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SHORT COMMUNICATION

Accidents and Incidents Related to Intravenous Drug Administration: A Pre–Post Study Following Implementation of Smart Pumps in a Teaching Hospital

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Abstract

Introduction Smart pumps are expected to prevent and reduce medication errors. The implementation of smart pumps requires a significant effort and collaboration of physicians, nurses, pharmacists, and other stakeholders.

Objectives The main objective of this study was to evaluate the impact of new smart pumps on reported drug-related accidents and incidents (AIs).

Method This is a descriptive retrospective pre–post study conducted at a women's and pediatric hospital with 500 beds. A strong multidisciplinary team (nurse, pharmacist, pharmacy resident, physician, biomedical technician, information technology technician, patient safety officer, manager) was involved in the planning, implementation, and monitoring technology implementation. A total of 1045 smart pumps were implemented in 2011 in our hospital. The reported number of AIs related to intravenous drug administration (AIIV) before and after the implementation of 1045 smart pumps were collected.

Results A total of 2911 AI events related to medications, devices, and equipment were self-reported by clinical staff in the pre-phase (Y0), 3523 in the post-phase (Y1), and 2788 in the post-phase (Y2). The total AIIV increased from 1432 in Y0 to 1834 in Y1 and decreased to 1389 in Y2.

Conclusions We observed no risk reduction associated with the implementation of smart pumps in a 500 bed mother–child hospital. Further studies are required to explore the details of the potential risk reduction associated with the use of smart pumps.

Key Points

Smart pumps have been designed and commercialized to reduce incidents, but there is still relatively little evidence regarding such risk reductions.

We observed no risk reduction associated with the implementation of 1045 smart pumps.

Further studies are required to explore in more detail the potential risk reduction associated with the use of smart pumps.

1 Introduction

Intravenous drug administration is a riskier route than almost any other used in a hospital setting [1–3]. Risks associated with an intravenous route are also increased in pediatrics due to the dose adjustments required according to weight, height or body surface, and sterile and not sterile compounding [4].

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There are numerous strategies that can contribute to medication error and patient harm risk reduction in the hospital drug-use process [4–10]. These strategies include good clinical practices, adequate training, and the optimal use of technologies. While two literature reviews suggest that smart pumps can contribute to a medication error risk reduction in healthcare settings [4, 6], there are still limited data supporting such a risk reduction in the field [11–20]. Technologies are not free of risk and do create new failure modes [18]. Also, intravenous pump use administration may not be necessary. In that context, Accreditation Canada adopted an organizational practice that requires the documented evidence of ongoing effective training on infusion pumps [21].

Smart pumps have mainly been commercialized in North America in the last decade. Unlike regular infusion pumps, smart pumps use dose error reduction software, which allows hospitals to customize a drug library, concentrations, dosing units, and dosing limits (minimum and maximum soft limits allow the user to bypass the alert messages; minimum and maximum hard limits do not allow the user to bypass the alert messages) [22].

In order to reduce the risks associated with the administration of parenteral drugs, and considering the need to replace the fleet of infusion pumps and mini-infusers at our hospital, we evaluated the impact of new smart pumps on reported drug-related accidents and incidents (AIs). The main objective of this study is to compare the reported number of AIs related to intravenous drug administration (AIIV) before and after the implementation of smart pumps.

2 Methods

This is a descriptive retrospective pre–post study undertaken at a mother–child teaching hospital with 500 beds. The pharmacy department offers a daily unit dose drug distribution from a large centralized intravenous admixture center.

2.1 Implementation of Smart Pumps

In our hospital, a strong multidisciplinary team (nurse, pharmacist, pharmacy resident, physician, biomedical technician, information technology technician, patient safety officer, manager) was involved in the planning, implementation, and follow-up of the technology. The libraries and limits were developed and approved by anesthesia, emergency, obstetrics/gynecology, pediatric critical care, neonatal critical care, and pediatric specialists. Training was provided to everyone in a simulation environment that involved clinical scenarios in the month prior to the go-live. Training covered the expected and appropriate operation of the pump as well as the expected change in practice. Support was offered 24/7 throughout the first 2 weeks. The implementation team met weekly to discuss issues and apply corrective measures.

