Patient Safety Incident Management in the UK

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Objectives to Cover

- Patient Safety and Incident Management timeline
- What is a patient safety incident
- Key players
- Reporting, supporting, investigating and learning
- Future direction of incident management

Pre 1999

1952 Establishment of national Confidential Enquiry into Maternal Deaths

1955 First guidance from the Ministry of Health to NHS hospitals on the reporting of accidents and untoward occurrences (HM(55)66).

1961 Joint Memorandum by the MDU, RCN, and National Council of Nursing, 'Safeguards against wrong operations'.

1963 Joint Memorandum by the MDU, RCN, and National Council of Nurses, 'Safeguards against failure to remove swabs etc., from patients'

1972 Guidance to hospitals on the prevention of surgical accidents (HM(72)37)

1999-2009

1999- Health Select Committee considers the handling of adverse incidents and occurrences in the NHS. The London Protocol

2000 - Department of Health report, *An Organisation with a Memory*, estimates that 850,000 patients (around 1 in 10) admitted to NHS hospitals encounter an adverse health event.

2001 - Establishment of the National Patient Safety Agency (NPSA)

Publication of Kennedy Report into Children's heart surgery Bristol Royal Infirmary
Department of Health report *Building a Safer NHS for Patients: Implementing An Organisation With A Memory*
Establishment of the Shipman Inquiry.

2002 - NPSA 1st patient safety alert, on preventing accidental overdose of intravenous potassium.

2003 - Establishment of National Reporting and Learning System (NRLS)

2005 - NPSA alert and guidance on Being Open: Communicating Patient Safety Incidents with Patients and their Carers

2008 Mid Staffordshire Enquiry

2009 to date

2009 Establishment of the CQC

2010 Francis Report into Mid Staffordshire

2012 NPSA abolished – fx transferred to NHSE

2013 Serious Incident Framework

2014 Duty of Candour legislation

2015 Morecombe investigation report

2016 establishment of NHSI

National Guardian Office and the Freedom to Speak – up Guardian

2017 Establishment Healthcare Safety Investigation Branch HSIB

2018 Gosport Report - prescription and administration of drugs such as diamorphine

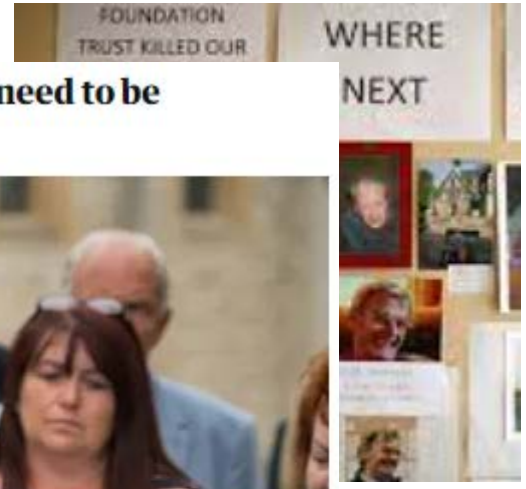
2019 Publication of the NHS Patient Safety Strategy which includes the Patient Safety Incident Response Framework (awaiting the implementation of the latter)

2020 Report of the Independent Inquiry into the Issues Raised by Paterson

2020 First Do No Harm: The Report of the Independent Medicines and Medical Devices Safety Review (Cumberlege report)
2020 Interim Ockendon report into maternity services at Shrewsbury and Telford Hospitals NHS

2021 Medical Examiner role

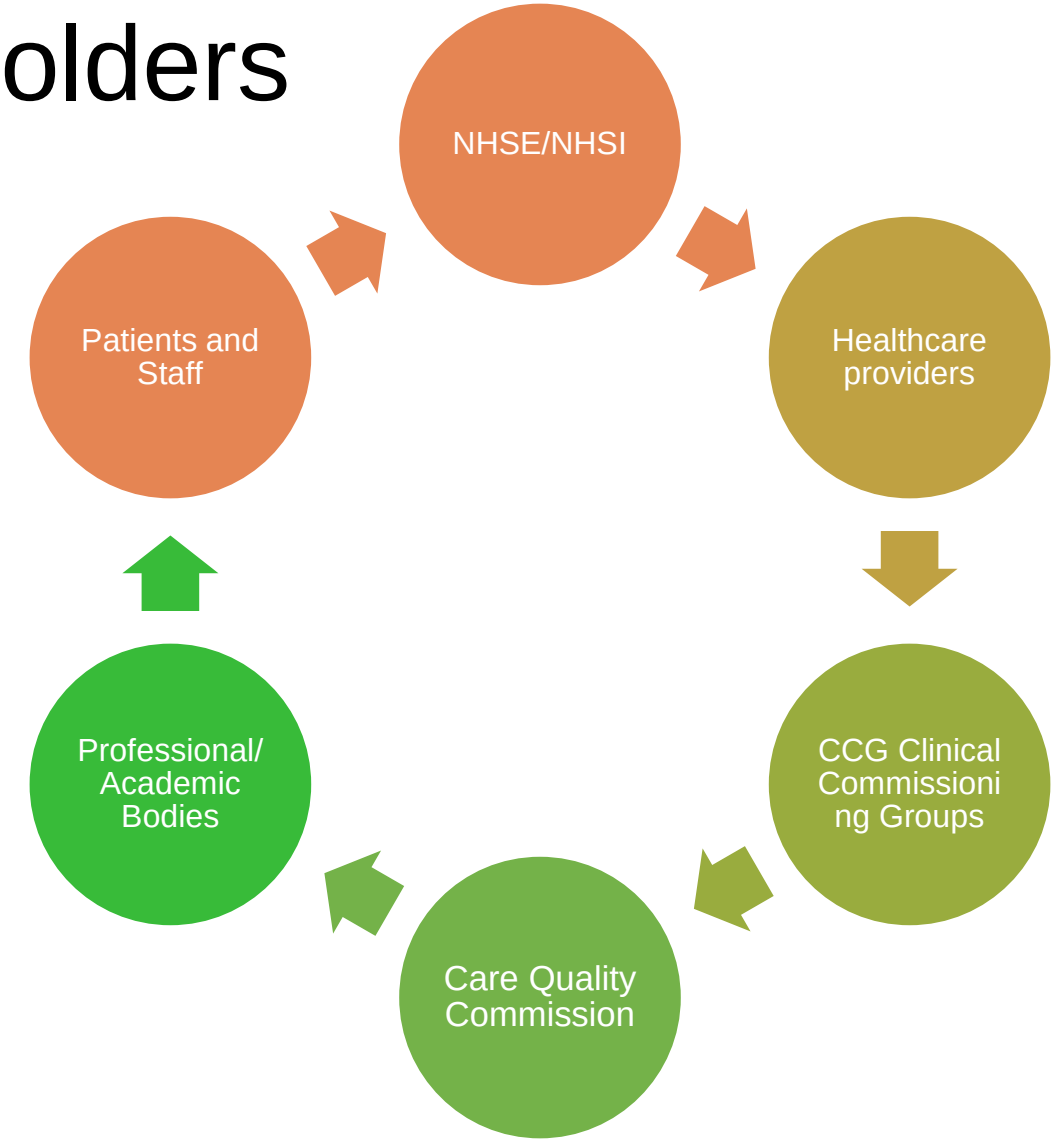
NHS Patient Safety Timeline – C. Sirrs –
https://warwick.ac.uk/fac/arts/history/chm/research/current/hazardoushospitals/patient-safety-timeline/



shameful, unforgivable actions need to be
urt'

