Critical questions in patient safety

Patient Safety in Estonia:
Linking Research, Education, Policy and Practice
June 3rd 2022

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UNIVERSITY OF OXFORD

The Health Foundation
Inspiring Improvement

For Debate

Research into medical accidents: a case of negligence?

C A Vincent

Public awareness of medical accidents is growing, as the rapidly rising rate of litigation and the corresponding increase in defence society subscriptions testify.[1] In many activities—for example, aviation, road and rail travel, industry—errors and accidents are the object of systematic study.[2] Aircraft accidents are extensively investigated and extraordinary measures taken to minimise the risks of air travel. The risk of death under anaesthesia is comparable to the risk of accident on a commercial flight.[3] Yet in anaesthesia, and medicine generally, accidents are seldom discussed publicly and few studies are conducted. Many doctors do, of course, review their work in morbidity and mortality meetings. This does not usually extend to systematic study, however, and the results are not usually communicated to the wider medical community. I suggest here that research into medical accidents has been greatly neglected but that accidents can and should be studied.

Accidents, errors, and negligence

A consistent finding in all accident research is that the main cause of accidents is human error,[4] often compounded by organisational factors.[5] Even catastrophes such as the accidents at nuclear power plants at Chernobyl and Three Mile Island were the result not of unusual circumstances but of quite ordinary slips and lapses.[3] Assuming some parallels with other areas, two points can be made about the study of medical accidents. Firstly, the main focus of investigation should be on the actions of those concerned, rather than on patient characteristics or technical faults. Secondly, the study of medical accidents should include errors and near misses (cases where an accident was narrowly averted).

Error does not necessarily imply negligence. Some accidents involve negligence, but most do not. Researchers should in any case not assess negligence, for three reasons. Firstly, few medical errors are likely to involve negligence; secondly, cooperation can be expected only if researchers treat information obtained as confidential;thirdly, the assessment of negligence is (ultimately) a matter for the courts. Blame, if any, should be assessed separately from cause and by people other than researchers.

emphasis is on packaging and the consequences of medication errors. The authors of the few papers discussing the actual errors are usually pharmacists or nurses.[6,7]

INCIDENCE

Official statistics are collected on many forms of accidents, but little is known about the overall incidence of medical accidents in the United Kingdom. The protection societies have information on the annual rate of claims and complaints, but this is only a fraction of the total number of accidents, many of which will not involve negligence. The Harvard medical practice study[8] will shortly provide detailed information on the incidence of medical accidents and negligence in New York State. The only published information, however, comes from a study conducted in California in 1974. Three million hospital admissions led to 140 000 injuries, 24 000 being due to negligence.[9] With five million hospital admissions a year in England alone[10] this might mean as many as 230 000 medical accidents in English hospitals, some 40 000 being due to negligence.

CONFIDENTIAL INQUIRIES

The confidential inquiries into deaths during childbirth, anaesthesia, and surgery[11-13] did not specifically set out to study medical accidents (that would have been prejudging the issue). Nevertheless, all have found that a high proportion of the deaths were avoidable, some associated with substandard care. For instance, the delegation of high risk obstetric operations to registrars appears to have contributed to several deaths.[11] The reasons for this can, however, only be guessed at. The delegation might have been due to staff shortages, overconfidence on the part of the registrar, inadequate supervision by the consultant, or a failure of communication between registrar and consultant. Only more detailed studies will reveal the causes of such accidents—and provide effective methods of prevention.

FROM MEDICAL RECORDS

When a case is brought against a doctor an expert opinion, based on an examination of the case notes, is sought by both defence and prosecution. These expert

Vincent, 1989

Index Medicus classifies accidents under several headings. There are also sections on prevention and accident proneness.
Medical errors and accidents, however, do not even merit a classification.

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Most audits stop short of identifying mistakes, or at least stop short of publishing the information.

Studies of medical errors are rare; studies of their causes are even rarer.

Patient safety – a very, very brief history

- 30 years ago – the dark ages
- 25 years ago – risk management, incident reporting & analysis
- 20 years ago – epidemiology, the scale of harm
- 15 years ago – process change, teamwork, culture, organisational change
- 10 years ago – prioritisation of interventions, evaluation, strategy
- 5 years ago – new national programmes, increasing equivalence to quality improvement

Cutting error and harm by 50% within 5 years

But what are the priorities for Estonia?

