al Consultative Ethics Committee for Health and Life Sciences

35, rue Saint-Dominique
75700 Paris
Tel. +33 (0)1 42 75 66 42
www.ccne-ethique.fr

Opinion n° 126 (15 June, 2017)

CCNE Opinion on Societal Requests for Medically Assisted Reproduction (MAR)

Composition of the Working Group
François ANSERMET (Rapporteur)
Christiane BASSET
Marianne CARBONNIER-BURKARD
Laure COULOMBEL
Anne-Marie DICKELÉ
Frédérique DREIFUSS-NETTER (until 2016)
Pierre-Henri DUÉE
Jean-Noël FIESSINGER
Florence GRUAT
Marie-Angèle HERMITTE
Frédérique KUTTEN (Rapporteur)
Xavier LACROIX (until 2016)
Michelle MEUNIER
Francis PUECH
Dominique QUINIO
Jean-Louis VILDÉ
Bertrand WEIL
Frédéric WORMS (Rapporteur)

Personalities auditioned
Marie-Josèphe BONNET, Specialist, History of Art and Women
Louis BUJAN, President of the *Fédération française des Cecos*
Colette CHILAND, Clinical Psychologist, *Université Paris V-René-Descartes*
Muriel FABRE-MAGNAN, Jurist, *Université Paris 1 Panthéon Sorbonne*
Marie-Anne FRISON-ROCHE, *Sciences Po (Paris)*
René FRYDMAN, Gynaecologist, specialist in reproduction and MAR development
Pierre LÉVY-SOUSSAN, Psychiatrist; Psychoanalyst and Director of Paris CMP
Karen PARIZER-KRIEF, (EHESS Paris)
Alain PROCHIANTZ, Neurobiologist, Director of the *Centre Interdisciplinaire de Recherche en Biologie au Collège de France*; Administrator, *Collège de France*
Jacques TESTART, Biologist (procreation), Founder and Honorary President of the *Fédération des biologistes de la fécondation et de la conservation de l'œuf*
Irène THÉRY, Sociologist, specialist on family matters
Jean-Pierre WINTER, French psychoanalyst and author
Yohann ROSZÉWITCH, (Advisor for fighting LGBT phobia, Interministerial delegation for fighting racism and antisemitism), Delphine PLANTIVE-POCHON
Alexandre URWICZ (President and co-Founder of the *Association Des Familles Homoparentales),* François RICO (Spokesman for the *Association Des Familles Homoparentales*)

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Foreword

Medically assisted reproduction (MAR) technology includes a number of techniques, developed by the medical professions and subsequently ordered by legislators, to treat various forms of infertility revealing physical dysfunctions. Society's[1] requests for access to MAR relate to the possibility of using these techniques for other purposes than treatment for pathological infertility. An increase in the number of such requests for MAR can now be observed which previously were not expressed or only to a limited extent. Underlying reasons are that society's expectations are evolving, French law and the law in some other countries have changed and technical innovation.

In this context, CCNE wished to review its thinking on the sum of society's demands for MAR. Ethical considerations refer to three of these demands: (1) autopreservation of young women's oocytes; (2) requests for MAR from female same-sex couples or from women on their own; (3) requests for gestational surrogacy, from heterosexual couples and also from male same-sex couples and from single men.

CCNE has developed a method to analyse these different requests for MAR, so as to develop pointers and criteria to clarify ethical reflection. These include technical and biological considerations as well as those changes in the organisation of human relationships which are part of the process. The method — explained in this chapter and applied to each case and each technique — can be used to identify and define the main issues from which originated views on recent demands for access to medically assisted reproductive technology.

I. The historical, legal and international context

Since the end of the 1960s, considerable social pressure has been deployed in favour of self-determining human procreation. Authorising the prescription of contraceptives, followed by the decriminalisation of voluntary termination of pregnancy (VTOP), have contributed to setting sexuality free from procreative intent. The wish, on the part of a couple to "have a baby" when they consider the timing is right has become a generally accepted claim. It implies recourse to medically assisted reproductive technology when spontaneous procreation meets with difficulty. The first of such techniques was donor insemination (DI). The medical teams who created the CECOS[2] to organise the procedure took care to list ethical principles which became law in 1994. The system was designed to deliver a medical remedy to an infertility problem and provide the future child with the kind of family environment that was customary at the time.

The French bioethics laws therefore made a number of choices. Donor insemination, like other forms of MAR, was reserved solely for couples, "*…a living man and woman, of childbearing age, married or able to provide proof of cohabitation for at least two years…*". Article L.152-2 of the Code of Public Health made it absolutely clear that the procedure was intended to *"...remedy infertility whose pathological nature had been medically diagnosed. It may also be used to avoid transmission to the*

[1] A societal indication is a demand that is unrelated to the specific indications authorised by law, these being infertilities caused by a pathological condition.

[2] *Centres d'étude et de conservation des oeufs et du sperme*, (Centres for the study and conservation of eggs and sperm), first established at the *Kremlin-Bicêtre* (Paris region) and *Necker-Enfants malades* (Paris) hospitals.

child of a particularly severe disease".

The assertion of such principles authenticated the notion that MAR was a medical[3] procedure designed to alleviate a pathological shortcoming (infertility, risk of transmitting a disease, treatment bringing about sterility justifying autopreservation of gametes). Legislators therefore chose to restrict the use of reproductive technology for exclusively therapeutic medical purposes.

Apart from choosing to reserve MAR for pathological cases of infertility, legislators also opted in favour of two fundamental principles concerning the donation of gametes: gratuitousness and anonymity. *(see Annex 1).* To date, they have never changed their views on these restrictive principles. CCNE, in recent Opinions, has only considered some of the aspects of MAR issues[4] of a medical nature.

A review of the international context reveals the great diversity of legislation governing access to MAR.

II. Technological disjunctions, new relationships, and their consequences

It was not just their availability that gave rise to increased requests for access to existing MAR techniques; evolving family structures also stimulated the new form of demand which is designated here as societal. These societal requests raise ethical issues, be they related to the new uses the techniques are put to or the new family environments that such uses contribute to the creation of. Because personal values people hold and their relationship to their origins, to the differences between the sexes and to successive generations are in question when such issues are raised, debate on such subjects is easily heated.

We have structured our reflection on societal demands for the use of MAR techniques by defining a method of analysis based on three points of reference:

- noting the "disjunctions" introduced by MAR techniques between procreation, as a biological fact, and filiation as a legal recognition[5], and fragmenting this process into separate phases. The disjunctions are simply factual; they are not ethical assessments or evaluations;
- the new forms of human relationships which are constructed when societal MAR demands are formulated, between those making them, those who are supplying the biological resources, the child born as their outcome, third parties in the medical professions or from society;
- the consequences of these new interactions, be they beneficial or constituting a risk. By "risk", we mean the possibility of harm or suffering caused by the use of MAR techniques to one or the other of the participants.

The aim of this method of analysing problems is to propose a method which everyone can use to orient their own thinking on the subject. It also serves to identify what we have described as "stumbling blocks" which need thinking about and clarification.

II-1. Technological disjunction

MAR techniques, regardless of whether they are used for a medical or societal purpose, disconnect the

[3] MAR not being literally a treatment, since it does not restore the failing function which it simply alleviates.

[4] In its Opinion n° 110 on issues raised by gestational surrogacy (GS) CCNE considered that this was not an ethically acceptable procedure, *even though it was performed in a medical environment and would be an extra chance for certain infertile couples.* In Opinion n° 113 "Request for medically-assisted reproductive technology after the death of the male partner", it was considered preferable to continue prohibition, although certain members of the Committee were of the opinion that a woman should be authorised, after her spouse's death, to the transfer of her "spare" embryos stored after IVF performed with her dead spouse's consent when he was alive.

[5] For the meaning to attach to these various expressions, see the Glossary.

various phases — origin, sexuality, procreation, gestation, birth and filiation — between procreation and filiation, with the consequence of isolating procreation as such. It is between procreation and filiation that other disjunctions materialise.

Disjunction between sexuality and procreation, between procreation and gestation
MAR techniques break the continuity between sexuality and the process of procreation: hence, obtaining gametes *ex corpore* and fertilisation to obtain an embryo are discontinuous and independent phases. Processing the embryo itself, separately from the body and sometimes cryopreserved before its transfer to the uterus, disconnects the link between procreation and gestation. With *in vitro* fertilisation (IVF) with donor oocytes or gestational surrogacy (GS), the embryo can be transferred into the uterus of a woman who did not donate the oocytes.

Disjunction between a person and the components of that person's body in both time and space
A separation of any kind between person and body component requires that the component be stored outside the body and then relocated, possibly in another body. The procedure takes on a special significance with gametes, which carry heredity and perpetuate a genealogy, therefore passing on both a genetic and a social inheritance. Cryoconservation of spermatozoa and oocytes removes them from the passage of time between the moment of extraction and the moment of use in the process of procreation[6]. Therefore, oocytes sampled when they are "young" would be transferred after fertilisation into a body which, in the meantime, would have aged (*see Chapter 2).* Similarly, cryoconservation of spare preimplantation embryos obtained during an IVF procedure and not immediately transferred to a uterus, puts a stop to their development. Such discontinuities could even, potentially, lead to skipping generations.

Disjunction between genetic transmission and filiation
Gametes carry genetic heredity (*via* the DNA sequence). Procreation with donor sperm, oocytes or embryos dissociates the genetic (maternal or paternal) lineage from filiation. Gamete donors (or the couple donating the embryo) are willing to relinquish a very personal item carrying their genetic heredity; by accepting this gift, beneficiaries are willing to interrupt their own genetic lineage. Embryo donation is distinctive in that the two genetic lines, both maternal and paternal, are not those of the couple accepting the embryo.

Before oocyte donation became a possibility, the situation could be described as "*mater certa est, pater incertus"*. With oocyte donation, there is a dissociation between genetic transmission and filiation on the maternal side: the woman giving birth will be automatically recognised as the child's mother by right of filiation. Only through technology can such disjunction be achieved. A double uncertainty (as far as the genetic heritage is concerned) could even be created, compounding "*pater incertus"* with *"mater incerta"* if oocyte donation and sperm donation were to be combined[7]. When oocyte donation is added to "gestational surrogacy" — currently prohibited in France — a dual uncertainty, genetic and gestational is created. All modes of transmission, both maternal and paternal, become uncertain. The certainty of motherhood has given way to the uncertainty of motherhood.

II-2. Consideration of the relationships created by MAR and their consequences
Division of the procreation process into separate phases requires the intervention of a third party. This is true of any MAR procedure, but the societal demands we are examining create new kinds of relationships with these third parties which need to be considered so that all their consequences can be evaluated. There is a fundamental need to recognise that these techniques offer new ways of giving birth to children and thereby of constructing new relationships, but when avoiding one form of hardship

[6] Use which could become posthumous, which is currently forbidden by law, but the *Conseil d'Etat* (highest administrative jurisdiction) recently challenged this prohibition . (CE, 31 May 2016, Mme C. A. N° 396848).

[7] Procreation with a double gift of gametes is currently prohibited by Art. L2141-3 of the Code of Public Health.

we must be sure we are not creating another form of unhappiness, particularly if it turns out that it is contrary to the best interests of the child born of this medically assisted reproduction process.
There are several kinds of situations and relationships to consider: relationship to oneself, to the child and to society, between the medical professions and the applicant; the introduction of a third party external to the applicant couple.

Relationship with self always involves relationships with others
While requests for MAR are partly induced by social evolution insofar as society is now more readily willing to accept new types of lifestyles or family relationships, they are also the result of individual decisions taken by women, consistent with their life plans, their intentions and their values. An autonomous individual who has been thoroughly informed, is capable of thinking over and processing the information received, of measuring risks and of making a fully conscious decision. Technical control exercised over procreation is perhaps a factor in favour of a more personal and voluntary comprehension of the subject, reinforcing the wish for autonomy expressed by a couple or by an individual deciding to "have a baby" when they themselves consider the time is ripe. This wish for autonomy also expresses a claim for equality in access to the gift of gametes, with the justification provided by awareness of oneself as a free individual, at liberty to take decisions concerning one's own body. However, exercising this freedom necessarily involves other people (members of the medical professions, a donor, children, society; *see Chapter 5*).

Relationships involving the child
Relationships involving the child are transformed twice over by MAR technology that makes "planning a child" possible and creates a parental relationship in situations that are biologically unattainable. The transformation is in the representation that applicants have of the future child and in the child's relationship to his or her origins. For children born of the various forms of MAR, one of the relationships which will play an important role in the construction of identity is the relationship with origins. In particular, they need to acknowledge that although the parental couple is made up of one genetic parent and a "social" parent with which they have no genetic tie, they also owe their lives to a donor, who must remain anonymous to comply with French law (*see Annex 1*). In France, past experience of MAR with DI in heterosexual couples show that some children entirely accept their social and legal filiation, whereas others see it as unacceptable deprivation, but it is not entirely clear whether this is due to the factual situation itself or to the legally enforced anonymity. The lives of children born or not born of artificial insemination in homoparental or single parent families have been the subject of more recent studies, but the methodology was frequently faulty and without statistical value. The studies are presented and discussed in Chapter 3 and corresponding annexes. Regardless of which disjunctions were involved in their conception, children will need to reassemble the pieces of the "puzzle" to reconstruct a history.

Relationships with the medical third party
MAR of any kind must have a medical dimension. With MAR we need to differentiate between two interpretations of the word "medical". There is the "medical objective" as defined by law, which for MAR is to treat medically diagnosed infertility. And in the current legal context, MAR procedures are medical or biomedical practices applied in an exclusively treatment-related environment although their use involves a variety of specific participants (members of the medical professions, but also non members of the medical professions.

In societal demands for access to MAR, the techniques are, as above, medical ones[8]; their implementation implies a specific relationship between applicants and the medical third parties for some length of time, in particular as regards deontological and technical relations such as the obligation to inform, to obtain or give consent, to care for with diligence and to monitor. In particular, all the professionals involved must deliver detailed information on the burdens and constraints of the technical

[8] Except for the techniques to arrive at a diagnosis which, in that case, are not necessary.

procedures[9]. But what would become of this relationship if, to respond to societal demands, practitioners were distanced from the therapeutical connection which is their specificity?

Relationships with providers of biological resources
MAR procedures involve other participants besides members of the medical professions, in particular gamete donors or, in countries where GS is authorised, "surrogate" mothers.

Relationships with gamete donors.
They are the most frequent third party. It is worth noting that this relationship with the third party "supplying" the gametes does not necessarily involve a gift. As in any exchange relationship, gametes may be given but they may also be the subject of a commercial transaction. It was for ethical reasons that French legislators preferred donation for the medical MAR indications, so that there is necessarily no charge, therefore no commercial relationship, and donors act on a voluntary basis without any legal obligation. Were societal indications entertained, the model and the primacy of donation would be called into question with the risk of gamete commercialisation (*see Chapter 3*).

Relationships with the gestational carrier.
Several kinds of specific relationships are created with the woman described as the "gestational carrier" or "surrogate mother": the close relationship that binds the "surrogate" to the foetus and therefore to the future child throughout pregnancy (including *via* biological and epigenetic traits, marks of the environment to which woman — and therefore child — are exposed during gestation); the relationships she may wish to have with the "intended parents"; finally, those which concern the family and the kith and kin of the surrogate mother herself. In *Chapter 4*, we will discuss issues of donation and commerce and risks of offence, including social offence.

Relationships with society
Society is a third party appearing at various phases of the process leading from procreation to filiation. It plays no part in the intimate sexual relationship, but recourse to technology intrudes on this intimacy and raises the issue of providing a structure for this technical procedure. The fact that it involves a certain number of collective resources and leads to the birth of children is generally sufficient to warrant the intervention of lawmakers[10]. Legislation regulates MAR technology (authorises it or not, organises it or not, finances it or not) while seeking a balance between individual autonomy and the consequences of that autonomy on third parties who must be protected from the risk of unfair treatment or social pressure.
In the French health care system as it now stands, physicians are not medical service providers that applicants are allowed to approach in order to respond to all their procreative wishes. The fact of reserving MAR for pathological infertility may be seen as a break with the principle of equality of access for those wishing to use reproductive technology. This difference in treatment could also, on the contrary, be considered as justified by the different circumstances of the various applicants.

Society is deeply involved in the allocation of the various resources devoted to health care and, insofar as it is related to the subject in hand, into MAR: this includes human resources, workloads and the cost of care. Although, so far it has been universally acceptable to finance action to remedy pathological infertility entirely at the expense of the community, the issue would arise in a different context in the event of an extension to societal demands for MAR.

Society then has to organise the consequences for legislation on filiation of the appearance of a third party in the procreation process. Laws on filiation will need to integrate the biological contributions of

[9] It is clearly stated in the information given by the Code of Public Health in article 2141-10, subpara.2, that possibilities of failure, constraints and complications must be mentioned.
[10] According to bioethics legislation, the law as elucidated by various deliberative bodies, the Estates General and Citizens' Conferences, expresses the political choices determining the limits set on the exchange of products of the human body and the rules for the use of biomedical techniques, MAR included.

third parties to what French law refers to as "the parental project". At the present time, French law has chosen: (i) presumption of paternity for the social father without the possibility of disputing this paternity, even in the event of DI[11]; (ii) to prohibit the possibility of disavowal of paternity; (iii) to deny right of access to origins in the event of possible DI; (iv) to the possibility of adopting the spouse's child for the wife of the mother. In the event of MAR requested by all-male or all-female couples, by women or men on their own, or by transsexuals, the laws on filiation would need to be reorganised.

To conclude, the existence within Europe of several different systems of law as regards bioethics means that it is possible to go abroad for procedures prohibited in France. It may be considered that this amounts to the circumvention of a democratic choice or else that it is a flexibility giving access to European, or even international opportunities. When DI is performed in another country, the resulting pregnancy benefits from full French health care management when the woman returns to France[12]. Conversely, with GS, the intended parents are confronted with a certain number of legal difficulties (*see Chapter 4*).

III. Stumbling blocks

This method of analysis used for various fields of investigation regarding societal demand for MAR has been an opportunity to consider a number of questions which arise again and again. CCNE considers that it is on these questions that reflection is needed: because they are the source of both perplexity and disagreement, they are stumbling blocks. Binary answers with a yes or a no, acceptance or rejection, authorisation or prohibition would not be adequate. These stumbling blocks need to be discussed, whatever the answer. It is important to spell them out and elucidate them, as otherwise they could alone block any progress in reflection, whatever the response that is finally given to societal demands for medically assisted reproduction.

[11] "For a married couple, paternal filiation is established automatically: the husband is presumed to be the father's child. His name is shown on the birth certificate. He need not acknowledge the child nor take any particular step to establish the child's filiation". (*Article 312 of the Code Civil*.)

[12] AI conception with donor sperm, if conditions contradict French law, is forbidden on French territory; but all pregnant women benefit from full French health care management during pregnancy and delivery, regardless of the mode of conception.

Chapter 2
Reflection on the proposal for autopreservation of young women's oocytes

Introduction

An increasing number of couples consult specialist centres for the treatment of infertility because, despite their eagerness to have a child, they are not achieving pregnancy. Doctors specialising in female infertility draw attention to the growing number of women wanting to have a child at an age where their chances of carrying one to term are dwindling due to the reduced ovarian follicle capital which is not favourable to successful IVF (in vitro fertilisation) using their own oocytes. It may then be necessary to resort to oocyte donation from a younger woman. Due to the scarcity of oocytes for donation, in France waiting times are rarely compatible with the age limit set on a MAR procedure.

Progress in oocyte cryoconservation, together with the relative rarity of oocyte donation in France and the increasing numbers of requests pending, have encouraged legislators to modify the recruitment policy for gamete donors. Introduced by the July 7th 2011 law on bioethics, oocyte donation has been authorised for nulliparous women. In compensation for their gift, autopreservation of their own gametes is on offer.

Continuing on the same path, specialists treating female infertility suggest that it would be wise to offer nulliparous women who are not donating the possibility of preserving their own oocytes while they are still young.

The context in which the possibility arose of autopreservation of oocytes, as a "precautionary" measure, is that the age at which women bear their first child in developed countries is advancing and this new form of use of a recent technique involves new considerations and constraints. CCNE considered there was good reason to reflect on how this could be achieved, and to examine the benefits claimed as well as the potential risks of oocyte autopreservation for young women in general. On this subject, we will refer to the conditions prevailing when the 2011 law was voted, which allowed autopreservation providing oocyte donation had taken place.

I. The history of legislation on oocyte autopreservation (*see Annex 2*)

Originally, MAR was intended to provide a medical response to infertility problems for people living together, of different genders and unable to procreate spontaneously. When legislators voted the 1994 bioethics law, they organised gamete donation based on anonymity and gratuitousness, and only allowed women who had already produced offspring to become donors. The intention behind this limitation was to enable oocyte donors to measure the significance of their donation and only consent to doing so if they were entirely and freely committed to the action, without any other motivation besides altruism. There was also the intention of avoiding the risk that nulliparous women who had consented to be donors would later be unable to have children.

Gamete autopreservation is only authorised in France in the case of pathologies or treatments affecting fertility (sterility as a result of treatment for cancer, genetic or autoimmune disorders, cf the 1999 decree and the 2004 law[13]). In 2011, legislators provided for a new possibility: oocyte autopreservation as a counterpart for oocyte donation (*see Annex 2*).

These two possibilities do not include autopreservation of young women's oocytes, so-called "precautionary" autopreservation, which is currently not authorised in France.

[13] Decree dated January 12, 1999 on good clinical and biological practices in medically assisted reproduction.

II. "Precautionary" oocyte autopreservation offered to all women

The tardiness of first pregnancies is increasing the frequency of age-related female infertility and the number of referrals to approved MAR[14] centres.
For women who did not have the opportunity of having the child they wanted earlier in life, the autopreservation of their oocytes when their fertility was still at its best would mean that they could use their own oocytes, preserved when they were younger, even if they delayed having children and then ran into difficulties. Although the follicle capital would have declined, the MAR success rate would be close to that of a MAR procedure at the time when the eggs were preserved. The success rate is determined mainly by the number and quality of the oocytes used in the procedure, but the oocyte puncture protocol is still burdensome and success is not a certainty (*see Annex 3*). Other factors contributing to a successful birth is the womb's aptitude for embryo implantation and the cardiovascular and metabolic health of the mother during gestation.
Most women would probably bear children spontaneously and would not therefore need to draw on their store of cryopreserved oocytes. Should that be the case and if women agreed to donate them, a supply of "young" oocytes would be available for MAR procedures.

III. Issues raised by the proposal to provide "precautionary" oocyte autopreservation for young childless women

The possibility of extending oocyte autopreservation to young women who are not infertile calls into question the restrictions set out by law n° 2004-800 dated 6 August 2004. Discussion of these principles is appropriate because society's views have evolved, as has the definition of the dividing line between "normal" and "pathological", because oocyte ageing must be taken into account and also because of technical developments, not the least of which is the possibility of cryoconservation by oocyte vitrification (*see Annex 3*).
We shall be considering these issues, using the method we outline in Chapter 1, i.e. setting out the disjunctions inherent to the procedure, a discussion of the relationships it creates and the consequences for the young women to whom the opportunity to benefit from oocyte autopreservation would be extended.

III-1. Disjunctions

As with any MAR procedure, harvesting and storing gametes *ex corpore* create a *disjunction between sexuality and procreation*. Oocyte autopreservation, however, involves specific disjunctions:
(i) it introduces an immediate dissociation between a person and components of that person's body, that is the gametes which are unique by their value as a symbol, since by essence they are able to give life and it forces a woman to use technology — an IVF procedure — to procreate at a later time. These women will know that somewhere in a gamete bank is a part of themselves, which may never be put to any use at all or, at best, only rarely.
(ii) Cryopresevation of gametes "*exonerates them from the passage of time*" between the time when they are sampled and the time when they are used for procreation. It changes the order in time of the procreative phases: oocytes are first separated from a still youthful body and reintegrated at a later date — after *ex corpore* fertilisation — into a body that the passage of time will not have spared and which will carry a child to term with less ease.
(iii) From this hiatus a third disjunction is born: it concerns the future of the oocytes. As noted above, the vast majority of women will give birth naturally. They will therefore need to decide, sometimes many years after the autopreservation procedure has been completed, on the future fate of their cryopreserved oocytes.
After consideration of these disjunctions, the new forms of relationships created by this particular "procreative model" offer need to be examined.

III-2. New relationships

[14] Statistical records show that the development in the number of MAR attempts has increased by 8.3% since 2009 (*see Annex 3*).

They are of three kinds: relationship with self and with society; with the medical professions; the introduction of a third party relating with the woman concerned.

