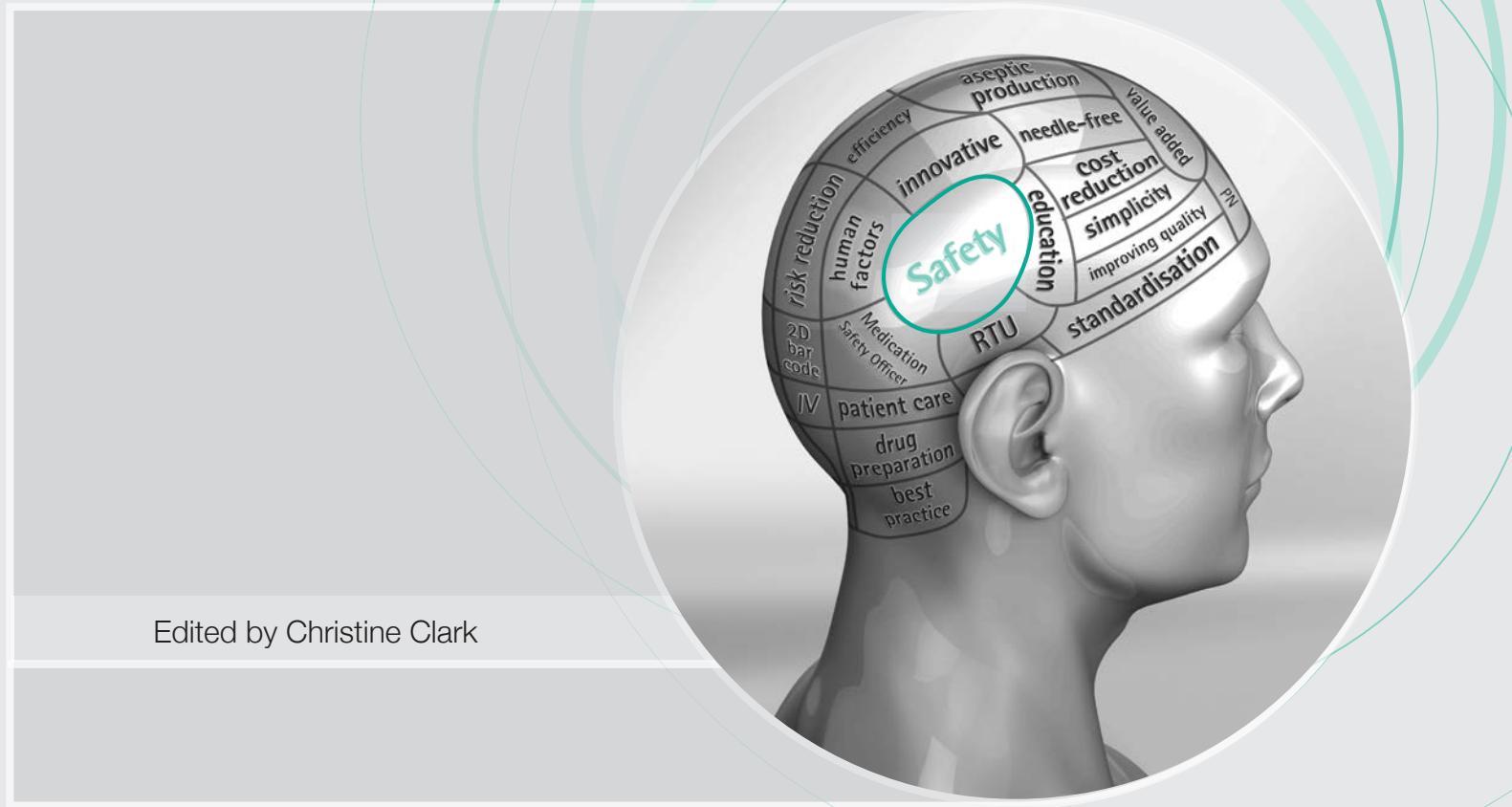


Supporting safer medication™

Reducing the risk of injectable medicines





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Foreword

18 months ago, in an effort to help remedy the faults in the complex medication use system, NHS England mandated all hospitals to appoint a medication safety officer (MSO) and a medical devices safety officer (MDSO). The aims were to maximise the reporting of medication/medical device incidents and to help minimise avoidable future patient harms through learning and system change following those incidents. We know from the National Reporting and Learning System (NRLS) that MSOs are achieving the first part but how are MSOs, in conjunction with their named trust board level director and the Chief Pharmacist, doing on the more difficult, and important, second part? This is extremely difficult to show even for the hardest working and most capable MSOs but we must remember that improvements in medication safety – the avoidance of harm caused by medication - is a marathon not a sprint and every 'marginal gain' in a healthcare organisation should be seen as a success.

One area where organisations must aim for success is in improving medication safety with injectable medication. The preparation and administration of intravenous medication is arguably one of the riskiest jobs performed by ward-based nurses and a recent systematic review found that medication errors may occur in a median of 85.9% of all intravenous doses administered, which is around 200,000 per year in an average hospital. All MSOs, and indeed most health professionals, understand how serious the consequences of injectable medication errors can be but how confident are they that their trust boards do?

This informative, interesting and thought-provoking guide is an excellent reference point for all MSOs and Chief Pharmacists interested in driving reductions in patient harms due to injectable medication. Each chapter brings clarity to all the important subject areas and summarises what MSOs should be doing and what hospital management boards need to know for success. In particular, it brings real insight from experts in specialist fields that MSOs may be less familiar with, or even intimidated by, including neuraxials, smart pumps, IV fluids, electronic prescribing and medicines administration and home care services for injectable medicines.

What is clear from all the experts is that MSOs are crucial but that they cannot improve injectable medication safety on their own. There is a clear need for collaboration with front line clinicians and hospital management, the standardisation of products and processes, a real understanding of human factors and dedicated time to train health professionals in the use of and the dangers of injectable medication.

To be successful in improving medication safety with injectable medication MSOs are going to need a sound strategy and this guide is a great blueprint.



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Chapter 1

Raising the profile of medication safety at board level

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Raising the profile of medication safety at board level

Introduction

There is little doubt that medication errors, in various shapes and forms, form a large part of patient safety alerts globally. They can range from missed drug administration times to wrong drugs being administered. Whilst recognising that being vigilant regarding this aspect of patient safety is important for every member of the healthcare team, it is also recognised that appointed and visible champions often lead to heightened awareness and consequent positive effect.

In March, 2014, recognising that both medicines-related and medical device-related incidents needed a better national reporting system, NHS England and the Medicines and Healthcare Products Regulatory Agency (MHRA) issued two patient safety alerts in the UK.¹ The alerts provided specific instructions in a bid to improve data collection quality. A significant instruction was to ask large healthcare providers and commissioners to nominate leaders in both medication and medical device safety roles. These 'champions' would be called Medicine Safety Officers (MSOs) and Medical Device Safety Officers (MDSOs). These leaders would be supported by two new national networks for medication and medical device safety. It was envisaged that a larger database with better quality data would allow a clearer analysis of adverse incidents, leading to better learning across the system.

Another significant change was a declared intent to work in partnership with the pharmaceutical and medical device manufacturers through their professional associations.¹

What type of information should the MSO be collecting?

Although each organisation will have the ability to select its own patient safety dataset, there is no doubt that the national reporting system will be producing a more uniform dataset. The newly appointed officers will need to liaise with their executive sponsors at board level to agree a dataset that will be useful for the board to examine on a regular basis. It is also important that the board sees a uniform and recognisable reporting framework. A solution to this may be a reporting system that uses the NHS Safety thermometer.² For medication safety, for example, the medication

safety thermometer measures medicines' reconciliation, allergy status recordings, medication omissions and also records harm from high-risk medications.³ The recommended sample on one day each month is 100% of patients on five surgical wards and five medical wards in acute care, and up to 200 patients for community services.

In addition, following the publication of the Berwick report⁴, it is also important for the board to recognise what has been learnt from the analysis of the data and what plans have been put in place to engender change. This, in fact, is part of the MSO and MDSO job role.

How the MSO can work effectively with the board sponsor

One of the keys to the success of the role of the MSOs and MDSOs will be to have support at board level in NHS organisations. This has been shown to be successful in several areas - very recently in medical education commissioning in the UK, where it has been made mandatory for a board member to have executive responsibility.⁵

There is also evidence that hospitals that carried out performance monitoring activities at high levels had significantly lower mortality rates than hospitals that did not do so.⁶

In a similar way, the Directive from the MHRA and NHS England has instructed organisations to "identify a board level director (medical or nursing supported by a senior healthcare professional) or in community pharmacy, or home health care, a senior manager (for example a Superintendent Pharmacist)" to take responsibility for this function.⁷

There are several advantages to this new governance structure. A hospital trust, for example, may have a number of reporting systems, internal and external. There may or may not be separately recognised systems for medication and devices errors that link in well with a general reporting system. Directing a single board member to take ownership of this issue is likely to create a system where this ownership becomes part of the role of member who has board level responsibility for overall safety.

This would also ensure that the MSO or MDSO does not simply report through via their own professional routes, e.g. to the Chief Pharmacist or Chief Biomedical Engineer, but that the information becomes visible by mandate at a higher level. It would also become easier for a board member to provide suggestions for whole system solutions and harnessing resources that may not be available through a single line reporting system.

Conclusion

The formation of a recognisable cadre of MSOs and MDSOs should be welcomed by all in healthcare as this forms a distinct approach to address an important aspect of patient safety. Healthcare organisations directed to do so, have to rise to the challenge by empowering the MSOs and MDSOs and also ensure that board level visibility of their work is present and that appropriate support is given to the role.

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Chapter 2

Working towards safer use
of injectable medicines

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Working towards safer use of injectable medicines

Summary

The use of injectable medicines is error prone and associated with greater harm than other routes. Our understanding of the causes of error is improving and we can identify behavioural aspects, but the available techniques for determining the 'why' have been transferred from other industries and may not always provide system solutions for preventing further patient harm. There is value in looking at the learning from error reports to the NRLS. Such evidence underpinned Alert 20 of the National Patient Safety Agency and this remains the most comprehensive instruction on the NHS to prevent errors related to injectable medicines.

Introduction

It makes intuitive sense that injection of any substance poses greater risks than medicines given by the oral or topical route - if only because injection introduces substances into the body much faster and at a higher peak level than topical or oral routes and it is much harder to recover from untoward consequences. Once the drug is in you can't get it back! This chapter provides some evidence of the relative importance of injection associated with patient harm and some insights as to the nature of errors associated with injectable substances together with a consideration of the possible ways of tackling the causes of errors.

Background

The evidence that intravenous (IV) routes are inherently harmful has been emphasised by a number of authors.¹ Moreover, the recent work of Ashcroft,² comparing medical and non-medical prescribing rates, showed that injectable medicines (intravenous, intramuscular (IM) and subcutaneous (SC)) were three times more likely (odds ratio (OR) 3.66; 95 % confidence interval (CI) 2.98–4.49) to be associated with serious (rather than minor) prescribing errors when compared to the oral route. Specifically, the team reported a 28-fold increase in the odds of serious compared to minor prescribing errors for injected gastrointestinal drugs compared with non-IV routes (OR 28.63; 95 % CI 10.59–77.45). An increase in the odds

of causing serious harm was consistently noted across the range of parenteral medication prescribed, and those for cardiovascular or endocrine disorders were highlighted.

A systematic review³ estimated that that errors occurred in a median of 85.9% (interquartile range 81.8–89.9%) of total opportunities for IV error. This corroborated earlier work by McDowell⁴ who estimated the probability of making at least one medication administration error in IV doses to be 73% and also that of McLeod⁵ who estimated that IV doses are five times more likely to be associated with such an error than non-intravenous doses.

In this chapter we will use the term 'injectables' to include injections given by IV, IM and SC routes. The figures appear alarming but should be treated with caution. There is considerable variation in the literature on medication errors in the NHS related to injectables. Moreover, error rates vary according to study methods, definitions of error and settings. Nevertheless, there appears to be sufficient evidence to conclude that IV prescribing and administration carries with it additional risks that warrant greater vigilance compared with other routes. Certainly, there does not appear to be a study that refutes this conclusion. A focus on minimising patient harms from IV prescribing and administration would, therefore, appear to be a justifiable use of time and effort.

The causes of harm

In order to minimise harm, it is necessary to understand its cause. It seems simple, but, in practice, it is anything but simple! Healthcare is complex, multifactorial and involves human beings. While practice strives to be 'evidence-based', the evidence is accumulating so fast that it is becoming ever more challenging to be safe.

Much of our current understanding has been orchestrated by James Reason⁶ who proposed that error can be categorised as due to unconscious slips (skill-based errors, attentional failures) or lapses (skill-based memory failures) or mistakes that are conscious rule/knowledge-based errors or routine, reasoned reckless or malicious violations.

This understanding was further refined by Croskerry⁷ who described how we manage and process information using the predominant, type 1, intuitive, subconscious thinking mode characterised by instinct and repetition, or the slower, conscious, analytic type 2 thinking modes. Errors occur in both modes.

So, we think we understand that error is not solely the domain of the ignorant, inexperienced healthcare practitioner, rather that there are cognitive states where the more experienced, instinctive practitioner is just as likely to make an error. We are simply amazed - how could it happen that errors occur despite the best apparent care and involving the most experienced healthcare practitioners? Such execution failures, occurring when nurses were working in familiar surroundings on routine tasks, but were either distracted or experienced changes in their immediate environment, was observed by Reason nearly 20 years ago.⁸

That we cannot locate error to the ignorant, is the basis of the argument for a systems approach to minimising patient harm. If practitioners are doomed to err, we should create a system that makes it harder to do the wrong thing. In this way we should be able to help practitioners help themselves. However, the literature, finds errors associated with situations that are less amenable to transparent, simple system fixes than we might want.

System 'fixes' to ensure safe injectable use

The multifactorial impacts on error and the complexity of the working environment we are trying to make safe, have been described in a recent publication by Keers who used the critical incident qualitative technique and conducted interviews with 20 nurses in two National Health Service (NHS) hospitals.⁹ The authors describe 21 incidents to analyse the underlying causes of intravenous administration errors. The understanding presented may ring true with many front-line, patient-facing healthcare professionals; they said, "The working environment was implicated when nurses lacked healthcare team support and/or were exposed to a perceived increased workload during ward rounds, shift changes or emergencies. Nurses frequently reported that the quality of intravenous dose-checking activities was compromised due to high perceived workload and working relationships. Nurses

described using approaches such as subconscious functioning and prioritising to manage their duties, which at times contributed to errors."¹⁰

Such insights are supported by the earlier work of Taxis who describes as underlying causes for IV error, high workload/rushing, poor supervision knowledge and training deficiencies, distractions and interruptions, inadequate communication and policies/procedures, sharing bad practices, lack of intravenous access for individual patients and deficiencies in the design of related equipment.^{10,11}

It is reasonable to ask whether a simple 'fix' could have an impact in this environment. It is recognised that nurses undertake the majority of medicines administration tasks in the NHS. The standard-setting Nursing and Midwifery Council specifies that all intravenous dose calculations should be independently checked and that where possible, IV administrations should be checked by a second registrant.¹² It has been reported that 85% of NHS hospitals in England have a double checking policy for intravenous doses¹³; however, the impact of this activity on error rates is still unclear.¹⁴ So a simple 'system fix' in the drug use process may only be partially helpful.

The lessons from studies of human behaviour applied to nurse decision-making during IV medication appear to make sense but, again, do not lead to simple system fixes.¹⁵ Perhaps the answer lies in techniques for identifying the causes or possible causes of error and the wealth of learning embodied in medication error reports sent to the National Reporting and Learning System (NRLS).

Finding the cause of error

There are several structured methods for considering a patient safety incident that may or may not have resulted in patient harm. The reasoning is that by identifying why an incident happened, 'fixes' can be implemented to prevent future recurrence. It should be noted that none of the current techniques was developed specifically for NHS activity; rather, they have been transferred from other industries.

Working towards safer use of injectable medicines

The approach that is most-commonly employed in the NHS is root cause analysis (RCA). In essence, it provides a structure for ensuring that all the known aspects that might have impacted on a situation are considered, be they human, procedural or physical. Commercial organisations charge between £20,000 and £60,000 for a team to undertake such reviews, which implies thoroughness, but does not necessarily provide patient safety outputs. A second technique is failure modes and effects analysis (FMEA). It is prospective, so the potential for failure is postulated. Shaqdan¹⁶ provides an overview of these methods and Jenkins¹⁷ has considered its use in medication packaging. A lesser known technique is fault tree analysis (FTA), one of the many symbolic-analytical logic techniques. It is mathematically orientated and uses symbols to denote relationships. Its use in the NHS has been argued,¹⁸ but is perhaps limited to medical device error.

So, there are accepted ways of looking at the causes of error. Unfortunately none of these techniques proposes solutions or system 'fixes'. The National Reporting and Learning System collects data with free text fields for 'Description of what happened', 'Actions Preventing Reoccurrence' and 'Apparent Causes'. This database is currently the responsibility of the NHS England Patient Safety domain. Between 2005 and 2010 over half a million medication error reports were received.¹⁹ The database is live and reports can be entered, altered and deleted over time. It takes three to six months for reporting to stabilise, thus extractions are made several months in arrears.

For this publication a snapshot of the reports has been interrogated for learning. Table 2.1 provides a quantitative view of reports from 1st July 2014 to 30th June 2015. Readers will note that for each of the categories of harm, numbers of reports associated with use of injectables, the difference between the number of reports received and what was expected was significant (adjusted residual $>\pm 1.96$). This adds further corroboration to the finding that the use of injectables is associated with greater harm than other routes. Table 2.2 breaks down the reports by category of error. It is notable that 'omission' is the most-commonly reported category for injectable medication incident reports.

Table 2.1: Association of route and harm for reported incidents to the NRLS

Level of Harm	Column count		Count
	Associated with injectable use	Remaining medication dataset	
No harm	Count	48057	106122
	Expected Count	49622.1	104556.9
	Adjusted Residual	-24.5	24.5
Low Harm	Count	7089	11044
	Expected Count	5836.1	12296.9
	Adjusted Residual	21.0	-21.0
Moderate harm	Count	1215	1679
	Expected Count	931.4	1962.6
	Adjusted Residual	11.4	-11.4
Severe harm	Count	76	97
	Expected Count	55.7	117.3
	Adjusted Residual	3.3	-3.3
Death	Count	25	27
	Expected Count	16.7	35.3
	Adjusted Residual	2.5	-2.5
Count		56462	118969
			175431

Notes to Table 2.1

1. Analysis excludes 1 count of Patient Group reported under Non-oral, non-topical Count and 11 in the Remaining medication dataset count
2. The expected count is the Chi Square expected value. The Adjusted Residual is the normalised value for the difference between actual and expected counts. A value than ± 1.96 is significant at the 95% confidence interval.
3. data based on Date of Incident occurring between 1st July 2014 and 30th June 2015 (exported to the NRLS on or before 28th September 2015, where Incident type equals Medication. All terms searched in IN07 Description of what happened, IN10 Actions Preventing Reoccurrence, IN11 Apparent Causes using search strategy ["inject", infusion, bolus, intravenous, epidural, intrathecal, subcut*, parenteral, intramuscular, syringe, iv, im, sc, pca] or [MD16 Route or MD16_a wrong route or MD16 Right Route is equal to epidural or intramuscular or intrathecal or intravenous]

Table 2.2: Errors with injectable by category

Error category	Count
Omitted medicine / ingredient	10,950
Wrong / unclear dose or strength	5,959
Wrong frequency	4,674
Wrong drug / medicine	4,183
Wrong quantity	3,699
Wrong route	1,784
other	13,361
Mismatching between patient and medicine, Wrong method of preparation / supply, Patient allergic to treatment, Wrong formulation, Adverse drug reaction (when used as intended), Unknown, Wrong storage, Contra-indication to the use of the medicine in relation to drugs or conditions, Wrong / omitted / passed expiry date, Wrong / transposed / omitted medicine label, Wrong / omitted verbal patient directions, Wrong / omitted patient information leaflet	11,853
Total	56,463

The real value of the NRLS is in the 'stories'. It is evident from the case study below that healthcare is indeed complex, that many factors can impact on patients as they transition through sectors of care, that behavioural aspects of error can be identified and that finding a single root cause is, at best, challenging. This case study demonstrates aspects of error, complexities in the reality of practice, the good intentions that go wrong, the difficulty in searching for a single root-cause of error, that no single 'fix' could have resolved all the issues, how behavioural insights enable us to dissect the patterns of error and the importance of questioning when common clinical practice enters the realm of error.

