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### The contribution of labelling to safe medication administration in anaesthetic practice

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The administration of medications is central to anaesthetists' care of patients. Errors are inevitable in any human endeavour, but should be distinguished from violations. The incidence of medication errors in anaesthesia has been estimated as 1 per 13 000 administrations, excluding errors in recording. Adverse medication events follow a proportion of these errors. Labelling is a key element of medication safety. There is a long-standing need for improvements in the labelling of ampoules and vials. An international standard exists for labelling syringes used during anaesthesia (ISO 26825). Australia has recently released national recommendations for labelling lines and injectable medications that complement this and other relevant standards. The provision of at least some medications in pre-filled syringes would reduce the number of steps involved in medication administration, increase the certainty that syringe labels are correct and probably reduce medication errors. Pre-printed, peel-off flag labels on ampoules and vials are a less expensive alternative to pre-filled syringes to facilitate correct labelling. The medication name on user-applied labels should be matched to that on the relevant ampoule or vial at the time of drawing up any medication. All lines and catheters should be labelled. Any medicine or fluid that cannot be identified (e.g., in an unlabelled syringe or other container) should be considered unsafe and discarded. Reducing adverse medication events will require the engagement of individual anaesthetists.

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The process by which medications are procured, stored, deployed, prescribed and administered to patients is complex; hence, it is not surprising that medication errors contribute substantially to most analyses of the overall problem of iatrogenic harm in health care. Labelling of vials, ampoules, syringes, bags and lines is an important part of medication safety. Three recent publications provide guidance to safe labelling practices in anaesthesia:

- In 2008, the International Organization for Standardization (ISO) published ISO 26825:2008(E) – *Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – colours, design and performance*<sup>1</sup> ('ISO Standard'). This draws heavily on AS/NZS 4375:1996 - *User-applied labels for use on syringes containing drugs used during anaesthesia*.<sup>2</sup> This standard is consistent with several other international standards,<sup>3–5</sup> which have now all been superseded by the ISO Standard.<sup>1</sup>
- In 2009, the Australian and New Zealand College of Anaesthetists (ANZCA) published *Guidelines for the safe administration of injectable drugs in anaesthesia*<sup>6</sup> ('ANZCA Guidelines').
- In 2010, the Australian Commission on Safety and Quality in Health Care published *National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines*<sup>7</sup> ('Labelling Recommendations'). The authors contributed to the development of this evidence-based resource, and have drawn on it in preparing the present article.

These publications complement each other. The ANZCA Guidelines deal with the entire process of medication administration in anaesthesia, of which labelling is one part.

The Labelling Recommendations apply to health care in general: many of the points made hold true in anaesthesia, but the intent is for the ISO Standard to apply to the labelling of syringes to be used by anaesthetists in the operating room (OR) and for the Labelling Recommendations to apply for other situations, such as infusions that will be continued after the patient is transferred from the OR. Table 1 outlines the differences and similarities between the two, and highlights the differing clinical situations in which each would apply.

**Table 1**

Brief description of similarities and differences between ISO 26825:2008 and the Labelling Recommendations.

	ISO 26825:2008 (or related standards)	Labelling Recommendations
Clinical situations where labels should be used in anaesthetic practice	On syringes containing medications used during anaesthesia	All other medications and all containers and lines prepared or administered by anaesthetists, including <ul style="list-style-type: none"> <li>• Infusions</li> <li>• Injections for use on the sterile field</li> <li>• Medications in syringes that will accompany patients to other clinical areas</li> <li>• Lines and catheters</li> </ul>
Information required	<ul style="list-style-type: none"> <li>• Pre-printed generic name of medication</li> <li>• Concentration of syringe contents</li> </ul>	Depends on label type. For bags, bottles and syringes label inclusions are as follows: <ul style="list-style-type: none"> <li>• Patient name (given name and family name)</li> <li>• Patient identifier (ID)</li> <li>• Active ingredient/s (medicine/s) added to the bag or syringe</li> <li>• Amount of medicine/s added (including units)</li> <li>• Volume of fluid (mL) - total in bag, or syringe</li> <li>• Concentration (units/mL)</li> <li>• Diluent (for syringes)</li> <li>• Date and time prepared</li> <li>• Prepared by (signature)</li> <li>• Checked by (signature)</li> <li>• Route of administration (where not specified by wording and colour)</li> </ul>
Colour coding and border indicative of	Medication class	Route of administration

## Medication errors in anaesthesia

Making decisions about medications is one of the primary responsibilities of anaesthetists, and a great deal of effort is invested into training them to do this. Nevertheless, pharmacology is a complicated field, and there are many factors to consider, particularly in the perioperative period; hence, it is understandable that mistakes can and do occur.

