

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

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Registration date 30/08/2023	Overall study status Ongoing	<input type="checkbox"/> Statistical analysis plan <input type="checkbox"/> Results
Last Edited 30/09/2024	Condition category Pregnancy and Childbirth	<input type="checkbox"/> Individual participant data <input checked="" type="checkbox"/> Record updated in last year

Plain English summary of protocol

Background and study aims

Excess bleeding is the most common complication of childbirth. Every year about 50,000 women in the UK lose 1L (2 pints) of blood or more. Many women develop post-traumatic stress disorder, need blood transfusion or admission to intensive care.

There is a lack of knowledge about how best to treat the excess bleeding.

A care bundle for managing bleeding after birth was developed in Wales and rolled out as a quality improvement programme called the 'Obstetric Bleeding Strategy' (OBS). The care bundle has four parts: 1) assessment of each woman's bleeding risk, 2) accurate measurement of blood loss at all births, 3) a consistent approach to escalation of care to more senior clinicians and 4) bedside tests to identify and treat abnormal blood clotting.

This contrasts with current UK guidelines which recommend measuring blood loss only after excess bleeding is identified. This national study follows on from our pilot study in which we found that the Obstetric Bleeding Strategy care bundle could be successfully adopted by maternity units. The results from this pilot were encouraging, but since this was a small study with limited data, we do not know whether the improvements seen were due to the change in care, or whether the care bundle is value for money. To find this out, this study will compare clinical outcomes, psychological wellbeing and cost of care for women in maternity units that use the care bundle with women receiving standard care.

Who can participate?

We will use routine NHS data on about 189,000 women from 36 NHS maternity units over 30-months. All women giving birth in these units will be included, whether they have excess bleeding or not.

What does the study involve?

All maternity units will start with a period of standard care, they will then adopt the Obstetric Bleeding Strategy care bundle over 9 months, followed by a period of Obstetric Bleeding Strategy care. To measure how effective the Obstetric Bleeding Strategy care bundle is, we will

compare rates of blood transfusion before and after it is introduced. We will also study intensive care admission, hysterectomy, breastfeeding rates and various other outcomes. Women with experience of excess bleeding have advised us on the study's importance, its design, and outcomes. Add-on studies will look at the effect of the Obstetric Bleeding Strategy care bundle on the psychological wellbeing of women and birth partners and how units adopt the care bundle, with special attention to ethnicity and organisational factors. This will include interviewing women, their birth partners and staff to understand their experiences of excess bleeding and whether the Obstetric Bleeding Strategy care bundle changes how teams deliver care. The cost of implementing the bundle and financial impact of having excess bleeding will also be studied. This research will establish whether (and how) the Obstetric Bleeding Strategy care bundle improves outcomes and experiences of women giving birth. We will share our findings widely with the support of UK maternity providers and patient representatives.

What are the possible benefits and risks of participating?

Where is the study run from?
Cardiff University (UK)

When is the study starting and how long is it expected to run for?
May 2023 to January 2027

Who is funding the study?
National Institute for Health and Care Research (NIHR) (UK).

Who is the main contact?
Dr Sarah F Bell, OBSUK@cardiff.ac.uk

Study website
<https://www.obsuk.org>

Contact information

Type(s)
Scientific

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Additional identifiers

EudraCT/CTIS number

Nil known

IRAS number

326510

ClinicalTrials.gov number

Nil known

Secondary identifying numbers

CPMS 57855, IRAS 326510

Study information

Scientific Title

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

Acronym

OBS UK

Study objectives

To test the effectiveness of the Obstetric Bleeding Strategy (OBS) intervention compared to standard care on clinical and psychological obstetric bleeding outcomes after childbirth and to evaluate the cost-effectiveness of the OBS intervention compared to standard care.

Ethics approval required

Ethics approval required

Ethics approval(s)

Approved 21/09/2023, North West - Greater Manchester Central Research ethics Committee (2 Redman Place, Stratford, London, E20 1JQ, United Kingdom; +44 207 1048 328; gmcentral.rec@hra.nhs.uk), ref: 23/NW/0242

Study design

Stepped wedge cluster randomized trial

Primary study design

Interventional

Secondary study design

Cluster randomised trial

Study setting(s)

Hospital

Study type(s)

Treatment

Participant information sheet

Not available in web format, please use the contact details to request a patient information sheet.

