Patient Safety Policies, Reporting Systems and Education in G7 countries:

Canada, France, Germany, Italy, the United Kingdom and the United States

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Table of Contents

1. Canada

1.1. Legal framework concerning patient safety

Legislations concerning patient safety are enacted at the level of provinces and territories. The content of legislations varies across provinces and territories, leading to differences in reporting and disclosure of patient safety incidents, apology protection and accountability or enforcement mechanisms for noncompliance (Status of Patient Safety Incident Legislation and Best Practices Across Canada (healthcareexcellence.ca). For example, mandatory reporting of patient safety is required in a few provinces and territories including New Brunswick (Health Quality and Patient Safety Act), Northwest Territories (Hospital Insurance and Health and Social Services Administration Act), Saskatchewan (Provincial Health Authority Act) and Manitoba (Regional Health Authorities Act) but the coverage of providers and reporting requirements varies among them.

At the federal level, the Protecting Canadians from Unsafe Drugs Act (also known as Vanessa's Law, overview of Vanessa's Law, Protecting Canadians from Unsafe Drugs Act (Vanessa's Law): Questions/Answers) was enacted on November 6, 2014 and led to the development of improved reporting of serious adverse drug reactions and medical device incidents that involve therapeutic products.

1.2. Main organisations responsible for patient safety

Healthcare Excellence Canada, an independent, not-for-profit charity, funded primarily by Health Canada, was launched in 2021. It is a single quality and safety organisation to improve healthcare for everyone in Canada, and committed to fostering inclusive and equitable high quality safe care through partnerships with different groups, including patients and caregivers, ethnic minorities, and health care providers. It brought together the Canadian Patient Safety Institute (CPSI) and Canadian Foundation for Healthcare Improvement after an external review of specialised pan-Canadian health organisations (Forest & Martin, 2018). Previously, CPSI, established in 2003, worked with federal, provincial and territorial partners and health system stakeholders to improve patient safety and the quality of care and it led an initiative to produce guidelines for the disclosure of harms to patients (CPSI, 2011).

Accreditation Canada delivers a wide range of assessment programmes for health and social service organisations, supported by Health Standards Organization, the only Standard Development Organization in Canada and around the world solely focused on developing evidence-based health and social service standards, assessment programmes and quality improvement solutions. It has been working with health, social and community service organisations to promote quality and safety for more than 60 years.

In some provinces and territories, patient safety is high on the agenda and a dedicated entity is assigned to work on this specific area. The British Columbia Patient Safety and Quality Council (BCPSQC) provides system-wide leadership that brings a provincial perspective to patient safety and quality improvement activities. Through collaborative partnerships with health authorities and other health care providers, BCPSQC promotes and informs a provincially coordinated, patient-centred approach to patient safety and quality improvement. BCPSQC also provides advice to the Minister of Health Services on issues of patient safety and quality of care. The Health Quality Council of Alberta (HQCA) is an arm's length organisation with a mandate to report directly to the population on the quality, safety and performance of health services and the health system. The HQCA collaborate with stakeholders such as regional health authorities, professionals and policy makers to identify best practices, and review various dimensions of health care quality including patient safety. The Manitoba Institute for Patient Safety (MIPS), created in 2004 by the provincial government in response to recommendations made by the Manitoba Patient Safety Steering Committee, promotes, coordinates and facilitates activities that have

a positive impact on patient safety throughout Manitoba while enhancing the quality of health care for the population.

1.3. Reporting mechanism for patient safety

Most provinces and territories require hospitals to report patient harms in hospital, but these data are publicly reported only in three provinces (Saskatchewan, Manitoba and Quebec) (Milligan et al., 2020; Boucaud & Dorschner, 2016). These are not standardised across the country, despite the guidelines developed by CPSI on the disclosure of harms to patients. There is limited data on patient harms at the facility or provider level. In order to have a comprehensive understanding of the occurring of adverse events which are often underreported, in New Brunswick, for example, patient safety was evaluated by using hospital-based reporting, medical record reviews and patient-reported incidents and such analyses highlighted the importance of patient-reported information to improve patient-centred safe care.

