**Digital online anaesthesia patient informed consent - an overview of the current implementation in Europe**

Claudia Neumann1, Grigorij Schleifer1, Nadine Strassberger-Nerschbach1, Achilles Delis1, Johannes Kamp1, Alexandra Görtzen-Patin1, Dishalen Cudian1, George John2, Andreas Fleischer3, Götz Wietasch4, Mark Coburn1, Ehrenfried Schindler1, Maria Wittmann1\*

1.   Department of Anaesthesiology and Intensive Care Medicine, University Hospital Bonn, Germany

2.   European Society of Anaesthesiology and Intensive Care, Brussels, Belgium

3.   KH xy

4.   University Medical Center Groningen, Netherlands

\*Corresponding author: PD Dr. med. Maria Wittmann, Email: maria.wittmann@ukbonn.de

**Abstract**[MW4]

Digitalisation in the health system is a topic that is currently being discussed a lot, not least because of the current pandemic. Technical progress and legal frameworks that facilitate remote patient education vary across Europe and were assessed in this work.

As in many areas of daily life, digitalisation is becoming increasingly important in the medical field due to the widespread use of computers and smartphones.

**Methods**

An online survey with a total of 27 questions was sent by the European Society of Anaesthesiology and Intensive Care (ESAIC) to their members in 47 European countries.

**Results**

The results of this survey show …

**Conclusion**

**…**

**Keywords:** Telemedicine; digital informed consent, legal basis, European practice

**Introduction**

In recent years, there have been more and more efforts to shorten patients' hospital stays and streamline processes [5].  On the one hand, these efforts have an economic background, but also medical advantages, since shorter hospital stays can for example lead to a reduction in nosocomial infections [6].

The WHO highlights Healthcare-Associated Infections (HCAIs) as a major issue for health providers, patients and public authorities worldwide [1].The ECDC reported that approximately 4 131 000 patients are affected by about 4 544 100 episodes of HCAI every year in Europe, with a mean HCAI prevalence of 7.1% [2]. In this context, HCAIs cause 16 million extra-days of hospital stay and 37 000 attributable deaths (and contribute to an additional 110 000). Associated costs: approximately € 7 billion annually [WHO (2011)], with a considerable variability in estimates with a range of 1.2 to 26.4 excess days due to HCAI [3].

Enabling remote contact and communication with patients without physical presence using digital media tools may facilitate reduction of HCAIs. Especially for surgical interventions it may help to keep the pre-operative hospital length of stay as short as possible. Currently however, pre-operative anaesthesiological evaluation is  carried out in most hospitals during the pre-operative stay or patients are invited into the hospital in advance. This could be amplified by the recommendations/guidelines of many medical societies, that physical contact is required for a patient to be legitimately informed. (Quelle?)

Especially, in light of the current COVID-19 pandemia, a reduction of the number and length of hospital stays is desirable. Social distancing is especially important for vulnerable patient groups such as those with multiple comorbidities, immunosuppression, or elderly patients [4], even beyond a pandemic situation.

**Methods**

To provide an Europe-wide overview on the current state of technical support and legal framework for telemedical consultation, a survey with a total of 27 questions was sent by the European Society of Anaesthesiology and Intensive Care (ESAIC) to their members in 47 European countries.

The survey was designed as a multiple choice questionnaire with the possibility to add comments or omit questions. Written answers were not analyzed for this study and did not contribute to the statistics presented here. The questionnaire could be completed in 7-10 minutes. It was possible to resume answering the survey if the session had to be interrupted.

The main focus of our survey was particularly on the general and technical possibility of digital education in the field of anesthesia and the assessment whether a remote online or telephone anesthesia consent procedure would comply with legal requirements across different European countries. We also assessed information on the time frame of the preoperative visit distinguished between low and high risk procedures,

As a subanalysis, perception of legal differences and technical implementation of tools facilitating remote consent process were investigated in relation to the respective structural resources, taking into account the gross domestic product per capita and the Digital Health Index as relevant benchmarks. In addition, the influence of population density on the results was analyzed. This was taken into account in the discussion if significant differences emerged. A detailed itemization can be found in the supplementary material Tabl….XY. To shed light on possible associations of technical progress in respect to economic health and geographical conditions, survey data was stratified based on European gross domestic product per capita, the Digital-Health-Index and population density.

