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**The Italian perspective on cross-border assisted reproduction: law
no. 40/04 in action***

1) Introduction: definition and data

National prohibitions or restrictive regulations on ART or IVF procedures have sensibly contributed, in the last decade, to the increase of a phenomenon, known as cross-border reproductive care (CBRC)¹, that involves biologically or socially infertile patients, gametes' donors and potential surrogates, who «cross international borders in order to obtain or provide reproductive treatment outside their home country»².

Among the reasons for CBRC, law evasion is surely the most relevant: it has been estimated that, at the European level, around 55% of patients seeking reproductive assistance abroad are escaping national prohibitions³. Other motivations could be identified in the length of waiting lists for access to reproductive techniques;

* The article represents the fruit of joint reflections by the two authors. Nevertheless, paragraphs 1-5 have been written by *Lucia Busatta*, paragraphs 6-8 by *Simone Penasa*.

¹ *G. Pennings et al.*, “ESHRE Task Force on Ethics and Law 15: Cross-border reproductive care” (2008) 23(10) *Human Reproduction* 2182–2184. Even if the phenomenon is known also as “reproductive tourism”, the term cross-border reproductive care has to be preferred: “We will avoid the terms ‘reproductive’ or ‘procreative tourism’ because of their negative connotations and will use instead the neutral term ‘cross-border reproductive care’”.

² *A.P. Ferraretti et al.*, “Cross-border reproductive care: a phenomenon expressing the controversial aspects of reproductive technologies” (2010), 20(2) *Reproductive Biomedicine Online* 261–266; *V. Rozée Gomez, E. de La Rochebrochard*, ‘Cross-border reproductive care among French patients eligible for ART funding in France’ (2013) 28(11) *Human Reproduction* 3103, 3104.

³ *V. Rozée Gomez, E. de La Rochebrochard*, “Cross-border reproductive care among French patients eligible for ART funding in France”, cit., 3104; *F. Shenfield et al.*, “Cross border reproductive care in six European countries” (2010) 25(6) *Human Reproduction* 1361.

the shortage of gametes, due to a lack of donors or to the insufficient number of centres performing it; the sought for a better quality of care or of less costly treatments⁴.

People that cross national borders for reproductive care might considerably differ with regards to personal characteristics, especially on the grounds of age, marital status and sexual orientation. Even though it is not possible to completely describe the reality of CBRC, some studies have been conducted in Europe and elsewhere, with the purpose of discussing issues and data concerning this highly problematic phenomenon⁵.

With particular reference to the Italian legal framework, it has to be remarked that the restrictive approach of the law and its consequent legal uncertainties determined a significant flow of people who sought artificial reproduction abroad. Even if this has been reported not only by academic and medical studies⁶, but also by newspapers⁷ and dedicated website⁸, it is quite difficult to draw a complete map of CBRC involving Italian patients, because most of these are “hidden” stories⁹ and it is necessary to directly refer to foreign IVF centres¹⁰. Besides, it has to be added that, whereas within the European Union the counting of patients seeking reproductive care

⁴ As pointed out by Eshre Task Force (2008) 23(10) Human Reproduction, *cit.*, 2182: “The main causes of cross-border reproductive care are as follows: a type of treatment is forbidden by law (*i.e.* sex selection), certain categories of patients are not eligible for assisted reproduction (*i.e.* lesbian couples), the waiting lists are too long in one’s home country (*i.e.* oocyte donation), the out-of-pocket costs for the patients are too high (*i.e.* absence of insurance), a technique is not available because of lack of expertise or equipment (*i.e.* preimplantation genetic diagnosis), a treatment or technique is not considered safe enough (*i.e.* cytoplasm transfer) and personal wishes (*i.e.* privacy considerations)”. V. Rozée Gomez, E. de La Rochebrochard, ‘Cross-border reproductive care among French patients eligible for ART funding in France’, *cit.*, 3104; G. Pennings *et al.*, “Eshre Task Force on Ethics and Law 15”, *cit.*

⁵ See, F. Shenfield *et al.*, “Cross border reproductive care in six European countries”, *cit.*

⁶ A.P. Ferraretti *et al.*, “Cross-border reproductive care: a phenomenon expressing the controversial aspects of reproductive technologies”, *cit.*

⁷ E.g., V. Pini, Fecondazione eterologa, attesa per verdetto Consulta. “Fermare turismo procreativo”, in La Repubblica, 6.04.2014; Turismo procreativo. Dati e mete, in IlSole24ore, 10.04.2014; Desiderio di avere un figlio: boom del turismo procreativo degli italiani, in La Stampa, 18.10.2012.

⁸ E.g., Osservatorio Turismo procreativo, available at http://genitoriallester.altervista.org/?doing_wp_cron=1417454785 (last accessed 1.12.2014), Mappa: il turismo procreativo, edited by VOX – Osservatorio italiano sui diritti, <http://www.voxdiritti.it/?p=2749> (last accessed 1.12.2014).

⁹ See L.L. Parolin, M. Perrotta, ‘On the Fringe of Parenthood: Othering and Otherness in the Italian Assisted Kinship’ (2012) 1 (2) About Gender 101.

¹⁰ In general terms, this difficulty has been pointed out in a 2009 report conducted by ESHRE: Comparative analysis of medically assisted reproduction in the EU: regulation and technologies, available at <http://www.eshre.eu/~media/emagic%20files/Guidelines/MAR%20report.pdf> (last accessed 01.12.2014). For example, it does not always happen that all of these structures are equally precise in giving a response.

abroad might be quite accurate¹¹, the same does not necessarily happen for other non-EU countries, which often candidate as quite attractive destinations, due to law rates they could offer or to the possibility to enter surrogacy agreements (forbidden in Italy¹²).

