Measuring safety in healthcare: a critical challenge

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Abstract

Considerable efforts have been made to improve the safety of healthcare. We still however cannot provide a definitive answer to a very simple but critical question. Are patients any safer? This paper addresses the challenge of how we can best measure safety in order to monitor improvement in the safety of health care systems over time and to inform future safety improvement. We argue in particular for greater transparency, more patient involvement, an expanded definition of harm, specific definitions of types of harm in different contexts and the development of proactive measures of system safety.

Introduction

For a decade and more healthcare professionals in many countries have expended considerable efforts on improving the safety of healthcare. We have implemented reporting systems, brought tools from industry to characterize risks, and developed standardization, protocols and guidelines and safety policies. We have attempted to assess the effect of actions at both local and national levels on outcomes, processes, incidents and adverse events. We still however cannot provide a definitive answer to a very simple but critical question. Are patients any safer? (1-3).

In contrast the medical treatment of many common diseases has shown a steady advance, with a continuing reduction of deaths, increased access to care, increased quality of life and healthy life expectancy. Public health indicators clearly show positive and continuing improvements in many areas such as cardiovascular disease and cancer survival(4, 5). The understanding gained from the application of evidence based medicine and formal evaluations from controlled trials seem at odds with the continuing anxiety about the risks of healthcare. In part this is due to media focus on rare but tragic events, but there is also a sharp contrast between improving outcomes and increasing evidence of poor reliability, high rates of errors and harm. The lack of integration of these different measurement strategies and systems is a critical problem. Studies of effectiveness do not give sufficient attention to risk and harm; studies of safety are not contextualised within broader measures of effectiveness and benefit.

Our inability to determine whether healthcare systems are safer is partly due to practical problems (such as lack of investment in usable measurement systems) but also reflects a lack of clarity about what we mean by safety, the purpose of measuring safety, what measures are appropriate and the barriers and unforeseen consequences of assessing safety. Measurement is essential to clinical engagement, team performance, board engagement, monitoring, and evaluation; the lack of reliable measurement is causing problems on all of these levels. This paper addresses the challenging question of how we can best measure safety in order to evaluate the impact of safety improvement interventions, to monitor improvement in the safety of health care systems over time (reduction of harm to patients) and to inform future

safety improvement. We consider the key challenges of safety measurement and offer suggested directions for research and practice over the next five years.

Defining safety

Safety comes from the French word, *sauf*, which means both "without" and "unharmed". The origin of the word lies in the Latin *salvus*, meaning uninjured, healthy or safe. Safety means both freedom from harm (in that we arrived safely after a train journey) but also freedom from danger (we believe that the railways are safe and we will arrive safely after our next journey). Ideally we wish to assess both the accident rate but also the likelihood of accidents.

The extent to which safety is focused primarily on instances of harm, as compared with a wider systemic vision, is reflected in definitions of safety. For instance the WHO World Alliance for Patient Safety Drafting Group for the International Classification of Patient Safety defined it as "the reduction of risk of unnecessary harm associated with healthcare to an acceptable minimum"(6), with others seeking more concise definitions such as 'freedom from harm'. In contrast Hollnagel(7), for instance, has argued for a more systemic approach based on a view that safety in an organisation is the ability to succeed under varying conditions (respond, monitor, anticipate, learn). This does not mean that we abandon measures of harm or cease to learn from past failures, more that we endeavour to broaden our perspective to consider how safety is achieved on an ongoing, pro-active basis and how we might assess the current safety of a healthcare system (8).

Defining harm

Defining harm and its relationship to the care received is not straightforward. Death following wrong injection of concentrated potassium chloride is immediate and clearly directly related to a failure in the process of care. In contrast, death following myocardial infarction (MI) in the absence of treatment with aspirin may be a natural process related to the increased risk of subsequent MI in someone who has established cardiovascular disease, in which the omission of aspirin played little part. The causal attribution of a negative outcome in any specific case remains a matter of clinical

judgement, which engenders considerable variability in the coding and reporting of such events. For instance, in a safety system heavily dependent upon reporting, the injection of potassium chloride is likely to be reported as an incident whereas death following MI in the absence of aspirin is not. There are however a number of on-going attempts to reduce this variability and standardize coding of patient safety indicators (9).

