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towards
implementing
laboursaving
technology
in
surgery
Anton M. Kooijmans

Towards implementing laboursaving technology in surgery

Towards implementing laboursaving technology in surgery

Dissertation

for the purpose of obtaining the degree of doctor
at Delft University of Technology
by the authority of the Rector Magnificus, prof.dr.ir. H. Bijl
Chair of the Board for Doctorates
to be defended publicly on
Monday 29 June 2026 at 17:30

by

Anton Martin KOOIJMANS

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Artwork on cover: Sofie van Thiel, *Untitled II* from the series *Senses in Transition*, 2022. Acrylic paint, oil stick, oil pastel, and pastel chalk on satin. Reproduced with permission from the original artist.

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Summary

In this dissertation, we investigate laboursaving technology in the operating room (OR), specifically geared towards tracking and tracing of surgical instruments and devices. While the development of new technologies continues swiftly, the implementation and effective use in clinical practice lags behind. There is a need for a comprehensive overview of factors involved in this.

The aim of this thesis is to provide an interdisciplinary overview of the implementation of laboursaving technology in the OR, using surgical instrument counting as an illustrative case.

In **Chapter 2**, we present the current situation of surgical instrument counting in clinical practice. Through observations, we found that OR nurses use various strategies and counting techniques to manage disruptions and limit workload. We also found that there is limited interest in the use of supportive technology during a surgical procedure; nurses prefer this support in the preparatory and closing phases of surgery.

In **Chapter 3**, we dive deeper into the current use of laboursaving technology. In **Part 1** we focus on weighing systems (i.e., scales). Introduced around twenty years ago, they were meant to standardise and automate surgical instrument counting. Instruments are weighed before and after a surgery, and if the weight matches, the instruments are complete. Around a quarter of Dutch hospitals still use a weighing system in their instrument lifecycle, but many mention that it is unreliable. This triggered us to investigate further. We visited several hospitals throughout the country to see how the system is used. We found that each hospital adapted their workflow in a unique way to accommodate the limitations of the weighing system, with a varying degree of success, or *fidelity*. It turns out that this fidelity is higher in hospitals where communication between departments and different user groups occurs more smoothly, thereby increasing trust in the system's accuracy.

In **Part 2** of this chapter we focus on a different technology, introduced around ten years ago in the Reinier de Graaf hospital in Delft: DORA (Digital Operating Room Assistant). DORA was developed to improve efficiency surrounding medical devices situated in the OR (like infusion pumps, laparoscopy towers). In case of a device malfunctioning, DORA allows for an immediate error report to the technical department instead of OR staff having to call a technician. In our evaluation study, we found that while most OR users are satisfied, some issues remain that nudge people to the old way of reporting device malfunctions. Technicians are less satisfied, as the relatively short battery life of the sensor requires them to find devices in the operating rooms just to replace a battery. However, the added value of the system when these issues are resolved is clear, as developments of a new DORA system are underway.

Chapter 4 presents the uniformity and variations in surgical counting protocols among Dutch hospitals. Two-thirds of all hospitals participated in this study, showing that surgical instrument counting is an important topic in the field. Compared to a similar study performed in 2006, various improvements have been made to increase standardisation and patient safety. However, perceived high-risk situations have remained largely unchanged, such as staff changes and emergency situations. In addition, most hospitals describe a shared responsibility of the instrument count in their protocol, a policy we speculate could contribute to uncertainty and unsafe practice. We also found that a quarter of hospitals use a weighing system in their instrument workflow, with half of them noting that this system is unreliable in its purpose to count instruments.

So far, no technology has managed to fully replace the manual process of surgical instrument counting. However, with continued interest and development of technologies for this application, such as computer vision algorithms, this might still happen in the near future. In **Chapter 5**, we analyse jurisprudence and legal precedence to determine who is actually responsible for instrument counting. According to national guidelines, the instrumenting nurse is responsible for performing the instrument count. Looking further, however, the surgeon and the hospital are liable for damages following a retained instrument. Adding to that, new technological innovations will likely make use of artificial intelligence (AI), where the way in which an algorithm comes to an output often remains unclear. Legal experts and lawmakers have not yet worked out how this will relate to the responsibility and liability of users in the medical context.

Samenvatting

In dit proefschrift onderzoeken we arbeidsbesparende technologie in de operatiekamer (OK), in het bijzonder technologie gericht op *track & trace* van chirurgische instrumenten en medische apparatuur. Terwijl nieuwe technologische ontwikkelingen zichzelf snel opvolgen, blijft de implementatie en effectief gebruik in de klinische praktijk vaak achter. Er is een behoefte aan een overzicht van factoren die hierop van invloed zijn.

Het doel van dit proefschrift is om een interdisciplinair overzicht te geven van de implementatie van arbeidsbesparende technologie op de OK, waarbij het tellen van chirurgische instrumenten als illustratieve casus wordt gebruikt.

In **Hoofdstuk 2** presenteren we de huidige situatie van het instrumententellen in de klinische praktijk. Door te observeren vonden we dat operatieassistenten verschillende strategieën en teltechnieken gebruiken. Zo kunnen ze beter omgaan met onderbrekingen en de werklast beperken. We vonden ook dat er maar beperkte interesse was in het gebruik van ondersteunende teltechnologie tijdens een chirurgische ingreep; operatieassistenten hebben deze ondersteuning liever in de voorbereidende en afsluitende fase van een ingreep.

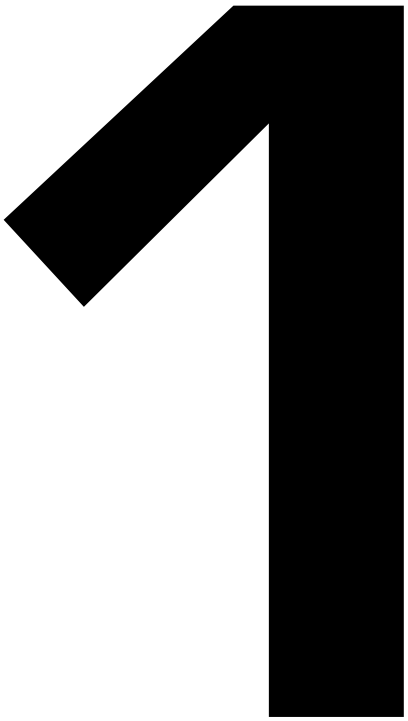
In **Hoofdstuk 3** gaan we dieper in op het gebruik van al bestaande arbeidsbesparende technologie. In **Deel 1** focussen we op weegsystemen; deze werden ongeveer twintig jaar geleden geïntroduceerd, met als doel het standaardiseren en automatiseren van de instrumententelling. Door instrumenten voor en na de ingreep te wegen, kan zo bepaald worden dat alle instrumenten weer terug op de juiste plaats zijn. Ongeveer een kwart van de Nederlandse ziekenhuizen gebruikt nog steeds een weegsysteem in hun instrumentencyclus, maar velen melden dat het wegen onbetrouwbaar is. Om deze reden zijn we verder gaan kijken. We hebben diverse ziekenhuizen door heel het land bezocht om te zien hoe het systeem gebruikt wordt. We vonden dat elk ziekenhuis op hun eigen manier werkprocessen hebben aangepast om het weegsysteem (en zijn beperkingen) in te passen, in verschillende maten van succes, of *fidelity*. Het blijkt dat deze fidelity hoger is in ziekenhuizen waar de communicatie tussen afdelingen en gebruikersgroepen soepeler verloopt, waardoor het vertrouwen in de accuratesse van het systeem hoger is.

In Deel 2 van dit hoofdstuk verleggen we de focus naar een andere technologie, die zo'n tien jaar geleden is geïntroduceerd in het Reinier de Graaf Gasthuis in Delft: DORA (Digital Operating Room Assistant). DORA was ontwikkeld om werkprocessen rondom medische apparatuur op de OK (zoals infuuspompen, laparoscopietorens) te verbeteren. In het geval van een defect apparaat, kan men met behulp van DORA direct een melding maken bij de technische afdeling zonder dat OK personeel

handmatig hoeft te bellen met een technicus. In onze evaluatiestudie vonden we dat gebruikers op de OK wel tevreden waren met het systeem, maar dat een aantal tekortkomingen ertoe leiden dat men terugvalt op oude gewoontes. Technici zijn minder tevreden, met name door de relatief korte batterijduur, waardoor er veel tijd wordt besteed aan het vervangen hiervan. Toch is de toegevoegde waarde van het systeem duidelijk; een nieuwe doorontwikkeling van DORA ligt in het verschiet.

Hoofdstuk 4 presenteert de uniformiteit en variaties in chirurgische telprotocollen onder Nederlandse ziekenhuizen. Twee-derde van alle ziekenhuizen deden mee aan dit onderzoek, wat laat zien dat de chirurgische instrumententelling een belangrijk onderwerp is in de sector. Vergeleken met een eerder onderzoek uit 2006 zien we dat er verschillende verbeteringen zijn doorgevoerd om de standaardisatie en patiëntveiligheid te verhogen. Specifieke hoog-risico situaties blijven echter grotendeels hetzelfde, zoals het aflossen van personeel en spoedsituaties. Daarbij blijkt dat bij een meerderheid van de ziekenhuizen een gedeelde verantwoordelijkheid voor de instrumententelling in het protocol wordt beschreven. Dit beleid zou kunnen leiden tot onduidelijke en mogelijk onveilige situaties. In dit onderzoek vonden we ook dat een kwart van de Nederlandse ziekenhuizen een weegsysteem gebruikt in hun instrumentencyclus waar we in Deel 1 van Hoofdstuk 3 verder onderzoek hebben gedaan.

Tot nu toe heeft geen technologie het handmatige proces van chirurgische instrumenten tellen kunnen overnemen. Met blijvende interesse vanuit het onderzoeksveld en ontwikkeling van technologieën voor dit gebruik, zoals *computer vision* algoritmes, zou dit wel eens kunnen veranderen in de nabije toekomst. In **Hoofdstuk 5** behandelen we de vraag wat er in dat geval met de verantwoordelijkheid en aansprakelijkheid van het OK-team kan of moet gebeuren. Volgens nationale richtlijnen is de instrumenterende operatieassistent verantwoordelijk voor het tellen, maar is de chirurg en het ziekenhuis aansprakelijk voor schade in het geval van een achtergebleven instrument. Daar komt nog bij dat nieuwe technologieën hoogstwaarschijnlijk gebruik zullen maken van kunstmatige intelligentie (artificial intelligence, AI), waarbij de manier waarop een algoritme tot een output komt vaak nog onduidelijk is. Juridisch experts en wetgevers zijn er nog niet uit hoe dit zich zal verhouden tot verantwoordelijkheid en aansprakelijkheid in de medische context.



Chapter 1: Introduction

1.1 BACKGROUND AND CONTEXT

Healthcare is currently facing significant challenges, with the most pressing being an aging population [1]. As the population gets older, the incidence of age-related chronic diseases and the subsequent demand for healthcare increase with it. Paired with a shrinking workforce, the pressure on society is significant. Currently, around 1 in 7 people in the workforce work in healthcare in the Netherlands. To cope with an increasing demand for care, this number would have to grow to 1 in 4 people by 2040 [1, 2], as is illustrated in Figure 1.1. Such a dramatic increase is impossible to achieve without major consequences for the workforce in other sectors. This means that care productivity per person will have to increase to meet the growing demand. In short, more care will have to be provided with less people.

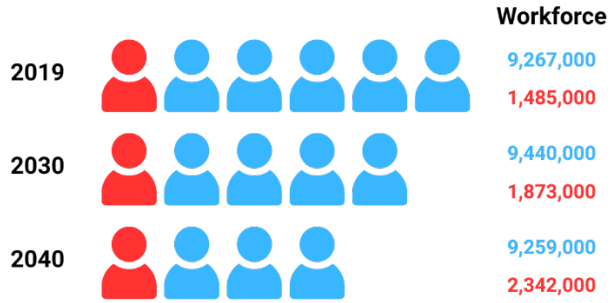


***Figure 1.1**. Size of healthcare workforce (red) as part of general workforce (blue). Adapted from [2]*

A possible solution to this problem is to use laboursaving technology. Many processes in healthcare organisations are done manually. Technology could take over more tedious tasks from staff [3], allowing them more time for the human side of caregiving.

However, implementing technology in complex healthcare organisations is not straightforward. An illustrative example of this is the process of *surgical instrument counting*. Before, during, and near the end of an operation, the instrumenting nurse is required to count all instruments involved in the surgery, so that none get lost or retained inside the patient. Thanks to counting, retained surgical instruments (RSIs) are a rare occurrence, with estimates ranging from 1 in 1000 to 1 in 10,000 surgeries [4, 5]. However rare, consequences of an RSI can be dire, with patients suffering from mild to severe complaints and even death [6].

Thought to be the result of the tediousness and repetitiveness of the counting, innovators sought to eradicate the occurrence of RSIs by removing the human factor from it. They hypothesised automated instrument tracking would not only reduce the incidence of RSIs [7], but it would also allow for automated instrument tray optimalisation, preventive maintenance [8], streamlined inventory management [9],

automated OR scheduling through surgical phase recognition [10, 11], and it would allow OR nurses to focus on other tasks, such as assisting the surgeon.

Over the years, many technologies have been proposed to aid in surgical instrument counting, with varying levels of implementation success. For example, data matrices (i.e., barcodes and QR codes) [7, 12] have the advantage of being easily affixed to instruments using for instance laser engraving, allowing for affordable scaling. However, regular use can wear or damage the engravings, making them harder to read. In addition, instruments need to be individually scanned by a scanning device, significantly increasing handling time.

Another technology that has received significant interest in the field is radio-frequency identification (RFID) [8, 13-15]. By attaching passive RFID sensors to instruments, a dedicated RFID antenna can pick up a signal from each instrument, thereby tracking their location in real-time. Challenges include scalability, reliability of the attachment method, and achieving an adequate detection rate in a real OR environment [16].

In recent years, the development of computer vision algorithms has taken flight. These algorithms have been adapted by many for the detection and recognition of surgical instruments [17-22]. A major advantage compared to other technologies is its scalability; instruments do not have to be modified. However, these algorithms tend to struggle when conditions are variable, as is often the case in an OR.

Providing a more low-tech solution, weight sensors (i.e., weighing scales) have seen a relatively wider dissemination and use in comparison to the technologies mentioned above. The simplicity of the technology allowed for easy implementation, but there are clear drawbacks as well, which will be discussed further in this dissertation.

While all the above-mentioned innovations tackle a specific issue, none of them have been able to provide a holistic solution reaching wide dissemination among hospitals. This suggests that there is a gap between current technologies and the complexity of clinical practice. The field of healthcare is a very heterogenous field with a strict hierarchy and can be incredibly difficult for an engineer to gain access to. To close this gap, a more holistic approach to this issue is warranted, integrating insights from various perspectives into a larger overview.

1.2 RESEARCH OBJECTIVE

The main objective of this dissertation is to explore and describe the intricacies of implementing laboursaving technology in surgery, using the surgical instrument count as an illustrative case study. To achieve this, we have specified several sub-objectives as described by the following research questions:

i. What is the current practice in surgical instrument counting?

ii. What lessons can be learnt from already existing laboursaving technologies in the OR?
iii. What is the OR nurses' sentiment regarding counting technology?
iv. Do current surgical protocols and professional standards support the implementation of laboursaving technology?
v. Does current jurisprudence support the implementation of laboursaving technology in surgery?

1.3 SCOPE AND OUTLINE OF THE DISSERTATION

As the objectives imply, this dissertation consists of a variety of research domains and methodologies. We encountered numerous challenges due to this interdisciplinary structure. However, we believe this approach is essential in order to gain a thorough, integrated understanding of implementing an innovation in clinical practice and achieving a sustained benefit from it. The research domains involved in this work are current technologies, the users, the context in which the technology is used, as well as the legal context of automating a manual task.

In **Chapter 2**, observational results are presented to describe current practices involving surgical instrument counting. In addition, OR nurse preferences regarding the use of technology are shown.

In **Chapter 3**, two studies will be discussed. In **Part 1**, the findings of semi-structured interviews among senior staff of hospitals that use a weighing system in their surgical instrument lifecycle. The study shows how over the years, despite implementing the same technology, hospitals end up with a variety of workflow integrations. With these variations, a variety in user sentiment can also be seen. **Part 2** describes an evaluation of the Digital Operating Room Assistant (DORA), implemented in the Reinier de Graaf hospital ten years ago. Based on the responses of various user categories, valuable lessons on implementation and long-term sustained use are presented.

Chapter 4 presents the uniformity and variations in surgical counting protocols among Dutch hospitals. Inspired by an earlier, similar study performed in 2006, this chapter shows the improvements that have been made over the years to the practice of surgical instrument counting.

Chapter 5 dives deeper into the what-if of automated instrument counting. A literature study on the jurisprudence surrounding RSIs provides a foundation for further discussion of the 'who' and 'what' of responsibility and liability.

In **Chapter 6**, the findings will be integrated and discussed, after which conclusions will be drawn.

REFERENCES

1. Aan de slag voor de zorg. Sociaal Economische Raad; 2021. https://www.ser.nl/-/media/ser/downloads/adviezen/2021/arbeidsmarkt-in-zorg.pdf.
2. Ministry of Health WaS. WOZO: Programma Wonen, Ondersteuning en Zorg voor Ouderen. Ministry of Health, Welfare and Sport; 2022. https://open.overheid.nl/documenten/ronl-63e851f8e45b8662a4d04b1d5832b98231d40670/pdf.
3. Vilans. Factsheet Tijdbesparende technologieën in de ouderenzorg. Vilans; 2021. https://open.overheid.nl/documenten/ronl-ee7ae283-0bfb-4066-bc64-45e2843ada19/pdf.
4. Lincourt AE, Harrell A, Cristiano J, et al. Retained foreign bodies after surgery. J Surg Res. 2007;138(2):170-4.
5. Williams TL, Tung DK, Steelman VM, et al. Retained surgical sponges: findings from incident reports and a cost-benefit analysis of radiofrequency technology. J Am Coll Surg. 2014;219:354-64.
6. Gawande AA, Studdert DM, Orav EJ, et al. Risk Factors for Retained Instruments and Sponges after Surgery. N Engl J Med. 2003;348:229-35.
7. Cima RR, Kollengode A, Clark J, et al. Using a data-matrix-coded sponge counting system across a surgical practice: impact after 18 months. Jt Comm J Qual Patient Saf. 2011;37(2):51-8.
8. Hill I, Olivere L, Helmkamp J, et al. Measuring intraoperative surgical instrument use with radio-frequency identification. JAMIA Open. 2022;5(1):ooac003.
9. Guedon AC, Wauben LS, van der Eijk AC, et al. Where are my instruments? Hazards in delivery of surgical instruments. Surg Endosc. 2016;30(7):2728-35.
10. Kusuda K, Yamashita K, Ohnishi A, et al. Management of surgical instruments with radio frequency identification tags. Int J Health Care Qual Assur. 2016;29(2):236-47.
11. Neumuth T. Surgical process modeling. Innov Surg Sci. 2017;2(3):123-37.
12. Kranzfelder M, Schneider A, Blahusch G, et al. Feasibility of opto-electronic surgical instrument identification. Minim Invasive Ther Allied Technol. 2009;18(5):253-8.
13. Hosaka R. Development of Identification System for Surgical Instruments Using UHF Band RFID and Low-Intensity Antennae. World Congress on Medical Physics and Biomedical Engineering 2018. IFMBE Proceedings 2019. p. 39-43.
14. Hanada E OA, Hayashi M, Sawa T. Improving efficiency through analysis of data obtained from an RFID tag system for surgical instruments. IEEE 5th International Conference on Consumer Electronics; Berlin, Germany 2015. p. 84-7.
15. Matsumura T TM, Saito K, Yamamoto E, Ito K. Performance evaluations on RFID tag antenna for managing surgical instrument. International Conference on Electromagnetics in Advanced Applications; Cape Town, South Africa 2012. p. 430-3.
16. Meeuwsen FC. Safe Surgical Signatures. TU Delft Repository: TU Delft; 2019.
17. Lee J-D, Chien J-C, Hsu Y-T, et al. Automatic Surgical Instrument Recognition—A Case of Comparison Study between the Faster R-CNN, Mask R-CNN, and Single-Shot Multi-Box Detectors. Applied Sciences. 2021;11(17).
18. Nakano A, Nagamune K. A Development of Robotic Scrub Nurse System - Detection for Surgical Instruments Using Faster Region-Based Convolutional Neural

Network –. Journal of Advanced Computational Intelligence and Intelligent Informatics. 2022;26(1):74-82.
19. Zhou Y, Liu Z. Detection of Surgical Instruments Based on YOLOv5. 2022 IEEE International Conference on Manipulation, Manufacturing and Measurement on the Nanoscale (3M-NANO)2022. p. 470-3.
20. Ran B, Huang B, Liang S, et al. Surgical Instrument Detection Algorithm Based on Improved YOLOv7x. Sensors (Basel). 2023;23(11).
21. Jiang K, Pan S, Yang L, et al. Surgical Instrument Recognition Based on Improved YOLOv5. Applied Sciences. 2023;13(21).
22. Haider SA, Ho OA, Borna S, et al. Use of Multimodal Artificial Intelligence in Surgical Instrument Recognition. Bioengineering (Basel). 2025;12(1).

2

Chapter 2: Current practices in surgical instrument counting

This chapter was published in *Human Factors in Healthcare* on 12 September, 2024 as: Kooijmans, A.M., de Rouw, L., van der Elst, M., van den Dobbelsteen, J.J. Surgical instrument counting: Current practice and staff perspectives on technological support.

Abstract

Background Surgical instrument counting is a manual, attention-intensive task of the operating room (OR) nurse. Many labour-saving technologies have been proposed, but few have been implemented successfully. Knowledge of current OR workflows and workload enables effective application of future developments.

Approach We observed OR nurses counting materials and instruments in 50 surgical procedures performed by various surgical specialties in a regional teaching hospital in Delft, The Netherlands. Additionally, we surveyed them on their experience of workload concerning the count.

Key findings Variations in performance of surgical counting were observed, with OR nurses using multiple strategies and counting techniques to manage workload. Workload increases mostly when the number of surgical instruments necessary for a procedure increases. Interest in using supportive technology is limited to the preoperative and postoperative phase.

Relevance This research is the first to relate observational data to experience of workload. Our findings may guide future developments of labour-saving innovations regarding surgical counting towards developing more effective applications and to ensure successful implementation.

2.1 INTRODUCTION

Globally, healthcare is facing challenges which necessitate new strategies to save time and resources [1, 2]. In this light, sustainable employability of personnel is becoming an increasingly discussed topic.

Laboursaving innovations have the potential to optimise workflows and thereby reduce workload, as well as save money, and improve quality of care. For example, currently, operating room (OR) nurses manually keep track of all instruments and materials used

during surgery with *instrument counting* (see Fig. 2.1 for an overview). Although the incidence is low, a retained surgical instrument (RSI) inside a patient may have serious consequences for patient outcomes.

Manual counting is a labour-intensive process, especially considering the complex and often acute conditions of an OR.

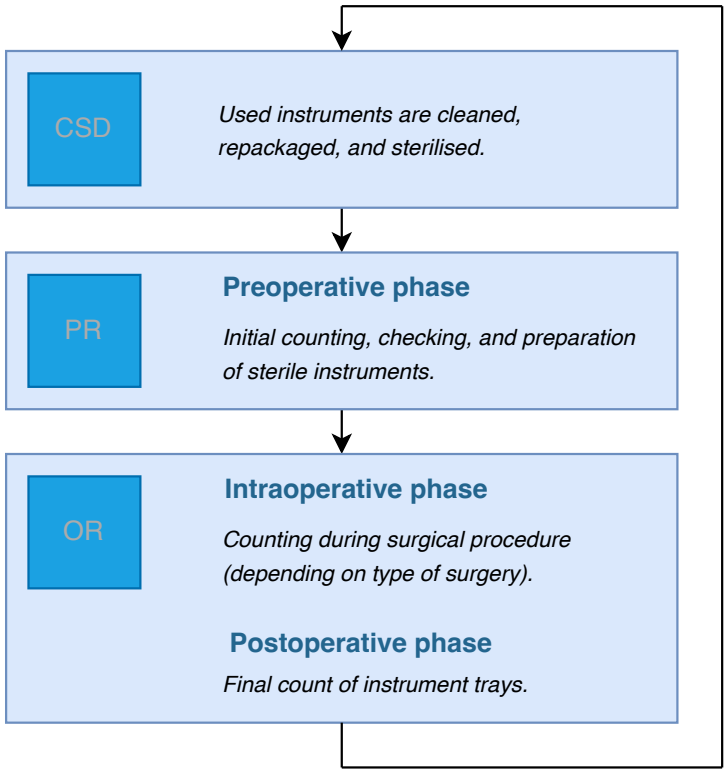


Figure 2.1 *Surgical material counting. After processing in the central sterilisation department (CSD), instruments are counted, checked, and prepared in the preparation room (PR), before they are brought to the operation room (OR) for the surgical procedure. Intraoperative counting depends on the type of procedure. After completion of surgery, materials are counted, and instruments are transported back to the sterilisation department, to be processed for their next cycle*

A system which can detect and recognise the instruments being used could potentially reduce OR nurses' workload [3], as well as optimise OR workflow. Potential uses beside automatic counting include preventive maintenance, automatic registration of used materials, and automatic OR scheduling.

A large variety of technologies have been investigated, such as data matrices (i.e., barcodes and QR codes) [4-6], weight sensors [7, 8], radiofrequency identification (RFID) sensors [3, 9-20], computer vision [8, 21-26], and even robotics [25, 27]. However, most solutions fall short in addressing the complexity of real-life OR

conditions [28]. For instance, many studies were performed in a lab environment with ideal conditions or an approximation of OR conditions [7, 8, 14, 16, 17, 25, 27]. Similarly, many proposed solutions interfere with regular surgical workflow, requiring specific instrument layouts, individual scanning of instruments, or a substantial setup time for each procedure [3-5, 15, 18, 19, 21, 26, 27].

Despite this lack of consideration for real-life OR conditions, some empirical research on the performance of the surgical instrument count exists. It is reported that OR nurses face many challenges that may affect their ability to count according to best practice principles. Reported challenges are interruptions, distractions, time pressure, and the pressure of an emergency procedure [29-32]. Solutions are often sought in changing the dynamics of the OR environment: eliminating interruptions and distractions or performing audits to ensure strict protocol adherence.

