

May 5th 2014

CCNE Observations for the Attention of the Conseil d'Etat (Council of State, highest French administrative jurisdiction)

By decision n° 375081 on February 14th 2014, the Conseil d'Etat, ruling on the dispute, invited the Academy of Medicine, the National Consultative Ethics Committee, the French Medical Council and Mr Jean Leonetti to submit “by the end of April 2014, general observations in writing providing constructive clarification on the concepts of ‘unreasonable obstinacy’ and ‘artificial life support’ as they relate to article L. 1110-5 of the Code of Public Health, and more specifically as they relate to persons in a minimally conscious state, such as Mr Lambert.”

The request was made for the purpose of examining the submissions, “in view of the magnitude and difficulty of the scientific, ethical and deontological issues in dispute.”

The National Consultative Ethics Committee’s general written observations are contained in the following document.

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I. Contextual elements

A. The concepts of “unreasonable obstinacy” and of “artificial life support”

1. Concepts applying to extremely different circumstances.

The law dated April 22nd 2005 on patients’ rights and end-of-life settled on two concepts: “*unreasonable obstinacy*” and “*artificial life support*”, but in extremely different circumstances.

- Indeed, the law provides for:
 - the case when people “*in an advanced or terminal phase of a serious and incurable disease*” are able to think, express their wishes, participate in a dialogue and “*with a member of the medical profession, to make decisions regarding their health taking into consideration the information and recommendations provided by the practitioner¹*”;
 - the case when individuals “*in an advanced or terminal phase of a serious and incurable disease*” are “*unable to express their wishes*”.
- In this second set of circumstances, if the person’s wishes had in fact been expressed, this could only have occurred at a time prior to the situation in which the question of withdrawing treatment arises and the physician has no way of verifying if those decisions still hold, nor *a fortiori* of informing patients “*of the consequences of their decision*”. Thereupon, the law differentiates between:
 - the case of those unable to speak for themselves but who drafted clear *advance directives* or designated a *trusted person*;
 - the case of those unable to speak for themselves but who did not leave *advance directives* nor designated a *trusted person*.
- Finally, the law provides for:
 - the case of persons “*in the terminal phase of a serious and incurable disease*”, i.e. *at the end-of-life*;
 - the case of persons in “*an advanced phase [but non terminal] of a serious and incurable disease*”, i.e. who are not at the end of their lives so that *it is the decision to withdraw medical care or treatment itself that will be the cause of death*.

¹ “ *The physician must respect the wishes of the persons concerned after informing them of the consequences of their decision.*” Article L.1111-4 of the code de santé publique (Code of Public Health).

2. Concepts applying to “medical care” and to “treatment”

In the wording consequent on the law dated April 22nd 2005, Article L.1110-5 para. 2 of the Code of Public Health links “*unreasonable obstinacy*” and “*artificial life support*” to “*medical care*”: “*Taking into account their state of health and the degree of urgency of medical intervention required, everyone is entitled to receive the most appropriate medical care and treatment of recognised efficacy guaranteeing the best clinical results in the light of proven medical knowledge. Acts of prevention, investigation and therapy must not, to the best of current medical knowledge, put patients at a risk disproportionate to the benefit they could expect to derive from them. These acts must not be continued by dint of unreasonable obstinacy. When they appear to be futile, disproportionate or having no other effect than artificially prolonging life, they may be withdrawn or withheld.*”²

As regards Article R. 4127-37 of the Code of Public Health pursuant to decree n° 2006-120 dated February 6th 2006 to implement the law dated April 22nd 2005, it links “*unreasonable obstinacy*” and “*artificial life support*” to “*therapies*” and “*treatment*”: “*In all circumstances, physicians must seek to alleviate patients’ suffering by means appropriate to their condition and to provide moral support. They must abstain from unreasonable obstinacy in their investigations or therapies and may decide to withdraw or withhold treatment which appears to be futile, disproportionate, or has no other aim or effect than artificially prolonging life.*”

This ruling goes on to specify: “*In the cases listed in the fifth paragraph of Article L. 1111-4 and in the first paragraph of Article L. 1111-13, the decision to limit or withdraw treatment can only be taken after a collective procedure has been applied*”.

Both of the cases concern persons who are “*unable to express their wishes*”.

Article L. 1111-4 applies to “*persons unable to express their wishes*, when a decision is made to withdraw treatment and this “*may put their life in danger*”. It does not, therefore, apply to a decision to withdraw treatment whose sole object or effect is *artificial life support*. Indeed, in such cases, withdrawing treatment would not just be life threatening: it would inevitably be the cause of death.

Article L. 1111-13, on the contrary, does concern, for *those unable to express their wishes*, a decision to withdraw a treatment whose only object is *to prolong life artificially*: “*When persons in an advanced or terminal phase of a serious and incurable disease, for whatever cause, are unable to express their wishes, physicians may decide to limit or withdraw treatment if it is futile, disproportionate or has no*

² “*In which case, physicians preserve the dying person’s end-of-life dignity and quality by providing the care described under Article L.1110-10 (palliative care), “in particular analgesic drugs and sedatives, with which to provide comfort to the dying*”.

other object than the artificial prolongation of the life of the person concerned”³. In this case, it is one treatment (not several) that the physician may withdraw.

And so, in the most extreme situation — when people in an advanced or terminal phase of a serious and incurable disease are *in a condition where they can no longer express their wishes* — the Code of Public Health provides that the decision which a physician may take is to limit or withhold *a treatment* which is futile, disproportionate or has no other *object* than to prolong artificially the life of the patient.

In the circumstances:

- withdrawal must be considered treatment by treatment, i.e. on a step-by-step basis;
- there is no longer mention of treatments that *appear to be* futile, but instead of *a treatment which is futile*;
- and it is the *object* of treatment (the sole artificial prolongation of life), i.e. the object for which it continues to be prescribed, which must be considered and not simply the *effect* of the treatment.

Treatment may be viewed as being part of medical care. But medical care cannot be reduced to treatment alone. Medical care is an integral part of a much more far-reaching undertaking: care⁴ in its broadest sense. And continuity of care must be emphasised once again. “*Care is a unique whole: it does not make sense to divide it into curative versus palliative care. [...] There should only be one continuous process of care.*”⁵

CCNE considers that it is only patients who are able to express themselves who can decide to request that certain *medical care actions* be withdrawn (including vital care such as natural nutrition and hydration). Conversely, for CCNE, suspending medical care which has apparently *no other effect than providing artificial life support* is completely unacceptable in the case of people whose *condition prevents them from expressing their wishes*.

The situation is different in the event of a decision to withdraw *treatment*.

³ There is ambiguity as regards the *object* and/or the *effect* of treatment or treatments. Indeed, Article L.1110-5 para.2 of the Code of Public Health designates medical care “*which appears to be futile, disproportionate or having no other effect than artificial life support*”, Article R. 4127-37 designates treatments which “*have no other object or effect than artificial life support*”, and Article L. 1111-13 designates treatment “*with no other object than the sole artificial prolongation of that person’s life*”. Another ambiguity arises with the nature of the medical acts concerned: those referred to are either *acts of prevention, investigation and care* (Article L.1110-5; or *treatments* (Article R. 4127-37); or *a treatment* (Article L. 1111-13). Yet a further ambiguity lies in the nature of the action taken: withdraw (i.e. suspend) or withhold (i.e. decide not to undertake). In fact, Article L. 1110-5 says that acts of prevention, investigation and care *may be withdrawn or withheld*; Article R. 4127-37 says that the physician may decide to withhold (not to undertake) or withdraw (cease) treatments; and Article L. 1111-13 that the *physician may decide to limit or cease* treatment. Finally, one last ambiguity bears on the description of the actions: either medical care or treatments *seem futile*, etc. (Articles L. 1110-5 and R. 4127-37), or they *are futile*, etc. (Article L. 1111-13).

⁴ The French word “*soin*” in the original of this document is to be taken in the meaning of the English word “*care*”, i.e. including its medical meaning and also the action of looking after or taking care of someone.

⁵ « *Penser solidairement la fin de vie*. Commission de réflexion sur la fin de vie en France », 2012.

(Thinking of the end-of-life in terms of solidarity. Commission on reflection on the end-of-life in France) <http://www.ladocumentationfrancaise.fr/rapports-publics/124000675/>

And by a combined interpretation of the provisions contained in Article L. 1110-5, Articles L. 1111-4 and R. 4127-37 of the same code, clarified by the preparatory work for the April 22nd 2005 law, the *Conseil d'Etat* considered that artificial nutrition and hydration are among the treatments which could be withdrawn for persons who are not in an end-of-life situation and are not in a condition where they can express their wishes, if continuing such treatment was a demonstration of “*unreasonable obstinacy*” (paragraphs 10, 11 and 12 of decision n° 375081 of February 14th 2014)⁶.

3. Artificial nutrition and hydration: a particular form of *treatment*

Artificial nutrition and hydration qualify as treatments, which must be medically prescribed⁷ before they are put in place and pursued, and which require the use of medical techniques.

Nevertheless, they differ from other treatments.

CCNE considers that the characteristics that differentiate between treatments and care deserve, at the very least, to be reviewed in the case of artificial nutrition and hydration, in particular if the person concerned is unable to communicate but is not dying.

Indeed, artificial nutrition and hydration are substitutes for food and drink which are essential and universal daily needs for human beings⁸. And while artificial nutrition and hydration are, very obviously, *treatments whose sole object and effect are to sustain the life of a patient*, the dividing line in this case between treatment and care is particularly nebulous: this is also palliative care, or to express it more adequately, care to provide support and solace, or ordinary care, or more simply still, basic primary human care (a possible reminder of the cultural and legal obligation to feed close relatives).

For these reasons, when it is considered that the continuation of artificial nutrition and hydration is an instance of *unreasonable obstinacy*, this is not so much referring to obstinacy in treating a disease, but rather unreasonable obstinacy in keeping someone alive.

⁶ “12. Considering, on the other hand, that by virtue of the provisions of Articles L. L. 1110-5 and L. 1111-4 of the Code of Public Health, clarified by parliamentary deliberations prior to the adoption of the law of April 22nd 2005, that legislators intended to include in the list of treatments that could be limited or stopped by reason of *unreasonable obstinacy*, all of the acts tending to ensure artificially the vital functions of patients, that nutrition and artificial hydration are among such acts and are, therefore, open to being stopped when their continuation was a manifestation of *unreasonable obstinacy*.”

⁷ Medical intervention is required in particular to prescribe and later adjust appropriate doses or quantities, the composition of nutrition (in calories and the glucide-protein-lipid balance) and also the hydro-electrolytic composition of hydration.

⁸ Over and above laws on the protection of life and on the protection of health, recognised by the Constitution, there is also a legal right to nutrition recognised by the 1948 Universal Declaration of Human Rights and by the 2008 Optional Protocol to the International Covenant on Economic, Social and Cultural Rights, ratified by France in 2012.

But, in general terms, what criteria can be used to qualify *obstinacy* in a particular instance as *unreasonable*? And how do we go about qualifying a certain *treatment* as *futile*, *disproportionate* or having *no other object but the sole artificial prolongation of life*?

4. The difficulty in qualifying treatment as “futile” or “disproportionate”

Although at first sight the expressions “*futile treatment*” or “*disproportionate*”, referred to in the Code of Public Health, may appear to be quite simple, in point of fact interpreting them is no easy matter.

