Summary

The study reported here was stimulated by a particularly difficult case of abstention at the Intensive Care Unit (ICU) where the author works as a head-nurse. The case raised the following questions:

- When can treatment be regarded as ‘medical futility’?
- Who decides on stopping treatment?
- What is the influence of the patient?
- What is the influence of the patient’s representative?
- What is the influence of the various members of the medical staff?
- What is the proper procedure for making an abstention decision?

In short: the central question in this study is what a careful abstention process looks like. In addition questions arise about regulation of the process: to what extent can one talk of self-regulation and to what extent is further regulation called for?

In the first part of this thesis it is shown that on the basis of the literature and case law theoretically a clear normative answer can be given to various aspects of the questions above. It also appears that it is not feasible to give a usable definition of the central concept ‘medically futile’. A decision of futility is mainly a matter of looking for a shared understanding among the medical staff and between the medical staff and the patient’s representative. Little is known about how decision-making concerning ‘medical futility’ actually takes place in ICUs in the Netherlands. That is therefore the subject of the second part of this thesis. The data were acquired in telephone interviews with the heads of medical and nursing staffs of 36 ICUs (1/3 of all the 118 hospitals) evenly spread over the Netherlands. The research was designed to obtain insight into current practise concerning abstention with mentally incapable adult patients in Dutch ICUs. Attention was primarily focused on the decision-making process, the patient’s influence, the influence of the patient’s representative, the way the decision are carried out and the existence of guidelines and other forms of (self)-regulation. The key question in this empirical part of the study is as follows:

What are the characteristics of the process of abstention - from the decision making through its implementation - in the case of adult intensive care patients and to what extent is this process regulated?

In the third, normative, part of the thesis, we allowed to formulate a framework for a national regulation of abstention for mentally incapable patients in ICUs, on the basis of the empirical part of the study and the existing literature. In this part, the key question is:

Is (national) regulation of the process of abstention in adult intensive care patients desirable, and, if so, what should it include?

Findings

Frequency of abstention in Dutch ICU’s

On the basis of the estimates of the respondents, Dutch ICUs for adults yearly decide on abstention resulting in death at least 6500 cases. This is about a quarter of the total mortality following an abstention decision in the Netherlands. Abstention account for about 51.5% of
the total death rate in the participating ICUs, a relatively low frequency compared with percentages found in prospective research in Europe and the USA. The large differences between Dutch ICUs in the death rate as a result of abstention do not deviate from what is reported in the literature.

**Organization of the decision making**

In 70% of the ICUs a abstention decision in the case of who stays on the ICU for more than 24 hours, is never taken solely by the attending physician alone, at 30% of the ICUs this is seldom the case. The way the participation in the decision making is organized, shows two main models:

1. In 80% of the participating ICUs a proposed abstention decision is discussed during a structured meeting, usually called ‘Multi Disciplinair Overleg’ (Multidisciplinary Consultation). However, the MOD operates 7 days a week at only a small fraction (14%) of the participating ICUs. On weekends and holidays it is usually not possible to discuss a case in the MDO.
2. At 20% of the participating ICUs a proposed abstention decision is discussed only informally fellow physicians.

Both forms of involvement of staff members are aimed at checking the subjective opinion of the attending physician concerning the ‘medical futility’ of further treatment against the judgment of others. In this way intersubjectivity (‘objectivity’) of the decision can be assured.

For patients staying on an ICU for less than 24 hours the pathology ‘forces’ the attendants to adopt a different decision making procedure. The course of the illness is often more rapid and dramatic than when a patient remains longer on an ICU. The concept of ‘medical futility’ is less applicable on this category of patients and the persons involved speak of ‘no chance of success’ or ‘untreatable’. As compared with patients remaining longer on an ICU the responsible doctor more often takes an abstention decision on his own. If discussion does take place this is usually in an informal way, with a co-attending physician or the referring specialist.

**Conclusion:**

At Dutch ICUs an attending physician does not usually take an abstention decision single-handedly. The discussion about the ‘medical futility’ of a treatment is usually conducted in a structured consultation with several other doctors in order to assure ‘intersubjectivity’. However, at 20% of the ICUs that is not the case and such a consultation only occurs informally. If treatment has no chance of success, it can happen that the physician in charge takes the abstention decision alone or after only informal consultation.

