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Web-based tutorial as supportive means to enhance quality and efficiency of the informed consent for cataract surgery

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Powers - Harris	Medical Negligence, Butterworths Law (Mar 1994)
Ratajczak Stegers (eds)	Risikoaufklärung, Arbeitsgemeinschaft Rechtsanwälte im Medizinrecht eV, Springer 2001

Roggo Aufklärung des Patienten, Abhandlungens zum Schweizer Recht, Bern Stämpfli 2002

Table of decisions

List of Abbreviations

AC	Law Reports, Appeal Cases (Third Series)
AI	Artificial Intelligence
All ER	All England Law Review
Am J Prev Med	American Journal of Preventive Medicine
Am J Public Health	American Journal of Public Health
Ann Behav Med	Annals of Behavioral Medicine
Ann Oncol	Annals of Oncology
Arch Int Med	Archives of Internal Medicine
Arch Ophthalmol	Archives of Ophthalmology
Arch Surg	Archives of Surgery
ÄrzteG	Austrian Physician's Act
BGE	Swiss Supreme Court (Bundesgericht)
BGH	German Supreme Court (Bundesgerichtshof)
BMJ	British Medical Journal
BMLR	British Medical Law Review Butterworths Medico-Legal Reports
Br	British
Br J Ophthalmol	Briotish Journal of Ophthalmology
Bul Civil	Bulletin Civil
CA	California
Cal Rptr	California Reporter (West's)
Can J Ophthalmol	Canadian Journal of Ophthalmology
Cancer Nurs	Cancer nursing
CC	Belgian of Frnech Civil Code (Code Civil)
CD ROM	Compact Disk
CLR	Commonwealth Law Reports California Law Review
DC	District of Columbia
DLR	Dominion Law Reports
Eds	editors
EHR	European Human Rights Convention
Eur J Cancer	European journal of cancer
F.2d	Federal Reporter, Second Series
FAQ	frequently asked questions
Fn	footnote
GG	German constitution (Grundgesetz)
GMC	General Medical Council
Inform Prim Care	Informatics in primary care
ITS	intelligent teaching system
J	Journal
J Am Acad Orthop Surg	The Journal of the American Academy of Orthopaedic Surgeons
J Clin Gastroenterol	Journal of clinical gastroenterology
J Med Ethics	Journal of medical ethics
J Med Internet Res [JMIR]	Journal of medical Internet research
JCP	jurisclasseur periodique

JW	Juristenwoche
KAKuG	Austrian Federal Hosptial Act
Med LR	Medical Law Review
NEJM	New England Journal of Medicine
NHS	NatioNAL Health Trust
NJW	Neue juristische Wochenschrift
No	Number
OGH	Austrian Supreme Court (oderster Gerichtshof)
Oncol Nurs Forum	Oncology nursing forum
OR	Swiss Obligationenrecht
öStGB	austrian ciminal code (Strafgesetzbuch)
P	page
P. & P.2d -	Pacific Reporter, First Series and Second Series
para	paragraph
Patient Educ Couns	Patient Education and Counseling
Rep	Repertoire
RgSt	collection of decisions of the former German supreme court, the Reichsgericht in criminal cases (Reichsgericht-Strafsachen)
RGSt	former German Supreme Court - Reichsgericht
Sec	section
Semin Urol Oncol	Seminars in urologic oncology
Seq	sequential
Ser	series
Surg	surgery
UK	United Kingdom
VersR	Zeitschrift für Versicherungsrecht
vs	versus
WLR	Weekly Law Reports
ZGB	Swiss civil code - Zivilgesetzbuch

1 Background

1.1 Medical and legal thinking

Physicians often chose their profession because of their sentiment of vocation. They act under the premises of "*salus aegroti suprema lex*" and accordingly their tendency is to take medical decisions for the patient often functioning as a guardian for the patient.

Legal professionals have a different notion of the relation between physicians and patients. Legal thinking is more in terms of mutual contractual obligations and, in particular in European and US legal traditions, legal thinking is strongly influenced by the constitutional guarantees and human rights that are granted to the individual.

In relation to health care and the relation between physician and patient, the most important human rights are the right of self-determination of the individual and the right of bodily integrity.

While doctors perform medical treatment with the subjective intention of healing, lawyers objectively qualify the medical treatment as such as bodily injury and intrusion into the right of self-determination [[1]] which is only justified by the subjective purpose of the intervention and the prior consent of the patient to the treatment as emanation of his right to determinate himself and to dispose over his bodily integrity.

It is obvious that legal thinking is completely alien and even disturbing to any medical professional. However, legal thinking gains importance as medical knowledge and medical treatments get more and more complex. Further, the expectations of patients to the due diligence of medical professionals have risen enormously. Nowadays, patients are more likely to not accept an unsuccessful treatment as destiny than a few decades ago. Questions of medical malpractice are frequently risen by patients but often difficult to prove. But not only malpractice and bodily integrity form a fruitful field of litigation, patients and their lawyers more and more often rely their claims on the patients' right of self-determination and the invalid informed consent.

To understand the legal reasoning in cases where the informed consent is involved, one should have a brief look at the historical roots of the informed consent. These

1 Eisner, p18

can be traced back to the 17th century's enlightment and is alien to pre-enlightment and extra-European legal and philosophical traditions.

1.2 Informed consent from the ancient world to these days

In the Ancient world, physicians were not helpers of individuals but conservers of the good (god-given) order of things. In mythology, Asclepiad was killed by Zeus because he tried to put back to life a person "already grabbed by death" thus disturbing the god-given order. Ancient Greek physicians had no duty of disclosing medical information to the patient. They could burden patients with infauste prognosis at their discretion and also reject treatment in untreatable cases just for reasons of their own reputation. Still *Hippocrates* held doctors not to inform the ill about their diseases, and cover things to come.

It was *Platon*, who fist discerned tyrannical slave-doctors, who never disclosed any information, and just gave instructions after examining the patient from the "free physician".

> *"The free physician tells the patients his impression, and while he gathers information about the patient, he is teaching the patient as far as possible. He does not prescribe, without having convinced the patient and with good advice he calms his patient and brings him back in a state allowing to take him back step by step to health"[2].*

Information of the patient, however, was a privilege to those who could afford to pay for medical help of a well-educated free doctor.

Another image of the physician-patient interaction is reported from Ancient Rome, where physicians entered into a public discussion with other physicians about patients' diseases.

Among citizens, physicians publicly defended their ideas about disease and treatment in the Forum. Patients chose the physician best performing in the public discussion. Needless to say that only wealthy Roman citizens, often disposing themselves over good medical education, could afford to get such a physician's help.

2 Platon, Nomoi 720 c-d

In no time, a physicians' *obligation* to provide medical information to the patient was identified.

Today's legal obligation to inform patients can directly be founded in Kant's philosophy of enlightment: In his treaty "*Was ist Aufklärung*" (What is enlightment) he defined "enlightment" as

> *"Ausgang des Menschen aus der selbstverschuldeten Unmündigkeit". (Exit of man from the self-inflicted immaturity)*

The term self-inflicted-immaturity is defined as the inability to use man's own intellect without the help of others. The concept is strongly linked to the concept of reason in the Kantian sense. A reasonable man would act and react according to his sense and intellect rather than on grounds of religious, superstitious or other sentiments.

Contrary to the Ancient times, enlightment was a concept for every human, not only for a small privileged group. Kant was also aware that the reasonable man would be an ideal. He clearly saw that the "*reasoning*" as well as the responsibility for one's actions was frequently delegated to paid experts. This seemed symptomatic to him for man's attitude towards immaturity. According to Kant, this immaturity is caused by man himself, as it is much easier to remain dependent (on experts) and immature.

From 17th century, it took a long time until the philosophy of enlightment was materialized in our societies' laws. Only two centuries ago, medical service was available only for a small elite of wealthy and aristocracy, while most people had to rely on "popular" medicine and welfare [3]. No question of providing an informed consent to a medical treatment. It was only along with the political turnovers in Europe of the 19th and 20th century that jurisdiction slowly accepted the idea of the informed consent as an emanation of enlightment's liberal and human rights.

In 1897, the German Reichsgericht first found guilty of violating the bodily integrity of a patient, a surgeon performing a resection of an infected foot against the expressed and confirmed will of the patients father [4 5]. In Germany, the legal construction was adopted that any medical intervention in principle can be regarded as "*Körperverletzung*" (body injury) unless it is justified by the patient's prior consent. At that time, this did not mean a formal acknowledgement of a duty of information of the

3 Nordt 38.
4 Decision of the Reichsgericht of 31.5.1894, Rep 1406/94, RgSt 25, 1894, p 375-389.
5 Deutsch, Medizinrecht, VI 2 No 101.

physician as other decisions make clear [6] and it took until 1954 when a formal obligation of information of the patient was first acknowledged. In another important case [7], the German Bundesgerichtshof (BGH) found a surgical intervention that extended over the initial consent to be illegal. The surgeon had hysterectomized a 46year old patient when he found that the myoma to be extirpated had already affected the uterus. This extension of the surgical intervention, however, was not covered by the initial consent, as the patient was not informed about this complication of the surgery prior to intervention. In this decision, the BGH could already rely on a constitutional right of bodily integrity and self-determination (Art 2 para 2 Grundgesetz (GG).

However, the European Human Rights Convention (EHR), governing those rights, which is regarded as one of the most important achievements of our western civilisation, was adopted by the European Council as late as 1950 and a similar picture is seen for the UN governed Human Rights treaties. It was therefore only in the years after World War II that patients' rights on information about disease, treatment and inherent risks were acknowledged in many countries around the world. Since then an enormous multiplicity of statutory and case law obligations were developed by the courts and still continue to do so.

1.3 Recent Problems with obtaining an Informed Consent

Informing the patient and obtaining the informed consent is one of the major duties physicians have to perform before beginning a medical treatment.

At the same time expectations of patients in modern high-tech medicine grow and so do the legal requirements on informing the patient. The complexity and amount of information that is deemed necessary for the patient's decision to undergo treatment or not is growing at the same pace. The medical information that is available is believed to double every two years since the 1980ies [8]. Consequently, information provided to patients gets more and more abstract and complex. This is resulting in

6 Decision of the Reichsgericht of 1.3.1912, 231/11 III, Berlin, in: JW 41.JG, Heft 10,1912, p 528-529.
7 Decision of 4.11.1975, VI, ZR 226/73, Hamm, in VersR JG 27, Heft 12, 1976, p 293-295.
8 Haag, Gesamtkonzept für die Entwicklung und den Einsatz von Computer-unterstützten Lehr-/Lernsystemen in der Medizinerausbildung an der Universität Heidelberg 1995.

patients having flawed impressions of the actual treatment [9]. Studies have shown that patients often cannot remember the most important and essential parts of the communication with their physician [10]. Consequently, the information level of the patient provided by the practitioner for purposes of the informed consent often is inadequate [11] in type, extent or form, in particular when the patient has to undergo surgical intervention [12]. Several reasons therefore can be identified (non-exclusive):

1. the growing requirements and lack of time of the medical professionals in particular in public hospitals,
2. difficulties in the assessment of the individual need of information of each individual patient
3. the patient's apprehension, emotional problems, stress and
4. the patient's unwillingness to be informed or take own decisions and responsibility.

It also seems that the use of printed information sheets providing patient information has not changed this dissatisfying situation [13 14].

By the law of many countries, the duty to inform the patient has to be carried out in a personal face-to face communication of patient and physician. In practice, however, time constraints have led to the use printed forms that are handed over to patients often by paramedical personal. Frequently, the informed consent of the patient is documented by signature on these printed forms. This procedure often is not sufficient to satisfy the patient's needs and is legally questionable (See chapter: 3.

9 Edwards MH (1990) Satisfying patients needs for surgical information. BrJSurg 77:463-465.
10 Robinson G. Merav A (1976) Informed Consent: recall by patients tested postoperatively. Ann Thor Surg 22: 209-212.
11 Edwards MH (1990) Satisfying patients needs for surgical information. BrJSurg 77:463-465.
12 Vahl CF, Meinzer P, Thomas G, Osswald BR, Hagl S (1996). Qualitätssicherung in der Herzchirurgie: acht Jahre Erfahrung mit einem Feedback-Control-System" in Heidelberg. Herz 21:371-382.
13 Cassileth BR, Zupkis RV, Sutton-Smith K (1980) Informed Consent – why are goals imperfectly realized? NEJM 302:986-900.
14 Priestley KA, Campbell C, Valentine CB, Denison DM, Biller NB (1992). Are patient consent forms for research protocols easy to read? BMJ 305:1263-1264.

Legal requirements derived from the contract governing medical treatment and statutory law.)

These factors together result in misunderstanding, dissatisfied patients and eventually litigation [15 16]. This “malpractice” crisis has led to a defensive medicine in particular in the USA trying to prevent damage claims with a bundle of over-diagnosis, over- therapy and over-information [17].

2 Scope of this thesis

Therefore, we are looking for means of improving the situation. Several parameters cannot be changed such as an unwilling-to-know patient or the time-constraints in a hospital. Purpose is to examine the legal and factual requirements of a web-based tool in addition to printed information matter that can be used for pre-informing the patient and preparing him/her to be able to follow the subsequent personal communication for the informed consent.

Of course, such a tool has to meet several restrictions, which will be defined in the course of this analysis.

2.1 New media and the educational benefit

New technologies like the internet, CD, DVD or more generally multi – media applications have revolutionized the way of information retrieval in the general population. An extensive number of health-related web-sites also indicate that the internet is a major source of information retrieval for the general public but also for patients.

New findings in the educational sciences indicate that multi-channel input, i.e. using all senses for the information input, has positive effects on the memorisation of the transported content: in teaching, only 10-15% of the read material, but 25% of the heard and 40% of the seen (images) is kept in memory in a long term, which

15 Krause HR, Bremerich A, Rustemeyer J (2001). Reasons for patient`s discontent and litigation. J Craniomaxillofac Surg 29:181-183.
16 Reynolds M (1978) No news is bad news – patient´s view about communication in hospital. BMJ 1:1673-16.
17 Pichler 315.

percentage rises to 75% of the present material, when all senses are used simultaneously [18].