Case study

Errors in patient care

Massive GI [Gastro Intestinal] haemorrhage on [place] ward [xxx] 87 years old man two weeks post small bowel resection for Crohns-related stricture. Brief post op ITU [Intensive Therapy Unit] stay. Transferred to SAL [Surgical Admissions Lounge] for ongoing recovery. Dropped BP and became hypoxic so transferred back to [place]. Seen by Med SpR and diagnosed as having likely PE

[Pulmonary Embolism]. Therapeutic dalteparin started. CTPA [Computed Tomographic Pulmonary Angiography] requested but deferred until the morning. I was called to see the patient following a bout of haematemesis and malena. The patient quickly decompensated and arrested. I requested protamine - no staff available at the time knew what this was & no one (including me knew where to locate it..... **Intended action knowledge-based error, Type 2 error**]. The Crash bell was pulled, runners sent for O2 - blood and a 2222 put out **[consistent with NPSA guidance]**. Assistance arrived quickly and in good numbers. As team numbers increased, so leadership of the situation decreased as multiple people started attempting to make suggestions and run the situation **[Violation Routine, Reasoned, Reckless and Malicious, Type 2 error]**. Anaesthetic support arrived and the patient was intubated. A time keeper was appointed. ROSC [Return of Spontaneous Circulation] was attained after 10 minutes. The surgical SpR had attained a slot in theatre for immediate OGD [Oesophago-Gastro Duodenoscopy]. Transfer was delayed by difficult IV access. The Anaesthetist wanted to transfer immediately to theatre with the one pink cannula whilst other people attempted to delay this and insisted on further attempts at cannulation **[Violation Routine, Reasoned, Reckless and Malicious, Type 2 error]**. A 14G was inserted into the Right femoral vein. It was assumed that this was a vein. No blood gas was run off the cannula to confirm its location in the femoral vein **[unintended action Slip a skill based Attentional failure error, Type 1 error]**. It did not occur to any team member (including me) to attempt IO [IntraOsseous] cannulation I have performed IO cannulation a number of times and am disappointed that I over looked this **[unintended action Lapse a skill based memory failure error, Type 1 error]**. It would have sped up transfer time. The patient arrived in Theatre [XXX] making respiratory effort but tolerating the ETT [EndoTracheal Tube]. It was decided that the decision to proceed with OGD should be questioned in the patient's best interests. The surgical consultant arrived and a team decision was reached to not intervene given the patient's age and significant comorbidities. (Reported outcome: death).

Source: NRLS verbatim incident report. Items in square brackets have been added.

Working towards safer use of injectable medicines

The NRLS dataset provided the underpinning for Alert 20²⁰ of the national Patient Safety Agency, which addresses many of the IV-related issues that demonstrably lead to medication error. This Alert is still in force and all NHS organisations have indicated compliance.

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Chapter 3

High-risk injections 1- neuraxial injections and other specialised injections

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She has spent her whole career within the NHS hospital sector, initially as a clinical pharmacist. Working in critical care she became aware of injectable medicine preparation concerns, which formed the basis of her PhD. She is an advocate of improvement science and sees this as an important yet practical way to help deliver quality care.



High-risk injections

1- neuraxial injections and other specialised injections

Summary

Neuraxial injections are those which are administered by the central (epidural or spinal routes) and peripheral nerve injections or infusions. It also includes injections given by caudal or lumbar spinal routes. The drugs concerned are primarily local anaesthetics and opiates. All of these are high-risk injections. The most common error types are wrong route, wrong product and contraindicated medications. The main risk factors have been identified and extensive guidance on how to minimise risks and assure patient safety has been published. The introduction of devices with non-Luer connections for spinal, epidural and regional clinical procedures is recognised as a key safety measure. Compliance with the published guidance is essential to minimise the risks to patients.

Introduction

Greater harm is attributed to medicines given by the injectable route than other routes of administration. Serious patient harm can arise from medication use via specialised routes of administration, especially when it involves high-risk medicines (those most commonly reported as causing patient harm to the NRLS). Examples of high-risk injectable practice would include the intra-arterial infusion of alteplase, spinal or epidural opiates, and intrathecal chemotherapy.

All injectable medicines practice falls within the scope of the Medication Safety Officer (MSO) role. Some very highly specialised practice may not be readily visible within the medicines use process as it takes place in interventional or theatres areas, where the medicine is stock and the procedure recorded in the patient's medical notes. For example, intravitreal antibiotic injection or botulinum toxin injected into the vocal chords. Although beyond the scope of this chapter, each of these practices should have been risk assessed and known to your organisation as described in NPSA Alert 20.¹

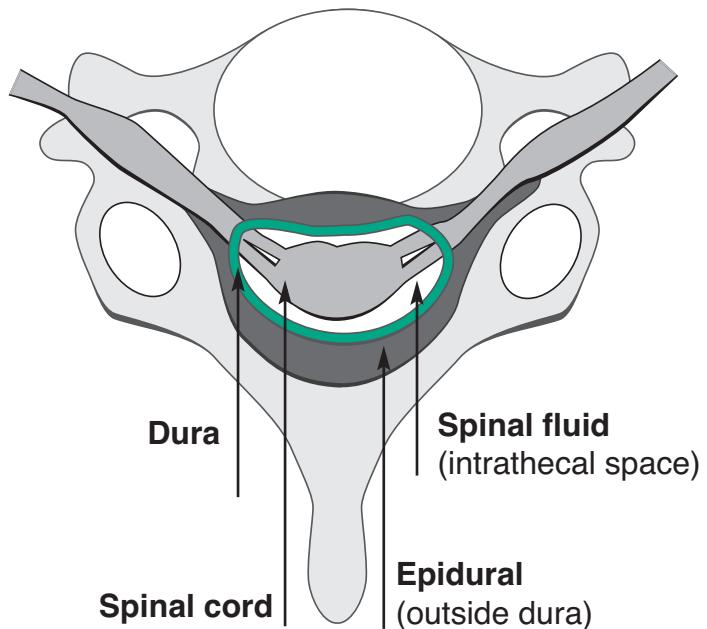
This chapter focuses on those medicines administered via neuraxial injection, primarily local anaesthetics and opiates. Therefore, it is applicable to acute hospital and acute emergency trauma settings. Local anaesthetic use in the minor

injury or emergency department setting and for minor surgical procedures is not addressed. Although guidance for England is referenced, arrangements in Wales, Scotland and Northern Ireland are similar.

What is neuraxial?

The term encompasses central (spinal, epidural) and peripheral nerve injections and infusions. The term 'intrathecal' refers to spinal, sub-arachnoid or intraventricular injections. Although the terms are synonymous, 'intrathecal' tends to be used for cancer chemotherapy and 'spinal' in anaesthetic practice. (See figure 3.1) The term 'caudal' refers to lumbar epidural injections that may be used in young children.

Figure 3.1: Diagram of spinal cord showing epidural and intrathecal spaces



Common errors with neuraxial injections

The main error categories associated with neuraxial injections were identified in NPSA Alert 21²; they are:

1. **Wrong route** – either the inadvertent spinal or epidural administration of a product intended for the intravenous route (although products for antiseptic skin preparation and intra-arterial use have also been administered); or the inadvertent intravenous (sometimes intramuscular) administration of a product intended for epidural or nerve infusion.
2. **Wrong product** selected leading to wrong preparation or wrong dose/concentration administered.
3. **Contraindicated concomitant medication – anti-platelet and anticoagulant medication.** NHS England issued a warning regarding low molecular weight heparin use and lumbar puncture/epidural/spinal anaesthesia within the previous four hours, or expected within the next 12 hours.³ If a haematoma develops this may press on the spinal cord and cause nerve damage. With the rapid growth in the anti-platelet and anticoagulant market it can be challenging to ensure relevant guidance is kept up to date.

What the evidence tells us

Deaths continue to be reported in Europe and worldwide, from the 'wrong route' administration of intravenous chemotherapy by the intrathecal route. There have been no such incidents reported in England since 2001, and should any occur in England, they have to be reported as 'Never events'.⁴ 'Never events' are serious incidents that are considered to be wholly preventable. Guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers.⁵

Between 2000 and 2004 three deaths from intravenous administration of bupivacaine epidural infusions were reported. Between 1.01.2005 and 31.06.2006 346 incidents involving epidural injections and infusions were reported to the National Reporting and Learning System (NRLS). Eight of these were

associated with moderate or severe harm.² Therefore, despite the well-recognised under-reporting, there was a clear signal that epidural medication was a risky area, and occasionally, with catastrophic consequences.

The 'wrong route administration of medication' Never Event category applies when a patient receiving NHS-funded care receives intravenous chemotherapy administered via the intrathecal route or intravenous administration of a medicine intended to be administered via the epidural route.⁶ Never event updates, published monthly on the NHS England website, reveal that these incidents continue to happen.⁵

Intrathecal chemotherapy remains a paramount patient safety issue; if vinca alkaloids (vincristine, vinblastine, vindesine and vinorelbine) are injected intrathecally they cause paralysis, almost always followed by death. The tragic death of Wayne Jowett as a result of mal-administered intravenous vincristine by the intrathecal route is all too well known.⁷ Ionic contrast media have been injected spinally instead of non-ionic water soluble ones.⁸

Other medicines that have been maladministered epidurally include antibiotics, ephedrine, morphine, oxytocin, potassium chloride infusion, ranitidine, rocuronium, thiopental, tranexamic acid and chlorhexidine skin disinfectant.^{2,9}

In healthcare the Luer connector is a small bore connector widely used as a universal connector, enabling different types of medical device to be connected, whether or not this was intended. (Small-bore connectors have an internal diameter of less than 8.5 mm and are used to link or join medical devices components and accessories for the purpose of delivering fluids or gasses). Despite guidance, education and vigilance patients continue to be harmed and more robust system defences are needed to protect patients.

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Toxicity of local anaesthetics

Local anaesthetics provide analgesia by blocking the transmission of pain impulses along the nerve fibre. This is achieved by exposing the target nerves to local anaesthetic that has been introduced close to the relevant nerves usually via a needle. The rate of systemic absorption depends on the dose, concentration, route of administration and vascularity of the administration site. Systemic absorption of local anaesthetics delivers high concentrations to highly perfused organs and therefore produces effects on the cardiovascular and central nervous system; at toxic doses there can be seizures and cardiovascular toxicity.

Guidance is available on the management of severe local anaesthetic toxicity.¹¹

Administration of neuraxial injections

Non-chemotherapeutic neuraxial infusions can be provided in several ways: via a single-use disposable infuser device, an infusion bag/syringe for administration via a dedicated infusion device or a cassette or cartridge to be used with a dedicated infusion device. Whenever possible these should be supplied to the clinical area in a ready-to-administer (RTA) form to avoid the need for complex preparation. Infusions are available as licensed and unlicensed infusions from the pharmaceutical industry and NHS production units, whilst some hospitals with aseptic facilities are able to provide for local need. Currently, there are several disposable infusion devices with catheters that are being actively promoted within the healthcare sector. It is important for the MSO to be aware of discussions about the introduction of disposable infusion devices.

for epidural administration) was connected by mistake. The inquest found that she had received 100-150 mls of the bupivacaine solution.

During the inquest the following evidence also came to light:

- There had been two previous near-misses involving the intravenous administration of bupivacaine at the same hospital
- A policy was introduced by the hospital to keep bupivacaine stored in a locked cupboard separate from other intravenous fluids but this policy was discarded when the hospital moved to new accommodation
- The midwife who connected the bupivacaine had at least six opportunities to check the fluid before administering it

A verdict of unlawful killing was recorded against the hospital trust. It was fined £100,000

Risk factors with neuraxial injections and solutions to minimise risks

The main risk-minimisation measures are compliance with existing guidance on epidural infusions and intrathecal chemotherapy, purchasing for safety and managing supply problems and shortages. NHS organisations should ensure that the best practice guidance from the NPSA Patient Safety Alert, *Safer practice with epidural injections and infusions*, is followed.² The same principles would also safeguard patients with peripheral nerve infusions.

This may well have been robustly implemented in your organisation in response to the alert. However, is this embedded into current practice as it is delivered, rather than as local guidance requires? For example, how have the ongoing supply problems with commercially-procured, licensed and unlicensed epidural infusions been tackled? A recent posting on a pharmacy e-mail group indicated that one organisation had reverted to adding fentanyl to epidural infusions because of this issue.

The ongoing small-bore connector work (see below) will provide a robust defence against 'wrong site' connection errors once it has been fully developed and implemented.

Table 3.1 lists the risk factors with neuraxial injections and the corresponding risk reduction measures.

Cautionary tale

A 30-year old theatre nurse suffered a cardiac arrest and died about two hours after giving birth to a healthy baby boy in an NHS hospital in the UK.¹² She experienced faintness and dizziness about 45 minutes after the birth and an intravenous infusion was prescribed. A 500 ml bag of bupivacaine (intended

Table 3.1: Neuraxial anaesthetic and analgesic injections: risk factors and risk reduction measures

Risk factors	Risk reduction measures
Failure to apply warning labels e.g. 'For epidural use only' Inadequate or no labelling of administration set and catheter, syringes and flushes Commercial infusions could make better use of safety engineering within their design	Clear labelling of infusion bags and syringes with 'for epidural use only' in large font Judicious use of colour and design to differentiate them from other routes of administration
Storage of medicines for neuraxial and intravenous route together Look-alike, sound-alike medication	Reduce risk of wrong medicine being selected by storing products for epidural use separate from those for intravenous use Use strategies to differentiate between similar sounding medication
Supply of neuraxial injections as general ward stock	Restrictions on which clinical areas may keep neuraxial products as stock, regularly reviewed and updated Dispense for an individual named patient
Removal of neuraxial preparations from an appropriate area e.g. theatres for use elsewhere	Guidance on medicines 'borrowing' and where to source supplies when needed
Preparation of neuraxial injections in the clinical area	Source a ready-to-administer preparation where possible
Not using a paper or electronic prescription proforma	Implement paper or electronic proforma for prescribing of neuraxial injections
Lack of agreed standardised nomenclature for medicines and concentrations. Failure to standardise and agree preparation to be used and maximum rates of administration	Minimise the likelihood of confusion between different types and strengths through product rationalisation Produce guidance on preparation and administration
Supply problems, lack of capacity to provide NHS ready-to-administer nerve infusion solutions (either in-house and/or commercially-sourced)	Agreed standard preparations either nationally or by professional bodies especially epidural and regional nerve block infusions to inform manufacturing. Increased manufacturing capacity
Widespread use of Luer connectors in healthcare for disparate applications Absence of a complete range of neuraxial non-Luer connectors and associated devices	Global medical device industry needs to provide a complete range of neuraxial non-Luer connectors and associated devices. Supporting test information on new non-Luer devices needs to be available pre-implementation e.g. drug stability
Lack of effective alternative to 'iv bag spike' for nerve infusions	NonivLok® have one in development that is being refined following feedback from a user clinical evaluation, www.nonivlok.com
Lack of dedicated infusion equipment, clearly differentiated from intravenous infusion devices	Use clearly labelled epidural administration sets and catheters, infusion pumps and syringe driver devices that distinguish them from those used for intravenous and other routes of administration (judicious use of the colour yellow to distinguish administration sets and infusion devices has been widely adopted)
Not employing independent verification of the patient, drug, concentration, pump settings and line attachment on each change of pump or drug and at handover	Employ independent verification of the patient, drug, concentration, pump settings and line attachment on each change of pump or drug and at handover

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Pump mis-programming; Not using IT to assist where possible e.g. bar-coding, 'smart' pumps	Implement smart pumps
Lack of trained and competent staff (for prescribing, preparation and administration)	Ensure all staff involved in epidural therapy are adequately trained and competent
Concomitant use of intravenous route and nerve infusion. (NB it is essential that patients on epidural infusions and other nerve blocks that may cause hypotension have iv access to enable this to be appropriately managed)	Use non-Luer connectors for neuraxial injections to prevent mix ups between IV and neuraxial injections
Inadequate patient monitoring Not having antidote and/or resuscitation equipment readily available, unsure how it should be used or no iv cannula in situ (naloxone should be available where opiates are used and intralipid for local anaesthetic toxicity)	Guidance on patient monitoring and the management of toxicity
Lack of awareness of safe practices, lack of adherence to guidelines and formulary restrictions	Audit practice annually Review and learn from incidents
Human fallibility and error-prone situations e.g. poor lighting, fatigue, distractions	Improve factors known to impair human performance. Create situational awareness

Intrathecal chemotherapy

Any organisation providing an intrathecal chemotherapy service will need to comply with the Department of Health guidance on the safe administration of intrathecal chemotherapy, (HSC 2008/001) and NPSA Rapid Response Report requiring vinca alkaloids to be provided as a small volume infusion, rather than in a syringe in adolescents and adults.^{13,14} There will be a lead person, referred to as the 'Designated Lead' accountable to the Chief Executive responsible for overseeing compliance with this detailed national guidance. It is envisaged that compliance with this guidance will ensure there are no further intrathecal chemotherapy maladministration incidents. However, a robust, safety-engineered defence that prevented cytotoxic medicines intended for intravenous use from being administered intrathecally became reality when non-Luer devices became available for intrathecal bolus chemotherapy. Hospitals were required to use only syringes and needles and other devices with non-Luer connectors when delivering intrathecal chemotherapy, as they cannot connect with intravenous devices.⁴

Pharmaceutical concerns had been raised about the use of non-Luer compatible neuraxial devices as storage containers for injectable medicines. This matter was resolved as long as a

locking-type syringe of specified brand was used and guidance on syringe filling and capping followed.¹⁵ The Intrathecal Chemotherapy Designated Lead would be the ideal contact to gain a deeper understanding of this area and to ensure there are aligned communication and reporting processes so that both parties are aware of any concerns.

Purchasing for safety – non-Luer connections

The former NPSA issued alerts recommending a 'purchasing for safety' initiative, whereby medical devices with connectors that cannot connect with intravenous Luer or intravenous infusion devices connectors should be used for spinal, epidural and regional clinical procedures, when available. It was recognised that devices with new design connectors would have to be manufactured and supplied by industry before the NHS could comply with the guidance (NPSA Patient Safety Alert 004, Safer spinal (intrathecal), epidural and regional devices - Part A, Part B and Part A update).^{16,17,18} Implementation dates were set for spinal bolus administration and lumbar puncture (part A), and later dates for epidural administration, spinal, epidural and nerve infusion (Part B) devices.

