Seven Steps to Medication Safety: A Development Resource for Pharmacists and Senior Pharmacy Technicians

A comprehensive learning tool that can be taken in divided doses!

Please note this resource is being reviewed and updated. The core content and messages remain valid, however the context and background have changed since the original publication in 2013.

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Introduction and general information about this resource

The need to learn from things that go wrong during NHS care has made patient safety a key driver for the NHS since the mid 1980s. The drive to improve patient safety is supported by the National Patient Safety Agency (introduced in 2004) and the National Reporting and Learning System (the national database for incident reporting). Together these provide national data analysis and guidance for the NHS on how to engage NHS staff at all levels to reduce the risk of incidents. More recent national developments continue to emphasise the importance of increased quality (and safety).

It is now well recognised that a significant proportion of incidents involve medicines. The DH publication in 2004 entitled “Building a Safer NHS for Patients: Improving Medication Safety” set the scene by exploring the causes and frequency of medication incidents, highlighting drugs and clinical settings that carry particular risks, and identifying models of good practice to improve safety.

In the past, pharmacy staff have been tasked with leading on medication safety issues. This was formalised in the Pharmacy White Paper 2008: “The Government considers that chief pharmacists of provider organisations, PCTs and other commissioners should have the lead role in ensuring that safe medication practices are embedded in patient care”.

Subsequently, the 2009 NPSA publication “Safety in doses” reported on trends in medication incidents and made recommendations based on 86,086 medication incidents which were reported to the National Reporting and Learning System (NRLS) in 2007.

It is against this backdrop that pharmacy staff, in particular pharmacy technicians and pharmacists at all levels of pharmacy practice, need to understand how medication safety must be embedded into their practice. Pharmacy staff are key to medication safety through the way services are delivered and also because they develop and support the patient safety culture of the organisation they work in.

Impact of the White Paper “Equity and Excellence: Liberating the NHS”

This resource was drafted before the publication of the White Paper but we have amended it to reflect the proposed organisational changes where possible. We have retained references and links to the NPSA as although this organisation will disappear in its current form, some of its functions will be transferred to the new NHS Commissioning Board.

It is also likely that web-links within this resource will change so users are advised to use a search engine to locate a resource should the link provided fail.

Why do we need this resource?

Much information and help is available for individuals and organisations to access and use to improve patient safety. This document will help you to find them and make sense of them. In addition not all pharmacists and pharmacy technicians will have been offered training in the key aspects of medication safety. A review of current pre- and post-qualification training available has found some gaps with respect to key elements of medication safety which this resource should help to fill.

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1 DH July 2010 “Equity and excellence: Liberating the NHS”
2 DH July 2010: “Liberating the NHS: Report of the arms-length bodies review”
Is it for me?

This resource has been developed for qualified pharmacists and senior pharmacy technicians. It aims to help you to understand and work within the current NHS frameworks for medication safety by bringing together the underpinning knowledge and resources to support you to deliver safe care wherever you practice.

This resource can support you at a personal and also at an organisational level. It will be useful wherever you practice and can support your personal development whether you are completing formal post-qualification training or whether you just need to brush up on some or all of the ways you can contribute to improving medication safety.

It may be that you will find some sections more useful than others and this resource has been designed so that you can choose to work through all steps starting at the beginning or you can dip into a single section if that’s all you need.

😊 Over 90 pages! Is it going to take forever to complete let alone print?

Don’t worry, the size of the resource is a result of collating all the information about medication safety into one place! The idea isn’t that you should use or complete every section or sub-section. This resource can be:

- dipped in and out of
- used as a reference resource or
- completed in full in an order that suits your needs.

It is up to you how many of the web-based and suggested tasks and references you explore. Whichever sections you read, this is a resource that can be used over time to consolidate or enhance your contributions to medication safety.

😊 Is it for my own development and CPD?

Yes it could be, but the resource has been designed so it can be used in lots of different ways:

- **For personal CPD:** Reading and completing the tasks in a section could form the basis for a Plan and Record CPD entry. You could use your learning as evidence for CPD portfolios and examples are given at the end of each section on how you might do this.

- **Supporting you with formal post-qualification programmes:** Most post-qualification programmes about medicines will include material on patient safety. This resource will help you with the underpinning knowledge and give you ideas about practical examples you could use to support your learning.

- **For use as a tool to support group discussions:** You may have staff meetings or other informal forums where the content of the resource can form the basis of discussions about medication safety issues

- **Helping you plan the formal inclusion of medication safety within a team:** If you need to provide formal training or increase the prominence of medication safety in the roles and responsibilities of other staff, sections or sub-sections of this resource can be used to develop plans for sessions with staff on a one-to-one basis or in groups. For example you could:
  - Use the practice examples and tasks as pre-session tasks or to fuel discussions
  - Use the content to support feedback to staff on medication safety incidents
  - Copy and paste relevant content into hand-outs, newsletters or slides
**Clinical Directorate**

**Introduction**

Seven Steps to Medication Safety

–

1. July 1

(DF/YJ)

**What if I already have some experience in patient safety?**

The sections are written to differentiate **general** information about the topics from **in-depth or complex information** that may be more relevant for senior staff with a remit for ensuring medication safety as part of their role:

If you are using it to help consolidate your professional role as a pharmacist or pharmacy technician delivering patient care, focus on the text in **black**.

If you want to extend your knowledge and skills in medication safety further - for example if you are a lead for medication safety or have an operational or education and training lead role- we have highlighted more advanced elements for topics in each Section. These elements are set out in **blue** - with an italic font so you can see it if you print it in black and white. **Blue sections will also support practitioners working to meet the ACLF competencies for Patient Safety.**

As there is a lot of diversity in how the pharmacy workforce is arranged in different sectors of practice and within the same sector, **it is up to you** to decide which aspects of each section are relevant to you or a group of staff you are leading.

**How do I use this resource?**

The resource is aimed at pharmacy staff working in all sectors. However some of the information and tasks may be less relevant to where you work. If you feel a particular section or task is not relevant to your organisation, then just move on to the next section.

The sections that follow are linked to the **Seven Steps to Patient Safety**, as set out by the NPSA. Once you are clear as to what the seven steps are, how to use them and which are key to your current professional practice (see Preface section P1), you can turn to study the sections relevant to your needs. There is also a case scenario and some prompts in Preface section P2 to help you decide what you need to learn and where this can be found within the main sections.

Each section has individual learning outcomes so you can see what you might achieve and each is set out in the same way as follows:

- Brief introduction and any essential background reading to get you started
- Case studies with reflective questions
- Answers which will point you to additional resources, or to short further tasks, or help you identify further learning needs. Disagreeing with the answers may also help you consider the issues further!
- Summary and next steps for embedding your learning in your practice:
  - More things to read
  - More things you could do
  - How to use your learning as a CPD entry

The web-links used may change and if so you will need to use a search engine to find their new location. You may also find that a particular site may not be accessible where you work which you could highlight to your line manager.
Using this resource to support your professional or personal development

Learning outcomes have been given at the beginning of each section. If you use either the General Level or Advanced and Consultant Level frameworks, a suggested link to the competencies in these frameworks has been provided in Appendix 1.

Within each section we have signposted information, learning programmes and tools that can help you and the pharmacy team meet their development needs for medication safety. The main sources are relevant for all sectors of pharmacy practice:

- NPSA NRLS web-site: [www.nrls.npsa.nhs.uk](http://www.nrls.npsa.nhs.uk)
- NPCi web-site: [www.npci.org.uk](http://www.npci.org.uk). This has a section on patient safety and risk (to which you navigate via the lift). Within this are a suite of topics about medication safety and risk management. The topics are covered by webinars, case studies, quizzes and references via a library.
- CPPE: There is a CPPE resource on Risk Management ([www.cppe.man.ac.uk](http://www.cppe.man.ac.uk)) which covers many aspects of medication safety.
- UKCPA ([www.ukcpa.org.uk](http://www.ukcpa.org.uk)) has a special interest group on Medication Safety and Quality. They organise training events and network meetings and host a discussion forum that could support you in delivering medication safety.

*If you are a practitioner developing a senior lead role in medication safety you can also use this resource to support demonstration of the Foundation level from the Patient Safety Specialist working group’s Expert Practice Development Framework for Medicines Safety (draft). Further information about this is available from Jane Nicholls ([jane.nicholls@nhs.net](mailto:jane.nicholls@nhs.net)).*

At the end of each section, one idea for CPD portfolio and/or Plan and Record entries is provided to help you meet your formal CPD recording need.

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Preface: Setting the Scene

Before launching into practical aspects of improving medication safety it is important that you are aware of the background on why patient safety incidents happen and the wider patient safety agenda. These three preface sections will provide you with the background information and resources that underpin all of the patient safety developments in the NHS over the last 10 years and how the remaining sections in this resource apply these safety developments to medicines.

P.1 Overview of the Seven Steps to patient safety

One of the first publications from the NPSA to support the patient safety agenda was the Seven Steps to Patient Safety available at www.nrls.npsa.nhs.uk. The Seven Steps to Patient Safety describe the steps that NHS organisations (including contracted providers such as Community Pharmacies) need to take to improve safety. They provide a checklist to help plan activities and measure performance in patient safety.

Task: Go to the NPSA web-site and find out what the Seven Steps to patient safety are from the overview document. Available at www.nrls.npsa.nhs.uk

Following these steps will help ensure that the care provided is as safe as possible, and that when things do go wrong the right action is taken. The NPSA produced a full reference guide which examines patient safety in more detail. This is also available at www.nrls.npsa.nhs.uk

The management of patient safety is not just a linear process. The seven steps overview publication illustrates this by using the diagram below. It highlights that continuous reporting and feedback on incidents and risks will provide organisations with evidence and confidence that they are maximising safety:

![Circle of safety diagram](image-url)
P.2 Applying the Seven Steps to medication safety: contents overview

This section will help you decide which sections of this resource you might like to complete. The following example is used throughout this resource and will be expanded where relevant. You can use it here to help you consider which sections of this resource you wish to complete.

**Example in Practice:** It is brought to your attention that a patient has received the wrong dose of medication. The mistake could lead to harm or undesirable clinical outcomes. When you look back at the pharmacy records, you find out that the supply was incorrectly dispensed against the prescription. There was no evidence on the pharmacy records including the prescription itself that any intervention had been made during the supply of the medication.

**Over to you**

- **What is the error theory underpinning what I should be doing?: Section P.3:**
  - Takes you through the background to error theory
  - Connects error theory to the way that serious risks have been addressed

- **Who should I tell about this? What should I do next?: Section 1** talks about:
  - Being open and fair blame, and suggests how you find out about this in your organisation or pharmacy
  - How to address incidents with individual staff and how this ties in with national structures

And **Section 4** explains:

  - How you go about reporting this incident based on what is expected
  - The use of trigger tools and how the national data set might be used more proactively

- **Why is it my business? Section 2** explores:
  - Why pharmacy staff are integral to the success of dealing with medication incidents and what the professional expectations are for delivering safe pharmacy services
  - Embedding pharmacy roles into practice
  - If you are involved in commissioning **Section 1.3** provides information on how medication safety can be built into the commissioning process

- **Why did this incident happen? Section 6** takes you through:
  - Root Cause Analysis
  - How you can handle incidents in a logical way
Weren’t the procedures in place good enough? Section 3 explains:

- How you apply risk assessment to medication pathways
- Section 3.2 considers how this may be applied to high risk medicines and pathways
- How you might be involved in doing risk assessments yourself

Are there specific things that should be in place? Section 7 provides:

- The background to the NPSA alerts and explores how these and local medication incidents are managed in your organisation or pharmacy
- Advice for those with more experience and examines implementation of alerts in more detail

Will I need to access or provide training as a result of this incident? Section 2 gives you:

- Help in finding out more about what is available for you and your team within your organisation or pharmacy, including how to embed medication safety into your CPD
- Ideas about what you could do to support other NHS staff in sharing and learning from medication incidents

How do I explain this incident to patients or their carers or relatives? Section 5 will help you:

- Find out how to develop skills to be open about medication incidents and to listen to patients and carers
- How to become involved in working with patients or carers.
P.3 Background to error theory: understanding the causes of failure

This section will help you to find out how error theory underpins what you should be doing about medication safety. By completing this section you will be able to:

- Explain the causes of failure and the personal versus systems approaches to incidents
- Connect this theory to the outcomes from injectable route incidents

Other sections in this resource will explain in more detail what you should be doing on a day to day basis about medication safety.

In the past accident prevention has not been the focus of the NHS. The medical model within which we work has tended to focus on training and perfecting the performance of individuals (i.e. the person approach) and hence when things go wrong the focus has been on the individual incident and the person who has made the mistake.

Lucien Leape (see further reading section for reference) developed the concept of the ‘Perfection Myth’ in which it is assumed that if people try hard enough, they will not make mistakes. This is very much the ‘person approach’ and has the following features:

- Focuses on mistakes at the sharp end
- Due to mistakes in process e.g. forgetfulness
- Counter-measures include blaming
- Dominant tradition in medicine

This approach may be only too familiar to readers who have been trained in the pharmacy profession. However, work led by Lucian Leape, James Reason and others have suggested that it would be better to assume that errors and failures are inevitable and to design systems to reduce the chance of them happening.

“Human beings make mistakes because the systems, tasks and processes they work in are poorly designed” Lucian Leape

This ‘system approach’ has formed the basis of the recent work and guidance by the NPSA and has the following features:

- Humans are fallible and errors are to be expected
- Origins are higher up and are systemic factors
- Counter-measures focus on defence systems

The recent focus has been on looking at the root cause of incidents in order to identify and repair the system weaknesses. This is the “system approach”. The systems approach focuses on processes or procedures that contributed to the incident, rather than simply on the members of staff involved. That is not to say that staff are blameless and do not need to take personal responsibility for their actions. The NPSA has developed tools including a “Decision Tree” to help organisations consider personal responsibility aspects of incidents (see www.nrls.npsa.nhs.uk).
It is also important to move away from the belief that an incident might have a simple cause which, if put right, will not happen again. You might have heard about the Swiss Cheese model proposed by James Reason. He suggested that “high technology systems have many defensive layers” that protect us from incidents. An example of a defensive barrier familiar to us is the accuracy checking of a dispensed medicine before it is supplied. However these barriers may have weaknesses which Reason likened to holes in a Swiss Cheese.

Applying this model to medicines (above) it is easy to see that if one defensive layer developed a defect i.e. “a hole” (for example if a dispenser didn’t realise they inaccurately typed in the dose from a prescription), we may be protected from disaster if the incident is spotted by another barrier further in the care pathway. However if all the defences fail (for example the pharmacist or checking technician failed to spot the same mistake and the patient went on to take the wrong dose) the ‘holes’ line up, and the end result can be catastrophic.

This type of scenario was tragically illustrated by an incident where vincristine was inadvertently administered intrathecally and the patient died. As a result of this and other injectable route administration incidents, a workstream to improve the safety of injectables was undertaken by the Purchasing and Supply Agency (PASA). This included the production of a Purchasing for Safety – injectable medicines knowledge pack which provides solutions at various steps where mistakes could be made in the pathway (further information is available at http://www.pasa.nhs.uk/Knowledgepack/)

In reality there are many types of barriers: those that are relatively tangible and more difficult to ignore such as physical barriers and alarms; and those that may be more fallible such as human actions, legislation, rules and procedures, training and briefings.

From thinking about adverse events in this way it can be seen that if the barriers such as rules or procedures that exist in a process are ignored or overridden, mistakes may get through, and these can be seen as ‘active failures’. There are also ‘latent failures’ in any system or process and these could be seen as ‘holes’ which are waiting to ‘line up’ e.g. look-alike packaging.
Over to you

- Read Section 3 of ‘Organisation with a Memory’ (available at [http://www.dh.gov.uk](http://www.dh.gov.uk)): This explains in more detail the causes of failure and the factors influencing learning from failure.
- Read HSC 2008/001 Updated National Guidance on the Safe Administration of Chemotherapy and the associated NPSA RRR 2008 about using minibags to deliver vinca alkaloids. Do a spot check to see if this guidance is in action locally.

What next?

Further Reading


Using this preface section for CPD

If you have considered which aspects of the resource you need to complete, you have identified some development needs! These can be entered as separate Plan and Record CPD entries starting at “Reflection”. As you work through the sections you can complete these entries. This will help you demonstrate a progressive and structured approach to meeting your learning needs around medication safety.
Section 1: Building a culture of medication safety

This section takes you through:

* The new culture of being open and fair blame
* How you find out about how this works in your organisation or pharmacy
* How medication safety can be built into the commissioning process (Section 1.3)

By completing this section you will be able to:

√ Describe the culture of fair blame and the human factors that affect this
√ Determine how to deal with staff involved in an incident and what professional consequences there may be for them
√ Explain local infrastructure, priorities and national requirements for medication safety
√ State the national contractual structures and quality standards that exist, relating to patient safety and medicines use
√ Define how medication safety can be included in the commissioning of services
√ Access information that supports the incorporation of medication safety within service specifications and service monitoring

Other sections in this resource will explain in more detail what you should be doing on a day to day basis to underpin this new safety culture.

1.1 Fair blame and being open

Being open and fair means sharing information openly and freely and ensuring fair treatment for staff when incidents happen. This is essential for patient safety and the well-being of those who provide patient care.

In the past the NHS has dealt with patient safety incidents by apportioning blame to individual members of staff. This led to a culture where people felt unable to be open about mistakes they had made or contributed to, as they feared being punished for it. Over the last few years this approach of individual blame has been replaced by a **systems approach** to incidents (to learn more see the preface section on page 6). The reason for this change is explained nicely in the Department of Health 2004 publication “Building a Safer NHS for Patients: Improving Medication Safety”:

“Although professionals must take responsibility for their actions, blaming doctors, pharmacists or nurses for errors does not encourage a culture of reporting or learning. In order to function safely an organisation needs to understand its risks so that it can minimise them by building in defences and safeguards. These risks can only be identified if there is commitment to an open culture of reporting throughout the organisation”
As incidents happen, risks are found in the processes used to deliver patient care. These processes are examined to see what contributed to the incident, then actions are agreed to reduce the risk of it happening again.

In a culture of openness and fair blame NHS staff will be still be accountable for their actions. However, they should be treated fairly and supported when incidents happen rather than blamed. With these underpinning principles, NHS staff are collectively able to contribute to safer care by being more likely to identify and report incidents. Instilling a culture of fair blame includes the need to take account of human factors. These encompass all those factors that can influence people and their behaviour. In a work context, human factors are the environmental, organisational and job factors, Together with individual characteristics (such as attitudes and response to stressful situations) which influence behaviour at work.

Top Tip: Have a look at the Feb 2010 Human Factors campaign and guidelines at www.patientsafetyfirst.nhs.uk. There are several short WebEx sessions and a 32-page “How to Guide” that highlight the contribution human factors play in contributing to incidents.

The NHS has made significant changes to embrace openness and fair blame. However, it is important to remember that there are still punitive consequences for specific professionals who are deemed responsible for a patient safety incident. A recent example for pharmacy is the conviction of a pharmacist for a dispensing error in 2009. This was because it is still a criminal offence to make a dispensing error. This has led to the RPSGB and other bodies working with the government to move towards decriminalising dispensing errors.

