

Retained vaginal swabs – The single most commonly retained item in UK healthcare

A vision to try 'Design out' the error
Get it as low as reasonably possible
With Human Factors- Ergonomics

2012-22



Slides 19-24 contains information about iCount system in different settings

A real story



- Sheila (name changed)– first-time mum
Gave birth to a lovely baby boy by forceps birth
- Had severe pain and foul-smelling discharge for days after birth
- Saw GP and midwife twice
- Brought in as an emergency with Sepsis
- Found to have a retained vaginal swab
- Pelvic infection
- Admitted in Intensive Care for a month
- Problems continued for a long time
- The registrar involved left the specialty. Midwife took early retirement

Facts of interest

Near-misses
(miscounts) in 2-5%

2012-2020

Retained foreign objects
901 independent events.
HES data shows possible
underreporting

First reported in 1884
by Dr Wilson

70% re-interventions,
80% morbidity
35% mortality in
Surgery

3 deaths in England
(last 10 years)

Swabs are the single most
common item retained –
vaginal swabs commonest
(UK)

The hindsight documentation always looks perfect.. Like here, where a swab had been retained

Patient Woman Lists Baby Lists Risk Lists Unit Reports Handover Unit Tasks Service Console CTG Traces eLearning

Enter new note...

Pregnancy Summary

Notes During Pregnancy

Fetal Medicine

Labour and Birth

Postnatal

Full Notes (Woman)

Social

Anaesthetic Summary

Perinatal Mental Health

Clinical Narrative

Task List

New Notes

Baby 1

Overview

Summary of Care

TC/PNW Care

Full Notes (Baby 1)

Labour and Birth

Summary Labour Onset Partogram Fluid Balance First Stage Second Stage Birth Third Stage Baby

Third Stage

Notes recorded (0)

Third Stage

Date/time placenta birthed

Placental birth method Controlled Cord Traction

Placental appearance Normal

Placental completeness Apparently Complete

Baby cord vessels 3

Episiotomy No

Tear 2nd Degree Tear - Perineal muscles but not involving the anal sphincter.

Blood Loss (first 24h) 300 ml

PPH No

Observations

SWAB, NEEDLE, TAMPON AND INSTRUMENT COUNT

Date and Time Recorded at 22:39,

Type of Pack Suturing

WHO checklist completed Yes

Pack Number 0

Pack complete following usage Yes

Size of swabs Medium

Swabs/mops checked by

Number of Pre Repair Swabs Used 5

Number of Post Repair Swabs Used 5

Number of Swab Recovered 5

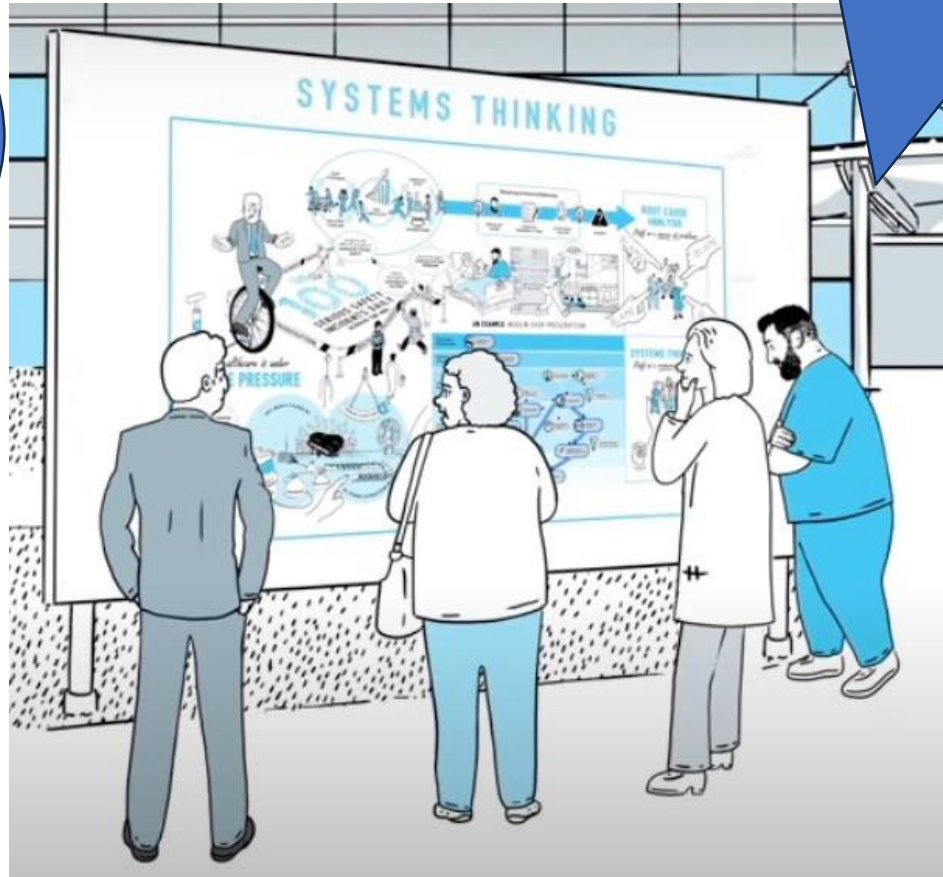
Swabs Checked By

Culture change - 'systems thinking' approach for reliability and resilience

Be more careful !
Counts are the midwife's or
doctor's job.
If a swab is retained, they
have not followed policy.
It's their fault !



The cause of incidents is
multifactorial, and staff are
accountable. But...
How do we make it easier for staff to
do the right thing?



1. Human Factors Analysis

2. Mapping action needed

- Engaging stakeholders
- Adoption sites
- Training package
- Champions
- Measuring impact –

Staff confidence

Near misses

Electronic medical records

Retention incidents

It started as a standard QI project and our team expanded

One of the team members went back to University (Loughborough) to do a qualification in human factors- Ergonomics and Patient Safety

