Informed consent of and information to persons accepting care or research procedures

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Monsieur Bernard Kouchner, Minister for Health and Humanitarian Action, on the occasion of his closing address to the CCNE's (*Comité consultatif national d'éthique*) Tenth Anniversary Conference on February 9th 1993, asked CCNE to conduct a study on information provided to persons accepting care or research procedures : "What should the notion of informed consent cover ? How should the physician's duty to inform truthfully be defined ?" B. Kouchner repeated this request on the occasion of the *Journées annuelles d'éthique* in January 1998.

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Preamble

The following report distinguishes between two ethical positions : the one (referred to as "teleological") based on the principle of beneficence, of doing good (or of not doing harm); the other (referred to as "deontological") based on the principle of respecting personal autonomy. In a care-giving or biomedical research situation, pains should always be taken to do as much good (and as little harm) as possible, while respecting the freedom of decision of those one seeks to help. In other words, efforts should always be made to reconcile the two principles. There are however situations where they are in conflict. For example, there are patients who refuse blood transfusion or transplants on moral or religious grounds and whose state of health is such that their doctors wish to give a transfusion and consider that to refuse this therapy is harmful. If negotiation on the subject fails, the only remaining choice is to transfuse against the will of the patient (i.e. give priority to the principle of beneficence over the principle of respecting the patient's autonomy) or respect the wishes expressed by the patient (and run the risk of a deteriorating state of health). Fifty years ago, doctors had no hesitation in imposing on patients, sometimes without any explanation, what they considered to be in their best interests, and such an attitude was socially acceptable. Nowadays, it has become standard practice to inform patients and obtain their consent to whatever health care or research is on offer. The evolution described above is still hesitantly moving from a state of society where emphasis was placed on the notion of doing good (since doctors know what is "good" in terms of health), to a state of society where the rights of individuals to choose their own

"good" and participate in decisions concerning them is gaining respect. As such, this evolution is neither good nor bad; it is a "societal choice", and goes with the choice of living in a more democratic society.

1. The present consensus regarding information and consent

Beginning in the early nineties in France, laws, regulations, and case law have abundantly asserted or confirmed the obligation on doctors and more generally on health care providers to inform patients and ask them to agree to any therapeutic investigation or action.

The **Code of Medical Deontology** (1995) [25] contains an article on information (Art.35), and an article on consent (Art. 36). Another article specifies conditions of consent for care given to minors or protected adults (Art. 42).

"Art. 35. The physician gives persons he examines, tends, or advises, honest, clear, and appropriate information on their state of health, the investigations and treatment he is proposing (...)"

"Art. 36. In all cases, consent must be sought from the person under examination or receiving treatment.

If a patient is in a fit state to express wishes and refused the investigations or treatment offered, the physician must respect this refusal after having informed the patient of consequences.

If the patient is unable to express wishes, the physician can only act once next of kin have been alerted and informed, unless there is an emergency or an impossibility."

The Hospital patient's charter (1995) (1) covers in Heading III "information of patients and next of kin", and in Heading IV "the general principle of prior consent".

This Charter stipulates (under Heading III) that health care institutions must guarantee to all "equal access to information", that the physician "must give simple, accessible, intelligible, and honest information to all patients" and respond "tactfully and appropriately" to their questions, that "medical confidentiality is not opposable to patients", that paramedical staff "participate in the effort to inform the patient within their field of competence", all of this "so that patients can participate fully ... in therapeutic choices which concern them and their day-to-day implementation".

The Charter also states (Heading IV):

"no medical action can take place without the patient's consent, except in cases where the patient's condition is such that consent cannot be given to a medical procedure which that state of health calls for. Such consent must be freely renewed for any subsequent medical procedure. Consent must be informed, which means that the patient must be told of any procedure about to be applied, of any related risk normally foreseeable according to up-to-date scientific knowledge, and the possible consequences of such risks."

Finally, the Charter recognises a patient's right to dissent :

"patients, on being informed by a practitioner of the risks incurred, may refuse diagnostic or therapeutic actions, or discontinue them at any time at their own risk and peril. They may also consider themselves insufficiently informed, and seek time for reflection or for another professional opinion."

These principles are also set out in the summary of the Charter, which should be displayed in all health care institutions;

"3. Information given to patients must be accessible and honest. Patients participate in therapeutic decisions which concern them.

4. A medical procedure cannot be performed without a patient's free and informed consent."

Finally, the Charter details (under heading V) medical procedures for which consent is governed by specific rules : research procedures (law n° 88-1138, modified), processing of nominative data (law n° 94-548), medically assisted reproduction and prenatal diagnosis (law n° 94-654), harvesting and use of components of the human body for therapeutic (transplantation (2)) or research purposes (law n° 94-654), genetic studies (law n° 94-653), screening tests, in particular HIV ("no screening can take place without the patient's knowledge").

Law n° 94-653 dated July 29th 1994, on respecting the human body [73] , which modifies the *Code Civil* , ties the rule of prior consent to the principle of respect for the integrity of persons :

"Art. 16-3. The integrity of the human body can only be disregarded in case of therapeutic necessity for the person concerned.

Prior consent must be obtained from persons concerned, except when their state of health is such that it demands therapeutic intervention to which they are in no condition to consent."

For research, **law n° 88-1138 dated December 20th, 1988 on the protection of persons accepting biomedical research, referred to as the Huriet law** (revised July 25th, 1994 [69] gives a detailed description of information provided so that a person's consent can be considered to be truly informed :

"Art. L. 209-9. Prior to the performance of biomedical research, the concerned person's free, informed, and express consent must be obtained after the investigator or a physician representing him has made known to the subject :

- the object of research, its methodology, and duration,

- benefits expected, constraints and foreseeable risks, including the case when research is discontinued before it was due to end,

- the opinion of the committee ... (CCPPRB)."

Where health care is concerned, a decision by the *Cour de Cassation* (1st Civil Division) [34] , dated February 25th 1997, not only states that there is an obligation on physicians to inform, but makes it clear that they must also be able to prove that this was done (3) .

"Those who are legally or contractually under specific obligation to provide information must supply proof that this obligation has been discharged. (...) A physician is under specific obligation to inform patients and must be able to prove that the obligation has been implemented."

The Court argues that failure to inform on the part of the physician has inflicted injury on the patient, the injury being "loss of the chance to make an informed decision", and that in case of a dispute regarding the fact of denial of information, the burden of proof falls on the physician because " receipt of informed consent based on information provided is the very condition of the right conferred on a physician to intervene on a human being. It is therefore incumbent on the physician to prove that this right was indeed conferred, which implies giving proof that the information needed for consent was in fact supplied."

These French rulings tally with many international instruments which apply the doctrine of "human rights" to the medical domain, as in the **European Convention on Human Rights and Biomedicine** (1997), [31] :

"Chapter II - Consent. Article 5 - General Rule

An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it.

This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks.

The person concerned may freely withdraw consent at any time."

The Lisbon declaration (1981, amended: Bali 1995, by the **World Medical Association** on "Patient rights" [5] , lists as one of these rights a "right of decision":

"All competent adults are entitled to give or refuse consent to a diagnostic or therapeutic procedure. They are entitled to receive information required to come to such a decision. They must clearly understand the object of the examination or treatment concerned, as well as the effects of their results and the consequences of denial of consent.

A patient is entitled to refuse participation in research or in the teaching of medicine."

CCNE notes that the doctrine which is now stated in French documents, is vigorous and consistent and concurs with a broad European and international consensus: **no medical intervention on a human being without his or her prior consent** , and for that choice to be made wisely, there is an obligation to provide honest and complete information.

Using the word "consent", presupposes that the physician, the possessor of technical proficiency, takes the initiative of offering one or several solutions to solve a patient's problem; the patient accepts or refuses but does not propose. This impression of inequality between he who knows and he who does not is corrected by the notion that the patient "participates" in a decision, or even that the patient is the ultimate author of the "informed choice", and the one who, by giving consent to the proposed procedure, gives the physician a right to intervene which the physician cannot appropriate without leave.

