The Simulation Training for Operative Birth – Evaluation (STROBE) Study

Protocol

NBT R&I number: 3961

EudraCT number: 2017-001791-38

Protocol version 7

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Glossary / abbreviations

Health Research Authority	HRA
Obstetrics & Gynaecology	O&G
Operative vaginal birth	OVB
Research Ethics Committee	REC
Royal College of Obstetricians and Gynaecologists	RCOG
Royal College of Obstetricians and Gynaecologists Operative Birth Simulation Training	ROBuST
Study Steering Group	SSG
World Health Organisation	WHO

1 Overview

Currently there is no recognised standardised training course for obstetricians in operative vaginal birth (OVB) that has shown significant benefits in patient-related outcomes. The existing Royal College of Obstetricians and Gynaecologists (RCOG) Operative Birth Simulation Training (ROBuST) course is routinely undertaken by trainees in England. This observational project seeks to compare routinely collected patient outcomes before and after training to establish the unit-level effect of participating in ROBuST simulation training for all practitioners in operative vaginal birth.

2 Background

2.1 Defining the problem

Prolonged second stage of labour is associated with increased risk of maternal haemorrhage (1), infection, and poorer neonatal outcomes (2). Therefore, birth attendants seek to shorten the second stage of labour, where clinically appropriate, using operative vaginal birth. The World Health Organisation (WHO) defines OVB as one of the five critical functions of basic emergency maternity care (3). However, it is a complex skill that takes time to acquire. Over recent decades the amount of time trainees in Obstetrics & Gynaecology (O&G) have had in supervised training before being independent operators has been reducing (4). This in turn has led to a reduction in trainee confidence using instruments to assist vaginal births, and is likely to have led to reduction in skill in using these instruments {Gale:2014gk}.

2.2 Current practice

In order to counter the loss of direct clinical experience, several simulation-based training programs in OVB have been developed. At present, the ROBuST course is mandatory for junior trainees in O&G each year in England. While there is substantial evidence of the benefits simulation training can have on unit-level outcomes in many other obstetric scenarios (shoulder dystocia, neonatal outcomes, post-partum hemorrhage etc.) (5), none has yet been demonstrated for simulation training in OVB.

2.3 Proposed development

This project proposes comparing clinical outcomes following OVB, at participating units, before and after structured simulation training (ROBuST). A successful training program

should promote all secondary drivers of quality in OVB, increasing practitioner familiarity, confidence and technical skills in OVB. This will lead to better communication with patients, as well as better technical performance by practitioners. These, along with better recognition and management of problems encountered during OVB, may lead to improved quality of care for women undergoing OVB and their babies.

2.4 Possible benefits and harms

2.4.1 Possible benefits

Reduction in adverse maternal and neonatal outcomes following OVB training

Reduction in adverse maternal and neonatal outcomes following OVB training

2.4.2 Possible harms

As this is an observational study of an already mandated RCOG training programme and so none are anticipated

2.5 Current research

A literature search (see Appendix 1 for search strategy) of the Cochrane Central Register of Controlled Trials (CENTRAL), and MEDLINE has demonstrated no published studies or current trails evaluating the performance of simulation courses in OVB on patient outcomes.