A study conducted by *Osservatorio Turismo Procreativo* in 2010¹³ has confirmed the trends shown in the results of an international survey conducted in Europe¹⁴: for Italians, the most “popular” destinations for CBRC are Spain, Switzerland, the Check Republic, but also Austria, Belgium, Denmark, Greece and Hungary. More precisely the comparative study among EU countries highlights that Italian patients are those who travel at most in the EU for CBRC: “In total, 1230 forms were received by ESHRE Central office, from 46 clinics participating in the 6 treating countries: 29.7% from Belgium, 20.5% from the Czech Republic, 12.5% from Denmark, 16.3% from Switzerland, 15.7% from Spain, and 5.3% from Slovenia. In Denmark and Slovenia, all clinics collaborated, in Belgium 50% of clinics, whereas in the other countries, only a few self-selected centres participated. The forms concerned patients coming from 49 countries. However, four countries were particularly represented, with more than 100 forms returned to Central office each: Italy (31.8%), Germany (14.8%), the Netherlands (12.1%) and France (8.7%), followed by 3 countries returning more than 50 forms each: Norway (5.5%), the UK (4.3%) and Sweden (4.3%). The remaining 42 countries of origin represented less than 19% of the received forms”¹⁵.

Moreover, the Italian research conducted in 2012 reports that in 2011 at least 4000 couples travelled abroad to have access to IVF procedures; half of them were forced to do so in order to have access to IVF *via* gametes’ donation (which was forbidden by law nr. 40/2004 until the recent decision of the constitutional Court nr. 162/2014¹⁶), whereas the other half apparently went abroad to undergo treatments that could have been available in Italy, under the current legislative framework¹⁷.

¹¹ Especially thanks to a common set of legal requirements that proscribe to those centres the compliance to some safety and security measures, as well as to have a register of patients and to comply with personal and sensitive data archiving regulations.

¹² Surrogacy is prohibited by article 12, para. 6, law nr. 40/2004.

¹³ CECOS, Osservatorio Turismo Procreativo, Turismo procreativo: la fuga continua, anche senza indicazione medica, available at <http://genitoriallester.altervista.org/?p=70> (last accessed 1.12.2014). For some comments see C. Flamigni, A. Borini, *Fecondazione e(s)terologa*, Roma, 2012, p. 19.

¹⁴ F. Shenfield *et al.*, “Cross border reproductive care in six European countries”, cit.

¹⁵ F. Shenfield *et al.*, “Cross border reproductive care in six European countries”, cit., 1362.

¹⁶ The English translation of the decision is available on the website of the Italian Constitutional Court:

2) CBRC and the legal framework

The Italian legal framework is particularly interesting for the study of CBRC, for two interrelated reasons: the first one is that most individuals have been forced to travel abroad to become parents due to the prohibitions established by law; the second reason is that, during the first decade of legislative enforcement, several uncertainties on the legislative interpretation arose and the lack of complete information on the availability of these services is largely considered as one of the reasons for CBRC for Italians.

The law nr. 40/2004 has been framed by the Italian Parliament after a long legislative *iter*. The result of this path could not be defined as an inclusive law, not even as a law that acknowledges and guarantees the pluralism which is naturally enrooted into the Italian society and constitutional order. Conversely, the law is sprinkled with bans, prohibitions and criminal offences¹⁸; it provides for quite restrictive limits for access to these techniques¹⁹ and, as a result, it brought to several jurisdictional interventions, among which two major decisions of the Italian constitutional Court²⁰ and one by the European Court of Human Rights (ECtHR)²¹ profoundly affected the texting of the law.

After the entry into force of the law, at the beginning of 2004, it was immediately clear, especially to doctors involved in the realisation of the procreative desire of infertile couples, that the strict limits imposed by the law would have forced several couples and persons to seek MAR abroad. Just after a few years, this perception become a concrete certainty and, still nowadays, despite the substantial interventions of the constitutional Court, which has substantially removed some of the most problematic aspects of the law, a very high number of persons is still seeking reproductive care in another country.

http://www.cortecostituzionale.it/documenti/download/doc/recent_judgments/162-2014_en.pdf

¹⁷ CECOS, Osservatorio Turismo Procreativo, Turismo procreativo: la fuga continua, anche senza indicazione medica, cit. The report underlines that the reason for travelling for those couples who sought treatments which were also formally available in Italy has to be identified in the legal uncertainties that surround the legislative framework and in the lack of proper information.

¹⁸ Article 12, law nr. 40/2004, established several bans and provides for quite severe criminal and administrative sanctions for those who do not respect the prohibitions.

¹⁹ For a first critical glance on the limits of the law, see V. Fineschi, E. Turillazzi, 'Spunti di riflessione medico-legale sulle norme "etiche" in tema di procreazione medicalmente assistita' (2004) 1 Rivista Italiana Di Medicina Legale 75-90.

²⁰ Italian constitutional Court, decisions nn. 151/2009 and 162/2014, on which see *infra*.

²¹ European Court of Human Rights, *Costa and Pavan v. Italy*, appl. n. 54270/10, 28 August 2012, on which see *infra*.

The destination for these treatments is – as we have seen above – often a European country (especially Switzerland, Spain, the Czech Republic and Greece), but the average does not fully represent the entire phenomenon: for those who seek surrogacy, the main destinations are Ukraine or India²², due to the very permissive legislations of those countries and to very low prices of commercial surrogacy, which have also raised some ethical concerns among the scientific community²³.