Such texts should prevent a reappearance of some past excesses as for instance, blood transfusion unbeknown to the patient, or sterilisation without the patient's consent or knowledge, etc.

But there is a discrepancy between the unity of stated principles and the disparity of real life practices. In many ways, our society can be viewed as going through a transitional phase, which may be temporary, of the patient-doctor relationship and of the relationship between citizens and their public health system.

B. Kouchner expressed in 1993 some concern about the way in which this transition is taking place, hastened by the blood transfusion tragedy:

"Medicine is going through a confidence crisis; mastery by divine right for physicians is faltering.

The medical profession has long benefited from the blind trust of patients, resting initially on absolute ignorance disguised by esoteric language as so ably depicted by Molière, then on the illusion of absolute knowledge which continued to be served by language opaque to intruders, that is to patients.

Let us beware of the swing of the pendulum: the blind trust of patients which rested on

absolute ignorance initially could turn into systematic mistrust, and then our whole health system could be disrupted.

We should constantly explain, we must keep ourselves informed and keep patients informed without cease. Transparency goes hand in hand with performance.

(...) Patients no longer expect from us a pretence of infallibility. They expect unfailing readiness to listen, to support humanely, and increasingly an attitude which empowers them. Let us not forget that in the therapeutic relationship, one man meets with another. One of them calls out for help from a position of distress and dependence. The other's responsibility is not simply to cure - cure what ? - but perhaps also to act so that care given and care received take on meaning in the life of the patient."

CCNE has tried to take stock of this ongoing evolution, and of its elements of risk.

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2. An evolving situation

Several authors involved in the drafting of the texts quoted above have underlined that between the 1950s and the 1990s the situation in France evolved swiftly.

Louis René, in his comment of the Code of Medical Deontology, demonstrates how in the four successive versions (1947, 1955, 1979, 1995) the Code was "thoroughly modified", to take account of evolving legislation and thinking".

On the subject of Art. 35 concerning information provided to the patient, he notes the difference between the patient as seen in 1950 and seen today. He quotes the first President of the French Medical Association *(Ordre des Médecins*) Louis Portes, and also the present President, Bernard Glorion:

"One can no longer consider the patient to be "an almost completely blind being, full of pain and essentially passive" (L. Portes). "Public opinion today is no longer passive and this evolution cannot be ignored" (B. Glorion)" [27] p. 107).

On the subject of Art. 36 concerning consent, René comments on the difference between the 1979 and the 1995 versions: "This article is much more explicit than the corresponding article in the previous draft in which it was stated that "the patient's will must be respected to the greatest possible extent". The last part of this sentence, because it was imprecise, led to abundant casuistical dispute. Criticism went so far as to refer to medical imperialism." René reasserts the Medical Association's present doctrine : "To respect the dignity of the patient, a diagnostic or therapeutic procedure is proposed, not imposed." [27] , p. 111).

To sum up, in the space of fifty years, we have moved from a society in which the physician imposed a course of action on a passive "trusting" patient, presumed to be incapable of personal judgement", (Portes), to a society in which the physician proposes a course of action (or even a choice between several options) to a patient who is presumed capable of understanding the proposal and of making a choice.

We should note in passing that Louis René himself, when he was President of the Medical Association (1987-1992), made efforts to further this evolution which is still incomplete: Paul Ricoeur mentions the "cases of tacit compromise which Dr. René managed to uncover behind the calculated laconicism of the Code of Medical Deontology in the 1995 version." (P. Ricoeur, in : [27] , p. 25).

For example, after stating the obligation to inform, the Code grants physicians the right to reserve some information : "in the best interests of the patient and for legitimate reasons which the practitioner appreciates in conscience, a patient may be left in ignorance of a

severe diagnosis or prognosis..." (Art. 35). René comments that the obligation to inform does not imply the right to throw the truth harshly at the patient, and that the right to keep silent is not permission to lie: "there is no reason in this situation to argue in favour of concealment". He notes that the 1947 Code advised the doctor to "conceal" the truth about a lethal affliction; the 1995 Code only permits non-disclosure to the patient ("but the family should be warned, unless circumstances are exceptional "). Compromise, although it has evolved in favour of informing (to inform has become the rule and concealment the exception), is still compatible nevertheless with varying personal medical information policies.

Mr. Pierre Sargos, arguing for the benefit of the *Cour de Cassation,* mentions the "evolution" of opinions and customs:

"times have totally changed since a speech in 1950 to the Academy of Moral and Political Sciences (*Académie des sciences morales et politiques*) where a well-known professor of medicine asserted that the notion of informed consent from a patient was a myth which he had vainly tried to found on fact! (...) Nowadays... information, i.e. *complete information* , is the rule, and silence or concealment the exception." [34] , p. 25).

Whereas habitually patients receive simplified or approximate information, and case law exonerates doctors from pointing out to a patient before an intervention the possibility of rare, albeit serious, accidents connected to this type of intervention, Mr. Sargos predicts that the obligation to inform (4) could evolve in the direction of an obligation to inform fully: "there seems to be no reason why a risk, exceptional no doubt, but severe and known to exist, should not be revealed to the patient."

In the case considered, the Court felt that the patient should have been warned before undergoing colonoscopy that there was an associated possibility of intestinal perforation. Had he known, he might have preferred to run the risk of not accepting the procedure instead of accepting it and incurring serious injury.

In comments concerning this recent decision of the *Cour de Cassation* , there is recognition of the fact that this change in jurisprudence was the end point of decisions taken by ordinary courts: "Courts judging on the merits had for quite some time been helping patients " (ibid., p. 28) to establish that they had been ill-informed, taking into consideration the difficulty of proving it. They also note that concrete reality is fairly remote from the model of complete information.

The "Patient's Satisfaction Index" (*Baromètre de Satisfaction des Patients*) published by the *Assistance Publique-Hôpitaux de Paris*) (1997, [3]), reveals that information (administrative, medical) which is the quality criterion judged by patients to be the most important, only obtains a low satisfaction score. For instance, at the Henri Mondor hospital in Créteil, in November 1997: 14.6% of respondents stated that they had received no explanation regarding the state of their health; 12.7% stated that they had had no explanation about their treatment; 22.8% stated that no explanation was given about tests.

As regards **biomedical research** on human beings, this has taken modest and rather furtive forms in France, more often than not unbeknown to the person concerned when that person was a patient, until the advent of the Huriet-Sérusclat law in 1988. Even physicians were poorly informed at the time about the reality of research, and of its ethical and methodological constraints which were in the process of elaboration in international fora (cf. [105] , [81] , [79] , etc.).

The law dated 1988 brought research out in the open. By requesting both prior examination of research projects by Consultative Committees for the Protection of Human Subjects in Biomedical Research (CCPPRB) on which sit citizens who are not all members of the health professions, and also a signature on a document testifying to their agreement and to information received, given by those who have been asked to consent to research, the law had educational value and simultaneously allowed biomedical research to prosper.

Promotion of this kind of research in the eyes of the general public was successfully achieved by associations such as the French Myopathy Association (*Association française de lutte contre les myopathie - AFM*), who have given some impression of the large amount of funds necessary to do high quality and effective research (which is beyond the scope of individual self-sacrifice both in subjects undergoing research work and research workers), and of the stakes underlying research decisions.

As a result, there are now citizens (members of CCPPRBs, chronic patients who have already participated in two or three trials, members of associations) who are well aware of the realities of experimental trials on human beings, and perfectly capable if they happen to be invited to participate in a research effort, of asking to see the complete protocol before taking a decision, of taking an interest in the methodology, of consciously accepting the constraints and risks connected to a research procedure, of asking questions about the research budget, or on the aims of the promoters, the fees paid to research workers, the publication in which results will be printed, etc.

They are however a minority. The vast majority of hospital patients do not even know the difference between research and care. Few French citizens are aware that their attending physician may ask them if they wish to be included in a clinical trial. This trial, for which their doctor will receive payment, will help to evaluate a new treatment.

