A SOCIO-TECHNICAL SYSTEMS APPROACH FOR THE PREVENTION OF RETAINED FOREIGN OBJECTS (RFOs) IN HEALTHCARE

Siobhán Corrigan, Alison Kay, Sam Cromie, & Katie O. Byrne
Centre for Innovative Human Systems, School of Psychology, Trinity College Dublin (Ireland)

Abstract

'Never events', like Retained Foreign Objects (RFOs) are typically rare but can lead to serious outcomes in healthcare. These can cause significant physical and psychological impact on the patient, financial cost to the state and personal cost and reputational damage to the medical practitioners who are often considered to be the 'second victim' of RFOs. While the rate and impact of RFO's is recognised there is little understanding of the human and organisational factors leading to RFO's or how to effectively manage them. The specific objectives of the research were as follows: (i) to analyse the problem and current practice in surgical and maternity settings; (ii) to develop hospital-specific RFO's interventions; (iii) pilot implementation and evaluation and (iv) consolidate an overall implementation roadmap for implementation of proposed interventions. A Socio-Technical Systems (STS) Approach (Corrigan et al., 2018; McDonald et al., 2021) was deployed as a key framework for data gathering and analysis. This model examined the socio-technical system from the current state of RFOs – the "As is" picture and how it could be in the future – the "To-be" picture. The overall research design involved a qualitative, multi-phase, multi-disciplinary approach actively involving core clinical and managerial staff at two pilot hospital sites. A range of methods were used including semi-structured interviews; focus groups and observations across two hospital sites. Several critical issues were identified, such as lack of alignment in goals related to preserving the accuracy of the count, different approaches to formally approving the count, and the impact on patient transfers between locations. There was also a lack of common reporting of count discrepancies and insufficient feedback when such discrepancies were reported. Furthermore, there was a lack of an open culture where staff felt comfortable speaking up, and challenges related to interacting with formidable personalities. The socio-technical approach was very effective in identifying the key facilitators and challenges to manging RFO's and this paper presents high level recommendations based on an STS approach.

*Keywords:* Retained Foreign Objects, socio-technical systems, human factors, patient safety.

1. Introduction

A retained foreign object or RFO occurs when an item is unintentionally left behind inside the patient following any invasive procedure (Health Service Executive, 2015). Although RFOs are relatively uncommon (Chen et al., 2011), they come with significant costs to patient health, as well as to the reputation of healthcare professionals and institutions and potentially to the state through legal claims. Regarded as a preventable event, RFOs continue to be a pressing concern for patient safety (Mehtsun et al., 2012; Patial et al., 2018). The literature reports varying incidence rates ranging from 1 per 1000 procedures to 1 per 19,000 procedures (Fencl, 2016). These figures are often underestimated due to the under reporting (Lincourt et al., 2007), which may be due to hospitals reluctance to disclose such incidents, given their sensitive nature and concerns about reputational damage (Lincourt et al., 2007). Moreover, differences in reporting classifications further complicate the issue. For instance, in Ireland, RFOs are classified as Serious Reportable Events (SRE) necessitating mandatory reporting. However, this requirement applies solely to unintentionally RFOs involving an enclosed body cavity (HSE, 2015). In maternity services, incidents of RFOs in unenclosed body cavities (i.e., vagina) are considered adverse event but are not categorised as SRE's.

Counting of supplies and instruments is a routine task conducted by nurses, midwives and obstetricians to mitigate RFOs. Incorrect counts following surgical and delivery procedures can lead to stress, prolonged procedures, and confusion among operating and delivery room staff (Rowlands & Steeves, 2010). Due to the absence of a standardised national policy, counting practices aimed at preventing RFOs vary among healthcare institutions and lack consistency and uniformity. Despite being the primary method to prevent RFOs in patients, these counting practices have proven to be unreliable, particularly as the complexity of patient needs and healthcare have evolved (Stawicki et al., 2013).

