

# Errors and pitfalls: Briefing and accusation of medical malpractice – the second victim

## Abstract

In June 2012, the German Medical Association (Bundesärztekammer) published the statistics of medical malpractice for 2011 (published at <http://www.bundesaerztekammer.de>). Still ENT-specific accusations of medical malpractice are by far the fewest in the field of hospitals and actually even in the outpatient context. Clearly most of the unforeseen incidents still occur in the disciplines of trauma surgery and orthopedics. In total, however, an increasing number of errors in treatment can be noticed on the multidisciplinary level: in 25.5% of the registered cases, an error in treatment was found to be the origin of damage to health justifying a claim for compensation of the patient. In the year before, it was only 24.7%. The reasons may be manifold, but the medical system itself certainly plays a major role in this context: the recent developments related to health policy lead to a continuous economisation of medical care. Rationing and limited remuneration more and more result in the fact that therapeutic decisions are not exclusively made for the benefit of the patient but that they are oriented at economic or bureaucratic aspects. Thus, in the long term, practising medicine undergoes a change. According to the §§ 1, 3 of the professional code of conduct for doctors (Musterberufsordnung für Ärzte; MBO-Ä) medical practice as liberal profession is principally incompatible with the pursuit of profit, however, even doctors have to earn money which more and more makes him play the role of a businessman. Lack of personnel and staff savings lead to excessive workloads of physicians, caregivers, and nurses, which also favour errors. The quality and even the confidential relationship between doctor and patient, which is important for the treatment success, are necessarily affected by the cost pressure. The victims in this context are not only the patients but also the physicians find themselves in the continuous conflict between ethical requirements of their profession and the actual requirements of the realities in the healthcare field. But also the technical and scientific progress bear new risks beside the therapeutic successes, further especially bigger hospitals require high efforts regarding organisation favouring errors in cases of deficiencies. Even the increasing juridification of the medicine that is expected to achieve a provisional highlight with the planned law of patients' rights leads to an important focus on the quality of medical care (see also [1]). The explicit legal regulation of patients' rights, which have never been out of question up to now, confirms the impression of patients who have to be protected from their doctors. This development favours a natural mistrust in the quality of the treatment and the desire of legal verification in cases of treatment failures. A totally perfect and error-free treatment, however, will never occur. Already this fact leads to the obligation to do everything possible to reduce the risk to an absolute minimum. The risks that might arise from a relation of treatment are manifold. Not only may the patient undergo risks that arise in particular from lacking or insufficient briefing, complications, or medical malpractice.

Also the doctor has to fear legal consequences if he does not stick clearly to the increasing requirements that jurisdiction and legislation impose – not least by the planned law of patients' rights. In the following, the basic principles and particularities will be described that apply for the patients' briefing. Further the different types of medical malpractice

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will be explained in relation to the resulting procedural consequences. Finally some current problematic fields will be described with regard to other possible liabilities or responsibilities of physicians in hospitals or doctor's offices.

**Keywords:** error in treatment, error in briefing, documentation, organization default, liability for medical malpractice

## 1 Basic principles and particularities of patients' briefing

The medical briefing of patients is an important part of the medical field of responsibilities and is required so that a patient may have an appropriate conception of the planned treatment for which he gives his consent. This briefing must contain all information that might possibly be significant for the patient's decision in favour of or against a therapy. In this context, the information on the diagnosis, the course and the risks must be mentioned. Information deficiencies lead to illegality of the whole treatment, regardless the success or failure. At the same time an illegal intervention is an actual fact of personal injury according to § 223 of the penal code (Strafgesetzbuch, StGB). The informative briefing must be clearly differentiated: The focus of the briefing is oral information and so written documentation is not necessary. The use of written information sheets and the written consent about the informative briefing in the patients' records only serve as documentation of the information and are relevant in cases of liability proceedings because the physician principally has to prove the proper briefing. The actual information is not necessarily the same as the documentation of the briefing, a fact that patients sometimes present in cases of compensation proceedings. Even electronic briefing documentation as it is meanwhile practice in many departments fulfils the requirements of documentation and also with regard to the probative value in case of damage it is principally not weaker than paper documents. However, the "Recommendations of the German Medical Association regarding medical confidentiality, data protection, and data processing in medical practice" [2] must be considered. In this context, security measures are described that must be observed imperatively such as the encrypting of files, making backups, and the protection against manipulations caused by the use of electronic signatures.

### 1.1 Therapeutic or safety advisory

In contrast to the information about the risks and prognostic success, the safety advisory is meant to inform and advise patients about their own behaviour for the therapeutic success by giving warnings and precaution in order not to compromise the therapeutic success. So it is no briefing in the actual sense but an accessory contractual obligation of the physician regarding advice and information [3]. In contrast to the information provided for self-determination, it does not influence the

effectiveness of consent to treatment. Among other aspects, the safety advisory includes working towards the acceptance of the consent to reasonable treatment, information about certain rules of conduct in cases of side effects or interactions during treatment and finally especially the follow-up to make sure that the patient does not compromise the treatment success and his person. Violation of this obligation by lacking or insufficient safety advisory is thus considered as medical malpractice with the resulting consequence of the burden of proof of the patient. The obligation for safety advisory *ex post* was accepted in one case of a patient who could not be informed about the risk of HIV infection by blood transfusion. In this case, the patient had to be informed after the intervention and HIV screening test was recommended [4].

### 1.2 Who has to inform?

The obligation of briefing includes the responsibility for information of the patient. Principally the physician who actually performs the intervention has to inform about the treatment. Delegation to non-medical personnel is not accepted. In case of delegation of the information to subordinate physicians, it must be observed that the personnel is sufficiently qualified for the informative briefing they have to perform and that the delegating physician assures the proper information by another physician, i.e. he has to speak with the patient or verify the patient's record with regard to properly performed information. If mistakes occur during information, the informing physician is liable because of information omission; the delegating physician is liable for organisational fault when he does not supervise the information or delegates to an unqualified colleague. In every department of a hospital and before every intervention, the patient has to be informed separately. The physician's responsibility is limited principally to his own speciality. If several physicians of different disciplines participate in an intervention, principally every physician has to inform about his part of the treatment that is performed with regard to his discipline. In this context the principle of legitimate expectations applies: an ENT specialist can rely on the fact that the patient is informed sufficiently by the anaesthesiologist about the risks related to anaesthesia before the intervention. This principle is also contained in the "Agreement on the cooperation in otolaryngology" between anaesthesiologists and ENT specialists [5]. Physicians of a cancer center must not rely on proper information if the referring physician contacted several times a specialised hospital for advice and

the local physicians have been involved in the indication for certain treatment options and have thus been responsible [6]. If a physician undertakes information outside his particular speciality he is liable in cases of information failure even if he did not perform the actual treatment. For the first time, the obligation to information by a physician shall be clearly laid down by legislation by means of the law of patients' rights. In fact, this step is not necessary because the objectives are actually assured also with consideration of the principles developed by legislation and jurisprudence and the amending general legal regulations. As for the legal matters of the treatment contract and the physician-patient relationship, there exists already a long-term established, very well differentiated jurisdiction of the German Federal Court of Justice (BGH, Bundesgerichtshof) meeting the current requirements of the medical practice. It brings into balance the mutual interests of physician and patient in a just and widely recognized way. It is positive that the primarily planned paragraph that a physician participating in the intervention has to perform the information of the patient is left out. Instead, according to § 630e Abs. 2 BGB-E the information – as usual until now – has to be performed by the treating physician or another person who disposes of the capacity that is necessary to perform the measure. However, there might be a problem with the newly included obligation to hand out copies of the documents to the patient he had signed in the context of information or consent. Modern systems for documentation of information are already compatible to those requirements, but in other places this new regulations will mean significantly more work and expenses.

### 1.3 The way of information

The patients' information has to be performed "in essence", i.e. the most significant treatment risks must be mentioned. It is not necessary to mention each theoretically possible complication; however severe risks have to be indicated even if they occur very rarely. The informative briefing itself must be an oral interview so that the mere hand out of an information sheet is not sufficient. The completing use of standardised information sheets, however, is reasonable and useful and is strongly recommended from a forensic point of view because the patient can read it through and clarify open questions with the physician. In cases of so-called gradual information the patient first receives an information sheet containing the basic information on the planned intervention and the most important risks. However, this cannot replace the oral interview but it prepares the conversation because based on the read information the patient may now ask further and specific questions. In the oral interview the individual and patient-specific information has to be performed considering the individual circumstances as for example concomitant diseases. Finally the patient must be asked if further questions exist or if the information was sufficient. The German Federal Court of Justice (BGH) made this clear in a treatment case where a patient

as result of endonasal ethmoid surgery with fenestration of the maxillary sinus went blind in one eye [7]. He had undergone this intervention because of massive polyposis of the nose, the ethmoid labyrinth, and both maxillary sinuses. Postoperatively, bleeding into the orbit of the patient's right eye was detected that resulted from an intraoperative trauma of the orbital wall. Even the relieving incision to reduce the significantly increased intraocular pressure could not avoid blindness. The information sheet only mentioned that severe complications during such interventions were very rare and that the patient should ask the physician in case of further need of information. The risk of blindness or other impairment of the eye muscles, vessels, or nerves was not clearly mentioned. The German Federal Court of Justice (BGH) supported that also a severe risk that are in the per mil area have to be included in the information. Further, the trivialisation of significant risks must not be compensated by the phrase that the patient could ask the physician if need be. As general rule, not the percentage of complications is decisive for the physician's obligation to inform the patient but if the risk in question is specific for the intervention and impairs his personal life in a particular way in case of realisation. If this is true, the manner and extent of the information have to adjusted, however it is principally not up to the physician but to the patient to decide whether the risk associated with the intervention shall be taken.

### 1.4 Time of information

Even extensive information is irrelevant if the patient is under time pressure and thus is not free to make a decision. So the informative briefing must occur in an appropriate timely distance to the intervention so that the patient can weigh the pros and cons of the intervention and make his own decision. In case of interventions that require inward stays, an informative briefing on the day of surgery is principally too late, this is especially true for already sedated patients. The patient must not feel under pressure to agree to the surgery only because the preparations for the intervention have already been performed and he fears to attract the resentment of the physicians or the other staff. For more extensive interventions, the informative interview should take place – if possible – even several days or weeks before surgery together with the diagnosis or the recommendation to surgery. For outpatient procedures the decision must be made for the individual case: for interventions with low risks, information is principally sufficient on the day of treatment, for more risky surgeries, it should be performed at least one day before intervention. In this context the timeliness of information depends on the circumstances of the individual case. If information occurs on the day before surgery at a time when the patient's right of self-determination is still guaranteed as he is still able to think about the intervention sufficiently and to discuss the matter with a confidant if needed, the informative briefing is considered to be timely. However, under certain circumstances it

may not be sufficient to inform about a risky intervention in the evening if surgery is planned for the next morning. In the case of a patient who should undergo heart surgery in the sense of a minimally invasive mitral valve repair, the Higher Regional Court (Oberlandesgericht, OLG) of Cologne made the above-mentioned decision. The informative interview was not objected regarding the contents and extent, but it had been performed too late so that the patient could not weigh the arguments for and against the intervention. The Court justifies its decision that too shortly before a surgical intervention patients were unable to cope with the communicated facts and the decision they were supposed to make. This was especially true if they – possibly suddenly – are informed about the severe risks that might influence their future life in a decisive way. Emergency patients who are taken to hospital unconscious have to be informed after the intervention [8]. Also for inpatient interventions, the informative briefing has to occur timely depending on the individual case. A small surgical intervention at the index finger of the left hand bears quite another risk for a waitress than for an advocate: Possibly a waitress can no longer pursue her profession in case of stiffening of the index whereas for the advocate in general such an event does not impair significantly the pursuing of his profession. Similar examples from jurisdiction exist for particular professional groups, e.g. professional sportspersons or opera singers who undergo surgical intervention at their legs or their vocal folds, respectively. The more severe the risks associated with the specific intervention are for the individual patients, the earlier and more intensive the informative interview has to be.

