Rules and regulations in reproductive medicine: sensible requirements that should start with evidence

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Introduction

Over the last decade, reproductive medicine in Western countries has seen a vast increase in rules and regulations, promoting or mandating the responsible application of available medical technologies. These regulations are meant to improve the quality and safety of the provided services and, in the case of the European Union (EU), to bring about harmonization over national borders (Pennings, 2004; Tatarenko, 2006; Johnson and Petersen, 2008). The issues considered relate to ethical, organizational and legal issues and set technical standards. In Europe, one of the most influential recent documents concerned with artificial reproductive technology (ART) is the EU Tissues and Cells Directive from 2004 (EUTCD; 2004/23/EC), with its supplementary Technical Directives (2006/17/EC, 2006/86/EC). The EUTCD and Technical Directives cover all transplanted tissues and cells, with the exception of blood and blood products. As a result, this also encompasses gametes, zygotes and embryos when processed outside the human body, irrespective of the relations between the people involved in the treatment. The EUTCD and Technical Directives cover all transplanted tissues and cells, with the exception of blood and blood products. As a result, this also encompasses gametes, zygotes and embryos when processed outside the human body, irrespective of the relations between the people involved in the treatment. The EUTCD and Technical Directives provide minimum standards that ought to be taken up in the legislation of EU member states within 2 years after the adoption of 2004/23/EC.

In this issue, Wingfield and Cottell present a critical appraisal of the regulatory aspects in the context of tissue and cell donation that they have been working with in Ireland since the recent introduction of mandatory testing regimes. They evaluate and question the regulations mandated by the European Directives and the national rules that these Directives have translated into in their homeland, focusing on the requirements relating to viral screening in ‘partner donation’ (the donation of cells between a man and woman who have an intimate physical relationship, according to the EU definition) (Wingfield and Cottell, 2010). The authors have scrutinized the medical and scientific evidence for the mandated procedures, complementing their literature search with a survey of the experiences in seven Irish ART clinics over the last few years. They come to the conclusion that there is no medical or scientific evidence for requiring virology screening in each treatment cycle of partner donation, and assert that it is both discriminatory and distressing. This is in line with ESHRE’s statement (2009) on the very same topic; both the statement and the overview make an appeal for reconsideration of the requirements concerned and, in general, call on professionals, politicians and others involved in making ART regulations to think about the fundamental reasons for various requirements in directives, laws, protocols etc. Are these requirements sensible and do they derive from evidence, or is ART approached as an exceptional branch of medicine for which the approach to rules may differ (Johnson and Petersen, 2008)? Wingfield and Cottell’s contribution presents a good illustration of cases that may deviate from reasonableness.

It may be useful to distinguish the two basic types of reasons for questioning the regulations applied in the context of partner donation of gametes. Both are touched upon, directly and indirectly, by Wingfield and Cottell (2010) and have been dealt with in other contributions (Mortimer, 2005; ESHRE position paper, 2007; ESHRE statement, 2009): (i) Gamete and embryo donation are atypical activities within the scope of tissue and cell donation. This appears to hold particularly in the case of ‘donation’ between partners. (ii) ART is just one area in which humans encounter risk, and is therefore not exceptional.

Gamete donation is an atypical form of tissue and cell donation

Among tissue and cell donation activities, gamete donation is atypical, as noted in the ESHRE position paper and statement on the EUTCD (2007, 2009), by Mortimer (2005) and others (e.g. Bhargava, 2005; Hartshorne, 2005): (i) Unlike other types of tissue and cell donation, gamete donation, in so far as semen is concerned, is a commonly practised activity in normal life, outside the medical environment. It occurs between spouses, partners and sometimes friends, depending on the people and particular situation. It even occurs regularly
between people little or hardly known to each other (the latter obviously being an activity akin to non-partner donation). Further, it is not uncommonly practised for reasons other than reproduction. (Strictly speaking, it is the males who transfer their semen to their partners, an activity denoted as ‘partner donation’ in the EU Directives which—somewhat oddly, it would seem—is considered reciprocal: ‘the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship’; 2006/17/EC; ESHRE position paper, 2007.)

