Risk assessment methods and tools used in the National Health Service, UK

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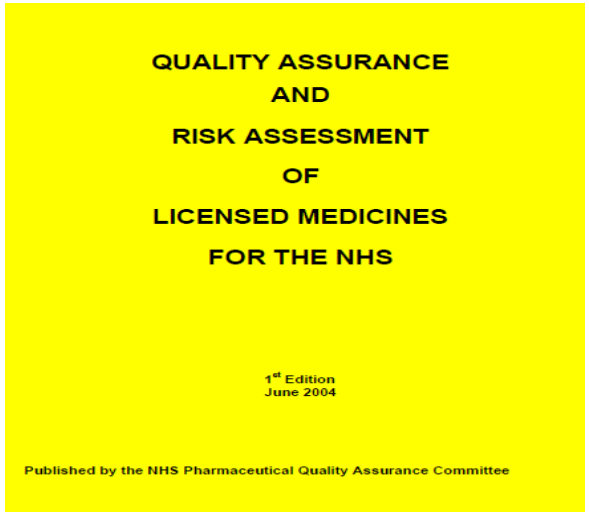
National Contracts
Purchasing for safety

- Department of Health Report – An organisation with a memory – 2000, 2001
- Good practice guidance
  - MHRA MLX275 – 2001, GN 25 – 2003
  - NPSA Design for Patient Safety, 2006, 2007
- NHS pharmaceutical quality assurance committee 2004
  - Risk assessment of licensed medicines
- Supply chain excellence programme (SCEP) 2004 involving pharmacy procurement, quality assurance, aseptic service and clinical staff – at local, regional and national level. Pharmacists have to be involved!
- Alldred A. Hospital Pharmacist 2006 ; 13:17-19

Aims of the national approach to risk assessment

- To learn from errors associated with medicines and contribute to the reduction in adverse events
- To use risk assessment criteria to ensure products with inherent risks are not awarded a contract and to reduce the errors associated with critical products
- To use risk assessment criteria to hold informed discussions with pharmaceutical industry about the importance of labelling and packaging to reduce errors
- To analyse the financial impact of basing the decisions making process on a risk assessment approach

Medication Error Potential Analysis



Overall Risk Assessment Score

Low = 0-99
Medium = 100-249
High = 250 and above

- **RISK ASSESSMENT**: Medication Error Potential

Contract Team .....

Medicine INN (generic name): Medicine Brand Name: Form & strength: NPC Code	Manufacturer/Supplier:	Date: Name of Assessor:

Aide-Memoire	MEPA score range	MEPA score	Tick where critical or high risk *	Brief description of risk
Consider error potential of confusing the medicine with another product due to poor labelling of critical information:				
Is presence of critical information clear, in as larger font as possible, and as stated in the SPC (name, form, strength)? • Generic name and form of medicine • Strength	0-2			
Where necessary (e.g. for patient packs): • Route of administration • Dosage • Critical warnings (are only positive warning statements used?)	0-1			
Consider error potential of confusing the medicine with another due to poor label and pack design characteristics:				

Situations requiring risk assessment

- Manufacturers unknown to the contracting team, or with poor track record
- New generic products
- Change of contract, new different supplier, or where notified by users of risks
- Where additional information required
- Different license indications
- Parallel imports, patient packs, A&E packs
- High risk products e.g. potassium, intrathecal
- Novel presentation e.g. prefilled syringes
- Products used in aseptic manufacture
- Products with look-alike, sound –alike names

Error potential analysis

- Confusing a medicine with another product due to poor labelling or packaging
- Confusing a medicine with another due similarity across a product range
- Confusing the medicine with another product when it has been removed from outer packaging
- Providing the incorrect dose due to complex manipulation before administration
- Providing the incorrect dose due to poor or insufficient technical data

Safer labelling and packaging in the UK

New UKMI Risk Assessment Tool

Tool for assessing the in-use patient safety characteristics of medicines and medicinal products – United Kingdom Medicines Information

To be used for 'new' medicine 'products' being introduced into use into a NHS organisation

Topics for review:

- License status
- Name, packaging and labelling, and other pharmaceutical issues
- Information provided with product
- Prescribing risks
- Known risks and management
- Preparation, calculation. Labelling and information
- Administration
- Supply chain issues
- Disposal
- Impact of clinical setting
- Summary and outcome

Risk theme feature: Identification of licensing Status	
A1	**Does the product have a UK marketing authorisation?**
A2	**Is it going to be used only within that marketing authorisation?**
A1-2 - additional	**Is the product one with UK marketing authorisation, but where the use is not included in the marketing authorisation?**
A1-2 - additional	**Does the product <u>not</u> have UK marketing authorisation?**
Risk theme feature: Questions for "off-label" and unlicensed medicines	
A3	Is there a suitable product available with a marketing authorisation for the indication in question?
A3 - additional (1)	Is the medicine a licensed generic product that is being used instead of a branded product?
A3 - additional (2)	What type of unlicensed medicine is being considered?
A4	Is the anticipated use supported by a reasonable evidence base?
A5	Is technical and patient information available in English to support the particular anticipated use?
A6	Do you have assurance of pharmaceutical quality? For example, If the medicine is unlicensed, is the supplier of the medicine suitably licensed? What type of assurance process does the manufacturer have in place?

