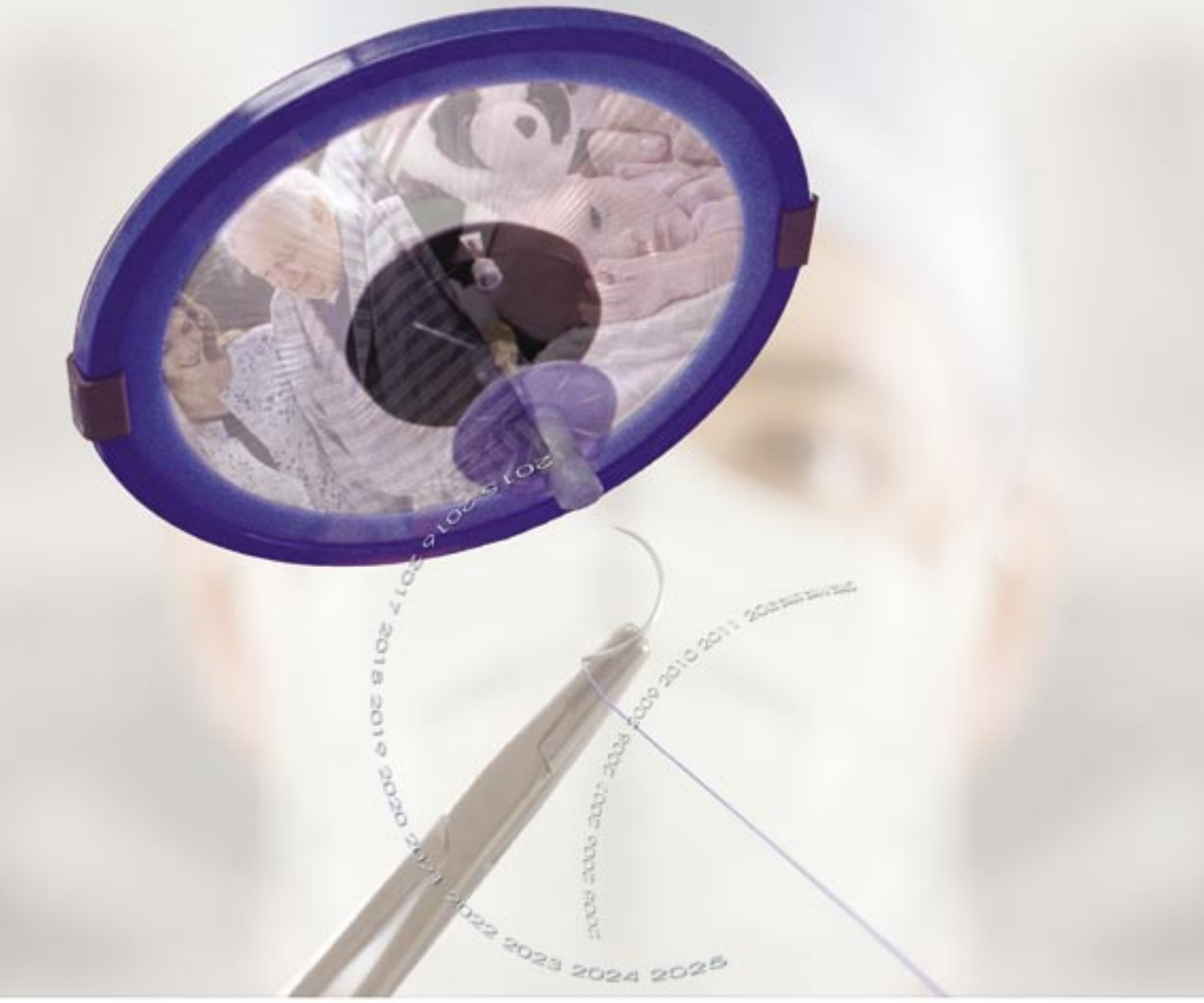
EUROPE

EIGHTH FUTURES FORUM

on governance of patient safety



Erpfendorf, Austria, 28–29 April 2005

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WORLD HEALTH ORGANIZATION
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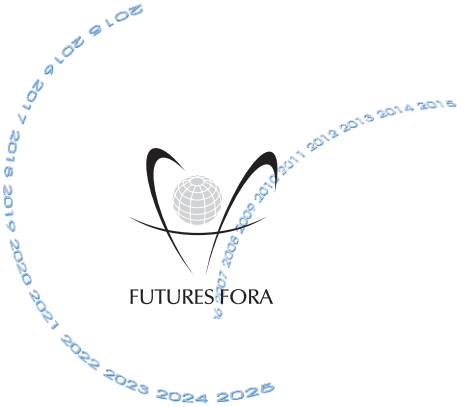
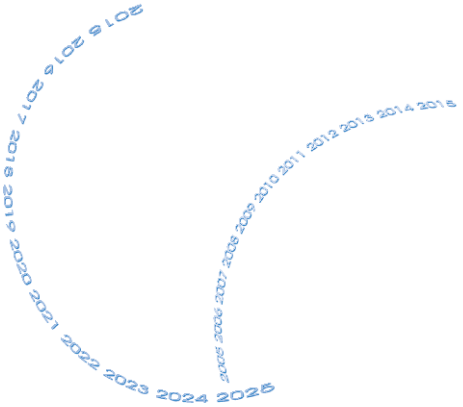


CONTENTS



1. Why a WHO forum on governance of patient safety?

Despite substantial improvements in the knowledge base on delivering safe health services, European countries still have a large incidence of adverse effects related to health intervention. Several retrospective reviews of clinical case reports provide powerful evidence of harm to patients. However, the scale of the problem in other areas of public health is unknown, as hardly any ongoing research and evidence are available.

The growing awareness of the problem has led to the emergence of an international drive to create a culture of safety in public health. The Fifty-fifth World Health Assembly in 2002 adopted a resolution urging countries to pay close attention to the problem of patient safety and to strengthen safety and monitoring systems. Since then, many patient safety initiatives have been established within national health systems, and WHO launched the World Alliance for Patient Safety.[1] There have also been substantial developments in countries in understanding the implications of governing patient safety. This Forum focused on experience and open questions in participating European countries related to the governance of patient safety. The aim was to exchange and learn from experience on governing patient safety, to identify the knowledge gaps on improving the governance of patient safety and to support the international drive towards increasing patient safety in the European Region of WHO.

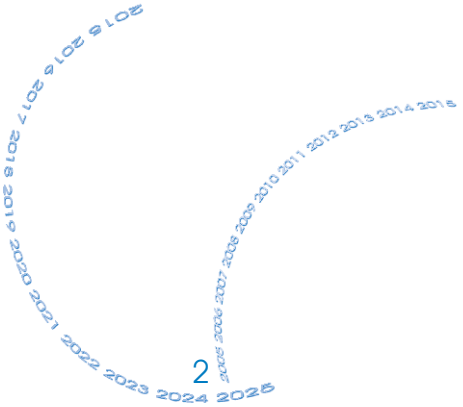
Launched in 2001, the Futures Fora are a series of meetings for policy-makers. They aim to generate insights into real-life decision-making issues that are often not available from academic sources. They provide an impartial environment for directors-general of health, chief medical officers and senior advisers to debate difficulties in policy-making. During the Fora, the participants share their experience in concrete decision-making issues, describe the solutions employed and draw the lessons. The Fora apply the Chatham House rule to ensure confidentiality. The Chatham House rule aims to guarantee anonymity to those speaking within it. It allows people to speak as individuals and to express views that may not necessarily reflect those of their organizations, thus encouraging free discussion.

The baseline theme for the Futures Fora in 2003–2005 is tools for decision-making in public health. Several Futures Fora have already been organized under this theme. These include a forum on evidence-based recommendations as tools for decision-making (Brussels, June 2003); one on rapid response decision-making tools (Madrid, December 2003); one on crisis communication (Iceland, May 2004); and one on unpopular decisions in public health (November 2004, Malta).

Following this introduction, **Chapter 2** deals with the problem of patient safety, setting out some facts and focusing on the context in which the problems of patient safety occur. **Chapter 3** addresses the causes of adverse events and errors in health care, focusing on two main types: those attributable to failures in health system design and those associated with the attitudes and traditions of health professionals and managers.

[1] World Alliance for Patient Safety [web site]. Geneva, World Health Organization, 2005 (http://www.who.int/patientsafety/worldalliance/en, accessed 15 September 2005).
World Alliance for Patient Safety forward programme. Geneva, World Health Organization, 2005 (http://www.who.int/patientsafety/en/brochure_final.pdf, accessed 15 September 2005).

Chapter 4 concentrates on the actions to be taken to mitigate and learn from adverse events and errors in health care, dwelling on two concrete case examples from Austria and Malta. **Chapter 5** deals with some of the conflicting questions in governing patient safety on which the Forum focused, including whether health care providers should report anonymously or identifiably and whether to opt for mandatory or voluntary reporting of adverse events and errors. **Chapter 6** illustrates how various countries in Europe currently work on improving the structures governing patient safety. Finally, **Chapter 7** draws conclusions from the Forum by providing some possible solutions for preventing errors in health care and ensuring patient safety.



2. The problem of patient safety

"There is a 1 in 3 million chance of an accident occurring in an aeroplane. The chance for an accident happening in a hospital is 1 in 300."

2.1 The scope of the problem

The facts

The statistics are alarming but, for some reason, the scale of the problem seems to not impress the way figures suggest it should. One possible explanation is that the victims of adverse events and errors in health care die one at a time, not in jumbo jets crashing down causing hundreds of simultaneous deaths. Another reason societies may disregard patient safety as a serious problem is similar to many other domains in public health and in society at large: dealing with it is just too difficult. Whenever a national government commits to surveying the problem, the results often reveal serious failures in patient care, and yet the health sector in general does not have a true perception of the risks it generates. The average attitude would be to see failures as the exception, a result of a private case and a personal failure rather than a problem of the health system.

However, there is ample evidence that when a mistake is made and a patient is injured or dies, most often this is not an issue of personality or crime. It is a fundamental system issue. When there is an error, there is a cause, and failures in the way the system functions are at the heart of most problems. For instance, there is a direct and proven link between the mortality in a hospital and the sophistication of the human resources practices in it, practices such as appraisal, access to a training policy or the proportion of staff working in teams.