These technologies are often considered to be a replacement for the OR nurse's work; with the main goal of reducing RSIs. However, the question whether the use of technology actually reduces RSIs and increases patient safety is still topic for debate [33]. The application of technology to reduce OR nurse's workload is currently not considered a priority, with some studies only briefly mentioning this topic [3, 34]. A broader analysis of the current counting practice and effective applications of counting technology from a workload perspective does not exist yet.

This study aims to analyse the current counting practice from a workload perspective and explore OR nurse's preferred applications of technology in general to aid in counting. By observing OR nurses during their work and conducting a survey on their perspective, we gathered valuable data which could guide future development of automatic instrument tracking solutions.

2.2 METHODS

2.2.1 Study design

This work consists of two parts: an observational study combined with a survey. For the observations, we developed a data collection form based on the hospital's counting protocol (Appendix A), national guidelines and standards, relevant literature, and feedback from OR nurses. We formulated the survey questions to gauge the opinion of OR nurses on the current process of the instrument count and the potential of adjunct technology in it.

2.2.2 Study setting

This study took place in the OR complex of the Reinier de Graaf Gasthuis, a regional teaching hospital in Delft, the Netherlands. Surgical specialties that use this facility include ear-nose-throat (ENT), urology, gynaecology, orthopaedics; as well as plastic, vascular, trauma, and general surgery.

2.2.3 Data collection

We attended 50 surgical cases from all the above-mentioned specialties between March and May 2023. Consent was obtained from the OR team to observe the surgical counting performance, conduct a survey, capture images, and identify opportunities for technological applications. We aimed to minimise disruptions of the regular OR workflow. Patient consent was not necessary as patient characteristics were not recorded. We ensured the team members' privacy by only referring to their professional role in the data recordings.

Observations were structured according to the data collection form. Descriptive data such as surgical specialty, nature of surgical procedure (elective or emergency), time of surgery, and number of instrument trays used were noted. Furthermore, we recorded how the counting in each surgical phase was performed: number of staff involved, method used, time spent, and occurrence of interruptions.

Survey questions were administered to the current circulating nurse. As both OR nurses alternate the role of scrub nurse and circulating nurse, we could survey both OR nurses while minimising disruptions to the surgical procedure. See Appendix B for an overview of the questions.

2.3 RESULTS

Table 2.1 shows baseline characteristics. Across all 50 observed procedures, 87 instrument trays were used (1-7 trays per procedure).

Table 2.1 *Observed surgical procedures (continued on next page)*

Surgical specialty	*Frequency*	*Percentage*
Ear-nose-throat (ENT)	14	28%
Trauma surgery	11	22%
Vascular surgery	7	14%
Gynaecology	6	12%
Robot general surgery	5	10%
General surgery	4	8%

Orthopaedic surgery	2	4%
Plastic surgery	1	2%

Nature of procedure	*Frequency*	*Percentage*
Elective	47	94%
Emergency	3	6%

2.3.1 Observations

Initial instrument inspection

Surgical trays were delivered from the sterilisation department covered in blue (96%) or green (4%) wrapping paper. Blue wrapping paper indicated all instruments were present, while green paper indicated an incomplete tray due to one or more missing instruments.

Most procedure preparations (72%) were done in the preparation room. The rest (28%) were performed in the OR itself. It was explained to the researcher that some procedures, such as ENT surgeries, are inherently unsterile and thus allow the preparation to be carried out in the OR itself, thereby saving time.

The initial check of the tray was always performed by the scrub nurse. The circulating nurse was not available for assistance in any of the cases. Instead, it was carried out with the help of a nearby logistics worker, or by the scrub nurse alone. A full inspection with each tray's accompanying contents list was deemed unnecessary, as trays wrapped in blue paper were assumed to be complete. These lists were only used when a shortcoming such as a defective or missing instrument was noticed, which occurred in 8% of cases.

Preparing the instrument table

A selection of instruments was placed on the instrument table in the anticipated order of use. This varied based on a nurse's previous experience of similar cases, as well as their knowledge of the surgeon's preference. We noted two approaches when multiple instrument trays were needed: each tray's instruments would be prepared on a separate table, or instruments from all trays would be prepared on the same table.

Counting techniques

Counting techniques varied between nurses and between instrument tray arrangements. For loosely arranged trays, scrub nurses focused on keeping track of the number of instruments removed from the surgical tray by placing them on the instrument table in even numbers or pairs, to 'facilitate memorisation and ease of counting'. Similarly, some practitioners group instruments by threading a specific number of them through one instrument's ear. Usually, no formal count is carried out. However, a precise scissor count is conducted exclusively in abdominal procedures. Fragile instruments were placed in specifically arranged trays with silicone clips. By scanning these, the nurses could determine if the surgical tray was complete.

Counting was deemed unnecessary if the likelihood of losing an instrument was considered to be minimal, for instance in the case of thumb fracture surgery or some gynaecological procedures where no incision is made.

Additional trays

In eight cases (16%), an additional surgical tray was opened (see Table 2.2). Five were opened in the preoperative phase and three were opened during surgery. During the preoperative phase, additions were necessary to replace an incorrect instrument or part of an instrument, or to replace a missing instrument. During surgery, additions were done because an instrument fell on the floor, or because the surgeon preferred a different instrument. The researcher could not determine the reason for one addition.

Table 2.2 *Reasons for opening additional surgical instrument trays and their frequency*

Reason for additional tray	*Frequency*
Incorrect instrument or part of instrument	3
Missing instrument	2
Instruments not in accordance with surgeon's preference	1
Unsterile instrument	1
Reason unknown	1

Retrieving and returning during surgery

The instruments used during surgery were not limited to those prepared on the instrument table; in some cases, additional instruments were retrieved directly from the tray, bypassing the instrument table. The surgeon could request a specific

instrument, but often the scrub nurse anticipated this and retrieved an instrument without an explicit request.

After use, instruments were returned to the instrument table if they might be needed again. If they were not needed anymore, they were returned to the tray intermittently. The nurse kept track of the instruments using the same counting techniques as during the preparation, returning them in pairs, and checking if all silicone clips were occupied. The nurses explained that this technique saves time, as all instruments are accounted for as they are returned to their tray, instead of having to perform a complete check after the procedure has concluded. The median time spent on returning instruments was 29.0 seconds, with a range of 5.6 to 372.9. As shown in Figure 2a, the time taken to return instruments increased with the number of trays in use.

Interruptions

The process of returning and counting of instruments was interrupted on many occasions, mostly due to the surgeon requesting assistance or a specific instrument from the scrub nurse. We noted a total of 41 interruptions across all cases, with a maximum of 6 in a single case. Figure 2b shows that the number of interruptions increases with the number of trays in use.

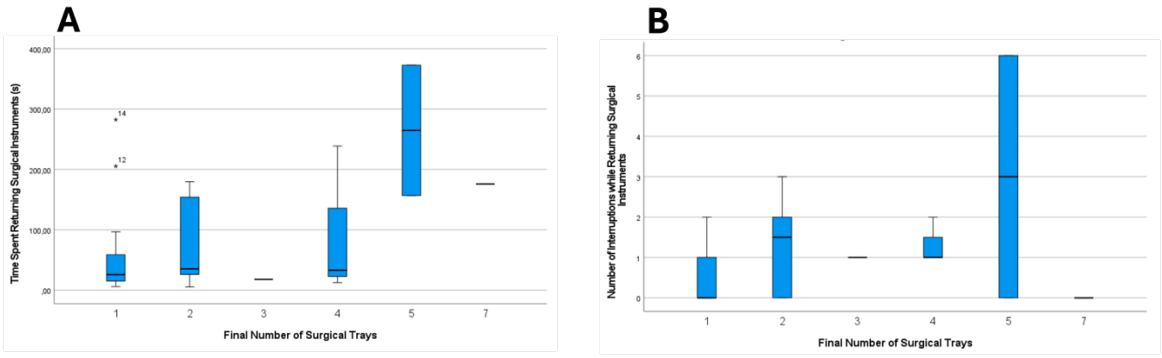


Figure 2.2 a. *The time spent to return instruments to their tray.* ***b.*** *The number of interruptions during this, related to the final number of surgical trays used. No procedures were observed where six trays were used*

Completion of surgery

After completion of the surgical procedure, no formal count of all instruments was performed in any of the observed cases. It was explained that if all fragile instruments were returned to their predetermined position in a silicone holder, and no single

instrument from the prepared pairs was missing, the instruments were considered to be complete.

2.3.2 Survey

Key findings will be discussed below. For a complete overview of the survey questions and results, see Appendix B.

Key findings

Currently, 39% of nurses indicate they do not count the entire surgical tray before surgery. The number of surgical trays in use is the leading influence on experienced workload (62%).

Most nurses (85%) see potential in reconfiguring the counting process to be more efficient, and all nurses are open to the use of technology, but only in the preoperative and postoperative phase of a procedure. None of the participants would be willing to use technology to aid in counting during surgery, as they consider that an unwanted additional distraction.

2.4 DISCUSSION

In this study, we observed a wide variety of procedures: from open to minimally invasive surgery, and from elective to emergency procedures. The hospital's surgical item counting protocol was developed according to the best practice principles as laid out in the AORN guidelines [35]. However, in every procedure OR nurses face challenges that affect their ability to count according to these principles, such as unavailable assistance, time pressure, interruptions, or distractions. To cope with this, various strategies and counting techniques are used depending on the requirements of each procedure.

2.4.1 Perioperative phases

The preoperative check of instrument trays is often adjusted to each procedure and its circumstances. Sometimes performed by the scrub nurse only, workload is managed by only counting instruments taken out of a tray to be placed on the instrument table. Abdominal procedures carry a greater risk for instrument loss and warrant a more precise scissor count.

The location of the preparation varies as well. Usually, it is carried out in the preparation room, where specially designed air circulation systems ensure a sterile

preparation environment. When procedures are inherently unsterile, as is the case with ENT or proctological procedures, the team bypasses the PR, thus saving time.

Postoperatively, a final count is not performed, as all instruments have already been accounted for when they were returned to the tray intermittently. It was explained that performing a complete check would add more time to the procedure. Despite these optimisations, a third of OR nurses still believe the counting process can be reconfigured more efficiently.

2.4.2 Intraoperative phase

During surgery, OR nurses are challenged with conflicting responsibilities. Keeping track of instruments and materials can be interrupted by a surgeon's need for assistance. Despite choosing optimal moments to count, interruptions and distractions still occur, with up to six in a single procedure during our observations. This forces nurses to perform more task-switching.

Interestingly, the time taken to return instruments increases linearly with the number of instruments. One would expect the effects of interruptions and distractions to worsen as counting time increases, because the 'window of opportunity' lengthens. This suggests that the effect of interruptions and distractions might not be as large an issue as was previously thought. Surgical procedures are complex, and stakes are high. The team members generally are quite attuned to each other and often work in a state of elevated focus or 'flow', which might explain the limited effect of interruptions on the counting time.

The survey confirms that OR nurses are quite satisfied with the current counting workflow during the surgical procedure, with only 10% seeing potential for improvement and none of them willing to use assistive technology in the intraoperative phase.

2.4.3 Surgical materials

Most research efforts to develop a tracking system for surgical materials focus on gauzes with barcodes or RFID sensors attached to them. When looking from a workload perspective, this might need to change. In the studied hospital, OR nurses are expected to be able to assist in any surgical procedure. This means they should be familiar with 642 different instrument trays, containing a various number of instruments (up to 160 per tray).

The survey shows that the number of instruments used is the major influence on workload during counting, rather than gauzes or needles. Similarly, only 27% of OR nurses would be willing to use technology to assist in counting gauzes, while 73% prefer technology to aid in counting instruments.

2.4.4 Recommendations

It has been put into question before whether the use of counting technology during a surgical procedure increases patient safety [4, 36], and our research suggests there is an obvious similar sentiment among OR nurses. Instead, there is substantial interest in applying counting technology to the preoperative and postoperative phase to alleviate workload. Performing a complete count of all instruments before and after a surgery is a time-consuming task which is currently managed with various strategies and counting techniques. Applying technology to these specific parts of the counting workflow could be a more effective way to optimise OR processes and alleviate OR nurse's workload.

2.4.5 Limitations

The observation tool we used was self-developed in an iterative process, without consultation of relevant OR team members. All observations were performed by one researcher (LR), which might have had a negative effect on noting intricacies of the counting performance.

Further research is needed to explore OR nurse's sentiment regarding safety, workload, and assistive counting technology. For this, we will conduct structured interviews based on a theoretical framework.

2.5 CONCLUSION

In this study, we explored surgical instrument counting from a practical workload perspective. We observed that OR nurses are faced with challenges that limit their ability to follow theoretical best practice principles. Depending on the specific requirements of each surgical procedure, various strategies and counting techniques are used to maintain an efficient workflow and limit workload. There is considerable interest in reconfiguring the counting workflow in the preoperative and postoperative phase among OR nurses, where they see potential for counting technology to assist in counting surgical instruments rather than gauzes or needles. There is little interest in the use of counting technology during a surgical procedure. This paper is the first to consider the instrument count and the place of counting technology from a workload perspective.

Based on our findings, future developments of counting technology should focus on the preoperative and postoperative phase to achieve the most effective reduction in OR nurse workload.

REFERENCES

1. Global strategy on human resources for health: Workforce 2030. World Health Organization; 2016. https://www.who.int/publications/i/item/9789241511131.
2. Naar een toekomstbestendig zorgstelsel. RIVM (Dutch National Institute for Public Health and the Environment); 2020. https://www.rijksfinancien.nl/bmh/bmh-2-naar-een-toekomstbestendig-zorgstelsel.pdf.
3. Yamashita K KK, Ito Y, Komino M, Tanaka K, Kurokawa S, Ameya M, Eba D, Masamune K, Muragaki Y, Ohta Y, Rinoie C, Yamada K, Sawa Y. Evaluation of Surgical Instruments With Radiofrequency Identification Tags in the Operating Room. Surgical Innovation. 2018;25(4):374-9.
4. Greenberg CC, Diaz-Flores R, Lipsitz SR, Regenbogen SE, Mulholland L, Mearn F, et al. Bar-coding surgical sponges to improve safety: a randomized controlled trial. Ann Surg. 2008;247(4):612-6.
5. Kranzfelder M, Schneider A, Blahusch G, Schaaf H, Feussner H. Feasibility of opto-electronic surgical instrument identification. Minim Invasive Ther Allied Technol. 2009;18(5):253-8.
6. Cima RR, Kollengode A, Clark J, Pool S, Weisbrod C, Amstutz GJ, et al. Using a data-matrix-coded sponge counting system across a surgical practice: impact after 18 months. Jt Comm J Qual Patient Saf. 2011;37(2):51-8.
7. Webster RJ, Yaniv ZR, Glaser B, Schellenberg T, Franke S, Dänzer S, et al. Surgical instrument similarity metrics and tray analysis for multi-sensor instrument identification. Medical Imaging 2015: Image-Guided Procedures, Robotic Interventions, and Modeling 2015.
8. Glaser B, Danzer S, Neumuth T. Intra-operative surgical instrument usage detection on a multi-sensor table. Int J Comput Assist Radiol Surg. 2015;10(3):351-62.
9. Rogers A, Jones E, Oleynikov D. Radio frequency identification (RFID) applied to surgical sponges. Surg Endosc. 2007;21(7):1235-7.
10. Meißner C, Neumuth T. RFID-based surgical instrument detection using Hidden Markov models. Biomedizinische Technik Biomedical engineering. 2012;57.
11. Neumuth T, Meissner C. Online recognition of surgical instruments by information fusion. Int J Comput Assist Radiol Surg. 2012;7(2):297-304.
12. Matsumura T TM, Saito K, Yamamoto E, Ito K. Performance evaluations on RFID tag antenna for managing surgical instrument. International Conference on Electromagnetics in Advanced Applications; Cape Town, South Africa 2012. p. 430-3.
13. Kranzfelder M, Schneider A, Fiolka A, Schwan E, Gillen S, Wilhelm D, et al. Real-time instrument detection in minimally invasive surgery using radiofrequency identification technology. J Surg Res. 2013;185(2):704-10.
14. Kranzfelder M, Zywitza D, Jell T, Schneider A, Gillen S, Friess H, et al. Real-time monitoring for detection of retained surgical sponges and team motion in the surgical operation room using radio-frequency-identification (RFID) technology: a preclinical evaluation. J Surg Res. 2012;175(2):191-8.
15. Hanada E OA, Hayashi M, Sawa T. Improving efficiency through analysis of data obtained from an RFID tag system for surgical instruments. IEEE 5th International Conference on Consumer Electronics; Berlin, Germany 2015. p. 84-7.

16. Dinis H ZM, Mendes PM. Performance assessment of an RFID system for automatic surgical sponge detection in a surgery room. Annu Int Conf IEEE Eng Med Biol Soc 2015. p. 3149-52.
17. Hosaka R. Development of Identification System for Surgical Instruments Using UHF Band RFID and Low-Intensity Antennae. World Congress on Medical Physics and Biomedical Engineering 2018. IFMBE Proceedings 2019. p. 39-43.
18. Olivere LA, Hill IT, Thomas SM, Codd PJ, Rosenberger LH. Radiofrequency Identification Track for Tray Optimization: An Instrument Utilization Pilot Study in Surgical Oncology. Journal of Surgical Research. 2021;264:490-8.
19. Hill I, Olivere L, Helmkamp J, Le E, Hill W, Wahlstedt J, et al. Measuring intraoperative surgical instrument use with radio-frequency identification. JAMIA Open. 2022;5(1):ooac003.
20. Zamith M MP. Towards an RFID microsystem for surgical instrument detection using millimeter waves. IEEE 4th Portuguese Meeting on Bioengineering (ENBENG); Porto, Portugal 2015. p. 1-5.
21. Toti G, Garbey M, Sherman V, Bass B, Dunkin B. A smart trocar for automatic tool recognition in laparoscopic surgery. Surg Innov. 2015;22(1):77-82.
22. Al Hajj H LM, Cochener B, Quellec G. Smart Data Augmentation for Surgical Tool Detection on the Surgical Tray. Annu Int Conf IEEE Eng Med Biol Soc 2017.
23. Hossain M NS, Hiranaka T, Kobashi S. Real-time Surgical Tools Recognition in Total Knee Arthroplasty Using Deep Neural Networks. Joint 7th International Conference on Informatics, Electronics & Vision (ICIEV) and 2nd International Conference on Imaging, Vision & Pattern Recognition (icIVPR) Kitakyushu, Japan 2018. p. 470-4.
24. Shimizu T, Hachiuma R, Kajita H, Takatsume Y, Saito H. Hand Motion-Aware Surgical Tool Localization and Classification from an Egocentric Camera. J Imaging. 2021;7(2).
25. Nakano A, Nagamune K. A Development of Robotic Scrub Nurse System - Detection for Surgical Instruments Using Faster Region-Based Convolutional Neural Network –. Journal of Advanced Computational Intelligence and Intelligent Informatics. 2022;26(1):74-82.
26. Lee J-D, Chien J-C, Hsu Y-T, Wu C-T. Automatic Surgical Instrument Recognition—A Case of Comparison Study between the Faster R-CNN, Mask R-CNN, and Single-Shot Multi-Box Detectors. Applied Sciences. 2021;11(17).
27. Zhou T, Wachs JP. Needle in a haystack: Interactive surgical instrument recognition through perception and manipulation. Robotics and Autonomous Systems. 2017;97:182-92.
28. Guedon AC, Wauben LS, van der Eijk AC, Vernooij AS, Meeuwsen FC, van der Elst M, et al. Where are my instruments? Hazards in delivery of surgical instruments. Surg Endosc. 2016;30(7):2728-35.
29. Edel EM. Surgical count practice variability and the potential for retained surgical items. AORN J. 2012;95(2):228-38.
30. Warwick VR, Gillespie BM, McMurray A, Clark-Burg KG. Undertaking the surgical count: An observational study. Journal of Perioperative Nursing. 2021;34(3).
31. Bubric KA, Biesbroek SL, Laberge JC, Martel JA, Litvinchuk SD. Prevalence and Characteristics of Interruptions and Distractions During Surgical Counts. Jt Comm J Qual Patient Saf. 2021;47(9):556-62.

32. Fang J, Yuan X, Fan L, Du M, Sui W, Ma W, et al. Risk factors for incorrect surgical count during surgery: An observational study. Int J Nurs Pract. 2021;27(4):e12942.
33. Sirihorachai R, Saylor KM, Manojlovich M. Interventions for the Prevention of Retained Surgical Items: A Systematic Review. World J Surg. 2022;46(2):370-81.
34. Weprin S, Crocerossa F, Meyer D, Maddra K, Valancy D, Osardu R, et al. Risk factors and preventive strategies for unintentionally retained surgical sharps: a systematic review. Patient Saf Surg. 2021;15(1):24.
35. Cochran K. Guidelines in Practice: Prevention of Unintentionally Retained Surgical Items. AORN J. 2022;116(5):427-40.
36. Gunnar W SC, Lynn MM, Neily J, Tesema Y, Nylander W. The Impact of Surgical Count Technology on Retained Surgical Items Rates in the Veterans Health Administration. J Patient Saf. 2020;16(4):255-8.

Chapter 3: Learning from laboursaving technology already in use

Part 1: Weighing systems

This chapter was published in *Implementation Science Communications* on 10 November, 2025 as: Kooijmans, A.M., van der Elst, M., van den Dobbelsteen, J.J. Streamlining surgical instrument counting: a matrixed multiple case study on the fidelity of weighing systems in the operation room.

Abstract

Background: Many technologies have been developed to aid in surgical instrument counting, but wide adoption is rare. A technology that has been widely adopted around 20 years ago is the weighing scale. Lessons can be extracted from its sustainment and fidelity and applied to the development and implementation of new laboursaving technologies in healthcare.

Methods: We conducted semi-structured interviews with experienced staff in four hospitals that use weighing systems in their surgical instrument cycle, which we analysed according to the Matrixed Multiple Case Study (MMCS) methodology. Hospitals were designated a low, medium, or high sustainment and fidelity score, after which influencing factors were identified. These factors were categorised according to the i-PARIHS domains of Innovation, Recipient, Context, and Facilitation. Within-site analysis and cross-site analysis was performed to identify influencing factors associated with a high or low level of sustainment or fidelity.

Results: All hospitals showed a high sustainment. Two hospitals showed low fidelity, and two showed high fidelity. Twenty-one total influencing factors were identified, divided among all i-PARIHS domains. All hospitals experienced similar limitations of the technology, and all hospitals showed signs of facilitation efforts during the implementation phase. In low-fidelity hospitals, interdepartmental coordination and trust in technology were limited, in contrast to high-fidelity hospitals. A large and/or complex surgical instrument inventory hindered fidelity of the weighing system.

Conclusions: 20 years after implementation, there is varying success concerning the fidelity of weighing systems for surgical instrument counting. All participating hospitals have adapted their workflow to the limitations of the technology in different ways. Given the relative straight-forwardness of weighing scales as a technology, our

findings underline the complexity of implementation processes, regardless of the complexity of the innovation.

3.1.1 BACKGROUND

Surgical material counting is a labour-intensive task of operating room (OR) nurses. For many years already, attempts are made to develop a technology that is able to support or fully automate this job [1-3]. However, these technologies rarely get implemented on a wide scale in hospital settings. Many of these developments don't leave the feasibility stage or are implemented in one hospital, after which dissemination is halted [4-6]. Understanding the factors that influence implementation and integration into clinical practice is essential. Engineers, clinicians, and administrators looking to implement a new technology in their hospital organisation could benefit from the lessons learnt from already existing technologies.

Around 20 years ago, in the Netherlands, weighing scales were introduced as a solution to aid in instrument counting, aiming to limit human error and increase patient safety [7]. A recent survey among all Dutch hospitals shows that around a quarter of them have implemented a weighing system in their instrument lifecycle [8]. Weighing scales are a straightforward technology but, according to the survey, they are not always used in the way they were originally intended; to count surgical instruments. This raises questions about the innovation's implementation success and long-term use.

Implementation science is a growing field in healthcare. While medical interventions or treatments are mostly focused on evidence-based effectiveness, they will not be effective if they are not implemented well. As such, implementation outcomes serve as necessary preconditions for making desired changes in clinical or health service outcomes [9]. A multitude of such outcomes have been described in the literature. Proctor et al's taxonomy of implementation outcomes provides a clear overview of concepts: acceptability, adoption, appropriateness, cost, feasibility, fidelity, penetration, sustainability [9]. Considering that implementation of the weighing system took place around twenty years ago, early-stage implementation outcomes are not relevant for this study. Penetration is not relevant as all investigated hospitals use the innovation. Relevant outcomes for this late stage of implementation are fidelity and sustainment. Both terms will be further explained below. See Figure 3.1.1 for a schematic overview of these terms and the subsequent analysis.

The fidelity of an implemented practice describes the level to which the practice is used as it was intended during implementation [9]. Many definitions of fidelity exist in the literature, but the framework proposed by Carrol et al. will be used in this study [10]. Carroll divides fidelity into several subcategories: content (the 'active ingredients'

of the intervention; or the knowledge the intervention seeks to deliver to its recipients); coverage (whether the intervention is used for all procedures it was initially intended for); frequency (whether the intervention is used as often as intended); and duration (whether the intervention is used as long as intended). Sustainability or sustainment is an implementation outcome that refers to the level of sustained use of the innovation, and the integration of the innovation into regular workflows [9]. Rabin et al. describes three stages of sustainment [11]: 1) Passage (a single event such as transition from temporary to permanent funding); 2) Cycle or routine (i.e. repetitive reinforcement of the importance of the intervention; organisational procedures and behaviours); 3) Niche saturation (the extent to which an intervention is integrated into all subsystems of an organisation). Passage indicates a low sustainment, cycle or routine indicates a medium sustainment, and niche saturation indicates a high sustainment.

