



An introduction to risk assessment

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Risks can be managed in several ways – reactively, after something has gone wrong – or proactively, to prevent situations from developing. For those who have not undertaken a risk assessment, this article describes where to start, how to do a risk assessment, rate a risk and prepare a risk register.

Why is risk assessment important?

In order to manage risk, first we need to be aware of risks, which might develop into harmful situations if nothing is done to prevent this from happening. For example, a technician preparing cytotoxic treatments might be exposed to a harmful agent. This is a risk. But what should be done? What is the exact risk? What can be done to reduce it to an acceptable level as risk cannot be eliminated? This article provides some straightforward tools to help pharmacists understand and manage these risks

What is a risk assessment?

A risk assessment is a process that helps identify:

- the range of risks an organisation faces
- the level or ability to control those risks
- their likelihood of occurrence
- their potential impact.

Typically, risks identified in this way are recorded in a risk register.

Pharmacists are responsible for complex systems that supply medicines and advice. There are risks associated with these processes as well as risks with the medicines themselves. Risk assessments in pharmacy should therefore look at both.

So, how do you decide where to start?

You could start by looking at your key functions as a department and asking what the risks are associated with them. A risk assessment is also valuable at various stages of change, e.g. prior to the development or implementation of a new project or service, or a change in

service or when a service is under financial or staffing pressure. An example would be when considering introducing a new service such as patients self-administering their own medicines. Other examples include following an investigation of an incident or complaint, or when you become aware that you are failing to comply with national guidance, standards or legislation, or when a change in legislation or guidance may affect practice or following the introduction of new equipment or a new drug. This may be particularly relevant for high-risk drugs such as IV medication.

You can also look at medicines and the processes around the supply of, and advice on, medicines, e.g. assess high-risk drugs such as anticoagulants.

What does a risk assessment consist of and how do you do one?

A risk assessment is best undertaken with a group of people who are familiar with the risk, and can identify all the relevant elements of the risk assessment including solutions (an action plan). The process is outlined below; the information should be captured on a risk assessment form.

Describe the risk

What is the risk you are attempting to manage? For example, the risk of inadequate numbers of staff to provide clinical pharmacy services, or is it a risk related to a specific area of medicine, e.g. the risk of giving a drug by the IV route instead of the intrathecal route.

Who is undertaking the risk assessment?

Record the people who are undertaking the risk assessment.

What could go wrong and what are the consequences?

Describe what could go wrong and what that would mean, e.g. inadequate numbers of staff could mean not all medications are checked and therefore there is an increased risk of error. For the IV example, what could go wrong is that the drug could be given by the IV route instead of the intrathecal route or vice versa. The consequences of either mistake are potentially fatal, depending on the drug [1].

Who is at risk and what is the frequency?

The risk group is usually patients, but may be staff or members of the public depending on the risk. The frequency is how often the group at risk is exposed to the risk, e.g. daily or weekly. The frequency often has to be estimated if data is not available.

What are the existing control measures?

These are the measures that are already in place to reduce the risk, e.g. for a risk associated with administration, current controls could include procedures, training and double checking.

Rate the risk

Having considered the risk, you then rate it using consequences and likelihood. The risk rating helps to identify the level at which the risk will be managed in the organisation, to assign priorities for action and to include the risk in the organisation risk register at the appropriate level. For example, red risks may be reported to the hospital Board whereas green and yellow risks could be managed locally.

Table 1: Consequence/impact descriptors

| Descriptor | 1 Insignificant | 2 Minor | 3 Moderate | 4 Major | 5 Extreme |
|--|---|---|---|--|---|
| Event affecting the safety of patients, staff or public (physical/psychological harm) | Minimal injury requiring no/minimal intervention or treatment No time off work | Minor injury or illness, requiring minor intervention Requiring time off work for >3 days Increase in length of hospital stay by 1-3 days | Moderate injury requiring professional intervention Requiring time off work for 4-14 days Increase in length of hospital stay by 4-15 days An event which affects a small number of patients | Major injury leading to long-term incapacity/disability Requiring time off work for >14 days Increase in length of hospital stay by >15 days Mismanagement of patient care with long-term effects | Incident leading to death Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients |
| Financial | Local management tolerance level | Loss less than Euros 0.5 million | Loss between Euros 0.5 million and Euros 0.999 million | Loss between Euros 1 million and Euros 4.9 million | Loss of more than Euros 5 million |
| Quality | Minor non-compliance with internal standards | Single failure to meet internal standards or follow protocol | Repeated failures to meet internal standards or follow protocols Potential to affect external standards | Failure to meet one or more external standards | Affects achievement of a significant amount of external standards |
| Statutory duty/inspections | No or minimal impact or breach of guidance/ statutory duty | Breach of statutory legislation Reduced performance rating if unresolved | Single breach in statutory duty Challenging external recommendations/ improvement notice | Enforcement action Multiple breaches in statutory duty Improvement notices Low performance rating Critical report | Multiple breaches in statutory duty Prosecution Complete systems change required Zero performance rating Severely critical report |

The number against the descriptor is the consequence score.

