Introducing technological innovations in Operating Rooms in hospitals

INTRODUCING TECHNOLOGICAL INNOVATIONS IN OPERATING ROOMS IN HOSPITALS

An implementation framework for technological devices

Navin Sewberath Misser

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The work presented in this thesis was funded by the HU University of Applied Sciences Utrecht.
This research was supported by the University Medical Center Utrecht.

ISBN: 978-94-6458-756-2
Lay-out: Publiss | www.publiss.nl
Printed by: Ridderprint | www.ridderprint.nl

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PROEFSCHRIFT

ter verkrijging van de graad van doctor
aan de Open Universiteit
op gezag van de rector magnificus
prof. dr. Th.J. Bastiaens
ten overstaan van een door het
College voor promoties ingestelde commissie
in het openbaar te verdedigen

op vrijdag 27 januari 2023 te Heerlen
om 13.30 uur precies

door
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geboren op 20 juli 1976 te Paramaribo, Suriname

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Onze hulp is in de naam des Heren, die hemel en aarde gemaakt heeft.
Our help is in the name of the Lord, the Maker of heaven and earth.

Psalm 124: 8

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Preface

In the past decades, use of advancing information systems and technological equipment to enhance and to support various activities in health care organizations increased. My interest in implementations of new equipment started during my studies, when I encountered the challenges to introduce new information systems in practice. One of the first learnings was that the introduction of new systems always influenced existing activities or processes, existing technology, and employees in organizations. During my specialization in change management, as a part of the Business Administration programme at the Rotterdam School of Management and in my professional career, I encountered and experienced the complexity of introducing new information systems in practice.

With support of my employer HU University of Applied Sciences, the University Medical Center in Utrecht, and the Open University, I had the opportunity to conduct research on implementations of technological innovations in hospitals. These technological innovations included devices that supported health care activities, such as medical and non-medical devices and information systems. In this thesis, I constructed and presented an implementation framework for technological devices in the operating room department of hospitals.

This research would not have been possible without the support and coaching of my supervisors prof. dr. ir. Johan Versendaal, em. prof. dr. Hein Gooszen, dr. ir. Joris Jaspers, and dr. Bas van Zaane.

A special word of thanks to em. prof. dr. Hein Gooszen. We met in 2014, when you performed scientific research on operative processes. You endorsed my research proposal and took the challenge to supervise, together with prof. Johan Versendaal. I am thankful that you were part of this team and thank you for your coaching and supervision, even after your retirement.

Maya, my friends, my colleagues, and family members supported me daily and I am very grateful for all their ongoing support. More words of appreciation can be read in the chapter ‘Dankwoord’ (‘Acknowledgments’).

Navin Sewberath Misser

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GENERAL INTRODUCTION AND OUTLINE

Medical technology to support health care has made great progress in the past decades and numerous technological advancements have been introduced in clinical care in a broad sense. However, fifty percent to ninety percent of prototypes of new devices and innovations do not succeed to complete a development process and are not introduced into market (Cooper et al., 2004; Heidenreich & Spieth, 2013; Wang et al., 2020). Moreover, medical technology development is expensive, and safety and efficacy are key issues, to be addressed prior to introductions in hospitals. Once safety has been proven, the next step is the introduction of new devices into practice. This introduction is a complex task for a variety of reasons such as complexity of, and interdependency in hospital activities, the number of involved stakeholders and hospital departments.

In this thesis, focus is on the introduction or implementation of new technological devices in health care environments. More specifically, focus will be on devices in the operating room department of hospitals (OR). Operating rooms are dynamic working environments, where specialized staff conduct operations or surgeries supported by advanced and highly reliable technological devices. Examples of these devices are anesthesia devices, surgical table, surgical lighting, diathermy apparatus, and information systems. Depending on the type of surgery, specialized equipment may be needed such as camera units, x-ray equipment, DaVinci robot, or artificial blood pumps. The OR-department is also a learning environment where doctors, nurses and other employees are trained to support and conduct surgery, anesthesiology, and to fulfill other job roles. This learning environment is crucial for a safe and effective working environment.

To contribute to safety in this part of the hospital, the OR-department is a restricted hospital area. Yet, there are interactions with other hospital departments such as the hospital pharmacy, sterilization department, laboratory department, wards and outpatient department, intensive and medium care unit, and technical department. In this dynamic working environment, specialized staff uses technological devices to prepare surgeries, and for logistical activities to provide patient care with surgical procedures.

The next two pictures visualize OR's before use and in use.

Picture 1: Empty OR

Picture 2: OR in use

Picture 1 shows an empty OR with standard equipment available for use. Additional resources such as equipment and devices are stored elsewhere in the OR-department. Picture 2 shows an OR in use, with tools, equipment and staff involved. Pictures 1 and 2 show the complexity of the OR with a wide variety of technological equipment in active use, staff, and different activities prior during and after surgical procedures. Operations or surgeries involve complex activities, performed by well trained and experienced staff working together as a collaborative team. Introducing new devices in this complex environment require structured implementation activities and planning.

Apart from the operative procedure as such, there are other procedures and supporting activities (Girotto et al., 2010; Ministry for Healthcare and Sport, 2010). Main activities that take place are activities related to surgical preparations, activities related to the actual surgery or operation, and administrative activities. Preparations for surgery include activities, such as preparing instruments, patient preparation, and preparing devices for use during surgery. Administrative activities involve surgical planning, scheduling of devices, safety procedures and completing surgical notes and logistical notes.

All these activities, in and around the OR, are performed by a collaborating group of employees (Kang et al., 2015):

- A medical specialist, a surgeon, who performs the operation. This surgeon is responsible for the surgical procedure to be conducted.
- The anesthesiologist is responsible for the anesthesia. He/she is responsible for the non-surgical care from the moment that the patient arrives in OR, until 24 hours after the surgical procedure. Other activities include administering anesthesia medicines mainly for cardiorespiratory support and pain medication.
- The anesthesia nurse supports the anesthesiologist during surgery, including non-surgical care. Activities include monitoring inventory of medicines, and other materials for anesthesia care, monitoring vital functions of the patient during surgery.

- Scrub nurses perform various activities within the whole surgery process, from preoperative to post-operative activities. Prior to the surgical procedure he/she prepares tools or instruments for use during surgery. During the operation scrub nurses assist the surgeon with instrument handling and in certain cases they are allowed to perform surgical activities such as suturing. Other activities include monitoring sterility of the surgical area as well as monitoring tools and sponges used during surgery.
- Circulation nurse (non-sterile). The circulating nurse is available for assistance during surgery by preparing material or instruments, necessary prior and during the procedure. They (scrub nurse and circulating nurse) are responsible for the availability of equipment needed for the surgical procedure. The circulating nurse assists by unpacking sterile instruments and assists preparing instrument trays. Other activities include monitoring sterility of the surgical area as well as monitoring the tools and sponges used during surgery. Furthermore, the circulating nurse is able to operate technological equipment according to protocols and this nurse responds to requests from the surgeon such as adjusting settings of diathermy devices. After the surgery, these assistants clear all instruments to prepare the operating room for further cleaning and following scheduled surgery.
- Other qualified medical or technical professionals can assist surgeons. Based on their role and discipline, they are allowed to perform predefined surgery related technical activities. These (technical) professionals are trained to operate devices such as a perfusionist who operates a heart-lung machine, i.e., an artificial blood pump used during cardiac surgery.
- Other supporting staff and departments. Other supporting staff can be responsible for logistics of materials, (medical) supplies, cleaning, sterilization of instruments. Staff scheduling activities are also executed by OR scheduling staff.

1.1 Practical motivation: towards implementation of devices in OR's.

Devices used in OR's need to comply with quality standards. Development of devices directly related to patients' care need to comply with the European rules and regulations, more specifically the Medical Devices Regulation (MDR) (European Parliament & Council of the European Union, 2017). Once they have passed these testing procedures, technological devices are ready to be introduced into clinical practice.

Hospitals in the Netherlands have agreed to define policies to acquire, implement, use, and to dispose medical equipment, devices and medical information systems for safe use, according to the covenant medical technology (Dutch Hospital Association, 2016). These policies are applicable for those devices and for equipment that play a role in patient treatment and influence outcome (i.e., medical devices). Apart from

these devices and equipment, there are other logistic and ergonomic devices to support activities in the OR. Information systems support scheduling and inventory planning activities (i.e., non-medical devices including software). Examples of supporting (ergonomic) devices are sensors to record door movements in OR's, camera stabilizing devices, electronically powered transportation devices to move heavy equipment such as endoscopy devices or C-arms for x-rays. It is reported that the introduction of new technological devices is notoriously complex (Hummel & Jaspers, 2018; Katen, 2017). At the same time, attention and focus on implementation practice of technological devices in complex hospital environments is limited. A series of studies is conducted to analyze, clarify and simplify new technological innovations in the OR-department.

Implementing new technological equipment

The studies presented in this thesis have been conducted in and around the OR and all studies illustrate the complexity of the OR. The OR is one of many departments in a hospital with interactions with a lot of other departments. The organization is also complex in a practical, logistical sense. Moreover, safety, quality and efficacy are key issues, more than in any other department (Kang et al., 2015; Roberts, 1990). Considering this web of stakeholders and complex technology to be applied in a safe and effective manner, implementation of new technological equipment is a complex process with varying success, despite the hospital policies resulting from the covenant medical technology. Many resources are involved in developing new technological equipment or tools to innovate surgical activities, to improve patient treatment or to improve supportive activities to the surgical procedures (Omachonu & Einspruch, 2010). These tools can vary from supportive information systems to the most complex, innovative, and expensive equipment. At the start of our research, we observed surgeries in which a new camera stabilizing device called Mofixx was introduced. Observations show that the use of this new device in practice varied per team, leading to varying set up times and varying satisfaction results from users. As this device was a supporting device and was not considered to be a medical device, some of the policies imposed by the covenant medical technology were exempted. Consequently, different implementation routes can be followed to introduce this or similar devices, depending on the local hospital context and procedures. These implementation routes can for instance vary between academic and non-academic hospitals. Implementation activities can vary from ad-hoc activities to systematically planned activities across various departments within the hospital. Various implementation routes and varying implementation activities for the introduction of medical and non-medical devices may result in different implementation success and outcomes. To my knowledge, a systemic implementation and broadly applicable framework with unified implementation activities for (non-) medical technological devices in OR's has not been developed.

1.2 Theoretical perspective for implementing new devices in OR's

Implementation activities of devices in a complex OR-environment, is characterized by many factors, e.g., varying user satisfaction, and varying implementation lead times. The complexity of the OR is among others related to communication and interaction between specialized staff, use of technological equipment and interdependencies with other hospital departments. To unravel the complexity of implementations, I purposively examined existing implementation experiences and models for technology based on the process of theoretical sampling (Bryman & Bell, 2007). A search on implementation theories, models, or related frameworks within the field of health care and technology was conducted.

Davis (1989) introduced the Technology Acceptance Model to assess the perception of new technology by users, with a focus on perceived usefulness, perceived ease of use, behavioral intention and use of new technology (Davis, 1989; Venkatesh, 2015). This model is used to measure the adoption of new devices by users during the development process or after implementation has been completed. Orlikowski (1992) introduced a structurational model for technology focusing on technology design as a product of human activities based on the institutional environment of employees of an organization (Orlikowski, 1992). This model indicates that the need for technology is identified by humans, and that they are involved in the development of innovative technology. The introduction of technology influences daily activities of employees as they are targeted employees to use new technology. Based on their experience they can provide input to modify the technology used or to shape the organizational context as the organizational setting is modified by using the new technology. With this model, the complexity of an OR, for introduction of new devices and technology in an existing organizational context and in existing work activities, can indeed be illustrated. Edmondson (2001) provides a definition for implementation from an organizational perspective. According to this definition, implementation of new technology can be qualified as successful when devices are integrated into day-to-day activities (Edmondson et al., 2001). In literature, many cases are reported focusing on the introduction of new technology or information systems. Meyers (2012) for example focuses on quality implementation and introduces a quality implementation framework, consisting of four main phases and related steps. They include considerations regarding the host setting prior to implementation, creating an implementation structure, defining an ongoing structure for technical assistance and feedback during implementation, and to improve future applications. With these considerations, he developed a meta model for quality implementation with the purpose to address and expand an interactive systems framework for dissemination and implementation (Meyers et al., 2012; Wandersman et al., 2008). Damschroder (2009) developed a Consolidation Framework for Implementation Research (CFIR), which provides insights in possible interventions to consider during implementations

of research. These insights were categorized according to constructs such as patient needs and organizational characteristics, culture, and implementation climate (Damschroder et al., 2009). Nilsen (2015) provided an overview of the implementation area, by highlighting process models, determinant frameworks, classic theories, implementation theories, and evaluation frameworks. In this overview, insights are combined from implementations of research, implementations of evidence and guidelines, interventions, and innovations. Moullin et al. (2013) introduces a generic implementation framework (GIF), with focus on implementation strategy, implementation factors and implementation evaluation.

A dedicated framework for the implementation of *technological* devices in health care environments, particularly for OR's, has not been developed while the applicability of the mentioned (more generic) models and meta frameworks above in these complex environments remains unclear. Moreover, the number of research studies focusing on implementation activities of technological devices in OR's seems limited. Yet, the mentioned models may well provide insights to derive determinants and activities for a framework for technological devices in an OR-environment.

1.3 Research question

With these theoretical and practical insights, the question on how to implement technological devices successfully in complex OR environments, remains unanswered. In terms of Nilsen (2015) we identify a need to develop a *determinant framework* for implementation of technological devices in OR's to facilitate implementation. In the thesis' subsequent chapters, 'a process for implementation or a protocol for implementation' is used to describe this implementation framework, with the intention to practically and directly link this research to healthcare professionals in the research context. The implementation framework should provide determinants and guidelines for an approach of implementations, addressing the complexity of introducing new devices in a dynamic working environment. Therefore, the following main research question was formulated at the start of this research:

> What are the key factors and guidelines related to a successful implementation of technological innovations within operating rooms?

With this main research question the purpose of this research is identified: to construct a framework for implementation for devices in the OR. This research question and purpose lead to the following sub-questions that are addressed in this research:

1. Which relevant activities, key factors (determinants) can be identified for implementations of technological innovations within Operating Rooms?
2. How can these activities be categorized in a framework for implementation?
3. How can this framework for implementation be evaluated for use in practice?

1.4 Research design

Many hospital departments and stakeholders are involved in acquiring and introducing new medical devices to ensure patient safety and to facilitate a highly trained and specialized OR-team. The road towards successful implementation is complex and can be considered solving a wicked problem. Therefore, a multidisciplinary view on the OR is required to construct an implementation framework. Design sciences research implies research on an existing and identified problem in a complex environment, in this research the operating room department. Hevner (2004) developed a research framework that addresses identified practical problems, and focuses on justified and validated contributions to the existing theoretical knowledge base (Hevner et al., 2004). This design science research method was leveraged to operationalize our research question and the purpose of our research (Peffers et al., 2007). According to this method, three phases need to be considered: problem definition and defining objectives for the solution, constructing an artifact (framework), and evaluating the artefact.

The first phase of this research involves identifying a problem definition, by creating an overview of the research context and an overview of available literature. Research shows, that overarching process models for implementation of medical devices are not available and that the number of studies focusing on implementation activities of devices in OR's is limited (Nilsen, 2015; Schoville & Titler, 2015). This phase addresses sub question 1 described in the previous section.

The second phase of this research is focused on constructing an artefact, in this research: a framework for implementation. As stated earlier, in the subsequent chapters the terms 'protocol for implementation' or 'process for implementation' are used to describe the implementation framework. This implementation framework is based on the empirical findings of the previous study and identified implementation factors, activities, and implementation instructions. This phase addresses sub question 2 described in the previous section.

In the third phase of this research, this framework will be evaluated by preparing and conducting two studies. Based on the findings of these studies this framework is revised and opportunities for further research are identified. This phase addresses sub question 3 described in the previous section.

1.5 Research method and outline

The research sub-questions were operationalized by preparing and executing various studies. In each study five general steps are followed, varying from preparation to reporting. These steps are:

1. Setting up a study protocol
For each study we set up a study protocol. In this protocol, the research goal and the study type are described. The study protocol includes all relevant research instruments tailored to the study and research goal.

2. Preparing for execution
Each study has been prepared and executed according to the study protocol. The research instruments varied per study, for instance questionnaires, tools for recording, coding, and processing.

3. Data gathering
Data was gathered, according to procedures described in the study protocol regarding data gathering. For instance, literature search and/or recording focus group sessions and so on.

4. Data processing and analysis
Gathered data were processed in predefined databases as described in the study protocol, for instance use of SPSS, Microsoft Excel for Windows, Nvivo for windows, or Microsoft Word for Windows. Based on predefined steps in the study protocol we analyzed data.

5. Reporting
Analyzed data and research results are reported in articles. These articles were reviewed by the members of the research group and the articles were submitted to various publication outlets such as peer reviewed journals and peer reviewed conferences. Full papers submitted to conferences were peer reviewed and these articles have been included in conference proceedings. Published articles are included in this manuscript.

Several research instruments are used to address research questions and to execute the different studies. An overview of these research methods and tools is included in table 1:

Chapter	Paper/chapter title	Research method
2	Transforming operating rooms: factors for successful implementations of medical equipment	Survey Descriptive statistics
3	Implementing medical technological equipment in the OR: factors for successful implementations	Systematic literature review
4	A protocol for implementation of new technology in a highly complex environment: the operating room	Mixed method: survey and literature review
5	Evaluation of a protocol for digitization and devices in operating rooms	Focus groups
6	Evaluating an implementation protocol for digitization and devices in operating rooms: a case study	Case study Questionnaire

Table 1: research method and tools

In chapter 2, I report a purposively sampled literature review, and we continued with an explorative survey. We use questionnaires completed by scrub nurses and circulating nurses and we analyze the quantitative and qualitative results (Bryman & Bell, 2007; Stefanidis et al., 2014). The purpose of this study is to identify factors (determinants) for implementation as well as activities for implementation. We use SPSS for windows and Microsoft Excel for windows to analyze data and to provide descriptive data to identify factors and activities for implementation.

In chapter 3, a systematic literature review is reported. The purpose of this review is to identify factors (determinants) for implementation as well as activities (Kitchenham & Charters, 2007). Databases are selected and relevant articles will be included to derive factors (determinants) for implementation of technological equipment. The tool Mendeley is used to organize and review articles and used Nvivo for Windows will be used to code these articles.

In chapter 4, a protocol (framework) for implementation is reported. The findings of the previous studies are combined to construct a protocol (framework) for implementation. Implementation activities are identified as well as instructions for implementations.

In chapter 5 research results are reported of the first evaluation study. With focus group sessions this baseline framework for implementation was evaluated (Gill et al., 2008; Morgan, 1997; Morgan & Hoffman, 2010). These focus group sessions consist of multidisciplinary experts in introducing new devices in hospital practice. Based on these findings, revisions to the framework for implementation are suggested.

In chapter 6, a case study to evaluate our baseline protocol for implementation is reported (Maimbo & Pervan, 2005; Yin, 2018). Different data sources are used to describe this case and to evaluate this implementation protocol such as semi-structured interviews, questionnaires, and project documents (Gagnon et al., 2012; Heijden, 2004; Tantiponganant & Laksitamas, 2014; J. Wu & Wang, 2005). Based on these findings, revisions to the protocol for implementation are proposed.

In chapter 7, a summary of previous studies is included, and the findings of this research are discussed. A revised framework for implementation is included in this chapter. We propose implications for practice and future research prospects.

In the latter chapters a Dutch summary of my research is added, as well as acknowledgements. The final revised protocol for implementation based on this research is included in the appendices.


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TRANSFORMING OPERATING ROOMS: FACTORS FOR SUCCESSFUL IMPLEMENTATIONS OF NEW MEDICAL EQUIPMENT

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Bled 2018 Proceedings. 24.
https://doi.org/10.18690/978-961-286-170-4.18

Abstract

Operating Rooms (OR's) are complex, high-tech environments with extensive use of medical equipment and information technology. The implementation of new medical equipment with the aim to increase safety, improve patient outcomes or to improve efficiency may initially cause disruptions in the OR, which influence its success. Between and within hospitals the implementation of medical equipment varies, and a generic implementation model omits.

The aim of this study is to identify factors for successful implementations according to supportive surgical staff. Results are compared with findings from other published studies.

In total 90 out of 235 surveys were returned (38%). Respondents, scrub nurses and circulating nurses, indicate that implementation and integration of new medical equipment in current activities and ICT systems remain a challenge. In this study we identified the following factors: a coherent and holistic implementation approach; effective integration of medical equipment in processes, systems and organization; knowledge and skill development and experience.

This work was originally published as: Sewberath Misser, N., Jaspers, J., van Zaane, B., Gooszen, H., & Versendaal, J. (2018). Transforming operating rooms: factors for successful implementations of new medical equipment. Digital Transformation – Meeting the Challenges, 279–289. https://doi.org/10.18690/978-961-286-170-4.18

2.1 Introduction

Operating Rooms (OR's) are one of the most complex, high tech and high reliability environments to implement radical transformations. In OR´s surgeries are performed by surgeons, supported by anesthetic (supportive) staff and surgical supporting staff (scrub and circulating nurses) (Frasier et al., 2017; Kang et al., 2015; Sheikhzadeh et al., 2009). To enable these surgeries additional stakeholders are involved, such as the sterilization department, logistical employees and in some instances operators, or manufacturers of medical equipment. The implementation of new medical equipment or new information technology requires a systemic approach, since many stakeholders and resources in the OR are affected and involved. The Dutch Hospital Association (NZA) agreed upon a set of rules regarding the implementation of new medical devices in hospitals: Covenant Medical Technology (CMT). This agreement provides policy guidelines throughout the life cycle of medical equipment to ensure patient safety: acquiring, implementing, using, and disposing medical devices (Dutch Hospital Association, 2016). In the CMT medical devices are defined as devices that have direct impact on the patient and the outcome of the treatment. These devices entail technical devices varying from mechanical equipment to electronic, and information processing devices (i.e., hardware and software). For the purpose of this study medical devices and (medical) information technology (i.e., hardware and software) are referred to as medical equipment. Hospitals in the Netherlands have implemented the CMT and these hospitals defined and implemented local policies throughout the life cycle of medical devices. The Inspectorate of Health care regularly audits the associated local policies regarding this CMT. Implemented local policies related to the CMT result in a variety of ways to implement medical equipment, resulting in a variety of implementation activities, implementation outcomes, and unexpected implementation lead times. In our opinion generic implementation guidelines for medical equipment in OR's should be available to contribute to patient safety, as patient safety is one of the main pillars in hospitals to ensure safe surgical and treatment interventions. Therefore, the aim of our study is to search for factors of importance regarding the implementation of new medical equipment in the OR among various stakeholders. In this study we focus on surgical supporting staff, as stakeholders in the implementation process and as members of the surgical team (Stefanidis et al., 2014). When new medical equipment is introduced in the OR, surgical supporting staff should be able to complete their tasks related to this new equipment. Surgical supporting staff is involved in preparatory activities prior to surgeries such as logistics, assembly, setup, and disassembly of medical equipment, and ensures compliance to other protocols such as safety, hygiene and sterility.

For this explorative study the following research question is defined:
Which factors for successful implementation can be identified from a surgical supporting staff's perspective, when introducing new medical equipment in the OR? Medical equipment also includes information systems.

2.2 Methods

The purpose of this study is to explore relevant factors for implementations of new medical equipment according to surgical supporting staff. In addition, we performed a literature review to compare our findings. To this end we searched for papers in the database PubMed using the following words: implementation of medical equipment, information systems, equipment in OR's.

2.2.1 Study population

The data gathering process took place at an annual two-day congress for surgical supporting staff (scrub nurses and circulating nurses) in The Netherlands. Surgical supporting staff from various hospitals visited this congress and this survey was included in the information package which was handed out during registration.

2.3 Survey

As many attendees were expected to attend the congress, we used a questionnaire or survey to gather data. Based on available literature, the following variables were identified for our study (Dutch Hospital Association, 2016; Stefanidis et al., 2014):

1. Implementation: needed steps for an implementation process; aspects for successful implementation; best practises and possibilities for improvement.
2. Training and governance: needed elements of and responsibility for the training process.
3. Readiness: readiness assessments.
   Aside these themes we explored other factors regarding the implementation process of technology:
4. Other: use of an implementation protocol; use of the Covenant for Medical Technology (CMT).

A survey was set up by the first author (NSM) and this survey was reviewed by members in the research team. The final survey consisted of two sections with 28 open ended and closed questions in Dutch language (Bryman & Bell, 2007). The first section is used to gather data about the respondent, their role within the OR, their working environment (hospital) and their specialisms. In the second section respondents provide information regarding implementations in their working environment. In table 1 the relation between variables and questions is explained, as well as the type of response.

