For personal use only. Not to be reproduced without permission of the editor (permissions@pharmj.org.uk)

NEW DRUG LABELLING SYSTEM IN THEATRES POSES RISK

Drug administration in theatres was a topic covered at the United Kingdom Clinical Pharmacy Association spring symposium, Birmingham, 7–9 May. Gareth Jones reports

Current practices of drug administration in operating theatres are potentially risky, said Carol Stevens, director of clinical pharmacy, Barts and the London NHS Trust, who has been awarded the Pfizer patient safety award 2004 for her work on managing risk in this area. The changeover to a new labelling system in theatres will increase that risk, she added. Ms Stevens encouraged pharmacists to work with colleagues in theatres, in finding out about their working practices, and to improve safety.

A study carried out in the trust found that many doses of drug used in theatres were not being adequately labelled when they were drawn up (Panel 1, p245). Interviews with staff working in theatres found that most were aware of mistakes or near misses with drug administration (Panel 2, p245). These findings followed a decision to investigate drug administration in theatres ahead of the implementation of a new labelling system.

Labelling change

Ms Stevens commented that, "In May 2003, the pharmacy department became aware that a group of professional bodies including the Royal College of Anaesthetists, in collaboration with the Department of Health, were advocating a change to an international drug labelling system in theatres." The drug labels used in theatres have the name of the drug preprinted, a space for the concentration to be added and are colour coded. They are used when the drug has been drawn up and is put to one side for the anaesthetist to use when required, and are different from the additive labels used on wards.

There was concern over the changeover because the new colour scheme was different to the established system, and there is a high association between colour and drug name in theatres, particularly in emergency situations. Using colour in drug identification situations is risky, as people tend to use the colour as a cue to the name of the drug, without reading the label. The situation is particularly risky if the colour coding systems are not consistent. The established labels have been used for decades in the theatres, and there did not seem to be any national plan for implementing the changes. "There appeared to be little awareness outside the field of anaesthetics about the proposed changes and the potential risks," commented Ms Stevens. The current labels were going to be out of print by December, and some hospitals had already made the changeover. A survey carried out a couple of years ago showed that the Medilabel system (the established system used at Barts and the Royal London NHS Trust) was in widespread use around the UK.

Mr Jones is editor of Hospital Pharmacist

Anaesthetist preparing a syringe for administration in the operating theatre

James King-Holmes/SPL

According to Ms Stevens, "It seems that although the Medilabel system is widely used, it was not implemented as part of a national standard." The different classes of drugs have different colours aligned to them and some drugs with different modes of action have the same colour, eg, all the cardiac drugs are labelled red. If the person administering the drug does not read the label and picks the wrong one, it may have a significant impact on the clinical outcome.

The international labelling system differs in that drugs which have opposite actions have the same coloured labels, but with white hatching across. For example, morphine is blue, and naloxone is blue with white hatching. Supporters think that this is a safer system, because if you do not read the label, but give a drug with the right coloured label, the clinical consequences will be less to the patient.

There is a risk that staff working with the international labels may pick a coloured label based on their knowledge of the old Medilabel system. There is little known about how hospitals have managed after making the change. One hospital reported, however, soon after switching to the international system, two incidents where a conscious patient was given suxamethonium instead of the intended fentanyl. When these incidents were investigated, it was found that the member of staff was familiar with the old system, and picked up a syringe believing it to be an opiate, when in fact it was a neuromuscular blocking agent.

Clinical governance

The suggested change was proposed to the clinical governance committee for surgery and anaesthetics at the trust. Three options were considered: maintain the current system and use the Medilabels, move to the new international standard or move to preprinted black and white labels either as a permanent or interim solution while changing from old to new international system.

A number of issues were considered by the committee. It was recognised that there is high colour association with different drugs by theatre staff. The National Patient Safety Agency, however, expressed caution with coloured coded systems. Letters in journals have expressed concern about

colour blind staff who might confuse coloured labels and staff wearing green lenses during laser surgery who may be unable to differentiate colours. A number of staff had joined the trust who were already used to using the international system, which is already established in the US, Australia and New Zealand. A further point for consideration was that the colleges of anaesthetics will be teaching with the new international system.

