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# The Potential Role of Smart Infusion Devices in Preventing or Contributing to Medication Administration Errors: A Descriptive Study of 2 Data Sets

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**Objectives:** Errors in medication administration are common, with many interventions suggested to reduce them. For intravenous infusion-related errors, “smart infusion devices” incorporating dose error reduction software are widely advocated. Our aim was to explore the role of smart infusion devices in preventing or contributing to medication administration errors using retrospective review of 2 complementary data sets that collectively included a wide range of errors with different levels of actual or potential harm.

**Methods:** We reviewed 216 medication administration errors identified from an observational study in clinical practice and 123 medication incidents involving infusion devices reported to a national reporting system. The impact of smart infusion devices in preventing or contributing to these errors was assessed by the research team and an expert panel.

**Results:** The data suggest that use of any infusion device rather than gravitational administration may have prevented 13% of observed errors and 8% of reported incidents; additional reductions may be possible with standalone smart infusion devices, and further potential reductions with smart infusion devices integrated with electronic prescribing and barcode administration systems. An estimated 52% to 73% of errors that occurred with traditional infusion pumps could be prevented with such integrated smart infusion devices. In the few cases where smart infusion devices were used, these contributed to errors in 2 of 58 observed errors and 7 of 8 reported incidents.

**Conclusions:** Smart infusion devices not only prevent some medication administration errors but can also contribute to them. Further evaluation of such systems is required to make recommendations for policy and practice.

**Key Words:** smart infusion pumps, medication errors

(*J Patient Saf* 2020;00: 00–00)

Medication errors are a global patient safety priority.<sup>1</sup> Errors at the medication administration stage are common but often not easily detected, unless direct observation is used as a research method. A meta-analysis of UK data based on observation of medication administration suggests errors to be more common in intravenous doses (35% of doses) than doses given by any other route (5.6%).<sup>2</sup> However, published error rates vary widely, from 18% to 173% of intravenous doses in studies using structured observation of medication administration.<sup>3</sup> Voluntary incident reporting systems, although known to be associated with considerable under-reporting, also reveal that errors involving injections and infusions are among the most frequently reported, accounting for more than half of medication administration reports<sup>4</sup> and associated with more harm.<sup>5</sup>

Many interventions, such as double checking, use of ready-to-administer infusions, and bar coding, have been introduced with the aim of reducing intravenous medication administration errors. For infusion-related errors, “smart” infusion devices incorporating dose error reduction software (DERS) have been widely advocated.<sup>6–8</sup> Dose error reduction software relies on a drug library, which is a list of standardized drug concentrations and predetermined limits, programmed within the device to trigger soft alerts (that can be overridden) or hard alerts (that cannot) if the limits are exceeded. Smart infusion devices may be standalone or integrated with electronic prescribing and/or barcode administration systems, and usually allow administrative data such as number and types of overrides to be downloaded for analysis. Although smart infusion devices are widely used in the United States,<sup>9</sup> use in the United Kingdom has been limited to date.<sup>10</sup> Evidence for their benefits in error reduction is also inconclusive, with a recent systematic review concluding that smart infusion devices can reduce but not eliminate error.<sup>11</sup> A recent observational study of 16 English National Health Service (NHS) hospital organizations involving 1326 patients and 2008 infusions revealed errors in 11.5% of infusions affecting 16.5% of patients. Smart infusion devices, as currently implemented, had little effect, with similar error rates observed in infusions delivered with and without a smart infusion device (10.3% versus 10.8%,  $P = 0.8$ ).<sup>12</sup> Evidence from implementation of other technology solutions, such as electronic prescribing, shows that there may be unintended and unanticipated consequences including new error types due to mis-selection from patient or medication infusion lists, or workarounds such as bypassing the DERS altogether.<sup>13,14</sup> There is also an apparent lack of evidence on the potential unintended or negative consequences of smart infusion devices.<sup>11</sup>

Increasing availability of smart infusion device functionality means that their use is becoming more widespread, with varying

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This work was supported by the National Institute for Health Research (NIHR) Health Services and Delivery Research program (grant number 12/209/27).

