11-1-2018

Implementation of Smart Pump Technology With Home Infusion Providers: An Assessment of Clinician Workflow and Patient Satisfaction.

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ABSTRACT

While hospitals have adopted smart pump technology (SPT) featuring drug libraries and medication safety software, most home infusion providers (HIPs) continue to use traditional infusion pumps that don't offer drug libraries or medication safety software. As infusion delivery is moving from the hospital to the home, the purpose of this study was to determine whether SPT was a feasible alternative at both a hospital-based and a rural HIP. HIP personnel were trained on an ambulatory infusion pump. Patients requiring home infusion used the pump and recorded daily pump interactions for 5 to 7 days. After the creation of a drug library, clinicians felt comfortable programming pumps after 7 uses. Patients reported 100% overall satisfaction, and the majority of alarms were resolved without contacting the HIP. Ambulatory SPT can be implemented successfully by HIPs and can be used effectively by patients.

Key words: ambulatory infusion, CADD, drug library, home infusion, medication safety software, smart pump

The ability of patients to receive intravenous infusions in a home setting has been an option for patients in the United States since the 1980s. The use of home infusion will continue to expand in response to the needs of an aging population, further adoption of outpatient surgical procedures, and the push to reduce health care costs. This shift is being accelerated as a result of compressed reimbursement and incentives to reduce hospital length of stay. Infusions in alternative sites are estimated to represent approximately $9 billion to $11 billion each year in US health care expenditures.[1] Although much of the current home infusion literature focuses on postoperative pain management, the backbone of the home infusion business remains hydration, antibiotic delivery, and parenteral nutrition (PN), with treatments also including inotropes, chemotherapy, and immunoglobulin therapy.[2-7] Infusion delivery has moved from the hospital to the home not only in the United States but also across the world, demonstrating cost savings and improving patients' quality of life.[8,9]

Although hospitals have adopted pumps with drug libraries and medication safety software, ie, smart pumps, most home infusion providers (HIPs) continue to use traditional infusion pumps that don't have drug libraries or medication safety software. Smart pumps are used ideally when an accurate and controlled rate of infusion is required, such as with chemotherapy (eg, fluorouracil [5-FU] or PN). However, questions remain about the amount of work and value smart pump technology (SPT) brings to HIPs and whether patients will be able to use the devices independently. A device with the potential to increase the safety of infusions, while at the same time decreasing home care visits or calls, would improve the efficiency of the HIP's

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The authors of this article have no conflicts of interest to disclose.

Open access funding provided by Smiths Medical. Mary Ward of Smiths Medical provided communication support for the author team but did not contribute to authorship of this article.

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DOI: 10.1097/NAN.0000000000000302

operations significantly, but only if patients accepted the device.

The purpose of this study was to determine whether SPT is a feasible alternative (versus manual pump programming) to previously used, traditional "dumb" ambulatory infusion pump technology, in both large, urban hospital-based HIPs and in small rural HIPs, by evaluating the implementation and satisfaction of clinicians in the HIP, as well as patient feedback on pump use and performance in the home.

METHODS

Study Design

This study was a prospective, dual-center, single-arm, postmarket study conducted in the United States in accordance with the ethical standards of the governing institutional review board (IRB) (ClinicalTrials.gov identifier NCT01997099). There were 2 independent phases of the study, conducted consecutively at each HIP. Following IRB approval of both phases, HIP clinicians were trained on a new ambulatory smart pump and medication safety software (CADD-Solis VIP; Smiths Medical, Minneapolis, MN).

Phase 1 consisted of data collection to describe the process that was used to introduce SPT to home health care organizations. Phase 2 included pump interaction and satisfaction data collection from patients who received home infusion therapy with a smart pump.

For phase 1, clinicians documented details of their training, drug library creation, pump data entry, and validation efforts. Each staff member performed 10 scenarios simulating pump programming, using the completed library, and assessed pump programming efforts.

The urban HIP trained patients how to use the pump, and clinicians subsequently answered questions about the implementation and patient training process. Both HIPs then assessed their overall workflow changes and evaluated the new system.

The objectives of phase 1 were to characterize the effort required to create a new protocol library and the ease of use associated with programming the pump; summarize and describe any possible programming errors; assess the home health nurses' perceptions of patient training and device setup in the home; and evaluate the needed organizational workflow changes when adopting the new system.

