Major Haemorrhage Protocol

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Approved by:	Trust Transfusion Committee 12th May 2021, Clinical Governance Group
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Target Organisation(s)	Worcestershire Acute Hospitals NHS Trust Worcestershire Health & Care Trust
Target Departments	All
Target staff categories	All staff involved in the transfusion process

INTRODUCTION

The aim of this protocol is to provide a clear management structure for massive blood loss to enable the provision of blood/blood components to be available as quickly as possible as required.

THIS PROTOCOL IS FOR USE BY THE FOLLOWING STAFF GROUPS:

All medical and nursing staff
Blood Transfusion Staff

Key amendments to this guideline

Date	Amendment	Approved by:
June 2018	New guidance for the management of major haemorrhage at KTC and ECH New guidance on the aims for therapy in major trauma included	Trust Transfusion Committee
November 2019	Inclusion of paragraph in Activation of Protocol	Trust Transfusion Committee
July 2020	Document extended for 6 months whilst review and approval process takes place	Trust Transfusion Committee
February 2021	Document extended for 6 months as per Trust agreement 11/02/2021	Trust agreement
July 2021	Changes to the identification of unknown patients in A&E Changes to the available components in MHP pack 1 Changes to the O Rh Negative unit availability countywide New Rotem guidelines for WRH	Trust Transfusion Committee
Jan 2022	Addition of algorithm for the management of major haemorrhage at KTC	Trust Transfusion Committee
May 2023	Document re-approved for 3 years	Clinical Governance Group/ TTC

MAJOR HAEMORRHAGE PROTOCOL

Contents:

1. INTRODUCTION

The aim of this protocol is to provide a clear management structure for massive blood loss to enable the provision of blood/blood components to be available as quickly as possible as required.

All staff involved in the process of transfusion must have undertaken mandatory training and competency assessment relevant to their role.

This protocol outlines the steps to follow during ***massive blood loss defined as:***

- 50% blood volume loss within three hours
- or 100% within 24hrs (70 ml/kg, >5 litres in a 70kg adult)
- or a rate of blood loss in excess of 150 ml/min

Successful treatment depends on

- prompt action
- good communication
- involvement from senior clinicians with the necessary expertise

THERE IS A SEPARATE POLICY FOR HAEMORRHAGE RELATING TO OBSTETRICS
Antepartum Haemorrhage Including Massive Obstetric Haemorrhage

Patients involved

All patients MUST wear an identity band.

The identification of the patient must adhere to the blood transfusion policy and related procedural documents. The NHS number MUST be used as the primary identifier except if the patient is unconscious and/or unidentifiable when unique A&E patient demographics are used. As per the Patient safety alert 2018 - *Safer temporary identification criteria for unknown or unidentified patients* NHS/PSA/RE/2018/008.
For **names**, a randomly selected first name and surname from the phonetic alphabet is generated. eg Foxtrot Whisky.
For **temporary numbers**, a unique hospital number is created.
For **DOB**, the 1st January with an estimated year of birth is generated

Assessing Blood Loss

It may be difficult to assess the amount of blood loss, but consideration of lost circulating volume may be useful in guiding transfusion management. The table below is a classification of hypovolaemic shock according to percentage blood loss, and the associated clinical signs. Red cell transfusion is indicated in Class III, massive transfusion is indicated in Class IV.

	Class I	Class II	Class III	Class IV
Blood loss mls	750ml	750 – 1500ml	1500 – 2000ml	>2000ml
Blood loss %	< 15%	15 – 30%	30 – 40%	>40%
Pulse rate	<100	>100	>120	>140
Blood pressure	Normal	Normal	Reduced	Low
Pulse pressure	Normal	Decreased	Decreased	Decreased
Capillary refill:	Normal	Slow	Slow	Slow
Respiratory rate :	14-20	20-30	30-40	>35
Urinary output ml/hr	>30	30-20	20-10	10-0
Mental state:	Alert	Anxious	Confused	Lethargic
Extremities:	normal	Pale	Pale/Cool	Pale /Clammy

2. Activation of the Protocol

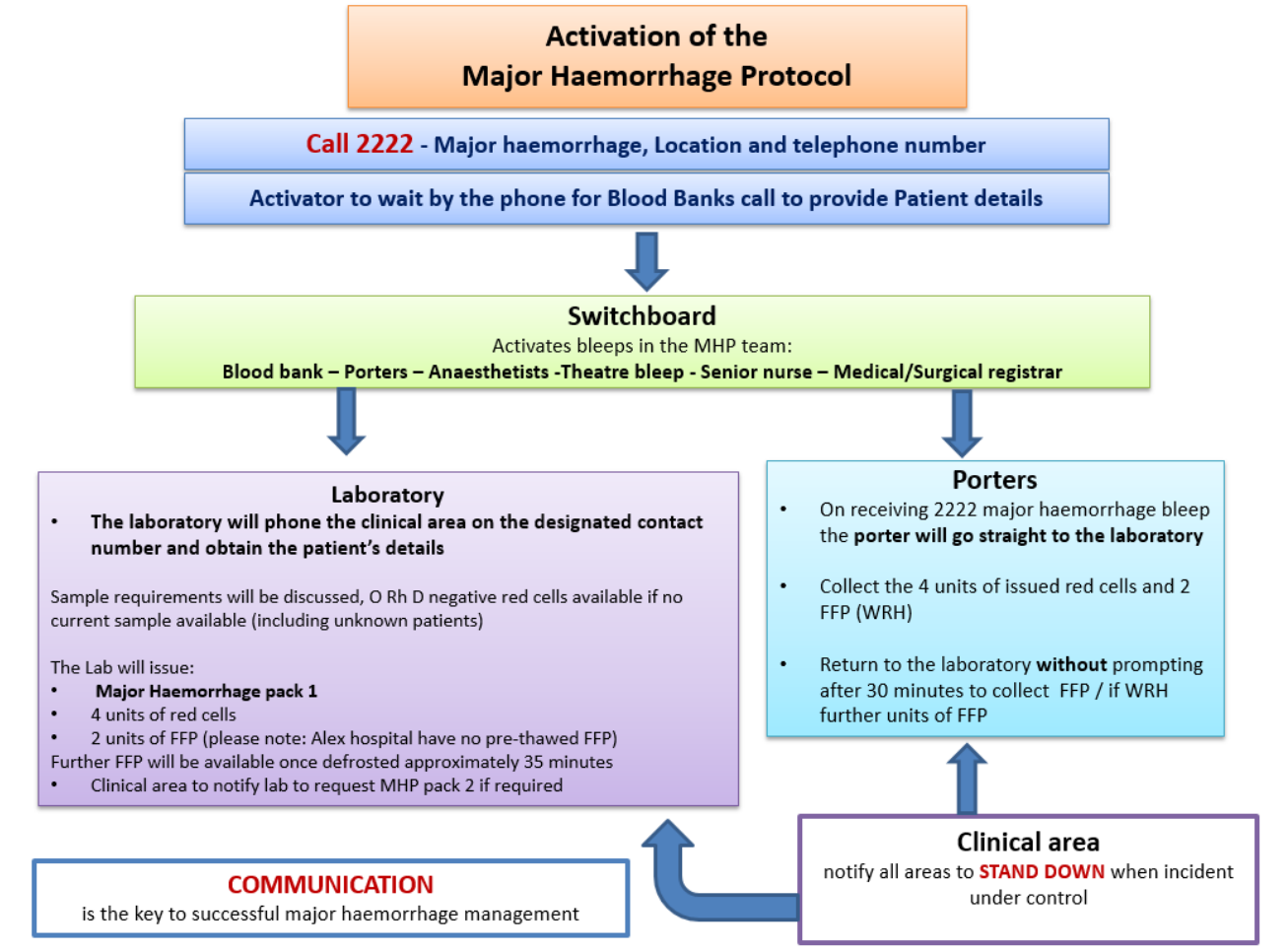
A consultant or senior clinician should make the decision to trigger the major haemorrhage protocol (MHP).

When a patient meets the above criteria, one person in the clinical area should take responsibility for communication between the transfusion laboratory and the clinical area. This person should act as the “coordinator” to avoid miscommunication and facilitate the speedy delivery of blood components.

In theatre emergencies where multiple disciplines are present the consultant anaesthetist is best placed to lead the major haemorrhage.

Communication between the anaesthetic and surgical teams is pivotal and formal consultant dialogue should be repeated regularly and marked by a pause in surgical activity for a **“command huddle”** to ensure appropriate management of the patient.

