Relevance of expert guidelines for assessing medical malpractice

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Although medical society and other expert committee guidelines are non-binding, they may serve as evidence to specify current medical standards. However, as such guidelines cannot be considered on the same level of importance as medical standards, their application to specific cases requires expert assessment.

Facts

The plaintiff was born in October 2010 at 31 weeks and six days and weighing 2.064g. He remained in intensive care unit until November 2010. In the postnatal period, the plaintiff suffered a kernicterus (ie, severe damage to the central nervous system triggered by an increase of bilirubin in the blood). Indirect bilirubin can get over the blood cerebral barrier and deposit intracellularily, particularly in the nerve cells of the basal ganglia, the auditory pathway and the visual pathway. The medical treatment for neonates therefore aims to avoid an increase of bilirubin and lower high bilirubin levels (among others) by phototherapy or a blood exchange. Different thresholds apply to healthy full-term newborn infants than sick full-term newborn infants. Sick neonates with acidosis or sepsis, in particular premature babies, display innefective bilirubin bonding and an increased risk of kernicterus.

Pulmonary hypoplasia was suspected in the plaintiff immediately after birth. On 1 November 2010 a significant increase of liver values was diagnosed; his bilirubin level was 9.81mg/dl. During the increase of transaminases, his direct bilirubin level also increased, which indicated to perform phototherapy, which was carried out.

From 5 November 2010 the plaintiff's bilirubin level increased significantly at the following rates:

- 16mg/dl on 5 November 2010;
- 20.3mg/dl on 6 November 2010;
- 20.1mg/dl on 7 November 2010;
- 18.6mg/dl on 8 November 2010; and
- 19.6mg/dl on 9 November 2010.

Concurrently, his serum albumin level was significantly low:

- 2.1g/dl on 6 November 2010;
- 2.4g/dl on 7 November 2010; and
- 2.3g/dl on 8 November 2010.

During this period, the medical guidelines at the clinic stipulated that the threshold for a blood exchange in neonates was 18.5mg/dl. Correctly applying the curves according to the National Institute for Health and Clinical Excellence, the plaintiff fulfilled the indication for blood exchange on 7 November 2010. By 6 November 2010, preparation for the blood exchange should have been made, particularly as the phototherapy was no longer possible because of 'bronze baby' syndrome and an unsuccessful albumin transfusion. A blood exchange is risky and applied only defensively in children weighing under 1.5kg. However, there was no alternative to a blood exchange on 7 November 2010 at the latest.

It could not be established from which duration the blood cerebral barrier or threshold transgression had damaged the brain. Certainly, the denied blood exchange increased the risk of kernicterus.

The plaintiff claimed damages and a monthly pension. The doctors had applied incorrect thresholds and therefore no blood exchange was performed leading to the plaintiff's kernicterus. The defendant argued that no authoritative standard applied to bilirubin thresholds. The 18.5mg/dl threshold was only an internal guidance level and its transgression would not constitute a breach of medical duty of care. The doctors had discussed with the plaintiff's parents that a blood exchange would not be made.

Decisions

The first-instance court granted the claim.**(1)** In addition to the abovementioned facts, the court established that in 2010 a blood exchange should have been performed at a total serum bilirubin between 15mg/dl and 18mg/dl at 32 weeks and 33 weeks and 6 days, respectively, at a total value of bilirubin level between 17mg/dl and 19mg/dl at 34 weeks and 34 weeks and seven days, respectively. The lower value should be applied for children with lower albumin values (ie, below 2.5g/dl) and who display a rapid increase of bilirubin. The blood exchange was never discussed with the plaintiff's parents. Moreover, the plaintiff's mother was told that only bilirubin values between 25mg/dl and 30mg/dl were dangerous.

The court therefore held that the doctors treating the plaintiff had underestimated the bilirubin values and should have prepared for a blood exchange on 7 November 2010 at the latest. Therefore, the omission of the blood exchange was judged to have significantly increased the probability of brain damage.