The belief of the committee was that sticking with the medilabel system would be outmoded over time. The black and white system was not without risks, and the anaesthetists overwhelmingly wanted to change to the new international system.

It was agreed that because of the risks involved, the medicines safety team would help manage the changeover to minimise the risk. This was a good opportunity to find out more about how medicines are administered in theatres. "The consequences to patients of getting the changeover wrong were serious, and so it was important to carry out some observations in the theatres to get a better understanding of what happens in there," said Ms Stevens.

Two students joined the department for a few weeks, and they carried out an observational study. Patients were observed from the moment they arrived in the anaesthetic room up to the recovery room or ward. Refrigerators were also checked to find if infusions were being stored overnight (Panel 1). Twenty-one theatre staff were also interviewed (Panel 2).

The findings of these studies were presented to the clinical governance committee. It was agreed that the change to the international system would be made, and that it would happen on the same day in all areas. New Year's day was chosen, because it was regarded as a quiet day across the trust. An anaesthetist and ODA were appointed on each site to oversee the changes, and remove all old labels and replace them with labels of the international system. Smaller departments, such as endoscopy, were also contacted and asked to nominate someone to make the change. A bulletin was circulated to all staff to inform them of the change and why it was happening.

Other initiatives were run at the same time to support the labelling change in theatres. A trust wide poster campaign to encourage staff to read the label was conducted. A system of risk assessing new products was introduced, as a result of the discovery that staff could confuse propofol and etomidate. Work is under way with ITU and theatre staff to produce a checklist, so that drugs are discussed at handover. To ensure that the changeover in labelling systems has been completed successfully, a pharmacy technician continues to check the theatres to ensure that no Medilabels have been reordered.

Carol Stevens receive her prize from Ian Hoban, commercial development manager, Pfizer

Panel 1: Observational study

The observational study found that:

- Half of doses are drawn up by anaesthetists, and half by the operating department assistants (ODA) or a combination of the anaesthetist and ODA
- Thirty-two issues with labelling were seen with 52 patients in the study
- Twenty-six doses were not labelled at all, five were labelled incorrectly and 13 were labelled inadequately
- Nearly half of doses that were not labelled at all were propofol, and many staff believed that it was not necessary to label this drug as it is easily identifiable
- In the five cases where doses were labelled incorrectly, all these errors were picked up by the anaesthetist before the drug was given to the patient. Examples of errors observed include labetalol being labelled metoprolol, metoprolol labelled calcium carbonate, and propofol labelled propofol and lignocaine
- Of the 13 doses inadequately labelled, nine had just a Medilabel with no concentration. In some cases, ampoules were taped onto the syringe, in lieu of a label
- Of the 80 infusions leaving theatres, 34 had drug additions
- Seven infusions were unlabelled, two were labelled incorrectly and 20 were labelled inadequately (eg, Medilabel applied, but no concentration stated)
- No errors were noted as a result of confusion between colours
- Some labels were not in stock
- There were no doses left in theatre at the end of the day

Panel 2 : Results of staff interviews

- Twenty-one theatre staff were interviewed, to establish their opinions on drug administration and the proposed change to the international system of labelling
- The interviews were conducted among a range of staff: 13 anaesthetists, 4 operating department assistants, 4 nurses
- Recovery nurses said that ongoing infusions were not always labelled adequately when patients left theatres
- Staff thought that those who were administering drugs should draw them up. However, this was not always possible, as on some occasions, staff changed part way through a procedure
- Staff believed that propofol was never labelled, because it is cloudy and therefore can be easily identified. However, Etomidate-Lipuro has recently been introduced into the theatres, and this is also cloudy
- The majority thought that the current labelling system was safe and effective and they thought that colours were helpful as they save time and are essential in an emergency
- Most staff were aware of mistakes or near misses
- The majority of staff knew about the proposed change to the international system
- Most staff thought that confusion was a possibility in the initial stages of changeover
- Overwhelmingly, staff agreed that there was a need for standardisation of labelling in theatres