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# BMJ Open

**Novel device for assisted vaginal birth: using integrated qualitative case study methodology to optimise Odon Device use within a feasibility study in a maternity unit in the Southwest of England**

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4 1 **Novel device for assisted vaginal birth: using integrated qualitative case**  
5 2 **study methodology to optimise Odon Device use within a feasibility study in**  
6 3 **a maternity unit in the Southwest of England**  
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9 4

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53 25 **Running title:** Optimising the use of the Odon Device  
54

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## 29 **Objective**

30 When novel devices are used 'in human' for the first time, their optimal use is uncertain  
31 because clinicians only have experience from pre-clinical studies. This study aimed to  
32 investigate factors that might optimise use of the Odon Device for assisted vaginal birth.

## 33 **Design**

34 We undertook qualitative case studies within the ASSIST Study, a feasibility study of the  
35 Odon Device. Each 'case' was defined as one use of the device and included at least one of  
36 the following: observation of the attempted assisted birth, and an interview with the  
37 obstetrician, midwife or woman. Data collection and thematic analysis ran iteratively and in  
38 parallel.

## 39 **Setting**

40 Tertiary referral NHS maternity unit in the Southwest of England.

## 41 **Participants**

42 Women requiring a clinically indicated assisted vaginal birth.

## 43 **Intervention**

44 The Odon Device, an innovative device for assisted vaginal birth.

## 45 **Primary and secondary outcomes measures**

46 Determining the optimal device technique, device design and defining clinical parameters  
47 for use.

## 48 **Results**

49 Thirty-nine cases involving an attempted Odon assisted birth were included in this study, of  
50 which 19 resulted in a successful birth with the device. Factors that improved use included  
51 optimisation of device technique, device design and clinical parameters for use. Technique  
52 adaptations included: applying the device during, rather than between, contractions; having  
53 a flexible approach to the application angle; and deflating the air cuff sooner than originally

1  
2  
3 54 proposed. Three design modifications were proposed involving the deflation button and  
4  
5 55 sleeve. Although use of the device was found to be appropriate in all fetal positions, it was  
6  
7 56 considered contraindicated when the fetal station was at the ischial spines.  
8  
9

## 10 57 **Conclusions**

11  
12 58 Case study methodology facilitated the acquisition of rapid insights into device function in  
13  
14 59 clinical practice, providing key insights regarding use, design, and key clinical parameters for  
15  
16 60 success. This methodology should be considered whenever innovative devices are  
17  
18 61 introduced into clinical practice.  
19

## 20 62 **Trial registration**

21  
22  
23 63 ASSIST Study registration: ISRCTN10203171 <https://doi.org/10.1186/ISRCTN10203171>  
24  
25

## 26 64 **Keywords**

27  
28  
29 65 Assisted vaginal delivery, qualitative research, translational research, Medical Devices  
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3 66 **Article Summary**  
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- 5 67 • Case study methodology was successfully used in an intrapartum setting to  
6  
7 68 evaluate the use of a novel device, the Odon Device, for assisted vaginal birth  
8  
9 69 • This approach enabled deep understanding of device technique, design and  
10  
11 70 clinical parameters for use, and how these may have influenced the outcome of  
12  
13 71 successful birth  
14  
15 72 • Iterative data analysis and feedback of findings enabled rapid dissemination of  
16  
17 73 findings to key stakeholders, and consensus regarding future alterations to  
18  
19 74 device design, technique, and selection criteria for optimal device use  
20  
21 75

## 76 Introduction

77 Each year approximately 82,000 women in the UK have an assisted vaginal birth (AVB).<sup>1</sup> In  
78 recent years, despite the known advantages of AVB, this rate has reduced with a  
79 corresponding increase in Caesarean births in the second stage of labour. Current devices  
80 for AVB require a high level of training and skill (with additional expertise required to define  
81 the fetal position) and can be associated with significant maternal and neonatal morbidity if  
82 used incorrectly.<sup>2</sup> An innovative device that is easier and safer to use, could increase  
83 women's access to AVB, which in turn would help to reduce the number of emergency  
84 Caesarean sections performed in the second stage.<sup>3,4</sup>

85 Before introducing devices into widespread practice, it is necessary to evaluate their safety  
86 and efficacy, and obtain CE marking. However, other factors – such as device technique,  
87 design, and clinical parameters for use – are not routinely assessed, yet may ultimately limit  
88 their success. Preliminary feasibility work exploring these other factors may be valuable  
89 prior to evaluation within a definitive randomised controlled trial. The Odon Device (**Figure**  
90 **3**) has undergone rigorous pre-clinical<sup>5</sup>, simulation<sup>6,7</sup>, human factors<sup>8</sup> and Phase 1 first-in-  
91 human investigation<sup>9</sup> which conclude that it appeared to be safe. However, the Odon  
92 Device has hitherto not been used in the intended population: women requiring an AVB.  
93 This study applied qualitative case study methodology to examine in detail how the Odon  
94 Device (version 4.1) is used for AVB, and to determine what factors may impact on optimal  
95 use. The study was embedded in the ASSIST Study – a feasibility study of the Odon  
96 Device.<sup>10,11</sup>

97 **Figure 1** Diagram of the Odon Device

## 99 Methods

### 100 *Research design*

101 The ASSIST Study<sup>10,11</sup> was conducted in a maternity unit in the Southwest of England with  
102 full detail published elsewhere.<sup>11,12</sup> Integrated within the study was qualitative research,  
103 using case study methodology to explore the factors that may influence optimum device



1  
2  
3 104 use. Case study methodology is particularly suited to answering 'how and why' questions  
4  
5 105 and providing in-depth contextual detail, essential in early evaluations<sup>13</sup> of complex  
6  
7 106 interventions,<sup>14-16</sup> such as use of a novel device for AVB,<sup>17</sup> and has previously been used to  
8  
9 107 explore surgical innovation.<sup>18</sup> In this study, each 'case' was defined as one use of the device  
10  
11 108 and included at least one of the following: observation of the attempted Odon assisted birth  
12  
13 109 and/or an interview with the obstetrician, midwife or woman. The researcher ensured that  
14  
15 110 the use of the device in the study was compared against the Instructions For Use (IFU)  
16  
17 111 document, which is mandated by regulatory bodies as one of the processes to ensure device  
18  
19 112 safety and efficacy. Given the focus of this paper is of the technical aspects of device use,  
20  
21 113 data presented reports observation and healthcare professional interview findings. Data  
22  
23 114 reporting experiences of women are presented separately.<sup>12</sup>

24 115

### 27 116 *Participants*

30 117 There were two groups of participants for the case studies: women and healthcare  
31  
32 118 professionals (obstetricians and midwives). All women participating in the ASSIST Study  
33  
34 119 were eligible to be included in the case study research and gave written consent.<sup>12</sup> All  
35  
36 120 trained operators and midwives provided written consent. There were five operators, three  
37  
38 121 consultants and two registrars.

40 122

### 43 123 *Sampling*

46 124 Typical sampling for observation was in part purposive and in part opportunistic (i.e.  
47  
48 125 dependent on the researcher being on site and available to conduct the observation). The  
49  
50 126 aim was to include a range of clinical indications for AVB and a range of operators.

52 127

### 55 128 **Patient and public involvement**

58 129 Patients and the public were involved in all aspects of the ASSIST Study,<sup>10,12</sup>

1  
2  
3 130  
4  
56 131 **Data collection**

7  
8  
9 132 Data collection for eight of the cases included observation of the attempted Odon assisted  
10 133 birth. Observations, including technical details, contextual factors and communication,  
11 134 were prospectively recorded on a bespoke observation schedule. Detailed observations of  
12 135 the operative steps performed by the obstetrician during AVBs were recorded enabling a  
13 136 stepwise account of the 'usual steps' to be generated and compared against the IFU. The  
14 137 original IFU were developed prior to the ASSIST study during phase 1 clinical and simulation  
15 138 studies and included 22 operative steps.<sup>8,9</sup> In these IFU, the AVB was divided into six  
16 139 domains according to purpose (**Table 1**). The IFU and instructional video for operators used  
17 140 for the Odon Device in the ASSIST Study can be viewed in Supplementary files 1 and 2.

18 141 All women who had the birth of their baby formally observed were invited to participate in  
19 142 an interview at day one postnatal and clinicians within five days following the assisted  
20 143 birth.<sup>10</sup> In line with usual practice in conducting case study research a flexible approach was  
21 144 taken to which data were collected for each case, based on the value of insights gained for  
22 145 each data source. Any method of data collection (observation or interview) could be  
23 146 suspended if it was observed to be delivering no new insights.

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4041 148 **Data analysis**

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43  
44 149 Data collection and analysis were iterative and ran in parallel using the six-step framework  
45 150 described for thematic analysis.<sup>19</sup> Data analysis was largely inductive although some  
46 151 deduction derived from using the IFU as a framework against which to evaluate what took  
47 152 place. All data for each case were read together to identify and organise codes. Codes were  
48 153 developed using text that captured significant views in the data, then grouped to reflect  
49 154 developing themes, with code descriptions and sample quotes assigned. Double coding of a  
50 155 proportion of interview transcripts (20%) was undertaken by JW. A narrative report was  
51 156 created for each case, triangulating all available data. Any issues requiring clarification were  
52 157 highlighted during the creation of the report, for exploration during subsequent interviews.

1  
2  
3 158 Commonality and variances across cases were discussed between the researchers and used  
4  
5 159 to further shape evolving themes and sampling. This systematic analysis supported rapid  
6  
7 160 within- and cross-case comparison. NVivo 12 (QSR International, Melbourne, Australia) was  
8  
9 161 used to organise data and support analysis.

10  
11  
12 162

### 13 163 **Feedback of findings**

14  
15 164 Iterative data collection and analysis enabled the rapid identification of key learning points  
16  
17 165 or corrections to technique for dissemination to operators (see Table 2). Key findings were  
18  
19 166 relayed rapidly to operators using messages via an end-to-end encryption platform, regular  
20  
21 167 face-to-face discussions and operator debriefs. Furthermore, following the 36<sup>th</sup> Odon  
22  
23 168 assisted birth, an interactive summit was held with key stakeholders (the clinical research  
24  
25 169 team, design engineers, statisticians, and funders), with the aim of sharing learning  
26  
27 170 experiences and gaining consensus regarding any changes that may be suggested.

28  
29 171

### 30 31 32 172 **Funding**

33  
34  
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37 174 grant conditions of the Foundation, a Creative Commons Attribution 4.0 Generic License has  
38  
39 175 already been assigned to the Author Accepted Manuscript version that might arise from this  
40  
41 176 submission.

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43 177

### 44 45 46 178 **Results**

47  
48  
49 179 Forty births were assisted with the Odon Device at North Bristol NHS Trust, UK, between  
50  
51 180 October 2018 and January 2019. One case had no qualitative data because the researcher  
52  
53 181 was unavailable, resulting in 39 case studies arising from 40 (97.5%) single uses of the Odon  
54  
55 182 Device (**Table 2**). Nineteen births were successfully assisted with the Odon Device. Of those  
56  
57 183 that were unsuccessful, 19 were assisted by forceps and two by Caesarean section.  
58  
59 184 Observations varied in length from 33 to 68 minutes. Interviews with women lasted 6.5 to  
60

1  
2  
3 185 9.6 minutes, interviews with operators lasted between 5.4 and 26.1 minutes and interviews  
4  
5 186 with midwives lasted 3.4 to 13.2 minutes.  
6  
7

8 187 It became apparent that there were three factors contributing to optimisation of device use:  
9  
10 188 (i) device technique, (ii) device design and (iii) clinical parameters for device use (Figure 2).  
11

12 189 **Figure 2** How case study methodology may be able to determine optimal device use through bridging multiple  
13  
14 190 factors relating to the device  
15

16 191

### 17 192 **Device technique**

18  
19 193 Suggested adaptations to the original IFU included (i) device application during rather than  
20  
21 194 between contractions, (ii) altering the application angle and (iii) deflating the air cuff as soon  
22  
23 195 as any aspect of the blue deflation line became visible.  
24

25 196

#### 26 197 *Device application with a contraction*

27  
28 198 The original IFU stated that the Odon Device should be applied between contractions, as  
29  
30 199 was standard practice with forceps and ventouse. It became apparent during the first two  
31  
32 200 attempted AVBs that this disimpacted the fetal head out of the pelvis and operators were  
33  
34 201 unable to correctly place the device:

35 202 *D1: 'Again, I had to use significant pressure to try and get the device over the fetal*  
36  
37 203 *head. And loads of liquor came down during the application suggesting that there*  
38  
39 204 *was some degree of disimpaction.'*  
40

41  
42 205

43  
44 206 By the third attempted birth, operators had adapted their technique to include fundal  
45  
46 207 pressure to aid application, which resulted in successful device application and the first  
47  
48 208 successful AVB. The use of fundal pressure, although successful, was not well tolerated by  
49  
50 209 women without a regional anaesthetic:

51 210 *M3: 'Significant fundal pressure that was used at the time...she was*  
52  
53 211 *uncomfortable...maybe that will be something up for review.'*  
54

55  
56 212

57  
58 213 Following feedback from qualitative findings, the application technique was adapted again  
59  
60 214 during the eighth birth. This was the first time the Odon Device was applied during a

1  
2  
3 215 contraction without the use of fundal pressure, resulting in a successful application and  
4  
5 216 birth. Fundal pressure was only used in a small number of births and quickly dropped from  
6  
7 217 the technique as soon as application with a contraction was found to be successful:

8  
9 218 D2: *'I haven't used fundal pressure since delivery number two or three for me, but*  
10  
11 219 *what has been very successful is putting it on during a contraction. I think.'*

12  
13 220

#### 14 221 *Device application angle*

15  
16 222 The original IFU stated that the device should be applied 'starting at 45° below the  
17  
18 223 horizontal'. By the eighth attempted birth it was apparent that this was not optimal and  
19  
20 224 operators naturally moved to a more 'horizontal' application:

21  
22 225 D2: *'I definitely pushed the device in at a much flatter angle, much more parallel with*  
23  
24 226 *the bed than I had in the past...'*

25  
26 227

27  
28 228 All operators quickly agreed that the angle required might be dependent on factors such as  
29  
30 229 fetal position and station:

31  
32 230 D1: *'So I was kind of like, "Oh, OP, it might be more, you know, it could be difficult*  
33  
34 231 *because it's an OP..."'*

35  
36 232 D2: *'I think we've still got to continue experimenting or changing the angle of*  
37  
38 233 *insertion. I think there may be an optimum angle of insertion or it may be that we*  
39  
40 234 *have to change angle of insertion for different stations...'*

41  
42  
43 235

#### 44 236 *Deflating the device*

45  
46 237 The original IFU stated that 'once you see the blue deflation line completely' the air cuff  
47  
48 238 should be deflated. By the third attempted birth it became apparent to the observer that  
49  
50 239 this was too late and that the optimum time for air cuff deflation seemed to be when any  
51  
52 240 section of the blue line could be seen:

53  
54 241 O5: *'Noticed that it was not the anterior blue deflation line that the operator was*  
55  
56 242 *looking at the deflate but the posterior deflation line, due to the fact that there is an*  
57  
58 243 *acute J curve and anterior line not seen. Will need to change this in training.'*

59  
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3 244

4  
5 245 These observations were fed back rapidly and iteratively to the Odon Device operators and  
6  
7 246 further discussed with the wider research team at the Odon Summit (Table 2).

