A protocol for the implementation of new technology in a highly complex hospital environment: the operating room

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Abstract: Medical equipment is implemented in highly complex hospital environments, such as operating rooms, in hospitals around the world. In operating rooms (ORs), technological equipment is used for surgical activities and activities in support of surgeries. The implementation of government policies in hospitals has resulted in varying implementation activities for (medical) equipment. These result in varying lead times and success rates. An integral and holistic protocol for implementation does not yet exist. In this study, we introduce a protocol for the implementation of (medical) equipment

in ORs that consists of implementation factors and implementation activities. Factors and activities are based on data from a systematic literature review and an explorative survey among surgical support staff on factors for the successful implementation of technological and (medical) equipment in ORs. The protocol consists of five factors and related implementation activities: the establishment of a project plan, organisational preparation, technological preparation, maintenance, and training.

Keywords: implementation; protocol; medical technology; (medical) equipment; healthcare; hospital; operating room; operating theatre; integration; scrub nurse; circulating nurse.

Reference to this paper should be made as follows: Sewberath Misser, N., Jaspers, J., van Zaane, B., Gooszen, H. and Versendaal, J. (2020) 'A protocol for the implementation of new technology in a highly complex hospital environment: the operating room', *Int. J. Networking and Virtual Organisations*, Vol. 22, No. 2, pp.199–217.

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This paper is a revised and expanded version of a paper entitled 'Transforming operating rooms: factors for successful implementation of new (medical) equipment', presented at the 31st eBled Digital Transformation Conference in Bled, Slovenia, 17 June 2018.

1 Introduction

Operating rooms (ORs) or operating theatres are examples of highly complex and dynamic environments where technological equipment is used before, during and after surgeries. Medical equipment is often introduced in ORs and affects the work-related activities of surgeons and surgical support staff. Many case studies have demonstrated the application of technological advancements to improve patient treatments, care and outcomes, but few studies have focused on successful implementations of (medical) equipment in ORs. Edmondson et al. (2001) described the implementation of technological equipment as the integration of new technology in day-to-day activities in an organisation (Edmondson et al., 2001). Implementation of technological equipment entails the integration of equipment that is new to the organisation, which includes new and innovative technology (Tatnall, 2009). The introduction of new and innovative technologies remains a challenge, and governments are becoming increasingly strict. For example, the European Parliament has adopted regulations to increase the safety and safe use of medical devices (Nguyen et al., 2011; European Parliament and Council of the European Union, 2017; European Union, 2017; Regulation of the European Parliament, 2017). These regulations must be implemented before the spring of 2020. In the Netherlands, the Dutch Hospital Association (NZA) has agreed upon a set of rules with regard to the implementation of new medical devices in hospitals: the Covenant Medical Technology (CMT). This agreement provides policy guidelines throughout the lifecycle of (medical) equipment – with regard to its acquisition, implementation, use, and disposal – to ensure patient safety (Dutch Hospital Association, 2016). In the CMT, medical devices are defined as devices that have a direct effect 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 for supportive activities to not directly affect the patient, their treatment or the outcome of a treatment. The CMT has been implemented in hospitals in the Netherlands, and these hospitals have defined local policies throughout the lifecycle of medical devices. The Health and Youth Care Inspectorate regularly audits these associated local policies. Locally-defined policies have resulted in hospital-specific methods of implementing (medical) equipment and thus in a variety of implementation activities. In turn, this variety has resulted in different implementation outcomes and increased implementation lead times, which can result in the increased use of resources, such as implementation time, funds, and involved members (Wickramasinghe et al., 2008). In our opinion, integral holistic implementation guidelines for (medical) equipment in ORs should be available to ensure safe surgical and treatment interventions. Therefore, we conducted research on necessary factors for the implementation of new (medical) devices in highly complex hospital environments, with a specific focus on ORs, to answer the following research question:

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

2 Method

The aforementioned primary research question is operationalised in two sub questions:

1 Which factors for the successful implementation of (medical) equipment in ORs 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 necessary to categorise, compose, and populate a protocol for implementation. We performed a systematic literature review to identify success factors for implementation (Sewberath Misser et al., 2018b). As a secondary research method, we prepared a survey. This survey was distributed among the participants of an annual conference for surgical support staff in the Netherlands (scrub nurses and circulating nurses). The following variables were included in this research: necessary steps for implementation, training and governance, user readiness, and other topics such as use of an implementation protocol and the use of the CMT (Sewberath Misser et al., 2018a). Based on these variables, we undertook the following steps to compose protocols for the 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 et al., 2018b). Venkatraman et al. (1993) described a strategic alignment framework, which we used to compare these categories. In this study, we used the dataset of papers that were included in the systematic literature review. We analysed articles in detail to identify factors and implementation activities based on coding results. We used NVivo (version 11 for Windows) to select and analyse related texts' coding results. Identified implementation activities were based on the analysis of the contents of these coded sections in articles. We reviewed and discussed the resulting implementation activities and grouped similar activities. . Included implementation activities were based on frequency and relevance, and were classified under one of the implementation factors. We provided an explanatory description based on the coded categories in NVivo version 11 for Windows.

