



HEALTHCARE SAFETY  
INVESTIGATION BRANCH

# Investigation without blame

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Life  
Changing

Fatalities

Reputation



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# National Investigation

- 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 SystemOne 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



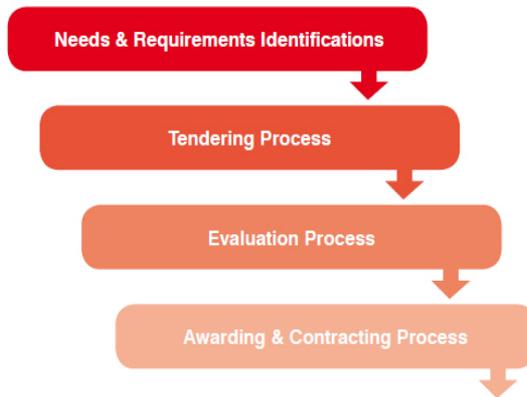
- 3 fentanyl overdose bolus incidents occurred in November 2018 across 3 different critical care areas within the same Trust
- Incidents were linked by the Trust to the introduction of smart pump technology – specifically when the “drug library went live”
- Fentanyl had been excluded from the drug library 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



**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...

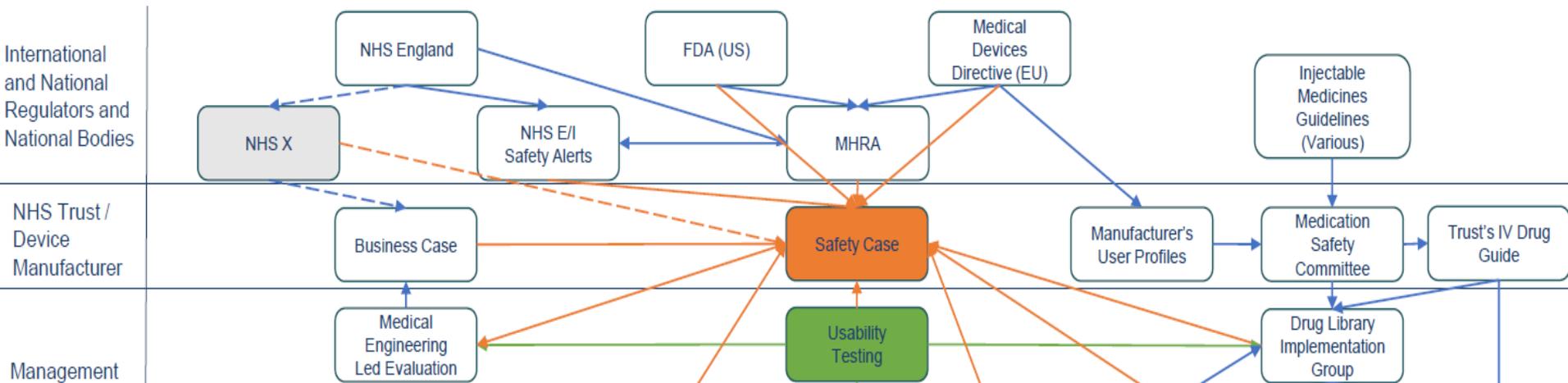
- **2016 (Q4)** – Funding obtained for drug library development

*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



# 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



NHS Digital Data and information

NHS Digital > ... > The Clinical Safety Team > This page

### Clinical Safety documentation

Documentation that supports Clinical Risk Management. They underpin the scope and requirement of the Clinical Safety team.

*Evidence:*

## Using safety cases in industry and healthcare

The Health Foundation  
Inspiring  
Improvement

A pragmatic review of the use of safety cases in safety-critical industries – lessons and prerequisites for their application in healthcare

