Describing voluntarily reported fluid therapy incidents in the care of critically ill patients: Identifying, and learning from, points of risk at the national level

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ABSTRACT

Background: Fluid therapy is a common intervention in critically ill patients. Fluid therapy errors may cause harm to patients. Thus, understanding of reported fluid therapy incidents is required in order to learn from them and develop protective measures, including utilizing expertise of pharmacists and technology to improve patient safety at the national level.

Objectives: To describe fluid therapy incidents voluntarily reported in intensive care and high dependency units (ICUs) to a national incident reporting system, by investigating the error types, fluid products, consequences to patients and actions taken to alleviate them, and to identify at which phase of the medication process the incidents had occurred and had been detected.

Methods: Medication related voluntarily reported incident (n = 7623) reports were obtained from all ICUs in 2007–2017. Incidents concerning fluid therapy (n = 2201) were selected. The retrospective analysis utilized categorized data and narrative descriptions of the incidents. The results were expressed as frequencies and percentages.

Results: Most voluntarily reported incidents had occurred during the dispensing/preparing phase (n = 1306, 59%) of the medication process: a point of risk. Most incidents (n = 1975, 90%) had reached the patient and passed through many phases in the medication process and nursing shift change checks before detection. One third of the errors (n = 596, 30%) were reported to have caused consequences to patients. One quarter (n = 492, 25%) of the errors were reported to have required an additional procedure to alleviate or monitor the consequences.

Conclusion: Utilizing national incident report data enabled identifying systemic points of risk in the medication process and learning to improve patient safety. To prevent similar incidents, initial interventions should focus on the dispensing/preparing phase before implementing active medication identification procedures at each phase of the medication process and nursing shift changes. Strengthening clinical pharmacy services, utilizing technology, coordinated by IV Fluid Coordinators and Medication Safety Officers, could improve patient safety in the ICUs.

1. Introduction

Fluid therapy is one of the most common procedures in the treatment of critically ill patients in intensive care and high dependency units (ICUs) and a variety of fluid products, administered intermittently or continuously, are used mainly in the three major indications: resuscitation; replacement; and maintenance.1 Fluids are also used to dilute electrolyte concentrates in small amounts to keep catheters open, and to dissolve or dilute medicines, all of which affect the patient's total fluid intake. Improper fluid selection or the volume administered may cause potential complications, increasing morbidity, prolonging hospitalization, and even increasing mortality.2 It has been estimated that approximately 20% of patients receive inappropriate fluid therapy.3 To prevent incidents and to provide optimal care for the critically ill patients, intravenous fluids should be considered as medications, taking into account individual patient factors, medical conditions and other treatments.1,2

Medication errors are one of the leading causes of iatrogenic errors in the critically ill population.3 The complexity of care for the critically ill patients with multiple comorbidities, organ dysfunctions, lower physiological reserve, polypharmacy, high frequency of intravenous administration of medication, and intensive care environment make practice in this specialty vulnerable and prone to medication errors and adverse events.4 The incidence of medication errors in the ICU environment varies widely and depends on the clinical setting, patient populations, study designs and definitions of medication error; the incidence ranges from 1.2 to 967 per 1000 patient days.5 On the other hand, the rate of fluid therapy errors

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may be 1.3 per patient during hospitalization in non-intensive care. The harm caused by most errors might not be great, but they can be warning signs of system failures that have the potential to lead to serious damage or death.

Internationally, clinical pharmacists are considered to have a key role within the critical care multi-professional team, offering their expertise in optimizing the medications of patients and preventing medication errors. However, in Finland, the role of pharmacists working in ICUs is slowly shifting from logistics, including fluid therapy, and aseptic medicine preparation, towards participation in patient care and systematic pharmacovigilance work. In 2016, clinical pharmacy services were offered in ICUs in all five university hospitals that provide secondary and tertiary healthcare services. Patient safety can also be supported by the correct use of health information technologies. In ICUs in Finland computerized prescriber order entry was introduced in the 1990s and it is now widely used (personal communication with GE Healthcare 9.4.2021), and the first automated dispensing cabinets were introduced in 2011. The implementation of closed loop medication management systems are currently underway in Finnish hospitals, including ICUs.

