Patient safety — a balanced measurement framework

John G Wakefield and Christine M Jorm

Abstract

Evidence of the unacceptably high incidence of patient harm associated with health care has resulted in patient safety becoming a major reform agenda. Despite significant investment by governments on strategies to reduce patient harm, confusion still exists on how to measure patient safety.

While the goal of patient safety is harm prevention, most of the measurement focus has been on counting incident reports. The (ab)use of reported incident data to measure both technical safety performance (injury rates) and evaluate the effectiveness of safety improvement initiatives continues to confuse and mislead consumers, funders and providers of health care.

This paper proposes a simple measurement framework for patient safety which balances the elements of: *learning, action, performance*, *patient experience, and staff attitudes and behaviour.* Application of this framework to current priority areas should be used as a basis for patient safety improvement at clinical unit, hospital, state and national levels.

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What is known about the topic?

It is hard to measure safety performance, that is, the true adverse event or injury rate. Incident reports are often incorrectly used for this purpose. Measures of harm alone are not sufficient to help us determine how to improve safety (ie, for harm prevention).

What does this paper add?

This paper introduces a comprehensive measurement framework for patient safety. Measures are suggested for the complementary elements of: safety learning, safety performance, patient experience, and staff attitudes and behaviour. Use of measures for all these elements tells us why incidents occur, whether corrective action is being undertaken, the quanta of harm, whether patients feel safe and about the organisational safety culture.

What are the implications for practitioners?

Application of this measurement framework produces a comprehensive assessment of patient safety. Use of the framework will ensure that the detailed understanding of a safety issue essential for effective improvement work is always available.

OVER THE PAST fifteen years, patient safety has become the focus of significant national and international health reform activity. Despite this, the measurement of patient safety has remained a challenge, particularly at jurisdictional level. This paper seeks to address this issue by proposing a simple patient safety measurement framework involving five measurement domains. All have limited scope, each being best for a specific purpose, but used together can assist an organisation in measuring and improving patient safety.

Multiple patient safety measures have been proposed and combined; however, very few assess patient safety performance (true rate of patient harm). It has recently been suggested that "while most hospitals measure some aspect of patient safety, there may not be comprehensive measurement in up to 44% of hospitals",[1] (p. 39) yet these authors did not define or justify a set of measures that would constitute comprehensive measurement for safety. The practical framework outlined in this paper, while pragmatic in its scope, represents a comprehensive view of patient safety measurement.

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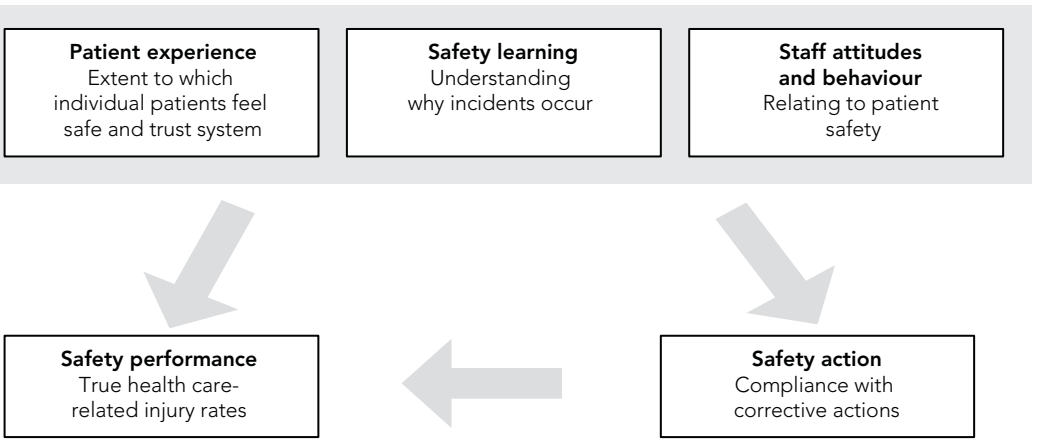
1 Proposed Patient Safety Measurement Framework



The measurement problem in patient safety

There has been an increasing worldwide emphasis on accountability and governance in the health system.[2] This has led to an increased organisational and public focus on measurement of patient safety.

Despite this, patient safety is an elusive concept to both understand and measure. What does it mean to be safe? — a system where no errors occur, or a system in which patient harm as a consequence of error is minimised? Measurement of patient safety is difficult, mainly due to our inability to define and accurately quantify patient harm, and an inappropriate focus on individual error. Particular problems include distinguishing safety from quality,[3] the negative connotations of error,[4] the poor linkage of error with patient harm,[5] and the emotion that surrounds preventable patient harm.

At the heart of confusion over patient safety measurement has been the misuse of *reported* clinical incident data as a measure of patient safety performance. Counting reported incidents is a futile exercise. Probably due to an absence of true safety performance data, this practice continues at facility, state[6-9] and national levels.[10] The figures are often misinterpreted as safety performance data, causing community and political concern.

