Safer Practice in Intrapartum Care Project
Care Bundles

March 2010
Content

1. Introduction 1
2. Project methodology 3
3. Electronic fetal monitoring care bundle 8
4. Placenta praevia after previous lower section caesarean segment care bundle 23
5. Project conclusions and recommendations 32
6. Next steps 33

References 34

Appendix 1: Electronic fetal monitoring care bundle compliance 35
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## Abbreviations

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>CTG</td>
<td>cardiocograph</td>
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<tr>
<td>DHSSPS</td>
<td>Department of Health, Social Services and Public Safety</td>
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<td>EBL</td>
<td>estimated blood loss</td>
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<td>EFM</td>
<td>electronic fetal monitoring</td>
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<td>FHR</td>
<td>fetal heart rate</td>
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<td>HDU</td>
<td>high dependency unit</td>
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<td>HoM</td>
<td>head of midwifery</td>
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<td>NHS</td>
<td>National Health Service</td>
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<td>NICE</td>
<td>National Institute for Health and Clinical Excellence</td>
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<td>NICU</td>
<td>neonatal intensive care unit</td>
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<td>NPSA</td>
<td>National Patient Safety Agency</td>
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<tr>
<td>PPH</td>
<td>postpartum haemorrhage</td>
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<tr>
<td>PROMPT</td>
<td>PRactical Obstetric Multi-Professional Training</td>
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<tr>
<td>RCM</td>
<td>Royal College of Midwives</td>
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<tr>
<td>RCOG</td>
<td>Royal College of Obstetricians and Gynaecologists</td>
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<tr>
<td>SVD</td>
<td>spontaneous vaginal delivery</td>
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<tr>
<td>VBAC</td>
<td>vaginal birth after caesarean</td>
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<tr>
<td>WTE</td>
<td>whole time equivalent</td>
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<td>WRP</td>
<td>Welsh Risk Pool</td>
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Executive summary

The Care Bundles Project was overseen by the steering group, whose aim was to oversee the development and testing of care bundles, as well as to develop an effective model of working. The steering group established three subgroups: the evidence criteria group to define the criteria for acceptable evidence for the development of the two care bundles and two expert groups to develop the electronic fetal monitoring (EFM) and placenta praevia after previous lower section caesarean segment (placenta praevia) care bundles. These three subgroups were chaired by independent leaders and the membership included a broad cross-section of carers and stakeholders.

The evidence group gave clear guidance on the importance of not only evaluating the scientific strength of the evidence available but also the relevance of the evidence to the question asked. This was particularly helpful in the placenta praevia care bundle, where good scientific evidence was lacking.

Both expert groups struggled to focus the care bundles, as it was obvious there were many areas that could be helped. However, the scope of the project necessitated close focusing. This was partly addressed by producing detailed documentation that supported the care bundles and provided further guidance. This approach was particularly helpful for the placenta praevia care bundle. The National Patient Safety Agency (NPSA) leads provided support and advice on the scopes and structure.

In parallel with the work of the subgroups, the steering group identified pilot sites and their agreement was secured. The project research midwife spent a great deal of time connecting with all the sites but also undertook an engagement exercise with the test sites. It was appreciated that the success of the project would be dependent in part on these preparatory and educational activities. In addition, good communication between the research midwife, the site leads and the sites would be an essential component throughout the project. This consisted of a pre-pilot information day at the RCOG, site visits, weekly telephone calls and a post-pilot feedback day. This continuous two-way dialogue was very informative to both those carrying out the pilots and for the evaluation of the project.

The EFM care bundle was trialled in five units. There was much enthusiasm in one unit, where compliance was the highest and many midwives found it helpful. However, although it was easy to use, the overall compliance was poor. The feedback from the pilot sites suggested that it was seen as an unhelpful exercise, an added burden to the already heavy workload of the midwives. This could of course be due to other reasons, including poor ‘selling’ of the care bundle by the project team. It was clear that there was no problem in collecting the information or understanding the components but that they needed to be incorporated into a system that was more helpful to midwives by easing their workload rather than adding to it. The benefit was not seen as sufficient to justify the perceived increase in work, although it took on average only two minutes to complete each care bundle. This is an important learning point, as the success of the care bundle was linked to the balance between perceived benefit and the amount of effort that went into implementing the activity.
This is demonstrated by the findings of the placenta praevia care bundle, which was well received, had high compliance and was seen to be helpful and beneficial. The users thought that, even in cases where nothing different was done, it was a good guide for ensuring that everything was in place. During the pilot, at least one caesarean section was delayed to make sure that all components were compliant. The success of this care bundle demonstrates the feasibility of care bundle use in maternity care. It also highlights that the care bundle is valued much more if the benefits are linked directly to the area of responsibility of those completing it. This care bundle was seen to be beneficial and the steering group considers that this care bundle, together with the supporting documentation, could be rolled out more widely.

This project has also demonstrated the value of multidisciplinary groups working together with a common goal. The choice of diverse topics for care bundle development has been very informative. Where a problem was unusual, the risks high and the planning difficult, as in placenta praevia, the care bundle was welcomed and it did its job well with praise all round. However, the EFM care bundle showed that, where a care covered is common and the poor outcome rare, the increased burden on staff is seen as non-beneficial, even though, when the EFM is abnormal, it could prove extremely helpful. This does not occur often enough to give positive feedback of the care bundle to the user. This approach therefore needs to be reconsidered, with components built into existing documentation to help ease the workload. Interestingly, the evidence group produced an algorithm which predicted this outcome.

This project has achieved its aims. It has been very informative about the methods of developing care bundles in maternity care and the ease of multidisciplinary working. The group has developed templates to allow others to develop more care bundles in the future. The methodology for piloting and testing is robust, which will make it easier to produce successful care bundles in the future. This is a good beginning in the area of care bundles, which can make a significant difference to the safety of women and their babies in the years to come.

**Next steps**

This final report will be submitted to the NPSA as agreed. The NPSA will consider the report and its recommendations. A summary of the report will be produced and published on the NPSA website. Based on previous discussions, the NPSA is considering issuing safety guidance advising on the use of a care bundle to reduce the risks associated with placenta praevia in women who have had a previous caesarean section. It is likely that this will be part of a package of interventions to improve patient safety in intrapartum care. It is hoped that further work to test the ‘sticker’ to improve the interpretation of electronic fetal monitoring will be supported by others, such as the King’s Fund Safer Birth’s Initiative.
1. Introduction

General background

Childbirth has become steadily safer for both the mother and the baby over the last 50 years. Much of this has been due to rigorous reporting and investigation of adverse events and the development of improved guidelines and care pathways. Mistakes still occur but they do not happen in childbirth any more commonly than in other areas of medicine. The consequences of these errors in terms of mortality, morbidity and litigation cost are, however, high.

The Reporting and Learning System of the National Patient Safety Agency (NPSA) collects errors that are reported and interrogation of these, together with the reporting of the Confidential Enquiry into Maternal and Child Health,¹ and the audits carried out by the UK Obstetric Surveillance System,² allow the trends in error occurrences to be studied and the possibilities of developing solutions. When studied, it is found that these errors are usually ones of omission, not commission.

Litigation data from the NHS Litigation Authority³ confirm that obstetric claims are a major issue, with claims for problems occurring in labour often being in excess of £6m per claim. Some of these adverse outcomes are a result of deficiencies in intrapartum care and problems in communication.⁴,⁵

Reducing risk in maternity services and ensuring the provision of safe care to mothers and babies is a priority for all, including the NPSA, the Royal College of Obstetricians and Gynaecologists (RCOG) and the Royal College of Midwives (RCM).

In 2006, the Department of Health published a report, Safety First,⁶ which identified key areas for improvement in patient safety in the National Health Service. These included simplifying the reporting of patient safety incidents, encouraging more rapid reporting, a drive to capture high-risk situations and support for the use of patient safety data to inform learning and action, both locally and nationally. In addition, the report highlighted the need for the NPSA to work much more closely with professional bodies and frontline healthcare staff.

