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Regulating open disclosure: a German perspective

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Abstract

The issue of open disclosure has received growing attention from policy-makers, legal experts and academic researchers, predominantly in a number of English-speaking countries. While implementing open disclosure in practice is still an on-going process, open disclosure now forms an integral part of health policy in various American states, the UK, Canada, Australia and New Zealand, with a number of measures having been put in place to encourage open disclosure and to mitigate some of the barriers to such open communication. In contrast, this issue has received little attention in non-English-speaking countries and there is currently no empirical data relating to actual practice or practitioners' attitudes and views in most countries in continental Europe. This article critically examines Germany's current approach to open disclosure. It finds that the issue plays no significant role in German health policy with very limited measures explicitly concerning such communication currently in place. While a number of aspects of the wider regulatory framework appear to be supportive, Germany is still in the early stages of a systematic approach and additional measures are required to further promote open disclosure within the self-governing German healthcare system. This exploration provides an example of a non-English-speaking country's approach to open disclosure and may be of particular interest to neighbouring German-speaking and civil law countries such as Switzerland and Austria.

Keywords: truth disclosure, medical errors, guideline, Germany

Open disclosure is the prompt, compassionate and honest communication with patients and families following a healthcare incident that has resulted in harm [1–3]. While the open disclosure process can vary, it typically includes an acknowledgment; an expression of regret or an apology; an investigation into the incident; providing a factual explanation of what happened and explaining the steps being taken to manage the incident and prevent recurrence [1, 2]. The issue has received growing attention from policy-makers, legal experts and academic researchers, predominantly in a number of English-speaking countries.

The development of open disclosure

The practice of maintaining 'a humanistic, care-giving attitude with those who had been harmed, rather than respond[ing] in a defensive and adversarial manner' was first articulated at Montreal Hospital [4]. Soon after this in 1989, Dr Steve Kraman, faced with a highly litigious environment and rising legal costs, began openly sharing incident information at the Veteran Affairs Hospital in Lexington. This approach not only led to a significant reduction in complaints and legal costs, but has improved collaboration within the healthcare relationship [5, 6]. Similarly, Richard Boothman *et al.* [7] have achieved impressive results with disclosure in a very challenging legal environment at the University of Michigan.

The disclosure of healthcare incidents, however, has evolved over the past two decades from a strategic response to rising legal costs focusing on organizational risk minimization, to an ethical practice seeking to re-establish trust by meeting patients' needs and expectations following an incident and to improve the quality of care. The Massachusetts Coalition for the Prevention of Medical Errors' 2006 document 'When Things Go Wrong', for instance, was explicit in privileging ethical considerations over legal, financial and reputational issues [3].

Barriers to open disclosure

There is, however, currently a large divergence between patients' preferences to be told about healthcare errors and current practice. While health practitioners typically endorse disclosure in principle, they often do not share information

in practice, with studies suggesting that as few as 30% of harmful errors are disclosed to patients [8].

The most often cited barrier to open and honest communication following an incident is the fear of legal liability—that communication may lead to a lawsuit against them, a lack of legal protection when providing information and apologies and the potential loss of liability insurance if they say too much or the wrong thing [8, 9].

Legal concerns, however, are not the only factor that may lead practitioners not to disclose incidents. Indeed, such concerns can often disguise deeper emotional fears. John Banja, for instance, has argued that a harm-causing error can be such an assault to the practitioner's sense of competency and adequacy that various protective, self-regarding and defensive psychological responses can be triggered which can often lead to open communication being avoided altogether or conducted inadequately [9].

Regulating open disclosure

Open disclosure now forms an integral part of health legislation and policy in a number of English-speaking countries, with various measures having been put in place to encourage disclosure and mitigate some of the barriers to such communication—a reflection also of the increasing focus on the systems approach to errors in healthcare [10].

Governmental and organizational standards and policies have been developed to promote a clear and consistent approach to open disclosure in various American states [11], the UK [1], Canada [12], Australia [2] and New Zealand [13]. A number of American states have also implemented specific 'disclosure laws' which mandate disclosure in certain circumstances and 'apology laws' to protect the communication from being used in a legal action as proof of the practitioner's negligence [14]. In addition, professional organizations' ethics standards in these countries often explicitly endorse open disclosure [9].

