

Impact of Intelligent Intravenous Infusion Pumps on Directing Care Toward Evidence-Based Standards: A Retrospective Data Analysis

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Abstract

Introduction: Published literature has successfully demonstrated the impact of intravenous (IV) infusion pump safety software on improving the quality of health care delivery. Much of this literature has focused solely on the ability of these devices to prevent potential medication errors, while overlooking the devices' additional valuable advantages. One non-reported benefit is the ability of IV infusion pump safety software to consistently administer doses of IV medication, which are based on evidence. This article describes the process undertaken to implement and evaluate the impact of IV infusion pump safety software on driving care toward evidence-based standards. **Methods:** An advisory group of expert users was convened for a 2-day session to develop consensus recommendations of best practices for IV infusion pump safety software. Using these recommendations, administrative data were collected from a community hospital to assess the endpoints identified by the advisory panel. **Results:** Data analysis of rescue agents (ie, flumazenil, glucagon, and protamine sulfate) showed reductions in utilization in the post-implementation period of the safety software. The decreased requirement for blood transfusions in patients receiving heparin infusions suggests that heparin infusions were more safely administered in the post-implementation period. The decreased length of stay and mortality rate observed in patients with complex respiratory infections during the post-implementation period suggests that by correctly infusing antibiotics consistently, patient outcomes may be improved. Additionally, alert and edit data from the pumps demonstrated that the IV infusion pump safety software alerted to and influenced edits on many critical dose rate errors for benzodiazepines, heparin, and several antibiotics. **Conclusion:** Intravenous infusion pump safety software improves clinical outcomes through consistent application of evidence-based standards of dose rates for IV drugs.

Keywords: intravenous infusions; patient safety; care guidelines

Introduction

Improving patient safety continues to be a priority for both policy makers and health care providers in the United States. Although newer technology increases identification and measurement of adverse medical events, some data suggest that ≥ 10 times more confirmed, serious adverse events occur than are reported voluntarily.¹ In fact, in a recent study, it was found that harm due to medical errors remains common, with little evidence of widespread improvement.² Literature that has quantified the impact of intravenous (IV) infusion pump safety software on quality of care has focused on the avoidance of medication errors and extrapolated error prevention to potential positive outcomes, such as cost savings, workflow improvement, and legal risk reduction.^{3,4}

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Many of the medications responsible for adverse drug events (ADEs) have narrow therapeutic indexes (ie, the difference between therapeutic and toxic doses is small). Adverse drug events associated with the delivery of IV medications negatively impact quality of care and lead to additional financial costs estimated at \$8750 per preventable ADE (annualized cost in the United States in 2006 of \$15.6 billion).⁵ More recently, data have been published that suggest that there is an annual incidence of 1.5 million preventable ADEs at a cost of \$13 000 per preventable ADE (annualized cost in the United States in 2008 of \$19.5 billion).⁶

The use of IV infusion pumps has revolutionized the manner in which medications are delivered, thus allowing the use of many high-risk medications to be administered safely.⁷ There is a further belief that by integrating IV infusion pumps equipped with safety software (ie, “intelligent” IV infusion pumps) with institutional information systems (eg, electronic medical records, barcode point-of-care, computerized physician order entry), medication errors may be reduced and nursing workflow simplified.⁸ In addition, patient care could be directed toward evidence-based standards, thereby increasing patient safety.

Many facilities have quantified the effects of intelligent IV infusion pump technology and have documented reductions in ADE rates based on reducing the frequencies of infusion rates thought to be associated with harm (ie, exceeding pre-set soft and hard dosing limits).³ However, no research has been published that addresses another possible mechanism accounting for the positive effects of intelligent IV infusion pumps (ie, driving of adherence to evidence-based guidelines).

This article describes an advisory panel’s consensus recommendations for best practices in the use of intelligent IV infusion pump technology. The article also reports on this panel’s recommendations as to which quantifiable clinical outcomes are related to the use of this technology. This article also analyzes infusion data from a single facility after the implementation of intelligent IV infusion pump technology related to the outcomes delivering improved care via evidence-based standards.

