OPEN ACCESS
OPUS AUGSBURG

Universität Augsburg
Universitätsbibliothek

Informed consent in German medical law: finding the right path between patient autonomy and information overload

Benedikt Buchner, Merle Freye

Angaben zur Veröffentlichung / Publication details:

Buchner, Benedikt, and Merle Freye. 2022. "Informed consent in German medical law: finding the right path between patient autonomy and information overload." In *Proceedings of the Young Universities for the Future of Europe (YUFE) Law Conferences 2021*, 1–17. Amsterdam: SSRN - Elsevier BV. https://doi.org/10.2139/ssrn.4088631.

Nutzungsbedingungen / Terms of use:

licgercopyright

Dieses Dokument wird unter folgenden Bedingungen zur Verfügung gestellt: / This document is made available under these conditions:
Deutsches Urheberrecht
Weitere Informationen finden Sie unter: / For more information see:
https://www.uni-augsburg.de/de/organisation/bibliothek/publizieren-zitieren-archivieren/publiz/

YUFE Conference Proceedings No.

01/2022

Informed Consent:

Comparative Perspectives on Duties to Inform in EU and Member States Law

YUFE – Young Universities for the Future of Europe is one of 41 alliances selected by the European Commission to create a true European University. YUFE stands for a radical change in European higher education and has set itself the goal of establishing a young, non-elitist, open and integrative European university, whilst at the same time promoting innovative and interdisciplinary thinking in research and teaching. YUFE is funded by European Union (EU), DAAD (German Academic Exchange Service) and by Bremen's Senator for Science and Ports.

Series Editors: Prof. Dr. Gralf-Peter Calliess, Dr. Nicholas Mouttotos

calliess@uni-bremen.de; nic_mou@uni-bremen.de

Electronic copy available at: https://ssrn.com/abstract=4088631

Informed Consent in German Medical Law[1]

Finding the right path between patient autonomy and information overload

Benedikt Buchner, Merle Freye

A. Introduction

Informed consent in German medical law has a long and controversial tradition. For more than 100 years, medical treatment – even where medically indicated and performed under medical standards – constitutes an act of personal injury and therefore requires the patient's consent.[2] The basis for this sustained understanding was the personal injury doctrine developed in 1894 when the Reichsgericht stated that only the patient's will could exclude the offence of personal injury resulting from medical treatment.[3] In the following decades, the courts supplemented this decision by stating that consent would be valid only if the physician has provided the patient with the necessary information to make an informed decision.[4] Since the patient's informed consent to medical treatment justifies the violation of the fundamental right of physical integrity, information and consent are consequently interrelated and inseparable.[5]

Nevertheless, the medical profession has neither understood nor shared

[1] This article is an updated and revised version of B. Buchner "Informed Consent in Germany" in T. Vansweevelt/N. Glover-Thomas, *Informed Consent and Health*, (2020) Edgar Elgar Publishing, p. 216 ff. The authors would like to thank Petra Wilkins for her help with the translation.

[2] A. Laufs/C. Katzenmeier/V. Lipp, *Arztrecht*, C. H. Beck (2021), chapter V para. 83 f.

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

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

[5] A. Jorzig, *Handbuch Arzthaftungsrecht*, C. F. Müller (2018), p. 217.

Electronic copy available at: https://ssrn.com/abstract=4088631

the personal injury doctrine. On the contrary, it has provoked severe criticism from the beginning.[6] In view of the fact that the main objective of medical treatment is to preserve the patient's health, it seems reasonable to claim that medical treatment without the patient's consent is not a violation of the patient's physical integrity but a violation of his or her autonomy and freedom of decision. Despite this perpetual criticism, the personal injury doctrine has remained applicable and has been enshrined in the German Civil Code (BGB) in 2013. Regardless of the chosen approach – the personal injury doctrine on the one hand or patient's self-determination on the other – it is informed consent that is central and indispensable for medical treatment. Thus, the academic debate has predominantly shifted from questioning the violated right to specifying the information duties and guaranteeing the patient's self-determination. Covid19 and the rapid technological progress have pushed this debate forward by constantly imposing new challenges to informed consent.