HOW TO ACTIVATE THE MHP PATHWAY



The Clinical area will:

Call 2222 – and state - **Major Haemorrhage, location, and the contact number and site**.

To prevent delay, they should remain by the phone to answer when the blood bank calls. The clinical area should have the patient's identity details of name, date of birth and NHS number easily to hand.

The Switchboard will:

Activate bleeps in the MHP team to inform them of the MHP activation, site and contact number

The MHP team consists of:

- Blood bank
- Porters
- All anaesthetists
- theatre bleep
- senior nurse
- medical
- surgical registrars

The Laboratory will:

- On receiving the **2222 Major Haemorrhage activation** the laboratory will phone the clinical area on the designated contact number and obtain the patient's details
- If there is no sample on the system one will be requested - O Rh negative red cells available in the interim

The Lab will issue:

Major Haemorrhage pack 1

- 4 units of red cells
- 2 units of pre-thawed FFP (Alex site does not have pre-thawed FFP, FFP will start being thawed and will take around 35minutes to be issued)
- Additional FFP will be thawed for use

- Clinical area to notify the laboratory to request MHP pack 2 if required

The porters will:

- On receiving 2222 major haemorrhage bleep the porter will go straight to the laboratory
- Collect the 4 units of issued red cells and 2 FFP
- Return to the laboratory **without** prompting to collect the further 2 units of or FFP

The porter will also act as a liaison between the clinical area and the laboratory and transport components, sample and products as required.

Communication is the key to successful major haemorrhage management.

The Clinical area should ensure that they notify all areas to **STAND DOWN** when incident under control.

Haematology advice

The coordinator can also contact the haematology consultant on call for advice, this is essential when the patient is on anticoagulant therapy or the haemorrhage does not subside after administration of pack 1. They can be bleeped via switchboard and will advise on the use of haemostatic agents including Vitamin K, Prothrombin Complex Concentrate, Factor VII and Fibrinogen Concentrate.
Although advice from the consultant haematologist can be sought the clinical judgement of balancing risks has to be made by the medical team on site.

If the patient has Autoimmune Haemolytic Anaemia (AIHA) or red cell antibodies, then concessionary, rapid release of the best matched red blood cells will be used.

If a blood shortage has been declared at the time of a MHP activation, you **must** contact the Haematology Consultant on call as they help with decision making on components/products can be released.

Drug reversal:

Antiplatelet drugs (Aspirin, Clopidogrel etc.)

- Platelet transfusion should be given as soon as possible

Vitamin K-antagonists (Warfarin and similar)

- give Vitamin K10mg IV and *Prothrombin complex concentrate* (Beriplex) dose calculated based on INR and estimated body weight

Rivaroxaban:

- *Prothrombin complex concentrate*: (Beriplex) can be used if the last dose was given within the last 24 hours - give 50 units / kg body weight max 5000 units IV

Dabigatran:

- if the last dose was given within the last 24 hours and conventional methods to stop bleeding fail consider *Recombinant Factor VIIa* at a dose of 80 mcg/kg max 14.4mg
- Consider activated charcoal for patients taking dabigatran and apixaban if ingested in the last 4 hours
- After discussion with a consultant haematologist give prothrombin complex concentrate (Beriplex) 25iU/kg (max dose 2500iU)
- If no improvement with prothrombin complex consider recombinant FVIIa (NovoSeven) 90 mcg/kg (rounded DOWN to the nearest 1000mcg), consideration should be given to a second dose 1 hour later if no response or loss of response.

3. IMMEDIATE CLINICAL RESPONSE

STOP THE BLEEDING & RESUSITATE PATIENT

- Maintain Airway, Breathing and Circulation.
- Apply direct pressure / tourniquet if appropriate
- The clinical team should administer Tranexamic Acid in appropriate cases; this should be given by bolus as soon a major haemorrhage is identified. (Tranexamic Acid is not recommended for gastric bleeding)
- Stabilise fractures
- Consider surgical intervention including cell salvage, interventional radiology and endoscopic techniques
- Prevent hypothermia by using fluid warming device and forced air warming blanket.

When blood loss exceeds 150ml/minute then emergency O Rh D negative red cells can be used to support the patient whilst waiting for the haemorrhage pack. Take all the samples prior to transfusion if possible.

Blood Components supplied during MHP

FLYING SQUAD BLOOD (Emergency O Rh D Negative Units)
Emergency O Rh D negative red cells are available from the blood banks at WRH, AGH and there are also 6 units in Kidderminster blood fridge.

4. Major Haemorrhage Pack 1

The response of the laboratory to the activation of this protocol is to provide a standardised set of blood components that meets the immediate need of the patient.
The aim is to make blood components accessible within the time limit according to the clinical situation.

When a consultant/senior clinician activates the MHP the local transfusion laboratory will provide:

Adult Major Haemorrhage Pack 1(MHP1)

- 4 units of red cells
- 4 units of fresh frozen plasma or Octoplas (solvent detergent plasma)

The ratio of FFP: RBC should be 1:2 to 1:1.

Paediatric MHP 1

Weight	**Red cells**	**FFP**
<5kg	2 paediatric units (80-100ml)	2 'neonatal' units of FFP (100ml) or 1 unit Octaplas
5-10.9kg	1 adult unit (250ml) , will require LVT unit if <12 months old	1 unit of FFP (225ml) or 1 unit Octaplas
11-20kg	2 adult units (500ml) or 2 LVT if <12 months old	2 units of FFP (450ml) or 2 units Octaplas
> 20 kg	4 adult units (1000ml)	4 units of FFP (900ml) or 4 units Octaplas

LVT: large volume red cell pack suitable for neonates and children 12 months or less

NB: Group AB cryoprecipitate is not routinely available: for group AB patients first choice is Group A and second choice is Group B

Time to receive at this clinical area WRH/ Alex:

- Electronic Issue red cells 5 minutes
- Group specific red cells 15 minutes
- FFP/Octoplas 30 minutes

MHP pack 1 (4 RBC and 4 FFP/Octoplas) will be collected and transported to the clinical area by a trained porter.
It is important for the clinical area to liaise closely with the transfusion laboratory to avoid miscommunication and to ensure that the appropriate components are issued in a timely way

At KTC the supply will be via taxi arranged by laboratory

5. Aims for Therapy

After giving pack 1 reassess the patient by repeating the FBC, PT, APTT, fibrinogen, UE & $CA^{2+.}$ The aim is to maintain the following parameters:

- Haemoglobin 80-100g/L
- Platelets >75 x 10^{9}/L
- PT ratio < 1.5
- APTT ratio <1.5
- Fibrinogen >1.5g/L
- Ca^{2+} >1 mmol/L (give 10 mls Calcium chloride (10%) over 10 minutes after pack 1. Repeat if necessary)
- Temperature > 36^{o}C
- pH > 7.35 (on ABG)

Monitor for hyperkalaemia

If haemorrhage is continuing, then order massive haemorrhage pack 2

6. Major Haemorrhage Pack 2 (MHP2)

Adult MHP2

This pack will contain:

- Red cells 4 units
- FFP 4 units
- Platelets 1 dose (ATD)
- Cryoprecipitate Give 2 packs if fibrinogen <1.5g/l (< 2g/L for obstetric haemorrhage)

Once administered, repeat the FBC, PT, APTT, fibrinogen, UE & $CA^{2+.}$

Paediatric MHP2

Weight	**Red cells**	**FFP**	**Cryoprecipitate**	**Platelets**
<5kg	2 paediatric units (80-100ml)	2 'neonatal' units FFP (100ml)or 1 unit **Octaplas**	1 single donor unit (40ml)	1 paediatric pack of platelets (50ml)
5-10kg	1 adult unit (250ml), will require LVT if < 12 months old	1 unit FFP (225ml)or 1 unit **Octaplas**	2 single donor units (80ml)	2 paediatric packs of platelets (100ml)
11-20kg	2 adult units (500ml) will require LVT if less than 12 months old .	2 units FFP (450ml)or 2 units **Octaplas**	5 single donor units (200ml)	1 adult apheresis pack (200ml)
> 20 kg	4 adult units (1000ml)	4 units FFP (900ml) or 4 units **Octaplas**	10 single donor units (400ml)	1 adult apheresis pack (200ml)

Further components will need authorisation from the consultant haematologist.