Health-related informational web-sites in the internet are booming. An estimated 320 Billion web-sites exist, of which approximately one-third contains health-related information. The quality of the information provided by the different health-related web-sites is variable. Today, high-quality and specialised health related information is available via web-sites that are run by doctor's organisations, public bodies or commercial providers of health-related services, pharmaceuticals or medical devices. Other providers of health related information might be influenced by commercial purposes or simply provide lower quality information.

It is known that many patients start to seek health-related information frequently via the internet. The internet has been reported as source of medical information already in 45% for some clinical specialities [19]. Particularly, the elderly patients use the internet for information retrieval [20]. It is therefore an important task to provide first-class and evaluated information.

2.2 Can a web-based information tool and tutorial improve the informed consent for a standard surgical intervention?

The use of multimedia-applications might be beneficial to transport complex medical facts, procedures, and risks of intervention, alternative treatments and postoperative behaviour to the patient [21]. The complex information that currently is contained in mere printed information sheets could be visualized and presented with audiovisual support using pertinent videos of interventions, risks and results in an interesting and understandable manner.

The information disclosed should be least biased by commercial or ideological interests. The health-care provider who already is bound by the contract governing

18 Heil H, Struck J (1992) Multimediale Lernsysteme als Ausbildungsinstrumente. In: Dette K, Haupt D, Polze C (eds) Multimedia und Computeranwendungen in der Lehre, S 40-47.
19 Diefenbach MA, Dorsey J, Uzzo RG, Hanks GE, Greenberg RE, Horwitz E, Newton F, Engstrom PF. Decison-making strategies for patients with localised prostate cancer. Semin Urol Oncol 2002; 20: 55-62.
20 Deber RB, Kraetschmer N, Irvine J. What role do patients wish to play in treatment decision making. Arch Int Med 1996; 156:1414-20.
21 Prinz A, Bühl W, Findl O. Advantage of three dimensional animated teaching over traditional surgical videos for teaching ophthalmic surgery: a randomised study. Br J Ophthalmol. 2005 Nov;89(11):1495-9.

medical treatment should among the least susceptible persons of providing biased information as his guideline is the "*salutio aegrorum*". Instead of leaving the patient alone with a plenitude of health-related information, the quality of which usually cannot be recognized by the patient, often leading to flawed information from questionable sources, health care providers could offer own medical content in web-pages accessible for the patient. These web-sites could provide for preliminary information just as printed documentation often does, which is handed over to the patient. Several advantages can be named:

1) The site is accessible whenever the patient wants to
2) It can repeatedly accessed, re-read and individually used by the patient, instead of the hand-over of printed forms, which are signed after a quick over-view by the patient because of time-constraints in hospital
3) Technically, it is possible to have the site communicating with the patient, pre-assessing individual states of the patient which might be important for the planned intervention and giving notice to the treating physician in order to individualize the subsequent personal communication of physician and patient.

The questions arise:

1. Can a multimedia supported web-site attract the attention of patients? The site could be accessed via the internet by the admitted in-house patients or by out-patients.

2. Can such a site help to improve the quality of the information offered to the patient, the memorization of the information by the patient?

3. Can such a site improve the decision process of the patient whether or not to undergo treatment?

4. Can such a site help in practice to filter out possible risk-patients already prior to the personal communication?

5. Can the site help in practice the physician to personalize the subsequent personal communication with the patient?

6. Is a web-supported information process is more time-efficient than the usual process of disclosing medical information by printed sheets.

7. Can such a tool be designed fulfilling the requirements of the documentation duties?

8. How can a web-based tool be designed so that the requirements of privacy – protection are fulfilled?

First legal publications seem to welcome the use of computer programs as a useful supplement for the physician. The use of multi-media applications also seems to be accepted by patients. Disadvantages might be the requirement of computer-literacy. This might be a problem in particular for the elderly patient [22].

3 Legal requirements derived from the contract governing medical treatment and statutory law

3.1 Contents of the duty to inform

In many European jurisdictions, doctors are required to give concise information about the diagnosis, treatment, risks of a specific treatment, course of the disease with and without treatment and even alternative treatments. With varying emphasis, it seems that the information to be disclosed must not only cover frequent and foreseeable risks of the treatment but also serious risks of the treatment even if low in occurrence.

The following summary of the requirements of disclosure of information shall give a rough overview thereof: In the following emphasis is laid on the information on risks as it is proven that in case of litigation, the most frequent claim is that there was insufficient information on the risks of a treatment, which subsequently materialized and in knowledge of that risk the patient would have abstained from treatment. The summary does not in particular treat with emergency cases and not with problems of mentally incompetent.

3.1.1 UK and Commonwealth

In English law, if one leaves aside rare cases of battery (assault) where patients are treated without consent, the information to be disclosed are rather small in relation to other countries fo the European Union. However, there might be a liability for

22 Roggo 199.

negligence if the risks of the procedure are not adequately explained. The professional standard seems to play a major role.

According to the "Bolam's principle" [23], a doctor who follows the practice to disclose of a "*responsible body of medical opinion*" will not be regarded of as negligent. In *Sideaway vs Bethlem Royal Hospital*[24] the court gave a more precise view on the professional body's medical opinion: not disclosing a risk of little more than one percent occurrence was considered as not negligent at that time (1985) in the context of the treatment. As a corrective, in *Bolitho vs City and Hackney Health Authority* [25] it was held that a court may reject a common medical practice when it is more reflecting a tradition or laziness than a reasonable policy adopted after consideration of risks and benefits. In any case, the patient is entitled to a correct answer if he asks for medical information [26]. There might also be a sort of "therapeutic discretion" maybe comparable to the therapeutic privilege" [27] in German or Austrian doctrine.

While British Common law thus bases the extent of the patient's self-determination on the *professional practice*, the Australian High Court adopted the theory of "material risk". In *Rogers vs. Withaker* [28]: a risk was considered as material if,

> *"in the circumstances of the particular case, a reasonable person in the patient's position, if warned of the risk, would be likely to attach significance to it or if the medical practitioner is or should reasonably be aware that the particular patient, if warned of the risk, would be likely to attach significance to it".*

In this very case, in an essentially cosmetic surgery on a blind eye, the plaintiff asked questions about complications on the affected eye but not on the fellow eye. In accordance with professional practice, no disclosure about the very rare complication of "sympathetic ophthalmia" (RR 1:14000) was performed. The rare complication occurred causing blindness of the fellow eye. The Supreme Court of Canada has

23 Bolam vs. Friern Hospital Management Committee [1957] 1 Weekly Law Reports (WLR) 582.
24 Sideaway vs Bethlem Royal Hospital [1985] AC 871.
25 Bolitho vs City and Hackney Health Authority [1997] 4 All England Law Reports (All ER) 771 at 779.
26 [1985] AC 871
27 Blyth vs Bloomsbury Area Health Authority cited in Faure – Koziol 228.
28 Rogers vs. Withaker [1992] Commonwealth Law Reports (CLR) 479.

adopted a similar test: “what would a reasonable person have done if full information had been given?”[29].

This “materiality” position was partially considered in the UK in *Chatterton vs Gerson* [30], but the court was using a more subjective assessment: not asking what a reasonable hypothetic patient would have attached importance to, but rather “what the very patient in question” would have done”. Of course, a court may hold that if a reasonable person would have submitted to the treatment, then so the claimant even if claimed otherwise [31] since the claim necessarily relies on the denial that the claimant would have submitted to the treatment. A more “objective” test was developed in *Canterbury vs Spence* [32] asking for what a reasonable “prudent” patient requires to know. Further cases show that British law is changing, from a professional standard rule to a “material” rule thus introducing a sort of “informed consent, e.g.

> *“If there is significant risk which would affect the judgement of a reasonable patient… it is the responsibility of the doctor to inform the patient so they can determine the course they wish to adopt” [33].*

The General Medical Council (GMC) has added to the obligation of physicians asking physicians to **make sure** that patients have understood [34]. More realistically, courts have ruled that physicians must take **reasonable care** to disclose [35] thus rejecting the GMC standard as being too high [36].

One could also identify legal arguments that not each and every complication is to be disclosed:

> *“The doctor impliedly contracts to act at all times in the interest of the patient…. No doctor in his senses would impliedly contract to give the patient all the information available to the doctor as a result of the doctor’s training” [37]*

29 Reibl vs Hughes (1980) 114 DLR (3d) 1.
30 Chatterton vs Gerson [1981] QB 433.
31 Smith vs Salford Haealth Authority (1994) 23 BMLR 137..
32 Mc Lean, 92 seq
33 Lord Wolfe in: Pearce v United Bristol Healthcare NHS Trust[1998] CA Civ 865.
34 www.gmc-uk.org/guidance/good_medical_practice
35 Lybert vs Warrington Health Authority [1996] 7 Med LR. 334.
36 Hamwi v Johnson and North West London Hospitals NHS Trust [2005] EWHC 206. para. 43.
37 Lord Templeman in his speech in Sideaway.

It seems evident that some information might confuse or alarm a particular anxious or otherwise influenced patient who then might refuse a necessary and indicated treatment a reasonable patient would accept to submit.

Summing up, in British Law considerably more attention is paid to the customary professional practice than to a hypothetical reasonable patient, when assessing whether or not a disclosure of medical information is deemed sufficient for purposes of obtaining a valid medical consent. In other Commonwealth States but also in US law (See: 3.1.2 USA), contrary, jurisdiction at least in parts seems to pay more attention to the patient's choice [38].

As a guideline derived from the Sideaway case, in British law,

1) the standard of a doctor's duty to disclose is the standard of the ordinary skilled man exercising and professing
2) the decision to what degree disclosure is to be done to assist a particular patient to make rational choice as to whether to undergo a treatment must be primarily a matter of clinical judgement
3) an issue whether non-disclosure of a particular risk or cluster of risks should be qualified as break of the obligation to disclose is an issue decided primarily on the basis of expert medical evidence. In the event of conflict of evidence thereof, the judge will have to decide whether a responsible body of medical opinion would have approved of non-disclosure in the case before him
4) in certain circumstances, the judge might come to the conclusion that a risk would be so obviously necessary to disclose that no reasonable prudent medical man would fail to do so, even if no opposite body of medical opinion existed[39].

3.1.2 USA

US common law is considerably different form the continental European jurisdictions. In contrast e.g. to Austrian, Swiss or German law, US claims on malpractice are uniquely based on the "unlawful act" (offence) and not on the "breach of contract".

38 McLean 85 seq and 98.
39 Powers-Harris 205

Malpractice is understood as violation of the due diligence in the sense of an unlawful act without respect to a contract. Unlike in Germany or Switzerland, no decisions in the US have regarded the medical intervention as bodily injury i.e. a criminal offence against the bodily integrity [40].

The right of self-determination and bodily integrity in the US, unlike in Europe, did not materialize in a "Human Rights Convention" but in Common Law. The first cases dealt with the intentional touching of a person ("battery") or the threat thereof ("assault"). In a medical context, because medical intervention is a wilful act, the consent of the patient was the consent to commit such a battery on his body. In *Schloendorff vs Society of New York Hospitals* it was held that:

> *"Every human being of adult years and sound mind has a right to determine what shall be done with his own body, and a surgeon who performs an operation without the patient's consent commits an assault for which he is liable in damages" [41]*

Beginning from the 1950ies to 1970ies, jurisdiction changed to legally qualify medical malpractice as negligence. The non-disclosure of adequate information about the risks of a treatment, the prognosis, risks or alternatives is regarded as negligence [42]. See for example *Cobbs vs. Grant*:

> *The battery theory should be reserved for those circumstances when a doctor performs an operation to which the patient has not consented. When the patient gives permission to perform one type of treatment and the doctor performs another, the requisite element of deliberate intent to deviate from the consent given is present. However, when the patient consents to certain treatment and the doctor performs that treatment but an undisclosed inherent complication with a low probability occurs, no intentional deviation from the consent given appears; rather the doctor*

40 Eisner 36 seq
41 Judge Cardozo in Schloendorff vs. Society of New York Hospital, 105 N.E. 92, 93 (New York 1914)..
42 Natanson vs Kline, 350 P.2d1093 (Kansas 1960).

> *in obtaining consent may have failed to meet his due care duty to disclose pertinent information. In that situation the action should be pleaded in negligence [43].*

Also in *Schloendorff vs Society of New York Hospitals* [41] the theory of the "informed consent developed" and was finally introduced in *Hunt vs. Bradshaw* [44] and *Salgo vs Leland Stanford Jr. University Bd. of Trustees* [45]:

> *A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise the physician may not minimize the known dangers of a procedure or operation in order to induce the patients consent…. Nevertheless it is to recognize that … in discussing the element risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an* ***informed consent****".*

as contrast to a previously assumed "simple consent" which was introduced mid of the 19th century in Slater vs Baker and Stapleton [46]. Two standards of assessment, parallel to what the jurisdiction in the UK, Australia and Canada ruled, evolved, namely the "professional community rule" [47] in older jurisdiction asking for the general practice of the professional community and the more recent "materiality rule" as decided in *Canterbury vs Spence [48]* asking to disclose all essential circumstances that have to be disclosed for a reasonable patient.

43 Cobbs vs Grant, 502 P.2d 1,8 (California 1972).
44 Judge Bobitt: concurring opinion in Hunt vs Bradshaw, 88, S.E..2d 762 (North Carolina 1955).
45 Salgo vs Leland Stanford Jr University Bd of Trustees, 317 P 2d 170 (California 1957).
46 Pichler 323.
47 Eisner 61.
48 Centerbury vs Spence 464F.2d 772 (D.C.1972).

Since these leading cases, the jurisdiction in the US has not evolved materially, so that by some authors it has been argued that the standards concerning the patients self-determination in the USA are not as high as in Europe[49].

