World Health Organization

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Technical assistance for establishing a patient safety system in Estonia

Mission report

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MISSION REPORT

JUNE 2017

ABSTRACT

This report is based on the findings of a visit to study health care settings and of interviews with health care decision-makers and local stakeholders in Estonia: the Ministry of Social Affiars, the Health Board, the Patients' Association, the Family Doctors' Society, the Estonian Nurses' Association, the University Clinic of Tartu, Tartu Health Care College, the Estonian Health Insurance Fund, East Tallinn Hospital and Rakvere Hospital. It includes a summary of the methods used, the information acquired from the interviews and recommendations for establishing a national patient safety system. The report describes experience in Denmark, Poland and Slovenia in establishing patient safety systems that was considered relevant to the Estonian context.

The aim of a patient safety and reporting system is to identify patient safety concerns in order to learn from them and prevent harm to patients in a complex, high-pressure, fast-moving health care environment, where errors can and do occur. Harm is prevented by identifying risks, responding to those risks and acting on lessons learnt in order to improve the safety and quality of patient care.

KEYWORDS

Patient Safety

Health Systems Plans - organization & administration

Delivery of Health Care

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1. Executive summary

The Ministry of Social Affairs in Estonia requested technical assistance from WHO in establishing a patient safety system in Estonia that involved reporting, learning from incidents and subsequent improvement. This report is based on the findings of a study visit to health care settings and from interviews with health care decision-makers and local stakeholders in Estonia. It includes a summary of the methods used, the information acquired from the interviews and recommendations for establishing a patient safety system. The report also describes experience in Denmark, Poland and Slovenia in establishing patient safety systems, which were considered relevant to the Estonian context.

The aim of a patient safety and reporting system is to prevent harm to patients in a complex, high-pressure, fast-moving health care environment, where errors can occur. Harm is prevented by identifying risks, responding to those risks and acting on lessons learnt in order to improve safety and the quality of care provided to patients. The learning component is a central element of a reporting system, so that errors in the system can be corrected to prevent recurrence.

WHO has stated[1]:

"The most important knowledge in the field of patient safety is how to prevent harm to patients during treatment and care. The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health care system. Health care errors are often provoked by weak systems and often have common root causes that can be generalized and corrected. Although each event is unique, there are likely to be similarities and patterns in sources of risk which may otherwise go unnoticed if incidents are not reported and analysed."

Section 6 of this report lists recommendations that reflect the expectations of the stakeholders interviewed and include international experience that can provide useful guidance and support for the design and implementation of a patient safety system in Estonia.

At national level:

- The Estonian health care system should establish a patient safety system to improve the quality and safety of care, based on reporting of and learning from adverse events.
- Clear legislation should be enacted for the reporting and learning system, which ensures "blame-free" reporting of adverse events and stresses the importance of learning.
- The legislation should emphasize the importance of an operational learning system.

[1] http://www.who.int/patientsafety/implementation/reporting_and_learning/en/

- The legislation should include the establishment of a national liability insurance and compensation system and ensure that learning and improvement are separate from the liability and compensation system.
- The Estonian health authorities should prepare a national strategy on patient safety and quality of care, with a clear governance structure for the system and awareness-raising among the public and health professionals.
- The Estonian health authorities should decide whether the patient safety system is to be based on local solutions or on a common national solution.
- Consideration should be given to developing systems for quality control and quality improvement.

At each level of the health care system:

- A learning environment should be developed as an integral part of the patient safety system to make risk visible and to respond to the identified risk.
- The learning system should be supported by clear organizational structures such as supervisory bodies.
- The patient safety system may include reporting of events that could have caused harm (near misses).
- Health care professionals at all levels should be encouraged to report.
- Patient safety systems should be designed for all levels of health care.

With regard to what is registered and reported, including the collection and generalization of data:

- The information to be reported should be clearly defined and described.
- The types of adverse events to be reported and their classification should be defined.
- A mechanism should be established for gaining insight from aggregated data on incidents.

For patients and users of the system:

- Users, patients, carers and families should be enabled and encouraged to report adverse events.
- The design of the reporting system should include involvement of patients, families and carers.

For educational institutions:

- Patient safety should be included in the curricula of health care professionals' education at all levels.

To ensure that providers and professionals are motivated to change their attitudes and culture:

- Health care professionals should be involved in implementing and (if possible) designing local patient safety systems.

2. Introduction

2.1 Policy context

Globally, health and development priorities converge on the critical importance of quality of care and patient safety in working towards well-performing health systems for improved population health and well-being. This is made explicit in the United Nations' Sustainable Development Goal 3, specifically target 3.8 on universal health coverage, where progress calls for access to quality, essential health services that are *safe* and acceptable to all people and communities.[2]

WHO has long recognized this link between quality and population health and well-being. Most recently, the endorsement of a global framework on people-centred and integrated health services[3] and approval of the European Framework for Action on Integrated Health Services Delivery[4] in the European Region, signals the commitment of Member States to uphold the principles of a primary health care approach and its vision for quality services and work towards systems-based, outcome-oriented transformations.

The WHO European Framework for Action on Integrated Health Services Delivery recognizes improving performance as a core process of services delivery to strengthen clinical governance and create a system of lifelong learning. Importantly, this also includes establishing the system conditions to realize this sustainably. This report is guided by these principles in working through a system's approach to improve patient safety.

2.2 About this report

The Ministry of Social Affairs in Estonia requested WHO to provide technical assistance for developing a patient safety system in Estonia that includes reporting, learning and improvement. The objectives of the intervention were to make recommendations and provide examples of patient safety systems in other countries. The terms of reference were to include:

- registering, reporting, collecting and pooling data on treatment complications, adverse events and near misses;
- a system for giving feedback to providers on their internal analyses and for continuous learning to improve the quality of care in hospitals and primary care centres;
- patients' views of the system, including feedback, dialogue with and compensation to patients and families;
- the role of the State (the Ministry of Social Affairs, the Health Board, the Estonian Health Insurance Fund);
- support for and development of patient safety systems in hospitals and primary care centres; and
- motivating providers and professionals to change their attitudes and culture to ensure greater transparency and openness.

The assignment was undertaken by Barbara Kutryba, National Centre for Quality Assessment in Health Care, Poland, and Simon Feldbæk Peitersen, Danish Society for Patient Safety, Denmark, who visited Estonia on 14–16 November, 2016. The country visit was preceded by telephone conferences organized by WHO Country Office in Estonia and the Ministry of Social Affairs.

This report is based mainly on the findings of the visit. It also includes a summary of the methods used, the information acquired in interviews with local stakeholders and recommendations for establishing a patient safety system in the Estonian health care system. Experience in Denmark, Poland and Slovenia is included, as it was considered relevant for establishing a patient safety system in Estonia.

[2] Transforming our world – the 2030 agenda for sustainable development. New York: United Nations; 2015 (https://sustainabledevelopment.un.org/?menu=1300, accessed 16 November 2017).
[3] Framework on integrated, people-centred health services. Geneva: World Health Organization; 2016 (http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_39-en.pdf, accessed 16 November 2017).
[4] Strengthening people-centred health systems in the WHO European Region: framework for action on integrated health services delivery. Copenhagen: WHO Regional Office for Europe; 2016 (http://www.euro.who.int/__data/assets/pdf_file/0004/315787/66wd15e_FFA_IHSD_160535.pdf?ua=1, accessed 16 November 2017).

The aim of a patient safety and reporting system is to prevent harm to patients in a complex, high-pressure, fast-moving health care environment, where errors can occur. Harm is prevented by identifying and responding to risks and learning from incidents to improve the safety and quality of patient care. The learning component is a major element of a reporting system, as it addresses system errors and their correction to prevent recurrence.

WHO has stated:[5]

The most important knowledge in the field of patient safety is how to prevent harm to patients during treatment and care. The fundamental role of patient safety reporting systems is to enhance patient safety by learning from failures of the health care system. Health care errors are often provoked by weak systems and often have common root causes which can be generalized and corrected. Although each event is unique, there are likely to be similarities and patterns in sources of risk which may otherwise go unnoticed if incidents are not reported and analyzed.

In June 2009, the Council of the European Union published a Council Recommendation on patient safety, [6] which states that

Poor patient safety represents both a severe public health problem and a high economic burden on limited health resources. A large proportion of adverse events, both in the hospital sector and in primary care, are preventable with systemic factors appearing to account for a majority of them.