December 2012

Identify Innovate Demonstrate Encourage

# Current Safety Case Guidance

## 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'*

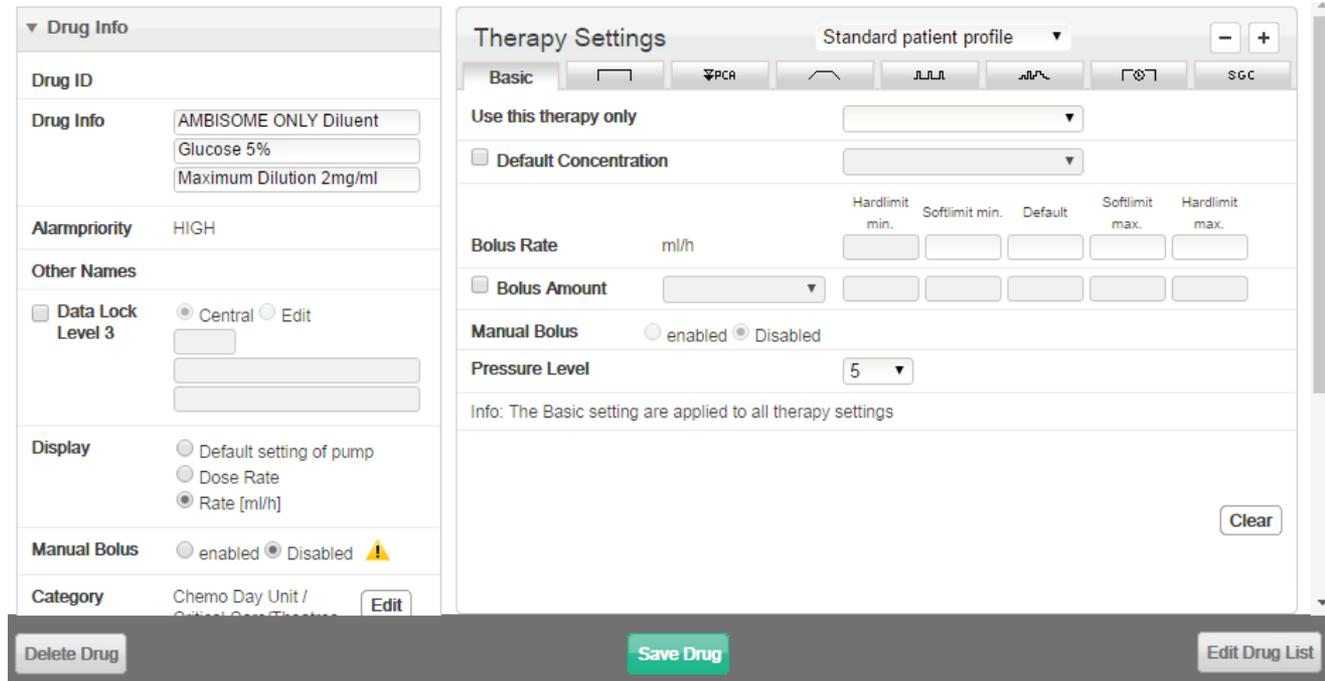
NHS Digital

NHS Digital Clinical Safety standards -

Compliance with DCB0129 and DCB0160 (previously known as SCCI0129 & SCCI0160)

# Secondary supportive software

- 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?



The screenshot displays two panels from a medical software interface. The left panel, titled 'Drug Info', contains the following fields and options:

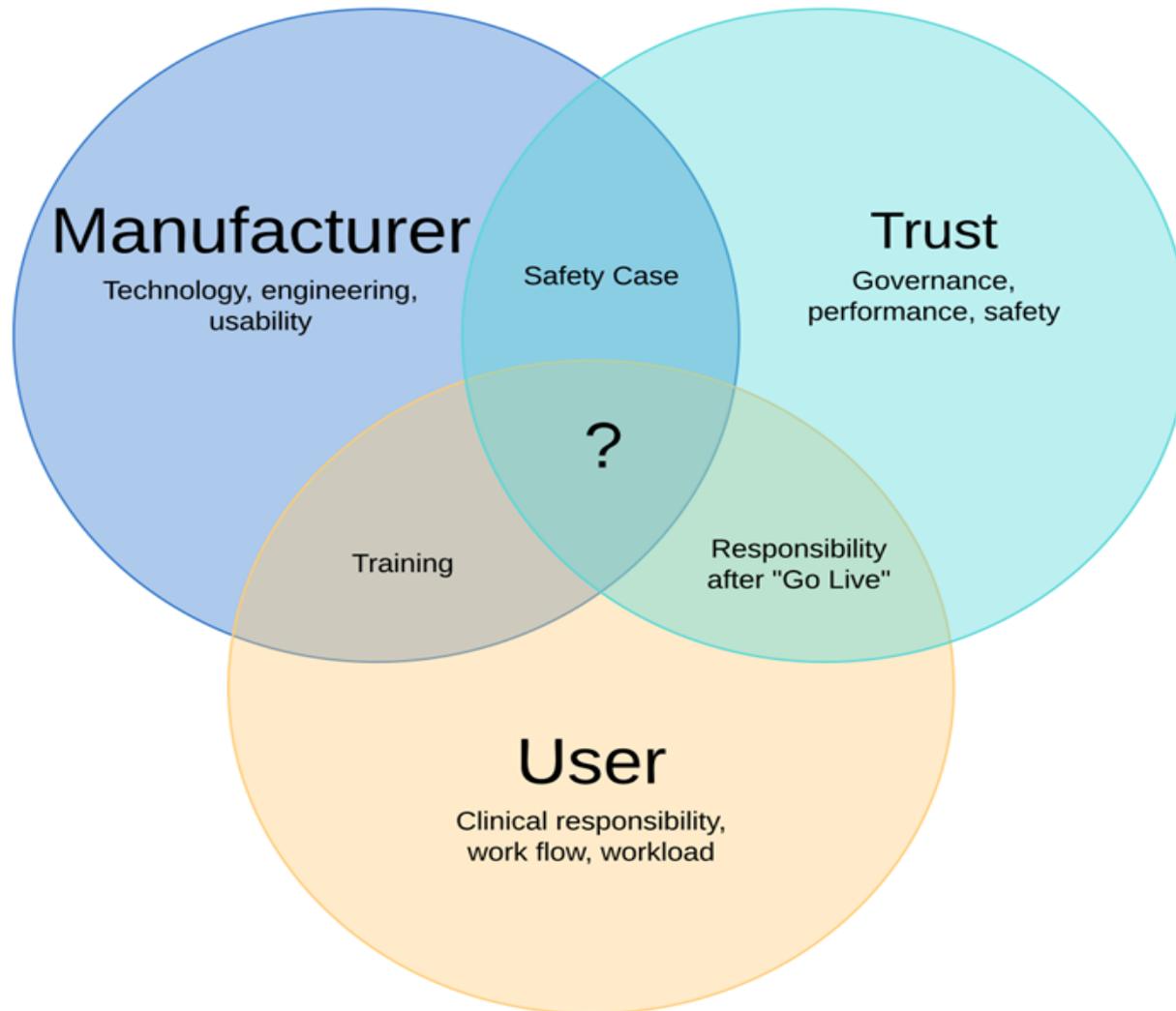
- Drug ID:** A text field containing 'AMBISOME ONLY Diluent'.
- Drug Info:** Two stacked text fields containing 'Glucose 5%' and 'Maximum Dilution 2mg/ml'.
- Alarmpriority:** A dropdown menu set to 'HIGH'.
- Other Names:** A section with a 'Data Lock Level 3' checkbox and radio buttons for 'Central' (selected) and 'Edit'.
- Display:** Radio buttons for 'Default setting of pump', 'Dose Rate', and 'Rate [ml/h]' (selected).
- Manual Bolus:** Radio buttons for 'enabled' and 'Disabled' (selected), with a warning icon.
- Category:** A dropdown menu with 'Chemo Day Unit / Critical Care/Therapy' selected and an 'Edit' button.

The right panel, titled 'Therapy Settings', is for a 'Standard patient profile' and includes:

- Basic:** A tabbed interface with various icons.
- Use this therapy only:** A dropdown menu.
- Default Concentration:** A checkbox and a dropdown menu.
- Bolus Rate:** A label 'ml/h' followed by input fields for 'Hardlimit min.', 'Softlimit min.', 'Default', 'Softlimit max.', and 'Hardlimit max.'.
- Bolus Amount:** A checkbox and a dropdown menu.
- Manual Bolus:** Radio buttons for 'enabled' and 'Disabled' (selected).
- Pressure Level:** A dropdown menu set to '5'.
- Info:** A text box stating 'The Basic setting are applied to all therapy settings'.
- Clear:** A button at the bottom right.

At the bottom of the interface, there are three buttons: 'Delete Drug', 'Save Drug' (highlighted in green), and 'Edit Drug List'.

# Ownership of Risk



# 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

## 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'



- 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**