The NPSA therefore developed a partnership with the RCOG and the RCM to address ways in which the patient safety agenda in maternity services could be strengthened. This included the development and testing of two intrapartum care bundles building on the principles developed by the Institute for Healthcare Improvement.⁷ These would be for the care of:

- women for whom electronic fetal monitoring is clinically indicated
- women with placenta praevia and a previous caesarean section.

The selection of these topics was based on priorities identified by clinical experts and scoping work carried out by the NPSA. This report sets out the findings of the project.
Background to care bundles

The concept of ‘care bundles’ was developed by the Institute for Healthcare Improvement in North America to describe a collection of interventions needed to effectively and safely care for patients. In a parallel development, the World Alliance for Patient Safety launched ‘a global patient safety challenge’ by testing the feasibility of using a surgical safety checklist to reduce operative complications. It aimed to reinforce established safety practices and to foster better communication and teamwork among clinical disciplines. The care bundle approach is concerned with all these aspects of clinical practice and collaboration, and it is beginning to gain credence as an approach to effective, safe practice; for instance, the Joanna Briggs Institute in Australia has also recently engaged with care bundle development.

Ideally, a care bundle should be concise and straightforward, comprising a set of three to five practices or precautionary steps. Each of these components is an intervention or practice in its own right, ideally with a sound evidence base. The Institute for Healthcare Improvement specifies that there should be no controversy surrounding the components of a care bundle, with the focus being on how to deliver the best care, and not what the best care should be.

A care bundle does not usually introduce any practices or techniques that are not in standard practice in at least some settings. The novelty of the approach is that it combines elements of ‘good practice’ into one cohesive bundle that, when implemented, improves both the quality of care patients receive and patient outcomes.

It is crucial that a care bundle contains components that can be applied to an individual in one clinical episode, so that each application of the bundle is self-contained. In this way, compliance with the care bundle is easily monitored. Each care bundle is applied to every patient, every time, so making the success of each care bundle application assessable with an ‘all or nothing’ measure. All components of the bundle must have been complied with to record a successful completion of the care bundle in that application. In summary, care bundles have to be complied with and this compliance recorded. A care bundle can be viewed as a way of prompting people to act in accordance with best-accepted practice.

Care bundles in obstetrics

In the UK, care bundles have previously been developed in the areas of critical care nursing, infection control and preventative antibiotics for surgery. They have formed a large part of the work of the Health Foundation’s Safer Patients Initiative. Obstetric care bundles within the UK have not yet been widely implemented. This joint NPSA/RCOG/RCM project is therefore pioneering within the field of obstetrics and midwifery.

The aim of introducing care bundles into this area is to achieve an improvement in outcomes, as:

- since 1995, 61% of all negligence payments related to claims arising out of birth
- the total cost of Clinical Negligence Scheme for Trusts maternity claims in 2007/08 was £163 million
- cerebral palsy claims accounted for 66% of these payments (and stillbirths 2%).

Royal College of Obstetricians and Gynaecologists
2. Project methodology

The project aims were to:

- develop, test and pilot two obstetric care bundles
- assess and evaluate the feasibility of implementing these two care bundles.

Project design and steering group

The care bundles project was directed and overseen by a project steering group. It involved three stages, with stages one and two running in parallel.

Stage one:

- the establishment of a steering group to develop and oversee the project.

Stage two:

- the establishment of an evidence criteria group (literature search and analysis)
- the establishment of two expert subgroups to develop the EFM and placenta praevia after previous lower section caesarean segment (placenta praevia) care bundles
- the recruitment of pilot sites and engagement with the testing sites.

Stage three:

- the pre-pilot testing of each care bundle
- the piloting of each care bundle
- the evaluation.

Evidence criteria group

The evidence criteria group was established to:

- review the various approaches to grading and classifying evidence to support the development of care bundles
- agree the level of evidence that would be considered appropriate for the support of interventions to be included in the care bundles
- agree how to address areas where the evidence base was poor.

The main aspect of the evidence criteria group that was adopted in the development of the care bundles was an algorithm for the identification of appropriate topics for care bundles and a process for the development of care bundles (Table 1, Figure 1).
<table>
<thead>
<tr>
<th>Aspects to consider</th>
<th>Question</th>
<th>Response</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 Importance of topic area</td>
<td>Is topic area either very frequently occurring and poorly performed OR rarely occurring but with high levels of serious morbidity/mortality?</td>
<td>If no to either, reconsider topic area</td>
</tr>
<tr>
<td>2 Importance of outcome(s)</td>
<td>Is the outcome important to the NHS/service users?</td>
<td>If no to either, reconsider outcome(s)</td>
</tr>
<tr>
<td>3 Evidence base</td>
<td>Is there strong evidence about the impact on the chosen outcome, and the clinical practice recommended, for all the elements in the bundle, at the level deemed to be appropriate for the topic area/element?</td>
<td>If not, reconsider the elements that fail this test. Consider recommending areas to be addressed by future research</td>
</tr>
<tr>
<td></td>
<td>Is there evidence that all elements in the bundle will produce a synergy greater than the sum of the individual elements?</td>
<td></td>
</tr>
<tr>
<td>4 All elements critical to achieving outcome</td>
<td>Would missing out any single element result in significant danger/loss of quality of care/loss of outcome?</td>
<td>If no, for any element, consider removing that element</td>
</tr>
<tr>
<td>5 All elements need to be undertaken together</td>
<td>Do all the elements need to be undertaken in the same clinical episode?</td>
<td>If not, consider whether this is a pathway or two (or more) separate care bundles</td>
</tr>
<tr>
<td></td>
<td>If the order of the elements within the bundle is critical, can it be achieved?</td>
<td></td>
</tr>
<tr>
<td>6 There is minimal risk that the implementation of the bundle will cause harm</td>
<td>Is there any evidence from any source that harm may be caused by the elements of the bundle, together or separately, specifically for subgroups of the population?</td>
<td>If so, specify any population groups that should be excluded from the care bundle</td>
</tr>
<tr>
<td>7 Care bundle elements are non-controversial</td>
<td>Is there controversy among clinicians or service users about any element of the bundle?</td>
<td>If yes, establish reasons and reconsider the element and/or the information giving process</td>
</tr>
<tr>
<td>8 n = 5 or less</td>
<td>Are there 5 or fewer elements in the care bundle?</td>
<td>If not, consider whether all the elements are critical — if not, remove those that fail this test; if so, consider whether this is a pathway or two (or more) separate care bundles</td>
</tr>
<tr>
<td>9 All elements achievable</td>
<td>Can all the elements be achieved during normal clinical practice with no, or a minimum of, extra resources?</td>
<td>If no, reconsider elements, or consider whether implementation can address this</td>
</tr>
<tr>
<td>10 All elements measurable</td>
<td>Can all the elements be measured during normal clinical practice with no, or a minimum of, extra resources, based on binary responses (yes/no, done/not done)?</td>
<td>If no, reconsider elements, or consider whether implementation can address this</td>
</tr>
</tbody>
</table>
Figure 1. Algorithm for the identification of appropriate topics
Subgroup development

Two subgroups were established, one each for EFM and placenta praevia. The remit of both groups was to develop the care bundles and accompanying evidence-based supporting documentation. Each subgroup was required to:

- agree the scope of the care bundle
- identify a cluster of interventions or practices within the care bundle
- commission literature searches, related to each of the interventions or practices, to identify all relevant research and evidence
- review and analyse Reporting and Learning System data related to interventions and practices
- review the categorised evidence against criteria defined by evidence criteria group
- and delete any interventions and practices that did not have adequate evidence base or were not feasible
- on the basis of analysed evidence develop evidence-based interventions and practices
- identify markers to measure compliance with the care bundle
- prepare a clinical protocol for consideration by the project steering group, making it clear that it refers to a grouping of components that must be practised together.

