

# Safe medication initiatives

## — sustaining good practice

By David Cousins, MRPharmS

This article, the last in the “safety of medicines in practice” series, highlights examples of good practice in medication safety and how these initiatives can be sustained and extended. Studies that have employed different methods of measuring safe practice are also described



Controlled Drugs cupboards are often small and overcrowded

**P**revious articles published in this series indicate that progress has been made in improving safe medication practice in hospitals.

Articles published early in the series focused on how improving the labelling and packaging design of medicines can make them safer.<sup>1,2</sup> Another article described how NHS purchasing groups can help reduce medicine-related errors by ensuring that the medicines they purchase have been assessed for their error potential and by purchasing medicines with safe packaging designs wherever possible.<sup>3</sup> The need for accurate and complete reports of medication incidents to enable the NHS to identify error trends and disseminate safety information was also described.<sup>4</sup>

Later in the series, a medicines governance team from Northern Ireland described the benefits of establishing a network of six pharmacists, one in each of the larger acute hospitals in Northern Ireland, to increase the levels of medication incident reporting, manage incident data, develop and imple-

ment medicines safety initiatives and provide medication safety education for staff.<sup>5</sup>

Finally, the potential of using failure modes and effects analysis to evaluate the safety of medicine packaging was discussed.<sup>6</sup>

It is apparent that much is being done in the safe medication practice field, but how can these initiatives be extended and sustained and what else needs to be done to improve safe medication practice?

### Improved packaging design

To further promote the safe design of medicines the National Patient Safety Agency, working with the Helen Hamlyn Research Centre, Royal College of Arts, recently issued “Information design for patient safety — a guide to graphic design of medicines”.<sup>7</sup> This report emphasised the importance of pharmaceutical manufacturers user-testing proposed labelling and packaging of their products. It also highlighted the benefit of considering the needs and capabilities of a wide range of potential users, in particular the elderly and the partially sighted, as well as the needs of health care professionals.

Good progress has been made by many UK generics suppliers in redesigning their

product ranges to present information to users more clearly and to minimise selection errors. However, some multinational pharmaceutical suppliers have been slow to move away from a uniform corporate design where products are poorly differentiated and the generic name is not given sufficient prominence.

Ideally, the guidance on information design would also be applied to other types of medicine such as parallel imported products that are overlabelled in English, and “specials” produced by NHS manufacturing units or commercial companies.

There is also the issue of an increasing number of non-active substances such as electrolyte solutions being marketed as medical devices. Medical devices have different regulatory requirements for labelling and packaging to medicines. This may cause possible confusion between medical devices and medicines.

Health care organisations are advised to assess the design of all medical products for risk and, where appropriate, medical devices. They are advised to broaden the scope of their “purchasing for safety” policies, provide feedback to suppliers and the NPSA when they identify medium to high risk products

David Cousins is head of safe medication practice at the National Patient Safety Agency

and request that these products are redesigned. At the same time, local arrangements should be made to manage these risks.

However, safe design does not only apply to licensed medicines. Labelling and packaging of dispensed medicines may also be suboptimal. The design and font size used on dispensing labels may be difficult to read or the dispensing label may obscure important information on the manufacturer's pack. Greater attention also needs to be given to avoiding the use of child-resistant closures on dispensed medicines given to the elderly or to other patients who may have difficulty opening such containers. The NPSA is currently undertaking a project to identify safer practice recommendations for dispensed medicines and this guidance is planned to be issued next year.

## — Design of storage areas

Ergonomics is the study of humans in relation to the working environment — the adaptation of products, equipment and general conditions to fit the individual so that they may work with maximum efficiency and safety.

Research evidence indicates that improving the lighting can reduce dispensing errors. Illumination levels of 146 foot candles (a foot candle is measured as the total intensity of light that falls on a one square foot surface that is one foot away from the point source of light) have been associated with significantly lower rates of dispensing errors.<sup>8</sup> This research suggests that improved lighting throughout the pharmacy department, wherever medicines are selected and dispensed (including the pharmacy stores) can improve safe practice. Medicines are also prepared in clinical areas adjacent to drug cupboards so improving illumination in these areas should also be considered.

