

HOLOGIC®



# A Game Changer in Fluid Management

Enhanced control & efficiency for better patient care\*

Simple and easy to use, the Fluent® fluid management system works seamlessly with the integrated MyoSure® controller, together with the Omni™ hysteroscope, to streamline your workflow in any patient setting.

#FluentFluidControl



[www.gynsurgicalsolutions.com/Fluent](http://www.gynsurgicalsolutions.com/Fluent)

ADS-03112-EUR-EN Rev 001 © 2020 Hologic, Inc. All rights reserved. Hologic, Fluent, MyoSure, Omni and associated logos are trademarks and/or registered trademarks of Hologic, Inc. and/or its subsidiaries in the United States and/or other countries. This information is intended for medical professionals and is not intended as a product solicitation or promotion where such activities are prohibited. Because Hologic materials are distributed through websites, eBroadcasts and tradeshows, it is not always possible to control where such materials appear. For specific information on what products are available for sale in a particular country, please contact your local Hologic representative or write to [euinfo@hologic.com](mailto:euinfo@hologic.com).

\* As compared to conventional fluid management systems currently on the market.

FLUENT®  
Fluid Management System

163

**Prevention of retention of vaginal swabs and tampons with novel device system**

**Desai, A<sup>1</sup>; Ogrodnik, P<sup>2</sup>; Desai, K<sup>3</sup>; Mapunde, V<sup>4</sup>**

<sup>1</sup>The Royal Wolverhampton NHS Trust, Wolverhampton, UK; <sup>2</sup>Biomedical Engineering, Keele University, Newcastle under Lyme, UK; <sup>3</sup>Eureka Inventions Ltd., Newcastle under Lyme, UK; <sup>4</sup>NIHR Surgical MedTech Co-operative, Leeds, UK

**Objective** Vaginal swabs, tampons are the single most common cause of retained objects reported annually and are currently classed as 'Never events'. They can cause significant morbidity - serious physical-psychological, infection, secondary PPH, sepsis, depression, lack of bonding, and trust loss. Although Never events are uncommon and may not always cause severe harm, they are 'red flags' indicating need for system solutions. As per hazard control hierarchy principles, a *human factors engineered solution* is more effective than just modifying human behaviour (standardised policies, checklists, training) where design solutions and behaviours complement each other, preventing human error.

**Design** Findings from formative *usability study* done in high-fidelity simulation look at user experience, safety and acceptability; also presenting the crucial role of *patient public involvement* (PPI) in development.

**Methods** Device description - iCount is a failsafe swab docking system ensuring swabs/surgical tampons are accounted for and removed accurately. There are visual and haptic cues making the process robust. The device has been ergonomically designed in a user-centred manner; developed collaboratively by midwives, nurses, doctors, Keele Biomedical Engineering. York Health Economic Consortium did a detailed formal cost-benefit analysis showing that each device used could save more than £100 of NHS costs per patient due to high litigation, management and morbidity costs (Ref-NHS Resolution). Proof of concept usability – Experienced diverse clinicians participated (NIHR Medtech, University hospitals, Birmingham). User session lasted 40 min involving audio-video content, hands-on in high-fidelity simulation, semi-structured interviews, and written survey feedback. Detailed structured large group PPI was done by NIHR Surgical MIC, Leeds.

**Results** Usability study: Users had positive attitude, supported the concept (simple, intuitive) and made some valuable design recommendations based on experience. The mechanical device is external to patient and poses no risk to user or patient as observed in simulation. The usability and PPI feedback suggested accommodating for red-green colour-blindness and improving some features, respectively.

The PPI was well organised and gave valuable insight into patient, healthcare users perspective. This valuable feedback led to further prototype iterations and pilot clinical study planning.

**Conclusion** The users and PPI group deeply cared about patient safety and proposed solution. They found the solution positive and acceptable. Further evaluation is required to establish reliability of the system and integrate it into clinical workflow. The aim is to have a 'human factors engineered system' with Safety II principles where a design solution and user behaviours complement, preventing error, adding system resilience. PPI also suggested engaging with NIHR Patient Safety Translational Unit.

It typically takes a claimant 30 months to bring a claim and then 20 months for damages to be agreed. The sum total to the NHS of these claims was five million, with total costs ranging from £60 000–£600 000.

**Conclusion** Findings confirmed known risk factors for OASI including primiparity, forceps delivery and occipito-posterior position. Half of the claimants had undergone subsequent surgery or had a plan for surgery once their family was complete.

These injuries have long-term effects on every aspect of life, with some claims including psychiatric injury, and all

women reporting an impact on their relationships and working life.

The financial costs of litigation are quantifiable and learning lessons to reduce this burden is essential.

I aim to review all 118 OASI claims that have been brought since 2010, where damages have been paid, to look at the population characteristics and pattern of claim, as well as the cost to the NHS, in terms of both financial costs and additional workload. This will feed into the OASI2 workstream.