When is treatment *futile* or *disproportionate*?

Parliamentary debate qualifies as *futile* a treatment which does not improve a patient’s state of health.

As regards the *disproportionate* aspect, Article L. 1110-5 applies it to the risks incurred by a patient: “*Acts of prevention, investigation and care must not, to the best of medical knowledge, put patients at a risk disproportionate to the expected benefit they could derive from them.*” The same can presumably be said for treatment, not forgetting that such risks may include not just pain and suffering but also risk to life and organ integrity.

From a physician’s point of view, *futile* or *disproportionate* treatment is one which does not conform to good medical practice. It seems *a priori* obvious that doctors should not undertake futile treatment and that they should withdraw it if it is tried and turns out to be useless. And the same is true for disproportionate treatment. Is this meant as a reminder that physicians must always comply with good medical practice whatever the circumstances?

But if this is the case, why is this reminder mentioned only as a possibility? Why does the Code of Public Health state that *futile* or *disproportionate* treatment “*may*” be withdrawn or withheld instead of specifying that they “*must*” be suspended or “*must*” not be undertaken? If they “*may*” be withdrawn or withheld, then it is also implied that they *may* be continued or undertaken. What possible purpose could there be in specifying that futile or disproportionate treatment *may* be undertaken?

There would appear to be at least three possible explanations:

- The first would be related to scientific uncertainty, that is the difficulty for a physician, even in certain cases with reference to good medical practice, to determine whether a particular treatment is futile or useful, proportionate or disproportionate. This is probably the reason for the use of the verb “appears” — “*treatment that appears to be futile...*”⁹. In this case, the use of the wording “*may decide to withhold or withdraw...*” does not signify that

⁹ Article R. 4127-37 of the Code of Public Health.

physicians are at liberty to prescribe or persist in prescribing futile or disproportionate treatment, but rather that it is difficult for them to evaluate if a treatment is in fact useful and proportionate and whether the time has come when treatment that was initially useful and effective has become futile.

- A second explanation could be an implicit recognition by the physician that treatment is held to be futile or disproportionate by the patient¹⁰. From the point of view of patients, who “*take decisions concerning their own health, in consultation with their medical advisers*”¹¹; the words “*futile*” and “*disproportionate*” have quite another meaning. This is treatment which can well be justified in terms of good medical practice but which the person concerned finds neither “*useful*” nor “*proportionate*”. It would therefore be in the eyes of the person concerned that such treatment is viewed (or, in the case of a living will, was viewed in advance) as *futile or disproportionate*.
- The third possible explanation is that the use of the verb “*may*” applies not only to medical acts, but also to the physicians, “*empowering*” them or giving them the possibility of withdrawing or withholding treatment; as a result, if any subsequent legal action was taken, they could argue their defence by the fact that they had performed an act authorised by law, which would have as a consequence absence of criminal liability¹².

It would therefore appear that the concept of “*futile and disproportionate*” treatment is complex, that it contains a considerable degree of uncertainty and calls upon compliance with good medical practice, in-depth consultation between members of the clinical team and finally, that physicians take into consideration whatever they are able to perceive of their patients’ expectations.

There is the possibility that the concept is purposely imprecise with the object of inciting physicians to engage in dialogue and cooperation.

But how is it possible to evaluate what would be *useful* and *proportionate* in the eyes of the persons concerned when they are *no longer able to express themselves* and have neither left *advance directives* nor designated a *trustee*?

¹⁰ *Usefulness* does not have the same meaning as *effectiveness*. From a medical viewpoint, that which meets the medical purpose intended — for example restore function to a previously non functioning organ — is effective. Only medical expertise can judge the *effectiveness* of a medical act. But this is no longer true as regards usefulness. A *useful* medical act is one which is *useful to the person concerned*. Consequently, a medical act that the person concerned finds *futile* could be viewed as futile.

¹¹ Article L. 1111-4 of the Code of Public Health.

¹² In the light of Article 122-4, para. 1 of the Code Pénal: “*a person committing an action prescribed or authorised by legislative or regulatory provisions incurs no criminal liability*”. In much more general terms, when patients’ state of health allows them to express themselves, this “option” would leave a degree of leeway to physicians, in particular when patients demand continuation or inception of treatment which medical professionals consider to be futile or disproportionate.

5. The difficulty in qualifying treatment as “having no other object than artificial life support”

The Code of Public Health mentions the possibility for physicians of withdrawing “*treatment which has no other object or effect than artificial life support*” (Article R. 4127-37) or for those who are no longer able to express themselves, treatment “*with no other object than the sole artificial prolongation of life.*” (Article L. 1111-13).

But what is meant here by the concept of *artificial* support or of only *artificially* prolonging life? Is this intended to compare with a concept of *natural* life support? Are we to understand that treatment opposes the “natural” progress of an organism in the direction of death? Are we opposing treatment and “nature”?

Following this line of reasoning can only lead to an impasse.

It is generally accepted that there are three possible purposes to treatment:

- to cure;
- to serve, temporarily or over time as a substitute for a failing vital function, in order to keep someone alive;
- to provide palliative or supportive care so as to ensure patient comfort and personal dignity (although the meaning of palliative treatment and palliative care should not necessarily be synonymous with end-of-life treatment, as is too often the case in today’s world).

Many forms of treatment, in particular the most effective ones, have no other object (or effect) than providing *artificial* life support. Artificial life support may be transitory — this is the case for resuscitation — and if curative treatment has brought about a cure, the person’s state of health will return to *normality*, without any need to resort any longer to artificial measures, i.e. treatment.

But for a great many people, treatment does not result in cure: it has no other object (or effect) than an “artificial” — as opposed to “natural” — long term prolongation of life, possibly throughout a patient’s life. This is the case, for instance, of insulin therapy for an insulin-dependent diabetic, of mechanical ventilation for a patient with chronic respiratory failure or dialysis for chronic renal insufficiency, etc.

It would be well, therefore, to explore more fully what is meant by “*artificial*”.

It appears quite obvious that it is not simply because treatment has as its sole object (or effect) the “artificial” prolongation of life that it should be either stopped or not even begun.

At least two very different situations arise:

- In the first case, those concerned are able to express their wishes and therefore able to think for themselves and make their own life choices: they are therefore able to make known their decision to continue treatment or not as the case may be. Their wishes must be respected.

- In the second case, those concerned are not able to take a decision because they “*are not in condition enabling them to express their wishes*”. The physician must take the decision to withdraw or not a treatment “*which has no other object (or effect) than artificial life support*”.

In this second case, it seems essential to take *temporality* into account and this leads us to distinguish between two radically different sets of circumstances, depending on whether the patient is, or is not, in an *end-of-life* situation.

- When patients are in the *terminal phase* of a serious and incurable disease, i.e. at the *very end-of-life*, and cannot express themselves on the unreasonable nature of the treatment contributing to their continued existence, while physicians are of the opinion that treatment is unreasonable, withdrawing treatment may bring death closer but can just as well be regarded as letting death happen, since it would be occurring in the very near future in any case as a direct result of the disease. In such a context, the concept of *artificial* prolongation of life can mean futile obstinacy because of the very short time that will elapse before life comes to an end. Withdrawing therapy in this instance is not so much bringing life to an end as recognising that medical science has reached its limits and allowing the patient to die naturally.
- But the situation is entirely different if the person concerned has *not reached end-of-life*. In this case, a decision to stop treatment becomes a *decision to put an end to the life of someone who has not asked that this be done*. When patients are *not at the end-of-life* and their *condition prevents the expression of their wishes*, then stopping treatment is stopping life, not just letting life ebb away. Physicians are no longer guided by the certainty of inevitable and imminent death, but by the wish of not allowing life to continue because the patient is in pain, or there is no foreseeable likelihood of a favourable outcome, or because of irreparable, irreversible and extremely severe after-effects. In this context, the apparent but non-explicit meaning of artificial life support, is that the person concerned would probably prefer death rather than be alive in such circumstances¹³. But when patients *are not at the end-of-life* and *cannot express their wishes*, who is to decide and how can it be decided that keeping someone alive is evidence of *unreasonable obstinacy*?

¹³There is, however, one set of circumstances where physicians must continue or begin medical care and treatment whose sole object (or effect) is “artificial life support” of human organs in a purely biological dimension: that is when someone whose brain-dead status has been duly, medically and legally certified is to become a donor for organ harvesting before organ transplantation. The task of the clinical team in this case is to make sure by providing medical care that the organs remain functional, although the donor is legally dead. This is “caring” for the organs, rather than “caring” for the donor.

In Opinion N° 115 of April 7th 2011 on “Ethical Issues in Connection with Organ Harvesting and Donation for Transplanting”, CCNE states that the determination of death is established on the basis of total absence of detectable cerebral activity — from which can be deduced the total absence of consciousness or of mental activity — even though some organs, with the notable exception of the brain, can be kept viable by medical care given to the body.

In other words, this is indeed a situation where the medical team continues for a while to provide treatment which can clearly be described as having as its sole object (or effect) the artificial preservation of the purely biological life of a body, and therefore of the functions of the organs to be harvested. But what makes this extreme obstinacy “reasonable” is a very specific motive: the hope, thanks to such “unreasonable” obstinacy regarding the deceased person, of “artificially” saving the lives of other people awaiting organ transplantation.

6. The difficulty in qualifying “obstinacy” as “unreasonable”

Article R. 4127-37 of the Code of Public Health states that physicians “*must abstain from unreasonable obstinacy in their therapies*”, but “*may decide to withdraw or withhold treatment which appears to be futile, disproportionate, or has no other object or effect than artificially prolonging life.*”

In other words, the “*unreasonable obstinacy*” qualification of treatment does not just apply to the initiation or continuation of treatment that “*appears to be futile, disproportionate, or which has no other object or effect than artificially prolonging life.*”

And there is a further dimension in the “*unreasonable obstinacy*” qualification which is not spelt out and which must be recognised and appreciated by the physician¹⁴.

What then do we define as reasonable medical behaviour? What behaviour can in fact qualify as being reasonable, or even as reasonable obstinacy applying to *treatment*?

We may consider that reasonable and well-reasoned medical behaviour implies:

- a knowledge of good practices and of the data corroborated by rational and reproducible statistical evidence or resulting from expert consensus (which form an integral part of what is called evidence-based medicine; i.e. taking in account and grasping, not only what is known and evaluated, but also as fine an appreciation as possible of even the degree of uncertainty inherent to any knowledge acquisition based on statistics, probabilities and common practice;
- taking into account another form of uncertainty than that which is intrinsic to medical science: the uncertainty stemming from individual patient singularities, their hopes and fears, (and if they were able to make known their wishes, to a reconstruction of their preferences based on the information they would have received in the course of their dealings with their doctors);
- physician readiness to reflect and to dialogue: physicians are reasonable if they are ready to enter into a discussion and possibly change their minds in light of the points put forward and the developments in the thinking of their partners in the discussion. Understood in those terms, a medical approach could be considered as reasonable if it is based on reflection, an open mind, a readiness to evolve and to consider in their entirety known facts, uncertainties and complexities.