3 Study objectives

3.1 Objective

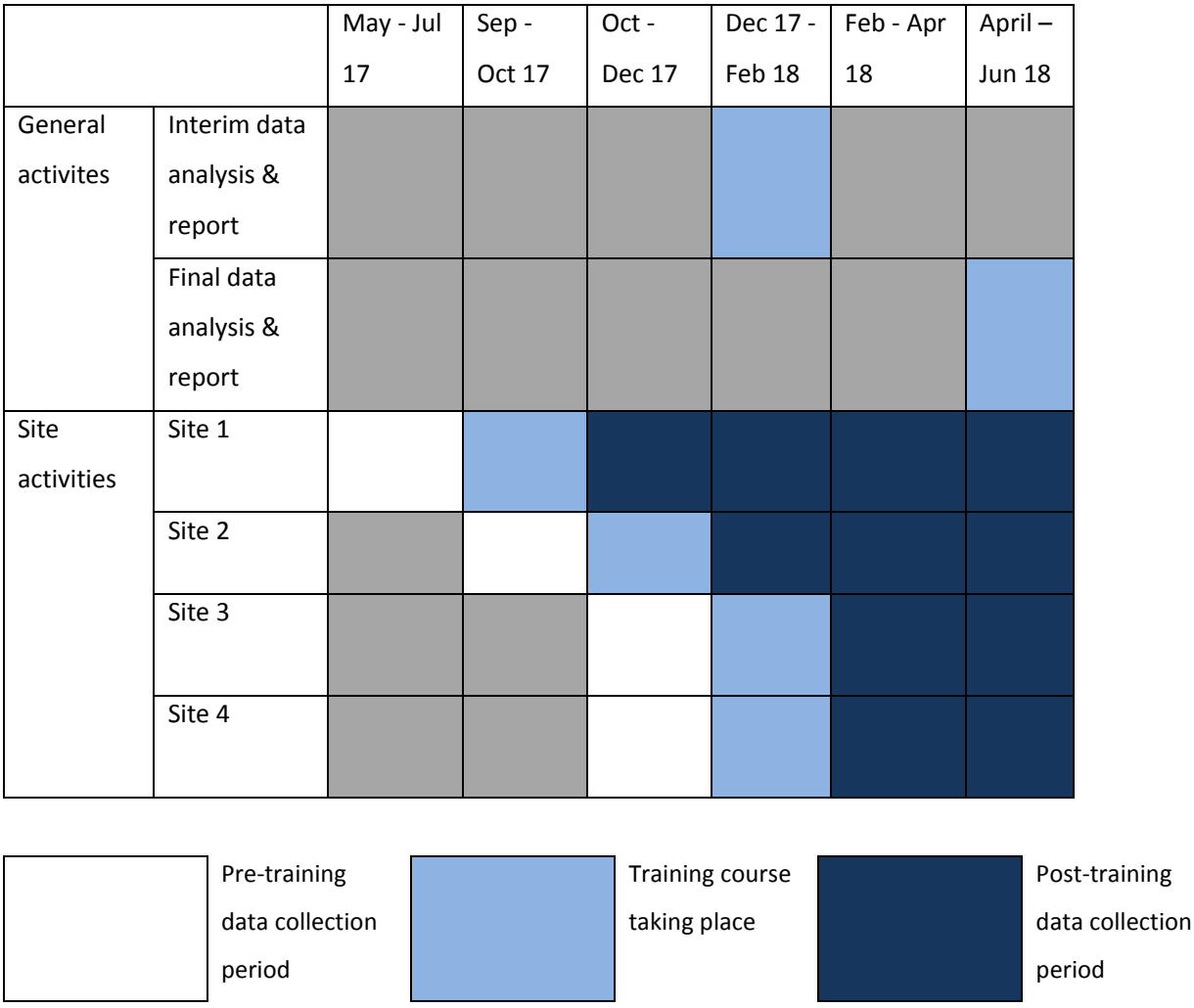
The project will establish if structured training in operative birth (ROBuST) is clinically effective across a health service, using failure to achieve birth with the first instrument chosen for operative birth as the primary outcome measure – this indicator is strongly associated with poor maternal and neonatal outcomes.

4 Plan of Investigation

4.1 Project design

This is an observational study of outcomes after OVB covering a time period which includes delivery of local simulation courses in OVB. The design is a stepped-wedge observational study. The stepped-wedge design is an adaptive approach which offers more scope for pragmatism than traditional fixed-time design, especially as every unit will receive the training course.

Figure 1. Stepped-wedge design of STROBE study



4.2 Training

The intervention studied will be the local provision of structured simulation training in operative vaginal birth (the ROBuST course) to trainees in O&G. The intervention will be delivered by local faculty of senior obstetricians and midwives. The ROBuST course is a one-day course that utilises simulation models to teach the spectrum of operative birth

manoeuvres – rotational and non-rotational forceps and vacuum deliveries, as well as techniques for complex Caesarean sections.

4.3 Participants

The study population will consist of women having an attempted OVB in the four maternity units during the study period (9 to 13 months per site, average of 600 women per site, at least 2,400 women in total).