### *Definitions related to medication error*

The literature contains many definitions of error. The following definitions are based on the cognitive processes involved in the genesis of failures in human performance, and have considerable utility in explaining medical error and providing insights into countermeasures that are, or are not, likely to be effective.

An error is “the unintentional use of a wrong plan to achieve an aim, or failure to carry out a planned action as intended”.<sup>8</sup> In simpler language, “an error is when someone is trying to do the right thing but actually does the wrong thing”.<sup>9</sup> A violation, by contrast, involves the “deliberate – but not necessarily reprehensible – deviation from those practices appreciated by the individual as being required by regulation, or necessary or advisable to achieve an appropriate objective while maintaining safety and the ongoing operation of a device or system”.<sup>8</sup> Thus, violations involve choice, while errors do not. Note that these definitions focus on process and intent, rather than outcome.

On the basis of the above definitions, a medication error can be defined as “any error involving the prescribing, ordering, selection or administration of a medication”. There is no intrinsic difference between the cognitive processes leading to medication errors and those leading to other errors. It would also be possible to define a “medication violation”, but it is probably simpler just to identify relevant violations in a general way.

An adverse medication event (AME) is “any injury related to the use of a medication;”<sup>10</sup> this should include any injury related to the omission of an indicated medication. An AME may or may not follow an error or a violation, and some AMEs are preventable, while others are not.

### *Classification of human error and implications for medication errors*

The Generic Error Modelling System described by Reason distinguishes failures in decision making (mistakes) from failures in the implementation of decisions (action failures).<sup>11</sup> Action failures, often made unconsciously, are typically slips or lapses. More recently, Thaler and Sunstein have presented a view that places less emphasis on the distinction between actions and decisions, and more emphasis on the degree to which the underlying cognitive processes are automatic or conscious.<sup>12</sup> In this view, rule-based errors have much in common with slips and lapses. Wegner has stressed the point that conscious effort to avoid error may, ironically, have the opposite effect.<sup>13</sup> Taken collectively, a key message of this substantial body of research is that simply trying harder to avoid errors is unlikely to be successful on its own: it is also necessary to make processes and systems intrinsically safer.

### *The frequency of medication error in anaesthesia*

The frequency of medication errors is difficult to determine accurately: most estimates are based on incident reporting, and the proportion of errors reported is usually unknown. Furthermore, it seems likely that medication errors often go completely unnoticed, and hence could not be reported even if the commitment to do so was strong. Denominator data are usually not available; therefore, accurate rates cannot be calculated. In the context of anaesthesia, studies using facilitated incident reporting (in which a form is completed for every anaesthetic to indicate whether or not a medication error occurs) suggest that the rate is at least 1 error per 130 anaesthetics.<sup>14,15</sup> However, anaesthetics vary; hence, an anaesthetic is not a constant unit of measure and it may be more appropriate to estimate errors per administration.<sup>15</sup> The same studies suggest that 1 error may occur every 1300 medication administrations.

### *The nature of medication error*

Errors may occur in the administration or recording of administered medications and may involve commission or omission. The objectives of medication administration have been summarised in six 'rights': the right patient, dose, medication, time and route of administration,<sup>16</sup> and the right (or accurate and comprehensive) record of the medications administered or wasted.<sup>17</sup> Thus, errors may include giving the wrong medication, repeating administration of the right medication inadvertently, giving the wrong dose of medication, giving a medication by the wrong route, or giving a medication at the wrong time, forgetting to give an indicated medication or failing to record accurately and legibly the medications that have been administered.

