DIGITAL RADIOGRAPHY AND ELECTRONIC DATA STORAGE FROM THE PERSPECTIVE OF LEGAL REQUIREMENTS FOR RECORD KEEPING

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ABSTRACT

In some countries physicians and dentists are required by law to keep medical and dental records. These records not only serve as personal notes and memory aids but have to be in accordance with the necessary standard of care and may be used as evidence in litigation. Inadequate, incomplete or even missing records can lead to reversal of the burden of proof, resulting in a dramatically reduced chance of successful defence in litigation. The introduction of digital radiography and electronic data storage presents a new problem with respect to legal evidence, since digital data can easily be manipulated and industry is now required to provide adequate measures to prevent manipulations and forgery. **(J Forensic Odontostomatol 2003;21:40-4)**

Keywords: Duty to keep records, digital radiography, electronic data storage, burden of proof

In some countries physicians and dentists are required by law to keep medical and dental records. Together with the duty to take due care and the duty to provide information, this requirement constitutes one of the most significant responsibilities towards the patient.[1,2,3] The practice of record keeping regarding to patient treatment is certainly as old as the practice of medicine itself and is a vital aspect of coherent, coordinated and cogent diagnostics and therapy. What have, however, undergone a fundamental change in the course of time are the legal classification, function and character of medical records. Whereas they were once seen largely as an informal "aide memoire" for the doctor, to ensure coherence and continuity of a treatment, a precedent ruling by the 6th division of the German Federal Court of Justice in 1978 [4] brought about a radical change in prevailing opinion on the legal status of mandatory record-keeping. Records, not only adequate for medical practice, but which left the individual doctor plenty of subjective leeway, ceased to be normal procedure. The new ruling by the Federal Court of Justice stated that the doctor had to make the necessary recordings on the findings and diagnoses made and on the measures and therapies implemented while carrying out his profession. It was thus mandated that the objective measure of the medical duty to take due care, deriving from § 276 of the German Civil Code, i.e. the objectively necessary care, [5] was now to apply to medical record-keeping too. Primarily, it is no longer what the individual doctor considers subjectively as adequate for records but rather what is objectively seen as being essential to meticulous record keeping that now becomes a legal requirement.

This precedent ruling was expressed in the regulations governing the medical and dental professions, which are largely consistent in their wording and spirit: "The necessary records are to be kept on the findings made and the measures taken while carrying out professional activities. Medical records are not merely reminders; they also serve the interests of patients in proper record-keeping."

According to case law and to the vocational regulations adapted to it, then, the physician and the dentist are contractually accountable to the patient with respect to what they have diagnosed and what measures they have taken.

The legal aspect of the duty to keep records develops its impact in medical liability litigation, especially in evidentiary law. Medical failure litigation is characterized by a specific lack of evidence provided by both parties, but especially by the patient. To illustrate this, some evidentiary principles of the law of civil procedure are outlined in brief.

Each party bears the burden of proof for the presence of the actual preconditions of the legal standard in its favour. If, then, one party asserts a claim for compensation, it is within its obligation to present those facts which are essential for the existence of such a claim according to civil law in order to convince the court. The burden of proof gains practical significance if the issue from which one party wishes to derive a claim, or individual facts relevant to the decision, cannot be verified even when all reasonable and available means have been exhausted (referred to as "non liquet", i.e. lack of clarity).

In those cases, the lack of proof will be detrimental to the party bearing the burden of proof for the respective fact. If, then, a "non liquet" remains in the lawsuit, the party bearing the burden of proof will lose the case. If, accordingly, a patient goes to law because they were or believed to have been treated defectively, they bear on principle the burden of proving in their submission that their physician or dentist had caused impairment negligently and culpably to them during the treatment. In most cases, however, the patient, as a medical novice, initially has substantial problems in furnishing this proof because of lack of medical knowledge. In many cases the issue can only be cleared up by accessing the medical records. If these records are unavailable or incomplete, the patient will find themselves in a hopeless situation because of their inability to prove their submission in the event of the categorical rule of the burden of proof being applied consistently. This would obviously be in crass contradiction of the supremacy of the rule of law and to the constitutionally guaranteed equality of the litigating parties. In such cases, the furnishing of proof by the patient was facilitated by giving the judges greater scope in interpreting this law. Such facilitation can go so far as to reverse the burden of proof completely if one party culpably makes the furnishing of proof more difficult or even impossible for the other. This applies in particular if a physician or dentist infringes their duty to keep medical or dental records, i.e. fails to take necessary notes, makes notes belatedly or even alters notes.

