The Epidemiology of Harm

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Session Overview

Learning objectives

Aim: To provide an overview of the epidemiology of harm in healthcare; prevalence, measurement, causality and improvement

- Focus upon practical local level monitoring and remedial systems

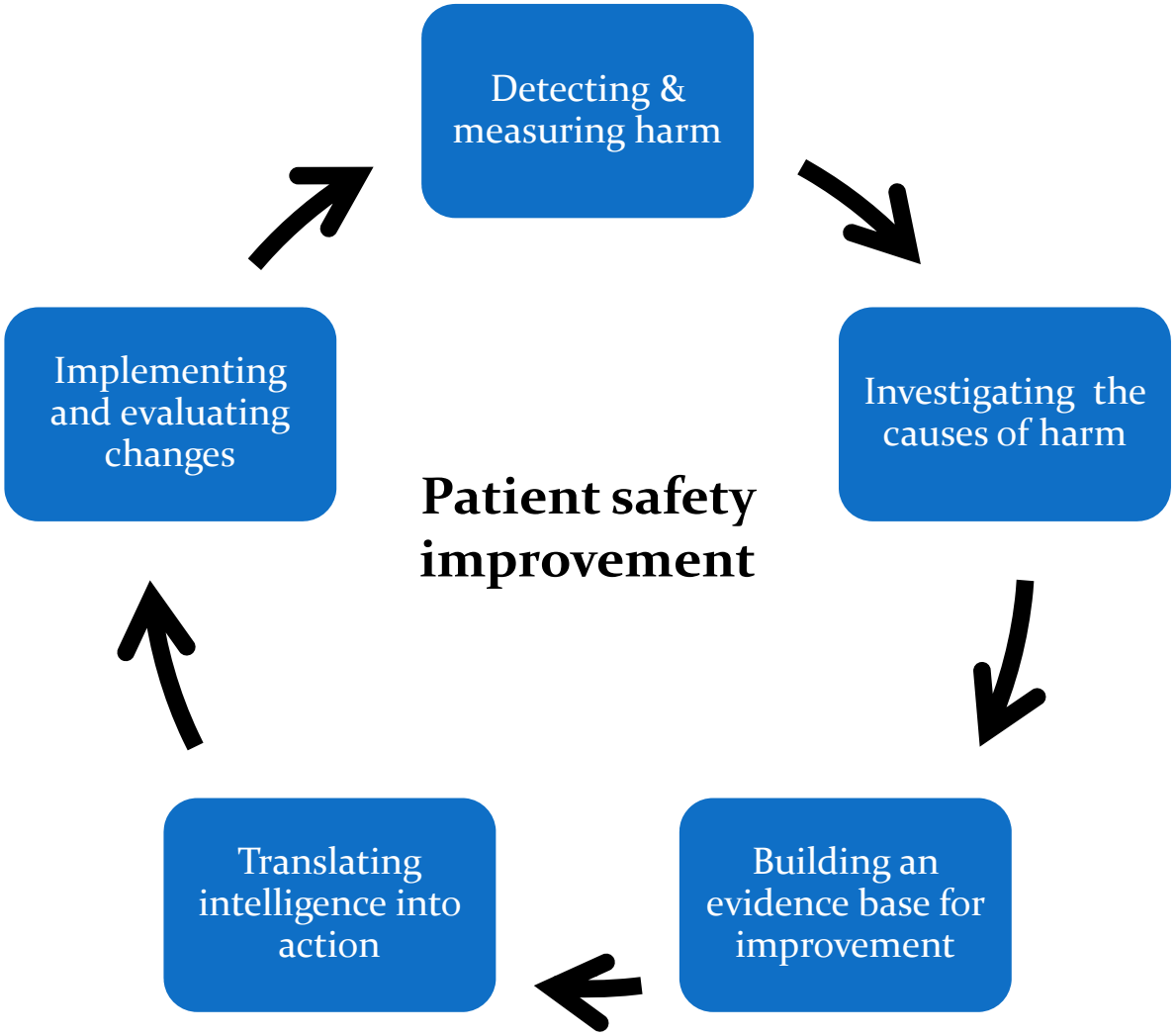
By the end of this session you should be able to:

- Cite key studies describing the scale of the patient safety challenge in health care.
- Critically discuss the main methods of monitoring adverse events in health care and the inherent difficulties in measuring harm.
- Describe current approaches to understanding and analysing the causes of harm
- Recognise key issues for monitoring variations in care delivery, through research examples

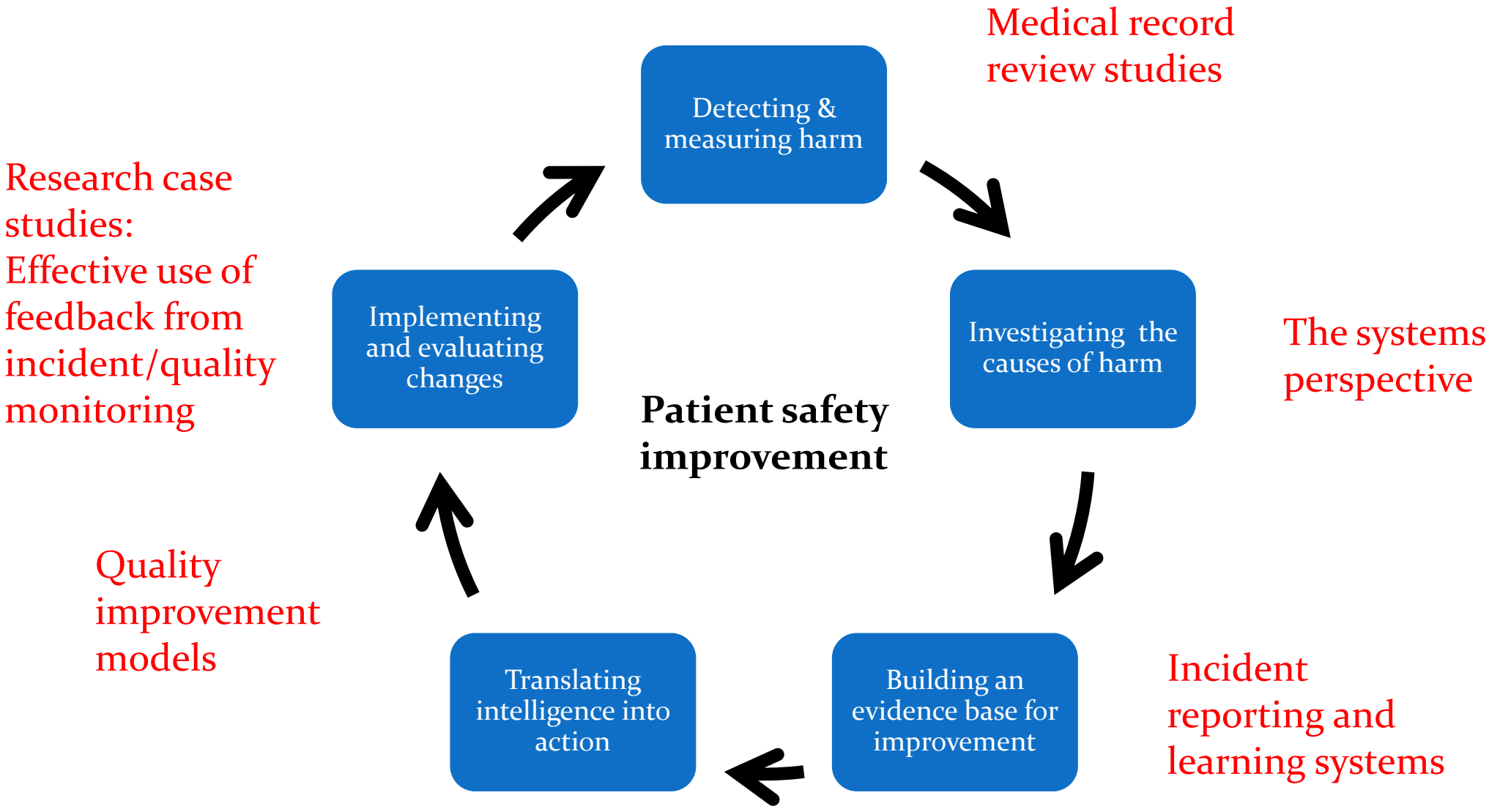
Session plan

1. The patient safety challenge: adverse event studies
2. Understanding the causes of harm: a systems perspective
3. Monitoring adverse events: incident reporting
4. “Harm” as process variation
5. Intervening to improve clinical systems
6. Research case studies:
   - Learning from incident reporting at local level
   - Learning from quality indicators in anaesthesia

The improvement cycle: an informatics view



Illustrative topics from the patient safety & quality improvement fields for this session



Key definitions

- **Adverse event** (health care): "an unintended injury caused by medical management rather than a disease process, resulting in death, life threatening illness, disability at the time of discharge, admission to hospital, or prolongation of hospital stay."
- **Iatrogenic harm**: harm caused inadvertently by the care delivery process itself, e.g. Nosocomial/hospital acquired infection, surgical complications resulting from medical error, etc.
- **(Human) Error**: the failure of planned action to be completed as intended or to achieve its intended aim.
- **Medical error**: a preventable adverse effect of medical treatment
- **Near miss**: a medical error or preventable event that did not result in a harmful outcome (but from which lessons may still be learnt – "free lessons")

1. The patient safety challenge: Adverse event studies

Estimates of the extent of the patient safety challenge

- The NPSA (2005): 572,000 reported patient safety incidents and 840 reported deaths from those incidents each year in NHS acute hospitals in England.
- DoH (2000): 850,000 incidents annually in the UK NHS
- US IoM (2000): >1,000,000 preventable incidents annually of which 44,000 to 98,000 are fatal (IOM, 2000)
- UK National Reporting and Learning System: 800,000 incident reports a year; 3 million over 6 years from English trusts.
- Evidence from UK Hospital Episode Statistics: 2.2% of all hospital episodes contain a mention of an adverse event. Nearly 4000 misadventures are recorded each year.

Estimating the prevalence of adverse events from retrospective record review

- 1 in 10 patients admitted to hospital suffer an adverse event
  - A third result in moderate to severe harm
  - Half are preventable

Table 1 Number of adverse events by specialty

Specialty	No (%) of records reviewed	No of patients with adverse events detected		Total No of adverse events detected	
		All (% of records)	Preventable (% of events)	All (% of records)	Preventable (% of events)
General medicine	273 (27)	24 (8.8)	18 (75)	25 (9.2)	19 (76)
General surgery	290 (29)	41 (14.1)	17 (41)	47 (16.2)	20 (43)
Obstetrics	174 (17)	7 (4.0)	5 (71)	7 (4.0)	5 (71)
Orthopaedics	277 (27)	38 (13.7)	12 (32)	40 (14.4)	13 (33)
Total	1014	110 (10.8)	52 (47)	119 (11.7)	57 (48)

*Vincent C, Neale G, Woloshynowych M. Adverse events in British hospitals: preliminary retrospective record review. BMJ. 2001;322(7285):517-9.

Review of adverse event studies across multiple health systems

The incidence and nature of in-hospital adverse events: a systematic review

E N de Vries, M A Ramrattan, S M Smorenburg, D J Gouma and M A Boermeester

Qual. Saf. Health Care 2008;17;216-223
doi:10.1136/qshc.2007.023622

Adverse event studies

Table 3 Adverse events, preventability and outcome

Reference	Brennan *et al*[32]	O'Neil *et al*[23 28]	Wilson *et al*[3]	Thomas *et al*[2]	Vincent *et al*[33]	Davis *et al*[24 30]	Baker *et al*[31]	Sari *et al*[29]	Median percentage (interquartile range)
No. of records	30 121	3141	14 179	14 700	1014	6579	3745	1006	–
No. of patients with at least one adverse event	1133 (3.8)	237* (7.5)	2353 (16.6)	475 (3.2)	110 (10.8)	850 (12.9)	255 (6.8)	110 (10.9)	9.2 (4.6 to 12.4)
No. of adverse events (if >1 adverse event per patient)	–	–	–	–	119 (11.7)	–	289 (7.7)	136 (13.5)	11.7 (7.7 to 13.5)
No. of preventable adverse events	–	103* (43.5)	1205 (51.2)	–	57 (47.9)	315 (37.1)	106 (41.6)	–	43.5 (39.4 to 49.6)
Outcome									
No or minor disability†	644 (56.8)	–	1073 (45.6)	253 (53.3)	73 (66.4)	524 (61.6)	161 (55.7)	–	56.3 (51.4 to 62.8)
Temporary disability‡	187 (16.5)	–	702 (29.8)	150 (31.6)	21 (19.1)	162 (19.0)	36 (12.5)	–	19.1 (15.5 to 30.3)
Permanent disability§	74 (6.5)	–	315 (13.4)	40 (8.4)	7 (6.4)	87 (10.2)	15 (5.2)	–	7.0 (6.1 to 11.0)
Death	154 (13.6)	–	112 (4.8)	31 (6.6)	9 (8.2)	38 (4.5)	46 (15.9)	–	7.4 (4.7 to 14.2)
Unknown	75 (6.6)	–	151 (6.4)	–	–	40 (4.7)	31 (10.7)	–	6.5 (5.1 to 9.7)

de Vries, E. N., Ramrattan, M. A., Smorenburg, S. M., Gouma, D. J., & Boermeester, M. A. (2008). The incidence and nature of in-hospital adverse events: a systematic review. *Qual Saf Health Care, 17(3), 216-223.*

Challenges in measuring patient safety

- "Safety is a dynamic non-event" – Karl Weick
  - "Harm"/adverse events are:
    1. Retrospectively focused
    2. Outcomes of safety "processes"
    3. An imperfect indicator of inherent safety/reliability in a care system
- Reliability of methods of identifying and monitoring adverse events is limited:
  - Only 6.2% of hospital admissions with a patient safety indicator had a provider adverse event report, and only 10.5% vice versa (Naessens, 2009 – US study)
  - Inter-rater reliability of adverse events identified by medical record review is low (Thomas, 2002 – US study)
  - Sari (1997) comparison of adverse events identified by case note review (CNR) and adverse incident reporting system (AIRS) within a UK hospital……..

Challenges in measuring patient safety

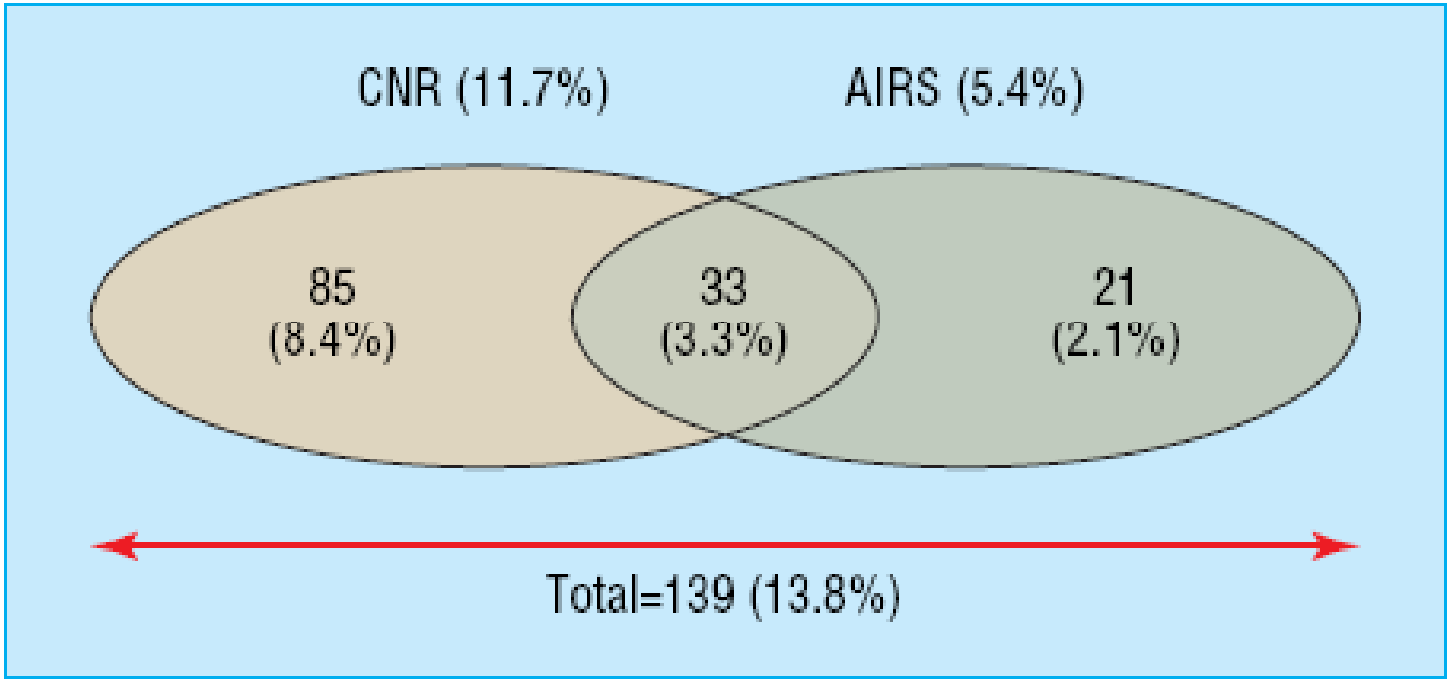


Fig 2 Group I patient safety incidents reported by case note review (CNR) and adverse incident reporting system (AIRS)

Challenges in measuring patient safety

The lack of reliable data on safety and quality over time hinders improvement efforts at every level of the health care system

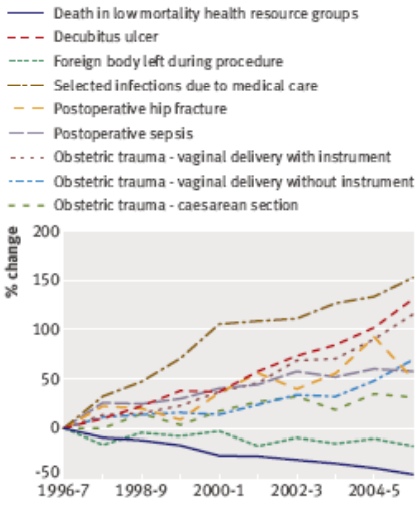
ANALYSIS

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

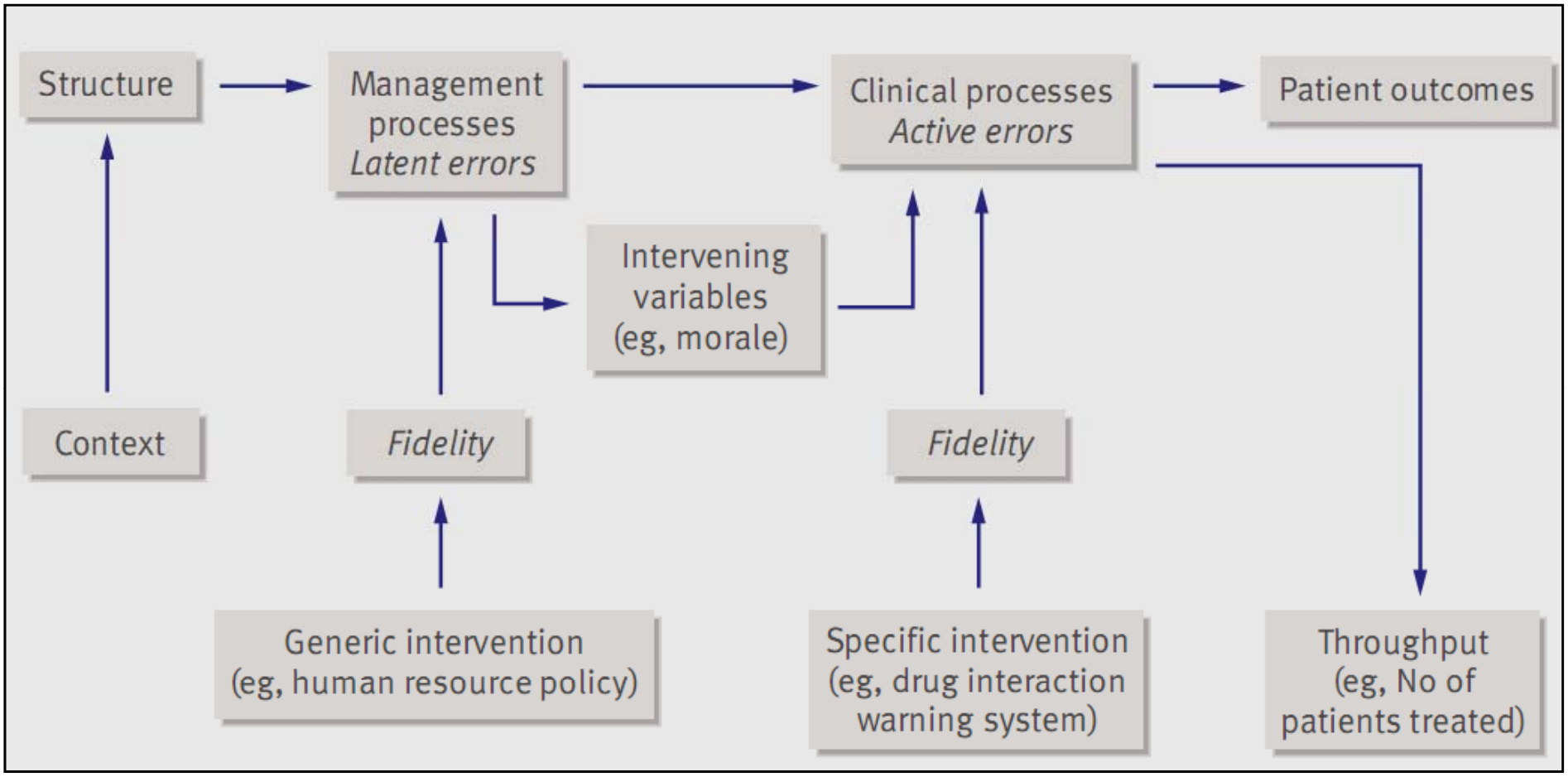
Patient safety has been high on the national and international agenda in health care for almost a decade. In the United Kingdom, reviews of case records have shown that over 10% of patients experience an adverse event while in hospital,[1 2] a figure reflected in similar studies around the world.[3] Considerable efforts have been made to improve safety, and it is natural to ask whether these efforts have been well directed. Are patients any safer? The answer to this simple question is curiously elusive. Although some aspects of safety are difficult to measure for technical reasons (defining preventability for instance), the main problem is that measurement and evaluation have not been high on the agenda. We believe that the lack of reliable information on safety and quality of care is hindering improvement in safety

Here, we use the example of the UK National Health Service to determine whether it is possible to assess change in several core areas that reflect the safety of health care and, if so, what changes are apparent. We focus on measures of outcome, in the sense of definable events that happen to patients (infections, morbidity, mortality) and on key measures of process (such as drug errors). We have not considered concepts such as culture or resilience that are held to reflect safety but are not proved indices of clinical process or outcome. Defining safety is itself a challenge, and we do not pretend that the indicators can provide more than a crude measure of overall levels of safety. The indicators we have chosen are, however, all important to patients.



