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Early-stage innovation report

iCount: a human-factors engineered solution to vaginal swab retention – an early-stage innovation report

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Although uncommon, unintentionally retained surgical items remain a persistent and poorly understood medical error with the potential to cause significant harm. They are termed patient safety 'never events' and are considered unacceptable and largely preventable.[1] The most commonly retained surgical item is the surgical swab, also known as 'sponge' in the USA, with the highest rates of swab retention found in the maternity setting. The UK never events database identifies vaginal swabs (used during perineal trauma repair) as the source of the largest number of swab retention events.[2 3] NHS England data identifies 338 separate incidents of vaginal swab retention between 2012 and 2022 with evidence of global under-reporting due to the significant reputational impacts of these incidents as well as the difficulty in diagnosis and identification of error.[1 3–6]

This long-standing problem, also called 'Gossypiboma', was first reported in 1884 by the American Obstetrician and Gynaecologist Dr Wilson.[7] Despite procedural and technical innovations to tackle this problem, a globally applicable, cost-efficient solution is lacking.

The impacts of swab retention prove debilitating to patients, healthcare staff and trusts which is emphasised when exploring a real case (described with some factual changes for confidentiality):

> LB was a first-time mum who delivered a baby boy via forceps delivery requiring an episiotomy. This was subsequently sutured. She suffered with persistent discomfort, pain and difficulty in passing urine postnatally and saw her community midwife twice. 9 days post-partum she visited her GP due to persistent offensive blood loss. She was prescribed antibiotics for a urinary

WHAT ARE THE NEW FINDINGS

⇒ Despite established policies and procedures when swab counting, issues such as distraction, confirmation bias, competing task priorities and changes in swab appearance contribute to swab miscounts and therefore swab retention.
⇒ Cases of count discrepancies/miscounts are under-reported, and their impact extends to patient's health, clinician's time and trust's reputation and finances.
⇒ iCount is a low-cost device designed and developed with human factors-ergonomics principles. It is a docking system that behaves as a physical checklist when swab counting and facilitates conscious engagement using visual and tactile cues when counting.
⇒ Users believe iCount to be a viable alternative to manual two-person swab counting with greater time efficiency and perceived safety. This could be valuable in emergency maternity situations.

HOW MIGHT IT IMPACT ON HEALTHCARE IN THE FUTURE

⇒ iCount has the potential to reduce or prevent retained swabs after vaginal deliveries along with appropriate policies, training and teamwork.
⇒ Additional clinical research and widespread adoption would be needed to validate this effectively.

infection, but her problem persisted, she continued to consult her GP several times who later changed her antibiotics. On day 17, the patient passed a large blood clot found to contain a swab. She lost a further 500 millilitres of blood and was admitted to the hospital via ambulance. Upon arrival, she was treated for sepsis and was discharged home 10 days later.

A retained vaginal sponge/swab is a source of high morbidity. Complications include pain, urinary retention, vaginal discharge, infection, secondary haemorrhage, stress and long-term psychological problems with potential impacts on mother-baby bonding. In the most severe cases, it can lead to maternal death from sepsis.[8 9] The repercussions can also harm professionals as a 'second victim' with feelings of guilt and shame. Organisational consequences can be legal, financial and reputational, as 'never events' are considered one of the indicators of quality and safety processes. In the USA, litigation resulted in a mean compensation of $77 175. The maximum payment was $2 350 000.[10]

STATUS QUO

The present gold standard requires a healthcare professional and assistant to conduct a two-person swab count preprocedure. Swab packs are opened, each swab unfolded and visualised (including exposure of the radio-opaque marker and tail) while audibly counting the swabs in tandem. Postprocedure, a two-person count-out is done. A proportion of maternity settings use whiteboards where assistants will document swab counts in multiples of 5.[11] While other safety measures exist, including counting bags and trays, clinical uptake is limited as labour rooms cannot accommodate the bulky stands required for these processes.

Why does swab retention happen?

88% of swab retention incidents happened despite what was perceived to be a correct surgical count.[12] Errors arise in the process, perception and documentation of counts.

Extensive human factors-ergonomics system analyses including: hierarchical task analysis, Systems Engineering Initiative for Patient Safety framework, AcciMap and human reliability analysis were explored to identify the factors that underpin swab retention events.[13–15]

Factors identified

- Swabs change shape and colour, can become sticky and look like bodily tissues.
- Confirmation bias during two-person counts.[16]
- Distraction, multi-tasking and time pressure.
- Emergencies in the rapid, unpredictable and dynamic specialty of obstetrics.[17]
- Changes in the responsible healthcare team.[8]
- Perception of vaginal delivery as 'less of a surgical procedure' meaning less stringent application of safety protocols in delivery rooms compared with traditional operative settings.[9]
- Inadequate staff.
- Environmental factors—ambient noise, low light, masks, gowns.

