North Bristol NHS
NHS Trust

Practitioner-reported confidence, competence and knowledge following training in assisted vaginal birth: an observational cohort study

Training in Assisted Birth – The TAB Study

This protocol has regard for the HRA guidance

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RESEARCH REFERENCE NUMBERS

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SIGNATURE PAGE

Signatures

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Funder	Bill and Melinda Gates Foundation

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1 Trial summary

Data category	Information
Primary registry and trial identifying number	ISRCTN registration:
Date of registration in primary registry	
Source(s) of monetary or material support	The Bill & Melinda Gates Foundation Limbs and Things Ltd, Bristol BD, Becton Dickinson
Primary sponsor	North Bristol NHS Trust
Contact for public queries	Research & Innovation, Floor 3, Learning & Research Building, Southmead Hospital, Bristol, BS10 5NB, UK Tel: 0117 3233741 Email: researchsponsor@nbt.nhs.uk
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Public title	Training in Assisted Birth: The TAB Study
Scientific title	Practitioner-reported confidence, competence and knowledge following training in assisted vaginal birth: an

Data category	Information
	observational cohort study
Countries of recruitment	United Kingdom
Health condition(s) or problem(s) studied	Assisted Vaginal Birth
Intervention(s)	Simulation training
Key inclusion and exclusion criteria	**Key inclusion criteria for consent** • Qualified doctor and working clinically in obstetrics • Able to provide informed consent **Key exclusion criteria for consent** • Physical disability or injury that would prevent participant from using the investigational device
Study type	Cohort
Date of first enrolment	June 2018
Target sample size	10 to 30
Recruitment status	Not open
Primary outcome(s)	Training success Change in confidence Change in knowledge
Key secondary outcomes	Expectations and experiences of training

2 Summary

This training assessment study aims to explore the effect of simulation training on a novel medical device in obstetrics across several domains.

3 Background

The BD Odon Device is a technological innovation to facilitate the performance of assisted vaginal birth (AVB). The BD Odon Device presents specific features that could potentially reduce the risk of maternal and fetal injury, as its mechanism of action is different to that of forceps and vacuum extraction.

The device is intended for use in AVB in women with term pregnancies and cephalic presentation (occiput anterior, occiput transverse and occiput posterior fetal head positions), who have reached full dilation with the fetal station at or below the level of the ischial spines (station 0 to +3). The placement of the device over the fetal head has been validated in simulation studies (1,2).

The device has been designed to be used by skilled birth attendants who are:

- Trained to recognise the conditions of safe and effective application of the device
- Trained to use the device

The device is made of a film-like polyethylene sleeve developed to be easily applied around the fetal head with the assistance of an inserter. Human Factors studies have been previously conducted (GLH-ODON2, GLH-ODON3, GLH-ODON4, GLH-ODON5 and GLH-ODON6) to assess and identify potential risks associated with the ability of the end user to use the BD Odon Device in simulation with the instructions for use (IFU) developed by the manufacturer. The fourth study (GLH-ODON5) confirmed the validity of the BD Odon Device v4.0, IFU and training materials (3).

A future study (the ASSIST study) will determine if the BD Odon Device is safe, effective and acceptable to women and maternity staff. All staff potentially

undertaking AVB as part of the ASSIST study will attend a half-day training session. This will include an instructional video on the use of the BD Odon Device and intensive 1:1 practical teaching of how to use the BD Odon Device on a high-fidelity pelvic simulator, as part of the current recognised Royal College of Obstetricians and Gynaecologists training course (ROBuST)(4,5).

Studies exploring trainees' exposure to AVB conclude that simulation and training should logically precede clinical experience, allowing for assimilation of basic knowledge and proficiencies in a safe environment (6,7). Simulation has been also suggested as an important training technique to increase trainees' confidence, as well as skills, for AVB (8). However, there are few direct data to support simulation-based training for AVB. A survey of trainees in 2017 demonstrated that trainee comfort levels with AVB is positively correlated with number performed (8). However, this was not the same with confidence levels, suggesting there is likely to be more to gaining confidence than merely the number of births performed.

Simulation based training for intrapartum obstetric emergencies has led to significant improvements in knowledge, behaviours and outcomes (9-11) and this has been both recognised and repeatedly recommended in national reports (12).

3.1 Current Practice

The Royal College of Obstetricians and Gynaecologists (RCOG) guidance on performing AVB has a clear assessment method through the objective structured assessment of training skills (OSATS)(13). This consists of evaluation of generic technical skills and evaluation of key operative steps. The AVB OSATS has four domains that could be assessed in simulation and that correlate with the IFU:

- Correct assembly and checking of equipment
- Correct application of instrument
- Appropriate direction, force and timing of pull. Ensures head descends with traction
- Appropriate alteration of traction with delivery of head

This assessment method does not go into detail on the application of the instrument, which for all methods of AVB (forceps, vacuum extraction and the BD Odon Device) has many steps to achieve this and is very different depending on the device used. We therefore have used the 20 steps on the IFU as the assessment steps, which include the domains assessed in AVB OSATs.

3.2 Proposed development

This evaluation is a simulated use study aiming to explore the effect of training of a novel medical device in obstetrics. The results from this study may be correlated with future research results. The study will not involve human subjects or materials derived from human subjects.

4 Objectives

4.1 Primary objectives

a) To determine whether the training package successfully teaches participants to perform a simulated delivery with the BD Odon Device.
b) To determine whether the training package successfully teaches participants to verbally recall the operative steps of an AVB with the BD Odon Device.
c) To determine whether the training changes participant's confidence with performing an AVB with the BD Odon Device.

4.2 Secondary objectives

d) To investigate participant expectations and experiences of training.
a) To investigate the relationship between perceived adherence to IFU and observer scoring.
b) To investigate the change in knowledge following training.

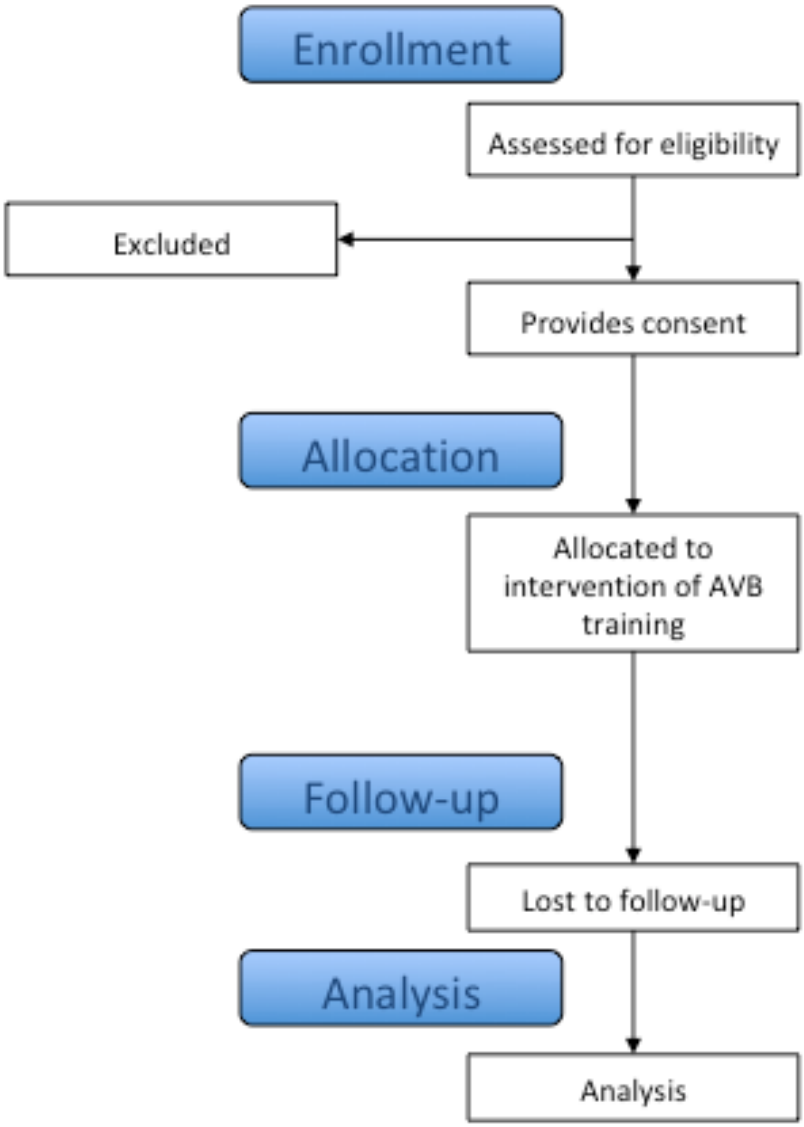
5 Plan of investigation

5.1 Study design

The TAB study is an observational cohort study of obstetricians undertaking training assessments for AVB using the BD Odon Device.

