Opinion on medical registries for epidemiological and preventive studies. Report.

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Opinion

The President of the National Cancer Commission *(Commission Nationale des Cancers*) requested the National Consultative Ethics Committee for Health and Life Sciences to study ethical problems raised by cancer registries. The Committee considered that these problems are in fact a particular case in a more general set of issues raised by the collection and use of nominative information for biological and medical reasons, with the help of computerised registries and files. These issues should be studied in the aggregate.

They should be examined with a view to combining two sets of considerations :

- On the one hand, out of respect for human beings, whose liberties could be threatened if they are locked into their individual or familial history by an accumulation and processing of information;

- On the other hand, by the need to assist - and not just avoid impeding - medical progress using new facilities offered by computers.

In the same way, although a solution to these problems is sought on the basis of our existing knowledge, of relations between those concerned and practitioners, of public opinion and deontology, it must also take account of desirable progress in medical research and in electronic data processing itself, and of changing moral environments.

The National Consultative Ethics Committee offers the following solutions :

1 - Collecting and processing of nominative information with the object of epidemiological research, and the expectation of better individual and collective medical prevention, must be subordinated to the following conditions :

guarantees to protect those concerned from an encroachment on their liberties if third parties gain access to items of information derived from data collection and processing.

guarantees concerning a possible but very limited concession regarding article 378 of the *Code Pénal* , which underpins medical confidentiality.

The Committee could consider, but only if it was essential, an addendum to the effect that for epidemiological research involving computerised records, medical confidentiality could be

shared on the following conditions : only the attending physician, after obtaining informed consent from the patient, may communicate information to physicians in charge of accredited organisations engaged in epidemiological research undertaken to improve collective and individual health and correlated preventive measures. Accredited organisations and institutions are therefore required to designate a doctor responsible for maintaining the confidentiality of the information communicated.

Collecting and processing medical information must be restricted to a limited number of organisations, cleared by the authorities for that purpose after an ethics committee has been consulted.

Before doing so, the committee :

- would make sure that the research or preventive measures for which collecting and processing information is planned are justifiable, taking into consideration both the interests of those individually concerned and of the general public;

- would check that collection of information would be performed in a satisfactory manner.

2 - Collecting and processing nominative medical information must be carried out in compliance with all articles of law n° 78-17 of 6th January 1978 on computerised information, records, and liberties.

In particular, information can only be sent to accredited organisations with the prior consent of those concerned, who must be informed as stipulated by article 27 of the law, that nominative information concerning them is being sent to an accredited organisation. In case of legal incapacity, written consent must be given by the legal representative.

The National Commission for Computerised Information and Liberties (*Commission Nationale de l'Informatique et des Libertés)* will be required to lay down the technical precautions to be taken for strict secrecy to be preserved regarding the information collected and processed, and guarantee anonymity as regards third parties.

3 - Legislation must be passed :

to depart from the existing rule preventing the communication of nominative medical information except between physicians treating the same patient, if in the particular case concerned shared confidentiality was unacceptable, and to define the conditions in which such information would be transmitted to accredited organisations (see suggestions in the 3rd sub-paragraph of paragraph 1, and in the 3rd sub-paragraph of paragraph 2 of this Opinion);

to reserve access to information collected and processed to doctors expressly authorised to do so by those concerned, and to doctors engaged in scientific research or called upon to act preventively or for an individual, all of whom must observe medical confidentiality ;

to prohibit any third party, legal or natural person, public or private, and in particular any employer or insurer, demanding from those concerned the production of information collected and processed by accredited organisations;

>to define the conditions in which access could be gained to information collected or processed after the death of those concerned.

4 - Once attending physicians have given due warning of risks incurred and means of averting them, those concerned must remain entirely free to draw their own conclusions.

Unless the law expressly stipulates, there can be no exception.