7. Stand Down

When massive haemorrhage has subsided the clinical coordinator must ensure that:

- The laboratory is informed
- Any used components are returned
- All documentation including traceability should be completed

Once the patient is stable thromboprophylaxis should be considered.

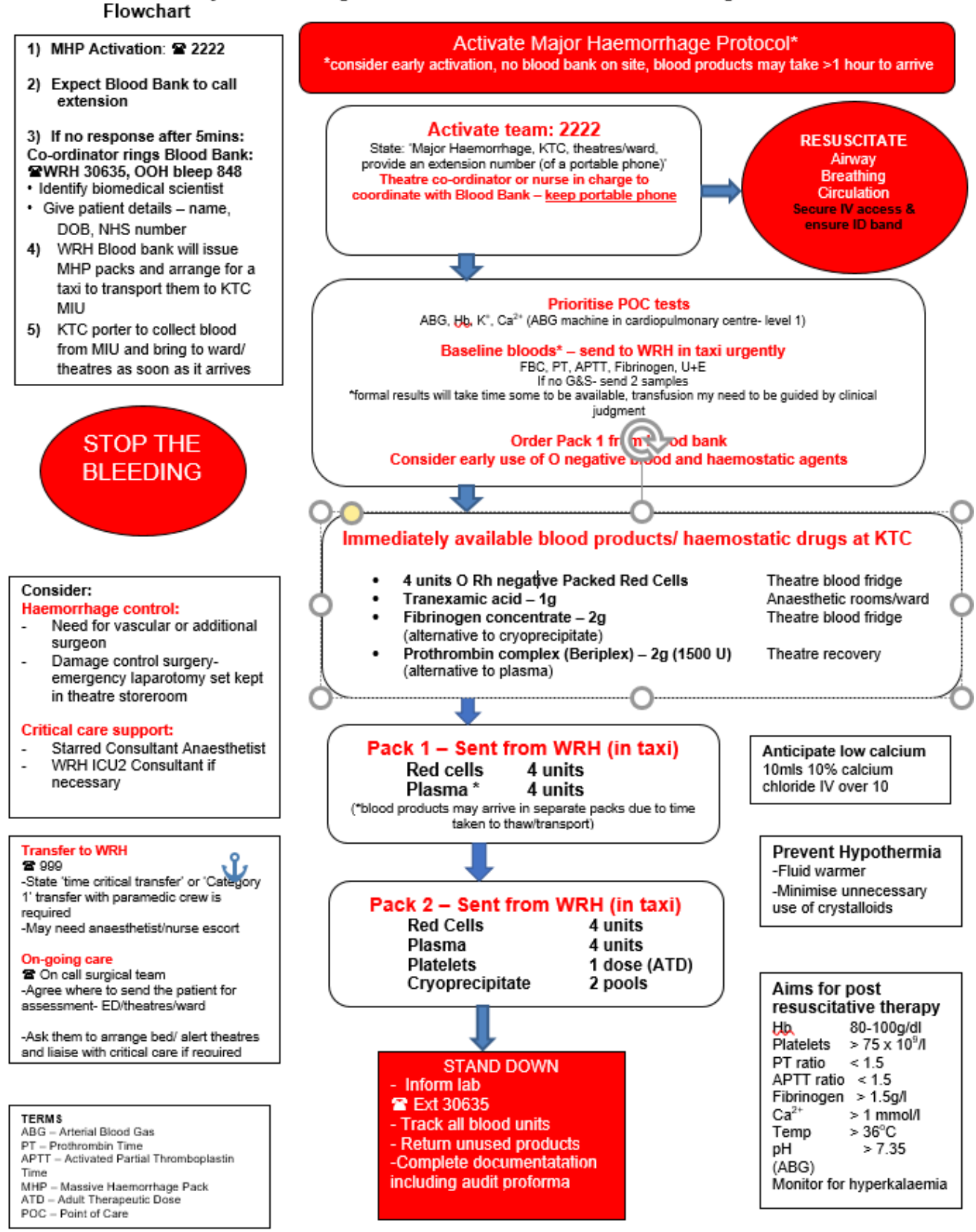
8. Major haemorrhage activation at Kidderminster Treatment centre (KTC) and satellite sites

At Kidderminster hospital there 6 units' O Rh Negative units available for use in an emergency. Fibrinogen concentrate and prothrombin complex are also available in theatre recovery. These can be used whist waiting for other blood components to arrive from the main laboratory.

- The Major haemorrhage protocol is activated by surgeon/anaesthetist responsible for patients' care
- A member of clinical staff will be allocated to act as coordinator
- The coordinator will call **2222 and state "Major haemorrhage, Kidderminster theatre/ward and telephone number."** This 2222 call will notify all areas of a MHP activation at KTC this includes the senior nurse, RMO, porters and minor injuries
- The coordinator should not leave the phone unattended as they will need to take the incoming call from the blood bank. They should have the patient's details of **Name, date of birth and NHS number** easily to hand.
- Upon activation of the 2222 MHP the laboratory will phone the clinical area and request the patient's details
- The blood bank staff will order a taxi through Alexandra hospital switch board. The taxi service should be informed that there is a major haemorrhage and the Site. He should also be advised not to break the speed limit whilst transporting the blood.
- The lab staff will issue and pack MHP pack 1 ready for transportation to KTC.
- The taxi driver on arrival at the lab should be instructed to take it to the minor injuries unit at KTC
- The KTC porter should go to Minor injuries and collect the blood as soon as it arrives and take it to the clinical area
- Should further units be required the laboratory should arrange the transportation via Alex switchboard

8.1 Algorithm for the management of major haemorrhage at KTC

11. Adult Major Haemorrhage in Kidderminster Treatment Centre Management Flowchart



9. Complications of Major Haemorrhage

- Disseminated Intravascular Coagulation in acute bleeding is rare outside obstetric practice – treatment is with platelets, FFP/Octoplas and cryoprecipitate given 'sooner rather than later'.

- Hypothermia may induce coagulopathy therefore both the patient and the blood should be warmed

- Transfusion of large volumes of red cells and other intravenous fluids that contain no coagulation factors or platelets causes dilutional coagulopathy. Major traumatic haemorrhage is often associated with activation of the coagulation and fibrinolytic systems and plasma fibrinogen predictably falls to sub-haemostatic levels (<1.5 g/L). Coagulation is also impaired by hypothermia, acidosis and reduced ionised calcium (Ca2+) concentration.

- TACO (transfusion associated circulatory overload) is defined as acute or worsening pulmonary oedema within 6 hours of transfusion. Typical features include acute respiratory distress, tachycardia, raised blood pressure and evidence of positive fluid balance. Poor pre-transfusion clinical assessment and inadequate monitoring during transfusion is a common feature of reported cases. The treatment of TACO involves stopping the transfusion and administering oxygen and diuretic therapy with careful monitoring and critical care support if required

- Toxic effects from citrates, changes in electrolytes and plasma pH

10. Audit

Audit is important to assess adverse events, timeliness of blood component support, patient outcome and component wastage. There should be multidisciplinary review of cases that trigger the major blood loss protocol to ensure it is being applied appropriately and effectively. All cases will be reviewed at the Hospital Transfusion Committee.

