OBS UK

Where did it come from? Where is it going?

Dr Rachel Collis

Consultant Anaesthetist

University Hospital of Wales

Cardiff

On behalf of Obstetric Bleeding Study collaborators

OBS1 Obstetric Bleeding Study

OBS2 Obstetric Bleeding Study 2

OBSCYMRU Obstetric Bleeding Strategy for Wales

OBS+ Obstetric Bleeding Study

OBS UK Obstetric Bleeding Study

Disclosures

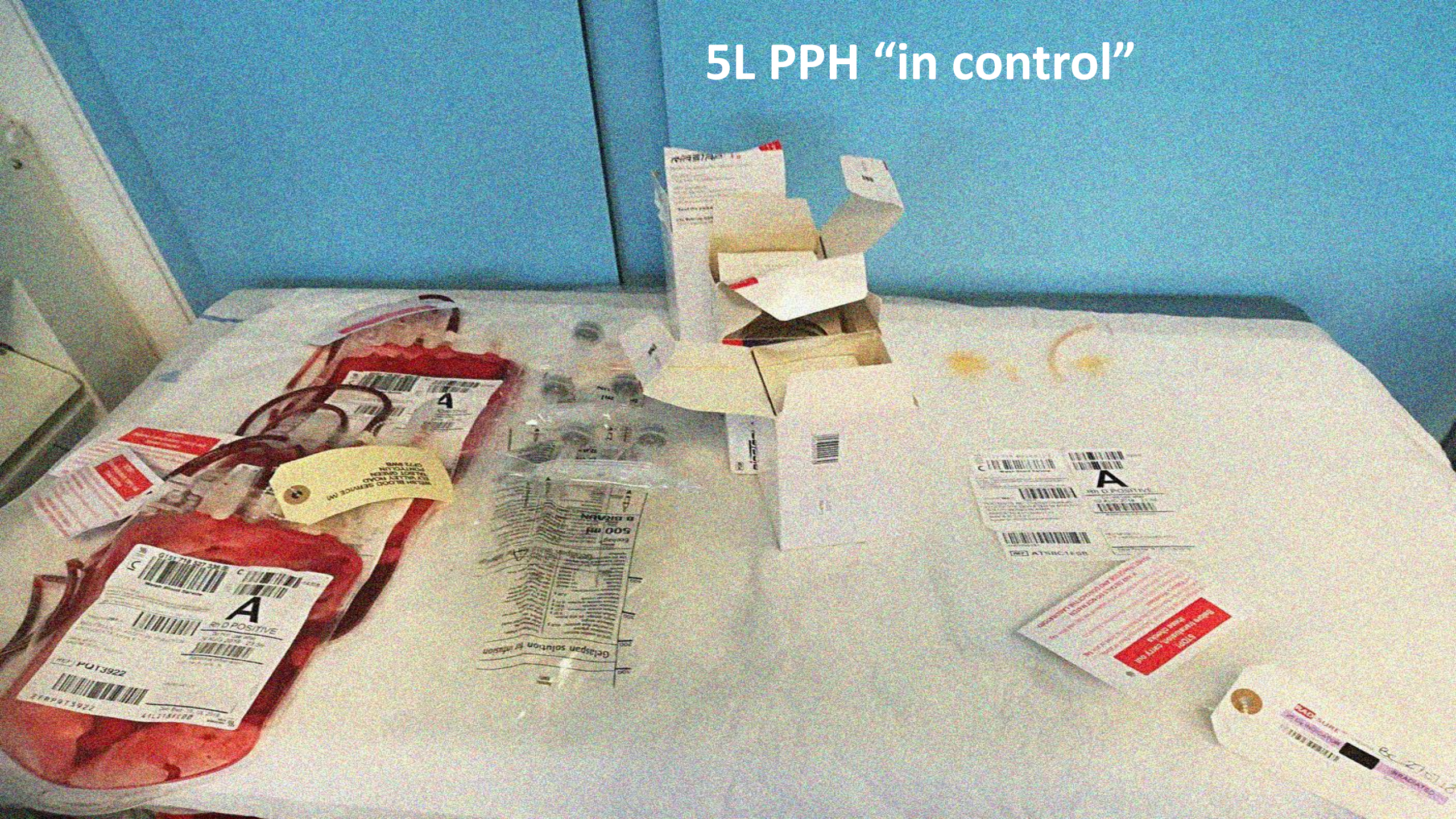
Study support from
Welsh Government, Werfen, Haemonetics, OAA, NIAA, NIHR

Off license use of fibrinogen concentrate in UK will be mentioned

UHW use ROTEM but I have used ROTEM and TEG and I believe reliability of devices very similar


Out of control

5L PPH “in control”



Causes of postpartum bleeding

- **Tone**
  - **Uterine atony**
- **Trauma/surgery**
  - **Perineal tears**
  - **Uterine rupture**
  - **Caesarean section**
  - **Episiotomy**
- **Tissue/placental**
  - **Retained products**
  - **Placenta accrete**
  - **Praevia**
  - **Abruption**
- **Coagulopathy (<5%)**
  - **Consequence of obstetric complication**

Four Ts

- **Tone**
- **Trauma**
- **Tissue**
- **Thrombin**

Causes of postpartum bleeding

- **Tone**
  - Uterine atony
- **Trauma/surgery**
  - Perineal tears
  - Uterine rupture
  - Caesarean section
  - Episiotomy
- **Tissue/placental**
  - Retained products
  - Placenta accrete
  - Praevia
  - Abruption
- **Coagulopathy**
  - Consequence of obstetric complication
  - Amniotic fluid embolus

Four Ts

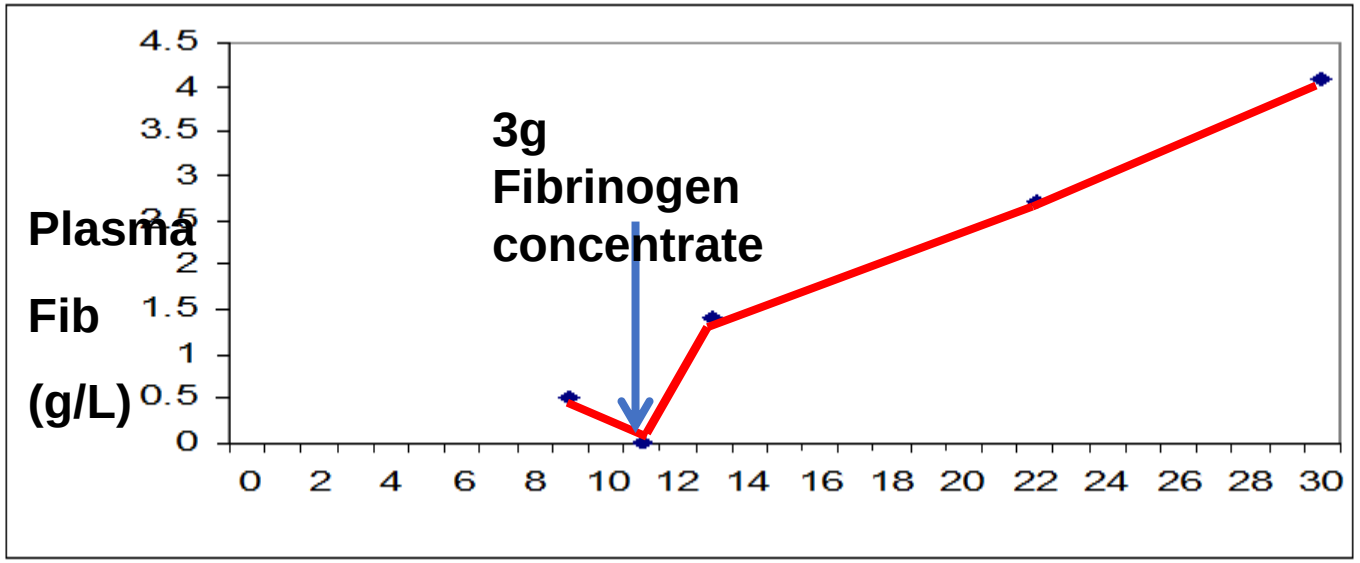
- Tone
- Trauma
- Tissue
- ~~Thrombin~~
  - Low fibrinogen
  - Increased fibrinolysis

Fibrinogen as rescue therapy

The use of fibrinogen concentrate to correct hypofibrinogenaemia rapidly during obstetric haemorrhage