8  
9 247

### 10 248 ***Device design and performance***

11  
12 249 Multiple potential device adaptations were noted during the case study research. Four  
13  
14 250 design modifications for future device adaptations were identified: (i) strengthening the  
15  
16 251 sleeve seal lines, (ii) creating a wider opening between the sleeve handles, (iii) altering the  
17  
18 252 design of the deflation button and (iv) address the manufacturing fault that was identified.

19  
20 253

#### 21 22 254 *Sleeve seal lines and opening between sleeve handles*

23  
24  
25 255 One operator noted that the sleeve seal lines tore during traction, on several occasions:

26  
27  
28 256 *D4: ‘... the sleeve is not sturdy... it might actually rip it open, which has happened*  
29  
30 257 *with me a few times.’*

31  
32  
33 258 During device inspection, it was noted that all devices had small tears (<2cm) in the seal  
34  
35 259 lines of the sleeve, and one had a significant tear (>7cm). There was no evidence any of  
36  
37 260 these tears had had a negative effect on the function of the Odon Device, indeed the device  
38  
39 261 with a significant tear achieved a successful Odon birth. Tearing was thought to have  
40  
41 262 occurred when operators opened the sleeve handles before and between tractions to  
42  
43 263 physically look at the station of the vertex. In contrast to standard devices used for AVB,  
44  
45 264 there was little proprioceptive feedback to ascertain the station of the baby, so visual  
46  
47 265 inspection was useful:

48  
49 266 *O5: ‘...I got the impression that the operator was unsure as to whether the head had*  
50  
51 267 *descended so opened the handles to look inside the sleeve.’*

52  
53 268

54  
55 269 Following interviews, it was suggested that the opening between the two handles was made  
56  
57 270 wider to enable operators to view the progression of the baby’s head more easily (Figure

58  
59  
60

1  
2  
3 271 S1). Ultrasound assessment was not used as this method was not routinely adopted in our  
4  
5 272 unit at the time of the study.  
6

7 273

8  
9  
10 274 *Deflation button*

11  
12 275 In six cases it was noticed that the operator accidentally pressed the deflation button. Each  
13  
14 276 time this occurred, the cuff was reinflated immediately. All operators agreed that the  
15  
16 277 design of the deflation button should be altered to reduce the risk of inadvertent activation  
17  
18 278 (Figure S2):

19  
20  
21 279 *O3: 'Operator accidentally pressed the deflation button 'oh, whoops that was my*  
22  
23 280 *fault, I'll just re-inflate.'*

24  
25 281

26  
27 282 *Manufacturing fault*

28  
29 283 All devices were disinfected and inspected following their use as per protocol.<sup>10,11</sup> During  
30  
31 284 this inspection, four devices were found to have an ineffective bulb pump (**Error! Reference**  
32  
33 285 **source not found.**) which resulted in inadequate cuff inflation (**Table 2**). Operators'  
34  
35 286 comments during the attempted births reflected this, as the device did not act in the  
36  
37 287 expected manner.

38 288 *D4: 'Yes, there was no grip... It just came out deflated, so it didn't feel right.'*

39  
40  
41 289

42  
43 290 This prompted a rapid retrospective review of all used and stored devices to ensure that no  
44  
45 291 other unsuccessful attempts were attributed to this fault, none were.

46  
47 292

48  
49 293 *Optimal clinical parameters for Odon Device use*

50 294 The Odon Device was used to successfully assist births in all fetal positions. Midwives  
51  
52 295 particularly noted how the device could help deliver a baby in the occipito-posterior  
53  
54 296 position which is a technically more challenging position:

1  
2  
3 297 M9: *'I think, probably, it could be quite universal as an instrumental device. It didn't*  
4  
5 298 *seem to matter whether the baby was OA [occipito-anterior] or OP [occipito-*  
6  
7 299 *posterior]...'*

8  
9  
10 300 However, although the device could be successful at assisting birth in all positions, it  
11  
12 301 became apparent that for women with fetal station at spines or a more complex  
13  
14 302 presentation (such as brow or nuchal arm) the device was not successful. Operators were  
15  
16 303 either unsuccessful at applying the device correctly onto the fetal head or the device simply  
17  
18 304 slipped off the fetal head with the initial traction:

19  
20 305 D1: *'So, it was direct OP at the spines, and it was almost coming to a brow, I could*  
21  
22 306 *feel the orbital ridges...I was thinking, "Oh, I'm really not sure that this is going to*  
23  
24 307 *work."...I didn't feel that was a failed Odon, that was a baby that was never going to*  
25  
26 308 *come out vaginally.'* [unsuccessful Odon-failed rotational forceps, emergency  
27  
28 309 Caesarean section]

29  
30 310  
31  
32 311 As experience with the device increased, it became apparent that the device could be used  
33  
34 312 comfortably without a regional anaesthetic (with only perineal infiltration of local  
35  
36 313 anaesthetic). Device use was noted to be better tolerated than bladder emptying by  
37  
38 314 urethral catheterisation, a procedure that is less invasive:

39  
40 315 D2: *'She actually found the catheterisation more uncomfortable than putting on the*  
41  
42 316 *Odon Device with no analgesia at all.'*

43  
44  
45 317

#### 46 318 **Feedback to operators**

47  
48 319 All qualitative case study findings relating to device technique, design, and clinical  
49  
50 320 parameters for use were presented to key stakeholders at the Odon Summit by the  
51  
52 321 qualitative researcher. The case study research provided suggestions for device technique  
53  
54 322 adaptation for some of the operative steps, but not for them all. It was agreed that there  
55  
56 323 were still unanswered questions regarding the technique (such as which angle to use for  
57  
58 324 application) and that further data was required to achieve this. Clinically important  
59  
60 325 adaptations to device design were agreed upon (including altering the deflation button



1  
2  
3 326 design) and the clinical parameters for use were confirmed, with an agreement that the  
4  
5 327 device should not be used if the vertex is at the level of the ischial spines.  
6

7 328

8  
9 329 **Discussion**

10 330 Case study research identified three areas that could optimise device use: (i) device  
11 331 technique, (ii) device design and (iii) acceptable clinical parameters. Principal technique  
12 332 adaptations were centred on device application and deflation of the air cuff. The initial IFU  
13 333 specified a particular angle for device application however, during clinical use it became  
14 334 apparent that this angle needed to be flexible and was less acute than originally specified  
15 335 however, there was no consensus on the exact optimal angle and it was surmised that more  
16 336 data would be required to achieve this. Device modifications of altering the sleeve and  
17 337 deflation button were recommended for useability rather than to transform the  
18 338 functionality of the device. The manufacturing fault was quickly identified and rectified by  
19 339 the manufacturer through post-use device inspection. Optimal parameters for device use  
20 340 were proposed and focussed primarily on the station of the baby, with use at station spines  
21 341 recommended to be prohibited. Adaptations to optimise device use were adopted by the  
22 342 manufacturer to create Odon Device (version 4.2) which was used in two further Odon  
23 343 Device feasibility studies, each studying 104 Odon assisted births. These have recently  
24 344 closed to recruitment in the UK<sup>20</sup> and France<sup>21</sup> and aimed to address the unanswered  
25 345 aspects of optimal device use, specifically the technique. These findings will be published  
26 346 once follow-up and data analysis is complete. Case study research enabled systematic,  
27 347 rapid generation of data and understanding of device use that enabled the researchers and  
28 348 manufacturers develop study protocols and device updates to support the ongoing  
29 349 investigation of the device.  
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31 350

32 351 **Strengths and limitations**

33 352 This was the first time that research has been undertaken on the Odon Device in clinically  
34 353 indicated cases and indeed the first-time case study research has been used to explore the  
35 354 use of devices for AVB. Device design and technique is unique to the device and although  
36 355 cannot be directly compared to other devices for AVB step-by-step, some comparisons and  
37 356 differences can be noted. The Odon Device, unlike other devices for AVB<sup>22</sup>, can only be  
38 357 successfully applied during a contraction or with maternal effort, even though techniques

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3 358 for traction once the device is applied appear similar. Clinical indications for use are slightly  
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5 359 different to that of forceps and ventouse in the UK.<sup>22</sup> In the UK, all currently used devices  
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7 360 for AVB are permitted to be used at station spines or below. We have demonstrated that  
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9 361 this is not the case for the Odon Device, as we have demonstrated that this will not be  
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11 362 successful. Interestingly, performing AVBs at station spines is not permitted in other  
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13 363 countries.<sup>23</sup>  
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16 365 An AVB is a complex intervention, and this makes studying the use of the device challenging.  
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18 366 Qualitative case study methodology has been used to explore technique in surgical  
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20 367 procedures<sup>18</sup> however, there are no published examples of case study methodology being  
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22 368 used to investigate novel devices. The case studies integrated participant observation as  
23  
24 369 well as interviews with operators, midwives, and women to explore the introduction of an  
25  
26 370 innovative device in context and in detail. The benefits of this were that experiences, and  
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28 371 views of all stakeholders were easily obtained, and we were able to investigate operator  
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30 372 views in detail. Triangulation of data linked to a particular case led to insights for  
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32 373 amendments for optimum device use being identified more rapidly than if a single source of  
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34 374 qualitative data (e.g., observation or interview only) had been used. Rapid dissemination of  
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36 375 findings resulted in prompt adoption of beneficial techniques for use. By using this  
37  
38 376 methodology and incorporating data from all stakeholders (operators, midwives, and  
39  
40 377 women) and observations we were able to gain a balanced and comprehensive assessment  
41  
42 378 of the use of the device. When trying to understand optimal device use, operator  
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44 379 interviews were found to be of crucial importance. Comparing case study data collected  
45  
46 380 under different conditions (such as different analgesia, different presentations of babies,  
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48 381 different operators) enabled commonalities and disparities in technique to be highlighted  
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50 382 and thoroughly investigated. This enabled the clinical research team to propose evidence-  
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52 383 based modifications to the device design and provide clarity on recommendations for  
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54 384 clinical parameters for use. Case study methodology encouraged operators to reflect,  
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56 385 critique and appraise their use of the device for each birth, resulting in enhanced and  
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58 386 enriched communication between operators regarding their experiences through  
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60 387 conversations and a dedicated operator messaging group. In future, data from encrypted  
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62 388 social media platforms could be incorporated into the qualitative data for analysis.

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3 389 Reporting was undertaken following the Standards for Reporting Qualitative Research<sup>34</sup>  
4 (Supplementary information 3).  
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8 392 There are limitations to this study. The aim of understanding the optimal operative steps  
9 393 for device use, and thus confirming a finalised IFU were not met. For some operative steps  
10 394 consensus was reached as to the recommended course of action (such as applying the  
11 395 device with a contraction). However, for others more data were required (such as what  
12 396 specific angle of application to use). Case studies within the ASSIST Study were finite.  
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14 397 Observations were undertaken where possible, however due to the unpredictable nature of  
15 398 AVBs it was not possible to attend all assisted births. Indeed, none of the more complex  
16 399 attempted AVBs performed in the operating theatre were observed. This could have an  
17 400 impact on the generalisability of the findings as births undertaken in the operating theatre  
18 401 are often more technically challenging for operators. All interviews with clinicians were  
19 402 undertaken within five days following the assisted birth. Recollections of the clinicians may  
20 403 have been less accurate the longer the time between assisted birth and interview. The case  
21 404 studies were undertaken by a specialist trainee in obstetrics and gynaecology meaning that  
22 405 pre-conceptions and existing knowledge may have influenced the collection and  
23 406 interpretation of the data, although at the time of commencing the case studies the  
24 407 researcher was naïve to the use of the Odon Device in the clinical setting. Lastly, operators  
25 408 may have changed their behaviours during observations, perhaps not reflecting their real-  
26 409 life practice.  
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411 There are two key next steps that should be considered. Firstly, feasibility of the use of the  
412 Odon Device for AVB should be undertaken in different healthcare settings. Thus far,  
413 research has been undertaken in high-income settings where AVB is used regularly.  
414 Exploring device using in low- and middle- income settings, including where rates of AVB are  
415 lower than the UK and France could help understand if there are further considerations for  
416 optimal device use that need to be addressed. Secondly, following the completion of the  
417 two further feasibility studies, a decision needs to be made as to whether the device is  
418 ready to be compared against available alternatives (forceps and ventouse) in a randomised  
419 controlled trial. As recommended by IDEAL-D,<sup>24</sup> researchers need to be satisfied that the

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3 420 technique, design and clinical parameters for use are sufficiently stable to enable this to  
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5 421 happen.