2. Understanding the causes of harm: a systems perspective

The upstream determinants of patient safety outcomes



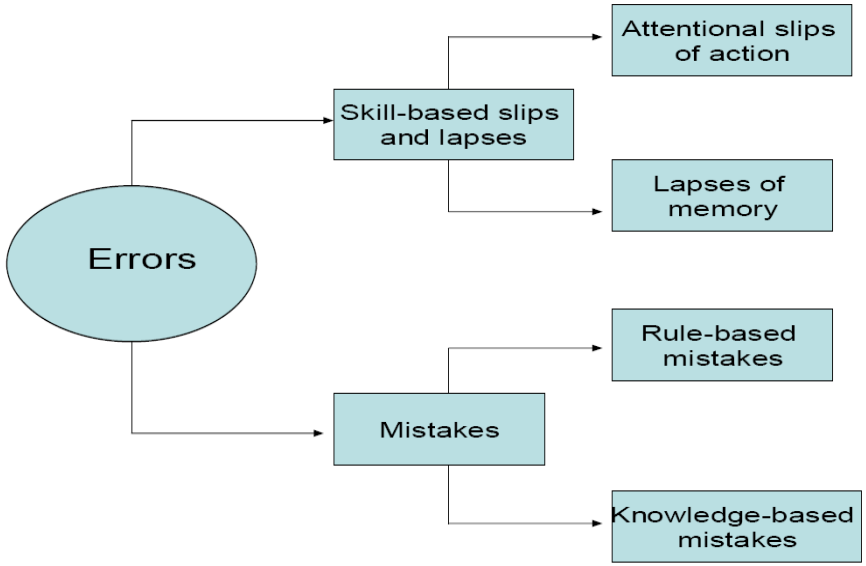
Causal chain linking interventions to outcomes. Source: Brown C, Lilford R. Evaluating service delivery interventions to enhance patient safety. BMJ. 2008; 337; a2764.

A culture shift towards a systems perspective on iatrogenic injury?

- The "old" culture: the Person approach
  - Human error at the route of adverse events
  - Individual healthcare professional is solely responsible for the quality and safety of care administered – hipocratic oath
  - Human Error = negligence/carelessness
  - "Just try harder"
  - "name, blame, shame and retrain"

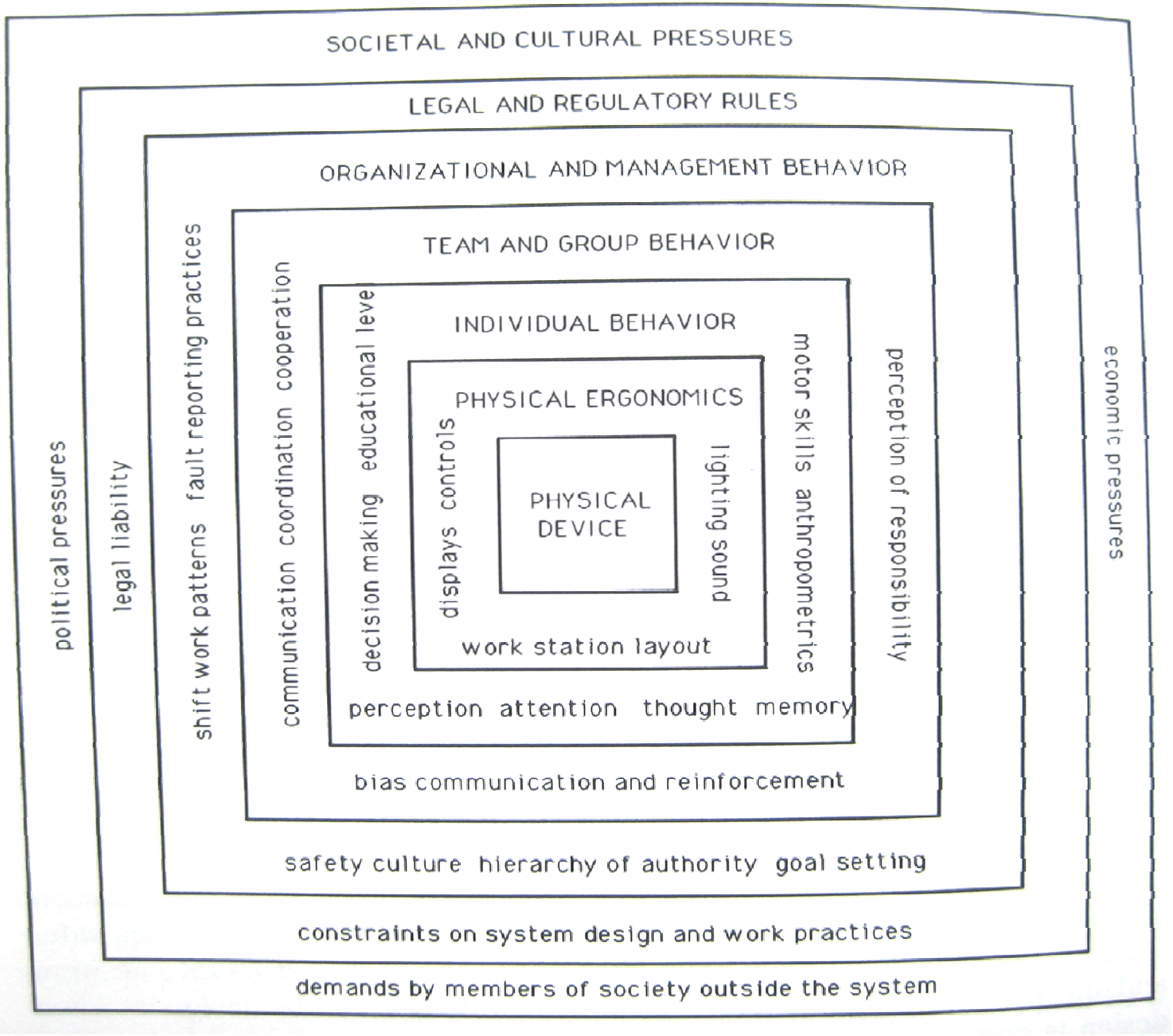
- An alternative approach: the "systems perspective"
  - The origins of failure are systemic (multiple causes) and therefore the basis of a solution will be systemic
  - Recognition that punishment/retraining/hiring & firing can't solve the problem
  - "Fair blame" rather than "full blame" or "no blame" – a balanced view

Human error: cause or consequence?



- Analysis should focus upon systems failure rather than human error which is often the result of inadequacy in the design of work systems (Reason, 1997)
- Human error is often the consequence of upstream factors, not the root cause of an adverse event.
- Human error is inevitable (evidence from cognitive science): we need to design error tolerant systems
- Error provoking conditions:
  - *Fatigue, inexperience, poorly designed procedures and equipment, inadequate information, high mental workload, time pressure, lack of cross-checking, environmental distractions/interference.*

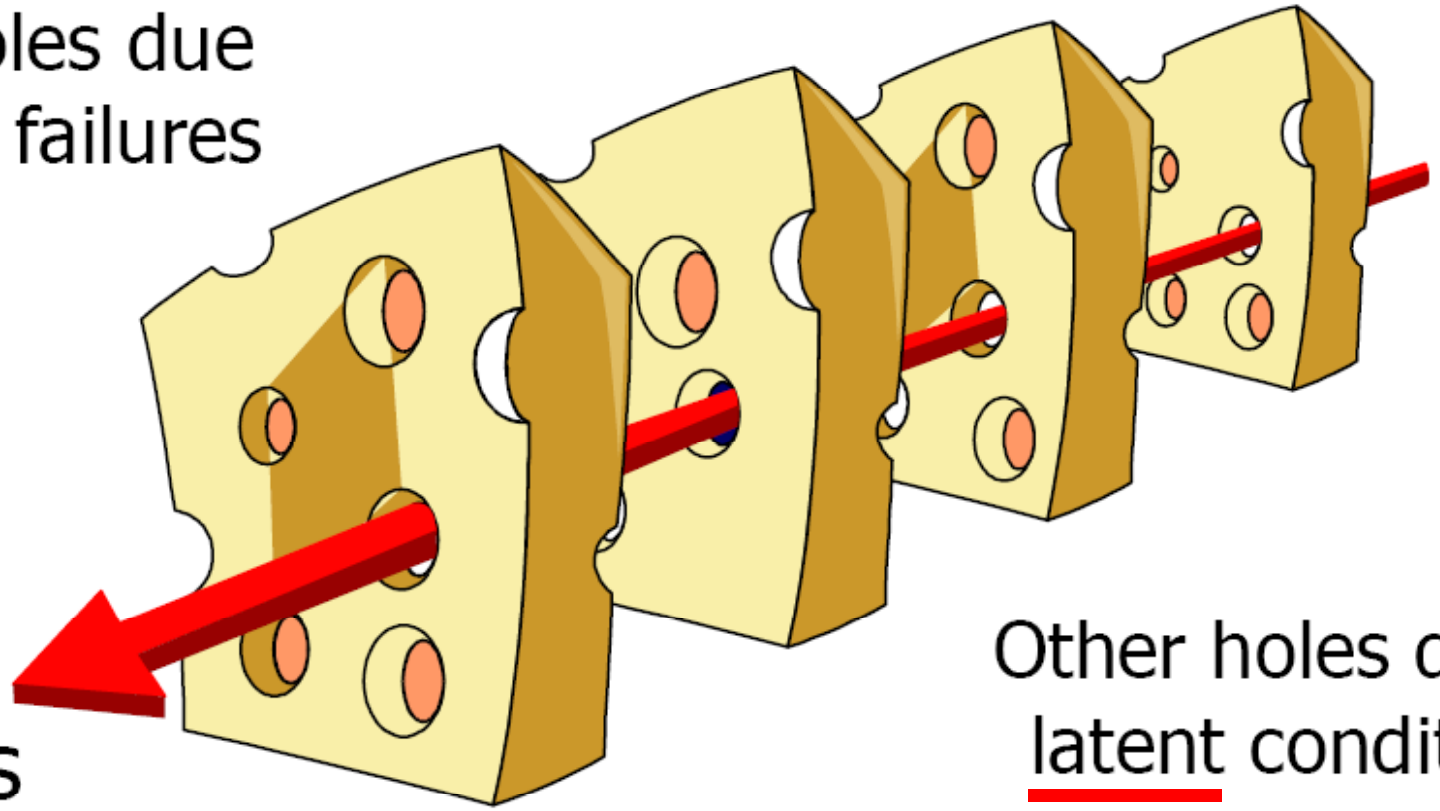
Care delivery as a complex system



Bogner, 1994

Reason's "Swiss cheese" model of accident causation

Some holes due to active failures



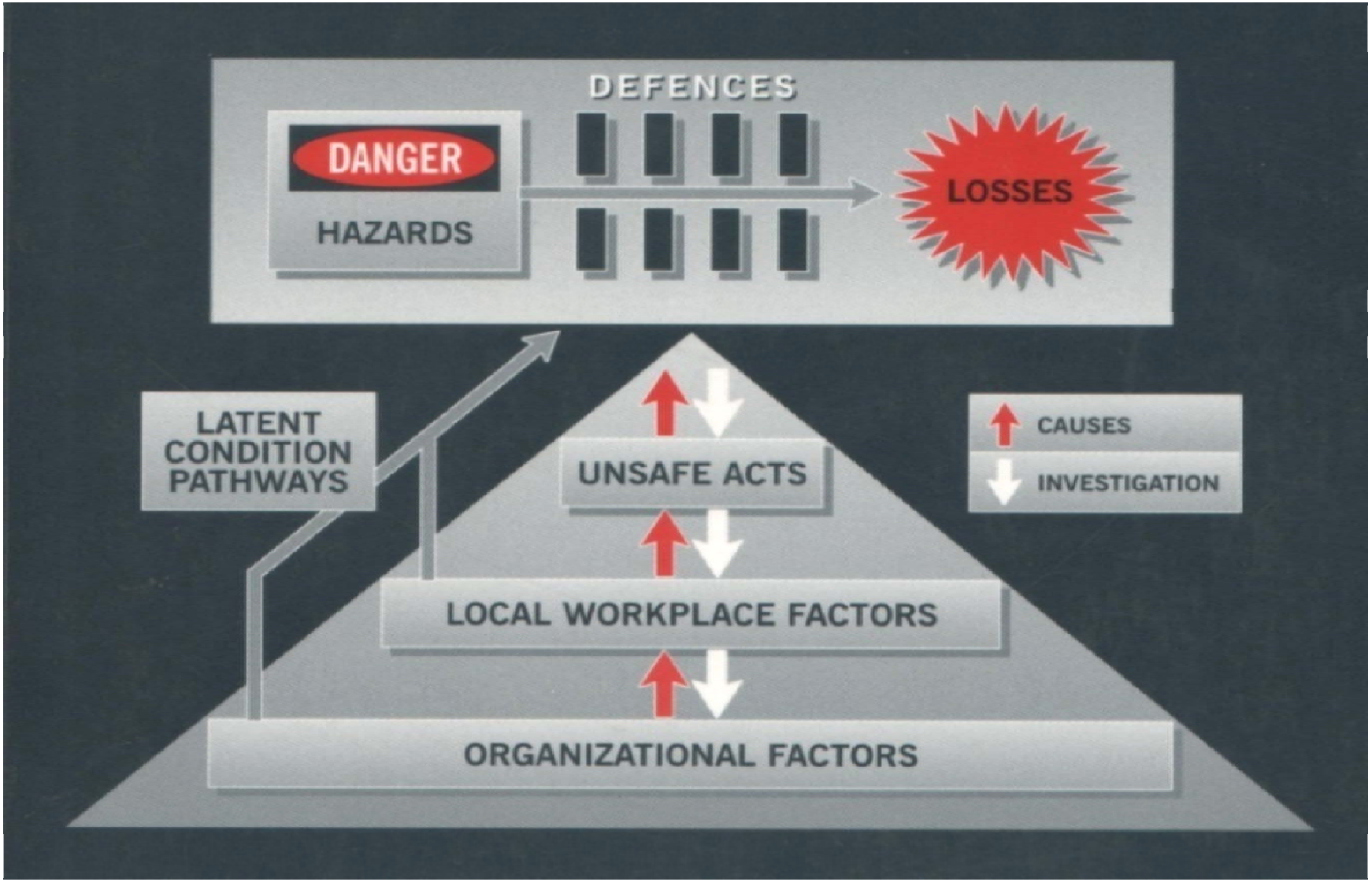
Hazards

Losses

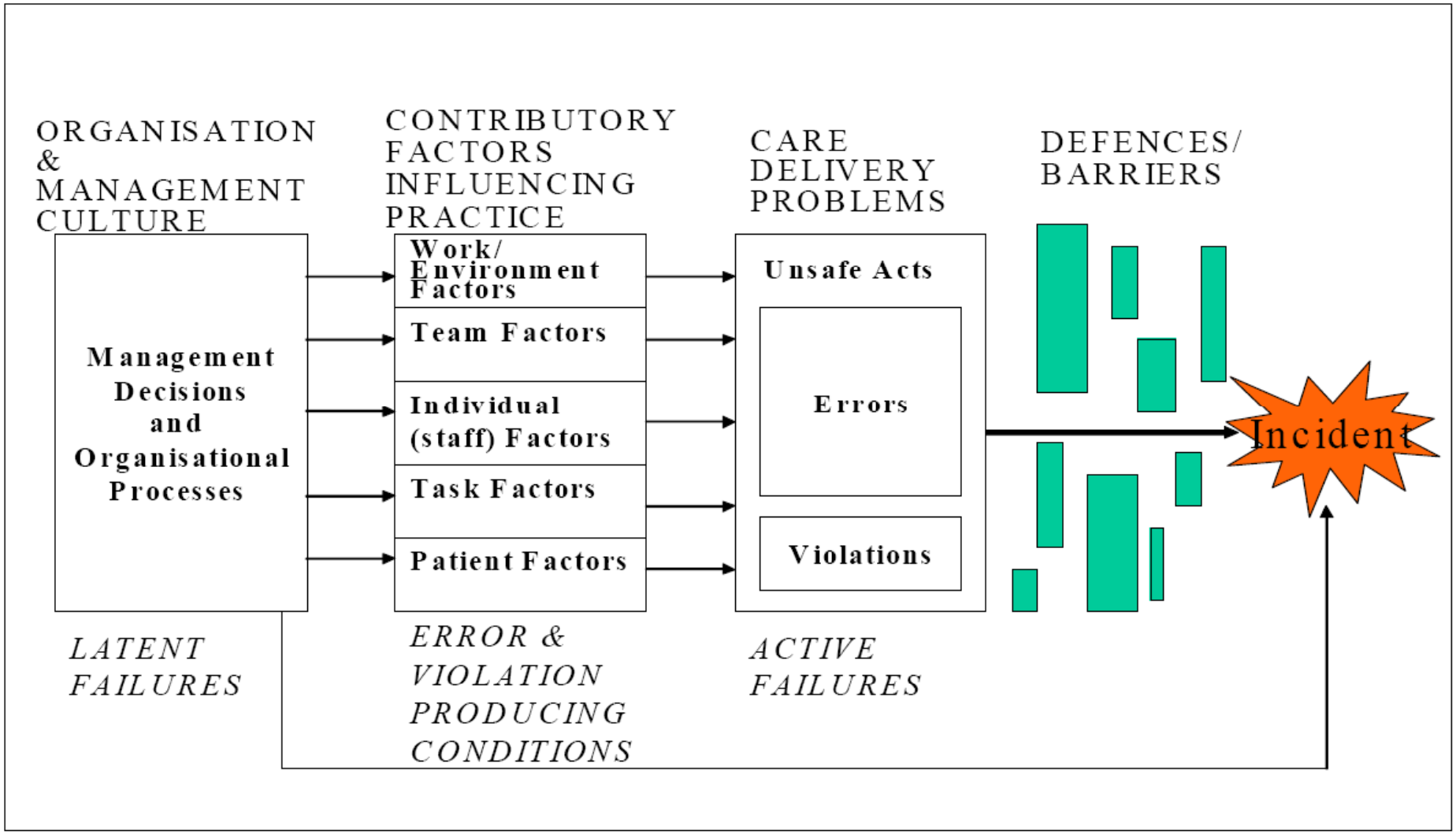
Other holes due to latent conditions

Successive layers of defences, barriers and safeguards *System defences*

A model of systems failure



Adverse events as systems failures 1



Vincent et al., 2000

Adverse events as systems failures 2:

The London Protocol for systems analysis of clinical incidents

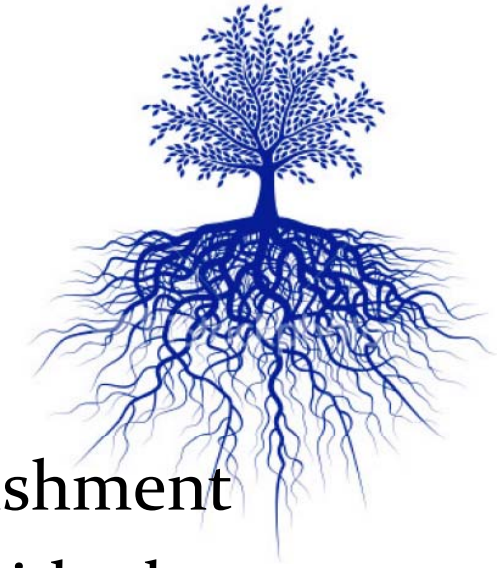
Factor types	Influencing contributory factors	Examples
Institutional context	Economic and regulatory context; national health service executive; clinical negligence scheme for trusts	Inconsistent policies, funding problems
Organisational and management factors	Financial resources and constraints; organisational structure; policy standards and goals; safety culture and priorities	Lacking senior management procedure for risk reduction
Work environment factors	Staffing levels and skills mix; workload and shift patterns; design, availability, and maintenance of equipment; administrative and managerial support	High workload, inadequate staffing, or limited access to essential equipment
Team factors	Verbal communication; written communication; supervision and seeking help; team structure (consistency, leadership, etc)	Poor communication between staff
Individual (staff) factors	Knowledge and skills; competence; physical and mental health	Lack of knowledge or experience of specific staff
Task factors	Task design and clarity of structure; availability and use of protocols; availability and accuracy of test results	Non-availability of test results or protocols
Patient factors	Condition (complexity and seriousness); language and communication; personality and social factors	Distressed patient or language problem

Vincent et al., 2000

Stages in incident investigation (the London Protocol)

1. Identification and decision to investigate
2. Select people for investigation team
3. Organisation and data gathering
4. Determine incident chronology
5. Identify care delivery problems
6. Identify contributory factors
7. Make recommendations and formulate action plan

Root Cause Analysis (RCA)



- A structured approach to incident analysis
- Focus upon prevention not blame and punishment
- Focus upon system vulnerabilities not individual performance
- Review by an interdisciplinary team with local process knowledge
- Aims to achieve a deep understanding of “what” and “why” across a broad spectrum of potential contributory factors
- Involves quantification of risk of recurrence (e.g. FMEA)
- Identifies potential solutions and remedial measures for action

Incident classification by severity

Consequence descriptor Impact on individual	Impact on organisation	Financial impact Complaint • Litigation
Minor • Minor injury • No apparent injury • Minor event	• Minimal risk to Trust	• Theft / loss up to £1000 • Complaint possible • Remote litigation risk
Moderate •Injury causing more than three days absence from work • Temporary incapacity • Short term monitoring or additional treatment needed	• Moderate risk to Trust • Potential for adverse publicity	• Theft / loss between £1,000 and £10,000 • Complaint likely • Litigation possible
Near Miss • Harm prevented • Adverse outcome averted	• Potential high risk to Trust • Possible media interest	
Serious • Injury needing major clinical intervention or unplanned admission to ITU • Injury causing permanent incapacity • Possible Serious untoward incident (SUI)	• High risk to Trust • Service restriction or closure • Probable media interest	• Theft / loss between £10,000 and £50,000 • Litigation expected • Prosecution risk
Major • An incident causing death • Serious untoward incident (SUI)	• Extreme risk • Media interest • Adverse publicity	• Theft / loss over £50,000 • Litigation expected • Prosecution risk

Risk assessment and action level

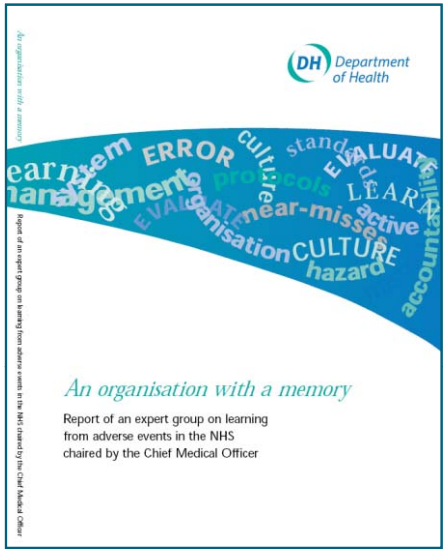
Likelihood descriptor	Consequence descriptor				
	Minor	Moderate	Near Miss	Serious	Major
Rare – don't believe it will happen again	1	2	3	4	5
Unlikely – don't expect it to happen again	2	4	6	8	10
Possible – may re-occur occasionally	3	6	9	12	15
Likely – will probably re-occur, not a persistent issue	4	8	12	16	20
Almost certain – likely to re-occur on many occasions	5	10	15	20	25

Score	Risk preventative measures to be taken or planned
1 – 3	Low risk – manage by routine procedure. Implement any action that will eliminate the risk of the incident recurring.
4 - 6	Moderate risk – management action must be specified. The departmental manager must investigate the incident and devise and implement an action plan to reduce or eliminate the risk.
8 – 12	High risk – senior management action needed. Managers must devise and implement an action plan to reduce, control or eliminate the risk.
15 - 25	Significant risk – immediate action needed. Must be referred to General Manager and an investigation and action plan started immediately to reduce, Controls or eliminate the risk. Must be reported to Quality or Risk Management Departments and if appropriate the Serious Untoward Incident Procedure Implemented as detailed in the Incident Reporting Policy.

3. Monitoring patient safety events: incident reporting

The requirement to learn from failures in UK care systems

- UK Dept of Health report: *An Organisation with a Memory (2000):*
  - NHS does not actively learn from failures
  - Existing systems took a long time to analyse information and generate recommendations
  - There is little or no systematic follow-up of recommendations
- National Audit Office survey of NHS trusts *A Safer Place for Patients* (2005):
  - Lessons learnt on a local level are not widely disseminated either within or between trusts
  - There is a need to improve sharing of solutions by all organisations
  - Considerable complexity in reporting and channels currently exists (multiple agencies responsible for producing guidance)



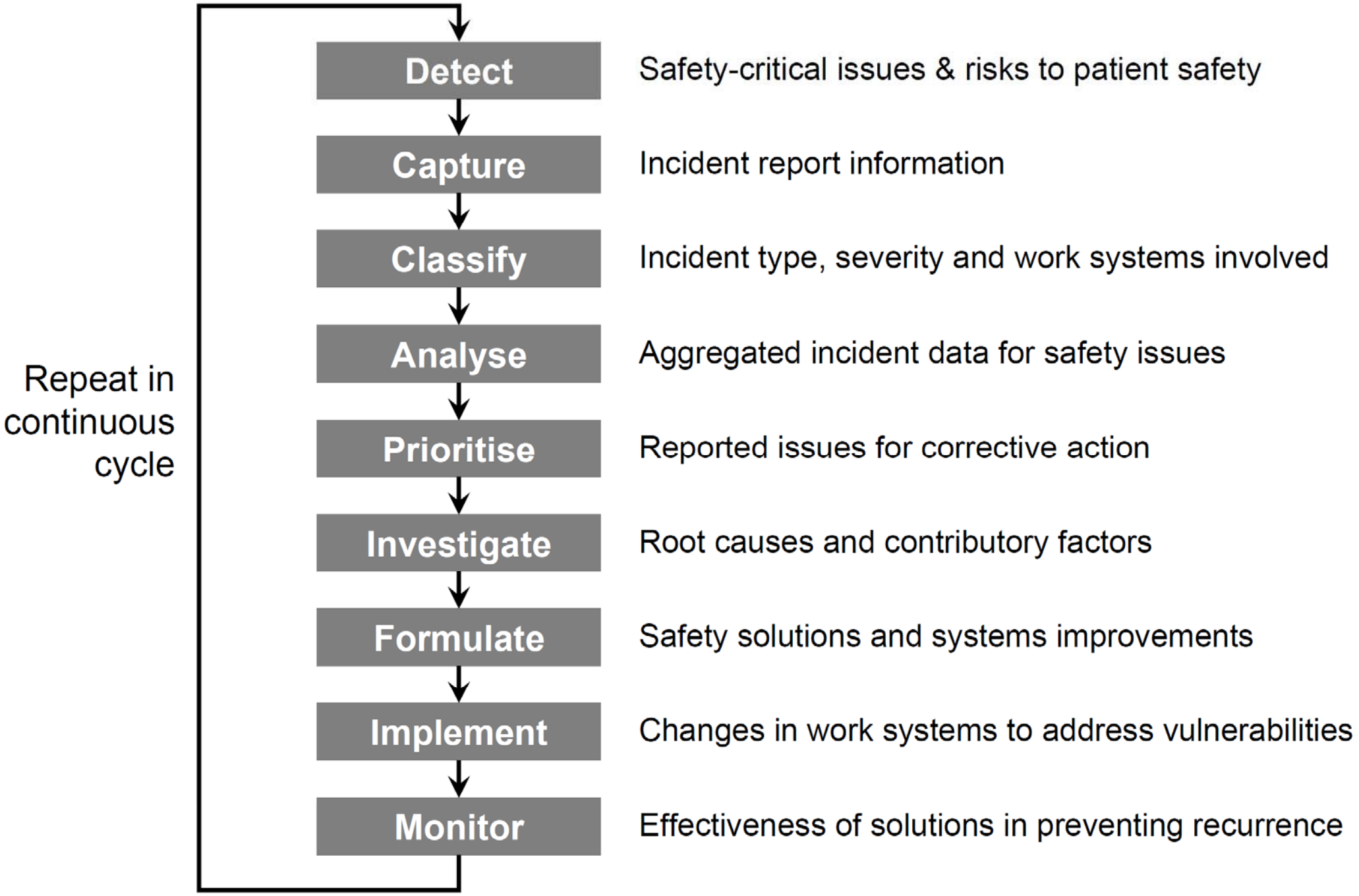
The concept of a reporting system

- Major UK and US patient safety reports called for reporting systems to be introduced within health care (DOH, 2000; IOM, 2000).
  - Based upon safety management system models developed in high risk industries and transport systems
  - Previously, local morbidity and mortality reviews and national confidential enquiries had been the principle means of understanding and responding to patient harm
  - Aim to understand failure through analysing incident reports
- Primary aim of a reporting system is to learn from experience (Leape, 2002).
  - External reporting allows sharing of lessons learnt within a specific context with the whole organisation and broader health service.
- Reporting systems use front-line experience to identify vulnerabilities in clinical work systems and improve their design (Morath and Turnbull, 2005).
- Reporting systems in high risk industries gather data on “near misses” as well as actual events with adverse outcomes.
  - In other industries, there are potentially many more near misses than actual adverse events

International models for reporting systems in various domains

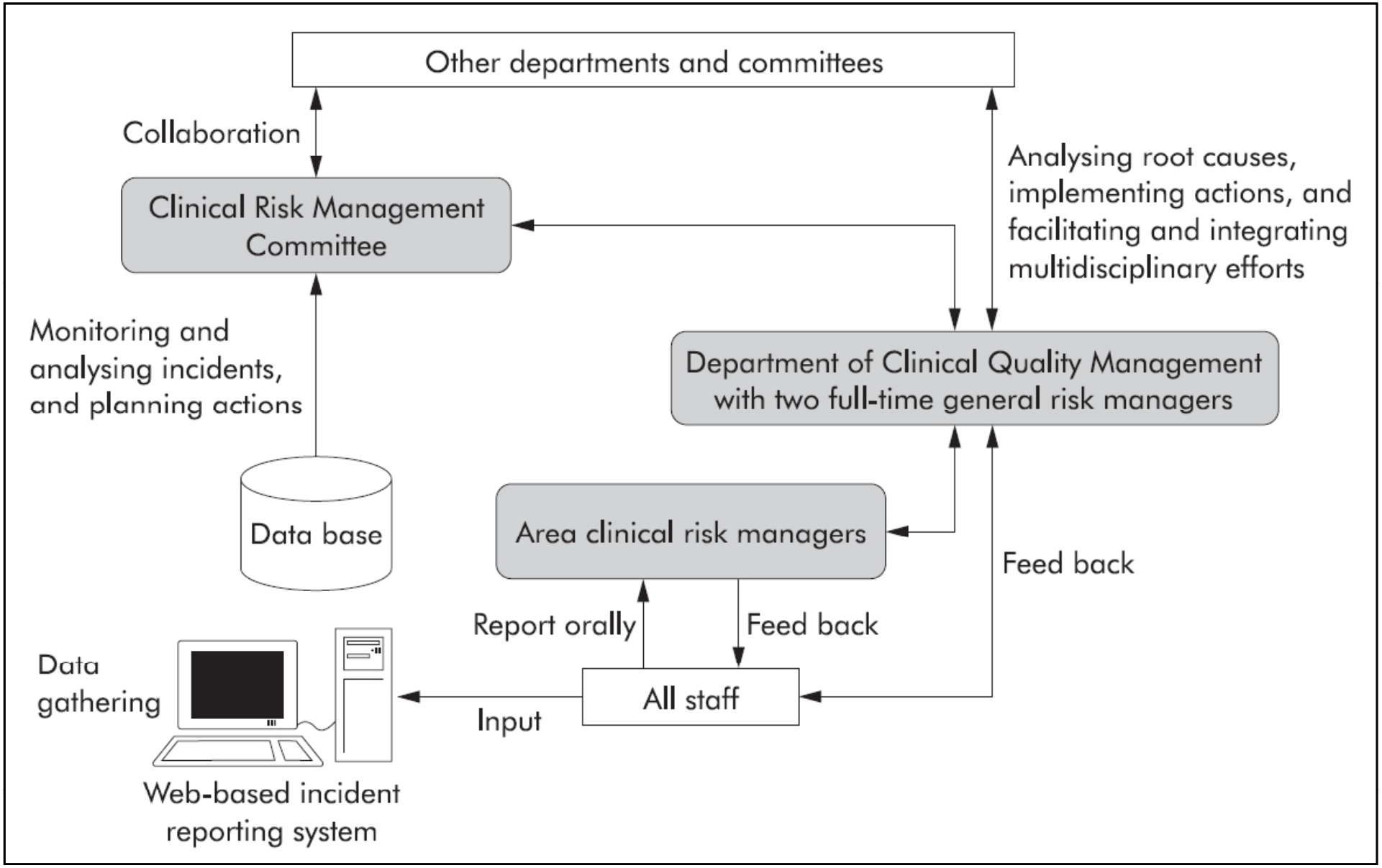
System	Domain
High risk industry and transport sectors:	
Aviation Safety Reporting System (ASRS)	US Aviation
Confidential Human Factors Incident Reporting Programme (CHIRP)	UK Civil Aviation
Confidential Hazardous Incident Reporting Programme (CHIRP)	UK Maritime
British Airways Safety Information System (BASIS)	UK Civil Aviation
Corrective Action Programme (CAP)	UK Energy
Confidential Incident Reporting and Analysis System (CIRAS)	UK Rail
Health care:	
Intensive Care Unit Safety Reporting System (ICUSRS)	US Health Care
Patient Safety Reporting System (PSRS)	US Health Care
NPSA National Reporting and Learning System (NRLS)	UK Health Care
Australian Incident Monitoring Study (AIMS)	AUS Health Care

Functional definition of a reporting system

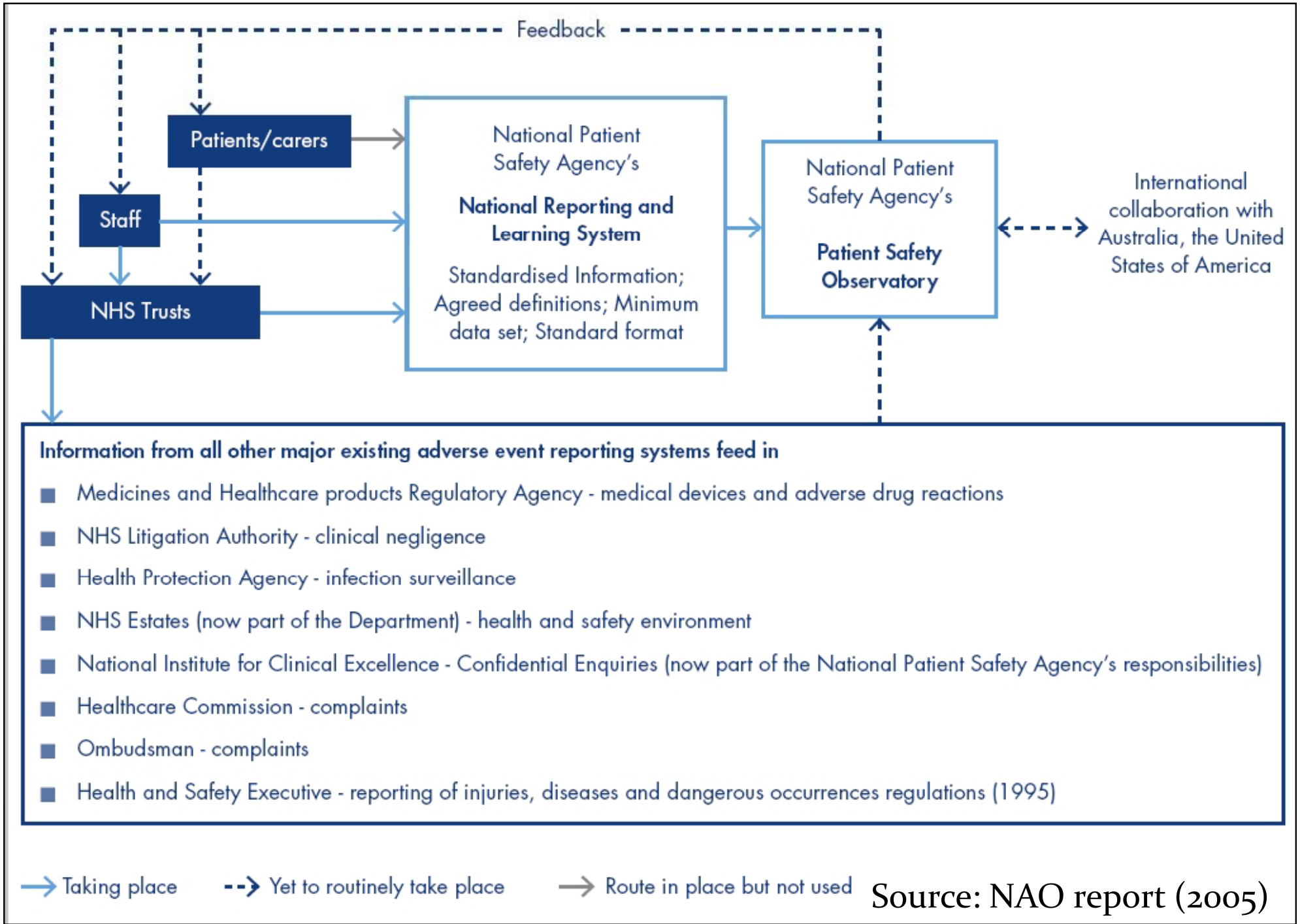


Example: local level reporting system overview

(Nakajima et al., 2005)



National Reporting and Learning System: Info flow



Source: NAO report (2005)

NRLS issues patient safety alerts and rapid responses

NHS
National Patient Safety Agency

PATIENT SAFETY **ALERT**

PROBLEM:

Research in UK and elsewhere has identified a risk to patients from errors occurring during intravenous administration of potassium solutions.

Potassium chloride concentrate solution can be fatal if given inappropriately.

ACTION FOR NHS BY 31 OCTOBER 2002:

This alert sets out action, including initial action in the following areas:

1. Storage and handling of potassium chloride concentrate and other strong potassium solutions
2. Preparation of dilute solutions containing potassium
3. Prescription of solutions containing potassium
4. Checking use of strong potassium solutions in clinical areas

For the attention of:

Chief Executives of NHS Trusts and Primary Care Trusts

For action by:

Chief Pharmacists and pharmaceutical advisers in NHS Trusts and Primary Care Trusts

For information to:

Regional Directors of Health and Social Care
Chief Executives of Strategic Health Authorities
Directors of Public Health: Regional, StHA, PCT
Medical Directors
Directors of Nursing
Risk Managers
Lead Consultants/Clinical Directors – critical care areas
Communications Leads
Patient Advice and Liaison Service (PALS)

Date: 23 July 2002

NHS
National Patient Safety Agency

Rapid Response Report

NPSA/2012/RRR001

From reporting to learning — 22 March 2012

Harm from flushing of nasogastric tubes before confirmation of placement

Issue

Misplaced nasogastric tubes leading to death or severe harm are 'never events.' The Patient Safety Alert *Reducing the harm caused by misplaced nasogastric feeding tubes in adults, children and infants* was issued by the NPSA on 10 March 2011 with an action complete date of 12 September 2011. Alongside other actions, this Alert requires all organisations to ensure that *'Nasogastric tubes are not flushed, nor any liquid/feed introduced through the tube following initial placement, until the tube tip is confirmed by pH testing or x-ray to be in the stomach.'* This advice is repeated in the National Nurses Nutrition Group *Good Practice Guideline: Safe Insertion of Nasogastric Feeding Tubes in Adults*.

