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OECD Health Policy Brief:

Measuring Patient Safety
Opening the Black Box

3rd Global Ministerial Summit on Patient Safety 2018

MEASURING PATIENT SAFETY

Opening the Black Box

April 2018

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Acknowledgements

The work presented here was undertaken by OECD ELS Health Division staff **Luke Slawomirski, Ian Brownwood, Rie Fujisawa** and **Niek Klazinga** for the 3rd Global Ministerial Summit on Patient Safety in Tokyo, in April 2018.

The work was enabled by a voluntary contribution from the Japanese Ministry of Health, Labour & Welfare. We would especially like to acknowledge **Dr Ken Taneda, Dr Kiwamu Nagoshi** and **Ms Ogusa Shibata** for their valuable input and support.

Within the OECD Health Division, we are grateful to **Francesca Colombo** for comments and suggestions.

Patient safety: opening the black box

1. Unnecessary patient harm from unsafe care occurs in all health systems, adding to health expenditure and raising political pressure. Harm can manifest in suffering and morbidity, in the need for additional care, in longer-term disability and even death. Globally, the disease burden of patient harm can be compared to that of tuberculosis and malaria. The majority of this burden falls on the developing world. Unsafe care also exerts a significant economic burden on health systems, communities and on societies more broadly. Many cases of harm can be avoided with simple and effective mitigation strategies.[1]

Unsafe care exerts a significant burden on health systems, communities and on societies.

2. Among the strategies, interventions and programmes to improve safety and reduce harm in health care, measurement is critical. But it is inadequate. Measurement of safety risks, occurrence of adverse events and patient harm is important because it enables all those who have a stake in safe care -- providers, patients, funders, regulators and politicians -- to **understand** the extent, impact and variation in patient harm; **monitor** performance over time and across settings and sectors; and **evaluate** the effectiveness of interventions to improve safety. [2]

3. This Policy Brief outlines the key ways to better measure patient harm to improve safety across health systems – from primary, ambulatory and community care, to acute and long-term care. It makes a fundamental point: a multi-modal approach that draws on different measurement methods is necessary to understand patient safety, because no single method will identify the same type of harm. Specifically, three types of safety measurement should be regarded as the **minimum components of a safety measurement system:**

1. **Adverse event reporting**. Adverse events are incidents that occur during health care which cause unintended and unnecessary harm to a patient. The integrity of adverse event reporting systems rely partly on incident disclosure and related processes of in-depth analyses and learning.
2. **Routinely collected data.** These data are collected for other purposes - such as funding or system management - but can nevertheless capture harm. Routine data include the medical record, which can be a rich source of information on safety lapses.
3. **Patient-reported measures.** Patients have a unique and valuable perspective on the health care process, when things do not go to plan and when they do. Information gathered from patients about their care is invaluable for learning and improvement. It also helps create people-centered health services.

4. While measurement is a critical starting point and component of safe, reliable health care, it is not an end in itself but a means to enable learning and improvement at all levels of provision. For this reason, measurement must be integrated into a

[1] www.oecd-ilibrary.org/social-issues-migration-health/the-economics-of-patient-safety_5a9858cd-en

[2] OECD (2018) The economics of patient safety in primary and ambulatory care (forthcoming)

broader policy framework that ensures appropriate indicators and metrics are **visible to relevant actors** (be they patients, individual providers, organisations or policy makers) with necessary provisions for privacy and confidentiality; and contains complementary **governance mechanisms, procedures and laws** to drive improvement and learning across the system in a timely, effective and efficient manner.[3,4]

5. Crucially, the value of measurement is equally high in developing and developed countries because, without good information, improving safety is impossible - regardless of context.

Adverse events reporting: the foundation of measurement

6. Safety lapses and harm occur in a considerable proportion of health care encounters. In order to improve safety for future patients, many countries have implemented reporting systems where adverse events, their causes and any relevant contextual information are recorded in a central repository. The information is then analysed and deployed to improve deficient processes where relevant, share lessons across relevant settings, and prevent similar incidents from happening again**.**

7. Such systems depend on genuine confidence that the information will be used to improve services and contribute to a 'learning' health care system, but also the understanding that organisations will be accountable for safety lapses and ensuring that these no longer occur. Open disclosure of harm with patients and medical harm compensation systems are therefore an important part of adverse event reporting. They require a just and learning culture to be built within organisations.