The survey was implemented by using an open source online questionnaire tool “LimeSurvey CE” (Version 5.1, <https://community.limesurvey.org/downloads/>), and was hosted on a secured Linux Debian (Version 10.11) server. The link to the questionnaire was distributed by the ESAIC communication committee (<https://kai-survey.de/limesurvey/733779/>) to 42,433 active members and the survey was conducted over a three-week period (July to August 2021). An ethical approval for this survey was not requested, because data was obtained completely anonymous. The members of the ESAIC did give their consent to take part in regular surveys on the membership homepage.

Absolute numbers and proportions of responses were provided for every question used in this observational survey. Differences in the study population and subgroups were compared using a chi-square test of independence. The nature of the dependence between the row (dependent) and column (independent) in contingency tables was interpreted by identifying cells with the highest standardized Pearsons residuals (r). These cells contribute the most to the total Chi-square score and thus show the direction and but also the streangth of effect between variables. Significance level was set to *p* ≤ 0.05 and all analyses were performed using the statistical language R (R Core Team, Vienna, Austria, Version 3.6.2). Pearson's residuals and Chi-Square statistics were calculated using a free online tool  An interactive web application was programmed to provide additional insight into the survey population (<https://kai-survey.shinyapps.io/ESAIC-KAI-survey-2021>). All code for statistical analysis and visualisation can be accessed online (<https://github.com/GrigorijSchleifer/EJA-ESAIC-survey>).

**Results**

The survey “Digital online Patient Informed Consent for Anaesthesia before Elective Surgery. Recent practice in Europe”, conducted by the University Hospital Bonn and ESAIC took place in July 2021, and aimed to capture state-of-the-art anaesthesiological consultation facts complemented by a judgment of online or telephone assessment / informed consent. The survey consisted of 63 questions, collected responses from 47 European countries and was completed by 1265 participants. Overall, data was provided by medical doctors (99 %, n = 920), nurses (0.2 %, n = 2) and physician assistants (0.6 %, n = 6). 56 % (n = 521) and 43.6 % (n = 406) of survey participants were male or female respectively and the consent was obtained predominantly by consultants (78.6%, n = 731) or residents (15.4 %, n = 143) (Table 1). Most answers were contributed by colleagues from Germany (n = 132), Spain (n = 73) and Switzerland (n = 65) (Table S1).

**Table 1.** Descriptive statistics of the study population stratified by gender.

|  |  |  |  |  |
| --- | --- | --- | --- | --- |
|  |  |  |  |  |
|  | **female** | **male** | **diverse** | **p** |
| n (%) | 406 (43.6) | 521 (56) | 3 (0.3) |  |
| **Profession (%)** |  |  |  | <0.001 |
| Medical doctor | 402 (99.0) | 516 (99.2) | 2 (66.7) |  |
| Nurse | 0 (0.0) | 1 (0.2) | 1 (33.3) |  |
| Physician assistant | 4 (1.0) | 2 (0.4) | 0 (0.0) |  |
| Other | 0 (0.0) | 1 (0.2) | 0 (0.0) |  |
| **Your expert level (%)** |  |  |  | 0.33 |
| Anaesthesia technician | 4 (1.0) | 6 (1.2) | 0 (0.0) |  |
| Consultant | 303 (74.8) | 426 (81.8) | 2 (66.7) |  |
| Resident | 75 (18.5) | 67 (12.9) | 1 (33.3) |  |
| Special trained nurse | 0 (0.0) | 1 (0.2) | 0 (0.0) |  |
| Other | 23 (5.7) | 21 ( 4.0) | 0 (0.0) |  |

To assess the availability of digital media that facilitate remote informed consent across Europe, we asked if it was possible to obtain consent via internet or telefone. In 70.2 % (n = 486) of the responses, informed consent via online was not possible or it was not uniformly implemented (6.6%, n = 46). However, 23.1 % (n = 160) of respondents stated that consent via internet was already used in clinical routine. Based on our observation, informed consent via telefone was more frequently used. Anesthesia consent could not be obtained in 56.7 % (...) as stated by the respondents. However, 37.2 % (...) of respondents answered that patient education via telefone was available and 6.1% (...) mentioned varying technical solutions (Figure 1). Based on this observation, consultation via telefone seems to be more frequently used for anesthesia informed consent.