The advice not to flush until after gastric placement is confirmed is important because:

- any flush could cause an aspiration pneumonia if the tube is misplaced in the lungs;
- pH testing for gastric placement relies on collecting aspirate via the tube; anything introduced down the tube will contaminate this aspirate, potentially leading to false positive pH readings.

Evidence of harm

The NPSA is aware of two patient deaths since 10 March 2011 where staff had flushed nasogastric tubes with water before initial placement had been confirmed. Staff then aspirated back the water they had flushed into the tube, including the lubricant within the tube that this water had activated. Because this mix of water and lubricant gave a pH reading below 5.5, they assumed that the nasogastric tube was correctly placed and went on to give medications and/or feed, although the tube was actually in the patient's lung. We are also aware of a similar incident which did not lead to harm to a patient.

The three organisations where the incidents occurred were aware of the NPSA Alert, but there appeared to be a widespread belief amongst their frontline staff that the 'never flush' rule did not apply where nasogastric tubes had a water-activated lubricant. This belief is incorrect, and the manufacturer's written guidance, enclosed with each new nasogastric tube, clearly states that gastric placement must be confirmed BEFORE the tube is flushed. The lubricant is not needed for placement, only to aid removal of the guidewire/ stylet from the tube **after gastric placement has been confirmed.**

FOR IMMEDIATE ACTION by all organisations in the NHS and independent sector where nasogastric feeding tubes are placed and used for feeding patients. The deadline for action complete is 21 September 2012.

1. Assign a named clinical lead to coordinate implementation of the actions in this Rapid Response Report (RRR) with any actions outstanding from the earlier Alert
2. Remind all staff responsible for checking initial placement of nasogastric tubes (including staff who support parents/carers who check initial placement of nasogastric tubes):
   a. NOTHING should be introduced down the tube before gastric placement has been confirmed;
   b. DO NOT FLUSH the tube before gastric placement has been confirmed;
   c. Internal guidewires/ stylets should NOT be lubricated before gastric placement has been confirmed.
3. This reminder should be given through:
   a. Distributing this RRR to all relevant staff;
   b. Providing warning notices and/ or overwraps with warning labels on all current and future stock of nasogastric tubes, until these are provided as standard by manufacturers;
   c. Reviewing and, if necessary, amending all local policy, protocol and training materials.

The NPSA has alerted device manufacturers of this risk and will promote the need for safer design and labelling. Any concerns related to manufacturers' instructions for use or labelling should be reported to the Medicines and Healthcare products Regulatory Agency.

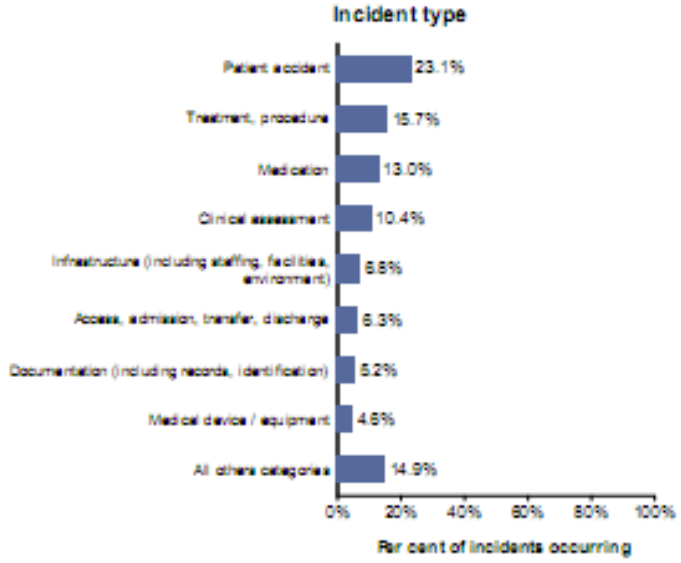
NHS Evidence accredited provider

Further information: This RRR should be read in conjunction with the previous Alert *Reducing the harm caused by misplaced nasogastric feeding tubes in adults, children and infants*. This remains in force and should be referred to for all other issues, including repeat placement checks after initial gastric placement has been confirmed.
For further queries contact rr@npsa.nhs.uk. Telephone 020 7927 9500.

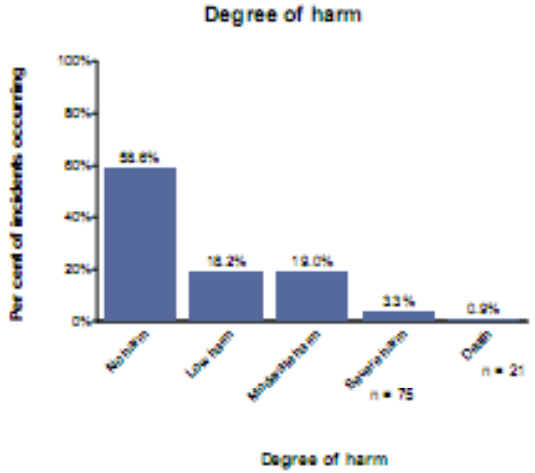
NRLS produces reports for healthcare organisations (2009)

Incident summary for the period April 2008 to September 2008

There were 2,269 incidents during the 6 month period between April 2008 to September 2008 submitted to the Reporting and Learning System (RLS) by the end of November 2008.



The graph above shows the type of incidents reported from comparable national breakdown is available at http://www.npsa.nhs.uk/datareports/



The graph above shows the degree of harm of incidents as reported by this organisation. Nationally, 66 per cent of incidents are reported as no harm, and

Reports submitted by month

The graph above shows the number of incidents submitted in each of the last 12 months. Consistent or increasing numbers of reports each month indicate that an organisation has a robust process for submitting data. Organisations should submit incidents to the RLS at least monthly, to allow timely national action to be taken. The median days between an incident occurring and being submitted to the RLS for the period April 2008 to September 2008 is 57 days: the time lag for this organisation over the same period was 59 days.

Includes:
- Breakdown by type
- Degree of harm
- Tracks reporting rates by month
- Benchmarks against other trusts

Characteristics of effective reporting and learning systems

- Leape (2002) summarises the characteristics of effective incident reporting schemes:

CHARACTERISTIC	EXPLANATION
Nonpunitive	Reporters are free of fear of retaliation or punishment from others as a result of reporting.
Confidential	The identities of the patient, reporter, and institution are never revealed to a third party.
Independent	The program is independent of any authority with power to punish the reporter or organization.
Expert analysis	Reports are evaluated by experts who understand the clinical circumstances and who are trained to recognize underlying systems causes.
Timely	Reports are analyzed promptly, and recommendations are rapidly disseminated to those who need to know, especially when serious hazards are identified.
Systems-oriented	Recommendations focus on changes in systems, processes, or products, rather than on individual performance.
Responsive	The agency that receives reports is capable of disseminating recommendations, and participating organizations agree to implementing recommendations when possible.

The limitations of incident reporting

- Incident reporting systems rely upon voluntary reporting by staff – subject to social and practical factors (e.g. culture; time pressures)
- Health care professionals and doctors in particular are unlikely to report an incident to superiors and most likely to report when an incident involves a violation of protocol with a bad outcome (Lawton & Parker, 2002)
- Other main reasons identified by Stanhope et al. (1999) and Firth-Cozens (2004):
  - Unclear as to what should be reported.
  - Fear of blame/repercussions
  - Perception of lack of feedback/follow-up of reported issues
- Reported incidents are not a perfect indicator of actual rates of underlying errors and adverse events that occur in practice.
  - International research suggests there is under-reporting of incidents to reporting systems
  - Organisations with higher rates of reported incidents may have a more developed safety culture (leading to increased reporting), rather than being less safe
- Incident reporting schemes are retrospective in focus. The challenge is to design more prospective monitoring approaches which can provide indications of when current variation on care systems and processes might become harmful.

4. “Harm” as process variation

Quality of care in the US

McGlynn, E., Asch, S., Adams, J., Keesey, J., Hicks, J., DeCristofaro, A., et al. (2003). The Quality of Health Care Delivered to Adults in the United States (Vol. 348, pp. 2635-2645).

Taking a "process variation" perspective means focusing upon the **reliability** of care delivery over time.

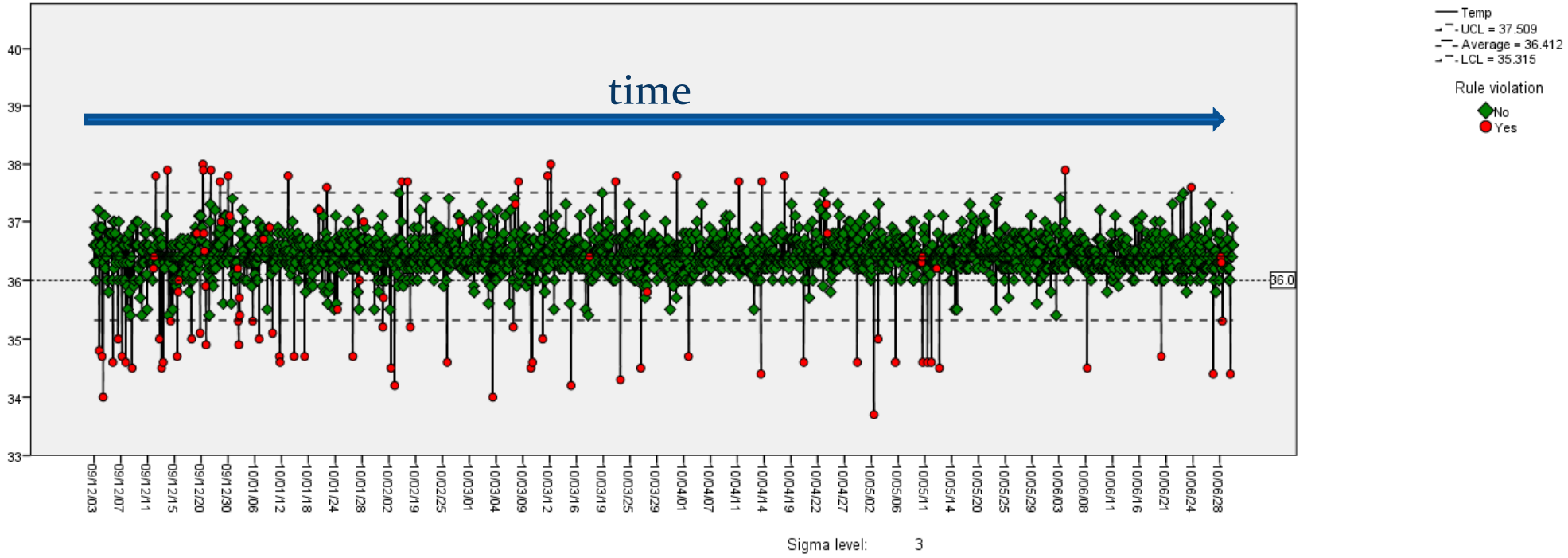
Is the rate of defects per opportunities in health care comparable to other industries?

Table 5. Adherence to Quality Indicators, According to Condition.*

Condition	No. of Indicators	No. of Participants Eligible	Total No. of Times Indicator Eligibility Was Met	Percentage of Recommended Care Received (95% CI)
Senile cataract	10	159	602	78.7 (73.3–84.2)
Breast cancer	9	192	202	75.7 (69.9–81.4)
Prenatal care	39	134	2920	73.0 (69.5–76.6)
Low back pain	6	489	3391	68.5 (66.4–70.5)
Coronary artery disease	37	410	2083	68.0 (64.2–71.8)
Hypertension	27	1973	6643	64.7 (62.6–66.7)
Congestive heart failure	36	104	1438	63.9 (55.4–72.4)
Cerebrovascular disease	10	101	210	59.1 (49.7–68.4)
Chronic obstructive pulmonary disease	20	169	1340	58.0 (51.7–64.4)
Depression	14	770	3011	57.7 (55.2–60.2)
Orthopedic conditions	10	302	590	57.2 (50.8–63.7)
Osteoarthritis	3	598	648	57.3 (53.9–60.7)
Colorectal cancer	12	231	329	53.9 (47.5–60.4)
Asthma	25	260	2332	53.5 (50.0–57.0)
Benign prostatic hyperplasia	5	138	147	53.0 (43.6–62.5)
Hyperlipidemia	7	519	643	48.6 (44.1–53.2)
Diabetes mellitus	13	488	2952	45.4 (42.7–48.3)
Headache	21	712	8125	45.2 (43.1–47.2)
Urinary tract infection	13	459	1216	40.7 (37.3–44.1)
Community-acquired pneumonia	5	144	291	39.0 (32.1–45.8)
Sexually transmitted diseases or vaginitis	26	410	2146	36.7 (33.8–39.6)
Dyspepsia and peptic ulcer disease	8	278	287	32.7 (26.4–39.1)
Atrial fibrillation	10	100	407	24.7 (18.4–30.9)
Hip fracture	9	110	167	22.8 (6.2–39.5)
Alcohol dependence	5	280	1036	10.5 (6.8–14.6)

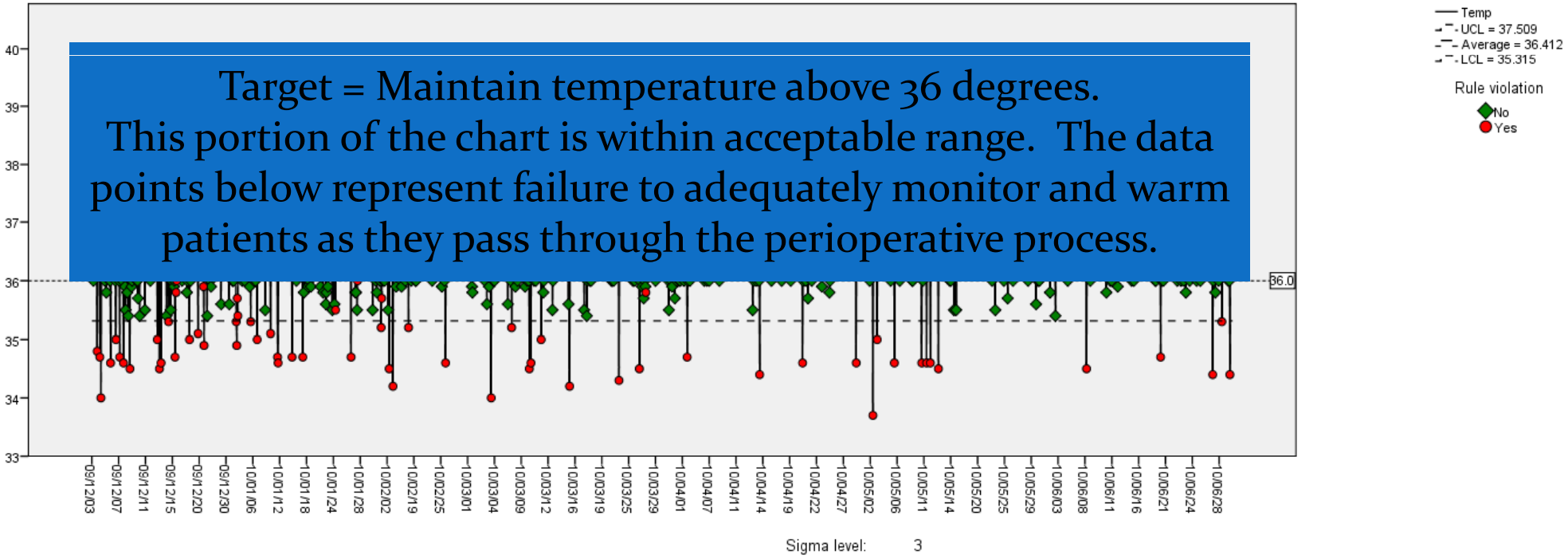
All human-intensive processes vary over time

Variation in core temperature upon arrival in the recovery room of 3200 consecutive surgical patients

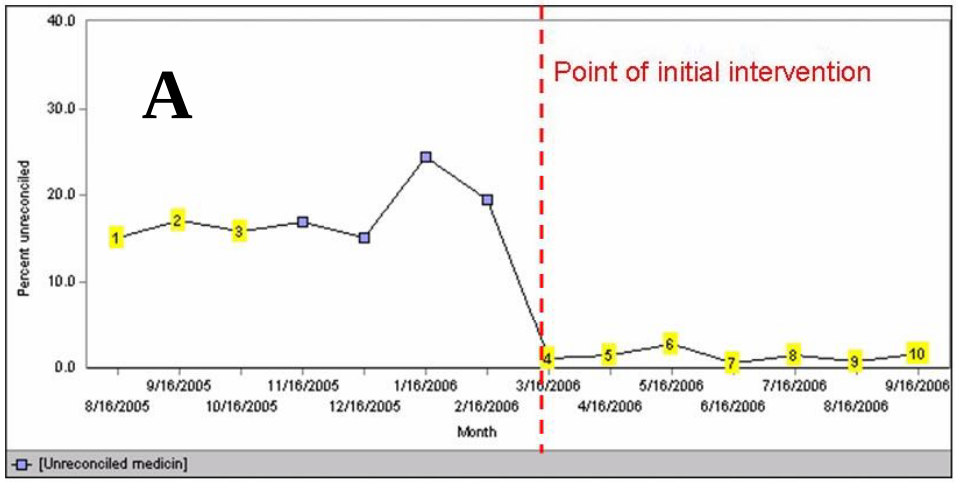


Quality improvement is about detecting and reducing unacceptable variation

Variation in core temperature upon arrival in the recovery room of 3200 consecutive surgical patients

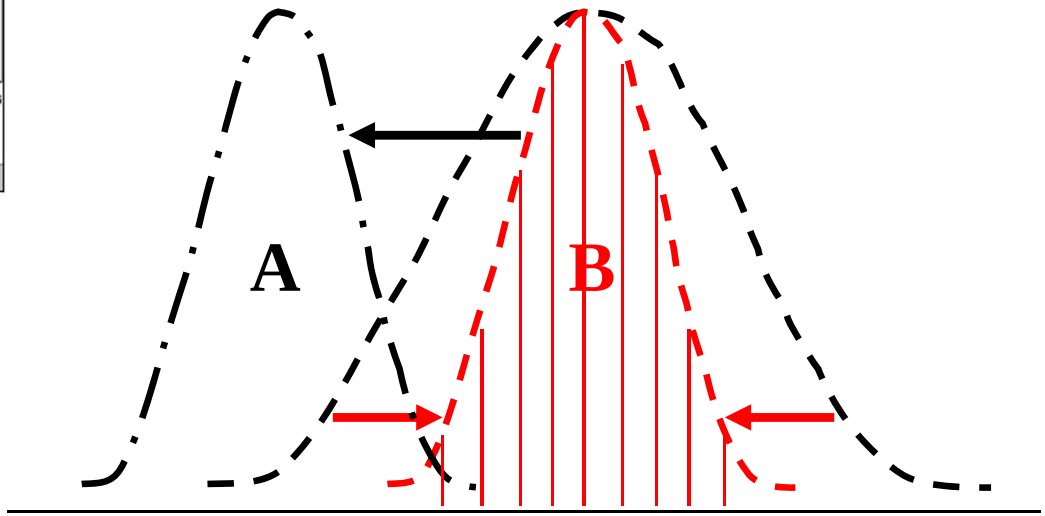


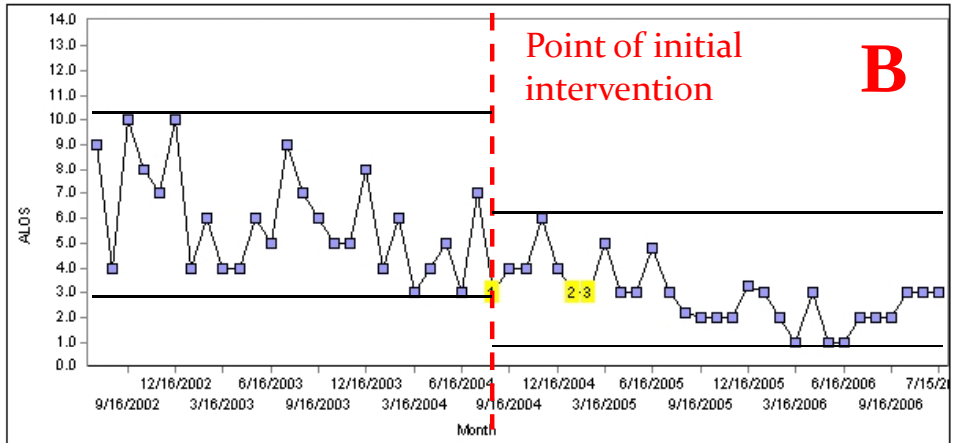
Statistical definition of improvement in process data