Each subgroup met on several occasions, although much of the work was completed electronically.

Site recruitment

Eleven units were invited to take part in the project as primary care bundle testing sites (five for the EFM care bundle and six for the placenta praevia care bundle). Selection of the sites was based on size and regional distribution. The selection of units allowed for maximum care bundle testing, across a diverse spread of populations, with different compositions of staffing levels and demands on local resources.

Letters were sent to each NHS trust clinical director or head of midwifery to invite their trust to participate and to nominate a clinical on-site lead. All 11 trusts responded positively. In the placenta praevia sites, clinical directors were asked to nominate an obstetrician; in the EFM sites, the heads of midwifery were asked to nominate a senior clinical midwife (ideally band 7 on the labour ward or birth unit).

The Department of Health, Social Services and Public Safety in Northern Ireland and the Welsh Risk Pool showed interest in the project. Both organisations were developing projects to improve patient safety in intrapartum care. Following discussions with both organisations, it was agreed that the DHSSPS in Northern Ireland would independently test the EFM care bundle in units across the province. The Welsh Risk Pool would review competencies for the interpretation of EFM. The Chair of the Welsh Risk Pool was invited on to the steering group and the NPSA’s Head of Child Health and Maternity Care was invited on to the Welsh Risk Pool’s project group. Independent project reports have been compiled for each of these projects.
Care bundle testing

Pre-testing took place for each care bundle in one unit. This involved the clinical leads from two of the biggest participating units meeting with the research midwife to discuss any potential problem areas that needed further work before beginning the test period.

Logistical running of the care bundles

Clinical lead responsibility

Each clinical lead took responsibility for their respective care bundle in addition to their routine duties as clinicians. They were required to arrange visits for the research midwife, commit to weekly telephone calls, attend the care bundle information days at the RCOG, collate the care bundles and return them to the research midwife, as well as being local ‘champions’ for the projects.

Care bundle information sharing day

The clinical leads were invited to the Care Bundle Information Sharing Day at the RCOG to be informed about the care bundles and the work of the NPSA and to be given an overview of the project, the testing process and their involvement. In addition, the day allowed discussion on the draft care bundles and supporting documentation and the opportunity to highlight and address any potential problems. A section of the day was dedicated to team working and human factors issues, as well as group discussions about the project logistics and potential barriers to implementation. Some of the issues raised resulted in changes to the pre-pilot care bundles.

Site visits and engagement

Two months before testing, the research midwife presented the project and launched the ‘care bundle countdown’ to the start date at each unit. A staff education programme was initiated prior to the implementation of care bundles, allowing maximum publicity within the unit and the opportunity for everyone to ‘get on board’ and to be aware of proposed plans. For the EFM sites, the meetings were aimed at labour ward and birth centre midwives and obstetricians, although all staff were welcome to attend. For the placenta praevia sites, the presentations were aimed at the obstetricians, anaesthetists and haematologists, to ensure full multidisciplinary involvement from the outset. At these meetings, the research midwife gave a 20-minute presentation with time for questions. Posters, supporting documents and additional information were provided in each unit to disseminate in advance of the start date.

Care bundle feedback day

Towards the end of the project, the clinical leads and the clinical director or head of midwifery were invited to the RCOG to hear the preliminary findings from both care bundle projects and to receive feedback from the leads as to how the project went from their point of view, as well as providing feedback from the project overall. Each lead completed a brief questionnaire about the project, as well as contributing on the day. The feedback day proved very informative for both care bundles and contributed to ideas on how the tools, especially the EFM care bundle, could be taken forward.
3. Electronic fetal monitoring care bundle

Introduction
Monitoring the fetal heart rate is a part of routine care in labour, using intermittent auscultation methods such as a Pinard stethoscope or a hand-held Doppler, or using a cardiotocograph machine for continuous EFM. Whichever method of fetal monitoring is used, the aim is to identify fetal heart rate changes during labour and to detect fetal hypoxia before it leads to complications and long-term neurological adverse outcome for the baby. Monitoring the fetal heart rate may lead to other interventions such as delivery by caesarean section or instrumental delivery to avoid significant fetal hypoxia. It is therefore necessary to clearly identify the babies at increased risk of hypoxic events and those who remain at low risk during labour.14

EFM subgroup
The EFM subgroup developed a care bundle around the care of women for whom EFM is clinically indicated. It constituted five components and supporting documentation (Figure 2). Midwives completing the care bundles were also required to collect some basic outcome information.

Care bundle information sharing day
During the care bundle information sharing day, the clinical leads and heads of midwifery were asked to identify any potential barriers to the EFM care bundle or logistical issues. The results of the discussions helped to prepare for the testing. The following is a summary of the points from the discussions:

Do you see any potential barriers to implementation or unwanted outcomes?

- Lack of understanding of what the pilot is about.
- Lost forms.
- Lack of teamwork.
- Incomplete forms.
- Lack of engagement.
- Lack of baseline data to compare change.
- Falsification of care bundles.
- Time to fill out forms.
## ELECTRONIC FETAL MONITORING CARE BUNDLE

**What is the clinical indication for commencing EFM:**

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<th>Assessment (at least hourly)</th>
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</tbody>
</table>

- **EFM machine set up and used as per NICE Guideline**

- **Maternal pulse checked and recorded**

- **Systematic assessment of EFM documented as per NICE guideline**

- **EFM assessed in context of labour and progress**

- **Plan of care documented and escalated as necessary (see below)**

**Practitioner initials:**

Plan of Care should include one of the following:
- **Discontinue EFM** - As no longer clinically indicated
- **Continue EFM**
- **Continue EFM with increased vigilance**
- **Escalate** - EFM assessment requires escalation to a suitably qualified person

**Outcome**
- **Time EFM discontinued:** ....
- **Reason:** delivery, de-escalation, emergency, other

- **SVD/Forceps/Ventouse/EM LSCS/Vaginal breech**
- **Baby’s Apgar score:** @1, @5
- **Cord gas results:** ....
- **Admission to NICU:** Yes/No

**PLEASE SEE OVERLEAF AFTER COMPLETION OF CARE BUNDLE**
Please answer questions after completion of the care bundle

1. Is this the first time you have used the electronic fetal monitoring care bundle
   □ Yes □ No

2. How did you find incorporating the care bundle into your practice?
   □ Quite easy □ Very easy
   □ Quite difficult □ Very difficult

3. How long did it take you to complete each application of the care bundle?
   ................Minutes

4. How helpful was the care bundle to your clinical practice?
   □ Quite helpful □ Very helpful
   □ It was not really helpful □ I fail to see its relevance

5. What difference did completing the care bundle make to the care you provided to the woman in labour? (Tick as many as applicable)
   □ It helped me with the EFM plan of care
   □ It helped me to escalate to a suitably qualified person
   □ It made no difference
   □ It got in the way of me providing care

6. Please use the space below to make any other comments on the care bundle
   ........................................................................................................................................
   ........................................................................................................................................
   ........................................................................................................................................
   ........................................................................................................................................

THANK YOU

Figure 2. EFM care bundle sheet
Concern that escalation may not be acted upon appropriately.

Competing priorities (lots of audits going on).

Flawed methodology – may not capture correct information – no definitive aim to the project.

How do you see the care bundle working/logistics? Any potential problems of implementation?

Getting people on board.

Keeping up the momentum.

Selling the benefits.

Difficult to chase non-completed forms.

Encouraging midwives to make constructive comments.

Midwives wary of reviewing their practice.

Cascading to all staff – careful selection of ‘champions’.

End point – completed forms – date.

