

Report on sterilisation considered as a means of permanent contraception.

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Report

On several occasions, the French National Consultative Ethics Committee has been asked for an opinion by practitioners who wished for a broader discussion on issues of medical ethics and deontology raised by certain requests for sterilisation. They were preoccupied by the consequences for medical and paramedical staff as well as for patients of developments in indications for sterilisation which seem to be moving in obvious contradiction to existing legal constraints. In particular, certain anaesthetists go so far as to refuse their assistance if they consider the planned procedure incompatible with existing law : they were recently reminded that insurance companies might not reimburse possible damages awarded in legal proceedings for alleged malpractice if the surgical procedure was considered illicit.

Indeed, interpretation of French law concludes that is illegal any injury to a person's reproductive functions, unless justified by therapeutic necessity, and for which, except in cases of extreme urgency, the patient has not given consent. Apart from such cases, it is thought by some that valid reasons exist for practising sterilisation for purely contraceptive purposes on persons who have so requested and who take a free and informed decision after giving the matter due consideration. This point of view seems to be gaining ground because progress in surgery makes it possible to envision a reversal of the procedure by further surgery. Some opinions go as far as to maintain that sterilisation can be considered as just another method of contraception . Yet, particularly for the person who has given consent for surgery to be practised, it is essential to know whether surgery causing a state of anatomic impossibility to procreate will in fact lead to temporary or irreversible sterility.

With that in mind, sterilisation of the mentally handicapped is a special case : in fact the request for contraceptive sterilisation is almost always made by a third party, which at the outset raises the issue of validity of consent by the person directly concerned. The needs of the mentally handicapped as regards contraception and the suitability of using sterilisation

for the purpose raise complex issues already analysed and specifically considered by CCNE in its opinion n° 49 of 3rd April 1996.

A response to problems raised by requests for opinions can only be given, if needs be, by legislators. However, CCNE considers as part of its mission a contribution to the debate, which the authors of such requests would like to see taking place, in the form of reflection on purely ethical problems arising out of sterilisation as it is currently practised. Such is the object of this report.

Contraception and sterilisation in France and abroad

In every society, since time immemorial, attempts have been made in a variety of ways to exercise an effect on fertility. Increasing or limiting conception and birth is therefore not a recent notion peculiar to our times (1) . However, since the beginning of this century, research on fertility, and in particular on hormonal regulation of the oestrus cycle, has led to many contraceptive applications, one of the characteristics of which is that they are particularly reliable. Even older and less efficient methods of contraception, referred to as "barrier contraception" because they aim to act as a barrier against fertilisation, have been perfected. Contraceptive sterilisation techniques, for men and women both, were developed at the beginning of this century but have since been much improved so that reversibility can now be envisaged. Thus, at the present time, sexually active individuals wishing to limit their fertility have available to them a whole range of contraceptive techniques.

Preferences for one or the other of the various techniques vary however from one country to the other and even from one region to another in the same country. A contraceptive method is the product of a national or local culture so that in each country and period, people choose preferentially techniques which suit them best (or in some circumstances, adapt to whatever methods are offered or imposed).

According to data published by the United Nations on contraceptives practices (2), female sterilisation appears to be at present the method of birth control which is most used world-wide : altogether, 17% of women with partners and of child-bearing age (usually defined as women aged 15-49) have been sterilised for medical or contraceptive reasons. If only developing countries are considered, the figure rises to 20%. In some of these countries, female sterilisation has been performed on a very high percentage of women (Dominican Republic, 39%; Korea, 35%; China, 34%). In many African countries however, the percentage is minimal - between 1 and 2%. In fact, on the whole contraception is rare in that part of the world (18% of sexually active men and women of child-bearing age are concerned). In developed countries, the percentage of sexually active women of child-bearing age who have undergone sterilisation is 8%, but in some countries such as Canada or the United States, sterilisation has been performed on respectively 31% and 23% of these women.

Male sterilisation as a means of contraception is not nearly so frequent. The world over, 5% of men are involved. The differences between developing and developed countries are not nearly so striking (4% and 5% respectively). Male sterilisation however, appears to be better accepted in developed countries, such as the United Kingdom (16%), the United States (13%), Canada (13%), and Australia (10%). A few developing countries also have quite high averages : Korea (12%), China (10%). For that matter, it is in this part of the world (China, Korea, Hong Kong) that contraception generally is most prevalent (up to 79% of sexually active men and women of child-bearing age) ; the rates are in fact higher than in the West.

In some countries, sterilisation is a preferred method of contraception because once done there are no further constraints on the user and because the cost is low compared to other means of birth control. Sterilisation is a once-only procedure with permanent effects and there is no need for long-term medical management. The fact that, in some countries such

as the United States, not all health insurance policies reimburse the procedure may also have a bearing on the couple's option to use male rather than female sterilisation - vasectomy is less expensive.

The effectiveness and permanence of sterilisation make it the method of choice for putting an end to fertility : such appears to be the main reason at least for massive use of sterilisation in Canada and in the United States. In these countries, the pill is simply used to space out births until the desired number of children is reached (3) .

However, in many countries including France, preference is given to reversible methods (intrauterine devices and the pill) even for terminal contraception and particularly so if contraceptive clinical follow-up is accepted by health insurance schemes.

In France, the law dated 28th December, 1967, authorises the manufacture and sale of contraceptives (pill, IUD, condom). According to an enquiry conducted by INED in 1994 (4), 65% of the twelve million women between 20 and 49 years of age were using a method of contraception. Were not concerned by contraception, 32% of women who were either already pregnant, trying to procreate, or sterilised for therapeutic or contraceptive reasons. Only 3% of women were not using contraceptives and yet did not wish to have any more children. The contraceptive choice of the first group was preferentially oral contraception (the pill), adding up to 36,8%. Second place was taken by IUDs in 16.1% of cases. Locally applied methods such as diaphragms, and sponges containing a spermicide, are seldom used (0.6%). Certain couples prefer abstinence (4.1%) , possibly using methods of observation of the woman's menstrual cycles (basal body temperature or cervical mucus). In other cases, use of a condom by the man (4.6%) or withdrawal (2.6%), is preferred. Unlike other industrialised countries, in France male sterilisation is rarely used but it should be noted that under current legislation it is illegal.

There is, in fact, no specific law regarding the use of sterilisation, but an interpretation of basic texts of French penal law leads to the conclusion that any procedure of which the outcome is sterilisation is only acceptable if there is therapeutic necessity. Sterilisation for exclusively contraceptive purposes therefore seems unacceptable (see below the section devoted to the state of law in France). Yet, according to the same inquiry confirmed by responses supplied by practitioners (5), almost nine hundred thousand women of child-bearing age (20 to 49) are sterilised not only for medical reasons, but also following requests made for contraceptive purposes. The annual number of sterilisations, including all indications, is estimated at 30 000 (5 000 gynaecologist-obstetricians practise in France).

However female sterilisation is not nearly as frequent in France as it is elsewhere. Again in 1994, the proportion of sterilised women aged 20 to 49 was 7.1% (inclusive of all motives). A previous inquiry shows that in 1988 the percentage was already as high as 7%. In absolute figures, the increase in the number of sterilisations is stable, it seems. The number of sterilised women aged 45 to 49 has increased since 1988, but at the same time, sterilisation figures for women aged 30 to 44 have regressed, and figures are almost stable for younger women aged 20 to 29. It may be supposed that sterilisation, which has never been very popular, is not favoured in our culture but that, with the approach of menopause, reluctance diminishes.

Figures supplied by the 1994 inquiry in fact show that sterilisation is mainly used for older women. The procedure is rare indeed for the under-35s : for those aged 20 to 24 and 25 to 29, the figure is 0.5%; between 30 and 34, the figure is 1.5%. In contrast, figures increase considerably beyond that age. In the 35 to 39 years of age group, the figure is 6.4% and this is doubled in the 40-44 age group (12.7%), and doubles again in the 45 to 49 age group (21.7%).

Development of this practice therefore mainly seems to concern older women. Of course, the figures do reflect the fact that major medical indications more frequently apply to older women. But the hypothesis that contraceptive sterilisation requests occur more frequently for women aged 35-49 cannot be eliminated. A generation effect may be involved here.

Women aged 20 and over in the seventies have had access to more efficient methods of contraception. As they near the age of menopause, they may be more receptive to the idea of sterilisation for contraceptive purposes. The number of sterilisations in younger women is still small and growth is stable. Therapeutic indications are more likely to be the rule in these cases. Mentally handicapped and psychiatric cases are probably also included but therapeutic necessity is open to debate.

State of medical practice in France

Techniques

Sterilisation for contraceptive purposes can be either masculine (vasectomy) or feminine (section, ligation, or occlusion of tubes with clips). However, the way in which sterilisation is performed and its consequences if the person concerned later regrets the decision to put an end to fertility, differ greatly between the sexes.

Vasectomy is a simple surgical procedure, takes little time and requires only local anaesthesia. Usual techniques by occlusion of the vas deferens have a minimal failure rate (0 to 2.2% pregnancies in partners of men who have undergone vasectomy) (6). Reversal of the result is possible, but the microsurgery required is much more difficult and results frequently unreliable. Of course, success depends on technical achievement and the presence of sperm in the ejaculate (success rates reported in literature are then fairly high, i.e. 50 to 85%); however, in the final analysis, success must be counted in terms of the partner's pregnancy followed by birth (on that basis, success rates are lower) (7). There is a possibility of retaining masculine fertility (using medically assisted procreation techniques) if sperm is frozen prior to vasectomy. However, there again, the measure of true success is at-term delivery.

Section, ligation, or occlusion of the tubes is a more complicated procedure requiring general anaesthesia. Failure rates are low (about 1% of pregnancies). Reversal requires further major microsurgery and general anaesthesia.

Recent data on results of oviduct reanastomosis in an experienced hospital setting (8) show a pregnancy rate of between 60 and 80% after two years; these figures are consistent with results of earlier studies quoted by the author. The age of the woman turns out to be the most important factor for success and the highest figures concern younger women.

However, other factors were also important, in particular the remaining length of tube after sterilisation and the method of sterilisation (occlusion with clips offers the best chance of reanastomosis). It must be underlined that these results refer to women who actually were treated and not to the number of women who had requested reanastomosis: some women were barred after pre-surgical examination which had included exploration of possible infertility factors in the partner.

In case of failure or impossibility of attempting reanastomosis, there is still, theoretically, the possibility of *in vitro* fertilisation. However, chances of giving birth are not high and are lowered in proportion to increasing patient age. Furthermore, this solution might be prohibited by interpretation of the law dated 29th July, 1994, which only authorises medically assisted procreation to remedy cases of infertility "of which the *pathological* nature has been medically diagnosed."

A distinction must be made between sterilisation techniques for contraceptive purposes and surgery of which the consequences are sterility (hysterectomy, endometrectomy, castration) performed for therapeutic reasons (for instance, cancer of the uterus, ovaries, or testicles; massive haemorrhage of the uterus). Such surgery comes under the general deontology of medical practice and does not raise the same issues as in first line sterilisation (see below the section on legal status in France).

Principal indications.

In the present state of medical practice in France, exclusively contraceptive motivation is rarely taken to be a valid indication for sterilisation of either men or women. Generally accepted indications comply with criteria defining medical necessity or even serious medical reasons which, in the opinion of certain practitioners, can also include social and psychological reasons. A high probability of bequeathing a hereditary disease to descendants is also accepted by certain practitioners as valid medical reason.