In phase 2, patients were enrolled if they required home infusion for at least 5 days and had no previous experience with the study device. Patients had to be 18 years of age or older. The study was conducted between February 2014 and June 2014 for the first site and January 2015 to October 2015 for the second. Patients' personal caregivers (PCGs) who were primarily responsible for device interaction were allowed to enroll patients and agreed to comply with the data collection requirements. Patients or their PCGs, referred to hereafter as *patients,* recorded pump interaction details for 5 to 7 consecutive days after the infusion began. Patients were allowed to provide free-text feedback, and they completed a questionnaire on their interaction.

The patients were called 24 to 96 hours after the infusion began to confirm pump diary completion and again at 7 to 10 days to answer questions about overall satisfaction with the pump and to confirm the return of the pump diary.

The primary objective of phase 2 was to assess the overall satisfaction of patients, as rated on a 6-point Likert scale, at the end of the study follow-up visit. Patients' experiences were prospectively considered a success if the overall satisfaction with the pump was rated as *somewhat agree* or better and is represented as a proportion of successful patient experiences to all patients enrolled. Secondary objectives of this phase were to summarize the number of alarms reported, quantify the ability of the patients to troubleshoot the alarms successfully without contacting the home health care provider, summarize any difficulties experienced with use of the device, and characterize the ease of use of the pump's various features, as reported on a 6-point Likert scale.

Statistical Analyses

Formal hypothesis testing was not planned or completed for this study. Descriptive statistics were used to summarize data from all clinicians and patients for each phase of the study. Because of the different HIP sizes and the types of patients they served, phase 1 data were evaluated individually for each HIP. For quantitative variables, N (total sample size), mean, median, standard deviation, minimum, maximum, and range were reported. For qualitative variables, frequency and percentage were reported.

RESULTS

Phase 1

The clinicians who participated in the study and evaluated the system implementation had varying experience in the home infusion profession and were either pharmacists or nurses.

Library creation: large, urban hospital-based HIP

Three clinical pharmacists championed an infusion implementation team, and each spent 9 hours completing online training modules and in-person software and pump training sessions by the device manufacturer. The team began the library creation process by choosing general pump settings after physically testing and observing the actual pump. Protocol template settings were then selected based on the HIP's preferences, being mindful of the specific population served and the therapies typically provided. Example protocols were created to help determine the best way to describe and develop the qualifier and drug name descriptions in the drug library.

To begin the actual library creation process, continuous and intermittent therapies were created first, since concentrations

and the compounding of these medications typically do not change, and it was easiest to transition the familiar standards into the library. PN was approached next, with the protocol qualifier based on a volume range, drug name, and infusion duration.

The team then created step therapy, which was designed based on branded dosing recommendations and rate increment increases. The qualifiers were chosen as weight (10-kg weight range), and the drug name was the branded product and concentration. Patient-controlled analgesia (PCA) protocols were the last created, and the team used broad programming (eg, hydromorphone 2 mg/mL with a hard upper limit of 200 mg/h) because hospice patients were primarily served. This approach allowed a balance between the need to titrate doses versus the need to have hard maximums.

The team created 266 protocols for the drug library over the course of 6 business days, spending a total of 27 hours on the process (Table 1). The team had a pharmacy resident spend 17.5 hours entering the protocols into the safety software and another 7.5 hours performing validation activities to ensure the accuracy and completeness of the protocols.

Library creation: small rural HIP

Two nurses and 1 pharmacist participated in the library creation process for site 2, reporting an average training time of 7.8 hours each, which included online modules and in-person training by the manufacturer. The team created a total of 12 protocols for its library in a total of 8 man-hours over 2 business days (Table 1). The first step for the team was to document a brief overview of the facility's current workflow, after which it was determined that a template library for each therapy type would be created, but without defining the drug, qualifier, or specific safety limits. After the 5 templates were completed, individual protocols were created and references consulted.

TABLE 1

Drug Library Creation Efforts

Criteria	Large, Urban Hospital-based HIP	Small Rural HIP
Participants	3 clinical pharmacists	2 nurses 1 pharmacist
System training time (mean)	9 h per person	7.8 h per person
Number of protocols created	266	12
Protocol creation time	27.0 h	3.5 h
MSS entry time	17.5 h	3.5 h
Validation time	7.5 h	1.0 h
Business days spent working on library	14	2

Abbreviations: h, hour(s); HIP, home infusion provider; MSS, medication safety software.