Relationship with self and the demand for autonomy
Oocyte autopreservation early in life creates a new relationship with oneself: the possibility of procreating when a woman wishes, with exemption from the biological constraint ageing oocytes.
This meets the claims for autonomy which today's society voices, more specifically as regards the freedom to do as one wishes with one's own body and to take decisions about one's own health. Autonomy would still not, however, be complete since a male partner or male gametes are needed for fertilisation. It is also incomplete since there is no guarantee of success.
Oocyte autopreservation, designed as a "precaution" against the fall in oocyte capital with the passing of time, can be experienced and/or presented to women as an "insurance policy": but it is unnecessary insurance since most of them will probably bear children spontaneously (*see below*); and also a pseudo insurance since autopreservation will necessitate an IVF-ICSI procedure (*intracytoplasmic sperm injection, see the glossary)* with their own stored oocytes, with a success rate estimated at 60-70% (*see Annex 3*).

Relationship with the medical third party
No MAR procedure can do without a medical dimension. Autopreservation of oocytes as a "precaution" generates early medical intervention although there is no immediate need for it, and therefore introduces new relationships with the medical professions. These will be mostly technical when oocytes are extracted and preserved and later, when they are used for a MAR procedure which will necessarily involve an ICSI procedure.

"Precautionary" oocyte autopreservation differs from procedures for harvesting and preserving body components from people affected by a diagnosed pathology so that they can be used later for a clear therapeutic purpose. Existing legislation as set out in the Code of Public Health, reserves the use of cells or tissues for known or probable pathologies. Apart from the sampling of gametes before a sterility-inducing treatment (generally for cancer) to preserve fertility (regulated by Article L2141 of the Code of Public Health), there is also the possibility of harvesting blood before elective surgery, or skin for an autologous graft (extensive burns) or haematopoietic bone marrow stem cells or peripheral blood[15].

Relationship with society
Oocyte autopreservation for medical reasons and donation with autopreservation is logically consistent with financial support provided by national solidarity. However, such support could be an issue in the case of precautionary autopreservation if it was on offer for all women regardless of whether a donation is involved and in the absence of any pathology or infertility (*see below*).

[15] In the particular case of placental blood, from the umbilical cord or the placenta, the Code of Public Health prohibits autologous cell storage (CSP, Article L1241-1). However, a derogation authorises a dedicated donation to a child or to siblings of a newborn child in a family suffering from pathologies. This was confirmed by a ruling of the *Conseil Constitutionnel*.

III-3. Consequences of precautionary autopreservation

A young woman in good health who did not have a fertility problem and who wanted to benefit from the possibility of oocyte autopreservation would find herself confronted with several issues: the procedure could make a positive contribution to her autonomy, but could generate a risk of social or professional pressures as well as medical risks without, *in fine*, any guarantee of success.

More autonomy for women

With this procedure, young women would have more autonomy since they would be in a position to decide if they wished to preserve their oocytes and procreate later in life and therefore be free of the threat of ageing oocytes and compromised fertility while they continued with their careers and personal fulfilment.

Risks of social and professional pressures

Although it is important that women should be warned in good time that oocyte quality deteriorates with ageing, oocyte autopreservation on offer for all women could backfire and give rise to new kinds of family and professional relationships.

It could be a problem for a young healthy woman to be presented with an offer to preserve her oocytes with all the constraints associated with this procedure at a time in her life when she has many other problems to cope with (completing her education, looking for work and somewhere to live, achieving a stable emotional relationship) and safe in the knowledge that she could very probably have a child spontaneously. Could not such an offer be perceived as an argument in favour of a duty to bear children, thus introducing a disparity between the life she wants and what might be seen as a duty to procreate?

There is also the risk that the possibility for a woman of having children at the most appropriate time and when she wants to might be called into question by excessive insistence on the call of duty if too much emphasis is put on work and performance. There have been media reports on offers to pay for oocyte conservation made by some American companies to female employees so that could devote their talents and energies to their jobs and delay their plans to have children[16]. Autopreservation could complicate the already delicate balance between the various facets of a woman's life as a spouse, a mother and a worker.

The constraints and risks inherent to the oocyte autopreservation procedure are not always well known and information on the subject is not readily available with the consequence that women tend to place excessive faith in MAR which accentuates the deferment of pregnancy for practical or professional reasons.

Medical constraints and risks of ovarian stimulation and oocyte extraction procedures

The stimulation-retrieval-preservation procedure is physically stressful, and there can be adverse side effects. Those concerned should be given all the information they need to gain a thorough understanding of the procedure they are committing themselves to so that they may give free and informed consent to a medical technique which is not without consequence and whose usefulness for the women concerned is probably marginal[17].

The ovarian stimulation protocol induces the simultaneous maturation of several follicles, instead of a single follicle in a spontaneous cycle. It consists in the injection of hormones at increasing dosages repeated over 8 to 15 days, timing and dosage being adjusted based on the results of follow-up,

[16] *Facebook et Apple pourraient subventionner la congélation d'ovocytes de leurs employées*. (Facebook and Apple may pay for cryofreezing of employee's oocytes. See http://www.lemonde.fr/pixels/article/2014/10/14/facebook-et-apple-pourraient-subventionner-la-congelation-d-ovocytes- de-leurs employees/Le Monde.fr 14.10.2014. See also: https://www.cnet.com/news/egg-freezing-so-hot-right-now/ (22 May 2017).

[17] A number of studies on the subject point out that information provided to the women concerned is imprecise and in particular that risks are underplayed (see Annex 3 § 5.3).

hormone levels and ovarian ultrasound examination so that there is a need for repeated testing and contacts with the medical team. The egg retrieval procedure is generally done under general anaesthesia. Several stimulation-retrieval cycles may be necessary in order to obtain a sufficient number of oocytes (generally estimated to be 15 to 19) so that an IVF/ICSI procedure, if it turns out to be necessary, has a good chance of producing a live birth.

There is some uncertainty about the clinical risks of ovarian hyperstimulation[18]. Immediate risks of ovulation stimulation are low, but not nil (*see Annex 3*). While it seems justifiable to run such risks to treat medically diagnosed infertility, does this hold true for a "precautionary" procedure in the case of young and fertile women who, in their vast majority, will not be needing their cryopreserved oocytes?
The long term consequences of heavy and repeated ovarian stimulation episodes and of major hyperestrogenic treatment on mammary tissue are poorly evaluated, in particular the risk of facilitating the emergence of cancer which cannot be ignored. Furthermore, although the risk is reduced by early pregnancies, it is on the contrary exacerbated with late pregnancies. This combination of factors: induced hyperoestrogenic states for a young woman and the possibility of tardy pregnancy, is certainly not an optimal hormonal climate for ovarian and mammary tissues (*see Annex 3*).

Risks inherent to the MAR procedure when cryopreserved oocytes are used
A young woman in good health to whom "precautionary" oocyte autopreservation is offered must be warned that there is no certainty of success when using her preserved oocytes later in a MAR procedure. For every IVF/ICSI attempt, the probability of a live birth is in the order of 20-25%. It is therefore frequently necessary to repeat the ICSI fertilisation procedures several times and, sometimes, embryo transfer[19], to arrive at the hoped for pregnancy and a live birth (this objective being achieved in 60-70% of cases).

Oocyte autopreservation introduces two possible risks inherent to the procedure itself: (1) the possibility of impairing oocyte characteristics by long term vitrification and its effects on the child's development; (2) risks induced by ICSI, this procedure being essential to fertilise vitrified oocytes whose membranes were weakened by freezing (*see Annex 3*).
Studies of these two techniques did produce reassuring results, but they are scarce and the total safety of long term vitrification can only be pronounced once prospective studies on a large number of MAR procedures using vitrified oocytes have been completed.

Advanced maternal age: individual and medical consequences
Were oocyte autopreservation to become the general case it could encourage the postponement of motherhood to over 40 years of age with a possibility of additional medical risks. The frequency of complications, both for the mother (high blood pressure, diabetes) and for the child (foetal hypotrophy, premature birth) increases steeply with the mother's age and requires special supervision appropriate to the risk incurred. And yet, such risks are little known and underestimated by women and their spouses. An increase in the frequency of advanced or very advanced maternal age (women over 40 and over 45 respectively), described as high-risk pregnancies, could be an unfavourable consequence of oocyte autopreservation (*see Annex 3*).

[18] The ovarian hyperstimulation syndrome risk is estimated at a frequency of 1-4% of oocyte donors and that of retrieval complications at 0.4%. These figures are highly dependent on the protocol, the woman's age and the context (intramarital MAR or donation).
[19] One or two embryos are transferred per attempt and good quality superfluous embryos are frozen.

III-4. Economic issues arising out of oocyte autopreservation and social risks for solidarity

The cost of oocyte autopreservation

Oocyte autopreservation comes at a not insignificant cost in medical, technical and medicinal terms due to the cost of stimulating ovulation, of oocyte retrieval and preservation at a very low temperature for several years[20]. It is important to remember that several ovarian stimulation cycles are necessary — when that is possible — to obtain a sufficient number of oocytes to be reasonably confident of success for a later IVF/ICSI procedure; several ICSI cycles and embryo transfers are generally required to achieve childbirth.

Paying for the cost

There is currently a consensus that the French national healthcare system should bear the cost of preventive oocyte preservation in the event of a pathology or treatment which could prematurely reduce the ovarian follicle capital.

In the context of oocyte donation and autopreservation, as offered to oocyte donors who have never given birth (2011 law), autopreservation is seen as gift in exchange for the donor's gift, so that the same logic for bearing the cost by the healthcare system prevails.

Conversely, there could be some doubt as to the suitability of "precautionary" oocyte autopreservation if it was on offer for all young women in the absence of any pathological cause to fear future infertility.

Should the cost be borne by the healthcare system or paid for by the patients themselves?

One sector of opinion is that it would be fair and equitable for this oocyte autopreservation procedure to be financially supported for all women, regardless of professional, social, financial and geographic status. It is a valid comment, however, that to offer oocyte conservation to all young women, although only a very few of them, *in fine*, would have any need for them, would be mobilising healthcaring resources to the detriment of other medical requirements financed by the community.

Others are of the opinion that a procedure of this kind when used without any medical indication should be organised on a private basis and paid for by applicants so that the principle of national solidarity should stay dedicated to pathological indications.

IV. "Precautionary" oocyte autopreservation is hard to defend.

If it were to be authorised, what recommendations should be made?

IV-1. Define a time limit for use of oocytes

If oocyte autopreservation were to be allowed considering that the new relationships it introduces do not contain any major risk of injury, it would be wise to set a time limit on using the oocytes in order to protect the women themselves and the future children from the risks associated with advanced maternal age. This would mean setting an age limit beyond which women could no longer use their preserved oocytes for a MAR procedure. Overstepping the deadline would mean excessive risks for both mother and child (*see above*).

The current limit of 43 years for MAR reimbursement by the French national healthcare system should apply[21].

[20] The cost of an IVF attempt is estimated at €3,000, to which must be added €1,000 for medication to stimulate ovulation and the annual cost of conservation (€200 to €300 per year). A further additional expenditure is related to later MAR, i.e. about €1,000 per cycle (cost of thawing the oocytes, of intracytoplasmic sperm injection ICSI), of the transfer *in utero* of the embryo or embryos during a natural cycle or including the mother's hormonal treatment). Physicians specialising in reproductive medicine have reached a consensus that it is necessary to obtain a sufficient number of oocytes, 15 to 19 on average, for the women to have an effective chance of achieving pregnancy with their cryopreserved oocytes. The total cost estimate for three attempts: drugs for ovarian stimulation + IVF + vitrification = €4,000 x 3 treatment cycles + annual conservation at €300 x 15 years + ICSI and transfer *in utero* €1,000 x 3 = €12,000 + 4,500 + 3,000 = an average global cost of €20,000/woman.

[21] Although no age limit is clearly formulated, reimbursement by French healthcare is only granted before the applicant's 43rd birthday.

IV-2. Consider the future of unused oocytes
Upon reaching the age limit, women whose gametes were preserved would be asked to choose: either donate their stored oocytes to another woman, or donate them to research or even ask for them to be destroyed[22], but this would not seem acceptable if oocyte preservation had been financed by society.

It could be useful to create a condition for access to autopreservation in the form of consent to donating the oocytes if they were not used. To respect the principle of personal autonomy it would be necessary to secure the truly informed consent of the woman concerned as part of the harvesting and autopreservation procedure. She would be consenting to donate her oocytes if they were no longer of any use to her or if she could no longer use them. This could be the subject of a contract signed by the woman concerned and the officially approved centre for storage and management of her oocytes.

This would help to increase the medium and long term stock of oocytes.

V. Possible alternative solutions to oocyte autopreservation to encourage pregnancy in younger women

The first prerequisite is information. And yet, it is apparent that by and large people are poorly informed about how fertility evolves as women get older. It is therefore very necessary to develop a public information policy and also to organise society in such a way that women are encouraged to plan for motherhood at an earlier age if that is what they wish to do.

V-1. Provide and disseminate more pertinent information
Information on the downturn in female fertility with increasing age should be accessible very early on to young people as part of their education. It should be imparted mainly by educators and healthcare professionals, particularly in the context of visits to a gynaecologist and contraception management at a time when women and their partners may be responsive to such information, but it should also be relayed by the media, women's magazines in particular. Information should also include references to the additional risk factors related to advanced maternal age, both for women themselves and for their children[23], as well as to the drop in success rates for tardy MAR procedures and the uncertainties regarding the future of children born of those tardy procedures.

V-2. A special effort to be made by society to facilitate motherhood for young women who wish to have children
A more determined and ambitious policy reconciling realistically the possibility of being a youthful parent and launching a career — for women more particularly — should be promoted nation-wide and locally so that motherhood is not synonymous for women with giving up their professional, social and personal life plans.

Among the steps that could be considered, only those specifically designed for integration into business structures — such as the Plan Egalité[24] — could provide women with sufficient security to combine employment, career prospects and quality of family life, on a par with the situation enjoyed by men who have recently become fathers. Finally, determined and ambitious policies together with measures to facilitate and develop acceptance and care arrangements for small children should be planned for throughout the country.

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[22] When couples have undergone an IVF procedure and have surplus embryos frozen, they are asked every year what they want done: keep the embryos to pursue a parental project, give up the embryos for research, donate them for embryo hosting by another couple or else cease to store the embryos.

[23] There is a tendency in some cases to present advanced maternal age pregnancies in a very positive manner while ignoring the increased risk to which are exposed women and their children.

[24] Law dated 4 August 2014 ;www.ega-pro.femmes.gouv.fr: law dated 17 August 2015, providing for, in particular, inspections and sanctions for recruitment discrimination.

CCNE's conclusion

The tendency to postpone parenthood may stem from a woman's legitimate wish to enjoy life for a time without the responsibility of looking after a family, or from the just as legitimate wish to be sure of having met a partner she also wants as the father for her children. Delayed motherhood can also be attributed to financial problems and a society organised in a way that does not encourage women to have children at an early age. But delaying pregnancy also entails the prospect of a decline in fertility due to the reduction of oocyte capital with increasing age.

In this context, the possibility of oocyte autopreservation appears as space for women's autonomy to be exercised without compromising future motherhood. It is therefore important to explain very clearly the constraints and risks of oocyte harvesting as well as the uncertainty of success with ICSI reproduction procedures which the vitrification of the oocytes renders mandatory. Nor must the oocyte autopreservation procedure be presented as the "magic wand solution" to delayed pregnancy guaranteeing successful motherhood after the onset of the decline in fertility.

This procedure should not be used to compensate for practical difficulties or to be a substitute for society providing the kind of organisation that enables women, as they themselves wish and in keeping with their own chosen lifestyle, to have children naturally and earlier in life instead of feeling obliged to postpone motherhood. Delaying the birth of children — taking into account the risks inherent to delayed pregnancy — can hardly be viewed as a positive contribution to the emancipation of women from biological limits. Apart from the possibility of misuse and the social and professional pressures to which this procedure could give rise, the expected benefits appear to be minimal in relation to the medical and economic expenditure that would need to be deployed. Among young women, since only younger women are concerned by this proposal, only a tiny minority (those who had not given birth spontaneously) would finally have any need for the cryopreserved oocytes. Expecting society to pay for the procedure also seems excessive.

In the circumstances, it would be essential to develop well-documented and precise information on the evolution of female fertility for the attention of youthful members of the public, to be imparted in an educational environment. The media should also play a part in raising awareness, women's magazines in particular, some of which have a tendency to present advanced maternal age pregnancy in a very positive light without adding information on the increased risk for women and their children.

In the light of the above, the proposal to provide oocyte autopreservation to all young women who request it, with a view to a hypothetical use at a later date, seems hardly defensible.

However, in the course of discussion, certain members of CCNE expressed a divergent viewpoint (*see divergent positions*)

Chapter 3
Thoughts on requests for medically assisted reproduction (MAR) by female couples or by a woman on her own

Introduction

This chapter aims to analyse the issues arising out of possible access to reproductive biotechnology by same-sex female couples or a woman on her own[25]. Our reflection will focus on a single MAR technique, donor insemination (DI). The demand goes beyond the situation currently provided for by law: alleviating medically diagnosed pathological infertility in couples formed by a living man and woman of childbearing age. This demand therefore calls into question the possibility of moving on from medical DI indications to requests from female couples or from a woman on her own for reasons described as "societal".

DI requests from same-sex female couples or a woman on her own are of two kinds: (i) calling on technology to procreate without a male partner, for reasons unrelated to any pathological infertility; (ii) recognition and institutionalisation by society of this mode of procreation.

Requests from female couples and from a woman alone are formulated and discussed together[26] in this Opinion but, as we shall see, there are some differences between the two situations[27].

Liberty is one of the founding values of democratic society. It includes the liberty for women to have children or not have children. This liberty, when it is exercised in a private domain, be it by a single woman or a woman who is part of a couple, does not give society any say in the matter although society takes on the financial burden of pregnancy and the protection of the child to come. Nonetheless, when society is requested to authorise possibility of access to medical procedures up to now reserved for the alleviation of pathological infertility, then society consider the interests of the women concerned in comparison with other interests.
Society's sole function is not promoting personal liberty and freedom of access to existing technology. It is also responsible for taking account of the consequences of new situations that it is asked to authorise and, therefore, to organise their implementation.

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[25] We shall not be referring here to "no sex" couples since the number of people concerned could be minimal. Nor shall we consider the situation of transsexual women which raises some specific problems which should be discussed in an Opinion dedicated to the subject of transsexual procreation.

[26] Countries who have allowed DI for female couples have also allowed it for women on their own.

[27] **The two situations have in common the need for donated sperm for non medical indications (currently not authorised by law), the fact there will not be in the child's life a father who is socially present or legally established, and the possible repercussions on the family structure in which the children are brought up, on the children themselves and on the medical organisation of the management of such requests.**

I. Disjunctions

DI, in all cases, leads to disjunction between sexuality and procreation as well as between procreation and filiation.

I-1. Disjunctions between sexuality and procreation
In the case of a request for DI by female same-sex couples or a woman on her own, procreation is distanced from a sexual relationship between a man and a woman since DI fertilisation implies the use of donated sperm.
Although the disjunction exists for any DI procedure, it has specific characteristics in this case since it introduces:
- an anthropological novelty when a female couple or a woman on her own choose to use technology instead of the fertilising sexual act to access procreation;

- *a medical disjunction: the request is no longer part of a context of infertility.*

I-2. Disjunction between procreation and filiation

The principle of this disjunction is not new: any form of DI leads to differentiating between the role of donor or "genitor" and that of the "father", designated as such by filiation law (see glossary). In this situation, there is a genitor, but no legally designated father.

I-3. Disjunction between oocyte (genetic) and uterine (gestational) motherhood. Some women in a same-sex relationship wish to alternate their maternal positions and pregnancies. Others choose to use IVF (*in vitro* fertilisation) with a sperm donor, so that one of them provides the oocyte and the other carries the child (which is a possibility in certain foreign countries. These are new situations in the way that biology and parental structure are combined, as are consequently, the family and sibling entities.

II. New relationships and their consequences

II-1. The justification for requests to broaden access: equality of access to MAR technology to satisfy the wish to have a child
The demand for DI in this context is part of an evolving story of personal emancipation and demands for liberty and equality as seen by the person requesting access to DI, without reference to the family structure in which the child will be reared and to the child's situation.
While the differences in the possibility of access or non access to DI — as defined by law — may well be experienced as "inequality of treatment" by women who do not at present have access to the procedure, extending access to DI could generate "inequality" for children born of MAR procedures since they would be deprived of a father in the case of same-sex female couples and deprived of a father and of a dual parental lineage in the case of a single woman.
In this same context of personal emancipation, the availability of certain technologies provides the means to satisfy certain wishes. It is thought by some that wishes are as good as wants and that gradually, step by step, wants become an obligation expressed as: "if it's possible, it must be done".

II-2. The child's relationship to the family environment
Resorting to DI signifies taking a moral stand on the possible responsibility of society and of legislators in particular, as regards the consequences of female same-sex couples and women alone using medical procedures in order to procreate. Our thinking will focus on the changes in human relationships, in particular the environment in which the child will be living.

Differentiating between requests for access to DI by same-sex female couples and by women on their own

We mentioned above the wish to have a child and the procreative demand common to both same-sex female couples and women individually. These two sets of circumstances are not totally interchangeable. In the first case, that of a same-sex couple of women wishing to have a child, two people are contributing complementary capacities and availabilities to meet the needs of a child and to cope with the unknown hazards ahead in the life and rearing of a child. We have remarked (see above) that women combine in various ways the biology and structures of parenthood, but we have not yet had any retrospective view of how these different situations are experienced by those concerned.[28]

The situations leading a woman on her own to consider using technology to give birth are numerous and are not pertinent to our reflection. In the same way as women couples, a woman on her own who wants a child without having sex with a man must find a sperm donor. But, as a result, she will be on her own to bring up and take care of the child.

Children's relationship to their environment: their origins, the absence of a father, family reference points

When female couples or an individual woman decide not to use fertilising sexual intercourse to procreate they need a sperm donor. He can be someone who is known to them for a self insemination procedure[29]; or he may be anonymous (see Annex 4). These various options influence the child's environment.

Although there have always been children who did not know their fathers, or who were reared by a single parent or a homosexual couple, there is a difference between creating such a situation *ab initio* and managing to cope when it arises spontaneously without anyone planning or organising it.

This raises three questions: what consequences could there be for the children's relationship to their origins? What does it mean to grow up without a father? And what family reference points will the children be able to hold on to?

- Relationship to origins

As always with DI, the fact that sperm must be donated implies a break in the link between the biological origins and filiation.

As regards origins, a child may wonder about two kinds of questions: how did I come to be born, or more generally, how are children born? And, more specifically, who are my parents and what are my origins?

All children may wonder about the first question but it is usually not essential to their well-being. For most children, regardless of the method used to conceive them, affection, attention and a sense of security are the essentials they need to receive from their parents. If a MAR procedure was used, the technique may be paradoxically less enigmatic than their parents' sexuality, and easier to explain.

The second question is of a more personal nature. It is connected to the child's origins and parents and

[28] We are just beginning to receive some feedback, but not enough to be pertinent, on difficulties arising in the event of divorce.

[29] Self insemination: insemination privately "at home" or "DIY". (*J. Testart. Faire des enfants demain. Seuil 2014*, p. 166): obtaining sperm without sexual intercourse, injection of sperm into a cup and intravaginal self-insemination. Used by "no sex" male-female couples or when the man has a premature ejaculation condition and the couple wants to have a child.

how he or she came into the world[30]. The answers will be essential for the construction of a child's identity. But the circumstances of birth have an influence on the way the question is asked. It has been noted that a certain number of children born as a result of DI, such as it is legally provided for in France and therefore to heterosexual couples, wonder about "their" donor and his lineage, despite the fact that they have a legally established father who, in the majority of cases, has filled that role from the very start[31]. For children born by a gift of sperm to a female same-sex couple or a woman on her own, there will not be any paternal lineage, nor reference to a succession of generations on that side of their genealogy. It would only be in the case of a known donor (*see Annex 4*) that children would be able to access their "origins" as they are usually referred to.

