

Veileder

National guide

Decision-making processes in the limitation of life-prolonging treatment

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Preface

The provision of health care to patients with an adverse prognosis is challenging in several respects. While every viable option for medical intervention should be pursued, the overtreatment of a patient who has only days or few weeks to live may be untenable. Life-prolonging treatment is the recourse where curative treatment is not possible. Serious decisions must be made either to initiate or continue life-prolonging treatment or to refrain from initiating, or to discontinue, such treatment. In these situations, it is crucial that the clinical, ethical and legal aspects are given due consideration in a manner that fosters public confidence. Clinical ethics committees, which have been established at many Norwegian hospitals, will be important contributors to dilemmas posed by these matters.

Health care, ethics and the law are founded on key values-based choices, for example, as regards the duty to provide medical treatment and supportive care and as regards the patient's co-determination. The knowledge and values intrinsic to these disciplines provide health personnel with a sound basis for providing health care to patients for whom assessment of life-prolonging treatment is required. Professional values, however, cannot be relied on as the sole arbiters; the patient's own values must be taken into consideration. If the patient is unable to convey those values, the next of kin will be an important source for determining what the patient would have wanted. However, these values-based components are among the factors that often make decisions to initiate or discontinue life-prolonging treatment difficult.

The present guide was first published in 2009 and was informed by the most reliable knowledge that existed, by the systems that were established, and the legal rules in force at the time. The guide was scheduled for revision after three years. A process has been undertaken in which we gathered experiences from those who had used the guide in their clinical practice. Based on this feedback, a revised version was submitted for consultation to the working party that had participated in the first version, and was also submitted for ordinary consultation. Certain legislative amendments also entailed minor modifications to the wording. In the revision process, the emphasis was on simplifying and systematising presentation of the different topics. As an aid in everyday clinical practice, we also provide a list of the key questions that are pertinent when confronted with the situation. One general aim was for the guide not to be overly comprehensive, and as such, certain clinical issues have not been included.

The need for a guide to the process surrounding decisions regarding life-prolonging treatment has proved great. We hope that with this revision we have arrived at a guide that will serve both as a helpful aid in everyday practice, but also as a basis for in-service training and ethical reflections in each care unit.

We would like to extend our thanks to all the main contributors. A special thank you to Reidun Førde who, in this version as before, devoted extensive efforts to the guide.



Bjørn Guldvog
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1 Background

All decisions concerning medical treatment must be professionally responsible and compassionate. This entails that health care must be based on sound medical, health and ethical assessments, which also respect the rights of the patient. All treatment must be in the patient's best interests. Modern medicine offers extensive options for prolonging life, yet prolongation is not in the best interests of the patient if the treatment serves only to prolong suffering. Assessments of what course of action best serves the patient may be difficult and conflicting.

The intention of the present guide is to quality-assure decision-making processes associated with withholding or withdrawing life-prolonging treatment of seriously ill patients with an adverse prognosis, who, in the absence of such life-prolonging treatment, will die within a short space of time, that is, within days or weeks.

The aim is for the guide to provide a framework for such decision-making processes and support professional care-givers, the patient and next of kin. Because the guide is aimed at the health service as a whole, the need may arise for more detailed guides within certain clinical fields or institutions (1-3).¹

Life-prolonging treatment in the present context denotes all treatment and any interventions that may delay the death of a patient. An example of this would be cardiopulmonary resuscitation*, other ventilation assistance and cardiostimulatory drugs, clinically-assisted nutrition and hydration (intravenously or by nasogastric or gastrostomy (PEG) feeding tube), dialysis, antibiotics and chemotherapy².

*The present guide replaces the Norwegian Board of Health Supervision's circular IK-1/2002 "forhåndsvurdering ved unnlåtelse av å gi hjerte-lunge-redning og journalføring av disse" (pre-assessment in the withholding of cardiopulmonary resuscitation and recording of such assessments in clinical case notes) (4). Based on this guide, institutions are urged to draw up their own procedures for cardiopulmonary resuscitation.

¹ The present guide is not aimed at the treatment of mental disorders.

² The divide between life-prolonging and palliative interventions is not always equally distinct and in some cases, antibiotics and chemotherapy, for example, may be administered principally as palliation.

2 Summary³

1. Decisions concerning life-prolonging treatment must be informed by what, from a medical and health perspective, is the responsible course of action and in the patient's best interests, and by the patient's own wishes. If the basis for a decision is uncertain, treatment must be initiated until its benefit has been ascertained. The next of kin must then be informed that the treatment may be discontinued once the basis for the decision has been more fully ascertained.
2. The attending physician⁴ has a duty to ensure that the benefits of life-prolonging treatment outweigh the adverse effects on the patient from the treatment or the disease. No one can be required to administer life-prolonging treatment that is futile, or which is not professionally responsible.
3. The medical basis for the decision must be as reliable as possible. In case of any doubt and uncertainty, the threshold for seeking the advice of other competent health personnel must be low.
4. A decision to limit life-prolonging treatment should always be based on discussions in the multidisciplinary care team assigned to the patient. But the final decision is made by the attending physician.
5. Health personnel shall, in a considerate manner, ensure that patients who wish to do so, are given the opportunity to communicate their values and wishes surrounding end-of-life care. This is especially important for seriously ill patients who might need life-prolonging treatment in the near future, and ahead of high-risk interventions. No one has a right to information about life-prolonging treatment that would be futile, or which would not be professionally responsible.
6. The patient's next of kin shall be treated with respect and consideration, and shall receive necessary information if the patient consents to this. If the patient is not competent to give informed consent, the next of kin are to be informed if this is not contrary to the patient's or the next of kin's interests. Where possible, information must be obtained from the next of kin regarding what the patient would have wanted.
7. If the patient is a child, the parents shall receive information and give their consent for treatment. The child shall be given information and be involved depending on its level of maturity. If the parents refuse treatment that is in the child's best interests, the Child Welfare Services may be authorised to make decisions on the child's behalf. The more uncertain the basis for the decision,

³ For an overview of the recommended decision-making process, see also the flowchart on the final page.

⁴ The doctor that does the day rounds, or the doctor on call.

the greater the emphasis should be on the parents', or the child's, values and perceptions.

8. An informed patient, who is capable of giving informed consent and who does not wish to receive life-prolonging treatment, shall have that wish respected. It is important to establish whether the patient's wish to forgo treatment is due to circumstances that could be remedied.
9. If the patient is not competent to give informed consent, the attending physician has an independent responsibility for determining what the patient would have wanted. Great emphasis shall be placed on reliable and relevant information from next of kin, a valid living will (advance directives), or health personnel who know the patient, regarding the patient's wish not to receive life-prolonging treatment. An electronic record of the patient's wishes should be entered in the national summary care record.
10. Effective analgesia and other symptomatic therapy may have a life-prolonging effect. When life-prolonging treatment is withdrawn, palliative care should be continued or increased. The patient shall receive adequate pain-relieving treatment and other symptomatic treatment even where it cannot be precluded that the effect may be to hasten death.
11. In case of disagreement or conflict that cannot be resolved by discussion, someone outside of the care team should be consulted, such as another medical expert ("second opinion"/"renewed assessment"⁵) and/or a clinical ethics committee capable of examining the case in broader terms and providing input for objective discussion.
12. Decisions to limit life-prolonging treatment shall be recorded in the national summary care record, with due justification provided. The record should state when a new evaluation is to be carried out. The record must state which treatment is to be administered, and which is not, the medical basis for the decision, what information has been provided to the patient and the relatives, and the patient's own wishes and, if applicable, what information has been provided by next of kin.
13. Before life-prolonging treatment is discontinued, the necessary palliation and nursing interventions must have been instituted.

