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Crossing borders for gametes donation and surrogacy: a legal puzzle?

Introduction

Ever since the beginnings of in vitro fertilization (IVF), national laws have responded to societal concerns about the status of and research on the embryo in vitro, and conditions of access to the many techniques of ART for women, whether married or not, in a couple or not, and (rarely) men in a same sex relationship. Third party reproduction involves the collaboration of others than the genetic or biological "intended parents". From the onset, this complicates the professional responsibility characterized in ART by the fact that this is due to two people rather than one, the usual case in other fields of medicine. Furthermore, we also have to take into account the welfare of the future child whether by statute (HFE Act 2008), or implicitly. In surrogacy arrangements, like in gametes donation, this also necessarily involves responsibility to third parties, and the usual bio-ethical frame of respecting the (infertile) patients' autonomous choice, optimizing their interests with maximizing beneficence and minimizing complications (non maleficence), must be balanced with the essential respect of such donors/collaborators/ third parties' interests and autonomy, and avoiding their exploitation; finally such principles also concern the respect of justice. Thus gametes donation has been one of the much discussed topics for many years (anonymous or known, compensated or even paid?), but whilst sperm donation is an "old" subject as it antedated the first IVF success by decades, only the latter technique enabled egg donation and full surrogacy, thereby also highlighting the specific female gender concerns when either is needed. However, amongst all issues of concern to society in the field, surrogacy has been one of the most contentious, as it involves a third party who may put her health at risk by being pregnant, undergo specific tests during her pregnancy, and have strong emotions including pre-birth attachment with the fetus, a future being, all on behalf of another person, mostly heterosexual couples, but in some cases where the law permits, homosexual couples as well. This technique – "where a woman carries a pregnancy and delivers a child on behalf of a couple where the woman is unable to do so, because of a congenital or acquired uterine abnormality, or because of a serious medical contra indication to pregnancy" (FIGO), and "where thintention is that the surrogate will relinquish the born child to the commissioning couple" is illegal in several European countries where a lot of other ART is commonly practiced, such as France or Spain. Surrogacy is also sometimes "supported by specific legislation, enabling the commissioning couple to become the legal parents", such as Greece, USA, the UK, or even practiced if a specific law does not forbid it (EU comparative study on surrogacy report, 2013). Europe, a leader in the field of ART, does not however present a homogeneous picture through its national ART laws, whilst the EU has only officially intervened in 2 relevant fields, one practical with the Tissue directive which affects keeping gametes and embryos, and their traceability (EU Tissue Directive, 2004/23/), the other concerning the free movement of citizens across Europe in order to obtain treatment, giving therefore an official blessing to the phenomenon of Cross border reproductive care (CRBC) (EU directive, 2011). This CBRC may also involve further borders, between continents, and /or between high and low resource areas in the world, highlighting other important issues, especially the possibility of exploitation of poor(er) women by rich(er) women or couples.

• We discuss here some of the legal issues which have made press titles and websites in Europe and worldwide, and which vary in different examples of CBRC. In surrogacy, they involve either the permission for commissioning couples to leave the birth country with their intended child(ren), or legal issues of parentage and nationality at return in their home country, where surrogacy is (often) banned. In gametes donation, there are some specific issues related to the status of the intended parents, especially if same sex when returning to countries where same sex assisted reproduction is forbidden (such as France), but all are intrinsically linked to the ethical issues highlighted above, as ideally the ethical underpinning of justice should be clear. The major question is of course whether "Justice "or the law in general is as

ethical (just, equitable) as it purposes to be semantically. As explained by Bernard Dickens, emeritus Prof of Law in Toronto and current president of FIGO's ethics committee, "law and ethics sometimes overlap and sometimes conflict" (in Shenfield and Sureau eds, 2004). Thus the purpose of this paper is to give examples of both propositions, and hopefully highlight means of achieving the "overlap" more often than the "conflict".

• Before detailing some examples of the legal issues of the recent years when parents return home after cross border gametes donation or surrogacy, we first highlight the nature of and specific ethical issues linked to CBRC, exemplified by egg donation in particular, as well as surrogacy. We specifically use the example of egg donation and its varied systems of compensation in Europe in order to reflect on the difficulties of defining fair compensation within a non commercial system, as required by the European Union for any tissue or organ donation.