Continuous infusions are the most common infusions at the site and were created first. For continuous infusions, the following qualifiers were used: 44h, 5-FU; 46h, 5-FU; 48h, 5-FU; hydration, 0.9% sodium chloride; nafcillin; Ancef (cefazolin). The next delivery mode selected was PCA. The 2 qualifiers were PCA naive and tolerant. These infusions were rarely administered, so the site used previously used rates and concentrations.

Intermittent and step therapies on electronic ambulatory pumps were not common at the site and were approached next. Previously used infusion rates and concentrations were used for the protocols. Finally, taper delivery mode for PN was examined. The HIP used a few sets of safe parameters in the template to be able to check volume and dose. A wide range was given to accommodate various infusion rates, and orders and all qualifiers were labeled PN 12 hour.

Pump programming and implementation evaluation

Once the library had been completed at both HIPs, clinicians (N = 13) completed a total of 130 pump programming scenarios, using historical patient orders from the HIPs. Seven programming errors (5.4%) were reported during the validation review (during the second pharmacy review): 3 related to the programming of the reservoir volume; 1 had an incorrect PCA lockout time; 1 had the maximum doses per hour for a PCA order; 1 had an incorrect infusion duration; and 1 did not use the drug library that was downloaded on the pump, because the pump was programmed manually. Clinicians rated the ability to view the pump status and view and adjust parameters on 1 screen as the most beneficial features of the pump. They reported with 99.2% (129/130) agreement that the pump was easy to program, and on average, they were comfortable with programming the device after an average of 6.85 uses.

Five clinicians at site 1, the large urban hospital-based HIP, subsequently performed a total of 28 implementations for the HIP's teaching evaluations on patients requiring infusions with continuous (n = 1), intermittent (n = 13), and taper (n = 14) therapy types. The mean training time per patient was approximately 40 minutes, with patients having an excellent (n = 13), good (n = 14), or fair (n = 1) understanding of the pump at the end of the sessions. Priming the pump was reported as the easiest feature to train on, and the most difficult was reported as resetting the reservoir volume. Pump features that clinicians consistently rated highest were the ability to view the pump status and the size of the pump screen. Clinicians reported that they were comfortable and confident training with the new pump after an average of 2 implementations.

Phase 2

A total of 42 patients were enrolled in the study across both sites, with a broad representation of ages, genders, and levels of experience with ambulatory infusion pumps (Table 2). All patients reported no hearing impairment;

TABLE 2

Patient Demographics

Characteristics	N = 42
Age (years)	
Mean (SD)	58.4 (13.3)
Median (min, max)	59 (24, 77)
Gender	
Female	21/42 (50.0%)
Male	21/42 (50.0%)
Experience using an ambulatory infusion pump?	
Yes	14/42 (33.3%)
No	28/42 (66.7%)
Patient's/caregiver's level of understanding of the training instructions	
Excellent	20/41 (48.8%)
Good	16/41 (39.0%)
Fair	5/41 (12.2%)
Therapy	
Taper	24/42 (57.1%)
Intermittent	12/42 (28.6%)
Continuous	6/42 (14.3%)
Disposable used	
Administration set	31/42 (73.8%)
Cassette	11/42 (26.2%)
Air-in-line sensitivity	
High	0/0 (0.0%)
Low	28/42 (66.7%)
Off	14/33 (33.3%)

Abbreviations: max, maximum; min, minimum; N, total participants; SD, standard deviation.

42.9% (18/42) required glasses for vision impairment, and 7.1% (3/42) reported decreased finger dexterity that could have an effect on pump interactions. An infusion nurse provided the patient or caregiver with pump training, including training with the pump's help screens and pump operation. All infusions were delivered intravenously (88.1% [37/42] by means of a peripherally inserted central catheter; 11.9% [5/42] via an implanted port). The types of infusions delivered were taper, intermittent, or continuous, using either an administration set (73.8%) or cassette (26.2%) and an air-in-line sensitivity feature set to either low or off (Table 2). Drugs administered for the taper therapy were all PN infusions. Intermittent therapies were primarily penicillin, Unasyn, nafcillin, or piperacillin/tazobactam, and the continuous infusions were milrinone (n = 1), Ancef (n=5), and 5-FU (n = 1).

Forty of the 42 patients (95.2%) completed the end-of-study visit form and contributed to the primary objective of assessing overall patient satisfaction. All experiences were successful, with each patient (100%) reporting overall satisfaction with the pump as *somewhat satisfied* or better (Figure 1).

