Health Services Safety Investigations Body

Investigation report

Procurement, usability and adoption of ‘smart’ infusion pumps

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Medical devices, Communication and decision making

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Executive Summary

Infusion pumps are medical devices that are used when administering medication to patients. The latest generation of infusion pumps, commonly referred to as ‘smart’ pumps, are being used in many healthcare settings. The smart functionality aims to prevent overdoses or underdoses that could result in serious patient harm or death.

This investigation focused on understanding the challenges involved in introducing smart infusion pump technology within NHS hospitals. Although the aim of smart infusion pumps is to improve patient safety, the technology can introduce new risks. The investigation reviewed the safety risks involved in introducing the technology, leading to safety recommendations about how these risks need to be managed.

The purpose of the investigation was not to endorse the use of smart pump technology by evaluating whether medication errors can be reduced; the evidence base is currently insufficient to allow this type of evaluation to take place. Instead the investigation is about understanding the emerging risks and barriers to the safe introduction of the technology and how data, which may help to demonstrate effectiveness, needs to be shared across the healthcare system.

Although this investigation was about NHS trusts in England, the same implementation risks were found in the Republic of Ireland and the USA. The investigation worked with device manufacturers, regulators, national bodies and academic institutions to understand why these risks are systemic. A system-wide approach to the management of these risks was needed, as they cannot be appropriately managed locally.

The investigation identified that introducing smart pump technology required significant changes to existing medication prescribing and administration processes across NHS trusts.

Dose error reduction systems (DERS) aim to prevent overdoses or underdoses. This is achieved by imposing limits on the dose associated with a particular drug. DERS requires the use of drug libraries. A drug library allows for dose calculations based on the class of drug and any relevant programmed patient parameters such as weight, including the setting of dose limits to identify miscalculations or ‘use errors’. Such errors occur as a person uses the technology, but simply attributing the error to ‘the human’ often prevents an understanding of how the medication system can be designed to be safer. These drug libraries were predominantly developed locally so that they aligned with trusts’ medications guidance and local policies, which the investigation identified were often outdated or did not document variations in medication practice across different clinical areas within the same hospital.

The investigation identified that in England there is currently no agreed national drug library for use in NHS trusts. Additionally, there are no national guidelines or standards on how to implement drug libraries. Using smart pumps requires staff to be trained in the use of a drug library and DERS. This is a complex and often unfamiliar task for many staff.

The infrastructure needed to implement smart pump technology requires the use of software to upload the drug library to the smart pumps, download data logs associated with usage (including alerts where DERS has prevented an ‘error’), and monitor the status of each smart pump in the system (including which version of the drug library it is using). The investigation also identified that maintaining the IT infrastructure required specialist staff. Smart pumps need to be connected to a trust’s IT network. This can be achieved by using a hardwired connection (where the device is plugged into a port in the wall) or a wifi network. Both of these methods required specialist IT provision.

Findings

- NHS Digital has specifically developed standards to be ‘technology agnostic’ (that is, applicable to any type of technology), so it was felt that specifically identifying smart pumps being within the remit of these standards would be contrary to this intent.
- NHS Digital notes that the standards were updated in 2018 to bring medical devices in scope. The rationale for updating the standards was to manage scenarios where a medical device is either embedded in or supported by health IT.
- NHS Digital believes that the current standards are appropriate when implementing smart pump technology.
- It is outside the remit of NHS Digital to be responsible for ensuring manufacturers are trained in clinical risk management. However, NHS Digital does provide training in this area and pro-actively promotes its training.
- NHS Digital’s standard DCB0160 mandates that a clinical safety officer within NHS organisations must be knowledgeable in risk management and its application to clinical domains. Training provided by NHS Digital is a means to achieve this.
- Medical device regulation is complex and slow to legislate. Attempting to incorporate regulations for device log data sharing is not feasible in the short term.
- NHS Supply Chain’s essential specification approach provides an opportunity to guide procurement decisions by prioritising patient safety concerns.
- An essential specification details the requirements of the procurement. It is the basis of all offers and therefore the foundation for a contract. A specification becomes a primary contract management document.

HSIB makes the following safety recommendations

Safety recommendation R/2020/104:

It is recommended that NHS Supply Chain develops an agreed specification that defines an open standard format for the sharing of event log data, thus allowing dose error reduction systems (DERS) to be evaluated to establish patient safety benefits.

Safety recommendation R/2020/105:

It is recommended that the MEDUSA (UK Injectable Medicines Guide) advisory board, in conjunction with other relevant multi-professional organisations, develops validated national drug libraries for smart infusion pumps.

HSIB makes the following safety observations

Safety observation O/2020/081:

Organisations involved in the development and deployment of smart pumps must adhere to DCB0129 and DCB0160 respectively where health IT is utilised to support the configuration and/or operation of the smart pump.

Safety observation O/2020/082:

Organisations involved in the development and deployment of smart pumps must ensure that their personnel are knowledgeable in clinical risk management. NHS Digital provides a programme of training to support this.

Safety observation O/2020/083:

Examples are needed of where safety cases have been used in the NHS to manage safety proactively, so that their value can be communicated and better understood. The NHS should always show evidence of rigorously considering safety in all procurement, and safety cases are a standard and widely accepted way of doing this.

Safety observation O/2020/084:

A configuration control/management system for drug libraries should be specified within a smart pump safety case.

Safety observation O/2020/085:

There is a need to develop and evaluate ways of training clinicians and pharmacists on the use of safety-critical devices within a hospital to ensure that all staff that may operate the devices are suitably trained. Consideration should be given to mandatory-level medical device training being established at induction for all clinicians.

1 Background

1.1 An infusion pump is a medical device that delivers medication into a patient's body. Infusion pumps offer advantages over the manual administration of medication, including the ability to deliver fluids at programmed rates and intervals.

1.2 The latest generation of infusion pumps, commonly referred to as 'smart' pumps, are operated by a user, who programs the rate and duration of the infusion through a software interface. Smart infusion pumps are equipped with safety features, such as alarms or alerts that are intended to activate in the event of it detecting a problem.

1.3 Smart infusion pumps are in widespread use in clinical settings such as hospitals. The smart functionality aims to prevent overdoses or underdoses that could result in serious patient harm or death. This is achieved by programming limits on the dose associated with a particular medication/drug. The previous generation of infusion pumps had an unrestricted range of dosing possibilities. Throughout this report, smart infusion pumps are referred to as smart pumps for conciseness.

1.4 Smart pumps have an inbuilt dose error reduction system (DERS). This provides either a ‘soft limit’ warning, which allows the user to override the limit and continue administering, or a ‘hard limit’ warning, requiring the pump to be reprogrammed using acceptable values. DERS uses a drug library, which is displayed on the device’s screen and selecting a drug activates a pre-set dosing range associated with that particular drug.

1.5 Smart pumps have an inbuilt event log. This creates a detailed record of medications that have been given including the drug name, dose, volume administered, infusion rate and time. The event log also includes instances where the DERS system has prevented an overdose or has been overridden.

1.6 The next generation of ‘smarter’ smart pumps are interoperable with other clinical IT systems such as a patient’s electronic prescription/administration or electronic health record systems.

2 Scope of the investigation

2.1 This investigation has focused on understanding the challenges involved in introducing smart infusion pump technology within NHS hospitals. Although the aim of smart infusion pumps is to improve patient safety, the technology can be difficult to implement within hospitals and this can introduce new risks. The investigation has reviewed the safety risks involved in introducing the technology, which has led to safety recommendations about how these risks need to be managed.

2.2 The purpose of this investigation was not to endorse the use of smart pump technology by evaluating whether medication errors can be reduced; the evidence base is currently insufficient to allow this type of evaluation to take place. Instead the investigation is about understanding the emerging risks and barriers to the safe introduction of the technology and how data, which may help to demonstrate effectiveness, needs to be shared across the healthcare system.