A CONSORT diagram of the cohort study is shown in Figure **1**.

Figure 1 CONSORT diagram of training assessment study



5.2 Participant population

Participants will be at least ten obstetricians recruited through semi-structured AVB training courses and semi-structured internal AVB training.

5.3 Setting

Southmead Hospital, North Bristol NHS Trust, Bristol.

5.4 Intervention

Participants will undertake an assisted vaginal births training session. This will include an instructional video on the use of the BD Odon Device and intensive 1:1 practical teaching of how to use the BD Odon Device on a high-fidelity pelvic simulator. Training will also include revision and practice in the correct technique for using ventouse and forceps. Staff will be exposed to AVB training, including hands-on practical teaching on a high-fidelity pelvic simulator, as part of the current recognised Royal College of Obstetricians and Gynaecologists training course, ROBuST (4).

5.5 Sample size

The participants will be divided into two distinct groups of intended users:

- Obstetricians with no BD Odon Device experience (Odon naïve)
- Obstetricians with previous BD Odon Device experience

The study will recruit a minimum of five to ten naïve BD Odon Device participants and a minimum of five to ten participants with previous BD Odon Device experience in simulation. We will endeavour to recruit across the spectrum of expertise from early-career trainees to experienced accouchers.

5.6 Study design

This study will be conducted in compliance with this protocol, Good Clinical Practice (GCP) and any other applicable regulatory requirements.

The study will occur over six months at North Bristol NHS Trust, Bristol, UK. Each user will participate in one or several visits, depending on availability and convenience. All participants will provide informed, written consent to take part in this study.

5.6.1 Inclusion criteria for all participants

- Participant should be a qualified doctor, currently practicing in obstetrics
- Currently employed in a clinical setting
- Able and willing to provide a signed consent form

5.6.2 Exclusion criteria for all participants

- Has a physical condition or injury which would make them unable to perform study procedures
- Works for a medical device company

Participants who read and sign the consent form and who have satisfied all inclusion/exclusion criteria will be considered enrolled into this study.

5.7 Participant agreement

Before participation, a signed and reviewed consent form must be obtained from each participant. Participants will be provided with a participant information sheet Participants that do not agree to complete or are unable to sign the consent form will not be able to participate. Participants can request a signed copy of the consent form for their records.

5.8 Confirmation of eligibility/subject numbering

Participants will only be identified by a study-specific ID number.

Minimal background information will be collated including; years of professional experience, grade of current practice and handedness.

Participants that do not meet the inclusion criteria will be designated as screening failures and will be unable to participate. Screening failure will be documented in the study source documentation.

Participants meeting all eligibility criteria will be consented and considered enrolled, and will be assigned a unique, one-letter, three-digit subject identification number such as D001.

5.9 P.I.C.O Model

Participants

Obstetric clinicians who are attending AVB training, including training of the BD Odon Device, who have had previous exposure to the BD Odon Device.

Intervention

Simulation training session on AVB, including training of the BD Odon Device.

Comparator

Obstetric clinicians who are attending AVB training, including training of the BD Odon Device, who are Odon naïve.

Outcomes

Training success, change in confidence, change in knowledge and training expectations and realities.

5.10 Study assessment process

Assessment will be based on five domains. Figure **2** demonstrates the pre-training domains and Figure **3** demonstrates the post-training domains.

