# Development of an Observational Protocol for Reducing and Mitigating Workload and the Risk of Retained Foreign Objects

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**Abstract.** Retained Foreign Objects are an uncommon but costly problem in today's healthcare. It regards the outcome after an unintended item is left behind in a patient after an invasive procedure. This paper presents the development of an observational protocol used for surgical observations in the FOR_RaM Project. The FOR_RaM or Foreign Object Retention – Reduction and Mitigation project aims to analyze and understand the problem of retained foreign objects in surgery and maternity settings in Ireland, develop hospital specific foreign object management processes and implementation roadmaps, with a focus on reducing and mitigating the risk of foreign object retention. This paper discusses the methodology used for developing an observational protocol as part of a socio-technical multi-methods approach in order to gain a better understanding of the existing practices that take place in these settings, including workload, operational processes and collaboration. Emphasis is placed on the observational template development and design,

observational tasks, critical points, procedures and protocols followed throughout. This observation protocol has facilitated the collection of critical data and been successful in identifying good practices and potential areas for improvement.

**Keywords:** Observations, Procedure, Protocol, Template, Retained Foreign Objects, Workload, Operational Process, Collaboration.

## 1 Introduction

The Health Research Board in Ireland is committed to analysing and understanding the problem of Retained Foreign Objects (RFOs) in surgical and maternity settings. This primarily involves developing hospital specific foreign object management processes and implementation roadmaps, with a focus on reducing and mitigating the risk of retained foreign objects. A retained foreign object or RFO is not only costly financially to the Health System in Ireland, but can also have an impact on patient health and recovery, thus the impetus for the reduction of RFOs in Irish Healthcare. A RFO is when an item used during an invasive procedure is unintentionally left behind in the patient after a procedure ends [1]. RFOs are considered an uncommon but serious event, the incident rate; often estimated as a result of underreporting ranges between 1 in 1,000 to 1 in 19,000 [2]. Retained items include soft goods (e.g. swabs/ sponges), sharps (e.g. needles), miscellaneous items (e.g. vessel loops or electrosurgical scratch pads) and instruments [3]. Complex environments such as surgical and maternity settings involve complicated procedures, group dynamics, technology and high risk medication use on a regular basis, these combined elements increase the potential for an adverse event to occur [4]. A RFO is a preventable adverse event, often referred to as a 'never event' meaning it should not happen [5]. The impact of an RFO may result in a number of negative outcomes: i) the patient may suffer from physical (pain) and psychological (depression) harm [6]; ii) damage to the reputation of the individual healthcare provider as well as the organisation; iii) financial implications can result in the case of a claim [6, 7]. The average cost of a RFO is $95,000 [8] but this can vary substantially depending on the location, outcome and impact. The cost can range from anything between $51–$3,988,829 [9].

One of the first crucial steps is to identify and understand what the key risk factors are in relation to RFOs. These include an emergency case, unexpected change to a planned procedure, no count performed or incorrect counts, multiple procedures or multiple surgical teams involved, lengthy procedures, procedures with a high blood loss and patients with a high body mass index

(BMI) [3]. Many of these factors can create an impact on the task at hand making it increasingly demanding in relation to both physical and mental workloads throughout a procedure. The Joint Commission's [10] analysis of the most common causes of RFO events reported to them include the following:

- A lack of policies and procedures
- Incompliance with current policies and procedures
- Issues related to hierarchy and intimidation
- Failure or poor communication with physicians
- Poor or lack of communication of necessary patient information
- Poor or incomplete staff education

This level of analysis alone does not provide the necessary understanding of what actually happens in normal operational practice, particularly in understanding the complexity of healthcare systems. It can tell us when RFOs are more likely to happen, but it does not suggest how or why they are happening. For instance, it makes sense that an incorrect surgical count would be a risk factor, but how and why do incorrect surgical counts happen? What are the key differences between surgical settings and maternity delivery suite settings? This is where a Socio-Technical Systems (STS) analysis and modelling of the human and organizational factors is critical especially in relation to implementing effective change interventions [11].