A retrospective analysis noted that one in eight surgical procedures involved a count discrepancy which multiplied the swab retention risk by 100.[18] Root cause analysis highlights multiple factors that assimilate to create an environment for swab miscounts which develop into swab retention events.

iCount: a novel solution

iCount serves as a 'physical checklist' when swab counting helping healthcare professionals eliminate task-related errors. It has two components—a purple plastic docking base, and familiar vaginal swabs and tampons with overmoulded plastic clips attached securely to their tails. The clips are inserted into a slim, rectangular docking base that can fit in the palm. iCount comes pre-assembled in independent sterile packages or as part of maternity sterile procedure packs. Procedures should begin and finish with a complete set (either five swabs or four swabs and one vaginal tampon) clipped into the device (figure 1). iCount uses design to promote safe human behaviour by engaging healthcare professionals with both visual and tactile cues when swab counting.

Successive iterations aim to incorporate camera vision/artificial intelligence (AI) technologies to record swab counts. This would capture completed iCount sets at the beginning and end of procedure and inhibit procedure closure with incomplete or inaccurate counts—acting as a technological adjunct and barrier to error. These technologies are widely adopted in many industries such as production engineering, rail, nuclear industry and aviation and this would prove a natural integration into healthcare.[19–21]

Objectives of this study

This paper will discuss the iterative design and development of iCount followed by an evaluation of its utility, efficiency and perceived safety when compared with the traditional counting method. The paper will explore simulation study data comparing the efficiency of swab counting and monitoring blood loss with both methods. The analysis will also explore qualitative user feedback on iCount's safety, usability and design.

METHOD

iCount was developed in as a collaboration between inventors, Keele University research innovation support, University of Wolverhampton, Faculty of Science and Engineering (SIRC Project), Manufacturing Technology Centre (government catapult) and the manufacturer KIMAL PLC. It is presently a manufacture-ready, testable prototype.

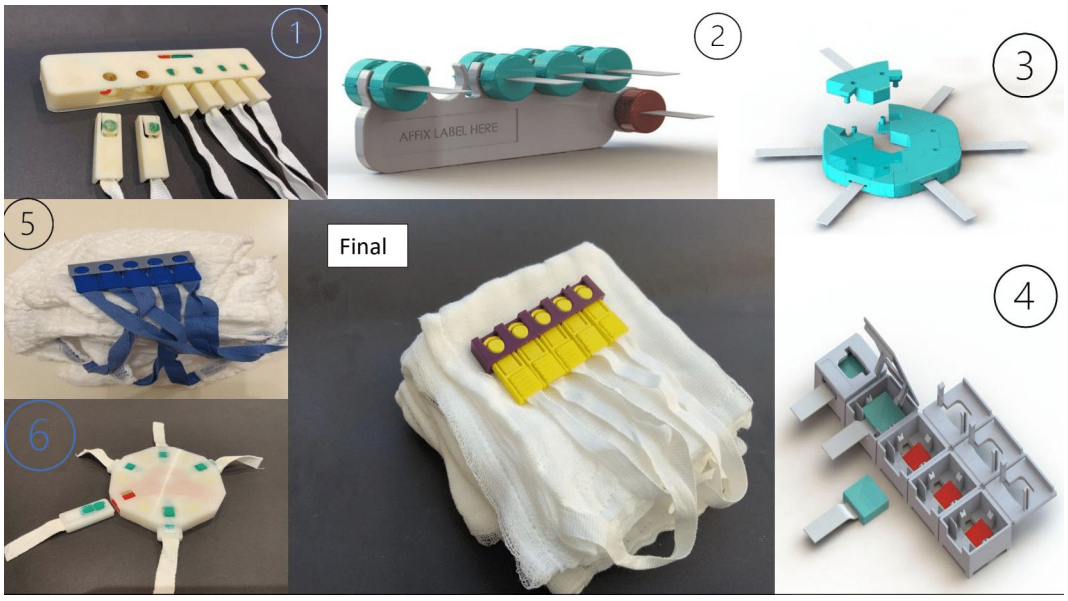


Figure 1 Multiple design concepts for iCount are highlighted in figure 1. Prototypes featured cylindrical clips, hexagonal jigsaw-like clips and 'clip windows' that would secure swabs if tails were correctly positioned in the docking station as well as a seat-belt like clip which was adopted in the final manufacture ready version.