3 Reference events

3.1 HSIB launched an investigation in May 2019 after being notified by an NHS trust (referred to in this report as ‘the Trust’) about three patient safety incidents that occurred in November 2018. The investigation used these incidents, referred to as reference events, to examine the emerging risks relating to the implementation of smart pumps.

3.2 The three incidents, all involving fentanyl (a powerful pain medication), occurred in three different critical care units. They were linked by the Trust to the introduction of the smart pump drug library.

3.3 A drug library allows for dose calculations based on the class of drug and any relevant programmed patient parameters such as weight, including the setting of dose limits to prevent unintentional miscalculations. • The three incidents involved the smart pump delivering more than the intended dose of fentanyl when using the drug library.

- All three overdoses occurred when a bolus dose of fentanyl was administered. Clinicians administer bolus doses of fentanyl to increase sedation (for example, if a patient becomes agitated) or for analgesia (pain control).
- The patients were not seriously harmed as the overdoses were identified swiftly.
- The incidents were reported via the Trust’s Datix incident reporting system.

3.4 HSIB suggested that these incidents should also be reported by the Trust to the Medicines and Healthcare products Regulatory Agency (MHRA) via the Yellow Card incident reporting scheme (Medicines and Healthcare products Regulatory Agency, n.d.). The MHRA enforces the regulations on medical devices in the UK and has investigatory and enforcement powers to ensure the safety and quality of such devices. The MHRA investigation concluded that the incidents were ‘use errors’, which implies that the design or configuration of the device may have made it harder to use the device safely. This term is carefully chosen to be different from ‘human error or user error’, which attributes blame to the healthcare professional who administered the drug. The MHRA works with manufacturers to reduce ‘use errors’. This often involves improving the usability of the device; if usability is lacking, the completion of user tasks may be slower and more error-prone. The manufacturer of the smart pump devices involved in the incidents found that the devices were incorrectly set up by the users, rather than being associated with a failure of the technical functionality of the smart pump.

3.5 The three incidents, summarised below, highlight that some drugs might have different concentrations. This means that when administering a drug, the concentration of the drug dissolved in a solution needs to be specified when programming a pump. This allows the dose to be calculated correctly. If the wrong concentration is specified, this results in a patient receiving the wrong dose of the drug (that is, the wrong volume (amount) of the solution, which

contains the drug, will be administered). It is critical that the pump is programmed with the appropriate drug concentration every time medication is administered if the drug concentration is not standardised.

3.6 The use of smart pumps allows different drugs to be selected from a set of information stored on the device, known as a drug library. This library is displayed on the device's screen and selecting a drug activates a preset dosing range associated with that particular drug. Dosing ranges aim to prevent overdoses or underdoses from being administered to a patient. However, in all three of these incidents, the smart pump did not prevent overdoses because dosage ranges are dependent on a correctly specified drug concentration.

Incident 1: A patient was receiving a fentanyl infusion at a dose of 2 millilitres per hour. A clinical fellow examined the patient and during the examination the patient appeared uncomfortable and was trying to pull on a tube. The clinical fellow attempted to deliver a 25 microgram (mcg) bolus dose of fentanyl by selecting that option using the smart pump's drug library. Five minutes after the bolus dose had been given, the clinical fellow was informed by nursing staff that the entire syringe of fentanyl had been administered. Approximately 600mcg of the drug had been administered instead of the intended 25mcg. The wrong drug concentration had been programmed when the fentanyl syringe was placed in the pump.

Incident 2: A fentanyl syringe was placed in the pump and the pump was turned off during intubation of the patient (the insertion of a tube into the patient's airway via their mouth). After the intubation, the pump was turned on and the infusion started. A bolus dose was administered by one of the doctors prior to an X-ray taking place. The pump alarm sounded, and when a nurse checked the syringe it was found to be empty. The doctor had intended to administer a 20mcg bolus, but the whole contents of the syringe was administered. The wrong drug concentration had been set.

Incident 3: A patient was coughing on the endotracheal tube (the tube used in intubation). A doctor proceeded to give an intended 50mcg bolus of fentanyl to ensure the patient was comfortable. A few minutes later the pump alarm sounded to signify that the bolus had been given. However, it was noted that the entire syringe was empty. The wrong drug concentration had been set.

Findings from the Trust's investigation: drug library development issues

3.7 The Trust believed that implementing a drug library increased the potential to intercept errors such as unintentional miscalculations.

- Drug libraries can be customised for different clinical specialities (such as critical care or paediatrics), which may use different types of drugs and doses. Although there is a need for different drug libraries, the introduction of a drug library provides an opportunity to

standardise the way many drugs are given. This opportunity for standardisation includes deciding on fixed drug concentrations, but also can encompass other aspects of medication administration.

    - There was a lack of standardisation of the concentration of fentanyl used by the Trust across the three critical care area units. This introduces a risk that a pump user may use a drug library without realising that the drug concentration is not standardised, and this may result in an overdose or underdose if concentration values entered by the user have been incorrectly specified.

- Initially, the trust pharmacist who was responsible for developing the drug library standardised the concentration of fentanyl across all three critical care units (which were later involved in the overdose incidents). However, when user testing was carried out, two senior nurses identified that the standard concentration used at one of the critical care units differed from that in others, and a decision was made not to standardise the concentration of fentanyl.
- The smart pump required the concentration of fentanyl to be entered before using the drug library since there was no standardised concentration. This changed the way that the smart pump was usually programmed and caused confusion. • It was claimed that the manufacturer warned the Trust about the risk of using drug libraries without a standardised concentration being agreed. However, this was not documented. The risk was considered by the Trust during the drug library development, but when user testing was carried out and the drug concentration standardisation was rejected, the risk was uncontrolled when the system went live.

Findings from the Trust's investigation: assumptions that were not challenged

- There was a manufacturer's assumption that "doctors prescribe, and nurses administer medications" that was not challenged. As such, doctors were not referred to in standard operating procedures and there was no provision of scenario-based training on the new smart pumps.
- There was a manufacturer's assumption that "training the nurses how to use the device" was an effective implementation solution that would address the patient safety risks introduced when switching over from the old to the new pumps. There seems to be a lack of understanding of the need to rigorously assess the functionality of smart pumps and how that might differ from what is currently being used and change working practice.
- It is straightforward to attribute safety issues to no training or ineffective training. However, training is only likely to be effective alongside an understanding of the risks that need to be managed using a variety of other risk controls (for example, changes in processes and procedures).

- Once a drug library update was produced to standardise the use of fentanyl, there were delays in distributing the updated drug library to the smart pumps. It was identified that there were issues with many of the IT network ports, which are needed to ensure updates to the drug library can be sent out to every device. This highlights a mismatch between the IT infrastructure needed and the one that was in place.

4 Investigation method

4.1 The investigation was undertaken between May 2019 and September 2020.

Investigative approach

4.2 The healthcare system was considered in its entirety to identify the factors that contributed to the patient safety incidents. This led to a focus on understanding the need for a proactive approach to risk management to improve an organisation's ability to manage both existing and emerging risks (Rasmussen and Svedung, 2000).

Investigation team

4.3 The HSIB investigation team was multidisciplinary and had expertise in safety science and medical device design, systems engineering and risk management. The team was supported by experts who specialised in medical device regulation, safety cases and clinical practice associated with the use of smart pumps (including pharmacists, nurses, and doctors).

Investigating the reference events

4.4 The reference event investigation involved five visits to the Trust to conduct semi-structured interviews with staff involved in the implementation and governance of the smart pump technology and users of the technology (see table 1). Staff responded positively to the investigation and provided investigators with the full range of documentation requested.

