National Patient Safety Agency

Risk Assessment of Injectable Medicines

STEP 1 – Local Risk Factor Assessment.

Carry out a baseline assessment in a near patient area (e.g., ward, clinic, home) in which injectables are prepared.

Identify high risk procedures and risk reduction strategies

STEP 2 – Product Risk Factor Assessment

Carry out a baseline assessment of individual injectable products stocked and used in a near patient area.

Identify high risk injectable products.

STEP 3 - Identify Risk Reduction Measures

STEP 4 - Implement Risk Reduction Measures

STEP 1

Risk Assessment of Local Risk Factors For Preparing and Administering Injectable Medicines		Suggested Risk Reduction / Elimination Strategies for Local Risk Factors with Injectable Medicines	Implementation Comments and Timetable
Name of Near Patient Area	**X =Risk Present**		
Use of “Open systems” (i.e. the solution under preparation comes into contact with the open air*)		Introduce closed systems	
Preparation of a cytotoxic drug outside of a safety cabinet/isolator (unless using a “closed system” licensed specifically for use in this way)		Prepare all cytotoxics drugs in an approved safety cabinet or use closed system products that can be prepared in near patient areas	
Preparation of / addition to Parenteral Nutrition, outside a pharmacy aseptic unit(unless using a “closed system” licensed specifically for use in this way)		Prepare all additions to TPN in a pharmacy aseptic unit or use closed system products that can be prepared in near patient areas	
Administration of a single container of a prepared injectable lasting more than 24 hours		Eliminate the use of single container parenteral products prepared in near patient areas with expiry dates of greater than 24 hours	
Admixture of two or more “active” medicines without pharmaceutical approval of compatibility		Discontinue the admixture of two or more medicines without pharmaceutical approval or compatibility information	
Use of an infusion pump indicated but not used		Ensure that adequate numbers of infusion pumps and syringe drivers are available for use, and users have knowledge of when this equipment should be used	
Use of unlabelled syringes and / or infusion bags (unless allowed by practice guideline)		Re-inforce and audit policy to ensure all parenteral syringes and infusions are labelled for use	
Use of an injectable medicine ampoule, vial or infusion to prepare more than a single dose (unless the product is specifically licensed for use in this way)		Re-inforce and audit policy to ensure that single use products are only used to prepare a single dose.	
Use of an unlicensed medicine or “off label” use of a licensed medicine (unless specifically approved by a written organisational protocol)		Re-inforce and audit policy on the use of 'off-label' injectable medicines. Ensure approved protocols include BNF-C recognised off label usage	
All or part of the preparation process is unfamiliar to the average operator (e.g. prepared by any individual fewer than six times in twelve months)		Re-inforce and audit policy on infrequently used products and make alternative arrangements for the preparation and administration of these medicines	
Risk assessment undertaken by : **Date**		**Name of pharmacist:**	**Name of clinical practitioner**

The identification of any local risk factor in the clinical area provides a high risk baseline for the preparation of injectables. Each risk factor present should be eliminated. Where this is not possible awareness of the implications should be raised at Risk Management / Drug and Theraputics Committee level. Healthcare organisations may choose to ratify the practice whilst recognising the risks.

NPSA Injectable Medicines Risk Assessment Tool

STEP 2

NPSA Risk Assessment Of An Individual Injectable Product

Name of Near Patient Area

Name and Strength of Injectable Medicine Product	**Manufacturer**	**X =Risk Present**

Therapeutic risk - where there is a higher risk of patient harm if the medicine is not used as intended e.g., cytotoxic, opioid, vasoactive, concentrated electrolytes, insulin or heparin infusions, drug therapy that is nephrotoxic or having a narrow therapeutic index.	
Use of a concentrate - where after reconstitution further dilution is required before use	
A complex calculation - e.g. double dilution or complex rate of administration such as microgram/kg/hour	
A complex method - e.g. non-standard diluent, syringe to syringe transfer, more than 5 manipulations involved	
Reconstitution of powder in a vial - where a dry powder has to be reconstituted with a liquid	
Use of more than one or part use of a vial or ampoule - eg. 5ml required from a 10ml vial or four x 5ml ampoules required for a single dose	
Use of a pump with associated calculation - All pumps require some element of calculation and therefore have error potential. However this potential is considered less significant than the risks associated with not using a pump when indicated.	
Use of non standard giving set (eg.light protected or low adsorption)	

Total Number of Product Risk Factors

Six or more risk factors = High Risk Product (Red). Risk reduction strategies are required to minimise these risks.

Three to five risk factor = Moderate Risk Product (Amber). Risk reduction strategies are recommended.

Less than three risk factors = Lower Risk Product (Green). Risk reduction strategies should be considered

Total

Risk assessment undertaken by : **Name of pharmacist:**

Date: **Name of senior clinical practitioner:**

STEP 3

NPSA Risk Reduction Measures That Can be Used to Minimise Risks With Injectable Medicine Products

Provide READY TO ADMINISTER or READY TO USE injectable products

Licensed products should always be used in preference to unlicensed products, where available. If licensed products are not available, use of unlicensed presentations should be considered in order to mitigate risks

Provide Appropriate Written Procedure-Specific Guidance

When coupled with competency assessment, this will reduce the risks associated with,for example, complex preparation methods and calculations.

Provide Organisational Approved Protocols

Continued use of practices identified as carrying inherent risks e.g. “off label “drug use, unfamiliar infrequently-used preparation processes or any local risk factors (see step 1) should only be allowed when supported by organisationally approved protocols which state clearly the circumstances in which they are and are not acceptable

Check Purchasing Appropriateness

Ensure that where there is a choice of licensed products, the safest e.g the most appropriate vial /ampoule size is purchased and available to ensure that preparation is as simple and as safe as possible

Provide Dose Calculating Tool

The risk of mistakes in complex calculations can be mitigated by the use of validated dose calculating tools and charts. Instructions for correct use of these aids must also be provided

Ensure Availability of Pumps & Non Standard Giving Sets where indicated

Set up a device library (NPSA 2004) or similar system to ensure the availability of the right device at the right time and facilitate effective management and safe use of all devices at all times

Introduce 'Smart' Infusion Pump/Syringe Driver Software

Error limiting software is available for many electronic devices. Administration risks will be reduced by its use. Bar coding and auto identification technologies will minimise errors associated with misidentification of products and patients.

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Step 4

Name of near patient area: Name of pharmacist

Date of risk assessment: Name of clinical practitioner

Product Risk Assessment and Risk Reduction Summary

	Therapeutic risk	Use of concentrate	Complex calculation	Complex preparation	Reconstitute vial	Part/multiple container	Use of infusion pump/drive	Non standard infusion set	Unlicensed route	Unfamiliar process	Total Risk Factors	Overall Risk Rating Red = 6 and above, Amber= 3-5, Green= 1-2	Risk Reduction Measure(s)	Total Risk Factors	Overall Risk Rating, Red = 6 and above, Amber= 3-5, Green= 1-2
Heparin infusion 50,000units in 50ml Sodium Chloride 0.9% infusion	Y	Y	Y	Y		Y	Y				6	Red	Supply ready to use product	2	Green
Vancomycin 500mg in 100ml Glucose 5% infusion	Y	Y			Y		Y				4	Amber	Supply ready to use product	1	Green
Amoxicillin 500mg in 10ml bolus					Y						1	Green			

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