

# Analysis of Event Logs from Syringe Pumps

## A Retrospective Pilot Study to Assess Possible Effects of Syringe Pumps on Safety in a University Hospital Critical Care Unit in Germany

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### Abstract

**Background:** Medication errors occur in approximately one out of five doses in a typical hospital setting. Patients in the intensive care unit (ICU) are particularly susceptible to errors during the application of intravenous drugs as they receive numerous potent drugs applied by syringe pumps.

**Objective:** The aim of this study was to analyse the effects on potential harmful medication errors and to address factors that have potential for improving medication safety after the introduction of a standardized drug library into syringe pumps with integrated decision support systems.

**Methods:** A team of physicians and nurses developed a dataset that defined standardized drug concentrations, application rates and alert limits to prevent accidental overdosing of intravenous medications. This dataset was implemented in 100 syringe pumps with the ability to log programming errors, alerts, reprogramming events and overrides ('smart pumps'). In this retrospective pilot study, all pump-related transaction data were obtained from the pump logs, by downloading the data from the pumps, covering 20 months of use between 1 April 2008 and 30 November 2009. Patient data were gathered from the electronic patient charts. The study was performed in a cardiothoracic ICU of the Charité University Hospital, Berlin, Germany.

**Results:** A total of 7884 patient treatment days and 133 601 infusion starts were evaluated. The drug library with the features of the dose rate was used in 92.8% of the syringe pump starts, in 1.5% of the starts a manual dosing mode without the use of the drug library was used and in 5.7% of the starts the mode 'mL/h', without any calculation features, was used. The most frequently used drugs were vasoactive drugs, followed by sedation medication. The user was alerted for a potentially harmful overdosing in 717 cases and in 66 cases the pumps were reprogrammed after the alert. During the early morning hours

a higher rate of alarms was generated by the pumps, compared with the rest of the day.

**Conclusions:** Syringe pumps with integrated safety features have the capacity to intercept medication errors. The structured evaluation of the bedside programming history in log recordings is an important benefit of smart pumps, as this enables the users to obtain an objective measurement of infusion practice, which can be used to provide team feedback and to optimize the programming of the pumps. Further research will show if the combination of these data with physiological data from ICU patients can improve the safety of pump-driven intravenous medication.

## Background

Clinical error is a major global problem. In a survey conducted in the US, 35% of physicians and 42% of the public had experienced an error in their own care or that of a family member, but only 5% of physicians and 6% of the public identify medical errors as an important issue in healthcare.<sup>[1]</sup> Despite this perception of errors by the public and physicians, medical errors account for 44 000–98 000 deaths in the US every year.<sup>[2]</sup> Medication errors occur in approximately one out of five doses in a typical hospital setting, and the percentage of error rated as harmful is about 7%.<sup>[3]</sup> In the National Library of Medicine Medical Subject Headings, medication errors are defined as “errors in prescribing, dispensing, or administering medication with the result that the patient fails to receive the correct drug or the indicated proper drug dosage.” For paediatric patients 54% of potential adverse drug events (ADEs) are reported to be associated with intravenous medications.<sup>[4]</sup> Intravenous medications are vital in the therapeutic management of hospitalized patients and are often delivered with syringe pump systems. Patients in the intensive care unit (ICU) are particularly susceptible to ADEs<sup>[5]</sup> and frequently receive potent intravenous drugs. Errors in administration of these drugs have a high risk for severe adverse events, including fatalities.<sup>[6]</sup> Closed claims analysis revealed that infusion devices are particularly relevant and may be responsible for the majority of deaths.<sup>[7]</sup> Numerous causes for errors in critical

care have been identified<sup>[8]</sup> and can occur at any time during the process of preparing the infusion, calculation of infusion rates, programming of the syringe pump and delivery of the infusion.<sup>[9,10]</sup> During the development of modern models of infusion and syringe pumps, additional safety features focusing on device failures, such as mechanisms to eliminate the risk of free flow, which has caused several fatalities, have been developed.<sup>[11]</sup> Several technologies have been demonstrated to be able to reduce serious medication errors, but most of these technologies had little impact on errors associated with the administration of intravenous drugs.<sup>[12]</sup> In an attempt to reduce human errors at the stage of drug administration to the patient in critical care and anaesthesia, new models of ‘smart pumps’ have integrated complex features, including drug/dose calculations, programmable volume and time calculation, improved alarms and inclusion of drug-specific libraries with the possibility of defining a safe dosing range for each drug.<sup>[13]</sup> These characteristics of modern pumps can result in a reprogramming of syringe pumps in response to alerts and thereby improve patient safety. Studies have shown inconsistent results on how medication errors and ADEs can be prevented using smart pumps.<sup>[14–17]</sup> In this study, we retrospectively analyse the data from 100 syringe pumps of 20 months of use in a cardiothoracic ICU and address factors that have potential for improving medication safety after introduction of a standardized drug library into syringe pumps with safety features and a data logging system.