At the national level, CIHI report on specific types of medical error in hospitals and long-term care facilities publicly at Your Health System: In Depth | CIHI, allowing benchmarking across regions. Among the indicators monitored, some of them are also used for international benchmarking and long-term care indicators such as fall, pressure ulcer and physical functioning are also reported.

Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a voluntary, confidential programme that collects, analyses and distributes information on medication errors nationally. The knowledge gained through analysing reports submitted to CMIRPS is used to make medication use safer. Precautions have been taken by the Institute for Safe Medication Practices Canada (ISMP Canada), an independent national not-for-profit organisation committed to the advancement of medication safety in all healthcare settings, to verify the information distributed on the website. ISMP Canada's mandate includes analysing medication errors, making recommendations for the prevention of harmful medication errors, and facilitating quality improvement initiatives. ISMP Canada works collaboratively with the healthcare community including regulatory agencies and policy makers, patients, families, patient safety organisations, the pharmaceutical industry and the public to promote safe medication practices.

A reporting mechanism is not established at the federal level to assure safety in long-term care but CAN/HSO 21001:2023 0 Long-Term Care services standards, developed by Health Standards Organization, includes general guidelines for reporting violation of residents' rights and safety incidents and disclosing safety incidents, and CSA Z8004:22 Long-Term Care Home Operations and Infection Prevention and Control, developed by the Standards Council of Canada, provides recommendations in areas including catastrophic event management, and training.

1.4. Education in patient safety

CPSI developed the second national patient safety education framework, the Safety Competencies - Enhancing Patient Safety Across the Health Professions and Healthcare Excellence Canada promotes the use of this framework for training, policy-making, regulation and accreditation (https://www.healthcareexcellence.ca/en/resources/safety-competencies-framework/) and it also includes some best practices in the country. For example, McGill University has developed and conducted a patient safety workshop series called "Safety is Everybody's Business: Applying and Teaching Patient Safety Competencies" which utilises the national competencies framework.

Accreditation is a quality improvement process that supports health education programmes, preparing graduates to deliver safe and effective care at entry to practice. In 2017, Accreditation Canada was selected by a group of health professions within Canada to provide accreditation services for professional, entry to practice, education programmes. The programme involves a six-stage accreditation process conducted over a six-year cycle.

Canadian Patient Safety Program, online learning programme, is available for professionals to equip with the required knowledge and skills to improve safety for and with patients, families and staff and to endeable safety culture change. This programme replaced, Canadian Patient Safety Officer Course delivered by the Canadian Patient Safety Institute and HealthCareCAN.

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2. France

2.1. Legal framework concerning patient safety

Public Health Act No. 2004-806 of 9 August 2004 put in place the principle of compulsory reporting of serious adverse events in France. The decree No. 2016-1606 of 25 November 2016 specifies the procedures for reporting care-related adverse events (CRAE) by professionals, health providers or medico-social services to the regional health agency. The decree also defines the organisation of regional structures to support professionals and providers to improve health care quality and patient safety.

Health Insurance Act No. 2004-810 of 13 August 2004 set up the High Authority for Health (*Haute authorité de santé*, HAS) which was entrusted the mission of accreditation of physicians in high-risk specialisations. In 2006, Article L1414-3-3-of the Public Health Code laid out details on HAS responsibilities in relation to the accreditation.

2.2. Main organisation responsible for patient safety

HAS aims to improve quality of health and social care for the benefit of people. It works together with other public authorities and professionals to optimise their practices and organisations, and support users to make informed decision about health and social care providers. Patient safety is one of the important areas that HAS works and HAS is dedicated to promoting positive safety culture and supporting the implementation of effective risk management programmes and high-quality teamwork to reduce medical errors and prevent their occurrences. HAS also undertakes the certification of hospitals based on criteria set out on quality and safety of care.

Between 2013 and 2017, the Directorate General of Offer of Care (*Direction générale de l'offre de soins*, DGOS) and the Directorate General of Health (*Direction générale de la santé*, DGS), in association with HAS, piloted the National Programme for Patient Safety, as part of the 2012 National Strategy for Health. The programme led to defining a stronger regulatory framework for patient safety and the development of educational guides and tools by HAS. *Haut Conseil de la santé publique* evaluated the programme and recommended 1) to promote new targets for promoting patient safety; 2) to develop a better structured patient safety policy, and 3) to determine the terms to strengthen the governance of patient safety policy (https://www.hcsp.fr/Explore.cgi/Telecharger?NomFichier=hcsps20180517_valuduprognatidescurdespati.en.pdf).

