

## Design template for a medication safety programme in an acute teaching hospital

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Note: This is an author-created version of an article accepted for publication in the *European Journal of Hospital Pharmacy* following peer review.

The final publication is available at <http://ejhp.bmj.com>.

Direct links to the definitive publisher-authenticated version [Relihan EC, Silke B, Ryder SA. Design template for a medication safety programme in an acute teaching hospital. *Eur J Hosp Pharm*. 2012; 19(3):340-344]:

<http://ejhp.bmj.com/content/19/3/340>

<http://dx.doi.org/10.1136/ejhpharm-2012-000050>

### ABSTRACT

**Background** Very limited data have been published about the design of medication safety programmes in hospitals.

**Objective** To describe a template for the structure and operation of a medication safety programme in an acute tertiary setting.

**Methods/results** A model of an ideal medication safety programme was developed by combining the lessons learnt by the lead author in the role of medication safety officer in an acute teaching hospital for 7 years with the published accounts of best practice from the literature.

**Conclusions** Given the limited guidance currently available regarding the structure and operation of such programmes, this template goes some way towards addressing a gap in the current patient safety literature. It should be of practical value to healthcare organisations considering either introducing a medication safety programme for the first time or expanding an existing system.

### INTRODUCTION

Although a wealth of research focuses on the individual aspects of patient safety systems, for example, safety culture, there are limited data relating to the establishment, structure and operation of a medication safety programme. Patient safety is a relatively new research area resulting in a lack of consistency in medication safety programmes in different organisations with 'a lot of places doing some of the things that need to be done, but few places doing all the things that need to be done in order to have a true failsafe medication use system'.<sup>1</sup>

In August 2004 a full-time medication safety officer (MSO) was appointed in one of the largest acute hospitals in Ireland to design and implement a medication safety programme. This hospital has over 1000 inpatient and day case beds involving all major specialities, with the exception of paediatrics and obstetrics. Since its inception 7 years ago the programme has been refined through a process of user feedback and experiential learning with the resultant emergence of a template for a model medication safety programme.

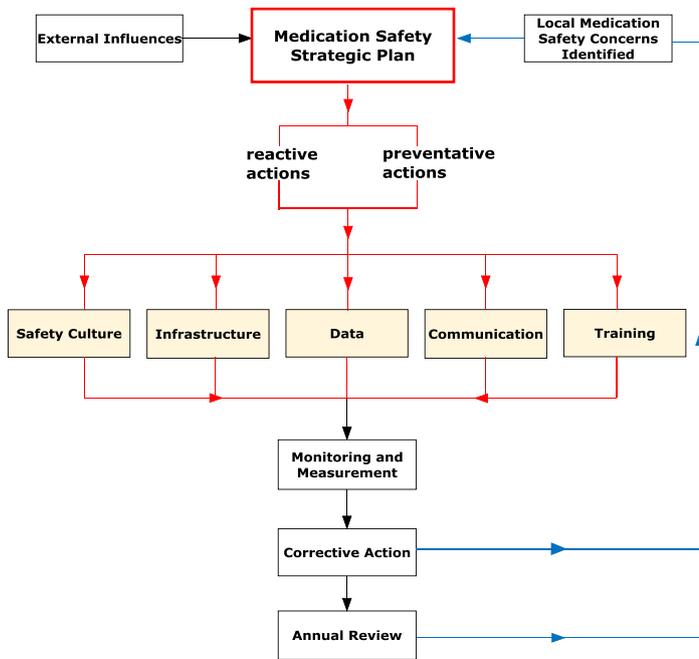
### OBJECTIVE

In this paper we aim to describe a template for the design and implementation of a medication safety programme in an acute teaching hospital.