## Methods

This study was performed at the Charité-University Hospital, Berlin, Germany, in an 11-bed ICU, which predominantly treats patients after cardiothoracic surgery. The ICU was equipped with 100 syringe pumps with smart technology (Alaris Asena CC, CareFusion, Rolle, Switzerland) replacing most of the pre-existing syringe pumps for evaluation purposes. The Institutional Review Board waived the necessity for informed consent (EA1/083/11). The syringe pumps share certain features with the pumps already in use in the ICU, including dose calculation functions, free-flow protection and occlusion alerts. As a novel feature, the pumps included a drug library with capability to standardize concentrations for commonly used drugs, which permitted weight-based volume and rate calculations, and provided dose and rate limits and alerts based on predefined limits, along with the ability to download all user entries during the use of the pumps (safety software Guardrails®, CareFusion, Rolle, Switzerland). During the start of the pumps, users have the option to select a drug and concentration from the drug library or bypass the drug library by entering a drug as a non-specific or generic infusion and thus not to use the feature of rate limit alerts or to apply the drug in an mL/h mode only. Using the drug library mode (Guardrails®), the user selects a drug and standard concentration for weight-based dosing of the patient's weight and, after entering the desired dose, the software calculates flow rates. The company and the hospital's medical engineering department, according to German national laws for use of medical products, educated all users in the ICU in the use of the syringe pumps. Not all the pumps were introduced at the same time: 30 pumps were delivered and installed 6 months prior to the investigation period. These data were not included in the evaluation.

The standardized concentrations for commonly used drugs and the alerts were worked out by a group of physicians and nurses from the ICU where the study was performed, according to already implemented standard operating procedures. For each drug, additional 'soft' and 'hard'

limits were defined and included in the pump's software, without the possibility for individual users to change the software. When a user attempts to use doses that exceed these defined limits, the pump software provides an alert and prevents infusion until the alert is addressed. For 'soft' alerts, the user can decide to override the alert, and for 'hard' alerts the pump will not allow the user to start the infusion. The user must reprogram the dose before starting the pump.

All pump-related transaction data were obtained from the pump log by downloading the data from the pumps before routine service work was performed, into a personal computer covering all user transactions between 1 April 2008 and 30 November 2009. Log reports included the pump identification number, key press dates and times, drug concentrations and rates, drug names (when selected from the drug library), the alerts and the actions of the users after the alerts. All user actions concerning the use of the pump of interest can be displayed in the event log history. This data is not linked to any other database, so a correlation to a specific clinical situation, such as resuscitation, is not possible. This allows the determination of a sequence of user interactions leading up to or occurring after an event. There are different types of events recorded by the pump – reprogramming: the alert was noted and nurse changed dose/rate; overrides: nurse confirms alert and stays with the original dose/rate; cancelled: nurse cancelled the infusion. An event was also logged in the pump's file if the user attempted to change the concentration beyond the defined concentrations (concentration limits) from the drug library. As only drug dosing-related events were evaluated in this analysis, all other alarms, such as syringe occlusion alarms or wrong syringe type, were not included in this evaluation.

The logs from the pump were analysed using the software Guardrails® CQI Event Reporter, Version 4.1 (CareFusion, Rolle, Switzerland). For further calculations, the software IBM SPSS Statistics 19 (IBM Corporation, Somers, NY, USA) was used.

The patient-related data are available in electronic patient records. The variables for the scores and patient age were obtained by an SQL Query

of the electronic patient records (COPRA System GmbH, Sasbachwalden, Germany) for the same time period the pumps were in use. The data were further processed using SPSS Statistics 19.

This was a retrospective pilot study; therefore, no power calculation was made.