Such measures are, of course, no panacea; there remains a challenge of translating statements of principle into practice, which is an on-going process in these countries. However, such interventions can play an important role in influencing professional, national and organizational cultures, which have a significant effect on the practice, values and individual attitudes in a workplace. While these cultures are dynamic, they also have considerable inertia which requires both strong interventions and time to change [15].

Indeed, research in these English-speaking countries suggests that these measures are making a difference. Rick Iedema *et al.* [16] in Australia, for instance, have found that the disclosure of incidents is becoming more frequent and that one of the driving forces behind this change has been state and health provider policies, along with the increase in specially trained staff.

Open disclosure in Germany

In contrast to the English-speaking countries described above, the issue of open disclosure currently plays no significant role in German health policy. While the importance of reporting incidents as part of quality improvement programmes has been recognized, lacking from the ongoing discussion has been the emphasis of the needs of patients in such situations. Although there was a factorial survey of the general public regarding medical errors in 2004 [17], there is currently no empirical data relating to patients' or practitioners' attitudes and views regarding open disclosure, and very little is known about current practice. Indeed, open disclosure has not yet received a lot of attention in non-English-speaking countries in general. There is, for instance, currently no empirical data relating to actual practice or patients' and practitioners' attitudes and views in most countries in continental Europe.

Wider context

Before examining open disclosure in Germany, it is helpful to have an understanding of the wider context in which this discussion is situated.

While commentators agree that a US-style malpractice crisis has not occurred in Germany, and is unlikely to do so, the increase in malpractice litigation is an issue of concern [18]. The increase in litigation began reasonably early in Germany, with ~6000 claims a year already being made by the end of the 1970s (compared with the 500 claims a year in England estimated by the Pearson report in the mid-1970s). The current figure is estimated to be around 20 000–35 000 (a recent study suggests around 6000 claims a year are made in England). The average cost of claims in Germany, including those settled or abandoned, also trebled between 1981 and 2001, and in some specialities such as gynaecology the increase has been six-fold [18]. The associated increase in liability insurance premiums for health professionals has received growing attention [19].

It was in response to the increase in malpractice cases and a growing climate of distrust between doctors and patients that had emerged, that led to the Expert Commissions and Arbitration Boards (*Gutachterkommissionen und Schlichtungsstellen*) being established in 1975 by the State Medical Associations (*Landesärztekammern*). This process provides free expert appraisal and extrajudicial conciliation where all parties consent to proceedings. The use of this mechanism has steadily increased over time, with a quarter of all suspected cases of medical liability now being assessed by the Expert Commissions and Arbitration Boards, and their non-binding decisions enjoy high acceptance rates (~90% of all cases settled) [20]. While data from the Expert Commissions and Arbitration Boards are pooled in the national Medical Error Reporting System for systematic learning, the adversarial proceedings themselves are focused on establishing whether or not there is a medical error for which the practitioner is liable to pay compensation.

It also appears that many German hospitals are currently not taking a systematic approach to medical errors. In 2010, the University of Bonn's Institute for Patient Safety conducted the first detailed national survey concerning the implementation status of clinical risk management in German

hospitals. The survey was sent to all 1820 German hospitals with 50 beds or more and had a total of 484 respondents. The results showed that clinical risk management and issues of patient safety were an integral part of the agendas for the meetings of the hospital management in only 39% of respondents and staff were regularly offered training in clinical risk management in only 25% of respondents [21].

Current measures

There are currently very limited measures explicitly concerning open disclosure in place in Germany. There are no governmental (federal or state) laws or policies relating to open disclosure. It also appears that the majority of German healthcare organizations do not have any internal standards concerning communication with patients and families following an error. The survey conducted by the University of Bonn included a question asking whether there is an internal hospital standard which ensures that patients or their relatives are informed of serious medical errors resulting in damage promptly and receive an offer of support. Only 22% of respondents currently have such a standard; 21% have no standard but plan to develop one and the remaining 57% have no standard and have no plans to develop one [21].

