Bioethics in Sweden

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Sweden is probably one of the most secularized nations in the world. Therefore religious arguments tend to play a smaller role in the public bioethical debate than in most other countries. Issues such as abortion, stem-cell research, and therapeutic cloning have been far less controversial in Sweden than elsewhere. Instead, other issues have dominated recent bioethical debates in Sweden, in particular those concerning privacy and the control over biological information about individuals.

In this contribution, we focus on the latter type of issue. More specifically we recount two recent cases in Swedish biomedical research ethics, both of which have repeatedly been in the headlines as well as on the news. The first case deals with forensic uses of a large biobank containing biological material from virtually everyone born in Sweden since 1975. The second concerns access to a large research archive collected for studies of neuropsychiatric disorders.

The Rights of Research Subjects versus the Administration of Justice

The PKU biobank, kept in a cold-storage room at Huddinge University Hospital, consists of some 3 million blood samples, taken from almost every baby born in Sweden since 1975. The samples are collected to scan newborns for phenylketonuria (PKU) and four other serious hereditary conditions for which early diagnosis is crucial. In addition to blood samples, the biobank also contains information from the mother's medical record.

On January 1, 2003, a new biobank law came into force in Sweden.[1] Described as the strictest biobank law in the world, it regulates how and for what purposes tissue samples may be collected, accessed, and handled. Its promoters argued that a uniform national policy was required both to protect privacy and to prevent commercial takeovers of biobanks.[2] The wording of the law restricts the usage of the PKU biobank to the diagnosis of metabolic disease, retrospective diagnosis of other diseases in individual children, epidemiological and clinical research, and evaluation studies.[3]

The new law was not welcomed in all quarters. Some researchers and patient organizations expressed worries that the consent requirements in the new law would stifle research.[4] However, although other parts of the law gave rise to controversies, the restriction of the PKU biobank to clinical and research purposes seems to have been rather uncontroversial at that time.

At 4:14 p.m. on September 10, 2003, a violent knife attack in one of the central department stores in Stockholm was reported to the emergency service

Cambridge Quarterly of Healthcare Ethics (2006), **15**, 285–293. Printed in the USA.

center. A few minutes later the police on the scene realized that the victim was the Minister for Foreign Affairs, Anna Lindh. She was brought to the emergency unit of the Karolinska hospital, but her life could not be saved. At 5:29 the following morning she was pronounced dead.

On September 22, representatives of the police arrived at Huddinge University Hospital. Armed with a permit signed by the chief prosecutor, they requested the PKU biobank blood sample of a 24-year-old man, Mijailo Mijailovic, who was suspected of having committed the murder. The police already had a partial DNA profile of Mijailovic but needed the PKU sample to verify that it matched traces from the scene of the murder, including the murder weapon. The PKU sample was handed over to the police and the subsequent forensic analysis confirmed that the samples were, indeed, identical. During the trial, which took place in January 2004, Mijailovic pleaded guilty and was convicted.

The forensic use of Mijailovic's PKU biobank sample soon leaked to the press and received massive media coverage. The hospital was publicly criticized by Mijailovics' lawyer and numerous other public figures, including the chairperson of the Parliamentary Standing Committee on the Administration of Justice.

Initially, representatives of Huddinge University Hospital refused to disclose whether or not they had handed over a blood sample to the police.[5] It was not until 25 October 2003 that a police spokesman confirmed that the blood sample had, in fact, been released by the hospital. A representative of the hospital claimed that they were authorized to release samples that were needed for the investigation of serious crimes. Indeed, blood samples had been given to the police on three separate occasions, all of which were connected to murder investigations.[6]

