



World Health
Organization



Patient Safety Incident Reporting and Learning Systems

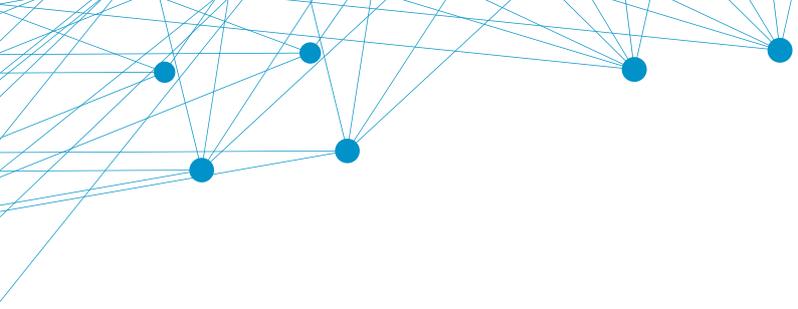
Technical report and guidance



World Health
Organization

Patient Safety Incident Reporting and Learning Systems

Technical report and guidance



Patient safety incident reporting and learning systems: technical report and guidance

ISBN 978-92-4-001033-8 (electronic version)

ISBN 978-92-4-001034-5 (print version)

© World Health Organization 2020

Some rights reserved. This work is available under the Creative Commons Attribution-NonCommercial-ShareAlike 3.0 IGO licence (CC BY-NC-SA 3.0 IGO; <https://creativecommons.org/licenses/by-nc-sa/3.0/igo>).

Under the terms of this licence, you may copy, redistribute and adapt the work for non-commercial purposes, provided the work is appropriately cited, as indicated below. In any use of this work, there should be no suggestion that WHO endorses any specific organization, products or services. The use of the WHO logo is not permitted. If you adapt the work, then you must license your work under the same or equivalent Creative Commons licence. If you create a translation of this work, you should add the following disclaimer along with the suggested citation: "This translation was not created by the World Health Organization (WHO). WHO is not responsible for the content or accuracy of this translation. The original English edition shall be the binding and authentic edition".

Any mediation relating to disputes arising under the licence shall be conducted in accordance with the mediation rules of the World Intellectual Property Organization (<http://www.wipo.int/amc/en/mediation/rules/>).

Suggested citation. Patient safety incident reporting and learning systems: technical report and guidance. Geneva: World Health Organization; 2020. Licence: [CC BY-NC-SA 3.0 IGO](https://creativecommons.org/licenses/by-nc-sa/3.0/igo).

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

Sales, rights and licensing. To purchase WHO publications, see <http://apps.who.int/bookorders>. To submit requests for commercial use and queries on rights and licensing, see <http://www.who.int/about/licensing>.

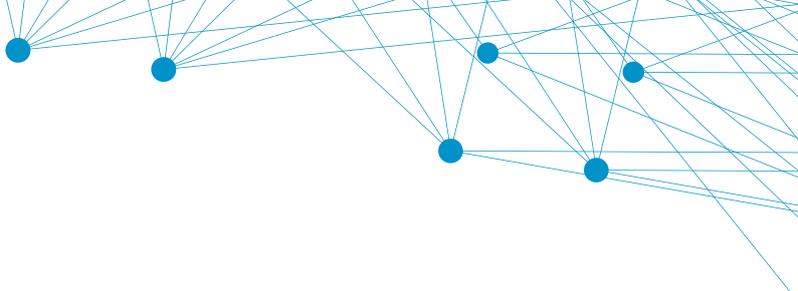
Third-party materials. If you wish to reuse material from this work that is attributed to a third party, such as tables, figures or images, it is your responsibility to determine whether permission is needed for that reuse and to obtain permission from the copyright holder. The risk of claims resulting from infringement of any third-party-owned component in the work rests solely with the user.

General disclaimers. The designations employed and the presentation of the material in this publication do not imply the expression of any opinion whatsoever on the part of WHO concerning the legal status of any country, territory, city or area or of its authorities, or concerning the delimitation of its frontiers or boundaries. Dotted and dashed lines on maps represent approximate border lines for which there may not yet be full agreement.

The mention of specific companies or of certain manufacturers' products does not imply that they are endorsed or recommended by WHO in preference to others of a similar nature that are not mentioned. Errors and omissions excepted, the names of proprietary products are distinguished by initial capital letters.

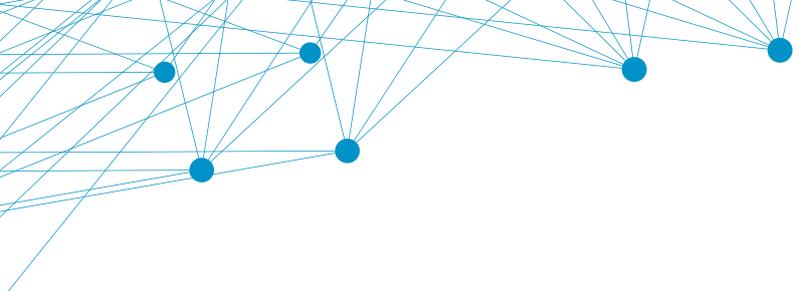
All reasonable precautions have been taken by WHO to verify the information contained in this publication. However, the published material is being distributed without warranty of any kind, either expressed or implied. The responsibility for the interpretation and use of the material lies with the reader. In no event shall WHO be liable for damages arising from its use.

Designed by: YAT Communication



Contents

Foreword	v
Acknowledgements	viii
Glossary	xii
Ten facts on reporting and learning systems	xiv
1. Introduction	1
1.1 Background to patient safety	1
1.2 Purpose of this document	2
2. Reporting and learning systems: current status	3
2.1 Reporting seen as central to safety improvement	5
2.2 Weaknesses of most reporting systems in health care	6
2.3 Lessons from incident reporting in other sectors	7
2.4 Improving the process of learning from incidents	10
3. Work of WHO on patient safety incident reporting and learning	12
3.1 Conceptual framework for the International Classification for Patient Safety	12
3.2 Minimal Information Model for Patient Safety Incident Reporting and Learning Systems	14
3.3 WHO consultation on patient safety incident reporting and learning systems	17
4. Developing and operating a reporting and learning system	19
4.1 Understanding a patient safety incident reporting and learning system	19
4.2 Creating a positive environment for reporting	19
4.3 Identification and recording of incidents	20
4.4 Choosing the information to be captured	21
4.5 Uses of incident reports	22
4.6 Review and investigation of individual incidents	22
4.7 Systemic insights from aggregated incident data	27
4.8 Learning, formulating action, and managing change	29
4.9 Openness and independence of data analysis	31
4.10 Information and clinical governance	32
4.11 Engaging patients and families	32



5. Guidance 34

5.1	Understanding a patient safety incident reporting and learning system	34
5.2	Creating a positive environment for reporting	35
5.3	Identification and recording of incidents	36
5.4	Choosing the information to be captured	37
5.5	Uses of incident reports	37
5.6	Review and investigation of individual incidents	37
5.7	Systemic insights from aggregated incident data	38
5.8	Learning, formulating action and managing change	39
5.9	Openness and independence of data analysis	40
5.10	Information and clinical governance	41
5.11	Engaging patients and families	41

6. Self-assessment based upon the guidance 43

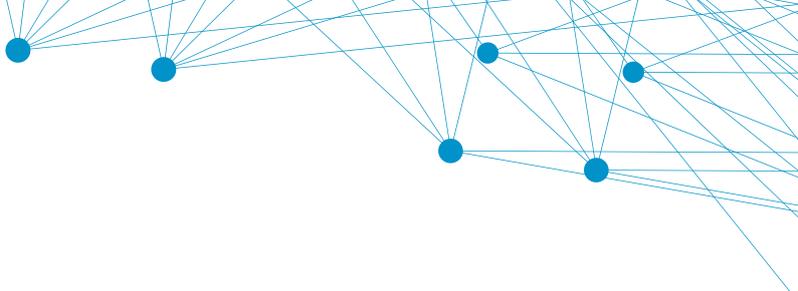
References 49

Figures

Figure 1.	Classification of patient safety incidents	4
Figure 2.	Responding to a patient safety incident report	10
Figure 3.	Conceptual framework for the International Classification for Patient Safety	13
Figure 4.	Minimal Information Model for Patient Safety Incident Reporting and Learning Systems (MIM PS)	16
Figure 5.	The Swiss cheese model: system weaknesses and defences	23
Figure 6.	Assessment of patient safety incident reports	25
Figure 7.	Complex combination of factors contributing to Lac-Mégantic runaway train accident	26
Figure 8.	Options for aggregating patient safety incident data	27
Figure 9.	Uses and limitations of aggregated patient safety incident data	29

Tables

Table 1.	Mismatch between principles and practices of incident reporting: other industries and health care	8
Table 2.	Patient safety incident reporting system: a self-assessment	44



Foreword

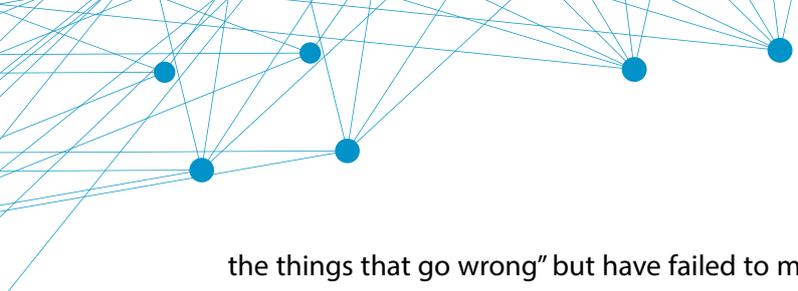
In an ideal world, all events and occurrences in a health service that cause harm or have the potential to cause harm to patients would be quickly recognized and managed appropriately at the point of care by alert, knowledgeable staff. They would carefully document and communicate their observations. They would be enthusiastic about their involvement in this activity because they would have seen many examples of how such reports had been used to improve the safety of care.

Incident reports would be reviewed and analysed by a dedicated team of patient safety specialists to identify the most important risks to patient safety and to coordinate systematic, non-punitive investigations into those problems. The resulting investigation would be impartial and multidisciplinary, involving expertise from relevant clinical specialties but, crucially, also from non-health disciplines that successfully contribute to accident reduction in other fields of safety.

Investigation would be carried out in an atmosphere of trust in which blame and retribution were absent, and disciplinary action or criminal sanctions would be taken only in appropriate and rare circumstances. Action resulting from investigation would lead to the redesign of policies, processes of care, products and procedures, and to changes to clinical care practices and the working styles of individuals and teams. Such actions would usually lead to measurable, sustained reduction of risk for future patients. Some types of harm would be eliminated entirely. There would be agreed processes to aggregate data and produce analyses that point to systemic weaknesses and enable solutions.

However, very few health systems or health facilities in the world can come near to this ideal level of performance in capturing and learning from incidents of avoidable harm. This is so for all sorts of reasons, ranging from an insufficiency of leaders skilled and passionate enough to engage their entire workforce on a quest to make care safer, a lack of transparency, a fear of retribution, the inability of health care professionals to freely report on events and occurrences of harm, errors, near misses and risks, through an inability to investigate properly the volume of reports generated, to the weak evidence base on how to reduce harm.

Many patient safety programmes around the world have raised very high expectations about the potential impact of incident reporting and learning systems. Indeed, many that have been established have been driven by the common-sense reasoning that “we *must* learn from



the things that go wrong” but have failed to meet that expectation because of a belief in the inevitability that “we *will* learn from what goes wrong”. Experience has been disappointing in this respect, as well as in comparison to the track record of other high-risk industries, such as the aviation industry. Some health care organizations and facilities around the world have shown that analysis of patient safety incidents can lead to safety improvements, but this is far from the norm. Most of the experience of patient safety incident reporting and learning systems has been in hospitals in high-income countries. There has been less experience in low- and middle-income countries and in the fields of primary care and mental health.

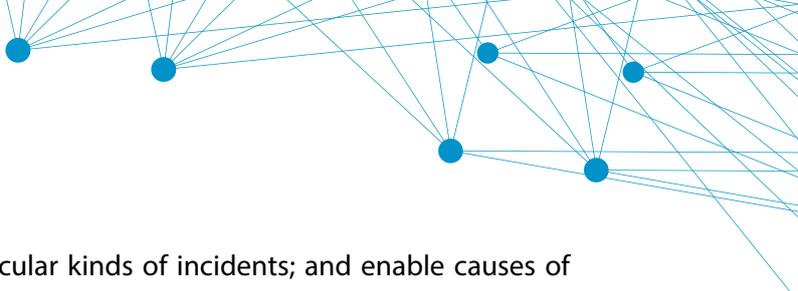
There are many challenges in trying to deliver greater benefits from patient safety incident reporting and learning systems, but three really stand out.

First, feedback from point of care staff around the world consistently highlights the difficulty that health systems face in establishing a safety culture that is based on blame-free reporting and in which learning is more powerful than judgement. Too often, individuals are held to account when poorly designed systems and processes of care have resulted in errors by conscientious members of staff. The consequences of using an incident of harm or death to track and punish a nurse or doctor are clear. More patients will die since staff will be too fearful to admit mistakes, nothing will be learned, and the source of risk will lie in wait for the next innocent patient to come along.

Second, the core data of many patient safety incident reporting systems are the reports initially made by a member of staff, sometimes with additional local information gathering. Thus, the cause of the incident and the prospects of learning from it are too often a matter of local opinion. Detailed multidisciplinary investigation, including expert inputs, in-depth interviews with those involved and reconstruction of the events that occurred, is less commonly undertaken, even though it would lead to much deeper insights into systemic issues. This is primarily for logistic reasons (too high a volume of incidents), insufficient resources, and lack of coordination to bring the right people together in the right way.

Third, the process of achieving sustainable reductions in risk and improvements in patient safety seldom works well. One element of this is the recognition that measures such as issuing new guidelines, one-off training initiatives and sending out alerts have been shown in other high-risk settings to be relatively weak change strategies.

In some countries, health systems and health care organizations have sought to create a system of reporting of patient safety incidents and then to establish and develop a database of such incidents that are used to: analyse the frequency of particular sources of harm; describe



trends and patterns overall as well as in particular kinds of incidents; and enable causes of harm and potential risks to be explored and solutions found to reduce risks to patients. They have perhaps been most successful in developing ways of monitoring incident patterns and trends and in identifying clusters of types of harm as well as spotting new sources of risk to patients. The distillation of actionable learning on a regular and routine basis has proved much more difficult.

In compiling this technical guidance I am indebted to many individual experts, to national patient safety agencies and patient safety foundations, to senior representatives of national ministries of health, and to World Health Organization (WHO) global, regional and country offices, who have shared with me their views and their related experience both within and outside the global consultations that WHO has held. I am also grateful for previous work undertaken by WHO in conjunction with certain Member States and the European Union on the design of incident reporting and learning systems and on an international classification. These initiatives are described in this document. This new guidance builds on the *WHO draft guidelines for adverse event reporting and learning systems: from information to action*. I strongly recommend that all who read this guidance document should also refer to these previous WHO draft guidelines.

My main message to readers of this document is to urge them to understand the purpose, strengths and limitations of patient safety incident reporting. Data derived from incident reports can be very valuable in understanding the scale and nature of harm arising from health care, provided that the properties of the data are reviewed carefully and conclusions are drawn with caution. The use of incident reporting systems for true learning in order to achieve sustainable reductions in risk and improvements in patient safety is still work in progress. It can be and has been done, but not yet on the scale and with the speed that compares with some other high-risk industries. That is what we must all strive for. I hope that this technical guidance will help the journey to a position where we can show patients and their families how we used this learning to give them care that is safe and dependable, every time they need it.

