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National survey on the opinions of French specialists in assisted reproductive technologies about social issues impacting the future revision of the French Bioethics laws

Running title: ARTs French specialists' opinion on social issues

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Introduction

Regulation of ARTs through legislation is not homogeneous in European countries and at the international level. France is known for its conservative approach in assisted reproductive technologies (ARTs). The French Bioethics laws were enacted in 1994 and revised in 2004 and 2011. The current French Bioethics laws state that ARTs must be used “to remedy infertility whose pathological character has been medically diagnosed or to avoid the transmission to the child or to a member of the couple of a disease of a sufficient serious nature” (article L.2141-2, Public Health French code). Article 24 of the Public Health French code declares that “the man and the woman forming the couple must be alive, of childbearing age, married or able to provide proof of a life together”. As a consequence to this law, techniques can only be applied in couples formed by a woman and a man presenting with documented medical infertility. ARTs are free for the patient, financed by the French Social Security system, both in public and private institutions, up to 6 intra-uterine inseminations (IUIs) and 4 in vitro fertilization (IVF) cycles resulting in an embryo transfer for a woman under 43 years old. Sperm donation, oocyte donation and embryo donation are also covered in the case of a woman under 43 years old in a heterosexual couple. Donors must donate solely for altruistic reasons and agree to remain anonymous, thus resulting in long waiting times for donation. Single heterosexual women or same-sex couples do not have access to ARTs, therefore, the only legal option for family building being adoption, which was legalized in 2013 for same-sex couples. Fertility preservation (FP) is only allowed for cancer patients or for medical reasons. Directed donation, surrogacy, elective oocyte cryopreservation and pre-implantation genetic screening for maternal age, repeated abortions or implantation failures are currently forbidden in France.

It is well-documented that French single heterosexual women, lesbian couples and heterosexual couples cross European borders in order to benefit from paid oocyte or sperm donation or in order to have access to techniques prohibited in France. The main destinations countries are Spain and Belgium where the access to ARTs is less restricted. As described by Shenfield et al. [1], cross-border reproductive care is not only used by French patients. Users from other European countries such as Italy, Germany, The Netherlands, Norway, Sweden and the United Kingdom also access cross border reproductive ARTs. Most of them travel to evade restrictive legislation in their own country.

To date, access and legislation for ARTs vary greatly in European countries and elsewhere in the world. The evolution of society combined with medical advances have promoted ethical reflections concerning new models of parenthood. France is one of the rare countries to offer reimbursement for ARTs.

Because of the uniqueness of France in relation to Europe and other countries in the world, we decided to conduct a national survey to examine the opinions of French specialists in ARTs about social issues in order to influence the future revision of the French Bioethics laws.

Materials and methods

A descriptive study was conducted in May 2017 by using an online, anonymous questionnaire, on current social issues concerning ARTs. The topics discussed were in keeping with the social indications debated by the French National Ethics committee: elective oocyte cryopreservation, ARTs for single women and lesbian couples, the legal framework for gamete donation. Other topics that were not discussed by the Committee were also included in the survey such as the extension of the indications of pre-implantation genetic testing and gestational surrogacy. For each proposal, physicians could choose between coverage of care at the patient's expense or reimbursement by the French social security system. Some questions were multiple choice questions and physicians could also choose not to comment.

A second part of the survey focused on the profile of physicians: region of practice, sex, age, medical specialty (clinician or embryologist), working in private or public institutions.

The online questionnaire was sent by email to 676 French specialists in ARTs, who represented the majority of physicians in the discipline. The listing was obtained from a French database of all clinicians and biologists specialized in ARTs.

In order to obtain the highest possible response rate, three e-mails were sent on May 15, May 23 and May 31, 2017. Respondents were able to reply only once and anonymously. A specific e-mail address was created to answer any questions or comments from participants. Data were expressed as numbers and percentages and all the results were analyzed according to the characteristics of the participants using a Cochran-Mantel-Haenszel test.