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9 423 **Conclusion**

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12 424 Case study methodology facilitated insights into optimal technique, design and clinical  
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14 425 parameters for use of the Odon Device. Optimising use of a device is an essential  
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16 426 prerequisite to evaluating outcomes, as it will impact directly on those outcomes and may  
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18 427 result in lower-than-expected success rates. There were two clear factors that enhanced  
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20 428 operator communication. Firstly, systematic triangulation of data from varying data sources  
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22 429 provided a comprehensive, contextual overview of device use and rapid understanding of  
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24 430 amendments required and secondly, rapid feedback of insights as they emerged to  
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26 431 operators. This also facilitated operator consensus building, which was key in  
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28 432 understanding and developing the iterative adaptations to the device technique, design and  
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30 433 clinical parameters for device use. This is of paramount importance for getting operator  
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32 434 buy-in for the next steps of device evaluation. This methodology should be considered  
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34 435 whenever innovative devices are introduced to clinical trials and settings. It allows for rapid  
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36 436 assessment of device use and can support timely iterative adaptations to ensure there are  
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38 437 minimal delays between device use in research and adoption in clinical practice.

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52 444 expressed are those of the author(s) and not necessarily those of the NIHR or the  
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56 446 innovation for Difficult and Complex randomised controlled Trials In Invasive procedures)  
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58 447 Hub for Trials Methodology Research (MR/K025643/1).

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3 449 **Competing interests**  
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6 450 Authors report no competing interests.  
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11 452 **Contribution to Authorship**  
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14 453 EJH, NSB and JW developed the concept for the study. EJH performed all data collection  
15  
16 454 and analysis with co-coding performed by JW. EJH wrote the initial draft of the manuscript,  
17  
18 455 with support from NSB, JFC and JW. EJH, NSB, NB, EL, TJD, JFC and JW reviewed and  
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20 456 approved the final manuscript.  
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26  
27 458 **Ethical approval**  
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29

30 459 The research was approved by South Central–Berkshire REC, UK on 3<sup>rd</sup> September 2018  
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32 460 (18/SC/0344), the MHRA on 9<sup>th</sup> August 2018 and the HRA on 3<sup>rd</sup> September 2018.  
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37 462 **Data sharing statement:** Data are available upon reasonable request.  
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3 465 **Table/figure caption list**  
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7 466 **Table 1** Original components of application of the Odon Device for an assisted vaginal birth  
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10 468 **Table 2** Summary of 40 cases investigating the Odon Device with adaptations made to  
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12 469 device technique  
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16 471 **Figure 3** Diagram of the Odon Device  
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19 473 **Figure 4** How case study methodology may be able to determine optimal device use through  
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21 474 bridging multiple factors relating to the device  
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25 476 **Supplementary file (S1)** Odon Device IFU for Clinical Studies  
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29 478 **Supplementary file (S2)** Instructional video for the ASSIST Study  
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33 480 **Supplementary file (S3)** Standards for Reporting Qualitative Research (SRQR)  
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554 **Table 1 Original components of application of the Odon Device for an assisted vaginal birth**

Component	Steps within component
Preparation	Checking clinical pre-requisites for AVB Lubricating the device
Device application	Removing the fastening band Applying the device onto a fetal head
Cuff inflation	Ensuring the cuff is fully inflated in the correct position on the fetal head
Applicator removal	Removing the applicator from the fetal head
Traction	Following the J-shape curve of the pelvis applying traction with contractions
Removal of device	Deflating the air cuff as the fetal head is crowning

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557 Table 2 Summary of 40 cases investigating the Odon Device with adaptations made to device technique

Case study no.	Successful (S) Unsuccessful (U) AVB with Odon and mode of birth	Observation	Women	Interviews Operator	Midwife	Device issues
1	U – Forceps	O1	W1	D1	M1	
2	U – Forceps			D2	M2	
<b>Fundal pressure during device application tried</b>						
3	S – Odon			D2	M2 M3	
<b>Deflation of the air cuff when only part of the blue line was seen introduced</b>						
4	S – Odon			D2	M4	
5	U – Forceps			D1	M2	
6	S – Odon			D2*		
7	U – Forceps	O2	W2	D1	M5	AD
<b>Accidental pressing of the deflation button first noted</b>						
<b>Altered the angle of device insertion</b>						
<b>Application during a maternal contraction introduced, use of fundal pressure removed</b>						
8	S – Odon	O3	W3	D2	M6	AD
<b>Opened the sleeve handles during descent to monitor progression of fetal head first noted</b>						
9	U – Forceps	O4	W4	D1		
10	S – Odon			D2	M7	
11	S – Odon	O5	W5	D1	M8	AD
12	S – Odon	O6	W6	D1	M9	AD
13	S – Odon	O7	W7	D3	M2	
14	U – Failed rotational forceps, emergency Caesarean section			D1	M7	AD
15	U – Forceps			D2	M4	
16	U – Forceps	O8	W8	D2	M10	IBP
17	S – Odon			D1		
18	S – Odon			D3	M11	
19	S – Odon			D4		SST
20	U – Rotational forceps			D4		IBP
21	U – emergency Caesarean section			D3	M6	
22	U – Forceps			D4		
23	U – Forceps			D1	M6	IBP
24	S – Odon			D1		
25	U – Forceps			D4		
26	U – Forceps			D4		
27	S – Odon			D1		AD
28	U – Forceps			D1		
29	S – Odon			D5		
30	U – Forceps			D1		
31	U – Forceps			D4		IBP
32	U – Forceps			D1		
33	S – Odon			D5		
34	S – Odon			D2		
35	S – Odon			D2		
36	U – Forceps			D4		
<b>Odon summit held</b>						
37	U – Forceps			D1		
38	S – Odon			D4		
39	S – Odon			D4	M6	
40	U – Forceps			D3		

\*Qualitative interview from Obstetrician not obtained for this birth

O = observation, W = woman, D = Obstetrician, M = Midwife

AD = accidental deflation, IBP = ineffective bulb pump, SST = significant sleeve tear

**Bold italic steps** = key stages in the study that impacted on technique

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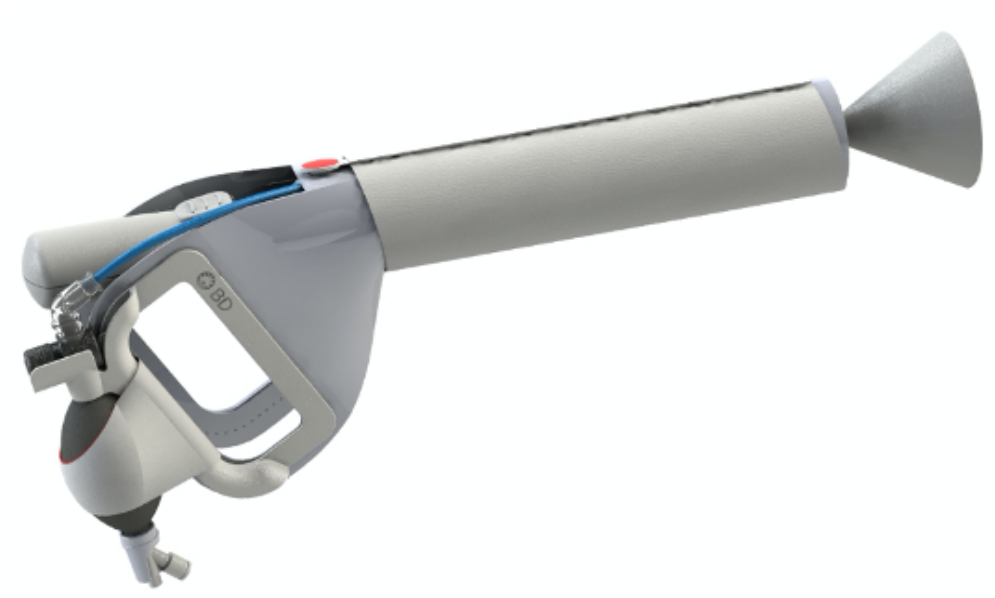
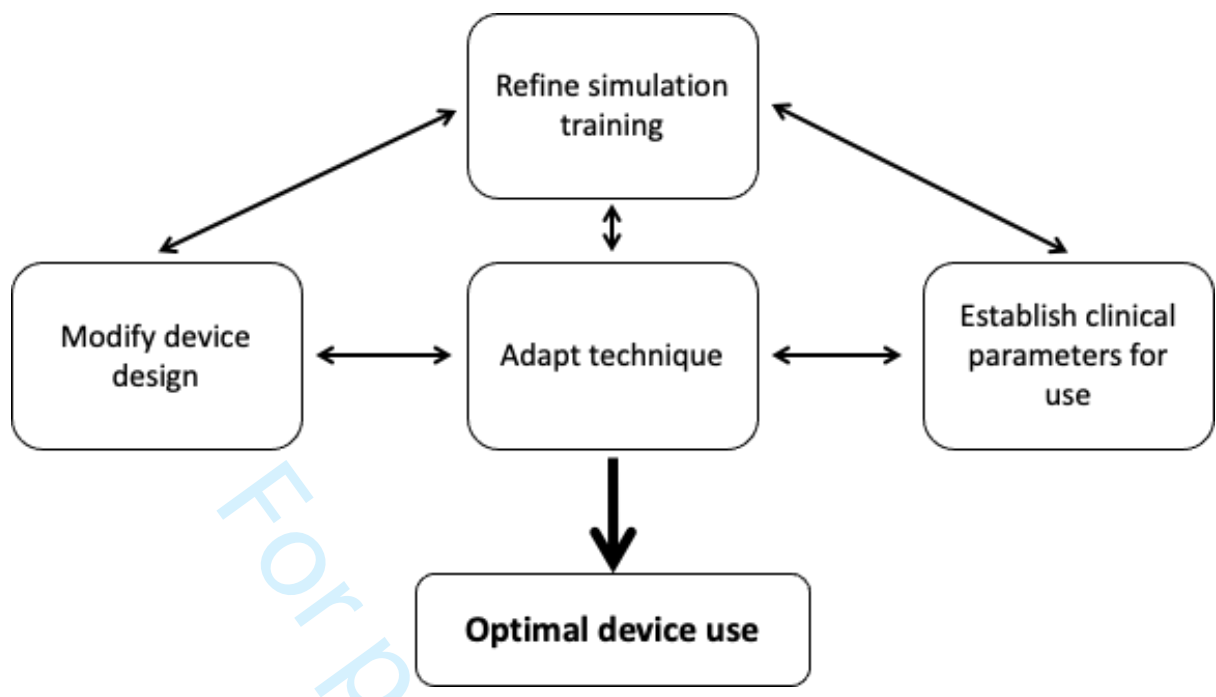


Diagram of the Odon Device

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REV (VER)	REVISION DESCRIPTION	CR NO.
01(A)	INITIAL RELEASE	CM500000111539

# BD Odon Device™

## Inflatable device for assisted vaginal birth – Instructions For Use

### Device Description

The **BD Odon Device™** is an instrument for assisted vaginal birth. The device uses a polyethylene sleeve and an inflatable air cuff to help ease the fetal head out of the birth canal. The BD Odon Device consists of an applicator, sleeve and fastening band.

### Indications for Use

The BD Odon Device is envisaged to perform assisted vaginal birth. The main indications for the BD Odon Device are as follows:

- Prolonged second stage of labour
- Suspected fetal compromise in the second stage of labour
- Other medical indications to shorten second stage of labour

### Contraindications

The use of the BD Odon Device is contraindicated in the following conditions:

- Cervix is not fully dilated
- Cephalopelvic disproportion/ irreducible moulding and large caput indicative of cephalopelvic disproportion
- Fetal head not fully engaged
- Undefined presentation
- Breech, transverse, face, brow presentations
- Membranes are not ruptured
- Contraindications for vaginal deliveries
- Untrained operator

### General Warnings

- The BD Odon Device should be used by skilled birth attendants who are:
  - Trained to recognize the conditions for safe and effective application of the BD Odon Device:
    - Full cervical dilation
    - Fetal head position defined
    - Fetal head station defined
  - Trained to use the BD Odon Device
- The BD Odon Device is intended for single use. Do not reuse. Device function may be impaired through reuse or cleaning. Degradation of materials or failure to correctly reassemble the device could result in harm for the mother and the fetus. Reusing the product after exposure to biological materials may cause adverse patient reactions due to contamination.

- As with other devices for assisted vaginal birth, the BD Odon Device could fail to deliver the baby. The criteria to define failure and to abandon the procedure are:
  - No progression in descent of the fetal head after a total of three pulls
  - No more than two attempts at application (no more than two device slippages)
  - Duration of procedure longer than 20 minutes

- As with other instruments for assisted vaginal birth, use of the BD Odon Device may result in maternal and neonatal complications. The most common complications with the use of
  - No progression in descent of the fetal head after a total of three pulls
  - No more than two attempts at application (no more than two device slippages)
  - Duration of procedure longer than 20 minutes

forceps and ventouse include maternal trauma, neonatal facial injury (forceps), cephalohaematoma, subgaleal haemorrhage, and retinal haemorrhage (ventouse). Presently human, animal and simulated studies have not identified potential complications specific to the BD Odon Device therefore this section will be updated after analyses of the safety outcomes of the proposed randomised clinical study.

- This BD Odon Device is exclusively for clinical investigation only.
- Ensure packaging is not damaged prior to use. Discard product if packaging is found to be damaged.

