HOSPITAL PHARMACY EUROPE

ROUNDTABLE REPORT

Reducing the risk of IV infusion errors – European insights on improving patient safety

Funded by

BD

Copyright © Cogora Limited 2018. The contents of this publication are protected by copyright. All rights reserved. No part of this publication may be produced, stored in a retrieval system or transmitted in any form or by any means without the written permission of the publisher. The views expressed in this publication are not necessarily those of the publisher or editorial advisors. While the publisher and editorial advisors have taken every care with regard to accuracy of editorial and advertisement contributions, they cannot be held responsible for any errors or omissions contained therein. Published in the United Kingdom by Cogora Limited, 140 London Wall, London EC2Y 5DN, UK.

T +44 (0)20 7214 0500 **E** info@cogora.com **W** cogora.com

A roundtable was recently convened to gain real-world insight into current intravenous (IV) infusion practices across Europe, and to determine possible strategies for improving safety in IV medication delivery, with a focus on administration. Recently, IV pump safety software has been designed for this purpose, however, the delegates – whose expertise spans a wide range of roles, specialities and working environments – identified several potential barriers to its implementation. Furthermore, they offered their suggestions on how safer IV administration could be achieved for all.

It is a reasonable assumption that patient safety sits high on the priority list of healthcare providers, medical product manufacturers and hospital management alike. Aside from the obvious benefits of improving patient care, minimising operational costs and improving efficiency are also closely linked to preventable adverse drug events.

Error reporting – the reality

Medication errors are defined as 'any incident where there has been an error in the process of prescribing, preparing, dispensing, administering, monitoring or providing advice on medicines'.[1] These incidents may include errors of commission such as the wrong medicine or wrong dose, or errors of omission, for example, omitted dose or drug monitoring parameter. We know there is a high prevalence of medication errors worldwide, but does the existing literature on this subject tell the whole story? Although the clinical literature aims to reveal a clearer picture, underreporting of such errors is almost a certainty.

There appear to be inconsistencies across Europe in terms of reporting practices. In some countries, reporting happens on a voluntary or ad-hoc basis, and with whom this responsibility lies is unclear; it may be an appointed pharmacovigilance agency, as is the case in France, or the obligation to report errors may fall upon the healthcare professionals themselves. In many European countries, reporting is done manually, by a physician or ward pharmacist, and the benefits for providing the level of human resource required for this time-intensive task may then be called into question. Issues surrounding blame and awareness of errors may also impact reporting. Everybody in attendance agreed that there is limited documentation of evidence base of medication error.

In the UK, there is a centralised reporting system for national errors, which feeds into NHS Improvement.[2] It currently records two million incidents per annum – and that is the tip of the iceberg. There is a dedicated team within that department, which looks at medical device errors (40–50 thousand annually) and medication errors. They also employ the services of a national network of medication safety officers and medical device safety officers to review reports.

Analysis of the data that is recorded can also be lacking, making it difficult to draw conclusions and bring about helpful change. It takes a great deal of time to analyse an error database, and 'defining' what counts as a mistake can add to this workload. For example, technically, there is an error if a physician takes a particular antibiotic for a certain patient when there is another one in the formulary. But for the patient, that may not be a mistake because it was an appropriate antibiotic. Unfortunately, there is a common view that data is not used to bring about change until the consequences of an error become as serious as patient loss of life, or when cost and litigation become factors.

IV pump safety software

IV pump safety software is a hugely beneficial tool in a hospital's armamentarium, yet there appears to be barriers to its use, evidenced by the lack of uptake among device users. For example, uptake of the dose error reduction system (DERS) comprehensive continuous quality improvement service remains low in the UK among pump users.

However, before we can propose ways to improve uptake, we must first identify what these barriers to use are. So, in this roundtable meeting, we gathered a group of experts from all over Europe to offer their perspectives and to share experiences on the safety of IV medication delivery and how it may be improved.