Design and implementation were conducted sequentially and in parallel, involving:

- **Statement of need:** problem and impact as described earlier.
- **Engaging stakeholders:** Keele University research innovation support, Accelerate associates and Pym's associates conducted a thorough engagement with stakeholders including: midwives, nurses, doctors, managers, representatives from the Healthcare Safety Investigation Branch, NHS England and patient safety organisations through surveys and interviews. Most stakeholders were aware of this problem and felt that there was a need for a technological adjunct. 60% of the NHS organisations surveyed had reported 1–10 swab retention events in the 3 years prior.
- **Human factors systems analysis**.
- **Development of technical specifications and design brief:**
  1. *Essential:*
     - There must be a signifier (acting as a flag) for each swab.
     - The system must be able to separate each swab/tampon.
     - The system must enable quick, visual accounting of swabs and highlight where swabs are at all times.
     - Ergonomic with tactile, visual and some sound feedback.
     - Count swabs in 5 s (established practice).
     - Low-cost and environmentally friendly.
  2. *Good to have:*
     - Technological integration to document when swabs are removed and replaced inside the docking system as well as an electronic failsafe to ensure that procedures cannot be completed with inaccurate/incomplete swab counts. An app is currently being designed for this purpose.
- **Design process**: computer-aided design (CAD), 3D printed and CNC machined prototypes. Successive design cycles with iterative feedback.
  - Multiple design concepts were considered with final manufacture-ready iteration (figure 1).
- **Usability studies** were undertaken locally and regionally.
- **Patient public involvement** was conducted by NIHR Surgical MIC and the Clinical Research Ambassador Group (CRAG), Birmingham which highlighted patient awareness and anxiety regarding the issues of surgical swab retention. Response to a technological, human-factors oriented solution was encouraging.
- **Health economic analysis conducted by York Health Economic Consortium**: identified a conservative economically justifiable price (EJP) of £29.50. This reflects the maximum price that could be charged for one iCount device such that it would still be deemed an efficient use of resources. The actual price is likely to be considerably lower than EJP, resulting in significant cost-saving for trusts.

Evaluation

Scenario-based simulation studies have been used to evaluate successive iterations of the iCount device. NIHR Medical Device Technical Evaluation Centre conducted independent simulations in 2020 and 2023. An in-house timed simulation study was conducted in 2023 by our research fellow. These simulation studies emulate real-world interactions with the device without exposing patients to potential risks.

Scenarios simulation (2020):

- Scenario 1 simulated the delivery suite/maternity room environment. Participants conducted swab counts with traditional swabs and the prototype. Participants simulated using the swabs to suspend bleeding on a model

perineum before replacing them in the docking station and conducting a count.
- Scenario 2 assessed whether iCount could make it easier to determine if a swab had been misplaced
- Scenario 3 involved transferring a patient into the operation theatre with a swab in place.

User insights led to iterative modifications in physical design including shape, colour and material as well as guiding the formulation of operating instructions. For example, the device colours were modified from the initial cream-coloured docking device with green/red clips to yellow clips and a purple docking base. These colours add clarity in detection of missing swabs and were modified based on feedback that green/red clips could be obscured from blood-soaking and liable to error due to colour blindness.

Timed simulation (2023):

A timed simulation study with 40 maternity staff (doctors, midwives and maternity assistants) was conducted in 2023. Participants were shown a training video both with traditional swabs and iCount. Participants in pairs then conducted eight timed, simulated stations.

The focus was to assess the time taken to 'count in' and 'count out' swabs as well as calculate actual 'blood loss' as is the gold standard with every vaginal birth.

The station designs are as below.

Station 1: two-person pre-procedure 'count-in'. Assistant confirms and documents the number of swabs on a whiteboard.

Station 2: one participant simulates swab use inside a model perineum (untimed) and then conducts a timed postprocedure 'count-out'. Assistant confirms and documents on the whiteboard.

Station 3: participant measures the swabs weight 'pre-procedure' and the assistant documents the weight.

Station 4: participant soaks the swab and places it inside the model vagina (untimed, simulating using the swab to suspend bleeding) and then conducts a timed removal of the swab followed by placement on scales to calculate measured blood loss. This is done by calculating the weight difference between preprocedure and postprocedure swabs which is then documented on the whiteboard by the assistant.

