

## 1. Introduction and Who Guideline applies to

Prothrombin complex concentrate (PCC) is used when rapid reversal of anticoagulation with warfarin and other Vitamin K antagonists (sinthrome) is required, and also has a role in reversing the action of direct factor Xa inhibitors ('xabans' – e.g. rivaroxaban, apixaban or edoxaban). PCC has no role for dabigatran for which a specific reversal agent, [idarucizumab \(Praxbind\)](#), exists. [1]

Indications for PCC use include

- Major (= life-, limb- or sight-threatening) bleeding  
**NB:** Life-threatening gastrointestinal bleeding in patients on rivaroxaban or apixaban (but not edoxaban) should now instead be given the specific reversal agent, [andexanet alfa](#) [1]
- Pre-operative anticoagulation reversal when an emergency procedure cannot be delayed until (for Vitamin K antagonists) Vitamin K has been effective or until (for inhibitors of activated factor X) the effect of the medicine has worn off

At any given time, UHL stocks one of the two products licensed in the UK (Octaplex or Beriplex P/N). The product is stored in the transfusion laboratories at each of the three hospitals as well as a designated drug cupboard in the LRI Emergency Department (ED) Resuscitation Room (ER).

Please note that PCC contains clotting factors II, VII, IX and X, derived from multi-pooled donor plasma. It is pasteurised and nanofiltered to remove viruses, but certain viruses such as Hepatitis A virus (HAV) and parvovirus may resist the inactivation process. The risk of transmission for prion diseases including variant Creutzfeldt-Jakob disease (vCJD) is as yet unknown.

This guideline applies to all UHL staff who request, prescribe or administer PCC as well as haematology and pharmacy staff involved in the logistics of dispensing and replenishing PCC stocks. It has been created to ensure that PCC is used as effectively as possible.

The use of PCC cardiac surgery for indications other than those described above is not licensed and outside the scope of this guideline.

## 2. Guideline Standards and Procedures

- 2.1 **PCC use requires documented agreement from a senior clinical decision-maker** (ST3 or above) but authorisation from a haematology doctor is no longer required in order to minimise administration delays
- 2.2 PCC administration carries a risk of thrombosis. It is contraindicated in those with known allergy to heparin or a history of heparin-induced thrombocytopenia (HIT) or IgA deficiency with known antibodies against IgA. It should also generally be avoided in patients with disseminated intravascular coagulation (DIC) or decompensated liver disease.
- 2.3 PCC should be administered within 30min of prescribing
- 2.4 **Staff should print off the entire guideline and then proceed as per the below**
- 2.5 ED staff should follow the [algorithm](#) shown in **Appendix A** (and discard **Appendix B**)
- 2.6 Staff in all other clinical areas should follow the [algorithm](#) shown in **Appendix B** (and discard **Appendix A**)
- 2.7 Use the [PCC request form](#) shown in **Appendix C** to request or replace stock
- 2.8 A [PCC preparation aid](#) is shown in **Appendix D**
- 2.9 Give the Information for Patients sheet '[Prothrombin complex concentrate injection to treat or prevent a severe bleed](#)' (available from UHL's [YourHealth](#) public web pages; leaflet number: 1259) to all patients deemed to have capacity before obtaining and documenting their verbal consent

### 3. Education and Training

No additional skills are required to follow this guideline.

### 4. Monitoring Compliance

What will be measured to monitor compliance	How will compliance be monitored	Monitoring Lead	Frequency	Reporting arrangements
Appropriate PCC use	'Appropriate use of blood components' audit program	Hospital Transfusion Committee	annually	EQB
Timely PCC use	'Appropriate use of blood components' audit program	Hospital Transfusion Committee	annually	EQB

