

## Medication safety in an acute teaching hospital: an Irish perspective

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### Abstract

#### Background

In line with international trends, patient safety has become a priority health issue in the Irish healthcare system in recent years. In August 2004, a medication safety facilitator (MSF) was appointed in an acute teaching hospital in Ireland for the investigation of medication safety events (MSEs).

#### Methods

The MSF designed a pilot medication safety reporting system for trial in three ward areas over seven months. The system was subsequently expanded to the entire hospital.

#### Results

During the first year of the appointment of the MSF, reporting levels increased by 290% relative to the same period the previous year. The majority of reports involved potential risks, near misses and medication errors that reached the patient but caused no discernable harm. For the more serious events, a root cause analysis was undertaken and action plans were developed by collaboration between the MSF and ward staff. A system of regular feedback to staff was introduced to encourage continued reporting and heightened awareness of medication safety issues. Proactive safety reviews were undertaken for high-risk medications, resulting in the introduction of system changes to optimise safety. Guidance was provided to staff in the form of bulletins, alerts and education sessions.

#### Future plans

Expansion plans for the second year of the project involve the development of a network of safety champions across the hospital. These individuals will undergo root cause analysis training and then liaise with the MSF with regard to the communication of safety messages and the implementation of action plans.

**Key words:** medication, safety, Ireland

### Introduction

#### Medication safety as a priority health issue

The vast majority of medication is prescribed, dispensed and administered safely to patients in hospitals.[1] Nevertheless, when medication errors do occur the consequences can be devastating for patients, their families and the staff members involved. In the United States it is estimated that 7,000 deaths are caused annually by medication errors. A recent study of over 18,000 patients admitted to National Health Service (NHS) hospitals in the UK found that 6.5% of admissions were related to an adverse drug reaction, with most reactions being either definitely or possibly avoidable.[1,2]

In addition to the human cost, medication errors also have a major financial impact on the

healthcare service. The direct cost of medication errors to the NHS is estimated to be in excess of £400 million each year, a figure that does not take into account the costs arising from litigation.[1,2]

Clearly, prioritising medication safety generates undisputable benefits for patients, staff and organisations alike.[1]

#### Medication safety in Ireland

No analyses have been published with regard to the volume or type of medication errors occurring in Irish hospitals. However, recent high profile investigations in the tertiary care sector in this country have highlighted weaknesses in the health service and focused public consciousness on issues surrounding patient safety.[3-5] The Irish healthcare system is reflective of international

trends in its development of a more open safety culture, with increasing focus on risk management initiatives.[1,6]

In August 2004 a full-time dedicated position was introduced in an acute teaching hospital for the investigation of medication safety events (MSEs).

## Medication safety prior to August 2004

Prior to the appointment of a medication safety facilitator (MSF), only a limited and delayed review of MSEs was possible and little detailed analysis of reports was undertaken. The low volume of reports sent to risk management suggested a significant degree of under-reporting. Furthermore, virtually all reports concerned actual events and therefore it was evident that valuable data on near misses was not being captured.<sup>[7]</sup>

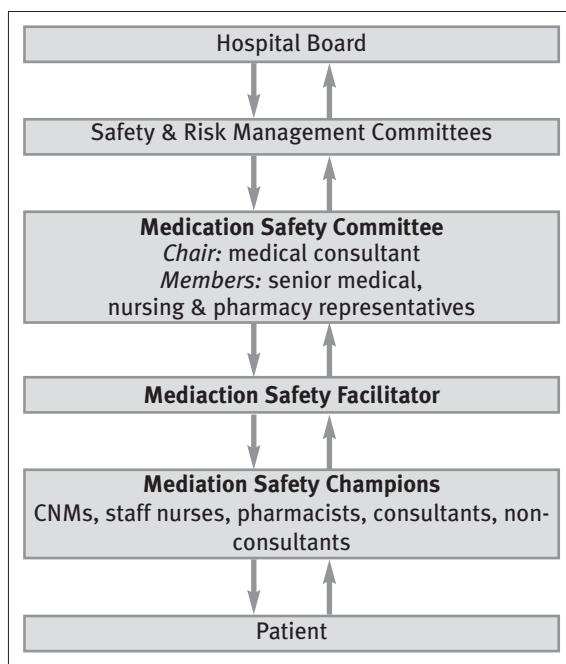
## Methods

## Current structure of the medication safety system

The medication safety system is structured as a component of the risk management framework (Figure 1). The MSF is a member of a multidisciplinary medication safety committee comprised of senior nursing, medical and pharmacy representatives and chaired by a medical consultant.[8] The medication safety committee is a sub-committee of the Pharmacy and Therapeutics (P&T) committee which reports to the Hospital Board.