The EFM clinical leads suggested that the elements of the care bundle that referred to the EFM machine set-up and assessment as described in the NICE Intrapartum Care guidelines should be provided as an aide memoire for midwives. Therefore, small laminated cards were produced to be attached to each EFM machine on all sites. Other issues raised and addressed were telephone communications to support clinical leads and to ensure that the research midwife was kept informed.

Testing period

The EFM care bundle testing period ran for 3 months at each site. This test period was chosen on predicted number of care bundles completed and the large volume of data expected. The total number of deliveries in each unit was used to calculate the projected number of care bundles to be completed in the testing period. It was estimated that 64% of women in labour would receive continuous EFM. The calculations suggested a care bundle testing period of 12 weeks in each unit.

Unit information

The five EFM testing sites comprised a variety of NHS units across England and Wales. They included units in inner city teaching hospitals and local district general hospitals. A description of the five units can be seen in Table 2, which includes some basic information about the EFM machine printout assessment policy. In four of the five participating units, the assessment criteria used for assessing fetal heart rate was from the Advanced Life Support in Obstetrics course.
Table 2. Electronic fetal monitoring: description of pilot site units

<table>
<thead>
<tr>
<th>Unit</th>
<th>Total deliveries, 2007 (n)</th>
<th>Spontaneous vaginal delivery (%)</th>
<th>Instrumental delivery (%)</th>
<th>Lower-segment caesarean section (%)</th>
<th>Labour ward midwives/1000 births (n)</th>
<th>EFM machines (n)</th>
<th>Unit policy for assessing CTG</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>6455</td>
<td>58</td>
<td>13</td>
<td>29</td>
<td>14.7</td>
<td>13</td>
<td>Dr C Bravado</td>
</tr>
<tr>
<td>2</td>
<td>3640</td>
<td>64</td>
<td>12</td>
<td>24</td>
<td>9.3</td>
<td>10</td>
<td>Dr C Bravado</td>
</tr>
<tr>
<td>3</td>
<td>2474</td>
<td>64</td>
<td>10</td>
<td>26</td>
<td>12.19</td>
<td>7</td>
<td>Dr C Bravado</td>
</tr>
<tr>
<td>4</td>
<td>3506</td>
<td>61</td>
<td>10</td>
<td>30</td>
<td>11.13</td>
<td>10</td>
<td>Dr C Bravado</td>
</tr>
<tr>
<td>5</td>
<td>3744</td>
<td>65</td>
<td>14</td>
<td>22</td>
<td>9.44</td>
<td>8</td>
<td>As NICE guidance</td>
</tr>
</tbody>
</table>

Site feedback process

It was important to keep the large numbers of midwives motivated and keen to participate throughout the testing period. The use of run charts to present feedback to staff was very effective, as it provided greater visual impact. Presenting data in this way allows staff to make quick reference to bundle compliance and should provide incentive for continuation and improvement.

Run charts illustrating care bundle component compliance were sent to the units every 3 weeks to depict the compliance for each of the five components. In addition, a summary of important issues was sent to the clinical leads, who were asked to convey the information to their staff by their preferred method (such as displaying posters, team meetings, ward meetings). A weekly telephone call between the leads and the research midwife allowed for discussion and clarification of any points prior to dissemination of the data.

Number of care bundle sheets

Table 3 demonstrates the number of care bundle sheets expected and the actual number of sheets returned per unit for the 3-month period. It is disappointing to note the low number of sheets returned by the larger units (units 1 and 2).

Table 3. Care bundle sheets expected and number returned

<table>
<thead>
<tr>
<th>Unit</th>
<th>Total expected (n)</th>
<th>Sheets Total returned</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>(n)</td>
<td>(%)</td>
</tr>
<tr>
<td>1</td>
<td>953</td>
<td>132</td>
</tr>
<tr>
<td>2</td>
<td>538</td>
<td>82</td>
</tr>
<tr>
<td>3</td>
<td>365</td>
<td>144</td>
</tr>
<tr>
<td>4</td>
<td>509</td>
<td>183</td>
</tr>
<tr>
<td>5</td>
<td>524</td>
<td>287</td>
</tr>
</tbody>
</table>
**Clinical indication for EFM**

Each midwife completing a care bundle was asked to document the clinical indication for using EFM; 828 care bundle sheets were completed across the five testing sites. The largest indicator (29%) for commencing EFM was induction of labour; the second largest indication (13%) was augmentation of labour. The full breakdown of clinical indications for EFM can been seen in Figure 3.

![Figure 3](image)

**Figure 3.** Clinical indication for electronic fetal monitoring

**Component compliance**

Care bundle compliance was the main short-term measure in evaluating the effectiveness of the care bundle, ranging from 94% to 96% (Table 4). A full breakdown of each unit’s compliance with each care bundle component is shown in Appendix 1.

**Table 4.** Compliance with care bundle components (all units)

<table>
<thead>
<tr>
<th>Component</th>
<th>Compliance (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>94</td>
</tr>
<tr>
<td>2</td>
<td>96</td>
</tr>
<tr>
<td>3</td>
<td>96</td>
</tr>
<tr>
<td>4</td>
<td>95</td>
</tr>
<tr>
<td>5</td>
<td>95</td>
</tr>
</tbody>
</table>

The care bundle was completed in less than 2 minutes (Table 5) and it is probable that the ease of completion may have had an influencing factor on compliance. One lead raised concerns that ‘there may have been cases of some midwives just ticking boxes’ because they thought that they were integrating all the elements of care anyway and did not see the point of the care bundle. It would have been ideal to audit practice against the care bundle sheets; however, this was not possible owing to the project’s time constraints.
Table 5. Care bundles completed in up to 2 minutes

<table>
<thead>
<tr>
<th>Unit</th>
<th>First-time use (%)</th>
<th>Subsequent use (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>70</td>
<td>82</td>
</tr>
<tr>
<td>2</td>
<td>88</td>
<td>61</td>
</tr>
<tr>
<td>3</td>
<td>83</td>
<td>92</td>
</tr>
<tr>
<td>4</td>
<td>64</td>
<td>73</td>
</tr>
<tr>
<td>5</td>
<td>78</td>
<td>81</td>
</tr>
</tbody>
</table>

Care bundle Component 1

Component 1 referred to the EFM machine set-up and use. It required the midwife to follow the NICE Intrapartum Care guidance\(^{16}\) for setting the correct date and time on the machine and having the printout correctly labelled. Across the sites, compliance with this component was the lowest at 94%. Appendix 1 identifies each unit’s 3-week period compliance with Component 1. Individual compliance with this component was not consistent throughout the use of the care bundle in labour. This component was often completed on first use, then not again until change of staff or later in the labour. Possible reasons for this may have been the wording of Component 1, the specific contents of the component (such as time correctly set, date correctly set). The results suggest that this component does not fit well within this care bundle.

Care bundle sheet compliance

Overall compliance with the care bundle components was good. Nonetheless, during the testing period the midwives were also asked to complete a small section in the bottom right-hand corner of the sheet on outcomes at delivery. Compliance with these sections was relatively poor, as can be seen in the following section.

Outcome data

During the care bundle testing, midwives were asked to collect some baseline data, including reason for discontinuing the care bundle, mode of delivery, baby’s Apgar score and any admissions to the neonatal intensive care unit (NICU). Overall data completion was very poor, with a large majority of the fields having incomplete data.

Delivery Method

Between 23–36% of care bundle sheets from each unit did not have the mode of delivery recorded. However, from the sheets that were completed it is reassuring to see that spontaneous vaginal delivery was the commonest mode of delivery amongst all units. A full breakdown of all modes of delivery can be seen in Figure 4.