**Figure 1:** Is it possible to obtain informed consent online via internet or telephone in your routine setting?

**Chart, pie chart

Description automatically generated**

Figure 2: … Is it possible to obtain informed consent online via internet or telephone in your routine setting? (stratified by Gross Domestic Product per capita)

Chart, bubble chart

Description automatically generated

Based on our previously published subanalysis on pediatric population, we could show that legal regulations vary considerably across Europe. Here, we assessed if online/telefone consent was in accordance with legal requirements for adult patient population. For simple procedures, 37.2 % (...) of respondents stated that remote informed consent was not in accordance with legal regulations in their country and was legally sound in 27.3 % (...). For complex procedures, remote consent was not possible due to legal requirements in 42.5 % (...) and only in 18.7 % (...) it was compliant with the law. In 35.5 % for simple and 38.8% for complex procedures respondents were unsure about legal regulation in respect to online/telefone informed consent (Figure 2).

Pearson’s chi squared test residuals for each catagories in a … Positive residuals are blue, suggesting a positive association between the corresponding row and column and negative residuals are red, suggesting a negative association.

**Figure 2:** Is a remote informed consent in accordance with the legal requirements for simple or complex procedures and would it be allowed for repeated anesthesia?

Chart

Description automatically generated

**Figure : …** Is a remote informed consent in accordance with the legal requirements for simple or complex procedures and would it be allowed for repeated anesthesia? (stratified by Gross Domestic Product per capita)

Chart

Description automatically generated

**Table 2:** …

|  |  |  |
| --- | --- | --- |
| **Is it possible to obtain informed consent online via *internet* in your routine setting?         p = 0.101** | | |
|  | **Yes** | **No** |
| **High GDP** | 89 (75) [1.5] | 222 (235) [-0.85] |
| **Middle GDP** | 49 (56) [-0.96] | 181 (174) [0.54] |
| **Low GDP** | 19 (25) [-1.18] | 83 (77) [0.67] |
| **Is it possible to obtain informed consent online via *telefone* in your routine setting?        p = <0.001** | | |
|  | **Yes** | **No** |
| **High GDP** | 175 (124) [4.56] | 139 (190) [-3.69] |
| **Middle GDP** | 56 (91) [-3.63] | 173 (138) [2.93] |
| **Low GDP** | 24 (40) [-2.57] | 78 (61) [2.08] |
| **Is an online telephone informed consent for elective surgery in accordance with the       p = <0.001**  **legal requirements in your country (*simple*)** | | |
|  | **Yes** | **No** |
| **High GDP** | 164 (108) [5.37] | 92 (148) [-4.59] |
| **Middle GDP** | 45 (77) [-3.64] | 137 (105) [3.11] |
| **Low GDP** | 9 (32) [-4.17] | 69 (45) [3.57] |
| **Is an online telephone informed consent for elective surgery in accordance with the       p = <0.001**  **legal requirements in your country (*complex*)** | | |
|  | **Yes** | **No** |
| **High GDP** | 110 (73) [4.33] | 130 (167) [-2.86] |
| **Middle GDP** | 30 (53) [-3.12] | 143 (120) [2.06] |
| **Low GDP** | 9 (23) [-2.98] | 68 (54) [1.97] |
| **Thinking of repeated anaesthesia, would an online telephone informed consent              p = <0.001**  **then be allowed for elective surgery due to legal requirements?** | | |
|  | **Yes** | **No** |
| **High GDP** | 187 (127) [5.35] | 70 (130) [-5.28] |
| **Middle GDP** | 54 (87) [-3.56] | 123 (90) [3.52] |
| **Low GDP** | 14 (40) [-4.21] | 69 (42) [4.15] |

It has been shown that shorter hospital stays can lead to a reduction in nosocomial infections. We therefore investigated if procedure severity had an effect on timing when informed consent was performed. For simple procedures, informed consent was obtained in 12.9 % (...) two or more days and in 54.2 % (...) 24 hours and less before surgery. In comparison, for complex procedures, consent was obtained in 33.6 % (...) two days or more and 51.6 % (...) 24 hours and less before the surgical intervention. On the day xof surgery, content was acquired in 32.9 % (...) for simple and 14.8 % (...) for complex procedures respectively. Based on expected complexity of the intervention we observed that patients who needed an extended procedure with higher chance of nosocomial infections were educated about anesthesia earlier compared to patients with simple procedures.

**Figure 3:** When do you need to obtain Informed consent for elective surgery based on legal requirements for simple and complex procedures?

**​​**

**Chart, pie chart

Description automatically generated**

**Discussion**

The use of telemedical support in the field of medicine has been available for years, but has so far only been used with restraint (Quelle). The objective advantages, such as cost savings, reduction of waiting times for patients, avoidance of unnecessary travel and thus more timely care, especially in rural areas, are obvious. In addition, since the beginning of the Covid-19 pandemic, there has been an increasing desire for social distancing, especially for patients with pre-existing conditions who are more at risk from the virus.

