



This proposal was prepared by a working group set up by the Danish Society for Patient Safety in 2007/2008, its members being drawn from the Danish Medical Association, the Danish Nurses' Organisation, Trade and Labour, the regional hospital owners, Local Government Denmark, organisations for the disabled and the combating of diseases, and the Danish Patient Safety Champions:

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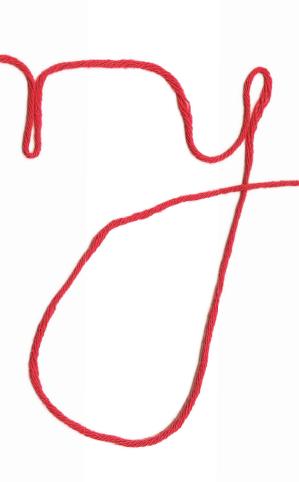
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Patients¹ often express their frustration about the inadequacy of information and apologies offered to them upon the occurrence of a serious adverse event. Similarly, staff² often mention that for a number of reasons it may be difficult to satisfy this need.

Even the strongest patient safety cultures and finely-meshed patient safety nets will not be sufficient to prevent patients from sustaining harm in their encounters with the health care services. That is why it is important for the health care services, their organisations and staff to act with professionalism in their encounters with patients having sustained injuries.

This booklet contains a proposal from the Danish Society for Patient Safety on how to satisfy the needs of patients for honesty and apologies as well as the need of staff for safety and the safeguarding of their legal rights when patients have been harmed or are exposed to a serious risk of harm in their encounter with the health care services.³ The first half of the booklet contains the reflections of the working group on the reasons for the absence up until now of a standard practice of apologising to patients that have experienced harm or been exposed to serious risk during treatment. The second half of the booklet contains the recommendations of the Danish Society for Patient Safety on how to offer an apology in practice.

Patient safety:

the protection of patients against harm and against the risk of sustaining injuries that occur as a result of the efforts and services of the health care sector or the lack thereof.

The health care services:

include both the primary and secondary health care sector.

- 1 Defined as citizens receiving health care service(s) and their families.
- 2 Providers cover everyone working under the Danish National Health Care Act. We distinguish between managers and providers, but we do not distinguish between the individual professional groups or hierarchies, or between staff in the primary or secondary sectors.
- The proposal is intended as a discussion paper for use by the secondary and primary sectors in their efforts to comply with the standards on "Patient information and communication 2.2.1. Important conversations with the patient" and "Quality and risk management. KOM 3.1.4 Reporting of adverse events" in the Danish Quality Model for the Health Care Services, 2008 respectively 2007.



Apologise

Just under one of every ten patients are exposed to an adverse event in the encounter with the Danish health care services. To this should be added an unknown number of patients who are unintentionally exposed to a serious risk during treatment. For instance, if you sustain harm or are exposed to a risk in your encounter with the health care services, what would you want and expect in terms of consequences?

Patients want to be offered an apology. An apology reflects the acknowledgement that something happened that ought not to have happened. By offering an apology, the health care services acknowledge explicitly that they accept responsibility for the patients, for the situation, for the process going forward and for preventing similar events from occurring again.

The explicit acknowledgement of responsibility and the offering of an apology for the event reflect recognition of the patient's feelings. According to the patients themselves, an apology helps them restore dignity. From that time on, the patient is able to regain trust in staff and the organisation. The subsequent dialogue, treatment, rehabilitation and prevention will underpin that process even further.

According to staff, having to offer information and an apology to a patient that has incurred an injury or been exposed to serious risk is one of the hardest conversations of all. What happened to the patient is downright antithetical to the motivation and ambitions of all providers: to cure, to alleviate pain and to provide care respectfully. On the

face of it, this may seem a logical reason for the absence in the health care services culture of a tradition of apologising to patients that have been harmed during treatment. But the offering of an apology is in the interests of patients and providers alike. Providers that have apologised to patients explain that having said they were sorry had a positive effect both in relation to the patient and to their perception of themselves as professionals and fellow human beings.⁶

However, for a number of reasons - some of them structural, others individual - the tradition has survived. And the very same reasons now act as the main barriers to a break with this tradition. The barriers may seem insurmountable – particularly from the point of view of the individual, but they can be removed. Some of the barriers can be eliminated by means of active support to staff provided by general management in the health care sectors via local management. Other barriers take the form of myths, traditions and standards that are rooted in cultures, such as an individual-focused culture in which health care professionals may look upon themselves as autonomous actors rather than as members of a team in the complex organisational structure that constitutes our health care services.

