Three Bioethical Debates in Sweden

SVEN OVE HANSSON

Three of the bioethical issues recently discussed in Sweden appear to be particularly interesting also to an international audience. A new law allowing restrictive use of preimplantation genetic diagnosis (PGD)/human leukocyte antigen (HLA) ("savior siblings") has been implemented, a new recommendation for the cessation of life-sustaining treatment has been issued, and the scope of individual responsibility for medical mistakes has been rather thoroughly discussed.

Life-Saving Siblings

In many countries, couples who carry certain genetic diseases are offered PGD. This means that implantation is performed with embryos that have been selected so that they do not have the genetic abnormality in question. For some diagnoses, if a sibling is born who does not have the disease, then this newborn sibling can act as a donor in a hematopoietic stem cell transplant to the sick child. However, a transplant is only possible if the new child has a HLA type matching that of the sick child. This can be achieved if PGD is combined with HLA tissue typing and an embryo is selected that is both free of the genetic disease and a suitable donor for a transplant to the existing sibling. This method (PGD/HLA) can save lives, but it also has the problematic ethical feature that an embryo is selected with the specific purpose of saving another person's life.[1]

This method is relatively new, and it was not foreseen in the previous Swedish legislation. It was therefore included among the topics to be studied by a Government committee of inquiry that also investigated other ethical issues related to genetic technology. In its report, published in 2004, the Committee pointed out that PGD/HLA was at that time a largely untested method that had only been used in a few cases (in Great Britain, the United States, and Belgium). The committee also emphasized that with this method, a fertilized egg is selected according to a "positive" criterion rather than according to the absence of a predisposition to disease.[2]

The Swedish National Council on Medical Ethics (SMER), an advisory board to the government, has an important role in decisionmaking in bioethical issues. The Council is composed of representatives of the political parties and, in addition, expert members. When the Government committee finalized its documents, PGD/HLA had been rather extensively discussed in SMER, but the

Cambridge Quarterly of Healthcare Ethics (2008), **17**, 261–269. Printed in the USA.
Copyright © 2008 Cambridge University Press 0963-1801/08 $20.00
doi:10.1017/S0963180108080316

https://doi.org/10.1017/S0963180108080316 Published online by Cambridge University Press

Council had not yet come to a conclusion. The committee then chose not to make a recommendation before SMER had finished its deliberations. In the committee's report it was concluded that further deliberations were necessary on both the medical and the ethical aspects of the method. The role of SMER in these continued discussions was particularly emphasized.[3]

Following the usual procedure, the committee report was sent out for comments to concerned agencies and organizations. In its comment on the report, SMER announced that it had now concluded its discussions on PFD/HLA. The conclusion was that the method is acceptable in cases when it can save lives that could not otherwise be saved.[4] Based largely on this advice, the government proposed in its bill that PGD/HLA should be made available but only under highly restricted conditions. Each particular use of the method would require a permit from the National Board of Health and Welfare.[5]

At that time, Sweden had a Social Democrat minority government that was supported in Parliament by the Left Party and the Green Party. The opposition consisted of four more right-oriented parties, namely the Moderate Party (Sweden's conservative party), the Centre Party, the Liberal Party, and the Christian Democrats. Two of the opposition parties, namely, the Liberal Party and the Christian Democrats, submitted motions to parliament on the PGD/HLA issue. They both recommended Parliament to turn down this part of the bill. Their main worry was that the donors may come to experience that they were born with the purpose of saving another individual.[6] In the Parliamentary standing committee responsible for the bill, the Moderates joined forces with these two parties, so that a minority of three parties opposed the legalization of PGD/HLA. In their minority report they emphasized the "complete instrumentalization" of the newborn sibling that the introduction of PGD/HLA would give rise to.[7]

In the debate in Parliament, a member from the Left Party who had previously been a member of SMER took a very active role in defending this part of the bill. She pointed out that the issue had been discussed for a couple of years in SMER and claimed that it was now time for a decision. "The possibility of PGD/HLA puts us in a difficult ethical dilemma. But should we refrain from acting because the issue is difficult?" Similarly, a representative of the Social Democrats complained that the three parties opposing the new legislation asked for more time for deliberation without specifying what aspects were in need of more deliberation. In the end, the government's proposal was adopted by a majority consisting of the Social Democrats, the Left Party, the Green Party, and the Centre Party (which was not active in the debate).[8] The law permitting PGD/HLA has been in force since July 1, 2006.[9] With this Sweden became one of four countries that allow the method. The others are Belgium, the United Kingdom, and the United States.[10]

A couple of months later, Sweden had a general election in which the Social Democrat government was defeated. The previous opposition (the Moderates, the Liberals, the Centre Party, and the Christian Democrats) formed the new government.

