



Studying a Computerized Integrated Infusion Safety System (CISS) for Preventing Drug Administration Errors: A Cost Effectiveness Evaluation Study Protocol

Anita Zeneli^{1*}, Mattia Altini² and Oriana Nanni³

¹Lead Research Nurse, Istituto Scientifico Romagnolo per lo Studio e per la Cura dei Tumori IRST IRCCS, Meldola, Italy

²Healthcare Director, Istituto Scientifico Romagnolo per lo Studio e per la Cura dei Tumori IRST IRCCS, Meldola, Italy

³Biostatition, Istituto Scientifico Romagnolo per lo Studio e per la Cura dei Tumori IRST IRCCS, Meldola, Italy

Abstract

Medication errors (MEs) can occur at various stages throughout the medication process, e.g. when prescribing, transcribing, dispensing, and/or administering a drug. MEs associated with IV pumps occur frequently, have the potential to cause harm, and are epidemiologically diverse. Although smart pumps are a useful component of a comprehensive safe medication system, these devices cannot generate meaningful improvements in patient safety until they can be interfaced with other systems such as the electronic medical records (EMR), computerized prescriber order entry (CPOE), bar coded medication administration systems (BCMA), and pharmacy information systems (PhIS). Based on this evidence, we propose a pre-post intervention pilot study to assess the efficacy of interfacing smart infusion pump servers with other information systems (CPOE, BCMA, EMR and PhIS) to minimize the likelihood of medication administration errors (MAEs).

Background

MEs are the most significant cause of medical injuries, representing 19.4% of all adverse events (AEs) [1-4]. Between 10% and 18% of all reported hospital incidents can be attributed to MEs with varied effects ranging from going unnoticed to causing death [5]. MEs can occur at various steps throughout the medication process, e.g. when prescribing, transcribing, dispensing, and/or administering a drug [1,2]. The most serious MEs recorded occur in the administration step because these errors are least likely to be intercepted before they reach the patient [4,6]. MEs during the administration of medications via the intravenous (IV) route often result in the most serious consequences [7]. Approximately 90% of patients receive medications intravenously and IV pumps are responsible for the majority of medication deliveries. The majority of drug AEs associated with IV infusion devices derive from nurses manually inputting incorrect settings into the pump [8,9]. An entire Computerized Interconnected Infusion Safety System (CISS) consists of: interfacing pump servers/smart infusion systems, computerized provider order entry, Pharmacy Information System, barcode-enabled point of care and electronic medication administration records [10].

Hypotheses and Specific Aims

The computerized infusion safety system (CISS) currently in use in the vast majority of Italian medical centres consists of: Computerized Physician Order Entry (CPOE), Pharmacy Information System, Bar-Coded Medication Administration and Electronic Medication Administration Records. This system enables the following MEs to be avoided: wrong drug, patient, dose or concentration, and clinician errors. Conversely, the system omits MEs associated with incorrect administration timing derived from incorrect infusion pump programming because the pump servers are not interfaced with the other information systems and infusions are programmed by inserting infusion parameters manually. We intend to test the following hypothesis: by interfacing the pump servers with the CISS in use at our Institute, we expect to have 50% fewer MEs than before. This new technology will guarantee a safer patient environment and a more streamlined workflow for the pharmacy and nursing staff.

Aim 1: To assess the effectiveness of CISS in improving patient safety by permitting the

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*Correspondence:

Anita Zeneli, Lead Research Nurse,
Istituto Scientifico Romagnolo per lo
Studio e per la Cura dei Tumori IRST
IRCCS, Meldola, Italy;

E-mail: anita.zeneli@irst.emr.it

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interception of infusion programming errors during chemotherapy administration.

Aim 2: To perform a pre- and post-CIIS implementation evaluation of the frequency and types of administration errors and AEs in cancer patients during chemotherapy administration.

Aim 3: To evaluate the organizational impact of CIIS implementation within the context of Health Technology Assessment.

Exp Design aim 1: After having obtained the approval of the Scientific Medical and Ethical Committees of AVR, a pre-post interventional, non pharmacological pilot study will be conducted at the cancer institute (IRST IRCCS) in Meldola. Patients will receive standard cancer treatments during all the study phases, in accordance with good clinical practice guidelines. Apart from the normal turnover rate, no changes will be made in the nursing staff of the Department of Medical Oncology Unit involved in the study.

T0: Pre-intervention study step: Around 600 chemotherapy infusions (calculated from the sample size) administered to cancer patients on an out-patient basis will be observed. Written informed consent to use personal clinical data will be obtained from all patients. For each chemotherapy infusion, data relating to MEs and their interception before reaching the patient, with a particular focus on administration stage and infusion pump programming errors, will be prospectively collected, in accordance with the study protocol, from EMRs. At the end of each working day, data collected from EMRs will be integrated with data downloaded manually from infusion pump memories by a dedicated research team and registered in an ad hoc database.

T1: Smart System Implementation (6 months):

The following activities will take place during this phase: Dedicated SMART infusion software for IV medication error-prevention that alerts operators when a pump setting is programmed outside of pre-configured limits will be developed

- The necessary changes will be implemented in institute's Wi-Fi network
- Placement of all pumps on secure Wi-Fi networks and interfacing of their servers with the other information systems
- The team will standardize competencies through staff training, coaching, checklists, competency assessments and audits to assess compliance with the new technology.

