

## **Rapid Response Report NPSA/2010/RRR012: Reducing the risk of retained swabs after vaginal birth and perineal suturing**

May 2010

### **Supporting Information**

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## 1. Background

Maternity services in England and Wales promote normal birth and for the majority of births, clinical intervention is not expected. It is recognised that there are a number of different birth environments, including the home. However, there is the potential risk of swabs being retained whenever they are used, and measures to prevent this during vaginal birth and perineal suturing are likely to be similar to those adopted in surgical settings.

The issue of retained swabs after a vaginal birth was brought to the attention of the National Patient Safety Agency (NPSA) by a patient safety midwife who reported nine incidents where a small swab has been left inside a woman's vagina.

Retained swabs following vaginal birth and perineal suturing can be a source of maternal morbidity, including pyrexia, infection, pain, secondary post-partum haemorrhage and psychological problems.

## 2. Scale of the patient safety issue

### *Incident data from the National Reporting and Learning System (NRLS)*

A search of NRLS data was undertaken on 3 August 2009 for obstetrics and gynaecology incidents reported between 1 April 2007 and 31 March 2009. The following terms were used in the search:

- speciality - obstetrics and gynaecology;
- incident category – 'retained needle/swab/instrument' or 'missing needle/swab/instrument' or 'unplanned return to theatre'.

A free text search included: 'swab', 'sponge', 'dab', 'cotton', 'rytec', 'mop', 'sling', 'needle', 'instrument', 'incorrect count', 'incorrect-count', 'drill', 'clip', 'bolt'.

During this period, the NPSA received 318 reports of incidents, of which 99 were found to be relevant to this issue. Only incidents where retained vaginal swabs were identified in the postnatal period were included. Non-vaginal swabs retained following a caesarean section and incidents where the swab count identified an anomaly and corrective action was taken were excluded.

Of these 99 reports, 34 described signs of infection, such as offensive/foul smelling lochia (vaginal discharge) and/or the prescription of antibiotics. The degree of harm assigned to these incidents ranged from severe to no harm.

### **Examples of incidents (taken verbatim from the NRLS) include:**

*"Patient readmitted to ward 8 days following Nbfd (Neville Barnes forceps delivery) having had a retained swab in her vagina after suturing. Patient had complained of an offensive odour but been reassured it was normal. She became itchy ... and when in the shower she retrieved a swab from her vagina. Seen by staff and appears to be a gauze x ray swab - sent to histology for confirmation. Oral antibiotics commenced, FBS and CPR (blood tests) taken. Speculum performed - no further swabs seen. HVS (High Vaginal Swab) taken and sent. For pelvic x ray to confirm no further swabs."*

*“Retained placenta - MROP (manual removal of placenta) sutured in theatre. Visited GP today who removed large swab from vagina . Offensive ++++ . Commenced on antibiotics.”*

*“Patient was in the shower when she realised something was protruding from her vagina. On inspection swab seen so taken back to bed and examined . Small x ray detectable swab protruding from vulva out of vagina - removed. Attempted to examine further but patient declined as vulva swollen and painful. Stated that everything felt normal now. Photos taken. Partogram checked prior to inspection - patient was sutured and swabs all accounted for at the time.”*

*“Prolonged 2nd stage - >forceps delivery - >vaginal tear. 1. PPH of 1300mls. Repair of tear at 18:30. 2. Missing small swab at the end of repair at 19:00. Nil in vagina, nil in yellow bin. Pelvic x - ray - >swab in vagina - >removed at 19:20” .*

### 3. Related evidence

#### *Data from the National Health Service Litigation Authority (NHSLA)*

A search of the NHSLA closed claims from 1 April 2007 to 31 March 2009 relating to retained vaginal swabs in obstetrics found 23 claims. Of these five related to gynaecological procedures and were excluded. The remaining 18 which resulted from a swab left in the vagina following birth or perineal suturing claims were reviewed.

