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How to use current practice, risk analysis and standards to define hospital-wide policies on the safe use of infusion technology

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Abstract: Infusion therapy is widely used in hospitals. It is well known that medication errors constitute one of the highest risks to patient safety, leading to numerous adverse events concerning incorrect application of infusion technology. Both clinical practice and *in vitro* studies show that infusion of multiple medications via one access point induces unwanted phenomena such as backflow and an incorrect system response to interventions. Within the Metrology for Drug Delivery project, we addressed the role of infusion devices in drug delivery. We surveyed current practices for application in hospitals to provide input to standards and quality norms for the materials used in infusion technology. Furthermore, we organized meetings with clinicians and other relevant stakeholders to set up a risk analysis-based infusion policy, accompanied by easy to access operating procedures on infusion technology. It was found difficult to establish clear-cut infusion safety guidelines based on quantitative data because of the many different application areas and stakeholders. However, both the expert team and the survey indicated the value of multidisciplinary qualitative discussion for defining best practices. We advise to incorporate specific requirements on infusion devices in protocols and standards, adjusted to specific applications, to ensure safe use of infusion technology.

Introduction

Infusion technology is very common in hospitals. An estimated 80–90% of hospitalized patients [4] receive intravenously administered drugs as part of their treatment. However, intravenous (IV) drug administration is frequently associated with adverse drug events. Several authorities [2, 7, 5, 19] have expressed concerns on the numerous adverse events concerning the incorrect use or application of infusion technology in hospitals. In the USA, IV medications were involved in 56% of medication errors [12] and 54% of adverse drug events [16]. Although not every medication error leads to patient injury, IV infusion errors lead to serious injury more often than other medication errors. The impact of adjusting a pump to a wrong set point is well known. By contrast, design flaws of IV devices and disposables can lead to dosing errors that are difficult to detect [10]. Better knowledge on the safe and sound use of infusion technology can significantly decrease adverse drug events.

Especially in the case of multi-infusion, when using very critical and potent drugs, and in neonatology, where vulnerable patients receive multiple drugs, it is important to prevent dosing errors. For the neonatologists, optimal control of drug delivery contributes to improved control on therapy of infants and better outcome.

Worldwide, many organizations and institutions have been introducing patient safety plans and procedures for the safe use of infusion technology. In 2006, when the World Health Organization (WHO) launched the High 5s Project to address continuing major concerns about patient safety around the world, they indicated “managing concentrated injectables” as one of the five widespread patient safety problems for which Standard Operating Procedures should be made [7]. In the Netherlands, the

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Dutch Association for Medical Physics, in cooperation with the Netherlands' Organisation for Applied Scientific Research and the Dutch Association for Pharmacists, charted and published an overview of the risks of infusion technology [14, 21]. The role of devices in drug delivery, especially the risks of multi-infusion systems, has been discussed in recent research [6]. Nevertheless, there is still a need for creating awareness on drug delivery safety.

Within the Metrology for Drug Delivery project (MeDD) [13], we carried out research directed to establish a best practice guide with specific guidelines for operating infusion devices in the entire infusion chain that are in line with current standards on infusion technology. To achieve this, we investigated the common practice in European hospitals regarding the use of written standards and protocols that refer to a safe drug delivery. We also performed a multidisciplinary risk analysis to identify causes and effects of infusion technology-related errors. Subsequently, we used the information from the tests of various drug delivery devices and accessories for the combined dosing accuracy [3]. Finally, we started the process of policy making by identifying which key issues should be included in the infusion policy in our hospital and by formulating a set of measures to improve infusion safety.

The objective of this article is to share the process that leads to formulating procedures and protocols aiming at the safe use of infusion technology. As the main focus lies on the policy, the results of the risk analysis will therefore be presented in broad outlines only.

Materials and methods

Surveys to investigate best practices and use of standards

A best practice refers to a commercial or professional procedure that is accepted or prescribed as being correct or most effective. However, it is not always easy to establish what the best practices of infusion technology actually are. Moreover, many techniques are not founded in objective regulations; they are merely customs. By establishing the current practices used in the daily practice of the clinic regarding infusion technology, we aimed at obtaining more insight in the best practices in infusion technology.