The difficulties experienced by some people born through DI are in part connected to the secrecy which shrouds the circumstances of their conception and which may have caused them pain when they were revealed. There is obviously no such secrecy when both parents are of the same sex. But the issue of anonymity remains — in France, the law guarantees it for donors[32] — as does the issue of access to biological origins which is not authorised, at this time, for children born of sperm donation.
But the question of access to origins is evolving, firstly because of trends in ideas and practices, such as for example, the public's increasing interest in the subjects of biological origins and transmission of a genetic heritage; moreover, legally, the current situation may be about to change. There must be a distinction made between the right of access to personal origins ("an element of structuring a person's identity") and the right of anonymity guaranteed to sperm donors. The two standards must not be lumped together. In another context, that of adoption and that of arrangements for anonymous childbirth, a balance between contradictory demands — secrecy and the right to access origins — was sought by legislators[33].
Another point to remember is that the European Convention on Human Rights considered that the right to disclosure of origins was in the best interests of a child (Article 8 of the Convention)[34]. It is therefore possible, as feared by some and hoped for by others[35], that the absolute anonymity enshrined by French law regarding the personal data of sperm donors, as confirmed by the *Conseil d'Etat*[36], may one day be called into question in a European context[37].

- To grow up fatherless is a situation created by medically assisted reproduction for female same-sex couples and women on their own.

The situation created by this reproductive procedure for female couples and women alone is a new one

[30] E. Morin. *«Les sept savoirs nécessaires à l'éducation du futur »* Essai. Ed Points. April 2015, p. 82 "Every human being, every community, must irrigate his life by mean of incessant communication between his past which he uses to reconstruct his identity by reference to his ancestors, his present where he states his needs and a future where he projects his aspirations and efforts".

[31] For a certain number of children born via DI to a heterosexual couple, the question of knowing who is the donor is important, both as far as it concerns their own origins and those of their children, therefore the relationship to a third generation: "The gift of a gamete creates life and the donor made me. My mother was concerned by that gift in her own body for nine months. For me, my whole life is concerned. It is also a gift of heredity which I shall transmit to my children who will themselves transmit this unknown quantity". http://www.genethique.org/fr/audrey-kermalvezen-souleve-les-paradoxes-du-don-de- gametes-64604.html#.V7bAxOmOySQ,.

[32] A number of countries have long ago lifted donor anonymity (Switzerland, Sweden, United Kingdom, Germany).

[33] The 22 January 2002 law n° 2002-93 on wards of the State and adopted persons created, among other things, a National Council for access to personal origins (CNAOP).

[34] CEDH 13 July 2006, Case .Jäggi v. Switzerland. On 14 January 2016, CEDH took the matter a step further, considering it "in the child's interest" to know the truth about his or her origins (Mandet judg.)

[35] Some examples of such questions are to be found in the requests addressed to the *Commission d'accès aux documents administratifs (CADA)* (Commission for access to administrative documents) in the CECOS Jean Verdier de Bondy case (Session on 27/07/2010) to communicate various documents concerning information on origins of their conception by donor insemination.

[36] *Conseil d'Etat*, 12 November 2015, Mme B. http://www.conseil-etat.fr/Decisions-Avis-Publications/Decisions/S...-objet-d-une-communication-particuliere/CE-12-novembre-2015-Mme-B.

[37] In fact, ECHR declared the Italian law on access to their origins of adopted children to be contrary to European law because it did not seek a compromise between the mother's right to remain anonymous and "the importance for everyone to be told the truth about their origins and their history". In the future, it is possible that the secrecy of data concerning donors may not be at odds with European law on the condition that a balance be found by some extension of a child's right to know the truth about his or her origins.

for children. Women on their own or partner in a female couple who choose to conceive with donor sperm make a deliberate decision to bring up a child in a parental environment in which there is no father. In all other such known circumstances, children have, or have had in the past, a father whose absence is the result of a random event: this may be the case of homosexual women who have had children previously in a heterosexual couple, or women who have chosen to leave their spouse or their partner or widows.
Orphans had a father whose memory is transmitted via the mother and paternal lineage. Adopted children had a biological father, even though in most cases he may be unknown, but they do have a social father, established as such by law (except in cases of adoption by a woman alone[38]). And it is still the case for children born of DI to heterosexual couples, who have a legally designated father.
In the parental environment created by a female couple or a women alone, the child's personal history would contain no father image, known or unknown, other than that of a donor.[39]
This raises the issue of the father's place within a family structure and of his role in the development of the child's personality and identity.
Traditionally, it is thought that the presence of a father is the first experience of otherness in learning to live in society. It contributes to the child's understanding, as a complement to the mother's role, of the sexual differentiation and masculine-feminine alterity, as a prelude to the gender diversity the child will encounter at school and later at work and in society generally.
Children born to female couples may benefit from alterity in character and parental position. For the child of a woman on her own, there is no possibility of observing at home different characters and sexual differences.
In another vision, paternal function is not identical nor reducible to sexual differentiation. In the child's subconscious, the parental couple is made up of a father and a mother rather than of a man and a woman. The absence of a man in the home does not signify that the child will exclude the symbolic representation of the father, no more than is excluded the representation of the other sex.
According to recent studies, children reared in homoparental families are no more or less content than children living in a traditional family environment. The situation seems to be different for children brought up in a single parent family (*see Annex 5*).

- Relationship to family references

"Family" can be defined as the grouping together within the same home of persons connected by bonds of kinship (legitimate, natural as well as adoptive), and by relationships of parental care. It evolves constantly, with an increase in the number of single parents, separated and step family set-ups, and of children brought up in homoparental families. In this latter case, until a few years ago, the exact proportion of children who were conceived using MAR procedures and those born to a heterosexual family but reared totally or partly by one of their two parents living in a homosexual relationship[40] was unknown. This diversity of familial forms has given rise to a growing number of studies, but points of view regarding these developments differ widely.

At this time, so an INSEE 2011 enquiry on family and housing informs us, 71% of children under the age of 18 live in France in a family structure with their two biological parents, father and mother, despite the increase in the number of divorces and separations, 18% live in a single parent family (most

[38] Single people (women, more often than not) had the possibility of adopting children in 1923 because of the devastating loss of life as a consequence of the 1914 war and the tragic disappearance of an entire generation of husbands and fathers.

[39] A number of children born via DI have described, each in their own way, the problematic nature of the presence in their lives of an anonymous donor: "And yet the sperm (...) comes from a flesh and blood donor (...) about which the child may wonder later on. Through these questions in their minds, the children "put life" into the donor (...). The children born of a gamete donor are the least of anyone's worries. (...) Taking into account the child's interest means that it should be possible to discover your origins when you have reached legal majority. Today, it is a kind of impossible closure for a child born of a gamete donor. As long as you have not seen the body of a close relative who has died, closure is impossible. Similarly, as long as a child has no access to his origins, he is burdened by these questions". Audrey Kermalvezen, author of *Mes origines : une affaire d'Etat*, entretien 18 http://www.genethique.org/fr/audrey-kermalvezen-souleve-les-paradoxes-du-don- de-gametes-64604.html#.VtcHTOl5SSQ.

[40] This absence of differentiation between the two very different situations, is a frequent bias in studies published so far.

with the mother) and 11% in a step-family. The Federation of homoparental families underlined a changing situation in a 2015 enquiry: 74% (163 out of 219) of children under the age of 5 born to a female same-sex couple were conceived via DI, in contrast with only 24% (45 out of 186) of those over the age of 5[41].

In this homoparental model, as is the case with more conventional models, children have two families to which they refer. Parents insert the child into their lineage[42] and therefore into family continuity. These parental lineages, the existence of grandparents, contribute to the framework with supports and ensures the child's development. In the single parent model of a woman alone, only one lineage is involved.

II-3. MAR applicants' relationship to the medical world and to biological resources

Practising a medical profession and societal requests for DI: consequences in the context of the French healthcare system

For members of the medical professions, their work is meaningful if its purpose is seeking to maintain or restore health. And for this they are accountable. To take care of a patient's health signifies not only preventing, diagnosing and treating ill health, but also considering patients holistically, the physical, moral, cultural and social self and the psyche. Care is given to enable a person to stay in good health or to regain an acceptable degree of physical and emotional well-being.

In the laws on bioethics, legislators sought to consecrate the strictly therapeutic role of medical practice exposed to evolving social demands. Infertility is an infirmity within a couple which is revealed when a wish to have a child cannot be satisfied. In these circumstances, the physician who is supporting a parental project does so at the behest of society. Extending DI to people who do not suffer from any disorder causing sterility would be conceivable to alleviate the suffering experienced as a result of infertility due to a personal preference. Such distress must be taken into account.

MAR procedures are exacting and costly. The scarcity of gamete donations currently impedes the satisfactory management of pathological infertility; the demand for DI access for non sterile persons and the claim for equality of rights to be applicable to two different conditions — pathological sterility and "societal" claims for MAR — would endanger two major principles of the French healthcare system, based on solidarity: products of the human body and donated organs, gametes included, are given without financial compensation and treatment for pathological infertility is at the expense of national solidarity. To satisfy these claims and demands would pave the way for the growth of parallel channels and would reinforce the pressure now building up for the development and deregulation of a "reproduction" market, which would profoundly alter the French healthcare system (*cf. below*)

Gamete scarcity and consequences on the risk of commodification of all the products of the human body

Be it for women on their own or female same-sex couples, having society institutionalise its support for reproductive medical assistance *via* anonymous sperm donation in the midst of a shortage of rare biological resources does raise some ethical issues.

The scarcity of gametes is in itself a problem. There are several reasons why altruistic donations are limited in number: as is the case in other contexts, demand tends to increase; gamete donation does not

[41] Martine Gross (2015): *L'homoparentalité et la transparentalité au prisme des sciences sociales : révolution ou pluralisation des formes de parenté ? Enfances Familles Générations n° 23*. http://www.efg.inrs.ca/index.php/EFG/article/view/636/273.

[42] Distinguish between 'line': descendants; and 'lineage': unilinear filiation group descending from the same ancestor.

respond to a vital need, strictly speaking — so that potential donors may not feel very concerned; it is more complicated to collect gametes than, for instance, blood [43]; for some people, gametes as the vessels of a genetic heritage, are not equivalent to other parts of the human body.

Because supply is insufficient, there is a risk, in the event of an extension of DI indications, of lengthening the waiting time for everyone, thereby increasing the age at which women could access DI and so reducing the chances of a successful outcome of the procedure[44].

One possibility would be to give priority to couples composed of a man and a woman whose infertility was pathological. Legally, it is doubtful whether such a system would be constitutional if legally extended and regulated DI were to put pathological and societal infertility on the same footing, thus curbing the possibility of treating them differently. Politically, a system of priorities would be difficult to defend. Finally, in practical terms, it would not be all that easy to organise. Should there be two waiting lists? If that were the case, unless there was an unprecedented increase in the number of sperm donors, the extension of DI to female couples or women alone would only very rarely give them the opportunity of actually obtaining a sperm donation.

The fact that it is illegal in France to be paid for sperm does contribute, to a greater or lesser extent, to the "shortage"[45]. Paying donors so as to minimize the shortage, as mentioned above, would raise difficult issues as regards the principles governing all donor parts and products of the human body (*see below*). Furthermore, among other drawbacks of payment for donor sperm, the most significant is probably the absence of traceability of sperm "donors" who might find it worth their while to "donate" frequently and in different collection centres since each occasion would represent a source of income (*see Annex 6)*.

To make the best use of their limited resources countries who are attached to free of charge donation take marginal steps to increase the supply: they augment the number of children per donor (in France, the maximum used to be five and is now ten), or they accept known or designated donors already widely in use by centres for medically assisted reproduction calling for egg donors in the context of pathological infertility of heterosexual couples.

Some countries (Spain, Denmark) have chosen to increase the supply of gametes by the prospect of payment (*see Annex 6*). The experience acquired in these countries shows that earning money is a factor influencing people's decision to do something which they would otherwise not have wanted to do unpaid, which is in its way a new form of aggression. Gratuitousness, the object of which is to channel the potential indignity of relationships connected to this form of gain, is obtained at the price of scarcity. To protect the freedom of supply means that not all demand can be satisfied. This is a fundamentally ethical and political decision.

Once the principle of gratuitousness is breached for gametes, there does not seem to be any barrier to following suit with other products and components of the human body, organs included. Even in situations where supply and demand balance out, as is the case for blood, paying for collection is less costly for the community than organising a donation circuit. There is, as demonstrated by the international market for blood and derivatives, for gametes and for surrogate mothers, an immense reservoir of people who are ready to sell components of their bodies to solve their financial problems.

The risk of merchandisation of course involves biological resources of human origin *per se*, but also reaches far beyond to biomedicine as a whole which requires the use and circulation of such resources, more or less industrially, in a context where the applicant's life is more or less under threat: blood,

[43] This is of course obvious for oocytes (see Chapter 2) but it is also true for sperm (several visits to medical facilities are required for tests, sessions to collect sperm after masturbation, etc.).

[44] See the figures for the fall in fertility with advancing age in Annex 3.

[45] In Canada and Belgium where giving sperm must be free of charge, the altruistic supply does not cover more than 10% of requirements; Belgium buys 90% of the sperm it uses from Denmark and Canada buys it from the United States (see Annex 6)

bone marrow, organs[46].

In countries where components of the human body are paid for, the practice of free public service persists, but it is subject to competition from private banks; efforts to distribute rare resources equitably (based on urgency, genetic compatibility, waiting lists, etc.) co-exist with preference granted to the highest bidder. Such systems are integrated into a network of private clinics providing more extensive and more flexible services than the public sector, particularly as regards the choice of the donor. Currently, some of these commercial resources circulate without hindrance since they can be easily bought *via* the Internet.

On this point, societal requests for access to MAR should be considered together, not separately. In other words, precautionary oocyte autopreservation for non medical reasons and requests for DI for societal reasons which respond to two very distinct objectives, nevertheless share the same logic of constant technification of reproduction and lead to an increase in the number of MAR procedures and stresses on women's health together with associated marketing activities: the trade in gametes, medications, harvesting, storing, transfers, etc. Again (*see Chapter 2*), reserving financing by the public healthcare system for medically diagnosed pathological infertility could be justified by the difference between infertility with a pathological cause — entirely supported financially — and infertility of a societal nature — not supported financially. Women in this latter situation would pay for the medical services and the cost of preparing the gametes, although donor services would continue to be unpaid. But this would mean that only wealthy women would be able to access MAR for societal reasons. Nor would such a step have any impact of the scarcity of available gametes.

[46] Jean-Daniel Rainhorn: *« La déshumanisation atteint aussi la médecine »* (Le Monde, Science et technologies, 13 July 2015).

III. Conclusion: stumbling blocks and recommendations

After an analysis of the facts — an essential step to enable debate — some stumbling blocks persist.

III-1. Stumbling blocks

The stumbling blocks are above all concerned with the role and the definition of the father, the difference in circumstances between female couples and women on their own, the issue of the scarcity of biological resources with the attendant risk of commodification, the dividing line between pathological and societal.

- As regards *the role and definition of the father*, the problem is not just knowing whether, by authorising MAR for female couples and women alone, the "absence of a father" is institutionalised, but also by the same token, whether several "absences": absence of a masculine image, absence of a legal father and of a genitor who remains inaccessible as long as he remains anonymous. Under the general heading of "father" there is a complex gathering together of all the specific disjunctions that MAR separates: the masculine genitor (sperm donor), the legal father recognised by the laws of filiation, the masculine image distinct from the feminine image, the double genealogical lineage compared to the singleness of single-parent families, the differences within the couple, each of these factors being of importance for the child in a material sense as well as in a symbolic and emotional sense for the construction of self and for society as a whole.
Not committing to a process which would be organising the absence of a father, or considering that this is a situation in which representations are in the midst of evolving and that at this point in time we do not know how the people concerned will be able to construct themselves in these new situations, is one of the ways in which this stumbling block can be stated.

It would be pertinent to be able to rely on studies exploring, in these new situations, the multiple aspects of the children's development (health, academic achievement, making friends). It does not seem possible at this point to gain a consensual assessment from the published literature on the development of children in single-parent families, in particular due to the diversity of circumstances of these families (*see Annex 5).* While the vast majority of these studies reach positive conclusions regarding the children's future, the methodological biases, the disparity in the criteria adopted and the, as yet, insufficient time elapsed for feedback introduce a degree of uncertainty.
Several multidisciplinary scientific studies, based on the social sciences as well as on medical and legal research, are under way in France and should improve the reliability of available data[47].

- One constantly recurring question concerns the *equivalence or non equivalence of requests from female couples and from single women.* Being a woman alone adds the absence of a couple to the absence of a father. Here, the stumbling block has a bearing on the consequences for a child of the presence of only one single parent and of one single family genealogy. There are a number of indicators to the effect that single-parent families encounter some problems, partly for socio-economic reasons, but also for a great number of other reasons (*see Annex 5*). The development of children born by DI to women who choose to be single has not been the subject of specific studies (except for a few qualitative English studies based on small numbers of very young children).

- The issue of the *limited availability of biological resources* and, the further issue of the *risk of "commodification" of products of the human body*, constitute another stumbling block which cannot be either eliminated or minimised. Women alone and women in couples, when they are not practising self-insemination, need to access sperm straws. But the mismatch between insufficient donations and the need to satisfy the total number of requests, from sterile heterosexual couples and also from women same-sex couples and women alone, when sperm is given without payment, can swiftly lead to

[47] One example is a multidisciplinary project "*Homoparentalité, fonctionnement familial, développement et socialisation des enfants*" (devhom) financed by ANR, researching the 18,000 children in the ELFE cohort. Its main object is to make a longitudinal study of the socialisation and development of children currently growing up in single-parent families.

the creation of a procreation market which would be unfettered by the current protective measures of control. *In fine*, this is a threat to the gratuitousness of donation — not just of gametes but of all components of the human body — and could lead to destabilising the entire French bioethics system.

III-2. CCNE's recommendations

Based on the method explained in Chapter 1, the working group considered the subject and the majority of its members had no objection to opening MAR procedures to all women but wanted conditions of access and feasibility to be defined.

Three arguments were viewed as favourable for access to MAR technology for female same-sex couples and to DI for women alone: women's expectations and the recognition of women's autonomy; the absence of any aggression related to the procedure itself; the relationship to the child in new family structures.

Women already exercise their autonomy in their accession to parenthood by other means: adoption by women couples or procreative steps taken privately. The DI procedure in itself, unlike gestational surrogacy, does not injure any third party as is evidenced by its approval for medical indications. Unlike oocyte autopreservation, there is no specific social pressure for this DI procedure since women's wish to procreate is an individual decision by the woman concerned. Were any social pressure applied, it would seem to be rather more against this form of personal decision.

In this evolving social environment, the medical profession's deontological dimensions, along with its boundaries and its objectives, are also evolving. The request for access to DI expressed by female same-sex couples is one aspect of society's growing influence on the use of medical practices to satisfy societal demands.

Although not all wishes can be granted, the plans women construct to have access to motherhood using procedures which were not previously open to them can be seen as deserving respect. To conceive a child in a homoparental context, for instance, is a plan that has been carefully concerted and thought out so that pregnancy becomes an elective and welcome event. It would, on the contrary, be keeping to the existing legal prescription — reserving DI for couples composed of a man and woman — that could constitute an injustice imposed on applicants by society.

Family structures are changing, as illustrated by the diversification of family life; in many families, children are brought up by female couples or women by themselves. Even though, for society, coping with a new and unexpected family situation and actually programming such a situation are two different concepts, the fact that such situations exist cannot be ignored when taking decisions regarding access to MAR for female same-sex couples and women on their own.

Homoparenthood and single-parenthood both, as the result of MAR, are realities in France and assisted reproductive technology for women in these circumstances is legally provided in a number of neighbouring countries. Every year, two or three thousand French women receive such assistance. That being so, it would rather be refusing access to parenthood for female couples or single women *via* DI that would constitute a problem. To which should be added that a majority of CCNE members believe that keeping to the legal *statu quo* could stigmatise these new family structures.

In these new families, the relationship to the child can be constructed as can be the children's relationship to the woman or women peopling their world. These family models, furthermore, share the same general concerns that any family needs to grapple with, in particular how they bring up their children.

A child's relationship to origins and filiation can indeed be constructed in these particular circumstances in the same way as in any other family circumstances. Several points need to be made: (i) the importance for a child's wellbeing to be told the truth about origins, including the fact that a donor was involved in conception; (ii) the importance of taking account of sexual references, both symbolic and social, beyond the female couple or the single woman, and (iii) the importance of taking account of the absence of a father in the child's upbringing since, whatever position is adopted, this is known to be a really substantial stumbling block.

Conditions for access and feasibility, however, need to be defined and applied to this extension to DI access for all women.

In addition to the points of convergence set out above which have led to the formulation of a

favourable opinion regarding access to DI to be extended to meet the requests of female couples and women on their own, consideration must be given to some issues regarding conditions for access and feasibility.

There is, first of all, the difference in circumstances between female same-sex couples and women on their own. To consider them all together in a single pronouncement raises some issues that we have already mentioned as being a stumbling block: for a women by herself, to the absence of a couple is added the absence of a father and studies converge in pointing out the greater vulnerability of single-parent families. Some CCNE members wish to distinguish between these two types of family situations before allowing extension of access. Others would like arrangements for counselling which could be similar to those applying to adoption or could use other models. Extending the possibility of access to DI to female couples, and possibly to women alone, which the majority of CCNE members are recommending, does not dispel entirely concerns regarding possible consequences for children in these new still controversial family configurations, even though studies agree on the finding that the structure of the family matters much less than a supportive environment, family dynamics, the quality of the relationship between parents and their children and the relationship between parents. Scientific research, free of any *a priori* assumptions, based on strict and consensual methodology, should be pursued, adopting a transdisciplinary approach with input from social sciences, medicine and law. This would be the only way of providing an unassailable answer to these questions.

There can be no question, however, of undermining the principles of national solidarity and unpaid donation. Maintaining the gratuitousness of donations of components of the human body will be one of the inevitable stumbling blocks in any discussion on extending access to MAR technology. Everyone concerned by the discussion will need to participate, regardless of their position regarding access to these resources. In the event of a broad extension of access to DI, it will be absolutely essential to organise effective recurrent campaigns to encourage an increase in sperm donation and thus respond adequately to the needs and demands that will presumably increase as a result of this new situation. The CECOS (Centres for the study and conservation of eggs and sperm), must exercise strict control to prevent the emergence of a private market in France and to support the call for donations in a framework that is clearly governed by the collective interest, with due respect for good practices and solidarity.

Finally the financial burden of recourse to MAR for non medical indications cannot be borne by the French public healthcare system. The obvious question then is: will female couples or women on their own have to pay the full cost for non medically required reproductive assistance, or could some form of solidarity be considered? This could perhaps be a partial contribution to the cost of the public service, following already existing models. The services provided by approved MAR centres could be billed at cost price and cashed under the heading of "own resources" by the medical establishments participating in the hospital public service.

In conclusion, with due consideration for all the above points, in particular the absence of any specific potential harm incurred by use of the procedure, the majority of CCNE members are agreed on the recommendation to open access to MAR to female same-sex couples and women on their own, providing conditions for access and feasibility are applied.

However, during the discussions, certain members of CCNE expressed a divergent viewpoint (*see divergent positions*).

Legislators are planning to revise the laws on bioethics in 2018. This will be an opportunity for CCNE to make arrangements for a citizen consultation procedure to consider, *inter alia*, recent developments in gamete donation and MAR technology and to define the conditions allowing extension of DI access to all women.

Chapter 4
Thoughts on societal demands for gestational surrogacy (GS)

Introduction: returning to the ethical aspects of GS

Almost seven years ago, in the context of the revision of the 2004 bioethics law, CCNE made known its thinking on the subject in its opinion n° 110 on *Ethical issues raised by gestational surrogacy* (GS)[48]. This Opinion concerned requests for GS made by couples composed of a man and a woman when uterine pathology caused infertility which prevented a woman from carrying a child, in the context therefore of a medical indication. At the time, CCNE considered that although the request was motivated by medical considerations, it would be an encroachment on the integrity of the surrogate mother, in physical and emotional terms and as regards the life of her family if it was granted. The Committee added that wanting to have a child is not equivalent to entitlement to have a child if, in so doing, it interferes with a child's or a woman's integrity, even if the woman concerned was volunteering altruistically. However compelling the desire to have a child, it could not in itself suffice to overcome the ethical obstacles to GS.

CCNE has examined new developments since 2010: claims for liberalising GS for societal reasons in favour of applicants who did not fit into the definition of infertility as described by law and therefore for reasons which were no longer purely medical; the diversity of national legislations on GS which encourages applicants to go abroad for gestational procedures which are prohibited in their own country; the emergence of transnational merchants organising GS on a commercial basis; the issues raised by filiation and civil status for children born *via* GS in other countries.

In its reflection on societal claims for access to MAR, CCNE considers that the method of investigation it adopted for other forms of MAR not included in the medical indications provided by law can be pertinently applied to the consideration of these new GS practices.

