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HEALTHCARE SAFETY
INVESTIGATION BRANCH

Medical Device/Medication Safety Investigations

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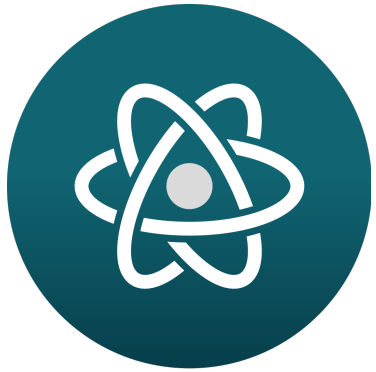
About us

Independent safety investigations in NHS-funded care

Do not apportion blame or liability



Focus on system-level (policy and regulatory) change

Professionalise the patient safety investigator role

Our approach

Wide ranging expertise from safety-critical industries

Multidisciplinary and inclusive teams; patient and family involvement

Focus on learning not blame to reduce further risk of harm

Transparent and collaborative to support learning

National investigations

77* reports published/completed

217 safety recommendations to **53** different organisations

187 safety observations

56 safety actions

*As of 30 September 2022

Recent publications:

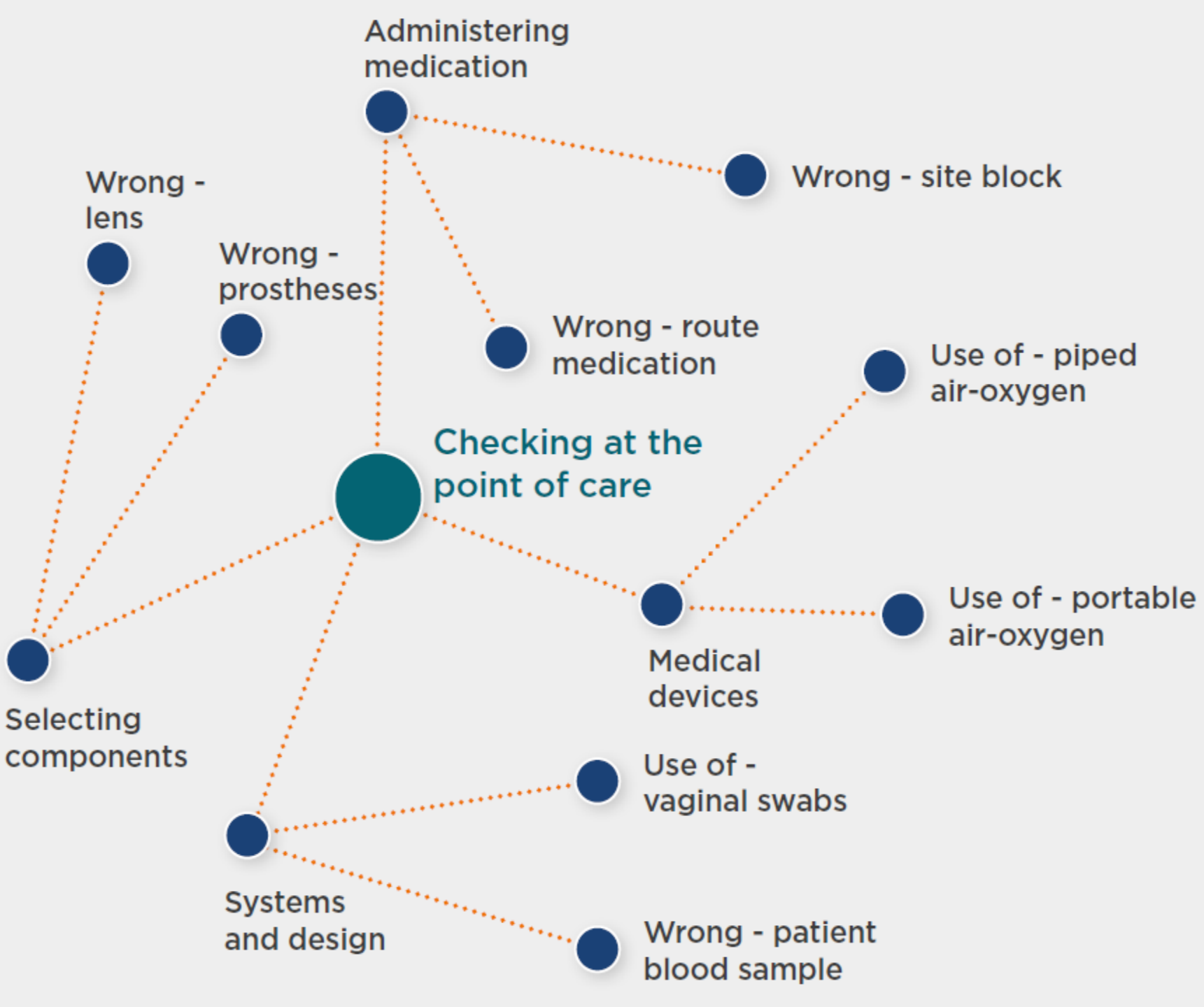
HSIB Thematic learning around medical device safety