The hospital's reading of the law was rejected by the National Board of Health and Welfare. Their legal department claimed that the law enforcement agencies had broken the law when requiring a sample from the PKU biobank, and commented "The law is unambiguous; the blood bank is not intended to be accessible to crime investigations."[7] The Board's Director General, Kerstin Wigzell, declared it a matter of maintaining public trust. However, the Board was not unanimous. Birgitta Rydberg, one of its 11 members, proposed a change in the law to ensure that PKU samples could be used in investigations of serious crimes such as manslaughter. "We cannot have murderers, who constitute a threat to other people, walking around in the streets."[8] In response to the concerns voiced by the Director General, she claimed that forensic use of the samples would neither erode the public's trust in biobanks nor make parents more likely to refrain from testing their newborns. "I do not believe that parents see their own child as a future murderer."[9]

The National Board of Health and Welfare launched an investigation into the release of Mijailovic's blood sample. By now the hospital claimed that what had actually taken place was not really an instance of the hospital voluntarily handing over a blood sample to the police but rather an instance of confiscation by the police. The hospital's legal representative claimed that because such seizure is regulated in the Rules of Legal Procedure, it has priority over the Biobank Law. "If a more restrictive interpretation is desired in the future, the law must be changed. It is our opinion that the National Board has nothing to investigate."[10]

On December 5, the National Board of Health and Welfare concluded that because the rules were unclear, the hospital had committed no crime and would therefore not be subject to a reprimand. The Board did, however, make a comment to the effect that the hospital could well have been somewhat less complaisant to the police. Citing the two conflicting laws involved, the Board then handed over the affair to the government. They proposed a review of the legislation in order to preserve public trust in biobanks and suggested a clear hierarchy where the Biobank Law would enjoy a higher priority than the Rules of Legal Procedure in cases of conflict. By that time, however, the Minister of Health and Social Affairs, Lars Engqvist, had already declared that he was prepared to tighten the Biobank Law if that was needed to prevent forensic uses of the PKU bank and other biobanks. "These archives should only be used for research purposes. They are not police records, nor a register for solving social problems."[11]

In the wake of these discussions there was a sharp increase in withdrawals from the PKU biobank. In 2003, up until the murder (which took place on September 10), only 17 persons had asked to be removed from the biobank. Between November 2003 and October 2004, a total of 445 persons demanded that their data be erased. (No reason has to be given by the individual who wishes to have his or her sample removed.)

About one year later, the PKU biobank again made front-page news. This time, however, the background was not crime, but a natural disaster.

In the morning of December 26, 2004, a gigantic tsunami swept in over northern Sumatra, Sri Lanka, and the west coast of Thailand. Five hundred forty-three of the victims were Swedish nationals, mostly tourists on the Thai coast. This was a national trauma, directly touching the lives of 4 out of 10 Swedes.[12]

The taxing identification process started shortly after the disaster. Dental records and other types of information that could facilitate identification, for example, DNA samples from close relatives, were gathered from the families of those reported missing. At this early stage no move was made to use the PKU biobank. On December 30 the Director General of the National Board of Forensic Medicine, Ulf Westerberg, commented that "the problem is not to receive material from close relatives, and I do not now see that the PKU register would help us very much. We will have to discuss this if such a need arises, but we are not in that situation yet."[13]

It did not, however, take long for that situation to come about. Many of the victims were children for whom no dental records were available, and the hope was that the PKU biobank could be used to identify them. As the law did not allow this, a committee was appointed to swiftly draft the necessary changes in the Biobank Law. The chair of this committee, Ingrid Burman, emphasized that the purpose was to use the PKU biobank only for identifying victims of exceptional accidents, not, for instance, victims of traffic accidents. According to the new law, passed on January 8, 2005, the National Board of Forensic Medicine and the National Swedish Police Board are both authorized to access samples from the PKU biobank for identification purposes after accidents with a large number of victims. It should be emphasized that because the samples have not been analyzed for that purpose, it is not possible to match DNA from an unidentified body against the whole PKU register. A body has to be tentatively identified with other methods before a sample from the PKU biobank can be used to confirm or disconfirm the proposed identification.[14] This is a temporary legislation; it only holds until the end of June 2006. The

National Board of Health and Welfare has produced a rather comprehensive report on the current Biobank Law, which is now under consideration by the Government.

