) However, Wolderslund did not find a similar effect on the ability to manage health problems.(28)

Recall and understanding

Recall of the consultation was measured in various ways and at different times. Often a general information test was used, although some studies measured recall based on participant-specific questions. Nine RCTs reported on objectively measured recall, of which four reported significant better recall in the consultation recording group compared to the control group.(20, 27, 32, 33) Hack reported only results for the subgroup of men and showed that patients who had the choice to receive a consultation tape recalled more than those who received the audiotape without choice or those who did not receive a tape.(24) Dunn, Bergenmar, Haerem, and Tattersall did not find a significant difference in objectively measured recall when comparing patients receiving a consultation tape to those not receiving a tape or written information only.(24, 26, 30, 35, 36) However, Tattersall indicated that patients scored the tape significantly more effective in reminding them of what the doctor said.(30) Patient feedback of most studies showed predominantly positive influences of the tape on recall.

Two studies by Hack and Hack reported that patients' perception of having been informed was significantly greater in the intervention group than in the control group.(17,18) Hack showed this only for information on side effects.(17) In another study Hack showed this for information on side effects, treatment alternatives and overall information.(18)

Additionally, Wolderslund described that patients who received an audiotape had greater fulfilment of their information needs than the control group.(28) Consultation tapes were deemed most useful for consultations in which new information or important issues were discussed and when the ability to take in information was impaired.(37, 38)

Patients' perceived understanding was not reported to be significantly different by two RCTs.(27, 35) On the contrary, the RCT conducted by Hogbin found a significant increase in understanding after approximately two weeks in the group that received an audio recording, but did not find this effect in the control group.(31) Patient feedback indicated that the recording helped to clarify possible ambiguities,

for instance about medical terminology; to encourage deeper reflection; to process information; to understand the condition; and to come up with new questions. Two studies reported that in some cases the recordings led to more uncertainties or unanswered questions.(28, 35)

Behavioural outcomes
Most studies indicated that a great number of participants listened to the consultation tapes. Often, consultations were replayed by 80% or more. The average listening frequency ranged between once and four times. In general, patients more often listened to part of the tape than to the whole tape.

Sharing recording
Consultation recordings were frequently shared with close family members. Some patients also shared the consultation recording with another healthcare provider. Patient feedback indicated that tapes eased communication with relatives by giving more accurate information; helping family to gain more knowledge of the disease; facilitating discussion about the illness; and reducing the need to repeatedly explain what was said during the consultation. The RCTs by Bruera and Uitdehaag, however, did not find a significant difference in the ability to discuss illness with friends and family in the consultation recording group compared to the control group.(23, 27)
Future contacts and consultations. Some studies showed an influence of recordings on subsequent consultations. Several studies reported that patients were more actively involved in following consultations, were better informed, or needed less repetition of previously provided information, saving time in subsequent consultations. The RCT by Wolderslund showed that the number of contacts with the clinic was significantly lower in the consultation recording group compared to the control group, although this difference was not significant after correction for multiple testing.(28) In addition, Hogbin showed that the number of visits to the general practitioner was significantly lower in the intervention group, but the control group did not make more attempts to seek further information or visit the nurse.(31)

Decision-making
Patients in the intervention group of the RCT of Wolderslund rated their involvement in decision-making higher than patient in the control group, although this effect was no longer significant after correction for multiple testing.(28) In addition, a comparative cohort study by Good showed that the mean decision regret score was significantly lower in the consultation recording group than the control group.(39) Patient feedback corroborated that recordings were useful for decision-making.

Effect on recorded consultation

A few studies illustrated that recordings altered the course of the consultation. Patients in the study of Lipson-Smith and Hyatt thought recordings made the doctor more attentive or could encourage doctors to communicate more effectively.(37, 38) Similarly, physicians in the studies of Hogbin and Johnson reported that the recorded consultations were more explicit.(40, 41) The two studies by Knox and Ong showed that the majority of the patients did not notice the recording during the consultation.(20, 22) In addition, few patients thought the tape limited discussion or felt discomfort because of it. (22, 29, 41)

Health outcomes

The studies by Good and Hogbin showed some indications of less physical symptoms in the consultation recording group compared to the control group, although the difference was only significant for bowel-related symptoms in the study of Good.(31, 39) The study of Haerem revealed that the tape group needed significantly less emergency help, was less often re-admitted and included less people on sick leave than the control group.(36) No studies found a significant effect on functional outcomes or quality of life.(17, 18, 20, 23, 39) The reported results on health outcomes must be interpreted in the light of the limited available evidence on these outcomes and the possibility of a placebo effect.

Consultation recording for older patients

We hypothesized that older patients would benefit most from consultation recording. To study whether there is an increased effect of consult recording in older patients, we compared the included studies which had a mean participant age above 65 years with the other included studies. Seven studies had a mean participant age of 65 years and over: four high-quality RCTs and three low-quality qualitative studies.(18, 21, 23, 32, 33, 37, 41) Consultation recording did not show an evidently greater beneficial effect in this patient group. Nevertheless, the effect of recording on recall seemed more profound in studies considering older patients, whereas there was less support for an effect on satisfaction. This finding is consistent with the observation of Ong that access to tapes seems more helpful in enhancing recall among older than younger patients.(20) Because of the very small number of studies considering the effect of consultation recording among patients aged 65 years and over, this conclusion must be interpreted with caution.

DISCUSSION

This literature review aimed to identify the beneficial and harmful effects of consultation recording for patients of 50 years and over. We have shown that recordings are mainly beneficial for patients and positively influence affective cognitive and behavioural outcomes, which are described as the two indirect paths by Lafata.(16) There is little evidence for a direct effect of consultation recording on health outcomes.

The main results of this review are consistent with previous reviews among other patient populations.(4, 10-12, 42) Similar to previous reviews, we have shown that the primary value of consultation recording is to increase patient satisfaction and recall. The value of consultation recording for older patients did not seem to differ much from the value for other patient populations, even though we found indications of a larger effect on recall and possibly a smaller effect on satisfaction in older patients.

The effects of consultation recording shown by the studies included in this review might differ from the effects of consultation recording in clinical practice. Patients in the studies included in this review were all provided with a consultation tape, whilst currently patients often bring their own device to a record consultation.(7) This difference in recording approach could affect the patients' reported outcomes of consultation recording because patients who take the initiative to record their consultation might be more inclined to listen to the recording and might also rate the value of recordings higher.

We have shown that recordings are mainly beneficial for older patients. However, the value of consultation recording must outweigh the concerns of health professionals in order to successfully implement consultation recording in clinical practice.(8, 43, 44) Physicians worry that consultation recording impairs the open discussion and undermines the doctor-patient relationship, and that patients may encounter interpretation difficulties when listening to the recording. In our review, we found that very few patients thought the tape limited discussion and that some studies even reported a positive influence on the doctor's appreciation. In addition, studies did not report that patients encountered interpretation difficulties, but even showed that patients were better informed. Hence, these concerns should not be a reason to withhold patients a recording. Another concern among doctors, presumably the most important concern, is the issue of privacy and legislation. Our review has not focussed on these concerns of doctors, but the literature review of Rieger has provided useful recommendations to deal with medico-legal concerns.(12) These recommendations could help to successfully implement consultation recording in clinical practice.

Three aspects of our review warrant further consideration. First, 19 of the 25 included studies involved exclusively cancer patients, which limits the generalisability of our findings to other consultation types. Second, we included all studies with an average participant age above 50 years, whereas we aimed to study the value of consultation recording for older patients. Preferably, we would have included only studies with a higher mean participant age, however, this was impossible given the very small number of studies performed among this patient group. Third, the included studies were very diverse in timing and measurement of the outcomes, which made data pooling impossible. Therefore, we provided an overview of the literature by structuring the findings of RCTs and comparative

cohort studies based on statistical significance. Although this method clearly shows the available evidence and current gaps in knowledge, this focus on significance does not inform about effect sizes and the dichotomization might misrepresent results.

Besides the limitations of this review, our work also has several important strengths. A strength of our methodology is that we included studies with different designs and that we did not exclude studies because of low quality. This choice made it possible to gain a thorough insight into all beneficial and harmful effects of recordings for patients. Most low-quality studies in this review were qualitative studies with a lack of information on the methodology, which does not mean those studies were not conducted properly. Another strength of this review is the open approach of data extraction: the three categories of Lafata were used as a directive for data analysis and smaller themes emerged from the included studies.(16)

This review has provided insight into currently known effects of consultation recording for older patients and has indicated areas that lack evidence in the existing literature. Additional research is required to investigate other patient populations than cancer patients. There is abundant scope for further progress in determining the effect of consultation recording among older patients because this patient group is underrepresented in the current literature, even though this patient population might benefit most from consultation recording.

CONCLUSION

This review has shown that consultation recording is an important and easy-to-use information tool for older patients. Recordings can positively influence patients' affective cognitive and behavioural outcomes. The reported negative effects of recordings are minor and predominantly related to anxiety. Further studies are warranted to explore the specific value of consultation recording for older patients.

TABLE 1: Inclusion and exclusion criteria

Inclusion	Exclusion
Published full-text articles	Abstract only
Studies in English	Studies in languages other than English
Peer-reviewed studies	Systematic reviews/meta-analyses
Studies of all dates	Conference proceedings
Studies that investigate consultation recording among patients aged 50 years and over	Editorials, letters to the editor and opinion pieces
Studies that evaluate the beneficial and/or harmful effects of audio or video recording doctor-patient interactions for patients	Studies that evaluate the use of audio or video recordings for educational purposes
Studies focusing on patients' perspectives on consultation recording	Studies that evaluate the role of general information tapes

FIGURE 1: Conceptual framework. "Patient-clinician communication model" by Lafata et al (2017), licensed under CC BY40

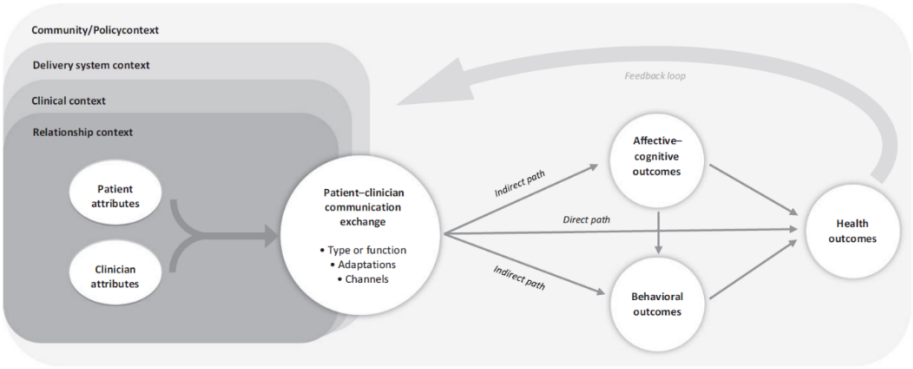

FIGURE 2: PRISMA flow diagram of included studies

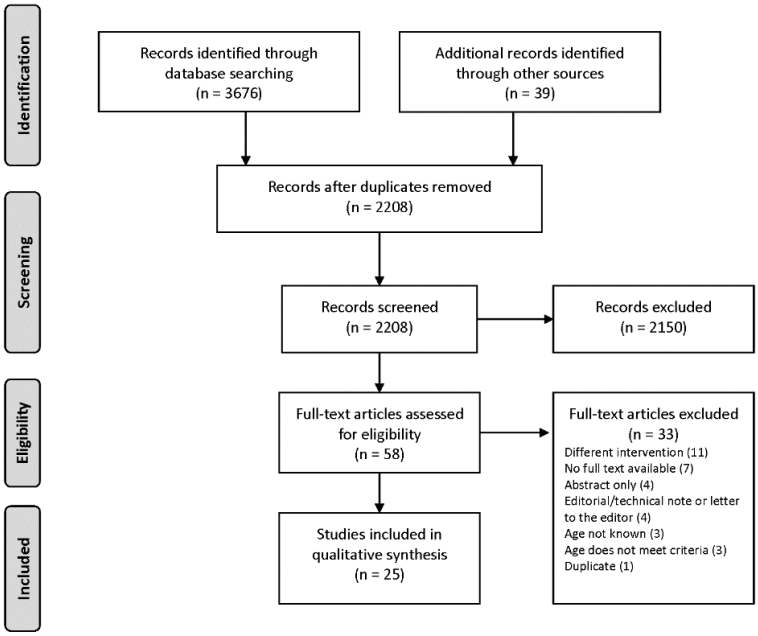

TABLE 2: Descriptives of included studies

First author year	Study design (n[a])	Q	Setting	Intervention	Timing measurement	Descriptives
Ah-Fat 1998	QS (94)	Low	Oncology	Consultation tape	6 weeks-10 months	58 yrs [29-83] Men: 44 (47%)
Bergenmar2014	RCT (130)	High	Oncology	Group I: tape, written information Group II: written information	1 week after affirming participation in trial	Group I: 55 yrs (10) Group II: 54 yrs (11) Men: 23 (18%)
Bruera 1999	RCT (71)	High	Oncology	Group I: tape, written information Group II: written information	Day 8	62 yrs (10) Men: 36 (60%)[b]
Butt 1977	QS (48)	Low	Outpatient Clinics	Consultation tape	Month 3-4	55 yrs [26-77] Men: 19 (42%)[b]
Dunn 1993	RCT (142)	High	Oncology	Group I: tape Group II: general tape Group III: no tape	Week 1-3	52 yrs (unknown) Men: 27 (16%)[b]
Good 2016	CCS (103)	High	Oncology	Group I: tape Group II: no tape	Month 12	Group I: 64 yrs [50-74] Group II: 64 yrs [43-83] All men
Hack 1999	RCT-pilot (36)	Low	Oncology	Group I: received no tape Group II: received tape Group III: choice to receive	Before and after consultation and after week 6	Men: 67 yrs [51-79] Women: 52 yrs [34-77] Men: 18 (50%)
Hack 2003	RCT (670)	High	Oncology	Group I: standard care Group II: taped, received no tape Group III: taped, received tape	Week 12	57 yrs (12) All women

				Group IV: taped, choice to receive		
Hack 2007	RCT (466)	High	Oncology	Similar to Hack, 2003	Week 12	67 yrs (8) All men
Hack 2013	QS (229)	High	Oncology	Consultation tape	Day 2 and week 1	60 yrs [36-86] Men: 54 (24%)[b]
Haerem 2000	RCT (50)	Low	Cardiology	Group I: consultation tape Group II: no tape	Week 1, 8 and 52	Men: 53 yrs (unknown) Women: 57 yrs(unknown) Men: 38 (76%)
Hogbin 1989	QS (46)	Low	Oncology	Consultation tape	Whenever finished listening	56 yrs [31-81] Men: 4 (9%)
Hogbin 1992	RCT (87)	Low	Oncology	Group I: tape Group II: no tape	After consultation, 2-3 days pre-operatively and 6 weeks post-operatively	Group I: 58 yrs [39-82] Group II: 58 yrs [36-79] All women
Hyatt 2018	QS (18)	High	Oncology	Tape and question prompt list	Week 2	63 [39-78] Men: 11 (61%)
Johnson 1991	QS (29)	Low	Oncology	Tape	Week 2	65 yrs [28-83] Men: 19 (66%)
Knox 2002	PCS (52)	High	Oncology	Tape, then summary letter (after 2 weeks)	Week 2 and 4	51 yrs [19-80] Men: 13 (25%)
Leahy 2005	QS (20)	Low	Cardiac Surgery	Group I: tape Group II: no tape	Week 6	Group I: unknown [50-78] yrs Group II: unknown [30-72] yrs Men: 15 (79%)[b]
Lipson-Smith 2016	QS-pilot (23)	Low	Oncology	Pilot intervention including information sheet, question prompt list and tape	Week 2	66 yrs [50-82] Men: 14 (61%)
Mishra 2010	RCT (84)	High	Cardiac Surgery	Group I: no tape Group II: general tape	At hospital admission	Group I: 67 yrs [63-68] Group II: 67 yrs [64-71]

				Group III: consultation tape		Group III: 66 yrs [62-69] Men: 60 (71%)
Newnham 2015	QS-pilot (20)	Low	Acute General Medicine	Discharge video with standardised script	Within 2 weeks	70 yrs [23-91] Men: 13 (65%)
Ong 2000	RCT (201)	High	Oncology	Group I: tape Group II: no tape	Week 1 and month 3	Group I: 54 yrs [25-85] Group II: 53 yrs [15-93] Men: 37 (18%)
Stephens 2008	RCT (58)	High	Oncology	Group I: tape Group II: no tape	Week 2	I: 66 yrs [48-88] II: 69 yrs [49-82] Men: 43 (74%)
Tattersall 1994	Cross-over RCT (182)	Low	Oncology	Group I: tape followed by summary letter (after 7-10 days) Group II: summary letter followed by tape (after 7-10 days)	Day 10 and 20	Group I: 51 yrs [28-78] Group II: 51 yrs [16-80] Men: 40 (22%)
Uitdehaag 2012	RCT-pilot (21)	High	Oncology	Group I: tape Group II: no tape	Week 1 and month 1	Group I: 68 yrs [50-89] Group II: 62 yrs [42-77] Men: 12 (71%)[b]
Wolderslund 2017	RCT (9143, 5834 received intervention)	High	Outpatient Clinics	Group I: standard care Group II: question prompt list and tape Group III: tape	13-16 days	Group I: 61 yrs (15.5) Group II: 61 yrs (15.1) Group III: 62 yrs (15.0) Men: 1926 (57%)[b]

Age is shown as mean or median and (SD) or [range]. Sex is shown as number (percentage of sample at baseline). [a]Number randomized for RCTs and number providing informed consent for qualitative studies. [b]Percentage of participants for whom results were shown. Q = quality of study, QS = qualitative study, RCT = randomised controlled trial, CCS = comparative cohort study, PCT = prospective cohort study

TABLE 3: Affective cognitive outcomes: the effect of comparative studies

Outcome	Study	Quality
Satisfaction significantly higher in intervention group		
General satisfaction	Ong, 2000[a]	High
Satisfaction with consultation	Bruera, 1999	High
	Dunn, 1993[b]	High
Satisfaction with treatment and physician	Wolderslund, 2017[c]	High
Satisfaction with interpersonal aspects	Ong, 2000[a]	High
Satisfaction not significantly different		
Satisfaction with consultation	Ong, 2000[d]	High
Satisfaction with communication	Hack, 2003	High
	Hack, 2007	High
	Ong, 2000	High
Depression not significantly different	Hogbin, 1992	Low
	Mishra, 2010[e]	High
	Stephens, 2008	High
	Tattersall, 1994	Low
Anxiety not significantly different	Hogbin, 1992	Low
	Mishra, 2010[e]	High
	Stephens, 2008	High
	Tattersall, 1994	Low
Psychological adjustment not significantly different	Dunn, 1993	High
	Hack, 2003	High
	Hack, 2007	High
Control of management of health problems significantly higher in intervention group	Mishra, 2010	High
Control of management of health problems not significantly different	Wolderslund, 2017[c]	High
Recall or knowledge significantly higher in intervention group		
Subjective recall	Tattersall, 1994[f]	Low
Objective recall	Bruera, 1999	High
	Hack, 1999[g]	Low
	Mishra, 2010	High
	Ong, 2000	High
	Stephens, 2008	High
Recall or knowledge not significantly different		
Objective recall	Bergenmar, 2014	High
	Dunn, 1993	High
	Haerem, 2000	Low
	Tattersall, 1994[f]	Low
Fulfilment information needs significantly higher in intervention group	Hack, 2003[h]	High
	Hack, 2007[i]	High
	Wolderslund, 2017[c,j]	High
Perceived understanding significantly higher in intervention group	Hogbin, 1992[k]	Low
Perceived understanding ot significantly different	Bergenmar, 2014	High
	Bruera, 1999	High

[a]Significantly different after one week but not after three months. [b]Increased linearly from no tape to generalized tape to consultation tape. [c]Results from intention-to-treat analysis. [d]Significant in entire sample but not when including only patients aged 55 years and over. [e]Consultation tape group scored significantly better than general tape group. [f]Difference between consultation tape group and consultation summary group. [g]Result only reported for the subgroup of men: patients who received the tape by choice recalled most. [h]Effect only observed for information on side effects. [i]Effect only observed

for information on side effects, treatment alternatives and overall information. [j]Only test results and treatment options survived correction for multiple testing. [k]Perceived understanding increased significantly in intervention group but not in control group, no between-group significance described.

TABLE 4: Behavioural outcomes: the effect of comparative studies

Outcome	Study	Quality
Ability to discuss illness with relatives not significantly different	Bruera, 1999	High
	Uitdehaag, 2012	High
Number of general practitioner visits significantly lower in intervention group	Hogbin, 1992	Low
Seeking further information significantly lower in intervention group	Wolderslund, 2017[a,b]	High
Seeking further information not significantly different	Hogbin, 1992	Low
Decision-making significantly better in intervention group		
Involvement in decision-making	Wolderslund, 2017[a,b]	High
Decision regret	Good, 2016	High

[a]Results from intention-to-treat analysis. [b]Correction for multiple testing results in loss of significance.

TABLE 5: Health outcomes: the effect of comparative studies

Outcome	Study	Quality
Symptoms not significantly different	Good, 2016[a]	High
	Hogbin, 1992	Low
Emergency help, re-admission and sick leave significantly lower in intervention group	Haerem, 2000	Low
Functional status or quality of life not significantly different	Good, 2016	High
	Hack, 2003	High
	Hack, 2007	High
	Ong, 2000	High
	Uitdehaag, 2012	High

[a]The tape group only scored significantly better on bowel-related symptoms than the control group.

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Chapter 3: Ethical issues and considerations concerning the last phase of life

Chapter 3.1: What do to when patients and physicians disagree? Qualitative research among physicians with different working experiences.

Rozemarijn L van Bruchem-Visser, Inez D de Beaufort, Francesco US Mattace Raso, Ernst J Kuipers

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ABSTRACT

BACKGROUND/OBJECTIVES
Impasses between patients, relatives and physicians occur frequently. With the growing attention for Shared Decision Making (SDM) it is valuable to know how impasses arise. To understand the challenges experienced by physicians when their opinion on medical decisions differs from those of patients or relatives.

METHODS
Fifteen physicians with different working experiences, from five medical specialties were interviewed using a narrative approach. Interviews were based on two patient-stories provided by the physician. First of a patient (or relative) who did not want to adhere to a treatment the physician deemed necessary, and second of a patient (or relative) who requested a treatment the physician felt was unnecessary. Data were analysed using a bottom-up approach, with identification of five themes (autonomy of the patient, communication, emotions, circumstances and metaphors). 20 subthemes were formed.

RESULTS
693 references were made. Six major nodes were identified: frustration experienced by the physician, role of the relatives, agreement, cultural/religious aspects, comprehension by the patient of the situation and the existence of an established relationship between patient and physician.

CONCLUSION
Physicians felt uncomfortable when there was disagreement between themselves and patients or relatives. Frustration was felt when relatives spoke on behalf of the patient, while there was no evidence the desired decision was ever expressed by the patient. A disagreement with a patient was described as being less frustrating, when the patient was able to explain the reasons for making a decision. Differences in background, especially religious, were often mentioned as complicating communication.

INTRODUCTION

In recent years, much effort was invested in implementing shared decision making (SDM). In this process, patients and health professionals together decide on clinical approaches, discussing all information, risks and benefits as well as patient values and preferences. The primary reason to promote SDM is to respect the autonomy of the patient, being the subject of treatment. Another reason is that engaged, informed patients are more satisfied with the chosen treatment.(1) From the point of view of the physician, the goal is to decide on treatment options in a dialogue with the patient, considering guidelines and with respect for his or her professional judgment.

As far back as the mid-1970's, attempts have been made to reduce medical overuse. Nowadays this struggle continues. Expectations and demands of patients can result in clinicians feeling pressured to provide low-value care. Furthermore, physicians tend to opt more easily to start a treatment, as opposed to withholding treatment. Initiatives such as the Choosing Wisely campaigns seek to advance a dialogue on avoiding unnecessary medical tests, treatments and procedures.(2) The goal of these initiatives is to improve quality of care. One of the most important findings in the International Health Policy (IHP) survey was that 57% of Dutch general practitioners (GP's) thought patients received too much health care.(3) A recent survey in the United States in over 2000 physicians revealed the belief among physicians was that 20.6% of overall medical care was unnecessary.(4) Reducing over-use also provides economic benefit. Previous studies reported that at least twenty percent of healthcare spending in the United States was unnecessary.(5)

This spiral of events has been described as a "Perfect Health Storm".(6) Four physician-related factors driving overuse have been identified: physician culture, fee-for-service payment, marketing and the fear of being sued for medical malpractice.(6) Dutch investigators described fifteen mechanisms that can lead to excessive and excessively prolonged treatment.(7) Besides suggested treatments patients or relatives can also request other treatments, based on their own beliefs. Problems arise if in the professional judgment of the physician the preferred treatment is unacceptable.

We interviewed physicians to gain insight into how they experienced an impasse between themselves and a patient concerning treatment options. The study goal was to understand the challenges experienced by physicians when their opinion on medical decisions differs from those of patients or their relatives.

METHODS

We interviewed physicians using a narrative approach. This allows participants to share their subjective experiences and by doing so also reinterpret and give further meaning to these experiences.(8, 9) We used this to do an in-depth exploration of how physicians experienced a difference of opinion with a patient or relatives regarding medical decisions. This method particularly suited this study as so far little is known about physicians' subjective experiences when being faced with patients with a different opinion about their clinical management.

Recruitment of participants

We purposively invited eighteen physicians to participate. Invitees were working in the south-west of the Netherlands with different years of working experience. Fifteen physicians, from five different medical area's (internal medicine, general practice (GP), intensive care, surgery, and oncology) agreed to participate. Their work experience ranged from one to thirty-five years. All interviews were conducted face-to-face. Before the interview, the participants were informed that the interview would deal with "disagreement between physician and patient". Participants were asked to think of two different cases from their experience; one in which the patient did not want to receive treatment, whereas the physician judged it necessary and one in which the patient wanted prolonged or more intense treatment, while the physician considered this unnecessary or harmful. No limitations were given regarding type of underlying disease, patients' age, sex or cultural background. Participants were given written and verbal information and gave informed consent. Ethical approval was not required.