A = A stable shift in the level of the process in a desirable direction

➡ **Improved "Capability"**

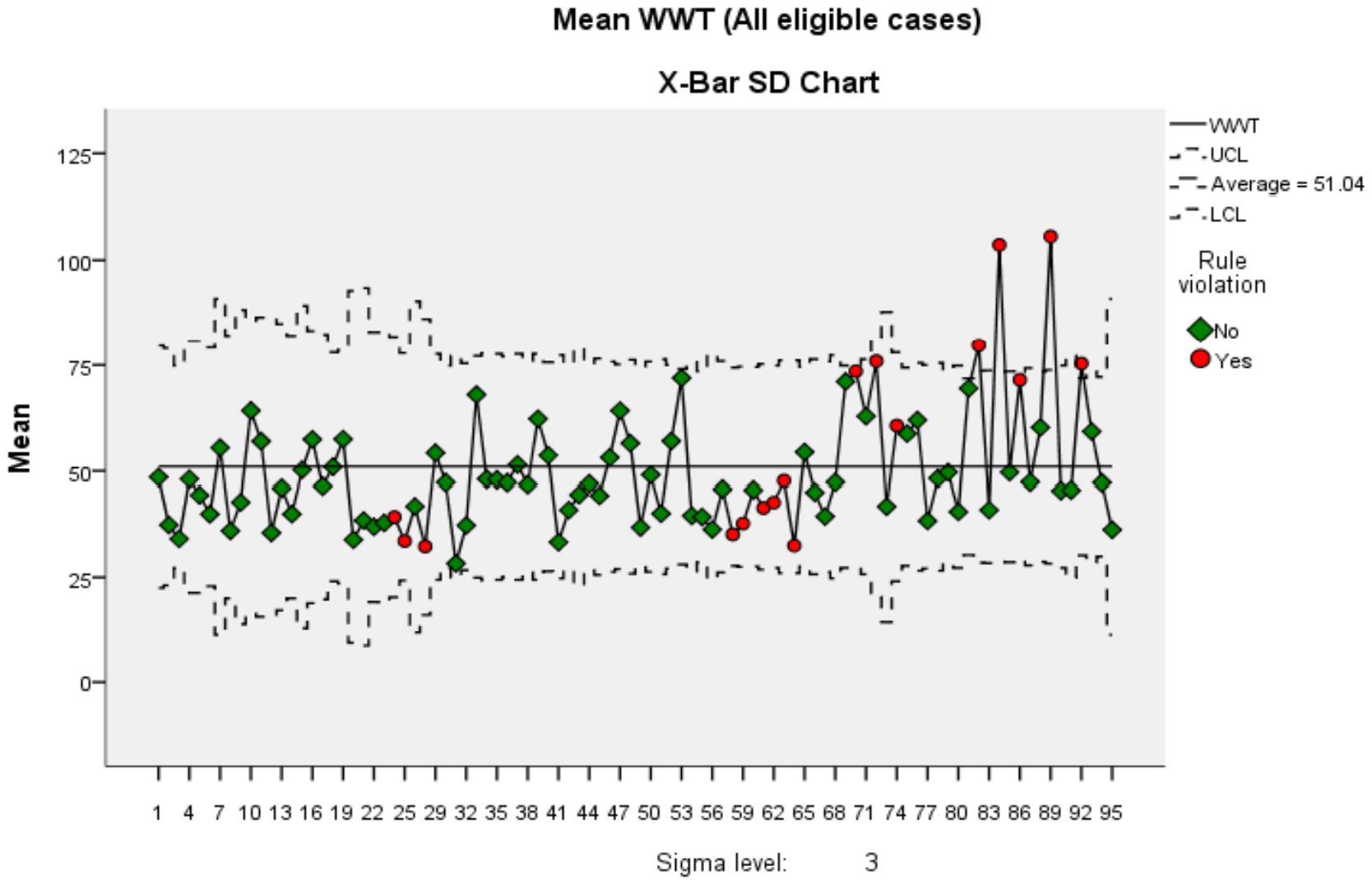




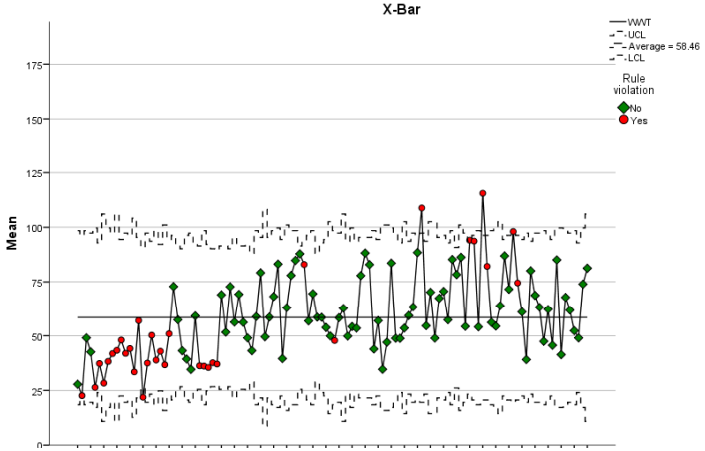
B = Reduction in degree of variation in consecutive data points over time

➡ **Improved "Reliability"**

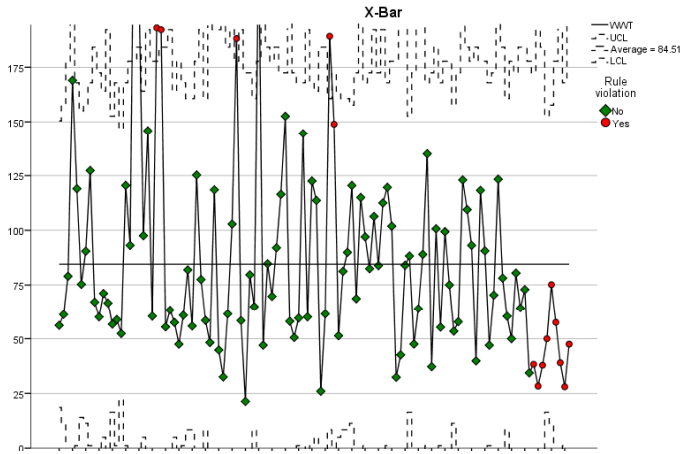
On sampling and aggregation:
Mean Ward Wait Time for patient collection from PACU



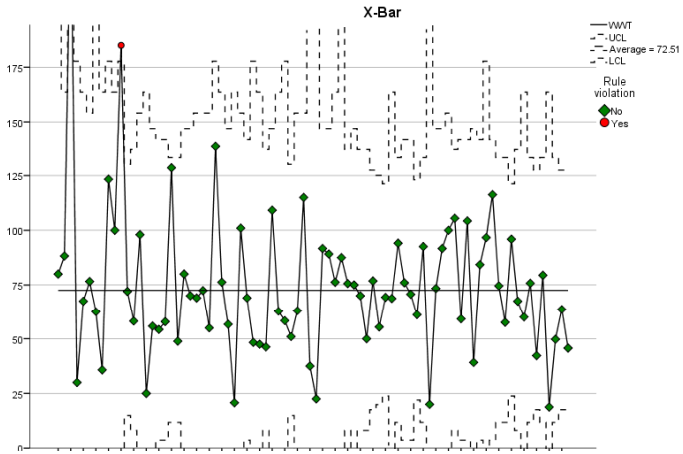
Mean weeky WWT - VEL



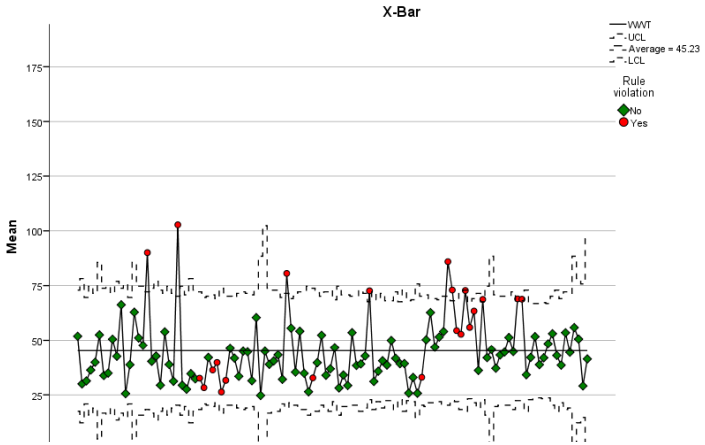
Mean weeky WWT - CPA



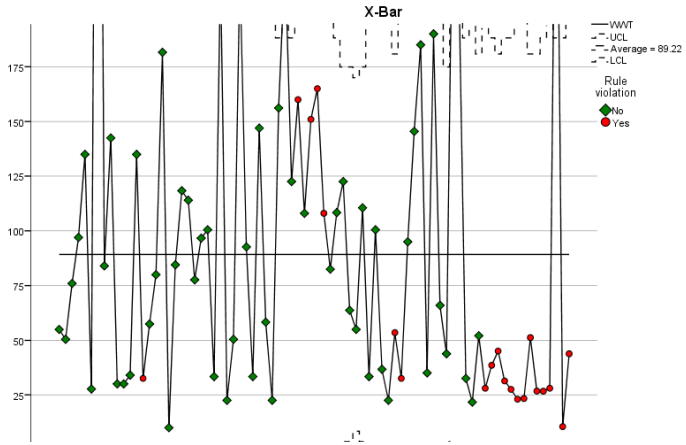
Mean weeky WWT - ZCH



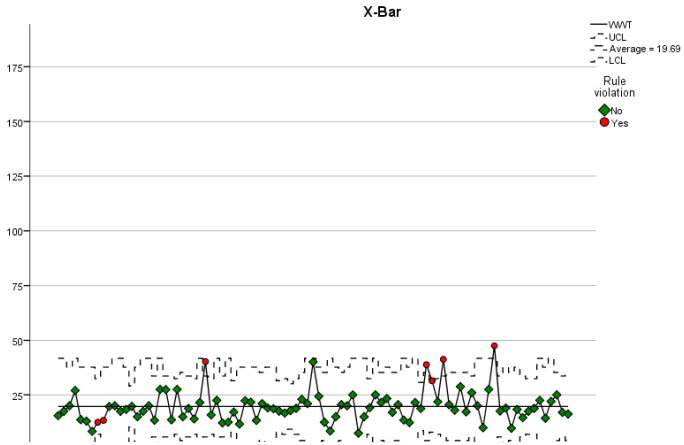
Mean weeky WWT - SAM



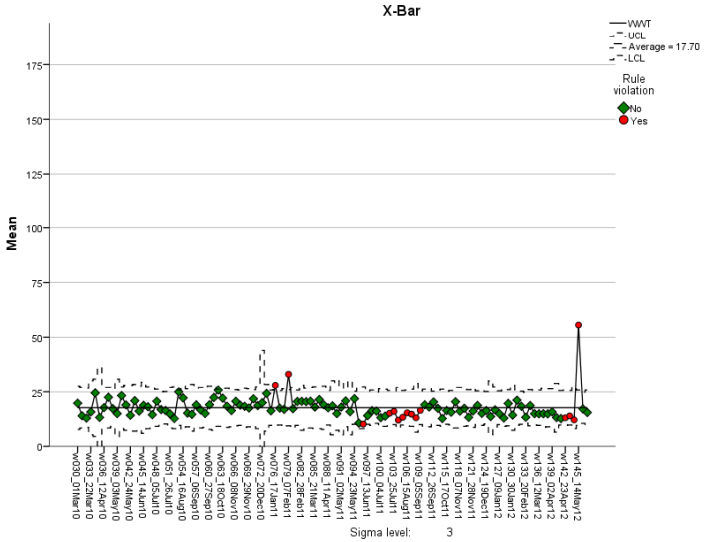
Mean weeky WWT - CPH



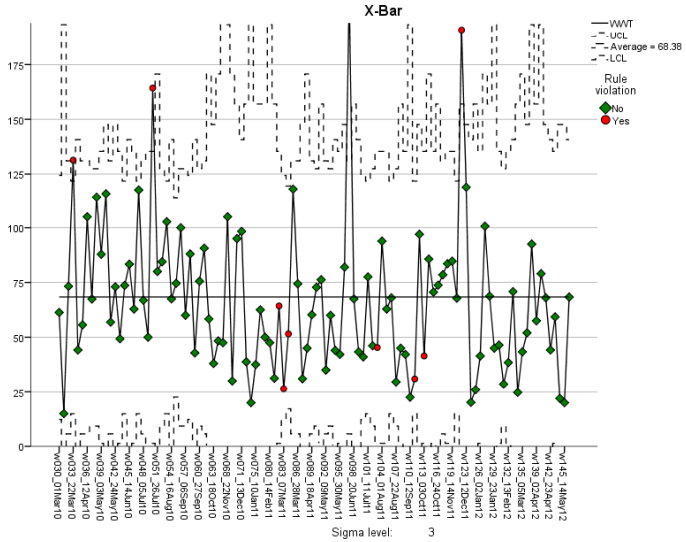
Mean weeky WWT - GW



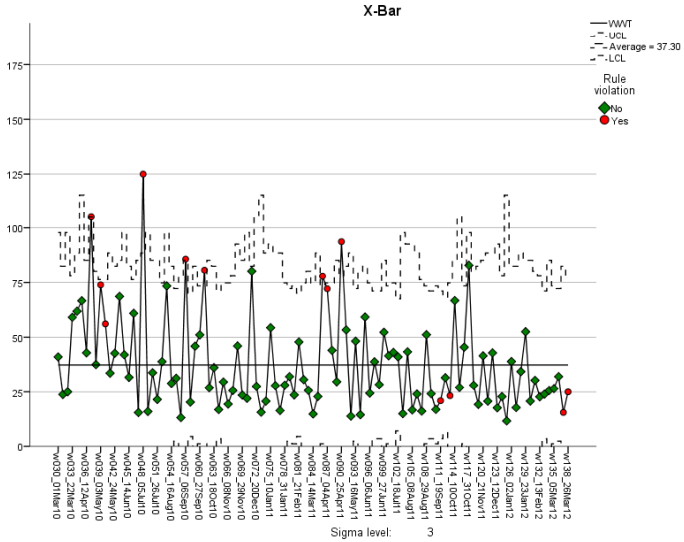
Mean weeky WWT - WW



Mean weeky WWT - ZCO



Mean weeky WWT - WIT

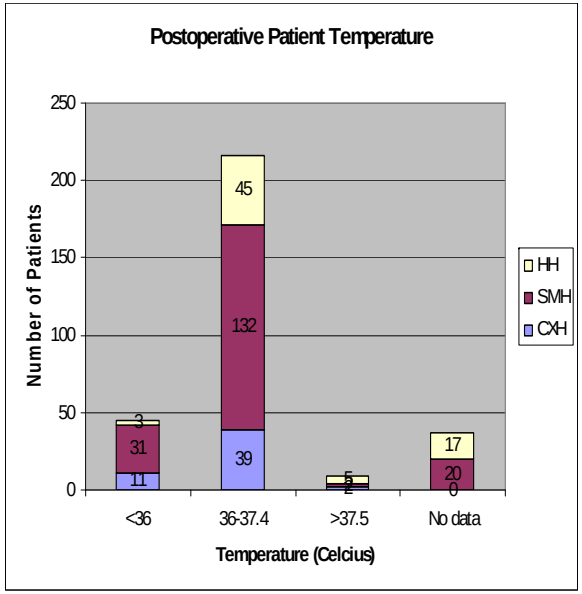


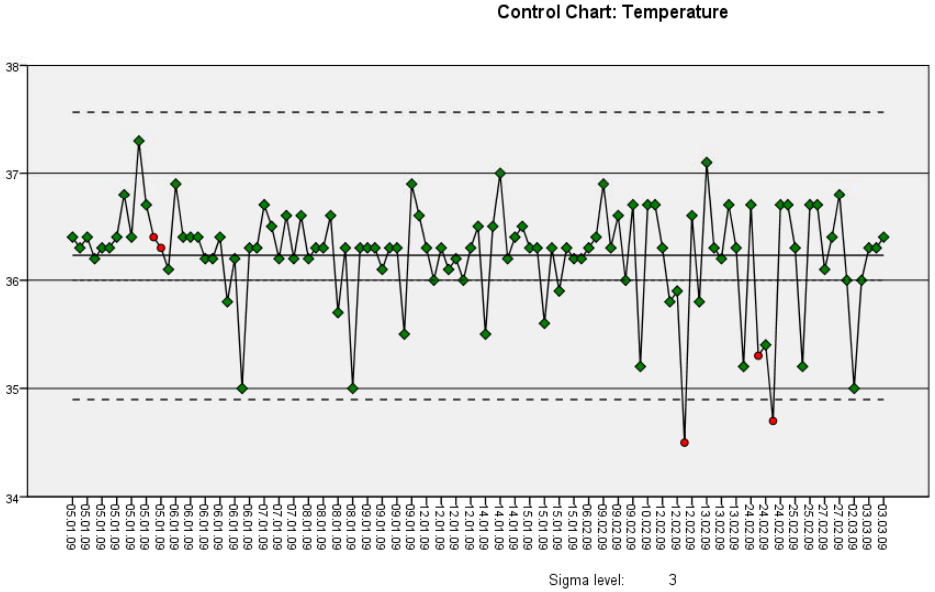
The case for local continuous process monitoring

- Process measurement and analysis using run charts is relatively easy to implement and capable of guiding local improvement efforts
  - Process measurement is an important component of quality improvement, as it makes quality problems visible to front line staff and allows them to understand when they have made an improvement
  - Provides useful data very quickly (within 25 repeated observations and even less for run charts)
  - Provides a dynamic rather than static view of the data – can be used for **real time monitoring**
  - Visual representation is easily understood and interpreted with limited statistical expertise

Periodic auditing & summary reports:

- Provides “Snapshot” summaries at specific time-points
- Masks natural process variation over time
- Supports periodic summative feedback that is retrospective in focus
- Supports summative pretest-posttest design but not iterative improvement work
- Is usually a “special project”





Continuous process monitoring:

- Provides continuous signal of variation over time
- Can identify significant underlying process change against background noise
- Supports real-time continuous feedback that can detect harmful trends early
- Effects of interventions are observable over time and can be used to guide improvement work
- Must be integrated within routine operations

5. Intervening to improve clinical systems

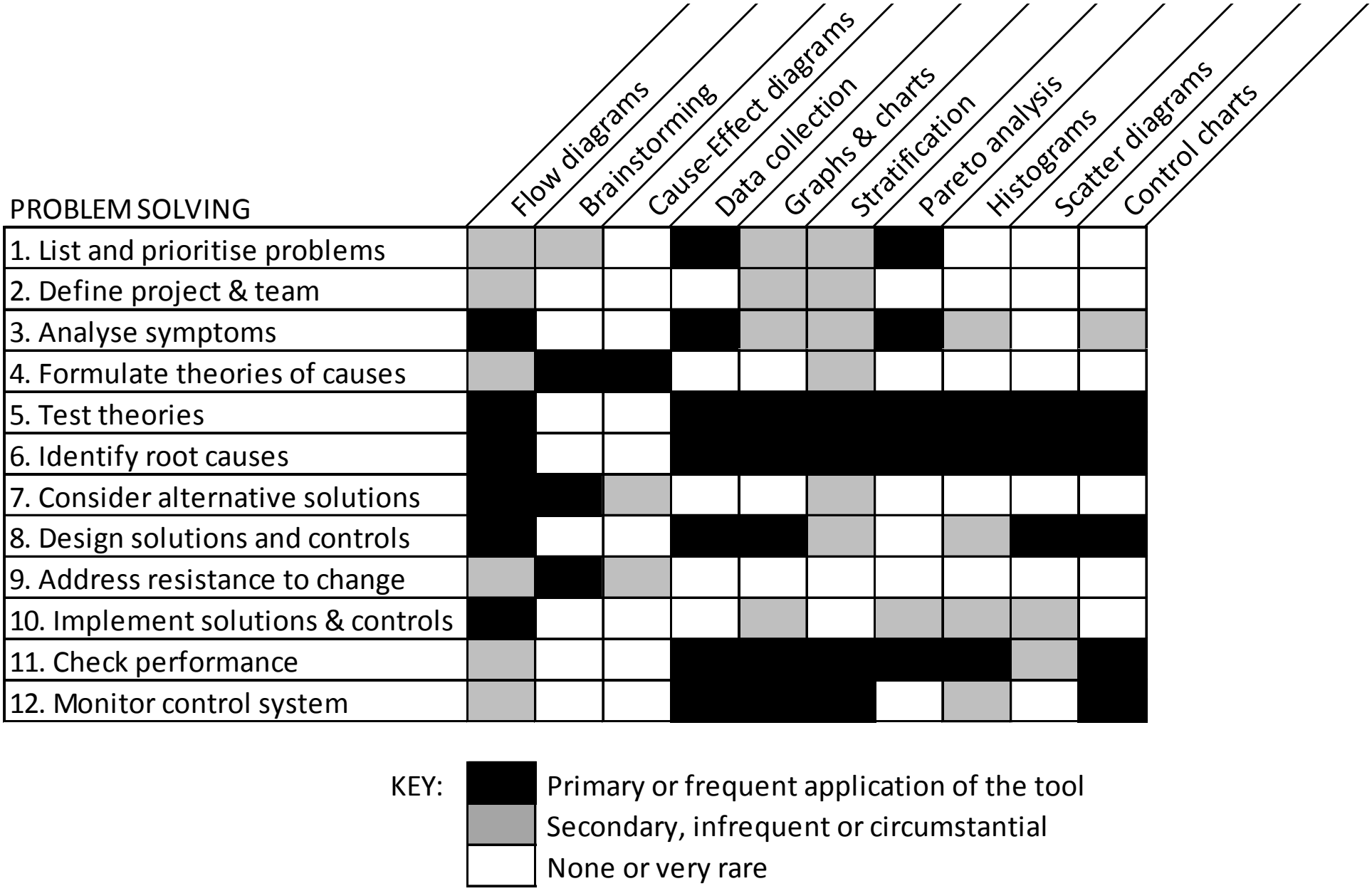
11 patient safety practices with strong evidence for efficacy (AHRQ, 2013)

- Appropriate use of prophylaxis to prevent venous thromboembolism in patients at risk.
- Use of perioperative beta-blockers in appropriate patients to prevent perioperative morbidity and mortality.
- Use of maximum sterile barriers while placing central intravenous catheters to prevent infections.
- Appropriate use of antibiotic prophylaxis in surgical patients to prevent postoperative infections.
- Asking that patients recall and restate what they have been told during the informed consent process.
- Continuous aspiration of subglottic secretions (CASS) to prevent ventilator-associated pneumonia.
- Use of pressure relieving bedding materials to prevent pressure ulcers.
- Use of real-time ultrasound guidance during central line insertion to prevent complications.
- Patient self-management for warfarin (Coumadin™) to achieve appropriate outpatient anticoagulation and prevent complications.
- Appropriate provision of nutrition, with a particular emphasis on early enteral nutrition in critically ill and surgical patients.
- Use of antibiotic-impregnated central venous catheters to prevent catheter-related infections.

