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Design and development of the BD Odon Device™: a human factors evaluation process

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Running title: Using human factors evaluation to improve the BD Odon Device™

Abstract

Objective

To (i) determine how intended users interact with and use the BD Odon Device in simulation, (ii) use these findings to progressively alter the design of the BD Odon Device and (iii) validate that these changes have improved the ability of practitioners to use the BD Odon Device

Design

Human Factors evaluation study

Setting

Simulation suite designed to mimic delivery room.

Population or Sample

390 simulated operative births, performed by 100 practicing clinicians.

Methods

Simulated operative vaginal births performed using the BD Odon Device and Instructions For Use were subjected to four human factors evaluations. Following each evaluation, findings were reviewed and the design of the BD Odon Device and Instructions For Use were modified.

Main Outcome Measures

Successful performance of steps required to perform an operative vaginal birth using the BD Odon Device in accordance with provided training and Instructions For Use.

Results

Using version one of the BD Odon Device, and following exposure to face-to-face training and written instructions, 25% of accouchers were able to successfully perform a simulated operative vaginal birth. In the final evaluation, following device design and training material

alterations, all accouchers were able to successfully perform a simulated operative vaginal birth using version four of the BD Odon Device.

Conclusions

Human factors evaluations have enabled a multi-professional device and training materials design team to alter the design of the BD Odon Device and the Instructions for Use in an evidence-based fashion. This process has resulted in a device which has a predictable and likely safe pattern of use.

Keywords

BD Odon Device, use, improvements, human factors

Introduction

Operative vaginal birth (OVB) is an important skill that can improve outcomes for mothers and their babies (1). However, performing an operative vaginal delivery is a complex, time critical technical skill and the misuse of forceps or vacuum can lead to significant injury to the mother and/or her baby (2). Such concerns led to the Food and Drug Administration (FDA) in the USA to release a Public Health Advisory Paper explaining the need for caution when using vacuum assisted delivery devices (3). Similar concerns have been expressed about the use of forceps (4). While forceps and vacuum are not inherently dangerous, inappropriate patient selection, level of technical skill or poor team working in using the instrument can all interact and have a significant effect on their safety.

The introduction into clinical practice of a new medical device to expedite vaginal birth is complex and requires detailed investigation; when is the device best used, for whom should the device be used, how is the device best used and how do clinicians train to use the device? The unique features of the BD Odon Device™ (Becton, Dickinson & Company, Franklin Lakes, NJ, USA) (e.g. air chamber and sleeve) seem to offer advantages in clinical practice but the novelty of the design means that the technique required for the BD Odon Device is markedly different from those employed during a forceps or vacuum assisted delivery. Therefore, before it is introduced into clinical practice it is crucial to ensure that accoucheurs use the BD Odon Device in a safe and effective manner. Ideally, the use of the BD Odon Device should be understandable, intuitive and reproducible. Moreover, the BD Odon Device and IFU should demonstrate that they can be used by representative users without producing patterns of failures that could result in poor clinical outcomes or harm to clinicians.

Human Factors Evaluation (HFE) focuses on the interactions between people and devices and is used to ensure that medical devices are as safe, reliable and effective as possible (5). Human Factors Evaluations are used to refine and improve the user-device interface. This interface includes all components with which users interact with the device; preparing the device for use (e.g. unpacking and set up) and using the device (e.g. how users perceive and interpret the information from the device, make decisions about what to do, and manipulate the device during use). Human Factors evaluations provide evidence to ensure that a device does not lead to failures and that the risk controls made by the design team, by altering the device or the supporting training materials are effective. The most important goal of the human factors evaluation process is to minimize use-related hazards and risks and thus improve safety (5).

This paper describes the human factors evaluations conducted to determine the usability of the BD Odon Device and describes the iterative modifications to the design of device (and associated Instructions For Use (IFU) and training materials) in response to user feedback.

