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Ready to use injectable medicines: how can we control the risks?

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Ready to use injectable medicines: how can we control the risks?

Contents:

Ways in which Ready-to-use (RTU) Injections are made available for patients

Risk Management for Injectable Medicines

- *What can you do to make things safer for the patients in your hospital?*

Four ways in which Ready-to-use (RTU) Injections are made available for patients:

	RISKS ?
Supplied as an Authorised (licensed) RTU product	Generally LOW. Has been through a safety, quality and efficacy assessment. <u>BUT</u> Are they available for the most appropriate products?
Prepared in pharmacy	No safety or efficacy assessment but quality should be acceptable (environmental controls, audit etc).
Outsourced and supplied via pharmacy	No safety or efficacy assessment. Quality depends on who pharmacy have outsourced to and how well responsibilities are defined and compliance monitored.
Made in the clinical area, eg ward or theatre	Highest risk, eg risk of calculation errors, microbiological contamination etc.

Ready to use injectable medicines: how can we control the risks?

A risk management system should be in place in every hospital. This consists of the following:

- Risk assessment
- Risk reduction and control
- Risk acceptance and communication
- Risk review

Risk Management for Injectable Medicines - Risk assessment

- Have an up to date injectable medicines policy defining roles and responsibilities and multi-disciplinary management arrangements
- Use a risk assessment tool (e.g. NPSA in UK) to establish a 'hierarchy of risk' (ranking) for injectable medicines.

Risk assessment allows prioritisation of products of higher risk for pharmacy preparation to make best use of the limited capacity in pharmacy aseptic units.

Risk Management for Injectable Medicines - Risk assessment

- Perform risk assessments and option appraisals for all areas where injectable medicines are made i.e. pharmacy or clinical areas?
- Decide if the location is appropriate in relation to the level of risk (as determined by use of your risk assessment tool).

This process should involve pharmacy in conjunction with nursing colleagues.

Risk Management for Injectable Medicines - Risk assessment

- Make sure there is a system for evaluating risks for injectable medicines before they are introduced to the organisation, for example by assessment by drug and therapeutics or formulary committees
- Make sure that a current list of risk ratings is available for all injectable medicines (as a minimum an up-to-date list of **high-risk** injectable medicines should be maintained.

  for the specific hospital).

Risk Management for Injectable Medicines - Risk assessment

Drug name	Form	Bag (B) / Syringe (S) / Infusor (I)	Therapeutic risk	Use of concentrate	Complex calculation	Complex preparation	Reconstitute vial	Part/multiple container	Use of infusion pump/driver	Non standard infusion set	Total Risk Factors	NPSA20 score	Availability of ready-to-use products in UK
Abatacept	IV infusion	B	Y	Y		Y	Y	Y		Y	6	High	
Abciximab	IV infusion	B/S	Y	Y	Y	Y		Y	Y		6	High	
Adrenaline	IV infusion	S	Y	Y	Y	Y		Y	Y		6	High	
Alteplase	IV infusion	B	Y	Y	Y		Y	Y	Y		6	High	
Amiodarone hydrochloride	IV infusion	B/S	Y	Y	Y	Y		Y	Y		6	High	YES (500mL infusion bag)
Amphotericin liposomal (AmBisome®)	IV infusion	B	Y	Y	Y	Y	Y	Y	Y		7	High	
Amphotericin (Fungizone®)	IV infusion	B	Y	Y	Y	Y	Y	Y	Y		7	High	
Amphotericin lipid complex (Abelcet®)	IV infusion	S	Y	Y	Y	Y		Y	Y		6	High	

Risk Management for Injectable Medicines - Risk reduction and control

- Do not make high risk products, eg potassium solutions, parenteral nutrition in clinical areas
- Make arrangements for provision when pharmacy is closed, eg for parenteral nutrition
- Minimise the time before administration
- Provide pharmacy support to clinical areas
- Have an appropriate pharmacy RTU / RTA product list (catalogue)
- Specify and monitor the quality of any outsourced RTU products

A thought-provoking (true) story

- *Hospital decides to 'just buy in' (outsource) chemotherapy*
- *The company they decide to outsource to tells them that it holds a manufacturing licence from the Regulatory Authority*
- *No-one checks their licence or audits the company to assess their premises*

A thought-provoking (true) story- End Result?

- Later discovered that this licence is only for pre-packing tablets and capsules– not for aseptic manufacturing
- Cytotoxic injections for the hospital's patients are being reconstituted in a laminar flow cabinet in a domestic living room
- Pharmacists give evidence in court about current standards for aseptic preparation and the company is prosecuted

Questions raised by this story

- How were the company assessed (if other than by price) ? Was there a specification?
- If so, did the specification require the company to hold an appropriate licence?
- Did anyone **check** that the company held the appropriate Regulatory licence?
- Was there a technical (quality) agreement defining on-going responsibilities of the company and the hospital?
- Was anyone monitoring whether the company was complying with quality agreement?

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Risk Management for Injectable Medicines – Risk acceptance and communication

- After as many risk reduction measures as possible have been put in place, any residual risks relating to injectable medicines that remain should be accepted by the hospital management (for example by recognising them on the risk register).

For example, certain monoclonal antibodies being reconstituted in clinical areas

Risk Management for Injectable Medicines - Risk review

- Review risk register entries regularly and update risk ratings as appropriate
- Have a system to review any errors or incidents in relation to injectable medicines and respond to these with additional risk reduction and control measures
- Have a system to learn from these types of incidents that occur in other hospitals and for responding to national alerts e.g. from patient safety bodies

Plethora of NPSA advice on injectables

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Ready to use injectable medicines: how can we control the risks?

Ready to use injectable medicines are useful BUT they are only part of the answer to controlling risks. We must make sure that we do all we can to reduce risks to patients from ALL injectable medicines – wherever they are made: pharmacy, clinical areas, or outsourced.

Questions?

Thank You