Data collection and analysis

Interviews were digitally recorded and transcribed verbatim with the interviewees' permission. The interviewer guides were flexible, allowing prompt and open questions to encourage participants to talk in depth about their experiences and perceptions. Basic demographic information of the patients (age, sex, ethnicity and religion was recorded (see Table 1). It was also noted whether or not there was an existing patient-physician relationship prior to the described situation) and whether or not an impasse between patient (or relatives) and the physician was described by the physician. Basic information of the physicians (sex, medical specialty, years of working experience) was also recorded (see Table 2). The study was facilitated by QSR NVivo 12 software (QRS International Pty Ltd, Melbourne, Victoria, Australia).

After conducting fifteen interviews, data were analyzed to see if new themes were emerging. This was not the case, therefore data saturation was reached.
The transcripts were coded by two independent researchers (RvB and LD) to ensure rigorous analysis. The first five interviews were used to compare coding strategies.

No significant differences were found. The first author developed further interpretation of the results with regular comments from the other authors.

We used a bottom up approach to identify recurring themes. This was performed according to the method specified by Braun and Clarke (2006):

1. transcripts were read and re-read to familiarize the researchers with the data
2. systematic line by line coding to identify common features
3. codes were reviewed to determine potential themes
4. themes were reviewed for internal homogeneity and external heterogeneity to ensure coherence and distinction
5. themes were identified and named

Five themes were identified: patient autonomy, communication, emotions, circumstances and metaphors. Twenty subthemes were formed based on the interviews (see Table 3). In total, 693 different references were identified as matching with at least one (sub)theme.

RESULTS

Fourteen physicians described two different patients. One physician only discussed a patient who wanted to continue treatment (interview no. 4).

In fourteen out of the fifteen patient-stories where the physician wanted to continue treatment and the patient wanted to stop, there was direct communication between physician and the patient. Of the fourteen cases where the physician wanted to stop treatment, there was direct communication between the patient in three cases. In the other eleven cases the relatives either played a prominent role, accompanying the patient (two cases) or the communication was between physician and relatives only (nine cases).

Six major nodes were identified: frustration experienced by the physician, the role of the relatives, agreement, cultural/religious aspects, comprehension by the patient of the situation and existing of an established relationship between patient and physician. Quotes are identified by participant number.

Frustration experienced by the physician

In 16 out of 29 cases, physicians spontaneously reported frustration on their part while dealing with patients or relatives. These comments were made both in relation to cases in which patients wanted to continue treatment, as well as those in which the physicians wanted to continue (8 vs. 8 cases). Physicians talked about their frustration and feelings of helplessness when they were unable to convince the patient or relatives of their views. ‘

I have no words to reach her, to relate to her inner world.’ (1.1)

In the cases where direct communication with the patient was possible, frustration occurred when the physician felt that the patient did not (or was not able to) understand the severity of the condition or the necessity of the proposed treatment. Physicians also expressed frustration when they felt relatives did not recognize them as being persons having emotions of their own.

'And nobody pays any attention to the physician. Same as in the case of performing euthanasia, the one crying, it was me.' (4.2)

In more than one interview, physicians described their challenges with relatives who demanded more intensive treatment than the physician felt comfortable with. In many of these cases the patient had never consented to the requested invasive treatments, and this caused physicians' discomfort. In other cases the physician considered the requested treatments futile.

'I gave her antibiotics, while that was already going against every fiber of my being, but the husband insisted, because that is what his wife would have wanted. And one of the sisters, the one that was most involved, she is a patient of mine, said "should we be giving all these treatments?" or something like that.' (8.2)

Remarkably, in the cases where a patient wanted to stop, against advice of the physician, and no frustration was felt, the patient was described as mentally competent and well aware of the options.

Role of the relatives

Almost all physicians mentioned the role of the relatives. In nine cases, the relatives requested treatments the physician thought would not benefit the patient. In all cases, this concerned a patient who was not able to speak for himself. Several physicians expressed their doubts whether the wish to prolong treatment was prompted by the concern of the relatives for the patient's wellbeing or for their own sake.

'We will never know what Mrs. X herself thought on the matter. It was entirely the wish of the relatives.' (9.2)

The fear of getting blamed for the death of the patient was mentioned, as well as the influence of religion. In twelve interviews, physicians described that they tried to accommodate the requests made by the relatives, until they felt their actions were no longer professionally and humanly justifiable.

'For me, that was the turning point, I was continuing (treatment), not for the sake of the patient, but for the sake of the relatives. And when I realized that, I thought: this must stop. This (treatment) should not be for the relatives, it should be about the patient.' (5.2)

In some cases, the physicians wanted to continue treatment but the relatives expressed a desire to stop, often referring to prior expressed wishes by the patient. They expressed a strong wish to honor the request made by the patient, even when both relatives and physician agreed continuation of treatment would be the better option. When a patient expressed a desire not to start a treatment, all physicians complied, be it reluctantly in some cases.

Physicians described relatives wanted to stop treatment because of complications, and they found it difficult to grant that request, as it was unsure what the point of view of the patient actually was. More importantly, the complications were, according to their professional opinion, an unfortunate but foreseeable result of a treatment the patient had consented to. As a result, sometimes the treatment was continued, against the wishes of the relatives.

Agreement
In 28 of the 29 cases physicians mentioned the topic of (dis)agreement. In most cases, they referred to reaching an agreement, or at least trying to do so, with patient or relatives. This was sometimes a smooth process and in other cases unsuccessful.

'And in the end, when he was extubated, we talked to him for quite some time, and as a result we agreed on what limitations he wanted regarding treatments.' (14.1)

'I had just become an oncologist, and had not yet realized that people could also chose not to start a treatment. So my assumption was that she would want the full chemo, and so I told her what the plans were. And that is when she turned completely furious.' (3.1)

When faced with a difficult, sometimes emergency decision, agreement was sought with fellow specialists, and in most cases this helped the physician to decide what to do. Other described strategies were: revisiting the patient or relatives and investing time and effort to build a relationship.

Cultural/religious aspects
Frequently the cultural or religious background of the patient and his relatives was mentioned. In the cases of the patient (or relatives) wanting to stop treatment, with the physician advising to continue, there was one comment regarding a cultural background. The physician thought the child of a patient would decide on behalf of the patient, but was surprised the decision was left to the patient. In other cases the relatives spoke on behalf of the patient, without consulting the patient.
Several physicians described how a difference in background between the patient, relatives and physician caused difficulties in communication.

'I think we still make a lot of mistakes, because we are not aware of the way bad news should be addressed in specific cultures. (..) So, in several years, I found out by trial and error that in some cultures it is not customary for younger relatives members, or those lower in the hierarchy, to be allowed to deliver bad news. They are not allowed to say that someone will die (..), or there is an incurable disease. (..) So we only found out after a long time (that the patient was not told the diagnosis). Because the daughter, who had been in the Netherlands for a very long time, spoke fluent Dutch, and was highly educated, understood perfectly well what was happening, but had not told her mother, because she just refused to tell her mother the bad news, the diagnosis that was made.'(1.02)

In the description of the patients, physicians often spontaneously emphasized the role of the religious background of a patient or relatives. Of the fourteen cases where the physician wanted to stop treatment, in ten cases a religious background was described by the physician. In five cases a Muslim background was described, in two cases a Christian background and in three cases the specific religion was not specified.

'This young man stood by his decision, he did not want to receive any blood, and accepted the consequences that that would be the end of it. His parents struggled, but were also Jehovah's witnesses, so in the end they supported his decision, but it was a real dilemma, he was so young.' (3.2)

Comprehension of the situation
In multiple cases, physicians expressed concerns regarding the level of comprehension of the patient of their situation. Physicians described their efforts to inform their patient in these situations. Multiple visits were made to the patient, help was sought from colleagues and time was invested.

'And then we try and talk to them (the relatives) a lot, explain it, show them the scans, as I do with all the patients who suffered a neurological trauma, to make it less abstract, and to explain why we are going to stop the treatment. But, if they have no clue of what is depicted on the scan, that does not help at all. So then we try to explain, what are the different functions of the brain, and what functions are now gone.' (5.2)

Sometimes, patients expected the outcome to be worse than the physician anticipated. In those cases, similar efforts were made to convey the (in the words of the physician) "more objective, expected outcome" to the patient.
'Often, people do not know, notwithstanding the severity of the situation, everything can turn out just fine.' (4.1)

Established relationship between patient and physician
In the case of an established relationship between the patient and physician, impasses occurred sporadically. Physicians described agreement was reached in multiple conversations, with enough time for all parties to think about the options.

'But my supervisor, who had known her for years, said: "she always talks that way when things are not going well".' (9.1)

However, in the case of no previously existing relationship, impasses were more often described.

'But well, when you do not know the patient at all, that is a major pitfall.' (3.1)

Remarkably, an impasse arose in all the cases without an existing relationship in which the patient or relatives requested treatment whereas the physician wanted to stop. Physicians told about their efforts to get to know the patient, who was in a number of cases unable to communicate. The acuteness of the situation was described as being a major contributor to arising impasses.

DISCUSSION

In the present study we found that for the physician the impossibility of direct communication with the patient was frustrating. The frustration seemed to stem from the fact that the right sparring partner, being the patient, was unable to take part in the discussion. If the patient was described as mentally competent and aware of treatment options, physicians still tried to convince them to "see the physicians' way" but accepted the divergent desired treatment strategy without frustration.

In several cases, physicians felt uncomfortable with starting the desired treatment, that they set clear boundaries. In almost all cases here was a line the physician was not willing to cross, in order to preserve professional and moral standards.

Relatives frequently have to make medical decisions for an incompetent patient acting as surrogate decision maker. Advance directives, in which the patient describes treatment preferences could guide the relatives in this process. In this study, no advance directives were mentioned. This is congruent with studies that show the community prevalence of advance care directives remains low, with percentages ranging between five and twenty percent.(10, 11) So, in most cases, the relatives cannot rely on such a document. Possible problems in communicating with relatives were (among others) identified as the failure to reach a shared view of the patients' medical condition (and prognosis), problems with applying the principle of substituted judgment, difficulties in addressing the full range of end-of life-decisions and offering the relatives "the wrong choice".[12] The wrong choice

explained as a choice between care and cure, where no cure is possible, as opposed to the choice between prolonging life and quality of life.(12)

Although it is to be expected relatives would be adequate in assessing the wishes of the patient, this is not shown by the existing literature. Several studies performed in different categories of patients such as cancer patients, patients with early dementia and dialysis patients, suggest that relatives are often unable to correctly assess the preferences of the patient.(13-15) An interview-based study including 750 patient-caregiver dyads showed that, in case of discordance, patients and caregivers often had an unrealistic optimistic view regarding extent of disease, treatment goals and prognosis.(16)

It seems comprehensible that relatives primarily opt for life-prolonging treatment for the patient. In a study on patients on the intensive care, relatives struggled with the conflict between honoring the patients' wishes and values, and their own emotional problems with "being the one letting a patient die".(17) We found that agreement was more easily achieved if the patient and relatives were already known by the physician. Establishing a relationship with both patient and relatives in early stages of a disease is important. The triad patient, relatives and physician can prove to be very helpful in case of difficult decisions.(18)

In our study most impasses arose when patients were "new" to the physician as a result of a transfer into a practice or due to an acute presentation in a hospital. Therefore, there was no history between the patient, relatives and physician. Impasses arose especially in the cases in which there was an acute treatment decision to be made (for instance in the emergency department or in the intensive care unit). The acuteness of the situation and the inevitability of the decision are likely to be important factors.

In our study, physicians told the perceived level of understanding the patient (or relatives) seemed to have of the actual situation was an important factor in the arising of an impasse. In a study including interviews of dyads of physicians and patients, unclear expression of values by both patient and physician, as well as the feeling of being uninformed caused uncertainty in both parties.(19)

It seems to be a challenging task to fully inform all patients. As described in the interviews, some patients seem to be unable to comprehend the information that is provided. This can be caused by cognitive impairment, fear or unwillingness to hear bad news. A study conducted in the Netherlands showed that patients with an incurable lung cancer "chose" to ignore bad news and showed a false optimism about recovery, not wanting to hear the bad news and only focus on treatment options.(20) A Belgian study advised to gradually deliver the message of a diagnosed incurable, terminal disease and prognosis.(21) Relatives of terminally ill patients told they were informed about the severity of the illness too late in the

process (often within one month of the patients death). At the same time, relatives did not know to what extent they wanted to be informed, and expressed difficulty in comprehending and accepting the message that they were told.(22) In another study among general practitioners (GP's) and patients receiving palliative care, apart from physicians' availability, the hesitation of both patients and GP's to talk about a bad prognosis was a main barrier to good communication.(23)

Cultural or religious differences in background between the patient (or relatives) and the physician played an important role. Physicians described they felt unable to reach patients or relatives from cultures they were not familiar with, and felt that often the relatives had a different perception of treatment or death. This was more often described in cases where the physician wanted to stop treatment, against the wishes of the patient or relatives. Different religions were described, with the majority being a Muslim background, or a specific Christian background (for instance Jehovah's witnesses). The physicians' lack of knowledge of the cultural and social background of their patients can complicate shared decision making. Those experiences will for a great part be the basis of the end-of-life preferences of that same patient.(24) Understanding the patients' explanatory models about illness, treatments and death can help make sense of seemingly unreasonable actions and decisions. The emphasis on patient autonomy and informed consent can clash with family-oriented cultures, where decisions are made by relatives. There is no reason to question requests from the appointed legal representatives, if a patient expressed the wish to let that person make decisions for them. Complying to the legal representative is a direct expression of following patient preferences.

Language differences can cause problems. This did not seem to be an important factor in the interviews, but can most certainly be of importance when communicating with patients. Translation by a relative may influence the content of the conversation, either due to misinterpretation of medical information, or driven by cultural beliefs patients should be shielded from bad news. Taboo topics may be left out in translation. The use of trained medical interpreters should perhaps be standard of care when dealing with patient who do not speak the same language the physician does.

In conclusion, we found that physicians felt uncomfortable when there was disagreement between themselves and patients or relatives. Frustration was especially felt when relatives spoke on behalf of the patient, while there was no evidence the desired decision was ever expressed by the patient. The physicians were in doubt whether or not the desire for treatment was prompted by the previous wishes of the patient, or stemmed from the personal wish of the family not to lose a relative. Although this was comprehensible seen from the point of view of the family, the patients' best interest was still the most important factor in the physicians' decision to not start or stop a treatment. Differences in background, especially religious ones, were often mentioned as complicating communication.

Although all physicians were trained in The Netherlands and now working within the same country, with its multicultural diversity, results can not automatically be extrapolated to other countries or cultures. However, it is likely many of the experienced situations and frustrations are recognizable to physicians and patients in countries and cultures all over the world.

RECOMMENDATIONS

Based on this qualitative research, impasses between physicians and patients are less likely to occur if the patient is well-informed, capable of making treatment decisions and there is an existing relationship between patient and physician. Efforts must be made to establish a bond of trust between patient, relatives and physician. The use of advance directives should be encouraged. In case of an impasse between a physician and patient or relative, advice can be sought from other professionals. However, in the end it is still the physician who will have to decide whether or not a treatment is to be started, with the best interest of the patient at heart, even when this is not congruent with the wishes of the family. Future studies including larger numbers of physicians, preferably from different cultural backgrounds, might help increase the generalizability of our findings.

STRENGTHS

To the best of our knowledge, this is the first study investigating the reaction of physicians on an impasse between them and a patient or relatives of that patient. A wide variety of physicians was interviewed, from hospitals as well as general practitioners.

LIMITATIONS

There are limitations to this study. First, participating physicians work in the same region in The Netherlands, therefore, the results cannot be extrapolated to other regions of the same country, other countries or different cultures. Second, in acquiring data from interviews, we express their narrative view of their experiences and perceptions. Third, we are aware that our interview group was relatively small.

TABLE 1: Descriptive characteristics of patients

	Physician wants to continue	Physician wants to stop
Total no of patients	15	14
Aged 25-45	2	6
Aged 46-65	4	2
Aged 65 years or older	9	5
Age not described		1
Male	10	3
Female	5	10
Unknown	0	1
Underlying disease		
Malignancy	5	5
Kidney disease	3	2
Diabetes mellitus	2	0
Neurological condition	2	4
Chronic Obstructive Pulmonary Disease	1	0
Infection	1	0
Complex surgery	1	1
Medically unexplained	0	1
Dementia	0	1
Religious background	1	10
Muslim	1	5
Christian	0	2
Other	0	3
Non-religious/not mentioned	14	4
Existing relationship	11	7
Impasse mentioned	5	10

TABLE 2: Descriptive characteristics of the interviewed physicians

Participant	Sex	Specialty	Working experience (years)
1	Female	General practitioner	22
2	Male	Intensive Care	10
3	Female	Oncology	11
4	Male	Surgery	30
5	Female	Intensive Care	35
6	Male	Internal Medicine	4
7	Female	Oncology	20
8	Female	General practitioner	11
9	Female	Internal Medicine	1
10	Female	Internal Medicine	15
11	Male	Surgery	1
12	Male	Surgery	10
13	Female	Oncology	2
14	Female	Intensive Care	6
15	Female	General practitioner	3

TABLE 3: Themes and subthemes, number of references and files

Theme	Subtheme	References	Files
Autonomy of the patient		38	18
	Rights	10	9
	Role of relatives	72	22
	Responsibility	33	19
Communication		14	10
	Providing information	51	23
	Listening	14	12
	Agreement	74	28
	Talking about death	22	9
Emotions		13	10
	Fear	15	6
	Anger	8	4
	Hope	10	7
	Frustration by patient	4	4
	Sadness	4	4
	Frustration by physician	37	16
Circumstances		17	14
	Culture/religion	24	11
	Financial matters	9	4
	Comprehension of situation	32	20
	Environment/setting	24	13
	Social network	26	15
	Patients' disease	61	28
	Relationship with patient	38	28
Metaphors		43	16

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Chapter 3.2: Requests for futile treatments, what mechanisms play a role? Result of qualitative study among Dutch physicians.

Rozemarijn L van Bruchem-Visser, Gert van Dijk, Francesco US Mattace Raso, Inez D de Beaufort

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ABSTRACT

BACKGROUND/OBJECTIVES
Overtreatment is increasingly seen as a challenge in clinical practice and can lead to unnecessary interventions, poor healthcare outcomes and increasing costs. However, little is known as to what exactly causes overtreatment. In 2015 the Royal Dutch Medical Association attempted to address this problem and distinguished several mechanisms that were thought to drive overtreatment. In fourteen qualitative interviews among Dutch physicians we investigated which mechanisms played a role in decision-making and whether all mechanisms were considered equally important.

METHODS
We asked physicians to present a case from personal experience, in which the patient or family requested continuing treatment against the advice of the physician. Fourteen physicians from five different medical areas agreed to participate and interviews were held face-to-face at the workplace of the physician.

RESULTS
From these interviews, it was found that three closely related mechanisms were mentioned most as being a driver of overtreatment, as perceived by the physician: 'death is not a common topic of conversation', 'never give up' is the default attitude in our society' and 'patients' culture and outlook on life influences their perception of death'. The mechanism 'medical view taking priority' was mentioned to be an inhibitor of overtreatment.

CONCLUSION
Of the fifteen mechanisms described by the report of the Steering Committee of the RDMA, not all mechanisms were mentioned as driving overtreatment. Three mechanisms were mentioned most as being a driver of overtreatment ('death is not a common topic of conversation'; 'never give up' is the default attitude in our society' and 'patients' culture and outlook on life influences their perception of death'), some played no role at all, and others were considered to be inhibitors of overtreatment, especially the mechanism 'medical view taking priority'.

INTRODUCTION

Overtreatment is increasingly seen as a challenge in clinical practice and can lead to unnecessary interventions, poor healthcare outcomes and increasing costs.(1) The occurrence of overtreatment is acknowledged by both patients and physicians in all patients groups, including the elderly.(2-4)

'Overtreatment' or 'too much medicine' can occur as a result of overdiagnosis, which occurs when people are 'labeled with or treated for a disease that would never cause them harm'. (5, 6) Overtreatment is defined in different ways: 'treatment that is unnecessary or inappropriate'; 'unnecessary investigations and treatment that lack patient benefit or bear the potential to cause harm';(7) treatment that is not 'in line with patient's wishes'; 'the provision of medical services for which the potential for harm exceeds the potential for benefit'(8) or 'treatment initiated when there is little or no reliable evidence of a clinically meaningful net benefit, where net benefit equals benefit minus harm'. (9) Overtreatment can concern interventions that can have a positive effect in specific patients , but can harm other patients, for instance percutaneous endoscopic gastrostomy (PEG)-tubes. PEG-tubes can be very beneficiary in some categories of patients, but will harm patients with advanced dementia.(10)

Subjective component

In applying the definition of overtreatment, the patient plays a crucial role. The assessment that a certain intervention is overtreatment in a specific situation can differ between patients, family and physicians. This can make it difficult to objectively determine whether overtreatment has occurred in a specific situation. For instance, what has 'benefit' for a patient can often not objectively be determined as patient preferences differ. Some patients will request as much treatment as possible and accept even a small chance of success and are willing to accept risks, while other patients will be much more reluctant in accepting interventions. Medical interventions can also have other benefits. For instance: an intervention that has little medical chance of success, can still be seen as 'useful' by the patient, as it can strengthen the feeling that 'something' or 'everything' has been done.

Foster appropriate care

The Royal Dutch Medical Association (RDMA) established a steering group to address the problem of overtreatment and to 'foster appropriate care for those nearing the end of life'. One of the main tasks of the steering group was to identify mechanisms that are thought to drive overtreatment. In 2015, the Steering Committee for Appropriate End-of-Life Care (SCoAEoLC) published a report 'Just because we can, doesn't mean we should, appropriate end-of-life care.'(11) The report investigated several mechanisms thought to drive overtreatment. These mechanisms play a role in several different domains: society in general, the health

care system, industry, professionals, and patients and the public. These mechanisms are in accordance with similar findings from a recent study in Germany.(7) Table 1 shows the fifteen mechanisms that were deemed to be the most important drivers of overtreatment.

Aim of the present study was to research which of the mechanisms as described by the SCoAEoLC were recognized by Dutch physicians of different medical specialties to play a role in driving overtreatment. As the SCoAEoLC has primarily focused on patients in the last phase of life, defined as "being of old age or a suffering from a terminal disease with limited life expectancy", we were wondering whether these mechanisms do play a role in the clinical practice of Dutch physicians.

METHODS

Study setting and population

We purposively sampled eighteen physicians differing in years of working experience and medical specialty to participate. Names were randomly selected from the different departments of (academic) hospitals or groups of local general practitioners by using the accessibility guide of the Erasmus MC as well as the list of General Practitioners in the region. Fourteen physicians from five different medical areas (internal medicine, general practice (GP), intensive care, surgery, and oncology) agreed to participate. Four physicians were interested in the topic, but were not able to find sufficient time in their schedule to participate. Their work experience ranged from one to thirty-five years. All interviews were conducted between March 2014 and November 2015.

A medical doctor (RvB, internist geriatrician) conducted semi-structured interviews with all physicians , face-to-face at the workplace of the physician. Before the interview, participants were informed that the interview would deal with "disagreement between physician and patient regarding the course of treatment". Physicians were asked to tell about a case from their own personal experience, in which the patient or family requested continuing or starting of treatment which was not offered or advised by the physician. No limitations were given regarding type of underlying disease, patients' age, sex or cultural background. After narrating the patient's story, the fifteen mechanisms described by the SCoAEoLC (see table 1) were presented and the interviewer asked them whether the mechanism played a role in that case. Participants were given written and verbal information and gave permission to record the interview and store them in a safe location, to be used for verbatim transcription. Ethical approval was granted by the ethical committee of the Erasmus MC.

Data collection and analysis

Interviews were digitally recorded and transcribed verbatim with the interviewees' permission. Basic demographic information of the described patients (age, sex,

ethnicity, religion, relationship with physician) was recorded (see Table 2) as well as of the physicians (sex, medical specialty, years of working experience) (see Table 3). The study was facilitated by QSR NVivo 12 software (QRS International Pty Ltd, Melbourne, Victoria, Australia). The answers to the mechanisms were coded by two independent researchers (RvB and GvD) to ensure rigorous analysis and to assess whether that mechanism was a factor in the described case. Disagreements were settled by consensus. The coding tree was based on the interview guide of the fifteen mechanisms. We used the SRQR checklist when writing our report.(12)

Patient and Public Involvement
Patients or the public were not involved in the design, conduct, or reporting of our research.

RESULTS

All physicians described a patient facing an end-of-life situation. In five patients' stories, the patient was the one requesting a treatment, in the other nine cases the relatives (surrogate decision-makers such as spouses or children) were requesting further treatment. Six patients were aged between 25 and 45 years, three between 45 and 65 and five were 65 years or older. Physicians explained their choice of patient by different reasons, either the young age of the patient, the acuteness of the situation or the frustration they felt when a treatment was requested or even demanded they had not proposed and felt was unnecessary, futile or even harming the patient.

Fourteen different mechanisms were mentioned to play a role in overtreatment, in total 103 times. This could be as a driver of overtreatment (fourteen different mechanisms, in total 86 times, see figure 1), or as an inhibitor (four different mechanisms, in total 17 times, see figure 2). Mechanism no. 11 discussing possible refusal of treatment is more time-consuming'' was not mentioned as being a driver or inhibitor of overtreatment. The problem of a lack of time was recognized but in all cases physicians explained they took all the time needed.

We found that according to the interviewed physicians, three closely related mechanisms were considered to be the main drivers of overtreatment: no. 1: "death is not a common topic of conversation"; no. 2: "never give up' is the default attitude in our society" and no. 14: the great unknown: patients' culture and outlook on life influences their perception of death". These three mechanisms were mentioned 37 times as being drivers of overtreatment.

When attributing the perceived drivers of overtreatment to the different parties, there was a distinct difference between the mechanisms. As is shown in figure 1, mechanism no. 1 'death is not a common topic of conversation' was in all cases attributed to the patient or family, whereas mechanism no. 14 'the great unknown:

patients' culture and outlook on life influences their perception of death' was assigned to the physicians themselves. Mechanism no. 2 "never give up' is the default attitude in our society" was attributed mainly to patients and family, with two cases assigning this mechanism to the physician or a combination of parties.

Of the mechanisms that were not seen as a driver of overtreatment but rather as a potential inhibitor, mechanism nine: 'medical perspectives often still take priority when it comes to making treatment decisions', was most frequently mentioned as an inhibitor (10 times). As is shown in figure 2, this mechanism was in all cases attributed to the physician.
In eleven cases, the physician was not able to communicate directly with the patient, either because the patient spoke a different language and the physician had to communicate by way of the relatives (five cases) or because the patient was incapacitated (six cases).