In 2007, the first four applications to use the method were submitted to the National Board of Health and Welfare. To gain public support for their application, one of the families stepped forward in public and gave interviews in the media. Several daily papers contained headings such as "A brother or sister can

https://doi.org/10.1017/S0963180108080316 Published online by Cambridge University Press

save Felix," with pictures of the 4-year-old whose life could possibly be saved by a transplantation from a sibling.[11] It was emphasized in these articles that no other donor was available and that there was no other way to save his life than by such a transplantation. The boy's disease was adrenoleukodystrophy (ALD), a rare metabolic disease that causes damage to the myelin sheath of nerve cells. Two of the other cases were children with thalassemia major, a metabolic disorder that leads to the production of severely defective hemoglobin.[12]

Interestingly enough, most of the public debate on PGD/HLA did not take place in connection with the government's bill but with the first clinical cases to be tried by the National Board of Health and Welfare. Britt-Marie Frost, a clinician who herself performs bone marrow transplantations on children with thalassemia major, wrote two newspaper articles in which she criticized the new legislation. She expressed optimism about alternative treatments, including transplantations from nonrelated donors. However, her main argument was that it does not seem right to select a human being to be "as similar as possible to someone else."[13] In a reply to Frost, two other physicians—a geneticist and a pediatrician—defended the law. They pointed out that the method would probably only have to be used in very few cases, and claimed that children born after PGD/HLA will be just as much loved by their parents as other children. They also emphasized that nonrelated donors are not always available. The donor registers are dominated by persons from the Western world. "Many of the unusual diseases where PGD-HLA would be applicable are overrepresented among immigrants from poor countries." These patients often have a HLA that makes the probability of finding a donor smaller than for other patients.[14]

On May 28, 2007, the National Board of Health and Welfare announced that it had authorized the use of PGD/HLA in these three cases. (In the fourth case the Board had requested additional information before making a decision.) In its announcement of the decision, the Board pointed out that the requirements for a permit to use PGD/HLA include that no alternative treatment is available and that the course of the disease is suitable for the PGD/HLA methodology.[15]

Less than two weeks before the decision was announced, the new Minister for Health and Social Affairs, Göran Hägglund (Christian Democrat) said that he was against what he described as the "principle" of the new law, namely, that a person can be used as a means to save another person's life.[16] "If the decision were mine, this law would not have existed."[17] However, there are no signs that the new majority intends to change the law. Possibly, the newspaper articles about individual children whose lives can be saved by PGD/HLA may have made such a step more difficult to take.

Discontinued Treatment or Physician-Assisted Suicide?

Physician-assisted suicide is prohibited in Sweden like in most other countries. Now and then, Swedish media have reported about Swedes who have gone abroad, for instance to Switzerland, in order to end their lives. This seems to be one of the reasons why the Delegation on Medical Ethics of the Swedish Society of Medicine decided to revise their guidelines from 1991 on the discontinuation of life-sustaining treatment. In December 2006 the Delegation's chair, Professor Niels Lynöe, said to a newspaper: "We cannot export our problems, instead it

https://doi.org/10.1017/S0963180108080316 Published online by Cambridge University Press

should be possible to help the patients here, but this is not a matter of euthanasia."[18]

In March 2007, the revised guidelines were published. The major change as compared to the previous guidelines was a clear statement that decision-capable patients have a right to refrain from life-sustaining treatment. As examples of life-sustaining treatment the delegation mentioned "ventilator treatment, dialysis, nasogastric feeding (PEG) and fluid therapy but also treatment with antibiotics, insulin, and diuretics."[19] The central formulation of the new recommendations reads as follows:

> If a patient is decision capable, well-informed and understands the consequences of different treatment alternatives, then the physician should respect the patient's wish that life-sustaining treatment not be introduced or that treatment that has already been introduced be discontinued. This applies also in situations when the patient is not in the final stages of life and treatment could benefit the patient from a medical point of view. The physician should always offer adequate palliative treatment.[20]

The major reason given for revising the guidelines was the strengthening of patients' rights that was said to have taken place since 1991.[21] Although the guidelines have no legal impact, in public debates they have been taken to regulate what a physician may or may not do. In the medical press the discussion on the new guidelines has focused on two topics: the specific issue of when it is justified to turn off a ventilator and the more general issue of what it means to be decision capable.

The debate on the first of these issues was, in a sense, initiated by the Delegation's chairperson Niels Lynöe when he said in an interview that, under the conditions given in the guidelines, "a physician can sedate the patient and then turn off the respirator. This applies also to patients who are not in the final stages of life and where treatment could benefit the patient from a medical point of view."[22] He made it clear that he did not regard such an action—or any other action supported by the guidelines—as euthanasia or physician-assisted suicide. This is important not least because both euthanasia and physician-assisted suicide are illegal in Sweden. Lynöe reported that the Delegation had informally discussed the new guidelines with the National Board of Health and Welfare. Based on these discussions he was convinced that a physician acting in accordance with the guidelines would not be subject to disciplinary measures.[23]

In an article published a few weeks later, Lynöe described in somewhat more detail how the guidelines should be applied in the case of a patient depending on a ventilator for his or her continued life:

> If a decision-capable patient under ventilator treatment wishes help to discontinue the treatment, then it is also foreseeable that without palliative treatment the patient will suffocate. Therefore we consider it unethical not to offer such a patient palliative sedation.[24]

In the debate that followed, some critics claimed that such a procedure is, in fact, physician-assisted suicide. One of the most prominent critics is Thomas

https://doi.org/10.1017/S0963180108080316 Published online by Cambridge University Press

Flodin, chairperson of the Swedish Medical Association's Council on Ethics and Responsibility. (Sweden has two major physician's organizations. The Swedish Medical Association, with about 40,000 members, is in its own words "both the physicians' trade union and the organization of the profession."[25] The Swedish Society of Medicine, with about 18,000 members, describes itself as "the scientific organisation of the Swedish medical profession."[26] Members of the latter organization are typically also members of the former.) In an editorial in the Swedish Medical Association's journal *Läkartidningen*, the major medical journal in Sweden, Flodin concurred with the new guidelines concerning the discontinuation of dialysis or chemotherapy. However, he expressed severe doubts about the case in which a physician turns off a ventilator.

> The situation is different if the patient receives ventilator treatment and the physician administers sedating medicine in order to turn off the respirator with death as the expected consequence. Niels Lynöe, chairperson of the Delegation on Medical Ethics of the Swedish Society of Medicine, holds the opinion that in the latter case the physician is not guilty of euthanasia or physician-assisted suicide, but instead respects the patient's right to make his or her own decision. Without legal decisions and a clear statement by National Board of Health and Welfare it is difficult today to determine whether this is in contradiction to current rules and Swedish legislation.[27]

The editorial had the heading "No to physician-assisted suicide," and Flodin gave a brief summary of the common arguments against physicians helping patients to commit suicide: that life is inviolable, that there is a risk of misuse, that the public may come to distrust the medical profession, the irreversibility of the measure, the difficulties in determining the future course of a disease, and the risk that palliative therapy will be given lower priority. He also pointed out that physician-assisted suicide is prohibited almost everywhere, with the exception of Switzerland, Belgium, and the Netherlands.