Advisory Panel Consensus Recommendations

Because the use of administrative databases to measure outcomes related to intelligent IV infusion pump technology is considered novel, an advisory group of expert users was convened to attend a 2-day session to develop consensus recommendations of best practices. Those in the user group came from 11 different facilities, were current users of this technology, and represented geographic locations across the United States (Appendix A).

After a review of administrative databases and their potential assets and liabilities, the expert panel discussed best practices in the use of intelligent IV infusion pump technology and identified quantifiable clinical outcomes that could be measured in a pre-/post-implementation assessment design (Table 1). These outcome elements met the following 2 criteria: 1) accessibility from routinely collected administrative data sources; and 2) any change in these elements was reasonably related to the use/nonuse of intelligent IV infusion pump technology. These outcome elements served as the primary outcomes for the subsequent data analysis.

Rescue Medications

The advisory group concluded that if intelligent IV infusion pump technology encouraged appropriate medication administration (due to use of customized drug library limits in the safety software) and reduced ADEs, there should be a decrease in rescue medication use in the post-implementation period compared with the pre-implementation period. Three injectable agents were identified as widely recognized rescue medications: flumazenil for benzodiazepines; glucagon for hypoglycemic agents; and protamine sulfate for heparin.

Heparin Infusions

The advisory group concluded that, by managing heparin infusions more carefully (including the “mandatory” correction of incorrect doses), complication rates (eg, bleeding from excessive dosing or venous thromboembolic events from suboptimal therapeutic effect from under-dosing)

Table 1. Clinical Outcome Elements Reasonably Related to Intelligent IV Infusion Pump Technology

Element	Measure
Rescue medication use	Use of glucagon, flumazenil, and protamine sulfate
Heparin infusions	Bleeding (including intracranial) and thrombosis rates
IV antimicrobial infusions	LOS, days of ventilator use, and mortality for recipients of parenteral quinolones, vancomycin, and piperacillin/tazobactam for lower respiratory tract infections (pneumonia)

Abbreviations: IV, intravenous; LOS, length of stay.

should decrease. Monitoring blood transfusion utilization rates would be a valuable marker of serious bleeding events.

Antimicrobial Agents

The advisory group concluded that by administering antimicrobials at proper doses and rates (per evidence-based guidelines), there should be clinical benefits, quantifiable as decreased length of stay (LOS), decreased ventilator days, and decreased mortality. Levofloxacin, vancomycin, and piperacillin/tazobactam were the target antimicrobials for this analysis.

Data Analysis

In the normal course of business operations, when a community hospital changed their group purchasing organization (GPO) membership, 1 year of administrative data were retrospectively collected by Aspen Healthcare Metrics (a MedAssets company) (Centennial, CO). Fortuitously, intelligent IV infusion pump technology was implemented at the hospital starting at the midpoint of this data-collection interval. Prior to this implementation, the facility did not utilize safety software integrated with their IV pumps. This allowed the retrospective analysis of clinical outcomes data from pre-, peri-, and post-implementation of intelligent IV infusion pump technology periods. Data received from materials management, decision support, finance/accounting, case management, and pharmacy (plus others) cost centers were allocated into “spend” and “patient” categories. The spend category primarily consisted of closed receipt files (eg, purchase orders, invoices), while the patient category primarily consisted of demographics (eg, UB-04), diagnosis and procedure codes, detailed charges, and facility-specific charge masters. All retrieved data underwent multiple levels of quality-assurance and quality-control checks, both automated and manual, per company policies and procedures. The check process may identify data containing irresolvable issues, which require a resubmission pending resolution of identified issues. Such issues would include lack of discharge status, inappropriate assignment of gender according to disease state, or notification of incomplete or missing data elements commonly anticipated with a procedure or diagnosis code.