T2: Post-intervention study step. Re-measurements of MEs and their interception after intervention implementation. Around 600 chemotherapy infusions will be observed using the same methods as the pre-intervention study phase. This time, however, data on pump programming and reprogramming will be also collected from EMRs.

Exp Design aim 2: All infusions pertaining to the evaluation of aim 1 will be eligible for the measurement of the frequency and types of administration errors and AEs in cancer patients during chemotherapy administration in each phase of the study (aim 2).

To identify MEs, the research team will compare infusion parameters (drug, dose, volume, infusion rate and duration) specified in the physician's prescription with those of the actual infusion recorded in the EMRs.

AE recording forms correlated with the respective infused

medications will be used to evaluate the frequency of adverse events. To identify expiration date errors, data relating to the expiration date on the label of single drug solutions will be compared with the time of completion of the drug infusion.

Exp Design aim 3: Simultaneously with the pre-post interventional study, designed for the evaluation of the aim 1, the total costs for the development, implementation and maintenance of the additional technology will be accurately calculated (aim 3).

Specifically:

1. Costs for the new technology implementation:
 - Software development;
 - Interfacing + equipment + supplies;
 - System maintenance;
 - Changes to the institute's Wi-Fi network;
 - Staff training and coaching
 - Results and compliance monitoring
2. Benefit calculation:
 - a) Saved costs:
 - % Reduction in errors with damage/total therapies administered in the pilot department in a year x cost of a single injury (differences between pre and post);
 - %Reduction in errors with potential to cause harm/total therapies administered in the Department in a year x cost of a single injury (differences between pre and post);
 - Greater bed occupancy from time saved by reprogramming infusion times
 - b) Benefits that cannot be calculated as saved costs:
 - Better infusion control with higher compliance to chemotherapy protocols
 - Improved quality of reporting of incidents /errors
 - Resolution of possible programming errors identified by the new technology.

Methodologies and Statistical Analyses

A pre-post pilot intervention study will be conducted. The intervention will consist of interfacing the current CISS at IRST with the pump servers. Primary study outcomes will be the nature and frequency of MEs detected during medication delivery processes. The sample size has been calculated on the basis of the estimated programming ME rate of 15% before implementing the new technology. We expect a 50% reduction in programming MEs with 587 chemotherapy infusions for each phase of the study and a level of precision of the estimated alpha error to 1-side of 5% and a power of 80%. Appropriate descriptive statistics will be performed on collected data. Continuous data will be reported as means \pm standard deviation or median, while categorical data will be reported as numbers and percentages. Chi-square test will be used to calculate the association between ADEs and MEs. In order to assess the adjusted OR and 95%CI of the AEs, a logistic regression model will be implemented.

Based on the literature, any type of administration error will be

considered for the outcome evaluation (see definitions bellow') [11].

Medication Errors

An error occurring in the medication use process and can occur at any stage in the medication use process, including prescribing, transcribing, dispensing, administering, or monitoring. Not all medication errors have the potential to harm a patient. The errors will be classified by error type, potential preventability, potential severity and actual clinical impact.

Medication administration errors: an error occurring at the administration stage of the medication process.

Programming error: an error that occurs when a pump setting is programmed outside of pre-configured limits.

Adverse drug events (ADEs): injuries due to a medication and are classified as preventable (associated with a medication error) or non-preventable.

A potential Adverse Drug Event (PADE): Near miss: a medication error that has the potential to cause harm but did not because it either was intercepted before reaching the patient (intercepted PADE) or reached the patient and because of luck did not cause harm (non-intercepted PADE)

Serious medication errors: include both preventable ADEs and non-intercepted PADEs, which either harmed the patient or were judged to have the capacity to do so.

SMART infusion systems are defined as infusion pumps equipped with IV medication error-prevention software that alerts operators when a pump setting is programmed outside of pre-configured limits.

The primary study outcome: will be evaluated by comparing pre and post intervention programming error data calculated as the difference between the incidence rates of programming errors in each study phase. Programming error incidence = total programming errors/total opportunities to err (number of IV drugs in all observed infusions) x 100.

The secondary study outcome: will be evaluated by comparing the difference between programming errors intercepted and errors not intercepted in each study phase.

Expected Outcomes

This pre-post intervention pilot study could provide an important scientific contribution to our understanding of whether the integration of computerized safety infusion systems with interfacing infusion pump servers can improve patient safety and quality of care.

Risk Analysis, Possible Problems and Solutions

The intervention does not pose risks to patients or healthcare professionals. A potential problem could be the non-capability of the current computer-based system to capture and detect pump programming errors which may result in an underestimation of administration errors in the pre-intervention study step. To avoid this, we will assign a specific code to each pump that will be matched

to individual infusion stations. At the end of each working day, the data stored in the memory of each pump will be manually downloaded by a dedicated research team member, matched to the chemotherapy infused at that station, and recorded in the EMRs. All pumps will be reset for the next day.

Significance and Innovation

Preventing the onset or limiting the severity of MEs is essential to reduce their potentially serious consequences, improve the quality of care, and decrease costs associated with treatment and hospitalization. At the best of our knowledges, there have been no previous studies aimed at testing the efficacy of the more 'complete' CIISS in preventing MEs. If our pilot results justify the use of this technology in terms of its cost-benefit, the system could be fully implemented at our Institute and the CIISS model could be proposed at the national level for cost-effective scaling up. This new technology will guarantee a safer patient environment and a more streamlined workflow for pharmacy and nursing staff.

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