S.F. Bell, R. Rayment,* P.W. Collins* R.E. Collis

International Journal of Obstetric Anesthesia (2010) 19, 218–234

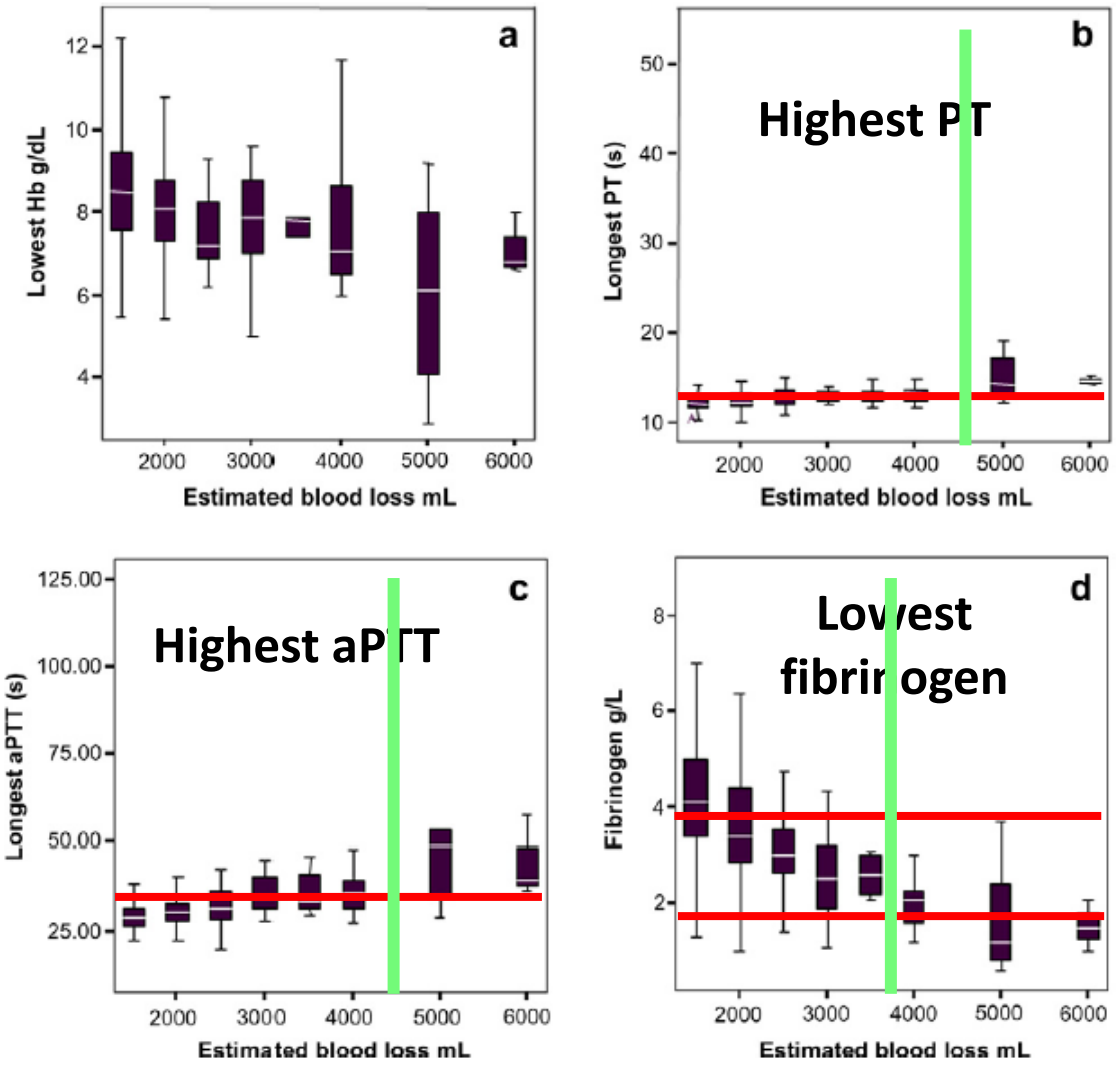


Standard haemostatic tests following major obstetric haemorrhage

International Journal of Obstetric Anesthesia (2011) **20**, 135–141

L. de Lloyd,[a] R. Bovington,[b] A. Kaye,[c] R.E. Collis,[a] R. Rayment,[b] J. Sanders,[c] A. Rees, P.W. Collins[b]

Normal range



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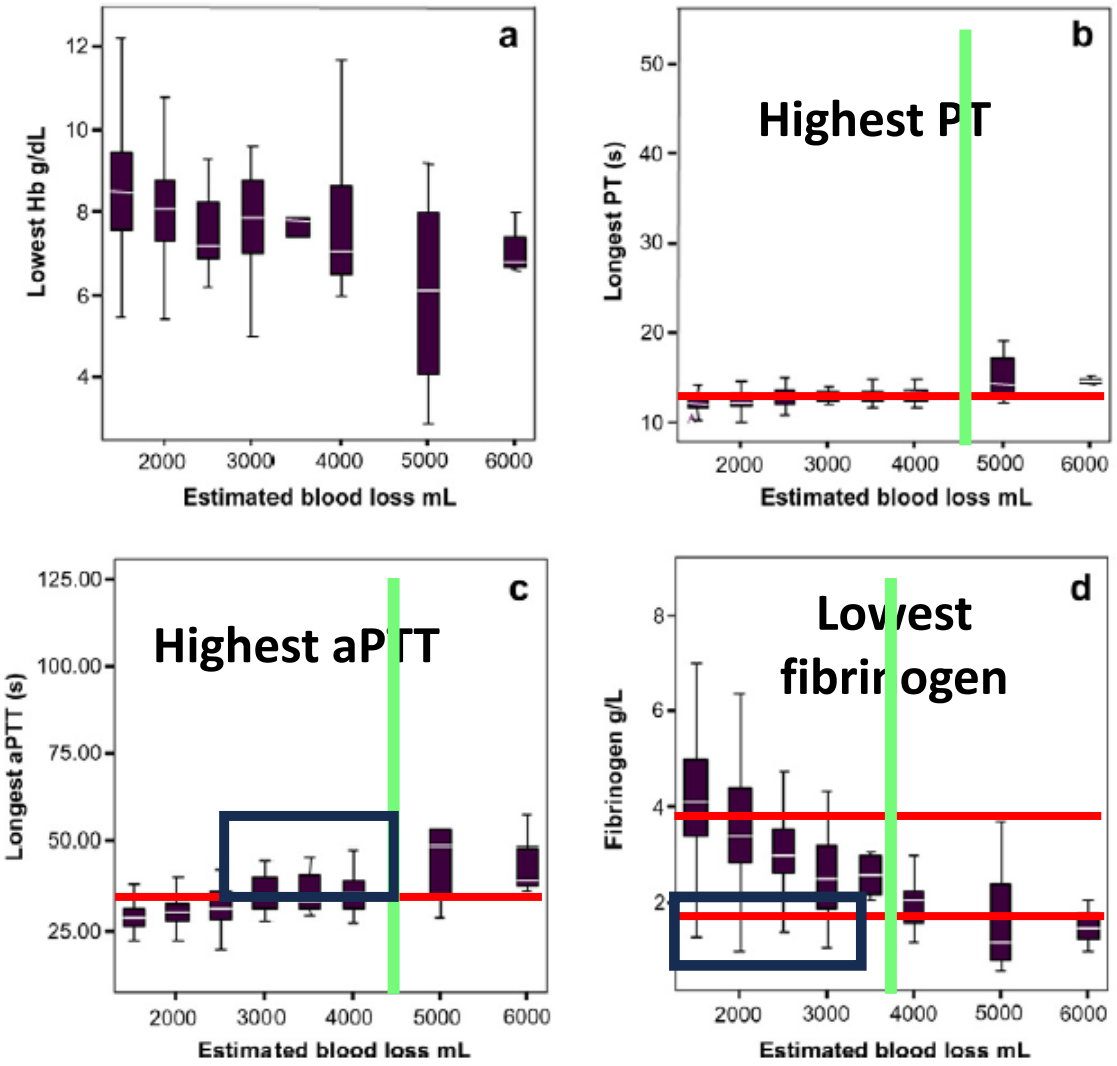


Obstetric coagulopathy can rapidly lead to massive and on-going PPH

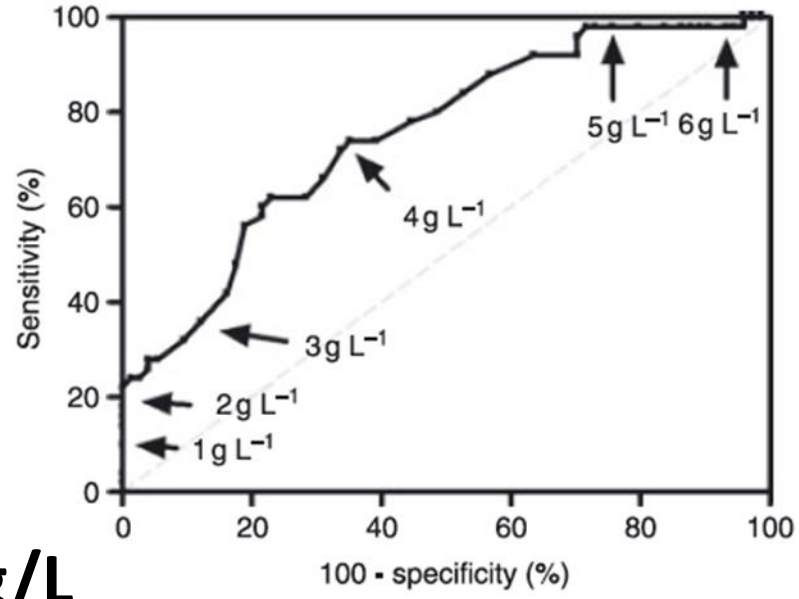
The decrease of fibrinogen is an early predictor of the severity of postpartum hemorrhage

B. CHARBIT,*† L. MANDELBROT,‡ E. SAMAIN,§ G. BARON,¶ B. HADDAOUI,‡‡‡ H. KEITA,‡¶
O. SIBONY,** D. MAHIEU-CAPUTO,¶ M. F. HURTAUD-ROUX,** M. G. HUISSE,¶‡‡
M. H. DENNINGER,†‡‡ and D. DE PROST‡†††‡‡ FOR THE PPH STUDY GROUP

J Thromb Haemost 2007; 5: 266–73.

EARLY fibrinogen was the only independent predictive marker

- **Fibrinogen less than 2 g/L**
  - **100% PPV for progression**
- **Fibrinogen above 4 g/L**
  - **79% NPV for progression**



8/128 had Fib<2g/L

Obstetric Bleeding Study 1: OBS1

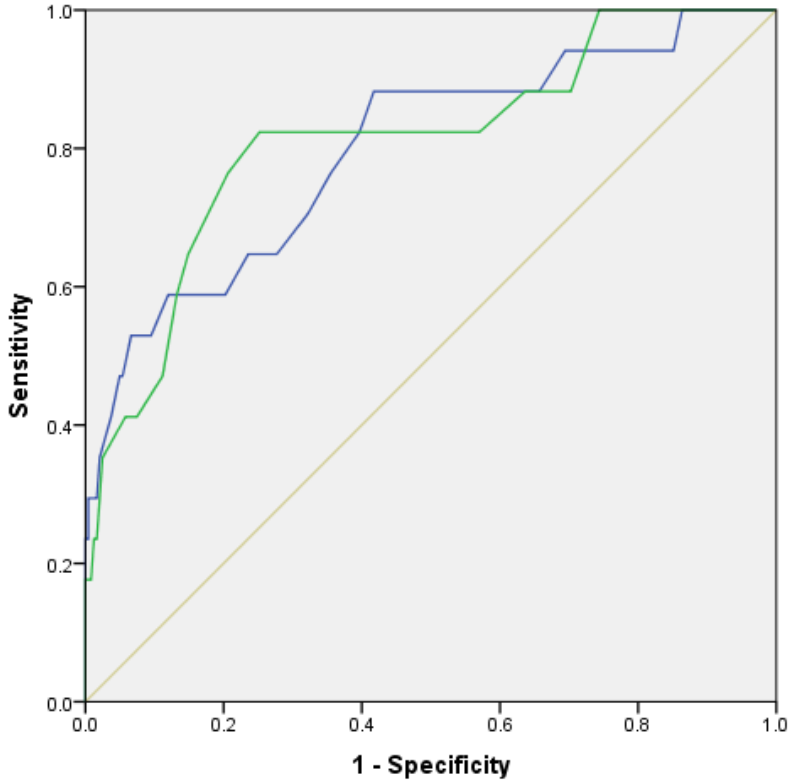
blood

Fibrin-based clot formation as an early and rapid biomarker for progression of postpartum hemorrhage: a prospective study

Peter W. Collins,[1,2] Graeme Lilley,[3] Daniel Bruynseels,[3] David Burkett-St. Laurent,[3] Rebecca Cannings-John,[4] Elizabeth Precious,[1] Vincent Hamlyn,[3] Julia Sanders,[4,5] Raza Alikhan,[1] Rachel Rayment,[1] Alexandra Rees,[5] Abigail Kaye,[5] Judith E. Hall,[2,3] Shantini Paranjothy,[6] Andrew Weeks,[7] and Rachel E. Collis[3] **Blood 124:1727-1736, 2014**

- **6187 deliveries in the 12 months**
- **346 consecutive women experiencing PPH recruited**
  - **1000-1500 mL**
    - **No exclusions**
- **Women recruited at pre-defined time <u>early</u> during PPH**
  - **Before transfusion or interventions**
- **Clauss fibrinogen and Fibtem measured**
  - **Outcomes recorded**

Fibtem and fibrinogen predict progression of PPH



Progression to 4 U RBC transfusion

-- **Fibtem** **0.81 (0.69–0.93)**
-- **Fibrinogen** **0.80 (0.68–0.92)**

BJA

British Journal of Anaesthesia, 119 (3): 411–21 (2017)

doi: 10.1093/bja/aex181
Advance Access Publication Date: 19 July 2017
Obstetrics

OBSTETRICS

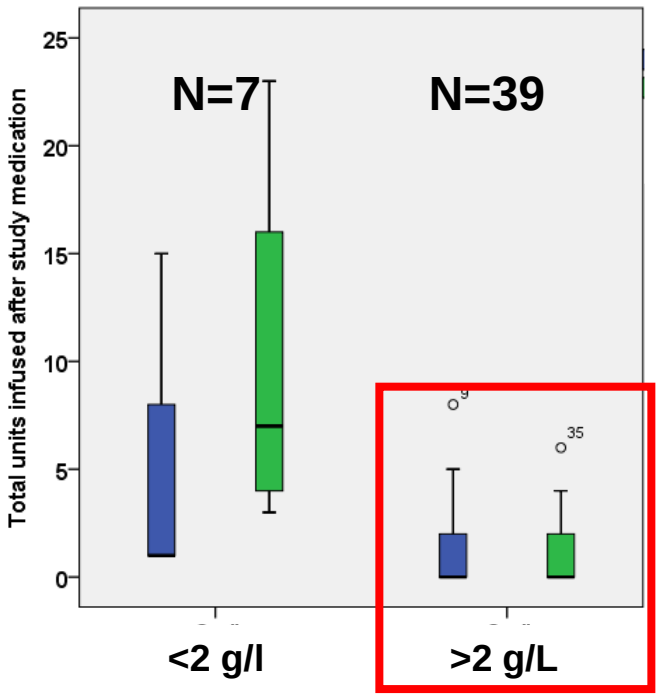
Viscoelastometric-guided early fibrinogen concentrate replacement during postpartum haemorrhage: OBS2, a double-blind randomized controlled trial

- **633 included in the study**
- **55 with FIBTEM<15mm randomised to fibrinogen concentrate**
- **7 had a fibrinogen <2g/L**