▲ Bridget Reeves (centre) speaks to the m
Independent Panel's report. Photograph: I

Key Stakeholders



Patient Safety Incident – NHSE/NHSI

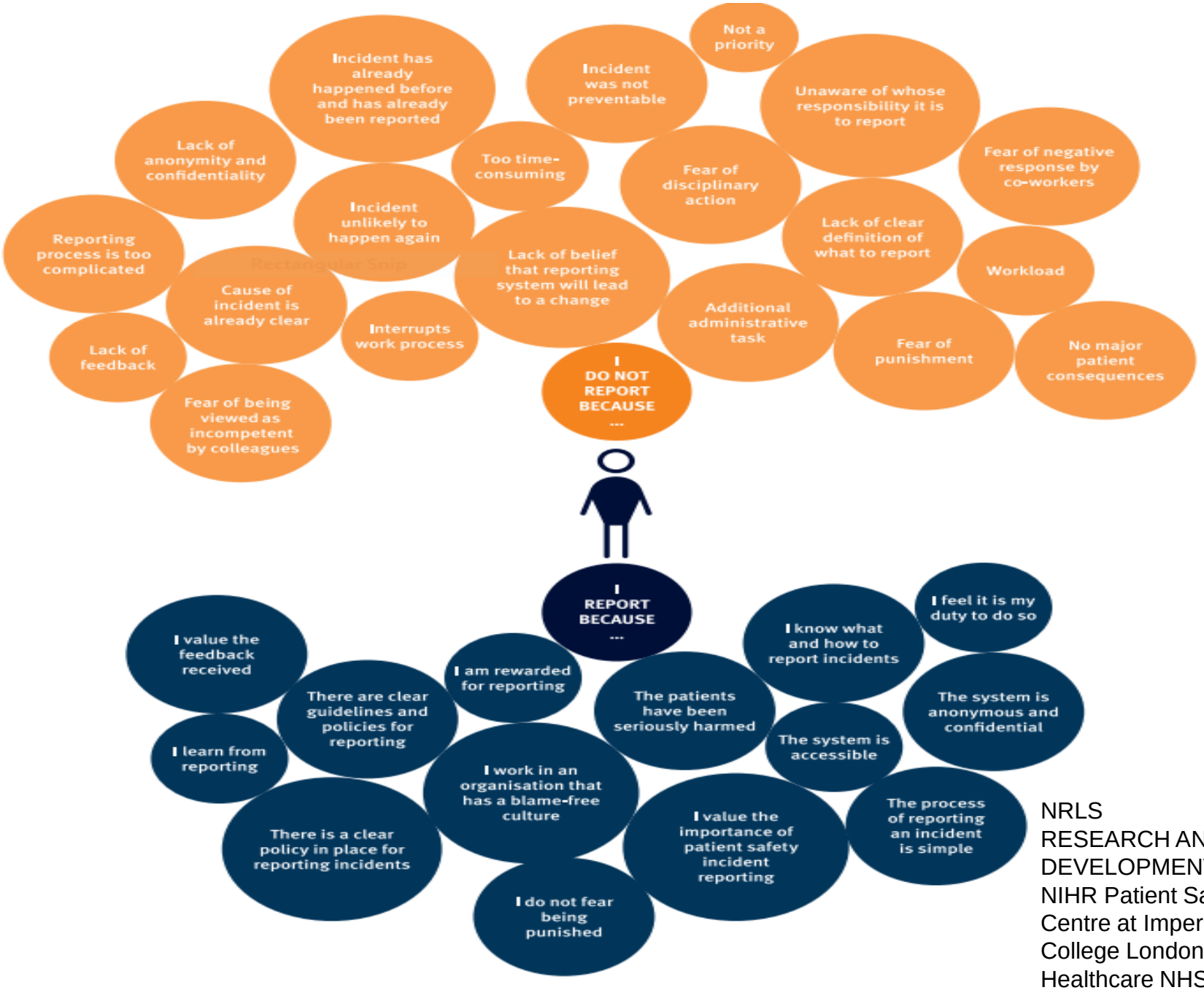
- “Patient safety incidents are any unintended or unexpected incident which could have, or did, lead to harm for one or more patients receiving healthcare. Reporting them supports the NHS to learn from mistakes and to take action to keep patients safe”. National Patient Safety Strategy 2019
- The number of incidents reported in England from April 2020 to March 2021 was 2,109,057, and represent a decrease of 6.1% compared to April 2019 to March 2020 (2,246,622). Most incidents are reported as causing no harm (69.3%) or low harm (27.1%). Fewer than 4% of incidents reported caused higher degrees of harm. (NHS NRLS national patient safety incident reports: commentary Sept 2021)

Reporting

Supporting

Investigating

Learning

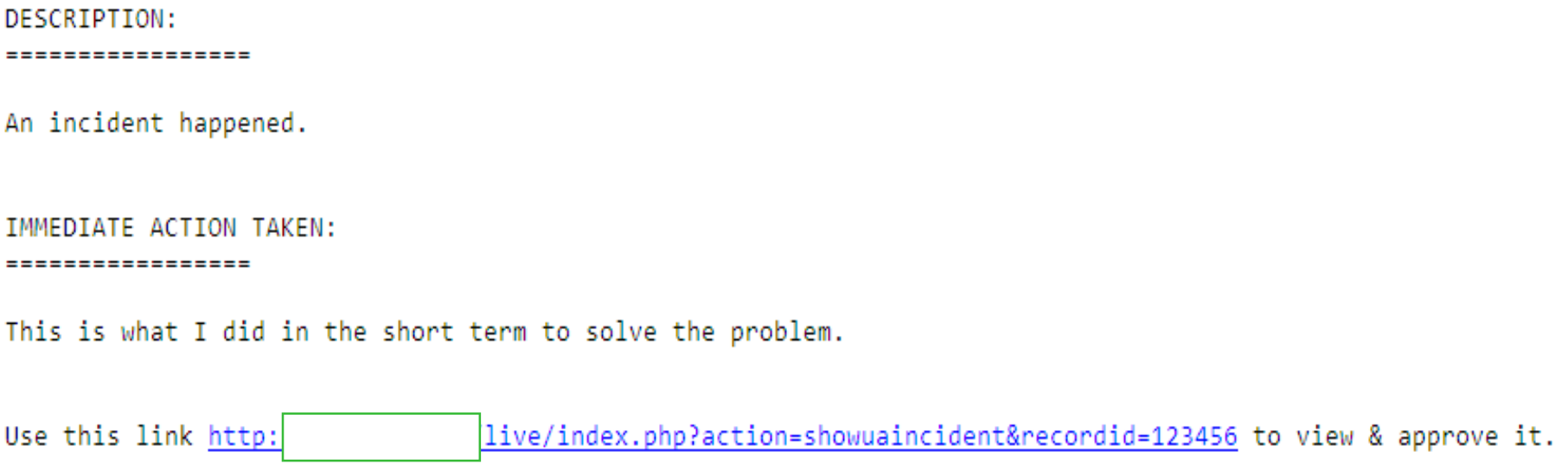


NRLS
RESEARCH AND
DEVELOPMENT
NIHR Patient Safety Translational Research Centre at Imperial
College London and Imperial College Healthcare NHS Trust

Reporting a Patient Safety Incident

Mostly electronic incident reporting in England which is beneficial for timely reporting, data analysis and good governance

Once this is submitted on the local incident management system it will create an automatic email that is sent to various leads responsible for that area



Incidents are triaged

All Incidents and Near Misses should be graded based on the actual ‘Level of Harm’, or ‘Potential Level of Harm’

The ratings in order of severity are:

GREEN → YELLOW → AMBER → RED

Incident grading guides how incidents should be escalated, resourced and investigated and also ensures the Trust meets its reporting requirements (e.g. to NHS England, Commissioners, etc.)