Ideal patient safety culture in ICUs should include multiple strategies for preventing medication, including fluid therapy, errors at all phases of the medication process. One strategy is to enhance the approach to medication incidents by improving non-punitive voluntary medication incident reporting both at local and national levels, recognizing the inadequacy of current approaches for preventing medication incidents, and understanding and enhancing human performance within the medication process.

Study Design

The aim of this study was to describe voluntarily reported fluid therapy incidents in the ICUs to a national incident reporting system, by investigating the types of the errors (reached the patient) and near misses (did not reach the patient), and the fluid products involved in the incidents, to describe reported consequences to patients and actions taken to alleviate them, and to investigate at which phases of the medication process the reported incidents occurred and were detected. By focusing on the nationally collected data on fluid therapy incidents, the study goal was to identify, and learn from, the points of risks in the fluid therapy process to develop protective measures, including utilizing expertise of pharmacists, and to improve patient safety in the ICUs at national level. To our knowledge, there are no previous studies in this field in the ICU environment.

2. Methods

This retrospective study analyzed all fluid therapy incident reports reported voluntarily and anonymously by healthcare professionals from all adult and pediatric intensive care and high dependency units (ICUs) in all Healthcare districts (n = 20) in the mainland of Finland to the national incident reporting system between 2007 and 2017. At the time, there were five intensive care beds per 100,000 inhabitants in Finnish ICUs and approximately 20,000 admissions annually.

The electronic national reporting system has been established to collect data on patient safety incidents, to learn from the reported incidents and to investigate at which phases of the medication process the reported incidents occurred and were detected. By focusing on the nationally collected data on fluid therapy incidents, the study goal was to identify, and learn from, the points of risks in the fluid therapy process to develop protective measures, including utilizing expertise of pharmacists, and to improve patient safety in the ICUs at national level. To our knowledge, there are no previous studies in this field in the ICU environment.

The research approval to use the national incident report data was obtained separately from each healthcare district (n = 20) for the 2007–2014 data set and centrally from the Finnish Patient Safety Association for 17 healthcare districts and separately from three hospital districts that are not members of the Association for the 2015–2017 data set. An additional ethical review was not required as no identifiable patient information is included in the reports. Awanic Ltd. that maintains the national reporting system provided all medication related incident reports with categorizations and narratives of the incidents in Microsoft Excel® spreadsheets. The researcher reviewed the reported incidents independently and discussed unclear reports together with another researcher to reach consensus. No data mining of medication incidents was available while analyzing these incident reports.

The incident reports include categorized information (e.g. type of error, fluid products involved, consequences for the patient and the phase of the medication process in which the incident occurred) and narrative descriptions of the incidents (the rapporteur’s description of any consequences to the patient and any action taken to alleviate them) both of which were used in the study. The types of errors were categorized according to the national reporting system, which follows The International Classification for Patient Safety (ICPS), and are: wrong medicine (i.e. fluid product); wrong dose or strength; omitted medicine; contraindicated medicine; wrong patient; wrong route; wrong storage; wrong time; and wrong documentation. For clarity, wrong dose or strength was divided into three error types: wrong concentration; wrong rate; and wrong dose. In addition to the above, based on the narratives, a new error type was added: interrupted administration (e.g. due to technical errors such as loose infusion tube connections, or malpositioning of intravenous (IV) cannulae or nasogastric tubes).

Fluid products were categorized according to the Anatomical Therapeutic Chemical (ATC) Classification system: Solutions affecting the electrolyte balance (Crystalloids); Blood substitutes and plasma protein fractions (Colloids); Other blood products (Blood products); and IV solution additives (e.g. electrolyte concentrates, vitamins and trace elements). In addition to the above, the following groups were added: parenteral and enteral nutrients were combined and named as Nutrients; Peritoneal dialysis, hemodialysis and hemofiltrates were combined and named as Dialytics; Special fluids comprised ready-to-use heparinized solution only used in the cannula flush system, sterile water, sodium bicarbonate, and solutions producing osmotic diuresis; and Others when no fluid product had been named in the incident report.