Variable	Question	Type of response
Implementation	Q14: Which steps are currently taken in the implementation process for new medical equipment?	Multiple responses
	Q16: Which aspects are important when implementing new medical equipment successfully?	Open ended question
	Q20a: Which aspects of the implementation process are currently going well?	Open ended question
	Q20b: Which aspects of the implementation process provide room for improvement?	Open ended question
	Q22: It is clear how new medical equipment are being implemented.	Likert scale (1-5)
Training and governance	Q15: Which elements should be part of training prior to the implementation of new medical equipment?	Multiple responses
	Q17: Who should be responsible for organizing and facilitating necessary training regarding the new medical equipment?	Multiple responses
	Q19: Who should assess if a scrub nurse is ready for using the new medical equipment?	Multiple responses
Readiness	Q18: How should the readiness for the use of the new medical equipment be assessed?	Multiple responses
Other	Q23: Currently an implementation protocol is in place for the implementation of new medical equipment	Likert scale (1-5)
	Q23 The covenant medical technology is currently in use in our hospital	Likert scale (1-5)

Table 1: Variables related to questions in survey

In the last part of the survey, respondents reflected on statements regarding implementation processes and activities in the respondents' working environment.

2.3.1 Data gathering and processing

Completed surveys were handed in by the respondents at the information desk of the congress. These surveys were processed in IBM SPSS Statistics version 23 and Microsoft Excel 2013. We mainly used descriptive statistics to analyze and evaluate the responses due to the explorative nature of this study. Responses to open ended questions were categorized traceably in Microsoft Excel.

2.4 Results

There were 235 surgical supporting staff visitors at the congress and surveys were handed out to these visitors. The number of completed surveys was 92 (response 39%). Two records were deleted (response=38%), since these records contained mainly missing values (n=90). The literature review resulted in 24 articles and relevant articles were used to analyze survey results.

2.4.1 Respondent information

Out of the 90 respondents, 8 were males and 84 females. Four of the respondents were scrub nurses in training, 18 had less than 5 years of experience and 58 had more than 5 years of experience. The respondents represented 43 Dutch hospitals; one respondent was a visitor from Luxembourg and two respondents worked in Belgium. The respondents had one or more medical specialties or focus areas, shown in table 2.

Focus area	Frequency	Percentage of total
All-round	27	19%
General surgery	20	14%
Orthopedics	18	12%
Ear Nose Throat	18	12%
Gynecology	11	8%
Plastic surgery	11	8%
Ophthalmology	10	7%
Vascular surgery	8	6%
Neurosurgery	7	5%
Traumatology	4	3%
Urology	4	3%
Bariatrics	3	2%
Cardiology	2	1%
Oral surgery	1	1%
Oncologic surgery	1	1%

Table 2: Focus areas of the respondents (Results)

Table 3 shows the frequency distribution of focus areas of respondents and the focus areas all-round, general surgery, orthopedics and ear, nose and throat (ENT) were mentioned often. The majority of the respondents (99%) stated that medical equipment was implemented up to two years prior to completing the survey. In table 2 the impact of implementations is presented.

Topic	Process changes n=89			ICT Changes n=86			Training n=86		
Response	Yes	No	Don't know	Yes	No	Don't know	Yes	No	Don't know
Percentage of responses	80%	16%	4%	62%	15%	13%	91%	9%	0%

Table 3: Impact of implementations (Results)

The respondents indicate that the implementation of medical equipment impacts the working activities (processes), resulting in alteration of processes and protocols (80%). In protocols for surgical supporting staff, instructions for work are described. In 62% of the cases medical equipment resulted in changes within information systems and 91% of the respondents indicated that they received training related to the implementation of medical equipment.

2.4.2 Implementation

Implementation of new medical equipment in OR's can be complex task, as many stakeholders are involved. Respondents provided an overview of undertaken activities to implement medical equipment, see table 3.

Undertaken Steps	Frequency N=90	Percentage
Introducing device	82	91%
Simulations	70	78%
Inform stakeholders	60	67%
Theoretical training	54	60%
Supervision by coworker	48	53%
Evaluating experiences	23	26%
Skills assessment	18	20%
Modifying Protocols	3	3%
Other	3	3%

Table 3: Needed steps in an implementation process (Results)

Respondents were able to choose which steps were taken when implementing medical equipment; they were able to add activities to the set of responses. Based on their experience, respondents recognized 5 relevant steps during implementation: introduction of the device, simulations, informing stakeholders, theoretical training and instructions, and supervisions by coworkers while practicing. Skills assessments, evaluation of experiences, and modification of working protocols were recognized less frequent as part of undertaken steps for implementation. Activities of importance during implementation were receiving information and instructions regarding the device, practicing with the device, and the need of clear procedures regarding the use of the device (question 16). Respondents defined the following activities that went well during implementation: practicing, with the device, collaboration with the manufacturer of the device and receiving assistance, information and instructions related to the use of the device. However, 35 respondents (38%) identified aspects needing improvement. These aspects were: introduction time, meaning that the implementation process was rushed and that more time was needed (n=9); a lack of

information regarding the device, limited instructions (n=9), and limited assessment regarding the use of the device (n=9). Based on the statement regarding the clarity of the implementation process, 15% of the respondents (fully) agreed and 38% indicated that more clarity in the implementation process is needed.

2.4.3 Training and governance

Training of users of new medical equipment is part of the implementation process, as training contributes to the safe use of medical equipment in the OR. Scrub nurses were able to select necessary features for training prior to the implementation of medical equipment. These features are shown in table 4.

Training feature	Frequency N=90	Percentage
Introduction to the device	83	92%
Simulate	77	86%
Knowledge sharing from an expert	76	84%
Video of device use	58	64%
Specific courses	48	53%
Online course	39	43%
Training changing ICT	37	41%
Training in changing protocols	32	36%
Congress visits	27	30%
Simulate on animate models	19	21%
Assessing previous research	15	17%
Other	7	8%

Table 4: Training features (Results)

Respondents indicated that instructions of and introductions to the new device are vital to the implementation process. Simulations, practicing with the device and expert knowledge should be parts of training as well. Furthermore, videos and courses regarding the device are marked as important. Respondents (n=68) indicated that the manager of the OR is responsible for organizing and facilitating trainings regarding the introduction of a new medical equipment. Senior scrub nurse (n=24), surgeons (n=21) and the technical department (n=17) are indicated as responsible stakeholders for organising and facilitating trainings.

2.4.4 Readiness for use

During training the question arises how the readiness for use of the new device should be assessed. Respondents preferred a self-assessment (n=43) and a demonstration

to colleagues (n=31) as preferred options for readiness assessments, followed by an exam with demonstration and an exam at an external institute. Assessments performed by manufacturers or supervisors are other preferred ways to assess the readiness for use.

2.4.5 Implementation protocols

In the last part of the survey respondents were able to reflect on statements regarding the presence of an implementation protocol and the implemented Covenant Medical Technology (CMT). The results to these statements are shown in table 5.

	Completely disagree	Disagree	Neutral	Agree	Fully agree	Don't know
Protocol present (n=85)	5%	22%	16%	20%	8%	31%
CMT implemented (n=81)	1%	12%	11%	32%	12%	33%

Table 5: Results on presence implementation protocol and implementation of the CMT

Almost 28% of the respondents agreed with the statement that an implementation protocol was present for the implementation of new medical equipment. In paragraph 3.1 the majority of the respondents (99%) indicated that medical equipment was implemented, and a large percentage indicated that either a protocol omits (27%) or that respondents were not aware of the existence of an implementation protocol (30%). Regarding the implementation of the Covenant Medical Technology (CMT), 41% of the respondents agreed with the statement that the CMT was implemented in their hospital and 31 % of the respondents was not aware of the implementation of the CMT. Only 12% of the respondents disagreed with this statement, meaning that the CMT was not yet implemented in their hospital.

2.5 Discussion

In this study we explored factors for successful implementations of new medical equipment according to surgical supporting staff, with a focus on scrub nurses and circulating nurses. Ongoing activities for surgeons and surgical supporting staff are disrupted by the implementation of innovations, which can be either updated or new equipment or procedures (Stefanidis et al., 2014). New medical equipment to be used during surgeries, require skill and experience regarding the use of the device. Skill and experience vary as many stakeholders are involved in preparation, during and after surgeries. The need for the perspective of surgical supporting staff is supported by Stefanidis' study (2014), as they are part of the surgical team. A notable finding is that respondents feel that the manager of the OR should be responsible for the organization and facilitation of training regarding new medical

equipment, whereas surgeons indicate that surgeons themselves are responsible for the monitoring of the introduction of new equipment (Stefanidis et al., 2014). An explanation may be that needed skills and experience regarding the new device differs surgeons monitor the functionality and use of the new device during surgery and surgical supporting staff is involved in supporting activities prior, during and after surgery. In literature there are many cases regarding new operative techniques and new medical equipment with varying success of the functionality of the device, but the number of studies and holistic methods for implementation of new medical devices in OR´s is limited. Respondents indicate that the success of implementations of new medical equipment varies and that implementations are perceived to be rushed through. A large group indicates that an implementation protocol omits and that awareness of the implementation of the CMT is limited. Although policies regarding the CMT should be in place, respondents indicate that more time is needed for implementation activities and communication needs to be improved. Stakeholders in the OR perform tasks according to protocols and respondents indicate that the integration of new medical equipment requires changes in protocols and ICT systems. Surprisingly, only a minority of respondents confirms that relevant protocols are actually updated due to the implementation of new medical equipment. Based on literature and experience we argue that implementation of new medical equipment should be approached in a holistic matter, taking multiple perspectives of stakeholders into account. We argue that implementation activities should result in integration in processes (protocols), systems and organization, knowledge and skill development, and increased experience. Therefore, respondents confirm the need for effective communication, training, time for and clarity of the implementation process. We propose that these are factors for successful implementation of medical devices. Careful preparation and planning is needed to identify the team members and to identify steps for implementation. Integration in (ICT) systems and regular activities by updating protocols is needed during the implementation (Frasier et al., 2017; Meyfroidt, 2009). Respondents confirm, in accordance with literature, that introductions to the device, simulations and training are necessary to work effectively and safely with the new device. They indicate that simulation and training is needed and they value expert instructions and videos (Carrino et al., 1998; Guédon et al., 2014; Marvik et al., 2004; Pennington & DeRienzo, 2010). Regarding readiness assessments surgical supporting staff prefers self-assessments and demonstration to colleagues, whereas surgeons suggest extensive training for use of the new device (Stefanidis et al., 2014). This distinguishes the roles, as supportive surgical staff is as responsible for setup and disassembly of equipment and surgeons are responsible for the safe use of the medical device and the patient outcome (Collar et al., 2012). During the implementation process involvement of the operating team and other stakeholders is needed facilitated by effective communication throughout the implementation process (Bhatt et al., 2014; Frasier et al., 2017; Marvik et al., 2004; Pennington & DeRienzo, 2010; Saleem et al., 2015).

2.6 Limitations

This study results in factors for successful implementations of medical technology in OR´s based on a survey from the perspective of surgical supporting staff (scrub nurses and circulating nurses). Other members of surgical supporting staff such as anesthetic (supporting) staff, operators of medical equipment and other departments are not included in this study. The identified factors for implementation still need validation based on empirical data.

2.7 Conclusion

Disruptions in OR's and enhancements of medical care are also influenced by introducing new medical equipment. In this study we focused on the research question "Which factors for successful implementation can be identified from a surgical supporting staff's perspective, when introducing new medical equipment in the OR?" Based on the survey results and literature we identified the following factors relevant for an implementation of medical equipment in the OR: a coherent and holistic implementation approach; effective integration in processes, systems and organization; knowledge and skill development and experience.

Acknowledgement

LVO for the opportunity to distribute surveys at their annual congress.

3

IMPLEMENTING MEDICAL TECHNOLOGICAL EQUIPMENT IN THE OR: FACTORS FOR SUCCESSFUL IMPLEMENTATIONS

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Journal of Healthcare Engineering
https://doi.org/10.1155/2018/8502187

Abstract

Operating rooms (OR's) more and more evolve into high-tech environments with increasing pressure on finances, logistics and a not be neglected impact on patient safety. Safe and cost-effective implementation of technological equipment in OR's is notoriously difficult to manage, specifically as generic implementation activities omit as hospitals have implemented local policies for implementations of technological equipment.

The purpose of this study is to identify success factors for effective implementations of new technologies and technological equipment in OR's, based on a systematic literature review. We accessed ten databases and reviewed included articles.

The search resulted in 1592 titles for review and finally 37 articles were included in this review. Six main categories of influencing factors on successful implementations of medical equipment in OR´s were identified: 'processes and activities', 'staff', 'communication', 'project management', 'technology', and 'training'. We argue that aligning these factors during implementation, impact the success, adaptation, and safe use of new technological equipment in the OR. The identified categories in literature are considered to be a baseline, to identify factors as elements of a generic holistic implementation protocol.

This work was originally published as: Sewberath Misser, N., Zaane, B. Van, Jaspers, J. E. N., Gooszen, H., & Versendaal, J. (2018). Implementing Medical Technological Equipment in the OR: Factors for Successful Implementations. Journal of Healthcare Engineering, 2018. https://doi.org/https://doi.org/10.1155/2018/8502187

3.1 Introduction

Operating Rooms (OR's) are complex technological environments and high reliability organizations (HRO's), in which technological equipment and information technology are used to perform (surgical) procedures (Baker et al., 2006; Dutch Hospital Association, 2016; Girotto et al., 2010; Roberts, 1990). Advancements and innovations in medical technology continue, which result in frequent implementations of new technological equipment in OR's. According to Edmondson (2001) the implementation of new technological equipment entails the integration of technology in day-to-day activities in an organization (Edmondson et al., 2001). In order to ensure the safe use of medical technology the Dutch Hospital Association (DHA) agreed upon a set of policies published in the Covenant Medical Technology (CMT). The CMT states that hospitals should have defined and implemented safety policies regarding medical technological equipment. Compliance to these policies are audited by the Dutch Health and Youth Care Inspectorate (HYI)(Dutch Hospital Association, 2016; Ministry for Healthcare and Sport, 2010). These policies involve acquiring, implementing, using, and disposing medical equipment. To comply with the CMT, hospitals have defined hospital specific local policies to implement new medical technological equipment. These local policies result in local procedures to implement new technological equipment, resulting in varying implementation activities, lead times, and success of implementations. We postulate that these variations result in inefficiencies and cause lower adaptation rates due to difficulties with the integration of new technological equipment in day-to-day activities and thus in clinical practice. Moreover, in contrast to the strictly regulated introduction of new drugs provided by the pharmaceutical industry, generic detailed guidelines for the implementation of medical technology do not exist. Within the field of information sciences, the success of implementations of information technology (IT) has increased and some scholars identify factors for successful implementations of IT for instance technological factors, organizational factors, job factors (Berg, 2001; Karsh, 2004). However, much remains unexplored, especially when considering all these perspectives holistically. The overall aim of our research is to develop a holistic model for implementation of new technologies in OR's, which helps hospitals and medical equipment companies to implement medical technology in a safe, efficient, and cost-effective way. For reasons of demarcating and focus, we concentrate on the implementation of new medical technological equipment, which includes medical equipment and medical information technology (i.e. hardware and/or embedded software). This study is the first step towards our overall aim, and we analyze existing recent literature available on implementations of technology in the OR, in order to identify success factors for efficient implementations. Results from this study will be included in the development of a holistic implementation model for new technology equipment in OR's. In the following section we explain the literature search and analysis procedure, followed by a section that describes the literature review results. In the discussion we reflect on the results. In the last section conclusions, limitations and plans for further research are provided.

3.2 Method

The aim of our systematic literature review is to identify all types of relevant factors on the implementation of medical technology in OR's, and to categorize these factors. To ensure quality and rigor, this systematic literature review commenced by setting up a literature search protocol following the guidelines of Kitchenham and Charters (see figure 1) (Kitchenham & Charters, 2007). The following databases were accessed in the search process: Academic Search, ACM, DOJ, Embase, NARCIS, Pubmed, Science Direct, Springerlink, Web of Science and Wiley. We entered the following terms and operators: "Implement" OR "Implementation" AND "Technology" AND "Operating Room". These terms were searched for in "all fields" of selected databases.

3.2.1 Inclusion and exclusion criteria

We used no date restrictions during the database search. Articles regarding the implementation of medical equipment as well as information technology were included in the reviewing process. Titles of articles included in reference lists related to the search criteria were considered. Articles published in other than the English language were excluded. We excluded secondary literature e.g. books. Conference abstracts, poster presentations and letters were excluded as well, due to limited availability of detailed information in proceedings and other sources.

We reviewed the results in three steps. Firstly, two members of the research team (NSM, BVZ) reviewed titles independently according to predefined inclusion and exclusion criteria. Titles with positive reviews by the two researchers were included for the abstract review; titles with a negative and positive review by the researchers were included in the abstract review; titles with double negative reviews were excluded for the abstract reviews (NSM and BVZ). Secondly, we reviewed selected abstracts independently (NSM and BVZ). Similarly, to the title review, we reviewed abstracts independently. Abstract review results were discussed, resulting in a selection of abstracts for full article review. Duplicate abstracts were removed. In the third phase the selection of full articles was reviewed for inclusion or exclusion, according to the purpose of the research (NSM). In case of doubt, the second reviewer (BVZ) was asked to assess the article. Results of the full article review were discussed, and articles were in- or excluded by consensus.

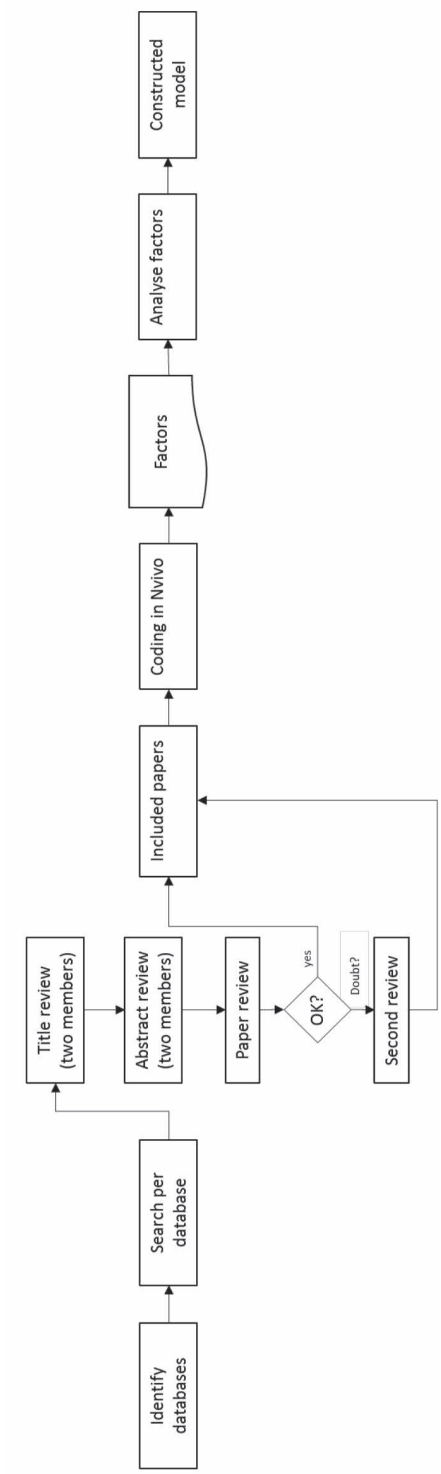

Figure 1 Overview of search activities and coding

3.2.2 Coding

Coding of included articles should be resulting in all types of influencing factors for the implementation of medical equipment in OR's as well as resulting factors of an implementation of medical equipment for instance performance. During a coding process, relevant sections in articles are marked and a descriptive name or code is added to the section. During coding of included articles, all relevant sections were coded inductively using NVivo (version 11 for Windows) (Saldaña, 2010). Through 'open coding' we identified factors or categories of importance in our literature sources, following principles as presented by Strauss & Corbin (1990) and leveraging Nvivo-tooling (Strauss & Corbin, 1990).

3.3 Results

3.3.1 Search results

Our searches resulted in 1592 potentially eligible articles (see figure 2). After screening titles 1451 articles were excluded. After reviewing abstracts of 141 studies, 49 articles remained. Reviewing these articles, and applying the inclusion and exclusion criteria, resulted in 35 remaining articles for detailed coding and analysis. Two articles were added to this selection based on references and feedback from co-researchers i.e. Raman et al. (2016) and Stefanidis et al. (2014) (Raman et al., 2016; Stefanidis et al., 2014). During the search and coding process the article of Raman et al (2016), was an accepted, not yet published, manuscript. This article provided insights on the implementation of checklists in OR and was therefore included in this research. The second article from Stefanidis et al (2014) was published as a set of guidelines for the introduction of new technology and techniques from a surgeons' perspective. This article did not include an abstract nor keywords that were related to this research. The research team advised to include these articles due to their relevance and the scope of this research.

Following the review process and criteria for inclusion and exclusion, 37 articles were included in this study.

Interval	Period (year)	Number of articles (n=37)
I	1997-2002	3
II	2003-2008	6
III	2009-2014	22
IV	2015-2016	6

Table 1 Results: distribution of articles according to the year of publication

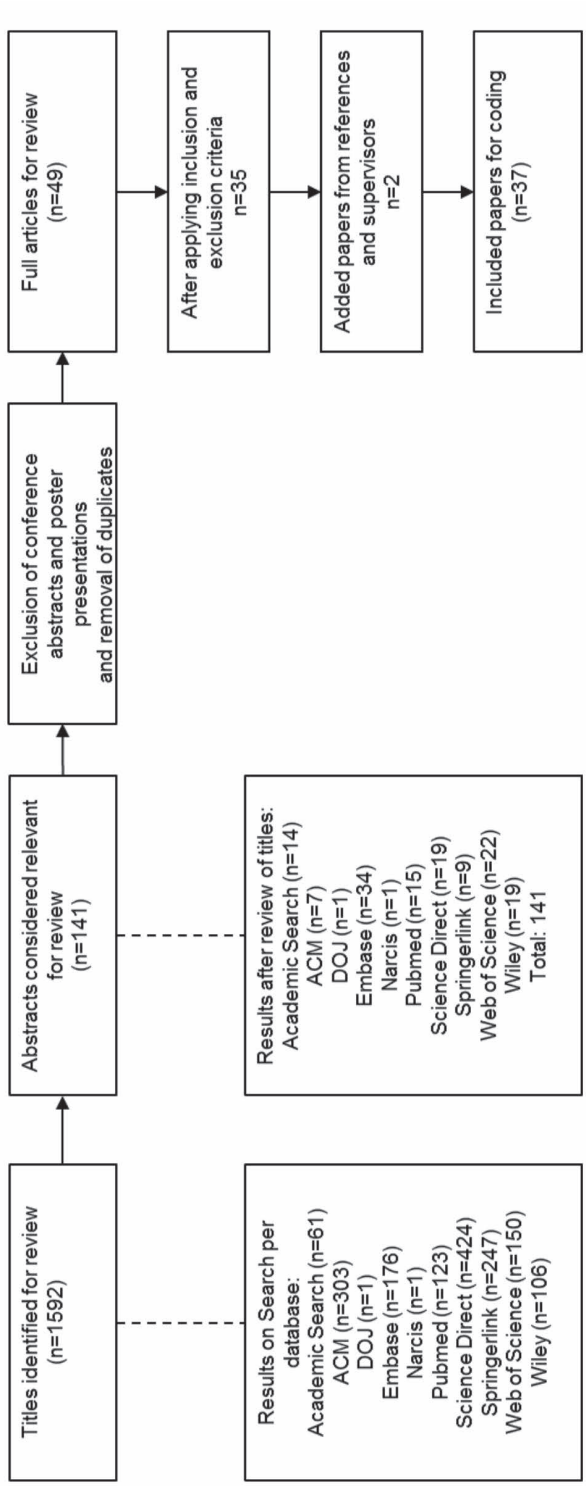

Figure 2 Search results

Table 1 provides an overview of included articles related to the year of publication, with intervals of 5 years. Three included articles were published in interval I, period 1997-2002. Six articles were published in the periods referring to interval II and IV. Most included articles (n=22) were published in interval III, corresponding to the period 2009-2014.

3.3.2 Coding Results

The coding process resulted in a longlist of descriptive names or items. Related items were grouped in categories or factors. This process is traceably and transparently performed in Nvivo.