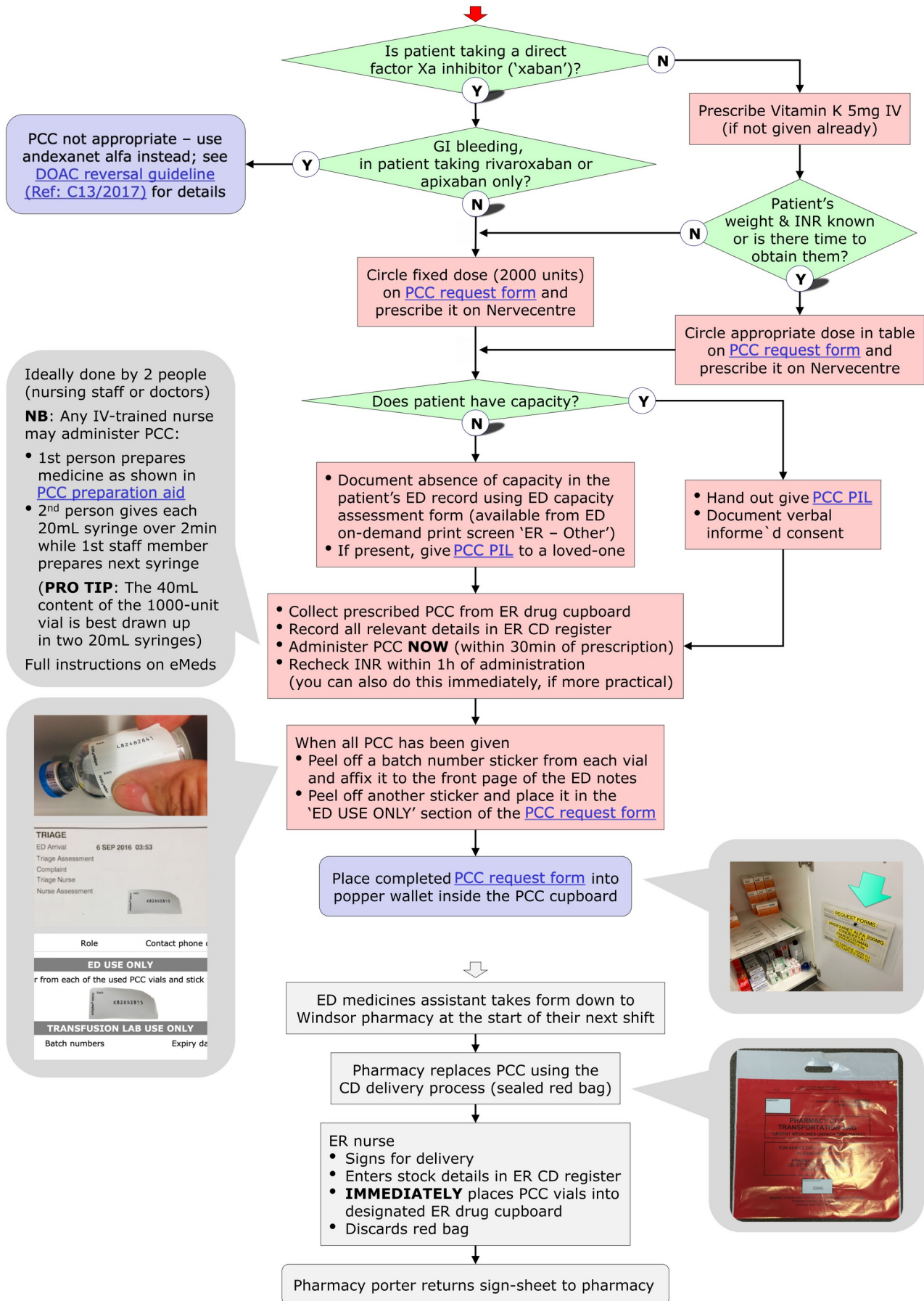
### 5. Supporting References and Related Policies

1. [DOAC \(Direct Oral Anticoagulants\) reversal in bleeding patients UHL Emergency Department guideline](#) (Trust Ref: C13/2017)
2. Thrombosis Canada [internet]. Whitby. 2016 [cited 07Jan23]. PCC (Prothrombin Complex Concentrate) Dosing Table [PDF]. Available from: <https://thrombosiscanada.ca/wp-content/uploads/2016/07/M221-PCC-Dosing-Table.pdf>
3. [Oral anticoagulation with warfarin and coumarins UHL guideline](#) (Trust Ref: B44/2016)
4. [Guideline for Patients on Oral Anticoagulant Therapy Requiring Urgent Surgery for Hip Fracture](#) (Trust Ref: C10/2017)

### 6. Key Words

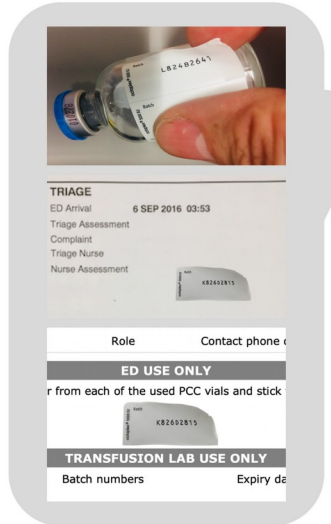
Bleed, haemorrhage, coagulation, warfarin, DOAC, apixaban, rivaroxaban, edoxaban, octaplex, beriplex, prothrombin, PCC, reversal, clotting, haematology, blood product, emergency