It is important that there is adequate provision for the storage of medicines on wards and in other clinical areas to ensure safe practice. In a recent consultation the NPSA has reported on safer practice for epidural infusions<sup>9</sup> and is considering issuing a safer practice notice on high dose diamorphine and morphine ampoules,<sup>10</sup> highlighting that inadequate and insufficient storage of medi-

cines has contributed to deaths and serious harm caused by selection errors.

It is also important that the storage of medicines in the hospital pharmacy and clinical areas of hospitals aids safe practice and minimises selection errors. The design of the storage area should be fit for purpose and risk-assessed.

In recent years the range and size of products required to be stored in Controlled Drug cabinets has increased. Traditional designs of CD cabinets (usually consisting of smaller metal cabinets or smaller cupboards within full size wooden cupboards) are frequently too small. Full size cupboards may be required in many areas to reduce overcrowding and enable adequate separation of products. Storage for general oral and injectable medicines may also be inadequate for the amount of stock to be held.

The design of open storage for intravenous infusions and sterile topical fluids in clinical areas is also frequently inadequate and may contribute to selection errors. The design should ensure separation of products and enable users to access products easily and without moving other products.

## — Safe practice initiatives

The NHS Litigation Authority's "Clinical negligence scheme for trusts" general risk management standards for hospitals in England<sup>11</sup> includes the following two standards for medication practice:

- That there is a trust-wide medicines management policy for the storage, prescription and administration of medicines
- That there is a trust-wide annual medicines management report and programme, with clearly defined objectives and progress

Patient safety is also the first domain of the Department of Health's "National standards for health and social care in England".<sup>12</sup> Core standard one requires that health care organisations protect patients through systems that:

- Identify and learn from all patient safety incidents and other reportable incidents, and make improvements in practice based on local and national experience and information derived from the analysis of incidents
- Ensure that patient safety notices and other communications concerning patient safety which require action are acted upon within required timescales

So how do health care organisations maintain and update their medication practice policies to minimise risks? How do they determine what issues are included in their medication practice improvement pro-

grammes and their reports to external accreditation organisations such as the NHS Litigation Authority and Healthcare Commission?

Monitoring patient safety incident reports helps hospitals obtain an overview of the numbers and types of patient safety incidents that involve medicines. It is important that there is only one system for recording medication incidents in hospitals and that clinical pharmacist interventions and dispensing error data are included as part of the reporting system. Confidential information from hospital risk management systems is shared with the NPSA as part of the National Reporting and Learning System.

Incident reports and information from other methods (see below) will help identify local priorities. In addition, the NPSA will identify national priorities and issue safer practice guidance each year. The NPSA is looking at the following medication practice topics over the next 12 months:

- High dose diamorphine and morphine ampoules
- Oral methotrexate (update on guidance issued in 2004)
- Epidural infusions
- Injectable medicines
- Preventing wrong route errors with oral liquid medicines, feeds and flushes
- Paediatric infusions
- Dispensed medicines

More information about these initiatives can be found at [www.saferhealthcare.org.uk/ihi/forums](http://www.saferhealthcare.org.uk/ihi/forums)

## — Measuring safe practice

The use of several methods to monitor the safety of medication practice in health care organisations is recommended in order to identify new risks and trends and to monitor the effectiveness of initiatives to reduce these risks.