A total of 1045 smart pumps (~60 % Infusomat® and ~40 % Perfusor Space® from B. Braun, Melsungen, Germany) were implemented in 2011 in our hospital. The implementation included a structured formation with onward support to all nursing staff; a planned standardization of practices and corresponding drug library parameters (adopted by trios of a pharmacist, pharmacy resident, and physician per clinical program) and relevant data; and intranet documentation and tools. The library includes 403 drugs, 283 of which have limits. In terms of bolus, 49 drugs have a quantity of bolus hard limit and 67 have a quantity of bolus soft limit. In terms of continuous dose rate (mg/kg/time), 103 drugs have a hard limit and 259 drugs have a soft limit. In terms of continuous rate (mL/time), 17 drugs have a hard limit and 56 drugs have a soft limit.

The implementation of all smart pumps was realized in a single 10-h shift on 9 November 2011. Clinical support was offered to all nursing staff over several weeks to solve clinical and practical problems. During the study period, drug libraries were reviewed once in order to add new drugs, delete other drugs, and modify some limits. To our knowledge, these minor iterations did not affect the rate of incidents/accidents.

2.2 Pre–Post Study Following Implementation of Smart Pumps

The pre-phase (Y0) was between 10 October 2010 and 5 November 2011 and the post-phase was between 10 November 2011 and 5 November 2012 (Y1) and 6 November 2012 and 5 November 2013 (Y2).

All accidents (i.e., undesired events that have caused personal harm or other damage) and incidents (i.e., undesired event that may cause personal harm or other damage) (AIs) related to drugs, equipment, and devices were extracted from our local registry of AIs and analyzed. AIs were coded by a patient safety officer at the patient safety office in the hospital. AIIV were analyzed for this study. While these events are not specific to the implementation of smart pumps, they were all considered in our analysis as potentially linked to the use of pumps. For each AIIV, we extracted the date, type, description, and severity of the event. The type was coded according a provincial classification adapted from National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) [23]. The severity was coded locally using the NCCMERP classification [24] (see the Electronic Supplementary Material).

Extracted data were further coded using the drug therapeutic classes according to the American Hospital Formulary Service Pharmacologic–Therapeutic Classification System [25].

We compared the total number of AIs, AIIV, categories of events (i.e., drug, equipment, and device), types of events, therapeutic classes involved, and the severity of each event between both phases. We also analyzed and estimated the proportion of AIIV related to intermittent and continuous parenteral drug infusion. Data were extracted in a spreadsheet format (MS Excel®, Microsoft, Seattle, WA, USA). Proportions were compared with a Chi-square test. A p value below 0.05 was considered statistically significant.

3 Results

3.1 Number of Events

A total of 2911 AI events related to medication, devices, and equipment were self-reported by clinical staff in the pre-phase (Y0), 3523 in Y1, and 2788 in Y2.

The total AIIV increased from 1432 in Y0 to 1834 in Y1 ($p = 0.023$) and was reduced to 1389 in Y2 ($p = 0.652$). We observed a 28 % increase in AIIV in the first year post-implementation of smart pumps (Y1) and a downward correction to 3 % in the second year post-implementation (Y2) compared with the pre-implementation data (Y0).

3.2 Categories of Events

Table 1 shows the profile of AIIV by category. Drug-related events represent the majority of the events reported by the clinical staff. At the same time, equipment-related events also went from an absolute number of 8 in Y0, to 92 in Y1, and 55 in Y2.

3.3 Type of Events

Table 2 shows the detailed profile of AIIV. Equipment-related events cannot be described with further details due to the current classification of events. Most events are related to malfunction or misuse of the equipment.

3.4 Therapeutic Classes Involved in Events

Table 3 shows the profile of AIIV by therapeutic class. The majority of drug-related events involved electrolytic, caloric, and water balance agents. There were no important therapeutic class differences between the pre- and post-phases.

