Key findings and recommendations on

Reporting and learning systems for patient safety incidents across Europe

Report of the

Reporting and learning subgroup of the European Commission PSQCWG

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1. Executive summary

This report presents the findings and recommendations of the reporting and learning systems (RLS) subgroup on reporting and learning systems for incidents in the Member States of the European Union.1 The remit of the subgroup was to provide a set of key findings and give recommendations to support the implementation of Council Recommendation 2009/C 151/01[2] regarding reporting and learning systems.

This report serves as a 'catalogue' of how Member States with established reporting systems have chosen to organise their own reporting systems. Member States who wish to establish a nationwide reporting system can use it to gain insight and as inspiration for how a reporting system could be organised.

This report takes as a basis the WHO Draft Guidelines for Adverse Event Reporting and Learning Systems[1], the Council Recommendation 2009/C 151/01[2] and the EUNetPaS library[3]. It shows how several European countries have in various ways applied knowledge from the WHO and the EU in the establishment and revision of reporting systems.

There are big differences between reporting systems in Member States. In spite of the different systems, the RLS subgroup has been able to identify key findings in the reporting systems and make recommendations for these.

It has been important for the subgroup to show the differences between reporting systems. These differences can help to understand the various setups available, and the advantages and disadvantages they may deliver.

This report does not describe how learning from incidents can be managed. Incidents should normally be combined with other data quality and safety sources for analysis. There may be a risk that separate analysis of incidents, complaints and other quality data can provide fragmented solutions that do not prevent the problem effectively.

[1] Norway is a Member State of the European Free Trade Association but not of the EU. Where this report refers to *Member States*, it means the EU Member States and Norway.

[2] Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections.

Key findings and recommendations

Overall set-up
1. Both mandatory and voluntary reporting systems exist in Member States. Each type of reporting system has its advantages and disadvantages.
2. A mandatory system should be accompanied by regulations on sanctions-free reporting and clear rules on confidentiality.
3. Types of incidents that can be reported vary. However, a broad definition allows the reporting of any concerns, including near misses and 'no harm' incidents, providing a rich resource for learning and systems improvement.
4. All staff in healthcare organisations, not only healthcare providers, should be able to report patient safety incidents.
5. Patient and family reports are a potentially rich resource for learning and patient safety improvement, and they should be encouraged. More information is needed on how best to facilitate this in different healthcare contexts.
6. The reporting system should be separated from formal complaints, disciplinary actions and litigation procedures. Healthcare professionals who submit reports should be protected from disciplinary or legal action. Confidentiality of the person reporting and appropriate anonymisation of the data should be ensured.
7. Anonymised reports of the data should be regularly published and learning disseminated widely to support the development and monitoring of initiatives to improve patient safety and prevent incidents across the EU.

Reporting and learning culture
Key findings:
1. System aim and objective is clearly explained to all stakeholders, including the frontline staff and patients.
2. Visible changes have been made after reported incidents
3. Patients and relatives are involved.
Recommendations:
1. All persons reporting an incident should understand their own benefit from reporting, since this will help to avoid the occurrence of incidents that could potentially be damaging to themselves and to the reputation of their organisations.
2. Top management of healthcare systems and providers should spread the message of a 'blame-free and non-punitive objective'.
3. Feedback should be given to healthcare providers on the results of an investigation and preventive measures taken.
4. To promote learning, patients and relatives should be authorised to submit reports separately from the complaints scheme.
5. Legislative changes must be considered concerning the protection of information in the event reports from courts or police as they are collected for different purposes.
6. Reports should be anonymised since these clearly indicate an absence of self-interest on the part of the individual but rather a primary interest in the incident.

Components of a reporting system
Key findings:
1. A mechanism to capture and store data is required.
2. A consistent reporting formula should be defined.
3. Feedback mechanisms should be in place.
4. Case handling should be undertaken by experts in collaboration with management.
Recommendations:
1. There should be differentiated reporting forms: one for healthcare professionals, one for patients and relatives.
2. In addition to stipulated data requirements, reporting forms should enable free-text reporting.
3. User-friendly electronic reporting should be preferred.
4. Feedback from central or regional levels is important to share knowledge about risk processes.
5. Feedback to those who are reporting is one of the most important tasks. To motivate health professionals to report future incidents, the person reporting should have the receipt acknowledged and be kept informed of action taken.
6. Both the case handling and analysis of an incident should be undertaken by experts who have insight into the subject and various methods of analysis. A management representative must be empowered to approve action plans.
7. The classification or taxonomy of events should be consistent with a generic classification system that facilitates the comparison of data across care providers. In addition, disease-specific classifications and other classifications can be used as needed.

Analysis
Key findings:
1. Incoming incident reports should be reviewed, anonymised and systematically analysed.
2. Preventive recommendations should be disseminated.
3. Prompt analysis and reviews should be undertaken by credible experts.
Recommendations:
1. Distinguish between local analysis of events and central or regional review of reports.
2. Assign appropriate resources for analysis and review, including experts who understand the clinical circumstances and care processes involved and who are trained to recognise underlying system causes.
3. Avoid the search for offenders when conducting analysis or central or regional review.
4. Establish a unified methodology for processing reports, including examples, and access to data and learning to support local use of data, facilitated by central level.
5. At all levels, focus on qualitative analysis rather than quantitative statistics.
6. Review each reported incident at the local level as soon as possible and prioritise reports for central analysis on a case-by-case basis.
7. Prioritise incoming reports centrally for review using an automated algorithm (e.g. by classification).
8. To educate those working on local analysis, provide feedback on qualitative analysis during central or regional review.
9. Disseminate preventive measures through already existing channels. In addition to issuing a separate alert document, consider updating existing policy documents directly

Technical infrastructure
Key findings:
1. Possibility of in-depth data analysis for both statistics and individual report content.
2. Facilitate participation of healthcare providers regardless of their access to IT equipment; at least one available PC with internet connection could be a minimum requirement.
3. Data to be transformed into electronic form as soon as possible.
4. Ensure online transfer and sharing of data during the case flow.
5. Ensure data security (availability, integrity, access restriction) during data transport and storage, sharing and archive.
6. Ensure continuing system improvements.
Recommendations:
1. Prefer data collection for each individual incident over collecting data summary tables for each healthcare provider on a central level.
2. Provide a data analysis engine that offers benchmarking and full-text search capabilities.
3. Allow online uploading and sharing of anonymised data from the more technically advanced healthcare providers, and web-based reporting forms for less technically advanced or small-size healthcare organisations.
4. Web-based reporting forms should allow patients to submit reports and the rewriting of paper reports. Web-based reporting should be able to serve as a single reporting point for frontline staff for internal reporting in any healthcare provider.
5. Basic data from all different sources of reports should be stored — or be able to be viewed as a unified structure — to allow integrated analysis.
6. Link automatically with pharmacovigilance and other similar systems to avoid duplication of reporting to these specialised systems.
7. Avoid batch transfer of data to maintain speed of data processing and to minimise delays between reporting and central or regional review. Use only online transfer and data sharing over secured internet connection.
8. IT capacity should be sufficient to ensure continuous system improvements.

Other
Reports to an agency or other national body from a local hospital or other healthcare organisation usually originate from a report within the local institution. While such reports may merely reflect statutory requirements, an institution that values patient safety will have an internal reporting system that captures much more information than that.
The objectives of an internal reporting system for learning are: to identify errors and incidents; and to redesign systems to reduce the likelihood of avoidable patient harm occurring. This can be achieved through investigation (root cause analysis) to uncover underlying system failures and unsafe practices.
The key conceptual point and heart of a non-punitive approach to incident reporting is the recognition that incidents or near misses are symptoms of defective systems or vulnerabilities, not defects themselves. Reporting, whether retrospective (incidents and errors) or prospective (hazards or ‘errors waiting to happen’), provides the entry point into investigation and systematic analysis of system defects, which, if skilfully done, can lead to substantial system improvements.

2. The reporting and learning system subgroup

The reporting and learning system (RLS) subgroup is set up under the European Commission's patient safety and quality of care working group.

The remit of the RLS subgroup was to provide a set of key findings and give recommendations to support the implementation of Council Recommendation 2009/C 151/01 regarding reporting and learning systems.

The working group mandated the subgroup to prepare this report and invited it to highlight information about existing RLS systems in Member States, identify key findings and provide some first recommendations concerning:

- organisational framework
- regulatory bodies
- anonymisation and confidentiality
- who can report
- types of report
- voluntary or mandatory reporting
- education
- components of reporting systems
- procedure of analysis and feedback
- implementation of improvement measures
- technical infrastructure
- security issues

Members of the RLS subgroup

Agency, Member State	Subgroup member
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In addition, representatives from the following organisations and projects participated:

- European Commission (EC)
- European Health Management Association (EHMA)
- European Patients' Forum (EPF)
- Pharmaceutical Group of the European Union (PGEU)
- European Federation of Nurses Associations (EFN)
- European Hospital and Healthcare Federation (HOPE)
- World Health Organisation (WHO)
- European Union of Private Hospitals (UEHP)

The following Member States contributed knowledge about their reporting systems:

- Austria
- Belgium
- Croatia
- Cyprus,
- Czech Republic
- Denmark
- Estonia
- France
- Germany
- Hungary
- Ireland
- Italy
- Latvia
- Luxembourg
- The Netherlands
- Norway
- Poland
- Slovakia
- Slovenia
- Spain
- Sweden
- United Kingdom

3. Recommendation on reporting and learning systems

3.1. EU Council Recommendation on patient safety

Council Recommendation 2009/C 151/01[2] regarding reporting and learning systems on incidents recommends that Member States:

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 healthcare 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 healthcare workers, and, where necessary, the legal issues surrounding the healthcare 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. [2]

A recent implementation report is available.

The recommendation builds upon, and complements, work on patient safety carried out by the World Health Organisation (WHO) through its World Alliance for Patient Safety, the Council of Europe and the Organisation for Economic Cooperation and Development (OECD).[2]

3.2. Council of Europe Recommendation on patient safety

According to the recommendation of the Committee of Ministers to Member States on management of patient safety and prevention of adverse events in healthcare, the primary objective of an incident reporting system is the enhancement of patient safety, by learning from incidents and mistakes made.

COUNCIL OF EUROPE CONSEIL DE L'EUROPE

Reporting and collection of incident data is meaningful only if the data is analysed and evaluated and if feedback is given to the professionals involved in the incident, and to all others who could learn from the incident. Incident reporting systems are not intended to identify and punish the individual staff members involved in patient safety incidents. Incidents may be reported by

health professionals, patients and relatives, or by other informal caregivers and suppliers. [4]

3.3. WHO Patient Safety Programme

WHO has drafted Guidelines on Adverse Event Reporting and Learning Systems, which are the subject of a consultation exercise during 2007-8.

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.

Reporting is fundamental to detecting patient safety problems. However, on its own it can never give a complete picture of all sources of risk and patient harm. The guidelines also suggest other sources of patient safety information that can be used both by health services and nationally.

Before deciding on establishing a nationwide incident reporting and learning system, states should carefully consider: what are the objectives of the system; whether they can develop the capacity to respond to reports; and what resources will be required. It is also important to decide the scope of what is to be reported and the data to be collected.

The WHO guidelines were published in 2005 and contain key messages for each topic addressed, containing simple statements on what should be done. There are ten basic recommendations. All the key messages and recommendations set out in the guidelines are still perfectly valid. [1]

4. The purpose and role of reporting and learning systems

The most important function of a reporting system is to use the results of data analysis and investigations to improve healthcare directly and help healthcare professionals to do safer work.