Below is a list of the most frequently occurring barriers that prevent staff from fulfilling the wish of patients for an apology and proposals on how to surmount them.

⁴ A large number of these events are probable complications that have been accepted in advance as a well-considered risk in connection with the treatment. DSI report, 2001.

⁵ The Danish Patient Safety Champions' Guidelines, April 2007.

⁶ See e.g. Joint Commission, 2007, p. 36 and 50f.

THE STAFF PERSPECTIVE >> THE PATIENT PERSPECTIVE

A medical error:

the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim.

An adverse event:

harm caused as a result of medical management rather than the patient's underlying disease; also sometimes called "injury" or "complication". Providers feel that they do not have to apologise for medical errors occurring as a result of busy days and strenuous work often involving conflicting demands from patients, families and management.

>> The patient needs an apology regardless of the reasons for the adverse event.

Providers feel that an apology is not required if everyone believe that they have done their best.

>> The patient looks upon the providers as representatives of the health care services, and patients expect an apology from the health care services in case they have been harmed or been exposed to serious risk.

Providers feel that they do not have to apologise for medical errors which, although discovered by the providers, are basically the result of factors beyond their control.

>> Patients see the providers as the representatives of the health care services. The providers must apologise on behalf of the health case services whenever a patient has sustained harm.

Professional pride may prevent experienced providers from admitting medical errors, much less expressing regret at or saying sorry for their occurrence.

Among the factors determining a patient's trust in the health care services is the ability of providers to admit medical errors, apologise for them and learn from them.

ORGANISATIONAL BARRIERS

SOLUTIONS

Providers may not feel convinced that they will get the support of management to an open and honest communication with patients and their families about injuries.

Docal management must draw up specific guidelines and procedures for the organisation's handling of openness and dialogues with patients having been harmed or having been exposed to serious risks during treatment. In that way management makes handling the responsibility of the whole care team and the organisation instead of making it the personal responsibility of the individual provider.

A harmful adverse event:

an event in which harm is inflicted upon a patient due to actions or omissions on the part of the health care services.

Providers may go through a personal crisis because of what happened, may feel guilty, responsible, unworthy and without the resources required to provide care to patients or survivors.

>> When a patient sustains an injury during the provision of treatment by the health care services, it often happens that the patient is not the only one needing help. An organisation with a mature patient safety culture has procedures for the provision of active support and care to those patients and providers that have been involved in a harmful adverse event.

Providers may not be in possession of the skills required to handle the conversation with the patient and apologise to the patient.

>> The organisation will make sure that providers are offered supplementary training and supervision enabling them to conduct the conversation with assurance, empathy and professionalism.



One of the myths peddled by some circles among providers is that, if an apology has been offered and the patient decides to lodge a complaint about event, the Patient Complaint Board will inevitably take disciplinary action.

>> The Patient Complaints Board does not take account of the apology in its processing of the case, but relies exclusively upon a comparison between the treatment provided to the patient and existing generally recognised professional standards in the field.

Colleagues having experienced or fearing disciplinary action by the Patient Complaints Board and some defence lawyers warn against apologising to patients and families, claiming that it is an indirect admission of personal guilt.

>> The making of an apology does not result in any individual legal sanctions in the form of e.g. disciplinary action or loss of licence.

The imagined legal barriers merit special attention, as they focus specifically on the legal position of the providers. Senior lecturer Helle Bødker Madsen, LLB, has drafted a report on the judicial implications of apologising for harmful adverse events in the health care sector. Having scrutinised the likely response of the supervisory bodies that decide the judicial implications of harmful adverse events in the health care sector in case a patient lodges a complaint with them after having received an apology, Helle Bødker Madsen reaches the following conclusion:

"..., that the fact that a health care provider, be it the directly involved provider or somebody else, apologises to a patient that has been exposed to a harmful adverse event during examination and treatment, does not in itself involve any judicial consequences in the form of e.g. the assignment of liability or a rebuke from the Patient Complaints Board of the health care sector."8

Helle Bødker Madsen also involves the Parliamentary Ombudsman who inspects the public hospitals. Besides the traditional basis of assessment used by the courts of law, the Ombudsman uses an extended basis of assessment in relation to "good administrative practice" when investigating cases concerning the actual behaviour of public administration systems.