However, the information to be disclosed must be what the individual patient in the individual circumstance requires [50] and what he or she **materially** requires for the informed consent. Every patient will have other requirements and priorities. The measure in *Canterbury vs. Spence defines the* requirement of the reasonable patient:

> *"in broad outline, we agree that a risk is thus material when a reasonable person, in what the physician knows or should know to the patients position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy"[51]*

This jurisdiction has been accepted in several states but newer decisions return to the professional community rule [52]. According to Eisner [53], the parallelism of Common Law and statutory Law in the different Federal US States and the lack of a unified Federal Law leads to an unintended lack of clear legal rules or prejuridication. Although, the legal situation in the US is widely scattered, some general principles can be derived:

The doctor has to inform the patient about [54]:

1) diagnosis
2) nature of the treatment, i.e. type of treatment, therapeutic or diagnostic, type of intervention (conservative of interventional) which parts of the body are touched, etc.
3) risks and effects of the treatment
4) dangers of non-treatment or non-performance of a diagnostic measure [55]

No precise jurisdiction exists about which risks are to be disclosed but there are significant, serious risks which have to be disclosed even if they occur seldom. Also

49 Eisner 121.
50 Eisner 127.
51 Centerbury vsSpence 464F.2d 772 (D.C.1972).
52 Eisner 128.
53 Eisner 117 seq.
54 Eisner 129.
55 Truman vs Thomas , 27 Cal 3rd 285, 165, Cal.Rptr. 308, 611 P.22d 902, 905 (1980).

the probability of occurrence matters in a sort of bi-variant flexible system e.g. as ruled in *Hook vs. Rothstein*:

> *As the probability or severity of risks to the patient increases, then the duty of the physician to inform the patient of these risks increases* [56]

Risks of 1: 100.000 do not have to be disclosed, but serious risks (e.g. death) have to be reported at risks of 1% to 5%. In an ophthalmological case, *Yeates vs.Harns* [57], it was ruled that a risk of the complete loss of the eye in a surgery of 1.5% does not have to be disclosed [58]

In the US, the doctor is responsible for the information. In practice, information disclosure is accepted from nurses and other paramedical personal, if patients only receive adequate information (subject to proof by the doctor [59]). Time of information is not much discussed in the USA[60] .No specific form for the information is required. In theory there is the institute of implied consent, when the patient undergoes the treatment in knowledge of the risks, but there is a risk of proof with the doctor. The *Joint Commission on Accreditation of Hospitals* asks that patient files include the written consent of the patient [61]. Most hospitals have issued written consent forms to be filled out by the patient. In some state, the signed consent form also offers a prima facie evidence of the information dispense [62].

Summing up, the legal situation differs from state to state within the USA. While in some states (in particular in the south), there seems to be no general obligation to obtain an informed consent prior to surgery or invasive diagnostics, other states require informed consent in elective cases but not in cases of emergency [63]. Moreover, generally known risks do not have do be disclosed. Nor need these risks be mentioned if patients could interfere with the appropriate management of their cases. In some federal states the requirements for obtaining the informed consent are much stricter [64]. The federal states are nearly evenly divided between those

56 Hook vs Rothstein 316 S.E. 2d 690 703 E 34 Fn5 (South Carolina 1984); South East Report Second Ser. 1984 Apr 16;316:690-705.
57 Yeates vs Harms, 393 P.2d 982 (Kansas 1964).
58 Eisner 135.
59 Eisner 122.
60 Eisner 124.
61 Eisner 124 seq.
62 Eisner 124.
63 Blackman – Bailey 194.
64 Blackman – Bailey 194.

requiring the customary disclosure (the professional medical standard) and those requiring "what a reasonable physician would have disclosed under the same conditions" (materiality standard)[65].

Blackman and Bailey [66] propose the following structure of the disclosure:

1) Patients must be told about their conditions in words they understand including in formation of what happens if left untreated
2) Explanation of the recommended diagnostic intervention or treatment also in terms of likelihood and success as well as accompanying risks of injury, disability or death. Very serious and common (1% and more) complications must be mentioned.
3) Possible alternative diagnostic or therapeutic approaches, risks and possible benefits thereof.

3.1.3 Germany

Following RGSt 25/375, German jurisdiction regards any medical intervention that is affecting the bodily integrity more than to a trivial extent as fulfilling the objective criteria of the criminal offence of bodily injury ("Körperverletzung", Sec 222 German Criminal Code), regardless whether the intervention is indicated by medical purpose, being executed *lege artis* or is successful. Only the consent of the patient is legalizing the medical treatment and makes the inherent risks of the treatment to accepted risks by the patient. In Germany, Switzerland and Austria likewise, statutory obligations to disclose information are clearly discerned from contractual obligations to disclose. The first are derived from the general human right of self determination, the latter form an integral part of the contract governing the medical treatment between the physician and the patient.

3.1.3.1 Statutory obligation to disclose

The obligation to provide for the informed consent of the patient and to avoid criminal charges is derived by the BGH from Art 2 para 1 and 2 GG. This article is protecting the bodily integrity of the human being. The consent of the patient is a necessary condition to the lawfulness of the medical intervention performed. German doctrine discerns the necessary "Selbstbestimmungsaufklärung" (informed consent for the

65 Blackman – Bailey 194 seq.
66 Blackman – Bailey 204 seq.

purpose of the self determination) which shall ensure that the patient validly consents to treatment avoiding the consequence of the qualification of body injury [67] and the "therapeutische Aufklärung" (informed consent for purposes for therapy) which shall be the guideline for the patient's conduct during the time of treatment and thereafter [68].

Naturally, the patient's consent only covers the indicated and lege artis performed medical intervention but if the informed patient consents to the medical treatment, the lege artis performed treatment remains lawful even if it is not successful or one of the inherent risks occurs.

The legal construction in Germany that the unconsented medical treatment is qualified as a body injury has faced severe criticism in literature, mainly relying on the fact that the subjective intent for the injury or the negligence in sections 223, 230 German Criminal Code (dSTGB) are not given. Whether or not a physician can be held responsible for a (negligent) bodily injury purely depends on the individual professional care that the physician has to ensure [69].

For purposes of obtaining an informed consent the German literature has identified the following compulsory content of the "Selbstbestimmungsaufklärung":

3.1.3.1.1 Information on the diagnosis

3.1.3.1.1.1 The diagnosis

This includes information on the actual or suspected disease. It shall enable the patient to understand and be confronted with the medical findings. Disclosure of the diagnosis is the necessary basis for the decision of the patient that a specific treatment shall be performed at all [70 71 72]. The disclosure of the diagnosis can be restricted to some general words in particular in common diseases (appendicitis) if the patient is a reasonable person [73] Some authors subdivide a category of information on the course of the disease (Verlaufsaufklärung) under which the

67 Laufs in Laufs- Uhlenbruck § 63 No 1 seq.
68 Laufs in Laufs- Uhlenbruck § 62 No 1 seq.
69 Maurach - Schroeder, Strafrecht, Besonderer Teil, §8 II 4, Teilband 1, 87.
70 Eisner 63.
71 Deutsch 83 No 113
72 Laufs in Laufs Uhlenbruck, § 63 No 13.
73 Deutsch 83, No 112.

disclosure of the normal course of the untreated disease is understood and disclosure of the effects of Non-treatment [74 75].

3.1.3.1.1.2 Scope of the disclosure of the diagnosis

According to literature, non-disclosure is lawful only in cases where disclosure would

1) lead to a massive psychological damage,
2) disclosure would lead to the risk of damage in particularly labile and endangered persons
3) disclosure would lead to endanger third persons (psychiatry)
4) would lead to the patient abstaining from the necessary treatment [76]

3.1.3.1.2 Information on the treatment

3.1.3.1.2.1 The treatment

Information on type, scope and performance of the medical treatment must be performed. The patient should be informed about the particularities of the treatment and the normal course of disease when he/she is not accepting the treatment. The patient shall get an impression of the scope of the decision to be taken. Jurisdiction asks, therefore, that the disclosure needs to be only of general nature. It is not necessary that the patient is informed of all details of the intervention to be performed [77].

3.1.3.1.2.2 Scope of the disclosure on the course of treatment and /or disease

The patient should get an impression of the treatment he is consenting to. It is not necessary to give a patient a full view of technical details [78]. Patients, however, have the right to obtain the following information [79]:

:

- the sure and likely effects of the intervention (operation) that occur in every treatment, e.g. scars, infertility etc.
- the likely scope of the intervention
- the likely effects and the postoperative state

74 Deutsch 83 No114 and 117.
75 Laufs in Laufs Uhlenbruck § 63 No 16.
76 Eisner 70.
77 Eisner 64.
78 Eisner 72.
79 Laufs in Laufs – Uhlenbruck § 63 No 16 -19.

- the chances of success and the chances of healing of the intervention
- the alternative treatments

Some authors also postulate an own duty to disclose the effects of medication that is administered [80]

3.1.3.1.3 Information on the risks of the treatment

3.1.3.1.3.1 The risks

Disclosure of risks: patients presume that the medical intervention improves their situation. It is, therefore, prerequisite that the patient is to be informed that the medical intervention can fail [81 82]. The disclosure of the risks must inform the patient about the inherent risks of the intervention that cannot be ruled out even in complete accordance with the professional standard. In general, doctors are liable for the performance but not for the result. The unwanted effects and incurred risks, however, are of such importance that the patient has to be given information in order to consider them when making the decision to submit to the medical intervention. The disclosure of risks must contain the disclosure of unwanted and imponderable effects as well as effects that cannot be handled or excluded. Disclosure of the risks, by far, is the most important form of medical disclosure to the patient incurring for most of the litigations [83].

3.1.3.1.3.2 Scope of disclosure of risks

Disclosure of risks, in German law essentially is determined by the individual circumstances of the patient. From the purpose of the obligation to inform, it follows that there cannot be a general unique scope of the information on risks without assessment of the personal risk structure of the very patient. The due scope of the information is difficult to assess. German jurisdiction asks for a scope of information that a reasonable patient would require [84]. There is no need to inform about unimportant and seldom risks if a reasonable patient would not take them into account when deciding about the treatment. However, the individual need of information of a patient is overruling the assumption of the need of the constructed

80 Deutsch 84 No 116.
81 Deutsch 84 No 115.
82 Laufs in Laufs – Uhlenbruck § 63 No 20 seq and § 64.
83 Eisner 64.
84 Eisner 73.

reasonable patient. The physician is obliged to extend information if he becomes aware of special conditions of a patient [85].

Usually, no information disclosure is needed for *obvious risks*, e.g. risk of wound infection [86]. Also *manageable risks* do not need to be disclosed if the management, i.e. treatment, of these risks does no lead to harm of the patient.

In older jurisdiction is has been stated that no information on seldom risks is to be disclosed [87]. More recent decisions and literature state that the mere statistical low occurrence of a risk is not a sufficient criterion to non-disclose. Of course, the more likely a risk, the more the physician has to inform the patient. On the one hand, in many areas of medicine, statistical data on the occurrence of risks are not available. On the other hand, a reasonable patient will also take into account the possible severity of the complication, though seldom. Minor complications are less likely to be subject to disclosure while important and severe complications even if seldom must be disclosed to the patient [88].

Further circumstances that influence the scope of information is the urgency of intervention. It has been argued that the more urgent the intervention is the less precise and extensive the information has to be.

3.1.3.1.3.3 Too much information

It might be that extensive information is unlawful. This might occur, if the patient gets a flawed, inadequate impression of the treatment which is exaggerated as to the risks leading to the patient denying the treatment in the following. Constellations discussed are:

- complete disclosure of all risks even if not subject to compulsory disclosure
- tendency of supplying information in favour of one type of treatment
- information on topics beyond the own clinical specialty

Over-informed patients are deemed not to be able to retain the information. This might have the same legal assumptions as if the patient would not have been informed at all [89].

85 Eisner 73 seq.
86 Eisner 74.
87 Eisner 76.
88 Eisner 77.
89 Deutsch 102 No 155.

3.1.3.1.4 Alternative treatments (if available)

Usually, physicians are held to disclose information on alternative treatment if available [[90]]. However, it is not clear to what extend alternative treatments have to be disclosed in particular if they are not part of the clinical specialty of the disclosing physician.

3.1.3.1.5 Economical consequences

According to recent German jurisdiction, the patient has to be informed about the economical consequences of the treatment [[91] [92] [93]] at least as far as it concerns the coverage of the costs by the social security.

3.1.3.1.6 General rule

The information disclosed to the patient has to be general and has to give a general idea of what the patient has to await. The physician, therefore, does not have to disclose single details. This is based on the experience that patients seeking more detailed information than usual take advantage and actively ask questions [[94]]. Information has to be adequate as to the scope of the intervention. For example, extraction of entire organs and parts thereof are not allowed if a minimal intervention is announced.

If even the basic information has not given the patient is considered to not have consented at all. While, whereas the basic disclosure is given, it is asked by the court whether or not the protective purpose of the duty to inform is violated (*Schutzzweckzusammenhang*) [[95]] and also whether or not the concrete risk that was not disclosed occurred (*Zurechnungszusammenhang*). In cases of complete lack of the basic disclosure, it is only asked whether or not the medical treatment is causative (for the damage incurred). On the other hand, if a disclosure was incomplete but a disclosed risk occurred, claims would be rejected by the German Supreme Court (BGH) [[96]].

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90 Laufs in Laufs- Uhlenbruck § 64 II No 4 seq.
91 BGH NJW 1983, 2630f.; BGH VersR 2000, 999.
92 Fenger H. Informed Consent in Aesthetic Plastic Surgery. Handchir Mikrochir Plast Chir 2006; 38: 64–67.
93 Deutsch 85 No 119.
94 BGH, Decision 28.2.1984. VI ZR 70/82, München, VersR, JG 35, Heft 22, 1984, p538-541
95 Eisner 59.
96 Faure - Koziol 125.

3.1.3.2Contractual obligations

In Germany, medical professionals are legally bound not only by statutory but also by a contractual obligation of informing the patient derived. This contractual obligation is derived from the contract governing the medical treatment ("Behandlungsvertrag" or "Spitalsaufnahmevertrag"). Usually, as in Switzerland and Austria, a contract governing medical treatment is qualified as service-contract including the service of disclosing medical information.

In civil law, the performance of a medical treatment without adequate information and subsequent valid consent is not only a breach of contractual obligations but also an unlawful act according to Sec 823 BGB. More, the German patient can rely on a special provision governing the compensation for pain and suffering "Schmerzensgeld" in cases of unlawful acts (Sec 847 BGB) that is applicable in cases of unlawful acts but not in cases of breach of contract. Hence, in Germany, if the patient claims compensation for pain and suffering based on insufficient information he clearly relies on an unlawful act, while the Swiss doctrine in assuming a contractual obligation that is covering also "Schmerzensgeld" [97].

3.1.3.2.1 The informing physician

Performing medical services is not only a prerequisite of medical professionals, but also a *non-delegable duty*. Only the medical professional disposes over the necessary professional knowledge to assess the necessity of a medical intervention. Accordingly, the physician is also solely responsible for the medical information dispensed [98] but off course, the disclosure can also be performed by another physician than the treating physician as long as he disposes over the necessary professional knowledge [99].