Reporting systems can be designed differently but their principal purpose should be learning and improvement

8. Most adverse events reporting are voluntary and open to all health care workers. The opportunity to report the facts of the specific incident from the perspective of the reporter, the contributing factors and how the event could have been prevented should all form part of the incident report.

9. A 'just culture' - where providers are not blamed or shamed for safety lapses but where organisational accountability for these lapses nevertheless exists – is fundamental to adverse events reporting. Few safety lapses will be reported – and little therefore learned – in organisations where the reports are used for punitive purposes. The emphasis should be on continuous learning and improvement. For this reason, reporting should extend to 'near misses' – incidents that could have, but did not – in that case - result in harm but from which lessens can nevertheless be learnt

3 https://ec.europa.eu/health//sites/health/files/patient_safety/docs/guidelines_psqcwg_reporting_learningsystems_en.pdf

4 http://www.pasq.eu/

10. In some countries– reporting is mandatory, usually for certain types of egregious adverse events. For example in Australia all hospitals have a statutory requirement to report a set of eight 'sentinel events' – adverse events that are, in the vast majority of cases, preventable (see Table 1). [5, 6]

Table 1. The eight, nationally agreed sentinel events, Australia

1. Procedures involving the wrong patient or body part resulting in death or major permanent loss of function	5. Haemolytic blood transfusion reaction resulting from ABO incompatibility
2. Suicide of a patient in an inpatient unit	6. Medication error leading to the death of a patient reasonably believed to be due to incorrect administration of drugs
3. Retained instruments or other material after surgery requiring re-operation or further surgical procedure	7. Maternal death associated with pregnancy, birth and the puerperium
4. Intravascular gas embolism resulting in death or neurological damage	8. Infant discharged to the wrong family

Source: www.safetyandquality.gov.au/our-work/indicators/australian-sentinel-events-list/

11. In the United States, 11 states have mandated reporting of the National Quality Forum 27 'never events'. A further 16 states mandate reporting of serious adverse events. Health care facilities are accountable for correcting systematic problems that contributed to the event, with some states mandating a root cause analysis and reporting of its results.[7] The mandatory nature of reporting – without sanction but with publication at jurisdictional level - sends a signal that notification is an important part of learning and improvement, not just where the incident occurred but in other settings where the learnings can be applied to improve safety and prevent similar incidents from occurring. This exemplifies the notion of a just culture.[8]

12. Adverse event reporting can be deployed in all contexts. Malaysia, for example, instituted a system of medication error reporting system in 2009. The objective is to obtain information on the occurrence of medication errors, maintain a database of medication errors, analyse reports, propose remedial actions and monitor the situations in an effort to minimise the reoccurrence of such errors and, ultimately, to improve patient safety.[9]

13. Regardless of the voluntary or mandatory nature, and what types of safety lapses are reported, a sound adverse event reporting system should capture all relevant information and data about an event and analyse the information to identify

[5] Several States and Territories also have their own mandatory 'sentinel event' reporting requirements.

[6] www.pc.gov.au/research/ongoing/report-on-government-services/2017/health/public-hospitals/rogs-2017-volumee-chapter12.pdf

[7] https://psnet.ahrq.gov/primers/primer/3/never-events

[8] Measuring safety culture can also be a useful lever to evaluate and build the right atmosphere for solid reporting and action. One example is the AHRQ Patient Safety Hospital Survey, a useful tool to measure and improve and institute a 'just culture' in the hospital setting https://www.ahrq.gov/sops/quality-patient-safety/patientsafetyculture/hospital/index.html

[9] http://www.moh.gov.my/images/gallery/Garispanduan/Med_Erro/MERS_Guideline_Final.pdf

opportunities for doing better. It should report this information back to the care organisation and the relevant actors involved in the incident, as well as any central agency that is responsible for safety. The importance of reporting to a responsible agency is to '**close the loop',** meaning that necessary corrective action are taken at the place where the incident occurred, and relevant information is forwarded to other location where similar risks exist

Gradual implementation with strong stakeholder engagement is advised

14. Implementing an adverse event reporting system should begin with a manageable set of common adverse events, as presented in Table 2. All of these events are preventable through targeted evidence-based mitigation practices, also presented in the table. It is critical to extend reporting across all care settings from acute to primary and ambulatory and community care.

