#EM3
East Midlands Emergency Medicine Educational Media

Scenario: GI BLEED on Warfarin

Setting: ED Resus
Clinical Focus: GI Bleed, Warfarin Reversal
Situational Factors: NIl

Learning Objectives:

- A-E Assessment & recognition of Critically Ill Patient
- Recognise GI bleed and apply Proforma inc management of shock
- Demonstrate appropriate reversal of Warfarin in ED

Stage/ Design/ Props/ Technical Setup

SimMan, Octoplex, SimBlood (O-ve), haematemesis image, GI bleed proforma, PCC guideline

Briefing to Participants:

Red Call to resus, 67 year old male with 24hrs of vomiting blood and dark stool. Tachycardic and hypotensive. pmh/ AF, hypertension and IHD. Weighs 80 Kg.

Presentation	Expected Response	Actors Notes
Examination: **A:** Patent **B:** sats 98% RR 16 **C:** HR 114 (AF) BP 86/57 **D:** Alert, BM normal **E:** Haematemesis and melaena INR - 4.2 (2 days ago)	Recognises haemodynamic instability - gives initial crystalloid followed by blood Reverses Warfarin - Vit K and PCC Follows AUGIB Proforma	24 hour history of vomiting blood, passing dark stool. Does not drink alcohol. PMH/ AF, hypertension, IHD Meds/ Warfarin, Ramipril Allergy: Beta blockers. INR - 4.2 (2 days ago)
Progress Improves: HR falls to 92 BP 114/56	Senior input/ gastro referral	
Progress Deteriorates: HR 126 BP 72/46 Further vomit and drop in GCS (E3 V4 M5 - 13)	Senior Help - ITU review	
Debrief	**Clinical**	**CRM**
As required based on identified issues/frames	AUGIB Proforma Warfarin Reversal	

Roche

Measurement report

12.12.2014 2:52
Serial number : 19241
Instrument ID : LRI A&E 1
Operator ID : blood
Leicester Royal Infirmary A&E

Pat. ID	S1234567				
Last name	Man				
First name	Sim				
Blood type	Venous				
FIO_2	0.21				
pH	7.30	(-)	[	7.350 -	7.450]
PCO_2	4.1	kPa	[	4.27 -	6.40]
PO_2	9.5	kPa (--)	[	11.07 -	14.40]
BE	-2.5	mmol/L			
$cHCO_3^-$	17	mmol/L			
Na^+	130	mmol/L	[	136.0 -	145.0]
K^+	3.5	mmol/L	[	3.50 -	5.10]
Ca^{2+}	1.5	mmol/L	[	1.150 -	1.330]
Cl^-	106	mmol/L	[	98.0 -	107.0]
Glu	6.5	mmol/L	[	3.5 -	5.3]
Lac	4.2	mmol/L	[	0.4 -	0.8]
Urea	11.5	mmol/L	[	2.5 -	6.4]
AG	18.2	mmol/L			
Osm	288	mOsm/kg			
Hct	45	% (--)	[	36.0 -	53.0]
Hct(c)	45	%			
tHb	65	g/L	[	115.0 -	178.0]
SO_2	98	%	[	94.0 -	98.0]
COHb	1	%	[	0.0 -	3.0]
MetHb	1.4	%	[	0.0 -	1.5]
HHb	2.5	%	[	0.0 -	2.9]
O_2Hb	38	%	[	94.0 -	98.0]
Bili	Out of range (-)		[	51 -	850]

Sample No.: S2588888
Patient ID:
Name: Sim 'LRI ED' Man
Comments:

Rack:
Ward:

Tube: 7.12.2014 12:34:35
Dr.:
Birth: Sex:
Inst.ID:XS-800i^65614

WBC	7.2	[10^9/L]	
RBC	2.08	[10^12/L]	
HGB	65	[g/L]	
HCT	0.184	[Ratio]	
MCV	88.0	[fL]	
MCH	29.8	[pg]	
MCHC	339	[g/L]	
PLT	192	[10^9/L]	
RDW-SD	42.4	[fL]	
RDW-CV	14.0	[%]	
PDW	11.3	[fL]	
MPV	10.5	[fL]	
P-LCR	27.7	[%]	
PCT	0.18	[%]	
NEUT	4.2	[10^9/L]	65.5
LYMPH	2.75	[10^9/L]	15.6 *
MONO	1.58	[10^9/L]	9.0 *
EO	0.04	[10^9/L]	0.2 *
BASO	0.03	[10^9/L]	0.2