Other health professions may face regulatory consequences if they admit to making a mistake. If you are trying to building a culture of openness for medication incidents with clinical staff as part of your role, you may need to be aware of these and take account of them when working with other professionals. The NPSA have produced a 19-page pack “Engaging Clinicians” containing ten resources to help patient safety leads obtain clinical engagement with building a safety culture in their organisation. This is available to download at www.nrls.npsa.nhs.uk within the resources section under Guidance.
Over to you

Having read the preceding paragraphs read the scenario provided and answer the questions below it. Possible answers are given at the end of this section but remember that for most incidents there may be several right answers!

Example in practice: A patient returns to the pharmacy clutching a box of nicorandil 20 mg. She accuses you of supplying her with the wrong medication as she usually has nicardipine 20mg. A friend of hers, who is a nurse, told her that this mistake could have made her very ill. She is very angry, hands you the box of tablets and asks you to sort this out and find out how she can claim damages! She plans to return later that afternoon and leaves before you can ask her for any more details.

When you look back at the records, you find out that the patient did indeed usually have nicardipine, but that the latest supply (corresponding with the returned box and label) was nicorandil. On retrieving the prescription, you find that the prescriber had prescribed nicardipine, hence suggesting that there has been mistake in dispensing. There was no evidence on the pharmacy record including the prescription itself about any intervention made during the supply of the medication.

- What would you do next?

- How do you think you might be feeling? Do you think these feelings would affect how you dealt with this event?

- Where do you think the mistake(s) could have been made and is individual accountability relevant?

- If the prescription had been for Nicronadil, suggesting the prescriber had made a mistake what processes would you need to consider that took place outside the pharmacy? (consider this from your own working environment i.e. a hospital outpatient clinic, ward or GP practice FP10 prescription).
What next?

Further Reading

Now you have completed this section you may be interested to learn more about how to work within openness and fair blame. If you do, there are a series of “Being Open” resources available to complete or download from the NPSA web-site:

- NPSA Being Open resources (Nov 2009): http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077
  - The relevant resources include 1 hour webinars covering:
    - The revised Being Open: what it means for clinicians
    - The facts about saying sorry: addressing barriers to being open
  - Written resources to download are also available:
    - A “Being Open” framework
    - Guidance document and supporting information
    - Being Open e-learning module split into four bite size sections

- A recent article in the Pharmaceutical Journal (Vol 284) 2/9 Jan 2010 p15-16: Available for members at www.pjonline.com describes fair blame in the pharmacy context and provides an example of how a group of pharmacies has embedded this.

- University Hospital of South Manchester NHS Foundation Trust have developed a reflective evidence tool that pharmacy and nursing staff complete following a medication error which they were directly involved in. To find out more, contact Steve Williams (Consultant Pharmacist in medication and medication safety) at steve.williams@uhsm.nhs.uk.

Practical next steps

The Human Factors “How to Guide” highlighting the contribution human factors play in contributing to incidents (available at www.patientsafetyfirst.nhs.uk) is separated into two parts.

- Have a look at Part 2: This lists seven contributing factors in many patient safety incidents.
  - How do these relate to your practice and the environment you have to work in? Are some factors more visible or more relevant than others?

- Have a look Part 1: How could you make use of these in relation to medication safety?
  - Take some time to think about the team you work with. This can be the pharmacy team or wider healthcare team. Consider whether you feel there is a culture of openness and fair blame within the team. List the things you think contribute towards and against this culture in your workplace:
    - If you can, share these with colleagues in the team and see if they agree or have additional thoughts to contribute. This could lead to a wider team discussion!
Using this section for CPD

By working through this section you will be able to record or include what you have learnt as a portfolio entry: For example you could:

- complete the further reading or practical next steps and document this
- use your written answers to the case study questions, compare these to the suggested answers and document any new development needs this identified for you.

The section could identify further learning needs that you can complete as Plan and Record CPD entries starting at “reflection”
Example in practice: some answers

What would you do next?

There should be written procedures available for you to follow that will tell you what to do. It is important that you follow these to document and refer this incident as per your employer’s policy. This will ensure the investigations into the incident support a systems approach to the incident. If after reading this, you are unaware of whether there are such procedures, please find out about this so you can use them! The next section of this resource may also help you.

How do you think you would be feeling? Do you think these feelings would affect how you dealt with this event?

Many people would feel threatened by this scenario even if you know that you are not involved in the incident itself. You may also feel angry with the patient for bringing this incident to your attention (i.e. why me?). You are likely to feel uncomfortable about taking the next steps. All of these feelings could provide a barrier for you to follow calmly the usual procedures for managing medication incidents. The “Being Open” resource in the further reading section will help you consider this issue further.

Where do you think the mistake(s) could have been made and what individual accountability might be relevant?

The obvious ones are 1) the selection of the wrong drug when dispensing the medicine and 2) the pharmacy team dispensing it failed to check this or failed to realise there was a mistake.

In the pharmacy there could be several staff involved in the checking and supply processes where an opportunity would have arisen for them to spot the mistake. Examples include
- checking the previous records of prescribed medication at part of the dispensing and clinical checking process
- routinely counselling patients when supplying new medicines as this could have highlighted the error

Video footage is not available to determine exactly what happened but a systematic analysis, including interviewing staff will be needed to consider all possible “holes in the swiss cheese” for this pathway rather than jumping to conclusions about a solution immediately.

Did you consider the processes outside of the pharmacy?

The pharmacy process should not be considered in isolation of the patient’s care pathway for accessing and receiving medicines.

The chain of events for this scenario began at the point where the decision to prescribe was made (e.g. when the patient requested the nicardipine as a repeat prescription from her GP). There will be a number of factors that contributed to the mistake and a range of steps where a mistake could have been prevented. This is true in any sector of practice and it is important that people in other parts of the pathway have an opportunity to consider what went wrong. This will ensure all points in the pathway are scrutinised for improvement to minimise future incidents. There should be information about how and when to share medication incidents with other stakeholders from within and outside the place where you work.
Section 1: Building a Culture of Medication Safety

1.2 Organisational requirements and infrastructure for medication safety

The organisation that you work for (or external organisations that deliver services on your organisation’s behalf) may have put in place an infrastructure to support the implementation of patient safety. To help organisations do this the NPSA’s *Seven Steps to Patient Safety* details actions for organisations within each step. How these steps apply to different settings has also been published (for example primary care, general practice and mental health care settings) and you may find it helpful to look at those which apply to you ([www.nrls.npsa.nhs.uk](http://www.nrls.npsa.nhs.uk)).

The following sections will help you gather information to understand how your organisation is set up to support the delivery of safer care.

1.2.1 Local infrastructure for safety

In order to deliver patient and medication safety, there will be an infrastructure within your organisation that is responsible for this. The scale of this infrastructure will vary depending on the size of the organisation.

**Top tip:** Look at the organisation’s web-site and intranet as a first step to completing these tasks. If these are unavailable or unhelpful, then try asking a senior colleague or manager.

If you are working in a hospital or a commissioning organisation, they are likely to have signed up with Patient Safety First ([www.patientsafetyfirst.nhs.uk](http://www.patientsafetyfirst.nhs.uk)) (registration required). Trust boards and healthcare organisations signing up to Patient Safety First (PSF) commit to implementing the Leadership intervention, and acute trusts commit to implementing at least one of the five clinical interventions, one of which is High Risk Medicines. The commitment includes monitoring improvement and sharing data. You can find out if your trust is signed up by checking on the PSF web-site.

**Over to you**

The following tasks will help you gather information about the infrastructure to give you an awareness of how patient and medication is managed by your organisation.

**Patient Safety**

- Within your organisation is there a named lead and/or department that leads on patient safety? If so write it down here
How does this department or lead report to the Trust Board or the organisation that commissions the services you deliver?

Are there any publications about patient safety aimed at public and staff that are published or circulated by your organisation? Does the organisation have a patient safety strategy? List the ones you find here:

If you have a lead role, make a list of all the people/post-holders who you could be linking with to implement patient safety both in your organisation and/or those whom you contract for services

Medication safety

Is there a named lead for medication safety in your organisation? If so write their name and job title here:

Is this a member of the pharmacy team?

Find out more about their roles and responsibilities:
- What is the scope of their role?
- What do they provide for Pharmacy staff and other healthcare professionals?
- How do they link with and report into the wider patient safety teams?

Top Tip: If you are the lead pharmacist for medication safety or are planning and developing this role, a summary by two pharmacists who are already doing this in their role was published in the Pharmaceutical Journal (Vol 284 2/9 Jan 2010 p17-18: Available for members at www.pjonline.com). Alternatively, find out from other trusts in your region whether they have a lead pharmacist and what their role is.
1.2.2 Local priorities for medication safety

Whether you work in a large NHS hospital, a commissioning organisation or a smaller organisation such as a GP practice or community pharmacy, it is important that you are aware of the priorities related to medication safety that exist where you work. These priorities can be influenced by the organisation that commissions or contracts services from your organisation.

Top Tip: If you are a community pharmacist your Local Pharmaceutical Committee will be able to advise you. For example they may have a lead for medication safety. They should have a web-site where you can find out more!

The following are examples of some drivers that may be relevant to your organisation’s prioritisation of medication safety:

1. **The Commissioning for Quality and Innovation payment framework** (CQuINs) links payment for commissioned services in acute, mental health, learning and disability and ambulance services to achievement of specific locally agreed quality improvement and innovation goals. From 2010, these are linked to the National Operating Framework for the NHS and some commissioner will be selecting medication-related indicators. Further information is available at: [www.dh.gov.uk](http://www.dh.gov.uk)

2. **Quality Accounts**: From April 2010 all providers of acute, mental health, learning and disability and ambulance NHS trusts will be required (by 30th June) to produce a Quality Account. This is an annual report to the public about the quality of services delivered. Organisations can select from a set of indicators for quality improvement (IQI available at the NHS Information Centre ([www.ic.nhs.uk/services/measuring-for-quality-improvement](http://www.ic.nhs.uk/services/measuring-for-quality-improvement)). Quality accounts will soon be required for all healthcare providers.

1.2.3 National requirements for medication safety

Specific requirements from the NPSA are considered in more detail in Section 7. In addition to these, organisations delivering healthcare have other standards they have to meet relating to patient safety. Medication safety forms a key part of many of these. Even though you may not directly influence these for your organisation, it is likely that procedures that you follow or audits that you are asked to complete will be a direct result of these requirements. This section provides some examples of where these standards are listed and what governance processes they fit into.

*If you are leading on medication safety for your organisation then a more in depth look at the relevant examples below might help focus your work on these requirements.*

1. **The Medicines and Healthcare products Regulatory Agency (MHRA)** is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. They have a web-site where you will find more details at [www.mhra.gov.uk](http://www.mhra.gov.uk)
2. **National contracts** for community pharmacy and GP practices (the General Medical Services contract) include requirements for embedding patient safety into the services delivered.

*If you are working in, or commissioning services from, community pharmacy or GP practices, you can find out more about the contractual requirements and service monitoring frameworks by visiting NHS Primary Care Contracting at [www.pcc.nhs.uk](http://www.pcc.nhs.uk) and the PSNC web-site at [www.psnc.org.uk](http://www.psnc.org.uk)*

3. Registration with the **Care Quality Commission** ([CQC- www.cqc.org.uk](http://www.cqc.org.uk)): The CQC is the independent regulator of health and adult social care services in England. From April 2010 (for NHS Trusts and NHS provider organisations) and from October 2010 (Independent Healthcare Providers) healthcare providers will need by law to be registered with them. Registration is likely to be extended to include prisons and community pharmacies in the future. The new arrangements will replace those detailed in “Standards for Better Health”.

There are specific compliance requirements for medicines management summarised as:

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Guidance about compliance: Essential standards of quality and safety” Outcome 9 (pages 104 to 109):

Management of medicines
People have their medicines when they need them, and in a safe way. People are given information about their medicines

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N.B. If you are working in a NHS Foundation Trust, then the regulator for your service delivery is **Monitor**. Further information about them is available [www.monitor-nhsft.gov.uk](http://www.monitor-nhsft.gov.uk)

4. **NHS Litigation Authority** requirements ([www.nhsla.com](http://www.nhsla.com)): The NHSLA works to improve risk management practices in the NHS that support reducing the potential for litigation. There is a set of risk management standards for each type of NHS organisation which incorporates organisational, clinical, and health & safety risks. These are divided into three different levels which organisations may choose to work towards. Achievement of increased levels of attainment results in financial rewards for the Trust. There are specific medicines management standards within all three levels.

**Over to you**

♦ Does your organisation (or the organisation commissioning your service) have a mission statement or list of goals that includes patient safety? *(Top tip: Look at the organisation’s web-site!)* If so write it down here:
Does your pharmacy or department have a work plan and/or strategy that is linked to the above goals? Write down how this affects your work:

- Find out if your organisation has included a safety indicator in their Quality Accounts that is directly related to, or can be linked with, medication safety. If they have, write it down here:

- Find out if your organisation (as a commissioner or provider) has a medication safety goal (CQuIN) for the current financial year. If they have, write it down here:

What next?

Further Reading

Now you have completed this section you may be interested to learn more about how your organisation is linked into national initiatives for patient and medication safety.

- **For Acute Trusts and other providers:** Patient Safety First is a campaign led by the NPSA to make the safety of patients everyone’s priority. Find out more about this and whether your organisation is signed up to it at [www.patientsafetyfirst.nhs.uk](http://www.patientsafetyfirst.nhs.uk)

- **For Community Pharmacies:** Have a look in more details at the Clinical Governance requirements in the contract within the Pharmacy Contract and Services section of the PSNC web-site: [www.psnc.org.uk](http://www.psnc.org.uk)

- **The following media links demonstrate the importance of clinical leadership for medication safety:**
  - [http://www.bbc.co.uk/news/health-10955432](http://www.bbc.co.uk/news/health-10955432)
  - [http://news.bbc.co.uk/1/hi/health/8516580.stm](http://news.bbc.co.uk/1/hi/health/8516580.stm)
Practical Next Steps

- What policies and/or procedures can you find that relate to medication safety? List them here:

- Which ones were written or led by the pharmacy team? Where did the remainder originate?

- Pick one of the policies or procedures that you think might affect how you work. Does it? And if so how?

- If you are responsible for medication safety in your Trust find out which NHSLA level your Trust has achieved and whether they are working towards a higher level. What specifications are there within the level currently achieved that relate to medication safety?

Using this section for CPD

By working through this section you will be able to record or include what you have learnt as a portfolio entry: For example you could:

- Draw a diagram showing the infrastructure for patient safety in your organisation and describe this in your own words
- Use your written answers to the tasks, and document any new development needs this identified for you.

The section could identify further learning needs that you can complete as Plan and Record CPD entries starting at “reflection”
1.3 Commissioning for medication safety

Commissioning is a cycle of activities which, in a nutshell, is an on-going process of buying in services from a range of health service providers (including GPs, dentists, community pharmacists, NHS and private hospitals, and voluntary sector organisations) to meet the health needs of local people, and monitoring how well they are being delivered.

At present commissioning is a function of PCTs and in the future there are plans for commissioning to be done by General Practice Commissioning Consortia. These will be made up of groups of GP practices that commission local services on behalf of their patients.

Hospitals commission services such as Homecare provision of medicines, while community pharmacies may subcontract (commission) enhanced services to a third party.

This section will help you to work through how to incorporate medication safety into the commissioning of services. If you are part of an organisation that delivers services the information will help you to consider how your service is linked to medication safety requirements or targets expected by the organisation commissioning that service from you.

1.3.1 National influences of commissioning for medication safety

As medicines form part of most care pathways for acute and long term conditions, it is important that all aspects of their safe use are considered when services are planned and commissioned. These include elements for:

- Safety of access (including continuity of care)
- Prescribing, including non-medical prescribing
- Procurement of medicines and medical devices
- Supply (including dispensing and Patient Group Direction use)
- Administration
- Waste disposal

For national contracts, such as the Community Pharmacy or General Medical Services (GMS), contract expectations are explicit in the contract specification documents (see Section 1.2). There is also a national contract for hospitals that includes a pharmacy section. This can be adapted to add in your local commissioner’s priorities or preferences (available at www.dh.gov.uk)

Top Tip: All healthcare providers will eventually be registered with the Care Quality Commission. Have a look at the registration requirements relating to medicines given in Outcome 9 of the “Guidance about compliance: Essential standards of quality and safety” (available at www.cqc.org.uk). Remember that NHS Foundation Trusts are regulated by Monitor and in the future Monitor will take over a role as economic regulator for all trusts: Further information about Monitor is available www.monitor-nhsft.gov.uk
If you are involved in commissioning pharmaceutical services or are interested in guidance about this as a provider, the DH 2009 publication “Primary care and Community Services: Improving Pharmaceutical Services” (available at www.dh.gov.uk) may help you consider the quality and safety aspects.

In future the commissioning of GP consortia will be overseen by the NHS Commissioning Board. As the supply and handling of medicines can be complex and may introduce risks to patients, the commissioner will need to ensure that medicines handling requirements, especially for high risk medicines (see Sections 3 and 7) are fully considered as part of the service planning, commissioning and monitoring process.

**Serious Incidents**

From April 2010 there are specific expectations for commissioning bodies detailed in the NPSA’s National Framework for Reporting & Learning from Serious Incidents Requiring Investigation (available at www.nrls.npsa.nhs.uk). These replace regional and local arrangements for dealing with serious untoward incidents (SUIs).

Commissioners need to have arrangements for the governance, reporting, investigation and action planning, learning and follow-up and media management for Serious Incidents. Within these expectations is the requirement for contracts with local healthcare provider organisations to clearly set out the provider organisation’s obligation to meet the requirements of the NPSA framework. Please see Section 7.3 for further information.

**1.3.2 Local influences on commissioning for medication safety**

When a service is commissioned locally there is usually

- A **tendering document** and/or a **service specification** that possible providers would apply to deliver.
- A **service level agreement** or **contract** once the service is awarded to a provider which the provider and commissioner sign.

Both of these documents may contain requirements about how medicines should be handled (from prescribing to disposal) and may also be explicit about the healthcare staff that are involved in the aspects of the service that involve medicines.

The commissioner may include a **performance monitoring framework** or process that requires providers to:

- Report against specific standards against the service level agreement or service specification
- Complete audits that show the safety aspects of medicines use (e.g. compliance with NPSA alerts) are being met.

To encourage providers that deliver services, commissioners could include an **incentive scheme** approach to encourage you to work and report on medication safety issues.
A recent article in Quality and Safety in Healthcare explored the development and use of 30 primary care medication error indicators in the US. They were able to categorise these into five areas:

1. Avoiding potentially inappropriate treatment
2. Avoiding potentially inappropriate dosing
3. Avoiding potential drug-drug interactions
4. Avoiding potential drug-disease interactions
5. Monitoring/preventing potential adverse drug events


Using the clinical IT systems they were able to show a reduction in the occurrence of incidents within these categories and that the organisations had a consistent approach for identifying and reporting them. Incidence avoidance was best achieved by incorporating a prompt to clinicians prior to prescribing. The approaches detailed in this article may provide you with some new ideas about how to tackle medication safety and incident monitoring in GP practices and for other prescribers.
To help you consider how medicines should be incorporated into care pathways and services you commission or deliver the following resources are available:

1. The East and South East Specialist Pharmacy Services have produced some resources (available at www.medicinesresources.nhs.uk/en/Communities/NHS/SPS-E-and-SE-England/Meds-use-and-safety/):
   - **Integrating medicines use into care pathways (2010):** This is a short document that details the options and elements you need to think about when medicines are part of a care pathway. It uses a medicines care pathway to highlight consideration of:
     - Who will decide whether a medicine is needed?
     - Who will supply the medicine?
     - How will the medicine be taken or administered?
     - How will the effects of the medicine be reviewed?