### General Precautions

As with other devices for assisted vaginal birth the following precautions should be taken before applying the BD Odon Device to ensuring that conditions for safe application of device are met:

- Verify full dilation of cervix, fetal head station at the ischial spines or below
- Verify cephalic vertex presentation (Occiput anterior, Occiput posterior, Occiput transverse positions)
- Verify rupture of membranes
- Provide adequate analgesia according to facility procedures
- Position women in lithotomy position
- Empty bladder
- Re-confirm fetal position
- Lubricate the birth canal

### Symbol Legends

	Sterilized using radiation
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Contains or presence of natural rubber latex
	Batch code
	Use-by date
	Date of manufacture
	Manufacturer
	Authorized representative in the European Community
	Consult instructions for use
	Caution
	Serial number

Manufacturer: Becton Dickinson Medical Products Pte Ltd, 30 Tuas Avenue 2, Singapore 639461

Authorised representative in the European Community:  
Becton Dickinson France SAS, 11 rue Aristide Bergès, ZI des Iles, 38800 Le Pont de Claix, France

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VENDOR INFO:

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NOT USE FOR DIMENSIONAL PURPOSES  
-IFU DIMENSIONS TO BE 210MM X 297MM.



REV (VER)	01(A)
CR NO.	CM500000111539
REVISION DATE	-

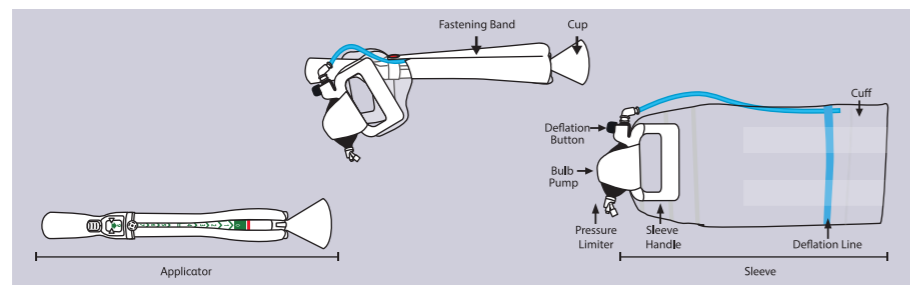
BDMP R&D  
30 TUAS AVENUE 2 S(639461)  
SINGAPORE

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TITLE			
BD Odon Device™ - Instruction For Use			
DESIGNED BY	Narayanan V	UNITS METRIC/INCHES UNLESS OTHERWISE SPECIFIED	SHEET 1 OF 2
DRAFTED BY	Narayanan V	SCALE Scale Size 1:1 NOT PRINTED TO SCALE	TYPE EXPERIMENTAL
CREATION DATE	24 NOV 2017	DRAWING NUMBER	SRD-DGP0036
FILE NAME	SRD-DGP0036_rev 01		

DEVICE USE STEPS (FOR CLINICAL INVESTIGATION ONLY)

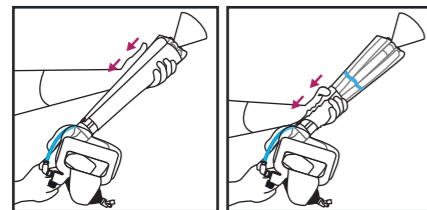
DEVICE USE STEPS (FOR CLINICAL INVESTIGATION ONLY)



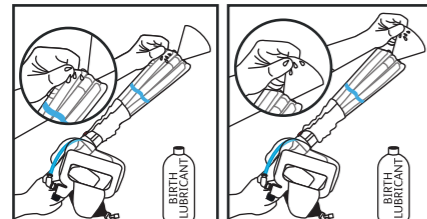
1. Ensure conditions for safe application of device are met:
  - a. Full dilation of cervix, fetal head 0 to +3 station, cephalic vertex presentation (OA, OP, OT positions), rupture of membranes
  - b. Provide adequate analgesia according to facility procedures
  - c. Position women in lithotomy position
  - d. Empty bladder
  - e. Re-confirm fetal position
  - f. Lubricate the birth canal

2. Remove BD Odon Device from packaging without compromising the sterility of the device.

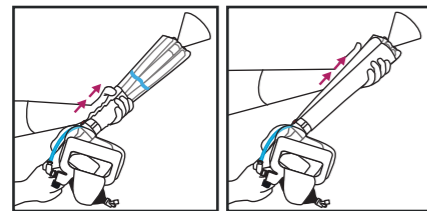
3. Pull back the fastening band until the blue deflation line is exposed.



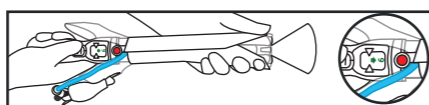
4. With the fastening band still intact, generously lubricate the inside and outside of the sleeve and the cup.



5. While holding the applicator handle gently slide the fastening band back to the top of the sleeve.



6. Grip the applicator handle and ensure the viewing window is facing upwards.



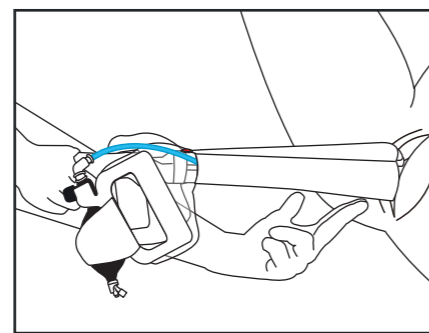
7. Fold the cup and gently insert it through the vulva and check it has regained its circular shape.



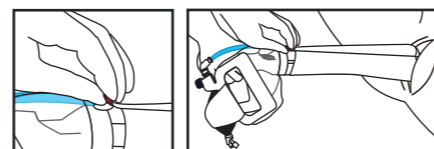
8. Check that there is no maternal tissue trapped between the cup and the fetal head.



9. With your hand on the handle of the applicator, gently push the device through the vulva. Use your other hand to guide the device and do not apply any force with it.



10. Unfasten the red button

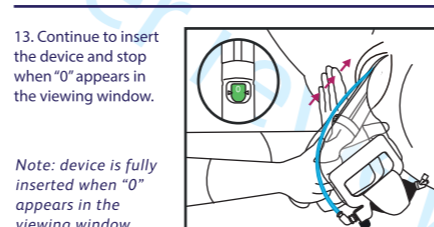


11. Open and completely remove the fastening band.



*Note: ensure the sleeve and applicator remain in place inside the vulva.*

12. Between contractions, keeping both hands away from the sleeve, continue to gently push the applicator, starting at 45° below the horizontal and following the curvature of the birth canal. Monitor progress by looking through the viewing window.



13. Continue to insert the device and stop when "0" appears in the viewing window.

*Note: device is fully inserted when "0" appears in the viewing window.*

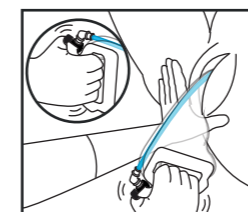
14. Squeeze the bulb pump fully and firmly at least 8 times to inflate the cuff.

*Note: There is a pressure limiter in the bulb which prevents over inflation of the cuff.*

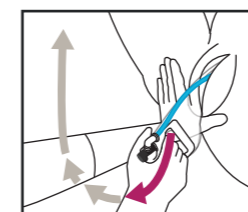
15. While protecting the perineum with one hand, use the other hand to completely withdraw the applicator and cup, leaving only the sleeve in place.



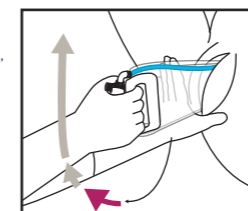
16. To compensate for possible reduction in cuff pressure, squeeze the bulb pump fully and firmly 2 more times prior to traction.



17. Grasp the sleeve handle, and during contractions pull gently and progressively following the J-shape of the birth canal.

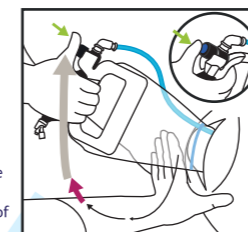


18. While continuing to pull gently along the J-shape of the birth canal, confirm the fetal head is descending with pulling efforts.

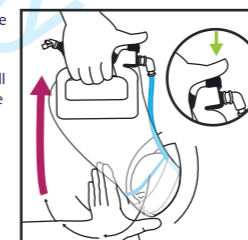


*Note: if baby is not delivered at the first contraction repeat steps 16, 17 and 18 with any subsequent contractions.*

19. Once you see the blue deflation line completely (approximately at crowning) deflate the cuff by pushing on the blue deflation button. Pull the sleeve handle continuing to press the deflation button following the J-shape of the birth canal.



20. Continue to pull the sleeve handle while pressing the blue deflation button to pull the fetal head until the sleeve detaches from the head.



21. Proceed to assist the birth of the baby as per normal procedure.

22. Discard disposable applicator and sleeve according to local appropriate procedure. Do not reuse.

VENDOR INFO:  
 -HOLDING LINES ONLY... DO NOT PRINT.  
 NOT USE FOR DIMENSIONAL PURPOSES  
 -IFU DIMENSIONS TO BE 210MM X 297MM.



REV (VER)	01(A)
CR NO.	CM500000111539
REVISION DATE	-

BDMP R&D  
 30 TUAS AVENUE 2 S(639461)  
 SINGAPORE

TITLE BD Odon Device™ - Instruction For Use			
DESIGNED BY	Narayanan V	UNITS METRIC/INCHES UNLESS OTHERWISE SPECIFIED	SHEET 2 OF 2
DRAFTED BY	Narayanan V	SCALE Scale Size 1:1 NOT PRINTED TO SCALE	TYPE EXPERIMENTAL
CREATION DATE	24 NOV 2017		DRAWING NUMBER SRD-DGP0036
FILE NAME	SRD-DGP0036_rev 01		

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**Table S3 Standards for Reporting Qualitative Research (SRQR)**

No.	Topic	Page number in manuscript
	<b>Title and abstract</b>	
S1	Title	1
S2	Abstract	2-3
	<b>Introduction</b>	
S3	Problem formulation	5-8
S4	Purpose or research question	5
	<b>Methods</b>	
S5	Qualitative approach and research paradigm	5-6
S6	Research characteristics and reflexivity	5-7
S7	Context	5-6
S8	Sampling strategy	6
S9	Ethical issues pertaining to human subjects	18
S10	Data collection methods	7
S11	Data collection instruments and technologies	7
S12	Units of study	7
S13	Data processing	7-8
S14	Data analysis	7-8
S15	Techniques to enhance trustworthiness	6-8
	<b>Results/findings</b>	
S16	Synthesis and interpretation	8-13
S17	Links to empirical data	8-13
	<b>Discussion</b>	
S18	Integration with prior work, implications, transferability, and contribution(s) to the field	14-17
S19	Limitations	14-17
	<b>Other</b>	
S20	Conflicts of interest	17
S21	Funding	8



No.	Topic	Item
<b>Title and abstract</b>		
S1	Title	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended
S2	Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions
<b>Introduction</b>		
S3	Problem formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement
S4	Purpose or research question	Purpose of the study and specific objectives or questions
<b>Methods</b>		
S5	Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/interpretivist) is also recommended; rationale <sup>b</sup>
S6	Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability
S7	Context	Setting/site and salient contextual factors; rationale <sup>b</sup>
S8	Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale <sup>b</sup>
S9	Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues
S10	Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale <sup>b</sup>
S11	Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study
S12	Units of study	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)
S13	Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts
S14	Data analysis	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale <sup>b</sup>
S15	Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale <sup>b</sup>
<b>Results/findings</b>		
S16	Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory
S17	Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings
<b>Discussion</b>		
S18	Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field
S19	Limitations	Trustworthiness and limitations of findings
<b>Other</b>		
S20	Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed
S21	Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting
<p><sup>a</sup>The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.</p> <p><sup>b</sup>The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.</p>		

ACADEMIC MEDICINE

# BMJ Open

## Novel device for assisted vaginal birth: using integrated qualitative case study methodology to optimise Odon Device use within a feasibility study in a maternity unit in the Southwest of England

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Manuscript ID	bmjopen-2021-059115.R1
Article Type:	Original research
Date Submitted by the Author:	12-Jun-2022
Complete List of Authors:	Hotton, Emily; University of Bristol; North Bristol NHS Trust Blencowe, Natalie; University of Bristol, Centre for Surgical Research, School of Social and Community Medicine Bale, Nichola; North Bristol NHS Trust Lenguerrand, Erik; University of Bristol School of Clinical Science, School of Clinical Sciences, Musculoskeletal Research Unit Draycott, Tim ; North Bristol NHS Trust Crofts, Joanna; North Bristol NHS Trust Wade, Julia; University of Bristol, Bristol Medical School
<b>Primary Subject Heading</b>:	Obstetrics and gynaecology
Secondary Subject Heading:	Qualitative research
Keywords:	QUALITATIVE RESEARCH, OBSTETRICS, STATISTICS & RESEARCH METHODS
Note: The following files were submitted by the author for peer review, but cannot be converted to PDF. You must view these files (e.g. movies) online.	
S2 Video.MOV	

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4 1 **Novel device for assisted vaginal birth: using integrated qualitative case**  
5 2 **study methodology to optimise Odon Device use within a feasibility study in**  
6 3 **a maternity unit in the Southwest of England**  
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9 4

10 5 Emily J Hotton<sup>1,2\*</sup>, Natalie S Blencowe<sup>3,4</sup>, Nichola Bale<sup>2</sup>, Erik Lenguerrand<sup>1,2</sup>, Tim J Draycott<sup>2</sup>,  
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53 25 **Running title:** Optimising the use of the Odon Device  
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55 26  
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57 27 **Abstract word count:** 300  
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59 28 **Word count:** 3939  
60

## 29 **Objective**

30 When novel devices are used 'in human' for the first time, their optimal use is uncertain  
31 because clinicians only have experience from pre-clinical studies. This study aimed to  
32 investigate factors that might optimise use of the Odon Device for assisted vaginal birth.

## 33 **Design**

34 We undertook qualitative case studies within the ASSIST Study, a feasibility study of the  
35 Odon Device. Each 'case' was defined as one use of the device and included at least one of  
36 the following: observation of the attempted assisted birth, and an interview with the  
37 obstetrician, midwife or woman. Data collection and thematic analysis ran iteratively and in  
38 parallel.