CONTACT AND REVIEW DETAILS	
<b>Guideline Lead (Name and Title)</b> Martin Wiese, Consultant Emergency Physician	<b>Executive Lead</b> Andrew Furlong, Medical Director
<b>Details of Changes made during review:</b> <ul style="list-style-type: none"><li>• Authorisation from haematology doctor no longer required</li><li>• Emphasis on PCC administration within 30min of prescribing in guideline standards section</li><li>• Table showing predetermined PCC dose based on ranges of weight and INR added for patients taking a Vitamin K antagonist</li><li>• Patients with unknown weight and/or INR and those taking a direct factor Xa inhibitor ('xaban') will receive a fixed dose of PCC (2000 units)</li><li>• Reference made to the need to use andexanet alfa instead of PCC in patients with life-threatening GI bleed who take rivaroxaban or apixaban</li><li>• Reference made to PCC now being prescribed on eMeds (Nervecentre) instead of paper drug chart</li><li>• Reference for dosing regime added [2]</li><li>• References to Medusa monographs removed</li><li>• Guideline rewritten and reformatted extensively to account for the changes above</li><li>• Compliance monitoring arrangements updated</li></ul>	



PCC not appropriate – use andexanet alfa instead; see [DOAC reversal guideline \(Ref: C13/2017\)](#) for details

Ideally done by 2 people (nursing staff or doctors)  
**NB:** Any IV-trained nurse may administer PCC:  
 • 1st person prepares medicine as shown in [PCC preparation aid](#)  
 • 2nd person gives each 20mL syringe over 2min while 1st staff member prepares next syringe  
**(PRO TIP:** The 40mL content of the 1000-unit vial is best drawn up in two 20mL syringes)  
 Full instructions on eMeds



• Document absence of capacity in the patient's ED record using ED capacity assessment form (available from ED on-demand print screen 'ER - Other')  
 • If present, give PCC PIL to a loved-one

• Collect prescribed PCC from ER drug cupboard  
 • Record all relevant details in ER CD register  
 • Administer PCC **NOW** (within 30min of prescription)  
 • Recheck INR within 1h of administration (you can also do this immediately, if more practical)

When all PCC has been given  
 • Peel off a batch number sticker from each vial and affix it to the front page of the ED notes  
 • Peel off another sticker and place it in the 'ED USE ONLY' section of the PCC request form

Place completed PCC request form into popper wallet inside the PCC cupboard

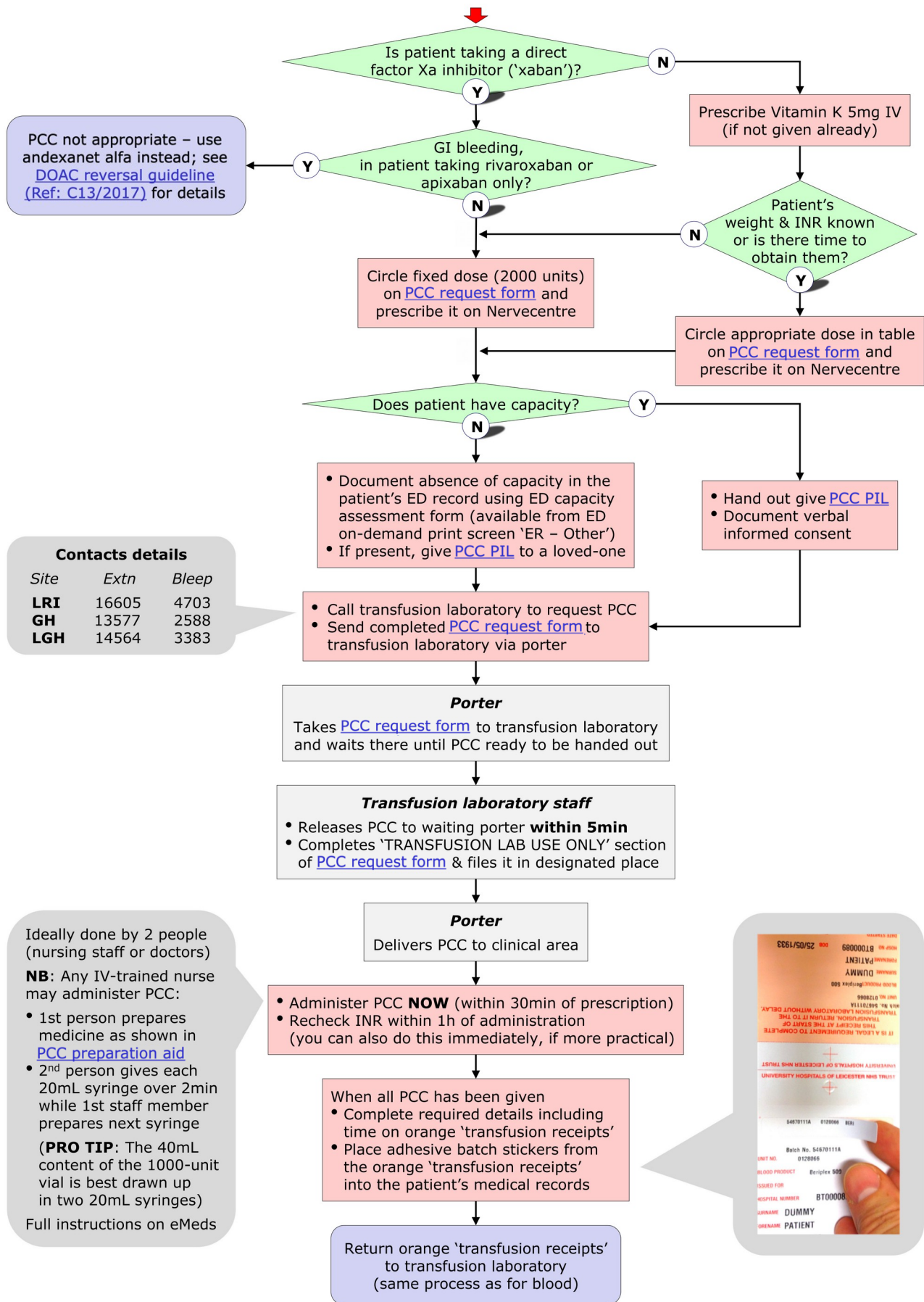
ED medicines assistant takes form down to Windsor pharmacy at the start of their next shift

