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Ministry of Health , Labour and Welfare

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Patient Safety Policies
– Experiences, Effects and Priorities;
Lessons from OECD Member States –

April 2018

Third Global Ministerial Summit on Patient Safety

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Patient Safety Policies – Experiences, Effects and Priorities; Lessons from OECD Member States –

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SUMMARY

Patient safety involves various aspects at three levels: health policy (system), in-hospital (organizational), and clinical practice. All of them are profoundly related to establishing a database for benchmarking, sharing information, staff training, monitoring of patient safety indicators, detection of adverse events, investigation, introduction of protective methods, compensation, patient/employee satisfaction, patient safety culture, and proper funding. In the last 20 years, many countries have learned that patient safety is a complex, composite issue which reflects the maturity and achievement of society. In an aging society, the mainstream of healthcare is moving from acute care hospitals to the community care setting, including home health care and nursing homes. In the latter, there are fewer resources available for ensuring patient safety, and so a more cost-effective and convincing patient safety system needs to be established. Such a system could be used in developing countries with limited resources.

This report examines the latest state of major policies related to patient safety in various countries, to serve as a reference for policymakers. A questionnaire survey was conducted in December 2017, targeting policymakers concerning patient safety in OECD member states.

In spite of the limited time, 18 of the 35 states (51%) answered the questionnaire, providing precious information for member states to share. More than half of responding states have a law that requires hospitals to establish a patient safety management system. Most accreditation systems are on a voluntary basis, but all hospitals are obligated to be accredited in the United Kingdom, and some provincial/territorial governments in Canada require hospitals to be accredited according to each law. How best to promote accreditation and standardization is an issue that needs to be addressed, since accredited hospitals accounted for less than 50% in most states. The assignment of personnel responsible for patient safety management (patient safety managers) in hospitals is reimbursed only in Japan and Korea, and the effects need to be investigated.

Most hospitals are submitting data using clinical indicators relating to patient safety. Most data submission systems are on a voluntary basis. The number of required indicators is 238 in Germany, and about 150 in Switzerland. The collected data are made public in such a way that the hospital can be identified in more than half of the states. A pay-for-performance scheme according to reported clinical indicators has been introduced in France, Korea, and Portugal. As a driver of quality improvement, benchmarking with a reference database seems to be more popular than pay-for-performance schemes. In most states, hospitals are requested to report serious adverse events to the government. Patients or family members are also able to report events to the national system only in Korea and Portugal. Alerts or aggregated data of reported adverse events are published in each state.

Regarding screening of adverse events, investigation of in-hospital deaths is obligated in some states. In France, in-hospital deaths that relate to surgery, anesthesiology or cancerology have to be reviewed by morbidity-mortality conferences. In Japan, all in-hospital deaths have to be reviewed irrespective of whether the case meets the reporting criteria of the Adverse Event Investigation System or not. In Spain, there are hospital mortality commissions in each hospital. In Germany, there is a financial incentive for post-mortem examination. Not only an autonomous reporting system but also other screening systems may be needed to identify problems, because low sensitivities or under-reporting by healthcare workers may conceal problems in the hospital.

In the case of adverse events, hospitals are expected to conduct an in-hospital investigation. In some states,

in addition to in-hospital investigation, external investigation by a third-party organization has been introduced. Attempts have been made to standardize the method of in-hospital investigation in most states with guidelines and recommended methods. A support system is also available in some states.

No-fault compensation has been introduced in several states. It is sometimes difficult to specify the cause of adverse events, and this system helps to support patients and establish good relationships between patients and healthcare organizations, and to encourage them to cooperate in establishing effective prevention methods. A no-fault compensation scheme for extensive adverse events has been introduced in Denmark, Finland, France, and Portugal. The scheme in Belgium, Japan and Korea covers some adverse events. The establishment of a no-fault compensation scheme for extensive adverse events may be a big challenge, but a scheme that focuses on limited areas, such as adverse drug events or newborns with cerebral palsy, may be easier to introduce as a first step.

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INTRODUCTION

In the early 21st century, major states recognized that patient safety is an urgent threat to the society and should be regarded as the cornerstone of health policy following several serious adverse events in renowned hospitals. Patient safety methods can be classified into three levels: health policy (system), in-hospital (organizational), and clinical practice. Most studies on patient safety belong to the in-hospital and clinical practice levels. Policymakers who are responsible for patient safety issues sometimes struggle to find information on the possible options and their effects.

At the last Global Ministerial Summit on Patient Safety in Germany, the OECD distributed a report entitled "The Economics of Patient Safety – Strengthening a value-based approach to reducing patient harm at national level". The report estimated the cost of patient harm, and outlined a strategy for policymakers and healthcare leaders to improve patient safety with limited resources. This information was very useful for policymakers in each state.

In April 2018, the 3rd Global Ministerial Summit on Patient Safety will be held in Tokyo. The Japanese Government, as the host, plans to provide the latest information on patient safety policies in OECD member states. This report clarifies the latest major policies related to patient safety in each state; we hope that it is helpful for policymakers in each state.

METHODS

The authors drew up a questionnaire that asked about major policies related to patient safety in each state and asked respondents to estimate the effectiveness and priorities of those policies. The effectiveness concerns the expected reduction of morbidity and mortality by introducing the policy, while the priority concerns the allocation of resources in each state in the near future. The questionnaire was revised several times based on comments from a project team of the Tokyo Summit and several experts on patient safety. Items in the questionnaire are shown in the Appendix.

The questionnaire survey was conducted in December 2017, targeting policymakers concerning patient safety in OECD member states. The questionnaire was distributed by e-mail by the Ministry of Health, Labour and Welfare of Japan to the delegates of OECD member states, transferred to the key persons involved in patient safety policies in each state, and collected by e-mail. We compiled the results of the questionnaire into a report on patient safety policies in each state. The respondents rated the effectiveness and priority of patient safety policies using a Likert scale of 1 (low) to 5 (high). For convenience, a favorable policy is defined as one that was rated high in effect ($\geq$3.5) and in priority ($\geq$4), and an unfavorable policy as one that was rated low in effect ($<$3) and in priority ($<$3). The evaluation depends on the mean values of the ratings for each policy.

RESULTS

The response rate of the survey was 51% (18/35). Most of the respondents or the counterparts of the survey were policymakers of the Ministry of Health in each state.

1. Safety standards

Hospitals are required to establish a patient safety system by law in 9 states. Among them, all hospitals are required to establish the system in 6 states. The contents of requirements vary, but guiding principles, organization, patient safety manager, in-hospital reporting system or staff training on patient safety were commonly cited. Measurements of patient safety and participation of patients and caregivers are defined in some states, and may be the subject of discussion.

1.1 Requirement for hospitals to establish a patient safety management system by law

All hospitals are required: CZE, FIN, FRA, ITA, JPN, PRT, GBR

Some hospitals are required: CAN, KOR, ESP

Not required: BEL, IRL, SVK, SVN, CHE

Others: DNK, DEU, MEX

1.2 Actions required for hospitals

		CAN	CZE	DNK	FIN	FRA	DEU	ITA	JPN	KOR	MEX	PRT	ESP	GBR
1.2.1	To define the guiding principles (or guidelines) for patient safety program	+	+	−	+	+	+	+	+	+	−	+	+	+
1.2.2	To define the organization for patient safety management	+	+	+	+	+	+	+	+	+	−	+	+	+
1.2.3	To define who is assigned in charge of the patient safety management	−	+	+	+	+	+	+	+	+	−	+	+	+
1.2.4	To define the in-hospital reporting system for adverse event and close calls (near misses)	+	+	−	+	+	+	+	+	−	+	+	+	+
1.2.5	To define procedures for identification, investigation and prevention of adverse events	+	+	+	+	+	+	+	+	+	+	+	+	+
1.2.6	To define the staff education and training for patient safety	+	+	+	+	+	+	+	+	+	−	−	+	+
1.2.7	To define patient and caregiver participation in patient safety efforts	+	+	−	−	−	+	−	−	+	−	+	+	+
1.2.8	To define the measurement and evaluation of methods for patient safety (including patient safety indicators)	+	+	−	+	+	+	−	−	+	−	+	+	−

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

1.3 Details in each country

Canada

Law

Canada has legislation specific to patient safety, but due to Canada's decentralized health system, patient safety legislation and management varies across jurisdictions and is managed at the provincial/territorial health system level. Provincial/territorial health ministries may describe guidelines or requirements for the establishment of patient safety management systems for hospitals. For example, it is required by law in Quebec: S-4.2 - Loi sur les services de santé et les services sociaux. Ontario has The Excellent Care for All Act, and Newfoundland has the Patient Safety Act.

Guiding principles (or guidelines)

Hospitals - with their Regional Health Authority (RHA) and/or provincial/territorial Health Ministries - are required to define guidelines for their patient safety program including: patient safety education; reporting and tracking systems for patient safety incidents; all elements of incident management including guidelines for disclosure and support to patients, families and clinicians; risk management; investigation; and follow up reports and surveillance.

Organization

In Quebec, the law S-4.2 requires hospitals to establish a Risk Management Committee that oversees all Patient Safety related investigations, projects and strategic priorities. The Law further outlined the role and composition of the committee. Otherwise, hospitals define which department within the hospital manages patient safety activities.

Ontario's Excellent Care for All Act (ECFAA) requires every health care organization to establish a quality committee responsible for monitoring and reporting on quality issues at the hospital.

Person in charge of patient safety management

This is not specified by law. Guidelines exist that describe the competencies and experiences required for this role. Each hospital/health region has a quality/patient safety/risk management department or lead who is in accountable for managing the comprehensive processes needed to ensure patient safety.

In-hospital reporting system

In some provinces, this is described at a higher level, for example by the regional or provincial level. Reporting systems for adverse events vary by province in Canada but within a province, consistency across sites allows clinicians and patients to become familiar and comfortable with reporting processes.

In Quebec, the law S-4.2 defines in-hospital reporting system for adverse events and near misses, requiring a central reporting of adverse events.

Procedures for identification, investigation and prevention of adverse events

This process varies across provinces and territories. Within institutions, strategies for identifying adverse events include self-reporting, use of trigger tools, audits, insurer collected information, and other methods; most rely on an examination of past harms. Investigation processes may range by province but can include a privileged process consisting of interviews, research, chart reviews, and the creation of a summary document. Others may use the LEAN method to do a systematic review focused on improvements that can be quickly and easily implemented to prevent future harm. Decision making for what type of investigation to do may be aided by the use of a severity and impact matrix. The Quebec Law S-4.2 requires the establishment of policy and procedure for incident reporting, analysis and disclosure.

Staff education and training

Patient Safety staff education and training is required for accreditation purposes (and all Canadian hospitals and most other health care facilities are accredited). There may be leadership regionally or provincially, but

typically every health authority or hospital creates their own patient safety education program. This includes general patient safety awareness for all staff at orientation, information on how to report an incident, what the best practices are in patient safety in hospitals, current hospital improvement activities aimed at improving patient safety, and where to get more information.

Patient and caregiver participation

Patient and family engagement in patient safety is also an accreditation requirement for Canadian Hospitals. This is, however, defined locally. There are various ways for patients and caregivers to be involved in improvement efforts, including: having patients participate on LEAN improvement teams; supporting a patient, family and caregiver advisory council; and hearing patient stories at board meetings, events and during patient safety week. To some extent, the direction may come from a regional health authority and in fact, they may also have regional-level activities and efforts to improve patient safety that include patient and caregiver participation. There are various sources across Canada that define patient and family participation in patient safety. These include:

- Engaging Patients in Patient Safety - a Canadian Guide, developed by the National Patient Safety Consortium.
- Accreditation Canada's accreditation program has embedded client and family centered care in all their standards, and included patient representatives in the accreditation team.
- Patients For Patient Safety Canada (PFPSC) is a patient-led program of CPSI. PFPSC is the voice of the patients and brings the patient's safety experiences to help improve patient safety at all levels in the health system.

Measurement and evaluation

Ontario and Quebec have province-wide requirements and require the reporting of various types of patient safety indicators such as rates of nosocomial infections, wait times for surgeries, etc. Except for indicators of nosocomial infections, Ontario indicators include a rate for Surgical Safety Checklist Compliance.

Czech Republic

Law

Act no. 372/2011 Coll.

Bulletin 16/2015 Coll. Minimum requirements for the establishment of an internal system of quality assessment and safety of provided health services.

Denmark

Law

Government provides national system.

Organization

It is required locally.

Person in charge of patient safety management

It is required locally.

Finland

N/A

France

Law

The 2009 law about "Hospital reform and concerning patients, health and territories" (2009-879 dated 21 07

2009) states in its first article that healthcare quality, patient safety and management of risks, including their prevention and control, are a policy target for all healthcare structures, whatever type of care they provide, whatever public or private status they are.

The ministerial decree, 2010-1408 dated 12 11 2010, established further obligations for this patient safety policy in hospitals. This decree states:

a) what is a healthcare adverse event in hospitals,
b) that the director and the president of the medical community of the hospital are both liable for the management of patient safety in the structure and for its operational framework for which
c) they assign a dedicated professional,
d) what are the targets of this organization: patient safety culture, coordination, expertise, putting up a program and its yearly evaluation, on-going training, etc.

These policy lines have been disseminated in a more operational and detailed document called "instruction".

Patient and caregiver participation

This specific theme is integrated in the National Patient Safety Program 2013-2017. Its first target (out of 4) is dedicated to partnership with patient and patients' representatives. It includes deliverables for both professionals and patients, and also for their representatives. All deliverables aim at a better communication and partnership.

Germany

Law

There is no specific law related to patient safety. However, the Social Code Book Five (SGB V), that is a law for statutory health insurance, obligates the Federal Joint Committee to define measures for the improvement of patient safety and to establish minimal standards for risk management systems and Critical Incident Reporting System (CIRS). The respective regulation of the Federal Joint Committee (Gemeinsamer Bundesausschuss: G-BA) that are binding for all parties in the statutory health insurance is the Quality Management Guideline (§§1-4 Qualitätsmanagement-Richtlinie: QM-RL).

Guiding principles (or guidelines)

In accordance with the QM-RL, the mandatory quality management achieves to define general methods for securing and developing the quality of the health care including patient safety (§3 QM-RL).

Organization

Structures of the organization, responsibilities, competences and decision responsibilities are to be established in a written form (§4(1)3 QM-RL).

In-hospital reporting system

Hospitals are obliged to establish an internal Critical Incident Reporting System (CIRS). Required features are a low threshold access for all levels and professions of staff and a customer friendly layout (§4(1)14 QM-RL). In addition, there is an incentive for hospitals to engage in multi-center Critical Incident Reporting System (CIRS) programs in accordance with Hospital Financing Act (§17b (1a(4))). The engagement is voluntary.

Procedures for identification, investigation and prevention of adverse events

The risk management system in a hospital is mandatory to establish. A systematic risk management strategy includes the systematic recognition, estimation, processing and oversight of risks as well as the analysis of critical and undesired events, damages and, finally, the elaboration and realization of preventive measures (§4 (1)13 QM-RL).

Staff education and training

Participation of all staff in trainings and educations that relate to their occupation is compulsory (§4(1)7 QM-RL). However, there is no special regulation to make patient safety a topic of these trainings and educations.

Patient and caregiver participation

According to the QM-RL (§4(1)13), the patient-and staff-perspectives are explicitly to be considered, but the elaboration of specific measures for patient participation is left up to the hospital.

Measurement and evaluation

According to QM-RL (§2), internal goals in each institution are to be elaborated in a systematic process that includes systematic planning, implementation, revision and, if necessary, improvement (so called PDCA-plan – plan, do, check, act). Quantitative and qualitative indicators are used to evaluate the benchmarks internally and to foster implementation.

Ireland

Law

The Irish Government has approved the General Scheme of Patient Safety (Licensing) Bill. This Bill is being progressed and all hospitals will be required to hold a license to operate. This license will require hospitals to meet core patient safety standards and have clinical governance frameworks in place.

Italy

Guiding principles (or guidelines)

The Italian Ministry of Health defines the guidelines, and the hospitals adapt these guidelines to their context.

Person in charge of patient safety management

Every hospital has a risk manager who is responsible of Patient Safety at hospital level.

Procedures for identification, investigation and prevention of adverse events

The MoH published a guide on the analysis systems with the aim of facilitating identification, investigation and actions for the prevention of similar events.

Japan

Law

Patient safety management in hospitals is requested by the Medical Care Act that covers broad contents concerning hospital management and standards. Under the Medical Care Act and the Ordinance for Enforcement of the Medical Care Act, all healthcare organizations including hospitals and clinics are required to establish patient safety policies, to organize a patient safety management committee, and to provide patient safety training for employees every year.

Person in charge of patient safety management

Special function hospitals, such as university hospitals that provide advanced medical care, are required to assign patient safety managers responsible for patient safety management. For other hospitals, assignment of patient safety managers is not mandatory, but is encouraged by financial incentives: hospitals with patient safety managers can receive more money from public medical insurance. Most acute care hospitals have already assigned patient safety managers.

All hospitals are required to designate a person responsible for pharmaceuticals safety and a person responsible for medical device safety. Those personnel are required to establish procedure manuals regarding medication, dispensing or medical device management, and to monitor alerts from related organizations.

In-hospital reporting system

All healthcare organizations are required to implement an in-hospital reporting system for incidents and accidents.