## 1.5 Information about alternative treatment options

Principally the physician is not obliged to explain voluntarily to the patient which treatment methods can be considered theoretically and provide the arguments in favour or against the one or other method. Rather the principle of therapeutic freedom applies: The choice of the treatment method is up to the physician. Among several methods that are equivalent with regard to the therapeutic outcome and the risk he may choose the one that seems to be most appropriate and for which he is most experienced as long as it is a therapeutic method that corresponds to the medical standard. Notwithstanding, information about alternative treatment options is always required when several indicated and useful therapies exist and when the treatment options significantly vary with regard to possible risks and complications or traumatic stress. In this context the term of “truly alternative treatment option” applies.

If an alternative treatment exist for the treatment of patients with statutory health insurance that does not fall into the scope of services covered by the health insurance agencies but that offer medically higher chances of success, the patient with statutory health insurance must be informed about this alternative. This issue was decided

in the case of dental prosthetic treatment: If a telescope prosthesis offers better chances of success in comparison to model casting prosthesis – which seems to be given –, the dentist has to mention the possibility also to the patients covered by statutory health insurance that they might choose a dental prosthesis that is not covered by the standard of statutory health insurance regulations against additional payment. It is only up to the patient to decide which medical care he can or wants to afford [9]. If the physician decides to apply a method outside the mainstream or if he deviates from established and recognized procedures, he has to meet the increased requirements to information. According to the Federal Court of Justice (BGH) the measure for the diligence regarding information about and performing the intervention is a “careful physician” [10]. This decision was made in a case where an orthopaedist treated vertebral complaints by means of an epidural catheter according to Prof. Racz. In this context, a cocktail of a local anaesthetic, a corticoid, an enzyme, and saline solution is injected into the affected spinal disc level via an epidural catheter into the spinal canal. At that time this method was considered to be innovative, long-term proofs for its effectiveness were still missing. Because of the physician’s therapeutic freedom, the BGH did not judge the treatment itself to be incorrect in case of occurring complication. The patient, however, had not only to be informed about the risks but also about the fact that the planned intervention was (not yet) medical standard and that the effectiveness was statistically (not yet) proven. The patient has to know what to expect in order to weigh if he wants to undergo the specific intervention or not. Also in the judgement that is well-known as “Zitronensaftfall” (lemon-juice case), the BGH decided that for treatments that do not meet the medical standard – in this particular case the surgeon had used lemon-juice he had produced himself for disinfection – the patients had to be informed [11]. So the information about the application of methods outside the mainstream corresponds to the increased need of information about treatment attempts with medical products that are not yet licensed. The requirements to information are even higher with the risk or the intensity of the intervention, especially when a surgical therapy is planned instead of conservative treatment.

## 1.6 Information in the context of merely aesthetic interventions

The general principle applies: the less indicated an intervention is, the more extensive the informative briefing must be. So for merely cosmetic interventions, high requirements must be met with regard to the extent of information. The physician has to rigorously explain the chances of success and the associated risks and inform the patient about the pros and cons of the intervention with all consequences [12]. Further the treating physician has to unmistakably inform the patient that possibly the health insurance agency would not bear the expenses of surgery. Caution is advised when “before and after” pic-

tures are shown: Editing of patients' photos, e.g. to describe the possibilities of nose correction, is useful and allowed also in order to discuss the desired result with the patient. However, the patient has to be informed unmistakably that the result may vary from the shown pictures and depends from the individual medical circumstances. Regarding the publication of "before and after" pictures for advertising, e.g. on websites or in practices, the legal principles must be observed as well: Principally it represents a non-compliance with competition rules of the Advertising of Medicine Act (§1 Abs. 1 Nr. 5 letter b) and bears the risk of unobjective information of the patient. For merely cosmetic intervention, an exception applies: The use of "before and after" pictures is only inadmissible if three criteria are met: According to § 1 Nr. 2 of the Advertising of Medicine Act it must be question of operative, plastic, and surgical measures. This aspect was decided in a case of a dermatologic practice that performed beside superficial fruit acid peelings also deep peelings by means of laser and promoted those interventions on the website with "before and after" pictures of faces and hands. The deep peeling was considered to be operative because of its effect and as surgical because of the laser application, but as there was no plastic measure the advertisement with those pictures was allowed because not all three criteria were cumulatively met [13]. With this background, the advertisement for dental veneers is allowed but not for nose corrections.

## 1.7 Economic information

If in exceptional cases, patients with statutory health insurance make use of private medical services that are not covered by the health insurance, the treating physicians are obliged according to § 18 Abs. 8 of the "Federal Master Treaty for Medical Practitioners" (Bundesmantelvertrag für Ärzte) to have signed a patient's written consent for performing the private medical services, i.e. to conclude a written contract. Without such a written consent, later liquidated of the private medical service is not allowed. However, this principle only applies for statutory health insurance physicians (SHI physicians). Physicians without SHI admission only have to comply with the specific medical association's professional code of conduct and have to inform the patients only about the expenses in a written form. Up to now this regulation was only meant for private medical treatment of patients with statutory health insurance and it has been extended for patients covered by medical expenses comprehensive insurance based on a consolidated version of § 12 Abs. 4 of the professional code of conduct for doctors (MBO-Ä). The respective § 12 Abs. 4 of MBO-Ä now reads as follows:

*"Prior to the provision of services of which the expenses are not clearly covered by a health insurance company or any other cost bearer, physicians have to inform their patients in a written form about the amount of the expected honorary according to the scale of charges for*

*doctors (GOÄ) that the payment of the costs is not or not certainly effectuated by the health insurance company or another cost bearer."*

*"Vor dem Erbringen von Leistungen, deren Kosten erkennbar nicht von einer Krankenversicherung oder von einem anderen Kostenträger erstattet werden, müssen Ärztinnen und Ärzte die Patientinnen und Patienten schriftlich über die Höhe des nach der GOÄ zu berechnenden voraussichtlichen Honorars sowie darüber informieren, dass ein Anspruch auf Übernahme der Kosten durch eine Krankenversicherung oder einen anderen Kostenträger nicht gegeben oder nicht sicher ist."* With this consolidated version the accounting of private medical services that are possibly not covered by the health insurance agencies becomes more difficult as the physicians concerned are now obliged by professional law to inform themselves previously about the eventual accountability of certain new medical services. This applies in particular for innovative treatment procedures and surgical services regarding aesthetic surgery that are manifest not to be covered by health insurance agencies. Even stricter than the regulation of MBO-Ä is the future wording of § 630 c BGB (German Civic Code) that is newly included in the context of the law of patients' rights. It reads as follows:

*"If the treating physician knows that a complete covering of the treatment costs by cost bearers is uncertain, he has to inform the patient prior to the beginning of treatment by means of a written text."*

*"Weiß der Behandelnde, dass eine vollständige Übernahme der Behandlungskosten durch einen Dritten nicht gesichert ist, muss er den Patienten vor Beginn der Behandlung in Textform darüber informieren."*

The wording of this rule suggests that the obligation of information of the treating physician is less far reaching than the obligation resulting from § 12 Abs. 4 MBO-Ä, stipulating that the patient has already to be informed in a written way in case of manifest missing coverage of the arising expenses as well as the uncertain coverage of the costs. According to the explanatory memorandum regarding § 630 c BGB, this rule goes far beyond than its wording because the treating physician is already obliged to inform the patient by means of a written text when he knows that it is "uncertain" that the treatment costs are completely borne by third parties, principally by health insurance agencies. This extensive obligation for the treating physician is not clear from the wording of the rule and it bears the risk not to be reimbursed for the treatment. So for the future it seems to be recommended to inform the patients rather as prevention in a written way in such treatment cases that certain innovative or individual medical services are not covered by the cost bearers. With those new regulations the national legislature turns the physician additionally into a solicitor of the economic interests of the patients – this is a completely new role that physicians will certainly only reluctantly accept.

## 1.8 Documentation of information

Originally, intent and purpose of the documentation do not consist of providing evidence in court but to serve as a reminder of the physician for further therapy by himself or the follow-up physician as well as fulfilling the obligation of the physician towards the patient to give account about the treatment at any time.

However, meanwhile there are always more patients who start liability proceedings against physicians based on the accusation that they have not been sufficiently informed – even if this accusation is often only made because medical malpractice or an error in treatment cannot be verified. In such cases, the physician can only defend himself by means of a careful documentation of the effected informative briefing. This aspect makes clear that not only appropriate information but even a possibly detailed written documentation of the information is required. Especially in times of increased numbers of liability or damage compensation proceedings as well as increasing requirements regarding the extent and quality of the information on the part of legislation, physicians have to place great importance on extensive and sound information of their patients and a careful documentation of the performed briefings. This applies also in order to be able to avoid the accusation of lacking information. The onus of proof for the proper information lies with the physician, i.e. he has to rebut the accusation of insufficient information which makes careful written documentation of the informative briefing essential.

For simple treatment cases, the necessary and performed information can also be proven by explaining that in similar cases the responsible physician always performs the briefing in this way. This so-called “as always proof” (“immer-so“-Beweis) can replace the specific written documentation in simple cases. Then, evidence via the quality management or testimonies of other physicians or nurses or assistants may have a probative value.

For missing or insufficient information, the physician can probably refer to the aspect that the patient would have agreed in the intervention also in case of proper information, i.e. the so-called hypothetical consent. The patient then has to show that in case of proper information there would have been a decision conflict whether to agree to the performed intervention or not.

## 2 Error in treatment – shortfall of medical standard

Measure for the medical treatment is the medical standard. This means that the physician owes the performance of a service that corresponds to the established and acknowledged state of the medical science at the time of treatment. The treatment has to be performed in that way that an experienced specialist, even if the physician has (not yet) passed the certification of his specialisation (specialist’s standard, Facharztstandard). If the treatment does not meet the medical standard,

medical malpractice is given. If the error in treatment is the reason for damage, the physician is liable for the caused damage in the sense of civil law. If the medical standard is observed, the civil law applies – in contrast to penal judgement – an objective standard of due care. The individual particularities of the physician or his personal circumstances that were present at the time of treatment are not taken into consideration. Missing experience or education, lack of personnel, or local equipment-related difficulties principally do not exonerate the physician or the hospital. The physician also bears the liability for a behaviour that might subjectively be excused but that objectively does not represent the medical standard. Besides, always penal liabilities must be considered based on the delict of physical damage according to § 223 Penal Code (StGB).

The preconditions and consequences, especially also the effective principles in civil compensation proceedings should be included in the law of patients’ rights and thus be clearly codified for the first time.

### 2.1 Specialists’ standard

Every physician owes the patient a treatment that must correspond to the standard of a carefully working specialist in the situation of the treating physician. In this context, an objective measure of due care: The required care is the one of a considerate and diligent physician of the respective discipline. The specialists’ standard can also be assured by physicians with other specialities. However, as soon as a physician works in an area outside his speciality, he has to carefully check if he has sufficient theoretical and practical skills to perform the treatment corresponding to the specific medicoscientific standard.

The Higher Regional Court of Oldenburg, Germany, substantiated the requirements to the standard a hospital must meet [14]. In the underlying case a patient suffered from severe bleeding complication after tonsillectomy. When the bleeding was stopped and the patient was stabilised, the physicians of the hospital decided to transfer the patient to a specialised hospital for further care. The patient took legal actions because transportation had caused damage to him. The hospital of primary therapy would not have been able to treat such a complication in an adequate way about what the hospital would have had to inform him. The judges took another view: The specialists’ standard could not be denied when the further treatment of a patient is transferred to a specialised hospital in case of severe complication. Only the fact that better care is possible in another place must not lead to the conclusion of own insufficiency. Contrariness is not given.