Not only is patient safety violated within and because of the health system; lack of patient safety affects the health system. It places a burden on health system financing and on its human resources. It also has an ethical dimension, damaging the credibility of the system and deteriorating its relationship with the users of health care. Adverse events and errors in health care also undermine the credibility of the health system as a whole. They make the society question its performance, although only one specific aspect of performance, a small part of the system, may be the weak point generating errors.

Where does the problem occur?

There is a critical period, with a high potential for error, after the initial contact of a patient with the system. Patient safety may also be at risk when a client is transferred from one structure to another, such as from primary to secondary care or after discharge from a hospital. Health professionals fail to diagnose or miss diagnoses and make errors in judgement within each part of the system. In fact, research shows that clinical scenarios often bear potential for mistakes to be made, and even in most advanced countries some treatments have not been fully validated.

How do we hear about errors and adverse events?

Stories about patients being harmed by the health system fill the headlines in the general press. The general public sees an obvious trend and starts asking why. Increasingly, patients demand more information and exercise pressure for transparency. Once this happens and patients themselves become the source of information about adverse events and errors, there is no return to the situation when the health sector did not disseminate information and cases were dealt with privately.

2.2 Patient safety in its context

Patient safety is a symptom of a syndrome. It is linked to how health care is organized and to the culture in a hospital or a primary care unit: the informal psychological and social climate and functioning of that unit. *Fig. 1* and *Box 1* show some system failures and institutional blindness underpinning the problem of patient safety.

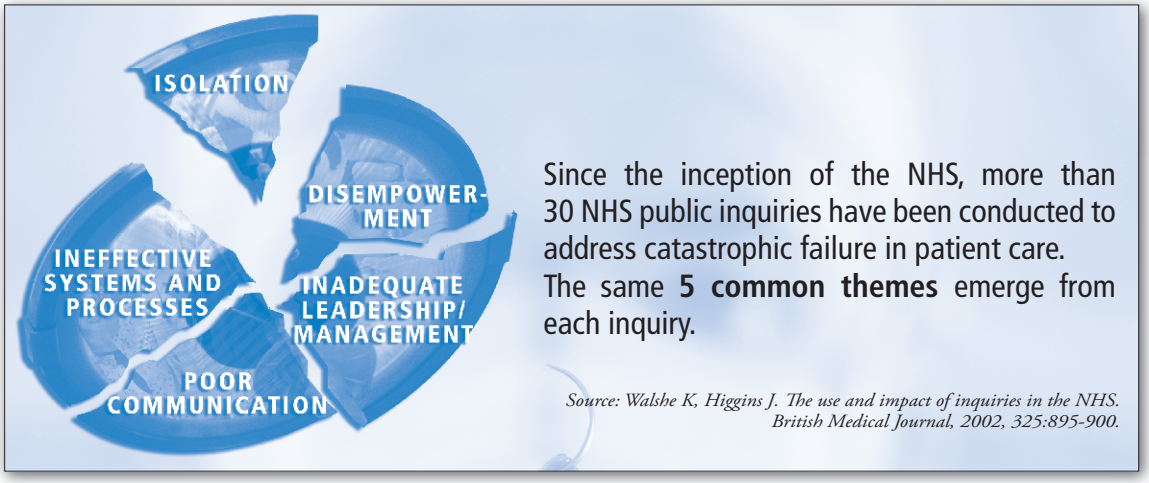


Fig. 1. System failures as reasons for problems in patient safety

INSTITUTIONAL BLINDNESS

"We're already doing that!" "We're developing a strategy on that"

"We're still developing our thinking on that"

"We don't think that applies here"

"We've already made someone responsible for that"

"That's a weakness we need to work on" "We've made some progress on that"

"My view on that is ..."

Box 1. Institutional blindness underpinning problems of patient safety

Patient safety is part of quality. Both nationally and internationally, patient safety is seen not in isolation but in the context of the quality of health systems. An internationally accepted and used definition from the 1990s describes quality as "the extent to which health services to individuals and populations increase the probability of desired treatment results and the extent to which they agree with the present state of the art". This general definition served well as a conceptual umbrella under which a culture of quality developed in health care. It includes parameters of quality such as: reduction of premature deaths; cure rates; lessening the impact of illness and pain and impairment associated with disease; and physical and mental recovery and rehabilitation after a disease or injury. These parameters of quality, however, did not sufficiently incorporate avoiding unwanted treatment results or errors and injuries as a result of diagnosis or treatment. Quality improvement is a leading movement in public health nowadays, and governments increasingly take up accreditation and quality assurance as useful instruments.

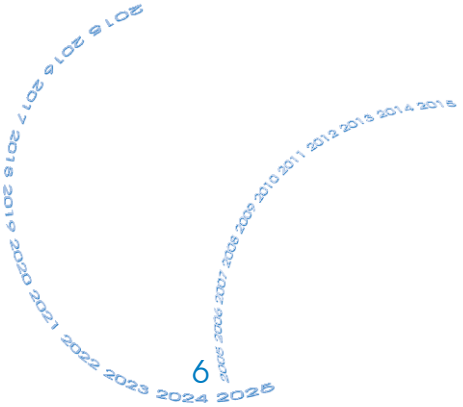
The European Union dimension. There is a core national dimension of the work on quality, and within the European Union, health care is a national-level competence. Nevertheless, some international coordination is possible related to information on health care and benchmarking. With the new generation of mobile users of health services, the national health systems need to ensure quality standards that are comparable from one country to another, although the day-to-day necessity to set these standards still remains the domain of national authorities. One possible, modern and down-to-earth definition of quality includes six parameters: safety, effectiveness, timeliness, patient-centredness, efficiency and equal access. Safety is a core element of quality.

An example from Germany illustrates the issues arising from trying to integrate patient safety into quality, looking at two areas: codes of professional conduct and a national policy recommendation on the appropriateness of health services.

Codes of professional conduct in Germany. "Errors" and "the error culture" in the codes of professional conduct in Germany do not yet figure prominently in the standards and values of the health professions; and if they do, it is usually not a positive role. A very recent example is the code of professional conduct published by the Niedersachsen state Chamber of Physicians. It mentions plenty of legal and professional responsibilities and regulates and compensates for adverse events; however, it does not mention learning from errors and failures nor establish any method for health professionals to benefit from this knowledge. Regulations and codes still regard errors as rare and as instances that do not constitute the everyday life of the physician. Physicians or other health care personnel who have been proven to make mistakes are frequently still regarded very negatively and are stigmatized. Further, although research illustrates that most physicians approve reporting adverse events, few hospitals in Germany evaluate the "near misses" – the acts of commission or omission that could have harmed the patient but did not cause harm as a result of chance, prevention or mitigation.

A national report on overuse, underuse and misuse of health services in 2001. The Health Council of Experts in Germany published this report, which made significant improvements; however, it regarded mainly overuse and underuse and barely paid attention to misuse. Assuming that there are no risk-free interventions, patient safety experts interpreted overuse and underuse as forms of misuse (for instance, when indicated treatment is not applied, underuse is a form of misuse). Nevertheless, owing to a lack of data, the report does not include the true misuse of services: where treatment is indicated and necessary but the procedure itself is incorrectly

applied and causes adverse events among patients. A later Council report in 2003 addressed safety specifically and summarized the available data on adverse events and errors in health care.



3. What causes adverse events and errors in health care?

"We are data rich and information poor."

3.1 Flaws in the system

The priorities. Quality is not always given the same level of priority as, for instance, financial security or management. This is why many guidelines are being issued but the degree of compliance with them varies significantly. For instance, one country introduced a new scheme for chemotherapy that was believed to increase quality. When authorities checked one year later how many hospitals had complied, many managers had not even heard about the new scheme, although the documents were lying under their desks. They were not, in general, poor managers or bad people. They simply had "the really important" things to take care of – such as balancing budgets or corporate issues. Quality and patient safety were not recognized as one of them.

The quality of data. An honest analysis of existing clinical results or reports shows that data are often meaningless. There are good documents and good routines to produce documentation, but often nothing changes as a consequence of making the reports, of having and storing abundant data. In a sea of data, no useful information has surfaced that would help highlight the patterns and trends of system failures.

The frequency of errors in health care are not seen as indicators of quality. The traditional medical audit comes down to retrospective analysis of a patient chart. Such an approach if used in isolation limits the information only to the adverse events that are documented as a standard routine and fails to incorporate data about serious events. Even the method of total quality management introduced during the 1990s in many countries threw little light on processes that occur as a result of systematic or individual error.

The gaps between the best practice that is preached and everyday practice that happens. The opinions of experts in quality assurance and patient safety differ vastly and obviously from those of medical professionals and hospital administrators. Theory and workplace reality do not always match. And even when practising physicians actually agree on certain measures, practice generally takes time to follow theory. Another gap that puts patient safety at risk is the broken interaction between the physicians in the ambulatory or primary care sector and the physicians in hospital care.

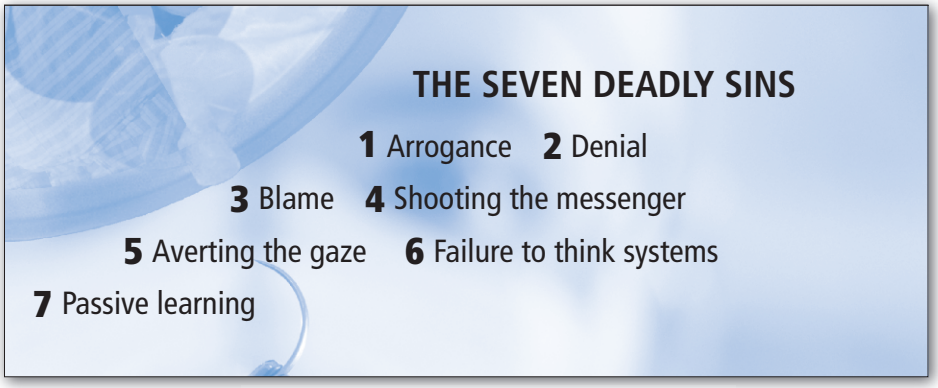
Design solutions. Failure is often rooted in design solutions. For instance, the branding of medicines through packaging may be more important than the contents. Preventing this source of error requires that design solutions be practical, reliable, error-proof, standardized and compatible with the system.