"Based on the principles of "good administrative practice", the Ombudsman has made the comment in several cases that the public administration system must act with politeness and consideration." and

"It is not possible to rule out the possibility that the Ombudsman would consider it good administrative practice for a health care professional employed in the public sector to apologise to a patient who has been exposed to a harmful adverse event during examination and treatment."9

Polite and considerate behaviour is what we all expect in our encounters with the public administration, including the health care services. Patients having sustained harm in their encounters with the health care services have defined what is meant by polite and considerate behaviour:

- Deal with the harm promptly
- Disclose everything and acknowledge responsibility
- Involve us in your root cause analysis
- Prevent the harm from happening to other patients.¹⁰

It appears that management and providers who accommodate the wish of patients to receive an apology are acting in accordance with the basis of assessment applied by the Ombudsman in relation to good administrative practice. Also, experience gleaned in the USA shows a marked decline in the number of patient complaints of injury at hospitals having implemented disclosure and openness and the practice of apologising to patients for harmful adverse events.¹¹

⁷ Helle Bødker Madsen: Redegørelse om retlige konsekvenser af at undskylde skadevoldende hændelser i sundhedsvæsenet. (The judicial implications of apologising for harm-causing events in the health care sector) 2 November 2007.

⁸ Bødker Madsen, 2007, p. 8.

⁹ Op.cit. p. 9. The author states subsequently: "As it appears that no statements by the Ombudsman are available that relate to this case, however, it is not possible to make any comments on it with any degree of certainty."

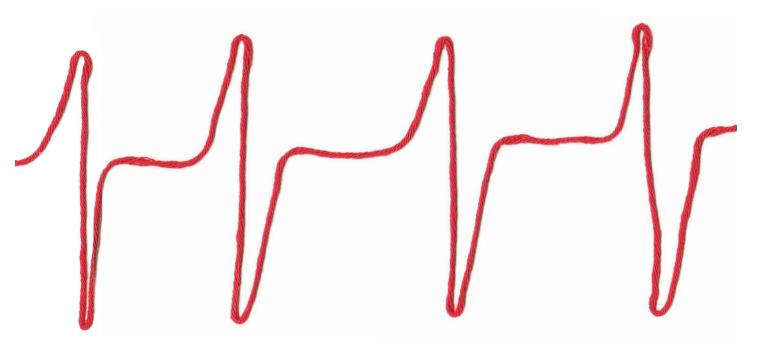
^{10 &}quot;Når skaden er sket" (When harm has been done) by the Danish Patient Safety Champions, April 2007.

¹¹ Joint Commission, 2007, p. 82 and 86.

Patients who have entrusted their treatment to the health care services and who sustain a harmful adverse event or are exposed to serious unanticipated risk during treatment ought to be offered an apology by the health care services. A considerable part of the treatment of the harmed patient consists of honest communication about what happened.

Honest communication of what happened involves giving the patient an open and honest explanation of the event as well as an apology. An explanation will give the people involved the knowledge they need to understand the event and the specific circumstances. The apology will help create acceptance and forgiveness and restore trust in the health care services, because the apology is a signal that responsibility for the event is being acknowledged.

By far the largest number of treatments proceeds as planned. Harm or serious risks are not everyday occurrences for patients or the individual health care professional. However, at the overall level they are everyday occurrences in the organisations of the health care sector, and for that reason local management must draw up procedures for how to respond when harm does occur. A set of guidelines will make patients, providers and management feel safe in the knowledge that everybody's needs will be fulfilled 'when harm has happened'. A set of guidelines also means that, in an emergency, it will not be up to the individual health care professional to decide on these highly complex and sensitive problems.



Making the apology

A health care sector that is safe for patients builds upon an honest and open dialogue, which is a prerequisite for continuous learning and improvement. The dialogue must be conducted across administrative, educational and hierarchical borders and across the groups of actors in the health care sector: management, providers and patients. If a patient sustains harm, it is important to not only continue the dialogue, but also to reinforce it. The dialogue should be conducted on the basis of the recipient's needs. At this time – if not before – it is relevant to ask and encourage the patient to include a family member or friend in the conversation.