### *Factors predisposing to medication error in anaesthesia*

It is relatively easy to prescribe and administer a single medication correctly, once. Anaesthetists typically administer several hundred thousand doses of medications over the course of a career, and doing this without any errors is obviously more challenging. Anaesthetists prescribe, prepare, administer and record these medications on their own, without the benefit of the safeguards and double checks provided by pharmacists and nurses that are typical in other fields of medicine. Anaesthetists often need to administer medications under pressure of time, often after working very long hours and often in settings characterised by distractions. Manufacturers often label ampoules poorly, and it is quite common for labels applied by users to syringes to be poorly designed or unavailable. Therefore, it is not surprising that medication errors occur in anaesthetic practice, and that inadequate labelling has often been identified as contributing to these errors.<sup>14,18–20</sup>

The opportunities for medication errors associated with adult anaesthesia also pertain to children,<sup>21–23</sup> but there are additional challenges in paediatric anaesthesia.<sup>17</sup> In particular, many medications are sold only in adult formulations, and thus dilution is regularly required, with its concomitant risk of errors in calculation and/or labelling.

### *The consequences of medication error*

There is no reliable way of knowing how often harm follows medication errors, but it is clear that the opportunity for harm is substantial, including serious or catastrophic harm.<sup>24</sup> Many of the ways in which errors of commission can produce undesirable effects are obvious, but the importance of errors of omission may be less so: awareness during anaesthesia<sup>19</sup> and nosocomial infection (associated with failure to administer timely prophylactic antibiotics)<sup>25</sup> are two examples of harm often attributable to medication errors of omission. Another form of harm, perhaps also under-recognised, relates to the potential to introduce infective organisms or glass into patients' circulation.<sup>26–28</sup> Children may be at greater risk from the consequences of medication errors than adults.<sup>29,30</sup>

### *The concept of just culture*

There has been a vogue in recent years for a blame-free culture in which the emphasis is on the system rather than the individual. However, the legitimacy of such an approach might depend on the nature of the failure one is trying to address. It seems reasonable that, if a practitioner is conscientiously engaged in practising safely, an emphasis on blame will be misplaced. On the other hand, if a practitioner chooses to ignore widely accepted safety practices (such as labelling syringes), then blame may be appropriate. In a just culture, the question becomes one of differentiating blameworthy behaviour from blameless behaviour.<sup>31</sup>

The definitions of error and violation given earlier provide some insight into the culpability of various failures in human endeavours. In general, errors are seldom blameworthy, whereas violations may often be. Further, errors are unlikely to be prevented simply on the basis of greater care alone, or by the threat of draconian punishment,<sup>31</sup> whereas violations may well be prevented on such a basis. An important point is that violations often predispose to error.

It is not always straightforward to differentiate between those violations that are clearly blame-worthy and those that are more understandable, and perhaps more a reflection of the difficulties of working under pressure in a complex and imperfect environment than of any disregard for patient safety.<sup>31</sup> There is also the question of where any culpability should lie: the legibility of many ampoules is notoriously poor – yet manufacturers and regulatory agents continue to promulgate this clearly undesirable situation with apparent impunity. Similarly, hospitals sometimes fail to provide adequate supplies of suitable labels for syringes, and to ensure that these supplies are reliably replenished, but it is rare for anyone to be held accountable for failures of this type.

## Labelling and medication errors in anaesthesia

### *Labelling in context*

There are many steps involved in drawing up a medication and administering it intravenously to a patient,<sup>32</sup> and even more in the overall process of medication administration, beginning with manufacture and ending with appropriate disposal of empty ampoules. Factors associated with the presentation, procurement and overall management of medications, together with fatigue, distractions and other pressures on anaesthetists all contribute to medication errors. In making labelling the central subject of this article, we would not wish to detract from the message that approaches to improving medication safety should be multifaceted.<sup>15,33,34</sup>

### *The importance of user-applied labelling*

There is considerable evidence to support the view that, whatever other factors might also matter, user-applied labelling is very important for medication safety and that poor labelling practices can result in patient harm. In the Australian Incident Monitoring Study (AIMS), problems with user-applied labelling were an important contributory factor to medication errors during anaesthesia.<sup>18,19,35</sup> In this study, over half the reported errors with intravenous syringes occurred after the syringes had been labelled.<sup>35</sup> This finding illustrates that it is very easy to misread labels, or not to read them at all.