In hospitals the duty for organizing and disclosing medical information is hierarchically structured. The trust / health care provider has to ensure the general structure for adequate information dispense. The head of the hospital is responsible for general guidelines and supervision, while each head-of-unit has to ensure the performance of the medical information in his unit. The treating physician is lastly responsible for actually disclosing the medical information to the patient.

97 Eisner 30 seq.
98 Eisner 65.
99 Deutsch 93 No 137.

In general, a delegation of doctor's prerequisites is not allowed to-non medical professionals or paramedicals [100].

3.1.3.2.2 Time and amount of information to be disclosed

The reason of the disclosure of medical information is to ensure the freedom of decision of the patient whether to undergo a treatment or not. Therefore, it is frequently argued that medical information has to be performed well before the beginning of the treatment, so that there is sufficient time for the patient to make up his mind. The more urgent an intervention the less intense the disclosure has to be [101 102]. There are no exact deadlines to be followed but it has been argued that in cases of severe intervention information should be dispensed three days before the event, in cases of minor interventions, disclosure should be done not later than one day before surgery [103].

3.1.3.2.3 Formal aspects

There are no formal requirements how to perform medical information of the patient. However, there is consensus that there must be a personal communication between the physician and the patient. In order to facilitate the better understanding, doctors may rely on brochures or printed forms in order to prepare and underline the personal communication [104].

In practice, medical information is dispensed in two steps:

1) basic information usually performed using printed forms and brochures
2) a subsequent personal communication between physician and patient with an in-depth discussion of personalized problems and questions of the patient.

German jurisdiction takes a restrictive stand-point as to the use of printed forms: The signature under such documents would not prove that the patient has read or understood the content, and there would be no proof that the content has been

100 Eisner 66.
101 Deutsch 87 No 121 seq.
102 Laufs in Laufs – Uhlenbruck § 68 No 7.
103 Eisner 68.
104 Eisner 68.

discussed in a personal communication [105]. However, a general deny of the use of printed forms is not indicated: Their agreed purpose is the preparation of the personal communication without replacement of the latter [106 107]. Printed forms with hand-written annotations and hand-made illustrations have better evidencing value of the performance and content of the information process [108]

3.1.4 Austria

Much of the legal framework in Germany applies for Austria likewise. Contrary to the German legal construction, §88 öStGB (criminal code) defines an exception to the crime of bodily injury:

> *§ 88 Fahrlässige Körperverletzung*
>
> *(1) Wer fahrlässig einen anderen am Körper verletzt oder an der Gesundheit schädigt, ist mit Freiheitsstrafe bis zu drei Monaten oder mit Geldstrafe bis zu 180 Tagessätzen zu bestrafen.*
>
> *(2) Trifft den Täter kein schweres Verschulden und ist entweder*
>
> *...*
>
> *2. der Täter ein Arzt, die Körperverletzung oder Gesundheitsschädigung in Ausübung der Heilkunde zugefügt worden und aus der Tat keine Gesundheitsschädigung oder Berufsunfähigkeit von mehr als vierzehntägiger Dauer erfolgt,*

Therefore, if a physician in exercising his profession negligently commits a bodily injury e.g. by not obtaining an informed consent, and if no injury of more than 14 days of duration occurs, then there is no fine. One could also argue whether or not the pure lack of an informed consent makes a medical treatment a bodily injury at all,

105 Eisner 69.
106 Eisner 69.
107 Deutsch 93 No 138.
108 Jungbecker in Ratajczak – Stegers, Risiko Aufklärung, 31 seq.

since the subjective element (purpose or negligence in injuring somebody might not be given).

As a corrective, the Austrian Criminal Code penalizes the pure offence against the free will and self determination of a patient. Medical treatment without consent further violates sec 110 of the Austrian Criminal Code (öStGB) which penalizes such unsolicited treatment even if performed according to the common standards of medical science (sec 110 para 1):

> *§ 110. (1) Wer einen anderen ohne dessen Einwilligung, wenn auch nach den Regeln der medizinischen Wissenschaft, behandelt, ist mit Freiheitsstrafe bis zu sechs Monaten oder mit Geldstrafe bis zu 360 Tagessätzen zu bestrafen.*
>
> *(2)*
>
> *(3).*

According to sec 8 para 3 Austrian Hospitals Act (KAKuG) a patient admitted to hospital must specifically agree to any medical act taken if there is enough time to acquire the this agreement without danger of life, serious harm to the patients health.

There also is a contractual obligation of the medical professional/hospital to provide for medical information disclosure, subject to prove by the practitioner/hospital. It has been ruled that the simple hand-over of a printed information sheet without subsequent discussion of the medical treatment does not fulfil the legal and contractual obligations to disclose information [109]. However, the physician/hospital must keep written records of the information process.

The Austrian Supreme Court (OGH) has ruled that there are no generally applicable criteria as to which possible risks and complications have to be disclosed. Instead, one has to look at the individual circumstances of each case. The question is whether a reasonable patient would undergo the treatment. This is to be presumed if the disease is life-threatening or affecting basic body functions [110]. It follows that the more urgent a treatment is, the less intense an information communication has to be.

109 Faure – Koziol 61.
110 Faure – Koziol 62 f.

The less imperative a treatment, the more intense the information disclosure must be. This is particularly important in aesthetic and purely diagnostic interventions [111]. Of course the statistical odds of occurrence of a risk can influence the decision to disclose or not but even rare complications must be disclosed if there might be an interest of the patient therein [112]. Typical risks always have to be disclosed, A risk is typical if it is in particular connected to the planned treatment even if rare and if cannot be completely ruled out with utmost care and if it would surprise an uninformed patient (e.g. infection). Not each and every risk is to be disclosed but only such risks that could influence the patient's decision.

The OGH has not stated that there is a minimum of information to be disclosed. In a more flexible system than the German BGH, there could even be less information but e.g. in a case of an overanxious patient in state of emergency have to be roughly informed about the inherent risks.

As in Germany, liability is not ruled out just because the risk eventuated was not to be disclosed. If patients did not receive any information, doctors and hospitals are liable for all negative events of the treatment [113].

As to the time of information, patients have to be informed early enough to enable a reasonable decision.

By sec § 49 Abs 2 Physician's Act (ÄrzteG) 1998 physicians are required to perform medical services *in personam.* It follows that physicians must mot delegate their duties (sec 2 para 2 ÄrzteG) to any substitute without the prior consent of the patient. As an exception to this rule that the physician has to perform medical services personally, they may, however, seek the help of other (than medical) personnel when these personnel is under his permanent supervision and acts on precise instructions from the physician (sec 49 para 2 second sentence). Physicians may further delegate certain single duties to other medical professionals (than physicians) if this specific duty is covered by the scope of professional performances of this medical profession. Supervision always is necessary unless these professionals' rules state otherwise. (sec 49 para 3 ÄrzteG). The performance of certain medical services may also be delegated to medical students being under supervision.

111 Faure – Koziol 63.
112 Faure – Koziol 63.
113 Faure – Koziol 64.

Another exception of the rule of personal performance is stated in sec 50a para 1 ÄrzteG. Physicians may delegate single medical services to relatives of patients, persons exerting custody of patients or persons who are in a local and personal proximity of patients if patients are domiciled in an institution of medical or psycho-social care. However, a professional conduct of these delegated duties is not allowed.

These rules designed for the independent practitioner are also applicable in teams of hospitals[114]. Consequently, the (KAKUG) states in sec 7 para 3 that medical service in hospitals may only be performed by approved physicians.

By statutory law, several duties of the physician apply, most of which can be found in both: statutory law and as ancillary duties of the contract governing the medical treatment:

These are:

- Information and obtaining an informed consent (sec 51 ÄrzteG)
- Documentation (sec 51 ÄrzteG)
- Access to the medical records (sec 51 ÄrzteG)
- Secrecy of all patient related data (sec 54 ÄrzteG)

3.1.5 Switzerland

Patients in Switzerland frequently rely in their claims of malpractice on insufficient information rather than professional blunder. Insufficient information of the patient has become a very popular claim. The reason therefore lies in the current jurisprudence that gives patients the burden of proof of the professional blunder, proof that frequently cannot be brought to the court. Claiming insufficient information has several advantages as the burden of proof is uniquely with the medical professional [115] Other bases like an “unlawful act” (Art 41 OR) are rather theoretical [116].

114 Barta 692.
115 Eisner 24.
116 Eisner 28.

Legally, the obligation of physician to inform patients usually is based on two different reasons: the concluded contract of treatment that regularly includes the duty of information and the statutory right of self-determination. (Art 27 and 28 ZGB).

Unlawful is an intrusion thereof in any case when it is directed like life, bodily integrity. Accordingly, for the Swiss Supreme Court (Bundesgericht, BGE) any medical intervention therefore is unlawful per se. As Art 28 para 2 ZGB indicates the unlawfulness may be overcome by the patients consent. This consent is the necessary condition for a medical intervention. The intervention in turn is only valid if preceeded by an adequate information of the patient [117].

Accordingly, an intervention without "valid" consent of the patient always is subject to penalization according to Art 123 Swiss Criminal Code. This position of the Swiss BGE is heavily contested by literature as the lege artis conducted medical intervention to the benefit of the patient cannot be qualified as an objective bodily injury. The criminalization of a medical treatment as bodily injury is rather questionable [118].

As a general guideline, apart from various purposes of information, one can determine the extent of the physician's duty to disclose information according to the actual circumstances of each and every patient. The physician obliged to disclose every information that a reasonable patient might attach importance to. In addition the doctor will have to answer further requests [119].

According to the BGE [120]:

> *A physician has to provide his patients with simple, comprehensible and true information on diagnosis, prognosis and therapy. As far as the last item is concerned, a patient has to be informed about the kind of treatment proposed as well as possible complications so that he can knowingly give his consent. Informing the patient should not, however, cause a state of anxiety which could impair his health.*

The disclosure has to include [121]:

117 Eisner 26.
118 Eisner 28.
119 Faure – Koziol 204.
120 BGE 105 II 284 et seq.
121 Faure – Koziol 205 seq.

a) the medical indication (factual urgency) of the doctor's action, including possible consequences of abstaining there from;
b) its urgency in time
c) the risks connected therewith in light of their quantity (frequency) and quality (seriousness and lack of possible cures), included the risks connected with possible medical alternatives
d) type and indication or necessity of the intended measure;
e) the progress of the measure to be taken and its effects;
f) the prospects of the measure (prognosis), thereby considering the desired medical success and possible side-effects (risks) which need to be accepted
g) possible alternatives to the treatment generally including measures the treating doctor cannot perform by him/herself.

3.1.5.1Disclosure on risks of treatments

Two kinds of risks are discerned: typical risks, which are inherent to the treatment and occur with a certain frequency in a particular treatment. Minimal and not serious risks can be ignored as well as risks that can be easily controlled even though they might occur quite frequently. The opposite applies for serious risks with severe consequences. Statistical occurrences are only a hint. Special risks in individual cases (e.g. due to a personal history) have to be considered. The more urgent a treatment is, the more acceptable the non-disclosure for the patient a risk seems, although maybe severe. But even in cases of high urgency, the patient's right of self-determination requires that the patient is to be informed as much as possible [122]. As a rule, high risks with severe consequences require more information.

According to the BGE, a physician is required to inform the patient about the type, the risks of the intended methods of medical treatment, unless these are everyday measures which do not entail any special danger or can cause final or lasting impairment of bodily integrity. The patient should know about the operation or treatment at least insofar as to allow him to consent thereto on the basis of sufficient knowledge of the facts [123].

122 Faure – Koziol 207.
123 BGE 117 Ib at 203 f E.3b.

A physician can in general presume that he is dealing with a reasonable patient who knows about familiar dangers of the planned operation based on the past experience. The physician, therefore, does not have to disclose complications which regularly occur in the course of any major surgery, such as bleeding, infections, thrombosis or embolism.

In disclosing, the physician must also take into account special circumstances. He does not have to tell the patient about all dangers of the intended operation in extensive detail, in particular if the patient already knows about the respective risks from prior or similar operations. There is a general rule that a physician who is about to perform surgery which is known to be highly dangerous and could lead to grave consequences will need to inform the patient more extensively, than in cases of common unproblematic measures [124].

According to newer doctrine a simple, comprehensible and true disclosure is asked for which is orientated at the reasonable average patient ("einfache, verständliche wahrheitsgetreue und eine am verständigen Durchschnittspatienten orientierte Aufklärung) „ is asked for. In special cases, an extended information is due, also if the patient wishes an extended information.

3.1.5.1.1 The informing physician

The BGH has not expressly dealt with the question who is obliged to inform the patient [125]. According to doctrine based on the OR (Art 398 para 2), the information disclosure has in principle to be performed in person by the physician. It has not been stated whether or not this task can be delegated to non-medical personal i.e. paramedical, nurses, students, etc. Delegating such duties to an assigned practitioner should be generally admissible, but as a rule the practitioner performing an operation will have to disclose to the patient. If the latter has been informed by another practitioner, there is no need that the disclosure is to be repeated. Delegation to non-medical staff is inadmissible unless the requirements of such instructions can be met by this staff [126]. According to *Eisner* [127] the German

124 Faure – Koziol 20.
125 Eisner 157.
126 BGE 116 II 519 seq.
127 Eisner 158.

solution is applicable rather than the US model, as only the doctors dispose over the necessary expert knowledge to dispense the adequate information.

3.1.5.1.2 Time of information

The patient must be informed as early as possible in order to enable a sincere decision. In case of routine operations the patient can be informed right before operation but in a reasonable timely interval to allow a proper decision-making process of the patient. In case of significant operations three days have been stated as reasonable time. Timing is also influenced by the necessity of the treatment. Performing the informed consent process the day before intervention might only be adequate in cases of minor risks [128]

3.1.5.1.3 Types of information

In Swiss jurisdiction several categories have been defined in order to categorize the information due [129] (a) requiring most intense information decreasing to (e):

a) the cosmetic intervention
b) the diagnostic intervention
c) relative indicated interventions, offering the patient to continue living and accepting their disease
d) absolute indications of the intervention to prevent severe damage to the health of the patient, and
e) vital indications, these are interventions to prevent a imminent present danger of life

However, in another line of jurisdiction, it has been found that doctors have to disclose typical risks of an intervention even if seldom occurred [130]

New aspects of information are also discussed in Switzerland though not being generally accepted in doctrine and jurisdiction:

- alternative treatment [131]

128 Roggo 199 - 203.
129 Eisner 80 seq.
130 Eisner 83.
131 Eisner 87 seq.

- information about the clinic (e.g. whether specialized clinics are associated in less risk for a specific intervention
- experience of the doctor
- economical information

3.1.5.2 Using forms

Using printed information leaflets is controversially discussed in Switzerland as well [132] namely citing German literature and BGH jurisdiction.