The example of myocardial infarction illustrates a further difficulty with measuring safety, which is that our understanding of what is safe and unsafe changes over time. In road and rail the concept of an accident remains relatively stable over time, though we may aspire to increasing standards of safety. In healthcare however a new standard of investigation of cancer symptoms within two weeks will change our definition of delay in diagnosis. As medicine continually advances the standard of acceptable care continually changes, and consequently also the standard of unacceptable care.

Defining the perimeter of patient safety

Most national patient safety programmes have given high priority to severe and fairly clear cut adverse events, such as drug errors, wrong site surgery and infections, all of which occur in a relatively narrow time frame. However there is a developing argument in the scientific community for widening the scope of patient safety to a longer time frame which encompasses care across different settings. In this broader framework an assessment of safety would consider the cumulative effects of all failures in the delivery of care and their impact on the final outcome for the patient, not just the specific incidents and adverse events within the patient journey(10). More attention would also be paid to the capacity of the healthcare system to detect and recover from adverse events. Ghaferi and colleagues(11) have shown that hospitals with the highest surgical mortality rates are not those with the greater number of surgical adverse events, but those with poorer capacity to deal with the timely recognition and management of complications once the adverse events occur. In this broader vision only the final result including the recovery from adverse event provides a fair judgment of the safety of either the individual patient or the system as a whole(12).

A typology of patient harm

The term `adverse event', broadly meaning harm due to medical management rather than disease, was coined in a medico-legal context and has been adequate for broad brush epidemiological analyses that revealed the scale of harm to patients; this term however is loosely and variably used (13).The phrase `patient safety incident' is useful in the context of reporting but cannot be defined closely enough to permit reliable identification and measurement. Similarly `medical error' is fraught with ambiguity and susceptible to a number of different interpretations (13).If we want to measure incidents, errors or harm we need to first classify the types of harm we are concerned with and then provide definitions of specific harms. We propose the following broad system of classification of types of harm to individual patients from healthcare:

Harm resulting from delayed or inadequate diagnosis

Some harm results because the patient's illness is either not recognised or is diagnosed incorrectly. A patient for instance may delay contacting their doctor for months after noticing rectal bleeding, delaying a cancer diagnosis. Alternatively they may be misdiagnosed by their primary care physician who fails to refer. In either case the cancer advances and outcome is probably poorer. This type of harm has not necessarily been traditionally considered within the realm of patient safety, unless in the context of a glaring diagnostic error, but to the patient it is clearly a form of harm.

Treatment specific harm

By this we refer to harm that may result from specific treatments or the management of a particular disease. This would include adverse drug reactions, surgical complications, wrong site surgery and the adverse effects of chemotherapy with varying causes and degrees of preventability in any specific case. Within these we can distinguish known complications of treatment, such as a post-operative stroke after an episode of hypertension during surgery, and events such as death from a spinal injection of vincristine which, while treatment specific, is clearly not an inherent risk

of the treatment. We should note that an important source of treatment specific harm is harm due to over-treatment. For example the overuse of antibiotics may lead to C difficile infection; excessive use of sedatives increases the risk of falls; dying patients both young and old may receive treatments which are painful or burdensome and of no benefit to them.

General harm from healthcare

While some types of harm result from treatments given for specific diseases, others reflect risks going beyond specific treatments. Hospital acquired infections, falls, malnutrition, and dehydration are the most obvious example in that any patient with any disease may be harmed in these ways. We should recognise of course that some patients, such as older patients or those in intensive care, are more likely to sustain these harms than others and that certain diseases render patients more liable to fall, sustain infections and so on.

Harm due to failure to provide appropriate treatment

We know that many patients, perhaps the majority, fail to receive standard evidence based care and that, for some patients, this means their disease progresses more rapidly than it might. Examples include failure to provide rapid thrombolytic treatment for stroke, failure to provide rapid and effective treatment for myocardial infarction, and failure to give prophylactic antibiotics before surgery.

The impact of failure to provide treatment can be hard to judge. In such cases it may be highly probable that failure to provide treatment led to harm; a surgical site infection, for example, would have been avoided in a young, fit person if the antibiotics had been given. In contrast, in the case of failure to give thrombolysis for acute stroke, we can predict poorer outcomes with a degree of certainty at a population level, but would be hard pressed to determine cause and effect at the level of the individual patient. Measuring harm from omissions is always going to require a degree of interpretation so we may prefer to measure the omissions themselves accepting that omissions cause harm even if it is hard to specify which individual omission caused harm. Process measures such as these have in any case a number of

advantages over outcome measures in tracking changes and improvements in care delivered (14).