Methods

Three formative evaluations and one Human Factors Validation Test (HFVT) were conducted. Participants in the formative evaluations were practicing midwives and obstetricians from South West of England and all testing was conducted in Southmead Hospital, Bristol, UK. Participants in the validation test were recruited from 14 countries (UK, Ireland, Germany, Spain, Italy, Denmark, Egypt, Nigeria, South Africa, Kenya, Jordan, India, Nepal and Australia). Testing was conducted in Southmead Hospital, Bristol, UK, the Pump Rooms, Bath, UK, and the RCOG Annual Congress 2017, Cape Town, South Africa. Each participant performed a

series of structured simulations of an operative vaginal birth using the BD Odon Device to deliver a fetal mannequin from an anatomical accurate maternal mannequin (PROMPT Flex, Limbs and Things Ltd, Bristol, UK) (6). In each simulation the fetal mannequin was placed in a cephalic presentation, in the occipito-anterior (OA) position, with the vertex 2cm below the ischial spines. To increase the environmental validity of the simulations, all assisted births were performed in a setting design to mimic a delivery room, with the maternal mannequin lying on a delivery bed or table. All simulations and interviews were recorded on a stationary video camera (GoPro Hero4 Session, GoPro, San Mateo, California, USA) and observed by an Obstetrician (SOB), Human Factors Expert (AM), Design Engineer (DA, TS or WLL). The inventor of the BD Odon Device (JO) was present for the majority of simulations.

Participants were provided with a prototype BD Odon Device and asked to attempt to deliver the fetus using the device. Expediting birth using the BD Odon Device requires three distinct stages to be completed by the operator: (i) preparation of the device, (ii) application of the device into the correct position around the fetal head, and (iii) use of traction to deliver the fetal head. These three stages, together with the individual steps required in each stage, are outlined in **Error! Reference source not found..**

At the start of rounds one, two and three (formative rounds) each participant was randomized to one of four groups: (i) using the device with no instructions for use (IFU), (ii) using the device after reading a copy of the current IFU, (iii) using the device after face-to-face training, and (iv) watching a training video. During the final validation evaluation, all participants were exposed to one-to-one training and the IFU before attempting to use the device. The individual objectives of each study varied based on the findings of the previous study and subsequent design changes made by the study team to the device and IFU, while the overall objective (to determine how participants interacted with the BD Odon Device

and IFU, and to mitigate any patterns of use which would compromise the safety and efficacy of the device) remained the same.

The ability of participants to perform each phase and step was recorded after their exposure to different training materials (IFU, video and one-to-one training). A step was defined as being successfully completed if it was performed safely, correctly and in the correct sequence.

Following the simulations participants were questioned on the design of the device and their understanding of (i) the BD Odon Device, (ii) the IFU, (iii) the face-to-face training module and (iv) training video.

Following each Human Factors Evaluation, the multi-professional device development team comprising Obstetricians, Midwives, Human Factor Specialists and R&D Engineers used the study findings to iteratively modify the device and associated IFU and training materials to address any user difficulties and/or risks observed during simulations. These evidence-based changes were evaluated in the subsequent round of testing to ensure the previously uncovered user errors had been mitigated and no new risks or problems had been created. Simulations and interviews were structured in accordance with Human Factor Evaluation guidance from the FDA and the Medicines and Healthcare products Regulatory Agency (MHRA) (5,7). The study was approved by the North Bristol NHS Trust Research & Innovation Department (Study Number 3671) on 29th February 2016. As per the UK Health Departments' Governance Arrangements for Research Ethics Committees (GAfREC) this study did not require ethical approval.

Results

Three formative studies and a Human Factors Validation Study were undertaken. Three hundred and ninety simulated births were conducted using the BD Odon Device. In total 100 naïve participants who had not previously been exposed to the BD Odon Device participated. The demographics of the four cohorts are summarised in Table .

The percentage of participants able to correctly perform at least 50% and 75% of the steps required in each phase (preparation, application and delivery) of the use of the BD Odon Device are provided in

. These data are further classified by device version (version two, three or four) and type of training (no IFU, IFU alone, IFU and one-to-one training, IFU and video) and the attempt number.

