The OASI Care Bundle – a lively topic for discussion

Sara Webb

ORIGINAL

Obstetric anal sphincter injury (OASI) is recognised as the most common cause of anal incontinence (AI) in childbearing-aged women (Marsh 2011), encompassing symptoms of flatus incontinence, passive soiling, incontinence of liquid or solid stool and faecal urgency. These symptoms can cause social and hygienic problems that lead to:

- **isolation, limiting occupational and social activity**
- **negative effect on sexual function and consequent impact on relationships**
- **reduced self-esteem and reduced quality of life**

(Leigh & Turnberg 1982, Boreham et al 2005, Lo et al 2010, Keighley et al 2016).

In the UK approximately 5.9 per cent of women will sustain an OASI, with UK data demonstrating a tripling of incidence over the past decade, possibly because of increased awareness and improved methods of detection (Gurol-Urganci et al 2013). However, it has also been suggested that changes in practice of the use of Manual Perineal Protection (MPP) — from 'hands on [the perineum]' to 'hands off' — and a reduction in episiotomies may also have contributed to this rise (Ismail et al 2015). In view of this rising incidence, and Denmark's and Norway's success in reducing their incidence of OASI from just over 4 per cent to just over 1 per cent by introducing interventions including MPP, an OASI Care Bundle was launched across the UK to see if the incidence of such trauma can be reduced (Gurol-Urganci et al 2020, Bidwell et al 2020).

Care bundles are a small set of evidence-based interventions for a defined patient population and care setting that, when implemented together, result in significantly better outcomes than when implemented individually (Institute for Healthcare Improvement (IHI) 2015). Ideally, a care bundle should be concise and straightforward, comprising a set of three to five practices or precautionary steps (IHI 2015). Each of these components is an intervention or practice in its own right, ideally with a sound evidence base. The focus should be on how to deliver the best care and a care bundle should not introduce any practices or techniques that are not in standard practice in at least some settings.

In summary, the OASI Care Bundle is a Health Foundation-funded initiative supported by both the Royal College of Midwives (RCM) and the Royal College of Obstetricians & Gynaecologists (RCOG). The OASI Care Bundle offers all women four elements (see Figure 1) that, when performed together and supported by an educational programme, may reduce the rate of third- and fourth-degree tears (RCOG 2010, Hals et al 2010).

As a midwife specialising in perineal trauma and OASI for over 15 years, and a labour ward coordinator for 10 years, in 2017 I was invited to speak at an OASI study day about the challenges of putting the OASI Care Bundle theory into clinical practice. The two elements of the Care Bundle that were most contentious among midwives were MPP and episiotomy. Since the HOOP trial in 1998, 'hands on or poised' has become the subject of a great debate and practice has veered into 'hands off' (McCandlish et al 1998). Research shows that 49 per cent of midwives prefer the 'hands off' technique, less experienced midwives are more likely to prefer 'hands off' and a higher proportion of midwives in the 'hands off' group would never do an episiotomy for indications other than fetal distress (Ampt et al 2015). Also, 'hands off'