Conversely, can be seen as unreasonable, excessive obstinacy, rigidity based entirely on *preconceived* ideas or ideologies, unwillingness to entertain any challenge and an incapacity to recognise the extreme difficulty inherent in reflection which may lead to

¹⁴ We may note that Article L. 1111-13, concerning persons *unable to express themselves, in an advanced or terminal phase of a serious and incurable disease*, does not refer to *unreasonable obstinacy*. But medical deontology implies that this *possibility* or this *empowerment* given to physicians to withdraw treatment when it *has no other object than artificial life support*, is in fact simply the *means* in the service of a physician’s *duty*, in a much more imprecise and general fashion: the *duty* to abstain from any form of *unreasonable obstinacy*.

an irreversible decision, in this instance to the withdrawal of life-supporting treatment.

But how is it possible to distinguish the reasonable from the unreasonable when such an irreversible decision is being made *for* someone else, *in his or her stead*, and the person concerned is in *no condition to express an opinion*?

7. A procedure leading to a decision taken by the physician alone

The Code of Public Health stipulates that physicians can only decide to withdraw treatment after:

- consulting the patient's *advance directives*, if there are any, or the *trusted person* designated by the patient, or should that not be possible, seeking the opinion of the patient's family or a person close to the patient;
- setting up a *collegial procedure*.

Physicians can set up this *collegial procedure* on their own initiative if they hold the view that continuing treatment or certain treatments would be an instance of unreasonable obstinacy.

Furthermore, on being shown the *advance directives*, physicians must launch the procedure — that is if the patient had previously requested that some or all treatments be withdrawn in the particular prevailing circumstances — or at the request of a patient's *trustee*, or of the family, or failing that, of a person close to the patient — that is if they testify that the patient had made known that wish to them or if they believe, knowing the patient personally, that he or she would not have wanted certain or all treatments to continue¹⁵.

¹⁵ Article R. 4127-37 of the Code of Public Health: “*The decision to limit or withdraw treatment is taken by the physician in charge of the patient, after consulting the clinical team, if there is one, and hearing the reasoned opinion of at least one other physician, called in as a consultant. There must not be any hierarchical connection between the physician in charge of the patient and the consultant physician. The reasoned opinion of a second consultant is requested by the first two physicians if one of them considers it appropriate.*

The decision to limit or withdraw treatment takes into account the wishes that the patient may have previously expressed, in particular in advance directives if the patient had written any, the opinion of the trusted person the patient may have designated, as well as the opinions of the patient's family or, failing that, the opinion of someone closely connected to the patient. The decision to limit or withdraw treatment must be reasoned. The opinions heard, the nature and direction of the consultations which took place among the members of the clinical team as well as the reasons underlying the decision are set out in the patient's case file. The patient's proxy, if one was designated, the family or, failing their availability, a person closely connected to the patient are informed of the nature and reasons underlying the decision to limit or withdraw treatment.

[...] the physician, even in the event that it is impossible to evaluate patient suffering due to cerebral dysfunction, initiates treatment to ensure patient comfort, including in particular the use of analgesic and sedative drugs.

[...] The physician also ensures that the patient's family and friends are informed of the situation and receive appropriate support.”

Article L. 1111-13: “*after respecting the rules of collegial procedure as defined by the Code of Medical Ethics and consulted the trusted person referred to in Article L. 1111-6, the family, or failing availability, a person closely connected to the patient and, if they exist, the patient's advance directives. The reasoned decision is set out in the patient case file.*

...physicians preserve the dying person's dignity and quality of end-of-life by providing the care described under Article L. 1110-10.”

As we can observe, when patients are not able to express their wishes, evaluation of the concept of “*unreasonable obstinacy*” is not unilateral; it is constructed on the basis of several different viewpoints:

- appreciation by the physician of the medical status of the patient under his or her care;
- the wishes previously expressed by the patient, as they may be understood from the patient’s *advance directives*, if there are any, or as they may be reported or inferred by the *trusted person*, or failing availability, by the family or a person closely connected to the patient;
- and the appreciation by the clinical team and the reasoned opinion of physicians involved in the *collegial procedure*.

But in the current state of legislation, once this consultation has taken place, it is the responsibility of the *sole physician* in charge of the patient to decide whether a situation of “*unreasonable obstinacy*” prevails and, should that be the case, to decide on limiting or withdrawing treatment.

The wording used, *collegial procedure*, may give the impression of a procedure based on collective deliberation, but this is not actually the case. The procedure is based on consultation. The physician’s decision is not made *with* the trusted person when there is one, nor *with* family, nor *with* loved ones (nor *with* the clinical team, nor *with* the consulting physician): the decision is his alone, after consulting the various participants and having heard their opinions.

It ensues therefore, that in the current state of legislation, starting from a *process of shared decision* — in which when patients are lucid and *capable of expressing their wishes*, they make decisions regarding their own health¹⁶ *with* their physician — or in other words, a *process of decision by the person concerned*¹⁷, whereas once patients are *unable to express their wishes*, we move on to a *process* of consultation and later *decision* where the *physician is alone* in taking that decision.

And yet:

- if the treatment that is to be withdrawn is artificial nutrition and hydration, and the sick person is not in an end-of-life situation, *withdrawing artificial nutrition and hydration* will have the effect of *causing death*;
- and it is in such circumstances — where the decision is pending to withdraw definitely the artificial nutrition and hydration of persons “*unable to express their wishes*”, who have not left *advance directives* nor designated a *trustee*, who are in the “*advanced or terminal phase of a serious and incurable disease*”, but *not at the end-of-life* — that the physician’s appreciation of the concept of “*unreasonable obstinacy*” raises the most complex issues.

¹⁶ Article L. 1111-4 of the Code of Public Health.

¹⁷ Article L. 1111-10 of the Code of Public Health: “*When persons in an advanced or terminal phase of a serious and incurable disease, regardless of its cause, decide to limit or withdraw treatment of any kind, the physician must respect their wishes after informing them of the consequences of their decision.*”

B. Minimally conscious state: medical data

The difficulty in defining consciousness, the various states of consciousness and in seeking out evidence of it in patients who are in a minimally conscious state.

There are many definitions of the word “consciousness”: philosophical, psychological, neuroscientific and medical, but even in medical terms, there is no consensus on what it covers precisely.

Some definitions of consciousness refer to particularly specific concepts: this is the case for example of the idea of *reflexivity*, i.e. the capacity to refer to one’s own mental states in the first person: “I perceive X”, meaning that not only do I perceive X, but I also know that I perceive X and I am aware of this.

Other definitions are not so precise, such as the concept of *primary consciousness*, a perception of the environment and of the self which does not integrate the reflexive character of this experience: this is the case of a person whose intentionality is based on feelings or perceptions, but who does not pay attention to its sources.

Yet others, conversely, link consciousness with more or less complex metacognitive states (not only the existence of reflexivity, but also a more evolved subjective evaluation of one’s own cognitive states, a form of introspection)¹⁸.

Finally certain neuroscientists consider that, independently of any reflexivity or intentionality, the capacity to experience emotional states — pleasure, pain, well-being, suffering — is one of the universal minimal manifestations of consciousness¹⁹.

The fact that there are *various* possible states of consciousness rather than just one *single* state is also illustrated by the existence of one particular state of consciousness — dreaming — which occurs during the rapid eye movement (REM) stage of sleep²⁰. The frequently irrational nature of dreams underlines the fact that a state of consciousness is not necessarily characterised by a capacity to think rationally, and therefore *a fortiori* to communicate rationally: dream hallucinations and the hallucinations which sometimes occur while awake are further particular manifestations of consciousness.

¹⁸ There are of course other meanings, such as moral conscience (*Science without conscience is but the ruin of the soul*) which refer to entirely different dimensions of the concept of conscience.

¹⁹ For certain neuroscientists, including Antonio Damasio and Jaak Panksepp, this capacity would even be the first manifestation of the emergence of consciousness, both during the development of human beings and at the level of the evolution of living beings (Damasio A, Carvalho G. The nature of feelings: evolutionary and neurobiological origins. *Nature Reviews Neuroscience* 2013, 14:143-52).

²⁰ During this phase of sleep, the body is paralysed, except for the eyes which move rapidly and involuntarily. The experience of dreaming is in fact a state of consciousness since the dreamer is able to recount some dreams, generally *a posteriori* but also while the dream is in progress in the case of *lucid dreaming*. (Nir Y, et al. Dreaming and the brain: from phenomenology to neurophysiology. *Trends in Cognitive Sciences* 2010, 14:88-100; Hobson JA. REM sleep and dreaming: towards a theory of protoconsciousness. *Nature Reviews Neuroscience* 2009, 10:803-13).

Consciousness, therefore, is not a single state but a *continuum*, presenting a wide variety of forms, a large number of possible states so that their mental contents may be extremely diverse (involving perception, memory, emotions, intentionality, cognition, reflexes, etc.).

A state of consciousness is a subjective experience. And for this reason, when people's capacity to express themselves, communicate their feelings and enter into relation with others are profoundly impaired, the existence of a state of consciousness, the level of that state of consciousness, its nature and the degree of reflexivity, intentionality and of emotional and cognitive content it implies, are particularly difficult to define and evaluate by anyone else²¹.

What medicine is in search of at this point is not the existence, as such, of the subjective experience characterising awareness, but a series of correlates as evidenced by clinical examination, a meticulous analysis of behaviour and certain functional brain exploration techniques.

There is at this time, in both medical and neuroscientific thinking, a consensus distinguishing between arousal (or vigilance) and consciousness: arousal is a necessary but not sufficient condition for the emergence of a state of consciousness²².

From a neurobiological viewpoint, vigilance depends on the activity of the "ascending reticular activating system" (starting from structures located in the brain stem and connecting up to other brain areas including the thalamus and the cerebral cortex) which enables real time and adaptive control of the degree of cerebral cortical arousal.

Total eradication of vigilance — subsequent to impairment of this arousal system — corresponds to a coma. In clinical terms, the patient is prostrate, with eyes closed and cannot be awakened, even by intensive stimulation²³.

Consciousness requires vigilance²⁴, but it also depends on the coordinated action of a vast cerebral network involving the cortex and its subcortical connections (in particular the thalamus), thus enabling integrated functional communication between

²¹ Giacino J, *et al.* Disorders of consciousness after acquired brain injury: the state of the science. *Nature Reviews Neurology* 2014, 10:99-114; Fernandez-Espejo D, *et al.* Detecting awareness after severe brain injury. *Nature Reviews Neuroscience* 2013, 14:801-9. "The limits of consciousness are hard to define satisfactorily...and we can only infer the self-awareness of others by their appearance and by their acts." (Fred Plum, Jerome Posner J. *The diagnosis of stupor and coma*. Wiley, 1983).

²² This dissociation is difficult to grasp since, most of the time, states of arousal are associated with self-awareness and awareness of the environment, tending to suggest that to be awake is to be conscious. And yet, there are pathological conditions marked by the absence of any detectable sign of consciousness although the person concerned is obviously awake: this is the case of what is called *unresponsive wakefulness* (or vegetative state) and certain partial epileptic seizures characterised by lapses of awareness (absence seizures) during which the person remains awake but no longer seems to be conscious.

²³ Coma patients show no sign of awareness of either themselves or of the environment and, by definition, this state persists for more than an hour.

