



Health Services Safety
Investigations Body

Investigation report

Investigation report: Detection of retained vaginal swabs and tampons following childbirth

Date Published:

13/12/2019

Theme:

Medical devices, Checking

This PDF was downloaded from the Health Services Safety Investigations Body (HSSIB) website. To make sure you are reading the latest version, and for accessible reports, please visit <https://www.hssib.org.uk>

Contents

[1 Background and introduction](#)

[2 The reference event](#)

[3 Involvement of the Healthcare Safety Investigation Branch](#)

[4 Findings and analysis](#)

[5 Summary of findings, safety recommendation and safety observation](#)

[6 References](#)

[7 Endnotes](#)

[Providing feedback and comment on reports](#)

1 Background and introduction

1.1 Introduction

1.1.1 There is a patient safety risk where a vaginal swab or surgical tampon may be unintentionally retained (left inside a patient's vagina) following childbirth. This investigation explores an incident involving a woman called Christine who was experiencing severe pain following the birth of her child. When examined five days after childbirth, a surgical tampon was discovered. This investigation identifies numerous factors which reduced the detectability of the tampon, including the way in which it was designed and used, and how swab and instrument count boards (boards in the operating theatre used to track the whereabouts of equipment) were used in practice.

1.1.2 The investigation identified that there is ongoing national work to improve the detectability of vaginal swabs and tampons.

1.2 Never Event[1] and incident data

1.2.1 According to Never Event data published by NHS Improvement (2019) 'retained foreign object' is the second most commonly reported Never Event. Table 1 shows that the reported numbers of these events has remained consistent from April 2015 to March 2018.

Table 1 Number of retained foreign object Never Events reported, April 2015 to March 2018

Year	Number of retained foreign object Never Events
April 2015 to March 2016	107
April 2016 to March 2017	114
April 2017 to 31 January 2018	102
1 Feb 2018 to 31 Mar 2018[2]	18

1.2.2 Within the published data, vaginal swabs are the most common 'retained foreign object' reported, with surgical swabs the second most common (Table 2). It is not clear if vaginal packs and tampons (see 1.3) were included in the vaginal swabs data.

Table 2 Number of retained vaginal and surgical swab Never Events reported, April 2015 to March 2018

Retained foreign object	April 2015 to March 2016	April 2016 to March 2017	April 2017 to 31 January 2018	1 February 2018 to 31 March 2018[3]
Vaginal swab	33	32	22	4
Surgical swab	18	23	15	4
Total of retained swab Never Events	51	55	37	8

1.2.3 The Strategic Executive Information System[4] (StEIS) database was searched for 'retained foreign object' events reported between 1 April 2017 and 31 March 2019[5]. This returned 229 results, of which 45 were reported in the 'Maternity or Obstetrics[6]' category.

1.2.4 The majority of the 'Maternity and Obstetric' StEIS incidents were related to retained vaginal swabs, which were put in place during perineal repairs (repairs to the area of skin and muscle between the vagina and rectum). Tampons were the second most common retained objects in these incidents.

1.2.5 Around three-quarters of reported incidents occurred in theatres, with 15% occurring in labour ward delivery rooms.

1.3 Vaginal swabs and surgical tampons

1.3.1 Swabs and tampons are used to absorb bodily fluids such as blood in a variety of obstetric procedures, both in the delivery suite and obstetric surgical theatres (National Patient Safety Agency, 2010). They can be used during a perineum repair following a perineal tear or an episiotomy occurring during vaginal birth (see 1.4 and 1.5), when swabs and tampons are used to absorb blood and/or push back the cervix, enabling the clinician to see the area being sutured (stitched). A vaginal pack (see below) can also be used to apply pressure to perineal tears to stem bleeding and may be placed into the vagina following insertion of a Bakri balloon[7] to keep the balloon in position. The investigation identified the following types of swabs and tampons used in obstetrics:

- Tampons: Tubes of absorbent material that fit into the vagina to absorb blood. Tampons used by maternity services are larger than commercially purchased tampons used by women during their menstrual cycle (Figure 1).

Fig 1 A menstrual tampon (above) compared to a surgical tampon (below)

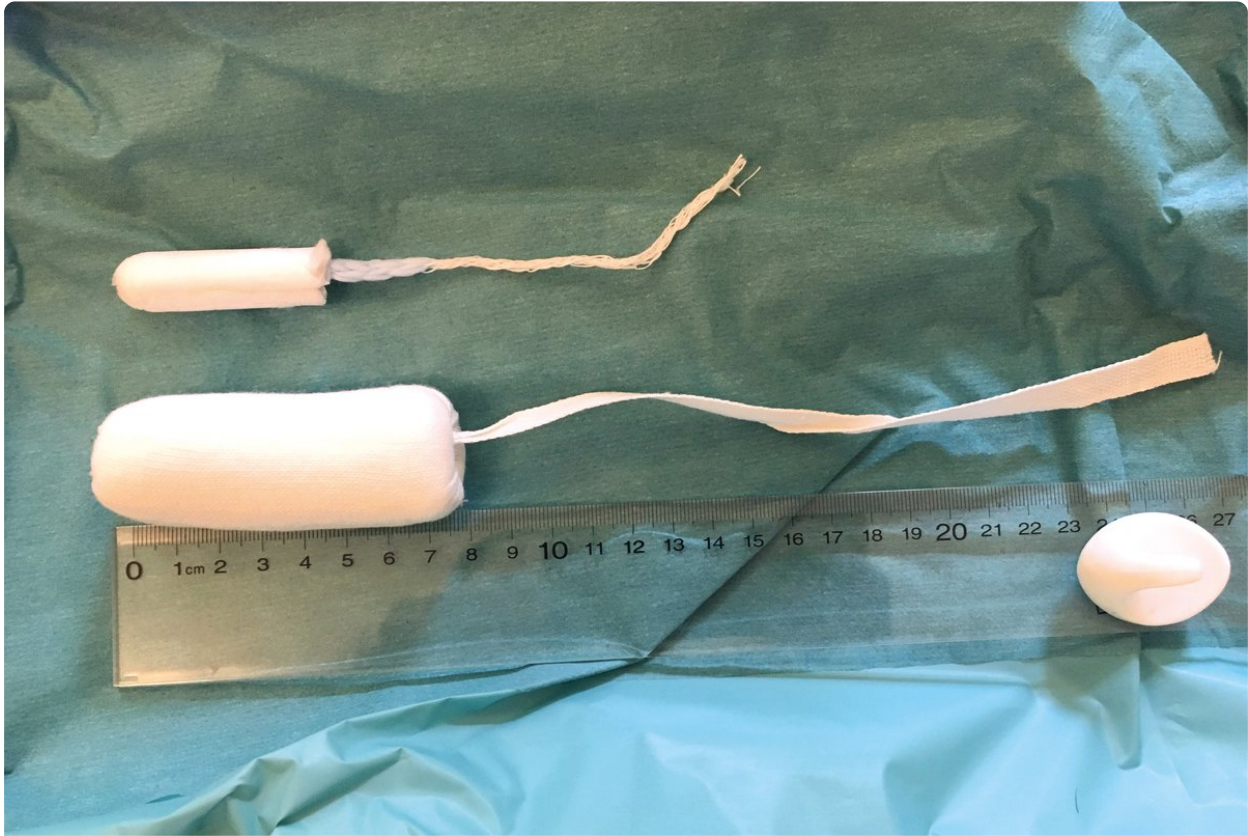


Fig 1 A menstrual tampon (above) compared to a surgical tampon (below)

- Large and small swabs: Square pieces of absorbent material, which can vary in size and thickness (Figure 2). In delivery and suture packs, swabs are usually pre-packed in bundles of five.

Fig 2 A 20 x 20cm swab



Fig 2 A 20 x 20cm swab

- Vaginal pack: 'Bandage-like' lengths of absorbent material which are approximately 2 metres in length.

1.3.2 Tampons and swabs are intended to be removed once a procedure is complete. A vaginal pack may be intentionally left in the vagina following a procedure and removed later.

1.3.3 Both swabs and tampons can have tails and a radio-opaque tape to aid detection via x-ray.

1.3.4 Swabs and sometimes tampons are contained within the delivery and perineal repair (del-peri) pack (Figure 3), which is opened in the delivery room or theatres at the beginning of a procedure (prior to birth of the baby) and counted.