## Results

During the study period, a total of 7884 patient treatment days and 133 601 infusion starts were evaluated. Table I shows general demographic data for the patients.

Figure 1 shows the number of alerts per month and the mean SAPS (Simplified Acute Physiology Score), SOFA (Sequential Organ Failure Assessment) and TISS (Therapeutic Intervention Scoring System) scores for the patients in a month. No overall trend in the development of the alerts can be seen, but there are 2 months (November 2008 and May 2009) with an increased number of alerts, compared with the rest of the year. In these 2 months, 85% of the alerts were caused by the attempt to give nitroprusside above the soft limit of 2.0 µg/kg/min.

Statistical analysis revealed that the number of alerts per month (20 months evaluated) significantly correlated with the mean APACHE (Acute Physiology and Chronic Health Evaluation) score for a patient (Spearman's rho correlation coefficient: 0.513, 2-tailed p-value: 0.021).

The drug library with the features of the dose rate alerts was used in 92.8% of the syringe pump

starts, in 1.5% of the starts a manual dosing mode without the use of the drug library was used and in 5.7% of the starts the mode 'mL/h', without any calculation features, was used.

## Medication Use

The number of started infusions, the number of applied boluses and the corresponding number of events (dose rate above soft or hard maximum limit, dose rate below soft minimum, concentrations for drug outside of the range of drug library) for different drug categories is given in figure 2. The most often selected drugs from the drug library for continuous infusion were norepinephrine with 39 230 infusion starts, glyceryl trinitrate with 17 990 infusion starts and insulin with 13 654 syringe pump starts. The bolus function was used 4741 times with norepinephrine, 3620 times with glyceryl trinitrate and 2289 times with propofol. The pumps were used in 62.5% of all cases for vasoactive drugs and in about 10.6% of all cases for analgesia and sedation. If the bolus function was used, it was used in 12.5% of the cases for vasoactive drugs and in 43.1% for analgesia and sedation drugs.

## Events

In summary, we recorded 1063 dose-rate alerts. Nine alerts were recorded, due to not entering a programmed concentration for a given drug at the start of an infusion, ten alerts were due to an attempt to apply a drug above the programmed hard maximum and 698 alerts were due to the application of a dose rate above the soft maximum. In these cases, the drug was started at the entered dose, but the user had to confirm the alert before the infusion was applied. 346 alerts were recorded because the selected dose rate was below the soft minimum dose of a drug. Figure 3 shows the distribution of soft and hard limit alerts for the different drug groups.

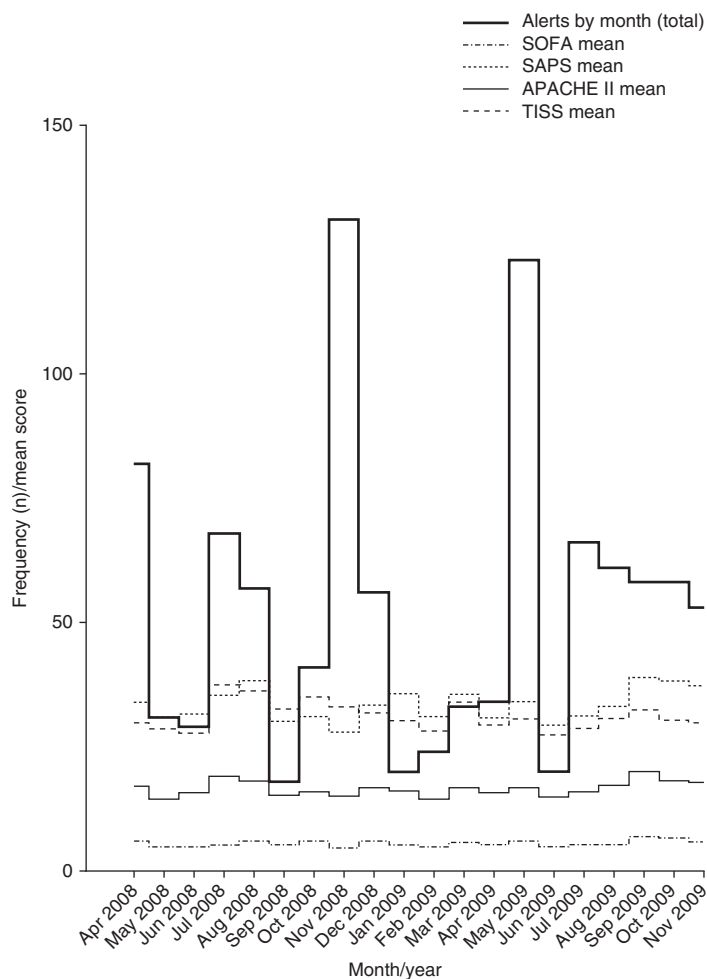
## Distribution of Alerts

Figures 4a and b show the distribution of the alerts for the pumps during different times of the day, in comparison with the number of patient