This research was carried out as part of the Foreign Object Retention - Reduction and Mitigation (FOR_RaM) project. This 2 year project was funded by the Health Research Board in Ireland (Grant No: RCQPS-2016-2) which aims to reduce or mitigate the risk of retained foreign objects in two specific healthcare settings; surgery and maternity. Overall objectives include; 1) analysing and understanding the problem surrounding RFOs in these two settings within Ireland 2) developing hospital specific foreign object management processes and implementation roadmaps 3) provide a foreign object management toolkit for the settings involved. The FOR_RaM project is deploying an integrated evidence-based assessment methodology based on sound social-technical theoretical principles. This approach is beneficial due to the complex nature of these settings which involve high risk tasks often requiring complex interventions to overcome risk. Over time multiple interventions (counting protocols, use of radiography and technology, education and training) have been implemented to eliminate RFOs, yet this remains an existing and preventable concern [12]. This could be due to the implementation of standardised interventions across multiple settings without considering the

differing cultures and norms or the high mental workload involved. This is referred to in the Medical Research Council guidelines where it is suggested that interventions may be more effective if they are adapted to fit the proposed setting [13]. This paper focuses on one section (unobtrusive observations) of the wider FOR_RaM project scope, placing recognition on the impact or influence mental workload can have within the bigger picture of reducing and mitigating RFOs. Mental workload can be described as the remaining cognitive capacity a person holds whilst carrying out a task [14]. Examining this concept in surgical and maternity settings may allow us to identify the common mental workloads that are experienced and assist in supporting ways to reduce demands that may impact the path to preventing RFOs.

It is argued that this overall approach can provide a better platform for understanding the current practices to prevent the risk of RFOs within these settings in which interventions can be developed and implemented successfully. First, using semi-structured research interviews we aim to provide a good baseline understanding of the existing practices, procedures and policies in place. Following this, in order to provide further information regarding; current practices and processes, team relations, dynamics, communication pathways and the specific tasks that take place in these complex settings, we will make use of unobtrusive observations. Observations involve investigation within natural settings, and it is considered central when one wants to capture "the whole social setting in which people function, by recording the context in which they work" [15, p308]. Observation is also a method for understanding how individuals construct their realities, and to better understand their experiences. It is suggested that observations support the holistic understanding of the phenomena under study [16].

This paper presents the development of an observational protocol used during surgical observations and the associated methodology to evaluate the data collected in a systematic and robust manner. The observation protocol was adapted from that used in the TAPOIA project which was reviewed and customized for the purpose of conducting observations in the healthcare setting. TAPOIA [17, 18] was an aviation project (Enterprise Ireland Commercialization fund 2012) to validate automated voice analysis technology in flight crew. The technology detected prosodic accommodation of flight crew speech as a measure of effective flight crew communication. The observation protocol was developed to measure multiple crew parameters against which to validate the technology - communication, situational awareness, decision-making, mission analy-sis, leadership, adaptability and assertiveness.

The TAPOIA observation protocol was considered a suitable starting point since, despite deriving from a different industry – aviation – the contexts being observed have much in common. Both require monitoring multiple actors working both individually and as a team in order to reach a safety critical operational objective within tight time constraints. In neither situation was it possible to halt proceedings and to question actors, so traditional formats and instruments (e.g. Situation Awareness Global Assessment Technique (SAGAT), Situation Awareness Rating Technique (SART), National Aeronautics and Space Administration Task Load Index (NASA – TLX)), for gathering data would not be appropriate. The rationale and the template used to derive the observation protocol will be presented below.

## 2 Related Work

### 2.1 Mental Workload in Healthcare

Human mental workload is considered the amount of cognitive effort required during task performance, therefore mental capacity is considered a person's limitation for dealing with information received [19]. Cognitive overload is considered one of the contributory factors towards error in the airline industry [20]. Similarly to aviation, healthcare requires both high mental and physical workload to perform and complete day to day tasks. High workload in healthcare settings has been linked as a concern to patient safety [21] and can be closely linked to burnout among staff members [22] For instance, take the surgical count during a procedure. The task demands involve the scrub and circulating nurse counting instruments and items (swabs, needles etc.) added to the sterile field, a simple task when taken out of the busy context it is performed in. Introduce issues such as interruptions, distractions, hierarchy, time pressures or noise to an already repetitive task and it becomes more difficult and demanding requiring increased level of concentration, attention and memory. It is known that complex tasks are closely linked with mental workload and fatigue [23]. Similarly for surgeons and anesthetists, these issues present the requirement for higher mental workload also increases allowing for minimal capacity to successfully address or respond to certain procedural events which presents concerns [23]. In a study by [24] noise including interruptions and informal discussions were identified as influencing factors on performance from a surgeon perspective.

If high mental workload is associated with poor performance in industries such as aviation and other industries [19], considering its impact on operational processes in settings such as surgery and maternity could provide a better understanding of the current challenges associated with measures to prevent RFOs. An observational template was developed to gather information on both mental and physical workload involved in these settings. The steps involved in the development of the observational protocol are discussed below.