Serious Incident Framework 2015

Acts and/or omission occurring as part of NHS funded healthcare (including in the community) that result in:

- Unexpected or avoidable death of one or more people
- Unexpected or avoidable injury to one or more people that has resulted in serious harm
- Unexpected or avoidable injury to one or more people that requires further treatment by a healthcare professional in order to prevent the death of the service user; or serious harm

Actual or alleged abuse where… healthcare did not take appropriate action/intervention to safeguard against such abuse occurring; or where abuse occurred during the provision of NHS funded care

All Never Events

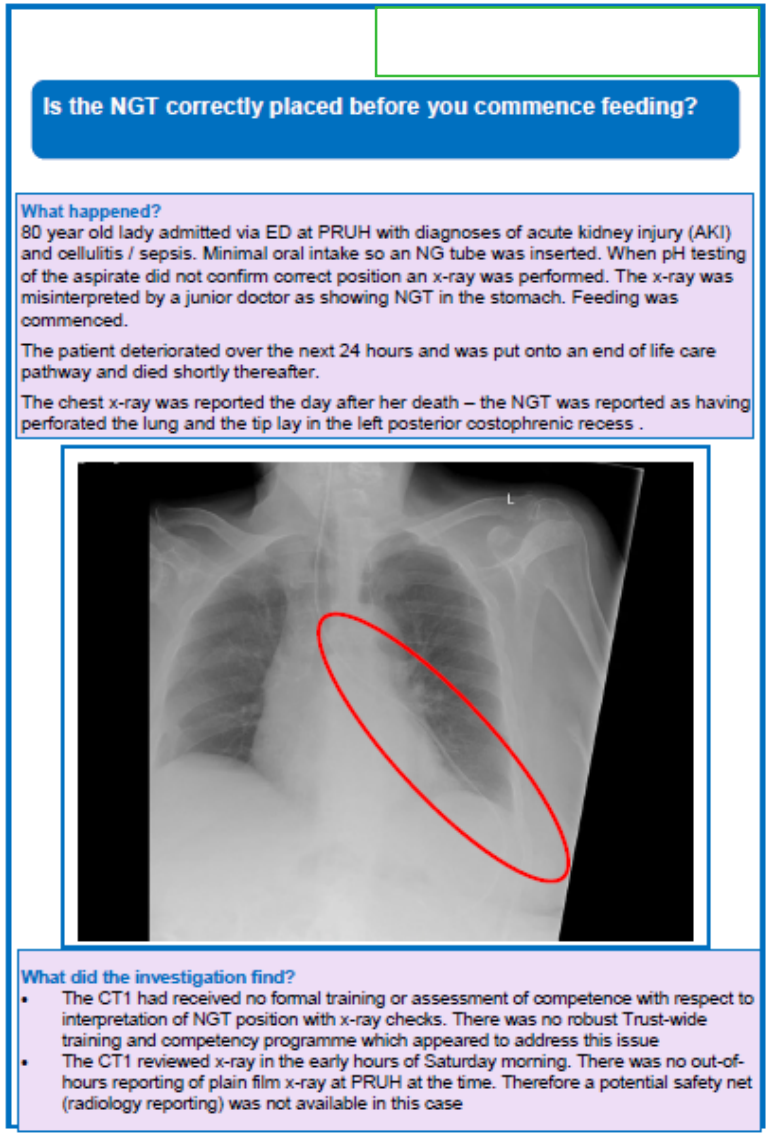
An incident (or series of incidents) that prevents, or threatens to prevent, an organisation's ability to continue to deliver an acceptable quality of healthcare services, including (but not limited to) the following screening, security, IG, activation of Major Incident Plan etc.

Where there is loss of confidence in the service (i.e. prolonged media coverage)

Level of Harm	Example
Minor Harm	Defined as any event or circumstance resulting in extra observation or minor treatment and caused minimal harm, to one or more persons. E.g. Graze or small cut sustained
Moderate Harm	Semi-permanent harm (1 month – 1 year) including a return to surgery, an unplanned re-admission, a prolonged episode of care (4-15days), cancelling of treatment, or transfer to another area such as intensive care as a result of an incident, fractured wrist or pubic rami, prolonged period of psychological trauma. The suggested time scale for 'prolonged' is 28 days.
Major Harm	Permanent lessening of bodily functions; including sensory, motor, physiologic or intellectual. Long term incapacity/disability. Increase length of stay >15 days.
Death (directly caused)	Unexpected death as a result of an act or omission in the context of health care delivery.

Never Event – Always Red/SI

- A type of serious incident, that is **wholly preventable**, where guidance or safety recommendations that provide strong systematic protective barriers **are available at a national level, and should** have been implemented by all healthcare providers



Is the NGT correctly placed before you commence feeding?

What happened?

80 year old lady admitted via ED at PRUH with diagnoses of acute kidney injury (AKI) and cellulitis / sepsis. Minimal oral intake so an NG tube was inserted. When pH testing of the aspirate did not confirm correct position an x-ray was performed. The x-ray was misinterpreted by a junior doctor as showing NGT in the stomach. Feeding was commenced.

The patient deteriorated over the next 24 hours and was put onto an end of life care pathway and died shortly thereafter.

The chest x-ray was reported the day after her death – the NGT was reported as having perforated the lung and the tip lay in the left posterior costophrenic recess .

What did the investigation find?

- The CT1 had received no formal training or assessment of competence with respect to interpretation of NGT position with x-ray checks. There was no robust Trust-wide training and competency programme which appeared to address this issue
- The CT1 reviewed x-ray in the early hours of Saturday morning. There was no out-of-hours reporting of plain film x-ray at PRUH at the time. Therefore a potential safety net (radiology reporting) was not available in this case

List of 15 current NE's as per the Never Event Framework 2018

Wrong site surgery	Wrong implant/prosthesis	Retained foreign object post procedure Medication	Mis-selection of a strong potassium solution	Administration of medication by the wrong route
Overdose of insulin due to abbreviations or incorrect device	Overdose of methotrexate for non-cancer treatment	Mis-selection of high strength midazolam during conscious sedation	Failure to install functional collapsible shower or curtain rails	Falls from poorly restricted windows
Chest or neck entrapment in bed rails	Transfusion or transplantation of ABO-incompatible blood components or organs	Misplaced naso- or oro-gastric tubes	Scalding of patients	Unintentional connection of a patient requiring oxygen to an air flowmeter

Supporting patients and their family

Saying sorry and explaining what went wrong – Duty of Candour – Pflicht zur Offenheit

- Statutory duty effective from November 2014
- Applies when a notifiable incident has directly led to **moderate or severe harm or death and includes psychological harm**
- Candour requires that a conversation be held (as soon as practicable) between patient or relative & their consultant which includes:
  - An apology;
  - A factual account of what happened;
  - What further action will be taken (eg. Investigation report)
- The conversation must be documented and followed up in writing
- The patient/relative should be invited to contribute to the review
- Findings must be shared with the patient/relative
- Candour Guardian as support but not standard

Local Staff Survey at NHS Trust 2019 – Duty of Candour

132 people responded, including 95 consultants.