In general terms, the reasons for CBRC could be summarised²⁴ as follows:

- Legislative bans and prohibitions;
- Subjective exclusion, in the case in which the national law provides access just for married couples, excludes singles or same sex couples or poses an age-limit for access to ART²⁵;
- Treatment efficacy is limited by the law²⁶;
- Unavailability of a treatment (lack of expertise, equipment, materials)²⁷;
- Limited availability of a treatment under experimentation;
- Length of waiting lists²⁸.

Hence, legislative bans are not the only reason that boost individuals, couples and patients to go abroad to have access to ART. With particular regard to the Italian framework, the above mentioned surveys and reports pointed out that about half of the couples who went abroad for ART in 2011 were not forced to do so by legislative bans.

3) Subjective limitations

²² As it is made evident by the recent decisions by Italian criminal Courts regarding false declaration made by couples who travelled abroad for surrogacy (*infra*).

²³ K. Schanbacher, 'India's Gestational Surrogacy Market: An Exploitation of Poor, Uneducated Women' (2014) 25(2) Hastings Women's Law Journal 201-220; R. Deonandan, A. Bente, "Assisted reproduction and cross-border maternal surrogacy regulations in selected nations" (2014) 4(1) British Journal of Medicine & Medical Research 225-236.

²⁴ This list of reasons for CBRC has been proposed by A.P. Ferraretti *et al.*, "Cross-border reproductive care: a phenomenon expressing the controversial aspects of reproductive technologies", *cit.*

²⁵ Article 5, law nr.40/2004.

²⁶ The Italian law, for example, prohibits the cryopreservation of embryos. For more references see A.P. Ferraretti *et al.*, "Cross-border reproductive care: a phenomenon expressing the controversial aspects of reproductive technologies", *cit.*

²⁷ This might be the case of donated oocytes, now that the ban on gametes' donation has been removed by the constitutional Court. See *infra*.

²⁸ This aspect might depend not only on the high number of MAR requests, but also on a shortage of gametes.

The identification of the reasons for CBRC is useful to develop an analysis of the Italian law, taking into account its limitations and the provisions that determined the flow of patients towards other countries.

Therefore, the analysis should depart from the consideration of subjects who are granted access to MAR techniques in Italy. Article 5 of the law indicates the subjective requirements for those who should be granted access to ART: eligible individuals should be heterosexual couples, either married or cohabiting, older than 18 and within the potentially fertile age. Neither the law nor the national guidelines, approved by the Health Ministry in 2008, specify the ultimate age limit for the woman who undergoes these treatments; the latter refers to preliminary medical exams that should be undertaken, in order to ascertain the possibility to procreate.

Some differences with regards to age limits might be observed at a regional level. Regions have, in fact, adopted guidelines that regulate access to ART at a territorial level and age limits have been differently regulated. In the Autonomous Province of Trento, for example, 43 years is the female maximum age to have access to IVF. Other Regions, conversely, decided not to set a precise age limit, opting for a case by case medical evaluation.

Moreover, the law (art. 5) excludes post-mortem fertilisation, establishing that both individuals should be living. With regards to this latter aspects, it should be pinpointed that the law does not provide for the case in which the male partner deceases between the moment of fertilisation and the one of implantation.

4) Medical requirements for ART and PGD

It should be remarked that the Italian Law on ART has been shaped as a statute exclusively addressed to the area of medicine. Since its very beginning (Art. 1), it immediately clarifies that its aim is to provide an instrument for the resolution of medical problems, i.e. procreative difficulties and sterility problems of the couple²⁹.

Article 4 of the law provides that access to ART should be possible just in the case of a medically ascertained infertility of the couple; moreover, MAR techniques should be “gradually” applied. The meaning of this wording raised, since the drafting of the law, some criticisms by practitioners. For example, some pointed out that the

²⁹ A. Gentilomo, A. Piga, “La procreazione tra natura e cultura. Alcune osservazioni sulla nuova legge in tema di procreazione medicalmente assistita” (2004) 1 *Rivista Italiana Di Medicina Legale* 41-74.

principle of gradualness does not make sense when infertility is already demonstrated by medical exams or when the couple is still potentially fertile, but very close to the maximum age limit. In these circumstances, it has been pointed out that the “gradual approach” may clash with the best medical practice³⁰.

Moreover, especially in the first years of legislative enforcement, this requirement determined the exclusion of those who wished to prevent the transmission of sexually communicable diseases or genetic illnesses. Nowadays, a remedy has been found without legislative change: on the one hand, thanks to the modification of national guidelines and, on the other hand, even though more problematically, through judicial interpretation.

As to sexually communicable diseases, the 2008 national guidelines specify that access to ART should be granted also to those couples in which the male partner is affected by HIV or hepatitis, because the prevention of the disease transmission determines the *de facto* infertility of the couple. For this reason, these (quite rare) cases are equalised to severe male infertility and therefore granted access to ART.

With regards to the prevention of genetic illnesses, a judicial intervention clarified the meaning and the interpretation of the law. In 2010, for the first time in Italy, the Salerno Tribunal stated that a married couple in which both partners were healthy carriers of spinal muscular atrophy should have access to ART, in order to prevent the transmission of the disease to the embryo.

To do so, the Tribunal had to reconsider the general *ratio* of the law and the amendments occurred in the meantime. In particular, pre-implantation genetic diagnosis was prohibited by the 2004 national guidelines, declared void by Lazio Administrative Tribunal, decision nr. 398/2008. As a consequence of the decision, the Health Ministry enacted the new guidelines, in which – as mentioned above – couples in which the male is affected by a sexually communicable disease are granted access to ART and in which it is stated that IVF centres should offer to couples a due psychological and medical support, considering the peculiarities of individual situations.

