Health Information and Quality Authority

An tÚdarás Um Fhaisnéis agus Cáilíocht Sláinte

International review of patient safety surveillance systems

January 2016

Safer Better Care

About the Health Information and Quality Authority

The Health Information and Quality Authority (HIQA) is the independent Authority established to drive high quality and safe care for people using our health and social care and support services in Ireland. HIQA's role is to develop standards, inspect and review health and social care and support services, and support informed decisions on how services are delivered. HIQA's ultimate aim is to safeguard people using services and improve the quality and safety of services across its full range of functions.

HIQA's mandate to date extends across a specified range of public, private and voluntary sector services. Reporting to the Minister for Health and the Minister for Children and Youth Affairs, the Health Information and Quality Authority has statutory responsibility for:

- **Setting standards for health and social services** – Developing person-centred standards, based on evidence and best international practice, for those health and social care and support services in Ireland that by law are required to be regulated by HIQA.
- **Regulation** – Registering and inspecting designated centres.
- **Monitoring children's services** – Monitoring and inspecting children's social services.
- **Monitoring healthcare quality and safety** – Monitoring the quality and safety of health and personal social care and support services and investigating as necessary serious concerns about the health and welfare of people who use these services.
- **Health technology assessment** – Providing advice that enables the best outcome for people who use our health service and the best use of reources by evaluating the clinical and cost effectiveness of drugs, equipment, diagnostic techniques and health promotion activities.
- **Health information –** Advising on the efficient and secure collection and sharing of health information, setting standards, evaluating information resources and publishing information about the delivery and performance of Ireland's health and social care services.

Overview of Health Information function

Health is information-intensive, generating huge volumes of data every day. Health and social care workers spend a significant amount of their time handling information, collecting it, looking for it and storing it. It is therefore imperative that information is managed in the most effective way possible in order to ensure a high quality, safe service.

Safe, reliable healthcare depends on access to, and the use of, information that is accurate, valid, reliable, timely, relevant, legible and complete. For example, when giving a patient a drug, a nurse needs to be sure that they are administering the appropriate dose of the correct drug to the right patient and that the patient is not allergic to it. Similarly, lack of up-to-date information can lead to the unnecessary duplication of tests – if critical diagnostic results are missing or overlooked, tests have to be repeated unnecessarily and, at best, appropriate treatment is delayed or at worst not given.

In addition, health information has a key role to play in healthcare planning decisions – where to locate a new service, whether or not to introduce a new national screening programme and decisions on best value for money in health and social care provision.

Under section (8)(1)(k) of the Health Act 2007, the Health Information and Quality Authority (the Authority or HIQA) has responsibility for setting standards for all aspects of health information and monitoring compliance with those standards. In addition, under section 8(1)(j), the Authority is charged with evaluating the quality of the information available on health and social care and making recommendations in relation to improving the quality and filling in gaps where information is needed but is not currently available.

Information and communications technology (ICT) has a critical role to play in ensuring that information to drive quality and safety in health and social care settings is available when and where it is required. For example, it can generate alerts in the event that a patient is prescribed medication to which they are allergic. Further to this, it can support a much faster, more reliable and safer referral system between the patient's general practitioner (GP) and hospitals.

Although there are a number of examples of good practice, the current ICT infrastructure in Ireland's health and social care sector is highly fragmented with major gaps and silos of information which prevent the safe, effective, transfer of information. This results in service users being asked to provide the same information on multiple occasions.

Information can be lost, documentation is poor, and there is over-reliance on memory. Equally, those responsible for planning our services experience great difficulty in bringing together information in order to make informed decisions. Variability in practice leads to variability in outcomes and cost of care. Furthermore, we are all being encouraged to take more responsibility for our own health and wellbeing, yet it can be very difficult to find consistent, clear and trustworthy information on which to base our decisions. As a result of these deficiencies, there is a clear and pressing need to develop a coherent and integrated approach to health information, based on standards and international evidence.

HIQA has a broad statutory remit, including both regulatory functions and functions aimed at planning and supporting sustainable improvements. In accordance with the Health Act 2007, (sections 8(1)(j) and 8(2)(d)), one of the key functions of the Authority is to provide advice to the Minister for Health and the HSE about deficiencies identified regarding health information. It is on this basis that the Authority is undertaking this project. The purpose of this international review is to inform the development of a set of recommendations on the coordination of patient safety intelligence in Ireland. These recommendations will be submitted to the Minister for Health for his consideration.

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Executive summary

The 2014 Chief Medical Officer's (CMO) report[1] to the Minister for Health on perinatal deaths in the Midland Regional Hospital, Portlaoise recommended the establishment of a National Patient Safety Surveillance System in Ireland. The report outlined that a gap currently exists in relation to the coordination of national patient safety information and there is a need to pool the information that exists across different agencies to create a better patient safety and risk profile of services nationally.
In accordance with the Health Act 2007, sections 8 (1)(j) and 8 (2)(d), one of the Authority's key functions is to advise the Minister for Health and the Health Service Executive (HSE) about deficiencies in health information.
The Authority therefore aims to address the deficiencies outlined by the CMO through the development of recommendations for the Minister for Health on the coordination of patient safety intelligence in Ireland. This international review is the first stage in a project to develop these recommendations. Specifically, this review documents recently published evidence relating to reporting and learning systems for patient safety incidents in Europe, and in particular examines in detail the approaches that have been undertaken in four international jurisdictions. This involved both desktop research and semi-structured interviews with key individuals in each of the countries and regions reviewed.

Across the jurisdictions examined, it emerged that a variety of approaches exists for the reporting of patient safety incidents. For example, Denmark and England have national reporting and learning systems in place. In Scotland, there is no national system and NHS regional boards use stand alone adverse event reporting systems. While Canada has no national system for reporting patient safety incidents, there are well established provincial systems in place, such as the British Columbia Patient Safety and Learning System (BC PSLS).There is also considerable variation in the regulatory frameworks in place. Some countries having mandatory reporting systems that are supported by law while other systems are voluntary. For example in England, reporting for all 'serious incidents' is mandatory, while in Denmark, reporting adverse events is mandatory and is provided for in legislation. Reporting onto the BC PSLS in British Columbia is voluntary for healthcare professionals and it is encouraged but not mandatory for healthcare professionals in Scotland.

The importance of involving patients and service users in capturing patient safety incidents emerged as a key focus area. In Denmark and England, patients and patients' relatives can report into the system, while the BC PSLS in Canada also captures patient and family perspectives. Legislation[2] is in place in Denmark to encourage reporting and to serve the 'just culture' concept by protecting the people

who report incidents. Scotland's National Framework[3] also promotes a just and positive safety culture.

Another area that is being considered by all the countries we reviewed was in relation to taxonomy and classification of definitions in the area of adverse event reporting. Efforts to standardise incidents and adverse event reporting were seen across all jurisdictions, with each using their own classification system, closely aligned to WHO's International Classification for Patient Safety (ICPS)[4].

The importance of coordination and sharing patient safety intelligence was a key theme discussed with all the countries and regions we reviewed. Data sharing agreements are in place in Denmark and England. The Danish Patient Safety Database is required under legislation to communicate learnings from the system nationally and with other agencies. In England, the NRLS has data sharing agreements in place and data from the NRLS is also triangulated as part of risk management and clinical review. In BC individual facilities determine appropriate levels of data sharing with external bodies, while there are voluntary participation agreements in place in Scotland where the development of an adverse event 'Community of Practice' aims to share key learnings from adverse event reviews. All of the locations reviewed also use their systems to deploy safety alerts. In particular, NHS England's new National Patient Safety Alerting System, alerts NHS organisations in England, Wales and Scotland to potential risks and provides guidance on potential patient safety incidents.

In all the jurisdictions reviewed, there are considerable developments under way, with NHS England working to re-develop its patient safety surveillance system. Healthcare Improvement Scotland is leading the development of a national strategic approach to adverse events. In Denmark the National Agency for Patient's Rights and Complaints intends to enter into relationships with key informed parties who have an in-depth knowledge of the context in which patient safety activities are to be implemented, while BC PSLS Cental Office is exploring new opportunities to expand the use of data and availability of data.

A number of countries have reviewed the impact of their reporting and learning system on the development of a patient safety culture in that country. In Denmark, an independent evaluation of their system in the first two years of operation found that there was significant reporting from physicians (89% of those involved in an incident reported same) and 70% of all adverse events had been followed up.[5]

In summary, this international review highlights the considerable variation in place across countries in relation to patient safety reporting. It is clear however, that the coordination and triangulation of patient safety intelligence for risk profiling is

extremely important. Incidents need to be combined with other quality and patient safety sources of information. In Ireland, as highlighted by the CMO, there is currently no single agency or body with overall line of sight at a national level in relation to the coordination of patient safety intelligence.

1. Introduction

1.1 Background

Safe, reliable health and social care depends on access to and use of good quality information. Information is essential to achieve a high-quality, value for money, healthcare system. Accurate, relevant and timely data is essential in order to identify and improve upon care provided, to inform decision-making, monitor diseases, plan services, inform policy making, conduct high-quality research, and plan for future health and social care needs, both locally and nationally. Patient safety is a central aspect of a healthcare system's performance, and good quality patient safety information is vital in order to accurately assess a healthcare system's performance.[6] After a series of studies in several countries, it is now generally accepted that approximately 10% of patients who receive care in hospitals experience some adverse effect in their course of treatment.[6] This is unacceptable in a modern healthcare system and needs to be addressed through reporting, analysing and acting on relevant patient safety information.

The 2014 Chief Medical Officer's (CMO) report[1] to the Minister for Health on perinatal deaths in the Midland Regional Hospital, Portlaoise, recommended the 'establishment of a National Patient Safety Surveillance System'. According to the Council of Europe Recommendation to Member States on the management of patient safety and prevention of adverse events in healthcare, the primary objective of an incident reporting system is enhancing patient safety by learning from incidents and mistakes made. The fundamental role of a patient safety surveillance system is to improve patient safety by learning from failures of the healthcare system.[7] Healthcare errors often have common root causes which can be generalised and corrected. There are likely to be similarities and patterns in sources of risk which may otherwise go unnoticed if incidents are not reported and analysed.

The CMO's report[1] indicated that had the data obtained during the course of his review been collated and examined by the hospital, it could have shown that there was good reason to suspect that there may have been an ongoing problem with the outcomes of care experienced by those using the service. While the CMO's report focuses on the services provided at Portlaoise Hospital, it also points to issues at a national level, highlighting the complexity of perinatal mortality statistics and the fact that reporting on these is further hampered by the lack of consistent definitions nationally and internationally. This results in discrepancies in reported rates of perinatal mortality. This is just one area where the evidence has been documented and it is likely that this is reflected across other patient safety areas.
In particular, the CMO's report recommended pooling of information that may exist across agencies in order to create better risk and safety profiling of services, and

that this issue be further considered as a critical gap in patient safety functions nationally. Such a system would be of benefit to the Authority, service providers, policy makers and most importantly the patient, as it could provide early warnings of potential safety issues and risks to the system.

1.2 Purpose of this international review and the overall project

In accordance with the Health Act 2007, sections 8 (1)(j) and 8 (2) (d), one of the Authority's key functions is to provide advice to the Minister for Health and the HSE about deficiencies identified regarding health information.

There are four stages involved in this project to develop recommendations for the Minister for Health on coordinating patient safety intelligence in Ireland. This document outlines the findings from the first stage of the project which aims to conduct an international review on patient safety surveillance systems, through documenting existing sources of patient safety surveillance in other countries and regions. The second stage of the project involves an 'as is' analysis which will document existing sources of patient safety intelligence in Ireland. The third stage of the project involves convening an advisory group to access expertise and engage with people on whom the final outputs of the project will have an impact. The international evidence, findings of the 'as is' analysis and advisory group input will form the basis for a set of recommendations to the Minister for Health on coordinating patient safety intelligence in Ireland.

Stage 1:	International review of patient safety surveillance systems
Stage 2:	'As Is' analysis documenting existing sources of patient safety intelligence in Ireland
Stage 3:	Convening of an advisory group
Stage 4:	Development of recommendations for a the coordination of patient safety intelligence in Ireland

1.3 Overview of international evidence regarding patient safety reporting

A number of key international and European patient safety reviews have been published in the past decade. These documents were identified during the course of this review and are listed in table 1 on the following page. A brief summary of each of these documents is provided following table 1.

Table 1. Previously published documents referenced throughout this review [1].

Title	Author and or source	Year published
WHO Draft Guidelines for Adverse Event Reporting and Learning Systems[8]	World Alliance for Patient Safety	2005
Council Recommendation of 9 June 2009 on patient safety, including the prevention and control of healthcare associated infections (2009/C 151/01)[9]	The Council of the European Union	2009
National Reporting Systems for Patient Safety Incidents – A review of the situation in Europe[6]	P. Doupi and the National Institute for Health and Welfare, Finland	2009
Information Model for Patient Safety Incident Reporting Systems (Summary Report of the Expert Review Meeting)[10]	World Health Organization	2012
The measurement and monitoring of safety[11]	The Health Foundation, UK	2013
Patient safety in practice – How to manage risks to patient safety and quality in European healthcare[12]	HOPE – European Hospital and Healthcare Federation	2013
Preliminary Version of Minimal Information Model for Patient Safety (Working Paper)[13]	World Health Organization	2014
Key findings and recommendations on reporting and learning systems for patient safety incidents across Europe[7]	Reporting and learning subgroup of the European Commission. Patient Safety and Quality of Care Working Group (PSQCWG)	2014

[1] Note: A complete table with background and purpose of each document listed in the table above can be found in Appendix 1.

1.3.1 WHO draft guidelines for adverse event reporting and learning systems – 2005

The World Alliance for Patient Safety[8] published draft guidelines for adverse event reporting and learning systems in 2005. The guidelines state that to enhance patient safety a successful reporting and learning system should have the following characteristics:

- reporting is safe for the individuals who report
- reporting leads to a constructive response
- expertise and adequate financial resources are available to allow for meaningful analysis of reports
- the reporting system must be capable of disseminating information on hazards and recommendations for change.

The World Alliance for Patient Safety[8] outlines the following key messages in relation to adverse event reporting and learning systems:

- The primary purpose of patient safety reporting systems is to learn from experience.
- A reporting system must produce a visible, useful response to justify the resources expended and to stimulate reporting.
- The most important function of a reporting system is to use the results of data analysis and investigation to formulate and disseminate recommendations for systems change.

1.3.2 EU Council recommendation – 2009

The 2009 EU Council recommendation on patient safety[9] (Council Recommendation 2009/C151/01) recommends that EU Member States support the establishment of 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 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, while avoiding multiple reporting where possible.

1.3.3 National reporting systems for patient safety incidents – a review of the situation in Europe, 2009

In a review published in 2009, plans for operational national patient safety incident reporting systems were identified in 13 European countries including Denmark, Ireland, Scotland, and the UK (England and Wales).[6] Three different types of national patient safety incident reporting systems were identified as follows. These were systems for:[6]

- sentinel events only (often mandatory by law)
- specific clinical domains (reporting often voluntary)
- healthcare system-wide comprehensive reporting (which also include 'near-misses').

At the time the report was published in 2009, operational systems of the latter type existed only in the UK, Denmark and Ireland, while there were plans in place to establish such a system in Scotland. In these systems, reporting was documented to be typically done anonymously by front-line personnel, but with differing levels of detail. Reporting by patients and or relatives was in place in the UK and was reported to be in development in Denmark. Collected data was reported to be most commonly used for hazard identification and issuing of alerts, as well as for trends-cluster analysis. Risk, causal and systems analysis, which are used in more mature large-scale reporting systems in the USA and Australia, were reported not to be available in European systems at the time.

1.3.4 Information model for patient safety incident reporting systems – 2012

The main conclusions of this report include the following:

- Learning from mistakes and system failures that lead to unsafe care is essential for patient safety management and improvement, as well as for international comparisons and global learning.
- Reporting systems help strengthen the patient safety culture and facilitate patient safety management in healthcare organisations.[8]

1.3.5 The measurement and monitoring of safety – 2013

A report on the measurement and monitoring of safety[11] published by the Health Foundation in the UK emphasised the importance of feedback, action and improvement as key elements of integration and learning. It is essential that healthcare organisations balance the focus of collecting and integrating safety information with appraising how it is used to deliver meaningful feedback, action and improvement. 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 it.[7] As such, while a dynamic reporting system is one indicator of a good safety culture, the response system is more important than the reporting system.

1.3.6 Patient safety in practice – How to manage risks to patients safety and quality in European healthcare – 2013[12]

The growing importance of patient safety leadership attracted the attention of researchers and policy makers. Miller and Bovbjerg (2002) emphasised that there are two determinants of success in improving patient safety:

- a demand for safety from external factors (legal, market, and professional)
- an appropriate organisational responses that depend on internal factors including leadership and governance, professional culture and information analysis.[12]

1.3.7 Preliminary version of minimal information model for patient safety – 2014

One of the long standing aspirations of the World Health Organization's (WHO) Patient Safety Programme, since it began in 2004, was to turn the failures of healthcare into global learning opportunities to accelerate and expand patient safety improvement. However, health players are still struggling to build effective learning systems based on the reporting of patient safety incidents. Weak safety cultures, together with the fear of punishment, prevent to some extent the reporting of adverse incidents. The scarcity of universally applicable and common standards for collecting, storing, classifying, analysing and interpreting incident reports as well as other clinical data is a significant barrier to effective reporting and learning.[13]

1.3.8 The Minimal Information Model is an initial step to overcome some of these limitations and to help harmonise patient safety incident reporting systems, and as a consequence, enhance comparison and learning across various reporting systems.[13] The model relies on the logic and coherence of the Conceptual Framework for the International Classification of Patient Safety (ICPS).[4] It also draws directly from the framework structure to which empirical analysis and experts' opinions have been added to arrive at the suggested data categories for the minimal, intermediate and full models.

1.3.9 Reporting and learning systems in practice – 2014

The reporting and learning system subgroup established under the European Commission's patient safety and quality care working group published a report[7] in 2014 documenting reporting and learning systems for patient safety incidents across Europe. The report outlines key elements to consider for reporting and learning systems. It cautions that before deciding on establishing a nationwide incident reporting and learning system, EU Member States should carefully consider what the objectives of the system are, 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 key findings in relation to the overall set-up of reporting and learning systems in European Member States are documented in the 2014 European Commission report as follows:

- 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 sanction-free reporting and clear rules of 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, would 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 action 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.

Table 2 sets out some of the key components of reporting systems across Europe as documented in the European Commission's 2014 report:

Table 2. Summary of key components of reporting systems across Europe

Key: HP = healthcare professionals; HO = healthcare organisations.

EU Member State	Mandatory (M) or voluntary (V) reporting	Who can report?	Is it regulated by law?
Austria	Voluntary	HP	No
Belgium	Voluntary	HP and patients	Partially
Croatia	Mandatory for HP, voluntary for patients	HP and patients	Partially
Cyprus	Voluntary	HP	No
Czech Republic	Voluntary	HP	No
Denmark	Mandatory for HP, voluntary for patients and relatives	HP, patients and relatives	Yes
Estonia	Mandatory	HP	Partially
France	Mandatory for HP, voluntary for patients, relatives, public	HP, patients, relatives and the public	Partially
Germany	Voluntary	HP, HO, patients, relatives and the public	In progress
Hungary	Voluntary	HP and HO	No
Ireland	Mandatory	HP and HO	Partially
Italy	Mandatory	HP and HO	Partially
Latvia	Voluntary	HP	Partially
Luxemburg	Voluntary	HP	No
Netherlands	Voluntary	HP	Partially
Norway	Mandatory	HP	Yes
Slovakia	Voluntary for HP, mandatory for HO	HP and HO	No
Slovenia	Voluntary for HP, mandatory for HO	HP and HO	No
Spain	Voluntary	HP	No
Sweden	Mandatory for HP, HO, mandatory for patients, relatives and the public	HP, HO, patients, relatives and the public	Yes
United Kingdom	Voluntary for HP, patients, relatives and the public. Mandatory for HO	HP, HO, patients, relatives and the public	Partially

1.3.10 Coordination of intelligence

While the previous sections outline the importance of reporting, responses to reporting and dissemination of learning, the coordination of intelligence and consideration of other sources of information are also crucial. The World Alliance for Patient Safety notes that reporting systems do not provide a complete picture of risks, hazards and system vulnerabilities and that there are other valuable sources of information that can be used within a health service and nationally to complement reporting.[8] *The Measurement and Monitoring of Safety*,[11] published in 2013, notes that in healthcare, one potential risk to the evolution of safety measurement is fragmentation of key safety information across national and local informed and interested parties. The net effect of this fragmentation is that producing single source safety measurement reports that triangulate data from many safety metrics relies on the collaboration of a broad range of informed and interested parties.

1.4 Methodology for detailed international review

While Table 1 outlines a summary of the key components of reporting systems across Europe, the following four countries and regions were selected for an in-depth review on the basis of an initial review of the literature and available evidence:

- British Columbia, Canada
- Denmark
- Scotland
- England.

The review involved both desktop research and semi-structured interviews with key individuals in each of these locations. The focus of the desktop review was to determine the current situation for reporting, analysing and learning from patient safety data at a provincial and or national level. Discussions with key individuals were held to ensure the information collected following desktop research was factually accurate. Disucssions were also aimed at exploring how the systems work in more detail and how information is shared with key stakeholders. This was to gain an insight into the benefits of the models in place, the challenges encountered and to explore lessons learned from their experiences. The themes that were explored in these discussions were as follows:

- patient safety structures in the jurisdiction
- system characteristics
- reporting processes
- data analysis
- key relationships and coordination and sharing of data
- future direction.

It is important to note that a cost-benefit and resourcing analysis was not undertaken as part of this review. In addition, aspects relating to the technical infrastructure of the countries and regions reviewed was not undertaken. The Authority instead concentrated on the systems in place, principles behind the systems and role of various stakeholders in the four countries and regions reviewed. The four locations listed above are now explored in detail in the following sections of the report in relation to their patient safety structures.

In-depth review of patient safety surveillance structures in place in four jurisdictions

2. High-level overview of four countries and regions[2]

2.1 British Columbia, Canada

Type of reporting system

In Canada, the province of British Columbia has a patient safety and learning system (British Columbia PSLS) in place since 2008. It aims to collect data on patient safety incidents and use this information to learn from previous incidents (http://bcpslscentral.ca/).

What is reported?

British Columbia PSLS holds data on all patient safety events, including adverse events, near misses, safety hazards, patient complaints and claims.

Who reports?

Reporting onto British Columbia PSLS is voluntary and reporting can be done anonymously. All healthcare professionals across the province of British Columbia, operational leaders and specialised staff (such as risk managers) can report to the British Columbia PSLS. British Columbia PSLS has since expanded the variety of people who can report through *Patient's View*, a version of British Columbia PSLS that captures patients and families' perspectives on safety.

How they report?

The British Columbia PSLS is a web-based patient safety event reporting, learning and management system, encompassing a collection of online modules and tools.

Analysis

All data submitted into British Columbia PSLS is managed and secured in a central database by the Central Office, who performs analysis, trending and reporting.

Response, sharing and applying results

British Columbia PSLS produces a number of reports, such as monthly reports for subscribers, annual reports and the articles published on the British Columbia PSLS blog, which has been a powerful tool in sharing information on how people are using data and the system to improve patient safety.

[2] Note: A comparision table of the characteristics and approaches to patient safety incident reporting in each jurisdiction can be found in Appendix 2.

2.2 Denmark

Type of reporting system

The Act on Patient Safety (2004)[2], which came into force on 1 January 2004, provided for mandatory reporting of specified adverse events for healthcare professionals to a national database called the Danish Patient Safety Database (DPSD). The DPSD is administered by the National Agency for Patients' Rights and Complaints (http://dpsd.demo.privatsite.dk/).

What is reported?

The National Agency for Patient's Rights and Complaints makes specifications for the regional and municipal councils on what adverse events are to be reported to the DPSD, when these reports are to be submitted and in what format. A definition of adverse events is provided in the Act on Patient Safety. Identifiable information is encouraged while the option to report anonymously is available.

Who reports?

Front-line personnel in hospitals and in the primary care sector are statutorily obligated to report adverse events to the national reporting system. Patients and patients' relatives can also report into the system, via their region.

How they report?

Reporting an adverse event can only be completed electronically.

Analysis

The head of the department where the adverse event has occurred usually performs analyses and risk assessments locally. More serious adverse events are analysed by staff from the National Agency for Patients' Rights and Complaints, who perform cluster and trend analysis and issue alerts where necessary.

Response, sharing and applying results

The National Agency for Patients' Rights and Complaints is required under legislation to communicate learning from the system nationally. It produces a number of outputs including an annual report. The Health Act (2010)[14] enables the sharing of reports on adverse events between agencies.

2.3 England

Type of reporting system

The National Reporting and Learning System (NRLS) was launched in 2004 in order to promote an open reporting culture and a process for learning from adverse events (http://www.nrls.npsa.nhs.uk/). Its purpose is to elicit reports of patient safety incidents, identify themes and patterns in the types of incidents being reported including major systems failures, and to develop and promote implementation of solutions. In addition, the Strategic Executive Information System (STEIS) system is the national system that enables the management and investigation of serious incidents.

What is reported?

Patient safety incidents to be reported to the National Reporting and Learning System are defined nationally. Reports are anonymous, although a NHS Trust identifier is maintained. All 'serious incidents' (defined by the Serious Incident Framework)[15] must be reported on the Strategic Executive Information System.

Who reports?

Any healthcare staff member can report a patient safety incident to the National Reporting and Learning System. Patients, their relatives, carers and the public can also report to the National Reporting and Learning System.

How they report?

Healthcare organisations with electronic risk management systems can use a technical link to submit reports directly from this local system into the National Reporting and Learning System. The National Reporting and Learning System also use an electronic reporting 'e-Form', for reports submitted independently of an organisation's risk management system (for instance, patients or carers).

Analysis

The Imperial College Healthcare NHS Trust manages the National Reporting and Learning System and is responsible for data extraction and handling data requests.

Response, sharing and applying results

Lessons learned from the National Reporting and Learning System are shared through the National Patient Safety Alerting System (NPSAS) and through feedback to reporting organisations on incident trends and solutions.

2.4 Scotland

Type of reporting system

There is no national system for adverse event reporting in NHSScotland. Individual NHS boards in Scotland use stand-alone adverse event reporting systems for reporting and managing adverse events. Healthcare Improvement Scotland has led on the development of a national approach with the publication of a *National Framework for learning from adverse events through reporting and review* in 2013[3], recently updated in April 2015 (http://www.healthcareimprovementscotland.org/).