3.2 Flaws in attitudes and traditions among health professionals and managers

A false perception among clinicians that no mistakes happen. The health sector is both the generator and the victim of this top-down attitude that sometimes lacks the culture of self-criticism and insight. Health professionals sometimes do not have the sensitivity to recognize that health systems imply that risks and errors are not necessarily an exception. Physicians invariably remain reluctant to talk publicly about adverse events and errors in health care or to publish current reports about them. This may contrast with the approach of those health insurance users, patients and citizens, who expect added value from learning from mistakes. These dynamics reflect the conservatism of medical curricula. In fact, adverse events and errors in health care are often not even mentioned in the course of medical education. The medical faculties do not find it necessary to open up medical education to the issue of how mistakes happen. As a result, students often do not know what to do when they make a mistake and do not consider learning how to prevent mistakes important. Learning from errors and failures is not part of medical curricula, and no methods exist to benefit from this knowledge.

Management culture. The informal psychological and social functioning of a hospital or a primary care unit can promote or hinder a patient safety culture in that unit. A negative, hostile, non-transparent management culture is not positively or systematically concerned with near misses and errors. As a rule, it is not technical mistakes or downright incompetence that cause disasters or adverse events. Most problems arise because of miscommunication between health professionals.

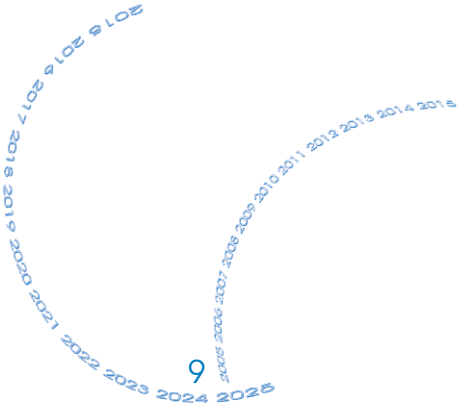
Box 2 illustrates challenges to clinical and management culture in recognizing and addressing patient safety.



Box 2. Challenges to health professional culture in recognizing and addressing patient safety

Some are just not for this job. Errors are not solely due to accidental failures in judgement, lack of skills, system flaws or cultural constraints. Sometimes people actually violate regulations. They usually repeat mistakes, again and again, whether or not they receive the best training and counselling. The system needs to identify these people and work with them to change their attitudes.

Accountability. Physicians often assume that they should be trusted owing to the nature of their profession. Physicians say they want to be accountable and transparent, but while declaring this, they wear a mask and glasses. The traditions in many countries make it difficult for physicians to understand and admit that they cannot take the trust of patients for granted. Patients' trust has to be won and deserved. To a certain extent, patients' perceptions nurture such a patronizing attitude: they often have an image of a physician that is illusory – reflecting their aspirations rather than reality. Real, two-way communication can prevent this, but this also means that doctors should be ready to be really accountable and patients should be willing to take some responsibility for self-determination. Charges are often brought against the health system because patients felt they were excluded or neglected. Doctors also need to realize that there is a subtle difference between responsibility and blame. Patients want and expect their doctor to take responsibility, so they would not blame in the beginning, but if they feel mistreated and ignored, they will fight for their right to safe health care.



4. What to do when an adverse event or error occurs?

"When you hear that an adverse event or error has happened, you know it is going to be tough, so your first desire is to run away and hide from the wave. Your responsibility is to stay, respond, act and learn."

4.1 Austria: Side-effects of a new vaccine

"In a crisis situation, stop the possible source of adverse events or errors immediately, take time to analyse the case and only then make a decision."

The case

On 4 February 2004, a very experienced physician from southern Austria reported severe side-effects among 20% of the children soon after she had started vaccinating them with a new vaccine. About 250 children affected had a strong general and local reaction (fever and a swollen arm).

The action taken

At that time, neither the doctor nor the national authority was aware that Austria was the first country to test this production series of the new vaccine and that it was the first time it was being tested in Austria. Consultations took place immediately with the national special advisory board for vaccines – a working group at the Supreme Health Advisory Board. Three decisions were made immediately:

- to stop using this vaccine until the production company provided more information;
- to send this series to an international reference centre for control testing; and
- to form a special assessment team and send it to the area to gather information from the local people, to interview literally everyone involved, including local teachers, physicians and parents, to determine what actually happened.

In a month, the first report was issued. Surprisingly, the report concluded that the doctor had failed to vaccinate correctly. Knowing that this doctor had 15 years of experience in applying the national vaccination programme, the members of the board questioned whether other factors had influenced this conclusion. It was revealed that the pharmaceutical company whose vaccine caused the side-effects had worked in the background during the assessment period, trying to influence public opinion and the information in the report. They had an economic interest and were also afraid to lose their European registration, so they exercised a lot of pressure. This added to the pressure in the mass media and increased the tension among the local community.

The advisory board decided to restart the vaccination with this production series. Within four days, the same 20% of side-effects occurred in several other regions. This was twice as high as the 10% incidence of severe side-effects mentioned in the official registration. A decision had to be taken on how to deal with such a product. It was recognized that such a high percentage of side-effects might reduce the acceptance by the parents and undermine the whole vaccination programme. The registration of the product could not be suspended because nobody knew the real cause of these side-effects.

The lessons learned

- Change the system of reporting: a new case-recording scheme was created to include all the cases with side-effects.
- Adjust the health system so that it accepts information from sources external to the health system – parents, teachers and social workers. Until then, only actors in the health system (hospitals and physicians) were expected to report adverse events, and there was no mechanism or culture for incorporating information from non-health sources.
- Use independent authorities: they can make decisions especially in a situation when an interested party (in this case the pharmaceutical company) exercises substantial pressure.
- Work with those whose credibility is questioned: now the company is producing a new vaccine, so that the tension between them and the national advisory board has declined.
- Beware of being the first to experiment: encountering a problem is more likely when you are the very first to use a specific new pharmaceutical product, especially if it is still in clinical trial.

4.2 Malta: a 7-month-old baby with life-long injury due to an error in clinical judgement and system failures

"Only when this case came up did we realize that we really had a serious system problem to deal with."

The case

A 7-month-old baby with severe diarrhoea was brought to a general practitioner. He prescribed anti-dehydration medicines. The condition continued on the second day. The parents called the general practitioner, who reassured them that nothing extraordinary was happening. On the third day, the mother brought the baby to the hospital, requesting admission since the baby's general health status had deteriorated. The doctor in the emergency and admissions department examined the baby, found no cause for the problem and discharged the baby back home. Several hours later the parents brought the baby again to the emergency department, with very serious symptoms – semiconscious and hardly breathing. The child was immediately admitted to a special intensive care unit. Slow improvement was achieved, but the baby is now physically and mentally retarded and has epilepsy. The parents reported the case to a court and to the Customer Care Authority.

The action taken

A peer review was conducted of the whole case. Several major flaws were found.

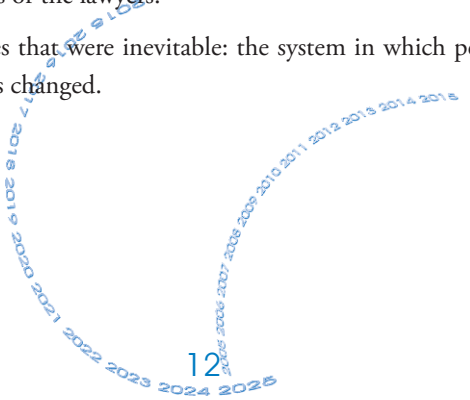
- The general emergency and admission staff covered the paediatric care of the emergency unit, and the doctor at the emergency admission unit had little paediatric experience.
- The record of the first visit was very poor.
- Nobody else was present when the doctor examined the child.
- The doctor had worked 38 hours over three days.

The paediatric and the emergency services were immediately separated. The system of supervision was revised. A special paediatric record card was introduced to facilitate good record-keeping. Group work with different levels of expertise was introduced, so that a good mix of professional experience and expertise was available within the emergency department.

An out-of-court settlement was achieved with the parents. Initially, they requested huge compensation sums. The authorities took the lawyers out of the discussion and worked directly with the parents, keeping complete transparency through the whole process and admitting that an error had been made. The approach chosen was to support the parents in bringing this child up from then on: a new house was offered, a yearly allowance for special care was granted, a special education programme for this child was put in place and a special allowance was given for professional care.

The lessons learned

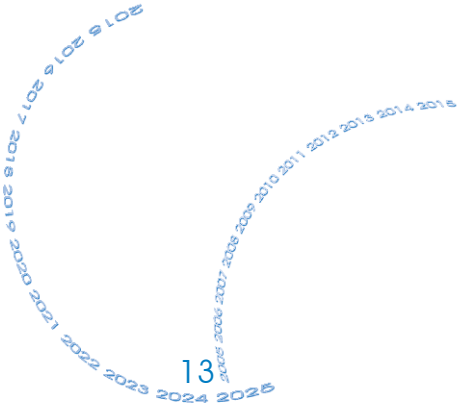
- Change the system: now, the doctors in the emergency unit have to have paediatric experience, and a dedicated nurse, preferably with paediatric experience, must be present whenever a child is brought to the emergency unit.
- Revise the supervision and control mechanisms: since this event, senior paediatricians supervise all junior doctors, and patients cannot be discharged without the permission of this supervisor.
- Do not stigmatize the doctor: little disciplinary action was taken against the doctor – only for not keeping adequate medical records.
- Deal with the legal issues by protecting the patient who was hurt: make sure that the compensation benefits the child rather than the parents or the lawyers.
- Use the case to advance changes that were inevitable: the system in which personnel have extremely long shifts in the emergency unit was changed.



4.3 A checklist: what to do when an error is registered

"Respond to the symptoms, but do not miss the cause."

1. Ask what the actual diagnosis was.
2. Step back from the diagnosis and try to see the case in its context of behaviour. Do not assume that the health professional was a criminal, but check this nevertheless. See the previous cases the health professional had treated in the past six months. When you track back, sometimes you find out this is not the first time a failure has happened and there is a trend of making errors.
3. Look at the supervisor of the health professional who made the mistake. Who is the supervisor? Have similar events happened with other health professionals under this same supervisor? This is an important question, because often the problem is not with the young health professional on the front line.
4. Debrief the whole team. Talk with the nursing staff: they know everything about how the hospital works, but people never ask them, although they can give valuable observations about behavioural issues and attitudes.
5. Support the team. The whole team is often traumatized by the error made by one of them; they are bruised and feel almost convicted because such a case happened.
6. Examine the path that led to the failure. Question the role and responsibility of each and every health professional who was involved. Take nothing at face value. It does not matter whether a certain doctor along the chain of events is prestigious and known to be experienced. What matters is ensuring that there is no trend of malpractice.
7. Examine the institutions outside the health system whose actions may have led to the threat to patient safety (for instance, in the case of Austria, the practices of the body that registers new vaccines).
8. What can be learned from this case? What changes should be made so that the error is not repeated?