### RESULTS

#### Overview of template

A medication safety programme can be viewed as comprising five main organisational elements: safety culture, infrastructure, data, communication and training (Figure 1). These components enable the operational objectives of the programme to be achieved.<sup>2</sup>



**Figure 1:** Operational structure of a model medication safety programme.

**Table 1:** Resources for establishing and operating a hospital medication safety programme.

<b>Information</b>	Multi-resource websites (journal articles, audiovisual materials, toolkits, etc) <sup>32</sup> Regular update bulletins <sup>33,34</sup>
<b>Event investigations</b>	Root cause analysis tools and templates <sup>35</sup> Report-writing tools <sup>36</sup> Incident analysis tools <sup>37</sup>
<b>Quality improvement</b>	Establishing medication safety measures <sup>38</sup> Trigger tool for measuring adverse drug events <sup>39</sup> Medication safety self-assessment <sup>30,31</sup> Safety culture measurement tool <sup>40</sup>
<b>Education and training</b>	WHO Patient Safety Curriculum <sup>41</sup> Improvement stories <sup>42</sup>

Ideally these organisational elements are monitored and measured leading to the formulation of corrective measures which in turn impact on the day-to-day operation of the programme. An annual review should be established to assess progress and identify medication safety concerns requiring attention during the upcoming year.

A strategic plan<sup>3</sup> is formulated by balancing consideration of the internal priorities of the hospital with the external demands and concerns highlighted by safety agencies and other stakeholders.<sup>3</sup> The plan should comprise two aspects: reaction (*i.e.* the response taken to address medication errors which occur in the organisation and are identified by the programme); and prevention (*i.e.* the action taken pre-emptively to reduce the risk of an error in the future).

Medication safety initiatives must be mapped along a timeline<sup>3</sup> with the aim of achieving them through one or more of the five elements—safety culture, infrastructure, data, communication and training. A key feature of such a plan is that it integrates the many ways by which medication safety may be improved. These include the audit of medication processes in conjunction with feedback to staff, development of safety indicators and measurement of safety culture.<sup>3</sup>

A number of free online resources which the authors believe are useful tools in guiding the establishment and operation of a medication safety programme are listed in Table 1.

### Safety culture

The establishment of a positive safety culture is recognised to be an essential foundation for a patient safety programme.<sup>4,5</sup> Safety agencies such as the Institute for Safe Medication Practices and the National Patient Safety Agency (NPSA) have deemed it to be the first step of a strategic plan for the creation of a successful patient safety programme in an organisation.<sup>4,5</sup>

The initial stage in establishing a safety culture involves measurement of the baseline status by means of a safety culture assessment.<sup>5</sup> The results can then be benchmarked against a pool of international data to assess the hospital's performance. Over time this historical data can be used to monitor the effectiveness of initiatives introduced to address safety concerns.<sup>4,6</sup> In addition, safety culture assessment allows frontline staff to identify weaknesses in a medication safety programme which can then be addressed by means of quality improvement projects.<sup>7</sup>

Safety agencies and subject matter experts have identified several strategies to promote safety culture in a healthcare organisation.<sup>4,5</sup> A critical factor in establishing and maintaining a positive safety culture is the visible commitment of hospital management to medication safety.<sup>5</sup> The fact that patient safety is considered a priority in the organisation can be demonstrated by the appointment of a clinician to the post of patient (or medication) safety officer<sup>4</sup> and by the inclusion of medication safety as a standing agenda item for discussion at executive level committee meetings.<sup>4</sup> The documentation of the organisation should reflect its safety focus: the mission statement for the organisation should emphasise that patient safety is a key priority<sup>3,4,8</sup> and a multidisciplinary hospital policy for patient safety should be developed which indicates the institution's endorsement of a non-punitive, just, and fair systems approach to clinical errors.<sup>2,5</sup>

Any investigations into medication safety events (MSEs) should be undertaken in a manner that is aligned with the medication safety policy, that is, conducted free from bias or hindsight over the outcome of the incident and with a focus

on shared learning and the development and implementation of safety initiatives.<sup>4,5</sup> To promote a positive safety culture, staff should feel supported by management in relation to the reporting of MSEs and in striving for the safest possible practices at ward level.<sup>5</sup> A positive attitude to MSE reporting should be encouraged by educating staff about the systems approach to error investigation in the hospital and emphasising the importance and benefits of reporting MSEs.<sup>5</sup>