Doctors, midwives and nurses

Theatre operating department practitioners

Psychologists – Keele University Biomedical engineers

Design engineers

Product manufacturing Engineers, Environment Sustainability Consultants

Medical technology consultants

Patient Public Involvement liaison – NIHR Surgical HRC, Leeds

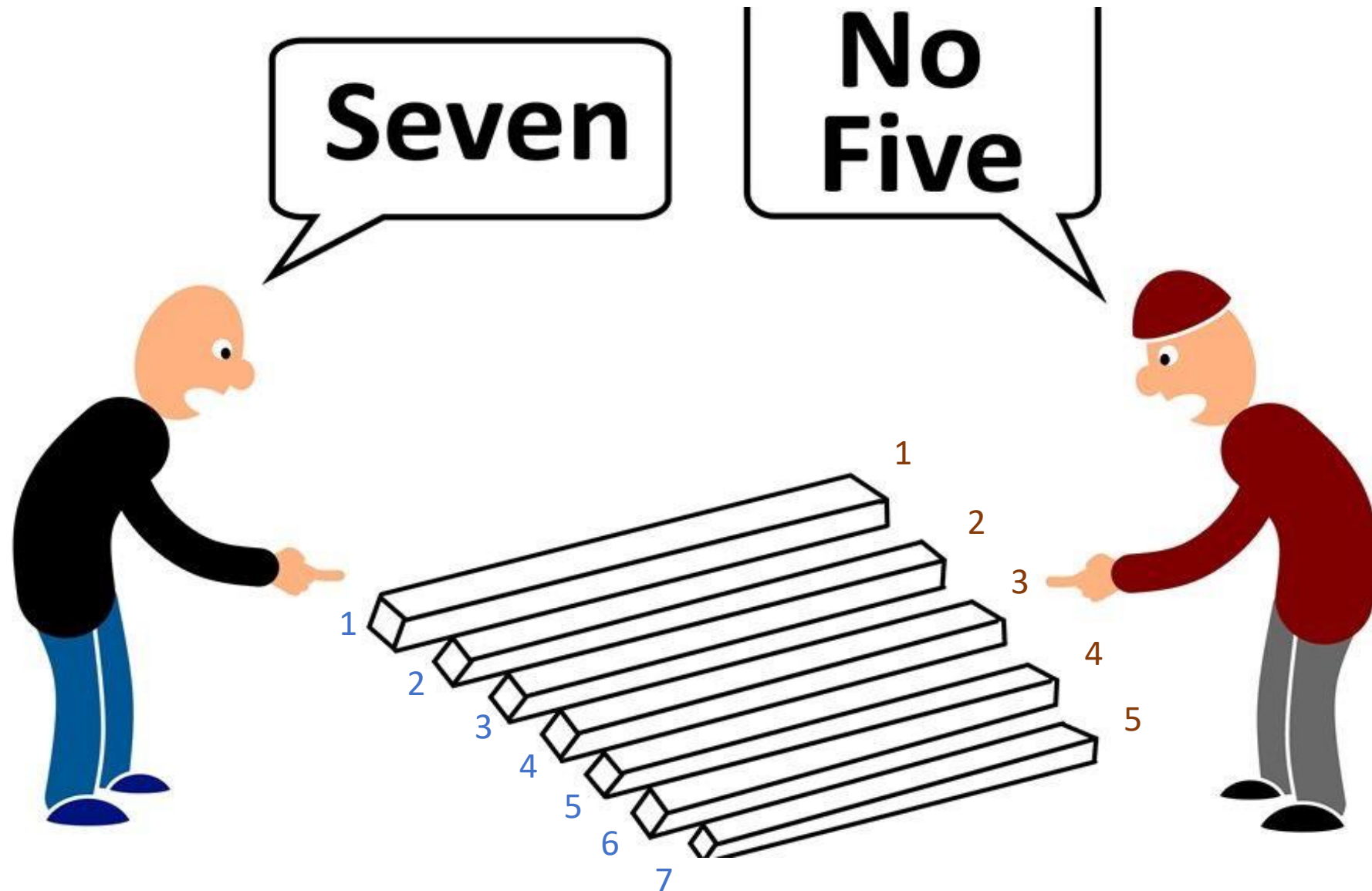
Our Collaborators and Supporters





Why ?

- Difficult to visualise
- Swabs look like body organs
- High pressure situations
- Competing priorities
- Long shifts



SEIPS 2.0 framework used to map the counts process - traditional/iCount embedded within



Tools and Technology

- Swabs held together with a red string in procedure packs OR separate packs
- Whiteboard for documenting count pre- and post-procedure
- Obstetric information system available on handheld iPads
- iCount docking device and swabs +/- software to integrate with electronic medical records

Environment

- Labour room
 - Limited space for patient, family members, baby resuscitaire
 - Labour is dynamic and unpredictable
 - Additional equipment may be brought into room (e.g. assisted birth with forceps)
- Delivery suite may be noisy and distracting
- Theatre : Patient may be transferred there with swab in situ (in the vagina)

Processes

Physical-Cognitive-Social

- Vaginal birth
 - Collaborative work
 - Indirect involvement - patients/ carers
- Traditional Swab Count process - Person conducting delivery/perineal repair. Counter-check done by assistant (not an independent check). Whiteboard documentation done by assistant
- iCount- Visual reminder - physical checklist. Reminder for staff Computer vision check of count tally (optional) Software integrated with electronic medical records recognise and allow completion of birth episode.

Outcomes

Reduction in retained swabs positively affects patients, staff and organisation:

Proximal outcomes - safer births, collaboration, safety culture

Distal Outcomes - Patient experience, trust, Team job satisfaction Optimal Key performance, lower litigation, high reputation long-term cost-saving

Patient

experience, workload, time of the day

Team: Midwives, Maternity Support Workers
Obstetricians (postgraduate doctors and Consultants)
Anaesthetists
Midwife coordinator

Tasks

- Get procedure pack/ swab packs in preparation for vaginal birth.
 - 2 person checking count,
 - Whiteboard documentation before and after.
 - With iCount - check all plugged in (+/- computer vision bar-code check on pack).
 - Post procedure computer vision check and upload to electronic records
 - Software completes birth episode.

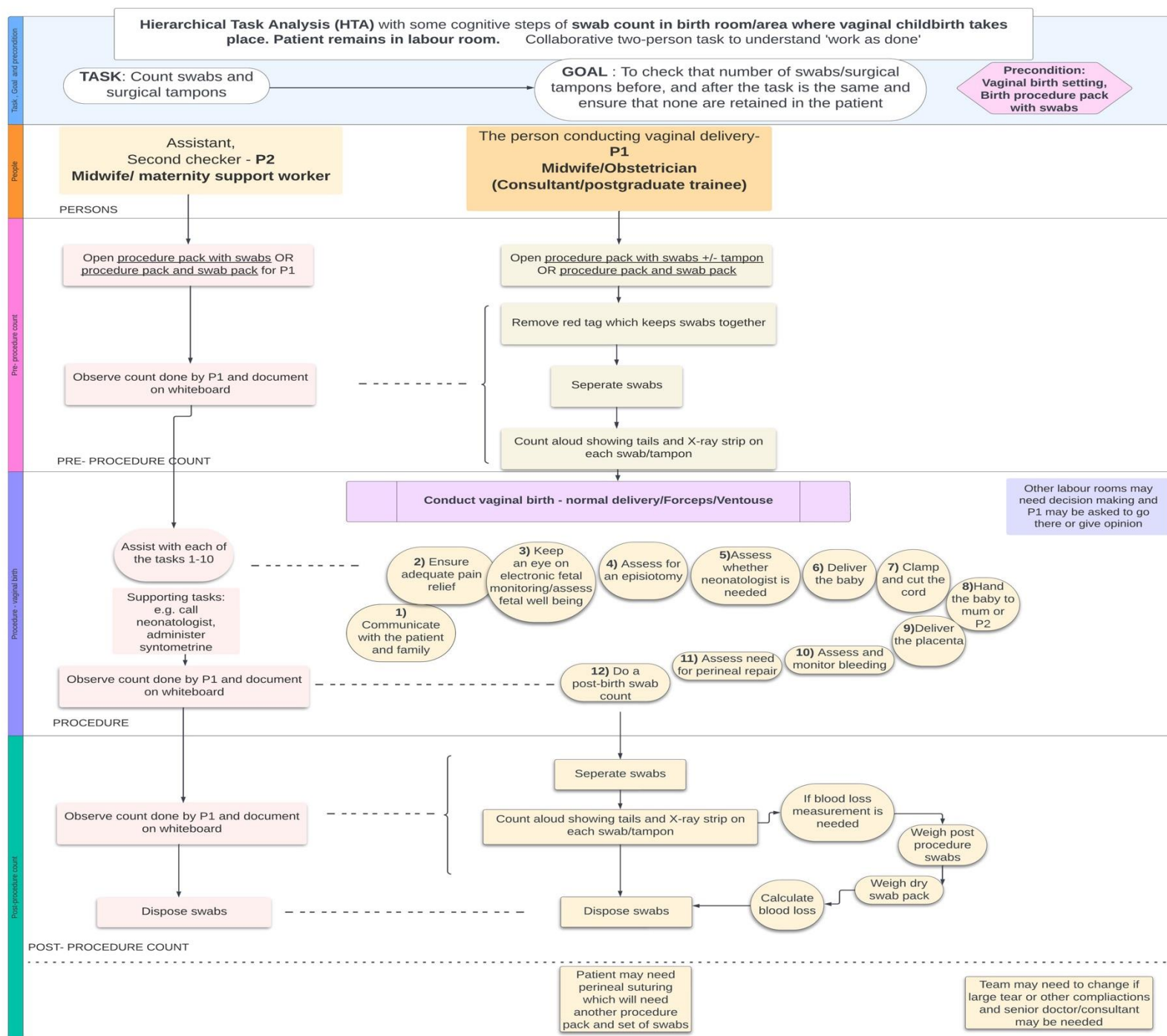
Organisation

- Providing strategic leadership and management:
 - Policies - LocSSIP*
 - Resources required for a safe count practice
 - Staff rosters, shift patterns and staff numbers for safe working
 - Good work culture