I. Disjunctions

Of all the MAR procedures, GS is the only one separating the woman and the child she carried and the only one also capable of dissociating entirely a biological transmission (genetic *via* gametes, epigenetic *via* pregnancy) from a social one (the child's parental host family at birth), since the intended parents may not have participated in any of the procreation and gestation phases.

I-1. Gestational disjunctions

Gestational surrogacy implies that a woman is ready to accept pregnancy and carry a child, whilst committing herself to give the child up to the "intended parents" at birth. There is, therefore, an initial disjunction between the woman who carries and gives birth and the child she is immediately separated from. Furthermore, there is a more or less total disjunction at the very start of the process between the woman carrying the child and the intended parents who will be receiving the child, therefore between the gestation accepted by the carrier and procreation wished for by the intended parent or parents. In some situations, the woman carrying the child may have donated the oocyte. This is called "reproductive surrogacy" since she will be both genitor and gestator, "oocyte mother" (genetic) and "uterine mother" (gestational). In other instances, an oocyte is donated by another woman, a second woman. This is "gestational surrogacy" in which there is a separation between uterine mother and oocyte mother. In both cases, the oocytes are fertilised in principle by the intended father who is also the biological father.

I-2. Disjunction between genetic origin and genealogy

[48] Link to CCNE's Opinion n° 110 du CCNE published in 2010: *Ethical Issues Raised by Gestational Surrogacy* (GS)
http://www.ccne-ethique.fr/fr/publications/problemes-ethiques-souleves-par-la-gestation-pour-autrui-gpa#.WQsZZ0Y2Vzk

When a child is born *via* GS, to which is possibly added procreation with a donated oocyte, there are a number of disjunctions between genetic origins and genealogy: the intervention of two different women to obtain an oocyte for fertilisation and then to carry it to term, dissociates the genetic origin from the gestational origin. As these two origins leave separate biological traces, this procedure introduces a disjunction between genetic and epigenetic determinants through the interaction of mother and foetus with their environment.

The child's origins may therefore involve up to five different people: one or two intended parents who will be rearing the child, a gestator, an oocyte donor or vendor, and possibly a sperm donor in the case of GS with two gamete donors.

II. Relationships and GS

Relationships are established between a substantial number of "players" participating in a GS: the intended parent or parents, the "surrogate carrier" or "gestator", the oocyte donor and the child, the procedure being more often than not organised by a large number of intermediaries.

II-1. Relationships introduced by the request from the "intended parents" in a so-called "societal" GS.

Male same-sex homosexual couples and men on their own

The most frequent case is the male homosexual couple since, if they want children with a biological connection to them, GS is a costly option but an easy one to implement. It is also considered to be the one which best meets the couple's wishes, while two other possible options are increasingly rejected: (1) co-parenting with a woman who will be the child's biological and legal mother, or with a female couple with one of the women being the biological and legal mother. This system is not considered satisfactory since it implies sharing legal custody of the children and they are no longer children of a male couple, but instead shared with one or two women. Option (2), legal adoption, is considered too lengthy and hazardous because there are not enough children who can be adopted to satisfy all requests and social services may be reluctant to give preference to a homosexual couple rather than to a heterosexual one. Also, some countries who accept international adoption refuse to hand over a child to a homosexual couple[49].

A man on his own, if he does not wish to have sexual relations or so-called "home[50]" insemination involving a woman, is in the same situation as a male couple.

Fertile women who do not wish to carry a child

Be they alone or one of a couple, some women claim the right to have someone else carry their child for the sake of convenience.

Persons without any biological connection to the child — a risk of human trafficking?

This configuration — GS with double gamete donation — unknown only a short while ago, was brought to light by court decisions (See Annex 7). These judgements in both cases were that it would not be possible to recognise the child's filiation. There is

[49] Furthermore, the countries to which most couples apply for GS are progressively inclined to reject requests from abroad: India, Thailand, Nepal, Cambodia.

[50] See footnote 29.

cause for concern that these cases might be the tip of the iceberg for the practice of giving birth to children with a view to their adoption by persons without any biological connection to them. This could be in response to a reduction of the number of adoptable children.

II-2. Relationships during a GS procedure, highly dependent on intermediaries

GS without intermediaries, a rare phenomenon

Intended parents may call on people they know and ask a woman, sometimes a member of their family, to oblige them without any intermediary or financial contract. This sometimes goes by the name of "altruistic" or "ethical" GS. More often than not, DI is the method used but IVF may also be chosen. Such a favour mobilises a year in a woman's life and exposes her to physical and psychological risk which may have an adverse effect on her loved ones. The main risk to be observed is a destabilisation of a family or friendly relationship, be it during gestation, at the time of giving birth — particularly if there are complications with serious or even life-threatening after effects for the surrogate carrier — or when the child is due to be handed over and this is disputed. There is also a risk of surrogate carrier intrusion in the first years of the child's life.

The central role played by economic intermediaries in the development of GS

When the subject is raised of the relationships specific to the GS procedure, the major role that intermediaries play in their development is bound to be very much in the foreground. Most GS procedures are organised by commercial agencies with headquarters in a country where GS is legal, but their activities are clearly international (transportation of gametes, intended parents and children and, in some cases, of surrogate carriers). It is worth noting that in France, where such agencies are prohibited, foreign agencies have illegal and "undercover" representatives[51].
The intended parents sign a contract with the agency which then arranges for contacts with several possible surrogate mothers and provides medical services, the purchase of gametes and legal services. The fees paid by intended parents are used by the agency to pay the various service providers[52].
These agencies enable applicants to enter into an organised arrangement with a number of players, in highly diverse circumstances. In the United States, the gestational carrier and the intended family more or less choose each other and get acquainted if they wish to; in India, the gestational carrier is generally anonymous and the only link is the agency. But most importantly, it is the agencies who organise the agreement between the parties: number of attempts, number of children wanted, price, etc. (*see Annex 8*).

Contrary to popular belief, nationals of countries where GS is authorised and regulated also turn to this international market when the number of surrogate carriers in their own country is insufficient, as in the United Kingdom where surrogates are not paid and only get compensation for their expenses. But they may also choose to go to countries in South East Asia for instance, where the cost of GS and the

[51] http://www.lalibre.be/actu/belgique/une-nouvelle-bourse-aux-bebes-a-bruxelles-fin-janvier-56992cec3570ed38951f2efa
[52] In the United States, the cost of GS ranges from 100,000 to 150,000 dollars, of which 20,000 goes to the gestator. In India, the same operation costs around 30,000 Euros, of which 3 to 4,000 is paid to the gestator.

protection of gestational carriers are less of a constraint than in their own country.

II-3. Relationships and situation of "surrogate carriers" or "gestational carriers"

Relationships with the intended parents

The relationship between intended parents and surrogate carriers has changed now that the number of "reproductive surrogacies" is diminishing and that of "gestational surrogacies" increasing. This development follows the advice given by intermediaries and agencies and also may be the preference of intended parents, because it is thought that there is less "risk of getting attached" to the child, and therefore of conflict between surrogate mothers and intended parents.
As the child has no genetic connection to the surrogate carrier, the existence of contracts requiring the carrier to hand over the child at birth, including by legal enforcement if she is reluctant, seems easier to defend. Thus, in the United States, eleven States authorise a *"pre-birth order"*, i.e. a legal statement of intended parentage at a very early stage. In this way, there is legal recognition of the intended parents during pregnancy and they can be designated as the child's legal parents in the "birth certificate" which is the administrative document on which all subsequent birth records are based. In these States, the birth certificate is therefore not the same document as the hospital's certificate of delivery. This discrepancy can be a problem when returning to France.

The various profiles of surrogate carriers

Surrogate carrier motivations, better researched nowadays, range from simply financial to entirely altruistic (which is exceedingly rare and almost always for intra-family surrogacies) but a large number of surrogate carriers refer to both. The altruism argument, which has become a leitmotiv in claims for access to GS, deserves to be considered carefully.

As regards surrogate carriers in developing countries, the medical environment in which they are pregnant is often trying and risky in countries where maternal death is still frequent. The financial compensation (around $4,000) of course may be out of all proportion to what a carrier might earn by other activities, but Indian anthropologists have often demonstrated that the financial gain was finally unlikely to enable any radical change in the surrogate carrier's situation (contrary to the initial plan of registering with a school or improving the house, the money is often spent on reimbursing debts, or is confiscated by the family or squandered[53]).
For poor surrogate carriers in prosperous countries or countries such as the Ukraine, the financial contribution is large and rather less subject to the vagaries of family pressure. On the whole the medical circumstances of the carrier are of superior quality but some specific risks may be present since doctors sometimes transfer an excessive number of embryos[54].

In both cases, the financial argument is the essential component of the procedure and solidarity with the intended parents seems to be a secondary, or even negligible, consideration.

[53]La gestation pour autrui : resituer la France dans le monde. International symposium, Muséum national d'histoire naturelle; 17-18 November 2016.

[54]The reasons given are frequently the increased chances of success and the intended parents' wish to have several children simultaneously (the special case of male same-sex couples who want in a single pregnancy to have embryos sired by each of the fathers) but above all because the main cost is for pregnancy and extra cost for a second child is small.

This situation is a little different for middle class surrogate carriers in developed countries. Some of the American laws authorising GS do not allow the employment of carriers who are covered by Medicaid or any other State compensation scheme. Medically speaking, they receive good care although of course they are subject to the risks pertaining to all pregnancies. Annex 8 lists the heavy burden of obligations they must submit to. They do claim they are acting for altruistic reasons, very often in connection with religious convictions of the need for benevolence and self-esteem. They also mention financial motivations, for instance to pay for their children's higher education[55].

Relations between the surrogate carrier and her own family

The decision to carry another person's child has an impact on the life of the surrogate carrier and that of her family and people she is close to, i.e. her spouse, her children, her parents, and even in certain cases her work environment. She may be kept away from her spouse while she is pregnant (in Asia), or, when she stays in her own home (United States), her spouse is marginalised during her pregnancy and delivery, even though the agencies consider that his cooperation is essential for the success of the endeavour. Her own children will be discovering the existence of a special relationship between their mother and a future baby and they will realise that the time and energy she is devoting to it is, to some extent, spent at their expense. The whole enterprise is performed within the bounds of a contract and, in the majority of cases, the bonds created will be cut short.

The relationship between the surrogate carrier and the foetus she is carrying and, later, the child she gives birth to.

From the very start of a GS contract, it is made clear that the surrogate is not carrying her own child, but instead the child of the intended parent or parents. She is therefore supposed to control her emotions in such a way that no bond of attachment to the foetus is created. American "carriers", who are those that have been the subject of the most university research studies, have stated that this requires a conscious effort and a denial of the feelings of biological and emotional attachment which characterise pregnancy[56].

II-4. Situations and relationships affecting the child

The repercussions of GS on the child, in particular on his relationship to the surrogate mother, during gestation, at birth and later on, is a matter of the utmost importance. It is also one of the questions that is least studied in research work on GS.

During pregnancy, the bonds between the surrogate carrier and the foetus, and therefore with the future child, are close and specific. Exchanges are biological and psychological, with epigenetic tags and marks of the environment to which the woman — and therefore the child — are exposed (*see Annex 9*). There is symbiosis between a mother and the foetus she is carrying. The foetus perceives her movements, her emotions, the variations in her cardiac and respiratory rhythms, her alternations of activity and rest. The child is receptive to what she eats, to the odours reaching her

[55] This explains why media reports often feature women from middle class families who emphasise their desire to help others. However, with rare exceptions, the financial trigger is essential and must reach a certain minimum, as the case of the United Kingdom illustrates. The amount paid to the carrier in the U.K. is capped, about €10-15,000, theoretically solely intended to pay for costs. As a result, the number of women volunteering is small.

[56] Van den Akker O.B. (2007). Psychosocial aspects of surrogate motherhood. Human Reproduction Update,13, 53–62.

nostrils, to familiar sounds, in particular to maternal and paternal voices.

At birth, a programmed break occurs. The child and the surrogate carrier are separated and the child is removed from the foetal life environment, to be transplanted into another world, the world of future life, of the intended parents' life where a different language is the rule, a world with sounds, odours and lifestyles which are not those which made up the child's life up to that point.
The handing over of the child by the surrogate carrier to the intended parents is one of the constituting acts of the GS contract while pregnancy and delivery, which are functions of the gestator's body, make no sense unless they reach the point where the child's is physically handed over. Although elements and products of the human body may, in certain conditions, be the subject of a donation, the human body can no longer, now that slavery is abolished, be the subject of a contract. In a GS contract, the body and person of a child are held to be the subject of a contract, which is incompatible with the general principles of law.
Being the subject of a contract has repercussions since the contract must stipulate what will happen if the subject of the contract does not conform to expectations. If, by reason of an infirmity (discovered *in utero*, or at birth), the child does not meet the expectations of the intended parents, the contract may be broken by the intended parents or the surrogate carrier, in circumstances which may not necessarily be fully respectful of the child's best interests and future.

After the child is born, some intended parents point out the excellent quality of the relationship they maintain with the surrogate. While some of them consider that keeping in touch with her may help children to gain a better understanding of their origins, other parents fear that contact with her may be detrimental to their own relationship with the child. In a majority of cases, no such relationship persists. The children will need to integrate into their personal life history both the surrogate carrier and the woman who sold her eggs. The intended parents may in fact choose a donor whose identity is known to them or an anonymous donor and, in both cases, the child may wish to know more about the woman who transmitted a part of her genetic heritage.

III. Consequences of a GS procedure for surrogate carriers and for the child

It is mainly the women recruited to be "surrogate carriers" and the children born to them who bear the consequences, which may be viewed as potentially harmful, generated by GS.

III-1. Consequences for surrogate carriers

Gestational carriers, in the vast majority, are women from poor countries and countries experiencing sharp economic disparities: South-East Asia, the Ukraine, Russia and, to a lesser degree, Mexico and Greece. The women who become surrogate carriers are from underprivileged sectors of the population, with the exception of America which is a model by itself, with however major disparities from one State to the other. The injury they undergo is mainly of an economic, legal, medical and emotional nature.

Economic injury

In a majority of countries, surrogate carriers volunteer so that they can meet their basic needs: health, housing, schooling for their children, sometimes to pay for studies or to start a business. As already noted, gestational surrogacy which generates the same physical risks as any other pregnancy or childbirth, implies that such risks are incurred for other people's benefit and for financial gain, even though the reasons may also be partly altruistic or religious. To be running such risks, motivated more

or less powerfully by financial inducements, constitutes a major instance of economic offence. Regardless of which legal forms of market control can be installed, such practices encourage the development and perpetuation of social inequality, even in developed countries.

Legal offences

In Asian and South East Asian countries, there is no great probability that surrogate carriers can give free and informed consent, both because their economic status curtails their freedom and because the educational differences are very pronounced between the parties concerned (intermediaries, healthcare professionals, intended parents), so that there is major inequality in the negotiation of contracts with agencies.
Payment depends on the contract being fully honoured: the carrier gets little or even no compensation if she has a miscarriage; money is paid for a child and not for the process of gestation. Several cases brought to the attention of the media have demonstrated that carriers whose health is impaired are simply sent home without compensation or that in the event of their death, their families are given no assistance.
Finally, a large number of clauses restrict the carriers' liberty, which is a violation of human rights. In India, there are cases of confinement to special centres where carriers are obliged to reside throughout their pregnancy; their freedom of movement is restricted as is the right for visits from their family. Furthermore, now that certain States have prohibited GS for foreigners, intended surrogate carriers are deported to a neighbouring country where legislation is not so strict. In every State, contracts are replete with multiple obligations restricting the carrier's personal autonomy and, even more fundamentally, the liberty to abort or to undergo medically-motivated induced termination in the event of a health problem (*see Annex 8*).

Violations of good medical practices

There are frequent violations of good medical practices in every country: in particular, transfers of an excessive number of embryos and embryo reduction to suit the wishes of the intended parents, or else an unnecessary use of Caesarean section with the possibility of complications. Some deaths have been reported, sometimes by the media, but GS-related morbidity is not reported in a separate category.
In South-East Asian countries, pregnancy, Caesarean section and post-natal healthcare are all undergone without any medical or life insurance for the carriers and there is no guarantee that post-natal care is appropriate to the carrier's health needs.
In certain centres, in order to achieve a 100% success rate, several carriers are recruited to satisfy the same request. Once one woman has safely given birth, the others are made to abort. As the number of GS procedures per carrier is not limited, some of them are exposed to multiple successive pregnancies.

An underestimated psychological consequence: impairment of the bond between the surrogate mother and her child, denial of that bond

Whether the woman is motivated by the need for money, as is most often the case, or a rarer altruistic desire to help and/or in some cases a feeling of wellbeing when pregnant, the feelings she has for the child she is carrying, who is growing and making its presence felt within her, are probably variable and ambiguous, but nevertheless undeniably present.
The child's birth is an event that fractures the bond which had developed. Even when carriers are aware of this and feel they have prepared themselves to accept it, they may be unhappy and depressed. This has been described as a "programmed abandonment" of the child. But this is abandonment that is not just accepted and organised by society, it is also authorised by the State.

This bond between surrogate carrier and her child becomes conspicuous in extreme circumstances, when she keeps the child or is coerced into abandonment by court decision. In the United States, where this situation has mostly been studied, testimonies have reported on the need for psychological preparation to avoid becoming attached to the child and feeling guilt on two counts: unease at experiencing closeness to the child and unease at having to deny maternal feelings prompted by an event taking place within her own body. Some agencies organise coaching sessions to manage these feelings.
Finally, one of the psychological difficulties confronting a carrier may be social stigmatisation, which takes on various forms in different countries and social environments.

III-2. Consequences for the child

Children born by GS are the subject of contracts entered into between parties with very unequal powers. This objectification of the child exposes it to injury, not only legal, but also physical and psychological.

Medical

Theoretically, the good health of the children transferred is the subject of meticulous attention as this is a necessary condition for this form of trade to develop. However, high-order multiple pregnancy which the doctors organising the procedure often favour in order to obtain optimal yield, is a cause of premature birth and complications which may lead to the child's psychomotor impairment. Discovering a malformation, either during gestation or at birth, which can sometimes be surgically repaired but can also lead to severe handicap, raises the issue of the child's acceptance by the intended parents. Some children have been abandoned by intended parents because of a handicap. Although this attitude can be encountered with natural pregnancies, here it is facilitated or even provided for in the contract. In some cases, the intended parents have separated in the interval before the birth. The children, in the best-case scenario, end up in an orphanage or an adoption agency.

Children and risks to the psyche

There is no first-hand information regarding trauma caused by separating the mother from the child she carried. There is, however, more data available on a child's points of reference at birth, which were acquired during the foetal period, the crucial nature of which is becoming more evident by the day. And yet, at birth, a child born through GS is separated from the surrogate carrier and handed over to the intended parents; this is a total severance from the environment that was familiar in the course of intra-uterine life.

It is certainly of vital importance not to conceal a child's origins nor the path followed by intended parents. How will a child feel about having been the subject of a contract, involving a woman paid for sharing the intimacy of her life during gestation? Intimacy which was followed by separation?
When the child reaches adolescence and depending on the conditions imposed on the surrogate mother, who may or may not be known to the child, he or she may be reproachful that the intended parents kept the identity of the carrier — and/or of the oocyte donor — anonymous, or may want to get to know the women concerned, in some cases against the wishes of the intended parents.

III-3. Risks for the intended parents

Intended parents may be confronted with various problems, the ones they fear the most being a change of heart on the part of the carrier who could abort, or keep the child or sometimes put pressure on the parents to pay more than was agreed. In the rare cases of intra-family GS, the surrogate's heavy-handed intrusion in the life of the family is mentioned. These setbacks seem to be a rarity in actual fact although they are feared by all, which seems to be a symptom of the sense of insecurity generated by having asked others to substitute for of the most intimate actions in someone's life.

IV. Developments in French law in the presence of demands for GS and GS procedures abroad

French institutions are having to deal with French nationals who went abroad for a GS procedure, which is currently illegal in France, and then ask for legal recognition in France of the effects of this situation, arguing that the procedure was legal where it took place (*see Annex 10 on European legislations*).

Attempts were made to take care of the difficulties arising out of this disparity by means of an international convention, but the conference in the Hague convened for that purpose has not, so far, managed to devise a compromise solution acceptable to its members.

The concept of international public order, which permits a "mechanism for the eviction of the foreign law when its articles are in conflict with the French vision of international public order in France" is the instrument for the ultimate protection of social choices, therefore of democracy within each State[57].

In France, the decision not to accept GS went through various stages.

- Associations whose object was to put in touch carriers and would-be intended parents were prohibited in the 1980s.
- In 1991, the *Cour de Cassation* declared that GS agreements were contrary to public order and therefore illegal[58].
- These arguments were enshrined in the first law on bioethics in 1994[59].
- In 2013, following the growing incidence of GS, not on French soil but abroad, the *Cour de Cassation* attempted to set up the most radical obstacle in its armoury — fraudulent evasion of law — to oppose the establishment of a legal bond of filiation between a child born of such an agreement and its intended parents[60].
- The intervention of the European Court of Human Rights (ECHR): the ECHR noted that there is no consensus in Europe on the legitimacy of GS nor on recognition of the filiation of children born by GS[61]. It therefore came to the conclusion that this situation opens up for States a broad margin for appreciation since they may legalise or forbid GS in their internal public order system and resort to the

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[57] G. Drago, *Cour de Cassation* (France's supreme court of appeal); public order is defined in Article 6 of the *Code Civil* as an essential limit to the liberty of freely formulating a contract: "special conventions cannot be used to derogate from laws of public order and morality". L. Gannagé, *L'ordre public international à l'épreuve du relativisme des valeurs*.

[58] On 31 May 1991, the Cour de Cassation's Plenary Assembly ruled that a surrogacy contract whereby "a woman agrees to conceive and bear a child and relinquish it at birth was contrary to the public order principles of the non availability of the human body and of civil status", and that the procedure was "a misuse of the institution of adoption".

[59] Article 16-7 of the Code Civil states that "*any agreement for gestational surrogacy is null and void*" and Article 16-9 that the nullity is a matter of public order. Furthermore, any natural or legal persons acting to incite a woman to abandon her child or who "*voluntarily simulate or conceal a substitution having led to an offence against the civil status of a child*" will be incurring criminal sanctions.

[60] In two cases judged in 2013, the *Cour de Cassation* referred to the concept of "fraudulent evasion of law" characterised by a GS performed in another country where such procedures are authorised. It also refused to transcribe a birth certificate for a child born by GS in another country.

[61] The ECHR detailed this finding. GS is expressly forbidden in 14 members States of the Council of Europe; in 10 other States, either it is prohibited by reason of general provisions, or it is either not allowed or the issue of its legitimacy is doubtful. It is only authorised, with various reservations, in 7 States and allowed exceptionally in 4 other States. Finally, in 13 States, it is possible to obtain recognition of filiation for a child born of gestational surrogacy legally practised abroad and less certainly in 11 other States.

international public order category when considering a situation created abroad. The Court does, however, state that while States are free to prohibit GS contracts, this must not prevent the children concerned from enjoying their rights to privacy, which implies protection for several elements held to be helping people to construct a "personal identity"[62]: filiation and nationality.

To comply with the ECHR's rulings, in two decrees on 3 July 2015 the *French Cour de Cassation* allowed the transcription of a foreign civil status record for GS, but made it clear that the allegations of this record correspond to the factual situation, the legal father being the French biological father and the designated mother in the birth certification being the surrogate mother.

V. Arrival in France of children born by GS abroad: legal situation

When intended parents wish to return to France with a child born by GS abroad, they may well come up against administrative reluctance to deliver a civil status document. These obstacles have been alleviated to some extent and it is the situation as it is today that should be considered, keeping in mind that the solutions which have been found do not in any way call into question the public order prohibition of GS (Articles 16-7 and 16-9 of the *Code Civil*).

When a child is born, the maternity hospital makes out a "certificate of delivery" for medical purposes, which features the name of the woman who gave birth, and a "birth certificate"[63] for legal purposes. It may be drafted by the registration officer of the embassy or consulate of the intended parents' home State, or more often than not, by the authorities of the State of birth according to it's own rules regarding birth registration. In California, for example, it is allowable to record only the intended parents' particulars. There are therefore two types of civil status records produced in a foreign country in relation to a GS procedure: (1) a civil status record conforming to the factual situation, described as "probative", where are inscribed the names of the biological father and of the "surrogate mother", without any mention of the second intended parent; (2) a civil status record where the names of the two intended parents are to be found (biological father and second intended parent), but no mention of the "surrogate mother". In this latter case, there is a discrepancy between the (medical) certificate of delivery and the (legal) birth certificate[64].