Individual case reports illustrating failures in medication administration related to labelling are published regularly. For example, the accidental administration of syntometrine instead of pethidine from an unlabelled syringe had a fatal outcome for the unborn child of a woman in labour.<sup>36</sup> In another example, an anaesthetist administered a medication he believed to be the sedative midazolam, to relieve a patient's anxiety while she awaited an operation. He did not read the label, and accidentally administered a muscle relaxant instead. The patient became paralysed while fully awake, and although the problem was recognised and the risk of death averted, she suffered long-term psychological trauma as a consequence. A complaint was upheld.<sup>9</sup> Unpublished and anecdotal data also abound that illustrate numerous variations on the theme of errors where failure to label, or correctly label, bags, syringes and lines have been a contributory factor.<sup>7</sup>

## What should be labelled?

In general, all containers of medications (including syringes, bags, bottles and bowls) should be labelled. In particular, it is essential that all medications removed from their original manufacturer's packaging are clearly identifiable.

In addition, all lines and catheters by which medication can be administered should be clearly identifiable. Administration of medications by the wrong route can be particularly dangerous, and the consequences are sometimes fatal.<sup>37</sup>

We suggest the safest approach is to label all lines and catheters (except urinary catheters, assuming that their nature is obvious) in accordance with Table 2 (and see Fig. 1).

There is evidence that medicines in well-labelled syringes are more likely to have been prepared correctly than those in poorly labelled syringes.<sup>38</sup> Further, acceptance of any unlabelled syringes may lead to dangerous assumptions: for example, medicines given with the assumption they were normal saline include aminophylline,<sup>39</sup> midazolam<sup>40</sup> and vecuronium.<sup>41</sup> A fundamental tenant of safe practice

**Table 2**

Colour coding of user-applied labels for target tissue (modified from AS4940:2002).<sup>63</sup> Reproduced with permission from: National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines, Australian Commission on Safety and Quality in Health Care 2010.

Target tissue	Route of administration	Colour	Pantone Matching System
Intra-arterial	Intra-arterial	Red	1787
Intravenous	Intravenous	Blue	2985
Neural tissue	Epidural/Intrathecal/Regional	Yellow	Pantone Yellow
Subcutaneous tissue	Subcutaneous	Beige	723
Miscellaneous	Other routes	Pink	806

mandates considering as unsafe, and therefore discarding, any medicine or fluid that cannot be identified.<sup>7</sup> Thus, the safest approach is to label all syringes and other containers of medications. This makes sense from a systems standpoint, encourages good routine and promotes standardisation between institutions.

The Labelling Recommendations indicate that it may be permissible not to label a syringe if it does not leave the hands of the person preparing it and that person administers the medication immediately. In anaesthesia, there may well be situations where there is time pressure to draw up a particular medication and administer it in response to a developing need (e.g., atropine for a sinus bradycardia). Many anaesthetists might therefore welcome this exception, and might even argue that undue insistence on labelling could reduce safety by increasing the time taken to administer a medication needed in an emergency.

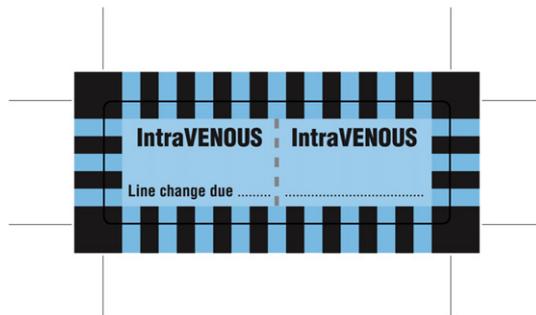
However, one disadvantage of this practice is illustrated by the case described in [Box 1](#), and we suggest that genuine need to omit labelling is rare.

## What should be included on medication labels?

### *Manufacturer's labelling of ampoules and vials*

Manufacturers have a responsibility to label products clearly, without ambiguity. They have the luxury of defined processes, repetition and quality control procedures in which the sole aim is to provide a sterile product, produced within specification, and correctly labelled. The contents of the labels are determined by various regulations, the details of which differ from country to country.

