HEALTHCARE SAFETY
INVESTIGATION BRANCH

Investigation without blame

Scott Hislop

&

Jonathan Back

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Life Changing

Fatalities

Reputation

National Investigation

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- 17 National reports published
- 20 National investigations ongoing
- Socio technical issues identified in 70%
  - Human Machine Interface / Human Computer Interface
  - System interoperability
- Example Recommendations:

  Implement interoperability between SystmOne and the Prison-National Offender Management Information System, enabling sharing of essential information across the prison service.

  Process to recognise and act on digital issues reported from the Patient Safety Incident Management System.

  Development of interoperability standards for medication messaging.

  Produce guidance for configuring the electronic discharge process, and how ePMA systems should be interfaced with such a process.

Case Study - Procurement and adoption of smart infusion pumps

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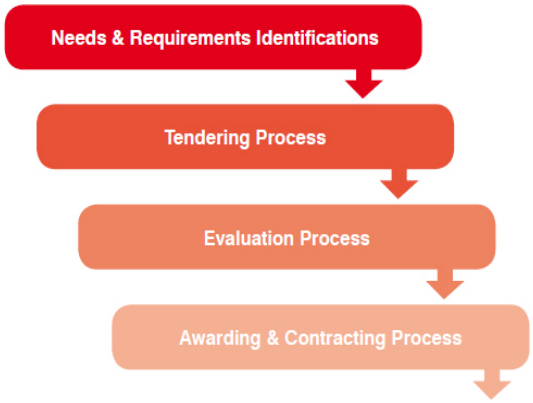
- 3 fentanyl overdose bolus incidents occurred in November 2018 across 3 different critical care areas within the same Trust
- Incidents were linked by the Trust to the introduction of smart pump technology – specifically when the “drug library went live”
- Fentanyl had been excluded from the drug library as the doses were not standardised – requiring dose-rates to be manually programmed or selected from a menu
- The user was required to check the fentanyl concentration in the syringe prior to programming, calculate the dose-rate, and program in a “new way” even though the hardware was familiar

MHRA

Adverse Incident Report

“…confusion between dose-rate and flow-rate due to introduction of new Drug Library”

Life Cycle



- **2016 (Q1)** – Ageing pumps, mobility and equipment standardisation, patient safety
- **2016 (Q2)** – User testing, start drug library development
- **2016 (Q3)** – Proceed on the basis that drug library will take 6-8 weeks develop and will **"go live"** later
- Manufacturer to support development of drug library and provide device training…

- **2016 (Q4)** – Funding obtained for drug library development

Development took 2 years – A bespoke implementation framework was designed

- **2018 (Q3)** – Training for drug library **"go live"** was provided **"in a compressed way"** to coordinate with EPR rollout

- **2018 (Q4)** – Shortly after **"go live"** the incidents occurred. Attempts at pushing out a new version of the drug library to prevent future incidents of that type were unsuccessful.

Reference Case Analysis

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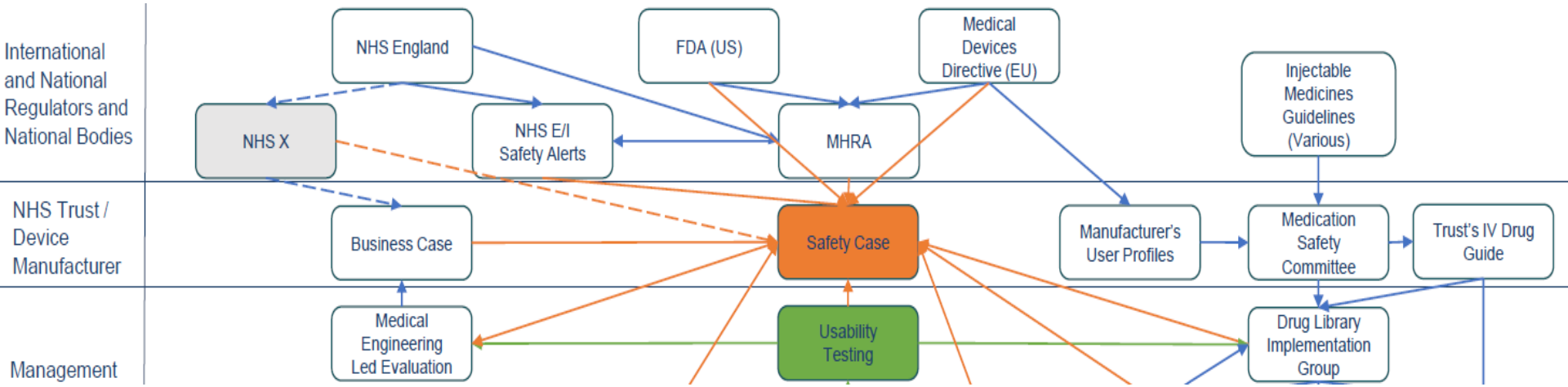