Admissions to Neonatal Intensive Care Unit

Twenty of the 828 babies (2.4%) were admitted to NICU. Six of the admissions were for pre-existing fetal conditions or prematurity.
Evaluation questions

The aim of the EFM care bundle project was to assess feasibility of the tool and test its implementation. To do this, data on care bundle compliance and midwives’ perceptions of the tool were collected. The midwives’ opinions on the care bundle were collated through six questions on the reverse of the care bundle sheet. Midwives were asked to complete these questions at each use of the care bundle. The rationale behind this was that after each application of the care bundle the midwife might have found it easier or harder, more helpful or less helpful as time progressed. Responses to these questions are discussed in the following section.

Ease of incorporating care bundle into practice

In Question 2, midwives were asked ‘How did you find incorporating the care bundle into your clinical practice?’ It is positive to note that midwives found the care bundle easy to incorporate into their practice, at both first and subsequent use (Figure 5). With repeated use, there was a positive increase in the percentage of midwives who found it ‘very easy’ to use in four of the units. However, it has already been identified that Component 1 relating to EFM machine set-up and use proved to be the component that the midwives had the most problems completing.

Although there was a positive increase in the number of midwives who found the care bundle easy to incorporate into their practice, Table 6 indicates the large percentage of care bundle sheets with missing data. A recurring trend was seen on subsequent use of the care bundle, when midwives in all units did not complete the questions overleaf of the care bundle sheets as frequently as on first use.

The ease of the care bundle use may be linked to the time it took to complete each application of the care bundle. In the majority of cases for both first and subsequent use, each care bundle was completed in less than 2 minutes.
Helpfulness of care bundles in clinical practice

Question 4 of the evaluation sheet asked midwives ‘How helpful was the care bundle to your clinical practice?’ On the whole, midwives found the care bundle ‘not helpful’, although in four of the units there was an increase in the number of midwives who found the care bundle ‘very helpful’ in subsequent use (Figure 6). In the majority, they did not find the content of the bundle useful and commented that it was an unnecessary additional piece of paper.

‘It was just another piece of paper, when there are many other pieces of paper to complete when there is a woman in labour.’

Table 6. Missing data on ease of care bundle use

<table>
<thead>
<tr>
<th>Unit</th>
<th>First-time use (%)</th>
<th>Subsequent use (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>16</td>
<td>45</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>44</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>37</td>
</tr>
<tr>
<td>4</td>
<td>6</td>
<td>35</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
<td>42</td>
</tr>
</tbody>
</table>

Figure 5. Ease of use of care bundle
Missing data

Table 7 shows the missing data for Question 4 on first-time completion; only a small percentage of midwives did not complete the data field. However, on subsequent use, midwives were more likely to leave the question uncompleted. This may be indicative of the midwives’ opinion of the care bundles or that they considered that they would be duplicating previous comments.

Table 7. Missing data on helpfulness of care bundle

<table>
<thead>
<tr>
<th>Unit</th>
<th>First-time use (%)</th>
<th>Subsequent use (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>13</td>
<td>46</td>
</tr>
<tr>
<td>2</td>
<td>10</td>
<td>45</td>
</tr>
<tr>
<td>3</td>
<td>5</td>
<td>38</td>
</tr>
<tr>
<td>4</td>
<td>6</td>
<td>34</td>
</tr>
<tr>
<td>5</td>
<td>10</td>
<td>41</td>
</tr>
</tbody>
</table>
Escalation of care

Component 5 focused on the plan of care and appropriate escalation to a suitably qualified person being documented in the notes. These terms were taken from the NICE Intrapartum Care guidance. The care bundle included a guide as to potential plan of care outcomes.

It is well documented that fetal problems associated with EFM often lie with a failure to escalate to a suitably qualified person, so it was hoped that the midwives would find some benefit to the care bundle in this area.

First time use of the care bundle and the effect on care in labour

Figure 7 demonstrates that, in the first-time use of the care bundle, a large majority of midwives in all units found that it made no difference to the care they provided and a small percentage found that it got in the way of them providing care to women. In one large inner-city unit and two smaller district general hospitals, a fair percentage of midwives did, however, find that it helped them with the plan of care (unit 2 – 20%, unit 4 – 12%, unit 5 – 16%).

Subsequent use of the care bundle and the effect on care in labour

In Question 5, midwives were asked ‘What difference did completing the care bundle make to the care you provided to the woman in labour?’ The majority of midwives who completed this question stated that the care bundle had made no difference to the care they provided in labour. The number of midwives who chose not to complete the question increased with time.
Missing data

With subsequent use of the care bundles, the percentage of missing data was almost equal to that of the response to Question 5: ‘it made no difference’. Again, it may be suggested that the midwives chose not to comply with the evaluation as a demonstration of their opinions of the care bundle’s value, effectiveness or usefulness.

Discussion

The two largest units had the poorest return rate and lowest compliance with the care bundles. The midwives across all units ‘did not see the point of the care bundle’. The reported comments include:

‘I have a sneaky suspicion that the midwives don’t like using it but are doing it because they have to, because I have asked them to.’

‘The midwives seem to feel like it doesn’t make a difference to them as they do this anyway.’

‘Some midwives are questioning more why they are using EFM, which is really good. Some still think, what’s the point as they do this anyway.’

As the project progressed, compliance worsened in all units to about 43%. The lack of compliance with the care bundle is significant and looking at the low numbers of care bundles returned and the percentage of missing data the reasons for this must be considered.

Other possible contributing factors for poor compliance include low staffing levels and units being overly busy. Moreover, the testing took place over July, August and September, which are notoriously the busiest months of year.

Paperwork overload

During testing, midwives using the bundles were asked to write additional comments. A large selection of the free-text comments was based around having too much existing intrapartum paperwork:

‘Very difficult to cope with extra paperwork.’

‘Just extra paperwork not necessary we have enough writing.’

‘I can see the reasoning behind this form but it causes more paperwork hence taking away time from your patient contact.’

This may well have been another contributory factor to the poor compliance with the care bundle.

EFM care bundle adaptations

In essence, the components of the EFM care bundle are relevant principles to the effective use of EFM in labour. However, midwives who tested the EFM care bundle during this project did not find it helpful to their practice. It may be the case that the presentation of the EFM care
### Figure 8. Proposed electronic fetal monitoring pro forma

<table>
<thead>
<tr>
<th>EFM Proforma</th>
<th>Reassuring</th>
<th>Non-reassuring</th>
<th>Abnormal</th>
<th>LOGO</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline rate (bpm)</td>
<td>110–160 Rate:</td>
<td>100–109 Rate:</td>
<td>&lt;100 Rate:</td>
<td>Comments:</td>
</tr>
<tr>
<td>N.B. Rising baseline rate within normal range may be of concern if other non-reassuring/abnormal features present</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Variability (bpm)</td>
<td>≥5</td>
<td>&lt;5 for 40–90 mins</td>
<td>&lt;5 for 90 mins</td>
<td>Comments:</td>
</tr>
<tr>
<td>Accelerations</td>
<td>Present</td>
<td>None for 40 mins</td>
<td>Comments:</td>
<td></td>
</tr>
<tr>
<td>Decelerations</td>
<td>None</td>
<td>Typical variable decelerations with &gt;50% contractions for &gt;90 mins</td>
<td>Atypical variable decelerations with 50% contractions for &gt;30 mins</td>
<td>Comments:</td>
</tr>
<tr>
<td>Typical variable decelerations with &gt;50% of contractions but for &lt;90 mins</td>
<td>Atypical variable decelerations with &gt;50%</td>
<td>Atypical variable decelerations with 50% contractions for &gt;30 mins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Typical or atypical variable decelerations with &lt;50% of contractions</td>
<td>Late decelerations for &lt;30 mins</td>
<td>Late decelerations for &gt;30 mins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>True early decelerations</td>
<td>Single prolonged decelerations for up to 3 mins</td>
<td>Single prolonged decelerations for &gt;3 mins</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Opinion</td>
<td>Normal CTG (all 4 features reassuring)</td>
<td>Suspicious CTG (1 non-reassuring feature/feature)</td>
<td>Pathological CTG (2 or more non-reassuring or one or more abnormal)</td>
<td></td>
</tr>
<tr>
<td>Cont's: 10 Maternal pulse: Liquor colour Dilation (cm):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plan of care (should include one of the following): Discontinue EFM: As no longer clinically indicated Continue EFM Continue EFM with increased vigilance Escalate: EFM assessment requires escalation to a suitably qualified person</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Action:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date: Time: Signature ____________________________ Print ____________________________ Designation ____________________________</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
bundle in ‘paper’ form contributed to the antagonism felt by the midwives towards it. The ambiguity of component 1 may have also caused elements of confusion. Considering these issues, the EFM care bundle recommendations include:

- modification of the care bundle to more ‘user-friendly’ format
- removal of Component 1 from the care bundle
- further testing and evaluation of the proposed new EFM sticker pro forma and ‘care bundle sticker’.