Sir Liam Donaldson
Patient Safety Envoy
World Health Organization



Acknowledgements

Leadership group

Liam DONALDSON
WHO Patient Safety Envoy
Geneva, Switzerland

Edward KELLEY
World Health Organization
Geneva, Switzerland

Neelam DHINGRA
World Health Organization
Geneva, Switzerland

Maki KAJIWARA
World Health Organization
Geneva, Switzerland

Main author

Liam DONALDSON
WHO Patient Safety Envoy
Geneva, Switzerland

Editorial support

Ian COLTART
World Health Organization
Geneva, Switzerland

Anthony FINNERTY
World Health Organization
Geneva, Switzerland

Laura PEARSON
World Health Organization
Geneva, Switzerland

Sorin BANICA
World Health Organization
Geneva, Switzerland

Expert group

Ahmed Salim Saif AL MANDHARI
World Health Organization
Cairo, Egypt

Tommaso BELLANDI
Centre for Clinical Risk Management and
Patient Safety
Florence, Italy

Andrew CARSON-STEVENS
Cardiff University
Cardiff, United Kingdom

William GHALI
University of Calgary
Calgary, Canada

Valentina HAFNER
Patient Safety Consultant
Bucharest, Romania

Peter HIBBERT
Australian Institute of Health Innovation,
Macquarie University
Sydney, Australia

Zdeněk HŘIB
Institute for Applied Research, Education, and
Health Care Management
Prague, Czech Republic

Basia KUTRYBA
National Centre for Quality Assessment in
Health Care
Krakow, Poland

Sang Il LEE
ASAN Medical Centre
Seoul, Republic of Korea

Carl MACRAE
University of Nottingham
Nottingham, United Kingdom

Stephen ROUTLEDGE
Canadian Patient Safety Institute
Edmonton, Canada

Eli SAASTAD
Norwegian Directorate of Health
Oslo, Norway

Ronel STEINHOBEL
National Department of Health Directorate
Pretoria, South Africa

Shin USHIRO
Japan Council for Quality Health Care
Tokyo, Japan

Reviewers and other contributors

Farahdina bt ABIDIN
Ministry of Health
Putrajaya, Malaysia

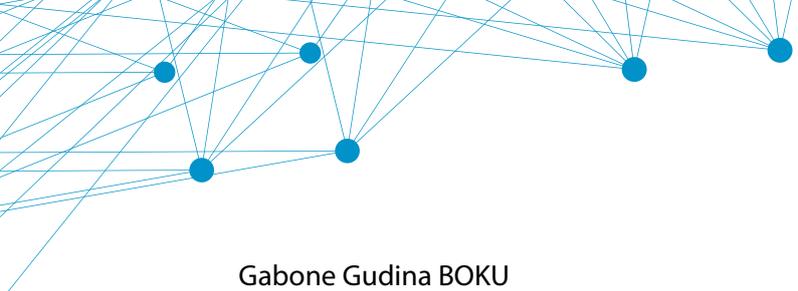
Nor'Aishah bt ABU BAKAR
Ministry of Health
Putrajaya, Malaysia

Samra Salim AL BARWANI
Directorate-General of Quality Assurance
Muscat, Oman

Asma Mohammed AL HADIFI
Khoula Hospital
Muscat, Oman

Karima Mayar AMIRI
Ministry of Public Health
Kabul, Afghanistan

Zouatni BAHIIJA
Hôpitaux et des Soins Ambulatoires
Rabat, Morocco



Gabone Gudina BOKU
Federal Ministry of Health
Addis Ababa, Ethiopia

Nikhil Prakash GUPTA
World Health Organization
Geneva, Switzerland

Minna Leena HAKKINEN
World Health Organization
Geneva, Switzerland

Phan Thi HANG
Hung Vuong Hospital
Ho Chi Minh City, Viet Nam

Katherine HAYES
World Health Organization
Geneva, Switzerland

Yagana IMAM
Federal Ministry of Health
Abuja, Nigeria

Robert JAKOB
World Health Organization
Geneva, Switzerland

A. JONES
Federal Ministry of Health
Abuja, Nigeria

Somphorn KAMPAN
Rajavithi Hospital
Bangkok, Thailand

Nguyen Trong KHOA
Ministry of Health
Hanoi, Viet Nam

Nenad KOSTANJSEK
World Health Organization
Geneva, Switzerland

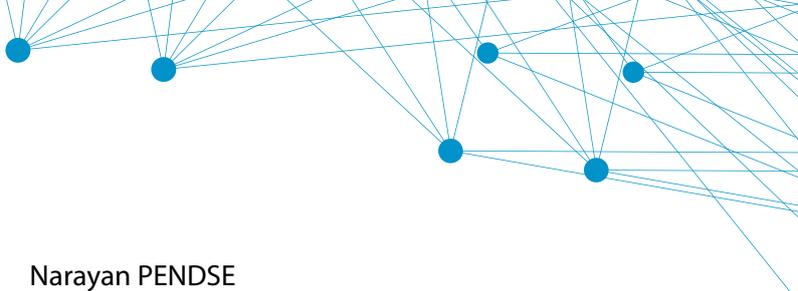
Piyawan LIMPANYALERT
Health Care Accreditation Institute
Bangkok, Thailand

Riad MOHAMMED
Centre Hospitalier Provincial d'El Jadida
El Jadida, Morocco

Alfredo NUÑEZ
East Avenue Medical Center
Quezon City, Philippines

Emmanuel OWUSU-ANSAH
Ministry of Health
Accra, Ghana

Irina PAPIEVA
World Health Organization
Geneva, Switzerland



Antonio Roque PARADELA
Vicente Sotto Memorial Medical Centre
Cebu City, Philippines

Narayan PENDSE
Project One Fortis
Gurgaon, India

Mohammad SALEM ASGHARKHIL
Ministry of Public Health
Kabul, Afghanistan

Lakshmi SOMATHUNGA
Ministry of Health and Indigenous Medicine
Colombo, Sri Lanka

Sathasivam SRIDHARAN
Ministry of Health and Indigenous Medicine
Colombo, Sri Lanka

Ayda Abdien Hago TAHA
World Health Organization
Geneva, Switzerland

Abiy Dawit TANTU
Federal Ministry of Health
Addis Ababa, Ethiopia

Michela TANZINI
Centre for Clinical Risk Management and
Patient Safety
Florence, Italy

Susana Larbi WUMBEE
Ghana Health Service
Accra, Ghana

Figures 2, 6, 8 and 9 were conceptualized and designed by Sir Liam Donaldson. He has assigned all rights to WHO. All other figures and tables are displayed with the necessary approvals.



Glossary

If there is no reference number mentioned, the glossary refers to the WHO conceptual framework for the International Classification for Patient Safety (11).

Adverse event: an incident that results in preventable harm to a patient.

Adverse reaction: unexpected and non-preventable harm resulting from a justified action where the correct process was followed for the context in which the event occurred.

Ameliorating action: an action taken or circumstances altered to make better or compensate any harm after an incident.

Contributing factor: a circumstance, action or influence that is thought to have played a part in the origin or development of an incident or to increase the risk of an incident.

Detection: an action or circumstance that results in the discovery of an incident.

Error: failure to carry out a planned action as intended or application of an incorrect plan.

Event: something that happens to or involves a patient.

Hazard: a circumstance, agent or action with the potential to cause harm.

Incident: any deviation from usual medical care that either causes an injury to the patient or poses a risk of harm, including errors, preventable adverse events and hazards.

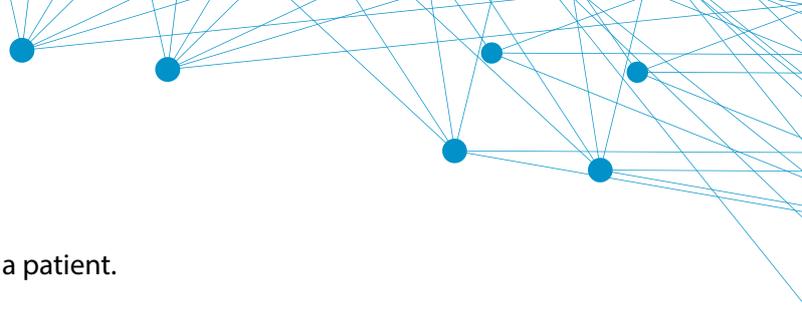
Incident characteristics: selected attributes of an incident.

Incident type: a descriptive term for a category made up of incidents of a common nature, grouped because of shared, agreed features.

Mitigating factor: an action or circumstance that prevents or moderates the progression of an incident towards harming a patient.

Near miss: an incident that did not reach the patient.

Never event: a patient safety incident that results in serious patient harm or death (this refers to particularly shocking medical errors - such as wrong-site surgery, that should never occur) (28).



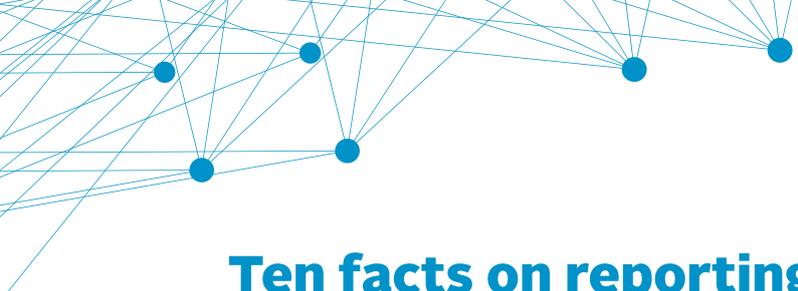
Patient characteristics: selected attributes of a patient.

Patient outcome: the impact upon a patient that is wholly or partially attributable to an incident.

Patient safety: a framework of organized activities that creates cultures, processes and procedures, behaviours, technologies, and environments in health care that consistently and sustainably: lower risks, reduce the occurrence of avoidable harm, make error less likely and reduce its impact when it does occur.

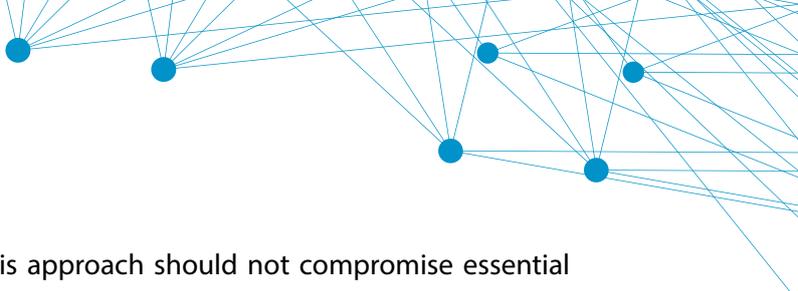
Root cause analysis: a systematic iterative process whereby the factors that contribute to an incident are identified by reconstructing the sequence of events and repeatedly asking why? until the underlying root causes have been elucidated.

Sentinel event: an unexpected occurrence involving death or serious physical or psychological injury, or the risk thereof. Serious injury specifically includes loss of limb or function. The phrase “or risk thereof” includes any process variation for which a recurrence would carry a significant chance of a serious adverse outcome.



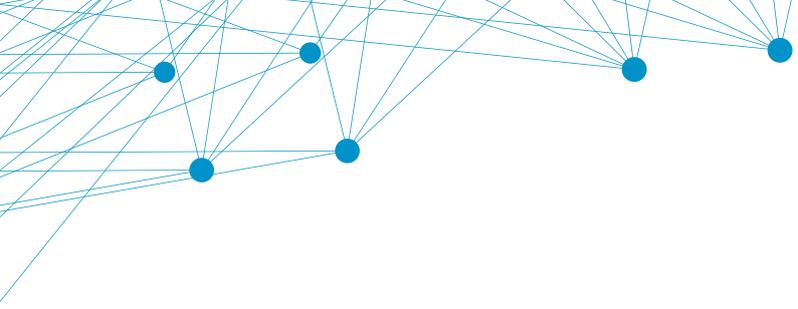
Ten facts on reporting and learning systems

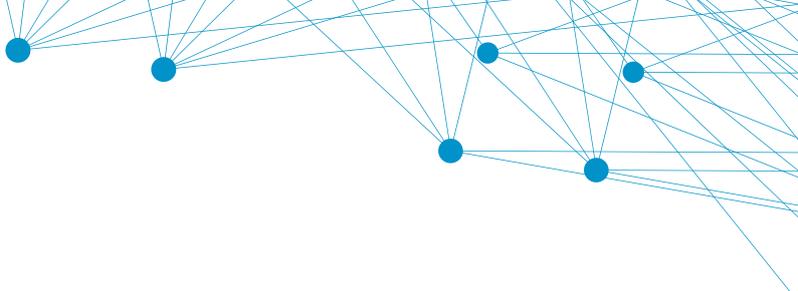
1. **Learning.** Reporting systems should yield learning to improve safety and not simply be a vehicle to communicate failure.
2. **Safety culture.** Point of care staff will report incidents if they are protected from blame and retribution, involved in follow-up investigation and improvement, and able to see regular reductions of risks to patients; in some jurisdictions, incident data and investigation reports are immune from disclosure to courts.
3. **Limitations of data.** Underreporting happens in the health care and other sectors; this should not lead to the value of patient safety incident reports being disregarded. Incident reporting offers a unique lens on the system from the perspective of those involved in, or witness to, incidents.
4. **WHO reporting model.** The WHO Minimal Information Model for Patient Safety Incident Reporting and Learning Systems helps to identify minimal data elements to be captured for incident reporting, including both structured information capture and free text narrative elements.
5. **Aggregation and systemic insights.** The aggregation of incident reports should use classification systems oriented towards creating systemic insights that help transform policies and processes.
6. **Causation.** An incident report can provide some insights into the causation of harm and its potential preventability but seldom a definitive view; further information gathering, review, investigation, analysis, and discussion are necessary to establish the factors and influences that led to the incident and their interrelationship (the how? and the why?).
7. **Investigation.** The lack of a consistently high standard of investigation and action planning too often hinders effective risk reduction within health care.
8. **Large-and small-scale systems.** Establishing and maintaining a comprehensive, large-scale patient safety incident reporting system at national level, or in a big health organization, requires technical expertise and resources. Consideration could be given



to starting on a smaller scale, although this approach should not compromise essential guiding principles of organizational safety culture and minimum standards.

9. **Improvement.** Finding and designing solutions that will prevent future harm is difficult. The process contains two important parts: first, the intervention itself (the “technical” part); and second, the implementation of the intervention within the complex organizational and social systems that comprise modern health care (the “management of change” part).
10. **Patients and families.** Involvement of patients and families who have suffered avoidable harm is vital and valuable in improving patient safety.





1 Introduction

1.1 Background to patient safety

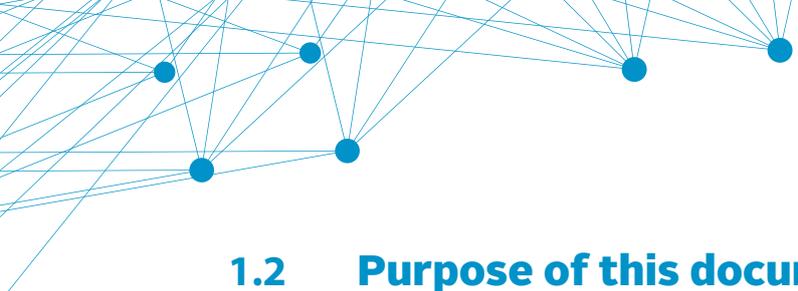
The modern patient safety movement began in the last few years of the 20th century and has gained momentum through the first two decades of the new century. Major reports from the United States of America, *To err is human: building a safer health system* (1) and the United Kingdom of Great Britain and Northern Ireland, *An organization with a memory* (2) scoped the subject, drawing attention to the scale of the problem, the parallels with other high-risk industries and the weakness of health systems in provoking human error. Around the same time, a series of observational studies in different countries (3–5) assessed the extent of so-called “medical errors” in hospital inpatient care.

Having been stimulated by greater involvement of academics and practitioners from the field of safety outside health care, and by public concern about the level of avoidable harm during patient care, many health care systems around the world launched programmes aimed at improving patient safety.

During this period of development in patient safety, it was widely stated – and uncritically accepted – that a key step in reducing the risks associated with health care was to learn from the things that had gone wrong. This rapidly led to the establishment of patient safety incident reporting systems at health care facility level and, in some countries, at national level.

The optimism that fuelled the rush to place reporting systems at the heart of patient safety programmes around the world has been replaced by scepticism (born of over a decade’s experience of such systems) that reporting is not a stand-alone mechanism for reducing risk and improving safety. It needs to be part of an overall culture of curiosity and understanding about how harm occurs, a determination to expose all sources of risk to patients, coupled with well understood rules and processes of investigation and effective methods to implement change based on these learnings (the most difficult part of all) to improve safety.

