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Exploring clinicians' perspectives on the 'Obstetric Anal Sphincter Injury Care Bundle' national quality improvement programme: A qualitative study

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3 **Exploring clinicians' perspectives on the 'Obstetric Anal Sphincter Injury Care Bundle' national**
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Abstract

Introduction: Obstetric anal sphincter injuries (OASI) can have severe debilitating consequences to women and health systems. The OASI Care Bundle Quality Improvement Programme was introduced in 16 maternity units across England, Scotland and Wales (January 2017 – March 2018) to address increasing OASI rates.

Objectives: To explore clinicians' (midwives' and obstetricians') perspectives of the OASI Care Bundle with respect to 1) Acceptability, 2) Feasibility and 3) Sustainability.

Design: A qualitative exploratory study using focus groups methodology.

Setting: A total of N=16 focus groups were conducted in 16 maternity units in England, Scotland and Wales where the OASI Care Bundle was implemented. Focus groups took place approximately three months following initial implementation of the care bundle in each unit.

Participants: A total of 101 clinicians participated. Participants volunteered to take part and comprised of 37 obstetricians and 64 midwives (including 8 students). The majority were female and the mean age was 36.5 years.

Results: Four main themes emerged: 'Implementation strategies', 'Opportunities to use the OASI Care Bundle', 'Does current practice need to change?' and 'Perceptions of what women want'. Midwives were more likely than obstetricians to report themes alluding to 'what women want' and variations in intrapartum perineal protection techniques. Both professional groups reported similar views of other themes, in particular regarding the supporting clinical evidence. Gaps were identified in clinicians' knowledge and experience of intrapartum perineal management.

Conclusions: Adoption of the OASI Care Bundle was associated with a number of cognitive and interpersonal factors, such as personal values, inter-professional working and the way the intervention was launched; which both facilitated and impeded adoption. The 'what women want' theme has implications for maternal autonomy and should be further explored. Our findings can be used by similar initiatives to reduce perineal trauma both nationally and internationally.

Trial registration: The OASI Project was retrospectively registered on the ISCTRN database (#12143325 date assigned 03/10/2017).

Key words:

OASI Care Bundle, obstetric anal sphincter injury, OASI, perineal trauma, quality improvement, maternity, focus group discussions, manual perineal protection, care bundle.

Article summary

Strengths and Limitations of this study

- This study explores the implementation of the OASI Care Bundle and highlights the importance of how interpersonal and cognitive factors affected adoption.
- Focus groups were conducted in 16 UK maternity units that implemented the OASI Care Bundle – the wide coverage and qualitative methodology provide deep insights into the barriers and enablers of improvement.
- Study generalisability may be limited due to participant self-selection to attend.
- The findings of this study provide a useful blueprint for the implementation of improvement interventions throughout maternity services.

For peer review only

1. Background

An obstetric anal sphincter injury (OASI), refers to any injury to the anal sphincter muscle sustained during childbirth. Graded as third or fourth degree tears, depending on severity, they can cause significant long-term morbidities including anal incontinence and post-traumatic stress disorder (PTSD).¹ These complications can severely impact a woman's quality of life and affect future birth choices.^{2,3} There are also significant long-term financial consequences for health systems associated with further treatment and litigation claims – in the UK these were an estimated £31.2 million between 2000 and 2010, making it the fourth largest number of maternity claims.⁴

There are known demographic and intrapartum risk factors for OASI⁵, but for some women there is no clear reason why they sustain these injuries. Identified contributing factors include lack of training, lack of awareness and variation with intrapartum practice - particularly with regard to a 'hands-poised' or 'hands-off' approach to the perineum.⁶⁻⁹ Adoption of interventions using evidence-based practice and increased awareness significantly reduced rates in Scandinavian countries¹⁰⁻¹² and in small-scale studies in England.^{13,14}

However, OASI rates continue to increase: in the UK, they tripled amongst primiparous women over a ten year period.¹⁵ Similar rising trends have been reported in several countries including Australia¹⁶, Canada⁵ and China.¹⁷ Clinical improvement to reduce this pattern is required.

This clinical need provided a strong driver to implement the 'OASI Care Bundle' quality improvement (QI) programme at national level to attempt to reverse this trend in the UK. The programme and evaluation background, design and methods have been reported in detail.¹⁸ Briefly, the QI programme involved an intervention comprising of a care bundle, an awareness campaign and multi-disciplinary training implemented across 16 UK maternity units (January 2017 – April 2018). Figure 1 shows the care bundle elements. Local implementation of the care bundle was facilitated by obstetric and midwifery champions within participating units.

Figure 1 here

Implementation of the care bundle reduced OASI rates from 3.3% to 3.0% ($p=0.03$), with over 55,000 women included in the analysis.¹⁹ In addition to assessing the clinical effectiveness of the intervention, the evaluation sought to understand the feasibility and utility of the implementation strategies of the bundle across units. The aim of this paper is to report a detailed exploration of clinicians' (midwives and obstetricians') perspectives of the care bundle implementation and adoption within their units.

2. Methods

Study design and methodology

Focus groups (FGs) were conducted with clinicians (obstetricians and midwives) across all 16 participating units to explore the acceptability and feasibility of the OASI Care Bundle. A standard set of questions were used (see supplementary material) as a basis of semi-structured FGs to explore the intervention (the care bundle, the local training and the awareness campaign), the implementation strategy and the local context within each unit.

Recruitment

Sixteen FGs were conducted between March and December 2017 – one at each maternity unit. The FGs were scheduled to take place 6-8 weeks after the start of implementation, however, for logistical reasons, in some units, this extended up to 12 weeks. Eligible participants were obstetricians and midwives (including student midwives) who were working in each of the 16 maternity units. The aim

was for participants to reflect a range of age and experience. The local champions at each unit assisted with recruitment by advertising when the FG would take place and the importance of the discussion for the implementation of the bundle and its long-term sustainability. As recommended, the intention was that each FG would involve between four and eight participants.²⁰ However, as participants typically comprised clinicians who were on shift at the time of the FG, the numbers pragmatically varied according to staffing levels and workload within each unit. Obstetricians and midwives who were interested in taking part came to the FG in their unit, where the lead researcher (PB) provided more information about the study. Those who consented then took part in the discussion. The number of participants in the FGs ranged from three to ten and the average number was six. Table 1 shows the FG composition across the four study regions.

Table 1: Focus Group composition across study regions

Unit number	Type of unit ^	Size of unit*	Midwives	Student Midwives	Obstetricians	Total
Region 1	2 OU+AMU 1 OU+FMU 1 OU+AMU+FMU	1 small 2 medium 1 large	14	1	17	32
Region 2	1 OU 2 OU+AMU 1 OU+AMU+FMU	1 small 1 medium 2 large	14	3	4	21
Region 3	4 OU+AMU	2 small 1 medium 1 large	13	2	8	23
Region 4	2 OU 2 OU+AMU	2 small 2 large	16	2	8	26
TOTAL			57	8	37	101

^Obstetric units (OU), alongside midwifery units (AMU) and free-standing midwifery units (FMU)

*categorised according to number of births per year: Small <3500, Medium 3500-5000, Large >5000

Focus Group conduct

FGs took place in meeting rooms within the maternity units. Sessions lasted on average 30 minutes (range 23 – 49 minutes). Before the FG began, participants were asked to complete a questionnaire to obtain basic, non-identifiable, demographic information (see supplementary material).

Patient and public involvement

No patient or public was involved.

Analysis

The FGs were moderated by an experienced researcher (PB) who also took contemporaneous field notes. Participants gave their consent for the discussion to be audio recorded. All audio recordings were transcribed verbatim for analysis. All transcripts were anonymised, with no personal identifiable markers. Analysis was based on the transcripts and moderator's reflections from the field (i.e. a form of auto-ethnography).

Grounded theory was used as it allows for emerging themes to be developed using an iterative process.²¹ Data were analysed inductively as we were interested in understanding new information and insights.²² NVivo 11 facilitated data analysis. Transcripts were read and re-read several times and coded by the researcher (PB). 'Axial coding' then determined causal or consequential relationships between the codes to identify dominant themes. An important part of Grounded theory is the ability to test concepts with colleagues who have experience in the area.²¹ To ensure such rigour, an additional researcher (JH) reviewed the codes and themes to develop new insights and minimise bias. For a theme to be confirmed it had to be indicated by the data on several occasions. This process indicated data saturation, meaning that no new themes would have been identified with the inclusion of further data. The collection and analysis of data adhered to the Standards for Reporting Qualitative Research (SRQR).²³

3. Results

In total, 101 clinicians participated, comprising 37 obstetricians, 56 midwives and eight student midwives. The characteristics of participants are presented in Table 2.

Table 2: Characteristics of all 101 participants

Demographic		N	%
Age group (years)	>30	29	28.7
	30-39	37	36.6
	40-49	14	13.9
	<50	21	20.8
Gender	Female	95	94.1
	Male	6	5.9
Clinical area (midwives only, n=56)	Labour ward	41	73.2
	Community / Birth Centre	13	23.2
	Other	2	3.6
Years' experience of maternity	>2	20	19.8
	3-5	17	16.8
	6-10	26	25.7
	<10	38	37.6

Four major themes were identified which describe the clinicians' perspectives on the implementation of the care bundle. Within these four themes, there were several subthemes. These are outlined in Figure 2 and described in full below.

Figure 2 here

1) Theme 1: Implementation strategies

This theme reflected the way with which the care bundle was introduced and implemented within participating units. There were three subthemes, namely: (i) No consultation about the change (ii) Introduction of the OASI Care Bundle and (iii) Training approaches.

No consultation about the change

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2
3 Some participants felt that the wider maternity team on the 'shop floor' had not been consulted about
4 the unit's involvement with the OASI Project and the changes this would bring. This perceived lack of
5 consultation created some reservations about the intervention. Some felt their autonomy had been
6 compromised and that there should have been a more collaborative approach in the early stages for
7 a sense of ownership, given that for many the intervention required a change in practice.