## 39 **Setting**

40 Tertiary referral NHS maternity unit in the Southwest of England.

## 41 **Participants**

42 Women requiring a clinically indicated assisted vaginal birth.

## 43 **Intervention**

44 The Odon Device, an innovative device for assisted vaginal birth.

## 45 **Primary and secondary outcomes measures**

46 Determining the optimal device technique, device design and defining clinical parameters  
47 for use.

## 48 **Results**

49 Thirty-nine cases involving an attempted Odon assisted birth were included in this study, of  
50 which 19 resulted in a successful birth with the device. Factors that improved use included  
51 optimisation of device technique, device design and clinical parameters for use. Technique  
52 adaptations included: applying the device during, rather than between, contractions; having  
53 a flexible approach to the application angle; and deflating the air cuff sooner than originally

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2  
3 54 proposed. Three design modifications were proposed involving the deflation button and  
4  
5 55 sleeve. Although use of the device was found to be appropriate in all fetal positions, it was  
6  
7 56 considered contraindicated when the fetal station was at the ischial spines.  
8  
9

## 10 57 **Conclusions**

11  
12 58 Case study methodology facilitated the acquisition of rapid insights into device function in  
13  
14 59 clinical practice, providing key insights regarding use, design, and key clinical parameters for  
15  
16 60 success. This methodology should be considered whenever innovative devices are  
17  
18 61 introduced into clinical practice.  
19

## 20 62 **Trial registration**

21  
22  
23 63 ASSIST Study registration: ISRCTN10203171 <https://doi.org/10.1186/ISRCTN10203171>  
24  
25

## 26 64 **Keywords**

27  
28  
29 65 Assisted vaginal delivery, qualitative research, translational research, Medical Devices  
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3 66 **Article Summary**  
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- 5 67 • Case study methodology including data from participant observation and/or  
6  
7 68 interviews (with operators, midwives and/or women), was successfully used in  
8  
9 69 an intrapartum setting to evaluate the use of a novel device, the Odon Device,  
10  
11 70 for assisted vaginal birth.  
12  
13 71 • Iterative data analysis and feedback of findings enabled rapid dissemination of  
14  
15 72 findings to key stakeholders, and consensus regarding future alterations to  
16  
17 73 device design, technique, and selection criteria for optimal device use.  
18  
19 74 • Observations were undertaken where possible; however, due to the  
20  
21 75 unpredictable nature of AVBs it was not possible to attend them all, potentially  
22  
23 76 impacting on the generalisability of our findings.  
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## 78 Introduction

79 Each year approximately 82,000 women in the UK have an assisted vaginal birth (AVB).[1] In  
80 recent years, despite the known advantages of AVB, this rate has reduced with a  
81 corresponding increase in Caesarean births in the second stage of labour. Current devices  
82 for AVB require a high level of training and skill (with additional expertise required to define  
83 the fetal position) and can be associated with significant maternal and neonatal morbidity if  
84 used incorrectly.[2] An innovative device that is easier and safer to use, could increase  
85 women's access to AVB, which in turn would help to reduce the number of emergency  
86 Caesarean sections performed in the second stage.[3,4]

87 Before introducing devices into widespread practice, it is necessary to evaluate their safety  
88 and efficacy, and obtain CE marking. However, other factors – such as device technique,  
89 design, and clinical parameters for use – are not routinely assessed, yet may ultimately limit  
90 their success. Preliminary feasibility work exploring these other factors may be valuable  
91 prior to evaluation within a definitive randomised controlled trial. The Odon Device (**Figure**  
92 **3**) has undergone rigorous pre-clinical[5], simulation[6,7], human factors[8] and Phase 1  
93 first-in human investigation[9] which conclude that it appeared to be safe. However, the  
94 Odon Device has hitherto not been used in the intended population: women requiring an  
95 AVB. The Odon Device was originally designed by Jorge Odón and has since been developed  
96 by a team of clinicians and medical engineers. It assisted birth using an inflatable air cuff  
97 attached to handles (Figure 1).

98 This study applied qualitative case study methodology to examine in detail how the Odon  
99 Device (version 4.1) is used for AVB, and to determine what factors may impact on optimal  
100 use. The study was embedded in the ASSIST Study – a feasibility study of the Odon  
101 Device.[10,11]

102 **Figure 1** Diagram of the Odon Device

103

## 104 Methods

105 *Research design*



1  
2  
3 106 The ASSIST Study[10,11] was conducted in a maternity unit in the Southwest of England  
4  
5 107 with full detail published elsewhere.[11,12] Integrated within the study was qualitative  
6  
7 108 research, using case study methodology to explore the factors that may influence optimum  
8  
9 109 device use. Case study methodology is particularly suited to answering 'how and why'  
10  
11 110 questions and providing in-depth contextual detail, essential in early evaluations[13] of  
12  
13 111 complex interventions,[14–16] such as use of a novel device for AVB,[17] and has previously  
14  
15 112 been used to explore surgical innovation.[18] In this study, each 'case' was defined as one  
16  
17 113 use of the device and included at least one of the following: observation of the attempted  
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19 114 Odon assisted birth and/or an interview with the obstetrician, midwife or woman. The  
20  
21 115 researcher ensured that the use of the device in the study was compared against the  
22  
23 116 Instructions For Use (IFU) document, which is mandated by regulatory bodies as one of the  
24  
25 117 processes to ensure device safety and efficacy. Given the focus of this paper is of the  
26  
27 118 technical aspects of device use, data presented reports observation and healthcare  
28  
29 119 professional interview findings. Data reporting experiences of women are presented  
30  
31 120 separately.[12]

32 121

### 34 122 *Participants*

36  
37 123 There were two groups of participants for the case studies: women and healthcare  
38  
39 124 professionals (obstetricians and midwives). All women participating in the ASSIST Study  
40  
41 125 were eligible to be included in the case study research and gave written consent.[12] All  
42  
43 126 trained operators and midwives provided written consent. There were five operators, three  
44  
45 127 consultants and two registrars.

47 128

### 50 129 *Sampling*

52  
53 130 Typical sampling for observation was in part purposive and in part opportunistic (i.e.  
54  
55 131 dependent on the researcher being on site and available to conduct the observation). The  
56  
57 132 aim was to include a range of clinical indications for AVB and a range of operators.

59 133

## 134 **Patient and public involvement**

135 Patients and the public were involved in all aspects of the ASSIST Study, as previously  
136 reported.[10,12]

137

## 138 **Data collection**

139 Included case studies comprised data from one or more of the following sources:  
140 observations of the AVBs and/or interviews with women, midwives and operators.  
141 Observations, including technical details, contextual factors and communication, were  
142 prospectively recorded on a bespoke observation schedule. Detailed observations of the  
143 operative steps performed by the obstetrician during AVBs were recorded enabling a  
144 stepwise account of the 'usual steps' to be generated and compared against the IFU. The  
145 original IFU were developed prior to the ASSIST study during phase 1 clinical and simulation  
146 studies and included 22 operative steps.[8,9] In these IFU, the AVB was divided into six  
147 domains according to purpose (**Table 1**). The IFU and instructional video for operators used  
148 for the Odon Device in the ASSIST Study can be viewed in Supplementary files 1 and 2.

149 All women who had the birth of their baby formally observed were invited to participate in  
150 an interview at day one postnatal and clinicians within five days following the assisted  
151 birth.[10] In line with usual practice in conducting case study research a flexible approach  
152 was taken to which data were collected for each case, based on the value of insights gained  
153 for each data source. Any method of data collection (observation or interview) could be  
154 suspended if it was observed to be delivering no new insights.

155

## 156 **Data analysis**

157 Data collection and analysis were iterative and ran in parallel using the six-step framework  
158 described for thematic analysis.[19] Data analysis was largely inductive although some  
159 deduction derived from using the IFU as a framework against which to evaluate what took  
160 place. All data for each case were read together to identify and organise codes. Codes were

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3 161 developed using text that captured significant views in the data, then grouped to reflect  
4  
5 162 developing themes, with code descriptions and sample quotes assigned. Double coding of a  
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7 163 proportion of interview transcripts (20%) was undertaken by JW. A narrative report was  
8  
9 164 created for each case, triangulating all available data. Any issues requiring clarification were  
10  
11 165 highlighted during the creation of the report, for exploration during subsequent interviews.  
12  
13 166 Commonality and variances across cases were discussed between the researchers and used  
14  
15 167 to further shape evolving themes and sampling. This systematic analysis supported rapid  
16  
17 168 within- and cross-case comparison. Nvivo 12 (QSR International, Melbourne, Australia) was  
18  
19 169 used to organise data and support analysis.  
20  
21 170

170

### 171 **Feedback of findings**

22  
23  
24 172 Iterative data collection and analysis enabled the rapid identification of key learning points  
25  
26 173 or corrections to technique for dissemination to operators (see Table 2). Key findings were  
27  
28 174 relayed rapidly to operators using messages via an end-to-end encryption platform, regular  
29  
30 175 face-to-face discussions and operator debriefs. Furthermore, following the 36<sup>th</sup> Odon  
31  
32 176 assisted birth, an interactive summit was held with key stakeholders (the clinical research  
33  
34 177 team, design engineers, statisticians, and funders), with the aim of sharing learning  
35  
36 178 experiences and gaining consensus regarding any changes that may be suggested.  
37

179

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41  
42  
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47  
48 183 already been assigned to the Author Accepted Manuscript version that might arise from this  
49  
50 184 submission.  
51

185

### 186 **Results**

52  
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55  
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57  
58 187 Forty births were assisted with the Odon Device at North Bristol NHS Trust, UK, between  
59  
60 188 October 2018 and January 2019. One case had no qualitative data because the researcher

1  
2  
3 189 was unavailable, resulting in 39 case studies arising from 40 (97.5%) single uses of the Odon  
4  
5 190 Device (**Table 2**). Data for the cases studies included eight observations and accompanying  
6  
7 191 interviews with the women, 19 midwife interviews, 37 operator interviews and two  
8  
9 192 operator reflections (Table 2). All births were assisted in the lithotomy position. Ninety  
10  
11 193 percent of women had a perineal tear, including 28 episiotomies and three women (8%)  
12  
13 194 sustained a third-degree perineal tear.[10] Nineteen births were successfully assisted with  
14  
15 195 the Odon Device. Of those that were unsuccessful, 19 were assisted by forceps and two by  
16  
17 196 Caesarean section. There were no serious maternal or neonatal adverse events related to  
18  
19 197 the use of the device and there were no serious adverse device effects. Four devices (10%)  
20  
21 198 were ineffective due to a manufacturing fault.[10] Observations varied in length from 33 to  
22  
23 199 68 minutes. Interviews with women lasted 6.5 to 9.6 minutes, interviews with operators  
24  
25 200 lasted between 5.4 and 26.1 minutes and interviews with midwives lasted 3.4 to 13.2  
26  
27 201 minutes. The shorter interviews with operators and midwives were all from cases in which  
28  
29 202 the Odon Device was used successfully. Interviews for cases in which the Odon Device was  
30  
31 203 unsuccessful were often longer as there were more aspects of device use to discuss.  
32  
33 204 Another potential reason some interviews were short is that all operators and midwives  
34  
35 205 were interviewed more than once, meaning they often did not have additional comments in  
36  
37 206 subsequent interviews.

38  
39 207 It became apparent that there were three factors contributing to optimisation of device use:  
40  
41 208 (i) device technique, (ii) device design and (iii) clinical parameters for device use (Figure 2).

42  
43 209 **Figure 2** How case study methodology may be able to determine optimal device use through bridging multiple  
44  
45 210 factors relating to the device

46  
47 211

#### 48 212 ***Device technique***

49  
50 213 Suggested adaptations to the original IFU included (i) device application during rather than  
51  
52 214 between contractions, (ii) altering the application angle and (iii) deflating the air cuff as soon  
53  
54 215 as any aspect of the blue deflation line became visible.

55  
56 216

#### 57 217 ***Device application with a contraction***

1  
2  
3 218 The original IFU stated that the Odon Device should be applied between contractions, as  
4  
5 219 was standard practice with forceps and ventouse. It became apparent during the first two  
6  
7 220 attempted AVBs that this disimpacted the fetal head out of the pelvis and operators were  
8  
9 221 unable to correctly place the device:

10 222 *D1: 'Again, I had to use significant pressure to try and get the device over the fetal*  
11  
12 223 *head. And loads of liquor came down during the application suggesting that there*  
13  
14 224 *was some degree of disimpaction.'*

15  
16  
17 225  
18  
19 226 By the third attempted birth, operators had adapted their technique to include fundal  
20  
21 227 pressure to aid application, which resulted in successful device application and the first  
22  
23 228 successful AVB. The use of fundal pressure, although successful, was not well tolerated by  
24  
25 229 women without a regional anaesthetic:

26 230 *M3: 'Significant fundal pressure that was used at the time...she was*  
27  
28 231 *uncomfortable...maybe that will be something up for review.'*

29  
30  
31 232  
32  
33 233 Following feedback from qualitative findings, the application technique was adapted again  
34  
35 234 during the eighth birth. This was the first time the Odon Device was applied during a  
36  
37 235 contraction without the use of fundal pressure, resulting in a successful application and  
38  
39 236 birth. Fundal pressure was only used in a small number of births and quickly dropped from  
40  
41 237 the technique as soon as application with a contraction was found to be successful:

42 238 *D2: 'I haven't used fundal pressure since delivery number two or three for me, but*  
43  
44 239 *what has been very successful is putting it on during a contraction. I think.'*

45 240  
46  
47 241 *Device application angle*

48  
49 242 The original IFU stated that the device should be applied 'starting at 45° below the  
50  
51 243 horizontal'. By the eighth attempted birth it was apparent that this was not optimal and  
52  
53 244 operators naturally moved to a more 'horizontal' application:

54 245 *D2: 'I definitely pushed the device in at a much flatter angle, much more parallel with*  
55  
56 246 *the bed than I had in the past...'*

57  
58  
59 247  
60

1  
2  
3 248 All operators quickly agreed that the angle required might be dependent on factors such as  
4  
5 249 fetal position and station:

6  
7 250 D1: *'So I was kind of like, "Oh, OP, it might be more, you know, it could be difficult*  
8  
9 251 *because it's an OP...'"*

10  
11 252 D2: *'I think we've still got to continue experimenting or changing the angle of*  
12  
13 253 *insertion. I think there may be an optimum angle of insertion or it may be that we*  
14  
15 254 *have to change angle of insertion for different stations...'*

16  
17  
18 255

19  
20 256 *Deflating the device*

21  
22 257 The original IFU stated that 'once you see the blue deflation line completely' the air cuff  
23  
24 258 should be deflated. By the third attempted birth it became apparent to the observer that  
25  
26 259 this was too late and that the optimum time for air cuff deflation seemed to be when any  
27  
28 260 section of the blue line could be seen:

29 261 O5: *'Noticed that it was not the anterior blue deflation line that the operator was*  
30  
31 262 *looking at the deflate but the posterior deflation line, due to the fact that there is an*  
32  
33 263 *acute J curve and anterior line not seen. Will need to change this in training.'*

34  
35 264

36  
37 265 These observations were fed back rapidly and iteratively to the Odon Device operators and  
38  
39 266 further discussed with the wider research team at the Odon Summit (Table 2).

