# 7 Patient Education and Implementation of Legislation

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## 7.1 Legal Basis in the Patients' Rights Act

With the Patient Rights Act, the doctor's duty to provide information was codified for the first time. According to § 630c BGB (German Civil Code), the treating physician is obliged to explain to the patient in an understandable manner at the beginning of the treatment, and, if necessary, during the course of the treatment, all circumstances essential for the treatment. In return, the patient undertakes to cooperate with the doctor to carry out the treatment. In particular, education includes diagnosis, probable health development, therapy, and measures to be taken during and after therapy. Detailed duties of clarification are codified in § 630e BGB. According to this, the treating physician is obliged to inform the patient about all circumstances essential for consent. These include in particular the nature, extent, implementation, expected consequences, and risks of the measure, as well as its necessity, urgency, suitability, and prospects of success with regard to the diagnosis or therapy. When providing information, it is also necessary to point out alternatives to the measure if several medically equally indicated and common methods can lead to significantly different burdens, risks, or chances of recovery.

The law therefore imposes a whole **catalogue of contents in need of clarification**. In everyday practice, it is not always easy to do justice to this. Standardized information sheets from relevant providers (e.g., Diomed-Thieme, Schattauer GmbH, perimed) have proved their worth here, which are available for the respective laser systems (vascular lasers, tattoo and pigment lasers, ablative lasers, etc.) and interventions (laser epilation, tattoo and pigment treatments, laser resurfacing, etc.). These list all relevant and educational content and provide additional space for personal comments and notes, which should also be used to document the personal educational discussion and any patient-related, special educational content.

On the other hand, the patient is also obliged to provide the physician **with all information relevant to the treatment**. If the patient conceals these or deliberately disregards the doctor's recommendations, this may constitute contributory negligence in the event of damage. An example from the context of laser therapy is the occurrence of post-inflammatory hyperpigmentation due to uncritical exposure of the patient to the sun after laser treatment.

According to § 630c Para. 3 BGB, there are special information duties. If the treating physician is aware of circumstances that justify the assumption of a treatment error, he must inform

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G. Kautz (ed.), *Energy for the Skin*, https://doi.org/10.1007/978-3-030-90680-1_7

the patient of these upon request; he must also inform without request if this is necessary to avert health risks. This seems to contradict the principle enshrined in German law that nobody has to incriminate himself. But even this objection has been formally excluded by the law. Thus, it is additionally regulated that in the event that the practitioner himself or one of the persons to be attributed to him has made a medical error, this information may only be used for evidence purposes in criminal or fine proceedings against the practitioner or his relatives with the consent of the practitioner. Here, however, there is the danger that the deliberate failure to take appropriate measures in accordance with § 630 h BGB in the event of a dispute may lead to the assessment as a gross medical error. Case law may also derive from this a right to negative information. Thus § 630c Para. 2 S. 2 BGB may also give the patient a claim to a declaration by the practitioner that no circumstances are recognizable to him which could justify the assumption of a treatment error (OLG Oldenburg, Beschluss vom 25.08.2015, AZ. 5 W 35/15).

## 7.2 Treatment Contract and Relationship

The basis for the interaction between patient and doctor is the treatment contract. According to § 630a BGB, the person who promises the medical treatment of a patient (**attending physician**) is obliged to **perform** the promised treatment, the other part (**patient**) is obliged for the granting of the agreed **remuneration** unless a third party is obliged to pay. The treatment is according to the existing at the time of treatment, **generally accepted professional standards** unless otherwise agreed. Through the treatment contract, the physician undertakes to **professional treatment** but not to the **treatment success** ("promise of success"). The practitioner is obliged to invoice his services in accordance with the regulations of the Gebührenordnung für Ärzte (GOÄ). Common GOÄ analog numbers in the context of laser treatments are, for example:

- 2440A (laser treatment <7 $cm^2$)
- 2885A (laser treatment 7–21 $cm^2$)
- 2886A (laser treatment >21 $cm^2$)
- 444 (surcharge for outpatient laser therapy)
- 530 (cooling of the skin)
- 209 (large fl. application Externa)

Increase factors greater than 2.3 shall be justified. Common arguments here are, for example, complex localizations or the number of laser pulses.