Death is not a common topic of conversation
The tendency to 'not give up' was considered to be a factor in thirteen out of the fourteen described cases. The difficulties of talking about death and end-of-life topics in general, were in most cases attributed to the patient and family.
'The problem was that, he (the husband of the patient) did not want to talk about his wife dying, because that was just not going to happen.' (interview 8)

'The family was not used to talk about the end of life, no. But they found it also hard to talk about bad news in general.'(interview 10)

It is sometimes thought physicians themselves find it difficult to talk about death, but this is not what we found in our interviews. Physicians described these kind of conversations as being part of their normal daily routine.

'Actually, we talked about it over and over again.' (interview 9)
'Only because she refused to talk about it, not because we were not willing to discuss the subject.' (interview 15)

However, two physicians described their own struggles with talking about death. In both cases their hope to cure the patient was the cause of reluctance to talk about a bad outcome.

'So, in this case, while I do possess the skills to talk about it, I found it extremely difficult. (interview 8) '
'It caused frustration on my part, and also a feeling of helplessness.'(interview 13)

'Never give up' is the default attitude in our society
In our interviews, we found this mechanism was recognized as being an important factor in almost all cases. In thirteen cases physicians described that the patient or

family did not want to give up, even when the physician had told them further treatment would be futile.

'This family, most definitely. They wanted us to pull out all the stops, give all possible treatments.'(interview 10)

The tendency to not give up, is not something that always arises from the patient, but can sometimes be pushed by relatives, not from a wish to harm the patient, but out of love and empathy:

'Yes. It does play a role. They would rather have her be subjected to a dozen futile treatments than… (...). They were not trying to make memories with their loved one, no, they were still searching the internet for some treatment the doctor had overlooked.'(interview 12)

In cases where there was an acute illness, with little time to decide and often little knowledge about the patient due to the acuteness of the situation, physicians described they automatically opted to initially start treatment. To end a treatment, or to not continue on a direction of treatment was described to be difficult.

'When you get a patient with acute renal failure, we have no time to think about other options. To act is the default position.'(interview 6)
'Yes, that did play a role. Especially with the patient, but also with my supervisor, at the start of this process. He was involved in the first part of this case, before I took over. He had been compliant to her wishes so far, had suggested and arranged the percutaneous endoscopic gastrostomy. So I do think this played a role in the first stage of this case.' (interview 15)

The great unknown: patients' culture and outlook on life influences their perception of death
Physicians described, sometimes in detail, their unfamiliarity with cultural differences between themselves and (family/relatives of) their patients.

'On their part, it was most certainly difficult. Because of religion and culture.' (interview 5)
'We found out too late that this daughter had never told her mother the diagnosis, because in their culture, younger family members were not allowed to convey bad news to their elders.' (interview 10)

Medical perspectives often still take priority when it comes to making treatment decisions
In our interviews we found physicians used the medical perspective to convince patients not to continue treatment.

'Well yes. I told them I would not perform a CAT scan because there was no medical reason to do so. So I use the medical perspective to explain why I withhold certain interventions.'(interview 7)
'In this case the medical perspective led to our decision to tell the patient 'enough is enough'. Locally, we would be able to do a lot of things, but the fact the same problem would come back in different places, or that the wound would never close, led to us saying 'we will not give any further treatment'.' [interview 10]

Taking a medical perspective can therefore mean different things: it can mean the physician takes a perspective in which too much focus is placed on a specific organ, but it can also be an argument not to continue treatment due to medical futility.

DISCUSSION

In the present study we found that of the fifteen mechanisms described by the SCoAEoLC , not all mechanisms were considered important in driving overtreatment. Three mechanisms were mentioned most as being the drivers of overtreatment ('death is not a common topic of conversation', 'never give up' is the default attitude in our society' and 'patients' culture and outlook on life influences their perception of death'), some played no role at all, and others were considered to be inhibitors of overtreatment, especially the mechanism 'medical view taking priority'. The three mechanisms that were mentioned most as contributing to overtreatment are closely intertwined.

Patients are often hesitant to discuss the approach to end of life and to accept the fact that they are going to die. This reluctance to talk about the end of life is sometimes enhanced by relatives, who can pressure patients not to give up.(13) To talk about death when the patient and family are still aiming for a cure is difficult. Furthermore, in certain cultures it is not customary to discuss the diagnosis, or the approaching death with the patient, making it even harder for the physician to find out what, in a certain case, appropriate care is. As patients and relatives find it difficult to discuss and accept approaching death, physicians often find themselves in a position where patients preferences and values are unknown to them, due to the impossibility to communicate directly with the patient in the acute setting of an end-of-life situation. This was the case in the majority of the narrated patient stories.

The general tendency in society is 'to not give up' in the 'fight' against a certain disease. Dealing with a disease is often seen as a 'fight' or as a 'war'.(14) When dealing with cancer, for instance, patients are supposed to 'fight' the disease. If they are cured they are seen as 'winners' who have 'conquered' the disease. These war-like metaphors are also seen in funding campaigns, such as 'the war on cancer'.

The cultural and spiritual background of patients can be contributing factors in the perception of physicians that the patient is being subjected to overtreatment. For instance, in some cultures it is not common practice to inform the patients of diagnosis and prognosis. Patients and relatives can also hold specific views on the meaning of suffering and whether pain medication is indicated: 'suffering is purification'. These views can put patients in a situation that physicians find difficult to accept professionally.

As the interviews were held with physicians, the judgment whether the specific treatment was indeed a case of overtreatment was seen from a physician's perspective. It remains unclear whether the patients or relatives also considered the proposed intervention to be a case of overtreatment. This would require further research. The question remains therefore, whether physicians and relatives have similar views on whether a certain intervention is to be considered overtreatment.

In their report, the the SCoAEoLC investigated these mechanisms in various ways, such as conducting literature studies, consultations with experts from a range of disciplines and independent research. However, the report was a consensus document and a wider evidence base is required, especially since the report focused on patients in the last phase of life. It is unknown whether these same mechanisms will apply to other cases of perceived overtreatment.
Interestingly, we found that one of the mechanisms found by Van der Wal et al; the 'medical view taking priority', was not a driver of overtreatment according to the interviewed physicians, but was often used as an inhibitor instead. In our findings the medical 'view, was used by physicians as an argument to refuse to provide the intervention under discussion, as the intervention was deemed medically futile by the physician. The SCoAEoLC considered one of the drivers of overtreatment to be the idea that physicians take too much of a 'medical' perspective, meaning they focus too much on the medical side of a disease, foregoing other important aspects, such as wellbeing of the patients, or social and cultural aspects.

According to the SCoAEoLC this means the 'medical perspective often dominates the decision-making process, even when multidisciplinary consultation (MDO) is involved. Such bodies often consist only of medical specialists, which can overshadow reflection on social, mental, spiritual, cultural and ideological aspects, as well as general well-being'.(11) However, in our interviews, we found this driver needs to be interpreted in a more nuanced way. In our findings the 'medical view', was used by physicians as an argument to refuse to provide the intervention under discussion, as the intervention was deemed medically futile by the physician.

This might be due to the fact we interviewed physicians, who might have difficulty recognizing this mechanism as playing a role in their relationship with a patient.

Another important finding was that, when asked for a case from their own experience, physicians often presented cases in which the patient was not able to communicate with the physician by her/himself, either due to a language barrier of mental incapacity. In these cases it was therefore the relatives and not the patient that opposed the advice of the physicians. In the presented cases relatives play a central role in the wish to continue treatment against the advice of the physician. The fact that the wishes of the patient were in all cases unknown to the physician and the relatives enhanced the problem.

One of the reasons for the fact that physicians presented a case in which the relatives played a crucial role might be the subjective aspect of overtreatment. As overtreatment is, at least partly, a subjective phenomenon, physicians might not consider an intervention to be overtreatment when it is the patient him- or herself that asks for a specific intervention, as the patient has consented or has specifically asked for the intervention. Patients can have different views on what is appropriate care towards the end of life, and physicians are likely to be willing to go along with the patient – within limits, as the physicians will not likely go along with wishes of the patients that are deemed medically futile - as long as the patient is well informed and is aware of the risks and possible benefits (or lack thereof) of the intervention.

However, when it is not the patient but relatives that go against the advice of the physician, physicians might sooner consider the intervention to be overtreatment, as they feel the intervention does not serve the medical interest of the patient, the patient has not consented to the procedure, and might actually suffer from it. A refusal of pain medication or sedatives, or a request for a certain intervention will probably be judged in a different manner by the physician if it comes from the patient as opposed to a request from relatives. Although relatives will almost certainly have the best intentions – 'do not let my loved one die' – these intentions might have negative consequences for the patient. It might be acceptable for a physician to see a patient suffer when that patient has deliberately accepted negative consequences of a certain intervention. However, in a mentally incapacitated patient, suffering because of medically futile treatments of any kind is more difficult to accept.

The important role of relatives is not mentioned by the SCoAEoLC as a distinct mechanism that drives overtreatment. This could be explained by the fact that the role of relatives was not a subject of their research. We suggest however, that future research should focus more on the role of relatives in the debate on overtreatment, and the reasons they have for continuation or start of treatments that are deemed inappropriate by the physician. For instance, it would be of interest to find out whether the relatives in these situations considered the intervention to be a case of overtreatment as well, or whether they considered the situation to be appropriate care.

All physicians described a case that had an impact on them. The described patients were generally younger individuals and the decisions to be made were related to end-of-life decision making. Interestingly, (younger) age is not described as a mechanism of driving overtreatment. However, it was mentioned by several physicians that age did play a role in the perception of the family/relatives that all should be done to save the patient's life.

CONCLUSIONS

We have found that three mechanisms were identified most often as a driving factor in overtreatment: 'death is not a common topic of conversation', 'never give up' is the default attitude in our society' and 'the great unknown: patients' culture and outlook on life influences their perception of death'.

The mechanism "medical perspectives often still take priority when it comes to making treatment decisions" was mentioned as being an inhibitor of overtreatment in the majority of interviews. In many cases the relatives play a crucial role in the wish to continue treatment against the advice of the physician. Overtreatment was defined from the perspective of the physicians. Further research is needed to investigate whether relatives of the patient define the same situations as 'overtreatment'.

The findings from this study underline the importance of advance care planning and a timely discussion on patients' wishes and preferences regarding the end of life, so as to avoid overtreatment and to foster appropriate care.

TABLE 1: Mechanisms described by the SCoAEoLC

1	Death is not a common topic of conversation
2	'Never give up' is the default attitude in our society
3	Action is better than inaction
4	Professional guidelines focus on 'action'
5	Education focuses on 'action'
6	Physicians are payed for treatment
7	With so many care providers and so little coordination, who is responsible?
8	No holistic view of the patient
9	Medical perspectives often still take priority when it comes to making treatment decisions
10	Palliative care is initiated too late
11	Discussing possible refusal of treatment is more time-consuming
12	To talk about death is difficult
13	Uncertainty about what to tell patients
14	The great unknown: patients' culture and outlook on life influences their perception of death
15	People document their wishes and preferences regarding end-of-life care too late, and often not (thorough enough)

TABLE 2. Descriptive characteristics of patients

Total number of patients	14
Age	
Aged 25-45	6
Aged 46-65	3
Aged 65 years or older	5
Sex	
Male	4
Female	10
Underlying disease	
Malignancy	5
Kidney disease	2
Diabetes mellitus	0
Neurological condition	4
Chronic Obstructive Pulmonary Disease	0
Infection	0
Complex surgery	1
Medically unexplained	1
Dementia	1
Religious background	
Non-religious/not mentioned	4
Muslim	5
Christian	2
Other	3
Existing relationship patient-physician	7
Treatment requested by patient	5
Treatment requested by one relative	3
Treatment requested by more than one relative	6
Mentally incompetent	6
End-of-life situation	14

TABLE 3. Descriptive characteristics of the interviewed physicians

Participant	Sex	Specialty	Working experience (years)
1	Female	General practitioner	22
2	Male	Intensive Care	10
3	Female	Oncology	11
4	Male	Surgery	30
5	Female	Intensive Care	35
6	Male	Internal Medicine	4
7	Female	Oncology	20
8	Female	General practitioner	11
9	Female	Internal Medicine	1
10	Female	Internal Medicine	15
11	Male	Surgery	1
12	Male	Surgery	10
13	Female	Oncology	2
14	Female	Intensive Care	6
15	Female	General practitioner	3

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Chapter 3.3: Organ donation after euthanasia, morally acceptable under strict procedural safeguards.

Rozemarijn L van Bruchem-Visser, Gert van Dijk, Inez D de Beaufort

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ABSTRACT

BACKGROUND/OBJECTIVES
In this paper, we will present a case of organ donation after active euthanasia (ODE) in the Netherlands from a patient who had his life ended at his explicit and voluntary request. The form of ODE we describe here concerns patients who are not unconscious and on life support, but who are conscious and want to have their life ended because of their hopeless and unbearable suffering, for instance due to a terminal illness such as Amyotrophic Lateral Sclerosis (ALS) or Multiple Sclerosis (MS). This form of ODE is of course only possible in jurisdictions where euthanasia is allowed. In these jurisdictions, organ donation after euthanasia is an option that may be considered.

METHODS
The case report is described in the first part of the article. The paper discusses several ethical issues such as who should broach the subject of organ donation and who should perform the euthanasia, and how a conflict of interest can be avoided.

CONCLUSION
We believe ODE is worthwhile to pursue, as it can strengthen patient autonomy, can give meaning to the inevitable death of the patient, and be an extra source of much needed donor organs. To ensure voluntariness of both euthanasia and organ donation and avoid conflict of interest by physicians, ODE does need strict procedural safeguards however. The most important safeguard is a strict separation between the 2 procedures.

INTRODUCTION

In 2010, Wilkinson and Savulescu discussed several options to procure more organs for organ donation. One of the options they considered was organ donation after euthanasia (ODE).(1) The paper specifically discussed patients who are permanently unconscious and patients that are on life support with a poor prognosis and will have life support terminated. Under current practice, these patients can only become organ donors once life support has been terminated, circulation has stopped for 5 minutes and the patient is declared legally dead. However, as many patients do not die within the specified time after cessation of life support, many organs are lost in this way. Therefore, Wilkinson and Savulescu propose that it should be allowed to harvest the organs while the patient is still on life support.

Technically, this would mean the patient would be killed in order to procure the organs for organ donation. However, according to Wilkinson and Savulescu, this would be morally acceptable as it would increase the number of organs, the organs would be more viable and, as all patients will be taken from life support anyway, no patient would die who would not otherwise have died. This proposal to harvest organs from patients who are still on life support is highly controversial. Some of the arguments against their proposal are that it could undermine the trust people have in the system of organ donation and bypass the autonomy of the patient, as the wishes of the patient would be uncertain. Their proposal would also violate the dead donor rule. In this paper, we will present another form of ODE: organ donation from a patient who had his life ended at his explicit and voluntary request. This is markedly different from the proposal by Wilkinson and Savulescu, as 'euthanasia' has a different meaning here.

The form of ODE we describe here concerns patients who are conscious and want to have their life ended because of their hopeless and unbearable suffering, for instance due to a terminal illness such as ALS or MS. This form of ODE is of course only possible in jurisdictions where euthanasia is allowed. In these jurisdictions, organ donation after euthanasia is an option that may be considered.

There are several reasons why this form of ODE is morally different from patients who are on life support: first, the patients can consciously and explicitly request to be an organ donor after euthanasia. Second, the reason why their life is actively ended is not influenced by the request to be an organ donor. In other words: their lives are not ended because of their organs, they will have euthanasia based on their own explicit request and they want to donate their organs after the euthanasia is performed. If there was no possibility for organ donation, the euthanasia would still be performed. Should organ donation become standard practice in eligible patients, the situation might change and these patients might feel pressured to donate organs. To avoid this, the subject of organ donation

should not be discussed before the process of legal requirements for euthanasia is completed.

Furthermore, there will just be a small number of patients requesting euthanasia who will meet the criteria to donate organs. Of this group, not all patients will express the wish to donate their organs. Therefore, the possibility of organ donation following euthanasia will only apply to a small number of patients. ODE also involves a lot of effort both from the patient and the physicians. Because of aforementioned reasons, we think ODE will never become 'standard' practice. However, this is a concern that needs to be monitored carefully in the future.

The Netherlands is one of the few countries in the world where euthanasia, the active ending of the life of a patient by a doctor at the explicit request of the patient, is legal if the physician acts according to the due care criteria under Dutch law. We are aware of the fact euthanasia is still controversial in many parts of the world. However, in the Netherlands, there is wide acceptance and support for the current law on euthanasia, both among the general public and physicians. Moral justification of euthanasia lies in a combination of patient autonomy and a duty of physicians to relieve hopeless and unbearable suffering. This paper does not further elaborate on the moral justification of euthanasia. We consider euthanasia to be an exceptional medical procedure, that is morally justifiable under certain circumstances, such as described in the Dutch law on euthanasia.

Under section 2 (1) of the Dutch Termination of Life on Request and Assisted Suicide Act, the physician must:

1. be convinced that the patient's request is voluntary and well considered;
2. be convinced that the patient's suffering is unbearable, with no prospect of improvement;
3. have informed the patient about his situation and prognosis;
4. have come to the conclusion, together with the patient, that there is no reasonable alternative in the patient's situation
5. have consulted at least one other, independent physician, who must see the patient and give a written opinion on whether the due care criteria set out in (1) to (4) have been fulfilled;
6. have exercised due medical care and attention in terminating the patient's life or assisting in his suicide.(2)

The Dutch law on euthanasia does not legally require the patient to have a terminal illness or a limited life expectancy. In 2016, there were 6019 cases of euthanasia reported in the Netherlands, which accounts for 4% of the number of deaths. Of

these, approximately 4000 patients suffered from malignancies. As malignancies are almost always a contraindication for organ donation, apart from certain non-metastasizing brain tumors—these patients would not have been medically suitable to become organ donors. It is to be expected that many of the remaining patients are also not suitable candidates for organ donation, due to age and/or medical restrictions. However, some non-malignant diseases do theoretically not preclude organ donation. This is particularly the case in degenerative diseases such as multiple sclerosis, Huntington disease, Amyotrophic Lateral Sclerosis or in certain cases after a stroke/CVA. It is suggested that about 10% of patients who receive euthanasia in Belgium could in theory become organ donors.(3) According to research in Belgium, the quality of the retrieved organs is generally better then 'normal' postmortem donors.(4)

So far, the combination of organ donation and euthanasia (ODE) has been performed 30 times in the Netherlands, 9 of which took place in 2015.(5) More cases have been reported from Belgium.(3)
The first case report of organ donation after euthanasia in Dutch was reported in 2013.(6) In this article, we describe a case from the Erasmus Medical Centre in November 2015. Based on our own experience, we provide some suggestions to ensure that the request for euthanasia is separated as much as possible from the wish to donate organs. Furthermore, we will discuss ways to inform possible candidates of the existence of ODE.

CASE REPORT

In July 2015, a physician from the Dutch End of Life Clinic (ELC) contacted the regional transplant coordinator (TC) of our hospital. The ELC offers euthanasia to people who fulfill the due care criteria for euthanasia, but cannot get euthanasia from their own health care provider, for instance for reasons of conscientious objections. The clinic is not a hospital or a hospice, but a foundation with teams of doctors and nurses who work separately and visit the patients at home.(7) A male patient between 50 and 60 years old had approached the ELC in June 2015 with a request for euthanasia, combined with organ and/or tissue donation. The ELC had concluded the patient met the due care criteria for euthanasia.

Subsequently, the legally required independent physician had confirmed this. Because of the additional wish to donate organs and/or tissues, our hospital was contacted. For the ELC, this was the first time they were faced with such a request.

As this was also the first time our hospital was confronted with a request for ODE, the TC referred the request to our End of Life Committee. This in-hospital-committee deals specifically with complex end-of- life questions. The committee consists of several physicians, nurses, ethicists, legal advisors, and pastors. After careful consideration during several meetings, the committee decided that the

combination of procedures would be allowed in our hospital, but only if the principles were followed that were stated in the practical manual that was published recently. This manual describes the organizational steps that need to be fulfilled to perform this combination of procedures. It also lists the various criteria the different stakeholders need to comply with. The manual was published in 2015 by a group of general practitioners and medical specialists from the Maastricht University Medical Center and the Erasmus University Medical Center Rotterdam.(8)

One of the main ethical problems that might arise is that the choice by the patient for euthanasia could be influenced by the possibility of organ donation. It is therefore of paramount importance the procedure of euthanasia should be kept as strictly separated from the procedure of organ donation as possible. It was therefore decided that the patient should be seen by an independent physician in our hospital, who was not in any way involved with the possible transplantation process. This needed to be done before the decision was made to grant the wish of the patient to donate organs and tissues after euthanasia in our hospital. RvB was asked to see the patient by the End of Life Committee, and to form an independent opinion of the patient and his wish for euthanasia, to ensure that the request for euthanasia was autonomous and not unduly influenced by the wish to donate.

The transplant coordinator would see the patient separately and explore and discuss the potential donation process. By working in this way, the 2 procedures would be kept separately as much as practically possible.

The committee used the list of criteria as stipulated in the practical manual. This manual describes the criteria needed to be met before the combination of procedures could be performed in our hospital.

1. To ensure the request for euthanasia would not be influenced by the possibility of organ donation, there needed to be positive advice regarding euthanasia by an independent physician, before the possibility of organ donation was discussed.
2. The euthanasia should be performed according to the Euthanasia protocol as formulated by the Royal Dutch Medical Association.(9)
3. There should be no medical contra-indications for transplantation.
4. Consent for organ and tissue removal by the public prosecutor has been procured.
5. Organ function and medical history screening with minimal invasive tests have been carried out.

RvB met with the patient in October 2015 as a representative of the Erasmus Medical Center. The patient was accompanied by close relatives. The patient was mentally competent, but due to a stroke was only able to answer in very short sentences, or answer direct questions with one-syllable words. His close ones helped relate his story. Patient history revealed, he suffered a dissection of his arteria carotis internal on the left side in 2009, followed by an ischemic brain infarction. As a result, there was hemiparesis of the right arm and leg, and a severe motor aphasia. The patient now lived in an assisted living environment, was unable to perform his former work and rated his quality of life as 1 out of 10 (1 being the lowest). He rated his life preceding his stroke as 9 out of 10.

The primary request for euthanasia dated from 2010. First, the patient had mentioned his wish for euthanasia to his treating psychiatrist. The psychiatrist suspected that the patient suffered from a depression, and prescribed treatment. The mental state had improved, but the wish for euthanasia persisted. The patient also discussed his desire to have euthanasia with his neurologist. For unknown reasons, both physicians decided they did not feel at ease at performing euthanasia in this specific case. The psychiatrist therefore referred the patient to the ELC in 2015.

During the visit to our hospital in October 2015, RvB spoke elaborately with the patient and his relatives and friends. In the weeks preceding the visit, RvB studied the medical files, conferred with treating physicians if needed and concluded there were no alternative treatments available, as already had been previously concluded by the independent consulting physician as well. The main reason for this visit was to assess that there was a genuine desire for euthanasia, unaffected by his concomitant wish to donate organs. The assessment was made by RvB that there was no reason to question the patient's competence, nor his genuine longing for euthanasia. The will to donate organs and/or tissues was secondary.

When it was determined that the request for euthanasia met the legal due care criteria for euthanasia and was not influenced by the desire to donate organs, the combined procedure of euthanasia and organ donation was discussed comprehensively with the patient and his relatives. It was emphasized that the euthanasia needed to be performed in the hospital. Eurotransplant protocol states ODE patients should be treated as 'regular' DCD-III donors. This means after death is pronounced, there should be a legal 5 minute 'no touch' period, after which the body is to be removed from the room and transported to the operation theater. Because of the wish to donate organs/tissues it would be necessary to perform some tests on the day of admission for the euthanasia procedure, as well as in the start-up phase. The patient and his relatives stated that they understood these conditions and the patient consented.

At the end of the meeting, RvB and the patient decided that future conversations would be conducted through email, as telephone conversations were too difficult for the patient, due to his aphasia. The initiative for contact regarding additional questions or a request to set a date for the euthanasia would have to be initiated by the patient. The reason for this being that the initiative for both the euthanasia and the organ donation needed to be with the patient. This gave the patient all the time needed to consider both procedures and leave room for a change of mind. It was also clearly stated by RvB that the patient, not the ELC or our hospital, should choose the date of the euthanasia.

After this meeting, the TC spoke with the patient, and his close ones. The TC provided more information about the tests that would be performed, and asked if there were any organs/tissues the patient did not want to donate and asked the relatives if they would appreciate a follow-up call 6 weeks after the euthanasia and organ transplant about the specifications of the transplantation procedure, and information about the donor recipients, as far as Dutch law would allow. The patient explained that he wanted to donate as much as possible.

The TC contacted the public prosecutor and the coroner beforehand informing them of the pre-arranged time of the euthanasia, so the body could be legally released directly after the euthanasia was performed. In all cases of euthanasia, the public prosecutor and coroner are informed ahead of the planned euthanasia, but in this case the public prosecutor was expecting the phone call, and the coroner agreed in advance to perform the examination of the body after the removal of the organs. As a result of these actions, the body could be released to the TC within minutes following the establishment of death.
The tests, needed for permission to be an organ donor, were performed and showed no impediments for organ transplantation. The liver, lungs, kidneys, pancreas were all thought to be eligible for non-heart beating transplantation. Furthermore, the heart valves, skin, bones, and cornea were considered for storage in the tissue banks. At the insistent request of the patient, inquiries were made to ensure that after death and removal of organs and other tissues, all remaining parts of the body that could be used for educational or scientific purposes, would be removed as well.

A few weeks later, RvB received an email from the patient with a proposition for a day and time for the euthanasia. After checking with the clinical ward, the physician from the ELC and the TC the date was confirmed. On the specified day, the patient and his close ones arrived at about 14:00 at our hospital. The time for the euthanasia was set at 16:00, as some last-minute tests for the donation were needed. The patient and his close ones had a room to themselves and spent the time until 16:00 reminiscing, while enjoying some wine, as was the patient's wish. It was already ascertained that a few glasses of wine would not diminish the quality of the organs.