Additionally, a goal of many health systems is to greater empower patients and their families so that they play an important role in identifying sources of risk and potential harm and helping to design safer systems, in addition to being fully engaged in their own care to prevent harm and reduce the risk of harm to them while receiving health care.



1.2 Purpose of this document

Against this background of nearly 20 years of experience of research, development and improvement in patient safety, the role of incident and adverse event reporting, as well as the benefits that derive from it, is still a work in progress.

In 2005, the World Alliance for Patient Safety published *WHO draft guidelines for adverse event reporting and learning systems: from information to action (6)*. These draft guidelines:

- set out the purpose and the role of incident reporting;
- described the components of systems then being used;
- assessed alternative sources of information for patient safety;
- gave examples of national reporting systems as they then were;
- specified the requirements for a national “adverse event” reporting and learning system;
- listed the characteristics of successful reporting systems: non-punitive, confidential, independent, expert analysis, timely, systems-oriented and responsive;
- made recommendations to Member States to assist in the development of reporting and learning systems, including a checklist for developing a reporting system.

There has been greater awareness of, and progress in, implementing and using patient safety reporting and learning systems in the 15 years since the draft guidelines were published. The guidelines have been widely used in different health care settings (national, local and facility levels) to establish priorities for data gathering and analysis in patient safety as well as in designing and evaluating reporting and learning systems. Much in these earlier guidelines is still relevant to the design and operation of patient safety incident reporting and learning systems.

Many countries have still not yet established national incident reporting and learning systems on patient safety. Even in such countries, however, there will often be individual hospitals (or other health facilities) that are using data derived from patient safety incident reporting in order to learn from service failure and take action to prevent harm to their patients. They may not be part of an official nationally coordinated system.

This document has two main purposes:

- to provide an up-to-date perspective on patient safety incident reporting and learning systems currently in place, including how to fill in existing gaps in these systems;
- to provide practical guidance on the establishment and effective use of patient safety incident reporting and learning systems.



2 Reporting and learning systems: current status

There is limited systemic information available about types of health care-related harm occurring in low- and middle-income countries. The information available from high-income countries shows similarities in the types of health care-related harm that occur. In North America, Europe, Australasia, and many parts of Asia and the Middle East, the analysis of information in patient safety incident reports and the findings of research studies show a strikingly consistent pattern.

Across the world, patients suffer harm in health care facilities and die unnecessarily. They are avoidably injured or disabled due to acquired infections, mistakes in medication use or in the conduct of procedures. They can be injured in falls, suffer missed diagnoses or experience poor clinical management of their acute illnesses. They can be harmed by pressure ulcers, faulty or misused equipment, or incompetent staff. These are just some of the sources of avoidable harm. The scale of each type of harm varies. The overall burden has not dramatically reduced over the last decade, despite the unprecedented priority that has been given to patient safety within these health systems. Many of these harmful events are potentially avoidable. The human cost to patients and families is of grave concern.

Less is known about the level and nature of harm in primary care, though important work is increasing understanding of it (7–9). Globally, as many as four out of 10 patients are harmed in primary and ambulatory care settings while receiving health care. Up to 80% of harm is preventable. Some of the most detrimental errors are related to diagnosis, prescription and the use of medicines. In Organisation for Economic Co-operation and Development (OECD) countries, patient harm may account for more than 6% of hospital bed days and more than 7 million admissions (10).

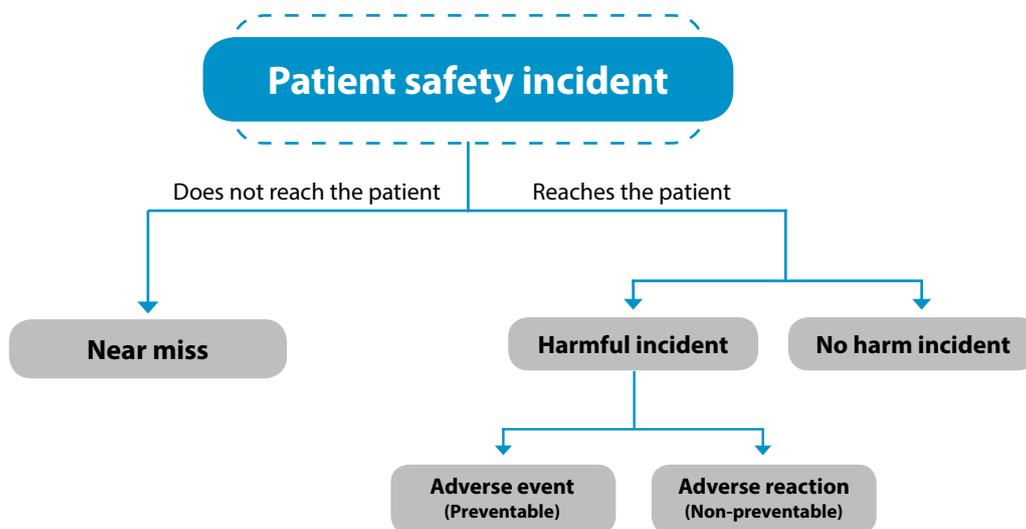
In low- and middle-income countries, the lack of infrastructure, facilities and access throws up additional and very fundamental causes of harm.

It is also helpful to keep in mind the conceptualization of patient safety incidents into three types – near miss, no harm incident, harmful incident – as explained in the World Health Organization (WHO) conceptual framework for the International Classification for Patient Safety (11) (Figure 1). The definitions of these three types are:

1. **Near miss:** an incident that did not reach the patient (for example, a unit of blood being connected to the wrong patient's intravenous line, but the error was detected before the transfusion started);
2. **No harm incident:** one in which an event reached a patient, but no discernable harm resulted (for example, if the unit of blood was transfused, but was not incompatible);
3. **Harmful incident:** an incident that results in harm to a patient (for example, the wrong unit of blood was transfused, and the patient died from a haemolytic reaction).

With regard to a harmful incident, an “adverse event” is an incident that results in preventable harm to a patient; an “adverse reaction” is non-preventable harm resulting from a justified action where the correct process was followed for the context in which the incident occurred.

Figure 1. Classification of patient safety incidents



Source: World Health Organization



2.1 Reporting seen as central to safety improvement

Reporting systems fulfil one or more of five main functions:

- public accountability
- response to the patients and families involved
- communications alert route
- barometer of risk within health care
- foundation for learning and improvement.

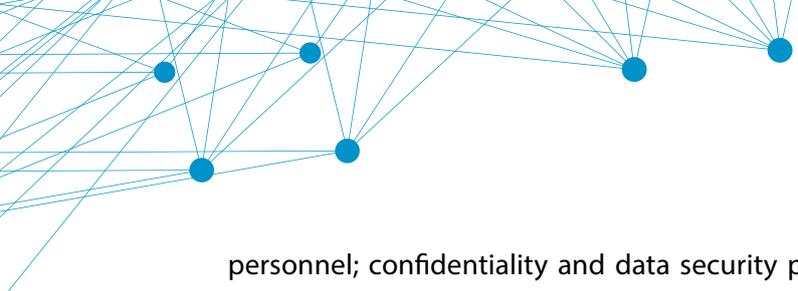
Some of these functions are not always compatible with one another. For example, the use of systems primarily for accountability purposes can disrupt their use in the process of improvement and learning. They may create an environment of fear and apprehension amongst staff that will reduce their willingness to report patient safety incidents.

There are two reasons that data reporting has come to be seen as essential to improving the safety of care. First, routine reporting and rigorous investigation of accidents and untoward occurrences has long been a core element of the safety programmes of other high-risk industries; such sectors have generally been more successful than health care in reducing their risks. Second, common-sense reasoning within health care has been that “we must learn from the things that go wrong”; few would disagree with this maxim, but it has been overinterpreted to imply that investigation of patient safety incidents is the predominant method of learning.

On the strength of the arguments for the importance of learning from failures in the provision of care, incident reporting systems have been established throughout the world, some at the health care facility or organizational level, some at the national health system level, some by groups of specialist clinicians (such as anaesthesiologists), and some covering particular fields of care (such as blood transfusion). They vary greatly in respect of:

- whether reporting is voluntary or mandatory
- the nature of the data captured
- the extent of public involvement
- which entity collects and analyses data
- the depth of the investigation undertaken
- the scale of improvement in patient safety induced.

Establishing a fully-fledged incident reporting and learning system on patient safety, whether at national, local, health facility or organizational level, requires: financial resources; information technology infrastructure; skilled informaticians, investigators and other



personnel; confidentiality and data security policies; analysis and interpretation; protocols for dealing with clinical governance concerns; reporting rules and channels; and feedback and release of information. Yet, some reporting and learning systems, even in well-resourced settings, have been set up without prior consideration of such matters and therefore do not achieve their full potential.

This causes a dilemma for health leaders in low- and middle-income countries, and in poorly resourced health facilities. Do they take the view that, because they cannot provide the full infrastructure required, they should abandon the idea of establishing a patient safety reporting and learning system? This cannot be the case, and so this technical guidance seeks to provide advice that will give a way forward for all health care contexts. There are functioning patient safety incident reporting systems in low- and middle-income countries, although they are less common.

2.2 Weaknesses of most reporting systems in health care

Worldwide, the problems associated with incident reporting are remarkably consistent, whichever system design is adopted.

First, underreporting is the norm, although its degree varies. Studies have found that reporting systems detect 7–15% of adverse events (12). This depends mainly on the prevailing culture and whether incidents are considered as an opportunity to learn or as a basis for enforcing individual accountability and apportioning blame. It also relates to staff perceptions about the difference their reports will make and how easy it is for them to convey the information that they are required to.

Second, if the staff are fully committed to reporting, the volume of reports made can be very high; for example, in a large hospital in the Midlands area of England there are 30 000 reports a year. In such circumstances there may be insufficient time, resources and expertise dedicated or committed to carrying out the analysis required. However, most airlines collect large quantities of reports, but still find sufficient time and resources to investigate most incidents. This emphasizes the need to make an active decision to allocate the resources required to do this properly. It is not a weakness of reporting and learning systems per se, but rather of how they are instituted and managed.



Third, as is the case with other databases in health care, the balance of activity within reporting systems often goes on collecting, storing and analysing data at the expense of using it for improvement (13). The mismatch between principles and practices of incident reporting is shown in Table 1.

Reporting rates are generally much lower in primary care services than in hospitals. This is not surprising, given the predominant focus on hospital-based safety. Even in high-resource settings, there is a need to develop an infrastructure for patient safety in primary care that can enable reporting from settings ranging from practitioners working single-handedly through to large consortia of collaborating practices. In low-resource settings, the challenge is to design systems that can adapt to the different forms of primary care with variable formats of patient records, including their absence.

Studies have repeatedly shown that insights into patient safety are hampered by:

- volume of data overload;
- poor specification of what is to be reported;
- overinterpretation of incident analyses to judge safety performance;
- selectivity and incompleteness of data;
- taxonomies and classifications that do not enable aggregation of reports into categories that reliably highlight system weaknesses;
- lack of investment in analysis compared to reporting.

2.3 Lessons from incident reporting in other sectors

Evaluation of actual and potential risk, as well as safety performance, in aviation and some other safety-critical industries is greatly helped by the availability of automated technical information. The mass of data, in digital form, provided on every flight, for example, is invaluable in identifying new sources of risks, creating opportunities to reduce further persistent risks, and evaluating incidents and accidents. The analysis of these data is closely linked with the operation of incident reporting systems (14). Large quantities of automated data are not yet widely available in health care; nor has the opportunity been taken, on any large scale, to adapt existing electronic monitoring in patient care for safety purposes.

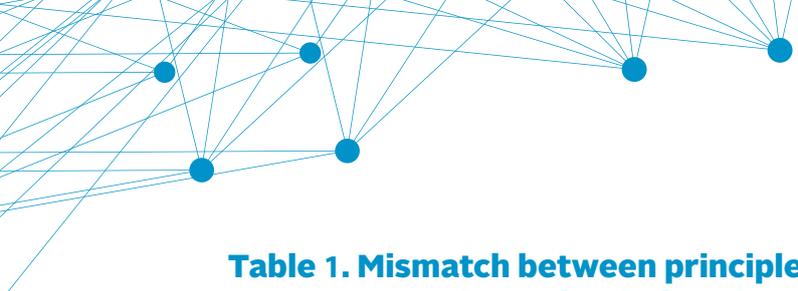
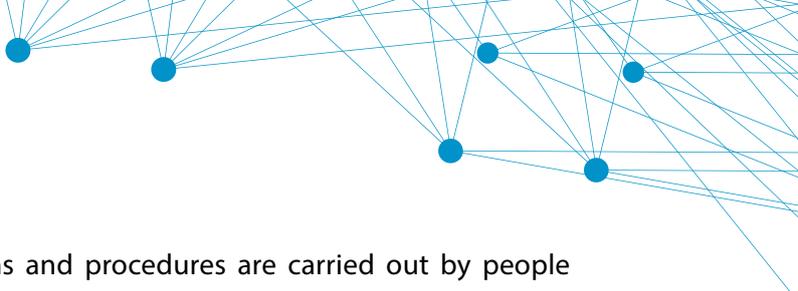


Table 1. Mismatch between principles and practices of incident reporting: other industries and health care

Key principles in other industries	Common practices in health care
Focus on reporting incidents that provide serious, specific or surprising insights into system safety	Encourage reporting on any and all incidents that may in some way relate to safety concerns
Avoid swamping the reporting system to ensure thorough review of all reported incidents	Celebrate large quantities of incident reports and aim for ever-increasing overall reporting rates
Use incident report to identify and prioritize significant, new or emerging risks	Quantify, count and chart different categories of incident report to monitor performance trends
Harness the social processes of reporting to generate increased awareness and reporting of current risks	Aim to increase reporting rates to address perceived epidemiological or statistical biases in reported data
Expect reports to be inaccurate or incomplete; focus on the investigation as the means of obtaining complete picture	Improve accuracy of incident reports through more comprehensive data collection processes
Apply pragmatic incident taxonomies that support basic analysis, improvement action and retrospective search	Expect incident taxonomies to accurately explain and map complex realities
Ensure incident reporting systems are managed and coordinated by an operationally independent group	Incidents reported to direct supervisors or other operational managers within organization
Reporting constitutes one component of broad range of conversations and activities focused on safety and risk	Incident reporting represents the most visible safety activity for many organizations
Create regimes of mutual accountability for improvement and peer review of actions around incidents	Use reported incident data as an indicator to monitor organizational safety performance

Source: Reproduced, with the permission of the publisher, from Macrae (13)



Also, in health care, currently more decisions and procedures are carried out by people than by machines. Inevitably, there has to be much more emphasis on observation than on automated provision of data – to assess risk, to identify poor safety performance, and to expose the occurrence of harm. However, even in a highly automated operational environment, observational data are essential. For example, flight recording data will record and flag up when a plane breaches the altitude limits it has been set for. Such data will not always be able to say why this happened. That information will come from further enquiry or from the confidential incident reporting system that is used by pilots and other flight personnel. Recognizing the occurrence of the breach and understanding why it occurred are both essential to preventing recurrences and improving safety.

Dr Charles E. Billings was chief of the Aviation Safety Research Office at the National Aeronautics and Space Administration (NASA) in the United States of America. He was the initiator of the Air Safety Reporting System (ASRS) that became the basis of similar safety reporting systems in many other countries.

He was asked in 1998: “Does the fact that pilots are at personal risk when flying have something to do with the success of the system [ASRS]? Is that the reason that you think this system might work much better in aviation than it might be made to work in medicine?” (15).

His answer deserves to be quoted in full (15):



There is no question about the motivation of the pilot community in general with respect to safety issues, none whatever. The reports are not grudging acknowledgement or pro forma filings but rather quite rich and human descriptions of troubling, often frightening events. I believe that the reporting to this system is motivated not by the sense of personal risk that attaches to flying but rather from two major factors: (1) the sincere interest in improving safety by identifying hazards and (2) the sincere belief that the system to which they are reporting uses that information productively and deliberately to improve safety rather than simply a means of counting failures.