Table 2 shows seven categories that are derived from the coded items: communication; performance; process and activities; project management; staff; technology, and training. Each category consists of one or more underlying items, resulting from coding articles in NVivo. Furthermore, table 1 shows the number of coded articles per category ("number of articles"). The categories process and activities, staff and technology are referenced in the majority of the coded articles, respectively 29, 30 and 27 articles. Table 2 also shows the aggregated frequency of coded items per category ("aggregated frequency of coding"). Based on the aggregated frequency of items, the categories project management, technology, process and activities, are coded most often, respectively 510, 355 and 240 times. These results imply that underlying items of these categories are coded more than once in corresponding articles.

Legend	Categories / factors	Number of articles	Aggregated frequency of coding
1	Communication	24	86
2	Performance	22	86
3	Process & activities	29	240
4	Project Management	24	510
5	Staff	30	190
6	Technology	27	355
7	Training	25	176

Table 2 Results: Frequencies of coded categories

The identified categories are explained in the following sections:

3.3.3 Communication

Communication is a category that was coded in 24 articles. When new technology (i.e. medical equipment) is introduced, disruptions in activities and workflow occur, which require communication and teamwork. Communication with relevant stakeholders is one of the factors to prevent errors when introducing new technological equipment. The use of updated checklists is described as one of the communication tools,

which regulates activities and the workflow for stakeholders such as surgeons, anaesthesiologists and surgical supporting staff. The use of these updated checklist contribute to improved safety in the OR (Beaumont & Russell, 2012; Bouamrane & Mair, 2014; Cima et al., 2011; Collar et al., 2012; Francis, 2006; Guédon et al., 2014; Kang et al., 2015; Kim et al., 2009; Kitzmiller et al., 2010; Low, Walker, & Heitmiller, 2012; Lowndes & Hallbeck, 2014; Peltokorpi et al., 2008; Raman et al., 2016; Ruurda, Draaisma, van Hillegersberg, Rinkes, et al., 2005; Samii & Gerganov, 2013; Stefanidis et al., 2014; Tan et al., 2014; Verdaasdonk et al., 2009; Wiegmann et al., 2010; Woodward et al., 2010; Yusof, 2015; Yusof et al., 2012; Zindel, 2000).

3.3.4 Performance

In 22 articles various indicators regarding performance are identified such as OR efficiency and performance, patient care, patient outcomes, finance, safety, ergonomics and user-friendliness of technological equipment (Cima et al., 2011; Crosby & Lane, 2009; Dey et al., 2007a; Edmondson et al., 2001; Ehrenfeld & Rehman, 2011; Haugen et al., 2015; Kang et al., 2015; Kitzmiller et al., 2010; Lowndes & Hallbeck, 2014; Meyfroidt, 2009; Peltokorpi et al., 2008; Rivkin, 2009; Ruurda, Draaisma, van Hillegersberg, Rinkes, et al., 2005; Samii & Gerganov, 2013; Stefanidis et al., 2014; Verdaasdonk et al., 2009; Wiegmann et al., 2010; Williams et al., 1997; Woodward et al., 2010; Yusof, 2015; Yusof et al., 2012; Zindel, 2000)

3.3.5 Processes and Activities

The majority of the articles included in this study showed that the introduction of new technology affects processes and activities of employees in the OR. Tasks and activities of OR-employees are recorded in protocols and checklists to ensure safety and quality in pre-, per- and postoperative activities of surgeries. Task deconstructions of involved employees are used to analyze the impact of a new device on performed activities, processes, and workflows. Alterations in processes and workflows result in updated protocols and checklists, affecting tasks and activities for involved employees (Ahmed et al., 2015; Baumgart et al., 2007; Beaumont & Russell, 2012; Bouamrane & Mair, 2014; Cima et al., 2011; Collar et al., 2012; Edmondson et al., 2001; Ehrenfeld & Rehman, 2011; Francis, 2006; Guédon et al., 2014; Haugen et al., 2015; Hiemstra et al., 2011; Kitzmiller et al., 2010; Kranzfelder et al., 2012a; Lowndes & Hallbeck, 2014; Meyfroidt, 2009; Peltokorpi et al., 2008; Raman et al., 2016; Rivkin, 2009; Ruurda, Draaisma, van Hillegersberg, Rinkes, et al., 2005; Samii & Gerganov, 2013; Stefanidis et al., 2014; Tan et al., 2014; Verdaasdonk et al., 2007, 2009; Wiegmann et al., 2010; Williams et al., 1997; Woodward et al., 2010; Yusof, 2015; Yusof et al., 2012; Zindel, 2000)

3.3.6 Project management

In the OR many stakeholders are involved, executing various protocolled tasks and activities. Implementation of new technological equipment as a project requires management to achieve predetermined goals. Identified elements for project management regard the identification of stakeholders, defining the purpose of the project, as well as benefits and gains. A project plan and planning is considered to be part of this category. During the process of implementation, team members are identified to execute a project plan. Multiple articles mention the allocation of a multidisciplinary team as one of the necessary factors for the implementation of new technology, as different perspectives to the implementation are addressed. Examples of these perspectives are change management, simulations and stakeholder management (Ahmed et al., 2015; Baumgart et al., 2007; Beaumont & Russell, 2012; Bouamrane & Mair, 2014; Cima et al., 2011; Collar et al., 2012; Crosby & Lane, 2009; Dey et al., 2007a; Francis, 2006; Guédon et al., 2014; Haugen et al., 2015; Kim et al., 2009; Kitzmiller et al., 2010; Low, Walker, & Heitmiller, 2012; Lowndes & Hallbeck, 2014; Meyfroidt, 2009; Peltokorpi et al., 2008; Rivkin, 2009; Steelman, 2011; Stefanidis et al., 2014; Tan et al., 2014; Verdaasdonk et al., 2009; Wiegmann et al., 2010; Williams et al., 1997; Yusof, 2015; Yusof et al., 2012; Zindel, 2000)

3.3.7 Staff

When referred to as staff in the OR, we refer to employees or surgical supportive staff who are involved in setting up, preparing, using and disassembling medical equipment. The ease of use of new medical equipment contributes to the adoption of this equipment by staff. During the project, staff need to be involved in activities regarding the new equipment, such as training, setup, using and disassembling medical equipment, and updating corresponding protocols and checklists (Bouamrane & Mair, 2014; Bounouar et al., 2012; Cima et al., 2011; Crosby & Lane, 2009; Dey et al., 2007a; Edmondson et al., 2001; Ehrenfeld & Rehman, 2011; Francis, 2006; Guédon et al., 2014; Haugen et al., 2015; Kang et al., 2015; Kim et al., 2009; Kitzmiller et al., 2010; Low, Walker, & Heitmiller, 2012; Lowndes & Hallbeck, 2014; Peltokorpi et al., 2008; Raman et al., 2016; Rivkin, 2009; Ruurda, Draaisma, van Hillegersberg, Rinkes, et al., 2005; Samii & Gerganov, 2013; Stefanidis et al., 2014; Tan et al., 2014; Verdaasdonk et al., 2009; Wiegmann et al., 2010; Williams et al., 1997; Yusof, 2015; Yusof et al., 2012).

3.3.8 Technology

In this review, technology is used as category for coding referring to medical equipment and (embedded) Information Technology (IT). Studies show that the implementation of new medical equipment involves integrating new technology in the daily processes and activities. Relevant training for staff is required which includes setup, use, disassembly of equipment, the interpretation of data and

screens (if applicable), and troubleshooting in case problems occur (Ahmed et al., 2015; Baumgart et al., 2007; Bouamrane & Mair, 2014; Cima et al., 2011; Collar et al., 2012; Edmondson et al., 2001; Ehrenfeld & Rehman, 2011; Francis, 2006; Guédon et al., 2014; Haugen et al., 2015; Hiemstra et al., 2011; Kang et al., 2015; Kim et al., 2009; Kranzfelder et al., 2012a; Lowndes & Hallbeck, 2014; Meyfroidt, 2009; Raman et al., 2016; Rivkin, 2009; Ruurda, Draaisma, van Hillegersberg, Rinkes, et al., 2005; Samii & Gerganov, 2013; Steelman, 2011; Stefanidis et al., 2014; Tan et al., 2014; Verdaasdonk et al., 2009; Woodward et al., 2010; Yusof, 2015; Zindel, 2000).

3.3.9 Training

Studies showed that staff needs training to setup, configure, use and disassembly new medical equipment. Training starts during the project with involved project members and based on the project plan and product requirements. Training elements are described in training programs, which entail technical and non-technical skills. Non-technical skills are described as skills regarding communication, teamwork, and leadership. Depending on the contents of training staff gains experience and skills to use medical equipment and to interpret data (on screens if applicable). Skills to troubleshoot when problems occur are needed as well. Based on the type of equipment and corresponding risks, manufacturers and educators should define ways of (ongoing) training assessment (Ahmed et al., 2015; Bouamrane & Mair, 2014; Collar et al., 2012; Crosby & Lane, 2009; Edmondson et al., 2001; Francis, 2006; Guédon et al., 2014; Haugen et al., 2015; Hiemstra et al., 2011; Kang et al., 2015; Kitzmiller et al., 2010; Low, Walker, & Heitmiller, 2012; Lowndes & Hallbeck, 2014; Meyfroidt, 2009; Rivkin, 2009; Ruurda, Draaisma, van Hillegersberg, Rinkes, et al., 2005; Stefanidis et al., 2014; Tan et al., 2014; Verdaasdonk et al., 2007, 2009; Wiegmann et al., 2010; Williams et al., 1997; Woodward et al., 2010; Yusof, 2015; Yusof et al., 2012).

3.4 Discussion

There is overwhelming evidence that the use of medical technology and information technology in OR's will increase. This will affect costs, quality of care, complexity of surgical procedures and, as a consequence, also patient safety. Current guidelines, available for implementation of new devices in the OR, in essence include safety based on the local policies according to the covenant medical technology in The Netherlands (CMT) (Dutch Hospital Association, 2016). The OR is a dynamic, multidisciplinary, multi-stakeholder and innovative environment, and the development and implementation of medical equipment should not only consider safety, but also cost and effects. Although the CMT policy represents a guideline for local hospitals and audits are performed by the Dutch Health and Youth Care Inspectorate (HYI), we learned from literature and experience that implementation of new medical equipment runs along all different sorts of pathways before being

accepted in clinical surgical practice. We also learned that implementations vary in duration and success. In this review coded seven main categories that are indeed relevant, and all have their impact in the process of implementation: ´processes and activities´, ´staff´, ´communication´, ´project management´, ´technology´, ´training´, and ´performance´. Table 1 shows that the number of referenced articles varies between 22 articles and 30 articles out of a total of 37 articles. The aggregated frequency of coding shows that the categories project management, technology and processes and activities are referenced 510, 255 and 240 times. Prior to the coding process, we expected that implementations of new technologies effected processes and activities, technology and staff; this is indeed confirmed by literature. Results show that the category project management scores high, due to the accumulation of frequencies of underlying coded items. These items are expected to be part of an integral implementation project of new medical equipment, consisting of various project activities.

We postulate that aforementioned categories provide a baseline for a holistic perspective on implementations of new medical equipment in OR's. The category performance can be identified as a resulting category related to the outcome of an implementation, while the other categories can be identified as influencing categories. We further postulate that tailoring or aligning these influencing categories and underlying items to the context such as organization, type of medical equipment, or involved stakeholders, affect the outcome of an implementation.

Based on this literature review, our logistical and clinical experience, we will focus on the alignment of the factors 'technology', 'processes and activities' and 'staff' to improve the success of implementations of medical equipment.

3.5 Conclusions and further research

Development and implementation of innovative medical equipment to improve safety, quality or efficiency is common practice in hospitals all around the world. Integral guidelines for implementations of new medical equipment are not yet available. This literature review shows that six main influencing categories can be identified based on the selected studies: 'processes and activities', 'staff', 'communication', 'project management', 'technology', and 'training'; the anticipated outcome of implementations is identified as the category 'performance'. As the integration of new technology in daily activities remains a challenge, we will develop a generic holistic model for implementations of medical equipment in OR's guided by the results of this literature review. The identified categories are considered to be a baseline, that identify influencing factors as elements of a generic holistic implementation model for new technological equipment in the OR. We suggest that this model is based on the alignment of the identified categories and the medical

equipment to be implemented. Principles from strategic alignment in Information Systems research are considered to be a promising approach for developing a model: aligning technology introduction with organizational processes and organization strategy (Venkatraman et al., 1993).

This study focused only on written scientific sources in hospitals or OR´s and therefor probably omits certain aspects that may become visible through performed case studies. We are conducting explorative case studies and anticipate that these studies will contribute to developing specific and reproducible routes for implementations of medical equipment and thus add other relevant categories to those we identified in literature. We expect that a model for implementation of medical equipment in OR's provides insight for various stakeholders and companies and that this model will enable various stakeholders in hospitals to implement new technological equipment in a generic way in OR´s, contributing to further enhanced safety as well as efficiency, and to shorten the duration of the implementation process.


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A PROTOCOL FOR IMPLEMENTATION OF NEW TECHNOLOGY IN A HIGHLY COMPLEX HOSPITAL ENVIRONMENT: THE OPERATING ROOM

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International Journal for Networking and Virtual Organisations
https://doi.org/10.1504/ijnvo.2020.10025195

Abstract:

Implementations of (medical) equipment in highly complex hospital environments, such as operating rooms, happen in hospitals around the world. In operating rooms technological equipment is used for surgical related activities and supportive activities to surgeries. Implementation of governmental policies in hospitals result in varying implementation activities, unexpected lead times and success. An integral and holistic protocol for implementation omits.

In this study we introduce a protocol for implementation of (medical) equipment in OR's, consisting of implementation factors and implementation activities.

Factors and activities are based on data from a systematic literature review and an explorative survey among surgical supporting staff on factors for successful implementation of technological and (medical) equipment in OR's. The protocol consists of five factors and related implementation activities: setting up a project plan, organizational preparation, technological preparation, maintenance, and training.

This work was originally published as: Sewberath Misser, N., Jaspers, J., Zaane, B. Van, Gooszen, H., & Versendaal, J. (2020). A protocol for the implementation of new technology in a highly complex hospital environment: the operating room. International Journal of Networking and Virtual Organisations, 22(2), 199. https://doi.org/10.1504/IJNVO.2020.105543

4.1 Introduction

Operating rooms (ORs) or operating theatres are an example of highly complex and dynamic environments where technological equipment is used prior, during and after surgeries. The introduction of (medical) equipment in operating rooms (OR's) occurs often and affects work related activities of surgeons and surgical supporting staff. Many case studies show advancements in technology to improve patient treatments, care, and outcomes, but few studies focus on successful implementations of (medical) equipment in OR's. Edmondson et al (2001) describes the implementation of technological equipment as the integration of new technology in day-to-day activities in an organization (Edmondson et al., 2001). Implementation of technological equipment entails equipment new to the organization, which includes new and innovative technology (Tatnall, 2009). The introduction of new and innovative technologies remains a challenge and governments are increasingly strict as the European Parliament adopted regulations to increase safety and safe use of medical devices (European Parliament & Council of the European Union, 2017; Nguyen et al., 2011; Regulation of the European Parliament, 2017). These regulations need to be implemented before spring 2020. In the Netherlands, the Dutch Hospital Association (NZA) agreed upon a set of rules regarding the implementation of new medical devices in hospitals: Covenant Medical Technology (CMT). This agreement provides policy guidelines throughout the life cycle of (medical) equipment to ensure patient safety and these policies regard acquiring, implementing, using, and disposing medical devices (Dutch Hospital Association, 2016). In the CMT medical devices are defined as devices that have direct impact on a patient and the outcome of a treatment. For the purpose of this study medical devices and (medical) information technology (i.e. hardware and software) are referred to as (medical) equipment. In this study, we also refer to non-(medical) equipment, which includes equipment that is used in non-surgical or supportive activities. It is possible that supportive activities do not directly impact the patient, their treatments, or the outcome of a treatment. The CMT has been implemented in the hospitals in The Netherlands and these hospitals have defined local policies throughout the life cycle of medical devices. The Health and Youth Care Inspectorate regularly audits these associated local policies. Locally defined policies result in hospital specific ways to implement (medical) equipment, causing a variety of activities to implement (medical) equipment. These hospital specific activities result in different implementation outcomes and increased implementation lead times, which may result in increased utilization of resources such as implementation time, involved members, increased implementation funds (Wickramasinghe et al., 2008). In our opinion integral holistic implementation guidelines for (medical) equipment in OR's should be available to contribute to safety, as safety ensures safe surgical and treatment interventions. Therefore, we did research on necessary factors for implementation of new (medical) devices in highly complex hospital environments, specifically OR's. The following research question is defined:

Which factors for successful implementation can be identified to compose a protocol for implementation of (medical) equipment in the OR?

4.2 Method

The primary research question mentioned in the introduction is operationalized in two sub questions:

1. *Which factors for implementation of (medical) equipment in OR's can be identified?*
2. *Which activities are related to the identified factors for implementation?*

We used a mix of research methods to address these sub questions and to explore relevant implementation factors. Relevant implementation factors are needed to categorize, compose, and to populate a protocol for implementation. We performed a systematic literature review to identify success factors for implementation (Sewberath Misser, Zaane, et al., 2018). As second research method, we set up a survey. This survey was distributed among the participants of an annual conference for surgical supporting staff in the Netherlands (scrub nurses and circulating nurses). The following variables were included in this research: needed steps for implementation; training and governance; user readiness, and other topics such as use of an implementation protocol; use of the Covenant for Medical Technology (CMT) (Sewberath Misser, Jaspers, et al., 2018). Based on these sources we undertook the following steps to compose protocols for implementation of (medical) equipment in the OR:

1. Composition of a protocol based on a systematic literature review (protocol A). In our previous study we identified seven categories for implementation (Sewberath Misser, Zaane, et al., 2018). Henderson et al. (1993) describes a strategic alignment framework, which we used to compare these categories (Venkatraman et al., 1993). In this study we use the dataset of included papers from the systematic literature review. We analyzed articles in detail to identify factors and implementation activities based on coding results. We used NVivo (version 11 for Windows) to select and analyze related texts of coding results. Identified implementation activities are based on the analysis of the contents of these coded sections in articles. We reviewed and discussed resulting implementation activities and removed similar implementation activities. Included implementation activities are based on frequency and relevance, and these were classified under one of the implementation factors. We provided a description based on the coded categories in NVivo version 11 for Windows.
2. Composition of a protocol based on findings of a survey among surgical supporting staff (Protocol B). In this study we processed the results of the survey in SPSS for windows and Microsoft Excel (Sewberath Misser, Jaspers, et al., 2018). This explorative survey was distributed among 235 visitors of an annual congress for surgical supporting staff (scrub- and circulating nurses).

There were 90 respondents (n=90). We used this dataset and analysed these results in more detail. We identified implementation activities based on the frequency of relevant activities and provided a description the input that was used to set up this questionnaire and on the outcomes of the completed surveys. These implementation activities are included in protocol B.

3. Composition of a combined protocol for implementation of (medical) equipment. To compose this protocol we used factors from protocol A and protocol B. We merged these factors in a longlist of (categorized) factors. This list was then analyzed and checked for similar activities. The purpose of this analysis was to identify unique and relevant implementation activities based on protocols A and B. We then discussed and analyzed the implementation activities based on the content, the frequency of coding, distinguishing factors, descriptions, activities and/or examples. This analysis resulted in implementation instructions, which are included in this combined protocol.

4.3 Results

The systematic literature review resulted in seven implementation categories (Sewberath Misser, Zaane, et al., 2018). In table 1, we show a mapping of identified categories in our previous study compared to the identified factors in this study.

Number	Factor (in table 2 and 4)	Category as identified in systematic literature research
1.	Set up a project plan	Project management Performance
2	Organizational preparation	Process and activities Staff Communication
3	Technological Preparation	Technology
4	Maintenance	Technology
5	Training	Training

Table 1: Mapping of categories compared to implementation factors

In the next sections, we present the results of our research, based on the sources of data collection. Firstly, we compose a protocol for implementation based on a systematic literature review, followed by a protocol for implementation based on survey data among scrub and circulating nurses. Lastly, we combine data based on literature and survey data to compose and populate a combined protocol for implementation of (medical) equipment in OR's.

4.3.1 Protocol A: an implementation protocol based on a systematic literature review

To compose a protocol for implementation of (medical) technology we identified implementation factors and derived implementation activities based on the coded parts of included papers. These implementation factors and activities are presented in table 2: Protocol A Implementation factors and activities. An explanation of activities is included in the column: 'description of activities' and examples of references to literature are provided.

A	Factor	Activities	Description of activities	Reference example
1	Set up a project plan			
1.1		Identify strategic and tactical topics	Identify topics that are relevant for the implementation plan, for example by selecting activities in this implementation protocol. Classify the topic as strategic or tactical.	(Guédon et al., 2015)
1.2		Identify performance	Select variables that define the performance of the project and define how these variables are measured and analyzed. Performance metrics for success could be efficiency, finance, ergonomics.	(Cima et al., 2011; Dey et al., 2007b; Yusof, 2015)
1.3		Identify stakeholders	Identify (groups of) stakeholders which are responsible, accountable, consulted and informed such as sponsors, champions, staff, teams.	(Collar et al., 2012; Yusof, 2015)
1.4		Identify Risks	Perform a risk assessment to identify risks and identify unintended outcomes as new technology may have unforeseen consequences.	(Peltokorpi et al., 2008; Wiegmann et al., 2010)
1.5		Identify activities for implementation	Identify relevant activities for implementation, based on listed activities.	
2	Organizational preparation			
2.1		Assemble a multidisciplinary implementation team	Assemble a team in which included various members of involved departments and stakeholders such as scrub nurses, circulating nurses, anesthesiologists, perioperative technicians, surgeons, administrators, and schedulers. Consider assigning an extra team member during implementation to increase familiarity with procedures e.g., setup.	(Collar et al., 2012; Francis & Winfield, 2006)
2.2		Foster team familiarity	Team familiarity and stability impacts teamwork, communication, and satisfaction during implementation. Assign a dedicated team for the implementation. Involve and inform this team well.	(Wiegmann et al., 2010)
2.3		Identify affected activities and/or processes	Introducing new (medical) equipment influences existing activities and work processes. Identify these processes and analyze how these processes are affected and which identified stakeholders are involved.	(Kitzmiller et al., 2010)

A	Factor	Activities	Description of activities	Reference example
2.4		Update checklists	Checklists improve safety and reliability prior to, and during surgical procedures. Assess if checklists need to be updated due to the introduction of (medical) equipment and update these according to the procedures to update checklists.	(Kranzfelder et al., 2012b; Verdaasdonk et al., 2009)
2.5		Perform simulations	Simulate with involved stakeholders (and departments) how processes and work activities are executed prior to introducing (medical) equipment.	(Baumgart et al., 2007; Woodward et al., 2010)
2.6		Identify and deploy activities to increase employees' engagement	Participation of employees when introducing new (medical) equipment increases employees' engagement. Deploy activities to engage employees e.g., involvement of work councils, create a communications council.	(Cima et al., 2011)
2.7		Identify and deploy activities to increase employees' adoption	Embedding new (medical) equipment in day-to-day activities as an accepted routine is a challenge. Identify and deploy activities to increase adoption with stakeholders such as demonstrating relative advantages, possibilities to observe and experiment, demonstrate benefits, use training, and assign key users or champions.	(Bouamrane & Mair, 2014; Guédon et al., 2015; Meyfroidt, 2009)
2.8		Communicate with stakeholders	Communication with stakeholders increases engagement and involvement of stakeholders. Communication activities can be: (pre-operative) group briefings, interviewing stakeholders, using videos and newsletters, developing patient centered information.	(Bouamrane & Mair, 2014; Cima et al., 2011; Guédon et al., 2015; Kim et al., 2009; Stefanidis et al., 2014; Wiegmann et al., 2010)
3	Technological preparation			
3.1		Prepare equipment	Involved stakeholders should be aware what their role is relating to the new (medical) equipment. For instance: nursing personnel should be familiar with the instrumentation needs and they should be proficient in properly connecting, calibrating, set up and use (medical) equipment.	(Francis & Winfield, 2006)
3.2		Consider ergonomic aspects	Positioning of new equipment in the OR requires attention, as space is often limited and involved staff is positioned near the patient. New equipment should not disturb other existing equipment and for example screens and tools should be visible and available for surgical (supporting) staff.	(Lowndes & Hallbeck, 2014; Rivkin, 2009; Zindel, 2000)
3.3		Prepare interfaces with other information systems	Introducing new equipment requires integration in and with other devices in the OR. Consider the connectivity to the clinical networks to ensure safety and reliability.	(Zindel, 2000)

A	Factor	Activities	Description of activities	Reference example
3.4		Integrate device within existing environment	The introduction of new equipment affects current workflows and processes. These workflows need to be amended and existing standard operating procedures need to be updated accordingly.	(Kranzfelder et al., 2012b; Lowndes & Hallbeck, 2014; Meyfroidt, 2009; Yusof, 2015)
3.5		Manage generated data	When introducing equipment data can be generated and/or stored, e.g., when introducing a new information system. Consider data processing and security aspects and develop or update procedures.	(Zindel, 2000)
3.6		Interpret screens and troubleshooting	In case of electronic equipment notifications may occur visibly on screens or lights or audibly (alarms). Involved personnel should be able to interpret these notifications and should be able to troubleshoot in case of occurring problems.	(Francis & Winfield, 2006; Kitzmiller et al., 2010; Samii & Gerganov, 2013)
4	Maintenance			
4.1		Set up maintenance program	New equipment in use should be maintained periodically and in case of problems, support should be available. To address and facilitate this, a maintenance program should be set up.	(Francis & Winfield, 2006; Meyfroidt, 2009; Rivkin, 2009)
4.2		Update safety (regulations)	The introduction of new equipment may affect work activities of personnel. Assess the safety procedures and if needed, update these procedures accordingly.	(Kranzfelder et al., 2012b)
5	Training			
5.1		Train involved staff	To ensure safety of preparation and use of newly introduced (medical) equipment, involved staff should be trained. Training should be focused on technical skills and non-technical skills. Technical skills may include knowledge training, demonstrations, simulation training (cognitive, integrative, and automatic skills). Non-technical skills may include decision making, communication, and leadership skills	(M. Ahmed et al., 2012; Collar et al., 2012; Crosby & Lane, 2009; Kang et al., 2015; Low, Walker, Heitmiller, et al., 2012)

Table 2: Protocol A Implementation factors and activities based on literature review

Based on our systematic review we distinguish five implementation factors: setup a project plan, organizational preparation, technological preparation, maintenance, and training. Table 2 shows that a project plan is to be set up prior to implementation, in which reasons for implementation of new (medical) equipment should be defined as well as involved and affected stakeholders. Based on the type of equipment, implementation activities should be selected by the project team. The second factor for implementation involves activities around the preparation of the organization for the introduction of equipment. It regards setting up an implementation team, identifying pioneers and ambassadors within the organization, and assessing affected

departments and activities due to the introduction of new (medical) equipment. These departments and employees should be involved in the preparation of the implementation. Protocols need to be updated, checklists need to be assessed for updates, simulations need to be performed to see how new equipment will be in use, and which day-to-day activities need to be adjusted. The third factor regards the technological preparation. Interfaces with other systems and equipment need to be considered and these interfaces should be working properly. A fourth factor for implementation is maintenance after implementation. A maintenance program should be in place to ensure safety of equipment after implementation. The fifth identified factor is training. Training activities are extensively described in literature, primarily technical training by surgeons. Training activities are classified as training in technical skills and non-technical skills and these activities should be included in a tailored training program to various involved stakeholders. For instance: in case of surgical (medical) equipment, surgeons need to be well trained in technical and non-technical skills. Surgical supporting staff needs to be trained in the setup and disassembly of this equipment.