Table 1 Trust staff interviewed during the investigation

Job role	**Number of staff**
Patient safety and governance	3
Pharmacy and drug library development	3
Implementation and medical equipment management including IT	2
Smart pump users	2

National investigation

4.5 Following investigation of the reference events, HSIB evaluated the potential for national learning. The following safety risks were identified:

- The lack of an evidence base to support the use of smart pump technology as a patient safety intervention.
- The lack of a national-level infrastructure for drug library development required for the implementation of smart pump technology.
- The lack of capacity for proactive risk management associated with medical devices, and the local- and national-level infrastructure needed to support this.

This included consideration of roles including the chief clinical information officer (CCIO), clinical safety officer (CSO), medicines safety officer (MSO) and medical devices safety officer (MDSO).

4.6 The identification of these safety risks led to a decision to broaden the investigation and identify opportunities to collect further data.

Table 2 Participants in the national investigation

Organisations	**Focus of investigation**
Device manufacturers	The investigation discussed the process of procurement, risk management and implementation with two manufacturers.
Smart pump implementation sites across the NHS in England	The investigation interviewed staff at three other NHS trusts where smart pumps had been implemented or were being implemented.
Academic departments	The investigation discussed the use of smart pumps and safety risks with two UKbased academic departments, a department in the USA, and a department in the Republic of Ireland.

Stakeholder engagement

4.7 Stakeholders across the healthcare system were contacted and interviewed to establish their perspective:

- National Association of Medical Device Educators and Trainers
- MEDUSA (UK Injectable Medicine Guide)
- Specialist Pharmacy Service • Safe Anaesthesia Liaison Group
- British National Formulary
- NHS Supply Chain
- NHS Digital

- Medicines and Healthcare products Regulatory Agency (MHRA)
- NHS England and NHS Improvement.

Evidence gathering

4.8 The investigation gathered and reviewed multiple sources of evidence, including:

- trust policies and procedures including procurement documentation and implementation documents
- manufacturer policies and procedures including procurement documentation and implementation documents drug libraries and technical device/IT specifications
- the findings of trust-level internal incident investigation reports
- the findings of MHRA's investigation reports
- relevant incidents reported using the National Reporting and Learning System (NRLS)
- national guidelines and standards
- peer-reviewed literature relevant to the identified safety risks.

4.9 The evidence gathering process adopted an iterative approach; as further information was gained, additional data sources were identified. Semi-structured interview plans were developed to gather information on safety risks, and a thematic analysis was performed across all the interview data gathered.

Analysis

4.10 The analysis process had the following aims:

- to generate findings by reflecting on the evidence gathered and discussing emerging findings with a multidisciplinary team of experts
- to develop a comprehensive understanding of the healthcare system so that safety recommendations could be identified, and their potential impact on the system could be considered.

4.11 These aims were achieved through the application of the following methods:

- AcciMap (Rasmussen, 1997), which was used to develop visualisations of the system. AcciMap allows consideration of factors across the overall system of activity, including regulatory levels, and factors can be linked both within and across different levels.
- The 'ten key considerations' implementation framework (Cresswell et al., 2013), which was used to describe the process of introducing new technology within hospitals.

4.12 These methods were used to consider local and national practices, and practices evidenced in the literature. Verification of findings

4.13 The findings were shared with the healthcare organisations involved in the reference events and with key stakeholders within the healthcare system. This enabled: checking for factual accuracy and overall sense-checking

- stakeholder groups to contribute to the verification and design of the improvement safety recommendations and observations.

Report structure

4.14 This investigation report is structured using the ‘ten key considerations’ implementation framework (Cresswell et al., 2013), which is used here to describe the process of introducing smart pumps within hospitals (see figure 1). This framework was chosen because it reflects the experiences of healthcare researchers who have evaluated large-scale technology interventions. It is often assumed that new technology will help with the quality, safety and efficiency of care. However new technology may prove frustrating for staff caring for patients as it may not fit their usual workflows, and the anticipated benefits may take time to materialise.

4.15 The ten key considerations framework is used by this investigation to describe the safety risks that need to be managed at each stage of the implementation journey within a hospital. The aim is to specify the infrastructure needed to manage emerging risks and barriers to the safe introduction of the technology. Safety recommendations and safety observations have been made where the prerequisite infrastructure was found by the investigation to be inadequate at a national level.

Fig 1 The ten key considerations implementation framework

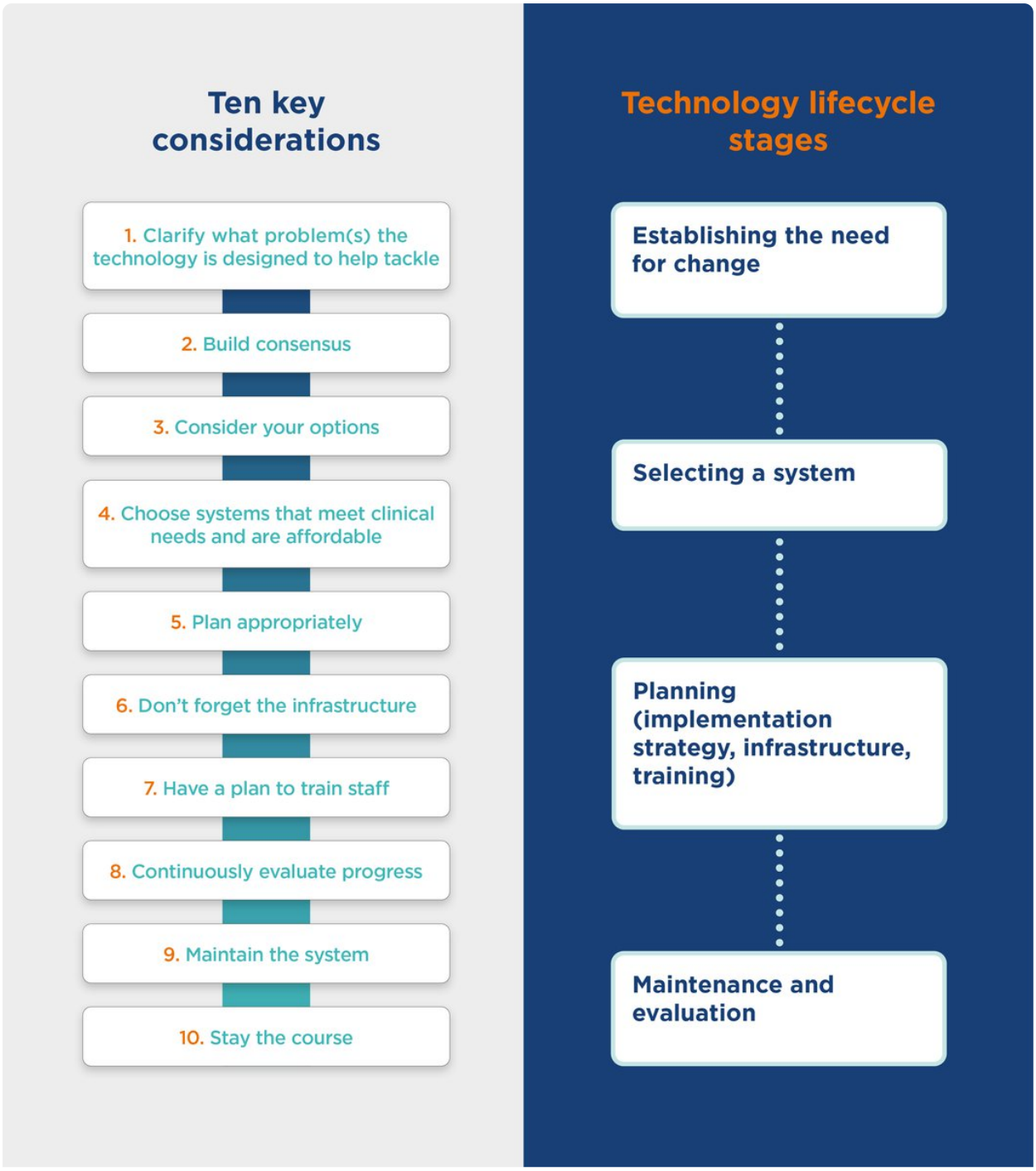

Fig 1 The ten key considerations implementation framework

1. Clarify what problem(s) the technology is designed to help tackle
2. Build consensus
3. Consider your options
4. Choose systems that meet clinical needs and are affordable
5. Plan appropriately

6. Don’t forget the infrastructure
7. Have a plan to train staff
8. Continuously evaluate progress
9. Maintain the system
10. Stay the course

Technology lifecycle stages

Establishing the need for change
Selecting a system
Planning (implementation strategy, infrastructure, training)
Maintenance and evaluation

5 Analysis of findings against the ten key considerations framework

1 Clarify what problems the technology is designed to help tackle

5.1 When introducing new technology within a hospital, it is important to understand what problems the technology has been designed to tackle and why change is needed. What makes smart pumps smarter and safer than the previous generation of devices?