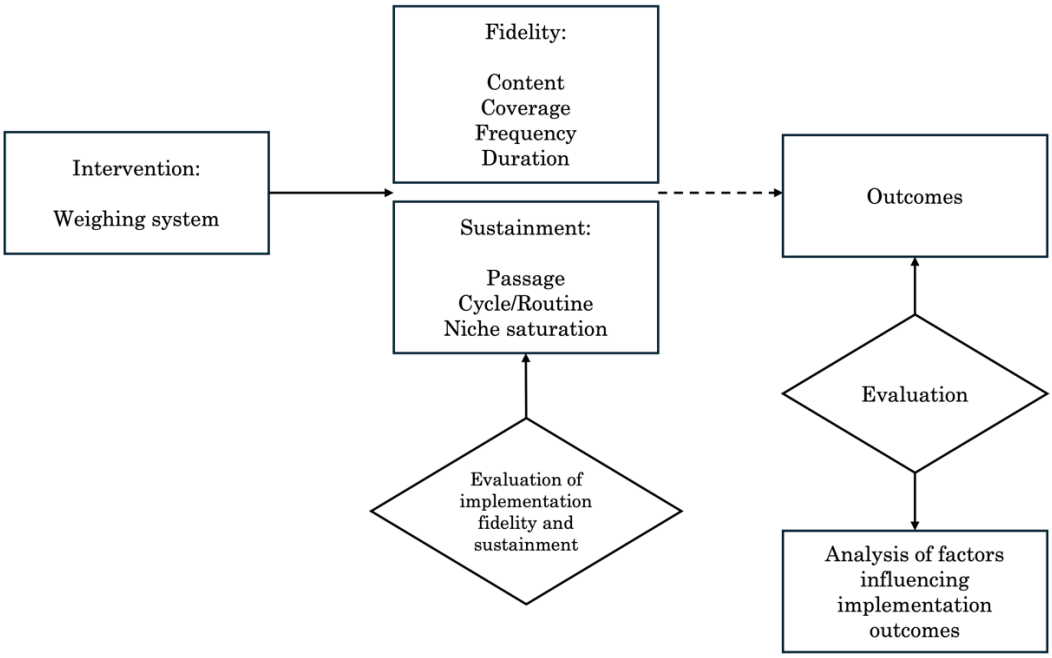


Figure 3.1.1. *Schematic overview of implementation fidelity and sustainment and the subsequent analysis of factors influencing these outcomes.*

In general, all hospitals use a similar instrument life cycle [12]: Starting at the end of a surgical procedure, instruments are brought to a processing room, from which larger batches of instrument trays are transported to the sterile processing department (SPD). There, instruments are first grossly cleaned to remove blood, tissue, and other material, after which they are manually scrubbed to further decontaminate them. Then, instruments are placed in large automatic washers, where they are further cleaned according to a strictly audited regimen. Cleaned instruments are then taken out of the washers into the 'clean zone', where they are assembled into their respective instrument trays. Fully assembled trays are then wrapped in a polypropylene wrap and subsequently sterilised. Sterile instrument trays are kept in storage until they are

needed again for a surgical procedure. Generally, instruments are weighed at the end of surgery and during assembly (after cleaning). The latter is then used as reference for the next postoperative weighing procedure. Weighing stations can also be added before start of surgery and when instrument trays arrive at the SPD (before cleaning).

The instrument lifecycle can be complicated, as large hospitals can manage over 100,000 instrument trays and 2.6 million instruments annually. Considering weighing specifically, it is estimated that 5.9% of trays contain broken instruments, potentially impacting their weight [13]. Furthermore, maintenance and repairs can alter an instrument's properties, exchanging its handle, or sharpening its cutting blade, for example [14]. Similarly, instruments can remain in use for many years before being discarded, given that the estimated lifespan of an instrument is 300-900 sterilisation cycles [13]. This means that several iterations of the same instrument type can be in circulation at the same time [15]. Lastly, variation of a few grams in a single instrument is amplified in a tray that could contain a hundred instruments.

In this qualitative study we investigated several hospitals that use the weighing system in their surgical instrument lifecycle, determining factors that influence the relevant implementation outcomes of fidelity and sustainment. To structure the analysis and to compare multiple hospital organisations, we used the matrixed multiple case study (MMCS) methodology, as described by Kim et al. [16]. This methodology encompasses nine steps of data collection, processing, and analysis, making use of research team consensus meetings to limit subjectivity in the study's findings.

3.1.2 METHODS

3.1.2.1 Data collection

This qualitative study was performed according to the COREQ checklist for reporting of qualitative studies [17]. We conducted semi-structured interviews with OR and SPD senior staff members with at least five years of experience in the current department, in hospitals that use weighing scales in their surgical instrument lifecycle. Informed consent for participation in the study was obtained from all participants. The study was approved by the TU Delft Human Research Ethics Committee. Interview questions can be seen in Appendix A. If possible, we recorded audio of the interviews, as well as meeting notes when necessary.

3.1.2.2 Data analysis

We used the matrixed multiple case study (MMCS) methodology's nine analytical steps to analyse the interview data [16]. Consensus was reached on all steps by the research project's three team members (the authors), as well as four additional research group members (see Acknowledgments). We determined the evaluation goal

(step 1) to be to identify the way in which fidelity and sustainment differed across the hospitals and which factors are of influence on this. Next, we defined fidelity and sustainment (step 2) as respectively: how the current usage of the weighing system compares to the intended use at the time of implementation (i.e. instrument counting as a replacement for manual counting), and how the weighing system is integrated in the instrument lifecycle and related processes.

We selected i-PARIHS' domains [18] - innovation, recipients, context, and facilitation – as relevant domains to categorise the identified influencing factors (step 3). We examined the data on potential factors influencing fidelity and sustainment, as well as categorising these factors according to the abovementioned i-PARIHS domains (step 4) by conducting a hybrid inductive-deductive content analysis approach [19] over multiple coding rounds using ATLAS.ti (version 24.0) software.

We assessed fidelity and sustainment per site (step 5) by examining each site's code summary and exemplar quotes. To assess fidelity, we divided this concept into subcategories as described by Carroll et al [10]: Content, Coverage, and Frequency. While a fourth subcategory is described (Duration), the researchers agreed that this category is irrelevant for this specific study, as the intervention (weighing) is intended to be used ongoingly at the participating sites. We assigned a higher fidelity level to sites that exhibited more characteristics of using the weighing scale for instrument counting, and a lower level if the weighing system was implemented in the instrument workflow, but did not contribute to the staff's knowledge whether all instruments are complete after surgery. Code summaries, based on the aforementioned subcategories, including exemplar quotes for each site were drafted by the main researcher (AK), after which they were reviewed and refined by all project team members. Review and discussion of the summaries of all four sites took approximately four 45-minute meetings after which a final discussion took place to synthesise the subcategory scores. Consensus was reached and each site was designated a final fidelity score.

To assess the level of sustainment, we used Rabin et al's three stages of sustainment as a guide. A higher sustainment was assigned to sites that showed a deeper integration of the weighing system into standard workflows, and where the weighing process is considered "just the way things are done". As in determining the fidelity scores, reviews and discussions of the four sites' code summaries were held, taking around 45 minutes each. Consensus was reached and each site was designated a sustainment score.

We then identified influencing factors per site (step 6), categorising them under the i-PARIHS domains. Potential influencing factor descriptions were drafted based on the above-mentioned code summaries. The summaries, factor descriptions, and exemplar quotes were then reviewed by the whole project team and similar factor descriptions were consolidated into one factor.

We organised the data, being the assessed fidelity and sustainment and identified factors per site into sortable matrices (step 7) using Microsoft Excel. Influencing factors were laid out on the horizontal axis, and fidelity and sustainment on vertical axes. We conducted a within-site analysis (step 8), determining whether a factor was 'present', 'somewhat present', 'minimally present', or 'not mentioned', based on the number of times the concept surrounding a specific factor was discussed in aggregate reports from the hospitals' participants. To illustrate, one participant from a certain hospital mentioning a concept two times was counted the same as two participants from the same hospital mentioning the concept once. Aggregate reports were used in the consensus meetings to limit complexity of the discussions and to allow for efficient analysis and decision-making. Then, each factor was determined to be of enabling, hindering, neutral, or unclear influence on implementation. Neutral factors were those we found to have both an enabling and hindering influence. Like earlier in this study, the frequency and type of the identified factors was initially proposed by the main researcher, after which consensus was achieved through discussion sessions with the whole project team.

Finally, we conducted cross-site analysis (step 9), assessing whether certain factors or combinations thereof were present across multiple sites and whether these factors were consistently present in higher or lower levels of fidelity and sustainment. As not every factor was present at all sites or did not come up in the conversation, the interview was finalised with an open question on whether the interviewee had anything to add that was not discussed yet.

As a team, we decided that factors were associated with high/medium/low fidelity and/or sustainment if they were at least somewhat present in all hospitals designated as high/medium/low fidelity and/or sustainment.

3.1.3 RESULTS

8 interviews across 4 hospitals (two academic and two regional centres) were conducted with key OR and SPD staff members. Both academic centres are equipped with more than thirty operating rooms, comprising regular, paediatric, and hybrid ORs, and perform mostly highly complex surgeries. One regional hospital has twenty operating rooms, both regular and hybrid, and perform both regular and highly complex procedures. The other regional hospital is equipped with five ORs, and performs routine surgical procedures as well as paediatric cases. All hospitals implemented the weighing system around the same period, approximately 20 years ago, to aid in instrument counting. Across all hospitals, weighing stations are set up in the OR and SPD, as well as the postoperative processing room in some cases. See Figure 3.1.2 for a schematic overview of workflows.

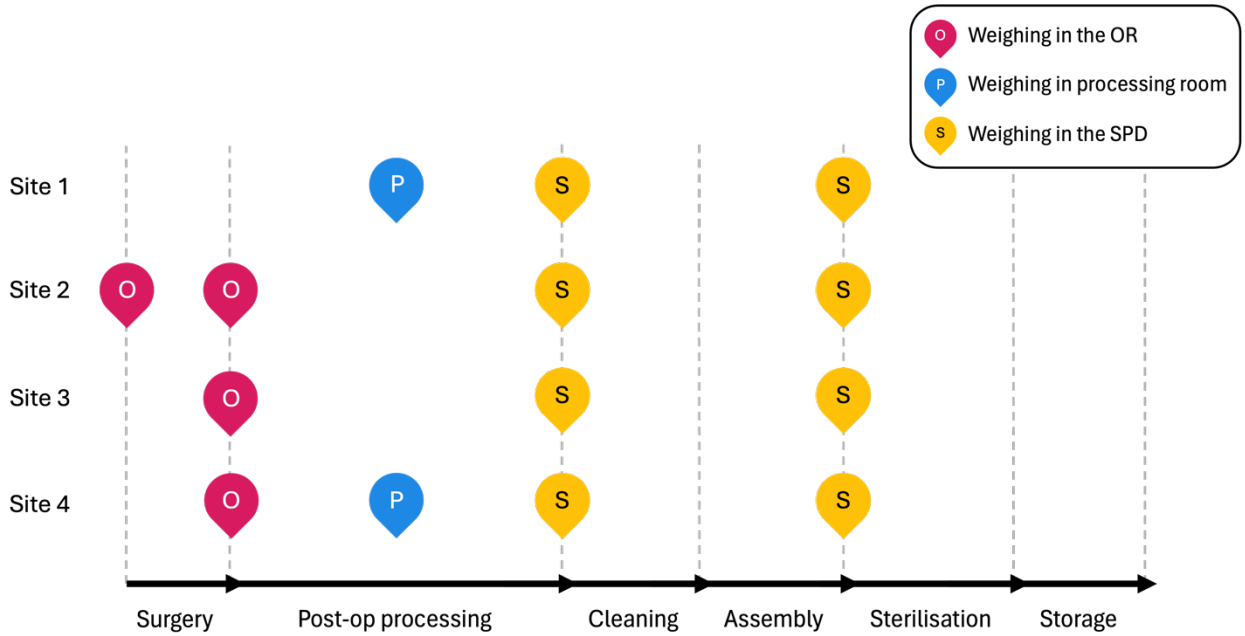


Figure 3.1.2 *Weighing workflows across studied hospitals (Site 1-4). Each marker denotes a weighing procedure. The location of the weighing system is denoted by the colour of the marker*

3.1.3.1 Participants

All participants were part of senior staff, averaging 20 (7-36) years of experience in the current hospital department, being either the OR or SPD.

3.1.3.2 Fidelity and sustainment score

The level of fidelity was split evenly across the participating hospitals, with two sites having a high score, and two sites having a low score. As all hospitals showed similar scores for the Coverage and Frequency subcategories, the research project team agreed to differentiate the different hospitals based on their Content scores. Sustainment was equally high among all hospitals, with all showing features of niche saturation of the intervention; the third stage of sustainment according to Rabin et al [11]. For this reason, factors influencing sustainment cannot be analysed in this study. However, sustainment-related findings in some cases did have an influence on the weighing system's fidelity, see the 'Adaptation of the innovation' section in the Discussion below.

Twenty-one total influencing factors were identified, categorised according to the i-PARIHS domains of Innovation (7), Recipients (4), Context (5), and Facilitation (5). Figure 3.1.3 shows these identified influencing factors by domain.

i-PARIHS domain	Influencing factor	Site 1 *(High fidelity)*	Site 2 *(High fidelity)*	Site 3 *(Low fidelity)*	Site 4 *(Low fidelity)*
Innovation	Variation in size and weight of instruments and materials	+	++	++	++
	Soiling and/or moisture (on instruments)	+	N/m	++	N/m
	Only unsterile instruments can be weighed	-	N/m	++	++
	Slim weight margins	++	++	+	++
	Limited flexibility in case of unexpected events during procedure	N/m	N/m	N/m	++
	Variation in tray wrapping paper	N/m	++	N/m	++
	Room for error in weighing process	N/m	+	+	++
Recipients	Experience / Knowledge of instrument tray contents	++	++	++	++
	Attitude towards technology / Trust in technology	++	++	+	-
	Interdisciplinary coordination / Trust in other people's work	++	++	-	-
	Teamwork / Collaboration	++	+	N/m	N/m
Context	Integration into IT subsystems	++	++	++	++
	Large and complex instrument inventory	-	++	++	++
	Large hospital / complex surgical procedures	-	+	++	++
	Continually updated tray reference weight	N/m	+	-	++
	Being able to weigh in the operating room	N/m	N/m	++	++
Facilitation	Removal of additional materials from tray before weighing	++	++	++	++
	Determining own weight margin	++	++	++	++
	Only certain surgical procedures require weighing	N/m	++	N/m	N/m
	Limited consideration for weighing process during renovations	N/m	N/m	N/m	++
	Addition of weighing stations	N/m	++	++	N/m

++	Present		Enabling
+	Somewhat present		Hindering
-	Minimally present		Neutral
N/m	Not mentioned		Unclear/Neutral

Figure 3.1.3. *Influencing factors and their presence and type of influence on the fidelity of weighing systems use in surgical instrument counting*

3.1.3.3 Key trends in influencing factors regardless of weighing system fidelity status

Three factors in the i-PARIHS domain of Innovation, one factor in the domain of Context, and three factors in the domain of Facilitation were relatively or strongly present in all hospitals with similar influence, regardless of weighing system fidelity status. They were the *Variation in size and weight of instruments and materials*, *Slim weight margins*, *Variation in tray wrapping paper*, *Integration into IT subsystems*, *Removal of additional materials from tray before weighing*, *Determining own weight margin*, and *Addition of weighing stations*. These factors will be discussed below.

3.1.3.4 Innovation-related factors

All hospitals experience difficulties related to the weighing system itself. Especially the *Variation in size and weight of instruments and materials* is a prominent factor with a hindering influence: participants mentioned that instruments of the same type can have slightly different shapes, sizes, and thus weights. Instrument tray wrapping paper also presents issues in some hospitals, as a participant mentioned that the amount of paper used depends on the preference of staff members. As a result, in hospitals with high fidelity, participants noted the need for human interpretation of weighing results, while participants in low fidelity hospitals place more emphasis on the variation of instruments as a flaw.

"One large-basic tray is not the other large-basic tray. One hook is narrower than the other, or it has a different handle." (Participant 2-1, high fidelity)

"We use these blue paper sheets in the trays. These days, they make some of these trays way too big, or too high, they need more than one sheet. Some people use two sheets, but some people use one and a half sheet. That's a difference of 5 grams." (Participant 2-2, high fidelity)

Slim weight margins were mentioned in all hospitals with a neutral to hindering influence on weighing system fidelity. While these margins are easily exceeded because of soiled or wet instruments, they cannot be increased, as some instruments only weigh a few grams.

3.1.3.5 Context-related factor

Integration into IT subsystems is strongly present in all hospitals with an enabling influence. In every hospital, the weighing system is connected to the electronic patient file software. When a tray is weighed, it is automatically registered to its corresponding patient file. This traceability is an important component of the weighing system's sustained use:

"Yes, you always have to weigh, otherwise it [the tray] cannot advance in the system." (Participant 1-1, high fidelity)

"For the SPD, the weighing system is a very important track & trace system. By weighing at specific moments in the process, we can accurately pinpoint where an instrument could have gone missing." (Participant 3-2, low fidelity)

3.1.3.6 Facilitation-related factors

In all hospitals, *Removal of additional materials from tray before weighing* is strongly present with a neutral or unclear influence. Excluding these items from weighing necessitates a manual count. Also strongly present in all hospitals is *Determining own weight margin*, with an enabling influence.

"Cups, kidney dishes, cables, and lids aren't weighed. There's too much variation in size and weight." (Participant 3-2, low fidelity)

"There's certain items that we don't weigh… kidney dishes, electrosurgery cables… Those are counted like usual." (Participant 1-1, high fidelity)

Hospitals in both the low and high fidelity group have added weighing stations somewhere in their workflow, with an unclear influence on fidelity.

"The reason we weigh twice is because in the past, we found that certain trays' weights were often incorrect." (Participant 2-1, high fidelity)

3.1.3.7 Key trends in influencing factors in low versus high fidelity hospitals

One factor in the Innovation domain, three factors in the Recipients domain, and three factors in the Context domain showed trends possibly related to fidelity status, namely: *Room for error in weighing process*, *Experience / Knowledge of instrument tray contents*, *Attitude towards technology / Trust in technology*, *Interdisciplinary coordination / Trust in other people's work*, *Large and complex instrument inventory*,

Large hospital / complex surgical procedures, and *Continually updated tray reference weight*.

3.1.3.8 Innovation-related factor

The factor *Room for error in weighing process* is somewhat present in low fidelity hospitals and minimally present in hospitals with a high fidelity, but with a hindering influence in all cases.

“In the SPD, they use a height-adjustable table on which the scale is placed. If this table is adjusted, the calibration of the scale is off. … Such an incorrect reference weight occurs multiple times a day and is very annoying.” (Participant 4-3, low fidelity)

3.1.3.9 Recipients-related factors

An important factor among OR nurses is their *Experience / Knowledge of instrument tray contents*, being strongly present in all hospitals. In hospitals with a low fidelity, this factor has a hindering influence, but in hospitals with a high fidelity, it has a neutral to enabling influence.

Participants from low fidelity hospitals found that the weighing of trays did not contribute to their knowledge of whether all instruments are complete. While participants in high fidelity hospitals share this sentiment, they acknowledge the added value of weighing.

“I know the contents of 200 different trays, so I already know if it’s complete before weighing.” (Participant 4-3, low fidelity)

"It is not for nothing, because you can really miss something. It's an extra check. Usually you get confirmation, and sometimes rejection, then you have to find out what's going on. Yes, that's a good thing." (Participant 2-1, high fidelity)

In low fidelity hospitals, the *Attitude towards technology / Trust in technology* is minimally to somewhat present with a hindering influence, while in hospitals with a high weighing system fidelity, it is strongly present with an enabling influence. Participants in low fidelity hospitals tended to see the limitations of technology in comparison to manual counting, while participants in high fidelity hospitals tended to see technology as a tool that supports them. However, interestingly, in both low fidelity hospitals, participants from the SPD considered the weighing system a valuable addition to their workflow.

"There will never be a technology that will replace manual counting in the OR. It will always remain a manual process." (Participant 4-3, low fidelity)

“Yes, I count way less now. I hardly count at all anymore. Because I have seen… I have trust in the system.” (Participant 1-1, high fidelity)

“For the SPD the weighing system is an important track and trace tool. By weighing at certain points in the cycle we can pinpoint where an instrument might have gone missing.” (Participant 3-2, low fidelity)

Another factor that differentiates low and high fidelity hospitals is the level of *Interdisciplinary coordination / Trust in other people's work*. This factor is strongly present with an enabling influence in high fidelity hospitals, while it is minimally present with a neutral influence in low fidelity hospitals. In one high fidelity hospital, a participant mentioned the quick communication that was very standard for that hospital. In low fidelity hospitals, this coordination was less visible. Instead, the technology seemed to be used to alleviate a lack of interdisciplinary coordination:

"It has solved a lot of discussions." (Participant 3-2, low fidelity)

"It doesn't matter how a tray comes in… When it comes in, we weigh it, and that is our reference." (Participant 4-2, low fidelity)

3.1.3.10 Context-related factors

Large and complex instrument inventory is strongly present in low fidelity hospitals with a hindering influence, while in high fidelity hospitals, this factor has a neutral to enabling influence when somewhat present. Similarly, *Large hospital / Complex surgical procedures* is strongly present in low fidelity hospitals with a hindering influence, and minimally to somewhat present in high fidelity hospitals with a neutral to enabling influence.

"Technology … could work for focus clinics and regional hospitals, but here we only perform highly complex surgeries, with many different trays… too many." (Participant 4-3, low fidelity)

"We're not very big, we don't have many sets. So if you make some hours, generally speaking, you know the contents of the trays." (Participant 1-1, high fidelity)

An interesting factor that influenced weighing system fidelity was a *Continually updated tray reference weight*. In high fidelity hospitals, the reference weight is updated for each tray as it is assembled in the SPD. In low fidelity hospitals, there is variation. In one hospital, the reference weight is only updated when a tray's contents are permanently changed:

"Another reason that weighing is not used for instrument counting, is because trays don't always have the same content, due to repairs or maintenance. But the reference weight stays the same… it's only updated after a permanent change."(Participant 3-1, low fidelity)

However, a participant from the SPD considered this an extra safety measure:

"It's an indication for the OR nurses that there's something different about the tray… that they should pay extra attention to counting." (Participant 3-2, low fidelity)

In the other low fidelity hospital, the reference weight is updated for each tray. However, in the OR staff's experience, this is not always done:

"It starts in the SPD… the reference weight gets updated for each tray, but this is sometimes forgotten." (Participant 4-3, low fidelity)

3.1.3.11 Influencing factors identified only for hospitals with high or low fidelity

Two factors were identified in only high fidelity hospitals. They were the factors *Teamwork / Collaboration* in the i-PARIHS domain of Recipients, and *Only certain procedures require weighing* in the Facilitation domain. Two factors were identified only in hospitals with a low fidelity status. They were *Only unsterile instruments can be weighed* in the Innovation domain and *Limited consideration for weighing during OR renovations* in the Facilitation domain.

3.1.3.12 Innovation-related factor

With a strong presence and hindering influence, the fact that *Only unsterile instruments can be weighed* is deemed a major limitation of the weighing system in low fidelity hospitals:

"If you can weigh earlier in this process, when the tray is still sterile, you might be able to use the weight for counting instruments." (Participant 3-1, low fidelity)

3.1.3.13 Recipients-related factor

While *Interdisciplinary coordination / Trust in other people's work* summarises the coordination that occurs between departments, *Teamwork / Collaboration* encompasses individuals working together. It is somewhat to strongly present in hospitals with high fidelity, with an enabling influence.

3.1.3.14 Facilitation-related factors

One high fidelity hospital facilitated the weighing system by excluding complex surgical trays from weighing. The influence on weighing system fidelity is unclear or neutral.

One low fidelity hospital renovated their OR complex in recent years. Even though weighing was part of the process for many years already, there was limited consideration for it during these renovations. Currently, weighing stations are placed on a small shelf in each OR, where space to adequately weigh trays is lacking.

3.1.4 DISCUSSION

Nationwide, around one quarter of hospitals have a weighing system in place, initially intended for surgical instrument counting. In this study, we examined factors influencing the fidelity of these weighing systems across four hospitals. We found that the fidelity level varied between hospitals, often with many factors influencing it. These factors, whether innovation-related, recipients-related, or context-related, seem to be closely related or dependent on each other, with facilitation-related factors taking a central position.

The weighing system as a tool to count surgical instruments is flawed, which is highlighted by the widespread presence of hindering Innovation-related factors within the i-PARIHS framework. Most importantly, all participants mentioned the variation in surgical instruments. As hospitals in general can process over 100,000 instrument trays on a yearly basis, it is unrealistic to assume all instruments are in similar condition due to maintenance or repairs, or, in the case of a single type of instrument, even of the same specification [13-15]. Variations of a few grams in a single instrument are amplified in a tray that could contain a hundred instruments.

Due to these common issues with the innovation itself, efforts were made in all studied hospitals to facilitate it. For example, each hospital determined a weight margin of error based on their own instrument inventory and situation. Similarly, all hospitals removed highly variable items, such as kidney dishes or cables from trays before weighing to increase accuracy. These facilitation efforts were done to increase the usability of the weighing system on the organisation-level (i.e. the hospital). However, some facilitation efforts took place on the department level (i.e. the OR or SPD). Both an OR and an SPD (in different hospitals) added a weighing station at the beginning of their workflow as to be less dependent on reference weights determined at the other department, as they were often found to be inaccurate. This highlights an organisational complexity where interdepartmental coordination is limited. Rather than holistically solving inaccuracies in the weighing process, each department, through facilitation, takes steps to mitigate the effect of inaccurate weighing of the other department.

The presence of an organisation-wide facilitator is an integral part of implementing an innovation [20]. In the absence of organisation-wide facilitation efforts, more inaccuracies in the weighing process occur, negatively impacting staff attitude towards it. Where participants in high fidelity hospitals acknowledge the technology as a helpful aide in their work, participants in low fidelity hospitals experience a more flawed technology that does not contribute to their manual instrument counting. This is a remarkable difference, since all hospitals experience similar issues relating to the innovation itself.

3.1.4.1 Adaptation of the innovation

As stated earlier, weighing surgical trays to determine whether all instruments are present is a flawed system. While some OR departments have found ways to make use of the system, its value is not apparent in all OR departments. In SPDs however, the weighing system is consistently deemed a valuable part of ‘track and trace’ systems on the instrument tray level. SPD participants mention that the various weighing stations allow them to determine where an instrument tray currently is, and, if an instrument is lost, pinpoint where it might have been lost. Thus, the weighing system has been adapted to a different use-case which allowed for its sustained use up until today. This shows that in some cases, in order to achieve a high sustainment,

an innovation's fidelity is reduced. This is in line with literature, where adaptation of the innovation leads to long-term sustainment [21-23].

3.1.4.2 Lessons learnt for implementing future technologies

We have investigated a technology that was implemented in various hospitals around twenty years ago. Several general lessons can be extracted from this long-term post-implementation study, which are applicable to future implementation efforts of new innovations.