Figure 2. Pre- training assessment domains

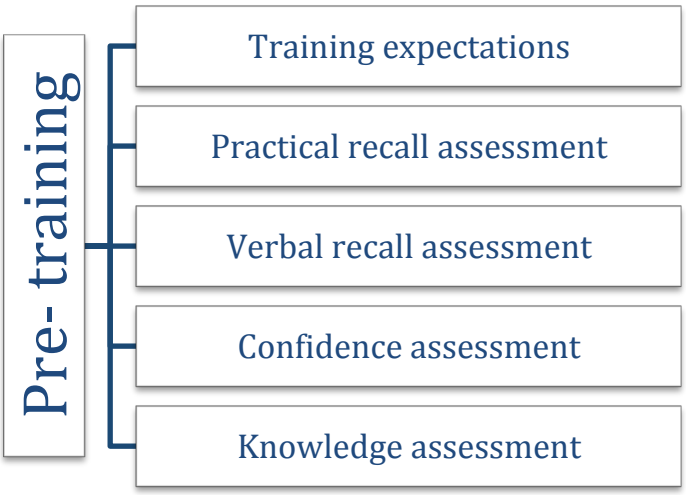
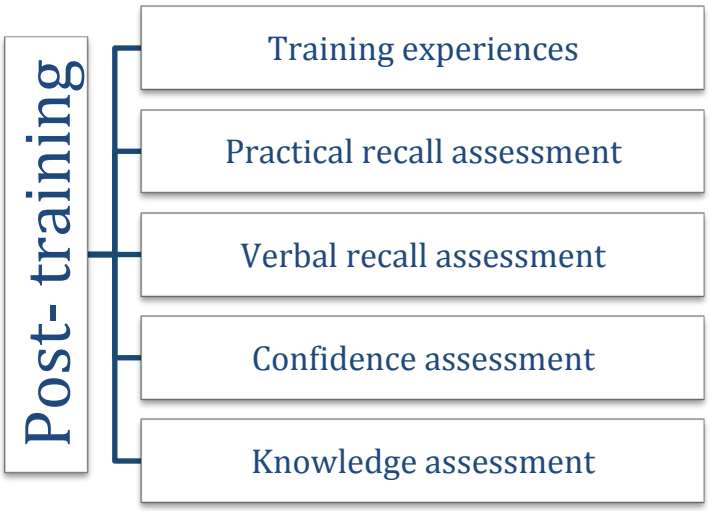


Figure 3. Post-training assessment domains



Each domain demonstrates the different assessments that the participants will undertake. Proposed timeline can be seen in appendix 1.

Throughout the assessment process, each participate will be evaluated on the BD Odon Device and accompanying IFU. The BD Odon Device will be used via simulated application on a PROMPT simulator.

Pre-training assessments

Pre-training assessments will start by enquiring about the participants training expectations.

Participants will then be given a BD Odon Device and the accompanying IFU to study for at least five minutes. The participants will continue to be provided with the IFU and will be asked to perform one simulated procedure. During the performance of the procedure, the observer will evaluate the participant's capability of the performed procedure. We will also ask participants to record how confident they were with adhering with the IFU following the simulated delivery. All scores will be recorded on the CRF (appendix 2). Participants will be assess on verbal recall without being given further access to the IFU. They will be assessed on their ability to successfully learn how to use the device solely by reading the IFU.

Participant confidence will be assessed upon their simulated delivery using the BD Odon Device using a modified version of a six-item, five-point tool previously validated for gynaecology trainees to measure self-confidence (14) and that has already been adapted to assess confidence in AVB (8).

Finally, participants will be asked five questions about their knowledge of AVB with the BD Odon Device. These questions require free text responses and have been devised by a multi-disciplinary team.

Post-training assessments

Post-training assessments will start by enquiring about training experiences, what was good, less good or could be improved. Participants will be asked what their training expectations were and whether these were met.

Thereafter, the same procedures for the remaining four domains will take place, enabling direct-paired comparisons between pre- and post-training.

Participants will be given a BD Odon Device and the accompanying IFU to study for at least five minutes. The participants will continue to be provided with the IFU and will be asked to perform a simulated procedure. During the performance of the procedure, the observer will evaluate the participant's capability of the performed procedure. We will also ask participants to self-score their delivery. All scores will be recorded on the CRF (appendix 3).

Without referring to the IFU, the participants will then assessed on verbal recall.

Finally, participant knowledge and confidence will be re-assessed.

6 Study administration

6.1 Responsibilities

The Principal Investigator (PI) is responsible for approving the study protocol, overseeing the use of the products, scheduling the protocol procedures, ensuring that the required documentation is completed, tracking subject test results, approving study conclusions/reports and otherwise ensuring the overall compliant executions of the clinical study as detailed in the protocol. PI will designate appropriate study staff and ensure they are properly trained in all aspects of the protocol.