1.3.5 The contents of the del-peri pack are bespoke to each trust and so there may be variation in contents.

Fig 3 Example of del-peri pack contents



Fig 3 Example of del-peri pack contents

1.4 Perineal tear

1.4.1 The perineum is the area of skin and muscle between the vagina and rectum. A perineal tear is a laceration or injury to the perineum which many women experience to some extent during childbirth (Royal College of Obstetricians and Gynaecologists, 2015). The Royal College of Obstetricians and Gynaecologists (2019) details four types of perineal tear (see Figure 4):

- First-degree tear: Injury to the perineal skin and/or the mucous membrane inside the vagina.
- Second-degree tear: Injury to the perineum involving perineal muscles but not involving the anal sphincter.
- Third-degree tear: Injury to the perineum involving the anal sphincter complex.
- Fourth-degree tear: Injury to the perineum involving the anal sphincter complex and the mucous membrane inside the anal canal.

Fig 4 Types of perineal tear

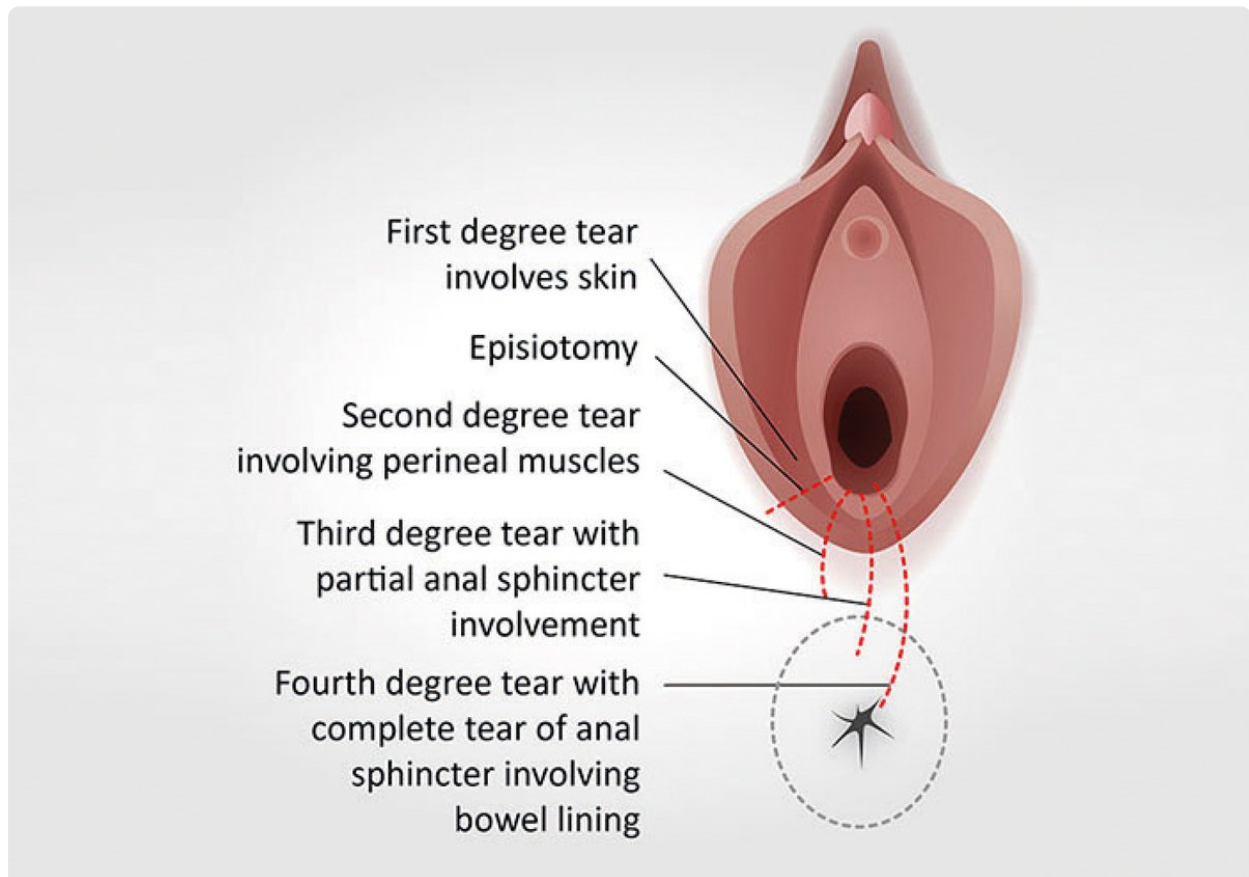


Fig 4 Types of perineal tear

(Royal College of Obstetricians and Gynaecologists, 2019)

1.5 Episiotomy

1.5.1 An episiotomy is a surgical cut to the perineum made during the second stage of labour to enlarge the space for the baby to be delivered (Royal College of Obstetricians and Gynaecologists, 2015).

1.6 Counting of swabs and instruments

1.6.1 In 2010, the National Patient Safety Agency (NPSA) published a Rapid Response Report which identified seven immediate actions for all NHS organisations providing maternity services that were designed to reduce the likelihood of retained swabs/tampons. According to the report Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list 2018 (NHS Improvement, 2018b), the NPSA's Rapid Response Report remains relevant. The 2018 report states: 'This Rapid Response Report highlights the requirement for swabs to be counted when used in a vaginal delivery (including for perineal

suturing) and the need to ensure that lead professionals (midwives and obstetricians) are aware of their responsibility for documenting the completed swab count in the woman's health record.'

1.6.2 A report by New Zealand's Health Quality and Safety Commission (2015) summarises the evidence and prevention strategies around retained vaginal swabs following childbirth. It is evident from this report that issues in counting are a key contributory factor in retained vaginal swab incidents. The report identified that recommendations for improvement should focus on:

- counting techniques
- equipment (types of swabs, barcoding, radio-frequency tagging, biodegradable swabs)
- education, audit, guidelines and policies.

1.7 Work by NHS England/Improvement

1.7.1 In 2014 to 2015, NHS England (now part of NHS England/Improvement) conducted investigations into retained vaginal swabs as part of the Patient Safety Investigation Branch (PSIB) pilot. Since 2015, NHS England and NHS Improvement have used these findings to engage in work to reduce unintentional retention of vaginal swabs and tampons. The result has been a focus on potential design solutions to aid detectability of swabs and tampons used in the maternity environment.

1.8 National guidance

Reducing the risk of retained swabs after vaginal birth and perineal suturing, by the National Patient Safety Agency

1.8.1 The National Patient Safety Agency (2010) identified seven immediate actions that were designed to reduce the risk of retained swabs post-delivery for all NHS organisations providing maternity services.

'NHS organisations should:

- have written procedures in place for swab counts at all births (including perineal suturing)
- audit swab count practices in their maternity services
- provide education and training about the counting procedure for all midwifery, obstetric and support staff

- ensure that lead professionals (midwives and obstetricians) are aware of their responsibility for documenting the completed swab count in the woman's health record
- in conjunction with their supplies department, risk assess sterile delivery and perineal suture packs and consider using x-ray detectable swabs
- ensure staff report incident of swabs retained after vaginal births and perineal suturing as patient safety incidents
- cascade the clinical briefing sheet to relevant staff to raise awareness of the risks of swabs being unintentionally retained following vaginal births and perineal suturing.'

National Institute for Health and Care Excellence (NICE) Guideline CG190:
Intrapartum care for healthy women and babies

1.8.2 The NICE (2014) guideline recommends several basic principles be observed when performing perineal repairs, including:

- 'Check equipment and count swabs and needles before and after the procedure.
- After completion of the repair, document an accurate detailed account covering the extent of the trauma, the method of repair and the materials used.'

2 The reference event

2.1 Local context

2.1.1 The reference event occurred at a large acute hospital. The hospital had five operating theatres for general and emergency surgical procedures. There were two further obstetric theatres, some distance away from the main theatres, but adjacent to the labour ward. Obstetric operating theatre 1 (OT1) was normally used for an elective obstetric list (a list of scheduled operations) starting at 08:30 hours, Monday to Friday. The second operating theatre, OT2, was available for obstetric emergencies during the day. OT1 was also used for emergency operations after the elective list had finished and overnight; it was the favoured theatre due to its larger size.