Table 1: Names of the reporting systems

EU Menber State	Name of the reporting system for incidents	Level
AUSTRIA	1. CIRSmedical.at. 2. Regional CIRS Network. 3. Local RLS	 Regional (stand-alone) Local (stand-alone)
BELGIUM	Reporting and learning system for incidents and near-incidents.	Local (stand-alone)
CYPRUS	Reporting systems for adverse events and near incidents in public hospitals	Local (stand-alone)
CZECH REPUBLIC	Nationwide incident reporting system.	National
DENMARK	Danish patient safety database.	National
ESTONIA	Different names in regional hospitals — local stand-alone systems.	National Local (stand-alone)
FRANCE*	Reporting and Learning systems at regional and local level have different names.	Regional (stand alone) Local (stand alone)
GERMANY**	1. CIRSmedical.de. 2. Hospital CIRS Network. 3. Error reporting and learning system for primary care in Germany. 4. Network CIRS Berlin.	Nationwide (1, 2, 3) Regional (4)
HUNGARY	National reporting and learning system (NEVES).	National
IRELAND	National adverse event management system (NAEMS).	National
ITALY	Sentinel events monitoring system.	National Regional Local (connection to a central system)
LATVIA	Some hospitals have established their own reporting and learning systems.	Local (stand-alone)
LUXEMBOURG	Hospitals have established their own reporting and learning systems at local level.	Local (stand-alone)
NETHERLANDS	Nationwide reporting and learning system for medication incidents: Centrale Medicatie-incidenten Registratie (CMR) is now extended to a system for all healthcare incidents. Local reporting systems in hospitals and primary care	National Local (connection to the central system)
NORWAY	Incident reporting system.	National
SLOVAKIA	Mandatory reporting of incidents and voluntary reporting of errors in the provision of hospital healthcare.	National
SLOVENIA	Nationwide incident reporting system.	National
SPAIN	Sistema de Notificación y Aprendizaje para la Seguridad del Paciente (SINASP)	National Regional Local (connection to a central system)
SWEDEN	Lex Maria. National IT support for RCA of adverse events (NITHA) and national database for	National Regional Local

	learning from RCA. The National Quality Registries Annual national medical record reviews (modified IHI Global Trigger Tool) to detect adverse events which are reported to the local and the national database. The RLS of the Patient Insurance LÖF. The RLS of Patients Advisory Committees. Further regional and local RLS.	
UNITED KINGDOM	National reporting and learning system.	National Local (connection to a central system)

*__France__: Reporting and Learning is one of the major assignments of the Patient Safety National Program (2013/2017). Reporting healthcare acquired infections or severe adverse events associated with healthcare to the Regional Regulatory Health Authority is a legal obligation. Further regulation is being prepared at the moment in order to organize and implement a comprehensive system for reporting and learning. Three Regional Regulatory Health Authority (out of 26) currently lead experimentations of organized reporting and learning systems (under different names). At local level, reporting and learning systems are in place in every public and private hospital.

**__Germany__: The Reporting Systems above mentioned are only examples of existing Reporting Systems in Germany. We can't give here an overview.

In seeking to improve safety, one of the most frustrating aspects for both patients and professionals is the apparent failure of healthcare systems to learn from their mistakes. It is very important that healthcare providers and organisations share what they have learned when an investigation has been carried out. It is a great opportunity to share lessons learned as widely as possible in order to improve healthcare. Health professionals should immediately report any accident or incident and to that end, it is needed that there is a reporting and learning system in place and a no-blame culture in relation to reporting injuries at their workplace[5].

We have to avoid the recurrence of mistakes in different settings exposing patients to harm or risk of harm from preventable errors.

One way to solve this problem is reporting, analysing the data and developing specific measures. Reporting should come through healthcare providers, patients and relatives to their local healthcare organisation, and by the organisation to a broader audience through a regional or nationwide reporting system.

A dynamic reporting system is able to give some of the most important information for improvements in healthcare practice and, within a hospital or other healthcare organisation, it is one indicator of a good safety culture.

At a minimum, safety reporting can help identify hazards and risks, and provide information as to where system vulnerabilities lie. This can help targeting initiatives for improvement and efforts to change practices and systems to reduce the likelihood of harming patients.

Table 1 lists the reporting systems in Member States, and at what level they operate. It shows that there are many different levels of operation. For example,

Austria not only has a national system, but also regional and local reporting systems that operate independently without links to other systems.

5. Method

This report is mainly based on practical experience in the development and operation of existing reporting systems in Member States.

The report was prepared in several phases. In the first period, from July to August 2013, all countries were asked to update information about their reporting systems in the EUNetPaS database. The aim was to identify a majority of the main reporting systems and ensure correct contact information.
In the second phase, from August to October 2013, we sought to agree the conditions to be described in the draft template for the report. Denmark prepared a draft template which was revised several times in the RLS subgroup. The draft template was supplemented with questions for each section. Each member of the subgroup was asked to complete the draft template with information about its own reporting system.

In the third phase, from November 2013 to February 2014, data were analysed and the report finalised.

The result was mostly information of an organisational or administrative character. The RLS subgroup therefore decided to be more systematic in collecting information in relation to the deliberations and decisions that had been taken at the genesis of reporting systems.

After thorough analysis, the subgroup identified key findings and presented experience-based recommendations on the development of reporting systems.

EU member states who have not responded to requests from the RLS Sub Group, or who are not registered in EUNetPaS database is not mentioned in this report.

6. Governance

Member States have chosen a variety of ways to organise nationwide reporting systems. The various models are a function of several aspects, including intention, aim, historical development, requirements from accreditation and quality standards, WHO recommendations.

6.1. The organisational framework

National or system-wide reporting systems are clearly of great value in terms of learning from others' experience. Many incidents occur only rarely, and so may seem — to observers in the institution — as isolated (outlier) cases. Commonality and common causation only emerge with an analysis of aggregated data. Demonstrating the occurrence of serious events in respectable peer institutions helps counteract a typical response of 'that could never happen here', which providers may genuinely feel when asked about a serious incident, such as wrong site surgery.

However, there are other valuable sources of patient safety information that can be used at both internal healthcare organisational level and national level. Many are less expensive, and therefore constitute important options for states and healthcare organisations that are unable to finance a large reporting system. They are also worth considering for those with highly developed reporting systems.

Reporting systems have their own history Member State -by- Member State and the systems are therefore different in their organisational framework. There are three types of framework: health frameworks, professional framework and local health provider organisations.

6.1.1. Health framework

The type of organisation responsible for reporting systems varies across Member States. In most, the responsibility lies with the Ministry or Department of Health or with agencies under its authority. Other Member States have assigned responsibility for the reporting system to health regulatory organisations. Some EU countries have no nationwide reporting system and responsibility for local reporting systems lies with individual hospitals.

In some Member States, reporting systems have moved to another organisation after a few years of experience.

Reporting systems should be independent of any authority with the power to punish the reporter or organisation and having a stake in the outcome. Maintaining a 'firewall' between the reporting agency and the disciplinary agency in a governmental system can be difficult, but it is essential, if trust in reporting is to be maintained.

Health framework

Agencies under the Ministry or Department of Health

The **Danish** patient safety database (*DPSD) was established in 2004 under the National Board of Health under the Ministry of Health. In 2011, the DPSD moved to the new* Danish National Agency for Patients' Rights and Complaints *(*NAPRC), which is an independent state institution under the Ministry of Health that focuses on patients' rights, compensations, adverse events and learning.

Norway has chosen a government-funded unit to run its NRLS, but it does not have any instruction power towards the healthcare system or personnel, nor any power to impose penalties. This ensures the necessary distance and independence, while also guaranteeing funding.

Sweden: According to the Patient Safety Act (2010:659) all healthcare providers are required to notify to the Health and Social Care Inspectorate which is separated from the regulating authority, The National Board of Health and Welfare.

According to the Patient Injury Act (1996:799), patients who have experienced a health care injury can seek compensation from the Patient Insurance LÖF. The patient claims form the basis of the RLS which is separate from punitive systems.

According to the Law of the Patients´ Advisory Committee (1998:1656), patients can report to a regional Patients Advisory Committee.

The **United Kingdom** National Reporting and Learning System (NRLS) was established under the National Patient Safety Agency (NPSA) in 2003. It facilitates the collection and analysis of patient safety reports at national level across the NHS in England and Wales.

Following the abolition of the NPSA in 2012, overall responsibility for the NRLS was transferred to NHS England.

NRLS data is part of UK National Statistics. However, the NRLS was established as a voluntary scheme for reporting patient safety incidents, and therefore it does not provide the definitive number of patient safety incidents occurring in the NHS.

6.1.2. Professional framework

Several Member States recommend involving several professional organisations, such as medical and nursing organisations, in the development of new reporting systems.

Professional framework

In **France**, a national reporting system of sentinel events dedicated to `at risk speciality` doctors has been launched in 2006. It is coordinated by the National Authority for Health and operated by each of the professional `at risk speciality` organizations. This R&L system is due to evolve (extension to adverse events, noticeably). The name is `*accreditation des médecins des spécialités à risques*`.

In **Germany,** the nationwide reporting system *www.CIRSmedical.de* started in 2005 and is organised by the Agency for Quality in Medicine, AQuMed. Cirsmedical.de is internet-based and open to everyone who wants to report a near miss and receive an analysis about it. Another nationwide German reporting system, *www.jeder-fehler-zaehlt.de*, founded in 2004, focuses on primary care.

In **Hungary,** in 2006 and following a WHO request, the Health Services Management Training Centre (HSMTC) of Semmelweis University launched a pilot programme for developing a national reporting and learning system. The core principles (anonymous, voluntary, confidential, independent, non-punitive, and analysis done by experts) were based on the recommendations of the WHO Draft guidelines for adverse event reporting and learning systems.

In **The Netherlands** a nationwide reporting system for medication incidents was developed by the Dutch association for hospital pharmacists (NVZA) in 2006. In 2010 the system was extended for use by healthcare professionals in primary care and mental healthcare institutions. In 2014 the database should be available for all incidents in healthcare.

In **Slovakia,** the reporting system started in 2007 and is organised by the Healthcare Surveillance Authority. HCSA was established under Act No 581/2004 as a legal person vested with performing surveillance over provision of healthcare and public healthcare insurance in the field of public administration.

6.1.3. Local health organisations

Local health organisations

Belgium, Cyprus, France, Latvia, Luxembourg, Norway and **Sweden** have no national database to which hospitals have to report their incidents systematically. The reporting and learning system for incidents and near-incidents is meant to be hospital-wide and applicable for all incidents.

6.2. Level of reporting systems

Most Member States have one nationwide reporting system or a nationwide reporting system associated with several regional or local systems. A few Member States have local independent reporting systems operating at individual hospitals. Table 1 shows the organisational level at which a reporting system operates.

6.3. The motivation to implement a reporting system

This section describes the overall justification or motivation to establish nationwide reporting systems for incidents or near misses.
Each Member State has a slightly different history and background in relation to

the establishment of their nationwide reporting systems for incidents or near misses; however, there are many common findings described below. Most Member States offer one or more of the following justifications.