Introduction

- HSIB have completed 15 national investigations on medication safety - https://www.hsib.org.uk/
    - In this this session we provide an overview of the learning from these investigations with a focus on medical devices.
    - We demonstrate why many safety risks have yet to be mitigated, despite some of these risks being known for decades.
    - Implementing interventions is not simple "**plug & play**" – we require an improved understanding of medication systems and how they can be better designed.

Checking at the point of care

- Many routine activities require healthcare workers to check that the intended treatment is being prescribed and administered correctly.
- The aim should be to reduce the reliance on checking by developing procedures that mitigate against known risks by design.



Thickening the ‘safety rule book’ does not adequately support staff in mitigating harm

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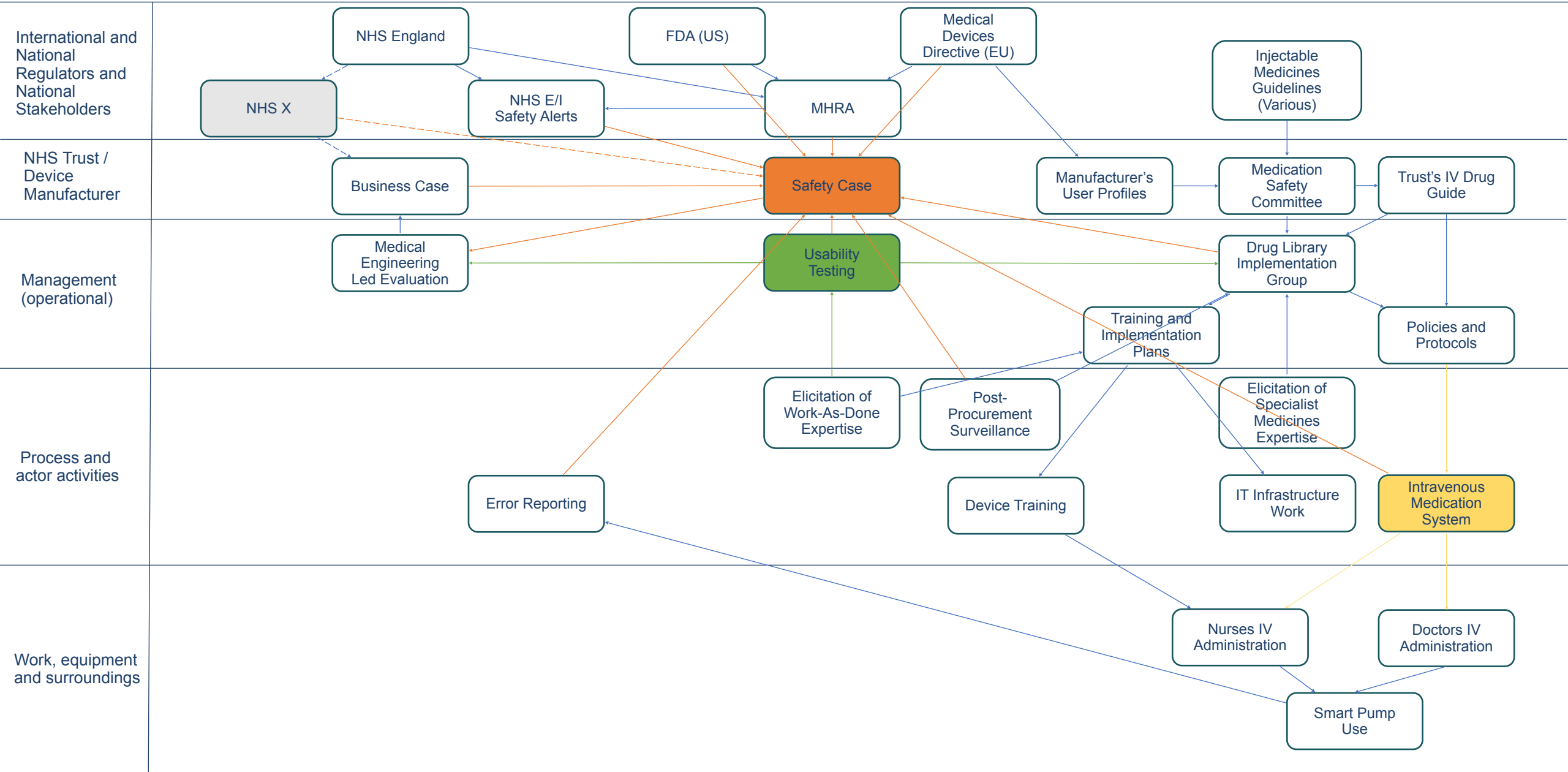
“it’s time to stop thickening the rule book…
…and to do *something* more sophisticated”

