Technical progress, health and societal models : the ethical dimension of collective choices

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Introduction

The world over, and particularly so in the more developed countries, health costs are increasing, not just in absolute value, but also in relation to the global wealth of nations : the amount spent on health expenditure globally is rising faster than gross domestic product.

There is no call to pass any *a priori* ethical judgement on trends towards increasing health costs, and it can be postulated that since the aim of economic development is the well being of all citizens, they could consider that it is legitimate to allocate an increased share of wealth they produce, or help to produce, to the protection and the improvement of their health. In other words, there is probably no standard which sets at a specific level the share of the fruit of collective and individual effort which it is legitimate to devote to the preservation and improvement of health. Such a level can only be the result of a choice, either personal, or collective in which case it must be the end result of a truly democratic debate.

The democratic debate on collective health care expenditure on the basis of which the size of the nation's effort will be set, will need to take into account ethical components by reference to fundamental values of the social contract (justice, solidarity), technical components (conditions for maximum effectiveness) and economic considerations (intrinsic costs and consequences on the national economy. The latter considerations should therefore integrate both "health care expenditure" and the positive effect of the "health care economy" on the national economy : employment, creation of purchasing power, maintenance of potential for work of the productive citizen, creation of health care products for export (drugs, products, equipment) etc.

However, whatever the circumstances, the health care effort cannot be limitless, so that in any case, the issue of its optimal use will arise and there is a profound ethical dimension to this demand for optimal use of the health care effort since it is alone able to guarantee the highest compliance with principles of justice and solidarity. In fact, any partial rerouting of this effort outside the bounds of maximum efficiency in the short, medium, or longer term, would lead to feasible improvements in health care not being achieved.

The thoughts of the National Consultative Ethics Committee (CCNE) on the subject have therefore focused on ethical dimensions of collective health care policies, identification of

priorities and procedures for solving inevitable conflicts between some individual aspirations and collective requirements.

The spectacular development of technical progress in this domain has taken our societies by surprise. It feeds a progression of health demand in circumstances which were excellently described in a report written in the setting of the 1993 Five Year Plan and published under the heading : *"Santé 2010".*

At least one dominant fact emerges from this report which is the importance given to such problems in developed societies. In 1996, France allotted 9.8% of GDP to health, i.e. 1.1% more than the average for Europe. In France, health expenditure has progressed faster than in other comparable countries, and it is now in second place in the European Union and ranking third in OECD, whereas in 1980, it was sixth (1) .

Health policy options will have to integrate financial constraints. Competition with other social expenditure -in particular unemployment, pensions, and training- will continue to have an influence and will necessarily limit the indirect share of salaries or income that our society can devote to health care needs.

France must therefore face up to the prospect of regulating health care expenditure as must all other countries at the same level of development.

The question does in fact arise in every country, regardless of how matters are organised. Furthermore, if one observes developments and reforms abroad, no economic system seems satisfied with its mode of regulation nor very sure about the validity of attempted improvements. A recent example of huge, but ultimately fruitless, efforts in the United States is significant. Control of this evolution is a notion which cannot be eluded, in spite of the fact that there is no obvious model for policy response (2) . Thus France is proceeding with reform in the framework of its combined system, which is organised on the basis of solidarity since the community shoulders the larger share of expenditure whereas the producers who are the professions, the pharmaceutical industry, or public hospital structures, are predominantly answerable for the extent of service. This situation confers immense responsibilities on policy makers, and CCNE has no intention of stepping in.

It simply considers that, regardless of policy, the very principle of containment of health care expenditure has raised ethical issues in society. By helping to identify these issues, it hopes to facilitate democratic debate. This debate is timely, when efforts on behalf of health in this country are set at a sufficiently high level to provide some leeway. This is not an attempt to dramatise deadlines. The aim is to find how to guide an evolution.

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The CCNE found that this ongoing evolution is generating fear in society : fear of the unknown as a result of progress in the life sciences; fear of exclusively economic tyranny; fear of ethical values being lost; fear of being one of the losers in the struggle for individual access to care.

In this report, CCNE proposes to take these fears seriously beginning with some considerations on the effects of technical progress.

The issue of the impact of collectives choices is then viewed from three aspects : economic, ethical, and individual access to care.

Findings lead to focusing attention on an analysis of health needs, that is on the components of those needs, and on the role played by evaluation and prevention.

A few thoughts on how democratic debate can respond to these issues will be given in

conclusion.

I. Health and technical progress

Health improvements in the 20th Century were the consequence of a triple evolution : scientific and technical progress, the development of systems based on solidarity and mutual help, and economic cultural development and its corollary, improved living conditions and hygiene. In the same way, hopes of therapeutic progress in the next century rest on continuing progress of knowledge and techniques... but are threatened by under development and extreme poverty.

Among the constraints which must be accepted in order not to impede chances of future improvement, prominent place must be given to a just balance between sober management of health resources... and necessary investments in research and development which can only hope to produce results in the long term.

Scientific and technical progress : essentials to improve health.

Most of the techniques which have brought about the revolution in health that the world has known over the last century were created thanks to scientific research, leading to better knowledge of the way in which living organisms including human beings, function either normally or pathologically. There is no need to set out in detail all the steps which have led to today's life expectancy at birth in developed countries to be now slightly over 81 for women and an average of 73 for men, whereas it was only a little more than 40 in the previous century. Louis Pasteur's discoveries have amply supported the importance of hygiene which transformed completely safety at birth and of surgery particularly. Furthermore, following Jenner's pioneer work on smallpox vaccination, the revolution triggered by Pasteur was the birth of vaccination strategies to fight infectious diseases. Later, before World War II, the discovery of sulfonamides, and then during the war, of penicillin marked the dawn of an era of antiseptic treatment of infectious diseases following on from prevention by asepsis and vaccination. After World War II, procedures evolved for effective treatment of hypertension thereby considerably reducing the cardiovascular consequences of this frequent ailment ; for treatment of peptic ulcers thus eliminating almost entirely major mutilating surgery which was still in use only a few decades ago; improvement in the management of mental disease; increasingly effective immunosuppressives improving the prognosis and thus the scope for organ transplants; the extraordinary development of medical imagery so that earlier and earlier diagnosis of diseases and lesions is now possible, and finally, combined with micro-surgical techniques, the development of ever less invasive methods. To this very incomplete list of obvious links between scientific and technical development and medical progress, should be added the notable individual and social revolution brought about by women's control over their fecundity.

The genetic engineering revolution

Since 1973, progress in genetics and the universality of rules governing the functions of genetic material have led to the transfer and expression of almost any gene of any species in any living cell to be come a possibility. Such developments introduce knowledge of the structure and the function of genes, preparation of new types of drugs, recombinant proteins, for instance human proteins synthesised by micro-organisms into which corresponding human genes were transferred. Ultimately, further understanding of the physiopathological mechanisms of diseases which cannot as yet be entirely controlled, leading to identification of new therapeutic targets, should open the way to development of new drugs, either conventional chemical molecules, recombinant proteins, or in some cases, genes themselves (gene therapy). As of now, genetic engineering has made it possible to discover in record time the structure of an infectious agent such as the HIV virus which

causes AIDS, to elucidate its pathogenic mechanisms, and only thirteen years after the virus was discovered, to develop a therapeutic strategy which is effective albeit insufficient for the time being. Many millions of diabetics receive treatment through insulin produced by genetic engineering, and the various factors stimulating production of blood components have totally transformed therapeutic possibilities in haematology. Thanks to genetic engineering, growth hormone secretion deficiencies can now be corrected without running the frightful risk of transmitting Creutzfeldt-Jakob disease. Probably, in the near future haemophiliacs will be treated with no risk at all of transferring hepatitis or AIDS viruses.

Finally, recombinant proteins, modified micro-organisms and DNA will revolutionise the vaccination scene.

Winning the battle... but it never ends

In spite of remarkable success in the battle towards improving the health of men and women, there remains a considerable way to go. Firstly because access to health is most unevenly distributed around the world : quite obviously, between rich and poor countries, many of which only benefit marginally from progress, for reasons mainly economic, but also political and cultural. Secondly, because even in rich countries, a growing portion of the population is excluded from these riches and is *de facto* excluded partially from the benefits of up-to-date prevention and therapy. Differences between longevity and infant mortality of these segments of the population and the rest of society are eloquent and cruel evidence of this. Furthermore, the pathological nature of infectious agents - to which cancer cells could be likened - is such that there is a permanent risk of emergence of resistant forms or of new agents. The fourfold multiplication of cases of tuberculosis world-wide in the last ten years, the AIDS epidemic, the extension of staphylococcal resistance to antibiotics and of malarial parasites to anti-malarial drugs are a perfect illustration of this point. Furthermore, a new kind of occasionally severe pathology is emerging as a consequence of therapeutic procedures and medication. This iatrogenic pathology has become a major factor of morbidity. Finally, fresh concerns are looming, connected to ways of life, pollution, some industrial activities, the organisation of working conditions, etc.

Associated to the fact that, in rich countries, the growing proportion of elderly people reinforces the burden of diseases connected to ageing, degenerative affections, and cancers, the above demonstrates that in the future, just as in the past, intense research is essential to respond to continuing threats to health, even though research alone cannot overcome social and economic obstacles.

Overcoming economic tensions

Without reference to the economic burden required to support research, through which tomorrow's successes can be brought about, economic conflicts may appear in connection with the development of new medication. For private companies, the profitability of new drugs is what enables them to finance research, development, and clinical trials... in particular the 99% of products which *in fine* are never marketed. In view of this, pharmaceutical companies owning new very innovating drugs for which they have a monopoly, tend to calculate prices to cover not just research but also to cover an uncertain future during which considerable efforts may have to be deployed without necessarily ending up with the discovery of new and profitable products. In other cases, a new product, a recombinant protein for instance which proves to be active, turns out to be hardly more efficacious than an existing product which may no longer be trademark-protected and is therefore sold at much lower generic prices. If that happens, there again two kinds of logic enter into conflict. Optimal management of a limited resource should lead to rejection of the new substance which may be ten times as costly as an old substance which is almost as effective. However, marketing this new substance which is the fruit of very considerable research efforts would help to pay for this research which might herald the discovery of a new and promising pharmaceutical family. Quite obviously, there is no infallible recipe for

solving conflicts of this kind where both short term optimisation of the use of resources and preserving future prospects demand consideration. The importance also of the consequences on health of such decisions give them a distinct ethical dimension.

II. Health care confronted with the concept of economic limitations

The concept of health care cost containment calls for clarification. The limit, or objective that Parliament sets at this time concerns the share of expenses that the community pays for.

Growth of expenditure also continues to be influenced by the market, in particular the international market.

The notion of cost containment does not imply that health care activities, even the share borne by the community, are a burden on the economy ; they are also an important component of wealth and growth.

New economic tools now available which seek to quantify health care make it possible to compare therapies in terms of an efficient allocation of resources.

However, the quest to find an optimal national policy while leaving space for considerations of economic efficiency is essentially based on ethical criteria. These factors are not necessarily contradictory since in all cases the intention is to censure waste. Economic and ethical approaches to health care must be complementary.

The emergence of the concept of economic limitations to health activities has been a source of great misunderstanding.

It is officially expressed in the finance law for the national health scheme which now sets an annual objective for sickness insurance expenditure. This objective is in turn applied to resources made available to public hospitals, and also to evaluations which serve as a basis for negotiation between authorities and medical professions.

Objective setting only applies to the share of expenditure which is borne by the community.

To understand the full scope of the issue, a broader view must be taken so as to embrace the characteristics of the economics of medical care.

As emphasised by Kenneth Arrow in an article published in 1963 which is often viewed as a "new departure" for health care economics (3) , the usual mechanisms which the market uses to ensure the quality of products play a restricted role in this sector. The "demand" for health care goods and services does not come directly from the "user" (patients); it is formulated by care providers whose decisions do not only reflect the needs of patients. They include other elements such as State regulations, professional ethics, and the prevailing sickness insurance system. Quality control is not related to client "sovereignty", but to an "internalisation" by care providers of a certain number of rules which guide them for the formulation of demand. Furthermore, directly or indirectly, a physician authorises public expenditure.

The demand for medical care in developed countries is virtually unlimited. Nothing is beyond reason in order to achieve a cure or relieve suffering. From an ethical viewpoint, there is some justification for the belief that such a demand is in fact legitimate. The demand is financed for the most part in developed countries by public funds, since the concept of mutual benefit insurance has been largely replaced by the idea of provision of global

welfare, of "the granting of the right to obtain care" when the need arises. In the last analysis, this welfare is provided by the community.

The demand is expressed with distinct energy when it emanates from the wealthier sections of the population, and gives rise to the development of complementary insurance schemes. This adds to the risk of aggravating the inequality of access to medical care. Finally, an expansion of the bid for preventive medicine will accentuate future difficulties in containing demand.

The supply of medical goods and services is furthermore part of a multinational context, because no country wishes in the long run to deprive its nationals of care and drugs which have proved effective in other countries. The supply is oligopolistic in so far as the pharmaceutical industry is dominated by several large companies in each "therapeutic category". Corporate growth of the firms in this sector is essentially based on the creation of new knowledge and therefore on highly risky and massive investment in research. Through its scientific activities in particular, the pharmaceutical industry's relations with the economy as a whole are complex and extensive.

This reminder of a few self-evident facts raises the following observation : limits as set out in official texts only apply to the managed sector and this sector does not cover the whole health care field. But above all, it is worth a reminder that the will to control expenditure is not in any way related to the reduction of a "cost" which would be detrimental to society as a whole.

Health care in fact is an employment platform, participates in the quality of human activities and in the creation of wealth. Health care costs are the monetary value of the ultimate transaction on health related goods and services. The contribution of health care expenditure to the activity of the country all in all is considerable, since the amount has been more than 9% of French GDP since 1991.

This expenditure contribute to maintaining and reinforcing the present and future potential of a population. It is a fountainhead of employment in activities which are bound to expand and they are a growth factor.

At this point, the debate could probably be clarified by pointing out what the science of economics does not say.

It does not say that for health care activities, and for those activities alone, there is an ideal figure beyond which efforts must be contained. Striving to achieve a defined level, with a fixed proportion of collective and individual efforts which can legitimately be devoted to the preservation of health, is out of the question. Or rather, there is no scientific foundation for the existence of such a limit ; it is the result at a certain time and in the light of history, of a choice which is itself a stage in a social, economic, and political evolution.