Continuous Quality Improvement (CQI)

- Non-health care origins: Continuous Quality Improvement is largely synonymous with Total Quality Management and indeed there are many similarities between CQI, TQM, Six Sigma and Lean (Boaden, 2008)
- Key components of a CQI approach (Locock, 2003):
  - Incremental improvement of existing processes rather than radical redesign
  - Repeated testing and evaluation of small scale changes
  - Responsibility for quality placed in hands of frontline staff (empowerment)
  - Collective team responsibility that crosses professional boundaries
  - Culture of open learning and analysing errors without fear of blame
  - Strong emphasis upon measurement
  - Systems approach to causes of high/low quality that takes in the whole care process
  - "Bottom-up" change rather than "top-down"

Tools to support continuous improvement



Plsek, P. (1999). Quality Improvement Methods in Clinical Medicine. Pediatrics, 103(1), e203.

Research on quality improvement programmes

- **Systematic review of evidence for the impact of quality improvement collaboratives (Schouten et al. 2008)**
  - Review of 9 robust studies showed mixed/limited positive results
  - Heterogeneity of interventions at this level limits our ability to conclude they have an effect
  - Inability to separate "intervention" from continuous internal development/processes
  - Studies generally do not capture what happens in the "black box" – studies focus upon outcome rather than process data

Evidence from reviews of quality improvement methods/models in health care

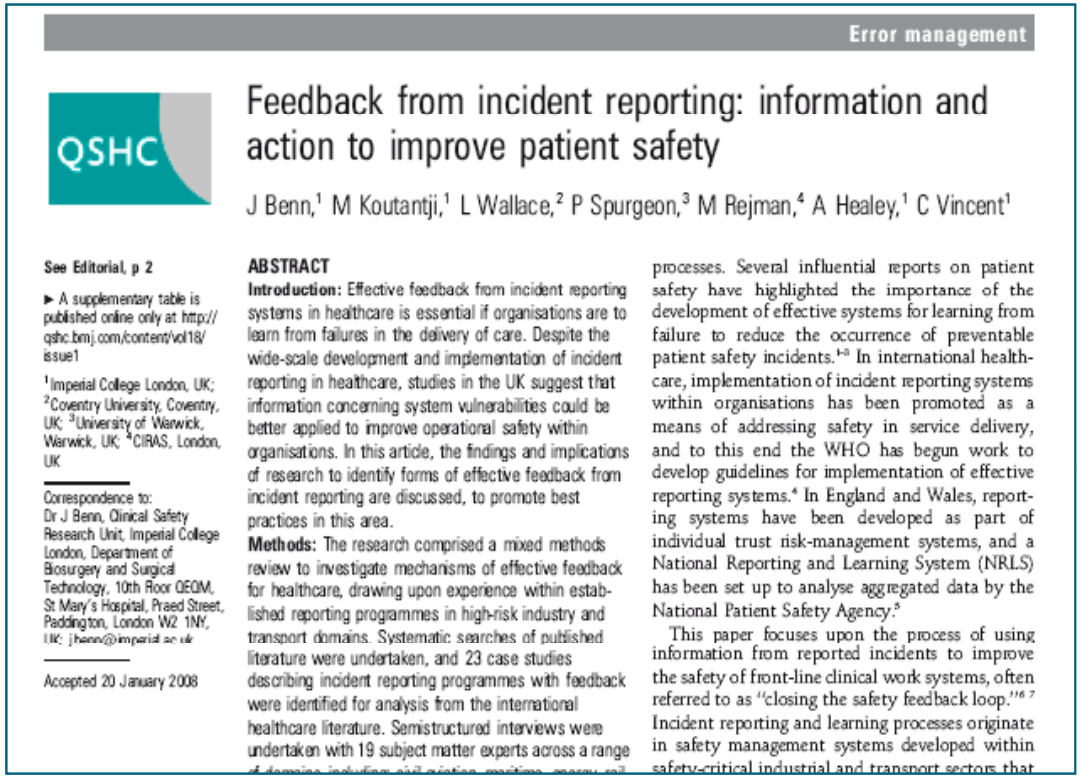
- The effects of implementing quality improvement models in health care are context-specific (Boaden et al., 2008)
- 'Necessary, but not sufficient' conditions for successful quality improvement:
  - Provision of the practical and human resources to enable quality improvement
  - Active engagement of health professionals, especially doctors
  - Sustained managerial focus and attention
  - The use of multi-faceted interventions
  - Coordinated action at all levels of the health care system
  - Substantial investment in training and development
  - Availability of robust and timely data through supported IT systems

(Powell et al., 2008)

6. Research case studies: Development of monitoring and feedback systems

6a) Learning from incident reporting at local level

Systematic scoping study of effective feedback mechanisms for reporting systems



Error management

QSHC

Feedback from incident reporting: information and action to improve patient safety

J Benn,[1] M Koutantji,[1] L Wallace,[2] P Spurgeon,[3] M Rejman,[4] A Healey,[1] C Vincent[1]

See Editorial, p 2

► A supplementary table is published online only at http://qshc.bmj.com/content/vol18/issue1

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ABSTRACT

Introduction: Effective feedback from incident reporting systems in healthcare is essential if organisations are to learn from failures in the delivery of care. Despite the wide-scale development and implementation of incident reporting in healthcare, studies in the UK suggest that information concerning system vulnerabilities could be better applied to improve operational safety within organisations. In this article, the findings and implications of research to identify forms of effective feedback from incident reporting are discussed, to promote best practices in this area.

Methods: The research comprised a mixed methods review to investigate mechanisms of effective feedback for healthcare, drawing upon experience within established reporting programmes in high-risk industry and transport domains. Systematic searches of published literature were undertaken, and 23 case studies describing incident reporting programmes with feedback were identified for analysis from the international healthcare literature. Semistructured interviews were undertaken with 19 subject matter experts across a range of domains including civil aviation, maritime, energy, rail,

processes. Several influential reports on patient safety have highlighted the importance of the development of effective systems for learning from failure to reduce the occurrence of preventable patient safety incidents.[1–3] In international healthcare, implementation of incident reporting systems within organisations has been promoted as a means of addressing safety in service delivery, and to this end the WHO has begun work to develop guidelines for implementation of effective reporting systems.[4] In England and Wales, reporting systems have been developed as part of individual trust risk-management systems, and a National Reporting and Learning System (NRLS) has been set up to analyse aggregated data by the National Patient Safety Agency.[5]

This paper focuses upon the process of using information from reported incidents to improve the safety of front-line clinical work systems, often referred to as "closing the safety feedback loop."[6 7] Incident reporting and learning processes originate in safety management systems developed within safety-critical industrial and transport sectors that

Briefing

Feedback from reporting patient safety incidents – are NHS trusts learning lessons?

Louise Wallace
Professor of Psychology and Health, Health Services Research Centre, Coventry University, Coventry

For the study, first published in 2006, the researchers examined how well NHS organisations had attempted to use the information they gathered from adverse clinical incidents and whether they were learning from it. By looking at existing relevant research worldwide, interviewing experts, surveying NHS organizations (acute

PAPERS

Improving patient safety incident reporting systems by focusing upon feedback – lessons from English and Welsh trusts

Louise M Wallace*, Peter Spurgeon†, Jonathan Benn‡, Maria Koutantji‡ and Charles Vincent‡

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Summary

This paper describes practical implications and learning from a multi-method study of feedback from patient safety incident reporting systems. The study was performed using the Safety Action and Information Feedback from Incident Reporting model, a model of the requirements of the feedback

Benn, J., Koutantji, M., Wallace, L., Spurgeon, P., Rejman, M., Healey, A., et al. (2009). Feedback from incident reporting: information and action to improve patient safety. *Qual Saf Health Care, 18(1), 11-21.*

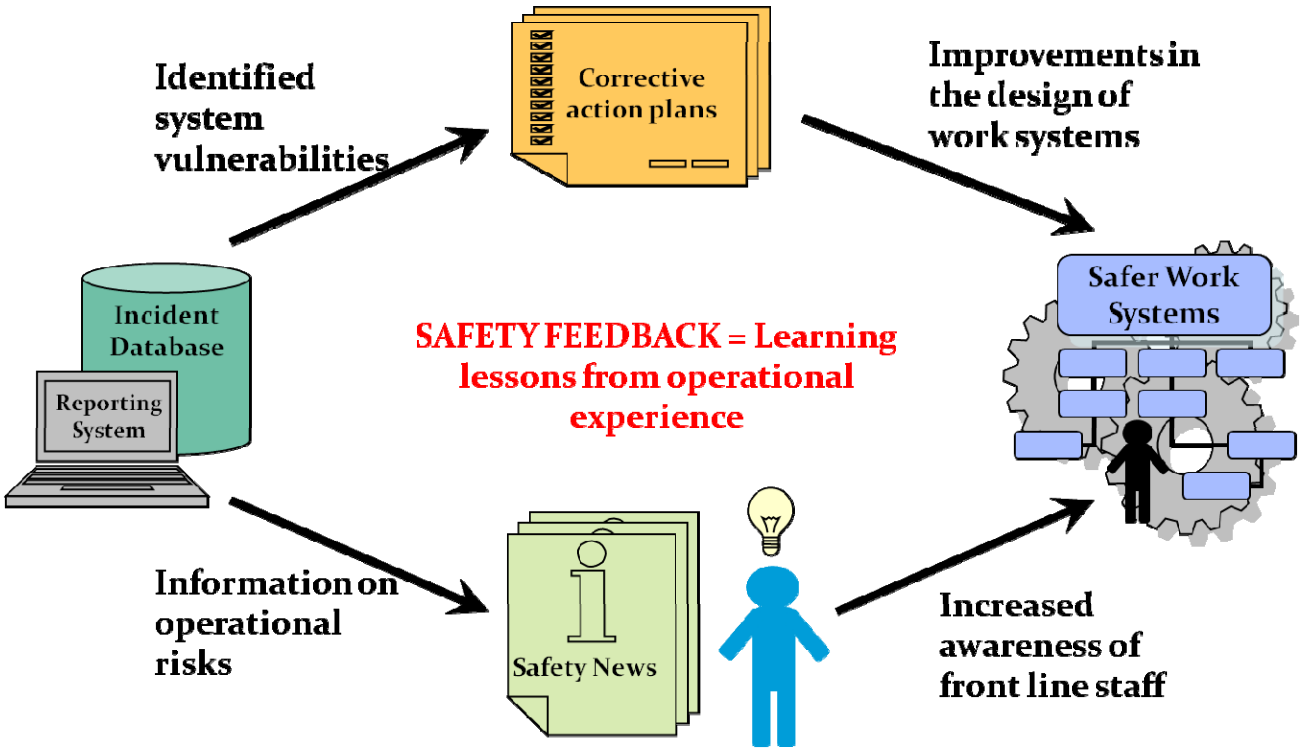
Wallace, L. M., Spurgeon, P., Benn, J., Koutantji, M., & Vincent, C. (2009). Improving patient safety incident reporting systems by focusing upon feedback - lessons from English and Welsh trusts. *Health Serv Manage Res, 22(3), 129-135.*

Wallace, L. (2010). Feedback from reporting patient safety incidents - are NHS trusts learning lessons? *Journal of Health Services & Research Policy, 15(suppl_1), 75-78.*

Research design

- Scoping review of literature:
  - 2000 records screened for relevance; 190 articles reviewed
  - 23 best case examples of health care reporting systems with explicit feedback mechanisms identified
- Consultation with expert panel on reporting and feedback (N=19)
  - Expert panel comprised safety and reporting systems experts from a range of high risk industries and international healthcare.
- Synthesis of qualitative findings into requirements for effective feedback systems and candidate mechanisms/channels
- Expert Review workshop with UK healthcare professionals, NHS risk managers and industry experts to develop consensus on emerging model

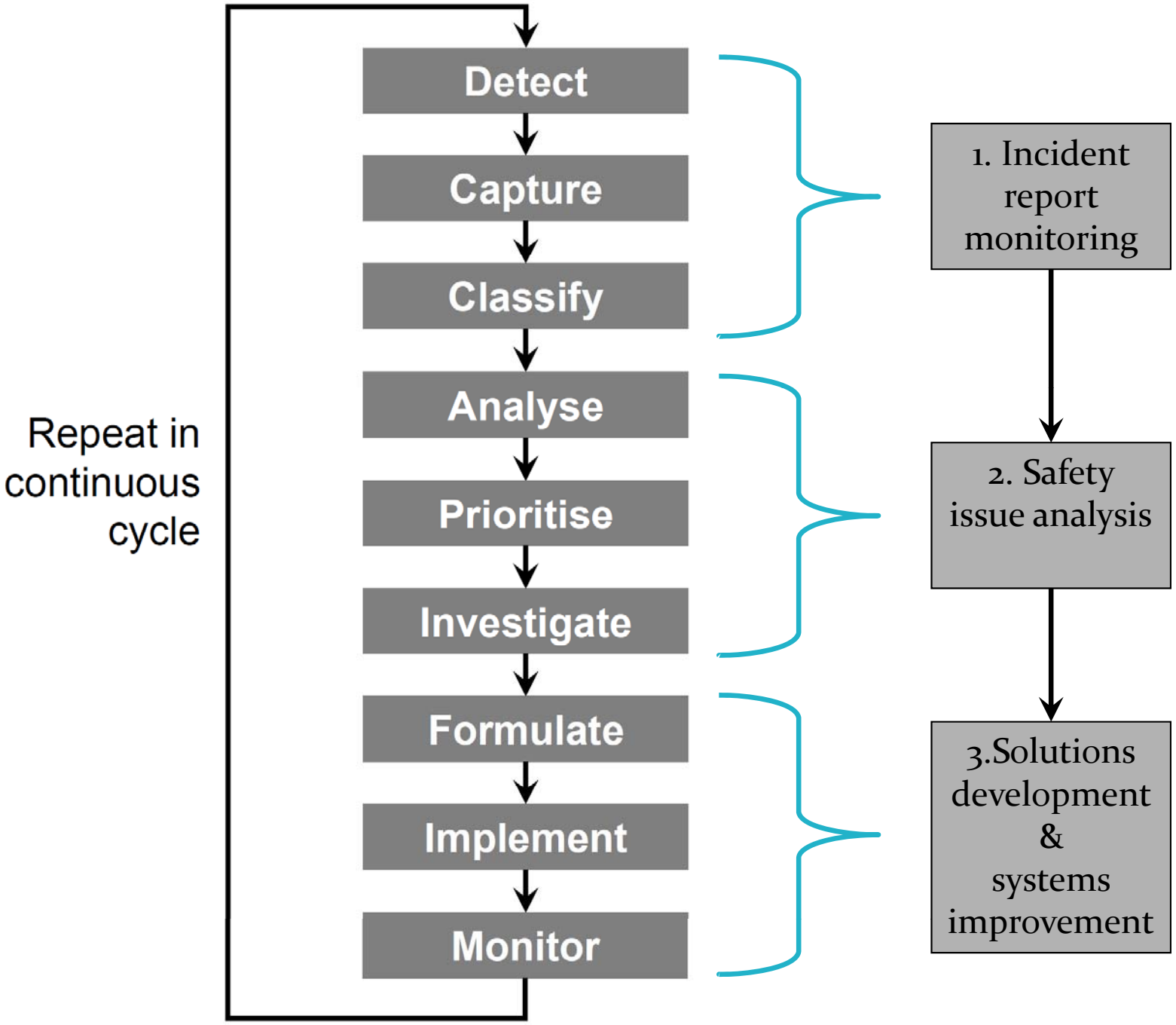
Feedback from incident reporting: Information and action



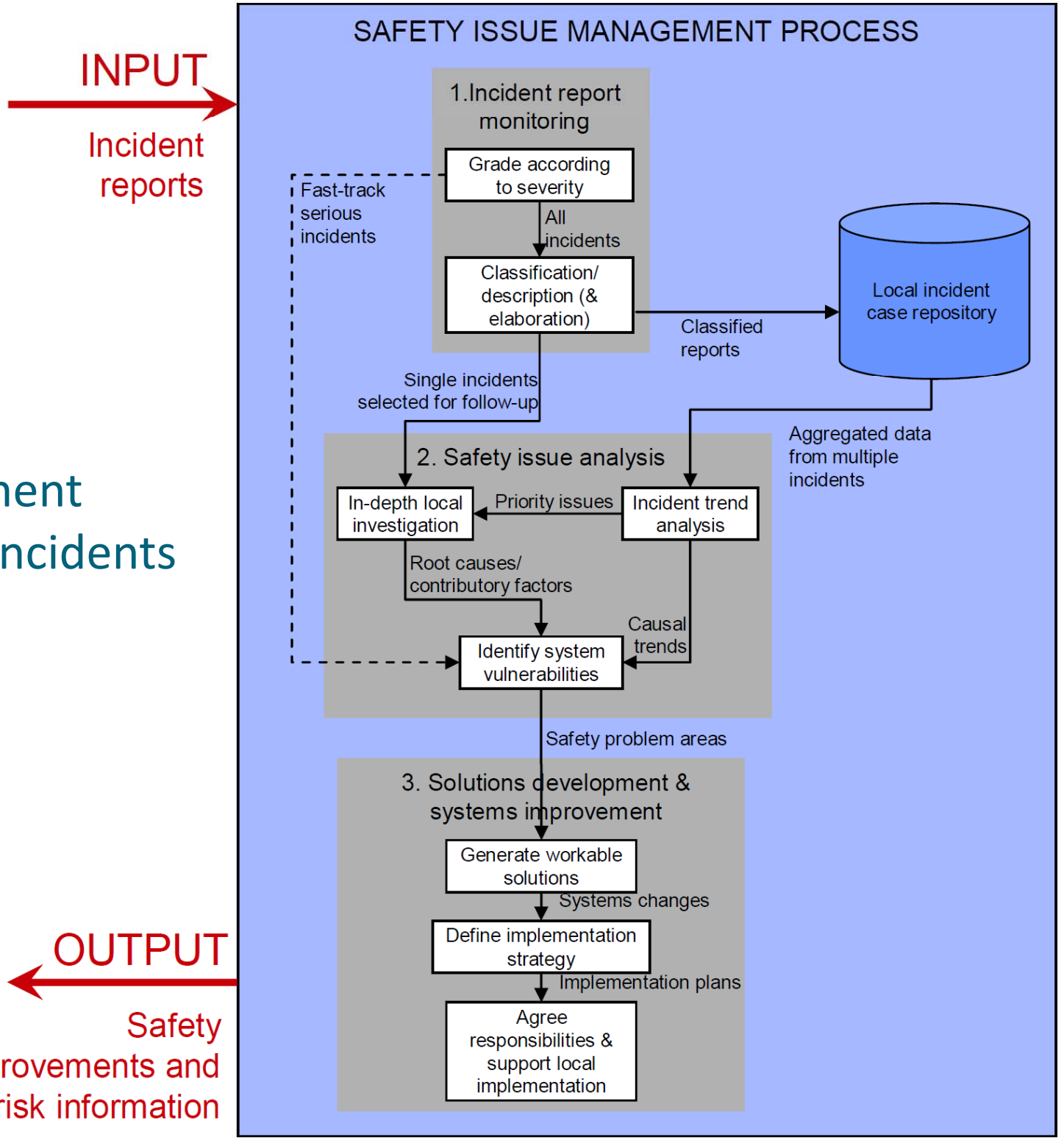
- "Closing the loop" involves effective feedback and follow-up:
  - More emphasis needs to be placed upon what happens after a report is submitted
  - *Feedback* publicises safety issues raised and actions taken to the original reporters and all levels of staff.
  - *Follow-up* involves prioritising safety actions, assigning responsibility and accountability and implementing the action plan.

