10. Informed consent in Germany

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1. GENERAL INTRODUCTION

1.1 The Doctrine of Personal Injury in German Case Law

Despite some strong criticisms, medical treatment – even where medically indicated and performed in accordance with medical standards – constitutes an act of personal injury under German law, and therefore requires the informed consent of the patient. This basic tenet can be traced back to 1894, when the *Reichsgericht* first held[2] that the offence of personal injury resulting from medical treatment cannot be excluded 'by the beneficial, reasonable character of the purpose or even success of the personal injury', or by the fact that 'someone has the ability, according to his own judgement or that of his profession, to understand the true interest of a fellow human being better than the latter himself, to be better suited to promote his physical and mental well-being than he is himself'. This can be done only by the will of the patient; only he or she can exclude the offence of personal injury.[3]

The courts base the requirement of informed consent of the patient to medical treatment to justify the violation of physical integrity on the basic right of physical integrity (Article 2(2) of the Basic Law (GG)) and the right of self-determination as a consequence of the right to human dignity (Article 1 GG).[4] The Federal Court of Justice (BGH) argues that this is to protect the patient's freedom of decision with regard to his or her physical integrity, which must not be overridden by an autocratic physician. The physician is required

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[2] RG, Jdg of 31 May 1894 – 1406/94, RGSt (RG Collected Decisions) 25, 375.

[3] RG, Jdg of 31 May 1894 – 1406/94, RGSt 25, 375.

[4] BGH, Jdg of 14 February 1989 – VI ZR 65/88, BGHZ (BGH Collected Decisions) 106, 391.

not only to take due care in the treatment of the patient, but also to ensure that the patient has given his or her consent to medical treatment. Consent will be valid only if the physician has provided the patient with the necessary information to take an informed decision. Without such valid, informed consent, the violation of physical integrity of the patient constituted by the medical treatment must be considered unlawful.[5] Invalid consent due to lack of information or insufficient information will thus result in medical liability. Information and consent are therefore interrelated and inseparable.[6]

1.2 The Model of the Responsible Patient

In the German debate, the requirement of informed consent as the basis of every medical treatment is closely linked to the model of the 'responsible patient'. According to this frequently quoted, though nonetheless controversial model, the responsible patient acts with increased self-confidence and responsibility towards his or her physician. Treatment decisions of the physician are no longer accepted unquestioningly; rather, the responsible patient and the physician aim to decide together on the optimal treatment choice ('shared decision making'). Expectations aimed at the responsible patient are rather high. Improved medical decision making, increased economic efficiency of healthcare, a reduction of deficient provision of healthcare and, last but not least, benefits for physicians – all of these positive effects are to accompany the informed patient and his or her self-determined decisions.[7] However, this model, although attractive, is also controversial. While this ideal constellation of 'shared decision making' leading to the best possible outcome achieved jointly by patient and physician may be conceivable, so too are constellations of everyday practice in which the patient is provided with so much information, to support responsible decision making and informed consent, that the overall effect is rather counterproductive (information overload).[8]

[5] BGH, Jdg of 14 February 1989 – VI ZR 65/88, BGHZ 106, 391.

[6] Joachim Laux in Alexandra Jorzig (ed), *Handbuch Arzthaftungsrecht* (C.F. Müller 2018) 217.

[7] For more detailed information on this and other aspects: cf Norbert Klusen/Anja Fließgarten/Thomas Nebling (eds), *Informiert und selbstbestimmt – der mündige Bürger als mündiger Patient* (Nomos, 2009).

[8] See also Benedikt Buchner, '*Sinn und Unsinn eines Patientenrechtegesetzes*' in Arbeitsgemeinschaft Rechtsanwälte im *Medizinrecht* (ed), *Qualitätsmängel im Arzthaftungsprozess – Brauchen wir ein Patientenrechtegesetz?* (Springer 2012) 98.

2. INFORMATION OF THE PATIENT

2.1 Purpose of Information

Leaving aside the debate on the model of the responsible patient, there is consensus on the purpose of patient information and its fundamental importance. Only an informed patient can be a 'reasonable partner' with regard to treatment decisions, and can exercise his or her right to self-determination in a reasonable manner.[9] This duty to inform, properly understood, may help to address the uncertainties of medical diagnosis and decision making by obliging the physician to inform about treatment options and the associated uncertainties and risks. However, this information may also entail considerable emotional distress for the patient – the inevitable 'downside of free self-determination'.[10]

2.2 Form of Information

The provisions of the German Civil Code (BGB) on the treatment contract broadly define how the patient should 'be informed about all circumstances of significance for consent' (§ 630e(1) BGB). They also outline how the patient is to be informed. § 630e(2) BGB states that the information must be provided orally by a qualified person (supplemented by documents, if necessary), in a timely manner, and that it must be understandable.

In the case of foreign patients, the physician must call in someone who can speak the patient's language if otherwise it would be impossible to ascertain whether the patient has understood the information provided.[11] If a family member assists as interpreter, the informing physician must ensure in an appropriate way that the interpreter has understood the information provided and can translate it into the patient's language. If there are doubts as to whether the patient has understood the information, the physician must enlist the services of an interpreter, at the expense of the patient.[12] The physician is not required to ensure at his or her own expense that the information is provided.