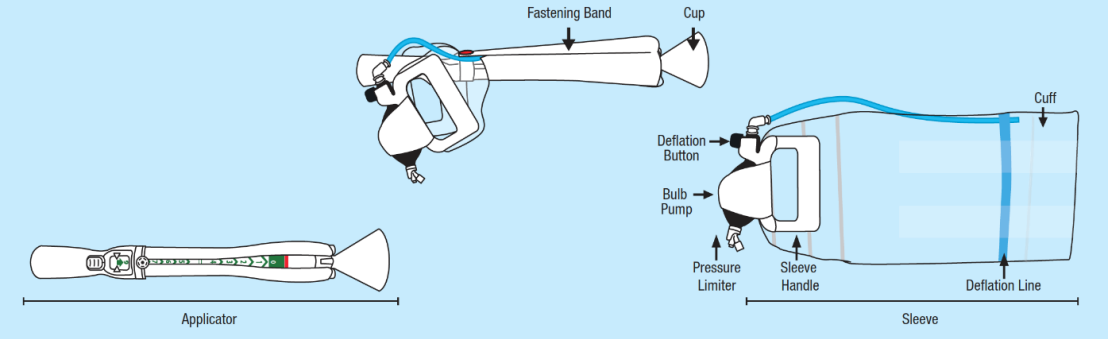
The PI will ensure that:

- Potential candidates have the appropriate qualifications
- Ensure that the consent form is signed by all potential participants
- Study staff provide the instruction to the participants at the time of the start of the evaluation
- Study staff serve as study observers
- Study staff correctly complete the required CRFs
- Transcribe the written responses for the appropriate sections of the CRFs

6.2 Study materials

The BD Odon Device (Figure **4**) is a technological innovation to facilitate the operative vaginal births. In comparison with available instruments for operative vaginal birth (forceps and vacuum extraction), the BD Odon Device works by a different mechanism and therefore, presents specific features that could potentially reduce the risk of maternal and neonatal injury. IFU have been developed by the manufacturer to accompany the BD Odon Device. During the study, the BD Odon Device will be used on a high-fidelity pelvic mannequin (PROMPT mannequin) that is widely used for simulation and teaching of obstetric procedures worldwide, including operative birth.

Figure 4. BD Odon Device components



7 Study methods

7.1 Subjects

No patient subjects will be recruited for this evaluation. The study will use the PROMPT simulators produced by the company Limbs and Things.

7.2 Withdrawal

Participants are free to withdraw from the study at any point. If a participant, who has given informed consent, looses capacity, the participant and all identifiable data collected would be withdrawn from the study.

7.3 Participant demographics

Participants will be asked regarding:

- Previous exposure to BD Odon Device
- Handedness
- Year of professional experience
- Current grade of profession
- Current estimate of usage of forceps and vacuum extraction per month

7.4 Training expectations and experiences

Participants will be asked to complete questions regarding their training expectations and training realities. The answers will be in the format of a free-text box.

7.4.1 Practical recall assessment

Preparation:

- Participants given the IFU and a BD Odon Device
- Participants given at least five minutes to read the IFU
- Prepare the PROMPT simulator for device simulation, with the fetal mannequin in the occiput anterior position and station +2

Practical assessment:

- Participants asked to perform one simulated delivery with the BD Odon Device
- Participants asked to score how well they felt they adhered to the IFU

7.4.2 Verbal recall assessment

Preparation:

- None

Recall assessment:

- Participants asked to verbally recall how to perform a delivery with the BD Odon device without assistance from IFU.

7.4.3 Confidence assessment

Participants will be asked to answer a five-item, five-point assessment tool for evaluating confidence during an AVB procedure.

7.4.4 Knowledge assessment

Participants will be asked to answer five free-text questions about the device use and their knowledge of the IFU.

7.5 Critical tasks

'Critical task' is defined as a user task, which if performed incorrectly or not performed at all, would or could cause serious harm to the patient or used, where harm is defined to include compromised medical care.

Based on previous Human Factor studies all operational steps in the IFU (with the expectation of step 1) are considered to be critical tasks.