Risk theme feature: the medicine's name	
B1	The brand name is:
	The generic name is:
B1	Could any of the medicine’s names be confused with those currently in existence?
Risk theme feature: packaging and labelling	
B2	Is the medicine’s generic name clearly identifiable in English on the packaging
B3	Is other critical information also clearly identifiable in English on the packaging?
B4	Is the critical information above clear on all sides of the packaging as well as on both primary (e.g. the ampoule) and secondary (e.g. the carton) packaging?
B**4 – contd**	For branded medicines, is the generic name also suitably prominent?
B5	Is pharmaceutical information such as the batch number, expiry date, and storage conditions clear and unambiguous on the packaging?
B6	Where medicines contain more than one active ingredient, are all generic constituents clearly stated on the packaging?
B7	Is the expression of strength stated on the packaging consistent with prescribing practice?
B8	Does the packaging encourage (or at the least not hinder) differentiation between a range of products from a single supplier, or between different products from different suppliers?

Risk theme feature: prescribing risks	
D1	Is the product an additional treatment option, or is it replacing another product or drug?
D2	Are there particular issues associated with non-familiarity or confusion with existing treatments?
D3	Is the dosing and prescribing of the medicine complex?
D4	Who will prescribed the item? And is the prescribing of the medicine likely to be within the normal scope of practice for expected prescribers?
D4 - contd	Is the process of prescribing likely to be familiar to the prescriber?
D5	Is the prescribed dose consistent with the way the strength, form, and (where applicable) base salt are presented?

Risk theme feature: known risks and management	
E1	Has the medicinal product (or any similar product) been the subject of any previous medicines safety alerts (such as an NPSA report, description as a never event, or inclusion on an MHRA drug safety bulletin)?
E2	Is the medicine under intensive regulatory surveillance?
E3	Are new or amended clinical or laboratory monitoring requirements associated with the introduction of the medicinal product?
E4	Does the medicine have the potential to cause significant harm in deliberate or inadvertent overdose? And if it does, are suitable reversibility and antidote strategies available? Or alternatively are clinical management strategies in such circumstances defined?
E5	Where necessary, is tailored patient facing information available to support safe use of the medicine? For example, are steroid or lithium cards present if necessary?

Risk theme feature: Operator safety	
F1	Are there current known operator safety issues with the drug?
F1 - contd	Is the medicine of a class where operator safety issues might be a concern? Is the medicine subject to COSHH regulations, for example?
Risk theme feature: Preparation and manipulation prior to administration	
F2	Is the medicine supplied to the end user in a presentation that is either ready-to-use (i.e. it is the correct volume and correct strength and is ready to draw up) or ready-to-administer (i.e. in its final container suitable for administration directly to the patient)?
F3	In the form presented, are commonly used doses easy to measure?
F4	If manipulation is required prior to administration, is it complex (i.e. does it have 5 or more defined steps)?
F4 - contd	Where manipulation is required prior to administration, does it involve any special or unusual complexities?
Risk theme feature: Calculations, information and labelling	
F5	Is a complex calculation (i.e. one with more than one step) necessary prior to preparation and/or administration?
F6	Does the product presentation easily enable essential labelling to be in place at the point of administration?

Risk theme feature: administration	
G1	Is administration of the product in any way complex?
G2	Is the route of administration of the product intrinsically high risk (such as intrathecal)?
G3	Does administration require the use of a device and/or disposables?
G3 - contd	Where the product requires the use of a device and/or disposables are there any issues related to their use?
G4	For injectable medicines, how safety critical is the rate of administration? And what mechanisms are in place to ensure it is correct?
G4 - contd	For injectable medicines, is any specific monitoring required during administration?
G4 - contd	If specific monitoring is required, is it practicable and achievable?

Risk theme feature: Availability	
H1	Is the product readily and reliably available from a recognised supplier
Risk theme feature: Storage	
H2	Are expiry dates (both for the product in its original form, and in-use as necessary) available and clear?
H3	Are there any specific storage requirements for the product?
H3 - contd	Are there any other particular issues in relation to storage? For example, is bulk and the space necessary to store the product an issue?
H4	Are there any issues in relation to security of storage? For example, is there a likelihood of misappropriation?
H5	Overall, consider whether the storage requirements can likely be met?

Risk theme feature: Disposal	
I1	Does the product pose any special risks during disposal to either the user or staff?
I2	Are there any specific disposal requirements of the product?

Risk theme feature: Impact of setting	
J1	Is the product for use in a highly specialist environment? For example in neonates, fluid restricted patients, or those in critical care scenarios.
J1 - contd	Where the product is highly specialist, is there the potential that it will be used outside such an environment? And if so have issues associated with such use been identified and addressed?
J2	Is the medicine one which is likely to be used across other boundaries of care?
J2 - contd	If the medicine is used across care boundaries, have issues associated with such use been identified and addressed?
J3	Is the medicine one for which self-administration by patients is a possibility? Have any issues associated with such use been identified and addressed?
J4	Where the manipulation of the product is complex, is the environment in which it is to be prepared conducive to its safe use? That is, will it be as free as possible from distractions and is it an otherwise suitable environment for complex manipulation?

Concluding questions	
K1	As a consequence of the product's introduction, will any changes to practice occur? If so, are those changes likely to introduce new risks? And/or do those changes have the potential to address patient safety risks known to be present currently?
K2	Overall, when considered against the status quo, are the risks identified in relation to the product's introduction reasonable?
K3	Where it is possible to assess, are any patient safety risks outweighed by the potential clinical benefits the product offers against available alternatives?
K4	Other Comments and Actions