Currently, the dissemination of safety messages to staff is dependent on the clinical management level of the organisation i.e. clinical nurse managers

**Figure 1. Structure of the Medication Safety System**



(CNMs) and consultants, supported by a team of pharmacists. The aim is to move from this hierarchical system of communication, where the authority gradient can present a barrier, to a more horizontal model which facilitates two-way communication between all grades of staff.[6,7] Over the coming year, representatives drawn from each directorate (a group of wards managed by a clinical director and directorate nurse manager) will undergo a training programme in root cause analysis techniques. It is envisaged that these individuals will then act as champions amongst their peers for the advancement of medication safety issues.[9,10]

## Reporting of medication safety events

The term 'Medication Safety Event' was adopted as an all-encompassing term for both medication errors and near misses. A dedicated form for the reporting of MSEs was designed and formatted as an online version on the hospital intranet to enable direct and immediate submission of a report to the MSF by all clinical personnel.

## Introduction of pilot project

A 7-month pilot medication safety project was undertaken on three ward areas between August 2004 and February 2005. Briefing sessions were conducted to assure staff that reports would be dealt with in the context of a 'just culture', with the focus on identifying system rather than personal failures and on the implementation of quality improvement measures.[6,7]

For the duration of the pilot, the reporting form underwent considerable modifications and supporting documentation e.g. a medication safety reporting policy, was developed. The pilot project was extended to all wards in May 2005.

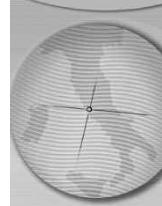
## Data management

An in-house database was developed using *Microsoft Excel*. Drop-down menus were created for all of the criteria on the form to facilitate rapid and accurate data input.

In addition, data on events was submitted electronically to a central database (*StarsWeb*) managed by the national Clinical Indemnity Scheme, which insures all health professionals working in public hospitals in Ireland. Access to *StarsWeb* will be extended to all Irish hospitals by the end of 2005 and ultimately it will provide data on national trends in medication safety and suggestions for risk reduction measures.

## Analysis of events

Events were categorised according to the National Co-ordinating Council for Medication



Error Reporting and Prevention system (NCC MERP), which grades medication safety events with a letter from A to I, according to the level of adverse impact on the patient involved. Within this system, categories A and B refer to potential risks and near misses, respectively; categories C-H refer to medication errors which have progressively greater adverse effects on the patient, and category I is assigned to fatal events.[11] All events were graded initially by the MSF and then independently by a medical registrar, in order to limit any potential bias. When a difference arose between the grading assigned to an event by the MSF and that by the registrar, the issues involved were discussed in detail in order to reach agreement on the most appropriate categorisation.

All events of category E and above were analysed in particular detail to identify contributory factors and root causes. Where appropriate, a team comprising individuals involved in the event and those with expertise in the specialist area was assembled, to define the safety issues and formulate an action plan to address them.