Braithwaite, J (2018): Changing how we think about healthcare improvement. In BMJ (Clinical research ed.) 361, k2014.

A system level understanding:
Actor & Artefact Map for the procurement, usability and adoption of smart pumps



Shifting safety away from the ‘rule book’

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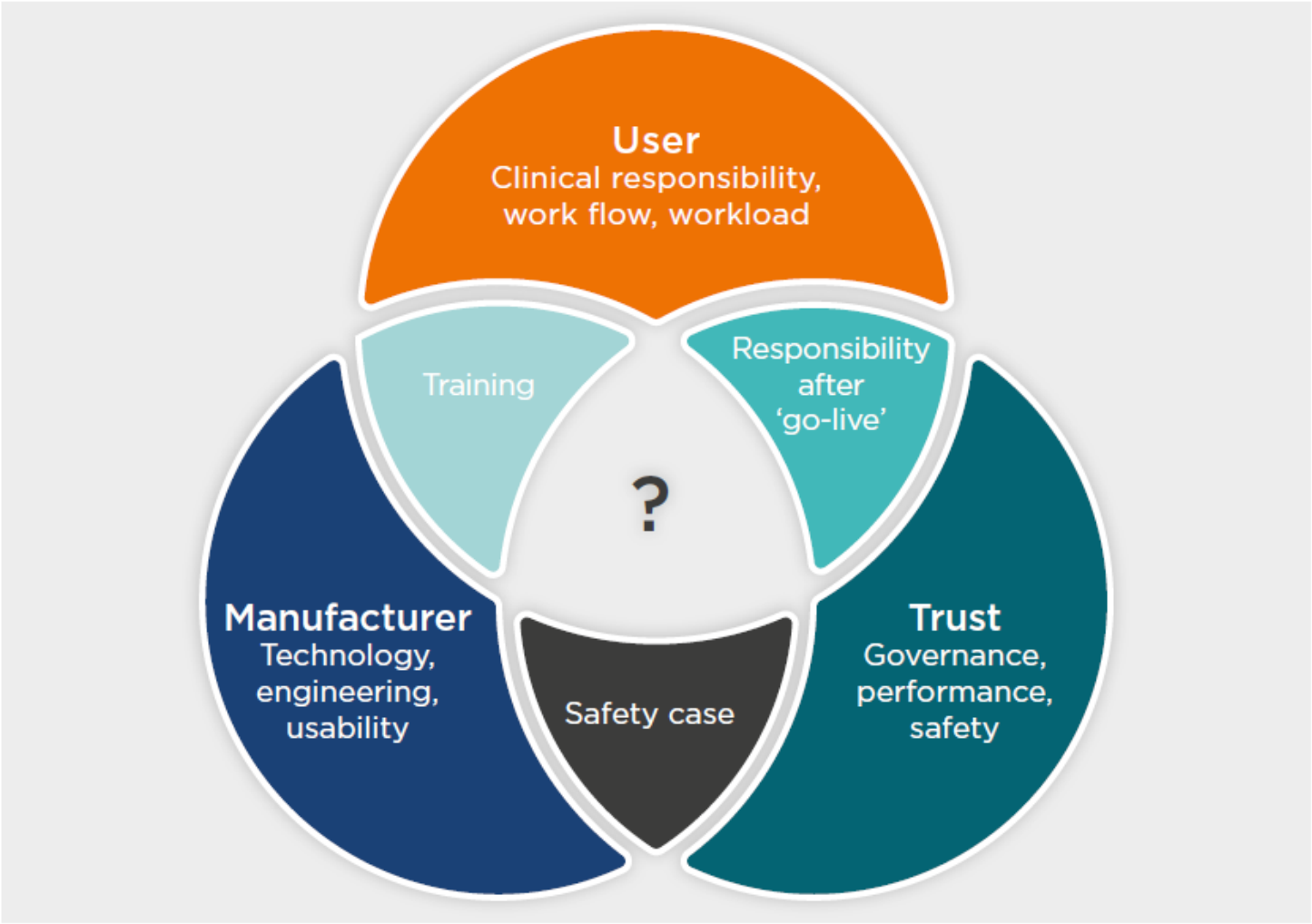
Ownership of responsibility for implementation