**Decision making leading to the judgment of ‘medical futility’ and the influence of various health workers.**

At the majority of ICUs the intensive care doctor is the central person in the decision making process on abstention. He is the person who usually initiates the decision-making procedure and whose opinion carries the most weight. If consensus is not reached, at most ICUs he will take the final decision.
At 75% of the ICUs the agreement of the referring specialist is required for a decision on abstention. This course of action is followed for the sake of collegiality, support and continued collaboration. However, it does not always lead to a decision that reduces the patient’s suffering and that corresponds with the opinion of the professionals at the ICU. At 25% of the ICUs the consent of the referring specialist is seldom or never required.

The part the nurses play in the decision making-process mainly amounts to ‘being involved and ‘being a source of information’ for the doctor in charge. As a rule the nursing staff does not have any real influence on the final decision. If the staff opposes an abstention decision, the decision is postponed at 30% of the participating ICUs in order to reach consensus with the nursing staff as well.

A ‘second opinion’ is only occasionally made use of. However, when this does take place, the ‘second opinion’ carries much weight. Requesting a ‘second opinion’ occurs if there are professional doubts, too little support within the team, or a difference of opinion on abstention with the family or the legal representative of the patient. Because of his neutral position, the doctor giving a ‘second opinion’ often serves to resolve conflict.

Conclusion:
The attending intensive care physician leads the decision making process on abstention at most ICUs. Consent of the referring specialist is normally required. Consensus (meaning ‘no opposition to’) within the team in charge is usually needed to reach an abstention decision. At one third of the ICUs reaching consensus includes the nursing staff, and in that case, too opposition to an abstention decision will lead to delaying the decision.

The right to self-determination of the patient: influence of a written treatment-refusal
Written treatment-refusals (negative advance directives) are not registered at ICUs. Respondents estimate that about 1/2% of the patients has such a written treatment-refusal. On a national scale we would arrive at about 600 written treatment-refusals per year at the ICUs in the Netherlands. Physicians estimate that about 2% of the patients dying at a ICU with an abstention decision, posses a written treatment-refusal.

Fewer than one in ten physician-respondents take the view that a written treatment-refusal should be regarded as ‘binding’ in the medical decision making. On the other hand almost one third of the physicians definitely do not consider a refusal ‘binding’. If medical insight and the written treatment-refusal do not match, about 10% of the physician-respondents are of the opinion that a treatment-refusal will be respected at their ICU. Nevertheless, more than 80% of the physician-respondents partly or completely agree that a carefully formulated written treatment-refusal has a considerable influence on medical decisions concerning the end of life. This may be explained because a vast majority of the physicians consider a written treatment-refusal as ‘supplementary’ to the medical decision making. The written refusal is experienced as supportive if the medical view points in the same direction as the advance directive. Only a small fraction (<10 %) of the respondents think that ‘supplementary’ is too weak a way of characterizing the role of a treatment directive and doe not guarantee the autonomy of the patient.

Senior nursing staff takes the view that a treatment refusal should be regarded as ‘binding’ four times more frequently than doctors. The opinion of the senior nurses about the actual
influence of treatment-refusals however, corresponds with the view of the intensive care physicians.

The following reasons for not complying with a refusal are given by intensive care physicians

- If a patient does not want intensive care treatment he should not be admitted to an ICU in the first place.
- Refusals are often too vague.
- The family often does not support the refusal.
- The professional autonomy of the physician prevails over the will of the patient as stated in a written treatment-refusal.

Physician-respondents do not have a clear and uniform idea of what a precisely formulated treatment refusal should contain. To a certain extent, nevertheless, criteria may be laid down that should be met by a carefully drafted advance directive, according to intensive care physicians, in order to influence the decision making as much as possible. These are:

- The treatment-refusal shows that the patient was mentally capable when it was drafted.
- The treatment-refusal applies to the specific situation of an ICU.
- The treatment-refusal does not merely reflect a patient’s general view, but specifically states what the patient does not want.
- The a treatment-refusal has been drafted in consultation with the family doctor.
- The time span between the drafting of the treatment-refusal and admission to the ICU is limited.
- The treatment-refusal is accompanied by the appointment of a representative and its contend have been discussed with the representative.
- The a treatment-refusal states that in some way or an other the patient’s family has been consulted about the contents of the treatment refusal and supports it.

**Conclusion:**
Written refusals of treatment are not common in ICUs. If present, they are mainly taken into account if their contents support the view of the physician in charge. If the refusal of treatment conflicts with the doctor’s judgment then, in spite of the strong legal status of the treatment-refusals in the Netherlands, it generally will carry marginal weight.