Results

Participation rate

Physicians' characteristics are described in Table 1. They were equally distributed over the French territory.

Table 1: Demographic characteristics of the physicians

Physicians' characteristics		Percentage	Number n=407
Sex	Women	67%	272
	Men	32%	131
	<i>ND</i>	1%	4
Age	Under 50 years old	60.4%	246
	Over 50 years old	39.3%	160
	<i>ND</i>	0.2%	1
Specialty	Clinicians	64%	260
	Embryologists	35.6%	145
	<i>ND</i>	0.4%	2
Type of practice	Public institution	53.3%	217
	Private clinic	46.2%	188
	<i>ND</i>	0.5%	2
Clinicians	<i>Public hospital</i>	52.5%	137
	<i>Private clinics</i>	47.1%	123
Biologists	<i>Public hospitals</i>	55.6%	80
	<i>Private clinics</i>	44.4%	64
ND			2

ND : not documented

Out of the 676 French ART specialists to whom the questionnaire was sent, only 650 received it, due to incorrect email addresses. The day after the first mailing, 108 responses (16%) were collected, then 316 responses in total in the week following the second mailing (48%). After a third follow-up, 407 responses were received in total, representing a final participation rate of 62.6% (407/650).

Survey results for the main social issues

The main results are described in Table 2.

Physicians' opinions	ART for heterosexual single women		ART for lesbian couples		Elective egg freezing		Preimplantation genetic testing for aneuploidies	
	%	n	%	n	%	n	%	n
n=407								
Agree if payed by patient	48.9%	199	45.5%	185	86.3%	351	54.4%	221
Agree if refunded	14.5%	59	24.5%	110	7.1%	29	25.8%	105
Against	34.9%	142	27.0%	100	6.6%	27	17.4%	71
No opinion	1.7%	7	3.0%	12	0%	0	6,2 %	25

Table 2: Main survey results for ART's in heterosexual single women and lesbian couple, elective egg freezing and pre-implantation genetic testing

Gamete donation

Regarding donor compensation, 77.4% (n=319) of the physicians were in favor, 21.8% (n=81) were against, and 0.8% (n=8) did not comment. Public physicians were statistically more likely to oppose (24.1%) compared to private physicians (15%), (p=0.04). There was no significant difference with respect to other parameters.

Concerning anonymity, 92% (n=372) of the physicians wanted the donors to remain anonymous at the time of donation, 6.4% (n=26) were against and 1.6% (n=9) did not express an opinion.

Concerning intra-familial or close acquaintance directed donation, 80.9% of the physicians (n=326) were against, 17.8% (n=73) were in favor and 1.3% (n=8) did not wish to comment. For these two questions, there was no significant difference related to the characteristics of the participants.

ART for single women or lesbian couples

As described in Table 2 and Figure I, when asked about opinions regarding access to ARTs for heterosexual single women, 63.4% (n=258) of participants were in favor: 48.9% (n=199) with costs paid by the patient and 14.5% (n=59) with financial coverage.

