

ESHRE's good practice guide for cross-border reproductive care for centers and practitioners[†]

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ABSTRACT: This paper outlines ESHRE's guidance for centers and physicians providing fertility treatment to foreign patients. This guide aims to ensure high-quality and safe assisted reproduction treatment, taking into account the patients, their future child and the interests of third-party collaborators such as gametes donors and surrogates. This is achieved by including considerations of equity, safety, efficiency, effectiveness (including evidence-based care), timeliness and patient centeredness.

Key words: cross-border reproductive care (CBRC) / equity / patient centeredness / safety / welfare of the child(ren)

Introduction and background

Cross-border reproductive care (CBRC) refers to a widespread phenomenon where infertile patients or collaborators (such as egg donors or potential surrogates) cross international borders in order to obtain or provide reproductive treatment outside their home country.

The reasons for traveling vary between countries, but the most common reason is law evasion when the technique is either forbidden *per se* or when a particular group is excluded from treatment. There may be other access limitations at home such as long waiting lists. Other reasons for travelling are better quality of care and cheaper treatment (Pennings *et al.*, 2008a; Shenfield *et al.*, 2010).

The ideal is fair access to fertility treatment at home for all patients. This ideal should be promoted at all levels (Pennings *et al.*, 2008b). However, when for some reason, treatment at home is not possible or not available, CBRC is a solution that enhances patient's autonomy. Furthermore, it fits with the principle of freedom of movement of patients within Europe (EU proposal directive, 2008).

This Good Practice Guide (GPG) provides guidance for centers and physicians treating foreign patients. The guidelines included here can help regulators and policy-makers create a framework to enable centers to abide by these rules. Although in principle, the care of foreign and local patients should be the same, and fit the best possible standards, there is evidence that this is not always the case.

The aim is to ensure high-quality assisted reproduction treatment, as defined by the European Union criteria for good quality medical treatment (European Union Council, 2006), and the ESHRE position paper on Good Clinical Treatment in Assisted Reproduction (ESHRE, 2008, www.eshre.eu).

This GPG focuses on the relevant principles for respectively patients, donors, future children, surrogates and professionals. The operational principles to be considered include equity, safety, efficiency, effectiveness (including evidence-based care), timeliness and patient centeredness. These principles are all equally important and have no fixed order of priority.

I. Equity in CBRC

I.1 Patients

Equity implies that similar protocols and fees are applied and that the same information, counseling and psychological support is provided for foreign as for national patients. Any difference between local and foreign patients should be justified—for instance, the extra cost for interpreters.

Crossing borders may also lead to increased shortage of scarce resources in the visited country to the detriment of local citizens. Clinics may want to introduce a system for fair allocation of scarce resources that takes into account the local needs such as a

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maximum number (or percentage) of treatments provided to foreign patients.

1.2 Donors

Donors should receive similar care to patients and local donors. No distinctions should be introduced based on their origin and/or motivation. National and foreign donors should be offered comparable compensation and the recruitment criteria should be the same.

2. Quality, safety and evidence-based care in cross border treatment

2.1 Patients

Quality, safety and evidence-based care provision should lead to minimal risks with a maximum chance of pregnancy. Patients should receive clear information about necessary investigations and their cost, about waiting list times and the expected time they will have to spend outside their country. Quality also implies that patients are not subjected to unnecessary procedures. Communication and collaboration between the clinical team in the home country and the team abroad should minimize the need for repeat tests, which are both expensive and cumbersome for the patients.

The provision of the accurate success rate of the center is important to enable patients to decide on a treatment plan. Furthermore, patients should be informed whether the treatment offered is (ideally) evidence-based, current practice or following an 'experimental protocol'. In the latter case, equity demands that foreign patients are given the same benefits and submitted to the same rules as local patients: if they are offered treatment which is still research for instance, the consent and cost should be the same as for local patients.

In the case of gamete donation, it is essential to follow the recommendations of the EU tissues directive, with special regard to the screening process and the non-commercialization conditions.