Barriers

The existing barriers to improving patient safety »

> There's more and more data now available in the UK to substantiate what people have been saying for a long time, which is that medication errors are happening all the time
>
> **Mr Paul Lee, UK**

DELEGATES

Professor Nick Barber
Professor of Pharmacy, University College London, UK

Dr Alexandre Benoist
Pharmacist, Hospital Centre William Morey, Chalon-sur-Saône, France

Mr Lars Gubelt
Director of Pharmacy, Hospital Essen, Germany

Dr Torsten Hoppe-Tichy
Chief Pharmacist, University Hospital Heidelberg, Germany

Dr Sun Hee Kim
Pharmacist, Universitäts Medizin, Mainz, Germany

Dr Stéphane Kirche
Head of Biomed IT, Hospital Centre William Morey, Chalon-sur-Saône, France

Mr Paul Lee
Medical Device Training Manager, Singleton Hospital, Wales, United Kingdom (UK)

Mr Tom Skelland
Lead Pharmacist, St George's University Hospitals NHS Foundation Trust, London, UK

Dr Marta Trojniak
Clinical Pharmacology Researcher, Burlo Garofolo Pediatric Institute, Trieste, Italy

Dr Theresa Saklatvala
Content Director and Chair, Cogora: The Agency

IV infusion safety

Mr Tom Skelland presented information from a UK advisory board that convened in September 2017 to better understand priorities and challenges faced by pharmacies with regard to assuring patient safety for IV infusion. The board wanted to gain consensus on the incidence of adverse events and publish the pharmacists' perspective on the impact of infusion errors on the NHS. Finally, the board aimed to define the cost to the NHS of infusion adverse events and to build a business case for implementing a DERS.

He identified three key areas of focus for the NHS today, relevant to IV medication use:
1 Enhancing patient safety
2 Reducing variation and standardising infusion protocols
3 Ensuring cost efficiency by minimising costs related to preventable adverse drug events

As reported earlier this year in a study involving 16 NHS hospital trusts,[3] 11 (69%) used smart pumps, ie. an infusion pump with a drug library and/or DERS enabled) in at least one clinical area. However, only 32% of infusions were administered using a smart pump.

The advisory board aimed to draft a publication from a large systematic review of the burden of IV medication errors in the UK. The goals were to identify the overall number of errors prevented as a function of opportunities for error, and to detect any trends among drug classes.

are likely to be multifaceted, and are here listed in order of relevance to the delegates:

Sociological issues may be preventing standardisation
Kotter, a Harvard professor, defined seven stages of change and organisation. The first step is that there needs to be a 'burning platform'.[4] This analogy involves a burning platform with an obvious and immediate need to escape: a motivator that cannot be ignored. The absence of this burning platform was suggested as the principle barrier for software implementation for many countries. The perception of the magnitude of known medication errors may not be great enough in incidence or consequence to provide that burning platform. However, the reality is the number is likely to be much larger and drug safety software is aiming to give an accurate account. There may also be an unspoken fear around accountability – if every decision is documented, does that open the physician up to a certain degree of risk?

Senior physicians in many European hospitals have a strong sense of ownership and pride over the way their hospitals or departments are run. Within that there may be an element of decision-making to carve their own 'identity' and set themselves aside from their competitors.

Confusion in roles
In addition to the variability in Europe between protocol standards, there are also key differences in responsibility for IV medication delivery infusion safety and specific roles are often unclear. Responsibility for patient safety ranges from an individual level to a departmental level, all the way to a national level, depending on where you are in Europe and which hospital you are in.

To illustrate this point, it was suggested that in the UK there is a common misconception that the national office, which used to be the National Patient Safety Agency and is now NHS improvement, is continually gathering and analysing safety data, but in reality, its role is to look at new issues; medication errors are not new.

> Reducing variation is seen as a major way to improve services, improve safety and so on, and that is what technology, if used properly, does. It reduces variation
> **Professor Nick Barber, UK**

Confusion around the software and differences in implementation
Confusion around the term 'drug safety software' may affect its implementation as there is no consensus as to what it means.

Implementation also varies between drug classes – tighter safety parameters and alerts may be issued for cytotoxics compared with antibiotics, for example. Differences in devices and software used can also exist between hospitals, and even departments in the same hospital – introducing the potential for error at various stages of the patient journey.