8
9 *"I'm sorry but I felt that it was implemented at [names unit] without any discussion about what
10 midwives wanted. I felt very strongly, as an autonomous practitioner, if there is a reason to do
11 something I will try and do it....Whilst I'm really willing to learn, for me, it didn't feel like a
12 positive step in the care that I give to women"* (midwife)

13
14 Conversely, some participants reported that engagement with the project had been created by pre-
15 implementation discussions about the care bundle and perineal trauma. This increased the
16 enthusiasm and appetite for the introduction of the care bundle. This atmosphere may have been
17 more marked in units who were in the later waves of implementation:

18
19
20 *"I think we'd been waiting for it and asking when it's coming. It's nice to know that it's here,
21 and hopefully we can see what impact that has on our third degree tear rate"* (obstetrician)

22 23 24 **Introduction of the OASI Care Bundle**

25 Prior to implementation, units were sent promotional materials to raise awareness about the project
26 and the long-term consequences of OASI. The local champions attended a Skills Development Day at
27 the Royal College of Obstetricians and Gynaecologists (RCOG) and were advised to plan a 'Launch Day'
28 for the first week of roll out. How this was approached seemed to affect engagement with the care
29 bundle. Many participants spoke about a well-advertised launch, which created a lot of 'noise' and got
30 the project off to a good start:

31
32
33 *"Yes, we had a launch day at the unit.....on that day they had many sessions talking about it.
34 We had the models.....they had pictures of how you would give an episiotomy, things like that,
35 to add to this...There was quite a lot of noise about this"* (midwife)

36
37
38 In some units however, participants seemed less aware of a launch day. This led to some confusion as
39 to whether the care bundle had officially started:

40
41
42 *"There might have been [a launch], but I couldn't say yes, for definite, so if it happened, I wasn't
43 aware of it...this comes back to the launch, that people don't think it's been launched"*
44 (midwife)

45 46 47 **Training approaches**

48 There were diverse experiences in the way training was conducted by the local champions. Some
49 participants expressed unhappiness about the lack of dedicated time for training sessions in order to
50 ensure a standardised approach:

51
52
53 *"There hasn't been dedicated time set aside to deliver a consistent message and get proper
54 training and it's just been on the job, come in when you can, do it when you can"* (midwife)

55
56 At the same time, some participants expressed their dissatisfaction at the 'fixed' nature of training
57 sessions. There was also disappointment expressed at the inability to attend the official session that
58 was facilitated by the clinical leads for the project:

1
2
3 *"I thought the times that to attend the training were really fixed and actually not really flexible*
4 *for midwives....I mean, not every midwife's free at half past eight to come" (midwife)*
5

6 The majority reported that training was done ad hoc, with participants being trained in groups or one-
7 to-one. Many talked about the positive and passionate way with which the champions delivered the
8 training. The presence of in-house champions was felt to be key to the success of the project as they
9 were able create awareness and encourage people to attend training:
10

11
12 *"She [the champion] was like a hound! if you weren't trained and you were on her list, she*
13 *would hunt you down....She would come in early to catch people on night shifts and stuff.....If*
14 *you have somebody like that who is passionate about the training and gets the training done,*
15 *then I think that's what makes it better" (obstetrician)*
16

17 The initial intention was for training to be cascaded within units using a 'train-the-trainer' approach,
18 thereby alleviating the training burden on the champions. This however did not happen, and the
19 champions did all the training within each unit. Lack of practice with the care bundle was cited by
20 participants as the most common reasons for this:
21

22
23 *"You need to actually practice and work it out in your head before you can then go on and*
24 *teach it" (midwife)*
25

27 **2) Theme 2: Opportunities to use the OASI Care Bundle**

28 This theme reflected operational factors to using the care bundle. Within this theme there were two
29 subthemes which acted as barriers to using the care bundle (Presence of student midwives and
30 Change takes time) and one which acted as an enabler (Inter-professional working).
31

32 **Presence of student midwives**

33 For midwives, one of main issues was that many of them worked with student midwives and so did
34 not have the opportunity to use the care bundle. This meant that many midwives felt that they didn't
35 get the exposure to the care bundle that they needed:
36

37
38 *"if you have a student every time you have a delivery sometimes you don't necessarily get the*
39 *practice you need" (midwife)*
40

41 **Change takes time**

42 Despite some lack of opportunities to use the care bundle, participants were philosophical about the
43 process involved with changing practice. The majority expressed their belief that time was an
44 important factor. Many reminisced about their first ever birth and how 'fiddly' this was and that the
45 care bundle, in particular the MPP element, was unlearning old techniques and getting used to a new
46 one:
47

48
49 *"It breaks the habits of a lifetime, what we've always done....How do you do that after you've*
50 *done that way for 20 odd years? It's weird. It's different" (midwife)*
51

52 **Inter-professional working**

53 For those who had used the care bundle, many reported that they had help, or had given help doing
54 this – particularly performing MPP during instrumental births as participants reported that as a single
55

operator it could be difficult to manage all the aspects. This required an additional layer of inter-professional working, with MPP being undertaken by midwives for obstetricians:

“So, you’d have a midwife supporting the perineal body while you did your instrumental delivery” (obstetrician)

And more ‘senior’ registrars performed MPP for trainees:

“If it’s just me, I would do it [MPP] myself but I’ve certainly done it for my juniors when I’m supervising deliveries....so that they’ve got their hands free” (obstetrician)

This team approach created genuine feelings of partnership between midwives and obstetricians, who felt that the OASI Care Bundle was a project which involved everyone:

“This is the only project involving all the shop floor people. The other projects are focused on just a few groups” (midwife)

3) Theme 3: Does current practice need to change?

This theme reflected how clinicians felt about their current practice and their acceptance and readiness to learn new techniques. There were four subthemes: (i) Research evidence, (ii) Clinical judgement, (iii) Comfort with current practice and (iv) The ‘ebb and flow’ of maternity practices.

Research evidence

There were conflicting views about the evidence for the care bundle. Perceptions surrounding the clinical evidence for the care bundle was a prominent barrier to uptake for both obstetricians and midwives:

“Because it would be nice to have a number needed to treat sort of thing for that. So if you have to do one thousand PRs to pick up one, is all that indignity worth it?” (obstetrician)

Participants also expressed their belief that whilst there may be evidence for the care bundle they felt it wasn’t applicable for their practice and so didn’t need to change:

“I know that there’s evidence that it reduces severe trauma but I’m not sure that the evidence is that it reduces the trauma for my particular practice” (midwife)

Clinical judgement

Clinical judgement was an important factor and there was a lot of discussion about the fact that no two births are the same. Whilst some participants believed that a benefit of the care bundle was that it provided a standardised approach to preventing OASI, others felt that it took away from their clinical judgment. Clinical judgement was associated with having autonomy:

“I think it’s [the care bundle] taking away autonomy from the practitioner....I think it’s good to have an option to use it. But I think that to a certain extent it is taking away that professional judgement” (midwife)

Comfortable with current practice

This theme was expressed by both midwives and obstetricians and created some resistance to change. Often more senior clinicians (obstetricians and midwives) had established their own delivery styles and were comfortable with their practice. This created some reservations about adopting the care bundle:

'The SHOs that are more like, 'Yes, that makes sense, we should do that' because they haven't got their own established technique yet. It's the senior regs [sic] that I've heard that find reasons not to do it' (obstetrician)

Some participants felt that their practice was not dissimilar from that outlined by the care bundle. Many midwives referred to the impact of the HOOP trial (a UK trial which looked at the effect of 'hands-on' versus 'hands-poised' on postnatal perineal pain)²⁴:

"We were trained before the HOOP trial, so we always did hands-on...it's not such an alien concept....there are lots of us that haven't really, probably, if we're all truthful, haven't really moved away from hands-on" (midwife)

The 'ebb and flow' of maternity practices

Participants felt that certain practices came in and out of fashion. As for the previous theme, reference was made to how 'post HOOP trial' practice had changed from a 'hands-on' to a 'hands-poised' approach. Midwives, in particular those who had been qualified longer, felt that the 'hands-on' requirement of the care bundle meant that practice had gone 'full circle' and a return to previous practice. Instead of finding this frustrating however, this was treated in a humorous way:

"There were a generation that were hands-off/hands-poised, which I always found really weird, but I was a hands-on, that's how I was taught" (midwife)

This theme wasn't unique to practices relating to hand position at the time of birth. It also emerged with relation to midwives performing episiotomies and to instrument choices for operative vaginal births. In terms of episiotomy it was felt that the pendulum had swung from midwives performing these for every primiparous woman, to only performing a few and this had created deskilling. There was unanimous agreement that neither extreme was correct practice, but there was a feeling that there should be a middle ground:

"They [episiotomies] were in fashion and every first-time mum had an episiotomy whether she needed one or not. So probably that's when I was trained....then we went through a stage where nobody was having an episiotomy - how can you teach anybody to do them?" (midwife)

In terms of instrument choice, whilst this was outside the scope of the care bundle, many participants talked about the shift towards the 'heavy use' of forceps and felt that this should be addressed:

"People pick the forceps culturally...there's such an element of fear amongst junior doctors of failing to do something in the room. The other thing that they get told off for is using two instruments, so if they use ventouse and they fail..." (obstetrician)

4) Theme 4: Perceptions of what women want

This theme reflected a number of factors expressed as reservations for using the care bundle, which related to clinicians' values and perceptions of what women wanted. There were three subthemes: (i) Philosophy of care, (ii) Personal values and (iii) Provision of information to women.

Philosophy of care

Participants, notably midwives, reported that the care bundle changed the current model of care and increased interventions. Midwives, as facilitators of vaginal birth expressed some reluctance to use procedures which they felt caused over-medicalisation. Some participants felt that births requiring minimal intervention and medicalisation were to be regarded as an achievement. Any interventions took away this feeling of triumph, though this achievement appeared to relate to that of the clinician, not of outcome for the woman:

"I haven't had a third or fourth degree tear, touchwood.....the intact perineum that's a bit of an achievement....And then it's almost like we're doing a PR, but that's no reward" (midwife)

Whilst others agreed that this was an intervention, it was felt good communication was key to using all elements consistently:

"It's quite a big intervention, isn't it, to touch the woman there....The woman we had this morning who had a pool birth, she had a lovely birth, lovely intact perineum, and when we were inspecting the perineum afterwards we said about the new guidance to do with PR and she had heard of it....so she consented" (midwife)

Personal values

Often participants expressed some anxiety about using some elements of the care bundle, when they themselves would not like it as part of their care:

"I've been doing it [PR check], because it's part of the study, but I don't like it. And if I was giving birth and I had an intact perineum, I don't think I'd particularly want somebody doing a PR on me" (midwife)

This feeling of not liking doing something was particularly prominent in midwives reporting of performing episiotomies. As indicated in a previous theme, there was universal agreement that there was deskilling around midwives performing episiotomies. This lack of confidence was sometimes driven by personal fear *"historically, midwives don't like doing them, do we....I just don't like that sound" (midwife)* and sometimes driven by women's fear, which in turn affected a midwife's confidence:

"Lots of people will say, 'I don't want to be cut, I'll just tear, if that's okay.' It's individual. At which point, it puts the whole fear of whether you can go through with that" (midwife)

Provision of information to women

There was a range in opinions as to whether the information sheet for women about the project was appropriate. Some felt that women receive too much information when they are pregnant and that they either don't read it or don't take it on board. Some felt the information was 'too scary' or 'too explicit'. However, most participants expressed their belief that women liked the information sheet; it had encouraged clinicians to talk about perineal trauma and educating women was a positive step:

"People feel really angry that actually they have no idea that these sorts of things could happen. This project can only really be a good thing in terms of educating them [women] on

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2
3 *what can be a normal part of a vaginal delivery. I think that's going to be really positive for*
4 *everybody” (obstetrician)*
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10 **4. Discussion**

11 This paper presents clinicians' perspectives of the OASI Care Bundle, implemented as part of a QI
12 programme with national reach and a complex evaluation attached to it. To our knowledge, this study
13 offers unique insights: previous studies to reduce severe perineal trauma have focused on the
14 effectiveness of interventions^{10 11 25 26} but have not reported in detail clinicians' attitudes towards
15 these interventions. The importance of such qualitative insight within maternity was recently
16 highlighted²⁷ as it has implications for implementation, adoption and fidelity of an intervention.
17
18

19 The OASI Care Bundle necessitated clinicians changing their behaviour, in terms of learning and using
20 standardised techniques for second stage perineal management and a change (for some) in the way
21 that they informed women about the risks of perineal trauma. Our findings suggest a mixed reaction
22 of both resistance and acceptance of the care bundle. Adoption of the care bundle within a unit was
23 dependent upon its acceptability to both service users and service providers, alongside institutional
24 support. Failure to adopt new practices is commonly reported in the improvement literature, even
25 when there is substantial evidence of potential benefits to patients and the health system^{28 29}.
26 Clinicians in our study placed high value on their ability to use clinical judgement and their personal
27 values are an almost unavoidable influence when providing care. Recent studies have shown that this
28 may vary depending on the nature and framing of the issue.³⁰ This ought to be a careful consideration
29 for any QI intervention that requires behaviour change.
30
31

32 Midwives were more likely to report themes alluding to 'Perceptions of what women want', especially
33 the subthemes of 'Philosophy of care' and 'Personal values'. The ability to understand women's needs
34 is an important midwifery skill and research has found that women give midwives authority to make
35 decisions, perceiving them 'to know best'.³¹ However, there were some suggestions that some
36 clinicians do not fully understand the balance between discussing risk and maintaining women's
37 autonomy.³² This is an important balance, as women have the right to make informed and
38 autonomous choices and indeed England's Better Births policy initiatives (as well as similar initiatives
39 in Wales and Scotland) aims for women to receive unbiased information, enabling them to develop a
40 personalised maternity care plan based on their decisions and not that of healthcare professionals.³³
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45 Midwives were also more likely to discuss what we termed the 'ebb and flow' of maternity practices,
46 particularly the 'hands on' or 'hands poised' approaches for perineal protection and this reflects the
47 often conflicting findings of studies.^{10 24 25 35} The observation that mentors found it challenging to
48 practice the MPP technique because their students attended births is an important issue to consider
49 when introducing an intervention as efforts need to be made to ensure that all clinicians get sufficient
50 opportunity to gain and become confident users of new skills.
51

52 Both midwives and obstetricians reported similar views regarding the need for current practice to
53 change, in particular the evidence supporting the elements of the OASI Care Bundle. There were some
54 participants from both professional groups reporting reluctance to perform PR checks as they didn't
55 consider they were indicated. However, undiagnosed, or 'missed' OASI are a breach of duty and
56 potential cause for litigation.³⁶
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3 Training gaps were dominant throughout – for obstetricians this focused on instrument choice and
4 episiotomy technique. For midwives this centred around when and how to perform episiotomies and
5 second stage perineal care. Episiotomies can be a contentious issue and in the NHS a restricted
6 approach to performing them has been adopted, which has created a practice gap amongst more
7 junior staff.³⁷ Midwife inexperience with this procedure has been found in other studies³⁸ suggesting
8 that this knowledge gap is widespread and requires continual professional development.
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11 In synthesising these themes and patterns in the dataset, we propose that early adoption of the OASI
12 Care Bundle was associated with a number of *cognitive, interpersonal and organisational* factors. For
13 instance, although the intervention had prominent central support, implementation within each unit
14 was subject to local organisational factors, particularly with the introduction of the intervention and
15 provision of training. Cognitive and interpersonal factors that we identified such as personal values,
16 unit-interprofessional and unit-level awareness have similarly been noted in other maternity
17 interventions and health psychology has been applied to offer theories of behaviour which explain
18 enablers and barriers to uptake.³⁹⁻⁴¹
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21 Adoption, or failure of adoption, of a new intervention is reliant on many components. This QI project
22 was designed with the implementation strategy given as much consideration as the intervention itself.
23 Despite best efforts, it is likely that some aspects of the implementation strategy may have impacted
24 on adoption and acceptability of the intervention – notably the issues voiced around the launch of the
25 intervention and any knowledge gaps that were identified. Other reasons for any failure to adopt the
26 intervention maybe because some clinicians, as autonomous practitioners, may not value the
27 intervention as they might have felt that other intrapartum perineal techniques, such as warm
28 compresses should have been incorporated into the OASI Care Bundle. Due to the quality of the
29 evidence⁴², there was much discussion about warm compresses during development of the OASI
30 Project; however, due to the wide variation in practice (whether the compress is held continuously,
31 what is used for the compress, the temperature, when it is re-heated and ability to have a facility for
32 heating compresses) it was decided that the clinical practicalities of ensuring standardisation made it
33 unfeasible to include as a component of the care bundle. Use of compresses was encouraged as part
34 of intrapartum care, but their omission from the care bundle may have caused some resistance. It is
35 clear from the findings here that gaining buy-in for an intervention is an important implementation
36 tool. Other areas to consider are the current strains on maternity services. Pressures such as staffing
37 level and increased complexity of births are well documented within the UK.⁴³ These issues did not
38 emerge as a themes within our data; however, it is possible that they were underlying factors which
39 could be additional barriers to adoption of a new intervention.
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44 This study has limitations. Whilst FGs produce data through social interaction and the dynamic
45 interaction can stimulate thoughts they can also inhibit participants from divulging their true opinions,
46 in a manner that does not impact one-on-one interviews. All the FGs were held in the participants'
47 place of work and when they were on shift. This on occasion meant that discussions felt somewhat
48 rushed (i.e. they could have lasted longer) and participants were called away to emergency situations.
49 An additional limitation was the sampling framework for the study – all the participants were
50 volunteers which is open to self-selection bias. The majority of participants were women under the
51 age of 40. Men and older women might have had different opinions. Lastly, this study only covers data
52 from frontline providers; further data are required to assess implementability and scalability of the
53 OASI Care Bundle from senior and service managers, as well as women using these services. The study
54 also has strengths. The sampling framework covered a large number of units with different
55 characteristics and varied clinical contexts across the UK. We were able to reach 101 participants from
56 a range of experience levels who were encouraged to speak freely which allowed for a wide range of
57 perspectives of the OASI Care Bundle. Findings from this study are therefore likely to be relevant to
58 other maternity units, both in the UK and globally, which may consider implementing this bundle.
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4.1. Conclusion

This study found that adoption of the OASI Care Bundle across 16 UK units was influenced by four main factors: (1) the way in which the intervention was introduced and implemented in units, (2) opportunities to use the OASI Care Bundle, (3) how receptive participants were to changing their practice and (4) personal perceptions of what women want. Our synthesis suggest that cognitive and interpersonal factors at the level of individual providers as well as organisational factors at the level of the unit and the central OASI programme team underlined the above and determined the level of success of implementation and adoption of the bundle across studied units. The study offers insights regarding introduction of QI initiatives within maternity, but also other healthcare settings. Future QI programmes should be informed by the above themes.

For peer review only

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We would like to thank all the clinicians who gave up their time to take part in the study. We hugely appreciate their engagement and openness. We would also like to thank the obstetric and midwifery champions at each of the 16 participating units for their hard work and dedication to implementing all aspects of this QI project. The OASI Care Bundle team would like to acknowledge the support of the Health Foundation, who fully funded both the implementation and the evaluation of the project.

Disclosure of Interests

NS is the director of London Safety and Training Solution Ltd, which provides patient safety advisory and training services on a consultancy basis to hospitals in the UK and internationally. NS' research is supported by the National Institute for Health Research (NIHR) Collaboration for Leadership in Applied Health Research and Care South London at King's College Hospital NHS Foundation Trust. NS is a member of King's Improvement Science, which is part of the NIHR CLAHRC South London and comprises a specialist team of improvement scientists and senior researchers based at King's College London. Its work is funded by King's Health Partners (Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, King's College London and South London and Maudsley NHS Foundation Trust), Guy's and St Thomas' Charity, the Maudsley Charity and the Health Foundation. EM is Trustee of the RCOG. BF is the co-inventor of Epi-scissors. The other authors have no competing interests to declare. The views expressed are those of the authors and not necessarily those of the Health Foundation, the National Health Service (NHS) or the Department of Health and Social Care.

Author's statement

RT, IGU, LS, BF and NS conceptualised the OASI Care Bundle. PB, IGU and NS led on the evaluation of the study. RT, LS, AH and VN led on the implementation of the study. PB organised and facilitated the focus groups, performed data management, analysis and drafted the manuscript. JH was an independent second coder for data analysis, reviewing the codes and themes in order to develop new insights and minimize bias. All authors critically reviewed the manuscript and provided input. NS provided significant overall guidance. All authors reviewed and approved the article before publication.

Details of Ethics Approval

This QI project was reviewed by NHS Health Research Authority in October 2016 and approved as a service evaluation (Ref 60/86/81). We thus sought and obtained relevant local approvals, including from the Caldicott Guardians across all the NHS trusts involved in this evaluation. Only named members of the Project Team have access to the data. They have completed mandatory Information Governance training and are aware of the requirements of confidentiality and understand that any breach will be reported.

The RCOG and LSHTM are registered under the Data Protection Act and are fully compliant with the NHS Information Governance Toolkit for Hosted Secondary Use Teams. Participants (clinicians) who took part in qualitative research activities all provided their verbal consent to do so and were made aware that they could withdraw this at any time.