The data comparison involved those from the 4 months immediately preceding implementation of intelligent IV infusion pump technology (ie, December 2008–March 2009, also called the pre-implementation period) and those from the 4 months after implementation (August 2009–November 2009, also called the post-implementation period). Implementation occurred during April and May 2009. By not

comparing consecutive data, the study attempted to control for bias that could be introduced while the facility staff became familiar with the new technology. Total discharges during these two 4-month periods for all Medicare Severity Diagnosis-Related Groups (MS-DRGs) were 4287 and 4115, which demonstrated a 4.1% decrease.

Results

Rescue Medications

As previously discussed, the target agents for this analysis were flumazenil for benzodiazepines, glucagon for hypoglycemic agents, and protamine sulfate for heparin. These agents were identified by their charge codes and charge descriptions in the finance/accounting software. Flumazenil, glucagon, and protamine sulfate use decreased by 36.1% ($n = 36$ to 23), 17.1% ($n = 41$ to 34), and 13.7% ($n = 196$ to 169), respectively, from the pre- to the post-implementation period. Flumazenil recipients were further analyzed to determine the number of milligrams required for benzodiazepine reversal. Mean pre- and post-implementation period doses of flumazenil were 1.5 and 0.52 mg, respectively. The reduction in the mean dose of flumazenil (65.3%) might be explained by the prevention of large benzodiazepine overdoses by the safety software, with such large overdoses necessitating high reversal doses of flumazenil. Thus, the incidence and severity of benzodiazepine overdoses appeared to be reduced by use of the safety software.

Heparin Infusions

The total number of heparin infusions utilized in the pre- and post-implementation periods were 430 and 322, respectively, a 25.1% decrease. The total number of transfusions decreased from 86 in the pre-implementation period to 35 ($P < 0.05$) in the post-implementation period, showing a 59.3% decrease. These data, in concert with the protamine sulfate utilization data provided in the previous section, suggest that serious bleeding complications manifested by the need for protamine sulfate reversal and/or blood transfusions were reduced by limiting the heparin infusion rates to those allowable by the safety software drug libraries.

Antimicrobial Agents

Levofloxacin, vancomycin, and piperacillin/tazobactam were identified in a manner analogous to that mentioned previously regarding the rescue medications. Antimicrobial agent recipients were stratified into their designated MS-DRGs. Patients treated for respiratory infections with/without comorbid conditions and major cardiovascular conditions

(MS-DRGs 177, 178, 179) were analyzed with respect to LOS and mortality. The number of patients treated under each DRG and the total number of patients were compared in the pre- versus post-implementation period. The results are illustrated in Figure 1. Figures 2 and 3 illustrate the LOS and mortality data for pre- versus post-implementation period comparison, respectively. The aggregated total volume was approximately the same. In all 3 MS-DRG groups, the mean LOS decreased in the post- versus pre-implementation period. For mortality, the overall numbers for volume and deaths, while small, showed a trend toward a lower mortality rate.