Consequences should be developed locally but an example of some descriptors is shown in Table 1. Other descriptors include quality and data security. Use the table to identify the most likely/appropriate level of how serious the consequence of the risk could be. Select the ‘best fit’ descriptors from the first column and map to the ‘best fit’ consequence descriptor from columns 1–5. This will provide the consequence score. If several consequences are applicable, use the highest score to determine the consequence.

What is the likelihood of the consequence occurring?

Use the descriptors in Table 2 to assess

the likelihood of the consequence occurring, selecting from either the probability descriptors or the frequency descriptors, whichever is most accurate or appropriate. It may be possible to use supporting data such as incidents reported and audit. Like the assessment of the ‘consequence’, the likelihood of a risk occurring is assigned a ‘best fit’ number from 1–5; the higher the number, the more likely it is the consequence will occur.

Multiply the consequence score C with the likelihood score L to obtain the risk rating and use the risk matrix shown in Table 3 to determine the risk rating.

For example, if the consequence is moderate (3) and the likelihood is almost certain (5), the result is Moderate (Orange).

Action plan

This is a very important part of the risk assessment and details what action will be taken to reduce the risk. The grading of the risk determines the level within the organisation responsible for overseeing the actions. For example red risk action plans will be overseen by the Board whereas orange risk actions plans could be overseen by a committee such as a Medicines Committee. Action plans should be SMART – Specific

Table 2: Likelihood descriptors

| Likelihood descriptor | 1 Rare | 2 Unlikely | 3 Possible | 4 Likely | 5 Almost certain |
|---|--|--|---|---|---|
| Probability Will it happen or not? | This is likely to occur in 1% of occasions | This is likely to occur in 20% of occasions | This is likely to occur in 50% of occasions | This is likely to occur in 80% of occasions | This is likely to occur in 90–99% of occasions |
| Frequency How often might it/does it happen in a defined period | Not expected to occur for years | Expected to occur at least annually | Expected to occur at least monthly | Expected to occur at least weekly | Expected to occur at least daily |
| Frequency How often might it/does it happen in general | This will probably never happen/recur | Do not expect it to happen/recur but it is possible it may do so | Might happen or recur occasionally | Will probably happen/recur but it is not a persisting issue | Will undoubtedly happen/recur possibly frequently |

The number against the likelihood descriptor is the likelihood score.

Table 3: Risk Matrix (Risk [R] = Consequence [C] * Likelihood [L])

| Likelihood | Consequence | | | | |
|-------------------------|-----------------|---------|------------|---------|----------------|
| | 1 Insignificant | 2 Minor | 3 Moderate | 4 Major | 5 Catastrophic |
| 1 Rare | Green | Green | Yellow | Orange | Orange |
| 2 Unlikely | Green | Green | Yellow | Orange | Red |
| 3 Possible | Green | Yellow | Yellow | Orange | Red |
| 4 Likely | Green | Yellow | Orange | Red | Red |
| 5 Almost certain | Yellow | Yellow | Orange | Red | Red |

An example of a risk assessment scoring system.

How do you rate these risks?

Risk assessment can be very subjective depending on interpretation of the risk and local priorities. For example discuss the following amongst your colleagues. Do you all agree on the risk rating?

Using the likelihood and consequence descriptors (see Table 1) and risk rating (see Table 3) identify the risk rating for the following risks:

- Patient receiving intrathecal vincristine instead of methotrexate
- Patient not receiving their drugs as prescribed whilst an inpatient
- Patient who is allergic to penicillin receiving piperacillin

assessment is only of value if it is used to reduce risks so implementing the actions agreed is perhaps the most difficult but most important part of the process.

Measurable, Achievable, Relevant and Timed, i.e. have timescales.

The risk register

This is a register of risks in the department or organisation and may have different formats but typically contains the following information:

- Description of risk
- Describe why it is a risk
- Risk rating
- Existing controls
- Action plan
- Person responsible
- Completion date for action

The register contains in one place all the information derived from risk assessments and can be used to manage the risks, e.g. selecting all red and orange risks every quarter and checking progress on actions.

Risk assessment should be part of the routine in any quality system. It should be part of training for every pharmacy professional. If risks are assessed and then preventive strategies are adopted, we have a proactive way of dealing with risk. This is much better than not taking effective action, but reacting only when a difficult situation has arisen. Finally, risk

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Reference

1. National Patient Safety Agency alert November 2009, ref. 0972A