Main legal reasons for CBRC in Europe and some facts

Infertile patients do cross national borders in order to circumvent their home countries' restrictions on procedures, long waiting lists or legal constraints on eligibility, but the regulatory differences may also result in potential risks, especially difficulties for patients in pursuing any legal disputes in overseas jurisdictions, or difficulties at their return home with a much wanted child. CBRC, a much preferred term to "tourism" as it does not penalises patients, is not wrong per se as it enhances patients' autonomy, but safeguards must be observed, especially in case of third party ART (ESHRE Ethics and law Taskforce, 2009). By the first decade this millennium it was also known that frequent reasons for CBRC were law evasion (treatment illegal or restricted), access limitations at home; quality of care, previous failure, or a wish for gametes donation (anonymous, direct) in varied circumstances. Facts however were few, so our ESHRE CBRC taskforce (Shenfield et al, 2011) decided to conduct a study on CBRC patients' characteristics by gathering foreign patients' data in 6 European countries where colleagues were willing to participate, and collected over 1 calendar month 1230 questionnaires from collaborating clinics in from Belgium, the Czech republic, Denmark, from Switzerland, from Spain, and Slovenia. We found that two thirds of CBRC patients came from 4 countries: Italy (32%), followed by Germany (14%), the Netherlands (12%) and France (9%). Furthermore, ee analysed the main socio- demographic characteristics (age, country of residence, marital status,

sexual orientation, education) of patients crossing borders for ART, their reasons for travelling including law evasion (treatment illegal or restricted at home), access limitations at home, seeking better quality of care, previous failure, wish for donation (anonymous, direct,...), and related all characteristics to the patients' country of origin and the women's age category (\leq 34, 35-39 and \geq 40). Finally we asked what information they received, their selection means of the chosen clinic (word of mouth, internet...), and if they were reimbursed in their country of residence.

The results highlighted vicinity as a factor of choice, and legal restrictions as the main reason for crossing borders: most Italians couples went to Switzerland and Spain, respectively for sperm and oocyte donation which were then both forbidden by law, most Germans to the Czech Rep for egg donation also forbidden at home, most Dutch and French patients to Belgium and Spain, and Norwegians and Swedish to Denmark.

Furthermore, this sample was extrapolated to one year, assuming an activity of 11 months a year, with about 50% clinics collaborating. This gave an estimate of 20 000 to 25 000 "cross border events" (cycles of treatment), and assuming that patients might go abroad for 1 to 2 cycles a year, about 10 000 to 15 000 infertile patients crossing national borders in Europe in one year.

This first international European research was followed by an ESHRE Good Practice Guide (GPG) for clinicians involved in CBRC (Shenfield et al, 2012), in order to enhance clinical standards ("good practice") and laboratory safety (a comparatively easy task within Europe at least with EUTD); to reduce multiple pregnancy and protect vulnerable collaborators, through abiding by the principles of equity, safety, efficiency, effectiveness, timeliness and patient-centredness. We advised disseminating information concerning standards via patients' organisation, and promoting communication between practitioners. By contrast the American Society for Reproductive Medicine (ASRM) ethics committee proposes that physicians who are asked to assist patients considering ART travel "may, but are not obliged to, offer guidance about the options for cross-border care", and that their duty of care at home "does not invoke a duty to inform or warn patients about the potential legal or practical hazards that may accompany such (CBRC) care" (ASRM ethics committee, 2013).

Specifically, in the case of surrogacy, the GPG recommends that "in order to ensure free and well-considered decision-making by the surrogate/gestating woman, it is required that the woman has at least one child" and highlight single Embryo Transfer (ET) as best practice, as it diminishes complications both for the pregnant women and future baby, mostly due to intrauterine growth retardation, preterm delivery, and their long term consequences. We stress that "single embryo transfer is the only acceptable option", that "continuity of care during pregnancy and childbirth must be planned prior to starting the surrogacy cycle". We also advice "the provision of legal advice about local rules is the remit of the local practitioner, or if not possible, through referral to appropriate local legal advisors".