6.3.1. Main focus on reporting and learning

All Member States have as their main focus an increase in patient safety culture to create learning from incidents, errors, hazard situations and incidents that have occurred. They seek to move on from a culture of blame and accountability to focus on learning to prevent errors from happening again, and thereby motivate reporting. However, there have been other factors: the need or the aspiration to be able to benchmark healthcare provider organisations on patient safety; political responses to media attention on patient safety; national hospital accreditation policies; responses to EU or WHO recommendations. These have all had an influence on Member States in establishing local, regional or nationwide reporting systems.

6.3.2. Benchmarking on patient safety

Member States that established their reporting systems before 2009 described their motivation being prompted by foreign studies. They conducted similar studies in their own settings, the results of which indicated a need to strengthen patient safety. Based on these, one or more national studies were undertaken to identify patient safety issues nationally.

The 1999 publication of 'To err is human' by the US Institute of Medicine increased awareness among politicians, managers, professionals and the general public of the importance of preventing unnecessary harm associated with healthcare. Since then, various organisations (including WHO, Council of Europe and Council of the EU) have recommended the development of patient safety strategies and programmes oriented to prevent errors and incidents related to healthcare.

According to a number of studies (starting with the 1991 Harvard Medical Practice Study, published in the US) the rates of incidents around the world are estimated to range between 3% and 17% in acute care hospitals. In Europe, these figures are 8-12%.

Denmark, Norway, the Netherlands, Spain and the UK are also motivated by benchmarking on patient safety.

6.3.3. Political pressure from the public, media or professional circles

In some Member States, the media has given particular attention to bad outcomes to patients as result of unsafe practices or systems. This has created internal political pressures to improve patient safety. The establishment of a national patient safety law and a nationwide reporting system in Denmark in 2004 is partly due to political pressure.

Denmark, Germany, Norway, Spain and the UK have also been motivated by political pressures coming from public and professional circles.

6.3.4. Accreditation programmes for hospitals

Some Member States stated that reviews on hospital accreditation programmes pointed to making it compulsory for individual hospitals to establish local reporting systems for incidents.
Belgium, Denmark and the UK have also been motivated by accreditation programmes.

6.3.5. EU recommendation 2009

Member States that established their reporting systems after 2009 attributed this — at least partly — to the EU Council recommendation of 2009, supported by international studies on patient safety.

The Council recommendation builds upon, and complements, work on patient safety carried out by the WHO through its World Alliance for Patient Safety, the Council of Europe and the OECD. The Recommendation calls upon Member States to 'set up, maintain or improve comprehensive reporting and learning systems so that the extent and causes of adverse events can be captured in order to develop efficient solutions and interventions. Patient safety should be embedded in the education and training of healthcare workers, as the providers of care.'

The Council recommendation further states that 'comparable and aggregate data should be collected at Community level to establish efficient and transparent patient safety programmes, structures and policies, and best practices should be disseminated among the Member States. To facilitate mutual learning, a common terminology for patient safety and common indicators need to be developed through cooperation between Member States and the European Commission, taking into account the work of relevant international healthcare provider organisations.'

The Czech Republic, Luxembourg and Latvia have been motivated to establish a reporting system by the Council recommendation.

6.3.6. HOPE Exchange Programme

Latvia has local reporting systems at some hospitals, but does not have any regional or nationwide system. This has led to consideration being given to a nationwide reporting system.

Latvia's rationale for establishing a reporting and learning system at the local hospital level comes from international experience. One hospital gained it from the European Hospital and Healthcare Federation (HOPE) Exchange Programme[3]. The Programme has been running since 1981 and offers a four-week training period intended for professionals with managerial responsibilities working in hospitals and healthcare facilities.

6.4. Implementation

Some methods are based on the principles of quality improvement; others are taken from project management. Implementation methods depend on the local context. Table 2 shows the most common implementation methods used to start implementing a new reporting system for incidents.

Table 2: How was the reporting system implemented?

Method	Member States
Pilot project	Austria, Cyprus, Czech Republic, Germany, Hungary, Italy, the Netherlands, Norway, Spain and United Kingdom.
Step by step implementation	Belgium, Croatia, Czech Republic, Hungary, Ireland, Luxembourg, the Netherlands, Norway, Spain and Sweden.
Full-scale operation at launch	Denmark, Slovakia and Slovenia.

6.5. Finance

The financing models of reporting systems have varied. In Member States, reporting systems can be financed by governments, project funds, WHO or by health insurance companies.

It has not been possible to specify with accuracy the costs of reporting systems. These will depend on many factors: system cost, licences, and invisible costs — such as time spent on development, education, case management, analysis, improvement and meetings. These costs are dispersed in healthcare organisations and are therefore difficult to quantify.

3 http://www.hope.be/04exchange/exchangefirstpage.html.

Governments have financed or given financial grants for reporting systems in **Belgium**, **Croatia**, **Denmark**, **Germany, Italy**, the **Netherlands**, **Norway**, **Slovakia**, **Spain** and **United Kingdom.**

The **Czech Republic** allocated an annual ministerial research grant in the pilot phase. Today, the system is under the authority of the existing governmental agency (Institute for healthcare statistics and informatics), which received extra financing to maintain the system. Analysis of the most severe incidents is done by an expert group housed in the ministry.

In **Denmark**, the reporting system is funded by the state. There is a shared responsibility: the state owns the reporting systems, but the data are the property of regions and municipalities, until such time as the analysis is completed and electronically transferred to central level. Regions and municipalities provide professional staff to handle events and analysis. Regions and municipalities pays for the time spent on analysis and learning.

The 2013 Patient Rights legislation in **Germany** aims to give additional finance to those hospitals that have not only internal reporting systems, but also reporting systems connected to others on a voluntary basis.

In **Hungary**, the original request for a reporting system was made by WHO. They initially financed the NEVES system. Today, system improvements are financed by the funds under the Hungarian accreditation programme.

In **the Netherlands** the development and implementation of the first nationwide database for medication incidents in hospitals was financed by the Dutch association of hospitals and the Dutch association for hospitals pharmacists. The adaptation of the system and implementation in primary care was partly financed by the government and partly by the (hospital) pharmacist associations. In 2012 an independent foundation has become responsible for further implementation of the nationwide reporting and learning system. The foundation is financed by contribution of pharmacists and temporary funding from the government.

In **Slovakia,** the reporting system is financed by the Healthcare Surveillance Authority, HCSA,

7. Key elements to consider

7.1. Regulatory framework

Member States have different approaches to the regulation of patient safety reporting systems. As seen in table 3, it is apparent that Member States with mandatory reporting systems have laws or guidelines to regulate the reporting scheme and confidentiality and anonymity. Member States with voluntary reporting do not necessarily have similar regulation.

Member States regulating the reporting of incidents have implemented laws or guidelines to regulate the following:

- the level at which reporting systems operate;
- to determine when it is obligatory and when it is voluntary to report an incident; and who is responsible for reporting;
- the types of incident to be reported;
- who is responsible for acting on reports;

- levels of anonymisation and confidentiality concerning the identification of the person reporting and (other) health professionals;
- ensuring that the person reporting is free from sanctions.

Table 3 shows who is authorised to report incidents, and the reporting requirements.

Member State	Healthcare professionals	Healthcare organisations	Patients	Relatives	Public	Regulated by law
AUSTRIA	Voluntary	No	No	No	No	No
BELGIUM	Voluntary	No	Voluntary	No	No	Partially
CROATIA	Mandatory	No	Voluntary	No	No	Partially
CYPRUS	Voluntary	No	No	No	No	No
CZECH REPUBLIC	Voluntary	No	No	No	No	No
DENMARK	Mandatory	No	Voluntary	Voluntary	No	Yes
ESTONIA	Mandatory	No	No	No	No	Partially
FRANCE	Mandatory	No	Voluntary	Voluntary	Voluntary	Partially
GERMANY	Voluntary	Voluntary	Voluntary	Voluntary	Voluntary	*
HUNGARY	Voluntary	Voluntary	No	No	No	No
IRELAND	Mandatory	Yes	No	No	No	Partially
ITALY	Mandatory	Yes	No	No	No	Partially
LATVIA	Voluntary	No	No	No	No	Partially
LUXEM-BOURG	Voluntary	No	No	No	No	No
NETHER-LANDS	Voluntary	No	No	No	No	Partially
NORWAY	Mandatory	No	No	No	No	Yes
SLOVAKIA	Voluntary	Mandatory	No	No	No	No
SLOVENIA	Voluntary	Mandatory	No	No	No	No
SPAIN	Voluntary	No	No	No	No	No
SWEDEN	Mandatory	Mandatory	Voluntary	Voluntary	Voluntary	Yes
United Kingdom	Voluntary	Mandatory	Voluntary	Voluntary	Voluntary	Partially

* Legislation in Germany: §137 SGB V

By 26 February 2014, the Federal Joint Committee is to set out in its guidelines on the basic requirements of an internal quality management system, referred to in paragraph 1, point 1, the major measures to improve patient safety and it shall specify the minimum standards for risk management and error reporting systems. Information on implementation of risk management and error reporting systems in hospitals is to be included in the quality reports referred to in paragraph 3, point 4. As a basis for agreement on compensation surcharges pursuant to §17b paragraph 1, sentence 5 of the Hospital Financing Act, the Federal Joint Committee stipulates requirements for overall error reporting systems that are designed to identify risks and sources of error in in-patient care, and to evaluate, and contribute to the prevention of, `adverse events.'

7.2. Mandatory or voluntary systems

In some Member States, reporting of incidents is mandatory. In others, it is voluntary. Member States with mandatory reporting have regulated this either under law or local requirements.

This section gives examples of the reasons Member States have given for their choices.

In **Germany,** reporting systems in hospitals are mandatory, the reporting is voluntary. The focus of reporting is on near misses.

In **Hungary,** the original goal of the NEVES RLS was to support healthcare provider organisations in investigating incidents by root cause analyses. To reach this goal, they have set up event-specific report forms. The system is voluntary to avoid the fear of punishment and personal responsibility.

The **Italian** system is mandatory under a 2009 Ministerial Decree and a 2008 agreement between regions and central government. The system is focused on very serious incidents. Health professionals signal incidents, choosing the appropriate category from a list of 16, to the regional level.

In **the Netherlands** healthcare professionals are obliged to report serious incidents to the Health Care Inspectorate. Reporting remaining incidents is voluntary and recommended by professional organisations

In **Norway**, hospitals and other specialist healthcare services carry the reporting responsibility according to the law. This means that hospitals have to establish and maintain a system that will enable employees to report. There has been a proposal to have healthcare personnel carry the legal responsibility, but this has never been decided. We do not know why this has not been followed up. Legally, the reporting responsibility for healthcare personnel is set out in their employment contract.

In **Poland,** the reporting system is mandatory in the sense that it is required for accredited hospitals by the accreditation standards. In the legal sense, however, it is voluntary, as accreditation for hospitals is voluntary. Therefore, the only persons reporting are hospital staff.

In **Slovakia**, reporting of errors during the provision of healthcare is voluntary and anonymous for health workers. Hospitals alone record and analyse their own errors, which must be reported annually to HCSA.

In **Spain**, the reporting system is voluntary and includes all kind of incidents. The current Spanish legal context does not protect the rapporteurs.

