Assisted reproduction – ethical aspects

Summary of a report

The Swedish National Council on Medical Ethics
Summary of the original report “Assisterad befruktning – etiska aspekter 2013:1”published in Feb 2013.

Background

In 1995, the Swedish National Council on Medical Ethics submitted a report on assisted reproduction to the Government. The report had a major impact on legislation in this area. Fifteen years later, in 2010, the Council held a conference on assisted reproduction, which also became the starting point for this report. At the conference it became clear that it was time to review the legislation in this area. The state of knowledge is now different and values have changed. Since the conference, the Council has discussed the issues with a number of experts on various topics in the field, and current research and debate have been surveyed. The Council has also consulted young people to obtain their views on several key issues.

The aim of the report is to highlight and analyse the ethical aspects associated with new and more established methods of assisted reproduction. The report is intended for the Government and Riksdag (the Swedish parliament) and to provide input for public debate and discussion among professionals, health care providers and interested members of the general public.

Problems and analysis

One of the starting points in the report is that involuntary childlessness is a major problem for many people.

The report defines the involuntarily childless as anyone who would like to have children but has difficulty doing so, whether this is due to medical problems or other causes.

The issues were analysed considering the actors who might primarily be affected by each method or procedure.

Another important starting point was the principle of the best interests of the child, as expressed in the UN Convention on the Rights of the Child.

In the report, the Council proposes amendments to current legislation and practice that, if implemented, would probably mean that more involuntarily childless people can receive treatment in Sweden. There was broad consensus within the Council with regard to the issues and conflicts of interest at stake. This resulted in joint positions on the majority of issues. Where opinions diverged, the considerations of both the majority and the minority are reported.

Rules and regulations in Sweden

Since 2006, assisted reproduction has been regulated mainly by the Genetic Integrity Act (2006:351). Several other acts, as well as regulations and general advice from the National Board of Health and Welfare, have an impact on regulations in this area. A number of international conventions must also be taken into account.

In Sweden, heterosexual and lesbian couples who are involuntarily childless are entitled to fertility treatment.

Women who cannot carry a child, HBT couples and single women and men are not offered fertility treatment. However, under a Riksdag decision of 2012, single women will be given the opportunity to undergo fertility treatment in Sweden.

There is no age limit for access to treatment in legislation. Nonetheless, the county councils, which take independent decisions on health and medical care in their respective areas, have limited access to treatment by introducing age limits. The upper age limit for IVF treatment is between 37 and 41 years for women, and 54 and 56 years for men.

Egg and sperm donation are permitted in Sweden. However, it is not permitted to combine donated eggs and donated sperm in the same treatment, or to use supernumerary embryos. The egg or sperm donor must also still be alive.

When couples use donated eggs or sperm, the physician must review whether, considering the medical, psychological and social circumstances, it is appropriate for treatment to take place. Insemination or fertilisation outside the body may only be carried out if it can be assumed that the prospective child will grow up under favourable conditions. Couples being treated with their own gametes do not have to undergo this special review.

Couples who have supernumerary fertilised eggs following IVF treatment can choose to donate them to research, but they cannot donate them to other infertile couples. The right of disposition over supernumerary fertilised eggs is currently a legal uncertainty.

As a general rule, fertilised eggs may be stored in a frozen state for five years. There are no rules on how long unfertilised eggs and sperm can be stored.

An egg or sperm donor cannot be anonymous, but is often unknown to the prospective parents. Donor-conceived children have a legal right to access the data on the donor recorded in the hospital's special record, when they have reached sufficient maturity. However, this requires that the parents have told the child about his or her orgins, including the fact that he or she is donor-conceived. The donor has no obligations to the child.

Under clinical practice, a donor's reproductive cells can be used to treat six families.

Surrogacy is not allowed in Sweden.

General conclusions

The Council's discussions and analysis of the issues clearly indicate that the separate methodological issues within assisted reproduction should be discussed from a holistic perspective.

New medical knowledge, opportunities and methods raise the need for a review of the current regulations.

Summary – the Council's considerations and recommendations

Adoption

In discussions of assisted reproduction, the question of adoption as a possible alternative to fertility treatment is often raised. Every year around 800 children are adopted from abroad by Swedish parents. However, adoption can be a complicated process associated with lengthy waiting times and high costs. Not all groups of involuntarily childless people have the option to adopt.