The Recommendation identifies four areas for action in patient safety: (i) policies and programmes, (ii) empowering patients, (iii) reporting adverse events and learning from errors, and (iv) educating and training health care workers. Member States are expected to:

support the establishment or strengthen blame-free reporting and learning systems on adverse events that:

- provide information on the extent, types and causes of errors, adverse events and near misses;
- encourage health care workers to actively report through the establishment of a reporting environment which is open, fair and non-punitive; this reporting should be differentiated from Member States' disciplinary systems and procedures for health care workers, and, where necessary, the legal issues surrounding the health care workers' liability should be clarified;
- provide, as appropriate, opportunities for patients, their relatives and other informal caregivers to report their experiences;
- complement other safety reporting systems, such as those on pharmacovigilance and medical devices, whilst avoiding multiple reporting where possible.

A study commissioned by the Directorate-General for Health and Consumers found that 8–12% of patients admitted to a hospital in the European Union had adverse events while receiving health care; most of the events could have been prevented. The main events were health care-associated infections, medication errors, surgical errors, medical devices failures, errors in diagnosis and failure to act on the results of a test.[7] A Danish study on adverse events in 2001[8] found that 9% of patients suffered harm, while a recent unpublished Polish study (2015) reported that 7.2% had adverse events. There are no current published data from Estonia, but there is no reason to believe that the problem is very different from that in other European countries.

The Estonian health sector is mainly a public, single-payer system, with almost universal coverage of the population of approximately 1.3 million. Health policy has introduced reforms and initiatives to ensure access to care and the sustainability of the health care system,[9] and patient safety and quality of care are beginning to receive attention at policy level. The previous Government formulated an action plan for

[5] http://www.who.int/patientsafety/implementation/reporting_and_learning/en/
[6] http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:C:2009:151:FULL&from=EN.
[7] Conklin A, Vilamovska AM, de Vries H, Hatziandreu E. Improving patient safety in the EU. Assessing the expected effects of three policy areas for future action. Prepared for the European Commission by RAND Corp.
[8] Incidence of adverse events in hospitals. A retrospective study of medical records. https://www.ncbi.nlm.nih.gov/pubmed/11590953.
[9] Lai T, Habicht T, Kahur K, Reinap M, Kiivet R, van Ginneken E. Estonia. Health system review. Health Syst Transition 2013;15(6). http://www.euro.who.int/__data/assets/pdf_file/0018/231516/HiT-Estonia.pdf.

2015–2019, which instructed the Ministry of Social Affairs to establish two systems to improve the safety and quality of care: national liability insurance and compensation for patients for any harm, and a national system for reporting complications and adverse events, with feedback to the provider organization for learning and improvement. The Ministry has also prepared a broader strategy for improving the quality of care, with a comprehensive, consistent policy framework for all structures.

Although little attention has been paid to patient safety systems at policy level, several local initiatives have been undertaken. For example, a surgical ward in Tartu University Hospital has adapted a system for monitoring surgical complications and adverse events (see Annex A2.4), and a similar initiative has been undertaken in the obstetrics and gynaecology department in East Tallinn Hospital.

A system for reporting ensures transparency about complications and adverse events. It requires local support for a culture of learning, a blame-free approach and, at national level, a legislative framework. According to the WHO draft guidelines for Adverse Event Reporting and Learning Systems, the absence of fear of retribution is a crucial element in the success of reporting systems, not only in health care but also in other sectors. Thus, staff who report incidents should be protected from any disciplinary action.

3. Methods

The report is based on the findings of meetings and interviews with local stakeholders in the Estonian health care sector. The interviews were conducted by experts and representatives of the WHO Country Office in Estonia and the Ministry of Social Affairs. The stakeholders that were invited to participate in the interviews and share their views and opinions on the proposed national patient safety system were:

- the Ministry of Social Affairs;
- the Health Board;
- the Health Insurance Fund;
- patients' associations, represented by the umbrella organization Patients with Disabilities;
- the Family Doctors' Association;
- the Estonian Nurses' Association;
- the Department of Nursing (nurses and midwives) at Tartu Health Care College and the Public Health Institute in the Faculty of Medicine at Tartu University;
- Rakvere Haigla Hospital (general);
- East Tallinn Hospital (municipal); and
- Tartu University Hospital.

The meetings were semi-structured, with open discussion about the barriers to and facilitators of establishing a national patient safety reporting and learning system. The terms of reference did not include a systematic or desk literature review or any other comprehensive data collection. The background papers received were the terms of reference; Health Systems in Transition, Estonia, 2013;[10] an overview of the Health Board questionnaire used in hospitals for reporting errors and complications in 2016; and the patient safety reporting system used at Tartu University Hospital. These documents provided useful information about local perceptions and developments in health care safety.

[10] Lai T, Habicht T, Kahur K, Reinap M, Kiivet R, van Ginneken E. Estonia. Health system review. Health Syst Transition 2013;15(6).

4. Findings

The findings from the interviews are described below.

4.1 Legislation

There is currently no legislation that would effectively support implementation of a patient safety system with reporting and learning from adverse events. Most stakeholders reported that medical staff feared the threat of victimization and punishment if they reported an adverse event. A report by the Health Board in 2016 indicated that reporting of errors and complications was compulsory only in certain cases, such as blood transfusions and pharmacovigilance.[11]

Although legislation on infection control has been in place for some years, Estonian hospitals do not yet have efficient systems for monitoring health care-associated illnesses.[12] The discussions held at the Ministry of Social Affairs revealed that, even when monitoring and infection control are in place, the numbers of cases may be underreported, as the numbers reported are lower than those in other European countries.[13]

4.2 National health policy initiatives on safety and quality of care

The Ministry of Social Affairs prepared a comprehensive, consistent policy framework for a new strategy to ensure the quality of care and patient safety in 2016, and the Health Board is planning a risk reduction strategy. The initiative is a response to awareness about adverse events occurring in health care from the patient complaints system and systems at a number of local hospitals. The Ministry is therefore drafting a law on patient insurance for incidents identified as adverse events by experts at the Health Board.

The Estonian Health Insurance Fund has set up a contract monitoring system, expected to be finalized in 2018, based on the Law of Obligations Act.[14] The contract is designed to ensure patient safety, a mechanism for collecting patient complaints and a system for recording adverse events. Other developments in patient safety and quality of care include the work of two committees at Tartu University that are preparing clinical guidelines and quality indicators. The Health Insurance Fund promotes establishment of a coherent framework applicable to all health care providers to ensure patient safety, such as registration of treatment errors and malpractice. The reporting and learning system should parallel the liability system (possible patient insurance), which is also under development.

4.3 Attitudes towards a patient safety system

In general, all the stakeholders we met during the country visit supported the idea of creating a national patient safety system, including reporting and learning from adverse events, with a clear will to transform the current patient safety culture at all levels of care. At national level, the Health Board recognized the need for a national patient safety system but commented on the lack of

[11] Regulation no. 128. Health services quality assurance requirements. Tallinn: Ministry of Social Affairs; 2014.
[12] 2005 – EU public consultation – preventing/controlling healthcare-associated infections; 2005 – EU report on prudent use of antimicrobial agents in medicine; 2006 – Comments on EU healthcare associated infection consultation. Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01).
[13] https://ecdc.europa.eu/en/healthcare-associated-infections
[14] https://www.riigiteataja.ee/en/eli/528032016012/consolide

clarity about roles. Local, hospital and primary care levels also expressed support. All interviewees recognized that the patient safety culture is immature, and this was considered a significant obstacle to implementing a reporting and learning system. Supportive legislation, leadership, communication and learning systems are required.

4.4 Culture of patient safety

The interviews revealed a reluctance to report and discuss adverse events because of fear of disciplinary action by employers and supervisors and penal sanctions in the courts. The absence of a blame-free environment was described as the main obstacle to implementing a patient safety system in Estonia. In order for such a system to operate, health care professionals must be able to report adverse events without fear of disciplinary investigations. It will take time to introduce and build a culture of reporting and learning, but the interviews showed strong will and support at all levels. A culture for reporting adverse events will require changes in information, training, education, awareness and transparency.

4.5 Reporting systems

Currently, there is no single national system for reporting adverse events. Local systems have been developed by individuals on the basis of regulation no. 128,[15]. One of the hospitals included used the national E-health system to collect data, whereas another used a local Microsoft Access database. Such local systems could serve as models for capturing local data and for the functioning of a national system. Interviewees raised the question of whether the registration system should be based on local systems, a national system or both. Health care professionals found a reporting system relevant; the doctors and nurses interviewed emphasized the importance of a system that was non-bureaucratic, easy to use and, if possible, integrated with current systems such as E-health. Currently, patients, family members and others cannot report adverse events in the local reporting systems. Some advantages and disadvantages of local and a national system are listed in the recommendations.