   - **Medicines in commissioning toolkit (Version 2 2009):** This toolkit uses a checklist approach based on a commissioning cycle. The toolkit will help ensure the critical factors and action points related to medicines use within the planned service are identified and addressed in good time, and that service specifications drawn up ensure that the service commissioned is safe and effective. The toolkit will also provide a starting point for commissioners monitoring existing services which involve the use of medicines.

     > In addition to the toolkit the resource appendices provide worked examples on how to use the toolkit for a warfarin monitoring and management service and a service to supply emergency hormonal contraception.

2. You may be involved in local decision making about commissioning of medicines for use in your area. As part of the decision making process, there is likely to be an emphasis on the safety of the medication both clinically and on the pathways within which it could be used. The NPC has produced a guide in 2009 “Supporting rational local decision-making about medicines (and treatments)” (available at www.npc.co.uk) that helps organisations consider all the elements needed to make a safe decision on which to base service commissioning.

3. In addition, at the time of writing this resource, the NPSA announced it is producing a commissioning toolkit to support local commissioning of anticoagulation services (www.nrfs.npsa.nhs.uk). Some of the principles in this toolkit could be extrapolated for other services.

The following tasks focus on looking at local services you commission or provide. When tackling them don’t forget to consider the national and local aspects of commissioning you have learnt about.

Over to you
Clinical Directorate

Section 1: Building a Culture of Medication Safety

Seven Steps to Medication Safety

What next?

Further Reading

- Department of Health World Class Commissioning (WCC) Competencies (2007) www.dh.gov.uk. These can be interpreted to include medicines issues in commissioning capability. Even though WCC is now extant, the principles underpinning commissioning competency are still useful.

- Healthcare for London (2008) “Guide for commissioning pharmacy services for polyclinics in London”: The toolkit provides a structured way to think about pharmacy services, the role of pharmacy in delivering a core service and the potential pharmacy has to provide a wider range of clinical services.
Practical Next Steps

- Choose a service that you are commissioning or delivering in a pharmacy (via secondary or primary care).

- Is there a formal contract and service specification? If you find one, write down where/how you found it.

- Are there standards or requirements within the service specification or contract that details safe medicines handling by the service?

- Are there details given about how the service will be monitored?

- Write down what you could do/have done to ensure that the risks related to medicines are identified and minimised.

Using this section for CPD

By working through this section you will be able to record or include what you have learnt as a portfolio entry: For example you could:

- Write down a reflective account of what you have learnt about medication safety in commissioning and how your local PCT includes this in their processes and service documentation.
- Print off the front cover of one of the resources you have accessed for this section. On the reverse side make a note of how you apply this resource in your practice.

The section could identify further learning needs that you can complete as Plan and Record CPD entries starting at “reflection”
Example in Practice: Some answers

What mechanisms for medication supply and administration could the service use?

Prescribing using independent prescribers or Patient Group Directions (PGDs). To help you work out whether a PGD will apply in this service the following resources “So you think you need a PGD (July 2007) including an algorithm “To PGD or not PGD” are available at [http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/](http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/)

List these in order of risk (highest first):

PGDs are an inherently higher risk. Local PGD development can be complex, it requires professional input from several people with individual professional accountability, and there are several points in the pathway of using PGDs where errors could occur! For example the PGDs need to be regularly reviewed and there is a risk of using out of date documentation; the training of staff used to supply the medicines is less rigorously defined; and the supply itself is difficult to audit. There is a web-site dedicated to PGDs available at: [http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/](http://www.medicinesresources.nhs.uk/en/Communities/NHS/PGDs/)

Prescribing is only possible by doctors or non-medical prescribers who are registered to prescribe independently and have completed additional qualifications that are annotated onto their regulator’s professional register. There may be some risks in capability/competence but the accountability rests with the individual prescriber via their own professional responsibilities for patient care and the supply is relatively easy to audit.

Who would you include as the healthcare professional(s) that could:

- a) complete the risk assessment to identify appropriate patients
- b) administer the vaccine to the patient

As both actions will result in a medicine being administered to a patient then using professionally registered health professionals such as pharmacists, nurses and registered pharmacy technicians (under the supervision of a pharmacist) will minimise clinical risks.

All staff involved in these aspects will need to complete appropriate competence-based training to ensure they are able to deliver the care safely.

Are there any additional safety considerations you would need to consider?

Procurement: Avoid too many brands that have different administration requirement; Storage of the vaccine (see NPSA Alert on Vaccine Cold Storage Jan 2010 at [www.nrsls.npsa.nhs.uk](http://www.nrsls.npsa.nhs.uk)); training requirements; arrangements for treatment of anaphylaxis; follow-up arrangements if the vaccine requires more than one dose (recording of patient lost to follow-up); Standard Operating Procedures that the provider has to develop and maintain; Communication of vaccination details to patient’s GP. Patient information material for the risk assessment and treatment elements including obtaining and documenting consent.

What could you include in a performance framework against the service specification and delivery?

Details on number of patients risk assessed and vaccinated; % Patients that completed vaccination programme who received the first dose; patient evaluation of service e.g. via questionnaire; submission of annual training records; copy of fridge temperature management protocols and outcomes.
Section 2: Leading and supporting staff

Pharmacy staff responsibilities as leaders for medication safety

This section:
* Gives you ideas about what you could do to support yourself and other NHS staff in sharing and learning from medication incidents
* Helps you find out more about what is available to you and your team within your organisation or pharmacy

By completing this section you will be able to:
- Describe what is in place to support pharmacy staff as leaders in medication safety
- Determine whether your organisation has the building blocks for safe medicines handling
- Influence other health professionals in delivering safer medicines use
- Strengthen your role and the roles of other pharmacy staff in training other health professionals in medication safety
- List the elements that contribute to the delivery of a safe pharmacy service
- Introduce medication safety objectives into pharmacy staff development and appraisals

Other sections in this resource will explain in more detail what you should be doing on a day to day basis to underpin this new safety culture.

By the very nature of their role in healthcare, pharmacy staff are now nationally recognised as leaders in the delivery of safer care with medicines. This section covers examples of where expectations of pharmacy have been published. It will then guide you in finding out about how pharmacy staff where you work are directly involved in supporting this both within the department (internal aspects) and for the wider healthcare team (external aspects).

2.1 Expectation of pharmacy as a profession

The leadership of pharmacy to deliver medication safety was mentioned in the 2008 White Paper “Pharmacy in England: Building on strengths – delivering the future”:

“The Government believes there is still a considerable way to go to improve understanding and knowledge of how providers of pharmaceutical services can contribute even more to everyone’s health and wellbeing. Further improvements would include: improving patient safety in hospitals and in the community through pharmacy’s leadership on the safe and effective use of medicines”
The RPSGB as the professional body for pharmacy considered the role of the profession in more detail as a direct result of the White Paper's aspirations. They produced a report in 2009 that examined the current state of knowledge about medication safety in the UK and considered the role of the professional body for pharmacy working across Great Britain in improving medicines safety. The report listed 17 recommendations detailing the leadership and strategic support the RPSGB should provide on behalf of and with the profession. The report “The Contribution of Pharmacy to making Britain a Safer Place to Take Medicines” can be viewed at www.rpsgb.org

“Building a Safer NHS for Patients: Improving Medication Safety” set the scene for NHS organisations to deliver medication safety in 2004. The box below describes for organisations what needs to be in place. These principles can be extended to all providers of care and the pharmacy team is generally tasked with leading on implementation of these.

**PCT and NHS Trust boards should ensure that local strategies are in place, including:**
- Systems for reporting and learning from medication errors
- Building error traps into medication processes
- Education and training for medication safety
- Improved communications at the interface
- Implementation of IM&T solutions
- Formal structures for managing medication safety
- Specific measures in high risk areas

*(Department of Health. 2004 Building a Safer NHS for Patients: Improving Medication Safety)*

What standards can pharmacy staff use to support medication safety?

To support this leadership at an operational level you will need professional guidance and information about what is best practice in terms of medication safety and also how to measure that this is met. There are some standards and guidance that exist to support pharmacy staff in delivering leadership in medication safety. Some examples that are available are listed below:

*These examples are key reference sources for pharmacists or pharmacy technicians leading on medication safety. The information held within them will help you determine whether your organisation has the building blocks of safe medicines handling in place.*

- “The safe and secure handling of medicines: a team approach” RPSGB March 2005:
  The guidance (replacing the 1988 Duthie Report) is intended to serve as a useful resource for those developing policy and guidelines for good practice on the safe handling and security of medicines in NHS hospitals and community healthcare settings. However the principles equally apply to other environments where medicines are handled such as Care Homes and Community Pharmacies.

- The Medicines and Healthcare products Regulatory Agency (MHRA) is the government agency responsible for ensuring that medicines and medical devices work, and are acceptably safe. There is a page for pharmacists that includes guidance, safety alerts and links to educational material to assist in the safe use and management of medicines and medical devices. The web-site is available at www.mhra.gov.uk.
Safer management of Controlled Drugs (CDs): Revised regulations and guidance on the handling of CDs have been introduced since 2006. These can be viewed at www.dh.gov.uk/controlleddrugs. Guidance has also been produced by the National Prescribing Centre (www.npc.co.uk).

Over to you

♦ Read Section 4 of “The safe and secure handling of medicines: a team approach” (www.rpsgb.org). Consider which elements in the medicines trail you are directly involved with in your day to day work.

♦ Which of the elements you are involved in are influenced by policies and processes led by the pharmacy team?

♦ Choose a discrete storage area in the pharmacy or in the care areas where you work and consider what changes you could implement to reduce stock selection error.
2.2 External aspects: instilling safe medication practice in others

This section, via a series of suggested tasks and information resources, helps you to find out how the pharmacy team influence medication safety in areas outside the pharmacy or directly delivered pharmacy services. It encompasses pharmacy’s (and pharmacist/pharmacy technician) responsibility to encourage a medication safety culture in other health professionals and to support patients directly in using and storing their medicines safely.

As a senior member of the pharmacy team or a leader for patient safety you may be involved in developing or contributing to an induction package that includes medication safety. The scope of this will depend on the type of staff who will access it (small pharmacy team vs. wider staff groups). By working through the sections in this resource you will be able to note the essential elements that an induction about medication safety could contain for both the pharmacy team and other staff groups within the organisation.

An NPSA resource about engaging clinicians is available at www.nrls.npsa.nhs.uk. This pack was developed to help NHS staff raise awareness in their organisation about:

• patient safety;
• the importance of reporting incidents;
• the benefits of sharing resources to improve patient safety

They have also published a specific training package for medical foundation training (i.e. F1/2 doctors) called “Safe Foundations” which you could use and adapt for other healthcare professionals.

**Top Tip**: Stuck for ideas about where to start? Why not contact a medication safety lead from another pharmacy team in your area or your local LPC or NPA lead? These may have resources or contacts they are willing to share.

**Over to you**

- Find out about pharmacy representation on multidisciplinary committees within and outside your organisation. E.g. Drug and Therapeutics or Medicines Management Committee, Area Prescribing Committee, Trust Safety Board, Health Partnership Boards, Clinical Networks, Practice Based Commissioning (PBC) groups
  - For one of these committees, who is the representative for pharmacy? Ask them how they influence medication safety as part of their contribution?
  - Alternatively look at the Terms of Reference. Is safety explicitly mentioned? If not can you identify any links to this yourself?
What other healthcare professionals do your pharmacy team come into contact with as part of the services they deliver? How do they influence them to improve and raise awareness of medication safety? Consider this in terms of:
- The role you or your team have in supporting the delivery of care by others
- Formal education and training support you or your team provide to others

Consider an aspect of your day to day work. What opportunities are there to influence and raise awareness of medication safety issues with other healthcare staff?

How do you think you or the pharmacy teams you work with or commission help to reduce the risks caused by medicines when in direct contact with patients?

You or the pharmacy team may also be involved in providing training on medication safety to other health professionals. Try and find out about what is delivered by the pharmacy team. List here the training you and others deliver:

Are you able to support this by raising awareness of this training to healthcare staff you come into contact with?

Are there barriers to developing and delivering training on medication safety to them? How could these be overcome?

Is a formal evaluation of the training provided by the pharmacy team conducted routinely? Could you contribute to this for the healthcare staff you work with, thus providing feedback to the pharmacy team directly?

Is feedback on medication incidents provided to other healthcare staff/teams that you come into contact with where the incident is relevant to them?

Think about a medication safety initiative you have been involved in implementing. What tactics did you use to engage staff outwith pharmacy? What have you learnt as a result and what might you do differently next time?
2.3 Internal aspects: Assuring pharmacy services are safe

This section is about “getting your own house in order” and considers the aspects of assuring and improving medication safety that are directly delivered by your pharmacy team. These are services relating to the supply of medicines and the clinical pharmacy aspects of care.

Medication safety sits within the wider framework of clinical governance. You can see how this fits in with pharmacy practice using the following headings:

- Accountability
- Audit
- Clinical effectiveness
- Continuing professional development
- Patient and public involvement
- Remediying underperformance
- Risk management
- Staff management

Should any of these fail, then the framework breaks down, leading to increased risk of incidents and patient harm from medicines. You can find out more about these in the current RPSGB Medicines and Ethics in Practice Guide (available at www.rpsgb.org). There is also a comprehensive area on the RPSGB web-site devoted to clinical governance in pharmacy (http://www.rpsgb.org/registrationandsupport/clinicalgovernance/).

Practical examples showing you how to improve safety in pharmacy premises and other environments relating to the preparation and supply of medicines (for example GP dispensing doctor practices) are provided in the NPSA publication “Design for Patient Safety: A guide to the design of the dispensing environment (2007)” which is available at www.nrls.npsa.nhs.uk.

In addition to safer premises and working environments, there have been new regulatory requirements for pharmacies and pharmacy staff to operate under written standard operating procedures (SOPs) in all sectors of pharmacy practice. The SOPs cover the dispensing process (from the time a prescription is received by the pharmacy or pharmacist) including the transfer of prescribed items to patients. They describe what should be done, where, when and by whom. The benefits of SOPs are given in the box below:

<table>
<thead>
<tr>
<th>Standard operating procedures:</th>
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<tr>
<td>help to assure the quality and consistency of the service;</td>
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<td>help to ensure that good practice is achieved at all times;</td>
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<tr>
<td>provide an opportunity to fully utilise the expertise of all members of the pharmacy team;</td>
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<td>enable pharmacists to delegate and may free up time for other activities;</td>
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<tr>
<td>help to avoid confusion over who does what (role clarification);</td>
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<tr>
<td>provide advice and guidance to locums and part-time staff;</td>
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<tr>
<td>are useful tools for training new members of staff;</td>
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<tr>
<td>provide a contribution to the audit process.</td>
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</tbody>
</table>

RPSGB Nov 2007 “Developing and implementing standard operating procedures for dispensing”
Over to you

**Example in Practice:** A patient comes to the pharmacy clutching a box of nicorandil 20 mg. She accuses you of supplying her with the wrong medication as she usually has nicardipine 20 mg. A friend of hers, who is a nurse, told her that this mistake could have made her very ill. She is very angry, hands you the box of tablets and asks you to sort this out and find out how she can claim damages! She plans to return later that afternoon and leaves before you can ask her for any more details.

When you look back at the records, you find out that the patient did indeed usually have nicardipine, but that the latest supply (corresponding with the returned box and label) was nicorandil. On retrieving the prescription, you find that the prescriber had prescribed nicardipine, hence suggesting a mistake has been made in dispensing. There was no evidence on the pharmacy record including the prescription itself about any intervention made during the supply of the medication.

The patient returns a few moments later and says “….and when I come back, I want to know about how you are supposed to work and what should have stopped this happening and who was in charge when you made the mistake!”

- List any standard operating procedures you would expect to be relevant to this scenario
- How could you show the patient whether the staff involved routinely use these procedures?
- Who would have been “in charge” at the time of the incident and how is this recorded?
- What other procedures might need to be followed that will also be relevant for the answer to the patient’s information request?
- Who else might want this information as well as the patient?
How could you audit dispensing services to examine the risk of adverse incidents?

- Find out what studies currently exist on the incidence of dispensing incidents. Look at your local data and compare this data with the prescribing data in the same sector of practice.

What Next?

Further Reading

- For Acute Trusts and other providers: In the NHS Outcomes Framework (2010) there are indicators relating to patient safety. Can you find these? Have these been met by your Trust or the Trust you commission services from?

- All Sectors:
  - The Department of Health has published a guidance document that provides best practice guidance on the design and layout of pharmacy and radiopharmacy facilities in hospitals [www.publications.spaceforhealth.nhs.uk](http://www.publications.spaceforhealth.nhs.uk) (registration required). Although the scope of the guidance is for hospitals, some of the principles within the document are equally relevant for other sectors of pharmacy practice such as community pharmacies and prisons.

Practical Next Steps

- Arrange for the collection of all incident data in a distinct area of pharmacy practice over an agreed period of time (e.g. dispensary, ward, production). Look at incidents that were detected both before and after they reached the patient then:
  - Write down some actions that you think might reduce the risk of these incidents happening again.
Look for evidence that the change will produce benefit in the available literature or online.
Find out from colleagues whether any of the actions you listed have been considered or implemented.

- Complete an audit of medicines storage either within the pharmacy you work in or in an area where you deliver or commission pharmacy services (e.g. ward, GP practice, care home, prison). To help you consider whether standards are being met, there are some useful resources that can help you (accessed July 2013):
  - Royal Pharmaceutical Society Quick Reference Guide to the safe custody of controlled drugs [link]
  - Royal Pharmaceutical Society. Safe and Secure handling of Medicines: A Team Approach (2005) [link]
  - Principles For Auditing The Safe And Secure Handling Of Medicines In Community Clinics And Other PCT Premises (2007) [link]
  - Audit tool for the safe and secure handling of medicines in prisons (2006) [link]

Using this Section for CPD

By working through this section you will be able to record how you have applied your learning as a portfolio entry: For example you could:
  - Complete the practical next steps and include the outcomes of the audit (e.g. an action plan)
  - Include a written summary of what you have found out about internal and external aspects of medicines safety relevant to your role.
Example in Practice: Some answers

List any standard operating procedures you would expect to be relevant to this scenario?

These may include: Dispensing and checking of the dispensed item; bagging and storage of the prepared medication; handing out procedures to the patient or the patient representative; filing of the prescription; receiving and storing medicines into the pharmacy;

How could you show the patient whether the staff involved routinely use these procedures?

You should be able to explain to the patient that the SOPs should include a section for staff to sign as a declaration that they have read the SOP, are competent to use it and agree to do so. A training record where specific training has been completed for the procedures within the SOP should also be documented. This training record can also form part of staff appraisals. If you do this then the appraisal process can also form part of the explanation you provide to the patient about how you assure the quality and accuracy of the service you provide.

Who would have been “in charge” at the time of the incident and how is this recorded?

The responsible pharmacist legislation now requires documentation of who is accountable for procedures in the pharmacy. You should have documented information about who was the responsible pharmacist on duty at the time the medicine was prepared and supplied to the patient. You can find out more about the responsible pharmacist requirements at www.rpsgb.org.

What other procedures might need to be followed that will also be relevant for the answer to the patient’s information request?

You may have to formally report the incident to another department within the organisation (see section 1 section 1.2.3 and ideally it should be reported to the NPSA (see section 4 of this resource). The patient should be told about these procedures as well as how this will impact on the error and process review that will be undertaken.