The situation in which we find ourselves is ambiguous. Patients are no longer passive but they are not, or not yet completely, their doctors' "partners" (or the partner of their health insurance scheme). Demand for information is more frequent than real information. In the light of ongoing change, ethical reflection wavers between hope and apprehension.

Even though it is **a fact** that today's patients expect more information from their doctor than used to be the case, their understanding of medical procedures is frequently approximate. Furthermore, patient participation in decisions which concern them varies a great deal from one case to another.

Sometimes, patients do not wish to be informed, or do not wish to take decisions concerning their state of health and prefer to leave matters to their doctor and say they trust him and would like him to take charge. Even volunteers for biomedical research do not always wish to have every detail of the research protocols explained to them in spite of the law designed to protect them which stipulates that complete information is required before consent. Finally, some patients are in no fit state to express consent, nor to receive any kind of information whatsoever and others do not have the capacity legally to take such decisions themselves (minors, incompetent adults).

Ethical reflection on the **duty to inform** is complex and subtle. Identical arguments (respecting human dignity, desire to avoid harming others) are used to prove that information must be given or must not be given. Consent requested from a patient (particularly in "written" form) is interpreted either as signing a "contract of trust" between patient and doctor, or else as an expression of mistrust arousing in the patient a suspicion that the doctor is trying to evade responsibility.

"Truth" when revealed to a patient is regarded either as gift or as a nuisance, depending on the angle from which it is viewed. Certainly, disclosure (particularly if it is given harshly, clumsily, and thoughtlessly) of a fact (e.g. HIV positivity, infertility, cancer) discovered by the physician may well be for the person concerned a shock, a trauma, a source of anxiety or of guilt-feelings. Clearly also certain affections (e.g. depression) induce a specially fragile state which must be taken into account. However, CCNE's report on *Ethics and knowledge* (1990, [18])

emphasised at the time that patients' vulnerability because of sickness should not constitute a reason in principle for denying them the information to which they are entitled. And the conclusions of the Consensus of Toronto (1991) on the doctor-patient relationship insist on

the importance of informing patients to alleviate anxiety and recommend "information" as a subject for inclusion in medical training.

CCNE considered factors which could throw light on the destination of the ongoing evolution.

3. An uncertain evolution

This ongoing evolution could be described as a transition from a climate of enlightened paternalism where it was accepted that physicians would decide more or less unilaterally on what was good for patients and then impose that decision on patients, to one in which physicians taking into account what patients consider to be good for them, then engage in a negotiation with them on the modalities of medical intervention. This evolution has been observed in all the member countries of the European Union. A European report (Koch et al., 1996, [56]) shows clear evidence of this in psychiatry.

In ethical terms, this evolution can be viewed, in broad outline, as a transition from medical ethics in the teleological style, giving prominence to the principle of beneficence, to medical ethics in the deontological style, allowing first place to the principle of respect of persons considered to be autonomous moral subjects. The Koch report [56] presents this evolution as being a direct successor to the European movement of Enlightenment although it now seems to be reaching us via a North American influence. In medical terms, it is the equivalent of the learning process of democracy as it applies to European politics and is linked to that learning process. The Evin report confirms this point of view when it says that the "philosophical" foundation of the obligation to inform is "everyone's right to treatment in the health care system as a free, adult, and responsible citizen" ([33] , p. 84).

However, this view is not unanimous. In France particularly, the situation differs from those prevailing in other European countries (cf. [86]). In the field of health and the human body, respect of the person is more often than not justified by the notion of non violation of the body rather than freedom of decision by and for the individual. One might think that this attitude is connected to a prolonged tradition where the centralising welfare state prevents citizens from endangering themselves by setting a limit on what they are authorised to decide for themselves. There is, however a possibility that this trend is simply a specific amplification (disputable and possibly damaging in certain cases) of a more fundamental ethical truth without which the sollicitude required to intervene in favour of other people and the care of which they stand in need, would be unfounded. Against this background in particular arises the question of whether in all and every circumstance, a citizen is free to do whatever he wishes with his own body. Be that as it may, French traditional values has permitted excesses such as the prohibition of vasectomy for individual convenience, 'indirect' access to medical files, etc. In the present state of affairs citizens do not enjoy fully the right to do what they wish with their own body. The State has and makes use of the right to interfere, both in the name of collective solidarity (e.g. mandatory vaccination, presumed consent for organ donation), and also to protect individuals from dangerous behaviour in which they might recklessly engage (e.g. sterilisation, drug abuse, reproductive cloning).

In that spirit which still prevailed in the 1994 "bioethic laws", the State endows physicians with a mission of protection, and what gives them the right to intervene on another person's body is not the consent to do so by that person, but "therapeutic necessity". However, increasingly numerous references to the need for consent demonstrates that doctrine according to which the patient must be protected (including from himself) is losing ground to doctrine based on individual responsibility .

But quite clearly, in France and in Europe generally, this evolutionary process is still uncertain of its direction. At this point, it is not possible to predict whether the end point will be a truly contractual patient-doctor relationship, or whether Europe will invent its own specific course, with the aim of trying to reconcile as much as is possible the demands of

the principle of autonomy with those of welfare. Physicians, while remaining attentive to wishes expressed by patients, would retain responsibility for decisions with due regard for respecting collective discipline judged to be beneficial to individuals.

Access by patients to their own medical files are a pertinent example of this partial evolution in France. Although access used to be troublesome, it is now a right (cf. for hospital files Article L. 710-2 of the Code of Public Health). However, access is indirect: the file is not given to the patient, it is sent to a doctor chosen by the patient. The Evin report goes a step further. It argues in favour of direct access, but "in the framework of an explanatory dialogue" with a doctor, and explains why the extreme of direct access without any mediation is not considered advisable ([33] , p. 95).

Another example is decision making at end-of-life. In Europe at this time, physicians caring for the dying (e.g. medical or surgical resuscitation, neonatal resuscitation) accept the notion that close relatives and if at all possible, patients themselves, must be kept informed and be heard and consulted. They consider, however, that to allow patients or relatives to decide whether care should cease would be cruel and morally unacceptable: the medical team takes that responsibility (cf. [83]). On the North American continent, there is a trend which allows for patients nearing their end to manage their own path to death; or to allow parents of a premature new-born baby whose prognosis is poor, to participate in the decision to cease care.

In Europe, only in the Netherlands are physicians allowed legally to take account of a request for euthanasia and, (if the request is considered to be well-founded after a codified procedure) to help a person to die. In other European countries, medically assisted euthanasia, if it exists at all, is covert. Taking into account "living wills" or other "guidance" varies considerably. On the whole, European medicine is more "protective" (paternalist) than medicine in North America.

As stated by the French Code of Medical Deontology [27] , in the previously quoted Art. 5:

"in the best interests of the patient and for legitimate reasons which the physician appreciates in conscience, a patient may be kept in ignorance of a severe diagnosis or prognosis, except in cases where the ailment puts others at risk of contamination. Circumspection must be exercised to reveal a fatal prognosis, but close relatives must be informed, with some exceptions...".

In any event, authoritarian paternalism is a thing of the past.

Factors underlying this evolution and its lack of completion should be laid at the door of society and its proprieties, on the one hand, and that of the massive expansion of biomedical disciplines, on the other.

The evolution of society

Medical care consumers nowadays have access to an overabundance of medical data through the media, a large variety of pharmaceutical sources or of "parallel" therapy via Internet, or through the technical facilities of multidisciplinary health care institutions. Attempts to "protect" consumers by censorship of information, or to forbid the sale of drugs thought to be dangerous but which can be obtained abroad, or to reduce them to the state of children willing to obey their doctor, have become illusory. In this situation, turning health care consumers into responsible citizens should be the aim.

Access to responsible citizenship is also made difficult however by media saturation itself which helps to turn patients into passive consumers and doctors into service providers. In this light, access to responsible citizenship must go hand in hand with an evolution of the doctor-patient relationship in the direction of a mutual trust compact based on honest individualised information leading to joint and truly shared decisions.