Statistical Analysis

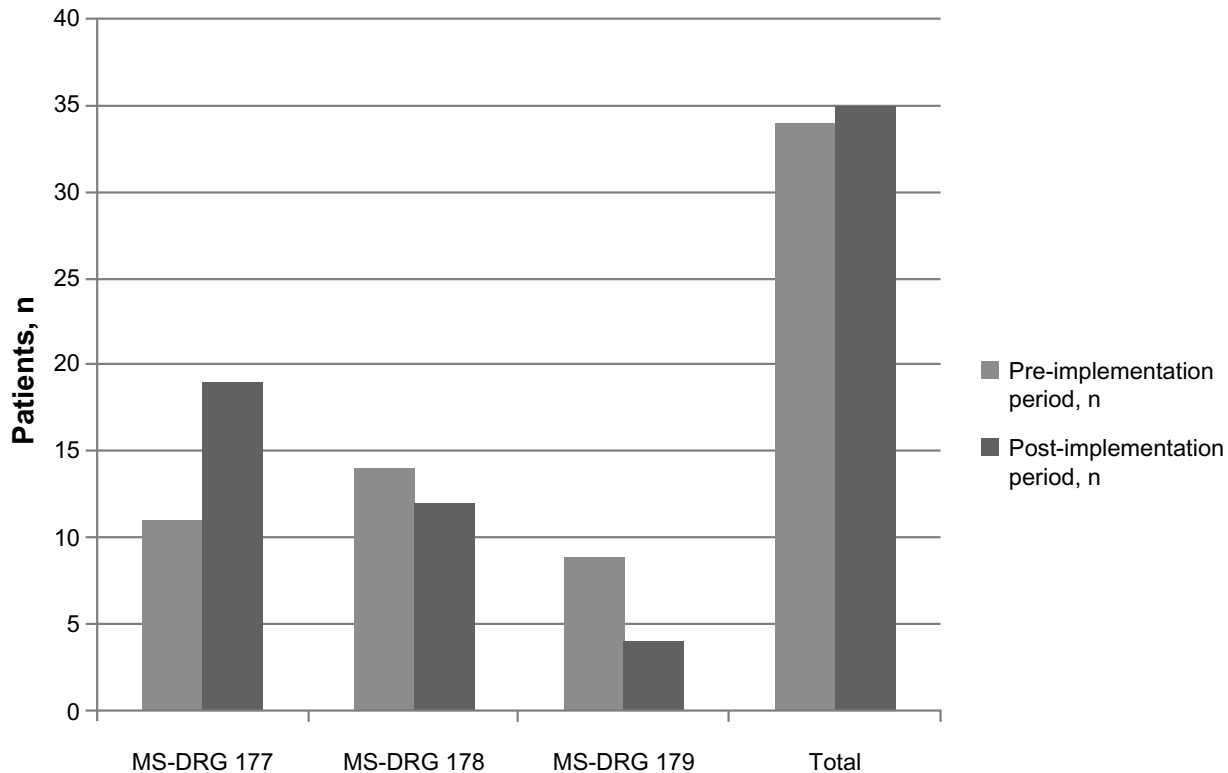
Analysis for statistical significance was performed on each of the outcomes listed in the Results section. Two different statistical tests to determine the *P* value were used, depending on the variables studied. Chi-square testing was performed for the analysis comparing volumes between the various target agents (pre- and post-implementation periods) and mortality comparison by MS-DRG. A *t* test was performed for the LOS analysis by MS-DRG and dosage for flumazenil.

Although all of the measurements showed a trend toward better outcomes, only the reduction in blood transfusions associated with heparin infusions was statistically significant. Lack of statistical significance is considered to be more of a function of volume, and further study should be conducted with larger patient populations.