Who else might want this information as well as the patient?

The PCT might require copies of incidents as part of your service delivery or monitoring. Should this incident reach the regulator, the SOPs and incident reporting processes will also be needed.

How could you audit dispensing services to establish the risk of errors?

Auditing of near misses, interventions as part of the dispensing process and (for hospitals and nursing homes) an audit of missed or delayed doses due to supply delays are three examples.
2.4 Developing the pharmacy team in medication safety

Training and professional development is an essential part of ensuring you and the pharmacy and healthcare staff you work with are able to deliver care safely within an overall culture of patient safety.

The following sections will help you identify what is available within your organisation and department and how you can access this. It will help you come up with ideas about how you can incorporate medication safety training into your own practice and personal development, and how you can share this learning with other members of the pharmacy team.

If you manage a service or group of staff, they will also help you identify where you can incorporate medication safety training within their CPD and Personal Development Reviews (PDR).

What is available in your organisation?

To establish a clear focus of patient safety throughout your organisation, the NPSA advises that organisations should:

“Build patient safety into the training programmes for all your staff and ensure this training is accessible and measure its effectiveness”. NPSA “Seven Steps to Patient Safety (Overview)”

If your organisation has embedded a culture of patient safety (see Section 1 to find out more about this), there is likely to be patient safety training included as part of staff induction programmes and mandatory or optional programmes. These may be available “in-house” or some of these may be provided by a local university or further education provider.

List here any patient or medication safety training you completed at induction and in the past 2 years. Do these cover the aspects of medication safety you need to apply to your practice?

Top Tip: Not had any training? Are there gaps and you want to find out what’s available? Has a new induction programme been developed since you joined that could have useful patient safety content? Check your organisation’s intranet or ask your education and training lead or your manager.

What is available for the pharmacy team?

In addition to the training you can access or deliver as part of the wider organisational programmes, there may be internal departmental processes and opportunities for training in medication safety. Examples include:

- Team meetings where pharmacy and/or organisational updates on patient or medication safety are shared. These could include feedback on NPSA alert
implementation, safety audits and reporting information, actions and outcomes from actual medication incidents.

- Access to formal modules aimed at pharmacy staff provided by external providers, such as elements within formal post-graduate training delivered via universities, or
- Programmes/events delivered by local and regional NHS pharmacy training and education teams and clinical pharmacy networks.

How are you contributing to this training activity? How are you using these opportunities to support your practice or personal development? If these are not available but you think they would be useful, who could you approach to share your ideas?

Providing opportunities such as those stated above create a team approach to medication safety and will assist you in embedding improved safety rather than relying on policy and procedure publication and circulation alone. They can provide you with “on the ground” feedback on how new procedures are working and how they could be improved.

As a manager or lead on medication safety, a review of communication and meeting opportunities available routinely for the pharmacy team could help you re-structure these to include a focus on medication safety in a regular way as a core agenda item.

**Top Tip: Stuck for ideas about where to start? Why not choose a straightforward intervention or dispensing near miss to discuss at the next staff meeting? Or you could identify a journal, newspaper or newsletter article about medication safety that could stimulate some discussions. Resources and presentations shared from the East and South East England clinical pharmacy network meetings could also be useful. These are available at http://www.medicinesresources.nhs.uk/en/Communities/NHS/SPS-E-and-SE-England/**

In learning and sharing the outcomes of serious medication incidents a more formal communication strategy with the pharmacy team is required. The NPSA Serious Incident Reporting and Learning Framework (SIRL) published in April 2010 (available at www.nrls.npsa.nhs.uk) provides detailed information about this and has a useful summary of points about dissemination of learning from a serious incident that could also be applied for less serious ones!

**Including medication safety in personal development plans and reviews**

You need to link the team approach to training in medication safety to your personal CPD and to your employer’s personal development processes.

Whether you want ideas about how to incorporate this yourself or whether you need to develop personal development plans (PDPs) to include medication safety for other staff, this section provides you with information about how to do this.

If you are working directly for the NHS, the knowledge and skills framework (KSF) is used by all staff. It defines and describes the knowledge and skills which NHS staff must apply in order to deliver quality services. NHS organisations use this KSF to underpin annual review and objective setting.
processes for staff such as personal development reviews and plans (PDPs). The full KSF document is available at www.dh.gov.uk. Details of the content and scope of dimension 3 at each of the 4 levels of practice is given in the box overleaf:

The following are examples of competencies and frameworks that include aspects of patient and medication safety that you could use to operationalise the KSF for your role:

The Competency Development and Evaluation Group (www.codeg.org) have developed frameworks that can be used by pharmacy staff in primary care, secondary care and community pharmacy. You can use these frameworks to consider the skills and knowledge you need to incorporate medication safety in your day to day practice:

- General Level Competency Framework for pharmacists delivering core pharmacy services. This contains competencies within the management and organisation cluster relating to clinical governance, and risk management.
- A competency framework for pharmacy technicians delivering medicines management roles. This contains competencies within the management and organisation cluster relating to clinical governance, and risk management.
- Advanced and Consultant level framework adopted by the Dept of Health in 2005 as the framework underpinning development of consultant pharmacists and adapted for developing pharmacists with a special interest development. The framework can be used by pharmacists delivering care at a senior clinical or managerial level in general care or specialist areas. There is a clinical governance competency within the leadership cluster and a managing risk competency within the management cluster.
- If you are interested in developing yourself as an Advanced Practitioner in medication safety, the UKCPA (www.ukcpa.org.uk) has a special interest group on Medication Safety and Quality. This group is developing a curriculum for medication safety based on the expert practice competency in the CoDEG Advanced and Consultant Level Competency Framework.

You can choose which of these frameworks is the most relevant for linking to your CPD or your employer may have a preference or a mandatory process. Whichever approach is used, the competencies for medication safety can be used as part of a portfolio of evidence and objective setting and learning needs analysis for your own practice.
Over to you

Example in Practice: A patient comes into the pharmacy clutching a box of nicorandil 20 mg. She accuses you of supplying her with the wrong medication as she usually has nicardipine 20mg. A friend of hers, who is a nurse, told her that this mistake could have made her very ill. She is very angry, hands you the box of tablets and asks you to sort this out and find out how she can claim damages! She plans to return later that afternoon and leaves before you can ask her for any more details.

When you look back at your records, you find out that the patient did indeed usually have nicardipine, but that the latest supply (corresponding with the returned box and label) was nicorandil. On retrieving the prescription, you find that the prescriber had prescribed nicardipine, hence suggesting a mistake in dispensing. There was no evidence on the Pharmacy Record including the prescription itself about any intervention made during the supply of the medication.

The Root Cause Analysis outcomes of this showed that:

- The initial error was caused by the incorrect item being dispensed on an ongoing or repeat prescription. The dispensing process did not have sufficient checks prior to the prescription being handed to the patient.

- Pharmacy staff were not routinely following the SOPs for checking dispensed items against the prescription and the PMR. These flaws occurred at the dispensing as well as the checking phase of the supply process.

- Pharmacy staff did not follow the SOP for handing out medicines which includes checking the medicine with the patient prior to supply.

- What training needs would you include in the action plan?

- How could these training needs be met for the different types of pharmacy staff?

- How could you incorporate this training as part of the pharmacy team induction and/or PDPs?
How to include medication safety in the PDP of your pharmacy staff:

1. **Consider which competency framework you are going to use for different staff groups/grades.**
2. **Identify the competencies relating to medication safety that could apply to some or all pharmacy staff groups/grades.**
3. **Provide some examples of evidence that staff could include in their CPD record.** For example, completion of training (e.g., sections from this development resource!) or evaluation of training they have delivered/developed; records of medication incidents and near misses; audits relating to practice (e.g., NPSA alert implementation or audits against policies/SOPs);
4. **Integrate this into the PDP process by liaising with senior managers and providing PDP reviewers with some options for medication safety elements for PDPs for objective setting and CPD planning.**
5. **Use the PDP process with individual staff members to refine the development plan and objectives that fit best with their role.** It is likely that as a PDP covers the whole of their role, unless they are developing themselves as advanced practitioners in medication safety, only one objective a year will be achievable for medication safety!

**What Next?**

**Further Reading**

- NHS Employers healthy workplaces shared learning: The KSF and patient safety ([www.nhsemployers.org/SharedLearning/Pages/TheKSFAndPatientSafety.aspx](http://www.nhsemployers.org/SharedLearning/Pages/TheKSFAndPatientSafety.aspx)). This describes an initiative to link the KSF formally to patient safety and integrate this into the appraisal process at the Luton and Dunstable Hospital

**Development of clinical leadership is highlighted in the following information:**

- Clinical leadership initiatives being developed by PCTs and successor organisations ([http://www.nhsleadership.org.uk/workstreams-clinical.asp](http://www.nhsleadership.org.uk/workstreams-clinical.asp))

**Practical Next Steps**

- Identify a recent medication incident. Ask to contribute to a clinical or staff meeting to share the details of this and ask the group to discuss the findings and training needs this may highlight. This will help promote the use of feedback on incidents as a learning mechanism.

- **Complete a formal review of staff meeting opportunities and formal training programmes available for pharmacy staff on medication safety:**
  - What is currently accessed by which staff?
  - How could these be improved or contain a greater focus on medication safety that involves feedback from staff?
  - List those that could be formally linked to PDRs and objectives.
  - Is medication safety implementation a core part of all pharmacy team roles and job descriptions?
Using this Section for CPD

By working through this section you will be able to record or include what you have learnt as a portfolio entry: For example you could:

- Use next feedback event for staff or other source where you found out about a medication error/incident as an opportunity for a CPD entry. This incident may not only lead to CPD on incidents in general but also trigger learning about the process or clinical topic relating to the incident.
- Identify a learning programme from one of the examples listed in this section. Complete this and document the learning and how you applied it as a CPD entry.

The section could identify further learning needs that you can complete as Plan and Record CPD entries starting at “reflection”.

Example in Practice: case scenario: some answers

What training needs would you include in the action plan?

Training is needed for the team of staff involved in the prescribing of continuing medication (i.e. repeat prescriptions or continuation of in-patient or out-patient prescriptions).

Within the pharmacy dispensing and supply processes, the root cause analysis (RCA) showed the need for further training to reinforce the requirements in the SOPs. This training may highlight flaws in the SOPs which could stimulate a review.

How could these training needs be met for the different pharmacy staff?

In a pharmacy environment training all grades of pharmacy staff together will support the review of the SOP from everyone that may have an involvement in following them. Concerns with individuals should be managed separately as part of a PDP process. You could include pre-session learning/reading and post learning activities to provide relevance for specific staff roles.

How could you incorporate this training as part of the pharmacy staff induction and/or PDPs?

You would need to review how the PDP process works for the staff involved and incorporate the above training into their next individual review and objectives. This will also provide you and them with the opportunity to discuss their individual roles in the prescribing or dispensing pathway pertinent to this incident.
Section 3: Integrating your own risk management activity

Incorporating risk assessment into your pharmacy practice

This section:
* Explains how you apply risk assessment to medication pathways as support for minimising incidents
* Considers how this may be applied to high risk medicines and pathways (section 3.2).

By completing this section you will be able to:

√ Explain the principles of risk management
√ *Contribute to risk assessments within your organisation*
√ Discuss methods of managing and minimising risks in medicines management within your everyday work situations
√ *Generate priorities for medication risk management and use these proactively*

Other sections in this resource will explain in more detail what you should be doing on a day to day basis in response to identified risks related to medicines and how to reduce those risks.

This section will help you, the practitioner, integrate risk assessment into your own practice.

One of the principal roles of pharmacists as individuals is to monitor the activities of others, for example to monitor prescriptions. In many ways as pharmacists we act as barriers to adverse events or to use the Theory of Reason, we act as a slice of cheese (see Preface Section P1.) However we also need to be monitoring and risk assessing our own activities and reducing the possibilities of something going wrong.

3.1 What is risk assessment?

“A risk assessment is simply a careful examination of what, in your work, could cause harm to people, so that you can weigh up whether you have taken enough precautions or should do more to prevent harm. Workers and patients have a right to be protected from harm caused by a failure to take reasonable control measures”.

*Health and Safety Executive “Five steps to risk assessment”*

When thinking about your risk assessment, remember:

- **a hazard** is anything that may cause harm, such as chemicals, electricity, working from ladders, an open drawer etc;
- **the risk** is the chance, high or low, that somebody could be harmed by these and other hazards, together with an indication of how serious the harm could be
The best way to learn about risk assessment is to read the booklet produced by the NPSA “Healthcare risk assessment made easy” (www.nrls.npsa.nhs.uk/resources/patient-safety-topics/risk-assessment-management/?locale=en). This explains how to complete risk assessment using five simple steps:

1. Identify the hazards (what can go wrong?)
2. Decide who might be harmed and how (what can go wrong? who is exposed to the hazard?)
3. Evaluate the risks (how bad? how often?) and decide on the precautions (is there a need for further action?)
4. Record your findings, proposed action and identify who will lead on what action. Record the date of implementation.
5. Review your assessment and update if necessary.

**Identifying hazards**
You may identify hazards from simply making observations in the workplace and consulting others. Hazards may also be identified from incidents that have happened or near-misses that have been reported. Further information about reporting medication incidents can be found in Section 4.

**Evaluate the risk**
To help you meet step 3 of the process, there is a Risk Matrix within the NPSA booklet that helps you to consider how high risk an issue you identify is. It is reproduced below:

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<tr>
<th>Consequence</th>
<th>Catastrophic</th>
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<th>Moderate</th>
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**Consequence** – For example catastrophic means death or debilitating permanent injury and minor means requiring first aid.

**Likelihood** – This must be estimated over a stated period or related to a given activity.

Recording risks

What is an acceptable level of risk? It is often hard to judge the level of risk that can be tolerated. This is because the existing risk of harm is balanced against the potential benefit of change and the cost of that change. It is reasonable to accept a level of risk and do nothing, if the risk from all the other alternatives is even greater. An existing risk is not acceptable if there is a reasonable and, it could be argued, affordable alternative that offers the same benefit but reduces the risk. Acceptable risk may become unacceptable over time or because circumstances change. It is best to use your organisation’s approved risk assessment forms but as not all organisations have developed risk assessment forms, model forms are provided on the National Patient Safety Agency’s website (www.nrls.npsa.nhs.uk).

Risk register

Residual risk is one that cannot be addressed immediately and may need to go in the departmental and/or organisational risk register.

If you are a senior pharmacist involved in medication safety you will need to have a good understanding of how your organisation completes risk assessments, how risks get on to the risk register and how such risks are managed.

Top Tip: The NPSA have published some useful resources that your Trust may have used to support this. These are available at http://www.nrls.npsa.nhs.uk/resources/patient-safety-topics/risk-assessment-management/?locale=en

A more comprehensive approach to risk assessment is the Failure Mode and Effects Analysis (FMEA) method. It has been used by the military and aerospace industries for over 70 years. A successful FMEA activity helps a team to identify potential failure modes based on past experience with similar products or processes, enabling the team to design those failures out of the system with the minimum of effort and resource expenditure, thereby reducing development time and costs. Failure modes are any defects in a process, design, or item, especially those that affect the customer, and can be potential or actual. Effects analysis refers to studying the consequences of those failures. There is a dedicated web-site for FMEA available at www.fmeainfocentre.com

Over to you

Consider the scenarios below and complete the answers to the one which relates most to your practice:
Example in practice 1: Dispensing risk assessment:
A patient brings in a prescription for 28 Nicardipine 20mg tablets for you to dispense and supply. There is a standard operating procedure for the dispensing and handing out processes. You have signed up to following these.

You decide to complete a risk assessment of the dispensing process using this prescription as an example.

Example in practice 2: Patient Group Direction (PGD) Supply
You are delivering/commissioning/developing a service where trimethoprim 200mg x 6 tablets can be supplied under a PGD. The PGD is being used by nurses and pharmacists as part of a minor ailments service being delivered by GP practices and community pharmacies and primary care centres in your area.

You decide to complete a risk assessment of the PGD supply process.

- What can go wrong?

- Who might be harmed and how?

- Evaluate the risks you identified above: How bad would the harm be and how often is this likely to happen? (Top tip: use the grid on the NPSA Risk Matrix to help you grade the risks)

- What actions are or could be taken to reduce or minimise these risks?

- Compare and contrast the risks vs. the benefits of supply using a PGD versus a qualified non-medical prescriber

What next?

Further Reading

- The Health and Safety Executive web-site has information on risk assessment: www.hse.gov.uk/contact/faqs/riskassess.htm

- NPSA Alert 20: Promoting safer use of injectable drugs has a suite of resources that could be applied or adapted for other risks: www.nrls.npsa.nhs.uk
NPCi resources on Risk Management: (www.npci.org.uk): If you use the lift to navigate to the Patient Safety and Risk section, you will discover a series of learning resources about “Reducing risk” (each taking about 15 minutes to complete).

CPPE resource on Risk Management (www.cppe.man.ac.uk): This pack contains sections on identifying risk and risk assessment and minimising risk.


Pathways for Medication Safety (www.medpathways.info/medpathways_app/index.jsp): This project comprises a set of tools which includes a risk assessment tool for pharmacists.

Practical next steps

- Risk Management Structures: Find out if your organisation has a Risk Register. Write down where this is located and the date of the version you have found:

- Are there medicines-related risks listed in it? If so list them here:

- Find out how your organisation completes a formal risk assessment:
  - Is there a risk assessment form
  - Is there an action plan for managing the risks?
  - Are any medicines risks in the plan?
  - Do you use this process for medication risk assessment? If not how are medicines risks incorporated into the organisation’s risk assessment processes?

Using this section for CPD

By working through this section you will be able to record or include what you have learnt as a portfolio entry: For example you could:

- Record the resources you used from the section to learn about risk assessment. Include how you have applied this in practice
- Use your written answers to the tasks and compare these against the suggested answers. Document any new development needs this identified for you.

The section could identify further learning needs that you can complete as Plan and Record CPD entries starting at “reflection”
Example in practice: some answers

Example 1: Dispensing Risk Assessment

What can go wrong?
- Failure to identify prescribing issues: Prescription may not be legal (i.e. unsigned); prescription may omit dosage instructions; prescriber may have selected the wrong product or the wrong patient
- Dispensing errors: Errors in preparation of the label/entering the information on the IT system; selection of the wrong medicine; using expired stock; dispensing the wrong quantity (e.g. using a part pack in error); placing the item for checking next to the wrong prescription; clinical interaction/contra-indication not spotted; handing out the dispensed items to the wrong patient
- Checking process errors: Failure to identify any of the above
- Failure to follow the SOP: May lead to one or more of the above failures

Who might be harmed and how? The patient- if the patient uses a medicine that has been prescribed or dispensed or administered incorrectly

Evaluate the risks you identified above: Just a couple are graded as examples from the above list using the NPSA grid:
- Prescription may not be legal: This has negligible risk of harm but is possible (green risk)
- Selection of the wrong medicine: This could be catastrophic if undetected prior to administration by the patient. The risk is possible if similar packages are stored together on the shelf and easily mis-selected (red risk)

What actions are or could be taken to reduce or minimise these risks? Re-arranging the storage of similar looking or sounding items would reduce the risk of mis-selection.