The Salerno Tribunal considered the new guidelines as a significant means to include among eligible subjects also those couples who are not *formally*, but *de facto*

³⁰ C. Flamigni, Appunti sulle tecniche di procreazione medicalmente assistita, in A. Santosuosso *et al.*, Le tecniche della biologia e gli arnesi del diritto, Pavia, 2003, 85-140.

infertile. The plaintiffs were actually satisfying this requirement, because of the high probability they had to conceive a baby affected by the genetic disease they were carrying, which leads to death in the very first years of life. To clarify the matter, the judge stressed that they previously had other “natural” pregnancies: in one case the child died after a few months, whereas another time they decided to undergo an abortion to avoid the same profound pain.

This same approach has more recently been confirmed by the ECtHR in the case of *Costa and Pavan v. Italy*³¹. In particular, the Strasbourg Court affirmed that the right to have access to ART in order to satisfy the desire to become genetic parents is guaranteed by the right to respect for private and family life: “The Court cannot but note that the Italian legislation lacks consistency in this area. On the one hand it bans implantation limited to those embryos unaffected by the disease of which the applicants are healthy carriers, while on the other hand it allows the applicants to abort a foetus affected by the disease. The consequences of such legislation for the right to respect for the applicants’ private and family life are self-evident. In order to protect their right to have a child unaffected by the disease of which they are healthy carriers, the only possibility available to them is to start a pregnancy by natural means and then terminate it if the prenatal test shows that the foetus is unhealthy” (paras. 57-58).

Moreover, the Court observed also that the Italian legal system lacks of consistency with regards to the regulation of beginning of life issues: «Having regard to the above-described inconsistency in Italian legislation on PGD, the Court considers that the interference with the applicants’ right to respect for their private and family life was disproportionate» (para. 64). For this reasons, the impossibility to have access to PGD when one or both partners are carriers of a genetic illness violates Article. 8 of the Convention.

Unfortunately, notwithstanding these two important judicial decisions, a correct information on the possibility to have access to these techniques did not quickly spread around potential addressees: actually, the report issued in 2012 by *Osservatorio Turismo Procreativo* (see above) confirms that some couples still go abroad for PGD, also because the test is not available everywhere in public MAR centres.

³¹ *Costa and Pavan v. Italy*, appl. n. 54270/10, 28 August 2012.

Furthermore, the Tribunal of Cagliari, applying the principles established in *Costa and Pavan*, obligated a MAR centre to perform the test and to implant just healthy embryos. In the concrete case, both partners were healthy carriers of thalassemia, were not admitted to IVF procedures with PGD and they were therefore forced to file a petition to have their right acknowledged and granted³².

More recently, in January 2014, the Tribunal of Rome referred to the constitutional Court article 4 of law nr. 40/2004 in the part in which it does not provide for a right to access to ART and PGD for those couples in which one or both partners are carriers of a genetic transmissible disease. The issue has still to be decided by the constitutional Court, but it could be argued that the principles established in *Costa and Pavan* will find application for a final definition of this highly controversial aspect.

5) Patients' rights in CBRC

The EU has recently intervened in the field of health, with the directive on patients' rights in cross-border healthcare³³. This act clarifies under which conditions a patient can get a medical treatment in a member State different from the one of residence and, once back, be refunded of medical expenses by the home healthcare institution. It is also aimed at guaranteeing the safety, quality and efficiency of care for cross-border patients and at promoting cooperation between member States on healthcare matters.

The drafting of the directive was particularly long, considering that the first draft was presented in 2008 and that its final approval arrived in March 2011. One of the reasons for this long legislative path has to be identified in the fear by some member States regarding the emerging of an obligation to reimburse also treatments prohibited within the national territory. For this reason, a provision was introduced to clarify that the state obligation to reimburse medical expenses for services undergone abroad is limited just to those treatments already included among those granted on the national territory³⁴. It is not just a matter of sustainability of healthcare services:

³² Tribunal of Cagliari, decision of 9 November 2012, in www.biodiritto.org

³³ Directive 2011/24/EU of the European Parliament and of the Council of 9 March 2011 on the application of patients' rights in cross-border healthcare.

³⁴ "An amendment was introduced to make it clear that the directive does not imply that member states would have to reimburse "ethically controversial medical 'service' like euthanasia, DNA-testing or IVF" when the relevant service is not allowed, or at least not financed, in the relevant member state. In fact, this abuse would be prevented by the general rule that the obligation to reimburse costs of cross-

member States were (and still are) quite concerned about the EU intervention in the field of health and in the space of their legislative autonomy to decide on ethically sensitive issues, such as abortion or MAR³⁵.

The directive's harmonising purpose entails several interventions to be taken at a state level, that are intended to pursue the EU obligation and grant legal certainty for patients travelling in the EU for health reasons. Unfortunately, for reimbursement eligibility, it is necessary that the medical treatment undergone abroad is already included among the services provided by the home healthcare institution³⁶.

Nevertheless, beyond reimbursability requirements, it should be pointed out that the directive poses some important targets on member States regarding the raising of healthcare standards at a national level. To this end, for example, European reference networks are going to be created in order to strengthen connections between centres of excellence for the treatment of specific illnesses or of rare diseases³⁷.

For the purposes of the present analysis, it seems that some of the principles established in the directive might be of help also for the development of a European understanding of CBRC and of the sets of rights connected to it. More specifically, the directive boosts the creation of professional and medical networks concerning health treatments, which are aimed at increasing the standards of healthcare in Europe and at improving conditions and practises for healthcare delivery in each member State. In this context, also MAR technologies are included within the number of treatments whose standards might be enhanced, even if conditions and requirements sensibly differ among member States.

