

Recommendations regarding local ethics committees. Report.

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Recommendations

The National Consultative Ethics Committee for Health and Life Sciences which was established by decree n°83-132 of 23rd February, 1983, notes that other Ethics Committees in France have no regulatory standing, and operate in various ways. Management methods also vary.

It considers that a number of these Committees have already done important work and that in order to pursue their activities with even greater effectiveness, they should receive official recognition and benefit from a certain degree of organisation. With that in mind, the National Consultative Ethics Committee formulates the following recommendations :

The existence of Ethics Committees will be governed either by a document creating them or by a decision of public authorities empowered to accredit them. In either case, the National Consultative Ethics Committee will be consulted.

Ethics Committees will be created in a hospital framework, or in a local or regional framework. Furthermore, there will be provision for the creation of specialist Committees and for Committees attached to large research centres.

Committees will be composed on a pluralist basis of representatives of the health professions and persons selected for their competence and interest in ethical issues, engaged in various occupations.

The Opinions issued by Committees have no mandatory effect.

Committees will make pronouncements on issues involving research on human beings, will formulate opinions on ethical problems arising out of research, and will contribute to training and public information based on their consideration of these ethical matters.

Report

Introduction

Ethics Committees stem from different origins.

The National Consultative Ethics Committee was created by a text : decree n° 83-132 of 23rd February 1983. This is not the case for local, regional, hospital, and specialist Committees. Their names do not appear in any law or decree, and a number of them are not established on the basis of any kind of document. There are, however, the *Comités de l'Assistance Publique de Paris* (Committees of the Paris public hospitals) whose organisation is governed by a circular signed by the Director General of the *Assistance Publique* , dated 25th June, 1981, and a further circular dated 30th July, 1984. It could be said that there has been a spontaneous, but uncoordinated, appearance of Ethics Committees, which was solely due to necessity and interest shown by certain individuals.

Which is the better system from the point of view of principles ? Legitimacy conferred by a text meets our concern for legal logic. It gives Committees official authority which reinforces the effectiveness of their pronouncements. Any other system only gives them as much legitimacy as is unofficially bestowed by local bodies (hospitals, universities), or by their own doing, or commanded by recognised and respected authority. It could of course be said that ethics are not decreed, nor organised, and that organisation should be limited to creating the body and then leaving it to devise its own methods of work. Nevertheless, minimal official recognition should help to discourage a proliferation of ill-formed groups and to give a stamp of authenticity and commitment to those which are created on the basis of certain conditions.

I - Missions of the Ethics Committees

The National Consultative Ethics Committee for Health and Life Sciences proposed that other Ethics Committees should be created in its Opinion of 1984 on the testing of new treatments on humans, in which it is recommended that "all trials on humans be submitted to such a committee for it to assess the benefits of any curative, preventive, or diagnostic intervention". It goes on to say : "they (the committees) should also examine all the moral and ethical issues raised by research into biology, medicine and health".

Other bodies consider a broader mission would be appropriate : the Committees' purpose is to facilitate decisions of physicians who encounter ethical problems in their practices, in particular in their dealings with patients and their families (information bulletin n° 32 by the Director General of the Assistance Publique de Paris, on the subject of hospital Ethics Committees, 30th July, 1984). Thus, over and beyond research evaluation, emerges the possibility of also advising physicians on matters of diagnosis and therapy.

Ethics Committees which have appeared on the French scene in the last few years carry out very diverse tasks. Some of them are only concerned with studying test protocols for new drugs. Others evaluate any research project planned by a university hospital centre. Yet others restrict their scope of intervention to a medical speciality such as cardiology or resuscitation. Finally, there are those which make a particular point of reflection and information activities broadly directed at the general public. This disparity may reflect historical situations which differ from one location to another, but experience has shown that wherever their interests lie, their common mission has been to encourage high quality medical research carried out for the benefit of society and individuals whilst respecting their rights. By maintaining a high level of ethical discipline, they encourage a trustful relationship between the scientific community and the public.

The issue of the Committees' mission has been analysed by international instruments.

