ROUND TABLE

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Smart infusion technology

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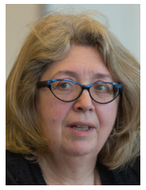
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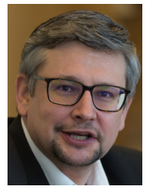
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Smart infusion technology

More than half of the most serious and most costly medication errors are associated with IV drugs. Of the 38% of errors that occur at the point of administration, only 2% are intercepted.

Many infusion pumps come with the option of installing dose error reduction software (DERS) and yet the vast majority of people either do not use it, or do not use it to its full potential.

A group of senior European hospital pharmacists and clinicians gathered recently to analyse the costs of implementing DERS and the associated benefits of using drug libraries while also sharing their practical tips for the implementation of smart pumps.

Smart pumps are infusion pumps that are DERS ready, that is to say, have the capability to receive a drug library. But how difficult, time consuming and costly is it to build and maintain a drug library and to what gain?

Not-smart infusion technology

Having invested in infusion pumps as a standalone safety technology, there are a number of reasons why hospitals may not use the DERS. Included among those reasons are the following:

- You can benefit from uni-directional connectivity without having to invest in the drug library.

- The introduction of smart pumps requires a champion who can lead staff in re-engineering processes for which physicians, pharmacists and nurses take ownership. It takes time to develop a drug library and change management is difficult and resource-heavy, if there is no perceived advantage over current practices.

- In oncology, the number of ways a drug might be administered (perhaps two drugs simultaneously), over varying time scales, makes the use of a drug library too cumbersome. If the pump reads a barcode and has all the information pertaining to that particular infusion, there is no perceived reason for a drug library.

- There is no point buying in smart pumps and investing in building the drug library if provision has not been made for maintaining the library.

- There will still be errors if smart pumps are not integrated with other systems, eg. barcode administration, Computerised Physician Order Entry and automatic dispensing systems.

- Use of smart pumps runs the risk of complacency from a less-vigilant workforce.

- All new technologies will introduce errors of their own.

Experience of users of DERS

In the case of St George's Hospital in London, when smart pumps were introduced, there was no buy-in from the organisation to introduce electronic prescribing software. However, as the existing pumps had to be replaced, the decision was taken to buy smart pumps, as a standalone technology. Why? Because errors in drug medication can be picked up, usually by the pharmacist, at the point of prescribing, but rarely at the point of administration – without a smart pump with a drug library, there can be no confidence that they can be intercepted. This safety gap was closed with smart pumps with a drug library.

In the case of the Gregorio Marañón in Madrid, the error that motivated the use of smart pumps with a drug library involved a nurse overriding a 5-FU protocol that required the infusion over 48 hours (clearly stated by the pharmacy), infusing over eight hours instead.

The following tips come from case studies, from hospitals in Madrid and London, of successful implementation of smart infusion technology.

Benefits of Smart pumps with a drug library

- During pump infusion, there is always the potential for error – to stop, to re-programme, to titrate. Where there is the potential for error, error will occur: can you ever have 100%

'We went for smart pumps as stand-alone safety technology because errors made at the point of drug administration generally will not be intercepted without them'
– Linda Murdoch

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confidence that no-one will touch the pump?

- The primary benefit of using DERS is risk management, followed by capacity planning – making best use of staff time.
- All drugs, including oncology drugs, are successfully programmed as part of the drug library.
- Many technologies are needed to keep the medication process safe. Smart pumps with a drug library are one of them.
- We are unlikely to eliminate human error and smart pumps with a drug library help to protect us from our own mistakes at the critical point of contact with the patient.
- Smart pumps with a drug library drive standardisation, where it is practical so to do.

Which units?

Neonatal and paediatric wards were an obvious focus for smart pump and DERS utilisation, as the weight-based calculations and manipulation required of nurses have considerable potential for errors. However, paediatric nurses are among the best trained. Geriatric nurses, for example, are not and problems with insulin administration highlight the need for smart technology. But by far the majority of mistakes actually occur on the wards and not, say, in intensive care units.

'We started working with smart pumps six years ago and we did not have wireless connectivity, so every time we had to upgrade the drug library, it was a nightmare. Wireless has to be the future'

– Silvia Manrique Rodríguez

Therefore, the decision was taken to introduce smart pumps on the wards with equal urgency as in the perhaps more obvious high-risk units.

Which drugs?