The achievement of a high level of quality and safety of treatments for patients are of seminal importance for those individuals who travel for medical care, regardless of their social and economic conditions or sexual orientation. Because they

border healthcare should be limited to healthcare to which the insured person is entitled according to the legislation of the member state affiliation". *W. Van Hoof, G. Pennings*, "Extraterritoriality for cross-border reproductive care: should states act against citizens travelling abroad for illegal infertility treatment?" (2012) 19(2) *European Journal Of Health Law* 187-200, 191.

³⁵ This profile is indeed taken into consideration in the text of the directive. See, among introductory acknowledgements, n. 7: "This Directive respects and is without prejudice to the freedom of each Member State to decide what type of healthcare it considers appropriate. No provision of this Directive should be interpreted in such a way as to undermine the fundamental ethical choices of Member States".

³⁶ See acknowledgement nr. 33: "This Directive does not aim to create an entitlement to reimbursement of the costs of healthcare provided in another Member State, if such healthcare is not among the benefits provided for by the legislation of the Member State of affiliation of the insured person".

³⁷ Article 6 on national contact point and article 12 on European reference networks.

are far away from their place of living, main interlocutors and human connections and also because they might have some information or communication deficits in accessing treatments abroad, they deserve a system of guarantees of health and safety standards that should be put in place also to avoid health damages, undue exploitation or illegitimate practises.

For these reasons, it could be argued that the directive's principles could find application even in the field of access to cross-border MAR, with specific regard to availability of information for patients and guarantee of quality standards, even if reimbursement procedures for CBRC might not be fully included, due to the profound differences that characterise national legislations in this field. As we have already mentioned, the spectrum of application of the directive does not completely concern ART, because the basic requirement for the application of its provisions concerns a "reciprocity standard" between the home state and the state in which the patient is undergoing the medical treatment in question. Being EU law so heterogeneous with regards to ART regulation, it means that for EU citizens moving from one member State to another for IVF requires a deep scrutiny of both the national legislation concerning ART and the requisites to access it.

Beyond the "reciprocity requirement", whereby a patient can obtain the reimbursement of medical expenses for treatments received abroad just in the case in which the same treatment is included among those provided by the home state, CBRC could hardly fall within the directive's provision for reasons of health coverage. In each country there are different provisions regarding the reimbursement or healthcare coverage of the costs of IVF practises³⁸.

Nevertheless, some aspects of the directive should be taken into consideration to clarify patients' rights in CBRC, especially with regards to the guarantee of an equal flow of information regarding reproductive services in the EU and with reference to the respect of safety standards by IVF centres in member States.

6) The constitutional debate on assisted reproduction via gametes' donation

³⁸ See *A.P. Ferraretti et al.*, 'Cross-border reproductive care: a phenomenon expressing the controversial aspects of reproductive technologies', cit., 263.

As mentioned early, the entry into force of the Italian Law 40/2004 provoked two groups of cases: a) those in which the phenomenon of CBRC derives from an explicit prohibition: surrogacy; gametes' donation; same-sex couples; b) those in which CBRC derives from uncertainty related with the concrete scope of the law: PGD and other techniques allowed by the Italian Law (see above).

Within the first group, gametes' donation and surrogacy represent the most relevant cases, in terms of both number of Italian couples accessing MAR services abroad and impact on the legal and constitutional dimension.

Focusing on **gametes' donation**, Article 4 of the Law originally introduced an absolute ban, by stating that access to "heterologous" ART is forbidden. It inevitably provoked a flow of couples that needed gametes' donation to bypass a condition of infertility, as the Law did not provide for any exception to the prohibition. At the same time, the very strict nature of the ban did not allow judges to find an interpretation flexible enough as to open this chance at least to those couples for which gametes' donation is the last resource for their reproductive project (ie. absolute infertility of the man). For these couples, CBRC represented, according to this legal framework, the only way to pursue a reproductive project. It must also be noted that the Law, in order to further strengthening the prohibition, provides for a fine between 300.000 and 600.000 euro for anyone who uses third parties' gametes for reproductive purposes (art. 12, first paragraph³⁹).

In general terms, it should be stressed that the ECtHR (Grand Chamber) in *S.H. and Others v. Austria* (3rd, November 2011) seems to consider reproductive tourism as a physiological phenomenon within the international legal framework. The Court, referring to the Austrian legal framework, states that "there is no prohibition under Austrian law on going abroad to seek treatment of infertility that uses artificial procreation techniques not allowed in Austria and that in the event of a successful treatment the Civil Code contains clear rules on paternity and maternity that respect the wishes of the parents». The Court declares the compatibility of the Austrian Law with art. 8 ECHR also on this ground: the fact that Austrian couples can freely go abroad in order to have access to gametes' donation is an element that «shows rather

³⁹ On the criminal effects of the ban and its compatibility with the constitutional dimension, see *E. Dolcini*, "La procreazione medicalmente assistita: profili penalistici", in *S. Canestrari, G. Ferrando, C.M. Mazzoni, S. Rodotà, P. Zatti*, *Il governo del corpo*, v. II, 1555-1560.

the careful and cautious approach adopted by the Austrian legislature in seeking to reconcile social realities with its approach of principle in this field” (para. 114⁴⁰).

According to the Italian Law, the effects of the violation of the prohibition provided for by Article 4.3 are extensively regulated by Article 9. The legal relationship between a child born via gametes’ donation must be recognised as the son of the husband/partner of the woman; accordingly, the donor does not have any legal relationship with the child, and he/she does not have any right/duty towards him.