3.5 Severity of Events

Table 4 shows the profile of AIIV per severity score according the NCCMERP. No deaths related to AIIV were observed in any of the three phases. The initial increase in events may be associated more with the technological change than the technology itself.

4 Discussion

In 2014, if a hospital wants to replace its existing inventory of infusion pumps it has to purchase smart pumps, which is why the majority of American and Canadian hospitals report the use of smart pumps. Pedersen et al. reported that 77 % of American hospitals were using smart pumps in 2012 compared with 32 % in 2005 [26]. In a Canadian survey, the use of smart pumps was reported by 75 % of respondents in 2011–2012 compared with 61 % in 2007–2008 [27, 28].

While smart pumps have been designed and commercialized to reduce AIs for a decade, there is still relatively

Table 1 Accidents and incidents related to intravenous drug administration by category

Categories	Pre-phase Y0 [*n* (%)]	Post-phase Y1 [*n* (%)]	Post-phase Y2 [*n* (%)]	*p* value (Y0 vs. Y1)	*p* value (Y1 vs. Y2)	*p* value (Y0 vs. Y2)
Drug-related events	1187 (83)	1432 (78)	1108 (80)	0.001	0.258	0.034
Device-related events[a]	237 (17)	310 (17)	226 (16)	0.813	0.667	0.879
Equipment-related events[b]	8 (<1)	92 (5)	55 (4)	<0.001	0.173	<0.001
Total	1432 (100)	1834 (100)	1389 (100)	NA	NA	NA

NA not applicable, *Y0* Year 0 (pre-phase, 10 October 2010–5 November 2011), *Y1* Year 1 (post-phase, 10 November 2011–5 November 2012), *Y2* Year 2 (post-phase, 6 November 2012–5 November 2013)

[a] Event relating to the use of the pump itself

[b] Event relating to the use of equipment such as tubing

Table 2 Detailed profile of accidents and incidents related to intravenous drug administration

Types of accidents and incidents	Pre-phase Y0 [*n* (%)]	Post-phase Y1 [*n* (%)]	Post-phase Y2 [*n* (%)]	*p* value (Y0 vs. Y1)	*p* value (Y1 vs. Y2)	*p* value (Y0 vs. Y2)
Drug						
Any types intercepted before administration	103 (7)	97 (5)	69 (5)	0.027	0.748	0.015
Wrong drug	186 (13)	245 (14)	194 (14)	0.795	0.641	0.0473
Wrong flow	178 (12)	220 (12)	178 (13)	0.706	0.482	0.734
Infiltration[a]	117 (8)	248 (14)	165 (12)	<0.001	0.183	0.001
Drug not administered	197 (14)	200 (11)	141 (10)	0.015	0.525	0.004
Wrong dose	87 (6)	122 (7)	78 (6)	0.518	0.239	0.631
Wrong administration technique	37 (3)	75 (4)	69 (5)	0.020	0.263	0.001
Wrong schedule (timing error)	56 (4)	48 (3)	51 (4)	0.044	0.099	0.768
Expired drug used	60 (4)	42 (2)	50 (4)	0.002	0.032	0.438
Others	70 (5)	41 (2)	24 (2)	<0.001	0.376	<0.001
Wrong drug concentration	27 (2)	32 (2)	21 (2)	0.792	0.676	0.470
Incompatibilities	15 (1)	22 (1)	20 (1)	0.741	0.639	0.397
Discontinued drug	23 (2)	14 (<1)	16 (1)	0.030	0.271	0.336
Wrong route	22 (2)	8 (<1)	16 (1)	0.001	0.023	0.417
Contraindicated drug used	9 (<1)	18 (<1)	14 (1)	0.332	1.000	0.299
Allergy	0 (0)	0 (0)	2 (<1)	NA	NA	NA
Device						
Break	182 (13)	238 (13)	188 (13)	0.833	0.674	0.540
Others	19 (1)	27 (1)	11 (<1)	0.767	0.098	0.200
Administration problem	13 (<1)	25 (1)	10 (<1)	0.253	0.088	0.677
Installation of supply/equipment	4 (<1)	7 (<1)	7 (<1)	0.765	0.602	0.380
Intervention parents	1 (<1)	0 (0)	5 (<1)	NA	NA	0.119
Wrong utilization	6 (<1)	13 (<1)	5 (<1)	0.356	0.236	1.000
Not available	10 (<1)	0 (0)	0 (0)	NA	NA	NA
Cleaning disposable material not available	2 (<1)	0 (0)	0 (0)	NA	NA	NA
Equipment-related events	8 (<1)	92 (5)	55 (4)	<0.001	0.173	<0.001
Total	1432 (100)	1834 (100)	1389 (100)	NA	NA	NA