Actions required

- ☐ Normal
- ☐ Abnormal but no immediate danger
- ☐ Significantly abnormal results –
  patient in imminent danger

document STAT actions taken

NPT samples processed by

NPT results

#EM3
East Midlands Emergency Medicine Educational Media

Created by Martin Wiese

LRI Emergency Department

Management of acute upper GI bleeding (AUGIB)

Version 38

For adults presenting with haematemesis, malaena or coffee-ground vomit

NB: there is NO place for PPI prior to endoscopy

Disclaimer:
This is a clinical template; clinicians should always use judgment when managing individual patients

Approved by ED senior team on 01Jun16
Review date: May17

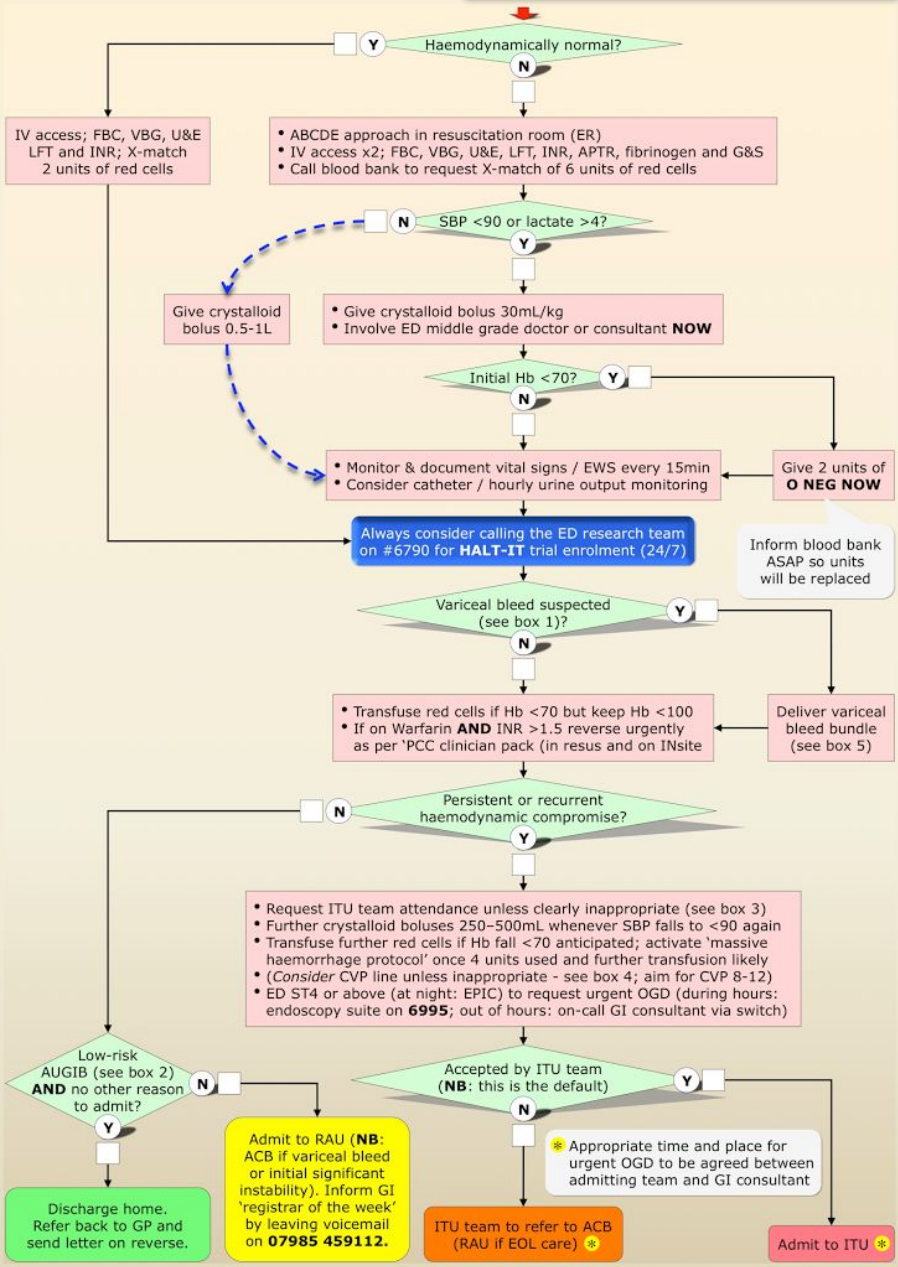
Patient details

Full name

DoB

Unit number

(use sticker if available)



- If patient takes low-dose aspirin for 2° prevention of vascular events, continue once bleeding stopped
- Stop any other NSAIDs (including COX-2 inhibitors) during admission; endoscopist will advise on future use
- If patient takes clopidogrel (or any other thienopyridine antiplatelet drugs), discuss risks and benefits of continued use once bleeding stopped with a cardiologist or stroke specialist (as applicable) and with the patient

This patient was managed by

Print name | Signature | Position | Date | Time completed

① Suspected variceal bleed?