## 2.2 Development of Template

### 2.2.1 Stage 1: Initial Observation Template Meeting

Emphasis was placed on the need to identify tasks and critical points, potential staff and participant involvement and a description of what was going to be observed. This highlighted some important points going forward:

*a)* Tasks and critical points; column needs to be empty to allow for data collection, focus placed on the process as well as communications and interactions, an agreed reference list available on each template page and identification of decision points.

*b)* Staff and participants; reference to staff and time of entering and exiting the operating theatre, minimal detail to be included and an area for a sketch of location of personnel within the room.

*c)* Description; this column requires as much detail and content as possible including communication to whom, from whom.

### 2.2.2 Stage 2: Content Analysis

Discussions were made on how to approach data collection from a content analysis perspective. It was highlighted that the structure of the observation template needed to correlate with NVivo coding and structure as well as facilitating ease of data collection. The TAPOIA observation protocol was used as a base to build upon and adapt to the surgical setting. Figure 1 shows the initial draft of the template. Researchers involved in the FOR_RaM project reviewed this draft and the need to simplify the columns in the template was recognised. The task and subtask columns were combined as one. Description, characteristics, communication and observed behaviour columns were integrated into one single column headed 'description'. Previous studies examining mental workload in the operating theatre setting link disruptions such as 'tel-

ephone calls' [25] and workflow interruptions [26] with increased mental workload. At this point the importance of monitoring and recording disruptions and interruptions was identified and a column for staff who entered or exited the area being observed was also included. This column was titled 'staff in/ out'. The 'comments/ remarks/ suggestions' column remained for the purpose of recording additional or more in-depth information on what was being observed. The simplified version of the template can be seen in Figure 2.
For ease at the analysis stages the use of syntax was applied [27]. This assisted in distinguishing between observers and participants comments, thus making the process of analysis more robust from a research perspective (less confusion with more reliability). This included:

- clear references of date and observation time frame
- quotation marks "--" around comments made by the participants
- straight brackets [--] around own ideas and comments
- plain text when describing working situations and critical episode

#### 2.2.3 *Stage 3: Observation Template Trial Run and Review*

A trial run was performed using the simplified version of the template on two scenarios: 1) a clinical scenario - Implementing the WHO Surgical Safety Checklist in an operating theatre and 2) a non-clinical scenario - video of NASA employees reacting to a time and safety critical mission. The purpose of this was to determine if the template previously used in aviation was suitable for use in the operating theatre environment. The non-clinical scenario was a fast-paced NASA/ Aerospace video excerpt with differing terminology to that of a healthcare setting. This gave the clinical researcher an idea of how out of depth the non-clinical researchers would be in this environment. At this stage the use of Performance Shaping Factors (PSFs) and Co-ordination Demand Analysis (CDA) [28, 29] was proposed on the basis of recognising workload and other factors that may impact the performance of tasks. The CDA was originally used in aviation research [17, 30, 31], but is highly applicable as it performs a measure of team co-ordination. The original research examined team co-ordination between air-crew on board NATO AWACHS, however, the safety critical nature of the surgical team setting is highly relevant for these measures. Following this it was discussed if PSFs and CDAs could be recorded after the observations (i.e. populated post-observation). Therefore this would be linked but become a separate document to the observation template.
We reviewed the roles of the observers; Researcher 'A' would follow the patient (i.e. from the anaesthetic room into the operating theatre and out to the recovery room). Researcher 'B' (with a clinical background) would remain in the operating theatre to observe set up and clean up. This was utilised to

maximise as much of the operational process as possible. This was agreed due to the familiarity Researcher 'B' had with the "normal" running of an operating theatre, layout, processes and procedures and ability to identify deviations from standard operating procedures.

#### 2.2.4 *Stage 4: Meeting to propose new draft template and CDA*

Proposal of the new template draft, PSFs, CDAs and recommendations from the observation trial run were reviewed. The PSFs and CDA methodology was approved for use but not as part of the formal process during observations but as a post-observational recall. This decision was made on the basis of insufficient time for completing these documents while observing. The proposition to keep the task/ subtask column blank for purposes of allowing the specific observation task flow dictate what is inputted was also agreed. Instead a structured table (Table 1) of reference was produced, based on a standardized/ generic procedure flow, location and personnel involved to allow those unfamiliar with the steps to easily refer to this where necessary. Abbreviations were made for both location and personnel involved in this reference list. A box below this contained more detail (Table 2).