Economic science does not act as an arbiter between public and private endeavour nor recommend one mode of production rather than another. Evidently, the circumstantial impact of an increase in collective expenditure may have an effect on the solution given to problems and harshly highlight the dilemmas that collective choices reveal. But it would be a fallacy to believe that to refer a problem to the market is sufficient to solve it as though it concerned ordinary consumer goods.

Finally, there is nothing to indicate that, from the point of view of economic science, there is any incompatibility between its own criteria and ethical criteria. On the contrary, the two sets of requirements are closely linked. For instance, making the best use of rare medical resources (consumables, durables, personnel time) meets the economic definition of efficiency. But it is also an ethical requirement since one must be sure that resources *which could be used otherwise* (for instance to cure other patients) are not misused. More specifically, the traditional economic analysis efficiency criterion (the Pareto principle) can

be read in ethical terms : when it is possible to do so without making anybody worse off, one should not neglect opportunities for reallocation of rare resources which make some individuals better off. Finally, economists allow that, generally speaking, strictly economic concepts of efficiency are insufficient to define a "social optimum" or "what should be done". Other considerations, in particular ethical ones, must be included.

Ethical and economic approaches must be complementary in the domain of health care.

New tools used in health care economics are an opportunity to improve evaluation of treatment efficiency and a comparison of the use of the same rare resources in competing situations. In this way, they throw some light on the collective search for an optimum.

If reasoning is based on an "envelope", the choice of the best health policy is naturally represented as an optimisation problem in budget constrained circumstances, which leads to a comparison between cost and expected improvement. Unlike the cost-benefit analysis, a cost-effective analysis does not define benefits in monetary terms, but as units of a certain function-objective. A certain social objective to promote is defined, and on that basis, an attempt is made to minimise the ratio of monetary cost to the attained level of promotion of that objective. The results of the analysis, for instance, will produce a computation of the number of francs per life saved. The first "objectives" stated concerned the number of lives saved, the number of deaths avoided, or the number of human life-years safeguarded.

In fact, an evaluation of the beneficial results of health policies or actions should definitely not be founded purely on survival. It is generally accepted that quality of life indicators related to health status can also play a major role. In recent years, countries in the western hemisphere have found traditional indicators lacking. The increasing public health concern with cancer, age-related disorders, and dementia, together with a relative pause in the rise of average life expectancy, make exclusive use of the "length of life" indicator and of its variants in the evaluation of policies or individual decisions in the field of public health somewhat obsolescent. The broader definition of health adopted by WHO as early as 1949, which describes it as social, physical, and mental well being, leads very naturally to giving some weight to notions such as perceived health, quality of life, or state of health related quality of life.

Indicators such as health status and state of health related quality of life are in fact and to a certain degree a response to those preoccupations. The result has been a major development of health quantification, going as far as subjective perception of health. It can be hoped that by contributing these indicators to the cost-effectiveness type of analysis it may be possible to arrive at a better operational definition of the aim which should be set for public health policies. The logical outcome of the cost-effectiveness analysis would then become the calculation of a cost to units of health or to quality of life ratio which would be obtained (or maintained) thanks to the expenditure under consideration.

CCNE considered in a critical light the advantages and limitations of existing approaches : criteria of the "cost-effectiveness" variety, the "Pareto principle" and its variants; and maximum number of years of life (per monetary unit) adjusted for quality (QALYs - quality adjusted life years).

The result was to prefer the course whereby there is total integration of "ethical" and "economic" principles. It is possible to define technical efficiency of medical care without recourse to ethics, but this is not the case when it comes to defining the economic effectiveness of public policies or of collective choices. The choice of an economic effectiveness criterion is in itself a decision which implies the ethical values of individuals and of the community. The implications of such choices may sometimes be disputed in the name of ethical principles, which makes it impossible to completely separate efficiency and ethics.

In Oregon, for instance, when criteria for reimbursement by state insurance were based on cost criteria through QALY, principles had to be progressively revised until they became practically meaningless because of multiple claims regarding the invidious or discriminating implications of earlier proposals (4) . At the level of collective choices, it is of course extremely difficult to rely on cost criteria through QALY, although it may be very pertinent at a lower level when engaged in one-time choices between several therapeutic procedures, or in a comparison between the relative merits of several drugs.

For that matter, the QALY cost criterion is far from flawless as regards collective choices : in this context, it leads to discrimination against the elderly or the handicapped, or even against people who are in poor economic or social circumstances and whose prospects in terms of quality of life are diminished. It further relies on an assumption which is rarely verified of the constant nature of arbitration between length and quality of life. Added factors of uncertainty are the mathematical hypotheses upon which are based the quantitative determination of these arbitrations. Finally, there is the very general problem of equity in the aggregation of indicators of well-being. As argued by Allan Williams in his vigorous defence of QALYs as an instrument for allocating public resources in the health sector (5) , in principle it should be possible to compensate for this difficulty by assigning different weightings to different individuals, based on the contrasted values representing for them "a year of life in good health". But this method which enshrines inequality in the treatment of individuals will be considered arbitrary if it has not been the subject of public debate, whereas it is certainly an inappropriate subject for public debate. In any case, is not the true problem a question of modulation according to degrees of severity or urgency, rather than one related to psychological variations in the enjoyment of life ?

Such difficulties, which only affect the more ambitious initiatives, do not prevent giving an important role to efficiency considerations. Waste is a form of economic inefficiency ; it is frowned upon because what is wasted could be used for a legitimate purpose, which is in itself an ethical concept. In fact, in the social ethic and the normative economy of today, principles based on economic efficiency are seen as principles of social evaluation among others, which more often than not are complemented by references which are more clearly identified as "ethical".

The decision not to allocate available resources arbitrarily can therefore be viewed as the ethical commitment of a community. If the aim of a collective effort is to promote the well-being of a population (which is in fact the case as regards health), evaluation of the best options includes an obvious ethical dimension.

In certain fields, achieving coherence appears to be fairly easy. Such is the case for prevention policies, but they do raise some specific issues. As and when knowledge improves about risks and they can be quantified, their inclusion in public decisions becomes more distinctly part of the health of the population promotion policy.

However, there are still many reasons for tension between an economic approach and ethical logic. We have already mentioned, for instance, that modulation of the count of years of survival by quality criteria is a risk of discrimination against the handicapped and the elderly. To overcome such tensions requires decision makers to integrate these various aspects of a single reality and refrain from mechanical application of specific criteria which, in particular circumstances, may turn out to be unreasonable.

Thus, several problems are still very open to discussion. A sociological or an economic approach will be needed to throw light on connections between individual behaviour and collective proposals for joint action which are, in this domain, extremely complex.

To sum up :

- an effort to achieve maximum efficiency is invaluable as regards decisions on the purchasing of equipment for care-providing establishments, and for allocating resources

within these establishments, for the reimbursement of various medications, for medical prescriptions;

- new economic health quantifying tools now available make it possible to produce sophisticated comparisons of medical treatments aiming at an efficient allocation of resources;

- however the effort to achieve optimal use of the global envelope at the level of a country's public health policy may certainly refer to considerations of economic efficiency, but must essentially be supported by ethical considerations.

III. Ethical references of health care

A number of fundamental principles, of which many are constitutional or have powerfully structured existing law, apply to health care.

Ethics demand that all these principles should continue to be respected and, in the debate on cost-containment, no argument has been put forward in favour of allowing them to take second place. However, CCNE's solemn reaffirmation to that effect at this point is not superfluous. It may help participants in the discussion to grasp the true dimensions of these principles in a new context.

Society cannot be content with declaring simultaneously that these principles bear no exception and that cost-containment is a necessity. It must also state how these rules can merge and how they fare when applied to individual cases.

CCNE does not take as a starting point that any reference to cost when discussing health care is in itself a breach of ethics.

But questions do arise as soon as this rule of competent management is to be combined with principles or rights that our society recognises, does not wish to question, and which have potent ethical implications.

The nation recognises the right to the protection of their health to all its citizens. This is stated in the preamble of the French Constitution and the *Conseil Constitutionnel* (French Constitutional Council) has had occasion to confirm it by case law. This right is supported by the principle which also has constitutional value, that all citizens are equal in the eyes of the law. The social security system in our country is based on fundamental principles which could only be tempered by legislation. This could be expressed as being a principle of solidarity, meaning that almost the entire population contributes to the risk of sickness and that the cost of care cannot impede access to care. Although the rule does not go as far as free medical care, these principles have given rise to a system of reimbursement in which the community bears the greater part of the cost burden.

At this same level of Constitutional sanction, the principle of respect for human dignity also applies. It is particularly relevant when appreciating the impact on individuals of new situations brought about by progress in the life sciences, and chance played no part in the fact that its most explicit formulation occurred when the *Conseil Constitutionnel* took a decision in 1994 regarding the "bioethical laws". The conclusion was that although protection of individual liberties is taken into account in these matters, as it should be, the principle that everyone is entitled to do as they like with their own bodies does not give unlimited license and the community's duty is to prevent and stand in the way of abuse of such scientific progress.

Furthermore, highly ethically charged rules govern the exercise of the right to health whenever that right is claimed. It has not yet been said in so many words that rules presiding over the patient-to-doctor relationship are of a Constitutional nature. But there is

every reason to believe that deontological principles protecting privacy and which set out boundaries for individual health-related decisions, are considered of primary importance by our citizens as regards the singular nature of the compact which binds patient and care provider, free choice of one's physician, and confidentiality. If trust was absent from the relationship, most of the health system's users would judge that their rights were being violated.

When users turn to the public service for health care, they are justified in expecting that service to fulfil its obligations which are particularly significant where health is concerned : user equality, a right to continuity and capacity to adapt to technical progress, specific deontology observed by medical personnel, on a par with precautions taken to protect the patient in private practice.

Finally, if those active in the health care system, public or private, are at fault, they are held responsible for their actions or their inaction. The principle of accountability which is a feature of a state of law is presently moving in new directions, as regards criminal law and also administrative or third party liability. The trend is to broaden the concept of accountability and to invoke it in specific cases with increasing frequency.

Such developments cannot be allowed to occur at the expense of the above principles. But it is not adequate to state simultaneously that primacy is given to these principles, and that priorities must be set. Some way must be found to combine the two objectives.

So far, there has been no attempt to adopt this brand of truthfulness. The omission leads to recurrent tensions and the threat of health rationing is rumoured. Parliament is careful not to bring the question up in debates on the setting of targets, as though it felt unable to respond to fears which are in no way justified by the very moderate shifts applied to foreseeable expenditure trends. This does not prevent the medical profession from using the argument of rationing to gain leverage in the negotiation on their share of the burden, but then it is true that the key to moving from the negotiated objective as regards fees and prescriptions onto the response to be given to a determined patient who could be affected by these measures is not as yet forthcoming.

One of the reasons for this difficulty is administrative. Containment signifies decision to choose, and the ongoing reform of the health system in our country is a reform of the decision making process, and since the reform tends to manifest a policy decision at a global level, Parliament is content to decide on the objective which will direct the expected shift in expenditure to be reimbursed. From then on, the objective has to be adjusted to the various levels of responsibility. What the reform proposes to do is to put in better order and rank the steps which enable supply and demand of health care to be channelled. It is for this reason that we find a parallel decision process in the hospital sector and the system under negotiation with the medical professions.

CCNE is not seeking to express scepticism about projects which are not yet fully operational and which should be judged according to their future achievements. But should it not be stated that, with such a complex decision tree, with its multiplicity of levels, partners, negotiations or consultations, arbitrations and contracts, the gap would appear to widen between the satisfaction of an individual's claim on the health system and the choices made at all these different echelons ? In a system where all participants should share in the burden of discipline, is it possible not to end up containing only the part that is under the direct control of the authorities - hospitals for instance - leaving out other activities which have an effect on this expenditure ? How should one go about preventing this diversification of constraints from producing artificially the drift in the allocation of resources and facilities into the specific directions to be avoided? How is it possible to put pressure on the private sector which drives the medical drug market's progression and motivates some of the more decisive directions for research, and yet may evade community control altogether ?

The second obstacle appears at this stage, together with the doctrinal clash which has

greatly exercised French opinion. In times of tension, there seems to be no bridge, no possible compromise between the deontology of singular consultation and the concept of collective choice.

CCNE believes that the objective to strive for is a common language to describe the stake at each level in the face of such a variety of situations. This is the way to rigorous analysis, transparency, and to matching decisions and the training of those who have to take them. CCNE postulates that identification of ethical stakes would facilitate this approach. It should also make it possible to either reject analyses, behaviours, or criteria which generate justified apprehension, or mobilise energies common to agents who are not governed by the same legal regime but are nevertheless ready to move in the same direction.

There are many signs, as can be observed in the workings in the last two years of the *Conférence Nationale de la Santé* (National Health Care Conference) and from recent publications by the *Conseil de l'Ordre des Médecins* (French National Medical Council), that many members of the health system would want to emerge from this kind of intellectual impasse.

In other words, this manichean conflict has become rather meaningless when we are surrounded by countries which have all, in their own way, tried to reconcile individual and collective interests in the face of growing health problems. The ethical argument could be one of the rare influential tools in fields which are largely regulated by international markets so that priorities which the market did not detect get sufficient attention. In addition, difficulties raised by certain technical developments could have a positive effect by instigating a change in outlook.

IV. Collective choices and individual access to health : a quest for criteria...

Where health is concerned, priorities can only be set, debated, and accepted once their impact on individual access to care is fully understood.

In this respect, any implicit selection or implementation of criteria for choice which have not been the subject of public debate, must be rejected.

Whether cost-containment implies reallocating resources so that comparatively wealthier insured persons get less support, is a controversial question.

Some opinions are that this is inevitable and that it is the most appropriate method of equating individual circumstances to priorities.

Others believe that if an important share of health care expenditure was to be passed on to individual contributions, in the long run, cost would be increased rather than reduced. Furthermore, the drawbacks of bureaucratic supervision entailed by means-testing for all insured persons could turn out to be unacceptable.

CCNE has no unanimous view to propose on the matter.

At this stage, CCNE stresses two points :

- In spite of the present magnitude of collective effort, inequality as regards health persists, to the detriment of the poor. Steps to eradicate inequality must be one of the priorities.

- Hesitation and doubt on the income criteria controversy is no reason why both parties to the debate should not try and make a lucid analysis of the health requirement.

For the general population, acceptance of collective choices depends on the way in which it understands their consequences on individual access to care.

CCNE considers that the debate would become clearer if an attempt was made to identify possible negative consequences of this nature as a result of prioritisation.

