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The OASI Care Bundle: a quality improvement project to reduce rates of severe perineal tears that occur during childbirth

Submission date
22/09/2017

Recruitment status
No longer recruiting

Registration date
03/10/2017

Overall study status
Completed

Last Edited
11/09/2020

Condition category
Pregnancy and Childbirth

[_] Prospectively registered
[X] Protocol
[_] Statistical analysis plan
[X] Results
[_] Individual participant data

Plain English summary of protocol

Background and study aim
Severe perineal tears, or obstetric anal sphincter injuries (OASI), sustained during childbirth can be severely debilitating for women. Short-term consequences of OASI include pain, bleeding and infection. Long-term consequences include urinary and faecal incontinence, chronic pain and painful intercourse. Such consequences can have a severe impact and affect future birth choices. Furthermore, there are significant long-term costs for the NHS associated with further treatment and negligence claims. In light of the reported rising trends in OASI rates in England, a team of national experts met to discuss strategies to reverse this trend. There was unanimous agreement that there was potential for a 'care bundle' of evidence-based actions to be developed to reduce perineal trauma. A care bundle is a collection of interventions that is best be delivered together in order to provide safe and effective care. A review of interventions that can reduce OASI rates was conducted and the results were discussed by the team before the four elements of the care bundle were determined. The care bundle was piloted in two maternity units before the intervention was introduced to 16 units. The OASI Care Bundle is aided by a Skills Development Module and a communications and awareness campaign. This study aims to assess the impact of the OASI Care Bundle on rates of severe perineal tears.

Who can participate?
Women who have a vaginal birth

What does the study involve?
Participating maternity units are randomly allocated one by one to start using the OASI Care Bundle. The care bundle is available for all women who have a vaginal birth at the participating units. The care bundle comprises four elements: information about perineal tears, manual perineal protection during childbirth, episiotomy (when clinically indicated) to be performed at a 60 degree angle at crowning, and perineal examination to include per rectum check following all vaginal births. The rate of obstetric anal sphincter injuries is measured using routinely collected patient data over an 18-month period.

What are the possible benefits and risks of participating?
Women who receive the care bundle as part of their care may benefit from reduced perineal trauma. There are no potential risks to anyone involved in the study.

Where is the study run from?
The study is managed by the Royal College of Obstetricians and Gynaecologists. The study is the result of a collaboration with the Royal College of Midwives, Croydon Health Services NHS Trusts, and the London School of Hygiene & Tropical Medicine. The study is being conducted in 16 maternity units across England, Wales and Scotland as follows:
Region 1: Warrington Hospital, Royal United Hospital Bath, Royal Gwent Hospital, Birmingham Women's Hospital
Region 2: Bedford Hospital, Milton Keynes University Hospital, Calderdale Royal Hospital, Nottingham University Hospital
Region 3: Chelsea & Westminster Hospital, Poole Hospital, Epsom General Hospital, St. Richard's Hospital
Region 4: St John's Hospital, University Hospital of North Tees, Queen Elizabeth University Hospital, Saint Mary's Hospital

When is the study starting and how long is it expected to run for?
October 2015 to October 2018

Who is funding the study?
The Health Foundation (UK)

Who is the main contact?
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Additional identifiers

Protocol serial number
Unique award number 7674

Study information

Scientific Title
The OASI Care Bundle: a multi-centre quality improvement project to reduce the incidence of obstetric anal sphincter injuries sustained in women who give birth vaginally in sixteen UK maternity units

Study objectives
The OASI Care Bundle is a package of evidence-based interventions which has been developed to reduce perineal trauma that is sustained during childbirth. It is hypothesized that the OASI Care Bundle, enhanced by a Skills Development Module and a communications and awareness campaign among clinical staff in maternity units, will improve clinical outcomes by addressing knowledge gaps and inconsistencies in training, skills and practice regarding the prevention of obstetric anal sphincter injuries (OASI).

The aim of this study is therefore to evaluate the clinical effectiveness of the implementation of the OASI Care Bundle and the acceptability, feasibility, coverage and sustainability of the intervention to provide recommendations for further scaling-up of the implementation process should the OASI Care Bundle prove to be clinically effective.