2 Composition of a protocol based on the findings of a survey that was conducted 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 et al., 2018a). This explorative survey was distributed among 235 visitors of an annual congress for surgical support staff (scrub and circulating nurses). There were 90 respondents (n = 90). We analysed the results of this dataset in detail. We identified implementation activities based on the frequency of relevant activities and provided a description of the input that was used to produce this questionnaire and of the outcomes of the completed surveys. These implementation activities were included in protocol B.

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

3 Results

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

Table 1 Mapping of categories compared to implementation factors

Number	*Factor (in Tables 2 and 4)*	*Category (as identified in systematic literature review)*
1	Establishment of a project plan	Project management
		Performance
2	Organisational preparation	Process and activities
		Staff
		Communication
3	Technological preparation	Technology
4	Maintenance	Technology
5	Training	Training

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. This is followed by a protocol for implementation based on survey data among scrub and circulating nurses. Lastly, we combine the data based on the literature and surveys to compose and populate a protocol for the implementation of (medical) equipment in ORs.

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

To compose a protocol for the 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. An explanation of activities is included in the 'description of activities' column and examples of references to literature are provided in the 'reference example' column.

Based on our systematic review, we distinguished five implementation factors: the establishment of a project plan, organisational preparation, technological preparation, maintenance, and training. Table 2 demonstrates that firstly, a project plan should be established prior to implementation, in which reasons for the implementation of new (medical) equipment should be determined, and involved and affected stakeholders should be identified. Based on the type of equipment, implementation activities should be selected by the project team.

The second factor for implementation involves activities to prepare the organisation for the introduction of equipment. It includes assembling an implementation team, identifying pioneers and ambassadors within the organisation, 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 must be updated, checklists must be assessed for updates, simulations must be performed to examine how new equipment will be used, 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 should function properly.

A fourth factor for implementation is post-implementation maintenance. A maintenance programme should be in place to ensure the safety of equipment after implementation.

The fifth factor is training. Training activities are extensively described in the literature, primarily with regard to technical training for surgeons. Training activities are classified as training in technical and non-technical skills, and these activities should be included in a tailored training programme for various involved stakeholders. For instance, in the case of surgical (medical) equipment, surgeons need to be extensively trained in technical and non-technical skills, while surgical support staff must be trained in the setup and disassembly of this equipment.

3.2. Protocol B: Survey-based factors and activities

The second protocol that we present is an implementation protocol based on survey data that was collected from scrub and circulating nurses. We used the same implementation factors as in protocol A, and the implementation activities were based on collected data. These results are presented in Table 3.

As mentioned in the description of activities for first factor in Table 3, ‘the establishment of a project plan’, respondents are advised to inform and involve stakeholders. For the second factor, ‘organisational preparation’, respondents indicated that protocols must be modified to accommodate the introduction of new equipment, and that simulations are needed to support this. For the ‘modify protocols’ activity, respondents indicated that day-to-day activities must 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 mainly concern technical skills and assessment.

Table 2 Protocol A implementation factors and activities based on literature review

A	*Factor*	*Activities*	*Description of activities*	*Reference example*
1	Establishment of 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 analysed. Performance metrics for success could be efficiency, finance and ergonomics.	Dey et al. (2007), Cima et al. (2011), Yusof (2015)
1.3		Identify stakeholders	• Identify (groups of) stakeholders which are responsible, accountable, consulted and informed such as sponsors, champions, staff and 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	Organisational 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, anaesthesiologists, perioperative technicians, surgeons, administrators, and schedulers. Consider assigning an extra team member during implementation to increase familiarity with procedures, e.g., setup.	Francis and Winfield (2006), Collar et al. (2012)
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 analyse how these processes are affected and which identified stakeholders are involved.	Kitzmiller et al. (2010)

Table 2 Protocol A implementation factors and activities based on literature review (continued)