3.1.6 Other EU Member States

In France, until 1998, only foreseeable risks (*risks normalement prévisibles*) had to be disclosed to the patient. This proved to be impracticable as the distinction between foreseeable and exceptional risks varied greatly from deciding court to court. In a landmark case, the Cour de Cassation (French Supreme Court) ruled that

> *"the physician is under duty to give a fair, clear and appropriate information about the serious risks associated with the test or treatment he is intending to carry out, and this is so, even if those risks are of exceptional occurrence" [133].*

The Cour de Cassation has not given a clear definition of the terms "serious risk" which is to be defined case by case. In any case, one can assume a serious risk when there is a danger of death, permanent disability or serious disfigurement [134].

Contrary to other legal systems, the law governing the medical treatment in public hospitals is public law, while private law when a private contract of treatment is concluded [135]. Usually, the same kind of duties applies for public as well as private hospitals. However, in some cases French law even seems to have adopted a "strict liability" for public hospitals for "therapeutic risks", namely if a new medical technique is tried out [136] or for exceptional risks [137].

132 Roggo 194 seq.
133 Cour de cassation, first civil division, 7.10.1998, Bul Civil 1, n° 291.
134 Faure – Koziol 107.
135 Faure – Koziol 270.
136 «Arrêt Gomez » - Cour administrativ d'Appel de Lyon, 21.12.1990, Jurisclasseur periodique (JCP) II, 1991, 21698.

According to Belgian Doctrine, the right to be informed is derived from the statutory right of physical and medical integrity and the statutory right of self determination. The obligation to inform the patient also is a contractual obligation of the physician. It is regarded as that fundamental that it cannot be delegated to any non- or paramedical personal [138]. The content of information depends on the circumstances. In general, the physician has to inform the patient about the diagnosis and the severity of the disease, the treatment, its benefits and risks, urgency and costs. Belgian doctrine adheres to the concept of "normal and reasonable foreseen risk theory [139]. The physician has to inform the patient only about "normal risks". There is no duty to inform the patient about serious but exceptional risks or more frequent but minor risks [140].

The physician has to inform the patient early enough to enable an assessment of the situation by the patient. There is no rule as when exactly an information communication has to be performed. Of course, it is too late, when the preparatory phase of the surgery has already begun.

In Belgium, the use of written forms for the informed consent is not common. It is argued that whenever such forms are used the patient has to be properly informed in a personal communication by the physician before signing the form [141].

The Dutch Medical Services Act (incorporated in the Dutch Civil Code) states that a physician has to inform the patient about the aspects of treatment and examination (Art 7:448 CC). The patient has to give prior consent (Art 7:450) [142]. With exception to special circumstances (e.g. therapeutic exception) the physician (health care provider) has to

> *"inform the patient clearly, and if requested, in writing, about the proposed examination, and treatment and about the*

137 «Arrêt Bianchi » – Conseil d'Etat, 9.4.1993 –Receuil Lebon 1993, 127 et seq ; JCP., II, 1993, 22061.
138 Faure – Koziol 86, 93.
139 Faure – Koziol 86.
140 Faure – Koziol 86.
141 Faure – Koziol 93.
142 Faure – Koziol 148.

developments concerning the examination, the treatment and the condition of the patient's health. (…)"

2. in pursuance of the obligation under paragraph 1, the health care provider shall be guided by what the patient reasonably needs to know about:

a) the nature and the purpose of the examination or treatment which he considers necessary and of the activities which are to be carried out;

b) the likely consequences for and risks to the patient's health;

c) other possible types of examination or treatment;

d) the prospects for the latter's health from the point of view of the field to which the examination or treatment relates;

3. (..)

The healthcare provider is not obliged to draw the attention of the patient to all possible risks. There is uncertainty, in literature as well as in jurisdiction, as to "what a reasonable person" needs to know in the given circumstance. In order to determine the necessary scope of disclosure, it is often referred to what *"a reasonable competent practitioner acting in a reasonable manner"* would do. This criterion is one of a "professional standard", i.e. the usual practice among fellows [143].

Other authors add further items to this list, namely information as to which personal will perform the treatment or intervention and their role therein, information about the availability of personal and on substitutes, information about practical issues as visit-hours, life-style advice etc [144].

The duty to disclosure is non-delegable under Dutch Law but delegation under colleagues of the same health care provider should in general be possible. Information should be disclosed in due time before examination or treatment to enable assessment of the patient.

143 Faure – Koziol 152.
144 Pichler 325.

In case of radical examinations or treatment, the information must not be disclosed immediately before the intervention. Contrary, it the examination or treatment involves minor risks, the patient might be informed immediately before treatment [145].

3.2 Comparative Summary

3.2.1 Amount of information

The issue how much information has to be disclosed to the patient is answered with different emphasis in several countries examined above.

In French law, the rule seems to be that a "fair, clear and appropriate information about the serious risks associated with a test or a treatment, even if those risks are of exceptional occurrence", has to be given. The rule seems to be more strict for public hospitals. (See Bianchi case) where even exceptional risks have to be disclosed.

Under English law, the amount of information to be disclosed is assessed using the professional standard. The same is true in part for US legal systems depending in the Federal State. In the Netherlands, the assessment uses the formula of the "reasonable patient" but also a criterion of "professional standard" while in Belgium, normal and reasonable foreseen risks have to be disclosed but there is no obligation to inform about exceptional risks or more frequent but less serious risks.

In other legal systems (Germany Switzerland and Austria), a quite complicated set of rules applies which considers the statistical occurrence and the seriousness of the risk in determining whether it has to be disclosed or not.

With different emphasis, there seems to be a duty to disclose serious risks in all countries. There might be some differences about the duty to disclose exceptional risks or manageable or less dangerous risks. However, in English law, a corrective to the rule of professional standard is introduced, as a professional standard might be rejected by the court if based on tradition or sluggishness rather than on medical ratio. Differences might be only nuances as the professional standard might include – in proper interpretation – the disclosure of all risks, a reasonable patient in his special medical condition and risk structure might attach importance to.

145 Faure – Koziol 153.

3.2.2 Use of Consent forms

For almost any state in this outline, it can be followed that signing a mere consent form does not fulfil the requirements in information disclosure to the patient. Although they might be used as preparatory material they are in no ways replacing the personal communication of the doctor which remains in any case necessary.

3.2.3 Who has to disclose medical information?

In many countries, the duty to disclose medical information is a personal duty of the doctor performing the test or intervention and cannot be delegated to non-medical personal. However, in many countries this duty can be delegated to fellow doctors at the same health care institution. However, the final responsibility remains with the doctor in charge.

From the right of self-determination, however, it can be followed that insufficient information disclosure might be overcome if the patient has got the necessary information from

3.2.4 Language and ability to understand

From the absolutely protected human right of self-determination and bodily integrity, it follows that the patient has to be able to understand what is being disclosed to him. This becomes the more important as consent forms are used which are frequently signed by the patient without prior reading the content.

Therefore, for a valid informed consent, the treating physician has to ensure that the patient can follow and understand what is being disclosed.

This position may also be adopted in case a patient cannot understand on other reasons than on mere language problems, e.g. insult, dementia or other mental states which do interfere with the patient’s apprehension.

3.2.5 Time of information

In all countries in this outline, it is the law that a patient has to be informed in due time before intervention. There has to be sufficient time between the disclosure of the medical information and the intervention to enable the patient to assess al benefits and risks in order to properly decide whether or not to undergo the treatment without being under pressure of timely constraints.

Disclosure which takes place immediately before intervention may not be considered as timely unless there is a certain timely urgency of the intervention which does not allow performing a complete and extensive disclosure as usually due. Another rule frequently adopted in many countries is that the more severe and associated with serious risks a treatment or test is the more time for reflection of the patient has to be given (unless there is some urgency of the immediate intervention).

4 The current state of disclosure of medical information

Claimed lack or flawed disclosure of medical information has been identified as a major source of litigation. The reasons therefore are to be found not only in the person of the disclosing physician but also in the patient's willingness and ability to take-up information, the heavy work-overload and tight time constraints in particular in publicly funded hospitals [146].

4.1 The current practice

In many surgery wards, it is common practice to use a 2-step procedure to disclose medical information to the patient. Patients are usually handed over a printed information folder with a line for signature. Patients may have some time to read these folders. Usually, the physician or a trainee repeats in a second step the content of the information sheet to the patient in a personal communication offering additional information upon request of the patient. Results of previous examinations (of other medical specialties) might be introduced into this personal communication in particular when it concerns the risk structure of patient.

Other, rather embarrassing issues might not be addressed at all: For example, there is also reason to believe that disclosure of important facts such as the participation of

146 Ehlers 107.

trainees in cataract surgery is often not disclosed to patients as this would raise anxiety of the patients, give rise to questions and to the and denial of surgery [147].

Usually, immediately after the personal communication the signature and hence the consent is given onto the information sheet. The patient therein confirms to have given the requested information. This practice seems to be dictated by the above mentioned constraints in particular in public hospitals.

It is no secret that the personal communication might be rather short and inefficient as well as insufficient and in some cases it might even lack at all if the time – constraints of the personal in charge so dictate.

4.2 Problems with the use of printed information material and consent forms

In nearly all legislations outlined above, the mere presentation of printed material to the patient is not sufficient for a valid consent. Usually a personal communication of the physician with the patient is asked for. Printed material is allowed as supportive means for the preparation of the subsequent communication and for dispense of the medical basis of what the patient has to be disclosed.

In practice, information sheets are frequently handed over to the patient in proximity to the planned intervention, often leaving no sufficient time for evaluation of the pros and cons of the treatment. In many cases, the information sheets are not fulfilling the basic requirements as set forth by the local legislation. In a survey conducted by *Botrell* et al [148] only 26% of 450 different information leaflets and forms examined fulfilled the basic requirements for informing the patient of all relevant information. Botrell also reported that forms tended to be written in order to exclude liability for the physician rather than fulfilling their proper purpose, namely informing the patient.

For cataract surgery, detailed results are available: *Brown* et al [149] evaluated information leaflets of 12 ophthalmology departments in the West Midlands at the criteria as published by the General Medical Council (GMC), British Medical Association and Medical Defense Union. While all leaflets provided for information on diagnosis, postoperative life-style changes, costs, preparation, and benefits but only

147 Nguyen TN, Silver D, Arthurs B. Consent to cataract surgery performed by residents. Can J Ophthalmol 2005;40:34–7.
148 Botrell MM, Alpert H, Fischbach RL, Emanuel LL. Hospital informed consent for procedure forms: facilitating quality patient-physician interaction. Arch Surg 2000; Jan; 135 (1): 26-33.
149 Brown H, Ramchandani M Gillow JT, Tsaloumas MD. Are patient information leaflets contributing to informed consent for cataract surgery?. J Med Ethics 2004; 30:218-220.

5 leaflets had information on the risks involved. Other necessary information was covered to an extent of 50-75%.

However, the principle benefit of printed material is already proven. Even in severe diseases, the distribution of informative booklets leads to greater satisfaction of patients, better information and less conflict in decision taking [150].

4.3 The fiction of the reasonable patient

4.3.1 Legal fiction and "real life"

Without needing to repeat the frequently-stated and diametrically different arguments of physicians and lawyers, it cannot be refuted that the legally imposed obligation to adequately inform the patient is in sharp contrast with the real world [151]. Even if one concedes that it is not possible for a physician to give medical lectures to laymen, and that medical information is only to be disclosed to a general extend in line with the intellectual and cognitive abilities of patients, it is nevertheless evident that a general disclosure of information becomes more and more fictive with the massive growth of medical knowledge [152]. Many lawyers concede that the obligation of disclosing patient – adequate information can hardly be met even by the most competent physician [153]. The need of information of the patient, the actual information of the patient, legal requirements of the informed consent and the reality of obtaining the informed consent of patients seem to be distinct worlds [154].

The inevitable simplification of medical facts often leads to misunderstanding of the patients. Further, it has to be considered that the patient's ability to freely dispose over his fate is diminished by the disease he/she suffers. The patient, clearly, is not the "*reasonable human being*" for whom he is taken by legal fiction. This becomes evident in severely ill patients, for whom the need for consent to treatment is abandoned even by the law but is also true for the average patient who also is strongly impeded in his free decision by the disease itself [155].

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150 Mancini J, Nogue C, Adenis C, Berthet P, Bonadona V, Chompret A, Coupier I, Eisinger F, Fricker JP, Gauthier-Villars M, Lasset Ch, Lortholary A, N'Guyen TD, Vennin P, Sobol H, Stoppa-Lyonnet D, Julian-Reynier C. Impact of an information booklet on satisfaction and decision-making about BRCA genetic testing. Eur J Cancer 42(2006) 871-881.
151 Ehlers 107.
152 Ehlers 110.
153 Ehlers 107 seq, with further references.
154 Ehlers 108.
155 Ehlers 109; Faber 83 seq.

It has been argued against the legal fiction of the reasonable patient that an "objective model patient" is in no way congruent with real patients. It has also been put forward that the patient needs the authority of the physician in a situation where he is in psychological jeopardy, anxiety and fear thus transferring decision taking and responsibility to the physician [156]. Some authors have argued that the physician is not only responsible for the correctness of the information disclosed but also for the impact of this information on the patient. It therefore would be nearly impossible that the physician acts in reasonable collaboration with the patient [157].

4.3.2 Rationality of patients from an economical point of view

From an economical point of view, rational acting is an acting which achieves the utmost outcome with the least means [158].This implies that the outcome has to be known for the acting subject, which is frequently not the case in many patients and for many medical procedures and treatments. Acquiring the necessary information to act rationally is associated to costs for the patient, which he is taking only to a variable extend [159].