In the debate caused by the use of the PKU biobank for the identification of Anna Lindh's murderer, it was frequently argued that although a biobank for forensic purposes would have been useful, a biobank collected for medical research should not be used for that purpose. In November 2004, the former National Police Commissioner, Björn Eriksson, and a leading law professor, Madeleine Leijonhufvud, wrote a joint article where they proposed the construction of a nationwide forensic DNA biobank containing samples from everyone who either resides in or was born in Sweden. This would be a highly efficient tool in law enforcement, it was argued. In addition, they defended the position that a nationwide register is less ethically problematic than a restricted one—as the latter is only adding extra punishment for those who have already been sentenced to imprisonment. The article authors also argued that if such a register had been in place, the identification of the tsunami victims would have been far easier.[15]

The government, however, was not in favor of such a complete forensic databank. The Minister of Justice, Thomas Bodström, said that "we have to be careful with gigantic registers. We should not have more registers than what is necessary. Further, it is uncommon that persons who commit serious crimes have not previously committed less serious ones."[16] Instead, the Government put forward a bill according to which the collection and storage of DNA samples was subject (only) to the same conditions as those for taking and storing a fingerprint. In practice, this means that the already existing police DNA register will be extended to include everyone who has been under arrest or in custody for a crime that could result in imprisonment. (Previously the register only contained samples from individuals sentenced to a minimum of 2 years' imprisonment.[17]) It has been estimated that this will increase the number of DNA samples in the forensic register from 3000 to approximately 200,000. Furthermore, the police will be authorized to collect DNA samples from persons who are not themselves suspected of a crime, if these samples can be used to facilitate the investigation. The government bill based on this proposal is currently in the process of being finalized.

The Rights of Research Subjects versus the Freedom of Information

Since the 1980s, professor Christopher Gillberg's group in Gothenburg has been recognized among colleagues as leading investigators of hyperkinetic and other related disorders in children. They have based much of their results on longitudinal studies of patients with what is now commonly called ADHD, attention deficit/hyperactivity disorder. In Sweden, the related term DAMP, deficits in attention, motor control, and perception, is commonly used. It was introduced by Gillberg and is defined as the combination of ADHD and DCD, developmental coordination disorder.[18]

Psychiatric research is often controversial, not least if it focuses on neurobiological hypotheses and theories. There is a fairly strong tradition in Sweden of criticism against neuropsychiatric diagnoses and psychopharmacological treatments, and in the past decade, Gillberg has been the primary target of much of this criticism. In 1997, pediatrician Leif Elinder wrote an article in *Läkartidnin-*

gen, the major Swedish medical journal, criticizing the DAMP diagnosis and claiming that it was applied indiscriminately to patients whose condition was cultural or social rather than biological.[19] In 2000, sociologist Eva Kärfve published a book highly critical of the DAMP concept and Gillberg's research in general.[20] Like Elinder, she claimed that these children have problems that are caused by social rather than biological causes.

Kärfe's book was vehemently criticized by outspoken parents of children with a neuropsychiatric diagnosis. They accused her of not understanding the children's problems. Her claims that these conditions have social causes were said to reinforce prejudices that put the blame on the parents. An attempt was even made to have her prosecuted for agitation against a minority, but because the mentally handicapped are not among the groups protected by the relevant law, the case was immediately dismissed.[21]

Both Elinder and Kärfve directed much of their criticism at Gillberg's so-called Gothenburg study, in which children have been followed from 6 years of age to adult age.[22] The study is based on extensive collection of information about all aspects of the patients' lives, including sensitive aspects such as sexuality, learning difficulties, criminality, and psychiatric records. Both Kärfve and Elinder claim that there are irregularities in the published reports that give them reasons to believe that the reports are fraudulent.