What is reported?

All NHS boards set out their own policy on how adverse events are to be managed including notification and escalation procedures. There are currently no common definitions around recording adverse events, with NHS Boards recording different information using different classifications. Some adverse events are required to be reported to national or UK-level systems.

Who reports?

All adverse events should be reported locally by healthcare professionals through local management systems in NHS Boards.

How they report?

Reporting methods vary between NHS boards and there are differing recording processes for adverse events. There is, however, mandatory reporting of certain specific events to national agencies, for example, to the Medicines and Healthcare Products Regulatory Agency.

Analysis

NHS boards analyse their own data on reported incidents.

Response, sharing and applying results

There is currently no national measurement around adverse events and Healthcare Improvement Scotland does not hold any national adverse events data. NHS boards share information with a number of different national and UK agencies.

3. British Columbia, Canada

3.1 Background

In Canada, there are a number of national agencies that hold a role in patient safety including the Canadian Patient Safety Institute (CPSI), Health Canada, the Canadian Institute for Health Information (CIHI), the Public Health Agency of Canada and the Institute for Safe Medication Practices Canada (ISMP Canada).

3.1.1 Canadian Patient Safety Institute

The Canadian Patient Safety Institute provides a leadership role in building a culture of patient safety and quality improvement in Canada through promoting best practices and advising on effective strategies to improve patient safety.[16] While there are national systems for collecting data specific to medication-related patient safety incidents, there is no pan-Canadian adverse event reporting system. It is now expected that the National System for Incident Reporting (NSIR) within the Canadian Patient Safety Institute, which collects medication incident data, will instead be expanded to fulfil this function.[17]

3.1.2 Canadian Institute for Health Information

The Canadian Institute for Health Information is an independent not-for-profit organisation that provides essential information on Canada's health system and the health of its citizens for the benefit of a wide range of stakeholders. The Institute has a number of ongoing initiatives in the area of patient safety.[18] It is collaborating with the Canadian Patient Safety Institute on the In-Hospital Patient Safety Project, which is anticipated for release in autumn 2015. Through this project, both organisations are using administrative data to develop a new patient safety indicator for inpatient care. The indicator will include unintended occurrences of harm that can be potentially reduced or eliminated by implementing known best practices. The Canadian Institute for Health Information is also developing several new indicators that will measure rates of a range of patient safety-related occurrences in Canadian hospitals.

3.2 British Columbia

British Columbia, a province on Canada's Pacific coast, has a population of 4.4 million people. The Ministry of Health in British Columbia works with the Provincial Health Services Authority, five regional health authorities (RHAs), and the First Nations Health Authority to provide high-quality, appropriate and timely health services to British Columbians. Within each health authority, there is an elaborate structure of governing bodies and committees; each health authority generally has a

governing board of directors (reporting to the Minister of Health), a medical advisory committee, and various quality of care committees among others.[19]
The Ministry of Health in British Columbia publishes a range of information on healthcare, including patient experience surveys, infection control surveillance reports and surgical waiting times. The Ministry of Health also shares health information with the Canadian Institute for Health Information, allowing for information to be shared across provinces to help improve healthcare systems across the country. The main structures within the health sector and their respective functions can be located in Appendix 3.

While Canadian Institute for Health Information maintains the National System for Incident Reporting (NSIR), a voluntary reporting system that collects data on medication incidents, there are also reporting systems for adverse events at the provincial and territorial levels. The British Columbia Patient Safety and Learning System (BC PSLS) was set up in 2008 and was the first provincial system for reporting adverse events in Canada. This review will detail the establishment and operation of British Columbia PSLS and the context in which it operates, with the aim of understanding its role in providing patient safety intelligence to other major actors at the provincial and national levels.

Patient safety in British Columbia is supported by a number of actors including the quality and safety programme areas in the health authorities, the Patient Safety and Care Quality branch in the Ministry of Health and the British Columbia Patient Safety and Quality Council. The British Columbia Patient Safety and Quality Council provides system-wide leadership in the area of patient safety at the provincial level. The work of the Canadian Patient Safety Institute is often reflected in British Columbia's safety policies and practices.[20] The Council has a number of work programmes, one being its work in supporting the province-wide uptake of the Institute for Healthcare Improvement (IHI) Global Trigger Tool which enables hospitals to identify adverse events, assess levels of harm and track the effectiveness of their improvement efforts.[21]

Patient safety stakeholders in British Columbia can draw on Canadian resources such as:

- Canadian Patient Safety Dictionary (2003)[22]
- Canadian Disclosure Guidelines (2011)[23]
- Canadian Incident Analysis Framework (2012).[24]

3.2.1 Patient safety and just culture in British Columbia

Creating a 'just culture' is an area of focus for the Ministry of Health in British Columbia. The Ministry released a Policy Communique on whistleblowing and safe

reporting that provides a foundation for enhancing a just and trusting organisational culture where individuals feel safe and encouraged to report allegations of wrongdoing.[25] This commitment to patient safety and just culture is also evident at the national level. The Canadian Patient Safety Institute's Canadian Incident Analysis Framework[24] supports a just-culture approach to incident analysis and Accreditation Canada requires patient-safety-culture surveys to be conducted periodically for those seeking accreditation. These patient-safety-culture surveys include questions regarding how patient safety incidents are handled and whether providers face negative consequences for making an error.[20] Two pieces of legislation in British Columbia that support what is defined as a just and patient safety culture are:

- The Apology Act (2006)[26] which promotes an open and non-punitive patient safety culture, allowing healthcare providers to apologise to patients and families when disclosing an adverse event, without concern that the apology would be used in legal proceedings.[27]
- Section 51 of the Evidence Act (1996)[28] which provides the legislative confidentiality of incident analyses that is necessary to protect a just culture from the punitive influence of the legal system.[20] This ensures that the discussion and analysis of medical staff committees and specially constituted quality committees cannot be released in legal proceedings.

A recent report entitled, *Developing a just culture in British Columbia's health system: recommendations for policy and implementation* (2013), noted that at the individual authority level, each health authority in British Columbia has an incident management policy in place that includes a commitment to a just approach for patient safety incidents.[20] Canada's Provincial Health Services Authority stated that it is committed to ensuring that all personnel are aware of the expectation that patient safety issues, such as hazard, adverse event and near-miss reports, will be addressed within a non-punitive system. Two of the Provincial Health Services Authority's policies relevant to this are *Commitment to a culture of patient safety* and *Non-Punitive Reporting: Hazards and Patient Safety Events (including near misses)*, both of which apply to all of its provincial agencies.[29]

3.2.2 Adverse events in British Columbia

In British Columbia, legislation puts an onus on healthcare organisations to report serious adverse events to the Minister of Health. The Hospital Act (1996)[30] and associated regulations establish definitions for serious adverse events and severe harm and the duty to report adverse events. The legal framework requires that the administrator in a hospital and the licensee of a private hospital must report to the Minister each serious adverse event immediately after the adverse event occurs and in the form and manner specified by the Minister. In 2012, the Ministry of Health

distributed the 'Provincial protocol for future adverse events'[3] to the health authorities. This protocol was developed to establish a consistent provincial protocol for reviewing and responding to large-scale future adverse events, including communication to patients and the public.

While influenced by the provincial protocol, each health authority in British Columbia defines its own approach to managing adverse incidents and each of the health authorities has its own incident management policy and review processes in place. Incident management policies are devised and among other things serve to establish accountabilities for managing, reporting, investigating and following up incidents. They often set out a list of mandatory reportable events. Examples of policies seen at health authority level are:

- employee incident reporting and investigation
- incident management
- disclosure of adverse incidents
- safety alerts and broadcasting system
- claims management.

3.3 British Columbia Patient Safety and Learning System (BC PSLS)

3.3.1 Background

In order to collect information on and learn from patient safety incidents in the province, a system called the British Columbia Patient Safety and Learning System (BC PSLS) was established in 2008 under the Provincial Health Services Authority. At that time, BC PSLS was the first provincial system for reporting adverse events in Canada. On its establishment, BC PSLS was seen as a system that would engage users in identifying safety concerns and would facilitate timely reporting, resolution, feedback and study of events, including incidents, claims and client feedback, across all programmes and services within all health authorities and would include an electronic interface to the Health Care Protection Program, British Columbia's insurance programme.

Features of BC PSLS

- Reporting onto BC PSLS is voluntary
- Reporting can be done anonymously
- BC PSLS is available to providers in all of British Columbia's healthcare settings
- BC PSLS holds data on all patient safety events, including adverse events, near misses, safety hazards, patient complaints and claims.

While all healthcare professionals across the province can report an event onto the system, operational leaders and specialised staff such as risk managers have the ability to report, track and manage all events such as incidents, near misses, client

[3] Please refer to Appendix 6 for the text of the 'Provincial protocol for future adverse events'.

feedback and claims.[31] Since its establishment, BC PSLS has become an important component of the patient safety policy framework in British Columbia.

The BC PSLS is a web-based patient-safety-event reporting, learning and management tool used by care providers across all healthcare organisations in British Columbia to identify, analyse and trend safety concerns.[32] Provincial data is stored in a single database and the information is shared with healthcare leaders across the province.[31] The system is managed by BC PSLS Central Office.

The BC PSLS concept was born in 2002, and following pilots at two sites in 2007, the system was fully operational in all care settings by mid 2011. Much effort was put into creating a system with a patient safety and learning focus as opposed to an accountability and claims focus.[32] The BC PSLS application has evolved significantly since its launch. Initially the system was focused on acute care, but it now works across the care system – from hospitals to home-care and community services. An updated interface and new speciality reporting forms are examples of further enhancements.[33]

3.3.2 Purpose

The ultimate goal of BC PSLS is to make healthcare safer. The goal in maintaining its database is to provide accessible, meaningful, reliable, and actionable information to leaders across British Columbia for use in its risk reduction and quality improvement efforts. Using BC PSLS, healthcare leaders can identify and explore systemic or clinic-specific issues and use lessons learned to drive quality improvement initiatives.[34]

3.3.3 Patient safety culture and the BC PSLS

The establishment of BC PSLS was intended to support a non-punitive reporting environment and a culture of safety. In training users of the system, a lot of focus is given to creating a 'just culture' and the no-blame aspect of the system. The Helander Report noted the BC PSLS as one of the key policies and programmes in the province that supports a just culture.[20]

3.3.4 Governance and operating model

The Provincial Health Services Authortity hosts the BC PSLS application and is custodian of Central Office, but the system has an independent governance structure. The Central Office team, located in Vancouver and headed by an executive director, is responsible for the management of operation of BC PSLS, providing system support, guidance and expertise to users. Central Office works collaboratively with three provincial committees, which are the:

- BC PSLS Steering Committee, which comprises senior representatives from each health authority and is chaired by the Provincial Patient Safety and Quality Officer for British Columbia.[4]
- Patient Safety/Risk Management Leaders Committee (PSRMLC), comprising risk and or safety leaders from each health authority
- Collaborative Working Group (CWG). It comprises the BC PSLS coordinators assigned to each health authority.

The BC PSLS Steering Committee is responsible for the overall strategic vision and direction of the programme and Central Office. The BC PSLS Executive Director reports to the Provincial Patient Safety and Quality Officer who in turn reports to the British Columbia Minister of Health Services.(35) Funding support to BC PSLS comes from the participating health authorities. Central Office is staffed by 12 staff members across three teams – Operations, Communications and Stakeholder Relations; Technical and Help Desk Support; and Data Quality Assurance and Special Projects. All three teams collaborate to manage projects in partnership with the health authorities. Each health authority is assigned a BC PSLS Coordinator to provide support to local BC PSLS users.

3.3.5 Participation agreement

A participation agreement is in place between the health authorities and the BC PSLS. There is no legislative remit for governance of the participation agreement; this is done on a goodwill basis. Central Office reviews the participation agreement regularly and refers to it when necessary to assess whether the rules and spirit of the agreement are being adhered to. The purpose of the participation agreement is to:(36)

- enable each participating authority to participate in the PSLS programme
- enable a participating authority to use the patient safety database and the software
- establish the relationship between Central Office and each participating authority
- describe the roles and relationships of each participating authority, the Steering Committee, the Patient Safety/Risk Management Leaders Committee, Central Office and the Collaborative Working Group
- describe the comprehensive set of governance principles by which the participating authorities will manage and govern their relationship regarding the agreement, the PSLS programme and the use and operation of the database and the software
- allocate PSLS annual costs among the participating authorities.

[4] The Health Care Protection Program, British Columbia's insurance programme, was involved in the establishment of the BC PSLS.

3.3.6 BC PSLS application

The BC PSLS encompasses a collection of online modules and tools. The modules include Safety Events; Complaints; Claims; Safety Alerts; Risk Register; and Recommendations. The following sections will outline the purpose of these modules. BC PSLS uses Datix and other support software, for which it holds provincial software licenses. SAP Business Objects Edge suite of tools is used for advanced data analysis and aggregated reporting. Footprints software is used by the Central Office team and BC PSLS Coordinators to track and manage BC PSLS issues and developments.[35] BC PSLS uses a modified version of the World Health Organization's Conceptual Framework for the International Classification for Patient Safety (ICPS) with expansion to reference other taxonomies and tools, such as the Agency for Healthcare Research and Quality (AHRQ) Common Formats.

3.3.7 Reporting into BC PSLS

All data submitted into BC PSLS is managed and secured in a central database by the Central Office, working in partnership with PHSA Information Management/Information Technology Services and Health Shared Services BC (a division of Canada's Provincial Health Services Authority). Health authorities 'own' and control their own data while Central Office is custodian of the data, using it for analysis, trending and reporting.[21]

Initially, only healthcare professionals could report onto the system. BC PSLS has since expanded the variety of people who can report through Patient's View. This is a version of BC PSLS that captures patient and family perspectives on safety, and a pilot at BC Children's Hospital in 2012 showed signs of success.[37]This initiative is seen as very powerful because it provides up-to-date information as patients are surveyed within 24 to 48 hours of discharge.

Reporting onto BC PSLS is voluntary and reporters have the option to report anonymously. Personal identifiable patient information is not included in data used for aggregated analysis or reports. As of 2012, approximately 100,000 healthcare professionals could report safety concerns and hazards with this tool with approximately 10,000 of these users being able to submit and withdraw data (based on their user permissions) and holding responsibility for responding to and following up on safety reports.[34]

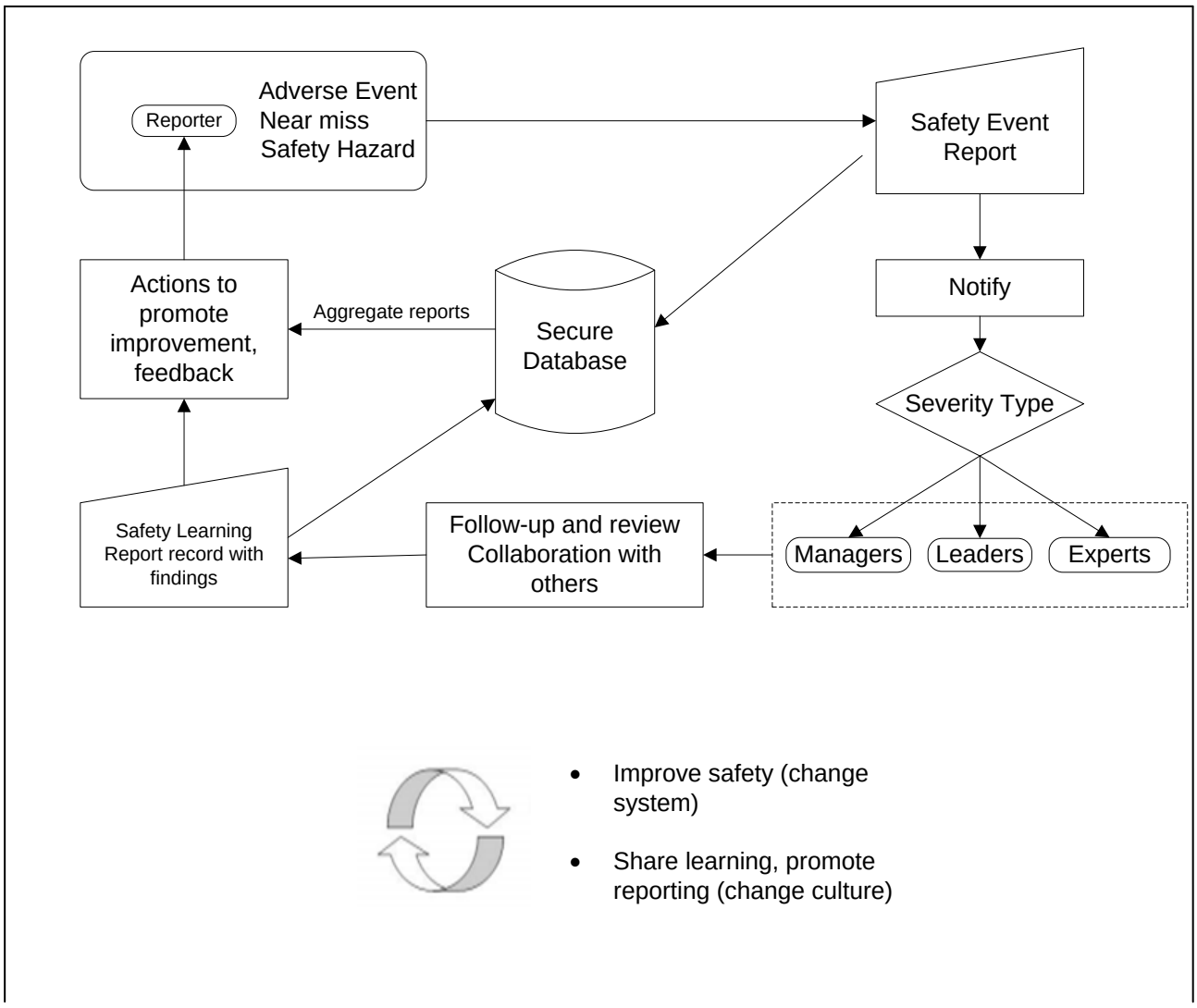
3.4 BC PSLS Modules

3.4.1 Safety Events Module

The primary module in BC PSLS is Safety Events, which accepts reports on near misses, safety hazards and critical incidents. Using this module and its various category-specific provincial forms allows healthcare providers to identify, follow up

on and learn from these patient safety events. Approximately 60% of events reported to BC PSLS are 'No harm' and approximately 80% of reports are made by nursing staff. When a safety event is reported, leaders are automatically notified and reporters receive an email notification unless reporting was carried out anonymously. In the case of a medication error, pharmacy may also receive an automatic notification or with a medical equipment failure, biomedical engineering may receive an automatic notification. From the Safety Events module, authorised users can create summary reports to support learning and improvement. Figure 1 outlines the workflow for the Safety Events module of BC PSLS.

Figure 1: BC PSLS Modules and Safety Events Workflow*[35]



*Note: This illustration was obtained from BC PSLS Shaping our future 2014-2018 Strategic Plan Document.[35]

A recent challenge experienced by BC PSLS Central Office was securing final approval status on all incident reports in the system. Central Office identified a 'black hole' where thousands of reports had not been reviewed and had not received final approval status. Without final approval status, these reports were not being included in health authority analyses, creating a lost opportunity to present the data alongside other aggregate data.[31] By using visual analytic tools to capture the extent of the problem, Central Office was able to demonstrate that organisations with visible leadership commitment to patient safety were more successful in addressing this issue. The BC PSLS coordinators in the health authorities were key to helping safety event managers learn to be efficient in the timely processing of event reports. Ongoing visual analytics provide an effective means to identify areas where delays in follow-up are occurring so support can quickly be offered. Table 3 details the other modules in BC PSLS.

Table 3. Further modules of BC PSLS

Complaints module	This module was set up to meet the specific requirements of provincial legislation. The Complaints module allows staff in the Patient Care Quality Offices (PCQOs) to easily and consistently respond to, track, and report on their complaints-handling work. Complaints data can be aggregated and analysed to identify trends in care quality concerns.
Claims module	This module supports health authority risk managers with handling risk and liability issues and communicating with the Health Care Protection Program (HCPP). This module facilitates timely response, workflow and tracking of actual and potential risks and legal claims. PSLS claims reports are among the evidence that may be provided to the HCPP.
Risk register module	This module supports the identification, assessment and management of high-level risks and issues so they can be analysed, addressed and monitored. This module is used primarily by the risk managers in the health authorities, therefore it is used differently in each authority.
Safety alerts module	This module allows users to distribute communications about alerts or recalls for products, drugs, and devices and other practice-advisory information. It enables response-tracking when action is required and collates information from other BC PSLS modules to create a comprehensive alerting and response system.[31] Data in the Safety Events and Safety Alerts modules can be linked and BC PSLS can also link to data from Health Canada and other alerts systems.
Recommendations module	This module supports the development, assignment and management of recommendations arising from critical incident and other types of reviews. This tool enables documentation, monitoring and analysis of recommendations from various sources (such as patient safety reviews, PCQO Reviews, coroners' reports, Accreditation Canada) and status of implementation.
Hot Spots module	The Hot Spots module is under development for use in BC PSLS. It will be used to pinpoint particular areas of concern in each authority. It will do this by identifying areas where there is an increased level of incidents so an organisation can identify a potential issue. The module can be configured to the particular parameters that an organisation wants to watch out for.

3.5 BC PSLS reporting outputs

Central Office uses the data collected into BC PSLS to produce different reports for a range of stakeholders. Central Office reports are used by front-line leaders, medical advisory councils and committees, executive leaders and boards and committees. Previously, system users could go onto the system and run reports, but this was only being done by a small number of people. Now a business intelligence tool pulls information together from the different system modules to deliver reports through BC PSLS Publications, a tool which is outlined in the table below. BC PSLS Central Office has worked with speciality groups from around the province to ensure that the new reports meet the needs of unique groups.[31] Table 4 sets out the key tools that Central Office uses for reporting.

Table 4. BC PSLS reporting tools

Tools	
BC PSLS Publications	This tool was launched in 2013 and provides all stakeholders with one consistent method of data review where all users can start with the same standard report on a topic such as falls and then dig deeper.[31] Over 1,000 subscribers receive reports automatically each month.
My Reports	This tool is a component of all modules. Leaders can access a selection of report templates so they can easily and quickly analyse and take corrective action on safety issues. Ad hoc searching and report building is also possible.
BC PSLS Analytics	This business intelligence initiative aims to provide senior leaders, health authority BC PSLS Coordinators and other designated users quick access to interactive reports about their health authority's BC PSLS data.

BC PSLS Central Office also publishes annual reports and hosts an online blog (www.bcpslscentral.ca), both of which are available to the public. The BC PSLS blog has been a powerful tool in sharing information on how people are using data and the system to improve patient safety, also serving to connect people across health authorities and gives recognition to good work done.

3.6 Regulatory structures in British Columbia

3.6.1 Regulation in the British Columbia health sector

The highest level of regulation in the British Columbia health sector is provided for in the Health Professions Act (1996) which serves as umbrella legislation that provides a common regulatory framework for health professions in British Columbia.[38]

Professional regulatory colleges[5], of which there are 23, self-regulate the majority of healthcare professionals, working to ensure that licensed professionals are qualified to follow standards, respond to complaints, and take action in the case of unsafe or unethical practice.(39) The colleges are only responsible for its own members and do not have the legislative ability or jurisdiction to work together to identify systemic issues and collaborate on system-wide improvements.(27) The regulatory colleges hold significant influence over the quality of services provided in British Columbia.(40)

3.6.2 Accreditation in the British Columbia health sector

Patient safety is a focus of Accreditation Canada, Canada's major accrediting body. Accreditation Canada is a voluntary, non-governmental organisation that accredits hospitals, health facilities and regional health authorities across the country. Accreditation is compulsory in some Canadian provinces, but this is not the case in British Columbia. Accreditation can be secured by individual facilities and the RHAs, for example, the Provincial Health Services Authority and its agencies are accredited by Accreditation Canada. Examples of Required Operational Practices (ROPs) that organisations are expected to comply with in securing accreditation include establishing a system for adverse events, sentinel events, including appropriate follow up and the production of quarterly client safety reports for the governing body.(41) Accreditation Canada has been very successful in building the profile of patient safety measurement at a national level(27) and is itself accredited by the International Society for Quality in Health Care (ISQua).

3.7 Management of complaints and claims

3.7.1 Complaints

The Patient Care Quality Review Board Act (2008)(42) establishes a clear, consistent, timely and transparent approach to managing care quality complaints in British Columbia, establishing both patient care quality offices (PCQOs) and patient care quality review boards for each of the health authorities. Prior to 2008, each health authority in British Columbia had its own client relations function, each differing in its approach. Patient complaints were not being tracked or reported on a provincial basis and there was no provincially coordinated means for identifying opportunities for quality improvement and sharing lessons learned.(43)

While there are multiple complaint management processes in existence (complaints are also received by the Ministry of Health Client Relations Program for example), the PCQOs[6] work to provide a single point of entry for complaints in the system. The PCQOs sit in the health authorities, receiving and processing care quality complaints

[5] Refer to Appendix 4 for a list of the professional regulatory colleges in British Columbia.
[6] PCQOs do not replace the complaint investigation authority of professional bodies.

while Patient Care Quality Review Boards are independent of the health authorities and receive complaints that are unresolved following processing by the PCQOs. Upon completion of a review, the Review Boards may make recommendations to the Minister of Health and the health authorities for improving the quality of patient care in British Columbia.[25] The Review Boards may also make recommendations on complaints data trends to the Minister of Health.

3.7.2 Medical negligence claims

The Health Care Protection Program is British Columbia's insurance programme and its core services include claims and litigation management and risk management advisory and education services, which are provided to public healthcare agencies across British Columbia. The Health Care Protection Program is delivered by the Ministry of Finance in conjunction with the Ministry of Health. In British Columbia, a healthcare agency, upon learning of an incident, act, occurrence, accident or demand which may lead to a claim, must promptly give notice to the Health Care Protection Program.