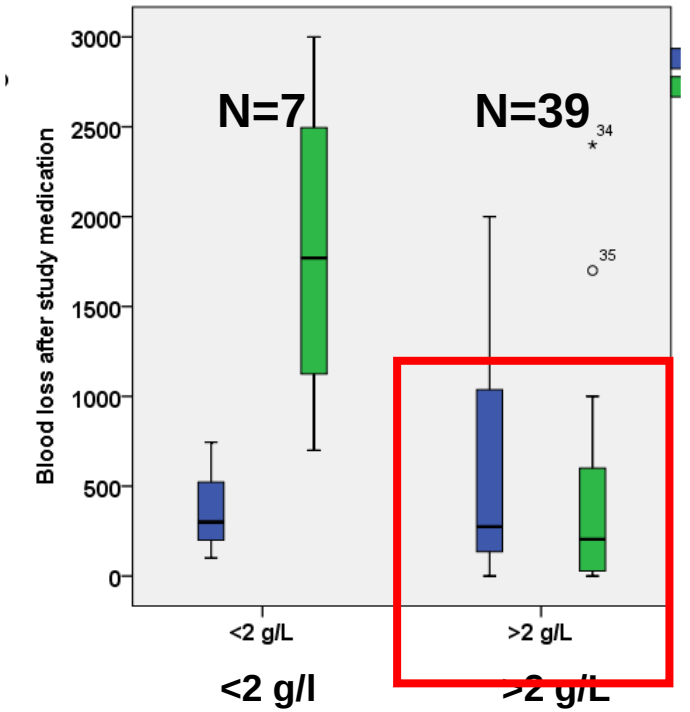
OBS2
Obstetric Bleeding Study 2

OBS2
Obstetric Bleeding Study 2

Total allogeneic units transfused after study medication



Measured blood loss after study medication

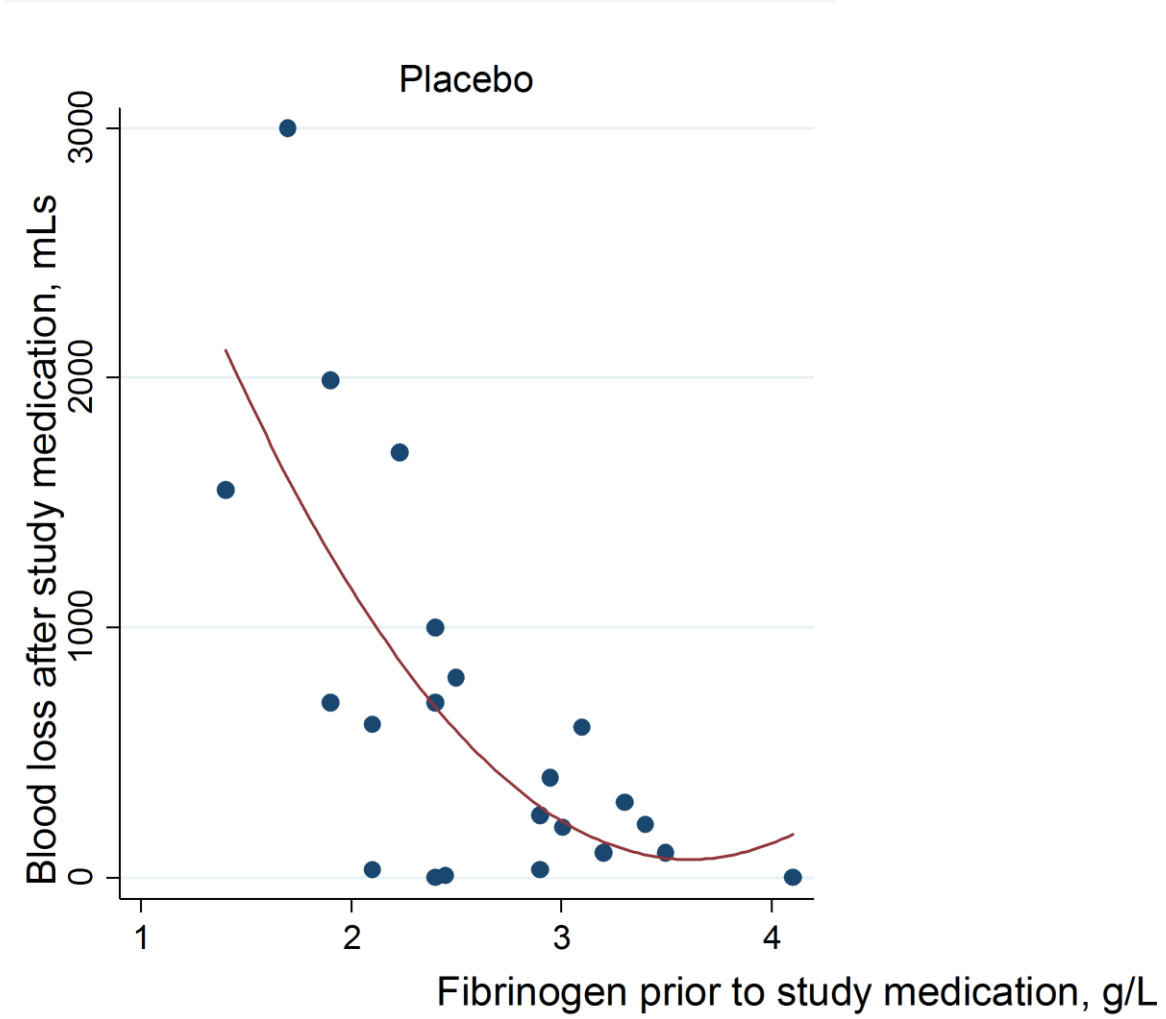


Fibrinogen concentrate group

Placebo group

BJA 119:411-421 2018

Effect of fibrinogen level on blood loss after study medication



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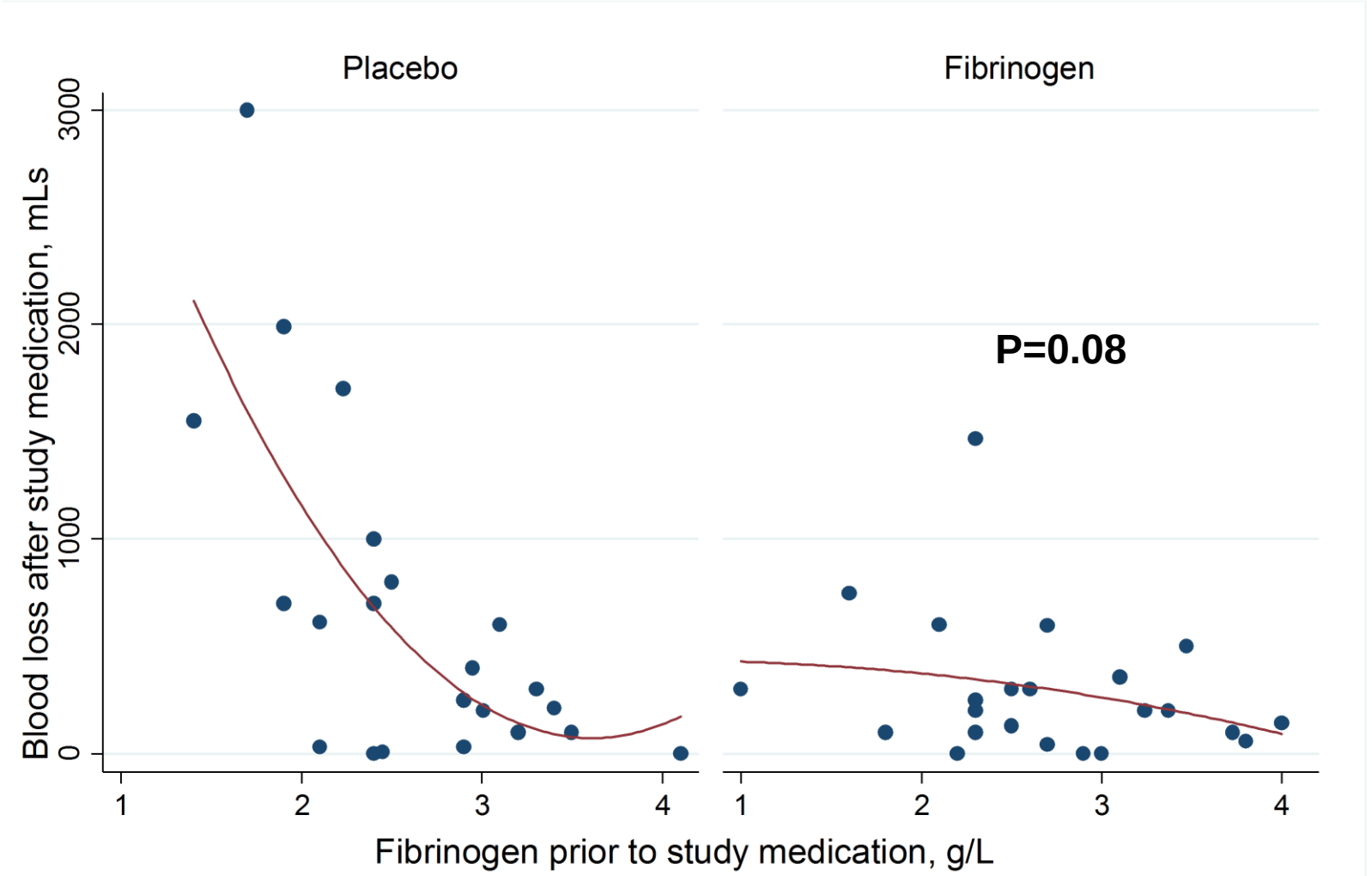
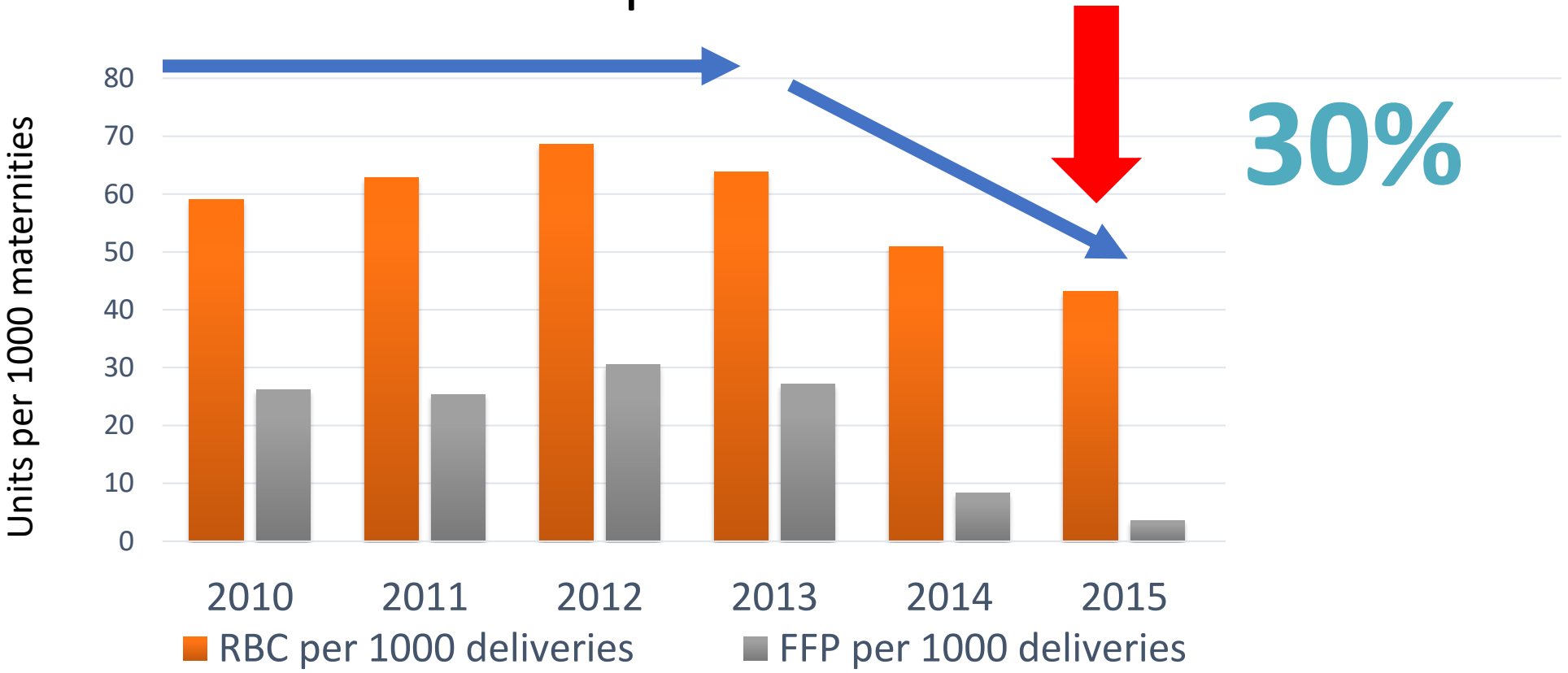


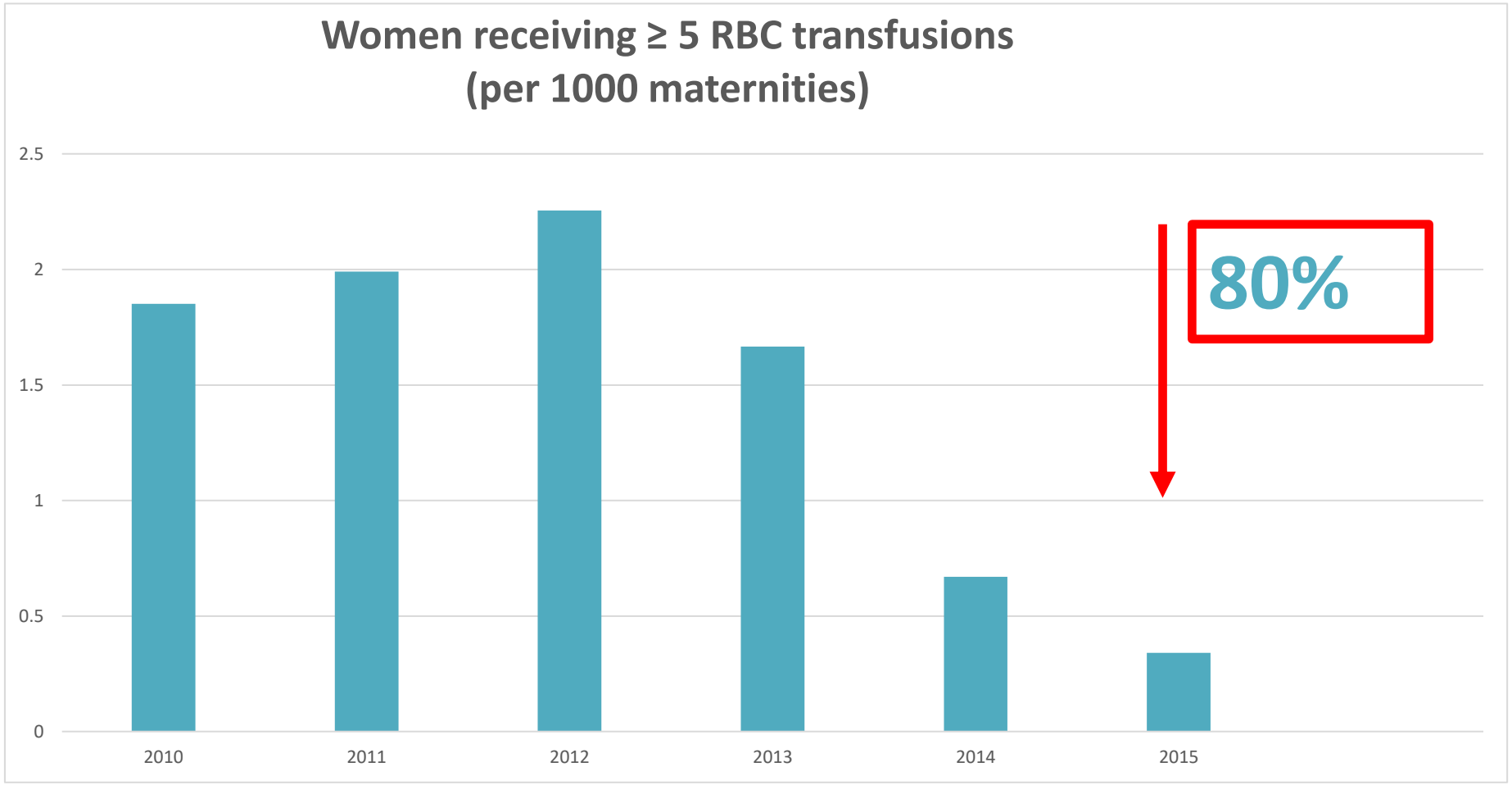
PPH outcome improvements in Cardiff?



Review > Int J Obstet Anesth. 2019 Feb;37:106-117. doi: 10.1016/j.ijoa.2018.08.008. Epub 2018 Aug 25.

Management of postpartum haemorrhage: from research into practice, a narrative review of the literature and the Cardiff experience

P W Collins [1], S F Bell [2], L de Lloyd [2], R E Collis [3]


Women receiving ≥ 5 RBC transfusions
(per 1000 maternities)
2.5
2
1.5
1
0.5
0
2010
2011
2012
2013
2014
2015
80%

What Changed?