The rising interest in the Socio-Technical Systems (STS) approach to understanding complex safety systems, particularly in healthcare, suggests a growing acknowledgement that numerous safety aspects are emergent properties of such systems (Carayon et al., 2015; Geary et al., 2022). An STS entails the 'synergetic interaction and integration of humans, processes, information and knowledge flows, technology, structures and the external environment in the workplace' (Corrigan et al 2018). Interactions play a pivotal role in the STS approach and recognising the broad STS and the respective interactions between the different levels contributes to a more comprehensive and integrated analysis of the current operational practice (Robertson et al., 2015) and priortising what needs to be changed (Geary et al., 2022). The CUBE – A Socio-Technical Functional Model (Geary et al 2022; McDonald et al 2021; Corrigan, et al 2018) was utilised as the primary model for both data gathering and analysis in the project. This model (depicted in figure 1) examined the socio-technical system regarding the current state of RFO'S in Irish Healthcare – the "As is" picture and envisioned its potential future – the "To-be" picture. It examined the crucial interdependencies of goals, processes, team, information/knowledge, technology and culture.

Figure 1. The Cube – a model adapted from Corrigan et al 2018; Mc Donald, 2021.
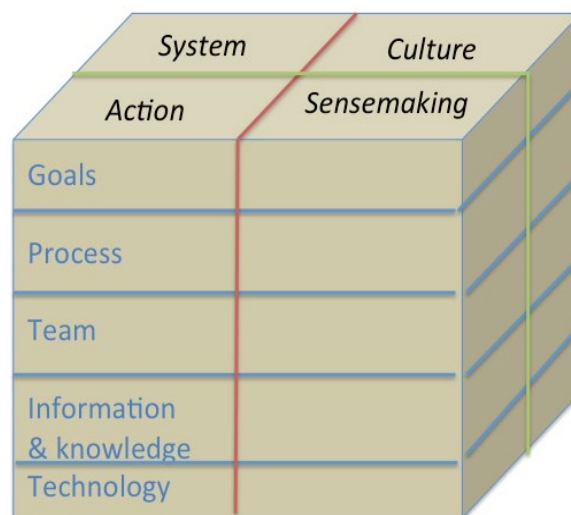
2. Methods

The overall research design involved a qualitative, multi-phase, multi-disciplinary approach actively involving core operational and managerial staff at two pilot hospital sites. Two hospital sites were selected to ensure that the research covered both surgical and maternity services. Phase 1 of the research involved conducting semi-structured interviews and observations. A standardised approach was applied to the sampling strategy for the semi-structured interviews across both hospital sites. The target participant sampling focused on key operational, managerial and support staff both for maternity and surgical processes. In the surgical based hospital site eighteen interviews were conducted and sixteen interviews were conducted in the maternity based. Each of the interviews followed a validated interview schedule and lasted between thirty and sixty minutes. All interviews were recorded, fully transcribed and a thematic analysis was carried out.

Observations were conducted to provide greater insight into the current processes and preventative practices. Focus of the observations were placed on the physical setting, social cohesion, teamwork, communication pathways, information and knowledge flows, constraints, and facilitators in normal operational practice. Observations were completed (across multiple specialties) in the operating theatre at the surgical site by two observers (one with a clinical background and one with a background in human factors). Observations were conducted in the maternity setting across two areas (the operating

theatre and the delivery suite) with 1-2 observers present. Due to constraints of space in the delivery suite, consent was granted for 1 observer to be present. At least two observers would be required for inter-researcher reliability, however, the research team were not permitted more than one as the ethics board felt it to be too intrusive for the patient given the size of the delivery suite. The results take this into consideration.

Phase 2 involved validation of the findings from the previous phase and selection of the agreed interventions. Four validation workshops (two in each hospital site) were conducted, and Phase 3 involved the pilot implementation and evaluation of the proposed interventions in each hospital site. The focus of this paper is on phase 1 and phase 2 and does not report on the pilot implementation phase.