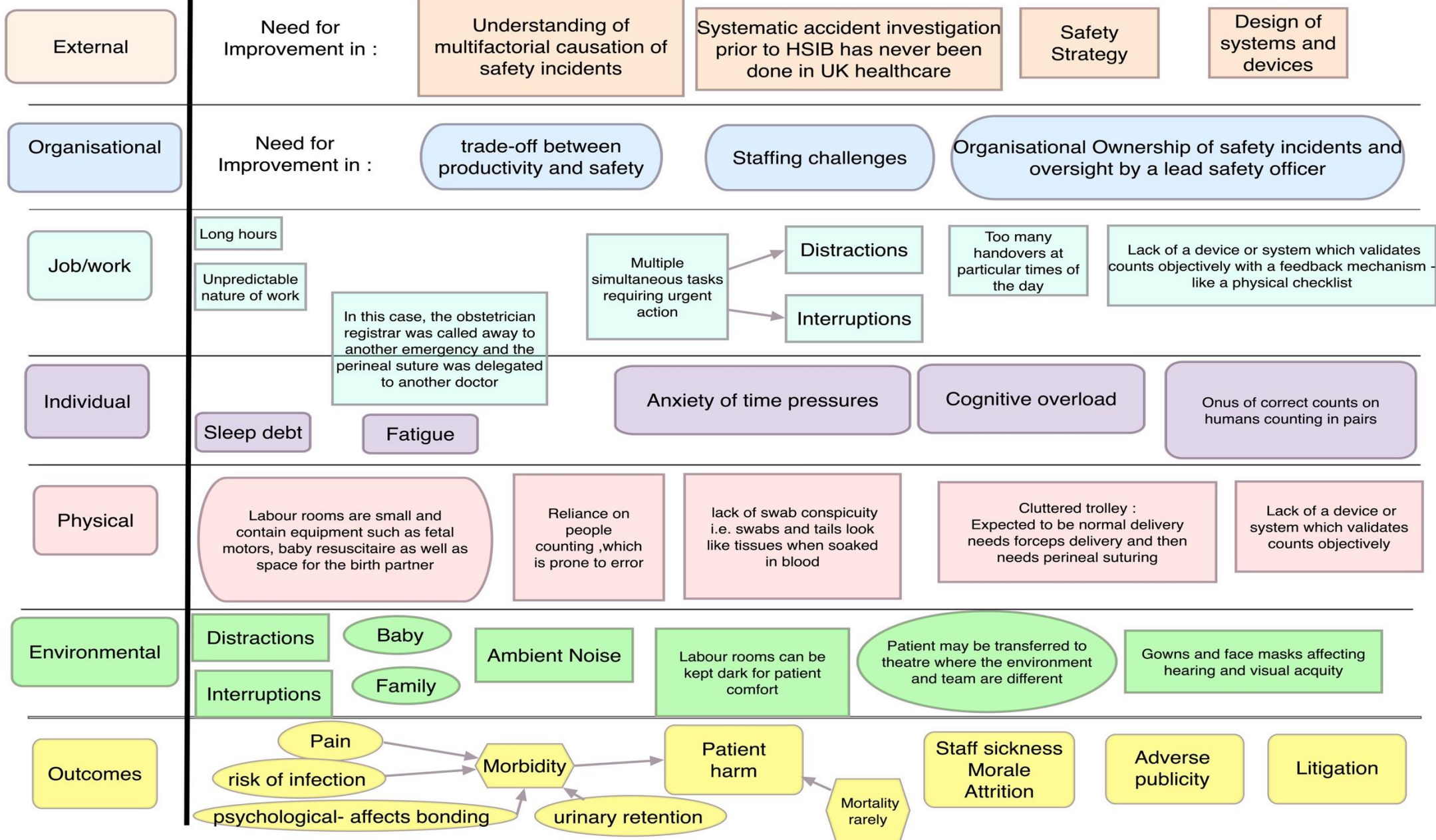
External environment: Retained swab classed as a patient safety incident – never event. -National Safety Standards of Invasive Procedures (NatSSIPs 2),
-Postnatal care guidelines,
-Funding, procurement policies

*LocSSIP- local safety standards in invasive procedures

Hierarchical task analysis- Understanding Work as done (WAD)



ACCIMAP- incident of retained swab after forceps delivery in labour room



Main Causative and contributory factors

- *Swabs change shape and colour*, can become sticky and look like body organs
- *Confirmation bias* during 2-person counts
- *Change in the team* either within the labour room or if the patient is transferred to theatre

Contributory :

- Competing task priorities
- Inadequate staff
- Environmental factors- ambient noise, low light conditions, masks, gowns



Two sides of the coin working together

Encouraging Human Behaviour

- Policies and Procedures
- Training
- Civility
- Situational awareness
- Teamwork
- Communication



Design and System Engineering

Design solution :

Aim- Task aid which acts as a counter minimising the risk of retention.