Clarity is certainly needed because as things stand, all the circumstances discourage debate and this, far from facilitating an acceptance of change, encourages paralysing anxiety on the part of both population and professionals. In some ways, it has been said and rightly so, that the very success of the system impedes any effort to become aware of shortcomings. CCNE's first recommendation therefore is to speak openly of these matters. If there is a general containment of the effort which the country devotes to these activities, if priorities are defined and observed, someone, somewhere, may run the risk of being less of a priority and facing a refusal for a service or an act to which he feels entitled by necessity, or the provider of this service or act will not be able to supply it, either in the absence of appropriate investments, or because financing and specifically financing by the community does not enter the equation.

I. A first precaution therefore must be to reject any implicit selection or implementation of criteria for choice which have not been the subject of public debate. CCNE does not see this as a minor postulate. For that matter, other institutions have already given prominence to the notion. The *Conseil d'Etat* said so forcefully in a recent report analysing contemporary implications of the principle of equality. A Swedish parliamentary committee tasked with examining health care priorities made this recommendation central to their proposals.

A plain fact must indeed be acknowledged : when the question arises of refusing or delaying health care or service, there is a temptation to keep silent on the selection criteria. Health care systems which are deliberately based on an authoritarian allocation of resources or of facilities find it very difficult to disclose the criteria they use and encounter vehement opposition when the public becomes aware of them. Experience has shown that when a health system is faced with a temporary overload or shortage, criteria are in fact applied. This was the case at certain times for dialysis, transplants, or combination therapy for AIDS. A resuscitation unit working at full capacity knows well enough the age at which it accepts yet another premature baby and which patient will have to try another hospital. It is therefore sound policy to state that if criteria are applied they must be made public knowledge.

Once that first step is taken, it is possible to continue and question whether reference to a given criterion can be the foundation of response to an individual health request with any degree of plausibility. This exercise should reveal the criteria which do not pass the test and which are more than likely to be somewhat flawed in ethical terms.

II . If one is ready to take into account the alarm expressed by those concerned, both patients and care providers, when they discuss health rationing, it suggests that the service could be refused and not supported whereas there is a need.

Let us be clear at the outset that in France where the issue is being discussed, these fears were on the whole unfounded. A country which allots almost 10% of GDP to health and where the intention is simply to curb a rate of progression, is nowhere near such an extremity. Perhaps this makes it more frightening. But it is precisely because there is this leeway and that a whole range of endeavour abroad gives food for thought that the discussion can take place.

We learn from neighbouring democracies whose principles are similar to our own that attempts at establishing criteria for the allocation of health care are entirely conceivable.

However, let us also be clear that there is never any intention of suggesting guidelines

which would justify a refusal of certain requests for whatever reason in the individual practitioner-to-patient relationship. But it is a recognised fact that studies which lead to the allocation of equipment or of staff, to rules for refund, to listing the value of medical acts, etc. do have an impact of individual access to health care and on the physician's actions.

Very sophisticated experiments have been conducted to try and rationalise the search for criteria. CCNE has particularly singled out those which had taken place in the Netherlands, Spain, Sweden, and Norway. This latter country made two separate attempts with a ten year interval in between. Ongoing controversy in the United Kingdom between those in favour and those against explicit setting of criteria, with the latter taking the upper hand for the moment, was also reviewed.

No one is claiming that the task is easy. On the contrary, those who are best able to make an evaluation of the situation emphasise that more data is required, and we shall return later to this fundamental point. But such studies are viewed as a true key to social policies of the future.

They are disconcerting in as much as they leave room for non medical parameters; the financial parameter, be it the cost of service rendered or the capacity of the user to make a financial contribution, is one such parameter, but one among many. Criteria such as age, familial circumstances, personal behaviour as regards risk factors, and above all personal means, have occasionally been mentioned to characterise individual positions as regards health. Although for the moment such conditions are never mentioned in France, the possibility remains of their being summarily applied. In other countries, there has been some reference to them and they may be applied indirectly, for instance when allocation of resources has led *de facto* to deny care to certain categories of patients whose case is not considered to be a priority.

For instance, the Swedish committee did not hesitate to examine this question in detail, and we shall consider as they did, the example of age. The age of a patient is not neutral as regards decisions. At the start and at the end of life, both diagnosis and prognosis take into account a set of considerations on the duration and the quality of survival and this has led in fact in some cases to simply considering the age of the patient. This is experience-derived data which cannot be denied, and the result may be that decisions regarding the organisation of services are conditioned by the age distribution of the population in the catchment area. But there must be no confusion whatsoever with the assumption that excluding patients from certain types of treatment beyond a certain age would be acceptable. The same uncertainty and doubt is manifest when familial status arises - is someone who has no family less likely to get help than a breadwinner ? Will dangerous behaviour as regards high risk sports or drug abuse limit a patient's rights at some future time ?

On all such points, ethical considerations will help us distinguish data provided by analysis in order to better understand the directions of change and recommendations for action. **A population's behavioural characteristic as regards its health is not bound to become a criterion for selection simply because it is perceived.** Ageing of the population and technological progress which facilitates aggressive and futile therapy justify giving further time to the study of what service is in fact given when life ends ; but this should never be taken as justification for so-called age limits which are contrary to human dignity and rule of law.

A certain number of disturbing questions can be drawn from a comparison of what other countries have done, which show the dangers of shifts in the wrong direction. Some quality of life assessments could in fact turn out to be a thinly disguised shame-faced method of selection ; when it has been possible to gain official recognition for the mode of operation of waiting lists, justification was based on conflicting rules of priority in favour either of the most sick or of the least sick.

All the above suggest the need for caution. There is a risk of deviation if non medical criteria

are poorly thought out or poorly controlled and if they are used too freely to evaluate performance. This excessively easy way out offers false objectivity and serves as a substitute for knowledge. It may also result in delaying what really needs to be done which is to know how to evaluate the health need.

Such matters could of course be debated, but CCNE is convinced that although the notion of applying implicitly any one or other of these criteria may be rejected, it would simply become one aspect of medical appreciation. However, since the subject is a cause for alarm, a procedure could surely be found so that anyone who thought a criterion of exclusion had been applied could appeal to a mediator.

III. CCNE has given particular thought to the criterion of income, which raises various problems. The idea that a distinction should be made between insured persons according to income and that the share of the cost borne by the wealthier should be increased, is one which will be on the agenda in the future.

Society is already accustomed to this criterion ; this mode of selection which has an effect on reimbursements, is already widely used. The amount of expenditure borne by the insured person has increased regularly, either by an increase of the non reimbursable portion, or by removing on the price of services for which the sum reimbursed remained stable (dental care or medical care in the non-fixed fee sector). These developments have had little influence on the hospital sector, but rate of cover for ambulatory care which was 67.6% of expenditure fifteen years ago is now at 57.7% (6) .

Income as a criterion is therefore at the core of two different discussions.

The first of them divided the Committee, which will attempt here to describe alternatives.

Should support for health care be governed by the logic of redistribution ? In other words, in an action which is an attempt to re-focus efforts on what is most essential, is it legitimate to subject all or some reimbursement to the beneficiary's resources ?

For those who believe that this is inevitable, it would be a step in the right direction. They consider that to slow the growth of health care expenditure through extra personal financial involvement is the best method of keeping resources available for the poor. The logic behind this argument is that cost inflation is due to services of any kind being given at almost no charge even to the wealthiest beneficiaries which leads to indiscriminate excessive consumption. Furthermore, this free dispensation to everyone in fact always ends up being consumed by those who are clever at making use of the system. A return to market conditions would set the situation to rights and would spare society from having to create a whole variety of specific constraints which are complicated and also curtail the freedom of medical prescription. This new set of rules would promote private insurance schemes which would play a complementary role and thus achieve the changes sought by society.

For those who oppose this view, there is a major difference between marginal use of such systems and systematic recourse to income criteria for the management of cost containment. They believe that a better distribution of effort should above all be founded on a better analysis of the health care need, which will be the subject of the next chapter.

It is a fact that in our country there is no discrimination between patients and this mode of organisation is now taken for granted. On this foundation were established certain types of behaviour which, in a country where unemployment takes its toll, still provide sickness insurance to the insured, their children and their parents. The result has been of obvious benefit to general state of health of the population, but the system is more fragile than is apparent. Even at its present level, it ensures the protection of a considerable number of people who are thought to be more prosperous than the jobless, but whose sparse resources are inadequate to make them secure.

This situation confirms that if the insured person's share of the burden were to be significantly increased there would be two categories : those who are exempted, and those who are not. How could they be sorted out except by adding bureaucratic constraints to the distress of sickness ? One hesitates to advise adoption of a generalised policy which would oblige the sick to submit to bureaucratic supervision of their financial and personal circumstances.

In practical terms, there are many difficulties : French society is only aware of income in the form of regular wages duly declared to tax authorities. Some higher incomes and any situation characterised by a multiplicity or a variety of sources of income remain largely unknown.

But the most pertinent criticism is of a general nature. Every time the burden of an essential service or of one for which consumption is mandatory is returned to the market forces, costs are not reduced, they increase. The service develops without control, sets it own price, and the example of the United States demonstrates that this paves the way to paying the highest price for health. In Europe, the idea of a two-tier health system is unacceptable and pressure of opinion would be such that services would have to be reintegrated into the collective share of the burden. In the meantime, no effort would have been made to give some substance to a proper assessment of the health need.

Clearly the debate is not easily concluded and ethical considerations do not suffice to give preference to one side or the other.

It might be possible to find a middle road between these two contentions.

It was suggested in some quarters that two sets of health needs could be evaluated with the greatest possible precision. The first set would include pathologies so severe, painful, or crippling that they would justify care to be given without any reference to financial circumstances in the name of the national community's solidarity with those who suffer.

A second set of circumstances related to health care needs which can be paid for with more or less difficulty depending on a person's financial circumstances, and which could be supported on a progressive basis proportionate to the patient's income.

One conclusion, however, meets with unanimous approval. Extra efforts must be made in any case to temper the effects of exclusion and inequality of access to health.

These are facts. Mortality varies with region and place of residence. An excessive death rate in adults, peculiar to France, affects preferentially the less privileged social categories. Gains in life expectancy have been greater in the wealthier classes. Density of service and therefore of access to service is a further inequality. None of the above must be interpreted as meaning that these findings are negated, nor as any denial that remedies must be found for that situation, nor that the concept of universal sickness insurance is rejected, nor that there is any dispute concerning the need to develop services and techniques, so as to generalise the system of initial payment of part of the bill by the health system *(tiers payant)* which is more suitable for the insurance of underprivileged patients.

It must simply be added that as regards severe cases of exclusion which are characteristic of certain failings in the system, the remedy is not confined to improving the health system. The problem must be tackled much further upstream in terms of housing, education, and financial support policies.

The second point which met with unanimous approval will be discussed in the following chapter : no modern reflection on priorities can dispense with a better analysis of the health need. For some, as we have seen, it is at the core of future policies and they even fear that referring to financial circumstances will serve as an alibi to delay this review. This is in no way the intention of those who are in favour of financial modulation; on the contrary, they

consider that they could very well be reserved for parts of health care and services which would precisely need to be defined by a study of health needs.

V. For a better analysis of health needs

The least disputable component of an assessment of health needs is the severity of the condition which must be dealt with and this notion is based jointly on an objective evaluation and on the experience of the persons concerned. If there has to be a modulation of collective support, it is on that appreciation that it can most legitimately be based.

The above analysis gives reason to believe that the only criteria for priority which at least in principle would not give rise to ethical misgivings would consist in taking into consideration the severity of the consequences of the affection for the person concerned. This is the conclusion that the more convincing of the foreign reports arrive at, and which the report of the *Haut Comité de la Santé Publique* (High Committee on Public Health (7)) adopted as its own at the 1996 National Health Conference.

Taking as an illustration the Norwegian research, this type of exercise consists in ranking medical activities - that is the response of medical services to various ailments - into several levels of priority. Level I is for essential basic services for which society sees to it that they can be dispensed adequately everywhere with equal access for everyone. This group is large : it includes any disease with a severe prognosis which includes risk to life and risk of impairment of physical or mental faculties, and also pain. To respond to this group of priorities must be included treatment which increases survival probability, restores capacities, controls pain, and insures recovery of a quality of life as nearly normal as possible.

In contrast, there is a level III which designates actions which have no documented effect, or may have a marginal effect, or else respond to conditions which patients can accept the consequences of. The Norwegian study identifies a group which has an even lower priority which includes conditions which bear little relationship to medical activity and in fact correspond to ordinary goods and services to which a medical flavour has been given. Obviously, the intermediate category called group II is the one which is most difficult to define.

The exercise is interesting because it seeks to be exhaustive ; the notion of usefulness is tested in the light of present consequences of technical progress. Procedures are also interesting. Groups of experts establish recommendations on the classification. These recommendations are then processed in two ways. First, to be expressed in terms of the allocation of means by competent authorities, and then into suggestions for good practices in terms of clinical activity. That is indeed a method which makes it possible to align collective priorities and individual access to health care.

CCNE is fully aware that such a classification can only be meaningful if an attempt is made to illustrate it through one or other specific medical situation, and feels that it could play a useful role in such a debate.

It carries the concept that the aim is to define clearly patients' needs, taking into account most recent advances. This differs from all the individual criteria which were analysed in the previous chapter, some of which fall short when seen in the light of the ethical issues they raise, and in any case could only be exceptionally acceptable.

A definition of health is the subject to which proper attention must be given. Criteria and priorities which are going to be used at the various levels of collective regulation must lead to the satisfaction of patients' legitimate expectations or, more generally, those of people who turn to the health system. But these persons are not able to integrate into their

expectations any real understanding of the usefulness of what is offered them, nor data such as the level of prevention required or conditions of accessibility which conform to the potential of today's technology. It is therefore essential to review the various classes of therapeutic action according to the degree of severity of the ailment or condition in order to give reality to the notion of priority.

One might think that within the health need perimeter there is a very broad field which is the true basis for solidarity and which has been modified by technical progress, and other tasks which in fact are only supported by solidarity because of habit and vested interests. If that is so, then solidarity would continue to cover the health need as comprehensively as it does now, but would not give coverage to any and every demand made on it. If modulation of reimbursement becomes necessary, it would be connected solely to this definition of need.

It is probably worth making clear that the endeavour extends to the whole field of medical activity, and not just to one section or another because it is new or disputed. An assessment should be made of the usefulness of current recognised activities so that possible progress and the notion of evaluation can be integrated.