Running a prospective interventional trial: VHA guided fibrinogen conc V placebo (OBS 2 study)
To improve study recruitment:

- More systematic risk assessment
- Quantitative measurement of blood loss to define study entry criteria
- Obstetrician and anaesthetist attended the woman at 1000 mL (if not already present)
- Introduction of point of care viscoelastometric coagulation tests

Worked harder and harder to recruit fewer and fewer patients

Human factors

Know the coagulation status of patient

Change Behaviour

Normal

- Bleeding has another cause
- Surgical focus on physical bleed (early return to theatre)
- Anaesthetic focus on appropriate monitoring and resuscitation

Abnormal

- Coagulopathy is contributing to the bleeding
- Rapid identification and early ordering of products
- Focused ordering of products (Plasma, platelets, fibrinogen concentrate)

CMQCC

California Maternal Quality Care Collaborative

Quality Improvement methodology

- Education
- Measurement of blood loss
- Robust escalation policy based on measured blood loss
- Early assess to blood products
- Feed back and local learning from events

Results -25.9%/1000 deliveries red blood cell use: P<0.01

OBSCYMRU

Obstetric Bleeding Strategy for Wales

National quality improvement initiative 2017-2019

Multidisciplinary collaboration

Midwives, obstetricians, anaesthetists, haematologists

Included all 12 maternity units in Wales

60000 births described

Action

Introduced package of care for postpartum haemorrhage

Using quality improvement methodology

Bell et al BMJ Open Quality 9:e000854, 2020

OBSCYMRU
Obstetric Bleeding Strategy for Wales

Care package

Universal risk assessment

Measure blood loss from delivery in all cases

Real time, quantitative accurate

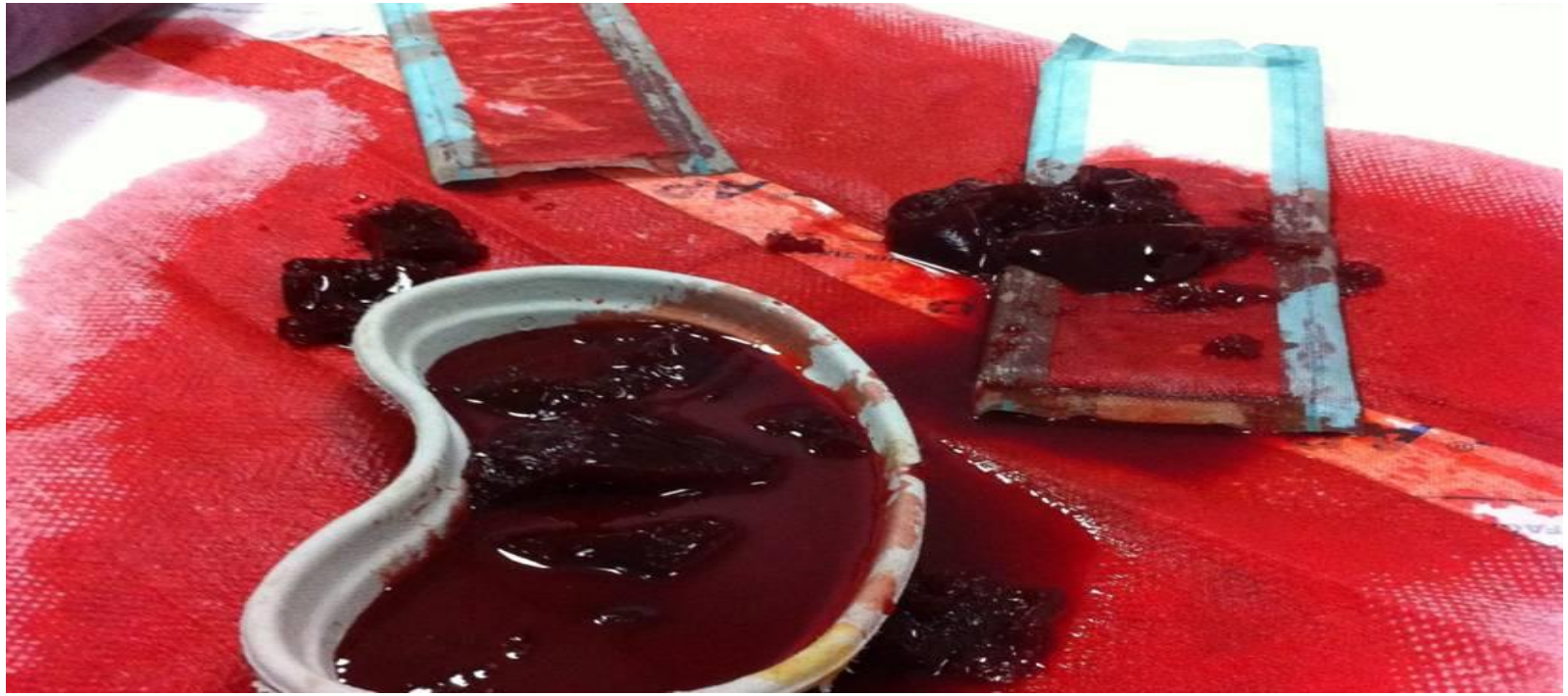
Multidisciplinary escalation
- 500ml Senior Midwife
- 1000ml Senior Midwife, Obstetrician and Anaesthetist MUST attend the mother
- 1500ml Consultants informed

1000ml Viscoelastic assays

Identify and correct low fibrinogen

Bell et al BMJ Open Quality 9:e000854, 2020

Measuring blood loss



International Journal of Obstetric Anesthesia (2015) 24, 8–14
0959-289X/$ - see front matter
http://dx.doi.org/10.1016/j.ijoa.2014.07.009

ORIGINAL ARTICLE

ELSEVIER
www.obstetanesthesia.com

Measurement of blood loss during postpartum haemorrhage

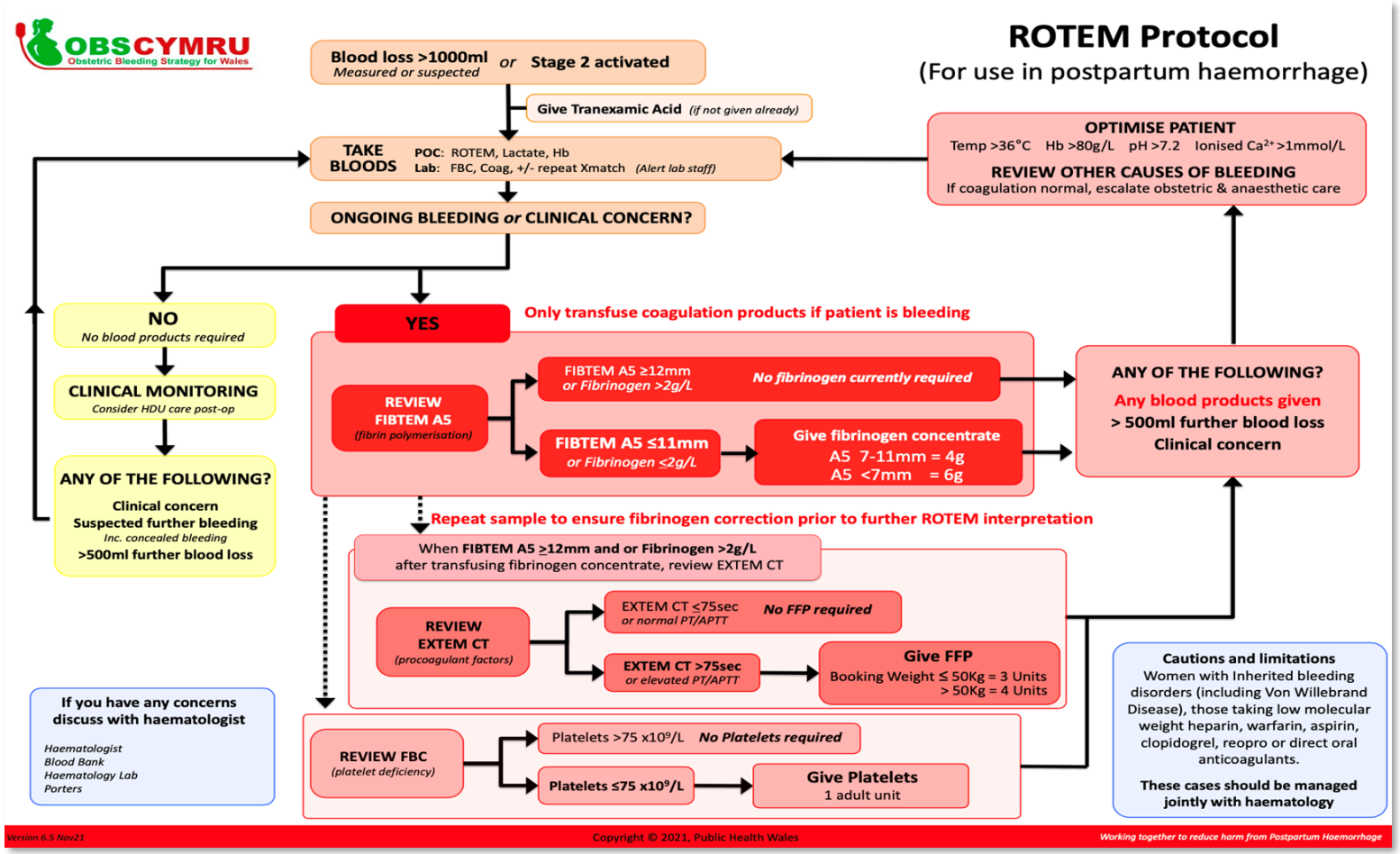
G. Lilley,[a] D. Burkett-st-Laurent,[a] E. Precious,[b] D. Bruynseels,[a] A. Kaye,[c] J. Sanders,[c,d] R. Alikhan,[b] P.W. Collins,[b,e] J.E. Hall,[a,e] R.E. Collis[a]
[a]*Department of Anaesthetics and Pain Control,* [b]*Department of Haematology,* [c]*Department of Obstetrics, Cardiff and Vale University Health Board, UK,* [d]*Institute of Translation, Innovation, Methodology and Engagement, South East Wales Trials Unit,* [e]*Institute of Infection and Immunity, Critical Illness Research Group, Cardiff University School of Medicine, UK*

Context of a validated VHA algorithm

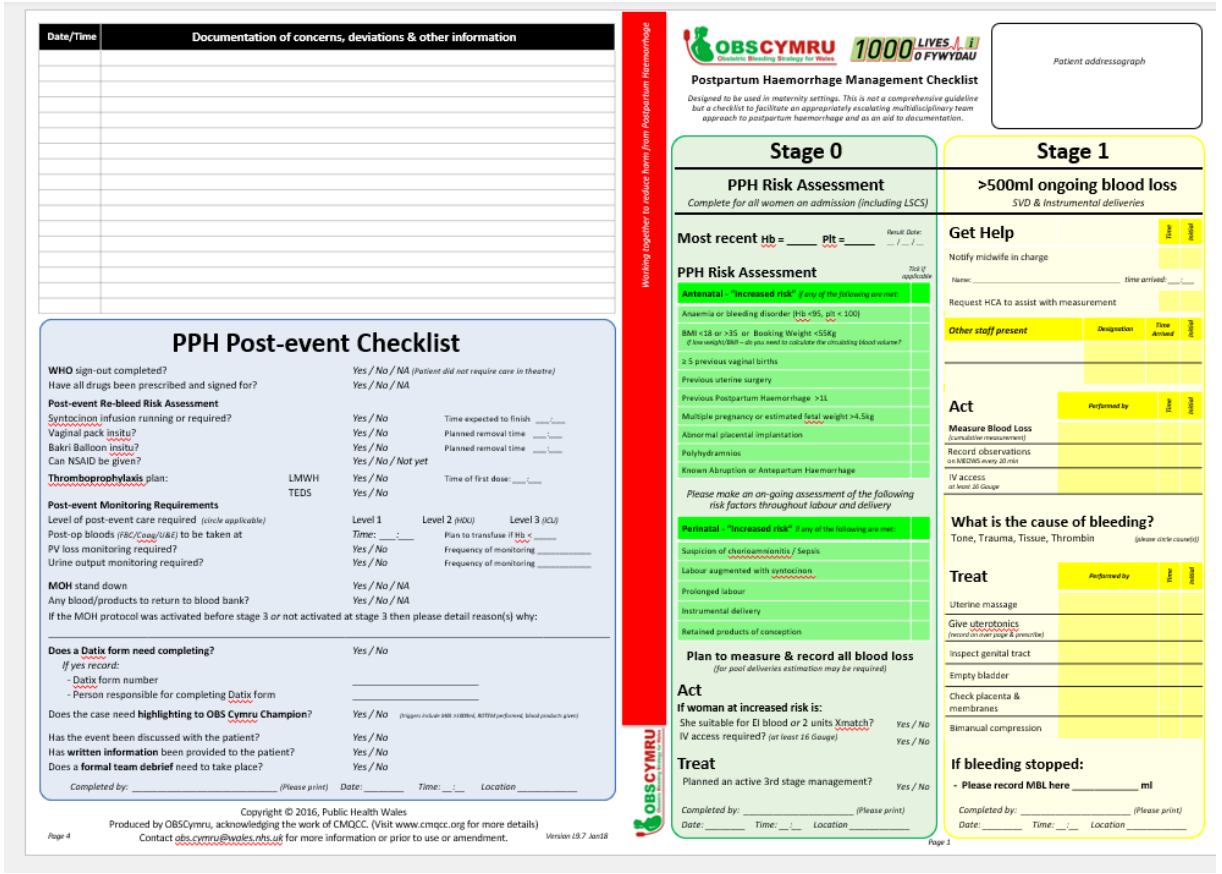
Complete buy in from clinical staff

Training in performing tests

Training in interpreting tests



Structured PPH proforma



Date/Time	Documentation of concerns, deviations & other information

PPH Post-event Checklist

WHO sign-out completed? — *Yes / No / NA (Patient did not require care in theatre)*
Have all drugs been prescribed and signed for? — *Yes / No / NA*