First, we have identified many influencing factors across all four i-PARIHS domains of Innovation, Recipient, Context, and Facilitation. These factors often relate to each other or are interdependent on each other. To drive new implementation efforts, it is essential to be aware of the presence of these factors. By using an established implementation framework, influencing factors can be identified at an early stage, allowing adjustments to the implementation process as needed.

Second, we have seen that as hospitals get larger and more complex, interdepartmental coordination lags behind. When a technology is used across multiple departments, a lack of coordination can leave procedural errors unresolved. This results in a lack of trust in the technology among users. As the innovation studied in this work was implemented around twenty years ago, we were unable to determine whether a facilitator was present then. A designated facilitator could be helpful in creating awareness of how specific procedures affect other users, as well as advocate for the needs of specific user groups to decision-makers. For example, one participating hospital renovated their OR department without providing a designated space for the weighing stations in the new ORs, which lead them to be placed on a small shelf that is inconducive to an efficient weighing process.

Third, despite using a similar weighing system, all hospitals adapted their workflow to the technology in a different way. These adaptations, however necessary for local implementation, hinder knowledge-sharing between organisations and thus broader implementation of innovations. A collaborative approach among facilitators from different organisations could improve knowledge sharing and reduce local variations, improving innovation dissemination.

We do note that these insights were obtained from a qualitative study in a limited number of hospitals. However, the current study already showcases a wide range of practices which underlines our conclusions.

3.1.5 CONCLUSIONS

While novel developments might have a positive effect on the healthcare labour shortage, implementing these developments warrants extended efforts. As our study

shows, practices and sentiments diverge significantly even in the case of straightforward technology such as a weighing scale. Gaining an overview of the influencing factors involved is essential to an efficient practice and positive user sentiments. For this, large hospitals with a complex organisational structure could benefit from a designated facilitator.

REFERENCES

1. Olivere LA, Hill IT, Thomas SM, et al. Radiofrequency Identification Track for Tray Optimization: An Instrument Utilization Pilot Study in Surgical Oncology. Journal of Surgical Research. 2021;264:490-8.
2. Toti G, Garbey M, Sherman V, et al. A smart trocar for automatic tool recognition in laparoscopic surgery. Surg Innov. 2015;22(1):77-82.
3. Hanada E OA, Hayashi M, Sawa T. Improving efficiency through analysis of data obtained from an RFID tag system for surgical instruments. IEEE 5th International Conference on Consumer Electronics; Berlin, Germany 2015. p. 84-7.
4. Kang HS, Khoraki J, Gie J, et al. Multiphase preclinical assessment of a novel device to locate unintentionally retained surgical sharps: a proof-of-concept study. Patient Saf Surg. 2023;17(1):10.
5. Hill I, Olivere L, Helmkamp J, et al. Measuring intraoperative surgical instrument use with radio-frequency identification. JAMIA Open. 2022;5(1):ooac003.
6. Nakano A, Nagamune K. A Development of Robotic Scrub Nurse System - Detection for Surgical Instruments Using Faster Region-Based Convolutional Neural Network –. Journal of Advanced Computational Intelligence and Intelligent Informatics. 2022;26(1):74-82.
7. Meijsen P, Meers E. Uitgeteld? ; 2006. https://sterilisatievereniging.nl/wp-content/uploads/2015/08/2006-Onderzoek-naar-compleetheidscontroles-van-instrumenten.pdf.
8. Kooijmans A, van der Elst M, van den Dobbelsteen J. Surgical materials counting in Dutch hospitals: a comparison of protocols and procedures over time. (submitted for publication). 2025.
9. Proctor E, Silmere H, Raghavan R, et al. Outcomes for implementation research: conceptual distinctions, measurement challenges, and research agenda. Adm Policy Ment Health. 2011;38(2):65-76.
10. Carroll C, Patterson M, Wood S, et al. A conceptual framework for implementation fidelity. Implement Sci. 2007;2:40.
11. Rabin B, Brownson R, Haire-Joshu D, et al. A Glossary for Dissemination and Implementation Research in Health. J Public Health Management Practice. 2008;14:117-23.
12. George RE, Bay CC, Shaffrey EC, et al. A Day in the Life of a Surgical Instrument: The Cycle of Sterilization. Annals of Surgery Open. 2024;5(1).
13. Stockert EW, Langerman A. Assessing the Magnitude and Costs of Intraoperative Inefficiencies Attributable to Surgical Instrument Trays. Journal of the American College of Surgeons. 2014;219(4):646-55.

14. Acland R. Notes on the care restoration and repair of microsurgical instruments. Indian Journal of Plastic Surgery. 2006.
15. Webster RJ, Yaniv ZR, Glaser B, et al. Surgical instrument similarity metrics and tray analysis for multi-sensor instrument identification. Medical Imaging 2015: Image-Guided Procedures, Robotic Interventions, and Modeling 2015.
16. Kim B, Sullivan JL, Ritchie MJ, et al. Comparing variations in implementation processes and influences across multiple sites: What works, for whom, and how? Psychiatry Res. 2020;283:112520.
17. Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ)- a 32-item checklist for interviews and focus groups. International Journal for Quality in Health Care. 2007;19(6):349-57.
18. Harvey G, Kitson A. PARIHS revisited: from heuristic to integrated framework for the successful implementation of knowledge into practice. Implement Sci. 2016;11:33.
19. Proudfoot K. Inductive/Deductive Hybrid Thematic Analysis in Mixed Methods Research. Journal of Mixed Methods Research. 2022;17(3):308-26.
20. Kim B, Sullivan JL, Brown ME, et al. Sustaining the collaborative chronic care model in outpatient mental health: a matrixed multiple case study. Implementation Science. 2024;19(1).
21. Olsson TM, von Thiele Schwarz U, Hasson H, et al. Adapted, Adopted, and Novel Interventions: A Whole-Population Meta-Analytic Replication of Intervention Effects. Research on Social Work Practice. 2023;34(8):860-72.
22. Hailemariam M, Bustos T, Montgomery B, et al. Evidence-based intervention sustainability strategies: a systematic review. Implement Sci. 2019;14(1):57.
23. Nevedal AL, Widerquist MAO, Reardon CM, et al. Understanding pathways from implementation to sustainment: a longitudinal, mixed methods analysis of promising practices implemented in the Veterans Health Administration. Implement Sci. 2024;19(1):34.

Chapter 3: Learning from laboursaving technology already in use

Part 2: DORA

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ABSTRACT

Purpose Surgical equipment workflows can be complex and labour-intensive. Ten years ago, laboursaving assistive technology was implemented in a regional hospital in Delft, the Netherlands: the Digital Operating Room Assistant (DORA). The aim of this study is to evaluate this innovation using the NASSS framework of implementation success based on qualitative and quantitative data collection from users in the operating rooms as well as technicians.

Major findings The different user categories have similarly neutral sentiments towards DORA, as the innovation does not hinder their work, but also does not improve their perceived efficiency as much as intended during development and implementation.

Conclusions Although the system's limited technical complexity supported its implementation success, its restricted functionality led to underutilisation of the innovation. Rather than developing a technology for the full range of user needs in a single solution, an effort to engage lower complexity levels could steer an innovation towards successful implementation. By identifying chauffeured users early in development, adjustments can be made to the Condition, Value proposition, and Adopters domains of the NASSS framework to ensure implementation success.

3.2.1 INTRODUCTION

Surgical procedures often require a significant number of medical devices such as infusion pumps, laparoscopy towers, and monitoring devices. In light of patient safety, it is essential for the surgical team to know whether these devices function as expected. A malfunctioning device may lead to adverse events during a procedure or prolong anaesthetic time due to delays when a replacement is required.

3.2.1.1 Laboursaving technology

Around ten years ago, in the Reinier de Graaf teaching hospital in Delft, the Netherlands, the general workflow surrounding malfunctioning devices was as follows: operating room (OR) staff must contact the equipment maintenance department, for instance via phone or e-mail, to explain which device malfunctions and where it is located so that a technician can be dispatched. Subsequently, the malfunction must be noted in a central OR logbook to prevent duplicate reports. Other hospital organisations may have similar processes. This workflow is labour-intensive. In addition, it is impossible for the surgical team to know whether all devices adhere to their planned maintenance interval.

To improve efficiency, a laboursaving solution was developed and implemented [1]. The Digital Operating Room Assistant (DORA) is a system developed with three functionalities in mind: 1) to inform the surgical team on the functional status of devices, such as infusion pumps or laparoscopy towers, in an OR; 2) to ease the reporting of malfunctioning devices without requiring manual phone calls; and 3) to aid technicians in locating the malfunctioning devices [2]. This is achieved by equipping each piece of OR equipment (not including sterilisable instruments or other procedure-specific materials) with a DORA module and each OR with a dashboard screen. The module communicates with the dashboard using radiofrequency identification (RFID) technology and uses RFID and infrared sensors to provide accurate location data. All DORA-equipped devices are linked to a centralised database embedded in the hospital's equipment management system. In this way, OR staff can report a malfunctioning device by pressing the report button on the device's DORA module (see Figure 3.2.1), which is then automatically sent to the technicians in the Medical Instrumentation (MI) department. Subsequently, DORA's dashboard screen changes colour from green to red, indicating that a malfunctioning device is present in the OR. The surgical time-out procedure was amended to include a check of this dashboard status.

DORA has been in use for ten years. As new sensor technologies emerge, an evaluation is warranted to assess whether the system is perceived to have contributed to more efficient OR device workflows, and to identify potential areas of improvement based on the perspectives of the specific user groups. The aforementioned three functionalities of DORA development serve as a guide for the current evaluation.

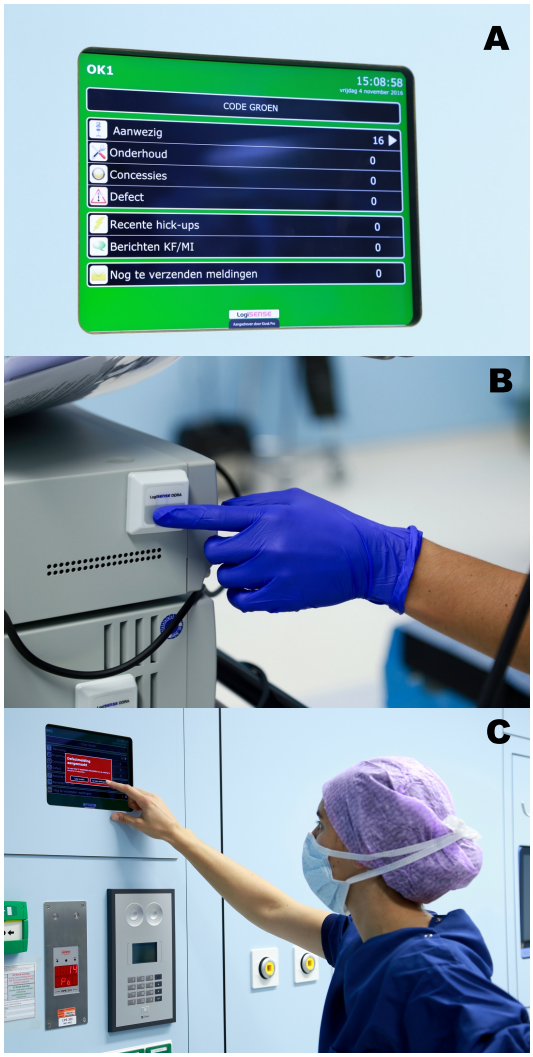

Figure 3.2.1 *Overview of DORA system in the OR a. Dashboard screen showing that no faulty devices have been reported in this OR. b. OR staff presses the error report button on a faulty device. c. Dashboard screen shows that a faulty device has been reported in this OR.*

3.2.1.2 Framework of evaluation

To evaluate the DORA system, we drew from the established NASSS framework (Nonadoption, Abandonment, and challenges to the Scale-up, Spread, and Sustainability of Health and Care Technologies) [3]. This framework considers seven domains that can affect the implementation success of an innovation (see Figure 3.2.2), namely 1) the *condition* or problem it is intended to solve, 2) the *technology* used in the innovation, 3) the innovation's *value proposition*, 4) the *adopters* or users, 5) the *organisation* in which the innovation is (to be) implemented, 6) the *wider system*, such as governmental policy, regulations, and public opinion, and 7) the *embedding and adaptation* of the innovation *over time*. NASSS is designed to consider these domains from a complexity perspective, meaning that the domains that contain the most complexity are the most likely to require careful attention during implementation efforts. Other frameworks, such as CFIR (Consolidated Framework for Implementation

Research) [4] and DSF (Dynamic Sustainability Framework) [5] consider similar domains and are perhaps more commonly used in healthcare implementation research. However, in this case, NASSS is preferred as it is targeted towards the implementation of technology, specifically.

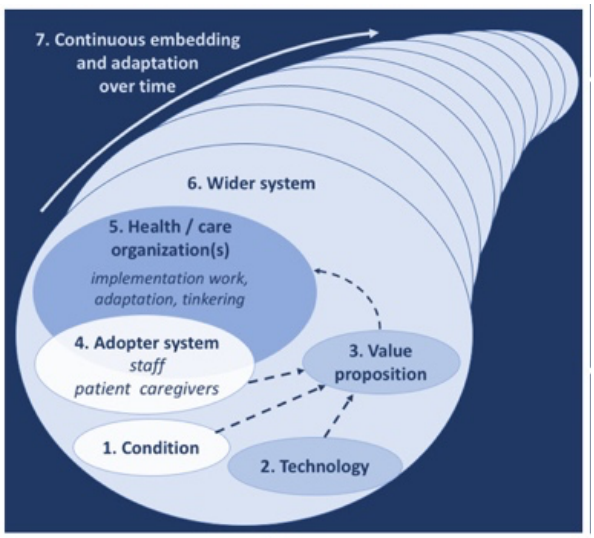

Figure 3.2.2 *Schematic overview of the NASSS framework. Source: [3]. Reproduced with permission from original author*

3.2.2 METHODS

3.2.2.1 Study design

We used a quantitative and qualitative study design to evaluate the current use of the DORA system according to the NASSS framework. We used a questionnaire with a combination of validated and self-developed questions to address the unique issues that are inherent to a technological innovation that has not been used in other hospitals. We augmented survey data with inventory management database analysis. Further insights were gathered from unstructured conversations with key stakeholders that are currently involved in the use of DORA as well as those that were involved during development and implementation of the system, ten years ago. We used the SQUIRE reporting guidelines [6] in writing this article.

3.2.2.2 Ethical considerations

Approval from the Human Research Ethics Committee of Delft University of Technology was obtained. Informed consent was obtained from participants prior to starting the online questionnaire.

3.2.2.3 Setting

The study was performed at the Reinier de Graaf Gasthuis, a regional teaching hospital in Delft that collaborates with Delft University of Technology on a regular basis

to promote research, education, and innovation between the engineering and healthcare sectors. In 2016, the Digital Operating Room Assistant (DORA) was launched following development involving Reinier de Graaf Gasthuis, Delft University of Technology, and a manufacturing partner.

3.2.2.4. Participants

Hospital staff working in the Reinier de Graaf teaching hospital in Delft that actively use DORA in their routine activities were recruited for this study, including operating room nurses, medical device technicians, surgical specialists, and department managers. Recruiting occurred via short oral presentations during morning handover meetings, via printed flyers linking to the digital questionnaire, as well as via e-mail by contacting each department's secretariat. Key stakeholders were identified based on the research team's own network, and were contacted directly.

3.2.2.5. Data collection

A survey was developed in consultation with key stakeholders from the various departments that use DORA (e.g., OR coordinator and technician team lead). Stakeholders were identified from the researchers' own networks and through a snowball method, with stakeholders identifying other potential stakeholders as sources of information. Baseline characteristics such as occupation and years of local experience were collected. Data collection was based on the NASSS framework [3]. For the framework's *condition, value proposition* and *adopters* domains (system use and user satisfaction), questions were based on customer satisfaction surveys (CSAT), including overall satisfaction, perceived usefulness, decision-making, and frequency of use. Department-specific sections were added to address system use experiences unique to each department. Additional anonymous data on system use was collected from the hospital's inventory management system Ultimo (IFS Ultimo BV, the Netherlands), such as the number of OR device error reports and reporting method (via phone call or using DORA's error reporting functionality). The *technology domain* was represented in the survey with questions relating to system quality (usefulness of system features and functions, ease of use, reliability) and information quality (relevance, legibility, format, and importance). Information on service quality (technical support) was gathered during unstructured conversations with key stakeholders. The *organisation* domain consisted of the structural and environmental context of the hospital. The structural context, such as the nature (type and size) of the hospital, culture, management structure and the environmental context, such as politics, localisation, population were evaluated through conversations with key stakeholders of the various departments that use DORA, and those that were involved in the development of it.

The final survey consisted of 20 questions with answer options being multiple choice, open ended, or on a 5-point Likert scale. All multiple-choice questions contained a free

text input option to ensure participants could provide answers that were not predefined. The survey was published online using Qualtrics XM version March 2025 (Provo, Utah, USA).

3.2.2.6. Data analysis

Statistical analysis was performed using Microsoft Excel and SPSS version 29. Baseline characteristics of the study population, questionnaire results, and database results were analysed using descriptive statistics (mean (SD), median (range), frequency). P values were calculated using independent sampled t-tests, Mann-Whitney U tests, and chi square tests to find statistically significant differences ($p<0.05$) between professional roles and across years of local experience.

3.2.3. RESULTS

3.2.3.1. Study population

Approximately 132 professionals were invited to participate in the study, consisting of 120 OR staff and 12 MI staff. In total, 50 questionnaire entries were recorded, of which 6 were incomplete and thus excluded from analysis. Of the 44 participants that completed the questionnaire, 32 work in the OR department (26.7%), 9 work in the MI department (75.0%), 2 currently work elsewhere, and 1 is unknown. Average time to complete the questionnaire was 15 minutes. Demographic characteristics of the participants can be found in Table 3.2.1.

Table 3.2.1. *Demographic characteristics of survey participants (n=44) (continued on next page)*

Department and role	*n (%)*
Medical Instrumentation	
Medical technician	8 (18)
Technician team lead	1 (2)
Operating room (OR) department	
OR nurse	9 (20)
Nurse anaesthetist	3 (7)
Nurse anaesthetist/OR nurse	1 (2)
Trainee OR nurse	1(2)
OR coordinator*	1 (2)
OR planner**	1 (2)
Surgeon	4 (9)
Trainee surgeon	1 (2)
Gynaecologist	8 (18)
Trainee gynaecologist	2 (4)
Urologist	1 (2)
Other	
Clinical physicist***	1 (2)
Unknown	1 (2)
Surgeon/researcher	1 (2)
Years local experience	n (%)
0-1 year	4 (9)
1-2 years	6 (13)
2-4 years	5 (11)

4-10 years	8 (18)
10-20 years	10 (23)
20+ years	11 (25)
*is also a nurse anaesthetist (not counted under 'Nurse anaesthetist' role). **is also an operating room nurse (not counted under 'Operating room nurse' role). ***no longer works at hospital since November 2024.	

3.2.3.2. Condition, technology, value proposition, and adopters domains

Error reporting workflow

Of the 32 participants working in the OR department, 25 (78.1%) shared their method of reporting a malfunctioning device connected to DORA. Of these 25, 15 (60.0%) report the issue directly to the OR coordinator. 4 (16%) press the designated 'report' button on the device's DORA module. 3 (12%) participants both press the 'report' button as well as report the issue to the OR coordinator. Some remarks from participants:

"I report to the coordinator and then press the button as well. This way the Medical Instrumentation knows what is going on. The coordinator needs to know in case the next patient must be cancelled because of it." (Participant 5)

"It [the DORA module] doesn't work more often than it does. That's why I also report to the coordinator." (Participant 7)

"In this way [reporting to the coordinator] you can be sure that it will be handled." (Participant 14)

"If the battery [of the DORA module] is dead, you have to choose a different option anyway." (Participant 31)

Other methods of reporting are: Delegate to OR nurse (n=2) and Call the Medical Instrumentation department directly (n=1).

In the event of DORA's screen being red (i.e., a device in the OR is reported to malfunction), determining whether a surgical procedure can proceed seems to depend on the given situation. Of 25 responses, 16 (64.0%) indicate that the whole surgical team together decide this. 5 (20.0%) participants point to the OR coordinator and 3 (12.0%) indicate the surgeon, respectively. One participant stated that the OR nurses usually make this decision.

Two participants have experienced a surgery being cancelled because of a device reported to be malfunctioning through DORA. Usually however, the issue can be solved and the procedure can continue. Of 26 responses, 21 (80.8%) have experienced this. Common reasons mentioned: the malfunction was deemed to not impact the safety of the procedure (n=6), the device was not required for the procedure (n=5), a "phantom error" (n=2), and the device could be exchanged for a functional alternative (n=1). One participant remarked that DORA was not green for a prolonged period of time but cannot remember the specific device that caused it. Another participant remarked that it could potentially go unnoticed due to DORA's screen

turning dark in Sleep mode, and that it sometimes gets confused with the air management system's screen, as it is located next to DORA's screen and is also green.

All error reports made to the MI department are logged in the hospital's equipment management software, Ultimo, see Figure 3.2.3. From the available data spanning the past six years (starting August 1st 2019 up until the 31st of July 2025), a total of 1228 reports were made, of which 90 (7.3%) via DORA module report buttons. The rest were made via telephone or e-mail. It should be noted that these reports not only include DORA-equipped appliances, but encompass all error reports made to the MI department from the OR, including for instance facility-related reports. Year-on-year (August through July), the number of reports both made via DORA modules and via telephone or e-mail remain relatively constant, with the mean yearly reports being 15 (6-23) and 190 (163-234) for DORA reports and other means of reporting, respectively.

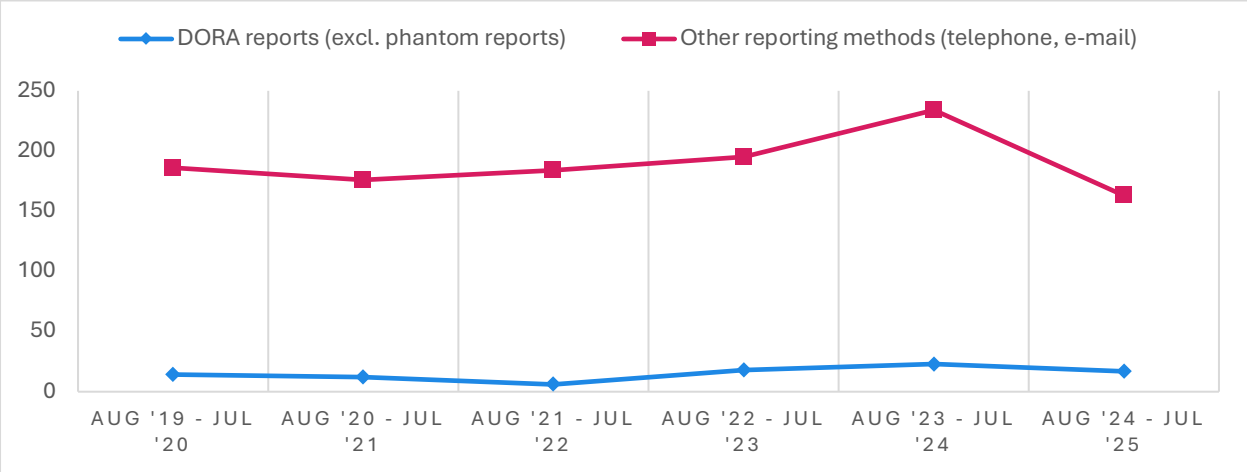

Figure 3.2.3 *OR department error reports made to the MI department*

Technician workflow

Of eight medical technicians, seven completed the technician workflow section of the survey. Two technicians (28.6%) remarked that they are not tasked with fetching malfunctioning DORA-connected devices from the OR department. Of the five that are, the estimated time spent looking for such devices is between one and five minutes. One technician mentions that OR staff makes sure that the device is ready at a designated pick-up area, so no time is spent searching.

Service quality

The manufacturer of the DORA system is a committed partner in providing technical support when necessary. However, due to changing circumstances in the availability of RFID sensors, production of the current DORA tags will be ceased in the near future. While the hospital purchased the remaining bulk of sensors to provide in-house repairs and maintenance, a reassessment of sensor technology to be used in DORA

is warranted. This evaluation study is an initial step in the reassessment of DORA's technology.

Based on stakeholder conversations, no educational programme is currently active to educate new users on the use and functions of the DORA system.

User satisfaction

On average, DORA users are Neutral to Somewhat satisfied with the system (mean score 3.36, SD 0.838). The mean satisfaction is similar among all role categories (3.38, SD 0.619; 3.43, SD 0.852; 2.50, SD 0.707; 3.33, SD 1.000; 3.67, SD 1.528 for the surgical specialist, surgical support, organisational, technician, and other roles, respectively), as seen in Figure 3.2.4a. While surgical support and technician roles' satisfaction is largely spread from Somewhat unsatisfied to Somewhat satisfied, with 35.7% and 33.3% being Neutral in these role categories, surgical specialist roles' sentiment is mostly Neutral (68.8%). Looking across years of local experience (Figure 3.2.4b), mean satisfaction scores are mostly similar (3.25, SD 0.500; 3.67, SD 0.816; 3.20, SD 0.837; 3.13, SD 0.641; 2.70, SD 0.675 for 0-1 year, 1-2 years, 2-4 years, 4-10 years, and 10-20 years' experience, respectively). The 20+ years' experience category scores significantly ($p < 0.001$) higher with a mean satisfaction score of 4.09 (SD 0.701), compared to a combined mean satisfaction score of 3.12 (SD 0.740) for the other categories.

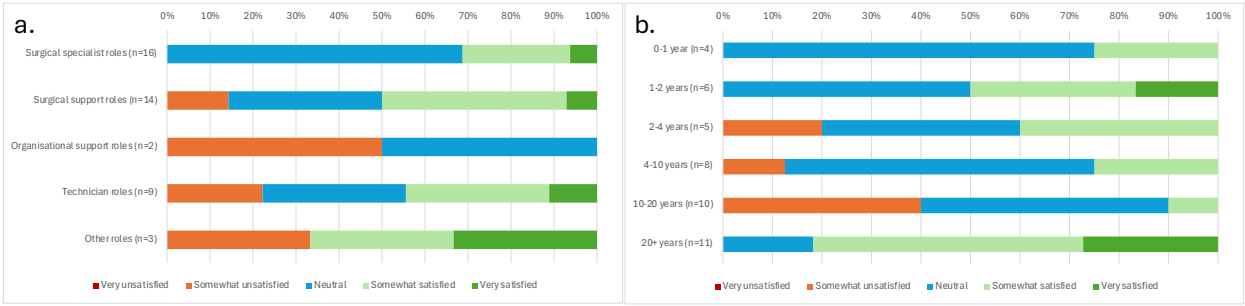

Figure 3.2.4 *User satisfaction across* ***a.*** *professional role categories,* ***b****. years of local experience*

Participants working in the OR department were asked to rate their agreement with the statement "DORA increases patient safety." on a 5-point Likert scale. The mean agreement score for all participants is 3.23 (SD 1.177), with the groups with 1-2 years' experience and 20+ years' experience scoring above average with 4.00 (n=4, SD 0.816) and 4.40 (n= 5, SD 0.548), respectively.