Table 2. Common adverse events

Adverse events	Mitigation practices
Health care-associated infection, e.g. ● Central line associated blood stream infection (CLABSI) ● Ventilator-associated pneumonia (VAP) ● Surgical-site infection (SSI) ● Sepsis	• Hand hygiene protocols • Catheter insertion protocols • Ventilator management • Surgical safety checklists
Medication errors, e.g. ● Adverse Drug Events (ADEs) e.g. wrong drug, wrong dose, wrong time, wrong route, wrong patient ● Adverse Drug Reactions (ADRs)	• Medication reconciliation • Computerised provider order entry • Medication administration protocols[10]
Venous thromboembolism (VTE)	• Risk assessment & anticoagulant protocols • Checklists
Pressure ulcers	• Prevention protocols
Patient falls	• Falls risk assessment
Failure to rescue	• Deteriorating patient protocols
Wrong / delayed diagnosis	• Diagnostic tools • Education
Wrong site procedure	• Checklists
Patient misidentification	• Patient ID protocols • Checklists

15. When developing and implementing an adverse event reporting system, the following can maximise uptake, and minimise stakeholder resistance:

- Information is not published for comparison, but reported back to all relevant actors, organisations and agencies for learning - with an emphasis on notification as a positive sign of safety culture.
- Accountability for implementing mitigation strategies is emphasised.
- Providers and health care organisations are engaged in the design and development.
- Patients are engaged in the development of the system.

[10] www.ihi.org/resources/Pages/ImprovementStories/FiveRightsofMedicationAdministration.aspx

Legal negligence claims are not considered useful in safety measurement and reporting

16. Some advocate the use of aggregate numbers of medical negligence court cases - and their content - for measuring safety and harm. However, this approach is not advocated as part of a safety measurement system. This is because of the costs – both direct (financial and emotional) and indirect (detrimental effect on reporting culture, openness; promotion of defensive medicine) – and the inconsistent nature litigation can be applied based on individual circumstances. However, openly discussing incidents with patients and their carers is an important component of adverse event notification, reporting and learning (Box 1).

Box 1. Open disclosure, learning and a reporting culture

The open disclosure and discussion of medical error and adverse events with patients, their families and carers[11] is important. It entails explaining what occurred, apologising for the incident, describing what steps are being taken to prevent recurrence, and discussing appropriate compensation. Several health systems have instituted open disclosure policies with varying statutory requirements and sanctions for failing to disclose error. For example:

- Canada www.patientsafetyinstitute.ca/en/toolsResources/disclosure/Pages/default.aspx
- United Kingdom www.nrls.npsa.nhs.uk/beingopen/?entryid45=83726
- Australia www.safetyandquality.gov.au/our-work/open-disclosure/the-open-disclosure-framework
- United States: Sorry Works Coalition https://sorryworks.net/

Open disclosure has been shown to convey a range of benefits. For patients, it allays feelings of anxiety and abandonment after harm and has also been shown to have a cooling effect on desires to litigate - most commonly motivated by patients simply wishing to find out exactly what happened when faced with evasion and lack of communication.[12] For providers, who can be seen as the 'second victims 'of harm[13], open disclosure can be a healing process. It also contributes to a sense of psychological safety about disclosing and reporting safety lapses. The frank two-way discussion with patients can reveal valuable information about the reason for harm from the patient perspective – enhancing learning and improvement (see section 3). Open disclosure - endorsed and supported by organisational leaders – also contributes to the 'just culture. A proactive approach has also been shown to reduce the amount of compensation and litigation.[14]

No-fault compensation schemes can facilitate better reporting, disclosure and learning

To encourage the open disclosure of harm and reduce burden and costs of adversarial

[11] Henceforth 'patients' refers to the patients as well as their surrogates.

[12] See https://www.safetyandquality.gov.au/publications/open-disclosure-standard-review-report/

[13] See http://www.bmj.com/content/320/7237/726

[14] See https://www.safetyandquality.gov.au/publications/open-disclosure-standard-review-report/

compensation procedures, many countries have instituted 'no-fault' compensation schemes for medical injury. These include Japan (for cerebral palsy for babies born since 2009) New Zealand (since 1972), Sweden (1975), Finland (1987), Norway (1988), Denmark (1992) and France (1994). No-fault models have been suggested or piloted in the United States[15]. Such system benefits patients and communities. They can be more efficient than tort-based processes. More importantly they can contribute towards cultural transformation, removal of barriers to reporting harm and can facilitate an open discussion with patients. The result is better and more complete data collection, encouraging good clinical practice and reducing defensive medicine. While concerns also exist about the potential cost of a no-fault scheme, based on the possibility that more claims be made under this type of system, little evidence of this can be found in systems listed above.