Thematic learning across investigations

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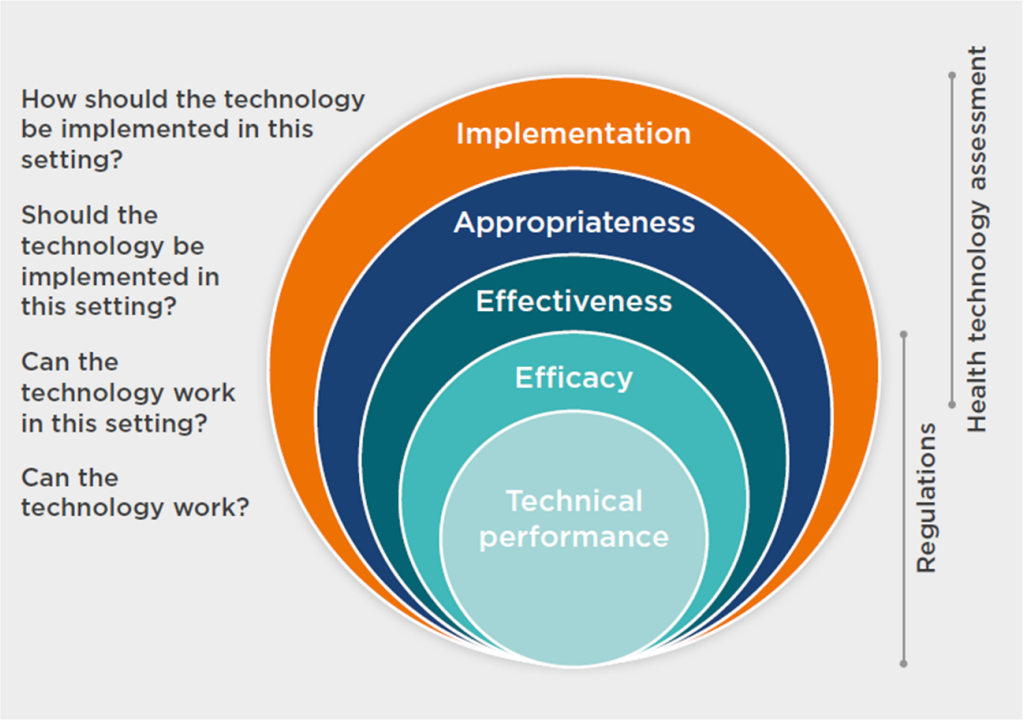
The status quo

- Safety controls reliant on staff checking can be eroded by organisational workforce and workload pressures.

Equipment and IT

- The procurement of medical devices does not always facilitate staff in managing risks.
- The design of medical equipment and associated IT does not always facilitate staff in managing risks - despite many risks persisting over decades and patient harm.

Health technology assessment (World Health Organization, 2011)



Thematic learning across investigations

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Regulation

- Regulators are not always proactive in acting on available evidence to reduce risks – moving to assure safety rather than proving something is unsafe and then reacting.
- Overarching regulatory and assurance frameworks needed to coordinate the management of risks are sometimes lacking or non-existent.