2.1.2 The theatre team of obstetric anaesthetists, scrub nurses[8] and operating department practitioners (ODPs)[9] was drawn from a central theatre staff list. A rostered day shift covered the elective list, and an emergency team was available

at short notice via a paging system to cover unplanned obstetric procedures. From 20:00 hours until 08:00 hours, a night shift of two scrub nurses plus one ODP was available via the paging system to cover the obstetric theatre.

2.2 Details of the event

2.2.1 Christine, a 30-year-old in her first pregnancy was admitted to a labour ward in October 2018 following an uneventful 39-week plus six-day pregnancy. Due to slow progress in the second stage of labour[10], a plan was made in the early hours of the morning to move Christine to the operating theatre to conduct an instrumental delivery by forceps[11]. At 05:04 hours the pre-operative checklist was completed by the midwife in anticipation of Christine going to theatre.

2.2.2 At 06:20 hours the decision was made by the obstetrician to take Christine to theatre. Christine was transferred to the obstetric theatres at 07:02 hours.

2.2.3 Earlier, the night shift theatre team had been called to a instrumental delivery for another woman, which commenced at 05:08 hours in OT1. Once this procedure was completed at 06:20 hours, the night shift theatre team of anaesthetist, ODP and two scrub nurses then transferred to OT2 to receive Christine.

2.2.4 At 07:02 hours Christine was accompanied to theatre by her partner and the midwife who had cared for her since coming on shift at 20:00 hours the previous evening. The team was then joined by an obstetrician and a specialty trainee junior doctor (ST2) who was on their second obstetric rotation and had joined the Trust two months earlier.

2.2.5 A healthy baby girl was born at 07:42 hours. As part of the Neville Barnes[12] forceps delivery an episiotomy was performed by the obstetrician.

2.2.6 Once the placenta was delivered at 07:43 hours, the obstetrician commenced the episiotomy repair. The obstetrician inserted a surgical tampon into the vagina to improve sight of the apex (end) of the cut and, after inserting two sutures, asked the ST2 to continue the repair. The ST2 was qualified to suture and had been present throughout the procedure. Suturing was completed by the ST2 at 07:59 hours.

2.2.7 Shortly after handing over the repair, the obstetrician left the theatre to check on another woman on the labour ward and to hand over to the on-coming day shift registrar. The exact time at which the obstetrician left the theatre was not documented. The shift handover for obstetricians was routinely conducted from 08:00 hours to 08:30 hours.

2.2.8 At approximately 07:50 hours one of the scrub nurses allocated to the elective list day shift entered OT2. The night shift scrub nurses handed over to her, including handing over the count of the swabs and instruments. The day shift scrub nurses allocated to cover unplanned obstetric procedures entered soon after each other. A second handover occurred, where the scrub nurse for the elective list handed over to the emergency theatre team. At around the same time, the labour ward co-ordinator informed the theatre team that there would be an unplanned caesarean delivery of twins in OT2. After the handover, the night shift scrub nurses left the theatre.

2.2.9 Christine was transferred from theatre and arrived in the nearby postnatal recovery room at 08:18 hours. She was then moved to the postnatal ward at 09:25 hours and discharged one day postpartum (after the birth).

2.2.10 Two days postpartum, Christine was visited in her home by a community midwife. During this visit Christine declined a perineum check. Over the next two days Christine experienced increasing perineal pain and at four days postpartum, visited her General Practitioner (GP). The wound was too painful for a physical examination, but the GP inspected it visually and gave Christine advice on wound care.

2.2.11 At five days postpartum, Christine was still experiencing perineal pain and called the NHS 111 at 07.55 hours. She was advised to see a GP within six hours. A community midwife visited her home later that morning and Christine was tearful when describing her pain. A visual inspection of the wound was conducted, and the midwife suspected an infection. The midwife also advised Christine to contact her GP. Christine contacted her GP and, following a telephone consultation, was prescribed antibiotics.

2.2.12 Later the same day, at 16:35 hours, Christine called the number for the hospital labour ward triage to report increasing pain. The advice given was to take paracetamol and to have a bath. A second call to the labour ward triage was made at 17:30 hours and Christine was advised to come into hospital. In significant discomfort and pain, Christine went to the labour ward at 19:20 hours. At 20:50 hours a review by an obstetrician revealed a retained surgical tampon in the vagina. Christine was admitted to the postnatal ward with her baby while being treated for pain and then for subsequent urinary retention (the inability to completely or partially empty the bladder). She was discharged home after eight days.

2.2.13 Three days after discharge, 16 days postpartum, Christine went to the hospital again owing to urological issues[13], returning home that evening. Less than two days later, at 18 days postpartum, she went to hospital again for urological issues, where she stayed overnight. She was then discharged home and was later referred to counselling services. After some difficulties gaining access to support, Christine has received physiotherapy and psychosexual therapy, and has received private counselling.

3 Involvement of the Healthcare Safety Investigation Branch

3.1 Referral of the reference event

3.1.1 The safety risk of delayed recognition of postpartum retained vaginal swabs was identified following a Safety Awareness Notification (SAN) to the Healthcare Safety Investigation Branch (HSIB). The SAN highlighted the potential for physical and psychological harm to women.

3.1.2 A review of the Strategic Executive Information System (StEIS) was conducted and a reference event was identified which matched the safety risk highlighted in the SAN.

3.2 Decision to produce a concise national investigation report

3.2.1 HSIB conducted an initial scoping investigation and assessed the findings against its investigation criteria. The assessment concluded that given the ongoing work by NHS England/Improvement (NHSE/I) to find a solution to reduce the risk of retained vaginal swabs and tampons, it was not an appropriate time for a full national investigation. As such, a decision was made to conduct a concise national investigation. The assessment against HSIB's criteria was as follows:

Outcome impact - What was, or is, the impact of the safety issue on people and services across the healthcare system?

A National Patient Safety Agency alert (2010) revealed that the delayed recognition of retained vaginal swabs can contribute to maternal morbidity (ill health), including fever, infection, pain, secondary postpartum haemorrhage and psychological problems.

A recent review of the StEIS[14] suggested the most common outcomes are severe pain, discomfort, odorous discharge and bleeding, and the reference event also identified that incidents of retained swabs and tampons can have a significant psychological impact on those affected.

Systemic risk - How widespread and how common a safety issue is this across the healthcare system?

The safety risk focuses on maternity care, but underlying contributory factors extend to retained swabs/objects and other risks common during other forms of surgery. Retained swabs and tampons postpartum is an issue that was identified in an alert over nine years ago (National Patient Safety Agency, 2010) and continues to be a concern. According to Never Event data (NHS Improvement, 2019), vaginal swabs were the most common 'retained foreign object', with surgical swabs the second most common. A review of the StEIS database revealed that 'retained foreign object' relating to maternity or obstetrics events continues to be an issue.

Learning potential - What is the potential for an HSIB investigation to lead to positive changes and improvements to patient safety across the healthcare system?

The investigation found that a number of national initiatives to redesign swabs/ tampons and improve traceability were underway. However, these initiatives were yet to be implemented and evaluated widely. HSIB therefore felt that it would be beneficial to undertake a concise national investigation to share the key findings and lessons identified to influence safety improvements in this area.

3.3 Evidence gathering and methodology

3.3.1 A range of methods were used in this investigation, including:

- a review of Christine's medical records
- interviews with Christine, her partner and key staff from the reference event Trust
- observations of two elective caesarean sections at the reference event Trust
- observation of the theatre environment and layout
- a review of relevant local and national policy and guidance
- discussion with NHSE/I about its work on increasing the detectability of swabs and tampons

- analysis of the reference event using two incident investigation approaches: Sequential Timed Event Plotting (Hendrick and Benner, 1987) and AcciMap (Svendung and Rasmussen, 2002).

3.3.2 Interviews were conducted with staff four months after the incident had occurred. Staff members' memory of events is useful for understanding perceptions and exploring other contextual factors. However, recall of events is prone to error; details of events can be forgotten, altered or falsely added into memory (The British Psychological Society, 2010). Therefore, where possible, the evidence gained through interview was corroborated with independent and objective evidence. In some instances, only interview evidence was available.

