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LEADING ARTICLE

Developing Strategic Recommendations for Implementing Smart Pumps in Advanced Healthcare Systems to Improve Intravenous Medication Safety

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Abstract
Avoidable harm associated with medication is a persistent problem in health systems and the use of preprogrammed infusion devices ('smart pumps') and data monitoring is seen as a core approach to mitigating and reducing the incidence of these harms. However, smart pumps are costly to procure, configure and maintain (in both human and financial terms) and are often poorly implemented. Variation in the manner in which medicines are prepared and used within complex modern healthcare systems exacerbates these challenges, and a strategic human-centred approach is needed to support their implementation. A symposium of 36 clinical and academic medication safety experts met virtually to discuss the current 'state of the art' and to propose strategic recommendations to support the implementation of medication administration technology to improve medication safety. The recommendations were that health systems (1) standardise infusion concentrations to facilitate the development of ready-to-administer formulations of frequently used medicines, and support 'out of the box' programming of infusion devices; (2) develop and implement drug libraries using human-centred approaches and the aforementioned standard concentrations, with a theoretical understanding of how devices are used in practice; (3) develop standardised metrics and outcomes to support the interpretation of data produced by infusion devices; (4) involve all stakeholders in the development of drug libraries and metrics to ensure broad understanding of the devices, their benefits and limitations; and (5) leverage input into device design, working with manufacturers and users. Using this strategic approach, it is then possible to envisage and plan real-world implementation studies using a uniform approach to quantify improvements in safety, efficiency and cost effectiveness.

1 Introduction

Medication safety has been a focus of work for academics and clinicians for at least 20 years, leading to heightened awareness of the causes of adverse medication events and the development of many interventions. However, there is limited evidence for a corresponding improvement in actual harm medication events. Globally, it is estimated that 25% of avoidable medical harm events are associated with medication errors [1]. More specifically, there is also growing concern that a large proportion of intravenous medication administrations are associated with an error [2], although the harm associated with these is unclear [3]. Additionally, in the context of the coronavirus disease 2019 (COVID-19) pandemic, patient safety and supporting healthcare professionals in the provision of safe care have never been higher on the global healthcare agenda [4].

The World Health Organization established its third global patient safety challenge in 2017 with a call for the reduction in harmful medication errors by 50% within 5 years [5]. Following this, the National Health Service (NHS) England Patient Safety Strategy advocated for the swift adoption of electronic prescribing and medication administration systems across the NHS at pace as an intervention to improve quality and safety of care. Medication administration systems include (but are not limited to) computerised physician order entry (CPOE), barcode medication administration (BCMA), automated dispensing cabinets and 'smart pumps'. It has been suggested that by using these systems together, closed loop medication administration processes can lead to reduced medication-related harm by cross-checking patients, medication and prescription using digital methods [6].

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Key Summary Points

Avoidable patient harm associated with medicines is common, and while the harm related to intravenous medication is unclear, there is a perception that a large proportion of intravenous medication administrations are associated with an error and the consequences of intravenous medication errors are much greater than with other medicines.

The use of technology has been advocated as a key way to improve medication safety and service efficiency, but technology is often implemented poorly and decision makers and policy makers have a poor understanding of how intravenous medication is administered in real life. The time to correct this is now, at a time when multiple recommendations are being announced directing healthcare organisations to 'change' their approach to medication safety.

A collaborative systems-focused approach to intravenous medication safety, including national standardisation of infusion practice, centralised smart pump libraries and data management, and end-user involvement in device development, are all recommended to foster a system-wide approach to intravenous medication safety.

2 Challenges and Considerations

Four high-level policy directives emerged in the UK in 2020, centred on intravenous medication safety (Table 1) and the interventions that UK health services should adopt. While these were specific to the UK NHS, the principles upon which they were based can be generalised into broader strategies that could be adopted by other developed healthcare services.