Standardisation and skills

- There is sometimes a lack of standardisation of approaches to medication prescribing and administration - including the roles and responsibilities of staff.
- More support is sometimes needed in the education and training of clinical practitioners that can facilitate the development of decision-making skills.

"…a shift from proving that something can be dangerous, to proving that things are safe".

Leary, A. (2021) Why does healthcare reject the precautionary principle? BMJ Opinion, 12 March [Online]

What would organised safety look like?

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- It may be beneficial for the NHS to explore how the application of safety management principles could build on the foundations developed by the NHS Patient Safety Strategy.
- It is unlikely that having one single safety management system would be feasible and that a more integrated approach of multiple systems, as seen in other high-risk industries, may be necessary.
- A greater adoption of the principles of a safety management system in the NHS may support more effective responses to safety recommendations.

ICAO SMS MODEL

International Civil Aviation Organization (ICAO)

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Ongoing medical device investigations:

- Air embolism risks from central venous catheters
- Ambulatory syringe pumps

Themes

- Both medical devices worked exactly as designed.
  - Haemodialysis Central Venous Catheter (CVC)
  - Ambulatory syringe pump
- No device malfunction or damage.
- Patients in both cases came to harm.

Haemodialysis CVC

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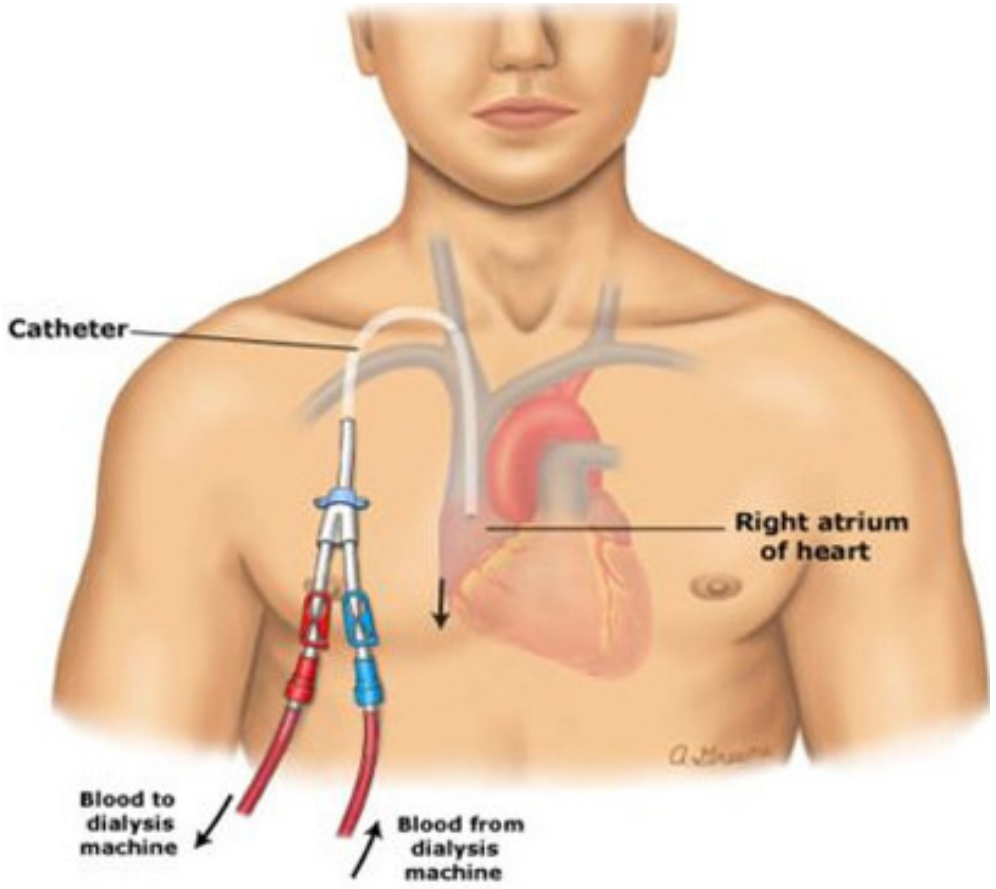