In **Sweden**, according to the Patient Safety Act, it is mandatory for health and medical care staff to report to the healthcare provider any risks of adverse events, and also incidents that have caused or could have caused an adverse event. It is also mandatory for all healthcareproviders, including private ones, notify serious adverse events to the Health and Social Care Inspectorate. However, reporting to the NITHA database and to other reporting systems is voluntary. Since 2011, under the same Patient Safety Act, it is also possible for patients and relatives to file a complaint concerning incidents to the Inspectorate and to the healthcare providers. Patients can also report to the Patient Insurance LÖF and to the Patient Advisory Committees.

Both mandatory and voluntary reporting systems exist in Member States. Each type of reporting system has its advantages and disadvantages. Any mandatory

system should be accompanied by regulations on sanctions-free reporting and clear rules on confidentiality.

7.3. Types of incident reported

Definitions of reportable event differ widely between established RLSs in Member States. The 'reportability' is usually defined in one of the following ways:

- severity of the incident — in some Member States, only serious harm to patients is reported (e.g. in Norway);
- incident type — in some Member States, only specified types of events are reported (e.g. in Hungary or Poland for accredited hospitals);
- combination of both (e.g. in Denmark and Italy);
- near misses (e.g. Germany).

Besides this, there are also systems operating on the basis of a broadly defined 'patient safety incident' that basically accept all reports (e.g. in Czech Republic, Denmark, Ireland, Spain, Sweden, United Kingdom).

All definitions and methods have their advantages and disadvantages, depending on the aim of the reporting system. A simple list explicitly specifying reportable incidents is usually easier to understand by persons reporting and facilitates a focus on certain issues. However, a broader definition enables persons reporting to simply report any concern they have without having to think if they are using the proper way to report: there is only one way for all reports. However, there must always be a clear and simple statement on what should be reported to avoid confusion.

In **Belgium,** only adverse events and near misses that concern patient safety are to be reported in the local reporting and learning system. Events concerning patient security (e.g. 'theft') should be reported using another, appropriate tool in the hospital.

In **the Czech Republic**'s methodology, the incident is defined as 'Event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. Also includes harm to staff or healthcare institution. The harm could be physical, psychological or economic.' In short: 'Problem you would like to avoid.' The Czech Republic provides hospitals with a simple tool to assess if the event is an incident. They should ask three simple questions: Is it OK if this happens, and if it happens again will there be no risk of harm to the patient, me or our hospital? Was this really necessary and was there no way how we could have done this better? If this were to happen to me or my relatives, would I be satisfied with the actions of our medical staff? If the answer to any one of these questions is no, then it is an incident.

The **Italian** system provides for defined steps and required data. The system's simplicity makes data management easier, as it facilitates aggregate data on defined classes of adverse events. Every two years, the Italian Ministry of health compiles a data analysis and publishes the results in a report, where it is possible to compare different years. This makes it possible to analyse data based on rankings and a comparison of performance for each type of event.

In **the UK**, the definition of incidents to be reported to the National Reporting and Learning System is: 'A patient safety incident is any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded care.'

In **Denmark**, there are various requirements according to which types of adverse event there have to be reported in the different health sectors. For example, hospitals must report all types of incident, but pharmacies only medical incidents. All serious incidents should always be reported.

In **Croatia,** under local legislation, criteria have to be fulfilled for the adverse event report to be valid: identifiable person reporting, identifiable patient, and incident.

The **Italian** system is focused on very serious incidents. Health professionals signal incidents, choosing the appropriate category from a list of 16, to signal it to the regional level.

7.4. Who can report

The RLS should provide a way for all staff of the healthcare providing organisation to be able to report. This should not be limited only to healthcare staff because serious incidents can also happen in technical areas or be witnessed by other staff. Some recommendations (e.g. WHO) suggest that the RLS should also accept reporting from patients and relatives. To date, this has been implemented in only a few Member States.

Czech Republic: Health professionals can currently report. No one can report into the system directly; they have to report through some hospital. The hospital has its own internal system, and the transfer of anonymised records is done in the background. In theory, patients, relatives and the general public could have access to the system, but it would require the hospital to put a link on its website. No hospital has yet done this. However, any information from patients, relatives or the general public could still be collected through a complaints mechanism, and — if it indicates an incident — the hospital can manage it as one.

Cyprus: all healthcare professionals in hospitals are encouraged to report all kind of incidents. Patient reports are collected through the patient complaints mechanism. In each public hospital there is a patient complaints office.

Denmark: Since 2004, health professionals connected to hospitals have been able to report incidents. It has been a political objective that patients and relatives are able to report incidents. In 2010, the law was extended to the entire healthcare system and, since 2011, patients and relatives have been able to report incidents. Patients and relatives were able to begin reporting a year after the system was open to municipalities. These therefore had time to prepare their organisations to receive and analyse incidents before patients and relatives were admitted to the system. In 2013, about 182 000 reports from the healthcare system were submitted to the database. About 1.5 % was reported by patients and relatives. The challenge is to treat and follow up all these events.

Belgium encourages hospitals to make it possible for patients to notify incidents, near-incidents and unsafe situations. They are an important source of information and their input can be relevant to improve patient safety. Currently patients can report an incident through a specific channel in 25 % of hospitals (compared to 10 % in 2010). In addition, an ombudsman (mandatory in every hospital) can also play a role in gathering information from patients.

France: Both healthcare professionals or hospitals may report. The Patient Safety National Program (2013/2017) encourages public and private hospitals to make it possible for patients to report incidents. The procedure should be different from that of the claims.

Germany: The reporting systems are public, so patients are also able to report. In fact, mostly healthcare professionals are submitting reports. The kind of information sought, and the way feedback is given, is compatible with the needs of professionals and their learning needs as professionals. The establishment in hospitals of a 'Beschwerdemanagementsystem' for patients is now mandatory, but differs from the reporting and learning systems described here.

Sweden: There are several reporting and learning systems available, at different levels. According to the Patient Safety Act (2010:659) all healthcare providers, including private healthcare providers, are required to notify to the Health and Social Care Inspectorate incidents that have caused or could have caused serious adverse events. Furthermore, all healthcare workers are obliged to report to the healthcare provider any risks of adverse events and incidents that have caused or could have caused adverse events (6:4 Patient Safety Act). The Health and Social Care Inspectorate may also receive information about adverse events through complaints from for example patients and/or relatives.

Furthermore, patients can report incidents to the health care providers, to the Patients Advisory Committees and to the Patient Insurance LÖF.

United Kingdom: Since 2003, healthcare providers have been able to report using the NRLS eForm. In 2005, an eForm for patients and the general public was made available on the National Patient Safety Agency website to facilitate direct reporting by patients and their carers.

7.5. Reporting by patients and families

The subgroup identified this as an area where there is a lack of knowledge, and where it would be useful to share experiences from Member States where patients and families have been given the opportunity to report. Areas of specific interest might include: how can patient and family reporting be facilitated; what are the specific requirements of the system, e.g. provision of feedback; what mechanisms are needed to capture the qualitative information provided by patients; are changes needed either in systems or culture; and what possible extra resources are needed.

Experience in some countries, such as Denmark, shows that the number of such reports is low, at least in the beginning, but that they have similar patterns to healthcare providers' reports. However, this reporting is seen in all countries as an extension to the healthcare providers' reporting and has usually been added to the RLS in later stages of development. The design may not, therefore, be optimal to encourage patient and family reporting. It is also unknown to what extent information and awareness has been provided to patients and the public about the possibilities to submit reports.

If incident reporting from patients is desired, they should have knowledge of this possibility in exactly the same way as patients are made aware of the possibility to complain or receive compensation.

Direct patient reporting in pharmacovigilance is well established in some countries, such as the UK (Yellow Card scheme), the Netherlands (Lareb) and Denmark. Experience has shown that patient reporting increases over time as awareness grows, and the quality of patient reports is equal to that of health professionals. In many cases, they provide a richer descriptive element that can be an important learning resource.[4]

To facilitate structured analysis of the data, reporting for patients and relatives should use the similar key structure and classification as the reporting for healthcare providers. However, the data entry form should be designed with the needs of laypersons in mind, including use of non-medical terminology, to be accessible for public users. This form should also ask users if they want the report to be forwarded to the healthcare providing organisation where the incident happened.

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[4] See for example: 'The importance of direct patient reporting of suspected adverse drug reactions: a patient perspective' by Claire Anderson, Janet Krska, Elizabeth Murphy and Anthony Avery, *British Journal of Clinical Pharmacology*, Volume 72, Issue 5, pp 806-822, November 2011; 'Direct Patient Reporting of Adverse Drug Reactions: a Fifteen-Country Survey & Literature review' by Andrew Herxheimer, Rose Crombag and Teresa Leonardo Alves (2010). Available at http://consumers.cochrane.org/sites/consumers.cochrane.org/files/uploads/10%20May%202010%20Report%20Direct%20Patient%20Reporting%20of%20ADRs.pdf; presentations from the second stakeholder forum on the implementation of the new 2010 pharmacovigilance legislation (European Medicines Agency), 2011 available at http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/events/2011/06/event_detail_000423.jsp&mid=WC0b01ac058004d5c3.

It is important that reporting for patients and relatives should be separated from formal complaint and litigation procedures and patients should be well informed about this. It is also important to provide feedback to the person reporting, and to raise public awareness about the existence and purpose of the system.

7.6. Protection of healthcare professionals

Regulation can provide important protection for healthcare professionals. Healthcare professionals should not be subjected to disciplinary action as a result of reporting an incident. This protection enables sanction-free reporting and is crucial for the willingness of healthcare professionals to report. Regulation can also protect the data from incident reports from being used in court or other legal actions.

Legislation in **Germany** under SGB V concerning the protection of persons reporting : The following paragraph 3 is added to § 135a: '(3) messages and data from internal and cross-institutional risk management and error reporting systems […] may not be used in legal proceedings to the detriment of the person who reported. This does not apply if the use is for an offence which carries the highest possible term of imprisonment of more than five years and in especially serious individual cases where to require the exploration of facts or tracing the whereabouts of the accused would be hopeless or would in other ways be much more difficult.

Legislation in **Denmark** under the health act concerning the protection of persons reporting: `*Reporting on adverse events from the regional council and the municipal council to the National Agency for Patients' Rights and Complaints shall be anonymised with regard to the patient concerned as well as the reporting individual.*`

`*Information on the identity of the person that has submitted a given report may only be shared with the individuals in the same region or municipality who are responsible for following up on the report*`.

`*The person reporting may not as a consequence of reporting be subjected to disciplinary investigations and measures by his or her employer, supervisory measures by the National Board of Health or penal sanctions by the courts …*`

7.7. Anonymisation and confidentiality

Anonymisation and confidentiality can be addressed at different levels: the person reporting (especially a health professional), the data submitted to the system, and the mechanism used to ensure confidentiality.

Experience from the RLS subgroup has shown that learning systems achieve most success when reports are confidential, and persons reporting do not feel at risk in sharing information about errors and near misses.

Indeed, some feel it is only with such safe reporting systems that subtle system issues and the multitude of potential contributing factors will be uncovered. From a pragmatic standpoint, many believe that protecting the confidentiality of

healthcare organisations and professionals significantly enhances participation in reporting.

There are various ways to keep incidents confidential and anonymous. In some reporting systems, the person reporting is fully anonymous throughout the process; in others, there is a manual or automatic anonymisation after having made a first analysis. In still other systems, anonymisation is implemented on transfer to the central system. In some Member States, the patient's identity is kept anonymous, while the reporter's identity is stored but confidentiality of the identity is secured.

In **Belgium**, several criteria for a hospital-wide reporting and learning system have been laid down. One is that anonymous reporting must be possible.