These dates have passed, and it is acknowledged that full compliance with these alerts in anaesthetic and non-chemotherapeutic practice was not possible, as the range of non-Luer and infusion devices for spinal, epidural and regional procedures remained incomplete. New products, especially infusion products, are still awaited from industry.⁴ Therefore, progress with these alerts will depend in part upon the clinical practice in your organisation. Specialist neuroscience practices and epidural infusions continue to pose problems. The continued use of Luer devices in neuraxial settings should have been recorded in your organisation's risk register, with additional safety precautions taken and suitable safer devices introduced into practice as soon as they are available.⁴ Advice on how the status of this patient safety guidance can be signalled to the Central Alerting System has been provided.⁵

There has been an international drive to reduce the risk of misconnections and the International Organization for Standardisation (ISO) has developed a series of new International Standards for small bore connectors and tubing sets in a range of medical devices (ISO 80369).¹⁹ The standards define the design of the non-interchangeable connectors for a range of different uses, so the risk of misconnections with other connectors for a different application is reduced. Intravascular and hypodermic applications (i.e. injections and infusion) will be the only setting where Luer connectors will be permitted (ISO 80369-7). ISO 80369-6 focuses on neuraxial use. A complete range of devices fitted with the ISO 'neuraxial' connectors is unlikely to be available in the UK before 2017.

Safe implementation of new devices

A clinical advisory group has been set up to advise NHS England on the safe introduction of devices with the new connectors. The group is linking with similar groups in Wales, Scotland and Northern Ireland to co-ordinate the introduction across the UK. Various resources to support organisations to prepare for the change are signposted and Medication and Medical Device Safety Officers will be informed when new content is added.^{20,21} It is important that in addition to managing the current risk of

misconnections, the transition from one connector to another is carefully planned to prevent both being in the clinical area at the same time and to mitigate other risks as they arise.^{21,22} Suggestions for managing these risks have been published.²³

What should the MSO be doing?

The MSO should take steps to

- Build awareness of what medicines are administered spinally and epidurally, and the indications for use (usually for anaesthesia and analgesia led by anaesthetists, but spinal and neuroscience services may also contribute; also consider antimicrobials for CNS infections and cytotoxics for cancer)
- Keep abreast of the neuraxial small bore connector work via the NHS England website (www.england.nhs.uk/ourwork/patientsafety/medical-device-incidents/small-boreconnectors/)
- Be familiar with the wrong-route, 'never event' definitions. Ensure near-miss incidents of this type are appropriately investigated, learning occurs and is shared
- Know who the Designated Lead for intrathecal chemotherapy is
- Determine progress on implementing safer non-Luer connectors for anaesthetic and non-chemotherapeutic practice. Review the entry on the risk register. Find out who is leading on these alerts and ensure appropriate pharmacy representation on the multidisciplinary group responsible for actioning these alerts
- Find out about the local arrangements for managing severe local anaesthetic toxicity
- Find out if your organisation is able to see reports submitted about your organisation to the NRLS via the Anaesthetic eForm
- Determine who the local stakeholders are that can advise and assist with neuraxial safety. This will vary by organisation and individual responsibility but examples would include medical equipment library lead, medical device training officer, pain service (acute and chronic), anaesthetic governance lead,

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theatres supply lead, procurement, materials management, Medical Devices Group, MDSO, risk management, intrathecal chemotherapy participants (adults and children may be different), neurosciences, microbiology/infection diseases, obstetric anaesthetist (big users of spinal and combined spinal-epidurals), matron, ward and theatres sisters, resuscitation team

- Be aware of local progress towards complying with the safer sharps requirements as this may impact on other areas e.g. sterile spinal or epidural packs

What does the board need to know?

The board needs to know:

- The risks to which the trust is exposed in relation to neuraxial injections
- About progress on implementing safer non-Luer connectors for anaesthetic and non-chemotherapeutic practice
- About progress towards compliance and implications of the ISO small bore connector work

Best practice recommendations

- Near-miss incidents with neuraxial injections should be acted upon
- Implement safe, non-Luer connectors for spinal, epidural and regional clinical procedures as soon as possible
- Ensure compliance with existing guidance on epidural, intrathecal chemotherapy, purchasing for safety and managing supply problems
- The risks to which the organisation is exposed in relation to neuraxial injections should be recorded in the organisation's risk register

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Chapter 4

Standardisation of injectable products for safety

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Standardisation of injectable products for safety

Summary

The incidence of errors in prescribing, preparing and administering injectable medicines is higher than for other forms of medicines. A number of drugs are recognised as 'high-risk' in most healthcare systems; these include opioids, insulin, anticoagulants and hypertonic injections. The use of standardised concentrations for injections and, wherever possible, the use of ready-to-use or ready-to-administer presentations can improve patient safety. A nationally-agreed list of standardised concentrations for ICU injections is available and should be used to guide local choices. NHS guidance documents and treatment protocols should be reviewed to identify opportunities for the introduction of standardised injections. The MSO should also keep a watching brief on the ways in which high-risk injections are used locally and monitor adverse incidents involving injectable medicines. The risks to which the organisation is exposed as a result of not using standardised injections should be recorded in the organisation's risk register.

Introduction

The preparation of injectable (usually intravenous) doses is always risky procedure and the more steps that are involved, the more opportunities for error arise. Common types of preparation error include selection of the wrong drug, inaccurate measurement of volumes, wrong diluent/carrier fluid and poor aseptic technique.¹ Studies indicate that the incidence of errors in prescribing, preparing and administering injectable medicines is higher than for other forms of medicines.^{2,3} One study showed that errors with antibiotic injections occurred more commonly than with other products⁴ although it is likely the dominant error-prone therapeutic class is different in different specialities.

Many errors are categorised as 'minor', but moderate and severe errors continue to occur. In practice fewer than 1% of medication errors or incidents are fatal.

Harm associated with IV errors

In one study of the incidence and severity of intravenous drug errors in 10 wards of a teaching and non-teaching hospital in the UK over a six and 10 day period, 249 errors were identified.² At least one error occurred in 212 (49 percent) out of 430 intravenous doses. Three doses (one percent) had potentially severe errors, 126 (29 percent) potentially moderate errors and 83 (19 percent) potentially minor errors.

Most errors occurred when giving bolus doses or making up drugs that required multiple step preparation. For example in one reported incident the whole contents of a vial containing 125,000 units of heparin were prepared as a continuous infusion, resulting in a five-fold overdose and the risk of life-threatening haemorrhage.¹

Studies that analysed the medication concentrations of infusions that were prepared and administered at the bedside have also found great variation in the contents of the infusions.⁵

A proportion of errors with injectable medicines could be avoided or mitigated by the use of standardised concentrations of drugs supplied as ready-to-use (RTU) or ready to administer (RTA) products.⁶ Guidance on this topic was provided the National Patient Safety Agency (NPSA) in 2007¹ (see below).

Guidance and recommendations regarding safe use of injectable products

NPSA Patient Safety Alert 20 recommended the following measures:

For high-risk injectable products:

- Simplify and rationalise the range and presentation of injectable medicines and provide the most appropriate vial or ampoule sizes
- Provide ready-to-administer or ready-to-use injectable products of standard strength. This will minimise risks when preparing and administering injectable medicines

High-risk injectable medicine products and procedures should be added to the local risk register if risk reduction methods cannot be introduced or they will not sufficiently reduce the risk. The NPSA recommends that in such a situation, the healthcare organisation investigates ways to introduce safer products and/or procedures as soon as possible.

- Implement a 'purchasing for safety' policy to promote procurement of injectable medicines with inherent safety features

The NPSA recommends that policies advocate the purchase of injectable medicines that include technical information about how they should be prepared and administered, and are designed in such a way as to promote safer practice.

It is preferable that only licensed ready-to-administer or ready-to-use injectable medicines are procured and supplied. The NPSA suggests that NHS organisations should work with the pharmaceutical industry to identify new products and formulations that could make practice safer.

Standardised injectable products

It is recognised that the major factors that contribute to adverse events with injectable therapy are calculation errors, lack of knowledge (on the part of prescribers), absence of information at the point of prescribing and/or administration and lack of standardised products. Many of the risks associated with these factors could be reduced by the use of standardised products

When a limited range of concentrations and volumes of injections is available, the opportunities for prescribing and selection errors are reduced and calculations may be simplified. If smart pumps (see

Chapter 5) are in use then standardised injections are essential. The introduction of standardised products also provides the opportunity to create simplified dosing administration charts and electronic prescribing routines. Standardised products may also offer the opportunity for economies of scale.

Ideally, there would be a nationally-agreed list of standardised injectable products but such a list does not exist. Practice varies

widely both between and within hospitals. In 2007 a survey of 154 critical care units (where large numbers of injectable medicines are used) reported that 20 commonly used agents were used in no fewer than 372 ways (excluding diluent factors).⁷ There were large variations in the way that some products were used, for example, 20 different concentrations of amiodarone were in use. Although noradrenaline use was clustered around three concentration/volume presentations, similar patterns were not observed with other products. Some 20 intravenous products for which there appeared to be 70% commonality were identified and a proposed list of standardised concentrations was compiled. In a second survey intensive care units were asked the question, "If the product were commercially available, would you be prepared to use it?".⁸ A total of 164 units responded, representing 63% of UK NHS trusts. The results showed that the majority of products (17) would be acceptable to about 80% of intensive care units. Accordingly, it was recommended that these be adopted as the national standard. As a result, the Intensive Care Society issued a statement supporting the adoption of standard concentrations for 16 agents commonly-used in critical care. (See table 4.1) Licensed products are now available in the standard concentrations for morphine, fentanyl, midazolam, dobutamine and heparin. In addition, the following injections are available in standard concentrations from NHS specials units: clonidine, noradrenaline, dopamine, magnesium and Insulin. (They can be found at 'Pro-file': <http://www.pro-file.nhs.uk/>)

Whilst the adoption of standard concentrations facilitates the introduction of commercially available RTU/RTA products, the lack of a commercial product does not necessarily mean that safety gains cannot be made. Standardised products can be compounded by the pharmacy department, for instance, resulting in products with reliably-high concentration consistency and removing the possibility of preparation errors made at the bedside.⁶

Standardisation of injectable products for safety

Table 4.1: Standard concentrations of injections for use in intensive care

Medication	Infusion Composition	Concentration
Morphine	50mg in 50ml 100mg in 50ml	1mg/ml 2mg/ml
Fentanyl	2.5mg in 50ml	50micrograms/ml
Alfentanil	25mg in 50ml	500micrograms/ml
Midazolam	50mg in 50ml 100mg in 50ml	1mg/ml 2mg/ml
Clonidine	750micrograms in 50ml	15micrograms/ml
Noradrenaline	4mg in 50ml 8mg in 50ml 16mg in 50ml	80micrograms/ml 160micrograms/ml 320micrograms/ml
	8mg in 100ml 16mg in 100ml 32mg in 100ml	80micrograms/ml 160micrograms/ml 320micrograms/ml
Dobutamine	250mg in 50ml	5mg/ml
	500mg in 100ml	5mg/ml
Dopamine	200mg in 50ml 400mg in 50ml	4mg/ml 8mg/ml
Arginine vasopressin	20units in 50ml	0.4units/ml
Amiodarone (loading dose)	300mg in 50ml	6mg/ml
	300mg in 100ml	3mg/ml
Amiodarone (continuation)	300mg in 50ml 600mg in 50ml 900mg in 50ml	6mg/ml 12mg/ml 18mg/ml
	300mg in 500ml 600mg in 500ml 900mg in 500ml	0.6mg/ml 1.2mg/ml 1.8mg/ml
Vecuronium	50mg in 50ml 100mg in 50ml	1mg/ml 2mg/ml
Heparin	20000units in 20ml 25000units in 25ml	1000units/ml 1000units/ml
Epoprostenol	100000nanograms in 50ml	2000nanog/ml
Magnesium Sulphate	20mmol in 50ml 20mmol in 100ml	0.4mmol/ml 0.2mmol/ml
Insulin	50units in 50ml	1unit/ml

Source: Medication concentrations in critical care areas. ICS 2010
(<http://www.ics.ac.uk/ics-homepage/guidelines-and-standards/>)

Barriers to success

The main barriers to success are:

- Achieving agreement amongst clinicians about the concentrations and volumes to be used
- The perceived costs of RTU and RTA products
- The lack of availability of suitable products from the industry and suppliers of unlicensed 'specials'
- Lack of awareness of the importance of the topic
- Organisational inertia

There is also an international perspective. The pharmaceutical industry works on an international scale and so standardised injection concentrations at a Europe-wide level would be the ideal as this would make investment in the manufacture of RTU and RTA products worthwhile.

Best practice examples

The examples described in the best practice vignettes illustrate two situations in which standardised injectable products have been introduced.

Best practice vignette 1

Glucose 20% for hypoglycaemia

In 2010 two reports described the risks associated with insulin therapy.^{9,10} Prescribing and administration errors with insulin rank amongst the most frequent of all drug prescribing errors and have been associated with significant morbidity and mortality. In addition, the danger of using 50% glucose to treat hypoglycaemia was emphasised. Both reports recommend the use of 75-80 ml of glucose 20% for treatment of severe hypoglycaemia. At the time, no RTU and RTA presentations of glucose 20% injection were available. In response, Medicines Safety pharmacists held discussions with the pharmaceutical industry and Hameln Pharmaceuticals launched a 100 ml vial of glucose 20%. Uptake of this product has steadily increased since its introduction.

Best practice vignette 2

Magnesium sulfate 20% for pre-eclampsia

In England, there have been case reports of fatalities caused by patients receiving the wrong dose of magnesium sulfate. Between January 2010 and December 2012, 1025 incidents relating to magnesium preparations were identified. Five incidents related to injectable magnesium were reported as causing death or severe harm.¹¹ The problems arose because the only available product was magnesium sulfate injection 50% w/v, but doses were variously expressed as grams, milligrams, millimoles, or percentages so that calculations and dilutions at ward level were required.

The complexity of the calculations led to frequent errors.

Magnesium sulfate is recognised to be a 'high-risk' injection.

As a result of this information, Wessex Academic Health Science Network (AHSN) undertook a local survey of magnesium use and recommended a series of measures to reduce the risks, including the use of 20% w/v RTU magnesium sulfate injection.¹² The AHSN report also recommended that The Medication Safety Officer (MSO) should lead a review of local practice in collaboration with the relevant medical, nursing, clinical pharmacists and procurement pharmacists.

It should be noted that 20% magnesium sulfate injection contains 0.8 mmol/L and is therefore more concentrated than the products in the ICS agreed list. The BNF states that for intravenous injection the concentration of magnesium sulfate should not exceed 20% (200 mg/mL or 0.8 mmol/mL)

What should the MSO be doing?

The MSO should be routinely reviewing reports of adverse incidents involving injectable medicines and should always keep in mind the question of whether any of the incidents could be mitigated or prevented by the use of standardised products, as in the examples in the best practice vignettes.

If the reporting culture of the organisation is good, the MSO is likely to be reviewing many reports. A simple system will be needed to identify emerging trends in order to identify potential target medications or therapeutic areas for action.

Standardisation of injectable products for safety

The first steps in identifying situations where standardised products might improve patient safety could be to:

- Check how many of the standardised concentrations/volumes in the ICS list are in use locally
- Review the ways in which high-risk injectable products (opioids, insulin, heparin etc.) are used locally and consider whether standardised products could improve patient safety

Once a list of products has been compiled it should be arranged according to local priorities and a strategy for implementation devised. A high-risk product affecting three patients may be more of a priority than thousands of products with medium risk in one organisation, but the reverse may be true in another. The organisation needs to agree to the risks it is carrying.

What does the board need to know?

The board needs to know:

- The risks to which the trust is exposed as a result of not using standardised injections, especially in relation to high risk injections
- The potential costs of introducing specific standardised products as well as the potential savings made, for example, savings in nursing time that would have been used to prepare the products. The whole system needs to be considered, so there are other considerations that also need to be included such as any specific quality assurance processes and storage requirements (space, refrigerators, etc)

Best practice recommendations

- A nationally-agreed list of standardised concentrations for ICU injections is available and should be used to guide local choices
- Glucose 20% injection, 100 ml should be used in the hypoglycaemia management protocol
- The usage (prescribing, preparation and administration) of injectable magnesium sulfate should be reviewed with a view to introducing standardised concentrations and prescribing protocols throughout the organisation
- In order to identify opportunities for the introduction of standardised injections, the MSO should keep a watching brief on the ways in which high-risk injections are used locally and monitor adverse incidents involving injectable medicines
- The risks to which the organisation is exposed as a result of not using standardised injections should be recorded in the organisation's risk register
- A whole system approach should consider benefits such as efficiency gains in nursing time as well as practical problems such as QA and storage

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Chapter 5

Smart pumps – technology for patient safety

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David has played a leading role in the clinical pharmacy movement in the UK and was a founder member of the UK Clinical Pharmacy Association. As a hospital pharmacist he developed special expertise in medication error reduction and in 2002 was appointed as Medication Safety Pharmacist with Alaris Medical Systems (now CareFusion). Much of his work was focused on the development and implementation of medication error reduction software designed to prevent accidental administration of erroneous doses from intravenous infusion devices. In 2009 he took up his current post in Sheffield.



Smart pumps – technology for patient safety

Summary

Smart pumps have been available in Europe since 2003 but uptake of this technology has been slow. Smart pumps contain inbuilt safety features (dose error reduction software and infusion rate calculation software) to prevent accidental overdosage or underdosage. They rely on the use of standardised concentrations of injectable drugs. They also have event memory logs that record the events that trigger alerts. Successful implementation of smart pumps requires the input of a multidisciplinary team and the compilation of a 'drug library'. Considerable patient-safety benefits accrue from the use of smart pumps but, in many organisations smart pumps are used as simple 'dumb' pumps with the safety features disabled. NHS organisations may be unaware of the risks to which they are exposed as a result of this practice. MSOs should take the lead in implementing smart pump technology.

Introduction

Recently, a conversation with a fellow Medication Safety Officer (MSO) led them to recall an approach from an infusion devices manufacturer wanting to demonstrate their latest product offering designed to enhance intravenous medication safety. The MSO's response was that they didn't know anything about infusion devices, as a consequence of which the approach was redirected to medical physics, "where it would hopefully all make more sense." Thus, a valuable opportunity for dialogue with the MSO on technological solutions to the risk of injectable therapy was lost.

Despite so-called smart pumps being available in Europe since 2003, there is still a widespread lack of familiarity among healthcare professionals with the concept of pumps equipped with error reduction software and the benefits and pitfalls of utilising this important technology to promote patient safety. A number of reasons for this apparent lack of awareness have been postulated.¹ However, regardless of their professional background, all MSOs should equip themselves with an understanding of smart pumps.

This chapter provides essential reading for those MSOs as yet unfamiliar with the topic and sets out the reasons why NHS organisations should strive to find the funding required for successful introduction of this important safety system.

What's different about 'smart' pumps?

Clinical infusion devices have historically been 'dumb' in that they were unable to recognise when a programmed infusion rate for a given drug was above the recommended safe maximum and could potentially cause harm to the patient. Basically, the devices would deliver to the patient whatever infusion rate was programmed into the pump, irrespective of the toxicity of the drug being administered. Wrong placement of decimal points and zeros has been a particular problem and led to the well publicised 'death by decimal' cases, in which patients received ten- and even hundred-fold overdoses, in the USA in the 1990s. The publicity generated by these fatalities resulted in calls for the infusion devices industry to take positive action to improve safety. The industry responded by developing smart pump technology at the end of the 20th century.