3.8 Coordination of patient safety data and intelligence

3.8.1 Sharing data

A key message from a foundational report on BC PSLS was that in order to grow and sustain the intervention in the long term, it would be important to constantly seek opportunities to leverage and build on other projects and initiatives and create partnerships.[44] Collaborative relationships exist between BC PSLS and various provincial and national groups and agencies including Health Canada, Canadian Patient Safety Institute and Canadian Institute for Health Information.[33] BC PSLS Central Office has outlined its intention to continue the partnerships it has established with specialised groups and other patient safety organisations in 2015, meaning it will be offering more speciality report forms and exploring new opportunities to expand the use and availability of PSLS data.[45]

There is no direct sharing of patient safety intelligence from BC PSLS to the professional regulatory colleges. Individual facilities determine the appropriate level of data sharing with external bodies, such as the regulatory colleges, where appropriate. A mandatory reporting requirement of hospital disciplinary measures is imposed by legislation in British Columbia,[46] where a member's privileges are restricted, cancelled or suspended as a result of any review. In such cases, the hospital must report this information to the relevant regulatory college. This reporting does not involve BC PSLS. In terms of litigation, information collected for quality review purposes (including much of what is reported in BC PSLS) is protected by legislation from use in legal or regulatory proceedings, providing the legislative requirements for protection from disclosure are met by the health authorities.

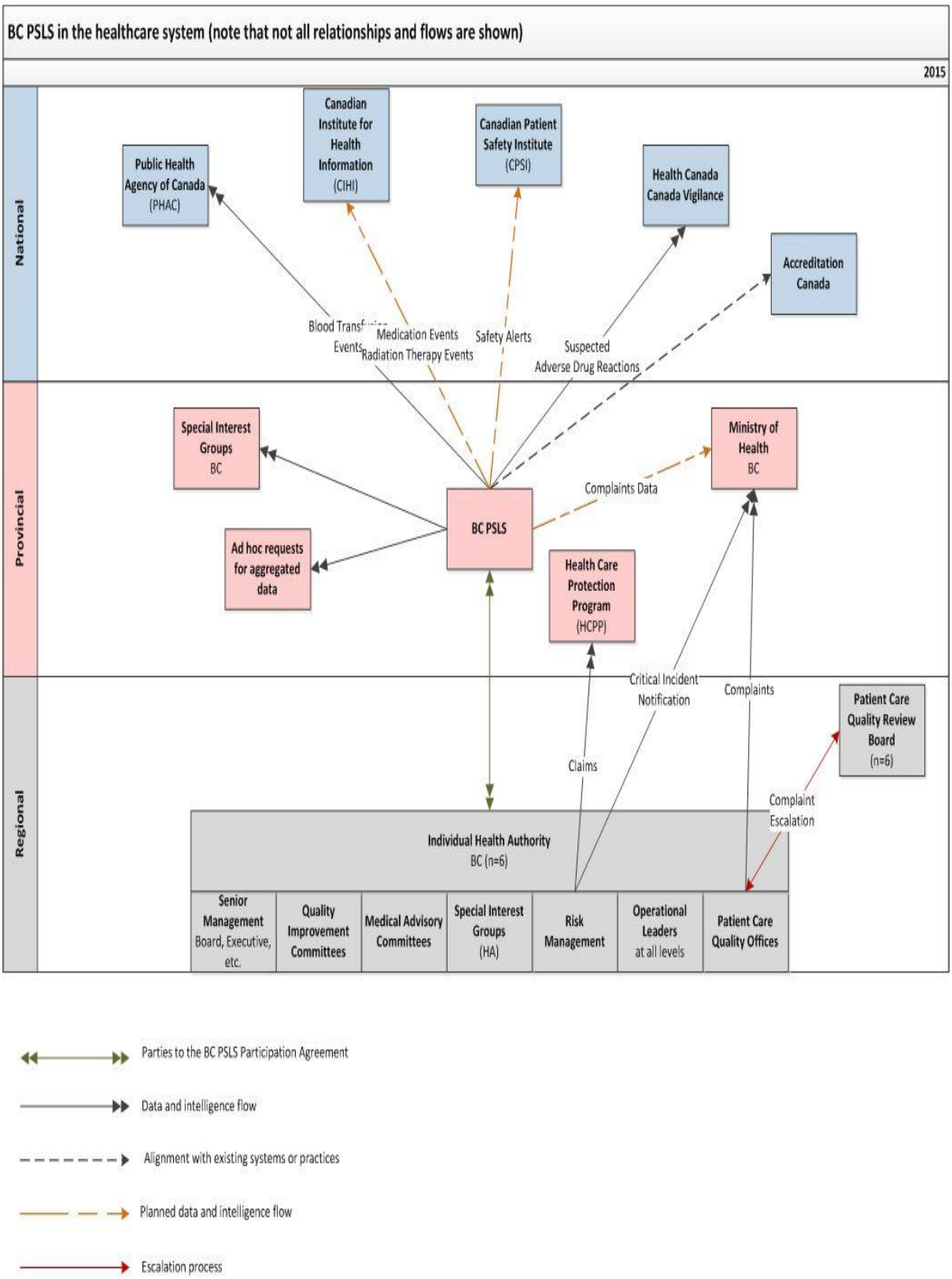
Information arising from the reporting and managing of complaints is generally not protected. Patient safety events that are reported in BC PSLS, and identified as potential claims, may be reported separately to the Health Care Protection Program by health authority risk managers as part of the claims handling process.

3.8.2 Key relationships of BC PSLS

Aside from supporting the work of the health authorities, BC PSLS engages with a number of other groups and agencies. For example, it engages with a large number of provincial 'special interest' groups (in the areas of falls, radiology, oncology and pressure ulcers for example). It brings learning to these groups through aggregate reports. Currently BC PSLS provides data to the Public Health Agency of Canada Transfusion Event Surveillance System (TESS) as part of an initiative led by the Vancouver Island Health Authority, and to Health Canada's Canada Vigilance Program for adverse drug reaction reporting through a pilot project at the Fraser Health Authority. With the support of WHO, the Canadian Patient Safety Institute manages Global Patient Safety Alerts, collecting, reviewing and indexing information from contributing organisations around the world. BC PSLS Central Office is positioning its Safety Alerts Module to allow British Columbia to contribute to Global Patient Safety Alerts.

Figure 2 presents BC PSLS and other stakeholders in patient safety in British Columbia and Canada, and outlines some of the different flows of data between these stakeholders in patient safety.

Figure 2: Flows of data between BC PSLS and other patient-safety stakeholders in the Canadian healthcare system*



*Note. While this chart shows some relationships and or flows, not all relationship flows are shown.

The Canadian Institute for Healthcare Information operates the National System for Incident Reporting, which collects medication incident data from some Canadian healthcare facilities. BC PSLS is working with the Canadian Institute for Health Information to pilot the electronic transfer of medication data from BC PSLS to the medication module of the National System for Incident Reporting. While the Canadian Institute for Health Information uses the National System for Incident Reporting (NSIR) to produce analytic reports to support enhancements to the medication use system, it also provides NSIR data for use to the Canadian Medication Incident Reporting and Prevention System, a collaborative pan-Canadian programme. Plans to expand the National System for Incident Reporting to capture data about radiation therapy events are underway and BC PSLS plans to collaborate with the Canadian Institute for Health Information on this initiative also.

Tools are employed to oversee the sharing of patient safety data and intelligence. The participation agreement covers data flows between health authorities and BC PSLS as well as data flows to some provincial actors such as the 'special interest' groups. A formal agreement is put in place for sharing data with external actors. For example, Central Office has an agreement with the Canadian Institute for Health Information that provides arrangements for data submission from BC PSLS to the Canadian Institute for Health Information's National System for Incident Reporting. Other organisations or individuals can request access to BC PSLS's data for purposes such as health system surveillance, patient safety and or healthcare planning. All requests for BC PSLS data are subject to approval by the BC PSLS Steering Committee prior to release. The BC PSLS Data Access Request Form stipulates that only aggregate data is available for release through BC PSLS Central Office.[31]

3.8.3 Alignment with other agencies

BC PSLS Central Office has attempted to align the BC PSLS system with other patient safety organisations to reduce duplication, as documented in its current strategic plan.[35] For example, Central Office has worked with the Provincial Infection Control Network (PICNet) which works to reduce Healthcare Associated Infections in order to define the necessary data elements to capture infection events in PSLS. Other examples of Central Office's efforts to align the BC PSLS system with other bodies is evident in its development of reports to support the evolving Required Organisational Practice of Accreditation Canada and its aligning of data elements to those collected by the Transfusion Event Surveillance System (TESS) under the Public Health Agency of Canada.[31]

British Columbia – summary and key learnings

- Within Canada, while there is a National System for Incident Reporting (NSIR, a voluntary reporting system that collects data on medication incidents), British Columbia was the first province to develop its own system for reporting adverse events.
- In British Columbia, legislation puts an onus on all healthcare organisations, including private hospitals, to report serious adverse events to the Minister for Health in accordance with the Hospital Act (1996).[30]
- The BC PSLS is a web-based patient safety event reporting, learning and management tool used by care providers across healthcare organisations in British Columbia to identify, analyse and trend safety concerns. It holds data on all patient safety events (for example, adverse events, near misses, safety hazards, complaints and claims).
- The BC PSLS encompasses a collection of online modules and tools. The modules include safety events; complaints; claims; safety alerts; risk register; and recommendations.
- The focus of BC PSLS is learning and improvement. It is designed as a safety improvement and learning tool rather than strictly an accountability tool.[20]
- Two pieces of legislation that support a 'patient safety' and 'just culture' are The Apology Act (2006)[26] which promotes an open and non-punitive patient safety culture, allowing healthcare providers to apologise to patients and families when disclosing an adverse event, and Section 51 of the Evidence Act (1996)[28] which provides the legislative confidentiality of incident analyses that is necessary to protect a just culture from the punitive influence of the legal system.
- The Patient Care Quality Review Board Act (2008)[42] establishes a clear, consistent, timely and transparent approach to managing care quality complaints in British Columbia, establishing both patient care quality offices (PCQOs) and patient care quality review boards for each of the health authorities.
- A participation agreement is in place between British Columbia PSLS and the health authorities which covers data flows between these authorities and BC PSLS. A formal agreement is put in place for sharing data with external agencies (such as the Canadian Institute for Health Information).
- BC PSLS uses a modified version of the WHO Conceptual Framework for the International Classification for Patient Safety (ICPS).

4. Denmark

4.1 Background

Denmark has a population of 5.6 million people. The Danish healthcare sector has three political and administrative levels: the state, five regions and 98 municipalities. The Ministry of Health and Prevention is in charge of the administrative functions in relation to the organisation and financing of the healthcare system, psychiatry and health insurance as well as the approval of pharmaceuticals and the pharmacy sector. The majority of healthcare is financed through taxation (85%) and the healthcare service is organised in such a way that responsibility for providing services sits at the lowest possible administrative level.(47)

In Denmark, the five regions[7] are responsible for general hospital services, psychiatric hospital services, health insurance, general practitioners (GPs) and specialists. Across the five regions, 98 municipalities have responsibility for preventative treatment, homecare, nursing homes, non-hospital rehabilitation, treatment of drug and alcohol abuse, local dental services, specialist dental care and social psychiatry.(48) The Danish government reaches agreement with the regions on high-level service goals, such as mortality or adverse event rates.(49)

Within the Ministry of Health and Prevention lies the National Agency for Patients' Rights and Complaints, the Danish Health and Medicines Authority, and the Statens Serum Institute. The Danish Health and Medicines Authority is the regulator of the system, and as such it is responsible for surveillance, counselling and supervision.(50) The Statens Serum Institute is responsible for research-based health surveillance, oversight of information technology in the Danish healthcare system, and prevention and control of infectious diseases, biological threats and congenital disorders.(51) The National Agency for Patients' Rights and Complaints is the independent state institution responsible for handling patients' complaints and for contributing to the prevention of mistakes being repeated within the health services. It focuses on patients' rights, compensation, adverse events and learning.(7) Under this remit, the National Agency for Patients' Rights and Complaints operates and supports the Danish Patient Safety Database, the national system for reporting adverse events that have occurred within the system. The National Agency for Patients' Rights and Complaints and the Danish Patient Safety Database are the focus of this review.

[7] The North Denmark Region; Central Denmark Region; Region of Southern Denmark; Region Zealand; and the Capital Region of Denmark.

4.2 Patient safety in Denmark

The Danish Adverse Events Study, published in 2001, put the spotlight on the area of patient safety. It reported that 9% of discharged patients had experienced an adverse event.[52] At this time, incident reporting systems in Denmark were reported as primarily focused on litigation.[53] The Danish Adverse Events Study contributed to the momentum for the establishment of the Danish Society for Patient Safety. Set up in 2001, the Danish Society for Patient Safety works to develop and build a quality improvement and patient safety focused culture and build long-term sustainability and capability to support improvements.

The Act on Patient Safety in the Danish Health Care System (2003)[2] followed soon after. The Act on Patient Safety has been described as beneficial in helping to formalise the work on patient safety, imposing patient safety obligations on healthcare professionals and communicating that adverse events can be reported without fear of sanctions. The Act provided a definition for an adverse event and describes the circumstances in which an adverse event may take place.[54]

The Act on Patient Safety in the Danish Health Care System provides that:

- front-line personnel in hospitals and in the primary care sector are statutorily obligated to report adverse events to a national reporting system
- hospital owners are statutorily obligated to act on the reports
- patients and relatives may report adverse events
- the National Agency for Patients' Rights and Complaints is statutorily obligated to communicate learning nationally.

Following the Act on Patient Safety coming into force in January 2004, the Danish Patient Safety Database was established later that year under the National Board of Health[8] as a mandatory national reporting system for adverse events. In 2011, the Danish Patient Safety Database was transferred to the newly established National Agency for Patients' Rights and Complaints, where it continues to reside.

In recent work on reporting and learning systems by the Patient Safety and Quality of Care Working Group of the European Commission, it was documented that Denmark has been motivated to implement a reporting and learning system due to[7]:

- benchmarking on patient safety
- political pressures coming from public and professional circles
- accreditation programmes.

[8] The National Board of Health and the Danish Health and Medicines Authority (DHMA) merged in 2012.

4.3 Danish Society for Patient Safety

The Danish Society for Patient Safety was formed in 2001. The Society has had a major impact in the area of patient safety culture, through its work in motivating staff and educating risk managers.[55] The Society played a role in the development and design of the Danish Patient Safety Database and today describes the purpose of the reporting system as 'to learn, not to punish'.[56] The Danish Society for Patient Safety has described its main focus as:[57]

- gathering, spreading and developing knowledge and initiatives
- providing advice to legislators and stakeholders
- arranging study tours and conferences
- suggesting standards for safe operation
- carrying out campaigns and lobbyism
- creating consensus
- initiating projects and or initiatives.

The Society has published a range of tools, both for patients and for those involved in adverse event management. A recent initiative by the Society was the Danish Hospitals Programme (2010-2013), a pioneering programme that encouraged hospitals to reach a number of goals including learning from data. The board members of the Danish Society for Patient Safety comprise different stakeholders in Danish healthcare – the healthcare providers, patient and research organisations, the Danish Regions, the pharmaceutical and medical device industry, the Danish Consumer Council and Local Danish government.[57]

4.4 Regulation in the Danish health sector

As the supreme health and pharmaceutical authority in Denmark, the Danish Health and Medicines Authority serves as the regulator of the system and administers a range of functions including:[58]

- licensing and monitoring medicines
- issuing and withdrawing authorisations for 18 different professions
- offering advice and providing information to citizens, healthcare professionals and authorities
- planning and approving care pathways, healthcare agreements and so on.

As the regulator of the system, the Danish Health and Medicines Authority has a legal remit to access all health and social care data and links with a number of external agencies to work with their data.[50] It uses the data to focus its inspections based on risk areas, risk personnel and risk organisations. The Danish Health and Medicines Authority maintains an adverse drug reaction reporting system, to which

doctors have a duty to report certain adverse drug reactions (ADRs) and consumers also have the opportunity to do so.[59]

The agencies that the Danish Health and Medicines Authority requests data from include:[50]

- National Agency for Patients Rights and Complaints
- Patient Compensation Association
- health professionals
- dentist complaints system
- national patient diagnosis and treatment register
- scientific societies
- accreditation programme (IKAS)
- the press.

4.5 Accreditation in the Danish health sector

The Danish Institute for Quality and Accreditation in Healthcare (IKAS[9]) develops, plans and manages the Danish Healthcare Quality Programme. The Danish Healthcare Quality Programme is a mandatory accreditation programme that covers all public hospitals, a number of privately owned hospitals, the pre-hospital sector and the majority of all Danish pharmacies. In principle, accreditation is mandatory. The Danish Healthcare Quality Programme is under development and is expected to incorporate GPs and specialist doctors in the future.[48] The governing board of IKAS includes representatives from the Danish Healthcare Quality Programme, the Danish regions and the Ministry of Health and Prevention. IKAS is accredited by the International Society for Quality in Healthcare (ISQua).

The reporting of adverse events is supported by the accreditation systems for hospitals in Denmark. All hospitals are obliged to:[55]

- have guidelines in place for reporting adverse events
- demonstrate that health professionals are familiar with the guidelines and are using them
- show that they have monitored adverse events, demonstrate action plans and demonstrate that action has been taken on these plans.

4.6 Danish National Agency for Patients' Rights and Complaints

The Danish National Agency for Patients' Rights and Complaints is the independent state institution under the Ministry of Health and Prevention that focuses on patients and their legal security. The agency was established under law in 2010. The National

[9] Institut for Kvalitet og Akkreditering i Sundhedsvæsenet.

Agency for Patients' Rights and Complaints works to contribute learning to the health system from adverse events, patient complaints and compensation cases. The strategic objectives of the National Agency for Patients' Rights and Complaints include:

- increasing risk awareness among health system operators
- building a knowledge database and ensuring the sharing of knowledge
- coordinating efforts with other authorities to support the implementation of practice that improves patient safety by entering into partnerships and through researcher services.

The National Agency for Patients' Rights and Complaints has three data sources: the adverse event reporting system (Danish Patient Safety Database), the compensation system and the complaints system. The agency is the single point of access for patients' complaints. The complaints received by the National Agency for Patients' Rights and Complaints relate to a number of areas including treatment, patient rights, and decisions made on medical negligence claims by the Patient Compensation Association. If the complaint is directed at a particular treatment site, the National Agency for Patients' Rights and Complaints will manage the complaint; if the complaint is directed at one or more healthcare professionals, then the complaint is decided by the Health Service Disciplinary Board.

4.7 Danish Patient Safety Database

4.7.1 Background

The Danish Patient Safety Database is intended to support patient safety by collecting, analysing and sharing knowledge on adverse events, thereby creating systematic learning.

In 2013, the National Agency for Patients' Rights and Complaints received over 182,000 adverse event reports onto the Danish Patient Safety Database; approximately 1.5% of these incidents were reported by patients and relatives.[55] The Danish Patient Safety Database, as well as the other two data sources on complaints and compensation cases of the National Agency for Patients' Rights and Complaints, contribute to only part of the overall risk picture. The health system therefore supplements knowledge of patient safety problems from the Danish Patient Safety Database with other tools and methods such as patient safety walk-arounds, audits using the IHI Global Trigger Tool method, procedural analyses and from negative and positive feedback received.[55]

4.7.2 Governance and operations

The government-funded Danish Patient Safety Database is administered by the National Agency for Patients' Rights and Complaints, which is located in Fredericksberg, Copenhagen. Within the National Agency for Patients' Rights and Complaints, the Learning Unit manages the patient safety database. The technical operation of the database is provided by a department of the Statens Serum Institut. The Learning Unit also handles enquiries about the Danish Patient Safety Database and adverse events from the press, parliament, health professionals and citizens. Regions and municipalities provide professional staff to manage adverse events and analyses and to fund the time spent on analysis and learning.[7] Access to data in the Danish Patient Safety Database is role-based. In the Learning Unit of the National Agency for Patients' Rights and Complaints, four staff manage the technical operations and adverse event reports. The agency has 250 associated health professionals that provide expert knowledge. There is a shared responsibility in the Danish Patient Safety Database – the government owns the reporting system but the data is the property of regions and municipalities until such time as the analysis is complete and the data is electronically transferred to the central level.

4.7.3 Patient safety culture

In Denmark, effort has been put into changing the patient safety culture, including the 'just culture'. The Danish Patient Safety Database is designed as a bottom-up process where the majority of work is rooted locally, meaning that adverse events that occur locally should be analysed and corrected at that level. This is thought to have a considerable impact on the development of a safety culture. Furthermore, having a learning focus rather than a blame or accountability focus is thought to reduce the repetition of mistakes and to positively motivate reporting.[55] The legislation in place enables a 'just culture'; under the Danish Health Care Act (2010), a healthcare professional cannot be subjected to disciplinary action as a result of reporting an adverse event.

> '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 [now the Danish Health and Medicines Authority] or penal sanctions by the courts...' [14]

While reporters can submit reports anonymously onto the patient safety database,

Features of the Danish Patient Safety Database

- mandatory reporting
- sanction free
- covers the health and social care sector
- patients and relatives can report
- anonymous reporting of adverse events is possible.

they are encouraged to identify themselves. Identifying themselves when reporting is seen as an expression of confidence in local management and colleagues and evidence of a developing positive patient safety culture. The National Agency for Patients' Rights and Complaints views the proportion of anonymous reporting at different levels as an indication of how, or if, the patient safety culture has changed over time.[60] The agency is working to develop a tool that will measure the proportion of anonymous reporting.

4.7.4 Data collection on adverse events

The National Agency for Patients' Rights and Complaints makes specifications for the regional and municipal councils on what adverse events are to be reported to the Danish Patient Safety Database, when these reports are to be submitted and in what format. The agency may also require the regional and or municipal councils to submit further information on reported events such as action plans for use by the agency or the Danish Health and Medicines Authority in the course of its work.[55]
The entire reporting process, from initial submission of an adverse event report to submission of the finalised report to the National Agency for Patients' Rights and Complaints happens in the Danish Patient Safety Database. Since 2010, reporting an adverse event can only be completed electronically.
While staff are supported locally to report adverse events, a survey on users' experiences of the Danish Patient Safety Database indicated a significant need for online guides, manuals and e-learning.[55]

4.7.5 Taxonomy

Denmark previously used a national customised version of the WHO's International Classification for Patient Safety (ICPS). In 2014, Denmark began to use a new customised Danish classification system that is similar to International Classification for Patient Safety, but with definitions that are more appropriate to the Danish context.[61]
In 2014, the reporting form for healthcare professionals was expanded. Classification of an incident in the Danish Patient Safety Database is now carried out by the individual healthcare professional reporting, not by the local case handler as was done previously.

For the categorisation of harm, a new classification for severity was introduced in 2010. There are five categories in this classification and there are different definitions for each category, depending on which sector the patient has originated from. The five categories are:

- no harm
- mild harm
- moderate harm
- serious harm

- death.

4.7.6 Reporting by patients, relatives and healthcare professionals

Since 2011, patients and patients' relatives may report an adverse event onto the Danish Patient Safety Database. Reports are made to the region or municipality, depending on where the adverse event occurred.

For healthcare professionals, reporting is mandatory and is provided for in legislation. Therefore, when a healthcare provider is involved in, or observes an adverse event or near miss, that provider is statutorily obligated to report it.(56) Adverse events that occur in the municipal healthcare sector are required to be reported to the municipality. This similarly applies to paramedics, pharmacists and pharmacy staff. Healthcare professionals face further reporting requirements regarding adverse events, for example, certain infectious diseases must also be reported to Statens Serum Institute and certain incidents involving medical devices and adverse drug reactions must be reported to the Danish Health and Medicines Authority.

It is the experience of the National Agency for Patient's Rights and Complaints that the number of reported adverse events depends more on whether the health professional has experience with follow-up or feedback on the reported adverse event.(55)

4.7.7 Coverage

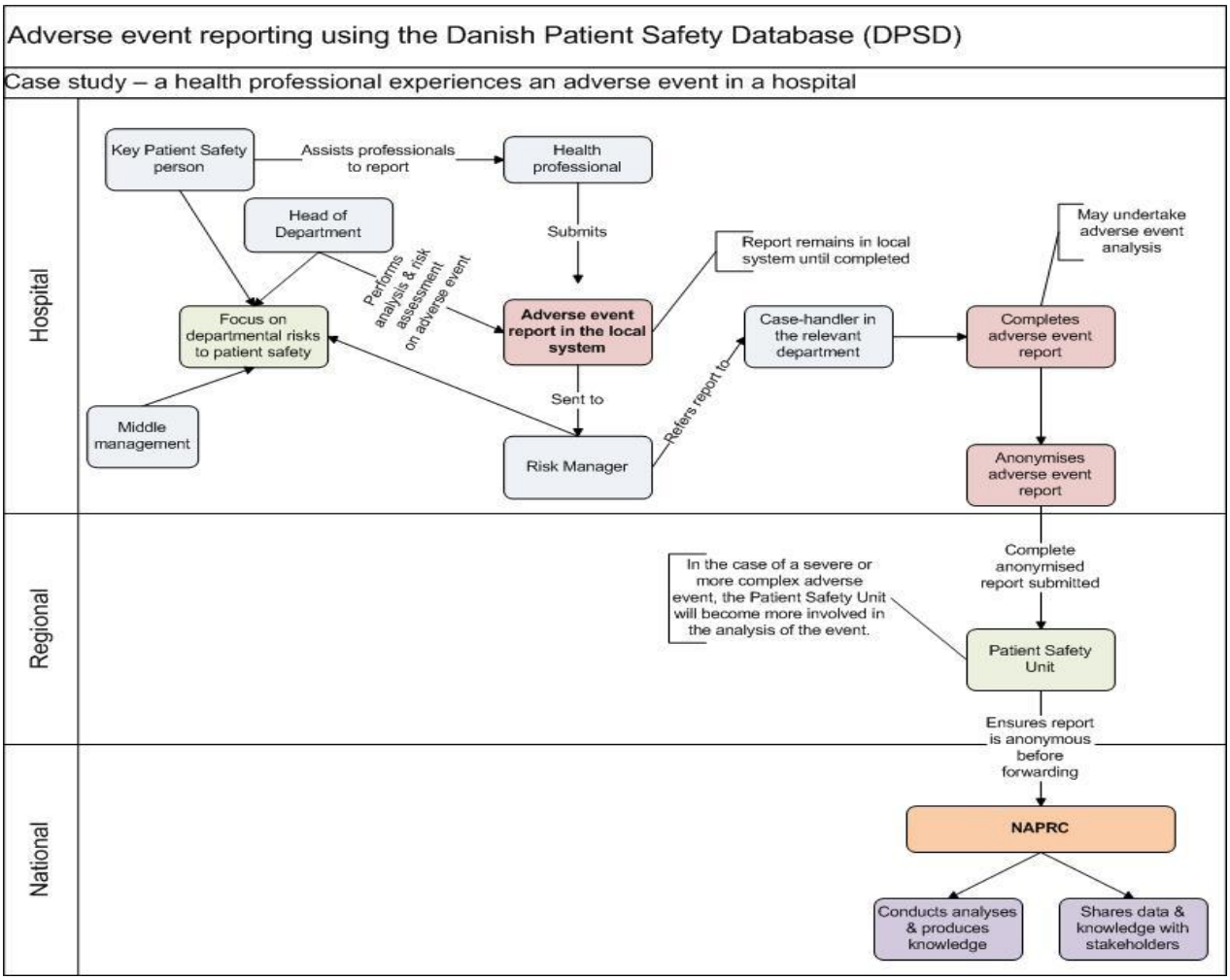
Representatives from the entire healthcare system are involved in collecting and analysing data on adverse events. Initially only hospitals could report onto the Danish Patient Safety Database, but legislation facilitated the expansion of the system. In Denmark, the following areas can currently report incidents onto the patient safety database:

- public hospitals
- private hospitals and healthcare providers
- pre-hospital
- primary care
- private care agencies
- family doctors, general practitioners
- pharmacies(7)
- nursing homes
- home healthcare.[10]

[10] The obligation to report sits with the healthcare professional, rather than the organisation.