[9] Cf BVerfG, Jdg of 25 July 1979 – 2 BvR 878/74, BVerfGE (BVerfG Collected Decisions) 52, 131.

[10] Cf BVerfG, Jdg of 25 July 1979 – 2 BvR 878/74, BVerfGE 52, 131.

[11] OLG Köln, Jdg of 9 December 2015 – 5 U 184/14, VersR 2016, 994.

[12] OLG Köln, Jdg of 9 December 2015 – 5 U 184/14, VersR 2016, 994; Karsten Schmidt in Maximilian Herberger et al (eds), *jurisPK-BGB* (8th edn, juris 2017) § 630e BGB, no 44.

2.3 Types of Information

German medical law traditionally distinguishes between information for safety purposes and information for purposes of self-determination. Where informed consent is concerned, the focus is on information for purposes of self-determination, which is always a prerequisite for informed consent. This information is intended to ensure, in the individual case, that the patient can make an informed and responsible decision about treatment. Information for the purposes of self-determination is generally focused on the risks of the proposed medical intervention. This is complemented by information on the diagnosis and the course of treatment (see the following sections for a more detailed discussion of information for purposes of self-determination).[13]

While information for purposes of self-determination is a prerequisite for the validity of informed consent, information for safety purposes is a necessary part of the professional medical treatment itself.[14] In principle, this includes all information required to ensure a successful treatment outcome and the compliance of the patient;[15] it is therefore also called 'therapeutic information'. If the physician does not comply with the therapeutic information requirements, this constitutes medical malpractice.

The BGB provisions on medical treatment contracts define the therapeutic information requirements (§ 630c(2) BGB). The physician has a duty to inform the patient at the beginning and, if necessary, during the course of treatment in understandable terms about all relevant circumstances – in particular, the diagnosis, the anticipated outcome, the treatment and the measures to be taken during and subsequent to treatment. Among other objectives, therapeutic information is intended to motivate the patient to adopt a lifestyle appropriate to his or her state of health, to use medication as prescribed and to take adequate measures of self-protection.[16]

The information requirements set out under § 630c(2) BGB are complemented by a duty to inform the patient, upon request or in order to avert health risks, of circumstances which give rise to the assumption of malpractice, where these can be recognized by the physician (§ 630c(2) sentence 2 BGB). In criminal or administrative fine proceedings pursued against the physician or a family member, such information may be used for evidential purposes only with the consent of the physician (§ 630c(2) sentence 3 BGB). Lastly, §

[13] Christian Katzenmeier in Adolf Laufs/Christian Katzenmeier/Volker Lipp, *Arztrecht* (7th edn, C.H. Beck 2015) Chapter V B I no 14.

[14] Katzenmeier (n 13) Chapter V B I no 16.

[15] Michael Quaas in Michael Quaas/Rüdiger Zuck/Thomas Clemens (eds), *Medizinrecht* (4th edn Nomos 2018) § 14 no 79.

[16] Katzenmeier (n 13) Chapter V B I no 16.

630c(3) BGB sets out an economic information requirement, obliging the physician to inform the patient in writing of the anticipated costs before treatment is commenced, where he or she knows or must assume that the costs of the treatment may not be fully covered by health insurance.

3. PRINCIPLE AND CHARACTERISTICS OF INFORMED CONSENT

As stated above, according to long-established principles of German law, medical treatment is lawful only if based on the informed consent of the patient. Since 2013, this has also been enshrined in § 630d(1) BGB, which requires a physician to obtain the consent of the patient for every medical measure – in particular, medical interventions relating to the body or health of the patient.

Under German law, consent to medical treatment is not classified as a legal declaration of intent, but is regarded as a decision about a personal legal interest. Therefore, the prevailing opinion is that the validity of consent does not depend on the patient's legal capacity to contract.[17] As a consequence, the rigid age requirement of 18 years for legal capacity to contract does not apply; instead, the physician must consider the circumstances of the individual case in order to assess whether the patient has the capacity to understand the nature, significance, consequences and risks of the treatment, and to make a corresponding decision.[18]

There are no formal requirements for consent; it may be given explicitly or implicitly.[19] Nevertheless, consent to a medical measure cannot be inferred – even implicitly – from the conclusion of a treatment contract, since consent must always relate to a specific intervention. Also, the consent of the patient can only legitimize treatment performed *lege artis* – that is, in accordance with generally recognized professional standards (cf § 630a(2) BGB). According to § 630d(3) BGB, consent can be revoked at any time, without stating reasons and without complying with a specific format.

[17] Walter Weidenkaff in Palandt, *Bürgerliches Gesetzbuch* (78th edn C. H. Beck 2019), § 630d, no 2.

[18] Katzenmeier (n 13) Chapter V B III no 51.

[19] Heinrich Wilhelm Laufhütte in *StGB Leipziger Kommentar* (12th edn De Gruyter 2018) § 203 no 77.

4. THE PERSON WHO GIVES CONSENT AND THE RECIPIENT OF INFORMATION

According to § 630d(1) sentence 1 BGB, the consent 'of the patient' must be obtained as a matter of principle, and the patient thus is also the recipient of information on the medical treatment.[20] If the patient is unable to give his or her consent, in accordance with § 630d(1) sentence 2, this must be obtained from the person entitled to consent, unless a living will permits or prohibits the proposed medical measure.