The concept of evaluation of trial protocols for experimentation on humans by independent Committees created with the specific aim of advising and counselling has been clearly set down on several occasions by the World Medical Association (Helsinki Declaration in 1964, and Tokyo in 1975).

In the international directives proposed for biomedical research by WHO and the Council for International Organisations of Medical Science, it is said : "In countries where medical research is not centrally directed, protocols are more effectively and conveniently reviewed from the ethical standpoint at local or regional level". The basic responsibilities of locally operative ethical review committees are two-fold:

- to verify that all proposed interventions, and particularly, the administration of drugs under development, have been assessed by a competent expert body as acceptably safe to be undertaken in human subjects.
- to ensure that all other ethical considerations arising from a protocol are satisfactorily resolved both in principle and in practice.

As regards France, four categories of activity can be defined:

EVALUATION OF RESEARCH PROJECTS

Any research protocol involving humans must be submitted for assessment to an Ethics Committee, be it originated by hospital centres, or public and private research institutions.

The two-fold aspect of opinion due to required complementarity brings up an essential issue concerning the proper functioning of Committees : the scientific nature of projects. In other words, can the various missions described above be left to a single Committee or should different structures be organised ?

In the United States, in hospitals there are International Review Boards which assess research protocols, and there are Institutional Ethical Committees which have a say in medical practice.

At this point of developments in France, it does not seem necessary to introduce this distinction. It is true that certain missions will be more prominent depending on local situations, but a free rein must be given to Committees regarding their consideration of problems submitted to them by doctors or researchers.

As has been said over and over again : "if it is not scientific, it is not ethical". This approach leads to breaking down into two phases the evaluation of a protocol and raises two questions : is it scientific ? is it ethical ? The two phases can be undertaken by the same Committee. On the other hand, there could be prior consultation of a scientific council composed of a few individuals who would themselves be able to consult, if necessary, outside experts. This is akin to the concept of speciality commissions, but the cascade of opinions would not always be required and in any event, should not introduce delays which would be detrimental to researchers.

CLINICAL PRACTICE

As regards the evaluation of research projects, the mission of Ethics Committees is universally accepted, but this is not always the case if their competence is extended to other areas. They may for instance have a say in clinical or therapeutic decisions.

Should the question be restricted to relations between a practitioner and his patients, obviously the Committees cannot intervene. However, it is quite conceivable that when a doctor encounters a particularly complex ethical issue, he may wish to consider it with the assistance of the Committee to facilitate his own decision. This consideration would be all the more pertinent and fruitful if multidisciplinary qualifications, not necessarily medical, are to be found within the Committee.

In such a case, care must be taken not to wrongfully cross the frontiers which separate deontology and ethics on the one hand, and medical practice and research on the other. These distinctions are not always obvious since several of these activities may be intertwined.

PROBLEMS OF A GENERAL NATURE

It is up to the National Committee to formulate advice and recommendations concerning moral issues raised by progress in fundamental research and clinical research. When this kind of problem is submitted to them, local Committees should refer to the National Committee. They can, however, play a major role if a consensus is sought. As they are close to research and medical practice activities, they are an ideal structure to reflect on these subjects with their authors. In such a case, however, the conclusions and recommendations of a local Committee should be seen not so much as an opinion, but rather as a contribution to more ample reflection.

INFORMATION AND TRAINING

Ethical reflection must be neither confidential nor confined to specialists. It is connected to problems which sometimes may affect the future of human beings and of society. It is for this reason that Ethics Committees must be involved in information and training.

It would be paradoxical if their members had no vision of the outside world.

In France, they already participate in education and meetings for the purpose of giving information at all levels. It therefore seems appropriate to define two areas where their intervention is particularly desirable : research and health professions, and education in both schools and universities.

Although participation of members of local Committees in training activities is natural and desirable, there are also other people who can do this, and it is not their main mission.

A certain amount of leeway must be given to them to adapt their intervention to local situations, for example by setting up a documentation centre.