This redefinition of the health need should not be restricted to a point of view which is confined to medical technology. For example, it would not necessarily lead to concentrating on what is more specifically therapeutic, letting market forces take over what is more closely related to everyday life. We have in mind here the trend towards increasing the lump sum which represents the non-medical (board and lodging) part of hospital expenses, increasing home care which is a systematic transfer of the burden to the patient's entourage, or the systematic increase of the amount charged to the family for the cost of treatment of a patient in long-term hospital care. Before the damage became obvious, a proper evaluation could certainly have shown that in an underprivileged neighbourhood when mothers are sent back home after delivery following an ever shorter stay in hospital, there are harmful effects for both mother and baby, or that too few paediatric beds lead to hazardous situations.

Other points to be taken into account are conditions of access to services, their relationship with the way people can organise their lives, in particular a satisfactory use of time, the impact of modern life including cars and telephones on the use of services, and the impact of losing access to services for someone who is sick or poor.

It also appears that health needs must be explored in more detail for vulnerable groups, and supplementary or different parameters must come into play for the permanently disabled, or fragile elderly people, or the very poor. What might well be true of the population at large could exclude the above from receiving care, whereas certain types of organisations or structures described by the term "integrated care" would be better able to cope with them.

To complete this definition and gain a better insight into health care needs is by no means an easy task. So far, the health system has largely been defined by producers of goods and services. In the future, society must acquire the necessary evaluation tools.

To present for discussion this type of anticipation and all the data which will adjust techniques, identify orphan research lines of action, use the language of ethics to persuade and co-ordinate when enforcement is an impossibility, are tasks which require a site where data for evaluation can be collected and processed.

It is a fact that no analysis of the health need can proceed without an evaluation of risks, of degrees of severity, of procedures, and of the consequences of prevention policies.

VI. Evaluation - a commanding necessity

A grasp of health needs, of the effectiveness of procedures, of the existence and importance of risk, which is essential to be able to implement effective and wise health policies, must rest primarily on the quality of evaluation. However, evaluations present various degrees of difficulty, so that there can be quite considerable residual uncertainty which is the point of convergence for the public's apprehension and sometimes, complaint. An example among others is the substantial tension created by risk potentials. In spite of growing reference to the need for independent evaluation, this emerging discipline is still insufficiently supported in our country and must be further developed. Evaluation criteria for the effectiveness of health policies incorporate ethical and social considerations which make it difficult to convert from one society to another. The introduction of qualitative criteria for well-being and quality of life is a case in point. This ethical dimension to evaluation techniques argues in favour of the creation of a close link between evaluation structures and CCNE.

The word "evaluation" is used in two very different contexts which require clarification. One hears of the evaluation of a risk, or a strategy, or a procedure. In the first case, the aim is to estimate or attach a value to a risk; in the second case, the aim is to find out whether the action turned out to be a valid response to the problem. Techniques required to solve these two kinds of problems are very different.

The notion of risk takes into account the probability of occurrence of a phenomenon and its danger level. When the subject is a disease, a risk factor is a factor which increases (not necessarily as a cause) the risk of contracting that disease, its frequency, and its severity. If there is certainty that a factor is indeed a risk factor, the term used is a **recognised risk** ; menopause is a risk factor for the appearance of bone deficiencies or cardiovascular ailments; high risk sexual behaviour increases the probability of contamination by HIV, etc. Judging the importance of a risk factor is dependant on the value of the risk in the absence of that factor, on the multiplication of the risk brought about by the factor, on the frequency of the risk factor, and of course on the severity of the disease or morbidity.

Evaluation of recognised risks is based essentially on epidemiology. It must be noted that numerous studies are generally required to determine what the risk factors are with any certainty.

Another concept besides recognised risk which is frequently mentioned is **potential risk** because since the dreaded phenomenon has not occurred, its actual consequences cannot be accounted for. Elements of evaluation in this case are indirect : based on knowledge gained in different systems which can serve as a model, there is a theoretical appreciation of the probability of occurrence of the phenomenon and its possible consequences.

In the case of diseases, potential risk is brought up particularly when, for theoretical reasons or on the basis of chancy extrapolations or of as yet inconclusive research, it is suspected that a certain factor increases the risk of becoming ill (e.g. is transfusion with the blood of a patient suffering from Creutzfeldt-Jakob disease a danger, albeit with a low probability ? does living close to a high voltage line increase the risk of leukaemia for children ?).

A situation of this kind is extremely difficult for experts and decision makers because there is a combination of two factors : by definition, there is much uncertainty, because of this, the public's fears are intensified.

There are two traps to be avoided by the decision maker : either not taking the risk into account, or launching a useless and unsuitable programme of prevention, which is not only ineffective but also confiscates a large share of public effort to the detriment of demonstrably useful action.. Recent discussions on the safety of foods, the safety of people

who live close to nuclear waste processing plants or nuclear power stations, transgenic crops, the quality of air, the presence of very small quantities of asbestos in construction materials, are so many examples of such difficult situations.

Evaluation is also a process of quantitative and qualitative analysis of a medical procedure or of a public health programme either to assess its progress, or to measure its effects, its positive or negative consequences in the short or long term, and its impact.

Evaluation is therefore action related, throughout the whole process from design to achievement and results. There are several stages :

1 - *A priori* evaluation of the planned strategy, according to scientific data and the results obtained with similar strategies which other countries have previously implemented.

2 - Evaluation of techniques used , of their reliability and their documented results, sometimes of the ethical problems which may emerge (see for instance, the case of multiple pregnancies triggered by ovulation stimulants, annex 2)

3 - A evaluation of conditions of feasibility is an essential step, but often a difficult one. On the basis of an appreciation of the risk, the rate of participation of the population must be measured, followed by the rate of commitment which is the proportion of subjects who will be submitting to the procedural protocol in its entirety ; this is the rate of compliance which is either excessive (too frequent mammographies or cervical smear tests) or on the contrary defective through premature termination of care or supervision. Finally, there has to be an evaluation of the commitment and degree of participation of the health care providers needed to implement the procedure. Furthermore, the social implications of certain programmes can modify the doctor-patient relationship. This last stage will lead to an evaluation of essential communication, of the quality of the message, of the best media to convey the information, and of its impact on the public and on health care providers.

Each stage of the evaluation will require expertise and because health is a very broad subject, experts in the required field will have to be called in. These experts will need to combine sufficient competence to make clear presentations of information acquired, and above all independence and discernment in their own field so as to resist any pressure from the professions, decision makers, or economists.

Two examples of evaluation are given in annex. (8)

4 - Evaluation of the cost-effectiveness ratio of procedures.

In its insistence on the role of evaluation, CCNE is placing at the crux of its proposals a concept which is not of its own invention. On the contrary, in the last few years and more particularly since there has been mention of setting a comprehensive objective to sickness insurance, evaluation is referred to constantly by administrative and political authorities. An illustration of this point of departure for reflection is given in the outstanding report (*Revue Actualité et dossier en santé publique*) published in December 1996 by the High Committee on Public Health *(Haut Comité de la Santé Publique).*

The concept of evaluation is the inspiration of the programme for giving medical significance to information systems (PMSI) which was launched to learn the cost of medical activity in hospital departments with the object of optimising allocation of resources to these establishments. It is one of the elements of the accreditation to be conferred on them and of an assessment of their activity.

It is also the concept of evaluation which will be used to constitute opposable medical references which will be playing a major role in negotiations with the medical professions. The French system's specific feature is this move to opposable references. To quote from

the *Cour des Comptes* (State Audit Office) report on Social Security, "these references selected from a set of medical recommendations are formulated negatively ("there is no cause to..."), designed not so much as strict prohibitions but to serve as aids to decision making so as to eliminate unnecessary or dangerous diagnostic or therapeutic options in a given clinical situation, without imposing any particular therapy". Made opposable by the combined effect of the medical convention and the law, such references should contribute both to cost containment and quality of care.

Since the end of the eighties, the *Agence Nationale pour le Développement de l'Evaluation Médicale,* ANDEM (National Agency for the Development of Medical Evaluation), has been doing working on evaluation, and in 1994 the *Agence Nationale d'Accréditation et d'Evaluation en Santé,* ANAES (National Agency for Health Accreditation and Evaluation) *,* was created to confirm and broaden their activities. Their mission is to establish a state of the art account on diagnostic and therapeutic medical strategies. Explicit methods or principles and professional experience are reviewed and then expressed in guides on methodology, references and recommendations for clinical practice or other similar works. This activity only represents part of the information which may apply to the notion of evaluation which of course is used consistently by industry when they wish to appraise the effects of a drug.

CCNE wishes to draw the attention of public opinion to the extreme importance of this very recent discipline.

There is a gap to fill between ubiquitous references to evaluation and the very limited instruments for its use which are so far available to the nation.

Confidence in the new technique cannot mask the fact that France does not as yet possess the investment capacity which would be required to make it operationally capable of facilitating the definition and implementation of priorities.

And yet, to compare different medical practices and then validate and recommend one of them, supposes a body of knowledge which is based on a sufficient sum of practices which enable a choice to be made. However valid, they are initially too dependent on the decision to study one sector rather than another from the mass of possibilities. Such work requires a great deal of qualification and expenditure. Furthermore, it would be illusory to suppose that simply referring to work done abroad will serve to make up a critical mass. It may have been done in such different economic and sociological contexts that the bias cannot be eliminated. It is worth remembering that a much of the work done in the United States is based on local private insurance organisations appraisal of their profitability and therefore of the risk they are willing to insure.

Ethical considerations therefore suggest that when cost containment is the aim, the initial priority is to make whatever investment is needed immediately for the instruments of evaluation.

Those in charge of evaluation are convinced that choosing the first subjects for evaluation and analysing comparatively the utility of various courses of action raise ethical problems.

This is the case as regards the value ascribed to financial criteria in these studies. As an extreme argument, it can be said that for many diseases which leave some disability in their wake, premature death is the most inexpensive outcome. This grim paradox is of course rejected but what is to be considered a positive result ? Although analysis is easy enough when an antibiotic clears up an infection, more frequently, modern medical practices lead to a situation where there can only be an appraisal of the quality of life which has been preserved. Who will be the judge of that quality for the disabled or the very old ?

CCNE believes, as do all those who are concerned by evaluation, that this concept requires substantial research and that specific competence and resources must be devoted to the task.

In so doing, more in depth analysis of new theories could arrive at a better understanding of what health means in today's terms. For example, evaluation must be made of both preventive and therapeutic action. It might also be worth investigating the typical request of a user at various ages in life and in relation to the impact of preventive action and expectations from health care systems. The object is not to define minimum service, but to adopt the service recipient's point of view when considering evaluation. There must be an effort to state the problems in terms of quality and not exclusively in financial terms which must be fully specified because evaluation is also a subject for "good practices". **Obviously, a *sine qua non* condition of the authority of those in charge of evaluation is independence . This requirement is expressed in the composition of the board of ANAES. It will be necessary to take this a step further by promoting the creation of a sufficiently tight network of qualifications so that debate can become a possibility. Professional associations and bodies must take part and universities must develop this type of research. An international dimension should be found for purposes of comparison and critique and if motivating themes are chosen, it should be possible to recruit major players in the private sector.**

The ethical implications of evaluation are such that CCNE considered the question of its own institutional relationship with evaluation organisations. This could be formalised by having members of the CCNE attending their meetings and vice versa. However, CCNE does not consider that this is the only way of solving the problem. The science of evaluation is still in the phase where it is defining concepts and methods and able like any other discipline to benefit from ethical deliberation, but it can do so by submitting questions to CCNE as and when they arise. To initiate this process, the Journées Nationales d'Ethique should consider evaluation issues on a regular basis, and CCNE should prepare to deal swiftly with any questions ANAES might submit.

Such contacts should pave the way for very unrestricted discussion because evaluation is not solely the business of experts and its principles can no doubt be readily explained to the public. It is the whole civil society which is concerned by the definition of health care.

VII. Prevention : an old concept to be modernised

Prevention of those ailments which can be prevented is an imperious ethical necessity and must be a health policy priority. This is particularly worth mentioning because France has gradually fallen far behind on this score. Evaluation must play a major role in the implementation of preventive measures : evaluating the risk, evaluating efficacy of preventive campaigns both before and... after, evaluating public reaction which can sway efficacy, etc... Sometimes, the most effective prevention is also the simplest, calling on well tried rules of hygiene which have unfortunately been allowed to lapse. In future, two new components with implications which are not yet fully understood will probably modify the context in which preventive measures are used :

-the emergence of preventive genetic medicine.

-the growth in demand for safety when potential risks are known.

In this respect, there is a particularly strong demand for in depth collective expert appreciation of the existence of danger, of the degree of risk, and of probable efficacy of preventive measures to be applied, because when, as is often the case, public emotion is at a peak, decision making is exceptionally difficult.

The diversity of parameters which need to be integrated when implementing a

preventive policy would justify the creation of a National Agency for Prevention which could coordinate and develop the activities of existing bodies.

It should not be necessary to justify the need for prevention; surely at a time when cost containment is of the essence, there is not likely to be any argument about the usefulness of taking action before medical help is requested. The authorities have quite clearly attached importance to such action in the presentation of the law to finance the social security system and in discussions aroused by the creation of an *Agence de Sécurité Sanitaire* (Agency for Health safety) .

It cannot be denied that in a country which has generated so much progress, prevention seems to stumble against the forces of inertia, and in certain sectors prevention has even regressed. Three comments support this observation :

- overall financial resources set aside for prevention are slender,

- surprisingly, the problem of reimbursement of expenditure for preventive action has not been taken very seriously,

- and finally, although prevention is at the core of official expression of health policies, it has not managed to break away from a negative relationship with public opinion. This was probably not the case when hygiene and the struggle to overcome social scourges were at their peak. Nowadays, however, reactions are very individualistic and probably suspicion has been bolstered by excesses committed in the name of improving collective health, and confusion fostered by openly or insidiously eugenic policies. Hygienic principles apparently accepted once and for all in the past now seem too simplistic to be worth defending. It would appear that triumphant technical progress is a vehicle for illusion : why bother to protect from infection, to wash your hands, since any infection will give way to antibiotics?

It follows that medical training gives but scant attention to the subject and it comes as no surprise that for younger generations if a subject is not solely medical, it is not truly medical.

CCNE does not hesitate to state that some advances attained through generations of discipline could be in jeopardy. It is also convinced that the time has come to induce a change in public opinion in favour of prevention. This is founded on avenues opened by predictive medicine which in any case will oblige society to deal with the gigantic problems arriving in the wake of new types of diagnosis. At the same time, the tendency to make liability claims - sometimes via criminal law - against those who let a risk with sanitary repercussions take shape and substance, is reaching Europe. Would it not be more convincing to take steps to prevent the risk rather than take to court all those who dabble in medical matters ?