This decision shows that the attention is focused on the safety and health of the patient and in the individual case a preventive consultation of specialists is even favoured when transportation of the patient is associated with this consultation as long as no additional risk for the patient’s health is expected. Finally the decision remained open if the damage to health of the complainant were really a

consequence for the transportation because the decision to transfer the complainant to another hospital was no error in treatment itself. This is why there cannot be any obligation to inform the patient prior to an intervention about the possible preventive transfer to another hospital when the own medical standard principally allows the secure handling of even severe complications.

## 2.2 Contributory negligence liability

If a physician performs services of another discipline he has to guarantee its standard, otherwise he is liable for contributory negligence which is an error in treatment. Also residents have to guarantee the standard of a carefully working specialist. If the knowledge or the skills of the treating physician are not (yet) sufficient regarding the medical standard in this discipline or if the technical equipment at his disposition is not appropriate, he has to consult a specialist or transfer the patient to a specialist.

Such a contributory negligence has been denied in a case presented to the Higher Regional Court of Brandenburg where a patient should undergo removal of a neck cyst by an ENT specialist. After the surgery it became obvious that in fact it was no neck cyst but a neurinoma which had been removed. The Court decided after having heard the expert that there was no need to consult a specialist of another discipline because neurinomas occur very rarely, the differentiation of a neck cyst was macroscopically not easily possible, and further the planned intervention was usual for a qualified ENT specialist. Neurosurgeons were only consulted when surgical interventions would have to be performed in the area of the spinal cord [15].

## 2.3 Presumption of proof for the patient

Principally, in every legal proceeding, each party has to prove those facts that it quotes for its interests. So the patient has to prove that the physician has committed an error in treatment that is causally related to the health damage. As this is – based on the unpredictability of the human organism – often rather difficult and the patient usually has only little knowledge about medical activities and the relevant medical issues, the jurisdiction has defined case groups under the aspect of the principle of equality of arms that partly dispenses the patient from the burden of proof.

### 2.3.1 “Gross” error in treatment

According to the German Federal Code of Justice (BGH) an error in treatment is considered to be “gross” when a physician has definitely violated established medical treatment rules or latest medical knowledge and committed an error that does no longer seem to be understandable from an objective point of view because it simply must not occur. A current decision of the BGH has confirmed this legal view [16]. Before Court the assumption

of a gross error in treatment leads to a reversal of the burden of proof in favour of the patient. However, if the Court assumes the presence of a gross error in treatment, the physician has to prove that the error had not been committed or is not causative for the health damage. The question if an error in treatment can be considered as gross or not gross is a legal assessment and no medical one. So the Court can assume the presence of a gross error in treatment even if an expert evaluates the medical procedure as clearly incorrect but still understandable without giving objective reasons for this traceability. But the requirements are rather high. A gross error in treatment cannot necessarily be assumed also in case of clear violation of established medical treatment rules.

So the Higher Regional Court of Cologne (OLG Köln) has decided that omitting a test of the vestibular function in case of vertigo complaints is clearly an error in treatment but that in this individual case it does not seem that incomprehensible to be qualified as “gross” [17].

In another case, the Regional Court of Munich assumed a gross error in treatment for the application of a too high dose of a medication: An ENT physician had injected postoperatively a medicament for elimination of pain to a patient who was known to suffer from asthma. The patient’s reaction was a bronchospasm and his brain was undersupplied with oxygen for some minutes. Also in the recovery room he remained unconscious and finally he had a brain damage that led to death. There was no documentation about the events in the recovery room. The judges stated that the medicament had not only been too highly dosed but it would not have had to be applied because of the asthmatic disease. Further the patient was in a massive state of shock without an adequate reaction that had been documented [18].

The Regional Court of Regensburg judged the intervention of tonsillectomy as gross error in treatment where the posterior wall of the pharynx of a patient had been injured by the application of an argon plasma coagulator outside the target area of the surgery. The result of this injury was a scarred stenosis of the posterior pharyngeal wall so that 12 additional interventions and tracheostomy became necessary [19].

If the time of hospital stay falls below the recommended duration of six postoperative days after tonsillectomy, this fact is not considered as (gross) error in treatment. In the case of a patient who was released from the ward on the fifth postoperative day and who suffered from significant bleeding, the Regional Court of Zwickau judged that the physician may – after due consideration – deviate from the recommended six days of hospitalisation [20].

### 2.3.2 Failure in the assessment of findings

If a physician does not assess the findings although it would have been necessary according to the medical standard, the physician is liable when his negligence is causative for the health damage of the patient. In such a case the difficulty of the patient becomes obvious to

prove the causal relationship in addition to the error and the damage.

In the above-mentioned judgement of the Higher Regional Court of Cologne, Germany, the question had to be answered if a timely test of the vestibular function would have allowed identifying an acoustic neurinoma [17]. Under certain circumstances, a presumption of proof in favour of the patient is applied leading to the fact that the causality needs not to be proven but that it is assumed which means that the physician has to exonerate himself. In such a case – presupposed that the diagnosis would have been made – if clear and significant findings were made with a probability of more than 50% that the negligence of these findings were considered to be fundamental or the missing reaction to it was considered to be a gross error in treatment. If those preconditions are fulfilled, the burden of proof falls to the physician to show that the omitted diagnostic measures were not causative for the damage.

These aspects of failed assessment of findings must not be confused with diagnostic errors. While a failed assessment of findings means that a measure for diagnosis has been omitted, a diagnostic error implies that the physician interpreted findings in a wrong way and fails in taking possibly further assessment of findings. The differentiation of both aspects is partly rather difficult and requires the assessment of the individual cases but sometimes it becomes decisive for the proceedings due to a possible reversal of evidence in case of a failed assessment of findings.

### 2.3.3 Organisational faults

According to the jurisdiction of the BGH the hospital operator is liable for organisational faults when the damage has been caused by a risk it should have fully controlled. This aspect is assumed for the fields of hygiene and operational activities as well as the technical equipment, i.e. when technical units or instruments do not work or work only insufficiently. As the physician or the hospital operator are in a position to supervise those areas by giving organisational instructions and thus certainly avoid damage, an error in treatment is assumed in cases of damage of which the physician or the hospital operator has to exonerate himself. Further the hospital operator has the organisational obligation not only with regard to the choice, number, and quality of the staff, but also to the scheduling of staff and the organisational structure in general.

### 2.3.4 Documentation failure

It is assumed that processes that have not been documented have not taken place. So if a certain measure was indicated that has not been documented an error in treatment is suspected. The physician can principally exonerate himself but without presenting adequate documentation he will hardly succeed. This shows the urgency of careful documentation.

The requirements to the medical documentation are also considered in the draft of the planned law of patients' rights and shall be codified expressly. One aspect that is new and only difficult to realise (especially with regard to the electronic patient record) concerns the requirement of the planned § 630 f Abs. 1 BGB that corrections of the patients' records must be made in that way that the original note can still be read. The regulation of § 630 f Abs. 2 BGB stating that also measures and results must be documented that might be important for the further treatment bears the additional risk of documentation failures of the treating physician because it is not always evident at the time of taking a measure what might be relevant for the future treatment of the patient.

## 2.4 The call for a change in the system

Regarding the existing practice that in general the patient has to provide the evidence for an error in treatment and the causality for the damage, the call for a change in the system becomes loud in issues of medical liability. The requirement consists in the claim that in case of treatment failure principally an error in treatment is suspected and that it is up to the physician to exonerate himself.

Finally this requirement was rejected with the draft of the law of patients' rights and the current practice was regularised: Thus in case of compensation proceedings it is principally the patient – in general by requiring an expert opinion – who must prove that the physician's activity did not correspond to the medical standard and is so an error in treatment being causative for the damage. Already in 1977, the BGH confirmed that not every failure or every complication that occurs during treatment can be valued as indication for an error in treatment and that the physician is not obligated to exonerate himself from the accusation [21]. This particularity of the medical malpractice law is justified because the human organism is unpredictable and thus physicians do not owe success to the patients, e.g. the complete healing, but "only" treatment according to the medical standard. As complications are typically possible also for treatment performed state-of-the-art and thus unavoidable, an error in treatment is not suspected. So the patient can be expected to prove an error in his individual case.

As this might be difficult under certain circumstances and the liability is excluded if an error or the causality is not provable, some countries meanwhile started to establish funds for damage. Especially in countries with a public medical system such as New Zealand or the Scandinavian countries the individual liability of the physician is replaced by an insurance solution based on funds. Each patient pays a certain sum in order to insure his treatment risks and he is compensated in cases of complications without the obligation to prove that the physician had committed an error in treatment.

On the one hand this means that the relationship between physician and patient is less strained. On the other hand, the preventive incitement to avoid failure is missing if the physician is not personally liable for the consequences.

Further the insurance solution does not offer the possibility to pay smart money. To change the system in favour of the insurance solution seems only to be conceivable when the expenses for liability insurance – in particular for high-risk disciplines such as obstetrics or orthopaedics – increase in such an enormous way that health care is jeopardised. Apart from that, the well-refined medical liability rules present a sound basis for decision based on decades of jurisdiction, a basis that can clearly be considered superior to the insurance solution for the physician and for the patient.

## 2.5 Horizontal division of labour and principle of legitimate expectations

Between physicians of different disciplines the principle of horizontal division of labour and liability is valid as well as the principle of legitimate expectations. This means that every specialist performs all examinations and treatment measures that are necessary for this activity and that he can expect that his colleague performs his activity in a correct and complete way (strict division of competences). The principle of legitimate expectations includes that on behalf of a regular process of patients' treatment the physicians involved can principally count on the correct collaboration of their colleagues from other disciplines. This is true for the penal responsibility as well as for personal liabilities. A radiologist can thus expect that a surgeon acts according to the medical standard with regard to indication, examination requirements, and follow-up. The surgeon himself can rely on the radiologist to evaluate the findings according to the medical standard. There is no obligation for mutual surveillance. The principle of legitimate expectations, however, is set aside if exceptionally indications exist that a physician who is included in a patient's treatment is not able to cope with the actual situation, e.g. because of drunkenness, sincere doubts regarding the evaluated findings, overstraining, sickness, or exhaustion. In such cases, for example a radiologist and a surgeon are liable together if one of them does not object the (apparent) error of the other or does not verify the diagnosis.

A risk can sometimes even occur only by the interaction when the measure taken is itself correct for the single physicians and the particular risk only results from a combination of both measures. So a patient received severe burn injuries of the face after an eye surgery because the surgeon had applied thermocautery although the anaesthesiologist had fed pure oxygen in high concentrations via a tube. Both physicians had not coordinated their treatment methods so that relevant development of flames occurred [22]. Thus it is important for the protection of the patient that the planned measures are coordinated in order to exclude the risk that the incompatibility of the methods or instruments considered by the involved disciplines may cause.

## 3 Current, liability-related question

After describing the basic aspects on the risks that might result from insufficient information or incorrect medical treatment, current problem areas will be focused on in the following that might represent different hazards for physicians and patients.

### 3.1 Liability for surgery-related positional damage

The correct positioning of the patient is a secondary obligation resulting from the treatment contract. Intraoperative positional damage bears a high liability risk for the hospital and the responsible physicians. The OLG of Hamm, Germany, now clarified that the hospital is principally obligated to guarantee the correct positioning of the patient and to involve in this context the necessary equipment and personnel [23]. As the correct positioning represents a risk area that a hospital can fully control it is principally the hospital that has to exonerate from the suspicion of positional damage being related to an incorrect positioning. This interpretation is an exception from the principle of the physician liability process based on which the patient has to prove the error in treatment, the damage, and the causality of the error for the damage. This means that in case of occurring pressure points the treating physician or the hospital, respectively, has to prove to have positioned the patient in a correct way. If general agreements or instruction regarding the positioning of the patient on the operating table are missing and/or if the position control is missing, it means an organisational fault for which the hospital and the responsible physicians are liable.