Korea

Law

Patient Safety Act

Guiding principles (or guidelines)

Patient safety standards (Article 9 of the Patient Safety Act; and Article 6 of the Enforcement Decree of the Patient Safety Act)

Organization

Tertiary hospitals (general hospitals) and hospital-level medical institutions with 200+ beds are required to establish and operate a patient safety committee within hospital. (Article 11 of the Patient Safety Act; and Article 6-7 of the Enforcement Rule of the Patient Safety Act)

Person in charge of patient safety management

Tertiary hospitals (general hospitals) and hospital-level medical institutions with 200+ beds are required to deploy personnel dedicated to patient safety within hospital (Article 12 of the Patient Safety Act; and Article 9 of the Enforcement Rule of the Patient Safety Act).

Patient and caregiver participation

Paragraph 2/Article 5 of the Patient Safety Act states the responsibility of patients and their guardians to participate in patient safety activities.

Measurement and evaluation

It is mandatory to develop and disseminate assessment standards (patient safety indicators) which can measure performance on patient safety and the quality of care (Article 10 of the Patient Safety Act; and Article 4 of the Enforcement Rule of the Patient Safety Act).

Mexico

Law

In September 2017, the General Health Council, published in the Official Federal Diary the Essential Actions for Patient Safety, this document is not considered a law, but it has a mandatory character to all hospitals in Mexico. The implementation of this actions will be supervised by the accreditation process that is necessary to be eligible to receive funds from the "Seguro Popular".

Organization

The hospital committee for quality and patient safety convenes at least 3 times a year, to analyze all potential risks in patient safety. All sentinel events must be analyzed by the quality and patient safety committee.

In-hospital reporting system

The Adverse Event report system is mandatory according to Essential Actions for Patient Safety.

Portugal

Law

The Ministry of Health published

(1) The National Plan for Patients' Safety 2015-2020 (Order nº 1400-A/2015) to establish the national patient safety strategic goals and

(2) the Quality and Safety Commissions Order (Order nº 3635/2013) to determine the creation of Commissions that have to implement the National Strategy for Quality in Health (Order nº 5613/2015) as well as the National Plan for Patient's Safety. These Commissions also have to submit an annual report of the activities developed and the action plan for the next year.

Organization

According to Order nº 3635/2013, all healthcare institutions (hospitals and primary healthcare units) are obliged to have Quality and Safety Commissions, and its president must be designated by the board of director of the Institution.

Slovakia

Law

There is not specific law oriented toward patient safety management, only partial topics are covered e.g. the regulation No. 553/2007 Coll., or quality systems ISO 9001:2000 and ISO 14001:2004. Legislation is in process of preparation. Separately system is required to establish for the purposes of clinical testing of the medicines too.

Slovenia

Law

This area is partly regulated in the Patients' Right Act. The Law on Infectious Diseases is also important. They apply to all healthcare organizations, not only for hospitals. The Quality and Safety Act is the process of preparation. This is an important part of the government project "Šilih". The project represents a government commitment to improve the quality and safety of healthcare.

Spain

Law

Some Health Regions have some patient safety requirements for authorizing healthcare centers. Others have specific laws on PS for all the healthcare centers, but the effects have not been evaluated yet. In addition to that, the national strategy of PS recommends to the Regions to have PS management systems in their healthcare centers (hospitals & primary care). Guideline varies by the Regions.

United Kingdom

N/A

2. Audits and accreditation of hospitals

Periodic audits of patient safety conditions by the government are a common policy in most states, but the audit items vary among states. Hospital accreditation systems and bodies vary among states. The proportion of accredited hospitals is high in Canada, Italy, Slovenia and the United Kingdom. Most accreditation systems are on a voluntary basis, but all hospitals are obligated to be accredited in the United Kingdom, and some provincial/territorial governments in Canada require hospitals to be accredited based on local law. Half of the respondent states have some systems or incentives to encourage hospitals to undergo hospital accreditation. Denmark stopped accreditation in 2015. The effects of accreditation on patient safety are not yet established, and how best to promote accreditation is an issue that needs to be addressed since the proportion of accredited hospitals in most states is less than 50%.

2.1 System of audit and accreditation for hospitals

			BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
2.1.1	Periodic audit for patient safety conditions by the government		+	+	+	+	+	+	±	+	+	+	−	+	+	±	+	+	−	+
2.1.2	Hospital accreditation system by an independent third-party organization		+	+	+	−	−	+	+	±	+	+	+	±	+	±	+	+	−	+
2.1.3	Systems or incentives to support hospitals to undergo hospital accreditation		+	±	+	−	−	−	−	−	+	−	+	+	+	±	+	+	N/A	±
2.1.4	Accredited hospitals	No.	30	N/A	208	N/A	N/A	N/A	N/A	N/A	N/A	2181	1688	3997	74	N/A	28	150	N/A	N/A
		%	16	97	N/A	N/A	N/A	N/A	40	N/A	95	26	44	18	33	N/A	100	33	N/A	100

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

2.2 Name(s) of the accreditation body(ies)

Belgium

Joint Commission International (JCI)

Netherlands Institute for Accreditation in Health Care (Nederlands Instituut voor Accreditatie Ziekenhuizen: NIAZ) - Qmentum

ACI

Canada

Accreditation Canada

Conseil Québécois d'agrement

Commission on Accreditation of Rehabilitation Facilities Canada

Canadian Association for Laboratory Accreditation

etc.

Czech Republic

Joint accreditation committee
Czech Republic Association for accreditation in Healthcare
e-ISO, a.s.
Tcert, s.r.o
EURO CERT CZ, a.s.
LL-C (Certification) Czech Republic a.s.
DNV GL Business Assurance Czech Republic s.r.o.
Czech Republic Quality Union

Denmark

N/A

Finland

N/A

France

Nuclear Safety and Radiation Protection (Haute Autorité de Santé and Autorité de sûreté nucléaire)

Germany

Co-operation for transparency and quality in the hospital (KTQ)
International Organization for Standardization (ISO)

Ireland

N/A

Italy

Regions

Japan

Japan Council for Quality Health Care (JQ)
International Organization for Standardization (ISO)
Joint Commission International (JCI)

Korea

Korea Institute for Healthcare Accreditation (KOIHA)

Mexico

General Directorate of Quality and Healthcare Education (Dirección General de Calidad y Educación en Salud: DGCES)

Portugal

ACSA
Joint Commission
CHKS

Slovakia

International Organization for Standardization (ISO)
Slovak National Accreditation Service (SNAS)
The Czech Society of Clinical Biochemistry
The Reference Laboratory for Clinical Biochemistry in the Czech Republic

Slovenia

Join Commission International (JCI)
Accreditation Canada (AC)
Det Norse Veritas GLAS (DNV)-NIAHO
American Accreditation Commission International (AACI)
Slovenian Independent Organization

Spain

Ministry of Health, Social Services and Equality (MSSSI)
Andalusian Agency of Quality
Cataluya Region, etc
Joint Commission (JC)
International Society for Quality in Healthcare (ISQua)

Switzerland

N/A

United Kingdom

The Care Quality Commission

2.3 Details in each country

Belgium

Audit by government

Only the Flemish government audit patient safety conditions in the Flemish region.
A thematic inspection on specific patient groups whereby safety components are inspected (e.g. high risk medication, patient identification, safe surgery checklist).

Accreditation by a third-party organization

Accreditation in Belgian hospitals is still an ongoing process (in Brussels and Walloon region the accreditation process is initiated only recently). Close to all Belgian hospitals who do not have a certificate yet, are in preparation and will obtain one in the next year(s).
Between 2012 and 2017, there was a financial support for hospitals that participated in a national patient safety program relating to topics of accreditation such as patient identification, safe surgery, high risk medication, integrated care, leadership, communication, patient empowerment, or safety management. From 2018, in a scheme of P4Q for acute hospitals, accredited hospitals will get points and a financial incentive.

Canada

Accreditation by a third-party organization

Hospitals in Canada and most other health care facilities are accredited regularly against defined quality and

safety standards. In most jurisdictions, accreditation is voluntary (exception Quebec where it is required by law, in Alberta where it is required under a directive from the Ministry of Health, and in all Canadian teaching hospitals, where in order to maintain teaching status from Canadian medical regulatory colleges, the hospitals much be accredited, which means that almost every hospital by default must be accredited).
The Quebec Law S-4.2 requires Quebec hospitals to be accredited. The health ministry then requires hospitals who received recommendations in the accreditation process to report to the government on their follow-up improvement activities.

Czech Republic

Audit by government

Adverse events and 8 National safety goals (patient identification, safety in the use of medicinal products, surgical procedures, procedures of hand hygiene, transfer of patients, etc.) are inspected by the government.

Accreditation by a third-party organization

It is not an obligation, but most of the hospital is accredited by independent third-party organizations.

Denmark

Audit by government

Risk based supervision (regulation) with all care units

Accreditation by a third-party organization

It ceased in 2015.

Finland

Audit by government

Patient outcomes/diagnoses are inspected by the government.

France

Audit by government

Inspections are organized on both national and regional levels (the national "Inspection générale des affaires sociales" has a branch in each of the 17 Regional Health Agencies [Agences régionales de santé]). These inspection departments perform the necessary inspections and controls:

a) conformity of settings, equipment and qualifications to existing regulation and
b) on the spot inspections in case of claims, proven risks, defective answers to patient's unexplained death or other difficult situations, and any other situation they consider at high risk.

Accreditation by a third-party organization

Accreditation of hospitals has been launched in 1999 (and ever since named "certification"). It is an external and compulsory process of quality assessment imposed on every healthcare structure, including autonomous plastic surgery settings. It is led by healthcare experts (medical and non-medical peers) appointed by an independent body, Haute Autorité de santé, and carried out every 4 to 6 years in each HC structure.

Germany

Audit by government

It is not a responsibility of the federal government to provide on-site medical care. It is regulated individually at state level. The Joint Commission (G-BA) put the Institute for Quality Assurance and Transparency (IQTIG) in charge of developing recommendations for establishing and explaining the state of quality management;

including the use of representative sample surveys (§ 6 QM-RL). So far, hospitals are obliged to report the state of their quality management and Critical Incident Reporting System (CIRS) in their annual "quality reports" (§§ 136a(3)2 and 136b(6)V).

Accreditation by a third-party organization

There is no compulsory accreditation of hospitals. However, many hospitals opt for a voluntary certification by an independent organization for their quality management. There are no official numbers of accredited hospitals because ISO does not publish them. It is estimated that 40% of the 1900 hospitals underwent certification.

Ireland

Audit by government

Via the Health Information and Quality Authority which is a service regulator under the aegis of the Department of Health. Hospitals follow the National Standards for Safer Better Healthcare (2012). Themes include maternity, hygiene, nutrition, and medication safety. Disability and social care services are regulated as designated centres under specific HIQA Standards.

Accreditation by a third-party organization

International accreditation systems are used by private hospitals. This is not prescribed by the government however it is required by health insurers.

Italy

Accreditation by a third-party organization

The accreditation process is performed by Regions. All the public hospitals are accredited. Private hospital can ask for accreditation with the National Health System. A small group of private health facilities are not accredited with the NHS.

Japan

Audit by government

Under the Medical Care Act, the prefectural government audits hospitals by an on-the-spot inspection every year.

Accreditation by a third-party organization

Accreditation is not mandatory. For some hospitals such as university hospitals and teaching hospitals, accreditation is recommended by the government. The Japan Council for Quality Health Care (JQ) is the biggest third-party accreditation body. Activities of the JQ include: (1) hospital accreditation, (2) clearinghouse of clinical practice guidelines, (3) nation-wide medical incident and accident reporting system, and (4) no-fault compensation of cerebral palsy babies.

Korea

N/A

Mexico

Audit by government

Through the accreditation and certification process, all facilities from the public and private sector need to prove that they comply with patient safety conditions. The General Health Council certificates the medical facilities. The medical facilities voluntarily request the certification. This process evaluates patient safety conditions, and is performed up to every 5 years.

The inspected items are the essential actions for patient safety measure: 1. patient identification, 2. effective communication, 3. correct medication process, 4. correct procedures, 5. control of healthcare associated infections 6, control of patient falls, 7. adverse events reports, 8. patient safety culture.

Accreditation by a third-party organization

The accreditation is performed by the General Directorate for Quality and Healthcare Education, and the certification is performed by the General Health Council, both are public entities. The accreditation is necessary for medical facilities to be eligible to receive funds from the "Seguro Popular".

Portugal

Audit by government

There is a protocol signed by the Ministry of Health and by the Portuguese Medical Association to audit regularly national guidelines. The annual plan for audits is defined by the Ministry of Health for specific national guidelines or specific clinical areas (Examples: prescription of antimicrobials and diabetes, WHO safety surgery checklist, etc.).

Accreditation by a third-party organization

ACSA accredits 54 hospitals and services; Joint Commission accredits 9 hospitals; CHKS accredits 11 hospitals. Portugal also have an accreditation of the Primary Care Units (42). The ACSA model is a no-profit Ministerial accreditation program.

Slovakia

Audit by government

There is no regular governmental audit system for patient safety conditions.

Accreditation by a third-party organization

Hospitals can use the ISO on a voluntary basis. It is regarding Integrated Quality Management and Environmental Management according to ISO 9001: 2000 and ISO 14001: 2004 standards. We do not have information about number of all certificated hospitals.

There is an external independent accreditation system for the medical or clinical laboratories only.

Slovenia

Audit by government

There are regular professional control and counseling. The regular surveillance program is public available. Administrative controls are also carried out. The Medical Chamber and the Health Care Chamber also obtained a public authorization to carry out inspections. The control is carried out for a particular area (health care, physiotherapy, etc.) or for a particular provider.

Protocol:

- verification of the adequacy of professional development and organization of work,
- checking the implementation of quality and safety in the field of expertise,
- checking the continuous tracking of the development of the profession,
- checking and complying with doctrines and guidelines in the field of work,
- verification of the performance of professional activities in accordance with professional and ethical codes,
- checking the appropriate staffing,
- consultations on the basis of the findings of expert supervision,
- team work.

Accreditation by a third-party organization

Certification and accreditation processes vary in Slovenia. All hospitals in Slovenia are accredited. For hospitals without accreditation, the pay activity was reduced by 0.3%.

Spain

Audit by government

The government audits patient safety condition for teaching hospitals and reference centers. Hand hygiene, patient identification, management of high risk medication, protocols of medication reconciliation and Reporting and Learning System (R&LS) are inspected.

Accreditation by a third-party organization

Some hospitals accredited in some of the Regions. The MSSSI accredited 150 teaching hospitals, and this figure refers only to public hospitals (451 in total). In Spain, there are 791 public and private hospitals in total. Incentives for accreditation varies by region, including funding by the Healthcare Region.

Switzerland

N/A

United Kingdom

Audit by government

The UK Care Quality Commission inspects all Hospitals and rates their performance against 5 key indicators, one of which is safety. This indicator includes information regarding safe staffing levels, patient monitoring, capability to investigate mistakes, cleanliness and contingency planning.

Accreditation by a third-party organization

Accreditation is a mandatory requirement.

3. Data submission requirements by hospitals

Most data submission systems of clinical indicators are on a voluntary basis. The number of required indicators is 238 in Germany, and about 150 in Switzerland. The collected data are made public in such a way that the hospital can be identified in more than half of the states. A pay-for-performance scheme according to reported clinical indicators has been introduced in France, Korea, and Portugal. As a driver of quality improvement, benchmarking with a reference database seems to be more popular than pay-for-performance schemes.

In most states, hospitals are requested to report serious adverse events to the government. Patients or family members are also able to report events to the national system only in Korea and Portugal. Alerts or aggregated data of reported adverse events are published in each state, and such information should be shared across the states.

A system to exempt liability for an adverse event when it is reported to the government or other organizations has been introduced only in Finland, Germany and Korea. According to newly introduced legislation in Ireland, open disclosure and apology cannot be regarded as admission of liability and cannot be used in litigation against the person making the disclosure.

3.1 System of data submission

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
3.1.1	Requirement for hospitals to submit data of clinical indicators concerning patient safety to the government or an independent third entity	±	+	+	+	+	+	±	+	±	±	+	+	+	±	+	+	+	±
3.1.2	No. of required indicators	1	Varies	8	Varies	N/A	24	238	11	5	Varies	27	8	56	21	4	50~60	150	5
3.1.3	Patient reported outcomes or experiences in the reporting indicators	−	+	+	+	−	+	−	±	−	±	−	−	+	−	−	±	+	N/A
3.1.4	Publication of the collected clinical indicators	+	+	+	+	+	+	+	+	−	±	−	+	+	+	±	+	+	+
3.1.5	Publication of the collected clinical indicators in a manner that identifies the hospital	+	+	−	−	−	+	+	+	−	±	−	+	+	−	−	−	+	+
3.1.6	A system to reward or penalize hospitals based on the reported data	+	−	−	−	−	+	+	−	−	−	+	−	−	−	−	+	−	−
3.1.7	Requirement for hospitals to report adverse events to the government or an independent organization	−	+	+	+	+	+	−	+	+	+	−	+	+	±	+	−	−	N/A

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
3.1.8	Voluntary reporting system of adverse events to the government or an independent organization	−	+	−	−	N/A	+	+	+	+	+	+	+	+	+	+	+	+	+
3.1.9	Voluntary reporting system of close calls/near misses to the government or an independent organization	−	+	−	−	N/A	+	+	+	−	+	+	+	−	+	±	+	+	+
3.1.10	Periodical publication of sentinel events based on reported adverse events and close calls	−	+	+	+	−	±	±	+	+	+	+	±	−	−	−	+	−	+
3.1.11	A system to exempt criminal or civil liability of adverse events when the case is reported to the government or the independent organization	−	−	−	+	+	−	+	±	±	−	+	−	−	+	−	−	−	−

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

3.2 Name of organization that collects the information of adverse events or close calls

Belgium

N/A

Canada

Some jurisdictions, MedEffect Canada, National System for Incident Reporting, safemedicationuse.ca (ISMP Canada) etc.