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3 **Figure legends:**
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5 **Figure 1: The four discrete elements of the OASI Care Bundle**
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7 **Figure 2: The four main themes and subthemes that emerged from the qualitative data**
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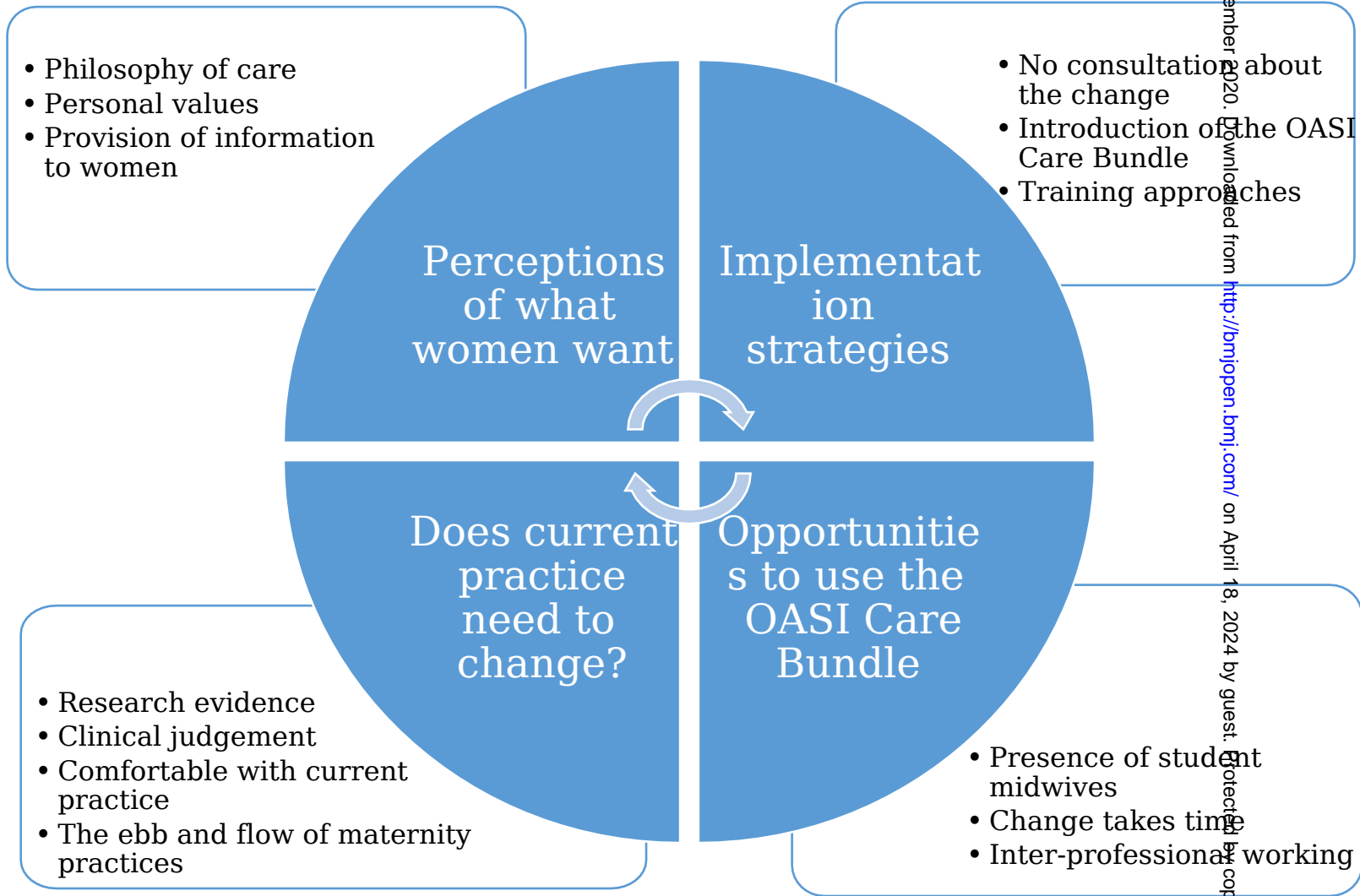
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- 1 **Antenatal information for women** about OASI and what can be done to minimize risk.
- 2 When indicated, **episiotomy** should be performed
- 3 **mediolaterally** at a **60-degree angle** at
- 4 **crowning**
- 5 Documented use of **manual perineal protection** (MPP):
 - For spontaneous births, MPP should be used, unless the woman objects, or her chosen birth position doesn't allow for it (e.g. water birth)
 - For assisted births MPP should always be used.

Following birth, the **perineum should be examined** and any tears graded according to the RCOG guidance. The examination should include **per rectum** check even when the perineum appears intact.

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**Focus Group Discussion for clinicians at participating units:
Topic guide**

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|---|
| <ul style="list-style-type: none"> • What are your attitudes towards the OASI Care Bundle? • What drove the positive/negative reaction? • Do you know anyone who have suffered long-term effects of perineal trauma? • What training did you receive on the care bundle? • What were your thoughts on the awareness campaign / promotional materials / Launch |
| <ul style="list-style-type: none"> • What are your thoughts on the 'train the trainer' model? • How did delivery suite support the training sessions? • Do you think your hospital was motivated to implement the care bundle? • What were the main issues around actually using the care bundle? • What do you think about having a sticker checklist as a reminder of important things one must not forget? • Do you think that women are happy with the OASI Care Bundle? |
| <ul style="list-style-type: none"> • Do you know who your local champions are? • Have you been involved in any monitoring of the care bundle? • What proportion of the staff in the hospital do you think are using the care bundle? |
| <ul style="list-style-type: none"> • Has your knowledge of OASI improved since the care bundle was introduced? • Has the care bundle been integrated into routine practice? • Do you think the rates of OASI have changed? • Did you feel comfortable with using the care bundle? Has there been sufficient training? Will you continue to use it once the project is over? • What were the barriers to using the care bundle? What were the enablers? • Do you think the care bundle is sustainable? • Of all the things we've discussed today, what would you say are the most important issues you would like to express about the care bundle? |

FOCUS GROUP: Demographic Questionnaire

Please answer the following questions in the spaces provided, circle or tick the most appropriate options.

1. Age :.....

2. Are you: (please tick as necessary) Male Female

3. What is your professional background?

Midwife

Student Midwife

Obstetrician - SHO

Obstetrician - Registrar

Obstetrician - Consultant

Other: (please describe) _____

4. Are you: (please tick as necessary) Full time Part time

5. How many years have you worked in this hospital?

<1 Year

1-2 Years

3-5 Years

6-10 Years

>10 Years

6. Overall, how many years' experience in maternity do you have?

<1 Year

1-2 Years

3-5 Years

6-10 Years

>10 Years

Thank you for taking the time to complete this questionnaire

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

	Reporting Item	Page Number
Title		
	#1 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	1
Abstract		
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Introduction		
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	4
Purpose or research question	#4 Purpose of the study and specific objectives or questions	4
Methods		
Qualitative approach and research paradigm	#5 Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research	5-6

paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. 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.

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10	Researcher characteristics	#6	5
11	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	
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18	Context	#7	4
19		Setting / site and salient contextual factors; rationale	
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21	Sampling strategy	#8	4-5
22		How and why research participants, documents, or events were selected; criteria for deciding when no further sampling was necessary (e.g. sampling saturation); rationale	
23			
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25			
26	Ethical issues pertaining to	#9	5 & 15
27	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	
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30	Data collection methods	#10	5
31		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	
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37	Data collection instruments	#11	5
38	and technologies	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g. audio recorders) used for data collection; if / how the instruments(s) changed over the course of the study	
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43	Units of study	#12	5
44		Number and relevant characteristics of participants, documents, or events included in the study; level of participation (could be reported in results)	
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47	Data processing	#13	5
48		Methods for processing data prior to and during analysis, including transcription, data entry, data management and security, verification of data integrity, data coding, and anonymisation / deidentification of excerpts	
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52	Data analysis	#14	5-6
53		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	
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1	Techniques to enhance	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member	6
2	trustworthiness		checking, audit trail, triangulation); rationale	
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5	Results/findings			
6				
7	Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include	6-11
8			development of a theory or model, or integration with prior research or theory	
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11	Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic	6-11
12			findings	
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15	Discussion			
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17	Intergration with prior work,	#18	Short summary of main findings; explanation of how findings and conclusions	12
18	implications, transferability		connect to, support, elaborate on, or challenge conclusions of earlier scholarship;	
19	and contribution(s) to the		discussion of scope of application / generalizability; identification of unique	
20	field		contributions(s) to scholarship in a discipline or field	
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24	Limitations	#19	Trustworthiness and limitations of findings	13
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27	Other			
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29	Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and	15
30			conclusions; how these were managed	
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33	Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation	15
34			and reporting	
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Exploring clinicians' perspectives on the 'Obstetric Anal Sphincter Injury Care Bundle' national quality improvement programme: A qualitative study

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3 **Exploring clinicians' perspectives on the 'Obstetric Anal Sphincter Injury Care Bundle' national**
4 **quality improvement programme: A qualitative study**
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Abstract

Introduction: Obstetric anal sphincter injuries (OASI) can have severe debilitating consequences to women and health systems. The OASI Care Bundle Quality Improvement Programme was introduced in 16 maternity units across England, Scotland and Wales (January 2017 – March 2018) to address increasing OASI rates.

Objectives: To explore clinicians' (midwives' and obstetricians') perspectives of the OASI Care Bundle with respect to 1) Acceptability, 2) Feasibility and 3) Sustainability.

Design: A qualitative exploratory study using focus groups methodology.

Setting: A total of N=16 focus groups were conducted in 16 maternity units in England, Scotland and Wales where the OASI Care Bundle was implemented. Focus groups took place approximately three months following initial implementation of the care bundle in each unit.

Participants: A total of 101 clinicians participated, with an average of six per focus group. Participants volunteered to take part and comprised of 37 obstetricians and 64 midwives (including eight students). The majority were female and the mean age was 36.5 years.

Results: Four main themes emerged: 'Implementation strategies', 'Opportunities to use the OASI Care Bundle', 'Does current practice need to change?' and 'Perceptions of what women want'. Midwives were more likely than obstetricians to report themes alluding to 'what women want' and variations in intrapartum perineal protection techniques. Both professional groups reported similar views of other themes, in particular regarding the supporting clinical evidence. Gaps were identified in clinicians' knowledge and experience of intrapartum perineal management.

Conclusions: Adoption of the OASI Care Bundle was associated with a number of cognitive and interpersonal factors, such as personal values, inter-professional working and how the intervention was launched; which both facilitated and impeded adoption. The 'what women want' theme has implications for maternal autonomy and need further exploration. Our findings can be used by similar initiatives to reduce perineal trauma both nationally and internationally.

Trial registration: The OASI Project was retrospectively registered on the ISCTRN database (#12143325 date assigned 03/10/2017).

Key words:

OASI Care Bundle, obstetric anal sphincter injury, OASI, perineal trauma, quality improvement, maternity, focus group discussions, manual perineal protection, care bundle.

Article summary

Strengths and Limitations of this study

- This study explores the implementation of the OASI Care Bundle and highlights the importance of how interpersonal and cognitive factors affected adoption.
- Focus groups were conducted in 16 UK maternity units that implemented the OASI Care Bundle – the wide coverage and qualitative methodology provide deep insights into the barriers and enablers of improvement.
- Study generalisability may be limited due to participant self-selection to attend.
- The findings of this study provide a useful blueprint for the implementation of improvement interventions throughout maternity services.