The Council considers that adoption as an alternative to assisted reproduction should be discussed early in the process of investigating alternatives for the involuntarily childless couple.

Children's right to know about their origins

In Sweden, donor-conceived children have the right to obtain information about the donor's identity when they have reached sufficient maturity. This is, however, dependent on the child knowing about his or her origins. Surveys show that not all parents tell their children that they are donor-conceived.

The Council wants to strengthen children's right to know about their origins.
This right is an aspect of the principle of the best interests of the child under the Convention on the Rights of the Child. All children born as a result of assisted reproduction should receive information about their origins. The parents should tell their

children about their origins at an early stage. Possible ways to strengthen this right should be considered.

Donation of fertilised eggs

No treatment is currently available in Sweden for couples who lack both viable eggs and viable sperm. In some other countries, treatment using donated fertilised eggs (embryo donation) and the combination of donated eggs and sperm in the same treatment are permitted. These treatment methods mean that the child has no genetic link to his or her prospective parents.

The Council considers that donation of fertilised eggs should be permitted in Sweden. The Council's overall view is that the genetic link between child and parents is of less significance to the child's wellbeing than other factors and that social interactions are more important.

Allowing donation of fertilised eggs may mean that more involuntarily childless people can become parents, and that fertilised eggs that would otherwise be disposed of are used. In the Council's opinion, neither the general view of human beings nor the view of gamete cells would be affected by permitting this method. On the contrary, it can be seen as positive, from several standpoints, that more fertilised eggs are used.

Follow-up studies of children's mental health and wellbeing will be important. A future inquiry should examine whether combined sperm and egg donation from individual donors should also be permitted.

Storing of fertilised eggs

When assisted reproduction is carried out using IVF, more fertilised eggs are often obtained than are needed for treatment. The fertilised eggs that are not used in the first round of treatment are frozen for use in any future treatment. At present, fertilised eggs may, as a general rule, be stored in a frozen state for 5 years.

The Council considers that the current five-year limit for the storage of frozen eggs should be extended.

Further consideration should be given to what time limit would be appropriate from a medical, psychological and social perspective.

Storing of unfertilised eggs

Freezing and storing of unfertilised eggs is offered within the health care system to women with medical reasons that require them to undergo treatment that would be harmful for their fertility. A new, successful freezing technique means that the method is now also offered commercially to healthy women who wish to store their eggs for fertility preservation reasons. There is currently no regulation concerning the storing of unfertilised eggs in a frozen state.

The Council considers that it is ethically acceptable to offer women the option to store their eggs in case of the risk of both medical and age-related infertility. One condition for this is that the woman has been informed of the risks of egg retrieval and is aware that future IVF treatment does not guarantee pregnancy. The cost of freezing and storing eggs for age-related reasons should be covered by the individuals themselves. When the need to store frozen eggs is based on medical grounds, society should contribute to the costs.

No medical problems have been reported as a result of freezing eggs or the length of frozen storage. However, there are gaps in the knowledge base, which is why further medical evaluations and long-term monitoring of children conceived using frozen unfertilised eggs are important. It is essential that this issue is followed up with guidelines and recommendations.

The Council also regards it as essential that future guidelines and recommendations concerning the freezing of egg and testicle tissue are considered.

Surrogacy

Surrogate motherhood is when a woman allows the use of her body and becomes pregnant with the explicit intention of giving the baby to another couple or person after the birth. The prospective parents' own gametes are often used for fertilisation, but several variations are possible. Compensation above and beyond pregnancy-related costs is paid to the surrogate in the commercial form of surrogacy, but not in the altruistic form. Surrogacy is not allowed in Sweden.

The considerations and viewpoints of the majority

A majority of the Council consider that altruistic surrogacy – under specific conditions – could be an ethically acceptable method of assisted reproduction. One condition is that there must be a close relationship between the surrogate mother and the prospective parents. The surrogate should have undergone pregnancy previously and have children of her own, and she should not be the genetic mother of the prospective child. Other conditions are that the surrogate and the prospective parents undergo a thorough suitability review and have access to support and counselling during the process. The prospective child should also be told at an early stage about how he or she came into being and should be entitled, at a mature age, to information about the surrogate mother.

In line with the principle of self-determination and autonomy, women should be able to decide what to do with their own bodies. However, surrogacy is a complex, multi-dimensional ethical issue and a future inquiry should examine what criteria should be applied in the assessment ahead of a decision on treatment through surrogacy. It is important to consider possible psychological consequences for the surrogate mother, as well as the risk of women being pressured into acting as surrogates.