It is recommended that there be no references to punitive consequences for committing medication errors in performance appraisals.<sup>3</sup> However, the organisation should consider adding a performance standard to promote the reporting of medication errors.<sup>3</sup> Management in the organisation should empower staff to refuse to proceed in the medication use process if they have a safety concern until a specified review process has been undertaken;<sup>3</sup> for example, nursing staff may be advised not to administer medications when the prescription is illegible and encouraged to escalate the concern up the line with medical staff until the order has been clarified and rewritten. Feedback to staff is critical to prompt continued reporting, to develop staff awareness of the status of medication safety in the organisation, and to encourage compliance with medication safety initiatives underway in the hospital.<sup>3,5</sup> The safety culture of the hospital can be further strengthened by its participation in available external reporting programmes, which enable shared learning on a national level and prioritisation of risks locally.<sup>3</sup>

## **Infrastructure**

The infrastructure of the medication safety programme relates to its underlying organisational framework for the management, governance, integration and collaboration of the activities of the system. The importance of a robust infrastructure for patient safety within healthcare organisations was recognised in 2001 by the Joint Commission for the Accreditation of Healthcare Organizations. This body released safety standards requiring US hospitals to create a formal patient safety infrastructure with strong commitment from senior leadership.<sup>10</sup> The key infrastructural components in a model of a medication safety programme are proposed below.

### *Medication safety officer*

Ideally, the medication safety programme in a large teaching hospital should be managed by a full-time MSO.<sup>11-13</sup> Because patient safety has only come to be recognised as a key consideration in healthcare recently, the role of medication or patient safety officers is still rapidly evolving. Descriptions of the role are limited and necessarily general with the form the role takes varying significantly between organisations.<sup>3</sup> Research has identified some of the ideal characteristics of the individual assigned to the post of patient or MSO. These include a strong clinical background and personal attributes such as an ability to negotiate across boundaries in the healthcare organisation, and communicate key messages to a diverse range of staff categories.<sup>14</sup> The appointee should be held in high regard by their peers, be results driven and attentive to detail<sup>1,8</sup> and of high rank in the institution so that the appointee will have sufficient authority to act effectively.<sup>8,15</sup> Finally, the Institute for Healthcare Improvement emphasises that the organisation needs to adequately resource and support the officer, for example by enabling access to educational opportunities, to ensure best practices can be implemented across the site.<sup>8</sup>

Kowiatek *et al.* suggested that performance standards should be built into the job description to ensure targets are met in relation to all aspects of the role; for example, standards relating to the volume of practice changes incorporated into the organisation per month.<sup>15</sup>

### *Medication safety team*

The operational lead for the medication safety programme is typically the MSO.<sup>12,13</sup> However, additional support is required to implement optimally a medication safety programme in a large teaching hospital.<sup>11-13</sup> This support should ideally be provided by scheduled part-time input from at least two other experienced and senior clinicians, who together with the MSO represent each of the three main disciplines involved in the medication use process, that is, pharmacy, medicine and nursing.<sup>12,16</sup> The role of these staff members would be to galvanise support from within their respective disciplines and thereby assist the MSO in the implementation of safety initiatives.