4.3.2 Protocol B: Survey based factors and activities

The second protocol we present, is an implementation protocol based on collected survey data among scrub and circulating nurses. In accordance with protocol A, we used the same implementation factors, and the implementation activities are based on collected data. These results are presented in table 3: Protocol B Survey based factors and activities.

B	Factor	Activities	Description of activities
1	Set up a project plan		
1.1		Inform stakeholders	During an implementation of new (medical) equipment stakeholders are involved. These stakeholders should be informed.
1.2		Involving stakeholders	Introducing new (medical) equipment requires involvement of stakeholders.
2	Organizational preparation		
2.1		Modifying Protocols	New (medical) equipment affects the existing workflow and procedures. Existing protocols need to be updated.
2.2		Perform simulations	As many stakeholders (and departments) are involved, the workflow regarding preparation, setup, use and disassembly should be simulated.
3	Technological preparation		
3.1		Introducing device	Introduction of the device is necessary, including technical aspects.
3.2		Demonstrate device	The new device needs to be demonstrated to involved stakeholders, tailored to their needs.
4	Training preparation		
4.1		Congress visits	To introduce a device, new to the OR, training is needed. Congress visits provide opportunities to get familiarized with the new device.
4.2		Introducing device	The device should be introduced by the manufacturer and the device needs to be demonstrated as well.
4.3		Assessing previous research	Insights from previous research activities and experiences should be shared with stakeholders, tailored to their needs.
4.4		Online course	Providing online courses regarding the new device is one of the training activities.
4.5		Video of device use	A video of use of the new device is considered to be valuable as one of the training activities.
4.6		Theoretical training	Theoretical training tailored to the needs of stakeholders is one of the options for training activities.
4.7		Knowledge sharing from an expert	Sharing knowledge from an expert user of the device is one of the options for training activities.
4.8		Specific courses	Based on the device specific training and courses can be developed and offered to the stakeholders.
4.9		Training changing ICT	As information systems may be affected by the introduction of the new device, training of changes in ICT and requirements for data entry might be needed.
4.10		Training in updated protocols	As workflows and processes change due to the introduction of a new device, stakeholders should be trained in the changed protocols.

B	Factor	Activities	Description of activities
4.11		Simulate on animate models	Based on the new device, training on/with animate models might be needed, tailored to the stakeholders' needs.
4.12		Assess Skills	To assess the readiness for use, a skills assessment program needs be developed and executed, tailored to the stakeholders. This assessment program can be developed by the hospital or the manufacturer
4.13		Supervision by co worker	As part of the introduction of the new device, supervision by a co-worker can be one of the assessment methods.
4.14		Evaluate experiences	Evaluating experiences and providing feedback regarding the use of the new device, provide input to optimize the device, the use of the device or the workflow.

Table 3: Protocol B Survey based factors and activities
Legend:
First column: table identification letter and identification number per row
Factor: identified implementation factor
Activities: identified implementation activities
Description of activities: A description of implementation activities

As mentioned in the description of activities of first factor in table 3: setting up a project plan, respondents advised to inform and involve stakeholders. Concerning the second factor organizational preparation, respondents indicated that protocols need to be modified due to the introduction of new equipment, and that simulations are needed. With included activity, the modification of protocols, respondents indicate that day-to-day activities need to be adjusted when implementing equipment. They identified introductions and demonstrations of new equipment as necessary activities for the introduction of equipment. These activities were classified as activities for technological preparation. Respondents indicated a number of relevant training activities prior to the introduction of new equipment. These activities are mainly referring to technical skills and assessment.

4.3.3 Protocol C: combined protocol for implementation

In this section we compose a protocol for implementation for (medical) equipment in OR's. This protocol is based on the merge of data from protocol A and B. Results are shown in table 4: Protocol C combined protocol for implementation. Similar to protocol A, we included factors for implementation and implementation activities. To define the origin of included activities, we added a locator column to table 3. If included activities are (partly) based on activities in table 3 (protocol B), we included a reference number such as Bx.y, referring to table 3, protocol B and activity record x.y. For each implementation activity, we added implementation instructions. These instructions are based on survey and literature data.

C	Factor	Activities	Locator table 3	Implementation instructions	Reference example
1	Set up a project plan				
1.1		Identify strategic and tactical topics		Identify topics that are relevant for the implementation plan, for example by selecting activities in this implementation protocol. Classify the topic as strategic or tactical.	(Guédon et al., 2015)
1.2		Identify performance		Select variables that define the performance of the project and define how these variables are measured and analyzed. Performance metrics for success could be efficiency, finance, ergonomics.	(Cima et al., 2011; Dey et al., 2007b; Yusof, 2015)
1.3		Identify stakeholders	B1.1; B1.2	Identify (groups of) stakeholders, which are responsible, accountable, consulted and informed such as sponsors, champions, staff, teams.	(Collar et al., 2012; Yusof, 2015)
1.4		Identify Risks		Perform a risk assessment to identify risks and identify unintended outcomes as new technology may have unforeseen consequences.	(Peltokorpi et al., 2008; Wiegmann et al., 2010)
1.5		Identify activities for implementation		Identify relevant activities for implementation, based on listed activities.	
2	Organizational preparation				
2.1		Assemble a multidisciplinary implementation team		Assemble a team in which included various members of involved departments and stakeholders such as scrub nurses, circulating nurses, anesthesiologists, perioperative technicians, surgeons, administrators, and schedulers. Consider assigning an extra team member during implementation to increase familiarity with procedures, e.g., setup	(Collar et al., 2012; Francis & Winfield, 2006)
2.2		Foster team familiarity		Team familiarity and stability impacts teamwork, communication, and satisfaction during implementation. Assign a dedicated team for the implementation. Involve and inform this team well.	(Wiegmann et al., 2010)

C	Factor	Activities	Locator table 3	Implementation instructions	Reference example
2.3		Identify affected activities and/or processes	B2.1	Introducing new (medical) equipment influences existing activities and work processes. Identify these and analyze how these processes are affected and which identified stakeholders are involved.	(Kitzmiller et al., 2010)
2.4		Update checklists		Checklists improve safety and reliability prior to, and during surgical procedures. Assess if checklists need to be updated due to the introduction of (medical) equipment and update these according to the procedures to update checklists.	(Kranzfelder et al., 2012b; Verdaasdonk et al., 2009)
2.5		Perform simulations	B2.2	Simulate with involved stakeholders (and departments) how processes and work activities are executed prior to introducing (medical) equipment.	(Baumgart et al., 2007; Woodward et al., 2010)
2.6		Identify and deploy activities to increase employees' engagement		Participation of employees when introducing new (medical) equipment increases employees' engagement. Deploy activities to engage employees, e.g., involvement of work councils, create a communications council.	(Cima et al., 2011)
2.7		Identify and deploy activities to increase employees' adoption		Embedding new (medical) equipment in day-to-day activities as an accepted routine is a challenge. Identify and deploy activities to increase adoption with stakeholders such as demonstrating relative advantages, possibilities to observe and experiment, demonstrate benefits, use training, and assign key users or champions.	(Bouamrane & Mair, 2014; Guédon et al., 2015; Meyfroidt, 2009)
2.8		Communicate with stakeholders		Communication with stakeholders increases engagement and involvement of stakeholders. Communication activities can be: (pre-operative) group briefings, interviewing stakeholders, using videos and newsletters, developing patient centered information.	(Bouamrane & Mair, 2014; Cima et al., 2011; Guédon et al., 2015; Kim et al., 2009; Stefanidis et al., 2014; Wiegmann et al., 2010)

C	Factor	Activities	Locator table 3	Implementation instructions	Reference example
3	Technological preparation				
3.1		Prepare equipment	B3.1; B3.2	Involved stakeholders should be aware what their role is relating to the new (medical) equipment. For instance: nursing personnel should be familiar with the instrumentation needs and they should be proficient in properly connecting, calibrating, set up and use (medical) equipment. Therefore, the device should be introduced and demonstrated properly.	(Francis & Winfield, 2006)
3.2		Consider ergonomic aspects		Positioning of new equipment in the OR requires attention, as space is often limited and involved staff is positioned near the patient. New equipment should not disturb other existing equipment and for example screens and tools should be visible and available for surgical (supporting) staff.	(Lowndes & Hallbeck, 2014; Rivkin, 2009; Zindel, 2000)
3.3		Prepare interfaces with other information systems		Introducing new equipment requires integration in and with other devices in the OR. Consider the connectivity to the clinical networks to ensure safety and reliability.	(Zindel, 2000)
3.4		Integrate device within existing environment	B2.1	The introduction of new equipment affects current workflows and processes. These workflows need to be amended and existing standard operating procedures need to be updated accordingly.	(Kranzfelder et al., 2012b; Lowndes & Hallbeck, 2014; Meyfroidt, 2009; Yusof, 2015)
3.5		Manage generated data		When introducing equipment data can be generated and/or stored, e.g., when introducing a new information system. Consider data processing and security aspects and develop or update procedures.	(Zindel, 2000)
3.6		Interpret screens and troubleshooting		In case of electronic equipment notifications may occur visibly on screens or lights or audibly (alarms). Involved personnel should be able to interpret these notifications and should be able to troubleshoot in case of occurring problems.	(Francis & Winfield, 2006; Kitzmiller et al., 2010; Samii & Gerganov, 2013)

C	Factor	Activities	Locator table 3	Implementation instructions	Reference example
4	Maintenance				
4.1		Set up maintenance program		New equipment in use should be maintained periodically and in case of problems, support should be available. To address and facilitate this, a maintenance program should be set up.	(Francis & Winfield, 2006; Meyfroidt, 2009; Rivkin, 2009)
4.2		Update safety (regulations)		The introduction of new equipment may affect work activities of personnel. Assess the safety procedures and if needed, update these procedures accordingly.	(Kranzfelder et al., 2012b)
5	Training				
5.1		Train involved staff	B2.2; B3.1; B3.2; B4.1 - B4.11	To ensure safety of preparation and use of newly introduced (medical) equipment, involved staff should be trained. Training should be focused on technical skills and non-technical skills. Technical skills may include cognitive, integrative, and automatic skills such as congress visits, demonstrations, research results, online courses, knowledge training, expert opinions, and simulation trainings. Specific trainings on changing ICT and updated workflows and activities should be included as well. Non-technical skills may include decision making, communication and leadership skills	(M. Ahmed et al., 2012; Collar et al., 2012; Crosby & Lane, 2009; Kang et al., 2015; Low, Walker, Heitmiller, et al., 2012)
5.2		Assess Skills	B4.12; B4.13	To assess the readiness for use, a skills assessment program needs be developed and executed, tailored to the stakeholders. This program may include supervisions by co-workers. This assessment program can be developed by the hospital or the manufacturer	
5.3		Evaluate experiences	B4.14	Evaluate experiences and gather feedback regarding the use of the new device, provide input to optimize the device, the use of the device, or the workflow.	

Table 4: Combined implementation protocol for (medical) equipment in the OR
Legend:
First column: table identification letter and identification number per row
Factor: identified implementation factor
Activities: identified implementation activities
Locator table 3: reference to table 3, shown as table identification letter followed by identification number
Implementation instructions: a description of implementation instructions
Reference example: example reference to one or more studies.

Similar to table 2 (protocol A) the combined protocol for implementation in table 4 shows five implementation factors and related activities. Setting up a project plan is one of the factors for implementation of new (medical) equipment. Identifying the purpose of the project, strategic and tactical topics, stakeholders, and performance factors should be included in this plan. Activities needed for implementation are to be identified and included in a project plan.

The second factor concerns preparation of the organization for the introduction of new equipment. Employees are involved in this process and a multidisciplinary team needs to be assembled, which will influence the familiarity of the team members. Preparation of the organization needs analysis, and affected activities and processes need to be identified. Checklists may need to be updated and simulations with new device need to be prepared. Communication activities need to be identified to involve employees and to increase employees' engagement and adoption.

Besides preparation of the organization and its employees, activities involving the technological preparation are required. Equipment needs to be available and prepared, as well as possible ergonomic changes in an OR. Interfacing with other information systems may require attention, prior integrating equipment in the OR-environment. The use of a new device may generate (new) data, and information systems should be prepared and managed. Staff needs to be familiar with the new device and they should be capable to troubleshoot if problems occur. A plan for maintenance of the new equipment should be developed and implemented.

The final implementation factor in table 4, involves training. Survey data shows that training is perceived as an important element of the introduction of equipment. These activities were included in the description regarding training of involved staff. Based on survey data two implementation activities are included in the combined protocol: assessment of skills and evaluation of experiences.

4.4 Discussion

Implementation of technological equipment in highly complex environments such as OR's requires careful preparation, coordination, involvement of stakeholders and training (Tatnall, 2009; Wu & Yezhou, 2011). Implementations of information systems in and outside healthcare have been research topics, and success factors for implementations of these systems have been identified (Bali & Wickramasinghe, 2010). However, research on implementations of (medical) equipment is limited and an integral protocol for implementation of medical equipment omits. In our experience, research on technological advancements and pilot studies in OR's occur often, but it remains difficult to follow up after a pilot study. In our view implementations of equipment in OR's exceed pilot studies regarding use of new equipment and includes integration of this equipment in day-to-day activities, and adoption by involved

staff. In this study, we introduce a holistic protocol for implementation of (medical) equipment in OR's (Protocol C). This protocol is based on a systematic literature review and an explorative survey among surgical supporting staff. In these studies, we explored factors for successful implementations. We reviewed various (case) studies of use and introductions of (surgical) equipment, information systems and quality assessment methods. The literature review resulted in five implementation factors: setting up a project plan, organizational preparation, technical preparation, maintenance, and training. In this protocol (table 4) these implementation factors are included, and implementation activities based on data from a explorative systematic literature review and a survey (table 2 and table 3) are provided. Comparison of survey data with the systematic literature review shows that many identified activities by respondents involve training activities, adjustment of protocols and processes, and involvement of stakeholders, whereas the systematic review provide a broader range of activities, including activities regarding maintenance.

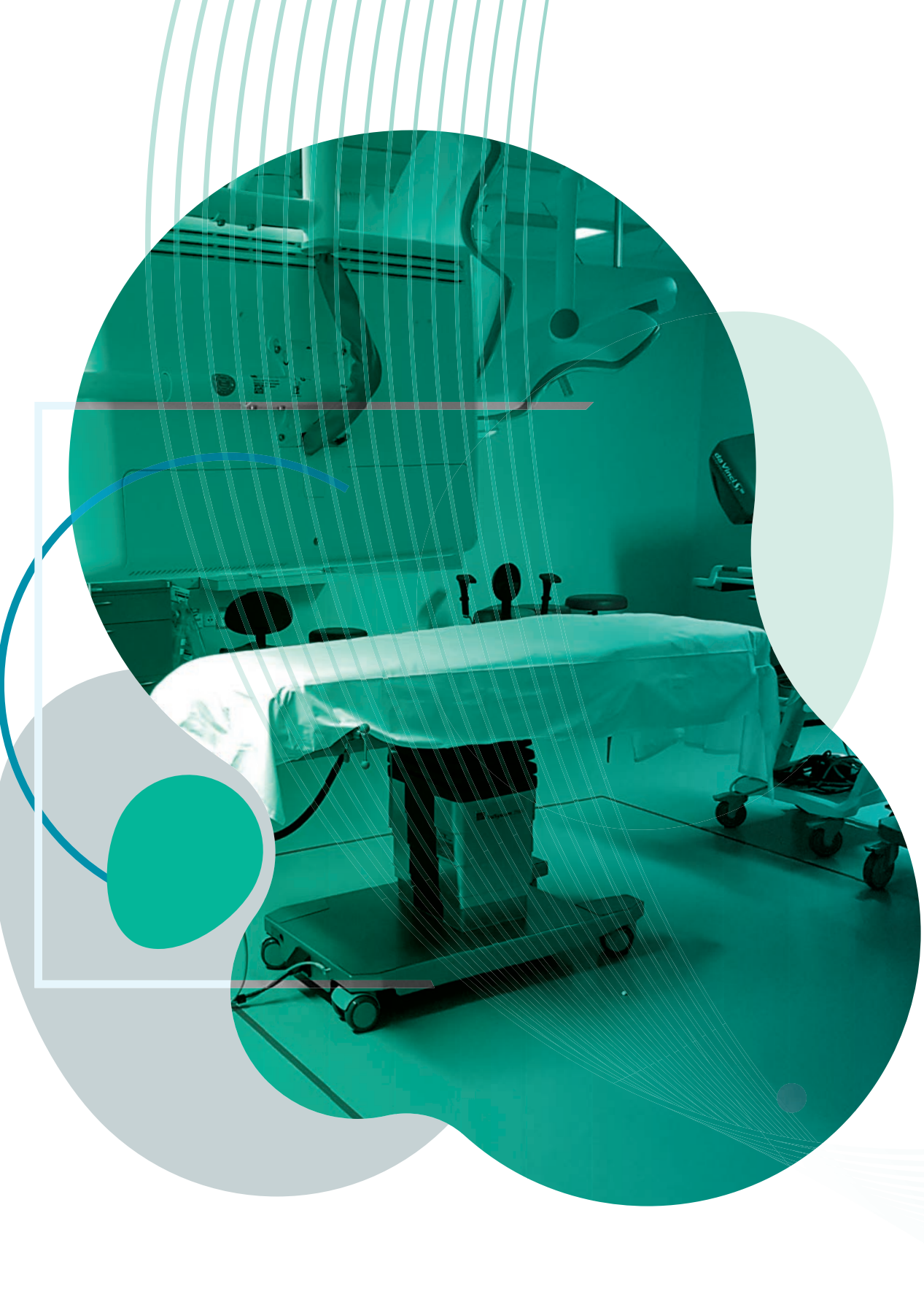
We postulate that the combined implementation protocol as described in table 4,has theoretical and practical relevance (Venkatraman et al., 1993). This protocol for implementation contributes to the theoretical knowledge base, and in practice we consider this protocol to be a baseline for the implementation of (medical) equipment in the OR. We expect that broad use of this protocol will reduce the variety of hospital specific implementation activities, resulting in more standardized implementation activities. As European regulations regarding the use of (medical) equipment are increasing, we expect that standardized implementation activities contribute to the safe use of (medical) equipment in OR's (European Parliament & Council of the European Union, 2017; Regulation of the European Parliament, 2017). Furthermore, we expect that this protocol provides the flexibility for implementation of (medical) equipment and non-(medical) equipment in highly complex environments such as OR's. Survey results show that integration of new equipment in day-to-day activities is a challenge. We expect that use of this protocol will result in integrated activities, more predictable implementation lead times, outcomes, efficiency and adoption (Edmondson et al., 2001).

4.5 Limitations

This protocol is based on various (case) studies of (medical) equipment and an explorative survey among surgical supporting staff. Other members of surgical supporting staff such as anesthetic (supporting) staff, operators of (medical) equipment and other departments are not included in this study. Their input can increase the number of implementation instructions. In this protocol, a distinction in activities for specific (medical) equipment as defined in the CMT and equipment for supporting activities omits. This distinction can be identified in coming studies as this protocol needs validation based on empirical data.

4.6 Conclusion and further research

Implementations of new (medical) equipment in OR's happen in hospitals around the world. Yet, an integral protocol for implementation of new (medical) equipment in OR's omits. Based on a systematic literature review and an explorative survey among surgical supporting staff we composed a protocol for implementation, consisting of five factors and related activities. These factors are setting a project plan, organizational preparation, technological preparation, maintenance, and training. In future studies we will validate this protocol and related activities. We will be using a pilot study of equipment to be introduced in the OR as an explorative case study. With a focus group, we will assess completeness and specificity of this protocol. Furthermore, we plan to validate this protocol by implementing equipment in a hospital according to the included implementation factors, activities, and instructions.



5

EVALUATION OF AN IMPLEMENTATION PROTOCOL FOR DIGITIZATION AND DEVICES IN OPERATING ROOMS

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AMCIS 2021 proceedings. 2.
https://aisel.aisnet.org/amcis2021/healthcare_it/sig_health/2

Abstract

Implementing new information systems and devices, in high-reliability organizations such as operating rooms (OR's) in hospitals, is complex. To improve the success and efficiency of these implementations we constructed a protocol for implementation for digitization and devices in OR's. This protocol consists of implementation factors, implementation activities, and implementation instructions. In this study, we evaluated this protocol. To gather data, we organized three focus group sessions with participants holding different job roles at different departments: a surgeon, a methodologist, anesthesiologists, a scrub nurse, a training officer, innovations officers, and OR-management. We gathered qualitative data regarding completeness, clearness, and the ability to execute. Sessions were video recorded, transcribed, and coded in Nvivo for Windows according to Toulmins Argumentative Pattern. Based on this analysis, revisions to factors, activities, and instructions are presented for protocol enhancement; experts confirm that an implementation protocol is needed to increase implementation efficiency and adoption of new devices.

This work was originally published as: Sewberath Misser, N., Jaspers, J., Van Zaane, B., Gooszen, H., & Versendaal, J. (2021). Evaluation of an implementation protocol for digitization and devices in Operating Rooms. AMCIS 2021 Proceedings, 0–10. https://aisel.aisnet.org/amcis2021/healthcare_it/sig_health/2

5.1 Introduction

Health information systems (HIS) and other devices are used in hospitals for patient-related and non-patient related activities. Manufacturers and hospitals invest to enhance medical equipment and information systems to support these surgical activities, for example use of robotics during surgeries, or an increased use of imaging support for development of patient specific implants (Ruurda, Draaisma, van Hillegersberg, Borel Rinkes, et al., 2005; Willemsen et al., 2019). HIS for supporting staff, such as scrub nurses or logistics employees in operating rooms (OR's), are increasingly available to support logistics inventory processes for example tools to record surgical instruments prior to and during surgery (Guedon et al., 2015). In our study, we focus on implementations of health information technology and devices in OR's of hospitals. OR's are considered to be high reliability departments, where complex activities (surgeries) are performed supported by complex technology and interdependent processes (Roberts, 1990). According to Edmondson (2001) implementations involve integration of new tools and systems in day-to-day activities (Edmondson et al., 2001). We observed that challenges arise when information systems or other devices on the market need to be implemented in hospitals and OR's. Adoption of these new systems and devices remain a challenge and in literature various factors to increase adoption have been identified (Fennelly et al., 2020; Venkatesh, 2015). To facilitate implementations and to address adoption of new systems and devices, we constructed an implementation protocol for digitization and devices in OR's. In this protocol, we distinguish and describe implementation factors, activities and we provided instructions for implementation. The purpose of this study is to evaluate and refine this protocol and the research question for this study is:

- To which extent is our protocol for implementation valid for use according to experts?