This research was also supported by the NIHR Imperial Patient Safety Translational Research Centre and the NIHR Healthcare Protection Research Unit for Healthcare Associated Infections and Antimicrobial Resistance at Imperial College London. The views expressed are those of the authors and not necessarily those of the NHS, the NIHR, or the Department of Health and Care.

A.B. and B.F. supervise a PhD student who is partly funded by Cerner, a supplier of electronic health record and electronic prescribing systems, unrelated to the present study.

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levels of integration with other technologies such as electronic prescribing and barcode administration systems. Our aim was to explore the role of smart infusion devices in preventing or contributing to medication administration errors, with a secondary aim of gaining insight on the potential influence of integration with other medication administration system technologies.

**METHODS**

**Study Design**

We conducted a retrospective review of 2 UK data sets. The first was the data set of observed medication administration errors identified from the observational study described previously.<sup>12</sup> The second was medication incidents involving infusion devices reported to the national reporting and learning system (NRLS), a database of voluntarily reported patient safety incidents from England and Wales.<sup>15</sup> These were considered complementary as they provided a spectrum of errors with different levels of actual or potential harm, allowing us to study less serious errors identified using observation and more serious errors reported to the national database.

**Observed Errors**

The observed errors were from a study of 16 English NHS hospitals. Briefly, between April 2015 and December 2016, 2 observers, usually a nurse and a pharmacist, observed intravenous infusions that were in progress or that should have been in progress in general medical, general surgical, critical care, and pediatric and oncology daycare areas and compared what was being administered against what was prescribed to identify any discrepancies. Likelihood of harm was classified using an adaptation of the U.S. National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) index.<sup>16</sup> Full details are reported elsewhere<sup>17</sup>; approval was obtained from an NHS research ethics committee. Each error rated NCCMERP level C (“an error occurred but was unlikely to cause harm despite reaching the patient”) or above was then reviewed by 2 clinical members of the research team (a pharmacist who was not involved in the observations and a nurse who was involved in the observations at one site only). A judgment was made as to whether the error may have been prevented using a smart infusion device, or whether a smart infusion device contributed to the error. We did not include any incidents rated NCCMERP level A (“circumstances or events that have the capacity to cause error,” but no error occurred) and B (“an error occurred, but the medication did not reach the patient), as we wanted to focus on those that reached the patient.

To increase the rigor of this analysis, members of an expert panel were invited by e-mail to assess a sample of the errors. Panel

members were a self-nominated group of 13 drug library experts identified through the Medication Safety Officer network for England. Members either had implemented or were in the process of implementing smart infusion devices in their organization. Those who agreed to participate were sent an anonymized random 25% sample stratified by smart infusion device use, traditional pump use or gravity administration, including the description of the error as recorded at the time of observations. They were not given any particular assumptions or criteria about how smart devices may be implemented but were provided with a list of predetermined categories and a simple definition of closed-loop smart pumps and those that are interfaced with electronic prescribing systems. Participants were invited to consider, for errors identified in infusions that were not given via a smart pump, which might have been prevented using a smart pump. For errors identified in infusions that were given via a smart pump, the extent to which they might have been prevented depending on the limits set in the drug library, or with an integrated system, or where the use of a smart pump may have contributed to the error. Participants were also requested to provide any comments about the errors listed and any assumptions they made. Agreement both among the panel and between the panel and the research team was assessed descriptively as discussed hereinafter.

**Reported Errors**

We requested data from the NRLS relating to medication incidents involving infusion pumps. After approval by NHS Improvement and signing of a confidentiality agreement, we obtained anonymized reports for all incidents reported to have occurred between January 1, 2005, and December 31, 2015, that contained search terms relating to infusions or infusion pumps in any of the following fields: “description of what happened” (field IN07), “action preventing reoccurrence” (IN10), “apparent causes” (IN11), and “device name” (DE03).<sup>18</sup>

From the data obtained, we selected incidents that were medication errors reported as being of “moderate” severity or above (Table 1) that occurred in hospital inpatient settings, excluding operating theaters. Those of “low” severity were not included, in order to provide a complementary perspective to the observational data. We then removed all those relating to subcutaneous or other nonintravenous infusions, those where an intravenous infusion pump was mentioned in the report but the patient safety incident was unrelated, those that related to different types of pump such as intra-aortic balloon pumps, and any others judged to be irrelevant. All other reports were included.