In contrast to this, the legal situation in many countries of the European Union is such that purely remote information for medical interventions is at least questionable. While this may be legally compliant in simple cases, in the event of a lawsuit the doctor must prove that the patient was informed just as well and comprehensively as in a face-to-face conversation despite the exclusive use of telemedicine.Quelle?

The requirement for written consent also still poses problems in practice, as an electronic signature cannot be implemented everywhere technically and has not yet become routine in the health sector, in contrast to its increasingly widespread use in other areas of daily life.

Thus, the results of this Europe-wide survey shed light on some interesting aspects of the points raised.

Regarding the possibility of obtaining anaesthesiological consent online or by telephone, most respondents stated that this was not the case, with the use of the internet being mentioned even less frequently as an alternative possibility. If one includes the results of the sub-analysis regarding the gross domestic product, it becomes apparent that in countries with a higher GDP, the use of telemedical support tends to be performed more often and is more widespread considered legal, at least for repeat anaesthesia and simpler procedures. This may reflect the better technical conditions in these countries.

The overall assessment of the legal situation shows a clear picture in this survey. Only .... percent believe that telemedical information is legal, whereas .... . As already mentioned, a very large proportion of respondents are unclear about the legal regulation(….%)

Looking at European law

Der bislang von Johannes erarbeitet juristische Teil ist am Ende des Papers zu finden…….

Overall, in most cases, the patient is informed about 24 hours before a procedure; this applies to simple and complex procedures (....% vs. ....%). Here, an alternative would be to provide information via the Internet as a video consultation, for example, and to personally call in only those patients for whom additional examinations are really necessary or cannot be performed by the general practitioner. This could save costs and possibly save the patient a long journey. Interestingly, same-day information is more often considered not in compliance with the law in low GDP countries.

The increasing proportion of responses to see the patient at least 2 days before complex procedures is not surprising in that there may be a need for further diagnostics or general preparation.

When it comes to the question of who is responsible for anaesthesia education, the consultants predominate in the overall comparison and only in exceptional cases are anaesthesia technicians or nurses involved. However, it is interesting that this also occurs and seems to be legally permitted.

As expected, the most commonly used guideline-recommended score is the ASA classification, followed by NYHA and Apple scores.

Even though the potential advantages of using telemedicine were positively assessed in the survey, especially with regard to less stress and reduced waiting times, the wish for the future, however, is still to carry out face-to-face patient information. This also did not differ between the countries with high, medium or low GDP, and might have been expected in the second year of the pandemic (status of the survey 2021). In the sub-analysis, only with regard to the time frame of a patient information did a significant difference emerge when looking at the responses from the countries in relation to population density. Here, same-day patient education is more often considered legal in countries with low population density, regardless of the severity of the procedure. This may be due to the infrastructure and thus influence the daily routine.

The statement of .... percent of the respondents that they are unsure about the legal framework conditions or even fear that it is illegal especially catches the eye.

Of course, fears are also expressed regarding trust, contact and the lack of preoperative observation of the patient. However, if a legal framework were created for the physician that legitimized telemedical information, many patient groups could benefit from this. In the age of increasing digitalization, it should be legally possible to put online medical consultations on an equal footing with face-to-face consultations. In cases of doubt, of course, the attending physician decides in consultation with the patient which procedure is most appropriate. In addition, personal contact should always be offered to the patient upon request, especially since many elderly patients may also lack access to technical media. However, legal pitfalls should not be an unnecessary obstacle here in times when communication via computers or smartphones has become the norm in many other areas of everyday life.

**Strength and Limitations**

This questionnaire was sent out to 42,433 active ESAIC members in XXX countries. The response rate was just 2.2%, with 930 responses and was not equally distributed across all countries, but nevertheless, anaesthesiologists from 47 different nations were obtained.

Furthermore, although the questionnaire was designed with maximum care by experienced clinical and research anaesthesiologists, response bias may have arisen. As the questionnaire was only sent out once by ESAIC, there was not the possibility of pre-testing in order to evaluate a possible bias effect of primer questions. Thus, the validity of the results found could be limited because of induced question-order effects. However, the survey was performed completely anonymously without any human contact and so socially desirable responses and interviewer bias should not be a concern.

**Conclusion**

Our survey was able to shed light on how differently the use of telemedicine support in the field of anaesthesia is handled in Europe, even though many professional societies have been recommending it for years (Quellen).