After a healthcare professional has voluntarily reported an incident to the national incident report system, a classifier, often the head nurse of the ICU, categorizes the consequences of the incident as minor (mild disadvantage demanding little or no treatment), moderate (disadvantage demanding treatment) or major (impaired the patient’s quality of life and requiring life-sustaining care). In addition to these categorized consequences, the original narrative descriptions of the errors reported by the rapporteurs were utilized in the analysis to identify any further consequences of errors to patients potentially missed by the classifiers.

In this study, the phases of the medication process were: prescribing (physicians); dispensing/preparing (mainly nurses and in some ICUs pharmacists during office hours); and administering (mainly nurses and physicians). The dispensing/preparing phase included also ordering, delivering and storing, and the administering phase included also documenting the administration of medication and monitoring response to treatment.

Finnish hospitals use a three-shift nursing working schedule, which was used as a timeline for the detection of the incidents. The medication processes and nursing shift change checkpoints were visualized into Swiss cheese diagrams. The holes in the cheese represented weaknesses in the system, preventing mistakes from spreading to other phases of the medication process. The holes in the cheese represented weaknesses in the system, preventing mistakes from spreading to other phases of the medication process. The holes in the cheese represented weaknesses in the system, preventing mistakes from spreading to other phases of the medication process.
between 2007 and 2017. Of these, 2089 (27%) incident reports were related to fluid therapy, including incidents which reached a patient (an error) and did not reach a patient (a near miss). These reports were further reviewed and scrutinized; duplicate or inadequate reports (n = 39) were excluded, and reports containing several incidents were divided into separate reports (n = 151), resulting into 2201 incidents related to fluid therapy (Fig. 1).

3.1. Fluid products involved in the incidents

The two most common fluid groups (Fig. 1) to be involved in the 2201 fluid therapy related incidents were IV solution additives (n = 667, 30%; most often potassium concentrates (n = 403) and sodium concentrates (n = 75)), and Crystalloids (n = 662, 30%; most often electrolyte solutions, e.g. 9 mg/ml sodium chloride and Ringer’s acetate, (n = 320) and electrolytes with carbohydrate, e.g. glucose 5% in 9 mg/ml sodium chloride and 5% in 3 mg/ml sodium chloride, (n = 227)). Other common fluid groups to be involved in the incidents were Nutritions (n = 373, 17%) and Blood products (n = 262, 12%). Fig. 1 shows all fluid groups and subgroups to be involved in the incident reports.

3.2. Types of errors associated with the fluid therapy incidents

Table 1 shows the reported error types with the nature of incidents, the fluids groups involved, the phases of the medication process at which the incidents had occurred, and the categorized consequences to patient. The most commonly reported error type was wrong fluid product (n = 711, 32%); the majority (n = 631) had reached the patient. Wrong fluid product incidents had occurred most often during the dispensing/preparing phase (n = 648, e.g. selecting a wrong fluid product instead of the one prescribed). Crystalloids (n = 347) were most typically involved in the incidents, followed by IV solution additives (n = 131).

The second most commonly reported error type was omitted medicine (n = 286, 13%); most (n = 272) had reached the patient. Here too, the incidents had occurred most often during the dispensing/preparing phase (n = 201). IV solution additives were most often involved (n = 102), followed by Nutritions (n = 57) and Crystalloids (n = 53). Other commonly reported error types were wrong concentration (n = 254, 12%) and wrong rate (n = 244, 11%) for which more detailed information is provided in Table 1.

3.3. Consequences of the fluid therapy errors

Of the 1975 reported errors (reached the patient), one fifth (n = 428, 22%) had been categorized to have caused consequences to patients (Table 2) by the local classifiers at the ICUs. However, while the classifiers had categorized 1773 errors either with no consequences to patient (n = 1368) or consequences not known/mentioned (n = 405), in 168 of the narratives of these reports the rapporteurs had described consequences of the errors. Thus, at least one third (n = 596, 30%) of the reported errors had resulted in consequences to the patients. The three most commonly described consequences to patients were extravasation / infiltration / skin irritation (n = 105, 18%), electrolyte disturbances (n = 96, 16%) and blood glucose changes (n = 89, 15%). In addition, a quarter (n = 492, 25%) of errors had been reported to have required 612 additional procedures (e.g. procedures with the cannula, bronchoscopy, resuscitation or operation), monitoring with additional laboratory tests, or administration of additional medicines to alleviate or monitor the described consequences (Table 2). In the majority of the reports, lasting harm after initial treatment was not mentioned; however, in one report, the error was associated with patient death.