3. Findings

The focus of this paper is on the analysis of the high-level recommendations categorised within the CUBE framework (McDonald et al., 2021; Corrigan et al., 2018). By systematically addressing these perspectives under the categories of goals, process, team, information & knowledge, technology and culture this provided a valuable insight into and understanding the challenges with RFO' in healthcare and provided a solid foundation for phase 3 of the research and the pilot implementation of key interventions.

Goals
- Emphasis the importance of raising awareness and fostering a sense of shared responsibility about RFO's among all members of surgical, midwifery and obstetrics teams and their supporting roles.
- Priortise maintaining the integrity of the count to ensure its continued use as a key practice.

Process
- Develop procedures for the safe transfer and handover of patients between hospital locations.
- Incorporate 'Quiet' for the count, Time-Out and Surgical Safety Checklists (SSCs) into training at all levels of medical education.
- Implement a two-person sign-out for the formal confirmation of the count outcome, with corresponding updates to relevant documentation.

Information and Knowledge
- Ensure verbal communication and acknowledgement of the count outcome to enhance procedural adherence and mutual respect.
- Consider advocates for patient liaison with various representatives, recognising the importance reported by patients.
- Encourage reporting of count inconsistencies as routine practice to capture valuable information or near-misses.
- Integrate lessons from near-misses in healthcare and from other safety-critical industries into RFO training at all levels.

Team
- Provide multi-disciplinary team training at RFO prevention and management from postgraduate level onwards and through continuous professional development.

Technology
- Conduct further research on the potential of technologies (e.g., bar coding, RFID, AI) in preventing and detecting RFOs.
- Design databases within relevant hospitals and agencies to facilitate anonymised patient record reporting in line with GDPR guidelines.

Culture
- Advocate for respectful treatment of staff following RFO incidents, recognising the significance similar to never-events in healthcare.
- Foster an open and supportive culture that encourages healthcare staff to speak up and ensure psychological safety.
- Offer essential support for staff immediately after RFO incidents, throughout investigations, and in the long term to safeguard their well-being and performance.
- Ensure comprehensive support and communication within the team where the RFO has occurred, emphasising a just culture.

4. Discussion

A consistent finding in articles on quality improvement in healthcare is that change is difficult to achieve (Gillespie & Marshall, 2015; Moffatt-Bruce et al., 2014). Much of the weakness in the research literature is due to a failure to develop the interventions systematically, using best available evidence and appropriate theory. While there are many examples of successful interventions, there are also numerous safety and quality improvement interventions that have failed to have an impact—particularly in terms of bringing about long-term behavioural change and improvements in patient safety. Through a systematic application of the STS approach focusing on goals, process, team, information & knowledge, and technology, an assessment of the current provided a basis for targeted change interventions to address the key risk factors and guide the key change interventions. Critical issues such as goal misalignment, varied approval processes, count discrepancies, insufficient feedback and challenges related to patients transfer were identified. Furthermore, a lack of an open culture was reported as staff didn't always feel comfortable speaking up, coupled with difficulties in dealing with staff with formidable personalities. To address the concerns identified, interventions were developed and implemented in the pilot phase of the research project. These interventions included the introduction of a requirements for two staff members to be present during baseline, final and count sign-off processes, the establishment of protocols for patient transfers and their relation to the count, the creation of a pathway for preventing RFOs, and providing training to address these issues. The pilot implementation phase was also guided by the STS CUBE which helped priortise the most effective strategies both preventing and continually managing RFOs.

References

Chen, Q. Rosen, A. K., & Cevasco, M. (2011). Detecting patient safety indicators: how valid is "foreign body left during procedure" in the veterans health administration? *Journal of the American College of Surgeons,212*(6),977-983. https://doi.org/10.1016/j.jamcollsurg.2010.12.053

Carayon, P., Hancock, P., Leveson, N., Noy, Y., Sznelwar, L., & van Hootegem, G. (2015). Advancing a Sociotechnical Systems Approach to Workplace Safety: Developing the Conceptual Framework. *Ergonomics, 58*(4), 548-564. https://doi.org/10.1080/00140139.2015.1015623