11. Adult Major Haemorrhage in Trauma Management Flowchart

MHP Activation: ☎ **2222**
- Nominate roles
- Distribute action cards
- Assess patient and MOI

Call Blood Bank:
WRH 30635 OOH bleep 848
ALEX 44719 OOH bleep 0255
- Identify biomedical scientist
- Give patient details
- State urgency of XM (15 min v 45 min) if known

Check availability and location of Emergency Group O red cells:
Use O RhD neg red cells if female <50 yr/ child known RhD neg/antibodies

Rapid assessment: Pre-hospital/hospital

SUSPECT MAJOR HAEMORRHAGE: HAS TXA BEEN GIVEN PRE-HOSPITALLY? NOT indicated in gastric bleeding. Significant MOI / severe bleeding / shock/ Poor physiological response to IV fluids/pre-hospital transfusion (RCC or plasma). Consider Blood to Scene or pre-activate hospital Major Haemorrhage Protocol

Activate Major Haemorrhage Protocol

Activate team: 222
'Major Haemorrhage, Specialty, Location'
Team collect action cards
Secure IV access & ensure ID band
Consultant involvement essential

RESUSCITATE
Airway
Breathing
Circulation

STOP THE BLEEDING

Consider:
Haemorrhage control
Interventional Radiology
Early surgery

Cell salvage Haemostatic component support may be required during use of intra-operative salvage of washed red cells

Haemostatic Drugs
Vit K and Prothrombin complex concentrate (PCC) for warfarinised patients
Other haemostatic agents and reversal of new anticoagulants: discuss with Consultant Haematologist

TERMS
ABG – Arterial Blood Gas
FFP – Fresh Frozen Plasma
PT – Prothrombin Time
APTT – Activated Partial Thromboplastin Time
MHP – Massive Haemorrhage Pack
TEG/ROTEM –Thromboelastography
ATD – Adult Therapeutic Dose
NPT – Near Patient Testing
XM - Crossmatch

Baseline bloods
XM (x 2), FBC, PT, APTT, Fibrinogen, U+E, Ca^{2+}
ABG, lactate (and if available, TEG / ROTEM

Order Pack 1

Pack 1
Red cells* **4 units**
Plasma **4 units**
(*Emergency O blood, or group specific blood). Anticipate need for platelets and cryoprecipitate

Reassess: Suspected continuing haemorrhage
Repeat Trauma bloods
FBC, PT, APTT, Fibrinogen, U+E, Ca^{2+}
ABG, lactate (and if available, TEG / ROTEM)

Pack 2
Red Cell **4 units**
Plasma **4 units**
Platelets **1 dose (ATD)**
Give 2 pools (of 5) Cryoprecipitate
if fibrinogen <1.5g/l or 2g/l and falling
(Fibrinogen concentrate may be available – use as per trust guidelines)

Goal directed therapy
Monitor patient
Adjust component support based on Pack 2

Prevent Hypothermia
Manage shock
Minimise unnecessary use of crystalloids

Aims for post resuscitative therapy

Hb	80-100g/dl
Platelets	> 75 x 10^9/l
PT ratio	< 1.5
APTT ratio	< 1.5
Fibrinogen	> 1.5g/l
Ca^{2+}	> 1 mmol/l
Temp	> 36°C
pH (ABG)	> 7.35

Monitor for hyperkalaemia

Anticipate low calcium
10mls 10% calcium chloride IV over 10 mins after pack 1.

STAND DOWN
- Inform lab
☎ Ext 30635/44719
- Track all blood units
- Return unused products
- Complete documentatation including audit proforma

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12. Paediatric Major Haemorrhage in Trauma Management Flowchart

Ongoing severe bleeding e.g.
Received 20 ml / kg of RBC or > 2ml / kg / min blood loss or >40 ml / kg of any resuscitation fluid in 3 hours. Signs of hypovolaemic shock and or coagulopathy
Administer tranexamic acid (in trauma) if < 3 hours post injury
Aim to give bolus within 1 hour

ACTIVATE PAEDIATRIC MAJOR HAEMORRHAGE PROTOCOL

MHP Activation: x 2222
ENSURE A CONSULTANT IS CALLED TO LEAD IF NOT ALREADY PRESENT
- Nominate roles
- Distribute action cards
- Call Blood Bank:

WRH 30635 OOH bleep848
ALEX 44719 OOH
bleep 0255
- Identify Biomedical Scientist
- Give patient details inc. age, weight and gender to Blood Bank. They will advise if a further sample is required or if blood can be issued straight away
- State urgency of XM (15 mins v 45 mins
- Patients born after 1/1/1996 will require MB treated FFP or **Octaplas (generically referred to as plasma in this flow chart)**
- Issue identification band

Activate team X 2222
'Paediatric Major Haemorrhage, Specialty, Location'

Team collect action cards
Consultant involvement essential. Paed SpR or Consultant

RESUSCITATE
Airway
Breathing
Circulation

PREVENT HYPOTHERMIA
- Use a blood warmer
- Use forced air warming

Baseline bloods
If needed obtain bloods and send to Lab with porter
1st XM, FBC, PT, APTT, Fibrinogen, U&E, Ca^{2+}

NEAR PATIENT TESTING: ABG, TEG if available
ORDER PACK 1

Give 0.2 ml /kg 10% calcium chloride or 0.3 ml/kg calcium gluconate after pack 1. Repeat if necessary. Max 10 ml

ADMINISTER PACK 1
RBC 20 ml / Kg + Plasma 20 ml / Kg RBC – Plasma ratio 1:1

Additional aims:
Ph >7.2
Lactate < 1 mmol/L

STOP THE BLEEDING

Reassess: Suspected continuing haemorrhage
Repeat Trauma bloods and send to lab:
2nd XM if possible, FBC, PT, APTT, fibrinogen, U&E, Ca^{2+}
NEAR PATIENT TESTING: ABG if available
Objectively evaluate after each 10ml/kg aliquot (max 250ml)
1) Extent of bleeding 2) Response to treatment 3) Evidence of TACO + repeat baseline lab tests every 30-60 minutes if on-going bleeding

IF REQUIRED ORDER PACK 2
RBC 1:1 Plasma
If > than 40ml / Kg RBC consider PLTS 15-20 ml / Kg + Cryo 10ml/Kg (aim to keep the PLT count above 100)

STAND DOWN
☎30635/44719
- **End fate all blood and components**
- **Return unused components to blood bank or transfer blood with patient**
- **Ensure adequate**

Consider:
1. Haemorrhage control:
- Appropriate Surgical Specialists
- Inform Theatres so they can prepare i.e. cell salvage

2. Call Interventional Radiologist
3. Call Haematologist for advice

ADMINISTER PACK 2

HAEMOSTATIC DRUGS
Patients on warfarin
Vit K (250 – 300 mcg / kg up to 5 mg slow IV) + PCC
Other haemostatic drugs
Discuss with Haematologists

After administering Pack 2 repeat bloods
2nd XM if not already gained, FBC, PT, APTT, fibrinogen, U&E, Ca^{2+}
NEAR PATIENT TESTING: ABG if available
Consider further calcium (keep the ionised Ca >1mmol/L)

Once bleeding under control laboratory testing should guide blood component therapy

Continue Transfusing to achieve:

Hb > 70g/L
Plt > 100
Fibrinogen > 1

Blood Components to request by weight

	20ml / kg	20ml / kg	15-20 ml / kg	10ml / kg
WEIGHT	**RBC**	**Plasma**	**PLTS**	**CRYO**
< 5 kg	80-100 ml	80-100 ml	50-80 ml	50 ml
5-10.9 kg	1 unit	1 unit	100 ml	80 ml
11-20 kg	2 units	2 units	1 unit	1 pool
20-50 kg	3 units	3 units	1 unit	2 pools
>50 kg	4 units	4 units	1 unit	2 pools

90ml /kg in term infants and 70-80 ml/kg in adolescence

13. Use of Rotational Thromboelastometry (ROTEM) at WRH

Contents

1. What is ROTEM and how does it work?

Rotational Thromboelastometry (ROTEM) is a point of care test which evaluates the quality of blood clot formation and stability by quantitative assessment of its viscoelastic properties. It can used in major haemorrhage for rapid assessment of coagulation and to guide correction of coagulopathy in major transfusion.

During the processing of a sample, whole blood is placed into a 'cup', activators are added as required, and a pin is placed into the middle of the blood. The pin is oscillated through a predetermined arc, and as the clot forms, the resistance to movement builds up due to formation of fibrin strands. This resistance is measured by changes in light transmission and is converted into a 'TEM trace' (or TEMogram).[1]

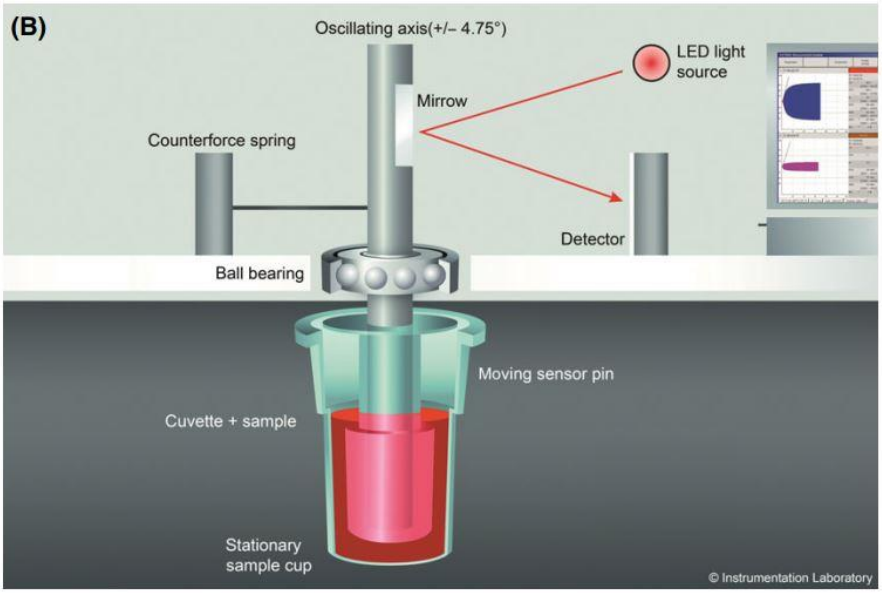


Figure 1 Graphical representation of how rotational thromoelastometry is performed[1]

2. Location and use of the ROTEM at WRH

The ROTEM will be situated in the Recovery area in Main Theatres, on level 2, Worcestershire Royal Hospital.