⁵ In the present guide, the Norwegian concept of "renewed assessment" is used synonymously with the international term "second opinion" in the sense of both a renewed assessment requested by the patient/next of kin, and renewed assessment at the initiative of the care providers. This is thus not consistent with the legal concept of renewed assessment used in Section 2-3 of the Patients' Rights Act (5).

3 When should limitation of life-prolonging treatment be considered?

3.1 When requested by the patient

The patient's request may also be communicated by next of kin.

3.2 Treatment is prolonging distress in the dying process

The treatment may delay death by hours, day or weeks, but pain and distress cannot be entirely alleviated. In some cases, active treatment may prevent a good end to life.

3.3 Treatment is prolonging a life in a state of great suffering

The treatment may be life-sustaining, but the physical and/or mental effects of the disease or of the treatment are very severe and distressing.

3.4 Permanent cessation of higher mental functions

The vegetative patient – persistent vegetative state. A vegetative state is characterised by wakefulness, but the absence of signs of consciousness as a result of major brain damage. Vital functions are retained (breathing, circulation and digestion of nutritional therapy), but the patient is wholly care-dependent. Awareness of "self" is presumed to be absent, although sleep-wakefulness cycles are retained. The patient has periods in which his or her eyes are open. The patient has no ability to interact with others, but reflexive reactions, including pain withdrawal response, may be retained. In order for this serious diagnosis to be made, the patient will have to have undergone thorough investigation by medical specialists (6-11). There is some discussion as to when a vegetative state may be regarded as persistent (chronic). Obviously this will depend on the cause of the brain damage. Patients with traumatic damage to the brain remain in a vegetative state only exceptionally. Moreover, the state should not be referred to as persistent until at least 12 months after the damage was sustained. In the case of non-traumatic brain damage, the probability of regaining consciousness is regarded as extremely low after 3-6 months. The vegetative patient must be distinguished both from patients in a so-called "minimally conscious state", which is characterised by severely reduced consciousness, but in which reliable non-reflexive behavioural responses are observed, and where the patient has retained a minimal awareness of self or the surroundings (12;13), and from coma patients.

3.5 Coma

A patient in a coma cannot be roused by any form of stimulus. Any behavioural responses are reflexive. The patient has closed eyes and no awareness of self or the surroundings. Coma rarely lasts for more than two to four weeks for patients who survive (14). If the prognosis indicates that the state is irreversible, with no prospect of improvement, it may be ethically defensible to withdraw life-prolonging treatment.

4 Frequently used terms

4.1 Acceptable quality of life

The majority of people hold that a minimum condition for acceptable quality of life is a certain ability to perceive one's own existence and that of others as expressed by contact and interaction, and that intractable pain or suffering can be alleviated. Quality of life must be assessed on the basis of the patient's expressed or assumed personal perception and expected prognosis with and without treatment. Patients with dementia may be capable of achieving acceptable quality of life.

4.2 Futile care

Both futile care ⁶ and quality of life are difficult to define and assess. No one is entitled to demand medical care that would be futile (15).

The following gives a few examples of what may be meant by 'futile care':

- Treatment with no effect, neither alleviating nor life-prolonging
- The likelihood of any positive outcome of the medical care is extremely small
- The benefit of the care is negligible in relation to distressing side-effects
- The benefit of the care is negligible in relation to the costs

There are different perceptions of how benefits and drawbacks should be weighed up. Personal, cultural and religious factors influence what is perceived as a life worth living. The wish for a dignified death will often influence what is perceived as futile medical care. In such cases, health personnel will be able to bring their knowledge and experience to bear. Their responses will also depend on the patient's opinions, or the patient's opinions as they are known to the next of kin.

Regardless of how futile care is defined, the drawbacks, distress and costs of the care are especially important to identify and consider when the probability of success or the anticipated effects are negligible.

In some cases it may be appropriate to initiate treatment even if it is regarded as unlikely that treatment will make a positive difference. The relatives will then have to be informed of this. In intensive care, for example, it may be difficult to say anything precise about the prognosis and the benefit of treatment initially.

There are no fixed criteria for when cardiopulmonary resuscitation is to be regarded as futile except in multiple organ dysfunction syndrome (16) and in cancer with extensive metastasis and functioning worse than WHO 2 (17). High age is no indicator in itself.

⁶ The term denotes the meaninglessness, ineffectiveness and purposelessness of care.

5 Central ethical perspectives

Patients have the right to supportive care and respect in all phases of life. The principles of beneficence, nonmaleficence ('first, do no harm'), respect for the patient's autonomy and dignity, and justice are central in any health service (18). The Norwegian health service is also deeply rooted in the ideal of solidarity, with a special responsibility for the weakest and those most in need of care.

- Respect for life and dignity. Respect for life is challenged in questions surrounding the withdrawal of life-prolonging treatment. Human dignity is linked to existence, not to functioning or abilities. The fundamental view of the inviolability of human beings cuts across creeds and moral values. This means that everyone has the same right to have their values confirmed and be treated with respect in all phases of life. Technifying and prolonging the process of dying when it involves suffering may violate the dignity of a human being. Respect for life includes respect for dying with dignity.
- The beneficence and nonmaleficence principles require, among other factors, that the benefit outweighs the drawbacks of treatment. Summing up for and against in this situation is rarely simple, and especially when death is a likely outcome. It is not necessarily in the interests of the patient to prolong life if it increases or prolongs suffering. The principal question is what is in the best interests of the patient from a medical and health perspective, that is, the most objective assessment and weighing of benefits and drawbacks entailed by the health care. This assessment must be supplemented by an individual approach to the patient's interests and values.
- All medical care is predicated on a valid legal basis; usually informed consent. The patient has the right to participate in decisions concerning his/her own health and own life. Patients may be generally opposed to medical care if they are competent to give informed consent and are free of undue pressure from their surroundings. Respect for the patient's autonomy and integrity requires productive and considerate communication with the patient and/or next of kin. This includes the requirement for health personnel to inform the patient so well that he or she is able to make the decisions that are right for him or her. The patient shall be given information about his/her own state of health and prognosis and about the effect of the treatment and side effects in an individualised, objective and balanced manner.

If the patient does not wish to receive information, or does not wish to participate in decision-making, this should be respected.

Respecting the patient's autonomy does not mean that the patient has the right to demand medically irresponsible or futile care.

- Competence to give informed consent entails that the patient is able to comprehend relevant information, apply the information to his/her own circumstances, and reflect on the basis of it, and is able to convey his/her own wishes (19-22). The greater the consequences of a choice, the stricter the requirements that should be made regarding competence to give informed consent. Competence to give informed consent is not an absolute and may be influenced by circumstances and vary from one hour to the next and depending on the nature of decisions to be made. The validity of informed consent should therefore be assessed specifically in relation to the decision to be made. In complex situations, it is helpful if competence to give informed consent is assessed by someone who knows the patient well. Simple resources are available for assessing competence for giving informed consent (23).