Post-event Re-bleed Risk Assessment
Syntocinon infusion running or required? — *Yes / No* — Time expected to finish ___:___
Vaginal pack insitu? — *Yes / No* — Planned removal time ___:___
Bakri Balloon insitu? — *Yes / No* — Planned removal time ___:___
Can NSAID be given? — *Yes / No / Not yet*
Thromboprophylaxis plan: LMWH / TEDS — *Yes / No* — Time of first dose: ___:___

Post-event Monitoring Requirements
Level of post-event care required *(circle applicable)* — Level 1 — Level 2 *(HDU)* — Level 3 *(ICU)*
Post-op bloods *(FBC/Coag/U&E)* to be taken at — *Time: ___:___* — Plan to transfuse if Hb < ____
PV loss monitoring required? — *Yes / No* — Frequency of monitoring _____
Urine output monitoring required? — *Yes / No* — Frequency of monitoring _____

MOH stand down
Any blood/products to return to blood bank? — *Yes / No / NA*
If the MOH protocol was activated before stage 3 *or* not activated at stage 3 then please detail reason(s) why:

Does a Datix form need completing? — *Yes / No*
If yes record:
- Datix form number _____
- Person responsible for completing Datix form _____

Does the case need **highlighting to OBS Cymru Champion**? — *Yes / No (triggers include BBE >1000ml, ROTEM performed, blood products given)*
Has the event been discussed with the patient? — *Yes / No*
Has **written information** been provided to the patient? — *Yes / No*
Does a **formal team debrief** need to take place? — *Yes / No*

Completed by: _____ *(Please print)* *Date:* _____ *Time:* __:__ *Location* _____

Version 19.7 Jan18

Working together to reduce harm from Postpartum Haemorrhage

OBSCYMRU Obstetric Bleeding Strategy for Wales — 1000 LIVES A FYWYDAU

Postpartum Haemorrhage Management Checklist

Designed to be used in maternity settings. This is not a comprehensive guideline but a checklist to facilitate an appropriately escalating multidisciplinary team approach to postpartum haemorrhage and as an aid to documentation.

Patient addressograph

Stage 0

PPH Risk Assessment
Complete for all women on admission (including LSCS)

Most recent Hb = ____ **Plt =** ____ *Result Date: __/__/__*

PPH Risk Assessment *Tick if applicable*

Antenatal - "Increased risk" *if any of the following are met:*
- Anaemia or bleeding disorder (Hb <95, plt < 100)
- BMI <18 or >35 or Booking Weight <55Kg *(if low weight/BMI – do you need to calculate the circulating blood volume?)*
- ≥ 5 previous vaginal births
- Previous uterine surgery
- Previous Postpartum Haemorrhage >1L
- Multiple pregnancy or estimated fetal weight >4.5kg
- Abnormal placental implantation
- Polyhydramnios
- Known Abruption or Antepartum Haemorrhage

Please make an on-going assessment of the following risk factors throughout labour and delivery

Perinatal - "Increased risk" *if any of the following are met:*
- Suspicion of chorioamnionitis / Sepsis
- Labour augmented with syntocinon
- Prolonged labour
- Instrumental delivery
- Retained products of conception

Plan to measure & record all blood loss
(for pool deliveries estimation may be required)

Act
If woman at increased risk is:
She suitable for EI blood or 2 units Xmatch? — *Yes / No*
IV access required? *(at least 16 Gauge)* — *Yes / No*

Treat
Planned an active 3rd stage management? — *Yes / No*

Completed by: _____ *(Please print)*
Date: _____ *Time:* __:__ *Location* _____

Stage 1

>500ml ongoing blood loss
SVD & Instrumental deliveries

Get Help
Notify midwife in charge — *Name:* _____ *time arrived:* __:__
Request HCA to assist with measurement

Other staff present	Designation	Time Arrived	Initial

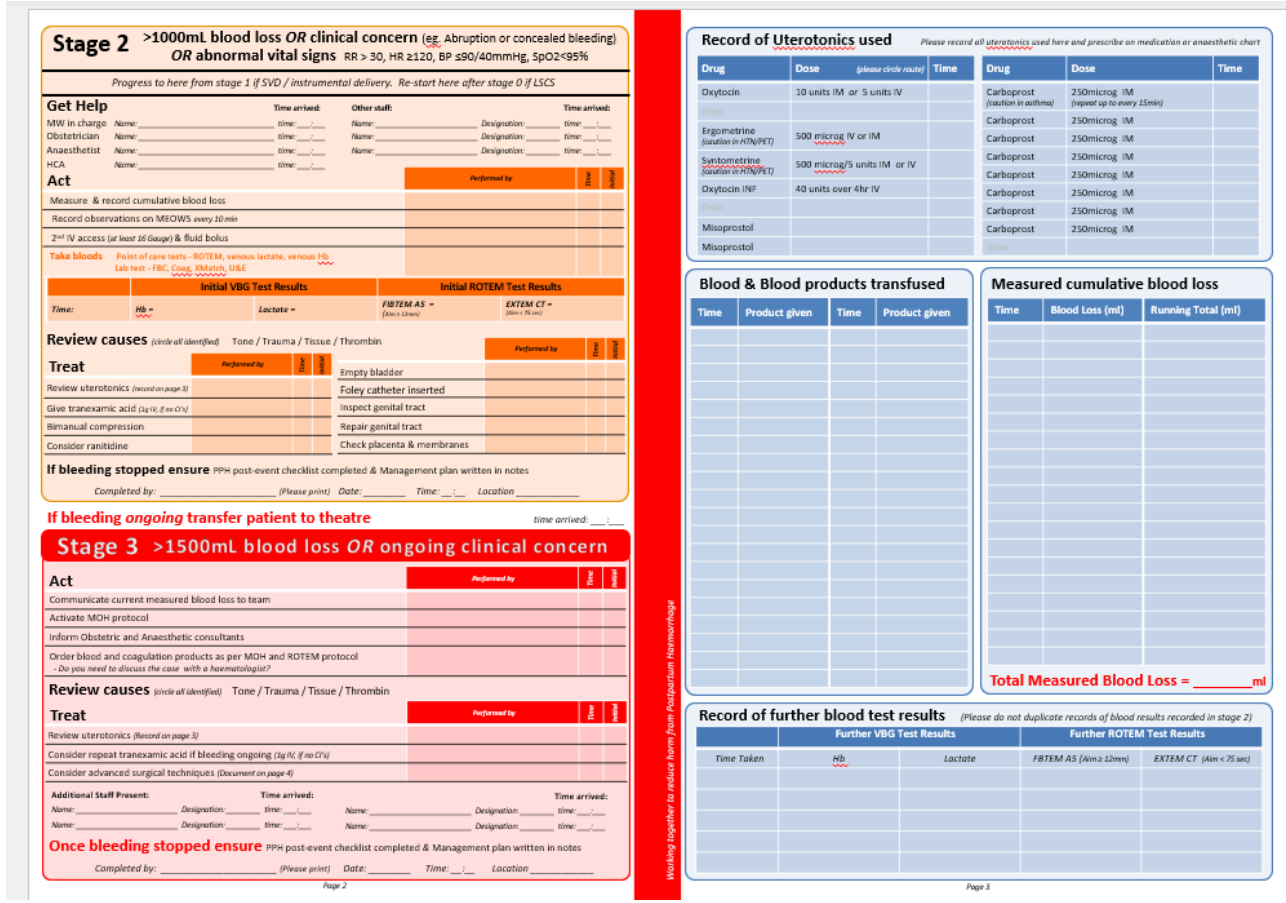
Act
	Performed by	Time	Initial
Measure Blood Loss *(cumulative measurement)*			
Record observations *on MEOWS every 30 min*			
IV access *at least 16 Gauge*			

What is the cause of bleeding?
Tone, Trauma, Tissue, Thrombin *(please circle cause(s))*

Treat
	Performed by	Time	Initial
Uterine massage			
Give uterotonics *(record on over page & prescribe)*			
Inspect genital tract			
Empty bladder			
Check placenta & membranes			
Bimanual compression			

If bleeding stopped:
- **Please record MBL here** _____ **ml**

Completed by: _____ *(Please print)*
Date: _____ *Time:* __:__ *Location* _____



Stage 2 — >1000mL blood loss *OR* clinical concern (eg. Abruption or concealed bleeding) *OR* abnormal vital signs RR > 30, HR ≥120, BP ≤90/40mmHg, SpO2<95%

Progress to here from stage 1 if SVD / instrumental delivery. Re-start here after stage 0 if LSCS

Get Help
	Time arrived:	Other staff:	Time arrived:
MW in charge	Name: ___ time: __:__	Name: ___ Designation: ___ time: __:__	
Obstetrician	Name: ___ time: __:__	Name: ___ Designation: ___ time: __:__	
Anaesthetist	Name: ___ time: __:__	Name: ___ Designation: ___ time: __:__	
HCA	Name: ___ time: __:__		

Act
	Performed by	Time	Initial
Measure & record cumulative blood loss			
Record observations on MEOWS *every 10 min*			
2nd IV access *(at least 16 Gauge)* & fluid bolus			
Take bloods — Point of care tests - ROTEM, venous lactate, venous Hb; Lab test - FBC, Coag, XMatch, U&E			

Initial VBG Test Results		Initial ROTEM Test Results	
Time:	*Hb =* / *Lactate =*	*FIBTEM A5 =* *(Aim ≥ 12mm)*	*EXTEM CT =* *(Aim < 76 sec)*

Review causes *(circle all identified)* Tone / Trauma / Tissue / Thrombin

Treat
	Performed by	Time	Initial
Review uterotonics *(record on page 3)*			
Give tranexamic acid *(1g IV, if no CI's)*			
Bimanual compression			
Consider raniditide			
Empty bladder			
Foley catheter inserted			
Inspect genital tract			
Repair genital tract			
Check placenta & membranes			

If bleeding stopped ensure PPH post-event checklist completed & Management plan written in notes

Completed by: _____ *(Please print)* *Date:* _____ *Time:* __:__ *Location* _____

If bleeding *ongoing* transfer patient to theatre *time arrived:* __:__

Stage 3 >1500mL blood loss *OR* ongoing clinical concern

Act
	Performed by	Time	Initial
Communicate current measured blood loss to team			
Activate MOH protocol			
Inform Obstetric and Anaesthetic consultants			
Order blood and coagulation products as per MOH and ROTEM protocol - *Do you need to discuss the case with a haematologist?*			

Review causes *(circle all identified)* Tone / Trauma / Tissue / Thrombin

Treat
	Performed by	Time	Initial
Review uterotonics *(Record on page 3)*			
Consider repeat tranexamic acid if bleeding ongoing *(1g IV, if no CI's)*			
Consider advanced surgical techniques *(Document on page 4)*			

Additional Staff Present:	Time arrived:	Time arrived:
Name: ___ Designation: ___	time: __:__ Name: ___	Designation: ___ time: __:__
Name: ___ Designation: ___	time: __:__ Name: ___	Designation: ___ time: __:__

Once bleeding stopped ensure PPH post-event checklist completed & Management plan written in notes

Completed by: _____ *(Please print)* *Date:* _____ *Time:* __:__ *Location* _____

Working together to reduce harm from Postpartum Haemorrhage

Record of Uterotonics used
Please record all uterotonics used here and prescribe on medication or anaesthetic chart

Drug	Dose *(please circle route)*	Time	Drug	Dose	Time
Oxytocin	10 units IM *or* 5 units IV		Carboprost *(caution in asthma)*	250microg IM *(repeat up to every 15min)*	
Other			Carboprost	250microg IM	
Ergometrine *(caution in HTN/PET)*	500 microg IV or IM		Carboprost	250microg IM	
Syntometrine *(caution in HTN/PET)*	500 microg/5 units IM or IV		Carboprost	250microg IM	
Oxytocin INF	40 units over 4hr IV		Carboprost	250microg IM	
Other			Carboprost	250microg IM	
Misoprostol			Carboprost	250microg IM	
Misoprostol			Other		

Blood & Blood products transfused

Time	Product given	Time	Product given

Measured cumulative blood loss

Time	Blood Loss (ml)	Running Total (ml)

Total Measured Blood Loss = _____ ml

Record of further blood test results
(Please do not duplicate records of blood results recorded in stage 2)

	Further VBG Test Results		Further ROTEM Test Results	
Time Taken	*Hb*	*Lactate*	*FBTEM A5 (Aim≥ 12mm)*	*EXTEM CT (Aim < 75 sec)*