Priority was first given to high-risk medications (meaning those drugs posing the greatest therapeutic, calculation, manipulation and hazardous risks), all of which carried the potential for error. But as the decision was taken to introduce the pumps with DERS using a drug library on all wards and all units, all Drug and Therapeutics Committee-approved medications were in the drug library. This included clinical trial drugs, which were simply entered with the tag 'trial drug'.

Connectivity issues

Connectivity with other hospital technologies in one direction and the generation of smart pump reports is a given requirement for extracting maximum value from the process. It is assumed that the next generation of pumps will have bi-directional wireless connectivity. For example, before the Madrid hospital had wireless connectivity, an upgrade was required to the library (new products, errors in limits), all the pumps had to be unplugged and connected to a computer to transfer the data. Additionally, every time the alerts were interrogated, to see what the nurses were doing, the pumps had to be unplugged, interrupting the workflow and introducing risk. Apart from the risk management offered by wireless capability, the saving in time and technical resources is huge. The glitch is possibly periods of lost connectivity, but the risk is still contained as the previous drug library will be maintained on the pump until it reconnects at which stage it will be updated to the newest drug library.

Which limits?

The whole point of the drug library is to keep things safe: hard limits keep things safe; soft limits are considered not compatible with risk management systems and either ought not to exist at all, or should be associated with an action. In the London case study, there are approximately 150 drugs in each library, with six or seven soft limits, each associated with an action, giving the nurse authority to exceed once she has checked with the physician. (Historically, soft limits came from America, but the EU is perhaps more safety driven.)

Abbreviations

CMU	Commercial Medicines Unit
DERS	Dose Error Reduction Software
EPS	Electronic Prescribing Software
GMP	Good Manufacturing Practice
MHRA	Medicines and Healthcare Products Regulatory Agency
CPOE	Computerised Physician Order Entry

'A process-orientated management approach is bottom-up – working with all the professionals, identifying bottlenecks and coming up with solutions together – with a strong leader acting as facilitator'

– André Rieutord

Which pump?

Sometimes certain pumps offer unique benefits for certain clinical care areas.

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So while it may be preferable to use the same make of smart pump throughout the hospital (facilitating use of the drug library and the movement of nurses across boundaries and care areas), the unique benefits in certain clinical care areas is one is one of the factors that will affect the decision. Another will be connectivity capabilities of the pump – some are wireless and therefore a reliable wireless connectivity will be a determining factor for the future.

Whose budget?

In Europe tenders often state that the cost of the pump should include the cost of DERS in one overall price. This means that the cost of DERS is unknown and as DERS is rarely utilised by Hospitals there is no motivation from companies to implement DERS or charge appropriately for it. In this current tender process DERS is not a fully funded project so Hospitals also lack the motivation and resources to follow through to implement DERS which would help greatly to improve patient safety by reducing medication errors.

There is an argument that says that having to pay for the DERS encourages its use. As the decision to adopt smart pumps is always taken centrally, the cost, including that for the DERS, is top-sliced, and no one department or budget takes the hit.

Driving the process

Buy-in from hospital board, executive and general managers was as important as that from the physicians, pharmacists and nurses.

A process-oriented change management approach, involving strong leadership, ideally from a physician who is committed to this means of minimising drug error and a team of all professionals involved in the drug administration process, ensured that solutions were found to all obstacles. Hospitals are increasingly business and commercially-focused. Decisions are made centrally and the business case to adopt smart pumps with DERS and build a drug library had to be escalated to committee to grant the finances. After that, it becomes a clinical project. In the case of St George's, it was then a committed, dedicated group of nurses who pushed smart pump adoption and drug library compliance out to several other London hospitals.

Building the drug library

In both case studies, it took the team of physicians, pharmacists and nurses a very long time – six or seven months in the Madrid example – before they had entered the generic name of every drug – high and low risk – into the library. It is the standardisation and the working out of rates that takes the time.

In Madrid it then took up to two weeks to train all the nurses to programme the infusions through the drug libraries – training is ongoing, as nurses need refreshers and new nurses join the units.

Then the smart pumps with drug library went live. For the first two months, there were frequent report downloads to check for compliance, to upgrade, to identify training needs and to redefine limits. Up until the end of year 1, there were three or four checks and annually thereafter. With the system fully implemented, they now have a target of between 90-95% compliance. Currently 90% of all infusions started on a pump are programmed within the drug library. The use of these pumps has intercepted hundreds of potential point-of-administration medication errors, which could have potentially caused serve patient harm or even deaths.