5. Pros and cons in governing patient safety

5.1 To admit or not to admit?

"How can the system admit its mistakes and still be trusted?"
"When I say 'I made a mistake!' I may be saving somebody's life."

Research shows that, once patient safety becomes a public issue, there is initially a period when anxiety and dissatisfaction burst out and shape the debate. The more health authorities demonstrate their transparency and willingness to change, the more patients come out to express their unhappiness with the quality of services or to report some personal or family experiences with adverse events and errors. This should not be a surprise, for obvious reasons. Any shift from a masked or suppressed debate on errors to an honest open public debate increases the uncovered incidence of errors in health care reported by both professionals and patients. In its early stages, the debate may accelerate and become passionate. Besides, this initial phase of disclosure may mislead everyone to think that the incidence of errors is constantly increasing, which does not tend to strengthen the feeling of safety among people. Careful or weak decision-makers may therefore have reasons for not admitting mistakes to avoid losing people's trust in health care.

However, another answer is that the positive outcomes of the publicity will outweigh the negative impact of talking about the mistakes that led to the introduction of these procedures. Thus, building a new culture of accepting that errors do and can happen with everyone anywhere is essential. Later, this attitude should be steadily integrated into the existing systems. If the health professions can demonstrate that they can learn from mistakes, public confidence will increase. An additional advantage is that, once the eyes of the professionals are open to the quality information in errors, there is no way back: no option to stick to the old culture of hiding and concealing errors. In the long term, the system will be trusted even more if it shows that it uses the things that go wrong as a source of knowledge on how to do better.

How much the patients will benefit from such a new culture of openness and readiness to change depends on how many resources are invested in health systems to endorse new best-practice standards for patient safety.

5.2 To name or not to name?

The mass-media approach to disclosing errors in health care is straightforward – they provide all the personal details they can obtain about the health professional(s) who erred. Anonymity does not sell well in societies based on freedom of speech, democracy and human rights. Nevertheless, health authorities are concerned that raging negative publicity might destroy professional careers in a single case if a mistake becomes public. In a health system, it is more beneficial to take time, analyse the case and evaluate the weight of personal factors versus system factors that led to the error and then draw conclusions and make decisions. Doing this is more

difficult in a situation of public anxiety and mass-media outrage, although sometimes they trigger the changes that are necessary.

In each country, patient safety decision-makers should therefore set the general, context-specific rules about when, by whom, how and for what purpose the names of the health professionals will be revealed. Here are some considerations.

- When thousands of reports are received, the main task is to extrapolate from them, to spot in them a trend, a serious persistent pattern of mistakes.
- If flaws in the system clearly cause certain commonly occurring problems, this should be addressed as a higher priority than disclosing the names of the individuals.
- If, however, certain continual types of behaviour are identified for a specific health professional, being able to deanonymize is required to make the case and take measures.
- At the local level, where the primary reports are made, there should be no anonymity so that the case can be investigated – in moments of extremeness, based on the demands of the patient or the public.
- At the national level, a certain level of anonymity helps in detecting the pattern. However, this does not mean total confidentiality and refusal to reveal the personal details, when needed.

5.3 To blame and sanction – or not?

"In aviation, there are built-in punitive mechanisms for the key personnel in case of mistakes. The health sector should learn from this – if you really did wrong, you should know there is a chance you will be sacked."

"Yes, but doctors do not die from their mistakes, whereas many pilots do. Doctors obviously won't be very motivated to report errors."

Many adverse events and errors occur and remain unregistered. The reason is that health professionals are unwilling to reveal what went wrong because they fear blame, stigmatization and punishment. On the one hand, it is important to motivate them to report their cases by ensuring that they will not be labelled as "the ones who failed" because of the blame culture of the professions. On the other hand, if a mistake was made, the person and the whole team involved must face it in order to learn from it. If some sort of sanction is exercised, that should not impact their attitude towards the system and should not discourage them from reporting. This problem adds to the issue of preserving anonymity discussed above. Noisy disclosures and public announcements about severe punishment inevitably impact whole health professions, especially in small communities.

Countries have explored various ideas of how to get around these risks.

- Develop a culture in which mistakes are fairly attributed rather than blaming the black sheep only to demonstrate that they are the exceptions that do not reflect the system.

- Reporting can be turned into a learning process that is continually fostered.
- To avoid individual blaming and promote transparency, all reports of errors may be compiled at an institutional level and published on the Internet.
- Make and publicize sample cases based on the knowledge of the typical mistakes made. Such stories can boost the discussion and trigger interest both within the profession and among the general public without blaming specific personnel or health units.
- Consider talking about the incentives for health professionals to learn from mistakes. For instance, HIV/AIDS quickly changed the whole system of handling sharps and other health care procedures. Is it only because personnel were afraid that future mistakes would put their own health at risk? Can we achieve the same quick reaction in other situations? What are the appropriate incentives to report and to change so that patients do not blame and seek punishment but rather trust that the same mistakes will not be repeated, even if the same personnel perform the work?

5.4 To report or not to report? If yes, nationally or locally? If yes, compulsory or voluntary? Anonymous or identifiable?

Some observations

One more analogy with aviation. As the number of reports increases, the number of serious incidents decreases. The link between compulsory reporting and the decrease in adverse events is a common phenomenon in many sectors.

Quantity does not guarantee quality. What people write in their reports sometimes differs from what actually happened. A scheme should be put in place to allow the accuracy of reporting to be cross-checked.

The tree and the forest. Reporting the root cause of each specific error is not enough. Reports should also analyse the system. Such analyses might be carried out both at the national (federal) and the local level – for instance, after identifying a pattern, the national authority can go back to the hospitals and ask them how many system analyses they have made. A general assumption is that the more such cases are reported, the better the hospital generally performs in improving its practices.

Insurance companies may be potential allies. Insurance companies collect huge quantities of very detailed data about incidents and cases and may therefore be potential allies in reporting on adverse events and errors in health care. They obviously use these data for commercial purposes, so there is an issue of confidentiality. Nevertheless, authorities may consider building such alliances because, through the consumers and their best interests, patient safety ideally is of common interest for all stakeholders.

Data must be aggregated and comparable. If the actual reporting is done at the local level, the national level should define the minimum data set and the criteria for reporting.

No reaction, no further action. Although reporting is important, acting on the reports is essential. If no action is taken as a result of this work, the people who did it will inevitably get demotivated and will resist the task of reporting.

It is not the data that make the difference but the story behind the data. Reports are a good tool for raising public awareness of patient safety, increasing transparency, publicity and public support and changing the perception of mistakes and risk.

The next two examples illustrate how countries deal with the controversial issue of reporting.

Denmark: report and analyse locally, conclude and act nationally

The local level is crucially important. Denmark's new system for reporting adverse events and errors in hospital care has been in place since 2004. It has a few core characteristics: reporting on errors, serious incidents and adverse events is mandatory for all health personnel; the reports are confidential; and they are not followed by sanctions. All reporting is originally done at the local level. At this level, there is no anonymity; reports include all personal details of the people involved. In Denmark, local authorities operate the hospitals, and the local level therefore decides how to organize the work on patient safety in practice. The national authorities make recommendations, such as recommending a link between quality assurance and reporting; however, the decision on when and how to do this is taken locally.

The national level maps out the main trends. The reports are further submitted to the national level, where they are gathered, packaged and analysed. Denmark has partial anonymity, with confidentiality at the local level and anonymity at the national level. All reports are published on the Internet: the information is totally open to public access and everybody can learn from it.

At the national level, experts have several responsibilities:

- aggregating the results from all reports;
- identifying and locating the errors that occur repeatedly; and
- drawing conclusions about best practices and developing national guidelines for avoiding and dealing with medical errors.

The plans for the future

The plan for the future includes:

- developing national standards for patient safety;
- setting up a system by which patients can also report cases; and
- preparing a national report on adverse events and errors in health care.

Lessons learned

- Having a smooth, transparent and modern reporting system is essential because it influences the attitudes and behaviour of health professionals.
- In the efforts to create a safety culture, working with patients and involving them is critical.

- Patient safety culture is largely related to education and communication.
- There is already considerable knowledge about epidemiology; the reporting is therefore not targeted at improving it further.
- Gathering this huge number of single reports is not a waste of time, effort or resources. It is a way to change the culture. Making reporting part of the everyday duties of health professionals forces them to change their thinking about accuracy and transparency and makes them much more aware of the issue of safety. Reporting is useful in very many ways.

Germany: a new reporting system

An important development since April 2005 is the creation of an Internet-based system of reporting medical errors introduced by the National Association of Statutory Health Insurance Physicians. This is a nationwide reporting system. Several universities supported its creation. This kicks off an ongoing process of changing the culture of errors and communicating better between all stakeholders. For example, since Germany has a federal system, any patient can go to the court in the physicians' chambers, meet lawyers and doctors and discuss his or her case. The new system is one among several tools for the system for reporting clinical incidents in place. This is hoped to bring a real change of climate in the medical profession.

5.5 Freedom of choice or patients' compliance?

The freedom of the patient to make an informed choice is a core value in public health. It may, however, sometimes entail tension with patient safety. The patients may not choose the best practice, whereas health professionals always have the duty to treat properly in the interest of the patient. In such situations, respect for patient safety can produce conflict and tension between health professionals and users of health services. Some countries set very strict criteria on how to balance patient's rights and patient safety: the need for patients' compliance.

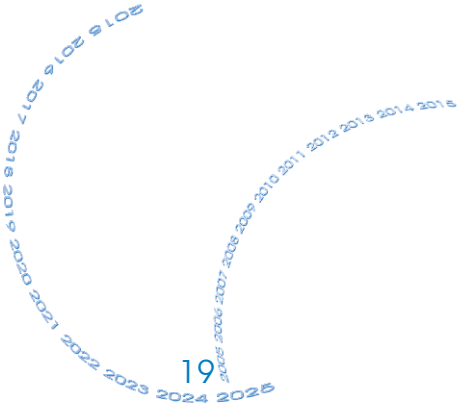
5.6 Targets, standards, regulations, guidelines and benchmarks

"If it isn't measured, it does not exist."