The medication for the euthanasia was collected from the hospital pharmacist, directly in the hands of RvB, according to the in-house euthanasia protocol. The physician from the ELC was present during the transmission of the medication, as she was to be the physician that was going to perform the euthanasia. On the clinical ward, RvB prepared the medication with the assistance of an experienced nurse.

At 15:57, the patient was asked one final time, in the presence of RvB as well as the physician from the ELC, whether or not he had any doubts at all about the euthanasia, and if he wanted to proceed. The answer was that he had no doubts at all and would like to continue with the procedure. This was noted afterward in the medical record. After the confirmation of the patient, the medication was administered by the physician of the ELC, according to national guidelines. First, lidocaine 20 mg was administered, then 2000 mg of sodium thiopental and after flush with sodium chloride 0.9%, 150 mg rocuronium. This last drug was administered at 16.03. Death was pronounced at 16:06. After declaration of death, the required 5 minutes 'no touch' period commenced. At the family's request, the body was taken out of the room and transported to the operation room at 16:09 pm. The family stated that they did not want to endanger not fulfilling the patient's explicit wish for organ donation by delaying transport to the operating theater.

At reaching the operation theater, the body was handed over to the TC and the organ procurement team. The lungs, kidneys, cornea, skin, pulmonary, and heart valve were removed for transplantation. The liver was rejected for transplantation during the surgery. Of the 5 patients that received an organ, 1 died because of surgery related problems, the other 4 patients are doing well. The skin and heart valves were transported to the tissue banks, awaiting a suitable receiver. The liver and pancreas were removed and will be used for the transplant-science program. The brain was removed and will be used for educational purposes, according to patients wishes.

Several weeks after the euthanasia, as was agreed in the pre-euthanasia meetings, the TC contacted the family of the patient to ask if they would like to know which organs and tissues were removed. After the affirmative answer, the aforementioned details were shared with the sister. In addition, family was told how old the receivers of the organs and tissues were, as well as their gender. During this conversation, the family expressed gratitude for the way the procedure had been carried out.

The case was reported by the coroner to the Regional Euthanasia Committee, as is required by Dutch law. The Committee ruled several weeks later that the physician had acted according to the due criteria as laid down in the Dutch law on euthanasia.

During the process, the patient expressed to RvB a wish to make his experience public, as he felt this combination of procedures deserved wider attention. The family of the patient gave permission for publication. Some details of the patient were changed for this paper, so as to ensure confidentiality.

ETHICAL AND LEGAL QUESTIONS

If a patient has an autonomous, well-considered request to donate his or her organs following euthanasia, are there any legal or ethical reasons why physicians should not accommodate this wish? For a patient whose death is imminent, as the request for euthanasia has already been granted, the prospect of the possibility of ODE can give meaning to his death and can thus be seen as a form of respecting patient autonomy.(10)
ODE can also be a new source of organ donors, and thus save lives, although it is uncertain how big this source exactly is. In 2015, 9 cases of ODE were reported, on a total of 265 Dutch postmortem organ donors.

Is ODE legal?
The Dutch law on euthanasia does not state what can or should happen with the body after euthanasia, as long as the euthanasia is properly reported to authorities. Therefore, euthanasia is not a legal obstacle to ODE. This is acknowledged by the Dutch minister of health and by the Dutch Model Protocol on organ donation, which explicitly allows for ODE.(11) This protocol states that all ODE-donors should be reported to Eurotransplant and non-heartbeating allocation rules should be followed. According to Eurotransplant protocol, organs retrieved after ODE can only be allocated to European countries where euthanasia is legal (currently only the Netherlands Belgium and Luxemburg). To further ensure ODE is done professionally and is morally acceptable, the Dutch Transplantation Society recently published an official guideline on ODE.(12)

Abandoning the dead donor rule?
In Savulescu's and Wilkinsons proposal one of the ethical problems is whether it is acceptable to abandon the dead donor rule and to harvest organs from patients who are not formally deceased. With ODE, the dead donor rule is not abandoned, as the patient is deceased when the organs are removed. Furthermore, as the patient's life is not ended because of the possibility of organ donation, no patient dies that would not otherwise have died. To ensure this, it has to be ascertained the request for euthanasia is voluntary and is not influenced by the possibility for organ donation. Organ donation should therefore not be discussed before the procedure for euthanasia is completed, including a positive assessment from the independent physician.

The date of the procedures should be set by the patient, and no pressure in any form should be put on the patient for a specific date or time.

Is there a conflict of interest?
Another possible ethical problem could arise if there is a conflict of interest by the physician that performs the euthanasia. This might be the case if there would be a personal, financial, or medical interest in organ donation or in retrieving (extra) organs. To avoid this possible conflict, the 2 procedures should be kept separate as much as possible. Therefore, neither RvB nor the physician from the ELC was informed beforehand about possible beneficiaries of the donated organs.

As there was a physician, not connected to our hospital, that had already established a relationship with the patient, from an ethical point of view, it was decided that the euthanasia would be carried out by that physician. Had the patient already been treated by a physician in our hospital, and the physician would have had no conflict of interest regarding organ donation, an ODE performed by a physician employed in this hospital would have been possible. However, an 'outside' physician performing the euthanasia is preferred, as this minimizes the possibility of a conflict of interest.

Can the patient still change his mind?
In most cases, euthanasia is performed at home, by the GP. Although this is no legal obligation, it is customary that the performing physician asks for a final confirmation of the wish by the patient before performing euthanasia, to ensure voluntariness. It is unknown however, if patients ever change their mind in such a moment. The situation with ODE is different from this common setting: the environment is more clinical and more medical staff is present. Another factor is that the patient is aware of the fact the potential recipients of the organs are already informed of the possibility of receiving an often long-awaited organ. This different setting might make it more difficult for patients to change their mind at the final moment, when the euthanasia is to be performed. However, considering the fact the patient has had many occasions to change his mind in the months leading to this moment, and knowing the patient put a lot of effort into getting the wish for ODE granted, we do not consider this to be a strong moral argument against ODE. Furthermore, consent for organ donation after euthanasia is much 'stronger' than it is in the case of deceased donation, as it is possible to communicate with the patient up until the final moment and consent is therefore the most recent possible.

Who should broach the subject of ODE?
In this case, the patient was the one to suggest ODE. As we consider ODE a morally acceptable combination of procedures, the question rises who and at what point should mention the possibility of ODE to people who request euthanasia. In our opinion, this should not be done by the performing physician. This might put undue pressure on the patient, thereby undermining the patient-physician relationship. In our opinion, the transplant coordinator or hospitals that perform transplants should also not broach the subject by themselves.

However, we do feel information about ODE should be available to patients. A possible way to inform possible candidates of ODE is through patient advocacy organizations societies of specific diseases, such as ALS, MS, and Huntington disease. The Dutch Society for Voluntary Euthanasia (NVVE) and the Dutch Transplantation Society could also be sources of information on the subject. We realize that not all patients will have equal access to his kind of information, and that this might lead to a situation in which a limited number of patients requesting euthanasia are made aware of the possibility of ODE. However, we feel it is not appropriate to push the information on all patients that request euthanasia, as it might appear patients can only receive euthanasia if they are willing to donate their organs. Further ethical research is required in this field.

ODE is a complex combination of two controversial procedures. It involves a lot of effort from both the patient and the physician. Because the euthanasia has to be performed in a hospital, it is necessary to move the patient to the hospital specifically for the euthanasia. And although both procedures need to be strictly separated, it is necessary —because of the time pressure—to coordinate both procedures. This requires coordination, professionalism, and team effort.

Despite these efforts though, we do believe ODE is worthwhile to pursue, as it can strengthen patient autonomy, can give meaning to the inevitable death of the patient, and be an extra source of much needed donor organs. As ODE involves a lot of effort, both from the patient and the physicians involved, we feel ODE will never become standard practice in suitable patients. To ensure voluntariness of both euthanasia and organ donation and avoid conflict of interest by physicians, ODE does need strict procedural safeguards however.

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Chapter 4: Interventions in vulnerable patients

Chapter 4.1: Ethical considerations concerning percutaneous endoscopic gastrostomy placement in a patient with dementia.

Rozemarijn L van Bruchem-Visser

Chapter 10, De dokter en de dood. Optimale zorg in de laatste levensfase. Diagnose uitgevers 2014 page 101-108.

ABSTRACT

BACKGROUND/OBJECTIVES
The physician is often confronted with death. From the beginning of times physicians have tried to fight death and keep the patient alive. But sometimes the road to death is too long and complicated by pain, dyspnea, exhaustion, loneliness and dependency and the physician is asked to hasten the moment of dying. So a lot is asked from physicians when it comes to dying: death should not come too soon, but certainly not too late, and it should be a “good death”.

METHODS
Based on a patient story, challenges are described that occur when relatives and physicians do not agree on treatment plans when death is imminent.

CONCLUSION
The interest of the patient should always come first, even if that means going against the wishes of relatives. In the case of a mentally incompetent patient (a patient that cannot be regarded as being capable of making a reasonable appreciation of his interests in the matter) the physician must speak to legal representative of the patient. However, a medical history as narrated by family is not always reliable. When there are doubts consult with other sources of information, such as the general practitioner, home care of nursing staff. Under Dutch law, a physician cannot be forced to start or continue a futile medical treatment. Training will help improve communication skills, even for experienced physicians

CASE REPORT

A 73-year old man, Mr. B, was admitted on Friday evening to the Emergency Department (ED), because of suspected dehydration. The paramedics inserted an intravenous (IV) catheter and started IV fluids. There was no referral letter present, but the paramedics revealed that the general practitioner (GP) told them Mr. B was diagnosed with vascular dementia and had been bedridden and unable to communicate for the last few years. The internist on the ED had a long talk with the wife of Mr. B, who related her husband had been living independently, up until a few days. She adamantly disputed the story of the GP. She requested full treatment options for her husband. The GP was not available for an intercollegial consult, and because of the inconsistency of the two stories the IV fluids were continued until more clarity was obtained. In the following days the renal function of Mr. B returned to normal values, however he was still unable to eat or drink by himself. Staff was not able to get a response when talking to Mr. B, who did not seem uncomfortable at that time, but did not show any signs of enjoyment either. The wife was very committed to her husband, stayed with him most of the day and was very thankful for the provided care.

On Monday, the GP was contacted, who confirmed the story of the paramedics. Mr. B had been diagnosed with vascular dementia years prior and had reached the end-stage of the disease. He was mutistic, unable to swallow and bedridden. He was totally dependent of his wife, who had taken care of him all these years, force-feeding him in the last weeks. The GP had witnessed B choking on several occasions. In his opinion, Mr. B experienced no quality of life anymore, had tried to talk about cessation of food and fluids with the wife, but each conversation ended with her leaving the room very angry, refusing to talk about it.

Because of the swallowing problems, the multidisciplinary team decided it was not safe to administer oral fluids or food. Feeding over a nasal tube was also deemed a futile medical treatment. In the end, the team decided to stop administering IV fluids to B because there was no perspective on improvement on quality of life. A comfort care policy was to be started, aimed at treating any discomforts B might experience. Treatments aimed at prolonging life were stopped.

The resident, accompanied by a nurse, talked to the wife and daughter of Mr. B, who were both very distressed by the decision that had been made. They claimed the diagnosis of dementia was incorrect, and they had never been told B suffered from dementia. They did not agree to stopping IV fluids and tube-feeding. The resident perceived the discussion as very offensive, and surprising as the GP had told her the diagnosis had been discussed at multiple times with both wife and daughter. The discussion was put on hold, and it was agreed to continue the discussion later that day with a staff physician.

In this second discussion, it was abundantly clear that both wife and daughter were very concerned with the health of their husband/father, and had great difficulties accepting the diagnosis of dementia. The daughter claimed it was just a week ago that her father had still been able to eat all by himself. The observations of the GP were dismissed as being untrue, the GP was never interested in Mr. B and had a completely false representation of the situation. They were convinced there had to be an alternative explanation for the sudden decline in function. Admission to a nursing home was out of the question, the wife was however willing to consider accepting home care. To stop administering fluids and tube-feeding in the hospital was unmentionable. In the end, it was decided that IV-fluids and tube-feeding were to be continued until the day of discharge. No IV fluids or tube-feeding would be arranged for the home situation. The staff physician suggested all other life-prolonging was to be stopped the day of the discussion. Comfort care would be continued, and no new treatments were to be started in the case of deterioration of the condition of Mr. B. The wife refused to agree to stopping the low molecular weight heparin injections, even though it was explained multiple times that these injections were unpleasant for the patient. She reluctantly agreed to the other suggestions. Support from social services or pastoral care was declined.

The treatment decisions were discussed with the GP, who agreed wholeheartedly to discharge Mr. B to his home, as well as to stop administering fluids and tube feeding. The GP was willing to take over medical care for Mr. B upon his return home.

Mr. B remained in the hospital for a few more days awaiting the arrangement of home care. Against medical advice, the wife and daughter kept feeding him semi solid foods and fluids. More often than not,Mr. B would refuse to open his mouth, choke or would let the food or fluid run out of his mouth. The medical team would keep explaining the major risk of an aspiration pneumonia, or even death by choking, but these explanations were all declared nonsense by the family.

After a total of 6 days in the hospital, on Friday all was arranged for discharge. The IV fluids were stopped awaiting the ambulance. Hours prior to discharge there was a phone call from the daughter. She felt angry, sad and worried. Discharging Mr. B was not possible, he had not recovered enough, and was still not able to eat or drink by himself. If the IV fluids were to be stopped, he would surely die. She demands the IV fluids were restarted and insisted on a second opinion regarding the diagnosis of vascular dementia. During this telephone call the resident explained once more that Mr. B would never be able to eat or drink again, as his swallowing problems were a symptom of his severe dementia. However, since it was anticipated that a discharge right before the weekend would result in a new hospital visit during the following weekend, discharge was postponed until the next Monday. On Saturday both the wife and daughter were seen feeding Mr. B applesauce. Later that day, the family demands a meeting with the geriatrician that

is on duty. They demand the IV fluids are restarted, since Mr. B was unable to drink a sufficient amount of fluids. The geriatrician felt pressured to indeed restart the IV fluids.

On Monday Mr. B was discharged home, IV fluids were stopped and the family was once more urged not to feed any food or fluids, as that would sooner or later cause an aspiration pneumonia.

After a week, Mr. B was referred to the ED by the GP on duty, because of an aspiration pneumonia. The GP on duty had no access to the medical files of Mr. B's own GP, and was told by the family that the patient had fallen acutely ill, not having suffered from any illness prior to that moment. After having heard that story and having examined Mr. B, who was indeed very sick, the GP on duty had called an ambulance. When arriving to the ED, Mr. B was considered to be very ill, so antibiotics were administered by the ED nurse before a physician was called, based on the principle of the "golden hour". The referring GP had failed to inform the attending resident of the arrival of Mr. B, so the resident had not examined the medical file of Mr. B prior to examining him on the ED.

The family revealed they had continued feeding Mr. B food and fluids in the days following discharge, with multiple choking incidents. At the moment of examination Mr. B was severely short of breath, was showing all the physical signs of a pneumonia and had developed significant pressure sores in the past week.

Mr. B was readmitted to the geriatric ward and a new meeting was arranged between staff physician, mrs. B and their daughter. In a lengthy debate, it was decided to stop the antibiotics and start a comfort care policy. Mrs. B requested for patient to stay in the hospital until his death, because of the abundant possibilities of intervening in case of deterioration. Comfort care at home, with round the clock home care or a hospice were nonnegotiable. At the end of the meeting it was decided to wait a few days to see how the situation would evolve, as it was unpredictable how soon Mr. B would die.

In the following days there was gradual deterioration of Mr. B's situation. There is a decreasing urine production, and the nurses witnessed he seemed uncomfortable at some moments. Low doses of morphine were administered at those moments. On a regular basis, meeting with family were held, and all agreed that the death process took more time than anticipated. Since hospital care was no longer needed, the possibilities of a hospice were discussed with the family on several occasions. The family refused this adamantly. They claimed to have a right to demand hospital care for Mr. B. After consultation of the legal department of our hospital, it became clear that discharge to a hospice would be legal, even without consent of the family. With this explanation, the family reluctantly accepted

discharge to a hospice, but did raise concerns whether or not Mr. B would be in the condition to be transported by an ambulance.

An elderly care physician from the nursing home where the hospice was located visited Mr. B in the hospital to perform a second opinion. She had a long meeting with the family, telling them she agreed with the opinion of the medical staff of our hospital that Mr. B suffered from a severe dementia, with accompanying swallowing difficulties. After the meeting, the family accepted the transfer without any more hesitations. The second admission to our hospital lasted 17 days. Mr. B died 5 days after being transferred to the hospice.

CONSIDERATIONS

Communication is one of the cornerstones of modern medicine. First, doing a thorough medical history is as essential and very valuable instrument.(1) Subsequently, suggestions for diagnostic tests, treatments are discussed and decided upon in a dialogue between patient and physician. Provided the patient is mentally competent on the matter at hand. It is the duty of the physician to ensure the patient is mentally competent regarding the decision that has to be made. Mental incompetence is described in CC, book 7, article 465 part 3: (the patient) *cannot be regarded as being capable of making a reasonable appreciation of his interests in the matter.(2)* If a patient is judged to be mentally incompetent in the matter at hand the physician is obligated to decide on medical matters in consultation with an authorized person, either officially appointed by the patient or an informal representative who is willing to take on the task.(3) This is also stated in Dutch law: *the care provider shall fulfil the obligations to the patient towards the person who is authorized in writing to act on the patient's behalf* (CC, book 7, article 465 part 3).(2) It is the duty of the professional to ensure that the authorized person is acting in the best interest of the patient, and decisions are not driven by emotions. The professional is bound by Dutch Civil law, book 7, article 453: *In providing the medical treatment, the care provider must observe the standards of a prudent care provider and, in doing so, he has to act in conformity with the responsibilities laid upon him by the professional standard for care providers.(4)* In case of a difference of opinion between the professional and the authorized person, the professional has to take responsibility that in resolving the issue, a decision is made that will benefit the patient.

In this case all parties agreed B was mentally incompetent, so by Dutch law his wife was his legal representative, with the daughter next in line. However, questions were raised whether or not they acted in the best interest of the patient. The wish of the family was to keep B alive for as long as possible. The medical team tried to maximize quality of life of B, and avoiding harm. In their opinion, the actions that were desired by the family, did not only not maximize quality of life, but was even harming him. After lengthy discussions with a multidisciplinary team of physician,

ethicists and jurists the team had to decide to observe the standards of being a prudent care provider and felt it was their responsibility to protect B from further harm by not starting or continuing treatments requested by family that were deemed medically futile.

When is a treatment deemed medically futile or fruitful? Often, the following definition is used: a treatment is considered fruitful when (a) it serves a reasonable cause and (b) the benefits outweigh the burdens for the patient.(5) As such, a physician must be able to substantiate why a treatment is not serving a reasonable cause, and/or why the burdens outweigh the benefits. In the case of B there is a progressive, severe dementia. Multiple medical professionals were of the opinion that the treatments demanded by the family did not result in an increase of quality of life. As a result, prolongation of life by providing medical treatment was deemed futile.

The decision to forego life prolongating treatment can only be made after elaborate, multidisciplinary deliberations, with involvement of the GP, or the nursing staff of a nursing home. In the majority of cases, the family is the most reliable source of information regarding activities of daily living. However, in the case of mr. B, the information obtained by the family was totally different from how all other parties perceived B's situation. Based on extensive observations in the hospital and multiple consultations with the GP, it was concluded that the report by the GP of B's situation was coherent with the observations made by the hospital staff.

In the Netherlands, family has no legal right to demand a physician to start or continue a treatment that is medically futile. In fact, a physician is not allowed to carry out a futile medical treatment. As a result, a physician is obligated to deny a demand made by family to carry out a medically futile treatment. Legally, it is an open and shut case. In reality, it is not that simple.
At the intensive care unit, conflicts with family regarding medical decisions arise frequently. Clear, consistent and honest information and communication are seen as the most important requirements to avoid conflicts.(6) A review of literature showed that often family needs time to come to terms with the fact that the patient has reached the final stage of a disease.(7) Complication fact is that it is seldom possible to give an 100% accurate forecast of the prognosis. In most cases, family is willing to accept some level of uncertainty if communication is clear, and they feel the proposed actions are in the best interest of the patient. If family is giving time, and information is consistently given by multiple experienced health care professionals, in most cases a conflict can be avoided.

It is important for the medical staff to work towards making medical decisions in harmony with the patient or family. Solid, argumentation-based explanation and sufficient time and attention will in most cases result in a mutually accepted

decision. In the case of B there were solid reasons to start a comfort care policy. However, the family and medical staff found themselves in complete opposition to each other, since the wife and daughter did not share the medical's staff observations and diagnosis of B's disease. In a standstill as such there are only two options: give in to the family or not.

In the case of B: giving in to the family would have meant continuing the antibiotics started on the ER during the second admission to the hospital, to prolong B's life. This medical treatment is fairly simple from a technical point of view, no difficult meetings with the family would have been necessary and there would have been no risk of receiving a complaint for malpractice from the family. To not give in to the family would most certainly cause problems: family would not agree, the relationship between family and medical staff would become problematic, intense and lengthy conversations would surely follow, and it was to be expected the family would file a complaint. Still, it was decided not to give in to the family. To start or continue a treatment aimed at prolonging the life of B was considered medically futile, and by giving in to the family harm would be done to mr. B. By force feeding, be it orally or with artificial nutrition, a new aspiration pneumonia was inevitable, and would have caused symptoms such as fever, pain and shortness of breath. Furthermore, the life of mr. B would be prolonged, with no signs of any quality of life. As difficult as it was for the family to accept these facts: no physician is forced to aid in providing treatment that will harm a patient more than it benefits him.

It is of course very important to acknowledge the perspective and sorrow of the family. Apart from meetings with physicians and nurses, the support from social workers, spiritual care workers of psychologists should be offered to the family. Spiritual care can be provided by the hospital, or the own congregation the patient and family. These kinds of non-medical guidance can help the family come to term with the situation of the patient and assist them during the death process, but also give the medical team insights of the motives of the family.

RECOMMENDATIONS

- The interest of the patient should always come first
- In the case of a mentally incompetent patient (a patient that cannot be regarded as being capable of making a reasonable appreciation of his interests in the matter) the physician must speak to legal representative of the patient
- A medical history as narrated by family is not always reliable, when there are doubts consult with other sources of information, such as the general practitioner, home care of nursing staff

- Under Dutch law, a physician cannot be forced to start or continue a futile medical treatment
- Training will help improve communication skills, even for experienced physicians(8)
- Sometimes good, argumentation-based explanation will not suffice in achieving harmony between family and medical staff. When there is difference of opinions, a second opinion can be helpful
- Acknowledge the position the family is in, offer support from social work, spiritual care works or a psychologist
- Written information regarding the situation of patients is always important, but is crucial in the last phase of life, especially regarding treatment decision

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Chapter 4.2: Why should we not tube-feed patients with severe dementia?

Rozemarijn L van Bruchem-Visser, Christian Oudshoorn, Francesco US Mattace Raso, Inez D de Beaufort

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ABSTRACT

BACKGROUND/OBJECTIVES
The outpatient clinic and geriatric ward of a hospital are visited by numerous patients with dementia. Some of these patients are suffering from advanced dementia, with decreased food and water intake. Several times a year, the question is raised whether or not these patients should be fed. Sometimes it is the family who wants their relatives to be artificially fed, in other cases the general practitioner or attending physician in a nursing home refers patients to the hospital to start artificial feeding by inserting a feeding tube.

METHODS
The rationale behind feeding patients with severe dementia using a percutaneous endoscopic gastrostomy or endonasal tube are described.

CONCLUSION
In patients with severe dementia and swallowing problems, there is no evidence that artificial feeding will prolong life or lower the risk of aspiration pneumonia. Therefore, artificial feeding is not recommended in patients with severe dementia and swallowing problems.

INTRODUCTION

At our outpatient clinic and on the geriatric ward of our hospital we see a lot of patients with dementia. Some of these patients are suffering from advanced dementia, with decreased food and water intake. Several times a year, the question is raised whether or not we should feed these patients. Sometimes it is the family who wants their relatives to be artificially fed, in other cases the general practitioner or attending physician in a nursing home refers patients to our hospital to start artificial feeding by inserting a feeding tube. In this letter, we would like to explain why it is not ethical to tube- feed patients suffering from advanced dementia.

Dementia is a common illness. In 2010, it was estimated that 35.6 million people suffered from dementia worldwide. These numbers are expected to double to 65.7 million in 2030.(1) The average life expectancy after initial dementia diagnoses ranges from four to nine years.(2) In advanced dementia there are profound memory deficits, an inability to recognize their spouse or family members, incontinence, decreased or sparse speech, and dependency in all daily activities, including eating and drinking.(3) Patients with severe dementia also have a loss of interest in eating and drinking, and/or suffer from dysphagia.(4)

Therefore, feeding problems are common among patients with Alzheimer dementia with numbers up to 86%.(5) Dysphagia can cause aspiration: misdirection of oropharyngeal content in the larynx and lower respiratory tract.(6) Untreated, an aspiration pneumonia will almost certain cause death. It has been shown that even when an aspiration pneumonia was treated in patients with Alzheimer dementia, 33.3% died during hospitalization, with six-month mortality being 51%.(7) The two most reported reasons by family to desire tube-feeding is to prolong life and to prevent new aspiration.(8) However, a Cochrane review reported no evidence of longer survival or lower risk of aspiration pneumonia in severe demented patients receiving tube-feeding.(9) On the contrary, there are major risks to feeding tube insertion. A study showed that 26% of patients needed to be physically restrained to prevent them from pulling out the tube, and another 30% of patients received medications to calm the patient for the same reason.(10) A different study showed agitation and self-extubation in 67% of patients.(11)

The guidelines by the British Psychological Society and National Institute for Health and Clinical Excellence (NICE) state that: ‘artificial feeding should not generally be used in people with severe dementia for whom dysphagia or disinclination to eat is a manifestation of disease severity’.(12)

However, even with clear guidelines and ample evidence present we are regularly asked to tube- feed patients suffering from severe dementia. It seems as though

the benefits of tube-feeding are still overestimated by general practitioners and other referring medicine providers as well as by family.

A concern of family members is that the patient may experience a sense of hunger or thirst. This is very hard to determine in patients suffering from severe dementia, and there are no systematic re- views. A study in cognitive intact, terminally ill patients concluded that refusal of food and water did not cause symptoms of hunger or thirst in the majority of patients.(13) If symptoms of thirst did occur, they could be relieved with mouth care and ice chips.