There may be a chance of public opinion changing and accepting more readily advice on prevention if it is directed at people in good health. Growing interest in the body, healthy food, return to nature, and generally environmental concerns would seem compatible with the adoption of new attitudes

Modernisation of the concept of prevention must be led, according to CCNE, by a sound analysis of the notion of risk and by the definition of risk preventing behaviours. It then remains to be demonstrated that these are the joint responsibility of individuals and of the authorities, who must be of like mind. Finally, and particularly so because we have entered an era of cost containment, it will be necessary to evaluate what investments must be made and set targets.

Genetic testing and prevention

In the coming decade, information which must be processed to define an optimal prevention stance, at both collective and individual levels, will be considerably enriched because of a growth in the numbers of variable susceptibility genetic tests for various pathological conditions (see Opinion n° 46, CCNE, 1995). In that Opinion, CNNE points out that sometimes such tests do not introduce any genuine possibility of preventing diseases to which susceptibility has been detected so that intensely difficult ethical and deontological problems arise, in both individual and social terms.

- However, whenever a pre-symptomatic diagnosis makes it possible to advise on effective measures to avoid onset of the disease, or give early and thereby more certainly effective treatment, then that advance in scientific progress will have benefited medicine and mankind. For instance, a pre-symptomatic diagnosis of hemochromatosis which is a frequent disease involving iron overload with cirrhosis and cancer of the liver as possible complications, would mean advising individuals who have inherited the mutant gene from both parents to be regular blood donors. Since that blood has a high iron content, this procedure will relieve overload. Similarly, the recent discovery of a gene of susceptibility to a hereditary form of open angle glaucoma opens the way to true prevention, possibly surgically, of the alarming potential complications of this condition.

- In other cases, effective measures could also be prescribed to genetically predisposed individuals, but possible weight of numbers, or of constraint, gives rise to doubts about compliance. To be convinced, one need only consider how difficult it is to prevent tobacco and alcohol abuse in spite of the fact that everyone regards them as harmful.

Another question concerns the development of "predictive" medicine based on genetic predisposition and its impact on health care expenditure. It is true that, on the one hand, it may sometimes be cheaper to use simple procedures to avoid the onset of a disease than to treat it once it appears. On the other hand, the intrinsic cost of genetic testing is high, and there could be an accumulation of such tests in the next few years. Finally, pharmaceutical firms would find advantage in the prescription of complete preventive treatment which might well benefit some susceptible individuals, but the obvious drawback would be that a large number of people would be medicated whereas only a few would in fact have developed the disease. Consequently, it is not at all clear that the advent of "genetic medicine" will solve the problem of health care expenditure inflation in industrialised countries.

Prevention of the risk

As we have discussed in the preceding chapter on evaluation, the risk to be prevented can be confirmed or latent. In the case of a confirmed risk, the problem to be solved is not whether prevention is desirable, which obviously it is, but whether it is possible and effective.

The effectiveness of a prevention policy is sometimes evident (vaccination, menopausal hormone replacement therapy, wearing seat belts, early detection of eye trouble, dental hygiene and early dental care, prevention of cardiovascular complications or of arterial hypertension, etc...) but frequently rather more difficult to demonstrate and therefore the subject of controversy and discussion (for example, prevention or better methods of early diagnosis of breast cancer, effect of the specific nature of dietary fats on atherosclerosis, etc...).

When the risk is simply potential, the first difficulty, which is substantial, is to evaluate its necessarily uncertain reality. Furthermore, because of that uncertainty, the theoretical necessity and effectiveness of possible preventive action can only be evaluated tentatively, which is often in sharp contrast to the measure of distress and anxiety in public opinion and to the anxious longing for clear information on the part of political decision makers. It is in

such situations that the painstaking expertise required as a basis for any evaluation procedure is most difficult to do and frequently misunderstood. In fact, the aim of such expertise, contrary to popular belief, cannot be to "prophesy the future". It is closer to presenting a state of the art, and on that basis, explaining various possible scenarios, and when applicable, the possible consequences of whatever choices are adopted depending on which theories are accepted.

As for the decision maker who, in the last resort and according to procedures habitual to democratic societies, will have to decide, he will have to integrate a principle of precaution which is not synonymous with a principle of immobility since quite frequently the *statu quo* is not the safest course.

Joint responsibility of the individual and of society

Effective prevention rests on the obligations of both the individual and the community :

· collective responsibility :

- early detection of new ailments, or of harmful effects of new technologies (e.g. effects on hearing of use of radio/cassette recorders...). For such detection, epidemiological research must be developed.

- after identification of a risk, of its causes and consequences, producing preventive measures to remedy, or even avoid, its appearance and effects. Such research has to be done by pluridisciplinary teams so as to devise the best technical, administrative, or possibly legislative measures. These must take into account certain criteria : feasability, acceptability, human and financial cost in terms of risk.

- informing the population at large about foreseeable dangers and means of prevention. Transparency and objectivity must be characteristic of such communication, and although the catastrophic scenario must be avoided, it must be sufficiently convincing.

- *a posteriori* evaluation of the effectiveness of preventive measures will be required along the lines set out in the paragraph on evaluation.

· on an **individual** basis, a responsible citizen should follow the community's recommendations for applying effective measures even though he may find them personally bothersome.

Motivating a population and getting it to accept the principles of prevention is no easy task. Examples in connection with the risks due to excessive consumption of alcohol or tobacco are particularly striking. Science does not doubt that alcoholic intoxication and smoking are harmful, and these are two major causes of mortality and morbidity in many countries, including this one. If cigarette smoking were to cease, that alone would save millions of lives every year in the long term, and there would be a drop of 20% of deaths due to cancer in this country. And yet, consumption of alcohol and tobacco are claimed to be essential liberties - which are in fact questionable since both these drugs lead to addiction (see the CCNE's Opinion n° 43, dated November 23, 1994). Another memorable case in point is reluctance to wear seat belts. Compulsion and penalty for non compliance had to be used to impose acceptance in spite of the fact that its efficacy had been amply demonstrated. Any individual constraint, particularly if benefits are not immediately visible, are experienced as a curtailment of individual liberties.

However, citizens are readier to submit to a modification of their individual habits if they see that the community is making an effort. Cardio-vascular diseases which are the primary cause of mortality in France, are an excellent illustration of this knit of joint responsibility, both collective and individual. It is up to the community to (i) identify causes (biological predisposition, stress, diet, physical exercise, etc...) which is why epidemiological studies

and alertness are important, and (ii) take measures. The individual must observe these measures.

The example of hygiene is a demonstration of individual apathy which could be ascribed to lack of encouragement on the part of authorities. For instance, one environment in which hygiene should reign supreme is surely a hospital. In fact, nosocomial infections are still abundant and their financial and human cost is high (9) . The effectiveness of antibiotics probably contributed to less stringent aseptic precautions which brought about not only the emergence of dramatic cases of pathogenic germ multiple drug resistance, but also the reappearance of infections that sound asepsis rules could probably have prevented, with the added penalty of microbial agents immune to most available therapies.

If treatment is at hand, prevention pales. And yet, frequently a set of simple, inexpensive precautions are beneficial to both the individual and the community. On the same lines, is there a risk of a recurrence of AIDS because the beneficial effect of combination therapy may encourage a **lesser** use of condoms ?

A priority objective

Failure, for whatever reason, to include in the public health policy a confirmed pathological risk once it is identified, is ethically unacceptable. On an individual basis, everyone must be able to obtain clear information about identified risk factors, and be certain that measures to minimise them will be taken if they exist. Really effective preventive measures on a collective basis are always mild compared to treatment of conditions which have not been prevented, even if such treatment is possible and usually brings about a cure.

- The ethical priority must be made known because in some cases, the demands of prevention may seem to contradict other requirements, in particular economic or political ones.

- A prevention policy has less "visibility" than spectacular decisions following sensational therapeutic breakthroughs. The general public is largely unaware of effects in the long term.

- Sometimes, a short-sighted economic analysis can lead to thinking that case-by-case treatment is less costly than implementing a broad prevention policy. This kind of conclusion should always be viewed with suspicion, even from a purely economic angle. In fact, a brutal awakening of public opinion to previously ignored dangers may lead to much greater expenditure than what would have been needed for probably effective first line treatment. Furthermore - and a good example of this is the ongoing recurrence of tuberculosis - when forms of the disease which are multiresistant to antibiotics emerge, its pathology and therefore the cost of treating what could have been avoided is mostly unpredictable. This is particularly true in the case of transmissible diseases.

- Another hurdle to overcome when implementing sustainable prevention policies is the influence of the pharmaceutical industry whose interests lie in the direction of treating the sick rather than avoiding sickness. However, this is now balanced by the arrival onto the market of preventive medication which is very likely to attract the attention and participation of pharmaceutical companies. We have already mentioned the example drawn from menopausal hormone replacement therapy to which could be added greater emphasis on the prevention of age-related disorders. A large number of experiments are being conducted for chemical prophylaxis of cancer, and several therapies now widely used aim at preventing atheroma and its complications in high risk individuals.

The need for prevention of pathologies is of course the primary concern of public health authorities... and of its administration. It also cuts across very many industrial and agricultural activities, as well as those connected to transport, the environment, and working conditions, etc... For that reason, the task given to the *Institut de Veille Sanitaire* (Institute for sanitary Alert) which would be created by a law now under discussion, would

perhaps need to be extended or complemented by the creation of organisations acting in synergy with the *Institut* to integrate all the various dimensions of prevention. In consultation with the *Agences de Sécurité Sanitaire des Produits* (Agencies for Product Safety), this organisation would act as a watchdog when new preventive needs were identified and could manage a budget item devoted specifically to preventive action.

VIII. The role of democratic debate in the establishment of health care policies

The tools of democratic decision and safeguarding of liberties have to be adapted to some of the issues raised by collective health care choices.

CCNE has identified several domains where innovation and adaptation are needed.

There are the new problems of confidentiality arising out of a greatly increased use of personal health data.

There is also the necessity of determining structures which can serve to discuss and redefine the health need and the way in which the citizen, in good health or sick, can influence factors governing his quality of life.

Finally, there is a need to give health care providers the capacity to forecast and analyse which will condition their will to accept technical progress and adapt to it.

Some renewal of the various forms of democratic debate will certainly be required to respond to ethical considerations underlying decision making in the field of health care policies.

CCNE has identified in particular three levels at which renewal and careful examination are required :

- protection of personal health data ;

- expression of user views ;

- observance of obligations which are accepted to follow recognised priorities, and therefore of monitoring.

But above all, reference needs to be made to the definition of a health care policy : to avoid the risk of health needs being defined in a climate of conflict and disarray by producers alone, democratic debate on the subject needs to be organised.

I. Achieving targeted development in evaluation and prevention presupposes much more systematic recourse nowadays to data-acquisition of a personal nature, which modern information technology has made more efficient. Society calls on individuals to supply this sensitive information more freely and has a duty to protect it. This is recognised as clearly shown by precautions taken when the *carnet individuel de santé* (booklet containing personal medical history)was introduced.

It is a fact that our country already has legislation to protect personal data, but it is being revised to suit European Community requirements. Furthermore, a complete change of scale is to be expected. There is every reason to believe that the use of information technology, which is appreciated by professionals, will greatly expand. This possibility of collecting and interpreting health data is a factor for progress. However, general use of this new tool introduces risks which should not be underestimated. Very frank comment in scientific publications about the situation in the United States shows that, despite

sophisticated data protection technology, the temptation to interrogate files out of pure curiosity, or malice, or to inform the media, is always there. Producing theories about who should be cleared to share medical confidential information does not suffice to appease the fears of the population and enlist its support. The rules of confidentiality must be defined clearly taking into account the now ubiquitous use of computers and the openly stated intention of collecting personal data.

In this respect, in order to obtain more willingness from the public to pool data, explanation is required. Most systems for data collection pursue in parallel two aims, one of which is the management of the organisation's tasks, in particular those connected with supervision, and the other which is the composition of scientific data bases. This duality is not encouraging for the public particularly if there is a fear that the end result will be cost paring. Another point is that many data acquisition operations are carried out for scientific purposes without the people involved being informed, although of course, their names are not mentioned. It appears that if objectives were explained more clearly, a major part of the public would not mind donating data, in the same way as blood is donated, if they were sure of adequate data protection.

Just this problem alone requires study, and some work is already being done in conjunction with the modernisation of French legislation and data protection to harmonise with European rules. The specific problem of medical personal data is part of this study (10) .

II. New legislation adopted for a modification of the decision making process in the field of health care, relies on a great number of decision levels and also, in most cases, on deliberation or consultation. Democratic debate, which is what everyone wants, is impeded by difficulties which are particular to the health sector.

Setting priorities should be the most democratic decisions of all because of the pervasiveness and seriousness of the issues. They also need to be formulated in such a way that the gap between their expression at various collective levels and at the individual level is reduced. There is however an element of specific technicality which precludes decision by producers alone, although they cannot be excluded.

It goes without saying that CCNE does not challenge the competence of the country's elected representatives to discuss such matters in Parliament, nor those of local representatives, nor the traditional participation of social partners in the administration of the social security system. However, for democracy to work it must be organised, not improvised.

In every European country, democratic institutions are being urged in that direction. But is this an expression of the wishes of the consumer or of the citizen, and is there really a demand for expression ? If not, who would be qualified instead to seek criteria for quality of life ?

The health care consumer is more than a little concerned by a definition of priorities. He does not hesitate to make this known loudly and clearly through patient associations, and AIDS, for which the major share of the impact was on younger people, has taught us a great deal on this subject. However, increasing the number of such associations would not solve the problem of making sure that citizens are aware and represented to have a say in preserving good health, ensuring satisfactory availability of capacity to cope with ordinary or exceptional risks, or think about taking decisions which condition their future, in particular in old age.

It would seem that two levers need to be used simultaneously to bring about awareness. One would be to plan for and organise representation at various levels, and the other to make it one of the chapters of health education.

A necessary step would be a structure for dialogue between elected political representatives at their levels of competence, and intermediate levels where matters can be explored,

explained, and elucidated. Links must be invented between the administrative and political levels on the one hand, and the clinical level on the other, so as to bring together priorities and their implementation. This is particularly needed because, at both these levels, there must be total transparency. Norway, as we have already seen, has had the benefit of two successive exercises in the setting of priorities at an interval of ten years, and has explored these possibilities. There is also the British system of citizens' juries, and the Spanish pluralistic panels. In all these cases, the organisation is pluralistic with both practitioners and members of the public participating. It hears experts, takes whatever time is needed for its own edification, and seeks to achieve a degree of continuity or regularity (11) .