II - Organisation

Creation and establishment

It was written in the National Consultative Ethics Committee's Opinion concerning research on in-vitro human embryos, that implementation of research projects must be submitted to an accredited Ethics Committee. This notion of accreditation represents a particularly important requirement. As matters now stand, it is worth a reminder that the National Consultative Ethics Committee is based on a regulatory text; the Committees of the *Assistance Publique de Paris* are grouped within a structure headed by a central Committee. That is sufficient no doubt to exclude the possibility of another National Consultative Ethics Committee springing into existence without the benefit of a text or that of a new Hospital Committee of the *Assistance Publique* being set up in Paris without the agreement of the central Committee. But apart from those exceptions, there is nothing to prevent the creation of an Ethics Committee who would choose to call themselves by that name

regardless of composition, location, or activity. The confusion that would ensue is easy to imagine if a Committee was created simply to contradict a disputed opinion or specifically to approve a hazardous experiment.

One possibility would be to follow the example of the National Consultative Ethics Committee's creation. A decree or a similar text would create various Ethics Committees throughout the country and thus would give them the official support which they presently lack. Such a document would require a geographical distribution, and would set down competence, composition, and procedure. The advantage would be legal clarity since it would appear as a complement to the previously mentioned decree of 23rd February 1983. However, if this is the chosen solution it would entail, in itself and by its consequences, meticulous organisation of the Committees.

Another possibility would be to use a simple procedure which would give the Committees official approval without detailed rules so that an elaborate regulatory text could be dispensed with. The Committees would retain their diversity to some degree as regards their organisational and functional modes of operation, but would have in common the fact that they were recognised as complying with minimum conditions entitling them to exist. In this way, their continued existence or creation would be conditioned by accreditation. It remains to decide by whose authority.

A first thought would be to consider giving this task to the National Consultative Ethics Committee. However this would entail decision making as opposed to proposing opinions and would lead to legal consequences which would be at variance with the spirit of the institution. Such accreditation can only be in the hands of public authority.

If this option was chosen, there would still be sufficient reason to consult the National Consultative Ethics Committee because of the expertise on these matters that has been acquired by this body. It would be asked to formulate an opinion, not give accreditation. Nor would it be intended to introduce fussy bureaucratic supervision. The National Consultative Ethics Committee would simply be asked to base its assessment on a few uncomplicated criteria such as pluralism in composition, appropriate location, and a mode of operation compatible with the spirit of the institution. There should be no attempt to make Committees fit a uniform pattern.

We are aware that this supplementary task will require the National Consultative Ethics Committee to create a unit in which local Committees are represented and which will study geographical distribution, conditions of creation, and the preservation of the methodology which permitted them to be accredited. This unit would not of course be intended to exercise any inquisitorial activities, but it could be the source of communication beneficial to all concerned.

Legal formulation and finance

The above considerations regarding the ways in which Committees would be authorised to function, imply that a uniform legal structure is not an obligation. Some regional Committees have set themselves up as an association governed by the law of 1st July 1901 (non-profit associations). This formula emphasises the non lucrative role of the Committees and the possibility of a separate budget. However, for most of the Committees, the problem of financing remains.

It is true that their members' activities are entirely voluntary and that they are not costly to run. Nevertheless, it would be useful to give some precise indication of status so that they can operate on clear financial lines, and some degree of harmonisation. Financial transparency is all the more desirable since it gainsays any ill-intended interpretation of bias. Such considerations make it inadvisable that any financial resources should be provided by individuals or organisations whose activities may in part depend on opinions issued. The same can be said about funds from research or health care organisations or

from private industry. However, criticism would be neutralised if a laboratory, a pharmaceutical firm, and research or health care organisations were to contribute to costs incurred by means of a lump sum to be paid, not to the Committee itself, but to a central body in charge of distributing funds to the various Committees who would then necessarily exercise some kind of financial control. In such a situation, the financial controllers could be a government agency.

Location

Distributing Committees around the country implies choosing between two options. Either there is an effort to distribute them evenly over the whole territory, or else they are set up pragmatically as and when they become necessary. It is true that a purely geographical distribution would be clear and logical and it would also obviate the difficulty of finding which Committee should be approached by those requesting an opinion. But to our present way of thinking such a system would be too reminiscent of the kind of bureaucratic rigidity which we feel should be avoided. A certain amount of flexibility in both organisation and mode of operation seems necessary for establishments dealing with a subject which is not compatible with structures and categories. Although we prefer this option, we feel we should attempt to chart the various other possibilities. Examples can be found in ongoing practices which included hospital, regional, and specialist Committees. Each of these merits reflection.