4 Findings and analysis

4.1 Use and detectability of swabs at the Trust

Policy and 'usual' process at the Trust

4.1.1 The policy at the Trust where the reference event occurred stated that swabs, needles and instruments must be counted before a procedure commenced, before closure of any internal cavities, before wound closure begins, at skin closures and at the end of a procedure. The swab and instrument counts were to be conducted by two scrub nurses, one of whom documents the count on a 'count board' – a whiteboard located on the wall in the theatre. Swabs came in bundles of five, held together with a red piece of string. The scrub nurse would normally untie the string and count the five swabs out individually, documenting '5' on the count board. Each additional swab bundle was documented as '+5' on the count board. According to the Trust's policy, both scrub nurses should sign the patient's theatre notes at the end of the procedure to confirm that the swab and instrument count was complete, after which the count board should be wiped clean. A precise record of the count was not documented in Christine's health record.

4.1.2 Staff described that usually the surgeon verbally stated when they were inserting a swab or tampon that was going to be left inside the patient during the procedure. A scrub nurse would then note on the count board that a swab/tampon had been inserted. When the swab/tampon was removed it was again vocalised by the surgeon and crossed off on the count board by a scrub nurse.

4.1.3 Some surgeons would also use a surgical clip (Figure 5), which looks like a pair of scissors, placing this on the 'tail' of the swab/tampon and attaching it to the surgical drape (the sterile material used to cover parts of a patient's body during surgery). The aim of the clip was to make the swab/tampon more visible.

4.1.4 The 'perineal tear repair and management of packs' policy in place at the Trust before the incident occurred stated that tampons should only be used by registrars undertaking perineal repair in theatre and must be included in the swab count. As such, the Trust's policy allowed for differences in tampon use depending on where and by whom the perineal repair was being undertaken. Specifically, that registrars could use them when in theatre but other staff such as specialty trainee doctors (ST2s) and midwives could not use them whatsoever. The investigation did not identify a rationale for this.

Fig 5 Surgical clip



Fig 5 Surgical clip

Changes to delivery and perineal repair (del-peri) packs

4.1.5 Staff commented there had been two changes to the del-peri pack in recent months. The Trust had been using a del-peri pack which included a tampon, however, staff reported that owing to procurement issues these packs had run out. Staff described that an alternative pack had been used for a period of time and that

surgical packs would often change in other specialities. The investigation was unable to obtain further evidence to substantiate staff claims as to how and why the del-peri packs changed despite pursuing this line of enquiry.

4.1.6 On the day of the reference event, the scrub nurses opened a del-peri pack which contained two bundles of five swabs and a tampon. This was the first time the scrub nurses reported seeing a tampon in a del-peri pack since they had been using the alternative pack. The scrub nurses documented the number of swabs on the count board as '5 + 5' and also documented the tampon on the count board.

4.1.7 The investigation concluded that staff may have become used to the tampon not being present in the del-peri pack and this could have been a factor in the reference event.

4.1.8 In response to the reference event, the Trust implemented a policy designed to mitigate against future incidences of retained tampons. The Trust has started a process to procure del-peri packs that do not contain tampons. However, existing stocks of del-peri packs will be used up before the new packs are made available. As an interim measure, and while packs which contain tampons are still in use, the Trust requires tampons to be discarded immediately upon opening the pack and documented as discarded on the count board.

4.1.9 The investigation noted that although completely removing tampons from del-peri packs reduces the risk of a retained tampon, it does not prevent retained swab incidents, as swabs can still be unintentionally retained. The investigation did not explore the potential unintended consequences of removing tampons, which may be legitimately required for certain procedures, from the del-peri pack.

Detectability of tampon in situ (in place in the vagina)

4.1.10 The obstetrician reported that she normally tucked the tail of the tampon underneath the drape to prevent the tail migrating into the vagina. However, the following factors were identified that may have made it more difficult to detect the tampon in situ on the day of the reference event:

- The obstetrician reported that the episiotomy had extended further up into the vagina. As such, it was possible the tampon may have been inserted higher into the vagina. A scrub nurse commented that if a tampon is pushed higher up it becomes more difficult to clip the tail to the drape and reduces the length of tail visible.

- The obstetrician did not attach a clip to the tail. The clip would prevent the tail moving up into the vagina. The clip was also a larger object to detect at the end of the tail.
- The obstetrician could not recall saying out loud that she had inserted a tampon. No one else in the theatre recalled seeing or hearing that the tampon was inserted.
- Staff told the investigation they were focused on other tasks at the time the suturing was commenced. The scrub nurses were conducting their shift handover, retrieving sutures and preparing for the next task. The anaesthetist was monitoring the mother, and the midwife was analysing cord blood gases (a routine test of blood from the umbilical cord) and weighing the baby.
- The ST2 commented there had been “brisk” bleeding from the episiotomy. As such, the tampon (and tail) may have become engorged with blood, reducing its visual contrast against the surrounding tissue.
- The ST2 only conducted a rectal examination and did not internally examine the vagina. As such, he was unable to feel the tampon. The obstetrician reported that following a perineal repair she would normally do a vaginal examination to make sure there were no clots and had this been done, the tampon may have been detected. According to the Trust’s Perineal Tear Repair and Management of Packs policy: ‘A rectal examination should be performed after the repair to ensure that sutures have not been inadvertently inserted through the anorectal mucosa. If a suture is identified it should be removed.’ The policy did not state that a vaginal examination should be conducted.
- The investigation observed two obstetric surgical procedures at the reference event Trust, during which the final count of swabs and instruments were not crossed off on the count board. This made it difficult to detect if an item was missing, as the count board indicated that many items were not accounted for (Figure 6). Staff reported that they would verbally run through the count board and mentally cross the items off.

Fig 6 Count boards as observed at the end of two obstetric surgical procedures, once swab and instrument counts has been completed

Count board at end of first observation

Into Theatre	08:55	Into Lithotomy	10:10	Start of Procedure	
Knife to Skin	09:25	Neville Barnes / Keillands / Kiwi		1 st Pull	
Baby Born	09:27 ^{Term I} / 09:29 ^{Term II}	Episiotomy		2 nd Pull	
Sex of Baby	F 2.69 / F 2.58	Head out		3 rd Pull	
Placenta	09:31	Baby Born		Swabs	
End of procedure		Sex of baby	1120	Maps	
Swabs	5 + 5 + 5 + 5	Placenta	500	Ties	
Mops	5 + 5 + 5 + 5	End of procedure	1920	Blades	
45x45		Out of lithotomy	550	Needles	
Ties	1 + 1 + 1 + 1 + 1 + 1 + 1 + 1	EBL	10:56 2470	Tampon	
Blades	2	Suction: 700		Medication	
Needles	4	Swabs 300		ERG given 09:38	
		3 x Extra sponge holders		TxA : 9:39 + 1007	
		1120		Heumabate 9:41	
				Haemobate 10:05	

Count board at end of second observation

Into Theatre	11:37	Spinal / Epi top up / CSE / GA	11:42	Start of Procedure	
Knife to Skin	12:06	Into Lithotomy		1 st Pull	
Baby Born	12:06	Neville Barnes / Keillands / Kiwi		2 nd Pull	
Sex of Baby	girl 3.50	Episiotomy		3 rd Pull	
Placenta	12:08	Head out		Swabs	
End of procedure	12:54	Baby Born		Maps	
Swabs	5	Sex of baby		Ties	
Mops	5 + 5	Placenta		Blades	
45x45		End of procedure		Needles	
Ties	1 + 1 + 1	Out of lithotomy		Tampon	
		EBL		Medication	
		Suction: 200 mls.		30 x 60 Swab inside	
		Swabs 340		ERGOMETRIN 12:37	
		740		TRANS. A. 12:38	

Fig 6 Count boards as observed at the end of two obstetric surgical procedures, once swab and instrument counts has been completed

- The ST2 was not aware a tampon had been or could be used for a perineal repair. The ST2 reported he had only been at the Trust for two months and tampons were not used at the previous Trust he worked at. The technique for repairing an episiotomy or perineal tear that the ST2 had been trained in did not require a tampon or swab to be left inside the vagina during the procedure. The midwife was also qualified to conduct perineal repairs and reported that she used a similar technique to that used by the ST2. The obstetrician stated that she often, but not always, inserted a tampon during a perineal repair to improve visibility of the area being sutured.