4.6 Links to other areas, such as reporting infections

The interviewees commented that data on adverse events could be collected from existing databases and structures, such as those for infection control, antibiotic resistance and pharmacovigilance. According to a report from the World Bank Group,[16] "all hospitals are required by law to report hospital infections, side effects of pharmaceuticals and side effects of blood transfusions to the health board". The survey conducted by the Health Board showed that many hospitals already have systems for reporting adverse events but do not report them to a national authority, mainly because there is no requirement to do so. The experience at the hospitals indicates that information could be extracted to form the basis for a future reporting and learning system.

4.7 Learning systems

Local follow-up of and learning from adverse events had been established at two of the three hospitals visited. The learning system usually consisted of multidisciplinary meetings within or among hospital wards, and no systematic approach to learning appears to be used, like "root-cause

[15] Regulation no. 128. Health services quality assurance requirements. Tallinn: Ministry of Social Affairs; 2014.
[16] The state of health care integration in Estonia. Washington DC: World Bank Group; 2015.

analysis", the London Protocol or "failure modes and effect analysis", and there was no systematic follow-up of the events. Furthermore, the systems were only local initiatives and, like the reporting systems, were not used throughout the hospital. Although updating guidelines and communication to staff were briefly mentioned, it was not clear how the findings led to change, due probably to lack of systematic approaches to learning and of a strategic, systematic approach to continuous improvement at both ward and hospital level.

There is no regional or national system for exchanging information on reporting, learning and quality improvement based on adverse events and no clear criteria for e.g. reporting and operational definitions. The type of information to be shared at different levels should be determined, as some information may be relevant only at local or ward level, whereas other information might be relevant at national level.

4.8 National health care system

In the interviews, the Ministry of Social Affairs, the Health Board and the Estonian Health Insurance Fund all supported improvement of patient safety and quality of care by implementing a reporting and learning system. Comments were made, however, about the division of work and the precise purpose of the system, who would do what in such a system and the responsibilities of different organizations, including whether the Health Board should analyse aggregated data on adverse events or investigate local events. Such uncertainty is to be expected when establishing a new national system before actual plans and policies are in place.

4.9 Primary care

The interview with the representatives of the Primary Care Association showed that there was already agreement about the need for a patient safety system. As reported by others, they noted the lack of a culture of openness, with a "blame culture" still in place. They highlighted the importance of a clear definition of an adverse event in primary care and what should be reported within that definition. Various safety issues were raised, including transitions along care pathways and coordination among sectors. It was suggested that the system be implemented in steps in order to find the optimal solution for primary care settings.

4.10 Patient organizations

The representative of patient organizations, like other stakeholders, said that patient safety was important and a patient safety system was essential. Patient organizations, patients and citizens should be made aware of the importance of a patient safety system and of the differences between reporting and learning from adverse events, a complaints system and a compensation scheme. Patients and their organizations are currently focusing on a complaints system and on obtaining compensation for patient harm and medical errors.

4.11 Patient involvement and feedback

Patients and families are not involved in local reporting and learning systems, and this was not mentioned during the discussions on patient safety. Although the WHO draft guidelines on adverse events reporting and learning systems recommend enabling reporting by the public and by

patients, even mature systems, such as that in Denmark, have only recently opened their reporting and learning system to the public. A clear distinction must be made between the complaints system and the reporting and learning system, and the principles of public reporting, including the purpose and whether feedback will be provided should be defined.

4.12 Educational system

The interviews indicated that the educational sector is highly motivated and willing to include patient safety and quality of care into the curricula at nursing and medical schools. Currently, such developments are more advanced in nursing education: the Faculty of Nursing at Tartu Health Care College has a voluntary 52-h course in patient safety. Education and training in patient safety and quality of care should be integrated into the curricula for undergraduates and postgraduates and into "life learning" for health care professionals. The content should cover reporting and learning as a critical element in the development of the Estonian health care sector.

5. Experience in and learning from other countries

5.1 Denmark

Fig. 1 illustrates the development of the Danish patient safety programme.[17] It shows that patient safety cannot be achieved rapidly but may take many years. Currently, the focus is on improving the culture of patient safety and ensuring reliable, safe systems at clinical level. Adverse events reporting and learning are the starting points for that work. The method for ensuring quality in services was presented in April 2015, when the Ministry of Health announced that hospital accreditation through the Danish model would be replaced by a national quality improvement strategy based on system- and value-based thinking to improve care and treatment.

Patient safety may rest on four main pillars (Fig. 2): (1) inspection and supervision, (2) compensation, (3) complaints and (4) learning. The bold bar between pillars 3 and 4 shows that data from the database of adverse events cannot be used under pillars 1, 2 and 3, while data from compensation cases and complaints can be used for learning and improvement. This clear division supports a blame-free learning environment, in which health care professionals who report adverse events cannot be subjected to investigation or disciplinary action by the employer, the Board of Patient Safety or courts of justice.

[17] Danish National Patient Safety Authority. Presentation made at the meeting on patient safety and quality held at the WHO Regional Office for Europe, Copenhagen, March 2014.

Fig. 1. Development of the Danish patient safety programme

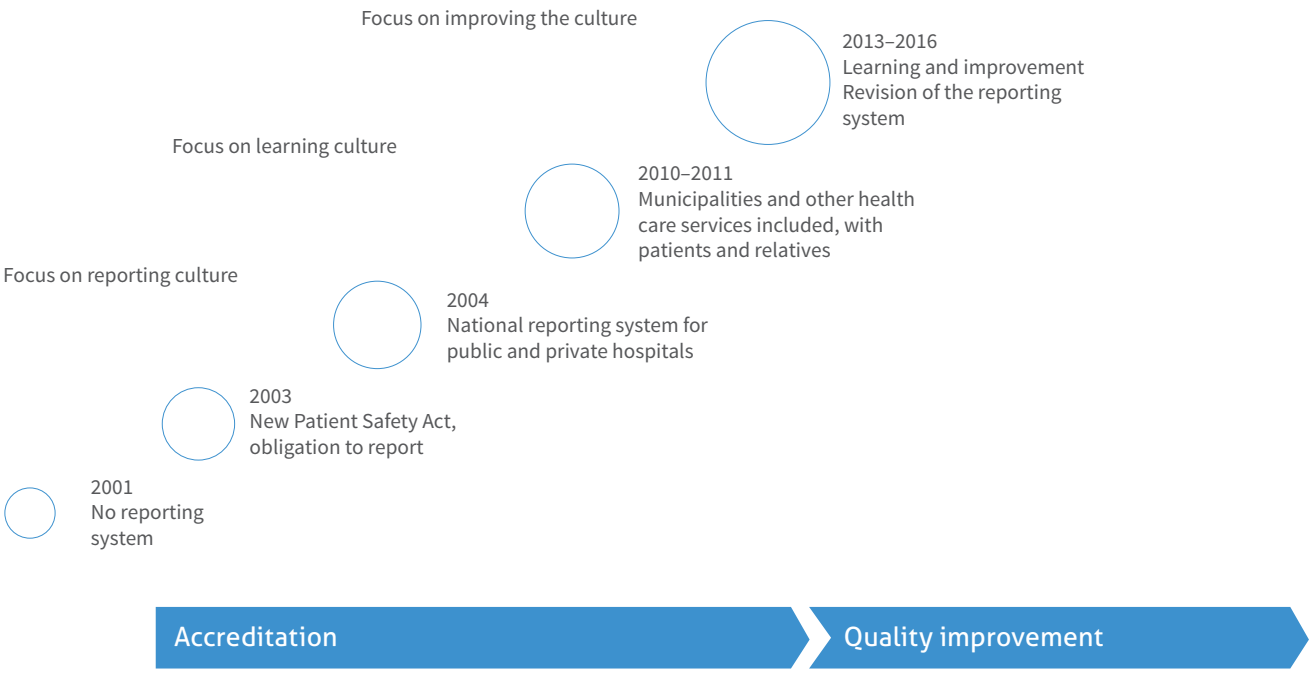
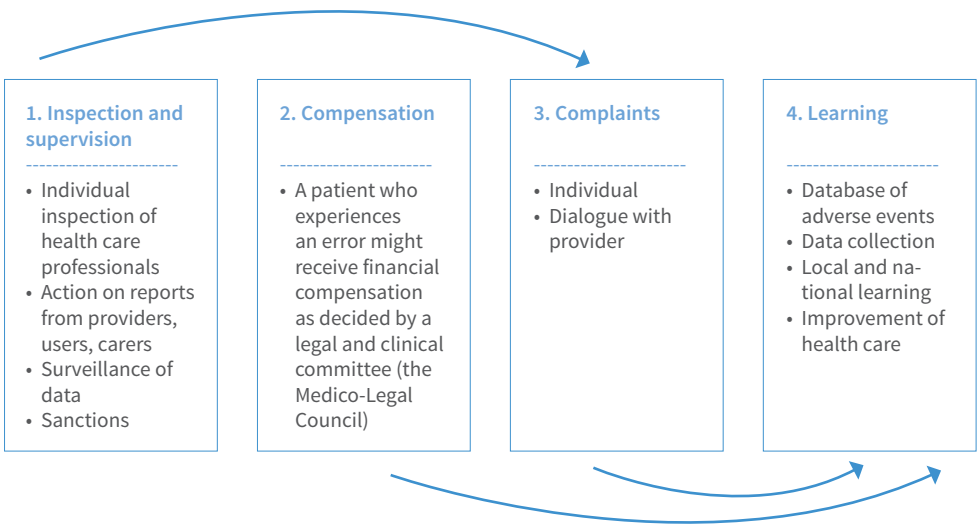