Dr Charles E. Billings

2.4 Improving the process of learning from incidents

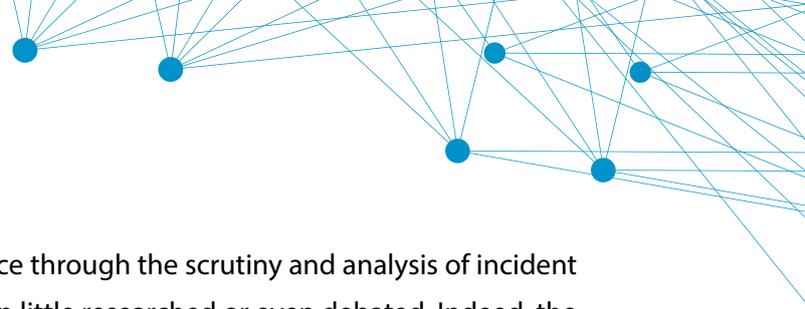
The most important capability of a patient safety incident reporting and learning system must surely be its effectiveness in reducing future harm of the kind that is being reported to it (Figure 2).

Unfortunately, there are few places around the world where there is a powerful flow of learning that moves from identifying instances of avoidable harm, through understanding why they did or could happen, to successful and sustainable elimination of the risk for future patients.

Figure 2. Responding to a patient safety incident report



Source: World Health Organization



The whole question of how learning takes place through the scrutiny and analysis of incident reports or through their investigation has been little researched or even debated. Indeed, the term “learning” itself is very loosely applied throughout the patient safety world. There is a large research literature on organizational learning, but little attention has been paid to the processes and practices of learning in patient safety incident reporting systems.

When learning is talked about in relation to incident reporting systems, it usually envisages an activity through which information about the incident and why it is thought to have happened is made available and discussed. Yet, the simple creation of insights from analytical data need not necessarily lead to any improvement or prevention of a similar event in the future.

The social or organizational meaning of learning is that a group or an organization actively changes what it is doing, adapts how it is working, and refines its understanding of how it is working. That social definition of learning implies that the people doing the learning are all those involved in changing behaviour, and the output is actual material change and improvement in the organization or system.

The ultimate output has to be tangible change in the way health care is organized to improve safety. Learning should be seen as a participatory process that engages a wide range of people and involves active changes to behaviour. A tight and limited definition of learning as being only about the discovery of new information is ultimately of limited value unless it is associated with behavioural and organizational change.

Yet, the way in which the word “learning” is repeatedly used in the context of patient safety implies more than increasing understanding. It suggests that it can guide which behaviour changes or actions are needed to prevent future harm. Unfortunately, although there are some exceptions, there is little to show that major gains in the reduction of harm have been achieved in this way.



3 Work of WHO on patient safety incident reporting and learning

3.1 Conceptual framework for the International Classification for Patient Safety

Shortly after the publication of the *WHO draft guidelines for adverse event reporting and learning systems: from information to action* (6), work was commissioned to develop an international patient safety classification (11).

A classification is “a set of concepts linked by semantic relationships. It provides a structure for organizing information to be used for a variety of other purposes, including national statistics, descriptive studies, and evaluative research” (11).

The work on a classification was undertaken by an international panel and involved extensive consultation and review by experts in the fields of safety, systems engineering, health policy, medicine and the law. This proved to be a lengthy and complex task that did not lead to a complete classification but instead to the production of a technical report, in 2009, setting out a conceptual framework (11).

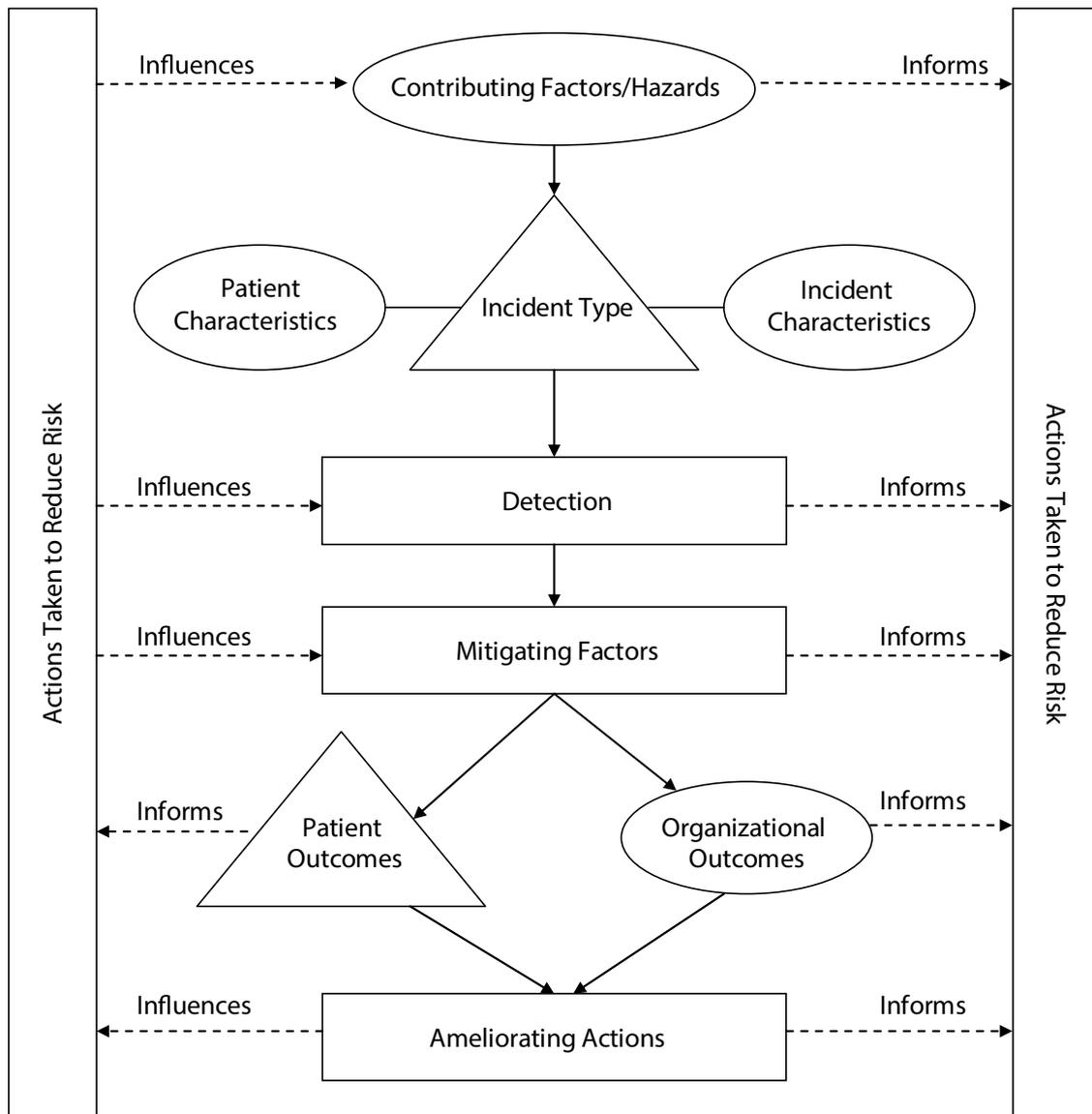
It consisted of 10 high-level classes that comprised the conceptual framework for the International Classification for Patient Safety (Figure 3). The framework aimed to provide a comprehensive understanding of the domain of patient safety and to represent a continuous learning and improvement cycle emphasizing identification of risk, prevention, detection, reduction of risk, incident recovery and system resilience, all of which occur throughout and at any point within the conceptual framework.

The 10 high-level classes were:

1. Incident type
2. Patient outcomes
3. Patient characteristics
4. Incident characteristics
5. Contributing factors/hazards
6. Organizational outcomes
7. Detection
8. Mitigating factors

9. Ameliorating actions
10. Actions taken to reduce risk.

Figure 3. Conceptual framework for the International Classification for Patient Safety



- System Resilience (Proactive & Reactive Risk Assessment)
- △ Clinically meaningful, recognizable categories for incident identification & retrieval
- Descriptive information

Source: World Health Organization



The publication of the work on the classification in 2009 provided a valuable source, not just in describing a conceptual basis for unsafe care and harm, but also in advancing thinking on terminology and providing formal definitions.

Feedback suggests that the structure and ideas have proved very helpful in creating a deeper understanding of the subject. Many see it as an excellent starting point in designing reporting and learning systems. Factors limiting its widespread use include: (a) many systems were already well established before the classification work was published; (b) the classification was designed to serve wider data definitional and aggregation purposes than solely incident reports; and (c) the classification is not widely known.

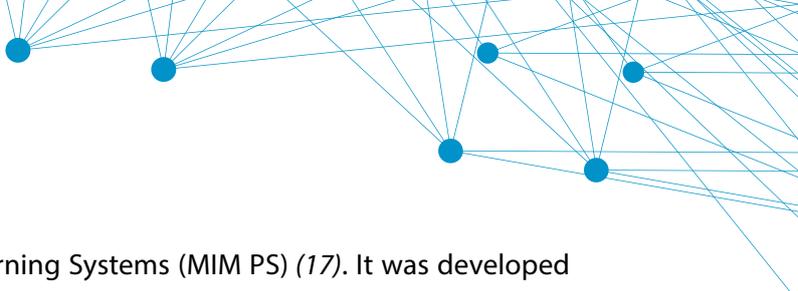
With the 11th Revision of the International Classification of Diseases (ICD-11) (16), patient safety events can be recorded based on the International Classification for Patient Safety. The conceptual model for quality and patient safety used in ICD-11 is based on the WHO conceptual framework for the International Classification for Patient Safety, and is compliant with the Minimal Information Model for Patient Safety Incident Reporting and Learning Systems (17). It had not been possible to document patient injuries properly with the previous revision of the ICD; however, ICD-11 includes a system for documenting patient safety events and near misses. ICD-11 will be used fully from 2022, with implementation currently under way (16).

3.2 Minimal Information Model for Patient Safety Incident Reporting and Learning Systems

Work on defining the rubrics of a minimal data set for reporting patient safety events was developed through a series of major projects by WHO and Member States of the European Union, working separately and together, to compare experience, test feasibility, and reach agreement on data scope and relevance.

With the needs of those running reporting systems in mind, WHO initiated a project in 2011 to address the lack of international consensus and paucity of standards for collecting data on patient safety incidents. It sought to help establish reporting systems that are simple, user friendly, easily standardized, and integrated into information technology systems.

The project built on the classification work and the 2005 *WHO draft guidelines for adverse event reporting and learning systems* to propose a minimal common architecture for incident reporting systems. This led eventually to the formulation of the Minimal Information Model



for Patient Safety Incident Reporting and Learning Systems (MIM PS) (17). It was developed based on the compilation of work done in collaboration with Canada, the European Union, Japan, the Netherlands, Norway and the United States of America.

A first evaluation was carried out by analysing incident reports from Belgium, Canada, Denmark and Japan. The detailed content of the reports was found to vary greatly depending on the intended use and the resources available, though broader data categories were more consistent.

A second evaluation was undertaken in 2015 in a joint project between the European Union and WHO (18). It comprised a sequence of phases, including country piloting, regional compliance review, and guidance to implementation. In all, 407 incident reports were reviewed in 25 different reporting formats from 10 European countries; some countries submitted more than one format of reports.

Key findings included the following.

- Most participating countries had one consolidated, standardized reporting system at national level.
- Seven out of 10 countries were fully compliant with MIM PS information categories.
- Most reporting formats included structured information and free text.
- The usefulness of the “learning” component of reporting systems was very limited.
- Information from incident reports was widely used to establish patient safety priorities and promote patient safety practices at national level.

Arising from these strands of work, there was further discussion of, and consultation on, the issues raised.

The final conclusions of the international expert consultation in 2015 were that (a) there is a recognized need to define a common approach to reporting and learning; and (b) a validated MIM PS can serve as the basic framework for sharing information and lessons learned in European countries and beyond (18).

The basic MIM PS, which consists of eight data categories, was recommended as a good model for initiating reporting systems in settings and countries where these do not already exist. The advanced MIM PS, which consists of 10 data categories, was accepted, and consensus was reached on its usability in settings with functional reporting systems already in place. In both cases, the MIM PS should have a free text part along with eight or 10 data categories (Figure 4).

Figure 4. Minimal Information Model for Patient Safety Incident Reporting and Learning Systems (MIM PS)

BASIC MIM PS	ADVANCED MIM PS
<p>a) Structured part</p> <p>PATIENT INFORMATION</p> <p>Age</p> <p>Sex</p> <p>INCIDENT TIME</p> <p>INCIDENT LOCATION</p> <p>AGENT(S) INVOLVED</p> <p>(Suspected) cause?</p> <p>Contributing factor?</p> <p>Mitigating factor?</p> <p>INCIDENT TYPE</p> <p>INCIDENT OUTCOME</p> <p>RESULTING ACTION</p> <p>REPORTER'S ROLE</p> <p>b) Free text part</p> <hr/> <hr/>	<p>a) Structured part</p> <p>PATIENT INFORMATION</p> <p>Age</p> <p>Sex</p> <p>INCIDENT TIME</p> <p>INCIDENT LOCATION</p> <p>CAUSES</p> <p>CONTRIBUTING FACTORS</p> <p>MITIGATING FACTORS</p> <p>INCIDENT TYPE</p> <p>INCIDENT OUTCOME</p> <p>RESULTING ACTIONS</p> <p>REPORTER'S ROLE</p> <p>b) Free text part</p> <hr/> <hr/>

Source: World Health Organization

The evaluation envisaged that the learning component of reporting and learning systems would be enhanced through comparability, shared and compiled analysis, and identification of emerging patient safety problems.

A third evaluation of the MIM PS was undertaken jointly in the regions of Africa, South-East Asia, the Eastern Mediterranean and the Western Pacific in 2015–2016. The evaluation method was the same as in the European study. Only four countries participated, and they were found to comply with the basic MIM PS. Resistance to change was the greatest challenge to implementing the MIM PS, the survey showed (19).

This work coincided with the collective thinking of the European Commission Expert Group on Patient Safety and Quality Care and its subgroup on reporting and learning systems. Subsequently, the European Commission produced guidance on patient safety incident reporting and learning systems (20).



The MIM PS has been very useful in helping countries establish systems of reporting in order to allow aggregation and analysis of data at a higher level. Further work is needed on data categories, especially those dealing with causation.

3.3 WHO consultation on patient safety incident reporting and learning systems

In an expert consultation in March 2016 in Colombo, Sri Lanka, WHO brought together staff from ministries of health and health experts from low- and middle-income countries to discuss their experience of establishing and operating patient safety incident reporting and learning systems (19). The three-day meeting was attended by representatives of 18 countries – Afghanistan, Bangladesh, Canada, Ethiopia, Ghana, India, Italy, Japan, Malaysia, Morocco, Nigeria, Oman, the Philippines, Poland, South Africa, Sri Lanka, Thailand and Viet Nam – and two WHO regional offices (for the South-East Asia and Eastern Mediterranean regions).

The following main points came out of the meeting.

- Levels of reporting are very low; to a large extent, this reflects a fear by staff of retribution against them as individuals.
- A lack of consistent leadership in patient safety at national and local levels means that awareness of the value of reporting is low.
- Reporting is labour intensive and too paper-based for staff who are already dealing with very high workloads.
- There is a great need for more information technology support.
- When key local champions move on to other posts, there is seldom succession planning and projects come to a halt.
- Many ministries of health only have jurisdiction over reporting in public sector facilities, not those in the private health care sector.
- There are few platforms to share information within and between countries.
- Examples of successful improvement in patient safety arising from analysis of reporting data are very scarce.

A review of the experience of low- and middle-income countries that participated in the WHO consultation found that many were at a relatively early stage of developing their patient safety incident reporting and learning systems. Most covered only hospitals in their country rather than all sectors of health care; in some cases, only a small number of hospitals were covered.



Such countries had the aspiration, or the intention, of scaling up their systems, and seeking to integrate the approach for public and private parts of the system. Most sought to operate a voluntary reporting system with some mandatory elements, usually for serious harm and death. The categories of serious harm were very diverse; they ranged, for example, from maternal deaths, to adverse events associated with transfusion of blood products, to the kinds of “Never Events” mandated for reporting in high-income countries.