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Health Research Authority (HRA) provided confirmation on 11/10/2016 (ref: 60/86/81) that the study did not require review by the NHS Research Ethics Committee and considered the study to be a service evaluation

Study design

Multi-centre trial based on a stepped-wedge design with continuous recruitment

Primary study design
Interventional

Study type(s)
Prevention

Health condition(s) or problem(s) studied
Obstetric anal sphincter injuries

Interventions
Great Britain (England, Wales and Scotland but not Northern Ireland) was divided into four geographical blocks. Within each region, four maternity units of different type and size were selected to obtain a total of 16 sites for participation in the study. The four regions were sequentially randomised to the intervention using a random number generator. The first region began implementing the OASI Care Bundle in January 2017 and the intervention is being introduced to the remaining regions every subsequent three months. The sites are informed of their allocation two months before their start date to allow for preparation time.

The local implementation of the project is led by clinical champions (midwives and obstetricians from each unit). All champions receive multi-disciplinary training at designated ‘Skills Development Days’ on the key elements of the care bundle. The first three months of the intervention constitute a defined 'transition phase', when the care bundle is launched at the units and the local champions start to ‘cascade’ the training and educational materials to their colleagues. Implementation of the OASI Care Bundle intervention is further enhanced by an ongoing communications and awareness campaign, and support from professional organisations and the project team.

The OASI Care Bundle contains four evidence-based elements:
1. Information about perineal trauma to women during pregnancy
2. Manual perineal protection during childbirth
3. Episiotomy (when clinically indicated) to be performed at a 60 degree angle at crowning
4. Perineal examination to include per rectum check following all vaginal births

The OASI rate is assessed via routinely collected patient-level data captured through each unit’s maternity information system (MIS). Regression analysis will adjust for differences in organisational characteristics and obstetric risk factors in women who gave birth before and after implementation of the care bundle. Weekly data will be collected in order monitor coverage and integration of the care bundle into routine practice to ensure that the study has no adverse impact on episiotomy and caesarean section rates.

Secondary outcomes are acceptability, feasibility, coverage and sustainability of the OASI Care Bundle, Manual and the Skills Development Module which will allow a detailed evaluation of how the bundle is implemented across the 16 study sites. These secondary outcomes will be measured prospectively using qualitative and quantitative methods at different stages. The first stage of the evaluation will assess readiness for change within each unit based on a questionnaire that will be sent to the champions at each site weeks prior to roll-out. Focus groups with clinicians will be conducted approximately eight weeks into roll-out. Focus groups with champions will be held at the end of roll-out period. Midwives from each unit will recruit women who have the received the care bundle to take part in an in-depth interview

approximately one month after the end of the roll-out period in order to explore their experiences. Finally, post implementation interviews will be held with the champions.

Intervention Type
Other

Primary outcome(s)
Rate of obstetric anal sphincter injuries (OASI), assessed via routinely collected patient-level data, captured through each unit's maternity information system (MIS) over an 18-month period

Key secondary outcome(s))
1. Acceptability (satisfaction with the intervention) will be measured using:
1.1. The Organisational Readiness for Implementing Change (ORIC) scale will assess the unit's commitment to change. This questionnaire will be completed by all champions prior to roll-out (January 2017, April 2017, July 2017 and September 2017)
1.2. Focus groups with clinicians at the maternity units will explore individual attitudes towards the care bundle, training and the awareness campaign. These discussions will be held six weeks after the start of roll-out in each unit (March 2017, June 2017, August 2017 and December 2017)
1.3. Focus groups with the champions from each maternity unit will explore the attitudes of staff within the unit towards the care bundle and what drove this reaction. These discussions will be held at the end of the three month 'transition' phase (April 2017, July 2017, September 2017 and January 2018)
1.4. Interviews with women who have experienced the care bundle will explore appropriateness and views of the intervention. These will be conducted six months after the start of roll out within each unit (July 2017, October 2017, January 2018 and March 2018)

2. Feasibility (extent to which intervention can be applied) will be measured using:
2.1. The Organisational Readiness for Implementing Change (ORIC) scale will assess collective commitment to change. This questionnaire will be completed by all clinicians at the maternity units who participate in the focus group discussions (March 2017, June 2017, August 2017 and December 2017)
2.2. Focus groups with clinicians at the maternity units will explore individual views on the 'train the trainer' approach, main issues with the care bundle and perceived women's attitudes towards it. These discussions will be held six weeks after the start of roll-out in each unit (March 2017, June 2017, August 2017 and December 2017)
2.3. Focus groups with the champions from each maternity unit will explore the support mechanisms and engagement with the care bundle. These discussions will be held at the end of the three month 'transition' phase (April 2017, July 2017, September 2017 and January 2018)
2.4. Interviews with women who have experienced the care bundle will explore whether the intervention is reasonable and practical. These will be conducted six months after the start of roll out within each unit (July 2017, October 2017, January 2018 and March 2018)