The problem consists in the fact that the positioning of a patients for surgery is always a cooperation of physicians of several disciplines (anaesthesiology and surgery) that are not mutually responsible regarding instructions (horizontal division of labour) and can principally rely on the other's diligence (principle of legitimate expectations). However, there is the obligation of the physicians involved to coordinate their processes (obligation for coordination) which implies in particular to avoid risks that may result especially from the interdisciplinary cooperation. In the field of the positioning of patients the principle of predominance of substantive requirements is applied in case of conflicts. This means that in the case of missing agreement between the surgeon and the anaesthesiologist the surgeon must take the final decision (especially for emergency interventions) and thus bears the responsibility for appropriate considerations. Sound documentation of such circumstances guarantees the avoiding of liability constellations. The requirements for correct positioning, however, must not be overstretched: Principally it is the surgeon (except for contrary instructions or regulations) who is responsible for the positioning of the patient during surgery and has to control also intraoperatively if the position is still appropriate during the course of surgery. But

this obligation to control has its limit where control is simply not possible, e.g. when the body is covered with sterile drapes. If in such a case positional damage occurs because the patient minimally moved, it is not considered as error in treatment but as unavoidable complication that must be accepted by the patient. Of course, if the surgeon or another physician notes that the patient is no longer positioned adequately or that at least reasonable doubts exist, the surgeon has to intervene. This typical risk of positional damage regarding surgical interventions of long duration must be included in the patient's information. If this information is not performed or if it is insufficient, the physician or the hospital is liable even if the damage cannot be related to an incorrect positioning. As in cases of doubt the physician has to prove that the patient was correctly informed, it is recommended in every case to carefully document the informative briefing.

### 3.2 No obligation to work only in the own discipline

The German Federal Constitutional Court decided that specialists – at least in the private medical sector – can work actively also outside the limits of the special discipline described for the respective code of continuing professional development [24]. A general interdiction to work in a completely different discipline is not necessary in order to permanently guarantee the performance standard achieved the specialist's training. It can be expected that the training of the skills related to the particular discipline is already achieved by the fact that the special activity comprises the vast majority of his total activity. The decisive proof of his qualification concerning the question to what extent and focus physicians are allowed to work is only the licence to practice medicine.

The call fixed in the professional code of conduct and in the legislation of health care professionals and Land medical associations to work only in the discipline of which a physician has his speciality recognition pursues primarily the objective to maintain the particular knowledge and skills of a specialist in his discipline. If this aspect is considered otherwise, the restrictions would have to apply without any exception. In such a case there would result in conflicts of values with regard to physicians with more or without speciality recognitions or physicians that are only working part-time.

A physician has to check in every individual case if he is able based on his skills and the circumstances – e.g. the technical equipment – to treat his patient according to the rules of medical art, i.e. the established standards. Subject to this check, however, he is entitled – independently from the existence of specialisations – to treat patients in all fields that are covered by his medical licence. In the case that was decided by the German Federal Constitutional Court, the part of activity outside his particular field of expertise amounted to about 5%. Up to now there is no decision to what extent this percentage of a physician's activity can be increased according to the decision of the German Federal Constitutional Court. But

according to the systematic explanations of the German Federal Constitutional Court it can be assumed that the medical licence alone is the basic qualification for medical activity and an additional qualification by specialisation does not exclude an activity outside this particular field of expertise. Also the systematic activity in a special field outside the area of specialism is then possible. In this context it must be kept in mind that the particular preconditions to work as contracted physician in the area of statutory health insurance are not given for private medical activity. The explanations of the German Federal Constitutional Court refer exclusively to the activity outside the contracted medical care (see also [25]).

### 3.3 Source of risk – lack of organisation

Many medical errors in treatment are finally based on an insufficient organisation of the working processes in hospitals or private practices. There a multitude of factors to be supervised and structured, for example the scheduling and qualification of the staff, the observation of hygienic standards, and the technical equipment. Regarding system problems in hospitals that often are the result of economic pressure, however, the hospital operators – and as their representatives the managing directors – and not the physicians are responsible.

#### 3.3.1 Lack of personnel as risk factor

The medical treatment must satisfy the specialist's standard. As a large part of the medical activity could not be performed without the supporting and additional activity of medical staff and caregivers, the quality of the activity performed also by this part of the personnel must be satisfying. So there has to be enough and sufficiently qualified personnel. Principally, the hospital operator is responsible for the quality of the medical and caring performance, i.e. in particular for the choice and the number of physicians and caregivers. According to the jurisdiction of the BGH it is the hospital operator who is liable if the medical standard cannot be guaranteed because of lack of personnel and errors result. Besides, however, the head physician has the ultimate responsibility for the organisation of his department. So he is obligated to indicate the deficiencies regarding the personnel and to ask to provide for sufficient medical and caring personnel in order to be able to fulfil his tasks (obligation to remonstrate). Acceptance of personnel-related deficits without objection could otherwise incur his personal liability because of organisational fault if errors in treatment occurred. If the lack of personnel or the missing qualification of the personnel lead to the fact that the specialists' standard can no longer be guaranteed and if the hospital operator does not show a reaction on the indication of the deficits, the (head) physician has no other choice than adapting the patients' care to the existing situation of the personnel and if needed even stop treatment. Otherwise he might be liable for organisational

fault. The same principles are valid for identified or manifest deficiency of the technical equipment.

### 3.3.2 Regulations according to the working hours law

Another consequence of under-staffing is that medical personnel and caregivers work longer because the medically mandatory treatment of patients has regularly priority over administrative orders. Conflicts can arise with regard to the principles of the working hours law that principally allows a maximal working time of 48 hours per week. The employer has to take care by taking appropriate organisational measures that the personnel does not exceed the legally imposed minimal rest break during the working time and minimal rest times after the end of the daily working time. Otherwise severe fines must be expected. However, this is only possible when sufficient staff exists. The head physician has generally the task imposed by the employment contract to take care for a well-regulated working process in his department. In contrast to a wide-spread opinion and handling, however, this does not lead to the obligation to control the observation of the working time or in case of exceedances to take the regulatory responsibility, because the employer of the hospital staff – to which also the head physician belongs – is the hospital operator. Only the operator can employ additional personnel and thus influence effectively the observation of the prescribed working time. Only the responsibility of establishing the schedule or the statement in the head physician's contract that he was responsible for the observation of the working time according to the working hours law is not sufficient to place this onus on him. Irrespective of this aspect, however, the responsible head physician is obligated to indicate early and in time to the employer when staff shortages exist and to ask for corrective action.

### 3.3.3 Standard of hygiene

According to the data of the Federal Ministry of Health about 400,000 to 600,000 patients receive an infection in the context of a medical treatment, 7,500 to 15,000 die from these infections (<http://www.bmg.bund.de>). About 20–30% of those cases of death could have been avoided if the hygiene rules had been observed. According to a decision of the BGH made in 2007, lack of hygiene can have striking consequences with regard to liability [26]. The BGH has clearly assigned the infection of a patient because of insufficient hygiene management to the field of fully controllable risks of the hospital. This means that causation and the fault of the physician are expected and he has to exonerate himself. This proof of exoneration can generally only be provided when the ensuring of the due care by observation of all necessary hygiene standards is given.

The amendment of the Law on the Prevention of Infection was associated with a further intensification: The federal Länder were obliged to issue decrees until the end of

March 2012 on infection hygiene and prevention of resistant pathogenic germs in medical institutions (hospital hygiene decrees). Those decrees contain among other aspects the obligation to define hygiene officers and to create hygiene commissions as well as to seek advice by a hospital hygiene specialist. Further there is the obligation of documentation, e.g. with regard to the occurrence of multiresistant pathogenic agents.

### 3.3.4 Interdisciplinary on-call service

For cost reasons, hospital operators increasingly start to establish an interdisciplinary on-call service. However, also the on-call service has to keep to the specialists' standard. But this standard can also be guaranteed by physicians without specialist qualifications or physicians of another discipline. This measure, however, is not only applied for medical treatment in the strict sense but especially also for the organisation and coordination in the hospital. Legislation considers the risks occurring in these areas to be fully controllable so that errors of the organisation of internal processes regularly lead to a reversal of the burden of proof and thus to liability.

With this background it becomes clear that an interdisciplinary on-call service bears significant risks under liability aspects and as a general rule it is rejected. For adequate care of patients of other disciplines, the physician on duty would have to regularly ask for advice of the on-call service specialist of the other discipline. The risk, however, lies in the fact that a physician of one discipline does not or not in time recognize the severity of a situation and the resulting necessity to call another physician of the on-call service because of his lacking theoretical knowledge and in particular also his missing practical experience. Finally, it can be expected that a court will assume in the context of a physician liability process that damage during the interdisciplinary on-call service is caused by the missing specialist's qualification. According counter evidence would then be difficult to provide by the treating part. Unless the hospital operator insists on the introduction of the interdisciplinary on-call service, the responsible head physician should communicate his concerns in written form and require written instructions. Additionally, the physicians deployed in the interdisciplinary on-call service should be instructed to call in really every case of doubt the specialist on duty.

### 3.3.5 Penal responsibility of decision-makers "far from patients"

According to the civil law, the hospital operator is liable for organisational faults if damage is caused by a risk that is fully controllable. This includes also the creation of an appropriate medical care structure and the provision of sufficient and qualified personnel.

According to the criminal law, however, this situation is another one. While the treating physicians are often accused of homicide or bodily injury caused by negligence,

the management or the executive board are generally not held legally accountable.

With this background, a sentence made in 2011 by the Local Court (Amtsgericht) of Limburg is interesting [27]. In this case, a dentist and an anaesthesiologist were found guilty for negligence causing death after a 10-year-old girl had died after dental surgery. Still sleeping she had been left alone with her mother in the recovery room who naturally was not able to cope with the suddenly occurring postoperative complications. The condemnation of the dentist was justified with the fact that he as the owner of the practice would have to take care from an organisational point of view that the unconscious girl had to be supervised by qualified personnel in the recovery room. In contrast to civil proceedings, however, the circumstances have to be completely clarified by the court and no reasonable doubts must prevail regarding the guilt and the relation between the violation of duty and the damage because otherwise the innocence of the accused must be assumed in the case of doubt ("in dubio pro reo"). So there is no possibility of condemnation based on the changed allocation of the burden of evidence as in case of gross error in treatment or because the physician cannot prove the proper clarification or treatment in absence of sufficient documentation. In the practice, it is therefore difficult to prove without any doubt that organisational deficiencies are responsible for the damage. Currently it is entirely open who jurisdiction will react on the judgement of the Local Court of Limburg. Possibly this means a first step in the direction to place the responsibility not only in the deficient infrastructure of the treating physicians but also and especially in the decision-makers in the background who pave the way to many damages caused by defects. Anyhow, it is recommended for (hospital) physicians to indicate in written form the existing organisational faults that do no longer allow keeping the medical standard of patients' care and to draw the attention to the fact that under those circumstances falling below that medical standard no liability or responsibility is assumed for possible incidents. This opens a window of liability and responsibility for "decision-makers far from the patients".

### 3.4 Guideline-compliant behaviour

In a current decision, the BGH stated that not only the violation of medico-scientific guidelines, directives, or other specific instructions might justify a gross error in treatment but also the violation of fundamental medical principles that were required in the single disciplines [28]. The previous courts of lower instance had considered the qualification as not given – despite the fact that the medical expert had described the behaviour of the anaesthesiologist and the further treating physicians of the patient as "incomprehensible" and "completely incomprehensible" – because to the best of his knowledge there was not guideline or specific instruction for this special case so that the physicians who had to cope with the situation for the first time could subjectively not be ac-

cused of having reacted in a "completely incomprehensible" way. The BGH judged this case in another way: Even if for this special case not explicit instruction of a manual existed, the physicians could be accused if they act against unwritten medical principles.

So latest medical knowledge of which the breach may allow to consider an error in treatment as a gross error, is not only the knowledge that is included in guidelines, directives or other specific instructions. It is also the fundamental medical principles that are required in the single disciplines. One of those principles is for example that an anaesthesiologist has to make sure for each of his actions that the supply of oxygen covers the patient's needs of oxygen because the most important guiding principle for performing anaesthesia is always the optimal provision of the patient with oxygen.

