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REVIEW

Evolving minimum standards in responsible international sperm donor offspring quota

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Abstract An international working group was established with the aim of making recommendations on the number of offspring for a sperm donor that should be allowable in cases of international use of his sperm. Considerations from genetic, psychosocial, operational and ethical points of view were debated. For these considerations, it was assumed that current developments in genetic testing and Internet possibilities mean that, now, all donors are potentially identifiable by their offspring, so no distinction was made between anonymous and non-anonymous donation. Genetic considerations did not lead to restrictive limits (indicating that up to 200 offspring or more per donor may be acceptable except in isolated social-minority situations). Psychosocial considerations on the other hand led to proposals of rather restrictive limits (10 families per donor or less). Operational and ethical considerations did not lead to more or less concrete limits per donor, but seemed to lie in-between those resulting from the aforementioned ways of viewing

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the issue. In the end, no unifying agreed figure could be reached; however the consensus was that the number should never exceed 100 families. The conclusions of the group are summarized in three recommendations.

KEYWORDS: cross border reproductive care, donor offspring limits, gamete donation, regulation, reproductive ethics, sperm donation

Introduction

Medical, social and economic developments, and a sense for opportunities among entrepreneurs, have given rise to the development of gamete banks providing reproductive services and material to patients around the world. These international services are accomplished either by people travelling for treatment to clinic(s) local to the donors, or by clinics exporting the reproductive material abroad. Services are readily arranged through present-day facilities such as the Internet, through reliable material transport facilities and as a result of the easy and increasingly affordable nature of international travel in modern society.

Most countries regulate the assisted reproduction technique activities within their borders (Gong et al., 2009; Janssens et al., 2011). Cross-border activities, however, with some rare exceptions (Spanish guidelines, German guidelines; Codigo ethico de la SEF, 2012; Thorn and Wischmann, 2013) defy national recommendations, regulation and supervision. There are international recommendations, suggested in papers (Blyth et al., 2011; Thorn et al., 2012) and in a guideline from ESHRE on cross-border reproductive care (CBRC) (Shenfield et al., 2011). These recommendations, however, are generally stated and not legally binding. In addition, no international body with relevant regulatory powers exists to oversee assisted reproduction technique activities.

One of the issues provoking regular debate concerns the number of offspring a gamete donor reasonably may have. We denote this issue here as 'donor quota'. The European Union Directives on Cells and Tissues (2004/23/EC, 2006/17/EC, 2006/86/EC) were enacted with the aim of protecting the health of donors and recipients and to increase the availability of safe cells and tissues. Meeting these laboratory standards constitutes a legal basis for the exchange of donor sperm between approved tissue facilities within the European Union and, of course, increases the availability of donor sperm throughout the European Union. How to combine this with differing national guidelines and legislations, however, including those on donor quota, is more complicated.

Basic to the issue of donor quota is the fact that a man is able to produce an effectively unlimited number of ejaculates to sire potential offspring without physical risk to himself. International use of donor sperm is a common practice, as shown by various sperm banks operating internationally. The international distribution of sperm, however, is unregulated. This international use of donor sperm, either distributed from sperm banks to multiple countries, or provided to foreign recipients travelling to local clinics, opens the possibility for these donors to have more offspring than donors whose sperm is used only on a regional or national scale. In an effort to establish recommendations on the number of offspring a donor whose gametes are used on an international scale may have, a working group of professionals from different European countries and professional backgrounds was established in 2012. Discussion within the working group rapidly led to the conclusion that any arguments on donor quota should take into account considerations from the field of genetics, psychology and social science, ethics, operational and legal aspects. Following a section considering the general considerations relevant for the issue at stake, we here describe the views put forward on each of these topics in the debates held within the working group.

General considerations

As a starting point for our discussions, it was noted that the existing national quota in different countries ranges from one (Taiwan) to no limits (Canada, Sweden) (Janssens et al., 2011). In some countries, professionals formulated the standards whereas in others politicians and Governments responding to 'public' concerns proclaimed the directives and laws. The wide range of quotas suggests that different arguments have been used in different countries, but also reflects variation in cultures, including the weight given to science, religion, professional insights, beliefs about kinship structures and public opinion on management of matters in reproductive medicine (Gong et al., 2009; Janssens et al., 2011; Van Hoof and Pennings, 2012). The international use of donor sperm may differ in some characteristics from the national use of gametes (**Table 1**), although some arguments playing a role in national donor quota are likely to be relevant for international donor quota as well.

A point of unanimity among the panel was that best practice in regulation should limit donations by numbers of 'families' rather than children or pregnancies. This allows families to be completed using one donor alone (if this is desired by parents), a principle that is broadly considered an optimal way of family building through donor insemination. Counting in terms of individual children (or pregnancies) risks the possibility that, at some moment, the permitted limit is reached before mothers having a child from a certain donor apply for another insemination, which then would have to be refused (or lead to use of another donor). Leaving aside any discussion on whether families function better or not when children are genetic siblings, such a system also reduces any risks attached to later contacts where more than one donor is involved in one family, such as one donor providing fuller information about themselves or being more receptive to contact than another.

Obviously international donor quota cannot be applied independently from national quota. If national regulations restrict the distribution or the use of gametes from or to another country, then institutions and professionals have to adhere to those national limits. In the international sphere, regulations from both the distributing and receiving country must be taken into account. As a result, the possibilities for using gametes on an international scale will vary. When considered in more detail, distinction should be made between regulations on distribution and acceptance of gametes to or from abroad