Fig. 2. Four pillars of the Danish patient safety system



Health regulatory bodies

The Ministry of Health provides the legal framework (Danish Health Act, including a section on patient safety) for the Danish health care system (see Annex 2.1). The Danish Patient Safety Authority is the national authority for the four pillars shown in Fig. 2.

Legislation

A section of the Danish National Health Act addresses patient safety, including reporting and learning. Article 61 of the Act states that front-line personnel are obliged to report and that hospital owners are obliged to act on the basis of the reports. The Danish Patient Safety Authority is obliged to communicate adverse events, and front-line personnel who report an adverse event cannot be subjected to investigation or disciplinary action by the employer, the Board of Patient Safety or a court of justice as a result.

Level of the system

Reporting is done locally at ward or hospital level. Once an adverse event is reported to the national database, it is automatically sent to the hospital or ward involved for local analysis and learning. The report is reviewed by the case worker based in the hospital ward or department, who specifies the type of incident and sends it to the head of the hospital quality or safety team, who decides on the level of analysis, which is conducted at the hospital. After the analysis, the report is anonymized and sent to the national database. If the head of the team decides not to analyse the event, he or she anonymizes the report and sends it to the national reporting and learning system.

At national level, the Danish Patient Safety Authority collects aggregated anonymized data from the national patient safety database for learning and quality improvement. Each year, areas of interest are identified for deeper analysis at national level.

Confidentiality

Front-line personnel who report an adverse event cannot be subjected to investigation or disciplinary action by the employer, the Danish Patient Safety Authority or a court of justice as a result of reporting.

Mandatory or non-mandatory reporting

Reporting of adverse events is mandatory under the National Health Act. The system is being revised, as the current system, which requires that front-line staff report every adverse event, is too bureaucratic, resulting in underreporting. Regular review of the system is part of the process.

Method and forms for reporting

Reporting is done on an online form on the home page of the Danish Patient Safety Authority. The form elicits information on the location, the type of event and what might have prevented the event.

Who can report

Municipal health care professionals, general practitioners and hospital professionals can report adverse events. Users, patients, carers and families can also report adverse events to the national database. Currently, users and carers do not receive feedback on the outcomes of reported adverse events.

Analysis

The hospital or ward conducts a systematic analysis of the adverse event, such as root cause analysis, although not all adverse events are analysed in such depth. The aim of a root cause analysis is to determine whether anything could be done differently to prevent a similar event from occurring.

Learning and quality improvement

Local interventions are initiated as a result of learning from the analysis. Aggregated data from the national database have been used for national quality improvement, e.g. in psychiatry, in which national data on suicides were used as one of many elements in suicide prevention in Danish mental health hospitals. The Danish Patient Safety Authority compiles annual reports of aggregated data from the national database. Information on the Danish experience has been published.[18]

The national reporting and learning system is being revised on the basis of recommendations from the Danish Society for Patient Safety:[19]

- Report only important incidents.
- Reporting should be effortless.
- The reporting system must maintain a clear division between disciplinary and learning functions.
- The reports must be handled at the right level.
- Learning must be shared across sectors (e.g. regions and municipalities).
- Incident reporting should not stand alone but should be an integral part of quality improvement initiatives and aims.
- Incident reporting should add to a transparent public system.
- The reporter must receive individual feedback about actions taken in response to the report.

These recommendations should be considered as learning points and suggestions for a reporting and learning system in the Estonian health care sector.

[18] Lundgaard M, Raboel L, Broegger Jensen E, Anhoej J, Pedersen BL. The Danish patient safety experience: the Act on Patient Safety in the Danish health care system. Ital J Public Health 2005;2:64–68.
[19] Rabøl LI, Gaardboe O, Hellebek A. Incident reporting must result in local action. BMJ Qual Saf 2017;26:515.

5.2 Poland

Poland does not yet have a national or regional system for reporting adverse events in health care. Reporting is local and done within the national accreditation programme for hospitals, established in 1998. Furthermore, reporting was introduced only in the second revision of the manual for accreditation standards, published in January 2010. Other reporting systems include regulatory pharmacovigilance and haemovigilance reporting and reporting of health care-associated infections.

Health regulatory bodies

The Ministry of Health provides the legal framework and supervises the system. The National Centre for Quality Assessment in Health Care, an agency of the Ministry of Health, was established in Krakow in 1994. It was designated as the WHO Collaborating Centre for Development of Quality and Safety in Health Systems for 2006-2016. Its main tasks are to develop accreditation programmes for hospitals, primary care centres, substance abuse treatment centres and day surgery facilities. The Centre is also responsible for developing patient safety programmes, including a surgical checklist, hand hygiene, medication reconciliation and, recently, undergraduate education for health care professionals. The Centre also serves as the international secretariat for the performance assessment tool for quality improvement in hospitals (PATH) system (www.pathqualityproject.eu) and works with OECD on health care quality indicators. The Centre conducts patient opinion surveys and staff surveys, manages the decubitus ulcers register, conducts educational assessments and evaluates highly specialized procedures. It supervises the national ranking of hospitals as "safe hospitals" and is a partner in the European Union Marquis and Handover projects and in projects financed by European Social Fund grants. Since 1995, it has organized annual conferences on quality in health care and provides education and training in quality for health care professionals, managers and professional teams.

The Chief Sanitary Inspectorate conducts surveillance, prevention and control of infectious diseases, health care-associated infections and antibiotic resistance. It also monitors pathogens that are the subject of alerts: *Staphylococcus aureus*, methicillin-resistant *S. aureus,* vancomycin intermediate *S. aureus,* macrolide-lincosamide-streptogramin B resistance, Enterococcus spp., vancomycin-resistant enterococci, high-level aminoglycoside resistance, *Streptococcus pneumoniae,* Enterobacteriaceae, extended spectrum beta-lactamases, *Acinetobacter* spp. and *Pseudomonas aeruginosa.*

The Office for Registration of Medicinal Products, Medical Devices and Biocidal Products, established in 1971, is now part of the Department of Pharmacovigilance, with five regional centres in the country. The National Centre for Haemovigilance was established by the Ministry of Health in 2006 and has 21 regional centres. It is responsible for monitoring adverse events in transfusions and blood management.

There is no link between the local hospital reporting system and regulatory monitoring. The legislation planned by the Ministry of Health – the Law on Patient Safety and Quality in Health Care – includes setting up a reporting and learning system both in local hospitals and nationally. The national, central system will be interconnected with other systems to allow synthesis of information and dissemination to health care environments.

Legislation

Adverse events are reported only by hospitals, as required by the voluntary national programme for accreditation of hospitals. The standards require that adverse events be identified and analysed and that action be taken on the basis of the results. There is a list of the most frequent adverse events, but hospitals are encouraged to extend the list. The most frequently reported events are patient falls, absconding and ignoring doctors' recommendations on e.g. patient mobility or medication; however, more and more clinical and medical adverse events are also reported. Although most reports are made by nurses, there are few medication-related adverse events, which indicates an underdeveloped hospital culture of openness. Hospitals are only beginning to learn from adverse events. Without adequate legislation to protect health care staff who report events, however, the reporting rate will not rise.