### 3.5 Liability for guidelines

The medical standard is evaluated according to the current state of the medical science. So especially the requirements included in the guidelines and directives are significant. In the legal action of a pharmaceutical company against the editors of the national health care guidelines, i.e. the German Association of the Scientific Medical Societies (AWMF, Arbeitsgemeinschaft der Wissenschaftlichen Medizinischen Fachgesellschaften), the Federal General Medical Council (Bundesärztekammer), and the National Association of Statutory Health Insurance Physicians (Kassenärztliche Bundesvereinigung), a legal issue arose in the context of the National Disease Management (NVL, Nationale Versorgungsleitlinie) for backaches that is also relevant for other guidelines who is liable for the correctness of the content of medico-scientific guidelines. In this context, the question must be further discussed if medico-scientific guidelines can be submitted to a justifiable assessment because of their general evaluative nature. Finally the questions must be answered who is liable for possible factual errors (untrue statements in the legal sense) in guidelines.

In the legal action pending before the Regional Court of Cologne, the pharmaceutical company states that in the context of the NVL for backaches the negative recommendation of the agent distributed by the company was based on false assumptions and had to be corrected. Further they claimed for compensation of losses of revenue for the diminished turnover because of the negative evaluation.

Principally, liability must also be assumed in the context of medico-scientific guidelines, if the evaluation of the guidelines is based on false factual situations or untrue statements. In addition to the AWMF as the publisher or internet distributor, also the involved medico-scientific societies and the authors of the guidelines commissions must be considered as possibly responsible. As in the context of omitting of false factual statements it is generally not the question of guiltiness of the responsible person, it is recommended that the institutions and persons involved in the creation of guidelines have an according

insurance coverage because it is never possible to exclude that the evaluations of the single medico-scientific guidelines are possibly based on false factual statements. Also the (external) financing and the associated controlled influencing of guidelines and their contents gains increasingly in importance. The only consensus in this context is that an externally controlled financial dependence is not allowed for the creation of medico-scientific guidelines. Thus, the institution of general specific promotion funds or foundations seems to be reasonable while the external investors and sponsors must not influence the decision about the use of the financial means. Even a public financing (tax funding) is conceivable.

### 3.6 Extent and organisation of the documentation obligation

Originally conceived as a reminder for the physician, the proper documentation of the treatment is one of the most important duties of a physician. Especially in cases when other physicians are involved a specific accompanying and further treatment of a patient can only be guaranteed by diligent and careful documentation. Further, a physician is obliged to answer the patient's questions about the treatment and to provide him with the treatment records (as copy). Another sense of documentation, which is the possibility of evidence in court, results from the increasing frequency of the physicians' obligation to prove the correct performance of the treatment in compensation proceedings. Finally the documentation is also the basis and the evidence for accounting of the medical performance towards the association of statutory health insurance. In proceedings for compensation, the patients declare more frequently that they had not been sufficiently informed, often also because the evidence of an error in treatment is not successful and the physician has to provide the proof for the adequate information. For this purpose, the proper documentation is essential and should contain at least the most important details of the information that had taken place. Especially in the context of electronic documentation, the recommendations of the German Medical Association (Bundesärztekammer) for medical confidentiality, data protection, and data processing in medical practice must be observed and security measures against changes, destruction, and the use and misuse by unauthorized persons must be taken. Regarding the retention period the following principle is applied: According to the medical association's professional code of conduct (Ärztliche Berufsordnung) ten years are mandatory, 30 years are recommended because the claims for compensation because bodily and health damages become time-barred only after that time and a legal action can definitely no longer be expected.

### 3.7 Treatment documents and data protection

The base of the confidentiality relations between a physician and his patient and thus the precondition of a promising treatment is the certainty of the patient that all information he reveals about himself and that the physician gains from the treatment, is not forwarded to third persons without his agreement. The medical confidentiality is an accessory obligation resulting from the treatment contract and an unauthorized breaching of this obligations by the physician leads to his punishability according to § 203 of the penal code (Strafgesetzbuch, StGB) because of betrayal. Besides, the Federal Data Protection Act (Bundesdatenschutzgesetz, BDSG) regulates the handling of sensitive data and prescribes the written consent of the person concerned regarding the assessment and use of personal data. This applies also for the communication of treatment documents and the information contained in medical reports. Further, § 73 Abs. 1b of the volume V of the German Social Insurance Code (Fünftes Sozialgesetzbuch, SGB V) explicitly states that before every communication of information about a patient, he has to give his written consent. This means that the family practitioner must not readily communicate the diagnosis, anamnesis, or treatment documents to the hospital physician to whom the patient is referred. The hospital physician, however, is obliged to ask the patient about his family practitioner but he also has to have the patient's written consent before sending medical reports to the family practitioner. However, it is not necessary to ask the patient before every single communication of information; it is possible that the patient gives a general consent at the time of his first presentation that he can withdraw at any time.

### 3.8 Legal issues of telemedicine

The use of telemedicine in the treatment of patients offers numerous new possibilities of improved patients' care, especially in less-favoured areas. This is not only true for the outpatient but also the inward field because not every hospital can offer all disciplines. The increasing technical development offers more and more possibilities to consult expert knowledge that is locally missing. In particular, the field of teleradiology is meanwhile wide-spread; additionally teleconsultation and models where the medical specialist observes and evaluates inventions via screens are increasing. However, it must not be forgotten that the limit of each technical progress must always be the patient's well being. The patient must not suffer any disadvantage by the application of telemedicine in comparison to standard treatment procedures.

Principally the difference must be made if the external contribution is only a consultation or a genuine (co-)treatment with various consequences. During consultation, only a diagnosis is made or the clarification of a difficult treatment case is discussed so that no individu-

al treatment is contracted between the patient and the consulting physician. In contrast to this, a co-treatment exists when the physician asked for advice contributes to the treatment, intervenes especially based on his superior expert knowledge or determines the treatment. In such a case a treatment contract is made between the patient and this physician leading to the fact that the co-treating physician is also liable for errors. According to § 7 Abs. 4 MBO-Ä the medical treatment of a patient must not exclusively be performed via print and communication media, i.e. in the sense of remote treatment. In the context of telemedical procedures it must be guaranteed that a physician treats the patient directly on site. Another physician contributing to the treatment may then be involved without direct personal contact to the patient via communication media. In order to keep the patient's freedom of choice over medical provision resulting from § 7 Abs. 2 MBO-Ä, the patient has to give his explicit consent to consult another physician via telemedicine. The patients must further be informed that he is always free to consult a specialist of his own choice personally. Currently it is still a problem to account telemedical performance. In the doctors' fee scale within the statutory health insurance scheme (Einheitlicher Bewertungsmaßstab, EBM) as well as in the context of DRGs and the GOÄ the accounting instructions relating to telemedical services are missing. This situation is expected to change in the near future. As part of the law of medical care structure, the evaluation committee was obliged to check until December 31, 2012, to which extent the outpatient telemedical services can be performed; until March 31, 2013, the EBM has to be adapted accordingly. Comparable adaptations would also be necessary in other remuneration-related rules for the private medical and inpatient sectors.

### 3.9 Delegation and substitution of medical services

Since March 22, 2012, the directive of transfer of medical science of the Federal Joint Committee (Gemeinsamer Bundesausschuss, G-BA) regulates which medical services may be transferred to health care and geriatric nursing professionals in the sense of substitution (<http://www.g-ba.de>). Those fulfil their specific tasks independently and on their own responsibility, also with the consequence of own liability in case of errors. Transferable for example are the following services such as the taking of blood samples, wound management, placement of catheters, or the issuing of consecutive prescriptions. In the practice it might be problematic that an additional qualification is required for the independent performance of such medical tasks that are beyond the contents of the usual training of nursing assistants. This is the principle of § 1 Abs. 1 of the directive in combination with the §§ 3 Abs. 7, 4a of the Act on Nursing Care and the Act on Geriatric Care (Krankenpflegegesetz, Altenpflegegesetz). However, it remains unclear what the exact contents

of those qualifications are, further the acquisition of the qualification is associated with expenses. If the hospital owner transfers those tasks to nursing personnel without additional qualification for independent performance, a liability because of organisations fault can be considered. The new version of § 28 Abs. 1 Satz 2 SGB V states that the partners of the Federal Master Agreements for Medical Practitioners (Bundesmandelvertrag) shall create a list of transferable services. According to the legislator the existing possibilities of delegation are not used to a sufficient extent. So for outpatient care shall be defined paradigmatically which services can be performed by non-medical nursing staff and which requirements must be fulfilled for this performance. Generally the obligation of personal performance of service is applied for medicals treatment in the statutory health insurance system. However, this does not mean that the physician has to entirely perform all services personally. He can transfer medical services to non-medical staff. The final responsibility of the physician remains with him – in contrast to substitution, which means that he has to supervise and instruct the assisting person according to the requirements. The delegation of a generally or in an individual case nontransferable task to non-medical staff is considered as an error in treatment with the consequence that the delegating physician is liable in case of occurring damage. For the practice, the question is relevant when it is a case of substitution or of delegation of a service because the transferable activities overlap to some extent. If it is an issue of substitution or delegation, is based on the specific instruction of the physician who – in both cases – has to transfer tasks to non-medical staff. In the context of substitution, he has to communicate the diagnoses and indication in a documented way so that an independent and responsible fulfilment by the personnel is possible. In the context of delegation, however, the actual supervision and instruction option of the physician must be continuously given.

### 3.10 Compensation in the case of missed surgery date

The risk to be subjected to compensation claims of patients may become relevant not only in cases of errors in treatment or insufficient information. If patients do not appear at a fixed date for surgery or cancel those dates at short notice or the physician is not at disposition for a surgery date in time, the question must be asked in which way the arrangement of a treatment date is binding. In this context, the question is interesting if the patient is obliged to bear at least part of the treatment costs or, conversely, if the physician has to pay a compensation – e.g. for lost earnings if he does not or not personally perform the planned surgery.

According to §628 BGB, the patient can principally claim for compensation when the physician cancels without any reason, i.e. because of negligent behaviour contrary to the contract, or does not perform the agreed service and the patient can prove a concrete damage. However,

if circumstances occur for which the patient is responsible that make keeping the date unacceptable for the physician, he can refuse to perform the service. This decision was made in the case of a patient undergoing an outpatient surgery under spinal anaesthesia who was not ready to give an emergency contact for the time after the intervention. The treating physician refused correctly to perform surgery [29].

In the same way, § 628 BGB is applicable for the patient. If he cancels (in legal terms) the treatment contract by not appearing to the agreed date or because of short-term notice without being prompted by a negligent behaviour contrary to good faith of the physician, the patient is principally liable for compensation towards the physician. This compensation consists mainly in the lost earnings by vain reservation of the date. So the Regional Court of Itzehoe decided that a short-term cancellation of a surgery date might be expensive for the patient under certain circumstances [30]. The judges think that if the patient suddenly decided two days before an extensive intervention in contradiction to former agreements not to undergo surgery, he would have to expect a claim for compensation for lost earnings of the treating physician. This is especially true when the operating room and the staff had been reserved and scheduled for a long time in advance and the patient had been informed about the importance to keep the appointment or to cancel at least 15 days before the planned intervention.

A uniform case law does not exist regarding the question if and which claims the physician can make when a patient does not appear and when a damage has occurred because during the given time other patients might be treated. The following principle is applied: When the patient does not allow the appointment to expire without any excuses but cancels it previously, the compensation of possible lost earnings depends on what had been agreed with the patients beforehand. To avoid litigation in this context, it is recommended to indicate in a written form that the planned surgery dates have to be kept or if necessary cancelled at least 15 days before the scheduled date. If the date is then cancelled without any comprehensible reason within this 15-days period before the planned surgery date, claims for lost earnings can be estimated. The rate depends generally on the honorary that the physician could have earned when the surgery had been performed as planned. However, in such a case the physician also has to prove that he was not able to treat other patients during the mentioned time because of the planned schedule, which is not easy according to the statements of some courts. Further it is also possible to make appointments according to an ordering system and to agree with the patients that the honorary has to be paid also without treatment in case of unexcused absenteeism [31]. It is worthwhile to announce that possibly honorary claims are made when the surgery date is cancelled short-term. This avoids later complaints and the patient is admonished to cancel his appointment in time in case of incapability.