To answer this question, we firstly focus on the background of our implementation protocol. In the next sections, we describe our study procedure to evaluate this protocol with focus groups. We will present results and provide adjustments. Finally, we will draw conclusions and describe possibilities for future research.

5.2 Background

We used Hevner's et al. (2004) model for design research to develop an artifact: a protocol for implementation of digitization and devices in OR's (Hevner et al., 2004). We based this protocol on a systematic literature review and outcomes of a survey among scrub nurses and surgeons. Based on this review, we determined success factors for implementation of new tools, medical and information systems in OR's (Sewberath Misser, Jaspers, et al., 2018; Sewberath Misser, Zaane, et al., 2018; Stefanidis et al., 2014). Based on these studies we developed an initial version of our protocol for implementation (Sewberath Misser et al., 2020).

5.2.1 A protocol for implementation

The initial version of our protocol for implementation consists of implementation factors, factor-related activities, and activity-related instructions. Identified implementation factors are 1) set up a project plan, 2) organizational preparation, 3) technical preparation, 4) maintenance plan, 5) training plan. In the description of these factors, we also present factor-related activities, and activity-related instructions (Sewberath Misser et al., 2020).

The first factor entails setting up a project plan and related activities are identifying strategic and tactical topics regarding implementation of the tool. Another activity related to this factor is to identify performance indicators referring to success of the implementation project with reference to efficiency, finance, ergonomics. Instructions state that identified performance indicators should be measured and analyzed accordingly. Other activities include identification of relevant implementation activities for the project, identification of potential risks, and identification of stakeholders such as sponsors, champions, involved staff, and teams. The second implementation factor addresses organizational preparation for implementation, with activities focusing on the project team, affected processes, and stakeholders. Team-oriented activities include assembling a multidisciplinary implementation team in which various stakeholders of involved departments are represented such as scrub nurses, surgeons, anesthesiologists, perioperative technicians, information system experts. Process-related activities involve identification of affected activities and/or processes caused by implementation of an information system or tool. Affected stakeholders need to be identified as well and based on this information, available checklists and/or protocols need to be assessed whether updates are necessary. Prior to going live with the new tool or information system, involved stakeholders need to simulate updated activities, checklists and protocols. As part of the organizational preparation, activities to increase employees' engagement towards implementation and use of the new system need to be identified and deployed. The third factor involves technological preparation, with activities related to (technological) preparations of the tool, interfaces with other information systems, ergonomics, data management, and troubleshoots. As the OR environment is a clean room, specific requirements and protocols for hygiene are in place. Involved personnel in the OR should be aware of their expected role and activities in relation to the new system, screen or device, for instance nursing staff should be proficient in setting up, connecting, and calibrating the tool or equipment. When space is limited, for instance in the sterile surgical area, ergonomic aspects for staff need to be considered. Screens should be clearly visible for the operator and other instruments should remain within reach as well. Staff should be able to interpret data presented on screens, interpret (audible) alarms (if applicable), and should be able to solve occurring problems. Integration of a new system or device within an OR-environment may require interfacing with existing clinical information systems and updating existing (digital) workflows and operating

procedures may be necessary. In case of impact on data management, existing data management procedures need to be updated. The fourth factor describes the necessity of a maintenance plan and updates to existing safety regulations. The fifth factor for implementation focuses on training of involved staff. Implementation activities include training, assessments, and evaluations of user experiences.

5.3 Method

In this study we focus on evaluation and justification of our developed artefact (Hevner, 2007; Hevner et al., 2004). Edmondson & McManus (2007) consider three archetypes for field research: nascent, intermediate, and mature research. With the protocol for implementation as developed artefact and based on a literature review and completed survey results, this research is considered intermediate. For intermediate research, qualitative research methods qualify to collect data (Edmondson & Mcmanus, 2007). We used purposeful sampling to identify respondents, involving stakeholders within the hospital, inside and outside the OR (Bryman & Bell, 2007; Patton, 2002). Stakeholders with experience, knowledge, or involvement with implementations of new systems and tools in OR's were identified and included. For data-collection purposes, we considered individual data collection with interviews or group data collection. Due to the multidisciplinary nature of this protocol for implementation, and expertise of the different stakeholders, group data collection with focus groups would address the research question. According to Gill et al. (2008) focus groups are common methods used in healthcare research and these focus groups can be used to clarify, qualify or challenge data collected through other used methods (Gill et al., 2008; Robinson, 1999). Based on Morgan (1997), we set up a study procedure consisting of three main sections 1) introduction and organization 2) planning, quality assurance and resources, and 3) data processing, analysis and reporting (Morgan, 1997). In the first section, we explained the purpose of this study and we identified the involved research team consisting of the research team (authors) supported by three research assistants. The research team identified participants for three focus groups, according to the inclusion criteria for purposive sampling. We selected participants fulfilling different roles and from different departments and organizations, with knowledge or experience with implementations of tools and equipment in OR's from two academic hospitals, a research center and an innovation center, all based in The Netherlands. Prior to each session, we shared various documents with participants to increase reliability of the data gathering process. In these documents, we explained the procedure and included questions that operationalized the main research question. These questions were open-ended questions referring to completeness, clarity, and the ability to execute activities or instructions. In each session, each factor for implementation, factor-related activities, and activity-related instructions would be discussed, followed by a general wrap up. In the second section of the study procedure, we predefined roles of research assistants:

research assistants were involved in preparing the discussion room, distributing printed material and they recorded these sessions, kept time, and kept notes. The primary researcher (first author) was moderator of these focus group sessions. In the third section of the study procedure, we described details regarding data processing and analysis: a transcript of each recorded session, followed by a coding process by research assistants. The primary researcher reviewed and analyzed coding results and these results were discussed with members of the research team. This study procedure was firstly peer-reviewed by experienced fellow research colleagues and secondly by the research team to increase rigor and credibility; the study procedure was refined based on their findings (Morgan, 1997; Morgan & Hoffman, 2010).

5.3.1 Data gathering, processing and analysis

Each focus group session was executed in the Dutch language. After a short introduction and an explanation of the procedure, each factor for implementation, corresponding activities, and instructions were discussed chronically. Each session was debriefed with another member of the research group and recordings were stored for data processing and data analyses. To ensure validity and to increase reliability of our analysis, each video recorded session was transcribed in MS Word 2016; these transcripts were imported in the software program Nvivo for Windows version 12 (Bryman & Bell, 2007; Long & Johnson, 2000; Noble & Smith, 2015). The transcripts were coded according to Strauss and Corbin's (1990) process of coding. Generally, a coding process consists of three cycles: open coding, axial coding and selective coding (Strauss & Corbin, 1990). During the first coding cycle, open coding, transcripts were coded according to the structure of the protocol for implementation: per activity per implementation factor. During the second cycle of coding, transcripts and codes were discussed, and additional codes according to Toulmins Arguments Pattern (TAP) were added (Erduran, 2004; Kneupper, 1978). Toulmins Arguments Pattern consists of three elements, claims, grounds, and warrants. Claims are general assertions made public, which are supported by facts as grounds. The warrant provides the link between claims and grounds for example an authority who asserts a grounded claim. As participants were experienced in introducing new tools in hospitals, they are considered experts; related to TAP these experts acted as warrants. TAP was used in the second and last coding cycle, respectively axial coding, and selective coding. Transcripts of the sessions were coded according to the codes 'completeness', 'clarity' and 'the ability to execute in practice'. The code 'completeness' was to check whether all necessary information was included in descriptions; the code 'clarity' refers to a clear description and the code 'ability to execute' refers to use of the activity or instruction in hospital practice. In the last coding cycle, selective coding, we analyzed and discussed different codes, with the purpose to evaluate and refine the protocol for implementation. In this analysis, we compared claims and grounds of implementation factors, factor-related activities, and activity-related instructions. Outcomes of these analyses were grounded claims, resulting in adjustments to

refine the contents of the protocol for implementation. These adjustments refer to factors for implementation, implementation activities, and instructions; in this paper, ungrounded claims are not reported.

5.4 Results

Sixteen different participants with different roles and expertise contributed in three focus group sessions. Table 1 provides participant information, including roles and information about the represented organization.

Session	Participants	Participants' roles
I	4	Anesthesiologist (Academic hospital 1) Clinical physicist (Academic hospital 1) Clinical information systems manager (Academic hospital 1) Medical technological advisor on clinical information systems (Academic hospital 1)
II	6	OR management (Academic hospital 2) Quality Assurance officer / scrub nurse (Academic hospital 1) Anesthesiologist (Academic hospital 1) Logistics coordinator (Academic hospital 1) Educations officer for scrub nurse training plan (Academic hospital 1) Technological innovations officer (Innovation Center)
III	6	Surgeon, professor in gynecology (Academic hospital 1) Methodologist for clinical research, assistant professor (Research Center) Process improvement officer (Academic hospital 1) Quality officers Sterilization department (2) (Academic hospital 1) Technological innovations officer (Innovation Center)

Table 1 Focus group sessions and participants

In the next sections, we present results of three focus group sessions. Each section refers to an implementation factor and, in these sections, revisions for factor-related activities and activity-related instructions are presented.

5.4.1 Implementation factor 1: Set up a project plan

The participants indicated that the description of the first implementation factor, '1. set up a project plan', needed clarification. They explained that an implementation is a phase of a larger project plan and that the description for this factor should be: 'set up a plan for implementation'. Participants (warrants) provided founded claims regarding activities '1.1 identifying strategic and tactical topics' and '1.2 identifying performance indicators'. They explained that a project plan is set up to develop or acquire a tool; implementation of the tool generally is a stage of a larger project (ground). Consequently, instructions in the protocol referring to this activity, needed clarification and adjustment: Strategic and tactical topics and performance indicators need alignment with overall project and organization goals. These topics and indicators can be operationalized in detail in this plan for implementation. The

description ‘1.2 identify performance’ was not described clearly and the description should be: ‘1.2 identify performance indicators’. In the current instructions, these performance indicators relate to the performance and use of the tool. Participants indicated that an instruction regarding the implementation process should be added ’identify performance indicators for the implementation project’. Instructions related to activity ‘1.3 identify stakeholders’ need to be completed with ‘identify a project manager for implementation’. Instructions referring to activity ‘1.4 identifying risks’ should be amended and clarified as risks of the project should have been addressed in an earlier stage of the project. The focus of instructions in this phase of a project should be: ‘1.4 Identify risks related to the implementation of the tool’. Instructions related to the last activity ‘1.5 identify activities for implementation’ should be completed with a planning and/or timeline for implementation activities. Revisions related to this factor, activities and instructions are included in Table 2: Revised activities and instructions implementation factor 1 ‘setup a project plan for implementation’.

Id	Activities for implementation	Instructions for implementation
1.1	Identify strategic and tactical topics	Operationalize overall strategic and tactical goals for the implementation stage.
1.2	Identify performance	Identify performance indicators define the performance of the implementation stage and define how these variables are measured and analyzed. Performance metrics for success could be efficiency, finance, and ergonomics.
1.3	Identify stakeholders	Identify (groups of) stakeholders, which are responsible, accountable, consulted and informed such as sponsors, champions, staff, teams. Identify a project manager for implementation
1.4	Identify risks related to implementation	Perform a risk assessment to identify risks and identify unintended outcomes as new technology may have unforeseen consequences.
1.5	Identify activities for implementation	Identify relevant activities for implementation, based on listed activities. Generate a planning or timeline for execution of these activities.

Table 2 Revised activities and instructions implementation factor 1 ‘setup a project plan for implementation’

5.4.2 Implementation factor 2: organizational preparation

The second implementation factor ‘2. organizational preparation’ was discussed and no remarks were made to the description of this this factor. The activities and instructions were discussed in detail, and regarding the first activity, ‘2.1 assemble a multidisciplinary team’, clarification was needed. Participants perceived ‘multidisciplinary teams’ ambiguous, because various multidisciplinary surgical or dedicated teams exist to perform complex surgeries. Based on these claims and grounds the description of this activity should be: ‘2.1 assemble a multidisciplinary *implementation* team’. Similarly, the second activity ‘foster team familiarity’ needed

clarification and adjustment. Following Kangs proposition (2015), that team familiarity increases performance of a surgical team, this instruction was initially included as activity for implementation (Kang et al., 2015). Clarification for the instructions entail that activities to improve team familiarity should be organized for the implementation team: activities need to be identified and executed for staff. Regarding the activity '2.3 identify affected activities and/or processes' no amendments were suggested. The activity '2.4 update checklists' needed clarification, because checklists in OR's may refer to (standardized) surgical checklists such as the WHO standardized checklist for safe surgery (WHO Patient Safety & World Health Organization, 2009). For the purpose of this protocol for implementation, this activity should be amended to '2.4 update existing protocols and/or checklists'. Instructions should indicate 'update operating procedures or protocols. If necessary, existing checklists need to be updated'. Clarified instructions related to the activity, '2.6 identify and deploy activities to increase employees' engagement' refer to *employees in an OR,* rather than employees in general. The activity '2.7 identify and deploy activities to increase employees' adoption' and related instructions, remain unchanged as no changes were advised. Instructions related to the activity 'communicate with stakeholders' should be amended and the adjusted instruction is 'set up a communications plan, consisting of communication activities over time'. A summary of these results are included in table 3: Revised activities and instructions implementation factor 2 'organizational preparation'.

5.4.3 Implementation factor 3: technological preparation

The next factor for implementation is '3. Technological preparation'. Instructions related to the first activity '3.1 prepare equipment' needed adjustment and clarification. The current instructions referred communication activities and participants indicated to move these activities to instructions related to the activity '2.8 communicate with stakeholders' (see table 2). An instruction to 'prepare technical facilities related to the use of equipment in the OR e.g. power and plugs (if needed)' should be added to this instruction. Instructions related to the activity '2.2 Consider ergonomic aspects' needed clarification: generally, changing ergonomic aspects should be considered in an early stage of an overall project. Prior to going live with the tool, ergonomic changes in the OR caused by the new tool should be considered (see '2.5 perform simulations'). No changes are advised for the activities or instructions related to '3.3 prepare interfaces with other information systems', '3.4 integrate device within existing environment', and '3.5 manage generated data'. With reference to activity '3.6 interpret screens and troubleshooting', participants indicated that this activity should be moved to implementation factor '5 training'. A summary of these results are included in table 4: Revised activities and instructions implementation factor 3 'technological preparation and evaluation.

Id	Activities for implementation	Instructions for implementation
2.1	Assemble a multidisciplinary implementation team	Assemble a team in which included various members of involved departments and stakeholders such as scrub nurses, circulating nurses, anaesthesiologists, perioperative technicians, surgeons, administrators, IT specialists, and schedulers. Consider assigning an extra team member during implementation to increase familiarity with procedures, e.g., setup procedures.
2.2	Foster team familiarity	Team familiarity and stability impacts teamwork, communication, and satisfaction during implementation. Assign a dedicated implementation team. Involve and inform this team well.
2.3	Identify affected activities and/or processes	Introducing new (medical) equipment influences existing activities and work processes. Identify these and analyze how these processes are affected and which identified stakeholders are involved.
2.4	Update checklists and/or protocols	Checklists improve safety and reliability prior to, and during surgical procedures. Update operating procedures or protocols. If necessary, update existing check lists.
2.5	Perform simulations	Simulate with involved stakeholders (and departments) how processes and work activities are executed prior to introducing (medical) equipment. Practise with a new tool or new (prototype) equipment on trial basis.
2.6	Identify and deploy activities to increase employees' engagement	Participation of employees when introducing new (medical) equipment increases employees' engagement in the OR. Deploy activities to engage employees in the OR, e.g., involvement of work councils, create a communications council.
2.7	Identify and deploy activities to increase employees' adoption	Embedding information systems or new (medical) equipment in day-to-day activities as an accepted routine is a challenge. Identify and deploy activities to increase adoption with stakeholders such as demonstrating relative advantages, possibilities to observe and experiment, demonstrate benefits, use training and assign key users or champions.
2.8	Communicate with stakeholders	Communication with stakeholders increases engagement and involvement of stakeholders. Set up a communications plan, consisting of communication activities over time. Involved stakeholders should be aware what their role is relating to the new (medical) equipment. For example, nursing personnel should be familiar with the instrumentation needs and they should be proficient in properly connecting, calibrating, set up and use (medical) equipment. Communication activities can be: (pre-operative) group briefings, interviewing stakeholders, using videos and newsletters, developing patient centered information.

Table 3 Revised activities and instructions implementation factor 2 'organizational preparation'

Id	Activities for implementation	Instructions for implementation
3.1	Prepare equipment	Prepare technical facilities related to the use of the information system or device in the OR e.g. power and plugs (if needed)
3.2	Consider ergonomic aspects	Introducing a new tool or system may affect ergonomic aspects of staff in the OR. Consider these aspects in an early stage of the project, prior to implementations. Simulations may lead to ergonomic changes and positioning of tools in the OR.
3.3	Prepare interfaces with other information systems	Introducing new equipment requires integration in and with other devices in the OR. Consider the connectivity to the clinical networks to ensure safety and reliability.
3.4	Integrate device within existing environment	The introduction of new equipment affects current workflows and processes. These workflows need to updated, and existing standard operating procedures need to be updated accordingly.
3.5	Manage generated data	When introducing equipment data can be generated and/or stored, e.g. when introducing a new information system. Consider data processing and security aspects and develop or update procedures.
3.6	Set up maintenance plan	New equipment in use should be maintained periodically and in case of problems, support should be available. To address and facilitate this, a maintenance plan should be set up. Provide instructions how to maintain (clean) tools/equipment such as screens in the OR and state who is responsible for this activity.
3.7	Update safety (regulations)	The introduction of new equipment may affect work activities of personnel. Assess the safety procedures and if needed, update these procedures accordingly.

Table 4 Revised activities and instructions implementation factor 'technological preparation and evaluation'

5.4.4 Implementation factor 4: maintenance

The factor for implementation 'Maintenance' was discussed during sessions, including activities and instructions. Participants indicated that these activities should be part of the technological preparation and therefore, and they indicated to move maintenance activities to implementation factor '3. Technological preparation'. One instruction needs to be added to the activity '4.1 set up maintenance plan': 'provide instructions how to maintain (clean) the new tool and equipment in the OR and state who is responsible'. No other clarifications or adjustments were advised related to activity '4.2 adjust safety regulations'. A summary of these results are included in table 4 (activity 3.6 and activity 3.7).

5.4.5 Implementation factor 5: training

The last factor for implementation in this protocol is '5. training'. According to findings instructions related to activity '5.1 train involved staff' should be: '(Recurrent) training is crucial for correct and safe use of the tool, but also for success of the implementation'. During the sessions, participants focused on the need for recurrent trainings with reference to the use of tools and equipment. Activity '5.2 Assess skills' is part of the

factor training. Participants advised to clarify related instructions: 'An assessment plan can be determined and executed by manufacturer, hospital and/or department'. The next instruction needs adjustment: '(if applicable) assessed skills need to be recorded and tracked'. Regarding the instructions related to activity '5.3 evaluate experiences', participants advocated that the implementation process should be evaluated as well. Therefore, an instruction should be added: 'Evaluate the implementation process and relate to performance indicators mentioned in the implementation plan'. A summary of the results of these sessions are included in table 5: Revised activities and instructions implementation factor 4 'training and evaluation'.

Id	Activities for implementation	Instructions for implementation
4.1	Train involved staff	(Recurrent) training is crucial for correct and safe use of the system or tool, and affects adoption and success of an implementation. Training focuses on technical skills and non-technical skills. Technical skills may include cognitive, integrative, and automatic skills such as congress visits, demonstrations, research results, online courses, knowledge training, expert opinions, and simulation trainings. Specific trainings on changing ICT and updated workflows and activities should be included as well. Non-technical skills may include decision making, communication and leadership skills.
4.2	Interpret screens and troubleshooting	In case of electronic equipment, notifications may occur visibly on screens, lights, or audible (alarms). Involved personnel should be able to interpret these notifications and should be able to troubleshoot in case of occurring problems.
4.3	Assess Skills	To assess the readiness for use, a skills assessment plan needs be developed and executed, tailored to the stakeholders. This plan may include supervisions by co-workers. An assessment plan can be determined and executed by a manufacturer, the hospital, or a department. (if applicable) Assess whether skills need to be recorded and tracked.
4.4	Evaluate experiences	Evaluate experiences and gather feedback regarding the use of the new device, provide input to optimize the device, the use of the device or the workflow.
4.5	Evaluate implementation process	Evaluate the implementation process and relate results to the performance indicators mentioned in the implementation plan.

Table 5 Revised activities and instructions implementation factor 4 'training and evaluation'

5.5 Conclusions

The purpose of this study was to evaluate to which extent this protocol was ready for use according to experts and to refine the composed protocol for implementation. This research question was operationalized in sub questions to identify completeness, clarity, and ability to execute in hospital practice. We gathered data in three multi-disciplinary focus group sessions and based on our analysis and results we conclude that factors, activities, and instructions are executable in hospital practice. Based on our analysis, the adjusted protocol should consist of four factors, related activities,

and instructions: 1. Set up an implementation plan, 2. Organizational preparation, 3. Technological preparation, 4. Training and evaluation. Based on the findings of this study, we revised factors, activities, and instructions for implementation. In table 2 to table 6, we described revisions in factors, activities, and instructions to complete this protocol and to increase clearness for use. Based on the results of this study, we propose using this protocol in hospital practice.

5.6 Limitations and further research

Although this study was carefully prepared and executed, this study is not without limitations. To reduce researchers' bias, a peer-reviewed study procedure was set up. Documents were sent beforehand to increase reliability of data during sessions and to reduce steering during discussions. The primary researcher moderated these sessions according to the predefined procedure and distributed questions. To increase validity, three sessions were organized to reach saturation in data. Gathered data was transcribed based on video and audio recordings and three research assistants coded these transcripts. These assistants gained experience in conducting, transcribing, and coding of focus groups in other research sessions and their knowledge of this implementation protocol was limited at the start of this study. As use of technology in surgical and non-surgical processes is increasing, participants confirmed a need of a protocol to facilitate implementations to increase efficiency, adoption, and quality. Participants prefer an agile tool for implementation with features to tailor implementation activities to the users' needs. In addition, they expressed a need for a protocol in which activities are organized in order of occurrence rather than categorization per factor for implementation. We shall address this need in further research. Other aspects for investigation are the sudden and fast introductions (and adoption) of new tools and communication equipment in hospitals due to the current Covid-19 measures, for example communication tools and tools to support distant working to facilitate staff and patients (Igra et al., 2020). As our protocol facilitates implementation, to reduce implementation lead times, and to increase success, and adoption of new tools, new research questions arise to investigate these rapid implementation successes. In future research, we can relate these phenomena to our identified factors, activities, and instructions for implementation.

6

EVALUATING AN IMPLEMENTATION PROTOCOL FOR DIGITIZATION AND DEVICES IN OPERATING ROOMS: A CASE STUDY

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Bled 2021 Proceedings
DOI https://doi.org/10.18690/978-961-286-485-9.26

Abstract

Digitization of activities in hospitals receives more attention, due to Covid-19 related regulations. The use of e-health to support patient care is increasing and efficient ways to implement digitization of processes and other technological equipment are needed. We constructed a protocol for implementation and in this study, we evaluate this protocol based on a case to implement a device in the OR. We used various data sources to evaluate this protocol: semi-structured interviews, questionnaires, and project documents. Based on these findings, this protocol, including identified implementation activities and implementation instructions can be used for implementations of other devices. Implementation activities include setting up a project plan, organizational and technological preparation, maintenance, and training. In future research, these activities and instructions need to be evaluated in more complex projects and a flexible tool needs to be developed to select relevant activities and instructions for implementations of information systems or devices.

