Perioperative quality of care and patient safety

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Chapter 12

Reducing medication error
A standardised user-applied drug label for high-risk anaesthetic drugs

*It is the duty of government to make it difficult for people to do wrong, easy to do right.*

*William E. Gladstone (1809-1898) British Prime minister*

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Anaesthetic drug error is a recognised source of patient harm. Administration of the wrong drug, the wrong dose, the wrong route, the wrong time, forgetting to give indicated drugs or inaccurate, illegible or failed recording of administered drugs are all examples of anaesthetic drug error.1 A recent study showed that medication errors in anaesthesia are as common as 1 in every 20 drug administrations.2 This study also showed that 79% of these errors were preventable.2 Labelling error was found to be the most common type of error (24.2%).2 Another study showed that in about 20% of cases the wrong drug was administered despite a correctly labelled syringe.3 Although most of these drug errors are likely to be caused by slips and lapses, the underlying “system design” might facilitate human error to occur. Standardisation is a way to eliminate unnecessary complexity of care processes in order to reduce the likelihood of human error and hereby increase patient safety. Back in 1993, the Australian Incident Monitoring Study (AIMS)3 suggested to introduce a standardised colour code for anaesthetic drug syringe labels to improve recognition of the right drug. Since the early nineties Australia, New Zealand, the United States and Canada are leading the way with a standardised specification with colour codes for anaesthetic drug labelling. In 2008 the ISO standard ISO 26825:2008(E) – Anaesthetic and respiratory equipment – User-applied labels for syringes containing drugs used during anaesthesia – colours, design and performance4 was published in order to extend this standardised anaesthetic practice globally. Unfortunately, there are still many countries, like the Netherlands, that do not have a standardised labelling system for anaesthetic drugs. In 2013 a survey was performed amongst several Dutch anaesthetic departments to assess the type of medication labels that were used in these departments.5 Fifty-five out of 97 (55%) departments responded. Figure 12.1 is a summary of all the different medication labels used in these departments, showing much inconsistency in anaesthetic drug labels used in the Netherlands. Thirty-six departments used a colour coded scheme; the ISO standard was used in only 4 of these hospitals. Nineteen departments used a white label with black letter system.
### Figure 12.1 Different colours of anaesthetic drug labels throughout the Netherlands
In an attempt to reduce medication errors, the Dutch Society for Anaesthesiology (NVA) initiated a project for national implementation of a standardised colour coding for anaesthetic drug labelling in 2014. This study describes the design and implementation process of standardised drug labels for anaesthetic drugs in the Netherlands.

**Methods**

Three important aspects were considered to be important for the design of the new labels: 1. the colour coded scheme, 2. the prevention of within-class errors and, 3. a possibility for automation of medication verification, double check and registration. Although colour coding helps to recognise the right drug, it can also give rise to drug error when no standard is used. This is particularly relevant if anaesthesia staff is moving from one anaesthetic department to the next because of training rotas or job opportunities. Coombes et al\(^6\) recognised that the variation in prescribing charts and systems with frequent staff changes gave rise to frequent drug error. By standardising the drug charts nationally, they observed a significant decrease in drug errors. Standardisation, as identified in many other high-risk industries, reduces errors caused by unfamiliarity and facilitates more efficient and effective training for staff moving between sites.\(^6\) For anaesthetic drug labels it is therefore recommended that colour coding should be nationally and according to the ISO standard.\(^1,7\)

It has been suggested that colour coding may reduce the risk of between-class drug errors but might give rise to within-class errors.\(^1\) In order to prevent within-class errors we incorporated the Tall Man Lettering\(^8\) system in our labels. In 2001 the Office of Generic Drugs (OGD) of The US Food and Drug Administration (FDA) initiated the “Name Differentiation Project.” This project set out to differentiate between drugs with look-alike drug names. The Institute for Safe Medication Practices (ISMP) maintains a list of drug names with recommended, bolded tall man (uppercase) letters to help draw attention to the dissimilarities in look-alike drug names. The Tall Man Lettering system can therefore aid in differentiating drugs from the same class and so prevent within class drug errors. In order to differentiate between different concentrations of the same medication, drug concentrations were highlighted in red if different concentrations were used (figure 12.2). Finally, in order to facilitate automation in drug administration and documentation a QR code was added to the label. Bar code-assisted syringe labelling systems help to provide automated medication verification (double check). Timing and dose of drug administration can also be captured accurately within the anaesthesia record with bar code scanning prior to administration. Bar code-assisted administration therefore has the potential to reduce wrong type, dose or route medication errors and documentation errors or omissions. Although more research is needed to establish the impact of bar code-assisted syringe labelling systems on patient
Figure 12.2 Proposed national standard for anaesthetic drug labels (update)
outcome, it has previously been shown to reduce drug errors.\textsuperscript{9-13} Examples of the labels can be found in figure 12.2.

The implementation process has followed the recommendations by the NICE guidelines on implementation.\textsuperscript{14-16} This guideline states that there are six key components to a successful implementation process:

1) board support and clear leadership
2) provision of a dedicated resource
3) support from a multidisciplinary team
4) a systematic approach to financial planning
5) a systematic approach to implementing guidance
6) a process to evaluate uptake and feedback.