The basis for patient safety can be established in different ways. Each country decides exactly the degree of regulation that would best suit its policy context and everyday practice in health care.

One approach is to set tough targets and assess them through strict regulations. Another approach is to opt for guidelines in specific areas. The problem with them is that health professionals are too busy to look at them in depth, unless they are linked to accreditation, evaluation of performance or other processes or mechanisms that regulate the sector. A third approach is to set very few targets that are absolutely mandatory and setting quality indicators (standards) for all other areas and monitoring adherence. This can be helped by academic discussions,

but more important is examining the performance of the system and evaluating where the real gaps in quality occur. The advantage of choosing standards is the recognition that, in an intelligent professional culture, people commit to what they can do best but respect the criteria for which they will be evaluated. Thus, with standards in place, health professionals know that they will be expected to assess performance against them.



6. Experience in governing patient safety in countries

6.1 The United Kingdom

"To err is human. To cover up is unforgivable. To fail to learn is inexcusable."

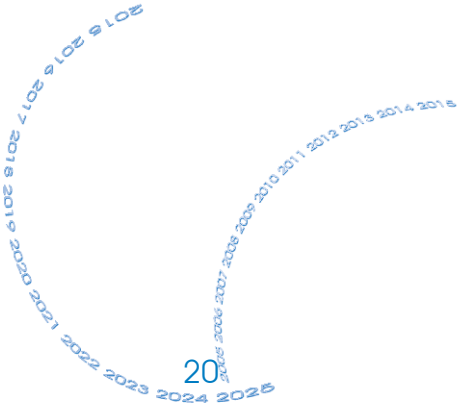
A complex network of stakeholders

Many different institutions work to ensure patient safety in the United Kingdom. The National Institute for Clinical Excellence generates standards for both the National Health Service and for health care providers. Various agencies employ specialists to generate guidelines in specific fields (such as cardiology, diabetes and oncology). Thus, frameworks for national standards are set, mainly designed for the providers, so that there is some consistency in these high-priority areas of public health. The Healthcare Commission monitors standards as "the police" – its teams have the right to make inspection visits to each hospital or trust. In parallel, the National Patient Safety Agency is responsible for implementing a national reporting system, so that locally developed reports are quantified, compared and analysed.

Clinical governance

The framework of clinical governance was introduced eight years ago. Through it, the National Health Service organizations are accountable for continually improving the quality of their services and safeguarding high standards of care by creating an environment in which excellence in clinical care will flourish. In practice, clinical governance means working alongside each trust to support them, in teams, and supporting their local leaders, so that the nationally set standards are applied. Clinical governance requires:

- effective leadership
- patient centredness
- teamworking
- authentic accountability
- systems thinking
- communication
- active learning.



Set the desired quality indicators and follow through

The National Health Service's core principle of ensuring patient safety is the sandwich approach. A National Health Service policy document *Standards for better health* outlines safety as its first domain. This document is agreed across the entire National Health Service. The standards formulated in it are and will be enforced. The document is intentionally brief. It gives the generic standards – the common goals to apply to whatever procedure is in place.

Only two targets were made compulsory – on financing and on waiting times. In terms of patient safety, two types of standards were set:

- core standards that are absolutely compulsory; and
- developmental standards towards which the health sector could eventually develop in the course of several years.

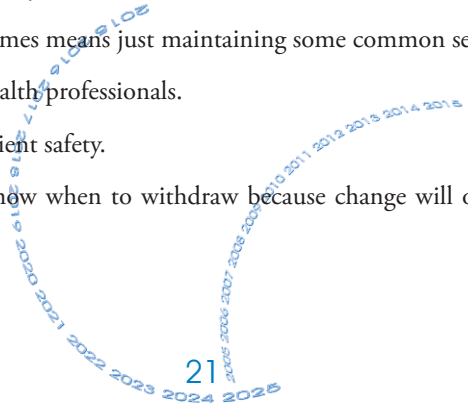
The first are the minimal standards accepted by everyone that set the basic level of care that should be present. The second reflect the lessons learned from looking at the failing organization of services over a decade. This approach engages the opportunity for improvement. Core standards are clearly the baseline when they are set, but the current developmental standards are expected to become the core standards in five years.

Get them to hold themselves up to the mirror

The way to involve the 1.3 million staff members of the National Health Service is to get people from every trust to hold themselves up to the mirror. Since professionals are much less interested in data and statistics than in experience and examples from everyday work, the approach is to link patient safety work to their own practice. Support teams of psychologists, probation officers, scientists and counsellors work with the teams of health care workers and with the boards of trusts. By spring 2005, 2313 support teams were involved in the exercise.

Lessons learned

- Health professionals have a sacred duty to meet the trust of the patients. It is therefore vital to be able to admit openly that health professionals do make mistakes. It is even more important to operate in a system where there is a basis to talk about this.
- Health professionals need to move from denial to acceptance.
- Implementing a system for national reporting ensures instant reporting of all errors but also minimizes the reporting burden throughout the system.
- Making reporting useful sometimes means just maintaining some common sense.
- Patients can be used to teach health professionals.
- Teamwork is a core value in patient safety.
- National authorities need to know when to withdraw because change will only happen from within the system.



- Standards may hinder people from being innovative. Avoiding standards becoming prescriptive rather than fostering is therefore essential.
- Appropriate leadership is the way to ensure adherence to a safety culture. When leadership is there and is effective, every single actor knows it and sees it.
- The people responsible for a health institution should be able to ensure not only output but also outcomes – for instance, by local ownership and innovation when applying the nationally set standards.
- Many of the National Health Service standards rely more on and relate to issues of behaviour rather than structure.

6.2 Switzerland

"No blaming. Only transparency."

Step by step

The national patient safety work started in 2000 with a statement by the federal government that it was about to launch a national programme for improving patient safety. The federal government announced that 2000–3000 patients were estimated to die each year in acute hospitals alone due to errors in health care. This resulted in heated discussion among the Swiss public. This estimate was based on the figures reported in the 1999 Institute of Medicine report on patient safety, as no national data were available. The health professionals reacted differently – some doctors and nurses were willing to have the topic brought into the light of day and some were reluctant. The mass media got very interested.

After the issue was put on the public agenda, several actions followed.

- The first national conference on errors in health care was held (December 2000).
- A task force was summoned that submitted to the health minister a proposal for action (March 2001).
- A second conference put this proposal on the table for a wide discussion with various stakeholders (April 2001).
- A period of 2.5 years then followed, with nearly no progress but debate on the possible roles various actors could play in a national plan for improving patient safety.
- In December 2003, the national Foundation for Patient Safety was created. Its mode of financing opened another round of debates. The federal government invested €140 000 as a start and then invited the cantons and other actors in the health care system to be partners in the programme. Now a joint financing scheme is in place, pooling together resources from the federal government, the cantons, professional bodies, physicians and other entities.
- In June 2005, an initiative was submitted to parliament mandating the federal government to take more leadership in improving quality and patient safety. Both chambers of parliament supported this initiative,

giving the federal government more support for specific action required to improve quality and patient safety.

- Several pilot projects are underway, some of them in the areas of mental health, hospital infections and e-health learning for general practitioners.
- A third national conference on patient safety is planned to be held in 2006.

The Swiss approach to improving quality and patient safety consists of six pillars *(Fig. 2)*.

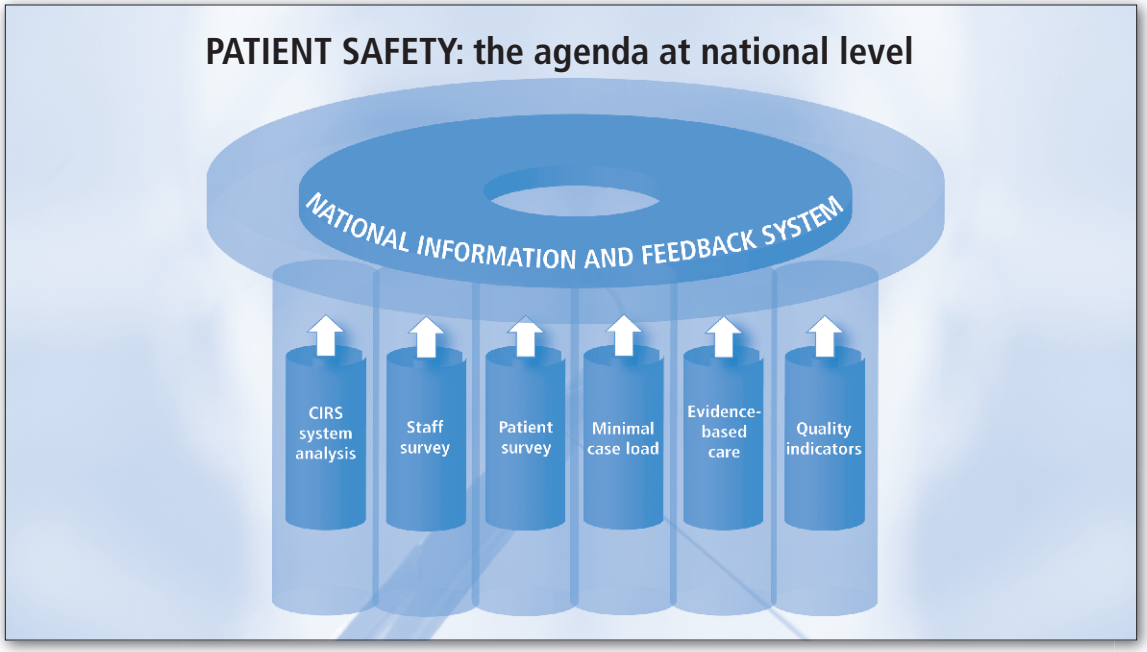


Fig. 2. Six pillars of the Swiss approach to improving quality and patient safety

1) Hospitals will be required to develop critical incidence reporting systems (CIRS) on a local basis. The federal government will define the minimum data set, so that data can be aggregated and compared at the national level. In addition, hospitals will be equipped with a system analysis tool to analyse the system failures that led to critical incidents in depth. A summary of the findings of these system evaluations will be shared in the national monitoring and feedback system.
2) Staff surveys will reveal what health professionals think about their own culture and practice in patient safety.
3) Patients' surveys will help determine the attitudes and opinions of consumers about the patient safety culture in the hospitals.
4) Minimal case loads will be defined for some critical interventions provided in hospitals.
5) For these critical interventions, the appropriateness will be estimated in prospective protocols.
6) Nationwide reporting on key quality indicators will be introduced.