5 - So as to be confident that collecting and processing of nominative information by

accredited organisations takes place in irreproachable moral and technical conditions which are worthy of the trust of those concerned, it is both necessary and urgent :

to train practitioners to deal with research and communication of data in a computer compatible fashion, and so that they can be compared to data from other sources;

to increase practitioners' awareness of the importance of their participation, and of the need to comply with the law in particular insofar as it protects individual rights and liberties. This applies to doctors in private practice or hospitals, those in charge of test laboratories, practitioners in various medical or para-medical occupations, as well as and specially so, doctors responsible for accredited organisations;

to encourage and develop teaching and training, which is sorely lacking for the time being, in epidemiological medicine;

to undertake and pursue a sustained educational effort to help public opinion gain a better understanding of the usefulness of registries for one and all;

to prompt, as a first step, collecting and processing nominative information relating to certain diseases or affections chosen in consultation with a committee of ethics, and to certain areas or professions.

Report

The President of the National Cancer Commission *(Commission Nationale des Cancers*) requested the National Consultative Ethics Committee for Health and Life Sciences to study ethical problems raised by "cancer registries". The National Cancer Commission sent two reports to the Ministry of Health, one of which dealt with problems specific to cancer registries, and the other attempted to define a national policy on registries.

The Committee considered that the cancer registry problems are in fact a particular case in a more general set of issues raised by the collection and use of nominative medical and socio-medical information on all kinds of diseases, and that these issues should be studied in the aggregate.

Furthermore, the National Consultative Ethics Committee emphasises, as it has done previously, that this report must attach the greatest importance to the relationship between patient and doctor which is almost always based on discretion and which still prevails in this specific form in our country in the majority of cases. More generally, this report takes into account medical deontology as it exists today, knowing full well that a number of the themes broached by the Committee will evolve, and that at some future time it will be necessary to review present thinking.

Objectives

The problem of what is referred to as "registries", bears on collecting, processing, and using information regarding all kinds of diseases, for many different purposes.

The essential objective is epidemiological research. The purpose is to identify the various physical, chemical, biological and social factors which may contribute to the appearance and course of a disease. Therefore, information from various sources is collected for each case, the main and primary source being the attending physician. Other sources are test laboratories, and possibly the patient's entourage, doctors engaged in preventive care such those in departments dealing with the welfare of mothers and children, or health care in schools and universities or in the place of work, or even social workers. This information is about the person concerned and his/her family or work environment.

Information has to be nominative to avoid duplication, be precise about the course of the disease from beginning to end, correlate medical and social information and highlight any other connection, and finally to evaluate the effectiveness of screening and prevention.

This is all the more important because epidemiological research and preventive measures are related in two ways.

In the first place, information which is collected and processed may throw light on the etiology of the disease and help to take collective preventive action such as for instance, a modification of the environment, vaccination, or disinfection.

In the second place, processing information gleaned from various sources about a single patient or a single family might help to spot risk factors to which some people might be particularly vulnerable. Once in possession of such information, the attending physician is able to prescribe individual preventive measures to avoid the risk.

This kind of research which is particularly beneficial, is nowadays facilitated by the use of computers, which can store the information, and then process it, make comparisons, draw conclusions from these comparisons in general or for individuals.

Very soon many doctors will be using computers or computer terminals which will make it much easier for them to manage their case files, and access information stored in collective computers which will help diagnosis and therapy.

Such prospects demonstrate both the size of the problem and the importance of the stakes.

On the one hand, new and almost limitless possibilities are offered to practitioners and for implementing health policies generally.

But, on the other hand, those concerned by accumulated and processed data could find themselves locked into their personal and family histories. This potential threat to individual liberties is the reason for legislation dated 6th January 1978 on computerised information, records, and liberties.

It would seem therefore, that although "registries" do raise ethical problems which are within the purview of the National Consultative Ethics Committee for Health and Life Sciences, these problems are also the province of the National Commission for Computerised Information and Liberties according to the mission given to it by the above law, and are also covered by medical deontology which is governed mainly by medical and para-medical associations.