Whilst safety must be paramount, the question of compensation for donation or surrogacy is also especially ethically sensitive. Whilst in Europe donation means no payment, the question of compensation, allowed in many ART legislations, and the concern of this possibly becoming "disproportionate payment" is very complex. With regards to surrogacy, focusing on the contrast between resource rich and resource poor countries, FIGO's ethics committee (EC)recommends in the case of surrogacy that "in general, compensation for expenses directly related to the pregnancy, and loss of income due to the pregnancy, is accepted", stressing that "urrogate arrangement should not be commercial, and are best arranged by nonprofit making agencies", and also highlights "trans border reproductive agreements, where there is increased risk of coercion of resource poor women from resource rich countries citizens". Whilst surrogacy has a contractual commercial basis in the U.S, and payment for the services of the surrogate are mostly clearly set out prior to signature of the contract, it is strictly regulated in the few EU countries where allowed, and must be non commercial. Again FIGO' EC states that "disproportionate payment given to surrogate women risks coercion of vulnerable women, and has the potential to lead to commercial exploitation, in particular recruitment of women of underprivileged background" (FIGO). The same requirements apply in Europe for gametes donation, and the very complexity of the possible slippery slope of compensation into payment, and of possible commercial exploitation of poorer women, may be illustrated here by findings of recent ESHRE research on egg donors characteristics and motivations in Europe (Pennings et al., 2014).

The meaning of "compensation" in Europe: a comparison with oocytes donation (OD)

OD is a major reason for CBRC within Europe, where it must be a donation (EUTD, 2004), unpaid by definition, as indeed both terms are actually contradictory (Shenfield and Steele, 1993). Compensation of various degrees, however, is not totally forbidden in several countries. The dilemma resides in the definition of a "fair" or "proportionate" compensation. The ESHRE European OD study analysed the motivations and characteristics of donors in 11 EU countries (Pennings et al, 2014). Five categories of motives were retained with the following results: pure altruism, 48%; mixed altruism + financial benefit, 38%, showing that financial compensation helps to persuade some women to actually donate. Interestingly 11% of women declared they donated for "pure(ly) financial benefit; whilst a few declared their motivation was altruism + own treatment, or "pure own treatment", which relates to the case of "egg sharing" where women agree to give some of their oocytes to another in need when they themselves go through IVF. Motivation to donate was also influenced by age (the older, the more altruistic); education (the higher educated, the more altruistic), and finally the amount of compensation (the lower, the more altruistic), all this corrected by a Purchasing Power Parity analysis, which also highlighted differences in the 11 countries sampled.

We also know there are large at variations of compensation (or payment) for surrogacy agreements worldwide, and a sharp contrast between non commercial and commercial surrogacy. In Europe, there is strict regulation in Greece and the UK, but we still face the difficulty of defining proportionate and fair compensation worldwide, in order not to entice and possibly abuse poorer women to take a risk on behalf of the intended parents. This is plea for such data collection, in order to avoid the situation where surrogacy is deemed "totally unethical" and "always" an abuse of women's dignity either per se or by "buying/renting their womb". This would serve 2 purposes: first finding out how many women define themselves according to categories similar to the model of the OD study, altruism; mixed altruism + financial benefit, or pure financial benefit; second to agree on evidence based policy both nationally and internationally as to what is an appropriate legal solution in order to prevent the coercion of surrogates, as well as a principled refusal of a technique needed for

women without a (functioning) uterus. The UK has made surrogacy legal since 1984 (Surrogacy Arrangement Act 1985), and offers an example worthy of analysis.

Can the law be a barrier to exploitation? The UK example in surrogacy

The Surrogacy Arrangement Act was passed by UK Parliament in 1985, and criminalised advertising, brokering and profit-making by third party. Couples have been eligible for a parental order (PO) since 1990 (HFE Act, 1990) if married, domiciled in the UK, at least one of them is a genetic parent; if the child's home is with commissioning parents, within 6 months of the child's birth, and finally if valid consent was established and only "reasonable expenses" had been paid. From 2008, Part 3 of the HFE Act amends the Surrogacy Arrangements Act 1985, makes new provisions, enabling "civil partners" to apply, as can unmarried opposite-sex couples or same-sex couples not in a civil partnership. The other provisions relating to POs remain the same as the existing provisions of the 1990 Act. Furthermore, the 2010 Regulations made clear that the "welfare of the child" would be paramount considered in any court decision.

