

Editorial

Medication handling: towards a practical, human-centred approach

S. D. Marshall¹ and N. Chrimes²

1 Senior Research Fellow, Department of Anaesthesia and Peri-operative Medicine, Monash University and Consultant Anaesthetist, Peninsula Health, Melbourne, Vic., Australia

2 Consultant Anaesthetist, Monash Health, Melbourne, Vic., Australia

Correspondence to: S. D. Marshall

Email: stuart.marshall@monash.edu

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Twitter: @Hypoxicchicken; @NicholasChrimes

It has been estimated that, on average, a serious mistake in medication administration occurs once in every 133 anaesthetic medications [1]. Anaesthetic medications often have a narrow therapeutic window, raising the potential for adverse outcomes including harmful physiological disturbances, awareness, anaphylaxis and even death. In this editorial, we will examine the causes of the medication-handling problem and discuss solutions that address the human factors considerations.

'Take more care'

A number of factors contribute to the risk of the incorrect intravenous (i.v.) medication or an inappropriate dose being administered during the peri-operative period. These include active factors such as distraction and time-pressure as well as passive factors such as the way medications are stored and presented. Anaesthesia is particularly problematic because so many injectable medications are stored in the same place and administered, often in rapid succession, during the course of an episode of care. The recent sixth National Audit Project of the Royal College of Anaesthetists (NAP6) demonstrated that a median of eight injectable medications are given per anaesthetic [2].

Arguably the commonest cause of medication-related adverse events is drug misidentification resulting in the wrong medication being in the syringe [3]. The most obvious strategy for addressing this is to make the packaging of different medications as distinct as

possible from one another. A less intuitive but often touted alternative approach is to do the exact opposite: make the packaging of all drugs so similar that great effort must be expended to ensure the correct medication is being given [4]. Proponents of this latter approach contend that providing distinctive packaging encourages clinicians to become reliant on these cues to identify medications, rather than concentrating on reading the label – and that this complacency may actually promote misidentifications. Their rationale is that by making all medication packaging as close as possible to identical, the clinician is instead compelled to perform the task required of them: vigilant checking of the medication label. Taken to its ultimate conclusion, this reasoning would also remove cues related to position in the storage drawer, thus advocating placing all of these identical medications into a single receptacle – a 'bucket of drugs', which could only be distinguished by reading the details on the label.

At first glance, this seems a ridiculous idea but has some basis in fact. Individuals modify their behaviour in the face of perceived risk, by, for example, driving more recklessly when wearing a seatbelt, offsetting some of the expected survival benefits of the intervention [5]. As a result, the anticipated impact of safety interventions is almost never fully realised. By increasing the perceived risk (or consequences) of committing a mistake, 'risk compensation' could counterintuitively result in improved outcomes.

There are of course many self-evident reasons why this extreme 'bucket of drugs' approach is impractical in an operating theatre environment. Apart from the challenges it would pose for ensuring availability and checking the expiry of stock, anaesthetic medications are not infrequently administered in time-pressured situations. A delay in finding a single adrenaline vial somewhere within a haystack of other medications could seriously compromise patient care. Within the conventional layout of an anaesthetic drug trolley, however, is there merit in the concept of making all medication packaging identical?

Apart from the logistic challenges of agreeing on an international standard for uniform medication packaging that manufacturers would likely oppose for commercial reasons, there are some practical challenges involved in obtaining a completely homogeneous appearance of all medications, which is essential to make this strategy viable. Ampoule size must inevitably vary as i.v. medications come in different volumes of fluid, determined by pharmaceutical considerations and the drive to provide drugs in clinically appropriate concentrations. Some medications require protection from ultraviolet light and therefore brown or tinted glass is used in their presentation. Some medications such as propofol or patent blue dye have a distinctive appearance, whereas others must be provided in powdered rather than liquid form. Other medications must be kept in a refrigerator and hence could potentially be distinguished by their temperature.

Consequently, variations in vial design, size, shape, colour and even temperature are inevitable and thus cues to the identity of medications beyond the labelling will always be present. Furthermore, without the completely random arrangement provided by the 'bucket of drugs', the position of a medication within a medication drawer or on a work surface may become familiar, providing an additional cue to its identity. These cues are substantial and often under-recognised [6]. The human brain is excellent at recognising and remembering patterns [7]. In the absence of a truly randomised arrangement and completely identical packaging it is inevitable that such patterns will still be unconsciously sought by clinicians. Thus, deliberately creating mistake-prone conditions to challenge the vigilance and perception of practitioners will fail due to the imperfect nature of the environment and of human perception. Minimising the distinctiveness between medications simply makes it less likely that mistakes in interpreting these residual cues will be detected. Providing only a single cue – that of medication labels – becomes analogous to a sign saying 'be more careful' rather than a barrier to incidents occurring.