All six pillars will provide input into the national information and feedback system.

The Swiss way – challenges

A key task ahead is to compile all different pieces of work at an institutional level. A second goal is to publish the findings on the Internet. By doing so, federal authorities do not aim to stigmatize and blame; their hope is that such full transparency will influence the attitudes of health professionals. Another element of the future work on quality improvement will continue to be at the level of institutions. For instance, when the federal authorities define the minimal number of cases a local hospital has to treat so that it receives money from the insurance fund, they ensure higher quality. Another element of the work on patient safety is developing evidence-based process indicators and quality indicators.

Lessons learned

- In Switzerland, most issues in health care are dealt with at the canton or local level. With the most recent health insurance legislation, the parliament introduced a mandate to the federal government to define quality requirements at the national level. As a first step, this mandate was delegated to the tariff partners (the associations of health care providers and health insurers). However, as the incentives in the health care system turned out to be too weak to implement substantial programmes for improving quality and patient safety, the federal government had to act and, with the support of the parliament, took the lead in ensuring patient safety.
- Ensuring patient safety is not only about making the decision. It is not only about putting in place systems, instruments and tasks. It is about communication and attitudes.
- The work with partners is essential – both within the country and internationally.
- The really hard work is changing the culture.
- Health care staff should be encouraged and supported throughout the whole process. Apart from being assessed, they should be given opportunities and tools to improve.

6.3 Belgium

"Answers come in the course of action. An integrated policy will be developed, but only after we have learned from experience."

The Belgian way

- ***A classic approach.*** Patient safety experts establish networks around different committees that already exist and work in different areas of health care; these networks are then linked with the work of hospitals and guidelines are developed by consensus.
- ***Legal framework.*** A patients' rights law in place since 2003 includes the right to quality of care and the right to complain. There is a national ombudsperson for patients and a similar function at the level of hospitals. A draft for a patient safety law is underway.

- ***The work on risk management – an interesting entry point to patient safety.*** A risk management survey was carried out in many hospitals to collect experience in the field. Interesting feedback was received that revealed how health personnel perceive risk management as a way to improve quality and patient safety. Many negative results came out that indicated the weak points in the system. For instance, only 60% of the staff had any training programmes available; only 50% of the members of the executive board had responsibilities in risk management; only 5% had the qualifications to perform risk management; and only 7% of the hospitals had a person specifically in charge of reporting.

Learn by doing

Several hypotheses were formulated to be tested. Answers were sought to questions such as the following.

- What should be the possible legal framework?
- Can certain patient safety principles be inserted into the work of each of the national committees in various areas, or does the country need to create a new, special patient safety committee?
- How can the mandatory incidence reporting be combined with the measures to be taken as a response to the reporting?
- How can the care of patients be optimized when an incident has already happened?
- What is the best approach to boost coordination between the various health professionals?

During 2004, eight pilot projects were selected, including the following.

- Risk management in a paediatric care unit is being monitored.
- A "risk committee" is being created in one hospital. This body is expected to make strategic choices on how to prevent clinical risk. If the current pilot project in one hospital is successful, the model will be implemented in the whole country.
- The minimum of data sets with clinical and financial data is being formulated, to review all the procedures of doctors. Various indicators of safety will be incorporated in these data sets with the long-term goal of having the same work at the national level.

Realizing these ongoing eight projects is already bringing preliminary results, with some conclusions and recommendations.

Lessons learned

- An internal committee that develops a patient safety programme, including indicators can be responsible for the recording system at the hospital level.
- This will lead to the creation of a more integrated model for hospitals, so that each hospital will have a safety plan based on the same indicators.
- This will be facilitated by linking the safety programme and the clinical path. Experience in Belgium shows that patient safety cannot reach far without such a link. The authorities have responsibility for creating the

necessary legal framework, with special highlights on reporting and confidentiality and on improving the education and training of personnel.

- International experience is much needed; without it the legal base and the developed reporting systems and safety plans will not be at the level desired by the national health authorities.

6.4 France

"Now it is time to move from a segmented to a coordinated approach."

Fig. 3 illustrates the institutional framework for patient safety in France.

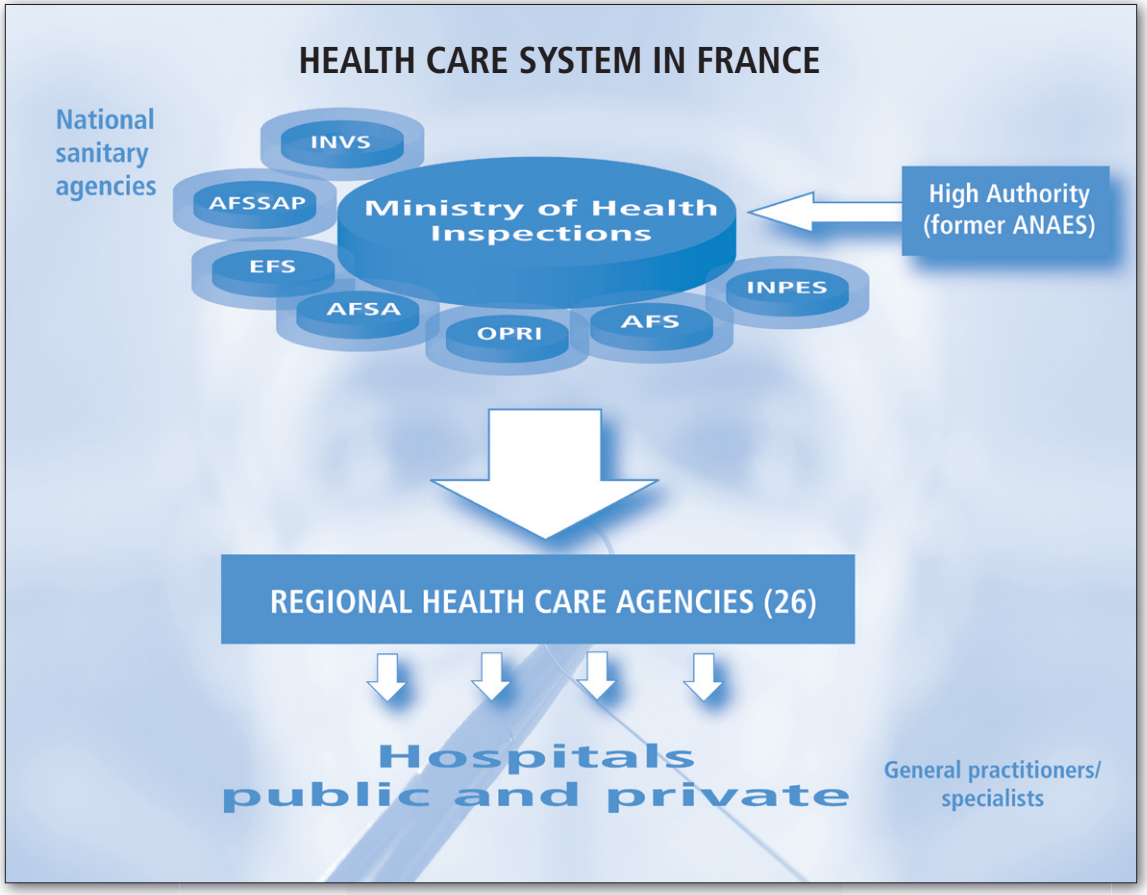


Fig. 3. The institutional framework for patient safety in France

Towards a safer culture – the French way

- The national accreditation agency developed ***national guidelines*** about risk management in 2003.
- During 2002–2004, two ***national conferences*** were held, on risk management and patient safety.
- In 2004, ***recommendations for integrated risk management*** were published on the Internet. They address various questions, including "how" (the proposal is to link the risk management committee to the existing accreditation committees) and "who" (at the hospital level, at the regional agencies and nationally).
- Since 2004, ***accreditation*** has focused on high-risk activities (such as surgical procedures and medicine management) and assessment of clinical practices.
- The first ***national survey related to severe adverse events*** is currently being carried out in public and private hospitals in France. This first prospective survey aims to estimate the frequency of preventable serious adverse events recorded in hospitals and to analyse their causes using root-cause analysis.
- ***Tools for risk analysis*** are being developed. For example, some tools from industry were adapted, and experiments are being conducted as to whether these could be applied in hospitals.
- A ***national audit programme*** on nosocomial infections is being carried out with a focus on hand hygiene.
- France has ***several systems for reporting adverse events.*** Some are mandatory: for example, on failures with health products and severe adverse events such as nosocomial infections. For nosocomial infections, the reports are gathered at the national level, which draws conclusions about best practices in preventing and controlling nosocomial infections, gives recommendations and develops national guidelines. Others are voluntary but still cannot be neglected – such as "near miss" events, which are linked to the accreditation of doctors and health care teams.
- ***Work is being done on indicators.*** For example, a national project on hospital performance with safety and quality indicators is being piloted in hospitals. Another example is a national indicator for nosocomial infections in hospitals.

Some challenges

- Training and communication need to be addressed more vigilantly, as highlighted in the 2005–2008 national programme on combating nosocomial infections the health minister presented.
- Assessing clinical practices and drawing guidelines based on such assessment continues to be a focus.
- Quality improvement is a national priority, but there is still a culture of fear, blame and little understanding of the systemic causes of errors in health care.
- The reporting systems lack legal protection.
- Feedback to the health professionals still needs to be improved.
- The key challenge is how to coordinate the activities of the various institutional actors working on improving patient safety in France.

6.5 Norway

"Where is the proof that reporting systems actually improve safety? Maybe even more important than collecting data is giving the data you already have to those in health care who will benefit from it."

The Norwegian way

Patient care is part of the second general national strategy for health care. An independent unit works in the Directorate for Health and Social Affairs. The unit is designed to provide patient safety information from national and international sources. It draws information from the National Patient Safety Registry, which collects and publishes information on patient safety events in Norway and provides classification and root-cause analyses.

Ask questions about what seems obvious and take nothing for granted

Does mandatory reporting really improve patient safety? Norway has a legally binding system for reporting events that have led to major harm. However, until recently this was done through a registry run by the same authority responsible for giving and taking away licences. As a consequence, the number of voluntary reports was very low, and there was no recognizable sign that the safety culture improved, although the reports from hospitals included many patient safety and quality indicators. Before investing many more resources in the reporting system, the Directorate for Health and Social Affairs carried out an in-depth analysis of all existing national and international evidence and experience. They identified some possible causes for the low impact of reporting systems on the real improvement of patient safety.