The appellate court reversed the judgment and remanded the case to the first-instance court.**(2)** The appellate court held that, on the date of the incident, the hospital had relied on medical guidelines to determine that the threshold for a blood exchange in neonates was 18.5mg/dl.

The Hospital Act allows department heads (but not medical directors) to issue functional directives to subordinate doctors. The guideline was a technical directive by the department head to which the subordinate doctors were bound. Because of the doctors' sovereignty, they were qualified to verify their superior's directive. The relevant benchmark are the rules of the medical profession. If a technical directive contradicts the rules of the medical profession, the doctor must inform their superior.

In the present case, the doctors treating the plaintiff should therefore have made the blood exchange when the threshold of 18.5mg/dl was surpassed, particularly as this measure had no alternative according to the established facts. Moreover, the guideline was not random but based on a National Institute for Health and Clinical Excellence study. Therefore, the doctors should have consulted with the department head and made the parents aware of the directive and any risks associated with giving them informed consent. Ultimately, the doctors failed to comply with their duty of care.

If medical malpractice is established and there is no doubt that it substantially increased the probability of damage, the defendant must prove that the breach of the duty of care did not cause the damage. The burden of proof for causality therefore shifts to the defendant. However, the first-instance court did not consider that the parents of the plaintiff – from an *ex ante* perspective – would have consented to a blood exchange of the plaintiff on 7 November 2010 having considered the risks of phototherapy and human albumin infusion. Had the parents not consented to the blood exchange, the defendant would not be liable. Therefore, the first-instance court would have to establish the hypothetical decision of the parents and the basis of the decision making the parents had or would have had if the proper information had been available.

On the defendant's appeal, the Supreme Court upheld the appellate court's decision.**(3)** Medical treatment must comply with the principles of medical science and the rules of the medical art. A physician does not act negligently if the method of treatment complies with a practice of respected physicians familiar with the applied method of treatment even if other competent colleagues prefer a different method.

In the present case, the court had to decide what importance the medical guidelines had for establishing the medical state of the art. Although such guidelines are legally non-binding, they may help ascertain medical standards. However, they must not be taken as medical standards at face value or substitute for expert opinion. They are abstract rules that must be applied to specific circumstances. The step from general standard to individual case requires an individual expert evaluation. Clinical practice guidelines may serve as a mean to investigate the applicable medical standard in connection with an expert opinion. On their own, such guidelines have only indicative effect for the state of the art.

In the present case, medical malpractice could be established based on expert opinion alone (ie, independent of the guidelines). Considering the multiple risk factors associated with the plaintiff, the expert held that the threshold for the blood exchange had been reached on 7 November 2010 and

had also existed on 8 and 9 November 2010. The expert also commented on the guidelines of the committee of scientific medical societies and explained that the threshold of 22mg/dl on which the defendant relied did not apply to the plaintiff because of the multiple risk factors. The first-instance court followed this opinion. The defendant's argument ignored this establishment that the applicable threshold was 18.5mg/dl and that the blood exchange was without alternative on 7 November 2010. As the first-instance court had found individual misjudgement of the situation by the treating doctors, the malpractice for which the defendant was responsible had to be affirmed.

Both lower instances held that the plaintiff's parents had received no sufficient information. However, the first-instance court did not consider the defendant's argument of rightful alternative behaviour and did not establish facts on this issue. Had the parents not consented to a blood exchange based on sufficient information on the chances and risks involved, the defendant would not have been liable. Therefore, the appellate court correctly remanded the case.

Comment

All three instances confirmed that medical society guidelines are no substitute for an individual assessment of a case's specific circumstances. Non-compliance with such guidelines is not negligent if different methods of treatment exist and are accepted by respected physicians. However, meticulous information about the patient is required to allow for informed consent.

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Endnotes

(1) Feldkirch Regional Court, 56 Cg 96/17y.

(2) Innsbruck Higher Regional Court, 1 R 79/19f.

(3) 8 Ob 110/19p, RdM-LS 2020/25.