Alert Data

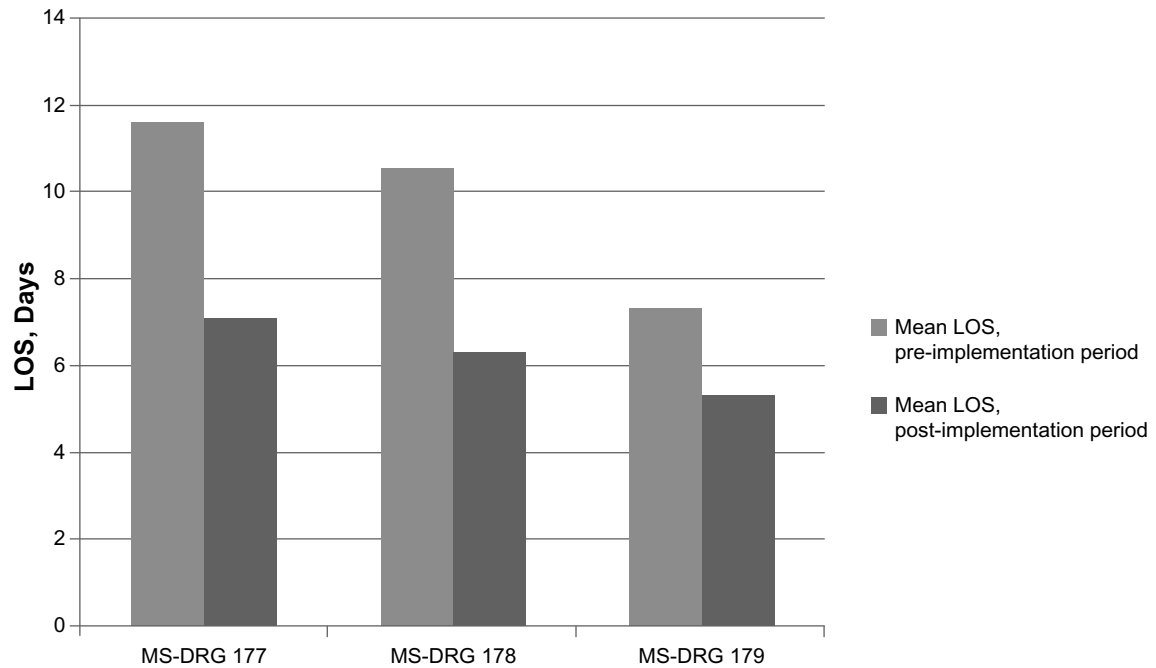
To further support the association between intelligent IV infusion pump technology implementation and patient outcomes, data output from the IV infusion pumps regarding the types and relative magnitudes of infusion alerts were studied with respect to quantity and types of alerts to end users. Table 2 illustrates these data over the course of the study period. The overall alert rate was 2.4% (2396/97 822). Soft limit alerts were 86.2% of the total alerts (2065/2396), and the remaining 13.8% (331/2396) were hard limit alerts. Of the soft limit alerts, 60.7% (1253/2065) were overridden by the end user and 39.3% were edited to comply with established acceptable rates. All hard limit alerts resulted in edits to comply with established acceptable rates.

Figure 1. Number of patients receiving IV antimicrobial agents for pneumonia in the pre- and post-implementation periods.



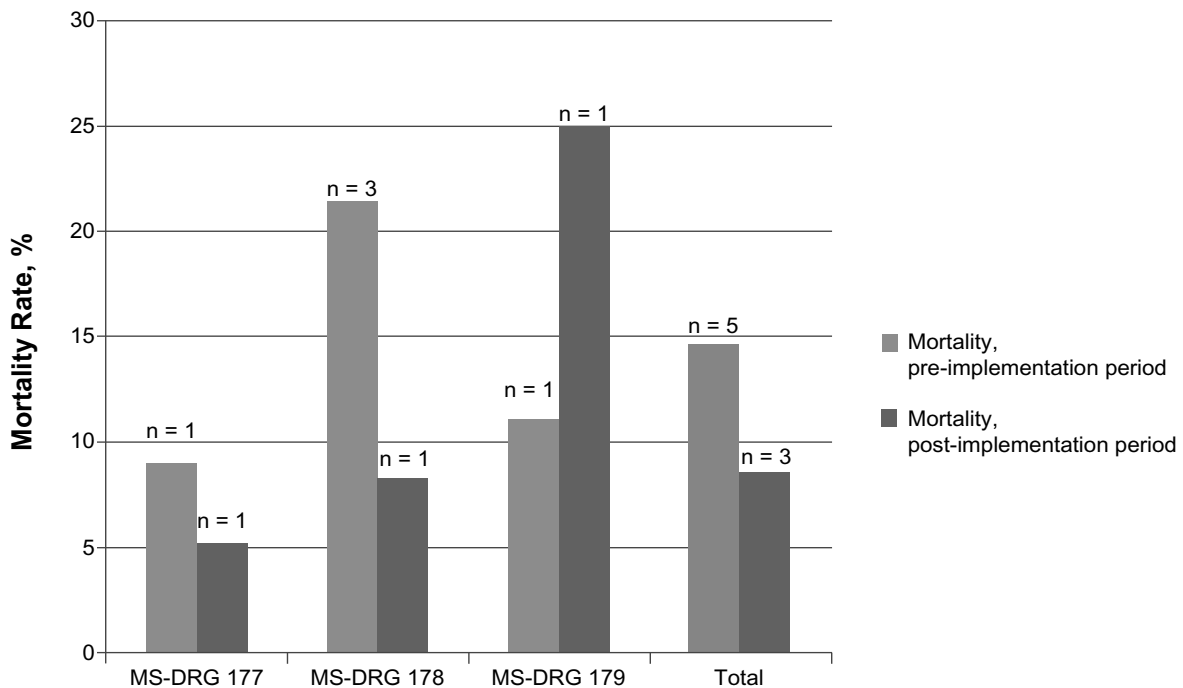
Notes: MS-DRG 177 = respiratory infections with CCs and MCCs; MS-DRG 178 = respiratory infections with CCs; MS-DRG 179 = respiratory infections without CCs or MCCs. Antimicrobials included: levofloxacin, vancomycin, and piperacillin/tazobactam.