Figure 3 displays the different actors involved in reporting and handling an adverse event that has occurred in a hospital and the process that occurs when a report is made.

Figure 3. The process of reporting an adverse event in a hospital setting in Denmark*



*Note. Not all stakeholders and processes involved in adverse event reporting are shown.

4.7.8 Analyses and learning at the local level

The focus of analyses on adverse event reports is the systems perspective and the ability to prevent similar adverse events from reoccurring. The head of the department where the adverse event(s) has occurred usually performs analyses and risk assessments locally. This is often done in cooperation with the department's patient safety officer and the risk manager, as well as front-line professionals and representatives from middle management. Locally, the system automatically generates reports and these can be customised to the specific needs of an individual caseworker.[55] Ideas for improvement are developed, tested and evaluated at this level.

The National Agency for Patient's Rights and Complaints cooperates with the Danish Regions and local government both on the reporting of adverse events and the sharing of learning. It remains the responsibility of the regional and municipal authorities to ensure that the knowledge that the agency communicates is converted into efforts that improve the quality and safety of patient care. Under legislation, hospital owners are required to act on adverse event reports. Action is taken on adverse events under the guidance of local leaders; ideas for change are developed, tested and evaluated by healthcare professionals.[55] Individual healthcare providers may publish statistical information and other material.

4.7.9 Analyses and reporting in the DPSD

Staff of the National Agency for Patient's Rights and Complaints are primarily tasked with analysing the more serious adverse events reported onto the Danish Patient Safety Database, performing cluster and trend analysis and sending out alerts where necessary. Different analysis techniques are employed depending on the adverse events involved. The National Agency for Patient's Rights and Complaints cooperates with external stakeholders from patient organisations and others, to analyse adverse events associated with specific areas.[55]

From the analysis of events reported onto the Danish Patient Safety Database, the National Agency for Patient's Rights and Complaints produces a number of outputs, as detailed on its website (www.dpsd.dk). The patient safety database automatically generates reports, which can be customised to the specific needs of an individual caseworker. The database publishes an annual report which contains two significant appendices, 'Learning activities of the National Agency for Patient's Rights and Complaints' and 'Contributions from Health Care'. To date, the sharing of knowledge from the Danish Patient Safety Database has taken place through a range of reporting including:

- newsletters
- articles
- patient safety alerts including medicines
- quarterly and annual reports
- thematic reports
- patient stories.

Patient safety alerts are shared with the regions and municipalities by email; the alerts are also published on the websites of the Danish Patient Safety Database and National Agency for Patient's Rights and Complaints. In addition, alerts are sent to approximately 5,500 healthcare professionals who voluntarily subscribe to the Danish Patient Safety Database's mail service.

The National Agency for Patient's Rights and Complaints also publishes learning from its complaints and compensations cases systems; two examples available on its website are patient complaints, and articles and reports relating to compensation. In developing thematic reports to share learning on specific issues, the Learning Unit of the National Agency for Patient's Rights and Complaints uses data from the Danish Patient Safety Database, the complaints system and the compensation system. The regions and municipalities also contribute to the development of thematic reports.

The agency has acknowledged that while there is a variety of reporting from the database, the reports produced have not been coordinated with action areas in the regions and only several evaluations of the output have been conducted. The agency advocates that close cooperation between all of the central health authorities is required to ensure the most effective use of the knowledge that can be produced from the three data sources (adverse event reports, complaints and compensation cases). The National Agency for Patient's Rights and Complaints has also acknowledged the need for coordination of the reporting and or outputs of the different national health authorities.[55] This coordination would ensure that the technical information shared by the different stakeholders in their respective guidance and information is consistent.

The National Agency for Patient's Rights and Complaints is in the process of changing its approach to sharing knowledge. The current methods of reporting will still form an important part of the sharing of knowledge, but will be scaled down as the agency bolsters the sharing of knowledge through other activities, such as the Knowledge Platform (Further details on this initiative can be found in section 4.8.3).[55]

4.7.10 Coordinating patient safety data and intelligence

The National Agency for Patient's Rights and Complaints, as the owner of the Danish Patient Safety Database, is required under legislation to communicate learning from the system nationally. It fulfils this requirement by producing different forms of reports from the database and also by sharing data with external stakeholders. This is evident in the agency's strategic objectives, which reference both the sharing of knowledge and the coordination of efforts with other authorities through partnerships. The Health Care Act (2010)[14] enables the sharing of information, and outlines the specified conditions under which reports on adverse events may be exchanged with specific agencies or systems without the consent of the individuals or healthcare professionals involved.

Data from the Danish Patient Safety Database is not provided to the agency's complaints system and compensation system. However, the Learning Unit that manages the database does receive some data from the complaints and

compensations cases systems in order to conduct analyses on different patient safety issues, which can be shared through thematic reports.

4.7.11 Strategic direction of the National Agency for Patient's Rights and Complaints

The overarching strategic aim of the National Agency for Patient's Rights and Complaints is for its knowledge of adverse events, complaints and compensation cases to create added value for the health system's operators. This is to enable the agency to contribute to improvements in the safety and quality of the health systems services.[55] Looking forward, it aims to work on the basis of a broader range of learning activities by:

- helping to reveal critical links and patterns in the three data sources and communicating these to health service players via (among other things) newsletters, advisory notices and subject reports
- contributing actively to the sharing of knowledge with key players through:
  - teaching of risk managers and other parties responsible for patient safety
  - entering into partnerships concerning specific patient safety activities
  - providing researcher services in which the agency makes data available
  - cooperating with international players so that learning takes place across borders.

4.8 National Agency for Patient's Rights and Complaints forums

4.8.1 National Strategic Council

The National Agency for Patient's Rights and Complaints operates a National Strategic Council (National Forum), which advises the agency on patient safety issues and themes that should be prioritised. The National Forum meets twice a year and its purpose is to coordinate cooperation on learning across the Danish Patient Safety Database, the compensation system and the complaints system. The National Forum comprises management representatives from across the healthcare system, trade unions and patient representatives. The National Forum can be used as an opportunity to discuss learning areas and initiatives across local, regional and national level.

4.8.2 National Professional Council

The National Agency for Patient's Rights and Complaints established a National Professional Council (Professional Forum) in 2015. The overall objective of the Professional Forum is to assist the National Agency for Patient's Rights and Complaints and the National Forum with learning activities. The tasks of the Professional Forum include:

- assist the National Agency for Patient's Rights and Complaints at the professional level
- review and evaluate project documents and thematic reports

- discuss results, for example, from learning activities
- propose topics that should be examined nationally
- support the use of Danish Patient Safety Database information in the Knowledge Platform (See section 4.8.3)
- exchange and discuss current issues, locally, nationally and internationally.

4.8.3 National Agency for Patient's Rights and Complaints Knowledge Platform

One of the strategic objectives of the National Agency for Patient's Rights and Complaints is to build and maintain a Knowledge Platform and ensure the sharing of knowledge. The agency's Knowledge Platform has been established and will gradually be expanded to include experience from its three main data sources (adverse events, complaints and compensation cases). The Knowledge Platform will be relocated to the Statens Serum Institute which holds knowledge and involves the active participation of lawyers and specialists at the patient complaints centre and the compensation centre. Examples of intelligence found on the Knowledge Platform include learning about solutions to specific risks (from action plans in the Danish Patient Safety Database, contact information and international evidence).

The National Agency for Patient's Rights and Complaints has indicated plans to gather knowledge from the Knowledge Platform on a single platform on the Internet. It is developing a national extranet for registered users of the Danish Patient Safety Database. This will provide a means to share knowledge about patient safety and adverse events across healthcare areas.[55]

4.8.4 Partnerships and researcher services

The National Agency for Patient's Rights and Complaints recognises that its data only represents the 'tip of the iceberg'. Against this backdrop, the agency has outlined its intention to enter into relationships with key stakeholders who have an in-depth knowledge of the context in which patient safety activities are to be implemented. Through these relationships, the agency's rich source of data and intelligence will be able to be exploited more effectively.[55]

The National Agency for Patient's Rights and Complaints expects its activities will be more based on demand from health system operators. The intention of this is to prioritise its resources and knowledge for areas considered relevant by health practitioners, patients and their families, and decision makers.

4.9 Key users of DPSD data

4.9.1 Danish Health and Medicines Authority

The National Agency for Patient's Rights and Complaints and the Danish Health and Medicines Authority have a collaborative relationship in the form of a cooperation agreement between the two parties. The National Agency is obliged by legislation to share information on incidents with the Danish Authority, which has direct access to the adverse event reporting system (anonymised information only) and hence, can identify patient safety issues.[62] While the Danish Authority does not have access to identifiable information, the information in the Danish Patient Safety Database can be used indirectly to select risk areas for supervisory activities. The Danish Authority uses the information from adverse events to generate standards and guidance. A working group meets twice each year to consider adverse events and to discuss how information on adverse events could be used to support the development of guidelines.[62] The Danish Health and Medicines Authority may also share anonymised reports of suspected adverse drug reactions (ADRs) with the Danish Patient Safety Database.

When a complaint is reported to the National Agency for Patient's Rights and Complaints, a copy of each complaint is also shared with the Danish Health and Medicines Authority (there are approximately 5,000 complaints per year) and again when the complaint is resolved or decided on by the National Agency. The Danish Health and Medicines Authority does not investigate complaints; rather it considers any threats to patient safety that the complaint may indicate. Before taking any action on a complaint received, the Danish Authority usually waits for the outcome of the National Agency's investigation, posing potential significant time delays. There is no structured prioritisation process for complaints notified to the Danish Health and Medicines Authority.[62]

4.9.2 Danish Institute for Quality and Accreditation in Healthcare

The Danish Healthcare Quality Programme of the Danish Institute for Quality and Accreditation in Healthcare (IKAS) combines and uses pre-existing data collected in the Danish healthcare system. One source of data for the Danish Healthcare Quality Programme is the Danish Patient Safety Database. Other sources include the National Indicator Project and various Danish national satisfaction surveys.[48]

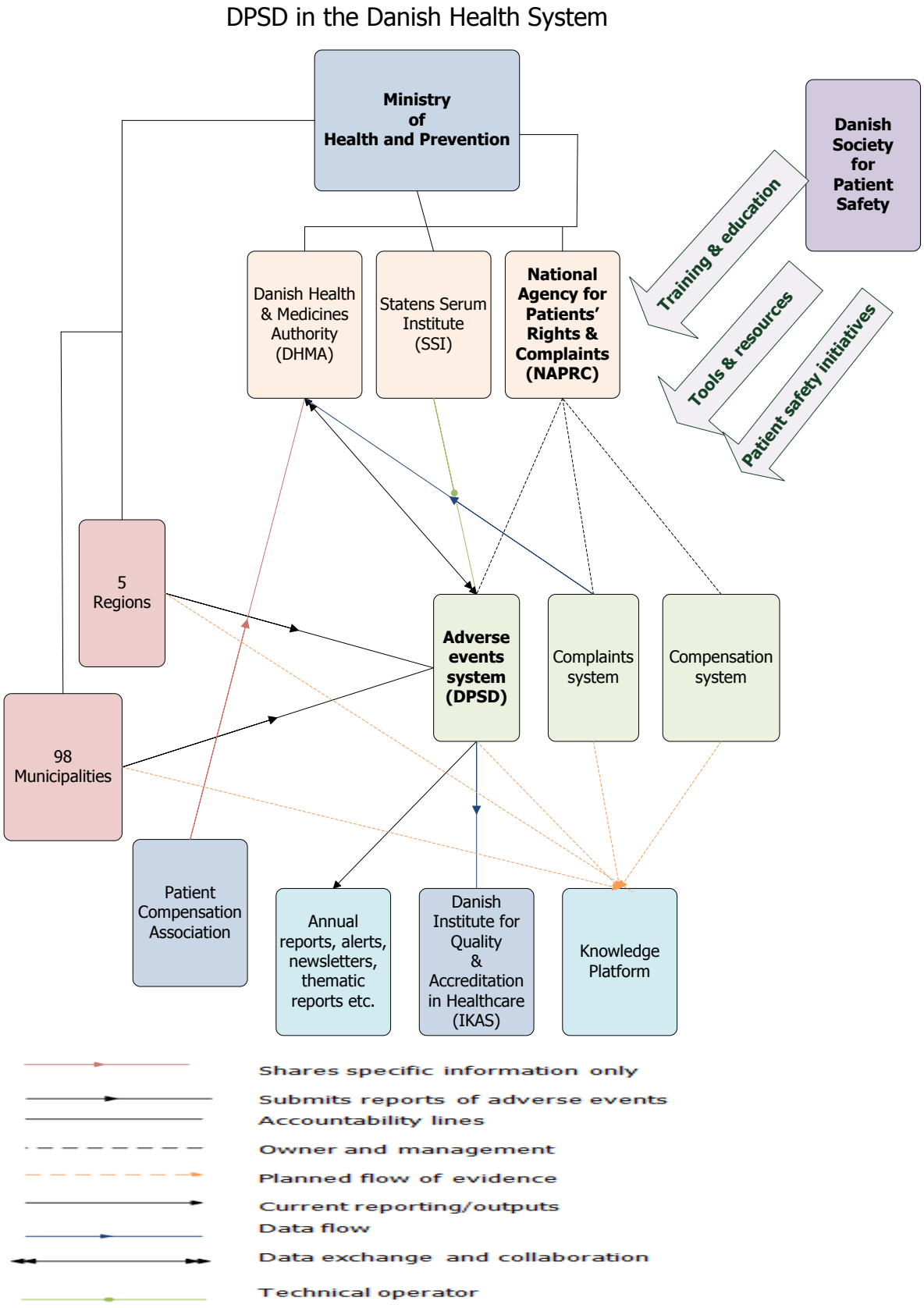
4.9.3 The Patient Compensation Association

The Patient Compensation Association is the independent association that decides compensation claims for patients injured in connection to treatment by the Danish Health Service.[63] The Association operates on a no-blame no-fault basis and aside from assessing damages, it does not take any legal action.[64] Information is not

generally shared between the Danish Patient Safety Database and the Patient Compensation Association. The legislation does provide for situations when there could be sharing of information between the National Board of Health (now the Danish Health and Medicines Authority) and the Patient Compensation Association, for example, when compensation has repeatedly been paid for injuries attributed to an individual healthcare provider(65) or in the case of drug-related claims.(66) The National Agency for Patient's Rights and Complaints and the Patient Compensation Association have cooperated on the development of thematic reports, one example being a project where both agencies worked to identify treatments with high rates of compensation.

Figure 4 presents a number of information flows from and into the patient safety database, and the National Agency for Patient's Rights and Complaints' other data sources.

Figure 4: Data flows between the National Agency for Patient's Rights and Complaints and the wider health system*



*Note. Not all stakeholders, data flows and relationships are shown here.

Denmark – summary and key learnings

- Denmark has a national system for patient safety incident reporting.
- The National Agency for Patient's Rights and Complaints is an independent, government institution, whose focus is on patients' legal rights.
- The National Agency for Patient's Rights and Complaints was established under the amendment of the law on complaints and compensation within the health service, which Parliament passed in June 2010 (Act No. 706 of June 25 2010).
- The National Agency for Patients' Rights and Complaints maintains three data sources which are not linked:
  - an adverse event reporting system (Danish Patient Safety Database - DPSD)
  - a complaints system
  - a compensation cases system.
- In working to achieve its targets and expectations, the National Agency for Patient's Rights and Complaints shares knowledge from its three data sources, draws on the expertise of experts within the agency and collaborates with operators in the health service.(55)
- The purpose of the Danish Patient Safety Database is to improve patient safety by facilitating the collection, analysis and sharing of knowledge on adverse events.
- In establishing the Danish Patient Safety Database, Denmark was the first country in the EU to put in place a national adverse event system that is accessible to all, including the public. Adverse event reporting is mandatory, as dictated by legislation.
- In Denmark, the following areas can currently report incidents onto Danish Patient Safety Database: public hospitals, private hospitals and healthcare providers, pre-hospital, primary care, private care agencies, family doctors, general practitioners (GPs), pharmacies,(7) nursing homes, and home healthcare.[11]
- Since its establishment, the focus of the Danish Patient Safety Database has evolved. There is an evidence focus on learning activities and a learning culture, so healthcare professionals and executives expect changes at all levels of the health sector, as a result of reporting and analyses.(55)
- Analysis and learning from adverse event reports is rooted at local level, meaning that events that occur locally should be dealt with at that level, where ideas for improvement are developed, tested and evaluated.
- In order to extract valid data from the Danish Patient Safety Database, which is a database with more than 550,000 files (2014 data), it is essential that the quality of the data is high and that system users are encouraged to collect and supply

[11] The obligation to report sits with the healthcare professional, rather than the organisation.

sufficient information.[55]

- To date the sharing of knowledge from the Danish Patient Safety Database has taken place through a range of reporting measures, including newsletters, articles, patient safety alerts including medicines, quarterly and annual reports, thematic reports and patient stories.
- The National Agency for Patient's Rights and Complaints is developing a Knowledge Platform that will include experience from the agency's three main data sources (adverse events, complaints and compensation cases), as well as knowledge on solutions to specific risks through action plans from the Danish Patient Safety Database, contact information and international evidence.[55]
- The legislation does provide for situations when there could be sharing of information between the National Board of Health (now the Danish Health and Medicines Authority) and the Patient Compensation Association, for example, when compensation has repeatedly been paid for injuries attributed to an individual healthcare provider[65] or in the case of medicine-related claims.

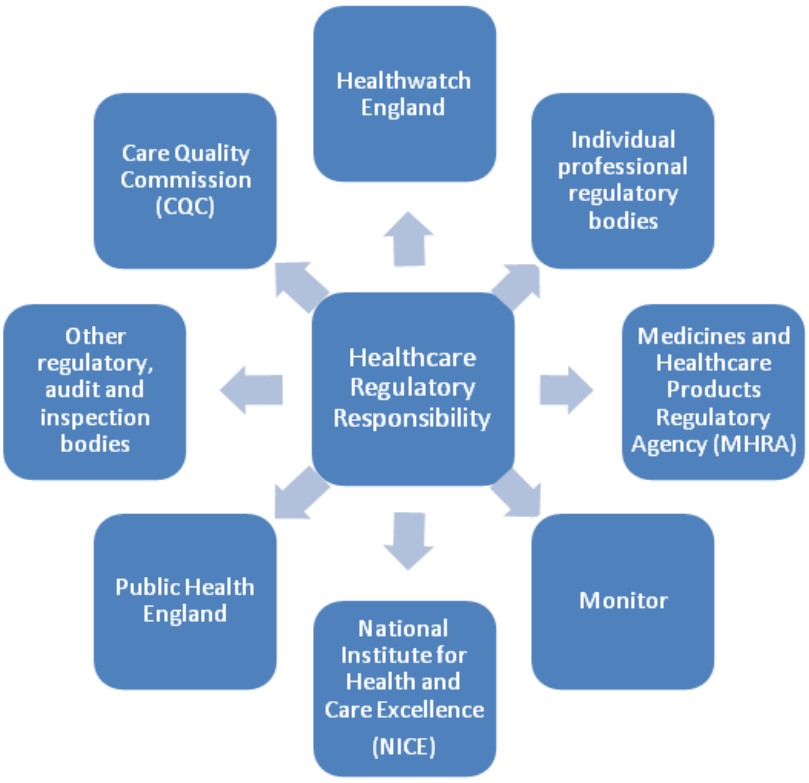
5. England

5.1 Background

England, a country of the United Kingdom (UK), has a population of 53.9 million. The Department of Health, a ministerial department, is responsible for strategic leadership and funding for both health and social care in England. The Department of Health is supported by a number of agencies and public bodies. Healthcare in England has been provided by the National Health Service (NHS) since 1948 and is largely free at the point of use.[67]

Following the Health and Social Care Act 2012, there were significant reforms in the sector. NHS England – operating at arm's length to the British government – oversees the operation of the clinical commissioning groups. These groups are statutory NHS bodies responsible for the planning and commissioning of healthcare services for their local area. The health and social care regulation system in England has experienced a number of changes since 2013. Regulatory responsibilities for different aspects of care are held by different agencies, as outlined in Figure 5.[68]

Figure 5. Overview of agencies with responsibility for health and social care regulation in England*



*Note: 'Monitor' is the independent regulator of NHS Foundation Trusts.

5.2 Patient safety in England

Patient safety in England and the UK became a high-profile issue in the late 1990s.[11] There were several notable cases of regulatory failure of healthcare organisations to provide quality safe care, such as in Stoke Mandeville Hospital, Mid Staffordshire and Tunbridge Wells NHS Trust.[69] In 2000, the publication of the report entitled *An organisation with a memory*[70] was instrumental in establishing that the NHS in England had to improve on its capacity to learn from patient safety incidents.[71]The report acknowledged that the NHS was failing to learn from the things that go wrong and had no system in place to rectify these failings. In terms of reporting adverse incidents, the report highlighted that incident reporting systems appeared to be especially poorly developed in primary care, and systematic reporting of 'near misses' was almost non-existent across the NHS. The report made a number of recommendations, most notably around the introduction of a mandatory scheme for reporting adverse events and near misses and the need for a more open culture. Following this report, the National Patient Safety Agency (NPSA) was established, followed soon after by the establishment of a National Reporting and Learning System (NRLS).

As a result of a request by the Prime Minister, Dr Don Berwick chaired the National Advisory Group on Patient Safety in England and conducted a review of safety in the NHS. In April 2013, *A promise to learning – a commitment to act* was published.[72] The report produced a number of findings and recommendations, including its first recommendation that the NHS should continually and forevermore reduce patient harm by embracing wholeheartedly an ethic of learning.

However, challenges still exist with regard to patient safety in England. In the Care Quality Commission (CQC) *State of Care Report (2013/14)*,[73] variation in basic safety was identified as a serious problem. Particular issues identified were a lack of effective safety processes, the lack of a culture that truly learns from mistakes, and near misses.[73] With increasing awareness of the scale and impact of adverse events, the Department of Health commissioned Frontier Economics to provide a rapid review of evidence about the financial benefits of safer care. This review entitled *Exploring the costs of unsafe care in the NHS* was published in October 2014 and focused on preventable adverse events. While acknowledging that the evidence base at the time of the report had limitations, the report suggested the cost of preventable adverse events was likely to be more than UK Ster £1 billion but could be up to £2.5 billion annually to the NHS.[74]

In 2015, the Department of Health published *Culture Change in the NHS: applying the lessons of the Francis Inquiries*.[75] This report sets out how the health and care system has changed to prevent the occurrence and reocurrence of poor or unsafe

care through the creation of a much more open and transparent healthcare system and the launch of a new national drive to improve safety in the NHS.

5.3 Agencies with responsibility for patient safety reporting

5.3.1 Background

In the recent past, the National Patient Safety Agency (NPSA) had been responsible for monitoring patient safety incidents in England and for setting up the National Reporting and Learning System (NRLS) in 2003. The NRLS is a national, non-mandatory patient safety reporting system linked to local risk management systems. The NPSA was abolished in 2012 and its key functions were taken over by the NHS England's Patient Safety Domain. The NPSA did not investigate reported incidents and were not involved with disciplinary procedures. It had a number of work areas such as reviewing every reported death or severe incident; medication safety; linking with other areas in the NHS and with researchers to develop papers; and developing rapid response reports or patient safety alerts, issued through the Central Alerting System.

5.3.2 NHS England's Patient Safety Domain

NHS England's national Patient Safety Domain has overall responsibility for identifying and acting on risks relating to patient safety within the NHS. In its usual day-to-day working, the Patient Safety Domain's main focus is identifying and acting on risks at a national level; while NHS England's regional teams main focus is ensuring risks specific to a local provider are shared, acted on and involve the provider's commissioners, regulators and other parties as appropriate. However, regional teams will at times identify risks that may be part of a national problem, that need to be escalated via the Patient Safety Domain to the wider healthcare system. The Patient Safety Domain may also identify risks specific to a local provider, through routes such as routine clinical review of all deaths and severe harm incidents reported to the NRLS or through concerned patients or staff who make direct contact with the national team.

Through the NHS England's Patient Safety Domain, a number of key patient safety initiatives are underway, including:

- developing the National Patient Safety Alerting System (NPSAS)
- publishing monthly data on 'never events'
- publishing key patient safety indicators by hospital on 'My NHS'
- launching the Patient Safety Collaborative
- rolling out NHS England's Patient Safety Concern Process.

The Patient Safety Domain also works towards mitigating the most common clinical risks and patient safety incidents types in the NHS, such as preventing medication

errors and pressure ulcers. It also leads several campaigns such as 'Patient Safety First', 'Clean your hands' and '1,000 lives'.

5.3.3 Other key agencies

There are many other agencies in England with varying responsibilities in the areas of patient safety as listed here:

- Health and Social Care Information Centre (HSCIC)
- Care Quality Commission (CQC)
- HealthWatch England
- Public Health England (PHE)
- Dr Foster Intelligence
- Medicines and Healthcare products Regulatory Agency (MHRA)
- Monitor
- Healthcare Quality Improvement Partnership.

