Northern Devon Healthcare NHS Trust

Risk Assessment for injectable medicines:

Need to specify route of administration and complete a risk assessment for each route

Location and clinical area: Emergency Department			**Date: 21/09/2021**	
Name and strength of prepared injectable product	**Route of administration**	**Diluent**	**Final volume (or range)**	**Bag or syringe**
Andexanet alfa	Intravenous	None	100-180mL	syringe

	Risk factors	Description	✓
1	**Therapeutic risk**	Where there is a significant risk of patient harm if the injectable medicine is not used as intended.	**x**
2	**Use of a concentrate**	Where further dilution (after reconstitution) is required before use, i.e. slow iv bolus not appropriate.	
3	**Complex calculation**	Any calculation with more than one step required for preparation and/or administration, e.g. microgram/kg/hour, dose unit conversion such as mg to mmol or % to mg.	
4	**Complex method**	More than five non-touch manipulations involved or others including syringe-to-syringe transfer, preparation of a burette, use of a filter.	**x**
5	**Reconstitution of powder in a vial**	Where a dry powder has to be reconstituted with a liquid.	**x**
6	**Use of a part vial or ampoule, or use of more than one vial or ampoule**	Examples: 5ml required from a 10ml vial or four x 5ml ampoules required for a single dose.	**x**
7	**Use of a pump or syringe driver**	All pumps and syringe drivers require some element of calculation and therefore have potential for error and should be included in the risk factors. However it is important to note that this potential risk is considered less significant than the risks associated with not using a pump when indicated.	**x**
8	**Use of non-standard giving set/device required**	Examples: light protected, low adsorption, in-line filter or air inlet.	**x**
	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 factors = moderate-risk product (Amber). Risk reduction strategies are recommended. One or two risk factors = lower-risk product (Green). Risk reduction strategies should be considered.	6 = RED
Risk assessment undertaken by: Hayley Carr		**Summary of risk reduction strategies if appropriate:** **Limit use to ED department only and ensure access to DOAC reversal guidelines on BOB** **Support ED with nursing and doctor training sessions**	

Suggested risk reduction methods that can be used to minimise risks with injectable medicines – see overleaf

Suggested risk reduction methods that can be used to minimise risks with injectable medicines (NPSA risk assessment tool)

1. Simplify and rationalise the range of products and presentations of injectable medicines (review stock lists). Where possible, reduce the range of strengths of high-risk products and provide the most appropriate vial/ampoule sizes

2. Provide ready-to-administer or ready-to-use injectable products – this will minimise preparation risks and simplify administration

3. Provide dose calculating tools – for example, dosage charts for a range of body weights that eliminate the need for dose calculations

4. Provide additional guidance on how to prescribe, prepare and administer high-risk injectable medicines (discuss as part of risk assessment process)

5. Consider the provision of pre-printed prescriptions or stickers – this will help to ensure that information on the prescription about preparation and administration of high-risk products is clearer

6. Provide locally approved protocols that clarify approved unlicensed and 'off-label' use of injectable medicines

7. Use double-checking systems – an independent second check from another practitioner and/or the use of dose-checking software in 'Smart' infusion pumps and syringe drivers

8. Use an infusion monitoring form or checklist – this will help to ensure that infusions are monitored throughout administration