Abbreviations: CC, comorbid condition; IV, intravenous; MCC, major cardiovascular condition; MS-DRG, Medicare Severity Diagnosis-Related Group.

Figure 2. Mean LOS of patients receiving IV antimicrobial agents for pneumonia in the pre- and post-implementation periods.

Notes: MS-DRG 177 = respiratory infections with CCs and MCCs; MS-DRG 178 = respiratory infections with CCs; MS-DRG 179 = respiratory infections without CCs or MCCs. Antimicrobials included: levofloxacin, vancomycin, and piperacillin/tazobactam.

Abbreviations: CC, comorbid condition; IV, intravenous; LOS, length of stay; MCC, major cardiovascular condition; MS-DRG, Medicare Severity Diagnosis-Related Group.

Figure 3. Mortality rates of patients receiving IV antimicrobial agents for pneumonia in the pre- and post-implementation periods.

Notes: MS-DRG 177 = respiratory infections with CCs and MCCs; MS-DRG 178 = respiratory infections with CCs; MS-DRG 179 = respiratory infections without CCs or MCCs. Antimicrobials included: levofloxacin, vancomycin, and piperacillin/tazobactam.

Abbreviations: CC, comorbid condition; IV, intravenous; MCC, major cardiovascular condition; MS-DRG, Medicare Severity Diagnosis-Related Group.

Table 2. Epidemiology of Alert Data Collected During the Evaluation Period (August 2009–November 2009)

Total infusions, N	97 822
Infusions with no alerts, n (%)	95 426 (97.6)
Total infusions with alerts by type, n (%)	2396 (2.4)
• Soft limit alerts	2065 (86.2)
• Hard limit alerts	331 (13.8)
Action taken on infusion alerts, n (%)	
• Dose rate alert overridden	1253 (1.3)
• Dose rate alert edited	1133 (1.2)
• Bolus alert overridden	1 (< 0.1)
• Bolus alert edited	9 (< 0.1)

Review of the individual alerts and edits provides strong support for the effectiveness of the safety software in changing end-user behaviors toward more appropriate and safer infusion administration (Table 3). For dose edits occurring during the evaluation period, multiple edits for soft and hard limit alerts occurred during the medication infusion phase. This suggests that the infusion practice prior to intelligent IV infusion pump technology implementation potentially led to dosing errors, some of which exceeded institutionally defined safe-dosing limits. It further suggests that when dose edits occurred, medication administration improved, resulting in fewer medication errors. Furthermore, when medication administration was edited to comply with appropriate dosing limits, it also suggests that the intended appropriate medical outcome was more likely to occur.

Regarding heparin infusion alerts (N = 49), the upper hard limit (1500 units/hour) was exceeded in 16 cases, resulting in dose edits in all cases. The upper soft limit (1000 units/hour) was exceeded in 17 cases, resulting in dose edits in 2 cases. The largest of these edits were from 25 000 units/hour to 1000 units/hour. The lower soft limit (100 units/hour) was violated in 16 cases, resulting in dose edits in all cases. The largest of these edits were from 15 units/hour to 1500 units/hour.