Whilst some countries were able to point to thousands of incident reports in a year, for many others the number was in the low hundreds or unknown because no incident data were captured from purely facility-based patient safety incident reporting systems.



4 Developing and operating a reporting and learning system

4.1 Understanding a patient safety incident reporting and learning system

No system of reporting and analysing patient safety incidents is perfect. Successful safety incident reporting systems are based on two fundamental principles.

- They make risks visible.
- They prevent harm.

So, reporting must make a major contribution to revealing the risks that health care poses for patients (and health workers) in all the settings in which care is delivered. This is most likely to happen if five supporting processes are in place:

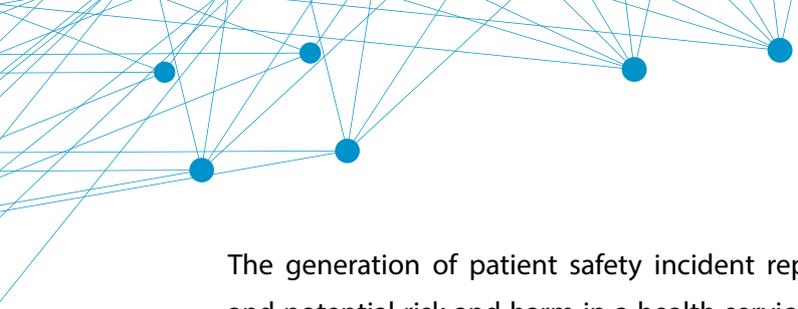
- robust ways of identifying new and existing risks
- clear prioritization of risks
- mechanisms to escalate serious risks
- methods for analysing and investigating sources of risk
- systematic monitoring of existing risks.

Reporting should also inform local responses to risks and drive the improvement in safety. Five processes could support this:

- setting of a clear safety agenda
- communication of risks to relevant staff
- allocation of accountability for resolving risks
- engagement of local staff in risk analysis and improvement processes
- production of actionable and practical information.

4.2 Creating a positive environment for reporting

All reporting and learning systems, whether large or small scale, must create first a positive culture in which reports are encouraged and valued, and staff are praised for participating. Leadership commitment, policies and practical steps should be in place to foster this sort of supportive and positive environment.



The generation of patient safety incident reports that make visible the sources of actual and potential risk and harm in a health service heavily depends upon the observations and experience of staff that are close to the point of care. Whether they make reports will depend on many factors. Some will be profound, such as the values and culture of their organization. Where there is an atmosphere of blame and retribution, reporting and learning will not flourish. Patients are likely to be at greater risk in such services because mistakes will not be admitted.

A positive reporting environment will be nurtured if education and training have equipped staff with an understanding about how systems fail, how harm occurs in health care, and how the impact of both can be reduced. Other influences will be more technical and practical, such as how much workload pressure operating environments are under, and how easy it is to file an incident report.

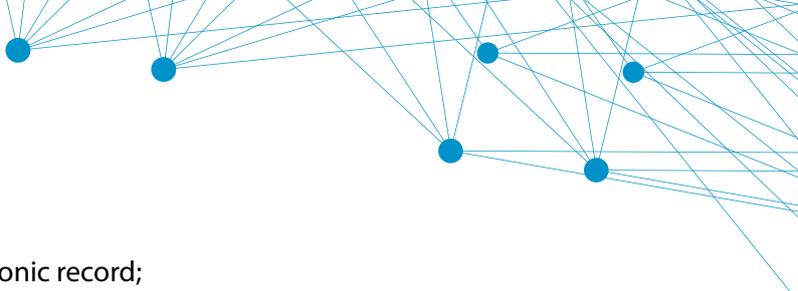
4.3 Identification and recording of incidents

There should be a clear policy about how incidents are defined and recognized, and all staff should be aware of it. It is important that staff are absolutely clear as to what constitutes an incident. This can be a broad and general specification (in which case, staff are allowed maximum discretion in what to report) or guidance that only certain categories of incident must be reported (in which case, reporting will be very focused, but staff may be uneasy about having to overlook incidents that they are concerned about). Some systems also encourage patients and family members (who are in the care environment) to identify incidents.

Identifying and recording that an incident has occurred is the very first step in a reporting and learning process. Everything flows from there. Even if a member of staff observes an incident, unless they identify and record that it has happened, there will be no analysis of its cause, no alert, and no chance of preventing its recurrence. Most reporting systems have a clear policy on whether reports are made voluntarily or are mandatory. Some have both, for example, with an absolute requirement to report patient safety-related deaths, occurrences of severe harm and never events, and voluntary reporting of less serious incidents.

The recording or capturing of information about incidents usually takes place in one of four main ways (which will vary between settings of different resource levels):

- on a paper reporting form with or without addition of later documentation;
- on a paper reporting form with information subsequently transferred by a data clerk to an electronic record;

- 
- directly by the reporter into an electronic record;
 - into an electronic record after follow-up work that may involve further information gathering or investigation before data entry.

Some reporting systems have an additional route of reporting, such as a telephone hotline, for serious incidents that require urgent escalation, and immediate investigation to protect patients.

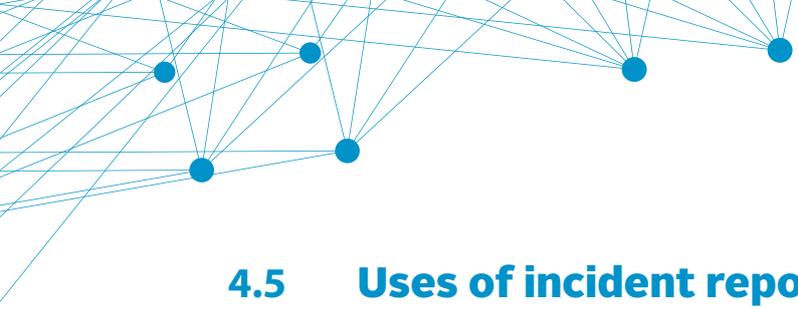
4.4 Choosing the information to be captured

Reporting and learning systems around the world have developed the content of their reports either by deciding, from first principles, what information they want to collect or by adopting one of the commercially available or open source-based tools (for example, software) for incident reporting. Generally, whichever approach has been used, such systems seek to capture and assemble information in three main domains:

- **description** (what happened), including patient characteristics, incident characteristics and location;
- **explanation** (why it happened), including perceived causes of the event, contributing factors and mitigating factors;
- **remedial measures** (the actions that were taken as a result), including reviewing processes and procedures, redesign, educational measures and organizational changes.

It is important always to be clear whether data falling into these categories are provided only by reporters (and therefore may be early, provisional, partial and possibly incorrect) or constitute information captured in the reporting system after more thorough investigation has taken place.

The value of any reporting system – to identify risk and harm, to assess differences by place and over time, to serve as the starting point for investigations into causation, to prevent repetition of similar incidents, to promote a culture of patient safety, and to engage the curiosity and commitment of point of care staff – is highly dependent on the information collected on each incident and how it is recorded.



4.5 Uses of incident reports

The information contained in, or extracted from, patient safety incident reports, sometimes added to by further information gathering or investigation, can be used for seven main purposes:

- to formulate action to prevent (or reduce the risk of) a similar incident in the care setting where it occurred;
- to communicate information that could lead to the prevention of a similar incident elsewhere in a country's health system or globally;
- to aggregate with other reports to produce larger volumes of data capable of providing the maximum possible understanding of the problems in the system that led to the harm (or risk of harm);
- for education and training;
- for research, development and improvement;
- for public reporting and accountability;
- for open disclosure to patients and families.

4.6 Review and investigation of individual incidents

Understanding why and how an incident happens involves establishing why and how errors occur within the context of complex systems and what part human behaviour plays in this process.

A system has been defined as “an interacting combination, at any level of complexity, of people, materials, tools, machines, software, facilities, and procedures designed to work together for a common purpose” (21). Health care is a complex system, and all the general and specialist services that make up the whole are also complex subsystems. Within such complex systems the propensity for error is high, and in some cases its consequences will be serious or even catastrophic.

There are many ways in which the influences on the occurrence of an incident have been described. However, there are three broad, and interrelated, ways to understand and engage with systemic risk, looking at the defences, at the causes, or at the interaction.

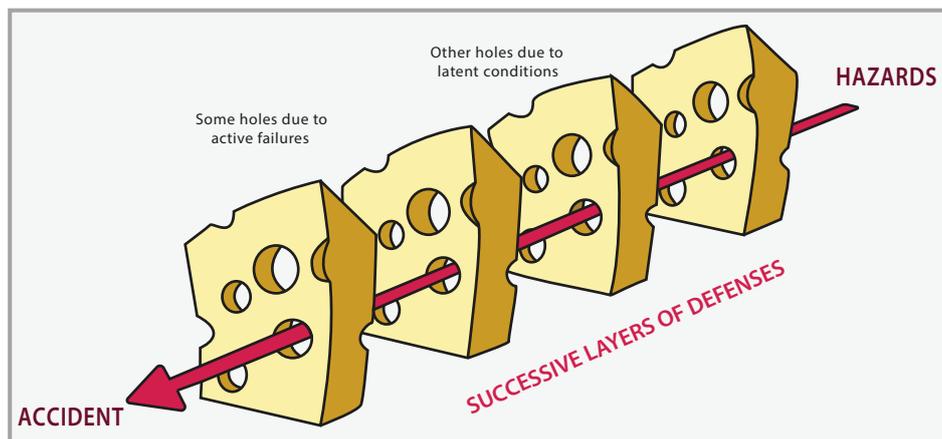
4.6.1 Defences

James Reason points to the weaknesses in defences, latent failures or unseen deficiencies within a complex system that can result in an incident. His theory is widely known as the Swiss cheese model (Figure 5) (21).

Reason has described the increasingly recognized importance of adopting a system approach to causation:

“When an adverse event occurs, the important issue is not who blundered, but how and why the defences failed” (22).

Figure 5. The Swiss cheese model: system weaknesses and defences

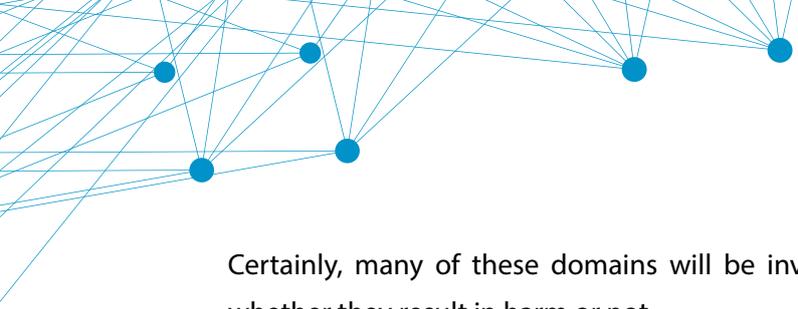


Source: Reproduced, with the permission of the publisher, from Reason (21).

4.6.2 Causes

Accidents and incidents can be examined across a wide field to build up a list of the antecedents or contributory factors to an error that should be looked for in any investigation (23), for example:

- individual operator
- multi-operator teams
- equipment
- the organization and its management
- the regulator
- societal and cultural factors.



Certainly, many of these domains will be involved in incidents that occur in health care, whether they result in harm or not.

In health care, the technique of root cause analysis has become regarded as the gold standard in investigation. To realize the full potential of root cause analysis, its users should bear in mind the following points. First, there are often organizational time pressures to finish the investigation prematurely. Second, not all staff or organizations will have had the necessary training to do the deeper analysis required to assess the interaction between contributory factors. Third, all the required specialist inputs may not be available, particularly those with content knowledge in the field of care and those with human factors expertise. Fourth, the investigation may lack independence and staff may be reluctant to uncover uncomfortable truths. All these limitations reduce the reliability of causal insights of root cause analysis.

4.6.3 Interactions

There is another school of thought that eschews the whole concept of “root causes”. The common feature of most thinking on this subject is that errors, incidents and accidents in complex systems are seen to result from more than one, usually multiple antecedents. These factors interact in a complex way and develop over time, and it is not possible to be certain how they came together at the precise moment that the incident occurred.

A further complexity to understanding why and how an incident happened is the risk of bias. There are several types of bias, but hindsight bias is particularly important; this is the tendency to assume that those involved in the accident should have recognized the situation that they were in. Hindsight too readily expects there to have been foresight.

4.6.4 The realities of reviewing incidents

Some of the arguments in these sections of the document may seem esoteric considerations to those responsible for trying to find answers to the problem of harm in health care. However, the relevance to incident reporting is that it is unlikely that an individual routine incident report will provide the depth or scope of analysis necessary to establish how and why the defences failed. Nor will it give a *definitive* assessment of causation. Indeed, it is too much to expect that it should. It is salutary to remember that 1000 incident reports in a database may represent 1000 different individual staff each giving their opinion on what caused an incident within minutes of its happening. Value is immediately added to that individual report by further information gathering and investigation. Moreover, an investigative or research team reviewing groups of incident reports, and aggregating their findings, will often produce a deeper understanding of causation (Figure 6).

When an incident happens, there is a tendency to investigate that specific problem, without looking for the broader systemic issues that it highlights. Incidents are often addressed in the department in which they occur, without asking whether they could have occurred in other departments in the health care organization.

The reality of most patient safety incident reviews at local service level is that judgements on how and why the incident happened will be based on information that is easily available, not on what is really needed to provide a complete picture. Staff involved in the incident may be too busy to take part in the discussions. The limited degree of direct involvement of point of care staff in discussing and seeking solutions to things that have gone wrong is a barrier. Yet, experience suggests that their practical and intellectual engagement, if well led, can spark great interest and commitment to patient safety. Staff with content knowledge of the area of service but who are independent are of great value, so too are additional specialist skills in fields such as human factors. The volume of reports to be reviewed will often be daunting. As a result, the pressure will be to conform to the bureaucratic requirements to complete the paperwork and forms rather than explore deeply and reflectively on the events that took place.

The lack of a consistently high standard of investigation and action planning too often hinders effective risk reduction within health care organizations. The necessary solutions will seldom be quick and easy but will involve longer-term developmental work.

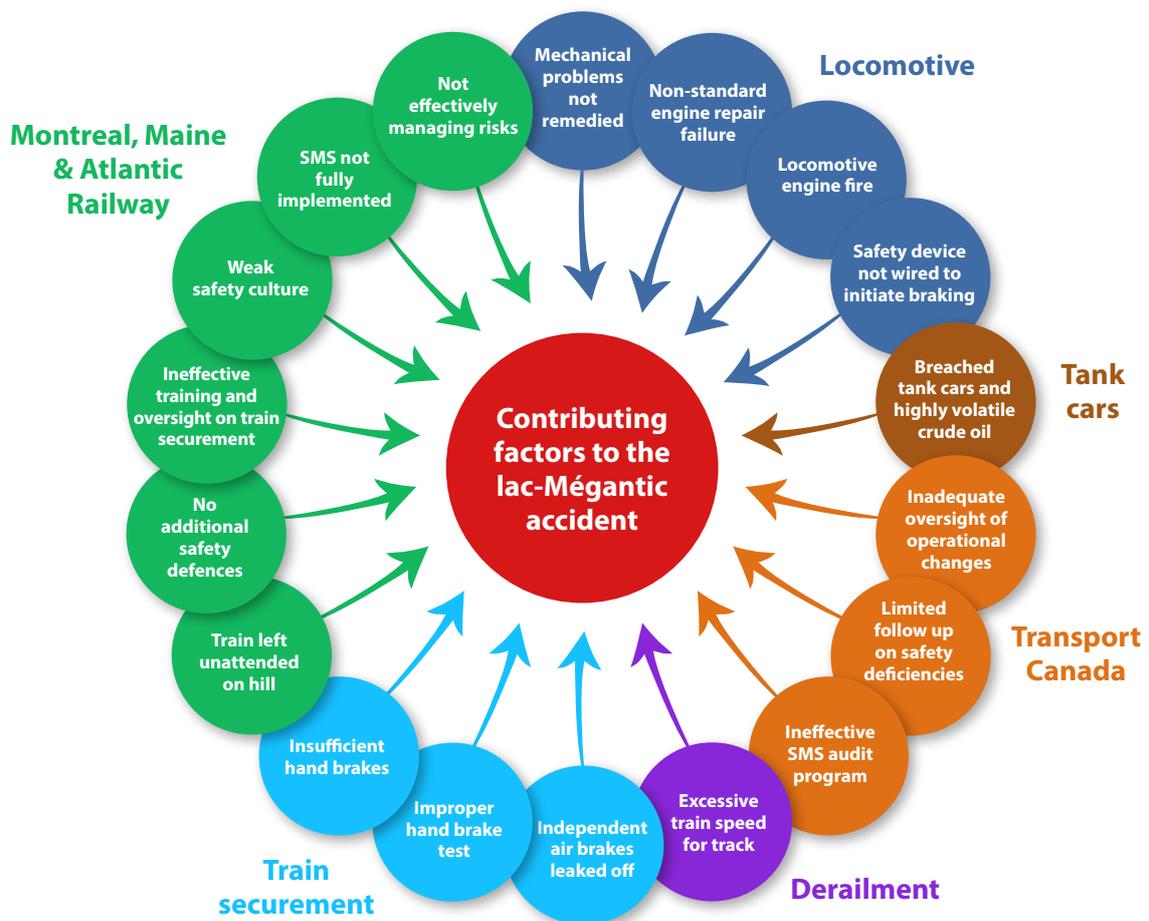
Figure 6. Assessment of patient safety incident reports



Source: World Health Organization

Figure 7 shows the complex combination of factors contributing to the Lac-Mégantic runaway train accident in 2013 (24). The train of 72 tank cars containing petroleum crude oil rolled downhill and derailed at high speed near the residential area of the town, causing a fatal blaze. The ensuing investigation considered many causal factors in addition to mechanical issues, including audit systems, safety culture and human factors.