Health condition(s) or problem(s) studied

Obstetric bleeding

Interventions

Maternity units will be randomised to one of six sequences, so there will be 6 maternity units in each sequence. Maternity units will initially collect data during a period of standard PPH care for between 3 and 18 months, depending upon the outcome of randomisation. In the first sequence, 6 maternity units will collect standard care data for 3 months. They will then undertake the 9-month implementation period. The second sequence of 6 maternity units will collect standard care data for 6 months. They will then undertake the 9-month implementation period.

Subsequent sequences will undertake the implementation period after 9, 12, 15, and 18 months of standard care respectively. Following the 9-month implementation period, maternity units will undertake a period of data collection whilst providing the OBS UK care bundle. This will last between 18 (first sequence) and 3 (last sequence) months depending on the randomisation.

OBS UK intervention

The OBS UK intervention consists of all three of the following:

1. The OBS UK postpartum haemorrhage (PPH) care bundle
2. Supported by standardised documentation
3. Introduced using quality improvement methods over a 9-month period

The OBS UK Care Bundle is

Assessment of every woman's bleeding risk

Quantification of blood loss for all women from the time of birth

Escalation of multi-professional care to more senior staff at defined volumes of blood loss with appropriate medical intervention

At 1L blood loss with ongoing bleeding, or earlier for clinical concern, a point-of-care test of haemostasis should be performed and the OBS UK blood component infusion algorithm followed

Comparator

Standard UK PPH care provided by maternity units prior to implementation of the intervention.

Setting

The study will take place in 36 NHS maternity units of different sizes and locations, including those serving areas of social deprivation and high proportions of ethnic minority populations.

Psychology sub-study:

This will study women who experienced PPH >1L and their birth partner's postnatal mental health (post-traumatic stress and postnatal depression symptoms), acceptability of and satisfaction with the intervention, breastfeeding and adverse effects of the intervention on mother, birth partner (and baby). The outcomes for the psychology sub-study will be collected via questionnaires at 6 weeks (± 1 week) and 6 months (± 4 weeks) after birth.

Health Economic sub-study:

This will study cost-effectiveness expressed as incremental cost per confirmed case of red blood

cell transfusion avoided and incremental cost per quality-adjusted life year gained over a lifetime horizon. The outcomes for the health economics sub-study will be collected via questionnaires at 6 weeks (± 1 week) and 6 months (± 4 weeks) after birth from women who experienced PPH $>1L$ and their economic partners. The economic partner may or may not be the same person as the birth partner. In addition, a comparator group of women who did not have a PPH and their partners will complete the economic questionnaires.

Process evaluation:

A mixed-method approach to understand implementation of the care bundle using quality improvement methodology during the pilot study in Wales (retrospective review) and during the OBS UK trial, exploring how the intervention was deployed and possible improvements to inform wider implementation. Interviews will be carried out with women who have had a PPH and staff who work in maternity units. Observations of training, births and PPH management in maternity units will also take place.

Data collection

Data will be collected through multiple media including on-line questionnaires for the psychology and economic sub-studies and interviews for the consented process evaluation sub study.

For the primary and secondary clinical outcomes data will be collected in following ways:

1. Aggregate data

The primary outcome data will be collected in aggregate form from the local sites on a monthly basis. Specifically, each month the site will report to the electronic database how many women have given birth and how many women had a blood transfusion for PPH. This data will be anonymous and will not be at individual level.

2. An anonymised research database will be created to ensure that primary and secondary trial outcomes are due to PPH and allow in-depth analysis of primary and secondary clinical outcomes, demographic and obstetric variables, economic outcomes and process measures to inform interpretation and generalisability of results. This will require linkage of targeted source data with extracts from routinely collected NHS databases.

a. Targeted source data

Individual, PPH-specific data will be provided by the sites for women who have a PPH of $>1.5L$ and/or receive a blood transfusion for PPH and who have not opted out of sharing data for research use.

b. Routinely collected data from NHS databases e.g. HES data

Routinely collected data retrieved from NHS databases will provide trial data for all women who have not opted out of the national digital datasets.

The psychological and health economic sub-studies will require consent for the completion of online or paper questionnaires. The process evaluation includes ethnographic observations that will not require consent and staff and patient interviews that will require consent.