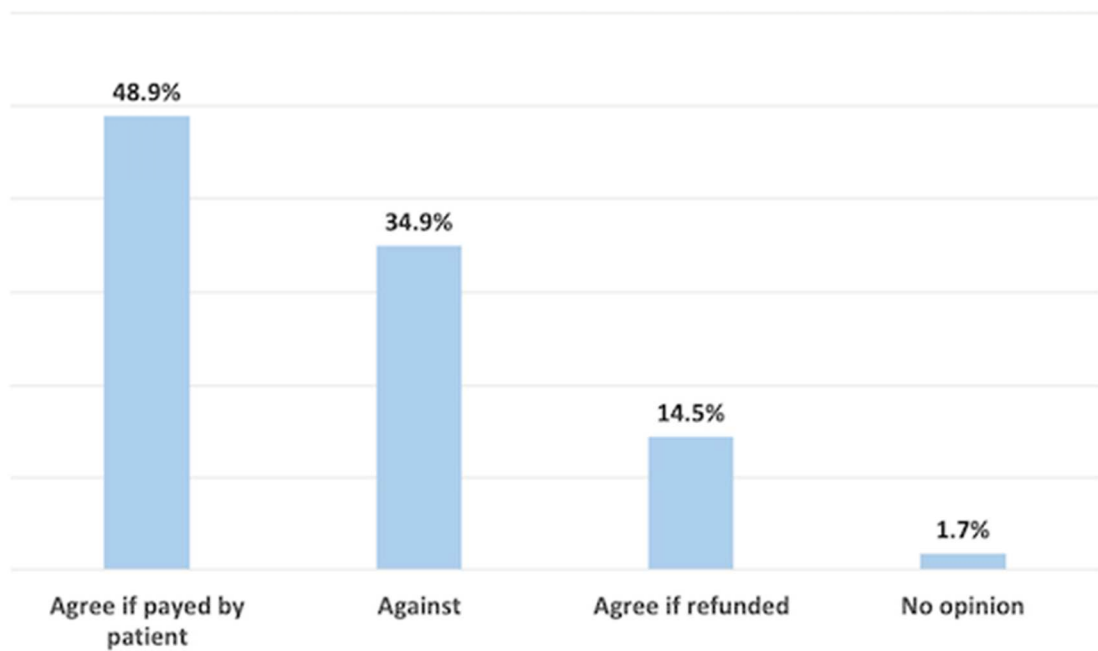


Figure I: physicians' opinions on ART's in single women

For lesbian couples, 72.5% of participants were in favor: 45.5% (n=185) with financial responsibility falling on the user and 27% (n=110) with financial assistance (Table 2 and Figure II).

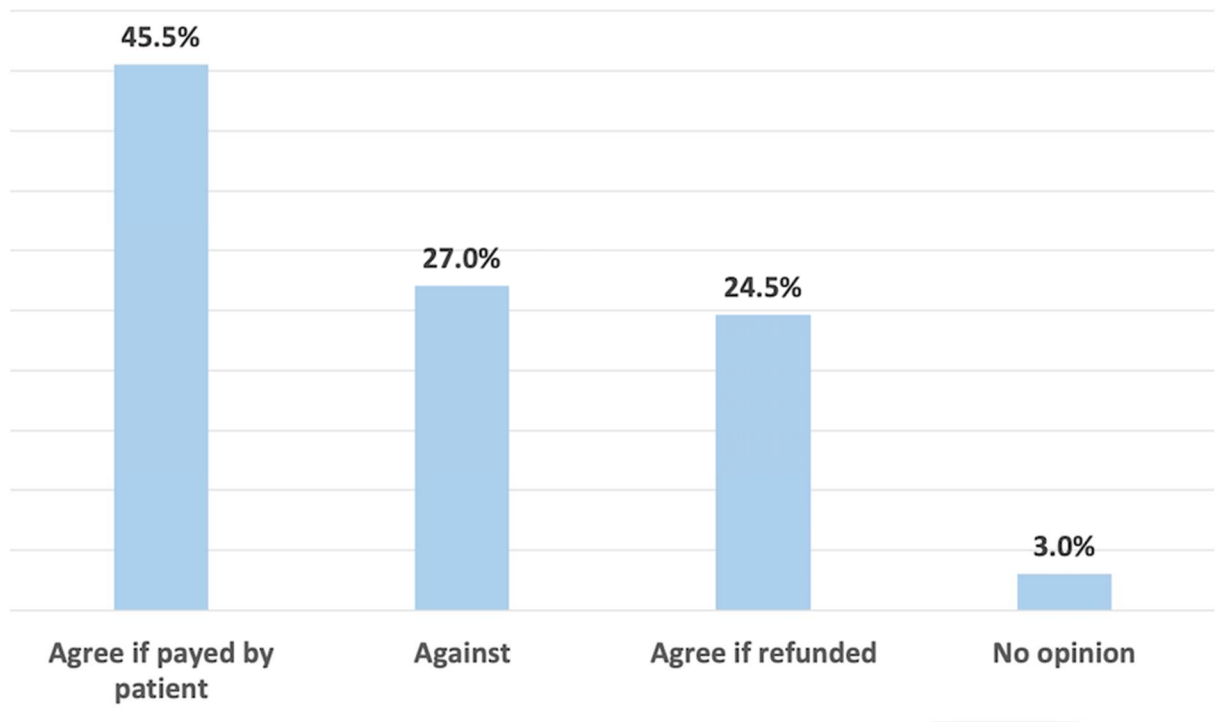


Figure II: physicians' opinions on ART's in lesbian couples

Both for ARTs in single women and lesbian couples, embryologists were less favorable than clinicians (36.1% versus 18.2%, $p=0.0008$) and male physicians less favorable than female physicians (30.8% versus 21.8%, $p=0.005$). Female physicians were more in favor for financial responsibility falling on the patients than male physicians (51.3% versus 33.0%, $p=0.005$).

Elective oocyte cryopreservation

Regarding access to fertility preservation for non-medical reasons, 93.4% ($n=380$) of the physicians agreed with the implementation of this practice: 86.3% ($n=351$) at the patient's expense, 7.1% ($n=29$) asked for government coverage (Table 2).

Regardless of opinions concerning financial management, 41% (n=167) were in favor of the donation of self-preserved oocytes to the French oocyte donation banks, when eggs were not used for themselves.

When compared by specialty, 13.9% of the embryologists were against elective oocyte cryopreservation versus 1.9% of the clinicians ($p<0.001$). Similarly, 10.7% of the male physicians were not favorable of elective oocyte cryopreservation versus only 4% of the female physicians ($p<0.005$). There was no significant difference by age or public/private practice.

Gestational surrogacy

Concerning gestational surrogacy (GS), as showed in Figure III, 55.1% (n=221) of the French physicians were favorable. Among the physicians who agreed: 83.3% (n=182) wanted an indication reserved exclusively for women with an impossibility or a contraindication to pregnancy, 18.3% (n=40) supported GS for gay couples, and 3.6% (n=8) were in favor of GS for unpartnered heterosexual men.