This study will assess the IFU (with the exception of steps 1 and 2) which refer to maternal and fetal conditions for safe use and maintaining sterility when opening the device which are not relevant when using in simulation.

7.6 Protocol incident/deviations

Procedures and forms for reporting clinical trial incidents/deviations will be provided during site initiation prior to study execution.

7.7 Data collection and quality

Trained observers will have the responsibility for observing and scoring the training assessments. Observers will be trained and experienced with the utilisation of the device being assessed. Observers will ensure data is collected correctly on the CRF.

Observers will review the CRFs for completion and accuracy prior to participant completing the study.

All data entered to a paper CRF should be made clearly in black or dark blue indelible ballpoint pen to ensure the legibility of self-copying or photocopied pages. If there are any mistakes, study staff must place a single horizontal line through any incorrect entry, so that the original entry can still be seen, and place a revised entry beside it. The revised entry must be initialled and dated by a team member. Correction fluid must not be used.

All participants, from the time they give consent to participation in the study, will have an individual participant file kept in the research office. All original forms will be kept in this file. All data recorded on paper relating to the participant will be located in these files.

7.8 Management and storage

All data held on secure computing networks (clinical and/or 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 within two years after the end of the study. Data will be stored for five years after the study is complete.

7.9 Data analysis

The following summaries will be performed:

- Background information: will be reported as frequency and proportions (mean, standard deviation, minimum and maximum or median and interquartile range, depending on the variable distribution). Categorical variables will be reported as frequency and proportions.
- Free text responses describing training expectations and experiences will undergo thematic analysis (manually or using NVivo dependent on volume of data).
- Verbal and practical recall assessments: will be reported as frequency and proportions, tabulated by clinical expertise or Odon naïve or not.
- Confidence assessment: will be reported as frequency and proportions, tabulated by clinical expertise or Odon naïve or not.
- Knowledge assessment: will be categorised into right, wrong and partially right. Categorised results will the reported as frequency and proportions.

Specific analysis details related to study outcomes:

a) Success is defined by all 20 steps being performed, therefore results will be dichotomised into success or not. Results will be reported a frequency and proportions pre and post training as well as by clinical expertise.
b) Success is defined by all 20 steps being performed, therefore results will be dichotomised into success or not. Results will be reported a frequency and proportions pre and post training as well as by clinical expertise.
c) Each item in part 5 will be reported as frequency and proportions pre and post training. Change in proportions will be examined. Non-parametric test for paired samples will be undertaken. Depending on the sample size some comparisons within professional expertise will be attempted.
d) Qualitative analysis will be undertaken using thematic analysis to identify any commonalities and differences across participants.
e) Correlation between total score of part 3A and response to part 3B will be undertaken pre and post training.
f) For each question in part 6, the participant answer will be categorised into right (R), wrong (W) or partially right (P). For each participant we will count

the number of R responses (0-5) pre training and compare this to the post training count using a non-parametric paired test. If there is a difference we will explore each domain individually.

Qualitative data will be analysed manually or using NVivo and statistical analysis will be conducted using R or Stata.

7.10 Risk analysis

No human subjects or human materials will be involved in the assessment of the device.

Participants enrolled in the study are subject to minimal health risk from the use of the device. It is recognised that being assessed on an unfamiliar device maybe felt as stressful by some participants, all participants will be made aware of this before signing the consent form and will be made aware that they can withdraw at any time. It will have no impact on participants training or medical practice (if applicable), all results are kept confidential.

No exposure hazard is expected. The BD Odon Device has been manufactured according to current manufacturing processes. All study staff are required to follow the site's Standard Operating Procedures (SOPs). The risk to study staff is minimised by compliance with procedures. All safety events will follow the site's SOPs.

8 Ethical considerations

8.1 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)

- UK Policy Framework for Health and Social Care

8.2 Ethical Review

Approval from a Research Ethics Committee service (UK) is required.

8.3 NHS approval

Approval from the North Bristol NHS Trust Research & Innovation Department is required prior to the start of the project in the UK.

8.4 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 and subsequent relevant legislation.

9.1 Data handling

Data will be uploaded to a purpose-designed database. Data validation and cleaning will be carried out according to recognised best practice for database use, data validation and data cleaning.

9.2 Data storage

All original data collection forms will be stored within the participant files, in a locked filing cabinet in the secured trial office. All study data will be uploaded following collation onto a study-specific iteration of a secure electronic database using password-protected computers.