No one method is ideal for measuring safe medication practice and health care organisations should consider using multiple methods to gain a better understanding of the safety of their systems. Methods available to study safe practice include:

- Patient safety incident reports
- Prospective incident reporting by pharmacists
- Prospective observation
- Retrospective review of patient records
- Retrospective use of trigger tools

The validity and cost-effectiveness of three of these methods for detecting medicine administration errors were examined in 36 hospitals and skilled nursing facilities in the US.<sup>13</sup> Medicine administration errors were detected by nurses and pharmacy technicians using incident report review, chart review, and

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## Panel 1: Errors detected by each method used

Method	No. of errors detected
Prospective (direct observation)	300
Retrospective chart review	17
Incident reporting	1

direct observation. Each dose evaluated was compared with the prescriber's order and any deviations were classed as errors. Efficiency was measured by the time spent evaluating each dose. A pharmacist performed an independent determination of errors to assess the accuracy of each data collector, and clinical significance was judged by a panel of doctors. There were 457 pharmacist-confirmed errors on 2,556 doses (an error rate of 18 per cent. Most errors were identified by prospective observation, as shown in Panel 1.

The mean cost of error detection per dose was \$4.82 for direct observation and \$0.63 for chart review. The technician was the least expensive observer at \$2.87 per dose evaluated, and nurses were the least expensive chart reviewers at \$0.50 per dose.

Of the 457 errors, 35 (8 per cent) were deemed potentially clinically significant; 71 per cent of these were detected by direct observation. Direct observation was found to be more efficient and accurate in detecting medicine administration errors than reviewing charts and incident reports. Pharmacy technicians were found to be more efficient and accurate than nurses in collecting data about medication errors.

Recently, a UK study was commissioned by the NHS Patient Safety Research Programme to pilot technology evaluations for reducing medication errors. The researchers developed an evaluation framework and [compared a number of different methods used to study medication incidents, finding that] each of the methods identified and measured different types of errors.<sup>14</sup> Using a combination of two or more methods was found to be the best technique to identify risks in medication practice and evaluate the effectiveness of safe medication practice initiatives.

Another report from the US described how a hospital identified and measured the effectiveness of a planned series of low cost interventions focused on high risk medicines, to decrease the incidence of patient harm.<sup>15</sup> As a result of intensive work on cultural change, incident reporting increased significantly from 35 per 1,000 patient days in 2001 to 132 per 1,000 patient days in 2003. All incident reports were entered into a single database and the process steps that

most frequently failed were identified. A patient safety group was able to identify the medicines most frequently associated with reported events and implement therapeutic protocols to improve medication safety.

In the same study, practice data was collected using an adverse drug event (ADE) trigger tool designed and tested by the Institute of Healthcare Improvement, in addition to practitioner reporting.<sup>16</sup> Ten to 20 randomly selected medical records of discharged inpatients were reviewed for ADEs each month for two years. Each record was reviewed by a clinical pharmacist and a nurse manager. The trigger tool was used to detect indicators of ADEs, the presence of which was confirmed or excluded by detailed manual chart review.

A failure mode and effects analysis conducted on the pharmacy dispensing system revealed a substantial number of opportunities for improving the safety of dispensing and all of these were instituted. Following this, median ADEs per 1,000 doses of medicine dispensed declined from 2.04 to 0.65. Median ADEs per 100 patient days declined from 5.05 to 1.3. The proportion of inpatients with one or more ADE in the baseline period was 31 per cent and this declined threefold. The severity of reported medication events also declined. The number of ADEs associated conclusively with patient harm was 1.67 per total doses delivered in the baseline period and declined eightfold.

## Conclusion

Progress has been made in improving the safety of medicines and practices used in hospitals. Extending the scope of safety design and purchasing initiatives to include parallel imported products, manufactured specials and some medical device products will further reduce risks to patient safety. Improving the design of dispensed medicines should also be considered. Giving greater attention to ergonomic issues in storage and preparation areas in hospitals will also help to minimise selection errors.

Health care accreditation organisations have issued standards that require a more systematic approach in identifying medication practice risks and the implementation of local and nationally identified improvements designed to minimise risk. No single method is ideal for measuring safe medication practice and health care organisations should consider using several methods to gain a better understanding of the safety of their medication systems.

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