Competence to give informed consent requires that it is reasonably certain that the patient is able to comprehend his/her situation and articulate his/her “actual” intent. Depression or pain may cause the patient to be opposed to treatment that he/she actually wishes to receive. Within a reasonable time frame, health personnel should take steps to ensure that the patient’s competence to give informed consent is as reliable as possible before his/her competence is assessed. This includes reducing sedative medication (hypnotics and anxiolytics) as long as this may be achieved without needless distress to the patient, talking to the patient when he/she is most lucid, and treating any medical condition or disorder that affects competence to give informed consent (such as depression, hormonal disorders, neurological disorders, pain).

In many cases, competence to give informed consent is lost gradually as the disease or dysfunction progresses. A common dilemma is posed by people with dementia who make choices other people find inappropriate or undignified. It is difficult to determine at what point respect for the patient’s right of autonomy is in fact caregiver neglect. But assessments of competence to give informed consent are also subject to values-based opinion.

If the patient is not competent to give informed consent, any wish to limit life-prolonging treatment on the part of the patient, as known to the next of kin and health personnel, should be respected. In order for next of kin to engage and act as the patient’s surrogate (meaning spokesperson), they will need to receive information. If the patient is not competent to give informed consent, health personnel consequently have a duty to provide information to the next of kin, unless this is patently in conflict with the patient’s or next of kin’s interests.⁷

- Justice, one of the four principles of medical ethics noted above, includes equality in health care and responsible distribution of resources. Ethical rules for doctors and nurses emphasise the responsible distribution of national economic resources. This is also enacted in law in Section 6 of the Norwegian Health Personnel Act. The use of resources in one area may be at the

⁷ Certain legal aspects of consent and competence to give informed consent are addressed in chapter 6.

expense of other patients whose need for treatment is greater. Where medical care is assessed as being futile or of having marginal or highly uncertain benefit, the use of resources becomes a particularly important factor to consider. However, cost-benefit assessments must not serve as the sole basis for withholding life-prolonging treatment in a given case. The severity of the medical condition, the benefit of treatment and cost-effectiveness are independent criteria applicable to the right to essential health care, including for seriously ill patients.

- Withholding or discontinuing life-prolonging treatment in a seriously ill patient results in the death of the patient from the original disease, while in active euthanasia and assisted suicide, it is the “treatment” that foreshortens life (24).

The rules of ethical conduct for doctors and nurses attach importance to respect for the patient’s right of autonomy at the end of life. They do not recognise active euthanasia and assisted suicide as ethical. These rules emphasise that the act of not initiating or of discontinuing futile treatment is not to be regarded as active euthanasia. This is in keeping with ethical guidelines in the other Nordic countries and with declarations adopted by the World Medical Association.

- The act of alleviating suffering is a strong ethical obligation. This applies also in cases where intense pain may be relieved solely by drugs in such high doses that they may well hasten death. (25). Earlier death is then an unwanted “side effect”, not the intention of the treatment and is thus ethically tenable (26).
- The Medical Ethics Council of the Norwegian Medical Association regards clinically-assisted nutrition and hydration as medical interventions. The act of withdrawing nutrition and hydration is to be regarded as limitation of medical care. Many next of kin and health personnel find this particularly difficult. There is little to indicate that the withholding of fluids in dying patients results in thirst sensation or other discomfort as long as the mouth is moistened (27;28). Artificial hydration may also in some cases cause discomfort to the patient in the form of hypersecretion of mucus, oedema and dyspnoea (29;30).
- There is no ethically or legally relevant difference between withholding life-prolonging treatment and withdrawing life-prolonging treatment if the patient’s prognosis has been adequately established. Both the medical circumstances and the patient’s wishes may not have been ascertained at an early stage of medical care. If treatment is initiated pending clarification of the situation, it is important to explain to the patient, and/or next of kin, that the treatment is being administered under uncertainty and will be discontinued if it does not have the desired effect. This must be done in a respectful and compassionate manner.

6 Specific aspects of Norwegian health care legislation

6.1 Responsible conduct

All health care must be professionally responsible and diligent. This is set out in the Section 4 of the Health Personnel Act (31), Section 2-2 of the Specialist Health Services Act (32) and Section 4-1 of the Municipal Health and Care Services Act (33). The professional responsibility requirement is a legal standard that lays down general principles which will change with professional advances and shifts in values-based attitudes. This requirement may be regarded as an extension of what at any time would be recognised as good professional practice and consistent with ethical requirements and diligence of care.

6.2 Consent

One of the principal rules of Norwegian health-care legislation is that it is the patients themselves who decide both if they wish to receive treatment and if they do not wish to. This is laid down in Chapter 4 of the Patients' Rights Act (5).

Health care may be provided solely with the patient's consent unless legal authorisation in a statute or other valid basis in law exists for providing health care without consent. For the consent to be valid, the patient is to have received the information needed for gaining insight into his/her state of health and the content of the health care. Further, the patient must be competent to give informed consent.

- Necessary information in this context means that the patient is to have received the necessary information about his/her state of health and the health care, including, aims, content, methods, expected benefits and possible dangers and risks (Sections 3-2 to 3-4 of the Patients' Rights Act (5)). The information shall be provided in a considerate manner, adapted to the recipient's capacities and shall not be provided contrary to the patient's own wishes. The amount of information needed by the patient in order to be able to give valid informed consent or to refuse further treatment must be determined in specific terms. Health personnel do not have an obligation to provide information about futile or professionally irresponsible treatment.
- Competence to give informed consent in the present context denotes the patient's ability to make decisions in matters concerning health care. It is the attending physician, who, following specific assessment in the individual situation, decides if a patient is competent to give informed consent. It must be assessed if circumstantial factors might influence the patient's competence to give informed consent (medication, co-morbidity). Best efforts must be made to remedy such circumstantial factors on condition that this does not render the burden of symptoms excessive. It is a requirement that the patient shall be patently incompetent. In any doubt, the general rule applies that the patient shall be presumed competent to give informed consent.

The patient's right of autonomy is not limited to decisions that may be construed as sensible and rational. As long as the patient is regarded as competent to give

informed consent, as a general principle, a patient's decision to refuse treatment must be respected.

Another question is whether health personnel must comply with the patient's preferences as regards choice of treatment. As a general rule, it is the case that the patient's treatment options are restricted to those regarded as professionally responsible. Patients may not, with any binding effect, instruct health personnel to provide health care that is not professionally responsible or is unnecessarily costly.

Forcing treatment upon a patient against his/her wishes requires explicit legislative authorisation. Examples of such special legal provisions exist in the Patients' Rights Act (5). Chapter 4A and Section 7 on the duty to provide essential emergency health care - Health Personnel Act (31) (see section 6.4 in the present guide).

If legally competent patients are unable to give informed consent for, or refuse, treatment, the rules in Section 4-6 of the Patients' Rights Act (5) apply. The first paragraph states that the health care provider may make decisions concerning health care that are not radical in nature as regards scope and duration. The second paragraph states that health care entailing a major intervention for the patient may be decided on by health personnel. The criterion must be that the health care is regarded as being in the patient's best interest, with the probability that the patient would have consented to such health care. The same act also requires that the decision is to be made in consultation with other qualified health personnel, and where possible, after obtaining information from next of kin as to what the patient would have wanted. In order for next of kin to act as surrogates for a patient who is not competent to give informed consent, they must be provided with satisfactory information. In such cases, the right to information is therefore accorded to both the patient and the next of kin; see Sections 3-2 – 3-5 of the Patients' Rights Act (5), unless health personnel are in possession of specific information indicating that this is contrary to the patient's interests.