3.4. The onset of the fluid therapy incidents and their detection in the medication process

Fig. 2 describes the phases of the medication process in which the incidents were reported to have occurred and the time point at which they were detected during the medication process and nursing work shifts. The phase
Table 1

The reported error types (n = 2201) with the nature of incidents, the fluid groups involved, the phases of the medication process at which the incidents had occurred and the categorized consequences to the patient.

| Error type               | Nature of incident, n | Fluid group involved in the incident, n | Phase of the medication process at which the incidents had occurred, n | Categorized consequence to the patienta,n |
|--------------------------|-----------------------|----------------------------------------|------------------------------------------------------------------------|------------------------------------------|
| Near miss                | 603                   | I.V. solution additives                 | Preparing                                                              | Serious                                  |
| Omitted fluid product    | 272                   | I.V. solution additives                 | Preparing                                                              | Moderate                                 |
| Wrong concentration     | 238                   | I.V. solution additives                 | Preparing                                                              | Minor                                    |
| Wrong rate               | 237                   | I.V. solution additives                 | Preparing                                                              | No                                      |
| Wrong storage            | 47                    | I.V. solution additives                 | Preparing                                                              | No                                      |
| Contraindicated          | 73                    | I.V. solution additives                 | Preparing                                                              | No                                      |
| Wrong patient            | 22                    | I.V. solution additives                 | Preparing                                                              | No                                      |
| Total                    | 1975                  | I.V. solution additives                 | Preparing                                                              | Total                                    |

a The classified consequences to the patient had been categorized as minor (mild disadvantage demanding little or no treatment), moderate (disadvantage demanding treatment) or major (impairs the patient’s quality of life and requiring life-saving care) by the classifiers at the ICUs.

b The total number of the nature of the incidents is also to the total number of the incident reports (n = 2201).

Table 2

The categorized consequences of the errors (n = 1975) as well as their descriptions and the correcting and monitoring actions to alleviate them, collected from narratives written by the rapporteurs.

| Categorized consequences of errors, n | Errors, n | Described consequences, n | Correcting and monitoring actions described in the reports, n | Total procedures |
|---------------------------------------|-----------|---------------------------|-------------------------------------------------------------|------------------|
| Extravasation/infiltration/skin irritation | 59 | 20 | 7 | 2 | 2 |
| Electrolyte disturbances               | 272 | 11 | 9 | 3 | 3 |
| Blood glucose changes                  | 237 | 14 | 12 | 1 | 1 |
| Incompatibilities                      | 73 | 2 | 1 | 0 | 1 |
| Hemodynamic changes                    | 22 | 1 | 1 | 0 | 1 |
| Secretion and fluid balance changes    | 1975 | 105 | 96 | 89 | 66 |
| Respiratory changes                    | 22 | 1 | 1 | 0 | 1 |
| Problems with cannula                  | 1975 | 105 | 96 | 89 | 66 |
| Blood value changes                    | 22 | 1 | 1 | 0 | 1 |
| Delayed operation                      | 1975 | 105 | 96 | 89 | 66 |
| Changes in pain or level of consciousness | 22 | 1 | 1 | 0 | 1 |
| Changes in blood gases                 | 1975 | 105 | 96 | 89 | 66 |
| Allergic reaction                      | 73 | 2 | 1 | 0 | 1 |
| Total                                  | 1975 | 105 | 96 | 89 | 66 |

a The additional procedures included e.g. procedures with the cannulas, bronchoscopy, operations and resuscitation. Several correcting and monitoring actions might have been required to alleviate a single harm.
of detection was mentioned in 79% \( (n = 1765) \) of all narratives of the fluid therapy incidents. Most of the fluid therapy incidents had been reported to have occurred during the dispensing/preparing phase \( (n = 1306, 59\%) \), followed by the administering phase \( (n = 700, 32\%) \) and prescribing phase \( (n = 195, 9\%) \) of the medication process (Fig. 2). Most incidents in this study were categorized as errors \( (n = 1975) \) and the majority passed through several checkpoints of medication processes and nursing shift change checks without detection. (Fig. 2).