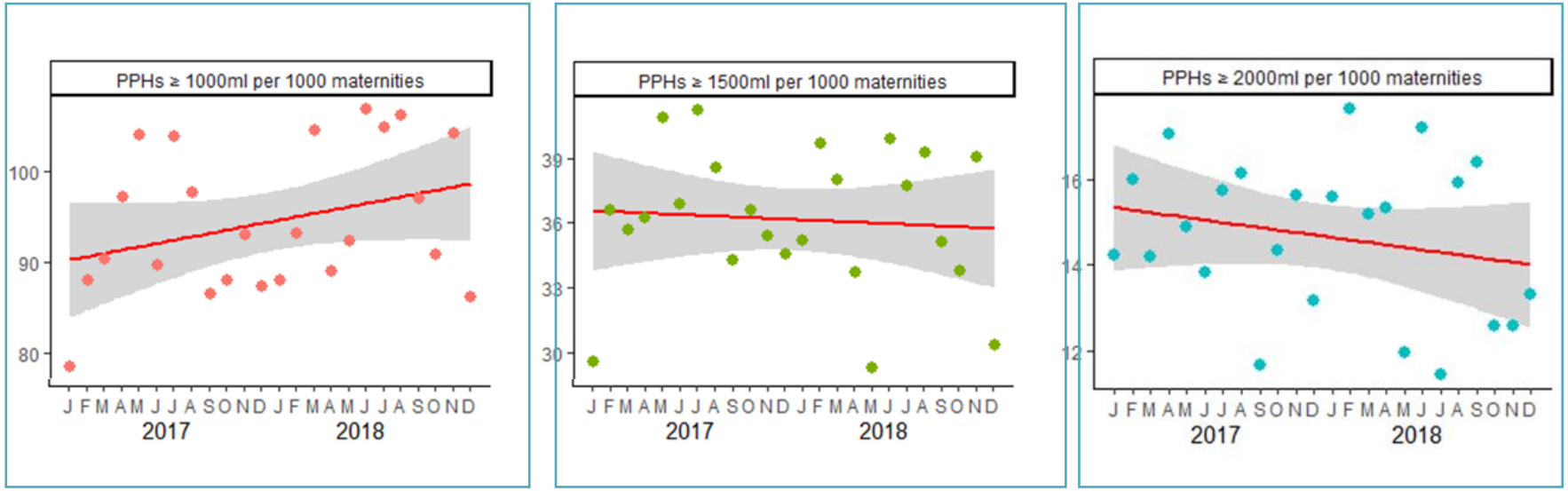
Bell *et al. BMC Pregnancy and Childbirth* (2021) 21:377
https://doi.org/10.1186/s12884-021-03853-y

BMC Pregnancy and Childbirth

RESEARCH ARTICLE Open Access

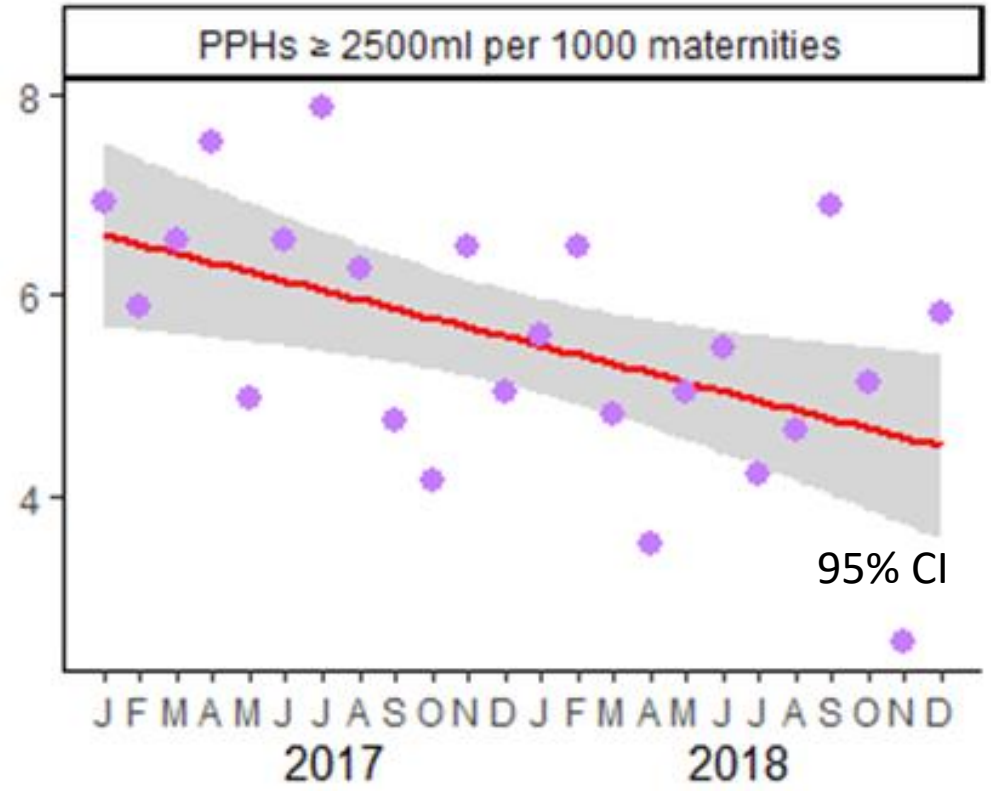
Reduction in massive postpartum haemorrhage and red blood cell transfusion during a national quality improvement project, Obstetric Bleeding Strategy for Wales, OBS Cymru: an observational study

Incidence of moderate and severe PPH



Incidence of massive PPH

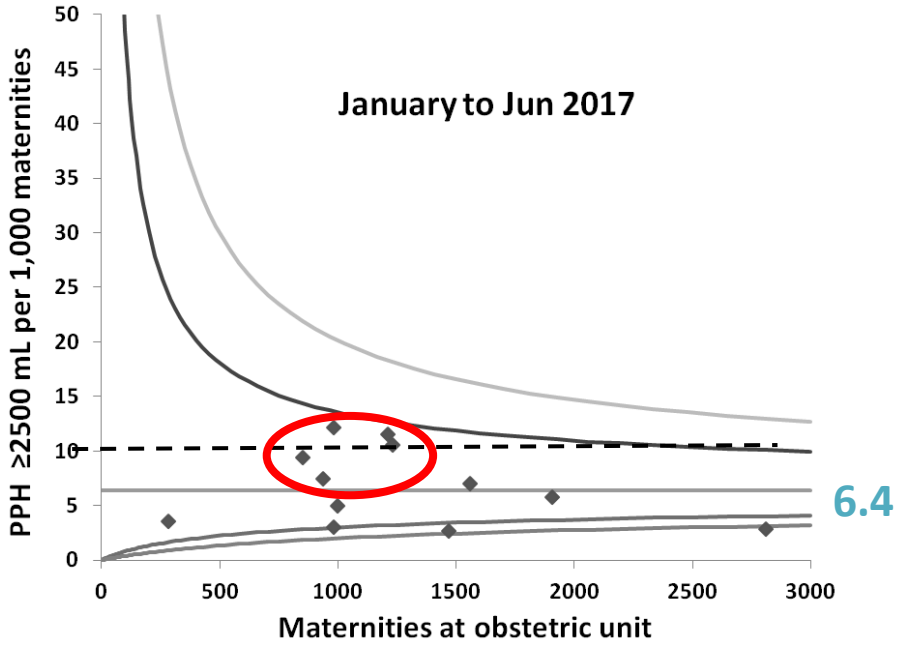
6.4/1000



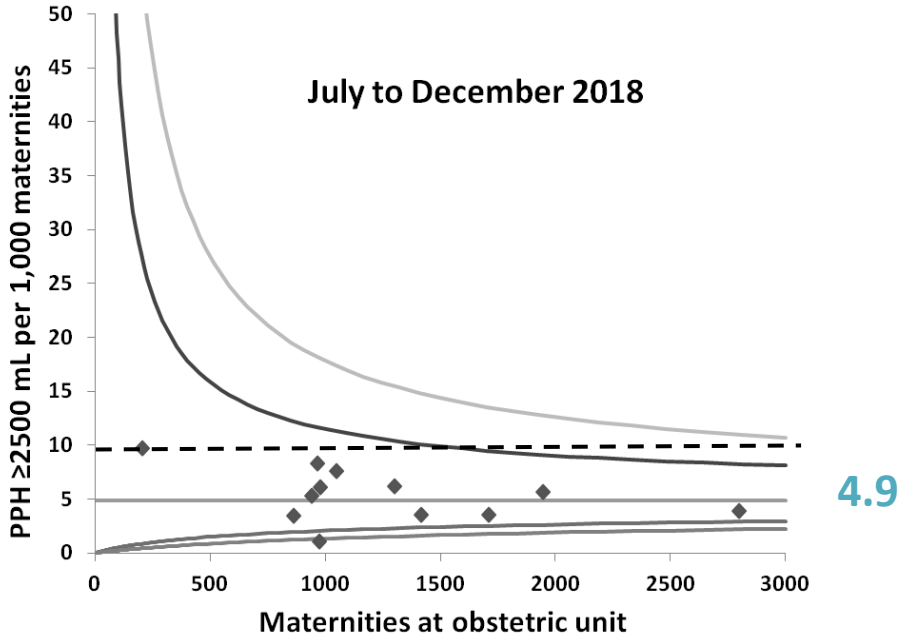
4.9/1000

Progression from 1000 mL PPH to 2500 mL
First 6 months: 97/1386 (7%)
Last 6 months: 74/1490 (5%) P=0.021

Incidence of massive PPH in units

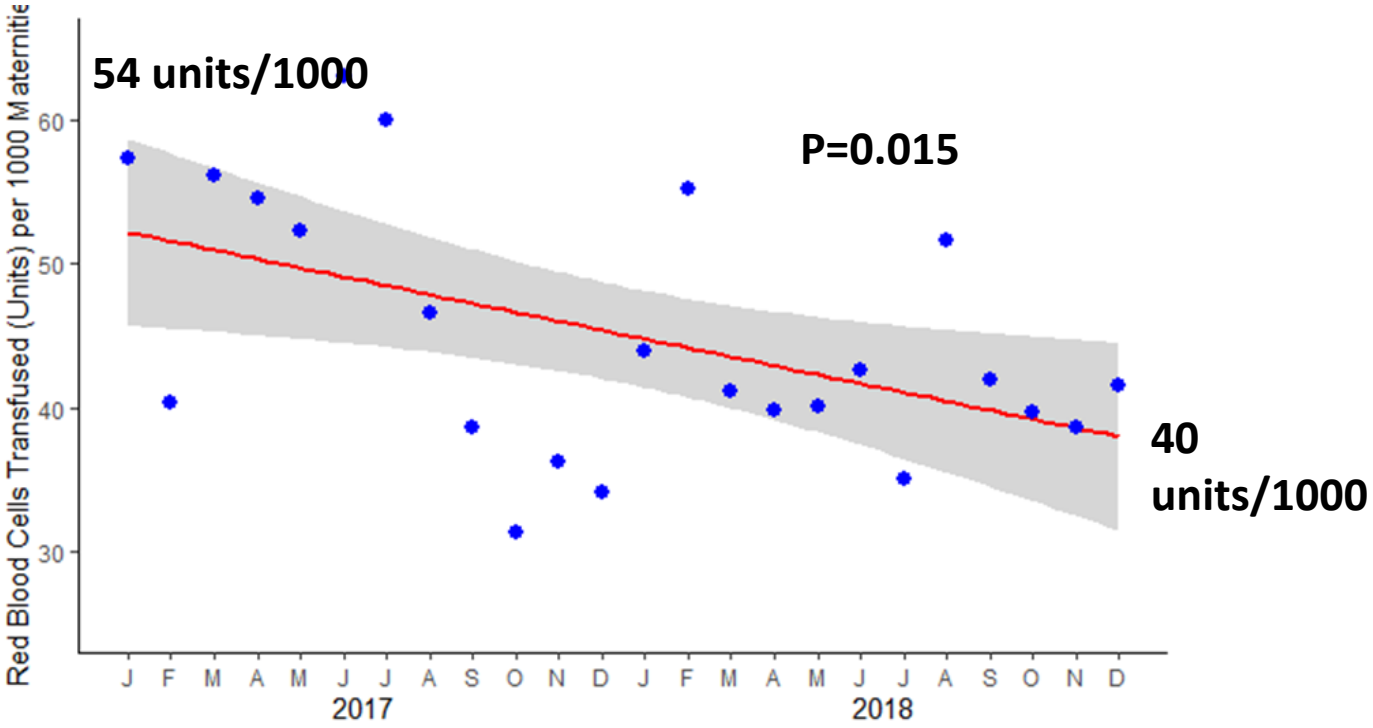


PPH ≥2500 mL >10/1000
3 of 12 units



PPH ≥2500 mL >10/1000
0 of 12 units

Total red cell transfusion for PPH



Proportion of women receiving a blood transfusion

- First 6 months: 350/15204 (2.3%)
- Last 6 months: 268/15150 (1.8%) P=0.015

Key components of reducing PPH

- Education
- Measuring blood loss
- Escalation

- Within a QI framework
- Robust risk management with institutional learning

Clinical and cost-effectiveness of a maternity quality improvement programme to reduce excess bleeding and need for transfusion after childbirth: the Obstetric Bleeding Study UK (OBS UK)

Primary objective

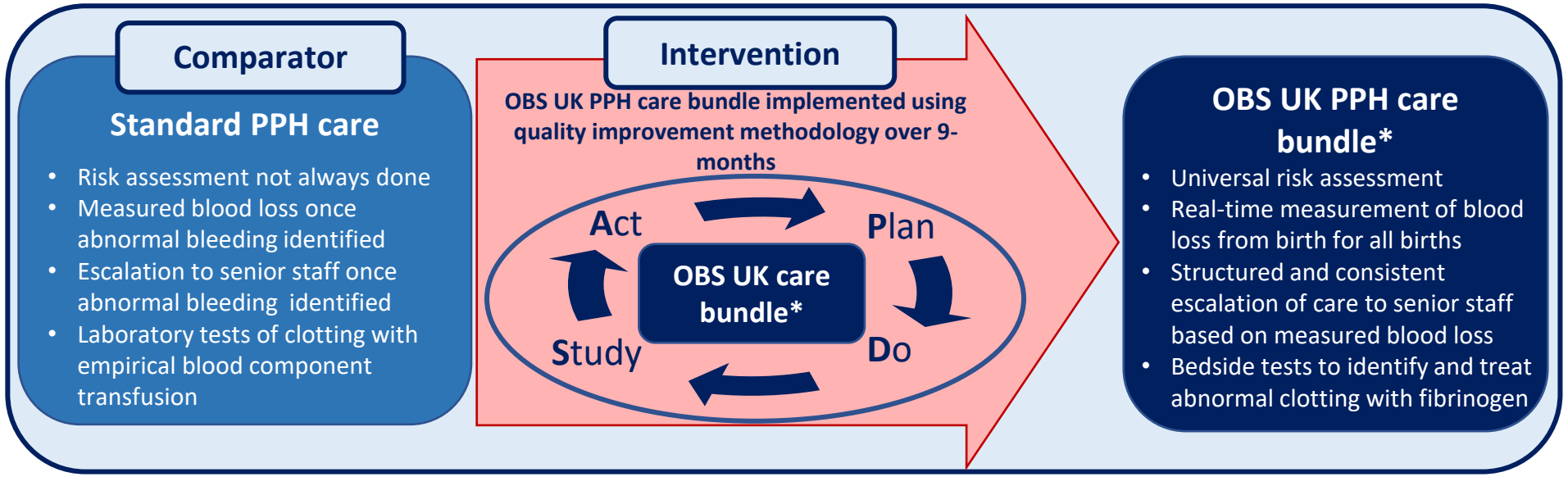
Test the effectiveness of the Obstetric Bleeding Strategy (OBS) intervention vs standard care on clinical and psychological PPH outcomes after childbirth and to evaluate the cost-effectiveness