1. Major medical indications

These are cases when pregnancy is a life-threatening risk : obstetrical conditions (for instance, rupture of the womb, repeated caesarean section); surgical problems (uterine malformation, cancers); medical conditions (serious cardiac or metabolic disorders, hemopathy). In such cases, contraceptive sterilisation performed during a surgical procedure without the patient's knowledge would be a violation of the code of ethics.

2. Indications and other considerations relating to contraception.

Some gynaecologists consider that contraceptive sterilisation can be justified for medical reasons when a certain number of conditions co-exist. More frequently, the female partner undergoes sterilisation, but in a number of cases husbands and partners offer or accept vasectomy.

Requests are evaluated on the basis of several factors : a woman's age, number of pregnancies and deliveries, age of the youngest child, presence of minor pathologies, inability to tolerate long-term use of other contraceptives (pill, IUD), history of previous abortions, and such social and psychological factors as the couple's life style and situation generally). The aim is to try and take into account behavioural changes in women and couples' outlook on reproduction. It is a fact that in the population as a whole, pregnancies tend to occur ever later in the life of a woman. This is particularly the case in urban environments : in 1980 in Paris, 40% of pregnant women were over the age of 30; in 1990 the figure is 50% (20% over the age of 35). Furthermore, if present trends continue, a third of all marriages will end in divorce. As for non-married couples, they are even more fragile. A new union may provoke a desire to have a child which did not exist a few years ago.

Physicians who are willing to perform contraceptive sterilisation take certain precautions :

- Thorough evaluation of medical, social, and psychological criteria for considering sterilisation.
- Providing information on contraceptive methods and also on the constraints and consequences of sterilisation.
- Allowing time to reflect - a few months - while wife (or husband) and couple are counselled taking into account their circumstances and possible psychological consequences of sterilisation.
- Obtaining written consent from patient after free informed decision.

The French National Association of Gynaecologists and Obstetricians has drafted recommendations based on these practices.

Requests for reanastomosis

Occasionally, after sterilisation, a woman or a man may request reconstructive surgery. In such cases, it could be considered that the original decision to sterilise was taken too hastily. The requests occur in particular after the death of one or several children, when very young women or men undergo sterilisation, and also when there is a change in partner. According to results of the tubal ligation study previously quoted (9), requests were made by women who had undergone sterilisation very early in life, during caesarean section, or immediately after delivery. Most of the requests, as many as 60%, were motivated by a profound change in marital circumstances.

The fact that such a group of patients exists justifies curiosity about the reversibility of the procedure. Sterilisation cannot be considered reversible simply because there exists a possibility of reconstructive surgery leading to anatomical normalcy. Reversibility is only effective if and when reconstructive surgery is followed by pregnancy and birth. This is an important point because, according to the literature, reversibility is referred to a request for reanastomosis, or a return to anatomical normalcy, or the number of pregnancies counted (and this includes ectopic pregnancies. In fact, it is only the number of live births as a proportion of the number of initial requests for reanastomosis which informs us adequately on the degree of reversibility of sterilisation techniques.

Generally speaking, little is known about psychosocial long term consequences of sterilisation. Only a few studies were made and methodology is a serious problem. A recent review of the literature (10) points out the variable definitions of parameters studied (regret, psychological and psychiatric consequences, effect on sex life) which make comparisons difficult. It points out, however, that regret is infrequent (according to studies and definition of regret, 2 to 7%) and to be found mainly in women for whom sterilisation was performed before the age of 30. Negative effects on sex drive are fairly rare. The authors consider however that long term studies would be necessary insofar as such phenomena could amplify over the years.

Regret, as reported in requests for reanastomosis, may not be representative of the issue as a whole. A inquiry, conducted over the telephone, questioning a representative sample of women who had had tubal ligation in Quebec (11) revealed that regret comes in "many shades and intensities" covering the range of "passing nostalgia felt for example in the presence of a new born infant, up to searing all encompassing regret with an urge to make every attempt to re-experience the joys of motherhood." Only 3.9% of these women had discussed the possibility of regaining fertility with their physicians, but 21.2% said they had felt regret but had not mentioned it to the doctor.

However, only half of the latter group (12.7%) stated that they would really have attempted to have another child if they had still been fertile. The inquiry confirms at least what is to be found in medical literature on reversibility, i.e. it is primarily early sterilisation which is the fundamental variable determining regret, and this is so in spite of the fact that the earlier the sterilisation, the more it applies to women who have had several children. The author concludes that "it is the length of time of exposure to the risk of regretting", that is, the number of years during which the changing circumstances of a life may lead a still fertile woman to reconsider the possibility of having another child, which is the determinant factor.

State of law in France

The word "sterilisation" is to be found neither in the *Code Civil* nor in the *Code Pénal*. It remains to be seen whether the procedure can be likened to an infraction or a source of liability.

1) Penal law

With either a male or a female patient, these are surgical procedures affecting the body. Any such injury is prohibited and punished by law and referred to, *inter alia*, as an offence by "violence leading to mutilation or permanent infirmity" (article 222-9 of the New Penal Code). Of course, doctors and surgeons affect the body but their action is justified by the ends pursued which are cure or prevention. This concept is now stated much more clearly than it used to be in article 16-3 incorporated into the *Code Civil* by law n° 94-653 of 29th July 1994 : "Injury to the integrity of the human body is allowable only in the case of therapeutic necessity for the person concerned. Consent of the patient must be previously obtained except if the condition of the patient prevents consent being given."

If the letter of this text is followed, there is no difficulty in applying it to sterilisation which is only licit if it is medically necessary for the individual concerned. The Criminal Chamber of the Supreme Court of Appeal (*Chambre criminelle de la Cour de Cassation*) followed this interpretation of the law in its decision of 1st July 1937. The Court upheld a decision of the Bordeaux Court of Appeal condemning non-medical individuals who had practised vasectomy on three consenting men. The Appeals judges had written : "It is a violation of rules governing law and order to knowingly commit such bodily injury whereas there is no imperious medical or surgical necessity to do so". The Supreme Court ruled that "the accused could not invoke consent given by the patients as excluding penal liability, since they could not grant the right to violate on their persons rules governing law and order." Since then, there has been no other truly representative decision on the subject. Does this mean that this one was sufficient to insure the observance of penal law on the subject ? Since it is a fact that a great many sterilisations are performed, one should presumably conclude that those upon which it is practised do not wish to complain or that they are performed in full compliance with the law. On this latter point, the major difficulty is defining what is meant by "therapeutic necessity" which may be invoked either with respect to the physical consequences in general brought about by a pregnancy, or to the consequences of the pregnancy itself. Furthermore, one should probably make a distinction between foreseeable consequences and those which are difficult to foresee and which might, for that matter, not be considered as having major importance.

To physical therapeutic necessity, should one add psychological therapeutic necessity because of, for instance, the state of distress in which a woman might find herself if she were to be pregnant ? The fact is that the effect would be to avoid recourse to abortion, but it could be thought that the condition of therapeutic necessity is not met because of the hypothetical nature of diagnosis of distress were pregnancy to occur.

A further issue is whether there is compliance with the law when sterilisation is performed to avoid possible transmission of a genetic disease to a future child. Is this a case of "medical necessity for the individual concerned" ? Such extensive interpretation of legal texts seem excessive.

If the above analysis is accepted as such, then sterilisation cannot be acceptable as a substitute for contraception. If the intention expressed by a woman or a man has no other justification than convenience or practicality, acceptance on the basis of these criteria alone is a penal offence.

The existence of medical necessity does not absolve the practitioner from obtaining free and informed consent from the person upon whom the procedure will be performed. It would be unacceptable and contrary to both principles and existing legislation if an unaware patient was sterilised when undergoing surgery unless an extreme emergency arose during the operation. Consent cannot be dispensed with and must include specific provision for prior information. For a patient to be informed means obtaining facts about the exact nature and object, methods, consequences and risks of a procedure. It also means being given the reasons behind therapeutic necessity. The complex nature of this expression of intention makes it desirable that there should be a written document which would also serve as a warning to practitioners.

2) Civil law

Apart from any penal offence or complaint to obtain sanction of such offence, a case of injury leading to the award of damages might arise if sterilisation without prior consent were to be performed except in an emergency. Inversely, if sterilisation was requested and resulted in failure, damages could be claimed from a practitioner if malpractice were proved as is the case for other medical or surgical matters. However, in such a case, the birth of an infant cannot be considered in itself a source of prejudice. A Supreme Court of Appeal (Cour de cassation) decision dated 9th May, 1983 states : "the birth of a child is not *per se* a cause of prejudice". It also seems that in this decision the licit nature of sterilisation was accepted fairly extensively when the following description was given of motives for practising the procedure : "precarious state of health of a woman of 28 who had had five previous pregnancies and could not use other methods of contraception". This was described by one author as a medico-social indication. In such a case, damages are justified by the onset of financial and health difficulties for the mother and also difficulties of a social and relational nature.

Problems arising out of present practices

To sum up the situation as described so far, two conditions are required for licit sterilisation in France : *therapeutic necessity* and *consent* of the individual concerned by the operation. These two conditions are necessary but neither of them alone is sufficient. As regards the requirement for prior consent, the sole possible derogation is for extreme emergency, i.e. imperious and unpredictable necessity during surgery to perform a procedure leading to sterilisation in order to overcome the effects of a discovery or of a serious life threatening surgical incident (for instance, massive haemorrhage of the uterus during a caesarean section so that excision of the uterus is unavoidable). In fact these extremely rare cases are only pertinent for female sterilisation since there is no such thing as emergency vasectomy. The Code of Medical Deontology of 1995 (Decree dated 6th September 1995) mentions these requirements in article 41: "No mutilation can be inflicted without very cogent medical motive nor without the knowledge or consent of the person concerned, except for reasons of urgency or impossibility."

And yet, sterilisation is performed in France and sometimes in doubtful circumstances as regards existing legislation, either from the point of view of consent or of the degree of severity of medical cause.

Surgery practised in the following circumstances may be considered dubious from the point of view of consent :

1. So called "undisclosed" sterilisation which in earlier times was regrettably frequent in particular in the case of women who were undergoing a second or third caesarean section. This is now less frequent. Such sterilisation may be justifiable in medical terms, but, if carried out without the patient's consent, is illicit.

2. Sterilisation which is the consequence of certain surgical procedures (such as hysterectomy) for specific medical indications. Patients are not always informed before surgery of the possibility or certainty of this outcome although they would be entitled to refuse consent if they were duly informed of possible consequences of their decision. A situation of *extreme urgency* may arise once the patient is anaesthetised : this very rare occurrence is the only exception to the rule of informed consent. Sterilisation for contraceptive purposes can never, as such, be accepted as an emergency procedure.

Other sterilisation practices are disputable to varying degrees as regards the nature and severity of the motive given.