²⁴ This is also the case of the state of consciousness particular to dreaming: although we are asleep, and therefore not awake, sleep neurophysiology shows that most dreams occur during a period of sleep which is called paradoxical sleep corresponding to a state of cortical arousal. In other words, this period of sleep, where vigilance seems to be totally abolished, in fact corresponds to a particular state of cortical arousal permitting the emergence of conscious memorable content. (Michel Jouvet. *Le sommeil et le rêve*. Odile Jacob, 2000).

distant areas inside the brain²⁵ which can be detected using various techniques for cerebral functional exploration.

Chronic disorders of consciousness in people who are awake can be classified as states of arousal devoid of clearly detectable voluntary functional communication.

In clinical terms, such people are awake: they open and close their eyes, but show little or no behavioural signs of self-awareness or of their environment.

These chronic disorders of consciousness are not to be confused with the *locked-in syndrome*, in which vigilance, consciousness and cognitive functions are intact, but all motor function is abolished, except that in most cases patients can blink voluntarily or are able to make voluntary vertical eye movements, thanks to which a code of communication can be devised²⁶.

With people who are awake but whose consciousness is impaired, two clinical states have been described, with different degrees of impairment: the *unresponsive wakefulness syndrome*²⁷, UWS, which used to be called vegetative state²⁸, and the *minimally conscious state*²⁹, MCS, recently identified in 2002.

With the *unresponsive wakefulness syndrome*, there is no speech, no behavioural response to sensory stimulation, no detectable sign of self-awareness, of the environment, nor of understanding language.

In the *minimally conscious state*, some of these responses and signs are present, more or less reproducible, but they are fragmentary and inconsistent.

This clinical classification into two kinds of chronically impaired states of consciousness, unresponsive wakefulness and minimally conscious, could lead to thinking that distinguishing between the two is easy. This is not the case at all, however, and certain studies have demonstrated that a diagnosis of unresponsive

²⁵ Mental activity, therefore, is not dependent on the activity of one single area, but rather on a global functioning mode within extensive cerebral networks. These results have also contributed to reveal the existence of numerous unconscious perceptive and cognitive processes. This latter point clarifies the reason why signs of localised cerebral activity are not sufficient to be taken as evidence of a person's state of consciousness. Dehaene S, *et al.* Towards a computational theory of conscious processing. *Current Opinion in Neurobiology*, 2014;25C :76-84; Kouider S, *et al.* A neural marker of perceptual consciousness in infants. *Science* 2013, 340:376-80); Casali A, *et al.* A theoretically based index of consciousness independent of sensory processing and behavior. *Science Translational Medicine* 2013, 5:198ra105; Sitt J, *et al.* Ripples of consciousness. *Trends in Cognitive Sciences* 2013, 17 :552-4; Dehaene S., Changeux JP. Experimental and theoretical approaches to conscious processing. *Neuron* 2011, 70 :200-27.

²⁶ *Locked-in syndrome* typically results from brainstem stroke, not cerebral stroke. People with locked-in syndrome are usually conscious and aware and are cognitively intact so that they can express thoughts, emotions, intentions and wishes, even though this is made more difficult since they are "locked-in", almost entirely paralysed and even in some very rare cases totally paralysed. It is worth noting that "cerebral signatures" provided by functional cerebral neuro-imagery as correlates of arousal and consciousness are present in these *locked-in* patients.

²⁷ Laureys S, *et al.* Unresponsive wakefulness syndrome: a new name for the vegetative state or apallic syndrome. *BMC Medicine* 2010, 8:68.

²⁸ The expression *vegetative state* came under criticism as being disrespectful to the person concerned as it compared the patient to a plant or even a "vegetable". It was replaced by *unresponsive wakefulness syndrome*.

²⁹ Giacino J, *et al.* The minimally conscious state: definition and diagnostic criteria: the Aspen Neurobehavioral Conference Consensus statement. *Neurology* 2002, 58:349-53.

wakefulness (formerly called vegetative state) may be faulty in as many as 40% of cases³⁰.

For people incapable of functional communication³¹, the evaluation of residual consciousness is arrived at with the help of meticulous, codified and repeated behavioural tests, so as to ascertain how much is due to involuntary reflex response and how much to more elaborate responses, possibly evidence of a state of consciousness³².

The very frequent fluctuations in wakefulness or of the degree of consciousness observed are a contributing factor to the divergent subjective interpretations made by both family and clinical teams. Because of the extreme difficulty, even for specialists, in distinguishing between purely reflexive or non-purely reflexive behaviours, standardised and repetitive testing is required.

It is in this context that several complementary kinds of functional cerebral exploration techniques are being developed to detect the cerebral activities associated to particular cognitive processes. They are based on various techniques for the functional exploration of the brain — functional magnetic resonance imaging (fMRI) or fluorodeoxyglucose positron emission tomography (PET)³³, electroencephalography (EEG), cognitive evoked potentials — and provide further evaluation points of reference to be combined with clinical, behavioural and neuroanatomical data so as to try and assess the person's state of consciousness as precisely as possible³⁴.

The increasingly detailed and codified characterisation of the level of consciousness in people deprived of functional communication, is evidence of the considerable disparity in the condition of patients in a minimally conscious state: in some cases responses are indicative of partial and fluctuating awareness of the environment (for instance, when responses to verbal instructions lack consistency), while in other cases there is some difficulty in establishing a univocal connection with a conscious experience (for example, an avoidance response to a stimulus, which may be entirely reflexive or reflect the perception of pain).

³⁰ Giacino J, *et al.* *Nature Reviews Neurology* 2014, 10:99-114, *op. cit.*; Fernandez-Espejo D, *et al.* *Nature Reviews Neuroscience* 2013, 14:801-9, *op. cit.*

³¹ When people are capable of functional communication, using muscular movements to create a coded signal — be it in words, gestures, eye or eyelid movements, etc. — it is easy to ascertain that they are conscious.

³² As an example, while an auditory startle response to noise may be a reflex mechanism, which can be explained simply by the reflexive function of the brain stem, visually tracking a target for several seconds in directions chosen by the tester (visual pursuit test, or the mirror tests in the Coma Recovery Scale-Revised or CRS-R) is evidence of the activity of a complex cerebral network as distinct from a reflexive one. However, even these complex responses are not univocal and indisputable reflections of the patient's subjective awareness of the perception of the stimulus.

³³ Stender J, Gossesies O, Bruno M, *et al.* Diagnostic precision of PET imaging and functional MRI in disorders of consciousness: a clinical validation study. *The Lancet* 2014; Published online April 16, 2014 [http://dx.doi.org/10.1016/S0140-6736\(14\)60042-8](http://dx.doi.org/10.1016/S0140-6736(14)60042-8)

³⁴ In this way, cerebral responses correlated to a state of consciousness or to becoming aware of an instruction — for example, the “cerebral signature” of the activation of a network involved in the simulation of an activity such as “playing tennis”, or of a cognitive spatial navigation task such as “walking around the house”, challenge the clinical diagnosis of an unresponsive wakefulness syndrome (or vegetative state). But only a positive result can be interpreted since a negative result cannot exclude that the person may be conscious but is unable to respond to instructions for various reasons: difficulty in understanding the instructions, attention or executive function disorders, fluctuations in wakefulness, and therefore of consciousness, during the course of the test, etc.

This heterogeneity has led clinicians and researchers, in particular at Liège University in the *Coma Science Group* to work on subdividing minimally conscious states (MCS) into MCS *pluses* and MCS *minuses* (MCS+, more conscious or MCS-, less conscious) according to not only increasingly detailed clinical scales, but also to responses observed when using various techniques for exploring brain function³⁵.

As a result, the terminology is currently in a state of continual flux due to the integration of clinical data with the results of brain function exploration techniques, themselves also evolving continuously.

But despite ever growing sophistication, this classification of minimally conscious states, although it is fundamental for the purpose of formulating a prognosis³⁶ is still very reductive as regards the *continuum* that chronic disorders of consciousness represent.

And the absence of a detectable proof of consciousness does not prove the absence of consciousness.

In minimally conscious states, numerous factors play a part in modulating a patient's state of consciousness and in the evaluation of the future prospects in each particular case.

The cause of cerebral injury³⁷, the patient's age, the length of the initial coma and the time elapsed since the onset of minimal consciousness are important factors for prognosis³⁸.

Somatic involvement, inevitably present due to the severity of the initial cerebral injury (in particular paralysis which can be as severe as quadriplegia), further adds to the gravity of the prognosis by increasing the likelihood of complications (tendon retraction, skin lesions, intercurrent infection, etc.) and confuses the analysis of behavioural response to various stimuli, thus even further complicating an evaluation of the level of consciousness. Any pre-existing complaint, all the more frequent in elderly patients, will add to the difficulty of arriving at a prognosis.

Together with the above factors, the medical and family environment whose role is essential in both the prevention of somatic complications and in the continuity of sensory and affective stimulation, adds to the radical singularity of each particular case.

³⁵ Giacino J, *et al.* *Nature Reviews Neurology* 2014, 10:99-114, *op. cit.* ; Fernandez-Espejo D, *et al.* *Nature Reviews Neuroscience* 2013, 14:801-9, *op. cit.*

³⁶ Prognosis is increasingly bleak as the impairment of consciousness lasts longer and is more severe. This classification of minimally conscious states is also fundamental when choosing the most appropriate therapeutic options, such as developing functional communication processes for patients who are conscious but unable to communicate.

³⁷ Concussion or, more frequently, a stroke or global cerebral ischemia.

³⁸ The minimally conscious state is generally described as chronic when it persists for more than a year and was caused by concussion or, for any other cause, when it persists beyond three months.

We should add that prognosing the possible developments of the state of consciousness is not the only issue: there is also the suffering that the patient may be having to cope with. These are two fundamentally different sets of values: suffering is related to that which is impossible to endure.

The issue of limits must therefore be considered, trying to gain an insight into the past — to try and assess as clearly as possible what may have been the person's wishes in the past that may have been made known to family or other loved ones — to try and explore the future — so as to formulate as accurate a prognosis as possible — and also probe the present — to try as best one can to perceive what the person is expressing and assess the possible existence and degree of suffering.

II. Ethical Issues

A. Decision making in a situation of deep uncertainty

As we have seen above (I. A), the assessment of “*unreasonable obstinacy*” as designated in Articles L. 111-5 and R. 4127-37 of the Code of Public Health, as well as the assessment of the qualifications for “*treatment which appears to be futile, disproportionate, or has no other object or effect than artificial life support*” (Article R. 4127-37) and for “*a treatment which is futile, disproportionate or with no other object than the sole artificial prolongation of that person’s life*” (Article L. 1111-13) raise problems of interpretation that cannot easily be solved.

And it is when the issue of withdrawing artificial nutrition and hydration concerns severely disabled persons “*unable to express their wishes*” — “*in an advanced [but not a terminal] phase of a serious and incurable disease*”, whose condition is not seriously life-threatening, who have neither drafted *advance directives*, nor named a *trusted person* — that interpreting the concept of “*unreasonable obstinacy*” raises the most complex problems:

- how can one go about qualifying a treatment as unreasonable on behalf of someone else (who is in a highly vulnerable situation)?
- how can one decide on behalf of someone else that treatment should be withdrawn because it is considered unreasonable, when it is precisely that treatment that is keeping the person alive and withdrawal of it will lead to death?
- can one decide to withdraw treatment because it is considered to be unreasonable, in lieu and on behalf of someone else, when it is keeping alive someone who is not at the end-of-life, when its withdrawal will cause the person to die and when the treatment is artificial nutrition and hydration?