6.3 Consent on behalf of minors

In the case of children, the parents give informed consent on behalf of the child until the age of legal consent at 16 years (or 18 years if the person is not legally competent to give informed consent due to mental impairment). This is what is known as surrogate consent by a legally authorised representative. Parents also have the right to withhold consent on behalf of the child, but this right of refusal is subject to limitations. If the best interests of the child indicate that treatment should be instituted, a legal decision for transfer of legal custody of the minor child may be made. A provincial board of health may make legal decisions regarding treatment. Emergency law may also be applied if the treatment is urgently required (see below).

The child is required to agree to the decision insofar as this is natural based on the age and maturity of the child. From the age of 12 years, a child shall have the opportunity to state his/her opinions in any matters concerning his/her own health. But children younger than 12 years also have the right to comment and to have their opinions taken into consideration.

References to age and maturity in the wording of Section 4-4 of the Patients' Rights Act (5) entail that the child's right to have its opinion heard and given due emphasis

must be weighed against the particular circumstances. The withdrawal or withholding of life-prolonging treatment is so radical a decision that it requires great maturity on the part of the child. Against that, the parents have no right to prevent the involvement of a child who is old enough to comprehend the situation. Research indicates that children under the age of consent who have serious illness may be capable of making complex and rational decisions concerning their own treatment (34).

The premise of Norwegian law is that both parents must consent on behalf of a minor child. For treatment of trivial and ordinary conditions, the consent of only one parent is sufficient. The same applies if qualified health personnel assert that treatment is necessary in order to prevent harm to the child. However, both parents must still be involved; under the law, both have the right to state their opinion. Further, should one of the parents disagree with the other parent's consent to health care which health personnel assert is necessary, the objecting parent may lodge an appeal with the office of the provincial governor, who may decide that treatment is to be suspended pending a ruling on the appeal.

Where only one of the parents has legal custody of the child, Norwegian law prescribes that this is the parent who gives surrogate consent. Section 47, first para, of the Child Welfare Act (35) prescribes the other parent's right to information about the child. The other (non-custody-holding) parent also has the right to receive information about the child from the health service, provided that its duty of patient confidentiality does not apply to disclosures to parents. Information may be withheld by the health service if this would be injurious to the child.

The foregoing rules concerning parents apply correspondingly to any other legal guardian of the child, such as the Child Welfare Services, if they have gained custody of the child.

6.4 The duty to provide immediate health care and the right to refuse such health care

The duty to provide immediate health care set out in Section 7 of the Health Personnel Act (31) is worded as follows:

Health personnel shall immediately provide the health care they are capable of when it must be assumed that the health care is of vital importance. Pursuant to the Patients' Rights Act section 4-9 (5), necessary health care shall be given, even if the patient is incapable of granting his consent thereto, and even if the patient objects to the treatment.

When in doubt as to whether the health care is of vital importance, health personnel shall perform the necessary examinations.

The wording of the duty to provide immediate health care is aimed primarily at accidents and acute cases of illness and short-term health care. This is to ensure that persons who are unable to summon assistance, or who, due to shock, panic or the like, refuse urgently needed health care, are still able to receive essential first aid and assistance. Norway also has a long-standing tradition for including suicide

attempts in situations comprised by the duty to provide immediate health care in cases where the patient is not treated under the authority of the Mental Health Care Act (36).

Section 4-9 of the Patients' Rights Act (5) contains special provisions regarding the right of patients to refuse treatment in spite of the duty to provide immediate health care in certain situations. The first paragraph concerns refusal to receive blood products, and the right to hold a hunger strike. These will not be discussed further here. The most relevant in the present context is presumably Section 4-9 (2): a dying patient has the right to refuse life-prolonging treatment. If a dying patient is not capable of communicating his or her wishes regarding treatment, the health personnel shall refrain from providing health care if the patient's next of kin convey corresponding wishes, and the health personnel find, upon independent assessment, that these are consistent with the patient's wishes and that those wishes should obviously be respected.

In other words, if the patient is not competent to give informed consent, then decision-making competence rests with those who hold professional responsibility, but the next of kin must be consulted. Problems of interpretation may arise over this provision concerning who may be regarded as "dying". How impending must the moment of death be for a person to be "dying"?

Reconciling the patient's right to autonomy with the health personnel's duty to provide immediate health care may be difficult in the context of patients who are intractably ill and dying. There might conceivably be cases that do not sort directly under Section 4-9 (2) of the Patients' Rights Act (5), but where the duty to provide health care "of vital importance" should still be waived out of respect for the patient's autonomy, for example, if a patient competent to give informed consent wishes, following good communication, to not have to live and suffer any longer. How far one should go in forcing patients to undergo life-prolonging treatment which is medically indicated, but which the patient does not wish to receive, is a matter more for ongoing ethical reflection than for the details of legislation.

If the health care is of vital importance, pursuant to Section 7 of the Health Personnel Act (31), and the patient is a minor, the exceptions set out in Section 4-9 of the Patients' Rights Act do not apply. This means that health personnel have a duty to provide health care, that parents cannot refuse life-prolonging treatment or blood products on behalf of minor children, and that it is not necessary to refer the matter to the child welfare services in such situations.

6.5 Second opinion

A second opinion may be appropriate if the care providers, the patient or the next of kin are in doubt or disagree on the diagnosis, prognosis or which health care is professionally responsible. A second opinion entails that a second competent health care professional performs a new assessment of the patient's condition. However, in Norway, the term for second opinion – renewed assessment (*fornyett vurdering*) - is also used in the national health legislation in a more restricted sense. It is consequently important to be clear about which type of second opinion is at issue. The rules concerning renewed assessment in Section 2-3 of the Patients' Rights Act (5) give the patient the right to renewed assessment within the specialist health

service in certain situations and on certain terms.

The responsible conduct requirement set out in Section 4 of the Health Personnel Act (31) requires each health professional to procure assistance or to collaborate with more qualified professionals concerning medical conditions requiring more competence than that possessed by the original care provider. Therein lies the distinction between the two senses of the Norwegian second opinion; the seeking of a second opinion in this act is not at the instigation of a patient, but is determined by the care provider's interpretation of the situation.⁸ The duty to procure assistance or collaborate with more qualified personnel does not, however, cover situations in which the care provider has sufficient competence, but where uncertainty or disagreement persists as to the right course of action. In such situations, a clinical ethics committee will be able to elucidate the case more broadly.

Norwegian health legislation concerning second opinion in its restrictive 'renewed assessment' sense thus does not provide for situations in which doubt or disagreement arise concerning life-prolonging treatment. Equally, it is obviously important to cooperate on a referral for a second opinion in any doubt or disagreement on such vital matters. For a detailed description of second opinion and the proper procedure for this, see Section 7.1.

⁸ The draft version of the act states that, while the extent of the individual's qualifications may be determined objectively, the requirement for responsible conduct requires that the individual health professional assesses whether he or she possesses the requisite qualifications ...; see Proposition to the Odelsting no. 13 (1998-99) p. 216 (37).

7 Decision-making process

7.1 Medical basis

A decision to provide or limit life-prolonging treatment shall rest on the most reliable assessment possible of the medical facts in terms of diagnosis and prognosis. Where the medical basis for assessment is more uncertain or does not provide clear indication of the responsible course of action, other assessments, not least values-based assessments, will take on greater significance. All assessments must be recorded in the clinical case notes together with their justifications.

Those who treat the patient and who are familiar with the patient's situation from different perspectives (parent department, nursing staff) shall as a general rule participate in the decision-making process. This arrangement secures the necessary information for comprehensive decision-support and ensures that different opinions are heard. The attending physician makes the final decision.