Human-centred approach

Even if the 'bucket of drugs' model were able to be practically implemented, its emphasis on reducing patient harm by getting clinicians to simply 'try harder to get it right' represents a failure to appreciate the cognitive processes involved in medication administration. These processes include decision making, the effects of medication design, positioning, size and shape coding and the effects of distraction [8]. The science of human factors tells us that the key to reducing the risk of unintended actions is to 'make it easy to get it right' by applying psychology and decision-making processes to system design and existing workflow [9]. These are the foundations of Human Factors (Ergonomics) Engineering (HFE) as a scientific discipline [10].

One of the pioneers of HFE, Alphonse Chapanis, was the first to recognise how the coding of controls in an aircraft could influence decision making and adverse events [11]. Following instances of damage to aircraft due to the confusion of levers for wing flaps and landing gear, Chapanis redesigned the knobs to feel different to the pilots – a round knob for the wheels and a flat one for the flaps, representing (or 'shape coding') the purpose of the control. This same principle is used on the oxygen knob of Boyle's anaesthetic machines – distinguishing the coarser fluting of the oxygen dial from the other gases [12]. Chapanis recognised that our perception is more than just visual recognition – there are also cues related to position, size and shape coding.

Human factors interventions are intended as supplements to – not substitutes for – clinician vigilance. Most clinicians are conscientious about confirming the correct identity of drugs and providing the safest possible care for their patients. Misidentification problems are not usually the result of complacency but result from a variety of factors affecting attention and perception [13]. These factors may pose an increased risk in situations of stress, time-pressure or fatigue. Human perception is influenced by what people expect to find in a given circumstance, aiming for 'coherence' between conflicting pieces of information and making them vulnerable to a confirmation bias [13]. This is particularly relevant when the information presented is difficult to interpret, as may occur when small text appears on a transparent ampoule. In such situations preconceptions may cause clinicians to misperceive information: mistakes resulting not from a failure to perform a check but a genuine belief that they have seen something other than what was actually there. Two-person checks of medications, a common part of nursing practice, are often

criticised for being ineffective but their efficacy can be influenced by the manner in which the two-person check is conducted. The question 'Can you confirm what this is?' may be much less likely to introduce a preconception leading to confirmation bias than the question 'Can you confirm that this is morphine?'

Preconceptions through position coding are also introduced by the location of drugs in storage areas. This is particularly problematic if shape, size or colour coding is not evident, such as if two different medications have similar packaging (lookalikes) [14]. Lookalike packaging arises particularly when colour and design elements of packaging are used to emphasise the manufacturer's brand rather than distinguish between two different products, predisposing clinicians to mistake one medication for another. Lookalikes represent 'latent conditions' – as yet unrealised disasters waiting to happen [15]. The combination of misplacement of drugs and lookalike packaging is an especially potent precipitant for misidentification of medications. Systemic problems with similar looking medications being sighted in the wrong place, or substituted for other intended medications, are perhaps more common than we recognise by their very nature.

Improving safety

Human factors interventions to reduce the chance of medication-related adverse events can be introduced at the level of the manufacturer, healthcare facility, department or clinician. As with all safety management interventions, systemic changes that produce conditions that prevent unintended actions are preferable to local and individual practitioners inventing unique workarounds. Comprehensive, specific and evidence-based recommendations have been suggested to minimise the risk of drug administration mistakes in anaesthesia. Unfortunately, the lack of adequately powered or well-designed trials has meant that these recommendations are often constructed from opinions or case reports rather than controlled trials [8]. A recent review of medication safety practices identified 78 references that included a total of 138 recommendations. These were diverse and not all were relevant to anaesthetic practice but they can broadly be considered in terms of the actions of regulators and manufacturers, those of the hospital processes and those of the individual [16].

Manufacturers and regulators

The authors are aware of several groups that are lobbying to improve medication safety at the manufacturer and

regulator level. EZDrugID is a global initiative founded to change the medication packaging design to minimise the effects of lookalike medications [17]. It has lobbied manufacturers and regulatory authorities for changes that maximise distinctiveness of different medications and consistency between similar medications. This involves colour coding packaging elements according to the existing internationally standardised system. Although such an approach could also increase the similarity of medications within a class, misidentifications of this type are less likely to lead to patient harm [8].

Other efforts have included the 'Safe Anaesthesia Liaison Group' (SALG) in the UK and more broadly the International Society of Pharmacovigilance (ISoP) special interest group working with industry representatives.

Some jurisdictions have produced formal guidelines on the storage and management of medications but the authors are not aware of any country in which universal mandatory standards exist to prevent manufacturers from producing lookalike medications [18]. Selective programmes are now in place, however, to mandate safe packaging of high risk medications such as neuromuscular blocking agents (NMBAs). The problem of accidental administration of a NMBA to an awake patient can result in serious physical or psychological harm, including death – with over 90% of such incidents being attributed to lookalike packaging [19]. The Therapeutic Goods Administration in Australia has recently introduced mandatory packaging standards for NMBAs that require manufacturers to provide the red colour-coded warning statement 'Warning: Paralysing Agent', for consistency with the existing colour-coding system for medications in place for user-applied adhesive labels and the barrels of dedicated syringes for NMBAs [20].