At court, the physician or dentist has to explain their treatment procedures to the patient instituting the legal proceedings. This requirement is fulfilled by submitting properly kept records. If the dentist or physician fails to submit appropriate, and adequate records, the "non liquet" in the legal dispute is imposed on them. The term "principle of the equality of litigious weapons" was introduced in this context. [6]

Another important advance in evidentiary law in favour of patients was made by the German Federal Court of Justice in 1982. With several lower-instance courts having affirmed the patient's right to inspect their records,[7,8] the Federal Court of Justice as the supreme court categorically gave the patient pre- and extra-trial access to these records. [9,10,11]

The fundamental right of the patient to inspect their records and to have them surrendered to them was confirmed and substantiated by a number of subsequent judicial decisions. According to the Federal Court of Justice, the physician or dentist is not allowed to oppose the serious wish on the part of the patient to view the notes of their health status and treatment administered. This additional contractual claim was derived from the patient's fundamental right to self-determination and personal dignity. [12]

This raises the additional question of what is covered by the duty to keep records, in particular whether radiographs are also classified as part of these records. Radiographs are not records in the narrower sense, but a verdict delivered by a German Higher Regional Court clearly illustrates that the principles underlying the duty to keep records are also applied to radiographs in court decisions. In the case adjudicated by the Higher Regional Court, [13] a female patient had had two dental implants inserted in the left and right lower canine regions. The implants had to be removed some time later because of fracture, loosening and inflammation. The patient sued the dentist for compensation and damages for personal suffering, asserting that the implants had not been placed in accordance with accepted proce-

dures. The Higher Regional Court explained that it is a principle that the patient has the burden of presentation and proof for all aspects underlying the claim. Under certain circumstances, however, the patient can benefit from facilitation that may go even as far as reversal of the burden of proof. [14] Consideration must be given to such a reversal if circumstances for which the physician or dentist is responsible have given rise to special impediments to clarification of the causes of the reported complications. This might be the case in the event of a gross treatment error, e.g. a fundamentally incorrect diagnosis, or of failure to perform control examinations, if the physician or dentist had failed to perform examinations and to record the findings, even though this was medically necessary beyond all reasonable doubt, or if incomplete records resulted in there being no opportunity to determine whether necessary measures were in fact taken.

Because there were no postoperative radiographs of the implant sites, the principles underlying the probative burden were applied to the detriment of the dentist. It could no longer be assessed whether the complications had been due to the implants having been incorrectly inserted or to inflammatory processes beyond the dentist's control. In such a case, postoperative radiographs are essential not only as evidence but also as a means of preventing harm to the patient. As faulty implantation is just as likely a cause of failure as any other factor, the dentist had to bear the consequences of being unable to clarify the reasons for failure.

This example shows that court decisions subject radiographs to the principles of the duty to keep medical records. Beyond their diagnostic and therapeutic purpose, radiographs have, of course, an exceptionally high documentary value.