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.	Verdaasdonk et al. (2009), Kranzfelder et al. (2012)
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.	Meyfroidt (2009), Bouamrane and Mair (2014) Guédon et al. (2015)
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 centred information.	Kim et al. (2009), Wiegmann et al. (2010), Cima et al. (2011), Bouamrane and Mair (2014), Stefanidis et al. (2014), Guédon et al. (2015)
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 and 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.	Zindel (2000), Rivkin (2009), Lowndes and Hallbeck (2014)

Table 2 Protocol A implementation factors and activities based on literature review (continued)

A	*Factor*	*Activities*	*Description of activities*	*Reference example*
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	• 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.	Meyfroidt (2009), Kranzfelder et al. (2012), Lowndes and Hallbeck (2014), 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 and Winfield (2006), Kitzmiller et al. (2010), Samii and Gerganov (2013)
4	Maintenance			
4.1		Establish a maintenance programme	• New equipment in use should be maintained periodically and in case of problems, support should be available. To address and facilitate this, a maintenance programme should be setup.	Francis and 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. (2012)
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	Crosby and Lane (2009), Ahmed et al. (2012), Collar et al. (2012), Low et al. (2012), Kang et al. (2015)

Table 3 Protocol B survey-based factors and activities

B	*Factor*	*Activities*	*Description of activities*
1	Establishment of a project plan.		
1.1		Inform stakeholders.	• During an implementation of new (medical) equipment, stakeholders are involved. These stakeholders should be informed.
1.2		Involve stakeholders.	• The introduction of new (medical) equipment requires the involvement of stakeholders.
2	Organisational preparation.		
2.1		Modify protocols.	• New (medical) equipment affects the existing workflow and procedures. Existing protocols must be updated.
2.2		Perform simulations.	• As many stakeholders (and departments) are involved, the workflow for preparation, setup, use and disassembly should be simulated.
3	Technological preparation.		
3.1		Introduce device.	• The new device must be introduced, including its technical aspects.
3.2		Demonstrate device.	• The new device must be demonstrated to involved stakeholders in a way that is tailored to their needs.
4	Training preparation.		
4.1		Congress visits.	• To introduce a device that is new to the OR, training is needed. Congress visits provide opportunities for stakeholders to become familiar with the new device.
4.2		Introduce device.	• The device should be introduced and demonstrated by the manufacturer.
4.3		Assess previous research.	• Insights from previous research activities and experiences should be shared with stakeholders in a way that is tailored to their needs.
4.4		Online course.	• One form of training activity is the provision of online courses with regard to the new device.

Notes: 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.

Table 3 Protocol B survey-based factors and activities (continued)

B	*Factor*	*Activities*	*Description of activities*
4.5		Video of device use.	• An instructional video in the use of the new device is considered to be valuable as one of the training activities.
4.6		Theoretical training.	• Theoretical training that is tailored to the needs of stakeholders is one of the options for training activities.
4.7		Knowledge sharing from an expert.	• An expert user sharing his or her knowledge of the device is one option for a training activity.
4.8		Specific courses.	• Specific training and courses can be developed for each device and offered to the stakeholders.
4.9		Training in changes in ICT.	• As information systems may be affected by the introduction of the new device, training in the changes in ICT and the requirements for data entry might be necessary.
4.10		Training in updated protocols.	• As workflows and processes change as a result of the introduction of a new device, stakeholders should be trained in any protocols that change.
4.11		Simulate with live models.	• Depending on the new device, training on/with live models might be necessary, and must be tailored to the stakeholders' needs.
4.12		Assess skills.	• To assess the readiness for use, a skills assessment programme must be developed and executed in a way that is tailored to the stakeholders. This assessment programme can be developed by the hospital or the manufacturer of the device.
4.13		Supervision by a co-worker.	• As part of the introduction of the new device, supervision by a co-worker is a potential assessment method.
4.14		Evaluate experiences.	• The evaluation of experiences and feedback with regard to the use of the new device can provide input to optimise the device, its use, or the resulting workflow.

Notes: 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.

Table 4 Combined implementation protocol for (medical) equipment in the OR

C	*Factor*	*Activities*	*Locator to Table 3*	*Implementation instructions*	*Reference example*
1	Establishment of a project plan				
1.1		Identify strategic and tactical topics.		Identify topics that are relevant to the implementation plan, e.g., 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 analysed. Performance metrics for success could be efficiency, finance, and ergonomics.	Dey et al. (2007), Cima et al. (2011), Yusof (2015)
1.3		Identify stakeholders.	B1.1; B1.2	Identify (groups of) stakeholders who are responsible, accountable, consulted and informed, such as sponsors, champions, staff, and teams.	Collar et al. (2012), Yusof (2015)
1.4		Identify risks.		Perform a risk assessment to identify risks and potential 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.	