B. The right dose of information

The critical challenge of informed consent in medical law – as in any field of law – is finding the "right dose of information". In order to enable a well-considered decision of the patient and ensure effective consent, it must be clarified which information is indispensable for informed consent and which information is not. On the one hand, physicians must provide all the information a patient needs to make an informed decision. On the other hand, complex medical information, including all aspects that are somehow relevant to the treatment, would rather prevent informed consent than promoting it. Separating essential information from redundant information is a concept, incorporated into the BGB, that

[6] C. Katzenmeier/A. Heldrich/P. Schlechtriem/E. Schmidt, *Festschrift für Helmut Heinrichs*, C.H. Beck (1998), p. 291, 310; Laufs, *op. cit.* note 2, chapter V para. 83 f.; G. Wagner "Vor § 630a BGB" in F. Säcker/R. Rixecker/H. Oetker/B. Limperg, *Münchener Kommentar zum Bürgerlichen Gesetzbuch*, 8th edition (2020) C. H. Beck, para. 13 f. with further references.

Electronic copy available at: https://ssrn.com/abstract=4088631

distinguishes between the therapeutic information and the information required for self-determination. Whereas information for purposes of self-determination is a prerequisite for the validity of informed consent, therapeutic information is not.[7]

1. Self-determination information

Following § 630e (1) sentence 1 BGB, information for purposes of self-determination requires information "on all circumstances essential for consent". Examples for such circumstances are listed in a non-limitative manner in § 630 (1) sentence 2 BGB and are generally summarised as information about risk, information about diagnosis, and information about the course of treatment.[8] Nevertheless, these groups can merge into each other[9] and are thus not as specific as they might seem at first sight. Furthermore, they cannot hide the fact that accurate information is always determined by the individual treatment situation.[10] As a result, only the many facets of detailed case law concretize informed consent in the medical field:

a) Examples of information

For example, risk information should also include information about rare risks if they would have severe consequences for the patient's lifestyle in the case of their occurrence and if they are specific to the medical intervention despite their rarity.[11] Accordingly, even for complication rates below 0.1 per cent, there is a duty of information if the risk might influence a responsible patient in his or her

[7] C. Katzenmeier "§ 630e BGB" in W. Hau/R. Poseck, *Beck'scher Online-Kommentar*, 61th edition (2022) C. H. Beck, para. 1; Wagner, *op. cit.* note 6, para. 4; Laufs, *op. cit.* note 2, chapter V para. 16.
[8] Katzenmeier, *op. cit.* note 7, para. 8.
[9] Katzenmeier, *op. cit.* note 7, para. 9.
[10] German Bundestag, draft legislation of the German Federal Government, Bundestag-Drucksache 17/10488, p. 24.
[11] Katzenmeier, *op. cit.* note 7, para. 15 with references to case law.

Electronic copy available at: https://ssrn.com/abstract=4088631

decision to consent.[12] Within the framework of risk information, the physician must inform the patient about all possible severe side effects of a prescribed drug since a mere reference to the package leaflet conflicts with the physician's obligation to give the patient a general idea of specific risks associated with the intervention.[13]

As another essential aspect of informed consent, the physician must provide information about existing alternatives to the proposed measure. According to the principle of freedom of therapy, the physician chooses the treatment method.[14] However, the physician must inform the patient about alternatives to the proposed measure if several equally indicated methods may lead to significantly different adverse effects, risks, or prospects of a cure, § 630e (1) sentence 3 BGB. When proposing an alternative treatment method that is relatively new and has not yet been generally adopted, the physician must expressly refer to the fact that the new method might involve unknown risks.[15] Consequently, informed consent is of even greater importance for a novel therapy than in the case of standard treatment. Whereas information about alternatives includes the treatment method itself, it does not necessarily cover institution-related information as well. A patient who is offered treatment that is standard in one facility needs not be informed that the same treatment might be performed with possibly better personnel and equipment at another.[16] It is not mandatory to

[12] B. R. Kern "§ 66 Inhalt und Umfang der Aufklärung" in A. Laufs/B. R. Kern, *Handbuch des Arztrechts*, 5th edition (2019) C. H. Beck, para. 23; OLG Stuttgart, Jdg of 17 November 1998 – 14 U 69/97, VersR 1999, 1500.

[13] Besides, this would not be consistent with the principle of oral information provided for under § 630e (2) sentence 1 no 1 BGB. BGH, Jdg of 15 March 2005 – VI ZR 289/03, BGHZ 162, 320.