The term 'smart pump' was originally coined by the Institute for Safe Medical Practices (ISMP) in the USA to describe an infusion pump with an integral drug library that contains pre-determined dosing parameters for all medications to be delivered by the pump. These safety software packages have now been available from the major infusion device manufacturers for more than 10 years. After initial experience was gained in the home market by the American companies, the first system was launched in Europe in 2003 with others following on quickly.

The new, 'designed for safety', smart pumps incorporated a combination of three key features, namely:

- Dose Error Reduction System
- Infusion rate calculation
- Event memory log

Dose Error Reduction System

Error reduction software enables the infusion device to recognise an attempt to programme an infusion rate outside a pre-determined dosing range. Should this occur, the attempt is blocked and the user alerted. The systems rely on the construction of a 'library' of infused drugs with specified dose limits. Depending on the system or the options preferred, these limits may be soft or hard.

A soft limit triggers an alarm that alerts the person programming the pump but also allows that person to override the alert and proceed with the infusion. A hard alert is absolute; the device will not infuse the drug beyond the pre-determined limit. Because lower as well as upper dosing limits are set, the software protects against under-infusion as well as against overdosage.

As well as protecting the safety of the patient there are also inherent benefits to all healthcare staff involved in the delivery of intravenous therapy, in particular the nursing staff. Smart pumps are good for nurses but as with any new technology there comes a responsibility to utilise the systems effectively. With all the DERS systems available it is still possible to bypass the infusion rate limits in the drug library and programme infusion rates manually (in millilitres per hour). When such systems are introduced, there is a professional obligation to use it effectively.

Infusion rate calculation

The library of drugs uploaded (by the user) into the 'smart pump' is based on one or more standardised concentrations for each drug. Therefore, rather than infusing an individually-prepared, weight-based concentration at a fixed rate, the pump automatically calculates the volumetric infusion rate required to deliver the prescribed dose of a standardised solution. In many respects this function is as valuable an aid to medication safety as the error reduction software itself. It removes the need for complex calculations (a particular problem in paediatric practice), discourages prescribing in millilitres rather than drug mass units and significantly increases the feasibility of using standardised, ready-to-administer infusions.

Event memory log

When a pump is being programmed, each time an alert is triggered the software captures a full record of the events leading up to that alert, thus providing invaluable 'near miss' data on errors averted. For the first time, a database of potentially harmful adverse events can be constructed without relying on voluntary staff reporting, which, it is generally acknowledged, will only ever capture the tip of the adverse events iceberg. Downloading this information can provide valuable evidence to support practice review and training

needs assessments. Just as important as the record of events leading up to an averted error is the memory log data that demonstrates how the operator reacted to the alert and what steps were subsequently taken. Of particular significance are the records of events where the operator has chosen to switch the pump off and re-programme the infusion outside of the DERS, thereby removing the protection afforded to the patient by the system. Arguably, this is akin to driving a car in the rain with the anti-skid system turned off.

Implementing a smart pump system – hurdles to overcome

Having understood the capabilities of a smart pump and recognised the potential safety gain how do we go about introducing them into our hospital? Sadly, while smart pumps have been around for a long time now, uptake on this safety technology has been low across Europe compared to the USA. The infusion devices industry does not now generally offer 'dumb' pumps to the market but what seems to be a depressingly common scenario is for sophisticated new equipment to be introduced into use without activation of the DERS software. This is a process that requires the upload of a completed drug library onto each pump. MSOs should ask if their NHS organisation is wasting precious resources by paying an enhanced rate for smart pump protection without following through the implementation steps necessary to reap the benefits in patient safety.

A number of potential obstacles to the implementation of smart pump technology have been identified:

- Historical lack of standardisation of infusion equipment
- Low and/or poorly targeted investment in new equipment
- Resistance to the adoption of standardised infusion concentrations
- A lack of robust supporting evidence
- Under-promotion by the manufacturers
- Reluctant involvement on the part of hospital pharmacists

If an acute care institution is not yet using smart pumps, has the MSO identified the local obstacles and actively campaigned to overcome them?

Smart pumps – technology for patient safety

Implementing a smart pump system – key steps

There are a number of important steps that must be considered to ensure that DERS works effectively. It is vital that key stakeholders are involved in the development and implementation process. The group should be led by the MSO and must comprise clinical leads (medical and nursing), pharmacists, medical equipment manager, risk manager, training leads and the infusion device provider (supplier) team. One of the first and most significant steps towards medication error reduction is the dialogue and team review that is the starting point for the drug library development. Rather akin to the restricted drug formulary scenario, the process and discussion that is stimulated locally creates the environment for a critical appraisal of current intravenous medication practice. While it is often helpful to access previous work carried out by others (equipment providers should have a database of drug libraries already in use and available on an anonymised basis), the opportunity to hold open discussion around local practice should not be missed.

The stakeholder team should review drug protocols and establish standardised drug libraries. This critical process can often uncover significant discrepancies in drug usage and administration but is often one of the main stumbling blocks when trying to agree on standard concentrations. Because many more potentially high-risk drugs are given in critical care areas than in other areas, and because most drugs in these areas are given by intravenous infusion, medication error rates tend to be higher in ICU². For these reasons it is common practice for the introduction of DERS into healthcare institutions to begin with critical care areas

- Upload to devices
- Staff training
- Produce final library version in the light of training feedback
- Library sign off by senior pharmacists/clinicians
- Go live
- Review initial pump event download data after three months
- Revise drug library if changes required in the light of download data

Promoting standardised concentrations

The need to standardise drug infusion concentrations as a safety measure is recognised internationally. In the UK there are a number of initiatives that promote standard concentrations. The UK Injectable Medicines Guide, Medusa (2012), provides information about injectable medicines and standard concentrations and is used by the majority of UK National Health Service (NHS) hospitals. The Medusa database contains guidance on the use of injectable medicines for paediatrics as well as adults and includes work from specific organisations such as the Intensive Care Society (ICS). For example, the ICS found that there was wide variation in infusion practice in UK critical care units and as a consequence now supports and promotes the adoption of standard infusion concentrations through a list of concentrations endorsed by the ICS Standards Committee.³ (See also Chapter 4)

Standardising infusion concentrations may lead to safety and efficiency gains through reduced training burdens, common nomenclature, reductions in preparation and calculation error rates and facilitation of mass production of ready-to-use products by the pharmaceutical industry.^{3,4}

In the United States the Institute for Safe Medication Practices (ISMP) and Vermont Oxford Network collaborated to identify and promote the standardisation of concentrations of typical neonatal drug infusions.⁵ The safety benefits associated with the use of standard concentrations were cited as:

Key steps to implementing smart pumps

- Obtain approval and funding for smart pump technology
- Procure the most appropriate system
- Establish MDT to take implementation forward
- Decide which clinical areas are to be included – phased or hospital wide?
- Draw up drug library

- Reduces medication error when critically ill neonates are transferred from one facility to another
- Stimulates the development of standardised infusion device drug libraries
- Provides the demand necessary for manufacturers to offer commercially prepared standard solutions (if not already available), thereby reducing the risk of extemporaneous compounding errors within hospitals

Interfacing with smart pumps

In order to function most effectively smart pumps need to be fully integrated into the hospital's electronic prescribing and drug administration systems. They also need to be wirelessly connected. This is an important consideration if the MSO is responsible for safety in a large organisation, which may utilise more than 2000 infusion devices. Given that the DERS software has to be activated on each device by upload of the drug library the speed and convenience of this process can be critical. Updates to the drug library can be transmitted to devices, through the wireless network, without interrupting their operation; they simply take on board the update next time they are restarted, rather like any other software update.

Using the event log data

Event log data for smart pumps should be reviewed regularly and reported by the MSO. It should be possible to identify drugs and concentrations that most often trigger alerts. Fine-tuning of the drug library may be required in the light of the data recorded. It should also be possible to see whether alerts occur at particular times. Such data can be used to identify training needs for staff and to identify risk-prone products or procedures. Reports of errors averted as a result of using smart pumps can also be useful.

Best practice vignette

Smart pumps in paediatric intensive care

Some of the highest risks are associated with drug administration in paediatric intensive care. At the Gregorio Marañón Hospital in Madrid new infusion pumps had already been introduced to enable more precise administration of intravenous doses but this failed to prevent programming error. For example, morphine 90 mg per hour was accidentally given instead of 9 mg per hour. As a result, the decision was made to introduce smart pumps and a multidisciplinary team, led by the pharmacy, was established. A drug library was compiled and standardised concentrations of injections were agreed with clinicians.

After three years of operation the scheme was working satisfactorily and was well-liked by users. A total of 92 errors had been intercepted, 49% of which were classified as moderate-catastrophic with a strong probability of causing serious adverse events had they reached the patients. Examples of these errors included a 75-fold insulin overdose and a ten-fold error in a loading dose of amiodarone.⁶

What should the MSO be doing?

MSOs should be taking the lead in the pursuit of smart pumps as a key component in the creation of a safe environment for care. In addition to the obvious benefits of preventing infusion rates that are above or below the optimum dose range, further significant safety gains are accrued from the secondary benefits of standardisation of equipment, of training, of prescribing practice and of drug solution concentrations.

If smart pumps are not already in place throughout the organisation then the MSO should:

- Build awareness of the benefits of smart pumps amongst prescribers
- Find out where high-risk injections/infusions are being used without the safeguards of smart pumps

Smart pumps – technology for patient safety

- Ensure that the board is aware of the risks of failing to use smart pump technology e.g. by identifying errors that could have been averted by the use of smart pumps
- Take the lead in the implementation of smart pumps in the organisation

If smart pumps are already in use throughout the organisation the MSO should

- Regularly review the event log data to see which drugs and concentrations are most-commonly involved in generating alerts and whether peak incident times coincide with changing staffing etc
- Use event log data to identify training needs
- Compile regular reports of errors averted as a result of smart pump use

What does the board need to know?

The board needs to know:

- The risks to which the organisation is exposed if smart pumps are being used as 'dumb' pumps
- About progress with the implementation of smart pumps
- About the numbers and types of errors averted through the use of smart pumps

Best practice recommendations

- The use of smart pumps should be the norm for safe intravenous drug administration
- The error reduction software should only be by-passed and infusions programmed in mls per hour in cases of genuine medical emergency
- The introduction of smart pumps should be used as an opportunity to review treatment protocols and to introduce standardised, ready-to-administer injections wherever possible
- Prescribing of intravenous drug infusions should no longer be in mls per hour but in mass units e.g. mg/hr, mg/Kg/hr

Conclusion

Smart pumps have been around for a long time now but uptake of this safety technology across Europe has been low. While they do not provide the total answer to intravenous infusion errors they are an invaluable component of a package of safety strategies which also includes standardisation of practice, bar coding and ready-to-administer intravenous medication. A combination of smart pump technology with standard drug concentrations and user-friendly medication labelling brought about a 73% reduction in reported errors relating to continuous infusion of medication).⁷ Under the leadership of MSOs, NHS organisations should be aspiring to at least match this achievement.

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Chapter 6

High-risk injections 2- fluid and electrolyte therapy

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High-risk injections

2- fluid and electrolyte therapy

Summary

Fluids may be administered parenterally for a number of reasons:

- Routine maintenance, replacement or resuscitation: Intravenous or subcutaneous maintenance fluid infusions are required for patients who cannot maintain an adequate oral or enteral intake. Intravenous replacement is needed for fluid deficits incurred through gastro-intestinal loss, inadequate intake, inflammation, sepsis, burns or bleeding. Resuscitation is required for patients with hypovolaemic, septic or anaphylactic shock
- Fluids are used intravenously as a diluent for drug infusions or as a flush for cannulae
- Pressurised flush bags are used to maintain patency of arterial or central venous lines

In all of these situations there is a potential for error and harm. We may categorise the risks around equipment, storage, monitoring, prescribing, administration and patient factors. Recent guidelines provide a framework for education, prescribing and monitoring of fluid therapy, with established guidelines providing guidance for training of health professionals who administer fluids.

Risks of fluid use

Equipment

Subcutaneous fluids require a subcutaneous cannula and intravenous fluid must be administered via an indwelling cannula or central venous access device. In recent years attention has focussed around the infection risks associated with these devices with the development of bundles for the care and maintenance of these lines¹, to reduce the rate of unnecessary cannulation and the rate of catheter-related bloodstream infections (*particularly Staphylococcus aureus*) which may be costly to the patient and the hospital. Hospitals should have protocols for the insertion and care of these lines. In general peripheral venous cannulae should remain in place for no more than 72 hours.² Extravasation of irritant or vasoconstrictive drugs into tissues may cause necrosis; some drugs and parenteral feed preparations must therefore be administered into central veins.

Pumps and giving sets

Accurately controlled fluid administration is only possible via a volumetric pump. In the resuscitation situation fluid may be given through a large vein with a pressure bag or pressure infusor attached. Using gravity-controlled infusions can result in considerable inaccuracy in the duration of the infusion. A vigilant nurse is required to know when the flow has stopped or finished, whereas pumps have an automatic warning when occlusion occurs, air is detected or the infusion is ended. Giving sets must be properly run through by trained individuals to minimise the risk of air emboli. Anti-reflux valves are designed to avoid infusions such as morphine or insulin backtracking up an infusion line when a cannula becomes blocked and then being administered as bolus when the blockage is later released. Compulsory training programmes for staff administering fluids are essential.³

Subcutaneous fluid administration

Subcutaneous fluids may cause irritation of tissues and the cannula may become infected. Replacing the cannula every 72 hours is appropriate in this situation. Particular care is required if potassium-containing solutions are administered subcutaneously as they may cause irritation.⁴

Stock control and storage of fluids

The pharmacy department is essential to maintaining and controlling fluid stocks, and pharmacists can prevent the supply of inappropriate fluids. An audit may show that each ward in a hospital has a huge variety of fluids in its store, some of which have specific indications and are rarely used. Reducing ward stock lists to a minimum of several 'standard' fluids can help to prevent errors such as hypertonic saline being administered to a patient instead of the prescribed phosphate polyfusor. Certain rarely used fluids, such as hypertonic saline, should be kept centrally and provided only on request to general wards.

Reducing the spectrum of available fluids in conjunction with a prescribing guideline reduces confusion amongst junior staff and makes the prescribing and administration of fluid a more straightforward process.

Fluids for diabetic patients can vary widely throughout a hospital if there is no control of administration protocols for patients on intravenous insulin. In one hospital different areas were using three different maintenance solutions for these patients, increasing the likelihood of error.

Monitoring of fluid status

Traditionally nurses have filled out a fluid balance chart for patients requiring parenteral fluids, who have significant losses or in whom renal function is a concern. This activity is one that has suffered with the reduction in nursing numbers on wards, but is vitally important to inform safe and accurate fluid prescription. Hospitals should ensure that fluid balance charting is done accurately and that its importance is understood by nursing staff of all levels. When reviewing charts it is often impossible to determine a patient's intake and output with certainty and this makes effective prescribing much more difficult. Triggers should be established for action when a patient's intake or output is dangerously low or high.

Prescribing

The 1999 NCEPOD report⁵ stated that junior doctors have inadequate knowledge and skill to prescribe fluids safely and that elderly patients are dying because of either being given too much or too little fluid. It recommended that fluid prescribing should be given the same status as drug prescribing. In many parts of the UK this shortfall in good practice has not been addressed and it is still possible to find major deficits in prescribing. The GIFTASUP⁶ and NICE Guidelines for Intravenous Fluid Therapy in Adults in Hospital of December 2013⁷ have gone some way towards rectifying these shortcomings by providing a framework for education and a logical approach to prescribing.

Errors can result in fluid overload or dehydration as well as electrolyte abnormalities which may have serious consequences. Doctors may regard fluids as low priority and fail to assess the patient's history, clinical state and fluid needs before prescribing, sometimes copying the previous prescription. Nurses likewise may present a junior doctor, who does not know the patients, with a number of fluid charts to fill in, with the expectation of a further prescription; busy juniors may not take the time to investigate whether the patient actually needs more fluid and why.

The type of fluid prescribed may be inappropriate; for instance the traditional maintenance prescription of 'two dextrose to one saline' is often corrupted to 0.9% sodium chloride alone, leading to excess administration of sodium and chloride. Another source of excess sodium chloride is the diluents used for drugs, many of which may be made up in 5% glucose instead.

The WHO recommendation for daily salt intake is 5g/day⁸ for adults, or roughly 1 mmol/kg/day; (4.6 g is 80 mmol). 0.9% sodium chloride 500 ml contains 75 mmol, so it is not surprising that the recommendation is exceeded in many hospital patients, leading to adverse effects.

Fluid overload may result in gastro-intestinal oedema with nausea, vomiting and ileus, as well as peripheral oedema resulting in increased pressure sores, delayed mobilisation and increased risk of deep vein thrombosis. Chloride is particularly detrimental to renal blood flow, leading to renal vasoconstriction.⁹ Pulmonary oedema, hyponatraemia, arrhythmias (particularly atrial fibrillation from a dilated left atrium) and confusion are other serious effects of fluid overload.

Dehydration from inadequate fluid replacement or resuscitation leads to acute kidney injury, postural hypotension, falls, confusion and inadequate organ perfusion. Particular care must be taken to ensure those with frailty or dementia are able to access drinking water or receive assistance if required and that their oral intake is monitored. The imposition of fluid restrictions is common and necessary in some patients but may lead to significant dehydration if the volume specified by the restriction is not met.

High-risk injections

2- fluid and electrolyte therapy

Audits in many hospitals demonstrate a range of iatrogenic harm as well as evidence of the over-administration of sodium and chloride, and the under-dosing of potassium. Junior doctors seem very reluctant to prescribe potassium routinely in maintenance fluids, despite a requirement of 1 mmol/kg/day according to the NICE guidelines.⁷ Although the serum potassium may remain in the normal range for many days, most potassium is intracellular and depletion of these stores by a lack of maintenance dosing in fasting patients may have significant effects on organ function and on recovery from acute illness.

Administration

Fluids are drugs and as such should be double checked with two members of staff before administration to avoid the incorrect fluid being administered. This is particularly important when low sodium fluids are used, as if used incorrectly they could lead to hyponatraemia (this has been fatal in children and the use of 0.18% sodium chloride/4% glucose has been prohibited in children).¹⁰ If these fluids are used it is wise to place a rate limit on their use to prevent inappropriate administration as replacement or resuscitation rather than maintenance.

Another example of harm was shown in the NPSA Alert around arterial lines¹¹, issued after two patients died when 5% glucose was administered as a flush bag into an arterial line instead of 0.9% sodium chloride. The blood glucose was measured from the arterial line, and the patients were treated with insulin for spuriously high blood glucose resulting from glucose in the sampled infusion line. Both patients died as a result of unrecognised hypoglycaemia. Compulsory protocols for setting up arterial line flush bags should make this error much less likely to occur.

If a bag is taken down before it is finished for another infusion to be put in its place, the first bag should not be rehung as this increases the risk of air embolus and infection.

Patient factors

Frail and elderly patients have less ability to tolerate over- and under-hydration due to limits in their renal and cardiac reserve. Patients with pre-existing chronic kidney disease in particular are more likely to develop acute kidney injury secondary to dehydration or hypotension than a patient with normal renal function. In hypertensive patients, renal auto-regulation of blood flow is reset to a higher level and minor reductions in blood pressure may lead to acute renal deterioration in the context of sepsis, dehydration, surgery or any acute illness. Similarly patients with impaired cardiac function may not tolerate large volumes of intravenous fluid and may develop pulmonary oedema. The NICE Guidelines⁷ recommend a goal for maintenance fluid of 20-25 ml/kg/24hours for frail elderly patients, and 25-30 mmol/kg/24hours for other patients. In addition, patients with head injuries should not receive dextrose-containing fluids or fluids with a low osmolality as these may increase the risk of cerebral oedema. Obstetric patients with pre-eclampsia need careful balance as they can easily become overloaded. Patients with renal failure or hepatic failure require careful fluid monitoring and advice from a senior clinician.