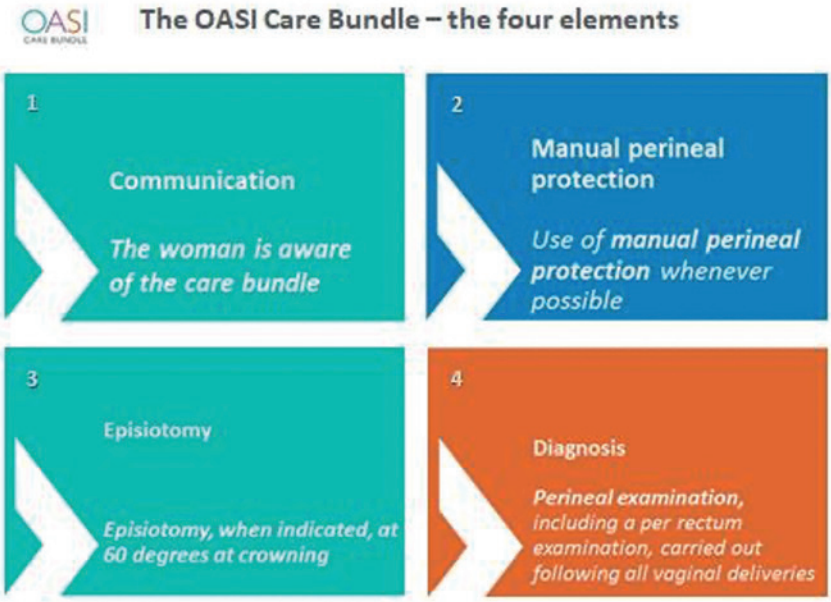

Figure 1. The elements of the OASI Care Bundle.

Source: The Health Foundation (2020) *OASI Care Bundle: a multi-centre quality improvement project to reduce the incidence of obstetric anal sphincter injury*. https://www.health.org.uk/improvement-projects/a-multi-centre-quality-improvement-project-to-reduce-the-incidence-of-obstetric

is preferred by 63 per cent of midwives for a low-risk birth, with most midwives adopting 'hands on' only in situations of high risk for OASI (Ampt et al 2015, Trochez et al 2011).

The comments from midwives about performing Manual Perineal Protection (MPP) included:

'You can only guard the perineum if the woman is in supported sitting or lithotomy.'

'This hands on will only encourage women to remain on the bed.'

'All this care bundle will do is stop women having waterbirths.'

'The HOOP trial showed that there is no need to guard the perineum.'

In response to these concerns I discussed the available evidence, especially the HOOP trial. I explained that this trial was designed with a sample size calculated with the main outcome measure of perineal pain at day 10 after birth — not OASI, which can lead to anal incontinence, and not to see whether the degree of perineal trauma was dependent on 'hands on' or 'poised'. Interestingly, there was no significant difference in all types of perineal trauma but a lower episiotomy rate in the 'hands poised' group. And even more interesting, women who were in the 'hands on' group had less pain at day 10. What should also be remembered is that, in the HOOP trial, 30 per cent of the women who were originally randomised to the 'hands off' group clinically required 'hands on'. Even though these women were analysed as part of the 'hands off' group, the results still did not show a benefit for 'hands off'.

Preliminary findings from work undertaken prior to the development of the Care Bundle showed significantly less OASI when using MPP, although a significant increase in labial tears (Naidu et al 2017), which have lesser longer-term complications and morbidities compared to OASI. I also explained that performing MPP does not mean the woman has to remain on the bed in a supported sitting position but that this manoeuvre is possible in left lateral and all fours positions. Unfortunately MPP is not possible during a water birth but the evidence underpinning the safety of water birth for mother and baby is currently lacking, hence the need for the current National Institute for Health Research (NIHR) Health Technology Assessment-funded 'The POOL Study' (Sanders et al 2018).

Since routine episiotomy for all nulliparous women was discontinued, midwives have moved towards performing them very rarely. Unsurprisingly, comments from midwives about performing an episiotomy, if deemed necessary, included:

'So you're telling me that I need to do an episiotomy on every woman?'

'Our episiotomy rates will go through the roof!'

'Episiotomy is a risk factor for third degree tears.'

Again, I discussed the available evidence. Yes, there is evidence that episiotomy may be causal for OASI (Andrews et al 2006), however there is also evidence that episiotomy is protective (Webb et al 2017). The inconsistent research findings as to whether mediolateral episiotomy has a protective or influencing effect on OASI could be due to the variation in position of the episiotomy incision, that is, too close to the midline. Evidence shows that an acute angle increases the risk of extension to an OASI (see Figure 3, angles 1, 2 and 3) whereas an angle of 60 degrees does not (see angles 4 and 5) (Kalis et al 2012). Use of the Episcissors-60, which ensure cutting at a 60-degree angle, has also been shown to reduce the risk of OASI (Koh et al 2020).