The Italian Constitutional Court (decision n. 162/2014⁴¹) has recently declared the incompatibility of the prohibition (Articles. 4.3; 9.1 and 3; 12.1) with the Constitution, referring to Articles 2 (human rights protection), 3 (equality principle and reasonableness) and 32 (right to health). According to the Constitutional Court, “the decision to have or not to have a son, even for a couple affected by an absolute infertility, is expression of the most inner and intangible sphere of the human person, and therefore it must be incoercible, when it does not violate other constitutional values, even when the decision is exercised through the choice to have access to gametes’ donation, as it belongs to this sphere too”.

In the decision, the Constitutional Court states that the prohibition lacks of an adequate constitutional ground, as its absolute nature is unreasonable and disproportionate when compared with the purposes of the Law 40 (Art. 1). The prohibition is not related to any international obligation, as its suppression does not clash with the principles declared by the Oviedo Convention (para. 5). It is the absolute scope of the prohibition that is considered unconstitutional. It violates at least two constitutional rights: on the one hand, “the decision of the couple to become parents and to found a family composed also by children”, intended as “an expression of the fundamental and general freedom of self-determination” guaranteed by Articles 2, 3 and 31 of the Italian Constitution; on the other hand, the right to

⁴⁰ P. Hanafin, ‘Rights, bioconstitutionalism and the politics of reproductive citizenship in Italy’ (2013) 17(8) Citizenship Studies 942-955, 950, focuses on this issue. See, critically, W. van Hoof, G. Pennings, “Extraterritorial Laws for Cross-Border Reproductive Care: The Issue of Legal Diversity”, cit., 191.

⁴¹ See G. Benagiano et al., “Italian Constitutional Court removes the prohibition on gamete donation in Italy” 29(6) Reproductive Biomedicine Online, 662-664. See also, in Italian, A. Morrone, “Ubi scientia ibi iura”; G. Sorrenti, “Gli effetti del garantismo competitivo: come il sindacato di legittimità costituzionale è tornato al suo giudice naturale (a margine di Corte cost., sent. n. 162/2014)”, both in Consulta Online (www.giurcost.org); V. Tigano, “La dichiarazione di illegittimità costituzionale del divieto di fecondazione eterologa: i nuovi confini del diritto a procreare in un contesto di perdurante garantismo per i futuri interessi del nascituro”, in www.penalcontemporaneo.it

health, which encompasses not only the physical, but also the psychological dimension.

The Court considers that the only counter-interest, which can reasonably limit the access to gametes' donation to couples affected by an absolute infertility, is the one of the child born from these techniques (para. 10). According to the Court, the legal framework deriving from the declaration of unconstitutionality can be interpreted as to adequately guarantee the child born from gametes' donation: the decision of the Court does not produce any legal vacuum, as a set of rules already regulates the essential issues of the case. The Italian law-maker, being aware that gametes' donation is allowed in many European countries, decided to adequately regulate the effects – especially with regards to the legal relationships among the subjects involved– which can derive from reproductive tourism. According to the Court, Italian citizens can go abroad in order to have access to techniques prohibited within the Italian legal framework, as it happened in a very high number of cases (para. 11).

The Court directly focuses on the impact of reproductive tourism on the effectiveness of access to ART for absolutely infertile couples, in terms of equality and reasonableness⁴². Its approach is different from the ECtHR's one. On the one hand, it recognises that the regulation of the effects of gametes' donation delivered abroad is correctly motivated by the need to protect the child; but, on the other hand, the Court outlines that this approach reveals a further reason of irrationality of the prohibition. The law, as it was originally drafted, determines an unjustified differentiation among couples affected by the worse pathology (absolute infertility), on the grounds of their financial capacity. The latter, according to the Court, becomes an intolerable prerequisite for the effective exercise of a fundamental right, which is denied exclusively to those couples lacking financial means to go abroad. Interestingly enough, the Court states this outcome is not due to factual reasons, but it is a direct effect of the legal prohibition, which is based on an unreasonable balancing among the interests at stake.

Therefore, the prohibition, although aiming at protecting a constitutional value (the interest of the child), does not provide for the less possible limitation of the

⁴² See A. Ruggieri, "La Consulta apre alla eterologa ma chiude, dopo averlo preannunciato, al "dialogo" con la Corte EDU (a prima lettura di Corte cost. n. 162 del 2014)" in www.forumcostituzionale.it (2014), 3.

competing interests involved (rights of the couple; right to health; right to found a family) and it provokes an evident and irreversible violation of such rights.

Therefore, after this decision, Law 40 allows gametes' donation for all couples affected by absolute and irreversible infertility. The decision immediately raised a huge political and social debate, concerning admissibility issues, conditions and requirements for gametes' donation in Italy, in absence of an explicit legislative intervention. As Constitutional Court's decisions are immediately enforceable and the declaration of unconstitutionality does not open any gap within the legal framework, the effects of the decision have been promptly enforced by ordinary judges.

The Tribunal of Bologna (14th, August, 2014), on the ground of the Constitutional Court's decision, allowed a couple to have access to MAR through gametes' donation by a male donor, recognising that the technique, once the prohibition has been declared unconstitutional, becomes lawful. Accordingly, the Tribunal ordered the defendant to provide for the service required by the couple, according to the best medical practice.

Given the inactivity of the Italian Government in updating the Guidelines required by Law 40 in order to adapt the regulation to the new framework, the Regions and the Autonomous Provinces signed an Agreement, to regulate practical issues related with gametes' donation, in order to guarantee a uniform and effective access to this technique on the whole national territory. One of the most relevant aspect of the Agreement is the demand for the inclusion of gametes' donation within the "essential levels of assistance", the list of basic health coverage services adopted in 2001 by the Government, the renewal of which is currently underway.