- 117 of those had spoken to a patient or relative about an adverse incident where there was moderate harm or more (a ‘candour case’).
- Of 132 respondents, only 5 felt that the initial Duty of Candour conversation had ‘not gone well’. And in general, patients and families were grateful for openness and apology.
- In 11 cases, the patient or family were confused by the need for the meeting, and in 2 they did not feel it was the right time for the conversation.
- When it came to sharing the outcome of investigations with patients/families, feedback was generally positive. 6 People felt it had not gone well.

Overall the survey showed
good engagement with an awareness of the Duty of Candour; that we can reassure clinicians that apology and openness is welcomed by patients and families the vast majority of the time.

Supporting Staff

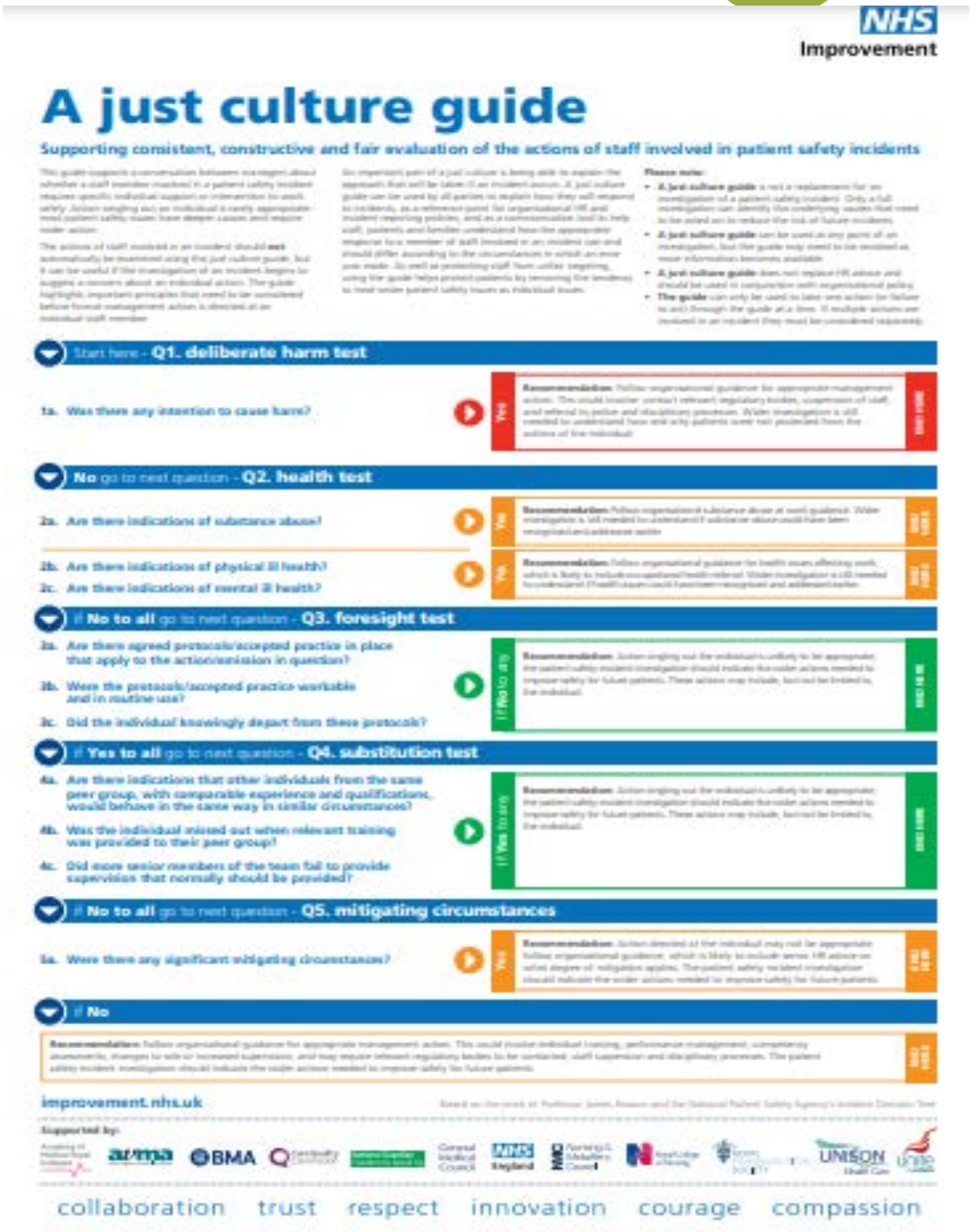
The six recognised stages associated with staff reaction in the aftermath of an adverse event

Chaos	Intrusive reflections	Restoring personal integrity	Enduring the inquisition	Obtaining emotional first aid	Moving on
Error recognised How/When	Haunted re-enactments of event	Managing gossip Fear	Realisation of seriousness Who can I talk to?	Seeking personal and professional support	- Dropping out (leaving profession) - Surviving (coping) - Thriving (learns from the event)

The Second Victim

Wu, Dr Albert, John Hopkins University, Adverse Events and the Second Victim, On-line Power Point Presentation.

Scott SD, Hirschinger LE, Cox KR, McCoig M, Brandt J, Hall LW. The natural history of recovery for the healthcare provider "second victim" after adverse patients. Qual Saf Health Care. 2009; 18(5):325-330.