There is no integration of hospital reporting systems, and dissemination of findings depends entirely on each hospital. Furthermore, no attempt has been made to collect the information and translate it into knowledge at national or regional level.

The best option for Poland would be to establish protective legislation such as the Danish Law on Patient Safety to ensure that professionals can report safely. This should be introduced in parallel with the planned national legislation on quality and patient safety.

Level of the system

A discussion on roles and responsibilities at each level of the health care system has just begun. Poland is open to learning from the good practice of mature systems in other countries.

Method and forms for reporting

At the beginning, both paper and online reporting should be allowed. The forms used for reporting should not be too complicated or complex in order not to discourage those who report. They should be standardized but also leave room for a free text description of the incident. Poland will follow the recommendations stemming from the WHO Minimal Information Model for Patient Safety Incident Reporting and Learning Systems project.[20]

Who can report

Poland plans to begin the reporting system with reports from professionals, in order to increase awareness about patient safety in medical and clinical environments. Later, patients and families will be involved.

Analysis

Hospital staff should be thoroughly trained in classification and in-depth analysis of adverse events (root cause analysis) and also in the tools and solutions of "improvement science".

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[20] Minimal information model (MIM) for patient safety incident reporting and learning systems. Geneva: World Health Organization; 2016.

Learning and quality improvement

Information and learning should be disseminated by health care organizations, regulatory agencies, professional corporations, scientific societies, patient organizations and health care-oriented nongovernmental organizations.

5.3 Slovenia

An adverse event reporting system was established in 2002 by the Ministry of Health, which is the national authority responsible for quality and safety in health care. All hospitals were informed of the rationale for the system and were given instructions on reporting adverse events to the Ministry.

Health regulatory bodies

Generally, the management and the oversight functions of the Ministry for adverse events are kept separate. Health care provider organizations have been given assurances of the confidentiality of reporting and the non-punitive nature of the system, although the Ministry advised them that it might conduct an administrative inspection of a hospital if it was made aware of an unreported adverse event through the media or otherwise.

Pharmaco-, haemo-, materials and organ vigilance are independent systems, managed by different competent bodies within the health care system, notably the Public Agency for Medicinal Products and Medical Devices. Reporting in those areas is done in accordance with relevant regulations, which determine the form and content of reporting each of these types of event. Reporting is mandatory.

Legislation

No specific legislation covers the national adverse event reporting system. Several bills have been drafted to include provisions on the system, but none has yet been passed. The question of formal, legally sanctioned confidentiality of reporting in case of litigation has been raised in the past, but no satisfactory solution has been found. In Slovenia, there are limits on the issues in criminal law that can be addressed in other legislation, such as health care regulations.

Level of the system

The Ministry of Health collects reports and analyses of adverse events from health care provider organizations nationally. These organizations designate internal patient safety officers to coordinate activities within the provider organization.

Confidentiality

The Ministry of Health receives reports of events that are anonymized with respect to the patients and health care workers involved. The hospital in which an event occurred is kept confidential, unless the incident is already public knowledge. The Ministry may release the total number of adverse events reported in a year and the types; however, the number of events reported by each provider is not shared or communicated.

Mandatory or non-mandatory reporting

Reporting of adverse events by hospitals is regarded as mandatory, although the system is not established by law or regulation. Hospitals are responsible for promoting reporting of adverse events by health care staff. An important incentive for an effective reporting system in health care provider institutions is accreditation standards. While hospitals are free to choose an accreditation institution, all the institutions that accredit hospitals in Slovenia require some type of adverse event reporting system. Most hospitals are accredited or are in the process of being accredited within the scheme of the private accrediting agency.

Reporting by individual health care workers to the patient safety officer at the institution or another relevant person is organized by the provider institutions themselves. Once patient safety officers or managers are made aware of an adverse event, they have to report it to the Ministry of Health within 48 h. A root-cause analysis must be performed within 45 days, and a summary of the findings sent to the Ministry, including planned interventions.

Some incidents that qualify as serious adverse events to be reported to the Ministry of Health are investigated during internal or external supervision. These investigations are not anonymous and may lead to disciplinary action. Such events are handled independently of the adverse event reporting system, and additional reporting or analysis is not required.

The reporting system has been established and promoted mainly in hospitals; however, reports from any health care provider institution are welcomed.

Method and forms for reporting

The Ministry of Health receives reports from health care provider organizations, which must also perform the relevant analyses. Reporting within health care organizations is not required. Generally, reports of incidents by patients and their relatives are not handled in the same way as those to the national reporting system.

Reports are usually received on paper, although this is not recommended. A report received by e-mail is accepted and processed, but reporting by e-mail is discouraged because of lack of confidentiality.

The form for initial reporting requires the date of the incident and a short description. It also requires identification of the contact person, who is usually the hospital manager or patient safety officer. A more detailed account of the event is given by reporting the results of a root-cause analysis, which must be done within 45 days.

Adverse event are classified according to type. The International Classification for Patient Safety has been translated and is available for use in all hospitals; however, it has not been used as the official framework for reporting adverse events nationally.

Only the most serious adverse events are reported and collected nationally. The list of such events is based on the sentinel events list of the Joint Commission. In Slovenia, the events to be reported are:

- unexpected death,
- major permanent loss of function,
- suicide of a patient,
- exchange of newborns,

- haemolytic transfusion reaction after administration of blood or blood products with major blood group incompatibilities,
- surgery on the wrong patient or the wrong body part and
- suspected criminal behaviour.

Individual hospitals investigate events and design interventions based on analyses of the events. The Ministry of Health may make recommendations to hospitals on the basis of the analysis and the nature of the event, if deemed necessary.

Analysis

The reporting system includes a form for reporting the results of root-cause analysis of events. The form is a guide for analysis by patient safety officers or other responsible people.

Learning and quality improvement

For every case analysed, hospitals identify interventions that might be useful to obviate a similar event. The Ministry of Health may make a recommendation to all hospitals and other health care institutions if the findings or the interventions made after an event are considered to be generalizable

6. Recommendations

The recommendations below should be useful in discussing, designing and implementing a system for reporting and learning from adverse events in the Estonian health care system.

At national level

The Estonian health care system should establish a patient safety system to improve the quality and safety of care, based on reporting of and learning from adverse events.

It is highly recommended that the Ministry of Social Affairs of Estonia, the Health Board, the Estonian Health Insurance Fund and other stakeholders discuss and continue to develop the patient safety system on the basis of reporting and learning from adverse events. The system should acknowledge "that the most important knowledge in the field of patient safety is how to prevent harm to patients during treatment and care. The fundamental role of patient safety reporting systems is to enhance safety by learning from failures." The system should recognize that "A large proportion of adverse events, both in the hospital sector and in primary care, are preventable with systemic factors appearing to account for a majority of them."

Clear legislation should be enacted for the reporting and learning system, which ensures "blame-free" reporting of and learning from adverse events and stresses the importance of learning.

Clear policies and legislation on registration, reporting, collecting and learning from adverse events is crucial for implementation of a national patient safety system, so as to remove the fear of blame and retribution. The legislation should differentiate between the learning and reporting system and all others, including the disciplinary system. The legislation should encourage (or oblige) health care professionals to report adverse events without fear of disciplinary action by employers or supervisors or penal sanctions by the courts. Therefore, it is recommended that it be a prerequisite that the Ministry of Social Affairs formulate a legislative framework for patient safety, including reporting and learning, that meets this recommendation. The framework could be based on regulation 128, "Health services quality assurance requirements", including mandatory reporting and learning. Inclusion of the legislation in the current Health Act should be determined by the Ministry of Social Affairs in agreement with the major stakeholders, the Health Board and the Estonian Health Insurance Fund. Furthermore, the law should provide clear guidance on what is to be reported, collected and registered and generalization from the data.

The legislation should emphasize the importance of an operational learning system.

A learning system should be a systematic approach to learning from reported adverse events and errors in order to improve the quality of care. The legislation should designate responsibility for each element and level of reporting and follow-up.

Incident reports should be used to formulate action to reduce the risk for a similar adverse event, to communicate information that could prevent a similar incident elsewhere, with other reports to

provide systemic insight, for education, training, research, development and improvement and for open disclosure to patients and families.

The legislation should include the establishment of national liability insurance and compensation and ensure that learning and improvement are separate from that system.