In other words, is it possible to determine, in a given situation, a course of action which would be considered “reasonable”, inspired by reason? And would this reasonable action be to withdraw or, on the contrary, to continue artificial nutrition and hydration?

In such a context, calling on reason means calling for reasoned deliberation. Such reasoned deliberation must be informed by what may be known facts but also must report on what is not known and on what it will not be possible to discover. It must delineate, as carefully as possible, the contours of ignorance so as to take into account the uncertainty inherent to any decision making in such an extreme situation.

1. Uncertainty regarding the person's condition and future outlook

1. 1. Is the person “unable to express wishes”?

The question's difficulty resides in the ambiguity itself of this borderline condition, the minimally conscious state.

Only meticulous examination of the patient by highly experienced medical specialists can be expected to provide an answer. In some cases, functional brain imaging or other similar techniques may succeed in establishing communication with patients. In such cases, their wishes could be taken into account in coming to decisions on their behalf.

In less than the past ten years, several studies have suggested that exploring activity in certain areas of the brain using neuroimaging techniques, in particular functional magnetic resonance imaging (fMRI), can detect in some *states of unresponsive wakefulness* (formerly known as *vegetative state*) or *minimally conscious states*, voluntary response to verbal requests although no detectable muscular movement has been observed, and therefore in the absence of any gesture or speech³⁹.

In two of these studies, using these methods, researchers were able to obtain from two people who had been for five and twelve years respectively in a state of wakefulness without any detectable response, correct replies, in the form of a *yes* or a *no*, to very specific questions on past or present events in their lives⁴⁰.

This research as a whole suggests the existence for certain people in a state of unresponsive wakefulness or of minimal consciousness, of a degree of awareness and attention (or even the capacity to communicate) that their failure or weakness in performing muscular movement had rendered undetectable.

³⁹ Giacino J, *et al.* *Nature Reviews Neurology* 2014, 10:99-114, *op. cit.*; Fernandez-Espejo D, *et al.* *Nature Reviews Neuroscience* 2013, 14:801-9, *op.cit.* The first of these studies, published in 2006, consisted in asking a patient who had been for five months in a state of unresponsive wakefulness, to imagine in response to a request, either that she was playing tennis or walking around her home. The cerebral activity of the patient as detected by fMRI in response to these requests was identical to those of conscious people to whom the same requests had been addressed. (Owen A, *et al.* Detecting awareness in the vegetative state. *Science* 2006, 313 :1402. Naccache L. Is she conscious? *Science* 2006, 313:1395-6). The condition of the person who had made these “replies” later evolved to a minimally conscious state before reawakening when she was able to describe her relief when doctors “communicated” with her. Over the last four years, several studies involving fMRI and using similar approaches have provided equivalent results for people who had been for several years in states of unresponsive wakefulness or minimal consciousness: Naci L, *et al.* Making every word count for nonresponsive patients. *JAMA (Journal of the American Medical Association) Neurology* 2013, 70:1235-41; Bardin J, *et al.* Pattern classification of volitional functional magnetic resonance imaging responses in patients with severe brain injury. *Archives Neurology* 2012, 69:176-81; Bardin J, *et al.* Dissociations between behavioral and functional magnetic resonance imaging-based evaluations of cognitive function after brain injury. *Brain* 2011, 134:769-82; Monti M, *et al.* Willful modulation of brain activity in disorders of consciousness. *The New England Journal of Medicine* 2010, 362:579-89.

⁴⁰ “*is your name...?*” followed by the person's name or some other name; “*is the name of the person looking after you...*” followed by the name of the assistant nurse or some other name; “*are you now in...*” followed by “*a supermarket...*” or “*a hospital?*”; “*are we in ...*” followed by the year in which the question is asked, or another year; “*are you in pain...?*” followed by “*yes*” or “*no*”. Naci L, *et al.* *JAMA Neurology* 2013, *op. cit.*; Monti M, *et al.* *The New England Journal of Medicine* 2010, *op. cit.* One of these patients still seems able to consign to memory the names of nursing staff and the concept of the passing of time.

If some method for reproducible communication can be established, either through movement or functional neuroimaging, questions on whether the patient wishes to continue living could be answered by a *yes* or a *no*⁴¹.

But even if the question of whether they wished to continue living or not was put to the very few people capable of replying with a *yes* or a *no*, clearly and reproducibly by means of the cerebral activity detectable with neuroimaging, how would it be possible to ascertain that, despite their cerebral lesions, their capacity to think and decide was sufficiently intact to assess fully the implications of their reply⁴²?

That a person is capable of hearing a question and answering it — in this very singular form consisting in thinking the answer without being able to express it otherwise than through the brain activity that is correlated to that thought — gives no indication of the capacity for reflection, memory, emotion and deliberation which the person may have exercised to arrive at the answer given.

In other words, the complex central issue at stake with these new modes of communication is whether, in this unprecedented form and context, the person concerned has, or has not, the capacity of expressing a decision based on “free and informed consent”⁴³.

It is possible to go as far as considering that a person with the capacity to respond in such circumstances would also be capable of making an informed decision and a free and informed choice? Can brain injury so severe as to be the cause of a minimally conscious state be compatible with making a “free and informed decision”⁴⁴?

1. 2. Is the person in the advanced phase of a serious and “incurable” disease?

More than whether the condition is *incurable* or otherwise — meaning whether medical science is capable of curing it — the real issue bears on *prognosis*, meaning the favourable or unfavourable outcome of the disease, be it due to treatment or spontaneous (and simply made possible by continuing with the long term treatment whose sole effect is artificial life support).

In this instance again, only a meticulous medical examination of the patient by highly experienced and specialised physicians can attempt to provide a reply to the question.

⁴¹ In the only two studies published to date, [see note 40], researchers did not ask the two conscious patients whether they wished to continue living or preferred to die.

⁴² As noted in Fernandez-Espejo D, *et al.* Detecting awareness after severe brain injury. *Nature Reviews Neuroscience* 2013, 14:801-9, *op. cit.*, “...it is important to consider whether a simple ‘yes’ or ‘no’ response to such a question would be sufficient to establish that a patient has retained the necessary cognitive and emotional capacity to make such a complex decision. Clearly, it would not.... In this context, decision-making capacity may be better considered as a continuum with different thresholds depending on the importance of the potential consequences of the decision, rather than an ‘all or nothing’ problem.”

⁴³ Petersen A, *et al.* Assessing decision-making capacity in the behaviorally nonresponsive patient with residual covert awareness. *American Journal of Bioethics (AJOB) Neuroscience* 2013, 4:3-14.

⁴⁴ We remark that these questions strengthen the case of the caution often expressed by CCNE on the subject of consent too hastily perceived as “free and informed”, in particular in highly vulnerable circumstances.

But the difficulty resides in the fact that prognosis is statistical and probabilistic: it cannot concern a particular person; it can only be pertinent to a group of people in a comparable state to which that person can be associated as nearly as possible⁴⁵.

Once the acute phase of resuscitation is past, and when care is being provided in rehabilitation centres of the finest quality, the proportion of people recovering (during the months following the traumatic brain injury that had caused their condition) a normal state of consciousness — attention and communication — was estimated at over 65% according to a recent study⁴⁶, and the proportion of people recovering a capacity for autonomous and independent activity at nearly 20%.

After the first year, however, and increasingly as time goes by, the proportion of people who recover a normal state of consciousness with no significant degree of neurological impairment gets progressively lower⁴⁷. Recovery after years in a state of unresponsive wakefulness or in a minimally conscious state has been reported, in one exceptional case as long as 19 years⁴⁸. But generally, the probability of recovering a normal state of consciousness after traumatic brain injury was recently estimated to be about 10% in one study⁴⁹, and 30% in another study⁵⁰ (CCNE suggests that anyone wishing to assess this data in more detail should refer to the studies mentioned in the footnotes to this document).

The difficulty in formulating a prognosis for any one individual is compounded by the fact that different people in a minimally conscious state may be affected by very different kinds and varying degrees of brain injury. The same detectable state of disorder of consciousness applies to a wide variety of situations.

As regards therapy — apart from preventing intercurrent infections — it consists of rehabilitation with the object of developing self-expression and interaction capacities as well as nursing and physiotherapy. But there is a great deal of on-going research on possible therapies⁵¹.

⁴⁵ "Prognosis should be evidence-based, yet adapted to the individual characteristics of the patient. Prognosis is a statistical concept. Prognostic accuracy is greater when determining the mean neurological outcome for a group of similar patients than for any individual patient within that group. Individual neurological outcomes can be expressed only in standard deviations from the mean. Physicians should frankly admit the uncertainty."

Jox R, et al. Disorders of consciousness: responding to requests for novel diagnostic and therapeutic interventions. *Lancet Neurology* 2012, 11:732-38.

⁴⁶ Nakase-Richardson R, et al. Longitudinal outcome of patients with disordered consciousness in the NIDRR TBI Model Systems Programs. *Journal of Neurotrauma* 2012, 29: 59-65.

⁴⁷ Lammi M, et al. The minimally conscious state and recovery potential: a follow-up study 2 to 5 years after traumatic brain injury. *Archives of Physical Medicine and Rehabilitation* 2005, 86:746-54.

⁴⁸ Voss H, et al. Possible axonal regrowth in late recovery from the minimally conscious state. *Journal of Clinical Investigation* 2006, 116:2005-11; Laureys S, et al. Tracking the recovery of consciousness from coma. *Journal of Clinical Investigation* 2006, 116:1823-5; Schiff N, et al. Hope for "comatose" patients. *Cerebrum* 2003, 5:7-24. This was the exceptional case of Terry Wallis, a man of 20 in 1984 when he had a car accident which put him at first into a coma and then, for 19 years in a vegetative state — which was probably a *minimally conscious state* (a state which was only identified in 2002). Terry Wallis woke up in 2003, aged 39. He can speak, but suffers from significant neurological after effects.

⁴⁹ Estreano A, et al. Late recovery after traumatic, anoxic, or haemorrhagic long lasting vegetative state. *Neurology* 2010, 75:239-45.

⁵⁰ Luaute J, et al. Long-term outcomes of chronic minimally conscious and vegetative states. *Neurology* 2010, 75:246-52.

⁵¹ Out of the therapeutic trials involving a pharmaceutical drug, only one randomised double-blind placebo-controlled trial has so far revealed statistically significant efficacy in improving the state of consciousness of minimally conscious patients. The substance is a dopamine agonist, amantadine. (Giacino J, et al. Placebo-

As is always the case with research, forecasting the general outcome of today's work several years ahead of time is obviously impossible⁵². New methods of communication using a brain-machine interface could emerge, or new therapeutic approaches to increase the level of awareness, expression and interaction with the environment and with other people. But again, there may be no such development of any significant practical value within the next few years.

It is therefore within the current medical and scientific context — notwithstanding the possibility of breakthroughs in the medium term emerging as a result of current active and promising research, although they are by no means a foregone conclusion — that today's decisions must be taken for people who have already spent several years in a state of unresponsive wakefulness or of minimal consciousness.