[14] § 2 (1) of the (Model) Professional Code of Conduct for Physicians (MBO-Ä); C. Katzenmeier "§ 630a BGB" in W. Hau/R. Poseck, *Beck'scher Online-Kommentar*, 61th edition (2022) C. H. Beck, para. 184; B. R. Kern "§ 3 Die Freiheit des ärztlichen Berufs" in A. Laufs/B. R. Kern, *Handbuch des Arztrechts*, 5th edition (2019) C. H. Beck, para. 13 f.

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

[16] BGH, Jdg of 22 September 1987 – VI ZR 238/86, BGHZ 102, 17; BGH, Jdg of 24 May 1988 – VI ZR 326/87, NJW 1988, 2300; G. Wagner "§ 630e BGB" in F. Säcker/R. Rixecker/H. Oetker/B. Limperg, *Münchener Kommentar zum Bürgerlichen Gesetzbuch*, 8th edition (2020) C. H. Beck,

Electronic copy available at: https://ssrn.com/abstract=4088631

inform the patient about such differences in quality since medical progress will inevitably entail differences in healthcare quality, depending on the personnel and material resources of the facility.[17] Information about such alternatives is required only if the new treatment method has become widely accepted and the possible advantages for the patient are so considerable that he or she must be informed to be able to decide whether to seek access to the state-of-the-art treatment.[18]

When it comes to cosmetic surgery, the German Federal Court of Justice (BGH) refers to a special responsibility of the physician and consequently establishes particularly strict information requirements.[19] The patient must not only be informed about the prospects of success but also about possible adverse effects.[20] Stricter requirements for informed consent also apply for clinical trials, which involve new treatment methods or drugs that have not yet been approved. The physician must provide comprehensive information about the lack of approval, and that unknown risks cannot be excluded at present.[21]

In light of the Covid19 pandemic, information affecting the entire population has recently drawn public attention and involves several of the aspects mentioned before.[22] Regarding Covid19 vaccines, the German Ethics Council and the Leopoldina stated that a self-determined decision about vaccination requires continuous, transparent information about vaccine efficacy and vaccine risks. The physician must not only inform about the side effects of

---

para. 24; Laufs, *op. cit.* note 2, chapter V para. 37. For another opinion see D. Hart "Patientensicherheit nach dem Patientenrechtegesetz" *Medizinrecht 31* (2013), p. 159, 161 f.

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

[18] *Ibid*; T. Neelmeier "Die einrichtungsbezogene Patientenaufklärung" *Neue Juristische Wochenzeitschrift 66* (2013), p. 2230.

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

[20] *Ibid.*

[21] K. Schmidt "§ 630e BGB" in M. Herberger/ M. Martinek/ H. Rüßmann, *juris PraxisKommentar BGB*, 9th edition (2020), para. 18; BGH, Jdg of 27 March 2007 – VI ZR 55/05 - BGHZ 172, 1 para. 31.

[22] For questions of Covid19 vaccination and information asymmetry see J. Drechsler "Selbstbestimmungsaufklärung und Pandemiebekämpfung" *Medizinrecht 39* (2021), p. 439.

Electronic copy available at: https://ssrn.com/abstract=4088631

the vaccine but also about alternative vaccines, with special emphasis on the different risks of mRNA vaccines and vector vaccines.[23] Additionally, stricter information duties arise when test persons voluntarily participate in clinical trials to evaluate the vaccine's safety and protective efficacy. Since medical research dealing with vaccine risks and vaccine efficacy has rapidly developed, Covid19 vaccinations exemplify that information must constantly adapt to changing circumstances and is thus not a static phenomenon.[24]

b) Exceptions of information

In contrast to the strict information duties mentioned above, some situations are less demanding for the physicians. 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,[25] unless the patient has further questions or appears to have misconceptions about the risks of the proposed measure.[26] Besides, some situations do not require information (and consent). According to § 630d (1) sentence 4 BGB, a measure may be performed without consent when the measure is in line with the patient's presumed will. Additional requirements for this particular case are that it is impossible to obtain timely consent, and the measure cannot be postponed. The patient's presumed will can be determined by reflecting on previous statements of the patient or by questioning close relatives and trusted persons.[27] Considerations of how an average patient could be