Risks of electrolyte administration

Potassium

Potassium-containing solutions are extremely irritant to veins and should be administered peripherally at no more than 4 mmol/hour i.e. 20 mmol potassium chloride in 500 ml of diluent at 100 ml/hour.¹² Solutions containing 40 mmol potassium chloride/500 ml 0.9% sodium chloride (unlicensed) are sometimes used, but need special care if given peripherally. Potassium may be administered via a central vein at faster rates and many intensive care units give it at 10 or 20 mmol/hour either diluted in 100 ml 0.9% sodium chloride via a volumetric pump or as a neat solution of 1 mmol/ml via a syringe driver. Administration of concentrated potassium solutions must be carried out in a critical care environment where there is a high nurse to patient ratio and continuous monitoring. Great care must be taken that the rate of 20 mmol/hour is not exceeded as a bolus of potassium can cause lethal cardiac arrhythmias.

Pre-mixed bags should be used whenever possible to avoid the risk of errors when mixing at the bedside. Storage of ampoules of potassium chloride concentrate 15% (or other concentrated potassium chloride injections) in ward drug cupboards is not recommended.¹³

Magnesium

Up to 4 g (16 mmol) of magnesium sulphate may be administered over 5-15 minutes for pre-eclampsia followed by 1 g per hour for 24 hours as an infusion. Monitoring for signs of toxicity is required. In acute asthma 1.2-2 g is given over 20 minutes (unlicensed indication) and for replacement of deficits 20 mmol in 250 ml 0.9% sodium chloride or 5% glucose over 8 hours.¹² In view of serious adverse events, including fatalities, involving administration of magnesium sulphate 50% injection, the maximum concentration that should be held on wards is 20% (equivalent to 0.8 mmol/ml).

Calcium

Calcium chloride and gluconate are indicated for treatment of hyperkalaemia and hypocalcaemia and are given as infusion or bolus. The main risk of calcium injections is the possibility of precipitation with other substances such as blood, phosphate and several other drugs. The cannula should be flushed after administration. Calcium chloride is irritant if it extravasates into tissues and should ideally be given centrally. A bolus of calcium may cause arrhythmias.¹²

Phosphate

Infusion of phosphate is indicated for the treatment and prevention of refeeding syndrome when the serum phosphate is below 0.5 mmol/l or if the oral route is unavailable. It should be remembered that phosphate preparations contain potassium and sodium. Over-administration of phosphate may lead to hypocalcaemia and metastatic calcification. Serum levels must be monitored.¹²

Benefits of standardisation of fluid therapy

The NICE Guidelines⁷ identify priorities for fluid management, suggesting that all hospitals implement fluid guidelines, appoint a fluid lead responsible for training, education and testing of all prescribers and follow a system for prescribing based on patient assessment and monitoring including weight, history, clinical examination, current medications, fluid balance information and blood results. An assessment of a patient's fluid and electrolyte needs should form part of every ward review. The patient response should be measured and documented. The guidelines are based around the five Rs: Routine maintenance, Replacement, Resuscitation, Redistribution (the complex fluid needs of patients with severe inflammation e.g. sepsis, pancreatitis, intra-abdominal pathology) and Reassessment. Fluids should only be given parenterally if needs cannot be met by oral or enteral routes and should be stopped as soon as possible. The guidelines suggest a low sodium-containing fluid such as 0.18% sodium chloride/4% glucose with potassium for maintenance, and a fluid with a sodium level between 130-154 mmol/l for resuscitation, advising against the use of starches for resuscitation. The guideline stops short of recommending balanced crystalloids over 0.9% sodium chloride acknowledging the lack of randomised controlled trial evidence favouring balanced solutions, whilst mentioning the observational studies favouring balanced solutions over 0.9% sodium chloride.¹⁴⁻¹⁶ Algorithms and weight tables are provided; for practical reasons these should be adapted for local use.

The benefits of standardising fluid therapy are that juniors have a clearer structure to follow when prescribing, that fluid stocks can be rationalised to prevent the use of many different fluids, and that audits of practice may be done to compare local work with the NICE recommendations.

Monitoring and reporting of fluid therapy

The pharmacy department has a role to play in keeping statistics on fluid use and costs, in ensuring uniformity of stocking of fluids, in challenging unusual fluid use and in helping to educate prescribers as part of pharmacists' educational role.

High-risk injections

2- fluid and electrolyte therapy

Audits of fluid balance charting and of prescribing should be repeated regularly to check that prescribing is in line with local guidelines and to ensure satisfactory completion of fluid balance charts. Clinical governance departments, senior charge nurses or a dedicated fluid therapy nurse should take responsibility for these audits.

Education packages should be made available to doctors, nurses and other prescribers; monitoring of these with testing of knowledge gained should be instituted.

If major changes in fluid prescribing are introduced, biochemistry departments should monitor renal function and electrolytes, particularly sodium, potassium and chloride, before and after the changes to ensure no harm is occurring as a result of the changes.

The NICE guidelines⁷ suggest the formal reporting of fluid-related critical incidents including iatrogenic fluid hypovolaemia, pulmonary oedema, peripheral oedema, hypo- and hyperkalaemia and hypo- and hypernatraemia. Other adverse events concerning monitoring, administration and equipment should also be reported. Achieving this in a culture when incident reporting is not yet commonplace will be difficult but would be worthwhile as an educational tool and also to focus improvement efforts on areas where harm is occurring.

What does the board need to know?

Any quality issue resulting in morbidity and mortality for patients should be of concern to the board of an NHS organisation. The NCEPOD 1999 report⁵ suggested there was a widespread problem, which has not yet been fully addressed in many parts of the country. Audit results of fluid balance charting and prescribing must be made available to a board to characterise the extent of the problem, and resource should then be made available to tackle the issues, under the leadership of an appointed Fluid Lead.⁷ There is potential to save significant sums of money on fluids if a strategy to improve fluid prescribing is put in place, (see Figures 6.3 and 6.4) to say nothing of the humanitarian benefit as well as savings that will result from a drop in the morbidity and mortality related to poor fluid management.

Best practice vignette

Improving safety of fluid therapy

In NHS Fife in 2009 a programme of audits was commenced covering orthopaedics, surgery and critical care. These audits demonstrated that many patients received either too much or too little fluid, excessive amounts of sodium and very little potassium. There was a great deal of use of 0.9% sodium chloride as maintenance and replacement fluid and few balanced solutions were used outside the critical care areas. An audit in the trauma wards was repeated after education of junior doctors according to the GIFTASUP guidelines⁶ and showed a marked improvement in fluid volumes and in amounts of sodium and potassium administered, with an increased use of balanced crystalloids for replacement and resuscitation and a large reduction in 0.9% sodium chloride administration.

The audit results were presented to various hospital meetings along with a presentation of how fluid prescription could be improved. Consultants responded enthusiastically and a Fluid Prescription Group was formed, which agreed local guidelines were required. These were drawn up following the GIFTASUP⁶ and later the NICE⁷ model but to be applied to medical as well as surgical patients. With the backing of the medical director and consultant body the guidelines were published and education of junior doctors was commenced.

It was clear that just having guidelines was not enough to change practice quickly as doctors were constantly arriving from other areas without knowledge of the changes made in Fife, so the group produced a revised fluid prescription chart (Figure 6.1) with a built-in decision aid summarising the key points of how to assess a patient's fluid status and pointers to appropriate fluids in different situations. On the back of this chart was the fluid balance chart, each side designed for a single 24 hour period.

Introduction of this chart required considerable resource and a Quality Improvement (QI) Nurse for Fluid Management was appointed for a year, with the help of a Research and Development Innovation Grant, to oversee the introduction of the charts. In the process of doing this the nurse discovered many flaws in the process for fluid balance charting, including

Figure 6.1

High-risk injections

2- fluid and electrolyte therapy

significant gaps in nurses' understanding which were addressed by an education programme and poster information in wards, for example a Volume Guide (Figure 6.2). After testing using quality improvement methods, the charts were introduced and are now in place throughout the acute hospital. All junior doctors and non-medical prescribers receive education on the guidelines and further nursing education is planned. An app has been produced and an E-learning package is in development. Consultants were kept informed of developments through mandatory training and were encouraged to be involved in fluid management, particularly in the complex and elderly patient. The neighbouring Lothian Health Board has adopted a similar strategy as have Edinburgh and St. Andrews Universities, with the aim of standardising education and practice across the region.

Monitoring of fluid use has demonstrated not only major shifts in the use of certain fluids but also a large cost reduction due to a drop in the average fluid use in litres per occupied bed day from 0.65 to 0.43 since the fluid programme began in 2009. (See Figures 6.3 and 6.4) Biochemistry results are also being monitored and so far have demonstrated minor improvements in renal function in critical care areas along with a reduction in acidosis and a small reduction in average plasma sodium levels from 137 to 136 mmol/l, not thought to be clinically significant.



Figure 6.2

Figure 6.3

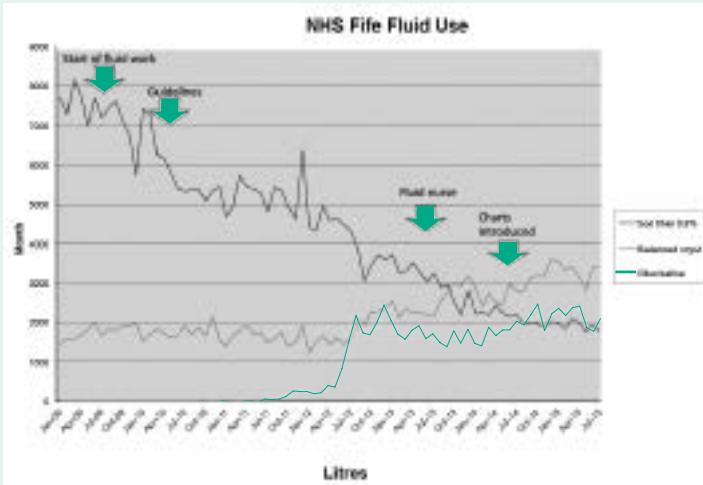
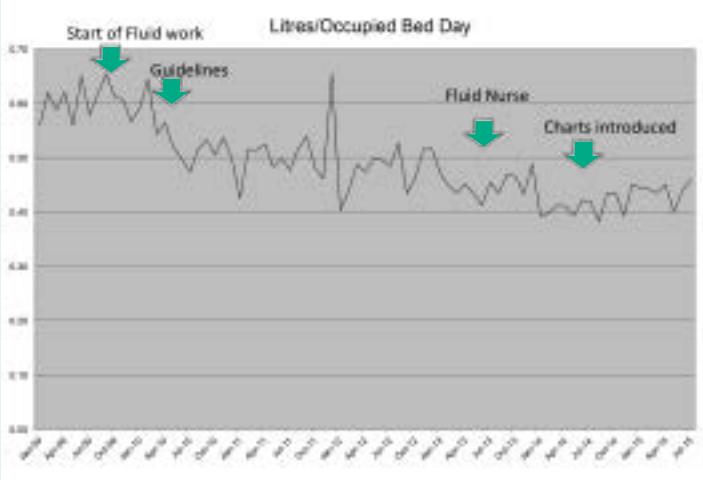


Figure 6.4



Fluid balance charting remains problematic and a mortality review during the year the charts were introduced identified several ongoing areas requiring improvement, specifically around the fluid management of the frail elderly, in whom monitoring was sometimes poor and whose fluid management lacked input from senior clinicians. Further education of nurses is required along with ongoing audit and medical education. Another part-time Fluid Therapy nurse has been appointed to take this work forwards.

Best practice recommendations

- The GIFTASUP consensus guideline and NICE Clinical Guideline (Intravenous fluid therapy in adults in hospital) should be used to guide local initiatives
- The MSO (in England and Wales) should work closely with the Fluid Lead to monitor the safety of IV fluid therapy and to identify and act upon opportunities for improvement
- Training for prescribers and nurses in the safe and appropriate management of fluid therapy should be a priority
- Ward/clinical pharmacists should monitor fluid therapy in the same way as all other prescribed drug treatment to ensure safe and appropriate use
- Fluid prescription documents that incorporate decision aids should be designed to guide and reinforce good prescribing practice
- A quality improvement approach should be used to identify and tackle barriers to successful implementation of safe systems for fluid therapy

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Chapter 7

Managing aseptic preparation capacity in a growing market

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In 2010 Alison was awarded a Professional Doctorate on the subject of medicines preparation and she was recently recognised as a Fellow of RPS. She is a Qualified Person and contributes to education, in particular via the Pharmaceutical Technology and Quality Assurance (PTQA) post graduate course.



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He is a member and former Chair of the NHS Pharmaceutical Quality Assurance Committee. He is also a member of the Pharmaceutical Aseptic Services Group and the Technical Specialists Education and Training Committee. He is Module Director on the PTQA course at Manchester University and he is a Qualified Person for investigational medicinal products.



Managing aseptic preparation capacity in a growing market

Summary

Managing aseptic preparation capacity is a critical consideration in underpinning a hospital's capacity to provide safe injectable medicines efficiently and economically. The need for aseptically-prepared injectable doses usually far outstrips the capacity of the available facilities and so judgments have to be made about the most advantageous way to use the available capacity. Factors that should be considered include identification of high-risk injectables, maximising capacity through standardisation of products and some outsourcing of injectable products. When considering outsourcing, the true costs of products made in-house (including all overheads) need to be compared with the true costs of outsourced products (including costs of quality assurance and contract management). Outsourcing changes the risks to which the organisation is exposed rather than eliminating all risks. Contingency planning and working with the pharmaceutical industry are also important elements of overall capacity management. The MSO should work closely with senior pharmacy managers to ensure that the available aseptic preparation capacity is adequate for the organisation's needs and is used effectively to maximise patient safety.

Introduction

Managing aseptic preparation capacity may not at first sight appear to be the most pressing medicines safety concern, but it is a critical consideration in underpinning a hospital's capacity to provide safe injectable medicines efficiently and economically. It is critical because the need for aseptically-prepared injectable doses usually far outstrips the capacity of the available facilities both locally and on a wider basis. For this reason it is relevant to the work of the MSO.

Capacity in this context refers to the resource available to undertake aseptic preparation - both the physical facilities (aseptic preparation areas, laminar flow cabinets or isolators and associated equipment and the manpower to operate them.

NHS hospitals are required to have capacity plans that set limits of activity and against which their current activity is regularly monitored. Several standards have been set that

require NHS pharmacies to do this.^{1,2} In addition, a report on improving practice and reducing risk in the provision of parenteral nutrition (PN) for neonates and children³ requires NHS organisations to produce a corporate PN capacity plan that must include a risk assessment of all processes and practices associated with PN and the procedure to be followed if demand exceeds the agreed capacity.

It is essential that any capacity plan is agreed at corporate level^{1,3,4} for it to be effective. For example, the introduction of an intestinal failure unit to a hospital will have a significant impact on pharmacy aseptic workload and this must be appropriately resourced – the hospital must not merely fund additional clinical staff.

Capacity planning

“Monitoring and management of the PN workload within a hospital is very important. If demand is unmanaged and allowed to exceed the capacity, which the nutritional support service was designed and resourced to provide, the risk of harm to patients as a result of errors, become more likely. Whilst management of the service capacity of the Pharmacy Aseptic Unit (PAU) may be considered the responsibility of the Chief Pharmacist, effective management of the overall demand for PN solutions needs input from a wide range of stakeholders and should be seen as part of a hospital's corporate responsibility for patient safety.

The availability of adequate numbers of competent individuals is the key element of any capacity plan. Hospitals must hold training records, which demonstrate the competence of those individuals involved in the process.

Hospital PAUs have, for many years, been required to formally assess their capacity and to document systems for monitoring workload. If workload threatens to exceed 'safe' levels, predetermined steps should be taken to increase capacity or reduce demand.”

Source: Improving practice and reducing risk in the provision of parenteral nutrition for neonates and children. A report from the Paediatric Chief Pharmacists Group. November 2011

The central issue is that most acute hospitals use a large number of injectable medicines and that the risks associated with injectables are higher than with oral dosage forms. Many injectables have to be prepared for use - they are not presented in a ready-to-administer form. This provides opportunities for error, for example, incorrect starting materials can be selected, incorrect diluents used, errors in calculations performed. Some products are clearly 'high risk' because the process of preparing a dose involves several steps. Preparation and administration of these is more prone to error. The former National Patient Safety Agency (NPSA) has provided a simple scheme for risk assessment of injectables and easy identification of high-risk items.⁵ This involves an assessment of the risks associated with specific injectable medicines and the allocation of a "traffic light" colour to indicate the level of risk. (Red is equivalent to high risk).

Ideally, high-risk (NPSA red) items should be provided to the point of use in a ready-to-administer (RTA) form. In RTA form the product is presented in its final container, e.g. a syringe. This may not however, always be possible, for example, for stability reasons. In some cases it may be possible to provide the product in a ready-to-use (RTU) form. In this case the product is in the required diluent at the correct concentration for use and only requires a simple 'draw up' into the administration device. Presenting products in RTA form could be achieved by preparation in pharmacy aseptic units or by purchasing RTA injectables. In-house preparation is attractive for many reasons, not least timeliness for patients, but surveys have repeatedly shown that there is insufficient capacity within the hospital pharmacy services even to prepare just the high-risk (NPSA red) items. This means that decisions have to be made about how to use the available capacity within hospital aseptic units to its best advantage. Clearly it would be foolish to use limited capacity to make low-risk injectables whilst leaving high-risk injectables to be prepared in clinical areas.

High-risk injectables

Wherever possible high-risk injectables should be prepared in the pharmacy.^{5,6} Pharmacies with very limited capacity may choose to purchase RTA and RTU products from other NHS units or from commercial manufacturers (outsourcing) if they are available and practicable. For example, the preparation of very short shelf-life products may have to remain in clinical areas, but the risks of such an approach should be assessed and recorded in the hospital's risk register. In any case, every attempt should be made to reduce the risk of preparation in the clinical area. For example, it may be possible to provide an approved dose calculation tool (such as a laminated sheet with standard doses and instructions) from pharmacy to assist clinical staff and to reduce the risk of calculation errors.

The first step is to identify the high-risk products in use. This will have been undertaken when the NPSA Alert 20 was first implemented but it is an ongoing process. As new injectable products are introduced, risk assessments should be made to ensure the register is kept up-to-date. Indeed an NPSA 20 risk assessment should be part of any formulary approval process for a newly requested product. It may be helpful to note that monographs for injectable medicines in the national injectable medicines guide⁷ include NPSA 20 risk assessment ratings.

Measures to reduce the risks associated with injectable products include:

- Provision of RTA and RTU products to clinical areas
- Standardisation of injectable products (see also Chapter 4)
- Use of smart pumps for administration (see Chapter 5)

The provision of RTA and RTU injectables is usually achieved using a combination of products prepared in-house and products that have been purchased. These could be both for individual patient's doses and products made as batches in units that hold MHRA licences.