Figure 7. Complex combination of factors contributing to Lac-Mégantic runaway train accident



Source: Reproduced from Transportation Safety Board of Canada (24).

The figure illustrates how diagrammatic presentation of contributory factors in the field of accident investigation can be used to enable systemic insights to facilitate action.

Three features determine the extent to which investigation of an incident results in a reduction in the likelihood of a recurrence:

- how deep the investigation delves into understanding the true systemic issues that caused something to go wrong;

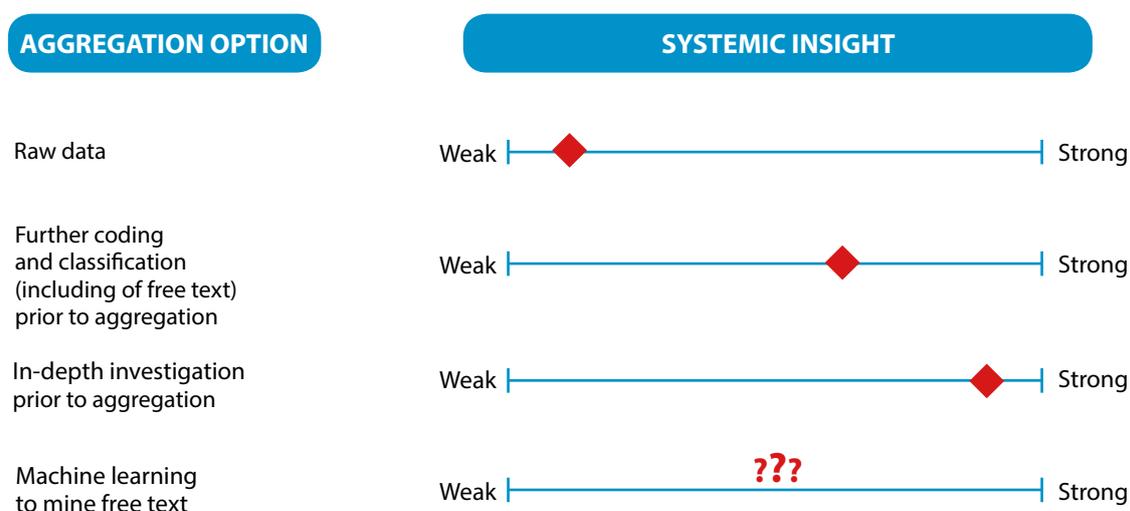
- how systemic the investigation’s focus is in considering where else a similar problem could have occurred beyond the local context in which it did occur;
- how strong the corrective actions are in actually, and sustainably, reducing the risk of a repeat.

4.7 Systemic insights from aggregated incident data

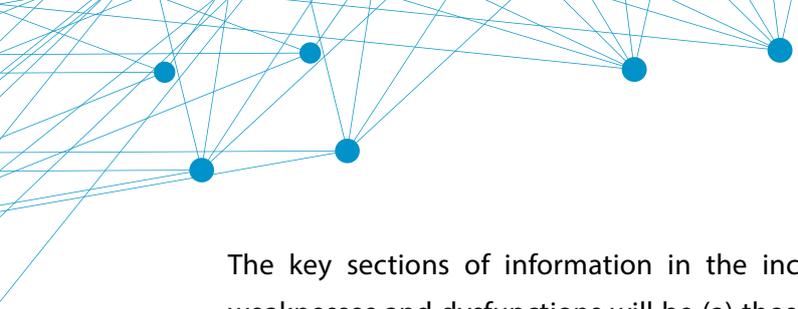
Most reporting forms or software tools contain structured information sections and free text. Each item of raw data will not provide strong systemic insight, so data analysis is necessary. Analyses of incidents in a database of reports will usually be based on aggregation into categories defined by the structured components of the reporting tool. Thus, for example, analyses will show numbers of incidents of different types by location, by age and sex group, and by trends over time.

In order to aggregate and compare incidents, reports should use modern classification systems such as ICD-11, which allows coding of harm in terms of cause, mode or mechanism, and outcome in digital health environments. Aggregated and comparable incident data will provide systemic insights that help transform policies and processes. Figure 8 shows options for aggregating patient safety incident data.

Figure 8. Options for aggregating patient safety incident data



Source: World Health Organization



The key sections of information in the incident reports for casting light on systemic weaknesses and dysfunctions will be (a) those that capture data on causal or contributory factors (always bearing in mind that these may only be the view of the reporter(s) and not derived from detailed investigation); and (b) the adverse outcome that is the subject of the report.

Based on information of this kind, analyses of aggregates of incidents can provide systemic insight enabling four types of activity (Figure 9).

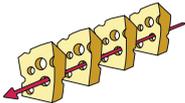
Type 1: surveillance activity. Systemic insight derived from aggregations of very large numbers of incident reports is of the least immediate value in acting on specific sources of harm. However, it is of value in large-scale surveillance and monitoring activity. Such analyses show broad influences that increase the likelihood of harm, for which solutions are generally long term and developmental in nature.

Type 2: detecting major performance failures. Systemic insights that derive from analyses of aggregates of incident reports highlighting a field of care where harm is being generated can be particularly valuable. They open a window on a circumscribed aspect of care where harm is clustering. The focus of attention is therefore very clear and well understood, though the analysis does not generally define the precise source of harm, as the underlying causes are likely to be multiple. The “view” from the window should prompt a major review and investigation of the service performance failure in order to understand why large-scale harm is happening. This could be followed by nationally coordinated local action, new regulatory rules, changes to clinical policies and procedures, or other measures that may bring about major reductions in risk to patients.

Type 3: probing for breakdowns in resilience. Systemic insight into situations where prevention or control measures should be in place but where harm has broken through defence mechanisms is another important use of aggregated incident report data.

Type 4: identifying new, serious sources of harm. Larger patient safety incident databases are particularly valuable in their capability to detect clusters of rare events in space and time that would not be easy to recognize from individual occurrences in small localities. This type of systemic insight emerges when an apparently new source of harm is noticeable from analysis.

Figure 9. Uses and limitations of aggregated patient safety incident data

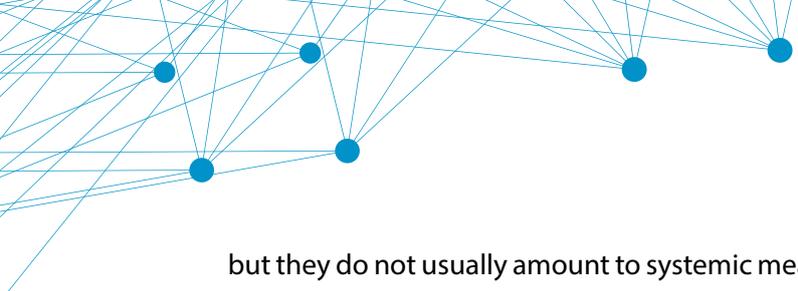
	ACTIVITY	SOURCE OF ANALYSIS	STRENGTHS	WEAKNESSES
	Surveillance	All incident types	Highlights broad patterns and trends	Weak on systemic insights; little immediately actionable
	Performance assessment	Incidents covering particular fields of care	Creates opportunity for system redesign and improved safety within a field of care	Requires extensive further investigation to assess nature of performance weaknesses
	Breakdown in resilience	Incidents pointing to failures in standards or control measures	Enables correction of breaks in defences	Causation can be wide ranging and restorative action complex
	New and uncommon sources of serious harm	Incidents of novel type showing clustering in time and space	Immediate opportunity to block harm and protect future patients	Needs highly active mining of data

Source: World Health Organization

4.8 Learning, formulating action, and managing change

The ultimate aim of investigation is to reduce the risk of harm, not simply to understand what went wrong. Corrective action is too often inadequate. There is no automatic link between understanding what went wrong and being able to reduce the risk of it happening again. Indeed, making the leap between investigation and risk reduction is in reality very challenging.

In many services, after an incident, efforts will be made to make staff aware that the incident took place, explain what went wrong, and circulate a description to other parts of the health system to share the learning. Such information-sharing actions should form part of the plan,



but they do not usually amount to systemic measures that will reliably and significantly reduce the risk to patients.

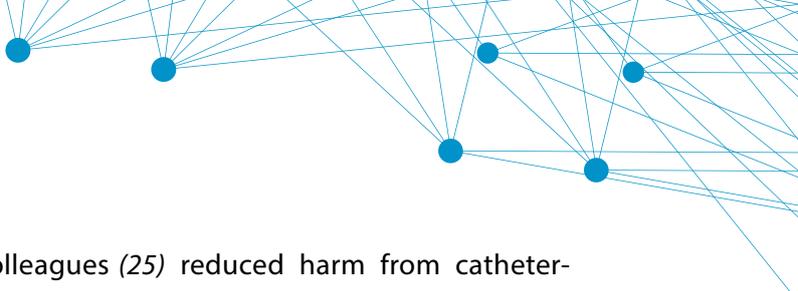
Specification of action plans is often done hurriedly, without sufficient review of research evidence, or experience of best practice elsewhere. Actions chosen are often selected because they seem to be common sense: for example, more training, new guidelines, better communication. Such actions are often imprecisely formulated, and their impact is not monitored. A better approach is to work through potential solutions using the methods of improvement science.

At the health system level within countries, much effort has been expended on how to secure adoption by local services of patient safety practices, procedures or redesigns necessary to reduce risk or prevent harm. These have taken, and continue to take, many forms: for example, advisory notes, guidance papers, standard operating procedures, warnings, alerts, regulatory rules, product changes or articles in professional journals. Despite this, in many parts of the world, history seems to repeat itself: cases of wrong-site surgery continue to occur; look-alike, sound-alike medicines still cause harm year in, year out; and laboratory results go missing or are not acted upon.

Learning across the health care system of a country as a whole requires communication and coordination and, almost always, an agency or organization to be charged with responsibility and accountability for this. Some countries have approached this need for systemwide action to reduce harm by establishing units within their ministries of health. This can work well but other countries have judged it important to establish an independent agency or organization to undertake these functions; such a body can fulfil the valuable public protection role of “speaking truth to power”.

Somewhat surprisingly, global patient safety learning mechanisms are quite rudimentary.

Improving patient safety often means adopting technical (sometimes technological) solutions but recognizing that they usually have to go hand in hand with addressing the social system – in other words, considering how change can be achieved. Sometimes reducing harm *is* a largely technical matter. For example, at one period of time, deaths in hospitals around the world were occurring because patients were inadvertently being given high doses of potassium during intravenous infusions. Reducing the risk involved locking up, in cupboards, the strong potassium chloride formulations and only issuing them through special authorization. This was a process design solution to that particular accidental cause of death.



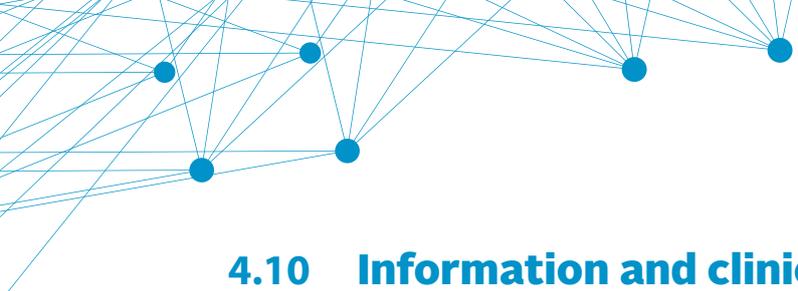
In contrast, the work of Pronovost and colleagues (25) reduced harm from catheter-associated bloodstream infection in the state of Michigan by implementing a bundle of interventions in the clinical management of intensive care patients. Attempts were then made to replicate the success elsewhere, but it was not enough simply to recommend the bundle of five technical interventions. To be successful, the clinical teams needed to be engaged by local leaders, cultural resistance needed to be addressed, and the organization (institution) needed to be developed. In other words, the social system needed to be fertile ground in order to sow the seeds of new practices.

4.9 Openness and independence of data analysis

It is essential to have a clear policy on what range of reports, based on analysis of the reporting data, is produced. The first step in formulating such a policy is a determination of who will be the beneficiaries of the data. These are likely to be substantial in number and include:

- local providers of care
- health care professionals
- professional and educational bodies
- regulators
- insurers and payers
- patients and the public
- ministries of health
- parliamentary and other law making and elected bodies
- clinical boards
- commercial bodies with a legitimate interest
- researchers
- innovators.

Since the ultimate goal of analysing reporting data is to improve the safety of care, it is good to have many parties that are interested in receiving and using the data. However, each beneficiary is likely to require analyses in a form that satisfies the need to support their operations or aspirations.



4.10 Information and clinical governance

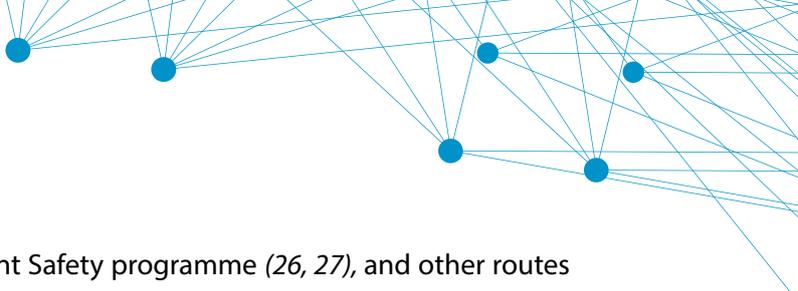
Patient safety incident reports are clinical information. A rigorous information governance policy (with commensurate training) should be in place to underpin the recording, storage and use of the data. The areas covered will include confidentiality and data protection, anonymity, record management, information sharing, legality, public release of information (including freedom of information requests) and other matters. The legal and regulatory framework in which this operates may vary greatly from country to country.

Any large database of incidents faces the challenge of public accountability and scrutiny of the effectiveness of action to protect patients. If something very bad comes to light, the media and public may ask: “Did you already know about this?” or “Did you look at your data thoroughly enough?” If a patient or patients have died in avoidable circumstances, questions about who knew what and when, and what they did about it, can put great pressure on health care leaders and health ministers. The larger and more diverse the collection of accumulated incidents becomes, the more difficult it is to discharge this accountability fully. Taking action on the risks that are highlighted by individual incident reports as well as clusters of, or trends in, such reports must be health leaders’ and managers’ clear responsibility.