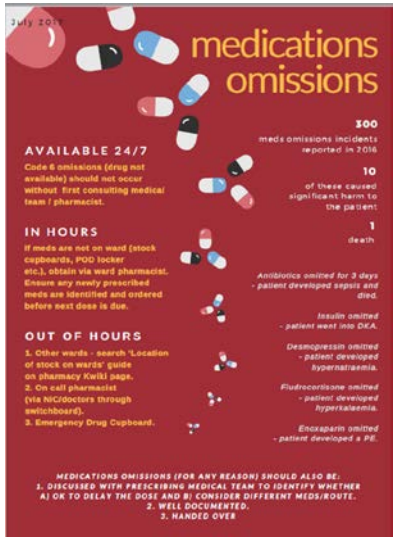
ASSIST ME MODEL (a tool for managers and staff)

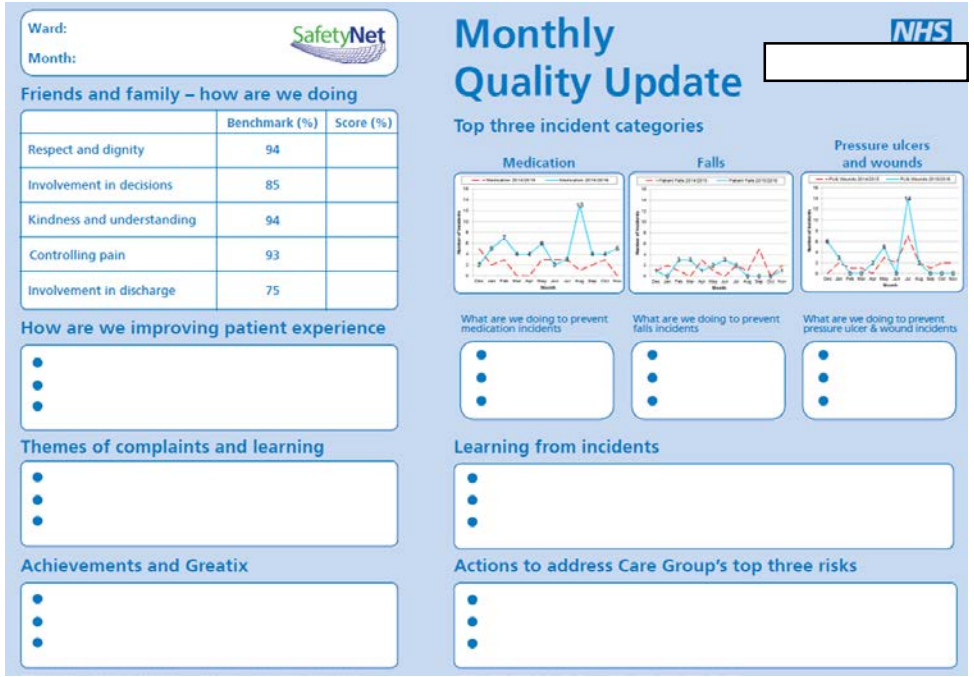
- **A** ACKNOWLEDGE with empathy the event and the impact on the member of staff
- **S** SORRY - express regret for their experience
- **S** STORY – allow time and space for them to recount what happened using active listening skills/SHARE personal experience
- **I** INQUIRE – encourage questions/INFORMATION – provide answers/information
- **S** SUPPORTS and SOLUTIONS (provide information on emotional and practical supports available)
- **T** TRAVEL – providing continued support and reassurance going forward and throughout the investigation/review process and open disclosure process
- **M** MAINTAIN contact/MONITOR progress/MOVING forward
- **E** END – reaching a stage of closure from the event./EVALUATE

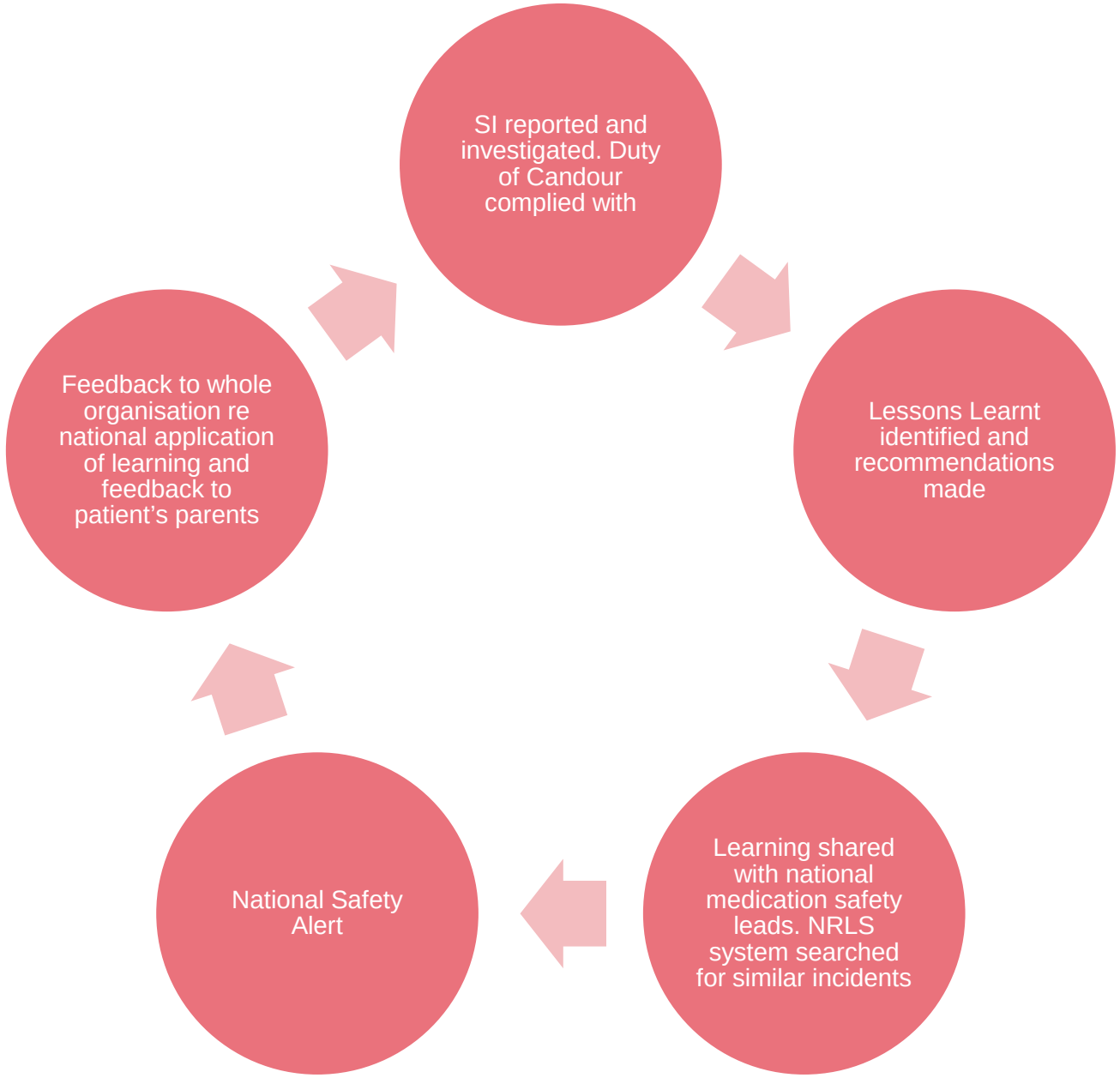
staff-guide-supporting-staff-following-an-adverse-event.pdf (hse.ie)

Learning from Incidents

SafetyNet



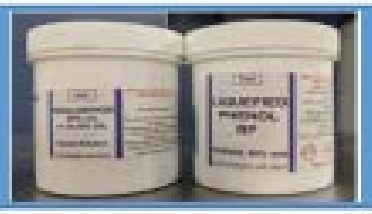



SI reported and investigated. Duty of Candour complied with
Lessons Learnt identified and recommendations made
Learning shared with national medication safety leads. NRLS system searched for similar incidents
National Safety Alert
Feedback to whole organisation re national application of learning and feedback to patient's parents

SafetyNet

Local Learning making a National Difference

A paediatric patient with a history of focal onset, drug resistant epilepsy required rectal paraldehyde at home, administered by his parents. He was receiving treatment at home as per his care plan (usually 20ml paraldehyde rectally). His parents noticed the medication smelt different to normal (paraldehyde has a distinct smell) and realised the medication administered was 7ml liquefied phenol 80% weight/weight (w/w) instead of 10ml paraldehyde 50% volume/volume (v/v) in olive oil; liquefied phenol had been erroneously dispensed instead of paraldehyde by Pharmacy. The patient was seen and treated at ED. The patient had surgical follow-up but did not suffer internal damage.