3. Understanding ROTEM results

Whilst processing the sample, the ROTEM produces continuous TEM traces.

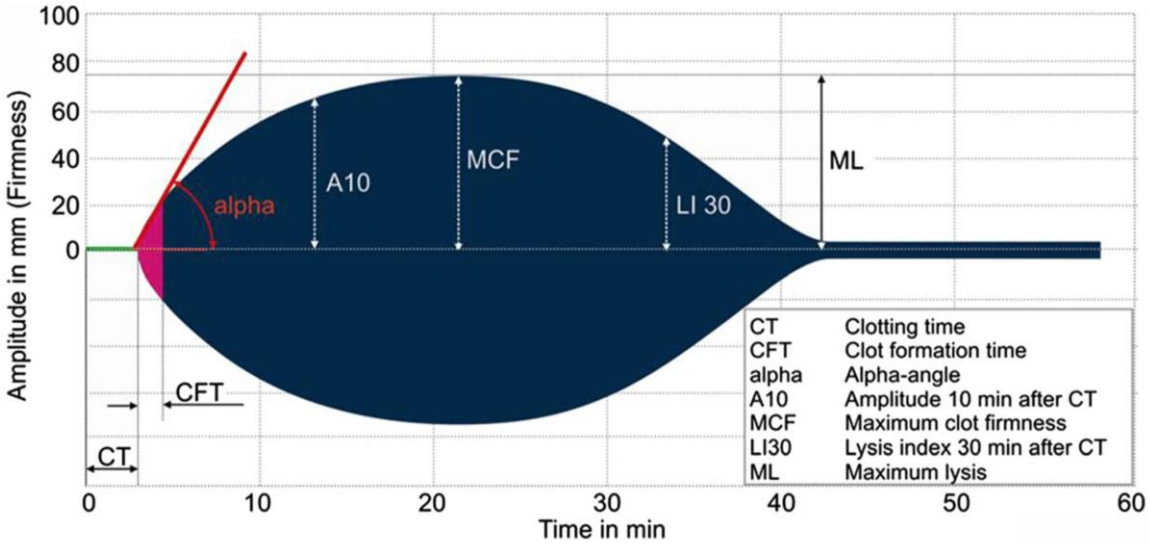


Figure 2: Example TEG trace[13]

As seen in Figure 2, the TEG trace gives rise to a number of numerical values:

CT	The time (s) taken for the first deflection from 0mm to appear
CFT	The time (s) for an amplitude of 20mm to be achieved
α-angle	A line is drawn from 0mm amplitude at the CT and 20mm amplitude at the CFT. The alpha angle is the angle between this line and the x axis.
A5 or A10	The amplitude (mm) of the trace at 5 or 10 minutes
MCF	The maximum amplitude (mm) reached
LI30 or LI60	The amplitude of the trace 30 or 60 minutes after the MCF, expressed as a percentage of the MCF
ML	The minimum amplitude of the trace after the MCF, expressed as a percentage of the MCF

The ROTEM machine will perform 4 or more tests simultaneously, displaying a TEM trace for each test being performed. Typically, INTEM, EXTEM, FIBTEM and APTEM tests will be performed, with HEPTEM and ECATEM being optional extras,[3] giving an overall result looking similar to the below image:

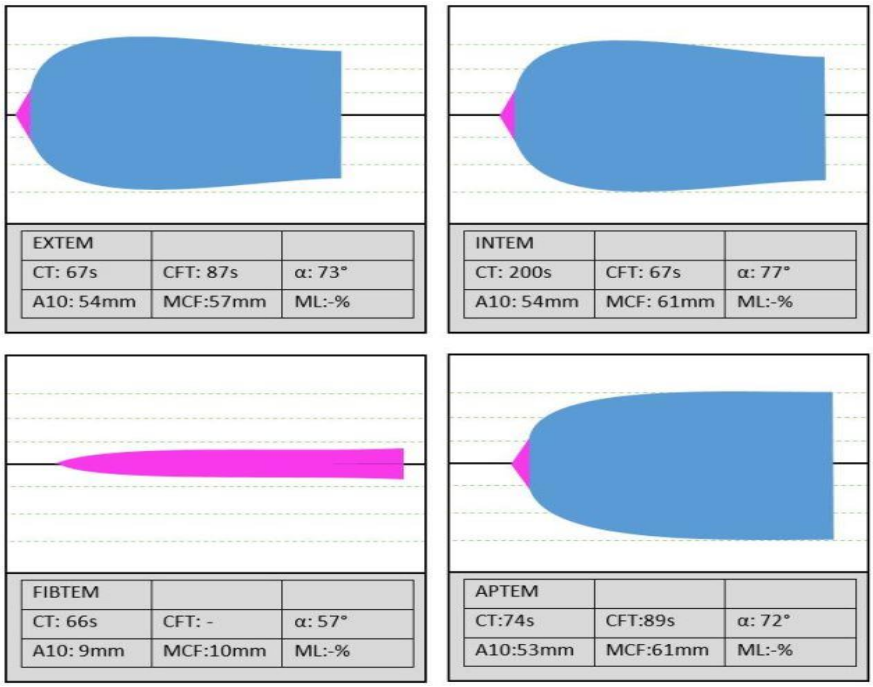


Figure 3[3]: Typical ROTEM printout from a non-coagulopathic individual

These tests will be considered in more detail below[3]:

INTEM – tests the intrinsic pathway
This test uses phospholipid and ellagic acid as activators and provides information similar to that of the APTT – the intrinsic pathway is being tested.

EXTEM – tests the extrinsic pathway
This test uses Tissue Factor as an activator and provides information to the PT – the extrinsic pathway is being tested. The addition of tissue factor greatly speeds up clotting time (CT) and ensures that maximum clot firmness (MCF) will be established within 10 minutes, but at the cost of all the useful information which can be derived from the CT.

FIBTEM – isolates fibrinogen function
Uses a platelet inhibitor (cytochalasin D) to block platelet contribution to clot formation. This allows observation of the functional fibrinogen to clot formation. Without platelets, however, the maximum clot firmness is dramatically reduced and rarely reaches an amplitude of 20mm.

APTEM – excludes fibrinolysis

This test uses aprotinin to inhibit fibrinolytic proteins, and is otherwise identical to EXTEM. A shortened clotting time (CT) and a higher maximum clot firmness (MCF) in an APTEM test (relative to EXTEM) suggests that hyperfibrinolysis is occurring.

HEPTEM – excludes the effects of heparin

This test uses lyophilised heparinise to neutralise the effects of heparin. It is otherwise identical to INTEM, and reports a result which reveals any coagulopathy coexisting alongside heparinisation. This test is useful for situations where the patient is heavily heparinised and the clinician is interested in the degree of coagulopathy that might be expected after the heparin is reversed.

ECATEM – tests for direct thrombin inhibitors

This test uses Ecarin (a prothrombin activator) and so is similar to Ecarin Clotting Time (ECT). In the presence of direct thrombin inhibitors, clotting time (CT) will be prolonged, whereas it will be normal in the presence of heparin or warfarin.