These four stations are then repeated using the iCount device, maintaining the same participant roles, thereby establishing eight data points.

To omit a potential confounding 'training effect', pairs were allocated to start with either normal swabs or iCount randomly—ensuring there were equal numbers for both. This aimed to eliminate skew that could arise from participants naturally getting quicker as they progressed through stations due to the development of increased competency with procedures.

The participants were then asked to complete a short-structured questionnaire focusing on their perception of efficiency and safety when using the iCount device compared with normal swabs.

RESULTS

Simulation study

The mean total counting time using traditional swabs and iCount was 41.06 s and 25.96 s, respectively. This represents a 36.8% reduction in the time taken to count in and out one set of swabs. A single-tailed, paired t-test demonstrated a p value of 3.91E-5 indicating a statistically significant difference (figure 2).

The mean total weighing time using traditional swabs and iCount was 28.24 s and 23.76 s, respectively representing a mean reduction of 15.9% in the total weighing time for a set of swabs when using iCount. A single-tailed, paired t-test demonstrated a p value of 0.031 again indicating statistical significance (figure 2).

Questionnaire data from timed simulation

Structured questionnaire feedback indicated that 100% of participants believed it was easy to spot a missing swab with iCount and that the device increased their confidence when conducting swab counts. 100% of participants also agreed that the device was simple to use and could be integrated as part of a systems-based solution to improve safety in maternity.

DISCUSSION

Medical device development can be a challenging yet fulfilling journey. Our development process has been problem-focused with end-user feedback as a cornerstone. With 60% of NHS institutions surveyed reporting 1–10 swab incidents within 3 years, supporting healthcare workers to eliminate error has been our north star. The device was accepted to be easier, more efficient and accurate for swab counts than traditional swabs with most users agreeing that this would increase safety. User feedback has been integral to both device and training development including development of a training video to tackle issues with a lack of familiarity with the device. It was also suggested that loose swabs should not be used along with this device as it can cause confusion and hence the operating procedures were modified to reflect these concerns.

Timed simulation highlighted a statistically significant time reduction for both counts and weighing times. In numerous childbirths where multiple swab packs are used (and hence multiple counts required) it can be assumed that efficiency savings would be multiplied further. In addition, the incorporation of an insert denoting the dry weight of the iCount device encourages and streamlines the weighing process—likely increasing the monitoring of blood loss in procedures. There is good evidence that routine measurement of blood loss also facilitates better management of postpartum haemorrhage.[22 23] Although not assessed in this simulation study, the potential time saving implications

Paired T-Test and CI: total Traditional swabs vs total iCount (Counting Time)

Descriptive Statistics

Sample	N	Mean	StDev	SE Mean
Trad swabs	20	41.06	12.81	2.86
iCount	20	25.96	7.40	1.66

Estimation for Paired Difference

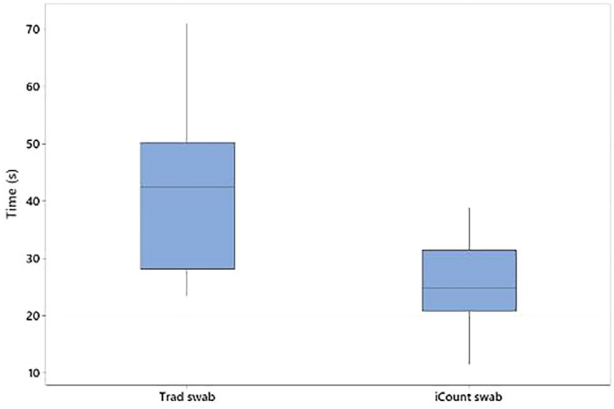
Mean	StDev	SE Mean	95% Lower Bound for μ difference
15.11	13.49	3.02	9.89

μ_difference: population mean of (total - total_1)

Test

Null hypothesis	H_0: μ difference = 0
Alternative hypothesis	H_1: μ difference > 0

T-Value	P-Value
5.01	0.000



Paired T-Test and CI: total Traditional swabs vs total iCount (Weighing Time)

Descriptive Statistics

Sample	N	Mean	StDev	SE Mean
Trad swabs	20	28.24	10.37	2.32
iCount	20	23.76	8.75	1.96

Estimation for Paired Difference

Mean	StDev	SE Mean	95% Lower Bound for μ difference
4.47	10.13	2.26	0.56

μ_difference: population mean of (total_2 - total_3)

Test

Null hypothesis	H_0: μ difference = 0
Alternative hypothesis	H_1: μ difference > 0