**Influence of the representative / family**
The number of appointed representatives of ICU patients probably do not outnumber the member of written refusals of treatment. This means that, under Law on Contents Medical Treatment (WGBO), a family member will usually be the patient’s legal representative. Respondents usually do not distinguish between the legal representative and the family when involving them in the decision-making concerning abstention.

Differences of opinion concerning abstention between the attending physician and the representative/family can be of two sorts; either the attending physician thinks abstention is in order and the representative/family does not, or the other way round.

The representative/family definitely wants abstention in the case of less than ½% of the patients admitted to intensive care, in the estimation of the physician respondents. Qualitative data show that the wish of the representative/family rarely leads to conflict.
If the initiative to abstain stems from the physician, two thirds of the physician-respondents state that the patient’s representative “seldom or never is required” to give his consent to an abstention decision. The difference between these ICUs and those that do require consent, however, proves to be qualitatively slight. All physicians try to achieve acceptance of the abstention decision. This applies to both groups of physicians. In addition, two thirds of the physicians think that if the representative cannot accept the abstention decision, this should definitely not bind the attending physician.

The influence of the representative does not primarily concern the content of the decision. The representative serves as a source of information for the physician, who wants information about the quality of life of the patient before admittance, the desired quality of life and the patient’s wishes. The physician while making a decision may take these into account. There are also physicians, however, who consider an abstention decision a purely medical decision and do not think the representative/family of the patient should have any influence on it.

**Conclusion:**
ICUs hardly distinguish between the representative of the patient, in accordance with the WGBO, and the patient’s family. A refusal of treatment has more influence, if a representative has been appointed in a written statement and the latter, as well as the general practitioner, have been involved in drawing up the refusal. If the views of the physician in charge and the patient’s representative differ, the representative’s influence will not be regarded as binding by the physician. If their views correspond, the opinion of the representative is experienced as supplementary and supportive. Physicians strive for acceptance of an abstention decision and not so much for agreement.

Dutch ICUs lack a procedure in which the patient’s representative is enabled to realize his task of acting on the patient’s behalf as the patient himself would have done while still competent.

**Conflict with the representative / family concerning an abstention decision**
The estimated number of conflicts with the representative/family of the patient related to abstention generalizing over the Netherlands one arrives at about 650 conflicts a year at ICUs. There is a markedly uneven spread of conflicts over the ICUs: one fifth of the ICUs report three quarters of the conflicts.

If in a case of medical futility the physician in charge proposes to abstain from further treatment and a conflict arises with the representative/family about one quarter of the attending intensive care physicians will continue the treatment. Half of the ICUs will accept a certain delay within reason ‘get used to’ the abstention decision. The period of delay varies, but is usually shorter than five days. Some ICUs, however, partly for reasons of capacity, delay strictly limits to a period of 24 - 48 hours, after which the treatment is ceased. The remaining quarter of ICUs do not allow a difference opinion to postpone, carry out, an abstention decision.

In the opinion of 90 % of the intensive care physicians in their ICUs the decision making process can be influenced by possible legal implications. When these occur the reaction will be: ‘more documentation’, ‘more discussion’ and ‘more time for the procedure’. According to 50% of the intensive care physicians legal implications maybe taken into account in deciding
to abstain, while the influence a decision to abstain, while the remaining 50 % do not agree because it is – in their view- a medical decision.

More than 80 % of the respondents take the view that ICUs should have a clear procedure for to deal with conflicts concerning abstention. None of the ICUs in fact has such a procedure.

**Conclusion:**

Although the number of conflicts about abstention with the representative/family is small, their impact seems to be considerable, especially when the usual problem solving strategies, such as delay and more talks with the representative/family, are unsuccessful. In case of a conflict there is no clear procedure to fall back on. Almost all physician- en nurse respondents will welcome such procedure.

**The use of opiates/sedatives in abstention cases**

In case of abstention the patient’s comfort seems to be the main indication for increasing the doses of opiates and/or sedatives. The size of the dose to be administered is sometimes tuned to what the people around the patient, in particular the patient’s family, can cope with. About two thirds of the ICUs generally double to quadruple the dose of opiates, taking into account a possible speeding up of the process of dying. A minority of ICUs exercises restraint in increasing the dosage and accepts that the process of dying may take longer. A similar number, however, will administer considerably increased doses analgesics/sedatives (> 10x the original dose). At one ICU in addition to sedatives also muscle relaxants are used, resulting in a direct connection between the moment of administration and the time of death of the patient. None of the other ICUs show signs of the use of muscle relaxants in relation to abstention.