It was agreed this would be made visible on each template page to allow for constant reference to be made. The surgical safety checklist (often referred to as 'Time-out') stages; Sign-in, Time-out and Sign-out (SSC 1-3) were also made available on every template page so they could be "ticked" as they were performed without having to revert back to the first page during the observation. A review of performance shaping factors from a number of safety critical human factors research projects was carried out. The researchers involved in FOR_RaM have considerable experience in carrying out ethnographic observations. A list of proposed PSFs (Table 3) was drawn up from the following projects:

- Aviation Maintenance, AITRAM project (EU funded FP5 project IST-1999-12241), [32].
- Process Industries, Virthualis project (EU funded FP6 project, Contract N. NMP-515831) [33, 34].
- Manufacturing, ManuVAR project (EU funded FP7 Contract N. CP-IP-211548)

| Observation: | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| **Operation** being observed:<br><br>Time started:<br>Time ended: | | | | | Quality of SSC scale:<br>0 = No problems at all<br>1 = minor problem only<br>2 = Small problem<br>3 = Major problem<br>4 = Catastrophic | | Count | Y/N |
| Task | Sub-task / Description | DP | Characteristics | Observed behaviour / Communication | Comments/Remark/Suggestions | | SSC1 | |
| Pre-op Anaesthetic checks | Identiying patient | | | | | | Time out | |
| …. | Identifying procedure | | | | | | Silence | |
| …. | etc | | | | | | Acknowledged | |
| …. | …. | | | | | | SSC2 | |
| Reception of patient in theatre | …. | | | | | | Time out | |
| …. | …. | | | | | | Silence | |
| …. | | | | | | | Acknowledged | |
| Patient under | | | | | | | SSC3 | |
| Operation commences | | | | | | | Time out | |
| …. | | | | | | | Silence | |
| …. | | | | | | | Acknowledged | |
| ….. | | | | | | | | |
| ….. | | | | | | | | |
| ….. | | | | | | | | |
| Patient handover in recovery complete | | | | | | | | |

**Fig. 1.** Initial draft of the observation template

| Observation: | | | | | |
|---|---|---|---|---|---|
| **Operation** being observed:<br><br>Time started:<br>Time ended: | | | | Count | Y/N |
| **Task /sub task** | **Description** | **Staff in/out** | **Comments/Remark/Suggestions** | SSC1 | |
| | | | | Time out | |
| | | | | Silence | |
| | | | | Acknowledged | |
| | | | | SSC2 | |
| | | | | Time out | |
| | | | | Silence | |
| | | | | Acknowledged | |
| | | | | SSC3 | |
| | | | | Time out | |
| | | | | Silence | |
| | | | | Acknowledged | |

**Fig. 2.** Simplified version of the observation template

This list was reviewed by researchers with a clinical background to ensure that the terminology was relevant and appropriate for the clinical setting and that there were no omissions. The 29 PSFs (Table 3) provide a detailed breakdown of the workload required at a task level. Tasks can be evaluated and allow for identification of the physical, mental and social workload demands observed among individuals performing tasks individually and together.

**Table 1.** Task and sub-task reference list

| Task / Sub-task | Location | Personnel |
|---|---|---|
| Pt arrives & checked in | HB | AN, A |
| Pre-op anesthetic | AR | AN, A |
| Sign-in (SSC1) | AR | AN, A |
| Anesthetic administered | AR | AN, A |
| Documentation check | AR | SN/ CN |
| Baseline count | OT/ Prep room | SN, CN |
| Patient brought into OT | OT | A, AN, P |
| Connected/ set up/ positioned | OT | TEAM |
| Time-out (SSC2) | OT | A, S, SN, CN |
| Operation commences | OT | A, S, SN, CN |
| First count | OT | SN, CN |
| Second count | OT | SN, CN |
| Final count | OT | SN, CN |
| Sign-out (SSC3) | OT | SN, CN, S, A |
| Operation ends | OT | |
| Pt transfer & handover to Recovery | OT/ R | A, SN/CN, P, RN |

**Table 2.** Abbreviations of location and personnel

| Abbreviation | Meaning |
|---|---|
| A | Anesthetist |
| AN | Anesthetic Nurse |
| AR | Anesthetic Room |
| CN | Circulating Nurse |
| HB | Holding Bay |
| OT | Operating Theatre |
| P | Porter |
| R | Recovery |
| RN | Recovery Nurse |
| S | Surgeon |
| SN | Scrub Nurse |

### 2.2.5 Stage 5: Final Observation Template Review

The final template draft was reviewed by the FOR_RaM research team and the best format for printing (booklet style) was agreed. Researcher roles during observations were confirmed:

- Researcher A: to follow the patient (pre-op in the anaesthetic room and post-op to the recovery room)
- Researcher B: to remain in theatre observing the set up/ clean up

**Table 3.** Performance Shaping Factors (PSFs)

| **Performance Shaping Factors (PSFs)** | | |
|---|---|---|
| Strength / Ability/ Body size required | Visual Access | Allocation of function to team members |
| Skill | Physical Access | Handover/ Shift handover |
| Understanding of system | Dexterity | Role ambiguity |
| Knowledge | Comfort | Communication difficulties |
| Physical effort | Team Culture | Interpersonal tensions |
| Experience | Stress | Team pressure |
| Assertiveness | Repetitiveness of the job | Personnel resources |
| Fatigue | Memory | Hardware resources |
| Noise | Concentration | Time |
| Lighting | Interruption | |

### 2.2.6 *Stage 6: Meeting with External Advisor*

Input from the Nursing lead of the external advisory group for the overall project was obtained. This provided us with two additional tools which had recently been utilised in a national leading teaching hospital in the UK. Two features were added to the final template as a result of reviewing these documents and advice from the external lead; 1) Identification of the procedure as being an emergency or elective case and 2) identification if there were any changes to the procedure list. These were the two outstanding items from the template.

### 2.2.7 *Stage 7: Further Review of the Template*

The PSF updates were agreed upon and were inputted with the finalised CDAs. The updated template was reviewed and the finalised template (Figure 3) was produced and printed. The finalised PSF document and CDA document (Figure 4) were printed as separate items from the booklet of templates.

A checklist for on-site observations was agreed as outlined:

- Diagram for each observation
- Time in and out recording for people entering and leaving theatre
- Coding of paperwork (site, number and observer)
- Need to synchronise time for start/end session