What is the nature and extent of harm?

Adverse events in British hospitals: preliminary retrospective record review

Charles Vincent, Graham Neale, Maria Woloshynowych

BMJ

Results 110 (10.8%) patients experienced an adverse event, with an overall rate of adverse events of 11.7% when multiple adverse events were included. About half of these events were judged preventable with ordinary standards of care. A third of adverse events led to moderate or greater disability or death.

Conclusions These results suggest that adverse events are a serious source of harm to patients and a large drain on NHS resources. Some are major events; others are frequent, minor events that go unnoticed in routine clinical care but together have massive economic consequences.

Vincent, Neale, Woloshynowych
British Medical Journal 2001

Research

BMJ

Sensitivity of routine system for reporting patient safety incidents in an NHS hospital: retrospective patient case note review

Ali Raba-Akbari Sari, Trevor A Sheldon, Alison Cracknell, Alastair Turnbull

Abstract

Objective To evaluate the performance of a routine incident reporting system in identifying patient safety incidents.
Design Two stage retrospective review of patients' case notes and analysis of data submitted to the routine incident reporting system on the same patients.
Setting A large NHS hospital in England.
Population 1006 hospital admissions between January and May 2004: surgery (n = 311), general medicine (n = 251), elderly care (n = 184), orthopaedics (n = 131), urology (n = 61), and three other specialties (n = 68).
Main outcome measures Proportion of admissions with at least one patient safety incident; proportion and type of patient safety incidents missed by routine incident reporting and case note review methods.
Results 324 patient safety incidents were identified in 230/1006 admissions (22.9%; 95% confidence interval 20.3% to 25.5%). 270 (83%) patient safety incidents were identified by case note review only, 21 (7%) by the routine reporting system only, and 33 (10%) by both methods. 110 admissions (10.9%; 9.0% to 12.8%) had at least one patient safety incident resulting in patient harm, all of which were detected by the case note review and six (5%) by the reporting system.
Conclusion The routine incident reporting system may be poor at identifying patient safety incidents, particularly those resulting in harm. Structured case note review may have a useful role in surveillance of routine incident reporting and associated quality improvement programmes.

about the cause, contributory factors, preventability, and impact of these incidents.[4–6] In this paper we evaluate the relative performance of a local routine incident reporting system that feeds into the national reporting and learning system, by comparing it with a well validated method of systematically reviewing case notes.[4,5]

Methods

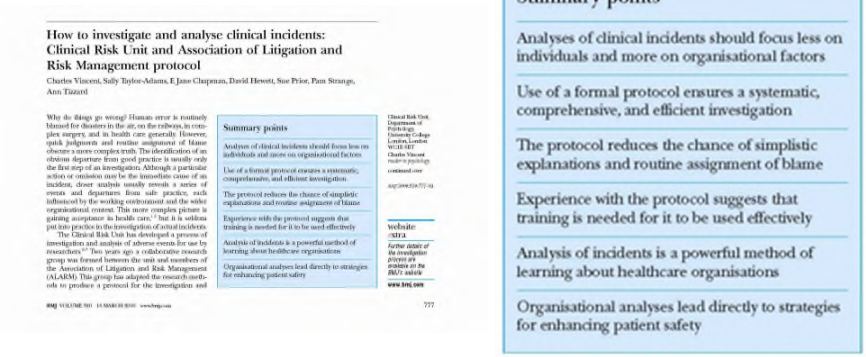
We did the study in a large NHS hospital trust in England in 2005. We selected a stratified random sample of 1006 admissions (>24 hours' stay) between January and May 2004 from eight specialties: surgery; urology; orthopaedics; general medicine; medicine for the elderly; oncology; ear, nose, and throat; and ophthalmology. All data extracted were anonymised and kept confidential. The study consisted of using structured data extraction tools to do a two stage retrospective case note review of the sample admissions and reviewing the patient safety incidents reported by the routine hospital reporting system for the same admissions.

Review of medical records

We used previously described methods to do the case note review.[4,5] Five trained nurses screened patients' records by using 18 explicit criteria (box). We used one (or more) positive criterion as an indicator of a patient safety incident and scrutinised these medical records in stage two. One of the other nurses independently reviewed a 10% sample to assess inter-rater reliability. In addition, medical staff fully reviewed 10% of admissions for which no routine criteria were identified to identify false

But incident reporting only detects 5% of harmful events

Why do things go wrong (and right)?