For midazolam 2 mg/mL infusion alerts (n = 2), the upper hard limit (100 mL/hour) was exceeded in 2 cases, resulting in dose edits in both cases. Both of these edits were from 999 mL/hour to 15 mL/hour. With the 1-mg/mL infusion alerts (n = 24), the upper soft limit (50 mL/hour) was exceeded in all cases, resulting in significant dose edits in 14 cases (58.3%), the remaining 10 being overridden and infused as programmed.

In the case of insulin infusion alerts (N = 67), 7 were programmed for initial rates of ≥ 30 units/hour. Edits resulted in 6 cases (85.7%). The largest of these edits was 999 units/hour to 50 units/hour.

Regarding antimicrobial agent infusion alerts, it was noted that the facility had 36 different vancomycin infusate concentrations in the library. The upper hard limit (300 mL/hour) was exceeded in 1 case, resulting in a dose edit. The upper soft limits (250 mL/hour or 15 mg/kg/hour) were exceeded in 75 cases, resulting in dose edits in 64 cases (85.3%). The largest of these edits was from 150 mg/kg/hour to 8.46 mg/kg/hour in a pediatric patient.

Table 3. Representative Examples of Clinically Significant Limit Alerts During the Evaluation Period (August 2009–November 2009)

Drug/Concentration, Rate	Limit Violated	Limit	Initial Value	Final Value
Heparin 100 units/mL, units/h	Upper hard	1500	25 000	1000
	Upper hard	1500	1900	19.1
	Lower soft	100	10.6	1060
	Lower soft	100	15	1500
Heparin 25 000 units/250 mL, units/h	Lower soft	100	10	1000
	Upper soft	1000	5500	5500
Midazolam 2 mg/mL, mL/h	Upper hard	100	999	15
Midazolam 1 mg/mL, mL/h	Upper soft	50	999	999
	Upper soft	50	999	20
	Upper soft	50	200	20
	Upper soft	50	100	50
	Upper soft	50	75	50
	Upper soft	50	100	100
	Upper soft	50	80	8
	Upper soft	50	1000	50
	Upper soft	50	100	50
	Upper soft	50	100	50
Insulin drip 100 units/100 mL, units/h	Upper soft	6	999	50
	Upper soft	6	30	30
	Upper soft	6	50	25
	Upper soft	6	105	1.5
	Upper soft	6	100	6

For levofloxacin alerts, the upper soft limit (150 mL/hour for levofloxacin 750 mg, 100 mL/hour for levofloxacin 500 mg, or 50 mL/hour for levofloxacin 250 mg) was exceeded in 79 cases, resulting in dose edits in 68 (86.1%) cases. The largest of these edits was from 750 mL/hour to 140 mL/hour. In 1 case, levofloxacin 500 mg was infused at 999 mL/hour; in another case, the dose rate was increased from 110 mL/hour to 200 mL/hour, or it was changed from 500 mL/hour to 104.7 mL/hour. Only 1 incident of an alert occurred with piperacillin/tazobactam when the upper soft limit (200 mL/hour) was exceeded, resulting in a dose edit.

Discussion

It is known that medication errors and ADEs occur more frequently than expected. Without measurement of these events and their costly complications at a facility level, the frequency and the true cost and adverse outcomes associated with the historical occurrence of these events is not known. More specifically, it is the fear that such ADEs could occur that drives facilities to implement technologies designed to reduce their occurrence. As a result, the speculative return on investment is never actually measured because the financial cost of continued errors that would occur by not implementing technology is not measured in advance.