The next phases include: obtaining authorisation for the child to enter France; establishing filiation; obtaining French nationality. Based on the contents of the "birth certificate" of the country in which the child was born on which at least one parent must be a French national, the embassy or consulate make out "travel documents" without reference to the circumstances of the child's birth[65].
On their arrival in France, the intended parents apply to the Service Central d'Etat Civil (SCEC – Central civil status department) in Nantes[66] for a transcription of the foreign civil status document which is allowable only when the foreign document is considered to be "probative"[67]. Transcription of

[62] For instance, the obligation for a State's social services to make available some of the data listed in the personal file of people who have been cared for by foster families for a length of time, so that the persons concerned may have access to their personal history, data on their childhood and education, all of which enables them to establish their identity as a human being (Gaskin 1989), or the right that the State does not set up excessive barriers to the possibility of accessing someone's genetic origins (Mikulic 2002).

[63] Information featured on this certificate: date, time and place of birth. Data relating to mother and father varies from one State to another, in particular in the United States. In some States, the birth has to be declared in their own civil registration service so that there is a need to ask the embassy or the consular services to transcribe the registration.

[64] As the law currently stands, the difference is crucial since the *Cour de Cassation* does not allow the transcription of the civil status record unless it is sincere, and ECHR which did not rule on this point, is also very attached to the principle of the truthfulness of the child's civil status, in particular biological authenticity.

[65] *"Laissez-passer consulaire"*. (Article L.521-2 of the Code of Administrative Justice; the judge for interim measures of the *Conseil d'Etat* (Council of State) ruled that this was mandatory, decree n° 401924 of 3 August 2016).

[66] In point of fact, this transcription is not mandatory but optional (Art. 509 of the instructions on civil status), but generally considered to be easier to use that the foreign civil status. Intended parents therefore prefer it.

[67] The probative character is evaluated according to Art. 47 of the *Code Civil:* a birth certificate produced outside France and set out in accordance with the rules enforced in the foreign country is deemed authentic, unless there is evidence to the contrary, or that it is falsified or that the facts in relates do not correspond to the truth. A problem arises if the "birth

a foreign civil status document is absolutely not acceptable if it does not conform with the facts of a child's birth. This meets the demand for transparency and truthfulness regarding origins which is owed to a child.
French nationality can be granted when there is a genetic relationship with a French parent[68]. Certificates of French nationality (CNF: delivered by the French nationality centre or by district courts) are irrefutable proof of French nationality. A child in possession of a CNF is entitled to a French passport and identity papers.

Daily life upon return to France
Whatever foreign civil status document was delivered can be used in France as it is. The child can live with the intended parents, have access to healthcare and to education[69]. If the intended parents want French civil status, there is no problem with transcription as long as the foreign document is "true to reality", i.e. that it mentions the carrier. In this case, the biological father is the legal father and the second parent has no legal bond with the child. However, there is the possibility of granting a "delegation of parental authority" to the spouse of the biological father (Article 377 of the *Code Civil* since this situation is true to the reality of the child's origins[70]. This would satisfy three conditions: recognition of biological filiation with respect to the father; a legal situation for the intended parent corresponding to social reality; acquisition of French nationality *via* paternal filiation. In this way, it is likely that the ECHR would cease to consider that there was a violation of the child's privacy.
The "dependent child" concept would serve to meet taxation requirements.
As regards inheritance law, the birth certification establishes filiation. The child is therefore the heir of the biological father. As regards the spouse, the child does not have full rights to the estate although he or she may benefit from a bequest for which some unfavourable tax conditions would apply. However, the *Affaires Civiles et du Sceau* Directorate of the French Ministry of Justice has requested the *Conseil Supérieur du Notariat* to arrange for children born *via* GS to be heirs in conformity with general law[71].

VI. Conclusion and recommendations

An analysis of the relationships between all those playing a role in a GS procedure revealed a number of risks and violations of a medical, emotional and economic nature. These are to be observed in all such procedures, although they are increased by the inequalities between partners, more radical in the

certificate" (the parents' identity) produced abroad does not conform to the data featured in the medical "certificate of delivery" which states the identity of the mother who gave birth.

[68] Circular JUSC 1301528C of 25 January 2013 regarding the delivery of certificates of French nationality (CNF) underlines that suspicion that a gestational surrogacy (GS) agreement was concluded outside France, is not sufficient by itself to reject a request for a CNF if the filiation with a French national of the child born subsequent to the agreement is based on a "probative" birth certificate in accordance with Article 47 of the *Code Civil*. Systematic reference to the Ministry of Justice's nationality department following all requests for a CNF entering into the scope of the 25 January 2013 circular was the subject of a reminder (by message of 23 April 2015) with a view to ensuring harmonisation of all cases on French soil by the approximately 220 tribunals with competence for nationality (Min. Justice- JO: Ass. Nat. 23 August 2016).

[69] Foreigners living and working in France are entitled to national health insurance coverage by the fact that they subscribe to it; the same covered applies to their children.

[70] This is the solution recommended by the French Senate's enquiry mission (Yves Détraigne and Catherine Tasca – 17 February 2016, SÉNAT, N° 409). Y. Détraigne and C. Tasca are in favour of having the matter settled by legislators instead of forcing judges to make major ethical decisions. They also recommend that the child, and the child alone (even if the parents act in the child's name) be authorised to apply for the establishment of filiation with due regard for the demands of French law, and therefore apply for recognition of his/her biological paternal filiation. The creation of a bond of filiation with the intended parent, however, would be impossible and the only solution would be an unlimited delegation of parental authority. The imperative of prohibiting GS would thus be respected. The rapporteurs also recommend a confirmation that no other action seeking to establish the reality of intended filiation as a sequel to the fraudulent process of resorting to GS would be allowed (e.g. later adoption of a spouse's child or "*action en possession d'état*" (legal recognition that a person is acting as a parent).

[71] Confirmed by the Minister for Social Affairs, Health and Women's Rights, 19 May 2015. http://questions.assemblee-nationale.fr/q14/14-79692QE.htm

so-called Indian model than in the so-called American model. CCNE was particularly struck by the acceptance of the low, but not inexistent, risk for the carrier of death or serious health impairment. Neither the intended parents nor the GS promoters appear to be concerned about it.
From the description of procreation and gestational surrogacy agreements, we can see how the large number of disjunctions leads children to need to integrate up to five people who have had a part to play in their conception, gestation, birth and education before they can construct a unified identity.

CCNE is extremely uneasy at the rapid expansion of the international market for GS under the pressure of commercially motivated agencies and lobbies seeking to showcase positive images of this market in the media. The Committee is particularly worried by the increase in the number of GS procedures which are, in fact, no more than the production of children for private adoption which are supposed to alleviate the scarcity of adoptable children, both in and outside France. Parents following the legal adoption procedure have less of a chance of achieving their aims than those who are in fact in breach of French law.

CCNE has examined the argument to the effect that forbidding GS would be an encroachment on women's liberty to gestate, an attitude often judged to be "paternalist". However, the Committee considers that the liberty allowing a surrogate to abandon, by contract, certain of her liberties (liberty to move, to live with her family, to essential healthcare) is no liberty at all. Nor is it a liberty that generates a contract of which the avowed object is to organise legally the transfer of a child's body and individuality, a transfer accepted by the surrogate in favour of the intended parents. A human being, in this instance a child, cannot be the subject of a deed of transfer or conveyance of property, be it for payment or free of charge. This is one of the reasons for the prohibition of adoption contracts between private parties.
Finally, CCNE finds that, following ECHR jurisprudence, most of the administrative obstacles which could have been obstacles in the past are about to be removed, so that the privacy of children can be preserved.

In conclusion, CCNE remains attached to the principles justifying the prohibition of GS, those principles which inspired legislators: respect for human beings, rejection of the exploitation of women, rejection of the commodification of children, inalienability of the human body and of the human being. Considering, therefore, that there can be no such thing as an ethical GS, CCNE's wish is that prohibition should be maintained and reinforced, regardless of the applicants' motivations, be they medical or societal.

Recommendations

- CCNE is in favour of drafting an international convention for the prohibition of GS and is particularly attracted by a diplomatic approach to this end. Along the same lines as in the information report on GS submitted to the President of the French Senate on 17 February 2016, CCNE recommends the launch of multilateral international negotiations.

- Concerning the recognition of the filiation of a child born of GS outside France, when a probative civil status record establishes biological filiation with at least one of the French parents, CCNE supports a delegation of parental authority to the intended parent who has no biological connection to the child, since this procedure is true to the reality of the conditions of the child's birth.

- The Committee recommends, in cases where the reality of biological filiation of a child born of GS outside France is open to doubt, that verification of genetic filiation by means of a DNA test be ordered before a foreign civil status record is transcribed as a French civil status document, so as to verify that there is indeed a biological link with at least one of the intended parents. The result and the situation should be open to examination. In the event of confirmation of child trafficking, the child could be proposed for adoption.

- The Committee further recommends that children's civil status records durably include the names and particulars of all those participating in the gestation agreement and that children are given access to the agreement which led to their birth so that they can "construct their identity" and reconstitute their full personal history.

Chapter 5
Stumbling blocks, issues and prospects

The variance in views expressed by society on the subject of opening MAR technology to societal indications reflect individual appreciations of society's role and responsibilities as regards access to these techniques: should society's sole function be to foster liberty and equality of access to existing techniques, or should it be held responsible for the consequences of the situations which it is asked to authorise and organise[72]? This ethical debate needs to explain the complexity of the issues raised by claims for societal use of MAR. This report and the data it contains attempts to make a contribution to the thinking of society and individual readers.

Using the same method of analysis to examine the three kinds of claims to access MAR procedures, CCNE identified several fundamental queries constituting stumbling blocks (*see Chapter 1),* common to all three situations, summarised below. Regardless of the positions held and the values on which they are founded, the issues they raise cannot be ignored.

I. Confrontation between personal and collective interests

Calls for MAR, in part induced by social developments, are first and foremost the fruit of individual decisions on the part of those concerned. A properly informed individual is able to deliberate, measure the risks and take informed and autonomous decisions.

Reproductive biotechnologies are the source of a paradox which is in itself a stumbling block. They are called upon to respond to the personal wishes of an individual or of a couple. The response they can provide is a step towards recognising these wishes as a right which clashes with social or legal norms, in other words the "collective" whose task it is to provide the technical and legal means of satisfying a personal project. Personal ambitions (a growing demand for individual autonomy and in particular the possibility of choosing a personal lifestyle), and collective possibilities (respect for certain principles such as protection for the individual, solidarity and accountability) are then in conflict.
Technology, as a response to individual wishes, generates in particular a demand for autonomy which is also expressed as a claim to freely control one's own body and to take decisions concerning one's own health. And yet, such autonomy is fettered by relationships, or even dependence, limiting its expression: dependence on the medical professions (of which the word "assisted" is a clear demonstration), dependence on third parties, for example gamete donors, dependence on society, not forgetting the relationship with the child. Such decisions may well be free, informed and autonomous, but they never concerns solely the individual taking them.

II. A fragile boundary between pathological and societal

Societal claims for recourse to MAR lead, first of all, to identifying the boundaries of concepts such as pathological and societal, health and the role of medicine. Current legislation which requires the pathological nature of infertility to be medically diagnosed, leads to excluding same-sex couples and single women from MAR[73]. However, a great many infertilities do not have any identifiable cause and

[72] Man transforms nature. His mastery of new technology modifies his relationship to nature, to health and to other humans, thus creating the illusion of power but tainted by immoderation. The research community and, more generally, engineering ensuing from the applications of research, must more than ever before call into question the significance of their applications. This ethical approach, following in the footsteps of the philosopher Hans Jonas, should become consubstantial with the adoption of progress, even if to do so is a revision of the very concept of progress in a climate of sharing and co-development with nature's domain. CCNE reflections submitted at the United Nations Climate Change Conference, COP 21, 24 September, 2015.

[73] And also excludes *post mortem* MAR and MAR involving an overage woman. French national medical health insurance

are diagnosed as idiopathic. For some women the only reason for infertility seems to be that they have reached an age when natural conception is more difficult. Even though the boundaries between what is viewed as pathological and what is not are sometimes blurred, the principle has never been called into question that MAR in France is not a medical service making all and any of the available technologies available on demand to any couple or woman who wants to use the procedure for personal reasons. One of the consequences is that societal requests are viewed as being separate from any form of pathology to which medicine could bring a remedy.

But the dividing line is not so sharp: it can be said that the medical profession's essential vocation is to treat and prevent pathologies; or it can be said on the contrary that the role of medicine and healthcare is broader, that it does not just consist in treating and preventing disease, but also to alleviate suffering. To be deprived of having children because of sexual orientation or by the absence of a companion can be an authentic moral and existential hardship, even though women in that situation are not medically speaking in the same situation as an infertile heterosexual couple seeking a solution in a medical framework, *stricto sensu*.

III. Children's rights in the context of reproductive biotechnology ?

One central issue in the ethical debate on opening access to MAR procedures is that of the situation of children born and reared in that context. While the assistance provided responds to the wishes of the person or of the couple, its effects on the child born as a result must also be considered. Whatever kind of parenthood is planned —all male or all female couples, a single woman or a single man — accountability to the child is an integral part of the ethical debate. Although "the right *to have* a child" is frequently quoted in societal claims, it has no legal foundation; on the other hand, a major ethical concern must the children's *own* rights, not the least of which is to be able to situate their life histories and family environments in the midst of the lives and family environments of other children, regardless of the reproductive mode used to give them birth (*see Chapter 3*).

Safeguarding the interests of a child, already alive or not yet born, is a major requirement and conforms with international law. With MAR, the law protects the child's interests and authorises the medical team to require their patients to observe a "cooling off" period "to protect the interests of the future child" (Art. L.2141-10 of the French code of public health[74]). The child's interests are implicit in the law: whether or not the articles of the law are found to be appropriate, whether or not it is thought they ought to evolve, it is in part for the sake of those interests that the law reserves access to couples composed of a man and a woman meeting certain conditions of age and status, forbids practices such as double donation or gestational surrogacy (GS) or confirms the anonymity of gamete donation. The risks, all of which are also "stumbling blocks", are not identical in the various claims for broader access and it is for this reason that they are discussed in Chapters 3 and 4. The question of consequences inevitably arises over and over again in discussions regarding reproduction in same-sex female couples or single women; on the one hand that of the immediate absence of a father and of the presence of a single genitor and, on the other, that of a mother whose identity may become uncertain because of the ovule was donated (thus dissociating genetic transmission and filiation in the maternal lineage) or of GS (which introduces a double uncertainty, genetic and gestational). The question of the absence of a mother would be identical in GS procedures requested by same-sex male couples or single men.

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only finances the procedure for women up to the age of 43.

[74]"Medically assisted reproduction must be preceded by private discussions between applicants and members of the multidisciplinary bioclinical medical team attached to the centre, which may call on, if necessary, the social service created to implement Article VI of the Code for the family and social aid. [….]. The application can not be confirmed before the expiration of a reflection period of one month following the last interview. Confirmation of the application is provided in writing. […]. MAR can not be implemented by the physician if the applicants do not meet the requirements set out in this ruling or if, after consulting the multidisciplinary bioclinical medical team, the physician considers that a further period of reflection by the applicants is needed in order to protect the interests of the future child."

IV. The issue of the availability of biological resources and beyond, of the "commodification" of products of the human body.

Societal claims for access to MAR rest on the availability of certain components of the human body, gametes in the case of oocyte autopreservation and extending access to DI, or the uterus viewed as a resource in the GS process. As in any process of exchange, gametes can be the object of a gift but also of a commercial transaction. In France, the laws on bioethics are founded on two principles, that of non payment and that of donor anonymity. The rule of no payment aims to prevent any economic pressure on people who are particularly vulnerable, that is the vast majority of those selling their blood, their gametes and renting out their uterus in those countries where paying for components of the human body is legal. But choosing non payment is not without consequence as regards response to demand. In France, in a legal framework limited to living heterosexual couples of child-bearing age, sperm donations are barely sufficient to meet demand, but egg donation is insufficient so that the situation can be described in economic terms as a "shortage".

We must therefore examine the consequences, in a context of scarcity, of extending access to MAR on (i) the delivery of healthcare by the French public health system, and (ii) on the risk of commodification of products of the human body. There are several possibilities:

- evidence the risk and act on it through the authorisation process by continuing to reserve access to DI to cases of pathological infertility;
- deny the risk and combine authorisation and gratuity to all types of requests, regardless of consequences in terms of scarcity for couples affected by pathological infertility;
- accept the risk and attempt to compensate by other measures (priority given to pathological cases, CECOS own resources transferred to benefit medical applications, etc.);
- finally, by certain currents of opinion, justify the change and go as far as accepting that gamete donors are paid and the liberalisation of the procreation market.

To CCNE's thinking, paying gamete donors and opening up the procreation market are not ethically acceptable solutions.

As for GS, it already constitutes a commodification of women's bodies in which the offspring is the result of a trade which transfers a child from one person to another.
In all the countries which have authorised the autopreservation of oocytes, DI to satisfy all requests and GS, a lucrative transnational market has prospered, illustrating a certain type of society.

V. Prospects: reproduction in tomorrow's world?

The method we developed — first carry out a meticulous analysis of facts and issues, then identify the stumbling blocks and their complexity — serves to get beyond, or at least clarify, problems common to all as well as opposing points of view and so avoid the polarisation of discussions. A recurrent difficulty, however, was that no reliable academic research was available, among other subjects on the life of children brought up in different types of families. This is an illustration of the need to continue research to provide as much comprehensive information as possible and is particularly important if we are to cope with the social changes that technological advances are bound to bring about, as regards procreation issues particularly.

Divergent European legislation
As everyone knows, certain actions that are not possible in France are possible outside France. Several profoundly dissimilar law systems co-exist in Europe: each of these systems can serve as a model to help French law to evolve or, on the contrary, serve as a counter model. The more permissive of these legislations are presented as "progressive", models to be imitated according to

some sectors of opinion, but better shunned in the opinion of others. Although practices may be viewed as claims to be taken into consideration, the "fait accompli" strategy must not be that of the lowest-bidder in ethical terms.

Procreation and prediction

The ample development of the debate on societal claims to medical assistance for reproduction could well mask an important stumbling block in connection with increased medicalisation of reproduction and with methods for prediction and selection. When medical technology plays an active part in procreation, with inclusion in the process of a predictive pre-conception or pre-implantation investigation, it become possible to "only give birth to children devoid of any genetic anomaly[75]" and it would also be possible to select certain phenotypical traits. The unpredictable — and therefore the uncertain — element existing today in conception would be minimised by a systematic search for a potential genetic "risk" (which is now becoming feasible thanks to rapid developments in genomic sequencing) instead of being limited as is the case currently, to situations where there is an averred risk of a disease-generating mutation.

While it is understandable that people might wish to adopt this approach to childbearing in view of the difficulties some women encounter in their plans for procreation, it would be unwise to underestimate the influence of such technological developments. In the long run, this rejection of uncertainty could be sufficient alone to justify turning to MAR technology with no longer the aim to alleviate infertility but the wish to bear a "perfect" child.

Thoughts on a changing world

A new world is in the making. It needs to be thought out and not just regulated, while we must be aware that, inevitably, there will always be a degree of unpredictability. We are in the midst of major anthropological changes in many aspects of human life, in particular in the way we conceive children and become parents. The world of reproduction is quick to change and certain technological barriers may well be breached in the near future; for example, the production of gametes *in vitro* using reprogrammed stem cells, targeted genome modifications so precise that they are applicable to the zygote, or the *ex vivo* reconstitution of certain stages of embryo development. All of these technologies which are today the subject of research and debate, will require us to make important choices. This changing world is also in need of ethical vigilance, in particular as regards the media-inspired method of communicating the results of research, by taking into account the context of how they were obtained.

Technology is the focal point of these changes and social debate seems to oppose in a reductive manner the defenders of two schools of thought: those who consider that the current standards must be reviewed to improve them in the light of existing technology and those for whom biotechnological developments may give rise for future generations to changes impacting personal vulnerability, family references and the foundations of society.

In consequence, CCNE considers that there is a crucial need for developing at national level a programme of information, discussion and education on the subject of procreation in tomorrow's world. This could be achieved for example by organising citizens' conventions to point out the advantages and drawbacks of each of the possible alternatives to be defined. Once civil society has made such enriching contributions, legislative debate can be initiated.

[75] See CCNE's Opinion n° 124: Ethical Reflection on Developments in Genetic Testing in Connection with Very High Throughput Human DNA Sequencing. January 2016.

Divergent positions within CCNE

1. Oocyte autoconservation: position in favour of extending the possibility of oocyte autoconservation beyond 35 years of age.

Although we subscribe to some partly common analysis in the attached Opinion, our conclusion differs. We consider that the possibility of preserving their oocytes should be accessible to women in the few years preceding the depletion of the ovarian pool of follicles after the age of 35.

These are the reasons which we believe support this point of view:

1. There is evidence to the effect that the success rate of MAR begins to fall when women reach the age of 35 and that the curve accelerates after 37 years of age. If women can autopreserve their oocytes this precaution will minimise the failure rate of IVF and reduces the number of attempts.
For this reason, oocyte conservation can be viewed as a way of reducing infertility in women over 35. As is the case for any preventive measure, counselling and medical advice are essential. Rather than being simply a "convenience", oocyte conservation is better defined as a "precaution" or a "preventive measure against MAR failure after the age of 35". Access to such a possibility would need to be governed by specific rules.

2. Not all women would be concerned by this offer of oocyte conservation. Only a minority of women over 35 wanting to have a child but unable to do so in the near future would be given access to the procedure[76].

3. Oocyte conservation does not seem to be an infringement of any existing legal ruling, nor raise any ethical issues.
The law dated 7 July 2011 includes a special article to the effect that a young nulliparous woman can preserve her oocytes (in the event her fertility was later impaired) if she also donates oocytes. Since the law permits it, it cannot be contrary to public order.
Nor does oocyte autoconservation raise any ethical issue: it has no ill effect on anyone else nor on the woman herself since, on the contrary, it protects her from having to undergo multiple IVF attempts with diminishing chances of success with increasing age.
The conservation of oocytes has no disturbing effect on filiation, nor any reversal of the generations since the delay between the time of conservation and that of implantation is less than ten years.

4. The possibility of preserving their oocytes would contribute to lessening the pressure on women when they do decide to have a child. Neither the feeling of urgency for a woman who does not feel ready to enter into motherhood, nor the stress of not being able to have a child if she waits any longer should not be the target of moral judgement, as should not be the importance she attaches to her education or pursuit of a career. Without the option of oocyte conservation, a woman has to choose between having a child when she does not feel the time is ripe or never being a mother. This dilemma contains no moral issue whatsoever and it would seem justified, insofar as that is possible, to lessen the pressure.

More generally, a new possibility open to women does not immediately become a norm, or an obligation depriving them of autonomy. Women exercise their autonomy. They deliberate reasonably and lucidly on the options open to them. They are therefore exercising their autonomy which is as much in evidence when they make an altruistic decision (when they decide to be donors) as when they select a course of action concerning their own fertility. Furthermore, although the "pressures" that society puts on women are to be deplored, restricting the number of decisions they can take to counter them is not the best way of solving the problem.

[76] INSEE (National Institute of Statistics and Economic Studies) data shows that 78.5% of women giving birth are under 35 while the figure is 17.2% for women aged 35 to 40. Less than 5% of women could be resorting to oocyte autoconservation since sterility only affects 25% of couples.

Finally, the taking on of the financial burden by the national healthcare system of a personal intimate decision, is an issue that must be faced. The authors of this document consider that oocyte conservation should be entirely financed by the national healthcare system for pathological situations, but that it should be at least partially paid for by the women concerned when this is not the case[77]. The preserved oocytes would obviously not be for sale, should not be traded and, once the age appropriate for reimplantation had elapsed, could be donated for research or to other couples.

Conclusion

The possibility of preserving oocytes around the age of 35 must be exercised in compliance with the general principles defined by the bioethics laws.

To offer this possibility in no way negates the need to inform women of the fall in fertility after 35, on the fact that there is no guarantee of success with MAR, that even though cryoconservation is widely used it is not devoid of risk, that the stimulation/retrieval/conservation sequence is a considerable strain on the woman concerned and that the risk of ovarian hyper-stimulation is not nil. Women must be clearly informed of these facts so that they can evaluate the risks and deliberate in consequence so that the autonomy of their decision is not illusory.

List of signatories:

Abdennour BIDAR
Carine CAMBY
Monique CANTO-SPERBER
Hervé CHNEIWEISS
Anne-Marie DICKELÉ
Francis PUECH
Bertrand WEIL

[77] Data from countries where oocyte conservation is authorised, regarding the number of women who could potentially be concerned, could give an approximation of the global cost of such an operation. The cost to be borne by the women themselves could be calculated using this data and reduced costs applied in view of the reduction in the number of subsequent MAR procedures.