Measures in place to reduce risks rely on people

4.1.11 Although counting was observed to be successful, the investigation found it was not a robust mitigation for preventing unintentionally retained swabs or tampons. The process and mitigations at the reference event Trust relied on staff performing many processes and procedures correctly. These included:

- the counts being correct
- the counts being conducted on all items
- the surgeon vocalising that a swab/tampon had been inserted
- the scrub nurse seeing and/or hearing the swab/tampon had been inserted
- the in-situ swab/tampon being documented on the count board
- the scrub nurse or surgeon remembering or noticing on the count board that the swab/tampon was still in situ
- the scrub nurse/surgeon seeing that the swab/tampon was still in situ
- the scrub nurse/surgeon having the knowledge that swabs/tampons may be used
- that all the completed counts were crossed off on the count board
- that counts were sufficiently handed over if there is a staff change mid-procedure
- remembering to retrieve the clip from the instrument trolley and attaching the tail of the swab/tampon to the drape
- that staff follow the same process and procedures
- the surgeon removing the swab/tampon after suturing was complete

- the tampon being discarded at the beginning of a procedure (a practice put in place following the reference event)
- that a sticker/wristband was used for intentionally retained vaginal packs
- that a sticker/wristband was available for when a vaginal pack was used.

There were numerous opportunities for error in the list above, especially considering that staff may be:

- distracted by other tasks such as shift handover, clearing up, setting up for next tasks, getting prepared to go home on time, caring for the mother, and caring for the baby
- focused on the task they were performing, for example, assisting delivery of the baby, conducting a perineal repair
- negatively affected by 'low arousal' and fatigue. Low arousal can occur during monotonous or routine tasks which have limited mental stimulation for an individual. The instrumental delivery by forceps and perineal repair were perceived by theatre staff to be routine, easy tasks.

4.2 Environmental and team factors in theatre

Differences between abdominal and vaginal theatre procedures

4.2.1 The investigation found that the process for controlling instruments and swabs differed between abdominal theatre procedures (such as caesarean section) and vaginal theatre procedures. For an abdominal procedure, the scrub nurse would remain sterile or 'scrubbed' throughout the procedure and give the surgeons the instruments and swabs they required, as well as retrieving them. For an instrumental delivery, which was a vaginal procedure, the scrub nurse would be scrubbed when laying out the instrument and swab trolley. However, they were no longer scrubbed during the procedure and the surgeon would help themselves to the items they needed from the instrument and swab trolley. Although the scrub nurse would count the swabs at the end of the procedure, they were not maintaining oversight of where swabs and instruments were during the instrumental delivery.

4.2.2 Since the reference event, the Trust has employed a policy stating that the scrub nurse is to remain responsible for the instrument and swab trolley during vaginal procedures. However, during these procedures there is no requirement for the scrub nurse to remain sterile.

Ownership and responsibility of procedure

4.2.3 During the reference event, there were stages of the procedure when staff were working independently and were focused on their individual task, which detracted from the overall task. For example, the scrub nurses focused on preparing and counting swabs and instruments, retrieving equipment for the surgeons and monitoring blood loss. The midwife focused on the parents and baby. The anaesthetist focused on the physiological monitoring of the mother while the surgeons focused on performing the procedure. When asked who had overall ownership of risk for a procedure, staff stated that responsibility was shared. However, the anaesthetist perceived that the surgeon would “call the shots” during the procedure, and that the ownership of risk for the patient was the anaesthetist’s responsibility.

4.2.4 Limitations in the perception of ownership of the overall procedure and risk for the patient could result in a lack of oversight and supervision of the procedure, or issues associated with diffusion of responsibility. Diffusion of responsibility is ‘the diffusion of one’s sense of responsibility to act in a particular situation owing to the presence of many other persons all of whom may be viewed as potentially responsible for acting’ (Reber and Reber, 2001).

4.2.5 The investigation concluded that diffusion of responsibility may have been a factor in the reference event.

Multiple handovers

4.2.6 The shift handover for the theatre staff (scrub nurses and operating department practitioner (ODP)) was at 08:00 hours. There was no overlap between night and day shifts. The handover between shifts relied upon staff either coming in early for their shift or staying late so that staff could hand over their duties and tasks.

4.2.7 While the episiotomy repair was being conducted, the day shift theatre staff were beginning to enter the theatre. Multiple handovers were conducted for the swab and instrument trolley and these handovers were staggered as staff arrived and left the theatre. It was likely the multiple handovers were a source of distraction and contributed to staff not detecting that a tampon had been inserted. The staggered handover may also have contributed to a breakdown in communication over the number and whereabouts of the swabs and tampon.

HSIB makes the following Safety Observation

Safety observation O/2019/052:

It would be beneficial for trusts to review their planned handovers and for all staff groups to have adequate time in their shift to conduct handover tasks and participate in team briefings.

Practices at the end of tasks

4.2.8 Interviews with staff and observations of elective caesarean sections revealed that there was a motivation to finish shifts on time. The motivation to complete the shift on time led to the scrub nurse who had undertaken the original swab count to sign documentation that the swab count was complete up until 08:00 hours, when she expected to go home. In fact, the scrub nurse handed over and left the theatre before 08:00 hours and before the final swab count was complete. The obstetric theatres were located away from the main theatres where staff changing rooms were located. As such, staff liked to leave the obstetric theatre prior to the shift ending so that it gave them time to get changed and leave on time.

4.2.9 Theatre staff (scrub nurse and ODP) shifts did not overlap; however, some members of the team did have an overlap between shifts. The obstetric and gynaecology surgeons and midwives had a 30-minute overlap between shifts where they could handover, and the anaesthetists had a one-hour overlap to allow for handover.

4.2.10 In the reference event, the obstetrician commenced suturing the episiotomy, however, upon completing two sutures, asked the ST2 to continue so that she could leave theatre to check on a patient with a severe infection (sepsis) and hand over to the day shift team. The obstetrician and ST2 reported there was no formal handover for the episiotomy repair because the ST2 had been observing the procedure including the forceps delivery up until that point. The ST2 reported he was not aware the tampon had been inserted.

4.2.11 The episiotomy repair commenced at approximately 07:46 hours and handover for doctors was between 08:00 hours and 08:30 hours. The obstetrician stated that she would not normally leave theatre before the World Health Organization (WHO) Safe Surgery checklist[15] 'sign out' had been carried out, but it had been "on her mind" that day that she needed to organise herself by checking patients before she handed over to the day shift. Evidence indicates that the obstetrician left theatre before the WHO sign out not only for the reference event but also for the previous procedure. Interview evidence suggested that it was accepted practice among teams for a surgeon to leave theatre before the end of a procedure. A scrub nurse said that in general there were occasions when those who

were present for the procedure were not all present for the WHO sign out. The anaesthetist also reported that it was “normal” and not uncommon for surgeons to leave the specialty trainee in theatre to finish off a procedure, such as suturing, if they deemed the trainee competent to do so.

4.2.12 During the reference event, towards the end of the procedure, the theatre team was informed by the labour ward co-ordinator that another emergency case (an emergency caesarean of twins) would immediately follow. An elective twin caesarean was also expected in the maternity theatre next door. One scrub nurse described the theatre as “hectic” when she arrived for her day shift. She commented there were a lot of conversations about the next task and a pressure to quickly turn the room around.

4.2.13 The investigation’s observations of elective caesarean sections found that towards the end of the procedure there was a focus on the next task. Soon after the baby/babies were born the theatre teams would fragment, focusing on their own tasks such as clearing up the theatre, measuring the baby’s cord blood gases, weighing the baby and monitoring the mother’s vital signs. In one observation, the anaesthetist had to remind staff there was another procedure to do following the birth, indicating there had been a sense of task completion in the room.

4.2.14 The investigation observed that once the procedure and sign out was completed the surgeons immediately left the theatre. It was evident that it was not the norm to conduct a debrief afterwards, even when a major event had occurred (for example, following a postpartum haemorrhage, which happened during one of the procedures observed by the investigation). As such, there were potentially missed opportunities to identify what went well and areas for improvement.