### *Leadership and governance*

Support for patient safety initiatives from the executive level of the organisation is frequently highlighted as critical to the success of a patient safety programme.<sup>2,4,5,11,13</sup> The MSO should report to a senior hospital manager who is the lead for the overall risk/quality programme in the hospital; this is frequently the chief executive officer (CEO) or deputy CEO.<sup>2</sup> The medication safety team should report to a multidisciplinary medication safety committee (MSC) which has a governance role involving review of the activities of the medication safety team. The MSC should also provide advice regarding the development of safety initiatives and follow-up investigation of critical events.<sup>15,17</sup> Gandhi *et al.* emphasise the importance of integrating the patient safety team into pre-existing committees and structures; in this way pre-existing groups experience patient safety as 'value added' rather than a 'threat to their current roles'.<sup>13</sup> The MSC can be established as a subcommittee of the Pharmacy and Therapeutics (P&T) Committee<sup>17,18</sup> and ideally a report from the MSC should be a standing agenda item for the P&T Committee.<sup>18</sup> This ensures that safety is always a consideration when policy development

or decision-making involving the medication use process is underway. The final layer of governance for the medication safety programme should be an overarching Quality, Safety and Risk Management Steering Committee, which is a subcommittee of the Hospital Board.<sup>19</sup> The role of this committee is to decide on the focus of the risk strategy for the organisation in the medium to long term<sup>19</sup> and present an overview of the risks facing the hospital and the safety initiatives designed to address them to the Hospital Board (Figure 2).

### Integration and collaboration

The NPSA has defined the integration of risk management activities as one of the key steps in the development of a medication safety programme.<sup>5</sup> A medication safety programme should be incorporated into the pre-existing quality, safety and risk structures in the hospital (Figure 2).<sup>13</sup> Integrated risk management entails an awareness of the overlap in relation to data input and action plan development between the individual programmes within the overall quality and risk management system. In practice, for the medication safety team, this involves the sharing of data and the development of collaborative action plans with the other safety/risk personnel, for example, the risk manager.<sup>13</sup> In addition to the obvious importance of collaboration with the clinical departments of nursing, medicine and pharmacy, time and effort should be spent developing working relationships with other diverse non-clinical departments across the hospital, such as Materials Management and Medical Physics/Bioengineering.

### Unit-based teams

It is well recognised that unit-based safety teams, that is, multidisciplinary groups comprising safety champions who are management-level nursing, pharmacy and medical staff, are a valuable component of patient safety infrastructure in hospitals.<sup>2,3,6</sup> In a large hospital, such unit-based teams could be incorporated into the pre-existing local management structure, for example, clinical directorates. These teams should be tasked with reviewing trends in medication errors reported at a local level and working with the MSO to develop action plans to reduce the risk of a recurrence.

## Data: Error detection and analysis

### Error detection methodologies

There are a number of modes of detecting medication errors focusing on structure, process or outcome data. These include safety culture measurement, recording of pharmacist interventions, observational studies, trigger tool systems and chart review.<sup>20</sup> However, the mainstay of medication error data in healthcare organisations is generally a voluntary reporting system.<sup>4,5,21</sup> Each method of error detection is best equipped to detect particular types of medication errors and no single method in isolation can measure the true frequency of medication errors.<sup>22,23</sup> Researchers have long recognised that a truly comprehensive overview of medication errors in an organisation can only be obtained by employing a combination of error detection methods.<sup>23,24</sup>

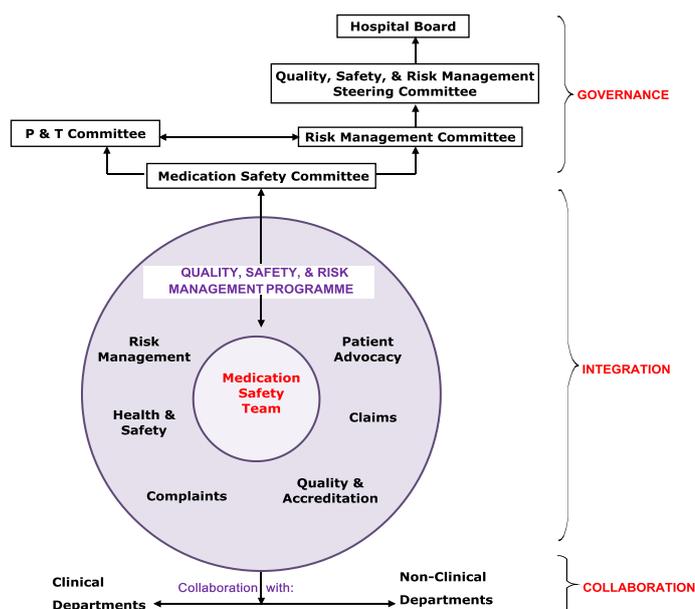


Figure 2: Template for the governance, integration and collaboration of a hospital medication safety programme.