- Smart pumps have an inbuilt dose error reduction system (DERS). This aims to reduce medication errors that could result in serious patient harm by preventing unintentional overdoses and underdoses. The previous generation of pumps had an unrestricted range of programming possibilities. Smart pumps can provide either a ‘soft limit’ warning, which allows the user to override the limit and continue administering, or a ‘hard limit’ warning, requiring the pump to be reprogrammed using acceptable values.
    - Although many newly procured pumps have inbuilt DERS functionality, smart pumps can be used without the DERS functionality being enabled.
- Smart pumps have an inbuilt event log. This creates a detailed record of medications that have been given including the drug name, dose, volume administered, infusion rate and time. The event log also includes instances where the DERS system has prevented an overdose or has been overridden. DERS alerts provide opportunities for learning and

improvement if medication incidents are analysed and understood, leading to changes in infusion practice (Ohashi et al., 2014).

    - Although event logs are potentially a useful data source for improving patient safety, the investigation found that they are often not routinely inspected unless patient harm has occurred. Deciding not to analyse this data as part of ongoing quality improvement is a missed opportunity. In other safety-critical industries, analysing log data that could potentially improve practice is often mandatory.

- The next generation of 'smarter' smart pumps are interoperable – that is, they can interact with other clinical IT systems such as a patient's electronic prescription/administration chart and electronic health record. These interoperable systems can capture a wider range of possible medication errors such as the wrong drug being administered. Within the NHS, hospitals are now beginning to procure smart pump systems that provide interoperability with clinical IT systems. There are hospitals in the USA that use these interoperable systems to deliver medication autonomously, based on an electronic prescription, and NHS trusts may be looking to procure this technology.

How does an NHS business case justify the need for new medical devices?

5.2 The investigation reviewed business cases that were used as part of the smart pump procurement process in four NHS trusts, and interviews were conducted with members of staff involved in the procurement process. These business cases did not focus on the problems that smart pumps have been designed to tackle, as described above. Instead the focus was on both the financial cost of maintaining ageing pumps that needed replacing, and a drive to standardise equipment.

- The investigation noted that most decisions to replace ageing pumps were based on obsolescence management. Obsolescence occurs when a component or piece of equipment is no longer available, it has served its purpose, or the cost of maintenance outweighs the cost of replacement. Obsolescence may also include scenarios in which a replacement has become available that, overall, has more advantages compared to the disadvantages incurred by maintaining or repairing the original.
- There was an understanding that standardisation takes advantage of economies of scale and potentially reduces the requirement to train staff on the use of different models of smart pump. Standardisation was also thought to facilitate a way of working, where the same pump remains connected to the patient, when transfers between different clinical areas occur in hospital.
- In 2015 the Medicines and Healthcare products Regulatory Agency (MHRA) produced a guide, 'Managing medical devices', which emphasised that procurement decision making should be informed by safety performance and reliability assessments (Medicines and

Healthcare products Regulatory Agency, 2015). None of the four NHS trusts involved in this investigation mentioned that they used this guidance, and central aspects such as ‘required systems of management’ were not referred to within the business cases reviewed.

5.3 Smart functionality, including DERS, event logs and interoperability with electronic prescription charts, were secondary considerations or were not included as part of the business cases reviewed. This is problematic because in the NHS, the business case is the central document where ‘overarching risks’ associated with procurement are identified. The risks most prominently considered included not achieving financial savings and encountering delays in implementation due to possible IT networking issues. Non-financial criteria such as clinical effectiveness, equipment compatibility and operational considerations were not the focus. Moreover, when included, nonfinancial criteria typically involved echoing device manufacturer patient safety claims (for example, medical errors will be reduced by DERS), which often have not been verified independently.

5.4 The investigation found that the procurement of smart pump technology was not primarily driven by the need for smart functionality. Therefore, smart functionality was considered within business cases to be an ‘added benefit’ and not subjected to a risk assessment or requirements analysis.

5.5 When no formal attempt is made to “clarify what problems the technology is designed to help tackle”, or establish why change is needed, associated risks are rarely anticipated. Likewise, although benefits may have been considered by individual advocates, who might have believed smart pumps can reduce medication errors, these were not communicated within business cases with supporting evidence.

1 Build consensus

5.6 Once the problems that the technology has been designed to help tackle have been understood, the next stage involves consensus building.

5.7 A lack of consensus was recognised as a barrier to effective implementation by all the NHS staff who were interviewed. The investigation found that it is not possible to implement smart pump technology effectively without first building consensus that change is needed. This involves sharing perceived benefits with staff involved in medication prescribing and administration (nurses, doctors and pharmacists). The technology fundamentally changes the way staff work. Staff need to understand why the change is needed. This is a challenging task to achieve across a healthcare organisation.

5.8 The investigation found that there was ambiguity associated with the remits of staff roles that could have driven consensus building. It was not clear if chief clinical information officers (CCIO) and clinical safety officers (CSO) were substantively involved at any stage. The medical devices safety officer (MDSO) role was underspecified, and not all trusts that took part in the investigation had an active MDSO.

5.9 Medicines safety officers (MSO) were central to the oversight of the implementation of smart pumps and were active on or led the implementation groups. They were responsible for co-ordinating consensus-building activities. Figure 2 highlights some of the complexities associated with resolving discrepancies within local practice so that smart pumps can be implemented. Without consensus that change is needed, the effort needed to reconcile practice across a hospital site places a burden on the trust's medication committee to do all the necessary work.

5.10 A trust's medication committee must be able to reconcile any discrepancies between national guidelines on injectable medicines, the manufacturer's suggested implementation examples, and the trust's existing prescribing and administration guidelines. This requires at least one individual within each clinical area to be 'fully bought-in to the idea' and, critically, have enough time and influence over their colleagues to share 'the vision' (these individuals are sometimes known as 'change champions'). Without this 'buy-in' it will not be possible to resolve discrepancies, and some clinical areas will be poorly represented and have underspecified requirements.

Fig 2 Consensus building

5.11 The investigation found that there were groups of people across different clinical areas who did not share the view that smart pump technology was worth implementing or thought it was 'too complex' to set up. This is a fundamental issue because smart pumps should not be perceived as a 'plug and play' technology (that is, technology that can be used without any further set-up or maintenance by the user). DERS cannot be simply introduced as part of existing systems for medication administration (Franklin, 2017). Although smart pumps are considered a patient safety intervention, the functionality of DERS is dependent on the use of a drug library.

5.12 Drug libraries need to be developed and approved for different clinical areas. The introduction of a drug library provides an opportunity to consider more efficient and safer ways of working across a trust (for example, standardised medication concentrations). The drug library, and the way that it has been implemented, is considered the responsibility of the trust, not the manufacturer. Effective implementation is currently dependent on the trust taking full responsibility for the configuration and use of the technology.