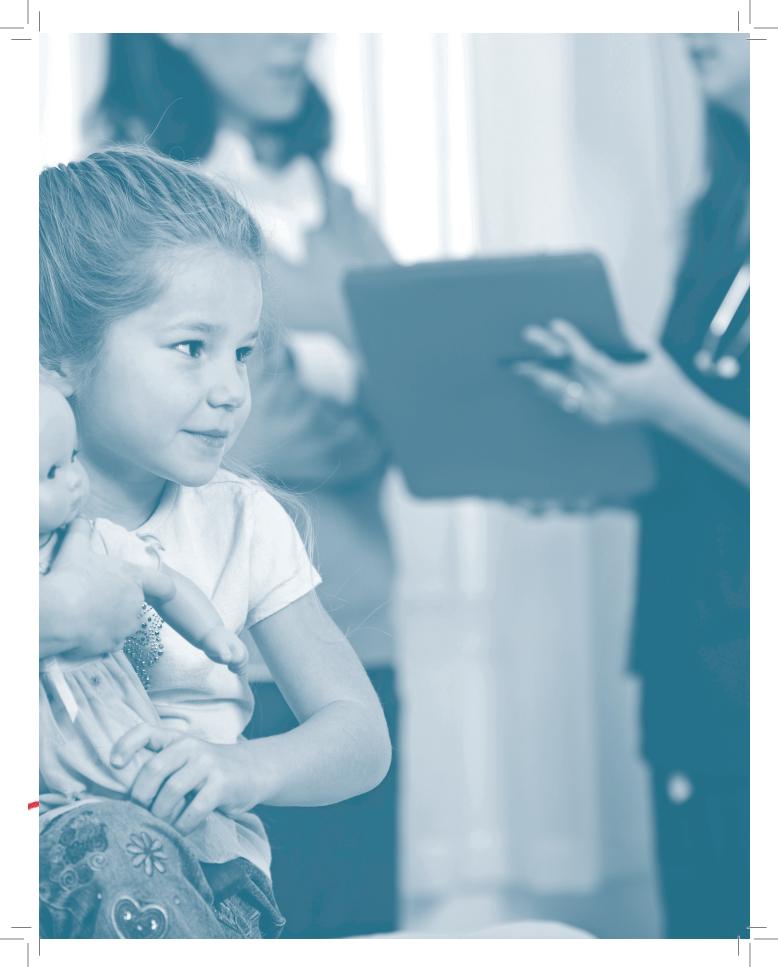
The act of making an apology to a patient that has sustained harm or been exposed to a serious risk consists of more than just saying the words or going through the motions. It takes the form of a dialogue that is followed by action. One of the reasons for making an apology is for the patient to feel that providers acknowledge responsibility for the situation and for the patient, and the patient needs to feel that in order to restore his or her trust in the providers, the organisation and the health care environment in which treatment of the patient has to continue. That is why it is important for the conversation to be conducted in the right manner and in the right spirit. When meeting with the patient, staff must be:

- Sincere and obliging
- Open and honest
- Empathic and listening
- Well-prepared and well-considered.

As in any other conversation conducted in a health care setting, the conversation with harmed patients must build upon the individual patient as well as upon the nature, severity and magnitude of the specific event. The nature of the injury or risk and the scope of the apology may be brought into line for instance by matching the follow-up and the language used to the specific event.

An apology offered to patients having sustained harm or having been exposed to a risk should build upon the following main principles:

• The patient must get the impression that someone is acknowledging responsibility



- The patient must get the impression that the apology is made out of respect for him or her
- The apology must be based upon the needs of the patient.

Building upon these three principles, the apology must be matched to the persons involved and the specific circumstances. Not all harmful adverse events or inflicted risks require lengthy explanations and analyses. In some cases it will be natural and sufficient for the providers to apologise to the patient as soon as the harm is discovered. Some cases may be more serious and complex, and the more serious and complex the situation, the more likely it is that a representative of management has to make the apology.

Below are the general recommendations of the Danish Society for Patient Safety with regard to the events that require an apology; when to apologise; how to apologise and who should make the apology.

WE RECOMMEND:

That an apology is made when a patient has been harmed or inflicting a risk of harm upon the patient.



Which events require an apology?

It is often a question of assessing the circumstances of the specific situation. As a general rule, an apology should be offered to patients sustaining harm or having been exposed to unnecessary risk.

However, it should be emphasised once again that not two patients are the same, and the same is true of the nature of events causing harm. It is not possible to make an exhaustive inventory of scenarios, dividing them into 'requiring an apology' or 'not requiring an apology'. It is always a question of an individual assessment, and that assessment must pay special attention to the patient's experience of what happened.