The system should ensure that patients who have been harmed while receiving health care can claim compensation. The complaint and compensation system is mentioned only briefly in this report but is included in the description of the Danish reporting system. Patients and families have the right to be informed about the possibility of claiming compensation and the necessary rules and procedures. Information about adverse events should not be used to claim compensation. An oversight body could be established to address criminal and intentional unsafe acts but should not interfere in the reporting and learning system.

The European Union Council recommendations also state "this reporting should be differentiated from Member States' disciplinary systems and procedures for health care workers, and, where necessary, the legal issues surrounding the health care workers' liability should be clarified."[21]

The health authorities should prepare a national strategy on patient safety and quality of care, with a clear governance structure for the system and awareness-raising among the public and health professionals.

Legislation to protect the reporting system should be supported by a national policy on patient safety and quality of care and an action plan. It should also have a clear governance structure to support national and local reporting and learning. Strong leadership and a clear national strategy are crucial. The strategy should also support development of patient safety systems in hospitals and primary care.

The strategy, policy or guideline should at a minimum define and describe: the aim of the system and its rationale; responsibilities at different levels in the Estonian health care system; what should be reported and registered, with definitions and examples; how reporting should be done; and how lessons can be learnt from incidents.

It is recommended that the national health authorities raise awareness both in the general public and among health professionals and stakeholder organizations. The aim of the patient safety system is to provide better, safer care. Despite modern health technology and advances in medical science, risk is inevitable in health services; adverse events cannot be entirely eliminated but can be prevented and reduced. The aim of the national patient safety strategy is to reduce health care-related risks with the support of professionals and increased the social awareness of citizens.

The Estonian health authorities should decide whether the patient safety system is to be based on local solutions or on a common national solution.

A decision should be taken about the level of the reporting system. Local solutions and a common national solution both have advantages and disadvantages.

A national reporting system allows an overview of all adverse events reported in the country. It also provides the possibility for aggregating data so that national trends and patterns can be analysed.

[21] Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of health care-associated infections (2009/C 151/01). Brussels: European Union Council; 2009

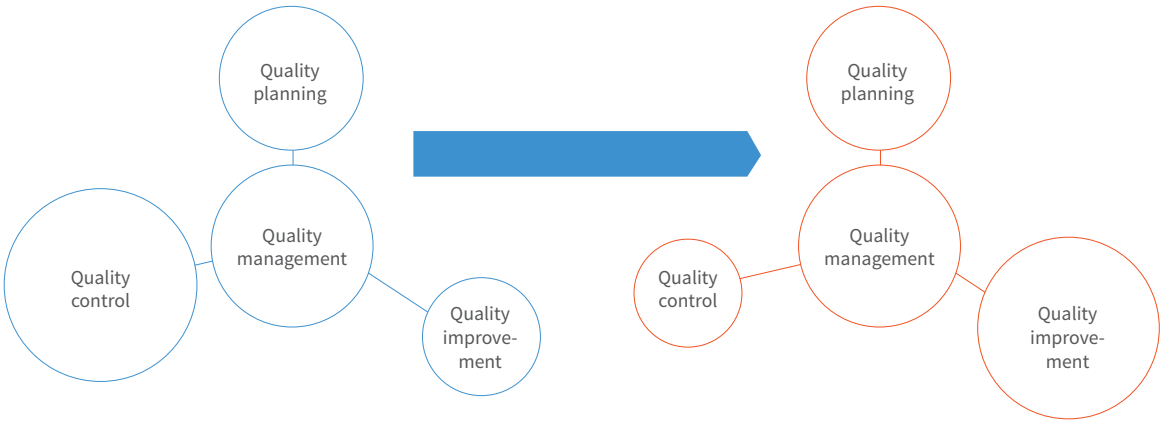
One potential problem with such a system is that it might be difficult to implement locally, with poor local support and contextual factors.

A local reporting system is theoretically easier to implement with, e.g. e-health systems and data infrastructure. As a few hospitals already have reporting systems, this might be the most feasible solution. Nevertheless, it might be difficult to aggregate data to identify trends in patient safety and types of adverse events.

If a local reporting system is chosen, updated legislation or policies should identify standards for the system, such as for extracting data and grouping events by severity, and what should be in place to support the system, including reporting, feedback, learning, training and communication to national level. To ensure a national overview, criteria should be set for providing anonymized data on e.g. categories and types of severe adverse events and the probability of occurrence. It is recommended that the Ministry of Social Affairs and other national bodies investigate various types of solution before making a decision.

Consideration should be given to developing systems for quality control and quality improvement.

Fig. 3. The Juran model for patient safety



The Juran model for patient safety[22] consists of three elements: quality planning, quality control and quality improvement. Organizations that address patient safety should consider all three elements. Fig. 3 illustrates the shift in health care and patient safety from a control-based approach to a quality improvement approach with the use of quality improvement tools such as the model for improvement, real-time data, process and performance optimization and user and carer involvement. It is recommended that the Estonian health care system establish the infrastructure for each element, with continuous quality improvement through clinical quality registries.

At each level of the health care system:

A learning environment should be developed as an integral part of the patient safety system to make risk visible and to respond to the identified risk.

[22] Scoville R, Little K, Rakover J, Luther K, Mate K. Sustaining improvement. Cambridge, MA: Institute for Health Care Improvement; 2016.

Health professionals and the health care environment should learn from incidents in the same way as in other complex, high-risk industries. Therefore, the patient safety system should include the development and establishment of a supportive learning environment, which should ensure that the organization learns from events by analysing them and responding to the results. The learning environment should also be supported by communication.

The two principles of reporting adverse events are making risk visible and responding to the identified risks. "Making risk visible" implies identification of risk through reporting and learning systems, clearly prioritization of risks, mechanisms to avoid serious risks, methods for analysing and investigating sources of risk and systematic monitoring of existing risks. "Responding to the identified risk" implies that the system can generate practical information, communicate risks to staff who are not aware of them, involve local staff in analysis and improvement and be part of patient safety, both locally and nationally.

Although health professionals learn from adverse events, they also learn from good practice.

The learning system should be supported by clear organizational structures such as quality control and supervisory bodies.

Learning should be local and be based on a systematic approach such as root-cause analysis. It should be supported by clear organizational structures such as quality control and supervisory bodies. Hospitals and wards should establish internal systems for quality of care and patient safety, including learning and improving care. The learning system could be integrated into existing structures such as supervisory boards or quality teams or councils. A learning system could cover a number of hospitals, regions or general practitioners and facilitate learning and improvement by formation of a group of risk managers. Major hospitals could establish a department for quality and safety, perhaps within existing structures for infection control, hand hygiene or antimicrobial resistance. The structure should be assessed and adjusted locally. Where relevant, a horizontal learning structure could be established, e.g. between wards or specialities in different hospitals. The aim of the structures is to ensure continuous learning from adverse events, follow-up and implementation of measures to prevent recurrence of the event.

The patient safety system should include reporting of events that could have caused harm (near misses).

Events that have the potential to cause harm, near misses, are an important source of learning. Some near misses are potentially lethal. Thus, a reporting and learning system, especially in countries with no legislation to protect people who report adverse events, could be based on reporting, analysing and learning from near misses.

Health care professionals at all health care levels should be encouraged to report.

All health care workers and ancillary staff should be encouraged to report adverse events. Furthermore, staff involved in serious incidents – the "second victims" – should receive appropriate counselling and support.

Patient safety systems should be designed for all levels of health care.

At hospital level, there should be a clear description of the kinds of adverse events to be reported, how data should be collected and the structure for learning and improvement. Communication and training of staff are indispensable for reporting. In hospitals, the communication strategy should include examples of existing reporting systems, possible new legislation and operation of the local system. Health care leaders should be the front runners; thus, hospital boards and chief executive officers should ask for data on adverse events.

At primary care level, a number of general practices should be selected for reporting, learning and improvement. It would be preferable to choose practices that have some experience in learning from adverse events. The aim of the pilot study should be to determine the events that are relevant for primary care practices. The learning process should be similar to that in hospitals, including systematic approaches such as root-cause analysis. [23]

With regard to what is to be registered and reported and how data are to be collected and generalized:

The information to be reported should be clearly described and defined.

In choosing the information to be collected and aggregated, the Minimal Information Model for patient safety[24] should be followed. Thus, the information should include:

- incident identification (patient, time, location and agent(s) involved);
- incident type or category;
- incident outcomes (consequences);
- resulting actions (to avoid recurrence); and
- person reporting.

All reported incidents should include structured information and a narrative account.

The types of adverse events to be reported and their classification should be clearly defined.

What should be reported and at what level should be defined. The reporting system should focus on important adverse events,[25] whether actual, moderate, severe or deadly, new or surprising and any events that the person reporting considers useful for learning.

Annex 2 gives as an example the reporting system used in Tartu University Hospital, which is based on the Clavien–Dindo classification of surgical complications.[26] It is recommended that the National Health Board review the systems used in different hospitals wards in order to understand how they work and whether anything useful can be learnt from them before recommending them to others or spreading a single system to the whole country.

A mechanism should be established to gain insight from aggregated data on incidents.

It should be possible to generalize reported data nationally or among health care providers. Aggregated data on patient safety incidents from the whole country can be used to identify trends and patterns and for learning at institutional, national and international levels. They also form the basis for national recommendations on selected patient safety issues. If data are to be aggregated,

[23] Safer primary care (Technical Series). Practical next steps. Geneva: World Health Organization; 2016.
[24] Minimal information model (MIM) for patient safety incident reporting and learning systems. Geneva: World Health Organization; 2016.
[25] Rabøl LI, Gaardboe O, Hellebek A. Incident reporting must result in local action. BMJ Qual Saf 2017;26:515.
[26] Clavien P, Sanabria J, Strasberg S. Proposed classification of of complications of surgery with examples of utility in cholecystectomy. Surgery 1992;111:518–526.

the kind of data to be forwarded to national level and the kind of analysis should be defined. The data to be anonymized and forwarded to national level, e.g. all severe and very severe or fatal events, should also be defined. It is important that learning from adverse events be primarily local.

For patients and users in the system:

Users, patients, carers and families should be enabled and encouraged to report adverse events.

The involvement of patients and families in reporting harm empowers them and contributes to civil society taking responsibility for its own care. Clear information should be provided about the differences between reporting and complaints systems. Patient reporting should be permitted at national level with an accurate description of the reasons, purpose and goals, including whether feedback will be given to individuals who report. Many mature reporting and learning systems have introduced reporting by patients and families only some time after reporting of adverse events was introduced for health care professionals.

The design of the reporting system should include involvement of patients, families and carers.

Patients, carers and families should be able to report adverse events. This possibility should be considered in the future reporting and learning system. Patients and families should be informed about the possibility of reporting as well as about the difference between reporting adverse events and receiving compensation for harm. It is recommended that patients, carers and families be involved in their own care at all levels of health care and also in learning and improvement at individual, ward, hospital and national levels. Information from users and their families is unique and is difficult to obtain by talking only to health care professionals. Patients and users are involved in the whole continuum of care and may have insights that are important for safety and the quality of care.

For educational institutions:

Patient safety should be included in the curricula of health care professionals' education at all levels.

Educating young doctors, nurses, midwives and other health care professionals on patient safety and quality of care is a cornerstone of a national patient safety system. Education and training in reporting, learning and improving care guarantee the long-term benefits of the system, with better scientific knowledge, attitudes and behaviour towards patient safety.

Education on patient safety should be provided in all medical faculties, in postgraduate and continuing education at hospitals and in general practices and other health care facilities. Training and education in patient safety systems, including awareness, communication, transparency and a blame-free culture, will support implementation of the system. A blame-free, open culture is crucial for the future development and implementation of the system, although it might be the most difficult element to achieve. Open communication on the benefits of a reporting system and positive cases of mature reporting systems will help promote the culture. It will take time to change the current culture, underlining the importance of training and education at all levels.

To ensure motivation of providers and professionals to change attitudes and culture:

Health care professionals should be involved in implementing and (if possible) designing local patient safety systems.

The team must have sufficient capacity to manage the complexities of introducing a patient safety system. Clinicians should be involved in this large-scale challenge. A successful change in culture will also require appropriate management capacity, leadership and monitoring. Physicians should not only understand the need to change the culture and participate in the reporting system but also be actively engaged in analysis and improvement.

When introducing a reporting system, patient safety and quality of care should be the primary goals of managers at all levels of a health care system.

Patients' stories that are supported by national or international data can help to motivate health care professionals and convince them of the importance of patient safety and avoiding adverse events.

All levels of the health care system should be informed about the value of prioritizing patient safety and quality of care. Both international figures and local learning can be used to explain the system and its rationale.

The main messages are "There will be no quick fix" and "Patient safety will not improve overnight".

Annex 1. Institutions visited

Programme of the visit and participants in the meetings

MONDAY, 14 NOVEMBER

9:00–11:00	Ministry of Social Affairs Ulla Raid, Agris Koppel, Heli Paluste
11:00–12:00	Health Board Mihhail Muzõtsin Eve Pilt
12:00–13:00	Patients' Association Puuetega Inimeste Koda Marek Jaakson
14:00–15:00	Family Doctors' Society Le Vallikivi, Helen Alter

TUESDAY, 15 NOVEMBER (TARTU)

11.00–12.30	Rakvere Haigla Ain Suurkaev, Sirje Kiisküla
14:30–15:45	Tartu Health Care College, nurses and midwives Kersti Viitkar, Saima Hinno, Reet Urban
16.00-17.30	Visit to University Clinic of Tartu, Faculty of Medicine, Tartu University Dr Murruste, Professor Raul Kiivet

WEDNESDAY, 16 NOVEMBER

9:00–10:00	Visit to East Tallinn Hospital Vladislav Fedossov, Chairman of Care Quality Commission
10:00–11:00	Estonian Nurses' Association Anneli Kannus
11:00–12:00	Estonian Health Insurance Fund Tanel Ross, Maivi Parv, Krister Põllupüü
13:00–15:00	Briefing to the Ministry of Social Affairs

Annex 2

A2.1 Danish Health Act (2003) (English translation)

http://arkiv.patientsikkerhed.dk/in-english/act-on-patient-safety.aspx

Act on Patient Safety – a reporting system for learning

- Front-line personnel obliged to report
- Hospital owners obliged to act
- National Board of Patient Safety obliged to communicate adverse events
- Front-line personnel who report an adverse event cannot as a result be subjected to investigation or disciplinary action by the employer, the Board of Patient Safety or a court of justice

The law below is the original from 2003. Corrections were made in Article 61 on patient safety in the current Health Act.

Part 1

Objective, applicability, definitions etc.

1. – (1) The objective of the Act is to improve patient safety within the Danish health care system. The Act shall apply to the reporting of adverse events occurring in connection with the treatment of patients within the health care system, however, cf. subsection (2) below.

(2) The Minister for the Interior and Health may lay down rules as regards the applicability of the Act to the primary health care sector including health care professionals in private practice. The Minister may specify deviations from the provisions of the Act which may be justified by special circumstances within the primary health care sector.

(3) The National Board of Health may lay down rules on which hospitals and other institutions of treatment are subject to the duty to report, and the Board may also lay down special rules for the reporting system of private hospitals.

(4) The provisions of this Act concerning counties shall also apply to the Copenhagen Hospital Corporation, the municipalities of Copenhagen and Frederiksberg and the municipality of Bornholm as well as private hospitals.

(5) The provisions of this Act shall not apply to other statutory reporting systems regarding adverse events or errors occurring during treatment. The National Board of Health may in cooperation with the authorities concerned lay down rules specifying and perhaps coordinating reporting circumstances, cf. the first sentence.

2. – (1) An adverse event shall mean an event resulting from treatment by or stay in a hospital and not from the illness of the patient, if such event is at the same time either harmful, or could have been harmful had it not been avoided beforehand, or if the event did not occur for other reasons. Adverse events shall comprise events and errors known and unknown. 2

(2) For the purposes of this Act health care professionals shall mean people who are authorised under special legislation to carry out specialist health care tasks and people acting on their responsibility.

(3) For the purposes of this Act treatment shall mean examination, diagnosis, clinical treatment, rehabilitation, specialist health care and prophylactic health care measures in relation to the individual patient.

Part 2

Patient safety systems

3. – (1) County councils shall receive, record and analyse reports on adverse events for use in the improvement of patient safety and treatment and for the reporting of information to the National Board of Health, cf. section 4 below.

(2) A health care professional, who becomes aware of an adverse event in connection with a patient's treatment or stay in a hospital, shall report such event according to subsection (1) above.

4. – (1) The National Board of Health shall receive reports on adverse events from the county councils and shall establish a national register for such events. On the basis of the information received the National Board of Health shall advise the health care system on patient safety.

(2) The National Board of Health shall lay down rules on which adverse events shall be reported by the county councils to the National Board of Health, when and in which format such reporting shall take place as well as its contents. Similarly, the National Board of Health shall lay down rules on the cases in which health care personnel shall report adverse events to the county council, when and in which format such reporting shall take place as well as its contents.