## Results and Discussion

### Number of reports

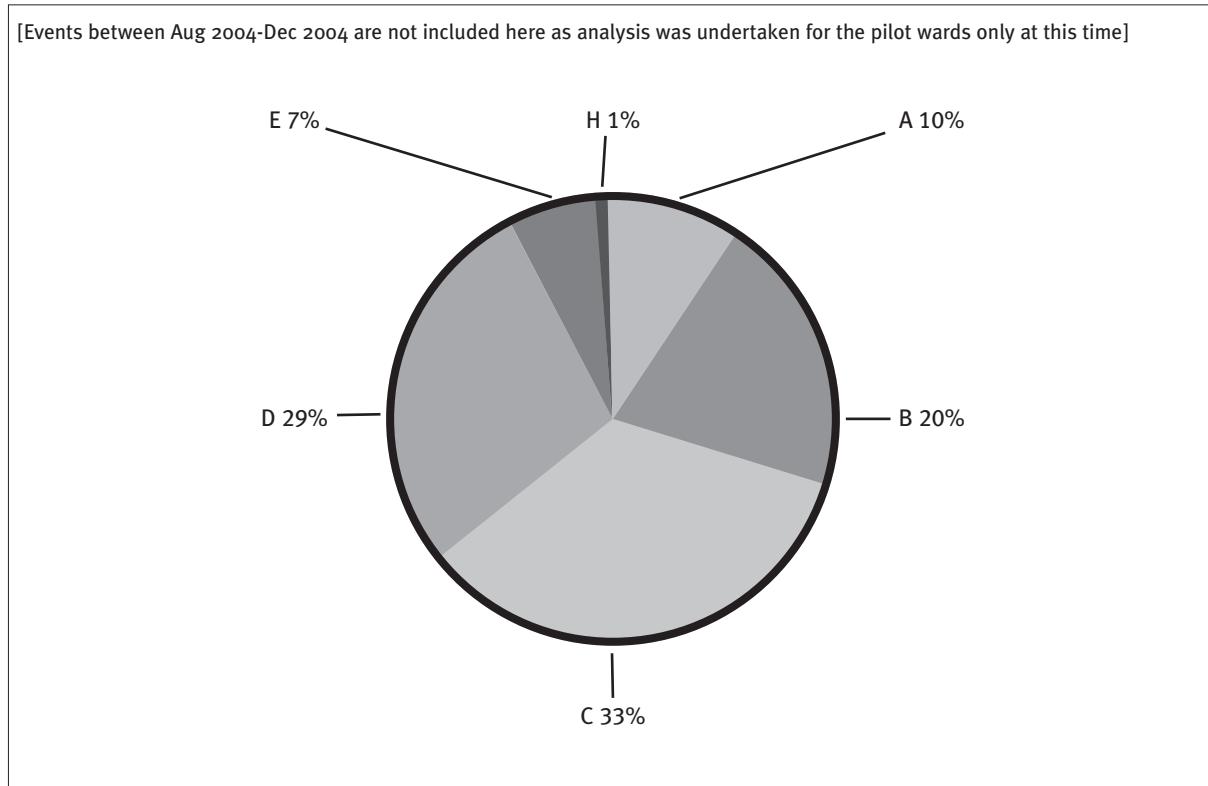
During the first year of the medication safety project (August 1<sup>st</sup> 2004 - July 31<sup>st</sup> 2005) a total of

543 events were reported. This represented a 290% increase in the volume of events recorded relative to the same period in 2003/2004. The projected estimate for the second year of the project is approximately 800 reports. Statistical comparisons with other well-established medication safety systems suggest that the annual number of reports for this hospital could ultimately be expected to be in excess of 1,000. An increase in the level of reporting is generally accepted as an indicator that an open and fair safety culture has been implemented.[9,12]

### Categorisation of reports

In line with international trends, the majority of events reported (63%) involved potential risks, near misses, or errors which caused no discernable patient harm i.e. categories A, B or C, respectively (Figure 2). The proportion of near misses (20%; category B) relative to actual errors (70%; categories C-I) would be expected to continue to increase as staff awareness of the importance of highlighting potential risk develops. Furthermore, over time the number of serious events (category F and above) would be expected to reduce as the medication safety culture becomes more established and the impact of risk reduction measures take effect.[7,9]

Figure 2: MERP Categorisation of Medication Safety Events Reported between Jan1st-Aug 31<sup>st</sup> 2005 (n=410)



### Role of the medication safety facilitator

The job description of the MSF can broadly be divided into two components:

I) Reactive role: responding to MSEs by means of investigation, root cause analysis and development of recommendations

II) Proactive role:

- initiation of safety reviews to assess compliance of systems and procedures with recommended standards
- provision of guidance to staff in the form of education sessions, bulletins and alerts.[12]

#### I) Reactive role

Trend analysis highlighted the following drug classes as requiring particular attention in terms of risk-reduction measures. All of these groups of medications have been identified previously as amongst those presenting the highest risk for medication errors.[1,13-18]

#### a) Opiates

Several serious errors involving opiates were reported where the incorrect drug or the incorrect dose was administered, requiring the antagonist naloxone to reverse the adverse effects. The root cause was identified as a flawed checking procedure prior to the administration of controlled drugs. The principle of undertaking an independent double check was a key learning point from these events; staff were advised not to give or accept prompts when checking an item to ensure that both parties have individually verified that the item being checked is correct [19].