In early 2002, Kärfve and Elinder wrote separately to Gothenburg University, demanding an investigation of possible fraud in Gillberg's research. The case was referred to the ethical review committee of the medical faculty. After studying the case, the committee concluded that there was no ground for the accusations.[23] At that stage, Kärfve and Elinder took an unusual step: They invoked the Swedish Freedom of Information Act and demanded access to Gillberg's research records. This was possible because Gothenburg University, like almost all Swedish universities, is a Government institution and because Sweden has a far-reaching legislation guaranteeing the public's free access to official documents unless secrecy is needed to protect important interests.

In September 2002, the University denied Kärfve and Elinder access to the research records, because these contain sensitive information about individual patients. The two critics both appealed to the Administrative Court of Appeal. In February 2003, the Court reversed the University's decision. According to the Court, Kärfve had shown "that she has a justified interest in access to the material in question" and was therefore granted access to it. Individuals mentioned in the material could be protected either by deidentification or by an order to Kärfve not to disclose information about identified persons.[24] In a parallel decision, the Court granted Leif Elinder similar rights.[25] The University was ordered by the court to make the documents in question available to Kärfve and Elinder. It was left to the University to decide on the exact conditions that were needed to protect the interests of the individuals from whom these data had been collected.

In April 2003, the University's vice-chancellor informed Kärfve and Elinder of these conditions. The two most noticeable conditions were that Kärfve's research project would have to be approved by the ethical review committee and that each concerned individual would have to consent before documents about her or him could be read by Kärfve and Elinder. It is probable that the latter condition would have efficiently prevented access to large parts of the material, because the patients and their parents tend to be highly critical of

Kärfve and Elinder. According to Gothenburg University, by August 2003, approximately 80 persons whose files were in the material had approached the University and expressed strong aversion to the prospect of the two critics reading their files.[26] It is therefore not surprising that neither of the two critics accepted these conditions. Again, they appealed to the Administrative Court of Appeal, and again, their appeal was successful. In August 2003, the Court reversed most of the conditions laid down by the University, including the conditions of individual consent and approval by an ethical review committee.[27]

After this court decision, the vice-chancellor ordered Gillberg to make the research records available to the University administration by handing over the key to the archive where it was kept. Gillberg refused to do so, claiming that he had to follow the principles of medical ethics. After his refusal the vice-chancellor took no further action. According to what he said later, he considered the possibility of asking for police assistance to access the archive with the help of a locksmith, but refrained from doing so because such drastic measures could endanger the University's reputation.

In parallel to these legal procedures, heated debates had been going on in public media for several years. Prominent academics took part in the discussions, primarily medical researchers in favor of Gillberg and social scientists in favor of Kärfve. The Court's decisions were, of course, welcomed by Kärfve's supporters, but rather bitterly regretted in the other camp. In one article 12 Swedish medical researchers claimed that the Freedom of Information Act was not intended for the release of sensitive research records and that Kärfve had misused this law by using it for purposes other than those for which it was meant. In cases of suspected misconduct in research, they said, established procedures should be used. "The persons who raise the accusations cannot also be judges, and the evaluation must be made by scientifically respected experts." They also warned that the ADHD/DAMP discussion followed a pattern from previous politicized debates on adult psychiatry "that for decades delayed the introduction of scientifically based treatments for several patient categories."[28]

The Press Complaints Commissioner, Olle Stenholm, wrote an article in which he supported the Court's decision. He said: "It is a misunderstanding that it should be against the original purposes of the Freedom of Information Act that it also covers research. The principle of access to public records is a tool to control public power. Research conducted in government institutions is part of this power."[29]

However, in spite of the Court's decision, Kärfve and Elinder were never to see the records of Gillberg's longitudinal studies. During May 7–9, 2004, three of Gillberg's closest coworkers destroyed all the material, 22 running meters of documents, in a paper shredder. The three (one of them Gillberg's wife) did this when Gillberg himself was in London. In a letter to the vice-chancellor, they reported that Gillberg was informed of the destruction only after it had taken place. One of them said to a newspaper: "We had no choice. It was not possible for us to hand over this material to unauthorized persons. We had promised the children and their parents full secrecy. This is a matter of ethics, not law."[30]