4.2.15 No or limited handover time, competing task demands, and limited time between procedures as described in this section can place pressure on staff and lead to behaviours such as short cuts, workarounds and reduced supervision so that tasks can be achieved on time. Dekker (2014) states that the gap between how a system was designed (or imagined) and how it works in practice can increase over time; this is known as ‘drift’. Factors that contribute to drift include an emphasis on efficiency, past successes (that is, no negative outcome has resulted before from staff leaving others to complete a task) and then staff complying to the new behaviours until they become routine (Dekker, 2014). It is likely that the accepted practices at the end of the reference event procedure have resulted from drift.

4.3 Fatigue

4.3.1 Fatigue can have a detrimental effect on people's performance and increase the likelihood of human error. Wagstaff and Sigstad Lie (2011) conducted a systematic review of the literature on the effects of work hours on various health outcomes, safety, and performance. The review found that work periods of eight hours and above carry an increased risk of an accident, and that the risk cumulates. This means, for example, that the risk of an accident 12 hours into a shift is twice the risk at eight hours. Wagstaff and Sigstad Lie (2011) found that shift work which includes nights carries a substantial increased risk, although it was found that being permanently on nights may bring some protection against this safety risk, as it allows staff to adapt their body clock to a new sleep-wake cycle.

4.3.2 The shift pattern for theatre staff was 08:00 hours to 20:00 hours for the day shift and 20:00 hours to 08:00 hours for night staff. The reference event occurred approximately 10 to 15 minutes prior to the end of the scrub nurses' 12-hour night shift.

4.3.3 The investigation found that some of the Trust's night shift theatre staff were on permanent nights with a seven-day-on and seven-day-off shift pattern. However, some theatre staff worked fewer nights, that is, four nights a week, before having days off. Some night staff would also work a few extra daytime shifts but would receive a day off between night and day shifts.

4.3.4 The obstetrician and ST2 were on a night shift from 20:00 hours to 08:30 hours. The ST2 commented that he normally felt tired for much of the time when on the night shift. The anaesthetist's shift was from 20:00 hours to 09:00 hours. The anaesthetist also commented on feeling tired towards the end of night shifts.

4.3.5 Staff commented that they generally do receive breaks, however, depending on the case load, breaks could be limited.

4.3.6 The reference event incident occurred at a time when there is a greater risk of fatigue-related error and so the 12-hour night shifts may have been a factor. Although most of the night shift theatre staff were on permanent nights, which may mitigate some of the negative effects of night work (Wagstaff and Sigstad Lie, 2011), there were staff who worked both day and night shifts. These staff carry a substantial increased risk of being involved in a fatigue-related incident.

4.4 Care after discharge from hospital and detection of the tampon

4.4.1 Christine had seven contacts with healthcare services in the community (community midwives, general practitioners, NHS 111 and the triage midwife) between the second and fifth day after giving birth (postpartum). Christine reported

she was experiencing too much pain to have a vaginal examination and so was only visually examined. The lack of vaginal examination may have contributed to the retained tampon remaining undetected during these visits.

4.4.2 When Christine visited her GP at four days postpartum, the general practitioner (GP) did not suspect infection and diagnosed that the episiotomy was the cause of discomfort. The following day, Christine was still experiencing perineal pain and called the NHS 111 at 07.55 hours. She was advised to see a GP within six hours. A community midwife visited her home later that morning and on visual inspection of the wound noted an offensive smell. The community midwife suspected Christine may have an infection and advised her to contact her GP. Christine contacted her GP and, following a telephone consultation, was prescribed antibiotics.

4.4.3 Both the Trust and a consultant obstetrician and gynaecologist subject matter advisor (SMA) told the investigation their maternity departments ran weekly perineal clinics because perineal issues were common after vaginal births. The SMA also commented that GPs and community midwives may frequently encounter patients with postnatal perineal pain, usually due to bruising or wound infection, and may not have come across retained swabs or tampons as a cause for concern. As such, the clinicians who saw and spoke with Christine may have been subject to 'confirmation bias', which is described as 'the seeking or interpreting of evidence in ways that are partial to existing beliefs, expectations, or a hypothesis in hand' (Nickerson, 1998). A retained vaginal swab/tampon which is not visible is difficult to recognise and detect via the symptoms it can produce. This could result in clinicians diagnosing a more common and likely cause, such as infection, rather than exploring other possible causes.

4.4.4 Christine continued to experience significant pain and later that day called the labour ward triage midwife. Christine told the investigation that she felt her pain was not taken seriously when she called the triage midwife about returning to hospital. She told the investigation she had been advised to have a bath; however, Christine explained it was too painful to get in the bath and only managed a shower. After a second triage call, a plan was made for Christine to come to hospital. The notes made by the triage midwife were limited in detail and she was not available for interview on the occasions HSIB investigators visited the Trust.

4.4.5 Christine again felt her pain was not taken seriously when she was admitted to hospital. Christine recalled experiencing a lot of pain when the registrar conducted a vaginal examination. She told the investigation she had asked the registrar to stop, at which point he removed the tampon.

4.4.6 The SMA commented that the extent of pain Christine was experiencing in the community offered a missed opportunity for further investigation at an earlier stage.

4.4.7 The SMA told the investigation that when pain does not make sense in the context of clinical findings, clinicians have a duty to investigate further. She also advised that there is no consistency in how reported pain is quantified in maternity medicine. The SMA reported that the recognition of pain and how it is perceived in healthcare is an issue which may not have been addressed adequately nationally, because of the lack of evidence that surrounds the topic.

4.4.8 Christine described the pain and subsequent urological problems she experienced to be traumatic. She told the investigation it affected her initial bonding time with her daughter, including being unable to pick up or carry her. She also felt it affected her relationship with her partner.

4.4.9 This investigation highlights a potential safety risk relating to how clinicians perceive and respond to reports of pain. This safety risk will be fed back to HSIB's intelligence unit to be reviewed as a potential area for investigation in future.

4.5 Review of current mitigations

4.5.1 The investigation identified mitigations that were currently being used nationally and internationally to reduce the likelihood of retained vaginal swabs and tampons postpartum. The investigation also explored mitigations that were due to be implemented; these are detailed in the following sections.

Work being carried out by NHS England/Improvement (NHSE/I)

4.5.2 NHSE/I has been conducting long-standing improvement work in light of its findings from investigations into retained vaginal swabs.

4.5.3 The NHSE/I investigation found there are several strategies being used to reduce the likelihood of vaginal swab retention. Mitigations in place focused on counting and included administrative 'add-ons' such as:

- forms
- white boards
- counting in a different room
- wrist bands.

4.5.4 The NHSE/I investigation found the lack of visibility of swabs to be a key contributory factor for retained swabs. The absorbent material used in swabs, including the tail, turn red when in contact with significant bleeding and could look like human tissue, making them difficult to detect.

4.5.5 NHSE/I are exploring potential technical solutions to these issues and will produce further information in due course.

Radio-frequency identification (RFID)

4.5.6 In the NHS, RFID has been used to track high-value implants used during surgery as part of the UK's Scan4Safety programme (Department of Health and Social Care, 2018a). A trust is also preparing to use RFID to automatically track patient location throughout the hospital (Department of Health and Social Care, 2018b).

4.5.7 According to Surgical Instrument Traceability Guidelines (GS1 UK Healthcare User Group, 2017), RFID technology can lead to improvements in patient safety and quality of care. These include:

- more efficient management of surgical instruments
- a reduction in errors and increase in quality
- easier and earlier identification of missing items
- reduction of instrument migration from set to set
- improved availability and planned use of instruments
- a full history of single instruments and sets used on a patient.

4.5.8 Trials using RFID tags on surgical swabs demonstrate that this could be an effective system in preventing retained swabs and should be considered as a method for tracking swabs in theatres in future (Lazarro et al, 2017; Inaba et al, 2016). However, further advances in RFID technology and clinical trials are required to confirm the reliability and applicability of the system (Lazarro et al, 2017).

4.5.9 Discussion with NHSE/I revealed that the implementation of technology such as RFID into swabs is unlikely to occur in the short term.

Review of mitigations against the hierarchy of hazard control

4.5.10 The hierarchy of hazard control is used by those in industry who plan and implement mitigations to reduce risks that have been identified in the workplace. Risks should be reduced to the lowest practicable level and the hierarchy helps decision makers assess and prioritise mitigations that are more likely to be effective (Health and Safety Executive, 2019).