The majority of prognostic assessments are subject to uncertainty. In case of uncertainty or disagreement surrounding the medical basis for the decision, the medical situation should be assessed by another unit beyond the patient's care team in the interests of a second opinion. If a second opinion is requested by the patient/next of kin,⁹ it should be obtained from a professional environment which both the health personnel and the patient/next of kin approve of and have confidence in. A second opinion has the status of an independent alternative to the first one. However, the second opinion does not take precedence over the first. If that were the case, one might end up with a situation in which one doctor decides how another doctor is to treat a patient, perhaps in conflict with that doctor's opinions. If the second opinion is at variance from the first, the patient shall be able to determine if treatment going forward is to be provided at the place where the second opinion was provided or at the original place of treatment. Where the patient is not competent to give informed consent, the rules in the Patients' Rights Act must be adhered to, as set out in Chapter 6.2.

The threshold for obtaining a second opinion in cases of doubt, uncertainty or disagreement concerning limitation of life-prolonging treatment should be low. This applies equally to decisions in care homes. Other care homes or the specialist health services may be consulted on matters concerning life-prolonging treatment; see the specialist health services' duty to advise local authority health services.¹⁰

⁹ In the present guide, the Norwegian concept of "renewed assessment" is used synonymously with the international term "second opinion" in the sense of both a renewed assessment requested by the patient/next of kin, and renewed assessment at the initiative of the care providers. This is thus not consistent with the legal concept of renewed assessment used in Section 2-3 of the Patients' Rights Act (5).

¹⁰ Section 6-3 of the Specialist Health Services Act (32) .

A second opinion may be given on the basis of a review of the patient's clinical case notes, by interview and/or examination of the patient by the health professional visiting the patient, or exceptionally, by the patient being transferred to the examining institution. Such transfers must be medically defensible and not cause unnecessary risk or discomfort to the patient.

7.2 Patient's co-determination, and communication with the patient/next of kin

7.2.1 Patient competent to give informed consent

A patient who is competent to give informed consent usually has the right to consent to or refuse medically indicated life-prolonging treatment. The patient's autonomy and co-determination are predicated on effective communication. Effective information and communication with the patient/next of kin are important in preventing uncertainty and disagreement.

Patients who are seriously ill and dying patients undergo different phases and have different needs for information and differing needs for active involvement (38). This makes it difficult to provide simple answers to when and how limitation of life-prolonging treatment should be discussed. Many seriously ill and dying patients, and their next of kin, fail to receive satisfactory information due to factors such as a lack of time, routine or competence on the part of health personnel (39;40). Many patients and next of kin have scarcely any knowledge of treatments, their side effects and about natural dying processes. Providing information about these aspects may allay fears and promote the ideal of well-informed choices and autonomy.

When initiating long-term life-prolonging interventions such as dialysis, connection to a respirator or PEG intubation, where possible, this provides an opportunity to discuss with the patient when and in what circumstances this treatment should be discontinued. In advance of major, high-risk interventions, following intensive care of patients with severe and chronic diseases (e.g. respirator treatment of a patient with advanced COPD or during dialysis), the patient shall be given the opportunity to convey her/his thoughts about the treatment. The attending physician, who might be the patient's regular GP, but above all, someone the patient trusts, should be responsible for discussions of this nature. Eliciting the patient's preferences in this way is a precondition for subsequently taking the patient's presumed wishes into account if competence to give informed consent is lost further down the line. The content of this type of preparatory discussion shall be documented in the patient's clinical case notes, communicated to the rest of the care team and transmitted in the event of hospital admission or transfer.

If he/she so wishes, a patient admitted on a long-stay basis to an institution such as a care home with nursing, shall be given the opportunity to talk about his/her situation, about what he/she regards as acceptable quality of life and a meaningful existence and asked to state their wishes in the event of a deterioration in their condition. If the patient so wishes, the next of kin should be invited to participate in such discussions. Studies indicate that many patients feel that the issues they face

are only rarely discussed, and that they are much concerned by these issues, as are the next of kin (41). Research also suggests that towards the end of life, next of kin have a greater need for information, while for the dying that need decreases (38).

Care homes must have well-established routines in place for discussions with patients and next of kin. Where possible, such discussions should be conducted while the patient is competent to make decisions, not least as a basis for sound decision-making in the event of acute disease when the competence to make decisions may be lacking. In the interests of providing sound and individualised care, it is the responsibility of the care home doctor to ensure that the patient's values and wishes surrounding life-prolonging treatment are ascertained well in advance, and that information about this is readily available if the patient is admitted to hospital or is referred for investigation and treatment by doctors who do not know the patient (42). A number of the Norwegian care homes have positive experiences of conducting preparatory discussions with patients and next of kin (43). It is recommended that discussions are conducted at the earliest opportunity, but the timing must be adjusted to suit the individual patient and the next of kin. The discussions should ideally be initiated in the form of general questions: How are you feeling now? What are your thoughts about the future? What would be the goals of the treatment for the patient and the health personnel? (44;45) The details of such discussions will need to be individualised (46). The care provider might provide information about life-prolonging treatment and inquire to what extent the patient would wish to receive such treatment (47). Patients, and where appropriate, their next of kin, should be asked to state how much information and detail they wish to be provided with, the extent to which they wish to participate in decision-making processes, and who should participate in those processes if the patient is not personally capable of, or interested in, participating (48).

In the case of short stays in hospital, the primary care providers, who know the patients, take on a particularly important role. The regular GP is responsible for addressing such matters in the care of seriously and chronically ill domiciliary patients (49;50), but must allow for the fact that the patient may decline to engage in this type of discussion.¹¹ The content of such discussions must be transmitted to the hospital or care home. Research indicates that it is important to hold this type of discussion early on when seriously ill patients are admitted to hospital (53;54). Studies conducted within the care home and hospitals sector suggest that the preferences of elderly patients are relatively stable (54;55).

Natural opportunities for raising the issues might be:

- on discharge/readmission due to complications/progression of chronic illness
- when the answer is no to the question "would you be surprised if the patient had died within a year?" (56)
- when curative treatment transitions to palliative care
- when the patient has irreversible organ failure requiring mechanical support (respirator, dialysis, heart pump)
- when the patient's prognosis is very poor based on clinical opinion or a recognised scoring system (57-60)

¹¹ Moreover, empirical evidence suggests that such discussions have been ill-received by patients and next of kin (40;51;52).

Often, it is the nursing staff who have close contact with the patient who are the first to pick up on the patient's wish to address concerns about life-prolonging treatment. Such wishes must be transmitted to other professionals and followed up by the attending physician for treatment if the patient so wishes. The patient/next of kin are typically in an emotionally vulnerable state. The arrangements for this type of discussion (time, place and setting), and the wording of the discussion should be chosen with care. Such discussions should be followed up.

Shortage of time should not prevent such discussions from being held. It is a managerial responsibility at both hospitals and care homes to ensure that the competence, framework conditions and routines exists for such discussions. Health-care personnel must acquire the skills required for conducting such discussions and both employers and institutions of education and training have a responsibility for ensuring that such skills are developed.

Where patients and next of kin lack adequate Norwegian language proficiency, an interpreter must be used. As a rule, it is preferable not to use next of kin as interpreters for the patient (61). It is important to be aware that patients from other cultures may have other ideals, preconceptions and preferences as regards both information and autonomy in the presence of serious medical conditions.