All reports were reviewed by the same 2 clinical members of the research team plus a third expert medication safety officer with

**TABLE 1.** Harm Categories and Associated Definitions Used Within the NRLS for England and Wales

<b>Harm Category (Relating to the Actual Harm Experienced)</b>	<b>Definitions Used Within the NRLS</b>
Low	Any unexpected or unintended incident that required extra observation or minor treatment and caused minimal harm to one or more persons
Moderate	Any unexpected or unintended incident that resulted in further treatment, possible surgical intervention, canceling of treatment, or transfer to another area, and which caused short-term harm to one or more persons
Severe	Any unexpected or unintended incident that caused permanent or long-term harm to one or more persons
Death	Any unexpected or unintended event that caused the death of one or more persons.

experience of setting up drug libraries. This team discussed each case and made a judgment as to whether the error would have been expected to have been prevented using a smart infusion device or, for those that were given by a smart infusion device, the extent to which the smart infusion device may have contributed.

**Analysis**

Each error was classified into 1 of 8 mutually exclusive categories (Table 2) with the classification of preventability using technology based on the minimum level of technology required. A series of assumptions were made by the researchers when reviewing and classifying both data sets. For errors involving infusions given via gravity feed where the rate was incorrect due to the clamp being set incorrectly, it was assumed that these would be prevented by any pump (not necessarily a smart infusion device). It was also assumed that if a smart infusion device were to be used, a suitable drug library entry would be available and that staff would select and use the correct entry, and not override any alerts. Based on our experience and previous literature,<sup>11,19</sup> we recognized that some errors would not be prevented using any kind of smart infusion device (Box 1) and others only if smart infusion devices were integrated with electronic prescribing and administration systems (Box 2). For the remaining errors (other wrong rate errors, dose/volume errors, wrong medication, concentration errors, and any other errors), each was reviewed individually with a judgment made on a case-by-case basis. For the expert panel’s assessments, we established the majority view regarding preventability or contribution by different types of pump and calculated the level of agreement.

**Box 1: Errors that would not be prevented by smart infusion devices**

- Omission errors, including those due to unavailability of pumps or giving sets, pumps not functioning, or staff not knowing how to use the equipment
- Errors concerning patient identification
- Errors involving the administration of expired medication
- Labeling errors
- Delay in starting or completing the infusion

**Box 2: errors that may be prevented by smart infusion devices integrated with electronic prescribing and administration system**

- Giving medication without a corresponding medication order
- Wrong rate errors where the rate was incorrect in relation to what was prescribed for that particular patient, but where the rate administered was within the usual range for the drug concerned
- Wrong rate errors concerning much lower (rather than higher) rates than those prescribed, in drugs for which very low rates are sometimes used in clinical practice

**RESULTS**

We analyzed a total of 339 observed and reported errors of different levels of actual or potential harm (Table 3).

**Observed Errors**

Of the 216 errors identified in the observational study, 157 involved infusions not given via a smart infusion device and 59 involved infusions given via a smart infusion device. Approximately half of the 157 errors not given via a smart infusion device were considered by the researchers to be possibly preventable with a smart infusion device integrated with an electronic prescribing and barcode administration system with details of the medication order populated from the electronic prescribing system. A breakdown by other categories is summarized in Table 4, and examples of errors considered to be preventable with smart infusion device are presented in Table 5.

Smart infusion devices were judged to have contributed to the error in 2 cases (Table 6); both involved piperacillin/tazobactam being given over 1 hour instead of the recommended 30 minutes, as the drug library concerned did not allow for a 30-minute infusion. Different limits or integration with an electronic prescribing system may have prevented the error in one further case relating to atracurium 500 mg/50 mL prescribed at 0 to 5 mL/h being given at 10 mL/h in a critical care area.

