

OASI 'CARE' BUNDLE: FIRST DO NO HARM

Margaret Jowitt argues that there is not enough evidence to support implementation of the OASI care bundle and explains why some of its recommendations could even cause injury.

In the decade preceding 2012 the incidence of obstetric anal sphincter injuries to first time mothers recorded in Hospital Episode Statistics tripled (Gurol-Urganci et al, 2013) from 1.8 to 5.9 per cent. Anal sphincter injuries (ASIs) are associated with faecal incontinence in the year after childbirth and can cause continence problems throughout a woman's life. These injuries are distressing for women and test the skill of midwives and surgeons who have to repair them. In spite of skilled repair, there may be ongoing pain and complications. Anal sphincter injuries are expensive in theatre time, follow up and in litigation costs and are seen as avoidable harm.



The Royal College of Obstetricians and Gynaecologists (RCOG) has put together a 'care bundle' to help prevent ASIs, with instructions in bold typeface that "each care bundle element is applied to every patient [sic] every time". Care bundles are groups of two or three individual interventions for specific clinical indications, with the components having been found effective by randomised controlled trial (Institute for Healthcare Improvement, 2015). One of the many problems with the OASI care bundle is that the recommendations are not all based on best available evidence. The RCM has endorsed this care bundle, despite it going against its own research evidence-based blue top guideline.

The bundle consists of discussion with the woman; consideration of episiotomy, and if done, then angled at 60° away from the anus; a very specific method of hands-on delivery known as Manual Perineal Protection (MPP); and rectal examination after the birth for all women, whether they or not they show signs of external injury.

There do not appear to be plans to subject the OASI care bundle as a whole to the test of a Randomised Controlled Trial (RCT), instead, it is introduced wholesale into units and audited. Audits from early adopters have shown a reduction of anal sphincter tears from 3.3% to 3%, (still above the ASI rate at 2000) (RCM news story December 2019). It is to be rolled out countrywide into all birth settings.

The main problem with this initiative is that the procedures are very prescriptive and are to be applied to all women, whatever their level of perceived risk. Obstetric anal sphincter injuries are very much seen as accidents waiting to happen to all women intending to give birth vaginally.

While there is scope for clinical judgment as to whether or not to cut an episiotomy, there is no scope for a hands-off birth:

"For spontaneous births, manual perineal protection should be used unless the woman objects, or her chosen position for birth doesn't allow MPP." "The only instance where it may not be possible to use MPP is when women are labouring in water or, on a birthing stool." (I wonder whether birthing stools will disappear from obstetric units.)

The guidance suggests words to be used in the notes when a woman declines an element of the care bundle. Is this documentation designed to serve as a defence in litigation for ASIs? Chapman and Charles (2018) are concerned that the care bundle contains mixed messages, Women are to be given choice in position for second stage but that choice is easily undermined by raising with them the spectre of anal sphincter injuries.

The accompanying document is inconsistent in that it says that the purpose is "not to replace reasonable clinical judgment" (again in bold typeface). Reasonable clinical judgment should include an idea of who is most at risk and how to act in individual circumstances.

At risk

The guidance lists most factors associated with ASIs: "nulliparous, of South Asian ethnicity, baby's birthweight greater than 4 kg, shoulder dystocia, occipito-posterior position, prolonged second stage of labour, previous OASI and instrumental delivery". Dr Rachel Reed (2019) adds other factors: hospital birth, particular positions (supine, lithotomy, squatting); directed pushing; syntocinon and hands-on with multiples – this last factor – that hands-on birth can itself be a risk for perineal injury - is very much at odds with the care bundle guidance.

Anal sphincter injuries are associated with forceps and ventouse deliveries; if vaginal instrumental deliveries increase, so too will anal sphincter injuries. For the baby who has his hand up by his head, or where there is shoulder dystocia, an anal sphincter injury may (in some cases) be largely unavoidable. The RCOG also cites maternal age and obesity as contributing factors (both of which now appear to be used to account for every worsening maternity care outcome).