Unfortunately, most of these regulations concentrate on information required for quality control of medication manufacture and distribution rather than on legibility, ease of identification and avoidance of look-alike labels. There are no consistent approaches to colour coding, container size, background, or font size and type and the use of look-alike sound-alike names and poorly legible labels developed by



**Fig. 1.** Example of a label for intravenous lines. Reproduced with permission from: National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines, Australian Commission on Safety and Quality in Health Care 2010.

**Box 1 Labelling does matter**

An anaesthesia trainee, working under supervision, decided to administer magnesium to treat a patient's elevated blood pressure during a prolonged but otherwise stable anaesthetic. He drew up and administered what he believed to be magnesium, in one uninterrupted process, without labelling the syringe, and without the syringe leaving his hands. Unfortunately, on account of an appearance very similar to that of magnesium ampoules, he inadvertently selected an ampoule containing 200 mg of dopamine and administered the contents of that as a single bolus. Because the patient was being monitored with an arterial line the mistake was identified promptly and active steps taken (successfully) to treat the episode of extreme hypertension that followed this injection, so the patient suffered no long-term consequences from this error. Labelling the syringe would have placed an extra defence into the process, particularly if an attempt had been made to match the name on the ampoule against the name on the applied label, as outlined in the text.

manufacturers has been cited as contributory factors in many reports of medication errors.<sup>42–44</sup> A coordinated international initiative to ensure clear and consistent presentation of the generic name of each medication, including the class to which it belongs and of its quantity and concentration in each container is long overdue.

In the United States, the Food and Drug Administration (FDA) has mandated the inclusion of barcodes at unit dose level on all medications.<sup>45</sup> As the use of barcodes in this way increases internationally, so does the potential for incorporating technology into checking the medications used in anaesthesia. Two products that have provided barcode-based anaesthetic record keeping and medication checking are the Safer Sleep™ System (Safer Sleep, LLC, Nashville, TN, USA),<sup>15,34</sup> and the DocuSys™ System (DocuSys, Inc, Mobile, AL, USA). Radio-frequency identification devices (RFIDs) offer more sophisticated possibilities, but are still much more expensive than barcodes.

*User-applied labelling: standards and recommendations*

A number of standards and recommendations exist internationally to provide a systematic approach to user-applied labelling.<sup>1,6,7,40,46–53</sup> Recommendations have also been included in several publications from individual researchers.<sup>54,55</sup> Not surprisingly, the courts generally expect labels to be applied and accurately read when medications are administered.<sup>24</sup>

*User-applied labelling: content*

Critical information for anaesthetic practice includes recording the medication name and concentration of prepared medication.

The name of any medication is always important. We advocate standardising practice to using only generic names.

The ISO Standard allows space on the label for medication concentration to be noted. There is no required format for expressing concentration.<sup>1</sup> The Australian Labelling Recommendations recommend recording the total amount of active ingredient in the container (e.g., in mg) plus the total volume of diluent (e.g., in ml) as well as the resultant concentration (e.g., in mg ml<sup>-1</sup>; Fig. 2(a)). This facilitates subsequent checking, particularly in transfer of care. Expressing concentrations as ratios (e.g., 1:1000, 1:10 000) increases the risk of error, and should be avoided at all times.<sup>55</sup>

The design details of medication labels can influence the likelihood of error.<sup>56</sup> Tallman lettering may be helpful.<sup>56</sup> It may be worth considering including the class name on pre-printed ISO Standard labels as well as the specific name of each medication.<sup>34</sup> This exceeds the requirements of the ISO Standard, but seems to create little if any risk, and is based on the concept that people tend to recognise word pictures more by their appearance rather than by the actual names. It may also be worth considering incorporating barcodes into user-applied pre-printed ISO Standard labels.<sup>34</sup> These can then be used for checking and recording the names of medications at the time they are administered. Technology of this

**a**

**For IntraVENOUS Use Only**

Patient .....

ID .....

Medicine/s	Amount (units)	÷	Volume (mL)	=	Conc (units/mL)
.....	.....		.....		.....
.....	.....		.....		.....
.....	.....		.....		.....

Diluent .....

Date ..... Prepared by .....

Time ..... Checked by .....