**Table I.** Patient demographic data for 1188 admissions (1 April 2008–30 November 2009)

Patient characteristics	Value [mean (±SD)]
Age [years]	63.93 (17.3)
ICU LOS [days]	6.03 (10.3)
APACHE II on admission	20.3 (7.97)
TISS	31.21 (2.81)
SOFA	5.62 (0.64)
SAPS	33.26 (3.29)

**APACHE II**=Acute Physiology and Chronic Health Evaluation, version II; **ICU**=intensive care unit; **LOS**=length of stay; **SAPS**=Simplified Acute Physiology Score; **SOFA**=Sequential Organ Failure Assessment; **TISS**=Therapeutic Intervention Scoring System.



**Fig. 1.** SOFA, SAPS, TISS and APACHE II score (means per month) for each patient treatment day, and the frequency (number of alerts by month). **APACHE II**=Acute Physiology and Chronic Health Evaluation, version II; **SAPS**=Simplified Acute Physiology Score; **SOFA**=Sequential Organ Failure Assessment; **TISS**=Therapeutic Intervention Scoring System.

admissions, for the same time interval. There is a peak of admissions between 12:00pm and 1:00pm and a second peak between 3:00pm and 4:00pm correlating to the respective end of surgical procedures. Pump alert incidents did not follow the distribution of admissions. The quotient between alerts and admissions is higher at early times in the morning, towards the end of the night-shift, up to 10:00am. Looking at the weekly distribution of alerts, there is significant correlation between the number of admissions and the alerts generated by the pumps (Spearman's rho co-

efficient 0.811 with a 2-tailed p-value=0.027). On Saturdays and Sundays there are about one-third of the admissions, compared with usual days during the week, and the number of events are correspondingly lower.

### Consequences

Potentially dangerous overdosing was avoided in 717 cases. In 66 cases the pump was reprogrammed using settings within the safe range given by the software (figure 5). In four cases, the

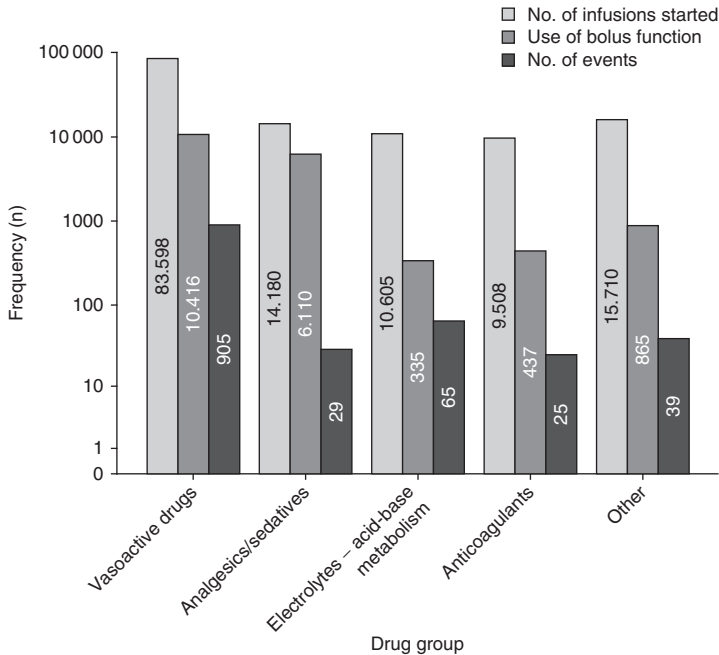
user cancelled the action and began the programming of the pump from the beginning. The reporting tools of the software allow a detailed analysis of the pump log file in order to evaluate the action of the user after encountering an alert. Examples are given in table II.