This evolution is in progress, helped along for instance by support groups (5) (e.g. AFD, AFH, AIDES, UNAPEI) that are gaining ground in their role of partners of the health system, who propose therapeutic strategies, design and promote research activities, and draw attention to the patient's viewpoint in the dialogue between patients and health care providers. With the support of such associations, patients have in some cases become valued partners for their attending physician because they understand their disease, enter into a real dialogue concerning therapeutic strategy and arrive at truly joint and shared decisions. But ordinary care consumers are frequently very ignorant about either their own physiology or for instance the overnight cost of stay in hospital, and are in fact very passive in their attitude to the health care system.

The massive expansion of biomedical disciplines

The practice of medicine used to be empirical but has become (at least to some extent) scientific and technical. Medical ignorance fostered peremptory medical attitudes. Once scientific exactness enters the medical scene, physicians are better at evaluating their own doubts and limitations. Scientific medicine is like a ship that sailors repair as they are sailing. Traditional practices are disputed and dropped, new practices replace them, the risk of being infatuated with novelty is tempered by the strict demands of validation (6) . The turnover of medical knowledge is such that no doctor can claim to know everything: acquired knowledge becomes obsolete so quickly that a practitioner needs to up-date it constantly. He cannot ignore the potential risk of any intervention, all the more so because training has taught him biological variability and the probabilistic aspects of medical science, and practice has made him familiar with the power of technology. In clinical practice, action frequently extends beyond science.

When practitioners, instead of simply applying what they were taught, join in the collective endeavour of acquisition and validation of knowledge, they participate in research protocols. Their patients then become both objects of care and of investigation. Understandably, doctors find it embarrassing to tell their patients that this is so, but if they do not, the situation is equivocal. (As a matter of fact, French law requires the truth to be told.) (This is also true ethically - Kant's law of publicity: if one is loath to reveal what one is doing, then one should not do it.)

The intricacy of the care and research relationship has become a major characteristic of 'scientific' medicine. This should be a subject of pride. When it engages in research, medicine questions its own principles, corrects its mistakes, and progresses. Good research is not sufficient in itself to ensure quality health care, but it does contribute. A health care institution which does research is at least one which maintains at the highest level the competence of its practitioners.

However, research on human diseases has to be done with the help of those who suffer from the diseases. They play a role in data acquisition (imagery, samples) and physio-pathological or therapeutic theories are tested on them ("clinical trials"). The trial process nowadays involves an ever increasing number of people. If you count the "healthy" volunteers who participate in preliminary phases of trials, and the sick included in therapeutic trials, at least 800,000 people in 1996 are estimated to have been involved in biomedical trials (7) in France. In a democratic country, these people cannot be forced to participate, nor recruited without being told. In particular, when the sick go to a doctor to receive care they must know when they are being cared for and when they are a source of data for research. Although contributing to research can be seen as a duty for the sake of solidarity, French law does not make solidarity compulsory (8) .

Assessment

Altogether at the present time, several factors combine in favour of total transparency in medical activity:

- official texts and the advance of jurisprudence,

- increasing intricacy in the relationship between research and care,

- the inherent risk of any medical act (medical infallibility does not exist),

- a thirst for information on the part of those who receive care.

Simultaneously, social and cultural factors (which may be viewed as the result of either inertia or caution) have a retarding effect in this country:

- dependency and passivity as ingrained patient attitudes in their dealings with the medical profession,

- paternalist traditions in the medical profession (there are still traces in the Code of Medical Deontology),

- State paternalist traditions (cf. [86]),

- intuitions about possible harmful effects of total liberty of decision regarding one's own body.

CCNE considers that present trends are positive and excludes a return to ancient practices based on authoritarian medical decisions. It pleads in favour of access for all citizens to responsible management of their own life and health and requests that this should be encouraged.

It is not so much a matter for legislation (in France, laws and regulations exist already), as of getting standards for satisfactory information and communication accepted in practice.

The aim is clearly to make the carer-patient relationship a more symmetrical one in ethical terms, in spite of the inequality in technical terms between he who knows and he who suffers but does not know. Such equality can be beneficial for both parties (not just for patients).

Nevertheless, problems brought about by this evolution must not be ignored. They are connected to the gradual progression of the therapeutic relationship towards a service providing situation, and to the not insignificant endangering of the quality of care by an extreme implementation of the medical contractualisation principle.

One of the more obvious dangers is drifting into excessive legalism and litigation and contractual relationships between health care providers and health care consumers replacing the personal trustful relationship which is so essential to participatory decision making. This drift would be harmful in its effects on health cost-containment as well as on the scientific nature of medicine if it were subjected to the pressures of market forces and advertisements for un-validated practices. Moreover, there is above all the risk of seeing doctors lose their sense of responsibility and feeling that their sole concern is compliance with the law's formal demands while living in fear of possible lawsuits. Therefore, shared decision is the most desirable form of decision: the competence and responsibility of the physician in an ideal alliance with full information given to the patient about the various possible options for state of the art therapy working in favour of an optimal and joint management of the patient's condition.

However, there could be some borderline cases when communication becomes powerless

and pain passes the bounds of acceptability, and decisions can no longer be shared. When that occurs, the predicaments referred to above as regards ongoing developments arise again, and only uncertainty reigns. Principles of dignity and rejection of the unendurable (however imprecise the notion) must then take over.

A proper balance between autonomy and the protection of patients is not therefore pre-set - it must be sought after and found. The exercise of autonomy remains an ideal, but it remains an illusion without adequate information. Information then must be the first step.

4. Recommendations. General case : a competent and autonomous person

Principle : All persons *a priori* should be presumed capable of receiving information and giving "free and informed" consent to a proposed medical act unless it has been established that they are incapable of doing so. It is the responsibility of physicians (more generally of health care providers) to inform them sufficiently clearly and appropriately for freedom of choice and of decision to take place. Information must be updated at the time of any new diagnosis or therapy.

Commentary:

- The principle implies that applying to a doctor or to health care providers is in no way an abdication of the capacity to understand and of the power to decide. If a doctor believes that his patient can neither understand nor choose, then he must ascertain that these capacities are missing. As long as this has not been established, the doctor has a duty to inform.

- Research and care are based on the same principle (9) : the person concerned must be properly informed. To present acts of research as though they were acts of care (a temptation for doctors sometimes, to elude the constraints of the Huriet law) does not relieve them from the obligation to inform. Moreover, information which conceals the research element of an investigative act is untruthful. Application of the principle can however take on different aspects, depending on the situation, as is suggested below in the discussion on distinguishing between care and research and the interconnection between the two.

- It is easy to explain why seeking express (and not tacit) consent before an intervention, arose in a research context: to presume that a patient agrees to an investigative procedure, the aim of which is acquiring scientific data, is not as easy as presuming agreement to curative therapy.

- Some people "don't want to know", and affirm that they "trust the doctor" to take the right decision. Everyone should feel free not to want to know. The wish to not be informed must be respected. The free rein given to the doctor in that circumstance is limited to therapy. It cannot cover research. If patients are willing to sign a consent form, then the least one can do is warn them that this is for a trial even if they do not wish to have any other information.

Practical problems and suggestions

- Improving the degree of information provided to persons undergoing care or research procedures depends not only on changes in the individual relationship between health care providers and patients. Health care establishments, health insurance schemes, patient support groups, research initiators and drug suppliers, in fact all those connected to the health system, must contribute to the process. It is difficult as a human being to be told

that one is suffering from a serious disease (diabetes, cancer, AIDS, multiple sclerosis, etc.) and comprehend at the same time that the therapeutic strategy which is on offer is part of an experimental procedure, in the framework of a "controlled", "randomised", and "double blind (10) " trial. Appropriate information available from the Admissions desk in hospitals, or from support groups, would greatly facilitate the painful personal experience of entering the world of severe ill health.

- Written proof of information and consent (a signed form) is legally required in France for research because there is no "therapeutic necessity" to justify imposing a research procedure on a patient (except in the case where a new therapy, as yet un-validated, only available in the framework of an experimental protocol, gives the patient a better chance than any standard treatment - but that also needs to be spelled out to the patient when the inherent constraints of inclusion in an investigative protocol are explained).