Intervention Type

Behavioural

Primary outcome measure

Number of women receiving allogenic red blood cell transfusion for PPH from 4 hours before birth until hospital discharge measured using patient records

Secondary outcome measures

Clinical outcomes measured using patient records:

1. Blood loss: Total blood loss volume within 4 hours prior to and 24 hours after birth
2. Hysterectomy: Number of women undergoing hysterectomy due to PPH
3. Maternal death: Number of women who died following PPH
4. Higher level of care: Number of women transferred to higher level of care (Level 2/3) outside of the obstetric unit for complications following PPH
5. Cardiovascular shock: Number of women transferred to higher level of care outside of the obstetric unit for vasopressor infusion following PPH
6. Organ dysfunction: Number of women transferred to higher level of care outside of the obstetric unit for organ support following PPH
7. Blood transfusion: Number of women transfused cell salvage red blood cells and the volume within 4 hours before birth up until discharge for obstetric bleeding
8. Other blood components/products transfused: Number of women transfused coagulation products including type of product (FFP, cryoprecipitate, platelets or fibrinogen concentrate) and number of units within 4 hours before birth up until discharge for obstetric bleeding
9. Coagulopathy: Number of women with fibrinogen levels $<2\text{g/L}$, ROTEM Fibtem A5 $<12\text{mm}$ or TEG CFF MA (by 10 minutes) $<17\text{mm}$, PT/APTT $>1.5\text{x}$ midpoint of normal reference range and platelet count $<75 \times 10^9$ within 4 hours prior to and 24 hours after birth
10. Haemostatic surgical and radiological interventions: Number of women requiring uterine tamponade balloon insertion, uterine brace suture, transfer to theatre or any radiological intervention for PPH
11. Neonatal death and stillbirth rate: Number of neonatal deaths and stillbirths
12. Length of hospital stay: Time from birth until mother's discharge
13. Breastfeeding: First feed timing, type, maintenance of breastfeeding including breast milk only at 6 weeks
14. Women and birth partner's postnatal mental health, women and birth partner's acceptability of and satisfaction with intervention, breastfeeding and adverse effects of intervention on mother, baby and birth partner: Psychological quantitative study (described below)

Psychology outcomes

The outcomes for the psychology sub-study will be collected via questionnaires at 6 weeks (± 1 week) and 6 months (± 4 weeks) after birth

1. Symptoms of depression (mother and birth partner): measured on the Edinburgh Postnatal Depression Score
2. Symptoms of post-traumatic stress disorder (mother and birth partner): measured on the Impact of Events Scale Revised with PPH as a specific event
3. Mother and baby bonding: Mothers' Object Relations Scale
4. Perspective on whether PPH was psychologically traumatic (mother and birth partner): Diagnostic and Statistical Manual V criterion via a specific criterion question: "You felt you/your birth partner were at risk of death or serious harm", yes/no
5. Interpersonal factors associated with the experience of childbirth (mother and birth partner): Semantic differential questions co-produced with the study's patient public involvement group, to capture what was important to them, and their birth partners at the time of their PPH (6 weeks only)
6. Initiation and maintenance of partial/exclusive breastfeeding (mother)
7. Access to professional support or intervention for psychological symptoms related to the birth experience. What, if any, support has been accessed and participant views on this. (mother and birth partner, 6 months only)

Cost-effectiveness outcomes

The outcomes for the cost-effectiveness analysis (including EQ 5D5L) will be collected via questionnaires at 6 weeks (± 1 week) and 6 months (± 4 weeks) after birth

1. Incremental cost per confirmed case of allogenic red blood cell transfusion avoided
2. Incremental cost per quality-adjusted life year gained over a lifetime horizon

Process evaluation outcomes

The outcomes for process evaluation

1. Prospective data from all sites

1.1. Surveys

Site context survey at study start and online staff survey at end of the 9-month implementation period

1.2. QI measures

1.2.1. Monthly run charts of PPH volume and RBC transfusion (run charts are displays of time-series data shown in graph form), throughout the implementation and OBS UK periods

1.2.2. Audit and case notes review during implementation (1, 4 and 7 months)

1.2.3. Assessment of sustainability and or decay of components of OBS UK care bundle

1.3. Audit and case notes review at end of study

1.4. Targeted source data

Failure to detect a difference between standard and OBS UK care may be due to changes in clinical care which impact on the primary outcome (eg. management of antenatal anaemia and timing of clinical escalation). Therefore haemoglobin and coagulation tests and time of clinical escalation will be collected as process measures for women who experience PPH >1.5L and or receive a blood transfusion due to obstetric bleeding,

2. Case studies

Prospective ethnographic and qualitative data collection from six sites (one per sequence) during standard care, implementation and OBS UK care periods and ethnographic and qualitative data collection in four maternity units in Wales where the intervention is embedded into standard care.