2. Women's access to DI: position recommending a *statu quo*

The signatories to this recommendation contributed to the preparation and drafting of Chapter 3 of this Opinion on the subject of women's access to artificial insemination with the benefit of a donor (donor insemination, DI). However, their perception differs and they have a divergent opinion on the conclusions and recommendations to be drawn.

The bioethics laws reserve medically assisted reproductive (MAR) technology for heterosexual couples affected by medically diagnosed infertility. The question put to CCNE is whether it is right to keep to the purely medical indications of MAR or to extend access to any woman making such a request. To want a child is a legitimate desire. But when satisfying this desire requires artificial insemination with donor sperm it involves third parties, mobilises collective resources, raises major ethical issues and calls into question fundamental legislative decisions.
Keeping this in mind, we have sought to evaluate the consequences of such requests for the people and resources involved, for the principle of national solidarity and on the values and coherence of the legal bioethical system France has possessed itself of.

The people involved: women, unborn children, members of the medical professions

Women:
The first to be involved are the women formulating such requests, same-sex female couples or single women, although they are not sterile and it is a known fact that they can satisfy their wish for a child by self-insemination without calling on medical help (see Chapter 3). They are expressing a sense of being treated inequitably, perhaps even unjustly and it appears that they want recognition that their claim for access to DI is legitimate.

The child, the primary and vulnerable third party:
The primary third party to be concerned is the unborn child. Children whose conception is the outcome of a declared determination of this nature will certainly be loved by their mother or mothers. However, with reproduction obtained by the sperm of an anonymous donor, they will have no identified father, no biological father and no "social" father. Nor will they have access to their origins which is viewed as an important contribution to the construction of an identity. The role of a father, interacting and cooperating with a mother's role, is essential for constructing a child's personality and the relationship to the diversity of society, including the masculine-feminine "otherness". Many children in today's world live without a father, not by intent but because of life's uncertainties. In the event of death, of parental break up, of abandonment, there is still a father in a child's history and often, a social or adoptive father takes over. Although society considers that the absence of a father is a loss that it seeks in certain circumstances to alleviate at least financially and at a time when the increase in the number of single parent families is worrying, it would seem paradoxical to institutionalise and organise fatherless births deliberately. A child brought up by a female couple will have two parental models and two parental lineages, but filiation separated from it biological reality. A child born by DI to a single woman will have only one parent and incomplete filiation. In both cases, particularly at school, the child will need to cope with the absence of an immediately proximate father, an absence for which the presence of other masculine referents will only be able to compensate imperfectly. Would legalising such situations suffice to tackle their marginalisation?

The members of the medical professions:
For the child to be born, the medical professions will have had to play a part (visits, examinations, treatment, etc.). The object of DI is to treat pathological infertility. For this to happen requires a specific relationship between applicants and healthcare professionals including mandatory information sessions, consent, care and follow-up. But how would this relationship evolve if practitioners were to be distanced from their primary mission, therapy, so as to respond to societal claims?

Biological resources, pathological infertility, societal claims.

Currently, sperm donation is only just sufficient to satisfy the needs of pathologically infertile heterosexual couples and there is a waiting time. If new requests are to be met there will be a resource problem and it will lead *de facto* to competition between medical and societal requests.

Campaigns for donation?
In France, past experience has shown that awareness-raising campaigns for gamete donation — the cost of which should not be underestimated — do give rise temporarily to a limited increase in donations but that there is a relatively rapid fall back to more or less pre-campaign levels: the gametes, the carriers of our heredity, are not donated in the same way as blood! We therefore believe that relying on campaigns to solve the problem of biological resources is illusory.
We have also observed the situation in other countries where donation is unpaid. Belgium, which opened DI to female couples and single women, is obliged to purchase 90% of the sperm supply from Danish catalogues. As for Canada, sperm donation fell dramatically when it became unpaid.

Any request for extension of access must be confronted with the need to consider:
1. either competition between claims for treating pathological *versus* societal infertility. Were it to be accepted as non discriminatory, priority granted to requests motivated by pathology would reduce to very little, if at all, access to sperm for societal requests and thus in fact negate the feasibility of extension.
2. or ending the practice of unpaid sperm donation which could be implemented by purchasing sperm from abroad as do Canada and Belgium or by paying donors and buying sperm straws in France.
Aiming to extend access while retaining the principle of the non commercial nature of products of the human body seems to be in contradiction with international data feedback.

Societal choices

In France, legislators have enshrined general principles with reference to ethical and political choices: reserving medical reproductive intervention financed by national solidarity for people suffering from pathologies; organising the circulation of human biological resources without payment, anonymously and within the public sector; giving a child born *via* MAR a family environment as unexceptional as possible. Such choices are not inalienable and the question is whether they ought to be modified.

Preserving the role of medicine as the remedy for pathologies and continue to call on national solidarity
We considered that French medicine was already faced with difficult challenges it was having trouble with: improving prevention, continuing to finance healthcare with the social security system, reducing territorial disparities. And yet, the demands on the system never cease to increase, not only to respond to all forms of suffering, but also to extend its activity beyond its traditional missions. Since neither human nor financial resources are infinitely stretchable, we believe they should be focused primarily on meeting pathological needs and reducing health disparities.

Preserving the principle of unpaid donation of products of the human body
Biomedicine, in its present configuration, requires the circulation of components and products of the human body and of organs. There is an elevated risk of economic violence when the prospect of payment encourages those who are most vulnerable to sell their bodies. Gratuitousness, the cornerstone of bioethics law, is accompanied by a shortage of organs for transplant, of gametes for MAR procedures together with crises and excessive costs in blood transfusion. Countries which have opted for paid donation do not suffer such shortfalls. There is no dearth of voices in favour of the claim that payment would be nothing but the deserved recognition of a service rendered which furthermore allows for a better distribution of resources. Despite the development of an international market for reproductive services, we believe that it is important that France should retain the principles of altruistic donation, non payment of products of the human body and their management by the public sector to guarantee health safety and traceability.

At a pivotal point in the evolution of biomedicine (as described in Chapter 5) stabilising societal choices that have successfully passed the test of time is a better option than throwing them into disarray.

In conclusion, it appears to us that society, and children most of all however adaptable they may be, have a pressing need at this time for security and stability, that with reference to the uncertainties raised by the extension of access to MAR to all women, maintaining the *statu quo* is the lesser risk and that it would be reasonable and prudent to reserve DI for cases of pathological infertility.

List of signatories:

Christiane BASSET
Yves CHARPENEL
Sophie CROZIER
Pierre-Henri DUÉE
Anne DURANDY-TORRE
Jean-Noël FIESSINGER
Florence GRUAT
Jean-Pierre KAHANE
Frédérique KUTTENN
Dominique QUINIO
Jean-Louis VILDÉ

GLOSSARY

Birth certificate
A birth registration or certificate is a civil status legal document, signed by a registration officer certifying the birth of a person. Registration must be made to the local registration officer within three days following birth.
Outside France, registration with diplomatic or consular officials must take place within fifteen days following birth. This period may be extended by decree in certain consular districts.

"The birth certificate states the day, time and place of birth, the child's gender, first names, surname, followed if applicable with the notation of joint statement of the parents as to the names chosen, together with first names and surnames, age, professions and addresses of the father and mother as well as, if applicable, those of the registrant. If the father and mother or other person involved are not designated to the civil status official, the register will bear no mention of the subject." (Art. 57 of the *Code Civil*).

Agence de la biomédecine:
The French *Agence de la Biomédecine* is a public body under the authority of the Minister for Health. It is active in four domains: organ procurement and transplantation, assisted reproductive technology, embryology and human genetics and is the reference authority on the medical, scientific and ethical aspects of these subjects. One of its missions is to participate in the preparation and observance of regulations and rules of good practice. Its "*Conseil d'Orientation*" writes its Opinions, among which an Opinion dated 6 July 2012 on gamete autopreservation and on 18 April 2013 on extending access to MAR to include female same sex couples.

Medically Assisted Reproduction (MAR):
clinical and biological practices comprising all necessary procedures to harvest and use gametes with the aim of achieving either artificial insemination or the conception in vitro of an embryo and its intrauterine transfer. The French acronym "*AMP*" *(Assistance Médicale à la Procréation)* has replaced in the text of the law the older acronym "*PMA*" (*Procréation Médicalement Assistée*) to signify that this refers to medical procedures which do not guarantee the birth of a child.

Centres d'étude et de conservation des œufs et du sperme humains (CECOS) (Centre for the study and conservation of human eggs and sperm): 23 CECOS centres are spread over French territory and form a federation. They are a part of the French public hospital network. Physicians working in the Centres are officially designated and are authorised to carry out a certain number of procedures required for the implementation of MAR, in particular the collection and conservation of gametes and embryos in compliance with the law.

ECHR: European Court of Human Rights

Certificate of delivery: the law does not in fact provide for any formal and mandatory medical document certifying that a child was delivered. The *Code Civil* only requires that a birth be registered so that the birth certificate can be established.
In practice, a birth document is drawn up by the doctor or midwife who attended the delivery and given to the person who will be registering the birth with the civil status officials so as to obtain a birth certificate.

CNAOP: *Conseil national d'accès aux origines personnelles* - the national Council for access to personal origins was created by law on 22 January 2002. Its essential purpose is to facilitate access to personal origins for wards of the State or adopted persons who are ignorant of their origins and to allow birth parents, who had in the past requested anonymity, to waive secrecy or reveal their identity if they so wish.

***Collège national des gynécologues et obstétriciens français* (CNGOF)** (College of Gynaecologists and Obstetricians)**:** Learned society based on the unity of the gynaecological and obstetrical discipline, the College engages in training and information missions and also "participates in multilevel local, regional, national and European planning for sanitary policy in this discipline".

Conception: synonymous with fertilisation, i.e. the action which conceives a living being, a child.

Cryoconservation: the process through which cells or tissues are cooled to very low temperatures, typically -196° C, which arrests all biological activity. Cryopreserved cells (gametes included) keep their properties intact after thawing (done to precise specifications). The procedure is known as cryopreservertion.

Gamete donation: making an individual's gametes available to allow a sterile person to procreate. In France, gamete donation is governed by a medical context conforming to the demands of the bioethics laws. The donation is discretionary, must be anonymous and unpaid. The donor and the gametes objects of the donation are tested with three objectives: biological security (verification of the initial sperm quality and mobility), absence of infection, relative genetic security (testing for genetic risk factors, chromosomal analysis).

Epigenetics. "While genetics is the study of genes, epigenetics are concerned with an extra layer of complementary information defining how the genes will be used by a cell…or not used by it. In other words, epigenetics is a study of changes in gene activity that do not involve changes in the DNA sequence but that may be heritable by cellular division. Contrary to changes affecting the DNA sequence, epigenetic changes are reversible". (Source Inserm website).

Fecundity/*fécondité*: the fact for a man and a woman to have produced offspring.

Fertility/*fertilité*: the potential for a man and a woman to produce offspring.

IVF (in vitro fertilisation): combining *ex vivo* male and female gametes to obtain one or several embryos. In most cases the gametes of two spouses are used. But sometimes, donor gametes are needed (spermatozoon or oocyte). In France, double donation is prohibited.

IVF is generally followed by the transfer of one or two embryos into the uterine cavity. Surplus embryos are usually frozen to enable new transfer attempts if the earlier procedure or procedures failed or if the couple want more children.

Filiation: word expressing the legal connection between a child and one or two parents. The woman giving birth to a child is automatically registered as the child's mother, unless she has requested the procedure for anonymity known in France as *"accouchement sous X"*. In the case of a married couple, the husband automatically benefits from the "presumption of legitimacy". When the man and woman are unmarried, the man may recognise his paternity, either voluntarily or with an affidavit establishing possession of status, or by a court decision. An adoption judgement can also be used to designate a father or mother.

Genitor: the word should have a general meaning, designating a man whose sperm was used to conceive a child, naturally or through DI. In the context of MAR, it is used to designate a sperm donor. This is to draw a distinction between genitor and "social father".

Genome - genomic: the genome is the genetic information concerning an individual; this information is contained in the DNA of the individual's organism, in the nuclear DNA (90%) on the one hand and in the mitochondrial DNA (10%) on the other. It is estimated that 1.5% of the human nuclear genome is made up of the protein coding sequences (exome) of our 23,000 genes. The exact function of the other 98.5% still remains to be identified. Some of the non coding sequences play a major role in the regulation of gene expression, others contribute to genome plasticity and probably also its evolution. "Genomics is the study of genomes, involving their mapping and sequencing, identification of the genes they contain and the functional characterisation of the genes." (Source: Inserm website).

Germinal: the *germen* (as opposed to the *soma*). Designates the reproductive cells (germlines) leading to mature gametes: oocytes and spermatozoa.

Gestation: the action of a woman "carrying" a child from conception to birth. When fertilisation procedures are artificial, gestation begins after transfer and implantation of an embryo in a woman's uterus.

Idiopathic: without an identified cause.

Artificial insemination (AI): practice consisting in the introduction of sperm into the female genital system, usually into the intrauterine cavity (IUI) using a small catheter inserted via the cervix (ICI). In France, medically assisted artificial insemination must take place in an approved facility. There are two types of AI: intraconjugal (IAI) with the husband's or partner's sperm in the couple being assisted for infertility; AI with donor sperm (DI) when sperm is a discretionary, unpaid and anonymous gift.
The above medically assisted procedures are different from others used in the home where sperm is collected into a vial without sexual intercourse, and intravaginal self insemination. "No sex" male-female couples or those where the man is affected by premature ejaculation use the technique when they wish to have a child.

ICSI *(intracytoplasmic sperm injection)***:** an *in vitro* fertilisation procedure in which a single spermatozoon is injected into the oocyte using a micropipette. This enables spermatozoa with impaired mobility to fertilise an egg although they would not be able to do so spontaneously. ICSI is required for the fertilisation of oocytes preserved by vitrification because their membrane is fragile and does not allow spontaneous sperm fertilisation.

Mother: in the vast majority of legal systems, the mother in the legal sense of the word is the woman who gives birth. But developments in reproductive technology now lead to a distinction between genetic mother, gestating mother, intended mother and mother in the legal meaning.

Surrogate carrier: a woman who is pregnant in the stead of another woman. She will carry the child but is committed to handing it over at birth to the applicants, described as the "intended parents". The woman carrying the child may be the one who donated the oocyte in which case this is called "reproductive surrogacy" since she is both the genitor and the gestator, "the oocyte mother" (genetic) and the "uterine mother" (gestational). In other situations, an oocyte was donated involving a second woman; this is known as "gestational surrogacy" where there is a separation between uterine mother and oocyte mother. In both cases, the oocytes are in principle fertilised by the intended father who is also the biological father (see Chapter 4).
In practice the two terms: surrogate carriers and gestational carriers, are used here without necessarily referring to the origin of the oocytes.

Genetic mutation: an alteration in the DNA sequence. There are several types of mutations, depending on whether they alter a single nucleotide or several, which may either be added to, or lost by, the sequence.

Oocyte: the oocyte is the female reproductive cell (female gamete). It is located in the ovary in the environment provided by follicles. Human foetuses are in possession, as soon as the ovaries are constituted, of a finite stock of ovarian follicles containing immature oocytes. From puberty onwards, with each menstrual cycle, several oocytes begin to mature although only one of the follicles reaches maturity; it then ruptures and releases a fertilisable oocyte.

Parent, biological parent, social parent: the word "parent" designates the man or woman who is legally recognised as a child's father or mother. The adjective "biological" is sometimes attached to it to signify that the legal assignation is identical to biological reality of filiation (a biological parent is a parent whose gametes contributed to the child's conception). The adjective "social" is sometimes appended to signify that the legal assignation is not identical to biological reality. The expressions are mainly in use in connection with MAR procedures. For example in the case of DI, the expression "social father" is often used to designate the parent who is legally the father as regards filiation and who is, presumably, not the sperm donor. Conversely, in the context of adoption, the wording used is "parents" or "adoptive

parents".

Parenting: the expression relates to the action of bringing up children, regardless of the biological or legal circumstances linking the children to those who are rearing them. The word is therefore used for stepfamilies to designate the relationship between stepparent and child and also for homoparental families to designate the relationship between the child of one member of the couple and the one who participates in raising the child but does not have a biological link with the child.

Intended parents: expression used to designate the persons who initiate a surrogate agreement or contract.

Procreation: the actions required to conceive and produce a child by uniting two gametes, male and female.

Spermatozoon/spermatozoa (pl): male reproductive cells (male gamete), produced in the seminiferous tubules of the testes. Spermatozoa originate in stem cells after multiple divisions and a very complex maturation phase which provides them with the properties required for fertilising the ovum, among which high mobility. Men produce 100 to 200 million spermatozoa every day, a number which diminishes with increasing age. Various quantitative or qualitative anomalies may deteriorate the fertilising ability of sperm and may be alleviated by the use of ICSI.

Hormonal stimulation of the ovaries: an injection of hormones to stimulate the development of ovarian follicles; when the follicles are mature (monitored *via* ultrasound and hormone levels), they are punctured to retrieve one or several ova. Hormonal stimulation is needed to harvest oocytes for both autologous IVF and/or oocyte donation procedures.

Vitrification: an ultra rapid cryopreservation procedure applicable to oocytes and embryos. They are secured in a straw and plunged directly into liquid nitrogen at -196°C. The temperature drop is around -2000° per minute (see Annex 3 for technical details.

Zygote: this is the name to designate the first diploid embryonic cell produced by the fertilisation of a haploid oocyte by a haploid spermatozoon once the two cells have merged and combined maternal and paternal chromosomes.

Annexes

The following annexes are intended to add some legal or scientific complements, purely for information, to the main body of the text which refers to them; they do not claim to be exhaustive.

List of annexes

1. French legislation: gratuitousness and anonymity of gamete donation
2. History of legislation on gamete autopreservation and donation
3. MAR with oocyte donation: facts and figures
4. Sperm donors
5. Studies on the development of children in homoparental and monoparental families
6. Sperm donation shortfall
7. Gestational surrogacy (GS) requested by persons lacking any biological link with the child. Risk of human trafficking.
8. Gestational surrogacy (GS): examples of clauses in contracts signed in the United States between surrogate carriers and intended parents.
9. Biological interaction between mother and child during pregnancy
10. Legal systems concerning gestational surrogacy (GS) in countries outside France.

Annex 1
French legislation: gratuitousness and anonymity of gamete donation

Code of public health

Article L1211-4
"No form of payment may be made to persons allowing components or products of their body to be harvested or collected.
The cost of harvesting or collecting is entirely borne by the health institution tasked with harvesting or collecting.
By virtue of Chapter II, title IV of book I of the first part of the above Code, the harvesting of organs, tissues or cells from a living person donating for the therapeutic benefit of a beneficiary is identified as an act of health care."

Article L1211-5
"Donor identity must not be revealed to the beneficiary. Nor can the beneficiary's identity be revealed to the donor. No item of data that can identify persons having donated a component or product of their body, nor any item of data that can identify persons receiving such donations, may be divulged.
The only exemption from this principle of anonymity is by reason of therapeutic necessity".

Code civil

Article 16-6
"No remuneration may be allocated to individuals allowing experiments upon their person or the harvesting or collection of body components and products."

Article 16-8
"No data identifying both the donor of a body component or product and its beneficiary may be divulged. Donors may not receive information on the beneficiary's identity, nor may the donor's identity be revealed to the beneficiary.

In the event of therapeutic necessity, only the donor's and beneficiary's physicians may have access to data identifying donor and beneficiary".

Annex 2

History of legislation on gamete autopreservation and donation

1. Autopreservation of gametes in the context of disease or treatment for cancer

The 1994 bioethics law did not refer to gamete autopreservation although the CECOS (*Centres d'études et de conservation des oeufs et du sperme humains* – Centres for the study and conservation of human eggs and sperm) were already highly active in the autopreservation of sperm prior to treatment which could have an impact on male fertility. Autopreservation is however mentioned in regulations, in particular the January 12, 1999 ruling on MAR good practices. In 2004, it was included in the French Code of public health.

Article 2141-11 (law dated 6 August 2004).
"Persons undergoing medical treatment that could impair their fertility or whose fertility could be impaired prematurely, may benefit from the harvesting and preservation of their gametes and germinal tissue so that they may be provided with medically assisted reproductive technology at a later date with the aim of preserving and restoring their fertility. Such harvesting and preservation is subject to the consent of the person concerned and the consent, should the case arise, of holders of parental authority, or legal guardian if the person concerned, minor or adult, is under guardianship".

2. Gamete donation

- By persons who have already procreated (1994 bioethics laws, modified in 2004).

Article 1244-2 (2004 wording)
"Donors must have already procreated. The donor's consent and, the case arising, that of the donor's spouse, is secured in writing and may be withdrawn at any time before the gametes are used.
Provisions are identical regarding consent from both members of the beneficiary couple".

- Authorisation to donate for persons who have not already procreated (bioethics law dated 7 July 2011)

The aim of this law was to broaden the base of oocyte donors by extending recruitment to young women who had not yet procreated. A third paragraph was therefore added to article 1244-2 quoted above:

"Legally adult donors who have not already procreated. That being so, they are given the possibility of harvesting and preserving some of their gametes and germinal tissues with a view to being a recipient at a later date of medical reproductive assistance in conformity with title IV of book I of the second part. Such harvesting and conservation require donor consent".

The law made no change to the principles of anonymity and gratuitousness governing the donation of gametes in France, but it modified the recruitment base of donors who might not have already procreated. The 2011 law also introduced for persons who have already procreated the further offer of autopreservation of their own gametes so that they could use them themselves should they have difficulty in procreating at a later time. The law would therefore provide a nulliparous woman donating her gametes with the possibility of autopreservation of some of her oocytes. However, decree n° 2015-1281 of 13 October 2015 modified articles R.1244-2 à R.1244-9 to detail the conditions governing the law's application, in particular rules of gamete allocation between those set aside for donation and those to be kept for the donor's own use. The rules take into account the need for a sufficient quantity of gametes to constitute a donation.

Annex 3

MAR with oocyte donation: facts and figures

1. Technical advances in the conservation of oocytes: vitrification

In the context of gamete cryopreservation, oocyte vitrification (rapid freezing) is now considered to be an effective technique. Although the first birth from a frozen oocyte was reported by Chen in 1986, the technique (slow freezing at the time) did not make much progress. In the meantime, ultra-rapid freezing technology producing oocyte "vitrification" was developed[78]. Since 2008, a large number of teams outside France have published MAR results obtained with vitrified oocytes which are identical to those achieved with fresh oocytes. Vitrification is therefore a major advance in that, not only is it more effective but it also allows for oocytes to be cryopreserved without having to fertilise them beforehand. Once this scientific data was confirmed, legislation in July 2011 authorised centres specialising in reproductive medicine in France to proceed with oocyte vitrification. Vitrification is being introduced gradually since 2012 but a transition phase is required to integrate technical constraints and increased cost. Initially, oocyte donation was not involved in the implementation of this procedure.

2. Evolving data on female fertility and requests for MAR (data for France)

Developments in women's age of pregnancy

In France, as in many other countries, there is an increase in the age at which women wish to give birth. The average age of pregnancy has been on the increase since the mid 1970s: it was 30.4 years in 2015 (28 years for the first child, 22 years in 1967). Five per cent of newborns have a mother aged 40 to 44 years (1.2% in 1980, 2.5% in 1994), and 0.5% ≥ 45 years.

Developments in women's fertility with increasing age

The number of ovarian follicles containing female gametes, the oocytes, is at its maximum level in the foetal ovary. Their numbers gradually decrease until there are none left around the age of 50 years (menopause). There is therefore a gradual involution of ovarian function, in both quantity and quality, associated with a reduction in the number and quality of oocytes, with the process accelerating between 35 and 38 years of age. The downturn in female fertility begins at 35 years. The probability of conception for each cycle ("fecundability") is 25% at the age of 25, 12% at 35 and 6% at 42). (data by *Agence de la biomédecine*.)

Developments in the number of requests for MAR in France

While MAR procedures, (IAI, DI, IVF, ICSI, FET) with all their technical variations lumped together[79], are still only marginal contributors to the number of births in France (25,208 out of 818,565 births in 2014, i.e. 3.1%) the number of MAR attempts is on the increase (+8.3% since 2009), particularly in the >38 years age group, and when the MAR procedure involves oocyte donation.