(Ghandi et al. 2005)

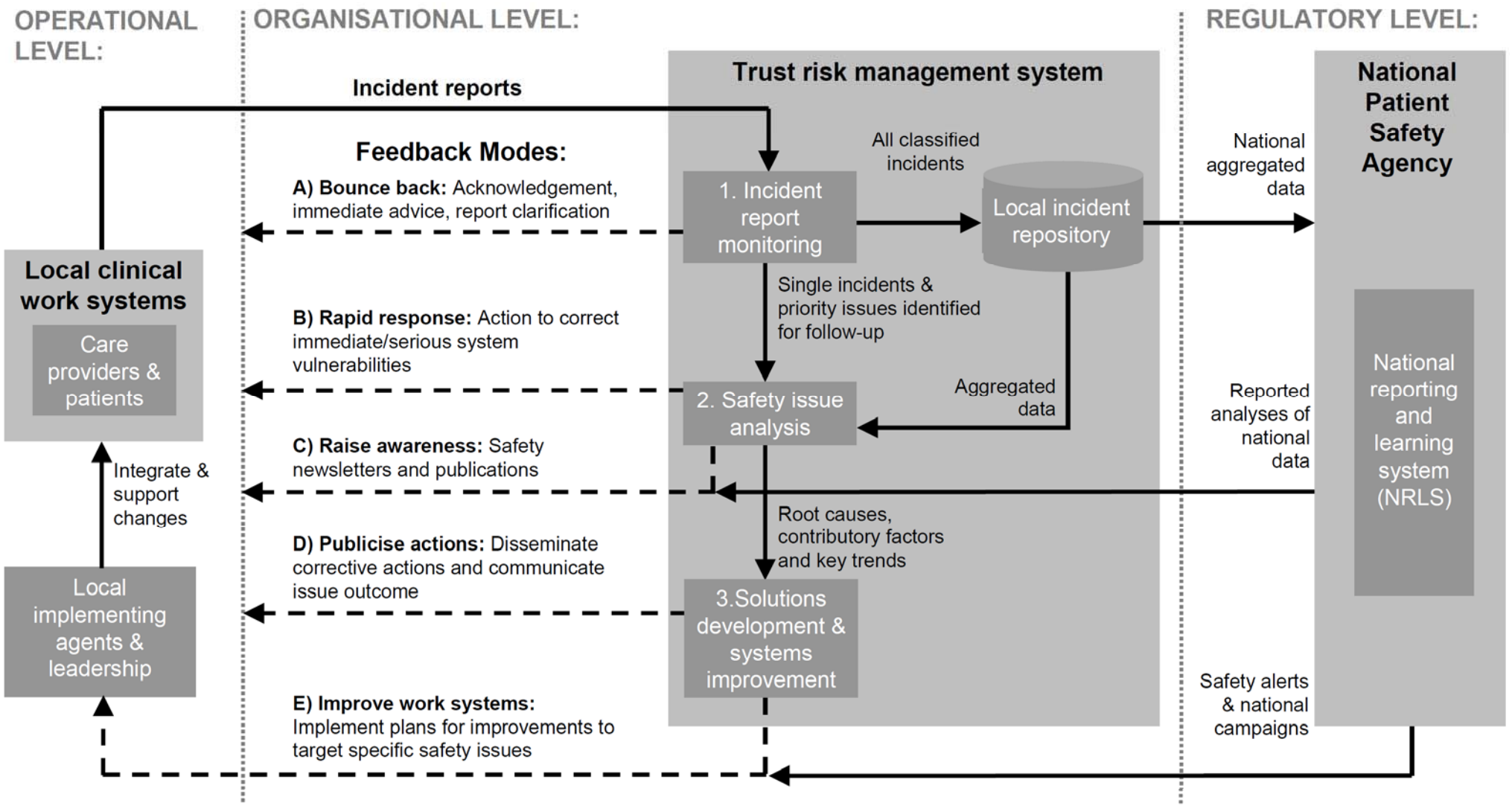
Functional definition of a reporting system



Safety issue management process for reported incidents



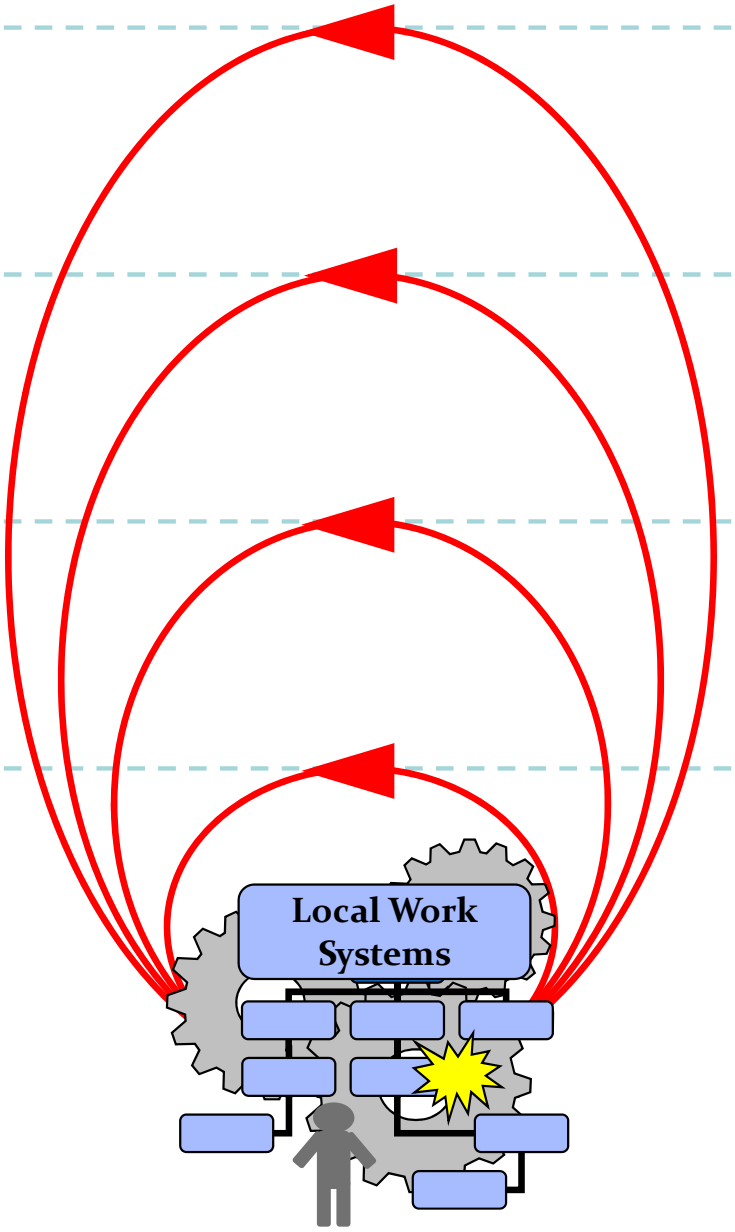
Learning from incident data: information flow



Modes of feedback from incident reporting

Mode A	**Bounce back information:** Acknowledgement, issue clarification and interaction with reporter. **[39% of best case systems reviewed]**
Mode B	**Rapid response actions:** Fast tracked measures taken against immediate and serious threats to safety. **[70% of best case systems reviewed]**
Mode C	**Risk awareness information:** Broad dissemination of safety awareness information to all front line staff on current system vulnerabilities (through newsletters and other channels of distribution). **[91% of best case systems reviewed]**
Mode D	**Inform staff of actions taken:** Debriefing the reporter and informing the reporting community of issue progress and actions taken. **[52% of best case systems reviewed]**
Mode E	**Systems improvement actions:** Development, implementation and evaluation of action plans for improvements to work systems that address specific vulnerabilities. **[100% of best case systems reviewed – pre-selected]**

Levels of feedback



Supra-organisational level

Mechanism: Regulatory/national level policy

Improvement: Lessons from experience in one institution applied across all similar organisations

Organisational level

Mechanism: Local organisation risk management

Improvement: Lessons from experience in one work setting applied throughout organisation

Department/team level

Mechanism: Internal safety/quality review

Improvement: Lessons learnt from performance monitoring applied to improve local working practices

Individual level

Mechanism: Incident debriefing, staff training and safety information publications

Improvement: Heightened risk awareness and safer behaviour

Increasingly widespread learning from local safety incidents

Conclusions from the review

- Wide variation in practice in terms of reporting and using information to improve clinical work systems
- Wide variation in the mechanisms by which reporting systems link to local action mechanisms
- There is a lack of evaluative evidence concerning effective modes of feedback
- Little evidence of capacity for rapid action in current “high level” systems
- Little evaluation of impact of feedback (and reporting systems in general) upon operational safety
- Further attention must be given to the use of information from incident reporting to improve safety – translating alerts into action

6b) Learning from quality indicators in anaesthesia

Anaesthetic quality indicators programme at Imperial College Healthcare NHS

- **Service Aim**: To establish a comprehensive continuous monitoring and feedback process for perioperative quality indicators:
  - Focus:
    - Quality of anaesthetic care and recovery
    - Efficiency of patient transfer from recovery
- **Research Aim**: To evaluate this initiative using a robust mixed methods design
  - Focus upon effectiveness and acceptability

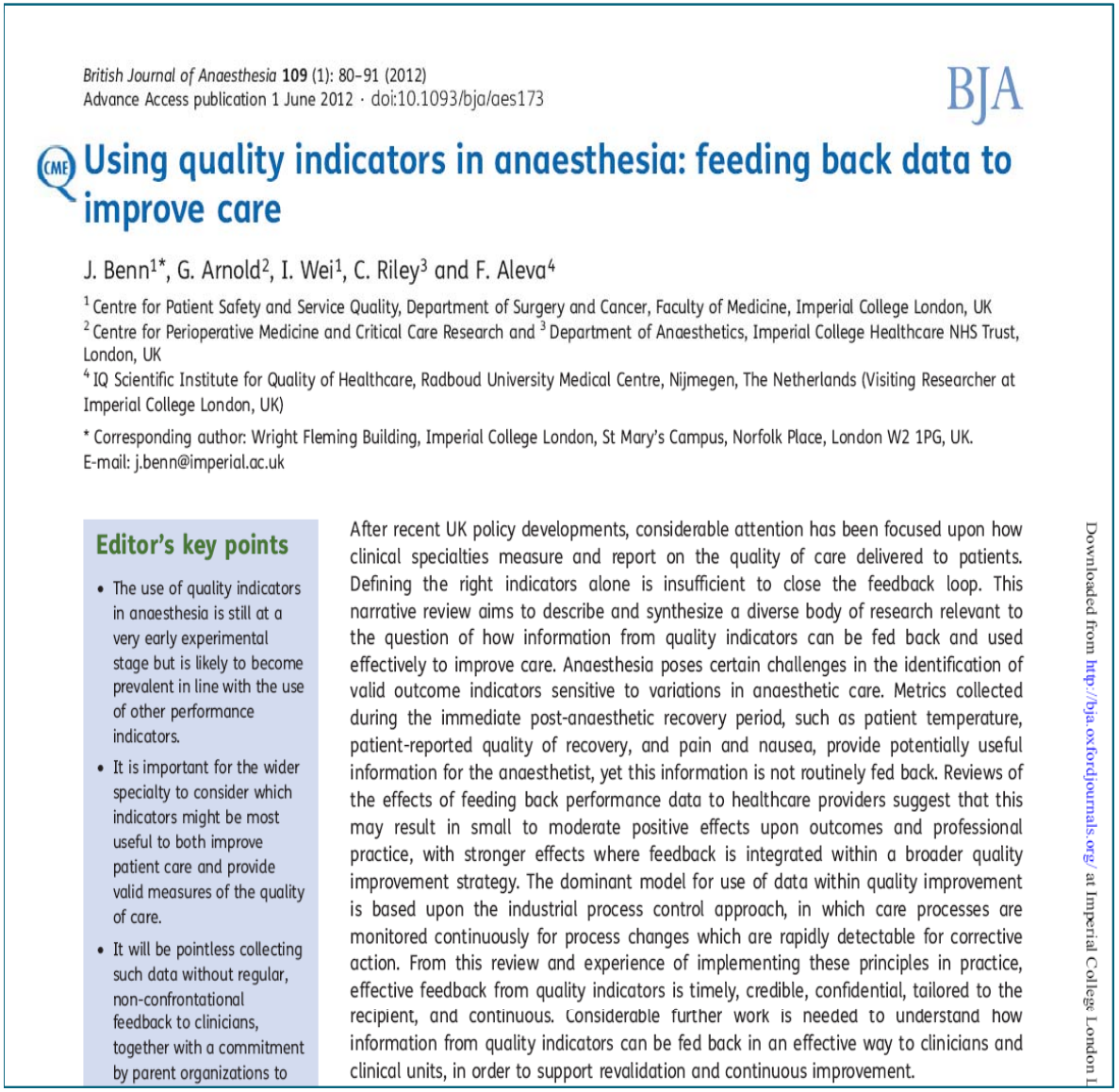
Towards a model for effective feedback

- Specifying valid and reliable measures is only the first step:
  - How can we use the data to drive improvement?

- Systematic reviews of the effects of audit and feedback on professional practice typically show small to moderate positive effects (Jamdvedt, 2005)

- Qualitative research suggests that effective data feedback for quality improvement has a number of characteristics (Bradley, 2004)
  - timeliness;
  - specific to the local context;
  - from credible sources;
  - non-punitive;
  - sustained over time

Concept for a data feedback initiative



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BJA

Using quality indicators in anaesthesia: feeding back data to improve care

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Editor's key points

- The use of quality indicators in anaesthesia is still at a very early experimental stage but is likely to become prevalent in line with the use of other performance indicators.
- It is important for the wider specialty to consider which indicators might be most useful to both improve patient care and provide valid measures of the quality of care.
- It will be pointless collecting such data without regular, non-confrontational feedback to clinicians, together with a commitment by parent organizations to

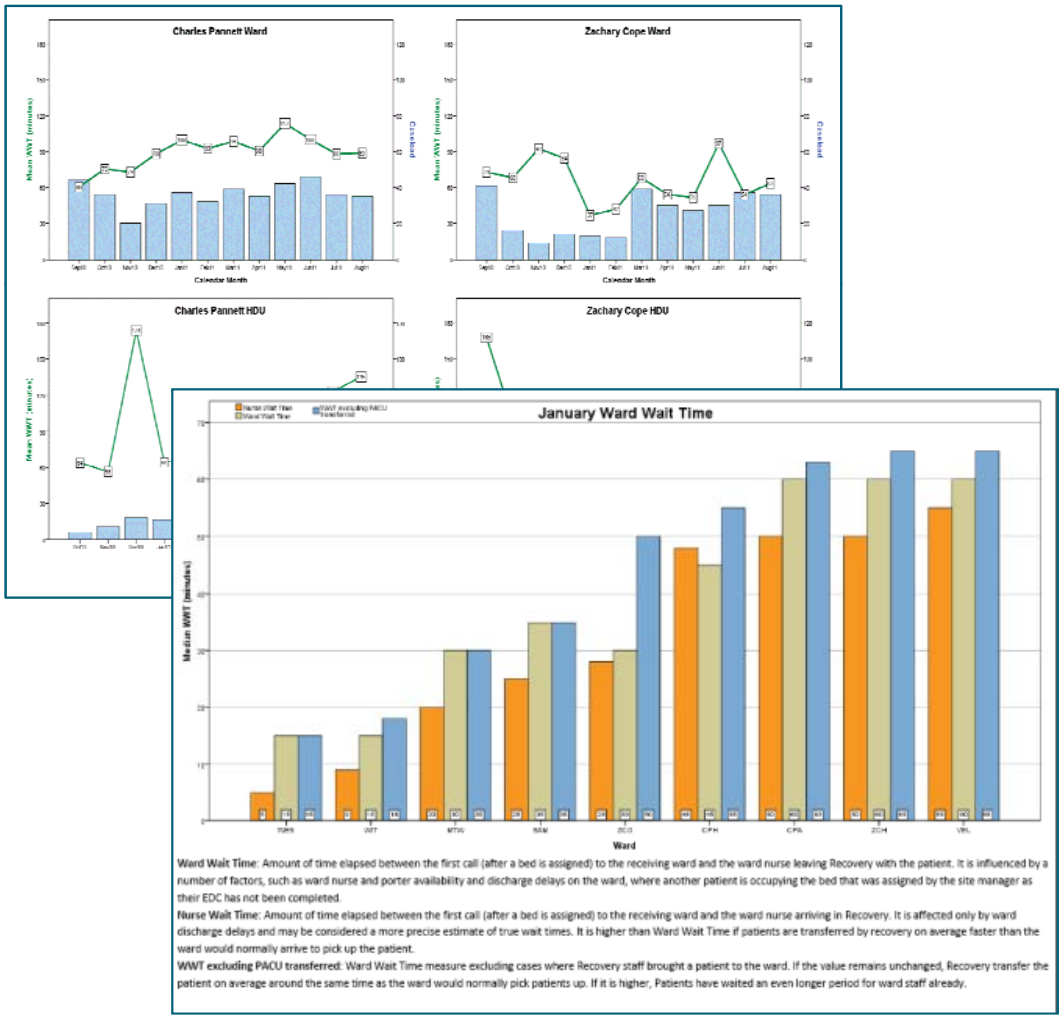
After recent UK policy developments, considerable attention has been focused upon how clinical specialties measure and report on the quality of care delivered to patients. Defining the right indicators alone is insufficient to close the feedback loop. This narrative review aims to describe and synthesize a diverse body of research relevant to the question of how information from quality indicators can be fed back and used effectively to improve care. Anaesthesia poses certain challenges in the identification of valid outcome indicators sensitive to variations in anaesthetic care. Metrics collected during the immediate post-anaesthetic recovery period, such as patient temperature, patient-reported quality of recovery, and pain and nausea, provide potentially useful information for the anaesthetist, yet this information is not routinely fed back. Reviews of the effects of feeding back performance data to healthcare providers suggest that this may result in small to moderate positive effects upon outcomes and professional practice, with stronger effects where feedback is integrated within a broader quality improvement strategy. The dominant model for use of data within quality improvement is based upon the industrial process control approach, in which care processes are monitored continuously for process changes which are rapidly detectable for corrective action. From this review and experience of implementing these principles in practice, effective feedback from quality indicators is timely, credible, confidential, tailored to the recipient, and continuous. Considerable further work is needed to understand how information from quality indicators can be fed back in an effective way to clinicians and clinical units, in order to support revalidation and continuous improvement.