It is still unclear whether, when and how all of these changes are having an impact on CBRC, as the effective implementation of the new asset at present is facing many difficulties in terms of both resources⁴³ and institutional coordination⁴⁴.

7) Surrogacy agreement under the current legal framework

⁴³ On the one hand, CBRC with gametes' donation will become reimbursable, under the EU framework; on the other hand, ART centres will have to buy (female) gametes abroad, due to their unavailability on the national territory.

⁴⁴ *G. Benagiano et al.*, Italian Constitutional Court removes the prohibition on gamete donation in Italy, *cit.*, 663, underline that "new Italian regulations must overcome a number of technical barriers before clinics can routinely offer gamete donation treatments".

Another relevant case of CBRC is represented by surrogacy agreements. Italian Law, together with many other European legal systems, prohibits any surrogacy agreement and punishes the violation of the ban with a detention up to two years of reclusion and a fine between 600.000 and 1.000.000 euro.

Although there is no evidence of the application of the criminal sanction, its effects have been twofold: to increase the phenomenon of CBRC and to create a relevant case-law related both to the definition of parenthood with regard to children born as a consequence of surrogacy (civil dimension) and of the couple's legal responsibility for the (criminal dimension).

Criminal dimension: A plurality of cases regarding the couple's criminal responsibility as a consequence of surrogacy agreements

One of the indirect consequences that Italian couples must face when deciding to travel abroad for surrogacy agreements is the possible responsibility for declaring – once back in Italy – to the Italian authorities competent for the civil status, to be the legal parents of the child.

In the last two years, many Tribunals have decided on the criminal responsibility of Italian couples charged for having declared the existence of a parenthood relationship with a child born abroad from a surrogate mother (*alterazione di stato*). In these cases, the crime is not directly established by Law 40, but it is an indirect consequence of the absolute ban on surrogacy. Even though the case-law is partially diverging, several similarities emerge: access to surrogacy combined with gametes' donation: judges diverge on the interpretation of the foreign (Ukrainian) legal framework.

On the one hand (Tribunal of Milano and Trieste, 2013), the declaration of parenthood made by the Italian couples before Italian authorities⁴⁵ was considered consistent with the applicable law – the Ukrainian one, according to the principles of international private law –; on the other hand (Tribunal of Brescia, 2013⁴⁶), the court gives a different interpretation, acknowledging the couple's responsibility for false declarations related to parenthood, on the grounds of the primary public policy

⁴⁵ See *T. Trinchera*, "Alterazione di stato e maternità surrogata all'estero: una pronuncia assolutoria del Tribunale di Milano", in www.penalecontemporaneo.it (2014)

⁴⁶ See *P. Frati et al.*, "Surrogate motherhood: Where Italy is now and where Europe is going. Can the genetic mother be considered the legal mother?" (2015) 30 *Journal Of Forensic And Legal Medicine* 4-8.

because the legal *status* of the new-born corresponds to a biological link. From this perspective, the concrete means of the procreation is decisive in order to recognise the parenthood relationship between the infertile couple and the new-born children. At the same time, the Tribunal – with regard to the relationship of parenthood between the male member of the couple, that provided his own gametes in the MAR process – does not deny the legal parenthood, as a consequence of the crime of “*alterazione di stato*”, leaving only the female member of the couple without any legal (and biological) link with the new-born children.

Civil dimension: The definition of legal parenthood following a surrogacy agreement performed abroad

Recent case-law provides for very different solution and interpretation: the Supreme Court recently denied the recognition of parenthood and the Tribunal of Varese, on the ground of the ECtHR case-law (*Mennesson v France*), has chosen a very different approach⁴⁷. According to the Tribunal, diverging from the Court of cassation’s interpretation of the scope and meaning of the principle of the best interest of the child, declared the lack of criminal responsibility of the couple, that consciously declared a biological link between the woman and new-born children (surrogacy agreement in Ukraine), and stated that the right of the children to have a sure parenthood relationship must prevail on the traditional rules provided by the Italian legal system in the context of the definition of legal parenthood. Interestingly enough, on the one hand, the *Cassazione* does not directly enforce the ECtHR case-law, giving its own interpretation of the concrete case; on the other hand, the Tribunal of Varese directly applies the ECtHR case-law, in order to bypass the Italian legislation in the context of legal parenthood.

The analysis of the two reasoning clearly shows a different approach to both the interpretation of the best interest of the child and the role of ECtHR case-law.

On the one hand, the *Corte di Cassazione* (Civil section, n. 24001/2014), after having preliminary declared the surrogacy agreement void according to the relevant national law (Ukraine) as both gametes were donated, states that the parenthood declaration made by the Italian couple was invalid too. The declaration is contrary to the public order, intended as shared fundamental national values, within which it must be intended also the prohibition of any surrogacy agreement, to

⁴⁷ The case is available at http://www.biodiritto.org/index.php/item/579-surrogata_varese14.

guarantee both the principle of human dignity of the woman and the legal institution of adoption. Interestingly, the Court clearly states that the decision not to recognise any legal relationship between the couple and the child does not violate the latter's best interest: according to the Court, "the legislature considered, not unreasonably, that the interest of the child is guaranteed by attributing motherhood to the woman giving birth to the child. Furthermore, adoption is the means selected by the legislature, instead of the mere agreement between private parties, to realise parenthood separated with any biological link".

The *Cassazione* goes to dismiss also the reference to the ECtHR case-law, differently from the approach of the Tribunal of Varese. According to the Court, the ECtHR – in the case *Mennesson v. France* – recognised, on the one hand, the statebroad margin of appreciation; and, on the other hand, the concrete case was different, as one of the men was the biological father of the child born *via* surrogacy agreement.