As clinicians, the care we provide to our women must be evidence based. Sometimes the evidence will be high level and robust, sometimes the research evidence may be limited. Sometimes there may not

be any actual evidence underpinning the care we give but it is something we have always done because it has been 'handed down' from our older mentors and colleagues (in these instances it is then our mission to find the evidence to either support or refute our practices — but that is a discussion in itself!) We will also have our own personal experiences and opinions about the care we provide. Sometimes these will be in stark objection/contrast to the evidence-based recommendations. But our role as midwives, as with other health care providers, is to provide women with all the information available to enable them to make their own informed choices and decisions; that is what is key.

Figure 2. Techniques for Manual Perineal Protection in different maternal positions.

Source: The Health Foundation (2020) *OASI Care Bundle: a multi-centre quality improvement project to reduce the incidence of obstetric anal sphincter injury*. https://www.health.org.uk/improvement-projects/a-multi-centre-quality-improvement-project-to-reduce-the-incidence-of-obstetric

So, it was to great interest that Thornton & Dahlen (2020) published *The UK Obstetric Anal Sphincter Injury (OASI) Care Bundle: a critical review*, outlining their views and concerns about the project (Thornton & Dahlen 2020). It was also very informative that the Care Bundle Steering Group was able to publish *Obstetric Anal Sphincter Injury (OASI) Care Bundle: response to a critical review* (Thakar et al 2020). It is important that research findings are questioned and challenged. But it is also vital that the responses to the challenges are heard and given the same consideration. As the saying goes: 'There are two sides to every story.' It is only through debate that we will learn, improve and facilitate change.

I hope you will read both papers and form your own evidence-based and informed views.

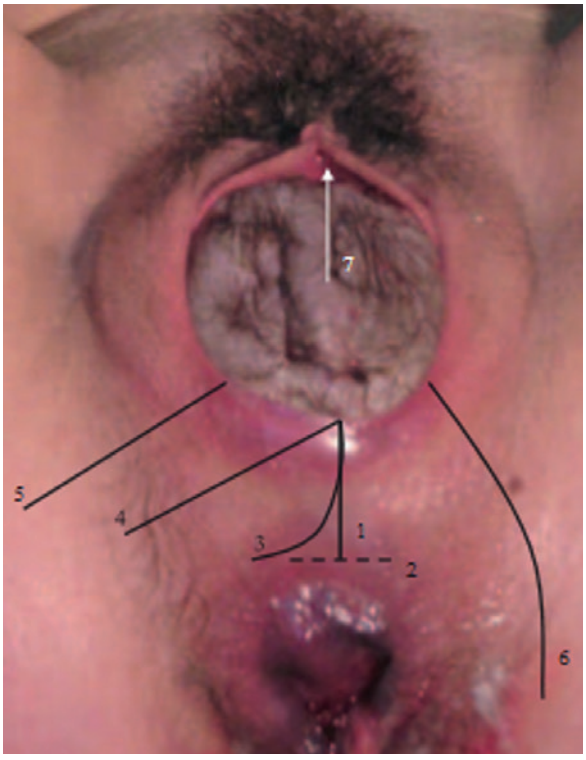

Figure 3. Angles of episiotomy used worldwide.

Source: Kalis V, Laine K, de Leeuw JW, Ismail KM, Tincello DG (2012) Classification of episiotomy; towards a standardisation of terminology. *BJOG* 119(5):522-6.

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The UK Obstetric Anal Sphincter Injury (OASI) Care Bundle: A critical review

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REPRINT

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Background

In 2014 the UK Royal Colleges of Obstetricians and Gynaecologists (RCOG), and of Midwives (RCM) responded to an apparent tripling in the rate of severe (3rd and 4th degree) perineal trauma (Gurol-Urganci et al., 2013) (SPT)[1] by recommending a *Care Bundle* (Royal College of Obstetricians and Gynaecologists RCoM 2016; RCOG. OASI Care Bundle Project Team 2018) with four main elements:

1. antenatal information
2. manual perineal protection for all vaginal births
3. episiotomy with a 60° mediolateral angle at crowning when clinically indicated
4. perineal examination, including per rectum after vaginal birth for all women

The project started as a pilot study and was eventually scaled up and implemented in 16 maternity units in England, Scotland and Wales from January 2017 to May 2018. In December 2019 it was rolled out to more maternity units (Gynaecologists RCoOa 2019). The group also set up an evaluation project (P Bidwell et al., 2018; P Bidwell et al., 2018).