- **Multilevel** feedback:
  - Individual clinician
  - Surgical ward
  - Clinical unit
- **Continuous** monitoring of quality of care and patient flow.
  - An industrial process control approach
- **Specific/targeted**:
  - Disaggregation of data onto a level that is meaningful to individual clinicians – local ownership

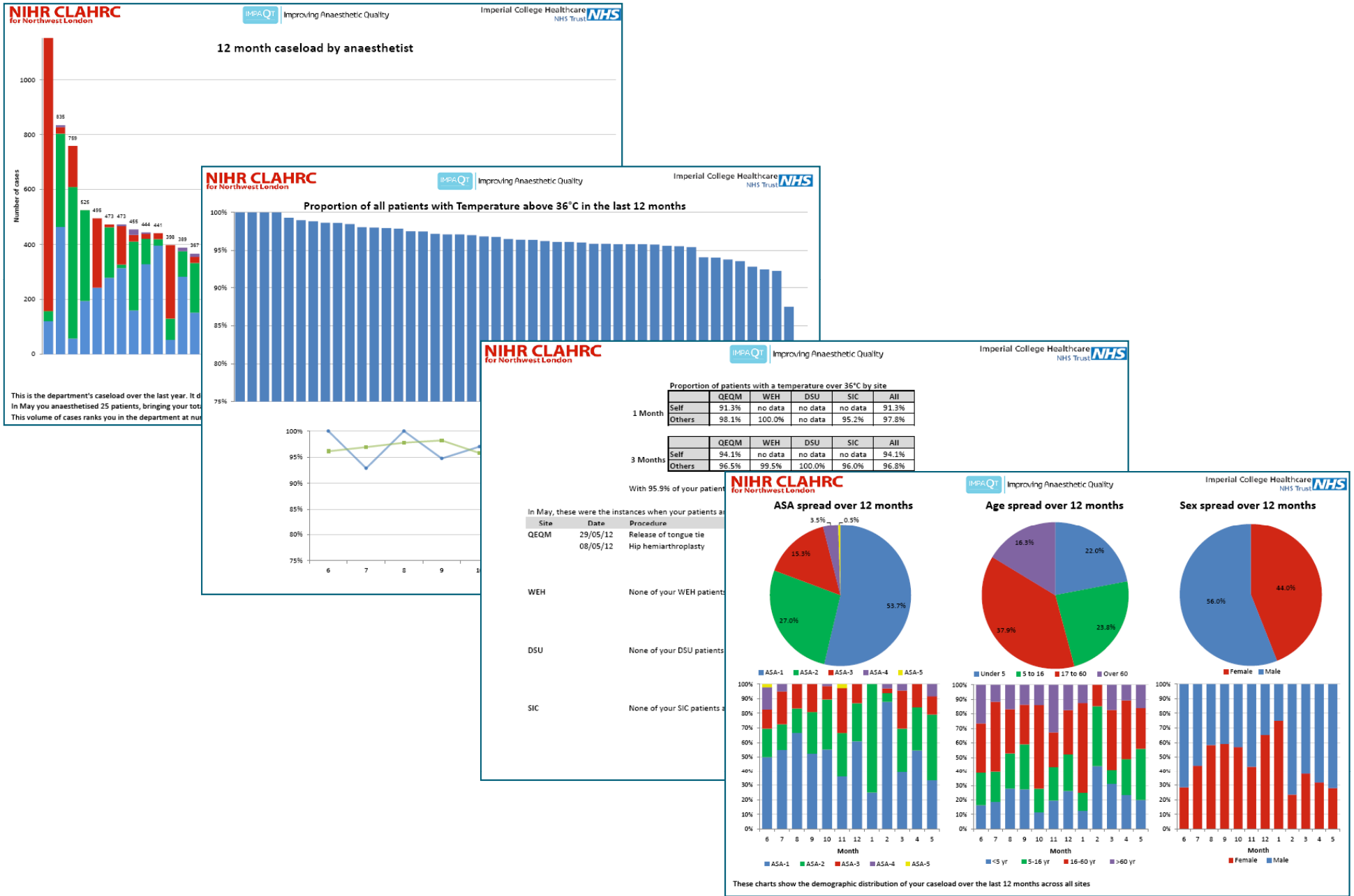
Monthly PACU & Ward Feedback

Data posted in recovery

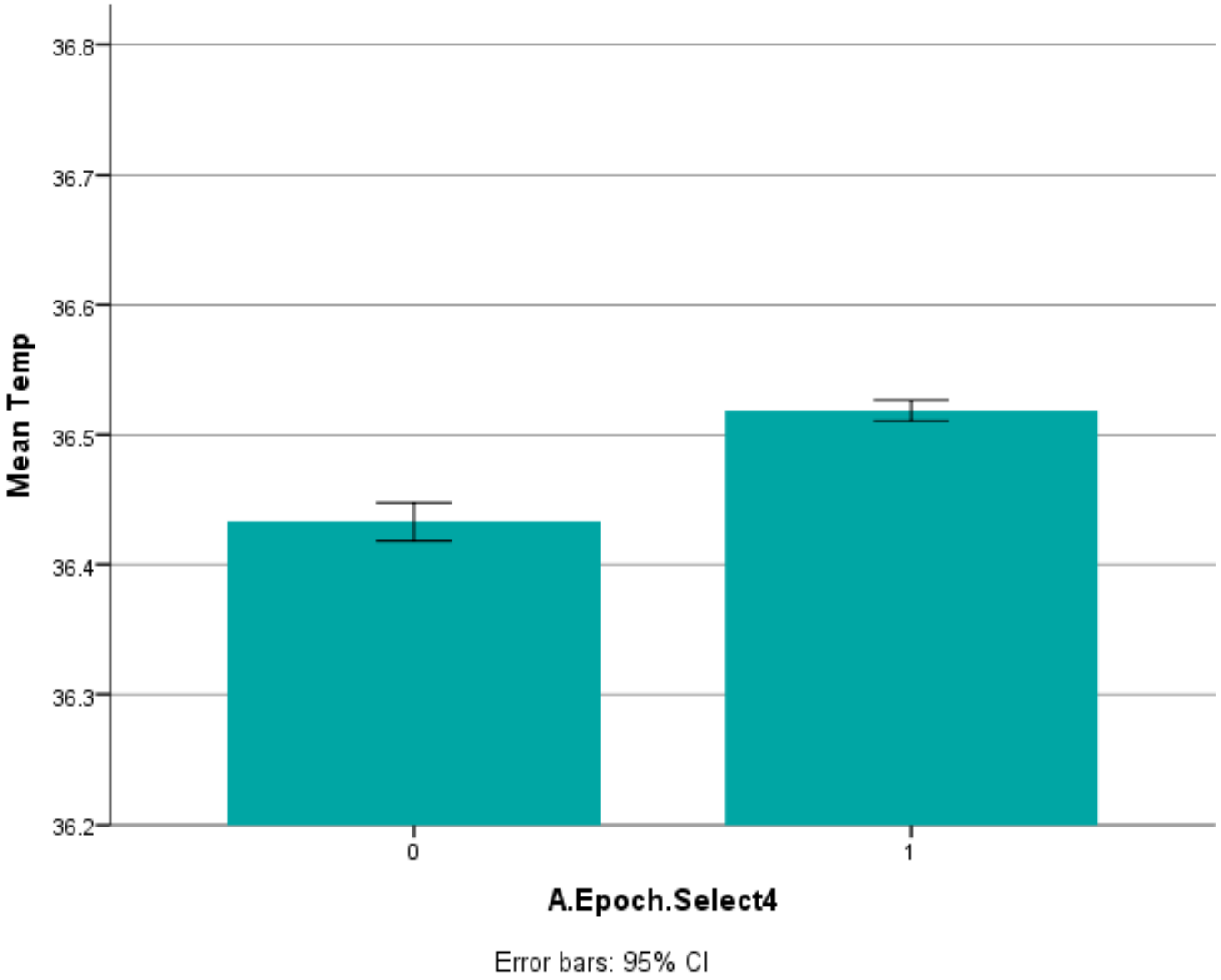
Surgical ward reports



Personalised anaesthetist feedback

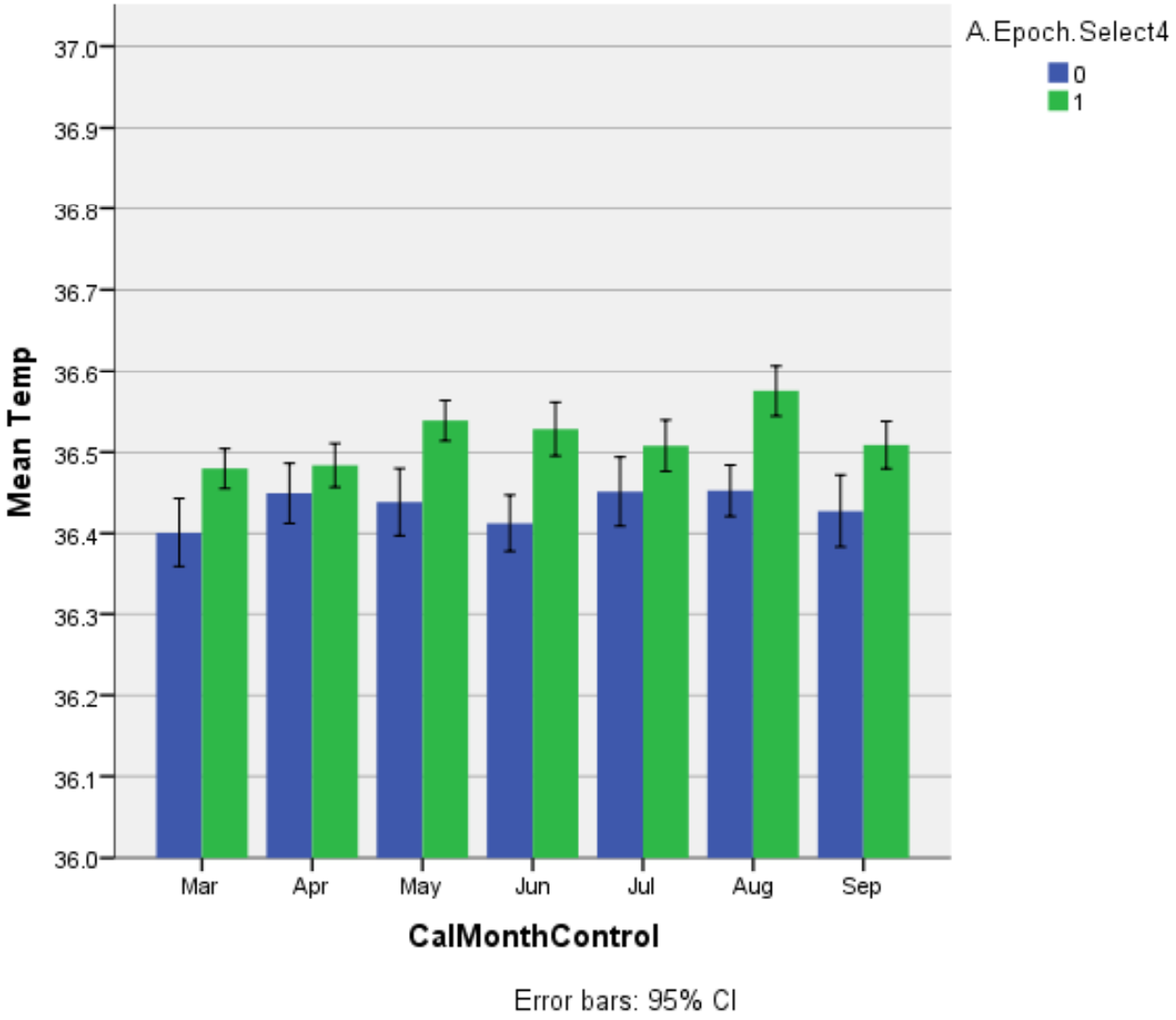


Temp – Comparison of pre and post intervention epochs

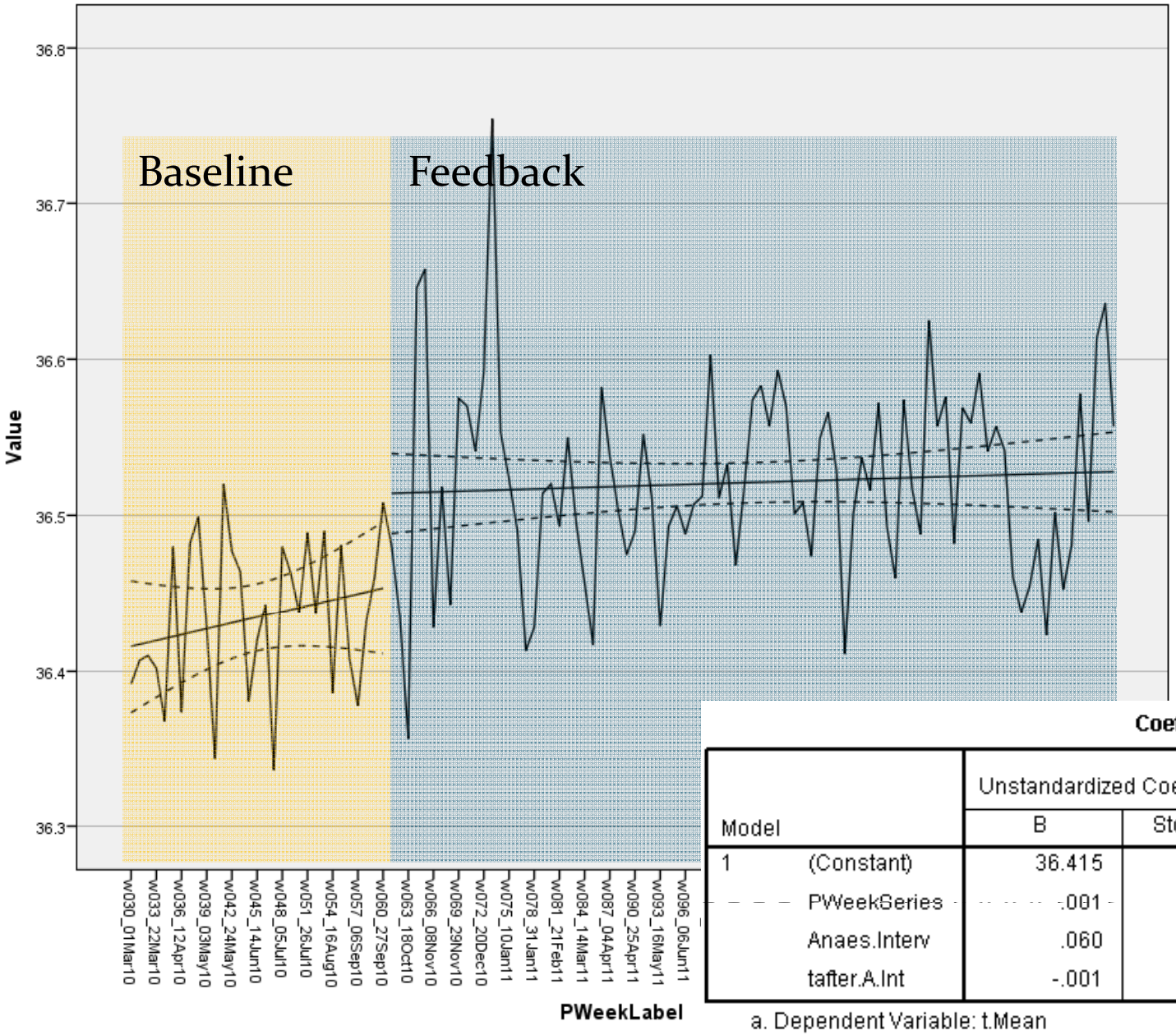


Change in mean = .086
t = -9.705; p <0.001

Temp – Comparison of epoch presented by month



Mean Temp by Week (ITSA)

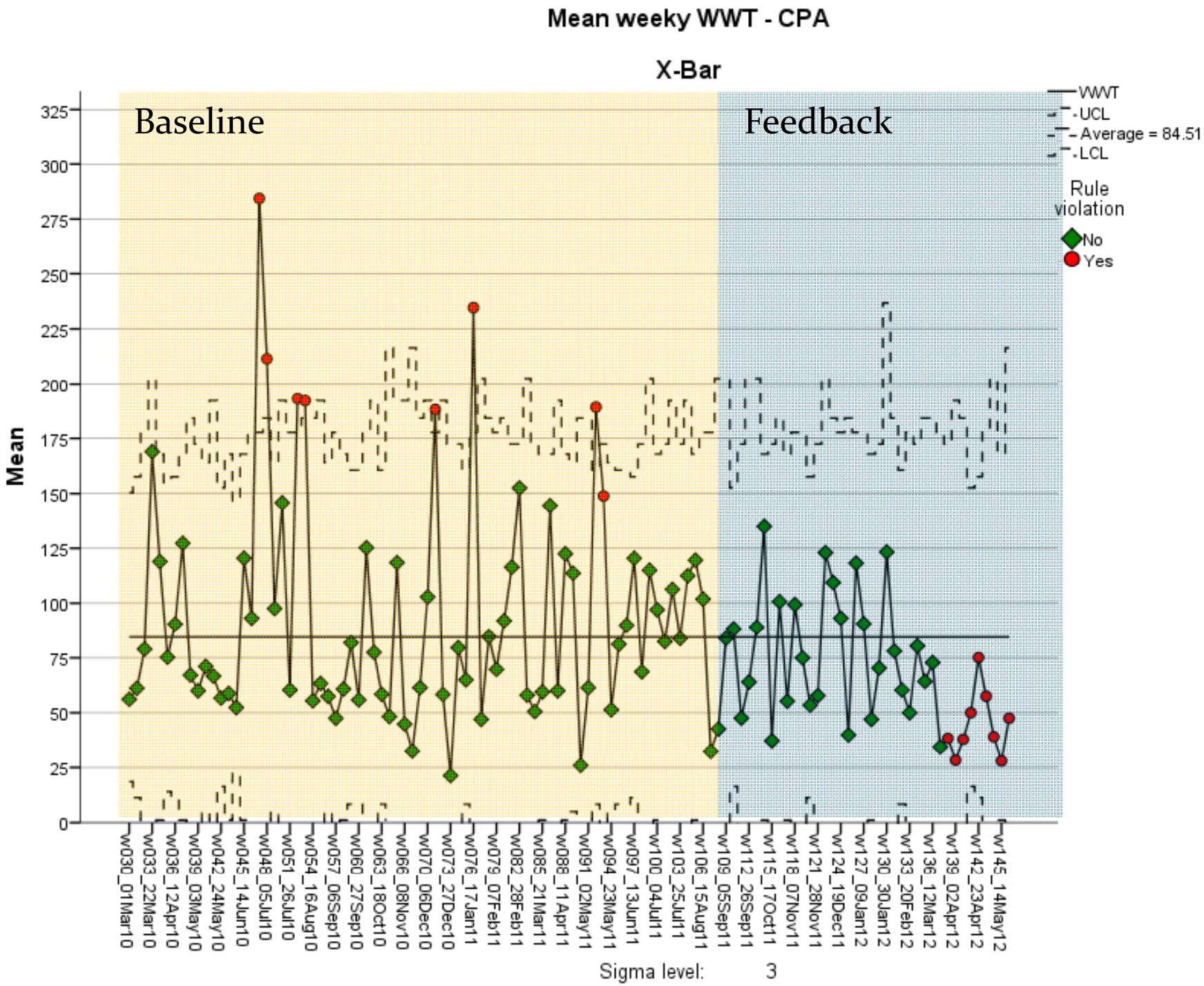


Coefficients[a]

Model		Unstandardized Coefficients		Standardized Coefficients		
		B	Std. Error	Beta	t	Sig.
1	(Constant)	36.415	.022		1627.583	.000
	PWeekSeries	-.001	.001	.601	1.027	.306
	Anaes.Interv	.060	.025	.373	2.408	.018
	tafter.A.Int	-.001	.001	-.446	-.877	.383

a. Dependent Variable: t.Mean

Mean WWT:


Mean weeky WWT - CPA
X-Bar
Baseline
Feedback
WWT
UCL
Average = 84.51
LCL
Rule violation
No
Yes
Mean
325
300
275
250
225
200
175
150
125
100
75
50
25
0
w030_01Mar10
w033_22Mar10
w036_12Apr10
w039_03May10
w042_24May10
w045_14Jun10
w048_05Jul10
w051_26Jul10
w054_16Aug10
w057_06Sep10
w060_27Sep10
w063_18Oct10
w066_08Nov10
w070_06Dec10
w073_27Dec10
w076_17Jan11
w079_07Feb11
w082_28Feb11
w085_21Mar11
w088_11Apr11
w091_02May11
w094_23May11
w097_13Jun11
w100_04Jul11
w103_25Jul11
w106_15Aug11
w109_05Sep11
w112_26Sep11
w115_17Oct11
w118_07Nov11
w121_28Nov11
w124_19Dec11
w127_09Jan12
w130_30Jan12
w133_20Feb12
w136_12Mar12
w139_02Apr12
w142_23Apr12
w145_14May12
Sigma level: 3

Future challenges for quality and safety monitoring systems

- Main challenges for effective monitoring and learning systems relate to data capture, analysis & feedback:
  - Getting complete, appropriate and high quality information into the system
  - Conducting meaningful, timely analysis
  - Developing effective feedback processes for safety-critical information
  - Linking information flows to effective local quality improvement actions