Notes: First column: table identification letter and identification number per row. Factor: identified implementation factor. Activities: identified implementation activities. Locator to Table 3: reference to Table 3, shown as table identification letter followed by the identification number. Implementation instructions: a description of implementation instructions. Reference example: example reference to one or more studies.

Table 4 Combined implementation protocol for (medical) equipment in the OR (continued)

C	*Factor*	*Activities*	*Locator to Table 3*	*Implementation instructions*	*Reference example*
2	Organisational preparation				
2.1		Assemble a multidisciplinary implementation team.		Assemble a team that includes various members of involved departments and stakeholders, such as scrub nurses, circulating nurses, anaesthesiologists, perioperative technicians, surgeons, administrators, and schedulers. Consider assigning an additional team member during implementation to increase familiarity with procedures such as setup.	Francis and Winfield (2006) Collar et al. (2012)
2.2		Foster team familiarity.		Team familiarity and stability affects teamwork, communication, and satisfaction during implementation. Assign a dedicated team for the implementation, and thoroughly involve and inform this team.	Wiegmann et al. (2010)
2.3		Identify affected activities and/or processes.	B2.1	Introducing new (medical) equipment influences existing activities and work processes. Identify these processes, analyse how they are affected, and determine which stakeholders are involved.	Kitzmiller et al. (2010)
2.4		Update checklists.		Checklists improve safety and reliability before and during surgical procedures. Assess whether checklists need to be updated due to the introduction of new (medical) equipment and update these according to the procedures to update checklists.	Verdaasdonk et al. (2009) Kranzfelder et al. (2012)
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.		The participation of employees in the introduction of new (medical) equipment increases employees' engagement. Deploy activities to engage employees, e.g., encourage the involvement of work councils and create a communications council.	Cima et al. (2011)
2.7		Identify and deploy activities to increase employees' adoption.		Incorporating new (medical) equipment in day-to-day activities as an accepted routine is a challenge. Identify and deploy activities to increase adoption by stakeholders, such as by demonstrating relative advantages, providing possibilities to observe and experiment, using training and assigning key users or champions as experts regarding the new device.	Meyfroidt (2009), Bouamrane and Mair (2014), Guédon et al. (2015)
2.8		Communicate with stakeholders.		Communication with stakeholders increases their engagement and involvement. Possible communication activities can be (pre-operative) group briefings, interviews with stakeholders, the use of videos and newsletters, and the development patient-centred information.	Kim et al. (2009), Wiegmann et al. (2010), Cima et al. (2011) Bouamrane and Mair (2014) Stefanidis et al. (2014), Guédon et al. (2015)

Notes: First column: table identification letter and identification number per row. Factor: identified implementation factor. Activities: identified implementation activities. Locator to Table 3: reference to Table 3, shown as table identification letter followed by the identification number. Implementation instructions: a description of implementation instructions. Reference example: example reference to one or more studies.

Table 4 Combined implementation protocol for (medical) equipment in the OR (continued)

C	*Factor*	*Activities*	*Locator to Table 3*	*Implementation instructions*	*Reference example*
3	Technological preparation				
3.1		Prepare equipment.	B3.1; B3.2	Involved stakeholders should be aware of their role in relation to the new (medical) equipment. For instance, involved nursing personnel should be familiar with the instrumentation needs and they should be proficient in properly connecting, calibrating, setting up, and using the (medical) equipment. Therefore, the device should be introduced and demonstrated properly.	Francis and Winfield (2006)
3.2		Consider ergonomic aspects.		The positioning of new equipment in the OR requires attention, as space is often limited and involved staff must be positioned near the patient. New equipment should not disturb equipment that is already present, and screens and tools should be visible and available to surgical support staff.	Zindel (2000), Rivkin (2009), Lowndes and Hallbeck (2014)
3.3		Prepare interfaces with other information systems.		Newly introduced equipment requires integration with other devices in the OR. Consider 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 must be amended, and existing standard operating procedures must be updated accordingly.	Meyfroidt (2009), Kranzfelder et al. (2012), Lowndes and Hallbeck (2014), Yusof (2015)
3.5		Manage generated data.		When introducing equipment (e.g., when introducing a new information system), data can be generated and/or stored. Consider data processing and security, and develop or update such 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 and Winfield (2006), Kitzmiller et al. (2010) , Samii and Gerganov (2013)

Notes: First column: table identification letter and identification number per row. Factor: identified implementation factor. Activities: identified implementation activities. Locator to Table 3: reference to Table 3, shown as table identification letter followed by the identification number. Implementation instructions: a description of implementation instructions. Reference example: example reference to one or more studies.