7.2.2 When a patient declines to be involved in decisions regarding life-prolonging treatment

Many patients prefer their doctor to make difficult decisions for them and do not want to be involved in the decision-making process. Such patients might find it offensive to have questions forced upon them about whether they wish to receive life-prolonging treatment, yet might still like to receive as much information as possible. It is important to establish what a particular patient wants regarding personal involvement and information. Basic forms are available for mapping the patient's preferences regarding information and participation in the decision-making processes, which may be useful for health personnel and patients alike (62). If the attending physician believes that a patient does not wish to be informed of his situation, the physician should elicit from the patient if the person's next of kin should be informed instead. If the patient declines this also, a record of this must be made in the clinical case notes and communicated to everyone in the care team. The next of kin should also be informed.

7.2.3 Adult patient who is not competent to give informed consent

A specific situational assessment must always be made of whether a patient is competent to give informed consent. Patients with pronounced dementia may also be capable of engaging actively in a discussion about discontinuation of treatment, and communicate this without words (63).

If a patient is not found competent to give informed consent, the doctor's decision regarding treatment shall be based on what, from a medical perspective, is in the best interests of the patient, and what is presumed to be the patient's own preferences (see Chapter 6.2). A conclusion on what may be presumed to be the patient's preferences might be based on:

a) Information from next of kin and health personnel who know the patient well

The majority of patients do not provide any advance directives in writing. Information from next of kin and health personnel who know the patient well, such as the patient's regular GP, is therefore of crucial importance. An assessment must be made as to the relevance and significance of the information and how recently it has been gained from the patient. Without this assessment, there may be uncertainty as to whether the information represents the patient's current wishes (64). The main focus is information about what the patient would have wanted in this specific situation, not what the next of kin or health personnel would want.

Information and good communication are crucial for the spirit of trust between the attending physician and the next of kin. Next of kin shall not be given responsibility for a difficult choice, which, by law, rests with the physician, but it is important to make every effort to achieve close cooperation between the care team and next of kin.

If information about the patient's own wishes is not wholly reliable, greater importance should be attached to a medical and health assessment of the patient's interests. If the medical basis for a decision, including a second opinion, does not provide an unequivocal indication of the next course of action, the wishes of next of kin should then be given greater emphasis.

b) Living will (advance directives)

In Norway, a living will or advance directives have no legal force. In executing a living will, the patient may have considered life-prolonging treatment and stated his or her own preferences in writing. Assessment of the extent to which this may be relied on might depend on how long ago the living will was executed, whether the patient may be presumed to abide by it still, or whether the patient has conveyed a change of heart to next of kin. The attending physician has a duty to assess specifically whether the living will applies to the situation at hand¹², or whether the patient might have had a change of heart. A living will may provide a useful opportunity for a discussion surrounding the patient's situation and the patient's own concerns. If a patient has a valid living will, this should be respected if it is clear that the criteria set out in the living will are met.¹³

c) Consultation with other qualified health personnel

Before limiting life-prolonging treatment in patients who are not competent to give informed consent, health personnel must consult other qualified colleagues in order to quality-assure difficult, discretionary opinions.

¹² But often the criteria set out in a living will do not entirely cover the clinical picture at hand. See, for example, Perkins 2007 (65).

¹³ The Norwegian Directorate of Health is in the process of drawing up a non-denominational living will template based on the current legal interpretation. In practice, this means that the signatory is required to have been in a sound state of mind, have understood the contents, and the will must have been renewed annually.

7.2.4 If the patient is a child ¹⁴

It is the right and duty of parents to make decisions in the best interests of the child. A child's personal involvement will depend on its age, maturity, experience and state of health. The parents have the right to be included in decisions concerning the child, but may not demand treatment which the attending physician does not find medically justified, and may not refuse treatment which the care team find to be in the child's best interest (see Section 6.3).

The care team must inform the parents objectively about the child's situation and prognosis and keep them updated on the child's condition. If the child has a progressive disease with an adverse prognosis, it will be helpful to have discussed what level of treatment is to be pursued in the event of a deterioration in the condition, where such decisions have to be taken rapidly. The child itself is also entitled to information and has the right to be heard.

It is the task of the health personnel to provide information in a manner adapted to the parents' situation. Above all, health personnel have a responsibility for ensuring that the child receives good health care and does not suffer needlessly. This includes providing the child and parents with the support and comfort they need.

¹⁴ The Norwegian Directorate of Health currently has a set of guidelines on palliative care in children in preparation. This is expected to be finalised by spring 2014.

8 Disagreement about the decision

Differing views of whether it is appropriate to initiate or discontinue life-prolonging treatment can be the source of highly emotional conflicts. This might be due to a breakdown in communication, disagreement on the medical basis for the decisions, or different personal values and lack of confidence in care providers. In any disagreement concerning diagnosis, prognosis and choice of treatment, a second opinion should be obtained, or the concerns should be referred to a clinical ethics committee¹⁵ (CEC). Consultation with a hospital chaplain, the medical department of the office of the provincial governor, the national patients' association, the consumer ombudsman for patients and users may also be helpful (see section below and the flowchart in Appendix 1).

8.1 Patient/next of kin assert that life-prolonging treatment should be discontinued, but the care team assert that treatment is in the patient's best interest

The care providers must provide thorough information about the purpose of the treatment and what can be achieved, and they must ascertain that this has been understood. If the patient is competent to give informed consent, is well informed and has not been subjected to undue pressure, the patient's right of autonomy shall be respected. It is important to establish why the patient is refusing treatment. If possible, and he/she consents, the patient shall receive counselling on any issues that influence the decision.

If the patient is not competent to give informed consent, the care providers must ascertain if the wishes of the next of kin correspond with what the patient would have wanted. Next of kin cannot prevent treatment which the care providers have reason to believe the patient would have wanted. In this assessment, health personnel shall take into account health assessments, but also information about what the patient would have wanted. If this information indicates that the patient would not have wanted treatment, this shall be respected.

8.2 Patient/next of kin want treatment, but the care team do not find it medically justified

Care providers must devote time to explaining the background to their own opinion, the medical and the values-based opinions. It is especially important to explain what state of health the patient would in all probability achieve through treatment, and the adverse effects that might be caused by treatment.

¹⁵ There are currently few CECs under the local authority health services, but several local authorities are working to establish them. CECs at hospitals should also be available to contact.

In such situations, the rationale for wanting treatment might be lack of confidence in the care providers. If so, a reassessment of the patient's condition would be appropriate. This may be achieved by further examinations, including repeats of previous tests (such as diagnostic imaging of brain damage). Bringing more assessments into play may help to instil greater confidence in the care providers' opinions in that the patient/next of kin might have the opportunity to talk directly with relevant specialists.

Obtaining a second opinion outside of the original hospital and referral to a clinical ethics committee may also serve to resolve disagreement.

In some cases, it may make sense to delay death on special grounds of concern, such as for example, to enable next of kin to be present at the time of death. In such cases, it is important to consider whether this might result in greater suffering for the patient. If not, and if continuation of treatment is not contrary to the patient's own wishes and is not unreasonably costly, there would conceivably be situations in which the decision is made to meet the wishes of a next of kin, for example, to administer antibiotics to a patient in a terminal phase, or to continue respirator treatment for a short period of time (hours or a few days). Prolonging treatment for a short period of time would also be justified if more time is required to resolve disagreements and/or come to terms with death.