Overall study start date

01/05/2023

Completion date

31/01/2027

Eligibility

Key inclusion criteria

Site inclusion criteria:

1. Maternity unit with >2000 births per year

2. Local NHS maternity leaders support the implementation of the OBS UK intervention and quality improvement time for the local champion team. This must include protected midwifery time (4 hours/week) and non-clinical time for consultant obstetrician, anaesthetist, and haematologist from supporting professional activity during the 9-month implementation period

For the psychology sub-study inclusion criteria are (requiring individual consent):

1. Women who have experienced a PPH of greater than 1L and their birth partners

For the cost-effectiveness sub-study inclusion criteria are (requiring individual consent):

1. Women who have experienced a PPH of greater than 1L and their economic partners

2. Women who have a blood loss of less than 500mL and their economic partners

For the process evaluation inclusion criteria are (interviews require individual consent, observation/ethnography study does not require individual consent):

1. Women and, if they would like to be involved, their birth partners who have experienced a PPH of greater than 1 L at one of four maternity units that were included in the pilot study (OBS Cymru) and selected for a site visit
2. Women and, if they would like to be involved, their birth partners who have experienced a PPH of greater than 1L at a maternity unit selected for a process evaluation site visit in the OBS UK study
3. Members of staff at four maternity units that were included in the pilot study (OBS Cymru) and are selected for a site visit
4. Members of the specialist and wider team who work in the maternity service at a maternity unit selected for a process evaluation site visit in the OBS UK study

All patients are included in the primary outcome, whilst those opting out will not be included in the datasets/targeted source data. The lower age limit is only for the consenting sub studies.

Participant type(s)

Patient

Age group

Adult

Lower age limit

16 Years

Sex

Female

Target number of participants

Planned Sample Size: 189,000; UK Sample Size: 189,000

Key exclusion criteria

Site exclusion criteria:

1. Maternity units that have adopted the entire OBS UK obstetric haemorrhage care bundle
2. Maternity units that use viscoelastic point-of-care tests of haemostasis on the consultant-led delivery suite or in obstetric theatres
3. If a Trust or Health Board has more than one maternity unit then only one can join the study

For the psychology sub-study exclusion criteria are (requiring individual consent):

1. Age <16 years, prisoners and individuals who lack capacity
2. Women and birth partners who have had experienced a stillbirth or neonatal death will be excluded from the psychology study component

For the cost-effectiveness sub-study exclusion criteria are (requiring individual consent):

1. Age <16 years, prisoners and individuals who lack capacity

For the process evaluation exclusion criteria are (interviews require individual consent, observation/ethnography study does not require individual consent):

1. Age <16 years, prisoners and individuals who lack capacity

Date of first enrolment

01/02/2024

Date of final enrolment

31/07/2026

Locations

Countries of recruitment

England

Northern Ireland

Scotland

United Kingdom

Wales

Study participating centre

Kings College Hospital

King's College Hospital NHS Foundation Trust

Denmark Hill

London

United Kingdom

SE5 9RS

Study participating centre

James Cook University Hospital

South Tees Hospitals NHS Foundation Trust

Marton Road

Middlesbrough

United Kingdom

TS4 3BW

Study participating centre

Southampton General Hospital

University of Southampton and University Hospital Southampton NHS Foundation Trust

Tremona Road

Southampton

United Kingdom

SO16 6YD

Study participating centre

Hampshire Hospitals NHS Foundation Trust
Basingstoke and North Hampshire Hos
Aldermaston Road
Basingstoke
United Kingdom
RG24 9NA

Study participating centre
Barts Health NHS Trust
The Royal London Hospital
80 Newark Street
London
United Kingdom
E1 2ES

Study participating centre
Royal Blackburn Hospital
Haslingden Road
Blackburn
United Kingdom
BB2 3HH

Study participating centre
The Rotherham NHS Foundation Trust
Moorgate Road
Rotherham
United Kingdom
S60 2UD

Study participating centre
Queen Alexandras Hospital
Southwick Hill Road
Cosham
Portsmouth
United Kingdom
PO6 3LY