4. Discussion

The well-functioning national incident reporting system and the aggregation of all fluid therapy incidents reported voluntarily in the ICUs enabled the detection of, and learning from, potential systemic points of risk in the fluid therapy process at the national level. These points of risk might not easily be identified at the local level; thus, a larger dataset is required to identify the risk for rare incidents.13 In the national incident report data, one of the most notable points of risk in fluid therapy was the dispensing/preparing phase, where most reported incidents had occurred. Other notable findings were that the majority of the reported incidents had reached the patients, i.e. they were errors, and passed through many phases in the medication process and several nursing shift change checks until, at last, they were detected fairly late during fluid therapy process. Almost every third error was reported to have caused consequences to the patients; some had even been life-threatening and one was related to patient death. A quarter of the errors was reported to have required an additional procedure, monitoring, or administering of an additional medicine to alleviate the consequences of an error.

While most incidents were reported to have occurred in the dispensing/preparing phase, a phase that nurses are mainly responsible for, most reports were completed by nurses and concerned incidents in which nurses had been involved. Nurses form the largest healthcare professional group within the ICUs. On the other hand, physicians, a smaller group within the ICUs, reported, and had been involved in, fewer incidents. The reported incidents represent the tip of the iceberg and these incidents may be much more common.18 However, the reported incidents described in this study are valuable as a starting point, especially when identifying potential systemic points of risk at a national level, to build safer ICU fluid therapy processes by creating system-based barriers against errors at the identified points of risk.

4.1. Strategies for building safer fluid therapy processes in the ICU environment

Safety within fluid therapy processes should be improved by utilizing more extensive system-based protective measures.2 The most effective way to improve medication safety locally in all healthcare systems, is to use patient safety incident reporting as part of a continuous system of safety improvement13; this was in place. The complex processes of medication systems require well-coordinated risk management activities and a broad understanding of medication safety.6 At the local level, an IV Fluid Coordinator19 or a Medication Safety Officer with an IV fluid multidisciplinary team,20 responsible for safe fluid therapy training and education, audit and review of IV fluid related incident reports and fostering and implementing safe IV fluid medication processes to ensure safe patient outcomes is recommended.19 The first Medication Safety Officer whose task is to develop medication safety culture through education and training, including supporting voluntary incident reporting, and research and development, was employed by one of the Healthcare districts in 2017; the second and third in two other Healthcare districts in 2020.21,22 At the national level, it is recommended to continue utilizing the medication error reporting system and to establish a national focal point for developing safe medication practices.12,13

In addition to administering medicines to patients, ICU nurses are responsible for ordering and storing, and dispensing and preparing medicines in Finland. Nationally, the latter phase was identified as a main point of risk. In some ICUs pharmacists work during office hours, and for the time being, their duties mainly include maintaining medicine stocks and preparing medicines. Locally, pharmacists should have a more multifaceted clinical role in the medicines management, working in a team with prescribers and nurses, preventing medication errors through building and implementing strategies for safer medication processes,13 including fluid therapy.23

Wrong fluid product incidents were reported to have occurred mostly during the dispensing/preparing phase. To prevent these incidents from occurring, the number of different IV fluid preparations in the ICUs should be reduced and fluid stocks should be organized in such a way that would minimize mix-ups24 and should be maintained by a pharmacist with the support of pharmacy technicians.