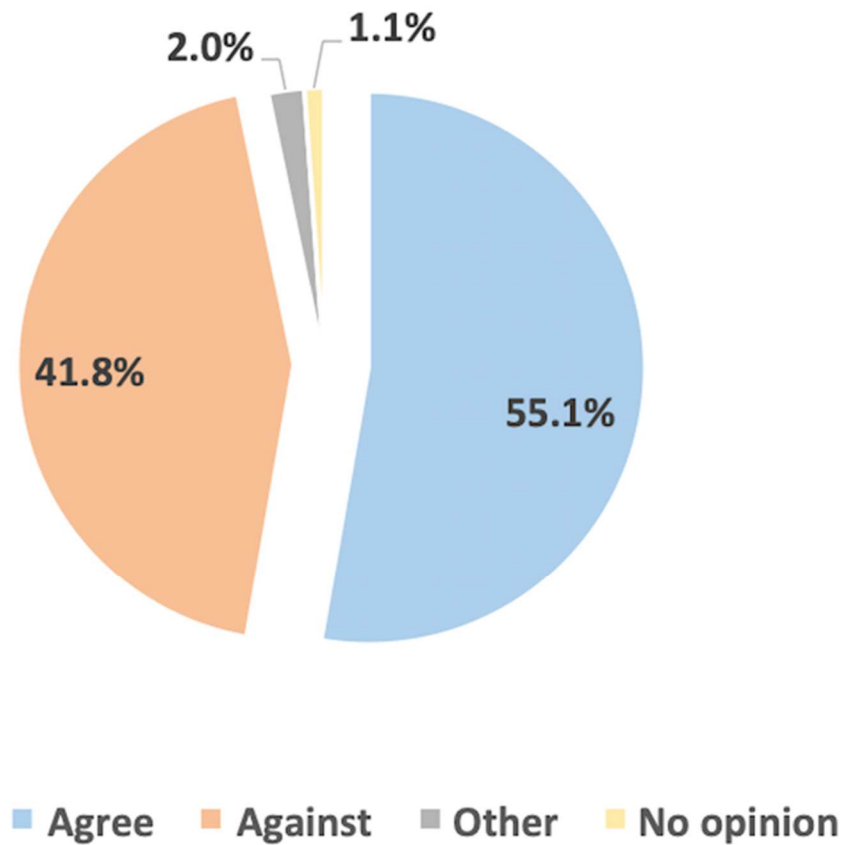


Figure III: physicians' opinions on gestational surrogacy

The only significant difference was in the analysis by medical specialty: 50% of embryologists were against GS versus 36.3% of clinicians ($p=0.03$).

Preimplantation genetic testing (PGT)

The PGT includes three sub-categories of PGT for aneuploidies (PGT-A), PGT for single gene / monogenic disorders (PGT-M), and PGT for chromosome structural rearrangements (PGT-SR). PGT-A is used to detect aneuploidies and previously it was known as PGS. PGT-M, formerly known as PGD, is intended to reduce monogenic defects. Previously known as PGS translocation, PGT-SR is PGT to identify structural chromosomal rearrangements.

In France, PGT is currently limited in France to couples who are at risk of transmitting a very serious and incurable genetic disease to their child, including PGT-M and PGT-SR. In our survey, 80.1% of the French physicians (326/407) were favorable to expanding PGT for aneuploidies (PGT-A) in case of maternal age, repeated abortions or implantation failures: 50.6% (n=206) asked for a social coverage, whereas 25.8% (n=105) were in favor but at the couple’s expense (Table 2 and Figure IV).