### 3.11 Consequences of target agreements on medical activity

The fact that even hospitals are commercial enterprises and need to treat sufficient "cases" in order not to go in the red also becomes clear with the target that are agreed between the board members and the physicians or that are set for the physicians. Inevitably the quality of the medical care suffers under the continuous pressure to fulfil those often unrealistic requirements. Currently there is a discussion caused by the accusation that too many surgical interventions were performed especially in the field of endoprosthesis because of economic considerations. According to current studies nearly half of the newly negotiated contracts for chief physicians contain the clause attaching the bonus payment to the achievement of special targets, mostly economic or financial ones.

For the conclusion of target agreements it is decisive that the negotiated targets are clearly defined between the hospital owner and the chief physician and that they can really be achieved. Otherwise there is the risk that the activity of the physicians concerned is primarily oriented at the defined objectives and not at the medical necessity. Generally, it has become accepted in the context of such employment-related target agreements that only SMART objectives should be negotiated. In this context, SMART is an acronym for formulating the objectives in the following manner:

- S = specific**
- M = measurable**
- A = achievable**
- R = realistic**
- T = timed**

UnSpecific objectives, i.e. objectives that do not belong to the field of responsibility of a chief physician, e.g. within his department, are principally not appropriate. Further, the achievement of the objectives must be clearly Measurable. The negotiated objective must also be Achievable. Non-achievable targets do not increase the performance but they lead to frustration. Realistic targets that are further Timed may be appropriate to increase the performance of a department without compromising the well-being of the patients and/or the staff members. So, special attention should be paid to negotiating well-defined objectives. Well-defined objectives are those that can be measured. One could imagine e.g. the obligation to visit medical education meetings. The agreement of so-called soft targets should be avoided. "Patient satisfaction", "quality improvement", or "reputation of the hospital" are not appropriate objectives because those factors cannot be easily measured. It is decisive that the remuneration of the head physician is sufficient and adequate even if the agreed objectives are not achieved. This statement already results from the professional right because according to § 23 Abs. 2 MBO a physician is not allowed to negotiate remuneration in the sense that the remuneration influences the independence of his medical decisions. But if the head physician depends on the

achievement of the objectives in order to earn an adequate remuneration, it is to be feared that he will try to achieve the negotiated objectives (e.g. number of surgical cases) even if the present patient structure does not justify such a number of cases from a medical point of view.

### 3.12 Inpatient treatment duration of ENT specific interventions

The postoperative duration of stay in the hospital after tonsillectomy is still controversially discussed because of the risk of severe postoperative bleedings. The postoperative duration of stay is often the subject of legal disputes in the context of accounting issues and in the context of medical liability. While the accounting litigations with the health insurances mainly deal with too long durations of stay, the medical liability cases generally accuse a too short postoperative period of stay after tonsillectomy.

The legislation certainly holds the correct view that the predominantly practiced duration of stay of six postoperative days after tonsillectomy is only a recommendation that is permitted to be deviated in the context of obligatory medical estimation because clear scientific evidence for the necessity of an accordingly long postoperative inpatient supervision are missing. So the difference must be made if the intervention is performed in a unit or in an ENT department of a maximum care hospital. The Regional Court of Osnabrück decided that in a case of an ENT unit the prompt reactions in a hospital can be compared to those after the call out of an emergency doctor at home [32]. As the ENT specialist as attending physician in the hospital is not continuously at disposition he would have to be called also in an emergency case in the hospital. This could be compared to the emergency care via the call out of an emergency physician at home. Thus the short duration of stay of three days does not represent an error in treatment.

If this decision can be transferred to hospitals that dispose of an ENT department can be questioned. In such a case the hospital, in contrast to the care by an emergency doctor at home, could provide the immediate care by an ENT specialist. So it can be doubted if the emergency care in an hospital can then be compared to the care at home.

Despite the decision of the Regional Court of Osnabrück, generally an early release after tonsillectomy cannot be considered. In every single case I must be discussed if the release can be considered from a medical point of view with consideration of all circumstances. Only when the course is without any complications, the patient is accordingly informed; the sufficient care of the patient at home and the possibility of medical emergency care located nearby are guaranteed the anticipated release can be discussed in the individual case. Further it is decisive to properly inform the patient before the intervention, especially about the risk of postoperative bleedings

as well as the requirement of immediate medical examination in case of postoperative bleedings.

Additionally, the legal regulations of § 39 Abs. 1 SGB V must be mentioned with regard to the inpatient treatment duration after ENT specific interventions. According to those regulations the patients who have statutory health insurance can claim inpatient treatment in a hospital if the admission after examination by the hospital is necessary because the treatment objective cannot be achieved by day patient, pre-and poststationary or outpatient treatment including nursing care at home. In this context every decision about the necessity of hospital admission and the duration of the residence time after performed surgical interventions is an individual decision so that it is not recommended to give specific and consistent instructions for the single ENT specific operative interventions. Catalogues of residence times are no appropriate basis for therapeutic treatment decision in individual cases (see also [33]).

### 3.13 Limitations of medical activity in respect of welfare

For the physician admitted to statutory health care in an hospital (by authorisation or in medical service centres) or in private practices (physician under contract) further "risks" result from the system of statutory health insurance and the applicable responsibilities in respect of welfare.

Regarding the participation in the contractual medical care of patients covered by statutory health insurance it is essential to exactly know the structure of the prescriptions concerning performance of services, budget, and accounting because if they are not observed, recourses and strict sanctions may be the consequence. In order to reduce the risk of recourses for young and inexperienced practitioners, the principle of advice before recourse was introduced with the law on the structure of supply. When the benchmark exceeds more than 25% for the first time, no recourse will be set in the future before the physicians concerned have been at least offered a single advice. In order to achieve a calculability of the economic risk because of exceeding the benchmark and to keep legal certainty, the practitioner further has the possibility in justified cases to apply for an assessment of the examining section about the recognition of practice particularities already in the context of this advice. The confirmation may be interesting for claimed practice particularities that have not been recognized previously or have not already been under investigation (see also [34]).

However, the possibility of recourses is still a risk leading to ruinous economic consequences under certain circumstances when the legal prescriptions are not carefully observed in the context of performance and invoicing of services for patients covered by statutory health insurance. The discrepancy between the budgets being capped, the obligation of the physician to do everything possible for the health of his patients, and the interest

of an adequate remuneration hides an enormous potential conflict. The principle that the medical service is subject to the demand for economic efficiency according to § 12 SGB V further leads to the fact that a physician is limited in his generally existing therapeutic freedom because not all known and applicable diagnostic and therapeutic treatment tools are covered by the statutory health insurance. The principle that the medical services are subject to the demand of economic efficiency, however, must not lead to the situation that the physician does not take all indicated measures and does not do or arrange everything necessary for the treatment of the individual case. Of course, the specialist standard has to be observed. In cases of doubt, this may lead to the circumstance that the physician has to perform the services that are not covered by the remuneration system of the statutory health insurance. Likewise, the physician must not neglect his obligation to be present for consultation for 20 hours per week only because at the end of the quarter the planned budgetary limit is achieved and his services are no longer profitable.

### 3.14 Particularities and risks regarding the claim of medical remuneration

#### 3.14.1 Action at the location of the hospital owner

The question which tribunal is responsible for an action against a patient who does not pay the fees for the treatment performed in the hospital could not be clearly answered by the jurisdiction in the past. It is a fact: the tribunal at the place of residence of the patient can always be seized so that in cases of doubt the action can be filed there in order not to risk the time barring of the dept.

Now the BGH had to answer the question of local jurisdiction in the case of a Serbian patient who had been treated in Berlin, Germany, and clarified that (also) the location of the hospital is relevant and thus the remuneration can be claimed also at the competent court of the hospital owner [35]. This means also an advantage because it is not a remote or possibly even foreign court that has to be seized and no great distances have to be overcome. In the opinion of the BGH it is a result of the character of the hospitalization agreement that the hospital services are performed in the hospital and the patient can only have them there. According to the BGH the hospitalization agreement has an exceptional character in that way that the payments for remuneration are due at the hospital site. So it is the tribunal of the location of the hospital that is responsible in case of remuneration claims. The hospitalization agreement included that the exchange of all services was focused on the hospital site and the patient quasi "bought" those medical services. The same applies for the treatment by attending physicians and for the use of private medical services.

#### 3.14.2 Substitution and delegation of services to be performed by a physician of the patient's choice

A judgment of the Regional Court of Essen is of great importance for physicians authorized to invoice; it has now been confirmed by the BGH. The chairman of a surgery department of a university hospital has been the subject of a final judgement for fraud among others because he had accounted private medical services according to the regulations of the GOÄ. De facto, however, he had not personally performed a major part of the treatment but a substitute treated the patient without have agreed this aspect with the patient. Further, the chairman of the department had left the hospital before the end of the intervention in order to participate in a meeting that had been planned previously. According to § 4 Abs. 2 Satz 1 GOÄ, a physician of choice can only invoice services he had performed personally. Such a personal service is defined as

1. a service performed personally by the physician of choice,
2. a service performed by his permanent medical substitute in the context of effective substitution regulation (agreement on private medical service) or
3. a service performed by another physician under supervision of the physician of choice following special instructions in the case of allowed delegation.

According to § 4 Abs. 2 Satz 3, the physician of choice can nominate a permanent medical substitute who is authorized to perform the services instead of the physician of choice if the latter one is absent. This is possible and allowed provided that an effective agreement for personal service as well as an effective regulation of substitution is signed and that the physician is not able to perform the personal service due to unforeseen circumstances. Further it is allowed to find an agreement with the individual patient regarding a substitution of the physician of choice. A delegation of subordinate physicians is generally allowed – apart from the services described in § 4 Abs. 2 GOÄ, e.g. rounds – and it can be accounted as "personal service". The delegated service must be performed under supervision according to instructions of the physician of choice. This means that he can always intervene and does not only give organisational instructions. This requirement is no longer fulfilled when the physician of choice is not present in the hospital building. The physician of choice must contribute to the service and give it his personal character. Additionally the service has to be appropriate for delegation. In this context, the difference must be made between core services and subordinate services. The patient concludes an agreement about the service performed by a physician of his choice trusting in the particular experience and outstanding medical expertise of the selected physician that he wants to secure for the curative treatment against payment of additional fees because of this concern about

his health. This leads to the consequence that the physician has to personally and independently perform the core service that is characteristic for his discipline. With the background, the core service that cannot be delegated must be defined as personal service of the physician of choice based on the respective discipline or speciality of the physician, e.g. the surgical intervention. Binding instruction which services can be called core services and which ones can be delegated is not provided by the delimitation model developed by the BGH. So it is always an assessment of the single case based on the respective treatment case what in the actual situation has to be considered as core service of the physician of choice to be personally performed and what can be evaluated as subordinate service that can be delegated. This decision must be made by the physician of choice himself based on the actual treatment case. The differentiation according to the speciality suggests only a first categorization what is principally the core duty of the physician.

One task of personal performance of a duty that can be generally delegated can additionally result for the physician from a special legal regulation. The hospital physician personally authorized according to §§ 95, 116 SGB V cannot delegate his services to medical staff members, except for substitution cases in the sense of § 32a of the Authorization Regulation for physicians (Ärzte-Zulassungsverordnung, Ärzte-ZV) because he is not allowed to employ physicians or assistants; in this respect he is always obligated to perform his services personally. The same is true – apart from unpredictable or individually agreed substitution cases – for doctor of choice in the hospital because based on the contract between the selected physician and the patient he owes his personal service to the patient. The physician of choice is further limited in delegating the services described in §4 Abs. 2 GOÄ.