## 7.3 Patient Education

### Time

In terms of time, the patient education must be provided in good time so that the patient can make a well-considered decision on consent, § 630e Para. 2 No. 1 BGB.

This wording seems vague, but in case-law, it has become clear that the distance between information and intervention must be longer the more the intervention is associated with health risks for the patient.

The patient must have the effective opportunity to decide against the procedure recommended by the doctor. It is assumed that the presence of the physician impairs the patient's freedom of decision and that the patient feels slightly pressured to make a positive decision. It is therefore not advisable to educate patients about the risks directly in the treatment room with seamless execution of the procedure. Better is a temporal interruption, e.g., by providing information in the treatment room and allowing time for reflection in the waiting room. This procedure has proven itself in daily practice. The frequently propagated reflection period of at least 24 h is usually not necessary for laser interventions. As already mentioned, however, the length of the reflection period should correlate with the risk or the anticipated side effects of the procedure. If, for example, the sclerosing of a senile angioma is usually well tolerated and has few side effects and can therefore be carried out

promptly for clarification, pain and stronger accompanying reactions are almost obligatory with laser skin resurfacing, so that it is recommended to grant the patient a longer reflection period of 24 h or more.

## Implementation and Documentation

According to § 630d Para. 2 BGB, the information must be provided orally by the practitioner or by a person who has the necessary training to carry out the measure.

Therefore, education cannot be delegated to nonmedical employees.

In addition, reference may be made to documents which the patient receives in text form; these are the classic information forms (Sect. 7.1).

What's important:

The handing over of an information sheet does not replace the information discussion, which can however be conducted with the aid of the information sheet.

If reference is made to written documents in the course of the clarification, copies of these documents shall be handed over to the patient, in particular insofar as the patient has signed this in connection with the clarification and consent.

The documentation of the clarification together with any clarification forms is part of the treatment documentation according to § 630f BGB. This means that there is a legal obligation to document the clarification. At the same time, the right of the patient to inspect the patient file in accordance with § 630g BGB (German Civil Code) expressly also extends to the documented information, whereby the physician must provide the patient with a copy of any information forms signed by the patient without being asked to do so.

Furthermore, the information must be understandable for the patient. This is demanding in two respects: firstly, because enlightenment often involves complex issues and, secondly, because language barriers can exist. Especially in the case of foreign patients who do not speak German or do not speak it well enough, the question arises as to who is responsible for providing proper information.

The doctor may only perform an intervention if he has the impression that the patient has understood the information.

If this is not the case, translation must be provided. The safest option here is to use an independent interpreter; translation by family members or other persons is also possible, but there is a risk that the translation will not be complete or that omissions may be due to the translator's own interests.

## Dispensability

§ 630d para. 3 BGB regulates the dispensability of clarification. According to this, there is no need for clarification insofar as this is exceptionally dispensable due to special circumstances, in particular if the measure cannot be postponed or the patient expressly waives clarification. However, it is only advisable not to routinely obtain a waiver of reconnaissance. If, in an individual case, a patient does not wish to be informed, the doctor carrying out the procedure is well advised to document such a waiver in writing, ideally with the patient's signature.

## Content and Scope

The obligation to provide information does not extend to all conceivable risks associated with a particular measure. However, the patient must be given a general picture of the nature and severity of the risks in question. In the case of treatment-specific risks, this must always be clarified, even if the risks are rare.

Does the duty to inform also extend to generally known surgical risks, such as wound infections or wound healing disorders? According to case law, the physician may in principle assume that the patient is aware of such general risks. However, in outpatient procedures, which are the order of the day in laser medicine, there is often insufficient risk awareness on the part of the

patients. This has to do with the fact that the laser therapeutic intervention is perceived as less invasive than the scalpel. In individual cases, the patient may not be aware that the intervention could be associated with dangers and possibly serious consequences.