Preparation guides were made available over the hospital intranet. Not all DERS systems flag medication incompatibility, for example as might occur in the case of simultaneous infusion. So compatibility charts were produced.

Regarding the design of the adult intensive care library, the London experience was that each of the wards was administrating drugs in different ways and it was necessary to unify and standardise in all those instances where there was no good reason for a difference. One key aspect of smart pumps is that they drove standardisation.

Smart pump wish list

- **bi-directional wireless capability**
- **compatibility with existing in-house resources**
- **connectivity with all relevant in-house systems**
- **to record administration and to then feed backwards into the patient's record, (EMR - Electronic Medical Record) as opposed to having to document the administration record**
- **batch-tracking abilities**
- **barcode scanning**
- **colour coding for different units**
- **reports that are clear and free from IT jargon**
- **reports that are easy to access**
- **to be able to set individual pressure limits**
- **to be able to set a maximum limit, ie. a dose may say 3mg per kilo with a maximum of 100mg**
- **the possibility to set minimum and maximum limits in concentrations**
- **ability to set independent limits for dose and infusion time**
- **a program prepared such that it is impossible to give a second dose within a certain timeframe**
- **software with knowledge of drug incompatibilities**

Is it necessary to start from scratch to build a library? First, consider the standardisation of protocols. In the UK, a national database of standardised monographs for each intravenous drug sits with the National Patient Safety Agency and all NHS organisations use them. All the monographs have been done, all the warnings, all the standardisation. This could be the basis for a drug library.

Regarding the London example, they designed much of their electronic prescribing in liaison with a couple of other organisations, to spread the load. They are all shared – legal issues notwithstanding, perhaps it is logical that hospitals also share drug libraries. Procurement decisions are underpinned by an organisational strategy of integrated governance, where cornerstones are accountability, responsibility and assurance of processes. Once the organisation has taken the decision to, say, invest in smart pump technology with DERS, the tender process opens and the finances will be top-sliced, as it is an organisational decision.

In the UK, the procurement regional framework is comprised of two channels: the Commercial Medicines Unit (CMU) for the regional purchasing of medicines and NHS Supplies for devices. Each region funds a person who represents the purchasing at the regional level in terms of tendering and arrangements. There are obvious advantages of volume to be had by tendering as a group. But the decision is always taken regionally (in line with all other European countries present).

'It is the software that is important and the benefits of the software that should be being sold. By charging for it you encourage its use'

– Linda Murdoch

Infusion bags

In terms of standardisation of infusions Nurses tend to prefer infusion bags to syringes. Oncology medicines are normally prepared in bags, but some drugs are delivered via a syringe push. Paediatric medicines and anthracyclines in syringes (in Italy, anthracycline in bags always) and other therapies generally in bottles, depending on volume.

Partly because of the limited capacity in pharmacy, the trend is away from compounding and towards ready-to-use preparations used in a dose banding method, which may cut down the risk of errors and may increase Pharmacy productivity.

Regulation

Good manufacturing practice (GMP) compliance defines the preparation standards of medication. In the UK, the Medicines Act defines, in Sections 9, 10 and 11, the conditions under which physicians, pharmacists and nurses,

respectively, can compound products. Stability for products compounded with this type of production is for 24 hours for the ward and seven days under Section 10.

A hospital can apply for a Medicines and Healthcare Products Regulatory Agency (MHRA) specials licence. This is a specials licence, in line with that for compounding centres. Because the facilities, processes and quality systems will be inspected on the basis of GMP, this enables the applicant to confer extended stability on their products of six months and to batch produce.

Conclusion

Smart pumps with DERS using a drug library has been shown to confer benefits of risk management and capacity planning to hospital wards and intensive care units alike. Humans are fallible and with only a 2% interception rate of medication errors occurring at the point of administration DERS offers a real opportunity for key advancements in patient safety.

Deployment has to be funded and driven by a process-oriented change management approach, with strong, committed leadership facilitating the problem-solving abilities of a multi-disciplinary team of stakeholders.

Hospitals will expect the next generation of smart pumps to come with bi-directional wireless connectivity.

The roundtable 'Smart infusion technology' was convened in Amsterdam on 1st February 2016, with the support of Hospira, a Pfizer company.

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