NA not applicable, *Y0* Year 0 (pre-phase, 10 October 2010–5 November 2011), *Y1* Year 1 (post-phase, 10 November 2011–5 November 2012), *Y2* Year 2 (post-phase, 6 November 2012–5 November 2013)

[a] Unintended iatrogenic leakage of fluids from intravenous drug delivery procedures

little evidence about such a risk reduction. In a literature review completed in October 2014, we found no meta-analyses, two systematic reviews, and three literature reviews dealing with the effectiveness of smart pumps [4, 9, 29–31]. No published study was able to demonstrate a significant risk reduction associated with the implementation of smart pumps. In 2014, Ohashi et al. [29] indicated that "smart pumps reduce but no not eliminate programming errors." In 2012, Benoit and Beney [8] indicated that "available studies do not have the sufficient power to demonstrate the benefits", Hertzel and Sousa [30] mentioned that "well designed research is still lacking," and Conroy et al. [4] indicated that "there is insufficient information to draw a conclusion because of a lack of research". In 2012, Scanlon [32] proposed some reasons to explain the limited benefits of smart pumps, including "poor design leading to usability issues including programming errors, varying degrees of end-user acceptance, and their contingent nature".

Clinical staff will experience a learning curve and people might be more prone to reporting difficulties related to the AIIV when such a major change is implemented in a hospital. It is important to note that we encountered air bubble formation in the tubing mainly in the first year; such an issue could have contributed to the increase of AIIV, but most events were dealt with by the implementation committee via

Table 3 Profile of accidents and incidents related to intravenous drug administration by therapeutic class

Therapeutic class[a]	Pre-phase Y0 [*n* (%)]	Post-phase Y1 [*n* (%)]	Post-phase Y2 [*n* (%)]	*p* value (Y0 vs. Y1)	*p* value (Y1 vs. Y2)	*p* value (Y0 vs. Y2)
Electrolytic, caloric and water balance	616 (43)	850 (46)	664 (48)	0.060	0.413	0.011
Unidentified	189 (13)	313 (17)	243 (18)	0.002	0.778	0.002
Anti-infective agents	250 (17)	252 (14)	185 (13)	0.004	0.755	0.002
Central nervous system drugs	121 (8)	149 (8)	93 (7)	0.749	0.138	0.088
Gastrointestinal drugs	41 (3)	37 (2)	41 (3)	0.133	0.105	0.911
Hormones	60 (4)	50 (3)	38 (3)	0.024	1.000	0.039
Antineoplastic agents	32 (3)	56 (3)	32 (2)	0.158	0.230	1.000
Blood formation and coagulation	38 (3)	28 (1)	29 (2)	0.024	0.280	0.387
Immunosuppressive agents	20 (1)	19 (1)	21 (1)	0.417	0.261	0.875
Autonomic drugs	29 (2)	20 (1)	12 (<1)	0.041	0.593	0.011
Cardiovascular drugs	14 (<1)	22 (1)	12 (<1)	0.614	0.389	0.845
Oxytocics	6 (<1)	6 (<1)	9 (<1)	0.774	0.201	0.447
Serums, toxoids, vaccines	4 (<1)	13 (<1)	3 (<1)	0.139	0.073	1.000
Vitamins	1 (<1)	4 (<1)	3 (<1)	0.393	1.000	0.367
Enzymes	0 (0)	1 (<1)	1 (<1)	NA	1.000	NA
Expectorants and cough preparations	1 (<1)	3 (<1)	1 (<1)	0.636	0.639	1.000
Anesthetics	0 (0)	0 (0)	1 (<1)	NA	NA	NA
Antihistamines	10 (<1)	8 (<1)	1 (<1)	0.347	0.087	0.012
Blood derivatives	0 (0)	3 (<1)	0 (0)	NA	NA	NA
Total	1432 (100)	1834 (100)	1389 (100)	NA	NA	NA