**b**

**Fentanyl**

µg/ml

**Fig. 2.** Examples of labels (a) for syringes of medications in general and bags for infusion where medicine is added, and (b) for syringes of medications to be used by anaesthetists during anaesthesia (see text). Fig. 2 (a) Reproduced with permission from: National Recommendations for User-applied Labelling of Injectable Medicines, Fluids and Lines, Australian Commission on Safety and Quality in Health Care 2010.

sort may be more practical and more acceptable than insisting on a two-person check during every administration of a medication during anaesthesia.<sup>57</sup>

#### *User-applied labelling: infusions*

Medications may be administered by infusion from bags or syringes. As indicated, even labelling a syringe for the bolus administration of intravenous medications takes many discrete steps, but preparation of medicines for infusion is often more complicated and may take much longer.<sup>58</sup>

Infusions tend to be used over time; they often involve diluting the medication to be infused; the rate of infusion may change frequently; and it is common for infusions to accompany patients from one area of care (e.g., an OR) to another (e.g., a PACU, ward or ICR),<sup>59</sup> setting the scene for problems related to inadequate labelling of injectable medications to follow.<sup>59,60</sup> A label that may be sufficient for the needs of the anaesthetist, who has started an infusion may be inadequate for a nurse on a ward, who has no other source of information about that infusion.

When syringes are used for infusions, it can be difficult to avoid obscuring labels by parts of the infusion pumps themselves. It may be a good idea to use a supplementary label on the surface of the pump, but this should be as an adjunct and does not replace the requirement to ensure the syringe itself is labelled, to avoid potential confusion if it is changed or moved to another pump.

Technology built into many infusion pumps now facilitates the calculation of infusion rates on the basis of patients' weights or body masses, from standard amounts of medication and diluent, but the details vary from pump to pump and not all pumps provide this capability. Devices delivering amounts of medication based on algorithms which predict target site concentration on the basis of pharmacokinetic (PK) and pharmacodynamic (PD) data make the landscape even more complex. These considerations call for discipline and attention to detail in the labelling of infusions.

On first principles, standardising the approach used in labelling infusions, at least within any particular institution, is probably more important than the exact approach chosen. A labelling system has been designed that facilitates a considerable degree of standardisation with several commonly used vasoactive agents. The labels facilitate the calculation of the volumes needed to dilute whole

ampoules of various medications to provide standardised rates of infusion (in  $\text{ml h}^{-1}$ ) for appropriate weight-based rates of dose administration (e.g., in  $\mu\text{g kg}^{-1} \text{min}^{-1}$ ).<sup>61</sup> Using this approach, staff can rely on the assumption that  $1 \text{ ml h}^{-1}$  of dopamine (for example) will deliver  $1 \mu\text{g kg}^{-1} \text{min}^{-1}$  of this medication to any adult patient, and that  $1 \text{ ml h}^{-1}$  of noradrenaline will deliver  $0.01 \mu\text{g kg}^{-1} \text{min}^{-1}$ . It is also the case that  $5 \text{ ml h}^{-1}$  will provide a reasonable starting rate for any of the medications incorporated within the system. There is some evidence that these labels can reduce errors with medication infusions.<sup>61</sup>

## Ensuring the correct user-applied label

### Standard procedure

There is little evidence to support or refute any particular suggestion on how to ensure that syringes (and other containers) are correctly labelled. The following steps are consistent with the Labelling Recommendations<sup>7</sup> and ANZCA's guidelines<sup>6</sup>:

- (1) The process of drawing up a medication and filling in or checking the user-applied label on the syringe (or other container) should be done one medication at a time.
- (2) The label on the medication ampoule must be read, checking, in particular, the name and the amount of the medication.
- (3) The name on the ampoule should then be matched to the name on the user-applied label. Matching in this way is not the same thing as reading the label. It involves finding the same word on both the ampoule and the user-applied label, which will usually be the generic name of the medication. To do this implies introducing a break in the sequence of drawing up, labelling and administering a medication, which may otherwise become so automatic that errors are missed.