Pharmacy replaces PCC using the CD delivery process (sealed red bag)

ER nurse  
 • Signs for delivery  
 • Enters stock details in ER CD register  
 • **IMMEDIATELY** places PCC vials into designated ER drug cupboard  
 • Discards red bag

Pharmacy porter returns sign-sheet to pharmacy







**Patient details**

Full name

DoB

Unit number

(use sticker if available)

**Request Form for  
Prothrombin Complex Concentrate  
(PCC - Octaplex or Beriplex P/N)**

Date DD/MM/YY

**Indication for PCC**

Intracranial bleed

Intraocular bleed

Life-threatening bleed (state source)

Other (give details)

**CLINICAL DETAILS**

Consultant

Area / ward

Patient weight  kg

Current INR

Hospital  LRI  GH  LGH

**Circle units to be released/replaced below**

		Patient on warfarin AND current INR and weight known				Patient on DOAC OR current INR and weight unknown
		1.6 - 1.9	2.0 - 2.9	3.0 - 5.0	> 5.0	
Weight	< 100kg	500 units	1000 units	2000 units	3000 units	2000 units
	≥ 100kg	1000 units	1500 units	2500 units		

**REQUESTER**

Print name      Signature      Role      Contact phone or bleep number

**ED USE ONLY**

Peel off a batch number sticker from each of the used PCC vials and stick them down in the space below

**TRANSFUSION LAB USE ONLY**

Specimen number      Batch numbers      Expiry dates      Vial size

Product supplied

Octaplex

Beriplex P/N

500 units     1000 units

500 units     1000 units

500 units     1000 units

500 units     1000 units

500 units     1000 units

500 units     1000 units

**PHARMACY USE ONLY**

Stock supplied by    Print Name      Initials      Date      Time



1. Open the Mix2Vial package by peeling off the lid.  
**DO NOT** remove the Mix2Vial from the blister package!
2. Place the solvent vial on an even, clean surface and hold the vial tight. Take the Mix2Vial together with the blister package and push the spike of the blue adapter end **straight down** through the solvent vial stopper.
3. Carefully remove the blister package from the Mix2Vial set by holding at the rim, and pulling **vertically** upwards. Make sure you only pull away the blister package and not the Mix2Vial set.
4. Place the product vial on an even and firm surface. Invert the solvent vial with the Mix2Vial set attached and push the spike of the transparent adapter end **straight down** through the product vial stopper. The solvent will now automatically flow into the product vial.
5. With one hand grasp the product-side of the Mix2Vial set, and with the other hand grasp the solvent-side and unscrew the set carefully into two pieces. Discard solvent vial with the blue Mix2Vial adapter attached.
6. Gently swirl the product vial with the transparent adapter attached until the substance is fully dissolved. **DO NOT** shake.
7. Draw air into an empty, sterile 20mL syringe. While the product vial is upright, connect the syringe to the Mix2Vial's Luer Lock fitting. Inject air into the product vial.
8. While keeping the syringe plunger pressed, invert the system upside down and draw the solution into the syringe by pulling the plunger back slowly
9. Now that the solution has been transferred into the syringe, firmly hold on to the barrel of the syringe (keeping the syringe plunger facing down) and disconnect the transparent Mix2Vial adapter from the syringe. Hand syringe over to your colleague to administer while you prepare the next syringe.

**NB:** For vials containing 1000 units, repeat steps 7 and 8 using a second 20ml syringe as the total volume contained in the vial is 40mL

Repeat until all vials have been administered