National Investigation

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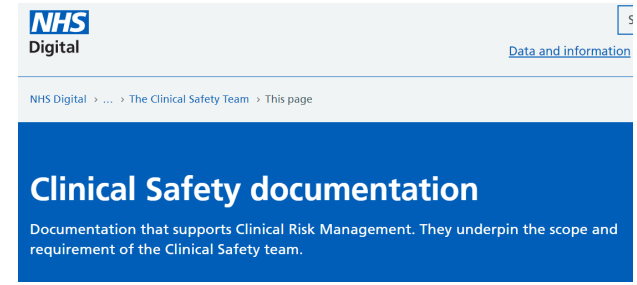
- **Safety Case**

A structured argument, supported by a body of evidence that provides a compelling, comprehensible and valid case that a system is safe for a given application in a given operating environment.

Ministry of Defence

ICAO • OACI • ИКАО



Current Safety Case Guidance

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Clinical Risk Management - Data Safety

'Health IT Systems are defined as products that comprise hardware, software or a combination of both.

Hazards to patients arising from hardware and software - both in normal operation and in cases where the hardware and/or software exhibit unintended behaviour. Assessing safety risks in hardware and software is a practice common to many industries and several strategies for managing these risks have been developed over the years. These strategies have typically been embodied in a variety of standards and best practice guides'

NHS Digital

NHS Digital Clinical Safety standards -
Compliance with DCB0129 and DCB0160 (previously known as SCCI0129 & SCCI0160)

Secondary supportive software

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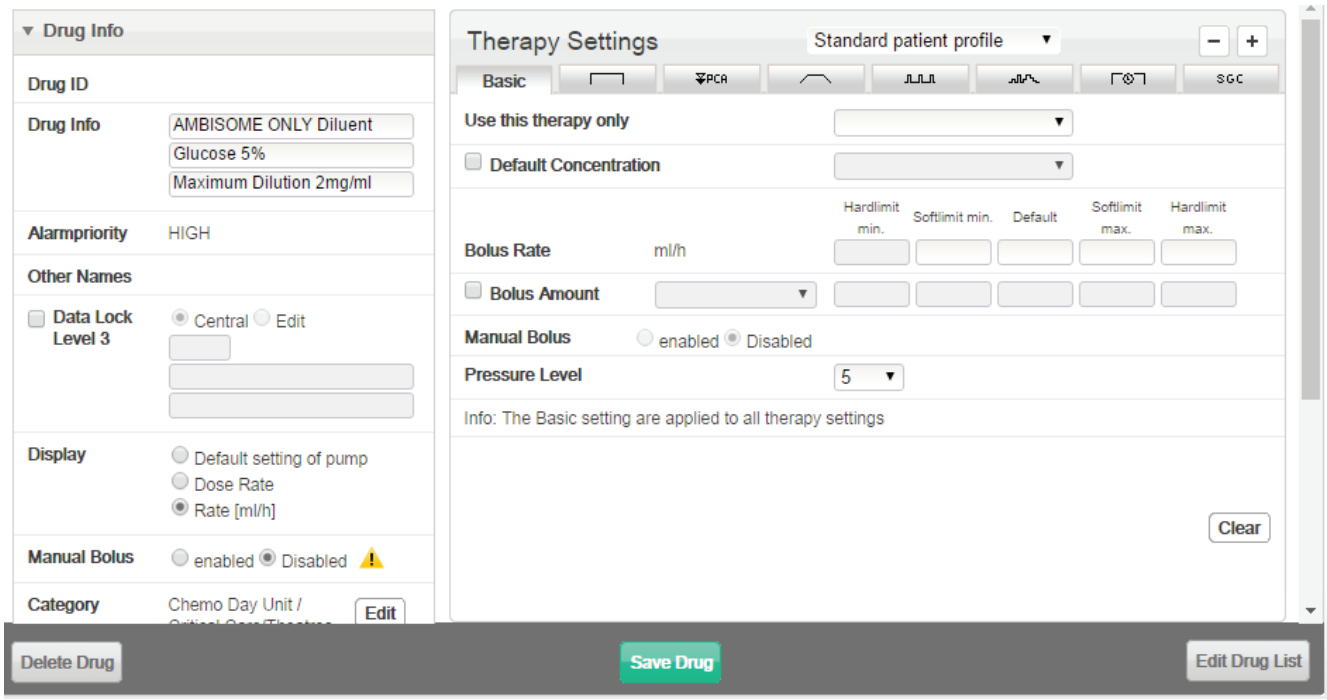
- Manufacturers supply and use proprietary software when developing and updating drug libraries
- Data inputted either by Trust or manufacturer
- Drug library then sent / installed on pump
- Who has ownership and responsibility that the data / drug library is correct?
- Why can't data from the pumps be easily shared?