In **Denmark, the Czech Republic, Norway** and **Spain**, the local or regional level case handler should anonymise reports with regard to patient data and data on the reporting individual. Information on the identity of the person who has submitted a report may only be shared with the individuals in the same local organisation that are responsible for following up on the report. The case handler at local level should also ensure that a person's identity is only included in specific fields of the reporting form (e.g. not in the full-text description). In this way, the identity of the persons can be erased before data is transferred to the central level. If the identity of a person is discovered in the full text in the national database, the case handler is asked to correct this and resend the report.

In the case of **Spain**, the SiNASP software automatically removes this information after a two-week period. In Denmark, fields intended to identify the person reporting and the patient are permanently deleted upon transfer to the central level.

In **Italy,** the patient is anonymised at the local level before data transfer to the regional level. Information on the identity of the person that has submitted a report is confidential.

In **Luxembourg**, reporting is anonymous in some hospitals but not in others.

In **Latvia,** all identification data are depersonalised, and confidentiality is always guaranteed.

In the **United Kingdom**, individual healthcare provider organisations are asked to anonymise their reports before submission to the National Reporting and Learning System. However, some healthcare provider organisations fail to meet this requirement at all times and a further manual anonymisation process is in place upon receipt of the reports, where any personal identifiable information flagged by an automated process is reviewed and redacted from the report. Patient date of birth is used to calculate the age of the patient at the time of the incident and deleted after that.

7.8. Key findings

- Both mandatory and voluntary reporting systems exist in Member States. Each type of reporting system has its advantages and disadvantages.
- A mandatory system should be accompanied by regulations on sanctions-free reporting and clear rules on confidentiality.
- Types of incidents that can be reported vary. However, a broad definition allows the reporting of any concerns, including near misses and 'no harm' incidents providing a rich resource for learning and systems improvement.

- All staff in healthcare organisations, not only healthcare providers, should be able to report patient safety incidents.
- Patient and family reports are a potentially rich resource for learning and patient safety improvement, and they should be encouraged. More information is needed on how best to facilitate this in different healthcare contexts.
- The reporting system should be separated from formal complaints, disciplinary actions and litigation procedures. Healthcare professionals who submit reports should be protected from disciplinary or legal action. Confidentiality of the reporter and appropriate anonymisation of the data should be ensured.
- Anonymised reports of the data should be regularly published and learning disseminated widely to support the development and monitoring of initiatives to improve patient safety and prevent incidents across the EU.

8. Education

8.1. Reporting and learning culture

Several Member States used their experience of the early years to develop a reporting culture by putting management focus on a blame-free culture and system factors rather than individual factors whenever something went wrong. It takes several years to develop a good reporting culture.

After a few years, management systems will be focused on the increasing consumption of resources used in the reporting system, and there will be demands for solutions and documentation for safer outcomes. The reporting culture will over the years migrate to a focus on learning from incidents.

8.2. Reporting training

It is important from the very start to plan training in both patient safety and the reporting of incidents for healthcare providers. Several countries regret that a reporting training programme for all potential persons reporting was not established from the start.
Several countries started training two or three super-users at each hospital. This rapidly led to demands from the healthcare provider organisation for education for all healthcare providers.
Various education arrangements are in place in healthcare provider organisations, as set out in table 4.

It is important that all training material and guidance is updated based on user feedback and as systems improve.

Table 4: The table shows how training in reporting of incidents organised in the early stages was managed.

Member State	No training	Staff meetings	Reporting form is self-explanatory	Training of all health professionals	Supervisor	E-learning	Instructions / guidelines on reporting
AUSTRIA		×	×		×		
BELGIUM		×	×		×		×
CROATIA			×				×
CYPRUS		×	×				×
CZECH REPUBLIC	×		×		×		
DENMARK		×	×		×		×
FRANCE		×	×				×
GERMANY			×				
HUNGARY		×	×		×	×	
IRELAND							×
ITALY		×		×		×	×
LATVIA		×	×	×			
LUXEMBOURG		×	×				
NETHERLANDS			×				×
NORWAY	×	×					×
SLOVAKIA	×						×
SLOVENIA			×		×		
SPAIN		×		×	×	×	×
SWEDEN		×	×	×			×
UNITED KINGDOM			×				×

8.3. Key findings

Reporting and learning culture

Key findings:

1. System aim and objective is clearly explained to all stakeholders, including the frontline staff and patients.
2. Visible changes have been made after reported incidents.
3. Patients and relatives are involved.

Recommendations:

1. All persons reporting an incident should understand their own benefit from reporting, since this will help to avoid the occurrence of incidents that could potentially be damaging to themselves and to the reputation of their organisations.
2. Top management of healthcare systems and providers should spread the message of a 'blame-free and non-punitive objective'.
3. Feedback should be given to healthcare providers on the results of an investigation and preventive measures taken.
4. To promote learning, patients and relatives should be authorised to submit reports separately from the complaints scheme.
5. Legislative changes must be considered concerning the protection of information in the event reports from courts or police as they are collected for different purposes.

   Anonymous reports should be anonymised since these clearly indicate an absence of self-interest on the part of the individual but rather a primary interest in the incident.

9. Components of a reporting system

9.1. Case flow

Figure 1 represents the usual flow of information in any RLS. Reports are transferred upstream and feedback flows back. This feedback is an important motivation factor for all levels of the system.

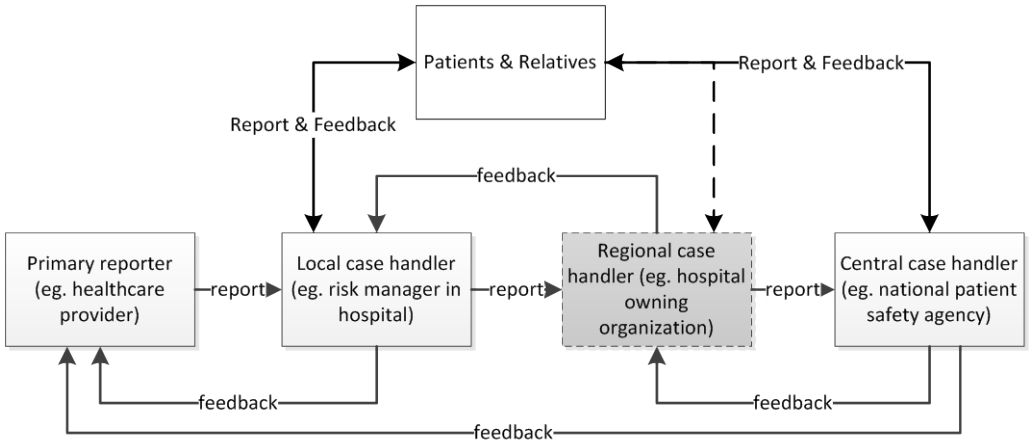

Figure 1: The case flow for incidents.

The regional level could be omitted, which is the case in most Member States. Under such conditions, the reports and feedback pass to the next level immediately.

In some Member States, the reporting system is structured such that each event undergoes a validation process at every step. Moreover, where the healthcare system is provided by regions, the step at regional level represents an important passage because of this adds another validation.

9.2. Mechanism for capturing patient safety intelligence

Generally, the prime mechanism for capturing patient safety intelligence is through an RLS enabling healthcare providers and, where allowed, patients and relatives to report. However, it is also common practice to employ other supplementary methods. These include integrating data from various sources that can contain key information of significance for patient safety:

- Complaints processing (complaint can indicate an incident occurrence);
- Automatic evaluation of administrative data (e.g. structured reports for insurance funds on care provided to discover unusual patterns in care provided);
- Automatic evaluation of laboratory data (to uncover unreported nosocomial infection);

- Automatic evaluation of pharmacy data (to uncover unreported drug-related incidents);
- Failure mode and effects analysis results (to uncover potential risks);
- Semi-automated evaluation of medical records;
- Analysis of mortality rates;
- Staff surveys;
- Patient surveys.

These methods usually have to be done at the level of the healthcare provider organisation but central or regional levels can support this effort by providing methodology recommendations and education. Suspect cases that are identified could immediately be transferred as such into an RLS or at a later time after confirmation.

These methods may be useful tools for uncovering non-reported incidents. However, it would be appropriate to consider that it involves a large amount of data and the analysis implies a big commitment for healthcare organisations. Moreover, some data are internal to the healthcare facility, such as laboratory data. Other data, however, as in the case of the interviews and questionnaires completed by patients, need a responsible person to compile them into a useable format. Their analysis requires the commitment of specifically dedicated resources.

9.3. Care setting

The general recommendation states that any reporting and learning system should cover all care settings and should enable reporting regardless of the public or private status of the healthcare provider organisation. In real life, however, this recommendation could encounter certain problems usually related to the specifics of the healthcare system in each Member State. For the purpose of this document, the inclusion of 'all care settings' means — besides hospitals (acute, long-term and mental) — laboratory settings, imaging services, rehabilitation institutions, outpatient clinics (including haemodialysis service), primary care, pharmacies, substance abuse treatment centres, ambulance services, home care agencies and providers of healthcare in social services (nursing homes).

The question of whether or not private healthcare providers should be allowed to access the reporting and learning system, which is mostly financed from public resources, is a financial matter only. The financing set-up of the RLS should allow healthcare providing organisations to participate regardless of their ownership because the primary beneficiary is always the patient. Table 5 shows the healthcare provider organisations that can report incidents.

The question of inclusion or exclusion of certain types of service is however more complicated. In some Member States, the RLS system is simply focused

only on care provided in hospitals. The RLS concept described in this document is generally appropriate for healthcare providing organisations where the care is delivered by multiple persons. This limits the use of this concept in primary or specialised outpatient care in some Member States, where these providers are very fragmented (for example, consisting of a single doctor with a single nurse as an independent private unit) and are not affiliated to any bigger organisational structure. In such care settings, some modifications of the concept have to be introduced to enable the functioning of the RLS in practice. Generally, the role of the local case handler is eliminated in such cases and the relevant competences are shifted to the regional or central case handler.

Table 5: Parts of the health system that can report incidents

Member State	Public hospitals	Private hospitals	Pre-hospital	Primary Care	Private Care agencies	Family doctors, GP	Pharmacies	Other practitioner
AUSTRIA	×	×	×	×	×	×	×	×
BELGIUM	×	×						
CROATIA	×	×						
CYPRUS	×						×	
CZECH REPUBLIC	×	×	×		×		×	
DENMARK	×	×	×	×	×	×	×	×
FRANCE	×	×						
GERMANY	×	×	×	×	×	×	×	×
HUNGARY	×	×					×	
IRELAND	×							×
ITALY	×	×						
LATVIA*	×	×	×	×	×	×	×	×
LUXEMBOURG	×	×						
NETHERLANDS	×			×		×	×	
NORWAY	×	×	×					
SLOVAKIA	×	×						
SLOVENIA	×	×						
SPAIN	×		×	×		×		
SWEDEN	×	×	×	×	×	×	×	×
UNITED KINGDOM	×		×	×		×	×	×

*Latvia: There is nationwide vigilance reporting of drug side effects, transfusions of blood components, and vigilance reporting of medical devices. Such reporting is mandatory and prescribed by regulations.

There could however be more subtle differences in reporting methods across the specific care settings. For example, the classification schemes for psychiatry could be extended in a different way to those for rehabilitation. Forms could contain a specific section for particular care settings to facilitate the collection of data tailored to the needs of the care segment. Our recommendation is to make the RLS general but open it up to adding the specifics of care settings in later

phases of development. This enables the use of RLS for further purposes by key stakeholders (e.g. medical associations).