Smart pumps are central to the digital safety revolution because of their capacity to cross-check and prevent inadvertent dose or concentration deviations. Smart pumps are infusion devices preprogrammed with parameters for drugs, concentrations, and dosing limits (referred to as a 'drug library') that are defined locally. They can alert users to programming outside these parameters and potentially prevent adverse medication events. However, the causes and contributory factors to adverse events associated with intravenous medications are many and multifaceted [16]. There is a complex interplay between devices, the customs, practices and experiences of the people who administer them, and the competing priorities of patients, organisations and other professionals that influence how these medicines are administered [3, 17–19].

None of the documents in Table 1 offer operational guidance and are written with a generalised focus on the prevailing issues. Thus, there is a need to provide material guidance on how these devices should be introduced and managed, to ensure that the systems within which healthcare staff work are fit for purpose, and developed with an appropriate understanding of how work is delivered in practice while supporting safety across the entire spectrum of care.

Standardising medication practices at a systems level requires considerable collaboration between policy makers, organisational managers, practitioners and researchers to develop and implement operational interventions. The increasing reliance on technology without adequate sociotechnical assessment presents a risk of wasted resource due to the implementation of ineffective systems. There is a need for clear strategies to support the NHS (and similar centralised healthcare systems) in implementing recommendations made by policy makers to deliver improvements in medication safety. These strategies need to ensure that the environment and technology in which healthcare practitioners work reflects the work they need to do. This can only be achieved though collaboration with clinical practitioners, patient safety specialists and human factors and ergonomics practitioners.

3 The Expert Symposium

In November 2020, 36 academics, clinicians and members of two prominent UK patient advocate groups (the Patients' Association and the Association Against Medical Accidents) came together to discuss the current state of intravenous medication management in the UK and Ireland. The symposium examined practical, real-world experience and knowledge of interventions to mitigate intravenous medication errors from both the UK and Ireland, and considered how to translate and scale up these interventions for system-wide use. Furthermore, the group considered the development of research partnerships for future study of intravenous medication safety. The intended outcomes of the symposium were to propose generalisable strategies for intravenous medication safety and to outline a research strategy to accompany this work.

3.1 Symposium Origins and Organisation

Two systematic reviews published in the last 10 years have highlighted both the potential burden of intravenous medication-associated harm [20] and the challenges in implementing technology to mitigate them (specifically smart pumps) [21]. In January 2019, Becton Dickinson (UK) Limited

Table 1 UK policy directives on injectable medication safety, 2020

Author(s)	Core themes	Recommendations
National Association of Medical Device Educators and Trainers (NAMDET) [7]	The use of Smart Pumps in NHS hospitals should be standard of care	Standardised smart pump datasets Sharing of event data at a national level
Health Safety Investigation Board (HSIB) [8]	Three non-fatal tenfold overdoses of fentanyl caused by non-standard practice across three sites in a single organisation highlights the need for operational standardisation	A nationally standardised drug library for smart pumps The sharing of event log data allowing independent third-party review and system-wide learning
NHS England and Department of Health and Social Care Aseptic Services Redesign [9] and regional equivalents [10]	To increase manufacturing capacity in the NHS to free up nursing capacity for care, and support work already delivered in standardisation of injectable medicines [11–14]	Standardise intravenous products where possible
Global Digital Exemplar (GDE) programme [15]	Drive to implement sophisticated electronic medicines administration systems in digitally mature organisations	Targeted funding for enhancements and provision of closed loop medication administration systems (e.g. barcode medication verification)

NHS National Health Service

brought together a group of 19 academics, clinicians, policy makers and patient organisations to consider how health services might overcome some of these barriers. Out of this, three pillars of action were identified:

- *Technology* Implement and use smart pumps; design out errors with technology; design technology with future care settings in mind.
- *Health System* Implement meaningful standardisation; reconsider assessment of device safety and efficacy; improve coordination of information across organisations; ensure that changes in practice are measured and evaluated robustly.
- *Workforce* Strengthen the culture of patient safety; provide staff with requisite support; ensure that professional standards reflect modern practice

In light of this, a follow-up symposium was held in November 2020 to consider how the technology and health systems pillars might be operationalised. This half-day symposium was hosted virtually and was attended by 36 invited experts (including the six authors and all acknowledged participants) to develop a practical strategy for mitigating the barriers and obstacles identified the year previously. BD provided access to a videoconferencing platform and assisted in the identification of participants. All participants were invited to the symposium through the corresponding author (AS). All participants gave their time freely and joined voluntarily.

The symposium was run over two sessions. Session 1 was a forum to share recent research in the context of the current understanding of intravenous medication error. BDF, MJ, MH, SA and AP presented overviews of their work on the causative factors of intravenous medication error, the science of information presentation, progress and feasibility of national standardisation of infusion concentrations, and the organisational aspects of smart pump introduction. Session 2 consisted of an open-floor discussion on how to scale up the work that has gone before and how to operationalise recommendations from recent directives as outlined in Table 1. There was also consideration of the work needed to build multidisciplinary partnerships between clinicians, academics, human factors and ergonomics practitioners, patients and industry to ensure that future interventions were evaluated robustly.

3.2 Areas of Discussion at the Symposium

The understanding of intravenous medication processes is poor, with a high prevalence of operational protocol deviations and low incidence of patient harm [22]. The symposium agreed that work to standardise processes and information may be beneficial. Difficulty finding and understanding

information on intravenous medication administration can be a cause of medication errors [23]. Assessing the performance of such guidelines in the hands of 'real' users and subsequently redesigning them to prevent problems might lead to safer medicines administration [24]. The organisation-wide standardised provision of infusions in ready-to-administer presentations in a large children's hospital led to the almost complete elimination of medication administration errors [25–27]. A similar project in Ireland demonstrated the feasibility of implementing smart pumps and standard concentration infusions in paediatric services using a single national drug library, with evidence of effectiveness [11, 28, 29]. However, the implementation of these interventions has required ongoing sponsorship and coordination at a system level and cannot be led or managed at a local level. To support this need for high-level support and sponsorship, the unpublished experience from a large multisite English NHS organisation was presented. Using localised implementation, drug library compliance was poor. When widened to include executive level leadership, robust outcome measures and adequate resource, the proportion of infusions administered via the drug library increased from 50% to over 80%. The ongoing non-compliance was related to physical device limitations and the ongoing burden of both training and maintenance. All symposium participants agreed that smart pump implementation is not something that can be done on a small scale, but needs to be system wide and executive led.

After panel discussion, the following strategic recommendations were agreed.

3.3 Recommendation 1: Standardise Infusion Concentrations

There are sufficient data to indicate that ward-prepared infusion solutions are often different to the concentrations prescribed [30–33]. This is not negligence, nor can it be 'trained out' [32] but is likely related to humans being human and the lack of suitable medical devices designed to measure very small volumes. The availability of manufactured ready-to-administer dosage forms, prepared from large-volume stock solutions, is likely to be the only way to mitigate these issues. Particularly in paediatric care, there is still a preponderance towards weight-based infusions that exacerbate the issues above with accuracy [34]. Variable infusion practices also lead to practice discrepancies and errors in preparation and administration [19, 35–38]. We recommend that infusion concentrations should be standardised. The NHS England Aseptic Services Review has standardisation of formulations at its core [9]. Considerable work has already been achieved in this sphere, with adult intensive care and paediatric solutions already defined [14, 39].

3.4 Recommendation 2: Develop and Implement Drug Libraries Using Human-Centred Approaches

While the data exploring the benefits of smart pump use are largely equivocal, this may be at least partly related to low uptake of smart pumps across healthcare systems, as well as poor drug library design [3, 40, 41]. However it is clear that smart pumps have a potential role in all areas where injectable medicines are used, to provide support for adoption and administration of standard infusions safely and consistently [29, 36], to offer opportunities for system-wide learning, and to protect patients [9, 36]. Smart pumps are most likely to prevent the most catastrophic events, with little impact on the day-to-day discrepancies and deviations seen in large, well-powered observational studies. Two multicenter studies in the US and UK both identified policy violations, including unauthorised administrations and failure to use the drug library where available, as the most commonly observed deviations [3, 42]. In a post hoc analysis of both studies, it was identified that smart pumps would not have prevented the most serious errors, although there may have been a slightly higher error rate in the English centres, where adoption of the technology lagged behind that of the US [19]. Many of the issues with compliance and overrides of smart pump programming may be overcome with a holistic programme of training, review and user support [19, 21, 40].

