

## Limiting donor conceptions to six: Time for change



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In terms of the Regulations Relating to the Artificial Fertilisation of Persons (R.175) of the National Health Act,<sup>[1]</sup> when gametes are removed or withdrawn from the body of a gamete donor, this is done for the purpose of artificial fertilisation. In the Regulations, artificial fertilisation is defined as ‘... the introduction by other than natural means of a male gamete or gametes into the internal reproductive organs of a female person for the purpose of human reproduction ...’. All information regarding the donated gametes is to be stored in an electronic central databank. No further gametes can be removed or withdrawn from the body of a donor once six children have been conceived through artificial fertilisation using the gametes of that donor. If a competent person involved in this aspect of reproductive medicine is informed or suspects that the maximum number of conceptions have occurred, s/he must make the donor aware of this and in addition must inform the donor that s/he may not make any further donation of gametes. This information must also be relayed to the central databank. A competent person is defined very broadly as a medical practitioner specialising in gynaecology with training in reproductive medicine, or a medical scientist, medical technologist or clinical technologist with training in reproductive biology and related laboratory procedures.<sup>[1]</sup>

Currently there is no information on what informed the limitation to six live births in the Regulations or how this figure was arrived at. In addition, there appears to be no information from valid population genetics in the country indicating that if the number of donor offspring was not limited to fewer than six, the possibility of inbreeding would increase. What the Regulations have also not taken into consideration is that a conception is not the same as a live birth. The facts that pregnancy losses do occur, and that there is a definite attrition rate during pregnancies from conception to birth, have been ignored. In addition, the Regulations are silent on donor siblings and leave very little room for consideration of family desires.

An appraisal of the international situation reveals that in order to decrease the chance of offspring intermarrying, donor gametes will not normally be used once the number of children believed to have been born from them has reached a certain number. The number

varies between different countries: for example, it is 10 in the UK, and 25 in Holland.<sup>[2]</sup> In the UK, the limit is set as families and not number of children,<sup>[3]</sup> which makes it possible for parents to choose the same donor for a second or third sibling without being told that the donor has reached his limit. This is not the situation in South Africa (SA), unfortunately, with the blanket limit of six stemming from the outdated and repealed Human Tissue Act No. 65 of 1983. The limit is not only restrictive but also lags far behind the required legal and ethical changes that are necessary in any country striving towards an enabling environment to accommodate the rapid global advances in science and technology. Furthermore, it does not take into consideration the changed political climate in SA. It is possible that the 1983 Act was restrictive because the pool of donors and recipients was limited to the small minority of advantaged individuals in the country at that time, when the possibility of consanguinity could have been a real fear. The question is: Is it a compelling and defensible argument today?

In The Netherlands, a limit of 25 children is used based on the principle that children from sperm donors may have, at most, a similar risk to children in the general population of having a relationship with a naturally conceived unknown half-sibling.<sup>[4]</sup> This calculation was based on specific population data in the country and included figures on the chance of having an unknown half-sibling, the average number of children parents have, the chance of donor-conceived children having children themselves, age and geographical factors determining the likelihood of meeting a partner in the district of a donor bank, and the size of the population being served by a donor bank.

The American Society of Reproductive Medicine recommends that the limit should be based on the population from which a donor is selected and the catchment area that may be served by a particular donor.<sup>[5]</sup> Using this recommendation, it came up with a figure of not more than 25 pregnancies for a population of 800 000 to avoid the risk of unintentional relationships between two genetically linked individuals.

The limit, while being set to minimise the possibility of two children from the same donor having a consanguineous relationship without knowing that they are genetically related, should ideally apply to sperm donations only, as sperm cells can be donated more easily and in larger quantities than eggs, and donation of eggs involves a complex medical intervention that could give rise to complications.

Section 8(2)(iii) of the SA Regulations states that once six conceptions have occurred, all gametes donated by the gamete donor and in storage must be destroyed unless the Minister of Health consents to the practitioner keeping those gametes.<sup>[1]</sup> This section does not stipulate the purpose of keeping the gametes and is open-ended and ambiguous. One can therefore only speculate as to the reasons for keeping the gametes. Could it be that those who drew up the Regulations did foresee the possibility of requests that would necessitate more than six conceptions per donor being allowed, e.g. in situations of donor siblings? Perhaps this should be a common sense approach to use when interpreting this aspect of the Regulations, which needs to be read together with section 3(1),

specifying that the purpose of removal or withdrawal of the gamete from the body of a gamete donor is that of artificial fertilisation.

The Regulations, as part of chapter 8 of the National Health Act, were promulgated in March 2012, at the same time as several other regulations to the same chapter were passed. A number of authors have criticised these regulations as being problematic and have underscored the difficulties that have arisen in practice because of the resulting legal limbo and confusion.<sup>[6]</sup> This editorial is another such critique, but is specific to Regulation 175, which also needs review and amendment so that ambiguities are removed and it is brought in line with current developments, the international situation and the SA local context. Amendments to the Regulations should include a move away from conceptions to children in families, and include a realistic limit on the number based on research and appropriate consultation.

## References

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