In recent times, the medical press and other information services with variably sustainable explanations have reported about the decision of the First Senate of the BGH dated January 25, 2012 – 1 StR 45/11 – as well as the decisions of the Higher Regional Court of Frankfurt/Main dated August 4 and September 1, 2011 – 8 U 226/10. The decisions deal with the preconditions of allowed substitution of head physicians in the context of private medical activities. Frightening slogans such as “fraud with regard to private medical accounting”, “new risks of punishment”, or “unconstitutional term of damage” have circulated. The really significant core statements of the new legal decisions and their consequences for accounting will be described in the following.

The performance and accounting of private medical services, especially in the inpatient area, was recently a question that the jurisdiction had increasingly to deal with. While the BGH concentrated at first on the effectiveness of the contents and the conclusion of special service agreements, it discussed its decision dated December 20, 2007 – III ZR 144/07 – in particular with the preconditions of substitution of the physician authorized to invoice in the context of performance and accounting of inpatient private medical services.

Based on this jurisdiction of the BGH, most hospital owners have meanwhile adopted the necessary corrections with regard to the effective conclusion of special service agreements and the implementation of the according liquidation claims so that in this respect the focus of the legal confrontations is no longer on the conclusion of the special service agreement between the hospital owner and the private patient.

Also the questions of effective substitution of physicians authorized to invoice are meanwhile mostly clarified by the jurisdiction of the BGH. Regarding the inpatient area, the according private health accounting agency provide certain forms in order to guarantee a service performance and accounting in the case of predictable and unpredictable absence of the physician authorized to invoice.

Meanwhile a criminally relevant criterion of private medical inpatient service performance and accounting is in the focus of legal and judicially discussed problems. In this context, in particular the decision of the First Senate of the BGH dated July 13, 2011, must be mentioned. With this decision, the BGH confirmed the previously issued judgement of the Regional Court of Essen dated March 12, 2010 (1 StR 692/10). Based on this judgement of the Regional Court of Essen the local accused person, a medical university lecturer tenured for lifetime, was condemned to three years of imprisonment because of corruption (§ 332 StGB) in 30 cases, associated in 3 cases with coercion (§ 240 StGB) and in one case with fraud (§ 263 StGB) as well as because of fraud, attempted fraud, and tax evasion. This judgement that was confirmed by the BGH got the attention of the medical specialised press and of the medical university lecturers, in particular with regard to the applied sentence and the associated loss of the rights of an official and the according remunerations and pensions.

Special attention was further paid to the above-mentioned decision of the first senate of the BGH dated January 25, 2012, that in case of accounting fraud because of not personally performed services transfers the normative term of damage of the Sozialgericht in the context of the accounting of private medical services to the criminal law. The up to now applied objection that the relevant private medical services – even if they were performed by a representative – have been medically indicated and necessary, is no longer in contrast to the assumption of a damage in the criminal sense, according to the opinion of the BGH. In this respect, the BGH presupposes also in cases of criminal assessment the presence of the normative term of damage. This means that a violation of the obligation of personal service for the performance and accounting of private medical inpatient services trespasses more easily the limit of punishability in the future than it has been up to now.

Up to now the normative term of damage was exclusively mentioned in social confrontations. It is well-known that a substitution of a hospital physician responsible for contractual care is not allowed in contrast to the situation of practitioners. As in the past there have been cases of substitution of authorized hospital physicians, some as-

sociations of statutory health insurances had claimed for significant recovery. In this context also criminal investigation proceedings have been introduced where the prosecution authorities regularly refer to the normative term of damage also in relation to the fulfilled offence of fraud (§ 263 StGB).

This normative term of damage becomes relevant for the private medical service performance and accounting so that the violation of the admitted possibility of substitution in the context of private medical activity may not only lead to a reimbursement of the illegally claimed fees but also criminal prosecution.

Regarding the field of inpatient private medical services and service accounting, the principles developed by jurisdiction should be observed in the context of the conclusion of special options contracts between the respective hospital owner and the private patient as well as in the case of the agreement of the service performance by substitutes. It is recommended to purchase the appropriate forms for predictable and unpredictable failure to perform from the private health accounting companies. The hospital owner is responsible because only the special options contract concluded between the hospital owner and the private patient is constitutively effective for the later claim for liquidation.

In this context the question was already asked if physician authorized to invoice can claim for compensation in the internal relationship towards the respective hospital owners if the hospital owner has not ensured that the applicable special options contracts have been concluded properly. In individual cases such compensation claims against hospitals owners have already been implemented in favour of the head physicians concerned. Finally such confrontations should be avoided by correctly managing the administrative conditions from the start.

The legal preconditions of outpatient private medical activity are completely different from the legal preconditions of effective service performance and implementation in the context of inpatient private medical treatment.

If a patient makes use of medical services in a private consultation of a head physician as self-pay or private patient, the treatment contract is exclusively concluded between the head physician operating the private consultation and the patient. Also for this treatment contract of private medical services the general regulations of the service agreement according to which especially services have to be performed in person in cases of doubt, see § 613 Satz 1 BGB (German Civil Code). Also the medical code of conduct justifies the principal obligation of the physician to perform the treatment personally as emphasized in § 19 Abs. 1 of the professional code of conduct that the physician has to operate the practice personally. Finally also the scale of fees (Gebührenordnung für Ärzte, GOÄ) confirms as the official fees that the physician can only account fees for independent medical services he has performed personally or that have been performed under his supervision according to qualified instructions (own services), see § 4 Abs. 2 Satz 1 GOÄ.

According to the regulations of the legislator and the jurisdiction of the Federal Supreme Court, especially in the context of the judgement of December 20, 2007 – 3 ZR 144/07 – also the substitution of the physician authorized to invoice is recognized in the inpatient as well as the outpatient area. The official justification of the most recent amendment of the GOÄ states:

*“With § 4 Abs. 2 Satz 3 GOÄ, the regulatory authority wanted to limit the possibility of substitution only for the mentioned certain single services to the permanent medical substitute of the head physician. In all other cases a further substitution by any physician should be admitted in the limits of the contractual law.”*

This possibility of representation should explicitly not be taken from the physicians authorized to invoice. The decision of the Federal Supreme Court and the justification of the legislator refer to the private medical, and inpatient treatment service of the physician authorized to invoice. As the requirements to the personal service of the preferred physician in the inpatient area are much higher compared to the physician performing outpatient services, the substitution must rightly be allowed for the performance of outpatient services that are accounted according to GOÄ.

This issue becomes understandable if compared to private practices where the physician can be regularly absent in the performance of their service and considering professional regulations, e.g. for reasons of leave, training, or disease. In such cases, practitioners may be explicitly substituted for up to three months per year. The time limit of this substitute possibility only refers to the care of patients covered by statutory health insurance. However, it is a fact that the possibility of substitution of practitioners is generally recognized. For self-pay or private patients the representative or the holiday substitute is actively involved in the treatment. The treatment contract with self-pay or private patients is concluded with the practice owner, who effectuates the accounting, regardless of the substitution. Within the internal relationship between the practice owner and the substitute the honorary for the substitute is arranged and accounted. If a private or self-pay patient consults the practice of a practitioner and if the practice owner is substituted by a representative because of a leave, the representative should reveal his position to the patient and offer the treatment. If the patient then declares his consent, a contract is concluded between the practice owner and the patient of which the part of the practice owner is fulfilled by the representative. The private patient is then obligated to pay the fees according to the regulations of the GOÄ to the practice owner.

The same is also true for the operation of a private outpatient consultation of a head physician. Further it must be observed that neither a written document is required for the treatment contract nor a corresponding substitute contract in the outpatient context. Principally the patient declares his consent to the treatment in an explicit or

implied way when the substitute of the head physician introduces himself as his representative.

As a precaution it is recommended to have a written consent that the patient agrees to a treatment performed by a substitute of the head physician in the private consultation. It serves only for evidence if the patient objects later in the context of possible liquidation proceedings that he had not agreed with the treatment effectuated by a substitute. From a legal point of view, however, such a written substitute contract is not necessary.

The discussion about the decision of the Higher Regional Court of Frankfurt came up because the decision of the Higher Regional Court of Frankfurt deals with an atypical case. It is different from pre-existing general situations especially because the head physician had agreed in written form with the patient concerned that he may be substituted by a certain colleague in case of unforeseen absence. In fact, he had performed the treatment later but it had never been explained for which reason the head physician had been prevented unpredictably.

Still the basic principle is valid that a substitution of the head physician in private consultation is admitted if a named physician or any other qualified physician of the department performs the service. So it is not necessary for the exercising of the liquidation procedures to transfer the enforcement of liquidation and the claim of the fees to the hospital owner. So it is recommended to contradict the reflections of the hospital owner and to refer to abovementioned statements. A more detailed analysis reveals that the decision of the Higher Regional Court of Frankfurt is due to the atypical circumstances so that the explanations of the Higher Regional Court of Frankfurt cannot be generalized.

### 3.15 About the admissibility of contract with fee-based physicians and other cooperation

There are risks on quite another side that may come up when illegal cooperation agreements are concluded. The interconnection of the outpatient with the inpatient sector plays a more and more important role in health care. Practitioners increasingly look for possibilities of cooperation with institutions offering inpatient service in order to establish another mainstay also with regard to their economic situation. On the other hand the hospitals pursue the interest to extend the value-added chain more and more into the outpatient field and thus to benefit from the outpatient budgets. Some types of cooperation are often supposed and accused without any justification to allow illegal assignments, also because of the unclear legal situation and the inconsistent case law. This is why the legislator reacted on pragmatic cooperation and provided legal clarification. The following types of cooperation are possible:

#### 3.15.1 Consultant

The term of consultant is often used in a wrong sense. This fact is also due to circumstance that cooperation contracts between practitioners and hospitals often use the term of contract with consultants even if the service described for the so-called consultant does not include consulting but core services of the hospital (surgery, anaesthesia etc.). However, the term of consultant is clearly defined in jurisdiction as a physician with another qualification who is consulted in an individual case during the inpatient stay by the treating physician, who examines the patient with regard to his speciality and suggests certain treatment procedures. This means that a consultant may be active on a mere diagnostic basis but he must not perform core services, i.e. the treatment itself.

#### 3.15.2 Fee-based physicians

If a practitioner is told to perform basic services (surgery, anaesthesia) for the hospital based on a cooperation agreement, it is the case of a fee-based physician. The feebased physician is a doctor who is self-employed, i.e. without insurable employment at the hospital, and performs services for the hospital on honorary basis. The admitted practitioner working as attending doctor is not a fee-based physician in the actual sense but an attending physician in the sense of § 121 SGB V and thus enjoys a special status with regard to the license. Uncertainty about the possibility to perform hospital services by external fee-based physicians came up because of a judgment made by the BSG on March 23, 2011 [36]. In this decision, the BSG declared cooperation between hospitals and external fee-based physicians as illegal.

The decision of the BSG was now the reason that the legislator changed the legal basis of outpatient surgeries in the context of the law of the supply structure described in § 115 b SGB V. As of June 1, 2012, it is now legally admitted contrary to the abovementioned decision of the BSG that outpatient surgeries in hospitals can also be performed by practicing physicians without license as attending physician and without employment contract on the basis of honorary agreements.

In § 115 a SGB V, the legislator clarified the cooperation of hospitals and physicians in the context of treatment before and after inpatient stays. So even hospital services before and after inpatient stays can be performed by fee-based physicians in the hospital or in the private practices, if the other preconditions for the treatment before and after the inpatient stay are fulfilled and the hospital owner is willing to perform such services.