As mentioned above, the guidelines were also debated from a more general point of view, with an emphasis on the notion of a patient being "decision-capable." Susanne Ringskog Vagnhammar, a psychiatrist specializing in suicide prevention, reacted against the new guidelines, claiming that they, in fact, endorse physician-assisted suicide. Her major criticism concerns the notion of decision capability. In her view, the delegation uses this concept in a way that reflects a "simplified, reductionist view of man, i.e. a view of man as an entirely rational being." To be truly decision capable, she said, an individual has to be not only rational but also psychologically capable, that is, in mental balance. Studies of terminally ill patients show that their will to live fluctuates over time.[28] Against this background, she said, the rationalist notion of "decision capable" is inadequate and may serve as an alibi rather than an adequate criterion for clinical decisionmaking. She also referred to cases in which patients who had previously wanted to die had later regained their will to live.[29]

In a reply to Ringskog Vagnhammar, eight members of the Delegation denied that the new guidelines favored physician-assisted suicide. "Respecting the patient's right to discontinue life-sustaining treatment with the foreseen consequence that the patient dies is not the same as helping a patient to die."

https://doi.org/10.1017/S0963180108080316 Published online by Cambridge University Press

Instead, a physician who does not discontinue treatment when the patient requires this may be breaking another law: "From a legal point of view there is no doubt that compulsory care is prohibited, with very precisely regulated exceptions."[30]

It is understandable that the legal category of physician-assisted suicide has played a major role in this discussion. If the new guidelines recommend physicians to take actions that fall under this category, then they recommend illegal actions. Surely, this is an issue that should not be taken lightly. However, it would be unfortunate if the discussion stopped there. Even if it turns out that the guidelines comply with national law, it does not follow that they are ethically defensible. And, conversely, if the guidelines are ethically commendable, then they may still be against the law, which would be an argument for changing the law.

Patient Safety

There is no doubt that patient safety is a basic responsibility for healthcare and for healthcare personnel. But how much personal responsibility does the individual professional have for mistakes or accidents that take place in a suboptimal organizational and technical environment? A tragic accident in a Swedish hospital in 2002 has given rise to an interesting debate on personal responsibility under such circumstances.

On May 19, 2002, a girl of three months died in a Swedish hospital after receiving a 10 times too high dose of the anticonvulsant Lidocaine (Xylocard®) in her infusion fluid. It turned out that the nurse who had prepared the infusion had used a solution with 200 mg/ml instead of one with 20 mg/ml. A forensic analysis of the dead baby's blood showed that it contained 43 μg Lidocaine/g serum whereas the therapeutic dose is <6 μg/g.

The hospital reported the accident to the National Board of Health and Welfare. This was mandatory according to a law from 1936 that requires the reporting of all events in which patients have been injured due to mistakes by medical personnel. Reports in the newspapers induced the chief district prosecutor to take up the case. In the district court the nurse was sentenced to a suspended sentence for manslaughter. The case was appealed twice and was finally decided in 2006 by the Supreme Court that sentenced her to a suspended sentence and fines for manslaughter.[31]

In a multi-author book published in early 2007, this case was one of the major starting points for a discussion of responsibility and safety in healthcare. The book's editor, Synnöve Ödegård, contributed a thorough analysis of the case, applying an accident investigation method that is used routinely for accidents in the industry and transport sectors. Such an analysis has its focus on finding both immediate and underlying causes in order to recommend how the same or similar types of accidents can be avoided in the future. In this it differs from a police investigation of the same event, because the latter type of investigation aims primarily at identifying persons who contributed to the event through actions that may have been illegal.

This analysis revealed a long list of organizational failures. The parallel use of two different concentrations of the same drug is a questionable practice, in particular as they were kept in the same cupboard. The two clinics between

https://doi.org/10.1017/S0963180108080316 Published online by Cambridge University Press

which the baby was moved, the children's clinic and the intensive care unit, had different routines for the preparation of Lidocaine infusions. One of them always used the solution with 200 mg/ml and the other that with 20 mg/ml. The prescription was given orally by the physician, and, as a consequence of this, the computer support for dose calculations was not used. The fluid record did not have enough blank space to write out prescriptions fully. Hence, in summary there was a long list of organizational and technical failures that contributed to the accident.