Even in cases where the patient is particularly at risk due to his disposition, he must be made aware of this increased risk.

It may come as a surprise that the attending also has to inform the patient about treatment alternatives if the patient comes to the practice with a specific treatment request. If several different treatment methods are available to achieve the same goal, it is up to the physician to present these alternatives to the patient in detail. This applies if the treatment alternatives are associated with different risks and chances of success. This also applies, by the way, if the treating physician does not offer the alternative treatment himself.

Special features exist in procedures without or with only a relative medical indication, as is the case with a purely aesthetic procedure ("cosmetic interventions"). Here, high demands must first be placed on education. In such a procedure, the doctor must carefully assess the patient's need to have the procedure performed and the associated benefit of the treatment and relate it to the risks involved, before discussing this with the patient. The possibility of deterioration and an imbalance between benefit and risk must be clearly addressed. If there is even the remotest risk of permanent disfigurement, such as scarring, hyper- or depigmentation, or permanent health impairments, these must be presented. However, these aspects are comprehensively taken into account in the standardized information forms described above.

## 7.4 Economic Education

Cost aspects are also covered by the duty to provide information; this is under the keyword of economic clarification or duty to provide information according to § 630c BGB.

If the treating physician knows that a complete assumption of the treatment costs by a third party is not ensured or if there are sufficient indications for this according to the circumstances, he must inform the patient about the expected costs of the treatment in text form before the beginning of the treatment.

Examples in the context of laser therapeutic interventions are the treatment of telangiectasias under the diagnosis "rosacea" or the laser ablation of Verrucae sebborhoicae as well as all other indications which are in the border area between medical-indexed and primarily aesthetic performance. In this context it should be taken into account that aesthetic services are subject to VAT – this additional burden due to VAT must also be included in the cost clarification. Supplementary, stricter formal requirements exist in the event that an SHI-accredited physician provides services outside the SHI system; in this case, the Federal Mantle Contract requires the insured to confirm in writing before the start of treatment that he wishes to be treated at his own expense (e.g., IGEL or waiver agreement).

## 7.5 Education of Minors

What about the treatment of minors, who is the addressee of the clarification – the parents or the minor himself? According to the case-law of the Federal Court of Justice, it is not decisive for effective consent whether the patient concerned is legally competent, i.e., has reached the age of 18, but whether the minor is able to assess the significance and scope of the intervention and its permission according to his mental and moral maturity.

The minor must therefore be able to independently weigh the risk and benefit of the intervention against each other and make an independent decision. There is no fixed age limit here.

As a guideline, it may be assumed that minors under the age of 14 are regularly assumed not to be able to give their consent, i.e., that the information must (also) be directed to the parents. In the case of older minors, it depends on the type of

intervention and the mental maturity of the person concerned.

The physician should document the evidence on the basis of which he assumes that the minor is able to give consent.

If parental consent is required for the treatment of a minor, the question arises as to whether one or both parents should be informed. The decisive factor here is custody. As a rule, both parents are entitled to this together, so that only the consent of both justifies an intervention and therefore both must also be clarified. Other applies only if one parent has sole custody, which cannot be assumed today even for unmarried or divorced parents, as they usually also have joint custody.

The practice here is as follows: It is assumed that one parent who appears with a minor for treatment is entitled to represent the other – with the result that only this parent's education is sufficient. The Federal Supreme Court has issued the so-called three-step theory and differentiates according to the severity of the intervention and the risk:

1. In the case of minor interventions and routine cases, the information and consent of the parent accompanying the minor are sufficient.
2. In the case of medium interventions, i.e., all operations requiring a detailed consultation, the doctor must ask whether the parent present is entitled to represent the other parent. As a rule, he may rely on the information provided but should document it.
3. In the case of serious interventions involving considerable risks, the doctor must obtain the consent of both parents, either by personal confirmation or at least by telephone from the absent person or by presenting a power of attorney. Of course, this should also be documented.