ROCG (RCOG. OASI Care Bundle Project Team 2018) supported the Institute for Health Care Improvement definition of a Care Bundle in this process as needing to: be comprise of a set of three to five practices or precautionary steps and each of these components should be an intervention or practice in its own right, ideally with a sound evidence base (Resar et al., 2012). We question the underlying rationale, and evidence supporting the *Care Bundle*, and fear that it may be ineffective long-term or even cause unintended harm. We divide our critique into three parts.

The apparent increase in Severe Perineal Trauma (SPT)

There is debate as to whether the rise in SPT is as significant as suggested. Even the authors of the paper quoted by the Care Bundle team (Gurol-Urganci et al., 2013) say, "the most likely explanation for the rising rate of reported severe perineal injury is improved recognition" (Gurol-Urganci et al., 2013) (page 1522). They argue: "changes in the main risk factors do not explain the observed increase" and "introduction of a standardised classification of perineal tears, and better training of staff in recognising and repairing perineal tears" has probably contributed (Gurol-Urganci et al., 2013) (page 1522). Research by Dahlen et al. (2015) also showed the impact of changing demographics due to migration patterns as having an impact on SPT rates in some countries (Dahlen et al., 2015).

Evaluation of the care bundle

In January 2016 a stepped-wedged cluster trial of *Care Bundle* implementation in 16 units in the UK started (P Bidwell et al., 2018). Funding was obtained in May 2016, the protocol was published in 2018, and according to the website of the funder (the Health Foundation) the project ended April 2018. We are still awaiting the publication. The primary outcome was the SPT rate amongst vaginal births. A cluster trial is a reasonable design for evaluating an intervention like this. However, the choice of stepped wedge, rather than a conventional cluster trial implies that the intervention was to be rolled out anyway, whatever the results. This appears to have been the case, as in December 2019 it was rolled out to more maternity units (Gynaecologists RCoOa 2019). Measuring the primary outcome as a proportion of only a subset of births creates the opportunity for post randomisation exclusions. For example, counselling about SPT might plausibly cause some women to choose elective caesarean, reducing the denominator of vaginal births. The rate of perineal injury might fall overall, but increase as a proportion of vaginal births - a misleading result.

Assessing the evidence for the components of the care bundle

Antenatal information

Since SPT is important, common and treatable we do not question informing pregnant women about it, so that if they are later offered invasive procedures such as episiotomy or rectal examination, they can give or withhold consent.

Manual protection of the perineum for all vaginal births

The *Care Bundle* website (Royal College of Obstetricians and Gynaecologists RCoM 2016) advocates the Finnish Grip but the evaluation protocol (P Bidwell et al., 2018), describes only manual perineal protection. The latest Cochrane review (Aasheim et al., 2017) includes one trial (1575 women) testing the Ritgen manoeuvre which showed no effect on SPT (RR 1.24 95% CI 0.78–1.96.) and three trials testing the effect of 'hands off' or 'poised' versus 'hands on'. There was also no effect of perineal protection on SPT (RR 0.73 95% CI 0.21–2.56). A more recent review (Pierce-Williams et al., 2019), identified two further trials, and estimated that the hands-on technique was associated with increased risk in third-degree lacerations (RR 3.41, 95% CI 1.39–8.37). Another systematic review and meta-analysis of manual perineal support including both randomised controlled trials (five trials) and non-randomised studies (seven studies) conclude the current evidence was insuffcient to drive change in practice (Bulchandani et al., 2015). However, change in practice is well underway in the UK and other countries.

Seven observational studies, purporting to show a reduction in perineal tears with use of different types of perineal support (MØ et al., 2015) all "failed to identify or appropriately control for known potential confounders, the comparison of the groups was not consistent in time, and exposures and outcomes were not measured in the same objective way in the exposed and non-exposed groups. [Typically] data in the exposed group were collected prospectively, while the data of the non-exposed group were collected retrospectively".