While national utilisation of the same software would undoubtedly improve standardisation, achieving this is fraught with difficulties that stem predominantly from the issues of regional budget management and the freedom of the physician to choose his or her own equipment in countries where hospitals are privately owned. All board members agreed that a realistic goal would be to have a range of software that is standardised and that can interface with each other.

Limited IV protocol standardisation
A key goal for enhancing patient safety as it applies to IV medication is to reduce variation and standardise infusion protocols. Although many European hospitals have infusion protocols in place, there is a significant degree of variation according to drug class/toxicity, hospital, department and how that protocol is presented among other factors.

In some cases, as in Germany, it is the physician's responsibility to outline the infusion protocol, but there is the very real chance that the physician may lack the pharmacokinetic knowledge of the drug to make the best decision on infusion rate – so standardisation is important.

In countries such as the UK, where there is a centralised health service, standardisation of protocols may be more achievable than in countries where hospitals are privately owned and funded. Often in the latter situation, the people in command expect more influence over protocols, politics and investments. Available guidelines vary widely by country too. Whereas in the UK there is the Medicines and Healthcare products Regulatory Agency (MHRA), Royal College of Pharmacy and Royal College of Nursing guidelines for infusion therapy, in other European countries there is a lack of guidelines in this area.

Furthermore, in some countries, such as Italy, inter-regional differences can affect the emphasis placed on the importance of minimising medication errors, and consequently, the funding available to do so.

The Biomedical Director delegate from France agreed with the pharmacists around the table that standardised protocols are very difficult to create and implement.

Usability and underuse of safety software
DERS has critics who may be reluctant to implement it because they feel it is too complicated or labour intensive for all staff responsible. In addition, people may be unaware of the capabilities of such software. They may not properly understand DERS or the benefits it can bring. The problem may be at a system level; underuse of safety software may arise from the technology not actually addressing a user's needs, because its specific problem has not been identified in the first place, owing to the absence of a well-documented evidence base. Additionally,

the safety software in itself will not reduce medication errors – manual activities are key to its deployment, implying additional risk and workload.

Although this software has the capability to record, it may not be used to the best of its ability – for example if you spot an error that happened historically, unless you know which pump was with which patient, it is hard to locate the error. This requires further manual recording from staff.

Delays in drug delivery can also affect staff willingness to use software. Alarm fatigue can be caused by managing over-sensitive limits and, more importantly, this can impact on therapeutic efficacy. Unnecessary alarms can cause significant delays in treatment, meaning the drug is not infused over the correct length of time and drug plasma levels remain lower than they should be.

The attendees noted also that they rarely see safety limits input by manufacturers. Even medications intended for low rate infusion are set to the maximum limit. This opens up the possibility of human errors, introduced through distractions, fatigue and so on. Were industry to offer templates and default drug libraries, development and processes would be adopted more readily, and patient safety implicitly enhanced.

Extracting data from software

Different infusion device suppliers can work with different software platforms, and employ different methods for recording errors, which can add to confusion. However, a valuable point raised by one attendee is that it is useful to have a national database to turn to when a serious issue is raised, even if it is not analysed otherwise.

Suggestions

What will help uptake of this technology and what features are most beneficial? All delegates agreed on the following wish list:

Raising awareness

The roundtable attendees agreed that there was a lack of knowledge around what is actually available to help improve IV safety, which translates to a major requirement to raise awareness among all involved in the procurement of safety devices and software. Stakeholders need to know what tools they have at their disposal to help them improve infusion safety, as well as exactly how they work and how they can help achieve their goals.

Standardisation

Collaboration from manufacturers may help ensure standardisation of safety protocols where possible. Furthermore, hospitals that choose a unique supplier for their equipment may benefit from in-house clinical evaluations from that supplier.

A step-wise approach to technology implementation

A step-wise approach to implementation may help simplify the process and make it seem a less daunting task. The suggestion was put forward that collaborating with safety organisations to identify the drugs most commonly associated with medication errors could help as the software could be used only on these infusions as a 'first phase'.