17. Open disclosure and no-fault compensation schemes can be an important part of safety measurement, reporting and improvement. But they do not to supplant disciplinary processes and sanctions where harm is the result of negligence and malpractice as opposed to failure of processes and systems.[16]

Routinely Collected Data Enhance Our Understanding of Safety

18. National datasets that are homogenous, standardised and consistent over time are an essential component of a comprehensive approach to safety measurement.

19. Health care services, particularly hospitals, routinely record and report data on patient care. These administrative data include diagnoses, treatments and procedures drawn from patients' health record. They contain a rich set of information -- medical, nursing and allied health documentation of diagnosis, care planning and monitoring of care provided, outcomes including the results of pathology and imaging tests, as well as demographic and other relevant information.

20. The resulting national hospital administrative datasets have been increasingly codified and intentionally standardised and harmonised. Many countries now have mature routine hospital administrative datasets -- with competent clinical coding workforce and strong adherence to data definitions, classifications and standards -- which are, in many cases, also used for reimbursement and funding.

21. These administrative data can differ, both in scope and coverage, from that which can be generated from retrospective audits of medical records or clinical and quality registers set up for specific purposes. But the routine nature of the data coupled with ICD standardisation enhances its utility for measuring safety.

22. These data can capture safety lapses at local (hospital), jurisdictional and national level. The information can be reported as necessary and for improvement, benchmarking and comparison. Learning can occur **not only from when things go**

[15] Clinton HR, Obama B. Making patient safety the centrepiece of medical liability reform. N Engl J Med 2006; 354: 2205-2208.

[16] http://iris.wpro.who.int/bitstream/handle/10665.1/11350/9789290617211_eng.pdf;jsessionid=B617154C05DE85BFFF0DC861069F4114?sequence=1

wrong but also from situations, settings and organisations **where safe care is delivered consistently over time**.

23. Australia, for example, has developed a set of 16 hospital-acquired complications (HACS) presented in Table 3. Many of the HACs represent adverse events whose occurrence – while perhaps difficult to prevent in each single case – may, in aggregate, be reduced through consistent mitigation strategies (Table 3). A similar approach has been taken in Canada.[17] These schemes rely on the existence and consistent use of a 'present on admission' flag, which denotes if the relevant HAC was acquired during the hospital stay or already present when the patient was admitted.

Table 3. Australian hospital acquired complication (HACs)

1. Pressure injury	2. Gastrointestinal bleeding
3. Falls resulting in fracture or intracranial	4. Medication complications
5. Health care associated infection	6. Surgical complication with unplanned return to theatre
7. Delirium	8. Persistent incontinence
9. Unplanned intensive care unit admission	10. Malnutrition
11. Respiratory complications	12. Cardiac complications
13. Venous thromboembolism	14. Third and fourth degree perineal laceration during delivery
15. Renal failure	16. Neonatal birth trauma

