AM 53012-15 (5000-K675951-15)

Background

During the period of June 2011 – July 2013, four transplants with synthetic trachea were been carried out at Karolinska University Hospital (below referred to as KS) in Stockholm on three different plaintiffs. All of the plaintiffs have passed away after being hospitalized and have been cared for during a majority of the time after the operations. The first plaintiff was operated on at the ÖNH clinic in Huddinge while the other two underwent surgery at the thoracic clinic in Solna.

The preliminary investigation

On April 14 2015 the Medical Products Agency filed a police report of a violation against the medicinal products act (1992:859). According to the report, permission had been required in part for performing the operations and a clinical trial and in part for manufacturing drugs for advanced therapy, since the synthetic tracheas are considered drugs. On 4 June 2015 the Health and Social Care Inspectorate (below referred to as IVO) filed a police report on violation of the law (2003:460) on ethical vetting of research on humans. In the report, IVO argued that the transplants using synthetic tracheas are to be regarded as research, for which there is no approved medical vetting. It has been established that permission according the medicinal products act had not been applied for and that no ethical vetting had been made. However, on 19 August 2015 the preliminary investigations were dropped because the crimes were barred.

However, a preliminary investigation was opened on June 3 2015, initiated by a prosecutor, for causing another's death, felony and causing bodily harm, felony, in one case. These crimes have a statute of limitation of ten years. The reason for classifying this as a case of causing bodily harm is that one plaintiff was still alive when the preliminary investigation was opened. However she passed away in 2017. As will be evident in this decision, the preliminary investigation has included the issue of responsibility for causing another's death or causing bodily harm concerning all plaintiffs.

The preliminary investigation consists of extensive material. An essential part consists of the plaintiff's medical records from KS and from their respective care facilities in Iceland, the USA and in Turkey. In addition to that there are several bronchoscopy images/films. Additional written information among other things consists of the investigation conducted by the Karolinska Institute regarding possible misconduct in research, including special investigator professor Bengt Gerdin's statement, Kjell Asplund's report "the Macchiarini case", Sten Heckscher's report "The Karolinska Institute and the Macchiarini case" and statements that have been collected from the National Board of Health and Welfare's legal counsel (below referred to as the Legal Counsel). In addition to this, a very large number of emails and an operation film have been collected.

Around 80 people have been questioned in this case as informers, plaintiffs or witnesses. Inquiries have been held in Iceland, the USA, Turkey, Belgium and England. The majority of these inquiries have been conducted by Swedish police with a Swedish prosecutor present. The preliminary investigation has also included the issue of whether there is a possibility that if charges are made KS should be charged with paying a corporate fine. The preliminary

investigation has also mapped out how the foreign plaintiff's medical care has been financed. PM has been questioned and has been informed that he is suspected of causing another's death, gross felony or causing bodily harm, gross felony.

The basis of the preliminary investigation has been to, from a criminal liability perspective, review the four operations and clarify if anyone can be charged with criminal liability for what has occurred.

According to information, the same operation method that has been used at KS has also been used by PM abroad. Operations in other countries cannot be included in the preliminary investigation that is being conducted in Sweden, with regards to chapter 2 of the penal code (1962:700) (below referred to as BrB).

General bases for the legal assessment

Science and tried and tested experience

According to chapter 6 § 2 of the Swedish Patient Safety Act (2010:659), medical staff is responsible for performing their work in accordance with scientific and tried and tested experience. Medical staff who does not meet this requirement may be criticized by the Health and Social Care Inspectorate and have their authorization revoked. In certain cases, medical staff may be criminally liable. However, science and tried and tested experience is not an unambiguous concept. All medical care is not built on research; instead some treatments have grown through experience with positive results. The first time a new treatment method is used on a human being it is obviously not tried and tested.

Although all medical care should be as safe as possible, new treatment methods may include risks. A basic question for whether a new method is acceptable to use is among other things to consider the risks and benefits for the patient. If the patient has a short survival expectancy without any treatment, untried methods may be easier to defend. However if the situation is not that acute but if instead the goal is to achieve less suffering or to prolong the patient's life, there are higher demands of carefulness before you use an untried method.

Who can objectively be criminally liable for operations at a hospital?

The responsibility for a completed operation has in each case been the surgeon who is the so called head surgeon during the operation. The chief of staff has an overall responsibility to ensure that the medical care is safe for patients.

Prerequisites for criminal liability in cases of negligence

In order for someone to be found liable for actions equivalent to chapter 3 §§ 7 and 8, BrB requires that this person has acted negligently. The assessment should be based on a normal carefulness standard. Each step away from this standard does not mean criminal negligence. The actions need to be regarded so reprehensible that it could be considered criminal negligence in an overall assessment, see NJA 2006 p. 228. The superior court (below referred to as HD) has in the same case found that a risk-filled operation generally has a higher need for carefulness

than any other operation. Since the preliminary investigation in question pertains to gross felony (not crimes of a normal degree that are barred) the action needs to include a deliberate risk-taking of a serious degree.