Adaptable technology

Some patients need more individualised care than others and this should be taken into consideration, for example, patients with rare diseases in university hospitals and those with kidney dysfunction. There may also be more of a need for safety software in some areas than others. The suggestion was made that specialist nurses may be more adept at carrying out the IV infusions in their field of work, whereas in general wards, nurses have a broader range of drugs to deal with and potentially less expertise in this area.

> To reduce human error factors, you need to improve the device interface
>
> **Dr Alexandre Benoist, France**

When it comes to actual features of the technology, a few suggestions were put forward:

- Different messages could differentiate between different situations. For example, if a physician makes a mistake on a prescription, the pump output message should indicate this is not standard protocol, whereas if the user inputs the wrong prescription dose into the pump, the message could read 'be careful, this does not match the prescription'.
- Updates and reboots should be easy and use wi-fi capabilities where possible, to save time, effort and money. Studies into community pharmacies found many dispensing errors were a consequence of not having updated the software because doing so required time and effort.
- Barcode scanning may help the technology become more adaptable – individualising it according to the patient's circumstances and the drug – and minimising both input time and the potential for errors (risk reduction and cost reduction). The financial value of this has been demonstrated by the UK government-funded project called Scan for Safety. In one hospital in England, a barcode scanning system for prostheses resulted in substantial cost savings.
- Alarm sensitivity should have the capability to be adjusted according to the drug/product to prevent alarm fatigue. One of the changes being considered is the 'near end of infusion' alarm – this may not be necessary for all drugs (for example a bag of saline) and may take up valuable nurse time. This would be one instance of intelligent alarm management being used to maximise staff resource.

Better training

At the core of everything is the need for training, and for that training to be updated and maintained. Learned skills must keep up with technology development. Ensuring software competency may require a collaborative effort between the hospital, its staff, the suppliers and the government. In addition, staff may be required to carry out assessments to monitor skills and ensure all staff are up to date. Currently, nurses may be passing their knowledge from staff member to staff member, which can propagate mistakes like a game of Chinese whispers.

To ensure all technology capabilities are explained properly, it is important to look at the needs of the individual department and adapt training accordingly. For example, one study shared anecdotally by an attendee identified an unmet need for heparin bolus administration. So, the decision was taken to adapt the technology to enable this task to be carried out by the machine, changing clinical practice and potentially reducing risk.

Underpinning effective training is the ability to empower the users to facilitate change by helping them to understand how the technology can assist their clinical workload management and reduce their personal risk; it is a safety net that is there to protect them. Imparting this knowledge may involve collaboration from nursing bodies at a national level.

> It's very, very important to have lots of training, lots of support for the team to change practice
>
> **Dr Stephane Kirche, France**

Manufacturer's input

There is an unmet need for data pooling and »

sharing among users that could be enabled by the manufacturer, so users can share data sets, learning, protocols and standardisation of the software. A similar scheme is being launched in the UK for BD pumps but is in its very early stages.

Further to this, it might be beneficial for the manufacturer to provide internal training, to equip pharmacists with the knowledge and skills they need to propose a compelling business case for the implementation of safety software within their hospitals.

Sociological incentives for safety software use

There is no doubt that transparency of medication errors becomes a risk to reputation. Publishing errors in a candid way offers a further incentive for hospitals to avoid them, and this may increase focus on safety measures, including technology. This is especially true in countries where there is an element of competition between hospitals.

Financial impact of safety software use

Depending on set-up in any given country, there may be the opportunity to use safety almost as a 'selling point' – one hospital in the UK that has implemented drug safety software on its devices right across the organisation highlights this in a footer on every email it sends out.

Economic modelling data could be tailored to meet countries' specific needs – it was suggested that there may be a role for a company to commission independent experts or teams to look at this. Economic modelling can be time consuming but it enables you to estimate financial savings. There is perhaps a place for a core economic model that can be adapted according to the individual country. For example, the staff carrying out the tasks would be different in different countries, so maximising their time would result in different cost savings. That would be a robust argument in defence of a business case. So, for example, if you have a shortage of nurses, then saving nursing time is a valuable benefit, so you might use that argument. That is critical because it addresses the issues of robustness of data and independence.

Although it is impossible to put value on human life, the return on investment might also come from better treatment. For example, if you have an infusion error and because of that somebody needs hospitalisation for a week, that is an easily calculated cost.