Over the course of 6 months, we surveyed doctors and nurses on the current practice of infusion application in their hospital. We used an electronic form for the survey [13] that was disseminated on the Internet in the English, Dutch, German, Portuguese and French language, among the joint research partners from the MeDD project. Subsequently, the survey was sent to several hospitals in order to reach the clinical personnel.

The survey consisted of 34 open questions regarding the use of infusion technology. The questions, which were structured along the

nine steps of IV drug administration, were composed in cooperation with a team of doctors and nurses. The survey questions can roughly be divided in four subjects:

- infusion medical devices, including accuracy and maintenance
- verification of infusion medical devices and software
- (standardization of) settings and infusion chain setup
- user training application

The open-question methodology was used to encourage the professionals involved to respond with extensive answers including a description of the background why and in what applications they use infusion in a specific way.

The data are presented quantity as well as percentage of the entire population. Subsequently, the important, non-repetitive answers were summarized for each question. Tips and wishes given by the physicians and nurses were identified as well.

Apart from this input to best practices for infusion technology, the common practice regarding the use and suitability of written standards for infusion technology was investigated. Hereto, for several EU countries, one or more hospitals, manufacturers, regulators (if existing) and standard development technical committees were approached with a common questionnaire in a shared effort of the MeDD consortium.

Multidisciplinary risk analysis and policy making

To assess the risks, the so-called hourglass (Dutch *zandloper*) model, devised by Vaartjes and colleagues [8, 22], was used. Vaartjes et al. found that most well-known risk analysis models, such as Swiss cheese [15], failure mode and effects analysis [11], and cause and effect analysis [1], were too focused on the details for the large socio-technical systems that are common in health care. As a consequence, health-care professionals have only time to carry out a few risk analyses yearly that need such elaborate study. The hourglass model combines elements of several prospective and retrospective risk analysis models and has a special focus on daily practice. As risk analysis contributes to better understanding and patient safety, the use of this alternative model gave us the possibility to emphasize only on the details when necessary.

A team of clinicians, nurses, pharmacists, and technical experts performed the risk analysis. The team consisted of two anesthesiologists, two hospital pharmacists, seven nurses from different specialties (intensive care, general nursing ward, pediatric ward, pediatric intensive care, oncology ward, internal medicine ward), one senior quality officer of the intensive care department, two hospital technicians specialized in infusion pumps, a medical physicist, and a PhD student. Care was taken that all of the involved professionals were familiar with the use of infusion technology on a daily basis to ensure that the procedures and protocols were patient-focused. The expert group convened in regular sessions and started by carrying out a risk assessment of infusion technology.

The process of drug delivery takes place in multiple stages or steps. During each of these designated steps, there exists a probability of error incidence. Within our clinical setting, the team identified nine steps in process of drug administration to the patient, from the arrival of the patient on the department, medication order, and preparation toward drug delivery. The multidisciplinary team attempted to describe as many full threefold causal sequences of risk factors, critical events, and results as possible.

Subsequently, a subgroup of the multidisciplinary team convened to indicate which key measures and topics should be included in safe infusion policy. The group consisted of two pharmacists, a medical physicist and a medical physics resident, an anesthesiologist, a nurse, a staff member of the intensive care unit, and staff member of the pediatric intensive care unit. During a kickoff meeting, the expert group carried out a sequence of 2-min brainstorming on the main organizational issues that were thought to be most critical for the safe use of infusion technology.

Then, the medical physics resident in individual sessions with each member of the expert group identified preventative and recovery measures on one or more policy topics.