(iii) Gamete donation, in so far as semen is concerned, is a transfer of foreign biological material ‘applied’ extracorporeally (not in the body), quite unlike other donated tissues and cells (and organs). The cavities of the vagina and uterus, although located intimately in the female body, are not internal and are covered with protective mucous membranes. This has, and should have, consequences for how certain safety issues in the context of the transfer of alien material are approached.

(iv) Gamete donation is an activity in which a ‘third party’ is involved that may experience the results of the process without being able to decide on it: the offspring.

These considerations, which are not unique to partner donation but hold for all donation of semen, demand an atypical approach. Much that is evident and responsible in the context of other tissue and cell donation may be far less so in the case of gametes, especially sperm. Taking into account that a great deal of gamete donation also occurs in everyday life without special precautions, for most people certain precautions seem far fetched as far as protection of the recipients is concerned. This could be said for the air quality specifications in facilities where ART is being carried out (Mortimer, 2005; ESHRE position paper, 2007). It can also be said for the requirement to perform a battery of tests for each separate donation to prevent cross-contamination of gametes and embryos processed, cultured or stored (2006/17/EC; ESHRE position paper, 2007; ESHRE statement, 2009; Wingfield and Cottell, 2010). In view of the available evidence, the latter can be said with even greater certainty in the case of partner donation when the current best practices are applied in processing and storage (Wingfield and Cottell, 2010).

As a pragmatic solution to the impractical requirement to perform viral screening for each donation, various EU member states have declared the viral test results to be valid for extended periods (e.g. 1–6 months in Ireland; 3–12 months in The Netherlands; 12 months in France and the UK; 12–24 months in Finland and 24 months in Denmark) (ESHRE statement, 2009; NVOG et al., 2010; Walsh et al., 2010; Wingfield and Cottell, 2010). These arrangements appear to be in agreement with the content of the EU Directives with respect to screening as well as with the imperative to translate the Directives into national laws and regulations (2006/17/EC). However, they might also be considered somewhat odd, as they apparently intend to circumvent the controversial requirements. Moreover, allowing for different national interpretations also makes way for arbitrariness in the regulations throughout Europe, which is contrary to the Directives’ original intention of bringing about harmonization within Europe.

The fact that a third party that is unable to speak for itself is involved in gamete (and embryo) donation, on the other hand, may well call for special precautions. It may justify and even warrant more elaborate and stringent testing than is commonly practised in other types of donation and between co-habiting partners in normal life. Here, too, it seems reasonable that the approach to the use of gametes and embryos by co-habiting partners and by people unknown to one another (anonymous) would differ.

**ART is one of many areas in which risks are encountered**

It might be expected that the regulations in reproductive medicine compare in severity to, and are not much more stringent than, the measures dealing with risks elsewhere in society. Why should an activity so akin to things happening between people in normal life be regulated with more and special safety precautions when it enters the medical domain? It may be useful to identify whom the imposed regulations are intended to protect. In short, the precautions are there for the purposes of:

(i) patients and offspring (patients being defined as all those who seek treatment, which also includes healthy women with infertile male partners or without male partners),
(ii) professionals (to protect themselves directly, but possibly also to safeguard them from claims) and
(iii) the equipment of institutes/departments (i.e. the system).

The first category is evidently the most important to protect. Indeed, this might even be considered a condition sine qua non for the intended offspring, which initially has no voice and no vote but may be affected by the results of the proceedings all the more.

The second and third purposes are not necessarily in the interests of patients (although patients are indirectly served by the mere presence of professionals and institutes that are willing and able to cater them). Sometimes, however, the interests of patients, professionals and institutes are synchronous. For instance, nobody benefits from treatment that has little or no chance of success (though patients sometimes need to be convinced of this). Wherever possible, measures in the interests of professionals and institutes should be taken such that the patient is not aware of them. And the patient should certainly not be disadvantaged by measures not taken primarily for his or her sake.