Corrigan, S., Kay, A., O'Byrne, K., Slattery, D., Sheehan, S., McDonald, N., Smyth, D., Mealy, K., & Cromie, S. (2018). A Socio-Technical Exploration for Reducing & Mitigating the Risk of Retained Foreign Objects. *International Journal of Environmental Research and Public Health, 15*(4), 714 https://doi.org10.3390/ijerph15040714

Fencl, J. L. (2016). Guideline Implementation: Prevention of retained surgical items. *AORN journal*, *104*(1), 37-48. https://doi.org/10.1016/j.aorn.2016.05.005

Geary, U., Ward, M., Callan, V., McDonald, N., & Corrigan, S. (2022). A socio-technical systems analysis of the application of RFID-enabled technology to the transport of precious laboratory samples in a large acute teaching hospital. *Applied Ergonomics, 102*, 103759. https://doi.org/10.1016/j.apergo.2022.103759

Gillespie, B. M. & Marshall, A. (2015). Implementation of safety checklists in surgery: A realist synthesis of evidence. Implementation Science*,10*(137).https://doi.org/10.1186/s13012-015-0319-9

Health Service Executive. (2015) *Serious Reportable Events (SREs)*. (HSE Implementation Guidance Document). Dublin, Ireland: Health Service Executive. Retrieved from https://www.hse.ie/eng/services/publications/performancereports/srejan15.pdf

Lincourt, A. E., Harrell, A., Cristiano, J., Sechrist, C., Kercher, K., & Heniford, B. T. (2007). Retained foreign bodies after surgery. *Journal of Surgical Research*, *138*(2), 170-174. https://doi.org/10.1016/j.jss.2006.08.001

Mehtsun, W. T., Ibrahim, A. M., Diener-West, M., Pronovost, P. J., & Makary, M. A. (2013). Surgical never events in the United States. *Surgery, 153*(4), 465-472. https://doi.org 10.1016/j.surg.2012.10.005

Moffatt-Bruce, S. D., Cook, C. H., Steinberg, S. M., & Stawicki, S. P. (2014). Risk factors for retained surgical items: A meta-analysis and proposed risk stratification system. *Journal of Surgical Research*, *190*(2), 429-436. https://doi.org/10.1016/j.jss.2014.05.044

McDonald, N., McKenna, L., Vining, R., Doyle, B., Liang, J., Ward, M. E., Ulfvengren, P., Geary, U., Guilfoyle, J., Shubaiber, A., Hernandez, J., Fogarty, M., Healy, U., Tallon, C., & Brennan, R. (2021). Evaluation of an Access-Risk-Knowledge (ARK) Platform for Governance of Risk and Change in Complex Socio-Technical Systems. *International Journal of Environmental Research and Public Health, 18*(23), 12572. https://doi.org/10.3390/ijerph182312572

Patial, T., Rathore, N., Thakur, A., Thakur, D., & Sharma, K. (2018). Transmigration of a retained surgical sponge: A Case Report. *Patient Safety in Surgery, 12*(21). https://doi.org/10.1186/s13037-018-0168-y

Robertson, M., Hettinger, L., Waterson, P., Noya, I. Y., Dainoff, M., Leveson, N. G., Carayon, P., & Courtney, K. (2015). Socio-technical approaches to workplace safety: Research needs and opportunities. *Ergonomics, 58*(4), 650-658. https://doi.org/10.1080/00140139.2015.1011241

Rowlands, A. & Steeves, R. (2010). Incorrect surgical counts: A qualitative analysis. *AORN Journal*, *92*(4), 410-419. https://doi.org/10.1016/j.aorn.2010.01.019

Stawicki, S. P., Moffat-Bruce, S. D., Ahmed, H. M., Anderson, H. L., Balija, T. M., Bernescu, I. Chan, L., Chowayou, L., Cipolla, J., Coyle, S.M., &, Gracias, V.H. (2013). Retained surgical items: A problem yet to be solved. *Journal of the American College of Surgeons, 216*(1), 15-22. http://dx.doi.org/03.02.19/j.jamcollsurg.2012.08.026