To convince referring doctors and family not to tube-feed demented individuals, we should not only explain the medical aspect of not prolonging life but also the aspect of inflicting major risks without benefit for the patient.

CONCLUSION

In patients with severe dementia and swallowing problems, there is no evidence that artificial feeding will prolong life or lower the risk of aspiration pneumonia. Therefore, artificial feeding is not recommended in patients with severe dementia and swallowing problems.

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Chapter 4.3: Percutaneous endoscopic gastrostomy in older patients with and without dementia: Survival and ethical considerations.

Rozemarijn L van Bruchem-Visser, Francesco US Mattace Raso, Inez D de Beaufort, Ernst J Kuipers

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ABSTRACT

BACKGROUND/OBJECTIVES
Notwithstanding multiple recommendations in guidelines, percutaneous endoscopic gastrostomy (PEG)-tube placement is still performed in patients with dementia. In this study we aim to investigate survival in patients with and without dementia after (PEG)-tube placement.

METHODS
We conducted a retrospective multicenter study in four different hospitals in The Netherlands. Furthermore, we explored the ethical considerations that may play a role in the decision whether or not to insert a PEG tube in a patient with dementia.

RESULTS
Three-hundred-and-three patients were included, mean age of 77.4 years. Forty-two (13.9%) patients had dementia. Short-term complications did not differ between patients with and without cognitive disorders (p 0.224). However, patients with dementia survived significantly shorter after PEG placement than did patients without dementia. Adjusted for age and sex, patients with dementia had a 49% increase of mortality (HR 1.49, 95% CI 1.01-2.19). In our exploratory literature search, we found several ethical concerns and considerations play a role in the decision process of PEG placement. These considerations are both medical and non-medical and include: beliefs regarding the benefits of a PEG tube, a lack of knowledge about the natural course of dementia in both professionals and family of patients, and a fear of letting a patient die hungry.

CONCLUSION
Patients with dementia had higher mortality rates after PEG placement than patients without dementia. Although multiple ethical concerns and considerations play a role, insertion of a PEG tube in patients with dementia is not appropriate.

INTRODUCTION

A percutaneous endoscopic gastrostomy (PEG) provides an alternative route of nutritional support in patients unable to orally feed, or be orally fed who require long-term enteral nutrition. (1) PEGs are inserted for various indications. In 2014, a group from the US published a list of 24 indications for PEG insertion, predominantly somatic or intercurrent conditions. Notably, dementia was listed as one of the top 10 indications.(1)

Survival with a PEG primarily depends on the underlying condition. A US cohort study followed 5.266 nursing home residents up to 12 months (median follow-up time 352 days). 10.5% had a feeding tube without further specification of type of tube. The tube-fed residents, with or without dementia, had a 44% higher one-year mortality rate.(2) A recent study reported no survival benefit for 165 PEG-patients with dementia (group A, 75% overall 12-month mortality) compared to 124 PEG-patients with other neurological diseases (group B, 58% overall 12-month mortality) nor 103 PEG-patients with head and neck cancer (group C, 38% overall 12-month mortality). PEG insertion was associated with shorter time to death (7.2 vs. 8.85 and 8 months for groups A, B, C respectively).(3)

In amyotrophic lateral sclerosis (ALS) patients, a systematic review showed that patients with a PEG tube had an increased 20-month survival as compared to ALS patients not receiving a PEG.(4) This increased survival was not found in stroke or dementia patients receiving a PEG.

The increased mortality was confirmed by other studies. (5, 6) In a cohort study, it was observed that with PEG placement, aspiration and pressure ulcers occurred more often.(7)
Therefore, with the exception of patients suffering from ALS, there is no evidence insertion of a PEG increases life expectancy in the presence of severe morbidity.

A prominent feature of advanced dementia, a phase that can last from six months to two years, is loss of appetite and interest in eating, often accompanied by dysphagia.(8) Guidelines recommend the insertion of a PEG tube should be foregone in patients suffering from advanced dementia, given the incurable nature of the disease.(9) (10) A request to place a PEG tube in an individual with advanced dementia should be considered with the utmost diffidence, and should only be executed after multidisciplinary agreement in favor of tube placement. (11) However, the decision not to insert a PEG tube is often met with resistance by family and professional caregivers.

From an ethical point of view the request for a PEG insertion should be countered with a question: is it the right decision to insert a PEG in this specific patient? Is it beneficiary to the patient? Or do we harm him? Especially with patients who

cannot speak for themselves, the benefits and risks should be weighed. In a patient with dementia, it is often family who requests a PEG. Apart from the medical point of view, there is also an appeal on the moral values of the physician, to not let someone die from a condition that could easily be treated. As a consequence, the decision to insert a PEG in a patient with dementia disorders is not easy.

The aim of the present study was to investigate survival rates after PEG placement in patients with and without dementia. Furthermore, we aimed to discuss different ethical considerations of different stakeholders (physicians, family members) in the debate on whether or not to place a PEG in a patient with dementia.

METHODS

We performed a retrospective multicenter study in four different hospitals in the South-West of The Netherlands. All cases of PEG placements in patients aged 70 years and over were included. Due to logistic reasons inclusion periods were different in the four centers.
In the Erasmus Medical Center, Rotterdam, we included data on PEG placements performed between August 2009 until October 2017. In the Albert Schweitzer Hospital, Dordrecht, we included data for the period of January 2012 to August 2015, in the Harbour Hospital, Rotterdam between July 2013 and March 2016 and in the IJsselland Hospital, Capelle aan den IJssel, between January 2011 and January 2016.

For each patient, we collected data regarding sex, age at the time of PEG insertion, indication for PEG placement, specialism of referring physician, and underlying disease. The following diagnoses were listed as dementia: dementia, Alzheimers' dementia, vascular dementia, Lewy Body dementia and Parkinsons' dementia. In the case of a diagnosis "cognitive disorders" alone, the referring physician was contacted to confirm and specify the nature of the dementia. When stated, we registered the severity of the dementia, based on the assessment of the referring physician.

Complications during PEG-insertion and complications which occurred within two months following the procedure were recorded. A complication was defined as a reported aspiration pneumonia, dislocation of the tube, need for re-insertion of the tube, insertion site bleeding or infection of the insertion site. The vital status of the patient at the time of the study was noted. Information on vital status was obtained by the hospital records, the general practitioner or nursing home, when applicable. Duration of follow-up was noted until death or data retrieval time, whichever came first.

An exploratory literature search was conducted in PubMed, using the keywords: "percutaneous endoscopic gastrostomy, PEG, dementia, cognitive". The reference

list of the retrieved papers was used to identify additional literature. The Institutional Ethical Review boards of the participating hospitals approved the study protocol.

Statistical analysis
All analyses were performed using the Statistical Package of the Social Sciences (SPSS version 21.0) and two-sided p-values <0.05 were considered statistically significant. Comparison of age between the groups with or without dementia was performed using an one-way-ANOVA.

Cox proportional hazards regression analysis, adjusted for age and sex was performed to estimate hazard ratios (HR) with corresponding 95% confidence intervals (CI) for mortality. The Kaplan-Meier method was used to estimate survival curves associated with cognitive status. Difference in complication rates was compared using the Chi Square test.

RESULTS

In total, 303 consecutive patients were included (Table 1). The mean age was 77.4 years (range 70-94 years SD 5.54), 166 (54.8%) patients were men. The majority was referred for PEG insertion because of dysphagia following a stroke, (n=106, 35%). Other indications were malignancies, in particular of the oropharynx and esophagus (n=72, 23.8%), cerebral diseases other than stroke (n=44, 14,5%), Parkinson's disease (n=23, 7.6%) and dementia (n=10, 3,3%) (Table 2). Forty-two (13.9%) patients had been diagnosed with dementia at the time of PEG placement. In 10 of those, dementia was the primary reason to request a PEG, in the other 32, dementia was mentioned as a comorbidity. The mean age of patients with and without dementia did not differ (78.4 years, 95% CI 76.5-80.3 vs 77.6 years, 95% CI 77.0-78.3; p=0.42).

After adjustment for age and sex, patients with dementia had a 49% increased risk of mortality (HR 1.49, 95% CI 1.01-2.19; see Figure 1) as compared to patients without dementia. There was no statistical difference in frequency or character of complications (during the procedure or in 2 months following PEG insertion) between patients with or without dementia (p=0.224) In the group without dementia (n=261), complications occurred in 55 patients (21.1%). In the group with dementia (n=42) there were complications in 9 patients. (Table 3).

ETHICAL CONSIDERATIONS

Fear of dying hungry
Why are patients with dementia treated with a PEG? Because of the fear of family members and professionals that they will die hungry? Do patients in the end stage of dementia experience hunger or thirst? In a prospective study, 32 terminally ill,

but cognitively intact patients were studied to determine the frequency of thirst and hunger. Of the 32 patients, 63% did not experience any hunger. 34% experienced some symptoms of hunger, but only initially. (12) In a review on hydration and nutrition at the end of life, it was concluded that familymembers are often more worried about anorexia than patients. Artificial nutrition was regarded by these familymembers as very positive. (13) A telephone survey among substitute decision-makers of tube-fed patients showed that though the majority of caregivers felt they understood the benefits of PEG-feeding, less than half expressed that they understood the risks. (14)

It is proven to be difficult to assess the hunger/and or thirst experience of individuals suffering from advanced dementia, due to the incapacity to verbalise and clarify their opinion as a result of the disease. A large proportion of people in the endstage of dementia will start to actively refuse food and/or fluids. This is an important indication that patients suffering from advanced dementia are not experiencing hunger and/or thirst. Furthermore, there is ample evidence that people, even in earlier stages of dementia, will have an impaired thirst-response, due to lower vasopressin levels. (15) (16). The physical need for nutrition or fluids seems to vanish in the final stage of dementia. If families, as well as their physicians would be more aware of this inevitable stage of the disease, it would be considered a normal symptom of the disease. More attention should be paid to explaining to patients and their family what the course of the disease will be. Clinicians should engage in a discussion about palliative care and whether or not a PEG tube placement is in the best interest of the patient. (17)

The significance of eating

From the point of view of the family, in the latter stages of dementia, eating and especially feeding is a very important factor of caring for a person, since often all other forms of communication have gradually faded. When the patient starts to refuse food, or is unable to swallow, the family loses this last connection with the patient. The family considers it a task to “defend the rights” of the patient to get food and fluids. The right to food is one of the 30 human rights by the United Nations. (18) But, artificial nutrition is a medical treatment and cannot be compared with food and the process of eating. This is often not clear to both family and professionals.

Beliefs regarding the medical benefits of PEG.

Often, family as well as nurses and physicians will opt for a PEG tube for a patient with swallowing difficulties in the natural course of dementia in the belief that a PEG tube will minimize the risk of an aspiration pneumonia. However, several studies found that feeding via a PEG tube will not lower the risk of aspiration.(19-21) On the contrary, a study including 16-PEG-tube-fed patients found 44% of patients showed agitation and/or self-extubation and 56% developed an aspiration pneumonia. (22) With or without nutrition, the life expectancy of patients suffering

from advanced dementia is very limited, and there is no survival benefit in PEG-fed individuals. (5, 23) It could be argued that dying from not eating and drinking is to be preferred over a death caused by an aspiration pneumonia. In a study in 2011, 486 family members whose relatives had died from dementia were interviewed. Almost 11% of the patients died with a feeding tube. To keep the tube in place, more than a quarter of these patients was physically restrained, and close to a third was pharmacologically restrained. (24)

In a study concerning the rationale behind a physicians' decisions regarding PEG insertion, it was found that more than 75% of the physicians believed PEG feeding would reduce aspiration pneumonia and improve pressure ulcer healing. Over half of the surveyed physicians was convinced a PEG tube would increase survival. (25) Fifteen years later an US group found in their study (2018) among 168 medical doctors that over a third of the interviewees was (partially) unaware of the recommendations stated by the American Board of Internal Medicine/American Geriatrics Society Choosing Wisely recommendations. Two-third of physicians stated that family of the patient often requested a PEG-insertion, against medical recommendations. (26)

Lack of knowledge regarding course of dementia

In a study in the US, 323 nursing home residents, identified with advanced dementia were followed for a period of 18 months. 54.8% died within the study period. (27) In another study, 104 patients with dementia were included, without specification of the stage of dementia. In this group one month survival was 46%, 12 months survival 10%.(6)

Several studies show that both the public and health professionals lack knowledge about dementia. In a study in the Northwest Indiana County, 527 elderly were surveyed. Results of this study indicated that misconceptions of Alzheimer Dementia were widespread.(28) In a study among 360 staff members from Queensland, knowledge about Alzheimer's disease was studied. Knowledge regarding course of the disease scored lowest.(29) Interviews with 179 general health care professionals found several deficits in knowledge of Alzheimer dementia.(30)

Role of referring physician and gastroenterologist

As is shown in our study, the indication for PEG-placement is, in most cases, made by a physician other than the gastroenterologist. The patient is sent to the GE-department for the procedure, often accompanied by family to whom the PEG is "promised". To refuse to perform the procedure at that moment poses a formidable challenge. The decision not to place a PEG tube should be made by the referring physician, where relevant in concertation with a gastroenterologists or a geriatrician, as is suggested by the in-house protocol for PEG insertion of the Erasmus Medical Center.(11) Nonetheless, the role of the endoscopist will increase, as not all referring physicians will have extensive knowledge of the role of PEG-

insertion in people with advanced dementia. In an elaborate review it is suggested endoscopists should actively advice referring physicians about the lack of benefits of PEG insertion in patients with advanced dementia. (31)

Increased risk of complications

In patients suffering from moderate to advanced dementia, post-operative longterm complications occur more often than do perioperative adversities. In an article published in 2002, a clear overview of potential complications was given.(32) In 1990, all PEG inserted patients in a nursing home (n=52) were studied and compared to a randomly selected comparison group. It was found that the PEG group did increase in weight, but suffered more aspiration pneumonia, decubitus ulcers and had to be restrained more often.(33) Continuation of nutrition and/or fluid will cause urinary and fecal incontinence. As a consequence, there is an increased risk of decubital ulcers as well as discomfort for the patient as more actions by the nurses are required. Insertion of a PEG will therefore not increase the quantity of life, but will also decrease the quality of life (QoL) in patients with dementia. A Europe-wide survey of more than 9000 people, showed QoL was found more important than quantity of life (71% vs 4%). The remaining 25% found quality and quantity of life equally important. (34) A similar American study "Living well at the end of life" revealed 71% of the surveyed people preferred to enhance QoL, even if that would mean living a shorter life.

DISCUSSION

Following PEG placement, patients with dementia have higher mortality rates when compared to patients without dementia.

Several factors can explain these findings. First, the incurable nature of dementia at least in part explains the high mortality rates in patients with dementia. Patients who reach a severe stage of dementia have average survival ranging from six months to two years (8). Second, patients with dementia have an increased risk on developing aspiration pneumonia. Not only does an aspiration pneumonia occur more often in patients with dementia, a PEG in itself is also a risk factor for aspiration pneumonia. Third, the continuation of nutrition and/or fluid after the PEG insertion will increase the risk of urinary and fecal incontinence with consequent decubital ulcers and infections. Fourth, because of the PEG, restraints have to be used more often as compared to a cognitive impaired patient group without a PEG insertion.(33) It might be speculated that the procedure of PEG insertion is the cause of long-term complications in patients with dementia, and therefore elevated mortality rates.

Multiple guidelines have stated recommendations, such as NICE-SCIE ("patients with severe dementia should not be artificially fed by means of feeding tubes", 2007), American Geriatrics Society ("feeding tubes are not recommended for older adults with advanced dementia", 2007-2014)(35) and Society for Post-Acute and

Long-Term Care Medicine: ("Don't insert percutaneous feeding tubes in individuals with advanced dementia",2013) (36) The ESPEN guidelines suggested providing artificial nutrition in patients with mild or moderate dementia for a limited period to bridge a crisis situation, but not in patients suffering from severe dementia.(37) Physicians, when confronted with the request to insert a PEG in a patient with dementia can utilize these guidelines to actively advice and decide against PEG placement.

Apart from the medical reasons not to insert a PEG in patients with dementia, as stated above, there is also the important issue of Quality of Dying which is at least as important as Quality of Life, if not more important.

As shown, there are several ethical and medical concerns surrounding the decision about PEG insertion in patients with dementia. The moral appeal on the physician not to let a person die hungry, the lack of knowledge on the natural course of dementia, and the medical implications of a PEG make for a difficult situation.

Limitations, strengths and recommendations

The limitations of our study include the relatively small number of patients as well as the lack of a prospective randomized approach. As this is a retrospective study, there may be outcome ascertainment bias. On the request form for PEG placements, often short, or no medical history was stated, limiting extensive information regarding the medical history or existing co-morbidities in both groups.

In some cases the motive for referral is not fully known, neither does this study provide information if there had been a previous discussion whether or not to insert a PEG between referring physician, family and gastroenterologist. Further, qualitative research is needed to find out why the guidelines are not followed. The influence of, for example, requests made by family members is not known.

Strong points of the study are that it was conducted in different hospitals, providing a combination of academic and non-academic patients. The selection process was based solely on age at the moment of insertion.

We strongly recommend that physicians will, starting from the moment the diagnosis of dementia is made, inform patient and family that a time will come oral feeding will no longer be possible, due to the course of the disease. When this final and irreversible stage of dementia is reached, everything must be done to ensure maximal comfort for the patient, but artificially providing nutrition and/or fluids is not appropriate.

An alternative to tube feeding is handfeeding. As described in 2005, feeding by hand may probably not prevent malnutrition and/or dehydration, but it will allow family to care for the patient(32). More research is needed to investigate which

ethical and medical reasons play a role in the decision of physicians to disregard the recommendations in the guidelines, and what should be changed in the process surrounding the decision to empower physicians and family to choose against inserting a PEG tube in patients with dementia.

TABLE 1: General characteristics

Total	N=303
Men	166 (54.8%)
Age	77.4 (70-94) years
No dementia	261 (86.1%)
Dementia	42 (13.9%)
Mild dementia	16 (5.3%)
Severe dementia	21 (6.9%)
Severity not mentioned	5 (1.7%)
Dead	199 (65.7%)
Hospital of PEG insertion	
Albert Schweitzer Hospital	78 (25.7%)
Erasmus Medical Center	193 (63.7%)
Harbour Hospital	10 (3.3%)
IJsselland Hospital	22 (7.3%)

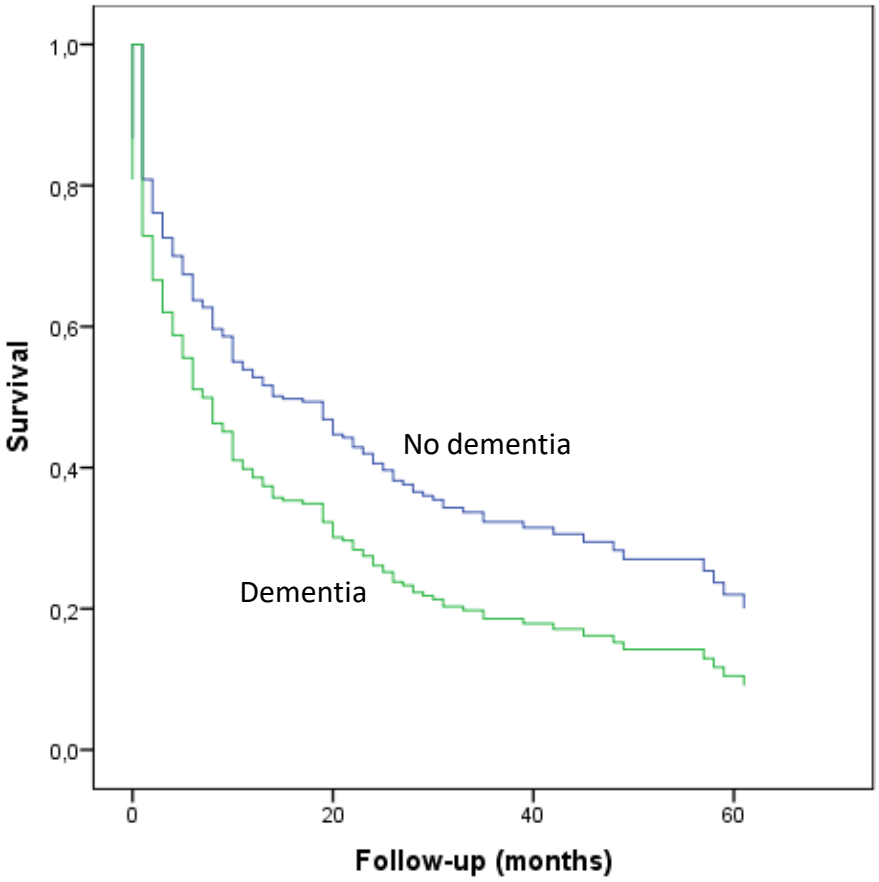
TABLE 2: Underlying disease

Underlying disease	N=303
Stroke	105 (34.7%)
Malignancy	71 (23.4%)
Cerebral (non stroke)	44 (14.5%)
Parkinson's disease	23 (7.6%)
Gastro-esophagal abnormalities	14 (4.6%)
Amyotrophic Lateral Sclerosis	12 (4.0%)
Dementia	10 (3.3%)
Dysphagia	8 (2.6%)
Peri-surgery	7 (2.3%)
Infections	6 (2.0%)
Aspiration pneumonia	1 (0.3%)
Coma	1 (0.3%)
Gastroparesis	1 (0.3%)

TABLE 3: Complications during and within two months following the procedure

	No dementia (n=261)	Dementia (n=42)	
No complications	206 (78.9%)	33 (78.6%)	p=0.224
Complications	55 (21,1%)	9 (21.4%)	

FIGURE 1: Survival in all patients (n=303)



Legend figure 1
Survival in months in all patients, divided in two groups, with or without dementia

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Chapter 5: Treatment decisions in vulnerable patients

Chapter 5.1: Ethical frameworks for complex medical decision making in older people.

Rozemarijn L van Bruchem-Visser, Gert van Dijk, Inez de Beaufort, Francesco US Mattace Raso

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ABSTRACT

BACKGROUND/OBJECTIVES
With an ageing population physicians are more and more faced with complex medical and moral situations. Medical professional guidelines are often of limited use in these cases. To assist the decision-making process, several ethical frameworks have been proposed. Ethical frameworks are analytical tools that are designed to assist physicians and other involved healthcare workers in complex moral decision-making situations. Most frameworks are step-by-step plans that can be followed chronologically during moral case deliberations. Some of these step-by-step plans provide specific moral guidance as to what would constitute a morally acceptable conclusion, while others do not.

METHODS
Three electronic databases (embase.com. Medline Ovid and PsychINFO Ovid) were searched from inception to January 24, 2020, with the help of expert librarians.

RESULTS
Twenty-three studies were included in the review, containing seventeen different frameworks. Twenty studies described step-by-step-frameworks, with the number of steps varying from three to twelve. In four studies suggestions were made as how to balance conflicting moral values.

CONCLUSION
Ethical frameworks are meant to assist healthcare professionals who are faced with morally complex decisions in older patients. In our view, these frameworks should contain a step-by-step plan, moral values and an approach to balancing moral values.

INTRODUCTION

Should physicians honour the request from relatives of a terminal patient not to implement a “do-not-resuscitate”-policy? Should a feeding-tube be placed in patients with advanced dementia? With an ageing population and the consequent increase in the number of patients with multimorbidity and frailty, physicians more often encounter these complex situations.

The issues raised in such complex situations are not just medical, but concern important moral questions as well, for instance as to what constitutes the best interest of the patient. Moral values play an important role in medicine. Moral values are general principles that define what is right and wrong. Moral values are used to guide and evaluate certain practices, such as medicine. The most commonly used moral values that guide medicine are beneficence, nonmaleficence, autonomy and justice.(1) Most well-known are the four principles as described by Beauchamp and Childress (beneficence, nonmaleficence, autonomy and justice) that are often seen as a cornerstone of medical ethics.(1) According to these authors these principles are based in a ‘common morality’, which means that the principles represent basic moral values which are shared by all moral persons. The principles are thus grounded in human moral psychology.

Currently, there is increasing attention for including frail populations in guidelines. However, in complex situations, physicians cannot solely rely on professional medical guidelines but need to balance moral values in individual cases. This means that a tailored solution has to be found in each individual case. As patients these days are almost always treated by a multidisciplinary team of healthcare workers, the decision that is taken will have to be a *shared* decision between healthcare teams and patients. The decision also needs to be both well-argued and transparent. It should be clear for all parties what arguments were offered and which method was used to reach the final conclusion. In this narrative review, we will present and discuss the ethical frameworks used for medically complex situations in older patients.

METHODS

Three electronic databases (embase.com. Medline Ovid and PsychINFO Ovid) were searched from inception to January 24, 2020, with the help of expert librarians. Together with the expert librarians, a search strategy was designed, with a combination of all terms related to ageing and ethical frameworks. Articles in languages other than English were excluded. Details of the complete search strategy are provided in Appendix 1. Two independent reviewers (RB, GD) screened the titles and abstracts. The full text of potential relevant studies were independently evaluated. Any disagreement regarding inclusion was resolved

through consensus. A predesigned data collection form was used to extract relevant information from the selected studies.

RESULTS

A total of 4738 records were identified. After removal of duplicates, 3629 records remained and were screened (title and abstract). As a result, 3456 records were excluded, leaving 173 studies to be assessed for eligibility. All 173 studies were read full-text (if full text was available) resulting in the exclusion of 150 studies. Reasons for exclusion were: subject of study not matching research topic (n=50), full-text not available (n=95), language other than English (n=1), research letter/ congress abstract (n=3) and duplicate with different title (n=1). Twenty-three studies were included in this review (See Figure 1).

In these twenty-three studies, we found seventeen different frameworks which can be divided in two categories: *with or without a step-by-step plan*. This distinction was made based on the provided information in the studies.