NIHR | National Institute for Health Research

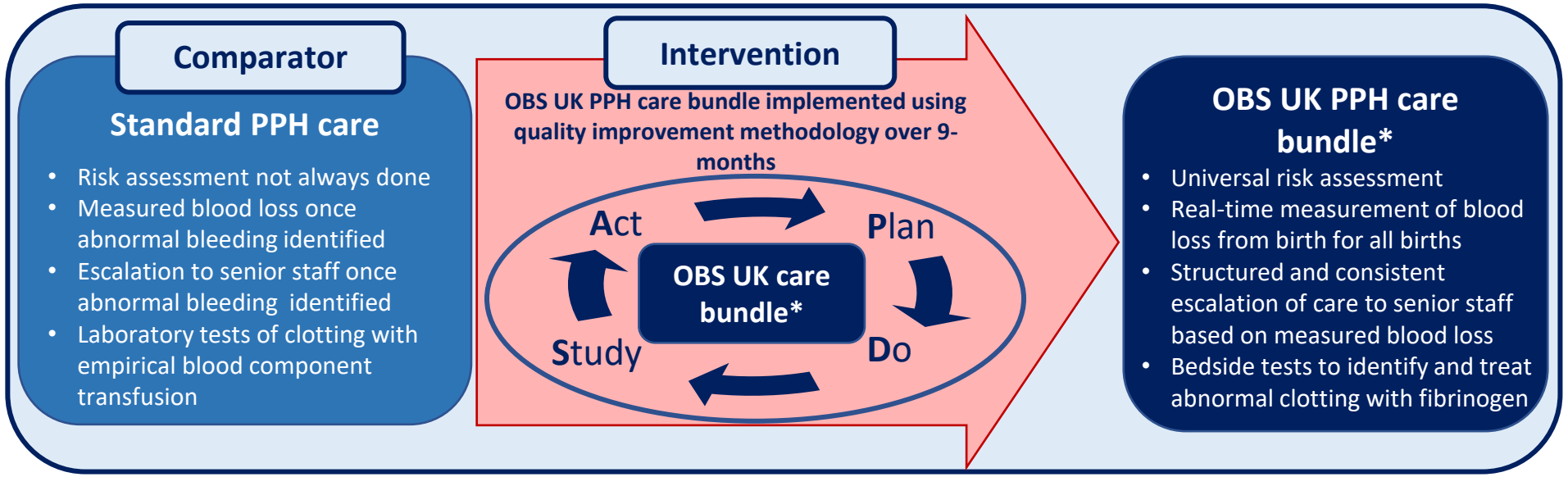
Outcome measures

Primary outcome: Proportion of women who receive a red blood cell transfusion for PPH

Study design

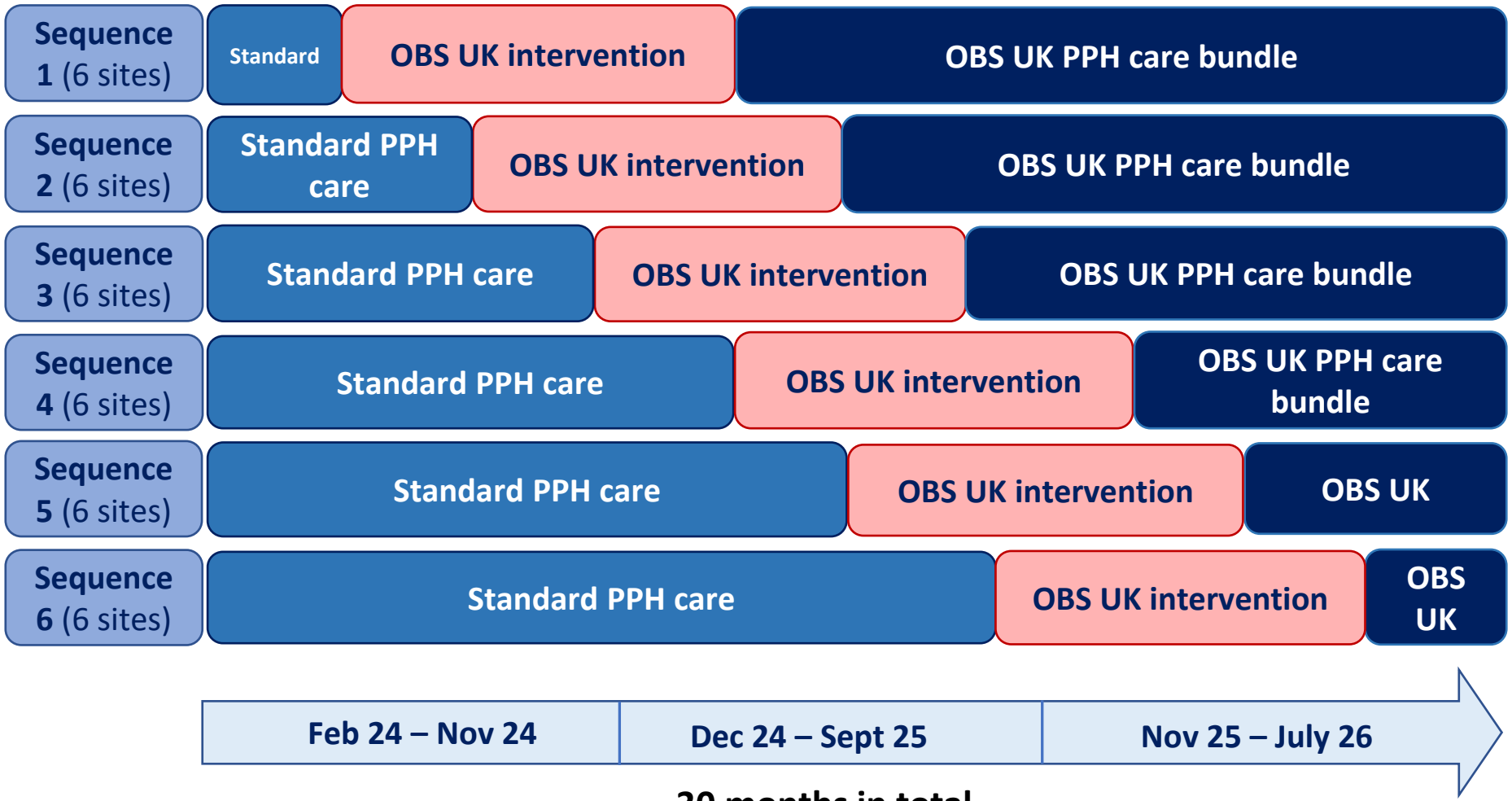


Study design

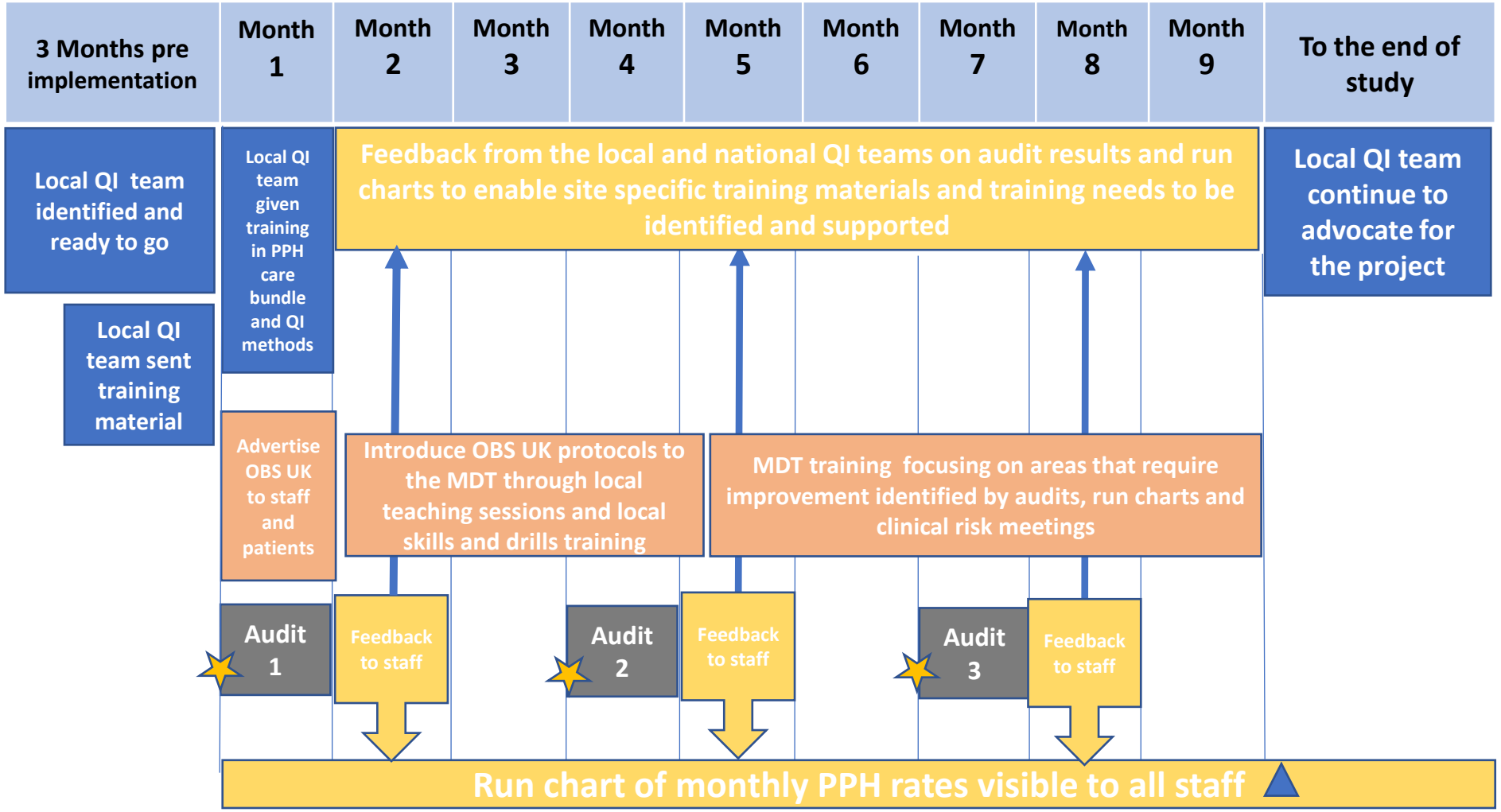


- Maternity unit intervention
  - 190,000 women giving birth in 36 NHS maternity units
- Individual consent not required