A recent Australian study showed no difference in SPT in primiparous women and an increase in multiparous women when a hands on/directed pushing approach is used compared to the hands poised/undirected pushing approach (Lee et al., 2018). Studies such as this one, and others showing success in reducing SPT using techniques other than the Finnish grip/hands on approach, have simply been ignored. Worryingly the unintended consequence has been an increase in the episiotomy rate wherever these manual support packages/bundles have been put in place (MØ et al., 2015).

- Even more worrying for some, is the intrusion of this practice to apply manual support to the woman's perineum into areas such as waterbirth, where limited touching of the baby prior to birth is recommended to prevent foetal stimulation underwater. Manual support during waterbirth appears to be emerging as standard practice in some Nordic countries such as Sweden where waterbirth is still a relatively new phenomena (Olfsdottir, 2019). There is also a potential that maternal choice of birth position will be impacted by the increasing pressure to manually protect women's perineums.

It is also possible there is a Hawthorn effect in the outcomes seen in some of these studies (Dahlen et al., 2015). A recent paper from Denmark demonstrated hospitals who implemented SPT prevention programs and those who did not had a similar decline in the rate of SPT (Jango et al., 2019).

Perineal warm packs are ignored in the Care Bundle

The only Level 1 intervention known to reduce SPT, is perineal warm packs (Aasheim et al., 2017) which were excluded from the *Care Bundle*. A systematic review and meta-analysis (7 RCTs) published in 2019 showed: a higher rate of intact perineum in the intervention group compared to the control group (22.4% vs 15.4%; RR 1.46, 95% CI 1.22 to 1.74); a lower rate of third degree tears (1.9% vs 5.0%; RR 0.38, 95% CI 0.22 to 0.64), fourth degree tears (0.0% vs 0.9%; RR 0.11, 95% CI 0.01 to 0.86) third and fourth degree tears combined (1.9% vs 5.8%; RR 0.34, 95% CI 0.20 to 0.56) and episiotomy (10.4% vs 17.1%; RR 0.61, 95% CI 0.51 to 0.74) (Magoga et al., 2019). The *OASI Care Bundle Project: FAQS*, responding to growing questions about the *Care Bundle*, stated with regards to perineal warm packs: "it was decided that the clinical practicalities of ensuring standardisation made it unfeasible to include as a component of the care bundle" (RCOG. OASI Care Bundle Project 2020). This seems an extraordinary comment to make about a simple, inexpensive and effective practice that has also been found to be highly acceptable to women and midwives (Dahlen et al., 2009; Dahlen et al., 2007).

Episiotomy with a 60° mediolateral angle at crowning when clinically indicated

There have been no randomised trials testing the effect of increasing the angle of episiotomy to 60°. Low quality, non-randomised studies report mixed effect, with an evidence rating of D (lowest level) given in the RCOG guidelines (RCOG 2015), though still recommended in the Green Top Guideline. A recent multicentre time series analysis on the introduction of the Episcissors-60 (scissors designed to achieve a mediolateral cut at 60° to the midline) demonstrated no change in the SPT rate (Ayuk et al., 2019).

Routine rectal examination

Although rectal examination is widely recommended to rule out anal sphincter damage or buttonhole tear in the presence of episiotomy or second degree perineal tear, the *Care Bundle* authors are the first to recommend routine rectal examination even in the presence of an intact perineum. It makes little sense since no-one knows whether digital rectal examination in the presence of an intact perineum can detect occult anal sphincter injury, and even if

it could, there is no treatment. No one advocates incision of an intact perineum after birth. The suggestion that it is to detect a buttonhole tear is equally misguided since we can find no reports after normal birth with an intact perineum. It is clear consent is not always sought before this occurs causing distress and trauma to some women, especially where there is a history of sexual assault.