T-Value	P-Value
1.98	0.031

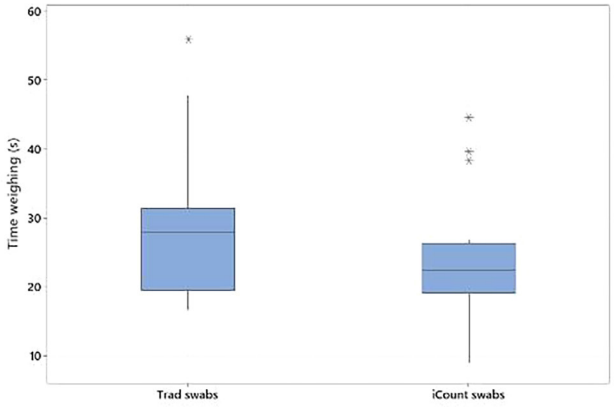


Figure 2 Statistical analysis of the data looking at combined counting times (counting swabs in and out) and combined weighing times (weighing swabs in, out and calculating blood loss) for both traditional swabs and iCount. This establishes the total time burden attributable to these processes for one set of swabs using each method—allowing direct comparison.

in cases of missing swabs are compounded further as iCount would likely identify these issues quicker (with visual cues) and hence enable quicker reconciliation.

Sustainability is of paramount concern when designing future healthcare development. While iCount contributes to the burden of single-use plastics in surgery, it offers compelling potential benefits to patient-safety, efficiency, clinician confidence and reduced readmission rates that justify additional plastic use. We are currently exploring production methods that use recycled plastics to further reduce the environmental burden of the device.

Limitations

Simulation lacks the scope to assess iCount's effect on safety with regards to the reduction/elimination of swab miscounts and retention events. While users perceive iCount to increase safety and confidence in counts, clinical testing is needed to quantify and demonstrate this benefit. Furthermore, there are well-acknowledged limitations of simulation studies including the 'artificial' nature of the testing environment limiting transferability of results to the clinical setting and the potential for individual bias when collecting qualitative data.[24]

Surrogate markers of efficacy such as time reduction offer a cost benefit to NHS trusts and qualitative data on user perception demonstrates increased confidence and speed when conducting counts. However, a clinical trial comparing iCount to the current gold standard is necessary to assess transferability to clinical practice. Such a trial is planned to take place in an NHS trust following iCount's preclinical approval process as per MHRA and UK-Medical Device Regulation.

CONCLUSION

iCount was conceived with the core principle of 'safety through design'. The device reduces error by organising work processes and increases awareness of task-related

human behaviour to create a system-based solution to vaginal swab retention. While significant work has been conducted to encourage safe human-behaviour and implement policy change through NatSSIPs, a design solution would be valuable to complement this. Although it is yet to be proven clinically, this paper presents compelling data to show the potential time saving and hence cost-saving implications of iCount while concurrently promoting safe and accountable practice.

User feedback has indicated that maternity staff feel more confident in the accuracy of swab counts when using iCount. Meanwhile, the increased efficiency offered by the device makes monitoring of important clinical parameters like blood loss easier and hence reduces barriers to safe practice.

The potential for further iterations to incorporate AI models with visual aid to monitor and confirm swab counts presents further value in the journey to eliminate swab retention.

While iCount presents an exciting innovation, there remains a necessity for training and culture change within current workflows to achieve system resilience.

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Contributors ANE conducted a timed simulation as part of the research academic placement during his specialised foundation programme. AMN conducted the statistical analysis. PO, JL and AF developed the prototypes. JF of NIHR Trauma Management MedTech Co-operative led by TC-B conducted the scenario simulation usability. EB and CR from Keele University did the innovation support project understanding role in safety critical systems and psychology behind human error. AD and ANE drafted the article.

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Competing interests ANE has received payment from Eureka Inventions through the Innovate UK grant-funded project towards disseminating the research findings. AD and KD are inventors and directors of small-medium enterprises (SME), which are the primary grant holders. Participants taking part in the simulation gave informed consent before participation and were given modest value vouchers in recognition of their participation.This project was supported by the NIHR Trauma Management MedTech Co-operative. The views expressed are those of the author(s) and not necessarily those of the NHS, NIHR or the Department of Health and Social Care.

Patient consent for publication Not applicable.

Ethics approval This study involves human participants. As this was a simulated study conducted in the simulated environment no ethics approval was required as there was no exposure to potential clinical harm for participants and there was no patient involvement. The participants gave informed consent prior to participation in the study and signed consent forms as a record of their consent.

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