Causing bodily harm and causing another's death are so called effectual crimes, meaning that in order for a person to be liable the erroneous action or the failure to take the proper actions must have caused the effect. The action must have been negligent in relation to the effect itself, i.e. the fatal outcome or the injuries.

The healthcare industry is a risk-filled field and therefore, as mentioned above, there are high requirements placed on doctors and other medical staff. At the same time, when making an assessment of an action one needs to base it on the situation that existed at the time and on the information that existed at the time. In addition, many actions that are taken in healthcare are not characterized as right or wrong. Instead, they are assessments and considerations that are made in the moment and here there has to be a certain amount of latitude. An assessment or action that in hindsight appears to have had a negative consequence or has perhaps even been erroneous is not necessarily negligent.

Prerequisites for assessment on a case causation

Liability for causing bodily harm, gross felony, and causing another's death, gross felony, assumes that the perpetrator has caused the injuries or the fatal outcome through the actions taken.

In addition, a trial should be made regarding what the outcome would have been if one had replaced what actually happened with the correct action. According to NJA 2007 p. 369, the effect – bodily harm or death – should to a degree of probability not have occurred if the correct action had been taken. If it appears highly probable that the effect would not have not have occurred it is a case of relevant causation. A comparison should be made between the actual outcome of the operations and the hypothetical outcome of other treatment methods.

Thus, HD's precedent entails significant difficulties to prove negligence of this nature, since it is the prosecutor's task to prove that the effect (death or injury) would to a high degree of probability not have occurred if one had used a different method.

Legal assessment

Was the method compatible with science and tried and tested experience?

The investigation shows that none of the plaintiffs were in what would have been viewed as an acute situation. However, all of them were in such critical conditions that treatment within a relatively near future would have been necessary.

The method used in the operations was an entirely new technology with tracheas manufactured from synthetic material which prior to being operated into the plaintiffs were prepared with stem cells which had been extracted from their bone marrow. Certain growth preparations were added to the implant.

This appears to be a case of further development of a method where decellularized donated tracheas were used with a similar approach. There were several reasons for developing this method. With donated tracheas there was a problem with strength. In addition to this, one wanted a quicker process independent of donators with the possibility of customizing implants for patients.

Animal testing to support the use and function of the synthetic tracheas was not performed before the operations. There are no indications that the method of using a synthetic trachea worked as intended on any of the plaintiffs.

An overall assessment of what has emerged in the investigation shows that the method, at the time of the operations and in general, has not been compatible with science and tried and tested experience. However, to act against science and tried and tested experience is not sufficient to warrant criminal liability, since the actions taken need to have been negligent and it should also be a case of causation, as described above.

Who may be held criminally liable?

The investigation shows that in each case, PM was responsible for the performed operations as he was the head surgeon.

Has PM acted negligently?

What has been found does not cause reason to question the fact that the main argument for performing the operations was to give very sick people the possibility of being cured in a situation where doctors assessed that there was no other treatment available. Thus, the goal has been to help the patients.

Under the headline *prerequisites for criminal liability in cases of negligence* above it is explained that many actions taken in the healthcare field cannot be characterized as right or wrong, and that in the assessments and considerations made at the time there needs to be some latitude. Furthermore, one must in a hindsight assessment look at the situation as it was at the time being. This approach is significant to the review of the medical assessments that have been made of the plaintiff's condition and the treatment alternatives that were considered possible.

Regarding the use of synthetic tracheas the situation is of a different nature. In situations with elevated risk levels, such as the use of unproven treatment methods, the need for carefulness increases as the stakes get higher. A stricter assessment must be made. The actual treatment method was unproven and there was a lack of sufficient scientific support. As mentioned, animal studies had not been performed. PM had good information about the research situation. Furthermore, the investigation has shown that it was not entirely evident to any of the persons in what way the transplanted synthetic tracheas were actually going to be developed. The fact that there was faith and hope in that this method would work cannot motivate that it was clinically used at such an early stage.

Also, the operations meant that the plaintiffs would be put in a particularly difficult situation if the synthetic trachea did not work. If one removes the implant the patient dies unless it is possible to perform extensive high-risk surgery and succeed at it in any of the cases.

There is no doubt that the use of synthetic tracheas has been negligent and that is has entailed a deliberate risk-taking of a serious nature. This is negligence that throughout a series of operations has also increased along with the continued absence of positive results, in part with the occurrence of negative findings.

Is there causation between PMs actions and the plaintiff's injuries or death?

This trial is conducted for each plaintiff as follows. By way of introduction one should point out that all plaintiffs were very sick with serious illness related conditions in and around the airways. The medical treatment that their conditions required and what treatment methods that were possible and available differ from patient to patient. However, that all plaintiffs' clinical profiles made it very difficult for medical staff to make assessments is obvious.