4.4 Inclusion criteria

Data will be included in data collection and analysis if all of the following apply:

- The birth was conducted within a study site during the applicable study time period
- An operative vaginal birth instrument (forceps or vacuum) was applied to a fetal head

4.5 Exclusion criteria

Data from births will not be included in collection and analysis if any of the following apply:

- An operative birth instrument was only applied during (and not before) a Caesarean section (i.e. use of Wrigley's forceps at Caesarean)
- If the woman is <18 years old at the time of birth
- If the woman is a prisoner

4.6 Time period of outcomes studied

18 months. Of this, 3 months prior to each unit of trainees attending OVB simulation training and 3 months after. This equates to 9 to 13 months of outcomes studied per site, due to variable data collection lengths of different sites.

4.7 Study sites

The following Maternity units will be used as sites for this project:

- North Bristol NHS Trust, Bristol
- University Hospitals Bristol NHS Foundation Trust, Bristol
- Royal United Hospitals Bath NHS Foundation Trust, Bath
- Gloucestershire Hospitals NHS Foundation Trust, Gloucester

4.8 Primary outcome measure

- Failed operative vaginal birth with first chosen instrument

4.8.1 Secondary maternal outcome measures

- Use of second instrument to achieve OVB
- Caesarean section
- Episiotomy
- Perineal trauma
    - $1^{st}/2^{nd}/3^{rd}/4^{th}$ degree tear
- Cervical tear requiring suturing
- General anaesthesia
- Estimated blood loss

4.8.2 Secondary neonatal outcome measures

- Apgar score at 1/5/10 minutes
- Umbilical artery pH
- Shoulder dystocia
- Admission to Neonatal Intensive Care Unit
- Death within 28 days of birth

4.8.3 Clinical variable characteristics

The following clinical variable characteristics will be collected and used for adjusting and comparing secondary clinical outcomes:

- maternal age
- body mass index (BMI) at booking
- parity
- history of previous Caesarean or vaginal birth
- length of gestation (weeks and days)
- duration of first and second stage (minutes)
- indication for assisted vaginal birth (presumed fetal compromise, delay in 2^{nd} stage),

- position of fetal head (right occipito-anterior, right occipito-transverse, right occipito-posterior, occipito-posterior, left occipito-posterior, left occipito-transverse, left occipito-anterior, occipito-anterior)
- station of fetal head (at ischial spines, +1cm below ischial spines, +2cm below ischial spines)
- presence and degree of moulding (none, +, ≤++)
- presence and degree of caput (none, 1cm, 2cm)
- analgesia (epidural block, spinal block, general anaesthesia, pudendal block, perineal infiltration, none)
- baby birth weight (g)
- grade of operator (ST1 – 2, ST3 – 5, ST6 – 7, Consultant)
- grade of supervisor (if applicable, as above)

4.9 Process measures

The following will be recorded as process measures.

- Number and proportion (%) of trainees exposed to intervention per site during training period
- Number and seniority of local facilitators of intervention

4.10 Volume of data collection

This project will gather data from all 4 units for at least 3 months before and 3 months after training. Using the most recent NHS Maternity Statistics, this will include a minimum of 2,400 OVBs over the course of the project (6).

4.11 Frequency of primary outcome measure and expected measure of effect

The primary outcome is failed OVB. Depending on the type of OVB, rates of failure in reported studies vary between 5.8% (rotational forceps) (7), 9.3% (non-rotational forceps), 14.1% (all types of ventouse) and 24.4% (hand-held ventouse) (8).

We propose to take 80% as an estimated real-world success rate (this is lower than that reported in other studies, as OVBs reported in studies will be subject to the Hawthorne effect. We also seek to reflect the mix of types of OVB performed).

4.12 Sample size

We will use a p-value (alpha) of < 0.05 as significance. With 90% power, and an inter-cluster co-efficient (ICC) 0.1, we have generated the following study power predictions based on differing assumptions of trainee and birth numbers:

4.12.1 Conservative estimate

Assuming each site has 12 trainees and 200 births are performed per 3-month step, the study will detect a difference of 10% (failure rate change from 0.2 to 0.1) with a power of 0.78

4.12.2 Optimistic estimate

Assuming each site has 16 trainees and 266 births are performed per 3-month step, the study will detect a difference of 10% (failure rate change from 0.2 to 0.1) with a power of 0.88

Given that both of these scenarios are plausible (both numbers of births and staff fluctuates), the study will proceed as outlined in Figure 1.