> *"a wealth of information, creates a poverty of attention"*
>
> *(Herbert A. Simon)*

Patients like every human being dispose over limited time and resources to memorize relevant facts for the decision to undergo or abstain from a treatment. The more complex the medical information gets and the more content to be disclosed (information overload), the more it will be ignored, even if it is to the patients disposition for free [160].

4.3.3 Evidence for patients inability to retain adequate information

Information requirements of patients, actual information and knowledge of patients and legal requirements of information disclosure are often argued as being different worlds [161]. It is argued that medical information is not understandable for the layman

156 Jaspers, quoted in Ehlers 109, Faber 83 seq.
157 Neidhardt, Behandlungsrecht des Arztes und ärztliche Aufklärungspflicht in der Sicht des Arztes und des Juristen, NJW 1956, 1097 seq.
158 Faber 83.
159 Faber 84.
160 Faber, 93.
161 Ehlers 108.

because of the medical terminology and the complex medical situations [162]. Further, it is argued that the sick patients more than the healthy human is less prepared to retain medical facts [163]. Jurisdictions in many countries therefore would use an inadequate criterion to establish legal obligations to inform patients [164].

Beside all cognitive arguments, there is also hard empirical evidence that the special circumstances of patients and the nature of medical information lead to the patients inability to retain adequate medical information:

In a study with hospitalized patients facing immediate surgical intervention compared with patients not being admitted to surgery yet, it has been found that hospitalized patients in contrast to non-hospitalized patient are not sufficiently able to take up relevant information. The overall memorisation of the disclosed information of all patients in that study was reported to be rather low arising to only 50% (right after reading) and 30% (long term) of the information in a printed leaflet handed over to the patients[165]. Other studies report of 30% memorisation [166].

It is also undisputed medical and psychological evidence that patients tend to repress or suppress medical information right after surgery. *Kraft* reports that 45% of patients could roughly repeat the disclosed information only 3 days after surgical intervention [167]. It also is reported that even with a sophisticated technique the rate of memorisation cannot be augmented. Many patients simply ignore or falsely deny that important questions have been discussed with them, others simply invented assertions of the physician [168].

Forgetting and repressing disclosed content already begins as early as during the disclosure and might be supported just by the disclosing physician who tries to give comfort, appease and to console [169].

After all these psychological mechanisms of repression and seem to be all too human in the light of the often threatening diseases und uncertain future patients have to deal with.

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162 Ehlers 108.
163 Ehlers 109.
164 Ehlers 109.
165 Mann F, Schrader R., Zur Schriftlichen Aufklärung vor medizinischen Eingriffen, in: Informationen des Berufsverbandes der Deutschen Chirurgen eV, No 5, 1983, 78 [reported in Ehlers 110].
166 Deutsch, NJW 1979, 1905-1907.
167 Cited in Ehlers 111.
168 Ehlers 111.
169 Ehlers 112 with further reference.

4.3.4 Different types of patients

Studies show that different types of patients (passive, shared Decision Making or autonomous) can be identified with an individual need to share decision making, mainly depended on individual setting of the patient and trust in their physician but also kind of disease or condition. Passive patients also identify themselves as less knowledgeable than autonomous patients [[170]]. Participation in decision-making whether or not to undergo cataract surgery (or a treatment in general) covers several dimensions. The preferred role of the patient might oscillate between a desire to be involved in decision making and a desire not to take charge. Some patients might prefer a purely passive role or an autonomous consumerist view [170]. Other patients find it disturbing and even useless to know about their own health state [[171]]. The latter tend to delegate responsibility and decision –taking to the treating physician rather than getting involved into a decision-making process [[172]].

4.3.5 Evidence of weak memorisation in eye surgery

In eye-surgery, in a study [[173]]it was reported that 97% of patients recalled that there was a personal communication, 40%, however, had forgotten that irreversible suture-material remained in the eye, 23% recorded only that the surgery could be complicated by infection or bleeding, and only 3% recalled that there could be other complications of surgery.

In a study conducted by *Kiss* et al [[174]], the procedure to obtain the informed consent did not seem to influence the decision making process of patients in cataract surgery, obviously because of delegation of the decision taking in its entirety to the physician:. 44% of patients of that study preferred a physician taken decision for surgery, and only 26% wanted shared decision making. Possible risks and adverse effects did not influence 77% of the patients' decisions to undergo surgery.

170 Kraetschmer N, Sharpe N, Urowitz S, Deber RB. How does trust affect patient preferences for participation in decision-making? Health Expectations, 7, 317–326.
171 Ehlers 112.
172 Faber 96.
173 Priluck cited in Ehlers 111.
174 Kiss CG, Richter-Müksch S, Stifter E, Diensdorfer-Radner G, Velikay-Parel M. Informed consent and decision making by cataract patients. Arch Ophthalmol. 2004 Jan; 122(1): 94-8

4.4 Summary

Both the community-related professional standard as well as the patient oriented standard of disclosure have their advantages and disadvantages. While the theory of the informed consent can be understood as an regulative for the unwanted outcomes of a professional standard. Forcing the physician to integrate the patient in the decision - making process, a patient oriented standard, as applied in many continental European countries might remain fiction to a large extent. The empirical data about patients' knowledge and reasonability can be summarized as "disastrous".

The request for a patient-adequate information disclosure that enables the patient to decide whether or not to undergo treatment might turn out to be rather unrealistic. From a medical point of view it is feared that this problem cannot be solved due to the above stated reasons but also because an adequate system to provide for improved informed consent is not affordable to the public [175]. Patients are frequently overwhelmed by the disclosed information and cannot keep the content in memory [176].

As *Weissauer* puts at clear, including the necessary information on anaesthesia and possible secondary interventions and risks thereof, the number of properly informed patients would probably converge to zero [177].

Younger European developments asking that the patient has to be informed at his/her intellectual abilities and that the actual information of the patient has to be confirmed and ascertained by the physician will be subject to further evaluation [178].

It seems astounding, however, that physicians in the future might have to take over teachers' functions in ascertaining and testing (?) the patients' understanding. This development will require physicians to be psychologist, teacher and physician (at the simple wage of a physician) and ignores the over boarding economical consequences this might bring in the future.

5 Economical analysis of the information retrieval

It is inherent to the fundamental right of self-determination of human beings that this right of self-determination is not limited by economic considerations. Neither the cost

175 Ehlers 113.
176 Faber 94.
177 Weissauer, cited in Faber, 94.
178 Pichler 335.

nor the efficiency of information disclosure to patients is taken into account when the lawyer asks whether or not a patient is properly informed.

The proper information of patients including all questions, the controlling whether or not the patient did understand with a view to the patients subjective conditions, is intensive and time-consuming [179]. Further, physicians, in particular in public hospitals, usually suffer from a severe lack of time. With good reason it is criticized that the jurisdiction on information duties puts not achievable demands on physicians; not only in respect to time [180].

Cuts in public spending on health service are rule rather than exception in almost any country, also covering costs on man-power. In the legal discussion of the informed consent, and the human right of self-determination economical analysis of the costs thereof seem to be a “do not touch issue” and never seem to be considered in any jurisdiction. However, information has its costs and somebody has to pay for it! So far, the author of this thesis is not aware of any economical analysis of the informed consent procedures for the health care providers, nor does it seem as if these costs have influenced legislation or jurisdiction.

Information that does not contribute to decision making, inefficient procedures or superfluous legal requirements without material impact on the purpose of the information duty in other terms is lost money and inefficiently used public resource. To put it different: Are there means of saving time of the physician that could be spent in treatment and hence reducing the cost of information transfer to the patient without touching the patients’ self-determination?

6 Computer-Aided Learning

The current state of disclosing medical information is insufficient and does often not meet the goal to enable the patient to take a proper decision.

As some of the above mentioned problems are unlikely to change, one relatively easily achievable amelioration is the optimisation of the information dispense to the patient.

179 Faber 103.
180 Faber 103.

A frequently used approach is the use of printed information sheets. The limits thereof have been established in jurisdiction. New media and e-learning facilities have not been widely in use so far but could prove to be more efficient as to time of the physician spent, learning effect and memorisation than sheer printed matter.

6.1 Physician training

The first electronic means for teaching were expert systems. Electronic expert systems try to mimic human thinking and decision - making. The first large expert system to perform at the level of a human expert was developed to provide physicians with advice about bacteraemia and meningitis [181]. They are quite common to aid the medical practitioner in diagnosis and treatment issues.

Soon, expert systems were developed not only for expert advice but for educational purposes. Those programs were designed to act like a “human” tutor, referred to as intelligent tutoring system (ITS). The characteristics of an ITS include the ability [182 183] to:

1. teach a given subject
2. detect student errors
3. analyze where and how the student made an error
4. correct flaws in the student's logic
5. clear up any misgivings or misunderstandings the student may have about the material.

Interactive multimedia applications are meanwhile frequently used for teaching purposes using the different senses of the human being. Multimedia applications help educate medical practitioners in many fields, e.g.: epilepsy diagnosis and treatment [184], ureterorenoscopy [185], hysteroscopy [186], dermatology [187], diabetes

181 Buchanan BG. In: Shortliffe EH, editor. Rule Based Expert Systems: The Mycin Experiments of the Stanford Heuristic Programming Project (The Addison-Wesley series in artificial intelligence). Reading, MA: Addison-Wesley; Jun 1, 1984.
182 Skinner CS, Strecher VJ, Hospers H. Physicians' recommendations for mammography: do tailored messages make a difference? Am J Public Health 1994 Jan;84(1):43-49.
183 Brown JS, Burton RR. Diagnostic models for procedural bugs in basic mathematical skills. Cognitive Science 1978;2(2):155-192.
184 Binnie C, Spreng M. The epilepsy tutorial. Stud Health Technol Inform 2000;78:213-284.
185 Michel MS, Knoll T, Köhrmann KU, Alken P. The URO Mentor: development and evaluation of a new computer-based interactive training system for virtual life-like simulation of diagnostic and therapeutic endourological procedures. BJU Int 2002 Feb;89(3):174-177.

management [188], cervical cytology [189], psychotherapy [190], and many other health-related areas.

The combination of expert systems and multimedia applications is a promising way in e-learning [191] being able to "learn" about the individual student and tailoring the transported content to meet the needs and the learning styles appropriate to the individual student.

6.2 E-learning

Further developments generalized expert systems for the public and were frequently referred to as “e-learning” tools. Multi media applications and web-based e-learning facilities have already been successfully tested for students and were shown to significantly increase abilities in medical students in family medicine [192] or oral surgery [193]. Virtual web-based Patient Case Simulation tools to be introduced into medical curricula have successfully been piloted [194].

6.3 Patient’s training

First experiences with web-based information tools are well indicating that online medical information may be a useful add-on to traditional physician-patient interaction [195 196]. Its advantage is that it is readily available for the patient, and can

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186 Müller-Wittig WK, Bisler A, Bockholt U, Los Arcos JL, Oppelt P, Stähler J, et al. LAHYSTOTRAIN development and evaluation of a complex training system for hysteroscopy. Stud Health Technol Inform 2001;81:336-340.

187 Zaharakis ID, Kameas AD, Nikiforidis GC. A multi-agent architecture for teaching dermatology. Med Inform (Lond) ;23(4):289-307.

188 Ambrosiadou BV, Ketikidis PH. DIABETOR computer aided tutoring in diabetes management. Stud Health Technol Inform 1997;43 Pt B:694-698.

189 Tambe M, Johnson WL, Jones RM, Koss F, Laird JE, Rosenbloom PS, et al. Intelligent agents for interactive simulation environments. AI Magazine 1995;16(1):15-39.

190 Binik YM, Servan-schreiber D, Freiwald S, Hall KS. Intelligent computer-based assessment and psychotherapy. An expert system for sexual dysfunction. J Nerv Ment Dis 1988 Jul;176(7):387-400.

191 Diefenbach M, Butz BP. Multimedia Interactive Education System for Prostate Cancer Patients: Development and Preliminary Evaluation. J Med Internet Res 2004;6(1):e3.

192 Schilling K, EdD; Wiecha J, MD, MPH; Polineni D, MD, MPH; Khalil S, MS An Interactive Web-based Curriculum on Evidence based Medicine: Design and Effectiveness. Fam Med 2006;38(2):126-32.

193 Correa L, de Campos AC, Souza S, Novelli MD. Teaching oral surgery to undergraduate students: a pilot study using a Web-based practical course. European Journal of Dental Education. 7(3):111-115, August 2003.

194 Zary N, Johnson G, Boberg J, Fors Uno GH. Development, implementation and pilot evaluation of a Web-based Virtual Patient Case Simulation environment – Web-SP. BMC Medical Education 2006, 6:10.

195 Biermann JS, Golladay GJ, Peterson RN. Using the internet to enhance physician-patient communication. J Am Acad Orthop Surg. 2006 Mar;14(3):136-44.

provide the patient with basic knowledge on a given topic. A feed-back tool may then be efficiently refining information and answering specific questions. Potential legal and confidentiality pitfalls in electronic communication may happen. Some patient concerns may be easily satisfied and communication enhanced through the use of e-mail. Confidentiality should be guarded.

The introduction of a FAQ module in chat - room of a pancreatic cancer web site increased the number of postings showing that the need of information of patients can be handled also in an electronic media [197].

Agre et al [198] found that a CD ROM with cancer-related patient education was more adequate for teaching patients than booklets or videotapes: CD-ROM would allow for greater depth in content and would have the ability to satisfy a broad range of educational needs.

Guendelman et al [199] developed a computer-based self-management program "Health Buddy" assisting children to assess and monitor their asthma symptoms, assessing the quality of life as well as to transmitting information to health care providers. The program proved to enhance self-management skills of children in a randomized controlled trial compared to an asthma diary.