Whether a patient can consent does not depend on his or her legal capacity to contract (cf section 3 above). Instead, a patient has the capacity to consent if he or she has the capacity to understand the information provided by the physician, and can weigh the benefits of the treatment against the risks and make a responsible decision based on this information.[21] Whether this is the case must be assessed by the physician under the circumstances of the individual case.[22]

German law does not specify a certain age at which children and adolescents have the capacity to consent or requirements which must be fulfilled before the capacity to consent can be presumed. This is to depend exclusively on the minor patient's ability to 'understand the significance and consequence of the intervention and his consent to it according to his mental and moral maturity'.[23] This vague regulatory guidance creates considerable legal uncertainty for the attending physician. Academic literature provides some general orientation, with an age requirement of 14 years: up to the age of 14, the physician should generally obtain the consent of the persons who have custody of the child. Between the ages of 14 and 17, capacity to consent must be determined in the individual case as outlined above.[24]

In principle, the parents have joint custody of a child who does not have the capacity to consent. According to established case law, the attending physician may generally presume that the parent accompanying the child is entitled to consent on behalf of the absent parent.[25] In the case of serious medical interventions, however, the physician is obliged to ensure that both parents have

[20] Karlmann Geiß/Hans-Peter Greiner, *Arzthaftpflichtrecht* (7th edn C. H. Beck 2014), Chapter C no 113.

[21] BT-Drs. 17/10488, 23.

[22] Schmidt (n 12) § 630d BGB, no 13.

[23] See also BGH, Jdg of 5 December 1958 – VI ZR 266/57, NJW 1959, 811.

[24] Christian Katzenmeier in *BeckOK BGB* (48th edn C.H. Beck 2018) BGB § 630d no 13.

[25] Cf Martin Rehborn/Susanne Gescher in *Erman BGB* (15th edn Dr Otto Schmidt Verlag 2017) § 630d BGB, no 11.

given their consent.[26] If parents refuse to consent to an essential medically indicated intervention, the physician is entitled to inform the family court and instigate proceedings to avert the risk in accordance with § 1666 BGB.[27]

If an adult is unable to look after his or her own interests due to mental illness or physical, mental or psychological disability, the guardianship court will appoint a guardian at his or her request or *ex officio* in accordance with § 1896 BGB. A guardian may also be appointed for 'healthcare' purposes, if the person concerned can no longer look after his or her own interests in this area. The guardian will then represent the person concerned in accordance with § 1902 BGB before the courts and out of court.[28] This is not to say, however, that the guardian will make all decisions of relevance for the health of the person concerned. It must be determined, with regard to the individual medical measure, whether the latter can give his or her consent. If this is the case, he or she will make the decision, not the guardian.[29] Even where the person under guardianship – who has the capacity to consent in the specific situation – refuses to consent to a clearly indicated medical measure of his or her own free will, the guardian as his or her 'assistant' must accept this decision as an expression of the person's right to self-determination.[30] The primary task of the guardian is to enable the person under guardianship to comprehensively exercise his or her right to self-determination.[31]

If a patient does not have the capacity to consent, the guardian must determine whether an effective living will has been made in which the patient, while he or she had the capacity to consent, set out in writing his or her consent to or rejection of medical interventions not imminent at the time. If this is the case, the guardian must ascertain whether the provisions made apply to the specific treatment situation, and if so, express and enforce the will of the person under guardianship.

If there is no living will or if the provisions made do not apply to the specific treatment situation, the guardian must determine the presumed will of the person under guardianship and decide on this basis whether to consent to a medical measure. In order to determine the presumed will of the patient,

[26] Jorzig, *Handbuch Arzthaftungsrecht* (C.F. Müller 2018) 237.

[27] OLG Sachsen-Anhalt, Jdg of 12 September 2013 – 1 U 7/12, VersR 2014, 507.

[28] Cf Andrea Diekmann, '*Der betreute Mensch als Patient – Wer entscheidet was und wer übernimmt welche Aufgaben im Rahmen der Gesundheitssorge?*' (2018) *BtPrax* 23.

[29] Cf Diekmann (n 28) 23.

[30] Cf Ernst Bühler/Konrad Stolz, '*Ärztliche Behandlung und "unterstützte Entscheidungsfindung" – Betreuung entbehrlich?*' (2017) BtPrax 167, 169.

[31] Cf Volker Lipp, '*UN-Behindertenrechtskonvention und Betreuungsrecht*' (2010) *BtPrax*, 263.

earlier oral or written declarations, ethical or religious convictions and other personal values of the person under guardianship may be taken into account.[32]

If the patient does not have the capacity to consent for the above-described reasons and consent must be obtained from the entitled person in accordance with § 630d(1) sentence 2 BGB, the latter must also receive the information. Nevertheless, under § 630e(5) BGB, where a patient is unable to consent the information requirement cannot be dispensed with altogether. The patient must nonetheless be informed about the essential facts of the proposed measures insofar as his or her level of development and understanding makes it possible to receive this explanation, and insofar as this does not interfere with his or her welfare. This aims to strengthen the rights of persons who are unable to consent.[33] Like any other patient, a person who is unable to consent must not be left in the dark as to whether and how he or she will receive treatment.[34]