How to investigate and analyse clinical incidents: Clinical Risk Unit and Association of Litigation and Risk Management protocol

Charles Vincent, Sally Taylor-Adams, E Jane Chapman, David Hewett, Sue Prior, Pam Strange, Ann Tizzard

Why do things go wrong? Human error is routinely blamed for disasters in the air, on the railways, in complex surgery, and in health care generally. However, quick judgments and routine assignment of blame obscure a more complex truth. The identification of an obvious departure from good practice is usually only the first step of an investigation. Although a particular action or omission may be the immediate cause of an incident, closer analysis usually reveals a series of events and departures from safe practice, each influenced by the working environment and the wider organisational context. This more complex picture is gaining acceptance in health care,[1–3] but it is seldom put into practice in the investigation of actual incidents.

The Clinical Risk Unit has developed a process of investigation and analysis of adverse events for use by researchers.[4,5] Two years ago a collaborative research group was formed between the unit and members of the Association of Litigation and Risk Management (ALARM). This group has adapted the research methods to produce a protocol for the investigation and

Summary points

Analyses of clinical incidents should focus less on individuals and more on organisational factors

Use of a formal protocol ensures a systematic, comprehensive, and efficient investigation

The protocol reduces the chance of simplistic explanations and routine assignment of blame

Experience with the protocol suggests that training is needed for it to be used effectively

Analysis of incidents is a powerful method of learning about healthcare organisations

Organisational analyses lead directly to strategies for enhancing patient safety

Clinical Risk Unit, Department of Psychology, University College London, London WC1E 6BT
Charles Vincent
reader in psychology

continued over

website extra

Further details of the investigation process are available on the BMJ's website

www.bmj.com

BMJ VOLUME 320 11 MARCH 2000 www.bmj.com

777

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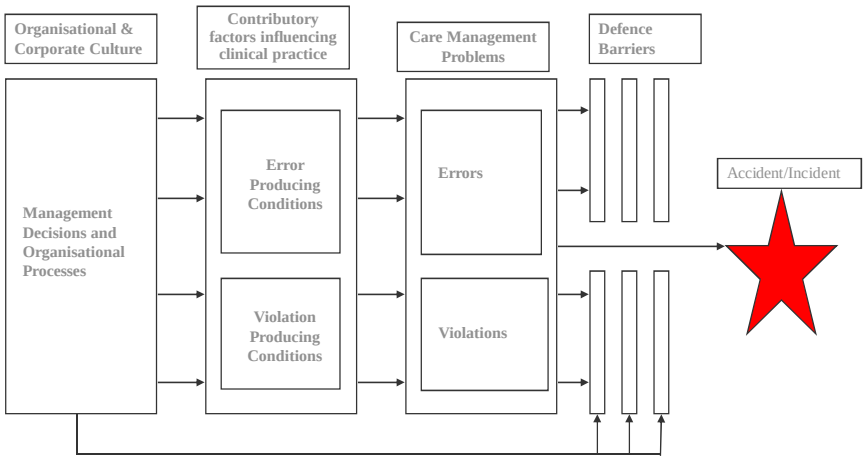
Stages of development of organisational accident



Adapted from Reason, 1997

The Process of Investigation: the 'moves'

The core of the process is to ask:

- What happened?
- How did it happen?
- Why did it happen?

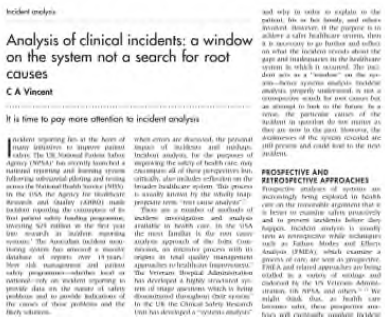
- Get the story (the real story not the one in the notes)
- Identify the care delivery problems
- Consider the contributory factors
  - And what does this tell you about your system?
- Prioritisation and action

Contributory factors: 7 levels of safety

- Patient
- Task
- Individual staff
- Team
- Working conditions
- Organisational
- Government and regulatory

Vincent, Adams, Stanhope 1998

Incidents are a window on the system



Incident analysis

Analysis of clinical incidents: a window on the system not a search for root causes

C A Vincent

It is time to pay more attention to incident analysis

Global child health

OPEN ACCESS

First do no harm: practitioners' ability to 'diagnose' system weaknesses and improve safety is a critical initial step in improving care quality

Mike English, Muthoni Ogola, Jalemba Aluvaala, Edith Gicheha, Grace Irimu, Jacob McKnight, Charles A Vincent

ABSTRACT

What is already known on this topic?