Interactive multimedia has been used to deliver information: about self-medication [200] in elderly patients, for patient colonoscopy education [201], for genital herpes education [202], for personal care of diabetes [203], for skin cancer prevention [204], for

196 Wu RC, Delgado D, Costigan J, MacIver J, Ross H. Pilot Study of an Internet Patient-Physician Communication Tool for Heart Failure Disease Management. J Med Internet Res 2005;7(1):e8.
197 Coleman J, Olsen SJ, Sauter PK, Baker D, Hodgin MB, Stanfield C, Emerling A, Hruban RH, Nolan MT. The effect of a Frequently Asked Questions module on a pancreatic cancer Web site patient/family chat room. Cancer Nurs. 2005 Nov-Dec;28(6):460-8.
198 Agre P, Dougherty J, Pirone J. Creating a CD-ROM program for cancer-related patient education. Oncol Nurs Forum 2002 Apr;29(3):573-580.
199 Guendelman S, Meade K, Benson M, Chen YQ, Samuels S. Improving asthma outcomes and self-management behaviors of inner-city children: a randomized trial of the Health Buddy interactive device and an asthma diary. Arch Pediatr Adolesc Med 2002 Feb;156(2):114-120.
200 Neafsey PJ, Strickler Z, Shellman J, Padula AT. Delivering health information about self-medication to older adults: use of touchscreen-equipped notebook computers. J Gerontol Nurs 2001 Nov;27(11):19-27.
201 Shaw MJ, Beebe TJ, Tomshine PA, Adlis SA, Cass OW. A randomized, controlled trial of interactive, multimedia software for patient colonoscopy education. J Clin Gastroenterol 2001 Feb;32(2):142-147.
202 Wardle J, Steptoe A, Smith H, Groll-knapp E, Koller M, Brodziak A. Breast self-examination: attitudes and practices among young women in Europe. Eur J Cancer Prev 1995 Feb;4(1):61-68.
203 Berridge E, Roudsari A, Taylor S, Carey S. Computer-aided learning for the education of patients and family practice professionals in the personal care of diabetes. Comput Methods Programs Biomed 2000 Jul;62(3):191-204.

nutrition screening and counselling [205], for hypertensive patients [206], and for numerous other diseases or treatments.

Gustafson et al [207 208] have developed a computer-based health information and support system for numerous diseases that is linked to improvements of quality of life, and increased participation in health care [209].

A pilot-social support Web site by low-income pregnant African American women, revealed that even in this social group, participants were able to learn to use the Web site easily and were able to access the discussion board. The discussion board was found to be the most effective way to deliver informational social support on a comprehensive social support Web site [210].

However, there is evidence that in low reading skills, neither printed material, video-tapes of computer presentations could rise the level of recall of the information provided [211].

Health–related sites have been successfully introduced for non-smoking programs, which give accompany patients while giving up smoking. Different programs are already in evaluation [212]:

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204 Hornung RL, Lennon PA, Garrett JM, Devellis RF, Weinberg PD, Strecher VJ. Interactive computer technology for skin cancer prevention targeting children. Am J Prev Med 2000 Jan;18(1):69-76.
205 Block G, Miller M, Harnack L, Kayman S, Mandel S, Cristofar S. An interactive CD-ROM for nutrition screening and counseling. Am J Public Health 2000 May;90(5):781-785.
206 Consoli SM, Ben Said M, Jean J, Menard J, Plouin PF, Chatellier G. Benefits of a computer-assisted education program for hypertensive patients compared with standard education tools. Patient Educ Couns 1995 Sep;26(1-3):343-347.
207 Gustafson DH, Bosworth K, Hawkins RP, Boberg EW, Bricker E. CHESS: a computer-based system for providing information, referrals, decision support and social support to people facing medical and other health-related crises. Proc Annu Symp Comput Appl Med Care 1992:161-165.
208 Gustafson DH, Hawkins R, Boberg E, Pingree S, Serlin RE, Graziano F, et al. Impact of a patient-centered, computer-based health information/support system. Am J Prev Med 1999 Jan;16(1):1-9.
209 McTavish FM, Gustafson DH, Owens BH, Wise M, Taylor JO, Apantaku FM, et al. CHESS: An interactive computer system for women with breast cancer piloted with an under-served population. Proc Annu Symp Comput Appl Med Care 1994:599-603.
210 Herman J, Mock K, Blackwell D, Hulsey T. Use of a pregnancy support web site by low-income African American women. J Obstet Gynecol Neonatal Nurs. 2005 Nov-Dec;34(6):713-20.
211 Campbell FP, Goldmann BD, Boccia ML, Skinner M. The effect of format modifications and reading comprehension on recall of informed consent information by low – income parents: a comparison of print, video and computer-based presentations. Patient Education and Counseling 53 (2) 2004: 205-216.
212 Etter JF. Comparing the Efficacy of Two Internet-Based, Computer-Tailored Smoking Cessation Programs: A Randomized Trial. J Med Internet Res 2005;7(1):e2.

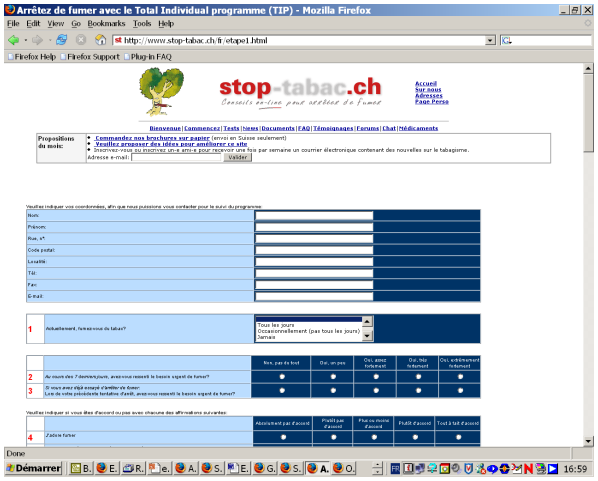

Figure: example of a site for smokers willing to stop

In a remarkable pilot project, Knobel et al [213] developed a CD ROM based computer-based training (CBT) fro certain interventions in oral and maxillofacial surgery. The patients had tutorial how to use the CD ROM and could navigate through the content. 97 % of the patients found the use of multimedia tools as very useful and 93% had the impression that the tool was helpful in answering their questions. The acceptance was excellent although many patients had little computer-experience. Similar high acceptance rates are reported by Kessler et al [214] stating that 98 of the patients having used the interactive computer program would like to informed again by an interactive computer program in case of another surgical intervention.

E-mail does not seem to be a frequently used means of communication between the general practitioners and patients [215 216].

6.4 Computer-Aided Tailored Patient Education

It is referred to “Targeted” health communications when health information is directed towards a particular subgroup of the population. “Tailored” information is designed to

213 Knobel A, Haßfeld S. Entwicklung eines multimedialen Patienteninformationssystems zur präoperativen Aufklärung auf CD-ROM und initiale Studien zur Patientenakzeptanz. Mund Kiefer GesichtsChir 2005, 9:109-115.
214 Kessler TM, Nachbur BH, Kessler W. Patients’ perception of preoperative inforamtion by interactive computer program – exemplified by cholezystectomy. Patient Education and Counseling 59;2: 135-140.
215 Goodyear-Smith F, Wearn A, Everts H, Huggard P, Halliwell J. Pandora's electronic box: GPs reflect upon email communication with their patients. Inform Prim Care. 2005;13(3):195-202.
216 Brooks, RG, Menachemi N. Physicians’ Use of Email With Patients: Factors Influencing Electronic Communication and Adherence to Best Practices. J Med Internet Res 2006;8(1):e2.

address individual characteristics of a person. Both targeting and tailoring depend on the assessment of group or individual characteristics that have been derived from prior data collections [217].

The aim of targeting and tailoring health communications is to increase the personal relevance of the message to the individual. Messages that are relevant to the person are better understood and better remembered [218] and more likely lead to behaviour change [191].

6.5 Computer-aided information for purposes of the informed consent

Experiences with tools assisting the physician in the informed consent process are rare. Müller [219] reports of a computer program assisting the physician in the process of disclosing the medical information to the patient. The program offers a selection menu of available interventions and submenus with alternative treatments and known risks. After input of relevant patient data, most issues are automatically included in a file containing all relevant information. Some points can be included or excluded. Individual information can be typed in. The file can be printed and used to back the communication.

However, the program only reports data that can be found in the database. Consequently, missing important information about risks to be disclosed cannot be ruled out completely. In absence of a feasible legal concept of information to be disclosed, this problem cannot be properly handled. However, the computer-aided communication has the advantage that usually content that is available will not be forgotten to be disclosed in contrast to the oral communication where the physician discloses out of his memory [220]. A careful formulation of the text to be disclosed and permanent evaluation of the readability ensures that problems of understanding can be minimized and the unwanted use of technical terms can be avoided. The program output can be much more individualized and used to help the physician than printed information sheets. The concept of Müller is rounded off by the use of little drawings

217 Kreuter MW, Strecher VJ, Glassman B. One size does not fit all: the case for tailoring print materials. Ann Behav Med 1999;21(4):276-283.
218 Butow PN, Dunn SM, Tattersall MH, Jones QJ. Patient participation in the cancer consultation: evaluation of a question prompt sheet. Ann Oncol 1994 Mar;5(3):199-204.
219 Müller, Computergestützte Patientenaufklärung, in: Ratajzak – Stegers, 45.
220 Müller 51.

and hand-written annotations on the output before it is handed over to the patient for reading. This should allow for proper documentation of the communication. Further, this process allows proving that no subsequent amendments have been added to the patients signature [221].

6.6 Problems in relation to the elderly

6.6.1 Multitude of health-related sites

An estimated number of 10 million *elderly* adults use Internet communities to gain information on any health issue [222]. The quality of some health- related web-sites is rather questionable and often biased by commercial or ideological interests of the provider of the web-site [223]. Accessing unbiased information might be a problem as the average internet-user looks for information via different search-engines.

A frequent practice of owners of web-sites is to repeat specific keywords users might want to search in the headers of their internet documents. This also yields a better ranking in the result list the search engine may produce.

6.6.2 Commercial interest of search–engine providers

The first hit in a search engine is often the one chosen by the user to retrieve the requested information. It is a frequent business practice of providers of internet–search engines to enable better ranking of specific internet-sites on specific search terms. Therefore, the result yielded by a search–request often does not report the site matching best with the search-terms but also reflects how much commercial web-sites are willing to pay for a better ranking in search-engines.

6.6.3 Discussion forums

A recent review demonstrates the potential risks deriving from biased information in discussion forums providing information through threaded discussion boards. These were identified to provide frequently for inaccurate information [222].

221 Müller 52.
222 Moore GA. On-line communities: helping "senior surfers" find health information on the Web. J Gerontol Nurs. 2005 Nov;31(11):42-8.
223 Kennedy Fahey D, Weinberg J. LASIK Complications and the Internet: Is the Public being Mislead? J Med Internet Res 2003;5(1):e2.

6.6.4 Low vision and deafness in the elderly

Apart from the inherent problems of retrieving accurate information in the internet, which are described above, the elderly may particular be affected from the ability to use the internet. We are aware of no studies that focus on the specific problems of internet use of elderly affected by low vision and/or deafness. Further, age-related decreased memory might lower the content that might be retained from an educational internet site. In particularly, elderly patients who are inexperienced internet-users might not be aware of the pitfalls of the internet.

6.7 Conclusion

Interactive web-based tools can be a useful supplement in the education of the patient. They, therefore, can be beneficial to prepare the patient – physician communication for the informed consent, but also be at the patient's disposition for the management of a chronically disease.

The technique, however, seems to be limited to persons willing to use the tool and whose intellectual abilities and in particular computer-literacy allow for a adequate use. Web pages offering self-help tools for anxiety disorders were found to be highly beneficial but only for patients who stayed in the program [[224]]. Drop-out rates of 55% in 1 ½ years for a web-based communication tool for heart failure patients have been reported [196].

However, the seriousness of the information and the absence of a commercial interest of the web-site provider should be given.

7 The state-of-the-art disclosure of medical information for cataract surgery

7.1 The Disease

224 Farvolden P, Denisoff E, Selby P Bagby RM, Rudy L. Usage and Longitudinal Effectiveness of a Web-Based Self-Help Cognitive Behavioral Therapy Program for Panic Disorder. J Med Internet Res 2005;7(1):e7.

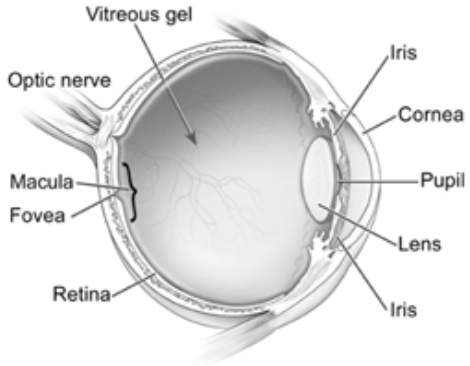

Figure 1: © National Eye Institute [225]

The crystalline lens is a contributes to focussing light-rays onto the retina, working like a lens in a camera. The retina is the light-sensitive tissue at the back of the eye, where light is converted into electrical signals that are sent to the brain by nerve-fibres. In the healthy eye, light passes through the transparent lens to the retina.

Cataract is the clouding of the lens which affects vision.

Most cataracts are related to aging and therefore are very common in the elderly. More than half of all Americans at the age of 80 either have a cataract or have had cataract surgery already [226]. Although most cataracts are related to aging, there are also other types of cataract, secondary to other eye diseases, after trauma, or already present at birth.

Since cataract tends to progress slowly, patients are initially often not aware of the gradual loss of vision. Symptoms are increased blurring of vision, haziness of vision, loss of contrast, seeing double images, sometimes glare, and a loss in colour contrast. The cataract may also induce myopia due to the higher refractive index of the central part of the lens, allowing some patients to be able to read without glasses. Due to cataract, it may be more difficult to read and perform the other usual tasks of daily life.

Apart from age, the risk factors associated with cataract are diabetes mellitus, smoking, alcohol abuse, prolonged lifelong exposure to sunlight, certain eye diseases and trauma.

225 http://www.nei.nih.gov/health/cataract/cataract_facts.asp.
226 http://www.nei.nih.gov/health/cataract/cataract_facts.asp.

7.2 Treatment

Apart form early forms of cataract which may be treated with symptomatic measures such as corrective glasses, bright lighting for reading, sunglasses for glare, surgery is the only effective treatment. In cataract surgery, the cloudy parts of the lens are removed and replaced with an artificial intraocular lens.

7.2.1 Indication

Surgery is indicated when vision loss impairs everyday activities, such as driving, reading, or watching TV. In most cases, delaying cataract surgery will not cause long-term damage to your eye or necessarily make the surgery more difficult.

