

**Opinion n° 85**

Information regarding the risk of blood transmission  
of Creutzfeldt-Jakob disease.

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On October 5, 2004, the *Directeur Général de la Santé* (Director General Health Services) referred to CCNE on the subject of whether information should be communicated to patients who had received blood products from a donor subsequently found to be suffering from Creutzfeldt-Jakob disease (CJD).

The question is connected to the probable, if not certain, existence of a causal link between the appearance of a new variant of CJD in two patients in England and the fact that they had received blood from a healthy person who had been diagnosed with CJD three years later.

Very understandable concern raised by this possibility has led to an immediate review of every possible form of protection against the disease, including in particular what is currently described as the 'principle of precaution'.

However, the essential point of the referral is more directed at the status of information than at principles of precaution themselves. The aim of information is generally to communicate knowledge, to draw attention to a fact, rather than to state ignorance. We must also remember that there is a considerable distance between the issuer of information and its recipient. Although the source of information seeks to circulate it rationally and soberly, the way that information is received depends on factors which may be totally irrational. This ambiguity between transmission and reception is not dependent on whether the information was circulated collectively or individually. However, when information is collective and about a risk, the population can discuss it freely. When information is individual, this is no longer the case.

Information needs to be in context; it cannot be taken in isolation.

### **1) Points to be taken into account**

Since the new variant of CJD was described in 1996, a large number of patients have received blood from donors who later turned out to be contaminated. It is true that a time lapse of under ten years is too short for certainties, but until now no case of CJD had ever been attributed to transfusion. Epidemiological studies had even shown that patients transfused with blood from donors contaminated with CJD had not expressed more CJD, in particular as regards the familial forms.

The two recent cases in England, even though they bring no certitude, do make blood transmission plausible, particularly so since, after overcoming significant methodological difficulties, experimental transmission has been demonstrated in animal models. In humans, proof of transmissibility is not as yet formally provided because of the absence of valid biological markers.

In France preventive measures were taken quite some time before these two cases were known. On the basis of the principle of precaution, donors who had lived in England before 1997 were barred from giving blood, because of the higher prevalence of the disease there than in France<sup>1</sup>. To this was added nanofiltration and systematic deleukocytation of blood products (because leukocytes are thought to harbour prions).

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<sup>1</sup> « Analysis of the risk of transmission of the new variant of Creutzfeldt-Jakob disease by blood and its derivatives : recommendations » (December 11, 2000, *Agence Française de Sécurité Sanitaire des Produits de Santé*) (French health products safety agency).

As regards research, English scientists are working on protocols to evidence the presence of prions in tonsils removed for medical reasons or during autopsies. In fact, one of the English cases was discovered through an autopsy.

## **2) Arguments in favour of providing clear information to recipients of such blood products.**

Supplying systematic and transparent information to all those concerned is an indisputable and undisputed ethical principle. In the circumstances, justification for providing such information to patients who had received a transfusion would theoretically be that they would later be able to gain access – following the line of reasoning applied to a “classic” infectious disease, such as tuberculosis or syphilis – to possible preventive care if there had been therapeutic progress in the meantime, and that the chain of transmission would be interrupted because they abstained from donating blood or organs. Such information also respects the increasingly recognised and claimed ‘right to know’. In fact, it would really protect the administrative and medical institutions from legal action on the part of people who had been contaminated. The HIV tragedy and accusations that public institutions had concealed for a length of time information about genuine dangers are still fresh in everyone’s memory.

## **3) Arguments against providing such information**

Although there are arguments in favour of informing those concerned, it must be accepted that the negative consequences of doing so are far from negligible. We are confronted here with a typical situation of uncertainty, where there is no possibility of preventive action, at least as regards people who may have been contaminated. The risk of transmission of CJD through the blood is uncertain and therefore not quantifiable. In any event, it is very low and in no way comparable with the risk of contamination by HIV or hepatitis C.

As for the argument that if information is provided, transmission by possibly contaminated blood donors can be interrupted, it no longer applies, because since 1997, recipients of blood transfusions can no longer donate blood themselves.

The likelihood that a transfused patient becomes an organ donor is so low that the multiplication of these two possibilities – having been contaminated and be an organ donor – equals an infinitesimally low probability of risk.

The point therefore is whether people who have had transfusions can live with this uncertain but terrifying threat, which is all the more frightening because it can be neither specified nor exorcised. For those who are informed, all they can do is wait for disaster to happen without any possible remedy. They could also be excluded from health care systems, as certain recent examples have shown<sup>2</sup>. One might well fear that they would be faced with the following dilemma: conceal information and feel guilty, or reveal it and feel excluded. This is a situation where an individual has everything to lose and nothing to gain.