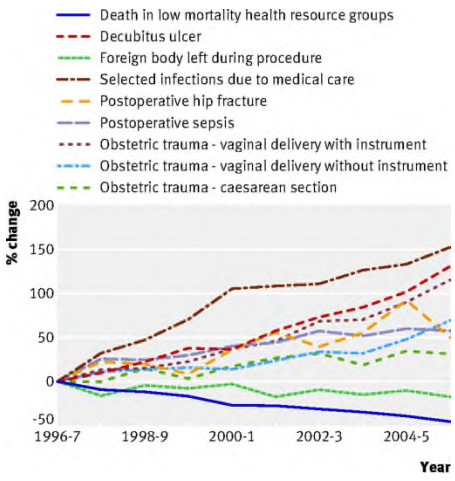
What this study adds?

INTRODUCTION

Are our services becoming safer?

Is health care getting safer?

Despite numerous initiatives to improve patient safety, we have little idea whether they have worked. **Charles Vincent and colleagues** argue that we need to develop systematic measures



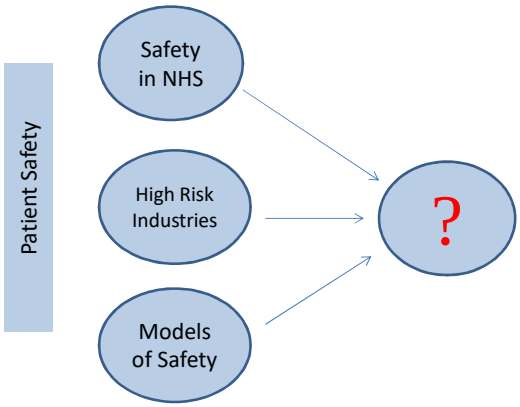
We do not know whether we are making progress or not

Vincent et al, BMJ 2008

Just tell me - are we safe?

Jane Carthey

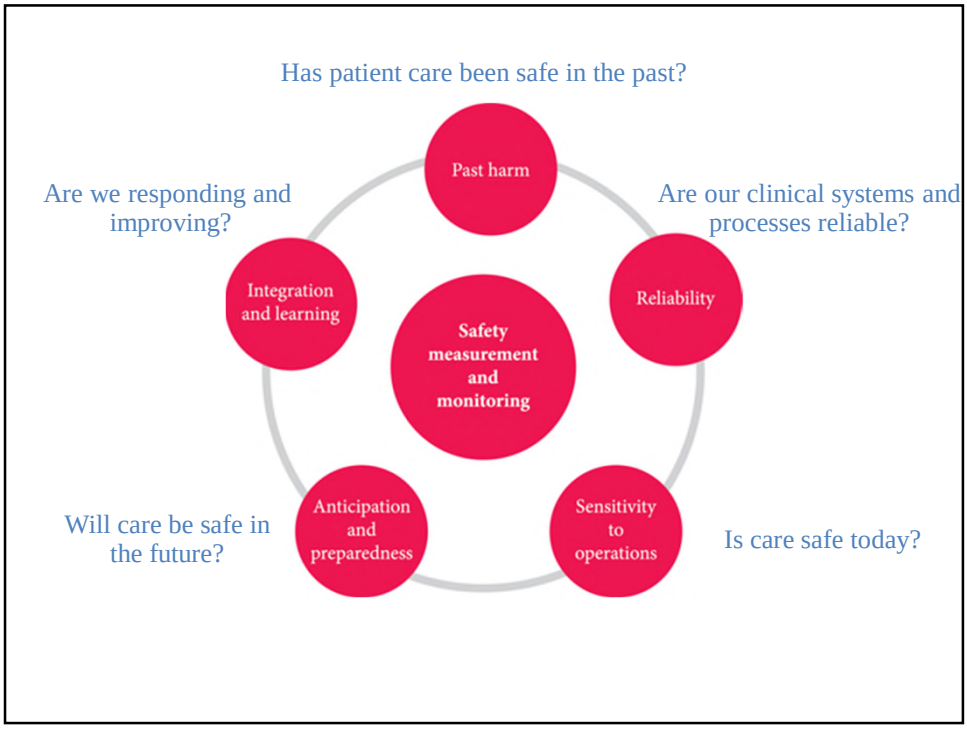
Susan Burnett



(Original idea was to develop a set of measures)

The fundamental questions

- Has patient care been safe in the past?
- Are our clinical systems and processes reliable?
- Is care safe today?
- Will care be safe in the future?
- Are we responding and improving?