Similar packaging & close proximity storage of medicines/products – are key risks in medication safety.

- In this incident, the packaging was very similar (image above) and both were stored in the 'flammable cupboard'. Other learning points that were identified:
- Procurement of similar presentation phenol and paraldehyde
- At the time, there was no automated dispensing robot in the Pharmacy
- On investigation, it was found that there had been one similar incident reported. There was no harm reported as the dispensing error was recognised before it could be administered.

The incident led to a rapid response by our staff. Phenol was immediately removed from the Trust and an alternative procured after the incident was reported. Learning from this incident was shared anonymously with the national medicine safety leads. The national team subsequently reviewed reported incidents on the national reporting system across England over a 5-year period and identified 30 further incidents including:

- Harm from use: e.g. referral of a child to a specialised burns unit for treatment of burns to the lower leg sustained when liquefied phenol 80% spilled from a bottle during treatment for toenail avulsion.
- Mis-selection: e.g. administration of unlicensed liquefied phenol 80% instead of licensed oily phenol 5% injection during a procedure to remove a rectal polyp

A National Patient Safety Alert NatPSA/2021/008/NHSPS was issued in August of this year requiring all NHS care providers to identify where liquefied phenol 80% is used and update procedures/guidelines to substitute use for a safer, suitable alternative. This ask and action is mandated.

Therefore – thank you for reporting and keep up the good work around sharing lessons learnt

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National Patient Safety Alert

Elimination of bottles of liquefied phenol 80%

Date of issue:	25 August 2021	Reference no:	NatPSA/2021/008/NHSPS

This alert is for action by: All acute trusts, trusts providing community services, and organisations providing podiatry services, including where these are provided by general practices.

This is a safety critical and complex National Patient Safety Alert. Implementation should be co-ordinated by an executive lead (or equivalent role in organisations without executive boards). In acute trusts, the executive lead should be supported by clinical leads in pharmacy, podiatry and surgery.

Explanation of identified safety issue:

Phenol, a caustic compound used for its antimicrobial, anaesthetic, and antipruritic properties, is highly toxic and corrosive. It can cause burns, severe tissue injury and is rapidly and well absorbed causing systemic toxicity.[1]

'High strength' phenol is available in different preparations:

- Bottles of liquefied phenol 80% (typically 7mL or larger): these can be ordered via pharmacy departments as an unlicensed pharmacy Specials product[2] or by clinical teams directly from wholesalers.
- Phenol swab packs: these contain an ampoule of phenol 89% with a cotton bud applicator attached (licensed as a medical device).

Current prescribing and supply data shows that the main use of 'high strength' liquefied phenol is in podiatry and orthopaedic foot surgery for destroying the nail matrix. This data also suggests some limited use in other clinical areas where it is no longer recommended.

Review of incidents identified a report where liquefied phenol 80% was administered to a child instead of the prescribed paraldehyde rectal enema,[A] used to treat status epilepticus. The patient required emergency admission to hospital and intensive treatment to minimise the corrosive effects of phenol on their intestinal tissue.

Subsequent review of reported incidents over a 5-year period identified 30 further incidents including:

- Harm from use: eg referral of a child to a specialised burns unit for treatment of burns to the lower leg sustained when liquefied phenol 80% spilled from a bottle during treatment for toenail avulsion.
- Mis-selection: eg administration of unlicensed liquefied phenol 80% instead of licensed oily phenol 5% injection during a procedure to remove a rectal polyp.

Oily phenol 5% injection, an analgesic sclerosing agent[3], is licensed for the treatment of haemorrhoids; it does not need to be eliminated as part of this Alert.

Actions required

Actions to be completed as soon as possible and no later than 25 Feb 2022

1. Identify where liquefied phenol 80% is used and update procedures/guidelines to substitute use for a safer, suitable alternative.
2. Ensure clinical areas have stock of agreed safer alternatives and then remove bottles of liquefied phenol 80% from clinical areas, and update stock lists.
3. Amend electronic prescribing systems to ensure liquefied phenol 80% cannot be prescribed.
4. Amend current purchasing systems, and introduce ongoing controls on purchasing, to ensure liquefied phenol 80% cannot be purchased inadvertently via the pharmacy department or any alternative purchasing route.

Professional guidance includes:

Chemical ablation of nail matrix: The Royal College of Podiatry[4], British Orthopaedic Association and British Society for Children's Orthopaedic Surgery do not support use of bottles of liquefied phenol 80% and advise use of licensed phenol impregnated swabs.

Pilonidal sinus: The Association of Coloproctology Great Britain & Ireland do not support the use of bottles of liquefied phenol 80% and advise use of safer, suitable alternatives.

Anaesthesia of tympanic membrane: British Society of Otology do not support the use of bottles of liquefied phenol 80% and advise use of safer, suitable alternatives.