Discussion

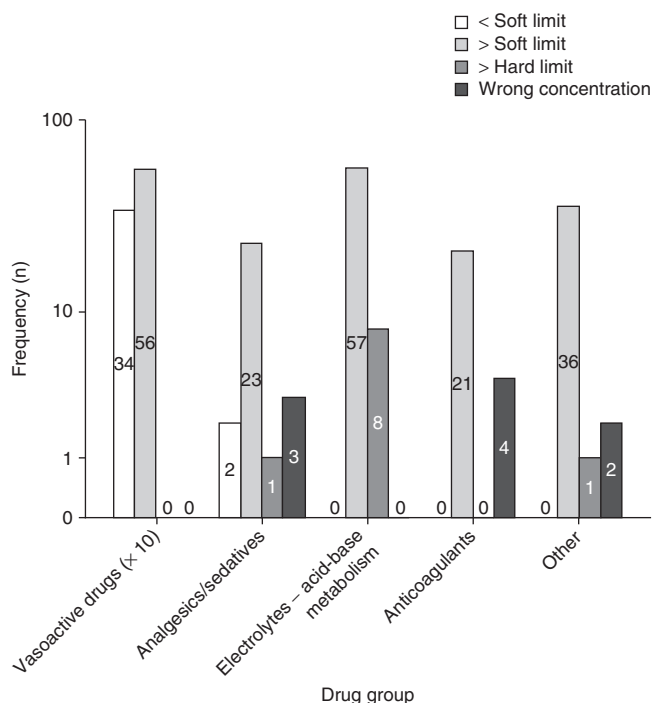
Syringe pumps with a built-in drug library including some safety features, such as dose limits for the accidental programming of very high doses, were introduced with a high compliance rate. In the distribution of the events over the time period of 20 months no trend can be detected; however, there are 2 months with an increased number of alerts. The reason for these peaks remain unclear; there were no changes in clinical routine, the deliveries with the medications from the pharmacy showed no noticeable problems

and there were no unusual fluctuations in the staffing of the ICU. The authors looked closely at the staffing plans of the ICU as newer studies have shown that the use of temporary staff in healthcare is associated with an increased risk of errors that are more harmful to the patients.<sup>[18]</sup>

In a controlled clinical trial by Rothschild et al.,<sup>[14]</sup> intravenous medication errors and ADEs were frequent and could be detected by the use of smart pumps. Their inability to demonstrate a measurable impact on the serious medication error rate was probably due, in part, to a poor compliance of 75%. One conclusion from this study is the fact that the extra programming needed for the use of these pump features is a potential barrier for widespread use. In our observation we were able to show a widespread use of the drug library, with use in 92.75% of the cases. As Carayon and colleagues<sup>[19]</sup> have demonstrated in an implementation study, user experience and acceptance improves



**Fig. 2.** Started infusions (n) for different drug classes, where a drug was selected from the drug library of the pump; use of the bolus function for different drug classes and number of events for different drug classes; data from 100 pumps for 1 April 2008–30 November 2009. Vasoactive drugs used were nitroprusside, norepinephrine, epinephrine, glyceryl trinitrate, urapidil, levosimendan, dobutamine, dopamine, enoximone and milrinone. Drugs used for analgesia and sedation were sufentanil, clonidine, propofol, midazolam, morphine, remifentanil and fentanyl. Drugs used for electrolytes and acid-base metabolism were KCl 7.45%, tris 36.36% and sodium thiosulfate. Drugs used for anticoagulation were heparin and argatroban. Other drugs used were furosemide, orciprenaline, hydrocortisone, iloprost (ilomedin), insulin, amiodarone, diltiazem, phenytoin, epoprostenol and esmolol.



**Fig. 3.** Frequency of event type for the drug groups. Drug groups are the same as in figure 2.

over time. But even 1 year after implementation there were problems reported that are caused by the hardware and software design. This fact emphasizes the importance of a close collaboration between industry and users in the real working environment.