40  
41 267

42  
43 268 ***Device design and performance***

44  
45 269 Multiple potential device adaptations were noted during the case study research. Four  
46  
47 270 design modifications for future device adaptations were identified: (i) strengthening the  
48  
49 271 sleeve seal lines, (ii) creating a wider opening between the sleeve handles, (iii) altering the  
50  
51 272 design of the deflation button and (iv) address the manufacturing fault that was identified.

52 273

53  
54 274 *Sleeve seal lines and opening between sleeve handles*

55  
56  
57 275 One operator noted that the sleeve seal lines tore during traction, on several occasions:

58  
59  
60

1  
2  
3 276 D4: *'... the sleeve is not sturdy... it might actually rip it open, which has happened*  
4  
5 277 *with me a few times.'*  
6  
7

8 278 During device inspection, it was noted that all devices had small tears (<2cm) in the seal  
9  
10 279 lines of the sleeve, and one had a significant tear (>7cm). There was no evidence any of  
11  
12 280 these tears had had a negative effect on the function of the Odon Device, indeed the device  
13  
14 281 with a significant tear achieved a successful Odon birth. Tearing was thought to have  
15  
16 282 occurred when operators opened the sleeve handles before and between tractions to  
17  
18 283 physically look at the station of the vertex. In contrast to standard devices used for AVB,  
19  
20 284 there was little proprioceptive feedback to ascertain the station of the baby, so visual  
21  
22 285 inspection was useful:

23  
24 286 O5: *'...I got the impression that the operator was unsure as to whether the head had*  
25  
26 287 *descended so opened the handles to look inside the sleeve.'*  
27

28  
29  
30 289 Following interviews, it was suggested that the opening between the two handles was made  
31  
32 290 wider to enable operators to view the progression of the baby's head more easily (Figure  
33  
34 291 S1). Ultrasound assessment was not used as this method was not routinely adopted in our  
35  
36 292 unit at the time of the study.  
37

38 293

#### 40 294 *Deflation button*

41  
42  
43 295 In six cases it was noticed that the operator accidentally pressed the deflation button. Each  
44  
45 296 time this occurred, the cuff was reinflated immediately. All operators agreed that the  
46  
47 297 design of the deflation button should be altered to reduce the risk of inadvertent activation  
48  
49 298 (Figure S2):

50  
51 299 O3: *'Operator accidentally pressed the deflation button 'oh, whoops that was my*  
52  
53 300 *fault, I'll just re-inflate.'*  
54

55  
56 301

#### 57 302 *Manufacturing fault*

1  
2  
3 303 All devices were disinfected and inspected following their use as per protocol.[10,11]  
4  
5 304 During this inspection, four devices were found to have an ineffective bulb pump (**Error!**  
6  
7 305 **Reference source not found.**) which resulted in inadequate cuff inflation (**Table 2**).  
8  
9 306 Operators' comments during the attempted births reflected this, as the device did not act in  
10  
11 307 the expected manner.

12 308 *D4: 'Yes, there was no grip... It just came out deflated, so it didn't feel right.'*

13  
14  
15 309  
16  
17 310 This prompted a rapid retrospective review of all used and stored devices to ensure that no  
18  
19 311 other unsuccessful attempts were attributed to this fault, none were.

20  
21 312

### 22 313 ***Optimal clinical parameters for Odon Device use***

23  
24 314 The Odon Device was used to successfully assist births in all fetal positions. Midwives  
25  
26 315 particularly noted how the device could help deliver a baby in the occipito-posterior  
27  
28 316 position which is a technically more challenging position:

29  
30  
31 317 *M9: 'I think, probably, it could be quite universal as an instrumental device. It didn't*  
32  
33 318 *seem to matter whether the baby was OA [occipito-anterior] or OP [occipito-*  
34  
35 319 *posterior]...'*

36  
37 320 However, although the device could be successful at assisting birth in all positions, it  
38  
39 321 became apparent that for women with fetal station at spines or a more complex  
40  
41 322 presentation (such as brow or nuchal arm) the device was not successful. Operators were  
42  
43 323 either unsuccessful at applying the device correctly onto the fetal head or the device simply  
44  
45 324 slipped off the fetal head with the initial traction:

46  
47 325 *D1: 'So, it was direct OP at the spines, and it was almost coming to a brow, I could*  
48  
49 326 *feel the orbital ridges...I was thinking, "Oh, I'm really not sure that this is going to*  
50  
51 327 *work."...I didn't feel that was a failed Odon, that was a baby that was never going to*  
52  
53 328 *come out vaginally.'* [unsuccessful Odon-failed rotational forceps, emergency  
54  
55 329 Caesarean section]

56  
57  
58 330  
59  
60



1  
2  
3 331 As experience with the device increased, it became apparent that the device could be used  
4  
5 332 comfortably without a regional anaesthetic (with only perineal infiltration of local  
6  
7 333 anaesthetic). Device use was noted to be better tolerated than bladder emptying by  
8  
9 334 urethral catheterisation, a procedure that is less invasive:

10  
11 335 *D2: 'She actually found the catheterisation more uncomfortable than putting on the*  
12  
13 336 *Odon Device with no analgesia at all.'*  
14  
15

16 337

### 17 338 **Feedback to operators**

18  
19 339 All qualitative case study findings relating to device technique, design, and clinical  
20  
21 340 parameters for use were presented to key stakeholders at the Odon Summit by the  
22  
23 341 qualitative researcher. The case study research provided suggestions for device technique  
24  
25 342 adaptation for some of the operative steps, but not for them all. It was agreed that there  
26  
27 343 were still unanswered questions regarding the technique (such as which angle to use for  
28  
29 344 application) and that further data was required to achieve this. Clinically important  
30  
31 345 adaptations to device design were agreed upon (including altering the deflation button  
32  
33 346 design) and the clinical parameters for use were confirmed, with an agreement that the  
34  
35 347 device should not be used if the vertex is at the level of the ischial spines.  
36

37 348

### 38 349 **Discussion**

39  
40 350 Case study research identified three areas that could optimise device use: (i) device  
41  
42 351 technique, (ii) device design and (iii) acceptable clinical parameters. Principal technique  
43  
44 352 adaptations were centred on device application and deflation of the air cuff. The initial IFU  
45  
46 353 specified a particular angle for device application however, during clinical use it became  
47  
48 354 apparent that this angle needed to be flexible and was less acute than originally specified  
49  
50 355 however, there was no consensus on the exact optimal angle and it was surmised that more  
51  
52 356 data would be required to achieve this. Device modifications of altering the sleeve and  
53  
54 357 deflation button were recommended for useability rather than to transform the  
55  
56 358 functionality of the device. The manufacturing fault was quickly identified and rectified by  
57  
58 359 the manufacturer through post-use device inspection. Optimal parameters for device use  
59  
60 360 were proposed and focussed primarily on the station of the baby, with use at station spines  
361 recommended to be prohibited. Adaptations to optimise device use were adopted by the

1  
2  
3 362 manufacturer to create Odon Device (version 4.2) which was used in two further Odon  
4  
5 363 Device feasibility studies, each studying 104 Odon assisted births. These have recently  
6  
7 364 closed to recruitment in the UK[20] and France[21] and aimed to address the unanswered  
8  
9 365 aspects of optimal device use, specifically the technique. These findings will be published  
10  
11 366 once follow-up and data analysis is complete. Case study research enabled systematic,  
12  
13 367 rapid generation of data and understanding of device use that enabled the researchers and  
14  
15 368 manufacturers develop study protocols and device updates to support the ongoing  
16  
17 369 investigation of the device.

18 370

### 19 371 **Strengths and limitations**

21 372 This was the first time that research has been undertaken on the Odon Device in clinically  
22  
23 373 indicated cases and indeed the first-time case study research has been used to explore the  
24  
25 374 use of devices for AVB. Device design and technique is unique to the device and although  
26  
27 375 cannot be directly compared to other devices for AVB step-by-step, some comparisons and  
28  
29 376 differences can be noted. The Odon Device, unlike other devices for AVB[22], can only be  
30  
31 377 successfully applied during a contraction or with maternal effort, even though techniques  
32  
33 378 for traction once the device is applied appear similar. Clinical indications for use are slightly  
34  
35 379 different to that of forceps and ventouse in the UK.[22] In the UK, all currently used devices  
36  
37 380 for AVB are permitted to be used at stations spines or below. We have demonstrated that  
38  
39 381 this is not the case for the Odon Device, as we have demonstrated that this will not be  
40  
41 382 successful. Interestingly, performing AVBs at station spines is not permitted in other  
42  
43 383 countries.[23]

44 384

45 385 An AVB is a complex intervention, and this makes studying the use of the device challenging.  
46  
47 386 Qualitative case study methodology has been used to explore technique in surgical  
48  
49 387 procedures[18] however, there are no published examples of case study methodology being  
50  
51 388 used to investigate novel devices. The case studies integrated participant observation as  
52  
53 389 well as interviews with operators, midwives, and women to explore the introduction of an  
54  
55 390 innovative device in context and in detail. The benefits of this were that experiences, and  
56  
57 391 views of all stakeholders were easily obtained, and we were able to investigate operator  
58  
59 392 views in detail. Triangulation of data linked to a particular case led to insights for  
60  
393 amendments for optimum device use being identified more rapidly than if a single source of

1  
2  
3 394 qualitative data (e.g., observation or interview only) had been used. Rapid dissemination of  
4  
5 395 findings resulted in prompt adoption of beneficial techniques for use. By using this  
6  
7 396 methodology and incorporating data from all stakeholders (operators, midwives, and  
8  
9 397 women) and observations we were able to gain a balanced and comprehensive assessment  
10  
11 398 of the use of the device. When trying to understand optimal device use, operator  
12  
13 399 interviews were found to be of crucial importance. Comparing case study data collected  
14  
15 400 under different conditions (such as different analgesia, different presentations of babies,  
16  
17 401 different operators) enabled commonalities and disparities in technique to be highlighted  
18  
19 402 and thoroughly investigated. This enabled the clinical research team to propose evidence-  
20  
21 403 based modifications to the device design and provide clarity on recommendations for  
22  
23 404 clinical parameters for use. Case study methodology encouraged operators to reflect,  
24  
25 405 critique and appraise their use of the device for each birth, resulting in enhanced and  
26  
27 406 enriched communication between operators regarding their experiences through  
28  
29 407 conversations and a dedicated operator messaging group. In future, data from encrypted  
30  
31 408 social media platforms could be incorporated into the qualitative data for analysis.  
32  
33 409 Reporting was undertaken following the Standards for Reporting Qualitative Research[24]  
34  
35 410 (Supplementary information 3).

36  
37 411  
38 412 There are limitations to this study. The aim of understanding the optimal operative steps  
39  
40 413 for device use, and thus confirming a finalised IFU were not met. For some operative steps  
41  
42 414 consensus was reached as to the recommended course of action (such as applying the  
43  
44 415 device with a contraction). However, for others more data were required (such as what  
45  
46 416 specific angle of application to use). Case studies within the ASSIST Study were finite.  
47  
48 417 Observations were undertaken where possible, however due to the unpredictable nature of  
49  
50 418 AVBs it was not possible to attend all assisted births. Indeed, none of the more complex  
51  
52 419 attempted AVBs performed in the operating theatre were observed. This could have an  
53  
54 420 impact on the generalisability of the findings as births undertaken in the operating theatre  
55  
56 421 are often more technically challenging for operators. All interviews with clinicians were  
57  
58 422 undertaken within five days following the assisted birth. Recollections of the clinicians may  
59  
60 423 have been less accurate the longer the time between assisted birth and interview. The case  
61  
62 424 studies were undertaken by a specialist trainee in obstetrics and gynaecology meaning that  
63  
64 425 pre-conceptions and existing knowledge may have influenced the collection and

1  
2  
3 426 interpretation of the data, although at the time of commencing the case studies the  
4  
5 427 researcher was naïve to the use of the Odon Device in the clinical setting. Lastly, operators  
6  
7 428 may have changed their behaviours during observations, perhaps not reflecting their real-  
8  
9 429 life practice.

10  
11 430  
12 431 There are two key next steps that should be considered. Firstly, feasibility of the use of the  
13  
14 432 Odon Device for AVB should be undertaken in different healthcare settings. Thus far,  
15  
16 433 research has been undertaken in high-income settings where AVB is used regularly.  
17  
18 434 Exploring device using in low- and middle- income settings, including where rates of AVB are  
19  
20 435 lower than the UK and France could help understand if there are further considerations for  
21  
22 436 optimal device use that need to be addressed. Secondly, following the completion of the  
23  
24 437 two further feasibility studies, a decision needs to be made as to whether the device is  
25  
26 438 ready to be compared against available alternatives (forceps and ventouse) in a randomised  
27  
28 439 controlled trial. As recommended by IDEAL-D[25] researchers need to be satisfied that the  
29  
30 440 technique, design and clinical parameters for use are sufficiently stable to enable this to  
31  
32 441 happen.