2.3. Reporting mechanism for patient safety

HAS receives anonymised declarations of CRAEs (defined as unexpected events with regard to the state of health and pathology of the person and the consequences of which include death, life-threatening and the probable occurrence of a permanent functional deficit) from the regional health agency (*Agences Régionales de Santé*, ARS). It produces an annual report of CRAEs declared in France, with recommendations for improving patient safety. This report is forwarded to the Minister of Health and also available publicly.

To have a more comprehensive understanding on the extent of adverse events occurring across hospitals, France has conducted three national surveys on health care-related adverse events (*Enquête Nationale sur les Événements Indésirables liés aux Soins,* ENEIS) in 2004, 2009 and 2019 (https://drees.solidarites-sante.gouv.fr/sources-outils-et-enquetes/enquete-nationale-sur-les-evenements-indesirables-lies-aux-soins-eneis). These studies covered incidents during hospitalisation and incidents leading to hospital admissions.

The most recent study led to a development of 2022 Action Plans on Patient Safety in the following 7 areas:

1. Promoting and facilitating teamwork;
2. Improving skills in mitigating actions;
3. Improving reporting systems and safety culture through education for professionals and patients, safety culture measurement and information campaigns;
4. Improving the quality of root cause analyses and feedback;
5. Analysing for improving and exploring the role of simulation;
6. Focusing on improvement in 4 specific areas (surgical theatres, critical care, implantable devices and discharge organisation); and
7. Strengthening monitoring (e.g., preventable rehospitalisation rate)

In addition, France reports quality and patient safety indicators at the provider level publicly at QualiScope, allowing benchmarking among providers. Indicators based on the data collected by providers and hospitalised patients (e-Satis) are used to evaluate quality and patient safety of each provider. In relation to patient safety, hospital-associated infection and preventive measures for infection are reported but adverse events are not reported as part of QualiScope. The data available at QualiScope are used as part of the certification programme. QualiScope is used by providers themselves to improve quality of care and patient safety as well as professionals for referral of providers and patients and their family for making informed provider choice.

Furthermore, patients and their families, professionals, and members of the public can submit complaints and grievances to regional health agencies. Regional health agencies register them and conduct on-site investigations when necessary.

2.4. Education in patient safety

A voluntary accreditation programme is available for hospital doctors working in 19 high risk specialisations (including surgery, anaesthesia, etc.) and they can carry out the programme individually or as part of a medical team. This HAS accreditation is valid for 4 years. Since 2021, funding of up to EUR 500 per year is made available by health insurance to each doctor who underwent the programme. But more can be done to improve the programme, so in 2022, an action plan was proposed to support and promote further improvement in accreditation programme.

HAS also developed three guides in collaboration with the Federation of Regional and Territorial Organizations for the Improvement of Health Practices (FORAP), to implement and measure a safety culture and set up actions for continuous improvement, and various tools to ameliorate risk management in general and also specific areas such as surgery, anaesthesia, medication (see Risk management at https://www.has-sante.fr/jcms/c_2042652/en/patient-safety).

Analysis of CRAEs showed that dysfunctional teamwork is a root cause for their occurrence, so HAS developed a number of education materials and voluntary programmes to improve teamwork and materials were also prepared for patient communication (see Teamwork and Patient Communication at https://www.has-sante.fr/jcms/c_2042652/en/patient-safety).

Accreditation is compulsory for long-term care institutions based on minimum safety and performance requirements.

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3. Germany

3.1. Legal framework concerning patient safety

Patients' Rights Act (26 February 2013) laid out patients' rights in health care including in the area of patient empowerment and participation and with respect to access to health information and adverse events. Following this law, other laws including Civil Code (BGB), Fifth Book of the Social Code (SGB V) and Hospital Financing Act were modified. BGB clarified medical treatment contracts, informed consent, adverse events and documentation standards for medical records. SGB V set out minimum standards for risk and error management and critical incidents reporting (CIRS) systems and made quality management compulsory for all health care providers. It also obliged hospitals to report the "use of quality improvement cycles (plan-do-check-act), process flow descriptions, quality measurement and risk management measures, such as the use of check lists and error reporting systems" (Blümel et al, 2020) in their annual quality report and to establish patient-oriented complaint management mechanisms.