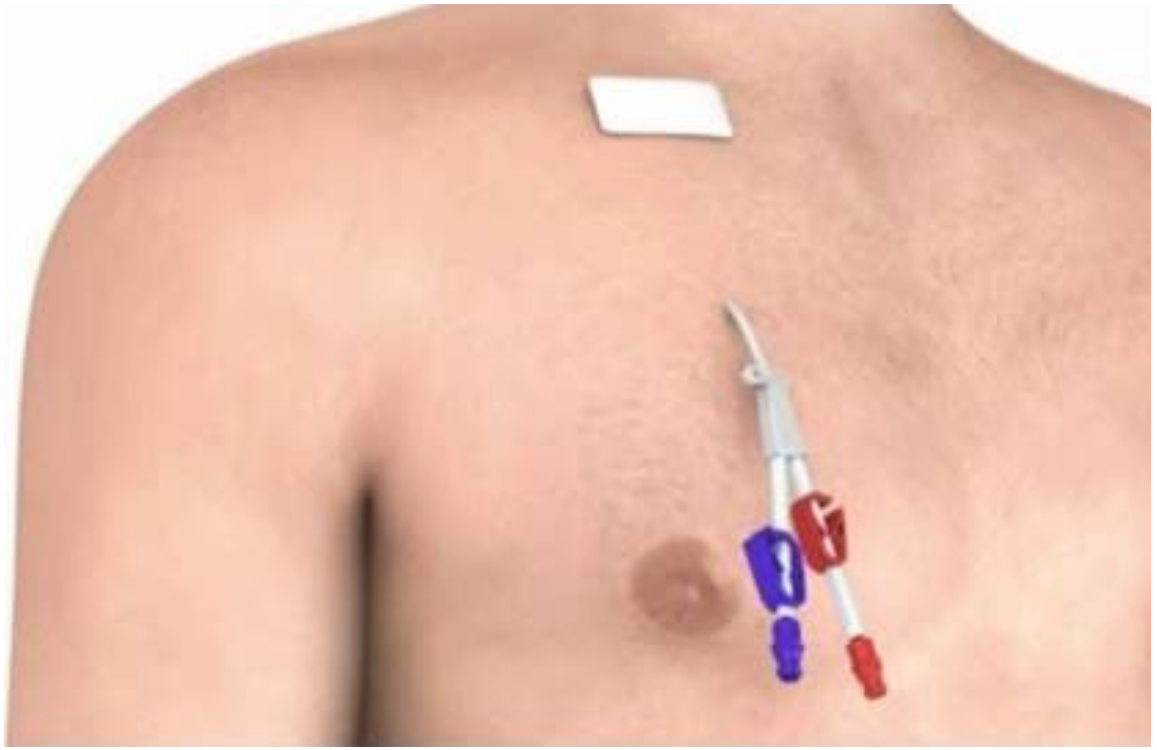

CVC - Reference Event

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- Blood cultures advised by microbiology from haemodialysis CVC.
- Medical student requested to carry out task, supervised by an FY1.
- Cap of CVC removed for cleaning and FY1 unclamped the port (without syringe attached), leaving the patients central system open to air.
- 4 minutes later, patient had a cardiac arrest, and died 2 days later.
- Coroner's Inquest concluded that a contributory factor to the patient's death was the cardiac arrest, secondary to air embolus.