[23] D. Hart "Impfstoffe gegen SARS-CoV-2: Zulassungskriterien, Aufklärungsvoraussetzungen und Auswahlmöglichkeiten" *Medizinrecht 39* (2021), p. 696.
[24] D. Hart "Zur Konkurrenz der Impfstoffe gegen COVID-19: Aufklärung und Auswahl" *Medizinrecht 39* (2021), p. 319; Hart, *op. cit.* note 23, p. 694.
[25] See BGH, Jdg of 23 October 1979 – VI ZR 197/78, NJW 1980, 633 on the example of appendix surgery.
[26] Schmidt, *op. cit.* note 21, para. 15; BGH, Jdg of 23 October 1979 – VI ZR 197/78, NJW 1980, 633 para. 22.
[27] W. Weidenkaff "§ 630d BGB" in C. Grüneberg, *Bürgerliches Gesetzbuch mit Nebengesetzen,* 81th edition (2022) C. H. Beck, para. 4; C. Katzenmeier "§ 630d BGB" in W. Hau/R. Poseck, *Beck'scher Online-Kommentar*, 61th edition (2022) C. H. Beck, para. 23; K. Schmidt "§ 630d

Electronic copy available at: https://ssrn.com/abstract=4088631

expected to decide only apply secondarily when a careful investigation does not reveal any specific circumstances indicating the individual presumed will of the patient.[28] Typical examples of presumed will are emergency treatments of unconscious accident victims.[29]

§ 630e (3) BGB describes two further exceptions to the principle of informed consent. First, informed consent is dispensable when the patient has explicitly waived the right to be provided with the information. For example, this option is explicitly mentioned in the anamnesis and consent sheets for vaccination against Covid19. Second, the physician can refrain from providing information if there are significant therapeutic reasons. In view of the immense infringement of the patient's right to self-determination, these situations remain exceptional and are subject to very strict requirements.[30] For example, the physician is not required to provide information for therapeutic reasons if this would seriously endanger the life or health of the patient.[31]

2. Therapeutic information

As described above, therapeutic information is not a prerequisite of informed consent and the absence of therapeutic information does not constitute a personal injury. Instead, therapeutic information constitutes medical malpractice if the physician does not comply with the therapeutic information requirements. According to § 630c (2) BGB, the physician must inform the patient at the beginning and, if necessary, during 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 after treatment. In

BGB" in M. Herberger/M. Martinek/H. Rüßmann, *juris PraxisKommentar BGB*, 9th edition (2020), para. 28; BGH, Jdg of 10 March 1987 – VI ZR 88/86, NJW 1987, 2291.

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

[29] Jorzig, *op. cit.* note 5, p. 219.

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

[31] German Bundestag *op. cit.* note 10, p. 25; BGH, Jdg of 7 February 1984 – VI ZR 174/82, NJW 1984, 1397 ff.; Wagner, *op. cit.* note 16, para. 67.

Electronic copy available at: https://ssrn.com/abstract=4088631

principle, therapeutic information aims to motivate the patient to adopt a lifestyle appropriate to his or her state of health, use medication as prescribed, and take adequate measures of self-protection.[32] Consequently, therapeutic information includes all information required to ensure a successful treatment outcome and the compliance of the patient.[33] In light of the German health system distinguishing between private and statutory health insurance, therapeutic information includes aspects of cost coverage and self-paying. Therefore and in accordance with § 630c (3) BGB, the physician must inform the patient in writing of the anticipated costs before treatment is commenced, where he or she knows or must assume that the treatment costs may not be fully covered by health insurance. As for information for purposes of self-determination, in rare circumstances the therapeutic information can be omitted as well. The requirements for this exception mentioned above are the same for both types of information since § 630c (4) BGB is identical to § 630e (3) BGB.

C. Liability and burden of proof

In addition to distinguishing between therapeutic information and information for purposes of self-determination, German medical law contains another particularity related to informed consent, which is related to the burden of proof. According to German civil procedure law, each party principally bears the burden of proof for the actual requirements of the legal provision favourable to it. For the case of compensation claims based on a violation of the duty to inform, this would mean that the patient would have to prove inadequate or missing information.[34] In view of the principle of "equality of arms" applied in legal proceedings, this

[32] Laufs, *op. cit.* note 2, chapter V para. 16.
[33] C. Katzenmeier "§ 630c" in W. Hau/R. Poseck, *Beck'scher Online-Kommentar*, 61th edition (2022) C. H. Beck, para. 7; G. Wagner "§ 630c BGB" in F. Säcker/R. Rixecker/H. Oetker/B. Limperg, *Münchener Kommentar zum Bürgerlichen Gesetzbuch*, 8th edition (2020) C. H. Beck, para. 13; M. Quaas/R. Zuck/T. Clemens, *Medizinrecht*, Nomos (2018), § 14 No 79.
[34] German Bundestag, *op. cit.* note 10, p. 27 f.