To get a "signature" on a consent form for care procedures ("properly validated" procedures, conforming to "up to date scientific knowledge", as defined by the medical profession's directives, consensus conferences, "RMO" (11) ...) is unusual in France, except for special cases (e.g. plastic surgery). In view of the way in which case law is evolving, making sure that the patient's file contains notes on what information was supplied, when, and how it was received, is advisable. For certain therapeutic options when the benefit to risk ratio is difficult to evaluate (e.g. applying prostheses, celioscopy, peridural as opposed to general anesthesia, blood transfusion), a trend in the direction of a more contractual arrangement is likely in the near future; it is considered desirable in some quarters (e.g. in the case of transfusion: [46]).

The prospect of patients being asked to sign a consent form before any therapeutic procedure involving a modicum of risk (e.g. anesthesia, surgery) is viewed with considerable apprehension in France. There are fears of "falling into American extremes", of which a possibly distorted image comes through. Predictable dangers would be a bureaucratisation of the patient-to-doctor relationship where a dialogue for the exchange of information would give way to a signature wrested from the patient minutes before diagnosis or therapy !

- Information given to persons concerned must be "honest, clear, and appropriate" (Code of Medical Deontology, [27] , Art. 35), "simple, accessible, intelligible, and honest" (The Hospital Patient's Charter, [24] , "complete" (*Cour de Cassation* , [34]). It must be repeated, the person imparting the information must make sure that it has been understood.

What information ? The Code of Deontology says that doctors must inform patients about "their condition, and proposed investigations and therapy". In the case of research, the Huriet law demands complete information on research procedure, except for psychological research for which there is a possibility of limiting information to a preliminary summary if volunteers are willing to defer learning about some aspects of research strategy until the end of the trial (Law n° 94-630, Art. 6-II).

The Code of Medical Deontology (Art. 35) permits maintaining silence on "a severe diagnosis or prognosis", or to be "circumspect" in the disclosure of a lethal prognosis. The Huriet law, in the event that a "diagnosis could not be revealed", provides the possibility of "keeping back some of the information connected to this diagnosis" (Art. 209-9). But silence is not the equivalent of falsehood, nor is there any text authorising members of medical professions to be deceitful.

The Code of Medical Deontology (Art. 35) stipulates that physicians "take into account the personality of patients when given explanations, and make sure they understand". A good way of checking is to see whether they can re-explain in their own words.

- **Duty to inform** does not imply that information is given harshly and abruptly (12). Time must be amply allowed for, the patient must be helped to grasp and perceive the diagnosis,

and information should be exclusively factual. A psychiatrist does not bluntly tell a patient that he is "paranoid" (or "hysterical"): he tries to get the patient to recognise that he feels persecuted (or that he is being over dramatic). A doctor does not make prophecies (he is not a fortune-teller) : a prognosis is always uncertain (probabilistic). Prudence whilst disclosing a prognosis is a scientific approach and follows traditional medical wisdom.

Time to think, consulting loved ones, seeking a second medical opinion, are frequently useful to those who have to take important decisions.

Bernard Hoerni's book ([50]), Medicine and autonomy. A new relationship between the sick and the carers. *(L'autonomie en médecine. Nouvelles relations entre les personnes malades et les personnes soignantes)* is illuminating. The author analyses with subtlety the way in which society can change as regards individual health-related decisions, and the patient-carer relationship. He states that "a sick person's autonomy depends on the autonomy of health care providers" ([50] , p. 100), and he quotes Paul Ricoeur : "Autonomy of the self is intimately connected to solicitude for those who are close and to justice for each human being" (in Oneself as others - *Soi-même comme un autre*, 1990, cit. [50] p. 185).

- Refusal of a medical procedure, coming from a presumably autonomous person, must be respected. To contravene this stated determination, it must be established that the person concerned is not truly autonomous (cf. below).

Abundant casuistic discussion refers to this point: what should be done about a person bent on suicide, a hunger striker (13), a Jehovah's Witness mother who refuses blood transfusion and is haemorrhaging during delivery ?

Present trends are to honour to the fullest the patient's stated determination and to encourage compatible medical practices (such as heart surgery using blood sparing techniques developed in Houston for Jehovah's Witnesses: c.f. ([46] , p. 112) (or such as the "contract" with young anorexics which has been a great improvement on forced-feeding in psychiatric wards).

Except for 'secure units' in psychiatric wards, inpatients who do not wish to continue treatment in a hospital are free to sign themselves out, and leave.

The critical point is an emergency: when a patient is in "imminent danger", and a doctor is aware that he can "save" him by "immediate intervention". It then becomes difficult for the doctor to abstain even when a patient refuses treatment. The interventionist attitude is justified in ethical terms by the principle of doing good (which for an interventionist minded doctor takes precedence over the principle of moral autonomy of the person in danger), and by the fear of sanction because of non-assistance (according to Art. 63 of the Criminal Code). To this, the jurist would reply : Nevertheless, an assessment of both urgency and of immediate peril, supposes on the part of the physician an enquiry to ascertain the presence of objective, well-established and irrefutable criteria. It is by disputing the assessment of these requirements, in particular through expert investigation, that a state of law can progress for the mutual benefit of physicians and patients." ([46] , p. 20). In other words, an obligation to help the sick is not sufficient justification for coercive therapeutic excesses.

- The only cases in which a legally competent adult may be subjected by a doctor to **coercive treatment**, are those provided for by law n° 90-527 of June 27th, 1990 covering the protection and rights of patients committed to hospital because of mental disorders, and it also covers their management while in hospital (Code of Public Health, Art. L. 333 to L. 351).

Commitment is enforced without the consent of individuals concerned, possibly against their formally expressed will, at the written request of a third party (*HDT (hospitalisation à la demande d'un tiers)*), or at the request of administrative authorities (*HO - hospitalisation d'office*), and following warrants written by two physicians unrelated to the hospital of

commitment, describing the psychic disorders present in the person concerned and certifying 1° that these disorders "preclude consent", 2° that the patient's condition "demands immediate attention as well as constant supervision in a hospital environment". These certification measures are controlled by government authorities (*Préfet*) and judicial authorities (Public Prosecutor - *Procureur de la République*).

However, the fact that patients are certified forcibly does not absolve from the need to inform them of the decision to do so and of their rights.

Forcible hospitalisation authorises doctors to impose treatment which they consider appropriate. But it does not authorise them to force research procedures onto their patients, nor to perform research unbeknown to them. Regarding research, psychiatric patients in a secure unit are governed by the same rules as **prison inmates**. The Huriet law states that "they cannot be asked if they consent to biomedical research unless direct and major benefit to their own health is plausible" (Art. 209-5). And there can be no question of subjecting them to research procedures without their consent. Their condition frequently improves after a few days of treatment to the extent that proper consent conditions can be met. If research procedures are to begin at the time of admission, the Huriet law's provisions on emergencies must apply (see below).

- Although health care and research are increasingly interconnected, two extreme situations are those of standard care on the one hand, and experimentation on healthy volunteers or research without direct individual benefit to the sick, on the other hand. In the first case, although patients would prefer it otherwise, they need care and expect medical management to effect a cure of their disease or at the very least provide relief from pain. In the second and opposite case, the physician doing research is the one asking for help and needing the co-operation of a healthy subject or of a patient to complete a research project. Consent to health care is tacit and implicit in the first case because of the very fact that the patient is consulting the physician, although one must repeat that information given must be as clear and complete as is possible with the aim of establishing a trustful relationship which is so essential to patient participation in decisions concerning treatment. However, in the second case, consent to participate in a research protocol must be explicit and in writing, according to rules set out by the 1988 law, referred to as the Huriet-Sérusclat law.