Adverse events in older people

- Errors, omissions
- Operative/procedural complications
- Hospital acquired infections
- Adverse drug events

Adverse events affecting all age groups

Adverse events in older people

- Errors, omissions
- Operative/procedural complications
- Hospital acquired infections
- Adverse drug events

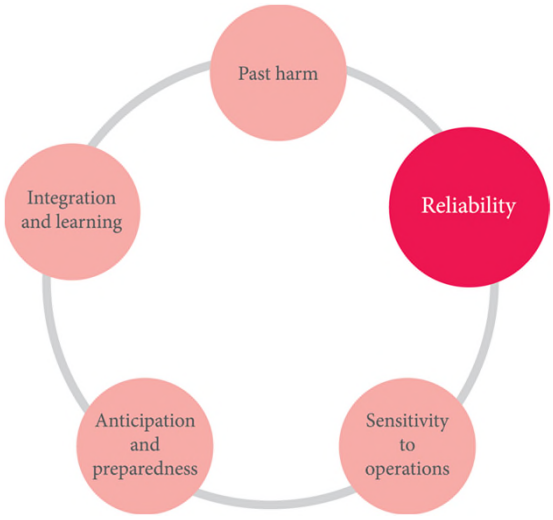
Adverse events affecting all age groups

+

- Falls
- Pressure sores
- Incontinence
- Functional ± mobility decline
- Delirium
- Depression
- Nutritional decline
- Dehydration

The geriatric syndromes

Should be thought of as adverse events
- Preventable?
- Prolonged hospital stay
- Increased morbidity and mortality



Original research

How reliable are clinical systems in the UK NHS? A study of seven NHS organisations

Susan Burnett,[1] Bryony Dean Franklin,[2] Krishna Moorthy,[3] Matthew W Cooke,[4] Charles Vincent[5]

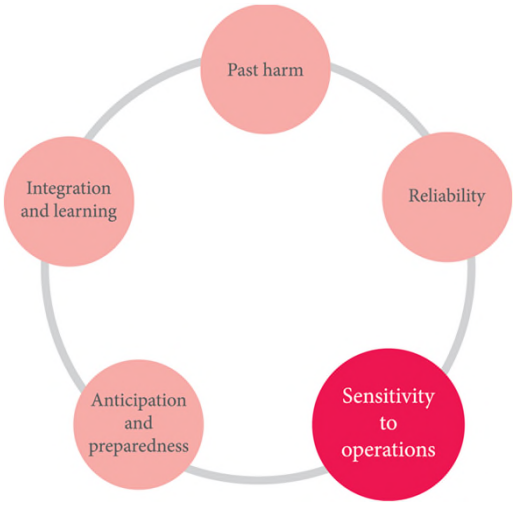
- Clinical information available in hospital outpatient clinics
- Prescribing for hospital inpatient
- Equipment availability in the operating theatre
- Equipment available for inserting peripheral intravenous lines

Missing & faulty equipment

Site	Total operations studied	Number of operations with equipment problems	Percentage operations with one or more equipment problems
A	258	50	19%
D	67	25	37%
F	165	19	12%
Total	490	94	19%

'We always need a colposcope with that list and time and time again it isn't there or it's broken or it isn't back or nobody knows where it is'

Surgeon 3 Organisation A

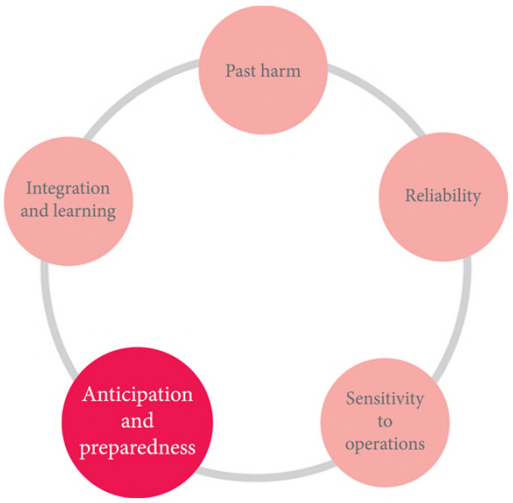


Sensitivity to operations

- Clinicians monitor their patients, watching for subtle signs of deterioration or improvement,
- Leaders monitor their teams for signs of discord, fatigue or lapses in standards.
- Managers have to be alert to the impact of staff shortages, equipment breakdowns, sudden increases in patient flow and other problems.