Electronic copy available at: https://ssrn.com/abstract=4088631

allocation is generally not deemed appropriate for informed consent:[35] generally having no insight into treatment procedures, the patient cannot prove the negative fact that he or she was not duly informed. In contrast, the physician may easily document the content of the information provided and can thus fully clarify the circumstances.[36] A shift in favour of the patient has therefore been evident in practice for some time and is also provided for § 630h (2) BGB, stating that the treating physician bears the burden of proof regarding the provision of information and valid consent. Nevertheless, this reverse burden of proof affects only the patient's information and his or her subsequent consent whereas the burden of proof for causality rests with the patient. Therefore, the patient must prove that the alleged injury was caused by inadequate information or a lack of (valid) consent.[37] As the burden of proof partly rests with the physician, case law argues that the physician should not be burdened with "unreasonable and excessive requirements" regarding the evidence that he or she must provide.[38] Hence, the court must take into account the particular treatment situation and the danger of abusing 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 thus to be assumed in favour of the physician that he or she has duly informed the patient in the specific case.[39]

[35] *Ibid*, 28 f.
[36] *Ibid.*
[37] C. Katzenmeier "§ 630h BGB" in W. Hau/R. Poseck, Beck'scher Online-Kommentar, 61th edition (2022) C. H. Beck, para. 31; M. Middendorf "Der Kausalitätsnachweis bei der Haftung aus Aufklärungsfehler" *Medizinrecht* 37 (2019), p. 37 ff; C. Lafontaine/K. Schmidt "630h BGB" in M. Herberger/M. Martinek/H. Rüßmann, *juris PraxisKommentar BGB*, 9th edition (2020), para. 101.
[38] BGH, Jdg of 28 January 2014 – VI ZR 143/13, NJW 2014, 1527.
[39] *Ibid*; BGH, Jdg of 10 March 1981 – VI ZR 202/79, NJW 1981, 2002 f.; see also Katzenmeier, *op. cit.* note 37, para. 33: "Immer-so case law".

Electronic copy available at: https://ssrn.com/abstract=4088631

D. Form and 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" decision about consenting to treatment. The right timing of information thus becomes a decisive element for guaranteeing the patient's right to self-determination.[40] In this context, the case's specific circumstances determine when to inform the patient: regarding normal ambulant treatment or diagnostic interventions, German case law deems information provided on the same day to be sufficient[41] as long as the information is not provided immediately before the intervention.[42] Nonetheless, informing the patient 30 minutes before the intervention is scheduled is regularly considered too late.[43]

The provisions of the BGB do not only refer to timing but also outline how the patient is to be informed. § 630e (2) BGB states that a qualified person must provide the information orally. By providing the patient with the opportunity to ask questions about the proposed intervention in a personal conversation, the law ensures that informed consent is not reduced to a mere formality.[44] Regarding language barriers, the physician must call in someone who can speak the patient's language if it would be impossible otherwise to ascertain whether the patient has understood the information provided.[45] If still in doubt whether the patient has understood the information, the physician must enlist the services of a

[40] Established case law; see BGH, Jdg of 25 March 2003 – VI ZR 131/02, NJW 2003, 2012 f.; BGH, Jdg of 17 March 1998 – VI ZR 74-97, NJW 1998, 2734; BGH, Jdg of 12 July 1994 – VI ZR 299/93, NJW 1994, 3009.

[41] BGH, Jdg of 25 March 2003 – VI ZR 131/02, NJW 2003, 2012 f.; BGH, Jdg of 4 April 1994 – VI ZR 95/94, NJW 1995, 2410 f.; BGH, Jdg of 14 November 1995 – VI ZR 359/94, NJW 1996, 777, 779.

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

[43] German Bundestag, *op. cit.* note 10, p. 25.

[44] *Ibid*, p. 24.

[45] German Bundestag, *op. cit.* note 10, p. 25; OLG Köln, Jdg of 9 December 2015 – 5 U 184/14, VersR 2016, 994; OLG Köln, Jdg of 23 January 2019 – 5 U 69/16, MedR 2019, 803.