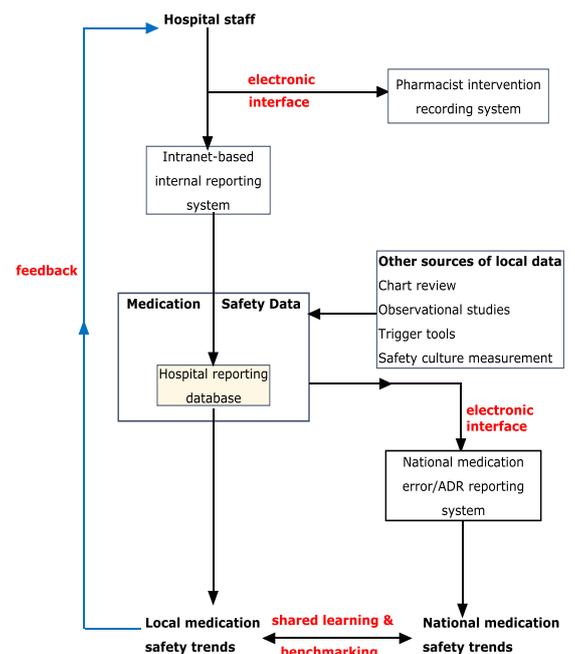


Figure 3: Model data management system for a hospital medication safety programme.

### *Management of error data from a voluntary reporting system*

An ideal model for data management in a medication safety programme is one in which the errors in an individual institution are highlighted through their internal reporting system, allowing an investigation to be undertaken into the contributory factors and action implemented to prevent a recurrence.<sup>25</sup> The error and the results of the investigation are then reported to an external body that aggregates and analyses data from multiple sources and disseminates the information broadly.<sup>25</sup> The ideal mode of reporting for an internal medication safety reporting system is electronic,<sup>23,26</sup> as this makes the reporting process quick and simple, features which are known to underlie successful reporting systems.<sup>25</sup> An ideal system would involve a single interface for both pharmacist intervention recording and medication error reporting. It is well recognised that a large proportion of pharmacists' interventions relate to the detection and resolution of medication errors<sup>27</sup> and having a single system would mean that such activities could be recorded in an intervention database and a medication error database simultaneously, if appropriate, without the need for duplicate data entry (Figure 3).

On submission of an event, data should download directly into a relational database, obviating the need for manual data entry.<sup>23</sup> During the process of review of submitted events, it should be possible for the MSO to amend criteria as required on the form resulting in automated updating of the database. The version of the form which was originally submitted by the reporter should be retained automatically by the system so that this form can be referred to in the future should the need arise. To create an entirely paperless system, a facility to upload documentation related to the investigation onto forms would be essential; this would allow data to then be archived electronically and retrieved as required in the future. The software supporting the database should allow trend analysis to be undertaken quickly and easily by automated cross tabulation of criteria and generation of customisable reports. A further feature of successful reporting systems is regular timely detailed feedback which demonstrates to the staff that reporting is worthwhile.<sup>25</sup> In the ideal system, unit-based teams would have password-protected access to view the forms submitted from their individual directorate and to run standardised aggregated reports, including graphical illustrations of data for their unit and the hospital overall.<sup>28</sup>

### **Communication**

The fourth element of a medication safety programme is communication. An effective communication system must be two way, that is, structures must exist for the transfer of data from the medication safety programme to staff, patients and external bodies, and vice versa. In addition, to be effective the system should be multimodal (*i.e.* involving verbal, electronic and written communication) and flexible (*i.e.* adaptable according to the varying requirements of the medication safety programme). The most suitable mode of communication between the MSO and hospital staff depends on the purpose of the interaction, the urgency of the message, and the target audience (*e.g.* nursing vs medical staff).