Managing aseptic preparation capacity in a growing market

Standardisation of products

Regardless of whether in-house preparation or outsourcing is planned, consideration must be given to standardisation of products. Standardisation (or rationalisation) of products means agreeing on a limited range of concentration/volumes (maybe only one). For example, for cytotoxic products dose-banding may be used where a limited number of doses are available rather than a tailored dose, based on body surface area, for each individual patient. It should be noted that dose-banding does not necessarily involve outsourcing of products – it can be carried out in-house. In addition to the safety benefits that standardisation of product ranges brings for prescribing and administration of injectables (see Chapter 4) there are also real benefits in terms of product quality and capacity management.

Standardisation may enable products to be manufactured in batches, both within the NHS and by commercial manufacturers, with an associated increased level of Good Manufacturing Practice (GMP). This will require the aseptic unit to hold a manufacturing licence from the MHRA, and will enable a longer shelf-life to be allocated to the product if stability data allows. It should be noted that units that do not hold a manufacturing licence from the MHRA are limited to allocating a maximum seven-day shelf-life to aseptic products.

In addition to a longer shelf-life, batch manufacture may enable some chemical analysis (to check for correct composition) to be undertaken prior to release. It may also enable prospective microbiological testing to be undertaken so that there is more assurance of the sterility of the product prior to administration to the patient. Usually, with patient-specific, non-batch products, only retrospective testing of a similar sample can be undertaken.

There are efficiency savings with batch production that can result in increased capacity regardless of whether the batches are produced in-house or are outsourced (bought in).

In-house preparation of RTU/RTA injectables

In-house capacity is best reserved for preparation of individualised doses, products that have short shelf-lives (and

therefore need to be prepared shortly before use) and products that are complex to prepare, for example NPSA 20 assessed ‘red’ products.

Individual cytotoxic doses and individual parenteral nutrition solutions (both being high-risk types of products) should always be prepared in aseptic units, not in clinical areas. In-house preparation of these types of products is preferable to outsourcing as it minimises turnaround time between prescribing and administration and this responsiveness has patient benefits. The remaining capacity (if any) is available for preparation of other products.

Another advantage of in-house preparation is that the pharmacist in charge has complete control over the process and can therefore assure the quality of the final products and manage the risks appropriately. This level of control and assurance is much more difficult (if not impossible) to achieve when products are outsourced.

Standards are in place for aseptically prepared products produced in the NHS.¹ A regular programme of audits is undertaken under the arrangements defined in Executive Letter EL(97)52.⁸ The results of these audits are made available to the Chief Executive of the NHS organisation preparing the aseptic products in-house, and also to NHS England (amongst others). Any deficiencies must be addressed in an action plan and are followed up by the NHS auditor.

Outsourcing of injectables to NHS production facilities or other providers

When in-house preparation capacity has been used up the question of outsourcing arises. This may be to a NHS production unit or to the pharmaceutical industry or a combination of the two.

In recent years there have been a number of drivers towards outsourcing of some or all aseptic preparation activity. There have been challenges in recruiting suitably trained and experienced staff to work in NHS aseptic units and also many trusts have struggled to find capital investment when refurbishment or expansion of NHS aseptic compounding facilities have been required.

There is a problem in that sometimes the same people who are responsible for aseptic preparation in-house are expected to be responsible for the quality of outsourced products. In fact, different skills are needed for these two roles. In some NHS hospitals there are specific Quality Assurance pharmacists who can take on these responsibilities, if adequately resourced. However, in many hospitals this is not the case. In order to protect the safety of NHS patients it is essential that the responsibility for undertaking this work is appropriately defined and adequately resourced. The MSO should ask the question, "Who has this responsibility in the organisation?" Usually, the products involved are high-risk unlicensed medicines and controls need to be in place in line with the specific NHS organisation's unlicensed medicines policy.

When outsourcing is planned there are a number of points that must be borne in mind. Outsourcing does not eliminate risks; rather, whilst the direct risks of aseptic preparation are moved elsewhere, the purchasing hospital in fact acquires a whole new set of risks that must be actively controlled. Outsourcing aseptically manufactured products to a third party puts the NHS organisation in the position of a "contract giver" legally. Both the contract giver (the NHS organisation) and the third party – the "contract acceptor" (either an NHS production unit or a commercial company), has responsibilities under EU GMP.² (See EU GMP – Outsourced Activities chapter.) These responsibilities should be defined in a technical (quality) agreement so that both parties are clear what is expected of them.⁹ For example, is the contract acceptor required to carry out any testing on the product and give the contract giver the results? Often this is in the form of Certificate of Analysis that summarises test results, with acceptable limits shown. Will they inform the hospital procuring the product if they have adverse environmental testing results in their facility so that the hospital is in a position to evaluate the risks of using products from that contract acceptor in their patients?

It is essential that specific individuals are identified within the NHS hospital pharmacy undertaking outsourcing to take on a role for monitoring quality in relation to outsourced products and services. It requires more quality input, not less, to outsource aseptic activities safely than to undertake preparation of them in-house, due to the remoteness of the third party contract-

acceptor. The NHS contract-giver must have adequate resource to assess the quality of any potential contract-acceptor both in relation to their facilities (often this involves audit) and the acceptability and stability of their products for the NHS organisation's patients. For example, how will the products be labelled? What are the release criteria? How will the products be transported to the hospital? All this work must be carried out before the start of any outsourcing arrangement. There will also be a requirement for continuous monitoring of the third party contract-acceptor to ensure that products and services are maintained to the quality specified at the outset of the arrangement. Failure to establish and monitor robust contractual arrangements with external providers of compounded aseptic products can put patients at risk. (See Cautionary tales below)

It may be necessary to review the models of contracting used for aseptically compounded medicines as, to date, the same models used for contracting for licensed products have just been applied to aseptically-prepared products. Whilst this system, based on two-year contracts, works well for licensed products, two-year contracts potentially do not offer enough stability to manufacturers of aseptic products to encourage or make financially viable investment in facilities and long-term capacity. Whatever contract model is used, it must reflect the true costs of the product which include not only the acquisition cost, but also the costs of setting up the contract and ongoing quality management. This requires close working with procurement colleagues.

If a hospital chooses to outsource a significant proportion of its aseptic workload, this will have the effect of increasing the costs of the remaining products that they make as many of the costs of running an aseptic unit are fixed, e.g. air handling, environmental testing, maintenance etc. These fixed costs will be spread over fewer products, potentially making them uneconomic to prepare in-house. When the time comes for the unit to be reprovided, there is a risk that it will not be considered viable and the unit will therefore close, thereby reducing NHS aseptic capacity further. It is important to achieve a balance and use the in-house capacity to its best advantage.

Managing aseptic preparation capacity in a growing market

Cautionary tale 1

Contaminated injections

In October 2012, an outbreak of fungal meningitis was reported in the United States. The U.S. Centers for Disease Control and Prevention traced the outbreak to fungal contamination in three batches of preservative-free methylprednisolone acetate for epidural injection. The medication was compounded and marketed by the New England Compounding Center (NECC), a compounding pharmacy in Framingham, Massachusetts. Doses from these three batches had been distributed to 75 medical facilities in 23 states, and doses had been administered to about 14,000 patients after May 21 and before September 24, 2012. Patients began reporting symptoms in late August, but, because of the unusual nature of the infection, clinicians did not begin to realise the cases had a common cause until late September. Infections other than meningitis were also associated with this outbreak, which spanned 19 states. As of October 2013, 64 people had died and 751 cases had been reported.

Multiple batches of products produced by this company were recalled. Investigations by the Food and Drug Administration (FDA) uncovered a number of critical procedural failures and poor practice including undertaking work beyond the authority of the licence and failure to act on reports of contamination in the aseptic areas.¹⁰ This led to a review of the regulation and inspection of compounding activities in the US and numerous law suits, with the eventual bankruptcy of the company involved.

Cautionary tale 2

Unsafe preparation

A hospital in the UK decided to purchase compounded chemotherapy and selected an outsourcing company that said that it held an MHRA Specials licence. No audit or inspection was undertaken. Later, it turned out that the licence was only for repacking of tablets and capsules and did not cover aseptic manufacturing. In fact, cytotoxic injections for the hospital's patients were being reconstituted in a laminar flow cabinet in a domestic living room. When this eventually came to light the company was prosecuted.

This episode raised a number of questions:

- Did anyone check that the company held the appropriate MHRA licence?
- How was the company assessed (if other than by price)?
- Did the hospital have a specification that stated its requirements?
- Was there a technical (quality) agreement?
- If it did exist, did the technical (quality) agreement require the company to hold an appropriate licence covering aseptic manufacturing?
- Was anyone monitoring whether the company was complying with the technical agreement?

Contingency arrangements

Any aseptic unit must have a contingency plan to be used, for example, if there is a facility failure such as the air supply failing. The contingency arrangements will be different from those used to manage capacity, but may be linked. Contingency arrangements are required because it is always tempting to believe that arrangements are more robust than they are: the air supply will never fail; the ceiling in the aseptic unit will never start to fall in; there will never be a sewage leak. All of these have actually happened in the past!

Taking a realistic view, no system can have 100% back-up. There remains an overall system risk - there is not a spare large aseptic unit sitting empty waiting to be brought into play when disaster strikes. The best that can be achieved is to make contingency arrangements with another aseptic unit (NHS or commercial) before any disaster. It is important to prioritise work so that plans are in place in advance to manage workload. For example, lower risk products could be transferred back to preparation in clinical areas with additional safeguards in place.

It may be possible to prepare a kit that will help clinical staff prepare the product more safely. It may be possible for a limited time to supply licensed PN bags without additions for some patients. Another option could be to outsource some products if arrangements have been agreed in advance. It should be noted that the responsibilities and quality requirements in relation to outsourcing are the same whether the outsourcing is a temporary contingency arrangement or a more permanent way of managing capacity (see Outsourcing section).

Relationship with the pharmaceutical industry

The pharmaceutical industry varies in the size and nature of companies and the types of products manufactured. Some pharmaceutical companies (commercial 'Specials' companies) hold MHRA 'Specials' licences for aseptic compounding in essentially the same way that NHS aseptic units do, and their product ranges are comparable. All their products are unlicensed.

Larger pharmaceutical companies hold a different type of MHRA licence (a Manufacturing Authorisation) that enables them to manufacture batches of licensed products, i.e. those products that have a Marketing Authorisation. Unlike unlicensed products, licensed products have been fully assessed for safety, quality and efficacy by the MHRA. These types of companies are sometimes termed 'big Pharma'.

From a capacity perspective it is important that the NHS has a good working relationship with both these types of pharmaceutical companies. Commercial Specials companies can provide helpful contingency and capacity back-up for NHS units.

These companies themselves have limited capacity, however, and can suffer from lack of robust contingency arrangements. The role of 'big Pharma' is therefore essential. If products normally made as unlicensed 'Specials' can be rationalised, then the increased scale could in some cases enable 'big Pharma' to manufacture them profitably as licensed medicines. Ideally, all injectable medicines would be available as licensed, ready-to-administer products. This will never be practical, but anything the NHS can do to help companies develop these products will be very beneficial to release NHS aseptic capacity.

What should the MSO be doing?

MSOs should be routinely reviewing reports of adverse incidents involving injectable medicines and considering whether any of these incidents could be mitigated or prevented by the use of products prepared in the pharmacy aseptic unit. If capacity problems are identified (e.g. resulting from growth in patient numbers, change in clinical practice) or predicted (e.g. as a result of planned development of new services) then the board should be made aware of the risks.

The MSO should work closely with the procurement pharmacist, aseptic services pharmacist and clinical pharmacists to identify opportunities to improve the safety of injectable medicines and to ensure that the available aseptic preparation capacity is adequate for the organisation's needs and is used effectively to maximise patient safety.

What does the board need to know?

The board needs to know:

- The risks to which the organisation is exposed as a result of having insufficient aseptic preparation capacity or facilities of inadequate quality

Managing aseptic preparation capacity in a growing market

Best practice recommendations

- An aseptic preparation capacity plan, agreed at corporate level, should be in place wherever there are aseptic preparation facilities in NHS organisations
- Ensure that high-risk injectables in use in the hospital have been identified and steps taken to mitigate or eliminate the risks
- Periodically review the opportunities for standardisation of injectable products with a view to improving the quality of products and patient safety
- Ensure that any outsourcing arrangements are covered by comprehensive technical agreements and adequate resources to manage safely
- The MSO should work closely with senior pharmacy managers to ensure that the available aseptic preparation capacity is adequate for the organisation's needs and is used effectively to maximise patient safety

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Chapter 8

Electronic prescribing for safer injectable therapy

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Electronic prescribing for safer injectable therapy

Summary

Electronic prescribing and medicines administration systems (ePMA) can reduce the incidence of medication related errors by almost 50% and could therefore contribute to improving the safety of injectable medicines. Likely benefits are more accurate prescribing, fewer diluent and calculation errors, positive patient and product identification, improved support for injection preparation and integration with fluid balance monitoring. Some new risks could arise including workarounds, misinterpretation of displays and inappropriate system prompts. Robust governance procedures must be in place to ensure that the risks of ePMA implementation can be managed appropriately. The MSO needs to be ready to minimise the risks of ePMA implementation and thereafter to use the medication safety information generated by the system effectively. The implementation and optimisation of ePMA should be treated as a journey rather than an isolated episode.

Westbrook and colleagues found nearly 70% of intravenous administrations had at least one clinical error, of which 25.5% were rated as serious.⁵ The four main error types were wrong rate, mixture, volume and incompatibility accounting for 91.7% of observed errors. Patient identification was only checked in 47.9% of administrations but was associated with a 56% reduction in intravenous error risk.

Impact of electronic prescribing and medicines administration systems on medication errors

Electronic prescribing and medicines administration systems have long been identified as having the potential to reduce the incidence of medication related error,⁶ by almost 50%.⁷ Whilst most studies do not differentiate between parenteral and other doses when evaluating ePMA systems their use in oncology has shown that dose calculation errors can be significantly reduced.⁸ The use of barcodes to provide positive identification of both patient and product led to a decrease in medication administration errors with a significant improvement in the correct identification of the patient.⁹ This demonstrates that there are potential areas available in which ePMA could have a positive impact.

Availability of ePMA systems in the UK

The prospectus for the recent NHSE Technology highlighted the introduction of ePMA systems as one of the priorities for implementation across the NHS. Following allocation of the funding it is now clear that a substantial number of systems are being implemented such that over 50% of acute hospitals will have some form of ePMA within the next two years. This represents a marked change from 2011 when only 13 % of sites had operational systems across inpatient beds.¹⁰

Whilst much has been made of the use of technology to support improvements in the quality of prescribing and administration there has been little focus on how this could support improvements in parenteral medicines' use.

How ePMA can guide good prescribing

This section outlines some of the main ways in which it might be presumed that the technology would have a positive benefit for parenteral medicines. It should not be forgotten that there will also be unintended consequences.

Support for the prescribing of intravenous infusions is challenging as there are a number of potential risks that systems must address. In addition to the known errors, there are new challenges that have to be overcome, some of which are technically difficult.

There are a number of ways in which systems can support the optimal prescribing of parenteral medicines. The most effective ways are likely to be those that guide and support the prescribing process using pathways that make it easy for prescribers to 'do the right thing'. Examples of this might include:

- Selecting the correct dose and dose unit of measure
- Ensuring that only appropriate routes of administration can be selected for an individual product
- Listing appropriate diluents for individual medicines
- Supporting the calculation of rates of administration and/or concentration

The main areas that systems would be likely to impact positively are described below:

Compatibility

One of the known areas of error is the selection of an inappropriate diluent or vehicle for the administration of an infused medicine. The error can be made at the time of prescribing, for example, if the prescriber selects an incompatible infusion fluid or, if the diluent or carrier fluid is not specified, then incorrect solutions can be selected at the preparation and administration stage.

Systems should be capable of configuration to guide prescribers to the selection of a compatible diluent or infusion solution. This

feature could also be used to support the creation of multiple component prescriptions, such as palliative care syringes where several medicines are mixed in a relatively small volume. Accessing information sources (for example, Medusa, with appropriate password access) should also be possible if compatibility is not configurable.

Calculation errors

The calculation of the amount to be administered to a patient is sometimes left to the nurse administering the medicine rather than forming part of the prescription. For example dopamine 400 mg/250 mL of sodium chloride 0.9% may be prescribed at a rate of 5 mcg/kg/minute leaving the nurse to calculate the concentration of the infusion solution and compute the rate to the given in mL/hour so that she can set the infusion pump. Systems can be designed to support all the calculations required to administer the medicine safely and appropriately (see Figure 8.1).

Figure 8.1: The prescription for an infusion of dopamine 400 mg/250 mL.

The prescriber enters the dose as 5 microgram/kg/min

The system automatically calculates the rate at which the infusion should run and shows the start time and duration.

Electronic prescribing for safer injectable therapy

Positive patient and product identification

Systems may support the use of barcode or other machine-readable codes that allow confirmation that the appropriate medicine is being administered to the right patient. The NHS has a standard for the use of barcoded wristbands (ISB09911) and the NHS supports the use of GS1 codes on medicines to facilitate this.

Support for preparation

One significant cause of error is in the preparation of injectable medicines; several studies have identified breaches in good practice, many of which can have potential clinical consequences. Electronic PMA systems should be able to provide context-specific links to guidelines for nurses if preparation on the ward is necessary. Further support using pre-configured worksheets that guide nurses to the selection of appropriate diluents and volumes is also possible.

Integration with fluid balance

Where systems are part of a wider electronic health record it is logical to integrate the documentation of volumes of infused medicines/fluids with the overall management of fluid balance.

New ePMA system-mediated risks

One of the unintended consequences of ePMA is the opportunity for new types of risk and users need to be aware of these.

The main areas of potential system-mediated risk include: workarounds, display issues, inappropriate system prompts and administration.

Workarounds

Where functionality is incomplete such as support for complex infusions like palliative care syringes or sliding scale insulin etc., systems may require the concurrent use of paper charts to support prescribing and medicines administration. Whilst this is not ideal, the availability of ePMA for other medicines carries

sufficient benefit for the temporary expedient of a paper work process to be worthwhile. If a workaround is being used it must be explicit from the electronic record that the user has to consult the paper chart. This process is, of course, prone to all the difficulties common with paper charts and to the fact that doctors must enter information into more than one system, which increases the risk of error.

Display

The details of the infusion prescription can be complex involving a dose or amount of medicine mixed in a volume of fluid to produce a concentration and a dose/rate of administration that might be specified either in 'dose terms' e.g. micrograms or mg per unit time or in volume terms e.g. in mL/hour. Where information is not clearly specified or easily understood this has great potential as a cause of error. Thus, systems can prompt for information to be complete and, where doses are expressed as dose rate, for this also to be calculated as volume rate ensuring that the prescriber's intentions are clearly communicated.

Inappropriate system prompts

Inappropriate system prompts represent an important source of potential system-mediated risk. Where continuous infusions are prescribed administration will generally require the use of consecutive infusion bags. If the current bag has residual volume when the next is scheduled for administration, the prompting of the system to hang the next one has led to over-hydration. To overcome this, systems should not prompt for subsequent infusion bags to be initiated until the current bag is documented as completed (Figure 8.2).

Figure 8.2: Scheduling of sequential intravenous infusions



The screen shot shows the scheduled administration of three sequential IV infusions. Nurse administration tasks are identified by boxes; the yellow box indicates that this item is 'due now' and the blue box indicates a task in the future. The white x in the blue task box indicates that this is a 'stop' task and until this is completed tasks to initiate the next infusion are not generated.

Administration

The scheduling, recording and monitoring of administration must be supported including the ability to identify and adapt the prescription when things do not go to plan, for example, a drip may run slowly or the cannula may be dislodged causing fluid to run into the surrounding tissue instead of the vein.