Women who cannot carry a child for medical reasons and homosexual men are not currently offered fertility treatment. For these groups surrogacy could be an opportunity to become parents. The issue of the possibility for single people to become parents using surrogacy should be dealt with by a future inquiry on assisted reproduction.

The considerations and viewpoints of the minority

A minority of the Council consider that surrogacy should not be permitted in Sweden. In the view of these members, surrogacy is not an ethically acceptable way to have children. There are too many uncertainties regarding the psychological consequences for the surrogate mother and the children born as a result of various types of surrogacy agreements. It is also difficult to ensure self-determination and informed consent in surrogacy arrangements.

This method contravenes the principle of human dignity, in the sense that a person is used as a means for other people's ends.

Although there are examples of altruistic surrogacy working well, even this form involves uncertainty and risks for all the parties involved. If altruistic surrogacy is permitted, there is a high risk that an acceptance will be created that would lead to commercial forms of surrogacy in the longer term. This in turn could lead to exploitation of socially and financially vulnerable women.

The prospective child risks being affected by conflict if the surrogate mother changes her mind and does not want to give up the child. The child may also be affected if the prospective parents no longer want the child. Nor do we know what effect it may have on the child's development if the (surrogate) mother actively avoids bonding with the child during pregnancy, or what the knowledge of having been born by another woman may mean for the child.

The Council's unanimous viewpoints

All members of the Council consider that commercial surrogacy is not an ethically acceptable method.

Commercial forms of surrogacy risk leading to the exploitation of women and the commercialisation of the reproductive process and the procreation of children. One could question whether surrogates in commercial activities are acting autonomously if their financial circumstances are straitened. The principle of self-determination and autonomy of surrogate mothers can therefore be questioned when it comes to commercial arrangements.

The Council considers that it is important that children born through surrogacy in other countries are given the same opportunities as other children. Today, children are born through surrogacy in countries outside Sweden. These children must be given the same opportunities as other children. The uncertainties concerning the arrival in Sweden of these children should therefore be clarified as soon as possible. The problem will remain whether or not surrogacy becomes a permitted method in Sweden.

Uterus transplantation

One type of infertility that has largely been medically untreatable is infertility in women whose uterus is absent or non-functioning. One technique currently being developed to treat this form of infertility is uterus transplantation. This means that a uterus from a living or deceased donor is transplanted into a woman who lacks a uterus, with the aim of making pregnancy viable. Clinical studies are ongoing, but so far no children have been born as a result of this method.

The Council considers that it is too early to approve the introduction of uterus transplantation within the healthcare system. The primary reason for this is that the method is still at the research stage and there are still considerable knowledge gaps. The child perspective is an important starting point and the risks in this respect are as yet unknown. There are also concerns regarding this method from the point of view of prioritisation.

Assisted reproduction using gametes from deceased persons

In Sweden it is not permitted to use eggs or sperm from deceased people in any form of assisted reproduction, regardless of whether the treatment is using the person's own or donated gametes. Nor may fertilised eggs (embryos) be used if the sperm or egg used for fertilisation comes from a deceased person.

The reflections and viewpoints of the majority

A majority of the Council consider that it should be possible, under certain conditions, to use fertilised eggs where the eggs or sperm used for fertilisation come from a deceased person. It should be possible for a couple/individual to complete IVF treatment already started with frozen fertilised eggs, even if the egg or sperm donor is deceased.

One condition for the use of fertilised eggs from deceased egg or sperm donors as outlined above is that the donor has given informed consent.

A majority of the Council also consider that it should be possible to use unfertilised eggs and sperm from a deceased person to complete fertility treatment already started.

The situation primarily alluded to is when a couple have started fertility treatment using the male partner's sperm and he subsequently dies during ongoing treatments. To allow further treatment with the deceased person's gametes should be possible out of consideration for those who are undergoing fertility treatments and whose partner dies. In these situations, the child will have one parent, which is comparable with when single women undergo fertility treatment.

The legal issues and social consequences that will arise must be clarified in a future inquiry.

The reflections and viewpoints of the minority

A minority of the Council consider that the use of eggs, sperm and fertilised eggs from deceased persons should remain prohibited. A prohibition is primarily motivated with regard to the prospective child. We do not know how children are affected by the knowledge that their genetic parent was deceased at the time of their conception. It therefore cannot be ruled out that a child who becomes aware that his or her genetic makeup originated from a deceased person may be affected in a negative way by this knowledge.