**Modification of the care bundle to more ‘user-friendly’ format**

North Bristol Trust has developed an EFM assessment tool, in the form of a sticker. This sticker is proving a very successful tool within their trust. With kind permission of North Bristol Trust and Advanced Life Support in Obstetrics, some small modifications to the tool were made to incorporate all elements of the existing care bundle (Figure 8). The midwife could attach the proposed sticker to the notes, or a pro forma could be included on the partogram page of the notes to be used as a guide. Further testing of the new EFM sticker pro forma is recommended.

**Removal of Component 1 from the care bundle**

Component 1 could be used as a separate care bundle. This could be presented in sticker format to be attached to the EFM printout, together with the woman’s identification sticker (Figure 9).

<table>
<thead>
<tr>
<th>Electronic Fetal Monitoring Care Bundle</th>
</tr>
</thead>
<tbody>
<tr>
<td>EFM Machine Set-up</td>
</tr>
<tr>
<td>Clinical indication for EFM:</td>
</tr>
<tr>
<td>Please circle appropriate answer</td>
</tr>
<tr>
<td>Date correctly set on EFM machine</td>
</tr>
<tr>
<td>Time correctly set on EFM machine</td>
</tr>
<tr>
<td>EFM machine trace labelled with mother’s name and hospital number/mother’s hospital sticker attached</td>
</tr>
<tr>
<td>Initials of midwife completing care bundle:</td>
</tr>
</tbody>
</table>

*Figure 9.* Proposed sticker for EFM machine set up
Further testing and evaluation of the proposed new EFM sticker pro forma and ‘care bundle sticker’

The aim of the EFM care bundle was to test the feasibility of implementation and the project achieved this. In addition, modifications are suggested to achieve increased use and user friendliness. It is recommended that longer-term testing is carried out to enable collection of outcome data that would allow for identification of any benefits of the intervention.
4. Placenta praevia after previous lower-section caesarean segment care bundle

Introduction
A morbidly adherent placenta occurs when the placenta adheres to or invades into or through the myometrium. It is more likely to occur when the placenta is located over a previous scar with a deficient decidua basalis and is more common with increasing numbers of previous caesarean sections but can also occur following myomectomies or after a previous manual removal of the placenta from the same placental site. Women with a morbidly adherent placenta (all types grouped together and termed ‘placenta praevia’ for the purposes of this document) have an increased risk of morbidity and mortality, owing to massive obstetric haemorrhage at delivery.

Placenta praevia subgroup
The remit for the placenta praevia subgroup was to develop a new care bundle around the care of women with placenta praevia who previously had a caesarean section. It produced a six-component care bundle and supporting documentation (Figure 10). The care bundle was a ‘one application’ bundle and required the user to complete outcome details from the delivery.

Care bundle information-sharing day
After receiving each completed care bundle, the research midwife contacted the site lead to clarify all aspects of the project.

The care bundle information-sharing day was designed to identify any potential barriers to the care bundle or logistical issues. The results of the discussions helped to prepare for the testing. The following is a summary of the points from the discussions:

Do you see any potential barriers to implementation or unwanted outcomes?
- Disruption of service (especially anaesthetics).
- Cancelled if not fulfilled.
- Sticker in notes – placenta praevia and previous caesarean section.
- Over-use of intervention.
PLACENTA PRAEVIA AFTER PREVIOUS CAESAREAN SECTION CARE BUNDLE

Consultant obstetrician planned and directly supervising delivery

YES / NO

Consultant obstetric anaesthetist planned and directly supervising anaesthetic at delivery

YES / NO

Blood and blood products available on site

YES / NO

Multidisciplinary involvement in pre-op planning

YES / NO

Discussion and consent includes possible intervention (such as hysterectomy, leaving placenta in situ, cell salvage and interventional radiology)

YES / NO

Local availability of level 2 critical care bed

YES / NO

Initials of obstetrician completing care bundle


Outcome
Type of LSCS: Elective/Emergency
Gestation at Delivery:
No of previous LSCS:
Placenta Accreta: Yes/No
Operation performed: LSCS/classical CS/hysterectomy/placenta left in
Total blood loss:
Blood transfused: Yes/No
Total No of donor units transfused:
Cell Salve available: Yes/No
Cell Salvage Used: Yes/No
Volume of cell saved blood transfused:
Balloon tamponade used: Yes/No
Compression sutures used: Yes/No
Any Radiology Intervention used: Yes/No, Pre-op/Emergency
Please specify:
Was this patient a Jehovah’s witness Y/N
Was this patient transferred from another hospital for specialist care Y/N
Maternal outcome: postnatal ward/ITU/transfer/death

PLEASE SEE OVERLEAF AFTER COMPLETION OF CARE BUNDLE

Figure 10. Placenta praevia after previous caesarean section care bundle
Please answer questions after completion of the care bundle

1. Is this the first time you have used the placenta praevia after previous caesarean section care bundle
   ■ Yes ■ No

2. How did you find using the care bundle?
   ■ Quite easy ■ Very easy
   ■ Quite difficult ■ Very difficult

3. How long did it take you to complete the placenta praevia care bundle? 
   .................. Minutes

4. How helpful was the care bundle to your clinical practice?
   ■ Quite helpful ■ Very helpful
   ■ It was not really helpful ■ I fail to see its relevance

5. What difference did the placenta praevia care bundle make to the management of the woman?
   ■ It helped with the preparation for delivery
   ■ It got in the way
   ■ It made no difference

6. Please use the space below to make any other comments on the care bundle:
   ..............................................................................................................................
   ..............................................................................................................................
   ..............................................................................................................................
   ..............................................................................................................................
   ..............................................................................................................................

THANK YOU
How do you see the care bundle working/logistics? Any potential problems of implementation?

- No problem in our unit.
- Interpretation of elements.
- Lack of consultant presence in clinic.
- Lack of awareness on the potential risk associated with placenta praevia and previous caesarean section.
- Dissemination of information to relevant people.
- Informing people: email documents, clinical teams briefings.
- Lag time between 32 and 40 weeks and delivery for pilot purposes.
- Tick box may create confusion – Yes/No (circle appropriate) would be clearer.

Testing period

Owing to the rare occurrence of placenta praevia after previous caesarean section and the low number of care bundles expected to be completed, the testing period for this care bundle was 5 months in each of the six nominated testing sites.

To maintain anonymity, it was not possible to relay the data back to the units until the end of the project.

Unit information

The placenta praevia care bundle was tested in six large NHS maternity units across England, to maximise the potential relevant cases. Details of each unit may be seen in Table 8, together with useful background information.

Number of care bundle sheets

During the testing period, 21 care bundle sheets were used and only two cases did not receive care bundle application. Both these cases occurred in the same unit, when the clinical lead was on sick leave. The distribution of returned care bundles can be seen in Table 9.