Results

Results for the surveys

There were 61 respondents, of which 34% were physicians, 51% were nurses, and 15% other (Table 1). The survey shows that many different practices exist for many different applications of infusion technology. For example, protocols on what devices to use in the infusion chain differ widely. Table 2 shows how many of the respondents use filters, anti-reflux valves, or manifolds. Infusion technology users feel a need to have more information on why and on what occasion they should use these medical devices and of what can be the drawbacks. For instance, filters are used to prevent particles entering the patient bloodstream, but they can affect the flowrate as well, especially during startup and set point changes. From the survey alone, no clear-cut answers could be given on the best practice for using components. There was agreement

Table 1: Population.

	n	%
Total	61	
Nurses	31	51
Physician		
Including residents	7	11
Total	21	34
Other	9	15
Departments ^a		
Pediatric intensive care/nursery	5	8
Neonatal intensive care/nursery	8	13
General/unknown intensive care	2	3
Operating room	15	25
Other/unknown/unclear	33	54

^aMultiple answers possible.

The percentages were derived from the entire population and multiple answers may be possible; therefore, the cumulative percentage may be higher than 100%.

Italic values are entries made by physicians, of whom part is a registered specialist and part is still in training.

Table 2: Use of components in the infusion setup.

	n	%
Filters (total=61)		
Uses filters for (parental) nutrition	3	5
Uses filters for administrating blood	3	5
Uses filters for unknown or others reasons	17	28
Other/unknown	38	62
Anti-reflux valves (total=61)		
Uses anti-reflux valves	34	56
Does not use anti-reflux valves (or very rarely) ^a	14	23
Other/unknown	13	21
Manifolds (total=61)		
Uses manifolds	38	62
Does not use manifolds	9	15
Other/unknown	14	23

^aSpecifically states to limit use.

The percentages were derived from the entire population and multiple answers may be possible; therefore, the cumulative percentage may be higher than 100%.

on the best practice for the right time to set up the infusion chain, especially in multi-infusion. Almost all respondents preferred to construct the infusion setup with multiple pumps at once.

Most users in our survey, more than 80% of those who answered the question, are aware of the fact that multi-infusion involves a higher probability of error and pay extra attention when using multiple infusion lines on the same catheter. However, they also state that the exact risks of multi-infusion are not entirely clear to them, and they are even less aware of what solutions to use in what specific application.

When using infusion technology, doctors and nurses are in general aiming at achieving an adequate dose of a certain pharmaceutical. They are less directed at applying a certain flow rate; this is considered a more technical point of view. Thus, only half of the respondents of our survey is either aware of when the pump was calibrated or knows how to check this, as is shown in Table 3.

These answers agree with the answers found in the questionnaire on regulations regarding infusion technology setup by the MeDD consortium. Calibration devices are provided, maintained, and calibrated by the manufacturers. Users deem it important that the technology is functioning correctly and therefore need indications on the device that it has been maintained properly. This is mostly seen as the responsibility of the maintenance department.

The respondents agreed on the importance of training when a new infusion device or technology is implemented. Most respondents (>50%) that elaborated on the question whether the frequency of training was sufficient

Table 3: Awareness of pump calibration.

Total	61	%
Is aware ^a	32	53
Is not aware	27	44
No answer	2	3
Frequency mentioned by those who are aware		
Once per year	4	7
Once per 2 years	2	3
Once per month	1	2

^aIs either aware of when the pump was calibrated or knows how to check.

The percentages were derived from the entire population and multiple answers may be possible; therefore, the cumulative percentage may be higher than 100%.

found this introductory training sufficient for safe use. However, the right frequency was deemed dependent on the application.

Results for risk assessment and policy making

A full description of the risks identified in the risk analysis can be found on the MeDD website [17]. For the purpose of this article, only a qualitative description of the risks with the highest impact is given.

From the risk analysis, it was found that most infusion errors occur within the phase where infusion of the pharmaceutical actually takes place. Alarm fatigue risks were found to be the highest. This is consistent with the Emergency Care Research Institute's top 10 health technology hazards of previous years, where alarm hazards were scored as the most risky type of hazard. Other important hazards that were identified were linked with hygiene and infection risks. A remarkable risk was that of applying the wrong dose because of mistakes originating from a poor interoperability of electronic patient records and the medication ordering system. Interestingly, adverse events related to multi-infusion did not show among the most critical risks.