(3) The National Board of Health may from county councils obtain additional information about reported events for use in the Board's advisory work, cf. subsection (1) above.

(4) The National Board of Health may from county councils obtain information from patient registers and other registers as well as information from accounts and budgets for use in the Board's advisory work, cf. subsection (1) above.

(5) In the reports of adverse events from county councils' to the National Board of Health pursuant to subsections (1) and (3) above both patient and health care professional shall be anonymous.

(6) The National Board of Health shall issue an annual report on its activities pursuant to this Act.

Part 3

Disclosure of information etc.

5. – (1) Reports on adverse events, which may be attributed to specific individuals, may without the consent of the patient or the involved health care personnel be exchanged within the group of people who locally, within the county council, handle tasks pursuant to section 3(1) above, and may be passed on to clinical databases and other registers where health information is recorded with a view to documentation and quality development within the patient safety area.

A2.2 Italian Law on Patient Safety and Health Professionals' Responsibilities[27]

(http://www.salute.gov.it/portale/temi/p2_6.jsp?id=238&area=qualita&menu=sicurezza; www.gazzettaufficiale.it/eli/id/2017/03/17/17G00041/sg)

Passed by the Italian Parliament in February 2017, the law is an important innovation because it recognizes patient safety as a fundamental individual right and at the same time offers a clear framework for safer practices, a safe space for reporting and learning and a fair compensation scheme. A national reporting system of sentinel events was set up in 2009 and became part of the mandatory requirements for public and private providers in 2011, with a set of goals on safe practices and continuous education. It is updated annually.

A list of national recommendations for patient safety was elaborated at the Ministry of Health in 2003, while the National Agency for the Health Care Services has held a repository of safe practices since 2008. http://buonepratiche.agenas.it/default.aspx

As Italy is a federated republic, each regional government is responsible for delivering health services. The Italian national health service constituted a specific function for clinical risk management after a national agreement on this matter in 2008. Since then, each provider has to integrate patient safety into its strategic plan, which is then subjected to evaluation.

The law is summarized below: [28]

Patient safety is a fundamental right of each individual within any health care service, and it is a primary goal of the National Health Service. Health care providers promote the continuous evaluation of clinical risks and appropriate delivery of care, in order to prevent harm.

Reporting and learning systems: minutes and documents resulting from the management of clinical risk cannot be acquired or used as part of legal proceedings.

The guidelines recognized by the National Institute of Health represent fair, balanced recommendations for health care professionals that, when applied, protect the health care professionals from legal prosecution.

Retaliatory action: recourse against the operator of the health care profession will be possible only for malice and gross negligence.

Risk management: the coordinating role of the risk management can be done by medical doctors as well as other employees of health facilities (i.e. nurses, pharmacists, psychologists, sociologists, engineers) with adequate training on the subject matter and experience of at least three years.

The scope of the law is also extended to the social health services.

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[27] Translated by Tomasso Bellandi, PhD, Eur Erg, Centre for Clinical Risk Management and Patient Safety of the Tuscany Region, WHO Collaborating Centre on Human Factors and Communication for the Delivery of Safe and Quality Care. Villa La Quiete alle Montalve, Via Pietro Dazzi 1, 50141 Firenze, Italy

[28] Bellandi T, Tartaglia R, Sheikh A, Donaldson L. Italy recognises patient safety as a fundamental right. BMJ 2017;357:j2277 ..

A2.3 United Kingdom National Health System

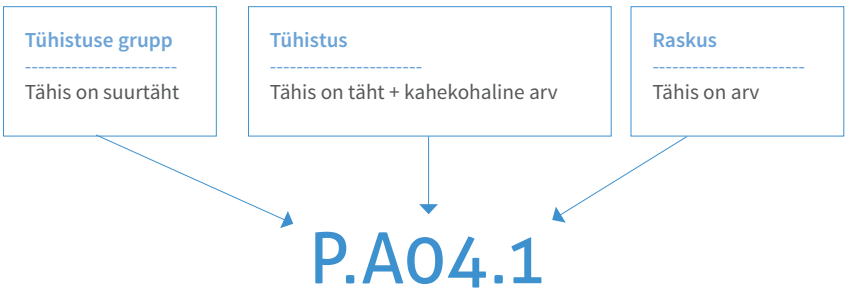
The safety and transparency of health care is of great concern to the public. Therefore, public interest concern (commonly referred to as "whistleblowing") is important. Information and legislation regarding whistleblowers can be found at:

http://www.nhsemployers.org/your-workforce/retain-and-improve/raising-concerns-at-work-and-whistleblowing/information-for-employers/raising-concerns-policy-and-legislation#2

The intention of NHS Employers is to be the authoritative voice of workforce leaders and experts in human resources so that they can negotiate fairly for patients' rights. Their programme "Freedom to speak up, policy, legislation and guidance" is designed to improve the organizational culture, reporting mechanisms and effective follow-up of concerns nationally and locally in the NHS.

A2.4 Tartu University Hospital pilot reporting and learning system

Based on the Clavien–Dindo classification of surgical complications[29]



Näide

(Postoperatiivne – P.Haava infektsioon – A04. Avati sidumistoas – raskus 1)

Group Adverse event
degree of severity

Example:
P - postoperative
A04.1 – Infection of wound (ICD-10)
Remarks: opened in the operating theatre
Degree of severity – 1

Group:

1.	Operatsiooniaegsetel tüsistustel	– **„O“** (operatsioon), **during the operation**
2.	Operatsioonijärgsetel tüsistustel	– **„P“** (postoperatiivne), **post-operation**
3.	Anesteesia tüsistused	– **„A“** (anesteesia), **anaesthesia**
4.	Endoskoopia tüsistused	– **„E“** (endoskoopia), **endoscopy**
5.	Radioloogia tüsistused	– **„R“** (radioloogia), **radiology**
6.	Muudel tüsistustel	– **„M“** (muu), **other**

Degree of severity according to the Clavien-Dindo classification

Grade	Case
I	Any deviation from the normal postoperative course without the need for pharmacological treatment or surgical, endoscopic or radiological interventions. The therapeutic regimens allowed include antiemetics, antipyretics, analgesics, diuretics, electrolytes and physiotherapy. This grade also includes wound infections that were opened at the bedside.
II	Complications that require pharmacological treatment with drugs other than those allowed for grade I complications. Blood transfusions and total parenteral nutrition are also included.
III	Complications that require surgical, endoscopic or radiological interventions.
IIIa	Interventions not under general anaesthesia.
IIIb	Interventions under general anaesthesia.
IV	Life-threatening complications (including central nervous system complications) that require treatment in an intensive care unit.
IVa	Single organ dysfunction (including dialysis).
IVb	Multiorgan dysfunction.
V	Death of the patient.

[26] Clavien P, Sanabria J, Strasberg S. Proposed classification of of complications of surgery with examples of utility in cholecystectomy. Surgery 1992;111:518–526.

A2.5 Other useful material

Draft guidelines on adverse event reporting and learning systems. Geneva: World Health Organization; 2005: http://www.who.int/patientsafety/implementation/reporting_and_learning/en/

Key findings and recommendations on reporting and learning systems for patient safety incidents across Europe. Report of the Patient Safety and Quality of Care Working Group of the European Commission. Brussels: European Commission; 2014:http://ec.europa.eu/health/patient_safety/policy/package_en

Conway J, Federico F, Stewart K, Campbell MJ. Respectful management of serious clinical adverse events. Second edition (IHI Innovation Series white paper). Cambridge, MA: Institute for Healthcare Improvement; 2011: http://www.ihi.org/resources/Pages/IHIWhitePapers/RespectfulManagementSeriousClinicalAEsWhitePaper.aspx

How do you get clinicians involved in quality improvement? An evaluation of the Health Foundation's Engaging with Quality Initiative – a programme of work to support clinicians to drive forward quality. London: The Health Foundation; 2010: http://www.health.org.uk/publication/how-do-you-get-clinicians-involved-quality-improvement

Dalton D, Williams N. Disclosing medical errors to patients. Building a culture of candour: a review of the threshold for the duty of candour and of the incentives for care organisations to be candid. London: Royal College of Surgeons of England; 2014: https://psnet.ahrq.gov/resources/resource/27745/building-a-culture-of-candour-a-review-of-the-threshold-for-the-duty-of-candour-and-of-the-incentives-for-care-organisations-to-be-candid?q=Building+a+culture+of+candour

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