Any national or large-scale patient safety incident reporting and learning system that involves electronic capture, storage and analysis of data will require a sophisticated information technology “back office” with skilled staff to manage all aspects of the data. Advice on this is beyond the scope of this guidance but it is an essential and “mission critical” set of functions. Before seeking potentially expensive commercial advice, which may not be impartial, those considering the establishment of a new reporting system or the upgrading of an existing paper-based system would benefit from independent advice.

4.11 Engaging patients and families

Those who regularly read reports of incidents of harm in health care frequently remark on their emotional power. This is especially so when the story of the incident is told by the patient themselves or, sadly and all too frequently, by a family member who has lost a loved one to unsafe care. Somehow, this emotional power is lost when the individual incident reports are aggregated into categories that contain hundreds or thousands of incidents. This echoes the often-quoted epigram (attributed to a variety of historical sources and formulations): “A single death is a tragedy; a million deaths is a statistic.”



Yet, WHO's team, through its Patients for Patient Safety programme (26, 27), and other routes of contact with victims of harm, has many examples of how the emotions released from listening to the story of harm can bring about beneficial change. Generally, this happens in two situations:

- inspiring and motivating health care professionals
- transforming health care organizations in their leadership, culture and priorities.

It is often only the patient, family member or carer who has a complete view of the entire journey of care surrounding an event; this emphasizes the value of involving patients, families and carers in investigating and understanding what happened and the circumstances surrounding an incident. The best reporting systems also include and encourage patient-generated reports.

Good practice around the world suggests that patients who suffer harm and their families should be fully informed about what has happened, how it happened and what will be done to prevent another similar occurrence. More than this, they should be fully engaged (should they so wish) in working with the organization to make change. Patient and family engagement is already an integral feature of the best reporting systems.

Governing body meetings that receive accounts of incidents of unsafe care within their organizations can use them as engaging and powerful moments of reflection. For this to be of value, board members must fully and whole-heartedly engage in these stories and provide the context and space in which staff and patients can come together to learn.



5 Guidance

This guidance aims to provide comprehensive advice for ministries of health, specific patient safety and quality agencies, hospitals and other health facilities, individual clinical services and clinical teams on how to design, operate and use a successful patient safety incident reporting and learning system. A self-assessment tool is also provided that aims to assess gaps, strengths and weaknesses of the incident reporting and learning systems.

The extent to which all aspects of this guidance are applicable to the patient safety incident reporting and learning system will depend on its scale. The size and scope of arrangements to collect, analyse, investigate, store and learn from patient safety incident reports will vary greatly. Thus, reporting and learning systems are likely to fall into one of three types:

- **small scale:** clinical department or team, 500 incidents or less per year;
- **medium scale:** large hospital or group of health facilities, thousands of incidents per year;
- **large scale:** national or regional health system or very large group of health care facilities, 10 000 or more incidents per year (in some cases tens of thousands).

Whatever the size and scale of the patient safety incident reporting and learning system, each of these areas in this guidance will be directly relevant and important for consideration in how the system is designed, coordinated and operated. The precise detail that is applicable in each guidance theme will vary according to scale (small, medium, large).

5.1 Understanding a patient safety incident reporting and learning system

5.1.1 Understand the importance, the fundamental principles, and the process of reporting and learning systems of patient safety incidents.

5.1.2 Establish a supporting framework so that new and existing risks identified by patient safety incident reports are specified, communicated and prioritized for action within a wider safety agenda, and accountability for controlling them is clearly allocated.



5.2 Creating a positive environment for reporting

5.2.1 Clinical and managerial leaders should be asked to play a strong role in motivating staff to report. Health care professionals face enormous pressures on their time, so they will often skip reporting incidents unless the leaders prioritize it.

5.2.2 Banish fear of blame and retribution from the culture of reporting. The organization should make a formal commitment to eliminate the blame culture and encourage blame-free reporting; this is by far the most widely cited factor influencing the success and failure of incident reporting systems across all sectors, not just health care.

5.2.3 Create the environment for health care professionals to make a report. Where feasible, electronic methods of reporting are preferable to filling of paper forms; reporting on portable electronic devices makes it even easier. The process of reporting should be made as user friendly as possible; the design of the tool for collecting information is essential in this respect.

5.2.4 Ensure that staff have time to make a report. This is linked to ease of reporting but also depends on the workload of individual staff. With a safety culture that places high value on reporting, most staff will make time to report, even if they are busy.

5.2.5 Demonstrate absolute clarity on what needs to be reported. Awareness raising and training will familiarize staff with what information is necessary in a report and why it is being collected.

5.2.6 Give staff regular feedback on progress with the investigation of the incident that they reported and the action that has flowed from it. This is one of the most difficult areas to deliver, because the volume of incidents will often preclude each one being investigated. However, if there is a clear policy that all understand, staff should still receive feedback, acknowledgement and encouragement to keep reporting, even if their incident report has not been selected for analysis.

5.2.7 Establish that demonstrable improvement in safety is being consistently made within the organization or health system as a whole. Unless health care is becoming safer, it is very difficult to sustain trust in the value of reporting amongst political leaders, the public and health care professionals (with implications for continuing financial investment). These successes should be shared and championed widely to show the value and purpose of incident reporting, and to strengthen reporting culture.



5.3 Identification and recording of incidents

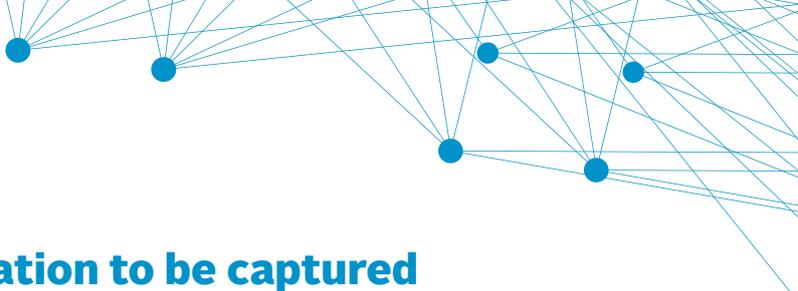
5.3.1 Make all health care staff fully aware of their responsibility to identify occurrences of harm as well as existing and potential risks to patients. It is a leadership challenge as well as an educational and communication task to instil in the values of staff that reporting is a professional duty that can often be lifesaving for patients and beneficial for staff, not just an information requirement of management.

5.3.2 Publish and communicate clear guidance and definitions for staff on what should be reported and what mechanism should be used to make the report.

5.3.3 A special strand of reporting should be established for patients and family members to make patient safety incident reports. It is essential that this is widely publicized, and that patients and family members are encouraged to report. All incidents in this category should be individually reviewed and appropriate action taken.

5.3.4 Where feasible, a telephone hotline or other urgent communication channel should be established to enable staff to report extremely serious incidents involving a real and present danger of early repetition of the serious harm. Immediate, high-level investigation can then be undertaken to prevent the source of harm transmitting to other patients. Where resources permit, there are also benefits to dealing with mandatory reporting requirements (such as never events and sentinel events) through such a system. This is a developmental area that needs extensive discussion before determining whether to proceed; setting up such a mechanism is a serious undertaking that requires careful planning, adequate resources and rigorous governance arrangements. It should be properly staffed by those with the right skills 24 hours per day; the reporter should have an absolute right of protection of their identity if they so wish; accountability for the incident management should be clear and ideally rest with a medical or nurse director or person of commensurate status within the organization; and the incident should only be closed if the risk has been controlled.

5.3.5 The right of staff who make an incident report to be protected from action against them (except in exceptional circumstances of wilful misconduct or reckless behaviour) should be enshrined in policies and, if necessary, legislation. The key is for staff to understand that the information in an incident report, or gathered as part of the subsequent investigation, will not be used punitively against them.



5.4 Choosing the information to be captured

5.4.1 Where a reporting system is already established, the content of the items of data currently captured should be reviewed to ensure that the 10 elements of the advanced Minimal Information Model for Patient Safety Incident Reporting and Learning Systems (MIM PS) are included or are mappable. This will allow international comparisons and benchmarking and exchange of experience.

5.4.2 Where a new reporting system is being planned, the basic (eight element) version of the MIM PS is a good starting point.

5.4.3 All incident reports should contain structured information gathering and a free text narrative account.

5.4.4 The part of the data collection and reporting tool (whether a paper form or electronic record) that addresses causation is the most difficult to design and special attention should be given to this.

5.5 Uses of incident reports

5.5.1 Information from incident reports should be used for a wide range of purposes. By using information, and gaining experience on its strengths and limitations, the scope for improvement in data quality and utility will be enhanced.

5.6 Review and investigation of individual incidents

5.6.1 Several point of care staff in each service area should receive training in reviewing incidents and in the techniques of in-depth analysis (whilst understanding the strengths and limitations of methods such as root cause analysis). Training should ensure competence in reviewing, analysing and designing responses to incidents; the emphasis should be placed on continuing practice of a skill, not just a certificate of competence.

5.6.2 Full reviews should be carried out locally on incidents, directly engaging those involved in the care that resulted in the incident; other participants should include staff with content knowledge of the area of service or procedure (but independent of the incident), and those with expertise in human factors.



5.6.3 Local incident review should seek to target systemic weaknesses that led to the incident and create insight for wider systemic strengthening across the organization and its services.

5.6.4 There should be a clearly understood policy on which incidents should be reported to any national-level reporting system, if existing.

5.6.5 When the volume of incident reports precludes looking at all of them, there should be a clear policy on which categories should be reviewed and investigated. This should include less serious incidents (including near misses) as well as serious incident reports.

5.6.6 Patients and families should be provided with support and care after an event.

5.6.7 Staff involved in serious incidents should receive counselling and support in the aftermath of the events that led to harm.

5.7 Systemic insights from aggregated incident data

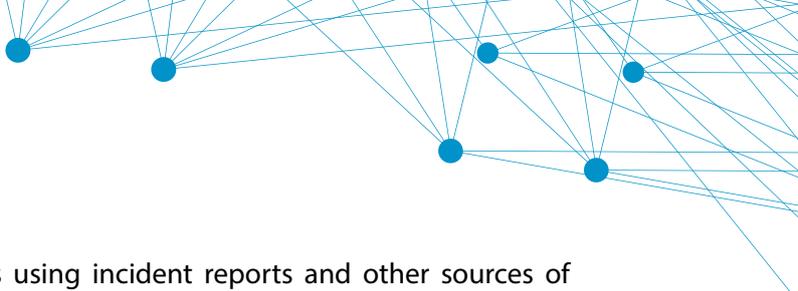
5.7.1 When examining aggregated patient safety incident data, always aim to understand the way the system is exposing patients to the risk of harm.

5.7.2 Review large-scale analyses as a way to regularly generate insights into trends and patterns of broader influences on patient safety or on incident type. It is important to be aware that differences in numbers of reports over time and between locations may simply reflect differing reporting levels, not true differences in their occurrence.

5.7.3 Use analyses to identify major sources of risk opening a window onto a problem and enabling a major review and subsequent strategy to reduce risk and harm. Action is likely to be multifaceted and require involvement of a wide range of interests to coordinate an effective response. Addressing system weaknesses on this scale will generally reduce a risk rather than eliminating it entirely.

5.7.4 Use analyses to probe apparent deviations from best practices in patient safety. Lapses can then be identified, and remedial action put in place to strengthen defences.

5.7.5 Establish procedures to review aggregated patient safety incident reports in order to identify new sources of harm, particularly those with serious impact on patients.



5.7.6 Carry out regular thematic reviews using incident reports and other sources of data. Such an approach (in areas such as anticoagulant therapy, insulin dosage errors and radiation overdose) can allow sources of risk to be explored and preventive measures to be instituted.

5.8 Learning, formulating action and managing change

5.8.1 Staff should understand that devising a solution to reduce risk, or the likelihood of recurrence of an incident, is a complex task requiring extensive discussion and expert advice. Many local responses to patient safety incidents are weakened by time pressure, lack of independent expertise and advice, and defined timelines to fill in and submit forms. Imprecise formulations of action such as increased training, better communication and new guidelines are seldom effective alone; using established improvement science methods and evaluation of solutions can be an important way to engage all staff in finding the best ways to make their care safer.

5.8.2 Action should be based on the principle that technical interventions and their implementation are two distinct though interrelated processes. Technical interventions are the specific, evidence-based procedures or technologies that are capable of making an improvement, but their successful implementation almost always requires committed local leaders, fully engaged clinical teams, removal of cultural barriers and viewing the organization as a social system.

5.8.3 Patient safety alerts, warnings, and advisory notices should be appropriately designed and piloted, and their communication targeted well. There are many reasons why systemwide action notices intended to bring about an improvement in safety do not work.

- They can take too long for the recipient to read or assimilate.
- They may not reach the places and people where they need to be received.
- Their content may not be well thought through.
- The action required may be complex or daunting to implement.
- The action, whilst theoretically correct, may not be adaptable to the local setting.
- There may be so many national patient safety communications that local recipients become overloaded and start to ignore them.



5.8.4 Some clinical specialties may set up their own safety incident reporting and learning systems. A small number of clinical specialties are able to make substantial improvements in safety by establishing specific systems. This works best when the specialty makes strong use of standard procedures and of equipment and technology and is less dependent on the wider workings of the organization. Anaesthetics (anaesthesiology) is a good example of a specialty that has systematically reduced risks by learning from adverse events. Such reporting systems generate strong clinical ownership, higher levels of reporting, more detailed reports and greater trust than managerially led reporting systems. In addition, certain surveillance systems (such as pharmacovigilance and haemovigilance) are the established methods of receiving, analysing and learning from adverse events. However, establishing too many stand-alone clinical incident reporting and learning systems often leads to fragmentation and may not be helpful in the long term.

5.8.5 Identifiable patient safety incident data should be immune from disclosure to the courts and those seeking opportunities to litigate. This is covered by legislation in some jurisdictions in the world and is essential to promoting an open culture of learning rather than one in which staff are fearful.

5.9 Openness and independence of data analysis

5.9.1 The agency or organization responsible for gathering, aggregating and analysing patient safety incidents should identify all individuals and organizations with an interest in the data, giving priority to those with a role (or potential role) in improving safety. Subject to resource constraints, and compliance with information governance safeguards, data should be provided in the format that best meets their needs.

5.9.2 This agency or organization should ideally be an independent entity separate from government and the health system and not required to seek approval for the content and timing of its reports. It should operate in the patient and public interest without fear or favour and with no perception that it has any conflict of interest.

5.9.3 Public release of information should be a priority, but in a form that is simple, open, and honest, provides genuine insight, and is properly contextualized and explained.



5.10 Information and clinical governance

5.10.1 Prior to being transmitted to the data storage (for example, database) of the reporting system, all reports of patient safety incidents should be anonymized so that no patient, staff member or other person can be identified. Special attention should be given to the free text elements of the report. This point may need to be interpreted differently in countries or health systems where government policy, with the support of civil society, is to include a patient's health record number in the incident report. Moreover, there may be personal information or privacy legislation that would also affect the extent to which information may or may not be shared.

5.10.2 When patient safety incident data are passed to a third party, such as a research group, the transfer of the data should be done under a formal, written, data-sharing agreement that specifies the information governance and legal safeguards required.

5.10.3 A comprehensive information governance policy should be in place. Staff should be trained in its use, and a mechanism should be established to monitor its effectiveness.

5.10.4 There should be an effective surveillance mechanism to identify, at an early stage, incidents or clusters of incidents that are signalling a real and present danger to patients (a "red flag" mechanism).

5.11 Engaging patients and families

5.11.1 All health organizations should have a "duty of candour" towards any victim of harm. All patients whose care has involved a patient safety incident should receive (a) a full disclosure of what went wrong; (b) an explanation of why it happened; (c) a full apology; (d) a description of the action being taken to prevent a recurrence (and an invitation to be involved in the implementation process); (e) the provision of practical and psychological support, including fair compensation; and (f) access to further treatment for the original condition and consequences of the harm. If the incident resulted in death or involved a child, then this disclosure process, and the other steps, should be with appropriate family members.

5.11.2 The stories of patients and families who have suffered avoidable harm (preferably told by themselves) should, with their formal consent, be a regular part of the discussions of health organizations' governing bodies and clinical teams.



5.11.3 Patients and families who have suffered avoidable harm should be invited to share their experience and stories as a core component of the educational programmes of health care professionals.