Nuckols et al.<sup>[17]</sup> performed a retrospective analysis of 4604 critically ill patients before and after introduction of smart pumps in two hospitals. The safety features of the smart pump technology did not match the frequently preventable ADEs in the ICU patients. In contrast to our study, the authors only evaluated medical records and did not evaluate smart pump logs or observe users. In contrast to these results, Hatcher et al.<sup>[16]</sup> analysed the software logs from infusion pumps and were able to show that in beta-testing the infusion error prevention support was comparable to the support given by a computerized physician order entry (CPOE) system. The CPOE is able to intercept errors during the prescription and the smart pump technology prevents errors

at the administration step of the medication use process. Husch et al.<sup>[20]</sup> observed the process of 426 medications during 1 day in a tertiary medical centre, and showed that the smart pumps failed to generate meaningful improvements in patient safety; however, the authors excluded areas of high patient turnover from this evaluation.

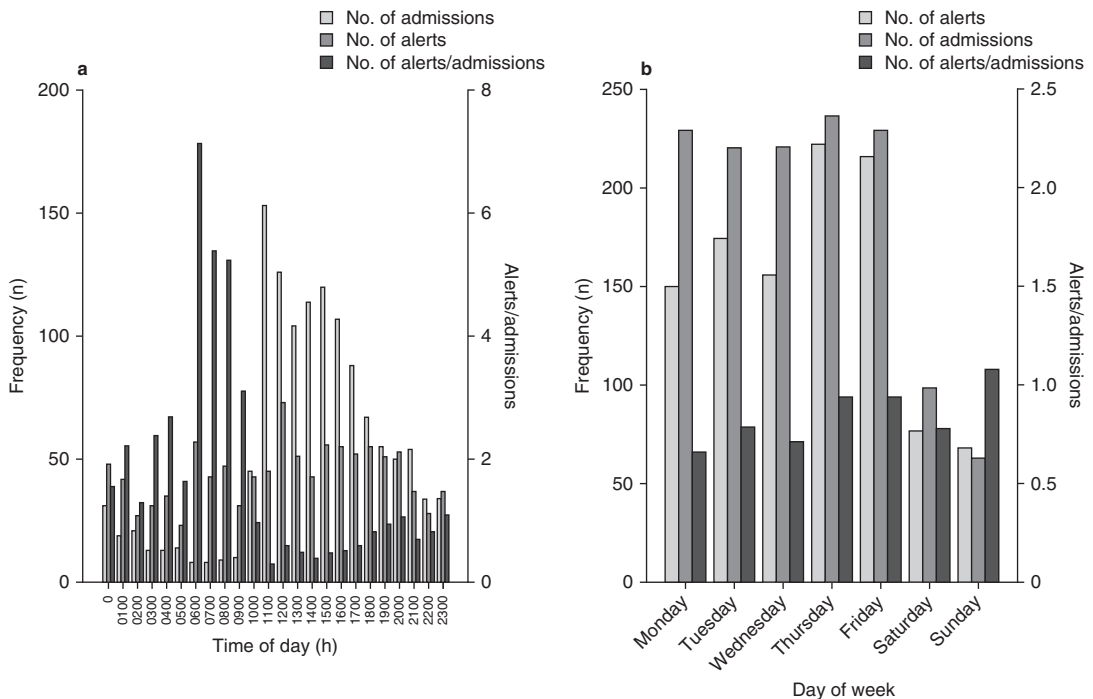
The results of the evaluation of admission frequencies from our study demonstrate that the rate of alerts generated by the pumps was independent of time of day with high patient turnover. Since we investigated the pump-log data covering a period of 20 months, 133 601 syringe pump starts were evaluated. The analysis of the pump data, together with the patient records, might also give an explanation as to why there was high monthly variation in the alert rate. By looking at the general patient data, no reason could be detected for this observation. In our study, during night-shifts with low admission numbers, the relative rate of alerts is elevated. Several studies were able to demonstrate a sub-



stantial decline in cognitive function in high-risk areas, such as the emergency department, during night-shifts.<sup>[21,22]</sup> Other investigators observed most error warnings between 3:00pm and 9:00pm, with a unexpected peak at 6:00pm.<sup>[15]</sup> These differences between the studies might be attributed to different organizations of the ICUs.