A consistent contributory factor to these events was the presence of opiate preparations of high concentration or strength at ward level (e.g. morphine concentrated solution 20mg/ml, morphine oral unit dose vials 100mg /5ml and hydromorphone slow-release capsules 24mg).[13] Where staff are unfamiliar with such products, they can confuse them with the more commonly prescribed preparations of lower strength or concentration and a several-fold overdose can result.

A variety of safety barriers were introduced to reduce the risk of a recurrence of these events. Firstly, where possible the access to the hazard was reduced or eliminated.[13] Pharmacists and CNMs were instructed to return controlled medications not currently in use to the pharmacy department as soon as possible. In addition, following a risk-benefit analysis, the decision was taken to no longer stock the 100mg/5ml strength of morphine oral unit dose vials because of the similarity of its packaging to the 10mg preparation.

A second action point addressed the confusion surrounding identification of the correct preparation because of the broad range of strengths and formulations available for many products. An opiate identification guide was designed for display on all controlled drug storage cupboards at ward level.[14] This listed the generic and proprietary names of all the commonly used controlled drugs, together with their strengths and formulations to facilitate nurses in the selection of the correct product.

Finally, 'error traps' were built into the dispensing procedure in the form of warnings programmed into the pharmacy software, alerting users to look-alike and sound-alike opiates, thereby reducing the risk of selection errors.

#### b) Insulin

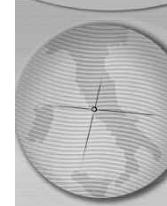
A contributory factor noted for several events involving confusion between short-acting and long-acting insulin preparations, was a flawed design of insulin kardex (drug administration record).[15] In response to this, a revised kardex was introduced for hospital-wide use in March 2005, with clearly designated sections for prescription of different insulin regimens e.g. sliding scales, infusions etc. An integrated booklet format replaced the previous design which had included tear-off pages that were frequently misplaced, resulting in an incomplete patient record.

A second source of concern was rate administration errors due to the inputting of incorrect data into infusion pumps.[15, 20] In order to address this a modification was made to the Nursing Intravenous (IV) Administration Protocol requiring nurses to seek a second check on pump settings.

#### c) Intravenous Infusions

Two category E events reported in the first months of the project highlighted a lack of intravenous administration training for junior doctors.[21,22] These events both involved the administration of an IV bolus of 25,000 units of heparin instead of 5,000 units, due to selection of the 5,000 unit/ml vial rather than the 1,000 unit/ml vial.[23,24] Although poor labelling by the manufacturer was identified as a contributory factor, the root cause in both cases was the absence of a formalised procedure for seeking an independent second check when preparing and administering IV medication.[24,25]

These events demonstrated the need for specialised training for doctors encompassing both the practical and theoretical aspects of IV administration.[25-27] An education programme,



modelled on that already *in situ* for nurse IV certification, was introduced for the first time in June 2005, prior to the commencement of the internship year.

#### d) Anaesthetic Agents

In April 2005, the International Colour Coding System for Syringe Labelling in Critical Care Areas was adopted into practice in SJH.[28] Regulatory bodies had recommended the introduction of this system in UK and Ireland to bring syringe labelling standards in line with those in North America and Australasia. Although authorities recognised that extra care would be required during the changeover period, it was believed that an internationally recognised colour coding system would, in the long run, reduce administration errors in critical care areas.

An extensive awareness campaign, co-ordinated by the pharmacy dispensary manager and the critical care clinical director, was launched in the hospital to advise all anaesthetists of the impending changes in label colours. A few weeks following the changeover date, a category H error occurred where atracurium was administered instead of ephedrine, requiring the patient to undergo emergency intubation. The registrar had selected a pre-prepared syringe with a red label, a colour which was previously associated with ephedrine, but which in the new system was

that assigned to neuromuscular blockers. Similar misidentification errors with anaesthetic agents have been documented in several other hospitals previously.[29,30]

A key system weakness identified was the practice of having pre-prepared syringes of both routine and emergency agents, in close proximity, on a single tray in theatre. The primary risk reduction recommendation was the physical separation of the two sets of medications either into separate trays or into clearly designated sections on a single tray, to reduce the risk of an emergency agent being selected in error.[30]