**Expert Panel Assessment for Preventability (Observed Errors)**

Seven of the 13 drug library experts agreed to participate. A total of 58 errors were sent for their review, of which 33 involved

**TABLE 2.** The Classification System Used to Determine the Role of Smart Infusion Devices in Errors

Smart Infusion Device Used in Practice?	Role of Smart Infusion Device in Preventing or Contributing to the Error
No or not applicable	<ul style="list-style-type: none"> <li>• Not preventable with any pump</li> <li>• Preventable with any pump</li> <li>• Possibly preventable with smart infusion device integrated with an electronic prescribing and barcode administration system</li> <li>• Possibly preventable with a standalone smart infusion device depending on limits set in drug library, or with an integrated smart infusion device as above</li> </ul>
Yes	<ul style="list-style-type: none"> <li>• No effect of smart infusion device in contributing or preventing the error</li> <li>• Different limits set in drug library may have prevented the error</li> <li>• Possibly preventable with an integrated smart infusion device as above</li> <li>• Smart infusion device contributed to the error</li> </ul>

**TABLE 3.** Harm Rating of Errors From the 2 Data Sets That Were Included in Analysis

Observed Errors	No.	Reported Errors	
		NRLS for England and Wales category	No.
C: An error occurred but is unlikely to cause harm despite reaching the patient	194	No harm	Not included in analysis
D: An error occurred that would be likely to have required increased monitoring and/or intervention to preclude harm	21	Low	Not included in analysis
E: An error occurred that would be likely to have caused temporary harm	1		
F: An error occurred that would be likely to have caused temporary harm and prolonged hospitalization	0	Moderate	109
G: An error occurred that would be likely to have contributed to or resulted in permanent harm	0	Severe	10
H: An error occurred that would be likely to have required intervention to sustain life	0		
I: An error occurred that would be likely to have contributed to or resulted in the patient’s death	0	Death	4
Total	216		123

traditional pumps, 16 involved smart infusion devices, and 9 involved gravity administration. In some cases, panel members did not differentiate between standalone smart infusion devices and those linked in a closed-loop manner to an electronic prescribing system.

Of the 33 errors in infusions given using traditional pumps, the majority view of the panel was that 24 (73%) would be preventable using a closed-loop smart infusion device or standalone smart infusion device with suitable limits, and that 9 (27%) would not.

For the 16 errors given via smart infusion devices, the majority view was that 9 (56%) would have been prevented using a closed-loop system; that in 5 (31%) cases, the smart infusion device had no effect in preventing or causing the error; and that in 2 (13%) cases, different limits would have prevented the error. A smart infusion device was considered to have contributed to one

error by one judge, a case involving administration of morphine in the incorrect diluent. In contrast, the research team’s assessment was that 11 (69%) would have been preventable only with a closed-loop system, and that in 5 (31%) cases, the smart infusion device had no effect in contributing or preventing the error.

Of the 9 errors in gravity administrations, the panel’s majority view was that 7 (78%) would have been prevented using a smart infusion device, 1 (11%) would have been prevented with any pump, and 1 (11%) would not have been prevented. The research team’s view was that 6 (67%) would have been prevented by any pump, 1 (11%) would have been prevented with a closed-loop smart infusion device, 1 (11%) was not applicable (an infusion of blood), and 1 (11%) would not have been prevented with any kind of pump.

The level of agreement among the 13 expert panel assessors ranged from 57% to 100% per error; median agreement was 71%. There was 100% agreement among panel members for 6 of the 58 errors given by traditional pumps or gravity as being possibly preventable using a smart infusion device, depending on the drug library limits. Narrative comments added by the expert panelists were mainly statements of assumptions made when assessing preventability. Generally, panelists based their decisions on a “best-case” scenario, that is, that smart infusion devices were set up with optimal limits and functionality, and drew data from the electronic prescribing system. There were contrasting views among panelists about whether smart infusion devices could prevent infusions being given beyond their expiry date and time, or their prescribed duration, or where they were not prescribed at all. All panelists assumed that smart infusion devices were programmable with soft and hard limits and would control the rate of delivery through the library or through linkage with an electronic prescribing system. The panelists also noted that smart infusion devices were unlikely to prevent all infusion errors.