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<sup>2</sup> It is a fact that patients from families suffering from familial forms of CJ have been excluded from health care institutions by reason of the principle of precaution. Patients who had received growth hormones before 1985 are not allowed to benefit from endoscopic procedures or surgery in normal conditions because of the fear that medical or surgical equipment could be contaminated.

In fact, the purpose of providing information is to increase the possibility for those who have received it to take decisions about themselves or about their relationship with others. In this case, information is given on a potential, non quantifiable risk, so that it is the procedural as opposed to the substantive version of the principle of precaution which is satisfied<sup>3</sup>. CCNE has in fact already written an Opinion on this subject (Opinion n° 79).

The central question therefore is still the risk threshold. There is however an added element of confusion because increasingly, information about a potential risk, however uncertain, is taken to mean that there is a proven risk. Risk is not seen as a statistic, but as a more or less avoidable danger.

The object of the principle of precaution is to take steps which may be effective in a situation of uncertainty, i.e. between two courses of action, choose the one which seems less risky. In this situation, informing people does not reduce the risk in any way, but instead creates psychological pressure which can devastate their lives without any possible remedy. In the present circumstances where little is known and nothing very much can be done, maximum precaution would be to abstain from worrying people. The logic of transparency, and the “erklärung” philosophy do not apply to the principle of precaution which can also consist in abstaining from providing non-information.

Recent events should not be reason to lump this issue with other transmissible infections. There is a real risk of paralysis through constant comparison with the past. In fact, the epidemiological data on CJD (148 cases in England and 8 in France of new variant CJD since the 1990s) do not in any way suggest an epidemic explosion.

CCNE therefore considers that at the present time, the benefit to risk balance rather inclines towards not giving information. The right to know (and by correlation the right not to know) would not seem to apply in this case, since we know practically nothing. In contrast, the “right not to know” in this case is the right not be assaulted by a doubtful threat which no one is in a position to define or combat. A distinction should however be made between informing the public and informing the individual. As regards the former, information must be as broad and complete as possible so that it is clear that experts, decision makers, and politicians are acting in the light of existing scientific data in the public’s best interests. For the latter, if an individual’s best interests have been carefully considered, information could be held in reserve, but not concealed, the public at large having been informed of the dilemma.

4) Awareness of the risk of providing meaningless information must not, however, be allowed to lead to inaction. Stringent traceability of blood donation by

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<sup>3</sup> Cf. **Opinion 79, September 18 2003, Transposition into French law of the European Directive relating to clinical trials on medicinal products: a new ethical framework for human research:** « The principle of precaution cannot be summed up as saying “when in doubt, abstain”; what it says is “when in doubt, evaluate the respective risks of action or inaction” (...)In its “procedural” version, the principle of precaution does not proscribe a risk bearing action; it calls for weighing the risks involved, it being clear that the only choice we ever have, is choosing between various risks (abstention itself is indirectly a source of risk: delaying progress, penalising innovation, etc.) »

patients with CJD needs to be organised<sup>4</sup>, on the one hand to provide epidemiological information, and on the other, so as to offer those affected the benefit of possible future therapeutic progress. Traceability is in any case the rule as regards blood transfusion. CCNE is however well aware that its efficacy, in the absence of information, diminishes over time.

Is it acceptable to identify people and not warn them? Past experience has demonstrated repeatedly that perfect traceability is frequently a problem in that it is a source of unjustified worry. There have been examples of information given to families after the death of a close relative or information regarding the risk of stable products from HIV infected patients which were in fact non-contaminating. The object of traceability is to establish cause and effect relationship in epidemiological terms, not to distress an individual without any useful purpose being served.

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In conclusion, although scientific findings once again suggest the possibility of a blood-borne transmission risk, CCNE's Opinion in 1997 remains valid, since the information would serve no other purpose than to alarm the people concerned without any benefit in return. It would be a paradox to include into the scope of medical deontology a new form of "ethical" duty consisting in always saying everything that can possibly be said, even about what one does not know. There is also a duty of discretion which sometimes compels doctors to abstain from saying everything.

The principle of precaution applies here not so much to the scientific information itself, but more to persons concerned by the information so as to protect them from pointless alarm.

November 4, 2004.

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<sup>4</sup> Comment: Implementation of monitoring through epidemiological studies is, at least in spirit, close to the procedural version of the principle of precaution as it appears in article 5 of the recent environmental charter : « When damage, although not a certainty in the present state of scientific progress, could affect the environment seriously and irreversibly, the authorities must see to it, by implementing the principle of precaution, that provisional and proportionate steps are taken to avoid that damage to be done, and that procedures for an evaluation of the risk incurred are established. »  
([www.charteEnvironnement.html](http://www.charteEnvironnement.html))