5. THE PROVIDER OF THE INFORMATION

The information must always be provided by the physician as part of his or her therapeutic task.[35] If a patient receives treatment from more than one physician or if different physicians take turns in the treatment, it must be decided according to the circumstances of the individual case who should provide the information and to what extent. In principle, each physician has the duty to inform about the interventions and treatment measures which he or she will perform.[36]

§ 630e(2) sentence 1 no 1 BGB allows for someone other than the attending physician to provide the information if this person has been trained to perform the proposed measure. The patient may thus be informed by someone who has the necessary theoretical knowledge, acquired through the completion of professional training, even if he or she lacks the practical experience needed for the independent performance of the measure.[37]

Case law has set strict requirements for the duty of organization and control of an attending physician who delegates his or her duty to inform to a third party. Since information of the patient is the medical responsibility of the attending physician, he or she must ensure that this requirement is duly fulfilled if delegated to another physician. A chief physician who must ensure that patients in his area of responsibility are duly informed must demonstrate

[32] Cf Diekmann (n 28) 23.
[33] Schmidt (n 12) § 630d BGB, no 32.
[34] BVerfG, Jdg of 23 March 2011 – 2 BvR 882/09, BVerfGE 128, 282.
[35] Burkhard Pauge/Thomas Offenloch, *Arzthaftungsrecht* (RWS Verlag, 2017) 200.
[36] BGH, Jdg of 15 June 2010 – VI ZR 204/09, NJW 2010, 2430.
[37] Katzenmeier (n 24) BGB § 630e no 38.

which organizational measures he or she has taken to guarantee that patients are provided with adequate information.[38]

6. THE TIMING, FORM AND CONTENT OF THE INFORMATION

6.1 Timing

In accordance with § 630e(2) sentence 1 no 2 BGB, the information must be provided in sufficient time to allow the patient to make a 'well-considered' choice about consenting to treatment. It is a prerequisite for such a (not merely considered, but well-considered) choice that the patient receives the required information in sufficient time to process it without pressure before making a decision – if necessary, after seeking further advice or consulting with a trusted person. Sufficient time must be allowed for a consideration of the arguments for and against the proposed medical intervention, in order to enable the patient to make a free choice and guarantee his or her right to self-determination.[39]

German case law assumes that it is sufficient to inform the patient on the same day in the case of normal ambulant treatment or diagnostic interventions,[40] as long as the information is not provided immediately before the intervention, causing the patient to believe that it is too late to extricate himself or herself from a course of events already set in motion.[41] If the patient is informed 30 minutes before the intervention is to take place, this is regularly considered to be too late.[42] Patients who are admitted to hospital must be informed on the day before the medical intervention at the latest. Information provided on the eve of surgery is assumed to overburden the patient in the decision-making situation – at least if this is the first time that he or she is made aware of serious risks which might impair his or her future quality of life.[43]

6.2 Form

In accordance with § 630e(2) no 1 BGB, information must be provided orally. This is to give the patient the opportunity to ask questions about the

[38] BGH, Jdg of 7 November 2006 – VI ZR 206/05, BGHZ 169, 364.

[39] Established case law; see BGH, Jdg of 25 March 2003 – VI ZR 131/02, NJW 2003, 2012, 2013.

[40] BGH, Jdg of 25 March 2003 – VI ZR 131/02, NJW 2003, 2012, 2013.

[41] BGH, Jdg of 15 February 2000 – VI ZR 48/99, NJW 2000, 1784, 1787.

[42] BT-Drs 17/10488, 25.

[43] Katzenmeier (n 24) BGB § 630e no 44 with references to case law.

proposed intervention in a personal conversation with the attending physician, and ensure that informed consent is not treated as a mere formality.[44] By way of exception, the information may be provided by telephone in simple, straightforward cases, as the physician may still meet the requirements of the respective doctor–patient relationship and individually answer questions of the patient in this way. Information by telephone is inadequate in the case of complicated medical interventions with significant risks. Also, patients are always free to insist on a personal conversation with the physician.[45]

The oral information may be supplemented by documents provided according to § 630e(2) sentence 1 no 1 BGB. These may not replace the required oral information, however. Trustful communication between the attending physician and the patient, as free from bureaucratic formalities as possible, is an essential requirement.[46]

The common practice of providing written information about routine measures such as vaccinations – combined with the offer of oral explanation if further clarification or information is required – can no longer be maintained in view of the clear legal requirements.[47]

6.3 Content

In accordance with § 630e(1) sentence 1 BGB, information must be provided on all circumstances relevant to consent. Risk information must relate only to the proposed intervention and the risks involved in general.[48] Detailed scientific information is not required; rather, the patient must be provided with adequate understandable[49] information on the seriousness and consequences of the proposed measure to make a choice and exercise his or her right to self-determination.[50] The form and extent of information are thus always determined by the specific treatment situation.[51]

§ 630e(1) sentence 2 BGB defines the circumstances relevant to consent, including the nature, extent, implementation, anticipated consequences and risks of the proposed measure, as well as its necessity, urgency, suitability and

[44] BT-Drs. 17/10488, 24.

[45] BGH, Jdg of 15 June 2010 – VI ZR 204/09, VersR 2010, 1183; Schmidt (n 12) § 630e BGB, no 29.

[46] BGH, Jdg of 08 January 1985 – VI ZR 15/83, VersR 1985, 361; Schmidt (n 12) § 630e BGB, no 30.