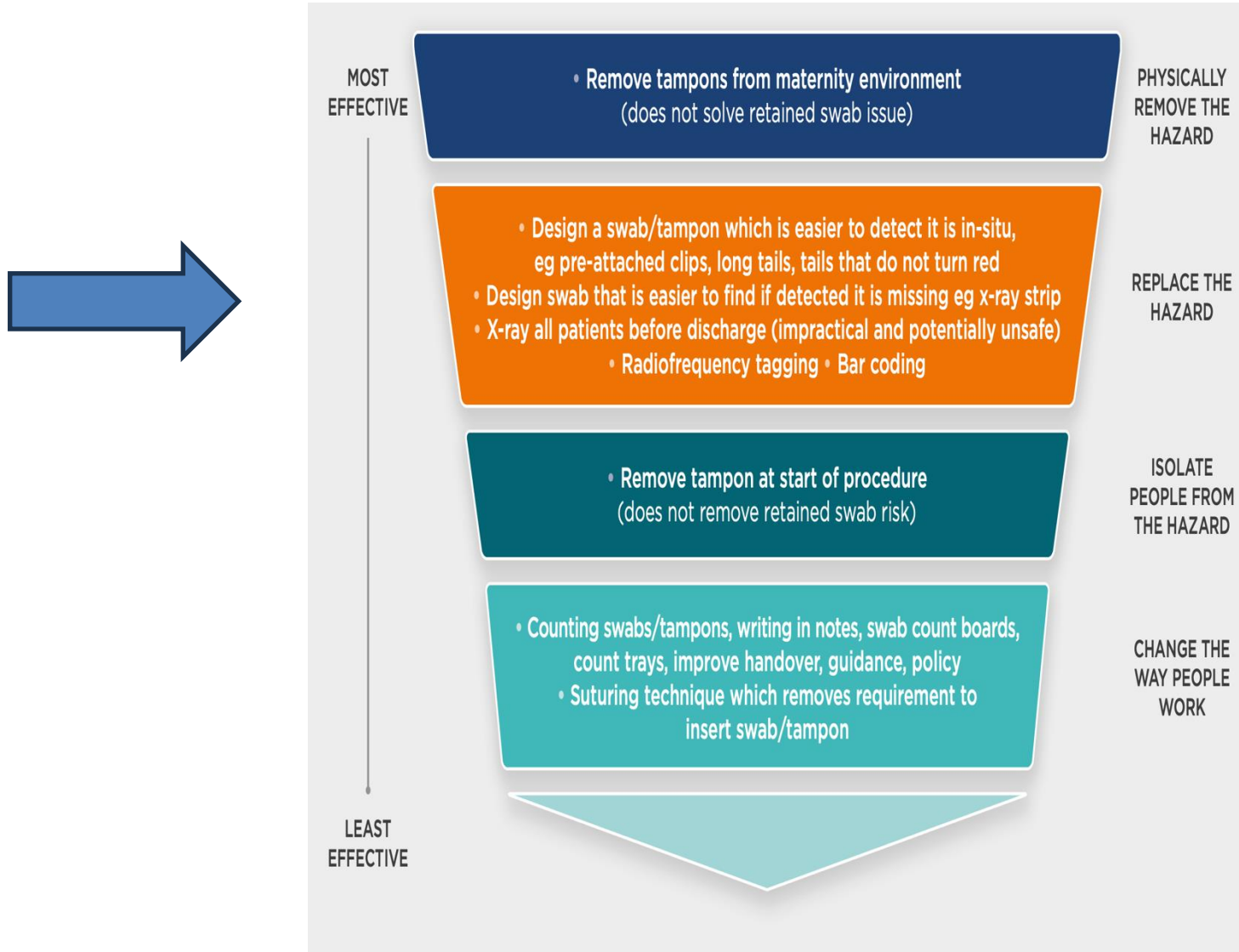
Identify design specifications

User-centric Design

Design- Build – Test iterative cycles

HSSIB investigation (2019 report)

Intervention effectiveness hierarchy



Design specifications for surgical-swab counter

Must haves :

Act as flags (signifiers) for each swab

Be able to separate each swab

Show the correlation between how many in and how many out

Count in 5s for count-out similar to count-in

Keep task in the sterile field (to avoid communication and transcription errors)

Low cost

Empowering the clinician with a device that acts like a physical checklist in sterile space

Nice to have :

Help with disposal

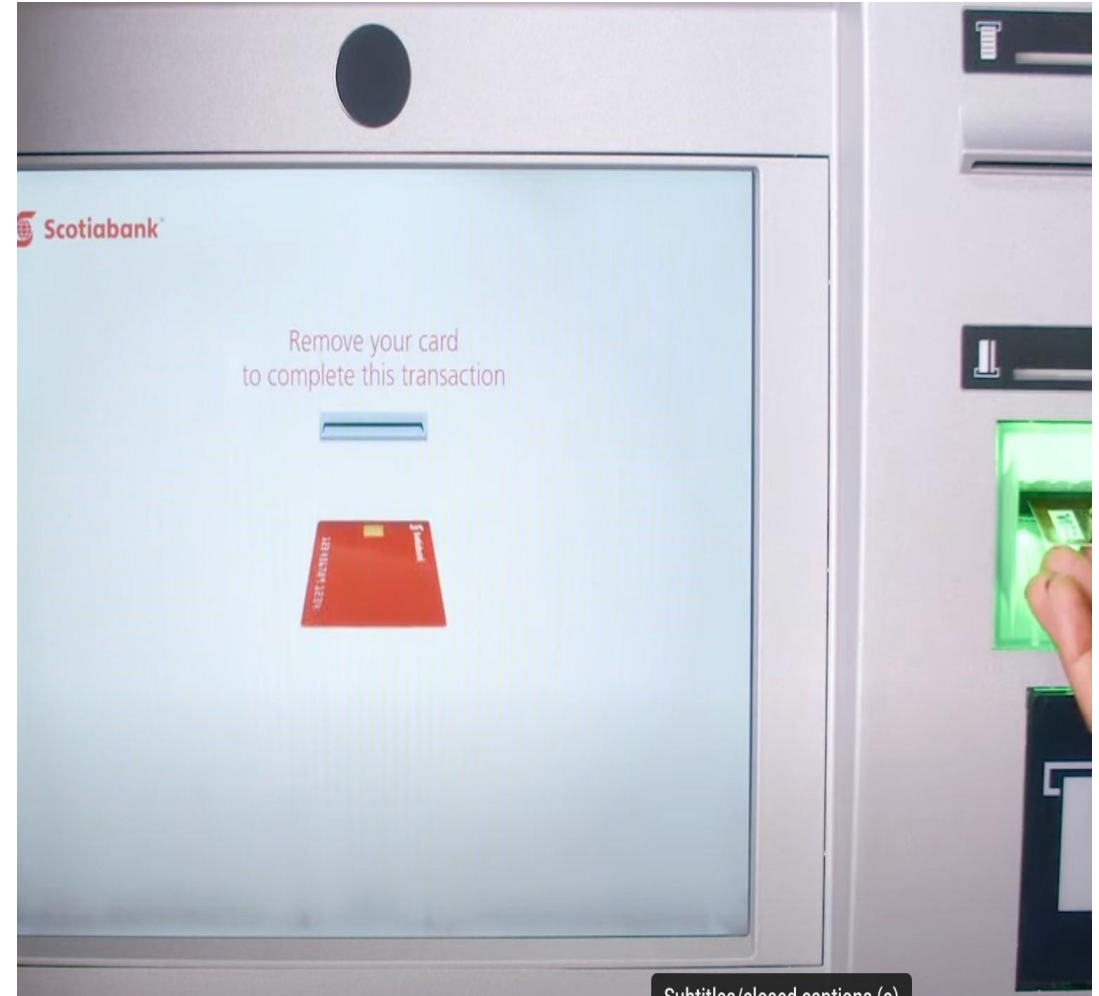
Integration with electronic medical records

Reusable ? (only possible if Sterilisation services department can ensure devices match number of swabs)



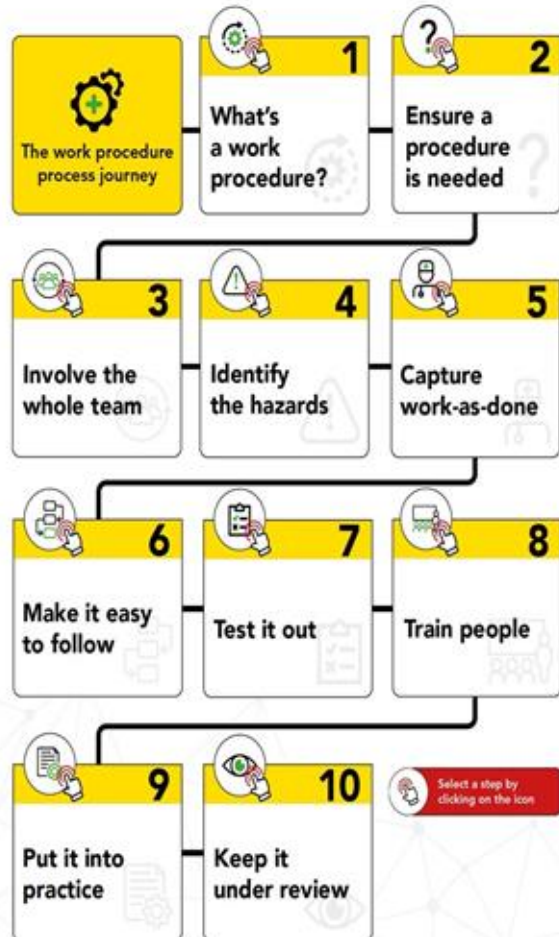
Real-life example of design intervention

- Cash machines were first introduced,
- No prompt to remove the card first **before** dispensing cash
- Thousands of cards got left in
- **The software was changed** to have a prompt.
- Cash would not be dispensed unless the **card was removed**.
- That stopped people leaving the card