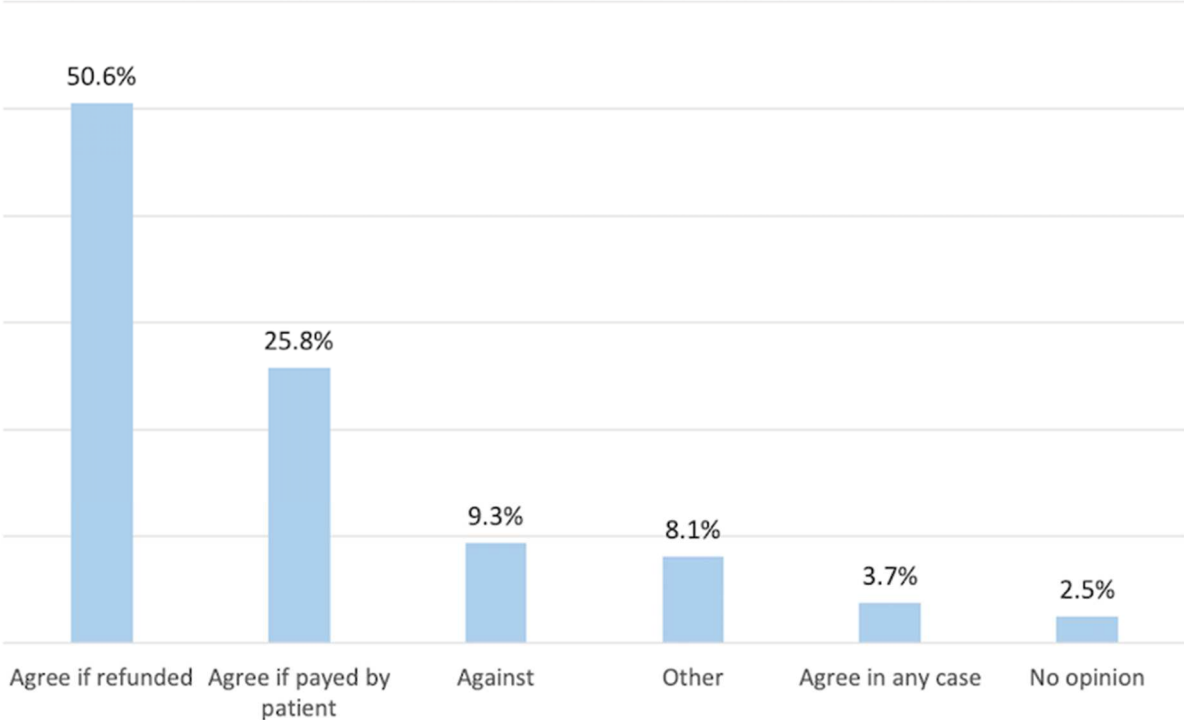


Figure IV: physicians’ opinions on PGT-A

Embryologists (13.9%) and physicians in public practice (13.9%) were statistically more likely to be against compared to clinicians (6.6%) and physicians (3.4%) in private institutions (p=0.005 and p=0.004, respectively). The analysis by age and gender did not demonstrate any significant difference.

Discussion

The constant improvement in ARTs and the current evolution of society towards new family models call into question the current French legal framework. Pending the future revision of the French Bioethics laws, widening access to ARTs for social indications is currently the subject of much debate among doctors, psychologists, psychiatrists, philosophers, lawyers and citizens. Surveying the opinions of French specialists in ART has become important because they, as providers, are the first to be confronted with the growing demand for treatment following cross-border care. This survey shows that French ARTs specialists seem to support the extension of ARTs indications for social reasons, with the exception of surrogacy and directed donation, but at the patients' expense for the majority of physicians surveyed, both in public and private institutions.

Concerning gamete donation, most of the French physicians were in favor of donor compensation. French legislation is presently based on the fundamental principle of free donation. The main consequence of this practice is a lack of donors, resulting in long waiting lists and cross-border care [2]. Donors in France, are only reimbursed for medical and transportation costs since January 2015. Donor compensation is authorized and practiced in many countries, in particular for oocyte donation (Czech Republic, Greece, Spain, some States of the United States). Financial compensation allows for the recruitment of younger and many more donors than in France. In our survey, contrary to their favorable opinion of donor compensation, participants mostly opposed a change in the legal framework concerning the lifting of anonymity in gamete donation and the legalization of directed donation. To date, donation is anonymous in France, Greece, Portugal, Russia and Spain, but Spanish law in 2006 has allowed children to obtain

general information about their donors when they reach the age of majority. There is a tendency in Europe and elsewhere in the world to lift the restriction of anonymity (Sweden, Germany, Switzerland, Netherlands, United Kingdom, Norway, Austria, Finland, Canada, United States) [3]. Some countries have a mixed system, for example Belgium and Denmark, with two donation systems: one anonymous and the other no [4]. The main argument for the lifting of anonymity is the right of children born through donation to know their genetic origins [3]. For others, the lifting of anonymity would be a means of resolving the issue of donor shortage, for example by authorizing intrafamilial directed donation or close acquaintance donation as is the case in Belgium [5]. Nevertheless, in some countries (Sweden, Netherlands, Great Britain), it was observed that the lifting of anonymity could lead to a decrease in the number of donors [6].