4. Typical patterns of results in different coagulopathies

Thrombocytopaenia or poor platelet function

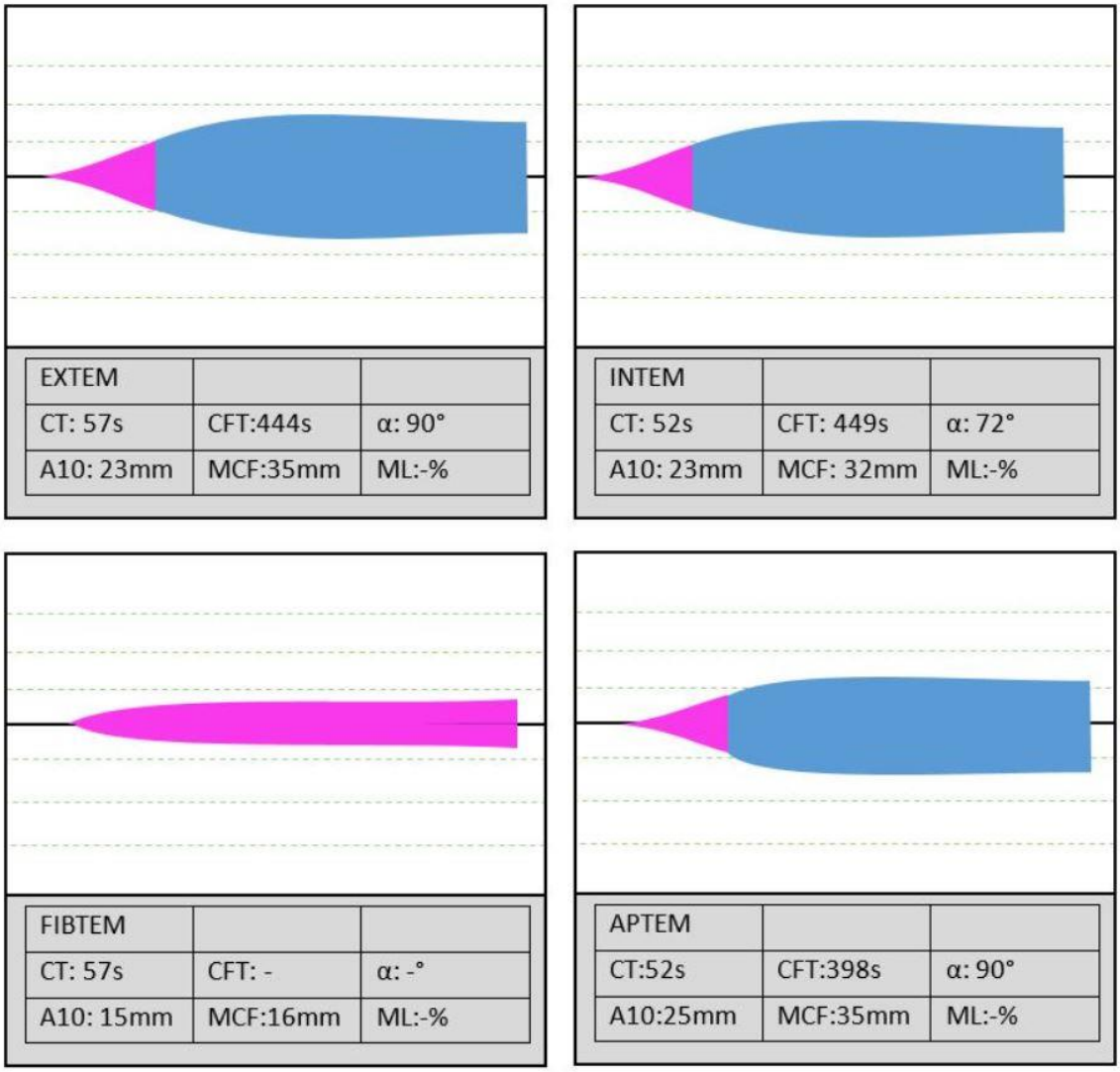


Figure 4: Typical ROTEM printout from a thrombocytopaenic individual[3]

EXTEM		
CT: ↔	CFT: ↑	α: ↔/↑
A5/10: ↓	MCF: ↓	ML:

INTEM		
CT: ↔	CFT: ↑	α: ↔
A5/10: ↓	MCF: ↓	ML:

FIBTEM		
CT: ↔	CFT:	α:
A5/10:↔	MCF: ↔	ML:

APTEM		
CT: ↔	CFT: ↑	α: ↔/↑
A5/10: ↓	MCF: ↓	ML:

EXTEM A5 MINUS FIBTEM A5 ≤30

Low Fibrinogen

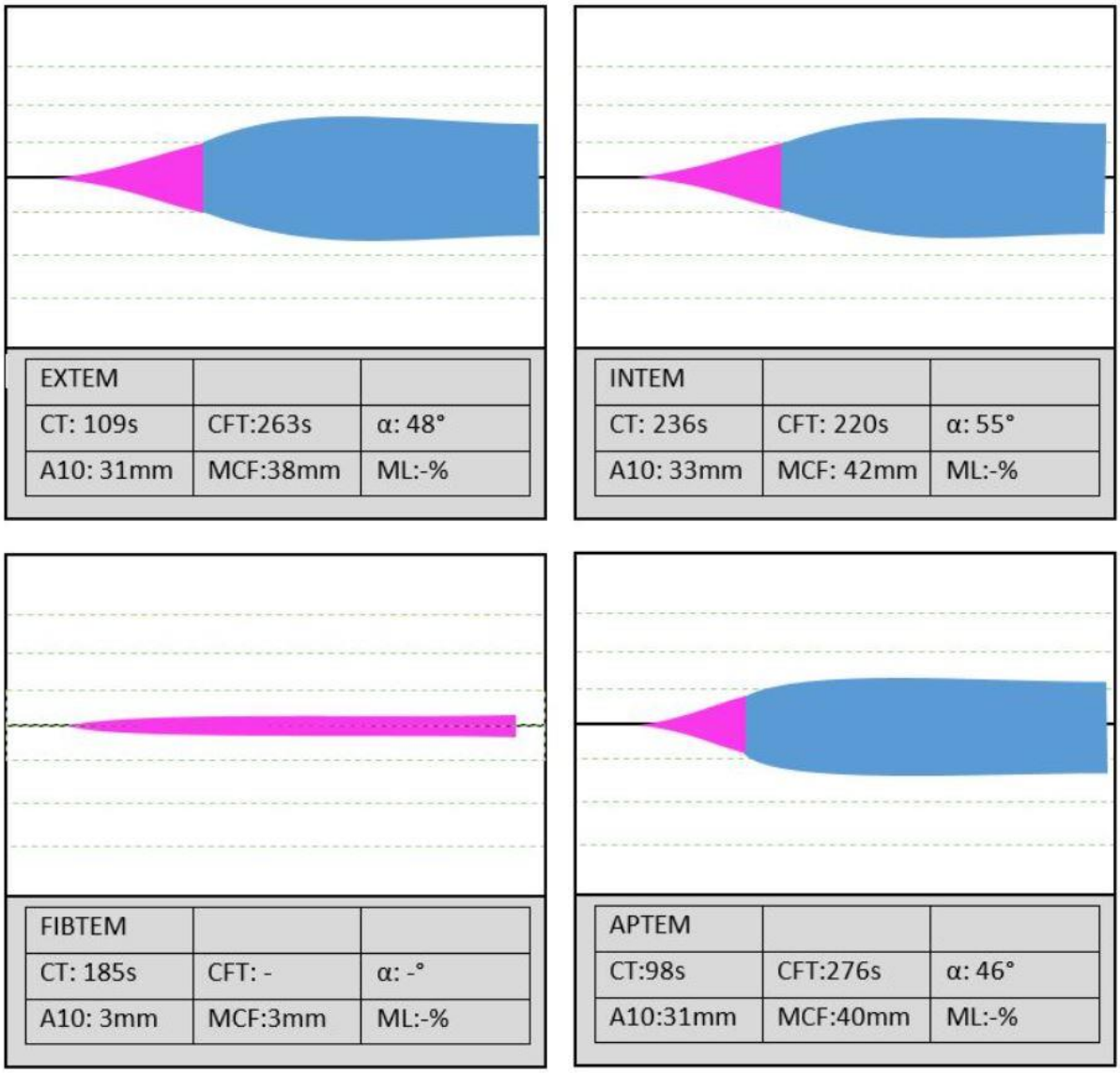


Figure 5: Typical ROTEM printout from a fibrinogen deficient individual[3]

EXTEM		
CT: ↑	CFT: ↑	α: ↓
A5/10: ↓	MCF: ↓	ML:

INTEM		
CT: ↑	CFT: ↑	α: ↓
A5/10: ↓	MCF: ↓	ML:

FIBTEM		
CT: ↑	CFT:	α:
A5/10: ↓	MCF: ↓	ML:

APTEM		
CT: ↑	CFT: ↑	α: ↓
A5/10: ↓	MCF: ↓	ML:

FIBTEM A5
≤11 (obstetrics)
≤10 (other)

5. Use of the ROTEM in major haemorrhage (MH)

Use of the ROTEM should be initiated early upon activation of the major haemorrhage protocol. An algorithm for ROTEM-guided correction of coagulopathy in MH[1, 4-6, 9-12, 14] can be found in appendix 1.