9.4. Method of reporting

The recommended method of data collection is to put data in electronic form as early as possible. The primary reasons are to promote data accuracy, to facilitate transmission or sharing of information and to simplify statistical analysis. Information in paper form is less easily analysed and has certain limitations in terms of further processing.

At first, healthcare providers should report incidents to the local risk management system inside the healthcare providing organisation. This allows the organisation to react immediately at the local level and to follow up the incident accordingly. However, there are several situations where this is not feasible:

- Some persons reporting would like to report completely anonymously;
- Some healthcare providing organisations are very small and do not have a local risk management system;
- Reporting should be available for patients and relatives.

For these reasons, it is recommended to authorise electronic reporting directly to the central level — bypassing the local case handler — as an alternative to automatic data transfer from the local risk management system.

It is essential to underline that systems throughout Europe differ. Some collect only the most serious incidents and, when they occur, the healthcare organisation must immediately react. Even though small organisations generally do not have the resources for a risk manager, the healthcare organisation's medical director is responsible for acting on any incident report and providing necessary assurances to patients.

Input to a central database at national level should accept both the upload, or shared access, from local risk management systems and the online completion of electronic forms. The upload can take the form of immediate online transfer after confirmation of the incident (not a spam) or alternatively a batch upload. As time can be critical in some incident types, immediate online transfer is recommended. Periodic batch transfer delays the process and does not have any methodological or technical advantages when online connection over wired and wireless networks is easily available. Whenever appropriate, as an alternative to data transfer, reports can be shared between organisations, for which security and access controls should be in place.

In systems enabling data collection from patients, information flows should be structured such as to capture and manage data coming from patients or caregivers. This is important because the presentation of such information could differ significantly, and moreover it is not possible to validate these data.

Standardised reporting forms (at least for key datasets) should be used from the commencement of the system. This is important for ensuring the same meaning

of form fields throughout the system and to avoid differences (e.g. field 'Harm' could be interpreted as 'Real patient harm' in one organisation and 'Potential maximum harm' in another).

Several RLSs initially enabled paper reporting in the early stages of their operation. Over time, many of these ended this and now only accept electronic reporting. Paper reporting with later conversion into electronic form could be some benefit in specific care settings or in the early stages of RLS development; however, our general recommendation is to capture the data in electronic form as early as possible. Converting data from paper to electronic form consumes valuable resources that could be better used directly for patient safety.

At present, we know of no experience with telephone reporting in Member States. There was a pilot project, which ran for several months in the UK but was discontinued. According to reports of foreign experience (e.g. Australia), the option to report by telephone could improve the number of reported incidents. Table 6 shows the various media that Member States are using for reporting incidents.

Table 6: How incidents are reported

Member State	PC / laptop	Paper	App on smartphones	Other
AUSTRIA	×			
BELGIUM	×	×		
CROATIA	×	×		
CYPRUS		×		
CZECH REPUBLIC	×			
DENMARK	×			
FRANCE	×	×		
GERMANY	×			
ESTONIA	×			
HUNGARY	×	×	×*	*Any internet device
IRELAND	×	×		
ITALY	×	×		
LATVIA	×			
LUXEMBOURG	×	×		
NETHERLANDS	×			
NORWAY	×	×		
SLOVAKIA		×		
SLOVENIA		×		
SPAIN	×			
SWEDEN	×	×		
UNITED KINGDOM	×			

Example from **Belgium**: Hospitals are required to stipulate the way in which adverse events can be reported. This can be described in a 'reporting procedure', available to all healthcare providers in the institution. In this procedure, it is important to mention how the reporting and learning system is organised (electronically, written, oral, by mail …) and which instrument (i.e. reporting form, free text, checklist …) is used for this purpose. The aim is to get a reporting and learning system that is fast, efficient, simple and user-friendly for everybody. The ability to report adverse events electronically increased from 63 % in 2008 to 73 % in 2012.

Example from **Norway**: Health institutions using electronic reporting systems can send reports to NOKC (Norwegian Knowledge Centre for the Health Services) electronically. Reports go directly from the internal report system to the national patient safety unit at NOKC. NOKC's feedback is sent electronically in the reporting system. Health institutions that do not have electronic reporting systems to send or receive electronic reports can use a web-based form through a separate website.

9.5. Reporting methods

The first person (healthcare provider) reporting, who is launching the whole process as the whistle-blower, has a crucial role in the RLS. Many recommendations emphasise the need for an 'as-simple-as-possible' reporting form from the perspective of the person reporting. Table 7 shows the selecting reporting forms.

Table 7: Showing selecting reporting form

Member State	Special form for patients and relatives	Electronic reporting	Paper reporting	Telephone reporting	Support and help by e-mail helpdesk	Support and help by call centre	Support and help by manuals	Support and help by colleagues
AUSTRIA		×					×	×
BELGIUM		×	×					
CROATIA		×	×		×		×	×
CYPRUS			×					×
CZECH REPUBLIC		×			×		×	×
DENMARK	×	×			×	×	×	×
ESTONIA		×						
GERMANY		×			×			×
HUNGARY		×	×		×		×	×
IRELAND		×	×	×	×	×	×	×
ITALY		×	×		×	×	×	
LATVIA		×			×			
LUXEMBOURG		×	×					
NETHERLANDS		×			×	×	×	×
NORWAY		×	×		×	×	×	
SLOVAKIA			×					
SLOVENIA								×
SPAIN		×			×	×	×	×
SWEDEN	×	×	×					×
UNITED KINGDOM	×	×			×		×	×

Generally, most countries ask the person reporting to provide a description of both the incident and the consequences. For setting out proposals for preventive actions, anonymising data and classification of event type, severity, processes and reasons, responsibility varies across established RLSs: the person reporting, the local case handler or the central case handler. All these approaches have advantages and disadvantages:

Advantages of giving responsibility to the person reporting:

- Ability to suggest preventive measures from the position of direct participant in the incident;
- Facilitates immediate reporting of the incident to an appropriate manager according to the type of incident;
- It eases the workload of case managers so they can focus on other patient safety tasks or it lightens the work at further levels of incident processing.

Advantages of giving responsibility to the case handler:

- Suggestion of preventive measures is more properly done through a root cause analysis that can uncover aspects of the incident unseen from the perspective of the person reporting;
- Classification by a specialist is more accurate since classifications (especially based on WHOs International Classification for Patient Safety) can be very complex and hard to understand for non-specialists in the field of patient safety;
- It puts less work on the person reporting, which can be important for securing acceptance of the system by others.

The choice between these approaches can depend on the particular setting. It is important, therefore, to assess carefully the RLS design and ensure that it is fit for the intended purpose. However, it is generally recommended that a local case handler checks all the above-mentioned information before transfer of data to the next level.

Initial analysis of the data, creation of action plans and follow up of results are the tasks of the local case handler. However, regional or central case handlers can support this process, provide advice and ensure the proper use of standard methodology. Support from the regional and central level is a vital factor to ensure standardised incident processing throughout the whole system — across different organisations and settings — which is a key factor for data comparability.

In some systems, information is requested on the corrective actions implemented by the healthcare organisation with indicators to monitor the efficacy of these preventive measures.

In most countries, the regional case handler does not participate in the RLS processing of incidents. This role only exists in some Member States with a national health service or a federal structure (e.g. Denmark, Italy and Spain).

9.6. Feedback loops

Figure 1 under section 10.1 on case flows describes feedback mechanisms in reporting processes. Feedback to the persons reporting an incident is important to motivate them to report future incidents.

Feedback to every person reporting will be a time-consuming task. It is recommended, therefore, that feedback be given from the central or regional level to the healthcare providing organisations. In this way, any manager can inform healthcare providers, including the person reporting, about action plans based on reported incidents.

If a healthcare provider reports an incident without knowing where the report ends, or whether any action is taken, there is a risk that they will — after a number of attempts — cease reporting incidents, even if this is mandatory.

To avoid this risk, it is essential to gather information regarding incidents and analyse the data. It is important to publish data and data analysis to highlight developments across different years. This can help to identify the changes caused by the corrective actions put in place by organisations.

9.7. Use of data (case work)

Datasets exchanged between local and central levels of RLSs vary across Member States, but the following is usually seen as a bare minimum:

- Basic profile of the patient (age at the time of the incident, gender, ethnicity — reports should be anonymised);
- Location of the incident (care setting, organisation, department, specialty);
- Identity of the provider organisation (to allow follow-ups and to identify broader organisational issues);
- Timing of the incident;
- Incident type (using classification scheme);
- Patient outcome (using classification scheme);
- Description of what happened;
- Description of the immediate action taken;
- Description of the root cause of the event;
- Description of preventative measures taken.

Methods for anonymising records depend on the Member State legislation; generally, the anonymity of records should be ensured by the healthcare providing organisation that submits reports. As this might be inaccurate, it is recommended to have procedures in place at the central or regional level to check all — or at least a sample — of submitted data for the inclusion of any personal identifiable information. Problems found should be corrected or communicated to the sending organisation, where the error should be corrected in the first instance.

Besides the anonymity of records, a process for ensuring the quality of submitted data — in terms of content — should by ensured at the central or regional level. This should ensure correct classification in the first instance. However, it can be also used as supervision mechanism to oblige a standardised methodology for analysis and further processing of the records at the local level in all participating healthcare providing organisations.

Example from **Denmark, Spain** and **United Kingdom**: To maintain confidentiality, personal identifiable information is redacted; there is a combined automatic and manual filtering process in place to identify and remove such information from free text fields. Patient names, dates of birth, case numbers, patient hospital numbers, staff names, etc., are removed from reports. For example, 'Paul Smith' will be replaced with the label '[Patient Name]'. The need for continuing to anonymise such information is currently under review.

Example from **Belgium**: Hospitals are asked to implement a reporting and learning system for adverse events and to classify them. To pave the way for future data aggregation, the application of a uniform taxonomy (ICPS) and of a minimum necessary dataset (incident type and characteristics, patient and organisation outcomes) was imposed. Finally, a code table for ICPS items and an XML export model were developed to facilitate data aggregation and exchange between hospitals. Guidelines for the use of the export-model were formulated to support hospitals and software vendors. Currently, five Belgian hospitals participate on a voluntary basis on a case-by-case basis on data aggregation.

9.8. Classification system

The purpose of a taxonomy or classification system is to produce valid data. Classification may help to seek the right events, for example, for use in aggregated analyses. Classification makes it possible to compare events across the healthcare system.

In their classification systems, several Member States draw on WHO's International Classification for Patient Safety (ICPS) taxonomy: Belgium, Czech Republic, Denmark, Germany, Latvia, Norway and Spain. However, the elements drawn by each from the ICPS are varied, leading to potentially big differences in the resulting schemes. There are also differences in the extent to which use is made of the WHO taxonomy. Usually, the 'type of incident' is used but the severity grading in WHO taxonomy is sometimes considered inadequate and is replaced by proprietary schemes. Some Member States use their own classification system, which is not derived from WHO taxonomy (United Kingdom), or do not have any standardised system at all (Cyprus and Luxembourg).

Table 8 shows the different classification systems used in reporting systems.