Component compliance

Compliance with the placenta praevia care bundle was extremely good, with overall compliance being 97.5%. Of the 21 care bundles returned, only one care bundle did not have 100% compliance for all the components. On this particular care bundle the components that did not achieve completion were: Component 1 ‘consultant obstetrician planned and directly supervising delivery’, Component 2 ‘consultant obstetric anaesthetist planned and directly supervising delivery’ and Component 4 ‘multidisciplinary involvement in preoperative planning’. This particular case was a planned elective caesarean section in a unit which completed seven other care bundle sheets.

The user of the care bundle was also required to sign it after use to officially ‘sign off’ completion. This occurred in 19 of the 21 cases.
Table 8. Placenta praevia: description of pilot site units

<table>
<thead>
<tr>
<th>Unit</th>
<th>1</th>
<th>2</th>
<th>3</th>
<th>4</th>
<th>5</th>
<th>6</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total deliveries, 2007 (n)</td>
<td>5143</td>
<td>7985</td>
<td>8959</td>
<td>3361</td>
<td>7322</td>
<td>5679</td>
</tr>
<tr>
<td>Spontaneous vaginal delivery (%)</td>
<td>51</td>
<td>62</td>
<td>66</td>
<td>65</td>
<td>68</td>
<td>65</td>
</tr>
<tr>
<td>Instrumental delivery (%)</td>
<td>16</td>
<td>12</td>
<td>12</td>
<td>13</td>
<td>13</td>
<td>11</td>
</tr>
<tr>
<td>LSCS (%)</td>
<td>33</td>
<td>26</td>
<td>22</td>
<td>19</td>
<td>19</td>
<td>24</td>
</tr>
<tr>
<td>Elective LSCS (%)</td>
<td>54</td>
<td>43</td>
<td>50</td>
<td>28</td>
<td>36</td>
<td>57</td>
</tr>
<tr>
<td>Non-elective LSCS (%)</td>
<td>46</td>
<td>57</td>
<td>50</td>
<td>72</td>
<td>64</td>
<td>43</td>
</tr>
<tr>
<td>Placenta praevia, 2007 (n)</td>
<td>34</td>
<td>34</td>
<td>16</td>
<td>14</td>
<td>20</td>
<td>28</td>
</tr>
<tr>
<td>Consultant obstetrician presence on ward (hours)</td>
<td>40</td>
<td>56</td>
<td>40</td>
<td>40</td>
<td>62</td>
<td>40</td>
</tr>
<tr>
<td>Consultant anaesthetist WTE/1000 deliveries</td>
<td>1.437</td>
<td>0.8761</td>
<td>2.232</td>
<td>2.691</td>
<td>0.57</td>
<td>1.097</td>
</tr>
<tr>
<td>Location of site for HDU</td>
<td>Delivery suite (4 beds)</td>
<td>Delivery suite</td>
<td>Delivery suite</td>
<td>Labour ward</td>
<td>Delivery suite</td>
<td>Labour ward</td>
</tr>
<tr>
<td>Cell salvage available in the unit</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>In main theatres</td>
</tr>
<tr>
<td>Interventional radiology available</td>
<td>Yes</td>
<td>Yes</td>
<td>On site</td>
<td>On site</td>
<td>No</td>
<td>Yes</td>
</tr>
<tr>
<td>Location of interventional radiology</td>
<td>Can be performed on delivery suite</td>
<td>Radiology division</td>
<td>Radiology division</td>
<td>Radiology division</td>
<td>None</td>
<td>Radiology division (main site)</td>
</tr>
<tr>
<td>Blood bank on site</td>
<td>Yes</td>
<td>No; 0.5 mile away</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Blood bank staffed 24/7</td>
<td>On call out of hours</td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
<td>On call out of hours</td>
<td>Yes</td>
</tr>
</tbody>
</table>

Table 9. Distribution of returned care bundle sheets

<table>
<thead>
<tr>
<th>Units</th>
<th>Returned care bundles (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>1</td>
</tr>
<tr>
<td>3</td>
<td>8</td>
</tr>
<tr>
<td>4</td>
<td>5</td>
</tr>
<tr>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>6</td>
<td>0</td>
</tr>
</tbody>
</table>
Outcome data

Outcome data collection consisted of 19 questions. All 21 care bundles were fully completed by users. Of the 21 caesarean sections performed, 12 were planned elective caesarean sections and nine were emergencies. All the emergencies were carried out before 37 completed weeks of gestation. Table 10 shows the gestation of all of the caesarean sections performed. This was in agreement with the pre-pilot predictions of the placenta praevia subgroup, leading to the recommendation in the supporting literature that maternal and neonatal risks should be weighed up to determine the optimal timing of delivery but this should not be done electively before 37 weeks.

<table>
<thead>
<tr>
<th>Gestation</th>
<th>Women delivered (n)</th>
<th>Type of caesarean</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt; 36 weeks</td>
<td>5</td>
<td>All emergency</td>
</tr>
<tr>
<td>36–37 weeks</td>
<td>4</td>
<td>All emergency</td>
</tr>
<tr>
<td>37–38 weeks</td>
<td>9</td>
<td>All elective</td>
</tr>
<tr>
<td>&gt; 38 weeks</td>
<td>3</td>
<td>All elective</td>
</tr>
</tbody>
</table>

Table 11 demonstrates the number of previous caesarean sections experienced by the women for whom the care bundle was used. The majority of women (12) had undergone one previous caesarean.

<table>
<thead>
<tr>
<th>Previous caesarean section (n)</th>
<th>Cases (n)</th>
<th>Caesarean type (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Elective</td>
<td>Emergency</td>
</tr>
<tr>
<td>1</td>
<td>12</td>
<td>6</td>
</tr>
<tr>
<td></td>
<td></td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>8</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td></td>
<td>3</td>
</tr>
<tr>
<td>&gt; 2</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td></td>
<td></td>
<td>0</td>
</tr>
</tbody>
</table>

There were ten placenta accreta among the cases included in the care bundle testing; of these cases, six women had one previous caesarean section, three had two caesarean sections and one had five previous caesareans. It is noteworthy that the majority of emergency caesarean sections were in women with only one previous caesarean delivery (Table 11).

The majority of cases resulted in lower-segment caesarean sections (14 cases); a full description of all operation methods can be seen in Table 12. Only six cases resulted in hysterectomy, all of which were cases of placenta accreta.

<table>
<thead>
<tr>
<th>Operation type</th>
<th>Cases (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lower-segment caesarean section (LSCS)</td>
<td>14</td>
</tr>
<tr>
<td>LSCS + hysterectomy</td>
<td>5</td>
</tr>
<tr>
<td>Classical caesarean section</td>
<td>1</td>
</tr>
<tr>
<td>Classical caesarean section + hysterectomy</td>
<td>1</td>
</tr>
</tbody>
</table>

The mean estimated blood loss for all cases was 1967ml (range 400–6500 ml).
Intervention

Eight of the 21 cases required blood transfusions, with the range of 1–23 donor blood units transfused. Cell salvage was available in 18 of the 21 cases and was used in six cases, with an average volume of 1625 ml of cell-saved blood transfused. Of the rest, seven women received blood transfusions. In the three cases where cell salvage was not available, it had been available in these trusts on other occasions. One case received balloon tamponade intervention; compression sutures were not used at all.

Radiology intervention

Radiology intervention was used in only one of the 21 cases. The intervention (insertion of uterine vessel balloons) was used preoperatively.

Maternal outcome

Data on maternal outcome after delivery were also collected (Table 13). Reassuringly, 15 cases post-delivery were transferred directly to the postnatal ward, four cases required high-dependency care and two required transfers to intensive care.