Across health systems, smart pumps will likely become the standard-of-care within 5–10 years as providers come to replace obsolete infusion systems [37]. Given the diversity of end-users of these systems, there is a risk that localised implementations will lead to degradation of the benefits of the systems as operators have to adapt to variant practices [43]. The burden and risk associated with the development, validation and implementation of drug libraries in modern complex healthcare systems should not be underestimated and needs to be resourced and overseen at an organisational level [8]. We recommend that drug libraries should be centralised across organisations, and constructed based on a standardised nomenclature derived from study and synthesis of existing datasets and practices, as has been demonstrated in the UK [34, 47]. Furthermore, this standardised nomenclature should ensure interoperability across platforms. However it would be naïve to think that one standard library will be suitable for all users. It is likely that a certain level of localisation will be necessary, which access to a predefined library could simplify.

In NHS organisations, oversight for this should lie with Drug and Therapeutics Committees, Medication Safety Officers, and Medical Device Safety Officers working in conjunction with Patient Safety Specialists and human factors and ergonomics practitioners. These groups must be aware that engagement with stakeholders involved in the

procurement and clinical set up of these systems is critical, and be sensitive to the range of differing perspectives. They must also have technological awareness of the capabilities of these systems. There must also be mechanisms in place to ensure that when changes are made to systems, infusion devices and smart pump libraries, that these are properly evaluated to ensure that the intended outcomes are achieved.

Drug libraries and smart pumps themselves may introduce potential for different types of medication error [43] because they are a complex technology that changes the way operators interact with them and the medications that are being administered [18, 44]. As few studies have taken a systems-focused approach to the development and implementation of smart pumps and drug libraries [45, 46], we recommend the engagement of human factors and ergonomics specialists to support this work.

In the UK, the Health Safety Investigation Board has already recommended that the NHS Injectable Medicines Guide advisory board should "… develop validated drug libraries for smart infusion pumps" [8]. These libraries would be applicable across all of the UK. They also observe that a configuration control and management system should be specified. We view the standardisation of drug concentrations and infusion products (including presentation and labelling) as an important potential outcome of this work and thus these two strategies are complementary, requiring collaboration with the same stakeholders.

3.5 Recommendation 3: Develop Standardised Definitions and Metrics

There is great variation in the definitions and metrics that have been used to populate and implement smart pumps, and evaluate the impact and outcomes associated with them. This is part of a wider definitional challenge around medication safety in general [39]. For onward analysis and to support system-wide learning, clear, consensus-based definitions for pump-related events, with reference to the limited contextual data held within smart pump systems, are needed to present reliable and robust data.

Formal research methods and iterative improvement approaches provide an opportunity to standardise the definitions and parameters used to evaluate the impact of these interventions. These metrics must define and capture patient outcomes (actual and potential) and economic outcomes (harm caused or avoided, costs, efficiencies and cost effectiveness).

Many organisations do not utilise smart pump data because of human resource limitations and a lack of reliable infrastructure, e.g. wireless connectivity of devices and real-time pump downloads [20]. In the UK, there is often a reliance on pump manufacturers to store and process the data. Furthermore, manufacturers do not currently collect or report data from their devices in a standardised way and this makes comparison difficult. Thus, using the parameters and definitions arrived at in Sect. 4.5 should enable these data to be held and managed by health systems and reviewed regularly at local and national levels by designated groups. There is evidence that regular review of smart pump data informs amendments to drug libraries and datasets and leads to a significant reduction in errors. By curating and managing these data, there is also the potential for it to be useful in the field of artificial intelligence and machine learning for the analysis of large healthcare datasets, which, to our knowledge, has not yet been employed for smart pump data. Given the potential size of these datasets, the strategies above open the door to innovation in this field but the resources required should not be underestimated.