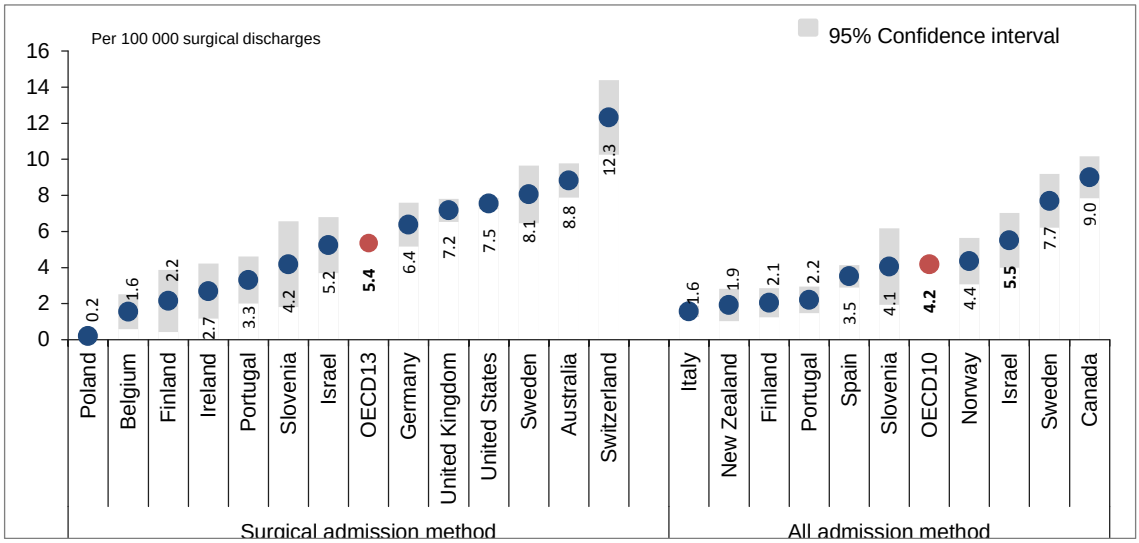
Source: https://www.safetyandquality.gov.au/our-work/indicators/hospital-acquired-complications/

24. These data can be used to identify serious adverse events such as a foreign object left inside a patient at the end of a procedure (Figure 1) or postoperative sepsis (Figure 2). The OECD has been working on making these measures internationally comparable since 2004.[18]

[17] See https://secure.cihi.ca/free_products/cihi_cpsi_hospital_harm_en.pdf

[18] See https://academic.oup.com/intqhc/article/21/4/272/1800987

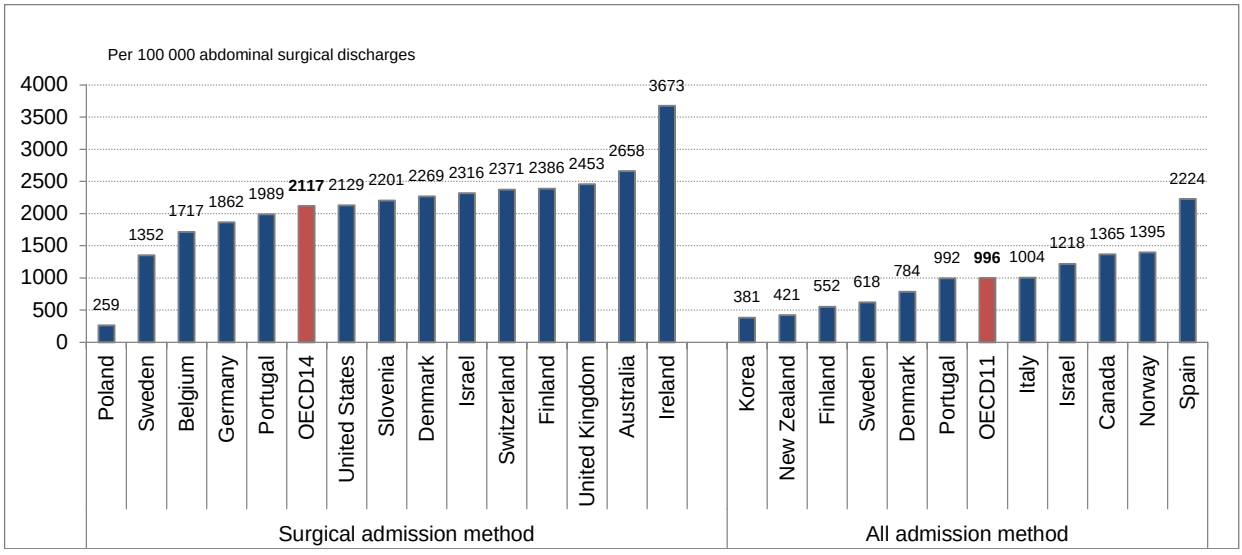
Figure 1. Foreign object left after procedure, 2015 (or nearest year)



Note: The **surgical admission method** uses unlinked data to calculate the number of discharges with ICD codes for the complication in any secondary diagnosis field, divided by the total number of discharges for patients aged 15 and older. The **all admission method** uses linked data to extend beyond the surgical admission to include all subsequent related re-admissions to any hospital within 30 days.