How can information on the possibility of further improvement, which can only be expressed as *a priori* very slight probabilities, be taken into account?

Compounding this basic uncertainty is a further problem related to the actual nature of a possibly favourable outcome: would the improvement apply only to the state of consciousness, to cognitive capacities and the capacity to communicate, will the person stay totally or seriously paralysed?

In other words, when we speak of an “incurable condition” as regards a minimally conscious patient suffering from brain injuries, what condition(s) are we referring to?

1. 3. Is the person suffering?

Some studies suggest that various approaches can be used to detect physical pain and suffering in minimally conscious patients and that it is therefore possible to provide appropriate treatment⁵³.

Since the exact state of awareness of patients and their capacity to express themselves is largely unknown, their gestures and expressions possibly revealing a state of well-being or of distress must be factored in to decisions regarding care and treatment, but they cannot be interpreted as a clear indication of the will to stay alive or not⁵⁴.

controlled trial of amantadine for severe traumatic brain injury. *The New England Journal of Medicine* 2012, 366:819-26). But in this therapeutic trial, patients were treated at the latest four months after the accident that had caused their condition. We do not, therefore, have information on the effect such treatment could have if it was administered to people who had been minimally conscious over several years. Further research, the results of which are still preliminary, are studying other medications or transcranial magnetic stimulation or even invasive neurosurgery, such as deep brain stimulation. (Schiff N, *et al.* Behavioural improvements with thalamic stimulation after severe traumatic brain injury. *Nature* 2007, 448:600-3).

⁵² “You can almost measure the importance of scientific research by the degree of surprise it causes. The really interesting part is the one you cannot foresee. Unpredictability is in the very nature of scientific undertakings. If what you find is really new, then by definition it must be something that was unknown before you found it.” François Jacob. *La souris, la mouche et l'homme*. Odile Jacob, 1997.

⁵³ Schnakers C, *et al.* Pain assessment and management in disorders of consciousness. *Current Biology* 2007, 20:620-6.

⁵⁴ Jox R, *et al.* *Lancet Neurology* 2012, *op. cit.*

If a reproducible mode of communication can be established, using either gestures or functional neuroimaging, questions on whether the patient is suffering could elicit *yes* or *no* responses⁵⁵.

In the absence of any clear and reproducible means of communication, the only very indirect indication on the degree of well-being or suffering a person in a lasting situation of total dependence who has difficulty in communicating is experiencing, and on whether that person wishes to stay alive or not, has been arrived at through a study of patients with locked-in syndrome.

This study by the *Coma Science Group* at Liège University, in cooperation with a French group, the Locked-in Syndrome Association (ALIS), analysed the responses of 65 people with locked-in syndrome for more than a year, on average for eight years. A majority of them, 72%, replied in the affirmative to the question “Are you in a state of well-being? A minority, 28%, gave an affirmative answer to the question “Are you unhappy?”⁵⁶.

The amount of contact with the social environment and how long a time had elapsed since the onset of the locked-in syndrome were the two main criteria correlating with a state of well-being.

This statement that they were in a state of well-being was made more ambiguous by the fact that half of the patients who said they were happy did not wish to be resuscitated in the event of cardiac arrest. Four of the people questioned replied that they did not wish to continue living⁵⁷.

The study suggests that neither the degree of well-being nor the wish to continue living or end life can be deduced *a priori* from the standpoint of an identical situation of extreme loss of autonomy and difficulty in communicating: the degree of well-being and the wish to stay alive or die varies with individuals and the different ways in which they experience their situation.

But it is extremely difficult, or even impossible, to draw from these results any conclusion on the well-being, the distress and the wish to live or die of minimally conscious people. Indeed, we must remember that people with locked-in syndrome differ greatly from those who are minimally conscious, in that they are fully aware and cognitively intact, and can communicate clearly, albeit with some difficulty.

⁵⁵ See note 40 (Naci L, *et al.* *JAMA Neurology* 2013, *op. cit.*).

⁵⁶ Bruno M, *et al.* A survey on self-assessed well-being in a cohort of chronic locked-in syndrome patients: happy majority, miserable minority. *British Medical Journal (BMJ) Open* 2011, pp:1-9. doi:10.1136/bmjopen-2010-000039. The questions aiming to refine the assessment of the states of well-being or unhappiness were numerous and featured a ten-point scale of possible replies to express their intensity.

⁵⁷ No data is available on the response given to these questions from doctors in the context of the 22nd April 2005 law on patient rights and end-of-life.

1. 4. The nebulous frontier between the concept of “an advanced phase of a serious and incurable disease, regardless of its cause” and the concept of disability

The 11th February 2005 law for equality of rights and opportunity, participation and citizenship of disabled individuals, states: “*Disability, as understood by the law, is held to be any limitation of action or restriction from participating in social activities that a person may experience due to substantial, long-lasting or permanent impairment to one or several physical, sensory, mental, cognitive or psychological functions, to multiple disabilities or an incapacitating health condition.*”

It is worth noting that:

- an appreciation of being *curable* or *incurable* is not, as such, a component of the definition of disability;
- in the context of severe disability, the concept of an *advanced phase of a serious disease* may have at least two meanings:
 - either the idea of an actively evolving condition — a disorder that is progressing and developing towards an increasingly serious, or even terminal, phase;
 - or a concept of stability — indicating that the stable condition is the outcome of prior and massive aggravation toward the current gravity of the disability, which is not life-threatening.

The situation of a person who has been minimally conscious for several years is a particular and extreme case of serious and stable non life-threatening disability, a situation which is also identical to that of other people suffering from multiple disabilities and unable to express their wishes.

In such a context, the problem of deciding whether continuing to provide artificial nutrition and hydration is, or is not, “unreasonable obstinacy” becomes even more complex.

2. Uncertainty about good medical practice

In the circumstances, what do the codes of public health, of medical deontology and good medical practice consider to be *reasonable*, *useful* and *proportionate* treatment?

Generally speaking, is it reasonable, useful and proportionate, or on the contrary, unreasonable, futile and disproportionate, to continue artificial nutrition and hydration for someone who has been minimally conscious for several years, who did not make any prior statement on the subject of withdrawing treatment, who is not in a terminal end-of-life situation, and whose state of health seems very unlikely to improve?

The number of people⁵⁸, who are and have been in a *minimally conscious* or *unresponsive wakefulness state* for several months or years, who are receiving care and artificial nutrition and hydration and in some cases additional therapy⁵⁹, is currently estimated to be 1,500.

And yet, there do not seem to be either in the Code of Public Health, or in the Code of Medical Deontology, nor in the publications of the *Haute Autorité de Santé* (French National Authority for Health) any clear and precise recommendations for good medical practice in such cases.

The *Société de Réanimation de Langue Française (SRLF)* (The French Intensive Care Society - FICS) has published recommendations on the withdrawal of treatment⁶⁰, but they only apply to the initial resuscitation phase and not therefore to people whose state of health has been stable over several months or years.

Circular DHOS/02/DGS/SD5D/DGAS n° 2002-288 dated May 3, 2002 provided some guidance. The creation of centres dedicated to caring for people in states of chronic vegetative or minimal consciousness implies that the default management — in the absence of any prior expression by the patient of instructions to withhold all forms of treatment in such circumstances — is to continue to provide care, artificial nutrition and hydration and long term human contact, regardless of the very low probability of any improvement in the patient's health⁶¹.

This is also the position adopted by the *Société Française de Médecine Physique et de Réadaptation (SOFMER)* (French Society for Physical and Rehabilitation Medicine) and also that of the main association of families of patients concerned by this same problem, *Union Nationale des Associations de Familles de Traumatisés Crâniens et Cérébro-lésés (UNAFTC)* (French Associations of families of patients with traumatic head injury).

According to existing practice and written rules, continuing to provide artificial nutrition and hydration should only be considered as “*unreasonable obstinacy*” if there was a prior expression of wishes to the contrary by the person concerned or if there is evidence of chronic suffering.

As long as there is no decision to the effect that continuing artificial nutrition and hydration would be unreasonable obstinacy and should therefore be withdrawn, attending to patients' needs and comfort and dignity — as well as keeping them as healthy as possible, caring for their body and fostering functional capacities in the hope that their condition could improve and they might recover awareness and the

⁵⁸ Circular DHOS/02/DGS/SD5D/DGAS n° 2002-288 of 3rd May 2002 on the subject of creating care centres dedicated to caring for patients in a chronic vegetative state or a minimally conscious state. The circular refers to 1,500 people, but this is no more than an estimate as there was no detailed survey.

⁵⁹ This is also the case of an unspecified number of people with multiple disabilities and incapable of expressing themselves.

⁶⁰ *Société de réanimation de langue française. Recommendations. Limitation et arrêt des traitements en réanimation adulte. Réanimation 2010, 19:679-98.* (Limiting and withdrawing treatment in adult resuscitation).

⁶¹ It is worth noting on the one hand, that the 3rd May 2002 circular was published before the law dated April 22nd 2005 and has not been updated since to take the law into account; and on the other hand, the circular's intention was that the creation of special care units for people in chronic vegetative or minimally conscious states would be backed up by legislation and, although twelve years have elapsed, this has not happened.

capacity to communicate — requires a programme of daily care, physiotherapy, human presence and contact, attention and sensory stimulation. Hygiene and physiotherapy are particularly important, as is vigilance regarding common intercurrent infections, so as to ward off various forms of invalidity and gradual deterioration of physical health.

CCNE considers that it would be useful to review good medical practice as regards artificial nutrition and hydration, and more generally treatment and care of people who, once the initial acute intensive care phase is over, are for months or years either minimally conscious or in a state of unresponsive wakefulness and have not made any prior statement to the effect that they wished for withdrawal of treatment were they to find themselves in such circumstances. The *Haute Autorité de Santé* could be asked to formulate recommendations for good and responsible medical practice⁶².

But since no two sets of individual circumstances are ever alike, drafting rules of good medical practice, however necessary and useful, will not in itself provide answers to the question of knowing if continuing artificial nutrition and hydration is, or is not, a case of *unreasonable obstinacy* for any particular patient incapable of communication and with no prior record of advance directives to that effect.

So that the essential point at issue then becomes whether it is possible to assess reliably if the person concerned is suffering and whether he or she had previously expressed clearly and categorically the will, in such circumstances, to reject or withdraw treatment whose sole object or effect was life support.

3. Uncertainty about the instructions a minimally conscious person had previously expressed

The existence of clearly worded *advance directives* (which, belying their name, are not really directives, since they are not binding and are only seen as a person's wishes⁶³) are the best guarantee that can be hoped for that a request to withhold or withdraw treatment, including artificial nutrition and hydration — from someone who is severely disabled, unable to communicate and who is not at the end-of-life — was in fact formulated in advance by that person.

⁶² For example, most of the care and treatment required for these patients is similar to that which is provided in palliative care centres (personal hygiene, comfort care, artificial nutrition and hydration, pain management); while other care (physiotherapy, stimulation, rehabilitation, attempts at communication), is similar to what is done in post-acute convalescence rehabilitation units (French SSRs, *soins de suite et de réadaptation*). That being so, the centres for the management of unresponsive wakefulness and minimal consciousness will be viewed differently depending on whether they are administratively connected to palliative care centres or to rehabilitation centres, particularly because palliative care is usually — and mistakenly — seen as exclusively concerned with end-of-life situations, so that the outcome for patients will probably be viewed in a different way by health care providers and families.