Electronic copy available at: https://ssrn.com/abstract=4088631

professional interpreter at the expense of the patient.[46]

Since trustful communication between the attending physician and the patient is essential, it should be as free from bureaucratic formalities as possible.[47] Although documents may supplement oral information according to § 630e (2) sentence 1 no 1 BGB, they cannot wholly replace the required oral information. The common practice of providing written information about routine vaccinations combined with offering oral explanation when required is therefore not appropriate in all cases.[48] Otherwise, information would not be supplemented by documents, but documents would be supplemented by information. As the BGH stated in 2000, the practice described is only lawful by exception – for example, when vaccination is publicly recommended or recommended by the Standing Committee on Vaccination (STIKO).[49] Since STIKO and several federal states in Germany recommend the vaccination against Covid19, there are good reasons to apply this ruling to Covid19 vaccination.[50]

In exceptional cases, the information may be provided by telephone if the patient agrees.[51] Nevertheless, information by telephone is adequate only in straightforward treatment cases and cannot be employed in cases of complex medical interventions with significant risks.[52] Besides, patients are always free to

[46] Katzenmeier, *op. cit.* note 7, para. 50; Wagner, *op. cit.* note 16, para. 55; Schmidt, *op. cit.* note 21, para. 44; OLG Köln, Jdg of 9 December 2015 – 5 U 184/14, VersR 2016, 99.

[47] BGH, Jdg of 8 January 1985 – VI ZR 15/83, VersR 1985, 361; Schmidt, *op. cit.* note 21, para. 30.

[48] Schmidt, *op. cit.* note 21, para. 30; Katzenmeier, *op. cit.* note 7, para. 33 with references to case law; M. Rehborn "Das Patientenrechtegesetz" *Gesundheitsrecht* (2013), p. 265.

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

[50] For another opinion on pandemic vaccination see Katzenmeier, *op. cit.* note 7, para. 33 and A. Spickhoff "Die Entwicklung des Arztrechts 2020/2021" *Neue Juristische Wochenschrift 74* (2021), p. 1717; unclear position of German Federal Ministry of Health, which states that information sheets combined with an optional oral explanation are not absolutely necessary, and refers to the patient's right to waive his or her right to information: https://www.zusammengegencorona.de/impfen/gesundheits-und-pflegeberufe-impfen/corona-schutzimpfung-in-arztpraxen-ablauf-und-aufklaerung/#id-bc009610-d31a-5054-bc09-d64fd6300d1f.

[51] BGH, Jdg of 15 June 2010 – VI ZR 204/09, NJW 2010, 2430; Schmidt, *op. cit.* note 21, para. 29; German Bundestag, *op. cit.* note 10.

[52] BGH, Jdg of 15 June 2010 – VI ZR 204/09, NJW 2010, 2430; Schmidt, *op. cit.* note 21, para. 29.

Electronic copy available at: https://ssrn.com/abstract=4088631

insist on a personal conversation with the physician.[53] Regarding the requirement of oral information and exceptions for communication by telephone, one particular intervention has been subject to legislation, court decisions and physician's professional law lately: consultation between patient and physician via video. Whereas in the past, distance communication has been considered lawful only in straightforward treatment cases in the past,[54] the legislator finally decided to endorse video consultation without this restriction by adopting § 365 SGB V in 2019. According to the legislator, video consultation is permissible due to the increasing technical quality and acceptance within the society, which would neither justify the former criticism nor the former restriction.[55] Legislation thereby reflects physician's professional law, which has approved remote treatment since 2018.[56] Considering the essential importance of information for the patient's right to self-determination and the disadvantages of remote communication in video consultation, it seems reasonable to offer video consultation only when adequate information can be ensured.[57] At least, waiving of information as mentioned in § 630e (3) BGB and referred to under § 365 (1) sentence 4 SGB V should not be possible in a video consultation.