#### Examples of claims

Retained vaginal swab discovered seven weeks post delivery which had been causative of a prolonged healing process and infection.	Unnecessary Pain
Following delivery of first child a swab was not removed from the vagina. This caused pain and discomfort and required a further procedure to remove the swab. An apology was made during the complaints process.	Unnecessary Pain
Claimant had to undergo an episiotomy to enable an easier birth. A swab was left in situ after being stitched which resulted in pain in stomach, vagina, an inability to bend and led to an infection as a result. Claimant claims that as a result of the negligence of the doctor she is emotionally distressed.	Unnecessary Pain
An episiotomy was performed to facilitate the delivery of the claimant’s child. Following the delivery the perineum was repaired - swabs were counted and notes signed to confirm that the count was correct. A week later the patient complained to community midwife of stinging when passing urine. On examination a gauze swab was noted to be protruding from the vagina. The swab was removed and prophylactic cefalexin was prescribed. Possible allegations of negligent episiotomy, as well as swab retention of course.	Infection

<p>Claimant delivered vaginally male infant. At time of delivery sustained a 2nd deg. tear which was sutured by a Registrar. Whilst stitching the perineum there was a failure to remove surgical swab. Claimant requested a visit by domiciliary midwife as she had been feeling unwell and could feel something in her vagina whilst in the bath. On examination edge of gauze swab seen which was removed.</p>	<p>Psychiatric/psychological damage</p>
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In addition, a 2006 review of all 3,149 NHSLA closed claims of obstetric incidents occurring between 1998 and 2004 identified 44 incidents of a foreign body left in situ. A further review of these claims undertaken for the current review identified 31 claims relating to retained swabs, six of which were following caesarean section and 25 following vaginal birth. The 25 cases of retained swab following vaginal birth resulted in total payments of almost £200,000.

### *Literature review*

Published articles and good practice examples were accessed from:

- Cited articles in the World Health Organization *Guidelines for Safer Surgery*.
- The US Joint Commission, Institute for Health Improvement and Association for Perioperative Practice (AfPP) websites.
- A search of CINAHL database in September 2009 using the search terms 'surgical sponges' (thesaurus term) and key word 'retained'. The search resulted in 24 citations, six of which were reviewed.

Studies in the United States (US) have examined incidents of retained swabs (sponges) and other retained foreign objects (RFOs). Some of these studies include reference to retained swabs following vaginal birth; others refer only to surgical procedures but are likely to be relevant to all situations in which swabs are used in cavities. Reviews of litigation data and patient safety incidents confirm that incidents of retained swabs, instruments and needles are rare, but may result in major injury or even death.

### *Risk factors*

Gawande et al (2003) studied retrospectively the medical records of 54 patients with a total of 61 RFOs.<sup>1</sup> Of these 37 (69 per cent) involved sponges and 12 (22 per cent) of the RFOs were left in the vagina. These cases were compared with 235 control cases. Significant risk factors for RFOs were found to be emergency surgery, unplanned change in the operation and high body mass index (obesity). Other studies have found that the risk of count discrepancies correlated with the length of surgery<sup>2</sup> and that personnel change was found to be more likely to involve a discrepancy than those where the personnel was the same.<sup>3</sup>

### *Frequency of discrepancies in the surgical count*

The process of counting is vulnerable to error and the number of count discrepancies (instances in which a subsequent count did not agree with the previous count) exceeds actual incidents. A study of the medical records of 1,062 patients whose surgery involved a reported count discrepancy showed that the missing item was found inside the patient in only 17 cases.<sup>2</sup> There were five false negatives when no discrepancy was detected but a foreign body was subsequently discovered.

Counting therefore identified over three-quarters of the 22 cases of RFOs. An observational study of 148 elective procedures in general surgery collected data on the type of item counted, discrepancies in the count, and activity involved in resolving discrepancies.<sup>3</sup> There were 2,476 counting episodes and 29 discrepancies were observed in 19 cases (one in eight cases). The most common reasons for the discrepancy were misplaced items and errors in the written record of the count. There were no incidents of retained swabs, instruments or needles. A discrepancy took on average 13 minutes to resolve.

### **No count undertaken**

The Gawande study found that counts were omitted in all 11 cases of retained swabs after the closure of an episiotomy or vaginal tear. The authors strongly recommend that hospitals actively monitor compliance with the existing standard of counting sponges in obstetrics.