Some examples of organisation may be found in what has been done under the aegis of the Assistance Publique de Paris which created a central Committee (see circulars by the Director quoted above). There are also some Committees which are part of the framework of teaching and research hospitals outside Paris. Clearly, any research activity in the hospital concerned must be in touch with the Committee and this is its obvious area of competence. That is the advantage. But there is also a drawback, at least virtually, it could become or be suspected of being a "tame" Committee. It is possible to side-step this difficulty by including non health professionals such as jurists, philosophers, and historians, or doctors in private practice, general practitioners in particular who should in no way be left out of any ethical debate, and representatives of other hospital and research facilities in the area.

The existence of hospital ethics Committees, even if they are only concerned with in house problems, does not preclude the establishment of other Committees created on a regional or local basis and also governed by conditions of accreditation. They could also be consulted on trial protocols. However, above all, they should deal with another aspect which has already been mentioned above as one of the objectives to aim for, which is to reflect on certain ethical problems, not connected to any specific case in point, and to try and stimulate public thinking on these problems through various channels of communication such as the media, education, and public meetings.

In this manner, the coexistence of both regional and hospital committees could represent their complementary roles.

Other Ethics Committees are organised by scientific associations, often on an international basis. They are part of a network that can be consulted on specific matters within their purview.

Their structures and relations with other Committees will merit special attention.

Composition

The question of the Committees' composition is not directly related to their location. However, it will become clear that, depending on the nature of the Committee, certain changes may be required. Before coming to these points of detail, a few guiding principles are required. The first of these is pluridisciplinarity or to use a less restrictive word,

pluralism. It is felt that it is essential that there should be a gathering of individuals drawn from different professions, philosophies, and religions. It is of course imaginable, and there are such examples, that Committees be composed of doctors only, or more generally, only representatives of the medical professions. Representing several medical specialities (from that angle, they are pluridisciplinary) they can with some justification produce observations which go beyond purely biological or medical technology to enter into general reflection on a situation particularly worthy of consideration, and on the circumstances and ethical consequences of that situation. They can discuss among themselves their own actions not just as regards the propriety of such actions, but in a context which goes beyond their professional sphere. Such a procedure does not seem fully satisfactory, for two reasons. First of all, it is difficult for these professionals, however distinguished, to escape from their own field and evaluate all of the issues arising. A fresh eye from outside is a precious contribution. Secondly, an opinion issued by a single-sphere Committee will be less credible in the eyes of the public than one given by a pluralist Committee. In the second instance the public will recognise an expression of its own preoccupations and will feel, with some justification, that they have been represented.

As regards the medical professions, representation should be as diverse as possible. To assess a protocol scientifically will often demand a specialist able to give fellow physicians a full picture. The specialist's presence will obviate the need to call on an outside consultant and thus save a great deal of time. By way of example, one would think that the more specific specialities should be represented on a Committee, such as psychiatry and pediatrics. Nurses, who are very close to patients' needs, and members of the para-medical professions, would be most welcome additions.

The demands of diversity would be even better satisfied if representatives of a hospital establishment in another city were to sit on a Committee.

As regards members of the Committee who are not members of the medical professions, they are there to add a dimension on subjects which are of interest to the community as a whole. The National Consultative Ethics Committee's composition might serve as a model. It will be recalled that it includes, apart from researchers, individuals belonging to the various philosophical and spiritual families and individuals selected for their competence or interest in ethical issues. It may of course be easier to find representatives of the various philosophical and spiritual families on a national level than on a local or provincial basis. One can see difficulties arising when people know each other and may complain that they have been neglected in favour of some opposite or even similar trend.

For instance, should a minimum number of followers of a given religion or doctrine be required to accept its representative? If only for that reason it seems preferable to lump together under one designation, "Individuals selected for their competence and interest in ethical issues" members of the Committees who are not research workers. Quite obviously, representatives of various schools of thought could also be part of that category. This flexible system would prevent disputes detrimental to the common cause.