Pump diaries were returned from 39 patients reporting experiences from 265 total pump use days. A total of 152 alarms were reported on 106 pump days from 28 of the 39 patients (71.8%). Alarms were not predefined, and patients reported the presence of alarms differently. Some considered any notification from the pump as an alarm (eg, infusion complete), while others only reported alarms that had an impact on therapy delivery. A breakdown of the alarm types and frequencies is presented in Table 3. *Infusion complete* notifications comprised 34.2% (52/152) of the total alarms reported. Of the 51 high-priority alarms reported, 39 were the result of occlusion with 17 downstream (43.6%), 12 upstream (30.8%), and 7 not specified (17.9%). One patient reported experiencing 10 downstream occlusion alarms in the same day. All 3 system fault alarms were resolved by the patients after removing and restoring the same batteries.

Patients reported on a daily basis, not per alarm, if they contacted the HIP for pump troubleshooting. Of the 106 days when alarms were reported, patients were able

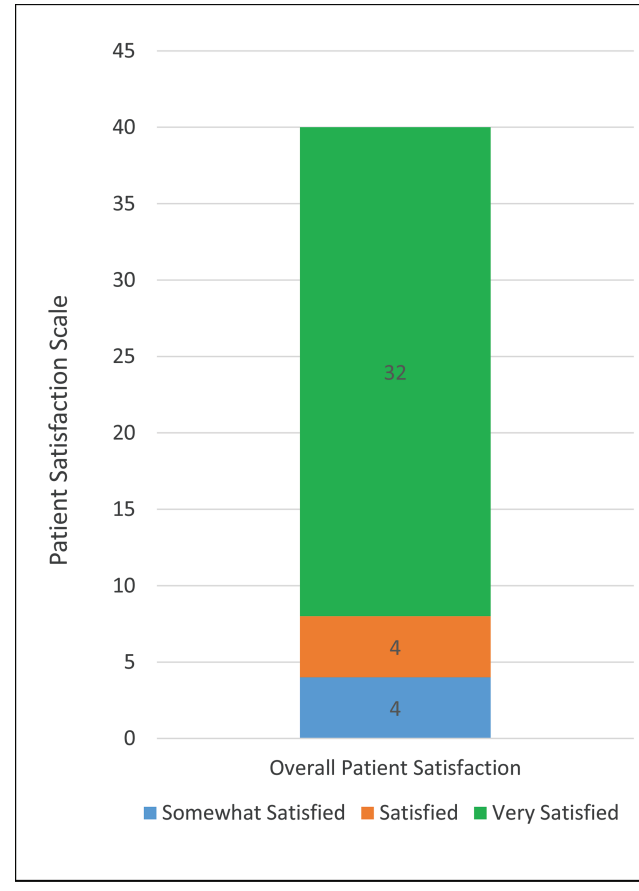

Figure 1 Forty of the 42 patients enrolled in the study (95.2%) completed the end-of-study visit form and contributed to the primary objective of assessing overall patient satisfaction. The 40 completed end-of-study visit forms indicated that experiences were successful, with each respondent patient reporting overall satisfaction with the pump as *somewhat satisfied* or better.

TABLE 3

Alarms Experienced by Patients

Alarm Type	Alarms Reported N = 152
Low priority	
Pump not started	2
Infusion completed	52
Low battery	6
Medium priority	
Low reservoir	28
Pump unable to be started without latched and locked cassette	13
High priority	
Occlusion	39
Air in line	9
System fault	3

to resolve the alarms successfully without contacting the HIP 86.8% of the time (92 days). Of the 14 days when the HIP was contacted about an alarm, a total of 17 alarms were reported: air in line (5), occlusion (4), other (2), low reservoir (1), starting pump (1), infusion complete (2), system error (1), and high pressure (1). Of the 92 days with alarms that did not require the patient to contact the HIP, patients were asked to rate the ease of resolving the alarm independently and indicate whether they used the help screens to resolve the issue. Of the questions answered, 79/81 (97.5%) rated the ease of resolving the alarm as easy, and 38/82 (46.3%) used the pump help screens.

Table 4 describes patient-reported device difficulties. Fourteen of the 39 (35.9%) patients reported experiencing device difficulties on 23 days (8.7%). Of the areas of difficulty reported, stopping alarm(s) and starting or restarting the pump were most common. Despite reporting difficulties with the pump on 23 days, the patients still reported satisfaction with the device on 99.6% of all the device-use days.