For peer review only

1. Background

An obstetric anal sphincter injury (OASI), refers to any injury to the anal sphincter muscle sustained during childbirth. Graded as third or fourth degree tears, depending on severity, they can cause significant long-term morbidities including anal incontinence and post-traumatic stress disorder (PTSD).¹ These complications can severely impact a woman's quality of life and affect future birth choices.^{2,3} There are also significant long-term financial consequences for health systems associated with further treatment and litigation claims – in the UK these were an estimated £31.2 million between 2000 and 2010, making it the fourth largest number of maternity claims.⁴

There are known demographic and intrapartum risk factors for OASI⁵, but for some women there is no clear reason why they sustain these injuries. Identified contributing factors include lack of training, lack of awareness and variation with intrapartum practice - particularly with regard to a 'hands-poised' or 'hands-off' approach to the perineum.⁶⁻⁹ Adoption of interventions using evidence-based practice and increased awareness significantly reduced rates in Scandinavian countries¹⁰⁻¹² and in small-scale studies in England.^{13,14}

However, OASI rates continue to increase: in the UK, they tripled amongst primiparous women over a ten year period.¹⁵ Similar rising trends have been reported in several countries including Australia¹⁶, Canada⁵ and China.¹⁷ Clinical improvement to reduce this pattern is required.

This clinical need provided a strong driver to implement the 'OASI Care Bundle' quality improvement (QI) programme at national level to attempt to reverse this trend in the UK. The programme and evaluation background, design and methods have been reported in detail.¹⁸ Briefly, the QI programme involved an intervention comprising of a care bundle, an awareness campaign and multi-disciplinary training implemented across 16 UK maternity units (January 2017 – April 2018). Figure 1 shows the care bundle elements. Local implementation of the care bundle was facilitated by obstetric and midwifery champions within participating units.

Figure 1 here

Implementation of the care bundle reduced OASI rates from 3.3% to 3.0% ($p=0.03$), with over 55,000 women included in the analysis.¹⁹ In addition to assessing the clinical effectiveness of the intervention, the evaluation sought to understand the feasibility and utility of the implementation strategies of the bundle across units. The aim of this paper is to report a detailed exploration of clinicians' (midwives and obstetricians') perspectives of the care bundle implementation and adoption within their units.

2. Methods

Study design and methodology

Focus groups (FGs) were conducted with clinicians (obstetricians and midwives) across all 16 participating units to explore the acceptability and feasibility of the OASI Care Bundle. A standard set of questions were used (see supplementary material) as a basis of semi-structured FGs to explore the intervention (the care bundle, the local training and the awareness campaign), the implementation strategy and the local context within each unit.

Recruitment

Sixteen FGs were conducted between March and December 2017 – one at each maternity unit in order to ensure representation from all participating units and give them all an opportunity to give their views of the bundle. In doing so, we expected data saturation to be reached after 6-8 FGs and

indeed reached saturation after 8 FGs. The FGs were scheduled to take place 6-8 weeks after the start of implementation, however, for logistical reasons, in some units, this extended up to 12 weeks. Local champions at each unit assisted with recruitment by advertising (via posters, email and face-to-face discussions), when the FG would take place and by highlighting that the discussion was an opportunity for clinicians to provide their views of the care bundle.

The aim was for each FG to reflect a range of age and experience, however due to staffing levels and workload within each unit a pragmatic approach was taken to recruitment. Using convenience sampling, eligible participants were obstetricians and midwives (including student midwives) who were working in each of the 16 maternity units. Obstetricians and midwives who were interested in taking part came to the FG in their unit, where the Moderator (PB) provided more information about the study. Those who consented then took part in the discussion.

The recommendation is that FGs comprise of between four and eight participants,²⁰ however, as study participants typically comprised of clinicians who were on shift at the time of the FG, one FG had less (n=3) and one had more (n=10) than this recommended number. The average number of participants was six. Table 1 shows the FG composition across the four study regions.

Unit number	Type of unit ^	Size of unit*	Midwives	Student Midwives	Obstetricians	Total
Region 1	2 OU+AMU 1 OU+FMU 1 OU+AMU+FMU	1 small 2 medium 1 large	14	1	17	32
Region 2	1 OU 2 OU+AMU 1 OU+AMU+FMU	1 small 1 medium 2 large	14	3	4	21
Region 3	4 OU+AMU	2 small 1 medium 1 large	13	2	8	23
Region 4	2 OU 2 OU+AMU	2 small 2 large	16	2	8	26
TOTAL			57	8	37	101

Table 1: Focus Group composition across study regions

^Obstetric units (OU), alongside midwifery units (AMU) and free-standing midwifery units (FMU)

*categorised according to number of births per year: Small <3500, Medium 3500-5000, Large >5000

Focus Group conduct

FGs took place in meeting rooms within the maternity units. Sessions lasted on average 30 minutes (range 23 – 49 minutes). Before the FG began, participants were asked to complete a questionnaire to obtain basic, non-identifiable, demographic information (see supplementary material).

Patient and Public Involvement

The OASI Project had Patient and Public Involvement (PPI) throughout inception, implementation and evaluation stages. The project was supported by an Independent Advisory Group, including lay representatives. The antenatal information sheet (first component of the OASI Care Bundle) was developed together with PPI groups in order to ensure that the material was appropriate.

Analysis

All 16 FGs were moderated by the same person (PB). As a midwife, the moderator (PB) had a good understanding of the topic and as an qualitative experienced researcher was able to build a productive and trusting relationship with the participants, none of whom were previously known to her. Participants were informed of the moderators credentials and profession during the introduction. Participants gave their consent for the discussion to be audio recorded. All audio recordings were transcribed verbatim for analysis. All transcripts were anonymised, with no personal identifiable markers. Analysis was based on the transcripts and moderator's reflections from the field (i.e. a form of auto-ethnography).

Grounded theory was used as it allows for emerging themes to be developed using an iterative process.²¹ Data were analysed inductively as we were interested in understanding new information and insights.²² NVivo 11 facilitated data analysis. Transcripts were read and re-read several times and coded by the researcher (PB). 'Axial coding' then determined causal or consequential relationships between the codes to identify dominant themes. An important part of Grounded theory is the ability to test concepts with colleagues who have experience in the area.²¹ To ensure such rigour, an additional researcher (JH) reviewed the codes and themes to develop new insights and minimise bias. For a theme to be confirmed it had to be indicated by the data on several occasions. This process indicated data saturation, meaning that no new themes would have been identified with the inclusion of further data. The collection and analysis of data adhered to the Standards for Reporting Qualitative Research (SRQR).²³

3. Results

In total, 101 clinicians participated, comprising 37 obstetricians, 56 midwives and eight student midwives. The characteristics of participants are presented in Table 2.

Table 2: Characteristics of all 101 participants

Demographic		N	%
Age group (years)	<30	29	28.7
	30-39	37	36.6
	40-49	14	13.9
	≥50	21	20.8
Gender	Female	95	94.1
	Male	6	5.9
Clinical area (midwives only, n=56)	Labour ward	41	73.2
	Community / Birth Centre	13	23.2
	Other	2	3.6
Years' experience of maternity	<3	20	19.8
	3-5	17	16.8
	6-10	26	25.7
	>10	38	37.6

Four major themes were identified which describe the clinicians' perspectives on the implementation of the care bundle. Within these four themes, there were several subthemes. These are outlined in Figure 2 and described in full below.

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Figure 2 here

1) Theme 1: Implementation strategies

This theme reflected the way with which the care bundle was introduced and implemented within participating units. There were three subthemes, namely: (i) No consultation about the change (ii) Introduction of the OASI Care Bundle and (iii) Training approaches.

No consultation about the change

Some participants felt that the wider maternity team on the 'shop floor' had not been consulted about the unit's involvement with the OASI Project and the changes this would bring. This perceived lack of consultation created some reservations about the intervention. Some felt their autonomy had been compromised and that there should have been a more collaborative approach in the early stages for a sense of ownership, given that for many the intervention required a change in practice.

"I'm sorry but I felt that it was implemented at [names unit] without any discussion about what midwives wanted. I felt very strongly, as an autonomous practitioner, if there is a reason to do something I will try and do it.....Whilst I'm really willing to learn, for me, it didn't feel like a positive step in the care that I give to women" (midwife)

Conversely, some participants reported that engagement with the project had been created by pre-implementation discussions about the care bundle and perineal trauma. This increased the enthusiasm and appetite for the introduction of the care bundle. This atmosphere may have been more marked in units who were in the later waves of implementation:

"I think we'd been waiting for it and asking when it's coming. It's nice to know that it's here, and hopefully we can see what impact that has on our third degree tear rate" (obstetrician)

Introduction of the OASI Care Bundle

Prior to implementation, units were sent promotional materials to raise awareness about the project and the long-term consequences of OASI. The local champions attended a Skills Development Day at the Royal College of Obstetricians and Gynaecologists (RCOG) and were advised to plan a 'Launch Day' for the first week of roll out. How this was approached seemed to affect engagement with the care bundle. Many participants spoke about a well-advertised launch, which created a lot of 'noise' and got the project off to a good start:

"Yes, we had a launch day at the unit.....on that day they had many sessions talking about it. We had the models.....they had pictures of how you would give an episiotomy, things like that, to add to this...There was quite a lot of noise about this" (midwife)

In some units however, participants seemed less aware of a launch day. This led to some confusion as to whether the care bundle had officially started:

"There might have been [a launch], but I couldn't say yes, for definite, so if it happened, I wasn't aware of it...this comes back to the launch, that people don't think it's been launched" (midwife)

Training approaches

There were diverse experiences in the way training was conducted by the local champions. Some participants expressed unhappiness about the lack of dedicated time for training sessions in order to ensure a standardised approach:

"There hasn't been dedicated time set aside to deliver a consistent message and get proper training and it's just been on the job, come in when you can, do it when you can" (midwife)

At the same time, some participants expressed their dissatisfaction at the 'fixed' nature of training sessions. There was also disappointment expressed at the inability to attend the official session that was facilitated by the clinical leads for the project:

"I thought the times that to attend the training were really fixed and actually not really flexible for midwives....I mean, not every midwife's free at half past eight to come" (midwife)

The majority reported that training was done ad hoc, with participants being trained in groups or one-to-one. Many talked about the positive and passionate way with which the champions delivered the training. The presence of in-house champions was felt to be key to the success of the project as they were able create awareness and encourage people to attend training:

"She [the champion] was like a hound! if you weren't trained and you were on her list, she would hunt you down....She would come in early to catch people on night shifts and stuff.....If you have somebody like that who is passionate about the training and gets the training done, then I think that's what makes it better" (obstetrician)

The initial intention was for training to be cascaded within units using a 'train-the-trainer' approach, thereby alleviating the training burden on the champions. This however did not happen, and the champions did all the training within each unit. Lack of practice with the care bundle was cited by participants as the most common reasons for this:

"You need to actually practice and work it out in your head before you can then go on and teach it" (midwife)

2) Theme 2: Opportunities to use the OASI Care Bundle

This theme reflected operational factors to using the care bundle. Within this theme there were two subthemes which acted as barriers to using the care bundle (Presence of student midwives and Change takes time) and one which acted as an enabler (Inter-professional working).