9.3 Archiving

All data held on secure computing networks (clinical and/or 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 within two years after the end of the study. Data will be stored for five years after the study is complete. Data procedures will be in keeping with the stipulations in the Data Protection Act 2000.

9.4 Data access

Complete anonymised datasets generated by the trial and any further correlations will be made publicly available on an online research depository hosted by the University of Bristol. The DOI for this depository will be included in the published results of the trial.

9.5 Dissemination of findings

All findings will be disseminated via the usual channels, i.e. national and international conferences and published in a peer-reviewed international medical journals.

We will collaborate with international professional bodies such as the RCOG to implement best practice in maternity settings across the world.

Furthermore, data from the study may will be included within the official RCOG-endorsed assisted birth training program, ROBuST.

9.6 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.

9.7 Financial disclosure

EH is a clinical research fellow with a post funded by BMGF

10 References

1. O'Brien SM, Winter C, Burden CA, Boulvain M, Draycott TJ, Crofts JF. Fetal head position and perineal distension associated with the use of the BD Odon Device™ in operative vaginal birth: a simulation study. BJOG: An International Journal of Obstetrics & Gynaecology. 1st ed. 2017 Sep;124(11):10–8.

2. O'Brien SM, Winter C, Burden CA, Boulvain M, Draycott TJ, Crofts JF. Pressure and traction on a model fetal head and neck associated with the use of forceps, Kiwi™ ventouse and the BD Odon Device™ in operative vaginal birth: a simulation study. BJOG: An International Journal of Obstetrics & Gynaecology. Wiley/Blackwell (10.1111); 2017 Sep 1;124(11):19–25.

3. O'Brien SM, Mouser A, Odon JE, Winter C, Draycott TJ, Sumitro T, et al. Design and development of the BD Odon DeviceTM : a human factors evaluation process. BJOG: An International Journal of Obstetrics & Gynaecology. 2017;124 Suppl 4:35–43.

4. Attilakos G, Draycott T, Gale A, Siassakos D, Winter C. ROBuST: RCOG Operative Birth Simulation Training. Cambridge: Cambridge University Press; 2013.

5. RCOG. Operative Vaginal Delivery: Green–top Guideline No. 26. London: RCOG; 2011.

6. Bahl R, Murphy DJ, Strachan B. Decision-making in operative vaginal delivery:

when to intervene, where to deliver and which instrument to use? Qualitative analysis of expert clinical practice. Eur J Obstet Gynecol Reprod Biol. 2013;170(2):333–40.

7. Yeomans ER. Operative vaginal delivery. Obstetrics & Gynecology. 2010 Mar;115(3):645–53.

8. Crosby DA, Sarangapani A, Simpson A, Windrim R, Satkunaratnam A, Higgins MF. An international assessment of trainee experience, confidence, and comfort in operative vaginal delivery. Ir J Med Sci. 2017;186(3):715–21.

9. Crofts JF, Lenguerrand E, Bentham GL, Tawfik S, Claireaux HA, Odd D, et al. Prevention of brachial plexus injury—12 years of shoulder dystocia training: an interrupted time-series study. BJOG: An International Journal of Obstetrics & Gynaecology. 2016;123(1):111–8.

10. Crofts JF, Fox R, Draycott TJ, Winter C, Hunt LP, Akande VA. Retention of factual knowledge after practical training for intrapartum emergencies. Int J Gynaecol Obstet. 2013;123(1):81–5.

11. Crofts JF, Bartlett C, Ellis D, Hunt LP, Fox R, Draycott TJ. Training for shoulder dystocia: a trial of simulation using low-fidelity and high-fidelity mannequins. Obstetrics & Gynecology. 2006;108(6):1477–85.

12. O'Neill O. Safe Births: Everybody's business. King's Fund; 2008 Jan.

13. RCOG. RCOG: Core OSATS [Internet]. [cited 2018 May 4]. Available from: https://www.rcog.org.uk/globalassets/documents/careers-and-training/core-curriculum-pre-august-2013/ed-core-osats.pdf

14. Geoffrion R, Lee T, Gynaecology JSJOOA, 2013. Validating a self-confidence scale for surgical trainees. Elsevier

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