Perceived expertise

Participants' perceived expertise varied (see Figure 3.2.5). Surgical specialist roles showed least confident in their expertise of DORA, with at least 50% of participants disagreeing with all three statements. In contrast, surgical support roles show greater confidence in their perceived expertise. Similarly, technician roles show great confidence in their perceived expertise of DORA. Interestingly, despite this confidence

in both professional role categories, both surgical support roles and technician roles score Neutral in their perceived knowledge of all strong and weak points of the system.

"I know exactly what DORA entails."	Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
Surgical specialist roles (n=16)	18.8%	31.3%	12.5%	18.8%	18.8%
Surgical support roles (n=14)	7.1%	0.0%	14.3%	57.1%	21.4%
Organisational support roles (n=2)	0.0%	50.0%	0.0%	0.0%	50.0%
Technician roles (n=9)	11.1%	0.0%	22.2%	0.0%	66.7%
Other roles (n=3)	33.3%	0.0%	0.0%	0.0%	66.7%

"I can explain DORA to a new colleague."	Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
Surgical specialist roles (n=16)	50.0%	31.3%	0.0%	18.8%	0.0%
Surgical support roles (n=14)	7.1%	14.3%	14.3%	35.7%	28.6%
Organisational support roles (n=2)	0.0%	50.0%	0.0%	0.0%	50.0%
Technician roles (n=9)	11.1%	0.0%	11.1%	22.2%	55.6%
Other roles (n=3)	33.3%	0.0%	0.0%	0.0%	66.7%

"I know all strong and weak points of DORA."	Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
Surgical specialist roles (n=16)	50.0%	37.5%	6.3%	6.3%	0.0%
Surgical support roles (n=14)	14.3%	21.4%	42.9%	14.3%	7.1%
Organisational support roles (n=2)	0.0%	0.0%	50.0%	0.0%	50.0%
Technician roles (n=9)	0.0%	11.1%	55.6%	22.2%	11.1%
Other roles (n=3)	0.0%	0.0%	33.3%	33.3%	33.3%

Figure 3.2.5 *Perceived expertise of DORA users across professional role categories*

When looking across years of experience, perceived expertise increases as participants are more experienced, with groups with two or fewer years of experience Strongly to Somewhat disagreeing with the statements "I know exactly what DORA entails." and "I can explain DORA to a new colleague.", while groups with four or more years of experience Somewhat to Strongly agreeing with these statements. Participants agreeing with the statement "I know all strong and weak points of DORA." only occur within more experienced groups: 10 participants with four or more years of experience (34.5%) Somewhat to Strongly agree.

Relieving workload

All participants were asked to rate their agreement with the following statements: "DORA makes my daily tasks more efficient." and "DORA is counterproductive to my daily tasks." (see Figure 3.2.6).

"DORA makes my daily tasks more efficient."	Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
Surgical specialist roles (n=16)	18.8%	6.3%	56.3%	18.8%	0.0%
Surgical support roles (n=13)	7.7%	30.8%	30.8%	30.8%	0.0%
Organisational support roles (n=2)	0.0%	0.0%	100.0%	0.0%	0.0%
Technician roles (n=8)	25.0%	0.0%	75.0%	0.0%	0.0%
Other roles (n=3)	33.3%	0.0%	0.0%	33.3%	33.3%

"DORA is counterproductive to my daily tasks."	Strongly disagree	Somewhat disagree	Neutral	Somewhat agree	Strongly agree
Surgical specialist roles (n=16)	43.8%	6.3%	50.0%	0.0%	0.0%
Surgical support roles (n=13)	61.5%	15.4%	15.4%	0.0%	7.7%
Organisational support roles (n=2)	0.0%	50.0%	50.0%	0.0%	0.0%
Technician roles (n=8)	62.5%	12.5%	25.0%	0.0%	0.0%
Other roles (n=3)	66.7%	0.0%	33.3%	0.0%	0.0%

Figure 3.2.6 *Workload relief sentiment across professional role categories*

Out of 42 responses, 9 (21.4%) indicate that DORA makes their daily tasks more efficient, while 1 participant (2.4%) agrees with the statement that DORA is counterproductive to their work.

Usefulness

A possible contributor to the sustainment of DORA is an optimistic sentiment towards the usefulness of the technology, regardless of one's own opinion. Out of 39 responses to this section of the survey, 17 (43.6%) indicated that DORA is useful for them. 14 (82.4%) of them think that it is also useful for users in different departments, while 3 (17.6%) think not. 10 (25.6%) respondents indicate that DORA is not useful to them, but 6 (60.0%) of them think that other departments have more use for the system. 12 participants (30.8%) (of which 9 (75.0%) from a surgical specialist role) indicated that none of the statements applied to them. Figure 3.2.7 categorises the responses across professional role categories.

	Helpful for me, helpful for other departments	Helpful for me, not helpful for other departments	Not helpful for me, but helpful for other departments	Not helpful for me, not helpful for other departments	None of the statements apply to me
Surgical specialist roles (n=14)	14.0%	0.0%	21.4%	0.0%	64.3%
Surgical support roles (n=12)	58.3%	8.3%	8.3%	16.7%	8.3%
Organisational support roles (n=2)	0.0%	50.0%	0.0%	0.0%	50.0%
Technician roles (8)	37.5%	12.5%	25.0%	12.5%	12.5%
Other roles (n=3)	66.7%	0.0%	0.0%	33.3%	0.0%

Figure 3.2.7 *Perceived usefulness of DORA across professional role categories*

User suggestions

This section of the survey contained a free text entry asking for improvement suggestions, resulting in many suggestions to improve the DORA system. The suggestions can be categorized into fixes of current issues and improved or increased future functionality. Notable mentions: longer battery life of DORA tags (n=3), increase resilience of DORA tag housing (n=2), improve feedback after reporting a malfunction (n=1), connect to OR planning to check whether devices can be borrowed from other rooms (n=1). See Table 3.2.2 for a complete overview.

Table 3.2.2 *User suggestions for improvements to the DORA system*

Current issues	*Future functionality*
Increase battery life of DORA tags Increase resilience of DORA tag housing Improve feedback after reporting a malfunction Location tracking outside of designated ORs Search function for devices at planner's office	Status indicator light instead of screen Connect to OR planning to check whether devices can be borrowed from other rooms Broaden functionality to include instrument counting Install DORA in storage rooms Add user manuals and/or treatment protocols to DORA

Features that are deemed important to retain for the improved version are: colour-coded device status insight during procedure time-out (n=7), reporting of malfunctions (n=4), location tracking of devices (n=3).

3.2.3.3. Organisation, wider system, and embedding and adaptation over time domains

The structural context of the hospital was studied through unstructured conversations with key stakeholders (n=4) involved in the development of DORA ten years ago as well as those involved in its current use. The Reinier de Graaf Gasthuis is a regional teaching hospital with a strong collaborative connection to the nearby Delft University of Technology, aiming to 'close the gap' between engineering and medical disciplines in research and clinical practice. The hospital is made up of semi-autonomous clinical departments (such as cardiology, surgery) combined with centralised MI and IT management functions.

In the wider context, a growing awareness of the healthcare labour shortage increases interest in laboursaving technology. After its launch, DORA enjoyed significant interest from both domestic and foreign hospitals. NIAZ (now Qualicor Europe), the healthcare accreditation institute in the Netherlands, marked the system as the new 'best practice' for medical equipment management.

Since its implementation, DORA has not undergone any major developments or changes. This is reflected in some user suggestions wishing for DORA to be more tightly embedded in the OR's IT systems.

3.2.4. DISCUSSION

In this study, we evaluated the current use of DORA using the NASSS framework. Whilst improvements could be made (discussed below), the system is a step forward in reducing workload and potentially increasing patient safety. Overall satisfaction across the three main professional role categories (surgical specialist roles, surgical support roles, and technician roles) is similar. Our findings show that DORA in some cases does increase workflow efficiency, but further improvements in this regard are hindered by technical shortcomings and a lack of continuous development over the years. While DORA was developed with both workflow efficiency and patient safety improvements in mind, its effect on patient safety remains unclear. Several mechanisms may underly these findings, which will be discussed below.

3.2.4.1. Technology

The first mechanism causing limited satisfaction or dissatisfaction with the current state of DORA pertains to limitations in the *Technology* domain. Most mentioned is the battery life of the DORA modules. Technicians remark that they often have to

replace these batteries outside of a device's regular maintenance schedule, costing considerable time as the device's location tracking does not function with a depleted battery. OR nurses and nurse anaesthetists mention that the error report button on the modules is unreliable because of it, moving them to report errors manually instead. While replacing the battery with a longer lasting one might seem the obvious solution, perhaps the wish exists to integrate a battery level indicator. However, adding such a feature could add complexity and costs to the DORA modules.

Further friction is created in this domain by suboptimal user feedback. First, OR staff mention explicitly that they prefer to phone the MI department versus pressing the report button on a DORA module because the phone call gives them direct feedback from a technician that the issue will be handled. Even though – when you press the report button on a DORA module - an automated confirmation email is sent to you, it seems that this does not provide users with enough confidence that the issue will be handled promptly. Similar situations arise in the field of IT helpdesk automation. There, the consensus formed that straight-forward issues, such as administrative requests, can be resolved automatically, while more complex issues should be handled by a human instead [7]. While it is unlikely that issues in an OR setting can be handled automatically, different levels of human involvement can be considered. Furthermore, regarding feedback, OR staff do not typically access their e-mail inbox during surgical procedures, making it a suboptimal method of notification delivery. Focus groups could provide insight into feedback preferences of the surgical support role user group.

3.2.4.2. Organisation

In the *Organisation* domain, OR staff mention that they prefer reporting the error to the coordinator directly, or a combination of pressing the report button and reporting to the coordinator, as they mention that the coordinator needs to know about the malfunction as well as the MI department. While this feedback loop is already in place, as there is a screen in the coordinator's office that will show any DORA error in any OR, the information it is able to convey remains limited. Straight-forward issues can be resolved this way, but more complex issues require a more personal approach. For instance, DORA is currently unable to show whether a device can be taken from a different OR to be used instead of a malfunctioning device. Situations such as those still require consulting the OR coordinator. Nonadoption due to (over)simplicity is a common mechanism described in implementation science literature. For instance, Papoutsi et al. investigated a telehealth solution for patients with heart failure and showed that its standardised intervention clashed with patients' multimorbidity [8]. A scoping review by Abell et al. of 44 implementation studies showed that the most common barriers to implementation success are that the innovation is not sensitive to the complexity of practice, and that the innovation does not fit with workflows [9].

3.2.4.3. Condition

Further implementation of DORA is limited as the *Condition* domain it is currently targeting is quite narrow: a strict status overview of the equipment in a specific OR. As some users suggested, further embedding DORA in the OR's IT systems would allow for broader functionality such as overlaying an ORs schedule and specific device needs over the devices currently present. This would allow for more efficient exchanging of devices between ORs without the need of manual coordination by the OR coordinator. However, this would add complexity in the sense that integration with the OR planning could mean DORA will be considered a medical device according to the EU's MDR, and as such would have to comply with its regulations.

3.2.4.4. Value proposition

The third mechanism is that the surgical specialist group is not a *direct user* group, but rather a *chauffeured user* group. As DORA is implemented in the time-out procedure, surgical specialists are required to acknowledge DORA's status, but any errors that arise are delegated to the surgical support group. A similar pattern was observed during the pilot period in 2012-2013 [1]. While DORA was built on three pillars (increasing patient safety, improving communication between OR and MI, and real-time equipment location tracking), a direct effect on patient safety has been difficult to assess [1] and thus champion, potentially leading to a belief among specialists that DORA exists primarily as a logistical tool. According to May and Finch's Normalisation Process Theory (NPT), a collective sense of the technology in the organisational setting and a shared vision of its potential are essential to successful implementation of a new innovation [10]. This so-called 'coherence work' could be compromised in this instance, as a large user group is uninvolved in its implementation success.

Further research should be carried out among the surgical specialist role group to determine when – according to them – patient safety is affected in the context of a digital surgery assistant or OR information system, and whether it is preferrable to nudge them towards direct use versus chauffeured use. Considering the NASSS framework, the *Value proposition* domain is uncertain for surgical specialist users. While in contrast, for surgical support users and technicians, the time savings of automated error reporting and location tracking provide a significant value proposition.

While the above-mentioned mechanisms show that the current use of DORA could be further optimised, it is important to acknowledge the positive effect DORA has already established on OR workflows. OR-based users are very positive about the information quality that DORA presents to them, with many participants wishing to keep the screen and its colour-coded device status presentation. In addition, the number of error reports has increased since the introduction of DORA, showing that the system can provide an easy and efficient alternative to manual reporting via telephone. For MI-

based users, DORA has improved registration of equipment malfunctions, as well as improved communication with the OR department. While our questionnaire findings do not necessarily show a negative sentiment towards DORA, conversations with MI stakeholders suggest that improvements to the system, mainly with regards to location tracking functionality, are warranted. Such equipment tracking functionality is not only helpful for OR equipment, but for equipment in all hospital departments.

3.2.4.5. Lessons for innovation implementation

While our findings are related to a specific technological solution implemented in a specific hospital organisation, lessons can be extrapolated for other potential laboursaving innovations. In developing technological solutions, complexity is easily added. By specifically establishing desired functionalities, the risk of added complexity is diminished. With DORA, for example, the developers limited scope and 'embeddedness' to achieve a core functionality. While this allowed for a relatively easy implementation process, a continuous process of evaluation and adaptation would have resulted in more significant improvements in workflow efficiency and patient safety.

Another lesson learnt, albeit commonly known, is the complexity of healthcare processes we encountered in this study, and how difficult it is to automate a certain task. Some situations could be handled digitally with ease, but adequate user feedback and the possibility to discuss an issue with a coordinator showed to be essential in more complex cases. While laboursaving innovations often target an entire workflow, an argument could be made for defining levels of complexity for the same task, where straightforward situations should be handled by technology, while more complex situations would remain to be handled manually, i.e. *adaptive support* [11].

Finally, we have seen in this study that a substantial number of intended users (surgical specialists) are actually rather uninvolved in the use of DORA. It is important to identify these chauffeured users early on in development, for instance during pilot phases, as they could indicate that the scope and usability of the innovation is not the same as intended.

3.2.5. CONCLUSIONS

A laboursaving technology was implemented ten years ago with the goal of increasing patient safety and improving communication and workflows between the OR and MI departments. During development, deliberate efforts kept complexity low, allowing for achievable implementation success. However, continuous developments and adaptations to the system have fallen behind due to limitations in the NASSS domains of *Technology*, *Condition*, and *Value proposition*, leading to an innovation that shows potential but remains underutilised in practice. Fixing current issues and implementing

future improvements such as adaptive support ensure the sustained use of the system in the current hospital, as well as communicate the value proposition to other hospitals.

REFERENCES

1. Guedon AC, Wauben LS, Overvelde M, et al. Safety status system for operating room devices. Technol Health Care. 2014;22(6):795-803.
2. Guédon ACP, Wauben LSGL, de Korne DF, et al. A RFID Specific Participatory Design Approach to Support Design and Implementation of Real-Time Location Systems in the Operating Room. Journal of Medical Systems. 2014;39(1):168.
3. Greenhalgh T, Wherton J, Papoutsi C, et al. Beyond Adoption: A New Framework for Theorizing and Evaluating Nonadoption, Abandonment, and Challenges to the Scale-Up, Spread, and Sustainability of Health and Care Technologies. J Med Internet Res. 2017;19(11):e367.
4. Damschroder LJ, Aron DC, Keith RE, et al. Fostering implementation of health services research findings into practice: a consolidated framework for advancing implementation science. Implement Sci. 2009;4:50.
5. Chambers DA, Glasgow RE, Stange KC. The dynamic sustainability framework: addressing the paradox of sustainment amid ongoing change. Implementation Science. 2013;8(117).
6. Ogrinc G, Davies L, Goodman D, et al. SQUIRE 2.0 (Standards for QUality Improvement Reporting Excellence): revised publication guidelines from a detailed consensus process.
7. Oshrat Y, Aumann Y, Hollander T, et al. Efficient Customer Service Combining Human Operators and Virtual Agents. arXivorg. 2022.
8. Papoutsi C, A'Court C, Wherton J, et al. Explaining the mixed findings of a randomised controlled trial of telehealth with centralised remote support for heart failure: multi-site qualitative study using the NASSS framework. Trials. 2020;21(1):891.
9. Abell B, Naicker S, Rodwell D, et al. Identifying barriers and facilitators to successful implementation of computerized clinical decision support systems in hospitals: a NASSS framework-informed scoping review. Implement Sci. 2023;18(1):32.
10. May C, Finch T. Implementing, Embedding, and Integrating Practices: An Outline of Normalization Process Theory. Sociology. 2009;43(3):535-54.
11. Guédon ACP, Spruit SL, Wauben LSGL, et al. Delicate balance: adaptive support to improve patient safety. BMJ Innovations. 2017;3(1):1-6.

4

Chapter 4: Development of standards of practice in surgical instrument counting

This chapter was submitted to *BMC Health Services Research* on 6 September, 2024 as: Kooijmans, A.M., van der Elst, M., van den Dobbelsteen, J.J., (*under revision*) Surgical materials counting in Dutch hospitals: a comparison of protocols and procedures over time.

ABSTRACT

Background Due to a rising demand on healthcare and a growing staff shortage, there is a need for labour-saving technology. Much research is being conducted on solutions concerning surgical materials counting, but real-world application lags behind. To guide further development and implementation of such technologies, a renewed overview of current counting practice is presented.

Methods Between July and September 2023, an online questionnaire was distributed to all Dutch hospitals to collect information on current counting protocols and standard practices. Results were then compared to earlier, similar research from 2006.

Results 46 hospitals participated in our survey, of which almost all have a counting protocol. While there is currently some variation in counting practice, compared to 2006, improvements have been made in standardisation, registration, and traceability. Perceived high-risk situations have remained largely unchanged: staff change (83% of respondents); acute/emergency situations (43%); hurrying/production pressure (30%). Uncertainty in counting is increased due to inconsistent registration by staff and a shared designation of responsibility for counting in protocols. A weighing system is used by a quarter of hospitals, but its advantages are unclear, as half of them note the system is unreliable.

Conclusion Surgical materials counting has become safer and more efficient in recent years. However, some challenges concerning standard practice and designation of responsibility remain. Technology has the potential to alleviate workload, but its compatibility with current practice is essential for successful implementation. Further research is needed to assess the effectivity of established technologies, such as weighing systems.

4.1 BACKGROUND

The Dutch healthcare system is under increasing pressure: an aging population will cause more demand, while the labour force cannot grow with it [1]. A larger focus on efficiency and process optimalisation highlights the importance of sustainable employability. Technology has the potential to make care processes more efficient [2], but implementation of such solutions lags behind.

One such process is *surgical materials counting*. During surgery, instruments, gauzes, disposables, and sharps such as suture needles must be accounted for to prevent a retained surgical instrument (RSI). While uncommon – RSIs occur between 1-1000 and 1-10000 surgeries – it can lead to serious complications, reoperation, or even death [3-5]. Intraoperative instrument tracking could support the operating room (OR) nurses' manual counting procedure. Such real-time insight is also useful for other purposes: it allows for automated instrument tray optimalisation, preventive maintenance [6], streamlined inventory management [7], and automated OR scheduling through surgical phase recognition [8, 9].

Over the years, many solutions have been proposed to aid in surgical materials counting. Examples include technological solutions such as data matrices (barcodes and QR codes) [10, 11], weight sensors [12], radio-frequency identification (RFID) [6, 13], computer vision [14, 15], and robotics [16], and non-technological solutions such as the SmartTray system [17], which uses special clamps to organise instruments. While most of these solutions are occasionally used, no single solution has been widely implemented. Developments often lack consideration for the complexity and dynamics of an OR environment, being validated in a lab environment, or negatively impacting current workflows.

It is essential for the development and successful implementation of instrument tracking technologies to understand differences and similarities in practice among healthcare institutions. The most recent overview of Dutch hospitals was published in 2006 by Meijsen & Meers [18]. In this study, it was found that surgical materials counting was not yet established as a standardised practice, with limited protocols existing.

The aim of this work is to give an updated overview of current counting protocols in Dutch hospitals, including standardised procedures, use of counting tools and aids, and perceived high-risk situations. Where possible, a comparison will be made with the overview from 2006.

4.2 METHODS

4.2.1 Design and development of the questionnaire

We collected hospital's policies and standard procedures using a digital questionnaire (Qualtrics; Provo, USA) in Dutch with both open-ended and multiple-choice questions. Questions were based on Meijsen & Meers' earlier study [18] to allow for comparisons to be made. Formulations were updated based on our own initial observations of counting practice, relevant literature, and current guidelines [19]. At the time, the survey questions were formulated in consultation with operating room nurses and risk managers of a medical liability insurance company. After updating the survey, expert opinions from operating room nurses were obtained, and feedback was implemented. The survey consists of several parts, each pertaining to the counting protocol of a category of surgical material: instruments, gauzes, disposables, and sharps (with an emphasis on suture needles), to allow for comparison to Meijsen & Meers' study. Following are some typical questions with their answer options in parentheses: 'According to the counting protocol, who is responsible for the counting of gauzes?' (Instrumenting nurse/Instrumenting and circulating nurse/Circulating nurse/Surgeon/Other, … [open field]); 'What are high-risk situations that occur during the counting of instruments?' (open field); 'According to the counting protocol, are instruments counted in every surgical procedure?' (Yes/No, exceptions are… [open field]). Only information on a hospital's policies and standard procedures was gathered; personal data of individuals was not collected. During development of the survey, it was decided to give respondents the opportunity to leave questions unanswered. Completion of the survey takes around 50 minutes. As OR staff, including management, works on a busy schedule, a requirement to answer each question could negatively impact response rate. As such, the number of respondents for each question varies. Four weeks after initial distribution of the survey in July 2023, a reminder was sent to the original recipients. Two weeks after this, a second reminder was sent.

4.2.2 Population

Participants were selected based on the following criteria:

- Inclusion criteria: Dutch general and academic hospitals with an operating room complex.
- Exclusions criteria: Specialist hospitals and independent clinics were excluded. Healthcare institutions with multiple locations were limited to one response, as they might use the same protocol and exchange personnel.

In total, 71 surveys were distributed. To maximize response rate, they were addressed to the head of the OR complex, or a team manager of the surgical department. This person could fill in the survey themselves, or delegate to another person with adequate

knowledge of the counting process. Informed consent was obtained from all participants. The hospital's name was recorded to check progress and stored separately from the survey data. All data analysis remained anonymous.

4.2.3 Data analysis

Survey data were processed in Microsoft Excel. Answers to open questions were first divided into groups, where a balance between general and specific divisions was sought. Comparisons were then made with frequency statistics.

4.3 RESULTS

4.3.1 Response

All 71 Dutch hospitals were contacted for this study. 46 of them (65%) participated in the survey (see Table 4.1). All Dutch provinces are represented, as well as all seven educational regions (in Dutch: Onderwijs- en Opleidingsregio). All Dutch academic hospitals and 39 general hospitals participated. All surveys were completed by a member of OR management.

Table 4.1. *Respondents*

Hospital description	*n (%)*
General hospital	39 (85%)
Academic hospital	7 (15%)
Hospital size	
1-5 operating rooms	5 (11%)
6-10 operating rooms	13 (28%)
11 or more operating rooms	27 (59%)
Unknown	1 (2%)

4.3.2 Gauzes

Protocol

96% of respondents (n= 44) have a protocol in place for the counting of gauzes. Responsibility for the counting process is described as follow: in 39% of cases (n=18) only the scrub nurse is responsible, while 2% (n=1) assign this to the surgeon. The rest (60%, n=27) shares this responsibility: 55% (25) hold both the scrub nurse and circulating nurse responsible; 5% (2) adds the surgeon to this.

Counting

Gauzes are not counted in all surgical procedures. Exceptions mentioned in protocols are ophthalmological procedures; transurethral procedures, procedures with an incision smaller than a specified length or no incision; when X-ray screening is performed during surgery; at the surgeon's discretion.

Gauzes are counted on the following occasions: opening new gauze packaging (98%, n=45); closing hollow organs and body cavities (98%, n=45); closing of the surgical wound (96% (n=44). In addition, 89% (41) mention gauzes are counted when the scrub nurse changes, and 26% (12) do the same when the circulating nurse changes. One hospital mentions the decision to count gauzes during staff changes is dependent on the complexity of the surgical procedure. Among all participants additional counts are performed if necessary.

Use of counting tools

All hospitals use tools to aid in the counting of gauzes. The most common tools are double control labels on gauze packaging (96%, n=44); whiteboard (83%, n=38); registration form (65%, n=30); a table on which to organise used gauzes (57%, n=26). Other tools mentioned are plastic bags, gauze counting rack, and a specially developed digital counting application.

Standard procedures

At the start of a new surgical case, it is important to check if no gauzes or packaging labels from the previous case are still present in the operating room, for instance in garbage bags. 70% of hospitals (n=32) specified in their protocol that this check needs to be performed, with one half designating a specific person or role to this task.

98% of hospitals (n=45) have a standard procedure in the event of an unreconciled gauze count. 93% of them (n=42) go through the following steps: inform surgeon → wound inspection → check surroundings → X-ray screening → report incident. Other procedures or steps mentioned: inform surgeon → surgeon decides further action; inform OR planning. One hospital established steps to undertake when the surgeon refuses to cooperate in reconciling the count.

4.3.3 Instruments

Protocol

89% of hospitals (n=41) have a protocol concerning the counting of instruments. Responsibility is assigned as follows: 46% (19) scrub nurse, 46% (19) scrub nurse and circulating nurse together, 7% (3) both operating room nurse(s) and surgeon together.

Counting

Instruments are not counted in all surgical procedures. Exceptions mentioned were the same as those mentioned in the section on gauzes. 42 hospitals (91%) formally register completeness of instruments after surgery. For this, the following methods are used (multiple answers possible):

- Digital registration in the patient's file with names of the team (n=40);
- Digital registration in the patient's surgery report written by the surgeon (n=6);
- A physical registration form with the patient's name, and team names and signature (n=3).