Summary

- The UK *OASI Care Bundle* was developed in response to potential misinterpretation of an apparent increase in SPT, which may in part be an artefact/changing demographics.
- The evaluation project was poorly designed and is still not published prior to further roll out.
- Of the four components of the care bundle, only the recommendation that women be informed about SPT is justified.
- The evidence from randomised trials, and systematic reviews, is that perineal guarding and other manoeuvres are ineffective or even harmful, potentially restrict maternal choice of birth position.
- Although there is some observational evidence of benefit from a perineal protection technique called the Finnish grip, this falls below the randomised trials in the hierarchy of evidence, and is of very low quality.
- Warm compresses to the perineum (Level 1 evidence) have completely been ignored.
- The recommendation for a 60° episiotomy angle is based on limited evidence, marketing a type of scissors now shown to be ineffective in reducing SPT. Countries taking on *Care Bundles* have shown a rise in episiotomy rates.
- The recommendation for routine digital rectal examination has no theoretical justification and may cause distress to women, especially where there is a history of sexual assault.

Recommendation

It is to be commended that the RCOG and RCM are working together to improve outcomes for women by making joint recommendations; however, it is disappointing that these recommendations are not evidence based. We recommend that the two Colleges convene a new *Care Bundle* group to consider the evidence cited in the present paper and the results of the current *Care Bundle* evaluation and produce a revised bundle. We would tentatively suggest the following:

1. Women should be informed and prepared for birth and hence given antenatal information about SPT.
2. Midwives and doctors should protect the perineum by slowing the birth of the baby with whatever technique they feel most appropriate. Hands on and hands poised are both acceptable along with verbal guidance. Specific manoeuvres such as head flexion, the C-Grip, Ritgen's manoeuvre and the Finnish grip are not recommended due to insuffcient evidence of benefit.
3. Perineal warm compresses are Level 1 evidence and should be included in the *Care Bundle*
4. Episiotomy should only be performed where indicated. Routine episiotomy is not recommended. Midline episiotomy is not recommended, but both 45° and 60° medio-lateral episiotomy are acceptable until higher level evidence is available.
5. For women with an episiotomy or a perineal tear, a digital rectal examination is recommended to exclude both anal sphincter injury and button-hole tears. For women in whom careful inspection of the perineal and lower vaginal skin reveals no tear, a digital rectal examination is not necessary. Consent must always be sought.

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[1] We will use the term severe perineal trauma (SPT) instead of OASI as women have told us during research they find this term disturbing

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Obstetric Anal Sphincter Injury (OASI) *Care Bundle*: Response to a critical review

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In their critical review of the OASI Care Bundle that was implemented and evaluated in approximately 55,000 women between 2016 and 2018 in 16 hospitals of the National Health Services (NHS) in England, Scotland and Wales (Gurol-Urganci et al., 2020; Bidwell et al., 2018), Thornton and Dahlen raise a number of critical points that lead them

to question the rationale for this care bundle as well as the underlying evidence. A criticism is that the implementation of the care bundle may cause "unintended harm". In fact, the OASI Care Bundle was found to reduce OASI rates by 20% without affecting the caesarean birth rates or episiotomy use (Gurol-Urganci et al., 2020). While we do not dispute the use of the suggested term "severe perineal traum" instead of OASI, we caution that severe perineal trauma might exclude women with severe vaginal injuries without anal sphincter involvement and also button hole tears, both injuries which can have serious consequences.

Below, we discuss the most important points of Thornton and Dahlen's review.

First, Thornton and Dahlen mention that the quoted rise in OASIs may be due to a result of improved recognition than a result of a true epidemiological increase in the rate per se (Gurol-Urganci et al., 2013). We tend to agree but this does not undermine the need for action considering that approximately one in 16 primiparous women (Gurol-Urganci et al., 2013) are reported to experience an OASI which can have long lasting consequences on continence, sexual function, mental health and quality of life (LaCross et al., 2015; Evans et al., 2020). As clinicians supporting women during childbirth, it is our duty to help prevent OASI cases where it is possible and to ensure women have the best outcomes after. More than half of the women with OASI experience on-going symptoms and close to half report an impact on their future birth choices (Evans et al., 2020). OASI has significant resource implications for healthcare providers due to ongoing follow-up (Mellgren et al., 1999) and can trigger claims of negligence against providers of maternity services (NHS Litigation Authority 2012). In addition, there is evidence from other countries that the OASI rates can be reduced through targeted quality improvement initiatives (Laine et al., 2008; Hals et al., 2010; Leenskjold et al., 2015; Rasmussen et al., 2016).