Example 2: Patient Group Direction (PGD) Supply

What can go wrong?
- Clinical Issues: Contra-indication/exclusion not identified; diagnostic error;
- Supply issues: Stock insufficient to meet demand; inappropriate labelling; wrong item supplied; Storage facilities inappropriate; Rx charges not collected
- Workforce issues: Not competent to follow the PGD; staff absence results in reduced capacity to deliver the service or risk of periods where service is not available

Evaluate the risks you identified above: Just a couple are graded as examples from the above list using the NPSA grid:
- Contra-indication/exclusion not identified: This could be catastrophic if undetected prior to administration by the patient. Lack of training or second checking will make this more likely (red risk)
- Staff shortages causing service delivery issues: Patient may experience delay (Orange risk)

What actions are or could be taken to reduce or minimise these risks? Competency based training with documented completion; workforce plan to ensure capacity planning
3.2 Where do I start applying this to medicines—there are too many risks?

The first place to start is to look at national information and “must dos” that reflect where priorities for medication safety have been identified. The top priorities for action are mainly provided via NPSA Alerts and the implementation of these is considered in Section 7 of this resource.

3.2.1. Priorities identified nationally

Medicine specific

The analysis for incidents in 2007 has been published as a report “Safety in Doses: Improving the use of medicines in the NHS” (available at www.nrls.npsa.nhs.uk).

The box below shows the most serious medication incidents reported to the NRLS:

<table>
<thead>
<tr>
<th>The most serious incidents</th>
</tr>
</thead>
<tbody>
<tr>
<td>- The NPSA received 100 medication incident reports of death and severe harm via the RLS.</td>
</tr>
<tr>
<td>- The majority of serious incidents were caused by errors in medicine administration (41 per cent) and, to a lesser extent, prescribing (32 per cent).</td>
</tr>
<tr>
<td>- Incidents involving injectable medicines represent 62 per cent of all reported incidents leading to death or severe harm.</td>
</tr>
<tr>
<td>- Three incident types – unclear/wrong dose or frequency, wrong medicine and omitted/delayed medicines – account for 71 per cent of fatal and serious harms from medication incidents.</td>
</tr>
<tr>
<td>- Types of medicines most frequently associated with severe harm include cardiovascular, anti-infective, opioid, anticoagulant and anti-platelet medicines</td>
</tr>
</tbody>
</table>

NPSA 2009 “Safety in Doses: Improving the use of medicines in the NHS”

These incidents will give you a useful starting point in considering which medicines and care pathways involving medicines might put patients at greater risk. These could be the first areas you tackle as a formal risk assessment!

Top Tip: In the Safety in Doses report, there is a list of action points in section 10. How are these being applied in your organisation?

Further areas of risk have been highlighted in the DH publication in 2004 entitled “Building a Safer NHS for Patients: “Improving Medication Safety” (available at www.dh.gov.uk). This highlighted drugs (many of which have since been the subject of NPSA alerts) and clinical settings that carry particular risks. Key operational risks for medicines included:

- Safer medication through information management and technology
- Safer medication through improved labelling and packaging
Patient care pathway

Risks also occur in the patient care pathways rather than with the medicines themselves. The main example is at a patient’s transfer of care between different healthcare settings. Risk assessment of pathways of care that include medicines as well as assessments for specific medicines is therefore important when you are considering the risks of medicines in your day to day work.

The following are areas of national focus where medication safety has featured as a priority:

- **Transfer of care**: This was a key pathway risk identified in DH 2004 publication and since then the Care Quality Commission have completed a study (“Managing patients’ medicines after discharge from hospital” October 2009 available at [www.cqc.org.uk](http://www.cqc.org.uk)) and made some recommendations about how this could be improved between hospitals and primary care settings.

- **Out of hours care**: Out of Hours care pathways have been a focus for the NPSA and DH as a result of some high profile safety incidents. A guide for commissioners on out-of-hours (OOH) services has been published by the NPSA as part of their risk assessment programme available at [www.nrls.npsa.nhs.uk](http://www.nrls.npsa.nhs.uk).

- **Venous thromboembolism (VTE)**: Another way of assessing how your organisation (or those you commission services from) has responded to the need for risk assessment relating to medicines is to find out how they have implemented the VTE Risk Assessment tool (available at [www.dh.gov.uk](http://www.dh.gov.uk)).

- **Care homes**: A recent national study researched the level of medication incidents in care homes for older people. The outcomes highlighted that there is a high prevalence of medication incidents in this care setting. The full report from the study can be found at: [http://www.haps.bham.ac.uk/publichealth/psrp/PS025_Project_Summary.shtml](http://www.haps.bham.ac.uk/publichealth/psrp/PS025_Project_Summary.shtml)

### 3.2.2. Locally identified risks

One way of assessing medication risks in your workplace is by looking at the local records of adverse events. These may be compared to the reports received by the National Reporting and Learning System (NRLS) led by the NPSA.

**Top Tip**: Use a local list of reported medication incidents (or the NRLS report for your organisation at [www.nrls.npsa.nhs.uk](http://www.nrls.npsa.nhs.uk)) as these may give you clues about which medicines or pathways are the highest risk. Completing risk assessments is also important in identifying high medication risks (see section 3.1.).

To help you consider how to focus on prioritising high risk medicines an NPSA Rapid Response Report “Reducing harm from omitted and delayed medicines in hospital” was published in February 2010 which requires organisations to do this. If you are working in primary care (including community pharmacy), you could think about this alert in terms of care homes, community hospitals and prisons where you commission or provide services. The first action on this report is:
An executive director, nominated by the chief executive, working with the chief pharmacist and relevant medical/nursing staff should:

1. Identify a list of critical medicines where timeliness of administration is crucial. This list should include anti-infectives, anticoagulants, insulin, resuscitation medicines and medicines for Parkinson’s disease, and other medicines identified locally;

- How would you go about identifying the local inclusions on the critical list of medicines?
- The alert considers the risk of missed and delayed doses only. How would you decide what other high risk medicines or high risk points exist in the care pathway?

### 3.2.2.1 High risk medicines prescribed by hospitals and shared care

There may be an increased risk to the patient if the availability of medicines or local policies mean that the supply of medicine is more complicated than usual. Often the medicines involved have a higher inherent risk because of toxicity or complexity. For example, the continuity of prescribing by hospital clinicians can pose a risk to patients if information is not shared with other clinicians who prescribe for the patient (e.g., GPs). Here are three examples that you may come across in your practice:

- **Continued supply from hospital:** Medicines that, due to local policies between commissioners and hospitals, are not prescribed by GPs and/or dispensed in the community but continue to be prescribed and supplied by secondary care including mental health clinicians (doctors and community psychiatric nurses). The risk with this system of prescribing and supply is that the information showing the patient is receiving this treatment is often not documented by GPs or available to community pharmacists. This means that it cannot be clinically checked for interactions with other medicines the patient subsequently receives. This creates a risk of adverse events. The East of England Patient Safety Programme has produced a toolkit to support prescribers and dispensers in all sectors of practice to reduce the risk of this usually hidden issue. The information is available at [www.eoe.nhs.uk](http://www.eoe.nhs.uk).

- **Homecare:** Medicines prescribed by hospitals and supplied via homecare arrangements: This involves the prescribing of medicines by hospital clinicians but the supply and/or administration of the medicine to the patient is commissioned to a homecare provider. This pathway has similar risks to those above but also has the additional risk that a third party (i.e., the homecare company) is arranging the dispensing and supply and administration to the patient. To ensure that hospitals and commissioners are able to assure and monitor that the quality of these services meet national standards and safety checks expected by the NHS, there are some nationally agreed service specifications and commissioning information and guidance developed by the NHS Purchasing and Supply Agency [www.pasa.nhs.uk](http://www.pasa.nhs.uk).

- **Shared care:** This pathway involves medicines that are initiated by hospital prescribers but continuity of care including monitoring and repeat prescriptions are prescribed by GPs. This can create a risk for patients if the shared care agreement:
Seven Steps to Medication Safety – Vs1.2 – July16 – (DF/YJ)

3.2.2.2 Unlicensed medicines including pharmaceutical specials

Licensed medicines
Most medicines that are prescribed will have a Marketing Authorisation (product licence). This means they have passed rigorous marketing and authorisation processes managed by the regulatory body the MHRA (see www.mhra.gov.uk).

To obtain a marketing authorisation for a medicine, pharmaceutical companies have to demonstrate that the product is both safe and effective. The evidence which is provided to the regulatory body includes the following:

- Effectiveness of the active ingredients
- Expected side effects and frequency
- The physical stability of the preparation
- Any interactions between the ingredients within the product
- Interactions with other medicines
- The bioavailability of the finished product (how much drug is absorbed by the patient)
- The acceptability and safety of the formulation

Within a marketing authorisation there are indications and dose ranges listed for the medicine (usually written in the Summary of Product Characteristics (SPC) which are available at www.medicines.org.uk/emc).

Sometimes prescribers find that a licensed medicine works well for a certain condition, age group, or at a dose for which it has not been licensed by the regulator. They prescribe it, based on their own and their colleagues’ experience, published studies, and findings presented at professional meetings.

This is called 'off label' prescribing.

MHRA "Licensing (marketing authorisation) at www.mhra.gov.uk"

Using medicinal products without a licence

There may be justifiable clinical reasons why a patient cannot use the licensed product. These include allergy or intolerance to the ingredients or difficulty swallowing a medicine when the licensed version is only available in a solid dosage form.

However as the safety checks and clinical effects are not carried out for an unlicensed product, these products have an inherent risk to patients as the clinical outcomes and potential adverse effects are unknown.

The following information resources provide more detailed information about unlicensed medicines including the professional responsibilities of prescribers and pharmacists and registered...
technicians when they are prescribed, procured and supplied. These apply whichever sector of practice you work in:

- RPSGB Legal and Ethical Advisory Service Fact Sheet Five (2007): The Use of Unlicensed Medicines in Pharmacy (www.rpsgb.org)
- East and South East Specialist Pharmacy Services QA Directorate (2001): Guidance on the purchase and supply of imported unlicensed medicines (www.nhsppu.uea.ac.uk/quality-assurance): This guidance has some useful flow charts that will help you consider how to manage prescribing, procurement and supply of unlicensed medicines
- Specials: East of England NHS Collaborative Procurement Hub (2010): Information and guidance on the prescribing and use of unlicensed pharmaceutical specials (www.eoecph.nhs.uk): This toolkit has relevant information for prescribers, dispensers and pharmacists about the use of specials. There are also other resources available on the web-site.

**Top Tip:** To ensure that the prescribing of unlicensed or “off-label” medicines only happens when there is no licensed alternative, all NHS organisations should ideally have an Unlicensed Medicines policy. This will include the need for obtaining informed consent from patients about the treatment and the fact that the product will be unlicensed!

**Over to you**

**Example in practice:** A mother presents a prescription for warfarin liquid 3mg in 5ml for her 3 year old daughter for use at a dose of 3 mg daily.

- Assuming the strength and dose are correct, what are the key risks associated with this prescription with respect to sourcing and supplying this medicine?
- List the things you would need to find out before you ordered and dispensed it?
- Find out where you might source this product. Has the manufacturer got a specials license? What does this mean in terms of the risk posed by the product? What liability do you have in relation to the product if you supply it to a patient?

- **Some specialist medicines are only prescribed by hospital doctors via agreements reached with commissioners. How would you find out if this medicine is one of them? What might be the risks in the patient care pathway should the medicine be:**
  - Continued by the GP via FP10
  - Continued as a hospital only medicine
What next?

Further Reading

- NPCi have a learning and resource section within General Medicines Management about shared care. This is available at [www.npci.org.uk](http://www.npci.org.uk). Take the lift to the General Medicines Management floor.

- The East of England NHS Collaborative Procurement Hub have developed a Homecare contract (awarded to five homecare companies) for delivery and dispensing of medicines via Homecare. Information is available at [www.eoecph.nhs.uk](http://www.eoecph.nhs.uk) – within the restricted area so registration is required.

Practical Next Steps

- Reflect on your day to day practice: Which drugs are considered high risk by
  - You (as a result of your practice): Describe a case example of your involvement in patient care when a high risk drug incident was avoided (e.g. intervention example).
  - Your team (via Trust or departmental audit/policy)? How was this list identified? How often is it reviewed? Are new medicines considered for inclusion as they become licensed?

- Choose one of the care pathway examples in practice described on page 51. Investigate the background information and draw up a list of risks for the patient for your chosen pathway. Using the risk matrix grid on page 45, decide if you think each of these risks red, orange yellow or green.

Using this section for CPD

By working through this section you will be able to record or include what you have learnt as a portfolio entry: For example you could:

- Use your written answers to the task and compare these against the suggested answers. Document any new development needs this identified for you.
- Document the resources you have accessed that are included in this section. Describe how these apply to your practice. Include the document reference and application description in your portfolio of evidence.

The section could identify further learning needs that you can complete as Plan and Record CPD entries starting at “reflection”.

Top Tip: If this task raises questions for you about specials there is further information about them in the Specials reference listed above and in section 6 of this resource.
Example in Practice: case scenario: some answers

What are the key risks associated with this prescription with respect to sourcing and supplying this medicine?

- Different formulations may result in different INR outcomes
- Delay in accessing the medicine may increase the risks of missed doses
- Potential sources may not provide certification of analysis that confirms the quality of the product so the quality is assumed rather than guaranteed

List the things you would need to find out before you ordered and dispensed it?

- Has the patient had this before and if so, where did they source it?
- Contact details for prior source to establish exact formulation
- Contact details of pharmacy/consultant team responsible for the patient if care is managed by hospital practitioners rather than the GP.
- Expiry of sourced product (to inform quantity supplied and re-order/repeat requirements)
- Estimated cost as ideally at least 3 quotes may need to be sourced to maximise the cost effectiveness of the supply

Find out where you might source this product. Has the manufacturer got a special license? What does this mean in terms of the risk posed by the product? What liability do you have in relation to the product if you supply it to a patient?

You would not dispense this item extemporaneously due to the bioequivalence required (unless you have a licensed manufacturing unit where you work!). The options are therefore:

- A pharmaceutical manufacturer
- Imported by a specialist importer
- Manufactured by a commercial or hospital MHRA licensed manufacturing unit

You would make sure the source was a licensed manufacturer as if you are a pharmacist ordering the special you have a professional duty to ensure that the product provided to the patient meets the prescriber's requirements. If these are not implicitly stated by the prescription then he/she needs to ensure the medicine is fit for the patients use. I.e. the pharmacist is responsible for the formulation, the bioavailability and the stability of the product they supply. This is why a certificate of analysis form the supplier is important.

Some specialist medicines are only prescribed by hospital doctors via agreements reached with commissioners. How would you find out if this medicine is one of them?

Commissioners have a list of medicines agreed locally that should only be prescribed by hospital clinicians for safety or financial reasons. The chief pharmacist at the local hospital or your local GP practice manager should be able to access this list for you.

What might be the risks in the patient care pathway should the medicine be:

- **Continued by the GP via FP10**: Incomplete communication of information for onward prescribing/supply will increase the risk of error for the next supply. Continuity of formulation may be at risk which may have a clinical impact on patient outcomes (e.g. INR)
- **Continued as a hospital only medicine**: Access issues for the patient may result in missed doses; incomplete records in primary care may occur resulting in interaction and other clinical risks if the information about the medicine is not shared with the GP and other healthcare professionals such as the community pharmacist.
Section 4: Promoting reporting

Incorporating medication incident reporting into your own practice

This section:

* Explains how you go about reporting an incident based on what is expected by your employer and the national reporting systems

By completing this section you will be able to:

√ Define patient safety incidents, medication errors and adverse drug reactions and events
√ Discuss with the team what should be reported and how
√ Explain the use of triggers tools to identify and monitor the frequency of adverse events
√ Describe what incidents should be reported locally and nationally
√ Use the national data set to identify serious incidents and examine trends

Other sections in this resource will explain in more detail what you should be doing on a day to day basis in response to identified risks relating to medicines and reducing those risks.

Ideally you will find that the processes you use for reporting fit into the organisational and national reporting processes outlined in Section 3.2.

4.1 What is a “Patient Safety Incident”?

Since 2004, terminology for incidents has changed. “Errors” was considered too emotive and liable to blame attachment and “adverse events” led to confusion about what to report, especially for medicines where we routinely use “adverse drug reactions” which are not necessarily medication incidents! The NPSA has now settled on the definition below:

Patient safety incident: Any unintended or unexpected incident that could have or did lead to harm for one or more patients receiving NHS-funded healthcare: The terms ‘patient safety incident’ and ‘patient safety incident (prevented)’ will be used to describe ‘adverse events’ / ‘clinical errors’ and ‘near misses’ respectively.

The corresponding definition of medication errors is:

A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of health professional, patient or consumer.”

Many medication incidents do not lead to harm and harm is often prevented by an intervention to avoid it. These “near misses” are still included as patient safety incidents and ideally should be reported.

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Adverse drug reactions (ADRs) are sometimes considered medication incidents but not when the reaction is due to predictable or known side effects of medicines. The World Health Organisation defines ADRs as:

An ADR is any response to a drug which is noxious, unintended and occurs at doses used for prophylaxis, diagnosis or therapy

To put this into a practical context the following diagram shows the relationship between medication incidents (these are called medication errors in this example) and adverse drug reactions:

Medication errors may be related to professional practice, products, procedures, environment or systems.

They may involve:
- prescribing and ordering;
- dispensing and distribution;
- preparation and administration;
- labelling, packaging and nomenclature;
- communications and education;
- use and monitoring of treatment;

Ideally all errors of type I and II in the diagram would need to be reported.

What could this mean for the amount of errors that would need reporting every day by your pharmacy team or the providers you commission?

Would you be able to report all of these?

Would you be able to analyse all this data if you did get it? A perception that "no-one listens" will discourage further reporting.
**4.2 What are you reporting locally?**

To avoid reporting overload but to ensure that there is a consistent and appropriate reporting of medication incidents and adverse drug reactions (ADRs) there will be local policies on incident reporting with links to national reporting processes (which are explained in the next section). Remember that you may gain a lot more from a relatively small number of comprehensive, well documented reports than from a larger number which omit important details.

The pharmacy team that you work with may have an agreed reporting strategy that identifies what type of medication incidents should be reported, to whom and how. This may include an IT-based reporting system (e.g. DATIX) as well as reporting via the National Reporting and Learning System (NRLS).

*Commissioners of your service may also have requirements for your service to report patient safety incidents or a summary of them as part of their service monitoring requirements.*

*If your pharmacy team or workplace does not have an agreed strategy for what medication incidents should be reported, the East and South East Specialist Pharmacy Services Clinical team have produced a reporting strategy ([available at](http://www.medicinesresources.nhs.uk/en/Communities/NHS/SPS-E-and-SE-England/Meds-use-and-safety/]).

The following priorities for reporting are suggested (with Item 1 being considered essential):

1. Report all medication incidents that actually result in patient harm, even when other work pressures are high. (Possibly report very brief information initially then add more detail later.)

2. Report all incidents (i.e. including those where harm was prevented) directly related to pharmacy processes (e.g. dispensing, compounding etc).

3. Report all incidents (i.e. including those where harm was prevented) which are considered potentially severe/fatal (e.g. prescribing, administration etc).

4. Carry out and report snapshot audits of all incidents in e.g. a chosen week (i.e. including those where harm was prevented) with all potential levels of harm for medicines associated with particular risk (e.g. anticoagulants, opiates etc or locally identified) over set time periods (e.g. one week/month).