3.2. Main organisations responsible for patient safety

The German Coalition for Patient Safety, non-profit association founded in 2005, is a platform for representatives of the health professions, their associations and patient organisations to work together towards improvement of patient safety in Germany. The coalition has interdisciplinary and multi-professional working and expert groups and they meet regularly and publish recommendations on various areas in patient safety for providers, information for patients and publications for a wide range of audience. Their recommendations are available free of charge to all institutions in the German healthcare system as well as patients and their carers (https://www.aps-ev.de/handlungsempfehlungen/, https://www.aps-ev.de/translations/).

The Independent Patient Advice Service (UPD), a non-profit organiastion, advises patients and consumers on health and health law issues independently. UPD also receives report of medical errors by patients and reports them in Patient Advice Monitor which is published annually.

Institute for Quality Assurance and Transparency in Healthcare (*Institut für Qualitätssicherung und Transparenz im Gesundheitswesen* – IQTIG), founded in 2015, is an independent scientific institute that advises the Federal Joint Committee on how to measure and improve the quality of medical care in Germany. It is in charge of harmonising various quality assurance programmes which exist in ambulatory and inpatient care and developing common tools and indicators to secure health care quality across hospital and outpatient care in Germany. Patient safety, however, does not appear to be one of the priority areas of IQTIG's work. IQTIG also develops indicators for quality-based hospital planning, quality improvement through selective contracting between sickness funds and hospitals and pay-for-performance in hospital care. IQTIG publishes annual report on health care quality at the national level, although reports were not published in 2021 and 2022.

3.3. Reporting mechanism for patient safety

There are two types of CIRS systems in Germany. Professionals can report critical incidents anonymously in an easily-accessible platform, without any sanction.

The first type of system is compulsory for hospitals and ambulatory care providers including dentists. Reported cases are analysed by experts who give recommendations for the future avoidance of similar events. However, there is a range of barriers including "a lack of support from authorities or the person

'causing' the error, fear of consequences, lack of knowledge and high workload", leading to underreporting (Litke et al., 2020).

The second type of systems is voluntary and critical incidents are reported online by provider in Germany while maintaining confidentiality of the providers concerned. Learning from cross-facility Incident Reporting Systems (LüFMS) project, completed in 2022, identified 21 voluntary CIRS systems existing in the country for specific regions, topics such as maternity, medication and anaesthetic incidents, or specific operators such as universities and national societies. Reported cases are analysed and commented by experts and the information, which does not allow tracking the cases and providers concerned, is shared and searchable online for mutual learning and information sharing for clinical risk management. Providers or professionals reporting in this type of systems are required to have a certificate of participation and those reported could negotiate to receive financial incentives (20 cents per inpatient case) from health insurers. One of the CIRS systems, Hospital-CIRS-Network 2.0 Germany was developed based on the Swiss CIRRNET – Critical Incident Reporting & Reacting NETwork, and run by German Hospital Federation, German Medical Association and German Nursing Council. The structured reporting form also allows reporting professionals to select factors contributing to the occurrence of incidents.

Critical incidents are not published in a national register, but expert commissions and arbitration boards of the medical associations record and publish anonymously these data including patient allegations (Bundesärztekammer, 2020a; Bundesärztekammer, 2020b). Patients and the public can also obtain information on medical errors at hospital complaint centre, the Federal Chamber of Physicians and the Federal Association of Statutory Sickness Funds.

3.4. Education in patient safety

While education and training in patient safety has not been well established and widely available, several training curricula and concepts have been developed recently in Germany, and following this development, the German Coalition for Patient Safety developed a catalogue of core competencies which is considered as the national patient safety education framework. This catalogue serves as an important source of information for developing patient safety education in the future (Hoffmann et al, 2015). The Coalition advocates patient safety education for all health professions but it is not yet clear how the framework is currently implemented for studies, training, continuous education of health professionals in the country.

Accreditation based on minimum safety and performance requirements is a condition for reimbursement for long-term care institutions.