Twenty out of twenty-three studies used a step-by-step approach. The number of steps in the frameworks varied from three to twelve steps. Most studies described frameworks with four steps (n=9). Details on the content of the included studies are shown in table 1.
Twenty studies describe the framework by applying it to a theoretical patient case.(2-21) Three studies reported how the framework was used, for instance which participants were present. (2-4) In two studies the group was small, consisting of three to four people.(2, 4) The third study described a more organised meeting, with an ethics consultant as chairman.(3) One study gave three concrete conditions how to use the proposed framework: providing a chair trained in medical ethics, organizing the discussion around the eight steps of the framework and identifying a consensual option at the end of the process as well as designating a person to oversee the implementation of the chosen option.(5)
Eleven of the studies were descriptive studies with a case discussion, five were case studies with application of a model, three studies were descriptive studies, three studies were case studies and one study was conceptual. Most studies described situations in hospitals (n=10), nursing homes (n= 5), or a combination of hospital and home situations (n=3). More details on type of study, aim of the studies as well as the context can be found in table 2.

Step-by-step approach
Most ethical frameworks (n=20) were so-called step-by-step frameworks (SBSF). These frameworks are meant to structure moral case deliberations and the different steps can often be used in chronological order. A total of fifteen different SBSF are described.

Six studies used the 'Four Topics Method', which states that four topics should be taken into account when deliberating morally complex cases: medical indications, patient preferences, quality of life issues, contextual features.(3, 6-11) Other SBSF can be seen as variations to this Four Topics method.

Steps that are often mentioned in many of the described SBSF are:

- **Identify the problem or dilemma.** Participants discuss the most urgent problem at hand, for instance: should we place a feeding-tube, perform cardiopulmonary resuscitation? It is important this problem is clearly identified, so as to ascertain the right problem is being discussed.
- **Medical indications.** What are the goals of treatment? Which medical treatment is available, how can it aid the patient? This criterion of sound medical treatment is based on the moral principles of beneficence and non-maleficence.
- **Identify and describe the different possible alternatives.** In complex situations, there are always several possible alternatives, that should be discussed.
- **Patient preferences.** Although there might be a medical indication for a certain medical intervention, this does not mean the intervention is appropriate. The burden of the treatment might not be justified by the possible benefits. Patient preferences as to the possible balance between benefits and burden might also differ. To decide upon the most appropriate course of action, patient preferences are therefore of crucial importance. This criterion is based on the moral principle of autonomy.
- **Quality of life issues.** What will be the quality of life with and without medical interventions? Quality of life issues are partly subjective as patients can appreciate different situations in a different way.
- **Contextual features.** These features can include social circumstances, such as whether the patient has a social network to provide medical care or other forms of assistance. Legal factors and scarce medical resources might also be factors to be taken into account.
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In ten frameworks the first step was the clarification of the medical situation of the patient.(2, 3, 6-10, 12-14) In seven frameworks the initial step consisted of an assessment of the ethical problem.(11, 15-20)
In one study a combination of assessing the ethical and clinical situation was used as the first step.(5) In two studies the starting point was not explicitly described as either ethical or medical.(4, 21)
In fourteen SBSF, the preferences of the patient were an explicitly mentioned step of the framework.(2, 3, 5-8, 10, 12-14, 17, 19-21)

No step-by-step approach
Three studies did not use a step-by-step approach, but used the four medical ethical principles as a basis for their framework (beneficence, nonmaleficence, autonomy and justice).(22-24) In addition, other values were used, such as fidelity, veracity and respect for persons.

Moral values and other considerations
Most frameworks offer step-by-step plans that can be followed chronologically during a moral case deliberation. In addition, most studies (n=21) describe certain moral principles and/or values and/or virtues that are to be used as a basis for the framework. The moral principles that were mentioned most (n=19) are beneficence, nonmaleficence, autonomy and justice, based on Beauchamp and Childress.(2-10, 13, 15, 16, 18-20, 22-25) In addition, one study used four theoretical considerations: goal of care, ethical constraints, structural constraints and nurses' ethical competence.(17) Ethics of care was used as a basis for the framework in one study.(21) In two studies, it was unclear what ethical principles were used.(11, 12)

Some authors mentioned other moral values, such as 'self-determination'(17), 'fidelity'(16, 18, 22, 23), 'veracity'(16, 18, 23), 'respect for persons'(22, 23), 'dignity'(5, 15), 'integrity'(5), 'vulnerability'(5), 'loyalty'(6), 'fairness'(6, 17), 'treating patients equally'(23), 'respect for dignity and worth'(23) and 'privacy'(15). Other considerations that were mentioned by authors were: 'relevant evidence-based knowledge'(17), 'the nurse's good life'(17), 'uniqueness of human being'(21), 'asymmetric relationships of power'(21), 'humans as relational beings'(21), 'common morality'(10), 'patient's rights'(19, 23), 'consequences'(19), 'sanctity of human life'(4), 'ethics of care'(21) and 'quality of life'(15).

Balancing of moral values
During moral deliberations relevant moral values, such as autonomy and beneficence need to be taken into account to ascertain all relevant moral and medical aspects are being taken into consideration.

Four studies described how moral values should be balanced against each other during the different steps, or how tensions that arise during the deliberation should be resolved.(5, 9, 17, 19)

In the first study it is suggested to make a priority list of all the different alternatives, weigh the order of priority against each other and take into account the ethical side-constraint of fairness. It should then be assessed whether this overall order of priority will be accepted by the involved parties. If the decision is not accepted, it should be assessed whether there are strong enough reasons to decide upon it anyway. If this is not the case, another order of priorities should be reached.(17)

The second study recommends to determine the best course of action and support that position with reference to one or more sources of ethical value. The best course of action is decided upon by reference to moral values, rights, consequences, comparable cases, professional guidelines, and conscientious practice. The conclusion can then be confirmed by looking at its adequacy and coherence.(19)

In the third study it is advised to clarify for each option how it helps or does not help to solve the conflicts between the principles. The most appropriate course of action should then be arrived at by identifying the consensual option that best integrates the values of the patient, stakeholders and health professionals.(5)

In the fourth study it is suggested to include the role of virtues in the situation: what does a given virtue mean in this case? 'Including the virtues with a careful balancing of appropriate principles serves to maintain the intimate nature of the physician-patient relation'. The outcome of this is then balanced against the moral claims of each of the other stakeholders in the case. According to this study, this enriches the discussion and 'provides more guidance than reliance on principles and rules alone'.(9)

Utilization of ethical frameworks

In our research several studies described the possible utilization of an ethical framework. One of the reasons was that an ethical framework can be an aid in clarifying a situation which at first hand might seem overwhelming: 'Adopting a step-by-step-approach can simplify the process of resolving ethical problems'.(11) A step-by-step-approach can help organise, give structure and help not to overlook aspects important to the case.

Another observed function of a framework was that it can substantiate moral intuitions from health care workers, stimulate critical thinking and protect against personal biases: 'However, to be able to arrive at such well-considered and well-founded ethical decisions, there is a need to reason in a structured way and not leave ethical decisions entirely to intuitive responses to the situations in question'.(17)

Another study mentioned a framework can also facilitate a dialogue between members of a health care team: 'The most important thing we can do is maintain an ongoing dialogue among the burn team, the patients and the families of the patients'.(3) It was also described that a framework can make participants more aware of the possible actions that can be taken: 'An awareness of the different moral frameworks and ethical principles and a systematic step-by-step approach can be helpful in opening up discussion, clarifying the situation, and increasing awareness of the possibilities, enabling us to resolve problems with compassion and an open mind'.(11)

Furthermore, frameworks were meant to ascertain that patients values and wishes are taken into account when deciding upon the right course of action: 'Most important is that patient values and a narrative construct compatible with them be seriously addressed if the healthcare team is to help patients make appropriate choices in terms of their care'.(9)

Using a framework can provide a justification for decisions that were not be shared by everybody, and make them more transparent: 'A practical and systematic approach to clinical ethical reasoning thereby not only enhances the clarity and content of ethical decisions, but also facilitates dialogue and cooperation between the participants who will live with the decisions that are made'.(19) 'By capitalizing on the way clinicians think, we believe this approach provides a practical means to articulate ethical justifications for challenging clinical decisions'. (19) 'By use of a model, (nurses) incorporate these roles into practice by methodically examining and addressing ethical issues as they arise in the clinical setting'.(15)

DISCUSSION

In order to deal with morally complex decision-making situations in older patients, several ethical frameworks are proposed. These ethical frameworks are designed to stimulate debate and guarantee a transparent, well-argued solution, accepted by all parties.
When dealing with complex moral decision-making situations, healthcare workers may suffer moral distress, in finding the right course of action. The use of a framework can give the team 'an opportunity to talk about their experiences in a structured way'.(26) Frameworks can help professionals by supplying them with good reasons for what they should do, even if the circumstances are suboptimal. A framework can also assist family members who have to decide for their next of kin what should be done. It is important to provide a structure for meetings concerning complex clinical ethical decision making as a study showed that family members as well as patients are often unclear of the purpose of shared care plan meetings. (27)

Most ethical frameworks found in literature are step-by-step plans that can be followed chronologically during moral case deliberations. We believe that frameworks that include a step-by-step plan are preferred by clinicians, as in our experience clinicians are generally not well trained in medical ethics and find the practical guidance of a step by plan more helpful, as they are already used to working with different consecutive steps in clinical practice. Further research is required to base this assumption on scientific evidence. Furthermore, in clinical practice it is important that a conclusion is reached, so further plans for the patient can be made. Not reaching a conclusion is not an option, as it has to be decided what to do, or not to do.

There is a wide variety of the proposed step-by-step plans. Some frameworks are composed of multiple steps, with explicit phases that have to be completed. Other frameworks are less specific and give more general, vague directions. Some of these step-by-step plans do not provide specific moral guidance on what to take into consideration and as to what would constitute a morally acceptable conclusion. Other frameworks have more moral content, meaning the presentation of moral principles and other considerations that can guide the decision making process.

The 'traditional' principles of beneficence, nonmaleficence, autonomy and justice were most commonly used. As these different moral principles often come into conflict with each other in morally complex situations, principles need to be balanced against each other. According to Beauchamp and Childress, this process of balancing requires participants to make judgments about the relative weight and strengths of moral principles in a specific case. This involves "sympathetic insight, humane responsiveness, and the practical wisdom of evaluating a particular patient's circumstance and needs".(25) However, only a few ethical frameworks provide a method for balancing moral values when they come into conflict with each other, which is often the case in morally complex situations.

Some of the frameworks are general in nature. These kind of very 'broad' frameworks are likely to be of limited use during a moral case deliberation, as they do not give enough practical guidance as to what is the best course of action. For instance, a framework consisting of 'encounter-ethical loading-ethical unloading' might not be easily applicable by healthcare workers who are not familiar with these ethical terms.

Ethical frameworks are meant to guide medical professionals towards an ethically acceptable solution in a morally complex situation. The reason why these situations are complex is because there is a tension between different moral values. This means that during deliberations moral values and medical issues need to be considered and balanced against each other, such as autonomy, patient preferences, beneficence, quality of life issues, chances of success of a certain medical intervention etcetera. To truly reach a morally well-balanced decision in a certain case, we consider it to be of vital importance that all relevant moral and medical issues are addressed during the deliberations.

To ascertain all relevant moral values are discussed during the deliberation we are of the opinion that ethical frameworks should be more than a step-by-step plan, but should also incorporate relevant moral values. For instance, a step such as 'identify different alternatives' could possibly fail to incorporate an important value like 'autonomy' or 'beneficence'. These moral principles might be the four principles as proposed by Beauchamp and Childress, supplemented by several derivative rules such as rules of veracity, confidentiality, privacy, and fidelity.

Ethical frameworks can be used in different circumstances. In our research, most frameworks were applied to a theoretical case, two described a meeting when the framework was used. In one study, a comprehensive moral deliberation led by an ethics consultant was described. Most hospitals provide ethics support services such as a moral case deliberation led by an experienced ethics consultant. During a comprehensive moral case deliberation, participants reflect upon a specific moral question, within a structured conversation led by a trained, neutral facilitator.

During moral case deliberations it will become clear which moral values will conflict with each other. These tensions need to be resolved during the deliberations. To avoid that this balancing of moral principles becomes a black box, and is solely based on intuition, we are of the opinion that an ethical framework should incorporate a method to balance values during the deliberations. This could be the method as described by Beauchamp and Childress, where participants add relative weights to the moral principles in question.

CONCLUSION

Healthcare workers are increasingly faced with morally complex decisions in older patients. To aid in these situations, several ethical frameworks are proposed. These frameworks can function as an analytical tool during (comprehensive) moral case deliberations. Most ethical frameworks we found are step-by-step plans, that can play a role in structuring these deliberations. We feel that frameworks with a step-by-step-plan are preferable, as clinicians who have to work with them are generally not well trained in medical ethics and are already used to follow consecutive steps in medical guidelines. Many of the frameworks we found are step-by-step-plans, that do not include any moral values that need to be balanced. These types of frameworks run the risk that certain moral values, such as autonomy or beneficence are 'missed' during the deliberations. Clinicians might not think of bringing these values up, as they are probably unfamiliar with them. If an ethical framework does not specify these values as being of importance in a moral deliberation, it is uncertain that these values are actually being taken into consideration, and there is no warranty the decision that has been taken is morally acceptable.

Moral dilemmas are often caused by a conflict between different moral values, such as autonomy and beneficence. However, we found that many frameworks do not provide a way to balance these possible conflicts between moral values. These types of frameworks run the risk that the final conclusion that is reached remains a black box, as it is not clear how the conclusion is reached. The conclusion and course of action might therefore be difficult to explain to outsiders who were not part of the deliberations.

Frameworks that do not include moral values and provide guidance as to how moral values should be balanced cannot guarantee that all relevant aspects and moral values are taken into consideration and that the final conclusion cane made clear to outsiders.

We therefore suggest that ethical frameworks should contain: 1) a step-by-step plan to structure moral deliberation; 2) moral values to guarantee morally relevant aspects are being taken into consideration, and 3) an approach or method to resolve possible conflicts between moral values. We realize morally complex situations cannot be resolved in one 'correct' way and several options might be morally acceptable.

TABLE 1: Included studies

First author (ref. no)	Year	Ethical principles	SBSF	Balancing values	Ethical framework	Pt pref	Steps
Bolmsjö IA (2)	2006	Teleological:, goal of care, ethical constraints (self-determination, fairness, relevant evidence-based knowledge and the nurse's good life), structural constraints, nurses ethical competence.	yes	Make a priority list of the alternatives, weigh the orders of priority against each other and taking into account the ethical side-constraint of fairness	Model developed by Sandman: identify and describe the normative situation - identify and describe the different possible alternatives - assess the different alternatives - decide, implement and evaluate	+	4 (12)
De Vries M (3)	2012	Ethics of care	yes	no	1 focus on the uniqueness of every human being and the particularity of every situation; 2 focus on dependence and asymmetric relations of power within the human relationships; 3 recognition and acceptance of the vulnerability of human beings; 4 focus on human beings as relational beings needing interpersonal relationships in order to be able to flourish	+	4
Ferrie S (4)	2006	Moral values unclear	yes	no	Step-by-step approach: express the question - guidelines? - gather objective information - define key terms - consider and discuss with stakeholders	-	5
Fins JJ (22)	1997	Beneficence, nonmaleficence, autonomy, justice	yes	no	1 assess the patient's medical condition; 2 determine and clarify the clinical diagnosis; 3 assess the patient's decision-making capacities, beliefs, values, preferences and needs; 4 consider family	+	10

					dynamics and the impact of care on family members and others intimately concerned with the patient's well-being; 5 consider institutional arrangements and broader social norms that may influence patient care; 6 identify the range of moral considerations relevant to the case in a manner analogous to the clinical process of differential diagnosis; 7 suggest provisional goals of care and offer a plan of action including plausible treatment and care options; 8 negotiate an ethically acceptable plan of action; 9 implement the agreed upon plan; 10 evaluate the results of the intervention; 11 undertake periodic review and modify the course of action as the case evolves		
Fleming DA (5)	2007	Moral values unclear	yes	no	Pellegrino: 1 clarify the facts; 2 identify that there is an ethical concern; 3 frame the issue (who decides, by what criteria, (biomedical good, best interests of the patient)); 4 identify and resolve the conflict; 5 make a decision	+	5(7)
Gordon JS (6)	2011	Beneficence, nonmaleficence, autonomy, justice, combined with common morality	yes	no	Four topics method: analysis of medical indications, patient preferences, quality of life issues, contextual features	+	4
Haslam L (7)	2019	Autonomy, non-malfeasance, beneficence, justice, fidelity and veracity	yes	no	Corey 8 step framework: 1 identify the problem or dilemma; 2 identify the potential issues involved; 3 review the relevant ethical codes; 4	-	8

					know the applicable laws and regulations; 5 obtain consultation; 6 consider possible and probable courses of action; 7 enumerate the consequences of various decisions; 8 choose what appears to be the best course of action		
Hayley DC (8)	1996	Beneficence, respect for persons, fidelity, justice	no	no	Framework based on beneficence, respect for persons, fidelity, justice	-	n/a
Kaldjian LC (9)	2005	Beneficence, nonmaleficence, autonomy, justice, rights, consequences	yes	Determine the best course of action and support it with reference to one or more sources of ethical value	Systematic approach: state the problem - data gathering and organizing - ask: is the problem ethical? - ask: more information needed? - determine best course of action - confirm adequacy and coherence of the conclusion	+	5 (9)
Kokiko J (10)	1995	Beneficence, autonomy, justice	yes	no	R.O.L.E.: risks of medical treatment, opinion of the patient, life quality, external factors	+	4
Low JA (11)	2017	Beneficence, non-maleficence, utilitarianism, distributive justice	yes	no	Four topics approach by Jonsen: 1 medical indication; 2 patient preference; 3 quality of life; 4 contextual features	+	4
Miller PL (23)	2000	Beneficence, nonmaleficence, autonomy, justice	yes	no	Four topics method: analysis of medical indications, patient preferences, quality of life issues, contextual features	+	4
Monod S (12)	2011	Autonomy, beneficence, nonmaleficence, distributive justice, dignity, integrity, vulnerability	yes	For each option, clarify how the option helps or does not help to solve the conflicts between the principles	Guide for ethical reflection: identify clinical relevant facts and clarify ethical situation – identify patient's sociofamilial context – identify care responsibilities of stakeholders – identify values considered by stakeholders – analyze ethical conflicts at stake – identify all possible	+	4(8)

					options – identify consensual option that best integrates values of the patient, stakeholders and health professionals – discuss moral justification		
Schenck DP (13)	2002	Beneficence, nonmaleficence, autonomy, justice	yes	Assess the role of virtues in the situation: what a given principle means in this case and balancing it against the moral claims of each of the others	Algorithm for biomedical decision-making: outline medical facts - outline non-medical issues - assess goods important to the case - apply principles to the case - assess role of virtues - compare with prior cases - make recommendations	-	7
Schroeter K (14)	2002	Autonomy, beneficence, nonmaleficence, justice, fidelity, veracity, respect for others, treating patients equally, respect for dignity and worth, supporting patients' rights and choices	no	no	Autonomy, beneficence, nonmaleficence, justice, fidelity, veracity, respect for others, treating patients equally, respect for dignity and worth, supporting patients' rights and choices	-	n/a
Schwarte A (24)	2001	Autonomy, justice, beneficence, sanctity of human life, non-maleficence	yes	No	Four stages ethical decision-making: 1 each team member states his opinion, 2 determining underlying reasons for initial position, 3 discussing concerns of the group 4 plan of action	-	4
Stinson CK (15)	2004	Utilitarism (positieve value over disvalue) Beneficence, Nonmaleficence, autonomy, justice	yes	no	Four topics method: analysis of medical indications, patient preferences, quality of life issues, contextual features	+	4
Tjia A (16)	2012	Beneficence, nonmaleficence, autonomy, justice	yes	no	Four topics method: analysis of medical indications, patient preferences, quality of	+	4

					life issues, contextual features		
van der Steen JT (17)	2000	Beneficence, nonmaleficence, autonomy, justice	yes	no	Checklist of considerations (value to patients health status, other important factors, role of family, role of nursing staff, decisive status)	+	7
Wells JK (18)	2007	Autonomy, veracity, justice, fidelity, beneficence	yes	no	The ethical encounter-the ethical loading-the ethical unloading	-	3
Wicclair MR (19)	1991	Beneficence, nonmaleficence, autonomy, justice	no	no	General framework of the four principles beneficence, nonmaleficence, autonomy, justice	-	n/a
Wlody GS (20)	1990	Beneficence, nonmaleficence, autonomy, justice, human dignity, privacy, quality of life	yes	no	Wlody model for addressing ethical issues in nursing: assessment, advocacy and action	-	3(12)
Wright MT (21)	2009	Traditional ethical rules or moral principles: e.g. beneficence, nonmaleficence, autonomy, loyalty, fairness	yes	no	Four topics method: analysis of medical indications, patient preferences, quality of life issues, contextual features	+	4

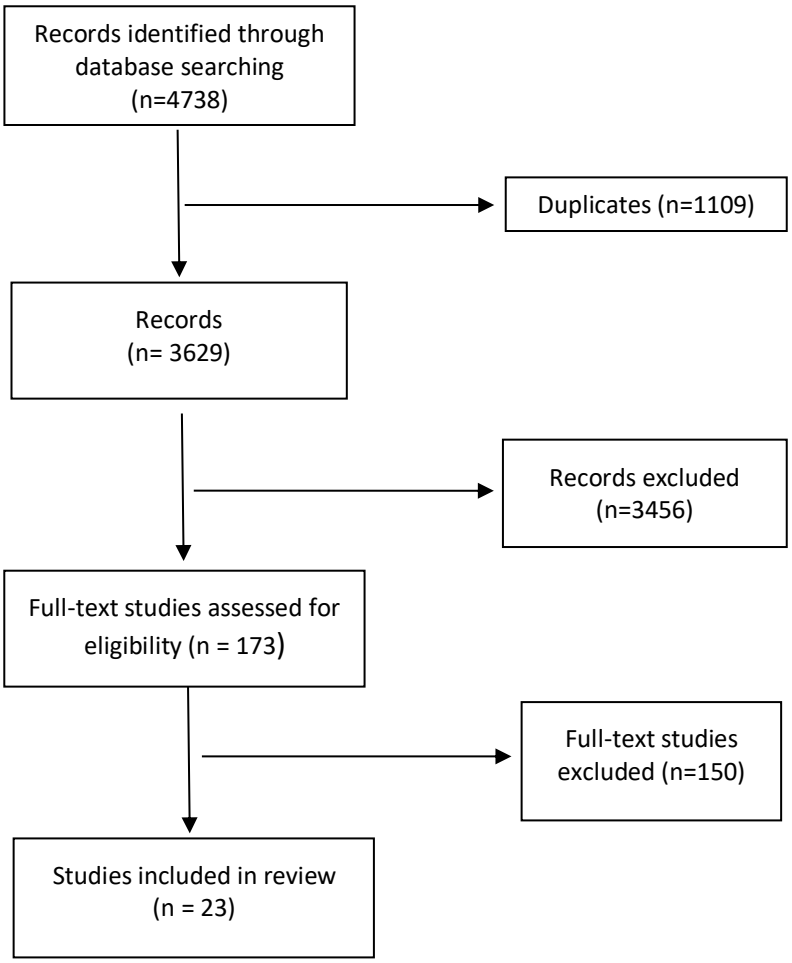
TABLE 2: Detailed information on type of study, aim and context

First author (reference no)	Type of study	Aim of the study	Context
Bolmsjö IA (2)	Descriptive study with case discussion	Use a teleological model for analysing nurses' everyday ethical situations in dementia care	Nursing home
de Vries M (3)	Descriptive study with case discussion	Introduction of an ethical approach, seen from the perspectives of traditional medical approach and ethics of care in older patients with cancer.	Home situation and hospital
Ferrie S (4)	Case study with application of a model	Quick guide to ethical theory in healthcare in nutrition support situations	Hospital
Fins JJ (22)	Case study with application of a model	Present a method of moral problem solving in clinical practice	Hospital
Fleming DA (5)	Descriptive study	Not mentioned	Nursing home
Gordon JS (6)	Case study with application of a model	Examine the methodological strengths and weaknesses of the applicability of the four-principle approach	Hospital
Haslam L (7)	Case study	Demonstrate the application of the Corey et al 8-step framework for ethical decision-making	Hospital
Hayley DC (8)	Descriptive study	Give an understanding of why ethical issues in the nursing home are different than in the hospital setting.	Nursing home
Kaldjian LC (9)	Descriptive study with case discussion	Offer a systematic strategy that situates clinical ethical reasoning within the paradigm of clinical reasoning	Hospital
Kokiko J (10)	Descriptive study with case discussion	Provide a framework to act as a springboard for thought in ethical decision making and to assist in the integration of ethical thought into everyday practice	Hospital
Low JA (11)	Descriptive study	To highlight relevant ethical red flags and discuss the 4-topics approach in patients with neurodegenerative disease	Home situation and hospital

Miller PL (23)	Case study with application of a model	Application of a model to guide ethical decision making in a burn treatment	Hospital
Monod S (12)	Descriptive study with case discussion	Propose a guide for health professionals to appraise ethical issues related to nutrition support in severy disabled elderly persons with nutrition difficulties	Unclear
Schenck DP (13)	Descriptive study with case discussion	An attempt to pursue the importance of character and virtue ethics in patients with head and neck cancer	Home situation and hospital
Schroeter K (14)	Descriptive study with case discussion	Help perioperative nurses relate the ANA code of ethics to their own area of perioperative practice	Hospital
Schwarte A (24)	Case study with application of a model	Discuss various ethical principles in relation to nutrition cessation in the terminally ill	Hospice
Stinson CK (15)	Case study	Explore legal issues, discuss ethical guidelines and identify techniques for conflict resolution in voluntary stopping eating and drinking	Hospital
Tjia J (16)	Descriptive study with case discussion	Review of ethical principles, how to apply a 4-stage ethical framework and provide practical considerations for medication discontinuation	Nursing home
van der Steen JT	Conceptual study	Describe a method for the development of a guideline that clarifies the steps to be taken in the decision-making process whether to forgo curative treatment of pneumonia	Nursing home
Wells JK (18)	Case study	Highlight the various ethical principles involved in clinical decision-making, and to suggest methods for resolution of ethical dilemma's	Home situation
Wicclair MR (19)	Descriptive study with case discussion	Describe how to distinguish between judgments based on clinical standards and those based on ethical principles	Home situation

Wlody GS (20)	Descriptive study with case discussion	Describe an original nursing model for addressing ethical issues at the bedside in critical care	Hospital
Wright MT (21)	Descriptive study with case discussion	A basic decision-making approach to common ethical issues in consultation-liason psychiatry	Hospital and nursing home

FIGURE 1: Flowchart



APPENDIX 1: Details of the search strategy

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('aged'/exp OR 'home for the aged'/exp OR 'nursing home'/de OR 'nursing home patient'/de OR 'aging'/de OR 'geriatrics'/exp OR 'gerontology'/de OR 'geriatric nursing'/de OR 'gerontological research'/de OR 'gerontologist'/de OR 'geriatric care'/exp OR 'geriatric patient'/exp OR 'elderly care'/exp OR dementia/de OR 'Alzheimer disease'/de OR (elder* OR ((for-the-aged OR older) NEAR/6 (care OR people OR subject* OR person* OR patient* OR home OR homes OR housing OR adult* OR women OR woman OR female* OR men OR man OR male*)) OR very-old* OR frail* OR old*-age* OR oldest-old* OR ((aged OR senior*) NEXT/1 (people OR subject* OR person* OR patient* OR population* OR care)) OR nursing-home* OR frail* OR aging OR ageing OR geriatric* OR Gerontolog* OR septagenarian* OR octagenarian* OR nonagenarian* OR centenarian* OR supercentenarian* OR gerontopsych* OR psychogeriat* OR geropsych* OR dementia OR alzheimer*):kw,ab,ti) AND ('ethics'/exp/mj OR (ethic*):ti) AND ('framework'/de OR 'model'/de OR 'theoretical model'/de OR 'decision tree'/de OR 'protocol'/de OR 'clinical protocol'/de OR 'clinical pathway'/de OR 'good clinical practice'/de OR 'practice guideline'/de OR 'professional standard'/de OR standard/de OR 'deliberation'/de OR 'ethical decision making'/de OR (framework* OR model* OR (decision NEAR/3 (tree* OR support*)) OR protocol* OR pathway* OR (good NEAR/3 practice*) OR guideline* OR Guidance* OR routine* OR recommendation* OR paradigm* OR guide OR standards OR regulation* OR code OR deliberation* OR decision-making):ab,ti) NOT ([animals]/lim NOT [humans]/lim) NOT ([Conference Abstract]/lim) AND [English]/lim

Medline Ovid

(exp Aged/ OR Health Services for the Aged/ OR Homes for the Aged/ OR Housing for the Elderly/ OR Nursing Homes/ OR exp Aging/ OR Geriatrics/ OR Geriatricians/ OR Geriatric Nursing/ OR Geriatric Assessment/ OR Geriatric Psychiatry/ OR dementia/ OR Alzheimer Disease/ OR (elder* OR ((for-the-aged OR older) ADJ6 (care OR people OR subject* OR person* OR patient* OR home OR homes OR housing OR adult* OR women OR woman OR female* OR men OR man OR male*)) OR very-old* OR frail* OR old*-age* OR oldest-old* OR ((aged OR senior*) ADJ (people OR subject* OR person* OR patient* OR population* OR care)) OR nursing-home* OR frail* OR aging OR ageing OR geriatric* OR Gerontolog* OR septagenarian* OR octagenarian* OR nonagenarian* OR centenarian* OR supercentenarian* OR gerontopsych* OR psychogeriat* OR geropsych* OR dementia OR alzheimer*).kw,ab,ti.) AND (* ethics/ OR (ethic*).ti.) AND (Models, Theoretical/ OR Decision Trees/ OR Clinical Protocols/ OR Critical Pathways/ OR Practice Guideline/ OR Practice Guidelines as Topic/ OR Standard of Care/ OR (framework* OR model* OR (decision ADJ3 (tree* OR support*)) OR protocol* OR pathway* OR (good ADJ3 practice*) OR guideline* OR Guidance* OR routine* OR recommendation* OR paradigm* OR guide OR standards OR regulation* OR code OR deliberation* OR decision-making).ab,ti.) NOT (exp animals/ NOT humans/)

NOT (news OR congres* OR abstract* OR book* OR chapter* OR dissertation abstract*).pt. AND english.la.