**Global Trigger Tool**

An additional tool that you might use for identifying and measuring medication incidents is the *Global Trigger Tool*. 
The IHI Global Trigger Tool for Measuring Adverse Events provides an easy-to-use method for accurately identifying adverse events (harm) and measuring the rate of adverse events over time. Tracking adverse events over time is a useful way to tell if changes being made are improving the safety of the care processes. The Trigger Tool methodology is a retrospective review of a random sample of inpatient hospital records using “triggers” (or clues) to identify possible adverse events. Many hospitals have used this tool to identify adverse events, to assess the level of harm from each adverse event, and to determine whether adverse events are reduced over time as a result of improvement efforts.

Institute for Health Improvement 2009 “Global Trigger Tool for measuring adverse events”

The tool includes some medication triggers. If you want to find out more about these you can download the guide at www.ihi.org

Over to you

Local systems for reporting

- Find out what has been agreed by the pharmacy department or your team about:
  - Who medication incidents should be reported to
  - What should be reported
  - Recording of pharmacy interventions: do you record pharmacist contributions to patient care (which you may know as interventions)? What is the data used for and how does this link to the formal reporting of patient safety incidents?
  - Audit related to medication safety: What process or clinical audits have you been involved in collecting data for in the past 12 months? How do these link with formal incident reporting by the pharmacy team and within the organisation?

Practice examples: (If you are a pharmacist working in a commissioning organisation consider these examples in the context of the commissioner i.e. what you would expect should be reported by your provider(s) and what should happen to the report).

- Examples from your own practice: Choose a medication incident that you have identified in the last 12 months. Using this example provide the following as information about what happened:
  - How did you report this incident within your organisation?
  - Who else did you discuss the incident with (e.g. other clinicians and patients)
  - What action you took to resolve the issue or minimise the risk of the same incident happening again in the areas where you practice
Example in Practice: A patient comes into the pharmacy clutching a box of nicorandil 20 mg. She accuses you of supplying her with the wrong medication as she usually has nicardipine 20mg. A friend of hers, who is a nurse, told her that this mistake could have made her very ill. She is very angry, hands you the box of tablets and asks you to sort this out and find out how she can claim damages! She plans to return later that afternoon and leaves before you can ask her for any more details.

When you look back at your records, you find out that the patient did indeed usually have nicardipine, but that the latest supply (corresponding with the returned box and label) was nicorandil. On retrieving the prescription, you find that the prescriber had prescribed nicardipine, hence suggesting a mistake in dispensing. There was no evidence on the Pharmacy Record including the prescription itself about any intervention made during the supply of the medication.

On further investigation with the pharmacy staff involved in dispensing the prescription you find out that none of the staff had queried the apparent change in medication. None of them can recall who handed the medicine to the patient or whether they were counselled.

How you would report and document this incident?
Who else would you discuss the incident with (e.g. other clinicians and patients)?
What action would you take to resolve the issue or minimise the risk of the same incident happening again in the areas where you practice?
Consider what might prevent staff from reporting incidents?
What information about this incident should be shared with commissioners?

What next?

Further Reading

NPCi resources: (www.npci.org.uk): If you use the lift to navigate to the Patient Safety and Risk section, you will discover a series of learning resources about “Reducing medication errors” (each taking about 15 minutes to complete). There is a useful 5-minute guide giving further information about definitions including what a medication incident is.
CPPE resource on Risk Management (www.cppe.man.ac.uk): Sections 2 and 3 include medication incident definitions and reporting. Section 2 also includes a list of areas of practice that you can choose to help you think about where incidents might occur that would need to be reported.

Practical next steps

- From the information you have about how you should be reporting medication incidents (or how providers you commission services from should be doing this) draw a decision tree diagram that shows:
  - When you would formally document a medication incident (or near miss): This may involve prioritising reporting on specific medicines or processes or the degree of potential or actual harm caused.
  - How you would document it?
  - Who would you inform about the incident?
  - What follow-up would you undertake?

- Is this process straightforward? Could it be made easier to encourage greater reporting by all levels of staff?

- Write down any issues here and feed these back to your colleagues or manager.

- If you do not already have one, use the team to develop an SOP that describes what should be reported and how. If you do have an SOP review the contents and check with a sample of staff to see if
  - they are aware of it
  - they are reporting incidents as specified in the policy

Using this section for CPD

By working through this section you will be able to record or include what you have learnt as a portfolio entry: For example you could:

- Print off the MHRA web-page about the Yellow Card scheme that shows what to report. Describe how using the scheme could form part of your practice.
- Use your written answers to the tasks and compare these against the suggested answers. Document any new development needs this identified for you.

The section could identify further learning needs that you can complete as Plan and Record CPD entries starting at “reflection”.
Example in practice: case scenario: some answers

How you would report and document this error?

As this patient would have been harmed if the nicorandil had been taken, the incident is likely to fall into the type of incident that needs to be reported. You should follow the local policy for documenting the incident. If there is none, ask your manager about this and find out if you or they could report it to the NRLS.

Who else would you discuss the error with (e.g. other clinicians and patients):

You would need to discuss the error with the people involved (staff and patient) to raise awareness and to explain that the incident will be formally reported. You may also need to report the incident to the PCT.

What action would you take to resolve the issue or minimise the risk of the same error happening again in the areas where you practice:

You or your manager should complete a root cause analysis to establish exactly where and why the errors were made. This will allow you to identify an action plan for minimising the risk of the same type of error happening again (see section 5).
4.3 Organisation specific data and national reporting processes

4.3.1 National Reporting and Learning Service (NRLS)

An essential contribution to increasing patient safety is the reporting of incidents to the National Reporting and Learning Service (NRLS) set up by the NPSA in 2004. The collation of incidents nationally provides a clearer picture of the patient safety issues that need to be prioritised across the NHS. As a result of analysis of the incidents reported to the NRLS, there have been many NPSA publications that focus on key risk areas with actions to minimise these risks.

You can report incidents directly to the NRLS on-line and if you work for an organisation they will also have their own policy and written mechanisms and systems for reporting patient safety incidents internally and to the NRLS. The decision about what to report to the NRLS will be based on their local incident reporting policies and risk management structures. Analysis of the NRLS data so far shows a poor level of reporting in primary care (including GP practices and community pharmacies).

The NPSA has produced some information to help organisations decide what to report and how to report it (www.nrls.npsa.nhs.uk):

- To promote consistent reporting of incidents, definitions of ratings have been published on page 100 of the full version of the “Seven Steps to Patient Safety”. This separates the level of harm into five categories: None/insignificant; Low/Minor; Moderate; Severe/Major; Death/Catastrophic
- In September 2009 the NPSA published standards for reporting patient safety incidents:

<table>
<thead>
<tr>
<th>No.</th>
<th>Criterion title</th>
<th>Minimum standard</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Reporting to the National Reporting and Learning Service (NRLS)</td>
<td>NHS organisations should submit all their reported patient safety incidents (PSIs) to the NRLS’s Reporting and Learning System (RLS).</td>
</tr>
<tr>
<td>2</td>
<td>Regularity of reporting</td>
<td>Every NHS organisation should submit reported PSIs regularly to the RLS — regularly is defined by the NRLS as at least monthly.</td>
</tr>
<tr>
<td>3</td>
<td>Exclusion of person identifiable information</td>
<td>Every NHS organisation should ensure that PSIs reported to the RLS do not contain person identifiable information in free text fields.</td>
</tr>
<tr>
<td>4</td>
<td>Recording actual degree of harm as a result of the PSI</td>
<td>Every NHS organisation should ensure that the degree of harm recorded for each PSI describes the actual harm to the patient as a direct result of the PSI.</td>
</tr>
<tr>
<td>5</td>
<td>Speed of reporting of the most serious PSIs to the NRLS</td>
<td>Every NHS organisation should report PSIs with an actual degree of harm of either “severe” or “death” (as described in 4) to the RLS within two working days of the incident occurring.</td>
</tr>
</tbody>
</table>

NRLS 2009 “Data quality standards
What does the NRLS data show about your organisation?

The NRLS shares the incident data in four main ways:


- Safety topic reports focusing on specific areas
- Organisation level patient safety incident reports including information on reporting levels, incident type and degree of harm
- Feedback reports to each NHS organisation that sends data regularly to the NRLS
- Quarterly data summary reports giving an overview of data from the NRLS

**Top Tip:** By choosing to look at one or more of these you can find out about incidents that have been reported in general as well as finding out about the incidents your organisation has reported (if they report regularly).

### 4.3.2 Other national reporting systems include:

- **MHRA Yellow Card Scheme:** ([www.mhra.gov.uk](http://www.mhra.gov.uk)): This is a national system of adverse drug reaction (ADR) reporting. Reports can be submitted electronically or by post (forms are available in the back of the BNF). Most healthcare professionals, coroners and patients are advised to report ADRs via this scheme. The MHRA describes what to report which includes:
  - All ADRs (serious and non-serious) resulting from black triangle drugs i.e. those medicines that are newly licensed medicines that are monitored intensively by the MHRA.
  - All serious suspected reactions to any established medicine. The web-site provides further guidance about how to decide whether to report an ADR in this category.
  - There are some other areas of interest listed by the MHRA on the web-site where ADRs should be reported.

**Top Tip:** Don’t forget there is an “Adverse reactions to drugs section” in every edition of the British National Formulary (BNF). This includes a section on the Yellow Card Scheme but also describes how to prevent ADRs and common oral side effects of medicines.

### 4.3.3 Serious Incidents (SIs)

NHS organisations must follow guidance within the NPSA Serious Incident Reporting and Learning Framework (SIoRF) published in April 2010 (available at [www.nrls.npsa.nhs.uk](http://www.nrls.npsa.nhs.uk)). This replaces previous regional agreements about serious untoward incidents and clarifies the definition of serious incidents (SIs) into six types involving one or more patients, staff, visitors or members of the public:

- Unexpected or avoidable death
- Serious Harm
The serious incidents have to be reported to specified partners and are graded on an individual basis into one of three grades 0, 1 or 2. The grade defines how the investigation and onward management of the incident will be undertaken and by whom. For further information about this see Section 6.

If you are lead for medication safety you may be involved more intensely in the identification, reporting and grading of medication incidents and may also help your organisation consider whether medicines played a part in a serious incident. You will find the NPSA framework essential reading to ensure you contribute to this process within the expectations of the NPSA.

There is also a requirement stated in the framework about reporting to a variety of linked organisations including the Care Quality Commission:

**NPSA Serious Incident Reporting and Learning Framework (SIRL) April 2010**

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**Over to You**

♦ Find out about the process of incident reporting your organisation uses for internal reporting and for reporting to the NRLS.

♦ Does this mention the NRLS reporting standards and whether these are being met?

♦ Are the categories of harm the same as those detailed by the NPSA? What do you think might be factors that influence how harm is graded?
Go to the NPSA web-site and find the dataset for your Trust (or one within your locality) for incidents reported to the NRLS. How does the reporting rate for the trust compare with similar organisations?

Why might there be a difference? What could you do to explore this further?

What next?

Further Reading

- NPSA “Safety in doses: Improving the use of medicines in the NHS”: Read Sections 2 and 3 and the Section most relevant (4-8) to the area(s) that you work in.

Practical Next Steps

- From the information you found out about in the “over to you” section, draw a diagram or write a pathway showing what happens in your organisation when a Serious Incident occurs, starting from the point of discovery of the incident to the point at which it is reported (internally and to the NRLS).

- Is this pathway straightforward? Could it be made easier to encourage greater reporting by all levels of staff?

- Identify internal and public trust-based reports on incidents. Do these show a breakdown of incident type? What proportion are medication-related incidents? Are the pharmacy staff contributing data to these reports?

Using this section for CPD

By working through this section you will be able to record or include what you have learnt as a portfolio entry: For example you could:

- Include the diagram and comments you have from the practical next steps example
- Include a description of what you found out about reporting to the NRLS by your organisation and how this applied to your practice

The section could identify further learning needs that you can complete as Plan and Record CPD entries starting at “reflection”.

Seven Steps to Medication Safety – V1.2 – July16 – (DF/YJ)
Section 5: Involving and communicating with patients and the public

Responding to adverse events/medication incidents: patient/carer involvement

Involving and communicating openly with patients, their relatives, their carers and the public is essential to improving patient safety. Experience shows patients’ definitions of harm sometimes differ from the definitions used by clinicians. And if a patient is harmed when things go wrong, they can offer insight into the reasons for the problem and inform solutions to prevent the incident recurring. To enable this to take place, the NHS must be open and receptive to engaging with patients.

A good place to start when considering how to involve patients and carers when things go wrong as a result of a medication incident is the NICE Clinical Guideline 76 Medicines Adherence (2009 www.nice.org.uk). Most of the key principles listed in this guideline are relevant when involving patients in reporting, analysing and acting on medication incidents.

Top Tip: Involving patients in decision making about their medicines may highlight potential risks to the medicine that may not have otherwise come to light. Improved patient involvement is thus a way of minimising medication errors.
5.1 What should your organisation be doing?

If you work for an organisation, the Seven Steps to Patient Safety suggests ways in which you can help ensure a two-way dialogue between NHS services and patients by:

- developing a local policy on being open;
- engaging with patients during investigations;
- designating key staff to have responsibility for being open;
- providing training and support to staff in communication skills;
- providing support for patients.

In what ways is this being enacted locally?

Organisations may have a local policy covering open communication related to incidents with patients and their families. You will need to work within this so you may find it useful to find out if you have one.

There may also be a policy on communicating with the press which you will have to follow. This may involve contacting the Public Relations (PR) team in your organisation.

The Patient Advice and Liaison service (PALs) are currently set up in hospitals and many PCTs. PALs support patients. More information about PALs is available at [www.pals.nhs.uk](http://www.pals.nhs.uk).

Top Tip: Find out where your nearest PALs office is or if you have one in your trust. How are they linked into patient safety for the organisation they are based in?

PALs may be linked directly as a partner or stakeholder in your organisation’s patient safety infrastructure. If not then there may be other ways your organisation involves patients and the public in patient safety and in particular in managing patient safety incidents.

What can you and the pharmacy team do?

You might think that the only time that you or the team involve patients in medication safety is during routine care such as:

- when they are handing out medicines as part of the supply process
- discussing individual medicines with patients as part of their care e.g. during a review
- having to explain that something has gone wrong such as a delay in supply or that their symptoms are due to a side effect of a medicine they are taking

Can you think of any more examples?

There may be other ways that patients could be involved in medication safety. For example if pharmacy is represented in the patient safety infrastructure of the organisation where a patient representative is also a member, then it is more likely that the patient context around medication safety will be considered at a strategic level.
Do you or your team involve patients when you implement NPSA recommendations? For example how are patients involved in medicines reconciliation or minimising risks with warfarin and other high risk medicines? Is this just at the point of care or do you involve them when designing how to implement the alerts?

**Top Tip:** How do I find a suitable patient representative?

- The expert patient programme (EPP) was set up in 2002 and is a NHS initiative that was launched in 2002 to help patients with chronic conditions to take control of their lives. The basis of the programme is a training course that teaches people how to manage their conditions. As a result many organisations have worked with expert patients on the planning and delivery of care for specific long term conditions. You may be able to identify expert patients to help you with medication safety initiatives. More information is available at [www.nhs.uk/conditions/expert-patients-programme/pages/introduction.aspx](http://www.nhs.uk/conditions/expert-patients-programme/pages/introduction.aspx)

- Larger patient support organisations may also have local representatives that could help you involve patients (e.g. Help the Aged, Arthritis Care etc.). The BMA web-site (with the patient and public area) has a section that will help you find specific patient support groups: [www.bma.org.uk/patients_public/selfhelporg.jsp](http://www.bma.org.uk/patients_public/selfhelporg.jsp)

5.2 Being open

To help you communicate effectively with patients about adverse events, there is a suite of “Being Open” resources published by the NPSA ([www.nrls.npsa.nhs.uk/resources/?entryid45=65077](http://www.nrls.npsa.nhs.uk/resources/?entryid45=65077)). The resources include an e-learning module with four short elements that cover the background and benefits of being open. It also provides guidance on how to communicate openly with patients and/or carers and gives you an opportunity to apply your learning using some case studies.

Written resources to download are also available. These include A “Being Open” framework, a Guidance document and supporting information.

**Top Tip:** Why not observe an experienced colleague talking to a patient/relative about an error? This might help boost your confidence before tackling this yourself

**Over to you**

Find out if there is a patient representative who is actively involved in the organisation’s patient safety structures and activities? If your organisation has a web-site patient representatives may be listed here.

Seven Steps to Medication Safety – Vs1.2 – July16 – (DF/YJ) 77
Example in practice: A patient comes into the pharmacy clutching a box of nicorandil 20 mg. She accuses you of supplying her with the wrong medication as she usually has nicardipine 20mg. A friend of hers, who is a nurse, told her that this mistake could have made her very ill. She is very angry, hands you the box of tablets and asks you to sort this out and find out how she can claim damages! She plans to return later that afternoon and leaves before you can ask her for any more details.

When you look back at your records, you find out that the patient did indeed usually have nicardipine, but that the latest supply (corresponding with the returned box and label) was nicorandil. On retrieving the prescription, you find that the prescriber had prescribed nicardipine, hence suggesting a mistake in dispensing. There was no evidence on the Pharmacy Record including the prescription itself about any intervention made during the supply of the medication.

On further investigation with the pharmacy staff involved in dispensing the prescription you find out that none of the staff had queried the apparent change in medication. None of them can recall who handed the medicine to the patient or whether they were counselled.

The patient returns in the afternoon as promised and asks to speak with you. She wants to know what went wrong, who is to blame and what you are going to do about it. She has also wants to officially complain about the error and would like to know how to go about this.

♦ What would you do first?

♦ What are the key outcomes you think are needed as a result of this communication with the patient?

♦ What would you tell the patient about what went wrong?

♦ Would you give her the names of specific staff involved?

♦ What can you tell her about how you are dealing with the incident (for example staff training)?

♦ Will you need to involve the patient further in this process or in letting her know the outcomes from it?
What is the process for the patient to make a formal complaint to the NHS or to your employer? Would you refer the patient to the GPhC? At what stage would the police become involved in an incident?

If a member of the press contacted you about an incident what would you do?

What next?

Further Reading

- NHS Evidence has a section within its specialist collections dedicated to Patient and Public Involvement. (www.library.nhs.uk/ppi/)
- CPPE Open Learning resource (www.cppe.man.ac.uk) “Patient Centred care” (2009): This 12 hour programme will support you to:
  - understand the concept of patient-centred care & the skills needed to provide it
  - incorporate patient-centred care into your everyday practice
  - help patients get the best from their medicines through patient-centred care
  - implement NICE guidance on medicines adherence
- NPCi resources: (www.npci.org.uk): If you use the lift to navigate to the Adherence to Medicines section, you will discover:
  - Adherence to Medicines section, you will discover a series of learning workshops about “Involving Patients in Treatment decisions” (each taking less than 10 minutes to complete).
  - Developing people and organisations section there are a series of materials about involving patients.
- A DH funded web-site has been set up by the Picker Institute to provide a one-stop shop for patient and public engagement: www.investinengagement.info
Practical next steps

- Consider an example from your own practice where you had to tell a patient about a medication incident. Answer the questions in the scenario in the “Over to you” section again, reflecting on what you actually did in this real example.

- Make a list of things you would do better next time when talking to a patient about an incident.

Using this section for CPD

By working through this section you will be able to record or include what you have learnt as a portfolio entry: For example you could:

- Use your written answers to the task and compare these against the suggested answers. Document any new development needs this identified for you.
- Document completion of one or more elements in the NPSA “Being Open” resources (or alternatively the further reading examples) and how you have applied this learning to your practice.