It is easy to imagine that new approaches of this kind require training for both users and producers. But what training, what edification ? Quite obviously, there cannot be two parallel streams of thought with no common ground.

Based on information and education, by some form of popular educational process, it should be possible to inspire the wish to participate at other times than when ill health sharpens awareness.

III. It cannot be denied that discipline must govern a health policy, and no discipline works if participants do not all have a clear view of their respective obligations, and if the respect of obligations is not enforced. On all these counts, the tools of democracy need adjusting.

So far, the definition of service rendered has been largely given by producers themselves. There is no intention of doing away with them. It is inevitably from the supply end that the impetus to achieve modernisation will come; but the question has to arise of what form of action is capable of inducing a better suited mode of production and sufficient acceptance.

Our society should be in possession of an independent instrument for observation, indicative planning and reporting in the health sector. As we have seen, one of the causes of standstill is that it is difficult for professionals to prepare for technical progress and understand the direction of developments over a ten year or more time span. Also, changes in attitude cannot be demanded in one sector if there is no information on the situation in other sectors which also influence expenditure. Everyone wishes to know whether targets proclaimed in various sectors are nearing fulfilment.

It is up to authorities to supply society with such instruments without which any public discussion will at first captivate, but will soon flounder in repetitious statements of good will and scepticism.

CCNE does not have any ready made answer to another essential question : how to enrol every kind of practitioner in a new health care defining exercise ? From its independent and purely consultative position, it proposes to assist in furthering reflection by organising an ample consultation of health practitioners on this subject. **The analysis which it has prepared and which it submits also for deliberation with other European committees of ethics, could serve as a starting point** . It would be ready to examine in more depth, if needs be by further study and in public debate, whatever subjects, even sectoral, for which the task of giving a clearer definition of health needs raises particular apprehension or difficulty.

Control is a necessity which we shall have to live with, and as we well know, when individual privacy and the privileged patient-to-medical practitioner relationship are concerned, it has always been a source of considerable difficulty. But is there not hope for very substantial progress if the basic premise of the social contract is better known and understood and if the objective to attain is the result of collective agreement ?

IV. For these reasons, CCNE considers that the greatest priority is **health education.**

In the last 50 years, there has been an exponential development of knowledge in biology generally, and of the human body in particular. Technical possibilities for observation, functional exploration, and therapeutic action have become very powerful and provide the doctor or the medical team with extensive means of intervention on the patient's body (including the nervous system). For meaningful dialogue between patient and physician, the former or his entourage must have a minimum amount of understanding of human anatomy and physiology.

Furthermore, every citizen must be aware of the consequences for his health, and more generally for his day-to-day life, when political decisions or general commercial practices are set in motion. For such information to be understood effectively, and so that a citizen can feel concerned if he so wishes, a degree of education must be supplied.

Health education is of course necessary because of the social, economic, and political consequences of health care on a collective or personal level. But it is also just as necessary in a more global way because it is through his body and his perception of that body, that an individual relates to himself and to others and the rest of society. A deficient representation of the body or of its physiology is frequently used for purposes of manipulation as is evidenced in sectarian and ideological statements or through advertising and marketing.

An excessively intellectualised conception of the body with excessive importance attached to the workings of the mind (this is more frequently a male characteristic, women because of physiology and maternal functions have a different approach) a representation of the body linked to an over idealised image of the bodily envelope, are cultural obstacles to pertinent health education. Accepting a real body bounded by its real limitations is fundamental for a better understanding of health needs.

Findings and recommendations

1°. Neither the public, nor health care professionals, nor administrative and political decision makers are adequately prepared for the mutations which technical progress in the health sector is bringing about.

Consequences of this progress and the fact that the health system is developing in cost containment context, engender apprehension which ethical reflection can in some degree alleviate. CCNE has identified some elements of response as follows.

2°. The concept of health care cost containment calls for clarification. The limit, or objective that society - Parliament at this time - has set for itself concerns the share of expenditure that the community pays for. The idea of a limit is confined to that part of expenditure alone.

This does not mean that health activities are in any way a burden on the economy, even that part of it which is reimbursed. These activities also contribute notably to the country's wealth and growth.

The market, and more particularly the international market, will continue to influence significantly the development of these activities.

A close examination of methods of economic analysis do not suggest any incompatibility between economic criteria and ethical considerations for health care activities : in the health sector, the economic and ethical approaches are complementary.

3°. Foundations for an ethical approach already exist : they are the outcome of principles which are either constitutional or recognised by the laws of the Republic and society attaches importance to them. Ongoing developments do not render them obsolete.

Ethical principles arise out of a combination of these rules with an effort to better share the burden, which gives rise to community driven priorities. Apprehension is due to the possible impact of such priorities on individual access to health care.

4°. There is the fear that implementation of criteria at various priority setting levels could insidiously affect access to care.

An important recommendation therefore is to reject any implicit selection criteria, and to endow citizens with a mediation procedure which they can use, if they feel the need, to raise any health care access issues.

5°. The notion that one solution to economic constraints related to the inflation of expenditure could consist in a modulation of collective coverage of this expenditure according to personal wealth, has provoked controversy.

Thinking in some quarters is that this is inevitable and is the most flexible response to the problem of adjusting individual circumstances to collective choices.

Others consider that this would be tantamount to allowing the market to decide on standards for allocation of resources to needs. Initially, this would be the case for the more prosperous classes. Rightful claims from less well-off citizens wanting the same benefits would lead to the opposite of the desired effect (an increase in expenditure) whereas if the claims were rejected the notion of a two-tier health system would find some vindication.

There is a consensus concerning the need to give priority to measures for the correction of inequalities as regards health; they must be a response to a number of particularly deplorable examples of exclusion.

There is no doubt in anyone's mind that none of the above considerations absolve society from an unprecedented effort of analysis of the substance of the health need.

6°. A better definition of health needs is essential, including an analysis of the situation now and also foreseeable developments in health care supply and demand, in particular those generated by technical and therapeutic innovation. Questions of possible access to health care depending on life style, age, and situations of exclusion should also be evaluated.

7°. An evaluation of medical conduct is therefore at the heart of the problem. This obligation is now recognised by authorities in charge of setting priorities. But evaluation can only contribute to a usable definition of priorities if it is on a sufficiently large scale et given adequate scientific and financial resources. A definition of its scope and of methods used do raise ethical issues and this alone is enough to warrant a permanent working relationship between evaluators and the CCNE.

8°. One of the key points of this definition is renovating the concept of prevention, the objective being that citizens should feel just as concerned by access to prevention as they are now by access to care. Society's commitment to satisfy what should be a prerogative should also lead to defining an achievement which can be followed up and checked. It could benefit from the creation of a national prevention organisation whose activities would complement those of the *Agence de Veille Sanitaire* , involving the various authorities concerned and effective across the spectrum of activities giving rise to a health risk.

9°. The instruments of democratic decision and the guarantee of liberties must be adapted to the importance of the stakes. CCNE has identified several levels at which democratic debate must take place : individual health data acquisition and conditions necessary for preserving confidentiality, the way in which users can be represented in the various bodies which deal with priorities, the means required to facilitate the task of informing and educating health care providers about these stakes, since this will condition their commitment to, and their acceptance of priorities and discipline.

CCNE considers that it is of the utmost importance that the multiple and varied world of health care providers should be called upon to integrate into their views the ethical considerations which are linked to collective choices, going beyond discussions which are purely connected to their topical situations. From its uniquely independent position, CCNE intends to facilitate recognition of these matters by organising with these professions a consultation based on this working document which is representative of its thoughts at this point.

An absolute priority to enable society to approach future developments lucidly, has to be health education, the improvement of which must be the result of specific reflection and action.

Annexes

ANNEX I

LA DEPENSE NATIONALE DE SANTE
DANS LES PAYS DE L'OCDE
PART DE LA DEPENSE NATIONALE DE SANTE DANS LE PIB (en %)

	1975	1980	1985	1990	1991	1992	1993	1994	1995	1996
Allemagne (1)	9,0	9,0	9,5	8,2	9,6	10,2	10,1	10,3	10,4	10,5
Australie	7,5	7,3	7,7	8,2	8,6	8,6	8,5	8,4	8,6	8,4
Autriche	7,3	7,9	6,7	7,1	7,2	7,5	7,9	7,8	7,9	7,9
Belgique	5,9	6,6	7,4	7,6	8,0	8,1	8,2	8,1	8,0	7,9
Canada	7,2	7,3	8,4	9,2	9,9	10,2	10,2	9,9	9,7	9,2
Corée	2,5	2,9	3,9	3,9	3,8	3,9	4,3	4,6	3,9	n.d.
Danemark	6,5	6,8	6,3	6,5	6,5	6,6	6,8	6,6	6,4	6,4
Espagne	4,9	5,7	5,7	6,9	7,1	7,2	7,3	7,3	7,6	7,7
Etats-Unis	8,2	9,1	10,7	12,7	13,5	14,1	14,3	14,1	14,2	14,2
Finlande	6,4	6,5	7,3	8,0	9,1	9,3	8,4	7,9	7,7	7,5
France	7,0	7,6	8,5	8,9	9,1	9,4	9,8	9,7	9,8	9,8
Grèce	3,4	3,6	4,0	4,2	4,2	4,5	5,0	5,5	5,8	5,9
Hongrie	n.d.	n.d.	n.d.	6,6	6,6	7,2	6,8	7,3	7,1	6,7
Irlande	7,7	8,8	7,8	6,6	6,8	7,1	7,1	7,6	6,4	4,9
Islande	5,8	6,2	7,3	8,0	8,1	8,2	8,3	8,1	8,2	7,9
Italie	6,2	7,0	7,1	8,1	8,4	8,5	8,6	8,4	7,7	7,6
Japon	5,5	6,4	6,7	6,0	6,0	6,3	6,6	6,9	7,2	n.d.
Luxembourg	5,1	6,2	6,1	6,6	6,5	6,6	6,7	6,5	7,0	n.d.
Mexique	n.d.	n.d.	n.d.	n.d.	n.d.	4,4	4,5	4,7	4,9	4,5
Norvège	6,1	7,0	6,6	7,8	8,1	8,2	8,1	8,0	8,0	7,9
Nouvelle-Zélande	6,7	6,0	5,3	7,0	7,5	7,6	7,3	7,1	7,1	7,2
Pays-Bas	7,5	7,9	7,9	8,3	8,6	8,8	8,9	8,8	8,8	8,6
Pologne	n.d.	n.d.	n.d.	4,4	5,1	5,3	4,9	4,4	n.d.	n.d.
Portugal	5,6	5,8	6,3	6,5	7,2	7,4	7,7	7,8	8,2	8,2
Royaume-Uni	5,5	5,6	5,9	6,0	6,5	6,9	6,9	6,9	6,9	6,9
Suède	7,9	9,4	9,0	8,8	8,7	7,8	7,9	7,6	7,2	7,3
Suisse	7,0	7,3	8,1	8,4	9,0	9,4	9,5	9,5	9,7	n.d.
Tchéque (Répub.)	n.d.	n.d.	n.d.	5,5	5,5	5,8	8,0	8,3	7,9	n.d.
Turquie	2,7	3,3	2,2	2,5	3,2	2,7	2,5	5,2	n.d.	n.d.
Moyenne OCDE (2)	6,4	6,7	6,9	7,1	7,4	7,5	7,6	7,7	7,8	7,9
Moyenne Union européenne (2)	6,4	6,9	7,0	7,2	7,6	7,7	7,8	7,8	7,7	6,2

(1) Länder de la République fédérale avant réunification, Allemagne réunifiée depuis 1991

(2) Moyenne calculée à partir d'estimations pour les données manquantes.

Année 1996 : Estimation de l'OCDE

Source : Secrétariat de l'OCDE

Relation entre la richesse nationale (PIB par personne) et les dépenses de santé 1996 - Pays de l OCDE		
	Dép. nation de santé	PIB par personne
	par personne ($ PPA)	($ PPA)
Allemagne	2222	21094
Australie	1776	21148
Autriche	1681	21283
Belgique	1693	21471
Canada	2002	21813
Danemark	1430	22330
Espagne	1131	14619
Etats-Unis	3708	26148
Finlande	1389	18608
France	1978	20525
Grèce	748	12625
Irlande	923	19015
Islande	1839	23238
Italie	1520	20032
Japon		23099
Luxembourg		32525
Mexique	384	8495
Nouvelle-Zélande	1251	17410
Norvège	1937	24470
Pays-Bas	1756	20527
Portugal	1077	13161
Royaume-Uni	1304	18852
Suède	1405	19162
Suisse		24688

ANNEX 2
Evaluation example

A. Extract from CCNE's Opinion n° "46 Genetics and Medicine :From Prediction to Prevention", 1995.
"Evaluation

EVALUATION OF GENETIC TESTS

Conditions of exactitude and reliability which need to be drawn up for the application of these tests will be covered by the implementation decrees mentioned in article 1 of the law of 4th February 1995 "providing various social measures".
Evaluation of genetic tests based on their *reliability*, their *specificity* and their *sensitivity*, conforms to rules usually applicable in biological testing.
The high degree of technicality and diversity of genetic tests implies specialised laboratories as this is an essential condition for sustained technical quality of results and of their interpretation.

Procedures for habilitation and quality control must be established in the immediate future.

EVALUATION OF EXTENSIVE APPLICATION OF THESE TESTS

For tests to be performed on a vast number of people, feasibility and reliability pilot studies must be undertaken before starting. The results will need to be examined with discernment since a pilot study is carried out in privileged circumstances which do not necessarily tally with those of a routine testing procedure (quality and motivation of participants, including, frequently, tested individuals themselves).

Evaluation raises problems :

- what is the predictive value of tests and according to what criteria should this be judged ?
- what is the value of preventive and curative action which will be recommended to those elements of the population selected by genetic tests ?