## **4. Potential risk reduction strategies**

Some of the risk reduction strategies outlined here will not be relevant to all births. However, it is always possible to record the number of swabs used in the intrapartum notes. Some notes now include a box to record the number of swabs used for perineal repair on the post partum section of the notes.

The importance of addressing the persistent problem of retained swabs (sponges) and other retained foreign objects during surgical procedures continues to be highlighted by the Joint Commission<sup>4</sup>, and is addressed by the World Health Organisation in Objective 7 of *Guidelines for safer surgery*<sup>5</sup>, and the NPSA Alert on the *WHO surgical safety checklist*.<sup>6</sup>

NICE clinical guideline *Intrapartum care: care of healthy women and their babies during childbirth* includes advice in section 1.9.31 on the basic principles that should be observed when performing perineal repairs.<sup>7</sup> These include:

- Equipment should be checked and swabs and needles counted before and after the procedure.
- Following completion of the repair, an accurate detailed account should be documented covering the extent of the trauma, the method of repair and the materials used.

It is standard practice to count swabs before and after invasive procedures. The AfPP publication *Swab, Instrument and needle counts: managing the risks*<sup>8</sup> suggests that recommendations for inclusion in local practice should cover:

- education/training;
- packaging;
- responsibility for counts;
- checking procedure;
- checking techniques;
- instruments;
- count discrepancy;
- documentation.

In the US a Health Care Protocol, *Prevention of unintentionally retained foreign objects during vaginal deliveries*<sup>9</sup> recommends a standardised process for all countable items, including swabs (sponges) and needles. This includes the following:

- There should be baseline, ongoing and final counts by two individuals, one of whom will be a registered nurse.
- There should be a dedicated receptacle for all used swabs.
- Used swabs should be separated prior to being counted.
- There should be a standardised form for the count process, which could be on paper, a whiteboard or electronic format.
- No items should be removed from the area until all counts have been reconciled and inspections completed.
- If a woman is transferred to surgery in an emergency during or immediately after a vaginal birth any count should be documented in the patient's record and communicated to the surgical team.
- There should be a reconciliation process for a count discrepancy.
- If an unintentionally retained foreign object is found during a patient examination following discharge, the facility at which the woman gave birth should be notified.

Key implementation recommendations are that organisations should establish and maintain processes for ongoing training, measurement and feedback for all involved staff and that results from audits should be used to inform these processes.

Standards for record keeping for midwives and physicians have been published by the Nursing and Midwifery Council<sup>10</sup> and the Royal College of Physicians.<sup>11</sup>

### ***Clinical network feedback***

In response to the original issue of retained vaginal swabs following a vaginal birth raised by a midwife, the NPSA asked members of the informal NPSA maternity patient safety network for comments. Several responses described action taken locally following incidents of retained swabs following caesarean sections and vaginal births. Midwives commented that whether a vaginal birth or perineal suturing procedure is done in the delivery room, at home or in theatre, the principles of swab counting should be the same.

It is acknowledged that there is a potential for confusion in responsibilities due to the differing roles of obstetrician and midwives, and the risk of an unintentionally retained swab is greatest immediately after birth.

Examples of local practice:

- Staff are expected to undertake swab counts pre and post delivery and pre and post perineal suturing. There is a section in the maternity records where this is recorded and staff sign that these checks have been undertaken. Random audits of compliance are done and feedback is given to individual staff members. This is felt to be valuable in ensuring staff maintain a high standard.
- A 'swab safe' system has been introduced. There are dry-wipe boards in all delivery rooms so that swab, instrument and sharps counts can be undertaken for

all procedures. All swabs have X-ray detectable strips in them and disposables are sourced separately from instruments.

- Swabs have been removed from all delivery packs. Single large swabs with tags are used.

There has also been a reminder of the importance of ensuring that any "swab" removed from the vagina or brought in by a woman saying she had removed it from the vagina should be examined to confirm it is a swab as there have been reports that retained "swabs" have, in fact, been toilet tissue.

## 5. Summary and conclusion

Incidents of retained swabs following vaginal birth and perineal suturing are reported regularly to the NPSA in England and Wales. There is additional evidence from other sources that this is a problem and causes harm to women who have recently given birth. The effects of infection and the psychological harm associated with these incidents can be significant and last beyond the immediate postnatal period.