Two of the factors most associated with anal sphincter injuries are instrumental birth and maternal position for the birth; and these two factors are themselves related in that ventouse and forceps deliveries are usually performed with a woman in lithotomy position.

Prevention - midwifery factors

We must ask ourselves how much anal sphincter trauma is ultimately caused by a failure to wait, whether for clinical

or operational reasons. A long second stage is not of itself necessarily dangerous if mother and fetus are doing well. Are mother and baby being given enough time to birth - is instrumental vaginal delivery overused? The association of ASIs with a 'long' second stage could be due to a rush to instrumental delivery – usually in lithotomy position.¹

The RCOG claims: "There is no clear evidence that any particular position has a significantly protective effect on the perineum." However, it fails to note the association with lithotomy position and ASI. More and more women are reporting being delivered in lithotomy under the care of midwives; will the care bundle accelerate this trend?

Midwives should be ensuring that women give birth in lithotomy only when required for obstetric manoeuvres. Side lying and forward leaning positions result in less trauma (Edwards, 2019 pages 54-55). Is the environment conducive to optimal positions for labour? Women giving birth under midwifery care at home and in birth centres have the freedom of being in their own space, plus a wide range of furniture enabling them to choose comfortable positions for themselves. Women labouring in hospital might have their birthing position constrained by monitoring devices, by space issues and by inappropriate labour ward furniture and lack of supportive accessories.

Evidence-based care

We are in the era of evidence-based medicine, and meta-analyses of randomised controlled trials (RCTs) are seen to trump all other evidence. A care bundle is a group of interventions to be considered together. Parts of some of the elements of the OASI care bundle have been tested by randomised controlled trial but by no means all. The HOOP trial (Sleep, 1998) addressed the question of hands-on or hands-poised at birth, but that trial took place before the dramatic rise in the rate of anal sphincter injury and the measured outcome was perineal pain, not perineal tearing. I have been unable to find an RCT on the specific hands-on technique described in the OASI care bundle. There is evidence from lower grade observational studies but this does not justify imposing an obstetric hands-on method of birth on all women. The audit evidence on the RCOG care bundle so far shows a reduction in ASI of three per thousand (3.3/1000 to 3.0/1000, a 10% reduction) which could be due to the Hawthorne effect alone and is still above the rate seen in 2000 (Gurol-Urganci, 2013).

The RCOG care bundle addresses few of the factors associated with perineal trauma. It almost seems to have been cobbled together to promote just one of its elements – manual perineal protection (MPP). Certainly the suggested statement: "[Patient name] is aware of the OASI Care Bundle. She has no objection to it being used if she is in a position for birth that facilitates the use of the care bundle" can refer only to the MPP element. The theory behind MPP is based on mechanical forces at the rim of

the introitus, measured on plastic models of the lower torso of a woman lying on her back (how accurately is the skin modelled? Has anyone measured the actual stresses on the perineum on a real woman – and in different positions?) It is a compelling theory and I'm all for biomechanical theories, I have plenty of my own (e.g. Jowitt 2018) - but they cannot and should not replace randomised controlled trials of specific treatments.

However, it could be that obstetricians do not see MPP as a treatment requiring RCT evidence before implementation. They may see it merely as a technique, instructions on what to do with your hands at a birth, not an intervention but a method of delivery. Other hands-on procedures (for example vaginal examinations and palpation) have not been subject to RCT but are merely taught. Surgery is very much a hands-on discipline, obstetricians exercise manual skills in their work. They will already be biased towards hands-on because, after all, that is often why they have been called to a birth in the first place – because there is an anticipated need for their specific manual skills. However, in midwifery (as opposed to obstetrics) the hands-poised/hands-on argument has not been resolved. Mandating the use of the care bundle in all settings denies midwifery skills.