Under-reporting of incidents is the norm, with as few as 1% of incidents being reported.[11] Reported incidents thus provide "only a very incomplete reflection of actual incidents".[12] (p. 71) Some authors suggest that while there is likely to be greater accuracy about counts of more serious incidents,[13] staff still have considerable discretion in regard to reporting. Incident data are biased, primarily comprising errors of commission (rarely including errors of omission) and mainly reported by nursing staff.[14-16] For all of these reasons, reported incident data are not suitable for measuring safety performance. The true value in incident reporting lies not in counting incident reports, but in the analysis and understanding of causation and the subsequent actions to prevent patient harm through "error proofing" the system.

While there has been an inappropriate use of incident data for performance purposes, there has been a lack of attention paid to the traditional components of safety management systems such as developing and implementing standard operating procedures, auditing, and managing noncompliance. Other industries have recognised the link between staff attitudes and behaviours (culture) on safety outcomes. While patient safety culture has not been extensively studied in Australia, there is emerging evidence of a similar link in health care.[17]

2 Balanced Patient Safety Measurement Framework

Measurement domain	What this measure is best for	Measurement source	What this measure cannot do	Use of this measure in Australia
Safety learning	Understanding *why* incidents occur	Incident reports Incident analysis findings Claims data	Determine safety performance (reported incidents actual incidents)	Well established
Safety action	Determination of whether the *corrective action* is being performed	Compliance audits of specific patient safety initiatives (eg, observation audit of handwashing)	Determine whether the action has led to improved safety (implementing a strategy does not guarantee improved safety)	Poorly established
Safety performance	Determination of true adverse event or injury *rate*	Coded medical record data for hospital acquired injury Trigger tools Standardised mortality data and variable life adjusted displays (VLADs)	Determine the underlying causes for incidents (merely knowing adverse event rate does not contribute to improved safety)	Variable
Patient experience	Understanding whether patients *feel safe* and trust health care staff and health care system and measuring patient reported harm	Patient surveys Complaints and compliments Online patient rating systems	Determine safety performance (feeling safe is important but is not necessarily equated with low rates of harm)	Variable
Staff attitudes and behaviour	Understanding organisational safety culture	Staff safety culture measurement tools (eg, Safety Attitude Questionnaire [SAQ]; Manchester Patient Safety Framework [MaPSaF])	Determine safety performance	Variable

Proposed Balanced Measurement Framework for Patient Safety

Our proposed Patient Safety Measurement Framework (Box 1) contains five interconnected domains. The table in Box 2 (derived from one developed for *Patient safety: from learning to action II*[18]) details this patient safety measurement framework which includes measures for the essential and complementary elements of: *learning, action, performance*, *patient experience, and staff attitudes and behaviour*. The left-hand column groups measurement sources into domains. The list is not complete, and new measures will be developed that can fit into this framework. The right-hand column is a rough reckoning of the current status of the use of these measurements in Australia. Many of these measurement domains are well developed in jurisdictions, but not universally so, and few are as yet advanced in integrating these measures to improve safety. Little of the substantial measurement performed by the private sector is publicly available. In the table are some notes explaining each domain, its significance and discussion of common measurement sources (a fuller analysis of the competing claims of measurement sources within each domain is beyond the scope of this paper).

Safety learning

Incident reporting and analysis are crucial for improvement: "Without an *understanding* of why

incidents occur, it is not possible to design and implement solutions".[8] (p. 16) In organisations with an emphasis on patient safety, especially when reporting is seen by the reporters to lead to action and improvement, reporting occurs more often.[19] Reporting similarly rises when organisational attention is paid to an area (eg, increased attention to medication incidents through education and awareness raising is likely to be associated with more reporting of medication incidents,[20] even though there may be no change to the number of patients suffering harm from medication incidents). Hence, no estimates of rates or trends are reliable and these data can neither be used to measure technical safety performance nor the effect of any improvement initiatives.[21]

Normal accident theory[22] would hold that errors will continue to occur, but the consequences of errors can be reduced by analysis and system improvements. However, in both the United States and United Kingdom the emotive term "never events"[23] is now becoming popular. This labelling is used to justify not just mandatory reporting of certain events but also sanctions — withholding payment when these events occur.[24] The introduction of financial and other sanctions may have risks for patient safety as it is known that a culture of shame and blame creates a negative environment for adverse-event reporting[25] and for the learning that is necessary for system improvement.

Safety action

This area is a relatively recent focus for managers. Implementation of improvements is hard. For instance, preventable deaths due to intrathecal vincristine continue to occur worldwide[26] and continuing patient mismatching errors (eg, wrong side and wrong site procedures) are reported in Australia[10] despite the "implementation" of the *Ensuring correct patient, correct site, correct procedure* protocol in 2004. Observational data (as yet unpublished) on compliance with this particular protocol suggest that compliance is poor. Clearly, there is a big difference between issuing a protocol and its universal adoption into practice. This is in part related to professional cultures of autonomy and individualistic concepts of care.[27] If we are serious about improving patient safety, then compliance with critical safety standardised operating protocols (SOPs) must be monitored and consequences for non-compliance defined and actioned.

