Evaluating an Implementation Protocol for Digitization and Devices in Operating Rooms: a Case Study

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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.

Keywords: implementation, operating room, implementation activity, implementation factor, digitization, medical equipment, medical innovation, change management

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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, Bohmer and Pisano, 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.

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.

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 and 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.

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 (Heijden, 2004; Wu and Wang, 2005; Gagnon et al., 2012; Tantiponganant and Laksitamas, 2014). 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.

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.

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).

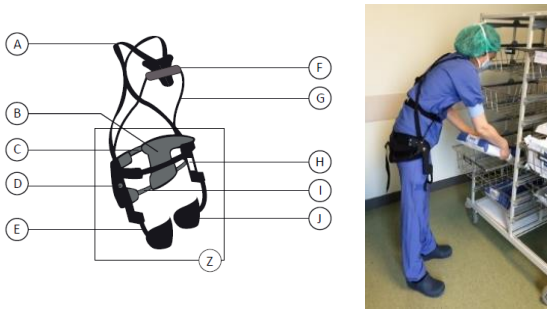

Figure 1: Leavo exoskeleton
Legend: A Suspender ; B Hip pads ; C Hip belt; D Smart joint ; E Leg structure; F Chest pad; G Torso structure; H Label ; I Buck belt; J Leg pad; ; Z Hip assembly
Source: http://www.Leavo.nl

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.

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.

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.

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

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

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.

Table 2: Factor 2: Organizational preparation and related activities

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

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 course of 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).

Table 3: Factor 3: Technological preparation and related activities

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

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.

Table 4:Factor 4: Maintenance and related activities

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

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.

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

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

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.

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 (Fennelly *et al.*, 2020; Rodriguez Socarrás *et al.*, 2020; Scott *et al.*, 2020; Beiser *et al.*, 2021). 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 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 (Rivkin, 2009; Ehrenfeld and Rehman, 2011). 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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