Czech Republic

Institute of Health Information and Statistics of the Czech Republic

Denmark

The Danish Patient Safety Authority

Finland

National Institute for Health and Welfare, Finnish Medicines Agency, National Supervisory Authority for Welfare and Health

France

Nuclear Safety Authority (L'Autorité de sureté nucléaire)

Germany

Association of Statutory Health Insurance Physicians, Chamber of Surgeons, German Hospital Federation

Ireland

N/A

Italy

Ministry of Health

Japan

Japan Council for Quality Health Care (JQ), Japan Council for Patient Safety Investigation

Korea

Korea Institute for Healthcare Accreditation (KOIHA)

Mexico

General Directorate of Quality and Health Education (DGCES)

Portugal

Directorate General of Health, National Institute of Pharmacy and Medicine (Instituto Nacional da Farmácia e do Medicamento: INFARMED)

Slovakia

National State Institute for Drug Control (Štátny ústav pre kontrolu liečiv)

Slovenia

Ministry of Health

Spain

Reporting and Learning System for Patient Safety (SiNASP)

Switzerland

Patient Safety Switzerland

United Kingdom

Care Quality Commission

3.3 Details in each country

Belgium

Data submission of clinical indicators concerning patient safety

Several initiatives collect indicators but there is no systematic and coherent approach on national level. Hospitals participate on a voluntary basis. The data is made public partially.

The P4Q-program starts in 2018, and it uses a structural indicator on coding patient safety incidents bases on the ICPS of the WHO. Hospitals will not be penalized but will not get a financial incentive for bad results on

the structural indicator on coding patient safety incidents.

Public reporting of adverse events or close calls

Hospitals notify incidents on a voluntary basis but notification is highly supported by the Belgian government. However, notifications are not required by the government. Radiotherapy incidents and blood transfusion incidents are required to be notified to specific bodies.

Canada

Data submission of clinical indicators concerning patient safety

Some provinces and territories mandate indicator submissions (ex. Ontario, Quebec, Nova Scotia) or cooperation with provincial health quality councils who assess health care system performance, but most do not. Provincial governments where applicable (ex. Ontario, Quebec) review hospital performance based on the indicator reports and incident reporting. Where indicated, the provincial government may request a follow-up action plan from the healthcare organization. In addition, several provinces have independent health quality organizations with mandates to report publicly on and to support efforts to improve patient safety in that jurisdiction.

Some national organizations, for example, the Canadian Institute for Health Information (CIHI) collects indicator data from provincial governments but participation in its processes is not mandatory. CIHI maintains a suite of patient safety indicators through its administrative databases, including measures related to Hospital Harm (a composite measure of 31 specific clinical groups), obstetrical safety, patient falls, infections, pressure ulcers, and the inappropriate use of antipsychotics.

Summary reports of collected data are produced and posted on websites (ex., Ontario, Quebec, Manitoba). CIHI maintains the publicly facing, searchable database "Your Health System" which includes many of their safety indicators. Hospitals are identified in some situations, and other times, the data is rolled up to a regional/provincial level.

Patient reported outcomes or experiences are not collected regularly, but efforts are underway in Canada to do so more frequently. CIHI is now collecting data from Patient Reported Outcome Measures (PROMS): PROMs are measurement instruments that patients complete to provide information on aspects of their health status that are relevant to their quality of life, including symptoms, functionality and physical, mental and social health. CIHI also collects and administers the Canadian Patient Experiences Survey - Inpatient Care. In addition, in Canada, many jurisdictions conduct patient experience surveys using a variety of tools and data collection methods. To support pan-Canadian comparisons of patient experience, CIHI worked with representatives from Canadian jurisdictions and other leading experts in the field to develop a standardized questionnaire. This enables patients to provide feedback about the quality of care they experienced during their most recent stay in a Canadian acute care hospital.

Public reporting of adverse events or close calls

Mandatory reporting of critical incidents is required in some jurisdictions:

Manitoba requires to report critical incident that is defined as "an unintended event that occurs when health services are provided to an individual and results in a consequence to him or her that is serious and undesired." Anybody can report a critical incident, including patients, family members or health care providers.

Quebec requires the reporting of incidents, accidents and near misses. 481,000 events were reported between April 1, 2014 and March 31, 2015. Among the events reported, 86% are accidents (adverse events), and 14% are incidents (near misses).

Saskatchewan requires to report critical incident that is defined as "a serious adverse health event including, but not limited to, the actual or potential loss of life, limb or function related to a health service provided by, or a program operated by, a health care organization."

In 2014, the Government of Canada put in place the Protecting Canadians from Unsafe Drugs Act (Vanessa's Law). Vanessa's Law introduced amendments to the Food and Drugs Act that will improve Health Canada's ability to collect post-market safety information, and take appropriate action when a serious risk to health is identified. These amendments include the mandatory reporting of serious adverse drug reactions and medical device incidents by healthcare institutions.

Voluntarily reporting system for medication safety administers by MedEffect Canada, National System for Incident Reporting, safemedicationuse.ca (ISMP Canada) Individual Practitioner Reporting System, etc.

Nova Scotia publishes quarterly reports on the Serious Reportable Events, but the system varies among provinces, territories and respective health authorities. According to the critical incident reporting, Patient Safety Alerts are published by Manitoba and Saskatchewan government. The Canadian Patient Safety Institute (CPSI) is working to support sharing across jurisdictions via the Global Patient Safety Alerts that is a growing repository of alerts and recommendations from around the world meant to support the identification of risks and solutions to prevent harm.

Ontario's Excellent Care for All Act (2010) legislates that hospital annual quality improvement plans must be developed, having regard to its aggregated critical incident data as compiled based on disclosures of critical incidents pursuant to regulations made under the Public Hospitals Act (PHA). In addition, as of January 1, 2011, the PHA Regulation 965 was amended to ensure that the administrator provides aggregated critical incident data to the quality committee at least two times per year.

Exemption system of liability of adverse events

There is no system to exempt criminal or civil liability of adverse events, but some protection does exist for some situation, and varies by jurisdiction. Legislative protection which prevents release of information concerning quality reviews from subsequent disclosure in the context of legal proceedings now exists in all Canadian provinces. For example, the Manitoba Evidence Act. In addition, almost all provinces have Apology Acts, whereby care providers can apologize to a patient or a family for a safety incident or undesirable outcome without that apology being taken as an admission of guilt in a court of law.

Czech Republic

Data submission of clinical indicators concerning patient safety

Bulletin 16/2015 Coll. Minimum requirements for the establishment of an internal system of quality assessment and safety of provided health services and Act no. 372/2011 Coll. There is no reward or penalization for the reporting.

Public reporting of adverse events or close calls

There is no voluntary system and we have obligatory system which is on high priority. Since 2018, all inpatient healthcare facilities will be obligated to report adverse events to the Ministry of Health and the Institute of Health Information and Statistics (IHIS). The Central system for adverse event reporting (CAERS) is serving rather as methodological support for quality of care improvement, sharing knowledge system and platform for methodological guidance production and implementation. On the national platform for CAERS, a part of sentinel event is published, but the portal is available only to certified person.

Exemption system of liability of adverse events

Criminal or civil liability AE are evaluated on local level of each hospital or facility. There are anonymous aggregated data reported to the government and IHIS.

Denmark

Data submission of clinical indicators concerning patient safety

The aggregated data is made public.

Public reporting of adverse events or close calls

All adverse events are mandatory to report.

Finland

Exemption system of liability of adverse events

According to Criminal Act, there is a system to exempt liability of adverse events.

France

Data submission of clinical indicators concerning patient safety

Every hospital has to publish (display on its website and on the hospital lobby walls) the results of a list of patient safety and quality indicators. The Ministry of Health specifies this list of indicators every year. The results of all hospitals are open to the public on both the Haute Autorité de Santé website (scope sante) and the Ministry website with other information and results, "certification", for example. For 2018, 24 indicators are listed and will be published. They are process indicators (22) and patient satisfaction (2).

There is a system to enhance hospital quality, called Incitation financière à l'amélioration de la qualité (IFAQ). It is based on the results of the above indicators and consists of rewards only (min 50 000 € and max 500 000 € for one hospital), as long as the hospital meets definite requirements of quality or has made a positive step towards better quality.

Public reporting of adverse events or close calls

Hospitals are required to declare serious adverse events related to health care to their Health Regional Agency. Since March 2017, a nationwide web-based adverse events reporting system has been provided to both HC professionals (hospital, in-town and elderly care) and patients. This reporting system integrates all regulated vigilances (medication, material such as medical devices, blood derived products, cosmetics, etc.) and is meant to enhance collaboration between the professionals who provide the specialized expertise in each of them.

The serious adverse events are reported in 2 times by professionals or organizations: at once when it occurs, and then within 3 months in order to allow the professionals to perform their analysis and put up corrective measures. The serious adverse event reports, once they are considered dealt with by the Regional Health Authority, are anonymized and transferred to the Haute Autorité de Santé, in charge of an annual report about the facts and issue the necessary recommendations to prevent those events. The first global report on declared serious adverse events is due by HAS in 2018.

There is a voluntary system for at-risk specialist doctors, called "accreditation des médecins des spécialités à risques" based on the reporting of 3 "risk baring events" each year but it is so far mostly implemented in primary care only. The specialists report to the Haute Autorité de Santé which is in charge of the whole process.

L'Autorité de sureté nucléaire provides extended information on the prevention and management of risks derived from interventional radiology, nuclear medicine, radiotherapy, etc. This information is based on a principle of shared reporting and feedback.

Germany

Data submission of clinical indicators concerning patient safety

According to "Social Code Book Five (SGB V) Statutory health insurance -§135a(2)1", hospitals are obligated to participate in cross-institutional measurements for quality assurance. The details are written in the Guideline on Quality Assurance Measures in Hospitals (Richtlinie über Maßnahmen der Qualitätssicherung in Krankenhäusern: QSKH-RL) that is published by the Joint Commission (G-BA). According to the QSKH-RL, that is a framework of external quality assurance, the Joint commission (G-BA) obligates hospitals to report 238 indicators including sentinel-event-indicators such as mortalities in obstetrics. In addition, the Joint

Commission (G-BA) deals with the hospitals which reported suspicious quality results. If a suspicious hospital does not manage to improve the quality, several measures are prescribed. Those include professional training, inspections of the hospital, or setting of milestones that lead to improve the quality.
According to "§136b (1)1.3", hospitals are obligated to publish annual quality reports, that contain patient safety indicators such as sentinel-event-indicators and information on risk management and Critical Incident Reporting System (CIRS). The quality reports of individual hospital publish 216 out of the 238 reported indicators. Many search engines and comparison websites make use of this data. The Institute for Quality Assurance and Transparency (IQTIG) publishes annual quality reports that include a summary of de-identified data.
In accordance with the Hospital Restructuring Act (Krankenhausstrukturgesetz), that was enacted in January 2016, the Joint Commission was ordered to identify services that are suitable for quality adjusted incentives and disincentives as well as the measures to introduce them.
As for patient reported outcomes or experiences, patient interviews are not part of the external quality assurance measures. However, the Joint Commission (G-BA) instructed the IQTIG to develop such patient interviews. Therefore, the external quality assurance will include such patient reported outcomes in the near future.

Public reporting of adverse events or close calls

There is an incentive for hospitals to engage in multi-center Critical Incident Reporting System (CIRS) programs. However, it is not a legal requirement.
There are multiple voluntary reporting systems that are established and run by non-government bodies. Publication rules of reported adverse events vary with the registry.

Exemption system of liability of adverse events

It is written in a law as follows:
"Reports and data from in-hospital and cross-institutional risk management and error reporting systems shall not be used in legal relations to the detriment of the reporting person. This does not apply if they are necessary to prosecute a criminal offence that carries a maximum penalty of more than five years of imprisonment, if it is a particularly serious case, and if it would be impossible or would be much harder to investigate the case or the whereabouts of the offender." (Social Code Book Five (SGB V) Statutory health insurance - §135a(3))

Ireland

Data submission of clinical indicators concerning patient safety

The first National Patient Experience Survey was completed for all adult inpatients in the month of May with 61 internationally validated questions.

Public reporting of adverse events or close calls

Serious Reportable Events (SREs) are reported to HIQA. SREs are a defined list of serious incidents, many of which may result in death or serious harm (e.g. wrong site surgery). All hospitals are required to report adverse events on the National Incident Management System. The Department requires all hospitals to publish a monthly patient safety statement. Reported events are published in the Health Service Executive (HSE) Performance Report on a monthly basis.
Maternal deaths are required to be reported to the National Women and Infant's Programme.

Exemption system of liability of adverse events

Legislation for Open Disclosure provisions due to be enacted early 2018 provides protections for staff who conduct open disclosure in line with the legislation. The open disclosure and any apology cannot be interpreted as admission of liability and cannot be used in litigation against the person making the disclosure.

Italy

Data submission of clinical indicators concerning patient safety

The hospitals are not required to submit PS indicators, nevertheless regions have to send data to the Ministry.

Public reporting of adverse events or close calls

Only the serious adverse events which defined as Sentinel Events are required to report to the Ministry of Health. The MoH defined 16 sentinel events. We are approaching to collect data on adverse events and also on near misses. Other adverse events and near misses will be collected in the next future by the agency Agenas.

Exemption system of liability of adverse events

The government approved in March 2017 a new law on the responsibility of health professionals.

Japan

Data submission of clinical indicators concerning patient safety

It is not mandatory. Hospital associations and organizations such as the National Hospital Organization collect data using clinical indicators, and publish summary reports of collected data. For example, the All Japan Hospital Association collects data from 42 hospitals using 22 clinical indicators, and the Japan Hospital Association collects data from 350 hospitals using 32 clinical indicators and publishes an annual report in which hospitals can not be identified. The National Hospital Association collects data from 64 national hospitals using 25 clinical indicators, and publishes an annual report in which hospitals can be identified. The Government encourages the standardization of clinical indicators (i.e. definition, calculation methodology).

Public reporting of adverse events or close calls

Based on the Medical Care Act, national hospitals and special function hospitals such as university hospitals (276 hospitals in total) are required to report serious adverse events to the Japan Council for Quality Health Care (JQ). In 2016, they reported 3,428 adverse events. The JQ also collects near-miss data from 608 hospitals on a voluntarily basis. The database of anonymized case reports is open to the public on the website of the JQ. The database contains more than 75,000 reports and the number is increasing every year.

In addition, another reporting system named the Adverse Event Investigation System was introduced in 2016, where every healthcare organization must report an unexpected patient death due to medical service to the Adverse Event Investigation & Support Center, which is administered by the Japan Council for Patient Safety Investigation (a third-party non-profit organization). According to the system, hospitals are required to conduct an institutional review of the adverse event, and to submit a final report of the investigation to the organization. In 2017, hospitals reported 370 patient deaths to the organization.

The JQ also administers a national reporting system from pharmacies. Among 68,000 pharmacies, about 7,000 are voluntarily reporting adverse events and near misses to the JQ.

The JQ publishes Medical Safety Information monthly, which provides alerts based on reported adverse events and near misses. The Ministry of Health, Labour and Welfare publishes Pharmaceuticals and Medical Devices Safety Information almost monthly. The Pharmaceuticals and Medical Devices Agency publishes PMDA Medical Safety Information almost monthly.

Korea

Data submission of clinical indicators concerning patient safety

Tertiary hospitals are required to submit data of clinical indicators to the Health Insurance Review & Assessment Service (HIRA). The data is used to determine the amount of government funding for care quality assessment, which goes to healthcare institutions showing excellent performance.

Public reporting of adverse events or close calls

In accordance with the Patient Safety Act, we operate the adverse event reporting & learning system, which is based on voluntary reporting. Korea Institute for Healthcare Accreditation (KOIHA) is commissioned by the Ministry of Health and Welfare to establish and operate the adverse event reporting & learning system (Article 8 of the Enforcement Decree of the Patient Safety Act; Article 15 of the Patient Safety Act; and Public Notice No. 2016-141 by the Ministry of Health and Welfare).

Patients are possible to report adverse events to the national learning system on adverse event reporting (Article 14 of Patient Safety Act; and Article 12 of the Enforcement Rule of the Patient Safety Act).

In accordance with Article 16, warnings are issued when there are legitimate reasons: if an adverse event is new or may cause serious harm. Analysis documents on adverse events, including annual statistics on patient safety are scheduled for announcement.

Exemption system of liability of adverse events

In accordance with Article 14 of the Patient Safety Act, if the person responsible for causing an adverse event reports the case, administrative dispositions may be mitigated or exempted.

Mexico

Data submission of clinical indicators concerning patient safety

INDICAS II is a system managed by the General Directorate of Quality and Healthcare Education (DGCES), and include 4 HAS indicators and 4 Nursing Indicators. The collected data is made public in a website of DSCES.

Public reporting of adverse events or close calls

According to the Essential Actions for Patient Safety published in September 2017 by the General Health Council, the adverse events must be reported in the Adverse Event Report System managed by the DGCES. Up to December 2017, there were more than 11,000 reports from more than 450 hospitals in Mexico. This system encompasses all adverse events, close calls /near misses and never ever events, and it allows a comprehensive study of the incidence, frequency of all events, sorted by work shift, personnel type, place in the facility, etc. Adverse Events Report System gives reports to the users on the frequency and incidence of adverse events, by type of event, personnel type, work shift, preventability, etc. The use of the system to report adverse events is mandatory for all medical facilities, but the report itself is voluntary to all healthcare personnel.