5 Trial methods

5.1 Observational design and strategy

The intervention studied (ROBuST training course) will take place over the space of 3 months in each site, in the stepped-wedge manner described in Figure 1.

5.2 Monitoring of effect size

The Study Steering Group (SSG) will meet 3 months after data collection has been completed at the first site and analyse gathered data. Should the preliminary effect of training be smaller than expected (i.e. 80% to 85% or less), data collection will be extended for a period of time to allow capturing of a statistically significant effect.

5.3 Data gathering

Anonymised routinely available data will be gathered by direct clinical care staff in the individual units, from paper-based and electronic patient notes, and electronically

transferred to a central secure University of Bristol electronic data capture program (*RedCap*).

5.4 Data analysis

5.4.1 Participation, loss to follow-up and withdrawal

Analysis and presentation of data will be in accordance with CONSORT guidelines for clustered trials (9). Unit recruitment, in-house trainers' participation in training and in-house training implementation will be documented.

Loss to follow-up will only occur if a maternity unit is closed. To our knowledge, no unit closures or merging are planned for the duration of the project.

Their success of attempted OVB at term prevalence will be compared at step 0 and compared at each step of their planned post-intervention period to the prevalence of those fully participating. Modified Poisson (with robust variance) or logistic regression will be used to compare the units' prevalence.

5.4.2 Baseline and Intervention description

The number of births (count) and rate of failed attempted OVB (%) will be tabulated by step (0 to 5) and by unit for the 4 units.

The number and proportion of staff trained and number of training sessions delivered by in-house trainers will also be reported for each of the 4 units. Proportions, means with standard deviation or median with inter-quartile range will be reported as appropriate by unit size. Proportions will be compared with Chi-square tests, means with ANOVA and medians with Kruskal-Wallis ANOVA. P-value of 0.05 will be accepted as the level of significance.

These analyses will be conducted once the relevant steps are finished and the data has been released by the maternity units to the SSG.

5.4.3 Main analysis

The outcome for the main analysis is the rate of successful attempted OVB in term infants, dichotomised into successful or unsuccessful. This dichotomous outcome measured for each birth will be analysed with a marginal logistic regression model (using Generalized Estimating

Equation). This will allow us to model population-level effects (odds-ratios and related 95% CI) and adjust for the correlations between births occurring in the same maternity units. An appropriate working correlation matrix will be selected.

Due to the frequent nature of the studied outcome, convergence or computational issues might be encountered and in these circumstances other modelling strategies will be investigated like generalized linear mixed models (linear, logistic or Poisson multilevel regression).

We will firstly assess the intervention effect (control period/step vs. intervention effect/step). We will then adjust this model for the time period to investigate time-trends during the project observation period (step 0 to end of step 5). We will either model the time periods with categorical fixed effect variables (with dummy indicators for each step i.e. step1 to step 5 and step 0 being the reference) or as a continuous factor (number of time-unit since the start of step 0) with appropriate polynomial function of time if required. Statistics such as the Aikeke information criterion will be used to select the best modelling for time.

The interaction between time and the main intervention effect will then be tested to investigate the timing and duration of the intervention effect.

This analysis will be conducted for the 4 units which have not been trained prior to the start of the project. We will use the Wald test and p-value of 0.05 to determine statistical significance.

No interim analysis is planned as the intervention cannot be “undone” once the staff have been trained.

These analyses and the additional ones listed below, will be conducted after the end of step 5, and as soon as the data are available to us.

5.4.4 Additional analyses

As the analyses are conducted on an intention-to-treat principle for the units which do not (fully) comply with the intervention, a sensitivity analysis will test the effect of the intervention on a per-protocol basis.

Moreover, if marked imbalances in terms of pace of training staff or rate of successful attempted OVB in the pre-project period and step 0 are observed by maternity unit volume, the regression will be adjusted for the unit size differences (births per month).