5.11.4 Patients and families who have suffered avoidable harm should be embedded as advisers in all governance and service design structures within health organizations.



6 Self-assessment based upon the guidance

This section aims to provide a way for health care organizations, health systems, clinical departments and clinical teams to undertake a broad assessment of their patient safety incident reporting and learning systems, based on WHO guidance. It is intended as a tool for exploration and discussion to identify gaps in, strengthen, and further develop systems, rather than as a formal audit process or to produce a score. It should also be of value to those who do not currently have a reporting and learning system but wish to develop one. In either case, careful deliberation and extensive discussion is required to have a system operating to a satisfactory standard.

The self-assessment aims to enable everyone who is responsible for identifying patient safety incidents, gathering information on them, and seeking to reduce future risks to patients to reflect on what they currently have and what they wish to develop further.



Table 2. Patient safety incident reporting system: a self-assessment

Rate your current or planned patient safety incident reporting system to assess its strengths against key points in the guidance.

Section	Details	Rating				
		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Environment for reporting	It is easy for health care professionals to make a report					
	Staff have time to make a report					
	Staff are absolutely clear on what needs to be reported					
	Staff receive personalized feedback on progress and action resulting from their report					
	Most staff are motivated to make reports					
	Staff are encouraged to make reports, and blame and disciplinary action are exceptional (i.e. only in cases of serious misconduct)					
	The leadership of the health care organization has provided and committed to policies that establish a safety culture and makes its commitment visible					
Reporting rules and content	There are clear criteria and definitions for what constitutes a patient safety incident					
	There are clear rules for what kinds of incident should be reported					
	Staff are provided with training on the purpose of reporting					
	Staff are provided with training on how to complete an incident report form, in terms of what information to include					



Section	Details	Rating				
		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Reporting rules and content	It is clearly understood whether reporting is voluntary or mandatory (or under what circumstances both operate)					
	The content of incident reports covers as a minimum the elements of the MIM PS					
	Incident reports contain structured information capture and free text narrative commentary					
	It is possible to return to a reporter to gather further information					
	It is clear what types of incident should be analysed locally (e.g. within a hospital) and what types nationally					
	A telephone hotline (appropriately staffed and skilled, and with rigorous governance arrangements) is in place for staff to report serious incidents that require escalation, immediate investigation, and action to protect other patients					
	Within the reporting system, there is a specific mechanism for patients and family members to make reports					
Analysis and investigation	Data are aggregated to a recognized classification system					
	Aggregated data regularly produce systemic insights					
	Feedback is provided to staff to acknowledge their report and to clarify any additional details needed					



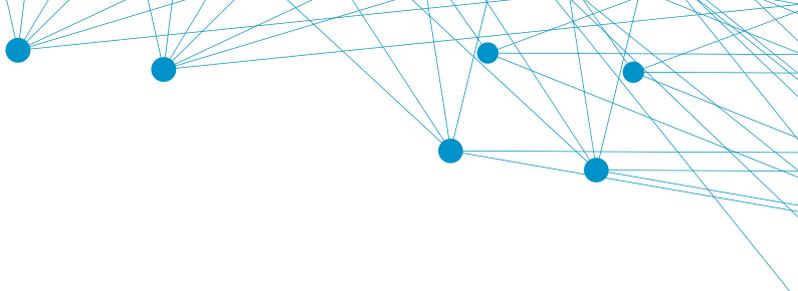
Section	Details	Rating				
		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Analysis and investigation	There is access for staff to analyses and a skilled analytical function to process raw data					
	Reports of aggregated data are regularly made public, with appropriate interpretative commentary					
	Reports of aggregated data are made available to agencies or organizations involved in, or accountable for, safety assurance or improvement, tailored to the needs of these agencies or organizations					
	A substantial proportion of incidents are further investigated at local level					
	Some incidents (or clusters of incidents) are further available at national level					
	Further investigation of incidents is not restricted only to those involving death or severe harm (some low harm, no harm and near miss incidents are also examined)					
	Further investigation of incidents involves a structured approach (such as root cause analysis)					
	Further investigation of incidents almost always involves appropriate expert input					
	Further investigation involves all relevant staff, patients and families, and regularly includes expertise in human factors					



Section	Details	Rating				
		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Analysis and investigation	Detailed and more robust data that are collected through investigation, and the resulting deeper analysis, are incorporated and recorded back into the reporting system					
Governance	The incident reporting system is managed and maintained by an independent agency or organization					
	Incident reports are anonymized so that no patient, staff member or other individual can be identified by reading the report					
	The management of the reporting system – with appropriate safeguards to confidentiality – would be able to identify situations where there was an immediate danger to patients					
	There is an oversight process to identify and resolve problems with any aspect of the incident reporting system					
	There is adequate technical and information technology infrastructure to maintain a high standard in all aspects of the incident reporting system					
Action and learning	A formal framework is in place to specify, communicate and prioritize action on the risks identified by reporting data and their analysis					
	Proper counselling and support is provided for staff who have been involved in serious incidents (the “second victims”)					

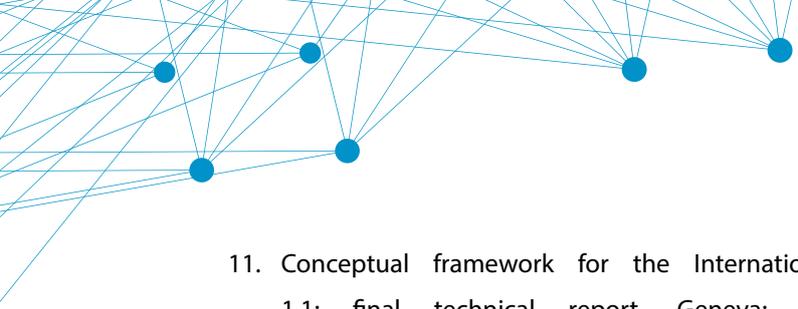


Section	Details	Rating				
		Strongly disagree	Disagree	Neither agree nor disagree	Agree	Strongly agree
Patient and family engagement	Incidents are always disclosed to victims of harm and their families					
	Accounts of patients' and families' experience of harm are regularly discussed at the governing body level					
	Patients and families who have suffered harm are provided with ongoing psychological and other support, free of charge, if they wish to receive it					
	Victims of harm are provided with additional treatment and care as required, free of charge, and by a new clinical team if that is their preference					
	Patients and families who have suffered harm are involved in designing action to reduce the likelihood of a recurrence (if they so wish)					
	Patients and families who have suffered harm play a major role in education and training of students and health care staff					

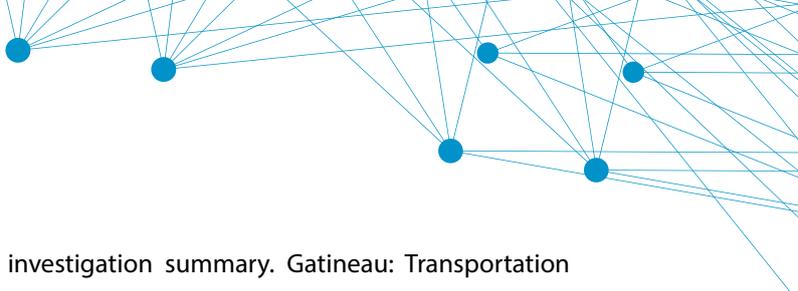


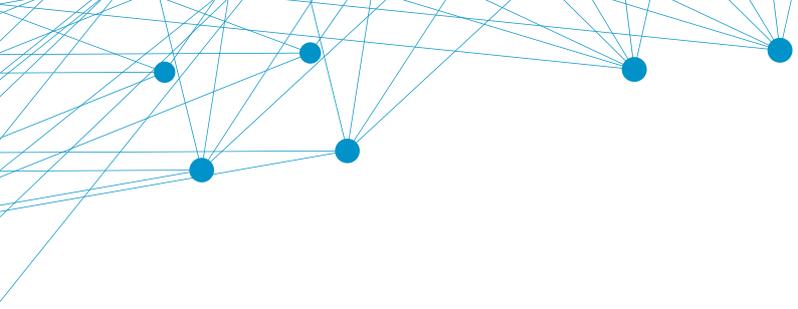
References

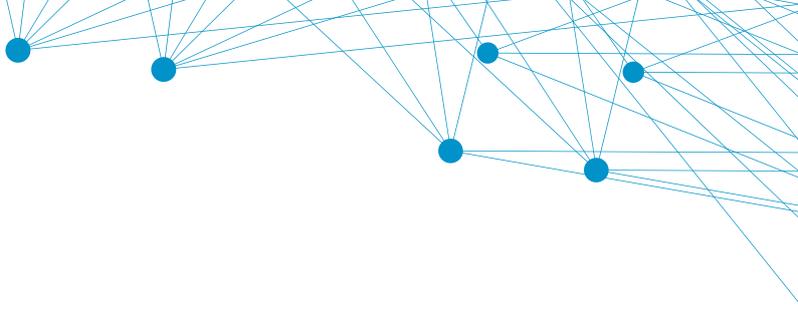
1. Kohn LT, Corrigan JM, Donaldson MS, editors. To err is human: building a safer health system. Washington (DC): Committee on Quality of Health Care in America, Institute of Medicine, National Academies Press; 1999.
2. Chief Medical Officer. An organisation with a memory: a report on learning from adverse events in the NHS. London: Stationery Office; 2000.
3. Brennan TA, Leape LL, Laird NM, Herbert L, Localio AR, Lawthers AG et al. Incidence of adverse events and negligence in hospitalised patients: results of the Harvard Practice Study. *New England Journal of Medicine*. 1991;324(6):370–6. doi:10.1056/NEJM199102073240604.
4. Wilson RM, Harrison BT, Gibberd RW, Hamilton JD. An analysis of the causes of adverse events from the Quality in Australia Health Care Study. *Medical Journal of Australia*. 1999;170:411–515.
5. Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. *BMJ*. 2001;322:517. doi:10.1136/bmj.322.7285.517.
6. World Alliance for Patient Safety. WHO draft guidelines for adverse event reporting and learning systems: from information to action. Geneva: World Health Organization; 2005 (<https://apps.who.int/iris/bitstream/handle/10665/69797/WHO-EIP-SPO-QPS-05.3-eng.pdf>, accessed 01 September 2020).
7. Carson-Stevens A, Hibbert P, Williams H, Evans HP, Cooper A, Rees P et al. Characterising the nature of primary care patient safety incident reports in the England and Wales National Reporting and Learning System: a mixed-methods agenda-setting study for general practice. Southampton, United Kingdom: NIHR Journals Library; 2016.
8. Cresswell KM, Panesar SS, Salvilla SA, Carson-Stevens A, Larizgoitia I, Donaldson LJ et al. Global research priorities to better understand the burden of iatrogenic harm in primary care: an international Delphi exercise. *PLoS Medicine*. 2013;10(11):e1001554. doi:10.1371/journal.pmed.1001554.
9. Sheikh A, Panesar SS, Larizgoitia I, Bates DW, Donaldson LJ. Safer primary care for all: a global imperative. *Lancet Global Health*. 2013;1:e182–3. doi:10.1016/S2214-109X(13)70030-5.
10. Slawomirski L, Auraaen A, Klazinga N. The economics of patient safety in primary and ambulatory care: flying blind. Paris: Organisation for Economic Co-operation and Development; 2018 (<http://www.oecd.org/health/health-systems/The-Economics-of-Patient-Safety-in-Primary-and-Ambulatory-Care-April2018.pdf>, accessed 01 September 2020).

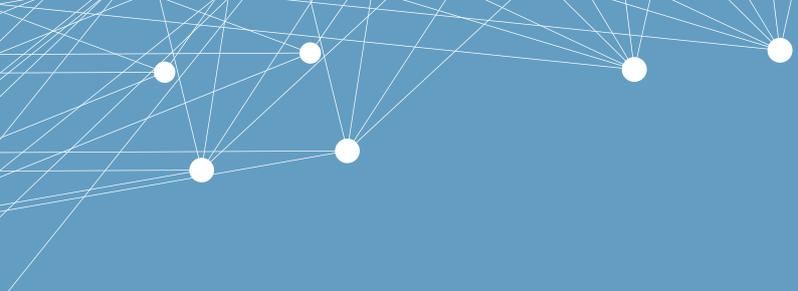


11. Conceptual framework for the International Classification for Patient Safety, Version 1.1: final technical report. Geneva: World Health Organization; 2009 (https://apps.who.int/iris/bitstream/handle/10665/70882/WHO_IER_PSP_2010.2_eng.pdf;jsessionid=F1AE0291DE8936C3DC2043C762EC7986?sequence=1, accessed 01 September 2020).
12. Blais R, Bruno D, Bartlett G, Tamblyn R. Can we use incident reports to detect hospital adverse events? *Journal of Patient Safety*. 2008; 4(1): 9–12.
13. Macrae C. The problem with incident reporting. *BMJ Quality and Safety*. 2016;25:71–5.
14. Macrae C. *Close calls: managing risk and resilience in airline flight safety*. Palgrave Macmillan; 2014.
15. Cook RI, Woods DD, Miller CA, editors. *A tale of two stories: contrasting views of patient safety*. Chicago: United States National Patient Safety Foundation; 1998.
16. ICD-11. *International Classification of Diseases 11th Revision*. Geneva: World Health Organization; 2018 (<https://icd.who.int/en>, accessed 01 September 2020).
17. *Minimal Information Model for Patient Safety Incident Reporting and Learning Systems: User Guide*. Geneva: World Health Organization; 2016 (<https://apps.who.int/iris/handle/10665/255642>, accessed 01 September 2020).
18. *International consultation on European validation of the Minimal Information Model for Patient Safety Incident Reporting and Learning: technical report, 12–13 May 2015, Warsaw, Poland*. Geneva: World Health Organization; 2015 (<https://www.who.int/patientsafety/topics/reporting-learning/euconsultation/en/>, accessed 01 September 2020).
19. *WHO Inter-regional Consultation on Patient Safety Incident Reporting and Learning Systems in Africa and the Asia Pacific Regions, 22–24 March 2016, Colombo, Sri Lanka*. Geneva: World Health Organization; 2016 (<http://apps.who.int/iris/bitstream/handle/10665/255146/WHO-HIS-SDS-2016.21-eng.pdf;jsessionid=C180214B373CF90F633C3D7D54A21578?sequence=1>, accessed 01 September 2020).
20. *Key findings and recommendations on reporting and learning systems for patient safety incidents across Europe: report of the reporting and learning subgroup of the European Commission*. Brussels: European Commission; 2014. (<http://buonepratiche.agenas.it/documents/More/8.pdf>, accessed 01 September 2020).
21. Reason J. *Managing the risks of organisational accidents*. Aldershot, United Kingdom: Ashgate; 1997.
22. Reason J. Human error: models and management. *Education and Debate*. 2000;320(7237):768–70. doi:10.1136/bmj.320.7237.768.
23. Strauch B. *Investigating human error: incidents, accidents, and complex systems*. Burlington, VT: Ashgate; 2002.

- 
24. Lac-Mégantic runaway train and derailment investigation summary. Gatineau: Transportation Safety Board of Canada (<https://www.tsb.gc.ca/eng/rapports-reports/rail/2013/r13d0054/r13d0054-r-es.html>, accessed 01 September 2020).
 25. Pronovost P, Needham D, Berenholtz S, Sinopoli D, Chu H, Cosgrove S et al. An intervention to decrease catheter-related bloodstream infections in the ICU. *New England Journal of Medicine*. 2006;355(26):2725–32.
 26. London Declaration: Patients for Patient Safety. Geneva: WHO World Alliance for Patient Safety; 2006 (https://www.who.int/patientsafety/patients_for_patient/pfps_london_declaration_2010_en.pdf?ua=1, accessed 01 September 2020).
 27. Patients for Patient Safety. Geneva: World Health Organization (https://www.who.int/patientsafety/patients_for_patient/en/, accessed 01 September 2020).
 28. Never events for hospital care in Canada. Edmonton: Canadian Patient Safety Institute; 2015 (<https://www.patientsafetyinstitute.ca/en/toolsResources/NeverEvents/Documents/Never%20Events%20for%20Hospital%20Care%20in%20Canada.pdf>, accessed 01 September 2020).







**World Health
Organization**