The analyses described in this article, derived from a facility implementing intelligent IV infusion pump technology, offers a new way to quantify the benefits of such technology. As previously indicated, the literature promoting the benefit of IV infusion pump safety software indicates the prevention of ADEs as the primary benefit. Indeed, many ADEs can be prevented. In difficult economic times, the notion that this technology can positively impact patient outcomes through promotion of adherence to evidence-based practice guidelines should make implementation even more appealing. As demonstrated in this evaluation, value can be measured in health care improvement due to technology-driving, evidence-based practice.

Examining the data outputs from the IV infusion pumps, one can see how safety software influenced end-user behaviors by encouraging more appropriate dosing of high-risk IV medications. Many potentially dangerous infusions were averted due to device alerts. To be realistic, it is not known precisely how many of these infusions might have been caught in the course of administration before harm occurred. In all cases, the safety software alerted to potential danger immediately and prior to commencement of the infusion, and did not rely on chance or later recognition. Review of the type and magnitude of the alerts confirms that potentially dangerous

dosing errors and ADEs were prevented. The behavior of the clinician inputting these doses is likely a carryover from the time period prior to implementation of the safety software. The realization of the impact of the safety software lends support to the notion that such technology can drive care toward evidence-based standards, better outcomes, and safer medication administration.

The concept that technology can positively impact clinical outcomes through adherence to evidence-based guidelines/standards is more appealing than its effect on theoretical ADE rates based on exceeding doses/rates thought to be associated with toxicity. As demonstrated in this article, measurable positive outcomes are associated with the implementation of intelligent IV infusion pump therapy. These benefits are in addition to the benefit of avoidance of potential dosing errors, ADEs, and associated patient harm.

Based on the findings of this study, a more novel approach to measuring the impact of IV infusion pump safety software can be designed and employed through the measurement of clinical outcomes. These endpoints could vary from facility to facility and do not need to be limited to those listed in this article. However, they should meet ≥ 2 criteria: 1) accessibility from routinely collected administrative data sources; and 2) any change in these elements would be reasonably related to the use/nonuse of intelligent IV infusion pump technology. With these criteria as a guideline, implementation of patient safety technology can better quantify improvement in care.

There are limitations associated with retrospective observational outcomes analyses utilizing administrative databases. The foremost of these is the inability to directly link cause (ie, intelligent IV infusion pump use) and effect (ie, positive clinical outcomes). Treatment covariates, including comorbidities, other therapies, diagnostic test results, and causes of death, were not available. No case-control matching was performed. The use of billing data can lead to bias due to missing data or coding errors. Finally, the results cannot be generalized beyond the source facility.

Even with the limitations, administrative data have been used to reveal startlingly small area variations in health care and clinical practice patterns since the 1970s.⁹ Research in the 1990s has led to the use of administrative data to screen for potential gaps in quality outcomes. The Agency for Healthcare Research and Quality now has a set of patient-safety indicators that can be quantified using administrative data.¹⁰ Although the evaluation protocol was developed to link technology implementation with outcomes, the true challenge was to ensure that any changes in outcomes were associated only with the implementation of technology. Because

this is a retrospective study, data collection was completed prior to the study, and because the study was conducted solely with administrative data, it is unknown if any other changes occurred. The associations found in this observational evaluation warrant further study on a broader scale.

Conclusion

The goal of medical care should be to treat patients using the best known standards of care and, during the provision of care, to do no harm. Further improvements can be made. This study complements previous literature showing that intelligent IV infusion pumps are effective in preventing ADEs and medical errors. The study goes further by showing a methodology that may demonstrate the positive outcomes that can occur through the consistent application of evidence-based medicine. By encouraging these standards, intelligent IV infusion pumps show a trend toward impacting health care outcomes while also contributing to the prevention of infusion-related ADEs and medical errors.

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Conflict of Interest Statement

M. Blane Schilling, MD and Steven Sandoval disclose no conflicts of interest.

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Appendix A. Work Group Participants in Advisory Board on Increasing Patient Safety By Directing Care Toward Evidence-Based Standards: Impact of Use of Intelligent Intravenous Infusion Pumps

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