With regard to the protection of professionals and the system, it is reasonable to have similar requirements for similar activities. This holds for laboratories as well as medical practice in general. Therefore, it is unnecessary and indeed strange if for certain aspects of ART laboratory work more stringent rules are required than elsewhere in laboratories. Consider, for example, safety measures to protect laboratory personnel (Mortimer, 2005). Why should it be necessary to apply stringent measures to protect personnel in fertility laboratories while this is not considered necessary for personnel doing
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similar work in other clinical laboratories (e.g. for clinical chemistry, microbiology, pathology)?

That similar requirements should hold for similar activities may perhaps be seen in the fact that Directive 2006/17/EC requires less stringent tests in the case of partner donation—at least, to some extent. Why investigate husbands for the presence of viruses when in everyday life spouses rarely ask this of each other, and, moreover, will most probably continue to have sexual contact irrespective of the fertility treatment? Accordingly, no donor selection and laboratory tests are required for partner donation of reproductive cells that are not stored (so-called ‘direct use’), (2006/17/EC). However, in cases where gametes and embryos for partner donation are processed, cultured or stored, the requirements for viral screening in partner donation approach those of non-partner donation, with testing regimes for each separate donation (2006/17/EC; ESHRE statement, 2009).

People making rules and regulations (professionals, lawyers, ethicists, politicians etc.) in line with their codes of conduct and professional practices often appear to be compelled to be responsible, such that the human behaviour beyond the hospital walls tends to be forgotten. If choices are to be made, the most stringent version of rules tends to be preferred, as this feels the most morally responsible (Pennings, 2004). This notion holds for people making rules and regulations at the European as well as the national level. In fact, there would seem to be no real need for national regulations to become much more stringent than the EU Directives. Yet moralism might play a role here without being recognized. The idea has been put forward that reasoning in the context of ART might be not only reasonable, logical and evidence-based, but also affected by the unconscious processes, religious convictions and reservations that reasoning in the context of ART might be not only reasonable, logical and evidence-based, but also affected by the unconscious processes, religious convictions and reservations towards ART of the decision makers (Johnson and Petersen, 2008). But should we always choose in favour of the neatest and best? We should certainly try, if the imposed regulations and rules are to have no drawbacks.

Sensible medical conduct

What are sensible recommendations? The supranational (e.g. EU) directives are worked out in national laws, which are subsequently worked out in professional guidelines. The latter (in sequence) are allowed to stipulate stricter provisions than the former, but not the other way round. Professionals are required to be obedient to all. Often, however, they have no idea where certain requirements come from. Apparently, the further away the rules are conceived, the less clear their origin is for them (and probably also their influence). This might hold especially for the requirements coming from Brussels. However, insight and understanding are crucial for acceptance. The least one might ask is: are the requirements based on evidence, as should be common practice in medical science? Doubts about this are by no means exceptional.

If the requirements are not based on sound scientific evidence, what makes us follow the rules or the directives as strictly as asked? We do so, or at least intend to do so, because it is expected of us, and/or we do not dare to do anything else. However, living up to the requirements may demand significant finances and efforts (ESHRE statement, 2009) and hinder the practice of helping people and providing ART. Too-severe regulations are not only morally debatable, but also waste money, in the worst case obstructing the possibilities for patients to afford, and for institutions and society to give, the requested care.

Given this situation, should we not at least feel challenged to comment critically on the regulations and call for better evidence? The 2006/17/EC states that ‘risk can be reduced by […] testing […] and the application of procedures […] established and updated according to the best available scientific advice’. Providing critical comment, refuting the evidence and calling for update: precisely this has now been done by Wingfield and Cottell (2010), and earlier the ESHRE position paper and statement on the EUTCD (2007, 2009) as well as Mortimer (2005). Well done, good, rightly so. Rules and regulations in ART ought to be sensible, clearly distinguish between moral and social motives, and reflect all the available evidence. With respect to 2004/23/EC, 2006/17/EC, 2006/86/EC and ART, we are waiting…

References