Predictive value of the tests

An evaluation of the predictive value of the tests is based on two concepts :

a) *positive predictive value for the tested individual* : that is the proportion of affected subjects in the population for whom test results are positive.
- It may be a very large proportion in the case of a presymptomatic diagnosis of a dominant single gene disease such as Huntington's chorea.
- It may be small, as is the case at present of genetic testing for predisposition to myocardial infarction.
- It may be difficult to evaluate because of the coexistence of hereditary forms detected by the genetic test and a greater number of sporadic forms as is the case of breast cancer.

b) the *prevalence* of carriers of the gene of susceptibility, that is the fraction of the population at large which is at risk and who might benefit from preventive action when the genetic risk factor is recognised, either for the index case or for descendants.
In a few cases, even with low prevalence in the population, the positive predictive value of the test and the value of prevention justify screening; phenylketonuria is a case in point. At the opposite end of the scale, on the basis of probabilistic tests should one select a group of increased-risk individuals for a frequent ailment when general preventive action can notably reduce the risk of incurring the disease ? Such would be the case, for instance, of myocardial infarction since a campaign focused on prevention aimed at the general public would be more effective than a strategy centred on an at-risk group.
This opposition between benefit for the individual or for the population at large will be the most difficult problem to solve when a choice of health policy is made.

Evaluation of preventive and curative methods

Evaluation of preventive measures applied to a population selected through genetic tests for susceptibility will be particularly difficult for multifactorial diseases. But such an evaluation is essential even if it means monitoring over many years.
Difficulties encountered in the evaluation of the usefulness of mammography for mass screening of breast cancer in the early stages of the disease are an example of the complexity of the problem.

EVALUATION CRITERIA

Evaluation cannot just be founded on medical criteria such as onset of the disease, its severity, life expectancy after diagnosis.... Such data is quantifiable but requires lengthy and careful evaluation.
Long term harmful effects must also be considered. The question arises for instance for immuno-suppressive therapy in order to prevent the onset of Type I diabetes. Nor must quality of life be omitted and this is even more difficult to evaluate :

- quality of life at the time of genetic screening and consequences of learning the results on personal behaviour (anxiety, stigmatisation) and on the life of the family and in the working environment (parenthood projects, education, career);

- quality of life connected to the constraints brought about by prevention : prenatal diagnosis and medical abortion as the only "solution" for single gene diseases, physical and psychological stresses induced by the observance of preventive action for multifactorial conditions.

EVALUATION OF REACTIONS TO SCREENING AND PREVENTION

A genetic screening and prevention programme will only be effective if it is accepted by the target population and the medical profession.

Population

The way in which the risk of onset of a severe illness is viewed varies a great deal in different groups and individuals. Many factors play a role : frequency of the condition generally, cases known in the family or elsewhere, characteristics of the clinical expression of the disease which make it possible to recognise an affected individual (Down's syndrome, or myopathy, for instance), high media profile of certain diseases through the activities of dynamic groups.

Inversely, certain diseases although frequent, remain obscure for various reasons: no characteristic phenotypic expression (cystic fibrosis) secrecy observed by unhappy families (frequently occurring in cases of mental retardation, for instance fragile X syndrome).
Previous studies may be of benefit to decide on attitudes to preventive action. Thus, studies already carried out on the subject of prenatal diagnosis of severe genetic conditions show a high degree of acceptance of the diagnosis and of the possibility of therapeutic abortion.
For multifactorial diseases, cancers in particular, studies have already been made of participation in screening operations for cancer of the cervix and breast cancer and have shown some of the difficulties encountered.

The acceptability of a screening protocol is a determinant factor in the results obtained. Participation ratios and proportion of individuals ready to accept the protocol in its entirety (compliance ratio) will also be determinant. Experience acquired in screening for breast cancer shows that 60% must be attained for the benefits of the measures to be acceptable collectively.

The medical profession

Participation by the medical profession as a whole is essential for a screening and prevention policy to be successful. But prevention has social implications which modify the relationship between physician and patient.

Apart from the physician's knowledge concerning the value of the methods and his personal analysis, several factors may influence his behaviour :

- fear of liability if he does not inform his patients;

- the difficulty of informing families. The physician is confronted with a complex situation: on the one hand, the obligation of protection of privileged medical information and of not informing directly members of the family of a risk discovered in one of his patients who refuses to warn them of the situation, and on the other hand the possibility of a complaint by members of the family about the physician who did not inform them of a risk when the family finds itself in a medically disastrous situation which could have been avoided if they had been informed in good time;

- financial concerns.

The reactions of the medical profession to indications for mammography as a means of breast cancer screening is an illustration of such behaviours. Various studies have demonstrated that it is best not to recommend mammographies before the age of 50 because of the absence of benefit from such screening for women aged 40 to 50. In spite of recommendations to that effect, it was found (in Sweden and North Carolina) that physicians continue to recommend mammographies on an individual basis independently of health programmes.

EVALUATION OF COSTS

It has often been said that prevention is less costly than curative action and that the public health budget will save money by it.
Similarly, scientific publications about genetic tests have stated that if such tests are made general the cost price of each test will be significantly lowered. In fact, the test itself represents only a small part of the cost.
When costs are evaluated, both direct costs such as for the predictive and preventive phases, the resources mobilised to organise the campaign, on the one hand, and indirect costs such as loss of income induced by absenteeism on the other hand, must be considered and integrated.

a) Cost of genetic testing proper including all components :

- sampling, despatch of samples, the test itself, storage of samples and data, quality control.
- information before testing, communication of results by qualified personnel, explanations of various kinds, in particular responding to telephone queries, secretarial work...
For genetic counseling (for genetic diseases) a calculation was made that on average, qualified staff spent up to one or two hours on each patient. In some cases, such as Huntington's disease, much more time has to be spent.

Studies on screening heterozygotes for cystic fibrosis insist on the relatively low cost of such tests as soon as they are practised on a large scale. But the modalities and the cost of information which will have to be given individually when the results are available are not considered. In the United States, it is thought that if such a policy was to be generalised, the process of informing parents would completely saturate the facilities of genetic clinics and that the cost of screening one affected foetus would be as high as 300 000 dollars.

b) Cost of prevention for those selected by a susceptibility test.
For this kind of prevention, there will frequently be a second phase of selection of at-risk individuals by repeat tests (mammography, coloscopy, testing of the stool for occult blood...), the cost of which must be added.

c) Cost of the constraints of prediction and prevention, defined in terms of repercussions on the life style of those involved in screening programmes.
All of these evaluations have an influence on public health policy in which the best interests of the individual and society's will to meet the cost of this policy for the greater benefit of the multitude will be in conflict.

In economic terms, the cost to the community of such screening must be adequately evaluated in relation to other expenditures.
Insofar as choices have to be made optimising expenditure and ranking objectives, policy makers must adopt a clear position on the importance they attach to genetic diagnosis.
In the present state of affairs and subject to the reservation that research remains non-limited and entitlement to testing with due medical justification is accepted, there seems to be no reason why genetic diagnosis should enjoy greater priority than other procedures,

either because the reliability of the test is disputable, or there is no effective therapy, or because the condition is not systematically and solely related to a particular gene defect.
Although it appears necessary to improve the community's management of truly preventive medicine, it would be hazardous to attempt to manage genetic predisposition with the help of seemingly preventive measures in view of the impossibility of calculating costs with any accuracy and uncertain effectiveness.

B. Ovulation induction in the treatment of infertility

A recent INSERM (Institut national de la santé et de la recherche médicale) report on severe prematurity was requested to analyse an adverse trend. After a notable reduction of premature deliveries between 1971 and 1980 as a result of the perinatal campaign, figures stagnated between 1980 and 1989, and then began to rise again in 1990.

The report analyses various possible causes of this trend and emphasises that multiple births play a major role in increasing the risk. In the last ten years, taking the total number of births, there has been an increase in the frequency of twin births (25%), and particularly triplets (400%). Most of these increased figures are due to increased use of ovulation induction in the treatment of infertility. Thus, there is a close relationship between national consumption levels of gonad stimulating medications and the number of triplets. Consumption of HMG (human menopausal gonadotropin) was 500,000 vials per annum between 1980 and 1985, but grew to 3,500,000 in 1995. This corresponds to treatment for at least 60,000 women per annum. More than 75% of triplet births are the result of such treatment. Similar worrying situations exist in other industrialised countries.

When analysing this data, a distinction must be made between :

- on the one hand treatment given in medically assisted reproduction centres (AMP, Assistance médicale à la procréation) in which case such activities are regulated by a decree dated May 6th 1995 to implement the "bioethic" laws of July 29th, 1994;

- on the other hand, treatment which is not regulated, prescribed by practitioners outside that framework.

1. In recent years, IVF (in vitro fertilisation) clinical and biological centres have initiated an evaluation of practices through an association called FIVNAT, with the help of INSERM. This ten year evaluation period will also serve to analyse the consequences of this data on modifications of medical practices during ensuing years.
For IVF, the frequency of multiple gestation is directly connected to the number of embryos transferred. From 1990 onwards, the AMP centres began to reduce the number of transfers but the reduction is meagre as seen in 1995-1996 figures. The number of triplet gestations, before foetal reduction, was 8% in 1989 and dropped to 4.7% in 1994, and the figures for reductions were respectively 3.4% and 2.6%. There is still a long way to go. Some medical centres transfer no more than two embryos and so bring down their rate of triplets to less than 1%.

In Opinion n° 42, CCNE wrote : "In this domain, there is a very real debate, and an ethical choice, between the success rate for IVF and the attempts to reach a record level on the one hand, and the serious consequences of multiple births with a record-breaking frequency that it would be better to avoid, on the other."

2. Only an indirect evaluation can be made of the use of ovulation induction outside AMP centres. Based on figures of vials sold, multiple gestations, and very immature births, it can be estimated that much greater use is made of this procedure than in AMP centres, probably twice as much.

A 1996 CNMBRDP (Commission nationale de médecine et biologie de la reproduction et du diagnostic prénatal) progress report explains the above as follows : "any doctor may prescribe ovarian stimulation

- there is public demand for such prescriptions as soon as a couple has any doubt about their fertility
- there is a convergence of resolve between the doctor (who gives assistance) and the patient (who feels supported) and yet there is neither ill health nor therapeutic necessity".

In the circumstances, use is made of a costly treatment, the efficacy of which remains to be evaluated but which is known indirectly to have adverse consequences, i.e. multiple gestation, which raises serious ethical issues :

- in many cases it serves no useful purpose and there is no evaluation of indications.
- consequences may be disastrous and are not evaluated :
- since this is "natural" fertilisation, the number of embryos conceived cannot be forecast, frequently because there is no ultrasonic monitoring of ovulation.
- embryo reduction is not a good solution and may lead to a termination of pregnancy (15% according to FIVNAT) (CCNE's opinion n° 24).
- female health, either immediately due to ovulation induction, or in the longer term (cancer of the ovary)
- children's health at birth and later
- stress for mothers and couples coping with children.

As regards reproduction, ethical issues raised by new AMP techniques have been viewed with concern by legislators so that such practices are carefully controlled by law (the 1994 bioethics laws and their decrees).

An evaluation of such techniques is the subject of annual reports so that the situation can be examined.
CNMBRDP in its annual report "wishes to extend its quality control of AMP procedures to the prevention of iatrogenic multiple gestations brought about by non-AMP ovulation induction protocols".

There is a great need for widespread dissemination of information to both physicians and public so that there may be a better understanding of natural fertility. This should help guide public demand and medical response.

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C. Screening for breast cancer

Breast cancer, the most frequent female cancer in our society, is a serious public health problem since one woman in twelve will be affected in the course of her lifetime.
Individually, women are very fearful of the disease.

Therapeutic progress achieved in recent years is due to early management, and therefore early detection, in particular through the use of mammography. Numerous articles have reported on the evaluation of these screening strategies in various countries, with quite a few controversial issues, in particular on screening mammography for women younger than 50, the benefits of which are much disputed.

The situation therefore is one where individual demand and collective benefit may be contradictory. This is illustrated by an analysis of the health index for 95-96 which shows that in the last three years approximately 60% of women older than 50 have undergone mammography, but that this is also the case for 37% of women younger than 50.

Screening and curative medicine raise different ethical issues : (Schaffer, 1998).

- "Unlike medical care which entails only the obligation to take all necessary measures, screening implies an obligation to achieve results. Benefits expected individually can only be probabilistic since by definition, there are false positives and false negatives, so that an obligation to achieve results seems difficult to apply individually. However, results must be an obligation for the population concerned by screening. This means that authorities, initiators, and medical participants in a screening operation are duty bound to provide as efficient a programme as is possible, of excellent quality, supplying maximum benefits and minimum negative or harmful effects, at the most reasonable cost.

- Quality must be impeccable and all the more so because, unlike diagnosis in curative medicine, it is on the basis of a single test - a single mammography for instance and in the absence of any sign or symptom - that a decision will be made:

- that there is no disease, in which case any error is irretrievable,

- or that there is a probability of disease whereas in most cases, it is not cancer.

- In curative medicine diagnosis is based on a battery of tests so that any deficiency can be corrected by the results of other tests or by non-response to treatment.

- **Screening must not be harmful**. Although it may be beneficial in terms of public health, its potential for damaging individuals must not be forgotten. For the sake of efficacy and ethics, prevention must not be detrimental in any major way. For instance, in screening for breast cancer, there are significant drawbacks and deleterious effects. Considering as a best

scenario, 1000 women aged 50 who accept screening mammography every two years until they reach the age of 70" :

The data*
45 women will develop breast cancer
40 are detected, of which:
24 would have survived without screening
16 would have died without screening

Benefits	*Adverse effects*
5 deaths avoided	100-250 women will undergo diagnosis procedures
955 women reassured correctly	40 women will undergo unneeded surgical biopsy
increase of chances of conservative surgery	35 women will be diagnosed 3 years earlier with increased chances of conservative surgery, but no extension of life. 0.01 radiation induced breast cancer 5 women will be given mistaken reassurance.

* According to Bouchardy Ch. and Raymond L.M & H 1994,52,2381-2385

Decision makers are under obligation to make sure on a continuing basis - both before and during application - that a screening programme does more good than harm.

Controversy on the usefulness of mammography below the age of 50 may lead to conflicts of interest as was the case in the United States in 1997.

Due to lack of favourable epidemiological results, in January 1997, NIH did not recommend routine mammography screening under the age of 50 and it was left to women to decide individually. As a result, health care professionals protested and there was a resolution by the Senate requesting a revision for the welfare of women. In March 1997, NIH recommended mammography screening from the age of 40 onwards.

Elsewhere, there might well have been a decision in the opposite direction based on economic considerations to the effect that routine screening before 50 years of age would be too costly for society.

A situation where the political establishment takes a position opposing an independent analysis based on purely scientific data, or rather on the absence of such data, has an obvious emotional and political impact. The necessity of evaluation unbiased by economic and political pressure is clear.