NA not applicable, *Y0* Year 0 (pre-phase, 10 October 2010–5 November 2011), *Y1* Year 1 (post-phase, 10 November 2011–5 November 2012), *Y2* Year 2 (post-phase, 6 November 2012–5 November 2013)

[a] Drug therapeutic classes according to the American Hospital Formulary Service Pharmacologic–Therapeutic Classification System: electrolytic, caloric and water balance (40.00); anti-infective agents (8.00); central nervous system drugs (28.00); gastrointestinal drugs (56.00); hormones (68.00); antineoplastic agents (10.00); blood formation and coagulation (20.00); immunosuppressive agents (92.00); autonomic drugs (12.00); cardiovascular drugs (24.00); oxytocics (76.00); serums, toxoids, vaccines (80.00); vitamins (88.00); enzymes (44.00); expectorants and cough preparations (48.00); anesthetics (72.00); antihistamines (4.00); blood derivatives (16.00)

audits, clinical tests with different tubing, and biomed team collaboration with very few written reports.

New healthcare technologies can create new opportunities for harm, and the Emergency Care Research Institute publishes an annual list of such health technologies. In their 2013 edition, the top two hazards were medication administration errors using infusion pumps and alarm hazards in which caregivers can become overwhelmed trying to respond to alarms or where they can become desensitized to alarms. Some articles shed light on the challenges and difficulties facing hospitals and clinicians to achieve the promises of smart pumps [18, 33–37]. A single intervention can rarely have a significant impact on complex processes. For instance, Husch et al. [18] reported that 97 % of errors related to continuous intravenous drug administration or intravenous fluid administration cannot be intercepted by smart pumps as these errors fall within soft implemented limits. Therefore, our study, like most studies already published, cannot demonstrate and support any risk reduction associated with smart pumps based on our voluntary reporting system of related AIs.

Trbovich et al. [38, 39] surveyed Canadian hospitals that had either implemented smart pump systems or were in the process of implementing them. They showed that one of the main reasons hospitals purchased smart pumps was because non-smart pumps were no longer available on the market. However, the hospitals did not involve a multidisciplinary team during implementation, made little effort to standardize drug concentrations or develop drug libraries and dosing limits, seldom monitored how nurses use the -pumps, and failed to ensure wireless connectivity to upgrade protocols and download use data. They conclude that these hospitals are failing to realize the safety benefits these systems can provide [38, 39].

Table 4 Profile of accidents and incidents related to intravenous drug administration per severity score according the National Coordinating Council for Medication Error Reporting and Prevention

Severity score according to NCCMERP	Pre-phase Y0 [*n* (%)]	Post-phase Y1 [*n* (%)]	Post-phase Y2 [*n* (%)]	*p* value (Y0 vs. Y1)	*p* value (Y1 vs. Y2)	*p* value (Y0 vs. Y2)
Incidents						
A	81 (67)	92 (5)	45 (3)	0.432	0.017	0.003
B	147 (10)	189 (10)	89 (6)	1.000	<0.001	<0.001
Subtotal: incidents	228 (16)	281 (15)	134 (10)	0.662	<0.001	<0.001
Accidents						
C	851 (59)	1069 (58)	923 (67)	0.519	<0.001	<0.001
D	298 (21)	311 (17)	149 (11)	0.006	<0.001	<0.001
E1	47 (3)	163 (9)	172 (12)	<0.001	0.002	<0.001
E2	8 (<1)	8 (<1)	11 (<1)	0.624	0.246	0.496
F	0 (0)	2 (0.11)	0 (0)	NA	NA	NA
Subtotal: accidents	1204 (84)	1553 (85)	1255 (90)	0.662	<0.001	<0.001
Total	1432 (100)	1834 (100)	1389 (100)	NA	NA	NA