3 Consider your options

5.13 Once there is consensus that a new technology is needed, the next stage is to select specific models of devices and associated software/hardware that would best meet requirements.

5.14 The World Health Organization (WHO) has produced guidance on the use of tools to support a ‘health technology assessment of medical devices’ (World Health Organization, 2011). Figure 3 outlines the WHO’s process for assessment when deciding to introduce new technology into a healthcare system. Importantly, the WHO guidance sets out the remit of regulation and limits this to ‘technical performance’ and ‘efficacy’. This is associated with the performance of the device as engineered with regards to operating tolerances. For example, a smart pump should be engineered to deliver the programmed amount of medication. The certification and qualification of smart pumps is predominately associated with the ability to deliver the drug accurately as specified by the device user. The investigation did not identify issues associated with the ‘technical performance’ of smart pump devices.

5.15 Errors that were investigated were ‘use errors’ associated with how the pumps were programmed when drug libraries and DERS were in operation. Attributing the error to ‘the human’ prevents an understanding of how the medication system in its entirety can be designed to be safer.

5.16 Questions such as ‘Should the technology be implemented in this setting?’ and ‘How should the technology be implemented?’ require a health technology assessment. The purpose of this is to inform technology-related policymaking in healthcare, and thus improve the uptake of ‘cost-effective’ new technologies and prevent the uptake of technologies that are of doubtful value for the health system.

Fig 3 Health technology assessment (World Health Organization, 2011)

Health technology assessment appraisal in the NHS

5.17 The National Institute for Health and Care Excellence (NICE) provides guidance to the NHS in England on the clinical and cost effectiveness of selected new and established technologies (National Institute for Health and Care Excellence, 2018). NICE carries out appraisals of health technologies at the request of the Department of Health and Social Care. There has not been an appraisal of the smart functionality associated with smart pumps.

5.18 Questions such as ‘Should the technology be implemented in this setting?’ and ‘How should the technology be implemented?’ become part of the procurement process rather than being subjected to a technology-specific risk assessment. Smart pumps are an ‘off-the-shelf’ (rather than a custom-made) medical device but should not be considered as a standardised solution. The technology cannot be integrated within existing medication practice

without significant changes to how medication is prescribed and administered. When selecting smart pump devices, it is important to consider how this is likely to impact on practice, however, this rarely drives the procurement process.

5.19 Describing the legislation that requires NHS bodies to put highvalue contracts ‘out to tender’ and understanding the implications that this has on the writing of business cases is beyond the scope of this investigation. Instead, this investigation considers only the ‘users and use’ elements of procurement.

5.20 The investigation was informed by NHS trusts that when choosing between manufacturers of smart pumps, an evaluation is always performed and documented if it is a high-value contract. The investigation found that this evaluation involved obtaining the expert opinions of staff. It was considered important to allow staff to test and compare the functionality of different devices. Often the testing involved the use of evaluation frameworks that were designed to capture usability requirements. For example, it was important to consider how many characters could be displayed on the device display, how values were entered, how the giving sets (IV tubing) were loaded into the device, battery life, what the device displayed when an infusion had been started and how ‘intuitive’ the user interface was to ‘navigate and use’.

5.21 The investigation found that trusts did not perform a detailed comparison of the smart features across different devices. Instead, the evaluation criteria considered the ‘non-smart’ functionality of the device. It did not include aspects such as: how DERS prevents overdoses and how DERS changes the way that devices were programmed (for example, how was DERS overridden and associated implications); how the drug library was created/updated and uploaded to the device; how event logs were downloaded from the device and how logs were analysed to understand when drugs were not administered properly.

5.22 There is currently no formal means of evaluating device functionality, which is needed to inform the identification of implementation risks. Having reviewed plans across four trusts, the investigation found that there was no systematic consideration of the risk management measures needed when implementing smart pump technology.

Medical device regulation and the regulation of healthcare services

5.23 Within the UK, medical devices need to comply with the requirements set out in The Medical Device Regulations 2002 (legislation.gov.uk, 2002). This is a regulatory framework and manufacturers must provide evidence that medical devices such as smart pumps comply. The essential requirements within the regulations include installation, use and training. The requirements describe what manufacturers must do to support their devices being implemented safely. The MHRA enforces the regulations on medical devices in the UK and has investigatory and enforcement powers to ensure their safety and quality.

5.24 The purpose of the medical device regulations is to regulate devices and manufacturers of devices. The regulation of the users of devices and how they use them is considered to be within the remit of the Care Quality Commission (CQC). The CQC has the role of regulating healthcare services and does require that trusts consider risks in how the healthcare service is run. Within the domain of health IT and medical devices, this is attempted by ensuring that trusts have people in assigned roles such as chief clinical information officer (CCIO), clinical safety officer (CSO), medicines safety officer (MSO) and medical devices safety officer (MDSO). With the exception of the MSO role, the investigation did not find that trusts' governance structures facilitated a proactive risk management approach.

5.25 The burden of implementing the technology safely appears to be the responsibility of individuals and working groups within trusts. They have to 'work it out for themselves'. This suggests the need for the use of tools and standards to support a more collaborative risk management approach. This is discussed within the next section of this report.

4 Choose systems that meet clinical need and are affordable

5.26 Once smart pumps have undergone a usability evaluation, a way of proactively identifying and managing risks that may emerge during clinical practice is needed. The identification of risks should involve a specification of the way that the devices will be configured and used (across different clinical areas), facilitating an assessment of whether organisational and clinical needs will be met. Patient safety should be the central consideration.

5.27 The investigation found that risks emerged after 'going live' and that NHS trusts were not able to anticipate some of these risks. As such, serious patient safety incidents were harder to avoid.

5.28 Choosing a system must involve more than just selecting a model of smart pump to purchase. A safety management system is needed when implementing and monitoring the use of smart pump technology. This is a systematic approach to managing safety, including the necessary organisational structures, accountabilities, policies and procedures. Several custom-made 'implementation planning' documents were reviewed by the investigation. These attempts, although well-intended, were not properly informed by risk management practice.

5.29 The NHS has developed clinical risk management standards. These standards aim to promote and ensure the effective application of risk management practice by both manufacturers and NHS organisations. The standards set out for manufacturers in DCB0129 (NHS Digital, 2018a), and for NHS organisations in DCB0160 (NHS Digital, 2018b), are issued by NHS Digital and compliance is mandatory under the Health and Social Care Act (legislation.gov.uk, 2012). These standards only relate to health IT systems. Examples of such systems include electronic patient record systems and electronic prescribing and administration systems.

5.30 Although smart pumps are classified as a medical device, they should also be considered within the remit of health IT standards. This is because smart pumps cannot offer smart functionality without the use of health IT components that can be considered part of a health IT system. The investigation found that both manufacturers and NHS organisations were operating on the basis that clinical risk management standards do not apply when implementing smart pumps.

Smart pumps require clinical IT systems for smart functionality

5.31 Smart pump technology requires the use of an IT system to update the drug library and download data logs associated with device usage. The drug library needs to be updated on a regular basis and usage data should be downloaded as part of regular audits, or whenever DERS has prevented a drug administration.

- An IT system is needed to store, organise, and modify drug libraries for different clinical areas within a hospital trust. Although patient data is not involved here, inaccurate drug library data can lead to serious patient safety incidents. Governance around the drug libraries for different clinical specialities is needed as updated versions replace previous versions and archiving is needed to investigate medication incidents.
- An IT system is needed to store, organise, and analyse smart pump usage data for different clinical areas within a hospital trust. This usage data can be linked to the care of a specific patient or cohort of patients. This is within the remit of clinical IT system standards.
- The next generation of ‘smarter’ smart pumps can record administered medication on a patient’s electronic prescription/ administration chart. This is within the remit of clinical IT system standards.