Psychological harm and feeling unsafe

Adverse outcomes in healthcare commonly have a psychological impact as well as a physical impact. More serious events may induce a range of psychological sequelae such as post traumatic reactions and depression(13). Both patients and staff may be affected. More generally, awareness of unsafe care may have consequences for the wider population, including loss of trust. For instance, people may be unwilling to receive vaccinations, give blood, donate organs or receive transfusions.

Measuring system safety

Safety measurement in healthcare has mostly been based on tallies of past adverse events. However a safe system is one which not only has a reasonable past record, but also responds to threats and pressures in the future, and maintains reliable performance in a changing environment. Such systems would also be able respond quickly to deviations and learn effectively from past failures(15). From a measurement perspective, this raises the difference between lagging and leading indicators: indicators of what has already happened in the past, as opposed to and indicators of the present state of the system and what may happen in the future.

Seeking to assess and measure system safety in a proactive manner is a wonderful ideal but is it feasible in practice? By way of illustration we consider some candidate measures which encompass both unsafe processes of care (process driven indicators) or unsafe conditions at the individual and system level (safety culture, organizational factors and system resilience).

Process failures and predictors of harm

We noted above that patients may experience harm through failure to provide appropriate care. This implies that one key indicator of the safety of a system is the extent to which care is reliably delivered in the sense that the processes of care

conform to accepted standards. In the context of harm we see these process failures as both potential predictors and preconditions for the occurrence of adverse events. Harm can in fact arise either from obviously unsafe care (such as using non-sterile instruments), for from more general failures to conform to accepted evidence based standards (such as not administering pre-operative antibiotics). Some process measures will be more strongly associated with potential harm than others(16)

External assessments

External quality and safety evaluation typically relies on a combination of organisational self assessments and inspection of standard procedures and processes. While they seek to assess the safety of clinical practice, they must necessarily rely on the existence of documentary evidence that standard procedures and practices are in place. As there are few solid measures of safety, we do not really know whether assessments by regulators bear any relation to either the past safety of organisations, still less on their likely performance in the future. For instance the UK MidStaffordshire foundation trust had a satisfactory external evaluation record but was later found to pose significant dangers for patients(17) .

Safety culture

Measures of organisational safety culture and climate can make important contributions to local safety improvement, and some studies have linked measures of either culture or organisational learning to substantive concurrent or past outcomes. For instance, the positive relationship found between measures of safety culture from staff surveys and hospital incident reporting rates is an encouraging finding(18). In a multicentre study conducted in the USA, perceptions of management and safety climate were moderately associated with outcomes (19).In contrast some studies have suggested that a positive safety culture could even inhibit improvements, by inducing a sense of complacency (20).The relationship between safety culture and various organisational characteristics is still being explored and, while culture is a potentially promising leading indicator, we cannot as yet predict the safety of an organisation on the basis of measures of safety culture.

Resilience

The term resilience is used in varying ways, but in this context encapsulates a more aspirational vision in which safety is seen, not simply as freedom from harm, but as the active and continuing achievement of safe operations in the face of hazard. This encompasses adherence to procedures and standards, but is necessarily coupled with anticipation, flexibility of response and the ability to deal with the unexpected. In order to manage the resilience of an organisation, it is necessary to measure system resilience on an ongoing basis. By basing measurements on positive outcomes ('things that go right') rather than adverse outcomes ('things that go wrong') resilience engineering avoids the 'regulator paradox' (21).This refers to the situation where practically all measurable (i.e., adverse) outcomes have been eliminated, and where therefore there is very little or nothing that can be used for the continued management of safety. By emphasising the importance of measuring things that go right, resilience engineering avoids this dilemma. Measurement of resilience is still in its infancy; however a Resilience Analysis Grid has been developed and is being trialled in several industries (8).

Technical issues in the measurement of safety

Measurement of healthcare processes and outcomes involves a host of technical issues relating to their definition, reliability, validity, sensitivity to change, comparability, practicality and cost. In this section we discuss three issues that are of particular relevance to the measurement of safety.

Measurement at different levels and for different purposes

Safety can be understood and measured at a number of levels in a health care system from the individual patient through to system-wide measures. Measures at different levels of the system have different characteristics and serve different functions.