Could the research be used in a more helpful way?

It is important to lean on experience from different countries and capitalise on others' experiences. Driving continuous quality improvement may come from publishing literature to make the case for more emphasis on patient safety.

Research carried out in each hospital that will be using the software, and potentially funded by the manufacturer, would give hospitals their own research evidence base and would overcome any biasing issues that might be seen to exist.

A collaborative effort

Appointing a 'champion for change' can help uptake of safety software. Clearly outlining responsibilities is key to this. An individual or a team of people should be directly responsible for enhancing drug safety and patient safety, setting standards, overseeing all training and ensuring those standards are met. The person or team chosen for that role will undoubtedly change according to the country or system set-up.

The IT department now has a bigger role than ever before, and its input is vital in implementing technology in hospitals. An IT department that is well trained in a clinical environment and has adequate, in-depth product training from the product manufacturer would be invaluable. Furthermore, it is imperative that involvement is extended to the procurement department within the hospital.

Is there a missed opportunity for a peer-to-peer exchange programme?

An onsite centre of excellence, housed in a hospital that is making the best use of this technology, could also bring about tangible change. This could involve hosting a peer-to-peer workshop or exchange to improve quality among clinicians and share best practices. One institution could spend two years implementing drug safety software, evaluating, fine-tuning, getting the datasets – sharing that data enables another to catch up very quickly.

Although competition may make peer-to-peer sharing trickier in some set-ups, it may still be possible to share experience in a very focused way. This might involve collaboration right at the beginning of the implementation process so there is a level of neutrality and it becomes about shared problem solving rather than competition. A shared exchange of information could also be possible through societies at the national level.

Patient involvement

As technology and the media evolves, patients are becoming more aware of medical errors. They have the biggest incentive for their own safety and care – so safety software may help enable them to manage their own infusion in the future. An example of this in practice is in Jönköping, Sweden, where patients have started doing their own dialysis. There is potential to drive patients to effect change in the treatment that they're getting.

Conclusion

Although there are clear barriers to the implementation of methods that will reduce IV medication errors throughout Europe, there is also a wide range of opportunities to be explored that may improve standardisation and uptake of safety software. Going forward, collaboration between all stakeholders, training that helps users of technology on a practical level, and better ways of communicating benefits, are all ways in which we can drive change and provide better patient safety for all.

The delegates 'wish list' for safer IV administration

- Standardising safety protocols
- Improving awareness around what's available
- Taking a step-wise approach to technology implementation
- Introducing technology that is 'intelligent' and adaptable
- Enabling better staff training and ongoing competency assessment
- Software and hardware manufacturers' involvement in training
- Increasing sociological and financial incentives for software usage
- Using research effectively, to make the case for more emphasis on patient safety
- Appointing a 'champion for change' and collaborating with all those involved in patient safety
- Introducing a peer-to-peer exchange programme
- Potentially involving patients in their own IV infusions in future

> You have to be aware that change will not happen immediately, you need to empower and train the person who is making the change
>
> **Dr Marta Trojniak, Italy**

The roundtable 'Reducing the risk of IV infusion errors – European insights on improving patient safety' was convened in Amsterdam on 9 March 2018, with the support of BD, and was attended by experts in pharmacy from Germany, France, Italy and the UK.

References
1 NHS England. Public Safety Alert. Stage Three: Directive – Improving medication error incident reporting and learning (NHS/PSA/D/2014/005). March 2014. Available from: https://www.england.nhs.uk/wp-content/uploads/2014/03/psa-sup-info-med-error.pdf. Accessed 4 April 2018.
2 NHS Improvement. Improving medication error incident reporting and learning. 2014. Available from: https://www.improvements.nhs.uk/news-alerts/improving-medication-error-incident-reporting-and-learning
3 Lyons I, Furniss D, Blandford A, et al. Errors and discrepancies in the administration of intravenous infusions: a mixed methods multihospital observational study. BMJ Qual Saf Epub ahead of print 7 April 2018. doi. 10.1136/bmjqs-2017-007476
4 Kotter, J. P. Leading Change. Boston: Harvard Business School Press, 1996.