E. Capacity to consent

In 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.[58] According to prevailing opinion, the validity of consent does thus not

[53] *Ibid.*
[54] German Bundestag, *op. cit.* note 10; BGH, Jdg of 15 June 2010 – VI ZR 204/09, NJW 2010, 2430.
[55] German Bundestag, draft legislation of the German Federal Government, Bundestag-Drucksache 19/13438, p. 70.
[56] See § 7 (4) of the (Model) Professional Code of Conduct for Physicians (MBO-Ä).
[57] Similarly E. Hahn "Eine fast gelungene Klarstellung zur Aufklärung des Patienten über Fernkommunikationsmittel" *Medizinrecht 38* (2020), p. 23.
[58] G. Wagner "§ 630d BGB" in F. Säcker/R. Rixecker/H. Oetker/ B. Limperg, *Münchener Kommentar zum Bürgerlichen Gesetzbuch*, 8th edition (2020) C. H. Beck, para. 9; C. Katzenmeier "§ 630d BGB" in W. Hau/R. Poseck, Beck'scher Online-Kommentar, 61th edition

Electronic copy available at: https://ssrn.com/abstract=4088631

depend on the patient's legal capacity to contract.[59] 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.[60] This vague regulatory guidance creates considerable legal uncertainty for the attending physician. The academic literature provides some general orientation: up to the age of 14, the physician should generally obtain the consent of the parents (or another person, institution or body having rights of custody). Between the ages of 14 and 17, capacity to consent must be determined in the individual case as outlined above.[61] If the parents' consent is needed, but 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.[62] Nevertheless, parents can still intervene although their children have the capacity to understand.[63] Accordingly, OLG Frankfurt affirmed the capacity of a 15-year-old boy to consent to Covid19 vaccination but demanded a co-consensus between the minor and his parents.[64]

Besides, the capacity to consent can also be in question when adults are concerned. If an adult is unable to look after his or her interests due to mental

(2022) C. H. Beck, para. 7; K. Schmidt "§ 630d BGB" in M. Herberger/M. Martinek/H. Rüßmann, *juris PraxisKommentar BGB*, 9th edition (2020), para. 11; BGH, Jdg of 5 December 1958 – VI ZR 266/57, NJW 1959, 811; for another opinion see H. Koziol "Fehlende Einwilligung des Patienten und Haftung in Österreich – Notwendigkeit neuer Lösungen?" *Medizinrecht 37* (2019), p. 12 with further references.

[59] *Ibid.*

[60] Laufs, *op. cit.* note 2, chapter V para. 51.

[61] Katzenmeier, *op. cit.* note 27, para. 13; Laufs, *op. cit.* note 2, chapter V para. 52.

[62] See § 1666 BGB. OLG Naumburg, Jdg of 12 September 2013 – 1 U 7/12, VersR 2014, 507; Lugani "§ 1666 BGB" in F. Säcker/R. Rixecker/H. Oetker/B. Limperg, *Münchener Kommentar zum Bürgerlichen Gesetzbuch*, 8th edition (2020) C. H. Beck, para. 78 ff.

[63] For the question of co-consensus see L. *Birck/T. Solscheid "Einwilligungszuständigkeit bei der Behandlung Minderjähriger" Medizinrecht 39* (2021), p. 970 ff.; Wagner, *op. cit.* note 58, para. 43; Laufs, *op. cit.* note 2, chapter V para. 52; *Katzenmeier*, *op. cit.* note 27, para. 14.

[64] OLG Frankfurt a.M., Jdg of 17 August 2021 – 6 UF 120/21, MedR 2022, 224.

Electronic copy available at: https://ssrn.com/abstract=4088631

illness or physical, mental, or psychological disability, the guardianship court will appoint a guardian at his or her request or ex officio.[65] 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 specific area. The guardian will then represent the person concerned before and out of court, § 1902 BGB.[66] However, this does not entail the guardian making every decision of relevance to the health of the person concerned: since the primary task of the guardian is to enable the person under guardianship to exercise his or her right to self-determination comprehensively,[67] it must always be determined whether the latter can give his or her consent to the individual medical measure. If this is the case, he or she will make the decision, not the guardian.[68]

The capacity to consent is crucial regarding the person that has to be informed: if the patient does not have the capacity to consent for the above-described reasons and an entitled person has therefore given consent, the latter must also receive the information, § 630d (2) BGB. Nevertheless, the patient must be informed to a certain extent as well: according to § 630e (5) BGB, the physician must inform about the essential facts of the proposed measures insofar as the patient's level of development and understanding makes it possible to receive this explanation, and insofar as this does not interfere with the patient's welfare.[69]

[65] In accordance with § 1896 BGB.