If the use of gametes from deceased persons is permitted in certain situations, there is a major risk of greater acceptance of further uses. Permitting this may lead to social consequences that are difficult to predict. The process also risks leading to illegal trade and abuse.

Right of disposition – fertilised eggs and gametes

The question sometimes arises within assisted reproduction of who is entitled to decide how gametes and fertilised eggs may be used. In this context we usually talk about the right of 'disposition' or 'use', rather than ownership. The legal situation in Sweden with regard to the right of disposition over supernumerary fertilised eggs in connection with IVF treatment is currently unclear.

Unfertilised eggs and sperm are covered by the provisions in the Biobanks Act.

The Council considers that the right of disposition over fertilised eggs should be limited to the couple undergoing treatment – regardless of whether the treatment includes their own or donated gametes.

The Council also considers that the right of disposition over unfertilised eggs and sperm needs to be clarified and regulated. It should be clear that a person who, for example, has frozen gametes stored for future use has the right of disposition over them and can demand to have them released for treatment abroad. Trading in eggs and sperm should continue to be illegal, however.

Age limits in assisted reproduction

There is currently no statutory upper age limit for IVF treatment for a couple using their own gametes. However, the county councils have upper age limits for IVF treatment ranging from 37 to 41 years for women and 54 to 56 years for men. When donated eggs or a woman's own previously frozen eggs are used, in technical terms the prospects of becoming pregnant are good even for older women.

The Council considers that it is inappropriate to set general age limits for fertility treatment, since people age in an individual way. The starting point must be to consider the age of the parent(s) with regard to all types of *in vitro* fertilisation, taking into account the best interests of the prospective child and the woman's medical prospects of a viable pregnancy. It should be plausible that the child will be able to grow up with at least one parent, which means that one parent must be young enough to be able to take responsibility for the child until he or she reaches adulthood.

Assisted reproduction for single people

Fertility treatment for single people is not permitted in Sweden. Many Swedish single women go abroad to obtain access to insemination. In March 2012, a majority in the Riksdag decided that single women should be granted the right to undergo fertility

treatment. The Government was then tasked with producing a legislative proposal on the issue as soon as possible.

The Council wishes to call attention to a number of ethical issues that should be taken into account when implementing the Riksdag's decision. These issues include the various consequences of giving single women access to various treatment methods. Assisted reproduction for single women should be preceded by a special review from the child's perspective, which should take account of factors such as the woman's social network. There are also grounds to consider whether sperm donors should be given an option to consent to donate to single women.

The Council wishes to point out that it is important to give immediate support to follow-up studies of children conceived through assisted reproduction for single women. It is important to follow up the psychological and social development of these children in order to be able to anticipate whether there is a need for special measures and support for this group.

Review ahead of treatment for involuntary childlessness

Under the current regulations, a special review must be carried out when donated gametes are used in fertility treatments. *In vitro* fertilisation using donated sperm or eggs and insemination using donated sperm may only be carried out if it can be assumed that the prospective child will grow up under favourable conditions. If a couple uses their own gametes, no such review is carried out.

The Council considers that the current rules on special reviews should be discontinued. In their place, a general review that considers the best interests of the prospective child should be introduced within all forms of assisted reproduction.

Special reviews for treatment using donated sperm or eggs should be discontinued, as there are insufficient grounds to treat this group differently. In the general review proposed by the Council, consideration should be given to the couple's/person's individual suitability to act as parent(s). However, the introduction of a general review should not excessively encroach upon reproductive freedom and personal privacy. The review should be adapted depending on the assisted reproduction procedures in each case.

Prioritisation and assisted reproduction

County councils have the right to prioritise between activities in the health and medical service. Priorities are to be set based on the ethical platform for priority-setting, in which the guiding principles are those of human dignity, needs and solidarity, and cost-effectiveness.

The Council considers that it is important that people who wish to have children have the opportunity to undergo assisted reproduction at a reasonable cost, and that the financial situation of the individual does not steer who does or does not have access to treatment. However, the county councils must be able to prioritise between fertility treatments and other activities based on the Riksdag's ethical platform for priority-setting.

Major differences in people's access to assisted reproduction between county council areas contravene the fundamental ethical principles of high-quality care on equal terms for the entire population.