[47] Schmidt (n 12) § 630e BGB, no 30.

[48] BGH, Jdg of 22 December 1987 – VI ZR 32/87, NJW 1988, 1514 (settled case law).

[49] § 630e(2) sentence 1 no 3 BGB.

[50] BT-Drs. 17/10488, p 24.

[51] Schmidt (n 12) § 630e BGB, no 4.

prospects of success with regard to the diagnosis or therapy. This list is not exhaustive and information about further circumstances may be required in the individual treatment situation.[52]

According to established case law, the risk information provided by the physician should include information about rare risks, if these would have severe consequences for the patient's lifestyle should they materialize and if they are specific to the medical intervention despite their rarity.[53] It is thus generally assumed that the physician must inform about the risk of paraplegia, even if this risk seldom materializes with respect to the intervention concerned.[54] In general, the average frequency of complication is of little importance for risk information and even a very low complication rate does not justify dispensing with information about the risk.[55] Correspondingly, even for complication rates below 0.1 per cent, case law rejects a duty of information only if the risk cannot be expected to be of any serious consequence for a responsible patient's decision to consent to the intervention.[56] In principle, the patient should get a general idea of the extent of the risks associated with the intervention.[57] The duty to inform arises not only when the scientific debate on certain risks associated with a medical measure has been concluded and led to generally accepted results; but rather as soon as serious voices in medical science have referred to certain risks associated with a treatment, which cannot be dismissed as insignificant outsider opinions, but must be perceived as serious warnings.[58]

In the case of surgery, the physician may expect every patient to know about the general risks of surgical interventions.[59] In cases where the general public is well informed about the course and seriousness of a frequently performed intervention, information about the nature and risks of the intervention may be kept brief,[60] unless the patient has further questions or appears to have misconceptions about the risks of the proposed measure.[61]

If medication is prescribed, within the framework of risk information, the physician must inform the patient above all of possible serious side effects of the prescribed drug. A mere reference to the package leaflet is not sufficient in

[52] BT-Drs. 17/10488, 24.

[53] Katzenmeier (n 24) BGB § 630e no 15 with references to case law.

[54] Bernd-Rüdiger Kern in Adolf Laufs/Bernd-Rüdiger Kern, *Handbuch des Arztrechts* (5th edn 2019) § 66 no 24.

[55] Kern (n 54) § 66 no 23.

[56] OLG Stuttgart, Jdg of 17 November 1998 – 14 U 69/97, VersR 1999, 1500.

[57] *Geiß/Greiner* (n 20) 298.

[58] BGH, Jdg of 21 November 1995 – VI ZR 329/94, NJW 1996, 776.

[59] BGH, Jdg of 17 December 1991 – VI ZR 40/91, NJW 1992, 743.

[60] See BGH Jdg of 23 October 1979 – VI ZR 197/78, NJW 1980, 633 on the example of appendix surgery.

[61] Schmidt (n 12) § 630e BGB, no 15.

this context, since it is the physician's obligation to give the patient a general idea of the seriousness of the intervention and the specific risks associated with it;[62] and this would further not be consistent with the principle of oral information provided for under § 630e(2) sentence 1 no 1 BGB.[63] Moreover, as is true for all risk information, the nature and extent of the information to be provided depend not on the probability of the occurrence of a complication, but rather on whether a specific risk is inherent to the intervention and whether it would impair the patient's quality of life should it materialize.[64]

In accordance with § 630e(1) sentence 3 BGB, the physician must inform the patient about alternatives to the proposed measure if several equally medically indicated and customary methods may lead to significantly different adverse effects, risks or prospects of a cure. According to the principle of freedom of therapy, the choice of treatment method is generally left to the physician. However, if there are several suitable methods of treatment with different risks and chances of success, so that there is a genuine choice, the patient's right to self-determination requires that he or she be allowed to decide which treatment option to take and which risks he or she is willing to accept.[65] Information about alternative methods of treatment must be provided – for example, if the medical alternative to immediate surgery is the continuation of conservative treatment.[66] If there is only a relative indication for surgery as a prophylactic measure, the necessity of which depends on the patient's subjective safety needs, the patient must be informed about the preventive character of the intervention.[67]

If the alternative treatment method is relatively new and has not yet been generally adopted, the information provided by the physician must expressly refer to the fact that the new method might involve unknown risks. The unpredictability and uncertainty accompanying a new method of treatment must be made unequivocally clear to the patient. Although the application of new methods of treatment may be essential for medical progress, this can never justify leaving patients in the dark about the novelty of a method of treatment

[62] BGH, Jdg of 15 March 2005 – VI ZR 289/03, BGHZ 162, 320.

[63] Schmidt (n 12) § 630e BGB, no 17.

[64] Established case law; see BGH, Jdg of 15 March 2005 – VI ZR 289/03, BGHZ 162, 320 with further references.

[65] BGH, Jdg of 22 September 1987 – VI ZR 238/86, VersR 1988, 179; BGH, Jdg of 6 December 1988 – VI ZR 132/88, BGHZ 106, 153; BGH, Jdg of 14 September 2004 – VI ZR 186/03, VersR 2005, 227; BGH, Jdg of 22 February 2000 – VI ZR 100/99, VersR 2000, 766; for literature see Reinhard Damm, '*Medizintechnik und Arzthaftungsrecht*' (1989) NJW 737, 741 ff; Katzenmeier (n 24) BGB § 630e no 25 f with references to case law.