Continuation of life-prolonging treatment in such situations will, however, not always reduce the conflicts¹⁶ and may also lead to false hope or even reinforce the disagreements. If life-prolonging treatment is continued in such situations, the rationale must consequently be communicated explicitly in order to avoid such outcomes if at all possible.

8.3 Disagreement among care providers

Disagreement and conflict within the care team¹⁷ should be discussed openly within the team. The basis for the disagreement, arising, for example, out of diagnostic and prognostic uncertainty, the patient's quality of life or what may be regarded as ethically tenable, should be established. If agreement is still not achieved, advice should be sought, for example from a clinical ethics committee, or an opinion should be requested from other specialists.

8.4 Disagreement among next of kin

It is not uncommon for next of kin to disagree both on what the patient would have wanted and on the right decision. According to Section 1-3 of the Patients' Rights Act, next of kin are accorded rights and obligations with regard to involvement, information, consent and right of access to clinical case notes: *"The next of kin is the person the patient identifies as such. If the patient is not capable of naming who is to*

¹⁶ According to a systematic review from 2004, antibiotics to treat pneumonia in end-of-life care of the very old have scarcely any life-prolonging effect and are therefore recommended only where they are the best means of relieving suffering (66).

¹⁷ Within local authority health services, the care team assigned to the patient has to cooperate on such decisions.

be recognised as next of kin, that person shall be the person who has the most lasting and regular contact with the patient, but based on the following order of precedence: spouse, registered partner, persons cohabiting in a quasi-marriage or quasi-partnership with the partner, non-dependent children (over the age of 18), parents or persons with custody of the child, non-dependent siblings, grandparents, other family members with a close relationship to the patient, legal guardian or special guardian."

Next of kin, including parents, may disagree amongst themselves. Efforts should be made to determine the basis for the disagreement. If the patient is not competent to give informed consent, the focus shall be the best interests of the patient and what the patient would have wanted. The final decision must be made by the doctor responsible for treatment, where appropriate following a second opinion or discussion within a clinical ethics committee.

8.5 Assistive procedures in case of ethical complexity, uncertainty and disagreement (see Appendix: Flowchart)

Clinical ethics committee (CEC) and right of appeal

In any case of disagreement, doubt or the absence of an unequivocal decision-making basis, the concerns may be discussed with the health trusts' clinical ethics committees. Some local authorities and care homes have established a clinical ethics committee. Local authorities/care homes that do not have a clinical ethics committee or similar body should consider establishing cooperation with a neighbouring local authority or health trust that has a clinical ethics committee, or establishing its own clinical ethics committee. These committees will be able to provide a multidisciplinary second opinion/renewed assessment, but on a broader basis than a purely medical second opinion. Above all, the committee will focus on values-based assessments drawing on the medical basis presented, and will take account of diagnostic and prognostic uncertainty, for example, by requesting a medical second opinion for further discussion. The mandate of the committee will also include interviewing all affected parties and ensuring that disagreement between different parties is clarified, taken seriously and discussed openly. The function of the committee is only to provide guidelines, although it may provide advice on request. The committee has no decision-making competence or any authority to issue sanctions.

Exceptionally, when conflict runs high, and the patient's/next of kin's confidence in the care team/health trust is minimal, it may be appropriate to bring a case before a clinical ethics committee under a different health trust in the interests of achieving the most impartial review possible.

If the issue mainly concerns uncertainty or disagreement surrounding a diagnosis or prognosis, then an independent medical second opinion which the patient/next of kin is confident in should be obtained.

The patient and next of kin can also seek assistance from the Norwegian Patients' Association, the Patients' and Users' Ombudsman or the office of the provincial governor. For any decisions already made, an appeal may be lodged with the office of the provincial governor.

9. Documentation, review and evaluation of the decision

A written record must be made of which treatment is to be given and not given, together with the basis for the decision. The record must also document which information was received from and given to next of kin and the patient, the patient's wishes, any disagreement and discussions along the way, and the values-based assessments informing the decision (see Sections 39 and 40¹⁸ of the Health Personnel Act) (31).

If the patient is transferred to a different institution or ward/department, a transfer record stating what the patient and next of kin have been told about the prognosis and treatment options, and also, if applicable, information about the patient's own wishes, must be forwarded. This may prevent misunderstandings and conflicts.

Once life-prolonging treatment has been limited, the patient's condition will still have to be reassessed on a regular basis, both because the situation may change and because of the need to ensure that the patient receives adequate palliative treatment and supportive care.

¹⁸ See also ordinance no. 1385 of 21 December 2000 on medical records (67).

10 When life-prolonging treatment is withdrawn

Once a decision has been to discontinue life-prolonging treatment, medical care shall be directed at the patient's symptoms and nursing needs and at the need for existential and psychological support.

A discussion will need to be held both within the care team, and if possible with the patient/next of kin as to whether life-prolonging treatment is to be discontinued rapidly or gradually, in order to provide individualised care. In making this decision, the main concern must be to prevent any suffering in the patient.

Withholding and withdrawal of life-prolonging treatment often happens in situations where the patient is mentally affected by illness or injury. In such cases, where there may be doubt about whether the patient is conscious or registering pain, the patient must be treated as if he/she feels pain and discomfort. If in doubt about whether the patient can hear, he/she shall be treated as if full hearing is present.

If agreement has been reached within the care team to withhold cardiopulmonary resuscitation in the event of cardiac arrest, this must be recorded in the clinical case notes. It may be important for the patient/next of kin to have consented to this decision. If cardiac or respiratory arrest occurs before information to withhold treatment has been provided, regard for the patient shall take first priority and non-medically-indicated CPR shall not be initiated.

The following provides advice about drug interventions following a decision to not initiate or to discontinue life-prolonging treatment. The assessments, information and rationale must be recorded in the clinical case notes as described in Ch. 7.1.

10.1 Treatment with medication:

A Regular medication

Many drugs may be withdrawn following individual assessment of whether withdrawal will cause discomfort and distress. This applies to drugs such as:

- drugs for endocrine disorders, including insulin
- drugs for lung diseases, including COPD/asthma medicine
- drugs to treat arrhythmias and heart failure
- anti-hypertensives and cholesterol-lowering drugs

B Symptom-relieving/sedative drugs/psychoactive drugs

Given that the focus of treatment is now to relieve symptoms, it is appropriate to continue this form of treatment, possibly in increased and adequate doses.

C *Antimicrobial treatment*

As a rule, it is appropriate to withhold antimicrobial treatment. Exceptions are where the treatment is for infection causing great discomfort such as local treatment for infections of the skin and mucous membranes. For expectorate-producing infections of the lower airways, the patient may be given glycopyrrolate or other expectorate-reducing drugs and morphine for suppression.

D *Vasoactive medication*

This class of drugs should be withdrawn, since they are used for supporting the cardiovascular system temporarily until it recovers its function.

10.2 Mechanical organ support

Mechanical organ support is usually withdrawn once a decision has been made to discontinue life-prolonging treatment. This does not always apply to ventilation support because of the risk of distressing breathlessness. A decision will need to be made as to whether this can be alleviated by opioids and sedatives.

10.3 Supplemental oxygen

In conditions relieved by supplemental oxygen, the patient may experience increased respiratory distress on withdrawal. The immediate relief provided by the oxygen must be weighed against any effect it might have in prolonging a distressful death. Often, symptomatic treatment with opioids and sedative drugs is important when oxygen therapy is curtailed.