In her contribution to the book, AnnSofie Fyhr pointed out that Lidocaine has repeatedly been involved in fatal accidents.[32] A major reason for this is that the drug is available in two concentrations, 200 mg/ml and 20 mg/ml. To avoid such accidents, the higher concentration was deregistered in the United States in the mid-1990s. As a consequence of the accident, it was also deregistered in Sweden in 2006, 4 years after the accident.[33]

Several of the contributors to the anthology are researchers with experience from accident investigation and prevention in other sectors. One of them, Carl Rollenhagen, made the observation that in healthcare, discussions on risk and safety seem to be more oriented toward individual failures than in other sectors of society. This, in his view, can be a negative factor for the development of patient safety. "Sentencing individuals for mistakes, where a closer analysis shows that the work organization and its context were such that the probability of error is large, of course sends the wrong kind of signal on the development of patient safety."[34] Research from other sectors (in particular aviation and nuclear energy) has shown that individual behavior in safety-critical situations depends, to a large degree, on the workplace organization and culture. "It takes a lot for individuals to go against the group pressure that normally exists in an organization, and this can have consequences for safety."[35] According to Rollenhagen, the healthcare sector has been slow in assimilating the available knowledge about safety culture. Experience from other sectors shows that, to increase safety, it is necessary to change focus from failing individuals to failure-inducing organizational and informal structures on the workplace. (One possible example of this, in the case under study, is that the nurse accepted an oral prescription instead of asking the physician for a written one.)

In his contribution to the book, Tore J. Larsson, another safety researcher, described the medical subculture as based on a norm of infallibility that prevents the development of a modern structure for dealing with deviations and mistakes.

> The medical subculture has not developed organized and systematic learning based on events that give rise to mistakes that affect the patients in healthcare. Mistakes are denied, infallibility is the norm, and when information about incorrect actions reaches outside of the system, the consequence is individual penalties. Instead of accepting a scientific view on human dispositions and organizational processes, the medical subculture is characterized by magical thinking and a ritual belief in the superhuman infallibility of the medicine man.[36]

Like Rollenhagen, Larsson proposed the introduction of modern accident and incident investigation systems and a shift in focus from individual to organizational failures.

https://doi.org/10.1017/S0963180108080316 Published online by Cambridge University Press

Two legal scholars, Madeleine Leijonhufvud and Lisa Nilheim, criticized current Swedish legislation for placing responsibility on too low a level in the organization.

> Work practices that do not follow the safety instructions of the National Board of Health and Welfare are often accepted in healthcare. . . . Due to the weight of professional medical responsibility the responsibility for patient safety is placed on the professional who works closest to the patient. Management cannot in practice be held responsible for systematically developing patient safety. Therefore their responsibility has the same *quasi* character as patient rights.[37]

The general conclusions from the book can be summarized as follows: More emphasis should be put on preventing future accidents by organizational learning. In situations where individual mistakes take place in a suboptimal organizational and technical environment, the emphasis should be shifted from prosecution of individuals to improvement of the conditions under which they work.

In parallel with these discussions in the research community, the National Board of Health and Welfare has worked very much in the same direction. In February 2006 the Board proposed a reform of the Swedish system for reporting malpractice. This system dates back to the 1930s and requires that healthcare personnel report cases of malpractice to the National Board of Health and Welfare. According to this proposal, the report system should be strengthened by a requirement that reports be made within 7 days. On the other hand, the Board wanted to abolish the obligatory referral of such reports to the Medical Responsibility Board for consideration of disciplinary aspects. The idea behind this change is that reporting should be encouraged. However, the Board did not go as far as to propose a system for anonymous reporting.[38] (Such a system is in place in Britain, whose National Patient Safety Agency encourages anonymous reports.)

In April 2007, the government called a committee that will investigate these proposals. A probable outcome of this investigation is a new legislation on the prevention of malpractice and medical accidents.