One of the consequences of carrying out the risk analysis in such a broad group of users and stakeholders was that certain hazards could vary in severity among different departments. This made it difficult for the expert group for policy making to assess clear-cut infusion safety guidelines that could be used in the entire hospital.

Therefore, the expert group decided to extract major issues from the risk analysis that should be addressed in a policy draft and give general guidelines on how to

treat them. The four major issues identified were the following:

- infusion device application errors
- inadequate procurement and introduction of infusion-related equipment
- dose errors in infusion pumps
- lack of standardization of infusion devices and pump settings

In addition, technical challenges, such as those encountered in multi-infusion, were identified as a possible cause of adverse events.

For these issues, the expert group identified preventative and recovery measures for each of the major issues from a general perspective:

- To minimize application errors, departments should appoint a “super user” for infusion equipment, who has a deeper knowledge of the technology than standard users. The role of the super user is to answer user questions concerning the use of infusion equipment and to act as an intermediary between the standard users and the medical technology department. The super user also analyzes the impact and requirements of hardware and software modifications in terms of patient safety, user trainings, and hospital organization for his or her department.
- Hospitals should use a procedure in which prior to the introduction or purchase of new infusion-related medical devices, a plan is established. This introduction procedure involves making a business case, performing a risk analysis, and setting up a training program. As part of the introduction procedure
 - the purchasing department establishes an agreement with the supplier concerning the procedure for updating and upgrading hardware and software
 - the technical expert adds the manuals for the equipment to the hospital's intranet site
- Clinicians were positive that dose error-reducing software in infusion pumps is a valuable tool. The opinion in the expert group was that users should therefore be obliged to make use of it. However, the implementation of dose error-reduction software can introduce new types of errors. The expert group warned that care should be taken to establish a system of validated, hospital-wide valid protocols that should be maintained by the pharmacy department.
- The hospital should strive for uniformity in infusion-related medical devices, including disposables. For different applications, it should use standard infusion devices if possible and specific devices where needed.

Neither in the survey nor in the expert team did the identification of technical challenges lead to defining special measures.

Discussion

We surveyed the current practice in the clinic regarding infusion technology to obtain more insight in what best practices in infusion technology exist and carried out risk analysis to identify preventative and recovery measures for the safe use of infusion.

The survey contained a wide variety of answers on how infusion technology is used, from which no clear-cut answers on specific guidelines could be extracted. However, three elements consistently appeared in the answers and therefore could be identified as elements of best practice:

- The function of infusion devices should be adequately monitored and verified.
- Application training, at least when introducing a new infusion device or application, is necessary to prevent errors.
- Mix-ups in multi-infusion should be prevented by labeling the lines or other measures.

The respondents explicitly stated that more information on why and on what occasion they should use specific infusion devices, for example, for what specific applications a carrier flow would be necessary to prevent fluctuations in the dose rate.

Administering the right flow rate seems a somewhat undefined responsibility of the doctor, nurse, pharmacists, and the maintenance department. However, there are various written standards that refer to the dosing accuracy and calibration of drug delivery devices:

- European Directive 93/42/ECC: medical devices
- IEC 60601-2-24: medical electrical equipment – requirements for the safety of infusion pumps and controllers
- ISO 28620: medical devices – non-electrically driven infusion devices
- IEC 62353: medical electrical equipment: recurrent test and test after repair of medical electrical equipment

The one most referred to is IEC/EN 60601-2-24. Manufacturers typically follow this written standard in developing and maintaining their devices. However, these standards refer to the infusion pump and syringe only and disregard the rest of the infusion device chain, although, especially

in multi-infusion setups, the application setup used can be more decisive for the actual flow rate and thus to the medication dosage.

Hospitals use their own protocols based on manufacturers' recommendations for maintaining and calibrating pumps. Calibration devices are provided, maintained, and calibrated by the manufacturers. There is only limited knowledge and insight into metrology in general and to traceability of measurements. This approach seems to work because patients are monitored closely with other equipment or approaches, e.g. measurement of pulse and blood pressure by highly dedicated, educated, and trained personnel. However, in high-risk applications or for critically ill patients, where accuracy counts most, this approach may not be adequate.