5.32 The investigation found that the implementation of smart pump functionality would benefit from the use of risk management practices, as implementation requirements are complex, and similar to the introduction of a new IT system. DCB0129 and DCB0160 are clinical risk standards that could provide a suitable framework, although this would need to be evaluated on an ongoing basis.

- The aim of risk management is to determine whether or not a system is safe to ‘go live’, meaning that risks that may lead to patient harm have been documented and processes have been developed to manage/mitigate these risks.
- DCB0129 mandates that the manufacturer conducts a risk assessment based on documented assumptions that have been made about clinical use.
- DCB0160 mandates that the NHS organisation conducts a further risk assessment, based on the manufacturer’s risk assessment, and documents additional risks associated with the local customisation needed for the system to ‘go live’.

- Both standards also require ongoing clinical risk management activities to be defined so that processes can be revised and documented in response to newly identified risks after the system ‘goes live’.

5.33 As part of DCB0160, every NHS trust is required to nominate a clinical safety officer (CSO) to oversee the application of clinical risk standards. This role involves the development of risk assessment and management processes and will need to coordinate responsibilities with a medication safety officer (MSO).

- A risk assessment should document outcomes for patients, staff and the organisation if controls to minimise identified safety risks are not implemented or fail.
- Risk management activities need to continue when the system is live and should be used to inform the future procurement of smart pumps and interoperable technologies.
- All these required activities can be achieved by developing and maintaining a safety case for smart pumps (see the next section on safety cases). A safety case is mandated by DCB0129 and DCB0160.

New risk management practices for smart pumps

5.34 The investigation identified that the implementation of smart pump functionality was not currently being guided by appropriate risk management practices. These issues were discussed with NHS Digital, the organisation responsible for clinical IT standards.

5.35 HSIB identified the following findings:

• NHS Digital has specifically developed standards to be technology agnostic (that is, applicable to any type of technology) so it was felt that to specifically identify smart pumps as being within the remit of these standards would be contrary to this intent.

• NHS Digital notes that the standards were updated in 2018 to bring medical devices in scope. The rationale for updating the standards was to manage scenarios where a medical device is either embedded in or supported by health IT.

• NHS Digital believes that the current standards are appropriate when implementing smart pump technology.

• Ensuring manufacturers are trained in risk management practices is outside the remit of NHS Digital. However, NHS Digital does provide training in this area and proactively promotes this training.

• DCB0160 mandates that a clinical safety officer (CSO) within NHS organisations must be knowledgeable in risk management and its application to clinical domains. Training provided by NHS Digital is a means to achieve this.

HSIB makes the following safety observations

Safety observation O/2020/081:

Organisations involved in the development and deployment of smart pumps must adhere to DCB0129 and DCB0160 respectively where health IT is utilised to support the configuration and/or operation of the smart pump.

Safety observation O/2020/082:

Organisations involved in the development and deployment of smart pumps must ensure that their personnel are knowledgeable in clinical risk management. NHS Digital provides a programme of training to support this.

Proactive safety management in the NHS: safety cases and the patient safety syllabus

5.36 The Health Foundation (2012) defines a safety case as a ‘structured argument, supported by a body of evidence, that provides a compelling, comprehensible and valid case that a system is acceptably safe for a given application in a given context’.

5.37 In other industries, safety cases are successfully used to demonstrate that risks to systems have been both identified and addressed (The Health Foundation, 2012). Safety cases can provide a means of promoting structured thinking about risk that facilitates a consensus between managers, healthcare staff and device manufacturers. The evidence gathered to support the safety case is used to demonstrate that risks within the system have been identified and can be managed by the processes that have been designed to ensure a safe implementation.

5.38 The investigation found that safety cases were not being used by NHS trusts when procuring and implementing smart pump technology. A safety case for smart pumps can demonstrate how safety can be managed proactively, rather than reactively (fixing problems after an incident has happened).

5.39 The first NHS England and NHS Improvement Patient Safety Strategy (NHS England and NHS Improvement, 2019) was launched at the Patient Safety Congress in July 2019. The Academy of Medical Royal Colleges has worked with colleagues from the University of Warwick

to develop the new National Patient Safety Syllabus (Academy of Medical Royal Colleges, 2020) which was included in the strategy as the basis for education and training throughout the NHS. The syllabus emphasises a proactive approach to identifying risks. Within the syllabus it is proposed that the principles of safety cases need to be part of ‘a step change in thinking about patient safety which will lead to significant gains as it reaches a critical mass of trained practitioners’.

5.40 A patient safety syllabus that includes proactive risk management and safety cases aims to educate and train NHS staff in these concepts. It will also be important to demonstrate the efficacy of proactive risk management by developing a range of examples and case studies. At this stage, it remains unclear which organisation will be responsible for developing the curriculum and learning materials that will be associated with the patient safety syllabus.

HSIB makes the following safety observation

Safety observation O/2020/083:

Examples are needed of where safety cases have been used in the NHS to manage safety proactively, so that their value can be communicated and better understood. The NHS should always show evidence of rigorously considering safety in all procurement, and safety cases are a standard and widely accepted way of doing this.

5. Plan appropriately

5.41 Implementation plans need to be tailored to organisational circumstances. In the NHS, smart pump implementation has involved a mixture of ‘partial’, ‘phased’ and ‘big-bang’ approaches. The investigation was told that some hospitals have decided only to ‘partially’ implement smart pump technology, in areas where pumps are needed the most and where high-risk medication is frequently administered (such as in critical care). In this scenario procurement and implementation is often driven locally by a small number of clinicians who maintain oversight. ‘Phased’ approaches often start with areas that are specialised (such as paediatrics) before planning to implement more widely. The ‘big-bang’ approach (when a new system goes live across an organisation at the same time) is the most challenging because it requires a consensus agreement on the elements of the implementation that will be standardised. Other elements will vary depending on local requirements. Irrespective what type of implementation is planned, NHS trusts cannot implement the technology without the support of the manufacturer. This is a recognised approach but needs to be appropriately managed and risks to be identified.

5.42 Figure 4 illustrates who is currently responsible for the key aspects involved in implementing smart pumps. The manufacturer is responsible for providing medical devices that conform to engineering and usability requirements, as specified by the relevant medical device standards. For smart pumps, the remit of manufacturer responsibility typically also extends to training staff in the use of devices, supporting the development of a drug library (to be uploaded to the devices) and advising on IT infrastructure. When the implementation ‘goes live’, the trust has sole responsibility for maintaining staff training and competency, maintaining the drug library, downloading/analysing event logs, and maintaining and operating the IT infrastructure. Clinical responsibility involving the management of local environmental factors, such as workflow and workload associated with use, is ‘owned’ by the smart pump user.

Fig 4 Ownership of responsibility for implementation

5.43 The investigation found that trusts have attempted to implement governance and assurance processes but have often relied on the manufacturer to guide them. Without a safety case, implementation plans did not describe risks and how these risks should be managed. Plans were rarely shared across stakeholders and typically remained in draft form. Although individually owned documents such as training plans, data security specifications and other requirements documents existed, there was no overarching structure, which would need to be detailed within a safety case.

5.44 At each stage of the implementation process, risks need to be documented and managed. Without this, latent safety risks will emerge when the system ‘goes live’ that could have been anticipated. These include latent risks associated with the development and roll-out of drug libraries. A new organisational infrastructure was found to be needed to successfully implement smart pump technology. This is discussed in detail in the next section.

1. **Don’t forget the infrastructure**

5.45 The investigation found that device manufacturers support NHS trusts during the implementation of smart pump technology, but then ‘step back’ when the trust ‘goes live’. The level of support is specified in the ‘package’ that is procured. NHS trusts do not have the resources or expertise to implement the technology themselves. The required organisational infrastructure to maintain the technology after ‘going live’ needs to be planned for. Trusts are reliant on manufacturer claims when implementing the technology.