Sometimes, specific instruments are needed that are not prepared beforehand. Usage of these separately packaged instruments is always registered in 63% of hospitals (n=29), while 9% (4) only register use when it is indicated. 26% (12) never register this, and in 2% of cases (n=1) no mention is made in the protocol.

Counting methods

We asked how instruments are counted during an open abdominal procedure, as these procedures – usually with a large surgical site - carry a high risk of retained materials. Two main counting methods can be distinguished: 1) all instruments in the tray(s) are counted (complete count) or 2) only the instruments that have been taken out of the tray(s) are counted (partial count). We considered usage of a SmartTray or weighing system to be a complete count, as all instruments are necessary for this. 74% of hospitals (n=31) employ a complete count, and 28% (14) use a partial count. Some hospitals mention using both a complete count (using a SmartTray or weighing system) as well as a partial (manual) count. In one hospital, instruments are not counted. It is unclear whether an alternative tool, such as a SmartTray or weighing system is used.

Varying levels of standardisation among counting methods exist. Generally speaking, they are either performed according to specified procedures or to the experience and judgment of the OR nurse. Complete counts are performed according to specified procedures (74%, n=23), or according to the experience and judgment of the OR nurse (26%, n=8)). Specified procedures include: the use of instrument tray content lists (44%, n=10), use of the SmartTray system (18%, n=4)), use of a weighing system (12%, n=3).

In partial counting, specified procedures such as preparing instruments in even numbers are used. Partial counts are performed according to these specified procedures in 57% of cases (n=8), and according to the OR nurses experience in 36% (n=5). See Figure 4.1 for an overview of standardisation in instrument counting over time.

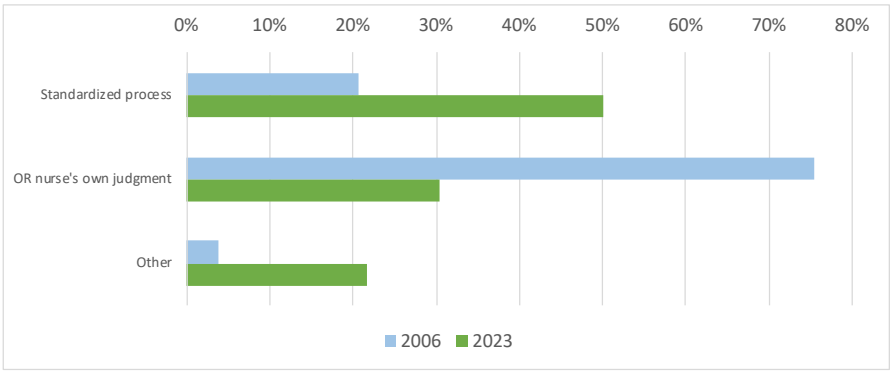

Figure 4.1 *The standardisation of surgical instrument counting within Dutch hospitals now, compared to 2006.*

Use of tools

89% of hospitals (n=41) use one or more tools for counting instruments. 24 hospitals (52%) use content lists (physical or digital); 26% (12) mention the whiteboard; 24% (11) use a weighing system; and 11% (5) use a SmartTray system. Of the hospitals using a weighing system, three are academic hospitals. All hospitals using a SmartTray system are general (non-academic) hospitals. One hospital mentions using a specially designed mobile counting application.

Associations between technologies and practices

While counting practices vary across participating hospitals, no association was found between these practices and the use of technology such as a weighing system (see Table 2). Regardless of whether a hospital uses a weighing system or not in their counting practice, the proportion of hospitals that perform a full count of all instruments versus a partial count of only used instruments is the same (Chi-Square p = .221). Similarly, the designation of responsibility for the counting is not significantly different between the weighing and non-weighing group (Chi-Square, p = .868).

Table 4.2 *Associations between use of technology in counting and counting practice.*

	Use of weighing system in counting practice				p
	Yes		No		
	N	(%)	N	(%)	
Instrument counting method					.221
Performing a full count of instruments	8	(80)	20	(59)	
Performing a partial count of instruments	2	(20)	14	(41)	
Designation of counting responsibility					.868
Instrumenting nurse	5	(50)	14	(45)	
Instrumenting + circulating nurse	4	(40)	15	(48)	
Instrumenting + circulating nurse + surgeon	1	(10)	2	(7)	

Traceability of missing instruments

In case the sterilisation department misses an instrument, 80% can trace the corresponding instrument tray to a specific surgery, including members of staff who were involved. The most common method (89%) is a barcode system which links an instrument tray to a specific patient in the electronic patient file. One hospital mentions having access to a track & trace system, but it is currently not in use.

4.3.4 Disposables

Protocol

89% of hospitals (n=41) have included the handling of disposables in their counting protocol. 39% of them (n=16) have drafted a list of high-risk disposables. 43% of all hospitals (n=20) do not make such a distinction, and in 17% (8) it is unknown whether such a list exists.

Responsibility for counting disposables is assigned as follows: scrub nurse (29%, n=12); scrub nurse and circulating nurse together (66%, n=27); circulating nurse (2%, n=1); scrub nurse, circulating nurse, and surgeon (2%, n=1).

Counting

89% of hospitals (n=41) count disposables in all surgical procedures they are used in. The remaining 11% (5) mention exceptions, such as small incisions, or only counting vessel loops.

98% (45) uses one or more tools to aid in counting disposables, including: whiteboard (70%, n=32); registration form (41%, n=19); keeping disposable packaging (39%, n=18). One hospital (2%) does not use any tools.

4.3.5 Suture needles

Protocol

93% of respondents (n=43) had dedicated a section of their counting protocol to the handling of suture needles. In 35% (15), the scrub nurse alone is responsible for counting; 60% (26) assign responsibility to both the scrub nurse and circulating nurse. In 5% of cases (n=2), the scrub nurse, circulating nurse, and surgeon are responsible.

Counting

93% of hospitals (n=43) count suture needles in all surgical procedures. 7% (3) have specified exceptions: small incisions, or specific procedures such as ophthalmological surgery.

Most hospitals (80%, n=37) use magnetic containers to aid in counting needles. Storing material packaging is also often used (78%, n=36). Furthermore, foam blocks (54%, 25), whiteboard (46%, n=21), registration form (35%, n=16), and use of a bowl (26%, n=12) are mentioned.

4.3.6 Perceived high-risk situations

This was an open question that was asked for each category of surgical material. Due to many similar results, the answers have been combined, removing duplicates. The five situations mentioned most often were: Change of staff (83% of respondents, n=38); Acute or emergency situations (43%, n=20); Hurrying, not caused by emergency (30%, n=14); Multiple surgeons/specialisms/surgical sites involved in one patient (22%, n=10); and Large number of materials to be counted (22%, n=10). See Figure 4.2 for an overview of all high-risk situations mentioned by at least 10% of respondents. A notable result is that concerning instrument counting, some hospitals mentioned not having experienced any high-risk situations anymore since the adoption of the SmartTray system.

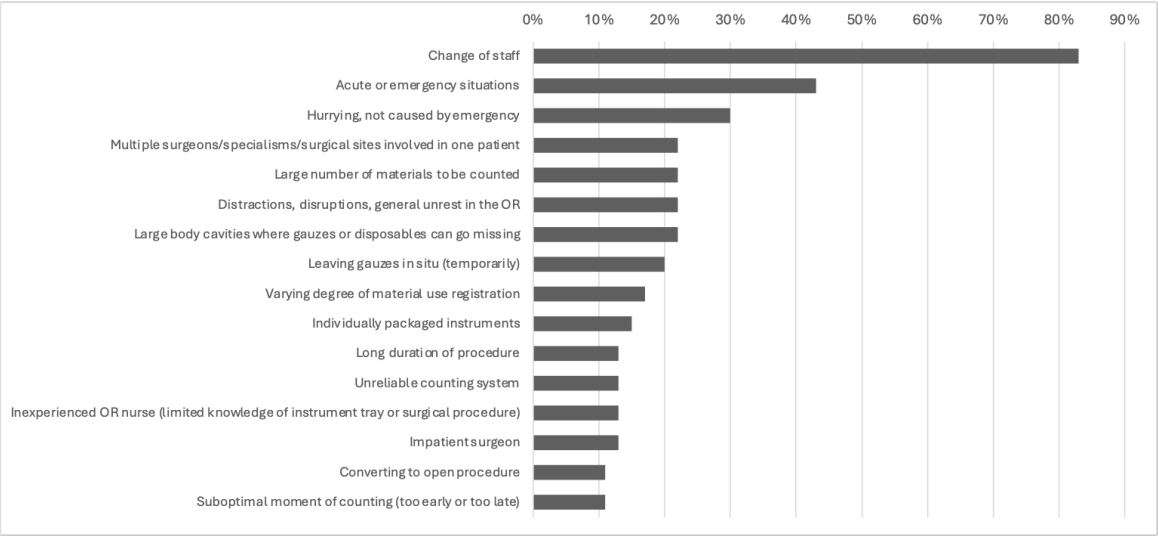

Figure 4.2 *Perceived high-risk situations related to counting of surgical materials, according to respondents. In 2006, the most commonly mentioned high-risk situations were: Change of staff; Ignoring guidelines or protocol; Acute or emergency situations; Unexpected events or haemorrhage; Unknown instrument trays.*

4.3.7 Responsibility for counting

As stated earlier in each surgical material category, responsibility for the counting of materials is sometimes shared between several people or roles in the OR. 40 respondents clarified their hospital's assigned responsibility for each material category. 22 hospitals (55%) showed a uniform assignment of responsibility, meaning that for each category of surgical material, the same person(s) or roles are established.

In 18 hospitals (45%), whoever is responsible for the counting of each category of material varies. See Figure 4.3 for a visual overview.

Figure 4.3 *Visual representation of sub-set of participating hospitals that use a non-uniform designation of counting responsibilities of the four surgical material categories: gauzes, instruments, disposables, and suture needles. Each horizontal bar represents a participating hospital*

4.3.8 Comparison to Meijsen & Meers

See Table 4.3 for a comparison of current results to the results of Meijsen & Meers. Figure 1 shows a comparison of instrument counting method in 2006 and now.

Table 4.3 *Comparison of Meijsen & Meers and current study*

Comparable questions	**2006** [18]	**2023**	**Sign.***
Gauzes			
Counting protocol present	93% (n=59)	96% (n=46)	.589
Responsibility for counting solely on scrub nurse	27% (n=55)	39% (n=44)	.212
Counted in all surgical procedures	35% (n=58)	70% (n=46)	<.001
Use of double control packaging labels	88% (n=59)	98% (n=46)	.063
Preoperative room check established in protocol	37% (n=59)	70% (n=46)	<.001
Counted in case of scrub nurse change	95% (n=59)	89% (n=46)	.266
Counted in case of circulating nurse change	51% (n=59)	26% (n=46)	.010
Standard procedure in case of unreconciled count	91% (n=44)	98% (n=46)	.152
Use of one or more tools	100% (n=59)	100% (n=46)	-
Instruments			
Counting protocol present	28% (n=58)	89% (n=46)	<.001
Responsibility for counting solely on scrub nurse	75% (n=20)	46% (n=41)	.033
Counting method based on own judgment	68% (n=59)	30% (n=31)	<.001
Partial count	47% (n=59)	28% (n=45)	.051
Complete count	42% (n=59)	74% (n=45)	.001
Registration of individual instruments (always + sometimes)	29% (n=59)	74% (n=43)	<.001
Use of one or more tools	31% (n=59)	89% (n=46)	<.001
Tray contents established in protocol	75% (n=59)	91% (n=45)	.032
Formal registration of tray completeness	17% (n=53)	91% (n=46)	<.001
Missing instrument able to be traced back to surgical procedure	58% (n=55)	80% (n=46)	.017
Disposables			
Counting protocol present	5% (n=58)	89% (n=46)	<.001
Responsibility for counting solely on scrub nurse	-	29% (n=41)	-
List of high-risk disposables in protocol	2% (n=57)	39% (n=46)	<.001
Counted in all surgical procedures	17% (n=57)	89% (n=46)	<.001
Use of one or more tools	30% (n=57)	98% (n=46)	<.001
Suture needles			
Counting protocol present	5% (n=58)	93% (n=46)	<.001
Responsibility for counting solely on scrub nurse	-	35% (n=43)	-
Counted in all surgical procedures	25% (n=57)	93% (n=46)	<.001
Use of one or more tools	26% (n=55)	100% (n=46)	<.001

*Chi-square test

4.4 DISCUSSION

The high response rate (65%) for this survey indicates that surgical material counting is a relevant topic for many hospitals, regardless of care level, size, or location.

4.4.1 Protocol and registration

At the time of Meijsen & Meers' research, there was limited standardisation in counting practice among hospitals. Counting protocols usually only concerned gauzes, registration was limited, and the method of counting was mostly left to the OR nurse's own judgment. Since then, major improvements have been made. 9 out of 10 hospitals have implemented all categories of surgical materials in their counting protocol. These protocols are also more extensive, establishing standard procedures, tray contents, improving traceability, and recording use of individual instruments. Standardisation of practice over the years has shown to reduce the risk of adverse events during surgery, including the risk of a retained surgical item [20, 21]. For instance, Norton et al. [22] started an initiative in Boston, USA, to review and improve hospital's counting policies, creating a more uniform counting practice, and reducing the number of count discrepancies. Similarly, Gomes et al. [23] initiated a quality-improvement program in São Paulo, Brazil, resulting in a substantial increase in compliance with best practice.

4.4.2 Uncertainties

Currently, most hospitals assign responsibility for materials counting to multiple persons. This shared responsibility was already common in 2006, even though in principle it is impossible. In 1991, a verdict issued by the Dutch Medical Disciplinary Board (Medisch Tuchtcollege) stated that primarily the scrub nurse is responsible for the counting of surgical materials. [24] While the surgeon is ultimately responsible for the surgical procedure, it is impossible for them to be aware of every action taken in an OR, hence why they can delegate certain tasks – such as materials counting – to qualified team members. Even though this argumentation has been embedded in the Dutch National Operating Room Nurses' Association's (Landelijke Vereniging voor Operatieassistenten; LVO) guidelines on surgical materials counting [25], it is surprising to see such variation in practice. An unclear division of responsibility creates uncertainty after an incident, as well as complicates potential implementation of counting technologies.

Unchanged since 2006, the number one high-risk situation is the changing of staff during a surgical procedure. While protocols and registration practice have vastly improved in previous years, some report that team members follow these protocols to varying degrees, leaving room for ambiguity in the counting process. Despite trainings, audits, and other interventions, these variations in practice seem to occur across all hospitals. However, this situation has greatly improved when compared to the situation in 2006. Then, the second-most mentioned high-risk situation related to counting was 'ignoring guidelines and protocol', whereas this is not mentioned anymore in the

current survey. When comparing these current findings with a meta-analysis on this subject by Moffatt-Bruce et al., many known risk factors mentioned are also present in our findings, for example: emergency operations, unexpected events during surgery, changes of staff, and long duration of surgery [26]. Interestingly, while this meta-analysis found some factors not to be associated to retained surgical items, our findings suggest they are still perceived as 'high-risk'. However, some factors are mutually exclusive. In our survey, respondents often mentioned a large number of materials to be counted as a perceived high-risk situation. Individually packaged instruments are also a cause of concern. While the most-common risk factors mentioned in our survey are unavoidable (change of staff, emergency situations), attention needs to be paid to the third-most common factor 'hurrying, not caused by emergency'. Currently, the healthcare landscape is changing, requiring more efficiency with the same number of resources. Maintaining patient safety in this growing need for efficiency should thus be a top priority.

4.4.3 Counting tools

Before 2006, the adoption of counting tools such as registration forms or whiteboards was mostly limited to the counting of gauzes. As other types of surgical materials gained attention, advocacy for the use of counting tools for them increased. In Meijsen & Meers' study, the authors advocate the use of a weighing system to check the completeness of surgical instrument trays; a technology that is relatively easy to implement, resulting in increased safety and efficiency. Currently, a quarter of all hospitals and almost half of all academic hospitals use such a system. However, its effect on safety and efficiency is unclear. Half of current users say the device's outcomes cannot always be trusted, with reports of insufficient accuracy in small instrument trays, retained tissue materials, and moisture. Furthermore, some hospitals mention performing a manual count in addition to the weight check. While there is limited literature on the use of weighing systems for instrument counting specifically, there is some published work on the physical properties of surgical instruments in this context. During routine use, instruments require maintenance and repair, which often alters an instrument's shape or weight [27]. Webster et al. discusses the similarities of different types of instruments in the context of automated instrument identification, finding a high weight variability in instruments with identical brand and model number [28].

In contrast, the SmartTray system generates more positive feedback. In one glance, OR nurses can see whether a tray is complete. Among study participants, this has resulted in a noticeable decrease in high-risk situations regarding instrument counting. In addition, participants mention that the amount of time it takes to check whether an entire tray is complete is substantially lower compared to performing a full count of all instruments. In an environment where practitioners are under substantial time pressure [29], this is a significant advantage. While promising, all hospitals using this

system are general hospitals, which often handle less complicated surgical procedures with a more general, simplified inventory of instruments. Academic hospitals, on the other hand, manage a more complicated collection of specialised instruments, making the SmartTray system a less viable option.

4.4.4 Future research

Based on the current study, we can conclude that over the years, significant efforts have been undertaken to standardise the surgical counting practice, resulting in a decrease in RSI risk. However, variety in practice still remains. Further research could be performed to explore this current variety. For instance, how does the use of a weighing system affect counting practice? Many hospitals use this technology, which was introduced in Dutch hospitals around twenty years ago, but at the same time, a large number of them are not satisfied with it. Opportunities exist for investigations into the implementation and sustainment of such technologies over the years, potentially extracting valuable lessons and best practices for implementing and sustaining future counting technology developments.

4.4.5 Limitations

This study's survey questions were updated from Meijsen & Meers' previous study. There are no examples of similar surveys with an established reliability and validity. While expert opinions were obtained to increase validity of the study, the survey is aimed at hospital's standard practices and protocols. It is not clear to what extent hospital staff adheres to these standard practices. While both our study and Meijsen & Meers' work surveyed approximately half of the Dutch hospitals, Meijsen & Meers used a different approach. A sample selection of 50% of Dutch hospitals was made, all of which completed the survey. In our study, all Dutch hospitals were contacted, but 65% responded.

There are some methodological limitations to this study related to the respondent population. As OR staff and management works on a busy and unpredictable schedule, we reasoned that requiring participants to fill in every question could result in early terminations of responses. By allowing them to skip a question we believe we increased the response rate, but at the cost of varying response rates between questions.

4.6 CONCLUSIONS

Surgical materials counting is an essential process to ensure patient safety. Over the years, increased standardisation and registration practice have further improved safety. Tools are widely used to make counting easier and less error prone, as well as improve traceability. Older, established tools such as instrument tray weighing

systems warrant renewed analysis considering current sentiments regarding their accuracy in practice.

Further improvements to the counting process can be made by eliminating uncertainty. Clearly assigning responsibility is not only important for improving task awareness and protocol adherence among staff; vague responsibility designations will hinder implementation of potential labour-saving technologies.

Due to a rising demand for healthcare and the growing staff shortage, sustainable employability will be an important topic. Technology might be a solution in this, provided it is compatible with current practice.

REFERENCES

1. Aan de slag voor de zorg. Sociaal Economische Raad; 2021. https://www.ser.nl/-/media/ser/downloads/adviezen/2021/arbeidsmarkt-in-zorg.pdf. (Accessed on 03-05-2023).
2. Gupta Strategists. Uitweg uit de Schaarste (Dutch report). Gupta Strategists; 2022. https://gupta-strategists.nl/studies/uitweg-uit-de-schaarste. (Accessed on 10-04-2023).
3. Gawande AA, Studdert DM, Orav EJ, et al. Risk Factors for Retained Instruments and Sponges after Surgery. N Engl J Med. 2003;348:229-35.
4. Lincourt AE, Harrell A, Cristiano J, et al. Retained foreign bodies after surgery. J Surg Res. 2007;138(2):170-4.
5. Williams TL, Tung DK, Steelman VM, et al. Retained surgical sponges: findings from incident reports and a cost-benefit analysis of radiofrequency technology. J Am Coll Surg. 2014;219:354-64.
6. Hill I, Olivere L, Helmkamp J, et al. Measuring intraoperative surgical instrument use with radio-frequency identification. JAMIA Open. 2022;5(1):ooac003.
7. Guedon AC, Wauben LS, van der Eijk AC, et al. Where are my instruments? Hazards in delivery of surgical instruments. Surg Endosc. 2016;30(7):2728-35.
8. Kusuda KY, K.; Ito, Y.; Tanaka, K.; Masamune, K., Muragaki, Y. Clinical Trial of Information Acquisition System for Surgical Instruments in Digital Operation Room. MICCAI; Granada, Spain2018. p. 78-85.
9. Neumuth T. Surgical process modeling. Innov Surg Sci. 2017;2(3):123-37.
10. Cima RR, Kollengode A, Clark J, et al. Using a data-matrix-coded sponge counting system across a surgical practice: impact after 18 months. Jt Comm J Qual Patient Saf. 2011;37(2):51-8.
11. Kranzfelder M, Schneider A, Blahusch G, et al. Feasibility of opto-electronic surgical instrument identification. Minim Invasive Ther Allied Technol. 2009;18(5):253-8.
12. Glaser B, Danzer S, Neumuth T. Intra-operative surgical instrument usage detection on a multi-sensor table. Int J Comput Assist Radiol Surg. 2015;10(3):351-62.
13. Hosaka R. Development of Identification System for Surgical Instruments Using UHF Band RFID and Low-Intensity Antennae. World Congress on Medical Physics and Biomedical Engineering 2018. IFMBE Proceedings2019. p. 39-43.

14. Shimizu T, Hachiuma R, Kajita H, et al. Hand Motion-Aware Surgical Tool Localization and Classification from an Egocentric Camera. J Imaging. 2021;7(2).
15. Lee J-D, Chien J-C, Hsu Y-T, et al. Automatic Surgical Instrument Recognition—A Case of Comparison Study between the Faster R-CNN, Mask R-CNN, and Single-Shot Multi-Box Detectors. Applied Sciences. 2021;11(17).
16. Nakano A, Nagamune K. A Development of Robotic Scrub Nurse System - Detection for Surgical Instruments Using Faster Region-Based Convolutional Neural Network –. Journal of Advanced Computational Intelligence and Intelligent Informatics. 2022;26(1):74-82.
17. SureCount Surgical. Introducing the SmartTray 2023 [Available from: https://surecountsurgical.com/wp-content/uploads/2023/09/introducing_smarttray-8-17-JK.pdf.
18. Meijsen P, Meers E. Uitgeteld? ; 2006. https://sterilisatievereniging.nl/wp-content/uploads/2015/08/2006-Onderzoek-naar-compleetheidscontroles-van-instrumenten.pdf. (Accessed on 11-08-2023).
19. Cochran K. Guidelines in Practice: Prevention of Unintentionally Retained Surgical Items. AORN J. 2022;116(5):427-40.
20. Norton EK, Martin C, Micheli AJ. Patients count on it: an initiative to reduce incorrect counts and prevent retained surgical items. AORN J. 2012;95(1):109-21.
21. Edel EM. Surgical count practice variability and the potential for retained surgical items. AORN J. 2012;95(2):228-38.
22. Norton EK, Micheli AJ, Gedney J, et al. A nurse-led approach to developing and implementing a collaborative count policy. AORN J. 2012;95(2):222-7.
23. Gomes ET, Galvão MCB, Shimoda GT, et al. Surgical counts in open abdominal and pelvic surgeries in a university hospital: a best practice implementation project. JBI Evidence Implementation. 2021;19(1).
24. Chirurg niet verantwoordelijk voor alle details van de operatie. Medisch Contact. 1991:1458-60. (Accessed on 23-09-2023).
25. Landelijke Vereniging van Operatieassistenten. Richtlijn Onbedoeld achterblijven operatiemateriaal. 2009. https://sterilisatievereniging.nl/wp-content/uploads/2015/08/2009-Richtlijn-LVO-definitief_print.pdf. (Accessed on 24-09-2023).
26. Moffatt-Bruce SD, Cook CH, Steinberg SM, et al. Risk factors for retained surgical items: a meta-analysis and proposed risk stratification system. J Surg Res. 2014;190(2):429-36.
27. Acland R. Notes on the care restoration and repair of microsurgical instruments. Indian Journal of Plastic Surgery. 2006.
28. Webster RJ, Yaniv ZR, Glaser B, et al. Surgical instrument similarity metrics and tray analysis for multi-sensor instrument identification. Medical Imaging 2015: Image-Guided Procedures, Robotic Interventions, and Modeling2015.
29. Warwick VR, Gillespie BM, McMurray A, et al. Undertaking the surgical count: An observational study. Journal of Perioperative Nursing. 2021;34(3).

5

Chapter 5: Legal considerations of laboursaving technology in surgery

5.1 BACKGROUND

5.1.1 The potential of technology

The aging population is becoming one of the most significant issues of the current time. While this increase in life expectancy, caused by advancements in modern science and medicine, is a positive development from a humanitarian perspective, it complicates the delivery of healthcare: the number of medical professionals cannot grow with the increasing demand, putting significant strain on the system [1].

Technology is often considered a solution: robotics that assist in logistic processes [2], Virtual Reality (VR) technology that can be used to more efficiently plan surgeries [3] are examples of such *laboursaving* technologies. Similarly, clinical decision support systems (CDSS) are key in improving healthcare quality, patient safety, and efficiency [4]. By collecting and synthesising data from a variety of sources, the advanced pattern-recognition capabilities of artificial intelligence (AI) can significantly accelerate the usefulness of these systems.

An example of an environment that could benefit from a CDSS is the operating room (OR). An OR is a complex and dynamic environment where many factors influence workflow and surgical outcomes. Patient characteristics (historic or current), room conditions [5] (air quality, temperature), medical device status [6], and surgical instrument use [7] are some examples of such factors. While the interplay of these factors is complex, impactful labour-saving technology does not necessarily need to target complex aspects of clinical procedures. Often, repetitive or administrative tasks are involved to ensure patient safety or traceability of materials.

5.1.2 The hidden complexity of counting

One example is the process of surgical instrument counting. Instrument counting is a mission-critical manually performed task to ensure the patient's safety during and after surgery. The occurrence of retained surgical instruments (RSIs) has been studied extensively, with risk factors being identified such as interruptions and distractions in the OR, working under time pressure, changing of personnel, and variability of counting practice [8, 9]. Since counting is error-prone, this necessity takes up time and attention from already scarce personnel.