4.5.11 Having studied the reference event and other work in this field, the investigation reviewed the mitigations that are in place, and due to be implemented, against the hierarchy of hazard control (Figure 8).

4.5.12 It is unlikely that swabs can be entirely removed from the maternity and/or theatre environment. Therefore, mitigations for reducing incidents of delayed recognition of retained swabs and tampons should ideally be aimed at the 'replace the hazard' level, to increase the likelihood that they are effective.

4.5.13 The investigation considered that current national guidance was mainly focused on the 'change the way people work' levels, which are less likely to be effective and provide weaker mitigation. This was demonstrated by the mitigations implemented by the Trust in the reference event.

4.5.14 At the time of publication of this report, the NHSE/I work is yet to be implemented and evaluated widely and so its effectiveness cannot be assessed at this time. NHSE/I told the investigation that future plans include:

- independent evaluation of a new swab design, including comparison with other interventions
- usability testing
- cost/benefit analysis
- impact analysis in relation to reduction of repeat incidents.

HSIB makes the following Recommendation

Safety recommendation R/2019/058:

It is recommended that NHS England/Improvement carries out its intention to commission and publish an independent evaluation of its alternative design for swabs and tampons. The evaluation should also consider other solutions or technologies and include usability, cost/benefit analysis and the impact on reducing harm.

Fig 8 Hierarchy of hazard control for postpartum retained vaginal swabs

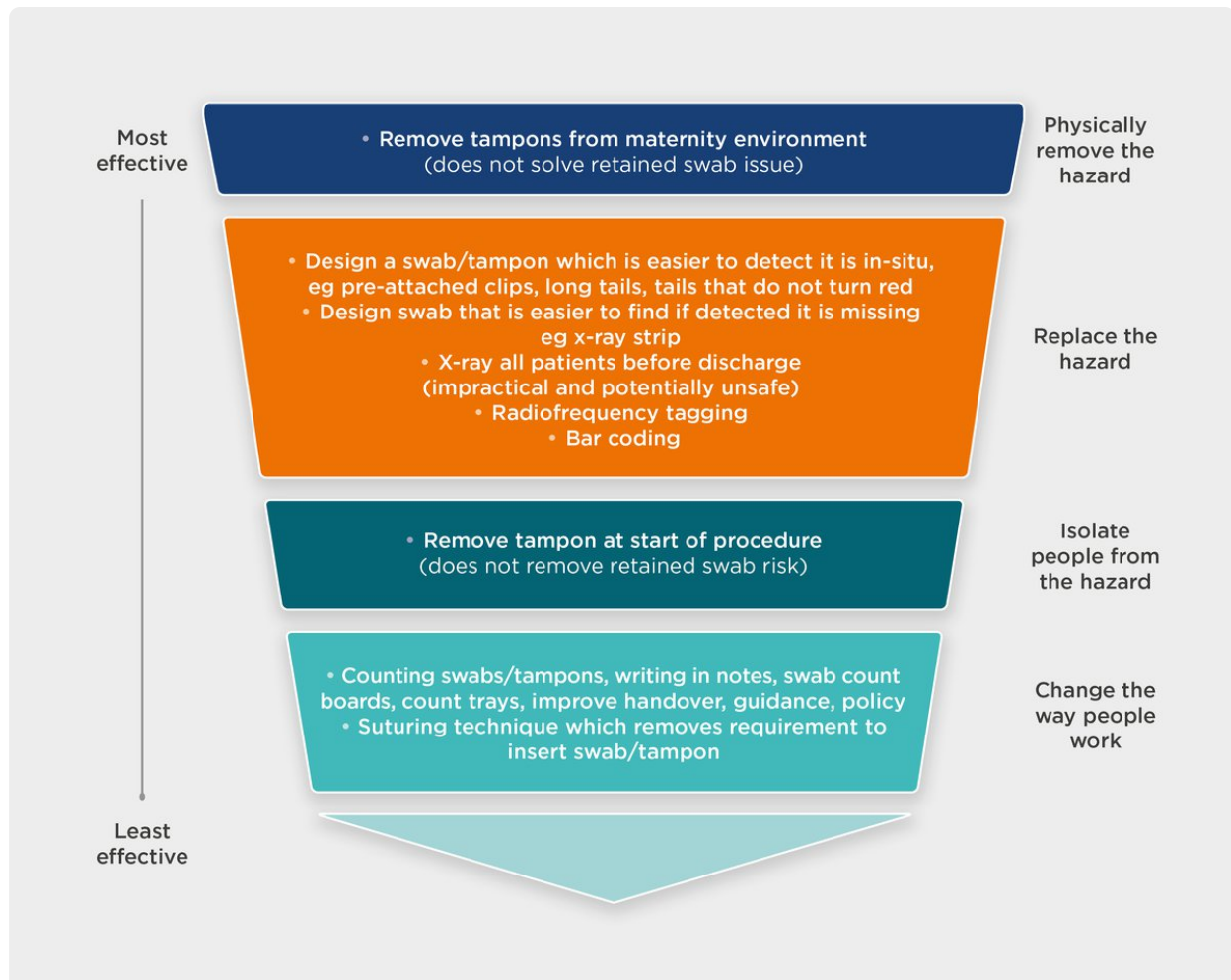


Fig 8 Hierarchy of hazard control for postpartum retained vaginal swabs

5 Summary of findings, safety recommendation and safety observation

5.1 Findings from the reference event

- Factors were identified which reduced the detectability of the tampon, including the way in which it was designed and used, and how swab and instrument count boards were used in practice.
- The specialty trainee doctor (ST2) was not aware a tampon had been or could be used during a perineal repair. The technique the ST2 was trained in for repairing an episiotomy or perineal tear did not require a tampon or swab to be left inside the vagina during the procedure.

- The Trust's process for swab/tampon insertion and mitigations against retention of swabs/tampons relied on staff performing many processes and procedures correctly. There were numerous opportunities for error, especially considering that staff may be distracted by other tasks, fixated on the task they were performing or negatively affected by 'low arousal' (lack of stimulation when carrying out a routine task) and fatigue.
- The process for controlling instruments and swabs differed between abdominal and vaginal theatre procedures. During the instrumental delivery (a vaginal procedure), the scrub nurse would count the swabs at the beginning and end of the procedure but did not maintain oversight of where swabs and instruments were during the procedure.
- Limitations in staff members' perception of ownership of the overall procedure and responsibility for managing risks to patient safety could result in a lack of oversight and supervision of the procedure, or issues associated with diffusion of responsibility.
- Multiple handovers of the swab and instrument trolley were conducted, and these handovers were also staggered as staff arrived at and left the theatre. It was likely the multiple handovers were a source of distraction and contributed to staff not detecting that a tampon had been used.
- Towards the end of the procedure there appeared to be a focus on the next task or activity, resulting in practices such as leaving theatre before a procedure was complete. The accepted practices at the end of the procedure were likely to have resulted from 'drift' driven by competing task demands, limited handover periods, task pressure, and a motivation to go home on time.
- The incident occurred at a time when there was a greater risk of fatigue-related error. The investigation concluded that the 12-hour night shifts may have been a factor in this incident.
- This investigation highlighted a potential safety risk relating to how clinicians perceive and respond to reports of pain.

5.2 Findings from review of current mitigations

- The investigation considered that current national guidance was mainly focused on changing the way in which people work, which is less likely to be effective and provides weaker mitigation for preventing the retention of vaginal swabs and tampons.
- NHS England/Improvement (NHSE/I) is developing and testing an alternative swab and tampon design that aims to increase their detectability.

- The effectiveness of the new swab and tampon design cannot be assessed at this time as it is yet to be implemented and evaluated widely. NHSE/I told the investigation that future plans include:
 - independent evaluation of the new swab design, including comparison with other interventions
 - usability testing
 - cost/benefit analysis
 - impact analysis in relation to reduction of repeat incidents.
- Trials using radio-frequency identification (RFID) on surgical swabs demonstrate that it could be an effective system in preventing retained swabs and tampons. Further advances are required and the implementation of technology such as RFID into swabs is unlikely to occur in the short term.