It has been difficult to obtain accurate data in the last 30 years, but a study of the number of parental orders issued by the UK courts has made very interesting reading (Crawshaw, Blyth and van den Akker, 2013), where a sharp increase in PO was noted from 2008 onwards: before 2008 they numbered 40-50 a year, but 73 were recorded in both 2008 and 2009; 75 in 2010; and 133 in 2011. Furthermore, there were initial discrepancies noted between the figures supplied by the surrogacy agencies and the number of court issued PO noted till 2007, but this changed to a very good match since. Lastly, in the years 2010-2012, the numbers of PO issued from surrogacy performed abroad were respectively 20 from India, 16 from the US, and 4 out the Ukraine out of a total of 190.

Interestingly, and going back to the constant dilemma of the proportionality of compensation or payment to the surrogate, the British Home office UK Border Agency issued guidance on «Inter-country surrogacy and the Immigration Rules" in 2009 It explains that "with regards to visa applications, the United Kingdom recognises surrogacy in India so long as it meets the conditions set out by the UK Human Fertilisation and Embryology Act 2008". This highlights not only the necessity "for a child to be treated in law as the child of a couple to be genetically

related to at least one of the commissioning couple", but also, our ethical concern that "no money other than reasonably incurred expenses has been paid in respect of the surrogacy arrangement".

In general the Agency also advised that the intended parents should try to obtain accurate information about their own national situation before embarking on the process, and that known legal problems or possible conflicts with the law in the home country should be explained to the patients. Indeed there are now legal firms specialising in specific legal advice on surrogacy, international or otherwise in the UK.

Some legal problems when intentional parents return to their country

We illustrate here some of the legal dilemmas encountered by European "intended parents" who had surrogacy abroad. The first two involve same sex parents, one Spanish male married couple with twins born in California in 2006 who had a pre-birth judgment issued by local court, but whose consulate refused to issue visas. This was eventually resolved in 2011, after the Spanish Ministry of Justice weighed the interests of the children v the interests of the Spanish government which prohibits surrogacy. At the time, the ministry stressed the need to obtain a judgment in the host country court for the legal validity of the birth certificate and to check that the contract for surrogacy was entered into "without fraud, overreaching or exploitation of the surrogate mother". Belgium also had a similar case where after a same sex couple had twins through a Californian surrogate, the High Court would only recognise one (genetic) father and asked the non biological father to adopt the children.

As surrogacy is forbidden in France, many French couples commission surrogate in Belgium, who will then deliver "under X" in France, whilst the intended father can "recognise" the child before delivery, and Belgium clinicians report few problems when caring for patients from other countries, although some practices were modified such as asking for advance payment, providing all appointments in one day, or providing interpreters (Brunet et al, 2013). Indeed and especially poignant for the almost 14 years old Menesson twins conceived by surrogacy in California, parenthood status and nationality has only just been resolved the European Court of Human Rights (EctHR). It stated that "totally prohibiting the establishment of a relationship

between a father and his biological children born following surrogacy arrangements abroad was in breach of the Convention", that there was no violation of Article 8 (right to respect for private and family life) of the European Convention on Human Rights concerning the applicants' right to respect for their family life; but there was a violation of Article 8 concerning the children's right to respect for their private life. On April 6, 2011, France's highest court - the Court of Cassation - had refused to allow French citizenship for the twins, which meant obstacles to school registration, healthcare access, and inheritance The consequence was that the ECtHR issued a groundbreaking decision in the Mennesson's case, ordering France to recognize and provide French citizenship to children born to surrogate mothers abroad, even though surrogacy is illegal in France. The decision was widely celebrated as a recognition of the "best interests of the child" standard and a sign of progress in France.

Conclusion

The legal puzzle of CBRC with third party may be solved nationally or internationally, such as in Europe with the above French example. Nevertheless recourse to the law can be a lengthy process after the facts, thus taking a long time to alleviate the respective family's anxieties. Gathering facts and furthering research allows transparency, an ethical duty to our patients and society at large. Thus the plans of The Hague Conference on private international law which has produced a "Study of legal parentage and the issues arising from international surrogacy arrangements" in April 2014, and stated the desirability of further work are welcome. The document highlights the (legal) "paradox" where "the internal laws of many States concerning the establishment and contestation of legal parentage have been very influenced by social, scientific and demographic changes, and the modern medical fact, that challenges genetic "certainty" and allows parental "intention" to be distinct from this, whether by gametes donation or surrogacy.