PsycINFO Ovid

(360.ag. OR Elder Care/ OR Nursing Homes/ OR exp Aging/ OR Geriatrics/ OR Geriatric Patients/ OR Geriatric Psychiatry/ OR dementia/ OR "Alzheimer's Disease"/ OR (elder* OR ((for-the-aged OR older) ADJ6 (care OR people OR subject* OR person* OR patient* OR home OR homes OR housing OR adult* OR women OR woman OR female* OR men OR man OR male*)) OR very-old* OR frail* OR old*-age* OR oldest-old* OR ((aged OR senior*) ADJ (people OR subject* OR person* OR patient* OR population* OR care)) OR nursing-home* OR frail* OR aging OR ageing OR geriatric* OR Gerontolog* OR septagenarian* OR octagenarian* OR nonagenarian* OR centenarian* OR supercentenarian* OR gerontopsych* OR psychogeriat* OR geropsych* OR dementia OR alzheimer*).ab,ti.) AND (* ethics/ OR (ethic*).ti.) AND (Models/ OR Decision Support Systems/ OR Treatment Guidelines/ OR Professional Standards/ OR (framework* OR model* OR (decision ADJ3 (tree* OR support*)) OR protocol* OR pathway* OR (good ADJ3 practice*) OR guideline* OR Guidance* OR routine* OR recommendation* OR paradigm* OR guide OR standards OR regulation* OR code OR deliberation* OR decision-making).ab,ti.) NOT (exp animals/ NOT humans/) NOT (news OR congres* OR abstract* OR book* OR chapter* OR dissertation abstract*).pt. AND english.la.

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Chapter 6: General discussion

INTRODUCTION

The aim of this thesis is to highlight some of the many medical ethical issues that arise when dealing with patients, especially vulnerable ones. The more vulnerable the patient becomes, the bigger the chance ethical issues will emerge. As education in medical ethics is often still an underrepresented part of medicine, research into the clinical perspective is important to substantiate an appeal for increased attention regarding this topic. All chapters of this thesis are based on real patients I met during my daily clinical practice.

The word ethics is derived from the Greek word ηθικός (ethikos), which means character, custom. Ethical behaviour is described as "doing good". Ethics as such has been described since the ancient Greek philosophers. In the 5th century AD, the first code of medical ethics was published. In the ensuing centuries, thoughts on how physicians should act were developed in different religious cultures. The concept of modern Western medical ethics has been introduced by Thomas Percival in a pamphlet in 1794.(1) In 1803 this was followed by the extended version "Medical Ethics, or a Code of Institutes and Precepts, Adapted to the Professional Conduct of Physicians and Surgeons".(2) Subsequently, the first Code of Ethics was published in 1847 by the American Medical Association. (3) In the following centuries there was no urgent need to re-evaluate this Code of Ethics. This changed in the 20th century. New ethical dilemmas arose, caused by, amongst others, the rapid and substantial developments in medicine, the expanding technical possibilities as well as the increasing life expectancy of people. In 1969, Jan Hendrik van den Berg caused a stir in the Dutch medical world when he described the increased medical technical possibilities and the accompanying ethical questions in his book "Medical power and medical ethics" in 1969.(4) Van den Berg argues that the new code of medical ethics should be "to preserve, save and prolong human life, if and when this is considered meaningful". Van den Berg narrates that the law to preserve life at all costs and efforts stems from a time where the physician had very limited possibilities to treat, let alone cure a patient. Thus, all medical power, little as it was, should be employed to prolong life. With fast-growing technical possibilities, the medical power increased, and people survived who would have had no chance of living decades ago. He calls them 'victims of medical power'. Van den Berg tells us: "It is not allowed / acceptable / justified to use medical power to keep a human being from dying his or her right just death". The important question, when is a life deemed meaningful, remains complex and unanswered by Van den Berg.

The oath of Hippocrates included a phrase not to treat those who are "overmastered by their disease, realising that in such cases medicine is powerless".(5) Another term that has been used more recently is medical futile treatment. In modern medicine, futility has been described in many different ways.(6, 7) Most often, it is described as a treatment that should not be provided, according to physicians, even if the patient or relatives request it.(6) The question whether or not a treatment is either futile or meaningful is not a matter of a simple yes or no. There often is disagreement between the physician and patients or relatives, or between different physicians

regarding futility. Goals of treatment may differ, increasing the possibility of different points of view. Two ethical reasons are described for refusing to provide treatment: providing treatment would harm the patient, or providing treatment would harm other patients.(8)

The most commonly used framework in medical ethics nowadays is the "four principles" approach as developed in 1979 by Tom Beauchamp and James Childress in the textbook "Principles of biomedical ethics".(9) The four basic moral principles described are autonomy, beneficence, non-maleficence (do no harm) and justice, that should be judged and weighed against each other in an ethical dilemma. When facing a medical ethical dilemma, these four principles can help to decide on what is in the best interest of the patient. Medical ethical dilemmas occur in all patients, and even more so in vulnerable patients with multiple (medical) problems, such as geriatric patients. In order to assist patients with shared decision-making and advance care planning, it is important to consider all aspects of the patient's life, and shift from a disease-specific approach to a patient-goals oriented approach.(10) It is nowadays standard operating procedure in geriatric medicine to perform a comprehensive geriatric assessment (CGA), which describes a patient in four domains: somatic, psychiatric, psychosocial and functional.(11) However, patient goals, preferences and values are not yet a standard item in the CGA, but it could be of added value to standardise them as a fifth domain. Instruments such as the outcome prioritization tool (OPT) could be used to facilitate the discussion on goals and preferences of older patients.(12) The treatment goals described in this instrument are: life extension, preserving independence, reducing pain and reducing other symptoms, representing values such as autonomy and quality of life. The patient is asked to prioritise the treatment goals, both giving insight in the preferred goals of treatment and providing the patient, relatives and physician an option to discuss those wishes.

SCIENTIFIC RESEARCH IN VULNERABLE PATIENTS

Vulnerable patients are often not included in scientific research. One of the consequences of this is that guidelines and treatment protocols might be not applicable to this category of patients. The solution for this problem seems easy enough: include vulnerable patients in research to test such hypotheses and move toward evidence-based medicine. However, due to the heterogeneity of the vulnerable older patients it is very difficult to find comparable groups. The increased mortality as a consequence of high age prohibits a follow-up that is long enough, and with the presence of different medical conditions in each patient, it is challenging to ascertain the effect of a single intervention. In patients with cognitive disorders, inclusion is a challenging task to begin with.
In chapter 2.1 we have found that the distribution of dementia research over the different subtypes of dementia does not correspond with the prevalence we see in clinical practice. Alzheimer's disease (AD) was investigated in 84% of the studies, while the prevalence of AD in the general older population is estimated to be around 30%.(13) A greater number of dementia patients could derive benefit from the

conducted research if the research agenda were more closely aligned with disease prevalence. As it is now, findings cannot reliably be extrapolated to patients with moderate to severe cognitive problems that visit our outpatient clinic. Patients in more advanced stages of dementia are almost always excluded from clinical trials. While this is understandable considering the impaired autonomy and fragility of this group of patients, it is also worrisome, since it is of the utmost importance that this vulnerable group of patients receives adequate and appropriate care. In advanced stages of dementia, patients require specific care, and without evidence-based medicine, treatment of these patients is often a case of trial and error, mostly based on the personal experience of the physician. This problem does not occur exclusively in patients with dementia. Frail older patients are more often than not excluded from scientific research, with a combination of obstacles that prevent them from entering research protocols.(14) As a result, older patients are vastly underrepresented, especially when compared to the burden of disease and the amount of health care consumption.

In collaboration with ethicists, statisticians and patient associations, ways should be explored to include frail and even demented older patients in research. Written consent, given prior to the manifestation of a neurodegenerative disease, could help to include patients in more advanced stages of dementia. Clear and broader inclusion criteria could help to include a more extensive range of frail older patients. Pragmatic studies could also be of use to extend the applicability of randomized controlled trials to real-life settings, as these studies focus on the correlation between treatments and outcome in real-world practice, and not primarily on causative explanation. As a result, in a pragmatic study in- and exclusion criteria are not as strict as in regular clinical trials.

It is a challenge to convey treatment options to the vulnerable older patients, in a way that reaches the patient. Recall and understanding of medical information is difficult in all groups of patients, as studies show patients forget approximately half of the information that they have been given.(15) This problem is most likely increased in older patients suffering from hearing loss and with cognitive problems. As described in chapter 2.2, we conducted a systematic review on the value of consultation recording in older patients. Consultation recording was found to be an easy-to-use information tool, with a positive influence on patients' affective cognitive and behavioural outcomes and minor negative effects. Consultation recording will help people to decide on treatment options with maximum knowledge. More effort should be put in equipping consultation rooms with consultation recording devices, and making digital patient files accessible to patients so they can listen to recordings of consultations in their own home, surrounded by people who are close to them and should be in the know of the wishes of their loved-one. Consultation recording could also be of use to inform patients about possible inclusion in scientific research. With expanding possibilities in the digital area, primary investigators should offer patients a record of the consultation in which information of the study was provided, so patients can re-listen to it at home, with a spouse, child, or with his or her physician. The use of consultation recording

will most probably enhance the patient's understanding of and compliance to proposed treatments, interventions and research. Increased understanding on the side of the patient will benefit shared decision-making, and patient-participation. Medico-legal concerns have been issued regarding consult-recording. For instance, the possibility of patients using the recording for other purposes, or spreading them on social media. Another concern is the way to store the recording, and the period of time the recording should be saved. Recommendations on dealing with these issues have already been made, although further research is needed.(16)

ETHICAL ISSUES AND CONSIDERATIONS CONCERNING THE LAST PHASE OF LIFE

All medical ethics codes state that a physician must act in the best interest of a patient. To do so, it is important to be familiar with the views, values and convictions of a patient. In the case of a mentally competent, communicative patient this seems rather easy: options can be discussed, decisions can be made. However, there is always the possibility that a patient – or a patient's relatives in the case of mentally incompetent patients – wants a different course of action than the physician is offering. We investigated how physicians handle such a situation, as described in chapter 3.1. Frustration was felt, especially when relatives requested treatments or procedures on behalf of a patient. Disagreement with patients was described as less frustrating, because they were able to explain the reasons for the request to the physician. Differences in background, in particular religious differences, were mentioned as complicating communication.

Relatives cannot always comprehend that there are situations which medicine is unable to fix.(17) Disagreement with relatives is described as frustrating for physicians when treatment is requested they are convinced should not be provided as it is considered to be futile. This observation is especially important in the field of geriatric medicine. After all, in a significant part of the group of older patients, a time will come that they are no longer able to decide for themselves. In that case, the legal representative has to step in and decide on their behalf. Differences of opinion on what treatment to provide may occur when this representative is not informed of the wishes, convictions and values of the patient. In an ideal world, people talk about their wishes and values in a timely matter. However, ours is not an ideal world. Accidents happen, people suffer from acute illnesses, and treatment requests can alter over time. It has previously been found that 28% of community-dwelling senior citizens had discussed what terminal care they would want with their relatives, and only 2% had discussed the same topic with their physician.(18) As a result, physicians are often confronted with representatives who do not know what the patient would have wanted and are themselves also unaware of the wishes of their patients. Physicians all over the world describe issues in dealing with relatives when decision must be made.(19)

This poses a challenge. With regards to the medical part of the problem, the physician can and must rely on the professional opinion on whether or not a treatment is in a patient's best interest. However, there is often a grey area. The

patient could be harmed by the procedure, but there is also a chance of benefit. How to weigh those possibilities against each other without knowing the view of the patient? Studies show that relatives are not very accurate in predicting the wishes of the patient, and neither are physicians. In a study on cancer patients, there was a 54% outcome on agreement between patients and their support persons regarding the preferred end-of-life care.(20) When assessing the goals caregivers and physicians had for frail older adults, there was a low level of agreement one week after performing a Comprehensive Geriatric Assessment with discussion of treatment plan and goals with the caregiver.(21) Advance care planning could be used to bridge this gap of knowledge. The aim of advance care planning is to extend the autonomy of patients to stages in life where they have become unable to decide for themselves.(22) However, only a small proportion of people in society have an advance directive, even though the majority of the population indicates they do think about end-of-life issues.(23) When an advance directive is present, sometimes these documents are no longer up-to-date, and thus do not reflect current wishes and goals. Even in long-term care facilities, the percentage of patients with advance care directives ranges from 0 to 77%.(24)

The use of advance care planning options, such as written documents, should be advocated. In order to ensure the document reflect the wishes of the patient, a regular update of those documents by the patient as well as discussing those wishes and values with treating physicians is mandatory. It is also important to inform relatives of the content of the documents. With advance care planning, there is a greater chance of the proposed treatment being in accordance with the wishes, values and convictions of a patient. Further options for advance care planning should be explored. For instance, there is evidence that complex advance care planning interventions may be more effective in meeting patient's goals than documents alone.(22) Discussions regarding end-of-life decisions should be scheduled when there is no imminent life-threatening disease, and repeated on a regular basis, as people can change their mind, especially when faced with disease or decreased functionality. Goal is to prevent harmful overtreatment, and at the same time avert undertreatment. Advance care planning as well as shared decision making between patients, their physician and relatives is crucial to avoid both overtreatment and undertreatment.

To make physicians aware of overtreatment, the Steering Committee of the Royal Dutch Medical Association on End-of-Life-Care reported fifteen mechanisms that were thought to be important in the tendency of physicians to start a treatment instead of deciding to forego treatment and opt for less invasive options.(25) We investigated which mechanisms play a role in the consultation room of physicians with different working experiences and described the findings in chapter 3.2. We found that not all mechanisms were deemed equally important. Surprisingly enough, physicians attributed the mechanisms they felt played a major role, more to the relatives or the patient, and not to themselves. For instance, physicians described how they had experienced that in many cases the patient or relatives felt uncomfortable speaking about an impending death, and as a result communication

was hindered. The mechanism of the medical view taking priority was often used by the physicians to substantiate foregoing a treatment, as the treatment was deemed medically futile. We conclude that not all mechanisms proposed in the aforementioned report are equally applicable to real-life cases. Describing mechanisms that can drive overtreatment, by patient, relatives or physician is important to create awareness of the existence of those drivers. When understanding the motivation for requests for treatments that are medically futile, ways can be sought to find agreement without harming the patient or putting an unnecessary strain on healthcare and its professionals.

Research in other countries shows similar results. The requests and demands of the relatives and uncertainty of lack of knowledge on patients' wishes were some of the described factors.(26) Some reasons why physicians provide futile treatment were the characteristics of the treating physician and the orientation towards curative treatment as well as inexperience with death and the process of dying. A second factor was the input from the patient or relatives, including requests and demands. The third major factor that was mentioned were hospital factors such as degree of specialisation and availability of tests and interventions. It is not easy to withhold treatment or tests that are readily available. To further reduce the provision of futile treatments, physicians should be trained in aiding patients through the dying process, society should be made aware of the limits of modern medicine and advance care planning should be implemented as a standard part of treatment decisions.(26) Making patient preferences standard content of the medical file will help making sure that the goals of the patient's treatment are reached.

INTERVENTIONS IN VULNERABLE PATIENTS

Percutaneous endoscopic gastrostomy

Some medical treatments are proven not to be in the best interest of a patient. For instance, in the case of an advanced dementia, with consequences such as swallowing disorders of food and liquids, insertion of a percutaneous endoscopic gastrostomy (PEG) tube is not indicated, according to several guidelines,.(27-29) In chapter 4.1, 4.2 and 4.3 we explore the effects of PEG insertion on survival in patients with advanced dementia.

In our study performed in several hospitals, including a relatively large group of patients receiving percutaneous endoscopic gastrostomy, we found that patients with dementia had higher mortality rates than patients without dementia. Reasons why this procedure is still performed in this particular group of patients, notwithstanding evidence of actual harm and higher mortality rates, are diverse and include both medical and nonmedical arguments such as beliefs regarding benefits of a PEG tube, lack of knowledge of the natural course of dementia, and fear of letting the patient die hungry. Consequently, relatives and physicians can struggle with the perceived concept of letting a patient starve. However, there is ample evidence that in this specific group of patients, it is both medically and ethically right not to provide artificial nutrition. As physicians, we should protect patients from this

harm, explain the reasons why to grieving relatives, but hold our ground when meeting with resistance. Insertion of a PEG-tube in a patient with advanced dementia and accompanying swallowing disorders is a medically futile and a harmful procedure that should be avoided.

Organ donation following euthanasia

As end-of-life situations are a common phenomenon in the group of vulnerable patients, the topic of how a patient wants to die should be broached. In the Netherlands, patients can receive euthanasia when due criteria are met. In more recent years, several patients have requested to donate organs following euthanasia. Organ donation following euthanasia (ODE) could be a new way to obtain scarce organs. However, the combination of two morally challenging procedures requires careful consideration of all pertinent arguments. In chapter 4.4 we explore whether ODE is morally acceptable, based on a case from our own hospital. We have mapped out the moral and procedural safeguards that should be installed to make ODE morally acceptable, such as strict separation of the two procedures. Several questions still remain. For instance, as ODE can be considered a possible source of donor organs, should the possibility of ODE be mentioned to all patients requesting active euthanasia to ensure a maximum number of organs? Is that morally acceptable? Should patients who are to receive euthanasia automatically qualify for ODE, or are extra precautions needed, to assess the request for donation apart from the request for euthanasia? ODE can give meaning to a patient's death, but further research is needed which extra safeguards are needed.

TREATMENT DECISIONS IN VULNERABLE PATIENTS

Making treatment decisions for the vulnerable patient is tailor-made medicine. Shared decision-making, advance care planning and taking wishes, values and convictions of the patients into account are all necessary to decide on treatment options. An ethical framework, designed for these decisions in the group of vulnerable patients, would be helpful to assist physicians and patients when making choices. Such a framework should ideally contain a step-by-step approach, moral values and an approach to balancing the moral values that are important in this specific case. In our review, described in chapter 5.4, we found that although several ethical frameworks for complex medical decision-making are described, none of those contained all the aforementioned aspects. As healthcare workers are increasingly faced with morally complex decisions in older patients, it is important that an ethical framework is developed that is easy to use, emphasizes the values at stake and provides a way to resolve possible conflicts between moral values. Such a framework can help to discuss a moral dilemma in a structured way, taking into account all values that play a role in the dilemma. In the end, a framework can assist patients, relatives and physicians in finding the best treatment option for a patient.

CONCLUSIONS AND FUTURE DIRECTIONS

In this thesis, the challenge of medical decision-making in the vulnerable, often older, patient is explored from different perspectives. There are several issues that are of great importance in this process.

Foregoing medically futile treatments or interventions

Medically futile treatments should not be performed. When a treatment or intervention is deemed futile, that is: has no chance of improving the life of the patient, the decision must be made to forego that treatment or intervention. Even when it means a conflict arises between physician and relatives. The interests of the patient should come first at all costs. As physicians we have an obligation to explain our decisions to patients or relatives to the best of our abilities, but we should hold our ground and not give in to demands for futile or even harmful treatments. We must identify futile treatments and formulate in clear guidelines why such treatments should not be started. Referring to other physicians, to let them "fight the battle" with patients or relatives is not the right thing to do, both from the point of view of the patient or relatives who are given false hope, but also on behalf of the other physician who now has to fight two battles: the first to contradict the words of the referring colleague and the second not to start the treatment. The policy that futile treatments will not be performed should be clarified at the earliest possible occasion, often by the general practitioner, or nursing home physician.

However, to move forward in avoiding treatments and interventions that will not benefit, the medical world must first decide on the terms we use. Perhaps, replacing the word "futile" by "medically inappropriate" might be a step in the right direction.(6) By adding the word medically, it might be clearer to patient and relatives that the decision is primarily made by the healthcare professionals. Furthermore, by using the term inappropriate, it would be logical to next discuss what actions are deemed appropriate, focusing on what can be done, instead of what will not be done.

Disclaimer for applicability to vulnerable older patients in research and guidelines

Guidelines and research should contain a disclaimer on which patients were not included, and who are therefore not eligible in receiving treatment according to the guideline. Every research article and guideline should clarify what patient groups were investigated, and what categories of patients were excluded. As a consequence, it should be clear in what patients the results of the study or the recommendations in a guideline are applicable, and in what patient tailor-made medicine should be the best option. In older, vulnerable patients, tailor-made medicine is almost always indicated, but this is not always clear in guidelines. Guidelines should have a separate section on vulnerable, older patients, as is nowadays more and more often the case. Researchers should think of novel

options to include vulnerable, older patients in research, such as clear and broader inclusion criteria, as well as pragmatic studies.

Awareness of wishes, values and convictions of vulnerable patients.
When a physician takes a patient history, composes a medical file or writes a letter to a colleague, there should be a separate section on the wishes, values and convictions of the individual patient. This will help both physician and relatives to decide on behalf of a patient, in case the patient has become mentally incompetent. Advance care planning should be an integrated part of our medical care, requiring regular updates as people can and will change their mind. As physicians, we should broach this subject as a standard part of decision-making. Questions such as: "Where would you like to die? In hospital or at home?" or "Have we ever discussed the topic of resuscitation or admission to the intensive care unit" have to become taboo-free subjects of conversation. This requires that we, physicians and other healthcare professionals, accept that death and dying is an inevitable part of living. Learning to talk about death has to become standard curriculum material.

Ethics as a valuable part of day-to-day clinical practice.
As a result of an ageing society and ever-expanding medical possibilities, physicians working with vulnerable patients will encounter medical ethical issues on an almost daily basis in clinical practice. In order to ensure physicians know how to decide on the best option for the patient, more attention should be given to education on ethics, not only in the bachelor or master phase, but also during the training to become a medical specialist and in additional training. An ethical framework has to be developed that is easy to use, emphasizes he values at stake and provides a way to resolve possible conflicts between moral values. Ethicists are indispensable in hospitals, but it is also important that physicians with an interest in medical ethics are given the opportunity to acquire knowledge of ethical theories and take training courses in clinical ethical deliberation. Hospitals should actively facilitate these developments. These ethics-educated physicians should be available to advise colleagues on the course of action and support them, if necessary, in withholding treatment when deemed medically futile and other difficult decisions. By familiarizing physicians with dealing with medical ethical issues, the overall knowledge of medical ethics will increase.