Presence of student midwives

For midwives, one of main issues was that many of them worked with student midwives and so did not have the opportunity to use the care bundle. This meant that many midwives felt that they didn't get the exposure to the care bundle that they needed:

"if you have a student every time you have a delivery sometimes you don't necessarily get the practice you need" (midwife)

Change takes time

Despite some lack of opportunities to use the care bundle, participants were philosophical about the process involved with changing practice. The majority expressed their belief that time was an important factor. Many reminisced about their first ever birth and how 'fiddly' this was and that the care bundle, in particular the MPP element, was unlearning old techniques and getting used to a new one:

"It breaks the habits of a lifetime, what we've always done....How do you do that after you've done that way for 20 odd years? It's weird. It's different" (midwife)

Inter-professional working

For those who had used the care bundle, many reported that they had help, or had given help doing this – particularly performing MPP during instrumental births as participants reported that as a single operator it could be difficult to manage all the aspects. This required an additional layer of inter-professional working, with MPP being undertaken by midwives for obstetricians:

"So, you'd have a midwife supporting the perineal body while you did your instrumental delivery" (obstetrician)

And more 'senior' registrars performed MPP for trainees:

"If it's just me, I would do it [MPP] myself but I've certainly done it for my juniors when I'm supervising deliveries....so that they've got their hands free" (obstetrician)

This team approach created genuine feelings of partnership between midwives and obstetricians, who felt that the OASI Care Bundle was a project which involved everyone:

"This is the only project involving all the shop floor people. The other projects are focused on just a few groups" (midwife)

3) Theme 3: Does current practice need to change?

This theme reflected how clinicians felt about their current practice and their acceptance and readiness to learn new techniques. There were four subthemes: (i) Research evidence, (ii) Clinical judgement, (iii) Comfort with current practice and (iv) The 'ebb and flow' of maternity practices.

Research evidence

There were conflicting views about the evidence for the care bundle. Perceptions surrounding the clinical evidence for the care bundle was a prominent barrier to uptake for both obstetricians and midwives:

"Because it would be nice to have a number needed to treat sort of thing for that. So if you have to do one thousand PRs [per rectal examinations] to pick up one, is all that indignity worth it?" (obstetrician)

Participants also expressed their belief that whilst there may be evidence for the care bundle they felt it wasn't applicable for their practice and so didn't need to change:

1
2
3 *"I know that there's evidence that it reduces severe trauma but I'm not sure that the*
4 *evidence is that it reduces the trauma for my particular practice" (midwife)*

5 **Clinical judgement**

6 Clinical judgement was an important factor and there was a lot of discussion about the fact that no
7 two births are the same. Whilst some participants believed that a benefit of the care bundle was
8 that it provided a standardised approach to preventing OASI, others felt that it took away from their
9 clinical judgment. Clinical judgement was associated with having autonomy:

10
11
12 *"I think it's [the care bundle] taking away autonomy from the practitioner....I think it's good*
13 *to have an option to use it. But I think that to a certain extent it is taking away that*
14 *professional judgement" (midwife)*

15 **Comfortable with current practice**

16
17
18 This theme was expressed by both midwives and obstetricians and created some resistance to
19 change. Often more senior clinicians (obstetricians and midwives) had established their own style of
20 practice and were comfortable with this, whereas more junior, or doctors in training (known in the
21 UK as senior house officers, SHOs) were more adopting of new techniques:

22
23
24 *'The SHOs that are more like, 'Yes, that makes sense, we should do that' because they*
25 *haven't got their own established technique yet. It's the senior regs [sic] that I've heard that*
26 *find reasons not to do it' (obstetrician)*

27
28
29 Some participants felt that their practice was not dissimilar from that outlined by the care bundle.
30 Many midwives referred to the impact of the HOOP trial (a UK trial which looked at the effect of
31 'hands-on' versus 'hands-poised' on postnatal perineal pain)²⁴:

32
33
34 *"We were trained before the HOOP trial, so we always did hands-on...it's not such an alien*
35 *concept....there are lots of us that haven't really, probably, if we're all truthful, haven't really*
36 *moved away from hands-on" (midwife)*

37 **The 'ebb and flow' of maternity practices**

38
39 Participants felt that certain practices came in and out of fashion. As for the previous theme,
40 reference was made to how 'post HOOP trial' practice had changed from a 'hands-on' to a 'hands-
41 poised' approach. Midwives, in particular those who had been qualified longer, felt that the 'hands-
42 on' requirement of the care bundle meant that practice had gone 'full circle' and a return to
43 previous practice. Instead of finding this frustrating however, this was treated in a humorous way:

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45
46 *"There were a generation that were hands-off/hands-poised, which I always found really*
47 *weird, but I was a hands-on, that's how I was taught" (midwife)*

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49
50 This theme wasn't unique to practices relating to hand position at the time of birth. It also emerged
51 with relation to midwives performing episiotomies and to instrument choices for operative vaginal
52 births. In terms of episiotomy it was felt that the pendulum had swung from midwives performing
53 these for every primiparous woman, to only performing a few and this had created deskilling. There
54 was unanimous agreement that neither extreme was correct practice, but there was a feeling that
55 there should be a middle ground:

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57
58 *"They [episiotomies] were in fashion and every first-time mum had an episiotomy whether*
59 *she needed one or not. So probably that's when I was trained....then we went through a*
60

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3 *stage where nobody was having an episiotomy - how can you teach anybody to do them?"*
4 *(midwife)*
5

6 In terms of instrument choice, whilst this was outside the scope of the care bundle, many
7 participants talked about the shift towards the 'heavy use' of forceps and felt that this should be
8 addressed:
9

10
11 *"People pick the forceps culturally...there's such an element of fear amongst junior doctors of*
12 *failing to do something in the room. The other thing that they get told off for is using two*
13 *instruments, so if they use ventouse and they fail..." (obstetrician)*
14
15

16 **4) Theme 4: Perceptions of what women want**

17 This theme reflected a number of factors expressed as reservations for using the care bundle, which
18 related to clinicians' values and perceptions of what women wanted. There were three subthemes:
19 (i) Philosophy of care, (ii) Personal values and (iii) Provision of information to women.
20
21

22 **Philosophy of care**

23 Participants, notably midwives, reported that the care bundle changed the current model of care
24 and increased interventions. Midwives, as facilitators of vaginal birth expressed some reluctance to
25 use procedures which they felt caused over-medicalisation. Some participants felt that births
26 requiring minimal intervention and medicalisation were to be regarded as an achievement. Any
27 interventions took away this feeling of triumph, though this achievement appeared to relate to that
28 of the clinician, not of outcome for the woman:
29
30

31
32 *"I haven't had a third or fourth degree tear, touchwood.....the intact perineum that's a bit of*
33 *an achievement....And then it's almost like we're doing a PR, but that's no reward' (midwife)*
34
35

36 Whilst others agreed that this was an intervention, it was felt good communication was key to using
37 all elements consistently:
38

39 *"It's quite a big intervention, isn't it, to touch the woman there....The woman we had this*
40 *morning who had a pool birth, she had a lovely birth, lovely intact perineum, and when we*
41 *were inspecting the perineum afterwards we said about the new guidance to do with PR and*
42 *she had heard of it....so she consented" (midwife)*
43
44

45 **Personal values**

46 Often participants expressed some anxiety about using some elements of the care bundle, when
47 they themselves would not like it as part of their care:
48
49

50 *"I've been doing it [PR check], because it's part of the study, but I don't like it. And if I was*
51 *giving birth and I had an intact perineum, I don't think I'd particularly want somebody doing*
52 *a PR on me" (midwife)*
53
54

55 This feeling of not liking doing something was particularly prominent in midwives reporting of
56 performing episiotomies. As indicated in a previous theme, there was universal agreement that
57 there was deskilling around midwives performing episiotomies. This lack of confidence was
58 sometimes driven by personal fear *"historically, midwives don't like doing them, do we....I just don't*
59 *like that sound' (midwife)* and sometimes driven by women's fear, which in term affected a
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3 midwife's confidence:
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5 *"Lots of people will say, 'I don't want to be cut, I'll just tear, if that's okay.' It's individual. At*
6 *which point, it puts the whole fear of whether you can go through with that" (midwife)*
7

8 **Provision of information to women**

9 There was a range in opinions as to whether the information sheet for women about the project was
10 appropriate. Some felt that women receive too much information when they are pregnant and that
11 they either don't read it or don't take it on board. Some felt the information was 'too scary' or 'too
12 explicit'. However, most participants expressed their belief that women liked the information sheet;
13 it had encouraged clinicians to talk about perineal trauma and educating women was a positive step:
14

15 *"People feel really angry that actually they have no idea that these sorts of things could*
16 *happen. This project can only really be a good thing in terms of educating them [women] on*
17 *what can be a normal part of a vaginal delivery. I think that's going to be really positive for*
18 *everybody" (obstetrician)*
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20 21 22 **4. Discussion**

23 This paper presents clinicians' perspectives of the OASI Care Bundle, implemented as part of a QI
24 programme with national reach and a complex evaluation attached to it. Our findings suggest that
25 there was a mixed reaction by both obstetricians and midwives towards acceptance of the care
26 bundle. To our knowledge, this study offers unique insights as previous studies to reduce severe
27 perineal trauma have focused on the effectiveness of interventions^{10 11 25 26} but have not reported in
28 detail clinicians' attitudes towards these interventions. The importance of such qualitative insight
29 within maternity was recently highlighted²⁷ as it has implications for implementation, adoption and
30 fidelity of an intervention. Reflection of the identified themes allows an opportunity to raise
31 awareness of potential barriers and enablers which would be considered before implementing
32 similar initiatives.
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35 **Theme 1: Implementation Strategies** Adoption, or failure of adoption, of a new intervention is
36 reliant on many components. This QI project was designed with the implementation strategy given
37 as much consideration as the intervention itself. Despite best efforts, it is likely that application of
38 the implementation strategy varied by units which may have impacted on adoption and acceptability
39 of the intervention – notably the issues voiced around the introduction of the intervention. The
40 launch event had the potential to create engagement within the unit. Our findings also highlight the
41 importance of a targeted communication strategy when starting an initiative. The project had a
42 staggered roll out, and with this came increased communications about the OASI Care Bundle over
43 time. It is possible that the opinions of clinicians in the later regions were affected by this however,
44 even in Region 4 there were mixed reactions to the bundle.
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48 **Theme 2: Opportunities to use the OASI Care Bundle** The observation that mentors found it
49 challenging to practice the MPP technique because their students attended births is an important
50 issue to consider when introducing an intervention as efforts need to be made to ensure that all
51 clinicians get sufficient opportunity to gain and become confident users of new skills. This theme
52 also captured the importance of time when implementing a new initiative. The OASI Care Bundle
53 necessitated both midwives and obstetricians to change their behaviour, in terms of learning and
54 using standardised techniques for second stage perineal management and a change (for some) in
55 the way that they informed women about the risks of perineal trauma. It is importance not to
56 underestimate the time that it takes for an intervention to be adopted.
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3 **Theme 3: Does Practice need to change?** Clinicians in our study placed high value on their ability to
4 use clinical judgement and their personal values are an almost unavoidable influence when
5 providing care. Recent studies have shown that this may vary depending on the nature and framing
6 of the issue.²⁸ This ought to be a careful consideration for any QI intervention that requires
7 behaviour change.
8