Portugal

Data submission of clinical indicators concerning patient safety

Hospital are required to submit data to the Ministry of Health regarding the Ministerial Order nº 3635/2015 and Ministerial Order nº 5739/2015 and by the financing procedures (GDH and Contratualization Contract).

All data is published at the official portal of the Ministry of Health “Portal da Saúde” and at the official websites of the institutions of the Ministry of Health (Directorate-General of Health and Hospitals).

Public reporting of adverse events or close calls

NHS Hospitals are required to report adverse events to the Ministry of Health.

The Ministry of Health developed a National Reporting and Learning System and issued National Guidelines to support the investigation of adverse events and health risk management. Adverse events and near misses are reported voluntarily to National Incident Reporting System and National System on Adverse medication reaction. The National Incident Reporting System is anonymous and not punitive. The national reporting and learning system also includes notifications from patients. The Patient’s Complaints and Suggestions are analyzed and action’s plan are developed accordingly.

Slovakia

Data submission of clinical indicators concerning patient safety

Only partial data are submitted (e.g. Indictors of Quality for hospitals) to the national Health Care Surveillance Authority (Úrad pre dohľad nad zdravotnou starostlivosťou: HCSA) and the National State Institute for Drug Control (Štátny ústav pre kontrolu liečiv: NSIDC).

There are 18 indicators of Quality and 3 Indicators for public health (§52 par. 5 letters A, F, and G of the Act of the National Council of the Slovak Republic no. 355/2007 Z.z. on the Protection, Promotion and Development of Public Health and on Amendments to Certain Acts).

Public reporting of adverse events or close calls

All health care providers are obligated to report adverse events during the process of the clinical testing of the medicines only. The NSIDC is an independent body for the adverse events reporting in the area of medicinal products.

Patients in Slovakia are able to report complaint for hospitals to the HCSA. The patients reported 1652 complaints to the HCSA in 2016. The patients are able to get expertize from the HCSA.

Slovenia

Data submission of clinical indicators concerning patient safety

The data on falls, pressure ulcers, MRSA and hand hygiene are reported to the Ministry of Health. The data are partially accessible to the public at the website of the Ministry of Health. A system to reward or penalize hospitals based on the reported data is not exist yet. Efforts are going in this direction.

In Slovenia, we started the projects of Patient Reported Experience Measures (PREMs) and Patient Reported Outcome Measures (PROMs) with the support of the European Commission Structural Reform Support Service. We also participate in the Paris project working group.

Public reporting of adverse events or close calls

The Ministry of health has established the Reporting and Learning System on adverse/sentinel events for Hospitals in 2002. The instructions and reporting forms were prepared and are published on the website of the Ministry of Health. Report from hospitals to the Ministry of Health is mandatory. The Ministry of Health requires hospitals to report seven of the most serious dangerous adverse events: unexpected death, major permanent loss of bodily functions, the suicide of a patient in a medical institution, the switching of newborn babies, haemolytic transfusion reactions after the transfusion of blood or blood products due to the incompatibility of the main blood groups, surgical intervention on the wrong patient or on the wrong part of the body and the suspicion of a crime. In 2016, eight hospitals reported 18 cases that included 12 unexpected patient's deaths, 4 patient's suicides in the hospital, and 2 reports on an event which was not the subject of reporting to the Ministry of Health. As for the reported adverse events, there is an upward trend in the number of sudden death of a patient, and a downward trend in the number of reports which are not the subject of reporting to the Ministry of Health. The highest number of reported events on an annual level was 25.

The publishing system of reported events will be established as part of the update.

Exemption system of liability of adverse events

The Quality and Safety Act will attempt to establish a system to exempt criminal or civil liability of adverse events.

Spain

Data submission of clinical indicators concerning patient safety

The hospitals have to submit data of PS clinical indicators to the Health Regions because it´s included in their

annual objectives, and the Regions send some of these data to the MSSSI. The indicators include medication, HCAI, surgery and other PSI indicators. Patient reported outcomes are included in indicators in some Regions (mainly satisfaction), but not yet at national level. The Regions have their systems to reward hospitals that reach the objectives proposed on PS.
Only aggregated data are made public. Data by hospital/Region are restricted to the teamwork.

Public reporting of adverse events or close calls
Adverse events reporting to the government is not mandatory.
As for voluntary reporting system, the MSSSI promotes a Reporting and Learning System (R&LS) that is used by 10/17 Regions (SiNASP). The others have their own R&LS (Vallejo-Gutiérrez P, et al: Lessons learnt from the development of the Patient Safety Incidents Reporting an Learning System for the Spanish National Health System: SiNASP. Rev Calid Asist. 2014 Mar-Apr;29(2):69-77).
Annual report is published in the web page of MSSSI.

Exemption system of liability of adverse events
The R&LS are separate from judicial proceedings. However, if a judge requires information, there is no national/regional regulation that prevents it.

Switzerland

Data submission of clinical indicators concerning patient safety
All cantons (member states of the Swiss Confederation) require participation on quality indicators measurements. Hospitals are required approx. 150 indicators mostly through administrative data. Some cantons have additional quality requirements. Mortality rates and case load for approx. 50 conditions and interventions such as surgical site infections, falls, bedsores, potentially avoidable rehospitalizations and reoperations. Most indicators are made public.
Patient reported outcomes or experiences are included in the reporting indicators in mental health.

Public reporting of adverse events or close calls
There is no mandatory nationwide reporting system, but one canton requires it.
The Patient Safety Switzerland is an independent foundation, and provides a voluntary reporting system. Its focus is on promoting and developing safety in medical and nursing activities. It is funded by the federal government, the cantons and other sponsoring agencies, as well as by attracting third party funding and selling its services.

United Kingdom

Public reporting of adverse events or close calls
There are a number of methods for reporting of incidents, depending on the cause. These include the National Reporting and Learning System; the Serious Incident Framework; and the legal requirement to publish data on the number of deaths thought more likely than not to have been due to problems in care.
When reported to a service, such as the National Reporting and Learning System, recommendations are published

4. Personnel responsible for patient safety management (Patient safety manager)

Training for personnel responsible for patient safety management is offered in most states, but the program varies among states or educational organizations. The competencies of personnel are also defined in some states.

There is no national certification system for personnel. The assignment of personnel in hospitals is reimbursed only in Japan and Korea. The assignment of a person responsible for patient safety management in a hospital should be encouraged with incentives, although the effects of the assignment may need to be established.

4.1 System regarding personnel responsible for patient safety management

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
4.1.1	The personnel regarded as a professional focus in patient safety management	+	+	+	+	+	±	±	+	+	+	+	+	+	−	±	+	+	+
4.1.2	Standard educational programs for training the personnel	+	+	+	−	+	+	−	−	−	±	+	−	+	−	−	±	−	N/A
4.1.3	Organizations that offer education or training for the personnel	+	+	+	+	+	+	+	+	+	+	+	−	+	−	±	+	+	N/A
4.1.4	National or other certification system for the personnel	−	+	+	−	−	−	−	−	−	±	−	N/A	−	N/A	−	+	−	N/A
4.1.5	Incentives to promote assignment of the personnel in each hospital	+	−	+	+	+	+	−	±	−	+	+	−	−	−	+	−	−	N/A
4.1.6	Networks which promote information sharing among personnel across hospitals	+	+	+	+	+	+	+	+	+	+	−	+	+	−	−	+	+	N/A

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

4.2 Major educational background of the personnel

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
4.2.1	Medical doctor	+	+	±	+	+	+	±	±	N/A		+	+	N/A		+	+	±	+
4.2.2	Nurse	+	+	±	+	+	+	±	±	N/A	+	+	+	N/A		+		±	
4.2.3	Other healthcare professionals	+	+	±			+	±	±	N/A		+		N/A	±			±	

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

4.3 Details in each country

Belgium

Organizations that offer education or training for the personnel

Federal government, universities, private initiatives

Major challenges in training or the assignment of personnel in each hospital

Involvement of hospital management, clinical leaders and implementation of safety practices at the bed side

Canada

Assignment of personnel responsible for patient safety management

Often a master's level trained healthcare professional with a clinical or healthcare management background with training in quality improvement and patient safety.

Standard educational programs for training the personnel

The Canadian Patient Safety Institute offers education to healthcare providers and healthcare educators: The Patient Safety Officer Course, The Incident Management Education Program and the Patient Safety Education Program.

The Patient Safety Officer Course provides an overview of the fundamentals of patient safety and equips health care professionals and leaders with information, tools and techniques. The Patient Safety Education Program is a conference based education program which uses a train-the trainer curriculum-driven approach to teach both content and how to disseminate it. The Effective Governance for Quality and Patient Safety program supports boards in their efforts to improve governance for quality and patient safety. Advancing Safety for Patients in Residency Education is geared towards medical educators and residents with a keen interest in teaching and implementing patient safety and quality improvement initiatives.

Organizations that offer education or training for the personnel

- Canadian Patient Safety Institute - National Organization Focused on Patient Safety
- ISMP Canada- National Organization Focused on Medication Safety
- Ontario Hospital Association - Member Association that represents hospitals in Ontario
- Health Quality Council of Alberta- Alberta based organization that promotes and works to improve patient safety and health service quality
- HealthCareCAN- National Organization that is the voice of healthcare organizations and hospitals to improve health of Canadians through evidence based and innovative healthcare systems
- Royal College of Physicians and Surgeons - National organization that works to improve health by leading in medical education, professional standards, physician competence and continuous enhancement
- Canadian Medical Protective Association
- Universities are also offering graduate programs in quality improvement and patient safety. The Centre for Quality Improvement and Patient Safety/ University of Toronto/ The University of Montreal.

National or other certification system for the personnel

The Canadian Patient Institute offers the Patient Safety Officer Course as a certification program but this is a voluntary program. There isn't a requirement for certification. Such decisions to certify Patient Safety Leaders would be local in nature.

Incentives to promote assignment of the personnel in each hospital

Incentives may be in the nature of the position being a management level position, thus the benefits (part of leadership team, salary, regular work hours, etc.) that would accompany of such a position.

Networks promoting information sharing among the personnel across hospitals

Each jurisdiction would have its own network that meet regularly either virtually or face to face.

Major challenges in training or the assignment of personnel in each hospital

Limited resources for training due to reduced budgets. Budget cuts limit training to those available locally, or those available virtually (eLearning). Budget cuts also reduce number of administrative positions or reduce hours available to staff in them to focus on safety.

Czech Republic

Organizations that offer education or training for the personnel

Institute for Postgraduate Medical Education, National Center of Nursing and Non-Medical Health Care

National or other certification system for the personnel

Certified courses and also one master degree program at College of Polytechnics Jihlava (Quality in Healthcare for non-medical staff).

Major challenges in training or the assignment of personnel in each hospital

Number of workers, especially non-medical staff - overburden, low interest in medical personnel in some AE which they recognize as nursing sensitive problems.

Denmark

Organizations that offer education or training for the personnel

A professional patient safety society/local operator

Incentives to promote assignment of the personnel in each hospital

Reporting is mandatory, resources must be allocated.

Networks promoting information sharing among the personnel across hospitals

There is a significant number of networks.

Major challenges in training or the assignment of personnel in each hospital

That personnel range from vocationally trained to highly specialized.

Finland

Organizations that offer education or training for the personnel

National Institute for Health and Welfare

Incentives to promote assignment of the personnel in each hospital

Honorary or monetary award from the employer

Major challenges in training or the assignment of personnel in each hospital

Usually not the main task of the person, hence lack of time

France

Assignment of personnel responsible for patient safety management

The 2010-1408 ministerial decree and its following instruction states that a coordinator of risk management has to be assigned in every hospital. Hospital “certification” checks if the assignment is fulfilled and how efficiently the management of risks operates in the hospital.

Standard educational programs for training the personnel

There are numerous diplomas open to most healthcare professionals. In order to provide all health care givers with a common doctrine including the human factor component, The National patient safety program 2013-2017 enabled the translation of the WHO Patient safety curriculum guide (multi-professional edition). An e-learning tool has been made out of it (2017) and a MOOC is to follow (2018).

Organizations that offer education or training for the personnel

Universities and institutions provide education. They also provide on-the-job training, together with insurance companies and private training organizations.

Major challenges in training or the assignment of personnel in each hospital

The hospital management (director and head of the medical community) must support the person responsible for risk management and place this person next to them in the hospital organizational chart. This requirement is progressively better understood and fulfilled.

Germany

Assignment of personnel responsible for patient safety management

It differs from hospital to hospital. There are continuing education programs for patient safety and risk management. Many hospitals opened a position of patient safety officer.

Standard educational programs for training the personnel

There are many programs but no binding standard.

Organizations that offer education or training for the personnel

There are many organizations but no standardized programs. Most of organizations are non-government organizations or institutions of the self-administration.

Incentives to promote assignment of the personnel in each hospital

It is a responsibility of each hospital.

Networks promoting information sharing among the personnel across hospitals

German Coalition for Patient Safety; partially National Quality Conference; German Network for Quality in Care; German Physicians Congregation (Deutscher Ärztetag)

Major challenges in training or the assignment of personnel in each hospital

To convince hospital management to invest in patient safety measures including the training and assignment of personal

Ireland

Assignment of personnel responsible for patient safety management

These are designated posts such as 'Quality and Safety', 'risk managers' or 'complaints managers'.

Standard educational programs for training the personnel

Patient safety is taught by a number of bodies within undergraduate and postgraduate education.

Italy

Organizations that offer education or training for the personnel

Public and private organizations organize courses on Patient Safety.

National or other certification system for the personnel

The new law establishes that everybody with five years of experience in this field can be responsible of patient safety.

Major challenges in training or the assignment of personnel in each hospital

Guarantee and maintain levels of competencies

Japan

Assignment of personnel responsible for patient safety management

Almost all acute care hospitals with >300 beds have already assigned patient safety managers who have a medical license. Most of them are nurses.

Standard educational programs for training the personnel

The Ministry of Health, Labour and Welfare has created a guideline for training programs.

Organizations that offer education or training for the personnel

Hospital associations, the Japan Nursing Association and other healthcare organizations.

Incentives to promote assignment of the personnel in each hospital

Hospitals are paid more money from public medical insurance when they assign patient safety managers.

Networks promoting information sharing among the personnel across hospitals

There is no professional society of patient safety managers. There are some informal networks; some of them are established by nearby hospitals, hospitals belonging to the same group, etc. The annual conference of the Japanese Society for Quality and Safety in Healthcare may be an occasion to communicate with each other.

Major challenges in training or the assignment of personnel in each hospital

The challenges include: (1) no concrete evidence of the positive effects on patient safety of assigning a patient safety manager, (2) continuous training, and (3) development of a model career path of patient safety managers.

Korea

Assignment of personnel responsible for patient safety management

The Patient Safety Act requires hospitals to deploy personnel dedicated to patient safety. There is no penalty, but it is a legal requirement.

Hospitals with dedicated patient safety personnel report details on the personnel deployment to the organization (Korea Institute for Healthcare Accreditation) responsible for operating the adverse event reporting & learning system.

Standard educational programs for training the personnel

Personnel dedicated to patient safety are required to regularly take courses on patient safety, if they work for tertiary hospitals (general hospitals) and hospital-level medical institutions with 200+ beds (Article 13 of the Patient Safety Act: and Article 10-11 of the Enforcement Rule of the Patient Safety Act).

- New course: Dedicated personnel are required to complete 24 hours of training within 6 months after deployment.
- Refresher course: Dedicated personnel are required to complete at least 12 hours of training per year.

Organizations that offer education or training for the personnel

Korean Hospital Association

Incentives to promote assignment of the personnel in each hospital

Long-term care services are reimbursed if tertiary hospitals (general hospitals) and hospital-level medical institutions with 200+ beds perform patient safety activities (including deployment of dedicated patient safety personnel, and establishment and operation of a patient safety committee). (1 time per day of hospital stay for inpatients)

Major challenges in training or the assignment of personnel in each hospital

Shortages of clinical nurses, and lack of incentives such as financial support for deploying dedicated patient safety personnel.

Mexico

Major challenges in training or the assignment of personnel in each hospital

There is a high level of rotation of the personnel in charge of patient safety implementation and supervision, both at the facilities and state level. Hospitals have a Quality Manager, who is in charge all quality strategies,

including Patient Safety. This position is usually occupied by personnel without the proper training for patient safety.

Portugal

Standard educational programs for training the personnel

The Ministry of Health approved a training program on patient safety.

Organizations that offer education or training for the personnel

Universities and Health Professionals Associations

Slovakia

Assignment of personnel responsible for patient safety management

There are no specific personnel for patient safety management.

Standard educational programs for training the personnel

There are not educational programs. There are only short seminars, workshops, lectures or presentations and courses.

Organizations that offer education or training for the personnel

Slovak Medical Chamber in cooperation with national Health Care Surveillance Authority, "Úrad verejného zdravotníctva Slovenskej republiky" (National Public Health Authority) as a competent body for the working conditions and internal process of patient safety in health care providers and safety of used equipment

Incentives to promote assignment of the personnel in each hospital

It is not a systematically regulated process in each hospital.

Networks promoting information sharing among the personnel across hospitals

Information is promoted and shared by only individual efforts of professionals in the hospitals. Information sharing process is not systematically led by the local chiefs in the hospitals or regional/national authorities.