For many years, attempts have been made to automate this manual counting with a wide range of technologies, including data matrices (barcodes, QR codes) [10, 11],

radiofrequency identification (RFID) tags [12, 13], cameras equipped with computer vision algorithms [14], weighing scales [15], and even magnets [16]. Despite these efforts, only a limited number of solutions have been implemented in clinical practice. This emphasises that, apart from technical developments, other challenges slow down or even prevent solutions from being implemented. One critical aspect is the assignment of responsibility and liability for the task at hand, the insurance of a reliable count.

The Dutch national guideline 'Unintentional retention of surgical materials' recommends that while the surgeon is ultimately responsible for the entire surgical procedure, the instrumenting nurse is solely responsible for the instrument count. Interestingly, our earlier research showed that in the Netherlands, two-thirds of hospitals assume a shared responsibility for the counting of surgical materials in their counting protocols. Often, both the instrumenting nurse and circulating nurse are held responsible, with sometimes even the surgeon being included. See Table 5.1 for an overview of the data.

Table 5.1 *Responsibility for the counting of surgical materials as described in hospital's counting protocols as of 2023*

	Scrub nurse	*Scrub and circulating nurse*	*Circulating nurse*	*Surgeon*	*Scrub + circulating + surgeon*	*Other*
Instruments (n=41)	46%	46%	-	-	7%	-
Gauzes (n=44)	39%	55%	-	2%	5%	-
Disposables (n=41)	29%	66%	2%	-	2%	-
Suture needles (n=43)	35%	60%	-	-	5%	-

As each protocol is continuously evaluated and tailored to its organisation's situation, one can find various approaches across hospitals or even clinical departments. Such variations hinder implementation efforts for novel labour-saving technologies, even in the case of a straight-forward task such as surgical instrument counting. Harmonising local policies across a larger context is preferrable for technology to have a better chance of reaching widespread adoption [REF]. To be able to harmonise local policies, it is necessary to assess the jurisprudence on which these policies are based. The guideline 'Unintentional retention of surgical materials' references several legislative and legal sources for their recommendations. However, a more in-depth assessment of relevant jurisprudence and historical legal cases of RSIs could add to the discussion and identify options for harmonisation. Relevant fields of law will be briefly introduced below.

5.1.3 Disciplinary law

In the Netherlands, most healthcare professions carry a protected title, requiring registration in the BIG register for Professions in Individual Healthcare (Beroepen in de Individuele Gezondheidszorg) [17]. They are required to uphold a certain standard of care, as is described in their corresponding professional society's guidelines. If this standard is (possibly) compromised, a complaint can be filed with a Regional Medical Disciplinary Board, which consists of legal professionals and medical experts. If the complaint is justified, disciplinary actions may be taken, such as a warning, a reprimand, a fine, or ultimately, removal from the BIG register [18]. Notably, the Disciplinary Board cannot award any financial compensation for damages.

5.1.4 Civil and criminal law

If a complaint escalates to a conflict, civil law could be involved. Its goal is to resolve conflict between people and/or organisations. From a medical perspective, civil cases often involve patients seeking damages from care providers. If a criminal offence is perceived to have been committed, criminal law is involved. The public prosecutor will assess each case and determine whether there are grounds for prosecution. In a criminal prosecution, consequences can involve a prison sentence.

5.1.5 Central liability

It can be difficult for patients to determine the right person to proceed against, given the complexity of healthcare organisations. Legislators aimed to strengthen the patient's position by formalising the relationship between patient and caregiver with the introduction of the Law on Medical Treatment Agreement (in Dutch: Wet op de Geneeskundige Behandelovereenkomst, WGBO) in 1995. This law introduced *central liability* (Article 7:462 Civil Code) [19]. Central liability relieves a patient from determining who is exactly responsible in the event of a medical error, as the hospital in which the treatment took place is always jointly liable for damages with the individual caregiver, regardless of the caregiver's employment position in relation to the hospital. Each hospital has their own agreement with its medical staff on how this liability is ultimately divided.

5.1.6 Alternative dispute resolution

Since introduction of the Healthcare Quality, Complaints and Disputes Act (in Dutch: Wet kwaliteit, klachten en geschillen zorg, Wkkgz) [20] in 2015, Dutch hospitals are required to employ an independently operating complaints officer (art. 15 Wkkgz), and to be associated to a dispute committee organisation (art. 18 Wkkgz) (in Dutch: geschilleninstantie). Alternative dispute resolution (ADR) was introduced to bridge the gap between disciplinary law and civil law. Filing a disciplinary complaint (in Dutch: tuchtklacht) is relatively accessible but does not lead to compensation for damages (art. 47 Wet BIG) [17]. Civil law can lead to compensation [21], but filing suit is more

costly and involved. With the introduction of the Wkkgz, this gap has been filled. Dispute committees have the authority to grant damages up to a maximum of EUR 25.000 [20].

Not all incidents involving an RSI result in a legal case. However, the ones that did can shed some light on our primary research question: What is the current designation of responsibility and liability for surgical instrument counting? These findings will then be related to the potential situation of an automated instrument count.

5.2 METHODS

For this study, we searched jurisprudence and relevant literature for cases involving the following: a surgical procedure performed in an operating room by one or more surgeons with the help of an instrumenting nurse, and the occurrence of a retained surgical instrument (RSI). A surgical instrument describes any material or tool used during a surgery, such as an artery clamp or a sterile gauze. In addition, the proceedings should discuss responsibility and/or liability of the RSI. Legal references used in the national guideline 'Onbedoeld achterblijven operatiemateriaal' were used as a starting point, from which a snowball method was used to find earlier publications. Dutch medical trade journal Medisch Contact regularly publishes noteworthy disciplinary cases. Previous editions going back to 1945 have been digitised on their website (www.medischcontact.nl). To find more recent legal cases, several databases were searched between June 2024 and January 2025 using keywords 'surg*' and 'retained': Dutch Ministry of Justice (www.rechtspraak.nl) (civil and criminal cases), Dutch Medical Disciplinary Board (www.tuchtrecht.overheid.nl) (disciplinary cases), ANWB Civil Damages (in Dutch: Smartengeld)(civil cases) (www.smartengeld.nl), and the database of the Medical Alternative Dispute Resolution Committee (in Dutch: Geschillencommissie Zorg) (www.degeschillencommissiezorg.nl).

5.3 RESULTS

In total, eight cases were found that concerned an RSI after a surgical procedure in an operating room performed by one or more surgeons with assistance of an instrumenting nurse. In five cases, the main point of discussion was to determine whether the surgeon was responsible for the occurrence of the RSI. In two cases, one disciplinary case and one criminal case, the main point of discussion was not who was responsible for the occurrence of the RSI, but rather whether the surgeon's actions were adequate after learning of the RSI. See Figure 1 for a flowchart of searches and results. The five relevant cases will be summarised below. The remaining three cases will be summarised under 'Supplementary cases'. Table 2 provides an overview of all cases.

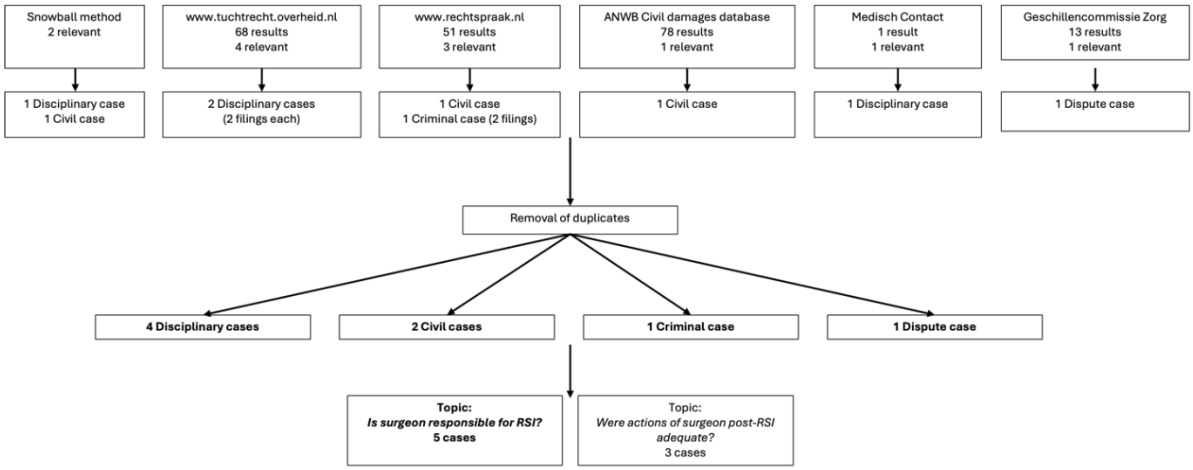

Figure 5.1 *Diagram of search strategies and results. Six search strategies were employed, resulting in eight cases concerning an RSI after a surgery performed in an operating room with one or more surgeons and assisted by an instrumenting nurse. Of the eight cases, five contained the discussion of interest, namely whether the surgeon is responsible for the occurrence of the RSI.*

5.3.1 Disciplinary Law Decisions

Inspectorate for Healthcare v. Surgeon, hereinafter 'Disciplinary Case 1' [22]

On the 4th of November 1985, a patient underwent gastric resection surgery. During the surgery, the presence of a malignancy was suspected. The procedure was halted to perform a pathological examination of lymph node tissue. Meanwhile, the operation site was covered in surgical blankets. After the pathological results were negative, surgery was resumed and completed as planned. During the surgery, a change of instrumenting OR nurse took place. The starting instrumenting nurse had added two arterial clamps to the procedure's instrumentation, of which the second nurse was not made aware.

Initially, the patient recovered well but was later readmitted to hospital with complaints of persistent nausea, vomiting, and abdominal pain. Assessments revealed the two arterial clamps had been left behind in the abdomen. Despite performing emergency surgery to remove the clamps, they caused severe damage to the small intestine. The patient died of sepsis on the 16th of December.

The healthcare inspector filed a complaint with the Medical Disciplinary Board arguing that the surgeon did not provide adequate care. The Board decided that the responsibility for ascertaining whether all instruments and materials used during surgery are accounted for lies primarily with the instrumenting nurse, not the surgeon. The Board argued that the surgeon should be able to concentrate solely on the medical aspects of the procedure. As such, it would be an overreach for him/her to be held liable for every detail of the operation. However, it is the surgeon's responsibility to make sure all team members are competent.

Plaintiff v. Gynaecologist, hereinafter 'Disciplinary Case 2' [23]

In March 1998, a patient underwent an open gynaecological procedure to remove uterine fibroid tissue. After discharge, she again presented with abdominal complaints. Radiological assessment showed a foreign body in the right-side flank in the shape of a cake server, a gynaecological tool commonly used during wound closure. An emergency reoperation was performed to remove the 32 cm-long instrument.

The patient filed a complaint to the Medical Disciplinary Board, stating that the surgeon did not adequately check the operative field before closing the wound, as well as failed to check whether the instrument count was adequately performed. It turned out that due to the size of the fibroid tissue, a second set of instruments had to be used, which was not weighed and labelled before the surgery according to protocol. Additionally, the wound was closed by a gynaecology trainee meaning the defendant did not handle the retained instrument at all.

The complaint was ultimately rejected. In addition, the board commented that the proceedings do not mean that the trainee should be reproached. Rather, it was "beyond the scope of this Board to determine the boundaries of responsibilities of the specialist-in-training and the instrumenting nurse."

The plaintiff appealed the decision to the Court of Appeal. She argued the failure to supervise the trainee and to enforce the counting protocol constituted a breach of professional duty. However, the Court concluded that although the count protocol was not fully observed, there was no evidence of deliberate misconduct or negligence from both the gynaecologist and the trainee. Accordingly, the Court dismissed the appeal and upheld the Disciplinary Board's decision.

Plaintiff v. Surgeon, hereinafter 'Disciplinary Case 3' [24]

In December 2010, a patient underwent an elective gastrointestinal procedure, during which a surgical gauze was retained in her abdomen. After undergoing a second surgery to remove it, she filed a complaint against the surgeon, claiming that the surgeon failed to adequately check the surgical site for retained materials. The surgeon stated that an inspection did take place, however brief. The OR nurses had made clear that there was no discrepancy in the number of gauzes before the surgery and during closing of the wound.

The Regional Disciplinary Board rejected the complaint, stating: "While the surgeon is ultimately responsible for the surgery and its outcome, this does not mean that he is responsible for or should check every task that takes place in this context. Not only would it distract from his primary task, it would also be impossible, as a part of the

counting takes place outside the sterile field. The surgeon should not have to instruct the experienced nurses to perform the counting according to protocol or question their expertise."

The verdict was appealed, with the patient arguing that the surgeon, as supervisor, is ultimately responsible for the whole operation and thus responsible for the counting of gauzes before closure of the wound. The Central Board rejected the appeal, confirming the Regional Board's argumentation and decision.

5.3.2 Civil Law Decisions

Aarts v. Nuboer, hereinafter 'Civil Case 1' [25]

The first known case concerning retained surgical materials in Dutch jurisprudence, the Nuboer arrest from 1968 describes a cardiac operation carried out by an independent surgeon, assisted by three doctors and an OR nurse. After the surgery, it came to light that an injection needle was left inside the patient's chest. An investigation revealed that the needle had been unintentionally concealed inside a reusable gauze during cleaning. The patient held the surgeon liable and sued for damages.

The court established that it is the OR nurse's job to keep track of all instruments and other materials used during the surgery. For the surgeon to be responsible for the OR nurse's mistake, the nurse would have to be a subordinate to him. However, the surgeon was independent, i.e., not employed by the hospital, while the OR nurse was. Thus, the court decided that each member of the surgical team was a qualified professional and responsible for their own actions, meaning the patient's claim was rejected.

The decision was appealed at the Supreme Court, which confirmed the court's arguments that the surgeon could not be held liable for the errors of his team members.

Plaintiff v. Surgeon & Stichting Ziekenverpleging Aruba SZA, hereinafter 'Civil Case 2' [26]

In 2015, a patient underwent an elective gastric surgery (Nissen fundoplication) on the Dutch constituent island country of Aruba. The surgery was performed by an independent (self-employed) surgeon in an operating room of the local hospital, in collaboration with an operating room nurse employed by the hospital. Insufficient care was taken to check whether all instruments and materials used during the surgery were complete. It turned out that a so-called Penrose drain was left behind in the patient's abdomen. A year later, another operation was performed to remove the drain.

During this time, the patient was not able to work due to the severity of abdominal complaints.

Both the surgeon and the hospital were defendant. During the court proceedings, it was emphasized that according to the LVO guideline “Onbedoeld achterblijven operatiemateriaal” (Unintentional retention of operative material) the surgeon is responsible for the surgery in its entirety, but would not be held responsible for details, such as instruments and materials counting.

However, the court mentions Article 6:76 of the Civil Code (Burgerlijk Wetboek), which states that if someone makes use of the help of other persons in fulfilling a contractual obligation, he is liable for the potential risk in a similar way as he is to his own [27]. This means that even though the instrumenting nurse made an error by not adequately checking the completeness of the used materials, the surgeon is liable for the damage caused by this error, even though the nurse may have acted independently of the surgeon. The court stated that the professional guidelines could merely function as a guide to determine who should ultimately carry these damages.

The court awarded the patient 20.000 Aruban florin (around EUR 10.000) in damages, to be initially paid by the hospital.

5.3.3 Supplementary cases

The cases described above all centred around the discussion whether the surgeon is responsible for the surgical instrument count. The following cases are centred around different discussions: the first two cases are about whether the surgeon acted adequately after an RSI was noticed.

Inspectorate for Healthcare v. Neurosurgeon, hereinafter ‘Disciplinary Case 4’ [28]

In September 2014, a neurosurgeon (the defendant) performed an operation on a ten-year-old patient to remove a brain tumour. During closing of the surgical wound, the surgeon was made aware a counting error had been made. The surgeon deemed it improbable that a gauze could be left inside the wound, as did the scrub nurse and circulating nurse. While the nurses continued to search for the gauze in the OR, the wound was closed and the patient brought to the paediatric intensive care unit (PICU). There, an X-ray was performed which showed a so-called “pattie” being retained in the patient’s head. A pattie is a surgical gauze with a string attached to it to aid visibility and to make it easier to remove. After discovery of the RSI the patient was reoperated, and the gauze removed.

In this case, the discussion is not whether the surgeon is responsible for the counting error. Rather, the discussion is focused on how the surgeon responded after it was made clear that a counting error had been made. This again underlines the

argumentation that while the surgeon is ultimately responsible for the surgery and its outcome, he cannot be held responsible for every action taken by the OR team members.

Plaintiff v. Surgeon, hereinafter 'Criminal Case' [29]

Between February and May 2009, a gastric surgeon did a procedure where he removed a gastric band. Nearing end of surgery, the instrumenting nurse mentioned that a gauze was missing. Surgeon briefly checked wound, and didn't find it there, instructed nurses to keep looking around the OR. Nurses asked to do radiograph to find gauze in patient, but surgeon denied, said it couldn't be there. At end of surgery, nurses asked again, but surgeon refused. One week after surgery, patient was assessed by surgeon, had swelling on abdomen. Surgeon said it was haemorrhage. No mention was made of an incomplete gauze count in the patient's medical record.

Surgeon was sued for wilfully causing bodily harm but was ultimately acquitted.

Complainant v. Hospital, Dispute Committee Hospitals, hereinafter 'Dispute Case' [30]

On the 2nd of April 2013, a patient with a psychiatric history underwent surgery due to rectal carcinoma. Postoperatively, many complications occurred, resulting in numerous admittances, painful drainages, and the dismissal of complaints due to his psychiatric history. Finally, on the 12th of May 2017, an investigative endoscopic procedure was performed by an independent provider, during which a foreign object was found which was deemed highly likely to be a medical object left behind after an earlier procedure. The patient initially filed a complaint with the hospital's complaints officer. But when this process did not resolve the situation, he filed a complaint with the ADR committee, seeking acknowledgment and justification for his years-long struggle. The committee decided that the hospital was liable for damages given the likelihood of the retention after initial surgery and the dismissal of complaints for multiple years. EUR 20.000 in damages were awarded to the patient.

Table 5.2 *Dutch legal cases involving an RSI, with characteristics.*

	Type of RSI	*Cause of RSI*	*Defendant*	*Verdict*	*Time between initial surgery and removal of RSI (days)*
Disciplinary Case 1	Two artery clamps, 22 cm in length in abdomen	Deviation from protocol	Surgeon (supervisor)	Surgeon not responsible for actions and errors of instrumenting nurse	39
Disciplinary Case 2	"Cake server" retractor/abdominal spatula, 32 cm in length in abdomen	Human error	Surgeon (supervisor)	Regional Board: Reprimand Central Board: Complaint rejected	8
Disciplinary Case 3	Gauze 25x25 cm in abdomen	Human error	Surgeon (supervisor) and Trainee (operator)	Complaint rejected	143
Civil Case 1	Needle (accidentally concealed in reusable gauze after cleaning) in chest cavity	Human error	Surgeon	Surgeon not responsible for actions and errors of instrumenting nurse	Unknown*
Civil Case 2	Penrose drain in abdomen	Human error	Hospital and Surgeon	Surgeon responsible for actions and errors of instrumenting nurse	356
Disciplinary Case 4	"Pattie" gauze in posterior cranial fossa (under the skull)	Human error	Surgeon	Complaint rejected	0
Criminal Case	Gauze 25x25 cm in abdomen	Human error	Surgeon	Acquitted from charges of deliberately causing severe injury	80**
Dispute Case	“Microtube” near surgical suture	Human error	Hospital	Patient awarded EUR 20.000 in damages	1501

**However, multiple hospital admissions took place before RSI was removed*

***Date of RSI removal not specified, only that it took place almost three months after initial surgery*

5.4 DISCUSSION

In this work, we studied the available Dutch jurisprudence and legal literature with the aim of determining the allocation of responsibility and liability in case of an RSI. While we found several cases where an RSI occurred, it should be noted that the incidence of RSIs is likely higher, as not all events lead to a legal dispute.

5.4.1 Common ground

In the legal cases described above, incidents occurred where an instrument or other surgical material was retained inside a patient's body. In almost all cases, the incident was caused by a human error during instrument counting. Only the incident described in Disciplinary case 1 was caused by a deviation from protocol through the addition of artery clamps to the instrumentation without informing the second OR nurse of this. In all cases, complaints were lodged towards the surgeon alone or both the hospital and the surgeon.

5.4.2 Disciplinary law versus Civil law and ADR

While final decisions seem to vary among cases, a general line of reasoning can be unveiled. Disciplinary cases are benchmarked on the hypothetical 'good careprovider' (in Dutch: goed hulpverlenerschap) as stipulated in article 7:453 BW [31], meaning that as long as the defendant was thorough and acted in accordance with professional standards, he or she is not at fault. As Disciplinary case 2 shows, it is not within the Disciplinary Boards' authority to determine where the responsibility of one practitioner ends and the other begins.

Civil lawsuits and alternative dispute resolution are often the result of a deeper conflict between the parties, with patients seeking compensation for damages. While the verdicts in the described cases seem conflicting, a distinction can be made between them: Before 1970, the Civil Code was based on legislation dating to 1838. In the following years, the 'New' Civil Code was gradually implemented, with the relevant Book on contractual law being implemented in 1992. Article 6:76 of this New Civil Code was highlighted as a decisive ruling in Civil Case 2 [26], stating that assistance of another person in the performance of an obligation results in the liability of that person's conduct in the same way as the debtor's own [27]. As such, the ruling of civil case 1 can be disregarded. While the operating room nurse is responsible for performing the instrument count, the liability for any damages incurred due to a counting error lies with the surgeon as well as the hospital in which the surgery was performed.

While the hospital's central liability is legally anchored in Dutch law [19], some international cases of RSIs highlight the hospital system's responsibility in other ways. For instance, in 2023, a surgical 'Alexis' retractor – the size of a dinner plate - was retained inside a woman's abdomen for 18 months [32]. Initially, the New Zealand's

Auckland District Health Board claimed the nurse assisting on the surgery had failed to exercise reasonable skill and care towards the patient. However, upon further assessment, the retractor was considered too large to be lost and thus was not part of the counting protocol. The initial claim was then retracted, and the hospital organisation was reprimanded instead [33]. Only recently before, also in New Zealand, a very similar case occurred, where the medical error was attributed to systemic issues for which ultimately the hospital was reprimanded [34].

5.4.3 The position of laboursaving technology

With developments in surgical instrument detection and recognition technology ongoing, it is not unthinkable that the task of instrument counting will be automated in the near future. Considering the Dutch legal climate, a significant deviation from the current situation would be unexpected. With the central liability of the hospital in which the procedure was performed, the main pathway towards compensation for injured patients remains. The surgeon's liability, however, is more nuanced.

The current basis for the surgeon's liability for damage from RSIs is through article 6:76 BW, as he/she makes use of an assistant (the operating room nurse) [27]. The use of an instrument counting device suggests a basis for liability through Article 6:77 BW: "If, in the performance of an obligation, a faulty device is used, the resulting shortcoming may be attributed to the debtor, unless this would be unreasonable in view of the content and necessary implication of the juridical act from which the obligation arises, the generally accepted principles (common opinion) and other circumstances of the situation." [35] While the unless-clause in this article provides judges room to consider each case individually, it is unclear what constitutes as 'unreasonable', as is illustrated in the highly-debated cases of the Miragelplombe [36] and PIP breast implants [37].

A further point of discussion is the position of the operating room nurse in relation to the technology: 1) the device replaces the OR nurse to perform the task and as such, the device is used by the surgeon, or 2) the OR nurse remains an intermediary between the device and the surgeon, interpreting the device's outcomes and relaying them to the surgeon. It can be argued that in both cases, the surgeon, ultimately, is liable. However, it could also be argued that in the first situation, it is unreasonable to attribute the shortcoming of a faulty device to the surgeon, as tasks originally performed by an OR nurse probably fall outside the scope of a surgeon's responsibilities [24]. More likely, the second situation will occur, given the operating room nurse's professional societies' stance on the use of technology during for instance instrument counting [38]. In that case, the operating room nurse would be liable for the use of the device through Article 6:77 BW, but subsequently the surgeon would be liable for any errors the OR nurse makes through Article 6:76 BW.

Another complicating factor is the fact that it is highly likely that laboursaving technology will involve the use of AI. A system that collects data, integrates and analyses it, and presents an outcome, creates a black box for its users (i.e. the healthcare practitioner). Following the example of surgical instrument counting, there is an increasing frequency of publications that use computer vision algorithms for this purpose [39-41]. The assumption of liability in the case of AI-based devices is still a point of discussion in the legal community [42]. The European Commission proposed an AI liability directive (AILD) in 2022 [43], but has since withdrawn it due to a lack of agreement among EU member states [44].

5.5 CONCLUSION

Following the study on Dutch legal literature and jurisprudence on the responsibility of RSIs in surgical practice, it is plausible that hospitals included a shared responsibility in their instrument counting protocols to reflect the current situation, wherein the instrumenting nurse is responsible for counting the instruments, but the surgeon as well as the hospital are liable for any potential damage caused by a counting error. This nuanced reality has implications for implementing laboursaving technology in surgical practice, as responsibility and liability for the task to be automated may lie with different persons. Harmonising these responsibilities and liabilities across hospital organisations could improve implementation success of laboursaving innovations.

REFERENCES

1. OECD. Ageing: Debate the Issues. Paris: OECD Publishing; 2015. Report No.: 9789264206601. (Accessed on 6 February 2022).
2. ICT&Health. Logistics robot lightens workload in Dutch hospital, 2024. [cited 11 June 2025]. Available from: https://icthealth.org/news/logistics-robot-lightens-workload-in-dutch-hospital.
3. Queisner M, Eisentrager K. Surgical planning in virtual reality: a systematic review. J Med Imaging (Bellingham). 2024;11(6):062603.
4. Kohn LT, Corrigan JM, Donaldson MS. To Err is Human: Building a Safer Health System. Washington (DC): Institute of Medicine Committee on Quality of Health Care in, America; 2000.
5. Hu N, Lans J, Gram A, et al. Ventilation performance evaluation of an operating room with temperature-controlled airflow system in contaminant control: A numerical study. Building and Environment. 2024;259.
6. Guedon AC, Wauben LS, Overvelde M, et al. Safety status system for operating room devices. Technol Health Care. 2014;22(6):795-803.
7. Neumuth T. Surgical process modeling. Innov Surg Sci. 2017;2(3):123-37.
8. Edel EM. Surgical count practice variability and the potential for retained surgical items. AORN J. 2012;95(2):228-38.