Three modes of operation appear to be followed by nurses administering opiates/sedatives in abstention cases. In the first procedure each change in dosage requires a special written instruction; in the second procedure the intensive care nurses can, within specific limits, titrate independently; in the third procedure, practiced in some ICUs, the intensive care nurses can more or less independently determine and administer the doses of analgesics/sedatives. Respondents report that the written documentation does not always reflect what is in fact administered.

**Conclusion:**

The doses of analgesics administered appear in many ICU’s to be determined not only by the patient’s condition. The dosage appears to be dependent on the ICU in question and the variation is rather large. The reasons for a certain dosage are not restricted to pain and symptom treatment.

At some ICUs intensive care nurses exceed their legal authority by determining themselves the doses of analgesics to be administered. Documentation in such cases is not necessarily accurate.

**Documentation**

The degree of thoroughness of the documentation of the decision-making process concerning abstention varies. Some ICUs do not document the process at all, but at about two thirds of the ICUs, according to the physician-respondents, registration always takes place. At most of
these ICUs, documentation is concise. At 20% of the ICUs documentation is detailed to very
detailed.
Doctors and nurses estimate that at about 90% of all ICUs the decision to abstain is always
entered in the patient’s records. At two thirds of the ICUs respondents state that the contents
of the discussions with the patient’s representatives are always recorded.
According to the physicians the way the abstention has been carried out is also always
documented at two thirds of the ICUs. In the view of senior nursing staff members this is true
at almost all ICUs.

Conclusion:
As far as documentation in abstention cases it appears that ICUs in the Netherlands generally
do register the decision-making, though at most ICUs, this is only done briefly. As mentioned
above, registration of the use of opiates is not always accurate.

Guidelines for abstention
At most ICUs there are no written guidelines whatsoever for abstention. Those that do exist
differ considerably in form and content. Nor do they defining the various concepts relating to
abstention in the same way. The status of a written refusal of treatment and the influence of
the representative/family are interpreted differently. The contribution of the representative /
family to decisions regarding the end of life, for example, may fluctuate between “the
family’s opinion should not carry any weight” to “the family takes part in the decision”. Nor
is there uniformity in the guidelines about how the decision-making should proceed and who
should take the final decision; they vary from “the decision rests with the physician, who may
consult a fellow-physician” to “the attending team decides and consensus should be reached”.

In five guidelines a ‘second opinion’ is mentioned as a possible means of lending support to
the decision-making, but it is not clear what importance should be attached to the views of the
consulted doctor.

Three guidelines elaborate somewhat on the role of the nursing staff. The most far-reaching
influence of the nursing staff is found in a guideline which stipulates that the nurses are
considered a member of the attending team and decisions are to be taken on the basis of
consensus.

Apart from the written guidelines oral agreements also exist. In this connection subjects were
mentioned such as: the daily review of all patients; who takes the final decision to abstain;
and that the patient should die during the shift of the person who has taken the decision.

The majority of the senior members of the medical staff at ICUs (86%) take the view that
every ICU should have a written guideline concerning abstention. This opinion is shared by
100% of the head-nurses. Respondents expect a guideline to have a positive effect on the
decision process, the quality of performance, and clarity / continuity of policy.

Many senior members of the medical staff at ICUs (80%) and of the nursing staff (94%) would support a national guideline concerning abstention. This guideline should be aimed at
the decision-making process and offer a general framework for local guidelines.
Conclusion:
Written guidelines are often missing at ICUs and, if available, they differ considerably in form and content. At the same time a vast majority of respondents declare that such a guideline is desirable. Also the idea of a national guideline to serve as a model for local guidelines is widely supported.

Normative conclusions
In the third part of this thesis the findings of the empirical study (part II) have been centred in light of the norms regarding abstention as they emerge from the literature and case law in part I. Based on these findings two flow-charts are worked out. One deals with the decision-making process in the case of a refusal of treatment by the patient or his representative, the other relates to the process in the case that the attending physician considers (further) treatment ‘medically futile’. The second flow-chart resembles the one published the American Medical Association, but has been modified on the basis of the normative and empirical conclusions of this study.

Normative conclusions such as the importance of ‘intersubjectivity’, the desirability of structured discussions in the attending team on the question whether (further) treatment is ‘medically futile’, the role of the referring specialist and the leading role of the attending intensive care physician, have been entered in the flow-chart. When structured discussion is not an option (e.g in case further treatment has no claim of success) a consultant should give, if possible, an expert opinion in order to achieve ‘intersubjectivity’. Hospitals should take organizational measures to facilitate consultation at all times.