The restrictive attitude may also be due to the fact that there is no clear legislation in this regard and the anaesthetist is on thin ice legally when it comes to the mere use of telemedicine media. A Europe-wide harmonisation would therefore be desirable, even if it will be difficult to implement this equally for all countries in the near future. The Covid 19 pandemic may have given an impetus here to use appropriate procedures where this is technically possible and advantageous for the patient.

The more widespread the use of telemedicine in the healthcare sector, the quicker the concerns described above could possibly be overcome. Examples in many other areas of life prove this at this time.

It remains a promising outlook for the future, from which the health care system as a whole and many patients will be able to benefit.

**Acknowledgements**

We thank the ESAIC for support and for distribution of the questionnaire.

**References**

**List of Supplemental Digital Content**

[1] World Health Organization (2011) Report on the burden of endemic health care-associated infection worldwide. World Health Organization, Geneva.

[2] European Centre for Disease Prevention and Control (2008) Annual epidemiological report on communicable diseases in Europe 2008 : report on the state of communicable diseases in the EU and EEA/EFTA countries. European Centre for Disease Prevention and Control, SE

[3] Manoukian S et al. (2018) Estimating excess length of stay due to healthcare-associated infections: a systematic review and meta-analysis of statistical methodology. Journal of Hospital Infection 100:222–235

[4] Bhaskar S, Bradley S, Chattu VK, et al. Telemedicine as the New Outpatient Clinic Gone Digital: Position Paper From the Pandemic Health System REsilience PROGRAM (REPROGRAM) International Consortium (Part 2). *Front Public Health*. 2020;8:410. Published 2020 Sep 7. doi:10.3389/fpubh.2020.00410

[5] Tsai HW, Huang SW, Hung YL, Hsu YS, Huang CC. Use of the Smart Lean Method to Conduct High-Quality Integrated Perioperative Management Prior to Hospitalization. Int J Environ Res Public Health. 2021 Dec 20;18(24):13391. doi: 10.3390/ijerph182413391. PMID: 34949000; PMCID: PMC8708543.

[6] Jia H, Li L, Li W, et al. Impact of Healthcare-Associated Infections on Length of Stay: A Study in 68 Hospitals in China. *Biomed Res Int*. 2019;2019:2590563. Published 2019 Apr 18. doi:10.1155/2019/2590563

[7] Neumann, C et al. “Digital Online Anaesthesia Patient Informed Consent before Elective Diagnostic Procedures or Surgery: Recent Practice in Children-An Exploratory ESAIC Survey (2021).” *Journal of clinical medicine* vol. 11,3 502. 19 Jan. 2022, doi:10.3390/jcm11030502

Juristischer Teil:

**Kurze Version**

The reason for face to face or telemedical education is to achieve an informed consent with the patient for the planed medical procedure. However, informed consent is not a requirement for anaesthesia or medical interventions itself. It is based on the right to self-determination enshrined in the constitutions, in Germany, for example, in Articles 1 I 2 II Grundgesetz. (Constitution).  So late as 2009 **the Charta of Human Rights** of the **European Community** came into legal effect after and oblige the member states in the implementation of the EC/EU-laws and regulations. (Article 3: Necessity of the informed consent). I e in Germany the informed consent is stipulated in § 630d civil code, in Sweden in the Patients rigts act (Patient lag, 4. kap Samtycke)

Though Article 168 TFEU (Treaty of Functioning of the European Union) assigns the responsibility for organising and delivering of health care to member states, there are no EU-wide regulations on telemedicine. But telemedicine has to be seen in the light of the free movement of services - health care service and information service (Articles 56, 57 TFEU) in cross border matters. Raposo VL. Telemedicine: The legal framework (or the lack of it) in Europe. GMS Health Technol Assess. 2016 Aug 16;12:Doc03. doi: 10.3205/hta000126. PMID: 27579146; PMCID: PMC4987488

Concerning information and telecommunication in telemedicine the Data Protection Regulation (GDPR) has to be taken in consideration particularly as well among other European data protection rules, I e 2002/58 EC. (Directive on Privacy and Electronic Communications). Concerning cross border health care matters the Cross Border Directive 2011/24 is probably the most important rule.

In some EU countries, telemedicine is now regulated by law: I e in Sweden, the law of Freedom-of-Choice (Lag om Valfrihetssystem, LOV, 2019) forms the legal basis for telemedicine. Telemedicine doctors can establish their services anywhere as long as they fulfil the Swedish regulation for health care providers.