5.4 Incident reporting systems

There are a number of incident reporting systems in England. These systems are used at different levels (local, regional and national) and for different purposes, such as those systems specifically for reporting complaints, medical negligence claims, and medical device incidents. In terms of patient safety incident reporting in the NHS, the following are in place:

- Local risk management systems (LRMS)
- National Reporting and Learning System (NRLS)
- Strategic Executive Information System (STEIS).

More detail is provided on the NRLS and STEIS systems in the following sections.

5.4.1 National Reporting and Learning System (NRLS)

The National Reporting and Learning System (NRLS) was established in 2003 as the central database of patient safety incident reports. The NRLS lay within the National Patient Safety Agency (NPSA) until the Agency was abolished under the Health and Social Care Act (2012).

The NRLS is the major tool for identifying risks that pose a danger to patients. Prior to June 2012, information regarding risk identified by the NRLS was shared by various means, developed and operated by the NPSA. This system was effective, however, the development process was lengthy, often making it difficult to issue timely alerts. The re-launch of a patient safety alert system was part of the government's response to the Francis report,[75] which was published in 2015 and

aimed to prevent the occurrence and reoccurrence of poor, unsafe care through the creation of a more open and transparent system.[75]

In terms of governance, the Patient Safety Domain of NHS England has responsibility for oversight of the NRLS. The Imperial College Healthcare NHS Trust is currently administering the NRLS on behalf of NHS England. The Trust manages the system, conducts data extraction and handles data requests among other functions.

The NRLS is a database of patient safety incident reports submitted by organisations across the NHS, specifically for purposes of learning. Most reports come from acute healthcare trusts, which regularly upload incident reports from their local systems to the NRLS, where they are interrogated by national patient safety experts to spot trends, specific incidents of concern, or emerging risks to patient safety. This analysis triggers action to help address the identified issues and or risks through the provision of advice and guidance, such as a patient safety alert. The primary purpose of the NRLS is to enable learning from patient safety incidents which happen in the NHS. The NRLS helps NHS organisations understand why, what and how patient safety incidents occur, learn from these experiences and take action to prevent future harm to patients. The establishment of the NRLS created momentum for each trust to develop its incident reporting processes and to work to increase incident reporting among staff.[11]

The NRLS receives approximately 1.4 million reports a year (including 'no harm' incidents), with around 75% from secondary care.[76] The NRLS retrieves data on a wide variety of incidents through local risk management systems.

5.4.2 Reporting requirements to the NRLS

Both patients and the public can report a patient safety incident to the NRLS. In 2010, it became mandatory for NHS organisations to report all patient safety incidents that result in severe harm or death to the NRLS. Since 2011, all NHS organisations have been required to flag 'never events' in incident reports to the NRLS.[77] Public and healthcare staff in NHS Wales are also required to report all patient safety incidents to the NRLS. Incidents reported by NHS Wales to the NRLS are managed locally. NHS organisations contracted under the NHS Standard Contract are contractually required to report serious incidents in line with the Serious Incident Framework. This framework explains the responsibilities and actions for dealing with serious incidents and the tools available.[15]

5.4.3 Taxonomy

England uses its own classification system, which is different from but closely aligned to the WHO International Classification for Patient Safety (ICPS). Individual organisations reporting incidents to the NRLS are responsible for grading the severity of the incident. Incidents are categorised by degree of harm as follows:

5.4.4 Reporting into the NRLS

- NHS staff and the public can report incidents directly to the NRLS using the NRLS web e-form or through their local NHS organisation.
- Reports are also submitted by other providers, such a general practitioners (GPs) and community pharmacies, which is less common, though there is work underway to help support these non-acute sectors of healthcare to report more.
- NHS organisations collect patient safety data on their local risk management systems, which can be uploaded onto the NRLS.[78]
- Low and no-harm incidents account for approximately 90% of all NRLS incidents and include near misses.
- Death, severe harm, 'never events' and moderate harm are generally statutory notifications.

The following minimum data quality standards apply in terms of reporting to the NRLS:

- NHS organisations should submit all their reported Patient Safety Incidents (PSIs) to the NRLS.
- Every NHS Organisation should submit reported PSIs regularly to the NRLS – 'regularly' is defined by the NRLS as 'at least monthly'.
- Every NHS organisation should ensure that PSIs reported to the NRLS do not contain personally identifiable information in the free text fields.
- Every NHS organisation should ensure that the degree of harm recorded for each PSI describes the actual harm to the patient as a direct result of the PSI.

Upon submission to the NRLS, there is a delay of approximately two days before the incident is exported to the NRLS database. During this two-day period, the Imperial College Healthcare NHS Trust runs pre-scripted tests to remove duplications and cleanse the reports of personal identifiers.

5.4.5 Review and analysis of incidents on the NRLS

Not all patient safety incidents reported to NRLS generate a patient safety alert. All serious incidents and incidents resulting in death are individually discussed on a weekly basis by a patient safety expert group within the NHS England's Patient Safety Domain. Serious incidents are regularly investigated through a more in-depth review of the circumstances surrounding the incident, carried out through contact with the organisation involved in the incident and through collaboration with clinical experts. This process allows for the development of recommendations to ensure that the risk of a future incident is minimised. Escalation of incidents is different in each organisation, which determine their own approach to this.

All patient safety incident reports submitted onto the NRLS that are categorised as resulting in 'severe harm' or 'death' are individually reviewed by clinicians within NHS England's Patient Safety Domain to identify incidents that offer potential for national learning or represent new and or emerging risks. If an incident is considered to meet that threshold, the wider NRLS is scoped for similar incidents (where reports of any level of harm are accessed), where appropriate action may then be taken at a national level. Such action may include, but is not limited to, staged alerts. Alternative action may include liaison with other national bodies (such as the Medicines and Healthcare Products Regulatory Agency or professional organisations). Throughout this process, the core objective of the NRLS to learn from patient safety incidents remains.

5.4.6 Reporting from the NRLS

The NRLS first began publishing organisational level data in 2008 and 2009. NHS England publishes NRLS data on its website on a quarterly basis, the latest of which included a trust level breakdown. Some of the NRLS data is designated as 'Official Statistics', which limits how the data can be used and puts a number of controls over the data. NRLS data is used for reporting and for the development of patient safety resources, such as rapid response reports, patient safety alerts, and safer practice notices. Organisation-level patient safety incident reports are published every six months in March and October. NRLS data is designated as official UK statistics and is made publically available in data workbooks, also released every six months. NHS England has announced it will begin publishing a monthly summary of reported never events in 2014/15. The NHS Patient Safety Domain does not investigate individual reports, but records public concerns and use this information to improve safety. There is a patient-concern process where an incident or set of incidents comes into NRLS and red flags are raised. The NHS Patient Safety Domain can then write to individual Chief Executives requesting that they conduct a review.

5.4.7 Strategic Executive Information System (STEIS)

There is a national system in place since April 2002 called the 'Strategic Executive Information System' (STEIS). This system is held within the Department of Health and was originally established for collecting management information from NHS England. All 'serious incidents' (as defined by the Serious Incident Framework) must be reported on STEIS.[15] STEIS is maintained nationally by the Department of Health on behalf of NHS England. Local STEIS accounts are maintained by NHS England regions and clinical commissioning groups. The Serious Incident Framework, which covers 'never events', requires serious incidents to be reported on STEIS within two working days.[15] 'Never events' must be reported to the Care Quality Commission (CQC) via the NRLS.

5.4.8 Serious Incident Framework

The Serious Incident Framework – recently revised in March 2015[15] – explains the responsibilities and actions for dealing with serious incidents and the tools available. This revised Framework builds on previous guidance that introduced a systematic process for responding to serious incidents in NHS-funded care. It replaces the National Patient Safety Agency (NPSA) National Framework for Reporting and Learning from Serious Incidents Requiring Investigation (2010) and NHS England's Serious Incident Framework (March 2013).

The Framework takes account of the changes within the NHS landscape and acknowledges the increasing importance of taking a whole-system approach, where cooperation, partnership working, thorough investigation and analytical thinking is applied to ensure organisations identify and learn what went wrong, how it went wrong and what can be done to minimise the risk of the incident happening again. The Framework also details contractual terms in relation to reporting serious incidents and provides guidance on reporting, disclosing, investigating and responding to serious incidents. Examples include the following:

- All serious incidents must be reported by the provider to their commissioners using the STEIS system to facilitate performance monitoring of the incident and its management, trend analysis and shared learning.
- All serious patient safety incidents must also be reported to the NRLS (via local risk management systems) to comply with Care Quality Commission (CQC) requirements regarding the reporting of incidents leading to severe harm or death and for the purpose of national learning. This should be done without delay.

5.4.9 Never events

All 'never events' are currently reported into both the STEIS and the NRLS. The NPSA devised a list of never events in 2009 which the Agency defined as 'serious, largely preventable patient safety incidents that should not occur if the available

preventative measures have been implemented by healthcare providers.' These events were those that must be investigated and reported to external authorities such as the CQC. As of 1 April 2015, there were 14 listed never events, as listed in Appendix 10.

Trusts are required to follow clear guidance in the reporting of and learning from never events when they happen. This is set out in the revised NHS Never Events Policy Framework 2015[79] and also the revised NHS England's Serious Incident Framework 2015.[15]

5.4.10 Comparison between the NRLS and STEIS systems

The NRLS captures all patient safety incidents (defined as 'any unintended or unexpected incident that could have led or did lead to harm for one or more patients receiving NHS-funded healthcare'). When reporting patient safety incidents to the NRLS, the actual (not potential) level of harm caused must be reported.
All serious incidents must be reported to STEIS. Serious incidents can include, but are not limited to, patient safety incidents.

Some organisations have expressed confusion when reporting serious incidents to STEIS and the NRLS because it is difficult to imagine that a serious incident can be reported as a no- or low-harm incident. However, the outcomes (that is to say, actual harm) of serious incidents can cover all degrees of harm. For example, all never events are serious incidents but not all will result in severe harm or death. Therefore the actual outcome that is reported to the NRLS may in fact be no or low harm, even though it is declared as a serious incident. Additionally, some serious incidents may not involve actual or potential harm to any patient (such as an incident related to loss of confidential information affecting staff).
All serious incidents which meet the definition of a patient safety incident should be reported to STEIS and to the NRLS. Organisations with local risk management systems that link to the NRLS can report via their own systems. Organisations without this facility report using the relevant NRLS e-form.

It has been reported that neither the NRLS nor STEIS is able to supply an entirely reliable picture of the prevalence of 'never events'.[77] Analysis of the numbers and types of 'never events' reported to both systems indicates that reporting is not consistent. A reconciliation process conducted on data from the two systems for 2011 to 2012 indicated that STEIS probably contained the more comprehensive data on 'never events'.[77] Table 5 provides a comparison between the NRLS and STEIS systems.

Table 5. Comparison between the NRLS and STEIS systems

NRLS	STEIS
Any patient safety incident	Only serious incidents (including never events)
Any degree of harm	Serious incidents only
Voluntary (but serious incidents mandatory)	Mandatory
Obliged to report at least monthly	Must be reported within 48 hours
For learning	For management and or investigation
Access by agreement	Commissioners have access
Operated by Imperial Health Trust	Operated by Department of Health

5.5 NHS National Patient Safety Alerting System (NPSAS)

The NHS launched the new National Patient Safety Alerting System[80] in January 2014. This new system allows for the timely sharing of relevant safety information to providers, as well as acting as an educational and implementation resource. The National Patient Safety Alerting System is a three-staged system and consists of:

- warning: aims to permit rapid sharing of information as new risks emerge
- resource: may follow at a later stage with further information, examples of good local practice, tools and resources to help implement solutions and learning resources
- directive: organisations are required to confirm implementation of specific solutions or actions to mitigate the risk.

The National Patient Safety Alerting System alerts NHS organisations in England, Wales and Scotland to potential risks and provides guidance on potential patient safety incidents. National Patient Safety Alerting System alerts are issued following analysis of NRLS data, enabling the identification of emerging patterns. The system issues alerts through the Central Alerting System (CAS), a web-based cascading system used by NHS England to issue patient safety alerts. CAS is also used to issue important public health messages and other safety critical information and guidance to the NHS and others, including independent providers of health and social care. Alerts are issued on the basis of a set of agreed principles and may cover issues including the following:

- new or under recognised patient safety issues
- widespread, common, and challenging patient safety issues not solved by alerts in isolation
- improving systems for clinical governance, reporting and learning.

Alerts are published as narrowly as possible to keep them relevant to those receiving them. The target audience is identified in consultation with the sponsoring NHS England Patient Safety Group (PSEG), which includes representation from relevant colleges and associations, patient and carer groups, and relevant experts. Final approval for all NHS England patient safety alerts comes from the Director of Patient Safety before they are released.

When a patient safety alert has been received, healthcare providers should implement all the actions that are relevant to them and ensure that all relevant parts of their organisation and staff are aware of the information and or the required changes. Once satisfied that the actions in an alert, including sharing of information, have been implemented in full, typically via board-level scrutiny, providers are required to mark the alert as 'complete' on the Central Alerting System. There will be a set deadline for organisations to sign off each alert as complete.

From April 2014, the National Patient Safety Alerting System will publish data monthly on any trusts who have failed to declare compliance with any National Patient Safety Alerting System alerts by their due date. Failure to comply is likely to be used by the CQC in its Intelligent Monitoring System. A failure to comply with a stage-three-alert directive within the deadline will be a cause for significant concern on the part of regulators, commissioners and most importantly patients. There are several advantages associated with the National Patient Safety Alerting System, which include giving organisations the opportunity to tackle emerging risks in their own way and to establish a sense of ownership. Through stage-two alerts, the system also provides organisations with potential solutions and resources to mitigate the risk. The system also encourages voluntary compliance for early adopters, allowing providers to find solutions that best suit their individual organisations and minimises the requirement for directives.

5.6 NHS England Patient Safety Concern process

The Patient Safety Concern process provides a framework by which assurances can be given to the NHS England Board that patient safety concerns identified by the national Patient Safety Domain have been shared and managed appropriately at regional level. It uses triangulation, employing NRLS data and information from other sources (such as communications from the public, coroners' letters, police enquiries and so on) to identify patient safety concerns.

When a patient safety concern is identified – including organisational systems or culture or the practice of an individual – by the Patient Safety Domain, and that concern poses a local risk to patient safety, then it is the responsibility of the Patient Safety Domain to seek confirmation from regional teams that all relevant organisations are aware of the issue and that it is being investigated and managed appropriately. This may include further raising of the concern or involving other national agencies. The Patient Safety Concern process is managed through the following three stages.

Stage One – identification and triangulation of concern

Once a potential Patient Safety Concern has been identified, the Patient Safety Domain team:

- checks if the incident is already known to regional teams via a 'serious incident' declared on STEIS; if it is, further raising of the concern is only needed if there is significant additional information of concern not included in the STEIS report
- triangulates the data where possible and appropriate using the NRLS or other applicable data sources, to assess whether the trigger incident or issue is isolated or if it appears to be part of a wider pattern of concerns
- reviews the potential Patient Safety Concern and any additional data. This is conducted by the most senior clinical member of the Director of Patient Safety's Senior Leadership Team or their nominated deputy
- decides that no further action is required if no significant risk meeting the criteria above is identified
- starts Stage Two (escalation) of the Patient Safety Concern process if a significant risk meeting the criteria above exists.

Stage Two – escalation

Once the decision to escalate the Patient Safety Concern is taken, the first consideration is whether the risk relates to a 'clear and present danger'. If this is the case, the communication is raised with the relevant nominated contacts. The regional team discuss the Patient Safety Concern with the geographical lead person and decides who will lead on the response and how this will be handled given the nature of the concern and the service (for example, commissioned by the Care Quality Commission).

Stage Three – confirmation and closure of PSC issue

Within two weeks, the regional team confirms with the Patient Safety Domain that appropriate investigation and mitigating actions are underway. The Regional Team provides feedback on whether relevant parties were previously aware of the concern. From a national perspective, the Patient Safety Concern is closed once the relevant assurances have been provided by the regional team to the Patient Safety

Domain. It maintains an audit trail of correspondence between the national and regional teams and provides, at a minimum, monthly reminders of any open Patient Safety Concerns, typically during monthly regional and Patient Safety Domain meetings.

5.7 Exchanges and data sharing

The importance and value in exchanging, sharing and collating patient safety information and intelligence was acutely recognised in the Mid Staffordshire[81] investigation report in England. Information on the deterioration of the quality of care at Mid Staffordshire had been plentiful, appearing from different sources such as patient, staff and carer complaints and quantitative metrics (including significantly high adjusted mortality rates compared with others across England).[72] The need to share data was also outlined in the Berwick report,[82] where it was recommended that 'transparency should be complete, timely and unequivocal' and 'all non-personal data on quality and safety, whether assembled by Government, organisations, or professional societies, should be shared in a timely fashion with all parties who want it, including, in accessible form, with the public'. In recent years, it has been recognised that some of the most valuable sources of information in terms of patient safety are the reports and voices of patients, carers and staff.[83]

5.7.1 Data sharing agreements

The NRLS has a number of data sharing agreements, for example, with the Care Quality Commission, the Medicines and Healthcare Products Regulatory Agency, Public Health England and specialised clinical groups such as anaesthesia, radiotherapy and so on. Organisations are provided with data following an application process; the application asks the applicant to provide assurances which it must be able to meet before a data sharing agreement is issued. The agreement lays out terms and conditions which the organisation signs up to. This includes information governance principles around the safe and secure transfer, storage and deletion of data.

Organisations that the NRLS supplies data to receive the entire incident report. However, the data sharing agreements are not monitored to ensure that the terms are adhered to. When an expiry date arises, the Patient Safety Domain will inform an organisation who has received data under such an agreement that the data must be deleted, and the Patient Safety Domain will receive assurance once this has happened. The NRLS also responds to data requests for aggregate level data.

5.7.2 Data sharing with the Care Quality Commission (CQC)

The NRLS and the Care Quality Commission (CQC) have a formal data sharing agreement in place. There is an automated weekly feed of data from the NRLS to the CQC. The CQC receives all incident level data that is identifiable at organisational level. CQC Regulations 2009 require that NHS bodies must submit certain notifications to the NRLS. These notifications are then shared with the CQC under an information sharing agreement. The notifications are as follows:

- certain deaths of people using the service
- allegations of abuse
- events that stop or may stop the service from running safely and properly
- serious injuries to people who use the activity.

Submitting these notifications is mandatory and reporting the relevant incidents to the NRLS meets this requirement. All notifications must be submitted within a required timescale and must include all the required information.
Since 2010, the NRLS incident reporting system has been used as the source of NHS trusts' statutory notifications about patient safety incidents, thereby avoiding duplication of reporting directly to the CQC. CQC receives notifications of all incidents on NRLS.
CQC can use all information within STEIS and may use the details of incident reports, investigations and action plans to monitor organisations' compliance with essential standards of quality and safety.

Under the Serious Incident Framework, CQC-registered organisations are required to notify the CQC about events that indicate or may indicate risks to compliance with registration requirements, or that lead to, or may lead to, changes in the details about the organisation in the CQC's register. The Health and Social Care Act sets out specific requirements for registered organisations in relation to the process of reporting incidents to them and the type of incidents that must be reported.

5.7.3 Data sharing with NHS Trust Development Authority (TDA)

'Never events' are monitored through the NHS Trust Development Authority's Oversight and Escalation scorecard and are looked at alongside other quality indicators. The NHS Trust Development Authority's clinical quality teams work closely with all healthcare trusts when a never event is reported. As with all Grade 2 Serious Incidents, healthcare trusts are expected to directly inform the NHS Trust Development Authority of never events (the authority also has access to serious incident reports via STEIS). When that happens, the clinical quality team links in with the relevant trust to understand the circumstances surrounding the event and establish whether any immediate actions are necessary. The authority then follows up with the trust to ensure actions are taken and, where helpful, puts them in touch

with other healthcare trusts to share best practices. Where trusts have had clusters of never events, quality teams may work more intensively with them.[84]

5.7.4 Other data sharing

All healthcare providers must notify Public Heath England (which now includes the remit of the Heath Protection Agency) about certain suspected infection cases and incidents. While there are no data feeds from the NRLS to the Department of Health, the Department of Health does receive a pre-release of all NRLS publications.

5.7.5 Development of the Patient Safety Incident Management System

A development project (known as DPSIMS) is underway for a redeveloped system. The name of the replacement system will be decided once the detailed plans of the system are finalised. As the NRLS is over 10 years old and due for an upgrade, the DPSIMS project aims to identify and assess the options for a successor system that will build upon its success of NRLS. It will also potentially expand its functions to create a Patient Safety Incident Management System (PSIMS) that will better meet the needs of patients and clinicians within current NHS delivery models, with the intention of delivering a new system in 2016/17.
The purpose of the DPSIMS project is, over three years, to identify the most appropriate option for a successor to the NRLS, develop a business case for this option, and procure it for delivery to the NHS.

The stated vision is to identify a solution with reduces the risks associated with duplication, a lack of standardisation and the gap between current NRLS capability and the needs of the NHS. It also aims to improve transparency and patient involvement, and to generate better learning that supports improvement across all sectors of NHS-funded care in England.

There is also a goal to consolidate the NRLS with other systems. One such system being considered is the STEIS, as duplication between the STEIS and NRLS is evident. The business case for this system is to be developed by 2016 and development of the system is planned for 2017, all subject to funding, human resources and other factors. The vision for the new system is to identify a solution which reduces the risk associated with:

- duplication
- a lack of standardisation
- the gap between current NRLS capability and the needs of the NHS, and which
  - improves transparency and patient involvement
  - generates better learning
  - supports more improvement across all sectors of NHS-funded care in England.

5.8 Management of complaints and claims

5.8.1 Complaints

Complaints are directed to the individual NHS organisation involved and if necessary, raised with the Parliamentary and Health Service Ombudsman. HealthWatch England found that a staggering 75 types of organisations in England have a role in complaints handling and support, from councils and clinical commissioning groups locally to national regulators.[85]

The NHS Patient Advice and Liaison Service (PALS) offer confidential advice, support and information on health-related matters. It provides a point of contact for patients, their families and their carers. A new NHS guide on feedback and complaints has also been published for patients. The CQC is now routinely examining how well organisations handle complaints, and any organisations that are underperforming in this area will have a note of this in their inspection findings.[75] The CQC's recent *Complaints Matter* report concluded that 'the quality of complaints handling was variable, and it raised concerns about the timeliness of responses to complaints'.[75]

The Health and Social Care Information Centre also holds data collections regarding complaints.

5.8.2 Claims

The NHS Litigation Authority (NHS LA) was established in 1995 as a special health authority. It is a not-for-profit part of the NHS, and:

- provides indemnity cover for legal claims against the NHS
- assists the NHS with risk management
- shares lessons from claims
- provides other legal and professional services for its members.

It is important to note that the NRLS does not share data with the NHS Litigation Authority. The authority aims to support the NHS in England to reduce harm by learning from claims, and to help the NHS to build a safety and learning culture through:

- '*Saying Sorry*' – Saying sorry when things go wrong is vital for the patient, their family and carers, as well as to support learning and improve safety. Of those that have suffered harm as a result of their healthcare, 50% wanted an apology and explanation. Patients, their families and carers should receive a meaningful apology – that is one that is a sincere expression of sorrow or regret for the harm that has occurred.
- *Duty of Candour* [79] – this is a legal duty on hospital, community and mental health trusts to inform and apologise to patients if there have been mistakes in their care that have led to significant harm. This came into force for NHS bodies in November 2014 and will extend to all providers registered with the CQC as of

April 2015. It will serve a no-blame and learning culture, requiring providers registered with the CQC to be open when things go wrong.

In 2013, the NHS Litigation Authority piloted an improved extranet service for its members. Through the extranet, the NHS Litigation Authority has been working towards greater sharing of data with members to assist them to reduce claims and improve patient and staff safety. This has involved sharing more real-time data. NHS organisations must report separately to the NHS Litigation Authority and in far more detail than what is submitted to the NRLS.

5.9 Coordinating patient safety intelligence

Following the publication of Quality in the New Health System; Maintaining and Improving Quality from April 2013 by the National Quality Board (NQB),[86] the NQB in England recommended the introduction of Quality Surveillance Groups (QSGs) to oversee quality in the health and care system. The following section briefly outlines the role of QSGs in coordinating patient safety intelligence from across the health and care system in England.

5.9.1 Governance structures for establishing Quality Surveillance Groups (QSGs)

Since April 2013, networks of QSGs have been established at local and regional level across the NHS, to ensure that different parts of the health and care system in England work together. QSGs were established across the health and care economy in England to pool the wealth of information gathered formally and informally about providers of services. There are a number of statutory organisations with distinct roles and responsibilities in the system, meaning that no one organisation will have a complete picture on quality of care provided. QSGs systematically bring together different parts of the system to share this information. They provide the health and care economy in England with a shared view of risks to quality through:

- sharing intelligence about the quality of care
- providing an early warning mechanism
- creating opportunities to coordinate actions to drive improvement
- respecting statutory responsibilities,
- ongoing operational liaison between organisations to reactively work together
- informed judgements about quality
- ensuring an aligned response to concerns.[87]

QSGs aim to ensure quality across the whole system to include primary, community, acute, mental health, public health services and ambulance services provided by NHS and independent sector organisations. The guidance documents on QSGs published by the NQB highlight that ensuring quality of health and care services

encompasses three dimensions that must be considered to ensure the quality. The guidance documents provide a definition of quality which has also been enriched in legislation through the Health and Social Care Act 2012. It states that quality encompasses three dimensions outlined below which must be present to provide high quality service:

- Clinical effectiveness - quality care is care which is delivered according to the best evidence as to what is clinically effective in improving an individual's health outcomes
- Safety - quality care is care which is delivered so as to avoid all avoidable harm and risks to the individuals safety
- Patient experience - quality care is care which looks to give the individual as positive an experience of receiving and recovering from the care as possible, including being treated according to what the individual want or needs, and with compassion, dignity and respect.[88]

The NQB published a number of guidance documents detailing how QSGs should operate, including information on the following:

- Members of the QSGs - should be determined locally and should comprise of representatives from key organisations including public health, professional bodies, and the health care regulator.
- Provide a statement of intent- outlines the purpose of the meeting and includes information on the frequency of meetings
- A publication scheme which sets out what information the QSG will routinely publish
- A Memorandum Of Understanding (MOU)/protocol for QSG participants that sets out the ground rules about how information shared at the QSG may be used e.g. handling FOI requests, what QSG bodies do with the information they obtain through QSG, when matters are shared or escalated.