#### Frequently occurring medication safety events

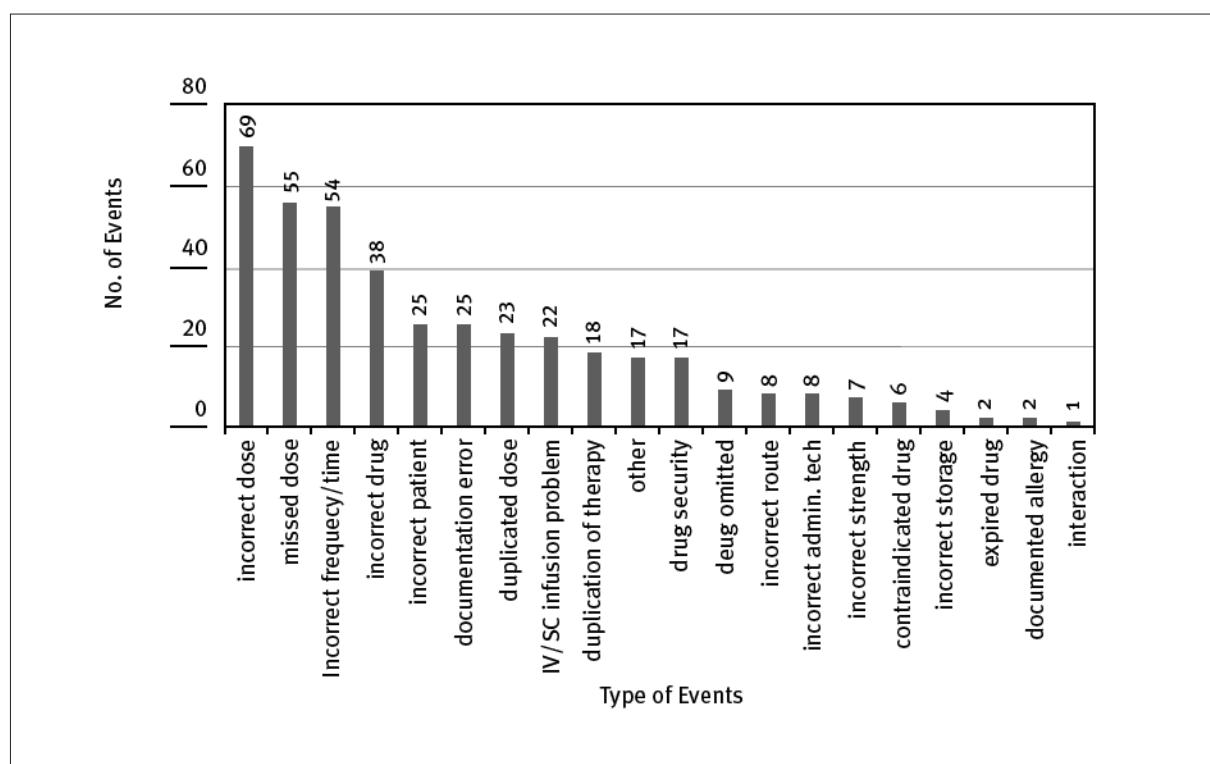
In addition to focusing on high risk medications, the frequency of occurrence of the different categories of MSEs was also used as a means of targeting risk reduction measures (Figure 3).

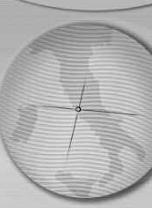
Action plans were devised as a response to these events and are detailed below for two of the more commonly arising categories - 'missed dose' and 'incorrect patient'.

#### a) Missed dose

One of the root causes identified on analysis of the error of 'missed dose' was the absence of peri-operative guidelines for the administration of medications. Nursing staff were frequently

Figure 3. Types of medication safety events reported between Jan 1st-Aug 31<sup>st</sup> 2005 (n=410)





confused about which medications should be stopped prior to a surgical procedure and which could be continued to within a couple of hours of the patient going to theatre.

This issue was highlighted by an event reported by an anaesthetist, where a patient experienced an episode of atrial fibrillation in theatre following omission of his daily dose of digoxin. The doctor's direction that the patient should fast was interpreted as an order to not administer any medications, in addition to not supplying the patient with food. A second event involved a patient who missed several days of therapeutic enoxaparin following surgery. This arose because the nurses understood the direction of 'hold' on the prescription to mean not to administer any further doses, although the prescriber had intended it to refer only to a single pre-operative dose.[31]

Following review of these and similar events by the P&T committee, the Anaesthetics department has undertaken to produce guidelines regarding the peri-operative management of medications.