Even with standardised central classification, the RLS can function at the local level of healthcare providing organisations by means of a parallel local classification that is later mapped to the standardised scheme. Sometimes, the reasons are historical, as the local risk management systems were usually in place before the RLS, but they retain their validity even in the present day. The most frequently used classification schemes are derived from WHO taxonomy. This is a highly complex classification scheme designed to be very general and

making use of a multidimensional structure. For these reasons, some of its concepts are not easily understandable by healthcare providers, who are often working in very specific conditions. It is recommended, therefore — even for a completely new RLS — to include the parallel local classification scheme in its design and enable healthcare providers to use a simplified classification tailored to their setting. The precise classification work related to the WHO taxonomy should be left to local case handlers.

Table 8: Classification system

Classification system	Member state
National customised version of WHO's ICPS	Belgium, Czech Republic, Denmark, Germany, Ireland, Latvia, Norway, Slovakia, Spain and Sweden
Local hospitals use different classifications	Austria, Cyprus and Luxembourg
Sentinel events monitoring system	Italy
Using own classification	Denmark (from 2014), United Kingdom
Selected incidents	Hungary

In **Hungary**, six different incident types were selected by an expert group to be included (pressure ulcers; patient falls; cancelled operations; cardiopulmonary resuscitation medication-related adverse events; and needle-stick injuries). Hungary uses structured reporting forms and closed-ended questions combined with free text, focusing on the causes of incidents, which force participants to think about the process. The number of reportable events will be 20 by the end of 2014.

9.9. Key findings

Key findings:

1. A mechanism to capture and store data is required.
2. A consistent reporting formula should be defined.
3. Feedback mechanisms should be in place.
4. Case handling should be undertaken by experts in collaboration with management.

Recommendations:

1. There should be differentiated reporting forms: one for healthcare professionals, one for patients and relatives.
2. In addition to stipulated data requirements, reporting forms should enable free-text reporting.
3. User-friendly electronic reporting should be preferred.

4. Feedback from central or regional levels is important to share knowledge about risk processes.
5. Feedback to those who are reporting is one of the most important tasks. To motivate health professionals to report future incidents, the person reporting should have the receipt acknowledged and be kept informed of action taken.
6. Both the case handling and analysis of an incident should be undertaken by experts who have insight into the subject and various methods of analysis. A management representative must be empowered to approve action plans.
7. The classification or taxonomy of events should be consistent with a generic classification system that facilitates the comparison of data across care providers. In addition, disease-specific classifications and other classifications can be used as needed.

10. Analysis

As nationwide reporting and learning systems usually rely on reports from healthcare providers, there should be a clear separation of local analysis and central or regional review.

10.1. Central or regional level review

The central or regional level reporting system should, at a minimum, permit identification of new and unsuspected hazards, such as previously unrecognised complications associated with use of a medication or a new device. A simple way to do this is by direct human review of incoming reports. For example, if even only a few people report that free-flow protection on a particular pump model can fail, this may be sufficient for recipients of the reports to recognise the problem, alert the suppliers and communicate directly with the pump manufacturer.

This type of analysis requires that knowledgeable experts review reports, but the reports do need to be based on extensive investigation by the reporting organisation. However, it is preferable to receive at least preliminary information immediately, allowing for later updates of the analysis of results over the single transfer of data after all analysis on local level has been completed.

10.2. Findings of a successful review process

A successful review process should include three key findings:

Expert — Reports must be evaluated by experts who understand the clinical circumstances under which incidents occur and who are trained to recognise underlying systems causes. While it might seem obvious that collecting data and not reviewing it is of little value, the most common failure of government-run reporting systems is to require reporting, but not to provide the resources needed to review the reports. Huge numbers of reports are collected only to be stored in boxes or on computers. Expertise is a major and essential resource requirement for any reporting system.

Credible — If recommendations are to be accepted and acted upon, a combination of independence and the use of content experts for review is necessary.

Timely — Reports should be reviewed without delay, and recommendations should be promptly disseminated to those who need to know. When serious hazards are identified, notification should take place rapidly.

The review process should identify hazards in the healthcare system and prioritise them for further evaluation. The system design should involve a decision on the amount of reviewed data and the selection criteria. It is possible to focus only on data from reports involving a real severe damage to patients, or it is possible to prioritise the reports according to perceived maximum possible risk from the reporter's perspective. Theoretically, it should also be possible to allocate enough resources to ensure evaluation of all reports, as their learning potential might not be clearly evident from the perspective of the reporting organisation.

The review process should result in preventive recommendations that should be disseminated using appropriate methods. Generally, it is advisable to use an already existing channel and to include changes in relevant, existing policies instead of merely issuing new stand-alone safety alerts. The recommendation status (voluntary vs. mandatory implementation) should be clearly stated and possible support for local implementation from central or regional level should be considered for which appropriate resources should be assigned.

10.3. Quantitative statistics

Feedback on benchmarking and data publication is often seen as a key findings of reporting and learning systems, even if its practical use is sometimes misunderstood.

Feedback on benchmarking, even when using a blind group comparison, could serve as key factor to motivate healthcare providing organisations to send reports. For this reason, it is a key findings of reporting and learning systems. However, as the quantitative figures based on passive reporting are influenced mostly by the quality of the reporting system setup and safety culture in that particular organisation, it could not be used as a direct and clear indicator of the quality and safety of provided healthcare but only of its reporting culture. The

data quality for certain types of incident could also depend on the focus of the healthcare provider on certain incident types, for example, in response to a currently running internal campaign or other factors.

In **Hungary**, the NEVES RLS offers an immediate and automatic feedback of results both in data tables and visually. Administrators can define pre-set statistics as a recommended way for interpreting reported events. A short explanation can also be added. Each user is able to run statistical queries on their own data. Descriptive analysis, trend analysis and pivot tables are available and can be set up on a graphical interface. Further analysis of the user's own data is possible by the data export feature.

Country average as a possible benchmark level can be shown as additional information in each analysis. This information (and the printable data collection sheets) is also available for non-registered users.

Giving or receiving feedback on the results is possible in regularly held discussion forums. Published case studies provide a better understanding of quality improvement opportunities. These studies are available on the platform.

In the **United Kingdom**, the biannual publication of official statistics on patient safety presents the figures for each of the reporting healthcare providers.

10.4. Analysis at local level

Incidents should be analysed at the level of the healthcare provider. It is important that analysis methods are selected according to the type and nature of the incident. The common findings of analysis are a description of the problem, conclusions and an action plan.

A reporting system must be capable of facilitating all of these. Action plans are particularly important sources of learning; they should be searchable as full-text in the reporting system.

1. In the sequential analysis model, the type of incident may be related to a simple linear model, with independent causes, failures and malfunctions. It is often present in incidents where failure, e.g. of medical devices, is related to the incident. An example of the analytical method in this category is the '5 Why' model.
2. In the epidemiological analysis model, the type of incident may be related to incidents in complex organisations, with cause and effect relationships. There must be a chronological sequence of the events or workflow to describe the incident. Analytical methods in this category include Root cause analysis (RCA), Failure Mode and Effects Analysis (FMEA), Man-Technique -Organisation model (MTO) and PRISMA.
3. The systemic analysis model can complement the epidemiological analysis model. The type of incident may be related to variability in complex socio-technical organisations. The purpose is to identify risk processes with variability, and to reduce variation through regulation. Analytical methods in this category include the Functional Resonance Analysis Model (FRAM).

Table 9: Analytical methods used in the countries

Analysis level	Analysis model	Analysis at local or regional level	Analysis at central level
Sequential analysis model	5 Why	Latvia (in one hospital)	
Epidemiological analysis model	Root cause analysis (RCA)	Austria, Belgium, Cyprus, Czech Republic, Denmark, Hungary, Italy, Latvia (in one hospital), Luxembourg, Slovenia, Spain, Sweden and United Kingdom.	
	NITHA*		
	Alarm method	Luxembourg	
	PRISMA	Belgium, Luxembourg	
	Failure mode effectiveness analysis (FMEA or HFMEA)	Belgium, Denmark, Latvia (in one hospital), Luxembourg and Sweden	
Systemic analysis model	Functional resonance analysis model (FRAM)	Denmark	
Other models	Descriptive statistics	Hungary and Spain	Denmark, Hungary Spain
	Aggregated qualitative analysis	Denmark Hungary (planned) Spain	United Kingdom, Denmark

* Sweden: National IT support for RCA of adverse events and a national database for learning.

** France: various analysis methods are used.

To ensure high-quality analysis at the local level, this effort should receive appropriate support from the central or regional level. Such support can have the form of a unified methodology, handbooks, onsite training courses, e-learning courses, or direct feedback on received and reviewed reports. Although many handbooks for conducting an analysis at local level are available in English, it is usually necessary — for a particular system set-up in a non-English speaking country — to translate and adapt selected training materials to facilitate the learning.

In the **United Kingdom**, NRLS analysts perform data and information retrieval operations on the NRLS analytical tables to provide information and analyses to support work on patient safety.
Analysis of NRLS patient safety incidents includes several types of activity and stages: programming IR queries to search for specific types, care setting or uniqueness of incidents; quantitative analysis of patterns and trends; and detailed review of individual incidents by clinical and patient safety experts.
NRLS quantitative and qualitative data analysis is performed for a variety of purposes:
• for NHS organisations across England and Wales to benchmark or compare local data with national data;
• for study or publication by a national organisation, such as the National Institute for Health and Clinical Excellence (NICE), Medicines and Healthcare Products Regulatory Agency, universities and the royal colleges;
• to respond to Parliamentary questions;
• to respond to media queries;
• to respond to requests made by members of the public under the Freedom of Information Act; and
• to inform other organisations, such as the regulator (CQC).

In **Sweden**, NITHA is a national electronic tool that provides support to healthcare providers in order to characterize adverse events and to perform root cause analysis. The results of the analyses are fed into a national database. The main objectives of NITHA and the database are to standardise RCA and terminology and to promote learning.

10.5. Key findings

1. Incoming incident reports should be reviewed, anonymised and systematically analysed.
2. Preventive recommendations should be disseminated.
3. Prompt analysis and reviews should be undertaken by credible experts.

Recommendations:

1. Distinguish between local analysis of events and central or regional review of reports.
2. Assign appropriate resources for analysis and review, including experts who understand the clinical circumstances and care processes involved and who are trained to recognise underlying system causes.
3. Avoid the search for offenders when conducting analysis on central or regional review.
4. Establish a unified methodology for processing reports, including examples, and access to data and learning to support local use of data, facilitated by central level.
5. At all levels, focus on qualitative analysis rather than quantitative statistics.
6. Review each reported incident at the local level as soon as possible and prioritise reports for central analysis on a case-by-case basis.

7. Prioritise incoming reports centrally for review using an automated algorithm (e.g. by classification).
8. To educate those working on local analysis, provide feedback on qualitative analysis during central or regional review.
9. Disseminate preventive measures through already existing channels. In addition to issuing a separate alert document, consider updating existing policy documents directly.

11. Technical infrastructure

The technical infrastructure required to support reporting systems may be very simple or quite sophisticated. Generally, the system should focus on incident reporting; collecting only summary data does not help to fulfil the primary aim of the reporting and learning system. Such a system could only focus on quantitative statistics, which in this area are always influenced by many factors. The system should support the review process and full-text analysis of the records.

Design of the central or regional database should take into account the current level of IT equipment of the healthcare providers.