⁶³ Article L.1111-11 of the Code of Public Health: “*All adults may draft advance directives for the case that they should find themselves at some time in the future incapable of expressing their instructions. Such advance directives set out their wishes in an end-of-life situation for the conditions attached to limiting or withdrawing treatment. The advance directives may be revoked at any time. On the condition that they were written less than three years before the onset of unconsciousness, physicians will take them into account when making any decisions to investigate, intervene or treat.*”

CCNE's Opinion n° 121⁶⁴ stated that there was a need to encourage the use of advance directives, and that "...a change in perspective is needed regarding the value to be given to advance directives." "When advance directives exist, they should be presumed to be binding on health professionals and any deviation from what the directives prescribe should be justified in writing and included in the person's medical record."

Designating a *trusted person* who will be "consulted in the event that [patients] are unable to express their wishes" and will receive "the required information for that purpose"⁶⁵ is a considerable guarantee, but less effective, because the *trusted person* does not represent the patient. Trustees can only report what a patient told them and they are only asked for their opinion.

When no *advance directives* were drafted and no *trusted person* designated, the law provides for consultation with family and loved ones.

Obviously, in such circumstances, evaluating the clarity of the patient's wishes is a much more difficult undertaking. The situation becomes one in which there is decision *for and on behalf of someone else*, of someone *who is not in an end-of-life situation*, the decision being to withdraw life-sustaining treatment and this action will cause the patient to die.

What are the "ethical issues raised by refusal of treatment by and for a third party?" asked CCNE in its Opinion N° 87. "Refusal of treatment by a third party is always also refusal for a third party. When a third party refuses treatment for a patient, he not only puts himself in the place of that patient, he also takes that person over, since refusing treatment for oneself and for a third party are two very different matters"⁶⁶.

When patients *incapable of expressing their wishes* have neither drafted *advance directives* nor designated a *trusted person*, then the *physician, deciding alone* — after consulting another physician, the clinical team, family and a loved one — is tasked by the Code of Public Health with the duty of deciding to withdraw or not to withdraw artificial nutrition and hydration.

⁶⁴ CCNE, Opinion N°121, *The End of Life, Personal Autonomy, the Will to die*.

⁶⁵ Article L.1111-6 of the Code of Public Health.

⁶⁶ "Personal convictions, emotional relationships and interests may overshadow or contradict the interests of the patient. The difficulties encountered when there is a transfer of consent from an incompetent person to the family or a trustee are well known. Proximity may be in contradiction with the patient's true interests. Refusal by a patient and refusal expressed by a third party can never be deemed to be one and the same. Nor is the issue confined to interpreting the refusal expressed by a third party; the central issue is the legitimacy of that third party, a subject on which controversy is endless. Who is this third party? Is he or she a member of the family, a friend, a legal representative? What interests come into play, known or concealed? Is the third party competent to judge the best interests of the patient and to make known his true wishes? These questions become all the more acute in a sectarian environment when the third party steps in without debate or hesitation to take over any true or apparent patient autonomy".

CCNE has already made its views known regarding the ethical consequences of consent for the benefit of another person. (Opinion n° 70, December 13th, 2001, *Opinion on Consent for the Benefit of Another Person*). One of the key elements was to attempt to differentiate between what was specific to the patient himself compared to the third party from whom consent was being requested. In the event of refusal, the doctor must seek to discover the difference between "what do you think" and "what do you think that the patient thinks". CCNE n° 87, *Treatment refusal and personal autonomy*.

CCNE considers that in these circumstances, the major ethical issue is that such a decision, taken in a situation so fraught with uncertainty, cannot be made solely relevant to medical expertise and, for that very reason, should not be made by the physician alone.

B. Exploring issues on a case-by case-basis, taking into account the radical singularity of each situation

"The purpose of ethical reflection is not to establish a more or less satisfactory legal solution" wrote CCNE in its April 14th 2005 Opinion N° 87 Treatment Refusal and Personal Autonomy, "...but rather to analyse and understand the value judgments which have been expressed and the involvement of all participants: the persons concerned, their families, society and the medical profession, with full respect for the dignity and beliefs of everyone."

While there is a marked convergence of opinion in favour of restraint in the implementation of medical technology and agreement on the concept of reasonable abstention from medical harassment ("letting go") in an end-of-life situation, the ethical dilemma is entirely unresolved in extreme situations of prolonged life.

Although the law ruled in favour of consent in the conflict of values between respect for life and for a sick person's right to consent — patients are entirely at liberty to make any decision about their own health, no one else is entitled to be a judge of their interests, and patients may request that any form of treatment, including artificial nutrition and hydration, be withdrawn or withheld. But what happens to this conflict of values when in fact free and informed consent cannot be expressed?

Or again, can awareness which has no external expression be the pertinent and sought after criterion for "artificial prolongation of life"? Even when self-awareness, autonomy, contact with others and the capacity to decide are all beyond our capacity to detect them, ethical reflection will always lead us to hold true that a person cannot be considered solely as a passive object of treatment and care.

Then physicians, carers, loved ones, must needs become explorers of extreme confines, seeking to associate the little that can be perceived of the patient's expression, what may have been learned from past pronouncements, the vast expertise of family and personal carers and of health professionals, born of shared experience from day-to-day, and all the various professional proficiencies, keeping in mind that whenever the frontiers of hierarchy, institutions and culture need to be crossed, then that must be done.

To which end, personal projection on someone else's life and its opposite, neutrality, must be avoided in order to:

- detect whether awareness, even minimal, of a deteriorated life is, or is not, unbearable and much more acute suffering than living unconscious,
- and take into consideration what loved ones believe are the wishes of the person incapable of expressing them.

1. Allowing for the expression of multiple viewpoints

People all react in various ways depending on how they consider the ethical issues, among which:

- The paradox of a person who is *present but inaccessible*⁶⁷, raising the question of what it is that constitute a person, a being capable of relationship or a being *other* than solely through communication within a relationship, *beyond* the sole capacity of being able to communicate.
- The regard given to a person's *autonomy*, depending on whether it is valued as of primary importance or being understood as arising first from a relationship of otherness — the person being received by another as much as acting on their own behalf.
- The regard given to the *vulnerability* and *fragility* of minimally conscious persons. In its Opinion N° 122⁶⁸, CCNE emphasizes that “*The sense of self cannot be diminished to measuring capacities or focusing on performance.*”
- A person's *dignity*, underlining that there is a legal obligation to “*ensure that dignity is preserved throughout a person's life*” and to “*preserve the dignity of sick people*”⁶⁹. Accordingly CCNE states in its Opinion N° 105: “*From the start, it had been noted that the principle of respect for the dignity of the human being could appear as having a "variable composition". It demands that people should never be considered simply as means towards an end, but an end in themselves, and should never be instrumentalised. For some, dignity is inherent to human nature whereas for others, it should be recognised that it is contingent on a more subjective assessment.*”⁷⁰. With similar emphasis, CCNE in its Opinion N° 121, also pointed out that allowing the most vulnerable people to live and die in circumstances of indignity⁷¹ was generally agreed to be unacceptable.
- The multiple dimensions of the *suffering* experienced by patients and their families, remembering that the law requires that a sick person's “*physical and psychological pain be alleviated*” and “*their families be given support*”⁷². Fighting pain is not without consequences on the decision making process, all the more so because the emotions are intrinsically involved. In this connection, current thinking in neuroscience views decision making in the following light: emotion gives rise to decision, rationalisation only arriving afterwards, retrospectively⁷³. The role played by emotion must be integrated into the ethical debate on decisions affecting life and death — all the more so because the decision is made in a situation fraught with uncertainty, in fertile

⁶⁷ Pont K, Vassal P, Respect de la famille et du patient en état végétatif chronique ou pauci-relationnel : un dilemme éthique, (Respect for the family and for the patient in a chronic vegetative or minimally conscious state) in *Ethique et Santé* (2013) 10, 27-33.

⁶⁸ CCNE, Opinion N°122, *The Use of Biomedical Techniques for “Neuroenhancement” in Healthy Individuals: Ethical Issues.*

⁶⁹ Art L. 1110-5 of the Code of Public Health.

⁷⁰ CCNE, Opinion N°105, Questions for the Estates General on Bioethics.

⁷¹ CCNE, Opinion N°121, *The End of Life, Personal Autonomy, the Will to Die.*

⁷² Art L. 1110-5 of the Code of Public Health.

⁷³ Antonio Damasio. *L'erreur de Descartes: la raison des émotions.* Odile Jacob, 2010. Bechara A, Damasio H, Tranel D, *et coll.* Deciding advantageously before knowing the advantageous strategy. *Science* 1997, 275:1293-5.

ground for subjective and divergent interpretations of the sick person's behaviour patterns.

- Our very understanding of the meaning of *solidarity*. In the deeply uncertain climate arising from the complexity of the circumstances and points of view needing consideration, continuing or withdrawing artificial nutrition and hydration, which is in fact equivalent to continuing or withdrawing life support, may in each case, depending on the specifics of each case, be one of the possible manifestations of solidarity and respect owed to anyone in the depths of extreme vulnerability. *“Ethical concern in matters related to the life and death of human beings touches upon the permanence of the social bond.”*⁷⁴ wrote CCNE in its Opinion N° 108.
- In the context of solidarity, reconciling the duty to provide ever better health care with the responsibility for spending public finances wisely must also enter into the equation. Let us not forget that *...since the beginning, respect for the constitutional principle that “The Nation provides for everyone’s health to be protected” was ensured not as solidarity depending on income, but rather solidarity between the healthy and the sick, taking only into consideration the disease and its cost. (...). Our system of solidarity retains as its ultimate goal the determination to make sure that no one needs to do without medical help in particular because of financial considerations*⁷⁵. Nonetheless, CCNE emphasized in *Opinion N° 101* that *“... guaranteeing fair access to quality health care is not incompatible with economic orthodoxy. The constant need to adjust health care to demographic requirements, epidemiological changes and technological advances is ample justification, more so than for any other human activity, for clear and courageous choices, which must be explicit in the eyes of citizens. Such decisions must be kept under constant review without ever losing sight of the central core objective: helping the most vulnerable. The ethical issue raised by an examination of the economic dimensions of health care is an exploration of the tension between autonomy and solidarity, between individual liberty and the public good. Such tension can only be relieved by seeking equity, in other words, justice.”*⁷⁶
- The meaning of life. *“For some, all life is meaningful and no one is entitled to decree that consciousness has entirely disappeared; as long as patients are alive they may benefit from future scientific progress... Others, on the contrary, consider that tube feeding, for example, is a form of disrespect and an unjustified aggression, that few people would care to survive in such*

⁷⁴ CCNE, Opinion N°108, *Opinion on ethical issues in connection with the development and funding of palliative care.*

⁷⁵ in the report dated March 22nd 2012 by HCAAM - Haut Conseil pour l’avenir de l’assurance maladie (Higher Council for the future prospects of sickness insurance) under the heading of “L’avenir de l’assurance maladie. Les options du HCAAM” (The future of sickness insurance. HCAAM options). The report also stated: “The sickness insurance system for example rejects the idea of no longer reimbursing certain treatments for the sole reason that they are “too expensive”. It is extremely attentive to technical and therapeutic innovation and to ensuring that they are used appropriately. This policy further reinforces the extreme care that is taken to arrive at an optimal mobilisation of our resources to avoid being confronted with increasingly difficult choices in the presence of certain costly innovations. Conversely, there is also an obligation to continue making use of and reimbursing certain early or first intention treatments, even if they are not very costly, so that good therapeutic management policies continue to be encouraged. However, these health protection objectives should not be mistaken — as they sometimes are — with the erroneous notion that reimbursing what is indeed beneficial to health means reimbursing anything and everything that the market has on offer.”