9. Moffatt-Bruce SD, Cook CH, Steinberg SM, et al. Risk factors for retained surgical items: a meta-analysis and proposed risk stratification system. J Surg Res. 2014;190(2):429-36.
10. Greenberg CC, Diaz-Flores R, Lipsitz SR, et al. Bar-coding surgical sponges to improve safety: a randomized controlled trial. Ann Surg. 2008;247(4):612-6.
11. Cima RR, Kollengode A, Clark J, et al. Using a data-matrix-coded sponge counting system across a surgical practice: impact after 18 months. Jt Comm J Qual Patient Saf. 2011;37(2):51-8.
12. Hill I, Olivere L, Helmkamp J, et al. Measuring intraoperative surgical instrument use with radio-frequency identification. JAMIA Open. 2022;5(1):ooac003.
13. Meeuwsen FC. Safe Surgical Signatures. TU Delft Repository: TU Delft; 2019.
14. Jiang K, Pan S, Yang L, et al. Surgical Instrument Recognition Based on Improved YOLOv5. Applied Sciences. 2023;13(21).
15. Glaser B, Danzer S, Neumuth T. Intra-operative surgical instrument usage detection on a multi-sensor table. Int J Comput Assist Radiol Surg. 2015;10(3):351-62.
16. Kang HS, Khoraki J, Gie J, et al. Multiphase preclinical assessment of a novel device to locate unintentionally retained surgical sharps: a proof-of-concept study. Patient Saf Surg. 2023;17(1):10.
17. Wet op de beroepen in de individuele gezondheidszorg (Wet BIG), (1993).
18. Disciplinary measures: Health and Youth Care Inspectorate; [Available from: https://www.igj.nl/onderwerpen/maatregelen/tuchtrecht.
19. Article 7:462 Civil Code, (2025).
20. Wet kwaliteit, klachten en geschillen zorg (Wkkgz), (2016).
21. Article 6:162 Civil Code.
22. Inspectorate for Healthcare v. Surgeon: Hearing before the Central Disciplinary Board for Healthcare, ECLI unknown, (18 March, 1991).
23. Plaintiff v. Gynaecologist: Hearing before the Central Disciplinary Board for Healthcare, Court of Appeal 's-Hertogenbosch, ECLI:NL:GHSHE:2004:AS3057, (7 December, 2004).
24. Plaintiff v. Surgeon: Hearing before the Central Disciplinary Board for Healthcare, ECLI:NL:TGZCTG:2013:YG2651, (14 February, 2013).
25. Aarts v. Nuboer: Hearing before the Attorney-General, Supreme Court of Justice, ECLI:NL:PHR:1968:AC4869, (31 May, 1968).
26. Plaintiff v. Surgeon & Stichting Ziekenverpleging Aruba SZA: Hearing before the Aruba Court of First Instance, ECLI:NL:OGEAA:2021:413, (11 Augustus, 2021).
27. Article 6:76 Civil Code, (2025).
28. Inspectorate for Healthcare v. Neurosurgeon: Hearing before the Central Disciplinary Board for Healthcare, ECLI:NL:TGZCTG:2017:208, (6 July, 2017).
29. Plaintiff v. Surgeon: Hearing before the Court of Appeal Arnhem-Leeuwarden, ECLI:NL:GHARL:2015:3126, (1 May, 2015).
30. Complainant v. Hospital: Hearing before the Dispute Committee Hospitals, Case no. 135513/157076, (29 April, 2022).
31. Article 7:453 Civil Code. Sect. Book 7 (2025).
32. Magramo K. 'Dinner plate sized' device found inside woman's abdomen 18 months after cesarean birth. CNN. 2023.

33. A Decision by the Health and Disability Commissioner (21HDC01479): Hearing before the Health and Disability Commissioner, Auckland District, New Zealand, (2023).
34. A Report by the Health and Disability Commissioner (Case 19HDC00159): Hearing before the Health and Disability Commissioner, (2021).
35. Article 6:77 Civil Code, (2025).
36. Patient v. Hospital (Miragelplombe arrest): Hearing before the Justice Court 's-Hertogenbosch, Supreme Court of Justice, ECLI:NL:HR:2020:1082, ECLI:NL:GHSHE:2022:1080, ECLI:NL:HR:2023:1002, (2023).
37. Prejudiciële vragen bij gebrekkige PIP-borstimplantaten. ECLI:NL:PHR:2020:176: Parket bij de Hoge Raad [Public Prosecutor at the Supreme Court]; 2020.
38. Association of periOperative Registered Nurses I. Guidelines for Perioperative Practice. Denver, CO: AORN; 2022. (Accessed on 8 March 2024).
39. Ran B, Huang B, Liang S, et al. Surgical Instrument Detection Algorithm Based on Improved YOLOv7x. Sensors (Basel). 2023;23(11).
40. Xu Z, Yu M, Chen F, et al. Surgical Tool Detection in Open Surgery Based on Faster R-CNN, YOLO v5 and YOLOv8. 2024 IEEE 7th Advanced Information Technology, Electronic and Automation Control Conference (IAEAC)2024. p. 1830-4.
41. Deol ES, Henning G, Basourakos S, et al. Artificial intelligence model for automated surgical instrument detection and counting: an experimental proof-of-concept study. Patient Saf Surg. 2024;18(1):24.
42. van Staalduinen JH. European Product Liability for AI-based Clinical Decision Support Systems. In: Prifti K, Demir E, Krämer J, Heine K, Stamhuis E, editors. Digital Governance: Confronting the Challenges Posed by Artificial Intelligence. The Hague: T.M.C. Asser Press; 2024. p. 15-40.
43. Proposal for an AI Liability Directive. European Commission; 2022. Contract No.: Document 52022PC0496. https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52022PC0496. (Accessed on 23 June 2025).
44. Duffourc MN. The Withdrawal of the AI Liability Directive: A Critical Reflection on AI Liability in the EU: Maastricht University. 2025. [cited 11 June 2025]. Available from: https://www.maastrichtuniversity.nl/blog/2025/02/withdrawal-ai-liability-directive-critical-reflection-ai-liability-eu.

6

Chapter 6: Discussion and Conclusions

6.1 The counting process

To implement laboursaving technology in a surgical context, understanding surgical processes is key. Around twenty years ago, instrument counting was not yet standard practice in many hospitals [1]. To formalise this practice and reduce the risk of adverse events for patients, counting protocols were widely adopted and expanded upon (Chapter 4). However, currently, variations in counting practice persist, both in our observations (Chapter 2) and in the literature [2]. While exact reasons for this remain unclear, this phenomenon could relate to what Goras et al. describe as 'resilience' [3]: OR staff are often time- and resource-constrained, and thus have to adjust their workflow to account for the requirements of specific procedures or unexpected events. This time-constraint is reflected in our finding that OR nurses would use supportive technology in the counting process, specifically during the preparation phase and wound closure phase of surgery (Chapter 2 and 3). This suggests that, while time-constrained, OR nurses prefer to manually count their instruments during surgery itself. Our interviews suggest that keeping an overview of the surgical situation is a major driver for this preference.

Ironically, automated instrument use detection in this phase of surgery would provide the greatest efficiency gains on a wider workflow level. Knowing which instruments are used when allows for advancements in surgical phase modelling and thus automated OR planning, automated instrument tray optimisation, as well as preventative maintenance of regularly used tools. The goal, then, is to develop a system that can positively impact both pathways: alleviating OR nurses' workload during the preparation and wound closure phases of surgery, as well as detecting instrument use during surgery without disrupting OR nurses' preferred workflows.

6.2 The technology

While we have investigated some technologies more closely in this work, more have been tested in the literature to aid in surgical instrument counting. The primary challenge in implementing laboursaving technology that is scalable, lies in balancing standardisation with adaptability to the surgical context. Guédon et al. suggest that technology should provide 'adaptive support', where it is as standardised as possible while allowing flexibility for context-specific variations [4]. Technologies that have been investigated for use in surgical instrument detection and recognition often fail to strike this balance.

For instance, data matrices, such as barcodes and QR codes have been trialled in surgical instrument management [5-7]. While highly standardised across a wide

variety of industries, practical issues arise in a surgical context, where instruments get soiled, sharpened, or repaired, reducing legibility of the matrices. An upfront cost is involved in applying the matrices to each instrument in a hospital's inventory. More importantly, the technology requires instruments to be individually scanned, making them poorly suited to a time-pressured surgical environment.

Radiofrequency identification (RFID) technology solves many of these issues, as a receiver antenna can detect multiple RFID tags at the same time [8-10]. Upfront instrument modification is more involved, as sensors need to be adequately affixed to a large variety of instruments, but issues such as soiling or instrument maintenance are mitigated. However, signal interference remains a challenge when using RFID for intraoperative instrument use registration [11, 12]. Some hospitals have adopted a workflow wherein each instrument is individually scanned [13]. However, this workflow poorly adapts to surgical reality. Alternatively, an enclosed 'detection box' could be considered: an instrument tray containing individually tagged instruments are placed in the box, so that interference from outside sources is eliminated [14]. While an effective intervention for determining whether all instruments have been returned to their tray, this method does not allow for automated intraoperative instrument use detection. Finally, the costs of attaching and securing these sensors to a hospital's entire instrument inventory, as well as maintaining the RFID infrastructure are not yet clear [15].

Weighing scales similarly balance standardisation and adaptability. The straightforward technology allowed for widespread adoption around twenty years ago, with workflows being adjusted to accommodate the system. However, the power of its adaptability (and thus its long-term sustainability) lies in maintaining an up-to-date database of reference trays, which hospital organisations often overlook (Part 1 of Chapter 3).

Moving further away from standardisation towards adaptability, computer vision using artificial intelligence (AI) is currently a hot topic in the instrument detection and recognition literature [16-20]. Using one or more cameras, these algorithms can detect and recognise the shape and size of surgical instruments without the need for modification. In theory, cameras could be placed over the instrumenting table, allowing for sufficiently accurate real-time intraoperative instrument use registration without interference of regular workflows [21]. However, maintaining this accuracy over time, as instruments are sharpened, repaired, or replaced, requires continuous updating and retraining of the recognition algorithm; a major challenge we also currently see with weighing systems. Wide implementation is labour-intensive, as each hospital requires its own algorithm training. While the technology could significantly contribute to achieving accurate surgical phase modelling, current algorithms are not yet able to distinguish large sets of

instruments [18]. Given the rapid advancements of artificial intelligence in recent years, however, this probably will not take long. The focus of achieving long-term sustainable use should be, as with other technologies, to maintain the infrastructure surrounding the system.

6.3 The user and hospital organisation

The technologies and processes that we investigated cover multiple hospital departments and user groups, as instrument counting is not only important in the OR, but also in the sterile processing department (SPD). In a similar fashion, tracking of OR equipment such as infusion pumps and laparoscopy towers is of importance for both the OR staff and the technicians of the medical instrumentation (MI) department, among others. The different needs and preferences of - and interactions between these user groups can affect the success of the implementation and sustained use of technological innovations.

McKnight et al. investigated the components and measures of trust in a specific technology [22]. In this paper, he makes a distinction between trust in people (i.e., other users), and trust in the technology itself. As the weighing system is a flawed solution for instrument counting, a critical interpretation of its output is warranted. However, we noticed that in low-fidelity hospitals, where instruments are weighed but are still manually counted as well, trust in other users of the system was limited as well (Part 1 of Chapter 3). Participants remarked that they would be able to trust the system more if users in the other department would follow the weighing protocol more accurately. As healthcare organisations are complex, the workflows targeted by laboursaving innovations will likely cover multiple departments, and as such interpersonal or interdepartmental trust is an important prerequisite for successful implementation and sustained use of these innovations.

An interesting observation that potentially warrants further investigation, is that while systems such as the weighing scales and DORA were implemented in practice and embedded in surgical protocols, it could be argued that their use is not *normalised*. In implementation science, the Normalisation Process Theory (NPT) describes four components that are necessary for an innovation, or process, to be normalised into practice (see Figure 6.1). When we put these components next to our findings, it seems that cognitive participation is limited, given the absence of interdepartmental coordination. This in turn diminishes collective action to improve the system and reflective monitoring of these improvements. While not normalised today, it is likely that these innovations were normalised during and shortly after implementation, given the facilitation efforts at the time. Further research could

deepen our understanding of the normalisation process and sustaining continued improvements of technological innovations.

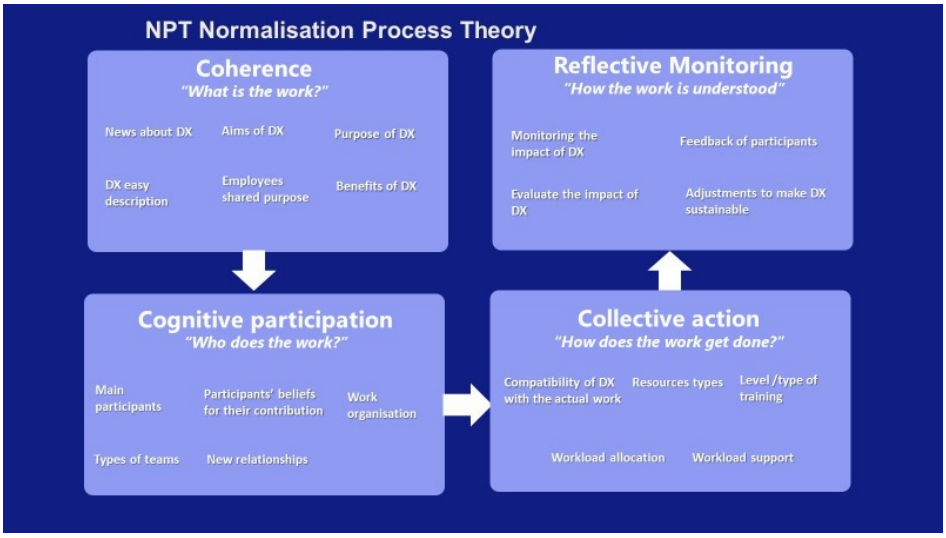

Figure 6.1 *The four domains associated with the Normalisation Process Theory (NPT). Image source: https://www.cmce.org.uk/article/normalising-digital-transformation*

6.4 Policy

In the previous section we discussed how user needs, preferences, and organisational challenges influence the implementation of laboursaving technologies. In this section, we discuss the potential effects of wider policy and law on it. As stated earlier, surgical instrument counting protocols have become widely adopted and expanded upon over the years (Chapter 4). However, as we have found, in two-thirds of Dutch hospitals, the responsibility for counting surgical instruments is shared among multiple professionals (e.g., the instrumenting nurse, circulating nurse, and the surgeon). In the 2006 report 'Uitgeteld?', Meijsen et al. already warn of the potentially confusing effect of these local policy variations. While it is unclear whether any negative consequences have arisen from them in practice so far, in the interest of facilitating widespread adoption of laboursaving innovations, harmonising these policy variations is recommended.

A potential reason these variations exist, we hypothesise, is due to the varying outcomes of RSI cases in either disciplinary law or civil law (Chapter 5), with the responsibility lying with the OR nurse, but the liability placed with the surgeon and the hospital itself. Another possible explanation that some of our results in Chapter 4 have alluded to is team culture, where, in some hospital organisations, it has been necessary to include all OR team members as being responsible for the instrument count.

Considering how instrument counting occurs outside of the sterile field and thus outside of the surgeon's field of attention, it would be unwise to assign responsibility to them for this process. As we have also seen in the use of DORA (Part 2 of Chapter 3), when a technology is not within the surgeon's field of attention, cognitive participation is low. Introducing automated instrument counting technology would lead to similar situations. Therefore, responsibility for the performance of the instrument count should be clearly assigned to the person(s) performing the count themselves. In addition, the protocol should clarify that the surgical team as a whole must be held responsible for creating an environment in which a thorough instrument count can be performed.

Even so, challenges relating to the implementation of technology in this context remain. At the time of writing, the official stance of the OR nurses' professional society (LVO, Landelijke Vereniging van Operatieassistenten) on the use of technology during instrument counting rules out a complete automation of the count: technology should be used as an aid in conjunction with, but not replacing, manual counting [23]. While this perspective reflects professional expertise and a commitment to patient safety, a growing labour shortage combined with a rapid development of new technological innovations raises questions on how best to reconcile automated and manual approaches. A constructive dialogue on their respective strengths and limitations would be valuable in furthering this cause. Often, expectations for the accuracy of technology are very high, whereas manual counting is considered the standard practice even though discrepancies still occur [24-26]. However, such discussions are complicated as data on the accuracy of manual counting practices is limited.

Another complicating factor in this discussion is the legal position of the laboursaving technology and its user. It is highly likely that artificial intelligence (AI) will be involved in such innovations. While a physical tool can be easily distinguished as a medical device, the same cannot be said for an AI algorithm. Determining whether an adverse event was caused by human error or a device malfunction will be increasingly difficult. In order to safeguard a robust pathway for patients to seek compensation for damages following an adverse event, national and international lawmakers need to provide clarity on the liability surrounding use of medical AI, which is a challenge in itself [27, 28].

6.5 Conclusions

Implementing laboursaving technology in a surgical setting can be challenging. Variations in surgical practice, on an individual, situational, and organisational level, require thorough investigation into the feasibility of automating certain tasks.

Furthermore, cognitive participation of the intended users is not only required during the development and implementation phases, but especially in long-term use to ensure the innovation remains normalised in practice. Finally, the emergent use of artificial intelligence in laboursaving innovations demand clarity from legislators on the assumption of liability when using such devices in a medical setting.

REFERENCES

1. Meijsen P, Meers E. Uitgeteld? ; 2006. https://sterilisatievereniging.nl/wp-content/uploads/2015/08/2006-Onderzoek-naar-compleetheidscontroles-van-instrumenten.pdf. (Accessed on 11-08-2023).
2. Weprin S, Crocerossa F, Meyer D, et al. Risk factors and preventive strategies for unintentionally retained surgical sharps: a systematic review. Patient Saf Surg. 2021;15(1):24.
3. Goras C, Nilsson U, Ekstedt M, et al. Managing complexity in the operating room: a group interview study. BMC Health Serv Res. 2020;20(1):440.
4. Guédon ACP, Spruit SL, Wauben LSGL, et al. Delicate balance: adaptive support to improve patient safety. BMJ Innovations. 2017;3(1):1-6.
5. Greenberg CC, Diaz-Flores R, Lipsitz SR, et al. Bar-coding surgical sponges to improve safety: a randomized controlled trial. Ann Surg. 2008;247(4):612-6.
6. Kranzfelder M, Schneider A, Blahusch G, et al. Feasibility of opto-electronic surgical instrument identification. Minim Invasive Ther Allied Technol. 2009;18(5):253-8.
7. Cima RR, Kollengode A, Clark J, et al. Using a data-matrix-coded sponge counting system across a surgical practice: impact after 18 months. Jt Comm J Qual Patient Saf. 2011;37(2):51-8.
8. Meissner C, Neumuth T. RFID-based surgical instrument detection using Hidden Markov models. Biomedizinische Technik Biomedical engineering. 2012;57.
9. Neumuth T, Meissner C. Online recognition of surgical instruments by information fusion. Int J Comput Assist Radiol Surg. 2012;7(2):297-304.
10. Hanada E OA, Hayashi M, Sawa T. Improving efficiency through analysis of data obtained from an RFID tag system for surgical instruments. IEEE 5th International Conference on Consumer Electronics; Berlin, Germany2015. p. 84-7.
11. Meeuwsen FC. Safe Surgical Signatures. TU Delft Repository: TU Delft; 2019.
12. Dinis H ZM, Mendes PM. Performance assessment of an RFID system for automatic surgical sponge detection in a surgery room. Annu Int Conf IEEE Eng Med Biol Soc2015. p. 3149-52.
13. Sawa TK, H. Shimane university hospital implements RFID technology to manage surgical instruments. 7th International Symposium on Medical Information and Communication Technology (ISMICT); Tokyo, Japan2013. p. 90-2.

14. RFID technology for hospitals KLS Martin2025 [Available from: https://www.klsmartin.com/mediathek/91-350-16-02_marManagement-RFID.pdf.
15. Moatari-Kazerouni A, Bendavid Y. Improving logistics processes of surgical instruments: case of RFID technology. Business Process Management Journal. 2017;23(2):448-66.
16. Ran B, Huang B, Liang S, et al. Surgical Instrument Detection Algorithm Based on Improved YOLOv7x. Sensors (Basel). 2023;23(11).
17. Xu Z, Yu M, Chen F, et al. Surgical Tool Detection in Open Surgery Based on Faster R-CNN, YOLO v5 and YOLOv8. 2024 IEEE 7th Advanced Information Technology, Electronic and Automation Control Conference (IAEAC)2024. p. 1830-4.
18. Yu J, Pan S, Lin Y, et al., editors. Performance Evaluation of Surgical Instrument Recognition Based on a series of YOLO Models. 2024 9th International Conference on Image, Vision and Computing (ICIVC); 2024 15-17 July 2024.
19. Zhang Y, Kim M, Jin S. Real-time Detection and Tracking of Surgical Instrument Based on YOLOv5 and DeepSORT*. 2023 32nd IEEE International Conference on Robot and Human Interactive Communication (RO-MAN)2023. p. 1758-63.
20. Zhou Y, Liu Z. Detection of Surgical Instruments Based on YOLOv5. 2022 IEEE International Conference on Manipulation, Manufacturing and Measurement on the Nanoscale (3M-NANO)2022. p. 470-3.
21. Glaser B, Danzer S, Neumuth T. Intra-operative surgical instrument usage detection on a multi-sensor table. Int J Comput Assist Radiol Surg. 2015;10(3):351-62.
22. Harrison McKnight D, Carter M, Thatcher JB, et al. Trust in a specific technology: An Investigation of its Components and Measures. ACM Transactions on Management Information Systems. 2011;2(2):12-32.
23. Landelijke Vereniging van Operatieassistenten. Richtlijn Onbedoeld achterblijven operatiemateriaal. 2009. https://sterilisatievereniging.nl/wp-content/uploads/2015/08/2009-Richtlijn-LVO-definitief_print.pdf. (Accessed on 24-09-2023).
24. Cochran K. Guidelines in Practice: Prevention of Unintentionally Retained Surgical Items. AORN J. 2022;116(5):427-40.
25. Greenberg CC, Regenbogen SE, Lipsitz SR, et al. The frequency and significance of discrepancies in the surgical count. Ann Surg. 2008;248(2):337-41.
26. Norton EK, Martin C, Micheli AJ. Patients count on it: an initiative to reduce incorrect counts and prevent retained surgical items. AORN J. 2012;95(1):109-21.
27. Commission E. Proposal for an AI Liability Directive. 2022.
28. Duffourc MN. Maastricht University. 2025. [11 June 2025]. Available from: https://www.maastrichtuniversity.nl/blog/2025/02/withdrawal-ai-liability-directive-critical-reflection-ai-liability-eu.

Appendix A

Data collection form used in Chapter 2

General	
Type of procedure: Name according to planning sheet RdGG:	ENT / Urology / Plastics / Robot/ Vascular / Gynecology / Surgery
Elective/emergency:	Elective / Emergency
Instrument set complete according to Combister:	Blue wrapping / Green wrapping
Missing/defect sheet filled in by operation assistant:	Yes / No
Start & End incision time	Start: End: Duration:
Years of experience operation assistant: In Reinier de Graaf:	
Staff turnover during procedure?	

Instruments	
Counting performed in prep room with 2nd nurse:	Yes / No
Number of instrument sets according to HIX:	
Addition of instrument sets during procedure?	
Time spent on returning instruments in correct net:	
Instruments returned in correct set without aid of Combister list	Yes / No

Counting of needles				
Needles counted in prep room (P) / OR Initial (I) / addition (A) / removal (R) / closing (C) count Number of needles counted:	1	2	3	4
Time spent on counting (sec)?	1	2	3	4
Counted without distraction/interruption? Yes / no – reason *Additional remarks:*	1			
	2			
	3			
	4			

Counting of gauzes								
Blood loss measured by weighing gauzes?	Yes / no							
Number of gauzes counted? Location: Prep room (P) / OR Initial (I) / addition (A) / removal (R) / closing (C)	1.	2.	3.	4.	5.	6.	7.	8.

Time spent on counting (sec)?	1.	2.	3.	4.	5.	6.	7.	8.
Counted without distraction/interruption? Yes/no – reason *Additional remarks:*	1.							
	2.							
	3.							
	4.							
	5.							

Appendix B

Results of survey questions from Chapter 2

Survey questions (n)		Frequency (%)
Do you count the entire surgical tray before surgery? (18)		
	Yes	11 (61%)
	No	7 (39%)
Do you experience an increased workload while counting? If yes, which materials? (20)		
	Surgical instruments	12 (60%)
	Gauzes	2 (10%)
	Needles	-
	No increased workload	6 (30%)
What is the cause of the increased workload? (13)		
	Number of surgical trays	8 (62%)
	No time-out/sign-out	2 (15%)
	Emergency procedures	3 (23%)
Can the current counting process be reconfigured to be more efficient? If yes, during which operative phase? (20)		
	Preoperative phase	7 (35%)
	Intraoperative phase	2 (10%)
	Postoperative phase	8 (40%)
	No potential	3 (15%)
Would you be open to the use of adjunct technology during the counting process? (15)		
	Yes	15 (100%)
	No	-
During which operative phase would you be willing to use technology? (13)		
	Preoperative phase	9 (69%)
	Intraoperative phase	-
	Postoperative phase	4 (31%)
For which surgical material would you be willing to use technology? (15)		
	Surgical instruments	11 (73%)
	Gauzes	4 (27%)
	Needles	-
What should the requirements for technology be according to your perspective? (12)		
	Speed	8 (67%)
	User friendliness	3 (25%)
	Cost	1 (8%)

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	…


CHAPTER 1: INTRODUCTION, CHAPTER 2: CURRENT PRACTICES IN SURGICAL INSTRUMENT COUNTING, CHAPTER 3: LEARNING FROM LABOURSAVING TECHNOLOGY ALREADY IN USE, CHAPTER 4: DEVELOPMENT OF STANDARDS OF PRACTICE IN SURGICAL INSTRUMENT COUNTING, CHAPTER 5: LEGAL CONSIDERATIONS OF LABOURSAVING TECHNOLOGY IN SURGERY, CHAPTER 6: DISCUSSION AND CONCLUSIONS
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TU Delft