- Perhaps there is improvement, but reporting systems cannot demonstrate it.
- Perhaps the sensitive nature of adverse events related to patient safety has been significantly underestimated.
- Perhaps reporting systems register only the tip of the iceberg.
- Perhaps there is underreporting because a critical report is seen as a risk for professional careers.
- The root-cause analysis avoids or deliberately misses the problem of sensitivity.

Is the information collected the information needed? Today's data collection schemes tend to underestimate the need for system output. Most of the people developing this field are doctors. They are trained to collect data useful for epidemiology. For this purpose, the root-cause analysis is good enough; however, it is not sufficient when system output is the goal. Data should be designed for feeding back useful information to hospitals, health care units and teams – the level at which improvement can be made. The way to do this is to develop and use learning information, in which sensitive data or any kind of data irrelevant to the purposes of learning can be removed.

Lessons learned

- Respecting confidentiality is difficult, especially at the local level but sometimes even at the national level. However, anonymous reporting is not an option. Authorities need to be able to trace each separate case.
- At the national level, you will be given information to which you should react and on which you have a clear position as the responsible authority or institution.
- Systems thinking can be valuable when trying to understand the meaning of the reports.
- The national authorities are responsible for creating interest in patient safety. Providing feedback to health care is more beneficial than asking for more and more information.
- Authorities concerned with patient safety should first deliver the "goods", that is, the useful learning information, before asking for the "payment", that is, the information from health workers about adverse events.
- The value of having a national patient safety registry (such as that in Norway) is that it gathers groups of people interested in and committed to the topic who bring national and international reflections to the Norwegian experience, with a focus on dialogue and systems thinking.
- The turning-point is to start asking whether the proposed major policies actually work: whether the clinical guidelines and existing systems make a difference. Bringing in international experience is crucial for finding the answers to these questions.

6.6 Finland

"Make all the actors work together."

The regulatory framework

Finland has had an Act on the Status and Rights of Patients since 1992. This act established a patients' ombudsperson scheme. Two other pieces of legislation that regulate the patients' right to quality of care are the Patient Injury Act from 1996 and the Act on Health Care Professionals from 1994. Since March 2005, new legislation has been passed dealing with the access to care.

The implementation

The National Health Project is underway, involving the whole health care community, to implement this new legislation. It has produced national guidelines for treatment criteria, which also cover safety issues. Quality development will focus on safety in the future. For instance, a development project of STAKES – National Research and Development Centre for Welfare and Health – for 2004–2005 focuses on patient safety and risk management.

Various institutions and agencies are involved in the various aspects of managing quality.

- A centre for developing pharmacotherapy (ROHTO) has been functioning since 2003.
- A national agency for medicines collects mandatory reports on the side-effects of medicines.
- Infection control bodies have been created for hospital districts with earmarked state budget allocations.
- The Finnish Medical Association has founded its own Quality Council, which works with the state institutions. The Council promotes quality projects and plans to collect data on medical errors, with a special focus on how to correct them and learn from them.
- Risk management is introduced on a voluntary basis, to be implemented by the hospitals themselves and not on a centralized, nationwide scale.
- A benchmarking project for all Finnish hospitals has been developed to improve the quality of data about processes and outcomes. The work now is to include all patient safety information in health care registers.

Box 3 summarizes the process of governing patient safety in Finland to date.

- Patient safety is based on the present legislation. However, existing regulations need to be intensified.
- The process aims at establishing the practice of independent risk management in health care units, which includes:
  a) systematic reporting and analysing of errors;
  b) practice to correct errors; and
  c) training of personnel.
- The Ministry of Health and Social Affairs coordinates the cooperation network of various actors to organize monitoring.
- The Ministry is also preparing proposals for further action in 2005 concerning the national report on patient ombudspersons.

Box 3. Governing patient safety in Finland

6.7 Austria

"Patient safety is based on cultural learning and on organizational structures that make such learning possible. Ethical decision-making is indispensable."

The regulatory framework

Austria has had a charter on patients' rights since 1998. The federal government has also introduced the function of a patients' ombudsperson. The national health care reform was considered to be finalized at the end of 2004. One of the key new elements of the new concept is quality assurance.

- Penalties have been introduced for the institutions that do not include safety and quality assurance elements in their programme. Health care institutions can lose their contract with the insurance sector if they do not implement this requirement within one year.
- There is a legal basis for data exchange.
- A new federal institute for safety in medical care will start operating.
- The Austrian Medical Chamber founded its own federal institute for quality assurance.
- The federal health ministry is developing national guidelines for quality assurance with which all institutions will have to comply.

A national project to improve patient safety

Medsafe is a national project to build a method of understanding the care provided in hospitals in four areas:

- the technology and structures within a hospital that govern the prescription, dispensing, administration and monitoring of medication use;
- the atmosphere that will help understand the activities that may lead to undesirable outcomes during the whole care process;
- developing indicators that will help establish the baseline for reporting adverse events; and
- the level to which staff understand the need to prevent or minimize the likelihood of errors in medication use.

Five hospitals have taken the challenge to pilot the Medsafe project. Each of them has taken six steps, and some surveys have been carried out.

Evaluation of the results achieved has been integrated in the concept of the project since the beginning. It is already completed in the five pilot hospitals. The initial results already demonstrate a very positive impact on staff. The plan is to introduce the same approach later in all public hospitals that have contracts with the health insurance fund, as a way to force them to be involved in improving patient safety. The approach will also be offered to the private hospitals in Austria.

A project on error management

This second national project focuses on improving the safety culture through a systematic and cultural approach. The goal is to establish structures that back up a new culture of dealing with errors in health care and learning from them. The underpinning principles of this approach are the following.

- Organizations should be able to learn and develop. Cultural learning requires an atmosphere of trust and respect. Change can be introduced only gradually and carefully.
- Palliative care poses special challenges for patient safety.
- The communication component of the change is crucial. It should be explored both at the personal level and the system level (how the system learns from its mistakes by talking openly about them).
- Learning from errors requires a round-table approach – all the relevant views should be voiced at the same time and in the same room.
- Cultural learning from errors inevitably requires analysing not only the health care issues but also the ethics of the decisions made: the possible contradiction of moral values. The ethical dimension of decision-making can either promote or constrain patient safety.

6.8 Germany

"Political decisions backed up with the readiness of experts to offer solutions."

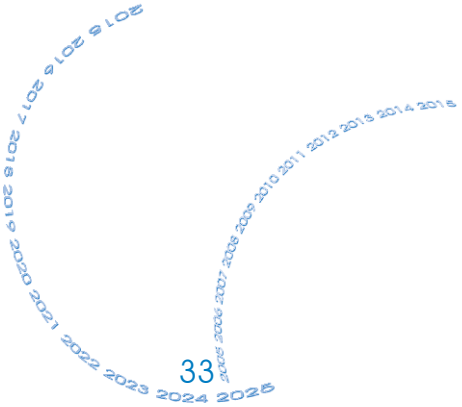
The framework

Since Germany is organized in a federal manner, no central power can regulate this field completely. The federal government creates the framework. In early 2005, a new Institute for Quality and Efficiency in Health Care (IQWIG) was set up to lead the work on quality assurance. Its mission is to check up each and every aspect of the technology of treatment and diagnosis and to go back and check retrospectively problems and issues that have been around for years. One important result is expected to be the elimination of some unnecessary steps or invalidated treatments from the procedure.

Another recent development is a guide on patients' rights. In Germany the recognized rights of patients include:

- the right to a free choice of a doctor;
- the right to a second medical opinion;
- the right to disclosure of information and to access to the documentation;
- the right to autonomy; and
- the right to not know about certain things (which is very difficult to reconcile with assuring quality).

Germany has also made a major political step in recognizing patient safety as an issue of national priority, as a new Office of the Federal Government Commissioner for Patients' Affairs was opened in January 2004. The Commissioner acts as a contact person for patients as well as for the groups representing patients. The function is supposed to consider patients' rights to counselling and information and their right to participate. This is an entirely political function, with the rank of a minister that is set at the highest political level as a new federal-level focal point for patients. This fostered the concept of patient safety in the country. Thousands of enquiries were received in the first year: too many to deal with. This public demand, however, was beneficial – it created opportunities for interaction with the other stakeholders involved, such as patients' self-help groups and medical organizations, to support the work of the Commissioner.



7. Some solutions in governing patient safety

"Safety is not only about money, nor is it only about technology. Money and technology will not solve our problems. The central issue is about will – professional and political."

Political will

Countries need political will to address patient safety. Without political commitment, this issue cannot be carried through. Such a commitment is needed at the level of parliament to secure the necessary legislation, of health ministries to define both the political and the health targets and to take up the leadership, and of the regional and local authorities to ensure that changes are implemented in a sustainable manner. The political debate can be beneficial because it triggers mass-media and public interest, forces the health professions to take on the challenge and provides an opportunity for the health authorities to take a leadership role. However, the political debate on patient safety hides risks – it can be swiftly turned into a shame-and-blame campaign that is counterproductive. Once the problem is put out for public and political debate, health authorities therefore need to be ready to establish a positive vision and constructive solutions for change.

Professional will

Health professions play a central, instrumental role in changing the culture of adverse events and errors. In several countries, progress started to be made only when health professionals took up the issue and got really involved.

Leadership

To get really involved, health care workers need support, incentives and leadership that leads them through. Physicians are often slow to make changes, even when they are indispensable – because of public demands or the new developments in the health sector. Some conservatism is initially bred in the medical profession owing to the nature of the academic medical education, and this is further deepened in medical practice. National health authorities therefore need to lead to counterbalance this, by setting the goals and providing specific tools and useful practical methods to implement change.

Leadership is also decisive for successfully bringing together all stakeholders. In several countries, the lack of an integrated approach based on a strong consensus among everyone involved was an obstacle for making progress in patient safety. Various solutions and interesting schemes were being built and tested, but separately; the challenge remained to coordinate them all. Patient safety cannot be established as a culture permeating health systems without consensus. Coordination and shared commitment are the way to achieve practical results that will convince the public that higher safety levels have been reached. For instance, physicians' chambers, professional associations, academic societies, the public health sector, private providers and insurers can agree on operational quality and ethical standards.