A few other professional categories would be usefully represented on Committees. The list which follows is not exhaustive :

- a) jurists (lawyers, magistrates, professors of law) could supply technical information required concerning problems in which legal considerations are frequently implicated (consent, integrity of the human being, filiation) or which reveal a gap in legislation which needs to be filled;
- b) representatives of the social sciences who could show the impact of current thinking in society on the matters being discussed;
- c) philosophers whose participation in certain debates adds a dimension appropriate to the principles at stake;

d) educators who could report on the aspirations of younger generations and pass on to them the message emerging from debate;

e) journalists, who are able to interpret public opinion and interpret a message back to public opinion.

Rather than continue to give general examples, what remains to be done is to consider the possible participation of two categories of people whose presence is both frequently suggested and frequently criticised. Firstly, we are referring to representatives of hospital or research centre management (directors or their deputies) when the Committee is part of their establishment. One possible objection is that deliberations may lose in objectivity. Experience acquired in certain Committees has demonstrated that this is not the case.

Another category raises a special problem : representatives of patients. In this case also, there are grave objections. The first problem is to decide what kind of patients should be included. For practical purposes, it is obvious that there cannot be representation of every category of patient. Furthermore, how would it be possible to define who would be representative ? Finally, members of the Committee, or at least most of them, have experienced being a patient and can speak with firsthand knowledge not just to present the viewpoint of any particular category of people, but to report the impact of an ethical problem on a given patient. Nevertheless, these objections are mainly of a practical nature but they do not seek to exclude patients from Committees.

Another recommendation is simply common sense. As the objective is that these Committees should be sufficiently representative of public opinion, there should obviously be a significantly even distribution of genders and age groups. Finally, rules should be drafted for renewal of membership with due regard to maintaining good balance between the categories represented.

III - Mode of operation

Requests for Opinions

If the object was to elaborate a highly structured and hierarchical system, it would be necessary to designate the geographic constituency of each Committee, make sure that each area is covered, and set strict rules for requesting an opinion with, as a counterpart, the possibility of declining competence. To sum up, a proper code of ethical procedure would need to be drawn up. Our way of thinking does not by any means lead us in that direction. We would want Committees to be established as rationally as possible so that researchers can contact whichever Committee seems most appropriate. If there was evident lack of good conduct in this respect, the Committee which had been contacted in vain should have sufficient wisdom to detect ulterior motives and to pass the matter on to a more qualified body. There would be some predictable drawbacks, but, in any case, an overly rigid and formal system could not be set up without lengthy delays, and would contradict the spirit which should preside over ethical reflection in our country.

We would add that the possibility of requesting an opinion should be very open and allow access to Committees by, for instance, those in charge of a trial or of drafting its protocol, or to members of a research team, or to the subjects of the experiment.

Better organisation of Committees should make it possible to avoid two or more of them giving divergent opinions on the same subject. The main risk of that occurring arises with multicentric studies. However, the importance of the problem should not be exaggerated, particularly since there are several remedies:

a) When a protocol is presented to a Committee for examination, it is good practice to append opinions already issued, or at least point out that they exist;

b) Not infrequently, members of the Committee consulted are aware of previous opinions and can see to it that due consideration in cooperation with other Committees be given before issuing a divergent opinion, or can organise a measure of agreement;

c) It could be expected that on a given subject the points of view expressed by various Committees are more likely to be convergent than divergent;

d) The National Consultative Ethics Committee, at the request of either the originators or the Committees, could solve difficulties arising out of divergent opinions by means of an agreed solution.

In the light of the above, it would seem that multicentric studies do not give rise to major ethical difficulties and should not motivate a rigid system.