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4. Italy

4.1. Legal framework concerning patient safety

The patient safety programme was initiated in 2003 by the Ministry of Health followed by the State/Regions Agreement signed in 2008. The agreement entrusted the Ministry of Health to monitor sentinel events. In 2017, Gelli–Bianco law (Law No.24/2017) introduced changes and regulations regarding patient safety and healthcare workers' liability.

4.2. Main organisations responsible for patient safe

National Agency for Regional Health Services (AGENAS), founded in 1993, is a non-economic public body and provides technical and operational support to regions and healthcare organisations in various areas including quality and patient safety. AGENAS monitors best practices for patient safety collected through the National Observatory on Best Practices in the Safety of Healthcare (see Section 4.3), and malpractice claims collected through the Information System for the Monitoring of Errors in Healthcare (SIMES, *Sistema Informativo per il Monitoraggio degli Errori in Sanità*; see Section 4.3).

Regional Centres for the management of healthcare risk (*Centro regionale per la gestione del rischio sanitario*), established in regions following Law No.24/2017, aim to increase the knowledge of patient safety, promote prevention measures and improve risk management at the regional level.

4.3. Reporting mechanism for patient safety

National Observatory on Best Practices in the Safety of Healthcare, started in 2008, is a web-based platform to collect, share and disseminate best practices between healthcare providers, health professionals and citizens. The standard form was developed by AGENAS based on SQUIRE guidelines for reporting of quality and safety improvement projects. Through Call for Good Practice conducted annually in collaboration with the Ministry of Health, Regions and Autonomous Provinces, the Observatory identifies and collects patient safety improvement interventions implemented by the Regions, healthcare organisations and professionals, and disseminates them online.

The Information System for the Monitoring of Errors in Healthcare (SIMES), started in 2009, collects information relating to sentinel events and claims reports throughout the country. The system is not open to everybody and Administrator designated by region acts as the regional contact and takes responsibility to manage system users in the region. The information provided through SIMES are monitored and used to develop recommendations and staff training.

4.4. Education in patient safety

There are six working groups in the National Observatory on Best Practices in the Safety of Healthcare and one of them is responsible for "identifying training needs and indicators for monitoring and guidelines for education of health care staff" (Cascini et al, 2020). It is, however, not known whether training programme has been already developed based on analyses of the information collected through the Observatory.

Even though safety of older patients in nursing homes needs to be ensured in Italy, risk management tools for long-term care setting are is not available in literature (Furmenti et al, 2020).

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5. United Kingdom

Policies around patient safety is more developed in England, Scotland and Wales compared to the Northern Ireland, so this section focuses on these three countries in the United Kingdom.

5.1. Legal framework concerning patient safety

In England, Health and Social Care Act 2008 (Regulated Activities) Regulations 2014: Regulation 12 aims to prevent people from receiving unsafe care and treatment and prevent avoidable harm or risk of harm, and the NHS Patient Safety Strategy was put together in 2019 and updated in 2021 (https://www.england.nhs.uk/patient-safety/; https://www.england.nhs.uk/patient-safety/the-nhs-patient-safety-strategy/). In Wales, the Health and Social Care (Quality and Engagement) (Wales) Act 2020 was passed and this Act which aims to improve quality and public engagement in health and social care, will be brought into force in spring 2023. Following this, national actions in patient safety were set out in the Quality and Safety Framework which was published in 2021 and the Quality and Safety Programme was established. In Scotland, the Patient Safety Commissioner for Scotland Bill was introduced in the Scottish Parliament in 2022, aiming to establish a Patient Safety Commissioner who would support improvement in the safety of health care.

5.2. Main organisations responsible for patient safety

In England, the Care Quality Commission, an independent regulatory body that performs external evaluation as part of its statutory role to inspect, monitor, and regulate health services, also acts as a regulatory agency to protect patient safety and enforce actions to improve care. Healthcare Safety Investigation Branch aims to improve patient safety through professional safety investigations, and it also uses concerns and complaints submitted by the public for continuous learning and improvement. In Wales, Health Inspectorate Wales (HIW) performs similar tasks as the Care Quality Commission in England, and Public Services Ombudsman Wales collects complaints about public services and independent care providers, investigate them and produce reports about them. In Scotland, Healthcare Improvement Scotland (HIS) has produced a national framework to support healthcare providers to effectively manage adverse events. It has a number of tasks and one of them is to manage an Adverse Events Network which allows representatives of NHS Boards to share experiences and develop best practice.