At the international level, WHO is perceived as the actor that should take the leadership role, offering recommendations, taxonomy and forums for exchange of information and experience among countries. The World Alliance for Patient Safety, created in 2004, is recognized as a key player coordinating international efforts and developments.

Finally, leadership is a way to ensure that health systems take up and sustain any change for improving patient safety. Without a change at the system level, the culture of errors cannot really be improved.

Changing culture

"Implementing cultural and behavioural change is more difficult than putting systems in place. The human factor is what we need to act upon."

No cultural change can come without proper leadership. Culture is not separate from the basics of health care work. Progress in safety emerges from the systems and culture together. Everything done within the health system contributes to changing the culture.

National policy-makers may consider several questions when they decide to address the problem of culture.

- Is ethics clearly visible in the way the health system functions? Are there ways to check and ensure that the personal and professional standards of health workers do not contradict ethical principles?
- How can the health system deal with the reluctance of health professionals to talk about errors? How can the health system understand better the sensitivity of the issue?
- What factors contribute to the culture of silence and denial? How can the health system deal with the fear of punishment, litigation, blame, shame, stigmatization and disruption of careers?
- Are appropriate legal and ethical mechanisms in place to deal with any increase in the number of reported errors?
- Are some people skilled in identifying when a negative climate and a hostile atmosphere in a health setting nurture the culture of silence and errors in health care?
- Influencing a change in culture depends largely on destigmatizing errors and improved communication at every level and among each actor of the health system. What are the country-specific ways of developing a new interactive culture within health care teams?
- How can the reporting systems be used to change culture? Sharing examples of errors, examining and looking for errors, reporting errors on a regular basis, offering ways to learn from errors may lead to a shift in mentality, attitudes and behaviour. Such a shift will slowly bring the health sector to a stage at which talking about errors is already a comfortable thing and the right thing to do, being part of the professional code.
- How can the stage be reached at which transparency and honesty are the standards not only within the health professions but also in the interaction of health workers with their patients?

Quality of data

"Give information that is concrete, visible and useful."

Health professionals need data that can convince them about three things: that there is a problem, that change is necessary and that they can benefit from the change. Such information needs to be red-flagged, reliable, reproducible, unassailable, clearly communicated, compelling, adjusted for risk, adjusted for case mix and user-friendly. Every single clinical scenario provides extraordinary quantities of facts that can help professionals to learn. But this information is most often ignored because it is hidden and unconvincing. For instance, there is abundant evidence about the direct link between mortality in hospitals and the sophistication of human resources practices, such as the existence of appraisals *(Fig. 4)*. This is the type of information that managers need to commit to implementing a change.

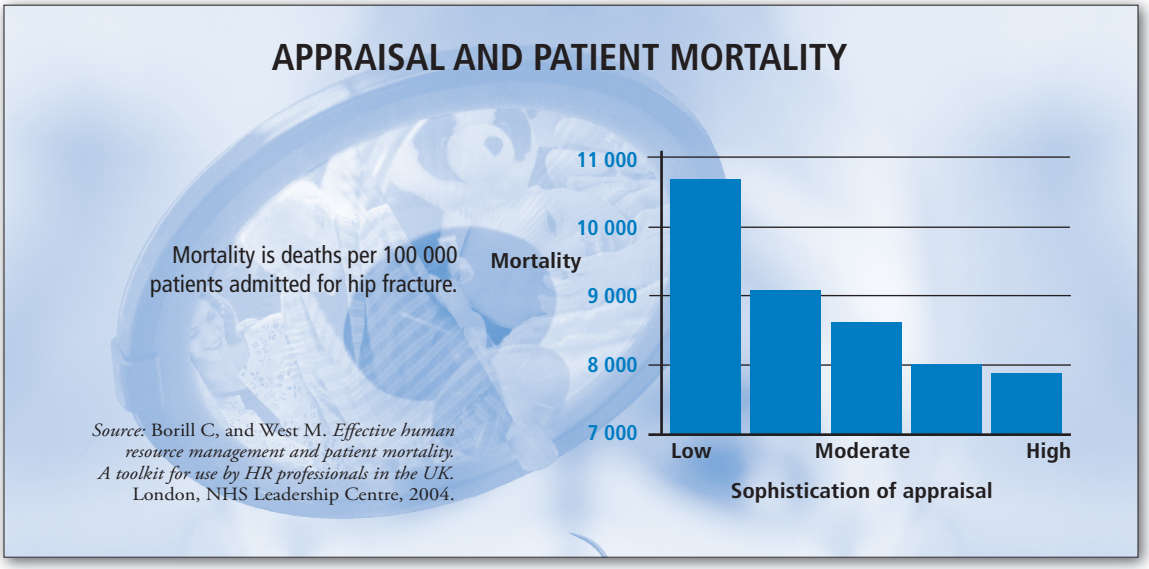


Fig. 4. Sophistication of health care staff appraisal and patient mortality in the United Kingdom

Unless it is locally used, owned and responded to, information from reports does not mean much. Patient safety data become useful and meaningful only when they are fed back to the health workers, hospitals and managers: to the health system settings where errors occur and where they can be avoided. Real feedback and real use of the reports empowers health care staff and encourages them to collect data and to be willing to work for change.

Bring in the patients

"The patients are making us move.
Before they trust us, they ask questions."

The end-users of health services have changed significantly. Patients have become consumers. They do not care who runs, owns or regulates a hospital; they only care where they will get the best and safest treatment. Patients can therefore play an essential role in increasing patient safety. This already happens in some market-based systems, where patients' choice lies in the heart of public health. The new, Internet-oriented patients are not only aware of their right to choose; they are also well informed, demanding and questioning. In this regard, they can be supportive and innovative; they can advise a new learning culture regarding errors. No patient safety plan can be successful without their participation.

Managing patient safety

"Real improvements happen at the level of institutions."

Health care managers can contribute to improving patient safety in various ways. One unexplored potential for this is interdisciplinary teamwork. With red-flagging mechanisms for learning that are steadily built into the system, training of staff and continuous improvement of human resources practices are a major factor for success.

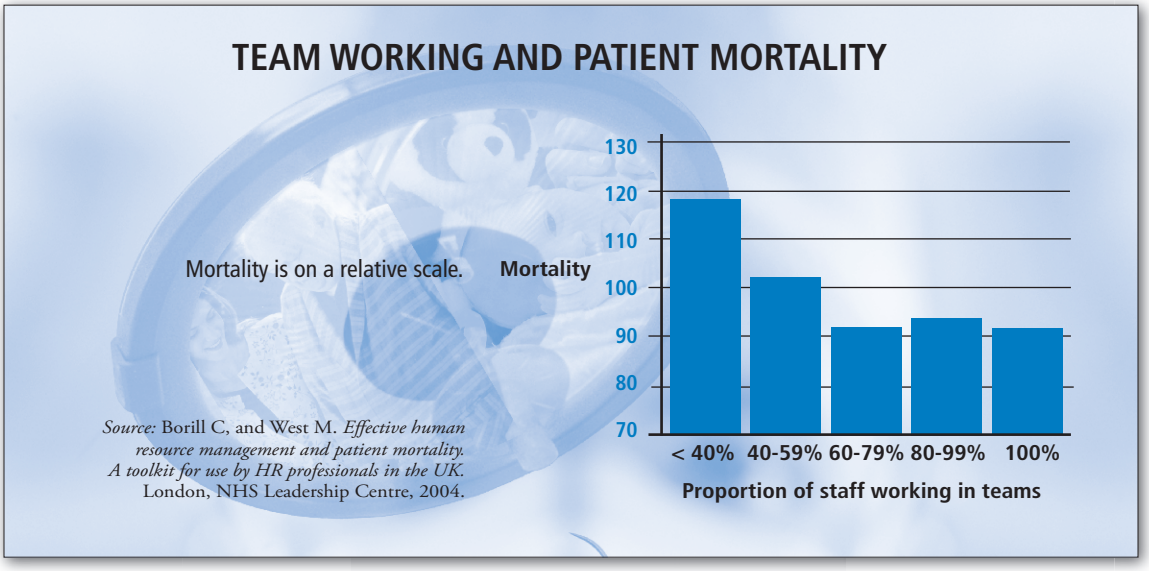


Fig. 5. Relationship between the proportion of health care staff working in teams and patient mortality in the United Kingdom

For instance, if the work done to improve quality is immediately integrated in staff training, different concepts can be combined (quality, accreditation and safety) to achieve similar and overlapping goals.

Evidence shows that 70–80% of errors in health care are related to poor communication and failure in interpersonal interaction and that patient mortality decreases with the proportion of professional staff working in teams *(Fig. 5)*. Thus, focusing on teamwork is an investment in developing a resource with huge potential.

An open and interactive working environment in health care is a prerequisite for creating a new culture in which professionals are willing to learn from the mistakes made in order to prevent new ones.

Some other management solutions that may be useful are being tested in various countries.

- Continuous training, including through simulation, is a good system for preventing errors in health care.
- Health systems should be prepared to change the operational schemes quickly and radically (for example, the levels of responsibility or the members of the teams) when clear evidence shows that the previous schemes led to systematic errors.
- Hospitals can develop specific approaches to quality management. For instance, evidence demonstrates that information on errors is best discussed in quality circles – groups of concerned individuals from the institution, its audience and patient interest groups (a mixture of governing and advisory board) who come together, debate and thus contribute to identifying patient safety issues within a hospital.
- Staff surveys are an excellent way to determine what hospital staff members think about their own culture in patient safety.
- Learn from experience in other areas of public health. For instance, in the efforts to destigmatize errors, mental health can offer interesting solutions that have already been tested and need only be adapted to patient safety. In return, mental health workers can see it as very useful for their everyday work to focus on safety issues.

Evaluation

"Public health needs to wake up to the reality of evaluation. At the very beginning of the work on quality improvement and patient safety, we have to put in place real indicators against which we agree to be measured. Without such commitment to evaluation, we will not be honest and will not fulfil our duty."

Successful national patient safety programmes include performance indicators that are developed at the start, together with the concept and the action plan. This is a way to gather knowledge about what really works and what not. Public health needs to have the courage to commit to reporting and evaluation. This means being ready to face criticism in case the initially agreed indicators are not met. Adopting such an attitude requires the whole sector to make a vast shift in culture. Patient safety is only one part of this process.

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