3. Situations which relate to contraindication for any hormonal or mechanical mode of

female contraception. Pathologies in this category are, for example,, severe diseases of the liver, hypercoagulability, thrombogenic conditions...). Some of these pathologies also constitute a major risk for the mother in case of pregnancy. Medical opinion is almost unanimous in considering that in such cases contraceptive sterilisation should be offered. Some gynaecologists also consider that contraceptive sterilisation is medically justifiable for women or the male partner when a number of social and medical conditions prevail concurrently : advanced age in a woman, repeated pregnancy and deliveries, difficulty in long term use of other contraceptives (pill, IUD), and previous induced abortions. With existing legislation, it is not entirely clear that such indications should be accepted as "therapeutic necessity" or "very serious medical reason". Nor is it clear that sterilisation of the partner is acceptable under law insofar as the indication is not based on his own state of health.

4. Sterilisation at the request and with the consent of an individual for purely contraceptive purposes. Such voluntary sterilisation is frequent in other countries and is considered to be a method of solving a contraception problem once and for all. As such, it is unacceptable under existing French law.

Finally, one situation is disputable on the two counts of consent and motive:

5. Sterilisation requested by third parties for persons judged to be incapable of rearing children although there is not necessarily any reason to believe that those making such requests have any eugenic or punitive motives in doing so. More often than not, the request is made on behalf of mentally retarded or psychiatric cases, women mostly, since the purpose is to save them from becoming pregnant. In a restrictive interpretation, such situations do not come under the heading of therapeutic necessity since sterilisation is certainly no cure for mental impairment or derangement. Sterilisation here is essentially meant as a contraceptive method which, furthermore, raises the question of whether the patient is capable of giving free and informed consent. The matter has been dealt with in opinion n° 49 of CCNE on contraception for the mentally handicapped.

To view in perspective the evolution of indications for sterilisation in France, one should keep in mind that many countries have made legal access to contraceptives and induced abortion, and also authorise voluntary contraceptive sterilisation. As we have already noted, the latter has in fact become the most popular contraceptive method in use world-wide and is particularly widely used in North America and some European countries. However, in those parts of the world, there is also some demand for reanastomosis.

It must not be forgotten however, that in the early part of this century, sterilisation was part of a range of measures (sexual segregation in institutions, prohibition to marry, restricted immigration) aiming to reduce the numbers of those considered to be "socially inapt". In certain European and North American countries, eugenic sterilisation laws were passed (compulsory sterilisation or without their knowledge of the mentally handicapped, the psychiatric cases, and the needy). Some of these laws included articles relating to those incarcerated for various offences, sexual crimes in particular.

In France during the same period, the situation was entirely different. Policy at the time favoured increasing the birth rate and so it was strictly forbidden to promote or use any means enabling women to restrict voluntarily the number of their offspring. Since the war in 1870, France was constantly preoccupied about the size of its population because, in contrast with the situation in neighbouring countries, Germany and England in particular, where two factors had led to a strong growth in population: decreased mortality due to better hygiene and a continued high birth rate, the French population growth had not been particularly strong. On the contrary, a gradual decrease in the birth rate during the XIXth Century in France had been followed by a large loss of human lives during the first world war. French authorities had therefore taken every possible step to encourage the birth of a numerous and healthy population, *inter alia* : financial encouragement to large families, legislation on working conditions for pregnant women and nursing mothers.

As early as the thirties, but even more so after the second world war, eugenic sterilisation legislation and practices were strongly opposed. They have not all the same completely vanished : in November 1994, China adopted legislation of this kind (12). Furthermore, although the concept of sterilisation as penal sanction is on the wane, in the United States long-term hormonal contraception is still imposed on female child abusers. Finally, in some countries, sterilisation is performed in highly disputable conditions.

Such differences in situations and practices which reveal different outlooks on sterilisation, call for an examination of reasons underlying its validity and legitimacy. For those who do not condemn outright any form of sterilisation, judgement on the matter demands more information and a better understanding of situations in which it is requested and performed.

Ethical considerations

The specific nature of the ethical issue raised by sterilisation resides in that, in fact, it eliminates a function which cannot be taken as being merely physiological. It is true that as a biological function, capacity to procreate is not essential to the survival of a given individual, although it is essential of course to the survival of the species. However, in an anthropological dimension, procreative capacity is significant in human and existential terms for each individual : the feeling that one is physically present and has a place in the world; the possibility of expressing oneself as a sexual being and of relating in procreative terms to others; the ability to make an alliance and prolong a blood line; the possibility of assuming in a web of relationships and in an existential plane, both interpersonal and social, all of the consequences of one's sexuality. The human stakes are too high in this respect for any society to have ever accepted total freedom of individual sexual and procreative conduct. Moral and religious traditions, relayed by various forms of diffuse moral and social pressures prescribe certain relationships as being more acceptable than others for the begetting and rearing of children. In law abiding communities, legislation defines such conduct and determines filiation. These various forms of moral, social and legal regulation give meaning and dimension to procreative capacity so that it cannot be reduced to the level of a purely biological process.

It so happens that in the last few decades several medical techniques make possible a relative independence of procreation and sexuality, so that the obviousness of the relationship has become blurred. This revolution in the anthropological conditions of sexuality and reproduction in the context of global population growth, raises novel issues regarding responsibility in procreation and more generally, on sexual morality when it restricts the value of a sexual act to its procreative purpose. Sterilisation is part of that context, in particular as regards the following :

1. Is there such a thing as the right to limit or even suppress procreative capacity ?

Every philosophy and religion recognises the right to exercise procreative capacity, which does not, at least in our culture, imply any moral obligation to do so, since otherwise for instance, chastity vows would be immoral. Recognition of this right demands that capacity to procreate be protected since it contributes to the possibility of founding a family, and this right is in fact recognised by the Declaration of Human Rights (article 16-1). There is however disagreement on the negative dimension of free exercise of procreative capacity, i.e. temporary or permanent limits - other than sexual abstinence - that an individual may apply.

In our own society we find various principles applying to the right of destroying one's procreative capacity:

- It is thought by some that there is no such right for an individual because injury to reproductive bodily functions goes beyond the exercise of tenancy of the body and is a violation and indignity inflicted on the being. A person must respect limits that natural morality imposes on the exercise of procreative capacity.

- Others believe that this is a right in the absolute, as a corollary to the right of freely exercising procreative capacity and of doing what one wishes with one's own body. Ownership of one's body is absolute. It is up to the individual, in the last analysis, to take any important decision on sexuality and reproduction, including decisions related to the integrity of the body. Any denial of free and informed requests for sterilisation would be unacceptable seen from that angle.

- Finally, for others again, the right exists but in conditional terms, insofar as it is the prerogative of the community to guarantee the safeguard of procreative capacity. It then becomes necessary to establish conditions and limiting criteria to the right of restriction or destruction of procreative capacity, so as to protect individuals against actions which would be contrary to their best interests. Restrictions of the right nevertheless need justification.

2. Is sterilisation "violence leading to mutilation or permanent infirmity", and "injury to the integrity of the human body" ?

A reply to this question depends a great deal on the light in which procreative capacity is viewed, its relationship to sexuality, and in more general terms, an anthropological, moral, and legal vision of the individual.

Most frequently, sterilisation is viewed as a mutilation because it constitutes anatomic bodily harm which renders an individual incapable of reproduction. The word "mutilation" assumes amputation of a limb or organ, or the infliction of a grievous wound which damages the physical integrity of the person concerned. Various surgical procedures for sterilisation may in fact be described by one or the other or both alternatives of that definition. Hysterectomy can be likened to amputation, whereas vasectomy or tubal ligation are closer to grievous wounding. The legal descriptions of mutilation and violation of bodily integrity seem all the more pertinent if the technique used for sterilisation is irreversible.

Any surgical procedure viewed in the light of the above definition can be described as a mutilation. From a legal viewpoint, it only gains exemption from the onus of "violence leading to mutilation or permanent infirmity" because of the therapeutic necessity to which it responds. The question then arises of whether surgical sterilisation can be justified by any other motive than therapeutic necessity, and in particular by advantage determined by the patient alone.

A more global way of defining injury to procreative capacity could be the following : such injury is not confined to the concept of mutilation and is extended to any interference with an individual's capacity to enter into procreative relationships, including by harming bodily integrity. Procreative capacity is not defined in merely physiological terms and is perhaps better defined as a human faculty which is rooted in the body but is of a relational nature and enables individuals to extend their being beyond their own existence by perpetuating their blood line.

However, seen as a human faculty, procreative capacity confers a right to its free exercise but also imposes a responsibility. There may well be differences of opinion as to conditions and means considered to be legitimately adequate for free and responsible exercise of that faculty. Depending on circumstances and points of view, sterilisation may be regarded as violence or as responsible action. If that is the case, then it becomes essential to determine who, in the last resort, takes decisions.

3. Can sterilisation be considered a reversible contraceptive procedure ?

Irreversible sterilisation is the inevitable consequence of some surgical procedures (endometrectomy, hysterectomy, castration). For women in particular, there can be no remedy after such action : essential organs (uterus, ovaries) are removed and they are henceforth deprived of any possibility of reproduction. More recent techniques for male and female sterilisation only modify the status of organs of reproduction: tubal ligation or of the vas deferens theoretically permits later reanastomosis.

In the past, questions have been asked about possible consequences of long-term daily dose hormonal contraception (ovarian inactivity), or even intrauterine devices (minor inflammation of the uterus so that implantation becomes impossible), insofar as they induce, by chemical or mechanical action, a state of sterility. However, these methods do not aim to eliminate reproduction functions but only to suspend them by making them temporarily ineffective. On the whole, they do not aim for permanent sterilisation and seldom provoke it accidentally (as in infectious complications produced by IUDs). Sterilisation on the other hand, has the immediate and specific aim of bringing about a situation of anatomical incapacity to procreate. Even though certain recent techniques make it possible to hope - though with no guarantee of success - for a reinstatement of prior physiological status (reanastomosis) or a palliative such as medically assisted reproduction, a new decision and further surgery will be required to achieve that end.

This technical problem is an essential component of the decision to consent to sterilisation. The person concerned must, if at all possible, take into account future reactions to an unforeseen event, such as divorce, death of spouse or of children, or quite simply the unexpected desire to bear another child, which might trigger feelings of regret over a past decision. Physicians are generally well aware of the problem and usually reluctant to perform sterilisation on young and childless individuals.

Sterilisation therefore is necessarily an act which has weighty consequences and implications for the reproductive future of the individual. Whatever might be the possibilities of restoring procreative ability after sterilisation, it would seem preferable for the sake of clear thinking and lucid information, to view it as a *permanent* suppression of fertility.

Notes

1. Angus McLaren, *A History of Contraception*, Oxford, Basil Blackwell Ltd., 1990.
2. United Nations, Department for Economic and Social Information and Policy Analysis, Population Division, *World Contraceptive Use 1994*.
3. Nicole Marcil-Gratton and Evelyne Lapierre-Adamcyk, "L'Amérique du Nord à l'heure de la troisième révolution contraceptive : la montée spectaculaire de la stérilisation au premier rang des méthodes utilisées", *Espaces, Population, Sociétés*, 2, 1989, 239-248. The special case of Canada should be emphasised : the 1941 population census revealed persistence of exceptionally high fertility, close to natural fertility in vast sectors of the population. The slowing down of the birth rate, only just starting in the thirties, has plunged dramatically in the last thirty years, much more so than in other industrialised countries. But this drop seems to be a complex phenomenon unconnected to massive use of sterilisation. Concerning the role played by contraception, the so-called "natural" methods of birth-control, and later on, the "barrier" methods, were initially most frequently used. Medical contraception (the pill and to a much lesser degree intrauterine devices (IUD)) said to be effective, began developing in the sixties, but was overtaken by sterilisation in the seventies, at least as a terminal contraceptive. These changes in methods used also reflect behavioural changes in the timing of child-bearing. Before the nineteen sixties, most couples did not seek to delay the birth of their first child, but this was no longer the case in

the seventies. See Catherine de Guibert-Lantoine, "Révolutions contraceptives au Canada", (Contraceptive Revolution in Canada), *Population*, 46, 2, 1990, 361-398.