Sometimes cataract surgery is indicated without impaired vision, e.g. if it prevents examination or treatment of another eye problem, such as age-related macular degeneration (AMD) or diabetic retinopathy or retinal detachment. Usually, cataract surgery is not performed on both eyes at the same time, but instead with a delay of 1-8 weeks between the eyes.

7.2.2 Cataract surgery

7.2.2.1Phacoemulsification and IOL implantation

Phacoemulsification, also referred to as "small incision cataract surgery" is the standard procedure today. This type of cataract surgery involves a small incision, made on the side of the cornea. A small probe is inserted into the eye that vibrates with ultrasound frequency to break and liquefy the lens material. The lens material is then removed by suction.

After the removal of the lens, an artificial intraocular lens is implanted into the capsular bag which is left behind after removing the cloudy lens substance. The IOL are usually made of acrylate or silicone and stay inside the eye permanently.

7.2.3 Is cataract surgery effective?

Cataract removal is one of the most common operations performed in the western world today. It also is one of the safest and most effective types of surgery accounting for about improvement of vision in more than 90 percent of patients. An estimated 1.5 million cataract surgeries are performed per year worldwide.

7.2.4 Usual course of cataract surgery

Before surgery, the eye will be washed and cleaned. Dilating eye-drops will be administered. Usually no general anaesthesia is necessary and local anaesthetic drops or an injection next to the eyeball is sufficient to enable painless surgery. The operation usually lasts about 15 to 20 minutes. If awake, patients will be asked to alert the surgeon if they are about to move, sneeze or cough. After the operation,usually a patch is placed over the eye. Most people who have cataract surgery can go home on the same day.

Itching and mild discomfort are usual symptoms after cataract surgery. The eye may be sensitive to light and touch. Symptoms should be relieved after one to two days.

Rubbing or pressing on the eye should be avoided during the first weeks after surgery. All usual daily occupations can be performed. Anti-inflammatory eye drops are prescribed for the first few weeks after surgery. In most cases, healing will be complete within about one month.

7.2.5 The risks of cataract surgery

7.2.5.1General risks of surgery

As with any surgery, cataract surgery poses carries risks. Many adverse events in cataract surgery are linked with the personal risk structure of the patient.

For example, postoperative infection might be more common in patients with chronic inflammation of the eye lids. In such cases, lid hygiene should be performed before and after surgery to reduce the risk. Infection of the inside of the eyeball, named endophthalmitis, is a rare but very serious complication that may result in very poor visual outcome up to complete loss of vision.

7.2.5.2Risks specific to cataract surgery

Cataract surgery carries some inherent risks. The complications can be subdivided into those that happen during or immediately after surgery and are mainly due to the surgical manipulation and complications during those, and those that are related to surgery but may appear with some delay and may appear after uneventful surgery.

7.2.5.3 Surgical complications

Examples of complications that occur during surgery and are often also related to concomitant eye diseases apart from cataract, are posterior capsule rupture with loss of lens fragments into the vitreous cavity, and prolapse of vitreous gel into the anterior segment, loss of support of the lens capsule bag, decompensation of the cornea or expulsive choroidal haemorrhage.

Examples of complications that can arise after surgery and are not necessarily related to intraoperative complications are an increased rate of retinal detachment, cystoid macular oedema, increased intraocular pressure shortly after surgery, endophtalmitis, after-cataract or refractive surprises due to problems ind pre-operative biometry or power calculation.

The complications can also be classified according to their frequency. As a rule of thumb we can inform the patient that in 95% of the cases there are no complications after surgery. In 5%, some problems may arise, even though most of these can be dealt with quite easily, such as additional medications or more rarely another surgical intervention. In about 1 out 500 patients, serious adverse events such as infection or bleeding within the eye may cause significantly worse vision than before surgery and can in the worst case result in a blind eye. However, this does happen very rarely.

8 A web based tool for informing patients on cataract surgery

In the previous chapters, legal requirements, state of the art information on cataract surgery as well as problems of the current practice have been outlined:

8.1 Probable benefits of a web-based tool

A few of these problems might be overcome with a web-based tool for patients:

- The patient can receive information to a variable extent, and this can be steered by the patient individually
- The patient could gain access to the web-site as soon as the diagnosis cataract is made – the time (usually several weeks to months) until surgery could be used to retrieve information at the pace and time requirements of the patient independent from the tight timely constraints of the physician

- The tool could also take some work-load from the physician
- The tool could be divided into lectures that can be accessed by the patient just like an e-learning unit. The interactions with the tool could be recorded for purposes of informing the physician where patients have major problems in understanding and keeping in memory of the content provided
- This information could be used to further improve the tool
- In future versions, individual information of the patient could be used to further individualize the content offered to the patient, i.e. show additional relevant information and risks if the patient has a another concomitant eye disease such as diabetes mellitus
- Contrary to printed information leaflets, magnifying tools and other tools could be added to the planned web-site to facilitate the information retrieval by the patient

In summary, the tool could replace printed material that is kept to the disposal of patients with an expected benefit for the patients.

8.2 Restrictions of a web-based tool

Several restrictions for such a tool apply:

8.2.1 Personal communication

Off course the tool cannot replace the personal communication as required from an ethical point of view and by law. With a view to jurisdiction rendered for printed information material, it can be used as preparatory means for the personal communication with the patient.

8.2.2 No diagnosis over the Internet

From the personal service that has to be provided by the physician, it follows that no treatment, diagnosis or consultation or other duty of a medical professional must be carried out via the tool, internet or telephone without personal contact.

8.2.3 Privacy Protection

Personal information of the patient, questions or data underlie privacy protection laws in many countries. Any web-based tool that provides for interaction with the patient has to comply with the laws of privacy protection. In any case to ensure the private sphere, the patient could be given a User Name and Password to access the site. The web-site should be encrypted to ensure that any flow of data is protected.

8.2.4 Need for documentation

Documentation of any medical act is required in many legislations. Its purpose is the securing of proof of any malpractice of omission in the treatment, but also as a positive proof that the documented act has been performed. Documentation of the disclosure of medical content to the patient is particularly important as the actual proof of the communication does mot materialize in any other form. In litigation, it is frequently argued that the patient did only sign a paper under pressure which he or she has not read before. The mere signature is often not sufficient for the proof that the patient has read or even understood the content of the information leaflet.

Any information given to the patient as well as any other performance has to be documented by the physician and has to be made available to the patient's inspection. This task possibly is more easily achieved than using printed material. As access to the web-page could be traced there could be proof that the patient has at least accessed the content.

In future versions of the tool, the learning curve of the patient could be evaluated (with the consent of the patient) by various means, namely interactive questionnaires, e-mail contact with the physician, etc.

8.2.5 Consent of the patient to the electronic processing of data

Much legislation provides that the storage of personal data is subject to data-protection.

8.2.6 Approval by the ethics committee

The pilot study of a web-based tool for providing pre-operative information on a planned intervention might be subject to approval by the competent ethics committee and must comply with the provisions of the Helsinki declaration. All recruitment of patients has to follow the standardized procedures. Taking part in the study must remain at the disposition of the patient.

8.3 Useful restrictions of the study population

Beside the legal framework, a useful pilot study for a web-based information tool has to follow several restrictions to facilitate scientific evaluation of the effect on the patient's level information.

8.3.1 Homogeneity of the medical procedure

As mentioned, medical content is rapidly growing. To test the impacts of an e-learning tool on patients, one has to choose to build a web-based tool for a standardised intervention with a low complication rate and only a limited number of types of complications, in order to keep the possible content to be provided in an acceptable amount for the patient. Also, alternative treatments should be rather limited or unavailable to limit the amount of information that has to be conveyed to the patient.

Cataract surgery, therefore seems to be an ideal procedure for this purpose. It is the only definite cure to cataract and offers a low complication rate. Complications are well described and may be conveyed with audiovisual support via the computer.

Disadvantage of this choice is that cataract affects visual acuity, and that being compromised may make it difficult for patients to follow the text and images on the screen For this reason, patients with severely compromised vision should not be candidates for this tool, and the text and images will be supported by a spoken text (See below.)

8.3.2 Homogeneity of the study population

In order to limit the variability caused by a heterogeneous study population, only patients with age related cataract should be included in the study. The inclusion criteria could include:

- Age 50>age>90 at time of diagnosis
- Age related cataract, subgroups of patients having cataract surgery on the first eye and for the fellow eye
- Absence of other ocular diseases affecting the vision (AMD, glaucoma, etc)

Exclusion criteria could be:

- low visual acuity (<0.1) or low near visual acuity affecting the reading from monitors

- deafness (facultative) or
- insufficient intellectual ability to apprehend
- no easily accessible internet connection
- persons under custody

8.4 Interview or questionnaire?

The planned study on the memorisation of medical content disclosed to patients requires a standardized method of evaluation. Usually, procedures applied are the standardized interview and the standardized questionnaire with open and pre-formulated answers to tick.

Standardised interviews have the advantage that difficulties in understanding the questions could be eliminated during the interview. Prerequisite is the interview with only one interviewer to exclude inter-personal bias between the interviewers. The use of standardized questionnaires does not allow testing the readability of the questionnaire. It also has to be ensured that no selection of patients occurs in distributing the questionnaires.

To determine whether or not a questionnaire offers the same reliability in the quality of answers, a pre-study is planned.

Patients receiving the standard medical disclosure in our clinic are selected under statistical guidelines to represent an adequate sample of the population in cataract surgery as to age, secondary education, sex, and profession. Patients will be interviewed 4 hrs after disclosure by one interviewer using the questionnaire as template. An equivalent sample of patients, pre-selected under the same statistical guidelines as above will receive the questionnaire to be completed.

The questionnaire could be adapted according to the results of the pre-study process until no significant difference in the mean scores between interview and questionnaire using the adequate inferential statistical method can be found.

9 Annex: study protocol

Prospective clinical study for the evaluation of a web-based tutorial to prepare cataract patients for surgery

Version 01

Datum 20.7 2006

Protocol

Oliver Find, MD

Study coordinator:
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Synopsis

Title	***Prospective clinical study for the evaluation of a web-based tutorial to prepare cataract patients for surgery***
Investigators	Oliver Findl, MD
Background	The process of disclosing medical information to patients frequently gives rise to complaints of patients and is a major source of litigation. In practice, patients are provided with printed information material right before the intervention takes place. The informed consent is usually obtained by signature on the printed form. Personal communication between patient and physician often is insufficient as to time and personalized content The use of printed information brochures has been found insufficient for purposes of informing the patient as a single means of information both by jurisdiction and by several outcome studies testing for the patients' memorisation of the content disclosed The process of disclosing medical information to the patient must be optimized. For patients, who are acquainted with the use of internet and the new electronic media, the question raises whether the preparation for the personal communication with their physician cannot be anticipated. The benefits are obvious: Time constraints, in particular in public hospitals could be avoided. The patient could acquire the necessary basic knowledge to enable him to conduct a personal medical communication with the physician at his own pace. We expect a better memorisation of medical content and better satisfaction of these patients.
Study objectives	To test the benefits of a web-based tutorial for patients undergoing cataract surgery for purposes of obtaining an informed consent

Study Design	prospective, randomised study, double-blinded for patients and physician performing the personal communication for obtaining the informed consent.
Study population	120 patients suffering from age related cataract
Investigated procedure reference	Web-based tutorial, standard printed information sheets and subsequent personal communication Standard printed information sheets and Standard personal communication
Main outcome variables	Memory score of the content provided, satisfaction with the tool, conflict in decision making
Additional outcome variables	Anxiety before surgery
Risk-benefit assessment	This study does not involve any additional treatment, surgical intervention or medication than required by standard cataract surgery. There are no additional risks. The standard personal communication as required by law ensures the full informed consent of the patients. The use of the tool may at worst have no effect on the patients' knowledge about the disease, surgery and the risks involved. Patients may however benefit from a better memorisation of the medical content offered in the tool, content which should be available for a reasonable patient's informed consent to treatment.

10 Annex: RCOPHTH consent form

Request / consent for left / right cataract extraction with lens implant under

☐ local anaesthetic
☐ general anaesthetic

Insert addressograph here

Statement of health professional (only complete if you have appropriate knowledge of this procedure as specified in consent policy). I have explained the procedure to the patient.
In particular I have explained:

The intended benefits of the operation
The main aim of the cataract operation is to improve the quality of your vision; it may also be of benefit to improve the doctors' view of the back of the eye. We will try to reduce your dependence on spectacles as much as possible, but you may require distance glasses for best vision and you will probably need reading glasses; in any case your glasses prescription will change after the operation.

Serious or frequently occurring risks during the operation
It is possible for a cataract operation to leave you worse off than you are now. One person in every 1000 will go blind in that eye as a direct result of the operation. One in 10,000 will lose the eye. There is virtually no risk to the other eye. Details on the most common specific complications are given below.

Ecchymosis - Bruising of eye or eyelids (quite common).

Posterior capsule rupture and / or vitreous loss - a split in the thin back wall of the cataract which can allow communication between front and back compartments of the eye.

Post operative glaucoma - raised pressure in the eye for the first day or so (common). This may require temporary treatment.

Posterior capsular opacification - clouding of the membrane behind the implant causing blurred vision.

Cystoid macular oedema - inflammatory fluid in the centre of the retina. This is commonly mild and needs no treatment. It can be severe and require prolonged treatment.

Refractive surprise - unexpectedly large (or different from expected) need for glasses.

Allergy - to drops given after the operation, causing an itchy swollen eye until the drops are stopped or changed.

Dropped nucleus - part or all of the cataract falls through a posterior capsule rupture into the back part of the eye, needing another operation to remove it.

Suprachoroidal haemorrhage - bleeding inside the eye which may require the operation to be completed on another day.

Corneal decompensation - clouding of the normally clear front window of the eye.

Detached retina - peeling off of the seeing layer of cells within the eye.

Endophthalmitis - severe (usually painful) infection inside the eye.

Dislocation of the implant - movement out of position of the lens implant.

Complications are rare and in most cases can be treated effectively. In a small proportion of cases, a further operation may be required. If you decide against a cataract operation, your vision will probably slowly worsen. If you need to discuss your options further, or at a later date, please contact (preferably in writing) the person whose details are given below.

Signature of Health professional..... Job Title.....

Printed Name..... Date .....

Statement of interpreter (where appropriate). I have interpreted the information above to the best of my ability and in a way in which the patient can understand.

Interpreter's signature..... Print name..... Date.....