Study participating centre
Royal Surrey County Hospital NHS Foundation Trust
Egerton Road
Guildford

United Kingdom
GU2 7XX

Study participating centre

NHS Grampian
Summerfield House
2 Eday Road
Aberdeen
United Kingdom
AB15 6RE

Study participating centre

Worcestershire Royal Hospital
Charles Hastings Way
Worcester
United Kingdom
WR5 1DD

Study participating centre

Ninewells Hospital
Ninewells Avenue
Dundee
United Kingdom
DD1 9SY

Study participating centre

Guy's & St Thomas Hospital
Westminster Bridge Road
London
United Kingdom
SE1 7EH

Study participating centre

Milton Keynes University Hospital NHS Foundation Trust
Standing Way
Eaglestone
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MK6 5LD

Study participating centre
Homerton Healthcare NHS Foundation Trust
Homerton Row
London
United Kingdom
E9 6SR

Study participating centre
Calderdale and Huddersfield NHS Foundation Trust
Trust Headquarters
Acre Street
Lindley
Huddersfield
United Kingdom
HD3 3EA

Study participating centre
St Peters Hospital
Guildford Road
Chertsey
United Kingdom
KT16 0PZ

Study participating centre
Darent Valley Hospital
Darenth Wood Road
Dartford
United Kingdom
DA2 8AA

Study participating centre
Pinderfields Hospital
Aberford Road
Wakefield
United Kingdom
WF1 4DG

Study participating centre
East Surrey Hospital
Canada Avenue

Redhill
United Kingdom
RH1 5RH

Study participating centre
Northampton General Hospital NHS Trust
Cliftonville
Northampton
United Kingdom
NN1 5BD

Study participating centre
Warwick Hospital
Lakin Road
Warwick
United Kingdom
CV34 5BW

Study participating centre
Mid and South Essex NHS Foundation Trust
Prittlewell Chase
Westcliff-on-sea
United Kingdom
SS0 0RY

Study participating centre
Sunderland Royal Hospital
Kayll Road
Sunderland
United Kingdom
SR4 7TP

Study participating centre
The Maidstone Hospital
Hermitage Lane
Maidstone
United Kingdom
ME16 9QQ

Study participating centre
Kettering General Hospital NHS Foundation Trust
Rothwell Road
Kettering
United Kingdom
NN16 8UZ

Study participating centre
Royal Albert Edward Infirmary
Wigan Lane
Wigan
United Kingdom
WN1 2NN

Study participating centre
East Sussex Healthcare NHS Trust Hq
St. Annes House
729 the Ridge
St. Leonards-on-sea
United Kingdom
TN37 7PT

Study participating centre
Northumbria Healthcare NHS Foundation Trust
North Tyneside General Hospital
Rake Lane
North Shields
United Kingdom
NE29 8NH

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Ulster Hospital
Upper Newtownards Rd
Dundonald
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BT16 1RH

Study participating centre
Chesterfield Royal Hospital NHS Foundation Trust
Chesterfield Road

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United Kingdom
S44 5BL

Study participating centre

Lanarkshire

Kirklands
Fallside Road
Bothwell
Glasgow
United Kingdom
G71 8BB

Study participating centre

Bolton Royal Hospital

Minerva Road
Farnworth
Bolton
United Kingdom
BL4 0JR

Study participating centre

Dewi Sant Hospital

Albert Road
Pontypridd
United Kingdom
CF37 1LB

Study participating centre

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Maes-y-coed Road
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United Kingdom
CF14 4HH

Study participating centre

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Sponsor type
University/education

Website
<http://www.cardiff.ac.uk/>

ROR
<https://ror.org/03kk7td41>

Funder(s)

Funder type
Government

Funder Name
NIHR Evaluation, Trials and Studies Co-ordinating Centre (NETSCC)

Results and Publications

Publication and dissemination plan

Planned publication in a high-impact peer-reviewed journal

Intention to publish date

31/01/2028

Individual participant data (IPD) sharing plan

Targeted source data: Anonymised targeted source data will be available on request and after appropriate approvals from OBSUK@cardiff.ac.uk

Linked datasets: we cannot make these available to other researchers due to the requirements of the data provider. However, researchers can apply directly to the organisations responsible, if they wish to access the data.

IPD sharing plan summary

Available on request, Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Interim results article		27/09/2024	30/09/2024	Yes	No