

## **AM 53012-15 (500-K195009-16)**

### **Background**

#### *Preliminary investigation*

Preliminary investigation regarding bodily harm, felony, has been carried out due to an operation that was performed on May 24 2011. The plaintiff claims he after the operation, which entailed that a part of the trachea was removed, lost a large part of his eyesight and ability to swallow. In addition to this his sense of balance and motor skills were also affected. The operation was performed at Karolinska University Hospital (below referred to as KS) in Huddinge.

The basis of the preliminary investigation has been to review a chain of events that consists of the operation and the subsequent medical care, with the object of clarifying whether anybody is criminally liable for what has occurred.

The preliminary investigation material consists mainly of the plaintiff's medical records from KS and of inquiry information from the plaintiff and doctors who have treated him or come in contact with him in other ways.

The National Board of Health and Welfare's legal counsel has submitted a statement in this case. We have also received information from a Lex Maria report submitted by KS.

PM has been informed that he is a suspect and has been questioned.

#### *The plaintiff's medical condition*

The investigation has shown that the plaintiff has a rare and complicated condition with several changes in the trachea and throat region as well as sleep apnea. He has been treated for an excess of mucus in the area in question several times and has also undergone other operations to decrease his problems, which is primarily his breathing. In order to secure his respiratory tract, a tracheotomy was performed in April 2010. Inquiries have shown that the plaintiff wished to remove the tracheostomy. The plaintiff's trachea was deformed and blocked, something that may partly have been due to an enlarged thyroid which may have been pushing on the trachea.

#### *The operation*

In the operation on May 24 2011, PM was one of several surgeons. The material available shows that the purpose of the operation was to remove the damaged part of the trachea in order to facilitate breathing, which would also mean that the tracheostomy could be removed. Possibly the part of the thyroid that was pushing on the trachea would also have been reduced.

The method used in the operation, removing a part of the trachea and attaching the ends to each other, is a tried and tested operation method, even though it appears to be relatively rare in Sweden.

### *Subsequent chain of events*

In the days following the operation there were no unexpected or problematic complications. On May 28 and 29 the plaintiff found it more difficult to breathe according to the medical records, and a growth of mucus membrane could be seen on May 29 and 30. However, there were no signs of airway obstruction. On the night of May 31 the plaintiff went into respiratory arrest and according to the legal counsel this was caused by upper respiratory blockage. Exactly what this blockage consisted of has not been determined by the legal counsel. According to the investigation that has been carried out in accordance with Lex Maria, there was most likely an excess of mucus which was sucked down towards the opening of the vocal cords. The respiratory arrest caused a cardiac arrest and the plaintiff was anesthetized between May 31 and June 2 with a tube placed in his trachea to secure ventilation. On June 2 it was discovered that the tube had slid out, which resulted in the plaintiff not being ventilated. Attempts to place the tube in the correct position failed, which is why the plaintiff had to undergo an emergency tracheotomy.

As a consequence of the events in May and June 2011, the plaintiff suffered brain damage, has impaired vision and a severely reduced ability to swallow. He continues to need the tracheotomy.

## **General basis for the legal assessment**

### *Prerequisites for liability in the healthcare industry*

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.

### *Assessment of criminal negligence*

For a person to be held responsible for actions according to chapter 3 § 8 of the penal code (1962:700), he/she needs to have acted in a negligent way. The assessment should be based on a normal standard of carefulness. Each step away from this standard does not entail criminal liability. The action needs to be regarded so reprehensible that it could be considered criminal negligence in an overall assessment, see NJA 2006 p. 228. The superior court has in the same case found that a risk-filled operation generally has a higher need for carefulness than any other operation. In the case in question the negligence should also be gross, i.e. the actions should include a deliberate risk-taking of a serious nature (the crime in question of a normal degree is statute-barred). The action must have been negligent in relation to the effect, i.e. the damages.

### *Negligence in the healthcare industry*

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.

### **Legal assessment**

*Was anybody negligent during the operation?*

The purpose of the operation was to rectify a deformation of the trachea which was affecting the respiratory function and at the same time remove the tracheostomy that the plaintiff wanted to get rid of. Judging from inquiries and the Lex Maria investigation, the operation appears to have been a success since the plaintiff was able to breathe well after the operation.

The legal counsel has emphasized the fact that the action of removing the tracheostomy resulted in the respiratory tract that was previously used no longer being available. According to what has come to light in hearings, a necessary condition for healing with the operation method in question is that air passes through the operation area, which required that the tracheostomy was removed. Furthermore, previous mucus excess had been rectified before the operation, so the only thing that was believed to aggravate normal breathing at the time of the operation was the deformed trachea. Thus, the decision to remove the tracheostomy cannot be regarded as negligent.

*The subsequent chain of events*

The plaintiff has been subject to continuous care from the operation up until complications arose and the damages occurred. A large number of people were involved in the care and it is unclear what caused the complications. It is not possible to clarify at what time the damages arose and how they could have been prevented. Thus, it is not possible to prove that one or several people acted in a way that might be considered criminally liable.

**DECISION**

The operation on May 24 2011 was performed in accordance with a tried and tested method. It is not possible to prove that it was negligent to perform the operation and there has been no information to indicate that anyone was negligent during the operation. In the subsequent chain of events, a large number of medical staff was involved in caring for the plaintiff. It has not been possible to determine the cause of the damages and time of the damages. Therefore, there is no indication that a crime has been committed and the preliminary investigation will be closed.