Making the system work effectively

Sites implementing systems must have robust governance procedures in place to ensure that they are able to identify and manage the risks of implementing ePMA systems. Before any system is introduced into a 'live' environment hospitals should ensure that a clinical safety case is completed and signed off by the hospital's clinical safety officer – this is a requirement within ISB016012 with which all NHS organisations should be compliant. Whilst in use there should be continued surveillance to ensure that any new issues are identified in a timely manner and addressed with system configuration or changes to processes for example.

Business transformation

In addition to technical challenges the introduction of digital systems requires a rethink of the way in which services are delivered. Successful implementation requires that existing work flow processes are revised to enable seamless use of the technology and thus to reap the efficiency benefits that might be expected. The use of technology at the bedside will bring

challenges to nursing staff in particular; as a user group they will have the most interaction with the system yet are often the least consulted during the procurement and implementation process. Easy-to-use and accessible bedside computing will be crucial in facilitating the use of the system, without which business change cannot occur.

The implementation process must include assessment of how existing processes and practices should be changed to make best use of the technology. For example, prescriptions will be available at all times from any device with access to the system. This means that moving paper copies of prescriptions to support supply requests need no longer be required, potentially impacting on a number of processes. For example, nurses can be alerted when medicines are due and will no longer have to check every chart at each medicines administration round. Whilst these may be positive, there are also negative consequences if changes are not thought through, for example, the availability of prescriptions remotely may mean that pharmacy staff stop visiting wards and screen prescriptions from their desk thus potentially missing any number of issues that can only be identified by talking to patients.

Consideration of these changes should be undertaken both before and after the implementation of the system. Where this is not undertaken it is likely that systems will be slow to bed in. True adoption requires a change in culture that will take some time to realise.

What should the MSO be doing?

The introduction of ePMA will potentially have a profound impact on the way in which an MSO works. The MSO should be aware of the types and frequencies of error in their existing processes and be able to identify how these might be ameliorated using ePMA systems. In line with the safety process outlined in ISB0160, the MSO should be taking steps to ensure that the potential risks associated with ePMA systems are effectively reduced as far as is practicable and certainly during the initial implementation and any upgrade phases.

Electronic prescribing for safer injectable therapy

The introduction of a new system that supports all of the processes around the use of medicines will undoubtedly impact on the types of errors reported. It will also, certainly initially, increase the number of errors identified. The MSO needs to be aware that an increase in error reporting is not necessarily associated with an increased occurrence of error but more with the ease of identification. That is not to ignore the likelihood that in the initial phases of the introduction of any new process errors are likely to increase as people adopt new ways of working. It is very easy to 'blame' the new system for problems when its introduction may be highlighting problems or poor practice that have been in place for a long time but have not been clearly visible. Many of these will be due to business process change, which may still need to bed in, something that MSOs must bear in mind when looking at potential mitigating measures.

In addition, systems will be able to provide considerably more insight into the ways in which medicines are used and managed. It should be possible to generate reports on medicines usage very quickly without the need to collect information manually. This increased availability of information needs to be carefully thought through to ensure that it presents the true picture. For example, if 20% of doses are omitted this would be a cause for concern but if half of these were appropriately omitted for good clinical reasons then that needs to be reflected in the report.

The easy availability of information could result in information overload and care has to be taken in focusing clearly on priority areas, at least in the initial stages. Areas that might be a focus should be known and new errors, for example, decision support over-rides, the use of 'antidotes' or routine reviews of omitted doses.

What does the board need to know?

The introduction of ePMA is probably the most difficult of all health IT system implementations. The system must meet the needs of three professional groups – medicine, nursing and pharmacy – all of whom want the system to deliver different things - and a business transformation agenda in an area that is crucial to day-to-day patient care. There are also technical challenges in meeting these needs, not the least of which is the requirement to have a system that is available 24 hours a day, every day.

The challenges are not just functional and cultural but also technical, with the need to provide an appropriate number and range of computers to support bedside working. It is interesting to note that the most common technical source of failure is the lack of a robust wireless network.

The introduction of ePMA should be seen as a facilitator for clinical change, as part of wider local organisational and digital maturity development. The programme must be clinically-led with executive buy-in and IT involvement. Without clinical buy-in implementation is likely to be unsuccessful.

There is no ideal system currently available in the current, relatively immature market. The board should focus on identifying the key benefits that are required locally and how these fit with other initiatives, and its IT strategy rather than looking for perfection. The board should also understand that what it thinks is required, as regards functionality, is likely to alter after implementation as the organisation learns how to use the system to adapt its processes. Looking to implement all of the potential functionality in one go is likely to create a real challenge that may take years to overcome.

The introduction of ePMA must be seen as a journey, of which the implementation is only the start. It is likely to take a number of years before it delivers significant benefits. Thus, resources to support and optimise the system to maximise benefits will be required for duration of the system life.

Information and resources to support the implementation and optimisation of ePMA are now available in the form of an on-line toolkit that has been produced by an NIHR research team. This can be found at www.eprescribingtoolkit.com

Best practice recommendations

- ePMA systems should be introduced to reduce the numbers of prescribing and administration errors with injectables
- Systems managers should be aware of the opportunities for new types of error and take steps to mitigate them
- Implementation of ePMA should be driven by a business and process transformation agenda

- Clinical leadership and buy-in is key towards supporting successful implementation
- Implementation should be seen as a the start of a journey; resources must be available for support for the duration
- The availability of 'bedside computing' is an important success factor

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Chapter 9

Ensuring safe use of injectable medicines in homecare practice

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Ensuring safe use of injectable medicines in homecare practice

Summary

In the UK the homecare medicines market accounts for about 20% of the NHS medicines budget and delivers services to more than 200,000 patients. It provides complex injectable therapies to patients at home and has advantages for both patients and the NHS. Guidance and standards for the delivery of homecare services have been published. Key areas of risk are purchasing arrangements, prescribing, choice of products, storage of injectable medicines in the home, administration of medicines, patient follow-up and monitoring of homecare service. The MSO should ensure that the homecare services used by the hospital comply with the published guidance and standards.

Introduction

The use of medicines via homecare in the United Kingdom has seen a large increase in the last few years, and there is no indication that this growth will stop or reduce. The homecare medicines market accounts for about 20% of the NHS medicines budget and delivers services to more than 200,000 patients.¹ The reasons for the growth in homecare are varied. There are great benefits for patients in that they can have complex therapies at home, rather than travel to the hospital, and so this development fulfils the Government agenda of delivering care closer to home. The use of homecare can also reduce the duration of hospital admissions; for example, long courses of antibiotics can be delivered at home thereby freeing beds for use within hospitals. There are also financial benefits; care of patients at home is generally cheaper than keeping them in hospital. Furthermore, there are VAT savings on the cost of medicines when supplied via homecare. This cost saving should not be the main driver for homecare. For some patients treatment will be life-long and the only option for them is the provision of treatment at home.

There is an increasing number of medications now available via the homecare route, with injectables accounting for a large proportion. With new injectable medications coming on to the market over the next five years, the range and complexity of homecare products is likely to increase.

Injectable medicines in homecare

The injectable medicines used in homecare include pre-filled devices for subcutaneous or intramuscular administration, more complex injectables requiring reconstitution and/or dilution and parenteral nutrition solutions, all of which pose different risks.

The range and types of medication that are commonly-used in homecare are shown in table 9.1. (For a more comprehensive list readers are referred to the Commercial Medicines Unit Procurement guidance for the provision of homecare delivery service of medicines to patients at home.²)

Table 9.1: Range and types of injectable medication commonly used in homecare

Medication	Route	Presentation	Clinical areas
Adalimumab	Subcutaneous	Prefilled syringe or pen	Rheumatology, gastroenterology, dermatology
Etanercept	Subcutaneous		Rheumatology
Methotrexate	Subcutaneous, intramuscular	Prefilled syringe	Rheumatology, gastroenterology
Parenteral Nutrition	Intravenous or fluids	Aseptic compounded bag	Gastroenterology
Teduglutide	Subcutaneous	Vial requiring reconstitution	Gastroenterology
Infliximab	Intravenous	Aseptic compounded bag	Rheumatology, gastroenterology
Antibiotics – various	Intramuscular, intravenous	Various	All clinical areas
Chemotherapy – various	Intravenous	Various	Oncology, haematology
Dalteparin	Subcutaneous	Prefilled syringes	Haematology
Golimumab	Subcutaneous	Prefilled pen	Rheumatology, gastroenterology
Milrinone	Intravenous		Cardiology
Iloprost	Intravenous		Cardiology
Epoprostenol	Intravenous		Cardiology
Blood factors V11, V11a, V111, 1x	Intravenous		Cardiology, haematology
Omalizumab	Subcutaneous	Pre-filled syringe	Respiratory
Apomorphine	Subcutaneous	Prefilled syringe, prefilled pen	Neurology
Pegylated Interferon	Subcutaneous	Prefilled syringe, prefilled pen	Gastroenterology
Fertility medication	Subcutaneous, intramuscular	Vial requiring reconstitution	Endocrinology
Somatropin	Subcutaneous	Prefilled cartridge with pen syringe requiring reconstitution	Endocrinology
Teriparatide	Subcutaneous	Prefilled pen	Endocrinology
Lanreotide, octreotide	Subcutaneous, intramuscular	Prefilled syringe, vial requiring reconstitution	Endocrinology
Darbepoetin, epoetin alfa, epoetin beta	Subcutaneous	Prefilled pen, prefilled syringe	Renal Haematology
Desferrioxamine	Intravenous	Aseptic compounded product	Haematology
Enzyme replacement	Intravenous	Vial requiring reconstitution	Endocrinology
Immunoglobulin	Intravenous	Aseptic compounded bag	Various

Ensuring safe use of injectable medicines in homecare practice

Guidance and standards

Since the publication in 2012 of the Department of Health report, *Homecare Medicines: Towards a vision to the future (Hackett Report)*³, there has been an increased focus on the governance arrangements for homecare and what should be in place to protect patients, purchasers of homecare and homecare companies. Two Royal Pharmaceutical Society publications, the Professional Standards for Homecare⁴ in 2013 and the Handbook for Homecare Services in England in May 2014⁵, clearly specify the processes and procedures that should be in place for all aspects managing the homecare process.

Risks with injectable medications in homecare

Injectable medications are known to be associated with a higher incidence of errors, as highlighted by the NPSA Patient Safety Alert 20, *Promoting the Safer Use of Injectable Medicines*,⁶ published in 2007. Although this related to practice in secondary care, the safety principles described are applicable whenever injectable medicines are used and so also need to be considered when purchasing or commissioning homecare services.

The NPSA alert showed that errors with injectable medicines, occurred at every stage of the process including prescribing, preparation of medicines or dispensing in pharmacy, administration, monitoring, advice and the supply or use of over-the-counter medicines whilst on injectable medicines. These categories can be further broken down to specific areas, all of which are still relevant to homecare.

The risk associated with the use of injectable medicines in homecare can be minimised by the measures described below.

Purchasing of homecare

Many homecare schemes already available for injectable medicines have been set up by pharmaceutical companies, using homecare companies to provide a delivery and sometimes nursing services for their own products. A prescribing hospital must ensure that these schemes fit within the hospital governance framework, are assessed for suitability for use and will benefit the patients. Each purchasing hospital should set up a service level agreement (SLA) with the homecare company, so that the company can be monitored on its service to their patients. The National Homecare Medicines Committee (NHMC) is currently working on a standard SLA that can be used between the homecare companies and the NHS for these schemes.

Other homecare schemes have been commissioned and purchased via national or regional tenders. Such services have been purchased by the NHS on behalf of the NHS and will have included NHS users in the design of the service specification. National purchasing schemes are often used for the more complex and rarer injectable medicines. In these situations, it is not possible for all hospitals to be involved in the design of the service specification, however clinical differences in practice should be taken into account.

When planning commissioning or purchasing of a homecare service for your hospital, consideration must be given to ensuring that quality and safety are integral elements of the specification. The Commercial Medicines Unit, in conjunction with the National Homecare Medicines Committee, has devised a standardised homecare specification⁷. This document must be used as a starting template that can then be amended as the homecare service to be commissioned requires. It is important to clarify the aspects of the service that are essential and how the service should operate. A working party with the correct skills required to develop the service specification should be established.

Prescribing of injectable medicines for homecare

The use of standardised prescription documents will not only help the prescribing hospital, but also the homecare company. Ideally, standardised prescription documents should be agreed at national level, rather than by each hospital, in order to prevent errors caused by having multiple different prescription formats. For example, one homecare company currently deals with around 200 different prescription formats for different products, indications and hospitals. This is likely to increase the risk of an error occurring. For home parenteral nutrition, a standardised ordering process and templates have been designed, although there have been some barriers to their uptake. The National Homecare Medicines Committee is currently designing a general homecare prescription that can be used for all medicines in the homecare situation.

Standardising the prescription format is one of the first steps in the implementation of electronic prescribing. Electronic prescribing, with an electronic clinical check by a pharmacist and electronic transfer of the prescription to the homecare company will reduce the chance of transcription errors.

Within hospitals, for each homecare area, there should be a process for prescribing that defines how it is done, who is authorised to do it and the training to be undertaken before prescribers can do this work. There must also be processes in place for a clinical check by a pharmacist prior to the prescription being sent to the homecare company. This is a requirement in the RPS Standards for Homecare.³ The clinical check by the pharmacist should also include, where appropriate, ensuring that any funding required is in place and will remain in place for the duration of the prescription.

Product choice for homecare

Injectable medicines come in a variety of formats including prefilled devices, aseptically compounded syringes, bags, pumps or ampoules or vials that may need to be reconstituted, and/or diluted before administration.

The NPSA Alert for safer use of injectables⁶, recommended the use of ready-to-use (RTU) or ready-to-administer (RTA) injectables in secondary care and the same safety considerations apply to the homecare market. Where there is a licensed RTU product, this should be used in preference to a product that is unlicensed or requires manipulation before administration. The reasoning behind this is risk reduction; licensed products will have information validating stability and shelf life. The use of compounded specials will ensure that errors in the preparation of product are minimised. However, as they are unlicensed, the liability for the product rests with the prescriber and the purchasing hospital. There are circumstances, normally due to stability or nature of the product, where the delivery of a RTA product is not possible, for example, some fertility medicines. In these circumstances, there should be procedures and control systems in place to ensure that the product is prepared correctly and that risks to the product and the person preparing the product are minimised.

Certain products, including chemotherapy and parenteral nutrition, must always be supplied in a RTA format so that they require no manipulation or additions prior to administration in a patient's home.

When providing injectable medication at home, consideration must also be given to the additional medication and ancillaries to ensure that the medication can be given safely. Arrangements for safe disposal of waste, including its removal from the patient's home, must be made.

Ensuring safe use of injectable medicines in homecare practice

Storage of injectable medicines at home

Many of the injectable medicines used in homecare, either licensed or compounded, will require refrigerated storage and suitable arrangements must be made before starting homecare.

For certain injectable medications for example, parenteral nutrition, it is essential that a refrigerator be supplied as part of the homecare package. Where this is the case, arrangements must be in place to ensure that replacement of faulty equipment will occur within set time limits to ensure that there is no wastage of medicines.

The majority of subcutaneous medications supplied are licensed, pre-filled devices (pens or syringes) that need to be stored in a fridge. In these cases, the homecare company will provide the medication via a cold-chain distribution process to the patient's home and request that they store it in their domestic refrigerator together with their food. However, this does not necessarily ensure the correct storage temperature. In an ideal world, a separate medication refrigerator with appropriate temperature monitoring equipment should be supplied, but each medication should be evaluated, taking into account best practice and practical considerations such as size of product, risk of contamination of product or food, space in a patient's home. It is important to have a process for ensuring that the patients are aware of how to store their medication, how long it can be out of the fridge and still be used, and what to do if this time is exceeded. There also needs to be a process to manage the medication when patients go on holiday. Some homecare companies deliver to holiday destinations within the UK and abroad, but it is important to check that appropriate safety mechanisms are in place. The cost to the NHS for such enhanced services must also be considered.

For non-refrigerated medicines, advice on appropriate storage of medicines should be given to patients to ensure that they are safe and not accessible to children and vulnerable adults.

Administration of injectable medicines

When thinking about administration, the first decision should be about where the first two doses should be administered. Some medicines are associated with an increased risk of anaphylaxis compared to others, and there should be a risk management strategy in place. If the patient has had the medication previously without ill effects, then the initial doses could be administered at home. However, if this is the patient's first exposure to the medication, then a risk assessment should take place, bearing in mind the possibility of an adverse reaction. The next decision is about who will be administering the medication in the long term, and what training and knowledge they have or need. For many medications, the patient will be self-administering. In these situations, it is important to ensure that the patient is fully trained on how to administer the drug and what to do if things go wrong. Consideration should be given as to where the training takes place, whether in the hospital or whether the patient should be trained by homecare nurses at home.

For each homecare medication, there should be a 'training ladder' for patients, setting out what they need to know in order to become independent.

If nurses are to administer the medication, then it is important to ensure that they have the appropriate knowledge and training. This should be stipulated in any specification or service level agreement that is in place.

When intravenous medications are administered at home, there are increased risks compared with other injectables, due to the patient having an indwelling intravenous access point. The presentation of the medication must be suitable for the intravenous access that the patient has, for example, some parenteral nutrition solutions are only suitable for administration via a central vein, and there must be maintenance of the intravenous access with appropriate flushes and ancillaries. In the UK there is not currently a standardised procedure for maintaining intravenous lines. For homecare companies, this increases the complexity of their task and may mean that nurses have to be familiar with a number of different protocols from different discharging hospitals.

Follow-up of patients receiving homecare

There is a risk that patients discharged from hospital on homecare may be overlooked and this can have serious clinical and financial consequences (see Best Practice vignette). For all homecare areas, there must be a procedure for each clinical team and pharmacy department for regular reviews of these patients, at a frequency that is suitable for the therapy that the patient is receiving. This follow-up care must be built into any service model for homecare provision, and a decision made as to by whom and how this will be done. This may require investment by the hospital for staffing and facilities.

Some homecare companies are now providing free, enhanced nursing services to patients and hospitals. This enhanced service often includes a clinical review of the patients, obtaining disease-related scores and taking bloods or other samples to ascertain disease status. Although this service initially seems to be of benefit to the patient and the hospital staff, it should not take the place of the clinical review by the team managing the patient's condition.

Monitoring homecare companies' performance

Once set up, homecare services require regular monitoring and review to ensure that the patients and the NHS are receiving the service required. The RPS Homecare Standards⁴, recommend that a hospital should meet with each homecare company at a minimum of four times a year to review the service provided, review the key performance indicators (KPIs), review incidents and complaints and discuss any changes from either side to the contract.

The CMU and the National Homecare Medicines Committee in conjunction with the homecare companies have standardised the KPIs.⁸ These cover areas such as number of active patients, number of prescriptions and orders, delivery information such as time and accuracy. The current KPIs do not contain information on complaints and incidents or on the nursing service, but should do in future. Once available, this data should also be available to the purchasing hospital. The Home Parenteral Nutrition

Framework for England does include a data set, so could be used for other homecare nursing services that are commissioned.

In summary, the use of injectables within homecare is increasing, and hospitals need to ensure that they are following the principles of the Royal Pharmaceutical Society Standards and handbook to ensure appropriate use of homecare and patient safety.