10.4 Nutrition and hydration

If life-prolonging treatment is judged not to be in the patient's best interest, withholding of nutrition and hydration should be considered (68-70). This decision should be discussed with the patient and next of kin. If the patient is able to drink, he or she must be offered oral fluids.

Withholding nutrition and hydration may be an emotional hurdle for the patient's next of kin and care team. Information about natural dying processes and the benefits and drawbacks of administering fluids should therefore be shared with next of kin well in advance. Every effort should be made to achieve consensus through information and dialogue. Liberal use of symptom-relieving medication is appropriate if there is reason to believe the patient is in distress.

Good oral care is important in preventing discomfort. Evidence suggests that patients suffer no discomfort when hydration is withheld when they are dying (71). Reduced fluid intake may be a natural element of the dying process and research indicates that cancer patients and end-stage dementia patients do not experience discomfort when oral intake ceases (72). Even though clinically-assisted hydration may in some cases reduce adverse drug reactions, it may also cause increased discomfort (27;29). The benefit of clinically-assisted hydration must be assessed on a case-by-case basis (73). Intubation may cause discomfort.

10.5 Diagnostics

Unless essential in relieving the patient's adverse symptoms or for revising the basis for the decision, clinical investigations and diagnostics are contraindicated. This also applies to blood glucose testing and arterial blood gas sampling which are not necessary in palliative care.

10.6 On implementation of the decision

Once a decision has been made, follow-up should be planned in the form of discussions after some time, particularly if there has been disagreement within the care team or between the care team and next of kin. Next of kin must be given every reassurance that they bear no responsibility for the final decision.

11 Implementation and evaluation of this guide

The contents of this guide should be implemented in all parts of the health service that provide somatic health care for seriously ill patients with an adverse prognosis. The contents should be disseminated to institutional managers, health personnel, patients and next of kin. It is the responsibility of the enterprise or institution to facilitate sound decision-making processes and ensure that health personnel are familiar with relevant aspects of jurisprudence and ethics. The enterprise or institution is also responsible for preparing procedural publications for health care areas such as intensive care medicine, care home medicine and for the treatment and care of seriously ill children. (Guidelines for palliative care of children are in preparation within the Directorate of Health and are expected to be published in spring 2014.)

The enterprise or institution is required to have procedures in place for communication with patients/next of kin. Sufficient time must also be set aside for performing multidisciplinary assessments and for the requisite training and coordination entailed by these processes.

Specific issues addressed by the present guide may be used as the basis for teaching and seminars. The clinical ethics committees at hospitals and the managers of institutions, equivalent decision-makers at care homes, doctors on call at hospitals and other emergency medical services have a special responsibility for implementation and follow-up of the recommendations in this guide.

Where the guide does not provide sufficiently relevant guidelines, local or clinically specific procedural handbooks should be prepared, which are founded on the inputs of management and clinical settings.

The guide will be evaluated and revised within 5 years' time.

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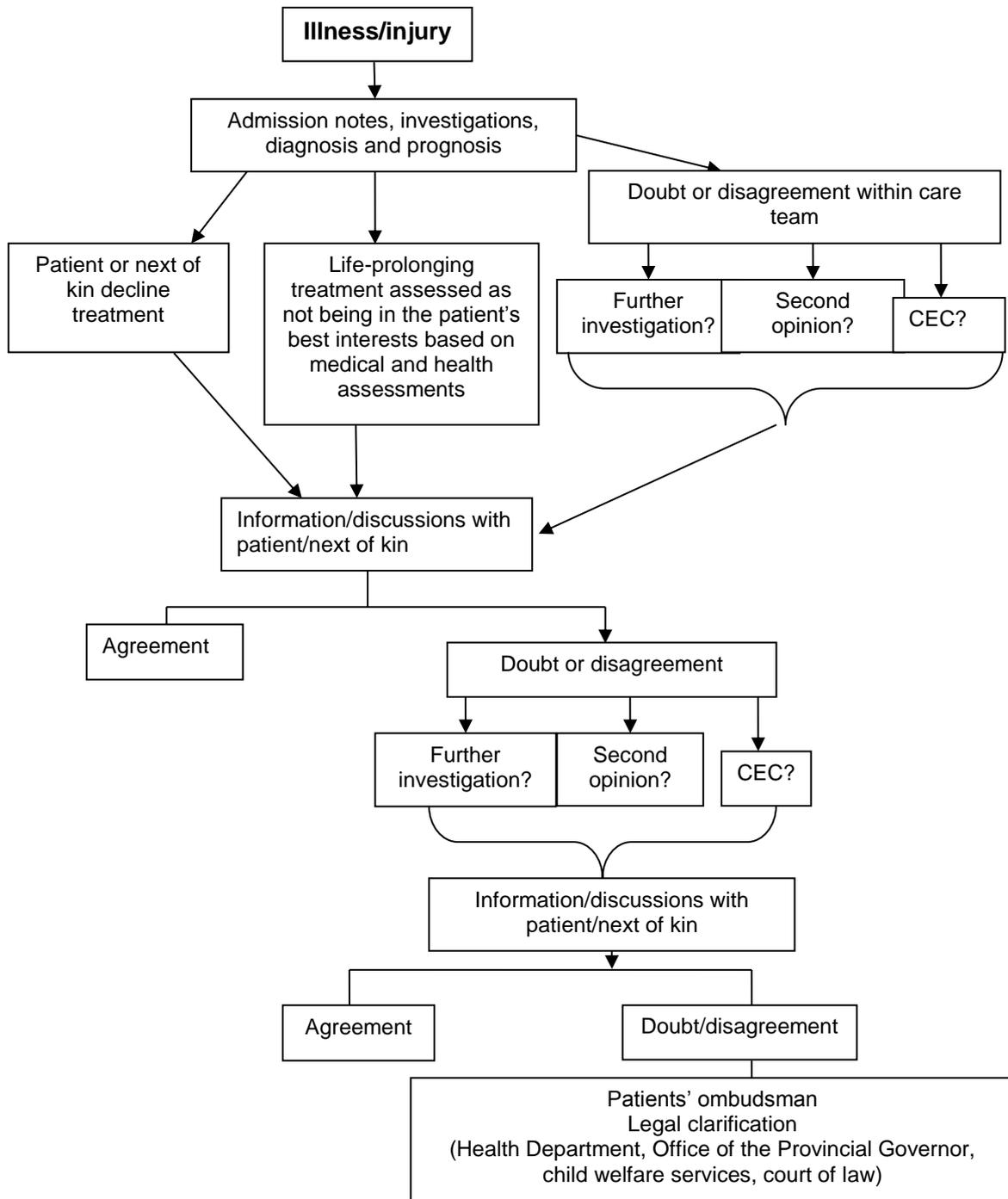
Appendices

12.1 Key questions in assessment of limitation of life-prolonging treatment

1. Is the medical basis for prognostic evaluation adequate?
2. Is the patient competent to make decisions in the given situation?
3. If not, have the next of kin been informed and consulted?
4. Are the patient's position on and wishes concerning life-prolonging treatment known?
5. What is the balance between the benefits and the drawbacks of treatment?
6. Have all viable treatment options been exhausted?
7. What interventions are to be limited?
8. Has this been discussed within the care team?
9. Has good palliative care and nursing been ensured, will patient dignity be maintained?
10. Is there any disagreement about the decision; who might need to be consulted?
11. Have the process, reasons and decision been documented?

12.2 Flowchart

Proposed decision-making process in assessing the withholding or withdrawal of life-prolonging treatment



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