4. Institut National d'Etudes Démographiques, *Enquête sur les situations familiales et l'emploi*, March 1994.

5. "La stérilisation tubaire" (tubal ligation) : inquiry by the National Association of French Gynecologists and Obstetricians", *Journal de gynécologie obstétrique et de biologie de la reproduction*, 1994, 23, 729-730.

6. "Vasectomy : New opportunities". Population Reports, Male sterilisation, Series D, n° 5 (March 1992), 23pp.

7. One author, comparing results in various studies, considers that chances of an on-going pregnancy followed by delivery of a child are globally about 50%. Hendry W.F., "Vasectomy and vasectomy reversal", *British Journal of Urology*, 1994, 73, 337-344. However, a review of recent literature on the subject in the Medline data base reports a lower success rate of about 20 to 40%.

8. J.B. Dubuisson, C. Chapron, C. Nos, P. Morice, F.-X. Aubriot, P. Garnier, "Sterilisation reversal: fertility results", *Human Reproduction*, 1995, 10, 5 : 1145-1151.

9. Dubuisson *et al.*, *ibid.*

10. E.M. Smith, E. Friedrich, E.F. Pribor, "Psychosocial consequences of sterilization : A review of the literature and preliminary findings", in *Comprehensive Psychiatry*, 1994, 35,2 : 157-163.

11. Nicole Marcil-Gratton, "Le recours précoce à la ligature des trompes au Québec : des suites indésirables ?" (*Early tubal ligation in Quebec : undesirable after effects ?*) *Sociologie et sociétés*, vol. XIX, n° 1, April 1987, p. 83-95.

12. "Chine: la loi eugéniste publiée", *Le Quotidien du Médecin*, 16th November, 1994. See also "Les troubles relents de l'eugénisme chinois", *Le Figaro*, 2nd January 1994; and "Pekin prône l'amélioration de l'espèce", *Libération*, 4th January 1994.

Considerations and proposals

In the light of the above analysis, two questions remain unanswered :

- Is destruction of one's own procreative capacity a right ? If so, is this right absolute or conditional ?

- Is destruction of another person's procreative capacity a right ? If so, in what circumstances and on what conditions ?

A current interpretation of non-specific articles in French penal law restricts licit practice of sterilisation to acts meeting two fundamental requirements : *therapeutic necessity* and *consent* of the patient. The only possible exception to prior consent is unpredictable *extreme urgency*. It might however be debatable whether moral options underlying this legal framework still appear rightful in view of major changes in the anthropology of procreation.

A modification of the judicial framework of the practice of sterilisation in France has to be the result of a political choice after democratic debate. It is not for the National Consultative

Committee on Ethics to make such a decision, but it seeks to make a contribution to the debate in the form of ethical reflection and proposals.

1. Unambiguous restatement of the principle of consent

Whatever legal framework is found for sterilisation in France, CCNE considers to be fundamental the ethical principle underlying the interpretation of the current state of French law, which demands free and informed consent to the sterilisation procedure, its variable irreversibility depending on which technique is used, and risks of failure which grow with the possibility of reversal. Even when medical considerations motivate the procedure, there is still an obligation on the physician to give the patient all of the information which make a choice possible. The only possible derogation from that principle must be extreme urgency which, it should be remembered, is a rarity.

In the case of individuals deemed unable to give consent, opinion n° 49 by CCNE, on the subject of contraception for the mentally handicapped lists a number of conditions to be met before third parties may consider the possibility of surgical contraceptive sterilisation :

- Incapacity of the individual concerned must be defined by thorough and multidisciplinary evaluation. Care must be taken to make sure that the state of health and behaviour of the individual thought to be incapable is not likely to improve.
- The individual must be potentially fertile, sexually active, be at least about 20 years of age. In all cases, efforts must be made to obtain consent.
- Sterilisation can only be envisaged if proof is provided that no other form of contraception can, in practical terms, be used by the individual concerned. In such cases, the most potentially reversible form of sterilisation should be used.

To guarantee the most equitable conditions for evaluation and decision making in each particular case, opinion n° 49 offers a set of steps and methods to be followed in decision making :

- have other consultants besides the attendant physician examine the request made by the individual or his/her entourage;
- require those requesting sterilisation to give explicit reasons and justifications;
- provide for collective and extremely strict decision making processes, rather than delegation of authority, including the possibility of appealing to the courts in case of conflict, so that the rights and interests of disabled individuals are protected to a maximum degree;
- make sure that follow-up of the person concerned is provided whatever means of contraception or even sterilisation is finally chosen.

A very small number of specialised centres must be allowed to practise such operations to be performed by the most competent micro-surgeons.

In its Opinion, CCNE underlines the importance it attaches to collective decision-making. Indeed, evaluation of a request for sterilisation is too complex a task and too serious a decision for a single person to undertake. This kind of evaluation requires such expertise and entails so much responsibility that it seems essential for the task to be given to a commission composed of experts in the field of mental handi including physicians, legal advisers, and social workers. The commission must be entirely independent of the family or guardians of the mentally handicapped. This is also quite essential: it is clear that those making the request must not be both judge and party to the decision.

CCNE's Opinion also points out that sterilisation procedures for those incapable of consent

most frequently concern mentally handicapped women. The aim is to protect them from pregnancy. It should not be forgotten however that this in no way protects them from sexual aggression. The problem of violence perpetrated on the mentally handicapped goes beyond the limited problem of contraception and therefore requires separate and specific response bearing on the entourage and environment of the mentally handicapped.

2. Reconsider categories and criteria used to justify sterilisation

The concept of therapeutic necessity as seen by existing law, refers to the notion of medical indication, i.e. criteria justifying an intervention proposed by medical personnel. The only court decision (Bordeaux in 1937) regarding justification of sterilisation did not concern physicians. Other judiciary decisions on the subject of liability in cases of sterilisation never doubted the licit nature of the act. Such jurisprudence seems to demonstrate that certain medical criteria, and more generally certain well defined pathological states, correspond unambiguously to the notion of therapeutic necessity. The situation is not so clear for minor pathologies which in no way demand surgical sterilisation.

The concept of medical indication does not however seem to be appropriate for contraceptive sterilisation requests (also called voluntary sterilisation). These requests are more often than not made by the party concerned.

- Firstly, there is no justification for the establishment of medical indication in the case of male sterilisation, except possibly a contra-indication of future pregnancy of the female partner. Justification based on medical indication in such a case seems disputable.

- Sterilisation considered exclusively as means to solve permanently a contraception problem corresponds solely to a patient's *wish* not to or cease to reproduce, even when that decision is based on the fact that the patient is a carrier for some hereditary or transmissible disease which he does not wish to pass on to offspring. If one were to use the concept of therapeutic necessity to justify a decision to sterilise in these circumstances, this would amount to creating a medical indication for eugenic ends.

Nor does therapeutic necessity seem to fit the case of sterilisation of an individual considered to be incapable of giving free and informed consent. In the absence of the usual criteria for medical indication, therapeutic necessity would refer to the disability which makes that individual incapable of giving consent. This is a highly disputable criterion for medical indication. Such a situation would be better described as a special case of a request for contraceptive sterilisation which brings us back to difficulties already encountered concerning the legality of such a practice, aggravated by the fact that more often than not, the request is made on behalf of another person.

Any legal reform related to sterilisation would lead to raising the question of whether the *will* of the individual not to or cease to procreate can be taken as valid reason for eradicating procreative capacities. Society must needs debate this point.

3. Whatever progress may be achieved in the matter of reversibility of surgical techniques, insist on the theoretically irreversible nature of sterilisation

In spite of new techniques improving the probability of reversing sterilisation, what differentiates sterilisation from contraception is the will to arrive, by one single action, at permanent suppression of the capacity to procreate. Reversibility of a sterilisation technique is a concept based on probability. Even if probability is high for any given method, reversibility cannot be guaranteed for each individual. It therefore seems desirable to consider any act of sterilisation as a *permanent* suppression of procreative capacity. Doubts regarding a state of permanent sterility or explicit expectations regarding reversibility may reveal ambivalent feelings on the part of the author of the request and should lead surgeons and patients to defer decision.

The principle of irreversibility demands that precautions - both oral and in writing - be taken so as to ensure that the patient's decision is not only fully matured but is also entirely informed as to possible consequences of the procedure (failure, possible reversibility and risks of failure of the procedure, operating risks). It is to be recommended that a grace period for reflection should be suggested or even imposed so that the person concerned may have time to fully explore, with the help of other consultants, his/her motives and justification.

4. Establish decision-making procedures compatible with respect of the right to exercise procreative capacity

All societies establish moral and legal rules, relayed by diffuse social pressures, which constrain individual liberties with respect to reproduction. These rules may, *inter alia*, prescribe what is considered acceptable for the establishment of a union and sexual conduct; rules of law to determine filiation and if there are no children, may authorise alternative socially acceptable practices.

Traditionally, the moral, social, and legal framework for the exercise of procreative capacity in our society, was marriage. Nowadays, marriage is still required by certain spiritual groups, but is no longer unanimously considered by our pluralist society as the single legitimate framework for procreation. Present day law in France supports that view, since for filiation and other legal arrangements pertaining to the exercise of procreative capacity, marriage is no longer viewed as the only acceptable framework. Only one recent article of law seems to reverse the trend to some extent : the law dated 29th July, 1994, concerning medically assisted reproduction, limits access to couples who are "married or able to prove they have been living together for more than two years..." (art. L.152-2 of the Code of Public Health). This article meets the legislator's wish to guarantee double filiation, both maternal and paternal, for the child born as a result of these circumstances. The child's interest, of course, does not play a role (except *a contrario*) in a request for sterilisation.

Since in our culture, there is no obligation to give effect to procreative capacity, only rarely would anyone oppose sterilisation for medical reasons. Furthermore, law as we know it does not stipulate that procreative incapacity is an absolute and determining cause for dissolution of a marriage. It is therefore fair to say that in the social, moral, and legal context we live in, there is minimal consensus to the effect that protection of the right to exercise procreative capacity is not an absolute obligation to procreate nor absolute prohibition to suppress the capacity. However, this right of free exercise of procreative capacity is not unanimously considered as an absolute right of the individual, and even less as a right, either absolute or unconditional, to limit or suppress that capacity.

Even those who speak in defence of an absolute right to use all available means to limit or suppress the capacity do agree that thoughtless acceptance of any request for sterilisation would, in certain circumstances, lead to abuse. Such abuse would be apparent to begin with in cases of requests for sterilisation from third parties on behalf of individuals considered to be incapable of consent. Even in cases of what is termed voluntary sterilisation, special features of today's life in society, such as younger age of first sexual intercourse, later age - increasingly so - of marriage and first child, frequency of divorce and remarriage with the wish to found a new family with a new spouse, all converge to suggest caution in the establishment of conditions in which sterilisation may be granted or offered.