Soft intelligence

- Safety walk-rounds
- Using designated patient safety officers
- Operational meetings, handovers and ward rounds
- Briefings and debriefings
- Day to day conversations
- And above all …. the patient voice
- …. *To which we can now add real time EHR derived data*



Experts are constantly thinking ahead

- Pre-mission planning for
- fighter pilots often takes longer than the mission
- Each part of the route is analysed for possible threats, whether from hostile aircraft, personal factors, weather or technical breakdown.
- During the flight pilots devoted over 90% of available time to anticipation
- Typically they developed a ‘tree’ of events that might occur over the course of the flight.

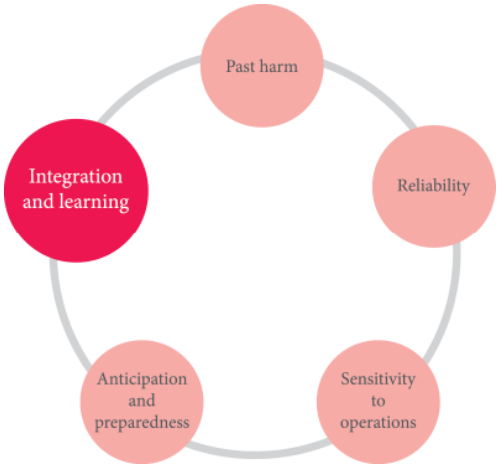
Amalberti & Deblon, 1992

Anticipation and Preparedness: Will care be safe in the future?

- WHO Surgery Checklist
- Risk assessments
  - (falls, pressure ulcers, self harm)
- Risk registers
- Safety culture assessments
- Safety cases

- Bringing available information in the organisation to anticipate safety in the future

Integration & learning. Are we responding and improving?



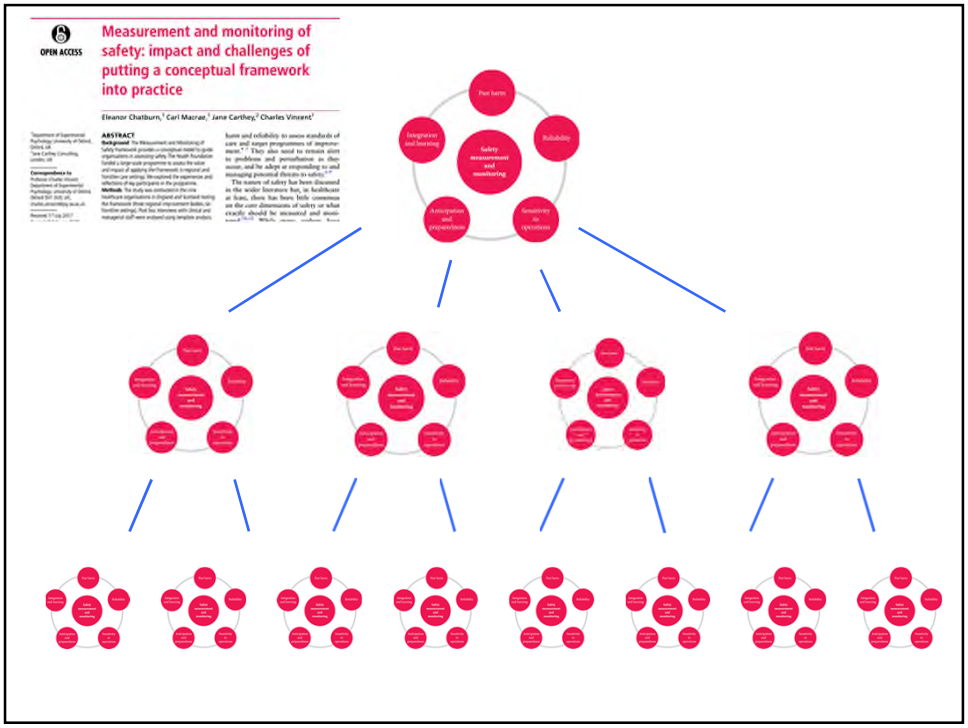
Berwick Report

"Most Health care organisations at present have very little capacity to analyse, monitor, or learn from safety and quality information. This gap is costly and should be closed and that early warning signals can be valued and should be maintained and heeded" (Berwick, 2013, p26)