There was no significant difference between the ability of midwives and obstetricians to perform an operative vaginal birth using the BD Odon Device (Table).

Formative round one (March 2016)

Thirty-five staff (15 midwives and 20 obstetricians) participated during the first formative study.

Version two of the BD Odon Device was not intuitive to use. During this evaluation only two of the 11 (18%) participants who were presented with the BD Odon Device and asked to conduct a simulated OVB (i.e. they did not see the IFU or receive any training) were able to complete at least 50% of the steps required for preparation. None of the 11 participants were able to correctly apply the device to the fetal head or deliver the baby. However, when 28 participants were provided with a copy of the IFU prior to attempting to conduct an OVB with the BD Odon Device, 25 (89%) were able to complete at least 50% of the steps

required for preparation. Yet, despite having a copy of the IFU, only eight (29%) participants were able to complete at least 50% of the steps required for application of the device and delivery of the baby. The addition of one-to-one training significantly increased the ability of participants to correctly use version two of the BD Odon Device ().

In response to observation of the device in use and participant feedback during the first formative evaluation, modifications were made to the design of the associated IFU and training materials (Table). Suggested device design mitigations were generated from this round of testing but not actioned as alterations to the device design at this stage.

Formative round two (May 2016)

Following modifications to the training materials in response to the findings of during formative round one (Table), 11 naïve staff (seven midwives and four obstetricians) participated in formative round two. No changes have been made to the design of the device following formative round one. Formative round two was conducted using version two of the IFU and version two of the device. In addition, a three-minute video was created to outline the correct technique in the preparation, application and delivery of the baby using the BD Odon Device. After exposure to the IFU only, none of the five participants able to successfully assist the birth of the fetal mannequin. However, when participants were able to watch the training video and were provided with a 10-minute one-to-one training session, all 11 participants were able to successfully deliver the fetal mannequin ().

The majority of new suggested changes generated by the evaluation related to the training material rather than the device itself (

Table). For example, to increase participant knowledge acquisition and retention, the training video was revised. The video was slowed down and segmented, with written 'bullet point' subtitles of information accompanying each individual step required to perform an operative vaginal birth using the BD Odon Device.

Formative round three (September 2016)

Prior to formative round three, modifications were made to the design of the device (those generated from both formative one and two, Tables 5 and 6). For example, the grip on the '*Applicator*' was enhanced to enable greater traction during removal of the '*Applicator*', and the '*Viewing Window*' (through which the operator can gauge how far the air cuff has travelled over the fetal head) was given a larger, relief border, to make it easier for the '*Viewing Window*' to be recognised by users. Minor modifications were also made to the training materials (generated from formative round two, Table).

Eighteen naïve staff (eight midwives and ten obstetricians) participated in formative round three, which was conducted using versions three of the BD Odon Device and training video, and version three of the IFU.

Participants were more likely to be able to correctly use the BD Odon Device in all three stages (preparation, application and delivery) following exposure to the device and IFU alone compared to formative round one (78% during formative round three, compared to 25% in formative round one). Following exposure to all training materials, all participants (18) were able to complete more than 75% of steps correctly in all stages of an OVB using the BD Odon Device. All 18 participants who successfully applied the device were able to successfully deliver the fetal mannequin.

Following formative evaluation round three, minor changes were made to the device and training materials - listed in Table .

Human Factor Validation Testing (March 2017)

Following minor modifications to the device and training materials made after formative round three (Table), a Human Factors Validation Test was undertaken. The purpose of the HFVT was to definitively demonstrate that the BD Odon Device and corresponding IFU and training can be used by accouchers without producing patterns of failures that could result in a negative impact to patients or harm to users. 36 naïve staff (18 obstetricians and 18 midwives) from 14 countries (UK, Ireland, Germany, Italy, Spain, Denmark, Nigeria, South Africa, Kenya, Egypt, Jordan, India, Nepal and Australia) participated in the HFVT.