The time-period used is three-month length, i.e. a step length. We will refine the investigation of the time-trend effects and timing of the intervention effect by modelling steps of smaller length. The potential minimal step length will be conditioned by the total number of births and births with a successful attempted OVB within each period.

We will also investigate the possibility to extend the analyses to the time-periods prior to this project to include a longer control period (Step 0 is the only one shown in Figure 1 but due to the routine nature of the data-collection more could be added).

We do not anticipate that there will be extensive missing data for the primary outcome and our primary analysis strategy will be on complete cases. However, it is known that for a small number of births the attempt to perform an OVB is not collected. We will describe any missing data in detail, and if required, will test the robustness of our primary analysis using the strategies outlined in White et al 2011.

5.5 End of the project

End of the trial is defined as the completion of data analysis.

6 Project Management

6.1 Day-to-day management

The project will be managed day-to-day by Dr Stephen O'Brien, Ms Laura Timlin, Ms Sharon Jordan & Mr Dimitrios Siassakos, in The Chilterns, Southmead Hospital, Bristol.

6.2 Monitoring of sites

The project will be monitored in accordance with the Research Governance Framework and the Medicines for Human Use (Clinical Trials) Regulations 2004. All project related documents will be made available on request for monitoring and audit by a Research Ethics Committee (REC) or any other regulating body.

6.3 Funding

Funding has been secured from the Health Foundation to the amount of £74,891.20, as a grant in 'Innovating for Improvement, Round 5'.

6.4 Insurance

As an NHS-Sponsored research project, normal NHS-indemnity processes apply, as documented in HSG(96)48. This covers negligent harm during the study, and covers NHS staff, medical academic staff with honorary contracts, and those conducting the study. NHS indemnity does not offer no-fault compensation and is unable to agree in advance to pay compensation for non-negligent harm.

6.5 Safety reporting

6.5.1 Safety of the intervention

This is an observational project, and as such no reports will be produced until after full data has been gathered and analysed.

6.5.2 Individual clinical incidents

This project involves the reviewing of a substantial number of clinical records in order to extract outcome data. It is therefore likely that untoward clinical incidents will be encountered. Should a potential clinical incident be encountered, the study team will inform the Patient Safety Midwife at the relevant study site, via secure NHSmail. This message will include the full patient details and a brief description of the incident. The Patient Safety team will then undertake an initial review of the incident and will escalate to a formal patient Safety Investigation if this is required. This would involve informing the patient that such an investigation is underway.

It is likely that the majority of these potential incidents will already have been investigated by the Patient Safety team.

The potential clinical incidents which will be notified to the Patient Safety teams are:

- Baby develops HIE level 2 or greater or requires head cooling
- PPH > 3000ml
- Unexpected hysterectomy

- Organ damage at Caesarean Section
- ITU admission
- 4th degree anal sphincter tear

7 Public and Patient Involvement

Women are at the heart of this study – this study will be conducted 'with women', rather than simply 'on women'.

Patient and public involvement (PPI) has been incorporated into this study at several keys stages –ethical justification, management and dissemination.

7.1 Ethical justification

This study involves the retrospective reviewing of patient case notes for anonymised data extraction without consent. While this is justifiable due to the nature of outcome data required and the study resources, the study team recognises that this course of action needs to be justifiable with women specifically. Therefore, the study team took part in a round of PPI to specifically address this issue – the results of which are attached as Appendix 2. This round of PPI confirmed that women are amenable to this approach, provided that strong safeguards regarding management of uncovered clinical incidents are in place (this has been enacted and is laid out in section 6.5.2).

7.2 Management

Patient representatives will play a prominent role in the management of the STROBE study. The founder of a group of ante-natal course providers, and therefore both a member and leader of the local maternity service user community (Iona Smith), will be a member of the SSG.

7.3 Dissemination

This study will develop a Communication Plan to disseminate the results in consultation with local women's groups. A dissemination plan has been drawn up by the SSG (including input from a patient representative) and following commencement of the study, will then be circulated to a North Bristol NHS Trust convened panel of maternity service users for input.