Source: ***https://www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2017/foreign-body-left-in-during-procedure-2015-or-nearest-year_health_glance-2017-graph89-en***

Figure 2. Postoperative sepsis in abdominal surgeries, 2015 (or nearest year)



Note: as for Figure 1

Source: *www.oecd-ilibrary.org/social-issues-migration-health/health-at-a-glance-2017/postoperative-sepsis-in-abdominal-surgeries-2015-or-nearest-year_health_glance-2017-graph91-en*

Deploying administrative data for safety measurement requires further work

25. The capacity to calculate reliable and comparable indicators is predicated on the quality of the underlying national data infrastructure. Robust coding quality and depth of data systems, especially with respect to the depth of coding of secondary diagnosis and condition onset flagging is crucial and has been achieved in some countries through sustained investment and development. In others, further evolution of their health data infrastructure is required.

26. Significant variations in secondary diagnosis coding depth across countries impact on the level of complication rates recorded.[19] Further, not all countries use a present on admissions flag to denote if a condition (such as an infection) was acquired during admission. Similarly, about a third of OECD countries lack or do not deploy a unique patient identifier that can link hospital admissions across hospitals over time, limiting the possibility to associate safety lapses with previous contact with the health care system.

27. Significant scope exists to further improve the access to and quality of national administrative data systems, and how these link with the broader health data infrastructure. Integration can greatly enhance the ability for providers, policy makers and patients to have a complete picture of safety and harm across settings and sectors.

28. In addition, while hospital administrative data are mature, they remain incomplete in primary and ambulatory care in most countries at every stage of development. Enabling the harvesting of adverse events indicators in other settings must therefore be rectified by improving the information infrastructure, especially the detail, coverage and consistency of administrative data in non-acute care. Until such time, another source of routine data – clinical records – can also be deployed, as discussed next.

Retrospective medical record review can identify undiscovered harm

29. Some OECD countries are giving greater attention to the use of retrospective record review processes to collect data and report on patient safety events.

30. The approach based on the US Institute for Healthcare Improvement's **Global Trigger Tool (GTT)** is of particular interest. It can be applied to all care settings where clinical records – both electronic and paper based – exist. It can also be applied in countries across the spectrum of development.

31. The GTT involves a two stage review process. In the first stage of the review, a registered nurse or other health professional scans a randomly selected sample of patient records for predefined triggers and possible adverse events connected to the trigger. Triggers are indicators that might show that an adverse event has occurred during admission (e.g. reoperation, transfer to the intensive care unit after surgery). In the second stage, a review team typically consisting of the registered nurse and a physician closely scrutinise all notes to confirm cases that had a possible adverse event.

[19] See https://www.ncbi.nlm.nih.gov/pubmed/21762143

32. National implementation of the GTT across all hospitals in Sweden and Norway is providing encouraging results in enabling a cost-effective and sustainable way to monitor patient safety at the national level, while providing regular routine access to helpful organisation-level data.

33. Sweden is now exploring the application of the GTT to psychiatric care, community care, long term care and paediatric care. Further consideration of the potential for extended international application of this approach is indicated, particularly in countries that are yet to establish mature national hospital administrative databases.

34. As health systems digitalise their health or medical records, deploying algorithms to conduct automated risk triggering has been shown to capture significantly more harms than the manual method.[20]

Patient-reported safety measurement is vital

35. Patients can provide a unique and valuable perspective on the processes and outcomes of care – including adverse events.[21] The value of eliciting this information directly from patients is accepted as a lever to improve quality of care. Information on care experience and outcomes can yield valuable insights into the success and failure of care, insights which are rarely detected by other methods. Only the inclusion of patient-reported measures will fill this gap and provide a complete picture of safety across the health system. It is also necessary to pivot towards a patient- and people-centred approach to care more generally, and provide information on whether resources spent on health care are delivering results for patients**.**

36. Most patient-reported questionnaires monitor three domains of safety: incident prevention, patient-reported incidents, and how incidents are managed. Each domain includes a number of sub-domains on which questions are based (Table 4).

Table 4. Domains and sub-domains in patient safety

Incident prevention	Patient-reported incidents	Incident management
Information sharing and management Information on illness and symptoms Infection prevention Medication safety Need for further care and treatment	Diagnosis and treatment-related incidents Medical complications and patient accidents	Incident reporting Incident handling (e.g. disclosure and discussion)

Source: OECD Survey for Selecting a Core Set of Questions.