Following exposure to face-to-face training and the IFU, at their third assessed attempt, all participants were able to successfully complete more than 75% of all steps required for use of the device (**Error! Reference source not found.**). All participants were able to successfully deliver the fetal mannequin.

Discussion

This is the first published study of the use Human Factors Evaluation to systematically evaluate and iteratively improve the design and training materials of a new obstetrical instrument to expedite vaginal birth. The findings highlight the value of formal human factors testing before a novel device is introduced into clinical practice. The observation of midwives and obstetricians using the device in a simulated setting revealed numerous potential user errors and difficulties that have now been mitigated through revision of both the device design and the associated training materials. All simulated births were observed

by an Obstetrician, R&D Engineer, the device Inventor and an expert in Human Factors. This multi-professional approach ensured that when a problem was identified, a solution could be rapidly developed, implemented and evaluated.

When presented with version three of the BD Odon Device and the associated training materials, all accouchers were able to successfully deliver a fetal mannequin using the device in a safe and competent manner, compared to 25% of accouchers using version two of the device and training materials. This finding suggests that the version four of the BD Odon Device is more intuitive and the training materials are more accessible and understandable to accouchers; a significant improvement when compared to version two.

The observation of 390 simulated operative vaginal births using the BD Odon Device informed numerous improvements to the device design, and also provided an opportunity to modify the associated IFU and training materials after the identification of common user errors. The use of simulation for investigation, rather than training, has previously been successfully used in obstetrics and has been associated with reduction in neonatal injury: the observation of 450 simulated births complicated by shoulder dystocia highlighted common user errors and provided an evidence base for practical training (8). The subsequent implementation of evidence based shoulder dystocia training was associated with an elimination of permanent neonatal brachial plexus injury associated with shoulder dystocia in one unit (9). Many neonatal injuries associated with vacuum or forceps are linked to user error (10), and therefore it is vital to learn from user errors and adapt training to mitigate risks associated with misuse before the BD Odon Device is introduced into clinical practice.

Participants had most difficulty preparing and applying the device, and comparatively little difficulty in using the device to deliver the fetal head once the device had been applied. In the second and third round of testing all participants who successfully applied the device were able to successfully deliver the fetal head. It is perhaps not surprising that participants struggled with the initial stages as the preparation and application of the device requires a completely novel technique. However, once the BD Odon Device is applied, the technique required to achieve a vaginal birth has similarities to that used during births assisted with both forceps and vacuum. Indeed, delivering the fetal head using a BD Odon Device mimics the dynamics of a spontaneous vaginal birth, a concept that should be familiar to all accoucheurs. When training accoucheurs to use the BD Odon Device the relative novelty of the preparation and application stages must be considered.

We chose to recruit both midwives and obstetricians to the study. Whilst specifically UK midwives are not the initial intended end-users of the BD Odon Device (although midwives in other international settings where midwifery practice routinely includes OVB may be), UK midwives in this study (represented in formative rounds one, two and three) represent a cohort of accoucheurs who are clearly familiar with the dynamics of a spontaneous vaginal birth, but have never performed an instrumental birth. When launched into practice it is hoped the BD Odon Device will be used to reduce morbidity in settings where instrumental birth is not currently commonly performed (11). Accoucheurs working in this environment will be familiar with the dynamics of a spontaneous vaginal birth, but are likely to be relatively unfamiliar with instrumental births. The device will also provide an alternative instrument to obstetricians who frequently perform instrumental births using forceps and/or vacuum. As such the intended end-users of the BD Odon Device will have vastly

different prior experience of instrumental birth; this may affect how users interact with, and use, the device. In an attempt to address this issue, we recruited midwives and obstetricians across a spectrum of clinical experience to participate in the study. It is encouraging, therefore, that following training there was no significant difference between the performance of midwives and obstetricians, using either the initial or final version of the BD Odon Device, IFU and training materials (Table).