[66] BGH, Jdg of 17 December 2013 – VI ZR 230/12, VersR 2014, 586.

[67] BGH, Jdg of 15 September 2015 – VI ZR 170/14, VersR 2016, 51.

and the risks associated with it.[68] The informed consent of the patient is therefore of even greater importance for a novel therapy than in the case of standard treatment. The final decision of whether the chances of a new method of treatment are considered to outweigh the accompanying risks is to taken by the patient, not by the physician.[69] The patient is to be enabled to carefully weigh whether to choose the conventional surgery method with well-known risks or the new method, considering in particular the prospective advantages and the as-yet not fully known risks of the latter.[70]

In the context of risk information, the institution-related duties of information are also subject to debate – especially in cases where a physician in a particular medical facility cannot guarantee that a medical service will be performed to a standard equivalent to that in other facilities. A typical example is a university hospital in a large city compared to a district hospital in a rural area. It is widely recognized that it is not always necessary to inform the patient about such differences in quality. According to case law, medical progress and the continuous generation of new knowledge will necessarily entail differences in the quality of healthcare. The required medical standard may therefore vary 'within limits', depending on the personnel and material resources of the facility.[71] A patient who is offered treatment that is basically standard in one facility need not be informed that the same treatment might be performed with possibly better personnel and equipment at another. Information about such alternatives is required only if the new method of treatment has become widely accepted and the possible advantages for the patient are so considerable that he or she must be informed about this in order to be able to decide for himself or herself – regardless of the standard treatment provided in the specific facility – whether to seek access to the state-of-the-art treatment.[72]

7. SPECIFIC RULES FOR SPECIFIC INTERVENTIONS

The less indicated a medical intervention, the stricter the requirements for risk information. This is particularly true where cosmetic surgery is concerned,

[68] Thus BGH, Jdg of 13 June 2006 – VI ZR 323/04, VersR 2006, 1073.

[69] Dieter Hart, '*Heilversuch, Entwicklung therapeutischer Strategien, klinische Prüfung und Humanexperiment – Grundsätze ihrer arzneimittel-, arzthaftungs- und berufsrechtlichen Beurteilung*' (1994) MedR 94, 101 f; Dieter Hart, '*Spannungen zwischen dem Haftungs-, Arzneimittel- und Sozialrecht*' (2002) MedR 321, 323.

[70] BGH, Jdg of 13 June 2006 – VI ZR 323/04, VersR 2006, 1073.

[71] BGH Jdg of 22 September 1987 – VI ZR 238/86, BGHZ 102, 17.

[72] BGH Jdg of 22 September 1987 – VI ZR 238/86, BGHZ 102, 17; Tim Neelmeier, '*Die einrichtungsbezogene Patientenaufklärung*' (2013) NJW 2230.

which requires the provision of extensive information on the prospects of success and possible adverse effects.[73] Patients must be told which improvements they may expect in the best case and which risks are involved. The possible adverse effects must be impressed upon the patient to enable him or her to carefully consider whether he or she is ready to accept such a failure. The Federal Court of Justice refers to a 'special responsibility' of the physician who performs cosmetic surgery in this context. It is his or her duty to clearly explain the pros and cons, 'with all their consequences', to the patient. The courts have therefore established particularly strict information requirements for patients undergoing cosmetic surgery.[74]

Stricter requirements for informed consent also apply for clinical trials, as opposed to standard treatment, which involve new methods of treatment or drugs which have not yet been approved. The increased uncertainties and risks accompanying a clinical trial result in increased requirements for informed consent: the physician must provide comprehensive information about the experimental nature of the proposed treatment and the potential (but uncertain) advantages and risks. The information provided must enable the patient to decide whether to take the chance of a cure offered by the clinical trial despite the potentially considerable risks involved.[75] If a new, not yet approved drug with uncertain risks is to be tested, the physician must inform the patient not only about the lack of approval, but also about the fact that unknown risks cannot be excluded at present.[76]

8. EXCEPTIONS TO THE RULE OF INFORMED CONSENT

In cases where it is impossible to obtain timely consent to a medical measure that cannot be postponed, the measure may be performed without consent in accordance with § 630d(1) sentence 4 BGB, if this corresponds to the presumed will of the patient. Typical examples of measures that cannot be postponed are the emergency treatment of an unconscious accident victim or unforeseen complications during surgery that must be addressed immediately.[77] In contrast, the principles of presumed consent do not apply if the scope of an operation is expanded and this might have been predicted with

[73] BGH, Jdg of 6 November 1990 – VI ZR 8/90, VersR 1991, 227.

[74] BGH, Jdg of 6 November 1990 – VI ZR 8/90, VersR 1991, 227 with further references to case law.

[75] Volker Lipp in Adolf Laufs/Christian Katzenmeier/Volker Lipp, *Arztrecht* (7th edn, C.H. Beck 2015) Chapter XIII D No 32.

[76] Schmidt (n 12) § 630e BGB, no 18.