Blix, Mårten; Jeansson, Johanna (2018) : Telemedicine and the welfare state: The Swedish experience, IFN Working Paper, No. 1238, Research Institute of Industrial Economics (IFN), Stockholm

In the Netherlands, patients' rights are governed by the Treatment Contract Act (Wet geneeskundige behandelingsovereenkomst, WGBO) which is part of Book 7 (Special Contracts) of the Dutch Civil Code (NBW). The WGBO obliges the physician to inform the patient in a clear manner ("op duidelijke wijz"), in writing if desired, about the examinations and treatments envisaged and treatments (Art. 7:448 para. 1 NBW).

Ivo Giesen, Arzthaftung in den Niederlanden (Ivo Giesen, Hoogleraar Privaatrecht aan het Molengraaff Instituut van de Universiteit Utrecht en UCALL (Utrecht Centre for Accountability and Liability Law)<http://ivogiesen.com/publicaties/> abgerufen März 2022

Other forms than "in writing" are not regulated in the WGBO. But the competence of a healthcare provider even in the field of telemedicine  - which includes the telemedical education -  will be assessed against the criteria of a “good caregiver”. This means that in providing the medical services, the healthcare provider must observe the standards of a prudent caregiver and, in doing so, has to act in conformity with the responsibilities laid upon him/her by the professional standard for healthcare providers.

Ellen Gielen, Judith Kok, Digital health apps and telemedicine in the Netherlands, 10.1, published 14.dec. 2020;<https://cms.law/en/int/expert-guides/cms-expert-guide-to-digital-health-apps-and-telemedicine/netherlands>

In Germany, video consultation 2020 was regulated for the area of contract physicians of the health insurance funds and reference was made in § 365 S 4 SGB V (German Social Code, Book V ) to § 630e BGB. The regulations on consent made there must also be observed in telemedicine. Although this standard governs contract physicians of the health insurance funds, it should be equally applicable to the education of outpatients or prospective inpatients.

In view of the rapid increase in the technical quality and social acceptance of means of distance communication, the legislator no longer adheres to earlier reservations, based on the case law of the highest courts in civil law, according to which information can also be provided by telephone in simple cases.

*Kania in: Schlegel/Voelzke, jurisPK-SGB V, 4. Aufl., § 365 SGB V (Stand: 10.11.2021) Randnummer 18;*

*Bundestag-printed matter 19/3438, page 70: Assuming that oral communication means simultaneity, but not in the same place.*

However, this regulation has no significance for the civil law treatment contract. Professional regulations are also irrelevant for the interpretation of § 630e BGB. The information to be provided to the patient in accordance with § 630e para. 1 BGB can already be carried out according to current law, as long as these can also be carried out using telecommunication means, as long as these - such as a telephone conversation or a communication that is also acoustically synchronous via video telephony or a video conference via the Internet (cf. Staudinger/Bork [2020] § 147 Rn 4) - allow the direct linguistic exchange between the patient and the person providing treatment. An extension of § 630e BGB for the distance treatment contract is not necessary.

Kommentar BGB, Staudinger/Gutmann (2021) BGB, § 630e, margin number 106 (Telecommunications)

**Alt:**

The reason for face to face or telemedical education is to achieve an informed consent with the patient for the planed medical procedure. But informed consent is not a requirement for anesthesia or medical interventions it self.  Informed consent can be defined as:

Informed consent is the essential process by which a competent patient, after being properly and fully informed, learns about and understands the purpose, benefits, and potential risks of an examination, treatment or procedure and then acting voluntarily agrees to receive treatment and/or procedures, or to participate in a research trial, or even refuses these.

*Beauchamp T. Informed consent. In: Veatch R, ed. Medical Ethics. 2nd ed. Sudbury, MA: Jones and Bartlett Publishers, 1997, pp. 185–208*

Even if in most cases this definition in its meaning is more or less anticipated by the person involved, medical staff as well as patient, this may have different origin and legal background in the participating countries.

The requirement of informed consent can be the expression of the human rights, grounded in the constitution of the respective country and led to corresponding jurisprudence. Or it is developed only from case law.

The Convention of human rights on Biomedicine, Treaty of Orviedo 1997,  was the first text, that binds the participating countries itself legaly  by an **international treaty.**

*Council of Europe. Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, CETS 164, Oviedo 1997*

It concretizes **the European Convention on Human rights (ECHR**) as an convention **of the Council of Europe (CoE, Europarat**). Even if the Council of Europe is represented by the same flag, it should not be mistaken with the European community (EC; EU) , even if the condition for new members joining the EU is the accept of the ECHR.