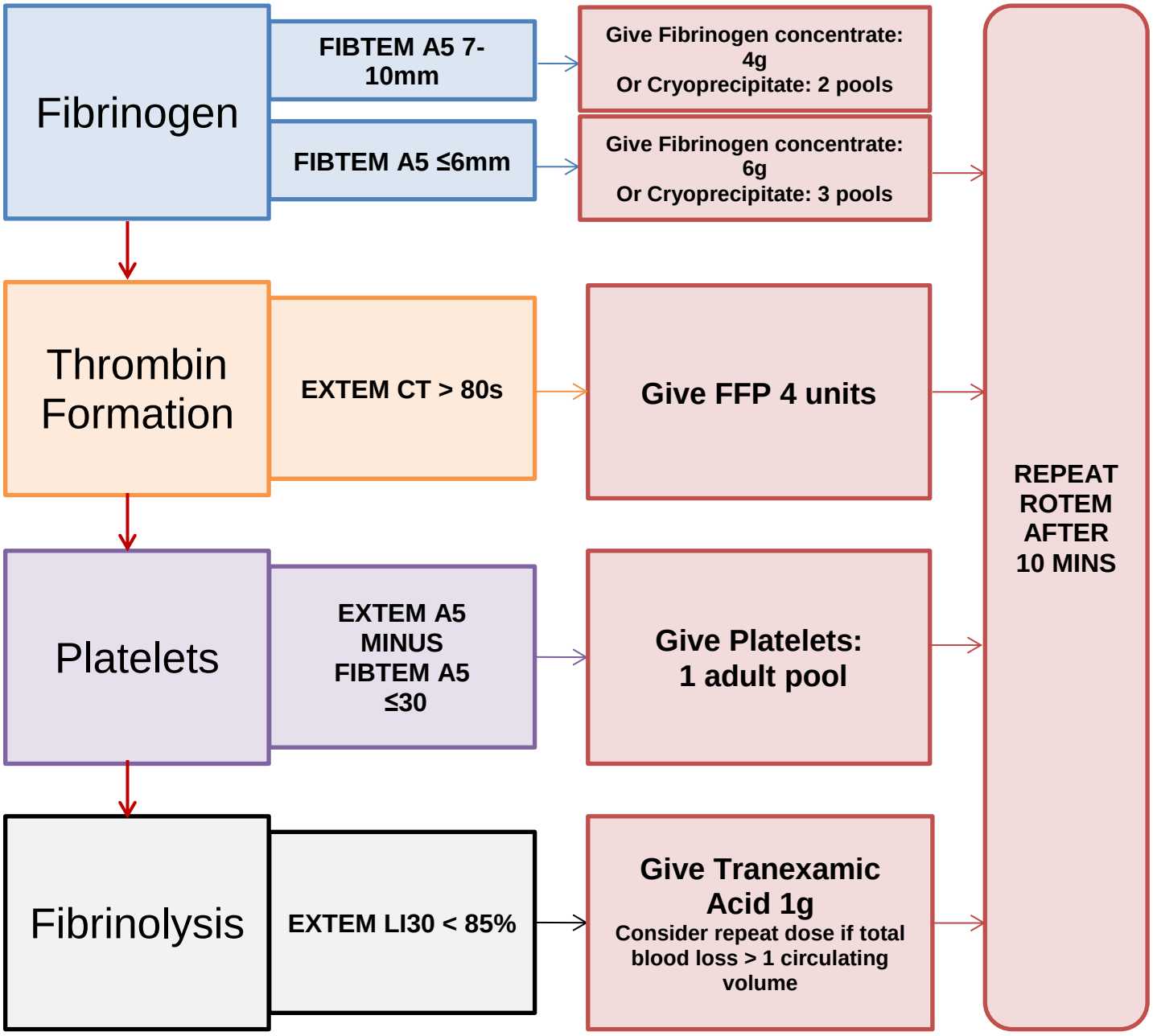
Further information on the management of MH is available in the trust major haemorrhage guideline WAHT-KD-001.

6. Use of the ROTEM in major obstetric haemorrhage (MOH)

Use of the ROTEM should be initiated early upon activation of the major obstetric haemorrhage protocol. An algorithm for ROTEM-guided correction of coagulopathy in MOH[7-8, 14-17] can be found in appendix 2. Note should be made that the 'normal' reference ranges for ROTEM are different in pregnancy.

Further information on the management of MOH can be found in the trust guideline WAHT-TP-094.

7. Appendix 1 – Algorithm for correction of coagulopathy in Major Haemorrhage



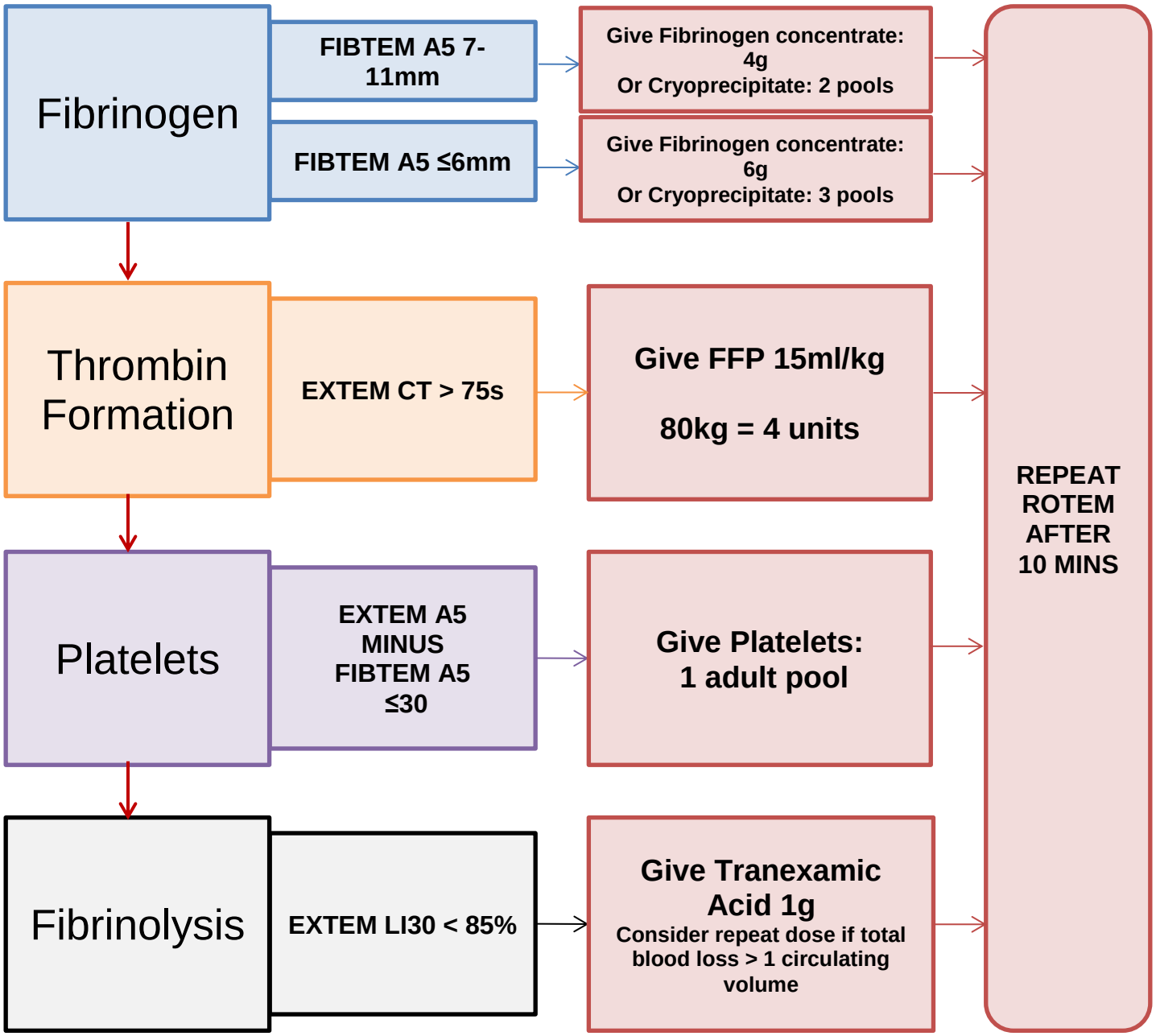
Maintain:
Temp > 36°C, pH > 7.2, Ionised Ca^{2+} > 1mmol/L, Hb > 80