Following this input, the plan will be actioned, with the intention that much of the public-facing roles will be taken by interested women themselves.

8 Ethical Considerations

8.1 Access to patient identifiable data without consent

This project will require detailed retrospective data collection from original patient notes, with an anticipated 2,400 sets of notes to be analysed, by members of the direct clinical care teams and does not require consent under GAfREC. Due to the high number of notes to be analysed, it will also not be possible to retrospectively seek consent from women to access their records.

8.1.1 Opportunity to decline consent

Patients will not be informed of the study. This is due to the data being gathered retrospectively from routinely collected clinical notes. Therefore the women will not be undergoing any study procedures which could conceivably place a quantifiable burden upon them. Furthermore, to inform women that such data was being gathered would involve reminding them of their potentially traumatic OVB . It has been established that OVB (regardless of outcome) is independently associated with a negative maternal experience and feelings toward labour and delivery (10) – providing a reminder of such an experience could be perceived as overly psychologically burdensome on women. Furthermore, asking women to read study documentation, sign a consent form and return it to postal address would impose an additional logistical burden on women who, by dint of being new mothers, are likely to have low reserves of time available to spend on non-core family tasks.

8.2 Confidentiality for staff at participating units

Staff at participating units, who will have undergone training and performing OVBs, may be concerned that they will be identifiable in any data collected and analysed. The only data collected relating to staff will be the proportion of those trained in each unit during the study period, as well as the grade of staff performing or supervising each OVB.
Together, these are not considered to be identifiable information, and therefore staff confidentiality will not be breached. Moreover, for this reason consent will not be sought.

8.3 Research governance

This project will be conducted in accordance with

- International Conference for Harmonisation of Good Clinical Practice (E6 ICH GCP) guidelines
- Declaration of Helsinki (World Medical Association 2000)
- Research Governance Framework for Health and Social Care
- European Union Directive 2001/20/EC on clinical trials

8.4 NHS approval

REC review is not reviewed under GAfREC as data will be accessed by clinical care team and only clinical data will be taken. Health Research Authority (HRA) approval and confirmation of capability and capacity from each local NHS Trust R&D departments is required prior to the start of the project.

8.5 Monitoring

All project related documents will be made available on request for monitoring and audit by the HRA or other regulating bodies.

8.6 Study Steering Group

The Study Steering Group (SSG) will be chaired by the Chief Investigator and will include:

- Principal Investigator
- Research Manager
- Senior Research Midwife
- Patient Representative

The SSG will meet at least every 4 months (or more frequently if needed). It will review study progress (data collection and analysis), and implement remedial action as required.

8.7 Data monitoring

A Data Monitoring Committee (DMC) will be established. This will consist of the study statistician (EL) and two independent members with a strong research background. One a midwife and the other an obstetrician. The DMC will review the collected and analysed data half-way through data collection. They will form a judgement as to whether the study should continue, and communicate this to the SSG. The study should be stopped if the primary

outcome measure differs following training by more than 50% from baseline, and if this is statistically significant – to continue would place a burden on local units to provide notes for analysis when clinically significant results are already available.

8.8 Clinical Trial Authorisation

This is not a clinical trial of either a medical device or IMP and therefore a Clinical Trial Authorisation from the MHRA is not required.

8.9 Investigators' responsibilities

Investigators accept the responsibility for compliance to the protocol and accuracy of the submitted data sets. The investigators will be required to allow access to project documentation or source data on request for monitoring visits and audits performed by the Sponsor or any regulatory authorities.