9 Midwives were more likely to discuss what we termed the 'ebb and flow' of maternity practices,
10 particularly the 'hands on' or 'hands poised' approaches for perineal protection and this reflects the
11 often conflicting findings of studies.^{10 24 25 29} Both midwives and obstetricians reported similar views
12 regarding the need for current practice to change, in particular the evidence supporting the
13 elements of the OASI Care Bundle. There were some participants from both professional groups
14 reporting reluctance to perform PR checks as they didn't consider they were indicated. However,
15 undiagnosed, or 'missed' OASI are a breach of duty and potential cause for litigation.³⁰ In response
16 to these concerns the project developed some 'frequently asked questions'
17 ([https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/oasi-care-
18 bundle/oasi-faqs/](https://www.rcog.org.uk/en/guidelines-research-services/audit-quality-improvement/oasi-care-bundle/oasi-faqs/)).
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22 **Theme 4: Perceptions of what women want:** Midwives were more likely to report themes alluding
23 to 'Perceptions of what women want', especially the subthemes of 'Philosophy of care' and
24 'Personal values'. The ability to understand women's needs is an important midwifery skill and
25 research has found that women give midwives authority to make decisions, perceiving them 'to
26 know best'.³¹ However, there were some suggestions that some clinicians do not fully understand
27 the balance between discussing risk and maintaining women's autonomy.³² This is an important
28 balance, as women have the right to make informed and autonomous choices and indeed England's
29 Better Births policy initiatives (as well as similar initiatives in Wales and Scotland) aims for women to
30 receive unbiased information, enabling them to develop a personalised maternity care plan based
31 on their decisions and not that of healthcare professionals.^{33 34}
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34 Adoption of the care bundle within a unit was dependent upon its acceptability to both service users
35 and service providers, alongside institutional support. Failure to adopt new practices is commonly
36 reported in the improvement literature, even when there is substantial evidence of potential
37 benefits to patients and the health system.^{35 36} In synthesising these themes and patterns in the
38 dataset, we propose that early adoption of the OASI Care Bundle was associated with a number of
39 *cognitive, interpersonal and organisational* factors. For instance, although the intervention had
40 prominent central support, implementation within each unit was subject to local organisational
41 factors, particularly with the introduction of the intervention and provision of training. Cognitive and
42 interpersonal factors that we identified such as personal values, unit-interprofessional and unit-level
43 awareness have similarly been noted in other maternity interventions and health psychology has
44 been applied to offer theories of behaviour which explain enablers and barriers to uptake.³⁷⁻³⁹
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48 Other reasons for any failure to adopt the intervention maybe because some clinicians, as
49 autonomous practitioners, may not value the intervention as they might have felt that other
50 intrapartum perineal techniques, such as warm compresses should have been incorporated into the
51 OASI Care Bundle. Due to the quality of the evidence⁴⁰, there was much discussion about warm
52 compresses during development of the OASI Project; however, due to the wide variation in practice
53 (whether the compress is held continuously, what is used for the compress, the temperature, when
54 it is re-heated and ability to have a facility for heating compresses) it was decided that the clinical
55 practicalities of ensuring standardisation made it unfeasible to include as a component of the care
56 bundle. Use of compresses was encouraged as part of intrapartum care, but their omission from the
57 care bundle may have caused some resistance. It is clear from the findings here that gaining buy-in
58 for an intervention is an important implementation tool. Other areas to consider are the current
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3 strains on maternity services. Pressures such as staffing level and increased complexity of births are
4 well documented within the UK.⁴¹ These issues did not emerge as a themes within our data;
5 however, it is possible that they were underlying factors which could be additional barriers to
6 adoption of a new intervention.
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9 Training gaps were dominant throughout – for obstetricians this focused on instrument choice and
10 episiotomy technique. For midwives this centred around when and how to perform episiotomies and
11 second stage perineal care. Episiotomies can be a contentious issue and in the NHS a restricted
12 approach to performing them has been adopted, which has created a practice gap amongst more
13 junior staff.⁴² Midwife inexperience with this procedure has been found in other studies⁴³ suggesting
14 that this knowledge gap is widespread and requires continual professional development.
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17 This study has limitations. Whilst FGs produce data through social interaction and the dynamic
18 interaction can stimulate thoughts they can also inhibit participants from divulging their true
19 opinions, in a manner that does not impact one-on-one interviews. All the FGs were held in the
20 participants' place of work and whilst they were on shift, which affected who was able to attend and
21 for how long. This on occasion meant that discussions felt somewhat rushed (i.e. they could have
22 lasted longer) and participants were called away to emergency situations. Some of the FGs were
23 attended by a smaller or larger (10) number of participants than ideally prescribed (6). This was due
24 to clinical pressures and unpredictability of people being available on the day as well as the
25 commitment of doing the FG on a single site visit to ensure it was feasible to conduct them all. As
26 the FGs took place over a period of time, we did not have any control on whether participants may
27 have met with colleagues across units and discussed their views of the OASI Care Bundle – although
28 this per se is not a methodological limitation, as our qualitative approach aimed at eliciting
29 participants' views regardless how these views were formulated. Additionally, the sampling
30 framework for the study meant that all participants were volunteers which is open to self-selection
31 bias. The majority of participants were women under the age of 40. Men and older women might
32 have had different opinions. Lastly, this study only covers data from frontline providers; further data
33 are required to assess implementability and scalability of the OASI Care Bundle from senior and
34 service managers, as well as women using these services.
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38 The study also has strengths. The sampling framework covered a large number of units with
39 different characteristics and varied clinical contexts across the UK. We were able to reach 101
40 participants from a range of experience levels who were encouraged to speak freely which allowed
41 for a wide range of perspectives of the OASI Care Bundle and data saturation was reached with the
42 emergence of no new themes. Findings from this study are therefore likely to be relevant to other
43 maternity units, both in the UK and globally, which may consider implementing this care bundle.
44 Lastly, the FGs were all facilitated by the same trained clinical researcher, which enhances the
45 consistency of the data collection. The fact that the facilitator (PB) was a clinician would be expected
46 to have had an impact on the nature of the discussion around the OASI Care Bundle: we consider it a
47 strength of the study as it facilitated trust in a colleague with experience of the frontline of a unit
48 and genuine expression of views, including concerns. We do acknowledge that a researcher of
49 different profile (e.g. scientist) might have elicited a somewhat different pattern of responses.
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54 **4.1. Conclusion**

55 This study found that adoption of the OASI Care Bundle across 16 UK units was influenced by four
56 main factors: (1) the way in which the intervention was introduced and implemented in units, (2)
57 opportunities to use the OASI Care Bundle, (3) how receptive participants were to changing their
58 practice and (4) personal perceptions of what women want. Our synthesis suggests that cognitive
59 and interpersonal factors at the level of individual providers as well as organisational factors at the
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3 level of the unit and the central OASI programme team underlined the above and determined the
4 level of success of implementation and adoption of the bundle across studied units. The above
5 findings have informed the development of OASI2, which will be introduced in 2020 in order to
6 scale-up and sustain uptake of the OASI Care Bundle ([https://www.health.org.uk/funding-and-
7 partnerships/programmes/oasi2-care-bundle](https://www.health.org.uk/funding-and-partnerships/programmes/oasi2-care-bundle)). These insights can further be used to introduce other
8 QI initiatives within maternity, and also other healthcare settings.
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Disclosure of Interests

NS is the director of London Safety and Training Solution Ltd, which provides patient safety advisory and training services on a consultancy basis to hospitals in the UK and internationally. NS' research is supported by the National Institute for Health Research (NIHR) Applied Research Collaboration South London at King's College Hospital NHS Foundation Trust. NS is a member of King's Improvement Science, which offers co-funding to the NIHR ARC South London and comprises a specialist team of improvement scientists and senior researchers based at King's College London. Its work is funded by King's Health Partners (Guy's and St Thomas' NHS Foundation Trust, King's College Hospital NHS Foundation Trust, King's College London and South London and Maudsley NHS Foundation Trust), Guy's and St Thomas' Charity and the Maudsley Charity. EM is Trustee of the RCOG. BF is the co-inventor of Epi-scissors. The other authors have no competing interests to declare. The views expressed are those of the authors and not necessarily those of the Health Foundation, the NIHR, the National Health Service (NHS) or the Department of Health and Social Care.

Author's statement

RT, IGU, LS, BF and NS conceptualised the OASI Care Bundle. PB, IGU and NS led on the evaluation of the study. RT, LS, AH and VN led on the implementation of the study. PB organised and facilitated the focus groups, performed data management, analysis and drafted the manuscript. JH was an independent second coder for data analysis, reviewing the codes and themes in order to develop new insights and minimize bias. All authors (PB, RT, IGU, JH, AH, BF, EM, VN and NS) critically reviewed the manuscript and provided input before publication. NS provided significant overall guidance.

Details of Ethics Approval

This QI project was reviewed by NHS Health Research Authority in October 2016 and approved as a service evaluation (Ref 60/86/81). We thus sought and obtained relevant local approvals, including from the Caldicott Guardians across all the NHS trusts involved in this evaluation. Only named members of the Project Team have access to the data. They have completed mandatory Information Governance training and are aware of the requirements of confidentiality and understand that any breach will be reported.

The RCOG and LSHTM are registered under the Data Protection Act and are fully compliant with the NHS Information Governance Toolkit for Hosted Secondary Use Teams. Participants (clinicians) who took part in qualitative research activities all provided their verbal consent to do so and were made aware that they could withdraw this at any time.

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Data availability statement: No additional data available.