Preparing IV medicines is a complex process prone to many errors,25 in this study, wrong concentration of the fluid product was the third most common error type and occurred mostly during the preparing phase. To prevent these incidents from occurring, the electrolyte infusions should be provided
by pharmaceutical industry in pre-filled syringes or bags, or dose banding should be used, or the preparation of fluid products should be centralized in the hospital pharmacy.26 a practice that is compulsory in some countries.13 Alternatively, introduction of ward-based clinical pharmacy services to take care of the preparing phase could be considered.27 At the very least, there should be a policy that would require fluid products that are dispensed and prepared by nurses to be double checked by another nurse or a pharmacist before administration.3 Double checking should cover the whole medication process and should also be used during the nursing shift changes.28 The use of different technology applications may reduce medication incidents during storing29, dispensing/preparing phases30 by using automated drug dispensing cabinets (ADC) which use bar-code technology, especially by integrating a computerized physician order entry interface within the ADC.29

While fewer incidents were reported within the prescribing and administering phases, such incidents should be prevented from occurring, and incidents should be detected earlier. Replacing handwritten or oral prescribing systems with computerized prescribing order entry and clinical decision support system provides timely alerts,31 and also introducing and strengthening clinical pharmacy services in ICUs, such as prescription reviews of medicines, including fluids, on a regular basis, and clarification of ambiguities, with the prescriber before dispensing and preparing medicines32 may improve prescribing phase safety.

The safety of the administration phase can be improved by using bar code medication administration technology33 and routine checks of infusions at every nursing shift change28 to improve the administering of the correct medicine to the patient. Multidisciplinary maintenance and correct use of drug libraries used in smart infusion pumps is recommended to achieve the correct infusion rate.34 Special attention should be paid to confirming the route of administration, especially when the patient has multiple lines, and the distal ends of all lines should be labelled to ensure that the correct site of access for administration of medicines or fluids can be easily identified.13

Although most of the above technologies are already in use in many hospitals, they are operated separately from each other and require manual programming and transferring of data by the end user which increases the opportunities of errors.35 A closed loop medication management system integrating such technologies would further enhance medication safety by enabling the use of real-time medication information at all phases of the medication process, and by ensuring that correct prescriptions are issued, and correct medicines are dispensed and administered to correct patients.35

4.2. Strengths and limitations

A key tool in developing medication safety, including fluid safety, is the use of voluntary incident reporting systems that makes patient safety incidents visible and enables learning from them.12 This study based on voluntary medication incident reporting identified some of the points of risk within the fluid therapy medication process, for which system based barriers should be developed to prevent errors. The main strength of this study is the utilization of the well-functioning, inclusive, nationwide voluntary incident reporting system comprising all fluid therapy incident reports from the Finnish ICUs from 2007 to 2017. The long study period and the multi-site study provided a comprehensive picture of the points of risk associated with fluid therapy medication process. In addition to the structured incident reports, all narrative reports connected to the same reports were reviewed to obtain further insight into the consequences of the reported incidents and any actions taken to alleviate the effect of the errors.

The main limitation of using data from a voluntary patient safety reporting system is the underreporting of incidents; with this method, only few percent of the errors are revealed.36 In Finnish ICUs, the voluntary reporting activity has remained stable during the last five years of the study. One explanation for the observed stability in reporting may be due to the safety culture of the ICUs, which may encourage reporting by healthcare professionals. The reporting activity of healthcare professionals is dependent on, for example, the encouragement from the management, an atmosphere at the workplace that encourages reporting, the ability of a healthcare professional to identify errors, the feedback received on the reported incidents, and the implementation of protective and preventive system based mechanisms, and communication and training on patient safety.37

Reporting, analyzing, learning from, and providing feedback on, medication errors should be part of routine and daily work. Data mining methods utilizing advanced computational techniques could also be made good use of to improve patient safety and practices.26 Unfortunately, this method was not available during the processing of the national ICU material. Reporting of incidents, including errors and near misses, is an essential component for improving safety, and learning from incidents is seen as an opportunity for quality improvement in high reliability organizations.13

This is what all intensive care units should aim for.

5. Conclusions

Utilizing national incident report data of all fluid therapy incidents reported voluntarily in the ICUs enabled identifying and learning from potential systemic points of risk in the fluid therapy process. To develop the safety of the fluid therapy process, initial interventions should focus on preventing dispensing/preparing phase errors, as well as well implementing checking procedures within the whole fluid therapy process and should also be used during the nursing shift changes. Multiple system based strategies, such as strengthening clinical pharmacy services and utilizing technology, coordinated by IV Fluid Coordinators and Medication Safety Officers, should be considered to improve patient safety at the local and national levels within the ICU environment.

Declaration of Competing Interest

None.

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