It is sad that the first element of the bundle should have to emphasise the need to give women information, as if that itself were an intervention. The information they are to be given is rather bland and in my opinion "manually supporting both your perineum and the baby's head as s/he is born" does not give an adequate description of MPP. The statement about having an episiotomy only when 'essential' (element 2) is rather more tricky – who is to decide when an episiotomy is essential? At one time it was thought that episiotomy was essential for all women. Are we to return to those days or should it be a matter of clinical judgment and, if so, what factors should inform clinical judgment? We already have RCTs to help clinicians decide. There is a danger that episiotomy rates may increase.



Elements of the OASI Care Bundle

There are **four** key elements:

1. **Inform the woman** about OASI and what steps can be taken to minimize her 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**, manual perineal protection should be used unless the woman objects, or her chosen position for birth doesn't allow MPP.
 - For **assisted births**, manual perineal protection should 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 (PR)** check even when the perineum appears intact and this should be documented in the case notes.

a. Spontaneous births

It is necessary for the clinician to **gauge the speed** at which the head is progressing to allow the use of appropriate pressure (enough to allow progress but prevent uncontrolled expulsion) at the correct time (at crowning, prior to birth).

- One hand is used to “cup” the fetal head and **control the speed and progress** of the presenting part.
- The other hand **supports the perineum** using the thumb and forefinger on the lower part of the labia, firm pressure is used while flexing (curling in) the remaining 3 fingers and pushing them against the perineum.
- As the face becomes visible use the middle finger of the perineal support hand to **assist with the birth of the chin** over the introitus.
- Encourage the mum to refrain from pushing and **breathe the baby out slowly**.
- Wait for restitution to occur, (still supporting the perineum) and encourage the mum to **push gently to birth the shoulders**.
- Continue MPP throughout the birth of the shoulders by **moving your non-dominant hand** to support the baby's body. Applying gentle axial traction until both shoulders are born.



Midwives (and some obstetricians, eg Thornton 2018) are up in arms about the fourth element, performing a digital rectal examination in the absence of any evidence of injury. Internal injury is vanishingly rare when there is no external injury, they say, and women should not be subjected to such an invasive examination when, theoretically, it may benefit only a miniscule proportion of them. (On the other hand, the authors of the Dublin active management of labour regime were of the opinion that women preferred rectal examination to vaginal examination – certainly not this author.)

The third element of the bundle itself bundles many interventions together. There can be little objection to this instruction to mothers: “encouraging you to slow your breathing to control the speed of the birth”. ‘Breathing your baby down’ is standard advice from the midwifery and natural childbirth communities and slowing the birth helps prevent tears. However, so complicated are the physical manoeuvres described as “manually supporting both your perineum and the baby’s head as s/he is born” that they constitute a care bundle in themselves.

Manual perineal protection requires the midwife to hold together the sides of the introitus nearest the anus. The thumb and forefinger of the dominant hand are placed at the posterior parts of the labia and press inwards. The other three fingers of this hand are bent inwards and push the fetal head away from the anus; this is known as the Finnish grip. The midwife controls the delivery of the head with the other hand. When most of the face is visible the middle finger of the hand supporting the perineum lifts out the chin from under the fourchette.

Any tears will now be towards the front instead. Midwives are now seeing tears that can extend as far forward as the clitoris, one midwife described a tear along the line of the buttock crease.

This very obstetric hands-on method of delivery seems to me to violate a very private space. Whether this feeling is something personal to me, or more widespread among women (and men perhaps) I don’t know. However, I’m deeply uncomfortable with the notion that a woman’s body is something to be forcibly manipulated while she is in the throes of giving birth, moreover, as a routine measure. Is this really the best we can do to prevent anal damage?

Perhaps the greatest danger in promoting this technique is that midwives may feel that they can perform it best only when a woman is in lithotomy position – but lithotomy position itself is a risk factor for anal injury. Manual perineal protection may simply counteract the harm associated with lithotomy position. To be fair to the RCOG, the guidance to midwives does say that the technique can be used in any position except in the birth pool or on a birthing stool, and that women should be free to choose their position for birth - I do wonder how it is realistic in any upright position. With each successive CQC Maternity Survey (2011 through 2019), apart from 2014 when there was a dip, the number of women reporting that they gave birth with their legs in stirrups increased and it seems likely that the care bundle will exacerbate this trend (CQC, 2007 27%, 2010 30%, 2013 32%, 2014 27.7%, 2015 35%; 2017 36% 2019 37%).