Further research into the role of relatives.
Avoiding conflicts with patients or relatives demanding futile treatments must be explored and addressed. Relatives are often not able to convey the wish of the patient, as it is rarely discussed before an acute moment of illness. On them befalls the difficult task to defend the patient's values, while not knowing what those values are, and being hampered by their own values, as well as the fear of letting the patient down, being held responsible for potential harm by society, or being blamed for the death of the patient, with whom they do not want to part yet. In a society that is putting more and more emphasis on involving the patient, advocating patient participation and making the patient the director of their own

medical journey, it is difficult to decide when to switch to the maternalistic way of medicine in which the professional decides that there are no more options left to benefit the patient. Studies show that physicians have concerns about the level of understanding of harms and benefits by both patient and relatives.(30) Further research is needed to look into the role relatives play, what the health professionals can realistically expect from them, and how to explain that not all requested treatments or procedures are going to be performed. The terms of futility, advance care planning, harm and benefit should be familiar to all physicians, and explained to non-medical society. Ideally, advance care planning should become an integrated part of all contacts between a patient and a health professional.

And then COVID-19 happened…

While writing the introduction and discussion of this thesis, the COVID-19 virus flooded the world as we knew it. The group of patients that are dearest to me, the vulnerable older patients, is the group that is affected the most. In nursing homes in The Netherlands, hundreds of people died. Some of my outpatients died. The majority of my patients was afraid. What if they became ill? They understood and accepted that the pneumonitis would be more dangerous to them. But would there still be a possibility to be admitted to the hospital, or would there be no place for them? Would younger people be favoured once again, as is so often the case in our modern society? They would isolate themselves, to avoid being infected. The ensuing loneliness was at first accepted, but acceptance is growing thinner as time goes by, and the side effects of isolation become more and more evident. When admitted to hospital, most patients do survive. But the impact of the disease and the functional decline all patients experience is impressive. The majority of older patients needs extensive rehabilitation, and it looks like most of them will be unable to regain the level of functioning they had before they became ill. In the case of COVID-19, higher age seems to be an important complicating factor. As a consequence, the Dutch Health Council has advised the government to prioritize citizens aged 60 or more in receiving a vaccine against COVID-19, as soon as it becomes available.(31)

As physicians, we are faced with new challenges. How do we make sure our patients will survive, or, if that is not possible, how can we allow them to die in an acceptable way? The presence of relatives at the side of a dying patient, common practice in modern medicine, was suddenly a huge issue. Physicians worldwide struggle with these topics.(32, 33)

As chair of the ethical committee on COVID-19 of the Erasmus MC I was, all of a sudden, faced with impossible questions, that could not remain unanswered. Decisions had to be made, plans had to be formed. In a major effort, all professionals teamed up to deliver the best possible care to as many patients as possible. Ethical issues emerged and are still emerging at this moment. In a multidisciplinary team of ethicists, jurists, spiritual counsellors, nurses and physicians, we continue to try and provide ethically just answers to all the new

scenarios we are facing. COVID-19 has proven that now, more than ever, ethics should be an integrated part of everyday medicine.

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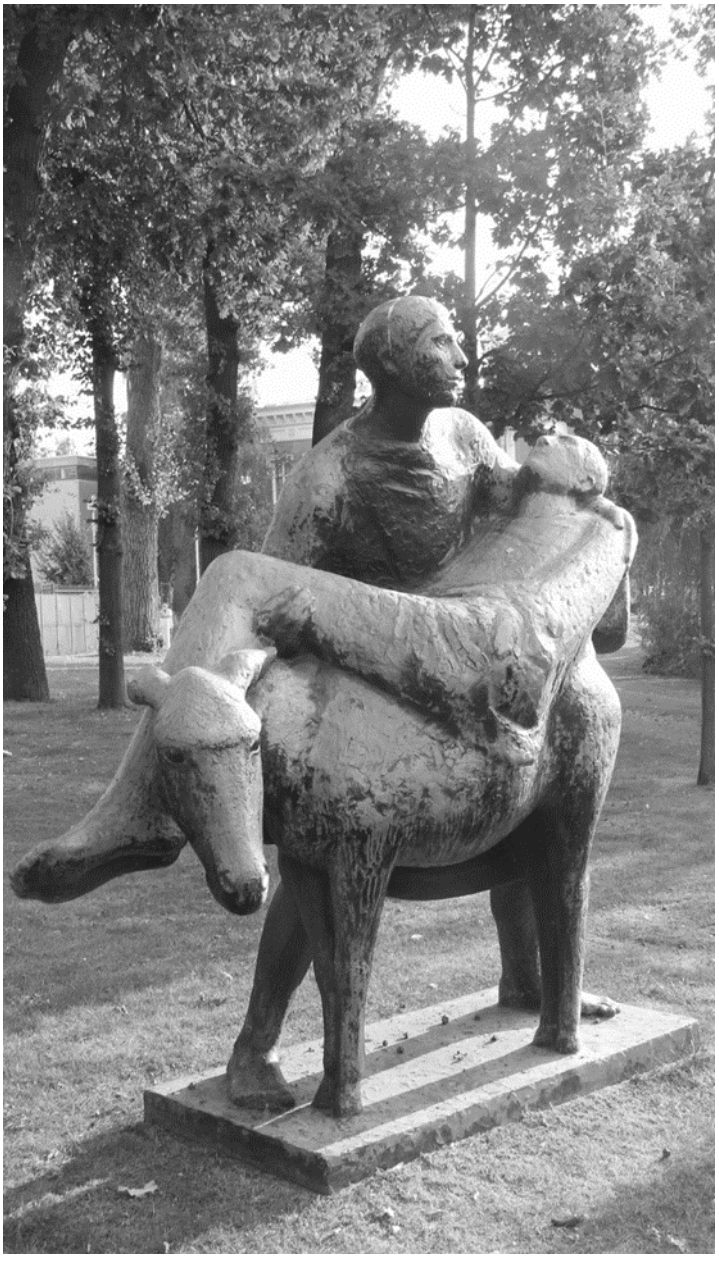
Chapter 7: Summary



Chapter 7.1 English summary.

Medical ethics has been first described in the 5th century AC, when the first code of medical ethics was developed. The concept of modern western medical ethics was first introduced by Thomas Percival in 1794, detailing the physicians' moral authority and independence in service to their patients. Percival emphasized on the profession's responsibility to care for the sick, and underlined individual honor. In the 20th century, with increasing technical possibilities and the accompanying expanding life expectancy new medical ethical dilemmas arose. Up until that point in time, a physician did all he could to save the patient, whereas the options were limited. In the 20th century, physicians were faced with rapidly growing developments in medicine, becoming able to treat diseases previously previous considered untreatable. One of the consequences was that physicians started to realize that perhaps an intervention, although technically possible, should not be performed. The intervention might harm the patient, even when life was prolonged. The term medical futility appeared, described by Jecker et al as "An intervention that is unlikely to produce any significant benefit to the patient". Medical futility includes both quantitative futility (the likelihood that an intervention will benefit the patient is exceedingly poor) and qualitative futility (the quality of benefit an intervention will produce is exceedingly poor)". Although this seems reasonable and ethically right, some physicians find it difficult to withhold possible treatments, Patients and their relatives often request physicians to "to all that can be done". Consequently, medical ethical dilemmas are much more common in the modern day and age than they were in the pre-technical age.

There is a great need for education on medical ethics, frameworks to support physicians in minor medical ethical dilemmas and access to ethical support for aid in complex situations. Beauchamp and Childress describe four principles of medical ethics (autonomy, beneficence, non-maleficence and justice) in their book "Principles of Biomedical Ethics (1974". These four principles are considered the cornerstone of medical ethics. Essential in applying these four moral principles is the weighing of the different aspects against each other. In vulnerable older patients, medical ethical dilemmas arise often, because of the multiple (medical) problems and the accompanying interference with social and cognitive aspects. This thesis focuses on a number of medical ethical dilemmas in these vulnerable older patients.

Chapter 1 gives a general introduction and provides the aims of the thesis, using the patient story of Mr. A. Mr. A is an 82-year man suffering from an aspiration pneumonia caused by swallowing problems as a result of progressive dementia. With the case of Mr. A as an outline, different aspects of ethical decision-making in a vulnerable older patient are depicted.

In **chapter 2** different aspects of the challenges of performing scientific research in vulnerable older patients are described. In **chapter 2.1**, an analysis is made of dementia research and its exclusion criteria. The aim is to obtain a clearer understanding whether the research participants represent the general dementia population. The distribution of dementia research is not consistent with the

prevalence of dementia subtypes in clinical practice. In **chapter 2.2**, a systematic review is conducted to provide medical professionals with insights into effects - both beneficial and harmful- of consultation recording for patients aged 50 years or older. Selected studies are analyzed on affective cognitive, behavioral and health outcomes. The results show that consultation recordings generally improve patient satisfaction, recall, fulfillment of needs for information and decision-making. Positive as well as negative effects on anxiety are reported. In conclusion, consultation recording is an important and easy-to-use information tool for older patients, as it can positively influence affective cognitive and behavioral outcomes.

Chapter 3 focuses on several different medical ethical issues in the vulnerable adult that are frequently encountered in daily clinical practice, with exploration of relevant ethical considerations. In **chapter 3.1**, the challenges that physicians encounter when their opinions on medical decisions differ from those of the patient or relative(s) are investigated. Physicians are interviewed on two patient stories from their own clinical practice, describing difference of opinion on treatments. In conclusion, physicians feel uncomfortable when a divergence of opinions turns into a disagreement, especially when relatives speak on behalf of the patient without evidence of the wishes of the patient. A disagreement between physician and patient is described as less frustrating, with patients explaining the reasons for their choice. Differences in background, particularly in religion, between physicians and patients or relatives are often mentioned as complicating factors in accomplishing good communication.

Chapter 3.2 describes a qualitative study on which mechanisms play a role when requests for futile treatments are made. With the fifteen mechanisms described in the report of the Steering Committee of the Royal Dutch Medical Association on End-of-Life-Care as a guide, physicians are asked what mechanisms had played a role. Of the fifteen mechanisms, three are mentioned most as being a driver of overtreatment: “Death is not a common topic of conversation”, “Never give up is the default attitude in our society” and “Patients culture and outlook on life influences their perception of death”. Some mechanisms are not mentioned at all as playing a role, and others are considered to be inhibitors of overtreatment. As an inhibitor of overtreatment, the mechanism “Medical view taking priority” is mentioned often. Physicians often use the medical perspective as an argument to explain why a treatment should not be started or continued.

In **chapter 3.3**, an exceptional ethical dilemma is described: a case of organ donation following euthanasia. A patient suffering from severe neurological disability requests euthanasia, accompanied by the wish to donate of as many organs as possible. Several different ethical issues are discussed. To summarize: organ donation following euthanasia could strengthen patient autonomy, give meaning to an inevitable death and create an extra source of donor organs. Organ donation following euthanasia can only be performed when physicians adhere to strict procedural safeguards. The most important safeguard is to keep the two

procedures, euthanasia and organ donation, as separate as possible, both during the preparations as at the moment of actual euthanasia and organ harvesting.

Chapter 4 focusses on futile medical treatments in vulnerable older adults, illustrated by the procedure of placement of a percutaneous endoscopic gastrostomy tube (PEG-tube) in patients with severe dementia. PEG-tube insertion in patients with severe dementia and swallowing disorders is described as being medically futile by multiple current guidelines. Swallowing disorders and inability to eat or drink is a sign of end-stage dementia, an incurable and lethal disease. However, insertion of a PEG-tube is regularly suggested and performed by physicians against the advice of these guidelines. Conversely, when physicians advice against or even refuse insertion of a PEG-tube, it is often the cause of a divergent opinion or even conflict between physicians and relatives. In **chapter 4.1** a case is described in which a conflict arose because relatives demanding a PEG-tube, against the advice of the physician. Next to a description of the case, considerations and recommendations for the physician are provided.

Chapter 4.2 provides an introduction to why patients with severe dementia and accompanying swallowing difficulties should not be tube-fed. Artificial feeding will not prolong life or lower the risk of an aspiration pneumonia. There is no evidence that patients with end stage dementia experience discomforting feelings of hunger and thirst. Furthermore, insertion of a PEG-tube creates major risks to the patients, such as the need for physical or medical restraints to avoid patients pulling out the tube, as well as distressing agitation. In conclusion, artificial feeding using a PEG-tube should not be started or continued in patients with severe dementia and accompanying swallowing disorders.

Chapter 4.3 reports on the prognosis of patients with dementia who receive a PEG-tube. All patients aged 70 years or older receiving a PEG-tube between 2009 and 2017 in four hospitals in the Southwest region of The Netherlands are included in the research. Survival and ethical considerations that play a role are explored. PEG-tube-patients with dementia have higher mortality rates than PEG-tube-patients without dementia. Patients and relatives should be informed in early stages of the disease of the natural course of dementia. In the end stage of dementia, safe ingestion of oral foods or fluids will no longer be possible. PEG-tube insertion and the administration of artificial nutrition does not prolong life, but decreases both quality of life, as well as quality of dying.

In **chapter 5.1** a narrative review of current ethical frameworks for decision making in the vulnerable older patient is presented. Multiple ethical frameworks are described, most of them step-by-step-plans. In conclusion, the suggestion is made that an ethical framework for decision making in the vulnerable older patient should contain both a step-by-step-approach to structure moral deliberations, moral values to guarantee all morally relevant aspects are considered and an approach or method on how to resolve possible conflicts between those moral values.

Chapter 6 contains a general discussion of the studies described in this thesis. This thesis provides novel insights in ethical dilemmas arising in the treatment of vulnerable older patients. It supplies suggestions on how medical ethics could be incorporated in daily medical practice. The wishes and preferences of the patient should become known to all parties involved in order to avoid that the patient would not have wanted. Medically futile interventions should not be started.

Chapter 7.2: Nederlandse samenvatting.

Medische ethiek werd voor het eerst beschreven in de vijfde eeuw voor Christus. Het concept van de moderne, westerse medische ethiek werd in 1794 geïntroduceerd door Thomas Percival. Hij beschreef de morele autoriteit en onafhankelijkheid van de arts ten dienste van de patiënt. Percival benadrukte de verantwoordelijkheid van de arts om te zorgen voor de zieke en diens individuele eer. In de twintigste eeuw, met steeds toenemende technische mogelijkheden en de daarmee samenhangende toenemende levensverwachting, ontstonden nieuwe medisch ethische dilemma's. Artsen deden tot die tijd alles wat in hun mogelijkheid lag om een patiënt te redden, maar de mogelijkheden waren beperkt. In de twintigste eeuw werden artsen geconfronteerd met snel toenemende medische ontwikkelingen. Ontwikkelingen, die hen in staat stelden voorheen dodelijke ziektes en aandoeningen te behandelen en zelfs te genezen. Als een gevolg hiervan begonnen artsen zich te realiseren dat een interventie, ook al was die technisch mogelijk, wellicht soms niet zou moeten worden uitgevoerd. De interventie zou de patiënt kunnen schaden, zelfs als het leven door de interventie zou worden verlengd. De term medische zinloosheid werd geïntroduceerd, omschreven door Jecker et al. als: "Een ingreep waarvan het onwaarschijnlijk wordt geacht dat het enig significant voordeel oplevert voor de patiënt". Medische zinloosheid bestaat uit zowel kwantitatieve zinloosheid (de waarschijnlijkheid dat een interventie goed is voor de patiënt is extreem laag) en kwalitatieve zinloosheid (de waarschijnlijkheid dat een interventie kwalitatief voordeel voor de patiënt oplevert is extreem laag). Alhoewel dit ethisch juist is en redelijk klinkt, zijn er artsen die het moeilijk vinden om patiënten behandelingen te onthouden die technisch mogelijk zijn. Patiënten en familieleden verzoeken artsen vaak om "alles te doen wat mogelijk is". Het gevolg is dat medisch ethische dilemma's zich tegenwoordig veel vaker voordoen dan in het pre-technologie tijdperk.

Er is een grote behoefte aan scholing over medische ethiek, frameworks met als doel artsen te helpen om te gaan met minder complexe medisch ethische dilemma's en om toegang te krijgen tot ethische ondersteuning in complexere situaties.

Beauchamp en Childress beschrijven vier principes voor medische ethiek (autonomie, weldoen, niet schaden en rechtvaardigheid) in hun boek "Principles of Biomedical Ethics (1974)". Deze vier principes worden beschouwd als de hoeksteen van de huidige medische ethiek. Essentieel in het toepassen is het afwegen van de diverse aspecten van deze vier morele principes. Medisch ethische dilemma's komen bij kwetsbare, oudere patiënten veelvuldig voor, als gevolg van de meervoudige (medische) problemen en de bijkomende wisselwerking met sociale en cognitieve aspecten. Dit proefschrift richt zich op een aantal medisch ethische dilemma's bij kwetsbare oudere patiënten.

Hoofdstuk 1 bevat een algemene inleiding en beschrijft de doelstellingen van het proefschrift, waarbij gebruik gemaakt wordt van het verhaal van meneer A. Meneer A is een 82-jarige man met een aspiratiepneumonie, ontstaan door slikproblemen bij zijn gevorderde Alzheimer dementie. Met het verhaal van meneer A als leidraad

worden verschillende aspecten van medische ethische besluitvorming bij een kwetsbare oudere patiënt besproken.

In **hoofdstuk 2** worden verschillende aspecten van de uitdagingen rondom het uitvoeren van wetenschappelijk onderzoek bij kwetsbare oudere patiënten toegelicht. **Hoofdstuk 2.1** laat een analyse zien van wetenschappelijk onderzoek naar dementie en de daarbij gebruikte exclusiecriteria. Het doel is inzicht te krijgen of de deelnemers aan deze onderzoeken een adequate weerspiegeling zijn van de algemene populatie van mensen met dementie. De distributie van wetenschappelijk onderzoek naar dementie komt niet overeen met de prevalentie van de subtypes van dementie zoals die wordt gezien in de spreekkamer.

In **hoofdstuk 2.2** wordt een systematische review beschreven. Onderzocht is wat de effecten zijn bij het maken van en beschikbaar stellen van een opname van een consult in de spreekkamer aan een patiënt (consultation recording). Hierbij is gekeken naar zowel positieve als negatieve effecten van consultation recording bij patiënten van vijftig jaar en ouder. Geselecteerde studies zijn geanalyseerd ten aanzien van affectieve, cognitieve, gedragsmatige en gezondheidsmatige uitkomsten. De resultaten laten zien dat consultation recording in het algemeen een positief effect heeft op patiënttevredenheid. Dat geldt zowel voor recall (welk gedeelte van het gesprek wordt onthouden) als voor de mate van tevredenheid over verstrekte informatie en de besluitvorming. Op het gebied van ervaren onrust worden zowel negatieve als positieve effecten van consultation recording beschreven. Concluderend is consultation recording een belangrijke en gemakkelijk te implementeren vorm van informatievoorziening voor de oudere patiënt: het heeft een positieve invloed op affectieve, cognitieve en gedragsmatige uitkomsten.

Hoofdstuk 3 richt zich op meerdere verschillende medisch ethische vraagstukken bij de kwetsbare volwassene, die regelmatig worden gezien in de dagelijkse medische praktijk, waarbij de relevante ethische overwegingen worden verkend. In **hoofdstuk 3.1** is onderzocht welke uitdagingen artsen ervaren wanneer zij met patiënten of familieleden over medische beslissingen van mening verschillen. Artsen zijn geïnterviewd over twee patiëntverhalen uit hun eigen praktijk. Gebruikmakend van een narratieve benadering hebben zij het verschil in opinie aangaande de beslissingen omschreven. De conclusie luidt dat artsen zich onprettig voelen als een verschil van inzicht verandert in een conflict, met name als familieleden namens de patiënt om behandelingen verzoeken, zonder dat bekend is welke wensen de patiënt daar zelf over heeft gehad. Een verschil van mening tussen arts en patiënt wordt als minder frustrerend beschreven, omdat een patiënt zelf de redenen voor een keuze uit kan leggen. Verschillen in achtergrond, zeker van religieuze aard, tussen artsen, patiënten en/of familieleden worden vaak genoemd als complicerende factor bij het streven naar goede communicatie.

Hoofdstuk 3.2 beschrijft een kwalitatieve studie waarin onderzocht is welke mechanismen een rol spelen als een verzoek tot een behandeling wordt gedaan, die medisch zinloos wordt geacht. Met de vijftien mechanismen, die worden beschreven in het rapport van de Stuurgroep Passende Zorg in de laatste levensfase van de Koninklijke Nederlandsche Maatschappij tot bevordering der Geneeskunst als leidraad, is aan artsen gevraagd welk van deze mechanismen een rol heeft gespeeld. Van de vijftien mechanismes worden drie het meest frequent genoemd als aanjager van overbehandeling: “Praten over levenseinde is niet gewoon”, “’Niet opgeven’ is de basishouding van onze samenleving” en “Cultuur en levensbeschouwing beïnvloeden de kijk op het levenseinde”. Sommige mechanismen worden niet genoemd, andere worden beschouwd als remmer voor overbehandeling. Het mechanisme “Bij besluit over behandeling is medisch perspectief vaak nog leidend” wordt vaak genoemd als remmer van overbehandeling. Artsen gebruiken het medisch perspectief frequent als argument om uit te leggen waarom een behandeling niet zou moeten worden gestart of gecontinueerd.

In **hoofdstuk 3.3** wordt een uitzonderlijk ethisch dilemma nader toegelicht: een casus met orgaandonatie na euthanasie. Een patiënt met ernstige neurologische restschade verzoekt om euthanasie, en heeft daarnaast de dringende wens zoveel mogelijk organen te kunnen doneren. Verschillende ethische kwesties worden in het artikel besproken. Samenvattend: orgaandonatie na euthanasie kan de autonomie van de patiënt versterken, betekenis geven aan een onvermijdelijk sterven en een extra bron zijn van schaarse donororganen. Het kan echter alleen als artsen zich houden aan strikte, procedurele richtlijnen. De belangrijkste voorwaarde is dat de twee procedures, euthanasie en orgaandonatie zo separaat mogelijk van elkaar worden doorlopen, zowel gedurende de voorbereidingsperiode als tijdens het moment van euthanasie en het uitnemen van de organen.

Hoofdstuk 4 beschrijft onderzoek naar medisch zinloze behandelingen bij kwetsbare oudere patiënten, geïllustreerd door de procedure van het plaatsen van een percutane endoscopische gastrostomie sonde (PEG-sonde) bij patiënten met een gevorderde dementie. Het inbrengen van een PEG-sonde bij patiënten met een gevorderde dementie en slikstoornissen wordt in meerdere actuele richtlijnen omschreven als een medisch zinloze handeling. Slikstoornissen en het onvermogen nog te kunnen eten of drinken is een teken van het eindstadium van dementie: een onbehandelbare en letale ziekte. Desalniettemin wordt door artsen het inbrengen van een PEG-sonde herhaaldelijk voorgesteld en uitgevoerd, tegen de richtlijnen in. Daartegenover staat dat regelmatig een verschil van mening of zelfs conflict ontstaat tussen een arts en familieleden van een patiënt met een gevorderde dementie en slikstoornissen als de arts negatief adviseert over het inbrengen van een PEG-sonde of deze interventie weigert. In **hoofdstuk 4.1** wordt een casus beschreven waarin een conflict is ontstaan omdat familieleden dringend verzochten een PEG-sonde in te brengen tegen het advies van de arts in. Naast een beschrijving van de casus wordt voorzien in overwegingen en aanbevelingen voor de arts.

Hoofdstuk 4.2 geeft een introductie in de redenen waarom bij patiënten met gevorderde dementie en slikstoornissen niet dient te worden gestart met sondevoeding. Kunstmatige voeding verlengt het leven niet en geeft geen verlaging van de kans op een aspiratiepneumonie. Er is geen bewijs dat patiënten verkerend in het eindstadium van dementie onaangename honger- of dorstgevoelens ervaren. Bovendien brengt het inbrengen van een PEG-sonde grote risico's en nadelen voor de patiënt met zich mee, zoals de noodzaak om de patiënt fysiek of medicamenteus te fixeren om te voorkomen dat de PEG-sonde door de patiënt wordt verwijderd. Bij de patiënt kan bovendien agitatie ontstaan. De conclusie is dat kunstmatige voeding via een PEG-sonde niet dient te worden gestart of gecontinueerd bij patiënten met gevorderde dementie en slikstoornissen.

In **hoofdstuk 4.3** wordt gerapporteerd over de prognose van patiënten met dementie die een PEG-sonde kregen. Alle patiënten van 70 jaar en ouder bij wie tussen 2009 en 2017 een PEG-sonde is ingebracht in vier ziekenhuizen in het zuidwesten van Nederland zijn geïncludeerd. Overleving en ethische overwegingen die een rol spelen zijn geëxploreerd. De uitkomst van het onderzoek luidt, dat PEG-sonde-patiënten met dementie hogere mortaliteitscijfers hebben dan PEG-sonde-patiënten zonder dementie.
Deze uitkomst leidt tot de aanbevelingen dat patiënten en hun familieleden al in de vroege fase van de ziekte dienen te worden geïnformeerd over het natuurlijk beloop van dementie. In het eindstadium van dementie komt een moment dat veilig innemen van voedsel of vocht niet meer mogelijk is. Het inbrengen van een PEG-sonde en het toedienen van kunstmatige voeding verlengt niet het leven, maar vermindert zowel de kwaliteit van leven als de kwaliteit van sterven.

In **hoofdstuk 5.1** wordt een narratieve review over de huidige ethische frameworks voor het nemen van behandelbeslissingen bij de kwetsbare, oudere patiënt gepresenteerd. Meerdere ethische frameworks worden beschreven, de meeste betreffen stap-voor-stap plannen. Concluderend wordt aanbevolen dat een ethisch framework voor het nemen van behandelbeslissingen bij de kwetsbare oudere patiënt dient te bestaan uit een stap-voor-stap-benadering. Het draagt bij aan het structureren van morele overwegingen, aan het waarborgen van morele waarden en het zorgt ervoor dat alle moreel relevante aspecten overdacht worden. Het is een methode om eventuele conflicten tussen morele waarden te beslechten.

Hoofdstuk 6 bevat een algemene discussie van de studies die beschreven worden in dit proefschrift. Dit proefschrift verschaft vernieuwende inzichten in ethische dilemma's die kunnen ontstaan bij de behandeling van kwetsbare oudere patiënten. Het geeft suggesties hoe medische ethiek kan worden geïncorporeerd in de dagelijkse medische praktijk. De wensen en voorkeuren van de patiënt moeten bekend zijn bij alle betrokken partijen om te voorkomen dat gestart wordt met behandelingen die de patiënt niet heeft gewild. Medisch zinloze behandelingen moeten niet worden gestart.

Chapter 8: Appendices

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