Patients were also asked to rate 14 overall "ease-of-use" statements related to their handling of the pump and reported 100% agreement with 10 statements and 94.3% to 97.5% with 4 statements. All but 1 patient (97.5%) agreed they would recommend the pump to others who needed home infusion therapy.

TABLE 4

Patient-Reported Device Difficulties

Measure	N = 265 Pump Use Days (% Infusion Days)
Daily device or component difficulties reported	23/265 (8.7%)
Patients with device or component difficulties	14/39 (35.9%)
Area of difficulty	n = 23 areas of difficulty[a]
Stopping alarm(s)	8/25 (32%)
Starting or restarting pump	5/25 (20%)
Changing bag, tubing, cassette	3/25 (12%)
Stopping the pump	2/25 (8%)
Resetting infusion volume	2/25 (8%)
Priming tubing	2/25 (8%)
Changing or charging batteries	2/25 (8%)
Volume of infusion "complete" tone too soft	1/25 (4%)
Daily satisfaction with pump	n = 258 responses
Very satisfied	209/258 (81%)
Satisfied	42/258 (16.3%)
Somewhat satisfied	6/258 (2.3%)
Dissatisfied	1/258 (0.4%)

[a]Patients may have reported more than 1 area of difficulty per day.

DISCUSSION

Medication errors can be a serious issue, and hospitals have been working on protocols to reduce their occurence.[10] SPT features drug libraries and medication safety software that have been developed to reduce medication errors.[11] While hospitals have adopted SPT, most HIPs are still using traditional infusion pumps that do not use drug libraries or medication safety software. This study indicates that SPT could be applicable in large urban and in rural HIPs. SPT in HIPs positively had an impact on pump programming, clinician workflow, and ease of use for patients in their homes.

The first step in the implementation of smart pumps was the creation of drug libraries. During this step, several improvement opportunities were identified, including tremendous variation in prescription labels for the same therapies and a lack of standardized concentrations. These were seen with both taper therapies and step therapies. With taper therapies, there was concern about ensuring that correct volume and duration were programmed. With step therapy, it was cumbersome to address specific disease-state dosing when there were different dosing parameters for different diagnoses, eg, chronic inflammatory demyelinating polyneuropathy versus primary immunodeficiency for Gamunex. In these cases, the more conservative dosing regimen prevailed. Package inserts were also used to determine protocol parameters, such as initial, maintenance, and maximum infusion rates. A standardization project was initiated to address the deficiencies noted, resulting in the creation of standard labels and the adoption of standardized concentrations.

The smart pump software encouraged the standardization of drug concentrations and prescription labels, and streamlined the pump distribution process. These

measures suggest a decreased risk of pump programming errors by eliminating the need to program manually or to copy from previous patients. Additional studies are needed to demonstrate an impact of these measures on drug programming error rates. Building a library is an investment of time and resources that can save time and increase safety in the long term. The financial effects of standardization were outside the scope of this study but should be considered for potential cost savings and improved risk management.

The user interface of the pump was robust and had a positive impact on the clinician's ease of use. The increased ease of use may have a direct impact on the ease in patient teaching, as reflected by 100% of clinicians reporting that it is easier to teach how to use a smart pump than other infusion pumps. The use of drug libraries minimizes the need for clinicians to learn extensive pump programming. This allows for increased focus on fewer tasks, such as confirming settings with the drug label, and leads to improved patient safety. It is anticipated that this robust user interface will facilitate the education of external or partner nursing agencies new to pumps.

Alarms were the most frequently cited difficulty associated with pump use. However, 96.5% of patients found it *somewhat easy* to *very easy* to resolve alarms using help screens, and 98% of the time, patients found it *somewhat easy* to *very easy* to resolve alarms without help from the provider. The ability to resolve alarms independently, without contacting the HIP for assistance, may have a workflow and a financial impact, although this study did not look at those factors. Increased patient ease of use, low alarm rates, and the ability to address alarms independently resulted in general satisfaction with the pump.

CONCLUSION

Ambulatory SPT can be implemented successfully in large urban and small rural HIPs. Clinicians indicated that the pump was easy to use and appreciated the drug library creation process for improved protocol consistency with potential improvements in patient safety. This study also demonstrated that SPT can be used effectively by patients with a high level of satisfaction. Smart pumps could be a feasible approach for HIPs of any size or at any location.

ACKNOWLEDGMENTS

Peter Kratz, MS, and Laura Seiberlich, MS, were previously affiliated with Smiths Medical and contributed to the authorship of this article.

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