**TABLE 4.** Research team’s Assessment of Likely Preventability of Errors Identified in Infusions That Were Not Given Via a Smart Infusion Device

Preventability Category*	Observed Errors	Reported Errors
	No. errors	
Not preventable	50 (32%)	59 (51%)
Preventable with any pump	21 (13%)	9 (8%)
Possibly preventable with a standalone smart infusion device depending on limits set in drug library	2 (1%)	35 (30%)
Possibly preventable with a smart infusion device integrated with an electronic prescribing and barcode administration system	80 (51%)	9 (8%)
Unable to assess	—	3 (3%)
Not applicable (blood products, or bolus)	4 (3%)	—
Total	157 (100%)	115 (100%)

\*The categorization indicates the minimum level of functionality for preventability with a smart infusion device. For example, for errors classified as “preventable with any pump,” there would be no added value with the other technologies.

**Reported Errors**

After data cleaning, there were 123 NRLS reports relating to errors in drugs given via infusion pumps that were classed as moderate, severe, or resulting in death by those who reported them. Of these, 8 included references to drug libraries or similar, suggesting that they involved smart infusion devices, some of which were patient-controlled analgesia (PCA) pumps; the remaining 115 had no evidence of being given via a smart infusion device.

**TABLE 5.** Examples of Errors Considered to Be Preventable With Smart Infusion Device

Preventability With a Smart Infusion Device	Example
Not preventable	Actrapid (soluble insulin) infusion expired but still running (observational data; category C)
Preventable with any pump	Vancomycin 2 g in 250 mL running faster than recommended rates through gravity feed (observational data; category E)
Possibly preventable with a standalone smart infusion device depending on limits set in drug library	Noradrenaline standard prescription chart specified 4 mg in 50 mL; 8 mg in 50 mL administered (observational data; category D)
Possibly preventable with a smart infusion device integrated with an electronic prescribing and barcode administration system	Piperacillin/tazobactam prescription specified a 3-h infusion due to impaired renal function but the nurses gave it via a bolus dose, which is what they would normally do (observational data; category D)

### Research Team Assessment of Preventability (Reported Errors)

For the 115 errors for which there was no evidence of the infusion being given via a smart infusion device (Table 4), a total of 59 infusions were given via a pump but involved errors that would not be expected to be prevented by a smart infusion device, such as wrong rate errors where the rate was incorrect for that particular patient, but within the usual range for the drug concerned. Nine involved omission errors due to pump unavailability or rate errors in infusions given by gravity and therefore could have been prevented by use of any pump. Thirty-five were judged potentially preventable with a standalone smart infusion device, depending on the limits set in the drug library. A further 9 were potentially preventable with a smart infusion device integrated with an electronic prescribing and barcode administration system in which the smart infusion device rate was set via an electronic prescribing system. In 3 cases, lack of detail or clarity in the incident report meant that we were unable to draw any conclusions.

Of the 8 errors in which it seems that the infusion was given via a smart infusion device, 7 concerned selection of an incorrect entry from the drug library such that the smart infusion device contributed to the error (Table 6). These involved 4 “wrong dose” errors, and 3 “wrong rate” errors. All were reported as resulting in moderate harm. In most cases, it seems that the error occurred due to the interaction between the user and the infusion pump, rather than either alone. In the eighth case, insufficient detail meant that we were unable to assess the case concerned (Table 7).

### DISCUSSION

We explored the role of smart infusion devices in preventing or contributing to errors in intravenous infusions using 2 complementary data sets: directly observed errors in routine clinical practice and review of the more serious errors reported to a national database. The data suggest that, for infusions not given via an infusion device, 13% of errors observed in clinical practice would have been prevented by the use of any pump. An additional 1% could have been prevented by a standalone smart infusion device, whereas a smart infusion device integrated with an electronic prescribing and barcode administration system could have prevented a further 51%. For the more serious errors in the national database, 9% could have been prevented by use of any pump, an additional 30% with a standalone smart infusion device and a further 8% with use of a smart infusion device integrated with an electronic prescribing and barcode administration system. In the few cases where smart infusion devices were used, these contributed to errors in 2 of 58 observed errors and 7 of 8 reported errors. All 9 of these involved programming errors, similar to those reported in the literature,<sup>20</sup> such as mis-selection of the medication, dose, or concentration, and may have been preventable if the smart

infusion device was fully integrated with an electronic prescribing and barcode administration system.