This work was originally published as: Sewberath Misser, N., Jaspers, J., van Zaane, B., Gooszen, H., & Versendaal, J. (2021). Evaluating an Implementation Protocol for Digitization and Devices in Operating Rooms: a Case Study. 34th Bled EConference Digital Support from Crisis to Progressive Change: Conference Proceedings, 351–364. https://doi.org/10.18690/978-961-286-485-9.26

6.1 Introduction

Digitizing health care activities within hospitals to support hospital and patient care have been of increasing interest due to the Covid-19 pandemic and related regulations. The Covid-19 pandemic shows the need for rapid implementation of digitized processes, information systems or devices in hospitals (Meyer et al., 2020; Rodriguez Socarrás et al., 2020). Digitizing activities or processes generally require well-planned development activities and implementation of digitized processes require well-prepared implementation activities in order to reach identified goals and to improve adoption among users (Fennelly et al., 2020). Edmondson (2001) describes the implementation of technological equipment as the integration of new technologies in day-to-day activities in an organization (Edmondson et al., 2001). Technological equipment includes technological devices and (medical) information systems. To support implementation of technological devices and digitization in hospitals, such as telehealth, electronic health records, management information systems, we constructed a protocol for implementation with a focus on the Operating Room department (OR) in hospitals (Dutch Hospital Association, 2016). This protocol consists of implementation factors, implementation activities, and implementation instructions (Sewberath Misser et al., 2020). These factors, activities and instructions are based on a systematic literature review and a survey completed by scrub nurses and circulating nurses (Sewberath Misser, Jaspers, et al., 2018; Sewberath Misser, Zaane, et al., 2018). The purpose of this study is to evaluate and refine this protocol for implementation and the research question for this study described as:

- To which extent is our protocol for implementation ready for use in practice, based on real life case studies?

To address this question, we describe the method and research instruments in the second section of this article. In the third section, we introduce a case and in section four, we evaluate our protocol for implementation based on implementation experiences and results. Finally, we will draw conclusions and describe possibilities for future research.

6.2 Method

In previous studies, we used focus groups with experts to evaluate this protocol for implementation. In this study, we address the research question by focusing on the evaluation of this protocol for implementation in actual projects. This study consisted of three stages: 1) setting up a study procedure, 2) data gathering, 3) data processing, and analysis.

6.2.1 Setting up a study procedure

We set up a study procedure consisting of sections regarding general information, procedures, research instruments and data analysis guidelines (Maimbo & Pervan, 2005; Yin, 2018). We selected a project for use of the protocol for implementation based on scope, implementation period and feasibility. Projects or cases entailed the implementation of a new device or digitization of a process in the OR, with a limited number of stakeholders during implementation. These cases needed to be implemented between March and April 2020. The selected case for this research involved using the protocol for a pilot study to introduce an exoskeleton for surgical supporting staff. A project leader was assigned to implement an exoskeleton in the OR for selected surgeries. The timeframe for data collection and reporting was extended up until December 2020.

6.2.2 Data gathering

In our study procedure, we considered and selected different instruments to gather data and to ensure quality and rigor: semi-structured interviews, questionnaires, and project documents.

1. Interview with a project leader. In a semi-structured interview, we focused on clearness, completeness, and ease of use of included factors, activities and instructions for implementation. The interview was digitally conducted with MS Teams due to Covid-19 measures.
2. Questionnaires. We composed questionnaires based on the technology assessment model, in which we focus on the intended use, perceived ease of use, and perceived usefulness. These questions could be scored on a lickert 5-points scale and participants were able to add comments to clarify their responses (Gagnon et al., 2012; Heijden, 2004; Tantiponganant & Laksitamas, 2014; Wu & Wang, 2005). We developed two sets of questionnaires respectively for project leaders and users. In the questionnaire for project leaders, we focused on the use of the implementation protocol and the questionnaire for users had a focus on the implemented tool.
3. Project documents. Project documents created during and after completion of the project relating to the implementation of the device were used as data source.

6.2.3 Data processing and analysis

Collected questionnaires were processed in MS Excel and the interview with the project leader was video recorded and transcribed in MS Word. This interview was conducted in the Dutch language. Evaluation results based on this case are described according to the structure of the protocol for implementation. Following the analysis of these results, suggestions for refinement for the protocol for implementation are provided.

6.3 Case: implementation study of the Leavo Exoskeleton

An exoskeleton is a wearable, mechanical external structure that enhances or supports the power of a person. Exoskeletons can be either 'active' or 'passive'. Active exoskeletons enhance human power with use of for example electric motors, hydraulic actuators, or other types of power. A passive exoskeleton is a mechanical structure using materials such as springs, belts or dampers to support a posture or a motion (Looze de *et al.*, 2016). The Leavo exoskeleton (see figure 1) can be classified as a passive exoskeleton, which supports chest and back. This wearable relieves back and spine muscles and which should reduce back pain and increase durability of people who frequently carry heavy items or keep static positions (Koopman et al., 2019).

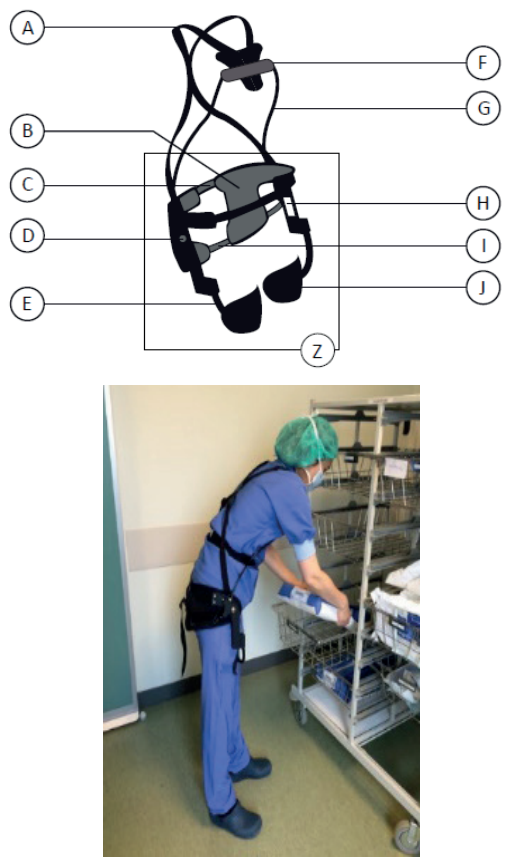


Figure 1: Leavo exoskeleton.
Legend: A Suspender; B Hip pads ; C Hip belt; D Smart joint ; E Leg structure; F Chest pad; G Torso structure; H Label ; I Buck belt; J Leg pad; ; Z Hip assembly
Source: http://www.Leavo.nl

In the OR, scrub nurses and circulating nurses prepare surgeries by setting up surgical instruments prior to surgeries. These instruments are stored in metal instrument baskets, which vary in weight. Depending on the surgical discipline, it often occurs that scrub nurses keep static positions during a surgical procedure. For the purpose of this study, the hospital (client) acquired four exoskeletons for use by scrub and circulating nurses in the OR and the client defined the data collection period. The novelty of this study is that this exoskeleton was used for the first time in an OR-setting. The client and the human resources department (HR) recruited and assigned a project leader. The first author informed the project leader via e-mail about the study procedure, the protocol for implementation, and the data gathering process. In a briefing session, the implementation protocol was explained, as well as the study procedure. As part of this study, the project leader used the protocol for implementation of the device, to complete the questionnaire for project leaders, and to distribute and collect questionnaires for users. Together with the HR-department, the project leader recruited four users for this device. For the purpose of our study, we interviewed the project leader after completion of the implementation. The project leader completed a questionnaire and users of the exoskeleton completed two out of four distributed questionnaires.

6.4 Evaluation results

The protocol for implementation consists of five factors for implementation, with related implementation activities and instructions for implementation. The factors for implementation are: 1.) setting up a plan, 2.) organizational preparation, 3.) technological preparation, 4.) maintenance, and 5.) training and evaluation. In the next paragraphs, we describe evaluation results regarding of the use of this protocol based on the introduction of an exoskeleton.

6.4.1 Evaluating implementation factor: set up project plan

The first factor for implementation refers to setting up a project plan. The interview with the recruited project leader shows that implementation activities such as 1.1 identifying strategic and tactical topics, and 1.2 identify performance, were determined in previous stages of the implementation project. The activities 1.3 identifying stakeholders and 1.4 identifying risks evolved during the implementation process, as the number of stakeholders increased as the project progressed. Identified stakeholders were client, HR, researchers, users of the device. During the interview, the project leader stated that these activities and instructions were clearly described, complete, and ready for use. In table 1, implementation activities for the first implementation factor are described.

Id	Description of activities
1.1	Identify strategic and tactical topics
1.2	Identify performance
1.3	Identify stakeholders
1.4	Identify Risks
1.5	Identify activities for implementation

Table 1. Factor 1: set up a project plan and related activities.

6.4.2 Evaluating implementation factor: organizational preparation

The project leader was responsible for the organizational preparation related to the introduction of this device. Together with stakeholders (client, HR and OR-team), three types of surgeries were selected to use this exoskeleton: vascular surgery, orthopedic surgery and cardiothoracic surgery. These surgeries were selected based on the duration of surgeries, positioning of the scrub nurse during surgeries and usage of instruments. The project leader assembled an implementation team (see table 2, activity 2.1) by recruiting four scrub nurses to use an exoskeleton prior to and during surgeries. The project leader was able to foster team familiarity (activity 2.2), as she provided instructions how to use the device and as she responded to users' queries. After the introduction of the device, scrub nurses were able to identify the affected activities (activity 2.3) caused by the new device, such as preparatory activities to assemble and to wear the device. According to the project leader, existing checklists or procedures completed by scrub nurses or circulating nurses were not updated (activity 2.4). She stated that simulations or sessions to practice (activity 2.5) were scheduled to identify the performance of the device and to assess whether the project goals could be met. In the interview, the project leader expected a gradual increase in adoption of the device. She expected an increased use of the device, as the intention of this device was to provide support during lifting and static positions. In contrast to her expectation, her encouragement and guidance was needed to convince users to use the device. This encouragement was needed due to some technical difficulties and extra work (activities 2.6, 2.7 and 2.8). After completion of the project, scrub nurses completed questionnaires and they confirmed that the project leader was responsive and available for questions and guidance. This evaluation shows that identified activities and instructions, related to the implementation factor organizational preparation, are ready to be used in practice.

Id	Description of activities
2.1	Assemble a multidisciplinary implementation team
2.2	Foster team familiarity
2.3	Identify affected activities and/or processes
2.4	Update checklists
2.5	Perform simulations
2.6	Identify and deploy activities to increase employees' engagement
2.7	Identify and deploy activities to increase employees' adoption
2.8	Communicate with stakeholders

Table 2. Factor 2: Organizational preparation and related activities.

6.4.3 Evaluating implementation factor: technological preparation

The third implementation factor, related activities, and instructions involve the technological preparation of the device and its environment. To prepare the device for use, the manufacturer of the exoskeleton tailored and adjusted each device to each users' body type (activity 3.1 in table 3). Ergonomic aspects for use were considered, according to the project leader (3.2) as the device supported static positions and heavy lifting (see figure 1). With reference to the information systems (IT) environment, no interfaces were needed, and no electronic data was generated, as the exoskeleton is classified as a mechanical device (activities 3.3 and 3.5). As the project progressed, integration of the device in the existing working environment (activity 3.4) was increasingly relevant after introduction. During the project, various troubleshooting challenges occurred: when lead aprons were used during surgeries to reduce effects of x-rays, the exoskeletons were difficult to adjust and wear. In simulations and during execution of regular activities, users had trouble with rotating movements when wearing the device (activity 3.6).

Id	Description of activities
3.1	Prepare equipment
3.2	Consider ergonomic aspects
3.3	Prepare interfaces with other information systems
3.4	Integrate device within existing environment
3.5	Manage generated data
3.6	Interpret screens and troubleshooting

Table 3. Factor 3: Technological preparation and related activities.

6.4.4 Evaluating implementation factor: maintenance

As part of the implementation protocol, an activity setting up a maintenance plan (activity 4.1 in table 4) is included. In the interview, the project leader stated that she did not set up a maintenance plan for the exoskeleton. She addressed safety issues regarding use of the device during instructions. Updates of safety regulations were not addressed in this stage of the project.

Id	Description of activities
4.1	Set up maintenance plan
4.2	Update safety (regulations)

Table 4. Factor 4: Maintenance and related activities.

6.4.5 Evaluating implementation factor: training

The final factor in the protocol for implementation refers to training activities (activity 5.1 in table 5), assessing skills (activity 5.2) and evaluating experiences (activity 5.3). Scrub nurses were trained to assemble, use, and disassemble the device. According to the project leader, attention and supervision was needed to adjust the exoskeleton properly, for optimal use of the device during observed surgeries. Reports regarding the use and functionality of the exoskeleton were gathered and reported to the client and the manufacturer. These reports mainly referred to the intended use of the device. Two scrub nurses completed a questionnaire to reflect on the implementation of the device.

Id	Description of activities
5.1	Train involved staff
5.2	Assess Skills
5.3	Evaluate experiences

Table 5. Factor 5: Training and evaluation, and related activities.

6.4.6 Evaluation of the protocol: perceived ease of use and perceived usefulness

The questionnaire for project leaders focused on the perceived ease of use and perceived usefulness of the protocol for implementation. The project leader stated in a completed questionnaire that activities and instructions were clearly structured, clearly described, and ready for use. In the interview, the project leader suggested a more user-friendly layout for this protocol in general, because the appearance and structure of the used protocol had a scientific lay out. She proposed to omit referrals to scientific literature and proposed to simplify some sentences to improve user-friendliness. The project leader stated that different factors and activities were

helpful to prepare and to introduce this new device. She also found that the protocol provides flexibility to adjust to this project or other implementation projects, by choosing relevant activities and implementation instructions. With reference to usefulness of activities and related instructions, the project leader agrees fully with the statement that the use of a protocol can improve efficiency and increase adoption of new devices with users. Users indicated in completed questionnaires that they were not informed of the use of an implementation protocol. One user, with more than 20 years of experience as a scrub nurse, stated that the introduction of this device was performed better than previous implementations. This scrub nurse indicated that this implementation performance was caused by the project leaders' involvement, as she was available for questions and instructions.

6.5 Discussion

In hospital environments, specifically in OR's, surgeons, and other involved staff such as scrub nurses and circulating nurses use information systems and technological devices to support or execute surgeries. However, possibilities for digitization of supporting activities remain a topic of interest and research continues (Beiser et al., 2021; Fennelly et al., 2020; Rodriguez Socarrás et al., 2020; Scott et al., 2020). The focus of this study was to evaluate an implementation protocol with a case to introduce an exoskeleton for use by scrub and circulating nurses. With reference to the first implementation factor 'set up a project plan' and activities, evaluation results show that the implementation stage of a project is preceded by several other project activities and project stages. Activities such as identifying strategic topics, performance, and stakeholders (activities 1.1 – 1.3) were addressed in previous stages of the project and prior to implementation. Examples of stakeholders are project leader, client, and human resources. Based on these evaluation results, we propose a change in the descriptions of included activities. In the implementation stage of the project, focus should be on topics and performance criteria related to the *implementation* of the device. Regarding the second factor 'organizational preparation', various activities were deployed to recruit users. In practice, many potential users refused to participate, possibly caused by social pressure, fear of wearing a shield, or fear for an uncomfortable fit. Activities related to the third factor 'technological preparation' were addressed, with focus on the activities preparing equipment, considering ergonomic aspects and integration within the existing environment. The last factor for implementation, training, was operationalized by providing instructions and simulations. Training plans and assessment plans were not developed for this device. Based on these evaluation results of this protocol, we consider two findings: 1.) implementation activities are sorted per factor and 2.) functionality and user-friendly design of a tool affect implementation success and adoption.

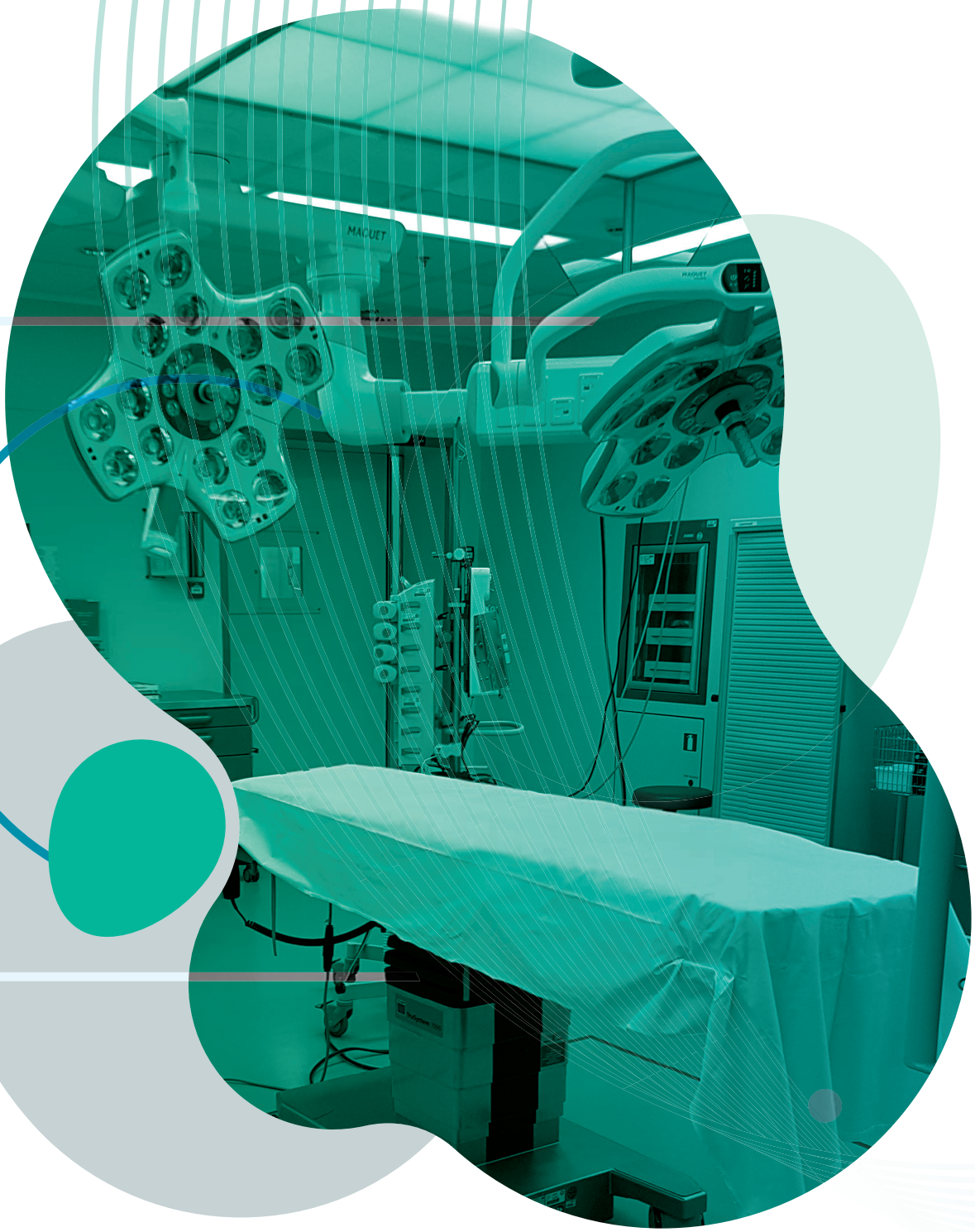
Finding 1: implementation activities are sorted per factor.
In the current protocol for implementation, activities and instructions are grouped according to theme or implementation factor. Results show that many activities are not performed sequentially, and some executed activities need adjustment during the implementation process. For example, preparation activities involving technology, organization, and training are interconnected: when the manufacturer tailored the exoskeletons to the user's body type, users were instructed, and users practiced with the device. Activities may need adjustment during the implementation process for example changes in stakeholders, implementation team, and communication activities.

Finding 2: functionality and user-friendly design affect implementation success and adoption.
Implementation of a device in an organization requires effort from involved stakeholders and users. Following the technology assessment model, we argue that functionality and user-friendly design should address a specific need of users within an organization. Considering these aspects during the development process of the tool, will affect adoption and implementation success (Gagnon et al., 2012). Based on the results of this case, a proven technology or device from a specific sector might not be transferrable to another sector or context due to situational factors or other environmental aspects.

6.6 Conclusions, limitations, and future research

In this study, we addressed the question to which extent a protocol for implementation was ready for use in practice. Therefore, we evaluated this protocol by using this protocol in a small-scale project to implement an exoskeleton in OR's. We conclude that implementation activities and implementation instructions included in this protocol are useful, complete, and ready for use in more complex projects. Refinement of this protocol can be achieved by clarifying instructions and removing scientific references. Although this study was carefully prepared and executed, several limitations can be identified. The intention was to evaluate this protocol with a case to digitize pathology inquiries at the hospital laboratory. This project was discontinued due to Covid-19 measures and priorities. We argue, that included activities in our protocol for implementation are relevant and similar for the digitizing activities in hospitals. In previous studies, we identified and relevant implementation activities and instructions. We based these activities and instructions on a literature research and questionnaire, in which we included implementations of information systems, electronic healthcare records and digitized processes in hospitals (Ehrenfeld & Rehman, 2011; Rivkin, 2009). Although results and findings to this case study are based on a small case and cross case analysis was not possible, we assured data quality and rigor by using various sources of data as triangulation measures. Data

collection was only conducted and analyzed after the device was implemented and after the protocol had been used according to the study procedure. In future research, this implementation protocol needs to be evaluated in other projects with increased complexity. Other future research should include refinement of this protocol based on the first finding, in particular, the development of a tool to select and sort implementation activities and instructions based on user preference and tailored to context.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7

GENERAL DISCUSSION

Implementations of new technological equipment in complex environments is a complex activity. The OR in hospitals is a complex environment in hospitals, where many people from various disciplines work in a high-tech environment. To address the complex activities of implementing new technological equipment in an OR, the following research question was introduced in chapter one:

> What are key factors and guidelines related to a successful implementation of technological innovations within operating rooms?

In this research, I conducted and reported five studies to address this research question and related sub-questions.

The related sub-questions were:

1. Which relevant activities, key factors (determinants) can be identified for implementations of technological innovations within Operating Rooms?
2. How can these activities be categorized in a framework for implementation?
3. How can this framework for implementation be evaluated for use in practice?

In the first two completed studies in this thesis, focus was on the first sub-question, to identify key factors for successful implementation of technological innovations. The second sub-question, to construct a framework for implementation, is addressed in chapter four. To address the third sub-question, to evaluate this framework for implementation, two evaluation studies were conducted and reported in chapter five and six. In the next sections, the evolution of the findings of our research, related to the main and sub-questions are described.

7.1 Main findings

The purpose of the study described in chapter two was to identify factors and activities for implementation based on a survey. Based on these findings, the following factors were identified: a coherent and multi-perspective implementation approach; effective integration of medical equipment in processes, information systems, and organization; and knowledge and skill development and experience.

In chapter three, identifying factors for implementations are reported, based on a systematic literature review. From literature six main categories of factors on successful implementations and related activities were identified: ‘processes and activities’, ‘staff’, ‘communication’, ‘project management’, ‘technology’, and ‘training’.

In chapter four, a first full version of the framework for implementation is presented, based on the results of the previously conducted studies. This framework consists of implementation factors, implementation activities and implementation instructions. Five factors and related implementation activities are included in this framework:

setting up a project plan, organizational preparation, technological preparation, maintenance, and training.

In chapter five, evaluation results are reported. The first evaluation was based on focus group sessions with participants who gained experience in implementing medical devices and equipment in the OR. In chapter six, the framework for implementation was evaluated with a case study by introducing a device in the OR. Based on the results of these studies, revisions are proposed to factors, activities, and instructions. These revisions are explained in the next section.

7.2 Revised protocol for implementation: a framework

Based on the evaluation outcomes, the revised framework for implementation was reduced from five to four key implementation factors. The key implementation factors include setting up plan for implementation, organizational preparation, technological preparation, and training and evaluation. Implementation activities involving maintenance and safety were added to activities related to the implementation factor technical preparation. Related activities and instructions are described in the next tables and this table is also included in appendix 1.