Article 5 of the Oviedo Convention reads:

***General rule***

*An intervention in the health field may only be carried out after the person concerned has given free and informed consent to it. This person shall beforehand be given appropriate information as to the purpose and nature of the intervention as well as on its consequences and risks*

So late as 2009 **the Charta of Human Rights** of the **European Community** came into legal effect after it was adopted in Nice 2000 and oblige the member states in the implementation of the EC/EU-laws and regulations.

Article 3 of the Charter commits the medical personal only to act within the informed consent with the patient:

*In the fields of medicine and biology, the following must be respected in particular: the free and informed consent of the person concerned, according to the procedures laid down by law.*

The World Medical Association determines in the Declaration of Lisbon on the Reichts of the Patient in 1981:

*A mentally competent adult patient has the right to give or withhold consent to any diagnostic procedure or therapy. The patient has the right to the information necessary to make his/her decisions. The patient should understand clearly what is the purpose of any test or treatment, what the results would imply, and what would be the implications of withholding consent.*

The WMA is an NGO, their members are individuals and medical association and  the declaration is not justiciable.

**Background in different countries about achieving the informed consent**

**Germany**

**Purpose:**

The Consent serves to protect the right to self-determination in accordance with the constitiution (Grundgesetz, GG) , Artikel 1 I and  2 II GG

**Legislation**

Patient Rights Act (Patientenrechtegesetz) regulates the information and consent since 2013. Before it was developed from case law on liability law on § 823 BGB (Bürgerliches Gesetzbuch).  The treatment contract was codified in the Civil Code, (§§ 630a et sqq BGB). Consent is now the duty of the treating person. But refraining a breach of duty within the framework of the treatment contract does not automatically lead to compensation. Failure to provide information only leads to contractual liability if damage has also occurred.

*Bundesgerichtshof, Urteil vom 27. 5. 2008 - VI ZR 69/07 in NJW 2008,* [*2344*](https://beck-online.beck.de/?typ=reference&y=300&b=2008&s=2344&z=NJW) *Rn.* [*18*](https://beck-online.beck.de/?typ=reference&y=300&b=2008&s=2344&z=NJW&rn=18)*;*

*Münchener Kommentar zum Bürgerlichen Gesetzbuch,8. Auflage, § 630e Aufklärungspflichten, Randnummer 73.*

Before, case law was developed by using the central norm in tort liability law: § 823 BGB. The legislator of the Patient Rights Act has transferred the figure of consent to contract law. The effective informed consent excluded the illagality of the physical injuriy associated with treatment. Transfer was necessary because a tort obligation to obtaining consent does not exist, but the absence of an effective consent merely excludes a justification for the intervention.

*Münchener Kommentar zum BGB, 8. Auflage, § 630d Einwilligung, Randnummer 2*

***Who educates?***

It is also required that the patient be informed either by the practitioner himself or by a person who has the necessary training to carry out the measure, § 630e II Nr 1 BGB. Information about medical interventions must therefore be provided by physicians. The law avoids further specifications. However, the Federal Court of Justice is quite strict: The physician who performs the procedure must explain what organizational measures he has taken to ensure and control proper education of the patient.

*BGH, Urteil vom 7.11.2006  in: NJW-RR 2007, 310, 311; Spickhoff, Medizinrecht 3. Auflage 2018, § 630e Aufklärungspflichten, Randnummer 4*

**Verbal education**

The oral education is now statued by law without exception, § 630e II Nr 1 BGB. However, supplementary reference may be made to documents (i.e. also written information forms) which the patient must receive in text form.  (stepwise education) This is possible not only by conventional paper documents, but also in the form of electronically created documents, such as e-mails.

*Spieckhoff, Medizinrecht 3. Auflage 2018, Randnummer 3a*

The Federal Court of Justice ruled that in simple cases, information can also be provided by telephone if the patient is free to insist on oral information.

*BGH, Urteil vom 15.6.2010 in NJW 2010, 2430*

But there has been criticism in the literature that anesthesia in a 3-week-old infant was considered a simple case.

*u. a. Andreas Spickhoff, NJW 2011, 1651-1654*

**Telemedicin**

There is no legal definition of oral communication in the German Civil Code. The information to be provided to the patient in accordance with § 630e (1) of the German Civil Code (BGB) can therefore also be provided under current law using telecommunications equipment, as long as this - such as a telephone conversation or a communication that is also acoustically synchronous via video telephony or a video conference via the Internet - allows direct verbal exchange between the patient and the person providing treatment. […] Professional regulations are irrelevant for the interpretation of § 630e BGB. […] However, problems associated with the loss of immediacy of communication are at the expense of the practitioner bearing the communication risk

*BGB Kommentar, Staudinger/Gutmann (2021) BGB § 630e; Randnummer 106*

Following the amendment of the Model Professional Code for Physicians in 2018, telemedical treatment is now permissible, Section 7 IV MBO-Ä: Physicians advise and treat patients in face-to-face contact. They can use communication media to support this. […]

In an announcement on how to deal with this regulation, the German Medical Association points out that the patient must also be made aware of the special features of telemedical remote treatment.