Ten key steps to design work better

Make your work procedures **safe** and **easy-to-use** for person-centred care

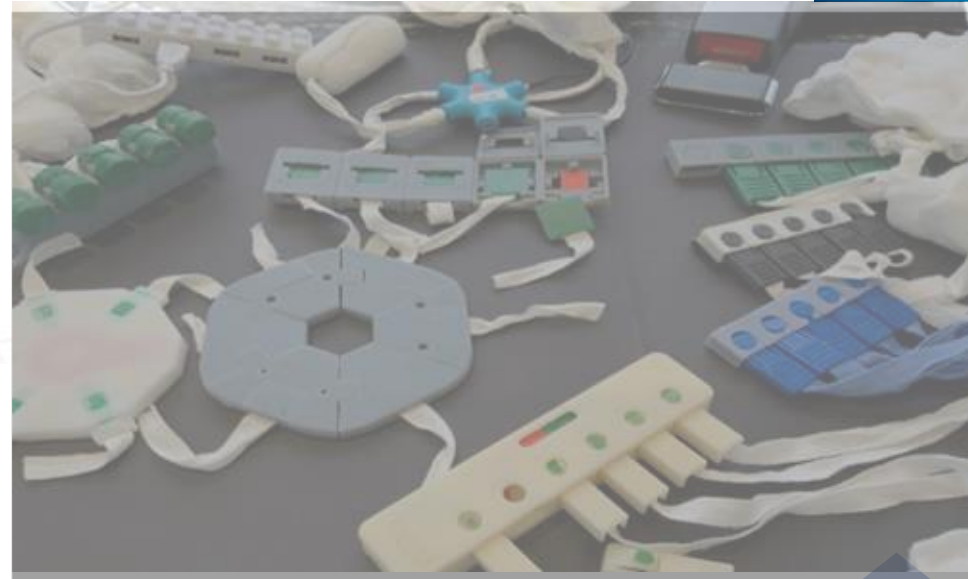


3 high fidelity simulations, usability by NIHR MD-Tec, University hospitals, Birmingham

4 in-hospital simulations and usability testing

18 design iterations with cycles of user feedback

Some of the prototypes



iCount Clip system for large tailed swabs (vaginal births)



Sterile swab Docking Clip – simple design



See swabs clearly and Count them accurately – A physical checklist



Patents 'granted' status in UK, Europe, USA, China and Australia

 Use swab ➡  Dock swab ✓ Confirm count



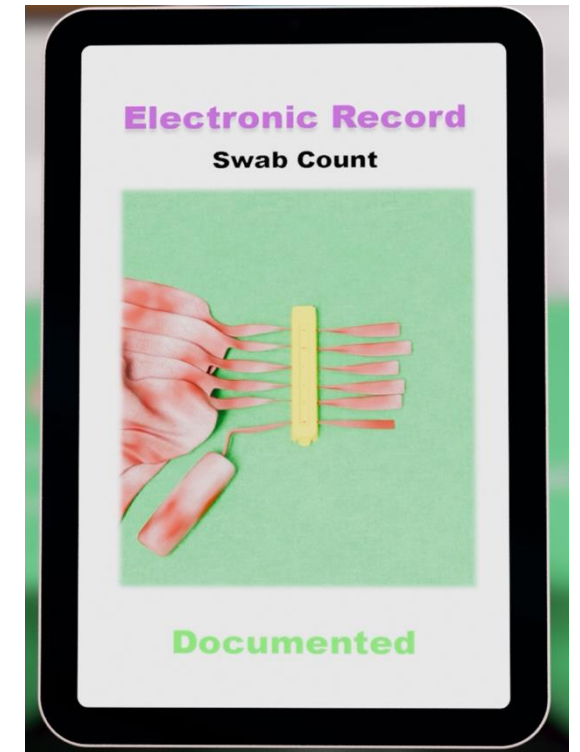
take photo for electronic records and audit (optional)



iCount™ in vaginal births Workflow: Counting & Reconciliation

Physical components :

- iCount clips for tailed swabs within sterile procedure packs with numbers co-ordinated with number of swabs
- Additional swabs used can be supplied as a swab – iCount clip pack
- iPad/tablet for taking the photo for a robust audit trail/
Or using computer vision app(still being refined)



iCount™ in vaginal births Workflow: Counting & Reconciliation



1. Staff Preparation
Sensitisation,
engagement
& training

2. Pre-op Count
In-count as
standard or clip
can be used

3. During Procedure
Swabs →
Clips

Additional
swabs →
Swab-clip
pack

4. Reconciliation
Empty slot =
Count
incomplete

NO EMPTY SLOTS =
COUNT COMPLETE
✓

**6. Audit trail-
Digital
Verification**
Photo/
Computer
Vision
verification
with real-
time alerts

**5. Only
dispose
with iCount
clip**

7. Discrepancy
Action
Follow SOP
Search in the
vagina + room
EUA –
X ray - CT

-
- [Click here - Link to IFU video](#)

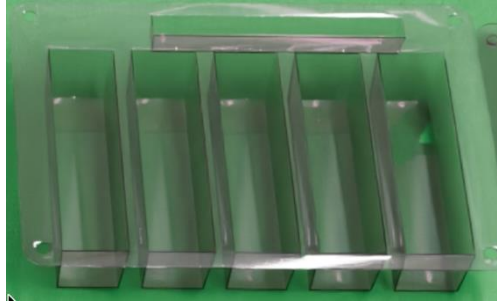
For maternity – vaginal birth settings



iCount™ draft Colposcopy Workflow

(development after 9th June'26 meeting for further iterative and adaptive work):

Counting & Reconciliation



NO EMPTY SLOTS = COUNT COMPLETE ✓

1. Staff Preparation

Sensitisation,
engagement
& training



2. Pre-procedure Count

Manual count
Record in-count and running count



3. **During Procedure**
Small swabs balls → Trays
We are confident that your provider can provide 5 swab balls and a tray together in a combined pack as they are likely to be one of our partners



4. Visual Check

Empty slot is a visual signifier
=
Count incomplete



5. Reconciliation

Count trays
against in-count



6. Audit trail/ Photo –

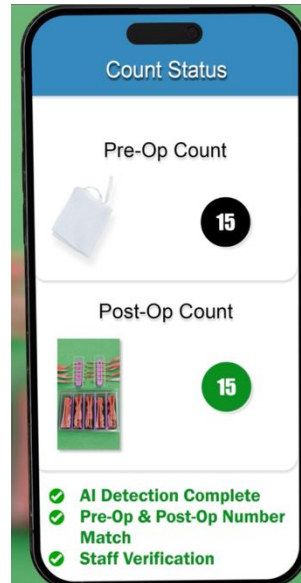
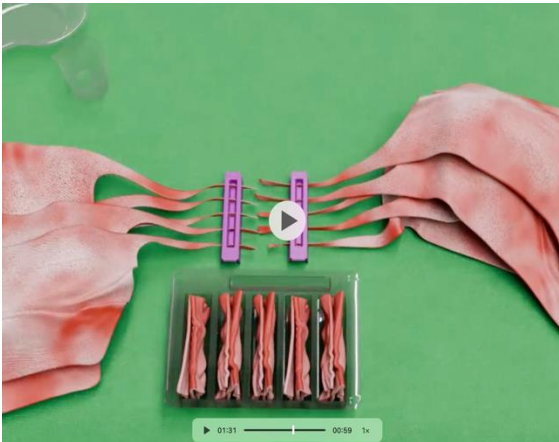
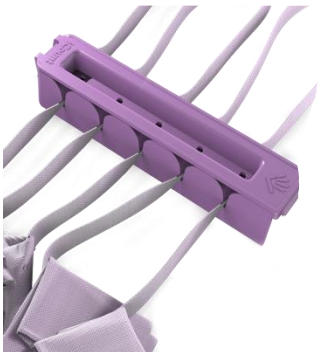
?? Opportunity for photo – Only if feasible within colposcopy electronic database