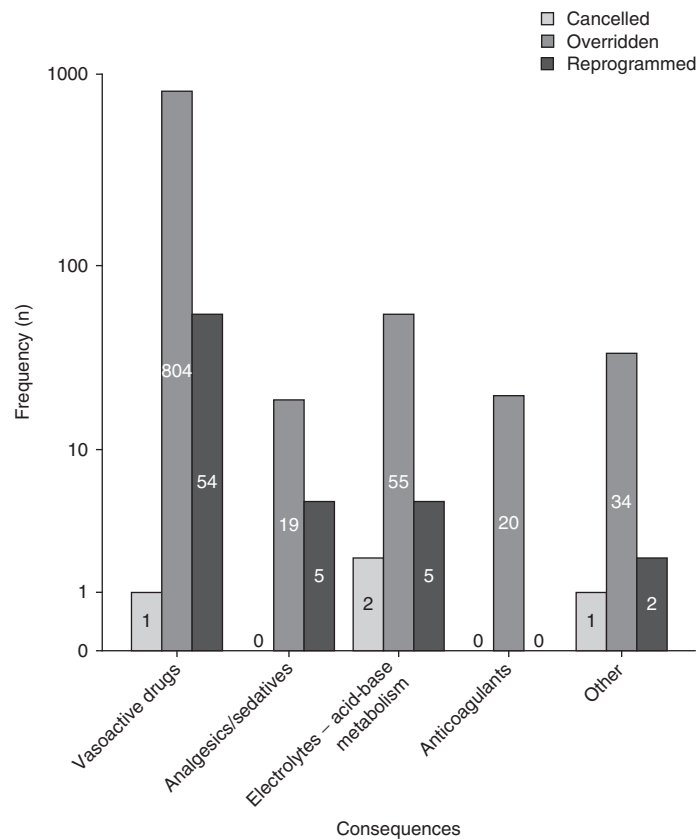
We were able to demonstrate that the pumps influenced the programmed dose rate of medications and prevented overdosing in numerous cases. Despite the use of a patient data management system in the ICU, there is no direct association between the pump data and patients' records. Therefore, at this point we cannot estimate the actual clinical relevance in terms of measurable safety improvement for the individual patient. Since the pumps record every alarm and push of any button, it is possible to analyse the actions of the users after an alarm. In our study the pump was reprogrammed in 66 cases. One has to keep in mind that the use of technology to solve one problem can cause new unforeseen ones. There

are examples from the aviation industry where the introduction of new flight deck instruments caused several crashes instead of improving safety.<sup>[23]</sup> For infusion devices, an example could be emergency situations, where very high doses of vasoactive and inotropic drugs must be applied within a short time. Users might be confused and distracted by the different alarms and limitations of the infusion devices. These aspects should be considered in the further development of infusion devices; for example, by easily accessible emergency functions. On the other hand, the staff in the ICU need to be able to use the infusion devices seamlessly and quickly. This enables them to make sudden changes in infusion therapy for unstable patients or program numerous devices at times with several admissions within a short time period. In order to fulfil these demands, ICU staff may be taking shortcuts or workarounds that violate safe infusion practice, as demonstrated by Small et al.<sup>[24]</sup> Taxis and Barber<sup>[25]</sup> have proposed that deliberate guideline violations for



**Fig. 4.** (a) Distribution of all alerts for the times of day in comparison with the admission times of the patients. Admissions and alerts from 1 April 2008 to 30 November 2009. The ratio of alerts per admission is given. (b) Distribution of the alerts over the week in comparison with the admissions.





**Fig. 5.** Clinical consequences of a pump alert for different drug groups. Drug groups are the same as in figure 2. 717 of these alerts were associated with upper alarm limits or the programming of a wrong concentration.

intravenous drug application are due to a lack of perceived risk, poor role models and available technology. Hard infusion limits are a potential solution for these unsafe infusion practices.

Clearly there are no scientific data available to define critical levels for hard limits. Our results show that even the use of our liberal soft limits, which can be overridden, led to a reprogramming

or cancellation of the programming of the pumps in 70 cases and probably prevented an ADE with this action. This can be derived from the information of the pump log data, which show at which rate the drug infusion was applied after the pump generated an alert. Regular adjustments of the alert limits, based on the evaluation of the pump log data, will probably further improve the

**Table II.** Examples of intercepted possible application errors by the use of programmed soft limits

Drug/attempted dose	Alert	Action
Amiodarone (900 mg/50 mL) 38.7 mg/kg/24h	Above soft limit, (20 mg/kg/24h)	Entry of wrong dose cancelled by user, start of infusion with 13 mg/kg/24h
Levosimendan (12.5 mg/50 mL) 1.230 µg/kg/min	Above soft limit (0.2 µg/kg/min)	Cancelled by the user, start of correct dose with 0.1 µg/kg/min
Glyceryl trinitrate (20 mg/50 mL) 4.0 µg/kg/min	Above soft limit (2.0 µg/kg/min)	Cancelled by the user, new dose 1.0 µg/kg/min

safety for the patients. However, unrestricted use in emergency situations should always be enabled by the software design.