Slovenia

Assignment of personnel responsible for patient safety management

In Slovenia, we have representatives of the quality management, such as assistant director of quality, assistant to chief doctor and chief nurse for quality, coordinators of the quality, coordinators of the quality management. Security officers have been operating since 2009. The tasks they perform are usually related to the quality and safety of health care. These are jobs that have a slightly higher initial payment grade.

Standard educational programs for training the personnel

There is no specific educational program. Organizations offer individual content. The initiatives to regulate this area are strong.

Organizations that offer education or training for the personnel

Prosunt operates in this area. It is a private company.

Incentives to promote assignment of the personnel in each hospital

According to the Health Care and Health Insurance Act, there are incentives that are provided by the Health Insurance Institute of the Republic of Slovenia. The financial resources provided by the MoH to ensure patient safety are limited. Our position: "Establishing a system means saving in practice".

Networks promoting information sharing among the personnel across hospitals

Some integration activities run within the Association of Health Care Institutes. They created a Quality

Commission in health care institutions. The purpose of the commission is to achieve development in this field and to act as an advisor and a link with the Ministry of Health.

Major challenges in training or the assignment of personnel in each hospital
Find the right people for this job. Make sure to report all sentinel and other adverse events.

Spain

Assignment of personnel responsible for patient safety management
In general, this person is also responsible of quality improvement in the hospital. Most of them are specialist in preventive medicine.

Standard educational programs for training the personnel
Each Region has its own educational program.

Organizations that offer education or training for the personnel
The MSSSI was in charge of this standard education, in collaboration with some universities, until 2014. There are several universities and other organizations offering masters and specific courses on PS.

National or other certification system for the personnel
Andalusia has a certification system for healthcare professionals.

Networks promoting information sharing among the personnel across hospitals
There is a national network around PS as well as regional level promoting information sharing and PS good practices.

Major challenges in training or the assignment of personnel in each hospital
Lack of resources and leadership.

Switzerland

Organizations that offer education or training for the personnel
Patient Safety Foundation and one more organization in the French speaking part of Switzerland

Networks promoting information sharing among the personnel across hospitals
There is a network only for quality officers, who are also responsible for patient safety.

Major challenges in training or the assignment of personnel in each hospital
Sensibilisation for patient safety not high enough. Patient safety officers are considered a “nice to have” and still not mandatory

United Kingdom

N/A

5. System for dispute resolution and compensation concerning patient harm

No-fault compensation has been introduced in several states. It is sometimes difficult to specify the cause of adverse events, and this system helps to support patients and establish good relationships between patients and healthcare organizations, and to encourage them to cooperate in establishing effective preventive methods. A no-fault compensation scheme for extensive adverse events has been introduced in Denmark, Finland, France, and Portugal. The scheme in Belgium, Japan and Korea covers some adverse events. The establishment of a no-fault compensation scheme for extensive adverse events may be a big challenge, but a scheme that focuses on limited areas, such as adverse drug events or newborns with cerebral palsy, may be easier to introduce as a first step. The number of cases of compensation is the largest in Finland. The annual amount of compensation is 759 million Danish kroner in Denmark. In Spain, the amount of compensation is calculated at present according to the scale of traffic accident, but the government is planning to present a law regarding a compensation scale for adverse events in 2018. In Japan. babies with cerebral palsy can receive 30 million yen from a private insurance scheme run by the Japan Council for Quality Health Care.

Systems of alternative dispute resolution (ADR) are classified into two types: one is run by national institutions and the other is an in-hospital system. In France, hospitals are required to involve patients' representatives for dealing with quality and safety issues, and the patients' representatives are able to serve as mediators if the patient requests. In Japan, hospital staff serve as mediators in many hospitals. Hospitals with trained mediators are paid more by public medical insurance.

5.1 No-fault compensation scheme for adverse events

Exist: BEL, CAN, DNK, FIN, FRA, JPN, KOR, PRT

Not exist: CZE, DEU, IRL, ITA, MEX, SVK, SVN, CHE, GBR

Others: ESP

5.2 Name of the administrative entity of the no-fault compensation scheme

Belgium

Fund for medical accidents

Canada

Healthcare Insurance Reciprocal of Canada (HIROC)

direction des assurances du réseau de la santé et des services sociaux in Quebec (DARSSS or AQESSS)

Denmark

The Patient Compensation Association

Finland

Finnish Patient Insurance Centre

France

Office national d'indemnisation des accidents médicaux (ONIAM)

Japan

Japan Council for Quality Health Care (JQ)

Korea

Korea Medical Dispute Mediation and Arbitration Agency

Portugal

National Health Service

Spain

Ministry of Health, Social Services and Equality (MSSSI)

5.3 Definition of adverse events which are compensated by the scheme

Belgium

The damage which has occurred since 2 April 2010, which is results of medical dispensation, and which meet one of the criteria as follows:

- a permanent disability of 25% or more
- temporary incapacity for at least 6 consecutive months or 6 non-consecutive months over a period of 12 months
- particularly severe damage, also economically, for the living conditions of the patient
- death of the patient

Canada

See websites of HIROC and DARSSS.

Denmark

All areas in the Danish healthcare system and all private authorized health professionals are covered by a publicly funded compensation scheme. The Patient Compensation Association determines whether a patient should be compensated, but the regions pay the compensation. The same is true of medicine injuries, for which the Ministry of Health and Prevention pays the compensation.

The scheme covers following injuries:

- Injuries which could have been avoided, because an experienced specialist in the same situation would have acted differently.
- Injuries due to failure or malfunction of technical devices and the like.
- Injuries which could have been avoided by another equally effective treatment, technique or method.
- Injuries which are very rare and serious in relation to the illness the patient is being treated for, and which exceed what one can reasonably be expected to tolerate.

Finland

As defined by the Finnish law

France

Damage caused by a medical accident or damage attributable to an activity of biomedical research, an iatrogenic condition (or side effect of medical treatment) or one nosocomial infection (or infection in a health care facility).

Japan

A no-fault compensation system for cerebral palsy babies was introduced in 2009. The insurance system is run by the Japan Council for Quality Health Care, and healthcare facilities are strongly encouraged by academic societies to buy the insurance; almost 100% of facilities dealing with delivery buy the insurance. Patients can receive 30 million yen if they are diagnosed with cerebral palsy; about 400 patients receive this payment each year. According to the Supreme Court, the number of lawsuits in the field of obstetrics and gynecology decreased dramatically after the introduction of this system.

Korea

Applies to only adverse events related to child delivery performed after April 8, 2013

- Cerebral palsy cases among newborns which occurred during child delivery or due to unusual reasons related to child delivery
- Deaths of mothers during child delivery or due to unusual reasons related to child delivery
- Deaths of unborn children during child delivery or due to unusual reasons related to child delivery

Portugal

Clinical execution error or clinical planning error

Spain

There is a compensation system for adverse events managed by assurance companies that try to mediate between the hospital and the patient/family. However, the government is planning to present a law regarding a compensation scale for adverse events in 2018.

5.4 Number of cases that were compensated by the scheme during the past year

Belgium

600

Canada

N/A

Denmark

N/A (In 2016, there were 11,212 claims, and 759 million Danish kroner was given as compensation to patients and their relatives)

Finland

2166

France

654 (with an average of 87,515€ paid to the claimer per case)

Japan

314 (30 million yen is paid per case)

Korea

11

Portugal

N/A

Spain

N/A

5.5 Alternative dispute resolution (ADR)

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
5.5.1	Availability of an alternative dispute resolution (ADR) for resolving medical disputes	±	+	N/A	−	−	+	±	+	−	+	+	+	+	±	+	+	−	+
5.5.2	Organizations that provide or help to find a mediator or an arbitrator for the ADR	N/A	+	N/A	N/A	N/A	+	+	+	N/A	−	+	+	+	±	+	+	N/A	+
5.5.3	Standard educational program to train mediators or arbitrators for medical disputes	N/A	+	N/A	N/A	N/A	+	−	+	N/A	+	−	−	+	−	+	±	N/A	N/A

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

5.6 Details of ADR in each country

Belgium

N/A

Canada

Organizations that provide or help to find a mediator or an arbitrator

HIROC and DARSSS

Czech Republic

N/A

Denmark

N/A

Finland

N/A

France

Scheme of ADR

Every hospital has to organize a procedure to answer patients' claims. The administrative manager is assisted by a medical and a paramedical mediator. The law n° 2002-303 dated 4th of March 2002 "relative aux droits des malades et à la qualité du système de santé" (loi Kouchner) has organized the system, including the creation of a

Commission des Usagers in every hospital, where patients' representatives deal with the management on quality and safety issues. Since the ministerial decree of July 1st 2016 this Commission has gained new prerogatives.

Standard educational program to train mediators or arbitrators for medical disputes

Patients' representatives in hospital are trained for their missions in the Commission des usagers (see 5,5) and may be consulted as mediators, if the claimer wishes it. Most of their training comes from the Union nationale des associations agréées d'usagers du système de santé (approx. 70 patient associations are represented in this Union nationale).

Germany

Scheme of ADR

It is not at a centralized level. However, there are dispensaries where patients can apply to if they suspect a treatment error (Schlichtungsstellen der Ärztekammern). Health insurances support patients as well.

Organizations that provide or help to find a mediator or an arbitrator

Independent patient counselling (Unabhängige Patientenberatung Deutschlands: UPD)
Health insurances are obliged to support the members in cases of treatment errors.

Ireland

Scheme of ADR

The Mediation Act (2017). Its objective is to provide a wide ranging statutory framework to promote a resolution of disputes through mediation as an alternative to court proceedings. The legislation requires that legal practitioners advise parties about mediation as a means of resolving difficulties and the Courts may invite parties to consider mediation. The Act contains general principles for the conduct of mediation by qualified mediators.

Standard educational program to train mediators or arbitrators for medical disputes

The Mediators' Institute of Ireland is the not-for profit professional association for mediators in Ireland. It has approved a range of training programs and CPD courses, which are not specific to medical disputes.

Italy

N/A

Japan

Scheme of ADR

ADR (not limited to healthcare) is recommended by the ADR Encouragement Act. Hospitals are encouraged to assign hospital staff as mediators, and hospitals with mediators are paid more by public medical insurance.

Korea

Scheme of ADR

In accordance with the "Act on Remedies for Injuries from Medical Malpractice and Mediation of Medical Disputes", the Korea Medical Dispute Mediation and Arbitration Agency undertakes the deliberation and resolution of medical disputes arising from adverse events.

Organizations that provide or help to find a mediator or an arbitrator

Korea Medical Dispute Mediation and Arbitration Agency

Mexico

Scheme of ADR

When a patient has a complaint regarding medical treatment, the patient is referred to the National Commission for Medical Arbitration that is in charge of resolution between medical staff and patients.

Organizations that provide or help to find a mediator or an arbitrator

National Commission for Medical Arbitration

Portugal

Organizations that provide or help to find a mediator or an arbitrator

Medical Association

Slovakia

Scheme of ADR

Except the compensation via court resolution, the patient can use the system of mediators on the base of mutual voluntary agreement.

Organizations that provide or help to find a mediator or an arbitrator

The help to find mediators is not needed because they are well-known.

Slovenia

Organizations that provide or help to find a mediator or an arbitrator

Some healthcare providers, especially among public health institutions, have established their own mediation referral services that offer mediation as a method of peaceful dispute resolution between their employees, patients and other users of health services. Tenderness to mediation and understanding of its importance is already strongly present in some healthcare providers, as they offer their patients free participation in the mediation process.

Standard educational program to train mediators or arbitrators for medical disputes

There are several providers of mediator education and training. As a rule, these are two strands: basic and continuing education. Runs Association of Mediators (NGO), which seeks to provide all the information in one place.

Spain

Scheme of ADR

Lawyers, experts and forensic doctors calculate compensation in cases of medical malpractice based on the scale of traffic accidents.

Standard educational program to train mediators or arbitrators for medical disputes

Not a national level

Switzerland

N/A

United Kingdom

N/A

6. Investigation of adverse events

In the case of adverse events, hospitals are expected to conduct an in-hospital investigation. In some states, in addition to in-hospital investigation, external investigation by a third-party has been introduced. Attempts have been made to standardize the method of in-hospital investigation in most states with guidelines and recommended methods. A support system is also available in some states. Reports of investigations are disclosed in limited cases in most states. In Japan, a nationwide reporting system has been introduced, and data on more than 75,000 anonymized cases are available on the website of the Japan Council for Quality Health Care. These reports contain useful information for preventing recurrence, and need to be shared among healthcare professionals.

6.1 Investigation by third-party organizations

6.1.1 Third-party organizations that investigate the causes of adverse events

Exist: FIN, IRL, JPN, PRT, ESP, GBR

Not exist: BEL, DNK, ITA, KOR, MEX, SVK, SVN, CHE

Others: CAN, CZE, FRA, DEU

6.1.2 Name of the administrative entity for patient harm investigations

Canada

Health Quality Council of Alberta etc.

Czech Republic

N/A

Finland

National Supervisory Authority for Welfare and Health

France

N/A

Germany

Chambers of Physicians (Ärztekammern)

Ireland

Health Information and Quality Authority (HIQA)

Japan

Japan Council for Patient Safety Investigation

Portugal

General Inspection of Activities in Health (IGAS)

Healthcare Regulation Authority (ERS)

Portuguese Medical Association

Spain

The insurance company

United Kingdom

Healthcare Safety Investigations Branch (HSIB)

6.1.3 Details of the investigation by the third-party organizations in each country

Belgium

The analysis and the resulting actions improvement must be done and formulated by the hospitals themselves.

Canada

Some areas have quality/safety organizations that have mandates from the provincial government to investigate specific or systemic issues that lead to patient safety incidents. For instance, the Health Quality Council of Alberta can lead public inquiries and system reviews when requested by the government.
In addition, health professionals have their practice of care overseen by regulatory colleges in Canada who have investigative authority as part of their ability to grant, restrict or withdraw license to practice in each jurisdiction.

Czech Republic

The CAERS is not serving as entity for patient harm investigation.

Finland

N/A

France

N/A

Germany

N/A

Ireland

N/A

Japan

According to the Adverse Event Investigation System in Japan introduced in 2015, every hospital is required to report an unexpected patient death due to medical service to the Adverse Event Investigation & Support Center, which is administered by the Japan Council for Patient Safety Investigation. Hospitals are required to conduct an institutional review of the adverse event, and to submit a final report of the investigation to the Center. In addition, hospitals and patients can request an external investigation by the Japan Council for Patient Safety Investigation. About 400 cases were reported, and external investigations were conducted for 7 cases at the request of hospitals, and for 32 cases at the request of bereaved families in 2017.

Portugal

N/A

Slovenia

There is no special body. From the hospitals, sentinel events are reported to the Ministry of Health. The new law foresees the establishment of a special body for these purposes.

Spain

It depends on the Region.

United Kingdom

The Healthcare Safety Investigations Branch (HSIB) is newly established. The aim is to review up to 30 serious cases per year, and HSIB also hold responsibility for investigating perinatal deaths.

6.2 Autonomous in-hospital investigation

6.2.1 System of autonomous in-hospital investigation

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
6.2.1.1	Guidelines for in-hospital investigation of adverse events	+	+	+	−	+	+	±	+	+	±	−	+	+	−	+	+	−	+
6.2.1.2	Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency	−	−	+	−	−	−	−	+	−	±	−	−	+	−	−	±	−	−
6.2.1.3	Recommended methods for investigating adverse events (e.g. root cause analysis)	+	+	+	−	+	+	+	+	+	−	−	+	+	−	+	+	+	+
6.2.1.4	External supporting systems for in-hospital investigation	+	−	±	−	−	+	±	+	−	+	−	+	+	−	+	+	−	+
6.2.1.5	Disclosure of the reports of adverse event investigations	−	±	−	−	−	+	±	+	−	−	−	−	+	+	−	−	−	+

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

6.2.2 Recommended methods for investigating adverse events

Belgium

Root Cause Analysis, PRISMA, BowTie

Canada

Incident Analysis (concise, comprehensive or multi-incident analysis), critical incident review committee procedures, use of LEAN methodology for ex rapid improvement events, and others.

Czech Republic

Root Cause Analysis

Denmark

N/A

Finland

N/A

France

N/A

Germany

Mortality and morbidity conferences, Case analyses

Ireland

N/A

Italy

N/A

Japan

There is no recommendation, but Root Cause Analysis is widely used.

Korea

N/A

Mexico

Root Cause Analysis

Portugal

National Guideline nº 11/2012

Slovakia

N/A

Slovenia

Root Cause Analysis

Spain

Root Cause Analysis (London protocol)

Switzerland

Root Cause Analysis (London protocol)

United Kingdom

N/A

6.2.3 Standardized items that are included in the investigation report

Belgium

N/A

Canada

When used by jurisdictions or facilities, the Canadian Incident Analysis Framework and the Patient Safety and Incident Management Toolkit include templates and examples for the incident report. The key components include: information about the incident (date, type, severity of harm, outcome, date, etc.), summary, background and context, scope of the analysis/ terms of reference, methodology (type of analysis, legislative framework), summary of findings, recommended actions, appendices (timeline, diagrams, implementation, evaluation and communication plan, references). Patient perspective and engagement in incident analysis is also discussed.

Czech Republic

N/A

Denmark

N/A

Finland

N/A

France

N/A

Germany

N/A

Ireland

Depending on the level and method of review, review reports may contain:

- the terms of reference
- the membership of the review team
- the methodology applied to the review process and the rationale for why the decision to use this methodology was made
- a summary of the background to the incident
- any actions taken immediately following identification of the incident and during the review process
- what happened during the incident or incidents
- why it happened
- any incidental findings
- an apology or expression of regret to all those affected
- the recommendations and actions identified for implementation
- a section relating to responsibility for implementing recommendations and arrangements for sharing the learning with other services nationally
- and a glossary of key terms used in the report.