33 442

### 35 443 **Conclusion**

37  
38 444 Case study methodology facilitated insights into optimal technique, design and clinical  
39  
40 445 parameters for use of the Odon Device. Optimising use of a device is an essential  
41  
42 446 prerequisite to evaluating outcomes, as it will impact directly on those outcomes and may  
43  
44 447 result in lower-than-expected success rates. There were two clear factors that enhanced  
45  
46 448 operator communication. Firstly, systematic triangulation of data from varying data sources  
47  
48 449 provided a comprehensive, contextual overview of device use and rapid understanding of  
49  
50 450 amendments required and secondly, rapid feedback of insights as they emerged to  
51  
52 451 operators. This also facilitated operator consensus building, which was key in  
53  
54 452 understanding and developing the iterative adaptations to the device technique, design and  
55  
56 453 clinical parameters for device use. This is of paramount importance for getting operator  
57  
58 454 buy-in for the next steps of device evaluation. This methodology should be considered  
59  
60 455 whenever innovative devices are introduced to clinical trials and settings. It allows for rapid

1  
2  
3 456 assessment of device use and can support timely iterative adaptations to ensure there are  
4  
5 457 minimal delays between device use in research and adoption in clinical practice.  
6  
7  
8 458

9  
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11  
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26  
27 467 Hub for Trials Methodology Research (MR/K025643/1).  
28

29 468

30  
31  
32 469 **Competing interests**

33  
34  
35 470 Authors report no competing interests.  
36

37 471

38  
39  
40 472 **Contribution to Authorship**

41  
42  
43 473 EJH, NSB and JW developed the concept for the study. EJH performed all data collection  
44  
45 474 and analysis with co-coding performed by JW. EJH wrote the initial draft of the manuscript,  
46  
47  
48 475 with support from NSB, JFC and JW. EJH, NSB, NB, EL, TJD, JFC and JW reviewed and  
49  
50 476 approved the final manuscript.  
51

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53 477

54  
55  
56 478 **Ethical approval**  
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59  
60

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3 479 The research was approved by South Central–Berkshire REC, UK on 3rd September 2018  
4  
5 480 (18/SC/0344), the MHRA on 9th August 2018 and the HRA on 3rd September 2018.  
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7 481  
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10 482 **Data sharing statement:** Data are available upon reasonable request.  
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For peer review only

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2  
3 484 **Table/figure/video caption list**  
4  
5

6 485 **Table 1** Original components of application of the Odon Device for an assisted vaginal birth  
7  
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9 486

10 487 **Table 2** Summary of 40 cases investigating the Odon Device with adaptations made to  
11  
12 488 device technique  
13

14 489

15  
16 490 **Figure 3** Diagram of the Odon Device  
17

18 491

19 492 **Figure 4** How case study methodology may be able to determine optimal device use through  
20  
21 493 bridging multiple factors relating to the device  
22

23 494

24  
25 495 **Supplementary file (S1)** Odon Device IFU for Clinical Studies  
26

27 496

28  
29 497 **Supplementary file (S2)** Instructional video for the ASSIST Study  
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31 498 Video detailing how to use the Odon Device using a mannequin  
32

33 499  
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35  
36 500 **Supplementary file (S3)** Standards for Reporting Qualitative Research (SRQR)  
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572 **Table 1 Original components of application of the Odon Device for an assisted vaginal birth**

Component	Steps within component
Preparation	Checking clinical pre-requisites for AVB Lubricating the device
Device application	Removing the fastening band Applying the device onto a fetal head
Cuff inflation	Ensuring the cuff is fully inflated in the correct position on the fetal head
Applicator removal	Removing the applicator from the fetal head
Traction	Following the J-shape curve of the pelvis applying traction with contractions
Removal of device	Deflating the air cuff as the fetal head is crowning

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575 **Table 2 Summary of 40 cases investigating the Odon Device with adaptations made to device technique**

Case study no.	Successful (S) Unsuccessful (U) AVB with Odon and mode of birth	Observation	Women	Interviews Operator	Midwife	Device issues
1	U – Forceps	O1	W1	D1	M1	
2	U – Forceps			D2	M2	
<b>Fundal pressure during device application tried</b>						
3	S – Odon			D2	M2 M3	
<b>Deflation of the air cuff when only part of the blue line was seen introduced</b>						
4	S – Odon			D2	M4	
5	U – Forceps			D1	M2	
6	S – Odon			D2*		
7	U – Forceps	O2	W2	D1	M5	AD
<b>Accidental pressing of the deflation button first noted</b>						
<b>Altered the angle of device insertion</b>						
<b>Application during a maternal contraction introduced, use of fundal pressure removed</b>						
8	S – Odon	O3	W3	D2	M6	AD
<b>Opened the sleeve handles during descent to monitor progression of fetal head first noted</b>						
9	U – Forceps	O4	W4	D1		
10	S – Odon			D2	M7	
11	S – Odon	O5	W5	D1	M8	AD
12	S – Odon	O6	W6	D1	M9	AD
13	S – Odon	O7	W7	D3	M2	
14	U – Failed rotational forceps, emergency Caesarean section			D1	M7	AD
15	U – Forceps			D2	M4	
16	U – Forceps	O8	W8	D2	M10	IBP
17	S – Odon			D1		
18	S – Odon			D3	M11	
19	S – Odon			D4		SST
20	U – Rotational forceps			D4		IBP
21	U – emergency Caesarean section			D3	M6	
22	U – Forceps			D4		
23	U – Forceps			D1	M6	IBP
24	S – Odon			D1		
25	U – Forceps			D4		
26	U – Forceps			D4		
27	S – Odon			D1		AD
28	U – Forceps			D1		
29	S – Odon			D5		
30	U – Forceps			D1		
31	U – Forceps			D4		IBP
32	U – Forceps			D1		
33	S – Odon			D5		
34	S – Odon			D2		
35	S – Odon			D2		
36	U – Forceps			D4		
<b>Odon summit held</b>						
37	U – Forceps			D1		
38	S – Odon			D4		
39	S – Odon			D4	M6	
40	U – Forceps			D3		

\*Qualitative interview from Obstetrician not obtained for this birth  
 O = observation, W = woman, D = Obstetrician, M = Midwife  
 AD = accidental deflation, IBP = ineffective bulb pump, SST = significant sleeve tear  
**Bold italic steps** = key stages in the study that impacted on technique

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**Pre-assembled  
Odon Device**



**Sleeve**



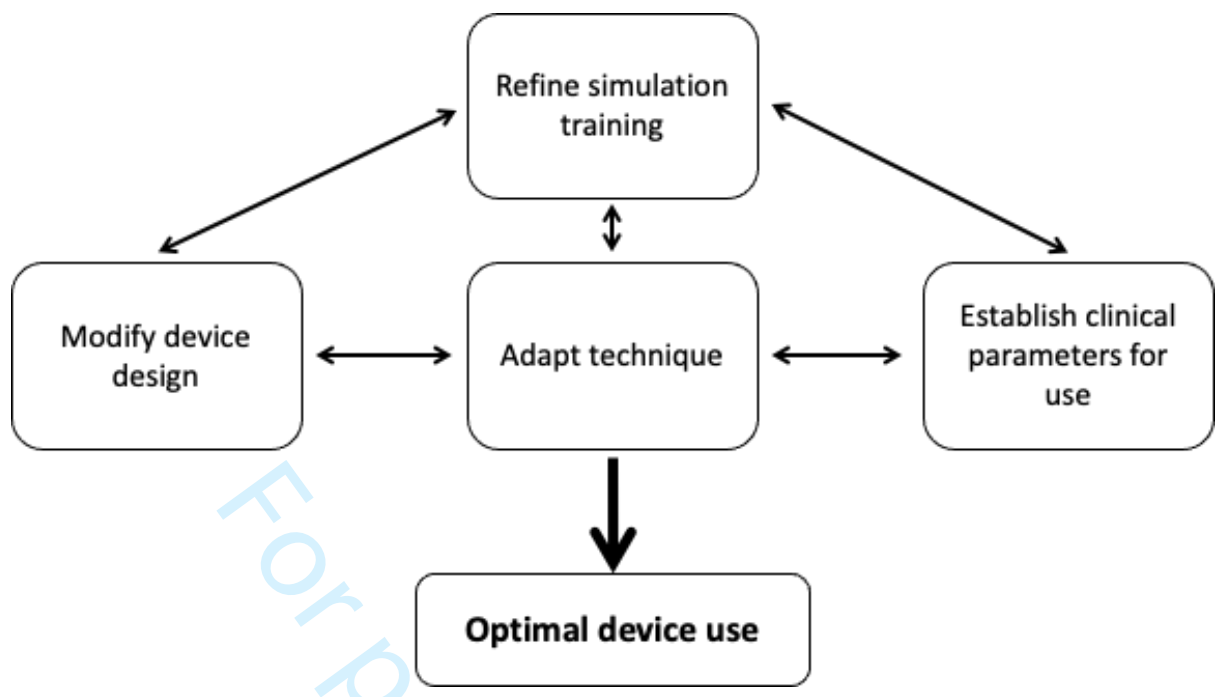
**Applicator**



Diagram of the Odon Device

225x190mm (81 x 81 DPI)

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REV (VER)	REVISION DESCRIPTION	CR NO.
01(A)	INITIAL RELEASE	CM500000111539

# BD Odon Device™

## Inflatable device for assisted vaginal birth – Instructions For Use

### Device Description

The **BD Odon Device™** is an instrument for assisted vaginal birth. The device uses a polyethylene sleeve and an inflatable air cuff to help ease the fetal head out of the birth canal. The BD Odon Device consists of an applicator, sleeve and fastening band.

### Indications for Use

The BD Odon Device is envisaged to perform assisted vaginal birth. The main indications for the BD Odon Device are as follows:

- Prolonged second stage of labour
- Suspected fetal compromise in the second stage of labour
- Other medical indications to shorten second stage of labour

### Contraindications

The use of the BD Odon Device is contraindicated in the following conditions:

- Cervix is not fully dilated
- Cephalopelvic disproportion/ irreducible moulding and large caput indicative of cephalopelvic disproportion
- Fetal head not fully engaged
- Undefined presentation
- Breech, transverse, face, brow presentations
- Membranes are not ruptured
- Contraindications for vaginal deliveries
- Untrained operator

### General Warnings

1. The BD Odon Device should be used by skilled birth attendants who are:
  - a. Trained to recognize the conditions for safe and effective application of the BD Odon Device:
    - Full cervical dilation
    - Fetal head position defined
    - Fetal head station defined
  - b. Trained to use the BD Odon Device

2. The BD Odon Device is intended for single use. Do not reuse. Device function may be impaired through reuse or cleaning. Degradation of materials or failure to correctly reassemble the device could result in harm for the mother and the fetus. Reusing the product after exposure to biological materials may cause adverse patient reactions due to contamination.

3. As with other devices for assisted vaginal birth, the BD Odon Device could fail to deliver the baby. The criteria to define failure and to abandon the procedure are:
  - a. No progression in descent of the fetal head after a total of three pulls
  - b. No more than two attempts at application (no more than two device slippages)
  - c. Duration of procedure longer than 20 minutes

4. As with other instruments for assisted vaginal birth, use of the BD Odon Device may result in maternal and neonatal complications. The most common complications with the use of
  - a. No progression in descent of the fetal head after a total of three pulls
  - b. No more than two attempts at application (no more than two device slippages)
  - c. Duration of procedure longer than 20 minutes

forceps and ventouse include maternal trauma, neonatal facial injury (forceps), cephalohaematoma, subgaleal haemorrhage, and retinal haemorrhage (ventouse).

Presently human, animal and simulated studies have not identified potential complications specific to the BD Odon Device therefore this section will be updated after analyses of the safety outcomes of the proposed randomised clinical study.

5. This BD Odon Device is exclusively for clinical investigation only.

6. Ensure packaging is not damaged prior to use. Discard product if packaging is found to be damaged.

### General Precautions

As with other devices for assisted vaginal birth the following precautions should be taken before applying the BD Odon Device to ensuring that conditions for safe application of device are met:

- Verify full dilation of cervix, fetal head station at the ischial spines or below
- Verify cephalic vertex presentation (Occiput anterior, Occiput posterior, Occiput transverse positions)
- Verify rupture of membranes
- Provide adequate analgesia according to facility procedures
- Position women in lithotomy position
- Empty bladder
- Re-confirm fetal position
- Lubricate the birth canal

### Symbol Legends

	Sterilized using radiation
	Do not re-use
	Do not re-sterilize
	Do not use if package is damaged
	Fragile, handle with care
	Keep away from sunlight
	Keep dry
	Contains or presence of natural rubber latex
	Batch code
	Use-by date
	Date of manufacture
	Manufacturer
	Authorized representative in the European Community
	Consult instructions for use
	Caution
	Serial number

Manufacturer: Becton Dickinson Medical Products Pte Ltd, 30 Tuas Avenue 2, Singapore 639461

Authorised representative in the European Community:  
Becton Dickinson France SAS, 11 rue Aristide Bergès, ZI des Iles, 38800 Le Pont de Claix, France

Odon Device is a trademark of Air Bag One. BD, the BD Logo, and all other trademarks are property of Becton, Dickinson and Company. © 2017 BD

VENDOR INFO:

-HOLDING LINES ONLY... DO NOT PRINT.  
NOT USE FOR DIMENSIONAL PURPOSES  
-IFU DIMENSIONS TO BE 210MM X 297MM.