5.46 Manufacturers’ marketing claims form part of their ‘intended use’ of the device and thus fall within the regulatory remit of MHRA. Manufacturer claims as perceived and interpreted by NHS staff interviewed by the investigation are detailed below. These claims need to be challenged by trusts and appropriately documented within a safety case. This will allow any misunderstood claims to be resolved with the manufacturer and help to ensure expectations are met.

5.47 “Medication errors will be reduced when smart pumps are introduced.” While dose error reduction systems (DERS) have the potential to improve patient safety, there is no robust evidence for the claim that they will significantly reduce medication errors based on currently published academic literature (Schnock et al., 2017). This lack of evidence was highlighted by a multicentre DERS study conducted within the UK (Lyons et al., 2018). Instead, smart pumps can be seen as an opportunity for improvement of medication practice by analysing where medication errors have occurred and investigating why (Franklin, 2017). The analysis of smart pump logs and the resources needed to investigate errors require the creation of specialist roles within hospitals. Smart pumps are not a ‘plug and play’ technology. A new organisational infrastructure is needed to provide these specialist roles.

5.48 The investigation has identified that some manufacturers claims associated with medication error reduction should not drive the adoption and implementation of smart pump technology. Instead, there needs to be a way of independently establishing how the use of DERS is improving patient safety. At present, many manufacturers supply proprietary software to download event logs from smart pumps. Software that is an accessory to a medical device, or that controls a medical device, is regarded as part of the device and subject to the same overall scrutiny as the hardware device by the MHRA. However, the event log and drug library data does not fall within this remit.

5.49 Using proprietary software means that data is also in a format that cannot be easily shared with others. If a common format or standardised format were employed, this would support the building of an evidence base for the use of DERS. This evidence base would identify and inform future revisions of the drug libraries and other quality improvement practices. Having an anonymised national dataset on smart pump drug administration would provide researchers and practitioners with new opportunities to improve patient safety. Many trusts use multiple manufacturers and models of smart pump. Therefore, there is no reliable way of comparing the utility of DERS across these devices within a trust and nationally. 5.50 HSIB has raised concerns with NHS Supply Chain that without being able to easily share and compare data, progress in patient safety related to the use of DERS is constrained. The sharing and analysis of this data is unlikely without being detailed in an ‘essential specification’ that must be met when procuring smart pump devices.

HSIB identified the following findings:

- NHS Supply Chain’s ‘essential specification’ approach provides an opportunity to guide procurement decisions by prioritising patient safety concerns.
- An ‘essential specification’ details the requirements of the procurement. It is the basis of all offers and therefore the foundation for a contract. A specification becomes a primary contract management document.

HSIB makes the following safety recommendation

Safety recommendation R/2020/104:

It is recommended that NHS Supply Chain develops an agreed specification that defines an open standard format for the sharing of event log data, thus allowing dose error reduction systems (DERS) to be evaluated to establish patient safety benefits.

5.51 “The process of developing a drug library for DERS is straightforward and can be completed in 6-8 weeks … with our help.” The investigation noted that trusts found this claim, perceived and interpreted by NHS staff, to be unrealistic and misleading. The investigation observed that working to this timeframe can lead to low staff morale or burnout and nurtured a culture of attributing blame to individual members of staff when deadlines were inevitably missed. The investigation was informed by two trusts that the drug libraries took more than 12 months to build; one trust reported that it took two years to develop its first iteration.

5.52 The investigation found that manufacturers were attempting to help trusts and accelerate drug library development by entering data on trusts’ behalf because the proprietary software was “difficult to use”. One trust found multiple transcription errors in the drug library made during the data entry process and time-consuming iterations were needed to correct the errors.

5.53 There was no configuration control/management system in place to ensure drug libraries were kept up to date so that risks to patient safety could be mitigated when problems were identified. The latest approved version of the drug library should be used at all times and there should be a clear audit trail of all proposed, approved and implemented changes. The investigation was provided with examples of processes and procedures that trusts employed to identify the configuration of drug libraries and smart pumps. The term ‘configuration control/ management’ was not routinely used or had not been the intended outcome of processes and procedures, nor did trusts recognise that configuration control systems can result in a reduction of patient safety incidents.

5.54 “The pump library can be updated at a push of a button and all the wifi-enabled smart pump devices will be updated within 48 hours.” There are many reasons why a library update might fail. The investigation identified that in one trust, despite considerable effort, a large number of pumps (more than 100) were not updated, and it took several days to locate them and resolve the issue. Serious harm can occur when drugs are administered with outdated drug limit settings due to delays in drug library updates on the pump (Hsu et al., 2019). Relying on the smart pump user to check drug library versions should be considered an unacceptable risk. When a significant problem with the drug library was identified, one NHS trust attempted to

upload a new drug library to its smart pumps to resolve the issue. However, despite having wifi-enabled pumps, some pumps never received the update and other pumps failed to update and reverted to an older version of the drug library.

HSIB makes the following safety observation

Safety observation O/2020/084:

A configuration control/management system for drug libraries should be specified within a smart pump safety case.

Understanding how drug libraries are developed

5.55 The investigation found that there is little transparency around how much work is required allowing for realistic drug library implementation timelines. Manufacturers are sharing old versions of drug libraries, which have been developed by other NHS trusts, in order to expedite the development of drug libraries at new implementation sites. This introduces the potential for patient safety risks that go undetected since there is no national validation process. Local sign-off by a pharmacy team is not a robust validation process as this is subject to the latent risks introduced during consensus building.

5.56 Manufacturers will often be asked to offer example libraries to trusts as a starting point for their own library, not just to expedite the process but also to allow pharmacists who have no experience of building a drug library to see how some of their colleagues have approached the task. The investigation focused on understanding this key safety risk associated with how drug libraries are being developed. No national drug libraries have been developed for use within the NHS in England.

5.57 The development of a national drug library that also includes drug libraries for speciality areas increases the likely benefits of DERS and reduces the likelihood of problems associated with medications that have no locally agreed hard and soft dosing limits or concentrations.

- The investigation found that drug libraries were developed locally so that they aligned with trusts' medications guidance and local policies, which were often outdated or did not document variations in medication practice across different clinical areas. This practice has led to patient safety incidents.
- The investigation identified that there was inadequate sharing of drug libraries or exemplars available to assist trusts in the early stages of developing drug libraries. Some of the sharing is done unofficially as "a favour". This introduces the potential for patient safety risks that go undetected.

- Although the British National Formulary (BNF) aims to provide healthcare professionals with up-to-date information about the use of medicines, this does not include information suited to the development of a drug library for smart pumps.
- The UK Injectable Medicines Guide, called MEDUSA, is an electronic resource containing information on the preparation and administration of injectable medicines. This is an important resource for sharing practice but does not contain information that facilitates the development of drug libraries for smart pumps.

5.58 The investigation identified that some trusts have well-developed drug libraries. However, these have taken considerable effort to develop. Within one trust the development of the drug libraries took nearly two years and patient safety incidents occurred due to the lack of a fully embedded/ workable drug library. Other trusts have abandoned drug library development or have ongoing problems with updating their drug libraries. The investigation could not identify any programme that is currently working on developing national drug libraries, or any programme that is capturing good practice.

HSIB makes the following safety recommendation

Safety recommendation R/2020/105:

It is recommended that the MEDUSA (UK Injectable Medicines Guide) advisory board, in conjunction with other relevant multi-professional organisations, develops validated national drug libraries for smart infusion pumps.

7. Have a plan to train staff

5.59 Using smart pumps requires staff to be trained in the use of a drug library and DERS. This is a complex and often unfamiliar task for many staff.