Table 13. Maternal outcome after delivery

<table>
<thead>
<tr>
<th>Transfer location after delivery</th>
<th>Cases (n)</th>
</tr>
</thead>
<tbody>
<tr>
<td>High-dependency unit</td>
<td>4</td>
</tr>
<tr>
<td>Postnatal ward</td>
<td>15</td>
</tr>
<tr>
<td>Intensive care unit</td>
<td>2</td>
</tr>
</tbody>
</table>

Of the four cases requiring high-dependency care, two were post-hysterectomy, one of which was for placenta accreta. Of the two cases requiring intensive therapy care, both were post-hysterectomy, one of which was a classical caesarean section.

Evaluation questions

The users were asked to give feedback on the user friendliness of the care bundle. The response to these questions was very positive with only three care bundles being left blank on most sections.

First-time users and helpfulness of care bundle

There were twelve first-time and nine repeat care bundle users. Overall, the average length of time it took to complete the care bundle was 7 minutes. The majority of users found it ‘very easy’ to use (12 of 21) and six found it ‘quite easy’; the remaining three users did not comment.
Helpfulness to clinical practice

The majority of care bundle users found that it was quite helpful in relation to their clinical practice.

Effect on management of care

Care bundles users were asked if the placenta praevia care bundle made any difference to their management of the patient. Eleven users stated that it helped with their management of care, seven said it made no difference and three evaluations were left blank.

The users were also given space to provide free-text comments regarding the care bundle; the following is a selection of comments:

‘Didn’t do anything I wouldn’t have done anyway - but useful as an aide-memoire (and I guess for those who haven’t great experience in potential issues).’

‘Planning = not acute + it is not clear to me when to ‘enact’ bundle. I planned over 2 wks period. I would have had same plan without bundle.’

‘Brought together multidisciplinary approach.’

‘Increased awareness, helpful.’

‘Doing care bundle has highlighted anticipation and preparation of these patients.’

‘Raising profile make preplanning clear.’

‘In this case presence of the bundle pilot highlighted the care just prior to c/s and management tightened up and c/s delayed till corrected.’

‘It helped us to manage the delivery in an effective manner.’

Discussion

Feedback from clinical leads

During the testing period, the research midwife and clinical leads tried to communicate every 2 weeks to identify any queries or missed cases. It was thought to be a useful process that allowed clarification of any issues on the care bundle sheets and updates regarding any local changes. In addition, the clinical leads participated in an open feedback session during the care bundle feedback day. This open feedback also allowed the leads to share information on the changes that had been made locally to ensure good practice in the other units. Feedback from this session included:

- Implement at 32/40 unless diagnosis made earlier/no limit to gestation.
- Anterior and posterior placenta included.
As easy in small district general hospital to get senior anaesthetic staff to be involved in antenatal care?

Availability of critical care bed can be an issue for all units + needs to be highlighted that this element is for elective cases.

Potential for women to get moved from some units.

Outcomes to be measured during next pilot but should be monitored by UKOSS when rolled out.

Include methotrexate regimen if required?

Radiology an issue – change of practice – placenta reaching os/within 1cm.

Picking up patients – guidance of who to call back at 32/40.

Referral to appropriate people.

Opportunity to build up experience.

Need for advancing imaging.

Need for auditing of use/outcome.

Lead person to ensure compliance with care bundle.

Mechanism for flagging up women with diagnosis at 32/40? Sticker put on notes by ultrasound scan.

It was easy because small group of people to influence.

Need for a ‘guideline’ rather than a care bundle?

Health professionals’ reception of the care bundle

The placenta praevia care bundle proved to be a very successful tool. It was well received by doctors, well actioned and found to be useful in clinical practice. All components of the bundle remain appropriate and no modifications are required. The presentation of the bundle was easily understood and was found to be user friendly. It was seen as a welcome intervention that triggered local changes in some cases and provided a guide for staff to follow.

Effect on practice and guidelines

The placenta praevia care bundle resulted in changes to the 20-week ultrasound scans (to highlight women with previous caesarean section in one unit), changes to the 32-week re-scan (to include all women with scars if they had low placenta overlapping the cervix or an anterior placenta within 1 cm of the cervix).

Recommendations

The placenta praevia care bundle developed and piloted by the project should be incorporated into routine clinical practice.
5. Project conclusions and recommendations

The aim of the project was to develop and test the feasibility of implementing care bundles in maternity care, using EFM and placenta praevia following previous caesarean section as the first topics for consideration. The project achieved its aims and has been very informative about the methodology for developing care bundles in maternity care and the ease of multidisciplinary working. It also highlighted the importance of team engagement and planning when considering care bundles as a tool for improving patient safety in intrapartum care. The project has been successful in developing templates to allow others to develop more care bundles in the future. The methodology for developing, piloting and testing is robust, which will make it easier to produce successful care bundles in the future. This is a good beginning for care bundles which could make a difference to the safety of women and their babies in the years to come.

This project has demonstrated that there is a role for care bundles in intrapartum care but topic selection needs careful consideration. It was evident that the reception and acceptance by local staff was hugely different between the placenta praevia and EFM care bundles. The placenta praevia care bundle was designed for use by obstetricians and the EFM care bundle for use primarily by midwives. Thus, the types and numbers of users were significantly different. The project therefore concluded that an area of obstetrics with clear processes, such as placenta praevia following previous caesarean, is ideal for care bundle development and use because these require clear actions and compliance is easily measurable. This was not the case with EFM because responsibility for professional decisions and actions rested with the clinicians and not with the users. They may also be unaware of the outcomes, making the benefits of their efforts rather opaque. One component of the EFM care bundle also required adaptation and this may also have played a part in users’ perception. A bigger pilot using lessons learned from this project could perhaps help better understand the reasons behind the differences in acceptability of these two care bundles. It is encouraging though that the algorithm (Figure 1) developed by the evidence criteria group predicted this outcome and could guide future topic selection.

For the successful development and implementation of care bundles the essential components include:

- suitability of the topic
- acceptability of each component of the care bundle
- good planning
- staff buy-in through involvement of clinical staff at all levels
- staff training and briefings
- project promotion
- feedback.

It is recommended that further discussions take place with other national initiatives, such as the King’s Fund Safer Births Initiative, as a vehicle for further testing and implementation.
6. Next steps

This final report will be submitted to the NPSA as agreed. The NPSA will consider the report and its recommendations. A summary of the report will be produced and published on the NPSA website. Based on previous discussions, the NPSA is considering issuing safety guidance advising on the use of a care bundle to reduce the risks associated with placenta praevia in women who have had a previous caesarean section. It is likely that this will be part of a package of interventions to improve patient safety in intrapartum care. It is hoped that further work to test the ‘sticker’ to improve the interpretation of electronic fetal monitoring will be supported by others, such as the King’s Fund Safer Birth’s Initiative.
References

2. UK Obstetric Surveillance System [www.npeu.ox.ac.uk/ukoss].
4. Ashcroft B, Elstein M, Boreham N, Holm S. Prospective semi structured observational study to identify risk attributable to staff deployment, training, and updating opportunities for midwives. BMJ 2003;327;584.
15. Advanced Life Support in Obstetrics [www.also.org.uk].
Appendix 1 Electronic fetal monitoring care bundle compliance

Unit 1 Care Bundle Component 1

![Graph showing care bundle compliance across weeks for Unit 1 Care Bundle Component 1.]

Unit 1 Care Bundle Component 2

![Graph showing care bundle compliance across weeks for Unit 1 Care Bundle Component 2.]

Unit 2 Care Bundle Component 1

Unit 2 Care Bundle Component 2

Unit 2 Care Bundle Component 3
Unit 3 Care Bundle Component 5

Unit 4 Care Bundle Component 1

Unit 4 Care Bundle Component 2
Unit 4 Care Bundle Component 3

Unit 4 Care Bundle Component 4

Unit 4 Care Bundle Component 5
Unit 5 Care Bundle Component 1

Unit 5 Care Bundle Component 2

Unit 5 Care Bundle Component 3
Unit 5 Care Bundle Component 4

Unit 5 Care Bundle Component 5