In recent times, the duty to keep medical and dental records and the legal problems inherent in this duty have taken on a new aspect with the increasing relevance of computer-aided documentation and digital radiographs. Electronically and digitally recorded radiographs and other data tend to be problematic from the judicial point of view because they can be manipulated. Manipulating conventional radiographs involves relatively high technical effort, whereas digital data can be modified with relative ease. This accounts for the problems involved in classifying digital radiographs as legally evidentiary records. [15]

Let us return to the case at the Higher Regional Court, where the burden of proof was facilitated for the patient because postoperative radiographs had not been taken. Had such radiographs been taken and had they shown the implants to have been inserted perfectly, the dentist would not have been made liable. On the other hand, the possibility of a postoperative digital radiograph having originally shown the implants to have been imperfectly inserted but having been manipulated – without the patient being aware of this – so as to represent normal findings illustrates the problems of digital radiographs being submitted as evidence. [16, 17]

This problem is very much the same with all digital medical records, [18] which – at least until now - have not been accorded the same authenticity as traditional, handwritten records because they can be readily manipulated. The latter can, of course, also be manipulated, but there seem to be greater scruples about doing this because the actions involved in forgery - such as erasing, overwriting and changing - are more likely to activate a sense of guilt than adapting digitally recorded data, which might be perceived as on par with correcting typing errors or merely exploiting modern technology. Moreover, there is a greater likelihood of such manipulations being detected in conventional rather than in digital records.

The criminal energy invested in manipulating a digital radiograph is probably equal to that involved in forging a hand-written record.

Nevertheless, there is a general consensus in the legal literature and in courts that digital radiographs and other digital data need protection from unauthorized manipulation and must be made secure. In the case of image data files, conservation of the unprocessed original records is essential and subsequent manipulations such as rotation, modification of gradation and brightness, correction of gamma values etc. must be saved to serve as a complete track record and evidence of the manipulation.

Another legal question arises from the risks concerning data security, especially the long-term availability of the image data and details of the imaging process and its circumstances. In addition to protecting personal data from unauthorized access and transfer to third parties, digital radiography requires an additional safety feature: protection against inadvertent loss. Twenty eight of the German Radiography Ordinance regulates the obligation to keep radiographs and notes on radiographs. It stipulates *inter alia* that radiographs have to be kept for at least ten years and thus stipulates indirectly that all technical systems required for data access have to be maintained for this period. This implies an exceptionally long-term technical and therefore economic dependence of the dental practice on the manufacturer of the digital radiography unit.

In addition to the Radiography Ordinance, the regulations governing the safekeeping period for medical and dental records mostly specify ten years unless a longer period is stipulated.

In addition, these regulations require special security and protective measures for digital recordings on electronic data carriers or other storage media to prevent them from being manipulated, irreparably damaged or used for unauthorized purposes.

Digital radiography has so many advantages over conventional techniques that banning its use in consideration of legal uncertainties would seem to be unrealistic. Manufacturers and users of digital radiography and computer-based documentation systems must bear in mind not only the organisational and economic aspects but also the value of the records as legal evidence. This can simply be solved by devising security measures, which have in fact already been implemented and involve only moderate expenditure on software supplementation, e.g. digital signature technology (DST). [19,20,21] Security against unauthorized access to digital records also has to be guaranteed.[22] It will probably take some time for these new systems to become widely used but there is no doubt that electronic data acquisition systems are here to stay and are an innovative fact of life.[23]

Apart from their fundamental importance, including dental identification, [24] dental records are also gaining steadily in importance as legal documents. Many patients will, once a lawsuit is under way, be seized by tactical amnesia and challenge everything that has gone before. In written briefs this is worded roughly as follows: All statements by the opposing party are disputed unless otherwise explicitly acknowledged. In such situations, well kept records are of inestimable value to the dentist, especially if they carry the probative burden (e.g. for correct informing of the patient and for the patient's consent to treatment), especially as the jurisdiction makes high demands on the quality of medical and dental records while taking the view that adequate records are plausible in general.[25] And yet, many liability cases expose the whole dilemma of inadequate or even missing documentation, inevitably leading to a deterioration in the dentist's litigious position.

As a conclusion, it can be stated that there is reason enough for the dentist or physician to pay attention not only to their duty to take due care and to provide the patient with adequate information but also to their record-keeping duty, to avoid being caught with their back to the wall. This is true for conventional as well as electronic records and radiographs

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