HSIB makes the following Recommendation

Safety recommendation R/2019/058:

It is recommended that NHS England/Improvement carries out its intention to commission and publish an independent evaluation of its alternative design for swabs and tampons. The evaluation should also consider other solutions or technologies and include usability, cost/benefit analysis and the impact on reducing harm.

HSIB makes the following Safety Observation

Safety observation O/2019/052:

It would be beneficial for trusts to review their planned handovers and for all staff groups to have adequate time in their shift to conduct handover tasks and participate in team briefings.

6 References

Dekker, S. (2014) The Field Guide to Understanding 'Human Error' (3rd ed.). Farnham: Ashgate Publishing Limited.

Department of Health and Social Care. (2018a) Cornwall boosts surgical safety with RFID. [Online] Available at: <https://www.scan4safety.nhs.uk/boost-surgical-safety/>

Department of Health and Social Care. (2018b) Leeds implements patient tracking. [Online] Available at: <https://www.scan4safety.nhs.uk/leeds-implements-patient-tracking/>

GS1 UK Healthcare User Group. (2017) Surgical Instrument Traceability Guidelines. GS1 UK. [Online] Available at: https://www.gs1uk.org/~media/healthcare-user-group/gs1_uk_hug_technologies_surgical_instruments_trace_doc.pdf?la=en

Health and Safety Executive. (2019) Frequently asked questions - what is a hierarchy of control? [Online] Available at: <http://www.hse.gov.uk/risk/faq.htm#hierarchy>

Health Quality and Safety Commission. (2015) Retained vaginal swabs following childbirth. [Online] Available at: <https://www.hqsc.govt.nz/assets/Reportable-Events/Publications/Open-book/OB-retained-vaginal-swabs-Dec-2015.pdf>

Hendrick, K and Benner, L. (1987) Investigating Accidents with S-T-E-P. New York: Marcel Dekker.

Inaba, K, Okoye, O, Aksoy, H, Skiada, D, Ault, G, Sener, S, Lam, L, Benjamin, E and Demetriades, D. (2016) The Role of Radio Frequency Detection System Embedded Surgical Sponges in Preventing Retained Surgical Sponges. A Prospective Evaluation in Patients Undergoing Emergency Surgery. *Annals of Surgery* 2016; 264(4): 599-604. doi:10.1097/SLA.0000000000001872

International Ergonomics Association. (2019). Definition and Domains of Ergonomics. [Online] Available at: <https://www.iea.cc/whats/index.html>

Lazarro, A, Corona, A, Lezzi, L, Quaresima, S, Armisi, L, Piccolo, I, Medaglia, C M, Sbrenni, S, Sileri, P, Rosato, N, Gaspari, A L and Di Lorenzo, N. (2017) Radiofrequency-Based Identification Medical Device: An Evaluable Solution for Surgical Sponge Retrieval? *Innovative Technologies* 2017; 24(3): 268-275. doi: 10.1177/1553350617690608

National Institute for Health and Care Excellence. (2014) Intrapartum care for healthy women and babies (CG190). [Online] Available at: <https://www.nice.org.uk/guidance/cg190/resources/intrapartum-care-for-healthy-women-and-babies-pdf-35109866447557>

National Patient Safety Agency. (2010) Rapid Response Report. NPSA/2010/RRR012. Reducing the risk of retained swabs after vaginal birth and perineal suturing. [Online] Available at: <https://webarchive.nationalarchives.gov.uk/20101201143200/http://www.nrls.npsa.nhs.uk/alerts/?entryid45=74113&p=1>

NHS Improvement. (2018a) Never Events policy and framework. [Online] Available at: https://improvement.nhs.uk/documents/2265/Revised_Never_Events_policy_and_framework_FINAL.pdf

NHS Improvement. (2018b) Recommendations from National Patient Safety Agency alerts that remain relevant to the Never Events list 2018. [Online] Available at: https://improvement.nhs.uk/documents/2267/Recommendations_from_NPSA_alerts_that_remain_relevant_to_NEs_FINAL.pdf

NHS Improvement. (2019) Never Events data. [Online] Available at: <https://improvement.nhs.uk/resources/never-events-data/>

Nickerson, R. (1998) Confirmation Bias: A Ubiquitous Phenomenon in Many Guises. *Review of General Psychology* 1998; 2(2): 175-220. doi:10.1037/1089-2680.2.2.175

Reber, A and Reber, E. (2001) *The Penguin Dictionary of Psychology* (3rd ed.). London: Penguin Books Ltd.

Royal College of Obstetricians and Gynaecologists. (2015) Information for you. A third- or fourth-degree tear during birth (also known as obstetric anal sphincter injury - OASI). [Online] Available at: <https://www.rcog.org.uk/globalassets/documents/patients/patient-information-leaflets/pregnancy/pi-third--or-fourth-degree-tear-during-birth.pdf>

Royal College of Obstetricians and Gynaecologists. (2019) Perineal tears sustained during childbirth. [Online] Available at: <https://www.rcog.org.uk/en/patients/tears/tears-childbirth/>

Svendung, J and Rasmussen, J. (2002) Graphic representation of accident scenarios: mapping system structure and the causation of accidents. *Safety Science* 2002; 40: 397-417.

The British Psychological Society. (2010) Guidelines on Memory and the Law. Recommendations from the Scientific Study of Human Memory.

US Food & Drug Administration. (2018) Radio Frequency Identification (RFID). [Online] Available at: <https://www.fda.gov/radiation-emitting-products/electromagnetic-compatibility-emc/radio-frequency-identification-rfid>

Wagstaff, A and Sigstad Lie, J-A. (2011) Shift and night work and long working hours - a systematic review of safety implications. Scandanavian Journal of Work, Environment and Health 2011; 37(3): 173-185. doi:10.5271/sjweh.3146

World Health Organization. (2019) WHO surgical safety checklist and implementation manual. [Online] Available at: https://www.who.int/patientsafety/safesurgery/ss_checklist/en/

7 Endnotes

[1] NHS Improvement (2018a) defines Never Events as ‘Serious Incidents that are wholly preventable because guidance or safety recommendations that provide strong systemic protective barriers are available at a national level and should have been implemented by all healthcare providers’. They cover all aspects of NHS-funded care.

[2] Note: the data is split into two in the report as the Never Event criteria were changed in February 2018.

[3] Note: the data is split into two in the report as the Never Event criteria were changed in February 2018.

[4] StEIS is a national database which facilitates the reporting of serious patient safety incidents and the monitoring of investigations between NHS providers and commissioners.

[5] Search conducted 3 May 2019.

[6] Obstetrics is the branch of medicine related to childbirth.

[7] A Bakri balloon is a device used for the temporary control of bleeding following childbirth.

[8] Scrub nurses assist on a number of different surgical procedures, conducting tasks such as setting up and handing out instruments to the surgeon, counting instruments and swabs, and cleaning up the theatre.

[9] ODPs work in the theatre preparing equipment, monitoring cleanliness, ordering and rotating stock and drugs, providing the surgical team with items they need during an operation and keeping accurate records. ODPs also work in partnership with the anaesthetist, assisting with anaesthetic care and monitoring vital signs.

[10] The second stage of labour starts when the cervix is dilated (10cm) and ends when the baby is born.

[11] The delivery of a baby through the vagina assisted by the use of instruments – in this case forceps.

[12] Neville Barnes refers to a particular design of obstetric forceps.

[14] The StEIS was searched on 24 July 2019 for incidents occurring between 1 April 2017 and 19 July 2019 that met the ‘retained foreign object’ Never Event criteria and were categorised as maternity incidents. This returned 44 results, 39 of which represented retained tampons, swabs or vaginal packs.

[15] ‘The checklist identifies three phases of an operation, each corresponding to a specific period in the normal flow of work: Before the induction of anaesthesia (“sign in”), before the incision of the skin (“time out”) and before the patient leaves the operating room (“sign out”). In each phase, a checklist coordinator must confirm that the surgery team has completed the listed tasks before it proceeds with the operation.’ (World Health Organization, 2019)

Providing feedback and comment on reports

We welcome feedback on our investigation reports. Please complete our [online feedback form](#) or email enquiries@hssib.org.uk.

We aim to provide a response to all correspondence within five working days.

This document, or parts of it, can be copied without specific permission providing that the source is duly acknowledged, the material is reproduced accurately, and it is not used in a derogatory manner or in a misleading context.

© 2025 HSSIB.