[77] *Jorzig* (n 26) 219.

due planning.[78] The presumed will is based on the individual hypothetical will of the patient. It must be determined, if possible, in the time available, based on earlier statements or by questioning close relatives or trusted persons.[79] Considerations of how a 'normal' or responsible patient could be expected to decide may provide some indication of the hypothetical will of the individual patient; however, this applies only if careful investigation does not uncover any specific circumstances indicating the individual presumed will of the patient.[80]

A further exception to the principle of informed consent under German law is provided by § 1906a BGB. This provision relates to cases where a medical intervention is inconsistent with the natural will of the person under custodianship (coercive medical treatment). The underlying principle is that every conscious person can establish a natural will, irrespective of his or her physical, mental or psychological condition. It is irrelevant whether this will is perceived to be reasonable from the point of view of a third party.[81] Nevertheless, the Federal Constitutional Court has ruled that Article 2(2) sentence 1 GG establishes a protective duty of the state to provide for medical treatment of persons under custodianship and without capacity for consent against their natural will, as a last resort, if there is a threat of significant health impairment – although only under strict conditions.[82] The requirements that must be fulfilled if the custodian is to legitimize the medical intervention with his or her consent by way of exception, although this is against the natural will of the person under custodianship, are set out in detail under § 1906a(1) sentence 1 BGB. In addition, § 1906a(2) BGB requires the consent of the custodianship court to the coercive medical treatment. The medical measure may be performed only if the custodian, as well as the custodianship court, has given consent.[83]

Another exception to the principle of informed consent applies if special circumstances render information about the proposed medical measure unnecessary. According to § 630e(3) BGB, this may be the case, in particular, if the measure cannot be postponed or if the patient has explicitly waived the right to be provided with the information. Lastly, information may be dispensed with if there are significant therapeutic reasons to the contrary. In view of the patient's right to self-determination, however, strict requirements are imposed on the

[78] BGH, Jdg of 16 February 1993 – VI ZR 300/91, VersR 1993, 703; BGH, Jdg of 17 September 1985 – VI ZR 12/84, VersR 1985, 1187.

[79] Weidenkaff (n 17) § 630d, no 4.

[80] BGH, Jdg of 13 September 1994 – 1 StR 357/94, NJW 1995, 204.

[81] Susanne Jaschinski in Maximilian Herberger et al (eds). *jurisPK-BGB* (8th edn, juris 2017) § 1906a BGB, no 25.

[82] BVerfG, Jdg of 26 July 2016 – 1 BvL 8/15, BVerfGE 142, 313.

[83] Jaschinski (n 81) § 1906a BGB, no 33.

unacceptability of information for therapeutic reasons; not providing information must remain the exception.[84] The physician must refrain from providing information, in particular, if this would seriously endanger the life or health of the patient. For therapeutic reasons, the information must be dispensed with altogether or at least restricted here, depending on the individual case.[85]

9. LIABILITY IN CASE OF NEGLIGENCE

9.1 Starting Point

If a medical intervention is performed without the valid consent of the patient – whether or not performed in accordance with medical standards – under German law, this constitutes a violation of contractual duties as well as an unlawful personal injury.[86] The consent of the patient is valid only if the patient has been informed by the physician as prescribed (established case law and now explicitly provided for by § 630d(2) BGB).

If the physician erroneously assumes that the patient has been provided with sufficient information and has therefore given his or her valid consent, the intervention remains unlawful. At best, there will be no fault on the part of the attending physician if he or she assumed the patient's consent to be valid. This requires that the error of the treating physician has not been caused by negligence within the meaning of § 276(2) BGB – that is, that the error could not have been prevented through the exercise of reasonable care.[87]

9.2 Information about the Actual Risk

If, in the case of a specific injury, the patient has been comprehensively informed about the actual risk that has materialized, the incompleteness of the information is not deemed injurious. According to case law, it will suffice if the patient has given his or her consent with knowledge of this actual risk and thus with full awareness of the one risk that later materialized. It is then irrelevant that he or she should also have been informed about other risks, which did not materialize in the specific case.[88]

However, liability for inadequate information can be excluded only if the patient has at least received basic information enabling him or her to judge the seriousness of the intervention and the potential adverse effects on physical

[84] BGH, Jdg of 07 February1984 – VI ZR 174/82, BGHZ 90, 103.
[85] BT-Drs. 17/10488, 25.
[86] Greiner in Geiß/Greiner (n 20) Chapter C no 1.
[87] BGH, Jdg of 7 November 2006 – VI ZR 206/05, BGHZ 169, 364.
[88] BGH, Jdg of 13 June 2006 – VI ZR 323/04, BGHZ 168, 103.

integrity and lifestyle which may result from it.[89] If this basic information has not been provided, the treating physician is liable for the resulting violation of the patient's right to self-determination, even where the risk that materialized is very rare and not one that the patient should have been informed about.[90]

9.3 Burden of Proof

German case law has developed a differentiated system of special rules for the allocation of the burden of proof in medical malpractice cases over the last decades. Since the Patients' Rights Act of 2013 was enacted, these special rules have been systematically summarized under § 630h BGB.[91]

9.3.1 Basic rule

It is a general rule under German law that each party bears the burden of proof for the actual requirements of the legal provision favourable to it. For compensation claims based on a violation of the duty to inform, this means that the patient would bear the burden of proof for a claim that information was inadequate or not provided at all, as well as for a claim that consent to an intervention was not obtained by the treating physician.[92] In view of the principle of 'equality of arms' applied in legal proceedings, this allocation of the burden of proof is generally not deemed appropriate. A shift in favour of the patient has therefore been evident in practice for some time and is now also provided for by § 630h BGB.