Some members of the Committee are of the opinion that there are also intermediate situations, in which the need to receive health care and the possibility of participating in a research protocol overlap. Some of these are difficult situations because the demands of respect of autonomy and of the necessary compassion expressed in the principle of doing good may come into conflict. This is particularly the case for severe diseases (cancer, AIDS, and other life-threatening pathologies) for which there are several possible treatments, the relative effectiveness of which have already been explored, but which still require comparative evaluation to determine which is the more active for a given form of the disease. As in a normal - but frequently more stressful - health care situation, patients expect their doctors to provide the most effective and the most appropriate treatment for their condition. The overly formal nature, almost bureaucratic procedure which is demanded for participation in a research protocol can in some cases be detrimental to the climate of trust which is essential to ensure the quality and the individuality of care which patients hope for. Patients may feel, rightly or wrongly, that their individual interests get second place behind the collective benefit of research, or even the personal interests of the physician running the research.

Many cases can occur :

- existence or otherwise of standard treatment applicable to the patient concerned with a reasonable expectation of success;

- comparative evaluation of several procedures equally applicable to the case concerned as far as medical knowledge is aware at the time;

- research with or without direct individual benefit, recognising that there again intermediate situations arise and that a rule of proportionality must be applied between reasonable expected benefits and risks inherent to the medical procedure.

Generally speaking, problems arising out of obtaining consent to participation in research programmes in various disciplines are so diverse that it becomes impossible to regulate them formally once and for all. The 1988 law is particularly helpful for problems arising out of therapeutic trials for new drugs. However, scientists, physicians, and patients have found on occasion that all the details of the procedure for obtaining consent are not best suited to every kind of situation in which healthy volunteers and sick patients are participating in research or evaluation protocols. For that reason, depending on circumstances, the legal procedure for consent should possibly be reconsidered.

In some cases, such formal procedures should be **reinforced**, for instance by demanding that a copy of the document describing the research be left with patients; or on the contrary **relaxed**, when for instance a treatment which in any case must be provided to respond to a patient's wishes, qualifies that patient almost automatically and with no extra risk, for inclusion in an evaluation protocol. (As we shall see below, in certain cases consent can be **substituted**).

As is suggested by one of the authors of the 1988 law, the rules resulting from the law could be modified to that effect and in particular make a distinction between comparative evaluation protocols (as is already the case for epidemiological research) and research proper (14).

5. Recommendations. Difficult consent issues

Incompetence and competence to consent

A distinction is made between competence as a **legal** notion, and *de facto* competence in **mental** terms.

The act of consent supposes dual competence (or ability, or capacity) : there has to be intellectually a clear understanding and also the power of self determination (autonomy of resolution). Individuals are considered unable of giving consent of acceptable quality if their understanding is weak or disturbed (e.g. confused or obsessed), or if their freedom of choice is incomplete (e.g. dependent subjects such as inmates of asylums for the insane, or prisoners).

To establish (relative) incompetence is to establish inability to understand information, or inability to take rational decisions for one's own good, or both. To test competence pre-supposes the existence of criteria to test the capacity to understand and criteria to test the rationality of decision. The Koch report ((56)) points out that there is some uncertainty in Europe on the subject of criteria and that European psychiatrists who are frequently called in as 'experts' on the subject, have in fact done little research with a view to developing properly validated evaluation procedures.

CCNE suggests that this is an important and interesting subject for research.

The category of legal incompetence includes minors (children under the age of 18), protected adults (individuals under guardianship by court order). One can be (temporarily or permanently) unable to consent but not legally incompetent (e.g. alcoholic intoxication, coma, senile dementia in the absence of legal proceedings). One can also belong to a legal category of incompetent persons and yet perfectly able to give satisfactory consent from an ethical point of view (e.g. an adolescent before majority).

'Legal incompetents' by definition have a 'legal representative' who will give consent in their stead. For minors who have not been emancipated, the person or persons invested with parental authority, and for protected adults, their guardian.

There are many difficult cases due to the non coincidence between real and legal competence. In particular, a number of legally competent adults are temporarily rendered incompetent because they are in pain, feverish, delirious, have suffered concussion, are comatose, inebriated, under anesthesia, etc..., and have no 'legal representative' to speak for them at a time when important health care or life-prolonging decisions may have to be made.

In such cases, there is some degree of arbitrary decision-making by doctors (medical paternalism). Doctors are presumed to 'do their best', but they are in a delicate position when they are not sure that their view of what is 'best' coincides with the patient's view. Various palliatives have been suggested : advance directives in writing or instructions from the patient, inter alia. Gromb & Garay ([46] , p. 65) argue in favour of explicit "advance refusal" of specific medical interventions (for instance, blood transfusion). Louis René, in his comment of the Code of Medical Deontology ([27] , p. 125), simply points out that there is a gap:

"For persons whose faculties have been impaired by old age (physically or psychologically) whose ability to consent is debatable, there is no provision for an agent in France as there is in some Anglo-Saxon countries. This is also the case for adults whose mental faculties are impaired but who are not under legal guardianship for various reasons."

Proposal

CCNE is proposing a study on the feasibility of a system whereby everybody could designate a " **representative"** (or " **agent"**, or " **spokesperson"**) empowered to dialogue with doctors when the person concerned is unable to express his/her own wishes.

The representative would be the first person that physicians inform and consult on any decisions that have to be made when patients are unable to do so themselves. The issue needs to be discussed of whether representatives only act in a consultative capacity or are empowered to participate in decisions, or even consent in the patient's name to research procedures.

The acceptability of this method was tested by an enquiry on "informed consent to designating a representative" over a period of five months (Feb. 97 - July 97) in a resuscitation unit in the Paris area (15). During this time, out of 589 patients admitted to the resuscitation unit, 279 were mentally competent at the time of admission (38%), and there were 105 interviews for the purpose of the enquiry. In this group, 76.2% designated a representative. It is worthy of note that the hospital admission form asks for the name of the "person to notify", and that in this group 86% of the admission forms did indeed supply a name. In 35% of cases, the designated representative and the person to notify are not identical.

CCNE suggests that other such studies could help to identify the type of representation which would be closest to what patients in these circumstances would like to see happen. In particular, a form of "assisted consent" or aid to execute consent could be studied on the same lines for people who are losing their autonomy (e.g. Alzheimer patients at onset), or for so-called "vulnerable" people whose ability to consent is precarious.

Meanwhile, momentous theoretical work could be done by legal experts. In a country where the right of self-determination about one's own body is limited, or has already been entrusted to physicians, how far can individuals go in delegating to someone close to them

the power of decision on various options, such as for instance how to cope with pain, or end-of-life situations ?

CCNE recommends a study on the feasibility of a system whereby a person can designate a "representative" who could tell health care providers what that person wishes or prefers. The representative would provide valuable guidance when a decision needs to be made about treatment options or to spare the patient superfluous care. The representative cannot be a miracle solution to ethical problems, but at least doctors would be speaking to an authorised spokesperson.

The representative's name could be given in the medical file (*carnet de santé*), or documented on admission to hospital.

Particularly difficult cases

MINORS AND PROTECTED ADULTS.

In these cases, there is a legally appointed representative (who was not designated by the person concerned). For either medical treatment or research, it is an accepted practice in France to consider that legal representatives (parents, guardian) can give consent in the name of their incompetent ward. However:

"Consent from minors or "protected adults" must also be sought if they are able to express their wishes. Their refusal or revocation of consent cannot be disregarded". (Huriet law, Art. 209-10).

However, this is only valid for research. For health care, the Code of Medical Deontology (Art. 42) simply says:

"A physician called upon to give care to a minor or protected adult must attempt to notify parents or the legal representative and obtain their consent.

In an emergency, even if they have not been found, the physician is bound to provide necessary health care.

If the opinion of the patient can be heard, the physician should take it into account as far as possible."

Some jurists point out that the situation in France is bizarre in that fifteen year olds can take decisions about their sex life (contraception) but are not allowed to make their own health choices. They suggest that over the age of thirteen, informed consent of minors should be "expressed and guaranteed" as is done for adults ([46] , p. 67). As long as this is not the case, the situation is that if parents are unavailable, physicians themselves become invested with parental authority to choose treatment. The Hospital Patient's Charter (1995) does provide that the doctor should take over when parents are absent or when health care providers and parents disagree on therapeutic options:

"When the health or physical integrity of a minor is endangered by refusal on the part of legal representatives or it is impossible to obtain their consent, the physician in charge may approach the Public Prosecutor to obtain information and assistance leading to providing essential treatment."