CVC - Device related information

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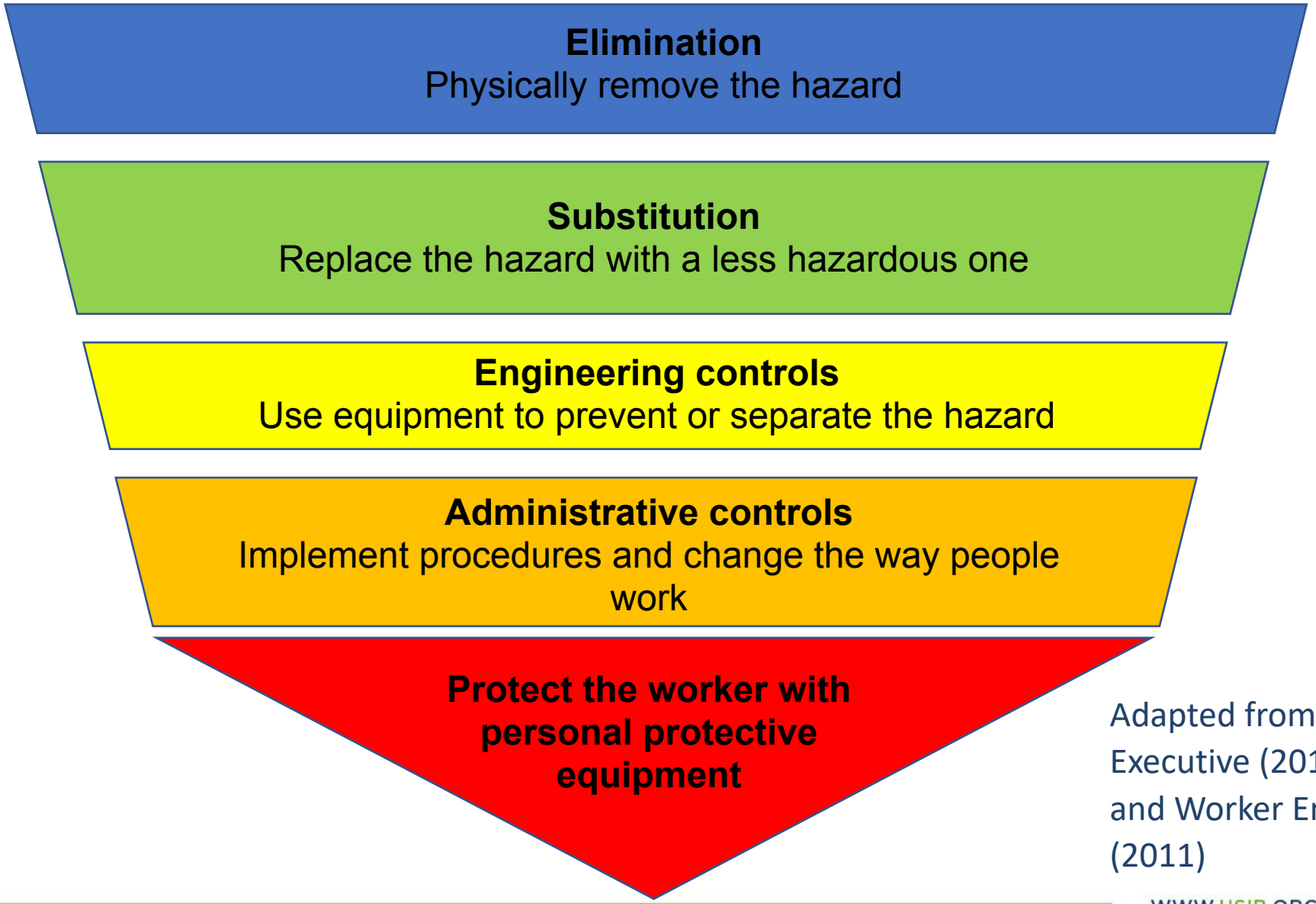
- Catheter-related air embolism avoidable, but occurring, and under-reported (including near misses).

- Air embolism mitigation, whilst using CVCs, places significant reliance upon people following a correct process.

- This ‘not-that-uncommon’ occurrence attributed to ‘a general deficiency in knowledge’ of this risk.

Hierarchy of hazard control

Most effective



Least effective

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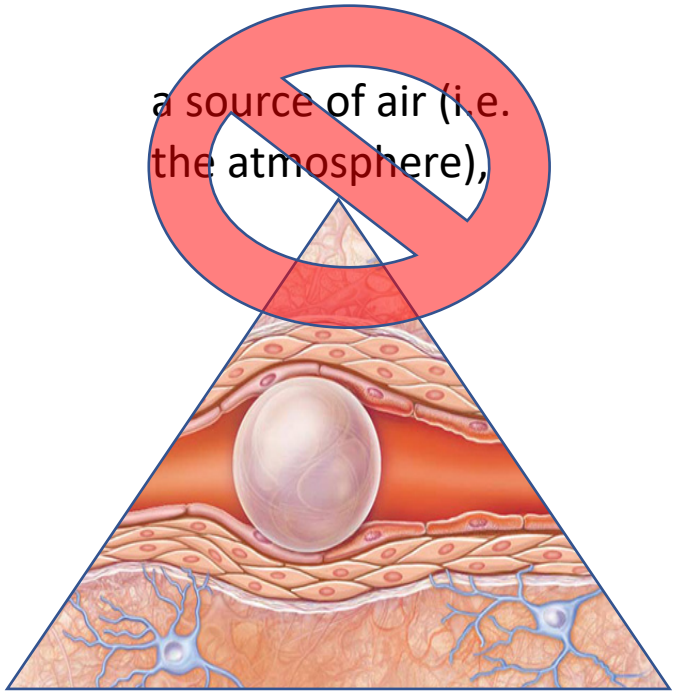
Adapted from Health and Safety Executive (2019) and Leadership and Worker Engagement Forum (2011)