9.3.2 Special provision of § 630h(2) BGB

In accordance with § 630h(2) sentence 1 BGB, it is not the patient, but rather the treating physician, who bears the burden of proof as regards the provision of information and valid consent. The physician must prove that he or she informed the patient in accordance with the requirements of § 630e BGB about all relevant circumstances of the proposed measure and obtained the patient's valid consent. The explanatory memorandum to § 630h(2) BGB states that, as a rule, a patient cannot provide proof of a negative fact (ie, that he or she was not duly informed or did not consent to the treatment). The treating physician, on the other hand, may easily document the content of the information provided and the consent of the patient, and thus fully clarify the circumstances.[93]

[89] BGH Jdg of 14 November 1995 – VI ZR 359/94, VersR 1996, 195.
[90] BGH Jdg of 14 November 1995 – VI ZR 359/94, VersR 1996, 195.
[91] BT-Drs 17/10488, 27.
[92] BT-Drs 17/10488, 27 f.
[93] BT-Drs 17/10488, 28 f.

The shifting of the burden of proof in favour of the patient provided for by § 630h(2) BGB is applicable only with regard to the information of the patient and his or her subsequent consent. According to general principles, the burden of proof for causality rests with the patient; it is up to him or her to prove that the injury for which compensation is sought was caused by inadequate information or lack of (valid) consent.[94]

Insofar as the burden of proof rests with the physician in accordance with § 630h(2) BGB, case law argues that the physician should not be burdened with 'unreasonable and excessive requirements' with regard to the evidence that he or she must provide.[95] The court must take into account the particular situation in which the physician finds himself or herself when treating the patient, as well as the danger of abuse of the allocation of the burden of proof for liability purposes. In case of doubt, if 'some evidence' for the conscientious information of the patient has been provided, it is to be assumed in the specific case in favour of the physician that he or she has duly informed the patient.[96]

9.3.3 Hypothetical consent

If the provision of information does not comply with the legal requirements, in accordance with § 630h(2) sentence 2 BGB, the physician may assert that the patient would also have consented to treatment if adequate information had been provided. In principle, however, there are strict requirements for the proof of such hypothetical consent. According to case law, in particular, it will not suffice that a 'reasonable patient' would have consented to the intervention if duly informed. Rather, it is decisive how the individual patient concerned would have decided in the specific case, since even a decision that appears unacceptable for medical reasons is in principle covered by the patient's right to self-determination.[97]

10. CHALLENGES, CONTROVERSIES AND REMEDIES

The principle of informed consent is a central element of the doctor–patient relationship. For a long time, the legal framework of this relationship was mostly defined by case law in Germany. The Patients' Rights Act of 2013 was

[94] Katzenmeier (n 24) BGB § 630h no 31; Christoph Lafontaine/Karsten Schmidt in Maximilian Herberger et al (eds), *jurisPK-BGB* (8th edn, juris 2017) § 630h BGB, no 98.

[95] BGH, Jdg of 28 January 2014 – VI ZR 143/13, NJW 2014, 1527.

[96] BGH, Jdg of 28 January 2014 – VI ZR 143/13, NJW 2014, 1527; see also Katzenmeier (n 24) BGB § 630h no 33: 'Immer-so' case law.

[97] BGH, Jdg of 7 February 1984 – VI ZR 174/82, BGHZ 90, 103.

supposed to transform this differentiated case law into written law, and thus created high expectations. It was hoped that the quality of the doctor–patient relationship would improve if patients were able to act and communicate as equal and responsible partners of physicians based on such legislation. This equal partnership was to be achieved not by creating more rights, but rather by setting down in law existing patient rights, in the hope that these rights, once incorporated into a special law, would not merely exist, but would be consistently exercised in the doctor–patient relationship. The Patients' Rights Act was intended to help overcome the frequently lamented deficits in implementation which were widely believed to be characteristic of patient rights.

A little more than five years after §§ 630a ff BGB came into force, it is still too early to assess whether the Patients' Rights Act has fulfilled these expectations. Insofar as the objectives of transparency and legal certainty are concerned, unsurprisingly, there are positive assessments (the main points of relevant case law have been 'incorporated correctly and [are] mostly comprehensible to the parties'),[98] as well as some negative reviews (no legal certainty achieved – 'on the contrary!').[99] As regards the principle of informed consent, the impact of the new law – both positive and negative – has been limited thus far. The experience with information duties set down in law in other areas suggests that there is little reason to expect that the legislation will lead to improved patient information. On the other hand, there is also a risk that the incorporation into law of patient rights such as informed consent might not encourage physicians to better fulfil their duty, but instead to adopt a formulaic approach to 'be on the safe side'.

[98] Karl Otto Bergmann, '*Vier Jahre PatRG – Fragen, Kontroversen, Perspektiven*' (2017) *VersR*, 661, 666.

[99] Martin Rehborn in *Medizin – Haftung – Versicherung, Festschrift für Karl Otto Bergmann zum 70. Geburtstag* (Springer 2016) 209, 219.