For this reason, the problem of registries was studied by the National Consultative Ethics Committee for Health and Life Sciences in close cooperation with the National Commission for Computerised Information and Liberties and the National Medical Association (*Conseil National de l'Ordre des Médecins*). This joint work has enable us to arrive at a number of comments and proposals, of which are presented in the report only those which are directly or indirectly within the purview of the National Consultative Ethics Committee.

The present situation

As of now, "registries" are organised and operate under various legal, administrative, and management methods, depending on local initiative.

To take only those concerned with cancer as an example, registries operate in the following frameworks :

- regional cancer centres (Caen, Toulouse),

- university hospital centres (Besançon, Caen, Dijon),

- non-profit associations created specially for that purpose based on the law of 1st July 1901 (Isère, Haute-Garonne, Dijon)

- a health care institution reporting to the Medical School (Strasbourg),

- a regional health Observatory (Hérault)

- a joint Service n° 17 of INSERM (*Institut National de la Santé et de la Recherche médicale).*

Some of these cover all kinds of cancer and others only certain cancers.

Each organisation has its own methods for collecting data, and sources also vary a great deal (private sector, hospital centres, sickness insurance authorities, anatomico-pathological laboratories).

At present, there does not seem to be any organised link between various registries.

This flourishing diversity which is probably also true of registries for other diseases, is not in itself a defect, and probably offers good opportunities for different approaches and fruitful comparison.

All the same, it is very important to try and find frameworks which permit maximum efficiency and a maximum degree of protection in ethical matters for those concerned.

Ethical problems

Ethical and legal problems raised by "registries" are mainly of two orders :

1) guaranteeing medical confidentiality

2) guaranteeing that information is collected and processed with the consent of those concerned.

Medical confidentiality

Medical confidentiality is both a fundamental ethical principle common to all medical and para-medical professions, and a precise legal rule subject to article 378 of the *Code Pénal*.

It is endangered, firstly, by the collection of information. Insofar as it is of a medical nature, which is almost always the case, confidentiality applies. It cannot therefore be disclosed to any third party. Now, it has become apparent, that more often than not, information contributed to cancer registries came from anatomico-pathological laboratories. Serious doubts have been expressed on whether it is allowable for the management of these laboratories to communicate nominative information to organisations in charge of registries. In fact, most laboratories have now ceased to divulge this information, thus depriving registries of their main source of material.

The problem, therefore, is whether practitioners may supply nominative information to organisations authorised to keep a "registry", and if so, on what conditions. The same problem arises for social workers who are also bound by rules of confidentiality.

Who should be authorized to keep registries ?

As is well known, medical confidentiality conforms to very strict rules, and the situation is close to identical for social workers. The person concerned by the information, however, is not bound. Furthermore, although jurisprudence is not very explicit on this subject, it is generally thought that information may be shared between practitioners engaged in caring for an individual. Sharing of confidential information is all the more allowable because the rule of secrecy does not aim to benefit the professionals, but solely to protect the individual concerned and sharing information in this case improves the chances of successful treatment. There is therefore good reason to ask whether sharing confidential information about a given person between the practitioner attending that person and an epidemiologist - the doctor representing the organisation keeping the registry - is allowable, keeping in mind that the epidemiologist is also bound by medical confidentiality.

On the basis of the principle which has just been set out above, the answer is in the negative if the registry is solely for epidemiological purposes. There can, however, be a hesitation if the registry could be, and in fact is, used for individual preventive action or to help doctors with diagnosis and therapy. If that is so, the recorded information can be used, and frequently is used, for the treatment given to those concerned by the information. The organisation in charge of the registry in that event, acts as a consultant, and it seems that sharing the secret could be acceptable.

Recognising this function for registries is all the more desirable since it would encourage practitioners to supply information to registries knowing that the reward would be the assistance that registries could give them for prevention, diagnosis, and therapy.