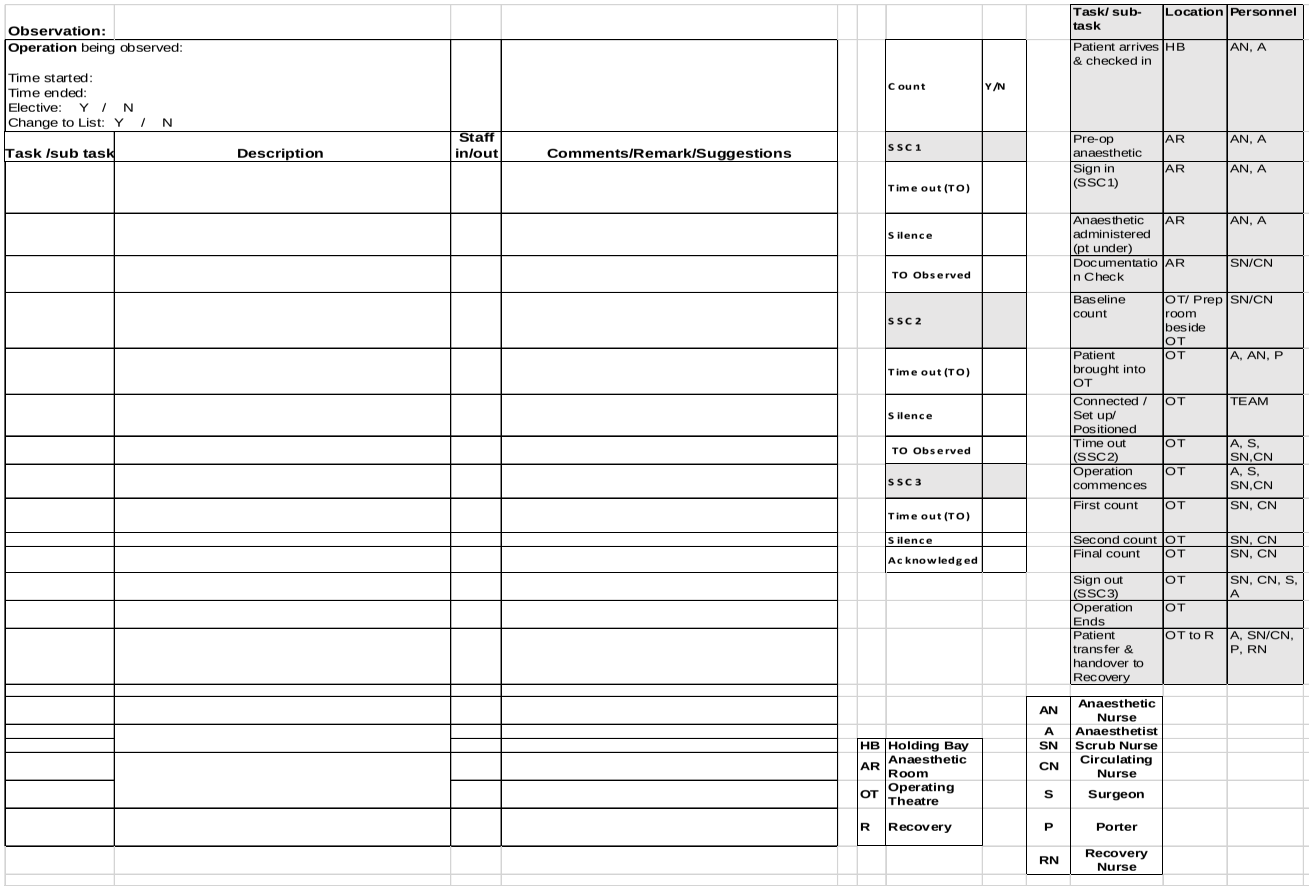


**Fig. 3.** Finalized version of the observational template

A time out for researchers after each session for PSFs & CDA prior to discussing observation (to prevent contamination of results)

| **Co-ordination Demand Analysis** | **Definition** | **Score (1-5)** | **Comments** |
|---|---|---|---|
| Communication | Includes sending, receiving, and acknowledging information among team members | | |
| Situational Awareness (SA) | Refers to identifying the source and nature of problems, maintaining an accurate perception of the patient location relative to the external environment, and detecting situations that require action | | |
| Decision Making (DM) | Includes identifying possible solutions to problems, evaluating the consequences of each alternative, selecting the best alternative, and gathering information needed prior to arriving at a decision. | | |
| Mission analysis (MA) | Includes monitoring, allocating, and co-ordinating the resources of the team, prioritising tasks, setting goals and developing plans to accomplish the goals, creating contingency plans | | |
| Leadership | Refers to directing activities of others, monitoring and assessing the performance of team member motivating members, and communicating mission requirements | | |
| Adaptability | Refers to the ability to alter one's course of action as necessary, maintain constructive behaviour under pressure, and adapt to internal or external changes | | |
| Assertiveness | Refers to the willingness to make decisions, demonstrating initiative, and maintaining one's position until convinced otherwise by facts | | |
| Total Co-ordination | Refers to the overall need for interaction and co-ordination among teams | | |

**Fig. 4.** Finalized Coordination Demand Analysis (CDA) template adapted from [28 in 29, p379]

It was agreed that the PSFs and CDAs would be completed as soon as possible (within minutes where possible) after each observation and before discussing any events relating to the observations. This decision was made on the basis of the high mental workload observers may experience while observing and recording critical

data. It was agreed this would have an impact on the data and critical information may be missed as a result.

# 3 Design and Methodology

## 3.1 Settings and samples

Observations were conducted in the operating theatres within an Irish Hospital with a bed capacity of over 400 and a total of 8 operating theatres covering a number of specialties. Multiple disciplines of the surgical team were observed during the observations, these included; Nurses, Anesthetists, Surgeons and Porters. The surgical specialties observed in this study included General, Orthopedics, ENT and Ophthalmology. These surgeries comprised of a combination of both open and laparoscopic procedures.

For the purposes of confidentiality no patient demographic characteristics were documented, only procedure type. Participant's professional roles only were documented during observations to ensure anonymity. Ethical Approval was gained from the School of Psychology Ethics Committee, Trinity College Dublin and the participating Hospital's Ethics Committee.

## 3.2 Observers

There were two researchers present throughout each observation. Researcher A: an experienced organizational psychology researcher, human factors trainer and consultant; who has worked on a wide range of human factors and risk management projects across a range of sectors (aviation, process, manufacturing, maritime transport as well as healthcare). Researcher B: a researcher with a clinical background, with experience in a number of roles across multiple specialties as a perioperative nurse.

## 3.3 Observation Protocol

A clear summary of objectives and themes prior to commencing observations were provided and agreed upon with professional leads (Table 4).

Participation was voluntary and the following observational themes were provided to participants on what areas were planned on being observed, this was to reiterate that participants were not being audited on their performance and to perform daily tasks "as normal".