A second point raised is that the potential impact of the care bundle on caesarean rates and/or episiotomy was not evaluated. This was not the case (Gurol-Urganci et al., 2020). The evaluation included all women who had a singleton live birth. As indicated above, the implementation of the OASI Care Bundle did not affect caesarean birth or episiotomy rates.

Third, Thornton and Dahlen give a detailed overview of the available evidence from randomised clinical trials on the effectiveness of the 'hands-on' approach compared to the 'hands-off/hands-poised' approach. We agree that a number of recent systematic reviews demonstrate that the evidence of the effectiveness of the hands-on approach for OASI is patchy (Aasheim et al., 2017; Bulchandani et al., 2015; Pierce-Williams and Saccone, 2019). However, 'no evidence of an effect' does not equate to 'evidence of no effect'. It is important to note that the OASI Care Bundle that we trialled includes, in addition to manual perineal protection, specific information provision to women during the antenatal period, use of mediolateral episiotomy at 60-degree angle when clinically indicated, and a requirement that the perineum should be carefully checked after birth, including digital rectal examination for sphincter integrity. All this follows the notion that the implementation of a care bundle including a group of three to five interventions is more likely to improve outcomes compared to the same interventions being implemented individually (Resar et al., 2012).

Fourth, we disagree with Thornton and Dahlen's statement that it makes little sense to carry out a digital rectal examination when the perineum is intact after vaginal birth. A review of women with missed tears demonstrated that OASI can occur in the presence of an intact perineum (Taithongchai et al., 2019). Without a digital rectal examination anorectal mucosal injury cannot be excluded (Royal College of Obstetrics and Gynaecology 2015). If it is unrecognised, and therefore unrepaired, it can lead to the development of a rectovaginal fistula and anal incontinence.

In this context, it is also important to highlight that women were involved throughout inception, implementation and evaluation and were represented on the project's Independent Advisory Group. Alongside the implementation of the care bundle, we carried out interviews with 19 women who had experience of the care bundle. All interviewed women felt that having a careful examination, including a digital rectal examination, was preferable to running the risk of having an undetected anal sphincter injury which supports the inclusion of a careful rectal examination in the care bundle (with prior consent).

Fifth, the inclusion of the use of a mediolateral episiotomy at a 60-degree angle when clinically indicated is fully in line with the most recent guidelines for intrapartum care developed by the National Institute of Health and Care Excellence (National Institute for Clinical Excellence (NICE) 2014). In their review, Thornton and Dahlen mention the Episcissors-60 but the care bundle does not stipulate that any specific type of scissors should be used.

Finally, there is indeed evidence supporting the use of perineal warm compresses (Magoga et al., 2019). However, the use of warm packs was not included in the care bundle because many units were unable to ensure that warm packs could be heated to the required temperature, especially given the risk of burns when compresses are too hot. We do support Thornton and Dahlen's view that in units where they are available, warm compresses should be offered to women during the second stage of labour as they would further improve prevention of OASI already

provided by the OASI Care Bundle. Throughout the project we encouraged clinicians to do this if this was part of their current practice (The OASI Care Bundle Project, 2020).

In conclusion, we argue that it is unfounded to follow Thornton and Dahlen's recommendation that the RCM and RCOG should convene a new Care Bundle group to consider the evidence on which the current OASI Care Bundle is based. The components of the care bundle are based on the currently available evidence and its feasibility and acceptability by clinicians (Bidwell et al., 2020), and importantly women, have been demonstrated. However, we welcome periodic review of its content and role in clinical practice which should consider emerging evidence on the effectiveness of the components of the care bundle as well as the ongoing evaluation of its implementation.

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