Great Ormond St: team level

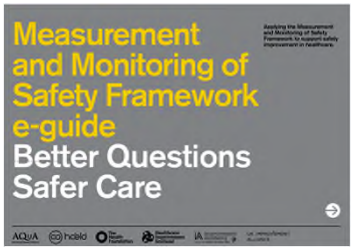
- Number of days since the last serious incident (SI)
  - narrative, lessons learnt and recommendations
- Central venous line, MRSA (MSSA) infection rates
- Hand hygiene compliance rate
- WHO Surgical Safety Checklist compliance rate per clinical unit
- Common themes identified in executive walk-rounds
- Medication errors
- Top three risks from the clinical unit's risk register.

Response & Evolution




A meta-review of methods of measuring and monitoring safety in primary care


RESEARCH
Open Access
Measuring and monitoring patient safety in hospitals in Saudi Arabia



Using the MMSF

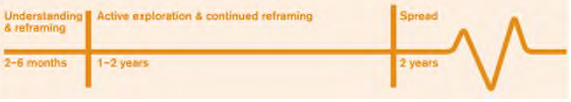
Planning and timelines

Consider the best time and likely timescales for introducing the MMSF.

Planning and timing
Your Theory of Change will have a huge bearing on your approach. More implicit approaches, designed to influence and structure existing safety planning, require less initial coordination than an approach that involves training large numbers of frontline staff.

Timeline
Even though the testing of the MMSF was supported by The Health Foundation, the timelines for the approach to the MMSF were quite long. Those who contributed to this e-guide found reframing, planning and creating a Theory of Change took between two and six months. The majority found it was more than four months before any explicit action was taken.

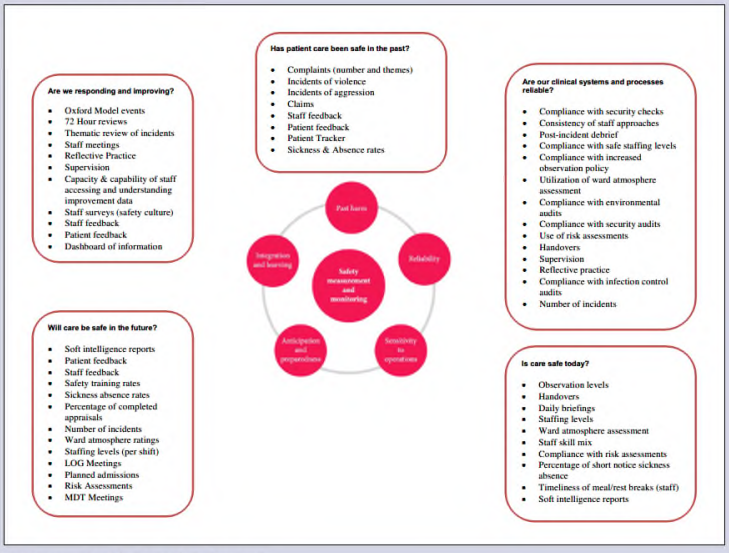
We completely underestimated how much time it would take us to understand, apply and engage our brains and behaviours around what the MMSF can offer.
Regional Improvement Body



Considering the MMSF

Mapping of existing work

Example of mapping current measurement and monitoring activity around the MMSF in a mental health setting (Source: Merseycare NHS Foundation Trust)