Italy

N/A

Japan

Date, time and place of the event/ Clinical department/ Name of healthcare facility/ Address/ Contact address/ Name of administrator/ Gender and age of the patient/ Items and method of investigation/ Clinical course/ Results of investigation to determine the cause of event/ Measures to prevent a recurrence if possible/ Responses and comments from family members of the patient

Korea

N/A

Mexico

24 items

Portugal

Causes, corrective measures, conclusions

Slovakia

N/A

Slovenia

11 items

Spain

It depends on the Region/Hospital.

Switzerland

The London Protocol - Systems analysis of clinical incidents
(Developed by Sally Taylor-Adams & Charles Vincent at the Clinical Safety Research Unit of the Imperial College London)

United Kingdom

Dependent on the type of investigations

6.2.4 Details of autonomous in-hospital investigation in each country

Belgium

External supporting systems for in-hospital investigation

The federal government Public Health

Disclosure of the reports of adverse event investigations

Impact is questionable and depends on the patient safety culture.

Canada

Guidelines for in-hospital investigation of adverse events

The Canadian Incident Analysis Framework, available through CPSI, includes a recommended incident analysis process which focuses on system improvement.

HIROC also offers an in-depth risk resource guide with evidence-informed practical advice on managing critical incidents and multi-patient events that covers the organization response; support for families, patients, and staff; and performing an impactful impact analysis.

An incident management toolkit is available from the Canadian Patient Safety Institute. It provides an integrated set of resources focused on immediate and ongoing actions following patient safety incidents (including near misses). Incident analysis guidelines, tools and resources curated from across Canada (including the Canadian Incident Analysis Framework) are available in this toolkit and presented as part of the patient safety and incident management processes.

Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency

Hospitals are not required to involve them, although some hospital based investigations may also involve a regional health authority investigator on their review team.

Disclosure of the reports of adverse event investigations

Some provinces have a legislated obligation to disclose patient safety events. For example, both Manitoba and Quebec have statutes (respectively the Regional Health Authorities Act, C.C.S.M., c. R34, s. 53.2(2) and an Act Respecting Health Services and Social Services (R.S.Q., c. S-4.2) which require health authorities or health institutions to disclose adverse events (in the case of Manitoba "critical incidents" as defined in the Act) to those impacted by the adverse event. However, these statutes fall short of requiring health professionals themselves from disclosing such incidents and do not encompass reporting to the general public. The Manitoba statute goes further and also requires disclosure centrally to the relevant regional health authority (section 53.3(4) of the Act) and to the Manitoba Minister of Health (section 53.3(5) of the Act).

Some organizations disclose this information publicly, in a de-identified way, while others do not. It is recommended that a summary report is made available to staff and the family or patient involved in the incident as well as merged in the organization's reporting and learning system (where analysis reports, coroner reports, patient complaints/complements and other relevant information is collected) to allow for the identification of trends and systemic actions to improve safety.

Czech Republic

Guidelines for in-hospital investigation of adverse events

Guidance are presented on National portal for each type of AE (for prevention, actions for planning interventions, checklists etc.).

Denmark

N/A

Finland

N/A

France

Guidelines for in-hospital investigation of adverse events

Haute Autorité de santé has provided two guides.

External supporting systems for in-hospital investigation

Hospitals can be accompanied in their own analysis of causes and corrective measures by expert bodies, specialized in quality of care and patient safety (medical, paramedical and management of risk staff). Since a ministerial decree dated Nov 25th 2016, every Regional Health authority is required to select a structure to perform this assistance to health care organizations and professionals that would ask for it, be there from primary care, hospital or elderly care. These structures are also meant to bring their expertise to the Regional Health Authorities, should they need it. These structures are NOT ADMINISTRATIVE. They are called Structures régionales d'appui à la qualité des soins et à la sécurité des patients. The system is currently being built up in every region. These structures do NOT "investigate" (the Regional Health Authority does the investigation if necessary) but they provide support in analyzing and dealing with risk management.

Disclosure of the reports of adverse event investigations

Some Regional Healthcare Agencies publish cases of (serious) adverse events with their feedback.

Germany

Guidelines for in-hospital investigation of adverse events

There are no binding regulations. The Alliance for Patient Safety published recommendations. Internal guidelines might be a part of the hospital quality management system.

Ireland

Guidelines for in-hospital investigation of adverse events

HIQA and the Mental Health Commission have published 'Standards for the Conduct of Review of Patient Safety Incidents'.

Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency

Depends on level of investigation required.

Italy

N/A

Japan

Guidelines for in-hospital investigation of adverse events

Several healthcare associations publish guidelines for in-hospital investigations.

Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency

As for in-hospital investigations based on the Adverse Event Investigation System, the Ministry of Health, Labour and Welfare strongly encourages hospitals to assign an external specialist. As for other in-hospital investigations, hospitals can decide whether or not to assign an external specialist.

External supporting systems for in-hospital investigation

Academic societies, hospital associations, medical associations and other healthcare organizations registered as supporting bodies for the Adverse Event Investigation System can recommend specialists at the request of a hospital which finds it difficult to identify an appropriate specialist.

Disclosure of the reports of adverse event investigations

In the Adverse Event Investigation System, hospitals are required to explain the results of the investigation to

the bereaved family and are also able to give the report to the bereaved family, but the report is not disclosed to the public.
In the Project to Collect Medical Near-Miss/Adverse Event Information, the reports from hospitals are anonymized and disclosed to the public on the website of the Japan Council for Quality Health Care (JQ). Anyone can browse more than 75,000 reports including not only adverse events but also near misses.

Korea

N/A

Mexico

Guidelines for in-hospital investigation of adverse events
Root Cause Analysis Guidelines

Portugal

Guidelines for in-hospital investigation of adverse events
The Ministry of Health developed a National Reporting and Learning System and issued National Guidelines to support the investigation of adverse events and health risk management.
National Guidelines nº 11/2012 and nº 15/2014.

Disclosure of the reports of adverse event investigations
Those decided by IGAS (General Inspection of Activities in Health), ERS (Healthcare Regulation Authority) and the Portuguese Medical Association.

Slovakia

N/A

Slovenia

Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency
The hospital can initiate for an extraordinary external control with counseling.

External supporting systems for in-hospital investigation
Control of quality and safety takes place within the framework of professional control with counseling on the basis of the Health Care Services Act and the Medical Services Act.
In accordance with the Rules on the implementation of expert control with consulting for individual groups of healthcare professionals not organized in professional chambers or professional associations with a public mandate.

Disclosure of the reports of adverse event investigations
Case studies will be created from the documentation, and the identity of the person involved will not be disclosed.

Spain

Guidelines for in-hospital investigation of adverse events
There are guidelines in some Regions. At national level, we are working on a national guideline

Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency

In some hospitals.

External supporting systems for in-hospital investigation

Supports by the Health Region

Switzerland

N/A

United Kingdom

Requirement for hospitals to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency

It is not a stipulated requirement, rather described as best practice. In certain investigations, independent scrutiny is mandated, such as coronial investigations.

Disclosure of the reports of adverse event investigations

The general findings and recommendations are shared with the system, and, depending on the type of review, also made public.

7. Other efforts

In most states, hospitals are required to measure patient satisfaction regularly. Measurements of employee satisfaction and patient safety culture vary among states.

Regarding screening of adverse events, investigation of in-hospital deaths is obligated in some states. In France, in-hospital deaths that relate to surgery, anesthesiology or cancerology have to be reviewed at morbidity-mortality conferences. In Japan, all in-hospital deaths have to be reviewed irrespective of whether the case meets the reporting criteria of the Adverse Event Investigation System or not. In Spain, there are hospital mortality commissions in each hospital. Not only an autonomous reporting system but also other screening systems may be needed to identify problems, because low sensitivities or under-reporting by healthcare workers may conceal problems in the hospital.

More than half of states make efforts to provide emotional support to the staff involved in adverse events. Most of them are voluntary efforts in each hospital, but a standardized program is offered in Belgium, Canada and Spain. Second victims may be able to use the scheme easily if there is a standardized program.

Legislative protection which prevents the release of information concerning quality reviews from subsequent disclosure in the context of legal proceedings exists in all Canadian provinces. Stipulating protection against lawsuits is an interesting effort, as healthcare professionals will be able to discuss adverse events freely when protected.

7.1 Systems of other efforts

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
7.1.1	Requirement for hospitals to measure patient satisfaction regularly	±	+	+	−	+	+	±	+	+	±	+	+	+	±	−	+	+	+
7.1.2	Requirement for hospitals to measure employee satisfaction regularly	±	−	+	+	+	−	±	−	−	±	+	−	+	−	−	±	−	+
7.1.3	Requirement for hospitals to measure patient safety culture regularly	+	+	+	−	−	−	−	+	−	−	−	+	+	−	−	+	−	+
7.1.4	Requirement for hospitals to offer education or training concerning patient safety for their staff	+	+	+	−	+	−	−	−	−	+	+	+	+	−	−	+	−	±
7.1.5	Requirement for hospitals to have a dedicate team that is available to respond to a deterioration or a sudden change of condition of patients	−	+	+	+	+	−	±	±	+	−	−	−	+	−	+	+	−	+
7.1.6	Requirement for hospitals to carry out periodic inspections for patient safety	±	+	±	+	+	−	±	−	+	−	−	+	+	−	−	+	−	±
7.1.7	Requirement for hospitals to investigate in-hospital deaths	±	+	±	−	+	+	±	±	+	±	−	+	+	+	−	+	−	±

		BEL	CAN	CZE	DNK	FIN	FRA	DEU	IRL	ITA	JPN	KOR	MEX	PRT	SVK	SVN	ESP	CHE	GBR
7.1.8	Standardized education/training programs for patient safety	+	+	+	−	+	+	±	−	−	−	−	−	+	−	−	+	+	+
7.1.9	Medical equipment/ device certification that is taken into account patient safety/ human factors concerns	±	+	+	−	+	N/A	±	−	−	+	+	+	+	+	+	±	−	±
7.1.10	Financial incentives for hospitals to support introducing electronic medical records	+	+	±	−	−	+	−	−	±	±	−	−	+	±	−	+	−	−
7.1.11	Efforts to standardize the way of sharing patient information across different facilities	+	+	+	+	+	±	+	+	+	±	+	−	+	+	−	+	−	+
7.1.12	Efforts to provide emotional support for the staff involved in adverse events	+	+	+	−	+	+	−	+	+	−	−	−	−	±	+	+	−	+
7.1.13	Safety standards for nursing homes or retirement homes	±	+	+	+	+	N/A	±	+	+	−	+	−	+	−	+	+	−	+

+; Yes/A requirement/Exist, −: No/Not a requirement/Not exist, ±; Others, N/A; Not applicable

7.2 Details in each country

Belgium

Periodic measurement

Almost all hospitals measure patient satisfaction, but it is not required. In the Flemish region, employee satisfaction is required to measure. Patient safety culture measurement is supported by the federal government and measured in 2007-2011-2015. Hospitals could participate at a benchmark study in collaboration with university.

Rapid response team

In 2015-2016, the federal government supported a scientific implementation study of the Rapid Response Team.

Investigation of in-hospital deaths

Hospitals are stimulated to analyze unexpected deaths and sentinel events.

Efforts to provide emotional support for the staff involved in adverse events

Program on second victim has been elaborated.

Safety standards for nursing homes or retirement homes

Nursing homes are the responsibility of the regions.

Canada

Periodic measurement

Client satisfaction is part of accreditation requirements for hospitals that choose to be accredited. Most regions and hospitals have a system with tools in place to gather patient/client experience feedback and use the responses as one crucial input informing quality improvement initiatives in hospitals. Many hospitals perform

employee engagement surveys, but it is not necessarily a requirement. Patient safety culture survey is required for those who are accredited by Accreditation Canada.

Education or training concerning patient safety for staff

Most hospitals will offer primary education on patient safety education to all staff at mandatory hospital orientations when they begin to work there. There will also be ongoing training that is provided, which may or may not be mandatory depending on the person's role in the organization. This is in addition to patient safety training provided in Canada's medical education programs (e.g. medical or nursing schools).

Rapid response team

All hospitals have a rapid response team to address medical emergencies, many have patient/family activated response teams.

Financial incentives for hospitals to support introducing electronic medical records

At the national level, Canada Health Infoway is funded to support the efforts of the provinces and territories to significantly increase the adoption of digital health technologies including use of electronic medical records (EMR). This includes:

- Supporting jurisdictions' EMR programs, which incent physicians and nurse practitioners to implement, adopt and use EMRs in their offices, primary care centres and out-patient clinics
- Upgrading and connecting EMRs so they are interoperable with the jurisdiction's electronic health record (EHR) components
- Helping clinicians achieve increased clinical value through the advanced use of EMRs, such as managing patient populations

To date, Infoway has invested in over 15,000 EMR systems in partnership with provincial and territorial governments. These investments leverage electronic health record (EHR) investments by making existing patient health information such as lab results, prescribed drugs, diagnostic images and selected hospital reports available to all clinicians. Provincially, there are several organizations also dedicated to the adoption of digital health solutions (ex., E-Health Ontario) which can provide incentives (often financial but sometimes tied to requirements of practice) to adopt and use EMRs.

Efforts to standardize the way of sharing patient information across different facilities

For non-safety specific information, aggressive Canadian efforts has been accompanied to link electronic health systems (EHRs) and to make all systems within a region/area interoperable, although this work is not yet optimal in Canada.

Efforts to provide emotional support for the staff involved in adverse events

There are formal processes such as Critical Incident Stress Management that can be used soon after the event, as well as more informal strategies such as conversation with one's manager and peer support for staff. Staff are encouraged to utilize their hospital's Employee and Family Assistance Plan, which offer free counselling and psychological support in most major health facilities.

Safety standards for nursing homes or retirement homes

Varies by province and by accreditation program, which currently set their own standards against which facilities are accredited.

Other systems for patient safety at the national level

■ Approval and post-market surveillance for pharmaceuticals and medical devices

As Canada's regulator of pharmaceuticals, medical devices and health technologies, Health Canada has considerable systems in place to determine when to provide regulatory approval of those things. In addition, it conducts post-market surveillance and analysis, which can lead to changes in the approval if required.

Its Marketed Health Products Directorate is also responsible for

(a) collecting, monitoring and analyzing adverse reaction, medical device and medication incident data,
(b) conducting benefit-risk assessments of marketed health products
(c) communicating product-related risks to health care professionals and the public
(d) overseeing the advertising regulatory requirements of health products
(e) providing policies to effectively regulate marketed health products.

In addition, The Canadian Medication Incident Reporting and Prevention System (CMIRPS) is a collaborative pan-Canadian program of Health Canada, the Canadian Institute for Health Information (CIHI), the Institute for Safe Medication Practices Canada (ISMP Canada) and the Canadian Patient Safety Institute (CPSI). The goal of CMIRPS is to reduce and prevent harmful medication incidents in Canada.

■ Education for each professional based on defined competencies

Early in its mandate, CPSI prioritized health professional education and competency related to patient safety as a key enabler in patient safety improvement. Prepared through collaboration of CPSI with the Royal College of Physicians and Surgeons of Canada (RCPSC) and several Canadian experts, the Safety Competencies Framework (2008) is a foundational publication that has supported curriculum development, patient safety practices, and health professional standards and competency assessments across Canada and beyond.

The Safety Competencies Framework has been integrated into the RCPSC CanMEDS 2015 revised Physician Competency Framework which guides licensing and credentialing requirements for all physicians in Canada.

CPSI and the RCPSC developed the Advancing Safety for Patients in Residency Education (ASPIRE) program, a national faculty development certificate program for physicians on teaching patient safety and quality improvement. This has been embedded in every post-graduate medical residency training program across Canada.

The Canadian Association of Schools of Nursing (CASN) has adopted new accreditation standards for nursing education in Canada that strengthen patient safety, and incorporate key elements drawn from the Safety Competencies.

The Association of Faculties of Pharmacy of Canada has mapped their educational outcomes to the Framework, and the National Association of Pharmacy Regulatory Authorities of Canada has included the domains of the Framework into their professional competencies for Canadian pharmacists and pharmacy technicians at entry to practice.

The Paramedics Association of Canada has integrated the Competencies into the National Occupational Competency Profile for paramedics and emergency medical technicians.

■ Legislative protection of information against a request for disclosure

The legislative protection which prevents release of information concerning quality reviews from subsequent disclosure in the context of legal proceedings now exists in all Canadian provinces. Protection of quality of care information generated by specified types of committees is often found in the provincial or territorial Evidence Acts. However, protection of this information may also be found in standalone legislation (e.g. Ontario's Quality of Care Information Protection Act), or legislation governing other aspects of health services (e.g. Quebec's Act respecting health services and social services).

Ontario's Quality of Care Information Protection Act provides that quality of care information may only be disclosed to management if the committee considers it appropriate for the purposes of improving or maintaining the quality of health care provided in a facility. The information may also be disclosed if it will eliminate or reduce a significant risk to a person or group of persons.

Generally, statutes require that a committee's activity be motivated by the desire to improve health-care services in order to receive protection. For example, for committees to be established and protected under Ontario's Quality of Care Information Protection Act, they must have a view to improve or maintain: 1) the quality of

health care; or 2) the level of skill, knowledge, or competence of the health-care provider. Under Quebec's Act Respecting Health Services and Social Services, an institution must establish a risk management committee that seeks, develops, and promotes ways to identify and analyze incident or accident risks to ensure the safety of users.