The section could identify further learning needs that you can complete as Plan and Record CPD entries starting at “reflection”
Example in practice: case scenario: some answers

What would you do first?

Firstly, in preparation for the patient’s return and as a result of dealing with the incident, you would have revised and understood your employer’s policy and processes with dealing with an incident. You may have referred the incident to your manager.

To carry out the discussions with the patient the first thing you would do is to direct them to an area where you can discuss the incident in private. You may need to have a witness present if this is your organisation’s policy.

What are the key outcomes you think are needed as a result of this communication with the patient?

These could include: A verbal apology and providing the patient with the correctly dispensed Nicardipine! That the patient should leave with the information and reassurance they need and are aware of what will happen next.

What would you tell the patient about what went wrong? Would you give her the names of specific staff involved?

Both of these questions should be informed by your organisation’s procedures. It is important to be open and honest with the patient but it is unnecessary to give the patient the names of the staff involved, especially as it is not known who was involved at every stage of the dispensing and supply process for this incident. The “Being Open” NPSA framework will give you further advice to answer these questions.

What can you tell her about how you are dealing with the incident (for example staff training)?

You can share a summary of the actions to date which will include how you have investigated or referred the incident to your manager and the outcomes so far. Where these have highlighted a training need, you can explain how this will be met for all staff (not just those involved with the incident).

Will you need to involve the patient further in this process or in letting her know the outcomes from it?

It is important to continue to involve the patient in the outcomes of the incident, taking into account their wish to be informed. You may need to continue to involve them in the investigation as it progresses. Providing the patient with a copy of any written information (e.g. reports or action plans with outcomes) will also inform the patient about progress and enable them to contact you about this if necessary. Further details of how to involve patients in the management of patient safety incidents is available on the NPSA web-site as part of the Root Cause Analysis Toolkit.

What is the process for the patient to make a formal complaint to the NHS or to your employer?

Your manager should know about local arrangements and the patient should be directed to information about this process. Additionally your organisation’s web-site or your local PCT web-site will be able to provide you with further information about local processes. They also need to be informed about reporting the dispensing error via the new GPhC.
Section 6: Learning and sharing safety lessons

Responding to adverse events/medication incidents: root cause analysis

This section:
* Takes you through root cause analysis and how you can handle incidents in a logical way

By completing this section you will be able to:

✓ Explain the role of root cause analysis in the investigation of incidents
✓ Use the Five Whys tool to help assess the causes of a medication incident
✓ Conduct a root cause analysis for a Level 1 investigation using a variety of available tools

Other sections in this resource explain in more detail about how you assess risk and implement safer systems to minimise incidents happening.

It is important to learn from medication incidents and adverse events that could have been prevented. In order to do this effectively you need to have a good understanding of what went wrong including all the contributing factors involved that led to the incident. It is very easy to jump to conclusions about what caused the event, based on our own perspectives and experience and without considering all the other influences and effects of which we may not be aware. The root causes are the fundamental issues that led to the incident happening. Identifying these will enable you to change processes or provide training that will help prevent a similar incident from happening again. The best way to do this is to set aside personal assumptions and to use a systematic and logical approach via root cause analysis.

6.1 Root cause analysis

Root cause analysis (RCA) provides a retrospective review of an incident or event in order to identify:

- What happened?
- How it happened?
- Why it happened?
- How solutions can be developed and fed back to staff

RCA uses a defined critical analysis approach. You can use it on your own or with groups of staff as a helpful investigative tool to identifying why something happened, keeps happening, or why there is a series of near-miss incidents.

A useful introduction to RCA is provided in Section 6 of the full NPSA “Seven Steps to Patient Safety Guide”. However, the best way to understand and help you carry out RCA is to use the NPSA RCA toolkit (www.nrls.npsa.nhs.uk). In particular there is a comprehensive but flexible e-learning programme to help you develop an understanding and skills in RCA. The programme is divided into 6 easy stages and complemented by a variety of useful resources.
The NPSA RCA toolkit includes some useful guidance and report templates for investigating and reporting incidents. These classify incidents into three levels which then inform the process of investigation and reporting:

**Level 1: A concise investigation** - Most commonly used for incidents, claims, complaints or concerns that resulted in no, low or moderate harm to the patient.

**Level 2: Comprehensive investigation** - Commonly conducted for actual or potential “severe harm or death” outcomes from incidents, claims, complaints or concerns.

**Level 3: Independent investigation** - as per level 2 plus must be commissioned and conducted by those independent to the provider service and organisation involved. This level is used when the incident has a high public interest or is attracting media attention.

If you are involved in facilitating, leading or supporting investigations into medication incidents the NPSA RCA toolkit and documents are essential reading.

To facilitate the RCA process and ensure all potential factors are unmasked and taken into account, there are a couple of techniques cited in the NPSA toolkit that you can use:

### 6.2 Five Whys technique

Five whys is also known as the why-why chart (Ammerman 1998) and its focus is to enable you to delve more deeply into the causes of a patient safety incident. The main purpose of this technique therefore is to constantly ask “Why?” through the various layers of cause, thus progressing towards the true root cause of the identified problem or issue.

**When do you use Five Whys?**

- to question each identified primary cause of a problem and to identify whether it is a symptom, an influencing factor or a root cause
- to continue the search for true root causes, even after finding a possible cause.

Further information about how to use the Five Whys technique is available in the NPSA RCA toolkit within the resources “Description of Tools” section where “Five Whys” document can be downloaded.

**Top Tip:** Find out whether your organisation uses a specific process of RCA and incident investigation and reporting. Has the organisation signed up to formal RCA training for staff? Has anyone in the pharmacy team accessed this?
6.3 Fishbone diagrams

This technique uses a diagrammatical approach to considering the potential factors contributing to an incident (see below). When completed it looks like a fishbone- hence the name!

There may be other factor headings you can use specifically for medication incidents and some factors may be more relevant than others for specific incidents. The key benefits of using this approach are:

- it provides a structured and semi-comprehensive system for considering influences affecting performance in an incident
- fishbone diagrams are easily constructed and understood by the novice investigator
- it allows more reliable improvement strategies to be developed, as they are based on verified causal information.

A more comprehensive document about this and other methods are available in the NPSA RCA toolkit resources.

Whatever methods you use to complete an RCA, the analysis is then used to identify areas for change and make recommendations and suggest solutions that aim to minimise the re-occurrence of the incident in the future. These areas for change may include identification of barriers that you can put in place to minimise the risk of the incident recurring. This is called “Barrier Analysis” which is a tool available via the NPSA risk assessment programme (www.nrls.npsa.nhs.uk). There is more information about this in Section 7 of this resource (Section 7.2)

Serious Incidents: The NPSA have published a framework with guidance on the reporting and management of serious incidents (www.nrls.npsa.nhs.uk). This gives details in section 2.4 on how the investigation including the RCA should be completed.
Over to you

Example in Practice: A patient comes into the pharmacy clutching a box of nicorandil 20 mg. She accuses you of supplying her with the wrong medication as she usually has nicardipine 20mg. A friend of hers, who is a nurse, told her that this mistake could have made her very ill. She is very angry, hands you the box of tablets and asks you to sort this out and find out how she can claim damages! She plans to return later that afternoon and leaves before you can ask her for any more details.

When you look back at your records, you find out that the patient did indeed usually have nicardipine, but that the latest supply (corresponding with the returned box and label) was nicorandil.

Scenario 1: On retrieving the prescription, you find that the prescriber had prescribed nicardipine, hence suggesting a mistake in dispensing. There was no evidence on the pharmacy record including the prescription itself about any intervention made during the supply of the medication. On further investigation with the pharmacy staff involved in dispensing the prescription you find out that none of the staff had queried the apparent change in medication. None of them can recall who handed the medicine to the patient or whether they were counselled.

You decide to undertake a Root Cause Analysis of this incident

Scenario 2: On retrieving the prescription, you find that the prescriber had prescribed nicorandil. There was no evidence on the pharmacy record including the prescription itself about any intervention made during the supply of the medication.

You contact the prescribing team/GP practice to let them know about the incident and ask them to contribute to the investigation into the incident. They feedback that the repeat prescribing process they use resulted in the wrong drug being written on the prescription which wasn’t rectified by the prescriber before signing it.

You decide to undertake a Root Cause Analysis of this incident

♦ Take one of the scenarios above and try to answer the following questions:

- Who would you involve in the RCA?

- What level of RCA would you do and why?

- Write down Five Why questions that could help inform the RCA for this incident
• Try and draw a fishbone diagram showing the factors that may have contributed to the incident. Draw this here or access the template to fill in from the NPSA web-site (in the resource centre of the e-learning programme)

• Has these two approaches provided you with some potential root causes? What actions could follow from these?

What next?

Further Reading:

- NP Ci resources: (www.npci.org.uk): If you use the lift to navigate to the Patient Safety and Risk section, you will discover a series of learning resources about “Reducing medication errors”.

- NHS Scotland Clinical governance: Managing clinical effectiveness web-site: (http://www.clinicalgovernance.scot.nhs.uk/section2/analysis.asp). This section describes RCA and also lists some useful links to further resources.

- CPPE resource: CPPE resource on Risk Management (www.cppe.man.ac.uk): Session 3 includes the topics ‘Significant event analysis’ and ‘Root Cause Analysis’ (Page 95-97).

Practical next steps

• Ask your manager or medication safety lead to help you find a real medication incident that has recently been reported within your team or to the wider organisation.

• Analyse the adverse event and note down the answers to some of the following:
  - The nature of the event and where it occurred
  - Who was involved?
  - Who reported the event?
  - How was the event graded via a formal risk assessment or RCA process?
  - Do you agree with the grading – should it be graded more or less severe in your opinion?
  - What were the contributory factors?
  - What was the action plan?
  - What are the implications for pharmacy?
  - How can the pharmacy team help to minimise the chances of a similar event occurring again?
  - What are the education and training requirements of various staff groups
Using this section for CPD

By working through this section you will be able to record or include what you have learnt as a portfolio entry: For example you could:

- Document completion of the relevant stages of the NPSA RCA e-learning programme.
- Describe how you have applied RCA to an error you have been involved with at work. Use the formal paperwork you used as evidence.

The section could identify further learning needs that you can complete as Plan and Record CPD entries starting at “reflection”

Example in practice: case scenario: some answers (Scenario 2 additions in blue italics)

Who would you involve in the RCA? Examples include: Relevant staff representatives who are involved in the processes contributing to the error or understand the processes involved; a senior manager; representative from the GP practice; the patient. You wouldn’t need to host a formal meeting but could involve them via individual discussions to complete the RCA.

Write down Five Why questions: Why was the nicorandil prescribed in place of the nicardipine? Why wasn’t the medication on the prescription checked with the prescriber as it differed from previous items? Why wasn’t this picked up at the dispensing and checking stages? Why wasn’t the patient asked about nicorandil as a new medication they hadn’t had before? Why didn’t current SOPs prevent this error?

The fishbone: You can use the NPSA factors which could be populated with the prescribing and dispensing processes to identify where failures occurred and where positive interventions could have reduced the risk.

Have these two approaches provided you with some potential root causes? Hopefully, yes!

What actions could follow from these? Review of SOPs; Review of GP prescribing processes; Training of staff may be required against dispensing and supply process.
Section 7: Implementing solutions to reduce harm

Responding to adverse events/medication incidents: NPSA alerts and managing local medication incidents

This section:
* Provides the background to the NPSA alerts
* Explores how these and local medication incidents (including Serious Incidents) are managed in your organisation or pharmacy

By completing this you will be able to:

- List the NPSA alerts and RRRs relating to medication safety and discover what has been done to implement these locally
- **Lead the review and implementation of an NPSA alert or RRR**
- Identify other risks that have been addressed within pharmacy processes
- **Describe other serious incidents in your organisation and what has been implemented to minimise the risk of recurrence**

Other sections in this resource explain in more detail about communicating and being open about incidents, and how you assess risk and identify the root cause of them.

7.1 Implementing NPSA alerts

Since the establishment of the National Reporting and Learning System (NRLS) by the NPSA, the incidents reported are analysed and then correlated with information gathered by patient safety managers, through other data collection systems and through research, to identify national priorities for action and change. The NPSA agreed a mechanism for prioritising these examples (i.e. number of incidents reported and degree of harm) and publish safety alerts with specific actions that organisations delivering healthcare are required to meet. There are three types of alert that have been published to date:

- Patient Safety Alert
- Rapid Response Report
- Safer Practice Notice

The alerts cover a wide range of topics and as medication incidents form a large proportion of incidents reported, many of the alerts are about medicines.

The alerts are available on the NRLS section of the NPSA web-site (www.nrls.npsa.nhs.uk).

It is important that you remember that the alerts and actions arising from them will need to be delivered continuously. You may remember the more recent alerts from the list, but older alerts are still relevant as the changes you or the organisation have made need to be regularly audited and reviewed to ensure the requirements are still being met and have resulted in safety improvements.
The NPSA continue to monitor incidents relating to the alerts they have published. It is reassuring to note that in the recent “Safety in Doses” report that analysed the 60,000 medication incidents in 2007, the analysts found that:

“Following earlier guidance on the safe use of potassium chloride injection and oral methotrexate, there were no incident reports of death or severe harm in 2007 involving these medicines”.

Never events

In addition to the publication of specific alerts, since 2009 the NPSA has published a “Never Events Framework” (http://www.nrls.npsa.nhs.uk/resources/collections/never-events/).

Never Events are serious, largely preventable patient safety incidents that should not occur if the available preventative measures have been implemented.

The core list of Never Events is:

- Wrong site surgery
- Retained instrument post-operation
- Wrong route administration of chemotherapy
- Misplaced naso or orogastric tube not detected prior to use
- Inpatient suicide using non-collapsible rails
- Escape from within the secure perimeter of medium or high secure mental health services by patients who are transferred prisoners
- In-hospital maternal death from post-partum haemorrhage after elective caesarean section
- Intravenous administration of mis-selected concentrated potassium chloride

What support is there and who could you link with for implementing NPSA alerts?

Within the structure of the organisation you work for there will be committees and processes set up to deal with patient safety. You can learn more about this by completing Section 2.

The NPSA generally publish implementation tools and resources to support you. These are all available on the website (www.nrls.npsa.nhs.uk).
How do you, the pharmacy team and your organisation respond to NPSA alerts?

The following questions will help you consider:

- Are you receiving information about NPSA alerts and at what stage (i.e. when published, during or after the implementation phase)?
- How you are involved in implementing and monitoring the requirements of the alerts as part of your practice?

Top Tip: You may find it useful to find out about the wider patient safety structures in your organisation first as this may be linked to how they respond to NPSA alerts. The tasks in Section 1, sub section 1.2.3 will help you to do this.

Have a look at the resources section of the NPSA web-site (www.nrls.npsa.nhs.uk) and find the list of alerts. On each page of the list, note down which of the alerts are medication related (including appliances for administration of medicines or feeds).

Were you aware of all of these?
Section 7: Implementing Solutions to Reduce Harm

How are these communicated to you?

Who has lead the pharmacy response?

How is the workload for implementing NPSA publications shared across the pharmacy team?

How is implementation monitored and how often? Does this include re-evaluation after a change in process is introduced?

How is NPSA implementation monitored by your commissioning or strategic performance monitoring organisation? Are you or your senior managers involved in this for medication-related alerts?

Another way of looking at this may be to select one of the following alerts from the NPSA web-site (www.nrls.npsa.nhs.uk) that is relevant to your practice:

- Improving compliance with methotrexate guidelines: Patient Safety Alert
- Actions that can make anticoagulant therapy safer: Patient Safety Alert
- Reducing dosing errors with opioid medicines: Rapid Response Report

….And answer the following questions for the chosen alert:

- When did you hear about this alert?
- Note down the main points of the NPSA alert you have chosen
- Write down what has been done in your organisation to implement the alert including:
  - Who leads this for the pharmacy team?
  - Who else is involved in implementing and monitoring it?
  - What you do to support implementation and monitoring of compliance to the requirements i.e. prescribing, supply, administration or directly with patients?
  - What actions have been taken by other healthcare staff within and/or outside your organisation?
  - Are there local guidelines that have been published to support implementation and if so how have these been communicated?
  - What training and education has been put in place for you, the pharmacy team and other healthcare staff?
Clinical Directorate

Section 7: Implementing Solutions to Reduce Harm

- What is being done to assure continued compliance with the recommendations? Are you involved with this?
  - As a lead for implementing one or more NPSA alerts consider the task above for an alert you have been leading on. Review whether the pharmacy team and other healthcare staff would be able to answer the questions easily. What could you do to improve communication or evaluate awareness of the actions you implemented for the selected NPSA alert?

What next?

Further Reading

- East and South East Specialist Pharmacy Services (Clinical Directorate) have produced resources to support NPSA alert implementation (e.g. Opiate alerts and anticoagulation).
- NPSA Never Events Framework 2010-11 Guidance  

Practical next steps

- Next time you come across a prescription or service that involves the supply of methotrexate, warfarin, morphine, or oral anti-cancer drugs, find out what the actions were on the relevant NPSA alert. Write down the ones that are relevant to your work.
- Are you or your service meeting the requirements? How could you evaluate this? List the barriers to implementing these actions?
- Consider the most recent NPSA alert that has been published relating to medication (but has not passed the action deadline) that you are leading on or which impacts on a clinical area you are responsible for. Find out and write down the implementation plans and actions to date:
  - Strategically: Who is the organisational lead; where is implementation planning taking place? Has a risk assessment or impact assessment been completed?
  - Operationally: What baseline audits have been carried out? Which stakeholders have been identified as being key to implementation?
- From the above consider whether pharmacy is involved enough in the implementation planning phase. How could you improve this?

Using this section for CPD

By working through this section you will be able to record or include what you have learnt as a portfolio entry: For example you could:

- Include the answers to the task about an NPSA alert to record in your portfolio what you found out and how you apply the requirements of the alert into your practice.
- Use an example where a medication incident relating to a published alert highlighted the need to review the processes that had been put in place for the alert.

The section could identify further learning needs that you can complete as Plan and Record CPD entries starting at “reflection”
7.2 Implementing solutions to local medication incidents

In addition to the requirements published by the NPSA, there will be actions that result from locally identified medication incidents. Section 1.2.1 will help you to identify the local infrastructure for patient safety and whether a member of the pharmacy team is involved in agreeing the actions required for local medication incidents.

From the root cause analysis of a medication incident (see Section 6) the local solutions will be in the form of an action plan. The plan will involve changes to the way medicines are prescribed, dispensed, supplied, stored or disposed of, and may also include staff training.

7.2.1 Barrier analysis

The plan would have taken into account the changes that could be put into the pathway that would reduce the risk of the incident happening again. This is called "Barrier Analysis" which is a tool available via the NPSA risk assessment programme (www.nrls.npsa.nhs.uk). This technique establishes what barriers (defences or controls) should have been in place to prevent the incident, or could be installed to increase system safety. Barrier analysis offers a structured way to visualise the events related to system failure. It can be used reactively to solve problems or proactively to evaluate existing barriers as part of a risk assessment (see Section 3).