[66] A. Diekmann "Der betreute Mensch als Patient – Wer entscheidet was und wer übernimmt welche Aufgaben im Rahmen der Gesundheitssorge?" *Betreuungsrechtliche Praxis* (2018), p. 23 ff.

[67] V. Lipp "UN-Behindertenrechtskonvention und Betreuungsrecht" *Betreuungsrechtliche Praxis* (2010), p. 263 ff.

[68] Laufs, *op. cit.* note 2, chapter III para. 14; A. Schneider „§ 1896 BGB" in F. Säcker/R. Rixecker/H. Oetker/B. Limperg, *Münchener Kommentar zum Bürgerlichen Gesetzbuch*, 8th edition (2020) C. H. Beck, para. 39 ff.; V. Lipp "Rechtliche Betreuung und das Recht auf Freiheit" *Betreuungsrechtliche Praxis* (2008), p. 51 ff.

[69] For details related to Covid19 vaccination see J. Kraemer "Die Corona-Schutzimpfung von hochbetagten Patienten" *Neue Juristische Wochenschrift* 74 (2021), p. 350 ff.

Electronic copy available at: https://ssrn.com/abstract=4088631

F. Information overload and other challenges to informed consent

The requirement of informed consent as the basis of every medical treatment is closely linked to the model of the "responsible patient": The responsible patient is supposed to act with self-confidence and with responsibility towards his or her physician. He or she does not accept the treatment decisions of the physician unquestioningly. Instead, the responsible patient and the physician decide together on the optimal treatment choice (shared decision-making). Aiming to improve medical decision-making, this requires an active patient in contrast to a patient who merely "consumes" the medical treatment.[70]

However, whereas the ideal constellation of shared decision-making may lead to the best possible outcome achieved jointly by patient and physician, there are constellations where the patient is provided with so much complex or even scary information that this might cause the incessantly feared information overload.[71] A physician providing a specialist lecture to inform the patient prevents rather than promotes responsible decision-making.[72] As the Constitutional Court stated, there is also the "downside of free self-determination"[73] since the information provided by physicians can turn out to be very distressing for the patient and anything but helpful for shared decision-making between physician and patient. In light of these considerations, it is questionable whether the so-called responsible patient reflects the reality of everyday medical treatment. The ideal of the responsible patient is inevitably associated with the risk that the physician-patient relationship will be overloaded with unrealistic expectations, and ultimately both patient and physician may be forced into roles that they cannot fulfil.

---

[70] Laufs, *op. cit.* note 2, chapter V para. 107.

[71] R. Schenk, *Die medizinische Grundaufklärung*, Springer (2015), p. 24; see also B. Buchner "Sinn und Unsinn eines Patientenrechtegesetzes" in Arbeitsgemeinschaft Rechtsanwälte im Medizinrecht, *Qualitätsmängel im Arzthaftungsprozess – Brauchen wir ein Patientenrechtegesetz?*, (2012) Springer, p. 98.

[72] C. Förster "§ 823 BGB" in W. Hau/R. Poseck, *Beck'scher Online-Kommentar*, 61th edition (2022) C. H. Beck, para. 844; BGH, Jdg of 6 July 2010 – VI ZR 198/09, NJW 2010, 3230 para. 12.

[73] BVerfG, Jdg of 25 July 1979 – 2 BvR 878/74, NJW 1979, 1925, 1932.

Electronic copy available at: https://ssrn.com/abstract=4088631

G. Conclusion

The principle of informed consent is a core element of the physician-patient relationship. For a long time, the legal framework of this relationship was mainly defined by case law in Germany. Based on the objective of turning patients into equal and responsible partners, the Patients' Rights Act of 2013 was supposed to transform this differentiated case law into written law in order to provide patients with a clear guideline as to their rights in the process of medical treatment. However, whereas the main points of relevant case law have been incorporated in the BGB, it is still case law that outlines the multiple facets of informed consent in the individual case, especially when it comes to new challenges in the medical treatment routine. Not only pandemic events but also the rapid technological progress in medicine constantly raise new questions to be answered, illustrating that informed consent is an evolving construct, steadily adapting to reality. In view of this dynamic development, it has to be kept in mind at all times that, in medical law as well as in other areas of law, informed consent must never be an end in itself, but must be able to guarantee that the patient can act as a self-dependent individual and thus actually decides in his or her own well-understood interest.

Electronic copy available at: https://ssrn.com/abstract=4088631