#### **b) Incorrect patient**

Analysis of events where a patient received medication intended for another individual, identified the root cause to be a lack of identity bands checks. Although this issue was continually highlighted in bulletins and education sessions, a more applied approach was considered justified.

A collaborative initiative between nursing staff and the MSF has led to the development of an assessment and education programme for medication administration procedures. It utilises a direct observation technique during an accompanied drug round, where the routine practices of the nurse administering the medication are assessed by a senior nursing colleague.[6,27,31] Adherence to best practice is measured according to a list of set criteria encompassing the 'five rights' of administration (right patient, right drug, right route, right time, right dose). It is expected that the benefits of this assessment will be twofold; firstly improved awareness amongst staff nurses regarding medication safety issues and secondly, the development of a number of key training and educational objectives, which should have relevance for the entire hospital.

The follow-up step in the programme will be the introduction of a self-directed learning package for nursing staff to address risks identified by the assessment.[32,33] Finally, the audit cycle will be completed with a repeat assessment to gauge the impact of any improvement measures.

The first stage of this programme is currently being piloted at ward level and if proven worthwhile will be extended hospital-wide. The objective is to involve all wards in a self-assessment of local risks in the administration process and formulation of safety initiatives to address them.

#### **II) Proactive safety review**

A risk assessment of procedures for the handling of IV potassium concentrates and of intrathecal chemotherapy was prompted by standards introduced by safety authorities in the UK, in response to the documented hazards associated with the use of these preparations.[7,16]

##### **a) Intrathecal chemotherapy**

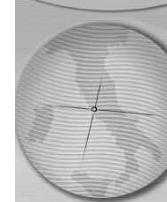
The manager of the Aseptic Compounding Unit and the chief pharmacist for clinical oncology services assessed compliance of systems for intrathecal chemotherapy in SJH with safety guidelines issued by the UK Department of Health.[34] This review resulted in modifications to processes at several stages in the handling of intrathecal products: packaging, delivery to wards, storage at ward level and record keeping.

##### **b) Potassium concentrates for intravenous administration**

The policy for the management of IV potassium concentrates in SJH was revised to ensure procedures adhered to standards recommended by the UK National Patient Safety Agency.[35] The new policy, introduced in September 2005, requires IV potassium concentrates to be treated in a similar manner to controlled drugs with regard to their ordering, storage and documentation requirements. With the exception of critical care areas, potassium chloride vials have been withdrawn from general supply, with stock on wards now restricted to 4 vials for emergency use to be stored in the controlled drugs cupboard.[36] In order to encourage the use of pre-filled infusion bags, a wide range of concentrations of potassium chloride (20mmol/500ml, 20mmol/1000ml, 40mmol/1000ml) in a variety of infusion fluids (dextrose 5%, sodium chloride 0.9% and Solution 18) have been made available to wards. An additional concentration, 20mmol/100ml, has been sourced for critical care areas and this is expected to dramatically reduce the usage of potassium chloride vials in these locations.

#### **Alerts and Bulletins**

Alerts are sent to clinical nurse managers and/or consultants to advise them of the action required



in response to urgent medication safety issues, such as product recalls and labelling or packaging changes that are likely to predispose to error.

Separate bulletins for nursing and medical staff, highlighting the risk reduction measures relevant to their scope of practice, are compiled on a quarterly basis.

All alerts and bulletins are available for review on the medication safety site on the hospital intranet.

### Feedback

Reports involving trend analysis of events and proposed action plans for the hospital as a whole are sent on a quarterly basis to the medical board, P&T committee, medical and surgical sub-committees and the Director of Nursing. In addition, individual reports are compiled for directorates which focus on local issues and outline action plans agreed upon following multidisciplinary review of key events.

### Education programme

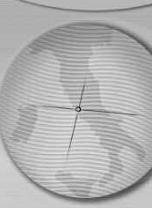
Medication safety issues are addressed at multiple forums including the hospital risk induction programme (mandatory for all new clinical staff); nurse study days and in-service sessions; intern orientation training and presentations at directorate, CNM and clinical pharmacy meetings.

### Conclusions

A multidisciplinary medication safety system has successfully been integrated into an acute teaching hospital and has reaped tangible benefits for patients and staff within a year of its commencement. The next step will be the development of an integrated safety network, comprising of ward-based safety champions liaising with the MSF and management, which is expected to advance us still further towards our ultimate goal: optimal patient safety in our hospital.

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