At a macro level major aims include assessment of national progress, comparison of organisations and assessment and monitoring of compliance with standards. Here high

level measures or indicators derived from routine data systems are likely to be the most reliable and cost-effective. An example here is the international work by OECD on development of safety indicators from administrative databases drawing upon experience in North America with AHRQ indicators (9). The following set of indicators was selected in 2009 as being the most suitable for international comparisons: foreign body left in during procedure, catheter-related bloodstream infections, post-operative pulmonary embolism, post-operative sepsis, accidental puncture and laceration, obstetric trauma (vaginal delivery with instrument), and obstetric trauma (vaginal delivery without instrument). Work is now devoted to making the data more comparable, for example, through the use of age-sex adjusted rates versus the use of crude rates. Further examples include hospital standardised mortality rates and hospital acquired infection rates, or measures derived from patient or staff surveys such as staff views on reporting culture.

At the micro level it can certainly be useful for units to compare themselves with benchmark organisations and national data. However it is even more important to track progress locally in order to reflect on and understand variations over time and to analyse serious individual incidents that provide a window on the wider system(22) Indicator interpretation for improvement is necessarily a local activity in that the factors that contribute to a 10% hospital acquired infection rate in one hospital may be very different from another hospital with the same infection rate. This cannot be determined by looking at the rate but requires analysis of the local processes of care and undertaking further in depth local investigation.

The context of measurement. What is good enough?

Measures of both safety and quality are open to bias derived from variation in recording practices particularly when they are used for judgement, accountability or pay for performance purposes (a characteristic of any indicator used in these ways). Alongside this is the continuing challenge of appropriate risk adjustment for case mix (23). There are real concerns that an emphasis on unachievable risk adjustment will deflect energy away from use of measures for improvement. Striking the balance between optimising the use of data and the perception that data is a threat is a key challenge.

The use and potential of indicators are context dependent. A comparatively weak indicator in psychometric terms could, if used in a particular way, be a very strong stimulus to improvement; a very good indicator used in the wrong way could have an adverse impact on improvement. Organisations can monitor safety and effect improvements in the absence of 100% risk adjusted patient information using measures which are strong enough to demonstrate local improvement over time in a relatively consistent patient population (24). Nevertheless in the longer term the goals of transparency, openness and patient engagement will increase both the need and demand for measures of demonstrated reliability and validity.

Measuring rare safety events

While reporting systems can never provide reliable measurement, they do serve a very important function in identifying very rare events. Runciman (25)makes a powerful argument for large scale reporting systems by pointing out that many of the rare events reported would not be identified by record review and would be dismissed as isolated incidents at a local level.

Some adverse events are rare but serious and have come to be regarded as completely unacceptable in a modern healthcare system. They appear, rightly or wrongly, to be caused by clear cut errors and failures and are seen as, in a sense, inexcusable. These 'never events' as they have been termed by the US *National Quality Forum(26),* include 'wrong patient', 'wrong site', 'wrong route of administration of medication', 'retained instrument post–operation', 'in-hospital maternal death from post-partum haemorrhage', 'misplaced naso or orogastric tube not detected prior to use', and 'inpatient suicide using non-collapsible rails'.

Measurement of rates of `never events' or other rare but serious events is problematic in that neither the numerator nor denominator of these events can be reliably assessed. The problem of under-reporting is so great that the rates of events generally grow as safety interventions are implemented, the usual interpretation being that fostering disclosure reveals the size of the problem. The denominator is also difficult to

determine, because it is almost impossible to determine the number of opportunities for error, although rates per patient day or per admission may be calculated.

Barriers and challenges

Encompassing the patient perspective

Patients (and relatives/carers) are keen and interested observers of their interactions with health services and health professionals and there is considerable potential for patients to contribute to the monitoring and enhancement of safety. In terms of defining safety, patients and the public can be involved in exploring what is important to them and in setting standards based on their expectations and experience as service users. In this way we can focus on the development of measures that mean something to the users of health care services.Patient reporting of incidents can be of particular value because the evidence suggests that patients may report a different profile of incidents to those reported by staff (27).Patients can also be asked about their views and experiences of safety through formal surveys that allow denominator data to be used to derive rates for comparability.