The techniques required to perform an operative vaginal birth using non-rotational forceps or vacuum are broadly standardised in internationally recognised national guidelines (Royal College of Obstetricians and Gynaecologists (12), American Congress of Obstetricians and Gynecologists (13), Royal Australian and New Zealand College of Obstetricians and Gynaecologists (14) and the Collège National des Gynécologues et Obstétriciens Français (15)) and we therefore do not anticipate that experienced users from different settings will interact with the device in a significantly different manner. This is in addition to the results of the Human Factors Validation Test within our study, which demonstrated similar levels of success across participants of 14 separate national backgrounds (Table). This suggests that there is a common degree of understanding of the process of normal and assisted birth amongst the intended future end-users of the BD Odon Device. This commonality of knowledge would potentially allow a desirable distributed model of training to be successful. Models such as this, where skills are taught by centrally-trained local faculty to local trainees, and which have previously been used to disseminate 'best-practice' strategies to deal with universal obstetric procedures, such as manoeuvres for shoulder dystocia, have been demonstrated to result in sustained knowledge acquisition (16), to be relatively low-cost (17), and to improve real-world outcomes in a variety of settings (9,18,19).

The adoption of the BD Odon Device into clinical practice necessitates the acquisition of a new skill by accouchers. This study has demonstrated that, with an appropriately designed device and simple training package, clinicians of all abilities are able to acquire and utilise the required skills efficiently and effectively. The challenge of introducing a novel medical device into obstetric practice should not be underestimated. However, the collaboration between clinicians, R&D engineers and human factor specialists has provided a rigorous evaluation and rapid cycles of iterative improvement of both the device and training package. The Human Factors Evaluations have not only aided in the development of the BD Odon Device and IFU, but have also ensured that the BD Odon Device is able to be used safely and intuitively as practicably possible prior to *in-vivo* testing.

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We would like to acknowledge all participants who generously gave their time to participate in this study

Disclosure of Interests

SO'B, CW, TD & JC are members of the BD Odon Device Scientific Advisory Board. Members of the Board receive no honoraria, and solely received reimbursement of travel and accommodation expenses to attend meetings of the Board.

JC, TJD, and CW are members of the PROMPT Maternity Foundation (a registered charity in England and Wales). They receive no financial benefit from this association.

CW and TD have been seconded to work with the PROMPT Maternity Foundation from North Bristol NHS Trust.

TD has acted as an independent advisor to Limbs and Things. TD has received payment for travel to meetings from Laerdal and has received payments for educational initiatives by Ferring pharmaceuticals.

AM, WLL, TS, DA, MM and AS are employees of BD. JO is employed as a consultant to BD. BD hold an exclusive license to develop and market the BD Odon Device.

Contribution to Authorship

All authors contributed to conception and design of the study. AM was responsible for the development of the design and methodology of HFE evaluations. SO'B & AM conducted all data gathering. SO'B analysed the data and prepared the first draft of the manuscript. All authors revised and approved the final version of the manuscript. SO'B and AM are both primary authors of the manuscript.

Details of Ethics Approval

This study was approved by the Research & Innovation Department of North Bristol NHS Trust, study #3671, approved 29.02.2016, and sponsored by Becton, Dickinson & Company UK Limited. Ethical approval was not required, in accordance with UK Health Departments' Governance Arrangements for Research Ethics Committees (GAfREC).

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via Becton, Dickinson and Company (BD). This report was prepared by investigators and does not necessarily reflect the views of the Saving Lives at Birth partners. BD hold an exclusive license to develop and market the BD Odon Device.

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List of Tables

Table 1: List of steps required to perform an OVB with the BD Odon Device

Table 2: Demographics of participants in HFE Rounds 1, 2, 3 & 4

Table 3: Ability of participants to successfully perform steps in stages of OVB using the BD Odon Device.

Table 4: Ability of participants to perform steps in stages of OVB using the BD Odon Device by profession

Table 5: Recurrent user difficulties and mitigations after Round 1 HFE testing (physical parts of device in italics)

Table 6: Recurrent user difficulties and mitigations after Round 2 HFE testing (physical parts of device in italics)

Table 7: Recurrent user difficulties and mitigations after formative round 3 HFE testing (physical parts of device in italics)