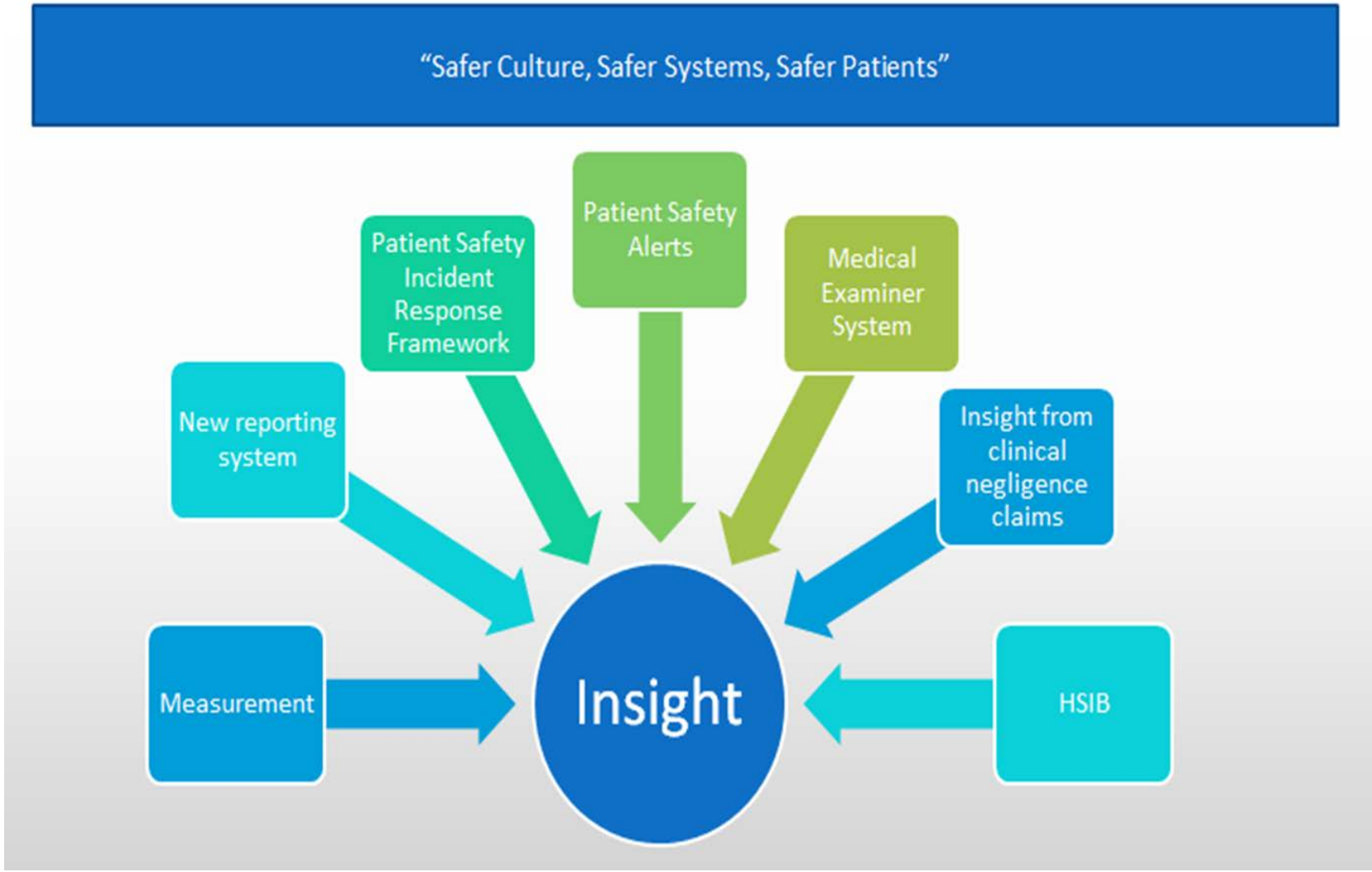
Genital molluscum infection: British Association for Sexual Health and HIV does not support the use of phenol.[5]

Pros and Cons of Current System

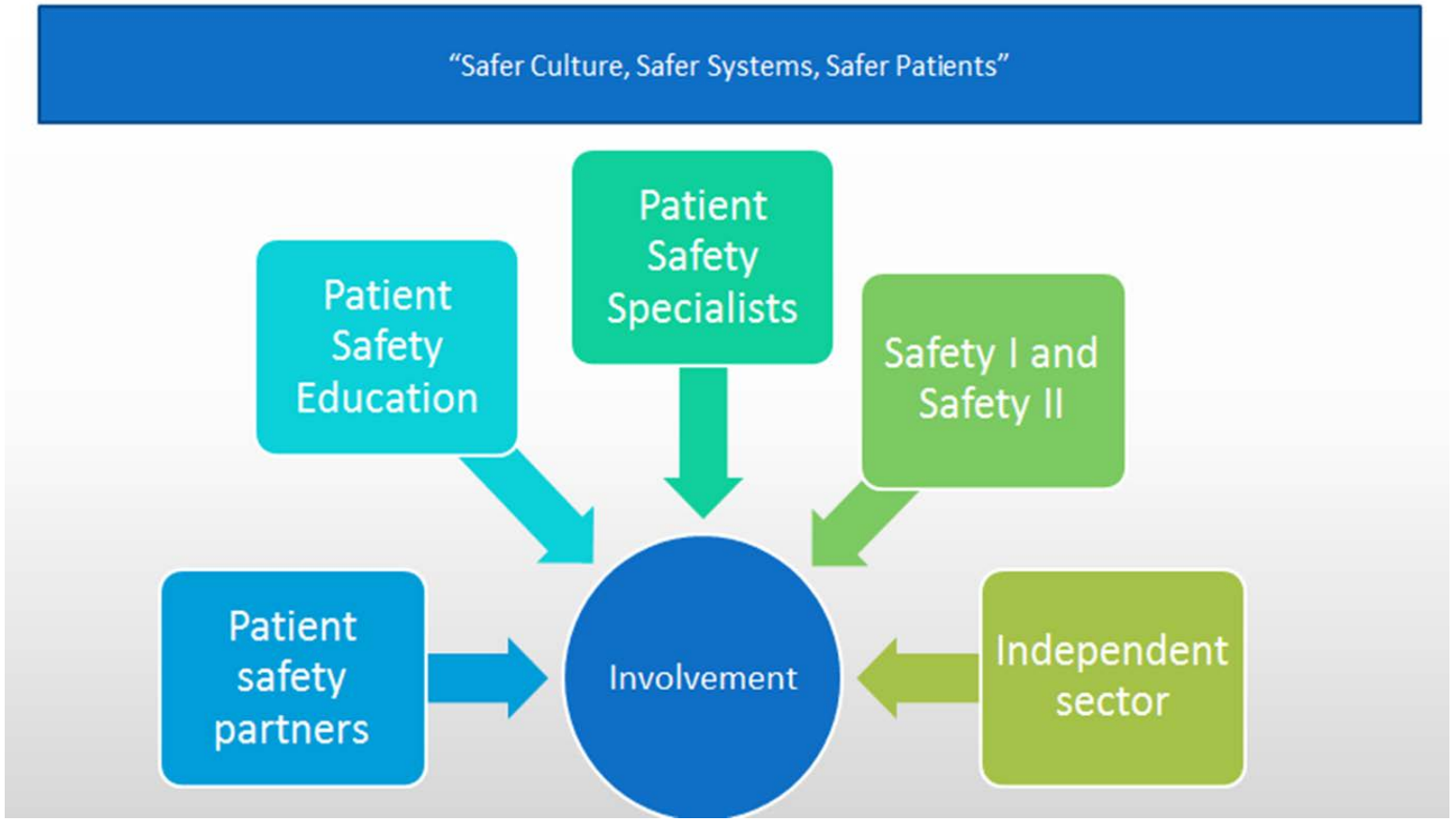
- Improved culture around openness and transparency
- High reporting of incidents
- Infrastructure in place to support the process
- Embedded in the system
- National learning shared

- Adverse events occur in up to 10% of all acute admissions in all modern health systems, and this rate has not altered for more than 50 years
  Braithwaite, J., Wears, R. and Hollnagel, E. (2015), Resilient health care: turning patient safety on its head. International Journal for Quality in Health Care, 27, 418–420
- Resource intensive
- Quantity v Quality
- Investigations linked to harm too often
- Blurred lines re remit and other investigations
- None standardised training