Pre-printed ISO standard labels are typically presented to anaesthetists in rolls, using dispensers. This is convenient and economical, but a large number of dispensers may be required, effort is needed to ensure that rolls are replaced when finished and the dispensers may be difficult to keep clean, and hence could act as fomites. An alternative approach has been described in which labels are supplied in sheets (Fig. 3).<sup>34</sup> These are for single use, and therefore are less likely to have missing labels or carry infectious agents. They can be customised to services or individuals, such that any one sheet contains all the labels likely to be needed in any one anaesthetic. Further, they can serve as prompts, allowing anaesthetists to review medications typically used in his or her practice and to see (by the absence of the relevant labels) which medications have, and have not, been given.

### Flag labels

A method of labelling ampoules designed to facilitate the correct labelling of syringes has been described.<sup>34</sup> This method involves peel-off labels that are provided on ampoules that allow anaesthetists to transfer both the contents of the ampoule and the peel-off label to the syringe (or other container) at the same time. Ideally, the peel-off labels supplement the information on the ampoule labels, so that the ampoules can still be identified after the peel-off labels have been removed. Reading labels and matching the names of the medication between the ampoule and the peel-off label (after it has been applied to the syringe) should still be done. If only one syringe and one ampoule are handled at any one time, this approach would seem to be very reliable. It has the additional advantage of ensuring that appropriate user-applied labels are always available.

### Pre-filled syringes

On first principles, presenting medications in pre-filled syringes rather than in ampoules removes many of the steps involved in transferring a medication from an ampoule to a syringe and putting a correct label on the syringe.<sup>34</sup> This seems to be the most certain way to ensure correct labelling of



DISCARD AFTER SINGLE PATIENT USE!

**Fig. 3.** A page of labels for use on syringes of medications used by anaesthetists during anaesthesia. These are laid out as a cognitive aid for promoting recall of relevant medications (e.g., antibiotics), and incorporating barcodes.<sup>34</sup> Reproduced with permission from Safer Sleep LLC.

syringes. Such syringes should be prepared in batches, using standardised processes and recognised manufacturing controls and the manufacturer (whether a commercial entity or a hospital pharmacy) should take responsibility for the correctness of labelling and presentation in the same way as currently pertains to ampoules.

Pre-filled syringes could complement technological solutions designed to facilitate checking (e.g., through the use of barcodes).<sup>34</sup>

One advantage of pre-filled syringes lies in the quality control associated with their preparation, given recent evidence that the concentrations of medicines in user-filled syringes may be very inaccurate.<sup>38</sup>

There is additional cost in the use of pre-filled syringes, but if manufacturers could be persuaded to present medications in this way rather than in ampoules, the cost may be reduced considerably. A logical compromise is to use pre-filled syringes for a selection of medications, and flag labels or a mixture of flag labels and conventional user-applied labels for the remainder.

The Labelling Recommendations endorse the view that pre-filled syringes should be used wherever possible,<sup>7</sup> as does ANZCA.<sup>6</sup> As always, labels should still be carefully read, and other aspects of medication safety still apply.<sup>33</sup>

### **Colour coding**

The value or otherwise of using colour coding to promote medication safety has not been settled. The concept of error management rather than error prevention suggests that it may be beneficial to change the nature of medication errors even if the actual number of errors is not reduced. Colour coding of user-applied ampoules by class of medication<sup>1</sup> may reduce the risk of between-class errors, possibly at the cost of more within-class errors, and, in general, it seems that the former are likely to be more dangerous than the latter.

Colour coding of lines and catheters according to route, on the basis of target tissue, may be helpful in avoiding wrong route errors.<sup>7</sup> The consequences of wrong route errors are potentially very serious, and every precaution to reduce this risk is appropriate. However, there may be some potential for confusion if two different systems of colour coding are used simultaneously (one for route and one for class of medication). This did not seem to be a problem when the Labelling Recommendations were trialled in anaesthetic practice, since the system of colour-coding by class of medication was restricted to syringes used by anaesthetists during anaesthesia.

Colour can be used to good effect but it should only be a supplement to text, and the primary mode of checking should always be the careful reading of every label.<sup>1,7</sup>

### **Labelling in sterile fields**

There have been a number of tragic errors involving medications placed into unlabelled bowls or other containers within a sterile field, and then drawn up from these containers for subsequent administration.<sup>52,62</sup> It probably better to avoid the use of such containers altogether if possible, but if they are used they must be labelled –which obviously also implies that suitable sterile labels must be made available.<sup>7</sup>

### **Other considerations in reducing medication administration error**

#### *Governance*

Any serious attempt to improve medication safety requires a formalised governance process of decision making and an effective operational process of implementing these decisions, educating staff members, promoting safe practices and monitoring all aspects of the system.