- The investigation found that training was required to incorporate a wide range of uses in different clinical areas. There was also a need to train staff using realistic clinical scenarios. For example, limits imposed by DERS may need to be overridden, which changes the way the smart pump should be programmed and operated, and this can be counterintuitive.
- Ensuring and certifying smart pump proficiency is not straightforward and often required a combination of approaches such as e-learning, simulation-based classroom training, and support from ‘super-users’. These ‘super-users’ were deemed to have a level of technical skill high enough to support others, after receiving training from the implementation team.
- There were no formal requirements for the development of ‘use cases’. This is an established systems-engineering approach that describes the interaction between the user

and the device to attain required goals. ‘Use cases’ would have allowed for the development of training that better addressed requirements.

5.60 The investigation identified that manufacturers are often only able to train nurses in the use of smart pump devices. ‘Use errors’ that have led to serious patient safety incidents have also involved doctors. Unlike nurses, who are often supported by a network of development practitioners, there was limited uptake by doctors of training opportunities.

HSIB makes the following safety observation

Safety Observation O/2020/085:

There is a need to develop and evaluate ways of training clinicians and pharmacists on the use of safety-critical devices within a hospital to ensure that all staff that may operate the devices are suitably trained. Consideration should be given to mandatory level medical device training being established at induction for all clinicians.

1. **Continually evaluate progress,**
2. **Maintain the system,**
3. **Stay the course**

5.61 When smart pumps ‘go live’, it is vital that ongoing evaluation is carried out and planned infrastructure and assurance processes are maintained throughout the lifecycle of the technology. It is often assumed that new technology will help with the quality, safety and efficiency of care. However new technology may prove frustrating for staff caring for patients as it may not fit their usual workflows, and the anticipated benefits may take time to materialise.

5.62 The investigation identified that some trusts have employed a specialist project manager to deliver smart pump implementation. They are assigned the task of ironing out variability in medication practice in order to facilitate the development of appropriate drug libraries. The project management should not stop after ‘go live’ and should be maintained throughout the lifecycle of the technology.

5.63 The use of a project manager who does not have ‘buy-in’ from some clinical areas means that it will often not be possible to resolve discrepancies, and some clinical areas will be poorly represented and have underspecified requirements. Possible patient safety benefits associated with the introduction of smart pumps have not been exploited by many NHS trusts because of

implementation problems. Moreover, attempts at implementing the technology with an incomplete understanding have resulted in serious patient safety incidents and low staff morale or burnout, and have nurtured a culture of attributing blame to individual members of staff.

5.64 The investigation identified incident reports where staff were instructed to undertake further training after ‘use errors’ had been identified. This can be interpreted as blame and will not help to address the system-wide issues, which this investigation report has highlighted.

6 Summary of findings, safety recommendations and safety observations

6.1 Risks associated with the implementation of smart pump technology have been identified in NHS trusts of different sizes across England. Although this investigation is about NHS trusts in England, the same implementation risks were found in the Republic of Ireland and the USA. The investigation has worked with device manufacturers, regulators, national bodies and academic institutions to understand why these risks are systemic. A system-wide approach to the management of these risks is needed, as they cannot be appropriately managed locally.

- The investigation found that introducing smart pump technology required significant changes to existing medication prescribing and administration processes across NHS trusts.
    - It is essential that existing medication processes have been studied in detail, so that the impact and risks associated with any new technology can be better understood. The investigation found that procedure and guidance documents often needed updating, and variations in medication practice were ‘locally managed’ and were rarely shared within and between hospitals in trusts. Locally developed procedure and guidance documents are not routinely shared beyond ‘organisational boundaries’ for peer review.
- Dose error reduction systems (DERS) require the use of drug libraries. Each drug within a library allows for dose calculations based on the type of drug and programmed patient weight, including the setting of dose limits to identify miscalculations or ‘use errors’. Such errors occur as a person uses the technology; simply attributing the error to ‘the human’ often prevents an understanding of how the medication system can be designed to be safer.
    - No national guidelines or standards on how to implement drug libraries exist. The investigation identified that in England there is currently no agreed national drug library for use in NHS trusts.
    - The investigation found that drug libraries were predominantly developed locally so that they aligned with trusts’ medications guidance and local policies, which the investigation

identified were often outdated or did not document variations in medication practice across different clinical areas (sometimes even within the same hospital).

- Using smart pumps requires staff to be trained in the use of a drug library and DERS. This is a complex and often unfamiliar task for many staff.
- The IT infrastructure needed to implement smart pump technology requires the use of software to upload the drug library to the smart pumps, download data logs associated with usage (including alerts where DERS has prevented an ‘error’), and monitor the status of each smart pump in the system (including which version of the drug library it is using).
    - The investigation found that maintaining the required IT infrastructure required specialist staff roles and often a new skill set.
    - Smart pumps need to be connected to the trust’s IT network. This can be achieved by using a hardwired connection (where the device is plugged into a port in the wall) or a wifi network. Both of these methods require specialist IT provision.
    - A computer server is needed to issue device updates from the manufacturer, update the drug libraries and download device use logs. Monitoring the status of each smart pump in the system, so that the trust can be sure that the latest device update and drug library is installed, was an essential requirement but NHS IT staff found this problematic without support from the manufacturer. Findings
- NHS Digital has specifically developed standards to be ‘technology agnostic’ (that is, applicable to any type of technology), so it was felt that specifically identifying smart pumps being within the remit of these standards would be contrary to this intent.
- NHS Digital notes that the standards were updated in 2018 to bring medical devices in scope. The rationale for updating the standards was to manage scenarios where a medical device is either embedded in or supported by health IT. • NHS Digital believes that the current standards are appropriate when implementing smart pump technology.
- It is outside the remit of NHS Digital to be responsible for ensuring manufacturers are trained in clinical risk management. However, NHS Digital does provide training in this area and proactively promotes its training.
- NHS Digital’s standard DCB0160 mandates that a clinical safety officer within NHS organisations must be knowledgeable in risk management and its application to clinical domains. Training provided by NHS Digital is a means to achieve this.
- Medical device regulation is complex and slow to legislate. Attempting to incorporate regulations for device log data sharing is not feasible in the short term.
- NHS Supply Chain’s essential specification approach provides an opportunity to guide procurement decisions by prioritising patient safety concerns.

- An essential specification details the requirements of the procurement. It is the basis of all offers and therefore the foundation for a contract. A specification becomes a primary contract management document.

HSIB makes the following safety recommendations

Safety recommendation R/2020/104:

It is recommended that NHS Supply Chain develops an agreed specification that defines an open standard format for the sharing of event log data, thus allowing dose error reduction systems (DERS) to be evaluated to establish patient safety benefits.

Safety recommendation R/2020/105:

It is recommended that the MEDUSA (UK Injectable Medicines Guide) advisory board, in conjunction with other relevant multi-professional organisations, develops validated national drug libraries for smart infusion pumps

HSIB makes the following safety observations

Safety observation O/2020/081:

Organisations involved in the development and deployment of smart pumps must adhere to DCB0129 and DCB0160 respectively where health IT is utilised to support the configuration and/or operation of the smart pump.

Safety observation O/2020/082:

Organisations involved in the development and deployment of smart pumps must ensure that their personnel are knowledgeable in clinical risk management. NHS Digital provides a programme of training to support this.

Safety observation O/2020/083:

Examples are needed of where safety cases have been used in the NHS to manage safety proactively, so that their value can be communicated and better understood. The NHS should always show evidence of rigorously considering safety in all procurement, and safety cases are a standard and widely accepted way of doing this.

Safety observation O/2020/084:

A configuration control/management system for drug libraries should be specified within a smart pump safety case.

Safety observation O/2020/085:

There is a need to develop and evaluate ways of training clinicians and pharmacists on the use of safety-critical devices within a hospital to ensure that all staff that may operate the devices are suitably trained. Consideration should be given to mandatory-level medical device training being established at induction for all clinicians.

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