In some cases, deviations from standard management may be appropriate (e.g. conversion from IUI to IVF during treatment cycle; use of techniques such as ICSI or blastocyst transfer). However, aggressive treatment that may endanger the woman's health by, for instance, disproportionate stimulation and deviations from the rules for embryo transfer are not justified (ESHRE good clinical practice).

Treatment options may also differ from local patients (stimulation from mild to standard) according to whether patients are returning. The ability to cryopreserve oocytes and embryos is an important consideration which should be discussed beforehand. Also a possible transfer of the gametes or embryos to a clinic at home has to be considered.

2.2 Donors

It is essential to propose a stimulation cycle that minimizes the health risk for the oocyte donors. Reliable data regarding risks are scarce, especially in the case of repeated donation. Donors may present themselves several times at the same center or at different centers. In order to obtain information on repeated donations and to be able to verify legal restrictions on donations, it is essential firstly to

establish national registers of gametes donors, and secondly for centers to participate in the collection of national or international data.

In order to prevent the abuse of donors coming from abroad, one should avoid using intermediate agencies, which may lead to violations of the rules of good clinical practice and, in the worst case, to trafficking. Post-donation care should be provided to the best possible standards at home or abroad.

Screening for sexually transmitted disease and genetic disease should be similar to national patients ([application of the EU Tissue directive](#)).

2.3 Surrogacy

Single embryo transfer is the only acceptable option. Continuity of care during pregnancy and childbirth must be planned prior to starting the surrogacy cycle.

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. The intended parents should try to obtain accurate information about their own national situation before embarking on the process. Known legal problems or possible conflicts with the law in the home country should be explained to the patients.

2.4 Children

Treatment should abide by the rules of 'good clinical treatment in ART' (ESHRE, 2008, www.eshre.eu). These rules state that 'the decline in the number of multiple births can be regulated only with a reduction of the number of embryos transferred. This restrictive embryo transfer policy could be accepted as the only means of eliminating high order multiple gestations'. Indeed, in spite of the mounting evidence that repeated single embryo transfer gives the same accumulated chance of pregnancy as multiple embryo transfer, many couples find it difficult to accept. Travelling couples may be even more reluctant to accept that because of the extra cost and stress of travelling several times. This endangers the welfare of the future child(ren).

Foreign patients should have the same stimulation protocol as local patients, taking into account age and previous stimulations. When donor oocytes are used, embryo transfer must be limited to two embryos.

Follow up of ART children, whether conceived after treatment at home or abroad, should be encouraged.

2.5 Professionals

Collaboration between doctors: If a home practitioner refers the patient to a specific clinic, the practitioner shares a responsibility for the general standards used in that center (such as the complication rate). The specific treatment of the individual patient abroad remains the responsibility of the local professional team.

Collaboration between the home practitioner and the receiving center offers the best chance of optimal care for the cross border patient. The only countries where this may pose a problem is where it is forbidden for doctors to give information about alternatives that are not legal in the country of residence of the patient.

Good communication in both directions includes details of previous investigations and treatment (stimulation dose, response, etc.). Patients should be given copies of their medical files both by the home practitioners when they go abroad and by the practitioners abroad when they return home.

3. Patient involvement

Professionals should take into consideration the specific circumstances of foreign patients by adapting their practical management. It may be difficult to ensure that patients understand enough to give appropriate consent. This may be particularly difficult when there is no common language. Given the number of nationalities of the foreign patients, it is impossible to have translators in all possible languages. This notwithstanding, counseling and psychological support should be available in a language understood by the patients. If a reasonable understanding cannot be guaranteed, it is recommended not to treat the patient.

Due to the extra pressure on foreign patients, there is an increased risk of ill-considered decisions. For instance, a rapid shift to third party conception in case of failed fertilization, or the acceptance of double rather than single embryo transfer. In all instances, however, we recommend that treatment offered is compatible with ESHRE 'good clinical treatment' position paper's recommendations.

Doctors in receiving centers should ask patients to obtain the relevant details of their previous investigations and care, especially when there is no possibility of direct exchange of information between the doctors.

Similarly, professionals abroad should provide the appropriate relevant information to the patients returning home in order to optimize their care at home.

4. Redress

The clinic should provide the name of their ombudsman or the person to whom complaints should be addressed.

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