If after debating these issues, it were decided to modify the legal and regulatory frameworks so as to grant legality to sterilisation for other reasons than "very serious medical reasons", it would still be necessary to decide on methodology to avoid over hasty or abusive sterilisation.

- One possibility would be to specify criteria allowing access to the procedure when there is no urgent therapeutic necessity. In fact, certain criteria such as previous procreation,

having reached a certain age or having had a certain number of children, or for the nulliparous, persistent and long established demand, are considered by many practitioners to be reliable indicators of future satisfaction if sterilisation is performed. Nevertheless, why certain criteria should be chosen in preference to others and by whom remains to be seen.

- Another possibility might be to set up a decisional framework, with time for reflection. Such criteria as were considered important, like for instance some of the above, could be those considered and discussed. However, within such a framework must be included the choice of who makes the final decision. Two points of view co-exist in society : there are those who consider that the physician should take the initiative of what is in fact a medical act, and those who take the opposite view, i.e. that in the field of reproduction, unless there is medical contra-indication, then the decision is in the hands of the person directly concerned.

The two approaches could also be merged : for instance there could be a definition of the decisional framework whilst setting certain limitations , such as sterilisation of minors being prohibited .

5. Providing strict rules for settlement of conflict

Must a doctor respond to any request for sterilisation recognised to be licit in a given legal framework ? Can medical and paramedical staff refuse to participate in a legally acceptable procedure ?

For some, refusal to practise sterilisation (or to take part in the procedure) may be a conscientious objection due to their own spiritual convictions or personal philosophy. Respect for such personal opinions does not exempt anyone, practitioners in particular) from referring any licit request to another consultant.

However, this refusal may be connected with a problem of deontology or of medical ethics which leads the practitioner or other medical and paramedical staff to doubt the wisdom of sterilisation in a certain set of circumstances. To settle such disagreement, or even conflict, particularly if consent is an issue, a strict procedure for decision making should be established thereby to explore the propriety of the request and/or of refusal to perform the procedure (see above on consent).

Conclusions

The above examination of problems arising in France in practical terms in connection with sterilisation leads CCNE to report a paradoxical situation : on the one hand, some individuals wishing to have access to contraceptive sterilisation run into difficulties because the law forbids it; on the other hand, others who quite frequently are amongst the more vulnerable, do not wish for sterilisation but have it offered to them in dubious circumstances as regards their consent. Furthermore, certain surgeons perform operations, the consequence of which is sterility, in full conformity with requirements for medical necessity, but in some cases neglect any obligation for informed and prior consent. CCNE finds that lack of clarity about existing law has as its counterpart divergent notions about what is acceptable in the case of sterilisation. The CCNE concludes that this state of affairs calls for a societal debate about circumstances in which it can be considered that suppression of procreative capacity is morally acceptable.

Several positions of principle could be proposed :

1. The first of these is that the Penal Code limits, and rightly so, circumstances in which sterilisation is legitimate to those where there is therapeutic necessity. This position is the closest to the concept of inviolability of the human body, considers that it applies more

particularly to procreative capacity in view of the importance of this faculty in social, personal, and familial terms, and for the future life of those concerned. Suppression of that capacity cannot simply, and for no other serious motive, be considered a personal right. If that is held as valid, it is up to substantive law to protect individuals to the fullest degree against any attempt to curtail that capacity. There exists no imperative moral reason, or any other reason, for modifying existing law.

Sterilisation in that case is only acceptable when it is required by therapeutic necessity or some other very weighty medical reason, and if the person concerned has been duly informed of these medical reasons and of the surgical risks, and has given consent. This position of principle excludes any request for sterilisation based on a desire on the part of the person concerned to suppress their fertility. Consequently, at its most strict interpretation, are also barred requests by third parties for contraceptive sterilisation on behalf of the mentally handicapped or the mentally deranged.

2. The second position is close to the first one, but is more receptive to the equity of some requests for sterilisation theoretically rejected by a completely strict interpretation of existing law. It is here considered that some flexibility could be introduced without completely overturning the principle of the inviolability of the human body, principle to which this view also grants priority. A range of fully justified and structured exceptions could be added, giving some leeway for contraceptive sterilisation based on less than major medical utility, but found more acceptable in certain social circumstances such as a woman's age, number of children, social and economic environment.

In practical terms, this added flexibility would be founded either on more lenient interpretations of the penal code as it stands, or on a bill specifically drafted for that purpose, with clear statement of criteria and situations for which sterilisation would be considered lawful.

Since this position maintains, as did the first one, priority of inviolability of the human body over the right a person has to suppress procreative capacity, requests for contraceptive sterilisation based on nothing else but the will of the person concerned to cease being fertile are bound to be excluded. This type of request can only be accepted if it can be made to fit in with the concept of medical utility. In this case, the acceptability of contraceptive sterilisation requests made by third parties on behalf of vulnerable individuals is unclear. Should this extension be given to the legal description of therapeutic necessity, standards of medical practice must needs be reviewed.

3. A third position is that the state of present practice reflects a deep change in anthropological conditions of procreation, which leads to accept as morally unobjectionable not just therapeutic sterilisation but also contraceptive sterilisation even though there may be no medical justification. In this case, it is up to moral beings to conduct their sexual behaviour and possible reproductive consequences in a free and responsible manner. Thus, this position states that the right of the individual to freely exercise his/her procreative capacity includes the legal possibility of limiting or even suppressing that capacity. The right does not contravene the principle of inviolability of the body if - and only if - pertinent information and time for reflection are provided to ensure a free and informed decision. This position implies in the long run a modification of law. The law should include a specific text on the subject of contraceptive sterilisation, and so provide a framework for exploring motives, both personal and medical, and for conveying pertinent information, so as to protect those concerned from over hasty decisions. The fact that contraceptive sterilisation would become licit would make it possible to take into account requests made by third parties for individuals considered incapable of making their own contraceptive choice. The text should also include strict evaluation and decision-making procedures such as those proposed by CCNE in Opinion n° 49 on contraception for the mentally handicapped, to ensure protection of the rights and interests of particularly vulnerable individuals. A legally recognised possibility of requesting one's own sterilisation for purely contraceptive reasons could be a source of difficulty for practitioners who, because of their convictions or for that matter their medical opinion, consider that no action should be taken in a particular set of

circumstances. The law therefore should include a conscientious objection clause, with an obligation to refer the patient to another practitioner and a set of procedures for decision making in case of conflict over whether sterilisation is appropriate.

CCNE considers it to be outside its purview to opt in favour of one or the other of these positions. In a democracy, the choice is up to society and the Legislator must have the final say. Members of CCNE however gave their personal opinions on these positions and the discussion was helpful in order to examine foreseeable or expected consequences of each of them. Out of this discussion, the following thoughts emerged :

The first position is the one which is most protective against hasty or abusive sterilisation. Protection is given by law which strongly curtails individual liberty as regards procreation, but this would be justified by the safeguarding of the principle of inviolability of the human body. However, by prohibiting sterilisation even in circumstances where it would be suitable and morally faultless contraception , this position leads to illicit sterilisation in conditions which do not adequately take into account the problem of consent. This is very probably the case in France at the present time.

The second position is less restrictive than the first insofar as it accepts a broader interpretation of derogation for therapeutic necessity. This interpretation reverts to implementation of the concept of indication by dialogue between physician and patient, so that the specificity of each individual case can be better observed. However, in the final analysis this means it will be up to the medical profession to define criteria for sterilisation. In these circumstances the limits of legitimacy in practice are much hazier and they would be inclined to change in line with changes in current practice. Furthermore, if current practice were to accept an extension in medical and social terms of therapeutic necessity, medical classifications would sometimes serve to respond to problems of another nature. This would lead to a confusion over what belongs to therapeutic justification and what is to be categorised as personal preferences and wishes of the person concerned. Over time, this position might facilitate improper or abusive interpretations of all kinds. The example of so-called eugenic sterilisation and its indications in the early part of this century is there to remind us of all the dangers brought about by confusion between therapeutic aims and solving the problems of society.

The third position, which is based on a different concept of the rights and responsibilities of a moral subject, is opposed to excessive restriction of individual liberties regarding the exercise of procreative capacity. Thus, although it does not reject the notion that therapeutic sterilisation requires guidelines and conditions, it accepts the view that motivated and well thought out willingness to stop or to abstain from procreation is a valid motive to suppress procreative capacity even though this constitutes a violation of the integrity of the human body without therapeutic necessity. It states that people have a right to take their own decisions as to whether they will continue or cease to be capable of procreation and that this is no violation of the human body as long as the right is exercised in conditions which guarantee free and informed decision. Those who defend this position do recognise however that it opens up the practice of sterilisation to situations in which personal over hasty and ill-advised decisions might be taken. Proof of this are requests for reanastomosis. Sterilisation differs from other methods of contraception in that it is in principle irreversible, as are risks connected to its performance and, in case of later regrets, and are also irreversible risks attendant to attempts at restorative surgery. It must be remarked that these risks are very different in men and women. Therefore this position of principle must address itself with thoroughness and directness to problems raised by ethical demands for pertinent information to be supplied and informed consent to be given. Adequate provision must be made in this respect. Very special attention must be paid to making necessary arrangements to protect the rights and interests of those for whom contraceptive sterilisation is requested by others. The history of sterilisation and some present day practices in parts of the world show that individuals and populations made vulnerable by a physical, mental, economic or social handicap are the most exposed to abusive sterilisation. Legal acceptability of this position rests on the quality of information,

particularly as regards consequences and risks of the intervention, and on the level of awareness of the implications of consent. It would be intolerable if advantage was taken of the situation to solve problems raised by sterilisation requests made by third parties on behalf of individuals incapable of giving consent. In the absence of free and informed consent, only imperious medical motive (such as absolute contraindication of progestogens) could justify sterilisation after demonstration of the fact that no reversible contraceptive method can be used.

This position of principle in fact accepts the idea that certain medical acts cannot qualify as therapeutic, but may nevertheless be justifiably requested by a patient. It therefore allows the possibility of conflict between patient and physician as to whether an intervention is opportune and well-founded, and in this case, measures and procedures for the settlement of such conflicts must be set in place. Indeed, decision to sterilise which must be informed and well thought out, would be in the hands of the person concerned in the last resort, but the necessary action for implementing the decision would require recourse to professional assistance entailing liability, in spite of the fact that no therapeutic necessity is found.

Regardless of the conclusions arrived at by public debate of the subject, CCNE considers that the cornerstone of any legal settlement of issues raised by sterilisation must remain the creation of a system in which precise information is given about procedures and their consequences, and in which consent or free and informed decision can be given by the person concerned. Even in the most restrictive system, a physician cannot be exempted from this obligation, with very rare exceptions. However, CCNE points out that any legal guarantee in this respect does not protect an individual from the constraints of personal and social circumstances which may force a choice which is not a free one.

Furthermore, CCNE points out that requests for contraceptive sterilisation made by third parties on behalf of the mentally handicapped clearly raise a moral issue, insofar as there can be doubt about the validity of consent given by the person concerned. CCNE draws attention to the need for specific provision to be made for such cases, irrespective of what kind of legal system governing sterilisation is adopted.

Society must debate upon the practice which it wishes to accept as legitimate, but remain aware that no legal solution can give absolute security against the risk of hasty or abusive sterilisation.