With the law on the supply structure, the legislator has not regulated the question if also inpatient and partially inpatient services can be performed by fee-based physicians so that regarding those services the use of fee-based physicians was reluctant, even if the scheduling of fee-based physicians for inpatient services was not explicitly forbidden according to the current legal situation. The legislator now want so close this gap and as

of August 01, 2012, a revision of § 2 of the Hospital Remuneration Law was issued that will come into effect on January 01, 2013. According to this statement inpatient and partially inpatient hospital services can also be performed by physicians that are not employed on a regular basis. This means that as of January 01, 2013, it is guaranteed that the use of external fee-based physicians is admitted without any doubt for the performance of inpatient and partially inpatient services.

### 3.15.3 Employment in a hospital

For practitioners further the possibility is clearly stated in § 20 Abs. 2 of the Authorization Regulation for physicians (Ärzte-Zulassungsverordnung, Ärzte-ZV) that they can be employed part-time in a hospital beside their contractual activity. The regulations of the BSG, that were valid up to now, stating that in case of full license other employment was limited to 13 hours and in case of part-time license it was limited to 26 hours has now been relaxed. It is most important that the physician is in a position to be at the patient's disposition to an extent that is appropriate to his service obligations and to offer consultation during the usual hours of practice. If this aspect is guaranteed (i.e. at least 20 hours per week consultation in cases of full license), a secondary employment will be allowed even beyond the limit of 13 hours. However, it remains open where the future limit of the extent of such secondary employments is; a matter that will have to be defined by jurisdiction.

### 3.16 No punishability of physicians because of corruptibility

The Grand Criminal Panel that is responsible for the assessment of principal legal issues has decided in its eagerly awaited principal decision that physicians who accept gifts or other benefits from pharmaceutical companies for the prescription of certain medicine are not punishable for corruptibility [37]. The decision was based on the question if physicians in private practices licensed for the contractual care must be considered as officials in the sense of § 11 Abs. 1 Nr. 2 StGB and/or as representatives of the statutory health insurances in the sense of § 299 StGB when they accomplish the tasks that are attributed according to § 73 Abs. 2 SGB V, in particular the prescription of remedies. These characteristics are the criterion for punishability according to the offence of corruption described in the penal code. The BGH now clearly stated in its decision published on June 22, 2012, that practitioners are neither to be considered as officials nor as representatives of the statutory health insurances so that punishability because of corruption is excluded according to the currently valid penal provisions.

This decision was based on a case where a pharmaceutical manufacturer paid provisions of 5% of the selling price to physicians when they prescribed a certain medicine. The Regional Court of Hamburg condemned to fines the doctor for corruptibility and the pharmaceutical rep-

resentative for corruption. The pharmaceutical representative appealed against this judgement at the Federal Supreme Court (Bundesgerichtshof, BGH). The BGH explained in its decision that on the one hand the health insurance companies have to be considered as institutions of public administration and the system of the statutory health insurances is one of the obligations resulting from the welfare state principle. On the other hand, however, physicians are not employed to cover tasks of public administration. A self-employed physician is neither an employee nor an executive of a public institution and thus he is not an official. Because of the individual choice of the patient covered by statutory health insurance, he becomes active. His relationship towards the patient – regardless the obligation to participate in the contractual service associated with the licence – is significantly characterized by the personal confidence and freedom that are mostly not subjected to the regulations of the statutory health insurances. The involvement of the physician in the system of the public services does not attribute the character of administrative functions of the government to contractual activities. Further, a physician is not an official representative of the statutory health insurance. On the one hand, physicians and health insurances must be considered as equal partners regarding the care of patients covered by statutory health insurances. On the other hand, it is not the health insurances that choose the doctor but the patients, a choice that the health insurance has to bear. So this is by no means an acceptance of the task by the physician for the health insurance, also in the context of the prescription of medicine. This decision is very welcome because it strengthens the medical profession as liberal profession and focuses on the relationship between doctor and patient. The BGH emphasizes correctly in its judgement that the self-employed physician is neither employee nor an executive of a public authority.

However, this decision must not be misunderstood in the sense that illegal benefits towards physicians are only measured based on penal regulations. Moreover such payments must be measured based on the valid regulations of the professional law, the social law as well as the competition rules and the law governing advertising of medical products that qualify the claim or acceptance of illegal benefits as illegal and sanction it accordingly. So according to § 31 of the professional code of conduct (Musterberufsordnung, MBO) doctors are not allowed to claim or accept money or other advantages for the prescription or the purchase of drugs or auxiliary means. Further, § 32 MBO contains the interdiction to claim or accept gifts or other benefits if the impression may come up that the independence of the medical decision is influenced. Those interdictions are the result of the obligation contained in § 30 MBO that physicians have to keep their medical independence for the treatment of patients in all contractual and other profession relationship toward third parties. Also in the SGB V such regulations can be found. According to § 128 of the SGB V, payments to doctors are forbidden in the context of the prescription

of medications, remedies, and adjuvants. This regulation was recently completed in the context of the law regulating the structure of supply by another paragraph in which the legislator clearly states that qualified physicians who claim or accept illegal benefits or who influence persons with health insurance to utilize private medical services instead of services to which the patient is entitled and that are paid by the statutory health insurances violate their contractual obligations. Violations against those regulations may finally lead to the loss of the licence and approbation.

Finally also the BGH emphasized in his decision that it the decision was only to make if corrupt behaviour of qualified doctors and staff members of pharmaceutical companies was a punishable offence according to the currently applied penal law. Regarding the question of this can be considered as criminal conduct and the creation of new penal regulations was required must be decided by the legislator. If the latter establishes new categories of punishable offences that allow also a criminal action against such behaviour in addition to the prosecution based on professional and contractual law remains to be seen.

## 4 Correct behaviour in case of damage

As already described, physician can be exposed to judicial disputes because of most different reasons. Beside civil compensation and smart money claims filed by patients, more and more the question of criminal responsibility has to be faced, for example for accusation of accounting fraud or bodily harm in the context of missing information and errors in treatment. Very special, additional risks result from the judicial management of medical accidents. If the treating physician commits an error in treatment or if at least he is accused to have committed such an error, there are some very important rules to be observed. It must be recognized and cared for by means of organisational instructions that treatment incidents are followed by adequate reactions.

### 4.1 Communication obligations and statements

In case of harmful events that may lead to compensation claims it is most important that the event is immediately communicated to the liability insurance, the administration of the hospital, and if needed to the superior or the physician who is responsible for the treatment of the patient. It does not matter if already a letter of a lawyer or an official complaint exists or the patient announces or asserts claims. Moreover it is decisive if solid evidence for the assessment of compensation claims are given even if personally an inappropriate behaviour is excluded. In the context of writing down statements on the course of the events to be submitted to superiors, the hospital

administration, or the liability insurer the following aspects should be observed: As in case of a judicial complaint all documents are confiscated and the addressees of the report might be called as witnesses, attention must be paid to statements. Everything that a physician reveals truly in this context can come to the notice of the prosecution authorities and possibly be used to the physician's disadvantage. Written statements should limit exclusively to unbiased description of the facts.

### 4.2 Behaviour towards patients

In case of impending confrontation with a patient or his relatives after a medical incident, the further development often depends decisively on the personal behaviour of the physician. An open personal dialogue often avoids at least the official complaint filed by the patient. If the patient searches the dialogue with the physician, the latter should not refuse. In this context, true statements do not put the physician's insurance cover at risk. Of course the physician is also allowed to tell the patient the truth when he is asked, even if it means the admission of an error in treatment. However, it should be avoided to confess any guilt or to recognize the liability because in this way the personal liability of the physician may be justified. Of course the physician may deny negligent behaviour or refuse to give information to the patient. Nobody is obligated to incriminate himself and contribute actively to his/her own prosecution. If an official complaint was already filed, the dialogue with the relatives or the patient concerned seems no longer to be reasonable because the official investigations are underway and the case is withdrawn from the exclusive handling of the physician and the patient. In every dialogue, witnesses should be included and the contents of the conversation should be documented.

### 4.3 Handing over of treatment documents

If required by the patient, (copies of) the treatment documents have to be handed over. However, he can only claim the objective documentation and findings, subjective annotations or suspected diagnosis can be blackened or deleted. But in the context of the law of patients' rights the planned new regulations may be problematic while personal impressions or subjective perceptions of the treating physician have to be principally revealed. Up to now, the jurisdiction of the BGH recognised that the patient's right to have access to the documents does not include the personal annotations of the physician. Not only because of the inevitable emotional character and the contained subjective perceptions but also because of the indications on later given up suspected diagnoses, this right of accessing those documents could be refused because those personal annotations were made especially aware that no one else will access them. Those annotations can thus be blackened in the documents before they are handed over to the patient as long as the

physician marks those passages. Also in the future this situation should remain. A total renouncement – as suggested according to the explanatory memorandum – of personal annotations does not represent an alternative.

#### 4.4 Behaviour towards police and public prosecution authorities

If searching or possibly seizures of patients' records are performed, readiness for cooperation should be demonstrated in any case. It is well-known that the public prosecution authorities generally do not work discretely. Already this may lead to a significant damage for the physician concerned – even if the accusations prove to be false. Should it turn out that searching can be expected, it is recommended to establish contact with the responsible public prosecution authorities via a specially qualified lawyer. In this context an absolute readiness for cooperation should be indicated and confirmed that all required documents will be handed over so that an eye-catching searching can be countered in advance.

#### 4.5 Procedures for regulation and mediation

The evaluation panels and conciliation boards for medial liability matters established since 1975 at the Medical Councils offers an independent assessment by experts and extrajudicial settlement of disputes in case of accusation of errors in treatment (<http://www.bundesaerztekammer.de>). About a quarter of all assumed cases of medial liability, are evaluated by the evaluation panels and conciliation boards. While the evaluation panels evaluated the medical activity itself, the conciliation boards clarify the matter and based on an expert's statement they submit a proposal for settlement of the dispute. Both procedures are free of charge and presuppose the consent of the patient as well as the physician. In the majority of the cases, those procedures lead to an extrajudicial settlement of the dispute. However, the patient remains free to bring a legal action against the physician, anyhow. Also for this reason, a professional legal representation is definitely recommended, also because patients sometimes attach the documents of the conciliation procedure to their complaint so that the statements of the physician gain in significant importance also in possible penal proceedings. If the physician receives a statement of claim, the proceedings are mainly performed before the Regional Court leading to the consequence that the physician is forced to be represented by a lawyer.

#### 4.6 The role of liability insurers

According to n° 5.2 of the General Terms and Conditions of Liability Insurance (Allgemeine Haftpflichtversicherungsbedingungen, AHB) the insurer is considered to be authorized in civil matters to make any declarations on behalf

of the policy owner that appear appropriate in order to settle the loss or defend against claims for damage. The insurer may so adopt any measures that are related to the regulation of damages and he may instruct the physician to behave in the according way. So he has the right to pay compensation, not to accept the claim of the patient, and to lead the action through several instances. Also the consent to perform mediation or the assessment by the expert evaluation panel must only be given after consultation and in accordance with the liability insurer.

### 5 Perspectives

Physicians in hospitals and private practices not only have to expect legal consequences when they negligently commit an error in treatment or do not or not sufficiently inform the patient about the upcoming intervention previously to surgery. Also with regard to accounting of medical services and the performance of services in the system of the statutory health insurances careful attention must be paid to observe the specific legal requirements. This aspect applies especially with the background that the legislator and the jurisdiction increasingly tend to emphasize the protection of the patient. This becomes not only obvious with the standardisation of the currently existing patients' rights in the law of patients' rights but also with the increasing requirements to the extent of information obligation. These aspects confirm the image of the patient who has to be protected from the physician. At the same time, the legal courts as well as the legislator start limiting the possibilities and medical cooperation of physicians by strengthening the formulations and the application of the rules about forbidden assignments. Further a general mistrust of the population towards the physicians is stirred up. In this context, significant risks and dangers are present with the signature of the treatment contract not only for the patients but also for the physicians. It would be desirable that the according legal conditions are again strengthened in the future so that the necessary basis of trust could be established between doctor and patient for a successful medical treatment.

### Notes

#### Competing interests

The author declares that he has no competing interests.

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