MAR attempts

143,778 MAR procedures where initiated in France in 2014, including 87,310 using IVF, ICSI and FET[80]. These figures did not change very much compared to 2012 and 2013. Most of the attempts were intraconjugal and therefore used the woman's own oocytes. Only a minority involved sperm donation (1,613 in 2014) or oocyte donation (1,246 in 2014, i.e. 1.4% of procedures).

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[78] Vitrification prevents the formation of cytoplasmic ice-crystals whose presence impairs oocyte viability and properties and therefore its fecundity and capacity of ensuring the first stages of embryo development.

[79] MAR technologies include intraconjugal artificial insemination (IAI, donor insemination (DI), in vitro fertilisation (IVF), intracytoplasmic sperm injection (ICSI), transfer of frozen embryos (FET) and embryo hosting.

[80] This refers to procedures where a surplus embryo that had been frozen at the time of a previous IVF for the same woman is transferred.

Regardless of the conditions in which they are conducted, intraconjugal MAR attempts involving the woman's own oocytes cannot guarantee a birth, particular beyond 38 years of age. Thus, globally, a successful (i.e. a live birth) IVF procedure (i.e. a stimulation-fertilisation-transfer cycle) occurs in some 21% of cases; several IVF attempts are necessary to achieve a birth (in France, the national sickness insurance scheme provides financial support for four attempts, but the success rate decreases with the number of attempts (less than 10% for the fourth cycle/attempt. Numbers of successful attempts diminish also with increasing female age: for example in two United Kingdom studies in 2009, estimates of a successful outcome after four attempts were 63% for women under the age of 35, but only 20% or less beyond the age of 40[81].
It must be underlined that arriving at precise figures for estimates is generally a difficult undertaking. This is due to the fact that potentially couples may have had any number of very different itineraries.

3. Oocyte donation in France

In France, the main indications for MAR with oocyte donation are the impossibility of procreation (pathological ovarian failure which represents the majority of indications), a high risk of transmitting a mother's serious disease to the child, repeated failure of fertilisation attempts in vitro within the couple, some of which are probably caused by ageing oocytes.
Due to the lack of sufficient historical data since the 2011 authorisation for vitrification which is gradually being implemented, the data below only relates to fresh oocytes or slow-frozen embryos.

MAR with oocyte donation
The numbers for oocyte donation are slowly increasing: in 2009, 933 attempts were made involving the use of donated oocytes (IVF, ICSI, FET). There were 1,144 in 2013 and 1,246 in 2014 (including 285 by FET). In France, in 2014, 5.3% of the 25,208 children born of a MAR procedure were born of gamete donation, of which 1,107 through sperm donation and 239 through oocyte donation.

Increasing age of women using MAR with oocyte donation.
In 2009, the majority (66%) of women receiving an oocyte donation (933) were under the age of 38, 34% were aged ≥ 38, and 26.5% were aged ≥ 40. The total number of MAR attempts with oocyte donation has increased by 18% for women aged ≥ 38 years, but was 40% for women aged ≥ 38 years between 2010 and 2014 (data by *Agence de la biomédecine*).
Studies in Europe also report an increase in the number of oocyte donations. In a 2009 report by ESHRE (European Society for Human Reproduction and Endocrinology)) 61% of the 21,354 European women receiving oocyte donations were aged ≥ 40 years[82].

Female donor characteristics

- **Insufficient number of female donors**. In 2014 in France, 501 women donated oocytes (8.8 oocytes per donation on average, 4.5 used per IVF/ICSI procedure). There were 401 in 2011 and 454 in 2013. A total of 861 couples had at least one chance of IVF/ICSI with oocyte donation in 2014 (and 871 new requests have been accepted). But donations still fall short of demand. The waiting list totalled 1,673 couples at the end of 2009. As of 31 December 2014, an estimate of the number is 2,450 couples. The *Agence de la biomédecine's* estimate of the number of supplementary donors needed is another 900 women. As a result, the number of requests from French couples for oocyte donation in a foreign country is growing annually[83].
- **Age of female donors often more than 35**. In France, up until 2015 (date of the decree implementing the 2011 law), the law restricted the possibility of oocyte donation to women who had already procreated; in 2014, 74% of donors were over the age of 35 (same proportion

[81] Malizia BA, et al. *N Engl J Med* 2009; 360: 236-43; Luke B, et al. *N Engl J Med* 2012 ; 366 : 2483-91. Furthermore, the number of drop outs from the MAR procedure must be mentioned, particularly as regards women over the age of 38. Over the age of 40, the number of drop outs may be as much as 80%. The drop outs mean that correction factors must be applied to the data which complicates statistical analysis.

[82] Calhaz-Jorge C, et al. *Hum Reprod* 2016; 31: 1638-52.

[83] Rozée Gomez V, de La Rochebrochard E. *Hum Reprod* 2013; 28: 3103-3110. See also the CNSE's 2015-2016 report (centre national des soins à l'étranger – National centre for healthcare outside France).

as in previous years) and the average number of oocytes per punction was 8.8. In Spain, where young childless women can donate oocytes, 60 to 80% of donors are under the age of 30 and the number of oocytes harvested is greater than 10 (generally about 15 and sometimes more). The quality of outcome, expressed as the number of oocytes per punction and of pregnancies per ICSI attempt for the beneficiary is very dependent on the age of the oocytes and therefore of the donor's age.

Most studies report that the age of the oocyte donor is a key criterion for the successful implantation of the transferred embryo[84] without prior freezing, and therefore of the birth rate, which is 27% (per attempt) for donors under 30 years of age and 13% for donors aged 40 years and above[85]. The age of the beneficiary, however, does not seem to be an important criterion (before 45 years). Which explains why, with equal beneficiary age, in every study the success rate of MAR procedures is better when oocytes are donated than when they originate from the woman herself post-stimulation. In France in 2014, data (all ages lumped together) obtained with donated oocytes and implanted without prior freezing show that 71% of oocytes fertilised *in vitro* develop into an embryo and that 70% of those embryos were transferable (for immediate transfer or for freezing). The percentage of births with embryo transfer is approximately 22% (IVF and ICSI).

4. Contribution made by the vitrification technique to oocyte cryopreservation.

Fecundability of vitrified oocytes

As vitrification was only authorised in France in 2011, data comparing the success rate of MAR procedures using vitrified oocytes and fresh oocytes is the result of studies carried out in other countries, i.e. Spain, the United States, Belgium and Italy, mainly involving donors.

Despite major heterogeneity in ovarian stimulation protocols and the ways results are expressed, plus the scarcity of prospective studies, it is now accepted that vitrified donated oocytes are in no way less capable of fecundation than fresh oocytes in MAR procedures[86]. These excellent results[87] are for oocytes from donors under 35 years of age, or even under 30, vitrified for a short time only (which would not be the case with precautionary self-preservation for which several years of preservation may be expected).[88]

The minimum number of oocytes required to ensure a live birth has not met with a consensus: some are in favour of a threshold of eight oocytes to ensure 50% of births for patients under the age of 38, while others prefer fifteen oocytes or even more to arrive at a live birth[89].

5. Medical risks in connection with the oocyte preservation procedure

Oocyte harvesting: risks for the woman

There are two stages in the oocyte harvesting procedure with a potential for adverse effects: the hormonal stimulation phase required for follicles to mature and the oocyte retrieval phase involving surgery in the form of a follicular puncture. Published studies only mention short term complications of these procedures. They are difficult to interpret since the analyses are retrospective; there is a great deal of variability in stimulation protocols (hormone dosage and type of product) which has an influence on the severity of adverse effects, and also in the evaluation of complications.

Apart from the 8 to 14% of mild adverse effects which nevertheless require medical attention, severe complications occur in 0.11% to 1% (mean 0.7%) of cases. These are mostly cases of severe ovarian

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84 Le Lannou D, et al. *Gynecol Obstet Fertil* 2010; 38: 23-9.

85 Wang YA, et al. *Hum Reprod* 2012; 27: 118-25; Sole M, et al. *Hum Reprod* 2013, 28: 2087.

86 Cobo A, et al. *Hum Reprod* 2010; 25: 2239-46; Cobo A, 2013; Chang CC, et al. *Fertil Steril* 2013; 99: 1891-7; Chang CC, et al. *Reprod Biomed Online* 2008; 16 : 346-9 ; Keskintepe L, et al. *Fertil Steril* 2009; 92: 1706-15; Sher G, et al. *Reprod Biomed Online* 2008; 17: 524-9; Nagy ZP, et al. *Fertil Steril* 2009; 92: 520-6 ; Mature oocyte cryopreservation: a guideline, ASRM , January *Fertil Steril* 2013; 99: 37-43; De Wert et ESHRE task force. *Hum Reprod* 2012; 27: 1231-7; Sole M. *Hum Reprod* 2013; 28: 2087.

87 The pertinence of such results must be interpreted with moderation, however, since there is a possibility that only the centres with the most favourable success rates published their data, so that it would be unwise to generalise.

88 Mature oocyte cryopreservation: a guideline, ASRM, *Fertil Steril* 2013 ; 99 : 37-43.

89 Rienzi L. Hum Reprod 2012; 27: 1606-12; Sunkara SK. *Hum Reprod* 2011; 26: 1768-74.

hyperstimulation syndrome which may require hospitalisation and also surgical complications of follicle retrieval (anaesthesia complications, haemorrhage, infection and ovarian torsion[90] , sometimes combined with thromboembolic disorders; some of these complications may be life-threatening. For young women donors without any history of pathology, the risk of complications after surgery or due to ovarian hyperstimulation seems to be smaller than for infertile women undergoing autologous stimulation as part of an IVF procedure; hormonal doses are often lower, ovarian stimulation is interrupted if there is a threat of hyperstimulation and there is no immediate pregnancy to increase the risk[91]. In France, two to six severe adverse events per year are recorded for oocyte donors (6 in 2014, all requiring hospitalisation, of which four were followed by surgery)[92].
As regards potential complications in the long term, the main question under review concerns the risk factor for ovarian or breast cancer since the sensitivity to hormone stimulation of these tissues is well known. However, while certain epidemiological studies have noted a tendency to increased risk, particularly within certain subgroups, they contain some methodological flaws and do not achieve statistical significance. There is an essential need for conducting credible prospective studies[93].

Are there any risks for children following oocyte preservation and ICSI?
Oocyte quality is essential since it contributes not only to the embryo's genetic heritage but also to the supply of the energy and nutriments needed for the early embryonic divisions. So neither ovarian stimulation, nor cryopreservation and the ICSI technology used in *in vitro* fertilisation must be allowed to interfere with the particularly fragile oocyte properties. Apart from the trauma inflicted on the oocyte membrane, ICSI bypasses the natural selection process of sperm since injected gametes are chosen by the physician.
Although a majority of authors agree on the excellent survival rate (85-90%) of oocytes when thawed after vitrification and exclude the existence of major differences compared to natural fertilisation, the risk induced by the ICSI procedure applied to young vitrified donor oocytes has not been the subject of specific study. Several authors are of the opinion that it would be premature to conclude that oocyte cryopreservation is totally innocuous[94].

Informed consent and procedure for obtaining consent
In view of the above mentioned risk factors, what oocyte donors should be told so that they are adequately informed before they give consent is a matter that requires consideration. Several recent studies outside France show that the presentation of the risks is often played down[95]. We should remember that French law mentions the importance of this information[96]. While it may be justified to take such risks in the context of an intraconjugal MAR procedure prescribed following a diagnosis of infertility and for which the expected benefit to risk ratio is high, extreme caution is required in the context of a donation. Be they donors or acting for the sake of autopreservation, these are young presumed fertile women, who are volunteers and are running a certain amount of risk on someone else's behalf or for their own benefit. But their own benefit is uncertain.

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[90] Maxwell KN, et al. *Fertil Steril* 2008; 90: 2165; Sauer M. *Am J Obstet.Gynécol* 2001;184:277.

[91] Bodri D, et al. *Rep Bio Med Online* 2008; 17: 237-43; see also the 2011 IGAS report.

[92] *Data provided by the Agence de la biomédecine* (medical report 2015).

[93] Brzezinski A, et al. *Gynecol Oncol* 1994; 52: 292-5; Ness RB, et al. *Am J Epidemiol* 2002; 155: 217-24; Brinton LA, et al. *Fertil Steril* 2005; 83: 261-74 ; Jensen A, et al. *Am J Epidemiol* 2008; 168: 49-57; Van Leeuwen FE, et al. *Human Reprod* 2011; 26: 3456-65; Yli-kuha AN, et al. *Human Reprod* 2012; 27: 1149-55; Merviel P, et al. *Rev Prat* 2013; 63: 1192; Reigstad MM, et al. *Int J Cancer* 2015; 136: 1140-8.

[94] Noyes N, Porcu E, Borini A. *Repr Biomed Online* 2009; 18: 769-76; Ponjaert-Kristoffersen I, et al, *Pediatrics.* 2005; 115: e283-9; Chian R, et al. *Reprod BioMed Online* 2008; 16: 608-10; BC Fauser, et al. *Rep Bio Med Online* 2014; 28: 162-82; Kurinczuk JJ, Bhattacharya S. *Sem Fetal Neonat Med* 2014; 19: 250-3.

[95] Alberta HB, et al. J Law, *Med Ethics*, summer 2014, 232-43; Maxwell KN, et al, *Fertil Steril* 2008, 90, 2165-71; Kramer W, et al, *Hum Reprod* 2009; 24: 3144-9.

[96] Article 1244-7, Code of Public Health. "The oocyte donor must be specially informed by members of the multidisciplinary medical team during the interviews of the circumstances of ovarian stimulation and of oocyte retrieval, of the risks and constraints inherent to the technique. She must also be informed of the legal stipulations applying to the donation, in particular the principles of anonymity and gratuitousness. She shall be reimbursed of any cost outlay related to the donation."

It is also worth noting that approximately one out of two prospective donors attending a preliminary interview is either not accepted and/or will drop out during the procedure (*IGAS – Inspection Générale des Affaires Sociales - 2011 report*).

6. Medical risks related to advanced maternal age: an argument in favour of caution

"Advanced maternal age" refers to pregnancy after the age of 40. After the age of 45, the term "very advanced maternal age" is used.

Today, pregnancies for women after the age of 40 are relatively frequent. The complications rate, be it for the mother (high blood pressure, diabetes, thromboembolic events[97]) or for the child (hypotrophy, premature birth) increases steeply with maternal age. These "high risk" pregnancies require monitoring commensurate with the risk incurred[98].

Maternal mortality rises with increasing age of childbirth: the risk of maternal death is three times higher in the 35-39 age group than in the 20-24 age group, eight times higher in the 40-44 age group and thirty times higher after the age of 45[99].

Very advanced maternal age pregnancies, over the age of 45 and *a fortiori* those after the age of 50, follow on from MAR procedures with oocyte donation, performed outside France since spontaneous pregnancy after the age of 45 is exceptional. In these very advanced pregnancies, several factors combine: the woman's age, failure of maternal-foetal immune tolerance, multiple births (in the case of transfer of several embryos). These pregnancies beyond the age of 45 are very "high risk" for both mother and child[100]; women should be informed of these dangers before calling on oocyte donation.

[97] Cleary-Goldman J. *Obstet Gynecol.* 2005;105 (5 Pt 1): 983-90; Ohl et al. *Gynécol Obstet Fertil* 2012; 40: 511; Luke B, Brown M B. *Hum Reprod.* 2007; 22: 1264–1272; Shrim et al, *J Perinat Med* 2010; 38: 645; Belaisch-Allard J, *Grossesse et accouchement après 40 ans* (Pregnancy and childbirth after 40 years of age).. *EMC* 2008 ; 5-016-B-10-

[98] Le Ray C, et al. *Hum Reprod* 2012; 2: 896-901.

[99] Weekly epidemiological bulletin by the *Institut national de veille sanitaire* (national institute for Public Health Surveillance), thematic issue on maternal mortality in France 2001-2006. 19 January 2010, n° 2-3.

[100] Paulson RJ, et al. *JAMA* 2002; 288: 2320-3; Banh D, et al. *J Assist Reprod Genet* 2010; 27: 365-70.

Annex 4
Sperm donors

In the event of a same-sex female couple or a woman acting on her own, the decision not to choose a fertilising sexual relationship implies calling on a sperm donor. In the circumstances, this is a choice exercised by women.

The donor may be known in which case insemination will be a private affair. If that is the case, the donor's responsibilities as regards the child will be determined by agreement between the woman or women concerned and the donor : his responsibilities will cease once donation has taken place; he may accept a purely moral commitment between the parties as regards possible questions by the child at an age to determined or left unspecified; he may agree to a legal declaration of paternity although the child is brought up by the female couple or the single woman. In health and genetic terms, the process is neither more nor less safeguarded than is a heterosexual relationship. In psychological terms, however, such a decision resolves potential difficulties in relation to donor anonymity and, in those cases when the genitor wishes to be involved personally, to the absence of a pater or social father. However, there is always the possibility for this type of arrangement, which is currently based on trust, to be endangered by the emergence of conflicts.

The sperm may have been anonymously supplied by a foreign sperm bank selling straws from an internet catalogue offering various physical or intellectual types of donors. Further diversification exists depending on whether the donor accepts or refuses to waive his right of anonymity and meet the offspring. Insemination takes place in a private location.

The donor may be anonymous and the sperm supplied by a medical institution from a country such as Spain or Belgium. From 2005 to 2007, over 2,000 French women have proceeded with DI in a Belgian centre[101].

The donor (anonymous or not) may be chosen on the internet, without calling on the services of a medical institution or of a sperm bank. Insemination may be either natural or artificial.

[101] Van Hoof W, et al. *Soc Sci Med* 2015 ; 124 : 391-7.

Annex 5
Studies on the development of children in homoparental and monoparental families

Studies on homoparental families[102]

Abundant literature exists in the United States, the United Kingdom and more recently in the Netherlands, on the development of children brought up by same-sex couples, more frequently by female couples. In France, as pointed out by M. Gross, no scientific study on gay and lesbian parents and their children was published before 2000[103]. Despite the existence of these very numerous studies, it is still difficult to formulate a fair evaluation of the development of children in homoparental families. Homosexual people have always produced children, but in a heterosexual environment, and only rare studies have been made of children born to homosexual couples as a result of MAR procedures. Methodological flaws in many early studies have contributed further uncertainties: low statistical significance, bias in the mode of selection of participants, narrowness of parameters under scrutiny, lack of uniformity in the methods used for data selection and absence of any follow-up. Some of these biases were due to difficulties, at the time, in circumscribing the homoparental population.

In 2005, the American Psychological Association (APA) had arrived at the conclusion that children brought up by same-sex couples were at no particular disadvantage. This conclusion came under criticism because of methodological deficiencies and interpretations sometimes inspired by partisanship (M*arks 2012, Allen 2015*). Several rather less tendentious conclusions were then published after exhaustive and critical re-analysis of earlier methodology and data interpretation (*Marks 2012, Schumm 2016*). They underline the difficulty of arriving at one solid positive or negative conclusion in a context rendered very complex by the extreme disparity of evaluation criteria, the diversity of composition and evolution over time of families included in the study, the wide range of children's ages and the complexity of defining the homoparental parental population. With the exception of a few recent studies, the children were often born to heterosexual parents, reared up to varying ages by one of the parents (more often the mother) who later entered into a homosexual relationship. Furthermore, the duration and stability of the new families differed. In fact, the studies only very rarely bore on the lives of a "planned and established lesbian family", meaning following DI and brought up for any protracted length of time by a female same-sex couple. But a couple's stability (*Schumm 2016 ; Rosenfeld MJ, 2015*) and the internal organisation of the family appear to be major confounding variables which have not been sufficiently taken into account. Furthermore, the child populations under study are generally young whereas it would be highly significant to extend the studies to include adolescents and young adults (time spans during which behavioural differences and critical distancing from parents are more marked; cf. *Regnerus 2012, van Gelderen 2015, Schumm 2016*), since if experience with children born *via* DI in heterosexual couples is reliable, it would be necessary to wait about thirty years for some children, once adult, to begin to make public their analysis of the situation, be it positive or negative. Some studies are under way to counterbalance such bias: they are based on selected samples of the general population using national registers in particular and they broaden the range of questions examined, compare responses from children, parents and observers such as teachers, consider the way in which the family functions and the progress of

[102] Only the most recent and extensive studies, in particular those providing a detailed analysis of their methodology, are referred to here. A fuller bibliography is available in the studies themselves to which the reader may refer. We are well aware of the very incomplete nature of the reference selection.

[103] Martine Gross, "L'homoparentalité et la transparentalité au prisme des sciences sociales : révolution ou pluralisation des formes de parenté ?" Enfances Familles Générations [En ligne], 23 | 2015- URL : http://efg.revues.org/287.

adolescents and young adults. It may still be difficult to harvest information of the family structure and the modes of conception. Although it may still be difficult to formulate definitive and consensual assessments of the progress of children brought up in a homoparental family, it does seem established that such children are not seriously disadvantaged (*Bos et al, 2017 ; Vecho et Schneider B, 2005 ; Gross M, 2015*). Prospective and longitudinal studies of this kind over a lengthy period of time, based on flawless methodology are essential if we are to differentiate between the respective repercussions on the development and wellbeing of the children concerned of the family structure (same-sex or different-sex parents) and the many factors which play a role and have, all too often, remained under evaluated (parents' educational and socioeconomic level, stability or non stability of the parental couple)[104]. As an example, we would mention the DevHom study in France which considers the "identity construction of children born in a homoparental context" and researches the qualitative data on these children's families from a socio-anthropological and clinical viewpoint.

Studies on single-parent families: data for France

According to an INSEE report (*Rapport Insee 2015. Couples et familles. 192p. www.insee.fr)*, there were 1.8 million monoparental families in France in 2013 out of a total of 7.8 million families, i.e. 23%). In 85% of cases, the single parent is a woman (and for 79% of them this situation was caused by parental separation. Most of the younger women (under the age of 25) were not in a stable relationship when they conceived. For women in the over 30 age group, the most frequent case is that the couple separated. There are major disparities in the situations of the families, but whatever their matrimonial circumstances and their previous history, in the absence of a partner, single mothers must single-handedly shoulder the burden of the family's upkeep, as well as the time and thought to be devoted to the family's existence, even though the situation may often be temporary[105]. Their resources are more restricted than those of two-parent families (average monthly standard of living is lower by 30% and 36% are poor). Lower incomes and a high proportion of unemployment (16%) are compounded by generally smaller homes of which they are less often the owners. The women in the youngest age group often accumulate a number of vulnerability factors: they are less likely to be qualified, their children are younger and get less support from in-laws. Children from single-parent families do less well in school than their peers from two-parent families so that they are outdistanced in primary and secondary school. Family help can only be provided by one parent. Achievement in school is largely influenced by the cultural level of parents and available financial resources. There have been few studies on the development and wellbeing of the children of "single mothers by choice" ("solo mothers"), born into that environment following DI. Most of such qualitative studies were done in the U.K. and concerned a small number of families and as yet very young children. Some authors point out signs of less warmth in emotional exchange and other interaction with children than there is in families with two parents, due to greater demands on the single parent's time. Unlike children from single-parent families currently under study, children of solo mothers do not have to face up to the psychological shock of their parents' separation nor to the ensuing feelings of depression experienced

[104] Allen DW. *Marriage and Family Review* 2015; 51, 1995-2013; Bos HMW, et al. *J Dev Behav Pediatr* 2016; 37: 179-87 ; Bos et al, *Family Process*, 2017 Feb 15. doi: 10.1111 (being printed); Cheng S, Powell B. *Soc Sci Res* 2015; 52: 615-26; Gartrell N, Bos H. *Pediatrics* 2010; 126: 28-36; Golombok S, Badger S. *Hum Reprod* 2010; 25: 150-7; Gross M. Enfances Familles Générations [on line], 23,2015; Manning WD, Fettro MN, Lamidi E. *Popul Res Policy Rev* 2014; 33: 485-502; Marks L. *Soc Sci Res* 2012 ; 41: 735-51. Regnerus M. *Soc Sci Res* 2012a; 41: 752-70; Regnerus Mark. *Soc Sci Res* 2012b; 41: 1367-77; Rosenfeld, MJ. *Demography* 2010; 47: 755-75; Rosenfeld, MJ. *Sociological Science* 2015; 2: 478-501; Schumm WR. *Psychological Reports* 2016; 119: 641-760; Van Rijn-van Gelderen L, Bos HMW, Gartrell NK. *J Adolesc* 2015; 40: 65e73.; Vecho O, Schneider B. *Psychiatrie de l'enfant* 2005; 48:271-328.