Id	Activities for implementation	Instructions for implementation
1	**Set up a project plan**	
1.1	Identify strategic and tactical topics	Operationalize overall strategic and tactical goals for the implementation stage.
1.2	Identify performance	Identify performance indicators to define the performance of the implementation stage and define how these variables are measured and analyzed. Performance metrics for success could be efficiency, finance, and ergonomics.
1.3	Identify stakeholders	Identify (groups of) stakeholders, which are responsible, accountable, consulted and informed such as sponsors, key-representatives, staff, teams. Identify a project manager for implementation
1.4	Identify risks related to implementation	Perform a risk assessment to identify risks and identify unintended outcomes as new technology may have unforeseen consequences.
1.5	Identify activities for implementation	Identify relevant activities for implementation, based on listed activities. Generate a planning or timeline for execution of these activities.
2	**Organizational preparation**	
2.1	Assemble a multidisciplinary implementation team	Assemble a team which includes various members of involved departments and stakeholders such as scrub nurses, circulating nurses, anesthesiologists, perioperative technicians, surgeons, administrators, IT specialists, and schedulers. Consider assigning an extra team member during implementation to increase familiarity with procedures, e.g. setup procedures.
2.2	Foster team familiarity	Team familiarity and stability impacts teamwork, communication, and satisfaction during implementation. Assign a dedicated implementation team. Involve and inform this team well.
2.3	Identify affected activities and/or processes	Introducing new (medical) equipment influences existing activities and work processes. Identify these and analyze how these processes are affected and which identified stakeholders are involved.
2.4	Update checklists and/or protocols	Checklists improve safety and reliability prior to, and during surgical procedures. Update operating procedures or protocols. If necessary, update existing check lists.
2.5	Perform simulations	Simulate with stakeholders (and departments) how processes and work activities are executed prior to introducing (medical) equipment. Practice with a new tool or new (prototype) equipment on trial basis.
2.6	Identify and deploy activities to increase employees' engagement	Participation of employees when introducing new (medical) equipment increases employees' engagement in the OR. Deploy activities to engage employees in the OR, e.g., involvement of work councils, create a communications council.
2.7	Identify and deploy activities to increase employees' adoption	Embedding information systems or new (medical) equipment in day-to-day activities as an accepted routine is a challenge. Identify and deploy activities to increase adoption with stakeholders such as demonstrating relative advantages, possibilities to observe and experiment, demonstrate benefits, use training, and assign key users or champions.

Id	Activities for implementation	Instructions for implementation
2.8	Communicate with stakeholders	Communication with stakeholders increases engagement and involvement of stakeholders. Set up a communications plan, consisting of communication activities over time. Involved stakeholders should be aware what their role is relating to the new (medical) equipment. For example, nursing personnel should be familiar with the instrumentation needs and they should be proficient in properly connecting, calibrating, set up and use (medical) equipment. Communication activities can be: (pre-operative) group briefings, interviewing stakeholders, using videos and newsletters, developing patient centered information.
3	**Technological preparation**	
3.1	Prepare equipment	Prepare technical facilities related to the use of the information system or device in the OR e.g., power and plugs (if needed)
3.2	Consider ergonomic aspects	Introducing a new tool or system may affect ergonomic aspects of staff in the OR. Consider these aspects in an early stage of the project, prior to implementations. Simulations may lead to ergonomic changes and positioning of tools in the OR.
3.3	Prepare interfaces with other information systems	Introducing new equipment requires integration in and with other devices in the OR. Consider the connectivity to the clinical networks to ensure safety and reliability.
3.4	Integrate device within existing environment	The introduction of new equipment affects current workflows and processes. These workflows need to updated, and existing standard operating procedures need to be updated accordingly.
3.5	Manage generated data	When introducing equipment data can be generated and/or stored, e.g. when introducing a new information system. Consider data processing and security aspects and develop or update procedures.
3.6	Set up maintenance plan	New equipment in use should be maintained periodically and in case of problems, support should be available. To address and facilitate this, a maintenance plan should be set up. Provide instructions how to maintain (clean) tools/equipment such as screens in the OR and confirm who is responsible for this activity.
3.7	Update safety (regulations)	The introduction of new equipment may affect work activities of personnel. Assess the safety procedures and if needed, update these procedures accordingly.
4	**Training and evaluation**	
4.1	Train involved staff	(Recurrent) training is crucial for correct and safe use of the system or tool and affects adoption and success of an implementation. Training focuses on technical skills and non-technical skills. Technical skills may include cognitive, integrative, and automatic skills such as congress visits, demonstrations, research results, online courses, knowledge training, expert opinions, and simulation trainings. Specific trainings on changing ICT and updated workflows and activities should be included as well. Non-technical skills may include decision making, communication and leadership skills.
4.2	Interpret screens and troubleshooting	In case of electronic equipment, notifications may occur visibly on screens, lights, or audible (alarms). Involved personnel should be able to interpret these notifications and should be able to troubleshoot in case of occurring problems.

Id	Activities for implementation	Instructions for implementation
4.3	Assess Skills	To assess the readiness for use, a skills assessment plan needs be developed and executed, tailored to the stakeholders. This plan may include supervision by co-workers. An assessment plan can be determined and executed by a manufacturer, the hospital or a department. (If applicable) assess whether skills need to be recorded and tracked.
4.4	Evaluate experiences	Evaluate experiences and gather feedback regarding the use of the new device, provide input to optimize the device, the use of the device or the workflow.
4.5	Evaluate implementation process	Evaluate the implementation process and relate results to the performance indicators mentioned in the implementation plan.

Table 7.1: Revised framework for implementation

7.2.1 Practical contribution

This implementation framework contributes to society in different ways (Hevner et al., 2004). The following entities are considered: regulating authorities, hospital departments, health care professionals and technicians, manufacturers, and scholars.

Regulating authorities are responsible for regulations regarding safe development, implementation, use and disposal of medical devices (Dutch Hospital Association, 2016; Regulation of the European Parliament, 2017). This implementation framework provides activities and instructions which facilitate introductions of medical devices and non-medical devices in OR's.

Furthermore, this framework can be used by hospital departments which handle acquisition and implementation of technological devices. Activities and instructions can be used as operationalization of implementation policies as part of a quality management system. As acquisition of technological equipment and implementation is organized differently in hospitals, we suggest that this framework to be used by staff members which are responsible for the introduction of new devices. These staff members can be part from decentralized departments or a centralized department responsible for technological devices.

As this framework includes perspectives from surgeons, anesthesiologists, scrub nurses and circulating nurses, we consider this multi-disciplinary framework to be a practical tool for health care professionals as well as professionals in other fields such as technicians, managers, and engineers. These perspectives were included by surveying scrub nurses and circulating nurses, by conducting a systematic literature review and by evaluating this framework with experts from different hospital departments and with varying implementation expertise. In our literature review, we included frameworks, studies on implemented devices and information systems and guidelines from surgeons.

In chapter one is described that many technological innovations ranging from 50 to 90 percent do not succeed to complete the development process and that these innovations are not introduced into market (Cooper et al., 2004; Heidenreich & Spieth, 2013; Techleap, 2021; Wang et al., 2020). For manufacturers of technological devices in healthcare, this implementation framework is a practical tool in the development process and implementation of new devices. Small and mid-sized manufacturers have developed instructions for use of their devices but are often not aware of varying acquisition and implementation policies in hospital environments. As a result these companies experience difficulties in increasing production volume of devices due to the complexity of the health care sector (Techleap, 2021). Use of unified implementation activities can help manufacturers to prepare for introduction of devices in OR's, contributing to quality assurance and implementation efficiency.

Scholars and students can gain knowledge about the implementation process and use this framework to implement new devices and tools in healthcare environments. This framework provides insights to consider in early innovation, and development stages of new devices and products. They can use the framework in education and training, and to enhance the framework by conducting additional research studies. This brings us to the section on the theoretical contribution.

7.3 Theoretical contribution

In the first chapter is described that development of technological innovations remains costly and challenging. Once a device enters the marketplace, hospitals may acquire these devices and implement these in one or more hospital environments. In this section is reflected on the theoretical perspectives in chapter 1.2 and these perspectives are related with the results of our research. Theoretical contributions are also addressed in this section.

When conducting a systematic review of literature as reported in chapter 3, we observed that introductions of technological equipment and information systems were mostly reported as case studies. Implementation studies of technological equipment in OR's until now were limited and an overarching implementation framework for technological devices in OR's has, to my best knowledge, not been reported (Damschroder et al., 2009; Hevner et al., 2004; Moullin et al., 2015; Schoville & Titler, 2015). In our implementation framework factors, determinants, strategies, processes or activities, stakeholders, and other activities are identified. I described implementation factors which are considered determinants that can affect implementation outcomes. Included activities and instructions are considered to be context specific enablers related to each identified determinant or factor (Nilsen, 2015). Reflecting on existing models and meta frameworks contributing to implementation in general, implementation guidelines and other aspects,

contributed to the revised implementation framework in this research. (Fennelly et al., 2020; Meyers et al., 2012; Orlikowski, 2000; Stefanidis et al., 2014; Venkatesh, 2015). Stefanidis et al. (2014) introduced guidelines for implementation for surgical devices from a surgeon's perspective, with focus on organizational preparation, and training and evaluation. The framework constructed in this research, includes additional activities related to implementation factors such as setting up a plan for implementation as well as technological and additional organizational preparation activities to enable implementation of technological devices. As described by Orlikowski (1992), introducing new technological devices affect the organizational context as well as the technological environment: activities performed by staff need adjustment, since technology needs to be used as intended. This research also describes that development and implementation of technology are different stages and involve different activities. It furthermore describes the effect of the development of technology on staff, and the effect staff has on the development of technology (Orlikowski, 1992). Based on this theory and the findings of our research, both the implementation of a new device and its environment need to be considered during the design and development stages. In view of these stages, adoption and acceptance of the new device should be included in an early (design and development) stage, to increase product and implementation success. The constructed implementation framework in this research provides possibilities to select relevant activities tailored to the device to be implemented and to the organizational context. The Technology Acceptance Model (TAM) focuses on adoption and acceptance of new innovations. In this model, the intended use, and behavioral attitude towards new devices are analyzed based on the perceived ease of use and perceived usefulness by users of the new device (Davis, 1989; Venkatesh, 2015). The revised implementation framework includes activities to address the intended use, ease of use, and the perceived usefulness of a new device. These activities include organizational, communication activities and training activities for users. By evaluating the implementation process and the functionalities of the implemented device, variables regarding perceived usefulness and ease of use can be investigated and reported to the manufacturers of the device.

Based on these reflections on previously described frameworks, guidelines, and models, this research shows that the revised framework contributes to the knowledge base in three ways. Firstly, this implementation framework focuses on technological devices in the OR-department, while other frameworks do not specifically focus on this context. Secondly, in comparison with other frameworks our framework provides additional levels of detail, starting with key implementation factors, followed by activities and implementation instructions related to the OR-context. Thirdly, various research disciplines are converged to construct this multi-disciplinary framework. Research methods and studies related to medical research are used as well as research methods and studies related to engineering, business management and information science.

7.4 Lessons learned

Successful implementation of technological devices depends on many factors. One of the first lessons from this research is that implementation activities should be started very early in projects and preferably from the moment hospital departments choose to acquire or (start to) develop technological devices. When conducting this research with the focus to identify the full implementation process, activities related to project management and strategy were identified. These activities were included in this implementation framework, as the implementation stage is a project on its own. In the evaluation studies, research data showed that the implementation stage and related activities are part of a larger project, for example many project goals, such as identifying performance criteria, are identified prior to the actual implementation stage of the device. Therefore, the focus of first factor or determinant 'set up a project plan' needs to be on a plan for implementation goals, activities, and evaluation.

Observations on the implementation of a camera stabilizing device show that manufacturers tend to have their own implementation needs for their invented devices. Examples of these needs are training requirements and assessment needs. Different training requirements need to be considered when setting up a training plan: a medical device may need other training activities and assessments compared to a device that supports logistic supportive activities. Variations in activities require flexibility of the activities included in the implementation framework. This example shows that manufacturers need to consider activities in this protocol and tailor these activities to their device and health care environment.

Furthermore, research results show that implementations of devices involve many stakeholders, different research disciplines and many departments. Based on gathered data and observations, stakeholders need to be involved and informed early, as these departments may need to adjust their working instructions or technical facilities to support the new device. For instance, in preparation of the implementation of a device called DaVinci Robot, the sterilization department needed to acquire and install specific equipment to clean and sterilize used instruments. In this case, the skills for the sterilization employees needed improvement as well. This example shows that introducing a new device may affect activities and equipment of other related departments. These findings are corresponding with the structurational theory, in which is the organizational context is related to the introduction of technology. Organizational environments need to adapt their activities when new technology or equipment is introduced (Orlikowski, 1992).

7.5 Prospects for further research

The presented framework may imply a sequential order of activities, which can result in longer implementation lead times. Agile ways of developing and introducing new tools and information systems have been of increasing interest with manufacturers such as scrum design and implementation (Abdallah, 2020; Kisielnicki & Misiak, 2017). Agile development of information systems and tools decrease development lead times as development is performed in short cycles with dedicated multidisciplinary teams. In further research, this framework needs to be evaluated to investigate whether these newer methods for development can provide insights to improve this framework.

Respondents of the evaluation study with focus groups identified a need for a more flexible process model, in which activities are presented sequentially in order of occurrence (Nilsen, 2015). A project leader should be able to go through the list of activities and identify and select relevant activities, like project goals, the need for a multi-disciplinary team, communication plans and training plans. This will help the user to construct a workflow and a checklist more accurately for well-structured implementation. Further research is needed to develop such a flexible implementation instrument to group activities in order of occurrence and with possibilities for users to select and deselect activities.

The context for use of this framework is mainly the OR. Many other complex hospital environments may require a similar framework to implement new and innovative technological devices. Further research needs to be conducted to assess the generalizability of this framework in other complex hospital environments and to identify possibilities for enhancement.

7.6 Limitations

This implementation framework has been evaluated with experts from different departments and hospitals. Additionally, the framework was used to introduce a device in te OR, which is reported as a case study. This implementation project was a relatively small project, with limited complexity. This case study was single center case study, and the number of stakeholders was limited. In further research, this protocol needs to be evaluated in larger, more complex projects. Variables that influence complexity are for instance the complexity of the device, the purpose of the device, the number of stakeholders and the number of hospitals.

The framework has so far only been evaluated in practice in a project with limited complexity. Therefore, further research needs to be conducted to improve the generalizability and applicability of this framework in a more complex environment and set-up, like intensive care units. Such research can be conducted in other

hospitals and with other combinations of stakeholders. Doing so, will tell whether our protocol only needs refinement in these other, more complex environments, or whether a completely new design will have to be developed.

8

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9

ENGLISH SUMMARY

In recent decades, medical technology has developed enormously and the use of technology in various care (related) processes in hospitals has increased significantly. The successful application of tools are results of both successful product development and implementation of these new tools. Successful implementation of technology in daily practice does, however, prove to be a challenge: many prototypes of new medical devices do not complete the product development process and therefore do not reach the market, and even fully developed products are sometimes not widely implemented in practice. This issue illustrates the need for improved implementation of these new tools.

In previous research, many cases are reported to introduce new information systems or devices in practice and few frameworks are developed to implement research or to disseminate implementation knowledge. The number of research studies focusing on implementation activities of technological devices in OR's seems limited. The applicability of other frameworks to improve implementation success are not clear and a dedicated framework for the implementation of *technological* devices in health care environments, particularly for OR's, has not been developed.

In this dissertation we focus on the operating room department, and we investigate the implementation of new technological devices. The primary location of research was de operating room department of the University Medical Center in Utrecht, The Netherlands. The following research question is addressed in this research:

> What are key factors and guidelines related to a successful implementation of technological innovations within operating rooms?

We identified three related sub-questions to operationalize this research question:

1. Which relevant activities, key factors (determinants) can be identified for implementations of technological innovations within Operating Rooms?
2. How can these activities be categorized in a framework for implementation?
3. How can this framework for implementation be evaluated for use in practice?

In this PhD research, I used these questions to conduct studies and I reported five studies in various research stages. The first research stage was an explorative research stage. In this stage the first sub question is addressed, and two studies were conducted. In the first explorative study activities and factors for successful implementations are identified. Scrub nurses and circulating nurses completed surveys and based on this data the following factors for implementation were identified: coherent and holistic implementation approach; effective integration of medical equipment in processes, systems, and organization; knowledge and skill development and experience.

In the second study, a systematic literature review is reported in which factors for successful implementations are identified. Six main categories of implementation

factors were identified: ‘processes and activities’, ‘staff’, ‘communication’, ‘project management’, ‘technology’, and ‘training’.

The second stage of research was to construct a framework for implementation of technological devices in OR’s. In this stage the second sub-question is addressed. Based on the previously completed studies, a base line framework for implementation is constructed, consisting of five implementation factors, related activities, and related instructions.

The final stage of research was dedicated to evaluating the baseline implementation framework. In this stage addressed the final sub-question was addressed. To evaluate the implementation framework, two studies were executed. In the first study, this framework was evaluated with implementation experts with varying background and working in different departments and hospitals. In the final study, a case study, this framework was evaluated by a project leader who introduced an exoskeleton with circulating and scrub nurses. Results of these studies provided recommendations for revision of our framework.

In this PhD research the focus is on improving implementation of technological devices in the OR-department of hospitals. In the conducted studies, key factors for implementations and related implementation activities and implementation instructions were identified. I finalized this PhD research, by processing the recommendations for revision and by presenting a revised implementation framework. This framework includes four key factors: setting up a plan, organizational preparation, technical preparation, and training and evaluation. Each key factor is operationalized in related activities and OR-specific implementation instructions relating to each activity. In identifying, operationalizing, and validating the key factors we contributed to the body of knowledge of implementation science and more specific the implementation of medical equipment in OR’s. Furthermore, this research provided insights and guidelines for implementations for professionals and provided practical guidelines for professionals, manufacturers, and scholars. A full version of this implementation framework is included in appendix 1.

10

NEDERLANDSTALIGE SAMENVATTING

In de afgelopen decennia heeft de medische technologie zich enorm ontwikkeld en is de inzet van technologie in verschillende zorg(gerelateerde) processen in ziekenhuizen erg toegenomen. Het succesvol toepassen van hulpmiddelen is toe te schrijven aan zowel een succesvolle productontwikkeling als de implementatie van deze nieuwe middelen. Succesvolle ontwikkeling en implementatie van technologie in de dagelijkse praktijk blijkt een uitdaging te zijn: veel prototypes van nieuwe medische hulpmiddelen voltooien het ontwikkelproces niet en deze hulpmiddelen komen dus niet op de markt. Ook uitontwikkelde producten worden soms niet breed geïmplementeerd in de praktijk. Dit probleem illustreert de noodzaak van een verbeterde implementatie van deze nieuwe hulpmiddelen.

In eerdere onderzoeken zijn cases beschreven waarbij nieuwe informatiesystemen of apparaten zijn geïntroduceerd. Eerder zijn enkele raamwerken ontwikkeld voor de disseminatie van implementatiekennis of de implementatie van onderzoek. De toepasbaarheid van eerdere raamwerken om implementatiesucces te verbeteren is niet duidelijk en er is geen specifiek raamwerk ontwikkeld voor de implementatie van technologische hulpmiddelen en apparatuur in zorgomgevingen, in het bijzonder in operatiekamers van ziekenhuizen (OK's).

In dit promotieonderzoek is onderzoek verricht op de afdeling operatiekamers (OK-complex) en het onderwerp van onderzoek is de implementatie van nieuwe technologische apparaten in het OK-complex. Op deze afdeling wordt veel gebruik gemaakt van technologische toepassingen door gespecialiseerd personeel. Dit onderzoek is uitgevoerd in het OK-complex van het Universitair Medisch Centrum in Utrecht. De volgende hoofdvraag stond centraal in dit onderzoek:

Wat zijn sleutelfactoren en richtlijnen voor een succesvolle implementatie van technologische innovaties in operatiekamers?
We hebben drie gerelateerde deelvragen geformuleerd om deze onderzoeksvraag te operationaliseren:

1. Welke relevante activiteiten, sleutelfactoren (determinanten) zijn te identificeren voor implementaties van technologische innovaties binnen operatiekamers?
2. Hoe kunnen deze activiteiten in een framework / raamwerk worden ingedeeld?
3. Hoe kan dit framework / raamwerk geëvalueerd worden voor gebruik in de praktijk?

In dit promotieonderzoek heb ik deze vragen gebruikt om studies voor te bereiden en uit te voeren. Vijf studies zijn uitgevoerd in verschillende onderzoeksfasen. De eerste onderzoeksfase had een exploratief karakter. In deze fase is de eerste deelvraag beantwoord en in deze fase zijn twee studies uitgevoerd. In de eerste verkennende studie zijn activiteiten en factoren geïdentificeerd voor succesvolle implementaties. Operatieassistenten en omloop-operatieassistenten hebben vragenlijsten ingevuld en op basis van de resultaten zijn factoren voor implementatie onderscheiden: een

coherente en holistische implementatieaanpak; effectieve integratie van medische apparatuur in processen, systemen en organisatie; ontwikkeling van kennis, vaardigheden, en ervaring. In de tweede studie is een systematisch literatuuronderzoek uitgevoerd. Het doel van dit onderzoek was om succesfactoren voor succesvolle implementaties van nieuwe technologische hulpmiddelen te identificeren. Er werden zes hoofdcategorieën van implementatiefactoren onderscheiden: 'processen en activiteiten', 'personeel', 'communicatie', 'projectmanagement', 'technologie' en 'opleiding'.

Het doel van de tweede fase van het promotieonderzoek was het bouwen van een raamwerk voor de implementatie van technologische apparaten en hulpmiddelen in OK's. In deze fase is de tweede deelvraag van het onderzoek beantwoord. Op basis van de eerder afgeronde studies is een raamwerk geconstrueerd dat bestond uit vijf implementatiefactoren, gerelateerde activiteiten en gerelateerde instructies.

De laatste fase van het onderzoek was gewijd aan het evalueren van ons raamwerk voor implementatie. In deze onderzoeksfase is de laatste deelvraag behandeld en zijn twee studies uitgevoerd. In de eerste studie is dit raamwerk geëvalueerd met implementatiedeskundigen in drie focusgroepen. Deze deskundigen vervulden verschillende rollen op diverse afdelingen in ziekenhuizen of onderzoekscentra. In de laatste studie, een case study, is dit raamwerk geëvalueerd door een projectleider die een exoskelet introduceerde bij operatieassistenten en omloop-operatieassistenten. Deze evaluatiestudies hebben geleid tot aanbevelingen voor aanpassingen van het eerste raamwerk. In het herziene raamwerk, opgenomen in appendix 1, zijn deze aanbevelingen verwerkt.

Het herziene raamwerk is het resultaat van dit promotieonderzoek. In dit raamwerk zijn, op basis van de onderzoeksresultaten, sleutelfactoren geformuleerd voor implementaties van technologische apparatuur en hulpmiddelen op de OK-afdeling. Deze sleutelfactoren zijn verder uitgewerkt, waarbij per factor OK-specifieke implementatieactiviteiten en – instructies zijn geformuleerd. Het herziene raamwerk bevat vier sleutelfactoren: het opstellen van een projectplan, de organisatorische voorbereiding, de technische voorbereiding, en training en evaluatie. Bij het formuleren, operationaliseren en valideren van de belangrijkste factoren en implementatieactiviteiten, wordt een bijdrage geleverd aan de wetenschappelijke kennisbasis op het gebied implementaties. Dit onderzoek levert specifieke kennis op het gebied implementaties van medische apparatuur in OK's. De inzichten op het gebied van implementatieactiviteiten en instructies dragen bij aan kennis en inzicht. Deze inzichten kunnen worden ingezet door professionals, fabrikanten van nieuwe apparatuur en studenten. Een volledige versie van dit implementatieraamwerk is opgenomen in bijlage 1.

DANKWOORD
ACKNOWLEDGMENTS

In 2013 begonnen de eerste gedachten om mijn onderzoeksvaardigheden in de vorm van een promotietraject op te komen. De vraag ontstond of ik een managementroute zou moeten kiezen of moest kiezen voor een wetenschappelijk traject. Ik had het gevoel dat een managementroute op dat moment vergelijkbaar zou zijn met de werkzaamheden die ik bij mijn vorige werkgevers had gedaan: bezig gaan met transformaties van organisaties ingegeven door de introductie van nieuwe informatiesystemen of technologie. Ik koos er daarom voor om mijn academische vaardigheden verder te ontwikkelen. Op dat moment ontstond de vraag hoe een dergelijk traject te starten en gelukkig bood de Hogeschool Utrecht (HU) steun, in de vorm van een pre-promotietraject. In dit traject maakte ik op wonderlijke wijze kennis met prof. dr. ir. Johan Versendaal. We hadden een klik en ik vertelde dat ik graag in een zorgomgeving, bij voorkeur in een ziekenhuis onderzoek wilde doen. Op een congres van de HU maakte ik deze wens kenbaar en in een workshop ontmoette ik dr. ir. Joris Jaspers. Hij heeft als onderzoeksgebied 'arbeidsbesparende hulpmiddelen in de zorg'. Na enkele verdiepende gesprekken ontstond vervolgens de wonderlijke mogelijkheid om onderzoek te doen samen met Johan en Joris in het UMC Utrecht. Het voelde als thuiskomen in het UMC Utrecht, want toen ik studeerde had ik bijbaantjes in het UMC, bij de facilitaire dienst - eerst in de schoonmaak en later als voedingsassistent en medewerker vergaderservice.