⁷⁶ CCNE, Opinion N°101, *Health, ethics and money: ethical issues as a result of budgetary constraints on public health expenditure in hospitals.*

conditions, that death is one way of protecting loved ones from suffering."⁷⁷. Everyone believes that people in a minimally conscious state are still people with every right to command respect; but for some, their life is made up of nothing but suffering and this guides their decision, while for others prolonging treatment and care means that "*the most vulnerable, the most deprived, the most fragile, the most endangered, the most desperate are also those who are most worthy of our respect.*"⁷⁸ When all is said, perhaps the question is not so much the meaning of life, to which there is probably no answer other than an individual one, but rather the intention of the form of caring attention given by doctors, carers and family.

- The relationship to *time*, to which are connected not only the difficulty of prognosis for one person when knowledge cannot be anything but statistical and probabilistic; not only life expectancy, as significant in quality as it is in time; nor only the important differentiation between a condition that is immediately life-threatening and one which is not. But to some thinkers, there is a need to reach for a diachronic meaning to time when the silence of a life suspended in timelessness evokes the mark of infinity on the finite.
- The *reality of care*. However qualified the clinical team, however devoted the family and loved ones, there are times of exhaustion when a condition is not evolving, when the difficulty of preventing complications such as bedsores, tendon retraction, intercurrent infections, all combine to bring about feelings of utter hopelessness or realising that adequate care and comfort can no longer be provided.
- The impossibility of *integrating death*, be it one's own or someone else's, when attempting to enter another person's mind. Death borders on the boundaries of what it is possible to have in mind. It borders on what the psyche is fundamentally incapable of representing. How can decisions be taken in such a context? This is the central question arising when anyone participates in a decision to discontinue the life of another person.

That being so, when can it be considered that artificial nutrition and hydration have reached a point where treatment "*has no other object or effect than artificial life support*" or "*no other object than artificially prolonging life*"?

As we have already noted, this definition — that of artificial life support, or of only artificially prolonging life — is particularly ambiguous.

In this context, the real question is in fact whether keeping someone alive whose consciousness is not communicated externally amounts to *artificial* life support or *artificial* prolongation of life⁷⁹.

Which brings us back to the central issue of making a decision for another person, in the absence of any sufficiently reliable and prior expression of that person's wishes: should we or should we not accept that someone else is competent to decide whether

⁷⁷ In « L'alimentation artificielle et l'hydratation chez la personne en état végétatif chronique : soin, traitement ou acharnement thérapeutique ? », (Artificial nutrition and hydration in chronic vegetative states: care, treatment or intrusive medical intervention?) Régis Aubry, in *Médecine palliative – Soins de support – Accompagnement – Ethique* (2008) 7, 74-85. Editions Lamarre.

⁷⁸ Didier Sicard, in *L'alibi éthique* (2006). Plon.

⁷⁹ In the meaning of Articles L. 1110-5, R. 4127-37 and L. 1111-13 of the Code of Public Health.

that person's life is worth living or not and is also capable of evaluating the quality of that life?

In other words, should we consider that another person's severely disabled life, if continued, is evidence of "unreasonable obstinacy"?

Replying to that question with an unqualified affirmative would radically call into question the pertinence of caring for and treating anyone whose loss of autonomy is extreme⁸⁰. CCNE is no advocate of such a sweeping reappraisal.

For CCNE, the sole fact of having to depend irreversibly, without any hope of improvement, on nutritional assistance to remain alive, is not in itself — emphasizing "in itself" — sufficient to qualify for "artificial life support" and "unreasonable obstinacy". For some grievously disabled people, life is made up of...obstinately staying alive. Regardless of the conditions in which such lives persist, such "obstinacy" cannot be described as unreasonable.

Likewise, consideration must be given to the wishes of those for whom it is of primary importance that they retain the right to refuse, for themselves and on their own behalf, any form of medical harassment. In such cases, continuing with artificial nutrition and hydration may be qualified as "artificial life support", particularly if — among other things — clearly recorded prior wishes were to "end it all".

But when patients have not made their wishes known, is it acceptable to presume on what they would have wanted?

In this deeply uncertain situation, deciding that to continue artificial nutrition and hydration is *unreasonable obstinacy* — for severely disabled patients who are unable to express their wishes and are not in an end-of-life situation — should not be permissible unless it is the result of a collective decision, with the full involvement of health care professionals, family and loved ones. The decision would also need to take into account, to the extent possible, the patient's individual circumstances as well as any impressions of how much suffering is being endured and what patients might have wanted for themselves.

2. Calling into question the current form of collegial procedure

"The law cannot be allowed to bypass further ethical reflection"⁸¹, wrote CCNE in Opinion N° 105.

With this statement, CCNE was pointing out the particular difficulties that the Code of Public Health's present definition of a supposedly *collegial procedure* raises for physicians. It involves consulting another doctor, the clinical team, family and loved ones, but then going on to taking the decision *alone*:

⁸⁰ Such reappraisal could lead to readdressing the controversial issue of legal liability incurred by the sole fact of being kept alive.

⁸¹ CCNE, Opinion N°105, *Questions for the Estates General on Bioethics*.

- the physician must first decide whether a situation of *unreasonable obstinacy* is indeed occurring, clinically speaking, taking into account the patient's specific medical condition and the actions prescribed by good medical practice,
- and then evaluate any available information on the patient's wishes as they may have been previously expressed to family or loved ones.

The physician must therefore be both *judge and party in passing judgment*.

And yet, as discussed above, a decision made in a situation of such uncertainty cannot build on medical expertise alone, which is good reason why it should not be made by a physician acting alone.

The *Coma Science Group* at the University Hospital of Liege, headed by Steven Laureys, published recently the results of an extensive survey⁸² questioning 2,475 medical and paramedical professionals in 32 member states of the Council of Europe, on the subject *inter alia* of attitudes towards people in a minimally conscious state for more than a year. Less than a third of the respondents considered that withdrawing artificial nutrition and hydration for people who were minimally conscious was acceptable, whereas two thirds of health carers would not have wished to be kept alive themselves in that condition.

This discrepancy is all the more thought provoking because it is evidenced in a population, that is health care professionals, who are responsible by law for evaluating the "reasonable" or "unreasonable" dimension of continuing or withdrawing life supporting treatment⁸³.

CCNE, in its Opinion N° 121, recommended a modification of the *collegial procedure* so that it could become a true collective deliberation and "*not seen as a collegial discussion among experts*" and for it to be implemented *on a "much broader basis as soon as complex decisions have to be made at the end of life, be it for medical reasons or following a patient's request."*⁸⁴

In such a collective deliberation, the input of medical professionals will of course be extremely valuable as will that of non medical carers, those who are closest to the patient and to the patient's physical reality and possible reactions, as will also be the opinions of the family and loved ones who have a different, more personal view of their relative's possible reactions and alone are able to throw light on what they believe to be past wishes, hopes and fears.

Some people believe that the opinions of the spouse or of the life partner should predominate, since as far as anyone knows, the patient's lasting decision was to choose the person sharing his or her life. Others, however, point out that such an

⁸² Demertzi A, Ledoux D, Bruno M, *et coll.* Attitudes towards end-of-life issues in disorders of consciousness: a European survey. *Journal of Neurology* 2011, 258:1058-65.

⁸³ Steven Laureys' comment on this study was that medical professionals needed to review their stance since "It is neither moral nor ethical to deny to others rights that we grant to ourselves".

⁸⁴ Thereby extending the recommendations of the *Commission de réflexion sur la fin de vie*. « Penser solidairement la fin de vie. Commission de réflexion sur la fin de vie en France », 2012, op. cit. ("Solidarity in France at the end of life". Report by the presidential consultation Group for France on the end of life.)

option is frequently fraught with difficulty. A more generic word comes to mind, such as “loved ones” to embrace the innumerable variety of individual situations.

In such a situation of uncertainty, of limited knowledge and at life’s limits, it would seem right and fitting that the arguments contributing to this collective process of deliberation should be considered collectively, on a basis of equality, leaving hierarchy aside, and not in the belief that the medical point of view is the only one entitled to render a “verdict”.

In other words, CCNE considers that thought should be given to make this *collective deliberation* process evolve into a truly *collective decision*.

3. How can an irreversible decision be taken in a situation of deep uncertainty? Arguing in favour of a collective decision procedure, on a case-by-case basis, providing for a possible appeal to mediation

The first step is to consider the time required to reconcile the various viewpoints, those of family and loved ones as well as those of doctors and carers⁸⁵. As is the case for informed consent, ensuring that dialogue takes as much time as is needed and is of the right quality will be much more useful than simply complying with administrative obligations. This is particularly true when discussing a decision to withdraw treatment, but equally so when explaining the care required for life in a minimally conscious state, and its possible complications.

If a consensus does not emerge from collective deliberation, despite protracted attempts to reconcile divergent opinions and arrive at a consensual position, a second stage for mediation could be helpful⁸⁶.

Mediation, in the generally accepted meaning of the word, is an ethically motivated process supported by the sense of responsibility and the autonomy of participants, in which a third party — who must be impartial, independent, neutral, without power of decision, empowered only by the authority the participants to the collective deliberation process are willing to invest in the mediator — facilitates the opening of a dialogue or its resumption, the social interplay and the capacity to make a joint decision.

This process of mediation must necessarily be entirely independent of all the parties involved — meaning also independent of the hospital or other health caring

⁸⁵ The time required to discriminate in a conciliation is all the more necessary because more often than not, dissensus leads to prolonging treatment and care.

⁸⁶ A further advantage should this kind of procedure be adopted is that it would fulfil a role in the observation of complex, borderline and exceptional situations. In its Opinion N° 121, CCNE expressed the wish that some kind of observation system be implemented since rather surprisingly, no national nor even regional data is available to serve as a factual basis to analyse actual situations of unreasonable obstinacy in extreme or complex situations where the various participants involved disagree.

institutions⁸⁷. It would probably be helpful if several people were part of the process⁸⁸.

The thoughts set out above are anchored in the freedom of principled discernment which remains as the ultimate point of reference, on the condition that conscience is enlightened by confrontation with another's understanding.

For this reason, rather than trying to establish a standard which could possibly apply to every conceivable case and which could give doctors a basis on which to construe a decision, CCNE considers that it would be preferable to set up a substantive process for deliberation and collective decision so that, in each case, in full awareness of the prevailing uncertainty, could emerge the best possible response to the radical singularity of each situation.

⁸⁷ The parliamentary evaluation report for the law on the rights of patients and on end-of-life recommended in 2008 (proposal 8) nominating appointees in each region who could step in to facilitate the law's implementation in complex situations.

⁸⁸ Taking the matter to court would always be a possibility as a last resort so that the dispute could be settled by traditional judicial procedure.