You are likely to find that the barriers to medication systems and procedures will fall into the following four categories:

- **Physical**: e.g. introducing a locked medicine cupboard; computer programmes which prevent the inputter from going further if a field is not completed

- **Natural**: e.g. barriers of distance, time or placement: such as administration of methotrexate and vincristine on different days by different persons; system for checking prescriptions in Community Pharmacy i.e. 10 min break between first check and dispensing of drug

- **Human action**: e.g. checking the patient’s pulse before administering a medicine

- **Administrative**: e.g. an extra check at the point of dispensing of a particular medicine; supervision and training; protocols and procedures

Of these four types of barrier, physical barriers are the most reliable in terms of providing failsafe solutions to safety problems. Natural barriers, whilst less effective, generally provide a more robust solution than human action and administrative barriers. The reason that human action and administrative barriers are considered to be the least reliable barriers, in terms of failsafe, is because they rely on human action and behaviour. As we know, all humans are known to make mistakes.
The implementation of changes to introduce barriers not only involves agreement about what to change, but also needs effective planning about how to change practice. This will need to involve all the key stakeholders who will be affected by the changes and who can embed the new systems within everyday practice. If you work for a small organisation then this may be relatively simple. Larger organisations such as hospitals or the large community pharmacy multiples may find this more challenging!

*Further consideration of change is outside the scope of this resource and is termed “change management”. If you are involved in implementing solutions to medication safety incidents on behalf of your department or team, then you will need to develop skills in this area.*

Interestingly in the NHS there is a tendency to use the human and administrative solutions, perhaps because they are perceived as being easier to implement both operationally and financially. One way to strengthen these types of measures is to implement multiple solutions or barriers at different stages of the process. Whilst many of these may also be administrative or human action controls, their collective strength always provides for a more successful safety improvement plan.

*If you are involved in agreeing and prioritising the solutions to local medication incidents, barrier analysis may help you to ensure the most effective solutions are implemented first.*

The NPSA tool suggests the following steps to completing a barrier analysis once an incident has occurred:

1. Identify the issue to be analysed e.g. Giving a controlled drug to a patient (right drug, right patient, right route, right dose).
2. List all the barriers that were/are in place to enable this to occur.
3. Consider the circumstances of the incident and assess the performance of each barrier on this occasion.
4. For barriers that are assessed as having failed, consider why they failed. (This is best undertaken in a group situation but can be done by individuals). Consider also the impact of each failure on the incident you are analysing i.e. was it influencing or causative? If the failure was causative, then your efforts should be focused on this aspect of the system in terms of quality and safety improvement, once you have developed an understanding as to WHY it failed.
5. Record your findings and identify the improvements recommended. N.B. you may occasionally have to explore the causative failures further using the Fishbone and Contributory Factors Classification Framework, or the Five Why Technique before recommendations can be made.

**Top Tip:** Don’t forget that for any medication incident there may already be examples of solutions from published articles or from similar incidents managed by other colleagues within your networks. Consider conducting a literature search via your local or regional Medicines Information team or asking for examples via local pharmacy and patient safety networks.
7.3 Local Serious Incidents

Serious incidents (SIs) have specific requirements for organisations to implement which are clarified for NHS service providers (including community pharmacies and hospitals), and at the time of writing this resource, PCTs and SHAs. These are detailed in the NPSA Serious Incident Reporting and Learning Framework (SIRL) published in April 2010 (available at www.nrls.npsa.nhs.uk). Definitions, and the grading and reporting of serious incidents is considered by this resource in Section 4 (Promoting Reporting).

Management of serious incidents by an organisation is explicit within the guidance and involves the setting up of an investigation team, completion of a root cause analysis (RCA), development of an action plan, completion of the actions and sharing of learning. However for SIs, the information is shared locally with commissioners, regionally and nationally (via the NPSA) for analysis and national action.

The other main difference between the management or patient safety incidents and SIs is the pace of investigation and action. There are explicit timescales quoted in the guidance for completing the RCA and investigation. The timescales and level of external involvement of commissioners and other organisations depend on the grade of the incident. If you are a lead for medication safety you will need to consider:

- How you are involved in supporting the SI process including identifying whether medicines are involved in the pathway/incident or not.
- What other pharmacy team involvement there needs to be at each stage in the SI process.

Over to you

**Example in Practice:** A patient comes into the pharmacy clutching a box of nicorandil 20 mg. She accuses you of supplying her with the wrong medication as she usually has nicardipine 20mg. A friend of hers, who is a nurse, told her that this mistake could have made her very ill. She is very angry, hands you the box of tablets and asks you to sort this out and find out how she can claim damages! She plans to return later that afternoon and leaves before you can ask her for any more details.

When you look back at your records, you find out that the patient did indeed usually have nicardipine, but that the latest supply (corresponding with the returned box and label) was nicorandil.

On retrieving the prescription, you find that the prescriber had prescribed nicardipine, hence suggesting a dispensing mistake. There was no evidence on the Pharmacy Record including the prescription itself about any intervention made during the supply of the medication. On further investigation with the pharmacy staff involved in dispensing the prescription you find out that none of the staff had queried the apparent change in medication. None of them can recall who handed the medicine to the patient or whether they were counselled.
The action plan shows the following changes and interventions that require implementation:

- Revision of dispensing SOPs to specify that checks must be undertaken by at least two different people: a dispenser and a checker, with a clinical check provided by a pharmacist.
- Revision of the SOP for handing out prescribed medicines to include showing the patient the medicines being supplied and counselling them on any changes. If a patient representative collects the items, then advise them that the patient should check these upon receipt and contact the pharmacy immediately if the medicines are different to what they are expecting.
- Training of all staff involved who work within the dispensing and supply SOPs, with the introduction of formal documentation to show completion of this training.

- What types of “barriers” have been introduced by the action plan?

- Of these which is/are the stronger barriers?

- Are there any other stronger barriers you could introduce?

- If the patient had taken one or more doses of nicorandil and had come to harm, how would this have changed the way this incident was handled? What would have been the time scales for actions?

Further Reading

- NPSA Barrier Analysis Tool (www.nrlls.npsa.nhs.uk)
- NPCi website (www.npci.org.uk): Take the NPCi lift and you will find some resources are available on the within the “Developing People and Organisations” section that will be useful if you are involved in agreeing solutions or leading the implementation of solutions of medication incidents.
- NPSA “Safety in doses” report 2009: Section 9 provides a list of medication safety references published during 2007. Some of these explore the impact of particular types of safety barrier.
Practical next steps

- Find a report from a medication incident that happened more than six months ago and was subject to a root cause analysis. From this report try and follow-up the implementation of solutions by finding:
  - The action plan for this incident
  - What actions needed pharmacy staff to change what they do
  - What actions needed changes by other healthcare staff
  - Which categories of barrier the actions belong in
  - What evidence can you find that the actions have been implemented (e.g. policy revision, new storage arrangements, training available, information available for staff i.e. posters/newsletters)
  - Did any of these actions result in a change to your practice (or should they have done but until reading about this incident you didn’t know about it!)

- Using the NPSA Serious Incident Reporting and Learning Framework (SIRL) as a reference (www.nrls.npsa.nhs.uk) find out whether there have been any serious incidents (SIs) reported in the last 12 months that are medication related. If there are, select one and find:
  - The action plan and any reports available about how the organisation handled this incident
  - Has the incident been graded in line with regional or trust grading of SIs? If so what level has the incident been graded at?
  - Does the management process appear to follow the NPSA SIRL Section 2.5 guidance?
  - Was a member of the pharmacy team involved in the management of the SI?
  - Is there evidence of implementation of the actions via:
    - Changes in staff practice (pharmacy staff or others)
    - Training
    - Physical barrier implementation
    - Other
  - From your understanding or experience of the process for managing incidents that are not defined as SIs, does the management of the SI suggest a more responsive action to the SI by your organisation?
  - Are there elements of the SI process that you may be able to apply to improve the management of non-SIs?
Using this section for CPD

By working through this section you will be able to record or include what you have learnt as a portfolio entry: For example you could:

- Use your written answers to the task and compare these against the suggested answers. Document any new development needs this identified for you
- Document details of a medication incident (e.g. a copy of the incident report form) and what you have learnt from the incident

The section could identify further learning needs that you can complete as Plan and Record CPD entries starting at “reflection”

Example in Practice: case scenario: some answers

What types of “barriers” have been introduced by the action plan?

Changing SOPs; ensuring a check is carried out by another person; providing training and audits are administrative barriers; showing the medicines to the patient for verification prior to supply is a human action barrier;

Of these which is/are the stronger barriers?

Both human action and administrative barriers are equally weak. Physical and natural barriers are stronger

Are there any other stronger barriers you could introduce?

Ideas include: Using IT warning for similar named items that comes up as they are dispensed (these could be locally agreed and added in - this is a physical barrier; Having a time lag between dispensing and checking that allows a longer separation of the two activities - this is a natural barrier.
## Appendix 1: Learning outcomes and Links to the General and Advanced and Consultant Competency Frameworks

<table>
<thead>
<tr>
<th>Learning Outcome (LO)</th>
<th>Resource Section/Sub-section</th>
<th>Relevant GLF competencies: Cluster¹: competency; behaviour</th>
<th>Relevant ACLF competencies: Cluster²: competency; level</th>
</tr>
</thead>
<tbody>
<tr>
<td>The LOs in blue - with an italic font are LOs for extending your knowledge and skills in medication safety further- see “Is this for me” section on page 5</td>
<td></td>
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<tr>
<td>Explain the causes of failure and the personal vs. systems approaches to incidents</td>
<td>Preface Sub-section P3</td>
<td>PS: Analysing information; Summarise information</td>
<td>EPP: Expert skills and knowledge; Foundation</td>
</tr>
<tr>
<td>Connect this theory to the outcomes from injectable route incidents</td>
<td>Preface Sub-section P3</td>
<td>DPC: Provision of drug product; labelling of the medicine</td>
<td>R&amp;E: Research evidence into practice; Excellence</td>
</tr>
<tr>
<td>Describe the culture of fair blame and the human factors that affect this</td>
<td>Section 1 Sub-section 1.1</td>
<td>PS: Analysing information; Summarise information</td>
<td>R&amp;E: Critical evaluation; Foundation</td>
</tr>
<tr>
<td>Determine how to deal with staff involved in an incident and what professional consequences there may be for them</td>
<td>Section 1 Sub-section 1.1</td>
<td>PC: Effective communication skills; medical staff; nurses; other healthcare professionals; pharmacy; other health staff; immediate pharmacy team</td>
<td>BWR: Communication; Foundation M: Managing performance; Foundation</td>
</tr>
<tr>
<td>Explain local infrastructure, priorities and national requirements for medication safety</td>
<td>Section 1 Sub-section 1.2</td>
<td>PC: Organisation; prioritisation M&amp;O: Organisations; Organisational structure</td>
<td>L: Strategic context; Foundation M: Implementing national priorities; Foundation</td>
</tr>
<tr>
<td>State the national contractual structures and quality standards that exist, relating to patient safety and medicines use</td>
<td>Section 1 Sub-section 1.2</td>
<td>M&amp;O: Clinical governance; clinical governance issues M&amp;O: Organisation; linked organisation</td>
<td>EPP: Expert skills and knowledge; Foundation L: Strategic context; Foundation</td>
</tr>
</tbody>
</table>

¹Key: DPC: Delivery of Patient care PC: Personal Competencies PS: Problem Solving M&O: Management and Organisation
²Key: EPP: Expert Professional Practice; BWR: Building Working Relationships; L: Leadership; M: Management; ET&D: Education, Training and Development; R&E: Research and Evaluation
| Define how medication safety can be included in the commissioning of services | Section 1 Sub-section 1.3 | M&O: Service provision; Quality of service; Service development | M: Implementing national priorities; Foundation; Standards of practice; Foundation  
| M: Strategic planning; Excellence |
| Access information that supports the incorporation of medication safety within service specifications and service monitoring | Section 1 Sub-section 1.3 | PS: Gathering information; Accesses information | M: Implementing national priorities; Foundation; Standards of practice; Foundation  
| M: Managing risk; Foundation  
| M: Strategic planning; Excellence |
| Describe what is in place to support pharmacy staff as leaders in medication safety | Section 2 Sub-section 2.1 | PC: Teamwork; pharmacy team; Professionalism; responsibility for patient care | EPP: Expert skills and knowledge; Excellence  
| L: Clinical Governance; Foundation  
| L: Vision; Foundation  
| ET&D: Role model; Excellence |
| Determine whether your organisation has the building blocks for safe medicines handling | Section 2 Sub-section 2.1 | M&O: Organisations; organisational structure; Clinical Governance; working environment | EPP: Reasoning and Judgement; Foundation  
| L: Service Development; Foundation |
| Influence other health professionals in delivering safer medicines use | Section 2 Sub-section 2.2 | PC: Communication skills; medical staff; nurses; other health professionals; Teamwork; multi-disciplinary team | BWR: Communication; Foundation  
| L: Clinical Governance; Excellence  
| L: Motivational; Excellence  
| ET&D: Role model; Excellence |
| Strengthen your role and the roles of other pharmacy staff in training other health professionals in medication safety | Section 2 Sub-section 2.2 | M&O: Training; other healthcare professionals | BWR: Teamwork and consultation; Excellence  
| L: Motivational; Excellence  
| ET&D: Conducting education and training; Excellence  
| ET&D: CPD; Mastery  
| ET&D: Educational policy; Excellence |
| List the elements that contribute to the delivery of a safe pharmacy service | Section 2 Sub-section 2.3 | M&O: Clinical governance; all behaviours | L: Clinical governance; Foundation  
| M: Standards of practice; Foundation  
| M: Managing risk; Foundation |
| **Introduce medication safety objectives into pharmacy staff development and appraisals** | Section 2 Sub-section 2.2 | M&O: Staff management; Performance management; staff development | M: managing performance; Excellence  
ET&D: CPD; Mastery |
|---|---|---|---|
| **Explain the principles of risk management** | Section 3 Sub-section 3.1 | M&O: Clinical Governance; risk management | EPP: Expert skills and knowledge; Excellence  
L: Clinical Governance; Foundation |
| **Contribute to risk assessments within your organisation** | Section 3 Sub-section 3.1 | DPC: Monitoring drug therapy; identification of medicines management problems  
PS: Analysing information; all behaviours | EPP: Reasoning & Judgement; Excellence  
L: Clinical Governance; Excellence  
M: Managing risk; Foundation |
| **Discuss methods of managing and minimising risks in medicines management within your everyday work situations** | Section 3 Sub-section 3.2 | M&O: Clinical Governance; risk management | L: Clinical Governance; Foundation  
M: Managing risk; Foundation |
| **Generate priorities for medication risk management and use these proactively** | Section 3 Sub-section 3.2 | DPC: Monitoring drug therapy; prioritisation of medicines management problems  
PC: Organisation; prioritisation | M: Managing risk; Foundation  
L: Service development; Excellence |
| **Define patient safety incidents, medication errors and adverse drug reactions and events** | Section 4 Sub-section 4.1 | DPC: Monitoring drug therapy; identification of medicines management problems | EPP: Expert skills and knowledge; Foundation |
| **Discuss with the team what should be reported and how** | Section 4 Sub-section 4.1 | DPC: Monitoring drug therapy; Record of contributions  
M&O: Clinical Governance; risk management | BWR: Communication; Excellence  
BWR: Teamwork and consultation; Excellence  
M: Implementing national priorities; Excellence |
| **Explain the use of triggers tools to identify and monitor the frequency of adverse events** | Section 4 Sub-section 4.2 | PS: Analysing information; Summarise information; Logical approach | EPP: Expert skills and knowledge; Excellence  
EPP: Reasoning & Judgement; Excellence  
M: Managing risk; Foundation |
### Appendix 1: Learning Outcomes with GLF/ACLF Mappings

| Describe what incidents should be reported locally and nationally | Section 4 Sub-section 4.2 | M&O: Clinical Governance; risk management | M: Implementing national priorities; Excellence  
M: Standards of practice; Foundation |
|---|---|---|---|
| Cite ways in which patients are involved in decisions relating to patient safety | Section 5 | DPC: Patient consultation; patient consent  
DPC: Medicines information and patient education; Health needs; Need for information is identified; Provision of written information | EPP: Patient care responsibilities; Foundation |
| Effectively communicate with a patient about an adverse event that has not resulted in actual harm | Section 5 | DPC: Patient consultation; Patient assessment  
PC: Effective communication skills; Patient and carer | BWR: Communication; Foundation  
EPP: Patient care responsibilities; Foundation/Excellence  
BWR: Communication; Foundation |
| **Involve patients in managing medication incidents and risks** | Section 5 | DPC: Patient consultation; patient consent  
DPC: Medicines information and patient education; Health needs; Need for information is identified; Provision of written information  
PC: Effective communication skills; Patient and carer | EPP: Patient care responsibilities; Foundation/Excellence  
BWR: Communication; Foundation |
| Explain the role of root cause analysis on the investigation of incidents | Section 6 | PS: Analysing information; Summarise information;  
PS: Logical approach  
PS: Expert skills and knowledge; Excellence  
EPP: Expert skills and knowledge; Reasoning & Judgement |
| Use the Five Whys tool to help assess the causes of a medication incident | Section 6 | PS: Analysing information; Logical approach  
PS: Expert skills and knowledge; Excellence  
EPP: Expert skills and knowledge; Reasoning & Judgement  
M: Managing risk; Foundation |
| **Conduct a root cause analysis for a Level 1 investigation using variety of available tools** | Section 6 | PS: Gathering information; all behaviours  
PS: Analysing information; all behaviours  
EPP: Expert skills and knowledge; Excellence  
EPP: Reasoning & Judgement  
M: Managing risk; Foundation |
<table>
<thead>
<tr>
<th>Task</th>
<th>Section</th>
<th>Outcomes</th>
</tr>
</thead>
</table>
| List the NPSA alerts and RRRs relating to medication safety and discover what has been done to implement these locally | Section 7 Sub-section 7.1 | **DPC**: Medicines information and patient education; *Use of guidelines*  
**PS**: Gathering information; *up to date information*  
**EPP**: Expert skills and knowledge; *Excellence*  
**M**: Implementing national priorities; *Foundation*  
**M**: Standards of practice; *Foundation*  
**M**: Managing risk; *Foundation*  

| Lead the review and implementation of an NPSA alert or RRR | Section 7 Sub-section 7.1 | **PC**: Professionalism; *Responsibility for own action; Responsibility for patient care*  
**M&O**: Clinical governance; *clinical governance issues*  
**L**: Strategic context; *Excellence*  
**L**: Innovation; *Mastery*  
**M**: Implementing national priorities; *Foundation*  
**M**: Standards of practice; *Foundation*  
**M**: Managing risk; *Foundation*  

| Identify other risks that have been addressed within pharmacy processes | Section 7 Sub-section 7.2 | **DPC**: Monitoring drug therapy; *identification of medicines management problems*  
**M&O**: Clinical governance; *clinical governance issues; standard operating procedures*  
**L**: Clinical governance; *Foundation*  
**M**: Standards of practice; *Foundation*  

| Describe other serious incidents in your organisation and what has been implemented to minimise the risk of recurrence | Section 7 Sub-section 7.2 | **DPC**: Monitoring drug therapy; *identification of medicines management problems*  
**DPC**: Evaluation of outcomes; *Assessing outcomes of contributions*  
**PS**: Follow-up; *Ensures resolution of problems*  
**M&O**: Clinical governance; *clinical governance issues*  
**EPP**: Expert skills and knowledge; *Excellence*  
**EPP**: Patient care responsibilities; *Foundation*  
**M**: Implementing national priorities; *Foundation*  
**M**: Standards of practice; *Foundation*  
**M**: Managing risk; *Foundation*  