The research team members were more conservative in their assumptions of what a smart infusion device would be able to do in terms of error prevention, whereas the expert panel made more aspirational assumptions. Akin to a sensitivity analysis, if we assume that the reality lies between the 2 extremes, then this suggests that 52% to 73% of the errors that occurred in doses given via traditional infusion pumps could be prevented with an integrated smart infusion device.

Our finding that approximately 1% of errors in observed doses given via traditional infusion pumps or via gravity could be prevented with a standalone smart infusion device is broadly similar to the finding by Husch et al<sup>19</sup> in a U.S. observational study that 1 (0.3%) of 389 errors could be prevented. If the very minor procedural errors are excluded from their data to be more comparable with ours,<sup>12</sup> the findings would be even more similar. We are not aware of any previous studies exploring the potential for integrated smart infusion devices to prevent errors.

Strengths of this study are that we used 2 complementary data sets to allow us to study both the less serious errors identified using observation and the rarer more serious errors reported to a national database. We also had input from a multidisciplinary research team and had external validation of the assessment of the observed data from an expert panel.

There are also a number of weaknesses. First, the underreporting and poor-quality reporting associated with all incident reporting systems mean that it is not possible to draw firm quantitative conclusions from these data. We were also limited by lack of information in many of the reports, which made it difficult to determine exactly what had happened. In particular, very few reports specified that a smart infusion device was used; lack of denominator data means that it is not possible to determine whether errors were less likely to be reported in infusions given via smart infusion device, whether smart infusion devices were not in common use during the period studied, whether some incidents did involve smart infusion devices but this was not specified in the report, or a combination of these. We sought complementary data sets by selecting “moderate” severity errors or above from the reported data. It is possible that preventability may be different for reported errors that were rated less severe or led to no harm. It was also noted that in many cases the researchers questioned the severity rating given by those reporting the error, with nothing in the incident description suggesting actual patient harm for many of the reports. Second, we were not able to perform expert panel assessments of the reported errors due to data protection restrictions around access to these data. A further limitation is that most of the expert panel were at an early stage of smart infusion device implementation and may not have been aware of the full consequences (intended and unintended) of using them in clinical practice. However, as our focus

**TABLE 6.** Summaries of Those Cases Where Smart Infusion Device Use Was Judged to Have Had a Role in Error Causation

Data Source and Number	Error Description and Level of Harm Recorded in Database (Reported Errors) or Judged by Research Team (Observed Errors)
Reported errors (n = 7)	<p>Amiodarone infusion completed 12 h earlier than expected. On investigation, it seemed that the infusion rate had been set for the wrong concentration, amiodarone having been added to a 500-mL bag rather than a 1000-mL bag (moderate severity).</p> <p>Patient-controlled analgesia pump setup. The patient weighed 59.4 kg so choice of bolus dose would have been 0.5 mg morphine. However, the patient had to have 1 mg morphine bolus doses as the pumps did not have this protocol set up in the library. The patient had 52 mg morphine in 8 h and respiratory rate dropped to 5 breaths per minute, requiring naloxone to reverse the effects of the opiate (moderate severity).</p> <p>PCA pump was programmed at 2 mg/1 mL, resulting in the patient receiving a 1 mg bolus of oxycodone every 5 min instead of 2 mg as prescribed (moderate severity).</p> <p>PCA pump incorrectly programmed for pethidine instead of morphine, resulting in wrong dose being received. The patient’s oxygen saturation on air was 81%. Given oxygen and saturation came up to 97% (moderate severity).</p> <p>PCA set up using morphine protocol instead of pethidine. Morphine is given at 2 mg/mL with 1 mg bolus and 5-min lockout. Pethidine is 10 mg/mL with a 10-mg bolus and 5-min lockout (moderate severity).</p> <p>A new infusion of dopamine was started using the drug library. The patient became tachycardic (300 beats/min) and hypertensive, and developed an arrhythmia requiring cardiac massage. On checking the dopamine infusion, it was running at 50 mL/h instead of 5 mL/h as the dose had been programmed on the pump as 9.6 (mg in the syringe) as opposed to 96 (mg in the syringe). The reporter noted that the pump had not alarmed to alert to any problems with dosage (moderate severity).</p> <p>Aciclovir infusion setup. Approximately 10 min later, the patient complained of discomfort at the infusion site. On checking the pump, the nurse found that it was set up for diamorphine and cyclizine instead of aciclovir. This resulted in the rate running at 100 mL/h rather than 2 mL/h (moderate severity).</p>
Observed errors (n = 2)	<p>Two reports in which piperacillin/tazobactam prescription states 30-min infusion. Smart infusion device set at 1 h. Outdated drug library does not allow for 30-min infusion, which is current best practice (category C).</p>