Best practice vignette

Monitoring of anti-TNF therapy for IBD

Patients receiving biological therapies for inflammatory bowel disease (IBD) should have their disease status reassessed every twelve months, according to current NICE guidance. This requires a robust system for monitoring and review. In 2013 clinicians at the Royal Alexandra and Vale of Leven hospitals set up a 'virtual clinic' to review patients who were receiving anti-TNF therapy for IBD. They reviewed the case notes and clinical data for 45 patients; 34 patients were receiving infliximab and 11 were receiving adalimumab. Over the next 12 months, treatment was discontinued in 19 patients - 14 receiving infliximab and five receiving adalimumab – because they had achieved clinical remission. Adalimumab dosing was reduced from weekly to fortnightly in two patients. No patients required steroid therapy or hospital admission following de-escalation of therapy. Treatment was switched from infliximab to adalimumab because of loss of response in six patients. One patient had died at the time of the review but had apparently continued to receive deliveries of adalimumab for four months. As a result of the discontinuation of anti-TNF treatment an estimated saving of nearly £250,000 (on drug costs alone) was made over a 12-month period.

As a result of this initiative a robust process for monitoring these patients has now been introduced.

Source: The clinical and financial impact of a virtual clinic for biological therapies in inflammatory bowel disease. Boal A et al. Poster PTU-060. Presented at the Digestive Diseases Forum, Edinburgh, June 2015.

Ensuring safe use of injectable medicines in homecare practice

What should the MSO be doing?

- Be conversant with the content of the RPS Standards and Handbook for homecare
- Find out what homecare services are used by the hospital and which medications are involved
- Work with the team looking after homecare to ensure service level agreements are reviewed to check arrangements for assuring and monitoring patient safety
- Identify weaknesses or gaps that expose the hospital to risk
- Keep abreast of developments on KPIs for homecare companies and national work being undertaken

Best practice recommendations

- Ensure robust governance processes are applied to new homecare services to ensure patient safety and robust performance of the homecare company
- Ensure that patient safety is emphasised in SLAs and that mechanisms are in place to make it happen
- Ensure staff are in place to monitor the patients and the services provided by homecare companies
- Involve the clinical teams in the monitoring and review of the homecare companies, as the patients may contact them when there is an issue
- Ensure compliance with existing standards and guidance on homecare services (i.e. RPS standards and handbook for homecare)
- The risks to which the organisation is exposed in relation to homecare services should be recorded in the organisation's risk register
- Where there are national standardised documents, use these over and above any hospital specific documents
- Work with regional homecare specialists to improve safety and standards across the region

What does the board need to know?

The board needs to know:

- What homecare services are used by the hospital and for which medicines
- The risks to which the hospital is exposed in relation to homecare services
- How well the hospital is performing in relation to the RPS standards for homecare services

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Chapter 10

Human factors and safety culture

Tony Jamieson

Tony's career has focussed on protecting patients from harm. Optimising the use of medicines achieves this by preventing worsening of morbidity and by reducing the incidence of avoidable adverse drug reactions. In 2013 Tony took up the role of Clinical Lead for Medicines in the Yorkshire and Humber Academic Health Science Network to advance these ideas. In this role he has advocated patient-centred care and the use of human factors theory to improve patient safety.



Human factors and safety culture

Summary

Errors when prescribing, supplying and administering injection therapy are common and the consequences can be devastating for patients and traumatic for clinicians.

Developing a culture of safety by focusing attention and action on addressing the human factors that affect the performance of clinicians can bring about safer clinical care and improved patient outcomes. Culture is manifest in the behaviours that are accepted by the people working in the organisation. Human factors are what shape the behaviours. Patients cannot be protected by an expectation that professionalism will somehow make human beings infallible. Patient safety can be improved by the application of engineering principles, psychology and sociology to give us an environment, processes and equipment that allow us to work effectively as a team to the best of our ability. This chapter explores the concepts of culture and human factors and how these can be affected in practice.

Introduction

Caring for patients is a complex and demanding process which, by its nature, is error prone. Care is provided by us mortals whilst we juggle with ambiguity and uncertainty and apply our accumulated preconceptions, formed from our life experiences. It is a credit to our dedication and professionalism that in the face of such a monumental challenge patients are treated safely and effectively and with great compassion for the overwhelming majority of the time.

Patients' safety is paramount in the minds of clinicians and managers alike and we have recognised that it is always possible to do more to prevent our patients coming to harm. The infographic in figure 10.1 depicts the medicines' safety challenge for the NHS and is a vivid reminder that providing care requires a great deal of risk management. Using medicines as safely and effectively as possible is one of the key components of managing the risk of harm. It has been said that the difference between a medicine and a poison is just a question of getting the right dose.

Figure 10.1: Medication safety in the NHS



Safe foundations

The NHS puts a great deal of effort into keeping patients safe from the harm that medicines could cause. There are strict regulations governing the development, production and distribution of medicines which ensures that the products administered to patients are of the highest quality possible. There is a post-marketing pharmacovigilance system which is effective at identifying unforeseen problems with medicines. In addition, high quality clinical guidance and medicines information is readily available. These are indispensable tools that allow us to get the best effect with the lowest risk of an adverse outcome. A medicines safety officer (MSO) can capitalise on these aspects of the medicines safety infrastructure by influencing:

- the organisation's drug purchasing strategy which will include mechanisms to prevent the purchase of counterfeit medicines and products with similar appearance(look-alikes) which might lead to errors of selection

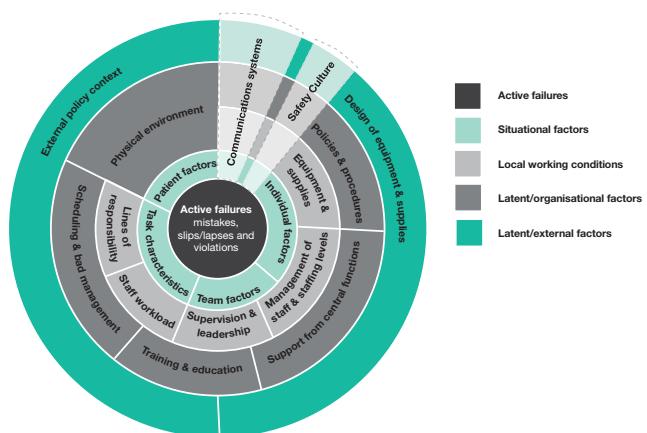
- the governance of clinical trials
- the promotion of MHRA yellow card reporting
- the promotion of evidence-based practice through mechanisms such as Drugs and Therapeutics Committees

Factors contributing to errors

Medication errors are a major cause of patient harm. Medication errors are common. Medication errors are made by diligent, competent and compassionate people trying their hardest to improve patient's lives. Accepting this as a fact is, arguably, the first step to fostering an effective safety culture through the application of Human Factors.

Research by Keers and colleagues has provided some insight into the human factors that affect intravenous drug administration.¹ Their work identified a number of factors that can increase the likelihood of making an error. It also showed that the systematic review of contributory factors by Lawton and colleagues² has direct relevance to the administration of parenteral therapy. This review generated a schematic that describes a broad range of contributory factors (See figure 10.2). The work has been further developed into a checklist which can be used when investigating patient safety incidents to help identify the dominant and most frequent contributory factors. (www.improvementacademy.org)

Figure 10.2: Factors that contribute to adverse drug events.



Source: BMJ Qual Saf 2012;21:369-380

To explore how patient safety can be affected using culture, measurement and human factors, the elements can be classified into four principles within a cultural context. The four principles are personal experience, psychology and sociology, engineering and practice. These are depicted in Figure 10.3



Figure 10.3: The Human Factors Wheel

In this Human Factors wheel, the healthcare worker, being any person providing care, is at the centre.

Understanding of past experience

Principle A asks us to understand our past experience - past behaviours being the best predictor of future behaviours. We all carry some baggage, some life events that have shaped our perceptions and beliefs. And this affects our actions, both consciously and subconsciously. We like to think we have common sense; unfortunately, it could be argued that that we have built up our 'common sense' based upon our uncommon experiences and ingrained prejudices.

We are comfortable when we are doing tasks which are aligned to our values and beliefs which are derived from our past experiences. However, when we are in a position when we are uncomfortable, our behaviours and decisions are affected. The scenario below illustrates how previous experience might affect performance.

Human factors and safety culture

Scenario

Patient education

Consider a scenario in which a patient is presenting for help with using inhalers because of worsening breathlessness caused by chronic obstructive pulmonary disease (COPD). The patient is a heavy smoker and appears to be quite content to continue smoking. You might be a smoker, an ex-smoker or a non-smoker. Consider how your personal life choices affect your opinions about your patient's decision to continue smoking. You could take it a step further and consider whether your life experiences affect the amount of effort you make to help the patient achieve improved lung function.

Improving teamwork

Principle B in the Human Factors wheel is about us and how we interact with each other. We try every day to be the best we can be because our patients need that from us, but we have limitations. We are fallible and we are often forgetful. In many ways our primitive brains and our developed intellect compete. We are built to overcome amazingly complex problems. We are also built to jump to conclusions, work on auto-pilot whenever we can and we see patterns where there are none. We lose track of time when mental workload is high, we go deaf under severe stress and we like to continue on a train of thought once we have invested some time in it.

Here is an example: Our 'working memory' (short-term memory used in problem solving activities) can only hold about seven items of information at one time.³ If you have a list of 10 medicines you are unable to retain all of them in your head at the same time. You will have forgotten at least one of them by the time you have read to the bottom of the list. So, imagine you're a bit pushed for time and you look at the list of 10 and think, "Do any of these interact?" By then you will have forgotten at least one of them so your check was not based on all the items on the list.

We can't help it....we're human.

The field of cognitive behavioural therapy has opened our eyes to thinking errors or cognitive distortions⁴ (see examples in Table 10.1). We are prone to making thinking errors in stressful situations.

Table 10.1: Thinking errors

Thinking error	Description
Mental filter	Application of context to thoughts which may or may not be relevant
Disqualifying the positive	Ignoring information that does not support a negative point of view
'All or nothing' thinking	e.g. "Nobody ever listens to my recommendations" might more accurately be said as "That consultant rarely accepts my recommendations"
Overgeneralisation	e.g. All obese people eat too much junk food
Jumping to conclusions	e.g. They have a rash, they are on penicillin. They are allergic to penicillin
Magnifying or minimising	Going over things in your head making thing either more or less significant than they really are
Personalisation	Everything is about you
Shoulds and oughts	Feeling compelled to do something because you feel you should without objectively assessing whether it is the right thing to do – this is like buckling to peer pressure
Emotional reasoning	e.g. deciding that a patient is unlikely to develop an adverse reaction just because you have a positive feeling about it
Labelling or stereotyping	"All obese people are lazy"

Source: Adapted from Burns 1989⁴

Situational awareness is another cognitive function. Situational awareness is the ability to assess a situation, form an accurate plan about what to do and go on to predict the outcome of any intervention that is tried. Situational awareness is what keeps us safe when crossing the road. We assess the gap between cars,

decide when to walk across and predict the likelihood of us reaching the other side of the road without injury. It is very easy to lose situational awareness, especially when the pressure is on to assess, plan and predict quickly in the face of uncertainty.

We rarely work in isolation from others. Everyone around us is managing their own psychological limitations at the same time as we are managing ours. Team work, together with leadership, communication skills, and assertiveness is critical to success in healthcare. One example of this is called the Gradient of Authority.⁵ If consultants are held up as gods who may only be addressed by high priest senior registrars there is clearly going to be an issue if a lowly pharmacist wants to raise a concern. However, a completely flat hierarchy also causes problems because no-one takes charge and no-one knows their role. It has been suggested that a shallow gradient of authority is about right for a multidisciplinary team.

Engineering and design

Our environment, including the space, layout, lighting and temperature will all have an impact on our performance. In addition, the design of the equipment we use - be it the computer system, the drug packaging, the inhaler device, or the prescription chart - decides how we use it.

Figure 10.4: Medication safety skills

Clinical staff	Clinical activities	Dispensing, prescribing and administration
<p>Drug therapy</p> <ul style="list-style-type: none"> • Appraises patients' drug therapies • Shares concerns or misunderstandings before action 	<p>Situational awareness</p> <ul style="list-style-type: none"> • Undertakes thorough preparation • Anticipates therapy and changes to drug documentation • Keeps a broad perspective 	<p>Professional style</p> <ul style="list-style-type: none"> • Abides by professional code • Aspires to high performance • Is conscientious and flexible • Is self-aware and seeks feedback
<p>Teamwork</p> <ul style="list-style-type: none"> • Recognises expertise in multidisciplinary teams • Is flexible and shows respect • Co-monitors drug therapies with other healthcare professionals • Thinks independently 	<p>Workload</p> <ul style="list-style-type: none"> • Recognises high workload • Priorities work • Avoids distraction and distracting during high-risk activities 	<p>Drug handling</p> <ul style="list-style-type: none"> • Is safe, effective, efficient • Follows and amends overall prescriptions • Is aware of unwanted effects and contraindications • Manage errors • Reports near misses and adverse events
<p>Communication</p> <ul style="list-style-type: none"> • Shares information and ideas • Listens to other healthcare professionals and patients and their relatives • Is assertive when required • Admits mistakes and doubts 	<p>Decisions</p> <ul style="list-style-type: none"> • Identifies problems with, and concerns about, medication delivery • Involves other healthcare professionals and patients and their relatives • Evaluates treatment outcomes • Takes account of safety structures 	<p>Applied knowledge</p> <ul style="list-style-type: none"> • Uses clinical devices appropriately • Works to guidelines appropriately • Applies protocols appropriately

Source: Armitage 2009⁷

We also engineer our day and the time we allocate to each task. In medicines management standard operating procedures (SOPs) are used extensively. These are another example of engineering in our workplace. It is not uncommon to find very detailed SOPs covering every decision and every possible contingency. SOPs are of very limited use when solving a novel problem but are essential when you need to work like a robot doing the same task in the 'one best way'. However, human beings are ingenious creatures who quickly learn how to reduce the burden of restrictive SOPs and work to 'practised operating procedures' (POPs). When the pressure is on humans tend to work to 'trimmed operating procedures' (TOPs), which are SOPs with all the avoidable bits omitted. Indeed, one method of assessing the effect of human factors is to ask staff to describe all the work-arounds they have put in place to make the SOPs work for them.

Putting human factors into every day practice

A helpful skill set – medication safety skills - has been defined based upon a human factors approach pioneered by the aviation industry called Crew Resource Management.⁶ (See Figure 10.4) By fostering this wider set of skills, building these skills in tandem with the technical skills we need to deliver clinical care we can embed human factors in everyday practice.

Human factors and safety culture

Culture and measurement

Surrounding the four principles of the human factors wheel are culture and measurement. There are numerous definitions of a safety culture, and this is probably because culture is very difficult to define. The Health Foundation says that culture concerns the values, beliefs and assumptions that staff infer through story, myth and socialisation, and the behaviours they observe that promote success.⁷

A reasonable way of thinking of culture is to say that it is manifest in the behaviours that are accepted by the people working in the organisation.

Behaviours that might make for a strong safety culture are:

- **Risk management** Being risk aware and trying to reduce risks in every decision leads to safer care. This has been described as a preoccupation with safety
- **Showing compassion** Worrying about the effect of decisions on patients and their loved ones
- **Listening** To enhance the patient experience and as the basis of good teamwork
- **Learning** Making use of experience to improve care
- **Being honest** Being open about when things go wrong and why they went wrong
- **Holistic approach** Trying to understand the patient holistically
- **Being assertive** Contributing opinion improves the quality of decision making and can provide a situational awareness check for others

There is significant overlap between these behaviours and the six Cs described by the Royal College of Nursing⁸ (see The Six Cs to the right).

The Six Cs

Care Delivering high quality care is what we do. People receiving care expect it to be right for them consistently throughout every stage of their life

Compassion Compassion is how care is given, through relationships based on empathy, kindness, respect and dignity

Competence Competence means we have the knowledge and skills to do the job and the capability to deliver the highest standards of care based on research and evidence

Communication Good communication involves better listening and shared decision making – “no decision about me without me”

Courage Courage enables us to do the right thing for the people we care for, be bold when we have good ideas, and to speak up when things are wrong.

Commitment Commitment will make our vision for the person receiving care, our professions and our teams happen. We commit to take action to achieve this

Source: RCN Nursing care essentials for reflection and practice. London.⁸

One approach to building a safety culture is to remove the barriers to the delivery safe care and to create the right environment and processes that enable people to deliver care to the best of their ability. Such barriers and enablers are the human factors described earlier. Not all barriers and enablers are of equal merit. Barriers and enablers have been classified into stronger, moderately strong and weaker categories depending on how well-aligned they are to the evidence base for their effectiveness (see Barriers and enablers below).⁹ Of particular note here is the weakness of double checks. Armitage provides some insight into why this might be the case; double checks represent a combination of submission to authority, reduced perception of rare events, seeing what is in the ‘mind’s eye’ rather than what is actually there and trust in the competence of co-workers.⁶

Barriers and enablers

Stronger

- Architectural/physical plant or equipment changes
- New device with usability testing before purchasing
- Engineering controls (interlock/forcing function)
- Simplify the process and remove unnecessary steps
- Standardise equipment or processes or care plans
- Tangible involvement and action by leadership in support of patient safety

Moderately strong

- Increase in staffing/decrease in workload
- Software enhancements/modifications
- Eliminate/reduce distractions
- Checklist/cognitive aid
- Eliminate look and sound-a-likes
- Enhanced documentation
- Enhanced communication

Weaker

- Double checks
- Warnings and labels
- New procedure/policy/training
- Additional study/analysis
- Disciplinary action

Adapted from Lee 2004⁹

healthcare settings.¹¹ Some organisations may prefer tools which are more easily administered such as the *Team Climate and Patient Safety Assessment*.¹² Measuring safety culture is beneficial when it forms the basis of dialogue across the organisation and generates improvement activity. Alternative sources of information about the safety culture can be found in the NHS Staff survey which has a section dedicated to the management of patient safety incidents.

Best practice recommendations

Medicines Safety Officers can protect patients from harm by:

1. Influencing the drugs purchasing policy to favour safer packaging
2. Focusing on human factors when creating risk management plans
3. Drawing out the human factors that contribute to medicines safety incidents
4. Implementing stronger barriers and enablers to prevent harm
5. Using a range of measurement tools to understand the safety of medicines in your organisation

Charles Vincent has worked with The Health Foundation (www.health.org.uk) to produce a framework for measuring patient safety which includes measures of culture, risk assessment, audit, case note review, patient safety walk-arounds and the monitoring of patient safety incidents and complaints.¹⁰ The framework provides a comprehensive approach to measuring patient safety which has relevance to the oversight of medicines safety that Medicines Safety Officers might require.

There are a variety of tools available to measure the safety culture of an organisation. The *Manchester Patient Safety Framework* is an evidence-based tool which has been tested in most

Human factors and safety culture

Additional resources

Design for patient safety: a guide to the labelling and packaging of injectable medicines

<http://www.nrls.npsa.nhs.uk/resources/collections/design-for-patient-safety/?entryid45=59831>

Yellow Card Scheme

[https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/Yorkshire Contributory Factors Framework and Checklist](https://yellowcard.mhra.gov.uk/the-yellow-card-scheme/Yorkshire%20Contributory%20Factors%20Framework%20and%20Checklist)

Human Factors in Patient Safety Course Handbook

http://patientsafety.health.org.uk/sites/default/files/resources/human_factors_in_healthcare_course_handbook_en_march_2013.pdf

Bradford University – Post Graduate Certificate in Patient Safety.

<http://www.brad.ac.uk/study/courses/view/?c=patient-safety-pg-cert>

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