Ownership of Risk

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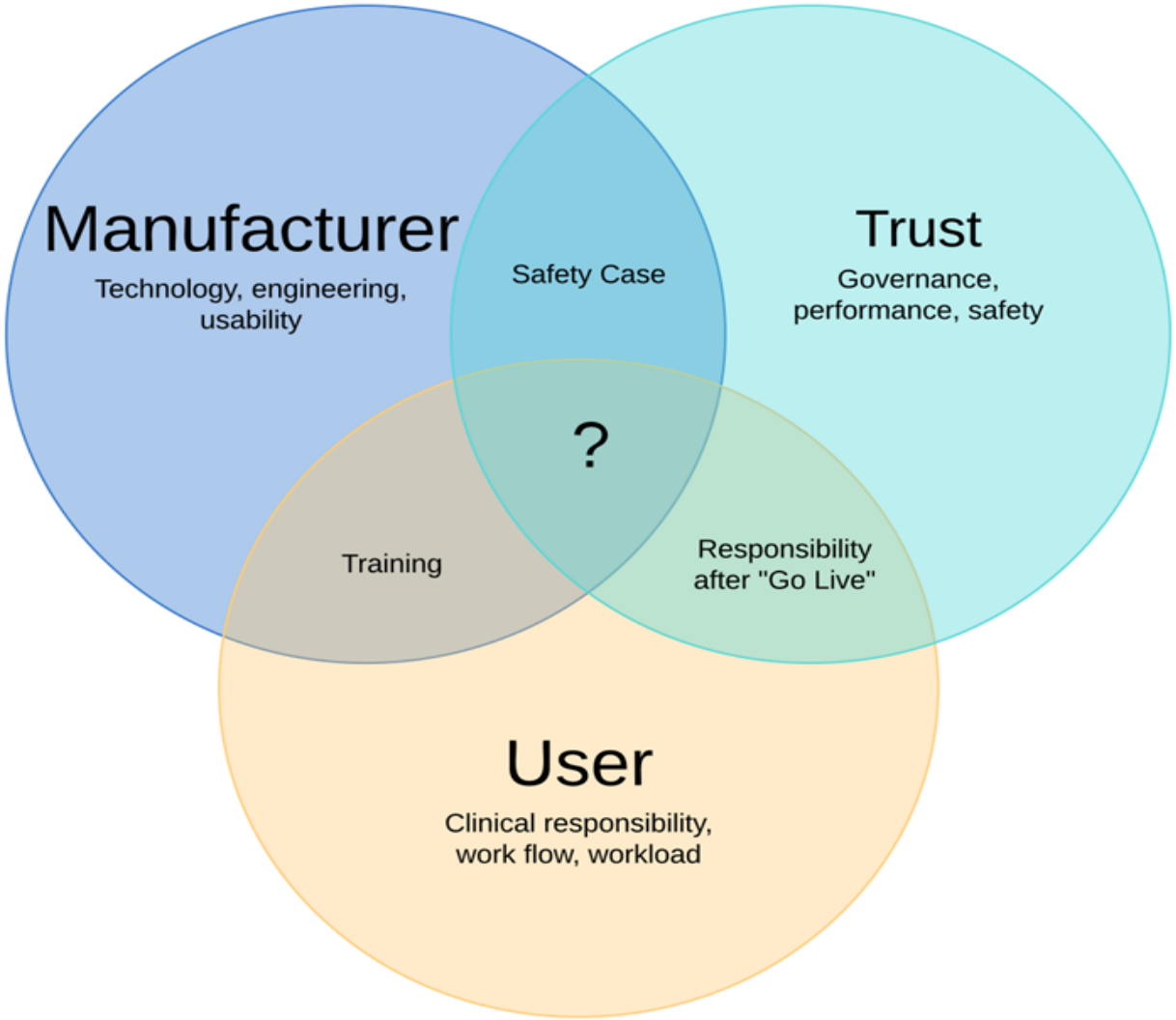

Open Standards

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- Standards for the development of safety cases that go beyond a description of the technical infrastructure needed for smart pump implementation
- Standards for the development of drug libraries – version control, assurance process
- Standards for sharing smart pump data in order to develop a robust evidence base

NHS X

Setting standards

- Developing, agreeing and mandating clear standards (for example, on user experience, open standards, information governance, and open source) for the use of technology in the NHS
- Making sure that NHS systems become interoperable and that the NHS can incorporate the latest innovations without breaking the technical plumbing underneath

Driving implementation

- Helping to improve clinical care by delivering agile, user-focused projects
- Developing digital care pathways and solving administrative challenges across the NHS
- Delivering APIs and documentation to empower developers and data analysts across the NHS and the health tech industry
- Driving digital and tech maturity in local NHS organisations

Summary and ‘Take-aways’

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- DERS can be a significant step within patient safety
- Creation of the drug library is not a simple task and risk needs to be system holistic
- A unified system safety case could deliver greater oversight to management of equipment through complete life cycle
- Having open standards could support faster wider learning

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Thank you for listening

Any QUESTIONS