Notes

1. Devolder K. Preimplantation HLA typing: Having children to save our loved ones. *Journal of Medical Ethics* 2005;31:582–6.
2. *Genetik, integritet och etik*. Statens offentliga utredningar, SOU 2004:20. Stockholm; 2004:292.
3. See note 2, *Genetik, integritet och etik* 2004:301, 305.
4. Regeringens proposition 2005/06:64 *Genetisk integritet m m*., Stockholm, pp. 99 and 102.
5. See note 4, Regeringens proposition 2005:100.
6. Socialutskottets betänkande 2005/06:SoU16 *Genetisk integritet m m*., Riksdagen [the Swedish parliament], Stockholm:15–16.
7. See note 6, Socialutskottets betänkande 2005:40.
8. *Kammarens protokoll* 2005/06:111, April 26, Riksdagen [the Swedish parliament], Stockholm.
9. *Lag 2006:351 om genetisk integritet m m*, §4:2.
10. Fasth A, Wahlström J. Val av syskon för att rädda sjukt barn etiskt försvarbart. *Dagens Medicin* 2007 Apr 12.
11. Lindqvist A. Syskon kan rädda Felix. *Aftonbladet* 2007 May 5.

https://doi.org/10.1017/S0963180108080316 Published online by Cambridge University Press

12. Nilsson J. Ja till gallring av embryon. *Dagens Medicin* 2007 May 28.
13. Frost BM. Har barn rätt att födas helt för sin egen skull. *Dagens Medicin* 2007 Mar 21. See also Frost BM. Lagligt att tillverka barn enbart för organdonation. *Dagens Nyheter* 2007 Mar 20.
14. Fasth A, Wahlström J. Val av syskon för att rädda sjukt barn etiskt försvarbart. *Dagens Medicin* 2007 Apr 12.
15. Socialstyrelsen. Socialstyrelsen har fattat beslut om en viss typ av genetisk undersökning. Pressmeddelande, 2007 May 28 [press release from the National Board of Health and Welfare].
16. Nilsson J. Socialministern kritisk till lag om skräddarsydda embryon. *Dagens Medicin* 2007 May 16.
17. Haverdahl AL. Ja till gentestat barn väntas i sommar. *Svenska Dagbladet* 2007 May 15.
18. Bondesson M. Fler får rätt att avbryta sina liv. *Svenska Dagbladet* 2006 Dec 18.
19. Etiska riktlinjer vid ställningstagande till att avstå från och avbryta livsuppehållande behandling. Svenska Läkaresällskapet; available at http://www.svls.se.
20. See note 19.
21. Örn P. Delegationen för medicinsk etik ändrar riktlinjerna. Beslutskapabel patient i respirator bör få läkarhjälp att avsluta sitt liv. *Läkartidningen* 2007;104(14–5):1120–1.
22. See note 21, Orn 2007:1120.
23. See note 21, Orn 2007:1120.
24. Lynöe N. Beslutskapabel patient bör ha rätt att tacka nej till fortsatt behandling. *Läkartidningen* 2007;104(17):1343.
25. Sveriges läkarförbund homepage; available at http://www.slf.se.
26. Svenska Läkaresällskapet homepage; available at www.svls.se.
27. Flodin T. Nej till läkarassisterat självmord! *Läkartidningen* 2007;104(32–3):2215.
28. Chochinov HM, Tataryn D, Clinch JJ, Dudgeon D. Will to live in the terminally ill. *The Lancet* 1999;354(9181):816–9.
29. Ringskog Vagnhammar S. Låt hittills rådande etiska bedömningar få fortsätta gälla. *Läkartidningen* 2007;104(28–9):2096–7, at 2096.
30. Eckerdal G et al. Etisk argumentation och klinisk verklighet kan med fördel förenas. *Läkartidnngen* 2007;104(28–9):2097–8, at 2097 and 2098.
31. Ödegård S, ed. *I rättvisans namn. Ansvar, skuld och säkerhet i vården*, Stockholm: Liber; 2007.
32. Edgar TA, Lee DS, Cousins DD. Experience with a national medication error reporting program. *American Journal of Hospital Pharmacy* 1994;51:1335–8.
33. See note 31, Ödegård 2007:175.
34. See note 31, Ödegård 2007:281.
35. See note 31, Ödegård 2007:281.
36. See note 31, Ödegård 2007:133–4.
37. See note 31, Ödegård 2007:103.
38. *Patientsäkerhet och tillsyn m.m.* Kommittédirektiv Dir, Swedish government; 2007:57.

https://doi.org/10.1017/S0963180108080316 Published online by Cambridge University Press