Safety performance

Detailed research reviews of medical records show large discrepancies in the reported rates of adverse events; major sources of variation appear to be reviewer interpretation and quality of the medical notes.[28-30] Such research is also very expensive. Australia, however, has outstanding collections of routinely collected coded ICD-10 (International classification of diseases, tenth revision) data. It is not a complete source of information and there can be errors in coding but the process of coding is routine and it is proving an increasingly recognised source of safety data.[31,32]

The review of medical records for specific indicators of harm or "triggers" was developed as a way of improving the detection of adverse events and reducing the cost of record screening,[33] but as data are increasingly available electronically, triggers have enormous potential as sources of routinely collected patient safety performance data. Examples include: biochemistry (eg, low blood glucose levels or high INR), pharmacy (eg, use of flumazenil or naloxone to reverse benzodiazepine and narcotic overdoses) and microbiology (eg, rates of resistant organisms). It is important that electronic medical records are designed to capture safety performance and to eventually ensure it by incorporating pathways for care, decision support and indicators.

Standardised mortality rates have also demonstrated promise as performance indicators for surgical quality.[34,35] Queensland has successfully applied statistical process control to measures of technical safety performance focussed on learning and improvement.[36]

3 Prevention of health care-associated infection (HAI)

Measurement framework example for HAI

HAIs are a frequent and preventable adverse event associated with health care. There are estimated to be 200 000 cases in Australia each year which use 2 million bed-days.[49] Preventive measures such as: hand hygiene, intravascular catheter care, perioperative antibiotics and antibiotic stewardship can reduce both the frequency of and associated morbidity and mortality of HAI.[49]

Safety learning	Case review and analysis of reported infections,[50] audits of infection practices such as perioperative antibiotic practices and epidemiological study of patterns of infection and resistance
Patient experience	Patient survey data on safety experience during hospital stay, hospital cleanliness, staff hand hygiene
Staff attitudes and behaviour	Staff safety culture, infection control beliefs and perceptions of behaviours, eg, in relation to disease transmission and hand-hygiene behaviours
Staff attitudes and behaviour	Staff safety culture, infection-control beliefs and perceptions of behaviours, eg, in relation to disease transmission and hand-hygiene behaviours
Safety performance	HAI performance data for surgical site infections, vancomycin-resistant enterococci, methicillin-resistant *Staphylococcus aureus* and *Clostridium difficile* rates, proven bloodstream infection, and norovirus outbreaks

Patient experience

Patients and staff have different understandings of both risk and safety in health care and patients may have difficulty in understanding numerical concepts of risk.[37] Patients use proxies to assess safety. These may include communication and listening skills of staff, empathy, cleanliness and tidiness of work areas, efficient manner of staff, etc. It has been shown that emergency department patients were attuned to environmental cues they perceived as linked to possible errors.[38] The staff culture required to ensure high levels of technical safety is also a culture that values empathy and patient centredness. Patient experience can be measured[39] and is an essential component of patient safety measurement.[40]

While understanding patient experience of safety is important in and of itself, patients are also able to provide data to assist with some of the other measurement goals. Patient-reported incidents[41] can assist with learning. Patients are likely to have an increasing role in assisting with measurement of performance via the development of patient-reported outcome measures (PROMs).[42,43]

Staff attitudes and behaviour

The attitudes and behaviours of staff are critical to fostering the workplace culture needed to ensure patient-centred care, effective communication and safety.[44] An organisational culture of safety has been described and can be measured using existing tools.[45-48] For medical staff, individualistic concepts of clinical care, opaque accountability[27] and absence of consequences for non-compliance with SOPs reduce the likelihood of organisationally endorsed strategies for patient safety being a high priority.

Illustrative use of the Framework

In order to best illustrate how such a framework may be used to effectively measure an aspect of patient safety, the example of the prevention of health care-associated infection is used (see Box 3).

Conclusion

It is generally agreed that triangulation of data from different sources is likely to enable more successful improvement in safety,[51] and the strength of the Framework proposed here is to encourage a structured approach to the use of the

different measures that are available. Some of these measures are more routinely used in Australia to measure patient safety than others. It has been suggested that external regulatory requirements have been the facilitator for the greater development of incident-reporting processes than other forms of safety measurement.[1] Therefore, there could be a possible role for more external regulation to encourage routine use of measures to capture the essential and complementary elements of: *learning, action, performance*, *patient experience, and staff attitudes and behaviour*.

Measuring technical safety performance remains a significant challenge. Without reliable data on rates of patient harm in key components of care, it is impossible to know how safe we really are, and whether the investment in strategies to improve patient safety is having an impact. In the absence of such measures, it is inevitable that the focus will remain in incident reporting as a de facto performance measure. This should be resisted for the reasons outlined above.

A starting point for use of the Patient Safety Measurement Framework could focus on high risk areas such as medication adverse events, falls injury, pressure ulcers, health care-acquired infection, and in-hospital suicide, with focussed measures for each in all of the five domains. Application of this balanced Framework will enable a more comprehensive assessment of patient safety as a basis for improvement at clinical unit, hospital, state and national levels.

Competing interests

The authors declare that they have no competing interests

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