These steps were adhered to both on a local level, as on a national level. A working group was initiated by the NVA. Within this group, a project lead and manager were appointed to coordinate the implementation process. Several national multidisciplinary meetings, including anaesthesiologists, intensivist, pharmacists and operating theatre managers were held to discuss the project and to aid dissemination of the labels. In order to augment awareness about this project amongst all anaesthesia departments in the Netherlands, staff was alerted to the project through the NVA mailing list. Furthermore, staff was invited to attend several open meetings and presentations at national conferences about the project. During these meetings staff were presented with sample labels, which they could take to their own hospitals free of charge, and with tools to help implement the labels. Locally, the multidisciplinary team also included a financial, technical and marketing manager. For example, our technical manager created a storage system for the labels on the Anaesthetic carts (figures 12.3). Other departments from our hospital also willing to use the labels, e.g. the Emergency department, Adult and Paediatric Intensive Care Unit were also involved. A prospective risk-analysis was performed by the multidisciplinary team. In addition, members of staff were alerted to the meetings and requested to join or send their concerns about the new labelling system by email. The risk analysis revealed the biggest concern to be incorrect labelling or administration of the wrong drug because of relying on a previous colour scheme for medication labels. In order to decrease the likelihood of these events, an e-learning was created to familiarise staff with the new labels. The e-learning consisted of a general information part and a game to train rapid recognition of the new labels. All staff had to complete the e-learning before the labels were introduced. Furthermore, several email alerts were sent, and presentations were held to increase awareness of the new labels before they were employed.
Figure 12.3. Example of storage of labels on the anaesthetic cart in the AMC. Method in which anaesthetic medication is prepared and used throughout the procedure per patient in the AMC. (Room below is for vials to be double checked, it is obligatory for two members of staff to sign the medication indicator (right hand side) prior to the start of the case).
Results

Currently 4 hospitals have implemented the labels. The Academic Medical Centre Amsterdam (AMC) was one of these pilot hospitals. The introductory e-learning was completed by 88% of staff in the AMC. Ninety-four percent felt that the e-learning was helpful to explain the system behind the labels. The 12% that did not complete the e-learning indicated that they had no time to complete this (3), that they deemed the e-learning unnecessary (2), that they had a technical problem preventing them to complete the e-learning (2) or that they were not aware that there was an e-learning (1). A voluntary survey after introduction of the labels was completed by 68 members of staff (about 40% of staff working in the anaesthetic department at that time). Despite 11 email alerts, 2 local presentations and 2 national presentations, one (2%) person indicated that he had not been aware of the introduction of the new labels. Most members of staff felt that the labels were clearer than the previous ones. During the pilot phase, a flaw in the design of the labels was pointed out by staff: as ambient light is switched to green during laparo- or thoracoscopic surgery, some colours become hard to distinguish. This problem was addressed, and the respective colours were intensified in the newly printed batch of labels. During the time of implementation we specifically looked at an increase in the number of reported drug administration errors. During the 3-month introduction period of the new labels, 7 drug errors with no patient harm were reported in 4715 anaesthetic actions. In the 3 months prior to this time, 6 drug errors were reported.

Discussion

Medication errors can be the cause of significant harm and should be prevented at all cost. Drugs administered during anaesthesia are often selected based on the look of the ampoule or syringe and the location of the drug. It has been emphasised that with more distinctive colours, contrasts and shapes it becomes easier to identify the drug syringe. Identification of the medication is subsequently verified by reading the label. It is therefore pivotal to optimise the colours, contrasts and shapes of medication labels. Since this had been done by the International Organization for Standardization it makes sense to use this standard in order to reduce medication errors. Some hospitals use a black and white colour scheme. The argument made for this practice is that all labels should be read. Fasting et al found no significant effect on the reduction of medication errors in switching from black and white labels to an ISO colour coded scheme. There is currently no hard evidence that a colour coded scheme will reduce drug errors when compared to a black and white scheme. However, we feel that if a user applied drug labelling colour coded scheme is used in a hospital, it should
be this proposed national standard scheme, as standardisation is essential in a safe system design.\textsuperscript{20}

During implementation we found that the most feared mistake was a swap in drugs that were labelled with a different colour after the introduction of the new labels. For instance, anticholinergic drugs and muscle relaxants (as muscle relaxants had a green label prior to the introduction of the new labels and anticholinergic drugs were labelled with a green label after the introduction of the new labels) and opiates and muscle relaxants (as opioids had a red label prior to the introduction of the new labels and muscle relaxants were labelled with a red label after the introduction of the new labels). However, with all preparations and precautions that were taken with the introduction of the new labels no such mistakes were reported.

There are many barriers in the successful implementation of new guidance and technology.\textsuperscript{21} We found that the most important factor in implementation of these new labels was the lack of hard evidence proving that a standardised colour coded scheme would reduce drug error and improve patient outcome. However, it seems only logical that a wide variety of drug labelling practices in hospitals across the Netherlands will cause error when healthcare personnel is rotating between these facilities. We therefore recommend this proposed user applied labelling system as a Dutch standard.

\textbf{Conclusion}

To reduce patient harm it is imperative to reduce anaesthetic drug error. Here, we describe the successful design and implementation of standardised colour coded labels resulting in a nationwide recommendation to use this labelling system. The impact of standardised labels on patient outcomes has to be determined in future.
References:


