From assurance to inquiry: a framework for the Measurement and Monitoring of Patient Safety

Moving Measurement into Action: Designing Global Principles for Measuring Patient Safety | Pre-Seminar Briefing Document on Monitoring Safety

Prepared by: Charles Vincent, Professor of Psychology, University of Oxford

Patients, clinicians, managers all want to be reassured that their healthcare organisation is safe. The organisation in question might be a family practice, a ward or department, an entire hospital or healthcare system. But what exactly do we mean when we ask whether a healthcare organisation is safe? People have many different views on what this question means and how to answer it. We produced a report and developed a framework (1, 2) to address this critical question. The development, methods and practical means of implementation are summarised in the appendices to this briefing paper.

Five fundamental questions

- *Has patient care been safe in the past?* We need to assess rates of past harm to patients, both physical and psychological.
- *Are our clinical systems and processes reliable?* This is the reliability of safety critical processes and systems but also the capacity of the staff to follow safety critical procedures.
- *Is care safe today?* This is the information and capacity to monitor safety on an hourly or daily basis. We refer to this as 'sensitivity to operations'.
- *Will care be safe in the future?* This refers to the ability to anticipate, and be prepared for, problems and threats to safety
- *Are we responding and improving?* The capacity of an organisation to detect , analyse integrate, respond and improve from, safety information

Has care been safe in the past? The measurement of harm

Most patients are vulnerable, to some degree, to infections, adverse drug events, falls, and the complications of surgery and other treatments. Patients who are older, frailer or have several co-morbidities may be affected by over-treatment, polypharmacy and other problems such as delirium, dehydration or malnutrition. In mental health suicide, violence and feeling safe on in-patient units are critical. To assess harm from healthcare, we ideally have to consider all these kinds of events (Appendix II).

Are our clinical systems, processes and behaviour reliable?

Reliability, defined as 'failure-free operation over time', is a central concern of all safety critical industries such as aviation and nuclear power for many years. The concept of reliability can be applied most meaningfully to relatively standardized aspects of healthcare. This would include compliance with hand hygiene procedures, the timely administration of antibiotics before operations, the timely ordering of diagnostic tests and many other fundamental

processes. It also covers clinical systems supporting the delivery of care, such as the availability of essential and medical records. Many healthcare systems have very poor reliability. In one study for 15% of patients essential clinical information was missing at the point when decisions were being made and that essential equipment was missing or faulty in 19% of operations. These levels of reliability would not be tolerated in other safety critical industries (3).

Is care safe today? Sensitivity to operations.

Problems and crises that potentially threaten safety occur on a daily or even hourly basis, such as a sudden influx of very sick patients, staff sickness or equipment breakdowns. We might have been safe yesterday but how can we know whether we are safe today?

When we drive a car, operate machinery or cross the road, we continuously monitor our own actions and attend to the environment adapting to emerging hazards. This vision can be expanded to consider how to monitor the safe running of a healthcare organisation. 'Sensitivity to operations,' describes workers' acute awareness of the workings of the organisation and sensitivity to subtle changes and disturbances. Specific mechanisms that support sensitivity to operations in healthcare include safety walk-rounds, handovers and ward rounds, briefings and debriefings and informal conversations. Such conversations are often thought of as ancillary to the real work of the organisation but are in fact critical to monitoring safety.

Will we be safe in the future? Anticipation and preparedness.

In clinical work, treating complex, fluctuating conditions requires thinking ahead and being prepared to adjust treatment as the patient's condition changes. Considering the safety of an organisation requires a similar but broader vision. Clinicians and managers need to anticipate and assess potential hazards and take action to reduce the risks over time. Safety, from this broader perspective, requires anticipation, preparedness, and the ability to intervene to reduce risks at the ward, department or systems level.

There is no special type of information that is suitable or unsuitable for reflecting on future hazards and potential problems. It is more that questioning needs to be encouraged, even when things are going well, creating opportunities for staff to envision scenarios. Formal approaches can however facilitate the creation of scenarios and proactive action. These include the use of human reliability analysis, safety cases and the use of indicators such as safety culture and mapping of staffing levels to anticipate potential risks to safety due to staff shortages.

Are we responding and improving? Integration and learning from safety information.

The final dimension of the framework addresses the need to bring all this information together and make effective use of it. In the UK, the Berwick review found that *'most health care organisations at present have very little capacity to analyse, monitor, or learn from safety and quality information.* Safe organisations actively seek out such information and attempt to harness the learning to influence future functioning. Instead of relying on recommendations from single incidents or metrics they integrate and analyse safety information from across the unit or organisation and use it to support longer term organisational learning and sustainable improvements. A safety information reporting system should really be seen as an 'information, analysis, learning, feedback and action' system.

Progress and challenges

- The framework has been implemented and tested in a variety of settings in the UK, Scotland, Canada and elsewhere.
- A website and teaching materials have been developed ***www.howsafeisourcare.com***
- The concepts have received widespread acceptance.
- A major strength is the commonality of concepts and language which are applicable in all settings and at all levels of an organisation
- There can be an immediate assumption that this is a 'tool' for immediate application, rather than a way of thinking that leads to a different way of approaching safety, which in turn leads to practical method of measurement and monitoring (4 Appendix III)
- Many programmes (and programme leaders) have not invested enough time in exploring the implications of the concept before launching into improvement.
- Jane Carthey has developed a maturity matrix for organisations to assess their capacity to measure and monitor safety.