The studies on this matter cannot always be compared directly because the process of intravenous administration also differs from country to country. In most German institutions, the intravenous medications are prepared and administered in the ICU ward by the nursing staff and there is no pharmacist involved in the preparation and administration process. Intravenous medication administration in the critical care setting is a complex multistep process, which delivers many opportunities for errors but also offers substantial opportunities for improvement.<sup>[26]</sup> Several publications have addressed the problem of dose calculations with associated medication errors,<sup>[27–29]</sup> due to difficulties of converting units. Evidence-based strategies for preventions have been published which cover the field of drug preparation, institutional factors such as standardization of medication concentration and syringe labelling.<sup>[30]</sup> Smart pumps can reduce some of these errors between prescription and administration as they have an integrated drug library, which covers all standard dilutions used in the ICU. Wilson and Sullivan<sup>[31]</sup> conclude that the smart infusion technology provides an additional layer of protection at the point of care, even if the hospital pharmacy is involved in the process of medication administration.

Our study has several limitations. It was conducted on a cardiac surgery ICU at a single hospital. This is demonstrated by the high number of started infusions and alerts for cardiovascular medications. In our study, the dosing alert limits were set relatively liberally. This was done for safety concerns. In emergency situations, the users did not want to risk a loss of time if a syringe pump gives an alert for a hard limit. In our study, the alerts for the bolus function of the syringe pumps were not activated for the maximum dose of a bolus and the infusion speed of a bolus was not programmed. The data show that there is a high number of boluses given, especially for analgesia and sedation medication. From the literature it is uncertain if a careful definition of the alert limits for the bolus feature can further

improve the safety and prevent an overdose for a patient.

The syringe pumps were used as standalone devices and not connected to the electronic patient documentation system. Therefore, no information is available about the direct clinical impact of the dose rate alerts. Another problem in the interpretation of the results is that there is no consistent ADE reporting system installed in the ICU. A critical incident reporting (CIRS) system is available but the use of this system is voluntary and anonymous and no information about the precise role of infusion technology is available.

Future research should focus on an integration of the pump data with patient-related data from the monitoring system as well as barcode technology and the integration of pharmacy information systems, which may offer new opportunities to further improve patient safety in the ICU. This integration would also enable the users to evaluate the possible ADE in a real-time mode and to discuss possible consequences within the team.

The evaluation of the data, which were available by the syringe pumps, allowed the analysis of potential medication errors that would have been difficult to identify through other methods of error detection. Although smart intravenous syringe pumps have the potential to reduce the number of serious medication errors, besides the definition of standard drug concentrations for syringe pumps, more attention on the widespread definition of a safe dosing range for various drugs, without limiting the workflow in emergency situations, is necessary.<sup>[15]</sup>

## Conclusions

We found that possible medication errors associated with intravenous syringe pumps in cardiac surgical patients are common and have the potential to cause serious harm to the patients. Syringe pumps with integrated safety features have the capacity to intercept medication errors.

The structured evaluation of the bedside programming history in log recordings is an important benefit of smart pumps as this enables the users to obtain an objective measurement of infusion practice, which can be used to provide

team feedback and to optimize the programming of the pumps. These log files can also be used to monitor nursing practices, including compliance with the use of the drug library and overrides of the drug dosing alerts. The data from the infusion systems are an underutilized rich source for capturing and understanding device usability and safety features. The discrimination between malfunctioning of the device or errors in the operation by the user would facilitate specific interventions to improve device safety and usefulness, such as optimization of the drug library or systematic device training. Further studies will have to show if the connection between the infusion pump technology with the CPOE and the patient documentation system can further improve patient safety. A careful definition and adoption in clinical practice for different areas (emergency room, paediatric intensive care unit, post-anaesthesia care unit, etc.) of the soft- and hard-limits of the syringe pumps is necessary to allow an increase in patient safety without limitation of the user in emergency situations.

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