Nurses should be structurally involved in the decision-making process on ‘medical futility’. To make the input of nurses as useful as possible, however, greater continuity in assigning patients is necessary than is the case at present. Leaving the nursing of each the patient continuously to the same small group of nurses will result in concentration of knowledge and insight, which is important for an effective contribution to the decision-process regarding ‘medical futility’. Realizing the nursing model of ‘Primary Nursing’ in ICUs will make it easier for nurses to participate in a right way in the decision-making process of abstention.

Written refusal of treatment
A written refusal of treatment has an strong legal status in the Netherlands. Contrary to common practice, it should be regarded as ‘binding’ in ICUs. If the interpretation of a treatment directive is unclear this should be discussed with the patient’s representative and if the refusal of treatment has been drawn up together with the general practitioner, also with him/her. Not following a written refusal of treatment is only allowed by law in case there are ‘valid reasons’ to do so and these cannot include subjective opinion and should be documented in the patient’s records.

The patient’s representative
The medical record of each intensive care patient should identify the legal representative of the patient. The representative should be given a brochure to inform him about the decision-making procedure concerning ‘medical futility’. Physicians must in principle regard refusal of treatment by patient’s representative as ‘binding’. The patient’s representative should have the possibility to lodge a complaint when his refusal of treatment is ignored. A specific procedure
has been designed for such cases (see 6.8.2 flow-chart 1: Procedure in case of refusal of treatment).

Family
In the decision-making concerning ‘medical futility’ the family does not play a formal part. The distinction between representative and family should be made clear to the next of kin. Also the staff of ICUs should take care to respect the unambiguous position of the representative in order to insure a correct procedure in the decision-making concerning ‘medical futility’.

A special contact person
At ICUs failures of communication can occur and these may result in conflicts about decision to abstain. The whole idea of ‘medical futility’ is rather precarious. A special contact person (intensive care physician) should be assigned to be responsible for all communication with the representative on matters concerning treatment and likewise of stopping treatment. Discussions with the representative should be extensively documented, something that is currently not done.

Carrying out the abstention decision
While carrying out abstention, analgesics and sedatives should be administered only in doses necessary for palliation. These must be accurately documented. Acting with the intention of terminating life may be legitimate in certain situations, but special norms and another procedure apply in such cases. The subject is outside the scope of this thesis.

Nurses must refrain from determining on their own authority the dosage of analgetics and sedatives and administering them. Hospitals should take measures to prevent intensive care nurses from being ‘forced’ to do so. If it is clear that the limits of palliation are being exceeded, intensive care nurses must not administer any analgesics/sedatives, not even after on a written instruction from a doctor.

Guidelines concerning abstention
Every ICU should have a local guideline concerning the procedure to be followed in connection with abstention. Such a guideline should deal with the points covered above and in particular with to be followed in case of a difference of opinion with the patient’s legal representative or the presence of a written refusal of treatment. Furthermore, it is also desirable to have a procedure in case treatment is refused. In part III the elements of such a guideline are suggested and two flow-charts bring all of these elements together.

Main conclusions
The following final conclusions are reached:

- The criterion ‘medically futile’ cannot be applied without taking ‘the quality of life’ into account. This makes the judgment of the individual practitioner inevitably subjective. The decision process should therefore be aimed at reaching ‘intersubjectivity’ as possible and at acceptance of the decision by those involved.
This is largely the case in the Dutch ICUs, but there are too many deviations and the process is not sufficiently regulated.

- The ‘binding’ character of written refusal of treatment is not sufficiently acknowledged in ICUs.
- The difference between ‘family’ and the legal representative of the patient and the strong legal status of the latter, are not sufficiently recognized in ICUs.
- Administration analgesics / sedatives in abstention cases should be limited to palliation. The difference between ICUs in the dosage of analgesics/sedatives intended for the ‘comfort’ of the patient while the treatment is being stopped, are significant and it looks that some ICUs regularly exceed a palliative dosage.
- Intensive care nurses at some ICUs exceed their authority in determining and administering analgesics/sedatives.
- Dutch ICUs definitely seem to be willing to engage in full and accurate documentation. The documentation of the abstention process, however, is usually rather summary. Reporting the exact doses of analgesics/sedatives does not always occur with sufficient accuracy.
- The process of abstention, including dealing with conflicts, should be regulated in general terms in a guideline at the national level and worked out in more detail locally.
- This thesis offers the building blocks for such a national guideline.