*Bundesärztekammer, Bekanntmachung; Deutsches Ärzteblatt DOI: 10.3238/arztebl.2019.mbo.fernbehandlung*

In 2020, video consultation was then regulated for the area of contract physicians of the health insurance funds and reference was made in § 365 SGB I  S 4 to § 630e BGB. The regulations on consent made there must also be observed in telemedicine. Although this standard governs contract phyicians of the health insurance funds, it should be equally applicable to the education of outpatients or prospective inpatients.

In view of the rapid increase in the technical quality and social acceptance of means of distance communication, the legislator no longer adheres to earlier reservations, based on the case law of the highest courts in civil law, according to which information can also be provided by telephone (only) in simple cases.

*Kania in: Schlegel/Voelzke, jurisPK-SGB V, 4. Aufl., § 365 SGB V (Stand: 10.11.2021) Randnummer 18;*

*Bundestag-printed matter 19/3438, page 70: Assuming that oral communication means simultaneity, but not in the same place.*

In order to make the technical implementation secure and in compliance with the General Data Protection Regulation, the KBV and the GKV-Spitzenverband concluded the "Agreement on the Requirements for the Technical Procedures for Video Consultations" as Annex 31b to the BMV-Ä on October 21, 2016 and revised it on February 25, 2021.

[*www.kbv.de/media/sp/Anlage\_31b\_Videosprechstunde.pdf*](https://www.kbv.de/media/sp/Anlage_31b_Videosprechstunde.pdf) *(abgerufen am 10.11.2021).*

In summary, after confirming the effectiveness of telephone information, together with the offer of a personal consultation, telemedical information was also codified for cases that are not simple. The already developed requirements of § 630e BGB and the publication of the German Medical Association on the subject must be taken into account.

§ Section 365 of the German Social Code, Book V deals with the care of outpatients, as the question of telemedical care for inpatients is unlikely to arise. However, a derivation for the education of future inpatients or patients to be cared for as outpatients in hospital is likely to be within the purpose of the norm.

**Supplementary Material**

**Table S1:** Number of responses

|  |  |  |  |
| --- | --- | --- | --- |
| **Country of employment? n (%)** |  |  |  |
| Albania | 3 (0.3) | Liechtenstein | 1 (0.1) |
| Austria | 32 (3.4) | Lithuania | 8 (0.9) |
| Belarus | 2 (0.2) | Luxembourg | 4 (0.4) |
| Belgium | 27 (2.9) | Malta | 6 (0.6) |
| Bosnia and Herzegovina | 5 (0.5) | Moldova | 3 (0.3) |
| Bulgaria | 8 (0.9) | Monaco | 1 (0.1) |
| Croatia | 26 (2.8) | Netherlands | 50 (5.4) |
| Cyprus | 4 (0.4) | Macedonia | 3 (0.3) |
| Czechia | 10 (1.1) | Norway | 8 (0.9) |
| Denmark | 11 (1.2) | Poland | 19 (2.0) |
| Estonia | 4 (0.4) | Portugal | 56 (6.0) |
| Finland | 12 (1.3) | Romania | 31 (3.3) |
| France | 24 (2.6) | Russia | 12 (1.3) |
| Georgia | 2 (0.2) | Serbia | 14 (1.5) |
| Germany | 132 (14.2) | Slovakia | 8 (0.9) |
| Greece | 45 (4.8) | Slovenia | 14 (1.5) |
| Hungary | 8 (0.9) | Spain | 73 (7.8) |
| Iceland | 1 (0.1) | Sweden | 43 (4.6) |
| Ireland | 18 (1.9) | Switzerland | 65 (7.0) |
| Israel | 6 (0.6) | Turkey | 23 (2.5) |
| Italy | 40 (4.3) | Ukraine | 7 (0.8) |
| Kazakhstan | 2 (0.2) | United Kingdom (UK) | 44 (4.7) |
| Kosovo | 3 (0.3) | Uzbekistan | 2 (0.2) |
| Latvia | 10 (1.1) |  |  |