Fire triangle

To generate the conditions for fire, three essential elements are required:

Venous air embolus triangle

To generate a venous air embolus, three essential elements are required:



the connection between a vein and the source (i.e. the catheter)

a pressure gradient that favours air migration into the vein

Venous air embolus triangle

To generate a venous air embolus, three essential elements are required:

a source of air (i.e. the atmosphere),

Straight male threaded

Barb valves

Bondable valve

CVC - Considerations

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- Risks – “ you don’t know what you don’t know”
- Engineered controls – devices to maintain a closed system
- Visual alerts for risk – Fistula patients have coloured wristbands and/or alerts cards.
- Repeated events – 2 recent further referrals for 3 air embolus safety events (more general CVCs)

Syringe pump - Reference Event

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- Patient had gastro-oesophageal cancer (where the food pipe joins the stomach). They received chemotherapy and had a food pipe stent inserted.
- The stent migrated into the stomach; patient admitted to an oncology ward for repositioning of the stent.
- Pain relief medication via a syringe driver, with additional subcutaneous morphine.

Syringe pump - Reference Event

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- 7th day of treatment an occlusion occurred; they did not receive pain relief medication for approximately 6 hours.
- After 6 hours there was patient harm.
- Staff were unaware of approximately 2 hours of syringe pump alarm (8 separate alarms), over a 6-hour period
- Inquest concluded that the patient was cancelling the alarm and restarting the pump.

Syringe pump - Considerations

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- Environment – the patient was in a bay furthest from the nursing station

- Staff checks – During this occurrence, the 4 hourly syringe pump staff check was missed

- Patient interaction – Keypad lockout for patients

Syringe pump - Considerations

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- **Engineering controls:**
  - Innovation in design of ambulatory syringe pumps to support safer care, for example:
    - Remote or centralised alarms and monitoring to mitigate environment challenges and the requirement for 4 hourly bedside checks.
    - Mitigation of ability for patient interaction – anti tamper

- **Administrative controls:**
  - Staff training and awareness of environment/human factor considerations for device usability, in addition to device specific training.

Summary / Themes

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- **In both investigations the medical device worked exactly as designed, the patients came to harm.**
  - System/human factors aspects related to medical device usability. Incidents were preventable.
  - Safety/reporting data shows repeated similar occurrences (Risk picture)
  - Mechanisms to encourage innovation for usability/safety improvements, driven in part by incident evidence?
  - Remove the burden for mitigation of safety risk from ‘people following process’, with more ‘effective engineered controls’.
  - Mitigate against identified risks by design, using national level reported incident data for proactive and strategic mitigation of safety risks – who and how?

Summary / Themes

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- **In both investigations the medical device worked exactly as designed, the patients came to harm.**
  - Recent CVC referral - reactive management of a safety risk at a local level, not proactive at a national level.
  - Onus on national organisations, that collect and hold national incident data, to use this for proactive safety management?
  - Trust awareness - do not collect or hold national risk data. How would Newcastle learn from the event in London, and therefore attempt to mitigate a known risk?
  - 12 incidents on a national reporting tool for uncapped and unclamped lines in the last 4 years, what has that driven, how is the risk being managed nationally?

Further Information

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Information relating to the current investigations:

https://www.hsib.org.uk/investigations-and-reports/safety-risks-associated-with-central-venous-catheters-used-for-haemodialysis-treatment/

https://www.hsib.org.uk/investigations-and-reports/risks-associated-with-medication-delivery-via-ambulatory-syringe-pumps/

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