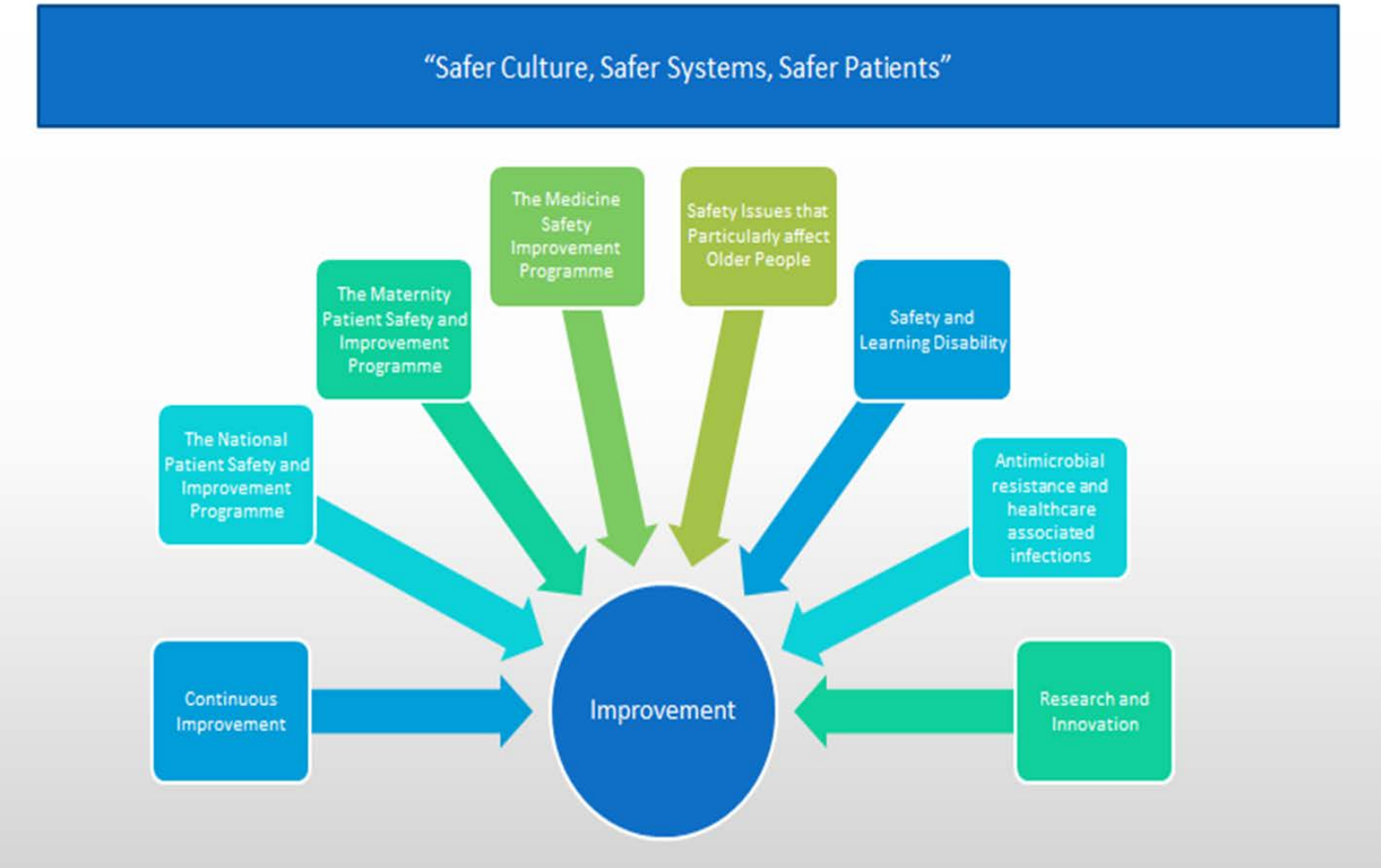
Patient Safety Strategy 2019



Patient Safety Strategy 2019



Patient Safety Strategy 2019



Patient Safety Incident Response Framework

- Currently being rolled out in pilot sites
- **Organisations should base their annual budget for PSIIs on their anticipated level of investigation activity but build flexibility into this because some demand-led/reactive activity will continue.** However, their PSIRPs must base and describe the planned PSII activity on past incident reporting data. Organisations should agree their PSIRP with their lead commissioner and monitor it annually.
- **Where an incident is of a relatively well understood type** – resources are better directed at improvement rather than repeat investigation.
- **Where the systems-based, interconnected contributory and causal factors of an incident are still not well understood,** a PSII may be needed to fully understand why it occurred.
- **Organisational leaders also must determine which categories of incident are priorities locally and require a PSII.** They should do this by reviewing past incident data (from the last three to five years where available) to identify those incidents representing the most significant risks. **This list must be set out in the PSIRP,** reviewed every two years and adapted as new risks emerge or diminish locally.
- **Organisations must also initiate a PSII for incidents which signify an unexpected level of risk and/or potential for learning and improvement but fall outside the predetermined national and local priorities.** These will be determined on a case-by case basis by key members of the patient safety team or equivalent responsible for reviewing patient safety incident reports and initiating relevant action through PSII leads. This process must not become a bureaucratic and burdensome panel assessment of each incident report. Instead, staff trained and experienced in patient safety should be empowered to determine the most appropriate action based on the available evidence, including that from clinical and patient/family/carer input.

DIFFERENCE TO SI FRAMEWORK

Investigator expertise, experience, time and authority: the framework clarifies that investigations must be led by those trained and experienced in patient safety incident investigation (PSII), with the authority to act autonomously and with dedicated time and resource.

Investigation timeframe: timeframes are more flexible and set in consultation with the patient and/or family. They should average three months and never exceed six.

Terminology: ‘systems-based PSII’ replaces the term root cause analysis (RCA). A systems-based approach means breaking down a complex arrangement into simple units to assist understanding of the complexity, interactive nature and interdependence of the various external and internal factors.

Governance and oversight: this is strengthened, with commissioners and local system leaders assuring plans and co-ordinating investigations spanning multiple settings. Provider boards now sign off PSII quality and safety improvements.

Incident Investigation Training under the PSIRF

Training for Lead Investigators

- Attended a theory and practical PSII training course which:
- – follows and promotes this PSIRF or its predecessor, the Serious Incident Framework
- – runs for a minimum of two days
- – follows and endorses current NHS PSII guidance
- – teaches recognised good practice approach(es) to systems-based PSIIs
- – includes modules on human factors, just culture and Duty of Candour
- – covers effective improvement/solution generation and implementation
- – promotes the use of NHS PSII tools and templates
- Should have conducted a full PSII within 12 months of training
- Should consider completing advanced training within three years of the initial two-day course to advance their skills in the above and in complex safety investigations spanning different care or organisational boundaries; engaging patients and staff in PSIIs; incident analysis; improvement science;25 and PSII report

Training for those overseeing, supervising or reviewing PSIIs

- Attended a theory and practical PSII training course which:
- – follows and promotes this PSIRF or its predecessor, the Serious Incident Framework
- – follows and endorses current NHS PSII guidance
- – runs for a minimum of two-days
- – teaches recognised, good practice approach(es) to systems-based PSII
- – includes modules on human factors, just culture, Duty of Candour and ‘being open’
- – covers effective improvement/solution generation and implementation
- – promotes the use of NHS PSII tools and templates
- • attended a one-day PSII oversight course
- • attended training in coaching, feedback and delivery of learning
- • conducted a full PSII within 12 months of training
- • considered completing advanced training within three years of the initial twoday course to advance their skills in the above, complex PSIIs spanning different care or organisational boundaries; engaging patients and staff in investigations; incident analysis; improvement science and PSII reports

The end – Q&A?

With thanks

Lorraine