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ANNEX 3

ETHICAL DIMENSION OF COLLECTIVE CHOICES

European approaches
NETHERLANDS
Government Committee on Choices in Health Care, *Choices in Health Care*, 1992

As part of a plan of reform of health care, the Ministry of Health asked the committee to consider how to set limits for new medical technology, how to deal with problems raised by scarcity of health care supply, rationing of treatment, and the necessity of selecting patients for care.

The committee's approach, based on value attached to equality and solidarity, offers the concept of "necessary" care (i.e. which guarantees normal function as a member of the community). Using this social definition of health, the committee considers that anyone who needs care should receive it. Services included in a "basic package" accepted by Government should satisfy four criteria (examples are given) :

- They must be necessary from the community point of view

- Their effectiveness must be confirmed

- They must be efficient (cost-effectiveness and cost-utility ratios)

- They should not be left to individual responsibility

The approach chosen by the committee implies that certain individual rights could be limited and health care providers' autonomy reduced.

These principles underlie the committee's recommendations on
- contents of the essential care basic package,

- establishment of waiting lists for rationed care,

- evaluation of medical technology, equipment, devices and their application by an independent agency,

- measures to promote more accountability from health professionals, and

- encouraging public discussion on these issues.

SWEDEN
Parliamentary Commission on Priorities in Health Care, *Priorities in Health Care, Ethics, Economy, Implementation*, 1995.

In the framework of a health care policy reform, the Commission began with an examination of ethical principles to be used as guidelines for prioritisation.

Fundamental priority principles	**Secondary principles**	**Unacceptable principles**
dignity	benefit	age
need/solidarity	lottery	prematurity
cost/efficacy	demand	individual responsibility
	autonomy	social and economic category
		nationality

The Commission then created two sets of guidelines (administrative/political and clinical) for prioritisation, both based on common ethical approaches :

- greater needs of care come before smaller ones;

- needs related to the quality of life carry as much weight as those relating to health;

- when a group of illnesses has high priority, all effective measures benefit from the same level of priority;

- special attention should be paid to the needs of persons with reduced autonomy;

- every opportunity should be taken of encouraging and teaching self-care;

- care inputs which have no benefit should not be taken and should not be included in the priority options;

- health care governed by special legislation can be deemed to have guaranteed resources.

Priority Groups (political/administrative level)	**Clinical priorities**
1.Life threatening diseases (severe chronic diseases, palliative terminal care, care of persons with reduced autonomy)	1A. Life threatening diseases or which will affect quality of survival 1B. Severe chronic diseases, palliative terminal care, care of persons with reduced autonomy
2. Prevention with a documented benefit (rehabilitation)	2. Individualised prevention during contacts with medical services. rehabilitation...
3.Less severe acute and chronic diseases	3.Less severe acute and chronic diseases
4. Borderline cases (involuntary	Borderline cases

childlessness, hormonal treatment for shortness of stature, psychotherapy in cases where the existence of a mental disorder is doubtful).	
5. Care for reasons other than disease or injury.	5. Care for reasons other than disease or injury.

Groups 1-3 should be publicly financed; for group 4, funding should be set aside, but if resources are insufficient, public expenditure for this group could be limited.

DENMARK
Danish Council of Ethics, *Priority setting in the Health Service*, 1996.

The Danish Council of Ethics offers some thinking on the priority setting process and society's fundamental values. It does not make concrete recommendations but it does introduce a discussion of factors to take into account when setting priorities becomes necessary. There is emphasis on the process with a view to stimulating public debate on the issue before political decisions have to be taken.

As does the Swedish report, the Danish Council sets out essential values and general criteria in administrative and clinical terms (but does not give examples). More inventively, it underlines the existence of some particularly vulnerable social groups who should in any event be given specific priority. It stresses the importance of public debate (transparency, dialogue), and the need to arrive at a clearer allocation of responsibility between the various actors and levels of the health system. Finally, it insists on the need to evaluate clinical techniques and procedures, integrating user views.

Crucial values :
- Equal human worth
- Solidarity
- Safety and security
- Freedom and self-determination

Common administrative and clinical criteria
- Equal cases are always treated in the same way
- People who have the greatest need are treated first
- No patient groups are left to their own devices and priority is given to weaker groups
- Aim at optimal efficiency

Clinical criteria	**Political / administrative criteria**
Severity of disease	Social and geographical equality
Urgency	Quality
Treatment benefit (efficacy)	Cost-effectiveness
	Democracy and user influence

Vulnerable groups : critically sick, incurable, and terminal cases; mental disorders.
NORWAY
Committee appointed by the Ministry of Social affairs. *Guidelines for prioritizations in the Norwegian Health Service (Lonning I)*, 1987.

The Government asked the Committee to establish guidelines to order priorities in the health service which was in the process of reform.
The Committee suggested that a minimum package of health care to be guaranteed for the whole population should be defined (in terms of diagnosis, treatment, rehabilitation, nursing care, and preventive medicine).

Ten years later, a new Committee with the same chairman was appointed by royal decision, to review the 1987 report. Their report was published in 1997 under the title : ***Prioritizations revisited. A review of guidelines for prioritization in the Norwegian Health Service (Lonning II).*** For some of the priorities defined in 1987 (mental health, psychiatric care, rehabilitation, care for the elderly) the situation has not improved; the waiting list system was a failure, the gap between needs and caring capacity has in fact increased for these categories which were considered to be priorities in 1987.

Essential criteria for prioritization

1987	**1997**
1. gravity of state of health (1st priority)	1. gravity of state of health
2. benefit of the treatment	2. benefit of the treatment
3. equality	3. efficient use of resources
4. economic factors (efficacy, quality)	
5. individual responsibility	N.B. The Committee places more emphasis on criteria 2. and 3. than in 1987.

Caring groups classified in descending order of priority

1. Essential treatment/care, in the absence of which there are life-threatening consequences for individuals, patient groups, or society as a whole (e.g. acute psychiatry, acute surgery, intensive medical care for neonates.	1. Basic health care
2. Care and treatment in the absence of which there are extremely serious consequences in the longer term (e.g. health care for severe and chronic ailments)	2. Care not covered by either group 1 or group 2.
3. Care and treatment with documented beneficial effects.	3. Low priority care
4. Measures which are assumed to have a beneficial effect on health and quality of life (e.g. DAI and IVF).	4. Care not financed by the public administration
5. Zero priority - health care in demand but neither necessary nor effective	
	N.B. For each group, the Committee clarifies criteria but does not give specific examples.

An analysis of developments in the health system since the 1987 Report, of the effects of priorities defined in the report, and of experience gained in other countries, led the second Lonning report to put more emphasis on the methodology for establishing priorities than had been the case in 1987. In fact, there is a complete reversal of methodology. The new model starts at the bottom and moves up to the central level in a four stage process :

1.Expert groups define criteria (gravity, benefit, cost-effectiveness) in respect of various groups of patients;
2. A permanent, co-ordinating prioritization committee would advises decision makers on financial priorities between "competing" patient groups;
3. Administrative and political decision makers distribute resources;
4. Experts formulate clinical guidelines to select patients for treatment.
Recommendations in the Lonning II Report, 1997.

1. Create specialist expert groups
2. Set up the permanent co-ordinating prioritization committee
3. Include information on prioritization in health carer training
4. Reinforce epidemiology, statistics, and health economics
5. Give responsibility for trial forms of treatment to central government
6. Adopt identical principles for performance of treatment overseas
7. Meet quality standards; group 1 (basic health care) is for central decision, whereas other groups are up to local decision
8. Review reimbursement schemes
9. Review financing systems
10. Examine the question of patient financial contribution (for group 3)
11. Improve the staffing situation as a matter of urgency , particularly as regards psychiatry, rehabilitation, and nursing care
12. Continue discussion on the possible introduction of a "treatment guarantee" (i.e. within a certain time-frame).

PORTUGAL

National Ethics Council - Portugal, *Opinion on Ethical issues related to distribution and use of health resources*, 1995.

This opinion precedes reflection specifically focused on the formulation of principles and criteria of choice in the framework of ongoing or projected reform. This is probably one of the reasons why it starts with an examination of the concept of health as one of the basic social human rights. Unlike reports from other countries, "... we will not analyse medical ethics, although their importance is decisive, nor the ethics that analyse the principles of economic theory (particularly the principle of 'utility', which underlies the excellent reports produced by health economics). Hereby we reaffirm the ethical considerations brought about by the distribution and application of health resources in the world today, when there are visible disparities in practically all countries, although on different scales".

Although the existence of social rights has been proclaimed at the highest level for more than 50 years, they are still not guaranteed to everyone. The right to health, based on the concept of human dignity, implies both individual and collective responsibility; it implies other rights - to enjoy life with one's family, to housing, to social well-being, to a healthy environment.

Disparities are glaring between underdeveloped or inadequately developed countries who have nothing, and highly developed countries where expectations are unlimited.
The Council highlights four major values as a basis for its consideration of the issue : human dignity, participation, equity, and solidarity.

Some conclusions
"...this Council believes that the basic health care package guaranteed to everyone is a priority turning point. Furthermore, the elements that constitute the basic package cannot be the object of discretionary decisions or the result of the cumulative effect of new services and technologies. (In the Council's opinion,) the implementation of the basic health care package is an ethical obligation.

Therefore, (the Council) considers the formulation of principles and criteria of choice, as the above mentioned countries have done, to be necessary and beneficial. It also takes the view that such work requires a specific mandate applied to the Portuguese situation. Such a mandate should include the obligation to analyse regularly the considerations raised in this area.

At the moment, the Council acknowledges the fact that rationing often hits weaker groups... Nor does the Council hesitate to say "the rationing of health care that is considered essential is unacceptable. The way forward is clear : "Whilst basic services are not available to everyone, services other than basic care are not considered to be part of the health care

services financed by the social security system". Furthermore, if resources are insufficient due to a greater demand by the public, the only solution is to determine which health care services should be removed from the basic package, so that everyone can have access to fundamental health care without being discriminated against".

ANNEX 4

"Evaluation of Health Choices"

Extract from Jo Lenaghan's (United Kingdom) statement

European Standing Conference of National Ethics Committees,

Paris, January 12th, 1998.

"Public involvement - legitimising health choices ?

Many of our countries are seeking to legitimise rationing decisions by developing methods to involve the public in these debates. In this paper I will briefly describe an innovative method of involving the public in health care choices called citizens' juries, which IPPR has piloted over the past two years.

Many people support the idea of consulting or involving the public in health care choices - the problem is how to do it. As Anne Bowling has pointed out, obtaining a representative view from the public can be difficult, and the methodology of ranking lists of treatments and services can be criticised as superficial in relation to the complexity of the decision to be made (12) .

The Institute for Public Policy Research has recently piloted a series of citizens' juries in the UK in an attempt to develop a more sophisticated technique for involving the public in these difficult decisions. In our first pilot, we commissioned a jury in Cambridge and Huntingdon to look at the issue of how rationing decisions should be made.

16 people were selected by stratified random sampling to represent their community. The jury sat for four days, and during this time the members were presented with information, including clinical case studies to help them to reach a number of decisions. Jurors were asked to consider how priorities for purchasing health care should be set, according to what criteria, and what role, if any, the public should have in these decisions. Expert witnesses gave evidence and jurors were given the opportunity to question them before debating the issues among themselves.

On the first day, jurors were asked to consider what values they would use if they had to 'shop' for health care for the Cambridge and Huntingdon area. What values they add to their criteria? After some discussion, the following guiding principles were suggested and written up in no particular order : severity of disease, quality of life, effectiveness, can we afford it?, how many will benefit?, clinical judgement, views of the individual, need, medical progress, best for general public, fairness, local flexibility.

The jury's list was similar in sentiment, if not language, to the criteria already adopted by the Health Authority (equity, effectiveness, efficiency, appropriateness, efficiency, accessibility, responsiveness), although the jurors were not shown the health authority's criteria until after they had generated their own. The key differences were that the jurors were more concerned with the need for 'progress', and the importance of considering clinical need. Following the jury CHHA agreed to amend their criteria accordingly.

At the end of the four days the jurors made a series of other recommendations, and

concluded that the government should set central guidelines (but not exclude services) to guide rationing decisions at the local level, and that the public should have an input into the development of these principles. The jurors deliberations and recommendations can be found in a full report published by IPPR (13) , and a summary and discussion of the first pilot was reported in the British Medical Journal (14) . IPPR has since published a report which contains an evaluation and discussion of all the five pilot citizens' juries carried out on health care choices in the UK in 1996 \- 1997 (15) .

Our pilots have demonstrated that given enough time and information, the public is willing and able to contribute to the debate about priority setting in health care. We are hopeful that this method, in conjunction with more traditional and other evolving techniques, may offer us a meaningful way of involving the public in decisions about health care choices.

Notes

1. See annex 1

2. *Les réformes des systèmes de santé. Spécificités et convergences*. In Actualité et dossier en santé publique, 1997, n°18

3. Arrow. K.J. *Uncertainty and the welfare economics of medical care*. American Economic Review, 1963, LIII, 5, 941-973

4. Hadorn O.C., *Setting health care priorities in Oregon*, JAMA, 1991, 265, 2218-2225

5. Williams A., *Cost-effectiveness analysis : is it ethical* ? Journal of Medical Ethics, 1992, 18, 7-11

6. Johanet G. *L'égalité d'accès aux soins*, Conseil d'Etat, Rapport public, 1998, Etudes et documents, n°49

7. See annex 3

8. See annex 2

9. Communication Partenaire santé, 1995, 11 : "For lack of precise national data, it is difficult to value with any certainty morbidity, and exact costs due to nosocomial infections in our country. However, it is estimated 600 000 to 1 100 000 infections are contracted in hospital every year. Extra cost due solely to extended stay in hospital is in region of 2 to 5 billion annually. As for mortality, it could probably be compared to the 10 000 motor traffic related deaths".

10. L. Cadoux, S. Vuillet-Tavernier, *Secret médical et Informatique*, Conseil d'Etat, rapport public, 1998 and Rapport Braibant, Données personnelles et société de l'information, Documentation française, 1998

11. See annex 4

12. A. Bowling, *Health care rationing. The public's debate*, British medical Journal, 1996, 321, 670-4

13. J. Lenaghan, *Rationing and rights in Health Care*, IPPR, 1996, London

14. J. Lenaghan, B. New, E. Mitchell, *Setting priorities : is there a role for citizens' juries ?* British Medical Journal, 1996, 312, 1591-3

15. A. Coote, J. Lenaghan, *Citizens' juries : theories into practice*, IPPR, 1997, London