5.3. Reporting mechanism for patient safety

In England, patient safety incidents have been reported to National Reporting and Learning System (NRLS) since 2005, and NRLS has become one of the most comprehensive databases in the world, including over 20 million incidents. In addition, Strategic Executive Information System (StEIS) was used to report and monitor the progress of Serious Incident investigations across the NHS. However, to establish a single reporting system, to reflect changes in healthcare delivery in the modern healthcare landscape, to take advantage of latest technology development to maximise opportunities for learning, NHS Learn from patient safety events service (LFPSES, previously, Patient Safety Incident Management System; NHS England » Introducing our new system for patient safety learning) is being developed and the full implementation is planned in mid-2023. Healthcare providers and professionals, not only in hospital but also in primary care, and patients are able to report the details of patient safety events electronically to LFPSES for analysis and learning at national level. The analysis will be enhanced by using latest technology including machine learning. LFPSE has already produced numerous outputs and reports and data are available online. Care and Quality Commission also publishes inspection reports covering various

dimensions including safety for a wide range of providers including care homes and they are available online to compare service providers. Moreover, the National Patient Safety Alerting System was launched in 2014 to strengthen and speed up the dissemination of urgent patient safety alerts. The System also supports implementation of safety and best practice measures and, for the highest level of alert, directs what action must be taken.

In 2008, Scotland launched the world's first national patient safety programme, initially focused on preventing avoidable mortality and harm in acute hospitals. Adverse event reporting in Scotland is done locally, not nationally, to foster local ownership and response. All Health Boards have an obligation to have systems for internal control for identifying and working with adverse events. There are, however, a number of regulations on the reporting of some types of adverse events to national agencies, such as technical errors in equipment and serious medication side effects. The legislative provisions also include the requirement for reporting at a national level, in the form of an annual report, on all incidents that come within the scope of the duty of candour procedure. The NHS Scotland Confidential Alert Line also enables healthcare professionals to make a confidential phone call to receive advice from legally-trained staff about how to report a patient safety or malpractice matter.

In Wales, the National Patient Safety Incident Reporting Policy came into effect in 2021 and reporting flow, guidelines and forms were developed (https://du.nhs.wales/patient-safety-wales/patient-safety-incidents/). Since 2022, patient safety incident reports have been submitted to the Once for Wales Concerns Management System (OfWCMS), and Welsh Government provides HIW with a weekly extract from the Once for Wales system. Patient Safety Incidents are analysed weekly by HIW and updates are provided at internal intelligence meetings. Incident details and analysis of trends and themes are shared weekly to HIW Relationship Managers, to help identify issues and risks within providers. OfWCMS aims to systematically report, record, learn and monitor improvements following incidents, complaints, claims and other adverse events that occur in healthcare. Previously, Welsh data were reported to the National Reporting and Learning System as done in England.

Coroners in England and Wales have a legal duty to report details of deaths in Prevention of Future Deaths reports if it appears that there are risks of other deaths occurring in similar circumstances. These reports are sent to individuals and organisations that are in a position to take action to reduce risks that have been identified. They then must reply within 56 days to say what action they plan to take.

There are also specific systems in place to report, collate and analyse adverse events associated with medical devices coordinated by the Medicines and Healthcare products Regulatory Agency (MHRA) in England and Wales, the Incident Reporting and Investigation Centre in Scotland, and the Northern Ireland Adverse Incident Centre. In England, for example, MHRA operates a system of post-marketing surveillance of medicines and devices. Its "Yellow Card" scheme encourages reporting of all adverse drug reactions, including over-the-counter, herbal and complementary preparations. Yellow Card reports received on suspected side effects are evaluated by pharmacists and doctors to identify previously unidentified safety issues or adverse drug reactions. Reports of suspected defective medicines are sent to the Defective Medicines Reporting entre (DMRC) who will take appropriate action, including issuing a recall if necessary. The MHRA also issues regular Drug Safety Updates (OECD, 2016).