It seems to me that in an all-fours or forward-leaning position, the stresses on the perineum will be directed away from the anus and that gravity will do the work of the Finnish grip.

However, we must not throw the baby out with the bathwater, the MPP can be useful in the delivery suite environment. When a woman is pushing for all her worth, just wanting that baby OUT, or when an epidural has removed sensation, when a woman finds it impossible to stop pushing, then manual manoeuvres can be helpful.

Comments by an anonymous midwife on social media give some positive feedback:

"I have only incorporated this into my practice in the past few months and used it a handful of times when it was absolutely necessary because the baby would otherwise shoot out due to the mother being in the grips of fear which means she is not as responsive to verbal instruction. It is a tool in the toolkit to be used on a case by case basis.

"We all work in different areas and every new technique or bundle is brought in supposedly for the greater good. In the case of the OASI care bundle the evidence shows that it can help reduce anal sphincter injury. I certainly wouldn't use it on everyone. I feel, if you need to use a hands-on technique because of a previous 3rd-degree tear then do it thoroughly. [There is] no point only putting minimal pressure on if the idea is to protect the perineum. If we need to have our hands-on, then let's do so with the best method we have available and currently, in my opinion, the Finnish Grip gives good support of the perineum with the flat part of your fingers while allowing for slow descent of the head with thumb and forefinger in 'the grip'. It is more prescriptive than simply saying 'hands-on' which of course could mean anything from a light pressure to a heavy grip.

"Theorising is all good and well but those of us on the ground have to use the tools we have to do what we can for the best possible outcomes."

Note that this midwife does not support using the Finnish grip at all times, but only in a handful of cases.

If not this care bundle what about a midwifery care bundle? In a discussion on an Australian website one midwife wrote:

"It is time we focused on promoting and supporting physiology as a risk management strategy – not routine intervention and disempowerment. Midwives need to say 'enough is enough' and refuse to implement this 'care bundle' as it contradicts their professional standards and philosophy. We need to take responsibility for our own practice and stop colluding in disrespectful maternity care. Midwives are in a powerful position – we provide the face-to-face care of women – we need to use that power to advocate for women." Comment in www.midwifethinking/ march 6 2018.

Biomechanics

If a large head must fit through a smaller hole, then the hole needs to stretch where the fetus needs it to stretch. If unable to stretch in one place, it must stretch elsewhere or tear. The fetal head extends backwards to be born and the fetus will find this easier when not having to lift his head against gravity. The fetal head pivots at the symphysis pubis. In a forward-leaning position, gravity will enable the head to be as anterior as possible, making more space near the anus to be stretched by the fetal forehead. A forward-leaning position will allow gravity to help, while a side-lying position will at least not hinder the movement. Women giving birth under epidural anaesthesia are less likely to tear when in a side-lying position (Cochrane). Lithotomy is counter-productive since it will tend to stretch

the perineum at the sides and exert pressure near the anus, both of which reduce available stretch.

Supporting the perineum in a variety of ways, according to individual circumstances, may very well be useful in helping to prevent injuries, indeed women sometimes do this for themselves. An RCT by Dahlen (2012) concluded that a warm compress should be a standard part of perineal care during second stage, coupled with a hands-off technique involving no routine hand manoeuvres to flex the fetal head or guard the perineum. Perineal massage may be useful if the woman finds it acceptable (Dahlen 2012).

Conclusion

It seems to me that the OASI care bundle is an attempt to impose obstetric control on midwifery care both inside and outside hospital. The clue is in the name of the bundle OASI – obstetric anal sphincter injuries, which are far less common in out of hospital care. Even in hospital under obstetric management, better ways might be found to reduce the rate, for example by observing the practice of midwives with particularly low rates. Has there ever been an RCT on the Finnish grip – or indeed lithotomy position for birth? How can a care bundle even be proposed in the absence of such evidence? Imposing this care bundle risks a return to the old days when episiotomies could be cut after the birth (yes very rarely, but it happened) to prevent disciplinary action. (Mary Cronk used to drop the scissors instead – but even that left her quaking in her shoes.) Fear driven practice is good neither for women nor their caregivers.