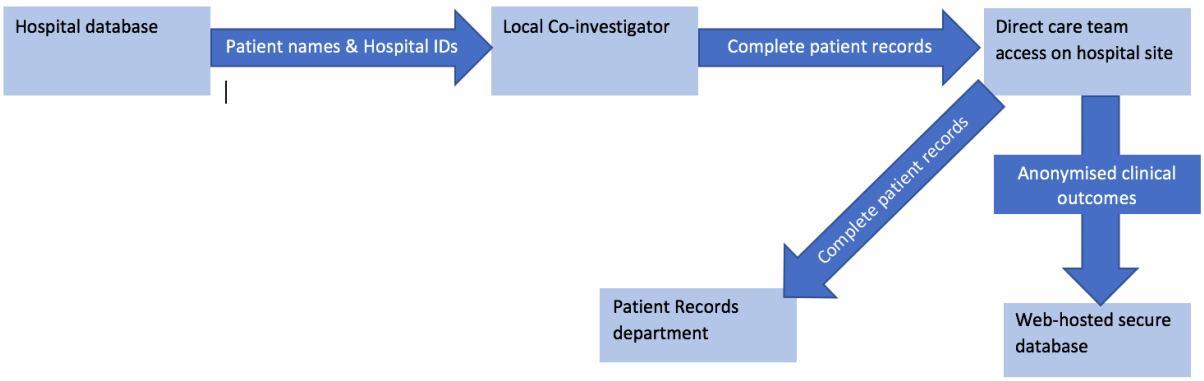
9 Data protection

Data will be collected and retained in accordance with the Data Protection Act 1998.

9.1 Access to data

Data will be gathered and inputted into the anonymised database by the study team at each site, who will members of the direct clinical team. All members of the study team are currently practicing clinicians working within the NHS. A data flow diagram is included below (Figure 2) to illustrate the flow of non-annonymised and anonymised clinical outcome data.

Figure 2. Data flow diagram



9.2 Data handling

Data will be uploaded to a purpose designed database provided by our collaborator, the University of Bristol. Data validation and cleaning will be carried out according to recognised best practice for database use, data validation and data cleaning.

9.3 Data storage

All study data will be uploaded following collation onto a study-specific iteration of a secure electronic database hosted by the University of Bristol (*REDcap*) using password-protected NHS computers.

All data held on secure computing networks (both NHS and University of Bristol) will be protected by using a combination of passwords and file permissions.

All files, paper and electronic data will be transferred to secure archiving no more than 3 years after the end of the study. Data will be stored for 5 years after the study is complete, in line with the MRC Guidance on Personal Information in Medical Research (11). Data procedures will be in keeping with the stipulations in the Data Protection Act 2000.

9.4 Dissemination of findings

All findings will be disseminated via the usual channels, i.e. national and international conferences and published in an open-access peer-reviewed international medical journal. Summaries will also be distributed using existing networks of patients (such as Maternity Voices, a maternity advocacy group within the South West of England). A lay summary of results will also be sent to all units who participated in the study, unless they express the wish not to receive such information.

10 References

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11 Appendix 1

We conducted a search for trials that directly evaluated simulation training in OVB in May 2017.

We searched the Cochrane Central Register of Controlled Trials (CENTRAL), and MEDLINE with the following keyword search: (simulation OR training OR course OR practice) AND (operative vaginal birth OR operative vaginal delivery OR forceps OR ventouse OR kiwi) AND (outcomes OR third degree tear OR post partum heamorraghe OR caesarean section OR success OR failure)

No studies fulfilled these criteria.

12 Appendix 2

Patient and Public Involvement in Research

Summary of patient responses to the STROBE study

Responses collected ante-natal women following attendance at ante-natal assessment unit on 23rd August 2017

All participants are women who are currently pregnant and anticipating a vaginal birth

Prior to discussion the women were presented with a brief precis of the STROBE study

Discussion question: What would your views be if we (the STROBE research team) carried out a review of patient's notes following birth, to gain knowledge about outcomes and the process of our systems and training, along with the type of birth you had, and how the care was delivered? Do you think it would be fair and feel that it is ethical to review such a batch of notes without contacting all of the individuals first?

Participant 1: ST
"That would be fine, I have no real feelings one way or the other. I think it is good that someone is bothering to look into these things."

Participant 2: RG
"I think that is fine, as long as that person's details are kept confidential, and not banded around. But If any harm issues were found, I would hope that would be communicated to the individual."

Participant 3: LB
"I would just be glad people care and everything is being looked into!"

Summary
Participants (representatives of the intended user population) have no objections to reviews of un-anonymised notes for the purposes of the STROBE study
Participants expect the STROBE study to have a robust process in place for the reporting of clinical incidents, and that these should be communicated to the women concerned.