Many institutions do have medication safety committees. Departments of anaesthesia need to be represented on these committees, but they need their own medication safety committees (or some equivalent) as well, because the challenges of medication administration in anaesthesia are different, in many key ways, from those that pertain in general.

One recommendation that seems very likely to make a difference is that of appointing a pharmacist (at least part-time) dedicated to the OR and the anaesthesia service.<sup>34</sup> This pharmacist should liaise with anaesthetists over all aspects of purchasing choices, inventory management, presentation of medications and other practical elements of medication safety.

### *Culture*

Medication safety depends on the engagement of individual practitioners, and effective engagement is more likely in a culture that places a high priority on patient safety and shows a low tolerance of poor practices in this regard. Achieving such a culture is not easy. It goes without saying that there is a particular onus on those in influence, notably heads of departments, to promote behaviours consistent with medication safety. It may be more difficult to achieve a safety culture in the absence of appropriate leadership. However, whether such leadership is present or not, culture is arguably just the sum of the attitudes of the individuals within a particular group, and attitudes are best demonstrated and measured through behaviour.<sup>9</sup> We suggest, therefore, that responsibility for generating a safety culture lies with every individual anaesthetist.

### *Incident reporting*

Feedback is widely recognised as important in improving performance. In the context of medication safety, an active system of anonymous incident reporting is an excellent way of providing such feedback. Incidents should be regularly reviewed in departmental meetings. The emphasis should be on the prevention of the recurrence of adverse events, and on managing such events when they do occur. The inclusion of positive incidents as well as negative ones is worth considering – stories are a powerful way of changing behaviour and accounts of things done well may be surprisingly inspirational.

To summarise, medication safety is of central importance to the practice of anaesthesia. AMEs associated with failures in medication administration (attributable to errors and/or violations) continue to occur. A focus on patient safety through the management of medication errors is more likely to be effective than an undue emphasis on simply reducing errors. The appropriate labelling of medications, whether by manufacturers or users, is critical to medication safety. Labels on ampoules and vials continue to contribute to medication administration errors and improvements are needed. User-applied labelling of syringes, other medication containers and lines and catheters, is central to safe medication practice. Recently published recommendations and standards are an important advance in guiding best practice in this respect. Pre-filled syringes and flag labels would facilitate appropriate labelling. All lines and catheters and all syringes and other medication containers should be labelled, and the name of the medication on the user-applied label should be matched to that on the ampoule or vial. Amongst other issues, research should address factors influencing the engagement of anaesthetists in safe medication practices, and the value of colour coding in reducing AMEs. Advances

#### **Practice points**

- The proper use of appropriate labels is a key part of safe medication management.
- All medications removed from their original packaging must be identifiable.
- This implies that any syringe (or other container) that contains a medication and leaves the hands of the person drawing up that medication must be labelled.
- Medications must be drawn into syringes (or placed in other containers), and the user-applied label of that syringe (or other container) checked, one medication and syringe at a time.
- Checking the labels of syringes (or other containers) should include the step of matching the medication name on the label with that on the ampoule or vial.
- Any medicine or fluid that cannot be identified (e.g., in an unlabelled syringe or other container) should be considered unsafe and discarded.

### Research agenda

- At present, the most elusive aspect of medication prescribing and administration in anaesthesia is probably an understanding of the factors that influence anaesthetists' willingness to adopt safe practices.
- The benefit, or otherwise, of colour coding by class of medication needs to be definitively elucidated.
- More data are needed on technological and systems-based initiatives to improve medication safety.

in medication safety will require the engagement of the individual anaesthetists who actually administer medications as a central part of their everyday work.

### Conflict of interest

AM has financial interests in Safer Sleep LLC, which promotes one of the two barcode-based systems described in the article, and has led several of the studies cited here, some of which report and evaluate features incorporated into the Safer Sleep system.

AM, DS and JL were all involved in the development of the Labelling Recommendations. AM also made a contribution to the development of the ANZCA Guidelines on the safe administration of medications in anaesthesia.

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