was implementation in the NHS, this group was considered the most appropriate and experienced in the field at the time of the study.

Our data suggest that where infusions are being given via gravity, using any pump will provide considerable safety benefits. The potential benefits of using smart infusion pumps are incremental, with most benefits likely to be accrued from the use of smart infusion devices integrated with electronic prescribing and barcode administration systems. However, there has been little evaluation of such systems to date, and any such recommendations for policy and practice should await further evidence. Benefits are also dependent on the optimal use of smart infusion devices and DERS technology by the end-user; evidence suggests that limited adoption or noncompliance is common<sup>21</sup> and therefore the potential benefits may be overstated. Our data also highlight that use of smart infusion devices can also contribute to errors, particularly where the drug library does not match clinical practice or where there is potential for mis-selection from the drug library. We also found that for half of the reported cases where the smart infusion device contributed to the error, these involved PCAs. This may be reflective of the limited use of smart devices in England and Wales to date for specialist or high-risk medicines.

Controlled studies are now needed to compare the impact on patient care of traditional pumps, standalone smart infusion devices, and integrated smart infusion devices, including any new types of error introduced. Complementary methods that provide a more holistic assessment of high-frequency, low-consequence, and low-frequency and high-consequence errors are necessary to assess the scale of any benefits including the impact on patient harm. Qualitative studies of end-user experiences and work processes could further highlight reasons for workarounds and unintended consequences of the technology.

Although not the focus of our study, feedback from the expert panel and the types of errors observed and reported highlight the

need for further work to consider challenges of building drug libraries including the governance, resource requirements, and associated infrastructure to set up and maintain a drug library. This is consistent with emergent evidence of the complex and interdependent nature of smart infusion device setup and use in practice, and the potential relationship with errors.<sup>22</sup> Human factor research is needed to explore how to minimize the risks of selection errors and the potential implications of alert overload. Improved reporting culture and reporting systems are also required to solicit pertinent information about the device type and configuration to enable in-depth research on human and device interactions.

**TABLE 7.** Likely Role of the Smart Infusion Device for Errors Reported in Infusions Given Via a Smart Infusion Device

Role of Smart Infusion Device	Observed Errors	Reported Errors
	No. Errors	
No effect of smart infusion device in contributing or preventing	8 (14%)	0
Different limits may have prevented the error	1 (2%)	0
Possibly preventable with a smart infusion device integrated with an electronic prescribing and barcode administration system	48 (81%)	—
Smart infusion device contributed to the error	2 (3%)	7 (88%)
Unable to assess	—	1 (12%)
Total	59 (100%)	8 (100%)

## CONCLUSIONS

Our findings suggest that where infusions are being given via gravity, using any pump will provide considerable safety benefits. The potential benefits of using smart infusion pumps are incremental, with most benefits likely to be accrued from the use of smart infusion devices integrated with electronic prescribing and barcode administration systems. However, there has been little evaluation of such systems to date, and any such recommendations for policy and practice should await further evidence. Our data also highlight that use of smart infusion devices can contribute to errors.

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