On the other, the Tribunal of Varese does not recognise any criminal responsibility for an Italian couple, in the light of guaranteeing the certainty of the legal *status* of the children born *via* surrogacy. Their interest, especially when one of the members of the couple is the biological parent, must prevail on the competing public interest to detect false declarations on legal parenthood. The children's best interest is performed by guaranteeing them a stable legal status, which is at the same time coherent with the social situation between them and the couple. The goal to pursue the children's best interest allows judges to overcome the possible violation of the duty not to declare a false parenthood status, in line with the recent ECtHR case-law stating that the way of conception is not relevant for the recognition of parenthood. The plain denial of parenthood, due to the presence of a surrogacy agreement, will consist in an intolerable violation of the identity of the children, according to the Tribunal, in a way consistent with the ECtHR in the case *Mennesson v. France* (2014⁴⁸). By directly enforcing the ECtHR case-law, the Tribunal recognises the prevalence of the social link on the biological one, in the light of guaranteeing the best interest of the children and their right to identity.

⁴⁸ See *T. Trincherà*, "Maternità surrogata all'estero e responsabilità penale: il dibattito prosegue con una sentenza del Tribunale di Varese che si adegua ai principi espressi dalla Corte EDU e assolve gli imputati", in www.penalecontemporaneo.it (2014)

On the 27th of January, 2015, the ECtHR ruled a case in which the two dimensions – the criminal and civil ones – are interlinked. In a case involving an Italian couple that signed a surrogacy contract in Russia, the Italian public authorities considered that the agreement was in breach of the public order, finding that the applicants had attempted to circumvent the national prohibition on surrogacy arrangements and the rules governing international adoptions. The child, indeed, was removed from the couple, that was charged with “misrepresentation of civil status” and violation of the adoption legislation. According to the ECtHR, the Italian authorities breached art. 8 of the Convention, as they did not strike a fair balance, by taking away from the original family the child for having violated Italian law and public order, without giving any relevance to the best interest of the child to stay with them, even if there was not any biological link between him and the couple⁴⁹. It must be underlined that, the Court found a violation of Article 8 on account of the child’s removal and his placement under guardianship. Therefore, the decision does not refer to the compatibility of the Italian rules on surrogacy with the ECHR.

8) Final remarks

CBRC represents a physiological dimension of health care delivery, based on the patients’ freedom of movement and on the principle of free choice of medical treatments. As the recent EU Directive distinctly shows, the need to clearly regulate this phenomenon and to foster legal certainty for these situations has recently strongly emerged.

But it is also unquestionable that specific medical issues, such as MAR, are particularly relevant and questionable. In this field, the highly sensitive nature of the legal and ethical values involved goes to inevitably increase the differences between national legal systems, as recognised also by the ECtHR. The flow of patients raises, together with the level of legal and social criticism and threat. When a regulation, such as the Italian one, is characterised for a very rigid and strict normative framework, based on prohibitions and sanctions, the phenomenon inevitably increases.

The judiciary can only limit the effects of a rigid legislative framework, but it cannot completely solve them: as statistics seem to show, CBRC of Italian couples is

⁴⁹ For a description of the case, see the Press Release of the ECtHR; see also *Gestazione per altri*, la Corte di Strasburgo condanna l’Italia, in www.articolo29.it (2015)

continuing even after the “rewriting”⁵⁰ of Law 40 realised by both ordinary judges and the Constitutional Court⁵¹. Moreover, some treatments, such as PGD and gametes’ donation, are very difficult to be accessed (see Tribunal of Cagliari e Roma, 2014), due to organisational, technical and allocative difficulties (many public hospitals are simply unable to perform and guarantee such services). Furthermore, there is still a certain degree of uncertainty (among patients and practitioners) regarding the rules effectively in force within the Italian legal framework: Italy is still a civil law system, and the role of judiciary – together with the effects of its decisions – cannot overcome and substitute the one of legislature. This leads to uncertainty, of both the legal system and the effective scope of protection of the rights of involved individuals.

From a more general perspective, the Italian case shows that the role of judiciary becomes essential, in order to adapt the legal framework to the changing reality, even when the interpretation provided by judges risks to be excessively far from the letter of the law, with the goal to restore coherence, reasonableness and legitimacy of legislative choices⁵². At the same time, the legislative framework constantly “suffers” for the permanent pressure provoked by both the international and supranational legal frameworks (*i.e.* ECtHR case-law) and the development of social phenomena (*i.e.* CBRC and scientific progress).

⁵⁰ See *G. Ferrando*, “La riscrittura costituzionale e giurisprudenziale della legge sulla procreazione assistita”, (2011) 5 *FAMIGLIA E DIRITTO* 517-524, 520; *E. Dolcini*, “La lunga marcia della fecondazione assistita. La legge 40/2004 tra Corte costituzionale, Corte EDU e giudice ordinario” (2011) 2 *Rivista italiana di diritto e procedura penale* 428-457, 428.

⁵¹ On the role of patients in this process, see *P. Hanafin*, “Rights, bioconstitutionalism and the politics of reproductive citizenship in Italy”, *cit.*, 942, that refers to “active “biological citizenship” on the part of those affected by the legislation’s prohibitions”.

⁵² See *C. Tripodina*, “Sul come scansare la briglia delle leggi. Ovvero, la legge sulla procreazione assistita secondo il giudice di Salerno”, in www.costituzionalismo.it (2011); *I. Pellizzone*, “Fecondazione assistita e interpretazione conforme a costituzione. Quando il fine non giustifica i mezzi” (2008) 1 *Giurisprudenza Costituzionale* 552-564, 552.