7. Discrepancy

Follow SOP – Search – surgical sweep- – further steps

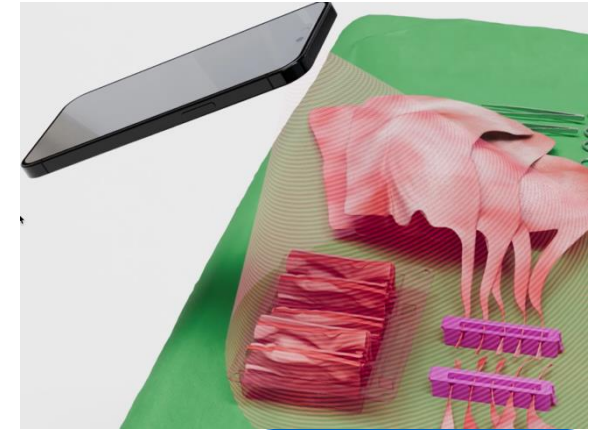
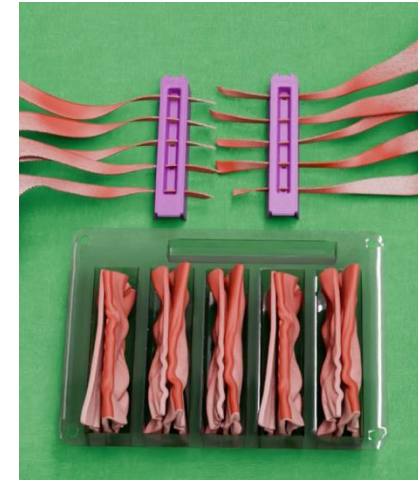
iCount in Surgery

[Click here - Link to iCount in Surgery - Operating rooms Explainer](#)



- Simple Design
- Acts as a physical checklist
- Clips for tailed swabs
- Trays for small swabs
- Included within sterile procedure packs and if needed, additional packs
- Count is complete when all docked in. No empty slots seen
- Optional Computer vision-AI verifies count and integrates with Electronic Medical Records (still being developed to improve accuracy)

iCount™ in Operating Theatres- Surgical Workflow Counting & Reconciliation



1. Staff Preparation

Sensitisation,
engagement
& training

2. Pre-op Count

Manual count

Record
in-count and
running count
on
Whiteboard/
CV App

3. During Procedure

Tailed
swabs → Clips

Small
swabs →
Trays

4. Visual Check

Empty slot =
Count
incomplete

5. Reconciliation

Count trays & clips
against in-count

6. Audit trail/ Photo

- Arrange
trays and clips with
docked swabs on a
separate trolley
and take photo
And of whiteboard
(if possible)

Digital Verification

Computer Vision
verification
with real-time
alerts

NO EMPTY SLOTS = COUNT COMPLETE ✓

7. Discrepancy

Follow SOP – Search –surgical
sweep- X ray – further steps

First Adopter sites EHR to store a photographic swab-count reconciliation audit record OR

Computer vision-AI digitally verified swab-count reconciliation record?

Environmental Impact of iCount

Life cycle analysis by Clean Atmos international

Carbon Reduction

~18% lower emissions per procedure
≈ 0.17 kg CO₂ saved per case

1,000 procedures = ~174 kg CO₂ saved

Water Savings

~45% reduction in water use
≈ 368 litres saved per case

1,000 procedures = ~368,000 litres saved



That's ~4–5 bathtubs of water saved per patient

A safer swab system with measurable sustainability impact
aligned with NHS Net Zero goals





Following our discussion: two potential high priority areas:

Area	Current issue	Potential iCount adaptation
Maternity	Tailed swabs	iCount clip in procedure pack and with individual packs of 5 swabs
Colposcopy	Loose swab balls Could all swabs be standardised into packs of 5 ?	Combined offering: Pack of 5 swab balls + iCount tray

Our partners now - Unisurge and Others have a good presence in these areas of practice



We cannot change human nature
(We all make mistakes),

but we can change the *conditions*
under which people operate to make
mistakes *less likely,*
easier to detect, and
easier to correct.

-Prof James Reason

A blue ribbon graphic with a 3D effect, featuring a dark blue shadow on the left and bottom edges. The text "Thank you" is written in white on the top surface of the ribbon.

Thank you

Questions for the hospital



CURRENT SYSTEM FOR
MANAGING COUNTS ?



HAS SEIPS BEEN MAPPED
OUT LOCALLY AND
WHAT ARE AREAS OF
PRIORITY ?



WHICH PROCEDURE PACKS
DO YOU USE?



WHICH SWABS DO YOU
USE AND FOR WHICH
SETTINGS?



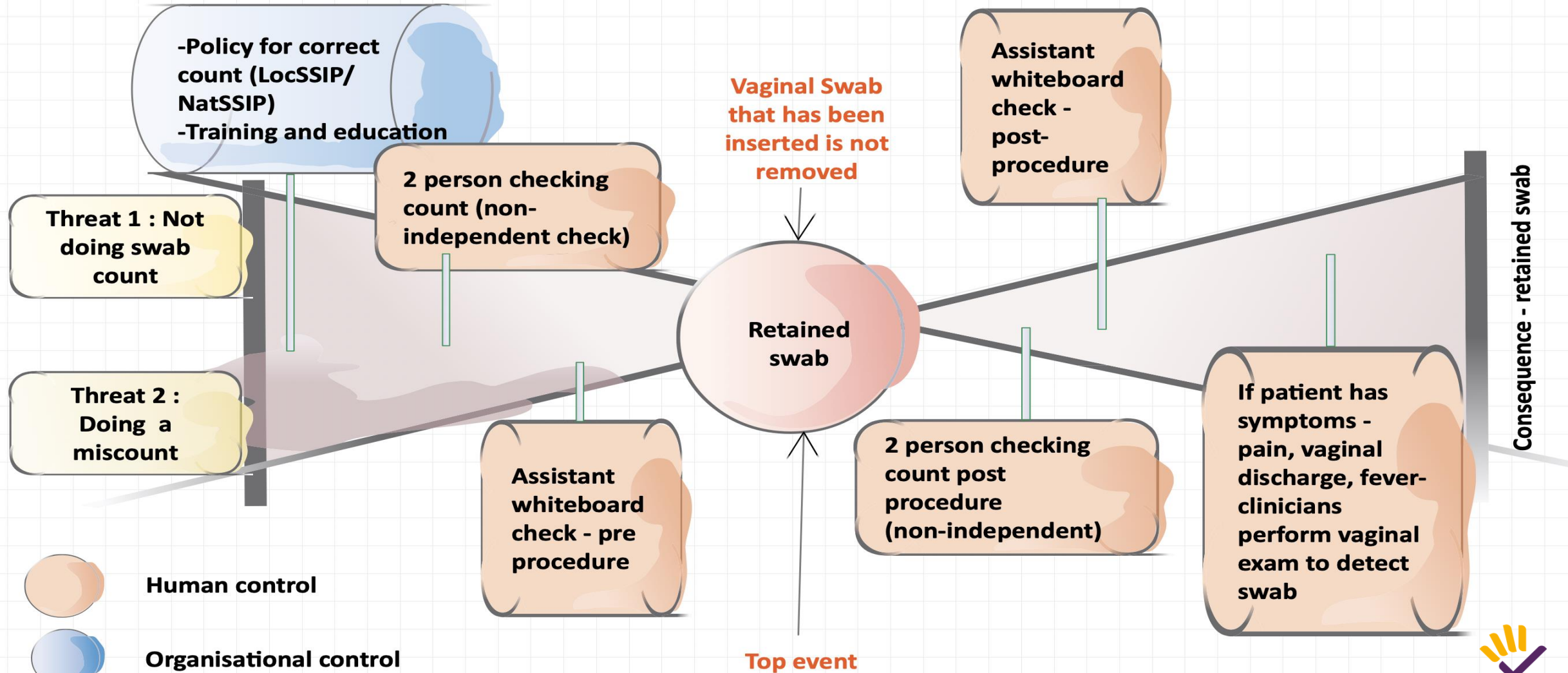
VIEWS ABOUT SYSTEM
AND DESIGN SOLUTIONS ?