If coagulation normal, escalate medical / surgical and anaesthetic care

NB: ROTEM does not reliably detect effects of: warfarin, aspirin, clopidogrel, direct oral anticoagulants, LMWH. It will not detect deficiency of von Willebrand factor

**DO NOT WITHOLD BLOOD PRODUCTS SOLELY ON THE BASIS OF NORMAL ROTEM RESULTS
RESULTS SHOULD BE INTERPRETED ALONGSIDE LABORATORY TESTS & CLINICAL ASSESSMENT
IF YOU HAVE ANY CONCERNS, DISCUSS WITH A HAEMATOLOGIST**

8. Appendix 2 – Algorithm for correction of coagulopathy in Major Obstetric Haemorrhage



Maintain:
Temp > 36°C, pH > 7.2, Ionised Ca^{2+} > 1mmol/L, Hb > 80

If coagulation normal, escalate obstetric and anaesthetic care

NB: ROTEM does not reliably detect effects of: warfarin, aspirin, clopidogrel, direct oral anticoagulants, LMWH. It will not detect deficiency of von Willebrand factor

DO NOT WITHOLD BLOOD PRODUCTS SOLELY ON THE BASIS OF NORMAL ROTEM RESULTS
RESULTS SHOULD BE INTERPRETED ALONGSIDE LABORATORY TESTS & CLINICAL ASSESSMENT
IF YOU HAVE ANY CONCERNS, DISCUSS WITH A HAEMATOLOGIST

Monitoring Tool

This should include realistic goals, timeframes and measurable outcomes.

How will monitoring be carried out?

Who will monitor compliance with the guideline?

Page/ Section of Key Document	Key control:	Checks to be carried out to confirm compliance with the policy:	How often the check will be carried out:	Responsible for carrying out the check:	Results of check reported to: *(Responsible for also ensuring actions are developed to address any areas of non-compliance)*	Frequency of reporting:
	WHAT?	**HOW?**	**WHEN?**	**WHO?**	**WHERE?**	**WHEN?**
	Each MHP activation should be reviewed by the Transfusion practitioner	Audit of the event.	On each activation.	Transfusion practitioners	Trust Transfusion Team and Committee	4 times a year

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Contribution List

This key document has been circulated to the following individuals for consultation;

Designation
Consultant Haematologist
Consultant Urgent care
Consultant Specialised medicine
Consultants Women's and Children's
Consultant SCSD
Consultant Surgery
Blood Bank Manager
Community IV team lead
Private Hospital lead
Deputy Chief Nurse
Transfusion practitioner

This key document has been circulated to the chair(s) of the following committee's / groups for comments;

Committee
Trust Transfusion Committee

Supporting Document 1 - Equality Impact Assessment Tool

To be completed by the key document author and included as an appendix to key document when submitted to the appropriate committee for consideration and approval.

Please complete assessment form on next page;

NHS
Worcestershire
Acute Hospitals
NHS Trust

Herefordshire & Worcestershire STP - Equality Impact Assessment (EIA) Form
Please read EIA guidelines when completing this form

Section 1 - Name of Organisation (please tick)

Herefordshire & Worcestershire STP		Herefordshire Council		Herefordshire CCG	
Worcestershire Acute Hospitals NHS Trust		Worcestershire County Council		Worcestershire CCGs	
Worcestershire Health and Care NHS Trust	✓	Wye Valley NHS Trust		Other (please state)	

Name of Lead for Activity	

Details of individuals completing this assessment	**Name**	**Job title**	**e-mail contact**
	Gill Godding	**Lead Transfusion practitioner**	**gilliangodding@nhs.net**
Date assessment completed	**02/07/21**		

Section 2

Activity being assessed (e.g. policy/procedure, document, service redesign, policy, strategy etc.)	**Title: Major haemorrhage protocol**			
What is the aim, purpose and/or intended outcomes of this Activity?	Safe Transfusion practice			
Who will be affected by the development & implementation of this activity?	❑ ✓ ❑ ❑	Service User Patient Carers Visitors	✓ ❑ ❑ ❑	Staff Communities Other _____

Is this:	✓ Review of an existing activity ❑ New activity ❑ Planning to withdraw or reduce a service, activity or presence?
What information and evidence have you reviewed to help inform this assessment? (Please name sources, eg demographic information for patients / services / staff groups affected, complaints etc.	NHS BT British Society for haematology guidelines Blood safety and Quality regulations NPSA safer practice notice No:14 MHRA Serious hazards of transfusion Serious adverse blood reactions and events
Summary of engagement or consultation undertaken (e.g. who and how have you engaged with, or why do you believe this is not required)	n/a
Summary of relevant findings	

Section 3

Please consider the potential impact of this activity (during development & implementation) on each of the equality groups outlined below. **Please tick one or more impact box below for each Equality Group and explain your rationale**. Please note it is possible for the potential impact to be both positive and negative within the same equality group and this should be recorded. Remember to consider the impact on e.g. staff, public, patients, carers etc. in these equality groups.

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Age		✓		This protocol will have neutral impact on all equality groups.
Disability		✓		
Gender Reassignment		✓		
Marriage & Civil Partnerships		✓		
Pregnancy & Maternity		✓		
Race including Traveling Communities		✓		
Religion & Belief		✓		
Sex		✓		

Equality Group	Potential positive impact	Potential neutral impact	Potential negative impact	Please explain your reasons for any potential positive, neutral or negative impact identified
Sexual Orientation		✓		
Other Vulnerable and Disadvantaged Groups (e.g. carers; care leavers; homeless; Social/Economic deprivation, travelling communities etc.)		✓		
Health Inequalities (any preventable, unfair & unjust differences in health status between groups, populations or individuals that arise from the unequal distribution of social, environmental & economic conditions within societies)		✓		

Section 4

What actions will you take to mitigate any potential negative impacts?	Risk identified	Actions required to reduce / eliminate negative impact	Who will lead on the action?	Timeframe
	None identified	.		
How will you monitor these actions?				
When will you review this EIA? (e.g in a service redesign, this EIA should be revisited regularly throughout the design & implementation)				

Section 5 - Please read and agree to the following Equality Statement

1. Equality Statement

1.1. All public bodies have a statutory duty under the Equality Act 2010 to set out arrangements to assess and consult on how their policies and functions impact on the 9 protected

characteristics: Age; Disability; Gender Reassignment; Marriage & Civil Partnership; Pregnancy & Maternity; Race; Religion & Belief; Sex; Sexual Orientation

1.2. Our Organisations will challenge discrimination, promote equality, respect human rights, and aims to design and implement services, policies and measures that meet the diverse needs of our service, and population, ensuring that none are placed at a disadvantage over others.

1.3. All staff are expected to deliver services and provide services and care in a manner which respects the individuality of service users, patients, carer's etc, and as such treat them and members of the workforce respectfully, paying due regard to the 9 protected characteristics.

Signature of person completing EIA	Gill Godding
Date signed	02/07/21
Comments:	
Signature of person the Leader Person for this activity	Gill Godding
Date signed	02/07/21
Comments:	none

Supporting Document 2 – Financial Impact Assessment

To be completed by the key document author and attached to key document when submitted to the appropriate committee for consideration and approval.

	Title of document:	Yes/No
1.	Does the implementation of this document require any additional Capital resources	No
2.	Does the implementation of this document require additional revenue	No
3.	Does the implementation of this document require additional manpower	No
4.	Does the implementation of this document release any manpower costs through a change in practice	No
5.	Are there additional staff training costs associated with implementing this document which cannot be delivered through current training programmes or allocated training times for staff	No
	Other comments:	None

If the response to any of the above is yes, please complete a business case and which is signed by your Finance Manager and Directorate Manager for consideration by the Accountable Director before progressing to the relevant committee for approval