As a general rule, patients should not be informed about near misses, defined as events that are prevented from happening due to timely intervention. This applies even if the near miss had a major potential. In situations where it is deemed that the patient may contribute information to help prevent a repetition of the event, it may be considered to inform the patient and issue an invitation to share his or her personal observations.

When should the apology be made?

In some cases it may be necessary to have more than one conversation with the patient about the harmful adverse event. It is often

useful to look upon the apology a multi-step process consisting of an initial interview in which the patient is informed about the event – keeping it down to the mere facts – receives an explanation and an apology, and followed up by one or more subsequent conversations in which the patient is told the reason why the harm occurred and what will be done to prevent similar harm from occurring.

In the initial conversation, the patient is told the name of the provider acting as his or her contact in relation to the event and how to reach the provider should the need arise. At this early stage the patient should be invited to share his or her understanding of what happened and why it happened.

If more than one conversation is required, the unit undertakes an explicit commitment to ensure follow-up by convening the follow-up meeting(s) at sufficient notice. Appointments and times must be complied with and must be arranged with a minimum of inconvenience to the patient, for instance by making arrangements for the patient's transport between home and hospital in connection with the follow-up conversation(s).

How should the apology be made?

Acknowledging responsibility involves providing verbal information about the injury when it is discovered and the patient is deemed capable of understanding the information.

Admitting that an injury has occurred involves

- Explaining what has happened
- Explaining when the harm occurred
- Explaining when the harm was discovered
- Explaining what measures have been taken, and what remains to be done, in order to contain the scope and magnitude of the harm
- Explaining the implications of the harm to the patient's state of health and prognosis.

The initial conversation must necessarily be limited to an account of the event and what is actually known at the time. Only in a subsequent conversation will it be possible to explain and inform about the reasons for the event.

An apology is made by expressing verbally that you are sorry – often by using the word 'sorry', expressing an understanding of and com-

WE RECOMMEND:

That the apology is made

- As soon as the harm is discovered
- When the patient is deemed capable of understanding the information
- Staff know the basic facts of the event.

WE RECOMMEND:

That the organisation

- Acknowledges responsibility.
- Admits that harm has occurred
- offers an apology
- commits itself to follow up on the process mov ing forward.

passion for the patient's situation and feelings and listening to the patient's feelings and understanding of the situation.

People usually attach strong feelings to the word 'sorry', and that applies to patients as well as to providers. For some patients it matters a great deal to hear that particular word 'sorry'. Similarly, some providers find it unacceptable having to use precisely the word 'sorry' in this particular connection. Since the purpose of making the apology is to give patients an honest and exhaustive explanation and apology, we recommend that providers use the language and phrasing that they feel most comfortable with.

The organisation undertakes a commitment with regard to the process moving forward by explicitly taking the initiative to arrange follow-up conversations. This will create an opportunity to explain to the patient what steps the unit intends to take to prevent the adverse event from happening again. It is also an opportunity to invite and encourage the patient to contribute to the unit's efforts to find out why the harm happened, to share his or her understanding of what happened and come up with any proposals for measures to avoid repetitions.

The initial conversation and the subsequent dialogue about the injury sustained must take place without interruptions, in adequate privacy and with the relevant persons in attendance.

Who will make the apology?

As a general rule, the apology to the patient should be made by the staff involved in the adverse event. The patient has chosen to entrust the staff with his or her treatment. That is a sign of trust, and the staff now have to reciprocate by apologising to the patient for not having achieved the desired and planned outcome.

There may be reasons and circumstances in a case that require the attendance of persons other than the staff involved in the event. In all likelihood, the more serious and complex the harm is, the more the patient expects the attendance of management in the conversation. This should obviously be decided on the basis of the specific circumstances of the case. What matters most is that a person is there to acknowledge responsibility on behalf of the organisation, to meet the patient and start up the dialogue about what happened.

WE RECOMMEND:

That the conversation is attended by the provider that was closest to the patient at the time the harm was discovered and the patient is able to take part in the dialogue about, alternatively to receive the information about what has happened.

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Say sorry, because:

- 1. It is the right thing to do
- 2. It helps the patient restore dignity
- 3. It helps restoring the trust of the patient in you, your workplace and the health care services
- 4. Your relationship with the patient builds upon mutual trust, respect and openness
- 5. It may help you



In the autumn of 2008 the Danish Society for Patient Safety will issue a tool kit on how organisations can acknowledge responsibility for staff involved in an adverse event.