3.6 Recommendation 4: Ensure Stakeholder Engagement and Representation

Intravenous medication administration is an extremely complex system made up of multiple actors. Stakeholders must be identified in order to:

- develop the components of this intravenous therapy strategy using all available data and evidence;
- agree and ratify interventions (including smart pumps, standard infusions, barcode systems, electronic patient record alignment with smart pump datasets);
- support the design and implementation of these interventions in the clinical setting.

There is a need to balance the clinical needs of health systems with the safety benefits that these systems may offer, as well as having a comprehensive and affordable package to implement. There should be drug library groups (local, regional, or national) who can oversee the content and nature of these (and, in turn, the wider intravenous system) and provide organisational insight and validation. Having nationally validated libraries and frameworks for implementation will reduce much of the operational burden associated with the introduction of these systems into routine practice. The work involved in the standardisation of infusion concentrations, packaging design, development of drug libraries and proposing standards for implementation is substantial. Adequate resources need to be provided to ensure these strategies can be implemented.

3.7 Recommendation 5: Leverage Input into Device and Systems Design

As large organisational purchasers of these technologies, healthcare systems have the opportunity to influence infusion device and management system design with manufacturers.

Additionally, as part of their commissioning and implementation, organisations should undertake review of their processes and systems within which devices will be used in order to inform the system-wide adjustments that will be required to accommodate these devices. Furthermore, these strategic recommendations should be used to influence regulatory agencies towards a human factors informed design approach to device interfaces [48]. It is important for there to be meaningful engagement between manufacturers, patient representatives and practitioners with appropriate support from human factors and ergonomics practitioners. It has been recognised that design disparities between systems can contribute to adverse events and that a more considered approach to the design and implementation of all facets of smart pumps, while ensuring compliance with digital safety standards, is needed. This includes how the devices interface with existing and future electronic patient record systems and how operators interact with the devices, software libraries and nomenclature and presentation of information [40].

4 Future Research Opportunities

The symposium also considered the necessary research that will underpin and secure the use of these systems. With a national strategy and standardised definitions, there is an opportunity to undertake real-world implementation studies using a uniform approach to quantify improvements in safety and efficiency. Suggested research questions are as follows.

- What is the best approach to the development and implementation of closed-loop medication administration systems in large complex distributed healthcare systems?
- What is the impact of closed-loop systems incorporating electronic prescribing and medication administration systems, smart pumps and standardised infusion concentrations on medication errors in a real-world context?
- What are the effects on nursing resource utilisation in acute care from the adoption of ready-to-administer intravenous dosage forms?
- Does the use of user-tested intravenous administration guidelines improve patient safety and/or nursing resource utilisation in real-world practice?
- What is the utility of machine learning and artificial intelligence to identify error-causing conditions from large smart pump datasets, and to identify unrecognised design issues?
- In relation to aseptic preparation of products, see the following.
- What is the drug stability data available and/or required for different drugs and diluents to present economically feasible products to practitioners?
- What is the safest approach for labelling ready-to-administer products to reduce the likelihood of administration errors?

5 Conclusions

Healthcare systems are at a turning point in their approach to intravenous therapy and systems redesign. Now more than ever, there is a clear need for an intravenous medication safety strategy that is evidence-based and rooted in real-world practice. We believe that this paper brings forward a comprehensive and actionable package of measures that is multidisciplinary in nature, and implementable at a strategic and operational level. Previous guidance has been abstract- and profession-specific, leaving service leaders, clinicians and researchers at odds or with conflicting goals. We believe that the principles outlined in this paper, although reflective of the UK policy context, can be adopted across the majority of healthcare systems. Technology has been seen as an 'easy' solution to systems safety in the past, but this is no longer the case. Current policy in patient safety increasingly requires the use of technology, but with a greater focus on implementation and adaptation [49]. This is a considerable expectation and delivery requires a considered, collaborative and coordinated approach. There is a risk that if left to individual organisations, a confused and variable landscape of implementation will emerge that will detract from the benefits that can be realised.

A strategy of definition and development, that is adequately resourced and lead, to support organisations to implement new technology and systems is recommended. A programme of research to support rational and rigorous evaluation of this system-wide approach to realise the true patient safety and economic benefits is also required.

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Declarations

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