Study design



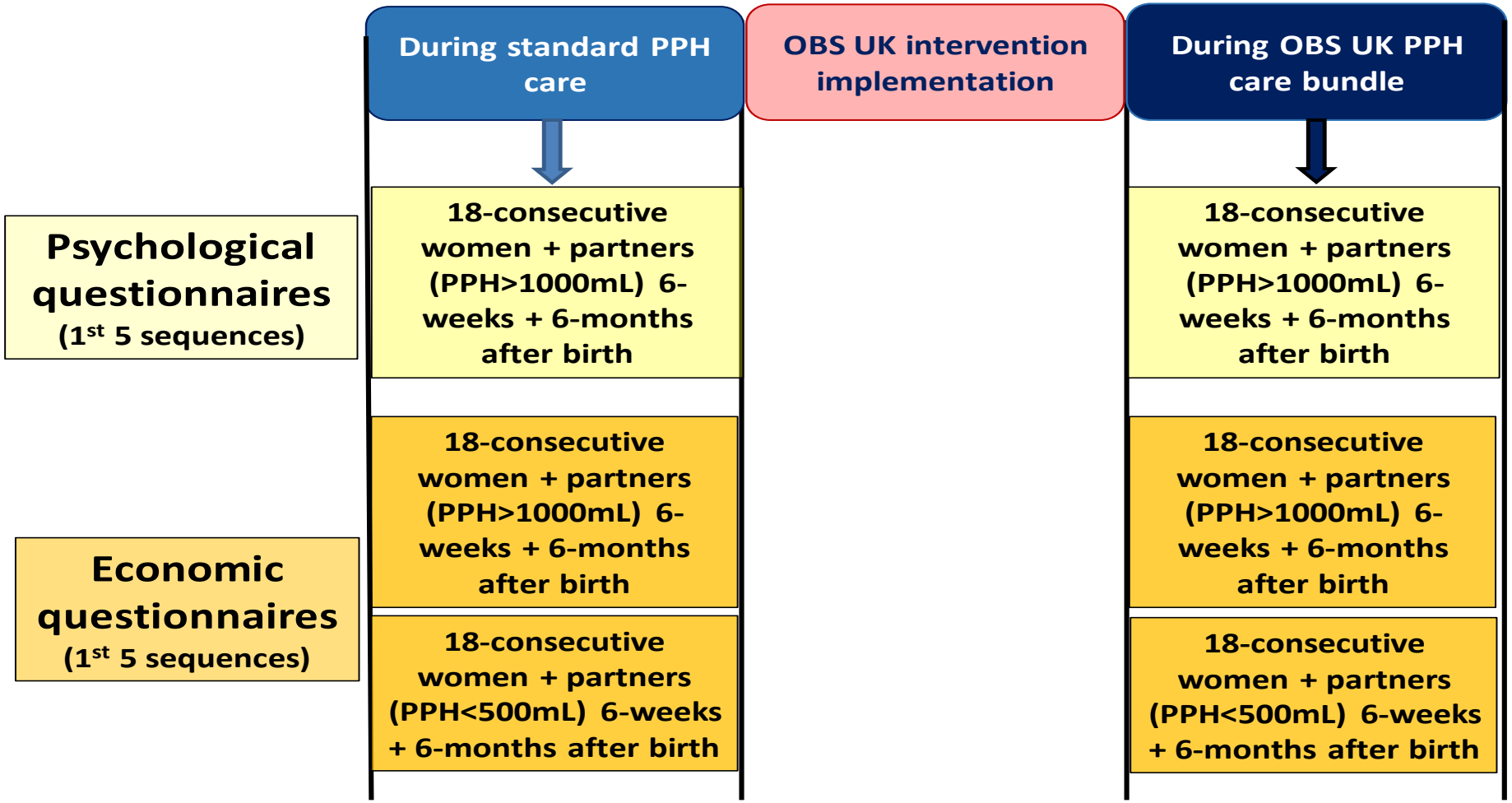
9- Month Implementation



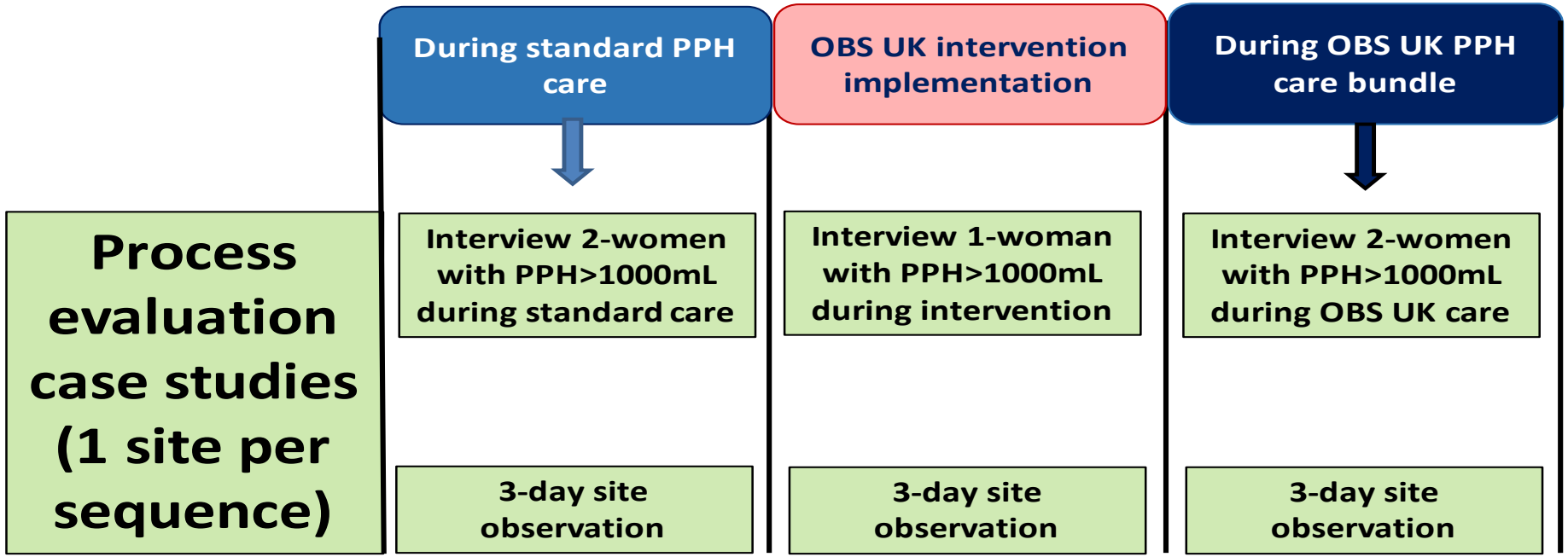
QI midwife: Audits of protocol compliance in 30 consecutive births, case notes review of 10 consecutive PPH >1L

Research midwife: Collate and report PPH rates which will automatically produce run charts available to QI team

Data collection for psychological, economic sub-studies



Data collection for process evaluation



Initial report Autumn 2026

Incidence of massive PPH in UK

- Maternal death due to PPH 12-22/100000
- Same over the last 15-years

- No significant sighs of improvement

Despite:

- Comprehensive guidelines
- Increase use of surgical / obstetric intervention in PPH management

MBRRACE-UK

Mothers and Babies: Reducing Risk through Audits and Confidential Enquiries across the UK

Haemorrhage and AFE 2020 & 2023

Many women who died had delayed or inadequate correction of their coagulopathy

VHA devices can minimise delays but must be interpreted correctly

Obstetric Bleeding Study plus

Acute obstetric coagulopathy during postpartum hemorrhage is caused by hyperfibrinolysis and dysfibrinogenemia: an observational cohort study

Lucy de Lloyd[1] | Peter V. Jenkins[2,3] | Sarah F. Bell[1] | Nicola J. Mutch[4] | Julia Freyer Martins Pereira[1] | Pilar M. Badenes[5] | Donna James[6] | Anouk Ridgeway[6] | Leon Cohen[1] | Thomas Roberts[1] | Victoria Field[1] | Rachel E. Collis[1] | Peter W. Collins[2,3]

jth https://doi.org/10.1016/j.jtha.2022.11.036

Study aim:

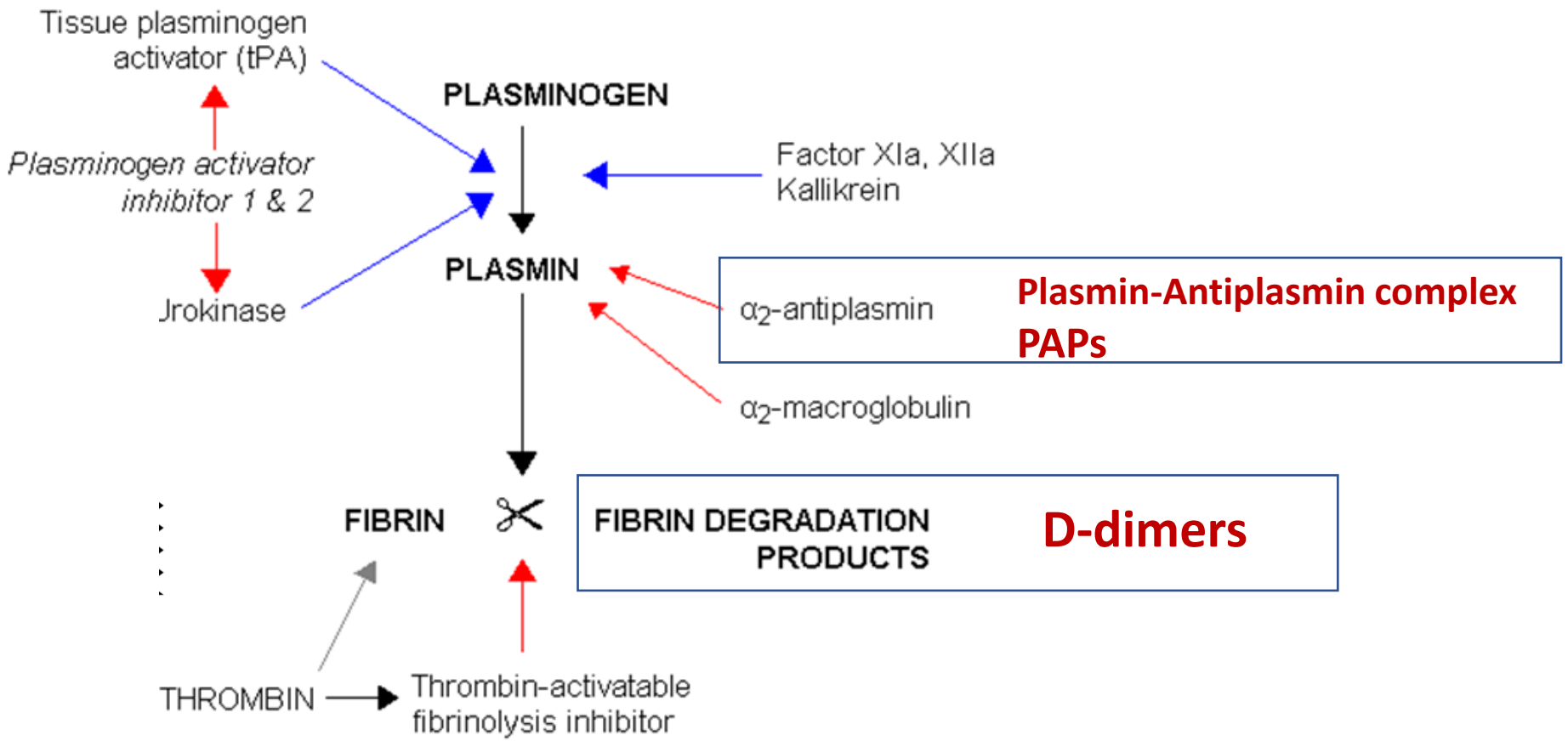
Characterise the coagulopathy of postpartum haemorrhage

Fibrinolysis pathway

MRC Medical Research Council

NHS National Institute for Health Research

Efficacy and Mechanism Evaluation Programme



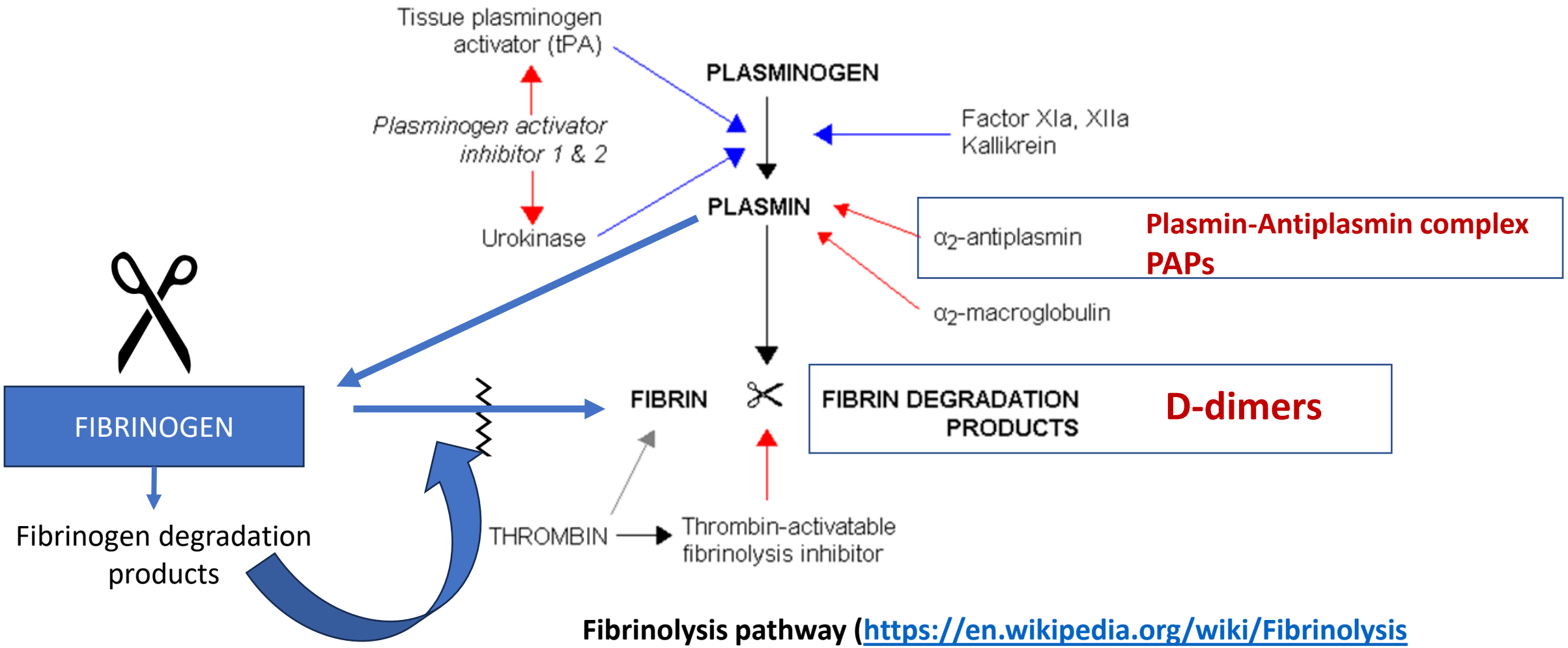
Fibrinolysis pathway (https://en.wikipedia.org/wiki/Fibrinolysis

Fibrinolysis pathway

MRC Medical Research Council

NHS National Institute for Health Research

Efficacy and Mechanism Evaluation Programme



Fibrinolysis pathway (https://en.wikipedia.org/wiki/Fibrinolysis

OBS UK
Obstetric Bleeding Study UK

OBS UK Study

OBS UK

Clinical and cost-effectiveness of a maternity quality improvement programme to reduce excess bleeding and need for transfusion after childbirth: the Obstetric Bleeding Study UK (OBS UK) Stepped Wedge Cluster Randomised Trial