The importance of a medication safety programme communicating effectively with patients and the public has been highlighted by safety agencies.<sup>4,5</sup> Guidance has been developed to help healthcare organisations encourage patient involvement in quality improvement projects, sustain patients and their families in the aftermath of an error, and develop community support for medication safety initiatives.<sup>4,5</sup> The key recommendations published by safety agencies in the UK and USA include the following:<sup>4,5</sup>

1. Develop a policy of open communication with patients and their carers in relation to medication safety issues.
2. Establish structures to support patients and their relatives in the aftermath of a medication error.
3. When medication safety walkabouts are established in the organisation, include patients as part of the review team.
4. Introduce tools that encourage patients to become involved in managing their own medication safety.
5. Involve patients and carers in the design process for systems to improve safety.
6. Educate the public regarding medication safety initiatives in operation in the hospital by means of videos and televisions in patients' rooms and posters in public areas of the organisation.

The medication safety programme in an organisation must communicate with national and international patient safety bodies. This entails the fulfilment of reporting responsibilities and participation in national networks, which should in turn have links with the international medication safety community.

### **Training**

When introducing a medication safety programme, every effort should be made to exploit existing hospital training structures by incorporating a medication safety dimension.<sup>13</sup> New training opportunities dedicated to medication safety can then be created as required. The ideal medication safety training programme would involve creating a core curriculum with module-based competencies tailored to suit the needs of the target audience.<sup>13</sup> A variety of teaching modalities should be utilised, such as e-learning programmes, interactive workshops using simulation, and didactic educational sessions.<sup>13</sup>

## MONITORING PERFORMANCE OF THE MEDICATION SAFETY PROGRAMME

Measuring the impact of a medication safety programme is a highly challenging task. Outcome measures such as the number of error occurrences as a proportion of the total number of opportunities for error, or the number of patients harmed by error as a percentage of the total number of error occurrences, are not feasible to measure, at least for any sustained period of time.

For this reason, structure or process measures need to be used to assess the performance of the organisation in relation to safety. Each of the five components of the medication safety programme can be monitored, measured, and/or quality assured to ensure the programme is functioning optimally and as intended. With respect to safety culture (a structural measure), the application of a measurement tool and the benchmarking of the results against international data validates the performance of units within the hospital. For infrastructure, standards can be established against which the performance of the MSO and medication safety team can be measured; for example, by setting time limits for the investigation of an event and development of an action plan. In relation to data, for example, process measures might include the proportion of near misses to actual events reported or the proportion of events which have undergone second person verification of event severity classification. For communication, a process measure might involve the assessment and response to alert publications produced by regulatory authorities within a specified time limit. Finally, training can be monitored by setting targets for the numbers and types of education sessions, staff participation levels and tests of staff competence before and after exposure to such training.

## CONCLUSIONS

Given the limited guidance currently available regarding the structure and operation of such programmes, this template goes some way towards addressing a gap in the current patient safety literature. It should be of practical value to healthcare organisations considering either introducing a medication safety programme for the first time or expanding an existing system.

## KEY MESSAGES

A template for the design and implementation of a medication safety programme in an acute teaching hospital is described. Given the limited guidance currently available regarding the structure and operation of such programmes, this template goes some way towards addressing a gap in the current patient safety literature. It should be of practical value to healthcare organisations considering either introducing a medication safety programme for the first time or expanding an existing system.

The overall performance of the organisation in relation to medication safety can be assessed by means of a medication safety self-assessment tool,<sup>29,30</sup> which allows the organisation to identify areas of weakness that may be addressed by medication safety initiatives in the upcoming strategic plan.

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