Although enforcement by regulatory bodies is a mechanism to ensure compliance with standardised packaging and labelling across a range of different manufacturers, it is difficult to achieve. However, in Canada, the Institute for Safe Medication Practices had made much progress through engaging pharmaceutical companies in a voluntary collaborative process to reduce lookalike packaging.

In addition to targeting lookalike medications, the EZDrugID initiative is also calling for drug concentrations to be consistently expressed as weight per unit volume (rather than percentages or ratios seen most commonly with local anaesthetics and adrenaline, respectively) in order to reduce mistakes in dosing. Ratios were removed from all single entity drug labels in the USA in 2016.

Hospitals and departments

At the level of the healthcare facility, medication safety can be improved by encouraging pharmacies to establish processes to liaise with end-users whenever packaging/purchasing changes to identify potential lookalikes and adopt purchasing practices that avoid these.

The storage of drugs can be used to improve medication safety. Infrequently used, high-risk medications can be stored in separate drawers from more routinely administered medications. Neuromuscular blocking agents are frequently stored in a separate container, and commonly refrigerated in between operating lists. The combination of position in a separate box and the feel of the cold medication vial give two important clues as to the nature of the medication. Furthermore, in Australia and New Zealand, red-barrelled 5-ml syringes are now standard for the administration of all NMBAs, again providing size and colour cues to reduce the risk of any mix up. The Australian and New Zealand College of Anaesthetists has recently released a professional standards document that outlines some of these actions that departments can implement including storage and purchasing decisions. This includes a standardised layout of the medication and provision of the international standard colour labels [18].

Individual actions

In spite of potential latent threats in the environment, there are simple actions that individuals can take to improve medication safety. These include instilling early habits in

anaesthetic training around the handling of medications to minimise risks. In the authors' experience, despite these foundations of safe care being written as College guidelines, they are not commonly formally discussed with trainees but are developed slowly from role modelling, observation and discussion at morbidity and mortality meetings. In contrast, we believe that explicitly teaching strategies that maximise the principles of coding on the basis of size, shape, colour and position of both the medication vials and syringes can lead to a safer workspace and reduced chances of medication swaps.

Although many anaesthetists already profess to have their own 'system' of syringe organisation, observation of our colleagues demonstrates that many times syringes are bundled together in a tray in a haphazard way. Attempts to order syringes with colour-coded trays have proven successful in several studies. The system outlined by Almghairbi et al. uses a 'rainbow tray' with colour coding of medications and was found to be a low cost and acceptable solution to cue syringe position and size [21]. More complex systems using barcode readers and prefilled syringes have also been trialled and proven to reduce the incidence of medication-related adverse events in anaesthetic practice but these come with a not-insubstantial financial cost [22, 23].

Any system requires some training and some basic safety rules. There may be some debate about the particulars of the 12 rules given in Box 1, but we believe these describe a safe medication-handling process based

Box 1 Twelve simple rules for anaesthetists to maintain a safe medication administration process (after Jensen et al. and Wahr et al.) [8, 16].

- 1 Only handle one medication at a time.
- 2 Quarantine medication preparation activities. Whenever possible do not allow distraction or answering of questions while preparing medications.
- 3 Check every vial yourself twice, once before drawing up and once after labelling
- 4 All syringes are labelled, ideally with standard colour-coded labels. If medications are injected into an i.v. bag for infusion the bag must be labelled.
- 5 Keep to a standard order and syringe sizing for each medication type (a tray or cognitive prompt helps).
- 6 Do not draw up medications until they are needed.
- 7 Relaxant and reversal are almost never needed at the same phase of the operation and should therefore never be placed on the work surface at the same time.
- 8 Always use a red-barrelled syringe for NMBAs and draw up the whole ampoule into syringe.
- 9 Never reuse a red-barrelled syringe for reversal.
- 10 Medications for emergencies (e.g. adrenaline), given via a route that is not i.v. (e.g. local anaesthetics), or that would be harmful outside of a specific purpose (e.g. oxytocin) are not kept in the same place as i.v. medications.
- 11 All i.v. access points must be flushed or have a running i.v. line before leaving the operating theatre.
- 12 All medication-related adverse events must be reported via an incident reporting system.

on our experience and the published guidelines on the topic.

The complex nature of anaesthesia delivery confirms that the system of medication presentation and preparation will never be free from latent threats. The language of adverse events due to medications is all too often along the lines of 'human error'. There needs to be a paradigm shift in medication safety to frame it as a systems problem, not an individual performance problem. Nevertheless, there are strategies that individuals can use to reduce risk and aid recovery from such events, and it is the anaesthetist's responsibility to make sure these are employed. In addition to system redesign there should be process redesign and early education of junior trainees about these processes. We strongly recommend that medication handling become an explicit, core competence of early clinical training.

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