There is also currently no mention of open disclosure in the Federal Medical Association's (*Bundesärztekammer*) (Model) Professional Code of Conduct, nor in the derived Professional Codes of Conduct of the State Medical Associations (*Landesärztekammern*).

Thomeczek *et al*. [22] have argued, however, that the wider legal framework that exists in Germany is generally supportive of communication with the patient after an incident. Indeed, unlike the situation in most English-speaking countries, the healthcare relationship under German law is almost invariably a contractual one [18], and the treatment contract places obligations on healthcare providers to inform patients of incidents and complications during the course of treatment. However, the predominant view is that there is no legal obligation on the doctor to inform the patient that they were at fault for the incident or complication [22].

In 2008, section 105 of the *Insurance Contract Law Act* (*Versicherungsvertragsgesetz*) was added to provide that insurance agreements that include 'non-cooperation' clauses, which releases the insurance company from its obligation to pay costs if liability is admitted without prior consent, are now invalid.

In principle, practitioners are now free to speak to patients about the incident, give them a report of the facts and express regret, and may also accept liability without losing their insurance cover [22]. However, if the practitioner accepts liability for an incident, they may have to prove to their liability insurer that this claim was valid to be covered. Legal commentaries therefore recommend that practitioners do not rely on section 105 without speaking to their insurance company prior to disclosing incidents to patients [23]. Unfortunately, it appears there is currently no consistent approach to this dilemma by the liability insurers, therefore denying practitioners legal security.

The legal dilemma is exemplified in a brochure for practitioners by the German Medical Insurance (*Deutsche Ärzteversicherung*) that is entitled 'Tips for proper behaviour in a liability claim' [24]. While the publication encourages practitioners to speak to the patient as soon as possible following an incident, to take the patient's concerns seriously and to be empathic and compassionate, it also cautions the practitioner not to accept any liability, as this could risk their insurance cover.

A positive step forward, however, has been the recent publication by the German Coalition for Patient Safety of a brochure entitled 'Reden ist Gold', a play on the German saying 'Talk is silver, silence is golden' (*Reden ist Silber, Schweigen ist Gold*). The Coalition for Patient Safety (*Aktionsbündnis Patientensicherheit*) (www.aktionsbuendnis-patientensicherheit.de) is a non-profit organization formed in April 2005 by health professionals, their associations and patient organizations to build a common platform to improve patient safety in Germany.

Rather than following its counterparts in Switzerland and Austria, which have translated the 'Massachusetts Coalition for the Prevention of Medical Errors' 'When Things Go Wrong' into German, the Coalition for Patient Safety wanted a more practical guide for practitioners in the German context, which includes an outline of the legal situation surrounding such communication. This is intended to provide practitioners with greater clarification and will hopefully lead to this issue receiving more attention in the German health system.

It should be noted, however, that the Swiss Patient Safety Foundation (Stiftung für Patientensicherheit) (www.patientensicherheit.ch) offers interactive and practical oriented workshops concerning communication with patients and families after an incident, something that is not currently available in Germany.

Further possible measures

While a number of aspects of the wider legal framework currently in place in Germany are supportive of open disclosure and the Coalition for Patient Safety's brochure is a positive step forward, Germany is still in the early stages of a systematic approach and additional measures are required to further promote open disclosure.

The need for strong interventions is arguably more important in Germany as it is (just like its German-speaking neighbours) seen to be a high 'uncertainty avoidance (UA)' country. As Helmreich and Merritt [15] note, the need for rules in a high UA country is seen as an emotional need to resolve ambiguity quickly and leave as little as possible to chance, and that discomfort over uncertainty can lead to either 'strict adherence to ineffectual rules (rules for rules' sake) or hasty, unreasoned action aimed at alleviating the emotional discomfort associated with the uncertainty'. Thus, in the absence of clear guidance and more legal certainty in relation to the communication of healthcare incidents to patients in Germany, it appears very unlikely that the

attitudes and behaviours of practitioners will change towards more transparency and openness.