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CR NO.	CM500000111539
REVISION DATE	-

BDMP R&D  
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SINGAPORE

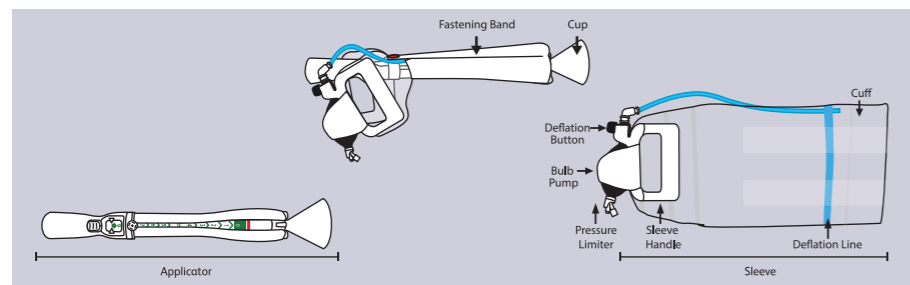
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TITLE		BD Odon Device™ - Instruction For Use	
DESIGNED BY	Narayanan V	UNITS METRIC/INCHES UNLESS OTHERWISE SPECIFIED	SHEET 1 OF 2
DRAFTED BY	Narayanan V	SCALE Scale Size 1:1 NOT PRINTED TO SCALE	TYPE EXPERIMENTAL
CREATION DATE	24 NOV 2017		DRAWING NUMBER SRD-DGP0036
FILE NAME	SRD-DGP0036_rev 01		



DEVICE USE STEPS (FOR CLINICAL INVESTIGATION ONLY)

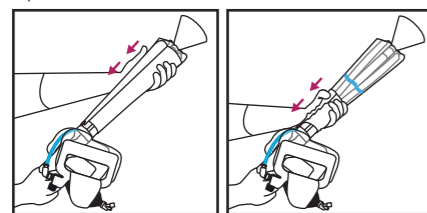
DEVICE USE STEPS (FOR CLINICAL INVESTIGATION ONLY)



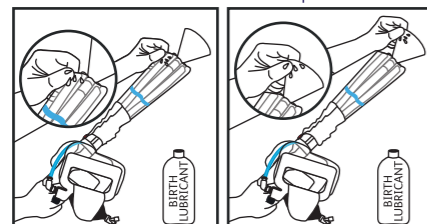
1. Ensure conditions for safe application of device are met:
  - a. Full dilation of cervix, fetal head 0 to +3 station, cephalic vertex presentation (OA, OP, OT positions), rupture of membranes
  - b. Provide adequate analgesia according to facility procedures
  - c. Position women in lithotomy position
  - d. Empty bladder
  - e. Re-confirm fetal position
  - f. Lubricate the birth canal

2. Remove BD Odon Device from packaging without compromising the sterility of the device.

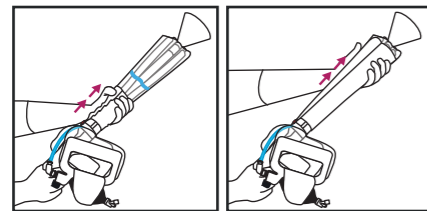
3. Pull back the fastening band until the blue deflation line is exposed.



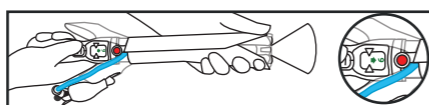
4. With the fastening band still intact, generously lubricate the inside and outside of the sleeve and the cup.



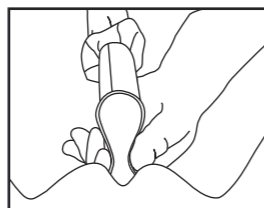
5. While holding the applicator handle gently slide the fastening band back to the top of the sleeve.



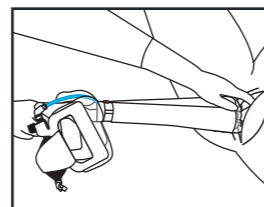
6. Grip the applicator handle and ensure the viewing window is facing upwards.



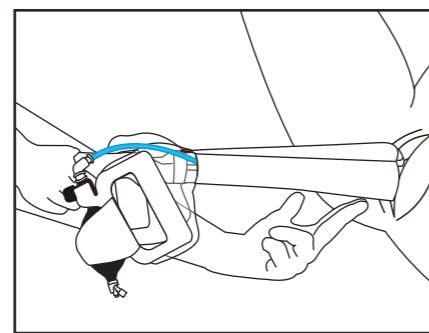
7. Fold the cup and gently insert it through the vulva and check it has regained its circular shape.



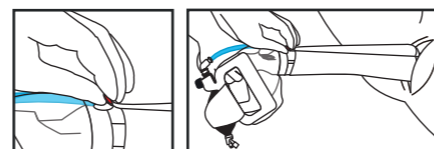
8. Check that there is no maternal tissue trapped between the cup and the fetal head.



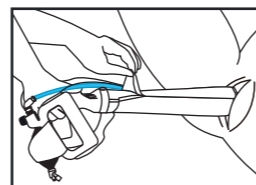
9. With your hand on the handle of the applicator, gently push the device through the vulva. Use your other hand to guide the device and do not apply any force with it.



10. Unfasten the red button

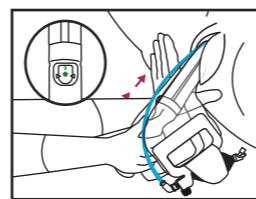


11. Open and completely remove the fastening band.

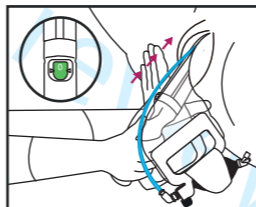


*Note: ensure the sleeve and applicator remain in place inside the vulva.*

12. Between contractions, keeping both hands away from the sleeve, continue to gently push the applicator, starting at 45° below the horizontal and following the curvature of the birth canal. Monitor progress by looking through the viewing window.

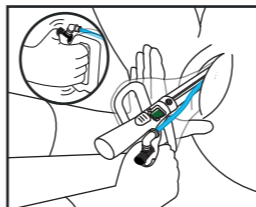


13. Continue to insert the device and stop when "0" appears in the viewing window.



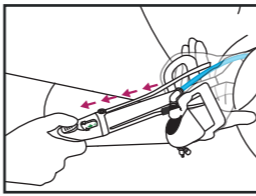
*Note: device is fully inserted when "0" appears in the viewing window.*

14. Squeeze the bulb pump fully and firmly at least 8 times to inflate the cuff.

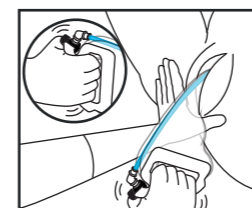


*Note: There is a pressure limiter in the bulb which prevents over inflation of the cuff.*

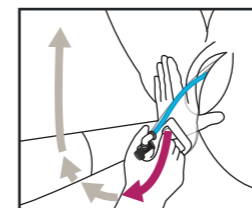
15. While protecting the perineum with one hand, use the other hand to completely withdraw the applicator and cup, leaving only the sleeve in place.



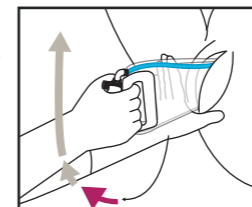
16. To compensate for possible reduction in cuff pressure, squeeze the bulb pump fully and firmly 2 more times prior to traction.



17. Grasp the sleeve handle, and during contractions pull gently and progressively following the J-shape of the birth canal.



18. While continuing to pull gently along the J-shape of the birth canal, confirm the fetal head is descending with pulling efforts.

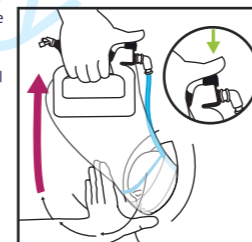


*Note: if baby is not delivered at the first contraction repeat steps 16, 17 and 18 with any subsequent contractions.*

19. Once you see the blue deflation line completely (approximately at crowning) deflate the cuff by pushing on the blue deflation button. Pull the sleeve handle continuing to press the deflation button following the J-shape of the birth canal.



20. Continue to pull the sleeve handle while pressing the blue deflation button to pull the fetal head until the sleeve detaches from the head.



21. Proceed to assist the birth of the baby as per normal procedure.

22. Discard disposable applicator and sleeve according to local appropriate procedure. Do not reuse.

VENDOR INFO:  
 -HOLDING LINES ONLY... DO NOT PRINT.  
 -NOT USE FOR DIMENSIONAL PURPOSES  
 -IFU DIMENSIONS TO BE 210MM X 297MM.



REV (VER)	01(A)
CR NO.	CM500000111539
REVISION DATE	-

BDMP R&D  
 30 TUAS AVENUE 2 S(639461)  
 SINGAPORE

TITLE BD Odon Device™ - Instruction For Use			
DESIGNED BY Narayanan V	UNITS METRIC/INCHES UNLESS OTHERWISE SPECIFIED	SHEET 2	TYPE EXPERIMENTAL
DRAFTED BY Narayanan V	SCALE Scale Size 1:1	OF 2	DRAWING NUMBER SRD-DGP0036
CREATION DATE 24 NOV 2017	NOT PRINTED TO SCALE		
FILE NAME SRD-DGP0036_rev 01			

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**Table S3 Standards for Reporting Qualitative Research (SRQR)**

No.	Topic	Page number in manuscript
	<b>Title and abstract</b>	
S1	Title	1
S2	Abstract	2-3
	<b>Introduction</b>	
S3	Problem formulation	5-8
S4	Purpose or research question	5
	<b>Methods</b>	
S5	Qualitative approach and research paradigm	5-6
S6	Research characteristics and reflexivity	5-7
S7	Context	5-6
S8	Sampling strategy	6
S9	Ethical issues pertaining to human subjects	18
S10	Data collection methods	7
S11	Data collection instruments and technologies	7
S12	Units of study	7
S13	Data processing	7-8
S14	Data analysis	7-8
S15	Techniques to enhance trustworthiness	6-8
	<b>Results/findings</b>	
S16	Synthesis and interpretation	8-13
S17	Links to empirical data	8-13
	<b>Discussion</b>	
S18	Integration with prior work, implications, transferability, and contribution(s) to the field	14-17
S19	Limitations	14-17
	<b>Other</b>	
S20	Conflicts of interest	17
S21	Funding	8

No.	Topic	Item
<b>Title and abstract</b>		
S1	Title	Concise description of the nature and topic of the study identifying the study as qualitative or indicating the approach (e.g., ethnography, grounded theory) or data collection methods (e.g., interview, focus group) is recommended
S2	Abstract	Summary of key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results, and conclusions
<b>Introduction</b>		
S3	Problem formulation	Description and significance of the problem/phenomenon studied; review of relevant theory and empirical work; problem statement
S4	Purpose or research question	Purpose of the study and specific objectives or questions
<b>Methods</b>		
S5	Qualitative approach and research paradigm	Qualitative approach (e.g., ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research paradigm (e.g., postpositivist, constructivist/interpretivist) is also recommended; rationale <sup>b</sup>
S6	Researcher characteristics and reflexivity	Researchers' characteristics that may influence the research, including personal attributes, qualifications/experience, relationship with participants, assumptions, and/or presuppositions; potential or actual interaction between researchers' characteristics and the research questions, approach, methods, results, and/or transferability
S7	Context	Setting/site and salient contextual factors; rationale <sup>b</sup>
S8	Sampling strategy	How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g., sampling saturation); rationale <sup>b</sup>
S9	Ethical issues pertaining to human subjects	Documentation of approval by an appropriate ethics review board and participant consent, or explanation for lack thereof; other confidentiality and data security issues
S10	Data collection methods	Types of data collected; details of data collection procedures including (as appropriate) start and stop dates of data collection and analysis, iterative process, triangulation of sources/methods, and modification of procedures in response to evolving study findings; rationale <sup>b</sup>
S11	Data collection instruments and technologies	Description of instruments (e.g., interview guides, questionnaires) and devices (e.g., audio recorders) used for data collection; if/how the instrument(s) changed over the course of the study
S12	Units of study	Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)
S13	Data processing	Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymization/deidentification of excerpts
S14	Data analysis	Process by which inferences, themes, etc., were identified and developed, including the researchers involved in data analysis; usually references a specific paradigm or approach; rationale <sup>b</sup>
S15	Techniques to enhance trustworthiness	Techniques to enhance trustworthiness and credibility of data analysis (e.g., member checking, audit trail, triangulation); rationale <sup>b</sup>
<b>Results/findings</b>		
S16	Synthesis and interpretation	Main findings (e.g., interpretations, inferences, and themes); might include development of a theory or model, or integration with prior research or theory
S17	Links to empirical data	Evidence (e.g., quotes, field notes, text excerpts, photographs) to substantiate analytic findings
<b>Discussion</b>		
S18	Integration with prior work, implications, transferability, and contribution(s) to the field	Short summary of main findings; explanation of how findings and conclusions connect to, support, elaborate on, or challenge conclusions of earlier scholarship; discussion of scope of application/generalizability; identification of unique contribution(s) to scholarship in a discipline or field
S19	Limitations	Trustworthiness and limitations of findings
<b>Other</b>		
S20	Conflicts of interest	Potential sources of influence or perceived influence on study conduct and conclusions; how these were managed
S21	Funding	Sources of funding and other support; role of funders in data collection, interpretation, and reporting
<p><sup>a</sup>The authors created the SRQR by searching the literature to identify guidelines, reporting standards, and critical appraisal criteria for qualitative research; reviewing the reference lists of retrieved sources; and contacting experts to gain feedback. The SRQR aims to improve the transparency of all aspects of qualitative research by providing clear standards for reporting qualitative research.</p> <p><sup>b</sup>The rationale should briefly discuss the justification for choosing that theory, approach, method, or technique rather than other options available, the assumptions and limitations implicit in those choices, and how those choices influence study conclusions and transferability. As appropriate, the rationale for several items might be discussed together.</p>		

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