[105] It is estimated that 80% of single parents remain in that situation less than ten years. Source: *Couples et familles* report (2015 edition) published by INSEE and public statistics.

by the parent they end up living with. They will, however, have to face up to the limitation on financial resources and on the time that their single parent can devote to them. It is probable that with the onset of adolescence there will be questions as to the absence of a father, the identity of their biological father and on the decision that he remain anonymous[106].

[106] Algava E. Etudes et Résultats, n°218. Drees, Feb. 2003; Weiltoft GR, et al. *Lancet* 2003; 361: 289-95; Crétin L. Education et formations, Dec. 2012, n°82, p 51-66; Martin MA. *Soc Sci Res* 2012; 41: 33-47; Insee Première. Depuis combien de temps est-on parent de famille monoparentale ? March 2015, n° 1539, 4p.; Acs M, et al. Dossiers Solidarité Santé. Drees, July 2015, n°67, 34 p. Rapport Insee 2015. Couples et familles. 192p. www.insee.fr; Observatoire des inégalités. Portrait social des familles monoparentales, 13 décembre 2016; Les familles monoparentales depuis 1990. Dossier Drees, Solidarité/santé N° 67 / July 2015.

Annex 6
Sperm donation shortfall

Figures for sperm donation in France[107]

Since legally sperm donation must be unpaid[108], donor recruitment is purely conditioned by donor generosity. Sperm straws from donors are currently collected in France by the CECOS Federation (centres for the study and conservation of human eggs and sperm) in conformity with the principles of gratuitousness and anonymity guaranteed to donors and users (see Annex 1). The number of sperm donors varies between 200 and 300 since 2010 (with an average of 48 straws, i.e. mini test tubes containing sperm, for each donor). In 2014, there was a marked drop in the number of donors approved for that year (238 in 2014, 303 in 2013 and 244 in 2012). In 2014, 2,392 couples made at least one attempt at MAR with a donor, while 2,205 couples made a similar request for that year. Waiting times are about 12 to 18 months. Sperm donations are only just adequate to satisfy current requests from heterosexual couples of child-bearing age with a fertility problem due to a medically diagnosed pathological condition. In France, the maximum number of children by the same donor is ten *(Article L1244-4: "The number of gametes from the same donor shall not deliberately cause the birth of more than ten children").*

Sperm donation: a number of different regulations

In other countries outside France, having to face up to requests for DI from female same-sex couples and women acting on their own, sperm banks experienced a shortfall despite a not very considerable reduction in requests from heterosexual couples following the introduction of ICSI (intracytoplasmic sperm injection of a spermatozoon into an oocyte *in vitro*) so that in a large number of cases the spouse's sperm could be used despite defective sperm function.

Similar examples can be found in other countries where unpaid donation is the rule and who have extended DI to female same-sex couples and single women.

In both Belgium and Spain, sperm donation is unpaid and the law prohibits any trade in human gametes — sperm or eggs — but economic compensation may be granted to the donor. This is on average €50-€100 per visit in Belgium, but it can be more. In the United Kingdom, the amount is £35[109], [110].

In Belgium[111], part of the increase in demand for MAR is accounted for by requests by women from other countries — France in particular — but this is not sufficient to explain the size of the shortfall which is now massive since Belgium now buys and imports 90% of the sperm used for DI.

This is bought, not in Belgium where such purchases are prohibited, but in Denmark (*Cryos* and *Nordic Cryobank)*. Cryos, the world leaders, sell hundreds of thousands of sperm straws (mini test tubes containing sperm) every year in over fifty countries. The price of two straws of unprepared semen from an anonymous donor is €210 and €666 if the donor is not anonymous[112]. Requests for sperm are made by three groups of women: same-sex female couples, women on their own and heterosexual couples in a ratio of 5:2:2[113].

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[107] Source: 2015 report of the *Agence de la biomédecine*.

[108] "An article of the law prohibits any form of payment to the donor but also stipulates that any outlay by persons accepting that components of their body may be harvested will receive compensation". The principle therefore of gratuitousness, or to be more precise, of the absence of any payment for donation, is expressed in correlation with the concept of financial neutrality for the donor. (Source: *Agence de la biomédecine*).

[109] Amount suggested by the HFEA (Human Fertilization and Embryology Authority).

[110] Ravelingien A, et al. *Reprod Biomed* online 2015; 31: 225-31; *Facts views and vision in* OBGYN 2014, 6, 57-67.

[111] *Facts views and vision in OBGYN* 2014 ; 6 : 57-67.

[112] Cryos website (June 2017) - https://dk-fr.cryosinternational.com/sperme-de-donneur/tarifs-et-paiement

[113] De Brucker M, et al. *Hum Reprod* 2009 ; 24 : 1891-9.

In other countries, such as the United Kingdom, requests are mainly from same-sex couples and women on their own[114].

In Canada, before the year 2000, there were some 80 to 100 donors per year. However, two events have modified these figures: an exacting regulation on the quality of sperm was introduced in 2000 and, even more pivotal, the prohibition of payment for donations which became law in 2004. The number of "altruistic" donors is now only about 60. To meet demand, *Health Canada* allows sperm from paid donors to be imported[115], the United States and Denmark being the main providers. In the United States, a donation is paid $70 to $125, varying from one sperm bank to another[116].
Banks and private clinics in foreign countries guarantee the sanitary safety of these donations and, in fact, there is no feedback reporting the transmission of infectious diseases. Several private sperm banks, Spanish and Danish, highlight the thoroughness of their enquiries into donor family backgrounds and genetic history, the existence of possibly hereditary disease and, more generally, the "excellence of donors"[117]. There have been, however, several warnings from competent authorities (Danish in particular) on the subject of the risk of transmission of genetic anomalies. Although certain sperm banks guarantee an upper limit on the number of children sired by the same donor and even have on offer, at rather high prices, "exclusive donors", there are reports, mainly it is true from the North American continent, of "multiple donors" fathering a large number of children (with numbers varying from 1 to 25 depending on the country concerned i.e. the Netherlands, United States and Denmark, or even unlimited in Canada and Sweden). Nevertheless, the growing demand for gametes, their commodification and, in particular the use of paid donors (which may be multiple for a single "donor") makes any verification and traceability of samples increasingly difficult[118].

[114] Hamilton M. *Hum Fertil.* 2010; 13:257-62.

[115] O'Reilly D, et al. Modélisation de l'adéquation entre donneurs et demandeurs pour le don de sperme au Canada. *Reproductive Health* 2017; 14 : 8.

[116] Payment with, in some cases, a limit of $1,500 per month for 3 donations per week and a six month commitment.

[117] Nevertheless, a recent scandal in Ontario reports on complaints from families who discovered that an American donor with a particularly high IQ who had been recommended to them by a sperm bank in the United States was in fact a psychotic delinquent drug addict. The follow-up was ongoing legal proceedings for misleading information on goods for sale. (CBC news, Toronto, 2016)

[118] The risk of falling unknowingly in love with a step brother or sister, often central to children's claims for the elimination of donor anonymity, cannot be ignored.

Annex 7
Gestational surrogacy (GS) requested by persons lacking any biological link with the child. Risk of human trafficking.

Several cases have thrown a spotlight on this practice which consists in using GS with double gamete donation to give birth to children intended for adoption by persons who have no biological link to them.

In Italy, there was the case of a couple of intended parents consisting of a man and a women neither of whom had any biological link with a child born *via* GS in Russia. The child was taken away from the intended parents by social services so as to be lawfully adopted. The European Court of Human Rights' Grand Chamber decided in 2017[119] that to remove the child from the home of the couple of intended parents who were looking after him had violated their rights but that this was justified by the desire to protect children against illicit practices which are akin to human trafficking.

In Switzerland, where the constitution prohibits surrogate motherhood, the Federal Court judged in 2015[120] that it was legitimate to oppose the acceptance of an American civil status document declaring the intended parents as father and mother following a judgement in the State of California. The tribunal's reasoning was that since the entire conception process had taken place in the United States with the obvious aim of circumventing the prohibition on surrogacy in Switzerland, registering children in the civil status registers was incompatible with public order in Switzerland. It was added that GS without any genetic link with the intended parents was akin to adoption, but adoption in circumstances contrary to legislation on adoption which was drafted with the specific intention of protecting children.

[119] Case of Paradiso and Campanelli v. Italy. (Application no 25358/12). ECHR judgment O34 (24 January 2017).

[120] Judgment 5A_443/2014 of 14 September 2015.

Annex 8
Gestational surrogacy (GS): examples of clauses in contracts signed in the United States between surrogate carriers and intended parents

To see how much of a burden is placed on the surrogate mother to ensure that everything goes "according to plan", that she is able to cope with potential medical problems and has fully accepted her commitment so that she will not want to keep the child at birth and also so that intended parents can be easy in their minds throughout the procedure, reference should be made to contracts signed in the United States since the clauses they contain were drafted in response to conflicts between surrogates and intended parents that actually arose at some point in the procedure. Obligations on the surrogate mother include:

- Certification of her physical and mental capacities.
- Acceptance of psychological counselling and medical monitoring as stipulated by intended parents, including regular medical tests.
- The husband's consent.
- A statement of the number of attempts accepted for an agreed price.
- A commitment to abstain from sexual intercourse during the periods of time when embryo transfers are attempted; a commitment to abstain from smoking, drinking alcohol or using illicit products during pregnancy; adopting a special diet, practising certain sports and activities.
- A commitment not to abort unless her own life is in danger; to accept embryo reduction at the request of the intended parents, and medical termination of pregnancy if the intended parents consider it necessary.
- A relinquishment of any right over the child after its birth in the knowledge that the child will be transferred to the intended parents as soon as possible (although contact after childbirth is sometimes accepted or sometimes refused, depending on the contractual terms). Although this contractual clause seems to be obvious to many observers, it is rarely mentioned that although the law does allow that a child be handed over to care and social services for adoption, it prohibits any private arrangements between a woman giving birth to a child and parents wishing to adopt.
- A possible commitment to accept that colostrum and mother's milk be drawn off and transferred for a price settled beforehand.
- An agreement on prices and fees: (to the agency and service providers the agency makes available; to the surrogate mother with details as to how much she will be paid if she gives birth or if her pregnancy is terminated before delivery, taking account of higher insurance costs if she is expecting twins, all pregnancy-related costs including for instance travel expenses should the case arise).
- The agency is required to verify and possibly adjust if required the surrogate mother's insurance cover.

Annex 9
Biological interaction between mother and child during pregnancy

Influence of the uterine environment on the embryo and foetus

There are two modes of maternal transmission: transmission of the genetic heritage contained in the DNA of the nucleus and mitochondria of the oocyte and the transmission of non genetic traits acquired by the interaction between the foetus and its uterine environment during pregnancy. Knowledge was only recently acquired of the mechanisms involved in the transmission of the maternal environment to the offspring during pregnancy and, although it is well investigated in animal models, it is still largely unexplored for humans[121]. After implantation in the uterus, the embryo is exposed to the uterine environment which is itself subject to external influences to which the mother may be exposed[122]. The embryo and foetus are very sensitive to these environmental influences since this is a phase of very rapid growth which depends entirely on uterine inputs. Development may be impaired by modifications to the nutritional intake (deprivation or excess), the presence of toxic substances (smoking) or stress. All this information is transmitted to the foetus *via* the placenta. These environmental events — albeit transient — may leave a mark and be "remembered" by foetal cells and effect the child's development at a later time, or even in adulthood. They may in some cases be inscribed in the foetal gametes, in which case the next generation may be impacted. The influence of maternal dietary intake was the subject of particular study. We now know the connection between low birth weight and the later onset of cardiovascular disease or impaired glucose tolerance, or again between maternal obesity, diabetes and the emergence of chronic diseases or early onset obesity in children. It is also known that for rodents, the consequences of some maternal behaviour (such as early separation, may lead to epigenetic modifications in the offspring. These environmental influences are "memorised" by the cells although this is not a genetic transmission and the DNA sequence is not modified. Such mechanisms (in animal studies) are still not completely elucidated. They may be the result of damage to cellular functions (in particular oocyte mitochondria) during foetal development (in the case of nutritional deficiency) or of epigenetic modifications. Epigenetics includes mechanisms essential for the control of genetic expression of every tissue or organ throughout life. The "epigenome" is always closely connected to DNA the expression of whose genes it regulates — that is activates or mutes depending on the tissue concerned. It is made up of proteins (histones) around which the DNA sequence winds, which may be modified by the addition (or loss) of chemical groups (methyl, acetyl) in response to environmental influence. Other regulating molecules (small nuclear non coding RNA) are also integrated into the epigenome. Unlike DNA sequences, these epigenomic modifications (these "marks") are dynamic and may disappear or appear at different times in response to the environment, so that they ensure our adaptation to the environment. These marks may persist during the whole life of an individual; if they impacted the germ cells they could be transmitted to the descendants of the exposed individual — although the descendants themselves are not exposed — which suggests the possibility of some degree of inheritance of acquired traits over several generations.

However, caution is of the essence and animal data should not be the subject of overly hasty extrapolation to human beings.

[121] Rando OJ, Simmons RA. *Cell* 2015; 161: 93-105. Szyf M. *Trends Mol Med* 2015; 21: 134. Rinaudo P, Wang, E. *Annu Rev Physiol* 2012; 74: 107-30.

[122] We are not considering at this point post-natal behavioural interaction during which is also transmitted the memory of the woman's experience during pregnancy.

Changes in brain activity in pregnant women

Pregnancy and motherhood modify the cerebral structure of a woman in childbirth, suggestive of increased plasticity of neural networks[123]. Multiple factors are involved, including the extensive hormonal modifications occurring during pregnancy as well as post natal interaction between mother and child. This restructuration could facilitate the acquisition of some examples of maternal behaviour. Several hormones regulating pregnancy interact with neurotransmitters activating neural networks involved in maternal nurturing behaviour after which they have an effect of the child's development and are transmitted to the child.

It is difficult to discover whether hormones present during pregnancy intensify maternal response to stimulation from the child compared to responses from a woman who is not the womb mother.

A recent study[124] involving the use of cerebral imagery (MRI) has confirmed and provided more detailed information on modifications to the cerebral structure occurring specifically in women who have just given birth (which does not exist for fathers or other men outside the couple). There is a systematic, significant and prolonged (two years at least) reduction of the volume of grey matter in specific (non random) areas involved in social relations. The authors speculate that such modifications could represent an adaptive process to facilitate "maternal" behaviour, in particular maternal recognition of the child's needs or of danger signals. Functional data acquired in the study (facial recognition, attachment) confirm the theory.

[123] Feldman R. *Trends Neurosc* 2015; 38: 387-99 . Rilling JK, Young LJ. Science 2014; 345: 771-6.

[124] Hoekzema E, et al. *Nat Neurosc* 2017; 20: 287-96.

Annex 10.

Legal systems concerning gestational surrogacy (GS) in countries outside France.

Law applicable to GS varies from one country to another. Some countries have standards, by law or by regulation, sometimes under the supervision of a constitutional court. Others have no government-regulated standard, contacts being established contractually, more or less regulated by "good practices" of a medical nature. This annex mainly lists legislative arrangements with some examples of jurisprudence.

There are several groups of countries: Europe, where the situation is very diverse (I), the United States and Canada, where there is also a good deal of diversity (II), countries in South East Asia (III).

I. Europe

In most European countries, GS is expressly prohibited, or else GS contracts are held to be null and void. Various general principles of law are cited: human dignity, non availability of the human body or individual rights. In most countries intermediaries are liable to criminal sanctions.

1- **Countries in which GS is prohibited:**, *Austria, Bulgaria, Croatia, Estonia, Finland, France Germany, Iceland, Italy, Malta, Moldavia, Montenegro, Serbia, Slovenia, Spain, Sweden, Switzerland.*

Germany. GS is prohibited through several different vehicles; (Civil law code, the 1990 law on protection of the embryo; laws dated 2002 and 2008 on adoption). In civil law, a GS contract is null and void and the mother is the woman who gives birth. In bioethics legislation, oocyte donation is prohibited in order to avoid any procedure favouring a fragmentation of motherhood. The right to information on genetic origins is recognised. Criminal law reinforces the efficacy of GS prohibition by sanctions on all intermediaries or professional activities connected to GS: fines, prison sentences, applicable to agencies facilitating the meeting of interested parties or physicians practising GS.

Spain. The law on medically assisted reproduction expressly forbids GS and a GS contract is automatically null and void, be it for reward or free of charge. Participants to a GS (individuals, agencies, institutions, medical centres) are liable to sanction. The mother is the woman who gives birth. The biological father may claim paternity in keeping with ordinary law.

Italy. GS is expressly prohibited by the law on medically assisted reproduction, as is all advertising to that effect. Any person participating in GS, including the surrogate mother and the intended parents, is liable to criminal penalties (fines, imprisonment); physicians may be suspended from the medical register.

Switzerland. The Federal Constitution prohibits all forms of GS.

2- Countries in which GS is legal and regulated by law

a) Countries where GS is authorised (or not prohibited) on the condition that it is free of charge or limited to reasonable compensation

Three countries provide for "reasonable compensation" and no more, for surrogate carriers (but tolerate, even when the case is brought before a court, overruns that finally amount to remuneration. Jurisprudence is clearly *contra legem*).

The United Kingdom. The British model is based on presumed personal autonomy of all parties to the convention. GS is authorised, be it traditional or gestational (*The Human Fertilisation and Embryology Act*, 1990 law, modified in 2008 and 2013). Intended parents may be single or a couple, homosexual or heterosexual. The only condition is that one of them be a resident on British soil.

Intermediaries are prohibited from receiving payment or from advertising. The surrogate mother may

only receive compensation for her expenses. As in all other European countries, the birth mother, i.e. the woman giving birth, is the legal mother. She is given a set time in which to decide if she wishes to keep the child or abandon it to the care of the intended parents, in which case a new birth certificate is drawn up. *The Parental Order* is a judicial statement of parenthood in the name of the intended parents ratifying the act of relinquishment of parental rights by the surrogate, and if applicable her husband. It cancels the initial birth certificate and eliminates any mention of the surrogate. There are few volunteers for gestational surrogacy in the United Kingdom and as intended parents are fearful of the surrogate's right to keep the child, a large proportion of them tend to prefer making arrangements abroad.

Greece. Laws dated 2002 and 2005 defined the conditions for MAR and GS in Greece. They authorise so-called "regulated" GS, as follows: indications must be medical, only gestational GS is allowed, the surrogate mother receives no financial reward and a prior written agreement signed by the parties is required. The intended mother must state that she is sterile and a judge must consent to the procedure. The judge must also verify that conditions are met (medical indication, altruism, informed consent) before GS can proceed. In a majority of cases, surrogate mothers are not nationals and not well off. Currently, GS is not allowed for male same-sex couples but is accepted for a single woman.

Russia. GS is legal in Russia since 1996. Conditions were detailed in 2011. Indications must be medical and only gestational surrogacy is allowed. The surrogate mother theoretically only receives compensation for expenses but judicial reality is not always clear in the Russian Federation and it is sometimes claimed that commercial GS is deemed acceptable. The surrogate mother giving birth is the child's legal mother and she may decide to keep it. However, if the surrogate agrees, the intended parents can immediately be registered as the child's legal parents on a birth certificate and the civil status register.

Portugal might be joining this group of countries in the future.
Portugal. It was only recently that Portugal authorised non commercial ("altruistic") gestational-only GS conventions. These are only approved for exceptional medical circumstances (no uterus or functional incapacity). The opposition is currently obstructing the passing of the law's implementation decrees.

b) Countries where commercial GS is authorised: Ukraine, Georgia

Ukraine. GS is the subject of detailed organisation by legislation favourable to the practice. It is authorised for Ukrainian nationals and foreigners alike, for married heterosexual couples and for strictly medical indications. In notarised contracts drawn up between applicants and the surrogate, intended parents are immediately recognised as legal parents. Theoretically, are accepted only intended parents from countries where legislation does not prohibit GS (which in principle excludes French nationals).

Georgia. Since 1997 GS is authorised for married intended parents who are declared as the child's legal parents on the basis of contracts translated from the intended parent's original language and notarised. The birth certificate bears no trace of the surrogate.

3. Countries in which GS is not prohibited, is tolerated in the absence of any regulation, but is not facilitated and meets with some difficulties: *Belgium, Denmark, Netherlands.*

Belgium. There is no legislation covering the GS procedure. It is therefore neither prohibited nor subject to any particular conditions. In the absence of any explicit legal guidance, a few hospitals practise GS under strict rules, with no payment (except for compensation of expenses) and with a preference for gestational GS. However, filiation law is an obstacle to the development of GS. The surrogate carrier is considered to be the child's legal mother and if she is married, her husband is deemed to be the child's legal father. The intended father can come forward to acknowledge parenthood if the surrogate is unmarried, or he can initiate adoption procedures. The surrogate is allowed two months in which she can decide to consent to the child's adoption by intended parents.

When GS takes place in another country (Ukraine, India, United States) the incomplete or modified nature of the birth certificate (with no mention of the surrogate mother) leads to judicial complications with various courts viewing the situation in a variety of ways depending on the arguments brought forward: genetic or intended fatherhood, existence of a family, the child's best interests, etc.

Denmark. Several laws inhibit GS: the law on adoption (2009/2015) prohibits any form of intermediation between a woman and another person wishing to become the parent of a child born to that woman. It also prohibits any advertising to that effect which is punishable by fines or imprisonment. According to a law for the protection of children (2001) GS agreements are held to be null and void. (Clearly the rules are drafted with a view to discouraging GS).
In both the above countries, civil legislation limits the development of GS. As in all other European countries, a child is the offspring of the woman who gave birth and her spouse. A change in filiation necessitates an adoption procedure.

The Netherlands. Legislation is based on a statement of principle and the acceptance of an exception. Civil legislation lays down the principle of the prohibition of GS; any action in favour of the procedure is punishable in criminal law (fines, prison). By exception, if GS is the only possibility for a woman to be a mother, in conditions defined by medical legislation, GS may be allowed with the proviso that the surrogate carrier receives no remuneration. The surrogate carrier is the child's legal mother and may decide to keep the child.

4- Countries without any specific legislation/regulation on GS: *Andorra, Bosnia-Herzegovina, Cyprus, Hungary, Ireland, Latvia, Lithuania, Romania, San Marino.*

These are countries in which the practice of GS is sanctioned, but *via* very general legal provisions, or in which the practice is not impeded, or in which the issue of whether GS is legal or illicit is not resolved.

II. The North American continent

*United States***.** There is no federal law on GS and some thirty States do not have legislation on the subject. The eleven States that accept the legitimacy of GS in various forms (unpaid, compensated for expenses or remunerated) are a minority (Arkansas, Illinois, Texas, etc.). California is one of them and it allows intended parents to obtain, before the child is born, a legal decision (called a "pre-birth order") attributing to them the filiation of the unborn child. This is immensely attractive to the rest of the world so that there is a tendency to export the State's legal system worldwide, *de facto* and *de jure.*
As is the case in Europe, some of the States prohibiting the procedure declare GS contract null and void (Kentucky, Indiana, Louisiana, Nebraska, etc.). Other States applying the same principle of prohibition, as a consequence draw the conclusion that GS is a criminal offence: (*New York, Washington, Michigan*, etc.).

Canada. Similarly to the United States, the issue of GS is of the competence of the provincial governments, as is legislation on filiation. Provincial law everywhere is based on the principle that the child's mother is the woman giving birth. But since the issue of human dignity is relevant, federal law has stepped in to prohibit expressly GS for payment and all intermediation activities. By *a contrario* interpretation, GS conventions which do not provide for any monetary exchange are held to be licit. Taking the province of Quebec as an example, the province's civil legislation deprives GS conventions of any effectiveness. But in several of the English-speaking provinces, regulations allowing the practical implementation of GS were not adopted so that the situation is very open to question and depends mainly on the wording of the contracts.

III. Israel

A 1996 law regulates GS on national territory. It is only allowed for couples composed of a man and woman, for medical reasons and with authorisation by a multidisciplinary commission after an interview with applicants and the convention signed by the parties has been inspected. The surrogate

mother is only entitled to receive reasonable compensation. Once the child is born, a *Parental Order* brings the procedure to a conclusion.
Single people and same-sex male couples go abroad.
There are some unpublished recommendations for dealing with GS performed outside Israel. Upon request by the intended parents, the Israeli embassy in the birth country arranges for genetic testing to check that there is at least one genetic link with the child. The *Parental Order* is delivered upon return to Israel.

IV. Countries in South-East Asia

The "*forum shopping*" trend has led to a surge of foreigners arriving in these countries, attracted by national legislations that either tolerate GS or consider it lawful. In the last five years, South-East Asian countries have been adopting laws raising the issue of legitimacy and increasingly restricting conditions for access to GS (India, Thailand, Nepal, Cambodia, Malaysia).