3. Coverage (extent to which the population receive the intervention) will be measured using:
3.1. Care bundle eligibility and compliance will be monitored through use of a sticker 'checklist'. All vaginal births are eligible if the attending clinician has been trained to use the care bundle and the birthing position allows for good visualisation of the perineum. For a birth to be compliant, all four elements of the care bundle must have been used. This will be monitored throughout the project roll out (January 2017 – April 2018)
3.2. Champions will be asked to provide weekly data on the number of obstetricians and midwives that they have trained to use the care bundle
3.3. Weekly birth statistics will be obtained to monitor vaginal birth rate, OASI rate and

episiotomy rate. This will be monitored throughout the project roll out (January 2017 – April 2018)

4. Sustainability (extent to which intervention is maintained) will be measured using:
4.1. Focus groups with clinicians at the maternity units will explore individual attitudes towards integration of the care bundle into routine practice and whether this can be maintained. These discussions will be held six weeks after the start of roll-out in each unit (March 2017, June 2017, August 2017 and December 2017)
4.2. Focus groups with the champions from each maternity unit will explore the barriers and enablers towards use of the care bundle with the unit. These discussions will be held at the end of the three month 'transition' phase (April 2017, July 2017, September 2017 and January 2018)
4.3. Interviews with women who have experienced the care bundle will explore their attitudes towards the intervention. These will be conducted six months after the start of roll out within each unit (July 2017, October 2017, January 2018 and March 2018)
4.4. In-depth interviews with champions at the end of the project will explore whether clinicians in the units are still consistently using the care bundle and whether it has been incorporated into local guidelines (April 2018)

Completion date
01/04/2019

Eligibility

Key inclusion criteria
All vaginal births are eligible for the intervention when the attending clinician (midwife or obstetrician) has been trained to use the OASI Care Bundle

Participant type(s)
Patient

Healthy volunteers allowed
No

Age group
Adult

Sex
Female

Key exclusion criteria
Women are excluded if they are in a birthing position (e.g. water birth) that makes it impossible to implement all aspects of the OASI Care Bundle

Date of first enrolment
16/01/2017

Date of final enrolment
30/04/2018

Locations

Countries of recruitment
United Kingdom

England

Scotland

Wales

Study participating centre
Warrington Hospital
United Kingdom
WA5 1QG

Study participating centre
Royal United Hospital, Bath
United Kingdom
BA1 3NG

Study participating centre
Royal Gwent Hospital
United Kingdom
NP20 2UB

Study participating centre
Birmingham Women's Hospital
United Kingdom
B15 2TG

Study participating centre
Bedford Hospital
United Kingdom
MK42 9DJ

Study participating centre
Milton Keynes University Hospital
United Kingdom
MK6 5LD

Study participating centre
Calderdale Royal Hospital
United Kingdom
HX3 0PW

Study participating centre
Nottingham University Hospital
United Kingdom
NG5 1PB

Study participating centre
Chelsea & Westminster Hospital
United Kingdom
SW10 9NH

Study participating centre
Poole Hospital
United Kingdom
BH15 2JB

Study participating centre
Epsom General Hospital
United Kingdom
KT18 7EG

Study participating centre
St Richard's Hospital
United Kingdom
PO19 6SE

Study participating centre
St John's Hospital
United Kingdom
EH54 6PP

Study participating centre
University Hospital of North Tees
United Kingdom
TS19 8PE

Study participating centre
Queen Elizabeth University Hospital
United Kingdom
G51 4TF

Study participating centre
Saint Mary's Hospital
United Kingdom
M13 9WL

Sponsor information

Organisation
Royal College of Obstetricians and Gynaecologists (RCOG)

ROR
https://ror.org/01bzmq497

Funder(s)

Funder type
Charity

Funder Name
The Health Foundation (UK)

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are not expected to be made available.

IPD sharing plan summary

Not expected to be made available

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	qualitative study results	09/09/2020	11/09/2020	Yes	No
Protocol article	protocol	13/08/2018	01/11/2019	Yes	No
Abstract results	results presented at the 2nd Annual UK Implementation Science Research Conference	01/07/2019	01/11/2019	No	No
Participant information sheet	Participant information sheet	11/11/2025	11/11/2025	No	Yes
Study website	Study website	11/11/2025	11/11/2025	No	Yes