[20] See for example http://www.jointcommissionjournal.com/article/S1553-7250(17)30010-7/pdf

[21] See http://www.euro.who.int/en/health-topics/Health-systems/patient-safety/publications2/2011/patient-engagement-in-reducing-safety-risks-in-health-care

37. Incident prevention, Patient-Reported Incidents and Incident Management are all important domains because they provide a description or 'story' of an incident - from the predisposing factors, risks and circumstances to managing and resolving the harm. Patients should have adequate scope to report the experience of safety and harm, but should not be overburdened with excessively long and complex surveys. Nine questions that could be prioritised in a patient-reported safety questionnaire, based on relevance and frequency of the type of harm, and on how the feasibility of concrete, effective action on the information derived, are presented in Table 5.

Table 5. Questions to measure patient-reported safety

1. Did the health professional you consulted know important information about your medical history?
2. Did a member of staff confirm your identity prior to administering your medication?
3. Did a member of staff confirm your identity prior to your procedure/operation/surgery?
4. Before you left the clinic/hospital, were you given any written or printed information about what you should or should not do after leaving the clinic/hospital?
5. Did a member of staff explain the purpose of the medications you were to take at home in a way you could understand?
6. Did a member of staff explain to you how and when to take the medications?
7. Did you experience a medication-related error (e.g. wrong prescription, wrong dose, wrong time, dispensing error in pharmacy, wrong administration route, reported allergic reaction, omitted by mistake)?
8. Did you see, or were you given, any information explaining how to provide feedback or complain to the clinic/hospital about the care you received?
9. If you experienced mistakes or unnecessary problems in connection with your clinic visit/hospital stay, did the staff handle the mistake or problem in a satisfactory way?

Source: OECD Survey for Selecting a Core Set of Questions.

Conclusion

38. Patient safety has gained policy attention over the past three decades. But the true extent of safety and of harm across all health care settings and sectors is still a black box, often because of fears from health professionals that reporting will lead to punitive action, but also because of a lack of the necessary systems and structures.

39. Measuring safety – both in terms of when things go wrong *and* when safe, reliable care is delivered – is the starting point to improve patient safety. Without measurement, actions to drive improvement are impossible.

Measurement is the starting point to improving patient safety and quality of care.

40. Measuring patient safety across an entire health care system comprises three key components.

41. The foundation is an **adverse events reporting system**. The rationale is to provide information for learning and improvement to relevant actors and organisations. This should therefore include, when relevant, 'near misses', as these can contain valuable information. Reporting can be anonymous, and voluntary or

mandatory. However, it must be underpinned by a 'just culture' free from blame and retribution. Open disclosure – the open discussion of incidents with patients – is an important part of encouraging the necessary openness and transparency for reporting to work. Involvement of providers, clinicians and patients in the design and implementation of adverse event reporting is key.

42. The second component is **routinely collected data,** which can be a rich source of information and learning on safety. Administrative data, generated by the clinical record, can systematically identify a number of safety lapses and adverse events, over time and across settings. This can enable comparison and learning, not just from instances of harm but also from situations where safe care is consistently delivered. However, such measurement depends on consistent and robust coding, an integrated data infrastructure and the use of a condition onset flag. Retrospective clinical record review – whether electronic or paper based – can also be used. Methods such and the Global Trigger Tool can be applied in all settings and in all countries to systematically measure the occurrence of harm.

43. The third component is **patient-reported measures**. These form an essential component of people-centred services. They also contain valuable, detailed information from the patient who has a unique and unrivalled perspective of the entire health care journey and the cascade of happenings that lead to harm. Much of this information does not appear in other data and is not detected using other measurement methods. A short patient questionnaire focusing on incident prevention, incident occurrence and incident management is an essential part of measuring and improving safety.

44. Measurement is important but is not an end itself. Policy levers must ensure that action is taken to improve where problems exist as well as learning from, and spreading, good practice. Action must be enabled at practice level, organisational level and system level through sound reporting and information sharing. Public reporting may be appropriate but without compromising the principles of a 'just culture'. Reporting and benchmarking at national and international level can be useful levers for learning and improvement.

The benefits of preventing harm and improving care far outweigh the costs of measurement and action.

45. Measuring safety and harm - as described in this brief - is essential in all settings across the developed and developing world. It is possible even with limited resources. The benefits of preventing harm and improving care far outweigh the costs of measurement and action.