☐ **YES**, as at least one of the below

- Previous variceal bleed / known varices ☐
- Known cirrhosis ☐
- Clinically jaundiced ☐
- Clinical ascites ☐
- Spider naevi / liver palms ☐
- Splenomegaly ☐
- Platelets < 100 (unless known other cause) ☐

☐ **NO**, as none of the above

② Low-risk AUGIB?

☐ **NO**, as at least one of the below

- Urea > 6.4 ☐
- Haemoglobin
  - < 120 ☐
  - < 130 and patient male ☐
- Systolic BP < 110 pre-hospital or in ED ☐
- Heart rate > 99 pre-hospital or in ED ☐
- Melaena (spontaneous or on rectal exam) ☐
- Syncope or collapse during current episode ☐
- Heart failure (known history or clinical findings) ☐
- Liver disease (known history, clinical findings or laboratory evidence) ☐

☐ **YES**, as none of the above

③ ITU care appropriate?

☐ **No**, because of the reason(s) below

- Advanced, incurable cancer ☐
- Has mental capacity & refuses critical care ☐
- Other (consider markers of frailty / poor functional reserve; state details below) ☐

☐ **Yes** – as none of the above

***NB**: ITU team must clearly document the specific reasons for declining critical care if it was felt to be appropriate by ED team.*

④ CVP line contraindicated?

☐ **Yes**, because of the reason(s) below

Consider platelet count (< 100), patient's wishes, quality of life and DNAR status

☐ **No**

⑤ Variceal bleed bundle

- Terlipressin 2mg IV STAT (and then QDS for 72h unless contraindicated)
- Co-amoxiclav 1.2G IV STAT (unless allergic, then TDS for 72h)
- If platelets <50 and still thought to be bleeding, consider replacing
- If INR or APTR >1.5, or if fibrinogen <1g/L, call haematology middle grade or consultant to discuss options to correct coagulopathy (e.g. Vit K, FFP)
- OGD should be performed within 12h (urgently if patient does not stabilise)

Prothrombin Complex Concentrate (PCC - Octaplex or Beriplex P/N) Clinician Pack

University Hospitals of Leicester NHS
NHS Trust

Introduction

Prothrombin complex concentrate (PCC) is the treatment of choice when rapid reversal of anticoagulation with Warfarin or other Vitamin K antagonists is required. At any given time, one or the other of the two products licensed in the UK - Octaplex or Beriplex P/N - will be available within UHL. The product is stored in the transfusion laboratories at each of the three hospitals, and its use requires the authorization of a haematology registrar or consultant.

This pack has been designed to ensure that patients receive PCC in the most effective and safe way possible, and to simplify the process of requesting and administering the product for clinicians.

It complements the following documents

- Guidelines on management of Warfarin overdose (Document ID: UHLSP-600-6234)
- Injectable Medicines Guide ('Medusa') – Dried prothrombin concentrate (Beriplex P/N)
- Injectable Medicines Guide ('Medusa') – Dried prothrombin concentrate (Octaplex)

Contents

- PCC algorithm for clinical users p2
- Beriplex P/N and Octaplex administration aid p3
- PCC patient information leaflet (PIL) p4
- PCC request form p5

Once authorised, give PCC without delay to ensure clinical outcome is optimal

How to use the pack

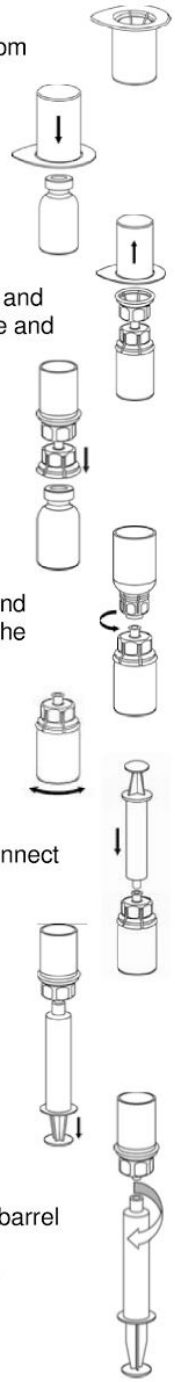
Follow process outlined in algorithm (p2) and the Beriplex P/N and Octaplex administration aid (p3).
Detach request form (p5) and gather all necessary information (patient's weight, indication for Warfarin or other Vitamin K antagonist, latest INR and PCC indication) before contacting haematology duty doctor.
Give the PIL (p4) to all patients deemed to have capacity before obtaining their written consent.