Czech Republic

Periodic measurement

Patient satisfaction: Bulletin 16/2015 Coll. minimum requirements for the establishment of an internal system of quality assessment and safety of provided health services (empowerment in Act no. 372/2011 Coll.)

Periodic self-inspections for patient safety in each hospital

The internal system of quality assessment and safety of provided health services are inspected.

Standardized education/training programs for patient safety

MoH certified course in the field. Patient Safety in Health Services was developed in accordance with the WHO Multi-Professional Patient Safety Curriculum Guide.

Financial incentives for hospitals to support introducing electronic medical records

Electronic records in inpatient facilities is common standard, there is no incentives as far as we know.

Efforts to standardize the way of sharing patient information across different facilities

Portal of Quality of Safety; booklets publication Patient's Guide, Ministry of Health - Patient Rights Support Unit

Efforts to provide emotional support for the staff involved in adverse events

Mostly at local level (the hospital level) it is based on local policy for each healthcare facility.

Denmark

Education or training concerning patient safety for staff

It is voluntarily, but most units do.

Investigation of in-hospital deaths

Only when unexpected

Efforts to provide emotional support for the staff involved in adverse events

It is not systematically.

Finland

N/A

France

Periodic measurement

Patient safety culture measurement is not required, but the promotion of patient safety culture measurements is an item of the National patient safety program 2013-2017.

Education or training concerning patient safety for staff

It is not required, but very much spread out.

Rapid response team

It is not required, but frequently put up.

Investigation of in-hospital deaths

Hospital morbidity-mortality reviews have been compulsory in some cases since 2010: in surgery, anesthesiology, cancerology.

Standardized education/training programs for patient safety

In order to provide all health care givers with a common doctrine regarding risk management and patient safety including the human factor component, the National patient safety program 2013-2017 enabled the French translation of the WHO Patient safety curriculum guide (multi-professional edition) and promotes its use. An e-learning tool has been made out of it (2017) and a MOOC is to follow (2018). Medical studies (3rd cycle) underwent a reform in 2016-2017 which made patient safety one of the 3 topics taught to all medical interns, whatever specialty they opt for. Patient safety has also been notably reinforced during the 2nd cycle of medical studies (reform issued in 2013) as well as communication/collaboration with other staff and with patients.

Financial incentives for hospitals to support introducing electronic medical records

A full strategy is implemented by the Ministry of Health. In order to make information systems more efficient, particularly in terms of quality and safety of care, the General Directorate for the Provision of Care (DGOS) launched the Digital Hospital Program in November 2011. The Digital Hospital Strategy defines a plan for the development and modernization of hospital information systems and aims to set priorities and objectives at 6 years. To support them in this process, a specific financing plan is proposed.

Efforts to standardize the way of sharing patient information across different facilities

On a person to person level, the national patient safety program 2013-2017 has promoted a better communication between professionals and patients such as letter of referral or SBAR [SAED in French]. SBAR is currently taught in some paramedical schools.

Other systems for patient safety at the national level

■ Approval for pharmaceuticals and medical devices

Medical equipment authorizations are a compulsory procedure for a number of care activities (conformity of settings, devices and staff qualifications to regulation requirements). They highly contribute to keep safety standards high.

Germany

Periodic measurement

There is no legal requirement. Hospitals undertake such measurements as a frequent part of quality management systems, especially when they are needed for certifications.

Rapid response team

Hospitals are required to be equipped with emergency equipment according to their patient and service spectrum (§4 QM-RL). This encompasses emergency equipment, competence and training. Whether special teams are established lies in the responsibilities of the hospital.

Periodic self-inspections for patient safety in each hospital

According to QM-RL (§2), hospitals are required to establish PDCA-Cycle that includes frequent check-ups of patient safety measures.

Investigation of in-hospital deaths

There is no explicit legal requirement to investigate each case. However, such investigations are generally an important part of the risk management.

There is a financial incentive for clinical dissections according to the Hospital Restructuring Act (Krankenhausstrukturgesetz, §9(1a)3).

Efforts to standardize the way of sharing patient information across different facilities
It is included in the digitalization strategy of the Federal Ministry of Health.

Safety standards for nursing homes or retirement homes
There is no legal requirement. Details unknown.

Other systems for patient safety at the national level
National Action Plan on Medications Safety. Widespread initiatives to fight AMR, nosocomial infections and sepsis.

Ireland

Periodic measurement
The first National Patient Experience Survey was completed for all adult inpatients in the month of May with 61 internationally validated questions. This will be repeated annually. An HSE annual staff survey occurs.

Rapid response team
The Department of Health has published a National Clinical Guideline for detection of the deteriorating patient - early warning systems.

Investigation of in-hospital deaths
Deaths in hospitals are covered by the Coronor's Act (1962).

Medical equipment/ device certification that is taken into account patient safety/ human factors concerns
HPRA role.

Efforts to standardize the way of sharing patient information across different facilities
The implementation of the EU General Protection Regulation (effective from 25 May 2018) directly affects the sharing between health services providers of patient identifiable information for patient care and safety across the health system. The planned Health Information and Patient Safety Bill provides a further legislative opportunity to address information sharing in the health system, including for patient safety.

Safety standards for nursing homes or retirement homes
HIQA Standards

Italy

Education or training concerning patient safety for staff
Hospitals can organize internal courses. Health professionals can attend also external courses.

Periodic self-inspections for patient safety in each hospital
Hospitals perform visits in the different wards in order to ascertain and guarantee quality levels.

Investigation of in-hospital deaths
Depending on the conditions of the patients and on the type of deaths.

Financial incentives for hospitals to support introducing electronic medical records
It is strongly recommended.

Efforts to provide emotional support for the staff involved in adverse events
A support is offered from the organization to the third victim of adverse events.

Japan

Periodic measurement

It is not mandatory, but most hospitals measure patient satisfaction regularly, and some hospitals measure employee satisfaction.

Education or training concerning patient safety for staff

According to the Medical Care Act and the Ordinance for Enforcement of the Medical Care Act, hospitals are required to provide training sessions for hospital staff concerning patient safety twice a year.

Periodic self-inspections for patient safety in each hospital

According to the Medical Care Act and the Ordinance for Enforcement of the Medical Care Act, hospitals are requested to have a patient safety committee. One of the activities of the committee is to perform an inspection tour through the hospital regularly.

Investigation of in-hospital deaths

According to the Medical Care Act and the Ordinance for Enforcement of the Medical Care Act, special function hospitals such as university hospitals are required to review all in-hospital deaths whether they are related to adverse events or not.

In the Adverse Event Investigation System, all hospitals are required to report unexpected patient deaths due to medical service to the Japan Council for Patient Safety Investigation. All hospitals are required to review all in-hospital deaths whether or not they meet the reporting criteria of the Adverse Event Investigation System.

Financial incentives for hospitals to support introducing electronic medical records

The Ministry of Health, Labour and Welfare provides the budget for developing healthcare facilities to each prefecture, and each prefecture is able to use the budget for introducing EMR in hospitals.

Efforts to standardize the way of sharing patient information across different facilities

There is no authorized standardized way of sharing patient information across different facilities, although care coordination among different facilities is regarded as an essential part of the Integrated Community Health System in an aged society. Electronic health records, which enable the exchange of patient information across facilities, have been introduced in several areas, but the systems are developed independently. Exchange of patient information among different systems is not guaranteed.

The regional cooperation pathway (pathway from acute to rehabilitation care) is usually paper-based, and is used to share patient information across different facilities. The pathway enables the sharing of patient information via a common format among different healthcare facilities in a certain area. A pathway for femur fracture is widely used for cooperation among acute care hospitals and rehabilitation centers, because use of the pathway is paid by public medical insurance.

Safety standards for nursing homes or retirement homes

Patient safety in facilities with fewer resources than acute care hospitals can become a serious matter. There are no standards or data for patient safety in nursing homes and retirement homes.

Other systems for patient safety at the national level

■Approval and post-market surveillance for pharmaceuticals and medical devices

The Pharmaceuticals and Medical Devices Agency (PMDA) provides approval and post-market surveillance for pharmaceuticals and medical devices. Companies and healthcare professionals are required to report adverse drug reactions, infections caused by use of pharmaceuticals and medical devices and adverse events caused by medical devices to the agency. The agency also provides compensation for death or health damage requiring hospitalization caused by appropriately used, prescribed and purchased drugs and by infections from appropriately used biological products.

Korea

Periodic measurement

Accredited healthcare institutions are required to monitor indicators on patient satisfaction. The Health Insurance Review and Assessment Service (HIRA) is working on introducing a patient experience-based hospital assessment system to tertiary hospitals with 500+ beds. Accredited healthcare institutions are required to monitor indicators on employee satisfaction. Patient safety culture measurement is recommended but optional.

Efforts to standardize the way of sharing patient information across different facilities

The Health Insurance Review and Assessment Service is piloting a project on patient referral and transfer. This pilot project aims to facilitate the sharing of patient information between primary and secondary healthcare institutions through an intermediate system, which will enable rapid and accurate patient referral and transfer. Moving forward, we plan to develop and implement a model that can be linked with EMR.

Safety standards for nursing homes or retirement homes

In accordance with the Welfare of Older Persons Act, safety standards are included in the facility standards for nursing homes.

Other systems for patient safety at the national level

In accordance with Article 12 of the Patient Safety Act, the job responsibilities of personnel dedicated to patient safety include healthcare personnel training on the prevention of new and repeated adverse events.

Mexico

Periodic measurement

All hospitals measure patient satisfaction of hospital personnel and representatives of the community that are called “Aval Ciudadano” in parallel, and the results are then compared in order to establish their credibility. This results are publicly presented to all hospital users and personnel.

The General Directorate of Quality and Healthcare Education coordinates the implementation of the patient safety culture survey, and 12,525 doctors and nurses answer this survey in 2017.

Education or training concerning patient safety for staff

It is not mandatory.

Other systems for patient safety at the national level

The General Directorate of Quality and Healthcare coordinates specific actions such as a national survey in quality perception and a national survey in hand hygiene in accordance with the multimodal strategy form the world health organization.

Portugal

Periodic measurement

The Ministry of Health (Directorate-General of Health) also measures patient satisfaction every two years and the hospitals also do it according to the National Strategy for Quality in Health. Hospitals are required to measure patient safety culture since 2013 (Guideline nº 25/2013) and according to the 1st Strategic Goal of the National Plan for Patient Safety.

Periodic self-inspections for patient safety in each hospital

According to the National Plan for Patient Safety, the National Guidelines and the Ministerial Order nº 3635/2013.

Standardized education/training programs for patient safety
The Minister of Health approved training programs on Patient Safety.

Efforts to standardize the way of sharing patient information across different facilities
Ministerial Order nº 2783/2013 and National Guideline nº01/2017.

Safety standards for nursing homes or retirement homes
These units participate in HALT - Healthcare-associated infections in long-term care facilities study developed by ECDC and the national guidelines of the multimodal strategy for Infection Control also apply to these units.

Other systems for patient safety at the national level
The Ministry of Health published "The National Plan for Patients' Safety 2015-2020 (Order nº 1400-A/2015)" to establish 9 national patient safety strategic goals. For each strategic goal, there are national guidelines with national indicators. Furthermore, the Ministry of Health also issued Order nº5739/2015 publishing the national indicators for quality monitoring (including Safety).
The national program "Health education, literacy and self-care" was created by ministerial order nº 3618-A/2016. In 2017, this program was merged with the program: "Prevention and Management of Chronic Illness" and a new program was created: "Health Literacy and Integration of Care" (ministerial order nº 6429/2017).

Slovakia

Periodic measurement
The Ministry of Health requires state hospitals to measure patient satisfaction voluntarily.

Investigation of in-hospital deaths
If the bereaved families agree, yes.

Financial incentives for hospitals to support introducing electronic medical records
It is in the process of national action plan.

Efforts to provide emotional support for the staff involved in adverse events
The Modrý anjel (Blue Angel, NGO) provides the support based on a request of the staff.

Slovenia

Periodic measurement
Measuring the quality and safety of health care is not yet fully equivalent to the interconnected planned interdependent activities and measures at all levels and segments of healthcare.
As for patient satisfaction, we started the PREMs and PROM project with the support of the European Commission Structural Reform Support Service.
Employee satisfaction is not automatically monitored in public health facilities. The system was established only in some hospitals. It is partially established at the primary level in family medicine practices.
A patient safety culture survey was conducted in 13 hospitals in 2011. The results were not good. In upgrading the monitoring system of sentinel and other adverse events is one of the important points is to improve the safety culture.

Education or training concerning patient safety for staff
The internal education system is well established only in some hospitals.

Rapid response team
Hospitals have a dedicate team which are available to respond to a deterioration or a sudden change of condition of patients.

Periodic self-inspections for patient safety in each hospital

The hospitals are performing regular security rounds.

Control of quality and safety takes place within the framework of professional supervision with counseling on the basis of the Health Care Services Act. The amendment to the Health Care Act, adopted on 19 September 2017, as an important novelty introduces systemic control and, in some other forms of supervision, emphasizes the possibility of control over quality and safety.

Standardized education/training programs for patient safety

Training for health professions is carried out in accordance with Directive 2005/36 / ES and Directive 2013/55 / EU (for full-time and part-time studies). Quality and safety is part of compulsory professional training of health professionals. Modules for the development of skills and skills for inter-professional cooperation are being introduced.

Medical equipment/ device certification that is taken into account patient safety/ human factors concerns

The area is partially regulated by the Rules on minimum sanitary health conditions for the provision of hygienic care and other similar activities. In some parts, the areas also touch on the provisions of the Law on safety and health at work.

Financial incentives for hospitals to support introducing electronic medical records

eHealth is a project at national level. Training of contractor was carried out. The facility of a national system is financially supported. The development of internal systems is in the domain of individual hospitals.

Efforts to provide emotional support for the staff involved in adverse events

This is primarily available in psychiatric hospitals, in others, depending on hospital management and the willingness of psychiatrists or clinical psychologists to work in hospitals, supervision is not provided to workers in health care.

Safety standards for nursing homes or retirement homes

Patient safety systems in homes for elderly people are partially established. The system for monitoring and implementing measures for sentinel and other adverse events in Slovenia are only established in some major public institutes, less in private institutions.

Other systems for patient safety at the national level

■ Continuing education for licensed professionals

The Rules on Medical Licenses and Regulations on the Register and Licenses of Performers in Nursing or Midwifery Care are important. Professional training in addition to the contents from the narrower field of expertise in which the worker performs his work, also includes compulsory contents from the quality and safety in health care, in the scope of 6 hours. The healthcare professional will have to complete the above mentioned contents at least once every seven years.

■ Contribution of patient associations

Cooperation takes place through patient associations (NGO Network 25 x 25), answering patients' questions, by completing questionnaires on satisfaction with services provided.

Spain

Periodic measurement

The Regions normally assess patient satisfaction annually. Employee satisfaction is not measured in general. The National PS strategy recommends to assess patient safety culture regularly.

Periodic self-inspections for patient safety in each hospital

It conducts in the framework of accreditation programs as well as some specific programs regarding PS good practices.

Investigation of in-hospital deaths

There are hospital mortality commissions in each hospital.

Standardized education/training programs for patient safety

There are standard programs in some Regions.

Medical equipment/ device certification that is taken into account patient safety/ human factors concerns

It is a responsibility of the National Medication and Medical Device Agency.

Financial incentives for hospitals to support introducing electronic medical records

The MSSSI provides specific budget to implement electronic clinical records nationwide.

Efforts to standardize the way of sharing patient information across different facilities

Annual national and Regional meetings to share the results of specific indicators among hospitals.

Efforts to provide emotional support for the staff involved in adverse events

There are supports in some Regions/hospitals. Also the MSSSI is working with experts and Universities to design a national program regarding this issue.

- Mira JJ et al.: Lessons learned for reducing the negative impact of adverse events on patients, health professionals and healthcare organizations. Int J Qual Health Care. 2017 Aug 1;29(4):450-460
- Mira JJ, et al.: The Second Victim Phenomenon After a Clinical Error: The Design and Evaluation of a Website to Reduce Caregivers' Emotional Responses After a Clinical Error. J Med Internet Res. 2017 Jun 8;19(6): e203
- Mira Solves JJ, et al.: In case of an adverse event don´t forget to say sorry. An Sist Sanit Navar. 2017 Aug 31;40(2):279-290

Safety standards for nursing homes or retirement homes

There are standards in some Regions/hospitals.

Switzerland

Periodic measurement

Patient safety culture has not measured regularly yet, but it is in consideration to be made mandatory (clarifications ongoing).

Standardized education/training programs for patient safety

Only in the French speaking cantons.

Safety standards for nursing homes or retirement homes

In some specific cantons.

Other systems for patient safety at the national level

National Breakthrough Programms (Safe surgery WHO checklist), Safe Medication (medication reconciliation), Safety in urinary catheters, Medication safety in nursing homes). Methodology: IHI Breakthrough Collaboratives

United Kingdom

Education or training concerning patient safety for staff

Factors taught in medical education curriculum

Periodic self-inspections for patient safety in each hospital

The Care Quality Commission independently inspects hospitals on a regular basis, in addition to when responding to incident notification.

Investigation of in-hospital deaths

Providers are required to investigate deaths thought to have been due to problems in care under the National Guidance on Learning from Deaths. The learning from investigations or reviews must then be published, alongside the steps that the provider will take in response. Additionally, the deaths of all children must be reviewed under the national guidance on Child Death Review.