In the survey, technical challenges, such as those encountered in multi-infusion, were identified as a possible cause of adverse events. However, no risk-mitigating measures were defined. We find, based on the research done within the EMRP, that these issues are typically not given enough attention. These aspects are therefore further discussed in [20].

Quantitative conclusions that can be drawn from the survey are limited. To receive a clear picture of the *status quo*, a much broader response would be necessary from respondents with a more varied background. However, both the survey and the risk analysis provide a qualitative perspective on the use of infusion technology and provide a good roadmap for further quantitative research. For example, from the clinical experience of our expert panel, which included key opinion leaders, it was suggested that many errors and adverse events in infusion technology are of unknown, and therefore possibly technical, origin. This stance is supported by literature [9] and by some respondents of the survey. A better understanding of the cause of these errors helps to define recovery measures. A more detailed research is therefore needed on the causes of errors to be able to point out the best recovery measures. The research on concentration modeling and measurement in multi-infusion medication schedules carried out in the MeDD project [20] is a good evidence-based starting point for more specific advice on how to use specific infusion applications. For example, both laboratory experiments [3, 20] and a literature review [18] were used for addressing technical issues. In this research, it has among others been identified that dead volume inside the tubes and infusion system compliance produce opposite deviations from the set point values in the actual drug output concentrations, making the net result hard to predict and often counterintuitive. Predictive modeling of concentration output, combined with *in vitro* experiments

from multi-infusion setups, can help clinicians to identify what evidence-based measures work best for specific applications.

Although drawing up detailed guidelines for specific applications is still ahead, general guidelines can already be made. Both the survey and the risk analysis provide valuable information about the current bottlenecks and recommendations for using infusion technology in the hospital. Our expert team advises to appoint super users to prevent application errors and to use established procedures for the introduction of new infusion devices to make sure that hazards are known and can be mitigated.

The clinicians were positive that dose error-reduction software could reduce the number of user mistakes and therefore should be used. This was also found in the survey of best practices. Our expert team advises to appoint a multidisciplinary project team, including the pharmacy and medical technology department, to tailor this software to the hospital's needs.

Future work should include a more extensive survey including key opinion leaders to establish best practice in the application of infusion technology.

Conclusions

In this article, we report on the potential issues that should be addressed in policies for the safe use of infusion. Risk assessment is an important step to identify the important topics that should be included.

From the survey of best practices and the discussions in our expert team, it was found that establishing clear-cut infusion guidelines that are intrinsically safe is difficult. Infusion is a very intricate process, with many applications needing different approaches. Because of this and the many stakeholders involved, there is not one solution that fits all.

However, risk assessment and discussion on policy issues contribute to increased awareness of the key issues that should be included in protocols and hospital policy. Multidisciplinary expert teams are useful in this process of identifying general guidelines for the safe use of infusion technology. They can use patient risks established during the risk assessment and organizational issues as a starting point for a set of agreements for the acquisition and introduction of infusion technology, the management of infusion pump settings, education of nurses and other users, and establishing responsibilities and authorities. Clinicians were positive that dose error-reduction software could reduce the number of user mistakes, provided

the use is closely regulated and responsibilities on use and management of settings are clearly targeted, with a central responsibility for the pharmacy department.

Safe application of infusion technology needs to be sustained by protocols and standards. We advise to further investigate possibilities to incorporate specific requirements on infusion medical devices in protocols and standards, adjusted to specific applications, to ensure safe use of infusion technology. The results from predictive modeling and *in vitro* measurements can be used to devise much needed application-specific protocols.

The results from MeDD could be used to improve the most commonly used standards for infusion technology, for example, they could feed into ISO 28620. The MeDD consortium plans to approach IEC/SC 62 D (for EN 60601-2-24) and the ISO standard technical committee on devices for administration of medicinal products and catheters (ISO/TC 84) to discuss where adding application-specific standards can have an added value for patient safety.

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