5.9.2 Quality Surveillance Group (QSGs) Members

The members of QSGs represent organisations with information and intelligence on quality and are nominated by their organisation. Some of the represented organisations who are members of the QSGs include:

- NHS Commissioning Board
- Clinical Commissioning Group (CQC)
- Monitor
- Public Health England
- Professional Regulators
- Health Education England
- Local government[87]

5.9.3 Types of intelligence used by QSGs

The QSGs use hard and soft intelligence from a range of sources including Intelligence from the National Quality Dashboard (being piloted) relevant to the QSG and other sources of intelligence including:

- Clinical Commissioning Group (CCG) data
- Care Quality Commission (CQC) warning notices and inspection activity
- Monitor risk ratings
- Staff feedback
- Public health intelligence
- Complaints data
- Intelligence from professional regulators
- "Never event" data

Regionally QSGs produce a summary report to share with other regional QSGs to ensure key information is shared nationally outlining any concerns or good practice that other regions should be aware of to share across the network.[87]

Quality Surveillance Groups – 'Risk Summits'

When statutory organisations have concerns about a serious quality failure or concerns about the potential for a failure within a provider, they should alert other QSG members to their concerns by triggering a risk summit. Concerns may arise from shared intelligence at a QSG meeting or from another source e.g. whistleblower, patient, media. Risk summits bring together QSG members relevant to the provider where there is a concern to give specific focussed consideration to the concerns raised, facilitating rapid, collective judgements. A risk summit provides these different parts of the system with an opportunity to align their actions with each other so that they do not fail to act on concerns or duplicate actions. It is primarily for the Care Quality Commission (CQC) to determine and make recommendations to the NHS Trust Development Authority (NHS TDA) and Monitor as to whether regulatory action is required as a result of a serious quality failing within a provider organisation.[89]

5.10 Other developments underway

5.9.1 Policy developments

There have been a number of key policy developments in relation to patient safety in recent years. A selection of key reports and forthcoming initiatives are outlined here. The NHS Patient Safety Strategy for 2014/15 outlined the following strategic objectives:[78]

- gain a better understanding of what goes wrong in healthcare
- improve completeness of reporting to the NRLS
- develop a new national patient safety incident management system

- develop patient safety thermometers
- create the first ever direct national measures of patient safety using retrospective case note review
- develop patient safety data pages on the NHS Choices website
- enhance the capability and capacity of the NHS to deliver patient safety improvement
- set up the Patient Safety Collaborative
- deliver a programme to identify and recognise Patient Safety Fellows
- further develop the investigation capability across the NHS
- develop an improvement programme, including change packages to tackle important clinical patient safety areas and vulnerable groups
- establish medication safety and medical device safety officer networks across England
- tackle key patient safety priorities
- set out specific work programmes to address a range of areas.

5.9.2 Measurement of patient safety and harm

The Health Foundation asserted in a 2013 publication, *The measuring and monitoring of safety*,[11] that measuring harm, so important in the evolution of patient safety, has been almost completely neglected. Most healthcare organisations at present have very little capacity to analyse, monitor or learn from safety and quality information. This gap is costly, and should be closed.[72] There are a number of national indicators measuring patient safety and harm, including incident reporting, the NHS Safety Thermometer, infection rates and pressure ulcers.[90] There is also a new national indicator on avoidable deaths in hospitals, measured through the introduction of systematic and externally audited case note reviews.

The NHS Outcomes Framework sets out five domains; Domain 5 relates to treating and caring for people in a safe environment and protecting them from avoidable harm. Within Domain 5 are a number of objectives, including:[91]

- improving the readiness of the NHS to report harm and to learn from it
- reducing serious harm caused by medication errors.

'MyNHS' is a new comparison website tool which has been developed by NHS England, together with the Department of Health, the Health and Social Care Information Service, the CQC and Public Health England. The online information currently covers hospitals, providers of social care and public health, and supports the wider commitment on ensuring more transparent health and care services. Specifically, the measures employed include publication of:

- infection control and cleanliness
- CQC inspection ratings
- recommendations by staff

- safe staffing numbers (appropriate number of healthcare staff on duty to ensure patient needs can be met)
- NHS England patient safety notices (these show whether or not an NHS organisation is signing off its response to patient safety notices that are issued by NHS England)
- open and honest reporting (this indicator combines several other indicators to give an overall picture of whether the hospital has a good patient safety incident reporting culture). A good patient safety reporting culture within a healthcare service means that patient safety incidents are being reported frequently allowing for greater opportunities to learn and improve from patient safety incidents.

England – summary and key learnings

- The National Reporting and Learning System (NRLS) is a voluntary reporting system, which was set up in 2003 under the National Patient Safety Agency to enable learning from patient safety incidents. The Patient Safety Domain of NHS England is now responsible for oversight of the NRLS.
- There is a second national system called the Strategic Executive Information System (STEIS) system held by the Department of Health that facilitates performance monitoring, management, trend analysis and shared learning from serious incidents. NHS organisations are contractually required to report all serious incidents to STEIS in line with the Serious Incident Framework.
- England uses its own classification system, different from the WHO's International Classification for Patient Safety (ICPS), but which is closely aligned to the WHO's classification system.
- The NRLS has a number of data sharing agreements with the Care Quality Commission (CQC) (an automated weekly feed of data from the NRLS to the CQC), the Medicines and Healthcare Products Regulatory Agency, Public Health England and specialised clinical groups.
- NHS England's Patient Safety Domain has overall responsibility for identifying and acting on risks relating to patient safety in the NHS.
- A key area of work by the Patient Safety Domain is the development and issuing of patient safety alerts. The National Patient Safety Alerting System (NPSAS) alerts NHS organisations in England, Wales and Scotland to potential risks and provides guidance on potential patient safety incidents.
- The Patient Safety Concern process provides a framework that ensures patient safety concerns identified by the national Patient Safety Domain have been shared and managed at regional level.
- A project entitled Development of the Patient Safety Incident Management System is underway and aims to redevelop current patient safety reporting systems.
- NHS England is setting up Quality Surveillance Groups which work to coordinate patient safety intelligence.

6. Scotland

6.1 Background

Scotland, a country of the United Kingdom (UK), has a population of 5.3 million. Scotland's health system has increasingly diverged from the health system in England. Since political devolution, responsibility for the health system has resided with the Scottish Parliament and government.[92] The National Health Service (Scotland) Act 1974 sets out how the health service functions in Scotland. Healthcare in Scotland is delivered through the publically funded system, NHSScotland. The Scottish Government Health and Social Care Directorates develop and implement health and social care policy and provide resources and strategic direction to NHSScotland. The Scottish Government is currently implementing a significant reform programme involving the integration of health and social care. This reform programme aims to ensure that adult health and social care provision across Scotland is joined up and seamless, particularly for people with long-term conditions and disabilities.[93]

NHSScotland consists of 14 regional NHS boards which deliver front-line health services as well as seven special NHS boards and Healthcare Improvement Scotland (Scotland's independent healthcare improvement body), which support the regional NHS boards by providing a range of important specialist and national services. The regional NHS boards have significant powers to determine the pattern of local care and to set local priorities.[92] NHS boards are accountable to the Scottish Ministers and Parliament for the performance of their services and the quality of care.[94] Healthcare Improvement Scotland focuses on helping NHSScotland and independent healthcare providers deliver quality, evidence-based, safe, effective and person-centred care.[95]

The focus of this review is the work carried out by Healthcare Improvement Scotland on patient safety, specifically its lead role in developing a national approach to learning from adverse events. The review will also explore the collection and sharing of adverse event data at a high level.

6.2 Healthcare Improvement Scotland (HIS)

Healthcare Improvement Scotland is the improvement and scrutiny body of NHSScotland and the regulator of independent healthcare services. It works closely with NHS boards to inspect and review their services, and works with them to apply evidence and provide appropriate improvement support. It gathers and shares evidence about best practices and independently scrutinises services and NHS boards.[96] Its work supports government priorities, in particular those arising from

the *Healthcare Quality Strategy for NHSScotland* (2010). Healthcare Improvement Scotland coordinates or leads on a range of programmes relating to patient safety, often in partnership with NHS boards and other agencies. It is governed by a board of 14 members. Through the work in assessing the quality and safety of healthcare, it:[97]

- regulates and registers independent healthcare services
- scrutinises NHS services to safeguard the public, provide public assurance and improve safety and standards of care
- proactively supports NHS boards to improve services through learning from data such as adverse events, complaints, claims and hospital standardised mortality ratios (HSMRs)
- supports and measures implementation of the Scottish Patient Safety Programme (SPSP) in NHS boards
- uses a range of data to assess the quality and safety of healthcare.

In fulfilling its remit, Healthcare Improvement Scotland produces a number of outputs including annual reports, standards (quality and clinical), audit reports, indicators, surveys, benchmarking reports and performance reviews.

Through its work, Healthcare Improvement Scotland links in with a number of agencies including:

- NHS boards
- NHS National Services Scotland (NHS NSS)
- NHS Education for Scotland
- professional bodies
- Care Inspectorate
- Scottish Government
- Audit Scotland.

Healthcare Improvement Scotland has a collaborative relationship with the Information Services Division Scotland, in the Public Health Intelligence Unit of NHS National Shared Services (NHS NSS).[12] Information Services Division Scotland provides health information, health intelligence, statistical services and advice that support the NHS in progressing quality improvement in health and care and facilitates strong planning and decision making. The products and services of Information Services Division Scotland are used for a wide range of purposes, including supporting patient safety initiatives.[98] It holds a number of administrative data sources as outlined on its website: http://www.isdscotland.org/A-to-Z-Index/index.asp.

[12] NHS National Shared Services is the special NHS board that supports Scotland's health by delivering shared services and expertise, supplying essential services such as information and health protection.

6.2.1 HIS strategic direction

Healthcare Improvement Scotland has developed *Driving improvement in healthcare, our strategy 2014-2020* to promote its three quality ambitions: safe, effective and person-centred care.[97] HIS sees advantages in leading both quality improvement and quality assurance from one organisation, believing it offers a unique opportunity to establish and embed change. In its strategy, Healthcare Improvement Scotland has outlined its commitment to:[97]

- make better use of information and data
- strengthen intelligence gathering and sharing mechanisms within, and between Healthcare Improvement Scotland and other bodies
- improve the responsiveness of its evidence processes to reflect the need for advice in the face of rapidly developing medicines, technologies and treatments and the increase of multi-morbidity
- proactively take a proportionate, timely and risk-based approach to scrutiny to support improvement in healthcare, considering how data and information can inform prioritisation of the areas that require review and support.

Healthcare Improvement Scotland has played a key role in driving improvements in patient safety across Scotland, as is evident in its recent work in leading on the Scottish Patient Safety Programme and the development of a national approach to learning from adverse events. Both of these programmes of work are now detailed in the following sections.

6.3 Patient safety in Scotland

The Scottish Government's prioritisation and commitment to patient safety and the prevention of avoidable harm is evident in the different strategies, policies and legislation. In fact, Scotland was one of the first countries in the world to mandate a structured safety improvement programme for its whole healthcare system, the Scottish Patient Safety Programme (see section 6.3.1 of this report). *The Healthcare Quality Strategy for Scotland* (2010) puts safe care as one of the key drivers for achieving Scotland's quality ambitions.[99] The schedule of the Patient Rights (Scotland) Act (2011)[100] sets out that people who provide NHS care must take into account a set of healthcare principles when providing services; Principle 10 states that no avoidable harm or injury is to be caused to the patient by the healthcare provided. Furthermore in 2015, the Scottish Government published *Health and Wellbeing Outcomes: A Framework for improving the planning and delivery of integrated health and social care services*. One of its nine outcomes centres on patient safety – 'People who use health and social care services are safe from harm'.[101]

6.3.1 Scottish Patient Safety Programme

Healthcare Improvement Scotland has played a key role in driving improvements in patient safety across Scotland, as is evident in its recent work in leading on the Scottish Patient Safety Programme and the development of a national approach to learning from adverse events. Through the Scottish Patient Safety Programme, NHSScotland has adopted a systematic, nationwide approach to improving patient safety. This programme is coordinated by Healthcare Improvement Scotland and has brought together NHSScotland, the Scottish Government, the Institute for Healthcare Improvement (IHI), professional bodies and patient representatives in an attempt to significantly reduce adverse events and improve patient safety.[102] Initially, the Scottish Patient Safety Programme focused on acute care, but its coverage has since expanded to maternity and children; mental health; primary care; pharmacy in primary care; improvement support to reduce the risk to patients of Healthcare Associated Infections; and medicines safety. The current phase of the acute adult programme is working to:

- further reduce mortality in Scotland's acute hospitals
- further reduce harm experienced by patients in Scotland's acute hospitals.

In the acute adult programme of the Scottish Patient Safety Programme, Healthcare Improvement Scotland is working to support the implementation of a Scottish Patient Safety Indicator. The indicator was developed following consultation across NHSScotland on the best approach to the measurement of harm in acute healthcare, The Scottish Patient Safety Indicator measures harm arising from:[103]

- cardiac arrest
- catheter associated urinary tract infections (CAUTI)
- falls with harm
- pressure ulcers (Grade 2 – 4).

In its Local Delivery Plan for 2015 to 2016, NHSScotland plans to continue to develop and deliver the Scottish Patient Safety Programme, supporting implementation within NHS boards, through local teams within hospitals, general practitioner (GP) practices, community services, mental health inpatient units and community pharmacies.[104]

6.3.2 Patient safety in NHS boards

All 14 regional NHS boards have a statutory obligation to protect their patients and staff from avoidable harm. These NHS boards hold a number of responsibilities relating to patient safety including to:

- encourage incident reporting by all NHS staff
- create a 'just culture' in which incident reporting is clearly separated from disciplinary processes

- analyse reported incidents and consider information from front-line staff when planning and implementing change
- clarify what is expected of staff after a patient safety incident, and what support is available to deal with it.

NHS England established the National Patient Safety Alerting System, which also alerts NHSScotland to potential risks and provides guidance on potential patient safety incidents. NPSAS alerts are issued following analysis of National Reporting and Learning System (NRLS) data, enabling the identification of emerging patterns. The National Patient Safety Alerting System issues alerts through the Central Alerting System, a web-based cascading system used by NHS England to issue patient safety alerts.

6.3.3 Patient safety culture

One of the responsibilities of NHS boards in the area of patient safety is described as creating a 'just culture' in which incident reporting is clearly separated from disciplinary processes.[105] A 2007 report, *NHS Incident Reporting Culture Extended Study – national summary report*, identified that there was a perceived blame culture in the NHS boards.[106] This was also a theme that emerged from the individual reviews of adverse event management in NHS boards (2012-2014) – where staff disclosed that they 'did not feel safe' reporting on adverse events.[107] Driving cultural change has been described as an area of focus of Healthcare Improvement Scotland and the organisation has acknowledged the significant challenges in encouraging reporting of adverse incidents while separating this from disciplinary procedures. The National Framework (2013) promotes a just and positive safety culture through its overarching principles which include:[108]

- Just culture – individuals are treated fairly. Organisational culture is based upon the values of trust, openness, equality and diversity which encourages and supports staff to recognise, report and learn from adverse events.
- Positive safety culture – avoidance, prevention and mitigation of risks is part of the organisation's approach and attitude to all its activities and is recognised at all levels of the organisation. Decisions relating to the management of adverse events are risk-based, informed and transparent to allow an appropriate level of scrutiny.

6.4 Reporting and learning from adverse events

Healthcare Improvement Scotland is supporting the implementation of the National Framework through national guidance, and is working to support professionals that have been involved in a patient safety incident to be open about what has happened and to discuss the incident fully and promptly with the relevant parties in a compassionate manner. To support this, Healthcare Improvement Scotland has

developed *Learning from adverse events through reporting and review: Being Open in NHSScotland*.[109] The Being Open guidance is currently being piloted in a hospital in Edinburgh.

6.4.1 Developing a national approach to learning from adverse events

There are a number of systems for reporting incidents in Scotland. All NHS Boards set out in policy how adverse events are to be managed and the notification and escalation procedures that should be followed following an adverse event. All adverse events should be reported locally through local management systems. Some adverse events will be required to be reported to national or UK-level systems. These are independent of local adverse event reporting systems; such systems include the Scottish Audit of Surgical Mortality (SASM), the Scottish Surveillance of Healthcare Associated Infection Programme (SSHAIP) and the Medicines and Healthcare Regulatory Agency Yellow Card Scheme.[110] While all of the NHS boards operate their own local adverse event reporting system, there is no national system for collecting all adverse event data in Scotland. There is a national system for collection and analysis of adverse events involving equipment, see http://www.hfs.scot.nhs.uk/services/incident-reporting-and-investigation-centre-iric/adverse-incident-reporting/. Until recently, there was no national definition of an adverse event.

Under the direction of the Scottish Government, Healthcare Improvement Scotland initiated a programme of work in 2012 to develop a national approach to learning from adverse events. This work was intended to ensure that all staff in NHSScotland are supported to effectively manage adverse events, to learn from these events and to allow best practice to be actively promoted across Scotland in order to work towards continually improving the safety of the healthcare system. Healthcare Improvement Scotland established a national programme board to oversee the implementation of a national framework for reporting and learning from adverse events. Following extensive consultation, Healthcare Improvement Scotland published the National Framework in September 2013, *Learning from adverse events through reporting and review: a national framework for NHSScotland*.[108] A second edition of this national framework was published in April 2015, and refines and clarifies areas based on further feedback from key interested and informed parties. A number of tools to support implementation of the framework have been developed in the past two years, and these are available on the Community of Practice website, see http://www.knowledge.scot.nhs.uk/adverse-events.aspx.[111] Other components of this programme have been:

- developing NHSScotland's 'Being Open' principles
- standardising processes of producing adverse event review reports to allow information to be freely shared
- developing mechanisms to share learning across Scotland.[112]

6.4.2 Standardisation of the management of adverse events

The National Framework serves to standardise approaches and processes regarding the management of adverse events. There is currently no national measurement on adverse events. NHS boards are not required to report key performance indicators (KPIs, specific and measurable elements of practice that can be used to assess quality and safety of care) on adverse events and Healthcare Improvement Scotland does not hold national data on all adverse events.

In developing the national approach to learning from adverse events, Healthcare Improvement Scotland undertook a mapping exercise of pre-existing systems and data used by all NHS boards to manage adverse events.[113] Findings from the review included the following:[113]

- NHS boards use stand-alone systems and manual processes to record adverse events, while differing recording processes and standards are in place.
- There appeared to be no common definitions around recording adverse events with NHS Boards recording different information using different classification and categorisation.
- NHS boards use their adverse events applications to report additional data such as risk register, litigation, information governance, dashboards, contacts, complaints, claims, alerts, actions and so on.
- Few NHS boards appear to use a systematic way of sharing learning from adverse events at a local level.
- NHS boards have reported a desire to bring events to a higher level and the learning arising from them, but there is no formal mechanism or platform to support this.
- NHS boards also noted that there is no peer forum of support and learning and that this is an existing gap in the management and learning from significant adverse events.

6.4.3 National Framework for NHSScotland for adverse events

Healthcare Improvement Scotland published *Learning from adverse events through reporting and review: a national framework for NHSScotland* in 2013, followed by a second edition in April 2015.[3] The National Framework provides a clear vision of the national requirements for helping learning through the sharing of experiences, and it sets out a number of actions for Healthcare Improvement Scotland.[108]

The National Framework outlines the actions to be taken when an adverse event occurs and provides consistent definitions and categories of events (in terms of harm). The Framework is designed to maximise the opportunities for NHS boards to share and actively learn from each other in order to put improvements in place. The Framework provides that local policies will define the notification and escalation

procedures that should be followed in the aftermath of an adverse event, while also serving as a guide to promoting a consistent national response. Ultimately, NHS boards remain responsible for determining the action that should be taken following an adverse event.[114] The National Framework:[108]

- requires that when an adverse event (including near misses) happens, the NHS board's electronic adverse event reporting system must be used
- provides the principles on which the national approach is based such as openness, a just and positive safety culture, accountability, teamwork, a systems approach and an emphasis on learning and promoting best practice
- outlines the steps that should be taken to manage adverse events
- defines the roles and responsibilities necessary to support the effective management of adverse events
- seeks to ensure that learning is shared and implemented across the organisation and NHSScotland to improve the quality of services.

The Scottish Government has stated that NHS boards are expected to adopt this framework to improve their local approaches to handling adverse events[115] and NHS boards have committed to reviewing their policies and processes to reflect the National Framework. Following the publication of the National Framework, Healthcare Improvement Scotland began a national programme of work to support its implementation. A number of tools to support its implementation have been developed in the past two years, and these are available on the Community of Practice website. This website has been set up to support care providers to share learning for improvement following adverse event reviews.[116] To date, the focus on developing a national approach to learning from adverse events has been on the acute sector. However, Healthcare Improvement Scotland's focus will now be in considering how to support implementation within primary and community services and how to support working towards integrating arrangements across health and social care.[3]

6.4.4 Adverse event reporting requirements of NHS Boards to external agencies

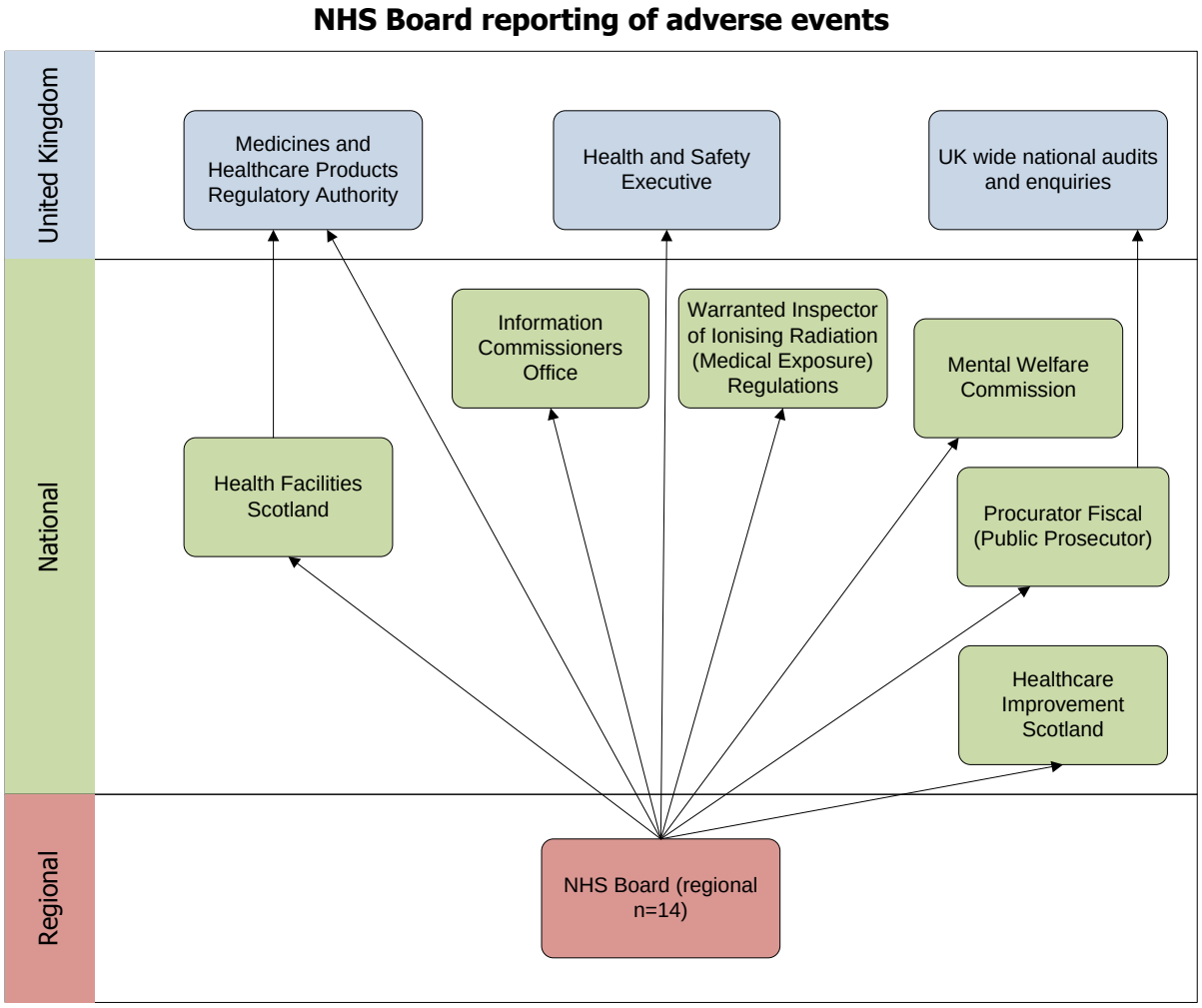
The National Framework states that specific events must be reported by NHS boards to external regulators at a national or UK level, listing a number of agencies. Table 6 presents the agencies to be reported to and the categories of events to be reported.

Table 6. Reporting to external agencies

Agencies to be reported to:	Events to be reported:
Health and Safety Executive	Deaths and injuries due to work related accidents
Incident Reporting and Investigation Centre (IRIC)	Events involving health, social care, estates and facilities equipment
Medicines and Healthcare Products Regulatory Agency (MHRA)	Events relating to blood, adverse drug reactions, defective medicines and counterfeit medicines via the Yellow Card Scheme
Healthcare Improvement Scotland	Suicides of individuals in contact with mental health services
Procurator Fiscal (public prosecutor)	Deaths associated with medical or dental care
Healthcare Quality Improvement Partnership (HQIP)	Relevant information to UK-wide national audits and enquiries
eHealth Division within Scottish Government/Information Commissioners Office	Information governance events
Warranted Inspector for IR(ME)R	Ionising Radiation adverse events
Mental Welfare Commission for Scotland	Serious crimes (homicides, serious assault, serious sexual assault) by an individual who is receiving care from Mental Health or Learning Disability Services

Figure 6 below presents the agencies to which the NHS boards are required to report adverse events data. Regarding performance of healthcare professionals, each NHS board has policies and procedures in place to handle performance concerns, which can be reported to the regulators of healthcare practitioners.[108] It is important to note that the national and UK agencies may also report incidents to another, for example Health Facilities Scotland (HFS), a division of NHS National Shared Services, works with the Medicines and Healthcare Products Regulatory Agency, notifying the Medicines and Healthcare Products Regulatory Agency of each adverse incident reported in Scotland and the results of any investigations.[117]

Figure 6: Each NHS board is required to report to a number of agencies, depending on the type of adverse event that has occurred*



Note: Not all reporting flows may be shown[13]

One of the main recommendations from Health Improvement Scotland's review of pre-existing systems and data used by all NHS boards to manage adverse events(113) was that discussion is required to explore how local systems might be aligned to support a national system for sharing learning from adverse events.(113) This would involve a national adverse events 'information, analysis, learning, feedback and action' system that could enable identification of trends at a national level, and enable learning to be shared across NHSScotland. However, a decision has been taken to cease work on developing a national system at this time, although the development and implementation of such a system remains a longer-term aspiration of Healthcare Improvement Scotland. From discussions with Healthcare

[13] All NHS boards whether regional or special need to have adverse event reporting processes in place. Some special boards, for example, the National Waiting Times Centre and the State Hospital are clinical and have very similar systems to the regional boards. Other special boards, for example, Health Scotland don't have patient facing components but still report to the Information Commissioners Officer or the Health and Safety Executive.