The NICE guidelines on intrapartum care refer briefly to the need to undertake swab counts, and there are recommendations about reducing the risk of retained swabs from the AfPP. With some adaptation, this guidance can be applied to maternity care in all settings. There is also a Health Care Protocol from the US that is specific to vaginal birth.

It is not known how many NHS organisations providing maternity care in England and Wales have effective procedures in place to prevent the retention of swabs following vaginal birth and perineal suturing. However, feedback from a small number of maternity units indicates that action has been taken in some organisations to address the risks of retained swabs.

## 6. References

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## Appendix 1

### Implementation checklist

This checklist gives examples of what should have happened before the Rapid response Report can be updated to 'Action Complete' on the Central Alerting System. NHS organisations should:

No	Recommendation	Action	Compliance Y/N
1	Have written procedures in place for swab counts at all births and perineal suturing.	A copy of the relevant procedures is available and signed off by the relevant committee.	
2	Audit swab count practices in their maternity services.	Evidence of results of audit and action plan available and reviewed at Labour Ward Forum.	
3	Provide education and training about the swab count procedure for all midwifery, obstetric and support staff.	Evidence of inclusion in annual mandatory updating programme. Training plan in place.	
4	Ensure that lead professionals (midwives and obstetricians) are aware of their responsibility for documenting the completed swab count in the woman's health record.	Evidence of dissemination and records of annual supervisory review of recordkeeping.	
5	In conjunction with their supplies department, risk assess sterile delivery and perineal suturing packs and consider using x-ray detectable swabs.	Evidence in minutes of discussion and decision at relevant meeting. Completed records risk assessment.	
6	Ensure staff report incidents of swabs retained after vaginal birth and perineal suturing as patient safety incidents.	Review incident reports, undertake root cause analysis and share learning.	
7	Cascade clinical briefing sheet to relevant staff to raise awareness of the risks of swabs being unintentionally retained following vaginal birth and perineal suturing.	Evidence in minutes of discussion at relevant meeting.	

## Appendix 2

### Summary of rationale for recommended actions

This table provides a summary of how the incident reports, local policy review, and literature explored above informed our recommended actions. NHS organisations should:

	Action	Summary of rationale
1	Have written procedures in place for swab counts at all births and perineal suturing.	Best practice recommendations on swab, instrument and needle counts during a surgical procedure are available from the AfPP and can be adapted for use in maternity services. Specific advice is also available for counts during vaginal deliveries, from the US.
2	Audit swab count practices in their maternity services.	Research studies suggest that swab counting reduces the risk of swabs being retained following interventional clinical procedures. However, swab counts can result in discrepancies (misplaced swab, miscount or error in documentation). Audits can help to identify reasons for discrepancies.
3	Provide education and training for all midwifery, obstetric and support staff.	Organisations need to satisfy themselves that all staff undertaking counts, including support staff, have the skills and knowledge required to provide safe maternity care.
4	Ensure that lead professionals (midwives and obstetricians) are aware of their responsibility for documenting the completed swab count in the woman's health record.	Midwives and obstetricians must ensure that they comply with their relevant regulatory body's guidance on record keeping. For example, the Nursing and Midwifery Council's guidance on record keeping, published in July 2009, and the Record Keeping Standards from the Royal College of Physicians.
5	In conjunction with their supplies department, risk assess sterile delivery and perineal suturing packs and consider using x-ray detectable swabs.	Swabs are extremely difficult to find when they are saturated with blood. Where facilities for x-ray exist, x-ray detectable swabs are generally accepted to be the "gold standard" for location of retained or misplaced swabs. The risk assessment should take into account the costs, location of the unit and the facilities that exist (access to x-ray).
6	Ensure staff report incidents of swabs retained after vaginal births and perineal suturing as patient safety incidents.	Retained swabs following vaginal birth and perineal suturing can be a source of maternal morbidity, including pyrexia, infection, pain, secondary post-partum haemorrhage and psychological problems.
7	Cascade clinical briefing sheet to relevant staff to raise awareness of the risks of swabs being unintentionally retained following vaginal birth and perineal suturing.	All staff need to be aware of the risks and the potential risk reduction strategies to prevent swabs being unintentionally retained.