Cautions

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.

Administration of PCC carries a risk of thrombosis and it should generally be avoided in patients with disseminated intravascular coagulation (DIC) or decompensated liver disease.

Beriplex P/N and Octaplex - administration aid



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 that 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 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 piexces. Discard the 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. Without delay, **colleague to give syringe over 2min by IV push while you prepare the next syringe**.

Repeat process until all vials have been administered.

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Prothrombin Complex Concentrate (Octaplex or Beriplex P/N)

Patient Information Leaflet (PIL)

At present your blood is too thin (you are over-anticoagulated) because of the therapy (Warfarin or a similar drug) that you have been taking. When your blood is too thin it may lead to bleeding problems (as you may have already experienced). Your doctors feel that it is important to reverse the effects of the Warfarin (or similar drug) and return your blood to a more normal state where it can clot normally.

It is felt that, in your particular situation at the moment, your blood-clotting problem is best treated using a treatment called Prothrombin Complex Concentrate, or 'PCC'. This is a clotting factor concentrate that is given by intravenous injections. It is manufactured from plasma drawn from several blood donations that are pooled together and then specially processed. The treatment contains all the clotting factors needed to reverse the effects of Warfarin (or similar drug).

As large numbers of plasma donations may have been used to produce this product, there is a theoretical risk of transmitting an infection. However, each plasma donation is carefully screened. In addition all clotting factor concentrates undergo a special procedure to eliminate certain viruses. Further, PCC is heated (pasteurised) to inactivate any potential viruses. This is a very effective additional safety measure. Virus inactivation processes such as pasteurisation might also reduce the possibility of transmitting any unknown viruses. The combination of testing, virus inactivation processes and the way PCC is manufactured all serve to make this treatment as safe as is possible.

Some concerns remain that illnesses such as new variant Creutzfeldt-Jakob disease (vCJD, or mad cow disease) could be transmitted by blood products, but the actual risk is unknown and probably very, very small. Some patients also experience a temporary rise in their body temperature (or fever). Also, as the purpose of giving you PCC is to restore the ability of your blood to clot, there is a small risk that it might cause a thrombosis (an abnormal blood clot) to occur.

All in all, PCC and other similar clotting factor concentrates have been used for many years and have helped many thousands of patients.

Very occasionally, allergic reactions occur with clotting factor concentrates but these are indeed quite rare. When you first receive the clotting factor concentrate, precautions are taken to monitor you for these reactions and to treat them should they occur.

Using the above precautions, PCC has been shown to be safe and effective and will correct your clotting problem very rapidly - within minutes of receiving the injections.

If you have any further questions about PCC that you wish to cover, please ask your doctor.

Patient details

Full name

DoB

Unit number

(use sticker if available)

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

Date DD/MM/YY

Clinical Details

PCC indication ☐ Intracranial bleed ☐ Intraocular bleed ☐ Life-threatening blood loss (state source) ☐ Other (give details)

Consultant

Indication for anticoagulation

Location **Extn**

Weight (mandatory) kg

Hospital ☐ LRI ☐ GGH ☐ LGH

Latest INR Date DD/MM/YY Time HH:MM use 24h clock

Vitamin K given yet? ☐ Yes, dose: mg ☐ IV ☐ PO ☐ No Date DD/MM/YY Time HH:MM use 24h clock

PCC Authorisation

Name of Haematology Middle Grade or Consultant

Time HH:MM use 24h clock

Total dose to be given IU

Additional IV Vitamin K? ☐ Yes, dose: mg ☐ No

Requested By

Print name | Signature | Role | Contact phone or bleep number

For Transfusion Laboratory Use Only

Did haematology doctor call transfusion lab staff? ☐ No had to be called ☐ Yes

Date DD/MM/YY Time HH:MM use 24h clock

Specimen number

Batch number Expiry date

Product supplied ☐ Beriplex P/N ☐ Octaplex

Number of vials issued

Number of vials received

To replace stock, GGH/LGH transfusion lab staff fax this form to LRI lab on 6607, LRI lab staff fax it to LRI pharmacy on 6924.

Faxed by (GGH / LGH staff) Date Time

Faxed by (LRI staff) Date Time

Stock received by (LRI) Date Time

Stock received by (GGH / LGH) Date Time

For Pharmacy Use Only

Stock supplied by Print Name Initials Date Time