In this way it has been possible to give transfusion to the children of Jehovah's Witnesses who had refused consent.

As regards research, this has raised problems on occasion for protected adults whose guardians sometimes refuse to respond when they are asked whether their wards can be

included in a clinical trial. The argument put forward is that a guardian is responsible for the proper management of worldly goods but not for management of the person.

The problem does not arise so acutely for children whose parents are their 'natural' representatives and ready to accept this kind of responsibility. But in other countries semantic reservations overcome the difficulty of accepting that in the case of research someone may take on the responsibility of consenting in lieu and place of someone else without any explicit delegation (in this case, the parents are said to "authorise", as opposed to "consent to", their child's participation in experimental procedures).

The European Charter for Children in Hospital (quoted in [33] , pp. 110, 133), adopted by the European Parliament on 13th May 1986, claims for health care, the "right of the child to information appropriate to his or her age, mental development, emotional and psychological condition, as regards the totality of medical treatment provided".

Questions such as 'how far can legal representatives designated by society go in their decisions on behalf of their wards ?' and : 'to what extent can a doctor take decisions instead of the legal representative?' remain controversial.

Be that as it may, it would seem that there are two gaps in French legislation on this subject : firstly, representation should be arranged for *de facto* incompetent adults according to conditions to be established by Parliament; secondly, as regards minors there is still some doubt as to the competence of guardian magistrates who are ready to take responsibility for the worldly goods of incompetent minors but more often than not refuse to act regarding hazards to the person. The law should be more precise and explicit on this point.

EMERGENCIES

Urgency is a justification for doctors to start what they deem to be appropriate **treatment** without waiting for explicit consent, if patients are unable to speak (state of distress), or if there is no time for explanations.

Consent is presumed if the emergency services were called in by the patient, or when they were called in by the family against the patient's will (e.g. attempted suicide) in which case doctors generally feel that this circumstance is authorisation enough. Patients' consent to care is requested retrospectively when they regain consciousness (or considered to be given implicitly if on awakening, they do not depart from the site of care and are free to do so).

If the state of distress and incompetence of patients persist, there has to be contact with "families". In the present judicial state of affairs, families are not legal representatives. They cannot consent to care in a patient's name. The Code of Medical Deontology simply requires them to be "notified and informed" (Art. 36). It does not say they should be "consulted".

In the circumstances, health care providers take decisions as long as patients are not in command of their mental faculties.

Difficulties arise if successful treatment has been given and the patient on awakening rejects that treatment. Examples are suicide cases confirming on becoming conscious that they wish to die, or victims of accidents who, on discovering the physical effects of the accident, declare that they will commit suicide. Staff in the resuscitation ward call in the psychiatrist ! This does not mean that patients who have regained consciousness are judged to be incompetent.

Similar difficulties arise in neonatal resuscitation wards when a premature baby at birth in a state of distress is resuscitated and later found to have such a disastrous neurological prognosis that it raises the question of whether care should be discontinued leading to death.

Such difficulties do not suffice to condemn the decision of principle taken initially by physicians in favour of treatment and life.

There is in this society a fairly broad consensus on the principle that therapeutic intervention should begin aggressively, even though this may lead to an unnecessary prolongation of the life of, for instance, the terminally ill. Within a few years, there will probably be increased thought devoted to the notion of the "futility" of some care options as has been the case in North America.

The most critical issue arising in emergencies is **research**.

Can a doctor initiate research in an emergency, concerning a patient incapable of expressing an opinion or of giving informed consent?

The Huriet law in its 1994 version, stipulates the following ([69] , Art. L. 209-9):

"In the event of biomedical research to be initiated in an emergency preventing the person subject to research from giving prior consent, the protocol submitted to the committee (CCPPRB) set up by article L. 209-11 of the present code may provide that the person's consent will not be sought and that the consent of family members if they are present will suffice, in the conditions given above. The person concerned will be informed as early as possible and consent requested for possible continuation of the research."

The concept of "family members " replaced the notion "those close to the patient" which appeared in the earlier draft (1988) (16). It is remarkable to note that the law gives family members the task of consenting on behalf of the patient when the latter is neither a minor nor a protected adult. The patient has given no mandate to family members. In this case, a "representative" designated by the patient would be, one might think, a better person to take part in discussion with physicians.

If there is no family member present, the law infers that physicians are allowed to launch a protocol without anybody's consent (but on the condition that the CCPPRB has issued a favourable opinion), and that patients will be informed on regaining competence so that they can cease to participate if they so wish. This means that physicians, under the supervision of CCPPRBs, are authorised by society to practise research with the purpose of improving the quality of emergency care, and in order to do so, enrol unwitting patients.

This conforms to international consensus ([81] , Guideline 10), which authorises research on "vulnerable" groups because it would be unfair to deprive them of research on the pathologies they suffer from, but the conditions under which such research is conducted are very exacting.

French law restricts research in an emergency to protocols from which can be expected "direct and major benefit" for the patient.

This qualification would be entirely reassuring if the Huriet law made a clear distinction between "research with direct individual benefit" and "research without individual benefit". The dividing line has been a source of some perplexity ever since the law was voted, *inter alia* in the deliberations of the CCPPRBs. It has been disputed internationally. This is not the place to enter into a discussion on the subject, except to say that in order to make matters clearer to those whose consent to research is asked for, and for discussions in CCPPRBs, a research protocol declared as being "with BID (*bénéfice individuel direct* - direct individual benefit)" should explicitly list the "direct benefits" that the participating 'beneficiary' can expect to gain.

A complete consensus has not been achieved internationally on research in an emergency situation. Everyone agrees that it is of great importance to conduct research to improve the quality of emergency care in all domains (cardiology, pneumology, neurology, traumatology,

etc.). But to what degree is it acceptable to forgo the principle of self-determination to make that possible ?

In the United States, up to 1996, the regulations of the Department of Health (DHHS) and those of the FDA prohibited any kind of research without a patient's consent, or consent given by a "legally authorised representative". To enable emergency research, researchers and ethics committees resorted to "deferred consent" from patients or their representatives, but this was never in fact officially accepted by the authorities. Since October 1966, FDA and DHHS have authorised a waiver to the rule of prior consent for emergency research. The conditions attached are that ethics committees (IRBs) supervise it closely, and that as soon as possible after the study starts, consent should be obtained from patients, or if they remain incompetent, from their representatives; if representatives cannot be found, then the family must be contacted and informed, and questioned as to whether they have any objection.

It is however difficult to approve the fiction of "after the event" consent. Although the legitimacy of starting some kinds of research (e.g. initiating care for a myocardial infarction) is allowable before either patient or representative can be consulted, in the second phase patient or representative should be informed of the fact. A patient might then wish to withdraw from the study, or even demand that data collected on the case not be published. Otherwise, the patient might approve the choice that was made on his behalf, but one can hardly claim that consent was given.

For emergency research, there is therefore a problem of collective discipline. If we want improvement in emergency care, do we accept (and if so with what provisos) the prospect of being enrolled in a research protocol in a medical emergency and only being told after the event ?

END-OF-LIFE

The problem of care at end-of-life is a thorny subject of discussion in France at the present time. Therefore, CCNE would simply recommend that efforts be made to discuss the subject publicly with some degree of serenity. On three counts alone, the problem merits thorough discussion:

- right of access, at home or in hospital, to palliative or comfort-giving care, in particular as regards pain relief (in compliance with law n°95-116 dated February 4th, 1995),

- abstention from superfluous treatment, so that economic or budgetary considerations do not govern that abstention instead of it being the result of carefully thought out choices made in the bests interests of persons concerned,

- euthanasia.

In reaction to a draft resolution on assistance to the dying adopted on April 25th 1991 by the Commission on the Environment, Public Health, and Consumer Protection of the European Parliament, CCNE rejected any notion of recognising euthanasia as an end acceptable in certain circumstances (Opinion n° 26, June 24th 1991).

Has that stand been overtaken by events ?