Medical equipment/ device certification that is taken into account patient safety/ human factors concerns

Medicines and Healthcare Products Regulatory Agency advise that manufacturers take human factors into account, and assess these factors when reviewing new devices.

Efforts to standardize the way of sharing patient information across different facilities

NHS Digital are leading on a project to make patient records available for investigative purposes.

8. National Patient Day/Week

More than half of the states already have a national patient day or week that aims to promote patient safety activities in healthcare organizations and societies. Not only posters but also videos, games and quizzes are provided in Canada and France. World Patient Safety Day would be welcomed to promote patient safety activities worldwide.

8.1 National Patient Day/Week

Exist: BEL, CAN, FRA, DEU, JPN, SVN, CHE

Not exist: CZE, FIN, IRL, ITA, KOR, PRT, ESP, SVK

Others: DNK, MEX, GBR

8.2 Activities on the Patient Day/Week

Belgium

Third week of November is a patient safety week.

Symposium and hospitals are asked to develop activities focused on patient safety during that week.

Canada

Canadian Patient Safety Week is a national, annual campaign that started in 2005 to inspire extraordinary improvement in patient safety and quality. As the momentum for promoting best practices in patient safety has grown, so has the participation in Canadian Patient Safety Week. Canadian Patient Safety week is relevant to anyone who engages with our healthcare system: providers, patients, and citizens. Working together, thousands help spread the message to Ask. Listen. Talk.

During the most recent Canadian Patient Safety Week, the following activities occurred:

- A quiz related to medication safety which was tailored to both patients and providers
- A podcast series entitled PATIENT which explores medication safety through a non-fiction medical drama.
- A contest entitled - Question Your Meds Catchy Phrase Contest which brought attention to the 5 Questions to Ask Medication Safety Tool.
- A National Conversation Webinar around Implementing Safer, More Efficient Care.

Denmark

N/A

France

Patient safety Week nationally hold every year since 2011.

Numerous activities are organized by the Ministry of Health, by the Regional Health Authorities, by the regional “structures d’appui à la qualité des soins et à la sécurité des patients”, by other experts’ bodies at national, regional or local levels (expert bodies for infections, for the safety of medication, etc.), by almost every hospital and in a number of elderly care structures. Events, symposiums and workshops are organized, talks, trainings, contests, etc. Videos, serious games, posters are displayed.

Germany

September 17th (International Day of Patient safety, celebrated in D, AUT, CH, LIE, LUX, CRO, BRA)
German Alliance for Patient Safety (Aktionsbündnis Patientensicherheit) sets a topic each year for outreach events that involve patients and all stakeholders of the health care system. An annual topic is chosen.

Japan

The week including November 25th is Patient Safety Week.
The Ministry of Health, Labour and Welfare makes a poster for Patient Safety Week and holds a symposium. Many healthcare organizations also hold symposiums or workshops around this week.

Korea

Starting from 2018, Patient Safety Day/Week will be celebrated.

Mexico

May 5th is the international day for hand hygiene, in accordance with the International Hand Hygiene strategy promoted by the WHO.
There is a nationwide campaign to promote Hand Hygiene with social media events, education programs, etc. All states in Mexico must elaborate a continuous improvement plan form the results of the Hand Hygiene multimodal survey.

Slovakia

Slovak day of oncology patients (Deň narcisov), Slovak day of obesity (Slovenský deň obesity), National week of antibiotic use and AMR (November) and others
Collecting donation of citizens for medical equipment, and informational campaigns about the illness

Slovenia

February 11 is World Patient Day.
Many events take place on that day. Chambers and professional associations make public statements, and civil associations of patients are active. In 2017, respect for the dignity of patients was the topic.

Switzerland

It is led by Patient Safety Foundation. Presentations in many hospitals, media contacts etc.

United Kingdom

N/A

9. Effectiveness and priorities of patient safety policies

The mean values of ratings of all items are shown in Figure 1 and in the Appendix. Ten policies were identified as favorable policies, six of which were related to the reporting and investigation of adverse events. Policymakers may consider establishing a public reporting system and standardizing the system for investigating adverse events. Two policies were identified as unfavorable policies. The effect of accreditation for patient safety or the certification of personnel responsible for patient safety management may be controversial issues that need further investigation.

9.1 Favorable policies

(1: low --- 5: high)

Questions		Effect of the policy		Priority in near future in your country	
		Mean	SD	Mean	SD
1.2.5	(Requirement for hospitals) To define procedures for identification, investigation and prevention of adverse events	4.0	0.9	4.2	1.2
1.2.7	(Requirement for hospitals) To define patient and caregiver participation in patient safety efforts	3.7	1.1	4.0	1.1
1.2.8	(Requirement for hospitals) To define the measurement and evaluation of methods for patient safety (including patient safety indicators)	4.0	0.9	4.3	1.0
3.7	Are the hospitals required to report adverse patient events to the government or an independent organization?	3.8	1.0	4.3	0.9
3.8	Is there a system for hospitals to report VOLUNTARILY adverse events to the government or an independent organization?	3.5	1.0	4.2	1.1
3.9	Is there a system for hospitals to report VOLUNTARILY close calls/near misses to the government or an independent organization?	3.8	0.9	4.4	0.9
6.4	Are there guidelines for in-hospital investigation of adverse events?	3.9	1.1	4.2	1.1
7.1.7	Are hospitals required to investigate in-hospital deaths?	3.7	1.0	4.1	1.1
7.2.3	Is there financial incentive support for hospitals to introduce electronic medical records?	3.6	0.9	4.1	0.8
7.3.1	Are there efforts to standardize the way of sharing patient information across different facilities?	3.8	1.1	4.0	0.9

9.2 Unfavorable policies

(1: low --- 5: high)

Questions		Effect of the policy		Priority in near future in your country	
		Mean	SD	Mean	SD
2.6	If “yes” in 2.3, are there any systems or incentives to support hospitals to undergo hospital accreditation?	2.4	1.1	2.8	1.7
4.6	If “Yes” in 4.4, is there a national or other certification system for personnel responsible for patient safety management?	2.3	1.6	2.6	1.5

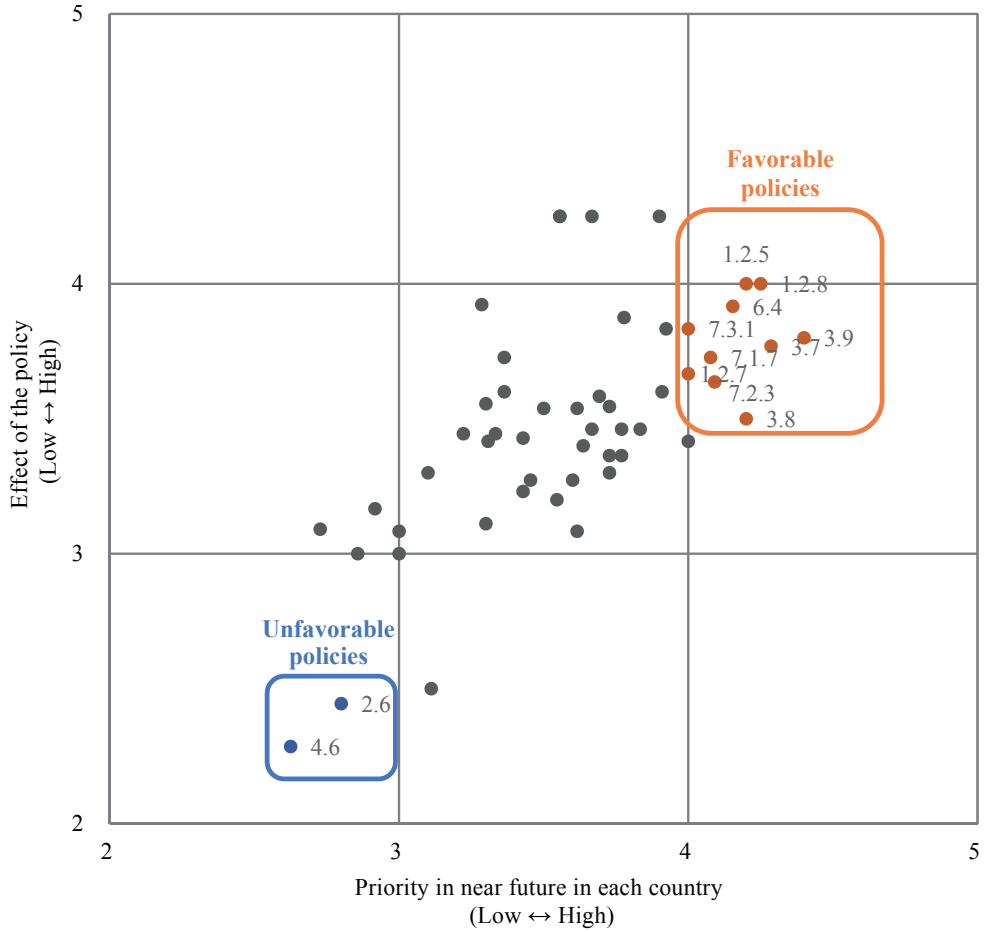

Figure 1 Distribution of ratings of all items

APPENDIX

Table. Ratings of effects and priorities of each policy

Questions		Effect of the policy		Priority in near future in your country	
		Mean	SD	Mean	SD
1	Safety standards				
1.1	Are hospitals required to establish a patient safety management system by law?	3.9	1.1	3.3	1.5
1.2	If "yes" in 1.1, choose the actions required by hospitals.				
1.2.1	To define the guiding principles (or guidelines) for patient safety program	4.3	0.8	3.6	1.3
1.2.2	To define the organization for patient safety management	4.3	0.8	3.6	1.3
1.2.3	To define who is assigned in charge of the patient safety management	4.3	0.8	3.7	1.4
1.2.4	To define the in-hospital reporting system for adverse event and close calls (near misses)	4.3	1.0	3.9	1.3
1.2.5	To define procedures for identification, investigation and prevention of adverse events	4.0	0.9	4.2	1.2
1.2.6	To define the staff education and training for patient safety	3.9	1.1	3.8	1.4
1.2.7	To define patient and caregiver participation in patient safety efforts	3.7	1.1	4.0	1.1
1.2.8	To define the measurement and evaluation of methods for patient safety (including patient safety indicators)	4.0	0.9	4.3	1.0
2	Please describe the required audits and accreditation of hospitals with focus on patient safety				
2.1	Does the government audit patient safety conditions regularly?	3.5	1.3	3.5	1.5
2.2	If "yes" in 2.1, what conditions or actions are inspected?				
2.3	Is there a hospital accreditation system by an independent third body organization?	3.7	0.9	3.4	1.1
2.4	If "yes" in 2.3, please provide the name(s) of the accreditation body(ies).				
2.5	If "yes" in 2.3, please provide the number and/or the proportion of accredited hospitals in your country.				
2.6	If "yes" in 2.3, are there any systems or incentives to support hospitals to undergo hospital accreditation?	2.4	1.1	2.8	1.7
3	Please describe the patient safety data submission requirements by hospitals				
3.1	Are hospitals required to submit data of clinical indicators concerning patient safety to the government or an independent third entity?	3.4	1.0	3.4	1.2
3.2	If "Yes" in 3.1, how many patient safety indicators are required?				
3.3	If "Yes" in 3.1, are patient reported outcomes or experiences included in the reporting indicators?	3.3	1.4	3.7	1.4
3.4	If "Yes" in 3.1, is the collected data made public?	3.6	1.0	3.7	1.2
3.5	If "Yes" in 3.1, is the collected data made public in a manner that identifies the hospital?	3.4	1.2	3.3	1.3
3.6	If "Yes" in 3.1, is there a system to reward or a penalize hospitals based on the reported data?	2.5	1.2	3.1	1.7
3.7	Are the hospitals required to report adverse patient events to the government or an independent organization?	3.8	1.0	4.3	0.9
3.8	Is there a system for hospitals to report VOLUNTARILY adverse events to the government or an independent organization?	3.5	1.0	4.2	1.1

	Questions	Effect of the policy		Priority in near future in your country	
		Mean	SD	Mean	SD
3.9	Is there a system for hospitals to report VOLUNTARILY close calls/near misses to the government or an independent organization?	3.8	0.9	4.4	0.9
3.10	If you answered "Yes" in any questions from 3.7 to 3.9, please provide the name of organization that collects the information of adverse events or close calls.				
3.11	Is there a system to exempt criminal or civil liability of adverse events when the case is reported to the government or the independent organization?	3.1	1.2	2.7	1.4
3.12	Are the sentinel events published regularly based on reported adverse events and close calls?	3.3	1.1	3.6	1.5
4	What training or experience is required for hospital staff responsible for patient safety management?				
4.1	Are personnel responsible for patient safety management regarded as a professional focus in patient safety management?	3.5	1.2	3.8	1.3
4.2	What is the major educational background among personnel responsible for patient safety management?				
4.3	Are there standard educational programs for training personnel responsible for patient safety management?	3.5	1.2	3.8	1.2
4.4	Are there organizations that offer education or training for personnel responsible for patient safety management?	3.5	1.5	3.6	1.3
4.5	If "Yes" in 4.4, what kind of organizations offer education or training for personnel responsible for patient safety management?				
4.6	If "Yes" in 4.4, is there a national or other certification system for personnel responsible for patient safety management?	2.3	1.6	2.6	1.5
4.7	Are there incentives to promote assignment of personnel to be responsible for patient safety management in each hospital? If so, can you elaborate?	3.1	1.6	3.0	1.7
4.8	Are there networks which promote information sharing among personnel responsible for patient safety management across hospitals?	3.2	1.4	3.4	1.4
4.9	What are the major challenges in training or assignment of a personnel responsible for patient safety in each hospital?				
5	Please describe the system for dispute resolution and compensation concerning patient harm in your country				
5.1	Is there a no-fault compensation scheme for adverse events?	3.4	1.3	3.2	1.5
5.2	If "Yes" in 5.1, please answer the name of the administrative entity of the no-fault compensation scheme.				
5.3	If "Yes" in 5.1, please provide the definition of adverse events which are compensated by the scheme. (e.g. the type or severity of adverse events, etc.)				
5.4	If "Yes" in 5.1, how many cases were compensated by the scheme during the past year?				
5.5	Is an alternative dispute resolution (ADR) available to resolve medical disputes?	3.2	1.2	2.9	1.4
5.6	If "Yes" in 5.5, are there organizations that provide or help to find a mediator or an arbitrator?	3.4	0.7	3.3	1.1
5.7	If "Yes" in 5.5, is there a standard educational program to train mediators or arbitrators for medical disputes?	3.0	0.6	3.0	1.0
6	Please define the standard methods for investigation of adverse events				
	(External organization)				
6.1	Are there third body organizations that investigate the causes of adverse events?	3.6	1.4	3.4	1.7

Questions		Effect of the policy		Priority in near future in your country	
		Mean	SD	Mean	SD
6.2	If "Yes" in 6.1, please provide the name of the administrative entity for patient harm investigations.				
6.3	If "Yes" in 6.1, how many cases were investigated by the third body organizations during the past year?				
	(Autonomous in-hospital investigation)				
6.4	Are there guidelines for in-hospital investigation of adverse events?	3.9	1.1	4.2	1.1
6.5	Are hospitals required to involve an external person in the in-hospital investigation team deliberations for guaranteeing fairness and transparency?	3.6	1.5	3.3	1.6
6.6	Are there recommended methods for investigating adverse events? (e.g. root cause analysis)	3.8	1.1	3.9	1.4
6.7	Are there external supporting systems for in-hospital investigation?	3.2	1.3	3.5	1.6
6.8	What standardized items are included in the investigation report?				
6.9	Are the reports of adverse event investigations disclosed to the public?	3.0	1.4	2.9	1.4
7	Others				
7.1	Requirements				
7.1.1	Are hospitals required to regularly measure patient satisfaction?	3.5	1.2	3.7	1.1
7.1.2	Are hospitals regularly required to measure employee satisfaction?	3.3	1.2	3.1	1.4
7.1.3	Are hospitals required to regularly measure patient safety culture?	3.6	1.3	3.9	1.3
7.1.4	Are hospitals required to offer education or training concerning patient safety for their staff?	3.5	1.2	3.7	1.3
7.1.5	Are hospitals required to have a dedicate team that is available to respond to a deterioration or a sudden change of condition of patients? (e.g. rapid response team, METS, etc.)	3.4	1.1	4.0	1.1
7.1.6	Are hospitals required to carry out periodic inspections for patient safety?	3.4	1.0	3.8	1.2
7.1.7	Are hospitals required to investigate in-hospital deaths?	3.7	1.0	4.1	1.1
7.2	Promotion of standardization in hospital				
7.2.1	Are standardized education/training programs for patient safety provided?	3.4	1.2	3.6	1.0
7.2.2	Are patient safety/human factors concerns taken into account when certifying medical equipment/device?	3.3	1.2	3.5	1.3
7.2.3	Is there financial incentive support for hospitals to introduce electronic medical records?	3.6	0.9	4.1	0.8
7.3	Others				
7.3.1	Are there efforts to standardize the way of sharing patient information across different facilities?	3.8	1.1	4.0	0.9
7.3.2	Are there efforts to provide emotional support for the staff involved in adverse events? If yes, please provide details.	3.1	1.1	3.3	0.8
7.3.3	Are there safety standards for nursing homes or retirement homes?	3.4	1.0	3.7	0.7
7.3.4	Describe other systems for patient safety at the national level, and please explain briefly.				
8	National Patient Day				
8.1	Is there a National Patient Day/Week?	3.1	1.4	3.6	1.4
8.2	If Yes in "8.1", what kind of activities are provided on the Patient Day/Week?				

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