The documents were gone, but the legal battle continued. In January 2005, Gillberg, the President of Gothenburg University, and the Chairman of the

University Board were put on trial for obstructing the court orders to make the documents available to Kärfve and Elinder. At the trial, Gillberg said that after the pubication of Kärfve's book, he had been the victim of media campaigns that were impossible to defend oneself against. He had spent about 80% of his work hours in the last 5 years on the conflict. His legal situation had been impossible. If he had given the critics access to the material, he would had been put on trial by the parents. If he refused access, he would also be prosecuted, and this had now happened.[31] His motive for refusing access to the material was ethical. Because he had promised the patients and their parents that no one besides the researchers would be given access to the material, he was under an ethical obligation to protect their privacy.

At the trial, several researchers testified in favor of Gillberg's standpoint that it would have been unethical to comply with the previous court orders. Martin Ingvar, professor in neurophysiology at the Karolinska Institute, said that it is "absolutely clear that such a material cannot be handed out. The privacy of the subjects prevails over all other considerations." Likewise, Carl Gerhard Gottfries, a retired professor in psychiatry from Gothenburg University, said that he would have acted in the same way as Gillberg.[32]

Gillberg was also strongly supported by parents of children with neuropsychiatric disorders. Two organizations for patients and their parents organized demonstrations in favor of Gillberg, both in Gothenburg and in Stockholm, at the time of the trial. One of these organizations wrote in a press release that they "fight for the right to secrecy in connection with medical research projects. We see it as self-evident that a person who participates in a research study should be guaranteed the same secrecy as patients in healthcare."[33]

The court found all three defendants guilty of breach of duty, for not having followed previous court orders to make the research material available to the critics. Gillberg was sentenced to a fine and probation, the other two to fines.

Conclusions

The two cases have much in common. In both of them, bioethical principles and arrangements for privacy protection were nullified when access to research data was requested for purposes other than the medical research for which they were collected. In both cases, the ethical review system turned out to have a weak status in relation to the legal system. In the second case, it is particularly interesting to note that the Court of Administrative Appeal nullified the decision by Gothenburg University to require individual consent and approval from an ethical review committee before giving access to sensitive data on individual research subjects. These are two of the cornerstones of the scientific community's own system for protecting research subjects.

Although these episodes both occurred in Sweden, we see no reason why similar events could not take place elsewhere. We propose that the medical ethics community has at least four important lessons to learn from these experiences.

1. When regulating uses of medical information, it is necessary to proactively consider possible future pressures for nonmedical uses, such as various types of legal and forensic investigations, nonmedical research, investigations of scientific misconduct, or perhaps even crime in the

research institution, commercial applications, and so forth. In both the cases we have reviewed, there was a lack of foresight in this respect.

2. The legal status of ethical review committees and their decisions needs to be clarified and probably in many cases strengthened. (This has recently been done in Sweden. Since January 1, 2004, ethical review is legally required, and the review committees have official status.) There is a similar need to clarify the status of committees for the investigation of scientific misconduct.
3. Researchers and ethical review committees should be more careful than what they have usually been with how promises of secrecy are expressed. It is common to promise that only the researchers conducting the particular study will have access to the data. If this promise cannot be legally upheld, it will have to be adjusted accordingly. Even more important, it should be in society's interest to adjust the legislation so that strong promises of secrecy can be both given and upheld.
4. In our second case, the law according to which research data had to be released was a Freedom of Information Act that only applies to Government institutions. We are not aware of any reasonable argument why patients and research subjects should have less privacy protection in governmental than nongovernmental healthcare and research. Freedom of Information Acts and other relevant legislation should be reconsidered to ensure that the privacy of patients and research subjects is equally protected irrespective of who owns the clinic or the research institution.

Notes

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