The intentions are laudable, obstetric injuries can be permanent and debilitating, but women need to be cared for as individuals. Midwives need to be able to use their clinical judgement as to when intervention is preferable to doing nothing. It looks as though it is worth teaching midwives the Finnish grip because, as our anonymous midwife has found it can be a useful technique, and if RCTs show that cutting an episiotomy at an angle of 60° is better than cutting at an angle of 45°, then the technique should change but this care bundle is not the way to disseminate best practice. For me, the anal examination was almost the worse aspect of each birth but given that I sustained 2nd degree tears each time, I could see that it was necessary and put up with it.

Perhaps even more concerning is the insistence on antenatal and peripartum discussion of ASIs which primes the woman to accept the blame for any injury she may sustain and may increase her fear – and thus the risk itself.

Giving birth is something that women – and their babies – should be supported to do themselves, not something that is done to them.

Note

1. WHO 2018 says, "women should be informed that the duration of the second stage varies from one woman to another. In first labours, birth is usually completed within 3 hours whereas in subsequent labours, birth is usually completed within 2 hours."

Appendix 1: Images of manual perineal protection (MPP) in various birthing positions

Recumbent/semi-recumbent



1 MPP in the recumbent or semi-recumbent position / Image courtesy of Dr. Katarina Laine, University of Oslo, Norway.

Lateral



2 MPP in the lateral position / Image courtesy of Dr. Katarina Laine, University of Oslo, Norway.

Demonstrations of MPP on a plastic manikin .

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About Margaret Jowitt

Margaret is an author, childbirth activist and campaigner. She has a special interest in biomechanics of the uterus.

The Royal College of Midwives Blue Top Guideline on Preventing Severe Genital Trauma

Preventing severe genital trauma

Evidence summary

There is good evidence that using a warm compress on the perineum, and some evidence that perineal massage during birth may help to reduce the rates of third and fourth degree tears¹.

There is low-quality evidence that hands-off (or poised) compared to hands-on techniques has no effect on the rate of third and fourth degree tears but may result in fewer women requiring episiotomy¹.

There is insufficient evidence to show whether Ritgen's manoeuvre or other perineal techniques could improve outcomes¹. More research is needed.

There is low-quality evidence that selective episiotomy for unassisted vaginal births, results in fewer women experiencing severe perineal / vaginal trauma than policies of routine episiotomy². There is low-quality evidence that selective episiotomy policies do not result in harm to women or babies². There is no evidence about the effect of selective or routine episiotomy policies for instrumental births².

Recommendations for practice

There is good evidence to recommend that:

- Midwives should ask women if they would like a warm compress to be used on the perineum to help reduce the risk of serious tears

There is some evidence to recommend that:

- Perineal massage may help to reduce serious tears; midwives should discuss techniques for this during the antenatal period
- A policy of routine episiotomy may result in more women experiencing severe perineal trauma

The evidence and recommendations presented in this section were derived from existing high quality systematic reviews as referenced below:

1. Aasheim V, Nilsen ABV, Reinar LM, Lukasse M. Perineal techniques during the second stage of labour for reducing perineal trauma. Cochrane Database of Systematic Reviews 2017, Issue 6. Art. No.: CD006672. DOI: 10.1002/14651858.CD006672.pub3
2. Jiang H, Qian X, Carroli G, Garner P. Selective versus routine use of episiotomy for vaginal birth. Cochrane Database of Systematic Reviews 2017, Issue 2. Art. No.: CD000081. DOI: 10.1002/14651858.CD000081.pub3.

The RCM Blue Top guideline on preventing severe genital trauma. This guideline is based on the best research evidence, compiled by Professor Helen Spiby's team at the University of Nottingham. Why has the RCM gone along with the OASI 'care' bundle? (Ed.)