## 7.6 Documentation of the Treatment

According to § 630f BGB (German Civil Code), the practitioner is obligated to lead a **patient file** in **paper form** or **electronic** for the purpose of documentation. The practitioner is also obliged to record all measures and their results which are essential from a technical point of view for the present and future treatment, in particular the **anamnesis**, **diagnoses**, **scrutinies**, **research findings**, **findings**, **treatments**, **interferences**, **consents**, and **elucidations**. The documentation of a laser therapy should include a selection of the following parameters:

- Laser quality (wavelength) and/or make
- Spot diameter (mm)
- Fluence (J/cm$^2$)
- Power (W)
- Pulse duration (ms or qs)
- Impulses
- Passes
- Pitch (for fractional treatments)
- Cooling
- Analgesia

**Corrections** and **alterations** of entries in the patient file are only permissible if it remains recognizable when they were made in addition to the original content. This must also be ensured for electronically managed patient files. While conventional patient documentation systems usually guarantee this in the meantime, this is often not the case with photo or image documentation. The document shall be valid for the duration of **10 years** after completion of the treatment, unless other storage periods exist according to other regulations.

### Inspection of the Patient File

According to § 630g BGB, the patient must be granted immediate access to his patient file upon request, unless there are significant therapeutic or other significant reasons for not doing so. This is usually not the case with laser therapeutic interventions. If the patient requests a copy of the file, he must reimburse the practitioner for the costs incurred.

## 7.7 Burden of Proof in Case of Liability

Normally, the burden of proof for the existence of a treatment error and its causality for the damage incurred lies with the patient in the medical malpractice trial. According to § 630h BGB (German Civil Code), however, the error of the treating physician is presumed if a general treatment risk has been realized, which was fully controllable for the treating physician and which has led to **injury to life**, **of the body,** or **health** of the patient. For the patient's consent, the burden of proof lies with the attending physician (§ 630d BGB), and he also has to prove that he has informed the patient in accordance with the requirements of § 630e BGB. If this clarification is not considered sufficient and if the patient, if properly informed, would have been in conflict with the decision about the implementation of the intervention, it is presumed that the patient would **not have consented** to the intervention. If the practitioner has not documented measures or events (documentation of the treatment, § 630f BGB), it is assumed that these measures were not taken or events occurred. If a practitioner was **not qualified** for the treatment he/she performed (here: qualification as laser safety officer), it is assumed that the lack of qualification was the cause of the occurrence of injury to life, body, or health. This shift in the burden of proof alone can determine the outcome of a liability process to the detriment of the practitioner.

## Conclusion

The proper clarification of the patient before an intervention is often considered to be unnecessarily annoying in everyday life. However, it plays a decisive role in the medical malpractice suit. The proof to be provided by the physician that the patient has been informed in a timely manner and in a personal discussion with the patient, and the documentation of this information can be decisive for the successful defense against claims for damages. But also for reasons of patient compliance, comprehensive information about expected costs and the risks associated with the procedure, should be provided, as this avoids any uncertainties the patient may have about the expected course of treatment. Should a treatment risk materialize in individual cases, the prior information provided protects the patient's trust in the attending physician and increases the probability that the patient first visits the attending physician, thus enabling prompt and adequate follow-up treatment. This means that education is also and not only for reasons of liability in the original interest of the attending physician.

## Suggested Reading

Gesetz zur Verbesserung der Rechte von Patientinnen und Patienten, "Patientenrechtegesetz"; online im Internet: http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/Patientenrechtegesetz_BGBl.pdf (abgerufen am 12.07.2017).

Informationen der Ärztekammer Nordrhein zur "Schönheitschirurgie"; online im Internet: http://www.bundesaerztekammer.de/fileadmin/user_upload/downloads/Patientenrechtegesetz_BGBl.pdf (abgerufen am 12.07.2017).