Points for discussion in the seminar

- The five questions appear to be fundamental to measuring and monitoring safety in almost any setting. Can we use them as a starting point for our discussions?
- It is tempting, but not desirable, to start by examining safety available metrics. In contrast, we advise starting from the workplace. What kinds of harm are prevalent here? What are the safety critical processes? What are the daily threats to safety?
- The framework represents a major shift from an assurance model of safety to one of inquiry. Is this appropriate for healthcare? And would it be equally appropriate for regulators as for the frontline?
- We need to decide whether we are primarily concerned with safety measurement (broadly speaking harm and reliability) or whether we are also concerned with monitoring (capacity to monitor day to day safety and anticipate problems).
- A major challenge both for measurement and improvement is the integration of safety information with other dimensions of quality. Safety measurement and monitoring needs to be set within a broader framework of quality assessment.

APPENDIX I

References

1. Vincent C, Burnett S, Carthey J. The measurement and monitoring of safety: drawing together academic evidence and practical experience to produce a framework for safety measurement and monitoring. The Health Foundation; 2013. https://www.health.org.uk/publications/the-measurement-and-monitoring-of-safety

2. Vincent C, Burnett S, Carthey J. Safety measurement and monitoring in healthcare: a framework to guide clinical teams and healthcare organisations in maintaining safety. BMJ Quality Safety 2014; 23(8):670-7. https://qualitysafety.bmj.com/content/23/8/670

3. Burnett S, Franklin BD, Moorthy K, et al. How reliable are clinical systems in the UK NHS? A study of seven NHS organisations. BMJ Quality Safety. 2012; 21(6):466-72.

4. Chatburn E, Macrae C, Carthey J, Vincent C. Measurement and monitoring of safety: impact and challenges of putting a conceptual framework into practice. BMJ Quality Safety 2018 Oct 1; 27(10):818-26.

Framework development

- We conducted three scoping reviews. Abridged versions of these reviews became chapters in the main report
- Safety measurement in a range of high risk industries. The scoping reviews on high risk industries and models of safety drew out the main practical implications for healthcare. We found that the measurement and monitoring of safety in other industries has evolved to encompass both lagging and leading indicators, to examine several different facets of safety and to use a variety of different methods of assessment and measurement. The specific tools, techniques and methods of other industries may not always transfer easily to healthcare. However, the understanding and principles behind safety measurement in other industries informed our approach to healthcare.
- We reviewed and considered the implications for measurement and monitoring: safety as defences in depth (Reason); systems safety (Reason, Vincent); high reliability theory (various authors); safety as collective mindfulness (Weick and Sutcliffe); safety as resilience (Hollnagel, Braithwaite et al; safety as resistance to system migration (Amalberti). In each case we considering the implications for measurement and monitoring of safety. Most theories pointed to general directions but were not specific about critical concepts or practical approaches to measurement.
- The review of the measurement of safety in healthcare, including the technical properties of metrics, safety indicators and the role of patients and families in monitoring safety.
- We also conducted interviews with a range of senior staff in national organisations in the UK and internationally. For our case studies in healthcare organisations we developed a template to describe the information we required. These covered acute, community, mental health and primary care services and specific services such as obstetrics and anaesthetics where measurement of safety is well developed.

APPENDIX II

Box 1 A typology of patient harm

Treatment-specific harm
Harm that results from specific treatments or the management of a particular disease, with varying degrees of preventability. This would include adverse drug reactions, surgical complications, wrong site surgery and the adverse effects of chemotherapy

Harm due to over-treatment
For example, polypharmacy and the consequent drug interactions are a major hazard, in that the benefits received from multiple treatments can be outweighed by the risks and adverse consequences

General harm from healthcare
Hospital-acquired infections, falls, delirium and dehydration are examples of problems that can affect any patient with a serious illness. Frailties or co-morbidities that increase vulnerability to falls, infections and so on

Harm resulting from delayed or inadequate diagnosis
A cancer diagnosis may be delayed because the patient delayed contacting their doctor or because the physician failed to refer. In either case the outcome may be poorer. To the patient this is harm, although not necessarily generally considered as an aspect of patient safety

Harm due to failure to provide appropriate treatment
Many patients fail to receive standard evidence-based care which may lead to harm; failure to provide rapid thrombolytic treatment for stroke provides an example. Such problems may be viewed as poor quality care, rather than safety, but for the patient may represent avoidable harm

Psychological harm and feeling unsafe
Patients may simply feel unsafe on psychiatric in-patient units and even on general wards. Awareness of unsafe care may have consequences for the wider population if it leads to a loss of trust. For instance, people may be unwilling to have vaccinations, give blood, donate organs or receive transfusions

APPENDIX III

Table 1 Assessing the five dimensions of safety

Dimension	Illustrative measures and assessments
Harm	
	Case record review
	Global trigger tool
	National audits
	Patient safety indicators
	Rates of surgical complications
	Incidence of falls
	Incidence of pressure ulcers
	Mortality and morbidity
Reliability of safety critical processes	
	Observation of safety critical behaviour
	Audit of equipment availability
	Monitoring of vital signs
	Monitoring of stroke care bundles
	Venous thromboembolism risk assessment
	Assessment of suicide risk
Sensitivity to operations	
	Safety walk-rounds and conversations
	Talking to patients
	Ward rounds and routine reviews of patients and working conditions
	Briefings and debriefings
	Observation and conversations with clinical teams
	Real time monitoring and feedback in anaesthesia
Anticipation and preparedness	
	Structured reflection
	Risk registers
	Human reliability analysis
	Safety cases
	Safety culture assessment
	Anticipated staffing levels and skill mix
Integration and learning	
	Aggregate analysis of incidents, claims and complaints
	Feedback and implementation of safety lessons by clinical teams
	Regular integration and review by clinical teams and general practice
	Whole system suites of safety metrics, for example, web enabled portals clinical unit level
	Population level analyses of safety metrics