It is, however, helpful to put any possible measures in the context of the wider theoretical framework for quality assurance that exists in Germany, which is consistent with the logic of the German social market economy. While health policy set by the Federal Ministry of Health establishes the legal regulatory framework in Germany, the regulatory details are generally set by corporatist bodies in the self-governing German healthcare system [25]. It is, therefore, very improbable that we will see in Germany the kind of national and state standards and laws introduced in some English-speaking countries.

Federal Medical Association. The Federal Medical Association (*Bundesärztekammer*) (www.bundesaerztekammer.de) is the umbrella organization of medical self-government in Germany and represents the professional interests of German doctors. As a working group of the 17 State Medical Associations (*Landesärztekammern*) the Federal Medical Association is not a public body itself, but an unincorporated association. The German Medical Assembly (*Deutscher Ärztetag*) is the annual general meeting of the Federal Medical Association and acts as the 'parliament of the medical profession', including delegates from all the State Medical Associations. The German Medical Assembly's tasks include setting nationwide regulations and articulating and adopting positions of health policy. Given the important role medical self-government has in Germany, the German Medical Assembly adopting a position in support of open disclosure would be highly influential. Such a position could be supported by the inclusion of open disclosure in the Federal (Model) Professional Code of Conduct, and the respective Codes of Conduct at the State level.

Statutory Health Insurance. Statutory Health Insurance (*gesetzliche Krankenversicherung*) is one of the five pillars of the German social security system under which ~90% of the population is insured. The National Association of Statutory Health Insurance Funds, together with the National Association of Statutory Health Insurance Physicians, the National Association of Statutory Health Insurance Dentists and the German Hospital Federation forms the Federal Joint Committee (*Gemeinsame Bundesausschuss*; www.g-ba.de). The Federal Joint Committee was established on 1 January 2004 by the *Statutory Health Insurance Modernisation Act* and in addition to deciding which benefits are to be included in the statutory health insurance catalogue, it has the duty to ensure quality in statutory health insurance accredited facilities and decides quality assurance measures for outpatient and inpatient health care. Since 1 July 2008 following health reforms, the Federal Joint Committee has made all decisions in a single cross-sectoral decision-making body capacity. By developing directives or guidelines that specifically include open disclosure as part of quality assurance, the Federal Joint Committee could set the framework for a broader implementation of open disclosure in the German health system.

Federal Ministry of Health. The Federal Ministry of Health is responsible not only for maintaining and enhancing the quality of the healthcare system in Germany, but for also strengthening the interests of patients. Situated within the Federal Ministry of Health, is the Patient Commissioner of the Federal Government (*Patientenbeauftragter der Bundesregierung*), currently Wolfgang Zöller. The Office of the Commissioner (www.patientenbeauftragter.de) was established on 1 January 2004 by the *Statutory Health Insurance Modernisation Act* to support the development of patient rights and publically advocate for patients' interests; particularly in relation to the right to information. Given the potential important role of open disclosure in quality improvement, respecting patient rights and reducing errors from escalating into formal complaints or lawsuits, the Patient Commissioner should be advocating open disclosure. A first step would be to explicitly recognize the patients' right to be informed about incidents and errors that occur in their treatment. A new patients' rights law currently being drafted by the Patient Commissioner could potentially provide an appropriate framework for this. An additional measure would be for the Patient Commissioner to lobby for legislative changes that would address the current legal dilemma for health practitioners in relation to accepting responsibility for healthcare errors.

Summary

Although the ethical, financial and quality improvement benefits of open disclosure have been shown in the English-speaking world, Germany still needs to provide a more supportive and consistent framework that allows practitioner to safely disclose incidents to patients. Without clear guidance and a consistent framework that is supportive of open disclosure, it seems unlikely that the attitudes and behaviours of practitioners will change towards more transparency and openness.

How this could be achieved within the unique structure of the German health system has been outlined in this article. Given the important role of medical self-government has in Germany, it is important that the Federal Medical Association show leadership on this issue. The adoption of a position in support of open disclosure by the German Medical Assembly would be highly influential. The Federal Joint Committee could also help set the framework for a broader implementation by developing directives or guidelines. Finally, explicitly recognizing the patients' rights to be informed about incidents and errors that occur in their treatment in the new patients' right law currently being developed by the Patient Commissioner of the Federal Government may help open disclosure receive more attention.

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