For that matter, it would seem strange, were the managers of a registry to discover that, according to information about a particular patient, the diagnosis or adequacy of therapy could be in doubt, if they then refrained from drawing the attending physician's attention to the fact. One might even raise the question of whether this would not be a breach of the law governing mandatory assistance to those in danger.

If the possibility of "shared secrecy" could be accepted, the *Conseil d'Eta* t should be asked to confirm this opinion. However, as there could be doubt in the absence of any specific jurisprudence, it would be preferable to enact legislation to the effect that practitioners and social workers who are all bound by rules of confidentiality, may, without breaking those rules, communicate information concerning an individual who has given informed consent, to medical epidemiologists in charge of organisations authorised to keep registries, on condition that precise instructions are given regarding the protection of confidentiality and absolute secrecy.

Consent of those concerned

The law dated 6th January 1978 on computerised information, records, and liberties, stipulates as follows :

Article 26 : A natural person has the right, for legitimate reasons, to oppose any personal nominative information being processed....

Article 27 : Persons who have been asked for nominative information must be informed of the following :

- whether answers are mandatory or voluntary;

- what consequences for themselves would ensue if answers were not given;

- which natural or legal persons would receive the information;

- and that they have rights of access and correction...

Article 34 : Any person providing proof of identity is authorised to question services or organisations in charge of computerised processing... to find out whether processing bears on nominative information concerning him/her, and in that event, to obtain communication of the work.

Article 35 : The owner of rights of access may obtain communication of information concerning him/her...

Article 36 : The owner of rights of access may demand that information concerning him/her which is erroneous, incomplete, ambiguous, or outdated, be modified, completed, clarified, up-dated, or erased...

In case of dispute, burden of proof is on the service to which rights of access are exercised, except if it can be established that the disputed information was communicated by the person concerned or with that person's consent...

Article 40 : When rights of access are exercised for information of a medical nature, such information can only be communicated to the person concerned through a doctor designated by that person.

The above rules represent the main features of the law of 6th January, 1978, and the essential guarantees that the legislative body wished to confer on natural persons to protect them from any breach of their liberties brought about by the use of computers.

The result is that medical or social information for a medical "registry" cannot be communicated to the organisation authorised to collect and process that information without the consent of the person concerned, and that the latter may at all times ask for communication of that information, through a doctor of his/her choice if the information is medical.

As we all know, to give a patient complete and precise information about his condition, is frequently inadvisable. The code of medical deontology (Decree of 28th June, 1979) specifically says in its article 42 : "For legitimate reasons appreciated in conscience by the doctor, a patient may be left in ignorance of a grave diagnosis or prognosis. A life-threatening diagnosis can only be disclosed with the greatest circumspection, but usually the family should be informed, unless the patient has previous prohibited such disclosure, or has designated third parties to whom it should be made."

Although, in the abstract, one might regret that individuals are not always ready to bear the burden of their state of health and their fate, it must be recognised on the one hand that humanitarian reasons can motivate concealing an incurable disease, and on the other hand, that public opinion in France would frequently disapprove of such disclosure. This is in fact the case for many cancers, and perhaps even more so for some genetic diseases for which there is no cure.

It is for this reason that the National Cancer Commission has requested legislation authorising, in such cases, practitioners to communicate information to an organisation in charge of a registry, without the patient's consent.

In spite of the validity of the arguments put forward, it does not seem possible to accept the request because, wilfully or otherwise, such a clause would undermine the very foundation of the law of 6th January, 1978, and there could be unpredictable repercussions if those principles were breached.

Consent then, that would be given by patients, means that they would be informed in compliance with conditions laid out in article 27 of the law dated 6th January, 1978, that

nominative information concerning them is to be communicated by the doctor to accredited organisations. We fully understand and regret, that if there were many refusals statistical data derived from registries could be biased. But in any event, making the computerisation of nominative medical information mandatory even for a single disease, cancer for example, seems unacceptable.