11.1. Dataflow automation

Reporting systems are usually multi-tiered as multiple organisations take part in the process. Therefore, the system must necessarily deal with the issue of effective data transfer between the levels of responsibility. To eliminate the additional workload for healthcare frontline staff or quality managers in hospitals, it is necessary to ensure an automatic dataflow instead of manual rewriting. This could be done in two ways:

1. **Cloud platform** — If healthcare providers have no existing local risk management systems to store their own internal records of incidents, it could be beneficial to provide a cloud-based system to merge the handling of events at local, regional and central level. Such a solution has the advantage of immediate visibility of reports for all authorised users at all levels and eliminates the need for potential error-prone integration to be undertaken independently by various software vendors.
2. **Integration** — If healthcare providers do have existing local risk management systems to store their own internal records of incidents, they would most likely prefer to integrate their own systems with the central or regional database. Such a solution enables them to avoid the re-education of their staff for a new user interface system and to keep their data inside their own security domains.

Whatever technical solution is selected, it should also be open to participation by patients and their relatives for reporting. Therefore, the system should always include web-based forms for public reporting.

If there is a mixed approach to data collection, the technical solution should enable the storage of the common dataset in a single unified structure, thereby facilitating unified data analysis regardless of the original data source.

System design should give consideration to the speed of dataflow. The report should be put in electronic form as soon as possible to allow convenient handling; the transfer of data between institutions or systems should be online and not batched. Since broadband internet connection is widely available, batch mode no longer has any relevant technical justification. Batch data transfer offers no methodological advantage compared with online transfer.

11.2. Support and continuous development

All systems should provide technical support to users who may require assistance, whether this is with paper forms or online reporting functions. For this reason, the vendor contract should also include an indication of the work required (man-days) each month or year for a fixed fee for further system development.

11.3. Security issues

Reports within a healthcare organisation often have rich detail and usually contain information that makes it possible to identify the people concerned. It is important, however, that such information is removed from any reports transferred to other national or regional systems and the reports are anonymised to protect patients, providers and persons reporting. This is usually mandatory under a Member States national legislation: personal data handling is certainly possible inside healthcare providing organisations but it is usually forbidden to transfer such data elsewhere without the informed consent of the persons and a sound reason to do so. Learning is generally possible without the identification of individual persons. Consequently, any justification is usually absent and informed consent is an unnecessary complication.

Protection of confidentiality from unauthorised access should be implemented through a data security system. This may include a process for anonymising reports upon receipt or once a follow-up investigation has occurred.

In addition to ensuring the protection of personal data, there should be common principles of data security (availability, integrity, access restriction) during data transport, storage and archiving. This includes a clearly specified service level agreement in the vendor contract based on the expected system availability.

11.4. Key findings

1. Possibility of in-depth data analysis for both statistics and individual report content.
2. Facilitate participation of healthcare providers regardless of their access to IT equipment; at least one available PC with internet connection could be a minimum requirement.
3. Data to be transformed into electronic form as soon as possible.
4. Ensure online transfer and sharing of data during the case flow.
5. Ensure data security (availability, integrity, access restriction) during data transport and storage, sharing and archive.
6. Ensure continuing system improvements.

Recommendations:

1. Prefer data collection for each individual incident over collecting data summary tables for each healthcare provider on a central level.
2. Provide a data analysis engine that offers benchmarking and full-text search capabilities.
3. Allow online uploading and sharing of anonymised data from the more technically advanced healthcare providers, and web-based reporting forms for less technically advanced or small-size healthcare organisations.
4. Web-based reporting forms should allow patients to submit reports and the rewriting of paper reports. Web-based reporting should be able to serve as a single reporting point for frontline staff for internal reporting in any healthcare provider.
5. Basic data from all different sources of reports should be stored — or be able to be viewed as a unified structure — to allow integrated analysis.
6. Link automatically with pharmacovigilance and other similar systems to avoid duplication of reporting to these specialised systems.
7. Avoid batch transfer of data to maintain speed of data processing and to minimise delays between reporting and central or regional review. Use only online transfer and data sharing over secured internet connection.
8. IT capacity should be sufficient to ensure continuous system improvements.

12. Objectives

Reporting is one way to get the information desired, but not the only way.

The objectives of a reporting system emerge from the perceived needs of a patient safety programme. Reporting is a tool for obtaining safety information. A nationwide reporting system, therefore, can usefully be regarded as a tool to advance public policy concerning patient safety. It should be the extension of a programme of quality improvement and error prevention. To be effective, lessons learnt from the analysis of reports should feed into a mechanism for developing and disseminating changes in policy and practice that improve safety.

If the commitment to improvement is weak, or if there is no infrastructure to implement changes — such as an agency with responsibility for improving safety — a reporting system will be of little value. Stating it simply, it is more important to develop a response system than a reporting system. If there is a commitment to improving patient safety and some infrastructure, but resources are scant, alternative methods of identifying problem areas may be preferable.

In addition to patient safety incident reporting, all other reporting systems and channels should be used to collect data. There should be a register of such sources, such as those for medical device failures, complaints, legal claims, applications for disability benefits, death inquests, and reports of adverse drug reactions. Mechanisms should be introduced at regional or national level to collect this information and share the lessons learned with those able to take action.

Key findings and recommendations

An overview of all key findings and recommendations can be found at the beginning of this report in section `*1.1 Key findings and recommendations.*`

13. Glossary

Incident: Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable incidents, and hazards.

There is some general confusion about the two definitions `incident` and `adverse events`. The definitions are used equally in several EU Member States. In this report, the RLS subgroup has chosen to use `incidens` which includes `adverse events`.

Adverse drug event (ADE): A medication-related incident.

Error. Error has been defined as 'the failure of a planned action to be completed as intended (i.e. error of execution) or the use of a wrong plan to achieve an aim (i.e. error of planning)'. Although reporting of errors, whether or not there is an injury, is sometimes done within institutions, if reporting of all errors is requested, the number may be overwhelming. Therefore, some sort of threshold is usually established — such as 'serious' errors, or those with the potential for causing harm (also called 'near misses' or 'close calls'). Establishing such a threshold for a reporting system can be difficult. Hence, most 'error reporting systems' are actually 'incidents caused by errors' systems.

Event: Any deviation from usual medical care that causes an injury to the patient or poses a risk of harm. Includes errors, preventable incidents, and hazards.

Failure Mode and Effects Analysis (**FMEA or HFMEA**) An FMEA is often the first step of a system analysis. It involves reviewing as many components, assemblies, and subsystems as possible to identify failure modes, and their causes and effects. For each component, the failure modes and their resulting effects on the rest of the system are recorded in a specific FMEA worksheet. The FMEA is in principle a forward logic analysis; however, the failure probability can only be estimated or reduced by understanding the failure mechanism.

Functional Resonance Accident Model (FRAM) assumes that adverse outcomes are the result of unexpected combinations of normal variability of system functions. In other words, it is the tight couplings that lead to adverse outcomes and not sequences of cause(s) and effect(s). Since the investigation furthermore looks for functions rather than structures, it is less problematic if the description is intractable. Indeed, functions may come and go over time whereas system structures must be more permanent. Functions are associated with the social organisation of work and the demands of a specific situation. Structures are associated with the physical system and equipment, which does not change from situation to situation.

Hazards and unsafe conditions. Reporting of hazards, or 'accidents waiting to happen', is another way to achieve prevention without the need to learn from an injury. If healthcare were as safe as some other industries, reports of hazards — potential causes of incidents (as opposed to near misses, which are actual errors) — would outnumber those of actual events. Of all major systems, the

Institute for Safe Medication Practices system for medication-related events has been most successful at capturing hazards (e.g. 'look alike' packaging and 'sound alike' names.) and calling for their remedy before a predictable error occurs.

Within a health-care organisation, hazard reports raise alerts about unsafe conditions. Providers can imagine accidents waiting to happen based on their observations of weakness in the system and their experience as users. With appropriate analysis, these reports can provide valuable information for changes to systems design.

Latent error (or latent failure): A defect in the design, organisation, training or maintenance in a system that leads to operator errors and whose effects are typically delayed. Many other terms have been used: adverse outcomes, mishaps, untoward or unanticipated events, etc. WHO has commissioned the development of an international taxonomy for patient safety in order to promote greater standardisation of terminology and classification. Meanwhile, for these guidelines we will use the simpler terms: errors, hazards, incidents.

Man-Technology-Organisation analysis. MTO-analysis, which explicitly considers how human, organisational, and technical factors can interact to constitute a risk, and therefore also serve to explain accidents that have happened. The basic questions in the analysis are how the continuation of the accident sequence could have been prevented, and what the organisation could have done in the past in order to prevent the accident.

The last step in the MTO-analysis is to identify and present recommendations. These should be technical, human or organisational. The MTO analysis thus produces a detailed description and a clarification of factors that either led to or contributed to the accident.

'Near miss' or 'close call'. ' A near miss' or 'close call' is a serious error or mishap that has the potential to cause an incident, but fails to do so by chance or because it was intercepted. It is assumed (though not proven) that the underlying systems failures for near misses are the same as for actual incidents. Therefore, understanding their causes should lead to systems design changes that will improve safety. A key advantage of a near miss reporting system is that because there has been no harm the reporter is not at risk of blame or litigation. On the contrary, he or she may be deserving of praise for having intercepted an error and prevented an injury.

This positive aspect of reporting of near misses, has led some to recommend near miss systems for internal reporting systems within health-care organisations or other health-care facilities where a blaming culture persists. However, any hospital that is serious about learning will also invite reports of near misses.

Potential incident: A serious error or mishap that has the potential to cause an incident but fails to do so because of chance or because it is intercepted (also called 'near miss' or 'close call').

Preventable incident: An incident caused by an error or other type of systems or equipment failure.

RLS: Reporting and learning system for incident

Root cause analysis (RCA) assumes that adverse outcomes can be described as the outcome of a sequence (or sequences) of events or a chain (or chains) of causes and effects. The investigation is therefore a backwards tracing from the accident, trying to find the effective cause(s). The method requires that the system is traceable since it otherwise would be impossible to carry out this backwards tracing. The method also requires that the system is only loosely coupled, since it otherwise would be impossible to feel confident that the correction or elimination of the root cause would prevent a recurrence of the accident.

Safety: Freedom from accidental injuries.

Sentinel events: Particularly serious incidents, potentially indicative of a serious system malfunction, which may result in death or serious harm to the patient and determining a loss of confidence among citizens for the health service. Because of its gravity is enough to occur only once because it is expedient immediate investigation to determine what factors have caused the elimination or reduction, or have contributed to and triggering the implementation of appropriate corrective measures by the organisation.

System: A set of interdependent elements (people, processes, equipment) that interact to achieve a common aim.

14. References

1 World Health Organization: WHO Draft Guidelines for Adverse Event Reporting and Learning Systems — from information to action, published in 2005.

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3 EUNetPas Library of reporting and learning systems, located in The Danish National Agency for Patients' Rights and Complaints. Updated 2013.

4 Council of Europe, Committee of Ministers: Recommendation Rec(2006)7 of the Committee of Ministers to member states on management of patient safety and prevention of adverse events in health care (Adopted by the Committee of Ministers on 24 May 2006 at the 965th meeting of the Ministers' Deputies)

5 European Federation of Nurses Associations. Report on the Implementation of Directive 2010/32/EU on the prevention of sharps injuries in the healthcare sector. http://www.efnweb.be/wp-content/uploads/2013/12/EFN-Report-on-Sharps-Injuries-DIR32-Implementation.pdf