If there is a move towards better dialogue between patients and doctors, and to more active patient participation in the decision-making processes which concern them, the issue of choices to be made at end-of-life cannot but arise. "The circumstances before death are so important for the dying, for loved ones and the process of mourning yet to come, for carers and their working conditions, and for society as a whole" ([50] , p. 153), that they truly deserve collective reflection.

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Conclusions and Recommendations

1. Information of patients, in care or research, is the necessary condition for the quality of consent. After being informed, patients can accept or refuse proposed procedures.

The Hospital Patient's Charter must be systematically made available to patients and its contents taught to health care providers.

2. The principal aim of testing new therapies is to care for patients, but also serves to expand the sum of the scientific and technical knowledge of hospital physicians. The border line between care and research is very hazy. Requesting patients' consent to either medical treatment or to research is based on identical principles (respecting a patient's autonomy), leading to the same aim : responsibility and trust shared by equally autonomous partners, patient and physician.

3. Certain waivers to this rule must be considered : for instance the consent of patients may be presumed in an emergency, and reiterated once they regain their faculties of judgment.

4. Patients referred to as "incompetent" frequently display sufficient command of comprehension to justify giving them information and to legitimately seek consent - which cannot be presumed - to treatment.

5. Two points which at present seriously dismay the medical profession should be considered : the definition of "direct individual benefit" that patients may receive from biomedical research, and the evaluation of biomedical care and techniques.

In protocols for the evaluation of medical treatment or techniques which will be increasingly common and become part of accreditation procedures for health care institutions, there will be a need to clarify the differences between evaluation and research, and for certain protocols, some alleviation of existing constraints.

In the case of biomedical research, legislation should distinguish between "research with direct benefit for health", and "research which does not aim to directly benefit health". In some quarters, there is the belief that the "direct aim" of a research protocol is the acquisition or validation of knowledge (and not directly caring for an individual patient); others argue that participation in a research protocol is in general "beneficial" for a patient, because in the framework of a research protocol, follow-up is at a higher scientific level than is necessarily the case otherwise.

6. The extremely difficult issue of biomedical research with patients whose condition precludes giving them information and who are therefore unable to give consent, must be

tackled. Severe cases of neurological impairment with no hope of recovery come under this heading. As underlined by WHO-CIOMS, it would be inequitable to deprive these patients altogether of research on the pathologies they suffer from.

7. It is also inequitable to assign defenceless people to research. When consent is an impossibility, the possibility of designating a "representative" or an "agent" would be a step forward.

Notes

1. The first version of the Hospital Patient's charter was annexed to a circular dated September 20th, 1974 (Ministry of Health). A second version [33] taking into account the hospital reform of 1991 and the "bioethical laws" of 1994 is annexed to circular DGS/DH/98 n° 22 dated May 6th 1995 (Ministry for Social Affairs, Health, and the City). The letter of introduction of the Charter, signed by S. Veil, Minister of State, and PH. Douste-Blazy, Minister of Health, specifies that "In establishments providing public hospital services, the full version of the Charter shall be annexed or inserted in the manual which is systematically given to each patient on arrival".

2. Regarding organ donation, conditions of consent for living donors are stated in the law dated July 29th 1994. They differ considerably depending on whether the donor is a minor or an adult.

For minors, donation is only allowed for siblings and is strictly limited to bone marrow. Parental consent must be given to the Superior Court Judge *(Président du Tribunal de grande instance*). A Committee of Experts then interviews the family in order to evaluate the conditions in which a young minor was proposed as a bone marrow donor. A minor whose donation is applied for and who has reached the age of reason is also heard by the Committee. *In fine* , this same Committee authorises or refuses to authorise donation by the potential donor.

For adults, the "right to donate an organ" for a living donor is strictly limited to very close relatives, i.e. father, mother, brother, sister, son or daughter, of the beneficiary. The only exception in an emergency is the spouse. This clause does not seem sufficient to guarantee that the donor has given consent in conditions of total freedom, and in particular that no immoderate pressure has been exerted. In order to avoid abuse a proposal could be made to set up Committees of the kind which evaluate the "quality" of consent for minors. If new legislation is drafted to extend to others (for instance, an unmarried partner) the "right to donate", it would also be preferable to provide this kind of procedure to monitor the sincerity of consent and the authenticity of the will to donate.

3. It should be noted, however, that since this is a decision by the *Cour de Cassation,* the court of appeal to which the case is referred must try it again. Therefore, it is only once a confirming decision is taken by that court, or failing that, once the *Cour de Cassation* in plenary session has finally decided, that the case is closed.

4. On the obligation to inform, see the pertinent comments of the *Conseil d'Etat* , 1998.

5. AFD : French Diabetes Association (*Association Française des Diabétiques*), AFH : French Hemophilia Association (*Association Française des hémophiles*), AIDES : Association for Information and Support to AIDS patients (*Association d'Information et d'Aide aux malades du SIDA*), UNAPEI: National Union of Associations of Relatives and Friends of the Mentally Handicapped, (*Union nationale des associations de parents et amis de personnes handicapées mentales*). A list of French support groups can be found in the Report of the Economic and Social Council on "the rights of patients" or requested from CCAH, 36 rue de Prony, 75017 Paris, telephone (33) 1 4227 7851, fax (33) 1 4440 4405.

Some mutual insurance schemes also engage in educational activities as well as support and research. For example, MGEN in association with LIGUE promotes the French component (E3N) of a vast European epidemiological study (EPIC) on diet and cancer. Information to persons participating in research programmes is particularly scrupulous in this study.

6. The French Medical Association has published brief and pertinent evaluations on "non tested medical practices" : acupunture, homeopathy, phytotherapy, etc. (cf. *Bull Ordre Méd* , Dec. 1997) and preventive strategies (e.g. cancers of the breast or the colon) which could do more harm than good if they were generalised without sufficient precaution (cf. *Bull Ordre Méd* , Feb. 1998)

7. Data given at the Journées Annuelles (1997) de l'Association Française de Pharmacologie Clinique by a representative of the Ministry of Health (DGS).

8. A certain lack of symmetry is however worth noting in the conduct of those who refuse to be the subject of research, but are quite serene about benefiting from the results of research performed on others.

9. The principle is unchanged but practices differ. The same action (e.g. taking a blood sample) is prescribed without comment in a health care context, but requires consent in a research protocol context. This discrepancy is sometimes described as "schizoidal".

10. **Controlled trial** : a comparison between two therapeutic (or diagnostic) strategies, one of which is new ('under trial'), and the other is already known and validated (it serves as a reference or "control" to evaluate the new one); if no properly validated reference strategy exists, the new treatment is tested against absence of treatment (or a neutral treatment: placebo).

Randomised trial : the distribution of persons participating in the experiment into the branches of the trial (group receiving experimental treatment / control group) is decided by lottery.

Double blind trial : neither the investigating physician, nor the person subjected to testing are aware of the results of the lottery throughout the duration of the trial. When this precaution is taken, it serves to avoid the results being influenced (biased) by knowledge of what treatment is being applied (enthusiasm or apprehension in the face of novelty, disappointment or relief at being given the reference treatment).

11. RMO = "opposable medical references"

12. The ethics committee of the Institut Curie, Paris, did some research work how to give information to patients without trauma.

13. About hunger strikes : see L. René's comment on Article 36 of the Code of Medical Deontology ([27], and also [95]).

14. cf. C. Huriet (1996), in *"Dans" la loi ? ou "hors" la loi?* On the subject of the law on clinical research, *Annales Françaises d'Anesthésie et de Réanimation* , 15: 7-8.

15. cf. Rodriguez Maria, essay for *diplôme d'université* , Department of Medical Ethics, Henri Mondor Hospital, 1997.

16. There was a Parliamentary debate on this point at the time of the 1994 revision. The wording "close to the patient" (*les proches* , in French) was judged to be too loose. Traditionally, members of the family are considered to be the "natural protectors" of a person. Many practitioners would prefer to revert to the idea of "close to the patient", since affection may be stronger than blood ties (see (6)). The possibility of designating an "agent"

would solve at least part of this problem. The person close to the patient, or the member of the family, would only be brought in if there were no designated agent.