NA not applicable, *NCCMERP* National Coordinating Council for Medication Error Reporting and Prevention, *Y0* Year 0 (pre-phase, 10 October 2010–5 November 2011), *Y1* Year 1 (post-phase, 10 November 2011–5 November 2012), *Y2* Year 2 (post-phase, 6 November 2012–5 November 2013)

In our study, a strong multidisciplinary team and a structured process certainly contributed to the success of the implementation, which was realized in a single 10-h period with sustained patient care unit support in the following weeks. We believe our implementation was optimized and our clinical staff were well supported.

We hope to achieve some gain in risk reduction with the implementation of the Wi-Fi bidirectional interface in the next year. In the 2011–2012 *Hospital Pharmacy Report in Canada*, only 24 % of respondents using smart pumps reported that they used a wireless network to upload and download data to smart pumps, but 58 % reported that they review and update the pump libraries at least annually [27]. In our case, we expect to complete the implementation (early 2015) of the current version of the firmware/software that manages the drug library and user data with a bidirectional interface for wireless updates of the drug library and the ability to run regular audits to identify adjustments that will maximize security and limit false positives.

While we did not observe a risk reduction of AIIV after 2 years post-implementation (the use of incidents/accidents reports is not designed to specifically measure the impacts of a new technology), we believe our project was successful and did contribute to an efficient and safe switch from one technology to another. AIIV represents a proxy measure of risk. To define the impact of smart pumps in more detail, other studies should be conducted. For instance, the analysis of smart pump data extracted from the Wi-Fi interface might contribute to identifying near-miss serious errors that could be intercepted by the drug library and software tool provided by these pumps. Moreover, risk managers are now more sensitive to AI related to specific technologies.

This descriptive study has some limitations. For instance, it uses the incident/accident reports, and such reports have been found to under detect and are associated with under-reporting of adverse events. Also, this study does not evaluate the quality of data reported, collected, and codified in the local registry by risk managers. Data are self-reported by clinicians in a standardized form that does not allow a very detailed description of events. An unknown but certainly important proportion of reports have been coded a posteriori without any prospective discussion with involved staff. Also, several factors may influence the quality of the data collected in this study, including the risk of duplicates, the risk of false events (i.e., not an AI according to the current legal applicable definition), and the risk of wrong codifications by risk managers. It is also very difficult to compare our results with the current literature, knowing that both definitions and codifications of drug, device, and equipment events/errors used in other studies vary according to countries or healthcare settings. It is also important to note that the current local classification has not been developed to closely measure the impact of a new technology implementation to date, while most events are drug related and not equipment related. We made the choice to include all intravenous AIs as a global proxy measure of the impact of new equipment in that context. However, smart pumps, or any kind of pumps, cannot reduce all AIs, as many drug doses are given intravenously without the use of such equipment. In future studies, we may also select more outcome indicators to evaluate the introduction of smart pumps,

such as cost change, nurse satisfaction, and workload change. Finally, AI reporting mechanisms are not designed to evaluate users' satisfaction.

5 Conclusion

We observed no risk reduction associated with the implementation of 1045 smart pumps in a 500 bed mother–child hospital. Self-reported AIIV increased significantly from 1432 in the pre-phase to 1834 in the first year and were reduced to 1389 in the second year. Further studies are required to explore in more detail the potential risk reduction associated with the use of smart pumps.

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Competing interests Aurélie Guérin, Julien Tourel, Emmanuelle Delage, Stéphanie Duval, Marie Johanne David, Denis Lebel, and Jean-François Bussières have no conflicts of interest that are directly relevant to the content of this study.

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