5.4. Education in patient safety

NHS Health Education England published patient safety training, and materials are available online (https://www.hee.nhs.uk/our-work/patient-safety). Scottish Patient Safety Programme (SPSP) aims to maximise learning opportunities by organising relevant webinars, sharing case studies and evidence, facilitating networks, providing practical and bespoke quality improvement and coaching support, and producing guidance and implementation toolkits (https://ihub.scot/improvement-programmes/scottish-patient-safety-programme-spsp/learning-system/). The Scottish Quality and Patient Safety Fellowship trains

people to develop and utilise quality improvement advisor competencies. In Wales, practical toolkits and guidance documents are available at Patient Safety Wales website to help NHS managers and health care staff to implement patient safety initiatives. Guidelines have been also developed that support staff learning from patient safety incidents and support approaches to preventing such incidents from happening again.

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6. United States

6.1. Legal framework concerning patient safety

The Patient Safety and Quality Improvement Act of 2005 (PSQIA), which became effective in 2009, provides for the improvement of patient safety and to reduce the incidence of events that adversely affect patient safety by authorising the creation of patient safety organizations (PSOs). PSQIA requires disclosure of medical errors to affected patients while protecting those who report voluntarily the errors by not allowing shared information to be used legally against them. A bill related to establishing a National Patient Safety Board, a nonpunitive, collaborative, independent body to address safety in health care, is under discussion.

6.2. Main organisations responsible for patient safety

PSOs work with healthcare providers to improve quality and safety through the collection and analysis of aggregated, confidential data on patient safety events.

The Joint Commission, an independent, not-for-profit organisation, is the oldest and largest standards-setting and accrediting body in health care in the United States. It evaluates and accredits over 22 000 health care organisations and programmes based on an on-site assessment by a survey team.

Agency for Healthcare Research and Quality (AHRQ) is the lead Federal agency for patient safety research and has developed materials covering a wide range of patient safety risks in different care settings including long-term care.

6.3. Reporting mechanism for patient safety

There is no nationwide reporting system across providers. The Joint Commission, however, requires hospitals to maintain a voluntary error reporting system. Incidents are often reported by frontline personnel directly involved in an event or the actions leading up to it rather than management or patient safety professionals. All hospitals are also mandated to conduct one prospective risk assessment regularly typically through performing an Failure Mode and Effects Analysis and a root cause analysis under certain circumstances (e.g., when a sentinel event occurs). Beyond these requirements, there are no uniform standards on how hospitals or clinics should assess their safety hazards, either prospectively or retrospectively. The Patient Safety Reporting System (PSRS), a non-punitive, confidential, and voluntary programme which collects and analyses safety reports submitted by healthcare professionals working in private and federal healthcare providers, is complementary to the internal reporting system in hospitals. PSRS is an external, independent system administered by the National Aeronautics and Space Administration (NASA). AHRQ also established a network of patient safety databases that can receive and aggregate nonidentifiable data that are submitted voluntarily.

Health care providers may choose to work with a PSO and specify the scope and volume of patient safety information to share with a PSO. Health care providers and PSOs may aggregate patient safety event information on a voluntary basis.

AHRQ has also developed Common Formats—standardised definitions and reporting formats for patient safety events—in order to facilitate aggregation of patient safety information. Since their initial release in 2009, the Common Formats have been updated and expanded to cover a broad range of safety events and AHRQ encourage use of Common Formats by hospitals in their reporting systems.

6.4. Education in patient safety

Various education opportunities in patient safety are available in the United States (Kirkman et al, 2015). AHRQ provides free continuing education and annual conferences in various areas including patient safety. Healthcare professionals can also use AHRQ's curriculum tools to make care safer and improve their communication and teamwork skills. AHRQ's PSNet provides resources for patient safety training and education. Institute for Healthcare Improvement provides Patient Safety Curriculum in a mobile-friendly format. The Joint Commission put together a document intended to help inform and educate hospitals about the importance of an integrated patient safety system and how to implement existing requirements to improve patient safety.

AHRQ runs a few Quality and Patient Safety Programs in long-term care settings including development of surveys, training materials toolkit, fall management program, ulcer prevention and antibiotics Accreditation based on minimum safety and performance requirements is also a condition for reimbursement for long-term care institutions.

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