Plaintiff 1

The plaintiff came to KS from Iceland because of a suspected cancer relapse. It has been established that no tissue samples were taken to confirm the cancer prior to the operation. The number one reason appears to be that one did not want to risk him hemorrhaging again, which might have been life threatening. However samples taken after the operation did verify a relapse of the plaintiff's earlier cancer.

The cancer type that the plaintiff suffered from is rare and is considered to be slow growing. Considering the fact that attempts to cure this cancer had been previously made in Iceland and that it had now relapsed indicated some aggressiveness and one could not rule out metastasis. Because of this it was necessary to treat the plaintiff as soon as possible.

The plaintiff died just under three years after the transplant from complications that in time arose as a consequence of the operation. There was information that suggested that the plaintiff was in relatively good health at different times after the operation. The legal counsel has pointed out a number of treatment methods that should have been examined as alternatives to the performed transplant. However, information in the investigation indicates that these alternatives were not possible, in part because they were not medically possible, and in part because they were not available alternatives considering the time frame. In all events they would have been difficult operations with a high risk.

Plaintiff 2

The plaintiff came to KS from the USA. In order to take the necessary samples with the purpose of assessing the possibilities of radical curative surgery, one had to open up the sternum to take samples. The legal counsel is of the opinion that these samples showed that the cancer was growing distally in both bronchi, which is why it was not possible to radically remove the tumor.

The plaintiff's cancer at the time of the operation had according to the legal counsel developed so much that successful curative treatment was no longer possible, and the operation that had been started should have been stopped. Instead of the surgery the best cure for the plaintiff would have been palliative efforts according to the patient's needs. The legal counsel cannot

say how long the plaintiff could have had left to live. He passed away approximately three months after the synthetic trachea was transplanted.

Plaintiff 3

The plaintiff came to KS from Turkey. Her medical condition posed a particularly difficult situation according to the legal counsel. The damages to her airways in combination with a thoracic cavity infection that was hard to treat meant that life-threatening complications could arise at any time.

Her medical records do not reveal whether any multidisciplinary treatment conference was held prior to her surgery on August 7 2012. There are many indications to suggest that such a conference was never held. Information in the investigation shows that alternative treatment methods were never discussed. The legal counsel suggests that other alternative methods should have been considered, especially considering the risks that are associated with using a synthetic material in an already infected area. Before the plaintiff's second operation on July 9 2013, a multidisciplinary treatment conference was held and it appears that PM was at that time considering and examining the possibility of using a different method. Even though a multidisciplinary treatment conference was held, yet another transplant using a synthetic trachea was performed.

With regards to the fact that PM prior to both operations must have known about the complications that had affected the first two plaintiffs, it is remarkable that the method of using synthetic tracheas was chosen again.

It is clear that both transplants have caused the plaintiff a number of serious injuries which have entailed a great deal of suffering, physically as well as psychologically. The legal counsel points to a number of possible actions that should have been considered as alternatives, while it also notes that there was no obvious curative treatment method. Information in the investigation also indicates that these alternatives were not possible, in part because they were not medically possible, and in part because they were not available. It further appears that the methods mentioned entailed extensive surgery with significant risks of complications.

DECISION

Plaintiff 1

It is not possible to prove that other curative actions would with a high degree of probability have lead to the plaintiff not passing away or even living longer. Furthermore, it appears that one cannot rule out that the plaintiff would have lived longer than what he did had only palliative efforts been made. In light of these circumstances it is not possible to prove a case of causing another's death, gross felony.

The information available in the investigation does not prove that the plaintiff would in all probability have suffered less with a different treatment method or palliative efforts. In light of these circumstances it is not possible to prove a case of causing bodily injury, gross felony, either.

As a result of the above mentioned, the preliminary investigation will be closed.

Plaintiff 2

An autopsy of the plaintiff has not been made and thus the cause of death has not been established. Therefore it is not possible to verify that the operation caused the plaintiff's death. Since causation cannot be established it is not possible to prove a case of causing another's death, gross felony.

Furthermore, information has emerged that indicates that opening the sternum may bring about complications. Therefore it is not possible to prove with a degree of possibility that the injuries and complications that actually affected the plaintiff would have failed to occur if the transplant had not been done. In light of these circumstances it is not possible to prove a case of causing bodily harm, gross felony, either.

As a result of the above mentioned, the preliminary investigation will be closed.

Plaintiff 3

It is not possible to prove with a high degree of probability that the plaintiff would have been alive today or that her complications would not have occurred if one had used any alternative treatment. In light of these circumstances it is not possible to prove a case of causing another's death, gross felony, or causing bodily harm, gross felony.

As a result of the above mentioned, the preliminary investigation will be closed.