There is no way in which such an obligation could be enforced in practice, and in countries where this has been attempted, the experiment always failed.

The desired result can only be achieved gradually by a persevering effort to educate public opinion and the views of practitioners.

On that score, it is likely that many doctors, most of them probably in a more or less near future, will be recording on a computer the information collected from their patients. They will therefore be under obligation to ask for the patient's consent and this will become a routine operation which patients who trust their doctors will easily accept.

In this climate of trust and remembering that patients will themselves become more familiar with computers and the process of recording data, written consent could be given to the doctor covering the possibility of communicating data to an accredited organisation under strict obligation to respect medical confidentiality and to which patients could apply for access as stipulated in the law of 6th January 1978.

Such consent would concern a specific medical condition, it being clear that the person concerned would be requested to renew consent if a different disorder was involved at a later time.

As the practice gradually expands, the population should become increasingly accustomed to computers being used for epidemiological study and preventive medicine.

The opinion of the Conseil d'Etat should very probably be requested on whether the procedure as suggested is compatible with the law dated 6th January 1978. If the answer was negative because information given at the outset to patients is considered insufficient, the only other possibility would be to add to existing legislation, i.e. to article 27 of the law, a new sub-paragraph to the effect that, by exception to the above article, an attending physician who considers that his conscience dictates that for legitimate reasons, his patient should not be informed of a grave diagnosis or prognosis, may communicate nominative medical information about that patient to an accredited organisation for the management of registries, without making that known to the patient beforehand.

Guarantees

Be it on the subject of medical confidentiality or of patient's consent, possibilities of success for the registries largely depends on guarantees given to those concerned and the trust they might be willing to invest in the managers of organisations authorised to collect and process data.

Guarantees should be the result of :

1) Accreditation of qualified organisations and the scientific and moral stature of their managers.

2) Strict enforcement of the law of 6th January 1978 on computerised information, records, and liberties.

3) Technical arrangements that the National Commission for Computerised Information and Liberties will be making to protect the confidentiality of information collected and processed, and to keep the information anonymous when third parties are involved.

4) Complementary legislation for the purpose of :

reserving access to information collected and processed to, on the one hand, doctors expressly authorised to do so by those concerned, and on the other hand, to practitioners undertaking scientific research or called upon to take preventive measures, collectively or individually, all of whom are under obligation to respect medical confidentiality.

banning any third party, in particular any public or private administration, any employer or insurer, from demanding that those concerned themselves produce information collected and processed by accredited organisations.

defining the conditions in which access to collected and processed information could be allowed after the death of those concerned.

5) Exclusion of any obligation on the part of those concerned, arising from communication to a physician, even if he is in charge of preventive measures, of data derived from collected and processed information. Patients who have been warned by their attending physician of the risks they may run and the means of avoiding them, must remain entirely free to draw the consequences of that warning. This should be the case unless the law specifically states otherwise, such as for instance in the case of mandatory vaccination. Personal liberty and responsibility must take first place unless contradicted by expressly recognised superior interests.

Operation of registries

So as to ensure that collecting and processing nominative medical information by accredited organisations is done in the best possible technical conditions and in conditions of moral rectitude likely to inspire trust, it is important to train practitioners to research and transmit data in a manner compatible with computerisation and comparison with data from other sources. It is also important to make practitioners aware of the importance of their task in this respect, be they doctors in hospitals or private practice, managers of test laboratories, workers in various medical and para-medical professions, social workers, and of course more specially, managers of accredited organisations. So as to improve epidemiological research activities, authorities must as a matter of urgency deal with the question of training medical epidemiologists.

It is just as important that efforts be undertaken and continued assiduously to educate public opinion so that the usefulness for each and everyone of us of developing registries is clearly understood.

It would probably be desirable, as a first step, to promote collecting and processing nominative medical information connected to certain diseases or disorders, to be selected after obtaining an opinion from an ethics committee, and to certain geographic or professional sectors.