Considerations and proposals

In the light of the above analysis, two questions remain unanswered :

- Is destruction of one's own procreative capacity a right ? If so, is this right absolute or conditional ?
- Is destruction of another person's procreative capacity a right ? If so, in what circumstances and on what conditions ?

A current interpretation of non-specific articles in French penal law restricts licit practice of sterilisation to acts meeting two fundamental requirements : *therapeutic necessity* and *consent* of the patient. The only possible exception to prior consent is unpredictable *extreme urgency*. It might however be debatable whether moral options underlying this legal framework still appear rightful in view of major changes in the anthropology of procreation.

A modification of the judicial framework of the practice of sterilisation in France has to be the result of a political choice after democratic debate. It is not for the National Consultative

Committee on Ethics to make such a decision, but it seeks to make a contribution to the debate in the form of ethical reflection and proposals.

1. Unambiguous restatement of the principle of consent

Whatever legal framework is found for sterilisation in France, CCNE considers to be fundamental the ethical principle underlying the interpretation of the current state of French law, which demands free and informed consent to the sterilisation procedure, its variable irreversibility depending on which technique is used, and risks of failure which grow with the possibility of reversal. Even when medical considerations motivate the procedure, there is still an obligation on the physician to give the patient all of the information which make a choice possible. The only possible derogation from that principle must be extreme urgency which, it should be remembered, is a rarity.

In the case of individuals deemed unable to give consent, opinion n° 49 by CCNE, on the subject of contraception for the mentally handicapped lists a number of conditions to be met before third parties may consider the possibility of surgical contraceptive sterilisation :

- Incapacity of the individual concerned must be defined by thorough and multidisciplinary evaluation. Care must be taken to make sure that the state of health and behaviour of the individual thought to be incapable is not likely to improve.
- The individual must be potentially fertile, sexually active, be at least about 20 years of age. In all cases, efforts must be made to obtain consent.
- Sterilisation can only be envisaged if proof is provided that no other form of contraception can, in practical terms, be used by the individual concerned. In such cases, the most potentially reversible form of sterilisation should be used.

To guarantee the most equitable conditions for evaluation and decision making in each particular case, opinion n° 49 offers a set of steps and methods to be followed in decision making :

- have other consultants besides the attendant physician examine the request made by the individual or his/her entourage;
- require those requesting sterilisation to give explicit reasons and justifications;
- provide for collective and extremely strict decision making processes, rather than delegation of authority, including the possibility of appealing to the courts in case of conflict, so that the rights and interests of disabled individuals are protected to a maximum degree;
- make sure that follow-up of the person concerned is provided whatever means of contraception or even sterilisation is finally chosen.

A very small number of specialised centres must be allowed to practise such operations to be performed by the most competent micro-surgeons.

In its Opinion, CCNE underlines the importance it attaches to collective decision-making. Indeed, evaluation of a request for sterilisation is too complex a task and too serious a decision for a single person to undertake. This kind of evaluation requires such expertise and entails so much responsibility that it seems essential for the task to be given to a commission composed of experts in the field of mental handi including physicians, legal advisers, and social workers. The commission must be entirely independent of the family or guardians of the mentally handicapped. This is also quite essential: it is clear that those making the request must not be both judge and party to the decision.

CCNE's Opinion also points out that sterilisation procedures for those incapable of consent

most frequently concern mentally handicapped women. The aim is to protect them from pregnancy. It should not be forgotten however that this in no way protects them from sexual aggression. The problem of violence perpetrated on the mentally handicapped goes beyond the limited problem of contraception and therefore requires separate and specific response bearing on the entourage and environment of the mentally handicapped.

2. Reconsider categories and criteria used to justify sterilisation

The concept of therapeutic necessity as seen by existing law, refers to the notion of medical indication, i.e. criteria justifying an intervention proposed by medical personnel. The only court decision (Bordeaux in 1937) regarding justification of sterilisation did not concern physicians. Other judiciary decisions on the subject of liability in cases of sterilisation never doubted the licit nature of the act. Such jurisprudence seems to demonstrate that certain medical criteria, and more generally certain well defined pathological states, correspond unambiguously to the notion of therapeutic necessity. The situation is not so clear for minor pathologies which in no way demand surgical sterilisation.

The concept of medical indication does not however seem to be appropriate for contraceptive sterilisation requests (also called voluntary sterilisation). These requests are more often than not made by the party concerned.

- Firstly, there is no justification for the establishment of medical indication in the case of male sterilisation, except possibly a contra-indication of future pregnancy of the female partner. Justification based on medical indication in such a case seems disputable.

- Sterilisation considered exclusively as means to solve permanently a contraception problem corresponds solely to a patient's *wish* not to or cease to reproduce, even when that decision is based on the fact that the patient is a carrier for some hereditary or transmissible disease which he does not wish to pass on to offspring. If one were to use the concept of therapeutic necessity to justify a decision to sterilise in these circumstances, this would amount to creating a medical indication for eugenic ends.

Nor does therapeutic necessity seem to fit the case of sterilisation of an individual considered to be incapable of giving free and informed consent. In the absence of the usual criteria for medical indication, therapeutic necessity would refer to the disability which makes that individual incapable of giving consent. This is a highly disputable criterion for medical indication. Such a situation would be better described as a special case of a request for contraceptive sterilisation which brings us back to difficulties already encountered concerning the legality of such a practice, aggravated by the fact that more often than not, the request is made on behalf of another person.

Any legal reform related to sterilisation would lead to raising the question of whether the *will* of the individual not to or cease to procreate can be taken as valid reason for eradicating procreative capacities. Society must needs debate this point.

3. Whatever progress may be achieved in the matter of reversibility of surgical techniques, insist on the theoretically irreversible nature of sterilisation

In spite of new techniques improving the probability of reversing sterilisation, what differentiates sterilisation from contraception is the will to arrive, by one single action, at permanent suppression of the capacity to procreate. Reversibility of a sterilisation technique is a concept based on probability. Even if probability is high for any given method, reversibility cannot be guaranteed for each individual. It therefore seems desirable to consider any act of sterilisation as a *permanent* suppression of procreative capacity. Doubts regarding a state of permanent sterility or explicit expectations regarding reversibility may reveal ambivalent feelings on the part of the author of the request and should lead surgeons and patients to defer decision.

The principle of irreversibility demands that precautions - both oral and in writing - be taken so as to ensure that the patient's decision is not only fully matured but is also entirely informed as to possible consequences of the procedure (failure, possible reversibility and risks of failure of the procedure, operating risks). It is to be recommended that a grace period for reflection should be suggested or even imposed so that the person concerned may have time to fully explore, with the help of other consultants, his/her motives and justification.

4. Establish decision-making procedures compatible with respect of the right to exercise procreative capacity

All societies establish moral and legal rules, relayed by diffuse social pressures, which constrain individual liberties with respect to reproduction. These rules may, *inter alia*, prescribe what is considered acceptable for the establishment of a union and sexual conduct; rules of law to determine filiation and if there are no children, may authorise alternative socially acceptable practices.

Traditionally, the moral, social, and legal framework for the exercise of procreative capacity in our society, was marriage. Nowadays, marriage is still required by certain spiritual groups, but is no longer unanimously considered by our pluralist society as the single legitimate framework for procreation. Present day law in France supports that view, since for filiation and other legal arrangements pertaining to the exercise of procreative capacity, marriage is no longer viewed as the only acceptable framework. Only one recent article of law seems to reverse the trend to some extent : the law dated 29th July, 1994, concerning medically assisted reproduction, limits access to couples who are "married or able to prove they have been living together for more than two years..." (art. L.152-2 of the Code of Public Health). This article meets the legislator's wish to guarantee double filiation, both maternal and paternal, for the child born as a result of these circumstances. The child's interest, of course, does not play a role (except *a contrario*) in a request for sterilisation.

Since in our culture, there is no obligation to give effect to procreative capacity, only rarely would anyone oppose sterilisation for medical reasons. Furthermore, law as we know it does not stipulate that procreative incapacity is an absolute and determining cause for dissolution of a marriage. It is therefore fair to say that in the social, moral, and legal context we live in, there is minimal consensus to the effect that protection of the right to exercise procreative capacity is not an absolute obligation to procreate nor absolute prohibition to suppress the capacity. However, this right of free exercise of procreative capacity is not unanimously considered as an absolute right of the individual, and even less as a right, either absolute or unconditional, to limit or suppress that capacity.

Even those who speak in defence of an absolute right to use all available means to limit or suppress the capacity do agree that thoughtless acceptance of any request for sterilisation would, in certain circumstances, lead to abuse. Such abuse would be apparent to begin with in cases of requests for sterilisation from third parties on behalf of individuals considered to be incapable of consent. Even in cases of what is termed voluntary sterilisation, special features of today's life in society, such as younger age of first sexual intercourse, later age - increasingly so - of marriage and first child, frequency of divorce and remarriage with the wish to found a new family with a new spouse, all converge to suggest caution in the establishment of conditions in which sterilisation may be granted or offered.

If after debating these issues, it were decided to modify the legal and regulatory frameworks so as to grant legality to sterilisation for other reasons than "very serious medical reasons", it would still be necessary to decide on methodology to avoid over hasty or abusive sterilisation.

- One possibility would be to specify criteria allowing access to the procedure when there is no urgent therapeutic necessity. In fact, certain criteria such as previous procreation,

having reached a certain age or having had a certain number of children, or for the nulliparous, persistent and long established demand, are considered by many practitioners to be reliable indicators of future satisfaction if sterilisation is performed. Nevertheless, why certain criteria should be chosen in preference to others and by whom remains to be seen.

- Another possibility might be to set up a decisional framework, with time for reflection. Such criteria as were considered important, like for instance some of the above, could be those considered and discussed. However, within such a framework must be included the choice of who makes the final decision. Two points of view co-exist in society : there are those who consider that the physician should take the initiative of what is in fact a medical act, and those who take the opposite view, i.e. that in the field of reproduction, unless there is medical contra-indication, then the decision is in the hands of the person directly concerned.

The two approaches could also be merged : for instance there could be a definition of the decisional framework whilst setting certain limitations , such as sterilisation of minors being prohibited .

5. Providing strict rules for settlement of conflict

Must a doctor respond to any request for sterilisation recognised to be licit in a given legal framework ? Can medical and paramedical staff refuse to participate in a legally acceptable procedure ?

For some, refusal to practise sterilisation (or to take part in the procedure) may be a conscientious objection due to their own spiritual convictions or personal philosophy. Respect for such personal opinions does not exempt anyone, practitioners in particular) from referring any licit request to another consultant.

However, this refusal may be connected with a problem of deontology or of medical ethics which leads the practitioner or other medical and paramedical staff to doubt the wisdom of sterilisation in a certain set of circumstances. To settle such disagreement, or even conflict, particularly if consent is an issue, a strict procedure for decision making should be established thereby to explore the propriety of the request and/or of refusal to perform the procedure (see above on consent).

Conclusions

The above examination of problems arising in France in practical terms in connection with sterilisation leads CCNE to report a paradoxical situation : on the one hand, some individuals wishing to have access to contraceptive sterilisation run into difficulties because the law forbids it; on the other hand, others who quite frequently are amongst the more vulnerable, do not wish for sterilisation but have it offered to them in dubious circumstances as regards their consent. Furthermore, certain surgeons perform operations, the consequence of which is sterility, in full conformity with requirements for medical necessity, but in some cases neglect any obligation for informed and prior consent. CCNE finds that lack of clarity about existing law has as its counterpart divergent notions about what is acceptable in the case of sterilisation. The CCNE concludes that this state of affairs calls for a societal debate about circumstances in which it can be considered that suppression of procreative capacity is morally acceptable.