Improvement Scotland as part of this review, it was evident that its current priorities are developing a national approach to learning from adverse events, ensuring that the local systems operating at board level are working well and facilitating greater sharing of learning from adverse events.

6.5 Management of complaints and claims

The healthcare regulatory landscape in Scotland continues to change at the time of this review. Ongoing or upcoming developments relevant to patient safety include developments on introducing a statutory duty of candour, an offence of wilful neglect and no-fault compensation.[118]

6.5.1 Complaints

NHS boards are directly responsible for collecting, monitoring and reporting of complaints received about services they provide. All NHS boards have local policies and processes in place to handle and learn from feedback, comments, concerns and complaints which have been outlined in the national framework.[108] In conducting a review of existing adverse event systems, Healthcare Improvement Scotland found that of 13 regional NHS boards, 10 were using their adverse events reporting systems to record complaints data.[113] In its report, *Listening and Learning: how feedback, comments, concerns and complaints can improve NHS services in Scotland*, Healthcare Improvement Scotland sets out measures designed to help NHSScotland improve how it listens to what people say about their experiences of using healthcare services.[119]

The National Health Service (Scotland) 1978 Act[120] sets out directions relating to complaints procedures, including the monitoring of complaints. Under the Act, each NHS board shall prepare reports at annual intervals for the purposes of:

- monitoring the arrangements made for dealing with complaints
- considering the volume of complaints
- monitoring the remedial action taken following the investigation of complaints.

Under these directions, each NHS body is to publish a report on its dealings with complaints within its annual report, which is to be sent to the Scottish ministers and Healthcare Improvement Scotland (where appropriate). At the national level, Information Services Division Scotland collects statistics on the number and type of complaints made to NHS boards and family health service practitioners.

Furthermore, the Patient Rights (Scotland) Act 2011 aims to improve patients' experiences of using health services and to support people to become more involved in their health and healthcare. Under the Act (2011) patients are encouraged to give feedback and or raise concerns or complaints about their healthcare experience. The

NHS body must consider any feedback, comments, concerns or complaints received in relation to their service with a view to improving the performance of its functions

6.5.2 Medical negligence claims

Medical negligence claims are handled by the Central Legal Office of the NHS National Shared Services (NHS NSS). Through its review of the existing adverse event systems, Healthcare Improvement Scotland identified six regional NHS boards that were using their adverse events systems to report claims data.[113] Scotland operates a fault-based compensation scheme for medical negligence claims, hence compensation is based on showing that the healthcare provider was negligent. The Scottish Government is currently considering implementing a no-fault compensation scheme in Scotland for injuries resulting from clinical treatment (that is to say, there would be no need to establish that any individual was negligent, although causation would still need to be established).[114]

6.6 Coordination of patient safety data and intelligence

The *NHSScotland Information Assurance Strategy* (2011-2015) – developed from a commitment within the *eHealth Strategy* (2011-2017)[121] – reflects the increasing value of information to the Scottish NHS and the collaborative way in which it is used and shared.[122] This strategy acknowledges that NHSScotland is transforming the way it uses information, sharing considerable amounts of data and joining up services and systems on an unprecedented scale. The Scottish Government is enabling the sharing of intelligence through the *Health and Social Care Information Sharing: A Strategic Framework 2014-2020* [123] and the *National Information and Intelligence Framework for Health and Social Care for Scotland: 2012-2017*.[124] The National Information and Intelligence Framework is outlined in section 6.17. Healthcare Improvement Scotland acknowledged that there are significant challenges in relation to sharing and using data across different organisations.[125] This finding correlates with a study of medical negligence claims (2012) which found that while there appeared to be mechanisms for institutional learning from errors within individual clinical teams, there was less opportunity for institutional learning across the NHS boards.[126]

Through its review of adverse event management in the NHS boards, Healthcare Improvement Scotland found substantial variation in the processes of managing adverse events across NHSScotland, making it difficult to share comparable information.[118] In the National Framework, Healthcare Improvement Scotland acknowledged that there were a number of challenges to implementing a consistent national approach to learning from adverse events, with one challenge being how to collate, analyse and learn from adverse events at a national level, and how to look to

integrate other data, such as from complaints and claims to inform improvements.[108]

The revised National Framework published in April 2015 and supporting guidance seeks to remedy or mitigate these challenges. The most recent National Framework provides a standardised approach across specialities and services, enabling better coordination and sharing of patient safety data and intelligence. Guidance documents such as *Data redaction and standardised adverse event review reports* will enable the sharing of appropriate learning, while safeguarding confidentiality for the different parties involved.[127]

6.6.1 National Information and Intelligence Framework (NIIF) for Health and Social Care for Scotland: 2012-2017

The Scottish Government published the National Information and Intelligence Framework (NIIF) for Health and Social Care for Scotland: 2012-2017. The National Information and Intelligence Framework was developed and agreed by the major organisations and stakeholders across the Scottish health and social care system. It represents a concerted effort in working to ensure that information and intelligence is developed and used in a coordinated and coherent manner across Scotland. The National Information and Intelligence Framework recognises that information and intelligence plays a vital role in producing high-quality care outcomes for citizens and for effective and efficient decision-making across health and social care services.[124] At the core of the framework is that information and intelligence is seen as a shared resource and can be used by many organisations. A shared services agenda serves to support the National Information and Intelligence Framework to ensure that resources such as datasets and information intelligence are available across services and inefficiencies or duplication are removed. The National Information and Intelligence Framework prioritises work in four key areas:

- national data and information collections
- present evidence for maximum impact
- develop and maintain the information evidence base efficiently
- maximise access to and use of intelligence and evidence.

Stakeholder view – the National Information and Intelligence Framework (NIIF) for Health and Social Care in Scotland: 2012-2017[124]

'Of particular importance to the quality improvement agenda is greater availability of 'real-time' data to enable rapid feedback and intelligence.'

6.6.2 Health Improvement Scotland – sharing intelligence

Healthcare Improvement Scotland has developed an organisational Business Intelligence Strategy (2014-2017). The aim of the strategy is to ensure that Healthcare Improvement Scotland, working with partner organisations, is making best use of data and information to improve patient care.(125) The initial priority of Healthcare Improvement Scotland's 'external facing' work as part of this strategy is better sharing and use of data about acute services by different national organisations to inform scrutiny functions. Under its strategy, the 'sharing intelligence' agenda is a joint enterprise involving Healthcare Improvement Scotland, Public Health and Intelligence in NHS National Shared Services, NHS Education for Scotland, Care Inspectorate and Audit Scotland.

Healthcare Improvement Scotland outlines that it concentrates its scrutiny and improvement support where most needed and is working to take a more systematic approach to the sharing of intelligence with other informed and interested parties.(128) Healthcare Improvement Scotland draws on a range of data and intelligence available to inform its scrutiny activities. Such data may include hospital performance data, patient experience surveys, patient complaints, mortality metrics, Healthcare Associated Infections, patient safety indicators and so on. Going into the future, Healthcare Improvement Scotland has outlined its intention to work more closely with other scrutiny agencies, especially in multi-agency reviews and the sharing of intelligence.(97)

As outlined previously, the NHS boards are required to report events to a number of different national and UK agencies. As there is no national system for adverse events, this creates a situation where the NHS boards are all independently reporting to various agencies at national and UK level.

6.6.3 Sharing Intelligence for Health and Care Group

In 2014, the establishment of a Sharing Intelligence for Health and Care Group was proposed, to be chaired by staff members from Healthcare Improvement Scotland and NHS Education for Scotland.[14] The intended purpose of the group is to bring together the key audit, inspection and training bodies of the health and social care system in Scotland to review their combined intelligence and information on the quality and safety of health and care, and to identify potential problems or concerns that may require further investigation. Initially, the work of the group is expected to focus on NHS healthcare services in Scotland. Membership of the group includes Audit Scotland, Care Inspectorate, Healthcare Improvement Scotland, Mental Welfare Commission for Scotland, NHS Education Scotland and the Public Health and

[14] NHS Education for Scotland (NES), a special NHSScotland board, is the education and training body that ensures patients and their families receive the best healthcare possible from well training and educated staff.

Information Services Division of NHS National Shared Services, with other bodies attending the group where appropriate.[129]

The group will provide a forum to share data and information in order to build as comprehensive a picture as possible about the quality of care in NHS boards in Scotland and to use this intelligence to determine how Healthcare Improvement Scotland and its other partner organisations can work to support scrutiny and improvement.

6.6.4 Collating data in the NHS boards

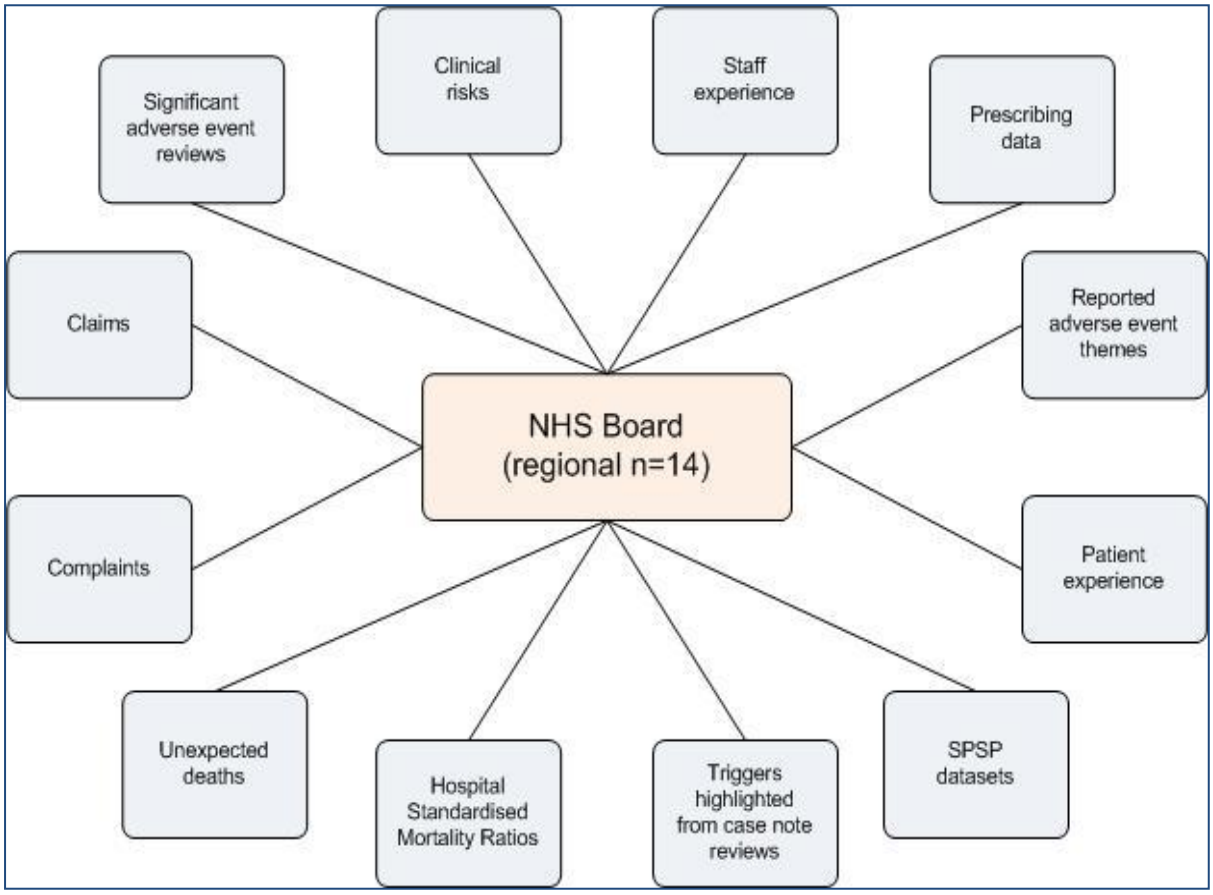
One of the tools developed by Healthcare Improvement Scotland to support implementation of the framework is 'Questions everyone should ask about safety' which asks healthcare providers if they receive the right information.[109] This tool asserts that:

> *'Learning from all sources of data together provides an organisation with a true reflection of where things are going wrong and what is needed to prevent minor events from becoming more major and serious adverse events.'* [109]

According to this tool, 'good' looks like an NHS board having an integrated approach to governance, drawing from a number of sources. The tool suggests the different data sources that could be drawn upon; these data sources are represented in Figure 7. The tool explains that 'good' also involves an NHS board scrutinising data effectively to assure that lessons learned are implemented, where relevant, throughout the organisation and not just the specific location where the adverse event occurred and that improvements are planned and carefully monitored. [109]

Healthcare Improvement Scotland has documented good practices relating to identifying themes for informing priority areas for improvement by analysing different data. NHS Fife has introduced an overarching 'reducing harm' action plan to take an organisation-wide approach to focusing on patient safety and quality improvement issues. Information is collated from a variety of sources such as adverse event reviews, complaints, medical and surgical profiles, morbidity and mortality data and Scottish Patient Safety Programme measures. A number of other NHS boards have developed dashboards which link data from adverse events, complaints and claims. The data can be presented at ward, directorate and organisational level to look at emerging themes.[118]

Figure 7. Data sources that a regional NHS board can draw upon[109]



Note: SPSP = Scottish Patient Safety Programme.

6.7 Sharing learning from adverse events

Following Healthcare Improvement Scotland's review on the pre-existing systems for adverse events and an options appraisal process, it was agreed that a network of learning portals (Internet sites) was the preferred option for capturing and sharing learning and improvement at a national level. Following this, Healthcare Improvement Scotland began working with the NHS regional boards to develop a national adverse events 'Community of Practice' to support sharing of good practice and learning from adverse-event reviews nationally. Healthcare Improvement Scotland has also agreed with the Procurator Fiscal (public prosecutor) to share learning points from investigations of deaths more widely across Scotland, to facilitate national learning and improvement. Both of these mechanisms are detailed below.

6.7.1 Managed community of practice

Healthcare Improvement Scotland has been working with the NHS regional boards to develop the national adverse events 'Community of Practice' which will serve to support sharing of good practice and learning points from adverse-event reviews nationally. The Community of Practice includes both an online site (www.knowledge.scot.nhs.uk/adverse-events.aspx) with a virtual network of members and complementary network meetings which will take place twice a year. The Community of Practice has a number of aims including:

- share key learning points from adverse-event reviews and the resulting process or service improvements
- support national discussion of key or topical issues.

6.7.2 Sharing learning points from death investigations

Healthcare Improvement Scotland has agreed with the Procurator Fiscal (public prosecutor) to share key learning points from investigations into deaths more widely across NHSScotland to facilitate learning and improvement. National learning summaries will include background to the case, key learning points for NHSScotland, improvements made by the NHS regional board; and actions for NHSScotland.[(95)] One-page national learning summaries will be shared on the adverse events Community of Practice website as well as through other channels such as the Scottish Patient Safety Programme networks. In the longer term, Healthcare Improvement Scotland will consider how to maximise the use of these learning summaries, for example, how to make them searchable. Healthcare Improvement Scotland is also considering the development of a key performance indicator on the completion of national learning summaries.

6.7.3 Current developments

In August 2014, the Cabinet Secretary for Health and Wellbeing announced Healthcare Improvement Scotland plans to introduce new comprehensive assessments of the quality of healthcare in Scotland.[(130)] Since 2014, Healthcare Improvement Scotland – through its quality of care reviews – has been working on a new approach to assessing the quality of care provided in Scotland. An Outcomes Assessment Group has been established and has produced a paper outlining a draft framework for measuring and monitoring the quality of care.[(130)] In this paper, the draft framework outlines what 'good' quality of care might look like and what evidence might be available to provide assurance of this. For example, in reviewing safety, 'good' might be whether the organisation demonstrates an effective patient safety and learning culture and this would be supported by evidence of adverse event management policies and procedures.[(130)] The aim of the quality of care reviews is to ensure that:

> 'People are confident that every part of our health and care system delivers high-quality care and are assured that processes are in place to ensure continuous improvement.'

Scotland – summary and key learnings

- There is no national system for adverse event reporting in NHSScotland at the time of this review. NHS regional boards use stand-alone adverse event reporting systems for managing adverse events. Therefore, the onus is on the NHS boards to report specific adverse event data to national and UK agencies.
- The focus in Scotland at the time of preparing this reivew is not the *measurement* of adverse events, but on the production and sharing of learning from adverse events and the conversion of this learning into improvements to patient care.
- The NHS boards use their existing reporting systems to different degrees; some NHS boards use their adverse event reporting systems for reporting additional data such as complaints and claims data.
- Healthcare Improvement Scotland has led the development of a national approach to learning from adverse events through reporting and review. From this, Healthcare Improvement Scotland has published a refreshed 'Learning from adverse events through reporting and review: a national framework' designed to maximise the opportunities for NHS boards to share and learn from each other. The National Framework supports a 'just' and 'positive safety culture'.
- A major priority for Healthcare Improvement Scotland is to ensure that the local adverse event reporting systems are functioning effectively and efficiently and are capturing, analysing and reporting data.
- Healthcare Improvement Scotland is supporting the sharing of learning from adverse events, leading the development of a national adverse event 'Community of Practice' to share learning and to support the development of national learning summaries.
- Healthcare Improvement Scotland has indicated that the development of a national adverse events 'information, analysis, learning, feedback and action' system is an aspiration and that such a system would reduce duplication of effort in reporting (for example, to regulatory agencies) and provide a rich central source of data for analyses and consequently learning.
- There is currently no national measurement around adverse events and Healthcare Improvement Scotland does not hold any national adverse events data.
- The Scottish Government has developed a new strategic framework for sharing data and intelligence on patient safety, covering the years 2014 to 2020.[(123)]

7. Conclusion and summary of findings

7.1 Overview of patient safety and learning systems in jurisdictions

This international review has focused on documenting the existing patient safety incident reporting systems across four jurisdictions. Across the jurisdictions reviewed, there was variation between the incident reporting systems in relation to scope, reporting, governance and legislation underpinning the systems. The importance of involving patients, service users and the public has been recognised in Denmark and England where the public can report to the system. A reporting and learning system is just one of a number of resources that can be utilised for monitoring patient safety incidents. For a comprehensive picture on patient safety there needs to be triangulation of existing and new data sources of patient safety intelligence.[6] It is imperative that follow up work through investigating incidents and subsequent dissemination of findings is undertaken in order to learn lessons from incidents and prevent their future occurrence. It is not enough to merely report to the system. The main objective of all the reporting systems examined in this review is to learn from past mistakes. Putting in place appropriate mechanisms for disseminating findings back to the local level, where the knowledge can have the most impact is crucial for the management of patient safety incidents. All the systems reviewed have undergone updates and improvements since their inception. The systems in Denmark and England have formerly evaluated their reporting systems to examine the impact the system has had on patient safety reporting. In Denmark, the evaluation found that there was a positive patient safety reporting culture, where 85% of physicians and 89% of nurses reported the adverse events that they were involved in. [5] In England, the evaluation of the NRLS system identified a number of areas for improvements to the system including enabling easier and more timely reporting and providing more targeted feedback to organisations.[6]

7.1.1 Reporting and learning systems for patient safety incidents

The national, provincial and regional adverse event reporting systems in place in Denmark, England, British Columbia in Canada, and Scotland provide valuable sources of data that can be utilised for learning, improvement and triggering action where patient safety is at risk.

In Scotland there is no national system in place, although a national framework for learning from adverse events through reporting and review has been developed by Health Improvement Scotland. NHS regional boards in Scotland use stand-alone adverse event reporting systems for managing adverse events.

The agency responsible for the reporting systems varies across the four regions and countries reviewed. In England, the Patient Safety Domain of NHS England has responsibility for the oversight of the National Reporting and Learning System (NRLS). The STEIS system is a separate system and is managed by the Department of Health in England. The adverse event reporting systems in Scotland are managed by local NHS boards, under the guidance of Healthcare Improvement Scotland, which leads on a range of patient safety programmes. In Denmark, the Danish National Agency for Patients' Rights and Complaints – an independent state institution under the Ministry of Health – is responsible for the Danish Patient Safety Database. The BC PSLS is hosted by the Provincial Health Services Authority, however, it is governed independently by a 'Central Office' which manages operations and provides system support.

7.1.2 Mandatory reporting and the legal and regulatory framework

There are different approaches in place to ensure regulation of patient safety reporting systems. In England, it is mandatory that all 'serious incidents' are reported to STEIS and the NRLS. NHS organisations within England and Wales are obliged to report all other patient safety incidents to the NRLS, but reporting is voluntary for professionals. In Scotland, reporting by healthcare professionals is not mandatory but the National Framework (2015) states that specific events must be reported by local NHS boards to external regulators at a national or UK level (such as NRLS). In Denmark, adverse event reporting by healthcare professionals to the Danish Patient Safety Database is mandatory and is enshrined in legislation (Act on Patient Safety, 2004). In British Columbia, healthcare organisations are required to report serious events to the Minister for Health, immediately after the adverse event occurs. Reporting onto BC PSLS is voluntary for healthcare professionals.
As users of adverse event data, accreditation and regulatory bodies also promote the adverse event reporting agenda. The accreditation body in Canada makes requirements on adverse event reporting systems and guidance for those seeking accreditation. In England, the NRLS serves as the channel through which NHS organisations fulfil their statutory obligations to notify the Care Quality Commission (CQC) of adverse events. Reporting adverse events is also supported by the accreditation systems for hospitals in Denmark.

7.1.3 Reporting to adverse event systems

Across all regions and countries reviewed, healthcare professionals are encouraged to report adverse events, and in some cases healthcare professionals must by law report adverse events. In Denmark, front-line personnel in hospitals and in the primary care sector are statutorily obligated to report adverse events to a national reporting system. All healthcare professionals across the Canadian province of British Columbia, operational leaders and specialised staff (such as risk managers) can report to the BC PSLS. In England, any healthcare staff member can report a patient

safety incident to the NRLS. Incident reports are submitted to the NRLS by NHS organisations in England and Wales and can also be submitted by other providers such as GPs and community pharmacies. Healthcare professionals in Scotland can also report to the NHS boards.

Reports on patient safety incidents submitted by patients and their families provide a rich, alternative perspective. In Denmark, patients and patients' relatives can also report into the system. BC PSLS has since expanded the variety of people who can report through Patient's View; a version of BC PSLS that captures patient and family perspectives on safety. Patients, their relatives, carers and the public can also report to the NRLS in England via an e-form on its website.

The approach to anonymity for those reporting adverse events also varies across the jurisdictions. Reporting to BC PSLS in British Columbia, NRLS in England, the Danish Patient Safety Database and in three out of 14 NHS regional boards in Scotland can be anonymous. Within England's NRLS, anonymity is enforced by the system operator while in British Columbia and Denmark, reporting professionals can chose to remain anonymous but this is discouraged as identifying oneself is seen as an expression of confidence in the 'just culture' and the reporting system.

7.1.4 Coverage

In British Columbia and Denmark, the reporting systems have expanded to allow reporting from private healthcare providers. In Canada, the BC PSLS system was initially focused on acute care, however, it now works across the care system from hospitals to homecare and community services. In British Columbia, The Hospital Act (1996),[30] requires that the administrator in a public hospital and the licensee of a private hospital to report to the minister each serious adverse event immediately after the adverse event occurs and in the form and manner specified by the minister. Private healthcare organisations in England and Scotland do not report on adverse events.

7.1.5 Classification and taxonomy in place

Efforts to standardise adverse event reporting were seen across the four jurisdictions. Since 2014, Denmark has begin to use a new customised Danish classification system that is similar to WHO's Conceptual Framework for the International Classification for Patient Safety (ICPS), but with definitions that are more appropriate to the Danish context. A modified version of the ICPS with expansion to reference other taxonomies and tools is in use in BC PSLS. England uses its own classification system, different from the ICPS but closely aligned to it. In Scotland, the National Framework (2015) provides consistent definitions on adverse events and categories of events.

7.1.6 Patient safety culture and legislation

The concept of a 'just culture' emerged across all the jurisdictions reviewed. In Scotland, the National Framework (2015) promotes a just and positive safety culture through its overarching principles. In British Columbia, creating a just culture is an area of focus for the Ministry of Health and there is legislation in place (The Apology Act, 2006) that promotes an open and non-punitive patient safety culture, allowing healthcare providers to apologise to patients and families when disclosing an adverse event, without concern that an apology could be used in legal proceedings. In British Columbia, The Evidence Act (1996) [21] provides legislation to ensure that the discussion and analysis of medical staff committees and specially constituted quality committees cannot be released in legal proceedings. In Denmark, there is evidence of strong legislation in place which serves the 'just culture' concept. The Act on Patient Safety in the Danish Healthcare System (2003) seeks to drive the reporting of, and learning from, adverse events by protecting people who report incidents, rather than prosecuting those who do not. The Act aims to deliver a cultural shift 'from blame and shame to need to know'.[5]

In England, a statutory duty of candour is in place since April 2015 for all health and social care providers regulated by the CQC. It places a legal duty on hospital, community and mental health trusts to inform patients, and to apologise to patients, if there have been mistakes in their care that have led to significant harm. In Scotland, plans to implement a statutory duty of candour within NHS Scotland are ongoing.