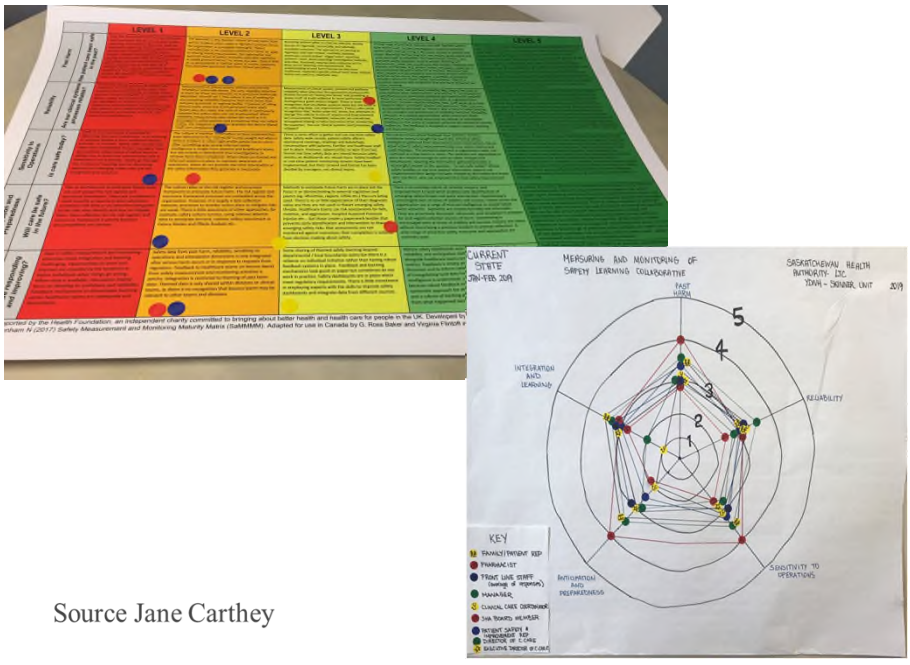


The Measurement and Monitoring of Safety Framework

Maturity Matrix

	Level 1	Level 2	Level 3	Level 4	Level 5
Past Harm Has patient care been safe in the past?	Very few mechanisms exist to learn from past harm and those that do are not used: under-reporting of incidents is the norm.	The approach is very reactive: lessons are only learnt from serious incidents when media or regulatory pressure forces the organisation to investigate thoroughly.	Improving patient safety is a tick box exercise: activity focuses on regionally and nationally mandated measures.	A broad range of past harm measures are used. Specialty-specific harm metrics exist. Incident investigation is used to proactively identify what could go wrong in the future, not just to identify root causes.	The cultural norm is that safety measurement should constantly evolve and complacency be avoided, even when safety performance is good.
Reliability Are our clinical systems and processes reliable?	Unreliable clinical systems, processes and pathways are accepted as the norm.	Measurement of clinical system, process and pathway reliability is externally driven: the only reliability measures in place are those set nationally or by commissioners.	Measurement of clinical system, process and pathway reliability takes place but the approach is bureaucratic.	System, process, and pathway reliability data shapes the focus of improvement work.	Unreliable systems, processes and pathways are viewed as unacceptable.
Sensitivity to Operations Is care safe today?	Little or no importance is attached to observing how care is delivered, or to listening to or seeking feedback from health care teams, patients or families.	The culture is reactive: information on how treatment has been delivered in the 'real world' is only sought out when a serious incident or high profile patient harm occurs.	There is some effort to gather and use real-time safety data.	The culture seeks feedback from patients, families and health care teams every day. Informal safety intelligence gathered from observations and conversations has an equal value to safety measurement data.	There is a system of early, pre-emptive identification of problems so that actions can be taken (today) before they cause harm to patients.
Anticipation and Preparedness Will care be safe in the future?	Little or no importance is attached to observing how care is delivered, or to listening to or seeking feedback from health care teams, patients or families.	The culture is reactive: information on how treatment has been delivered in the 'real world' is only sought out when a serious incident or high profile patient harm occurs.	There is some effort to gather and use real-time safety data.	The culture seeks feedback from patients, families and health care teams every day. Informal safety intelligence gathered from observations and conversations has an equal value to safety measurement data.	There is a system of early, pre-emptive identification of problems so that actions can be taken (today) before they cause harm to patients.
Integration and Learning Are we responding and improving?	Few or no measures to anticipate future harm are used except the risk register and assurance framework.	The culture relies on the risk register and assurance framework to anticipate future harm.	Methods to anticipate future harm are in place but the focus is on demonstrating to external regulators and commissioners they are being used.	There is an evolving culture of curiosity, enquiry and empowerment to lead which enables early identification of emerging safety threats and quick intervention.	A culture of curiosity, enquiry and empowerment to prevent safety threats is fully embedded within the organisation and throughout the whole health economy.

Carthey & Downham, 2017



Source Jane Carthey

The fundamental questions

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