- Physical setting
- Social setting (formal & informal interactions)
- Interplay of different roles (nurses, consultants etc.)
- Social cohesion & team-work
- Information & knowledge flows (key decision points)
- Constraints & facilitators in normal operational practice

**Table** 4 : Observation plan

| **Activity** | **Objectives** | **Description** |
|---|---|---|
| Theatre Observations | Formal and structured description of the surgery to be performed, including all communications and relevant performance shaping factors. In details:<br>• Detailed Task Analysis of all relevant procedures including deviations from standard practice and their consequences<br>• A breakdown of all personnel and equipment involved in the process;<br>• A map of the task according to a time, information and task flow (i.e. logic of process from start to finish) | Hierarchical break down of a task with main sub-tasks according to a nominal path for every stakeholder.<br><br>Identification of exchange of information and communication among stakeholders.<br><br>Identification of consequences of deviation on the task sequence/ outcome of the process.<br><br>Interactions of note<br>• Surgical Safety Checklist SSC<br>• Recognition of all SSC<br>• Patient "going under"<br>• Challenge & responses between nursing staff and surgeons, anesthetics team (all) and surgeons,<br>• Decision Points<br>• Patients "coming around" |

### 3.3.1 Pre-Observation Activities

Professional leads representing the operating theatre department were liaised with prior to conducting observations. Information about the study was distributed through verbal and written communication (i.e. information on noticeboards). Patients were provided with written and verbal information about the purpose of the study on the day of the observations. Patients were invited to participate in the study, verbal consent was obtained from all patients involved. Written consent was

obtained from Staff members involved in the observations. Staff were briefed before the observations or de-briefed immediately afterwards if they were not present prior to observation commencement. All stakeholders were informed of their rights with respect to withdrawal of participation, anonymity, confidentiality, data protection and security as per the agreements set out during ethical approval with the hospital ethics committee and the School of Psychology ethics committee in Trinity College Dublin.

### 3.3.2 Observations

Due to limited space in the anesthetic rooms and as a courtesy to the vulnerability of patients undergoing an anesthetic, observations commenced either prior to or on arrival of the patient into the operating theatre. Therefore the Sign-in phase of the Surgical Safety Checklist was not observed as this took place in the anesthetic room. The Time-out and Sign-out phases were included in the observations. Observations finished after the patient left the operating theatre. The patient was not followed to the recovery room as to respect patients' dignity in the "coming around" and transfer periods.

### 3.3.3 Post-Observation Activities

On completion of the observation the researchers completed the PSFs and CDAs after each observation on site. The researchers did not discuss any events relating to the observations prior to completion of the PSFs and CDA to ensure that there would not be any contamination of results. Within 1-2 days after the observation was conducted the researchers reviewed their notes and findings collectively and produced an agreed CDA score for each observation.

## 4 Results and Discussion

A total of 6 observations have been conducted on procedures in the operating theatres thus far. All procedures observed were elective or planned cases. The total observational time was 6 hours 54 minutes (414 minutes). Observational time ranged between 25 minutes and 2 hours 30 minutes. CDAs and PSFs were completed for every observation. A further 2 observations are planned at this site and a minimum of 5 further observations are planned within a maternity setting. No results have been included in this paper as we are currently in the data collection phase and more observations are planned. While the data collected as part of the observation protocol will be analyzed in its own right this data will also be cross-referenced with the other methods used in the study, including interviews, focus groups and an analysis of finalized claims pertaining to RFOs nationally.

## 4.1 Overcoming Challenges

It was agreed upon with the professional leads that observations would not take place as planned when the patient entered the anesthetic room, but instead on arrival into the operating theatre. This decision was made with respect for the patient during the sensitive time of receiving an anesthetic, as well as a combination of limited space in the anesthetic rooms and the nature of 'unobtrusive' observations.

## 4.2 Discussion

It is without doubt that surgical procedures require a great deal of technical and non-technical skills, which are often dependent on communication and collaboration among a number of disciplines. The high physical and mental workload required during surgery can be demanding for both the individual and the entire surgical team. These demands can often present at different levels, to different disciplines at different stages throughout the perioperative phase. Taking a systems approach and the use of this observational protocol facilitates and supports the following;

- The collection of critical data pertaining to the workload required during a surgical procedure.
- A better understanding of the existing practices that take place in the surgical setting, including workload, operational processes and collaboration in preventing RFOs in Ireland.
- Provides powerful information to assist in the development of hospital specific foreign object management processes and implementation roadmaps.
- Creates an awareness and focus on reducing and eliminating problems associated with foreign object retention, through identifying good practices and areas for improvement.