Several positions of principle could be proposed :

1. The first of these is that the Penal Code limits, and rightly so, circumstances in which sterilisation is legitimate to those where there is therapeutic necessity. This position is the closest to the concept of inviolability of the human body, considers that it applies more particularly to procreative capacity in view of the importance of this faculty in social,

personal, and familial terms, and for the future life of those concerned. Suppression of that capacity cannot simply, and for no other serious motive, be considered a personal right. If that is held as valid, it is up to substantive law to protect individuals to the fullest degree against any attempt to curtail that capacity. There exists no imperative moral reason, or any other reason, for modifying existing law.

Sterilisation in that case is only acceptable when it is required by therapeutic necessity or some other very weighty medical reason, and if the person concerned has been duly informed of these medical reasons and of the surgical risks, and has given consent. This position of principle excludes any request for sterilisation based on a desire on the part of the person concerned to suppress their fertility. Consequently, at its most strict interpretation, are also barred requests by third parties for contraceptive sterilisation on behalf of the mentally handicapped or the mentally deranged.

2. The second position is close to the first one, but is more receptive to the equity of some requests for sterilisation theoretically rejected by a completely strict interpretation of existing law. It is here considered that some flexibility could be introduced without completely overturning the principle of the inviolability of the human body, principle to which this view also grants priority. A range of fully justified and structured exceptions could be added, giving some leeway for contraceptive sterilisation based on less than major medical utility, but found more acceptable in certain social circumstances such as a woman's age, number of children, social and economic environment.

In practical terms, this added flexibility would be founded either on more lenient interpretations of the penal code as it stands, or on a bill specifically drafted for that purpose, with clear statement of criteria and situations for which sterilisation would be considered lawful.

Since this position maintains, as did the first one, priority of inviolability of the human body over the right a person has to suppress procreative capacity, requests for contraceptive sterilisation based on nothing else but the will of the person concerned to cease being fertile are bound to be excluded. This type of request can only be accepted if it can be made to fit in with the concept of medical utility. In this case, the acceptability of contraceptive sterilisation requests made by third parties on behalf of vulnerable individuals is unclear. Should this extension be given to the legal description of therapeutic necessity, standards of medical practice must needs be reviewed.

3. A third position is that the state of present practice reflects a deep change in anthropological conditions of procreation, which leads to accept as morally unobjectionable not just therapeutic sterilisation but also contraceptive sterilisation even though there may be no medical justification. In this case, it is up to moral beings to conduct their sexual behaviour and possible reproductive consequences in a free and responsible manner. Thus, this position states that the right of the individual to freely exercise his/her procreative capacity includes the legal possibility of limiting or even suppressing that capacity. The right does not contravene the principle of inviolability of the body if - and only if - pertinent information and time for reflection are provided to ensure a free and informed decision. This position implies in the long run a modification of law. The law should include a specific text on the subject of contraceptive sterilisation, and so provide a framework for exploring motives, both personal and medical, and for conveying pertinent information, so as to protect those concerned from over hasty decisions. The fact that contraceptive sterilisation would become licit would make it possible to take into account requests made by third parties for individuals considered incapable of making their own contraceptive choice. The text should also include strict evaluation and decision-making procedures such as those proposed by CCNE in Opinion n° 49 on contraception for the mentally handicapped, to ensure protection of the rights and interests of particularly vulnerable individuals. A legally recognised possibility of requesting one's own sterilisation for purely contraceptive reasons could be a source of difficulty for practitioners who, because of their convictions or for that matter their medical opinion, consider that no action should be taken in a particular set of circumstances. The law therefore should include a conscientious objection clause, with an

obligation to refer the patient to another practitioner and a set of procedures for decision making in case of conflict over whether sterilisation is appropriate.

CCNE considers it to be outside its purview to opt in favour of one or the other of these positions. In a democracy, the choice is up to society and the Legislator must have the final say. Members of CCNE however gave their personal opinions on these positions and the discussion was helpful in order to examine foreseeable or expected consequences of each of them. Out of this discussion, the following thoughts emerged :

The first position is the one which is most protective against hasty or abusive sterilisation. Protection is given by law which strongly curtails individual liberty as regards procreation, but this would be justified by the safeguarding of the principle of inviolability of the human body. However, by prohibiting sterilisation even in circumstances where it would be suitable and morally faultless contraception , this position leads to illicit sterilisation in conditions which do not adequately take into account the problem of consent. This is very probably the case in France at the present time.

The second position is less restrictive than the first insofar as it accepts a broader interpretation of derogation for therapeutic necessity. This interpretation reverts to implementation of the concept of indication by dialogue between physician and patient, so that the specificity of each individual case can be better observed. However, in the final analysis this means it will be up to the medical profession to define criteria for sterilisation. In these circumstances the limits of legitimacy in practice are much hazier and they would be inclined to change in line with changes in current practice. Furthermore, if current practice were to accept an extension in medical and social terms of therapeutic necessity, medical classifications would sometimes serve to respond to problems of another nature. This would lead to a confusion over what belongs to therapeutic justification and what is to be categorised as personal preferences and wishes of the person concerned. Over time, this position might facilitate improper or abusive interpretations of all kinds. The example of so-called eugenic sterilisation and its indications in the early part of this century is there to remind us of all the dangers brought about by confusion between therapeutic aims and solving the problems of society.

The third position, which is based on a different concept of the rights and responsibilities of a moral subject, is opposed to excessive restriction of individual liberties regarding the exercise of procreative capacity. Thus, although it does not reject the notion that therapeutic sterilisation requires guidelines and conditions, it accepts the view that motivated and well thought out willingness to stop or to abstain from procreation is a valid motive to suppress procreative capacity even though this constitutes a violation of the integrity of the human body without therapeutic necessity. It states that people have a right to take their own decisions as to whether they will continue or cease to be capable of procreation and that this is no violation of the human body as long as the right is exercised in conditions which guarantee free and informed decision. Those who defend this position do recognise however that it opens up the practice of sterilisation to situations in which personal over hasty and ill-advised decisions might be taken. Proof of this are requests for reanastomosis. Sterilisation differs from other methods of contraception in that it is in principle irreversible, as are risks connected to its performance and, in case of later regrets, and are also irreversible risks attendant to attempts at restorative surgery. It must be remarked that these risks are very different in men and women. Therefore this position of principle must address itself with thoroughness and directness to problems raised by ethical demands for pertinent information to be supplied and informed consent to be given. Adequate provision must be made in this respect. Very special attention must be paid to making necessary arrangements to protect the rights and interests of those for whom contraceptive sterilisation is requested by others. The history of sterilisation and some present day practices in parts of the world show that individuals and populations made vulnerable by a physical, mental, economic or social handicap are the most exposed to abusive sterilisation. Legal acceptability of this position rests on the quality of information, particularly as regards consequences and risks of the intervention, and on the level of

awareness of the implications of consent. It would be intolerable if advantage was taken of the situation to solve problems raised by sterilisation requests made by third parties on behalf of individuals incapable of giving consent. In the absence of free and informed consent, only imperious medical motive (such as absolute contraindication of progestogens) could justify sterilisation after demonstration of the fact that no reversible contraceptive method can be used.

This position of principle in fact accepts the idea that certain medical acts cannot qualify as therapeutic, but may nevertheless be justifiably requested by a patient. It therefore allows the possibility of conflict between patient and physician as to whether an intervention is opportune and well-founded, and in this case, measures and procedures for the settlement of such conflicts must be set in place. Indeed, decision to sterilise which must be informed and well thought out, would be in the hands of the person concerned in the last resort, but the necessary action for implementing the decision would require recourse to professional assistance entailing liability, in spite of the fact that no therapeutic necessity is found.

Regardless of the conclusions arrived at by public debate of the subject, CCNE considers that the cornerstone of any legal settlement of issues raised by sterilisation must remain the creation of a system in which precise information is given about procedures and their consequences, and in which consent or free and informed decision can be given by the person concerned. Even in the most restrictive system, a physician cannot be exempted from this obligation, with very rare exceptions. However, CCNE points out that any legal guarantee in this respect does not protect an individual from the constraints of personal and social circumstances which may force a choice which is not a free one.

Furthermore, CCNE points out that requests for contraceptive sterilisation made by third parties on behalf of the mentally handicapped clearly raise a moral issue, insofar as there can be doubt about the validity of consent given by the person concerned. CCNE draws attention to the need for specific provision to be made for such cases, irrespective of what kind of legal system governing sterilisation is adopted.

Society must debate upon the practice which it wishes to accept as legitimate, but remain aware that no legal solution can give absolute security against the risk of hasty or abusive sterilisation.

Considerations and proposals

In the light of the above analysis, two questions remain unanswered :

- Is destruction of one's own procreative capacity a right ? If so, is this right absolute or conditional ?
- Is destruction of another person's procreative capacity a right ? If so, in what circumstances and on what conditions ?

A current interpretation of non-specific articles in French penal law restricts licit practice of sterilisation to acts meeting two fundamental requirements : *therapeutic necessity* and *consent* of the patient. The only possible exception to prior consent is unpredictable *extreme urgency*. It might however be debatable whether moral options underlying this legal framework still appear rightful in view of major changes in the anthropology of procreation.

A modification of the judicial framework of the practice of sterilisation in France has to be the result of a political choice after democratic debate. It is not for the National Consultative Committee on Ethics to make such a decision, but it seeks to make a contribution to the debate in the form of ethical reflection and proposals.

1. Unambiguous restatement of the principle of consent

Whatever legal framework is found for sterilisation in France, CCNE considers to be fundamental the ethical principle underlying the interpretation of the current state of French law, which demands free and informed consent to the sterilisation procedure, its variable irreversibility depending on which technique is used, and risks of failure which grow with the possibility of reversal. Even when medical considerations motivate the procedure, there is still an obligation on the physician to give the patient all of the information which make a choice possible. The only possible derogation from that principle must be extreme urgency which, it should be remembered, is a rarity.

In the case of individuals deemed unable to give consent, opinion n° 49 by CCNE, on the subject of contraception for the mentally handicapped lists a number of conditions to be met before third parties may consider the possibility of surgical contraceptive sterilisation :

- Incapacity of the individual concerned must be defined by thorough and multidisciplinary evaluation. Care must be taken to make sure that the state of health and behaviour of the individual thought to be incapable is not likely to improve.
- The individual must be potentially fertile, sexually active, be at least about 20 years of age. In all cases, efforts must be made to obtain consent.
- Sterilisation can only be envisaged if proof is provided that no other form of contraception can, in practical terms, be used by the individual concerned. In such cases, the most potentially reversible form of sterilisation should be used.

To guarantee the most equitable conditions for evaluation and decision making in each particular case, opinion n° 49 offers a set of steps and methods to be followed in decision making :

- have other consultants besides the attendant physician examine the request made by the individual or his/her entourage;
- require those requesting sterilisation to give explicit reasons and justifications;
- provide for collective and extremely strict decision making processes, rather than delegation of authority, including the possibility of appealing to the courts in case of conflict, so that the rights and interests of disabled individuals are protected to a maximum degree;
- make sure that follow-up of the person concerned is provided whatever means of contraception or even sterilisation is finally chosen.