Nature of the Opinions

The effectiveness of Ethics Committees is frequently questioned. One hears, here or there, that practices which have been frowned upon, continue nevertheless, and that recommendations remain unheeded. However, the practice of reporting to the Committee on results achieved once the trial is completed already exists. On a more general point, it should be demanded that any modification to a protocol be submitted to the Committee which approved it. In some circles, it has been suggested that compliance should be made mandatory. On the matter of principle, a suitable reply is that *a general opinion cannot be evaluated on the scale of immediate results*. It acts a spur to reflection aimed at public opinion, and its success can only be appreciated in the light of subsequent events. On the subject of Opinions formulated on the subject of a specific request or test protocols, given mandatory power, they would become decisions which would require Committees to be empowered to enforce them on the one hand, and the possibility of appealing to higher authority for those involved, on the other. If that were the case, Committees would be part of an administrative structure and would closely resemble the judicial system. Is this desirable? We have already made our feeling known on this point, but it bears emphasis. Not to mention all the practical and organisational demands entailed, let us simply consider whether ethicality, the nature of which is unwritten, can be enforced. Coercion is an option in the name of a law, or even of a custom. But it is an impossibility by our habitual standards of enforcement in the name of a moral certainty. Only persuasion, powers of conviction, highlighting a succession of consequences, a reminder of the moral foundations of society, can be of service here.

Another point is that any procedure for appeal to higher authority would generate delays in the test procedures and supposes the National Consultative Ethics Committee to be of nobler essence than other Committees, in the same way as learned and experienced magistrates in a court of appeal are above a tribunal. This is not so. The composition of the various Committees does not lend itself to ranking.

Finally, there is no way in which an opinion once expressed can be undone because a different opinion has been rendered. A Committee formulates its thinking on a submission; it is not delivering an order or an injunction. A different process of thought may lead to a different outcome. The second way of thinking has no power of destruction over the first. However, with a view to avoiding too flagrant contradiction between Opinions, the National Consultative Ethics Committee could be given powers of reference which should be used parsimoniously.

At this point in our study, we cannot propose any element of compulsion for the Opinions of Ethics Committees without a complete reversal of our view of their mission. Obligation can be at two other levels: an obligation to apply to Committees in certain cases; and obligation for the Committees to base their pronouncements on arguments of extreme clarity. However, the power of their opinions must be apparent beyond any enhancement

contributed to thoughts expressed in publication, or granting of credits for research, or liability in courts.

Ethics are not to be decreed. The formulation of ethics is a component of collective thought, an invitation to query, an instigation to finding solutions. It cannot be imposed. There is therefore no need to burden it with bureaucracy.

Relations between Committees

Existing Committees work in isolation. Apart from personal connections between respective members, they ignore each other. The inconvenience of such a state of affairs is obvious. They may be consulted on similar problems and adopt opposite positions concerning identical questions with the attendant risk of disconcerting the scientific community and public opinion. It is certainly not healthy to try and define a sacrosanct ethical line. However, closer relations could help to formulate clearer reflection and thereby lead to opportune modification of certain positions. Efforts in that direction are ongoing.

To improve this situation and bring Committees out of a state of isolation which is harmful to them for a variety of reasons, some practices could be generally adopted. Annually, each Committee could send a progress report of its activities to the National Consultative Ethics Committee, listing tasks accomplished and highlighting ethical principles identified or applied. With the same minimal frequency, Committee representatives could meet with the National Consultative Ethics Committee for a study session to discuss these reports. This meeting would also serve to solve any difficulties arising out of conflicting opinions on the same subject. It would not be desirable that this meeting should coincide with the "*Journées Nationales*" (annual meetings) which have a different object but could also serve as another occasion to meet.

There is also the possibility that in the interval between meetings, a local Committee might wish to consult either the National Consultative Ethics Committee or another Committee about a particularly complex question for which they feel in need of assistance.

Furthermore, whenever it is desirable and possible, inter-Committee meetings covering for instance a region, could be organised.

Finally, it appears highly desirable that the Committees' activities be made known to hospital staff and the population in general. One method for such communication could be organising meetings for that purpose.

Conclusion

Throughout this study, we have tried to reconcile two rather incompatible courses of action. We wished to propose some organisation for Ethics Committees without imprisonment in rigid bureaucratic structures. Between the two extremes of arbitrary disorder as we now know it, and bureaucracy born of elaborate regulation, we were seeking a median course. We have tried to sketch it out with a light touch, leaving room for initiative, imagination and wisdom. We thought that ethics cannot be imposed by institutions, however worthy. We also thought that for ethics to have the impact that its inherent strength can bring about, it was necessary to give just a little assistance. This was the true, albeit modest, aim of our study.