### 4.2.1 Use of CDA to gather data on situational awareness

Situation awareness is described as the perceived understanding an individual has of their active surroundings and their decision-making ability based on the changing environment [35]. Whilst it may be reasonable to query the lack of more objective measurement of concepts such as situational awareness and workload, the rationale behind not doing so is justified by the complex and dynamic nature of the safety critical working environment. It can be argued that self-assessments of situational awareness can often be influenced by the individual's level of confidence [36]. It would also be folly to ask a surgical team to pause and complete instruments such as SART and SAGAT, indeed doing so would not only pose extreme risk to the patient, but would also interfere with the natural flow of the operational process at hand. It would also interrupt the co-ordination and team dynamics which is precisely what the research team is mapping and analyzing. This is why the CDA

was utilized, there would be no interruption to the operational process, and observers could collect data whilst being as unobtrusive as possible. The rating scale of the CDA was changed from 3 to 5 as previous research had shown there to be overemphasis on the middle value [17].

### 4.2.2 Measurement of Workload

Measures of workload commonly discussed in the literature include subjective (perceptions), objective (physiological) and procedural [37]. It is argued that the concept surrounding workload measurement is to determine if certain increased workloads cause inadequate performance [38]. A decision was made not to use subjective rating instruments such as the NASA-TLX or the SURG-TLX involving pre-and post-observations for participants. This decision was made on the basis that asking a participant to complete this instrument may also interfere with the overall objective of the FOR_RaM research project as it may make staff feel that they are being monitored regarding their workload. This may alter their behavior during observations and it would not give a measure of workload throughout the entire operational process which is what the research team was attempting to elicit. Although there is evidence in the literature of workload measurement using the NASA-TLX and the SURG-TLX both in the operating theatre and in simulation settings, much of the literature on surgery focuses specifically on surgeons measures of workload, with little emphasis placed on a multi-disciplinary perspective which is of importance in the FOR_RaM project. There was also a lack of suitability to the wider FOR_RaM project to obtain objective measures of workload (i.e. linking autonomic and cognitive activities as an indirect measure), due to its invasive nature [21]. Instead it was agreed that a NASA–TLX would be performed by outside observers for every critical point in the operational process. Therefore the NASA-TLX could accommodate recognition of workload involved and allow for a structured assessment of perceived physical and cognitive demands required throughout the operational process [39]. A minimum of 3 researchers (including one with a clinical background) would individually score each critical point in the operational process to ensure inter-rater reliability. Considerable effort will be made to ensure there are no ecological fallacies resulting from the analysis [40]. To do so, each individual will be scored (individually) using the NASA TLX and the Team Workload Questionnaire [41, 42] will be used to score the team workload at that critical point. Whilst it is not ideal that subjective measures (i.e. researchers rating an individual's workload as opposed to the participant rating the workload themselves) of workload are used, it is important that we have some measure/ assessment of workload throughout the operational process. It would not be possible to ask individual participants to do this without interfering with the process flow. With the current dearth in appropriate team measures, it is important that triangulation of results is carried out. This will be done extensively as FOR_RaM will interrogate the data from multiple perspectives:

- Operational Process Maps
- Performance Shaping Factors

- Co-ordination Demands Analysis
- Workload (from both team and individual levels)
- Content Analysis

The FOR_RaM research project is on-going and the results will be made available when the final phase of data collection and analysis has been completed.

## 6 Conclusion and Future Work

This paper has identified the observational protocol utilized during observations conducted in a surgical setting and discusses the stages involved in developing the observational template used within the operating theatre. With this protocol we were able to identify a more in-depth picture of the mental and physical demands as well as the technical and non-technical skills used during the intra-operative phases. Applying this protocol to both the surgical and maternity setting will highlight differences in; tasks, priority of tasks, demands, norms and the physical and mental workloads involved. This information will highlight similarities and differences providing progress and understanding towards implementation of effective change interventions for reducing and mitigating the retention of foreign objects. The FOR_RaM project is currently in the data collection phase, thus further data collection and analysis will be conducted in both surgical and maternity settings before interventions are implemented. It is hoped that this tool will aid analysis and the understanding of current practice, support development of foreign object management processes and implementation roadmaps whilst addressing the level of mental workload involved in these two settings.

### 6.1 Limitations

Due to the dynamic and complex nature of the operating theatre environment we had no control over who entered the operating theatre under observation after commencement. This resulted in some staff members who briefly entered and exited the theatre but who were not directly involved in the observation and were unidentifiable; full written consent in some instances was not achievable, despite researchers' attempts to locate staff after the observation. This was highlighted to the clinical leads and the ethics committee at the hospital.

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