Daarom gaat mijn eerste woord van dank uit naar mijn promotor prof. dr. ir. Johan Versendaal. Johan je bent op mijn pad gekomen en je bent vanaf het begin mijn inspirator en motivator. Je hebt mij geduldig getraind en hebt altijd perspectief geboden op momenten dat ik het even niet zag zitten. Ontzettend veel dank voor alles!

Mijn eerste copromotor, dr. ir. Joris Jaspers. Ik koester de tijd die ik met je door heb gebracht gedurende mijn onderzoek. Je hebt enorm veel tijd geïnvesteerd en jouw oplossingsgerichte en vernieuwende denkwijze heeft mij geïnspireerd om verder te denken dan slechts de methoden en technieken. Jouw innovatieve blik op de wereld inspireerde mij om na te denken over projecten en cases die konden worden meegenomen in het onderzoekstraject. Joris, dank voor jouw persoonlijke begeleiding en coaching.

Met Johan als supervisor en Joris als werktuigbouwkundig ingenieur, begon de begeleidingsgroep vorm te krijgen. Dit onderzoek vond plaats in de OK, dit betekende dat de medische discipline ook zou moeten worden toegevoegd aan het begeleidingsteam. Immers, voor een onderzoek waarbij verschillende disciplines zijn betrokken, moest een multidisciplinair begeleidingsteam actief zijn.

Met dank aan Joris heb ik kennis gemaakt met mijn tweede copromotor dr. Bas van Zaane, anesthesioloog en epidemioloog. Bas heeft mij geleerd om kritisch te zijn, en methodologisch verantwoord te werken. Bas, jouw kritische blik en jouw coaching hebben mijn leerproces enorm ondersteund. Bij ieder artikel, hoor ik jouw coachende stem: “als je de methode goed hebt opgeschreven dan volgt de rest vanzelf” of “weet wat je wilt schrijven en schrijf het kort en krachtig, dus niet te wollig” of “in de resultaten sectie beschrijf je alleen de resultaten uit je dataverzameling – al het overige komt in je discussie!”. In mijn beleving zijn deze aanwijzingen waardevolle lessen, die ik de rest van mijn (academische) leven meedraag. Enorm veel dank Bas!

Mijn tweede supervisor em. prof. dr. Hein Gooszen ben ik enorm dankbaar dat hij het vertrouwen heeft gehad om mijn onderzoek te ondersteunen. Je vertrouwde op de begeleiding van de collega’s en gaf aanwijzingen waar nodig. Zo trok je mij er regelmatig bij, als ik een poos was ondergedoken en niets van mij liet horen. Toen het dal in het promotietraject diep was, en ik de moed niet meer had om door te gaan, hebben jouw interventies geholpen om mij weer op het goede spoor te krijgen. Ik kan me de vergadering nog levendig herinneren, in Joris’ kamer. Het thema voor mij was doorgaan of stoppen – en ondanks mijn onzekere gevoel op dat moment, wist je de juiste snaren te raken om de draad weer op te pakken en vervolgens stug door te werken aan de promotieplannen. Deze kritische vergadering heeft mij geholpen om resultaatgerichter door te werken. Dank voor jouw supervisie en bijdrage Hein!

◆

Het promotietraject is -zeker in de beginfase- deels gefinancierd door de Hogeschool Utrecht. Do Blankestijn en Monique van Deelen hebben mijn onderzoeksvoorstel en -ambities ondersteund. Dank voor jullie support zowel aan het begin als gedurende het promotietraject.

◇

Een promotietraject vergt focus en concentratie. Met mijn coördinerende rol binnen de opleiding Technische Bedrijfskunde en later mijn managementrol bij de opleiding Built Environment, was een part time promotietraject vaak moeilijk te combineren. Dit heeft geresulteerd in een langere onderzoeksperiode ten koste van vrije tijd in de avonden en in de weekenden. In deze periode hebben mijn collega’s van TBK én BE mij ondersteund; mijn collega’s bij Built Environment hebben enorm met mij meegeleefd. Regelmatig informeerde ik hen van mijn activiteiten in het weekend en in de vakanties, waar ‘het doen van onderzoek’ toch de boventoon voerde. Mijn directe collega’s uit de regiegroep BBE (Barbara Bart, Maike Mertens, Barbara Meijer, Saskia van der Kruit), de collega’s uit het instituutsmanagementteam, dank voor jullie support en betrokkenheid. En toch noem ik graag twee namen specifiek: Rozemarijn Capiau en Henk Brinksma. Jullie fungeerden regelmatig als luisterend oor en we hebben urenlange gesprekken gevoerd over onder andere mijn promotietraject, de voortgang, de strategieën om verder te gaan en de keuzes die gemaakt moesten worden. Ik waardeer jullie steun enorm en deze steun heeft geholpen om de eindstreep te behalen.

De collega's van het Lectoraat Digital Smart Services en later Betekenisvol Digitaal Innoveren (BDI) hebben mij regelmatig uitgedaagd met betrekking tot mijn onderzoek. Koen Smit enorm bedankt voor jouw support. Lector Martijn Zoet, eveneens dank voor jouw support en ondersteuning in deze periode. John, Robin en Jurre dank voor jullie bijdragen bij onderdelen van mijn onderzoek.

◈

Collega's van het UMC Utrecht – zonder jullie zou ik geen onderzoeksomgeving hebben gehad. Ik vind het nog steeds geweldig en inspirerend om rond te lopen in het UMC en op de OK. Danielle Vossebeld, dank voor de urenlange gesprekken over onze promotievoortgang en soms niet-voortgang. Dank dat we veel hebben gedeeld en dat je mij motiveerde om verder te komen. Ik kijk uit naar jouw promotie, Danielle. Go for it!

Herke Jan Noordmans, Maurits Konings en Annemoon Timmerman, dank voor de intervisie en coachingsmomenten. Dank voor de vele gesprekken en de gelegenheden om de collega's te informeren over onderzoeksresultaten.

Jeffrey Kanters van het OK Centrum UMC Utrecht, veel dank voor de mogelijkheden die je hebt geboden om onderzoek te kunnen doen in de OK-omgeving. Met jouw support kreeg ik toegang tot het OK-complex en je hebt me verwezen naar verschillende collega's.

Ik wil graag de operatieassistenten, anesthesiemedewerkers, anesthesiologen, en chirurgen dankzeggen. Met hen mocht ik meekijken bij de voorbereiding, tijdens en na operaties.

Annelies van Wandelen, Kwaliteitsmedewerker OK UMC Utrecht en operatie-assistent. Annelies, je bent als een van de eersten aan de slag gegaan met het implementatieframework. Je inspireerde mij om door te zetten en met dank aan jou konden we aan de slag met een casus die ik zou kunnen meenemen in dit onderzoek. Helaas werd dit onderzoek door Covid-19 en herziene prioriteiten gestaakt. Annelies, enorm veel dank tot nu toe voor jouw rol in mijn onderzoek!

Ook dank aan de landelijke vereniging voor operatieassistenten (LVO). Dank voor de mogelijkheid om een vragenlijst af te nemen en de resultaten te kunnen presenteren.

◈

Dan nu vrienden en familie.
Ik wist dat het starten van een promotietraject offers met zich zou meebrengen. Ik wist niet van tevoren wat de impact zou kunnen zijn. In het begin dacht ik er best lichtvaardig over: iets minder sociale activiteiten voor een bepaalde periode - dat gaat wel goed komen. De impact was groter dan ik had verwacht. Mijn vrienden en familieleden hebben het effect echt gemerkt! De eersten die ik noem: mijn broer en

chotki – Navin Kisoensingh en Ashnie Jawalapersad. Zij woonden in de straat, op 1 minuut loopafstand in De Meern, en toch voelde de promotie als een stevige last die ervoor zorgde dat we minder tijd met elkaar doorbrachten. Ik bedenk mij dat twee van de drie kinderen mij altijd studerend hebben gekend tot nu toe. Erg hè? Enorm veel dank voor jullie hulp en support en de mogelijkheid om regelmatig samen een hapje te eten na het werk.

En de hele familie en vriendengroep, aan jullie allen veel dank voor jullie steun en betrokkenheid. We hebben elkaar in de afgelopen jaren weinig gezien en gesproken en wat heb ik jullie gemist. Ik noem in willekeurige volgorde (en de lijst is verre van volledig)– Sharda & Kees, Rinish & Zahira, Charini & Vijay, Sieta, Gieta, Ashra, Rene, Shanti, Vikash, Yogita, Amar, Navin R., Arun, Indra, Radha, Urmila, Cherryl, Boyke, Nandani, Saroj, Karin, Robert, Irma phoewa, Nadia phoewa, Pieter J., Yashvir, Norani, Sanjiv, Marcel, Pamela, Hydi, Joan, Jerry, Savita, Pim, Shanti, Robin, Rob, Shashikala, Anil, Shantoesha. En ook Soenita Sitabi, Arwin, Zino, Jean, Jayant & Varsha, Sharmy & Ricardo. En niet te vergeten: Robert & Marja, Pieter Dorst, Pieter van Oostrom (†), Oom Jan, Tante Urmila en Oom Sew & Tante Indra, Radjin & Gisla, Soenita & Soedesh, Sandra & Hans, Ruben & Sjarita en mijn lieve schoonmoeder Indra Ramautarsing.

En dan Satish Jong- Doekharan (†), één van mijn grote supporters. Wat vind ik het ontzettend jammer dat je er niet bij bent op deze dag. We missen je allemaal ontzettend en ik ben blij dat je meekijkt en blijft motiveren vanuit jouw hemelse woning. Satish toch, we missen je!

Dear Phil and Ada, so much happened in the past few years. I am so grateful to have you in my life. You both have supported me and I am so grateful that I could visit and even study and write pieces of articles in the bright shining sun in Dubai. Thank you, Ada, for the countless motivational talks and sharing your experiences. These are valuable and you were there to help. Thanks a lot brother and sister. Elias en Joel, you are wonderful guys, and it is so good to spend time with you and to share experiences. Thanks a lot, and good luck with your own studies and career!

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Ik ben erg dankbaar dat ik dit proces van 'onderzoek doen' heb doorlopen en dat ik deze gelegenheid heb gekregen (en genomen). Hoe gaaf is het om te werken aan nieuwe onderzoeksonderdelen en stapsgewijs een raamwerk te ontwikkelen binnen jouw interessegebied en omgeving. Het doen van onderzoek, brengt ook enige (historische) reflectie met zich mee. Volgens mij is het bijzonder dat zowel mijn broer als ik bezig zijn een promotietraject af te ronden. Om een historische schets te geven: de eerste voorouders van vaderszijde (Sewberath Misser) zijn volgens de archieven rond 1874 in Suriname aangekomen als contractarbeiders uit India, elf jaren na de afschaffing van de slavernij in Suriname. Rond 1895 is de naam Sewberath Misser aangenomen. En van moederszijde zijn de eersten tussen 1874 en 1894 in Suriname aangekomen,

eveneens als contractarbeiders, volgens het Nationaal archief. Mijn grootmoeder van moederszijde (nani) heeft niet de gelegenheid gehad om naar school te gaan en sprak dus alleen Sarnami, een afgeleid Surinaams-hindoestaans dialect en van origine uit India. Scholing zoals wij die nu kennen, hadden zij niet allen genoten. De gedrevenheid binnen de familie(s) is ondanks de beperkte mogelijkheden, altijd groot geweest. Zo was studeren in het hoger onderwijs pas mogelijk in de generatie van mijn ouders, circa 3 generaties dat de contracttijd. En niet iedereen uit de generatie van mijn ouders had de mogelijkheid, middelen of gelegenheid om te studeren. Mijn ouders dus ook niet. Ik vind het daarom bijzonder zowel mijn broer als ik nu op het punt staan om deze academische graad te behalen. Ik hoop dat dit resultaat ook een inspiratie mag zijn voor andere familieleden, neefjes, nichtjes en vrienden.

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Mijn broer Vinoj en mijn schoonzus Sunita, jullie staan aan de wieg van mijn ontwikkelingen in het hoger onderwijs. Jullie hebben mij opgevangen toen ik na de middelbare school in Suriname naar Nederland kwam om te studeren. Jullie hebben mij geleerd om zelfstandig te worden en mijn weg te vinden. Jullie hebben altijd klaar voor mij (en Maya) gestaan. Erg veel dank. Ook de kinderen Vyasa (& Fayrene), Toorya (& Raoul) en Vidya wil ik noemen. Want jullie hebben de ontwikkelingen en de struggles en overwinningen van mij meegemaakt. Dank dat jullie er waren en meeleven. Ik vind het geweldig om deel te zijn van jullie leven en ik vind het gaaf om te zien hoe jullie je tot nu toe hebben ontwikkeld en verder gaan! Ga zo door!

Mijn ouders Harold en Bea zijn een voorbeeld geweest voor mij. Zij hebben mijn broer Vinoj en mij met discipline en doorzettingsvermogen opgevoed. Zij zijn niet in de gelegenheid geweest om verder te studeren in het hoger onderwijs; als de mogelijkheden er waren ben ik ervan overtuigd dat het zou zijn gelukt. In plaats daarvan hebben zij mijn broer en mij op de voorgrond geplaatst. Zij hebben geknokt en keihard gewerkt opdat het ons aan niets ontbrak (ook in tijden van dictatuur, angst en onzekerheid in Suriname) en zodat wij alle ruimte zouden hebben om verder te kunnen studeren. Pa en Ma, dankzij jullie sta ik nu hier. Zonder jullie steun in alle jaren zou het ons (Vinoj en ik) niet zijn gelukt. Ik ben ontzettend dankbaar voor de kansen die jullie hebben gegeven, de offers die jullie hebben gebracht en de dingen die jullie hebben moeten laten, zodat wij succesvol kunnen zijn. Ontzettend bedankt voor alles!

En de belangrijkste persoon in mijn leven bewaar ik natuurlijk voor het laatst. Maya, mijn schat, steun, toeverlaat, mijn wonder! Wat heb jij mijn leven verrijkt. Sinds 2017 ben je in mijn leven. Een moment dat werk en studie centraal stonden. Ik ben zo dankbaar dat je mij hebt ontmoet en dat we zijn getrouwd in 2019. De beste keuze die we beiden hebben gemaakt tot nu toe. Ik vind het soms moeilijk te verwoorden: je hebt mij zoveel gesteund, je hebt mij altijd de gelegenheid gegeven om te kunnen studeren of om te kunnen schrijven. Ik hoefde mij vervolgens niet zoveel zorgen te

maken over de andere zaken thuis. Je vond het (ahum in het begin) niet erg dat ik de weekenden in de kamer of op zolder bezig was te studeren. Gelukkig hebben we niet gewacht tot de afronding van mijn promotie voor onze bruiloft, want anders zouden we pas in 2023 zijn getrouwd. Onze tijd samen vind ik zo kostbaar dat ik geen moment zou willen missen. Dankjewel voor wie je bent, dat je mij inspireert en hebt gemotiveerd om dit proefschrift af te ronden. Ik hou van je! Maya, je hebt mij nog niet gekend zonder studiedruk – deze druk is bijna voorbij. Wat kijk ik uit naar onze tijd samen. Ik dank God dat we mogen leven met Zijn zegen en dat Hij met ons is!
Dank iedereen en dank U Heer!

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CURRICULUM VITAE
NAVIN SEWBERATH MISSER

Navin R.R. Sewberath Misser (20-07-1976) was born and raised in Paramaribo, Suriname (South America). I am married to my lovely wife Maya Goercharan.

Educational Career

I started my learning experiences at OS Gijsbertusschool and J.E. Dennertschool followed by completing secondary school at Mr. Dr. J.C. de Miranda Lyceum in Paramaribo, Suriname. In 1999 I achieved my bachelor's degree in Industrial Engineering and Management (Technische Bedrijfskunde) at te HU University of Applied Sciences in Utrecht (Hogeschool van Utrecht). In 2000 I started my professional career, while pursuing a master's degree in business administration at the Rotterdam School of Management / Erasmus University. I obtained a master's degree with a specialization in Change Management, in 2006. In 2014, I started (in part time) with a PhD – trajectory focusing on implementing medical technology in OR's.

Professional career

After achieving my bachelor's degree, I started working for Centric in the role of consultant. For almost three years I was responsible for planning activities related to the development and implementation of a financial information system at the Ministry of Foreign Affairs, in The Netherlands. After this job, I did some project leading activities at ING Bank. From 2004 up until 2007, I worked for Kennis Management Groep B.V. in Capelle aan den IJssel, and I fulfilled various process consulting roles for various clients such as Ministry of Foreign Affairs, Ministry of Spatial Planning, Ahold Retail. In 2007 I switched jobs and fulfilled the role of Management Consultant at PA Consulting group for clients in banking, pharma and healthcare. In 2010 I started as a lecturer and soon after I picked up other roles as member of the examination board, coordinator of the bachelor program. Since 2019 I fulfill the role of Head of Department of the Built Environment undergraduates' program, now responsible for approximately 600 students and ~32 fte.

Academic career

HU University of Applied Sciences is an employer who focuses on personal and professional development. In 2013 I was on a verge to choose the path of management or to develop my academic skills by starting a PhD trajectory. In 2013 the HU University of Applied Science granted me a PhD voucher to do part time research. Together with my professors from Radboud UMC and Open University and coaches from the University Medical Center Utrecht, we focused on implementing technological innovations in OR's. I visited many conferences to gain knowledge and to present research results such as Bled, AMCIS, EAES, SMIT, EORNA, LVO, SMSH, Carpe. Few abstracts were published in medically related conferences, and articles from this thesis were published in journals and included in peer reviewed proceedings of conferences. To develop my writing and reviewing skills, I reviewed many articles for conferences and journals such as journal of networked business, international journal for networking and Virtual organizations, Bled conference, PACIS, AMCIS, ECIS.

Summary

20-07-1976	Born in Paramaribo, Suriname
1991-1994	High School (VWO) at the mr.dr. J.C. de Miranda Lyceum, Paramaribo, Suriname
1995-1999	Industrial Engineering and Management (Bsc) at HU University of Applied Sciences, Utrecht
1999-2006	Business Administration (Msc) at Rotterdam School of Management / Erasmus University, Rotterdam
2000-2004	Consultant at Centric Managed ICT Services
2004-2007	Senior Consultant at Knowledge Management Group, Netherlands
2007-2010	Management Consultant at PA Consulting Group
2010 – 2019	Coordinator of the undergraduate program Industrial Engineering and Management at HU University of Applied Sciences
2019 – now	Head of department of the undergraduate program Built Environment at HU University of Applied Sciences
2014 – 2021	PhD Candidate (part time) in collaboration with HU University of Applied Sciences Utrecht, University Medical Center Utrecht, Open University and Radboud University Medical Center.

Detailed profile at www.linkedin.com/in/navin-sewberath-misser-5569352

ADDENDUM

The published articles in this dissertation are slightly amended compared to the originally published articles, to improve the structure and ease to read these articles. The following amendments were processed:

- Identified typos and grammar errors
- Articles originally published with English spelling were converted to American English spelling
- Original figure and table captions have been updated according to the format of this dissertation.
- In the originally published articles we use the term 'protocol for implementation' instead of framework, as the term 'protocol' is a familiar term in the OR.

APPENDIX 1: FRAMEWORK FOR IMPLEMENTATION

Revised framework for implementation

Id	Activities for implementation	Instructions for implementation
	Set up a project plan	
1.1	Identify strategic and tactical topics	Operationalize overall strategic and tactical goals for the implementation stage.
1.2	Identify performance	Identify performance indicators to define the performance of the implementation stage and define how these variables are measured and analyzed. Performance metrics for success could be efficiency, finance, and ergonomics.
1.3	Identify stakeholders	Identify (groups of) stakeholders, which are responsible, accountable, consulted and informed such as sponsors, key-representatives, staff, teams. Identify a project manager for implementation
1.4	Identify risks related to implementation	Perform a risk assessment to identify risks and identify unintended outcomes as new technology may have unforeseen consequences.
1.5	Identify activities for implementation	Identify relevant activities for implementation, based on listed activities. Generate a planning or timeline for execution of these activities.
2	**Organizational preparation**	
2.1	Assemble a multidisciplinary implementation team	Assemble a team which includes various members of involved departments and stakeholders such as scrub nurses, circulating nurses, anesthesiologists, perioperative technicians, surgeons, administrators, IT specialists, and schedulers. Consider assigning an extra team member during implementation to increase familiarity with procedures, e.g. setup procedures.
2.2	Foster team familiarity	Team familiarity and stability impacts teamwork, communication, and satisfaction during implementation. Assign a dedicated implementation team. Involve and inform this team well.
2.3	Identify affected activities and/or processes	Introducing new (medical) equipment influences existing activities and work processes. Identify these and analyze how these processes are affected and which identified stakeholders are involved.
2.4	Update checklists and/or protocols	Checklists improve safety and reliability prior to, and during surgical procedures. Update operating procedures or protocols. If necessary, update existing check lists.
2.5	Perform simulations	Simulate with stakeholders (and departments) how processes and work activities are executed prior to introducing (medical) equipment. Practice with a new tool or new (prototype) equipment on trial basis.
2.6	Identify and deploy activities to increase employees' engagement	Participation of employees when introducing new (medical) equipment increases employees' engagement in the OR. Deploy activities to engage employees in the OR, e.g., involvement of work councils, create a communications council.
2.7	Identify and deploy activities to increase employees' adoption	Embedding information systems or new (medical) equipment in day-to-day activities as an accepted routine is a challenge. Identify and deploy activities to increase adoption with stakeholders such as demonstrating relative advantages, possibilities to observe and experiment, demonstrate benefits, use training and assign key users or champions.

Id	Activities for implementation	Instructions for implementation
2.8	Communicate with stakeholders	Communication with stakeholders increases engagement and involvement of stakeholders. Set up a communications plan, consisting of communication activities over time. Involved stakeholders should be aware what their role is relating to the new (medical) equipment. For example, nursing personnel should be familiar with the instrumentation needs and they should be proficient in properly connecting, calibrating, set up and use (medical) equipment. Communication activities can be: (pre-operative) group briefings, interviewing stakeholders, using videos and newsletters, developing patient centered information.
3	**Technological preparation**	
3.1	Prepare equipment	Prepare technical facilities related to the use of the information system or device in the OR e.g., power and plugs (if needed)
3.2	Consider ergonomic aspects	Introducing a new tool or system may affect ergonomic aspects of staff in the OR. Consider these aspects in an early stage of the project, prior to implementations. Simulations may lead to ergonomic changes and positioning of tools in the OR.
3.3	Prepare interfaces with other information systems	Introducing new equipment requires integration in and with other devices in the OR. Consider the connectivity to the clinical networks to ensure safety and reliability.
3.4	Integrate device within existing environment	The introduction of new equipment affects current workflows and processes. These workflows need to updated, and existing standard operating procedures need to be updated accordingly.
3.5	Manage generated data	When introducing equipment data can be generated and/or stored, e.g. when introducing a new information system. Consider data processing and security aspects and develop or update procedures.
3.6	Set up maintenance plan	New equipment in use should be maintained periodically and in case of problems, support should be available. To address and facilitate this, a maintenance plan should be set up. Provide instructions how to maintain (clean) tools/equipment such as screens in the OR and confirm who is responsible for this activity.
3.7	Update safety (regulations)	The introduction of new equipment may affect work activities of personnel. Assess the safety procedures and if needed, update these procedures accordingly.
4	**Training and evaluation**	
4.1	Train involved staff	(Recurrent) training is crucial for correct and safe use of the system or tool and affects adoption and success of an implementation. Training focuses on technical skills and non-technical skills. Technical skills may include cognitive, integrative, and automatic skills such as congress visits, demonstrations, research results, online courses, knowledge training, expert opinions, and simulation trainings. Specific trainings on changing ICT and updated workflows and activities should be included as well. Non-technical skills may include decision making, communication and leadership skills.
4.2	Interpret screens and troubleshooting	In case of electronic equipment, notifications may occur visibly on screens, lights, or audible (alarms). Involved personnel should be able to interpret these notifications and should be able to troubleshoot in case of occurring problems.

Id	Activities for implementation	Instructions for implementation
4.3	Assess Skills	To assess the readiness for use, a skills assessment plan needs be developed and executed, tailored to the stakeholders. This plan may include supervision by co-workers. An assessment plan can be determined and executed by a manufacturer, the hospital or a department. (If applicable) assess whether skills need to be recorded and tracked.
4.4	Evaluate experiences	Evaluate experiences and gather feedback regarding the use of the new device, provide input to optimize the device, the use of the device or the workflow.
4.5	Evaluate implementation process	Evaluate the implementation process and relate results to the performance indicators mentioned in the implementation plan.

De naam des Heren zij geprezen, van nu aan tot in eeuwigheid.
Let the name of the Lord be praised, both now and forevermore.

Psalm 113:2

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