Investing in safety

Everyone involved in the healthcare system wants safety, although the pursuit of safety may conflicts with other objectives. As patients we regard safety as an absolute and overriding priority but, as citizens, we may make a more detached assessment of what levels of safety we are prepared to pay for in healthcare and other systems. Wolff (28) has argued for careful consideration of how resources are best invested in safety and quality improvement so as to be most cost-effective. For instance, heavy investment in the reduction of very rare, but serious and egregious, events may have significant opportunity costs by diverting scarce resources away from more common but less prominent problems that ultimately have a higher impact at a population level. A further problem is that the costs of poor care do not always fall on the provider of that care; for instance, failures to effectively manage post-operative infections will often place a large burden on families and primary care than on the surgical unit concerned.

What is the way forward? What can we do now?

Developing methods to measure and monitor safety over time, encompassing both measures of failure and harm and measures of system safety, is clearly a massive challenge. We believe however that it is tractable and achievable in the next five years.

1. We need clarity, transparency and openness

We need to be much more open and transparent with professionals, media and the public on the different forms of harm that can result, both generally and in the treatment of specific diseases. We must also be clearer that safety is not the only goal in the quest to improve care, but one of a number of potentially competing objectives. Care is always a matter of arbitration between access, efficacy, cost and safety. In addition the constant stream of innovation constantly poses new challenges and new risks at the same time as producing new benefits. Trust in healthcare appears to be declining, even though the benefits of healthcare continue to increase. The only way forward however is greater openness about both benefit and harm and particularly about changes over time as we seek to reduce risk while simultaneously increasing benefit.

2. We need greater involvement of patients in safety assessment and measurement

Patients can play a crucial role in preventing and detecting safety problems both as *participants* in care and as *observers* of care. In the past, patients tended to be treated as passive victims rather than active players. Today, there is evidence that patients can play a key role in avoiding unnecessary interventions, in choosing safe providers, in providing accurate information, in asking questions, sharing treatment decisions, monitoring treatment, managing self-carer, reporting complications, reducing infections, and providing feedback on problems.

Survey instruments have been developed specifically to monitor patients' experience of safety-related events and these may prove to be a useful addition to the

armamentarium of safety monitoring techniques if they prove acceptable to patients. Questionnaires that focus solely on identifying errors could be alarming for participants and are unlikely to be embraced enthusiastically by providers. A more feasible approach is to add selected 'safety' questions to more general surveys of patients' experience of care. For example, the national patient survey programme in England routinely asks patients to report on medication side-effects, hygiene and hand-washing practices, and support for self-care.

3. We need to monitor the safety of the entire patient pathway

We need to consider safety across boundaries and beyond the acute setting. The cumulative risks to patients of poor care are many times greater than the risks of single incidents. A wider vision of patient safety is necessary to minimize all adverse events, including those associated with poor quality of care. Patients receive most of their health care in primary care settings. Although the immediate risks may be lower than in hospitals, the large volume of contacts and procedures suggests that safety is likely to be equally critical in primary care. We need pathway indices which span primary, secondary and tertiary care. We also need to assess the risks associated with primary care, mental health, community care and treatment in the home ideally assessing both benefit and harm along the entire patient journey.

4. We must move beyond reporting to reliable measurement of safety

We need to expand the definition of harm and to define the types of harm relevant to each specific context which will in turn mean relying on a number of different data sources. It is clear that data derived from reporting systems are insufficient for monitoring or measuring safety, although they can play an important role in organisational learning and in the development of a safety culture. Measurement of safety must take account of a range of data sources and employ systems of data collection that allow for reliable numerators and denominators (29).This latter argument underpins the use of routine data for assessment and for derivation of safety indicators.

A further challenge is to get the balance right between measurement of events and outcomes on the one hand, and measuring the effective delivery of care on the other.

For the latter, we need a stronger and more extensive evidence base than exists at present to inform safe practice. This would enable us to measure evidence based processes linked to reduction in adverse events in the same way as we can measure evidence based processes to predict good outcomes of treatments.

5. Development and validation of pro-active measures of safety

We will always need to monitor harm and track improvements over time. However in parallel with this we need to develop indices of the safety of organisations which are associated with future reductions in harm and, in time, might function as positive measures of system safety. Such measures become paradoxically more important the safer a system becomes. The purpose of safety management is to reduce or eliminate harm and undesirable variation. However this variation is also the ultimate source of information about the effectiveness of safety management. Therefore, the better safety is managed, the less information there is about how to improve (30). In healthcare we are still a long way from the happy state of insufficient harmful events; we are in fact still unable to determine whether patients are more or less safe than a decade ago (1). We believe however that the problems of both measurement of harm and measurement of system safety are tractable and within our grasp and that the measurement of safety is the defining challenge for the next five years.

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