INTENTION TO PILOT AND
PROVIDE FEEDBACK ?

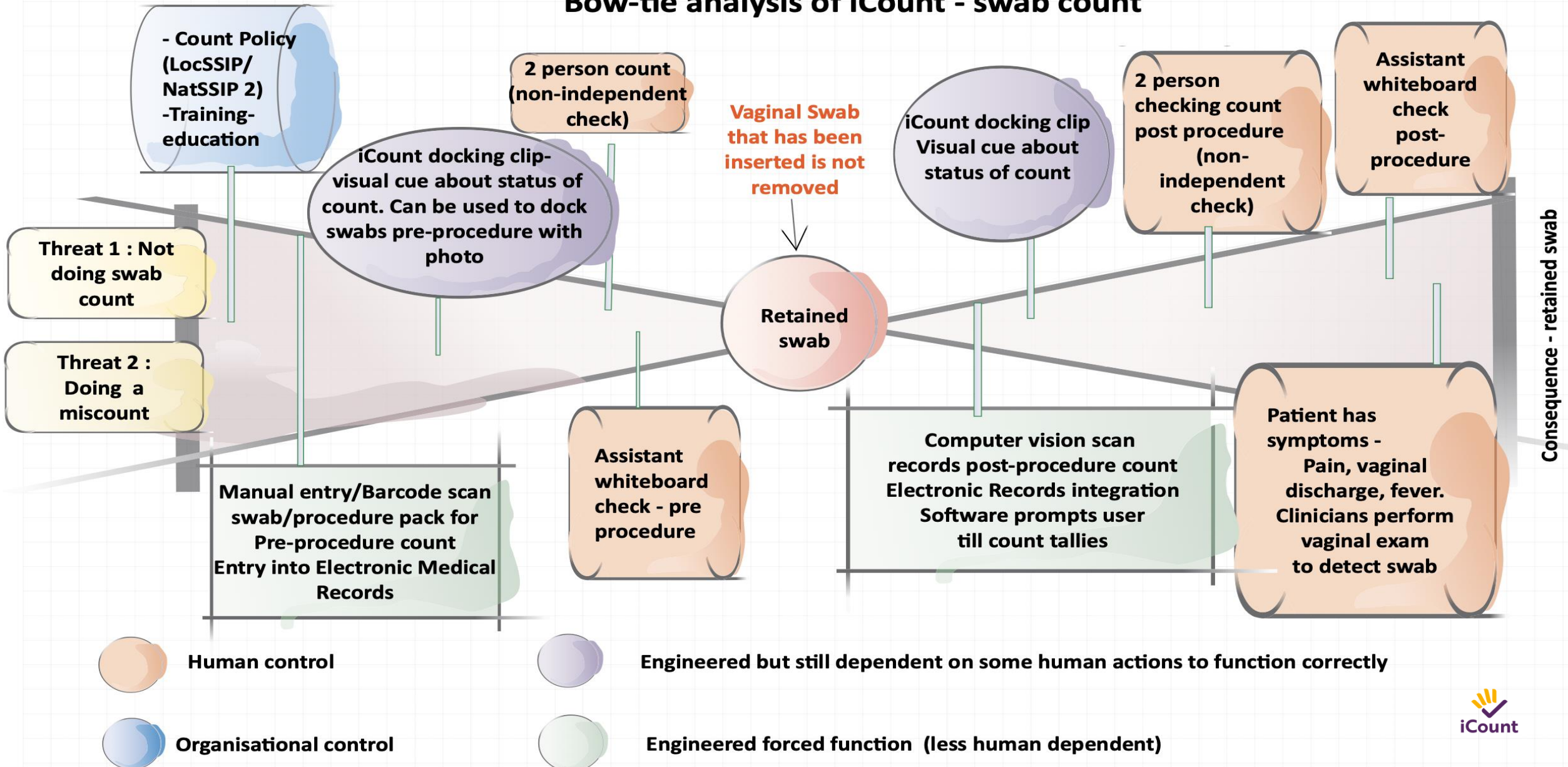
Assessing and Improving Human Reliability and System Resilience

Bow-tie analysis of traditional swab count in maternity



Assessing and Improving Human Reliability and System Resilience

Bow-tie analysis of iCount - swab count



Health Economic Analysis by York Health Economic Consortium – presented at a World Congress Health Economics Conference

Health economics: Cost-consequence model for an innovative device for prevention of accidentally retained surgical items (swabs)

Dr Aditi Desai¹, Samuel Harper², Dr Kiran Desai¹ & Joyce Craig²

1. Burela Investments- Med ICA, University of Keele, ST5 5NL, UK.
2. York Health Economics Consortium, University of York, YO10 5NQ

Background of problem and intervention developed

In UK, retained swabs after vaginal birth and perineal suturing are classed as "Never events".¹ Retained vaginal swabs have accounted for around 30% of retained foreign object -'never events' reported on an annual basis for a number of years.² Retained vaginal swab post delivery could cause significant morbidity. The patient may experience serious physical and psychological complications including infection, secondary post-partum haemorrhage, sepsis, depression, lack of bonding with their baby and loss of trust in the healthcare system.³

Although it is a rare event, there has been a case report of a maternal death from it. A retained swab is a "Never event" under the OOH Policy (Department of Health, 2013).

Annual Incidence of retained surgical items

According to never event data published by NHS Improvement (2019) retained foreign object is the second most commonly reported never event. Vaginal swabs are the most common retained foreign object reported and the surgical swabs, the second most common.

Swabs are anchored by their tapes into the device before and after procedures, creating a visible, countable array. The docking mechanism supports manual counting and complements standard protocols, reinforcing count fidelity with a 'physical checklist'. The aim is to ensure that all swabs are returned and not retained in the patient. ICount is a docking device anchoring all the swabs, thereby making it extremely unlikely to leave a swab behind.

Cost Consequence Analysis(CCA)

Cost consequence analysis (CCA) is a type of economic evaluation which assesses a wide range of costs and consequences of the intervention. It includes all types of effects including health non-health negative and positive effects of patients and other parties giving decision-makers a comprehensive summary of the costs and effects.

Advantages:
Simple broken-down (disaggregated) summary of costs and effects of the device. Includes a broader range of effects than other analyses, such as user experience and convenience of care

Disadvantage:
may be less generalizable because the choice of relevant costs and effects and the weighting attached to them is often context-specific

References

1. NHS England. Never Events List 2018/2019.
2. NHS Improvement. Never Events reported as occurring between 1 April 2017 and 31 March 2018 - Real update 2019.
3. Mahraz, M. A., Towler, E. & Morris, E. P. (2017) The mounting problems of retained swabs and interventions - Best Practice and Research: Clinical Obstetrics and Gynaecology, 37 (4): 489-495.
4. Health and Safety Executive (2019) Frequently asked questions: what is the hierarchy of control? (Online) Available at: <http://www.hse.gov.uk/cond/faq/hierarchy/>
5. NISRA, 2019a, Cost consequence analysis

Health Economics, Health Policy and Healthcare Management

September 10-11, 2023 London, UK

YHEC

Decision Problem, Model structure and pathways

Population Women undergoing vaginal birth, Alternative population of people undergoing abdominal surgery available in the model
Intervention ICount device system with surgical swabs/surgical tampon
Comparator Standard care comprising of standard 5 surgical swabs
Perspective NHS. Outcomes Costs, Economically justifiable price of the device (break-even price)

Results	Intervention	Comparator
Mean cost per patient	£229.50	£229.50
Mean cost per patient (95% CI)	£229.50 (229.50, 229.50)	£229.50 (229.50, 229.50)
Cost difference (95% CI)	£0.00 (-£0.00, £0.00)	£0.00 (-£0.00, £0.00)

The model displays the cost breakdown per person (countdown) cost line per person in each situation

The model displays the clinical outcomes. ICounted has more outcomes of correct swab counts, whilst standard care has more outcomes of incorrect swab counts and potentially retained swabs.