ART for single, heterosexual women and lesbian couples was favored by most of the French specialists. This is in accordance with the opinion of the French Ethical Consultative Committee published in September 2018. Currently, the representation of a family unit is limited to children of a father and a mother. Today, ARTs are possible for all women, regardless of their marital status and/or sexual orientation in Spain, Belgium, the Netherlands, Finland, Latvia, Luxembourg, Greece, some states in the United States, Canada, Israel, South Africa, Sweden (only for couples), Iceland, Denmark and the United Kingdom [4]. In France, opening ARTs access to lesbian women would end discrimination based on partner gender, but would also reflect broader inclusivity of all those seeking to build families. One argument in favor of opening ARTs access is that, despite their heterogeneity and sometimes their methodological weaknesses, most of the studies conclude that marital status or sexual orientation do not influence the

psychosocial development of children [7-10]. Supportive co-parenting is more determining of child development than the sexual orientation of parents [8].

Elective oocyte cryopreservation is increasing in popularity as more women delay family building but are aware of the decline in chances of pregnancy for older women [11,12]. Although vitrification of oocytes is a recent technique with a lack of long-term follow-up, results are reassuring and promising [13-15]. In our survey, elective egg freezing was largely supported by the French specialists in ARTs. Nevertheless, the French National Ethics Committee report of September 2018 proposed to limit excessive use of elective oocyte cryopreservation. Indeed, some uncertainties remain in literature concerning elective egg freezing. First, only a minority of patients will return to use their oocytes: 2.9% for Garcia-Velasco *et al.* [16], 9.3% for Cobo *et al.* [15] and 12% in Devine *et al.* study [17]. Indeed, the vast majority of women will be able to have children by natural methods. If oocytes are not used, options include either destroying oocytes or donating them to research or to an infertile couple. In our survey, 41% of physicians wanted the unused oocytes to be transferred to the donation pool. This would also improve the shortage of oocyte donors. The second uncertainty about the usefulness of this technique is the lack of guarantee of results. Cobo *et al.* showed that in an elective fertility preservation program at least 8-10 metaphase II cryopreserved were necessary to achieve a reasonable success rate in women < 36 yo, and much more in women older than 36 yo [15]. In practice, items of discussion are the age limit and ovarian reserve parameters that should be established in order to provide reasonable chances of pregnancy. Nevertheless, an argument in favour of this technique is the beneficial reassurance aspect associated with using preventive oocyte vitrification [18]. Another argument in favor elective FP would be economic. Devine *et al.* estimated

that for women who wanted to delay their pregnancy after the age of 40 yo, the use of oocytes cryopreserved would be less expensive than ARTs if elective FP was performed before the age of 38 yo [17].

Concerning gestational surrogacy (GS), the French National Ethics Committee has confirmed prohibition of GS stating that this technique undermines the integrity of the woman's body. In our survey, opinions remained divided concerning GS and only 55.1% of the French physicians supported the legalization of GS. Among the physicians who were in favor, the majority preferred an indication exclusively reserved for impossibility or contraindication to pregnancy in women, rather than for gay couples or unpartnered heterosexual men. Practices in the world are very heterogeneous. France, Germany, Spain, Italy and Switzerland prohibit GS. However, GS is authorized in the United Kingdom, Russia, Greece, South Africa, Israel, Canada, Brazil, Iran, Australia and Thailand [4]. Countries allowing GS for gay couples or unpartnered men are few in number, mainly represented by the United States and Canada. Some countries allow GS only if the surrogate mother receives no remuneration (Australia, Canada, some states of the United States, United Kingdom, Netherlands, Denmark, Hungary, Portugal). In some countries such as Thailand, India, Nepal and Cambodia, GS is allowed but not able to be accessed by foreigners in order to prevent exploitation foreigners. However, for couples in serious procreative difficulty, GS appears to be a more popular alternative than adoption because of the possibility of transmitting the genetic heritage and of participating in the pregnancy process and care for their child from birth. Similarly, it is the only way for unpartnered men or gay couples to obtain genetic paternity.