A very small number of specialised centres must be allowed to practise such operations to be performed by the most competent micro-surgeons.

In its Opinion, CCNE underlines the importance it attaches to collective decision-making. Indeed, evaluation of a request for sterilisation is too complex a task and too serious a decision for a single person to undertake. This kind of evaluation requires such expertise and entails so much responsibility that it seems essential for the task to be given to a commission composed of experts in the field of mental handi including physicians, legal advisers, and social workers. The commission must be entirely independent of the family or guardians of the mentally handicapped. This is also quite essential: it is clear that those making the request must not be both judge and party to the decision.

CCNE's Opinion also points out that sterilisation procedures for those incapable of consent most frequently concern mentally handicapped women. The aim is to protect them from pregnancy. It should not be forgotten however that this in no way protects them from sexual aggression. The problem of violence perpetrated on the mentally handicapped goes

beyond the limited problem of contraception and therefore requires separate and specific response bearing on the entourage and environment of the mentally handicapped.

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In spite of new techniques improving the probability of reversing sterilisation, what differentiates sterilisation from contraception is the will to arrive, by one single action, at permanent suppression of the capacity to procreate. Reversibility of a sterilisation technique is a concept based on probability. Even if probability is high for any given method, reversibility cannot be guaranteed for each individual. It therefore seems desirable to consider any act of sterilisation as a *permanent* suppression of procreative capacity. Doubts regarding a state of permanent sterility or explicit expectations regarding reversibility may reveal ambivalent feelings on the part of the author of the request and should lead surgeons and patients to defer decision.

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Must a doctor respond to any request for sterilisation recognised to be licit in a given legal framework ? Can medical and paramedical staff refuse to participate in a legally acceptable procedure ?

For some, refusal to practise sterilisation (or to take part in the procedure) may be a conscientious objection due to their own spiritual convictions or personal philosophy. Respect for such personal opinions does not exempt anyone, practitioners in particular) from referring any licit request to another consultant.

However, this refusal may be connected with a problem of deontology or of medical ethics which leads the practitioner or other medical and paramedical staff to doubt the wisdom of sterilisation in a certain set of circumstances. To settle such disagreement, or even conflict, particularly if consent is an issue, a strict procedure for decision making should be established thereby to explore the propriety of the request and/or of refusal to perform the procedure (see above on consent).

Conclusions

The above examination of problems arising in France in practical terms in connection with sterilisation leads CCNE to report a paradoxical situation : on the one hand, some individuals wishing to have access to contraceptive sterilisation run into difficulties because the law forbids it; on the other hand, others who quite frequently are amongst the more vulnerable, do not wish for sterilisation but have it offered to them in dubious circumstances as regards their consent. Furthermore, certain surgeons perform operations, the consequence of which is sterility, in full conformity with requirements for medical necessity, but in some cases neglect any obligation for informed and prior consent. CCNE finds that lack of clarity about existing law has as its counterpart divergent notions about what is acceptable in the case of sterilisation. The CCNE concludes that this state of affairs calls for a societal debate about circumstances in which it can be considered that suppression of procreative capacity is morally acceptable.

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that is held as valid, it is up to substantive law to protect individuals to the fullest degree against any attempt to curtail that capacity. There exists no imperative moral reason, or any other reason, for modifying existing law.

Sterilisation in that case is only acceptable when it is required by therapeutic necessity or some other very weighty medical reason, and if the person concerned has been duly informed of these medical reasons and of the surgical risks, and has given consent. This position of principle excludes any request for sterilisation based on a desire on the part of the person concerned to suppress their fertility. Consequently, at its most strict interpretation, are also barred requests by third parties for contraceptive sterilisation on behalf of the mentally handicapped or the mentally deranged.

2. The second position is close to the first one, but is more receptive to the equity of some requests for sterilisation theoretically rejected by a completely strict interpretation of existing law. It is here considered that some flexibility could be introduced without completely overturning the principle of the inviolability of the human body, principle to which this view also grants priority. A range of fully justified and structured exceptions could be added, giving some leeway for contraceptive sterilisation based on less than major medical utility, but found more acceptable in certain social circumstances such as a woman's age, number of children, social and economic environment.

In practical terms, this added flexibility would be founded either on more lenient interpretations of the penal code as it stands, or on a bill specifically drafted for that purpose, with clear statement of criteria and situations for which sterilisation would be considered lawful.

Since this position maintains, as did the first one, priority of inviolability of the human body over the right a person has to suppress procreative capacity, requests for contraceptive sterilisation based on nothing else but the will of the person concerned to cease being fertile are bound to be excluded. This type of request can only be accepted if it can be made to fit in with the concept of medical utility. In this case, the acceptability of contraceptive sterilisation requests made by third parties on behalf of vulnerable individuals is unclear. Should this extension be given to the legal description of therapeutic necessity, standards of medical practice must needs be reviewed.

3. A third position is that the state of present practice reflects a deep change in anthropological conditions of procreation, which leads to accept as morally unobjectionable not just therapeutic sterilisation but also contraceptive sterilisation even though there may be no medical justification. In this case, it is up to moral beings to conduct their sexual behaviour and possible reproductive consequences in a free and responsible manner. Thus, this position states that the right of the individual to freely exercise his/her procreative capacity includes the legal possibility of limiting or even suppressing that capacity. The right does not contravene the principle of inviolability of the body if - and only if - pertinent information and time for reflection are provided to ensure a free and informed decision. This position implies in the long run a modification of law. The law should include a specific text on the subject of contraceptive sterilisation, and so provide a framework for exploring motives, both personal and medical, and for conveying pertinent information, so as to protect those concerned from over hasty decisions. The fact that contraceptive sterilisation would become licit would make it possible to take into account requests made by third parties for individuals considered incapable of making their own contraceptive choice. The text should also include strict evaluation and decision-making procedures such as those proposed by CCNE in Opinion n° 49 on contraception for the mentally handicapped, to ensure protection of the rights and interests of particularly vulnerable individuals. A legally recognised possibility of requesting one's own sterilisation for purely contraceptive reasons could be a source of difficulty for practitioners who, because of their convictions or for that matter their medical opinion, consider that no action should be taken in a particular set of circumstances. The law therefore should include a conscientious objection clause, with an obligation to refer the patient to another practitioner and a set of procedures for decision making in case of conflict over whether sterilisation is appropriate.

CCNE considers it to be outside its purview to opt in favour of one or the other of these positions. In a democracy, the choice is up to society and the Legislator must have the final say. Members of CCNE however gave their personal opinions on these positions and the discussion was helpful in order to examine foreseeable or expected consequences of each of them. Out of this discussion, the following thoughts emerged :

The first position is the one which is most protective against hasty or abusive sterilisation. Protection is given by law which strongly curtails individual liberty as regards procreation, but this would be justified by the safeguarding of the principle of inviolability of the human body. However, by prohibiting sterilisation even in circumstances where it would be suitable and morally faultless contraception , this position leads to illicit sterilisation in conditions which do not adequately take into account the problem of consent. This is very probably the case in France at the present time.

The second position is less restrictive than the first insofar as it accepts a broader interpretation of derogation for therapeutic necessity. This interpretation reverts to implementation of the concept of indication by dialogue between physician and patient, so that the specificity of each individual case can be better observed. However, in the final analysis this means it will be up to the medical profession to define criteria for sterilisation. In these circumstances the limits of legitimacy in practice are much hazier and they would be inclined to change in line with changes in current practice. Furthermore, if current practice were to accept an extension in medical and social terms of therapeutic necessity, medical classifications would sometimes serve to respond to problems of another nature. This would lead to a confusion over what belongs to therapeutic justification and what is to be categorised as personal preferences and wishes of the person concerned. Over time, this position might facilitate improper or abusive interpretations of all kinds. The example of so-called eugenic sterilisation and its indications in the early part of this century is there to remind us of all the dangers brought about by confusion between therapeutic aims and solving the problems of society.

The third position, which is based on a different concept of the rights and responsibilities of a moral subject, is opposed to excessive restriction of individual liberties regarding the exercise of procreative capacity. Thus, although it does not reject the notion that therapeutic sterilisation requires guidelines and conditions, it accepts the view that motivated and well thought out willingness to stop or to abstain from procreation is a valid motive to suppress procreative capacity even though this constitutes a violation of the integrity of the human body without therapeutic necessity. It states that people have a right to take their own decisions as to whether they will continue or cease to be capable of procreation and that this is no violation of the human body as long as the right is exercised in conditions which guarantee free and informed decision. Those who defend this position do recognise however that it opens up the practice of sterilisation to situations in which personal over hasty and ill-advised decisions might be taken. Proof of this are requests for reanastomosis. Sterilisation differs from other methods of contraception in that it is in principle irreversible, as are risks connected to its performance and, in case of later regrets, and are also irreversible risks attendant to attempts at restorative surgery. It must be remarked that these risks are very different in men and women. Therefore this position of principle must address itself with thoroughness and directness to problems raised by ethical demands for pertinent information to be supplied and informed consent to be given. Adequate provision must be made in this respect. Very special attention must be paid to making necessary arrangements to protect the rights and interests of those for whom contraceptive sterilisation is requested by others. The history of sterilisation and some present day practices in parts of the world show that individuals and populations made vulnerable by a physical, mental, economic or social handicap are the most exposed to abusive sterilisation. Legal acceptability of this position rests on the quality of information, particularly as regards consequences and risks of the intervention, and on the level of awareness of the implications of consent. It would be intolerable if advantage was taken of the situation to solve problems raised by sterilisation requests made by third parties on

behalf of individuals incapable of giving consent. In the absence of free and informed consent, only imperious medical motive (such as absolute contraindication of progestogens) could justify sterilisation after demonstration of the fact that no reversible contraceptive method can be used.

This position of principle in fact accepts the idea that certain medical acts cannot qualify as therapeutic, but may nevertheless be justifiably requested by a patient. It therefore allows the possibility of conflict between patient and physician as to whether an intervention is opportune and well-founded, and in this case, measures and procedures for the settlement of such conflicts must be set in place. Indeed, decision to sterilise which must be informed and well thought out, would be in the hands of the person concerned in the last resort, but the necessary action for implementing the decision would require recourse to professional assistance entailing liability, in spite of the fact that no therapeutic necessity is found.

Regardless of the conclusions arrived at by public debate of the subject, CCNE considers that the cornerstone of any legal settlement of issues raised by sterilisation must remain the creation of a system in which precise information is given about procedures and their consequences, and in which consent or free and informed decision can be given by the person concerned. Even in the most restrictive system, a physician cannot be exempted from this obligation, with very rare exceptions. However, CCNE points out that any legal guarantee in this respect does not protect an individual from the constraints of personal and social circumstances which may force a choice which is not a free one.

Furthermore, CCNE points out that requests for contraceptive sterilisation made by third parties on behalf of the mentally handicapped clearly raise a moral issue, insofar as there can be doubt about the validity of consent given by the person concerned. CCNE draws attention to the need for specific provision to be made for such cases, irrespective of what kind of legal system governing sterilisation is adopted.

Society must debate upon the practice which it wishes to accept as legitimate, but remain aware that no legal solution can give absolute security against the risk of hasty or abusive sterilisation.