7.2 Coordination of patient safety intelligence

The importance of the coordination of patient safety intelligence is recognised in the four countries and regions examined as part of this review. In Denmark, the Danish National Agency for Patients' Rights and Complaints has three separate data sources comprising the adverse event reporting system (the patient safety database), the compensation system and the complaints system. The Danish Patient Safety Database is intended to support patient safety by collecting, analysing and disseminating knowledge on adverse events, thereby creating systematic learning. Features of the DPSD include mandatory, sanction-free reporting.

The National Agency for Patient's Rights and Complaints, as owner of the Danish Patient Safety Database, is required under The Health Care Act (2010) to communicate learning from the system nationally. In an effort to communicate learning from the system, the agency and the Danish Health and Medicines Authority have a collaborative relationship where a cooperative agreement exists between the two parties. The agency is obliged by legislation to share information on incidents

with the Danish Health and Medicines Authority, which has direct access to the adverse event reporting system and hence, can identify patient safety issues. The Danish authority uses the information from adverse events to generate standards and guidance.

Within British Columbia, there is no direct sharing of patient safety intelligence from the BC Patient Safety and Learning System (PSLS) to the professional regulatory colleges. The BC PSLS is a web-based patient safety event reporting, learning and management tool used by care providers across all healthcare organisations in British Columbia to identify, analyse and trend safety concerns. The BC PSLS encompasses a collection of online modules and tools. The modules include safety events, complaints, claims, safety alerts, risk register and recommendations. Individual facilities determine the appropriate level of data sharing with external bodies such as the regulatory colleges where appropriate. A mandatory reporting requirement of hospital disciplinary measures is imposed by legislation in British Columbia. In terms of litigation in British Columbia, information collected for quality review purposes is protected by legislation from use in legal or regulatory proceedings, provided the legislative requirements for protection from disclosure are met by the health authorities. Information arising from the reporting and managing of complaints is generally not protected. Patient safety events that are reported in BC PSLS and identified as potential claims may be reported separately to the Health Care Protection Program by health authority risk managers as part of the claims-handling process.

There is a voluntary participation agreement in place between the health authorities and the BC PSLS in relation to the provision of data. All data submitted into BC PSLS is managed and secured in a central database by Central Office. Health authorities 'own' and control their own data while Central Office is custodian of the data, using it for analysis, trending and reporting.

Other jurisdictions, such as England, have data sharing agreements in place. NHS organisations contracted under the NHS Standard Contract are contractually required to report serious incidents in line with the Serious Incident Framework. All serious incidents must be reported to the National Reporting and Learning System (NRLS) and to the Strategic Executive Information System (STEIS) to facilitate performance monitoring, trend analysis and shared learning. The NRLS has a number of data sharing agreements, for example, with the CQC, the Medicines and Healthcare Products Regulatory Agency and Public Health England. There is an automated feed of data from the NRLS to the CQC where the CQC receives all incident level data that is identifiable at organisation level. CQC Regulations 2009 require that NHS bodies must submit certain notifications to the NRLS. These notifications are then shared with the CQC under an information sharing agreement and include certain deaths of

people using the service. Data collected from the NRLS is also triangulated with other data and information as part of risk management and clinical review. For example, the Patient Safety Concern process uses NRLS data to identify patient safety concern issues. If the Patient Safety Concern process finds that an incident and or concern is part of a wider pattern, it is escalated to the relevant nominated contacts and confirmation is sought that appropriate investigation and mitigating actions are underway.

Complaints and claims data also form part of the coordination of patient safety intelligence in the four countries and regions reviewed. In England, complaints are directed to the individual NHS organisations involved. In Scotland, NHS boards are directly responsible for collecting, monitoring and reporting of complaints received in relation to their services. Healthcare Improvement Scotland found that of 13 regional NHS boards, 10 were using their adverse events reporting and learning systems to record complaints data. Medical negligence claims are handled by the Central Legal Office of NHS National Shared Services in Scotland. Healthcare Improvement Scotland identified 6 regional NHS boards that were using their adverse events systems to report claims data. The National Agency for Patient's Rights and Complaints in Denmark is responsible for handling patients' complaints and has also published learning from its complaints and compensation cases systems. In British Columbia, the BC PSLS 'complaints module' allows for complaints data to be aggregated and analysed to identify trends in care quality concerns.

7.3 Sharing of learning and use of information

7.3.1 Patient safety alerts

Adverse event reports, when submitted onto the system provide an opportunity to take immediate action, particularly when there is a possibility to inform the system on how to address or mitigate an immediate risk to patient safety. All of the locations reviewed use their systems to deploy safety alerts.

The National Patient Safety Alerting System, managed by NHS England Patient Safety Domain, alerts NHS organisations in England, Wales and Scotland to potential risks and provides guidance on potential patient safety incidents. Alerts are issued following analysis of NRLS data, enabling the identification of emerging patterns.

7.3.2 Sharing of learning

All four jurisdictions work to share learning through various forums: BC PSLS produces a number of reports, such as monthly reports for subscribers, annual reports and the articles published on the BC PSLS blog.[31] The blog has been a powerful tool in sharing information on how people are using data and the system to improve patient safety.

In Denmark, the National Agency for Patient's Rights and Complaints is developing a Knowledge Platform' that will include experience from its three main data sources (adverse events, complaints and compensation cases) as well as knowledge on solutions to specific risks through action plans from the Danish Patient Safety Database, contact information and international evidence.

The NHS England has developed a website tool called 'My NHS' that allows health and social care providers to compare on a range of outcomes.

In Scotland, Healthcare Improvement Scotland has developed an adverse event 'Community of Practice' with the aims of sharing key learning points from adverse event reviews and the resulting processes or service improvements, and supporting national discussion of key or topical issues.

7.4 Future developments

In all the regions and countries reviewed, there are considerable future developments under way in terms of patient safety surveillance. NHS England is working to redevelop its patient safety surveillance system by updating its National Reporting and Learning System (NRLS) in order to expand its functions and potentially consolidate it with other systems. One such system being considered is the Strategic Executive Information System (STEIS) as duplication between the STEIS and NRLS is evident.

Healthcare Improvement Scotland is leading the development of a national strategic approach to adverse events in order to ensure that all staff in NHSScotland are supported to effectively manage adverse events, to learn from these events and to allow best practice to be actively promoted across Scotland in order to work towards continually improving the safety of the healthcare system.

In Denmark, the National Agency for Patient's Rights and Complaints has outlined its intention to enter into relationships with key informed and interested parties who have an in-depth knowledge of the context in which patient safety activities are to be implemented. Through these relationships, the agency's rich source of data and intelligence will be able to be exploited more effectively.

In British Columbia, BC PSLS Central Office is exploring new opportunities to expand the use and availability of PSLS data. For example, BC PSLS is working with the Canadian Institute for Health Information to pilot the electronic transfer of medication data from BC PSLS to the medication module of the National System for Incident Reporting.

7.5 Next steps in the development of recommendations on the coordination of patient safety intelligence in Ireland

The first stage of the project on developing a set of recommendations for the coordination of patient safety intelligence in Ireland for the Minister for Health is now complete. The next stage of the process is to undertake an 'As Is' analysis to document existing sources of patient safety intelligence in Ireland as outlined below.

Stage 1:	International review of patient safety surveillance systems	☑
Stage 2:	As Is' analysis documenting existing sources of patient safety intelligence in Ireland	☐
Stage 3:	Convening of an advisory group	☐
Stage 4:	Development of recommendations for a the coordination of patient safety intelligence in Ireland	☐

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Appendices

Appendix 1- Previously published documents referenced throughout this review

Title	Author/Source	Year published	Background/purpose of the document
WHO Draft Guidelines for Adverse Event Reporting and Learning Systems[8]	World Alliance for Patient Safety	2005	The World Alliance for Patient Safety is a global effort launched by the WHO to galvanise and facilitate efforts by all Member States to make healthcare safer. These draft guidelines introduce adverse event reporting and focus on reporting and learning to improve the safety of patient care.
National Reporting Systems for Patient Safety Incidents – A review of the situation in Europe[6]	Persephone Doupi and the National Institute for Health and Welfare, Finland	2009	The purpose of this report, undertaken by the Finnish Working Group on Patient Safety, was to investigate the experiences of other European countries with national level patient safety reporting and monitoring systems, to analyse the data and provide information that would be meaningful in supporting the decision making process at a national level. The key purpose was to determine whether it is worth investing in implementing a national reporting system and if yes, what features it should have.
Information Model for Patient Safety Incident Reporting Systems (Summary Report of the Expert Review Meeting)[10]	World Health Organization	2012	Summary report of the expert review meeting held in Tokyo in September 2012. The specific objectives of the meeting were to: ▪ Share experiences and methodologies on the analysis of incident reports ▪ Discuss the advantages and challenges for seeking comparability of patient safety reporting systems ▪ Review progress on research project for minimal common template for patient safety incident reporting.
The measurement and monitoring of safety[11]	The Health Foundation, UK	2013	This report draws together academic evidence and practical experience to produce a framework for safety measurement and monitoring. The authors have synthesised this evidence and proposed a single

Title	Author/Source	Year published	Background/purpose of the document
			framework that brings together a number of conceptual and technical facets of safety. The framework provides a starting point for discussions about what 'safety' means and how it can be actively managed.
Patient safety in practice – How to manage risks to patient safety and quality in European healthcare[12]	HOPE – European Hospital and Healthcare Federation	2013	Report on the European Hospital and Healthcare Federation's (HOPE's) exchange programme – a four week training period intended for hospital and healthcare professionals with managerial responsibilities.
Key findings and recommendations on reporting and learning systems for patient safety incidents across Europe[7]	Reporting and learning subgroup of the European Commission. Patient Safety and Quality of Care Working Group (PSQCWG)	2014	This report serves as a 'catalogue' of how Member states with established reporting systems have chosen to organise their systems.
Preliminary Version of Minimal Information Model for Patient Safety (Working Paper)[13]	World Health Organization	2014	This report is the result of a project coordinated by the World Health Organization (WHO) Patient Safety Programme in 2011 and 2012. The project builds on a longer-term WHO programme with important milestones including the Draft Guidelines for Reporting systems and the Conceptual Framework for the International Classification of Patient Safety. The purpose of a minimal information model for patient safety is to strengthen effective reporting by identifying the key data features that can provide minimal meaningful learning.

Appendix 2- Comparison of characteristics and approaches to patient safety incident reporting

Characteristics/approach	British Columbia, Canada	Denmark	England	Scotland
System(s) in operation				
Is there a national system for patient safety incident reporting?	No	Yes	Yes	No
System(s) in operation	BC PSLS	DPSD	NRLS	Independent systems
When was the system established?	2008	2004	2003	n/a
Legal/regulatory framework				
At what level does this system operate?	Provincial	National	National and local	Regional
Is there no-fault compensation in place?	No	Yes	No	No
Are there statutory requirements for organisations to act on adverse event (AE) reports?	No	Yes	No	No
Features of the system				
Can private service providers report into the system?	Yes	Yes	No	n/a
Are healthcare professionals protected from sanctions when reporting an adverse event (AE)?	No	Yes	No	No
Reporting onto the system				
Who can report onto the system?	Healthcare professionals (HCP)	Private service providers, HCPs	HCPs, patients and the public	HCPs
Can reporting be done anonymously?	Yes	Yes	Yes	3/14 NHS boards
Is reporting onto the system mandatory for professionals (P) and/or organisations (O)?	No	Yes (P)	Yes (O)	No
Definitions and taxonomy				

Characteristics/approach	British Columbia, Canada	Denmark	England	Scotland
Is there a national definition for an adverse event/patient safety incident?	No	Yes	Yes	Yes
Is the WHO International Classification for Patient Safety (ICPS) in use?	Yes, a modified version.	Yes, a modified version.	No	No
Disclosure				
Are healthcare professionals encouraged to disclose adverse events to patients?	Yes	Yes	Yes	Yes
Other data in the system				
Are claims data held within the reporting system?	Yes	No	No	Some NHS boards
Are complaints data held within the reporting system?	Yes	No	No	Most NHS boards
Are Safety Alerts reported/produced from the system?	Yes	Yes	Yes	2 NHS boards
Is there a mechanism for recording and tracking recommendations in the system?	Yes	No	Yes	No
Public reporting				
Are national statistics on adverse events made publically available?	Yes	Yes	Yes	No
Sharing learning				
Is there a forum for sharing learning that has emerged from adverse event analyses?	Yes	Yes	Yes	Yes
Coordination of data and intelligence				
Are data sharing agreements employed?	Yes	Yes	Yes	-
Is data shared with special interest groups e.g. pressure ulcer?	Yes	Yes	Yes	Planned
Is data shared with the health and social care regulator(s)	No	Yes	Yes	n/a

Appendix 3- Main structures in the British Columbia health sector (131)

Body	Function
Ministry of Health	Responsible for establishing expectations and target outcomes for health authority performance; monitoring and evaluating health authority performance against those expectations; and reporting to the public.
Regional Health Authorities[15] (RHAs)	Plan and deliver health care services within their geographic areas and while operating at arm's length from the provincial government, are required to align their work with provincial strategies.
Provincial Health Services Authority (PHSA)	Works with the five RHAs to plan and coordinate the delivery of provincial programs and provides highly specialised services across the province, operating agencies such as BC Transplant, BC Cancer Agency and Emergency Health Services.
First Nations Health Authority	Plans, designs, manages and fund the delivery of First Nations health programmes and services in British Columbia.

[15] Fraser Health; Interior Health; Northern Health; Vancouver Coastal Health; Vancouver Island Health.

Appendix 4- Professional regulatory colleges in British Columbia (BC), Canada

BC College of Social Workers
College of Chiropractors of BC
College of Dental Hygienists of BC
College of Dental Surgeons of BC
College of Dental Technicians BC
College of Denturists of BC
College of Dieticians of BC
College of Licensed Practical Nurses of BC
College of Massage Therapists of BC
College of Midwives of BC
College of Naturopathic Physicians of BC
College of Occupational Therapists of BC
College of Opticians of BC
College of Optometrists of BC
College of Pharmacists of BC
College of Physical Therapists of BC
College of Physicians and Surgeons of BC
College of Podiatric Surgeons of BC
College of Psychologists of BC
College of Registered Nurses of BC
College of Registered Psychiatric Nurses of BC
College of Speech and Hearing Health Professionals of BC
College of Traditional Chinese Medicine Practitioners and Acupuncturists of BC

Appendix 5 – Provincial Health Services Authority

Agencies of the Provincial Health Services Authority

- BC Cancer Agency
- BC Centre for Disease Control
- BC Children's Hospital and Sunny Hill Health Centre for Children
- BC Emergency Health Services
- BC Mental Health and Substance Use Services
- BC Renal Agency
- BC Transplant
- BC Women's Hospital and Health Centre
- Cardiac Services BC
- Perinatal Services BC

Programmes and services of the Provincial Health Services Authority

- Aboriginal Health Program
- BC Autism Assessment Network
- BC Early Hearing Program
- BC Surgical Patient Registry
- Health Shared Services BC
- Lower Mainland Pathology & Laboratory Medicine
- Population & Public Health
- Provincial Blood Coordinating Office
- Services Francophone
- Stroke Services BC
- Trauma Services BC
- The Provincial Language Service
- Provincial Infection Control Network of BC
- Mobile Medical Unit

Appendix 6- Provincial protocol for future adverse events[25]

Lead – Ministry of Health (Health Authorities Division)
Establish consistent provincial protocol for reviewing and responding to large scale future adverse events, including communication to patients and the public.
Consistent processes for the management of adverse events and service issues are now in place within and across the health authorities. The Adverse Events Protocol was distributed to the Health Authorities in Spring 2012. This principles-based approach to patient-centred disclosure ensures an appropriate, streamlined and coordinated response by British Columbia's health system to adverse events and service issues.

Principles include:

- Adverse events and service issues require open, honest, and ongoing communication between patients and health care providers, as patients need to have an accurate understanding of matters that affect them.
- Effective management of adverse events and service issues requires open dialogue and cooperation between all parties involved.
- Adverse events and service issues of significance require coordinated, joint management across the health system.
- Adverse events and service issues should be managed as consistently as possible across the province, recognising each situation is unique and response levels may vary.
- The response to adverse events and service issues should be timely and occur as close to the point of service as possible.
- The response to adverse events and service issues must comply with legislative requirements and be consistent with current ethical frameworks.
- Lessons learned from adverse events and service issues should be used to improve the practices, processes and systems of health care delivery.
- Disclosure must be considered in all adverse events and service issues, even when the risk assessment rating is low.

Appendix 7- Glossary of abbreviations that may appear in related literature

Term	Explanation
ACS NSQIP	American College of Surgeons National Surgical Quality Improvement Program
ADR	Adverse Drug Reaction
AHRQ	Agency for Healthcare Research and Quality
APSF	Australian Patient Safety Foundation
BC	British Columbia
BCAHC	BC Academic Health Council
BCAS	British Columbia Ambulance Service
BCPHP	BC Perinatal Health Program
BC PSLS	British Columbia Patient Safety & Learning System
BC PSQC	British Columbia Patient Safety & Quality Council
CAERL	Canadian Adverse Event Reporting and Learning System
CAUTI	Catheter Associated Urinary Tract Infections
CAS	Central Alerting System
CCG	Clinical Commissioning Group
CIHI	Canadian Institute for Health Information
CLO	Central Legal Office
CMIRPS	Canadian Medication Incident Reporting and Prevention System
CMO	Chief Medical Officer
CPSI	Canadian Patient Safety Institute
CQC	Care Quality Commission
CWG	Collaborative Working Group
DDKM	Danish Healthcare Quality Programme
DH	Department of Health
DHMA	Danish Health and Medicines Authority
DPSD	Danish Patient Safety Database
DPSIMS	Development of the Patient Safety Incident Management System
EC	European Commission
E2E	Evidence to Excellence
FHA	Fraser Health Authority
FNHA	First Nations Health Authority
GP AC	Guidelines and Protocols Advisory Committee
GPSA	Global Patient and Safety Alerts
HCLABC	Health Care Leaders' Association of BC
HCPP	Health Care Protection Program
HFS	Health Facilities Scotland
HSCIC	Health and Social Care and Information Centre
HIS	Healthcare Improvement Scotland
HSE	Health Service Executive
ICPS	International Classification for Patient Safety (WHO)
IHA	Interior Health Authority

IHI	Institute for Healthcare Improvement
IKAS	Danish Institute for Quality and Accreditation in Healthcare
Infoway	Canada Health Infoway
ISD	Information Services Division
ISMP Canada	Institute for Safe Medication Practices Canada
ISQua	International Society for Quality in Health Care
JCAHO	Joint Commission on the Accreditation of Healthcare Organizations
LRMS	Local Risk Management Systems
OHSAH	Occupational Health and Safety Agency for Healthcare in BC
MHRA	Medicines and Healthcare Products Regulatory Agency
MoHS BC	Ministry of Health Services BC
NAPRC	National Agency for Patient's Rights and Complaints
NaPSAS	National Patient Safety Alerting System
NHA	Northern Health Authority
NHS	National Health Service, UK
NHS LA	NHS Litigation Authority
NHS NSS	NHS National Shared Services
NIIF	National Information and Intelligence Network
NIP	National Indicator Project
NPSA	National Patient Safety Agency
NPSF	National Patient Safety Foundation, UK
NRLS	National Reporting and Learning System
NQB	National Quality Board
NSIR	National System for Incident Reporting
PALS	Patient Advice and Liaison Service
PCBO	Provincial Blood Coordinating Office
PCQO	Patient Care Quality Office
PHAC	Public Health Agency of Canada
PHC	Providence Health Care
PHE	Public Health England
PHSA	Provincial Health Services Authority
PHMS	Portlaoise Hospital Maternity Services
PSLS	Patient Safety and Learning System
PICNet	Provincial Infection Control Network
PSRMLC	Patient Safety/Risk Management Leaders Committee
PSQCWG	Patient Safety and Quality of Care Working Group
QSG	Quality Surveillance Grooup
RHA	Regional Health Authority
RMB	Risk Management Branch
ROP	Required Organizational Practice
SASM	Scottish Audit of Surgical Mortality
SPSI	Scottish Safety Patient Indicator
SPSP	Scottish Patient Safety Programme
SSHAIP	Scottish Surveillance of Healthcare Associated Infection Programme
SSI	Statens Serum Institute

STEIS	Strategic Executive Information System
TDA	Trust Development Authority
TESS	Transfusion Event Surveillance System
VA	Veterans Administration (US)
VCHA	Vancouver Coastal Health Authority
VIHA	Vancouver Island health Authority
WHIN	Western Healthcare Improvement Network
WHO	World Health Organization

Appendix 8- Glossary of terms

Term	Explanation
Acute care	Services including all promotive, preventative, curative, rehabilitative or palliative actions whether orientated towards individuals or populations, whose primary purpose is to improve health and whose effectiveness largely depends on time-sensitive and frequently, rapid intervention. (132)
Accountability	Being held responsible.(4)
Audit	The assessment of performance against any standards and criteria (clinical and non-clinical) in a health or social care service.
Adverse Drug Reaction (ADR)	An undesirable response associated with the use of a drug that either compromises therapeutic efficacy, enhances toxicity, or both. (4)
Adverse event	An incident which results in harm to the patient. (4)
Benchmarking	A continuous process of measuring and comparing care and services with similar service providers. (133)
Business Intelligence (BI)	Business Intelligence includes the applications, infrastructure and best practices that enable analysis of information to improve and optimise decisions and performance. (50)
Complaint	An expression of dissatisfaction on the part of the patient or career that represents a particular perception of events. A complaint may or may not reveal that a mistake or error has occurred. (4)
Data	Data are numbers, symbols, words, images, graphics that have yet to be organised or analysed.(50)
Healthcare	Services received by individuals or communities to promote, maintain, monitor and restore health. (50)
Health information	Health Information is defined as information, recorded in any form, which is created or communicated by an organisation or individual relating to the past, present of future, physical or mental health or social care of an individual (also referred to as a cohort). Health information also includes information relating to the management of the health and social care system. (134)
Healthcare organisation	Entity that provides, co-ordinates, and/or insures health and medical services for people. (4)
Incident reporting	A system in many health care organisations for collecting and reporting adverse patient occurrences, such as medication errors and equipment failures. It is based on individual incident reports. For several reasons, including fear of punitive action, reluctance

	of nonphysicians to report incidents involving physicians, lack of understanding of what a reportable incident is, and lack of time for paperwork, the effectiveness of the incident reporting is limited. (4)
Information and Communications Technology (ICT)	The tools and resources used to communicate, create, disseminate, store and manage information electronically. (135)
Just culture	An environment which seeks to balance the need to learn from mistakes and the need to take disciplinary action. (4)
Key Performance Indicators (KPI)	Specific and measurable elements of practice that can be used to assess the quality and safety of care. (133)
National Health and Social Care Date Collections	National repositories of routinely collected health and social care data, including administrative sources, censuses, surveys and national patient registries in the Republic of Ireland. (135)
Near miss	A deviation from best practice in health care delivery that would have led to unwanted harm to the patient or to the mission of the organisation, but was prevented through planned or unplanned actions. (4)
Negligence	Failure to exercise the skill, care and learning expected of a reasonably prudent healthcare provider.(4)
Never Event	Serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented by healthcare providers.
Patient safety	Actions undertaken by individuals and organisations to protect health care recipients from being harmed by the effects of health care services. (4)
Patient safety data	The broad heterogeneous information that includes, but is not limited to, the description of incidents with medical errors and near misses, their causes, their follow-up corrective actions, interventions that reduce future risk, and patient safety hazards.(4)
Patient Safety Incident	An event or circumstance which could have resulted, or did result, in unnecessary harm to the patient. (4)
Regulation	A sustained and focused control exercised by a public agency over activities that are valued by a community.(50)
Risk	The likelihood of an adverse event or outcome.(50)
Secondary Care	Specialist care provided by an ambulatory or inpatient basis usually following a referral from primary care(136)
Surveillance	Routine collection and review of data to examine the extent of a disease, to follow trends, and to detect changes in disease occurrence. (4)

Appendix 9- Danish agencies and systems

- Ministry of Health and Prevention – Ministeriet for Sundhed og Forebyggelse
- National Agency for Patients' Rights and Complaints – Patientombuddet
- Danish Patient Safety Database – Dansk Patient Sikkerheds Database
- Danish Health and Medicines Authority – Sundhedsstyrelsen
- Danish Institute for Quality and Accreditation in Healthcare – Institut for Kvalitet og Akkreditering i Sundhedsvæsenet
- Danish Patient Compensation Association – Patienterstatningen
- Danish Patient Safety Society – Dansk Selskab for Patientsikkerhed
- Statens Serum Institut, National Institute for Health Data and Disease Control
- Sundhedsvæsenets Disciplinærnævn – Health Service Disciplinary Board

Appendix 10- Never events

To be a 'Never Event', an incident must fulfil the following criteria:

- The incident has clear potential for or has caused severe harm/death.
- There is evidence of occurrence in the past (i.e. it is a known source of risk).
- There is existing national guidance and/or national safety recommendations on how the event can be prevented and supported for implementation.
- The event is largely preventable if the guidance is implemented.
- Occurrence can be easily defined, identified and continually measured.

NHS Never events List 2015/2016

- Wrong site surgery
- Wrong implant/prosthesis
- Retained foreign object post-procedure
- Mis-selection of a strong potassium containing solution
- Wrong route administration of medication
- Overdose of Insulin due to abbreviations or incorrect device
- Overdose of methotrexate for non-cancer treatment
- Mis-selection of high strength midazolam during conscious sedation
- Failure to install functional collapsible shower or curtain rails
- Falls from poorly restricted windows
- Chest or neck entrapment in bedrails
- Transfusion or transplantation of ABO-incompatible blood components or organs
- Misplaced naso- or oro-gastric tubes
- Scalding of patients

Appendix 11- International agencies contacted

Jurisdiction	Organisation	Name(s)	Title of contact
British Columbia, Canada	Provincial Health Services Authority – BC Patient Safety and Learning System	Annemarie Taylor	Executive Director
Denmark	The Danish National Agency for Patients' Rights and Complaints	Martin Bommersholdt	Senior Patient Safety Officer
Scotland	Healthcare Improvement Scotland	Donald Morrison	Head of Data, Measurement and Business Intelligence
		Jenny Long	Senior Programme Manager
England	Patient Safety Domain, NHS England	Alison Walne	Senior Head of Delivery and NRLS Oversight
		Kerri Kirwin	Patient Safety NRLS Oversight and Business Support Manager
		Frances Wood	Patient Safety Lead (Clinical Review)
		Frances Healy	Head of Patient Safety Insight