The EJP is £229.50

The unit costs included within the model were taken from national databases, including:
-PSRA for the costs of contact with various healthcare providers
-National Schedule of NHS costs for appointments in secondary care
-BNF for the costs of drugs
-Litigation costs are based on data provided in response to a freedom of information request (FOI reference number 3352 NHSLA litigation claims)

This model was presented in a focus group of Obstetricians, Midwives and Nurses. The data was modified to represent some probabilities more realistically and a graph was plotted. This never event leads to Total Direct costs per person shown in the table and graph

Limitations: this model uses many inputs which have values based on assumptions (usual with an early model). The model takes an NHS perspective and does not capture cost borne by the patients i.e. personal legal costs. It also assumes that there are no longer term impacts such as mental health disorders. Successful litigation claims may increase hospital payments to NHS resolution which have not been accounted for.

Conclusion

CCA helps decision maker understand how ICount compares to standard care for each individual cost and effect component by understanding incremental differences. EJP (estimated justifiable price for NHS) is at least £229.50. As ICount would likely cost less, it offers significant cost savings. The CCA helps to refine economic methods, identify relevant costs, outcomes and generate hypotheses for definitive cost-effectiveness studies. It will help to focus further health economic evaluation.

Consequence of retained swab

Additional examinations

Additional imaging

Investigation under PSIRF

Possible readmission

Litigation risk

Reputation impact

Impact

Patient burden

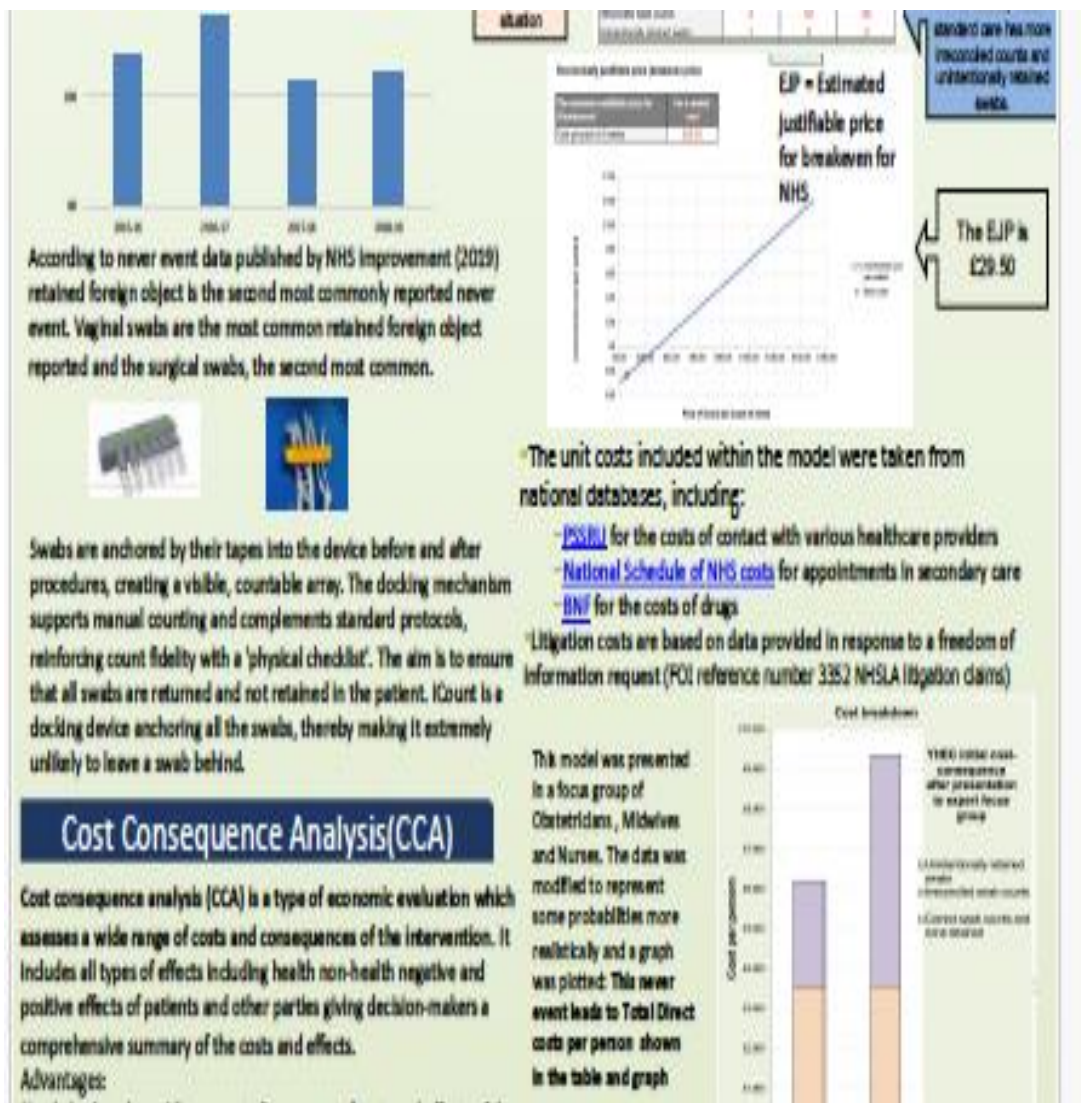
Cost

Staff time

Cost + harm

Financial exposure

Organisational risk



Potential Economic Benefits

- Reduction in retained swab investigations
- Reduction in clinical time spent on discrepancy resolution
- Reduced risk of litigation and harm

Independent cost-consequence analysis performed by York Health Economics Consortium identified positive economic value at NHS pricing levels.

Preventing even a single retained swab incident may avoid substantial investigation costs, additional treatment, patient harm and reputational impact.

Questions by hospitals

Is there a plan for having a tampon along with the swabs in the device ?

We are also able to provide a 6-slot iCount version in the procedure pack OR as standalone sterile pack for 5 swabs and 1 tampon

How will training happen ?

Video has been developed, and we continue to invite any further development from stakeholders

In vaginal births (labour wards) most swabs (95%) are tailed but we do use non-tailed ones in certain settings

System Engineering and human factors science recommend standardisation. Our human factors work suggests that most users prefer medium-sized tailed swabs for births and suturing

How is the surgical swab problem different from the vaginal swab problem + design ?

Surgical Size and tailed/non-tailed – maternity are all 30x30 and tailed typically.
Most maternity users prefer 22cm x22cm tailed swabs as per our extensive usability studies

Counting more differently complex in surgery – done several times in the procedure and many more swabs may be needed to be opened at different times.
However, there are more team members and better environment – theatre is bigger than delivery rooms.
Light is better. Lesser distractions and interruptions.

In surgery - Small swabs without tails are also used

There is part 2 presentation for human factors analysis of swabs retained in surgery and more system and design solutions if you are interested!

Surgical swabs and tampons used in maternity: What, How, and Why they are retained



Human Factors Analysis of the Socio-technical System

- SEIPS – System Engineering in Patient Safety
 - Hierarchical task analysis
 - Accident investigation analysis - AcciMap
 - Reliability analysis – fault tree, bow-tie analysis
 - Derive causative and contributory factors



For more Info Please visit
www.icountcorrect.com