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3 **Figure legends:**
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5 **Figure 1: The four discrete elements of the OASI Care Bundle**
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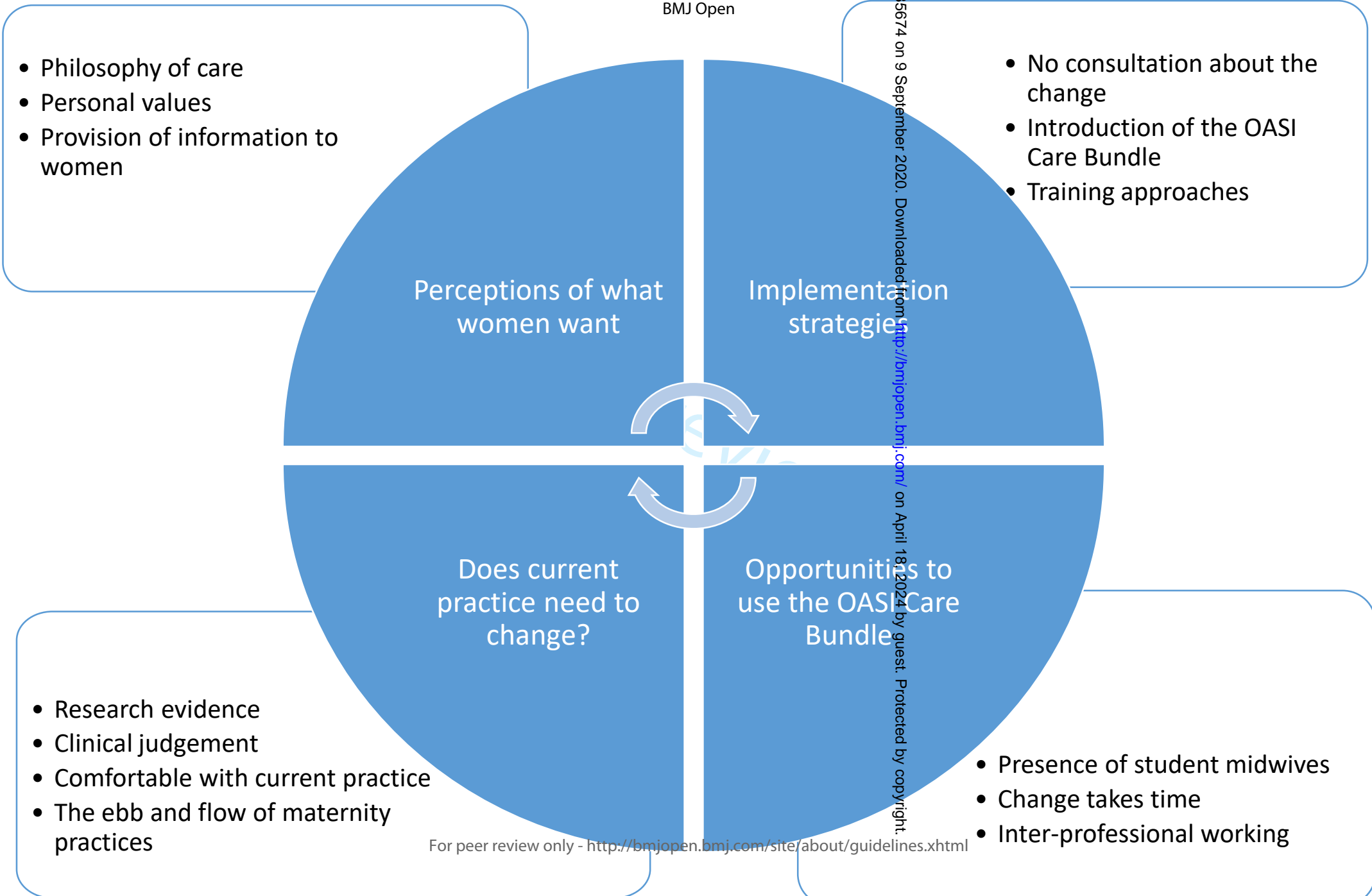
7 **Figure 2: The four main themes and subthemes that emerged from the qualitative data**
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- 1 **Antenatal information for women** about OASI and what can be done to minimize risk.
- 2 When indicated, **episiotomy** should be performed **mediolaterally** at a **60-degree angle** at **crowning**.
- 3 Documented use of **manual perineal protection** (MPP):
 - For spontaneous births, MPP should be used, unless the woman objects, or her chosen birth position doesn't allow for it (eg. water birth)
 - For assisted births MPP should always be used.
- 4 Following birth, the **perineum should be examined** and any tears graded according to the RCOG guidance. The examination should include a **per rectum** check even when the perineum appears intact.

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**Focus Group Discussion for clinicians at participating units:
Topic guide**

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|---|
| <ul style="list-style-type: none"> • What are your attitudes towards the OASI Care Bundle? • What drove the positive/negative reaction? • Do you know anyone who have suffered long-term effects of perineal trauma? • What training did you receive on the care bundle? • What were your thoughts on the awareness campaign / promotional materials / Launch |
| <ul style="list-style-type: none"> • What are your thoughts on the 'train the trainer' model? • How did delivery suite support the training sessions? • Do you think your hospital was motivated to implement the care bundle? • What were the main issues around actually using the care bundle? • What do you think about having a sticker checklist as a reminder of important things one must not forget? • Do you think that women are happy with the OASI Care Bundle? |
| <ul style="list-style-type: none"> • Do you know who your local champions are? • Have you been involved in any monitoring of the care bundle? • What proportion of the staff in the hospital do you think are using the care bundle? |
| <ul style="list-style-type: none"> • Has your knowledge of OASI improved since the care bundle was introduced? • Has the care bundle been integrated into routine practice? • Do you think the rates of OASI have changed? • Did you feel comfortable with using the care bundle? Has there been sufficient training? Will you continue to use it once the project is over? • What were the barriers to using the care bundle? What were the enablers? • Do you think the care bundle is sustainable? • Of all the things we've discussed today, what would you say are the most important issues you would like to express about the care bundle? |

FOCUS GROUP: Demographic Questionnaire

Please answer the following questions in the spaces provided, circle or tick the most appropriate options.

1. Age :.....

2. Are you: (please tick as necessary) Male Female

3. What is your professional background?

Midwife

Student Midwife

Obstetrician - SHO

Obstetrician - Registrar

Obstetrician - Consultant

Other: (please describe) _____

4. Are you: (please tick as necessary) Full time Part time

5. How many years have you worked in this hospital?

<1 Year

1-2 Years

3-5 Years

6-10 Years

>10 Years

6. Overall, how many years' experience in maternity do you have?

<1 Year

1-2 Years

3-5 Years

6-10 Years

>10 Years

Thank you for taking the time to complete this questionnaire

Reporting checklist for qualitative study.

Based on the SRQR guidelines.

Instructions to authors

Complete this checklist by entering the page numbers from your manuscript where readers will find each of the items listed below.

Your article may not currently address all the items on the checklist. Please modify your text to include the missing information. If you are certain that an item does not apply, please write "n/a" and provide a short explanation.

Upload your completed checklist as an extra file when you submit to a journal.

In your methods section, say that you used the SRQR reporting guidelines, and cite them as:

O'Brien BC, Harris IB, Beckman TJ, Reed DA, Cook DA. Standards for reporting qualitative research: a synthesis of recommendations. Acad Med. 2014;89(9):1245-1251.

	Reporting Item	Page Number
Title		
	#1 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	1
Abstract		
	#2 Summary of the key elements of the study using the abstract format of the intended publication; typically includes background, purpose, methods, results and conclusions	2
Introduction		
Problem formulation	#3 Description and significance of the problem / phenomenon studied: review of relevant theory and empirical work; problem statement	4
Purpose or research question	#4 Purpose of the study and specific objectives or questions	4
Methods		
Qualitative approach and research paradigm	#5 Qualitative approach (e.g. ethnography, grounded theory, case study, phenomenology, narrative research) and guiding theory if appropriate; identifying the research	5-6

paradigm (e.g. postpositivist, constructivist / interpretivist) is also recommended; rationale. 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.

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10	Researcher characteristics	#6	5
11	and reflexivity	Researchers' characteristics that may influence the research, including personal	
12		attributes, qualifications / experience, relationship with participants, assumptions and	
13		/ or presuppositions; potential or actual interaction between researchers'	
14		characteristics and the research questions, approach, methods, results and / or	
15		transferability	
16			
17			
18	Context	#7	4
19		Setting / site and salient contextual factors; rationale	
20			
21	Sampling strategy	#8	4-5
22		How and why research participants, documents, or events were selected; criteria for	
23		deciding when no further sampling was necessary (e.g. sampling saturation);	
24		rationale	
25			
26	Ethical issues pertaining to	#9	5 & 15
27	human subjects	Documentation of approval by an appropriate ethics review board and participant	
28		consent, or explanation for lack thereof; other confidentiality and data security issues	
29			
30	Data collection methods	#10	5
31		Types of data collected; details of data collection procedures including (as	
32		appropriate) start and stop dates of data collection and analysis, iterative process,	
33		triangulation of sources / methods, and modification of procedures in response to	
34		evolving study findings; rationale	
35			
36			
37	Data collection instruments	#11	5
38	and technologies	Description of instruments (e.g. interview guides, questionnaires) and devices (e.g.	
39		audio recorders) used for data collection; if / how the instruments(s) changed over the	
40		course of the study	
41			
42			
43	Units of study	#12	5
44		Number and relevant characteristics of participants, documents, or events included in	
45		the study; level of participation (could be reported in results)	
46			
47	Data processing	#13	5
48		Methods for processing data prior to and during analysis, including transcription, data	
49		entry, data management and security, verification of data integrity, data coding, and	
50		anonymisation / deidentification of excerpts	
51			
52	Data analysis	#14	5-6
53		Process by which inferences, themes, etc. were identified and developed, including	
54		the researchers involved in data analysis; usually references a specific paradigm or	
55		approach; rationale	
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1	Techniques to enhance	#15	Techniques to enhance trustworthiness and credibility of data analysis (e.g. member	6
2	trustworthiness		checking, audit trail, triangulation); rationale	
3				
4				
5	Results/findings			
6				
7	Syntheses and interpretation	#16	Main findings (e.g. interpretations, inferences, and themes); might include	6-11
8			development of a theory or model, or integration with prior research or theory	
9				
10				
11	Links to empirical data	#17	Evidence (e.g. quotes, field notes, text excerpts, photographs) to substantiate analytic	6-11
12			findings	
13				
14				
15	Discussion			
16				
17	Intergration with prior work,	#18	Short summary of main findings; explanation of how findings and conclusions	12
18	implications, transferability		connect to, support, elaborate on, or challenge conclusions of earlier scholarship;	
19	and contribution(s) to the		discussion of scope of application / generalizability; identification of unique	
20	field		contributions(s) to scholarship in a discipline or field	
21				
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24	Limitations	#19	Trustworthiness and limitations of findings	13
25				
26				
27	Other			
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29	Conflicts of interest	#20	Potential sources of influence of perceived influence on study conduct and	15
30			conclusions; how these were managed	
31				
32				
33	Funding	#21	Sources of funding and other support; role of funders in data collection, interpretation	15
34			and reporting	
35				
36				

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