Pre-implantation genetic testing (PGT) was legalized in France in 1994. In the French law, this technique is allowed only to prevent couples suffering from or carrying a very serious and incurable genetic disease being transmitted to their children (for example, myopathy, cystic fibrosis, neurofibromatosis, beta-thalassemia, retinitis pigmentosa, Becker's muscular dystrophy, hemophilia A7 or Huntington's disease). It also applies when one of the partners of a couple has a chromosomal abnormality of balanced structure in him, but which may lead to an unbalanced pathogenic or lethal genotype in the fetus (a balanced reciprocal translocation, a Robertsonian translocation or an inversion). Currently, nearly 180 genetic anomalies or diseases fall within the legal framework of PGT. Genetic predisposition to adult cancer (i.e. BRCA 1/2 mutations) is not part of PGT in France. So, currently, in France, PGT is allowed either in case of single gene/monogenic disorders (PGT-M) or of chromosome structural rearrangements (PGT-SR). PGT for aneuploidies (PGT-A) is forbidden in France so far. To expand PGT to aneuploidies and take into consideration maternal age, repeated abortions or implantation failures has not been discussed by the French National Ethics Committee. Indeed, PGT-A is still controversial, with a low level of benefit in the scientific literature [13, 19, 21-23]. For this reason, some authors have asked for studies with higher significant standard of proof before putting PGT-A into practice for all patients [24-26].

France is one of the rare countries to reimburse ARTs. Most French specialists in ARTs were against a social security coverage for social indications. Concerning elective FP, the majority did not support social security reimbursement. Thus, elective egg freezing has appeared as a "comfort" care, in the same category as esthetic care. Concerning PGT for aneuploidies, half of participants wanted to reimburse PGT-A. To justify social security coverage, it is first essential to confirm its real effectiveness in

terms of pregnancy rates. Finally, most of the French specialists promoted ARTs for single women and lesbian couples but at the patients' expense for the majority.

However, if as described by the French National Ethics Committee, the possible access to ARTs for single women or lesbian couples is based on a desire for equality, it will be difficult to defend not treating these patients in the same way with respect to the social coverage or the access to sperm donation.

Concerning variations according to physicians' characteristics, embryologists were statistically less favorable than clinicians, and men less favorable than women regarding ARTs for single women or lesbian couples, elective FP and GS. An explanation for this could be that embryologists and men are more conservative than clinicians and women. It is noteworthy that the proportion of female clinicians is higher than female embryologists.

The strengths of this survey are its originality, the large number of physicians surveyed, representing the majority of physicians in ARTs in France, a satisfactory participation rate and the importance of seeking the views of physicians in this debate. Moreover, the implications of our survey are not limited to the debate around French laws. Other countries limit regulations around ARTs, and this survey may serve to separate policies in those countries from the preferences of physicians practicing within them.

Limitations are a possible selection bias resulting in the lack of response from some physicians. Another limitation is that these data are limited to French physicians.

In conclusion, whereas France is known for its conservative ART legislation and its coverage by social security, this study shows that most of the French specialists in ARTs seem to support the enlargement of ARTs indications for social reasons except for surrogacy and directed donation, but specialists prefer patients be financially responsible for expanded indications. For the time being, similar to the physicians in this study, the French National Ethics Council, the French National Assembly seem rather in favor of an evolution of French law and opening ARTs to social indications. However, the law has not yet been passed and the debate remains open. To enhance this debate, it was important to have the opinion of French specialists in ARTs. Thus, this survey would be useful in preparing the future revision of the French Bioethics laws. The results of this survey also reflect the progression of social values in France, and the incongruity between the laws and values among French physicians, a phenomenon which could be applied to other European countries or other countries in the world. A consensus of ART practices in Europe or more generally elsewhere in the world is recommended.

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Authors' roles

H.C. was directly involved in the study design, development of the questionnaire, literature review, preparation of the initial manuscript. M.D. performed the data collection, statistical analysis, the literature review and preparation of the initial

manuscript. M.G. actively participated in the critical revision of the manuscript. L.C.D, J.T., S.F., A.P.R, C.J., N.C. and C.H. participated in the review of the manuscript.

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