Whilst there is a corpus of evidence on gametes donation, there is a need for more evidence and data concerning the frequency of surrogacy especially in low resource countries, the amount of compensation and other transactions for the surrogates and intermediaries if they exist. From acceptance of the technique to emotive press titles, the major questions are about: what kind of surrogacy, which surrogate?

Can the legal status, parentage and nationality ensure that the "welfare of the (future) child", or best interest of the born child are maximized, and at what (ethical) costs? Where do we turn to when recommendations and guidelines to promote professional responsibility and respect for women's autonomy are challenged, especially through economic pressure (Shetty, 2012)? Failing effective action by medical professional associations and/or licensing authorities, only the law, with its symbolic and coercive strong arm, may then, we hope, provide the solution. It is encouraging that India's legislators are following this arduous path in the case of surrogacy, but it remains to see what means of implementation will be enacted.

References

Brunet L et al, 2013, A comparative study on the Regime of Surrogacy in EU Member States, Directorate General for Internal Policies, Policies Department C: Citizens' Rights and Constitutional Affairs, Legal and Parliamentary Affairs, European Parliament, Brussels.

Crawshaw M, Blyth E, van den Akker (2013) The changing profile of surrogacy in the UK – Implications for national and international policy and practice. Journal of Social Welfare and Family Law.

Commission of the European Communities. Proposal for a Directive of the European Parliament and of the Council on the application of patients' rights in cross-border healthcare, Presented by the European Commission on 2 July 2008, Copyright: European Communities, 2008; Directorate-General for Health and Consumers, European Commission – B–1049 Brussels, http://ec.europa.eu/dgs/health_consumer/index_en.htm

Commission of the European Communities 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells, http://eurlex.europa.eu

Dickens B (1997), Interfaces of assisted reproduction ethics and law, in Ethical Dilemmas in Assisted reproduction, eds F Shenfield and C Sureau, Parthenon, New York and London.

- Ethics Committee of the American Society for Reproductive Medicine American Society for Reproductive Medicine, Birmingham, Alabama Cross-border reproductive care: a committee opinion, Fert and Ster 2013, Vol. 100, No. 3, p 645-650.
- FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health (2010): Cross border reproductive services, Int J of Gyn & Obs, 111(2):p 190-191.
- FIGO Committee for the Ethical Aspects of Human Reproduction and Women's Health (2008): Surrogacy, Int J of Gyn & Obs, 102 (3), p 312-313.
- HFE Act 2008, www.legislation.gov.uk/ukpga/2008/22/contents
- Mennesson v. France and Labassee v. France hudoc.echr.coe.int/webservices/content/pdf/003-4804617-5854908
- Pennings G et al on behalf of ESHRE Task Force on Ethics and Law 15 (2008): Cross-border reproductive care. Hum Reprod.
- Pennings et al (2014), Socio-demographic and fertility-related characteristics and motivations of oocyte donors in eleven European countries Hum Reprod.29, No.5 p. 1076-1089.
- Shenfield F and Steele SJ (1995). A gift is a gift is a gift, or why gametes donors should not be paid. Hum Reprod (10): 253–254.
- Shenfield F et al on behalf of ESHRE Task Force on Ethics and Law (2005), Surrogacy, Hum Reprod 20 (10):. 2705–2707.
- Shenfield F, de Mouzon J, Pennings G, Ferraretti AP, Andersen AN, de Wert G, et al (2010). Cross-Border Reproductive Care in Six European Countries. Hum Reprod. 25(6): 1361-1368.
- Shenfield F et al on behalf of the ESHRE Task Force "Cross Border Reproductive Care" (CBRC) (2011), ESHRE's good practice guide for cross-border reproductive care for centers and practitioners, Hum Reprod, 26 (7): 1625–1627.
- Shetty P, India's unregulated surrogacy industry, The Lancet, www.thelancet.com Vol 380 November 10, 2012, 1633-1634