3.3 Protocol C: combined protocol for implementation

In this section, we compose a protocol for the implementation of (medical) equipment in ORs. This protocol is based on the merging of data from protocols A and B, and results are presented in Table 4. As with protocol A, we included factors for implementation and implementation activities. To specify the origin of included activities, we added a locator column to Table 4 that refers to the corresponding section in Table 3. If included activities were (partly) based on activities in Table 3 (protocol B), we included a reference number, such as Bx.y, which refers to Table 3, protocol B and activity record x.y. For each implementation activity, we added implementation instructions. These instructions are based on data from the surveys and literature.

Like in Table 2 (protocol A), the combined protocol for implementation in Table 4 presents five implementation factors and related activities. The establishment of a project plan is one of the factors for implementation of new (medical) equipment. The purpose of the project, strategic and tactical topics, stakeholders and performance factors should be included in this plan. Activities that are necessary for implementation should be identified and included in a project plan.

The second factor concerns the organisation's preparation for the introduction of the new medical equipment. Employees are involved in this process, and a multidisciplinary team must be assembled to increase the familiarity of the team members with the new equipment. The organisation's preparedness must be analysed, and affected activities and processes need to be identified. Checklists may need to be updated, and simulations of the new device must be prepared. Communication activities need to be identified to involve employees and increase their engagement and adoption.

Besides preparation of the organisation and its employees, activities involving technological preparation are required. Equipment needs to be available and prepared, and the OR must be pre-emptively adjusted to accommodate any potential ergonomic changes. Interfacing with other information systems may require attention prior to integrating new equipment in the OR environment. The use of a new device may generate (new) data, and information systems should be prepared and managed accordingly. Staff should be familiar with the new device and capable of troubleshooting if problems occur. A plan for the 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 training activities were included in the description of the training of involved staff. Based on the survey data, two implementation activities were included in the combined protocol: the assessment of skills and the evaluation of experiences.

4 Discussion

The implementation of technological equipment in highly complex environments, such as ORs, requires careful preparation, coordination, involvement of stakeholders, and training (Tatnall, 2009; Wu and Yezhou, 2011). The implementation of information systems in and outside healthcare has been the topic of research, and success factors for the implementation of these systems have been identified (Bali and Wickramasinghe, 2010). However, research on the implementation of (medical) equipment is limited and lacks an integral protocol. In our experience, research on technological advancements and

pilot studies on ORs are often conducted, but following up after a pilot study remains difficult. In our view, the implementation of equipment in ORs includes the integration of this equipment in day-to-day activities and its adoption by involved staff and an implementation is more comprehensive and complex compared to a pilot study.

In this study, we have introduced a holistic protocol for the implementation of (medical) equipment in ORs (protocol C). This protocol is based on a systematic literature review and an explorative survey that was conducted among surgical support staff. We explored the factors for successful implementation that were identified in these studies. We reviewed various (case) studies on the use and introduction of (surgical) equipment, information systems and quality assessment methods. The literature review resulted in the identification of five implementation factors: the establishment of a project plan, organisational preparation, technical preparation, maintenance, and training. In this protocol (Table 4) these implementation factors are included, and implementation activities that are based on data from an explorative systematic literature review and a survey (Table 2 and Table 3) are provided. A comparison of survey data with the systematic literature review reveals that many of the activities that were identified by respondents involve training, the adjustment of protocols and processes, and stakeholder involvement, whereas the systematic review provides a broader range of activities, including those with regard to 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 standardised implementation activities. As European regulations on the use of medical equipment increase, we expect that standardised implementation activities will contribute to the safe use of medical equipment in ORs (European Parliament and Council of the European Union, 2017; European Union, 2017; Regulation of the European Parliament, 2017). Furthermore, we expect that this protocol provides flexibility for the implementation of (medical) equipment and non-medical equipment in highly complex environments, such as ORs. Survey results demonstrate that the integration of new equipment in day-to-day activities is a challenge. We expect that the use of this protocol will result in integrated activities, more predictable implementation lead times, and improved outcomes, efficiency and adoption (Edmondson et al., 2001).

5 Limitations

This protocol is based on various (case) studies of (medical) equipment and an explorative survey that was conducted among surgical support staff. Other members of surgical support staff, such as anaesthetic (support) staff, operators of (medical) equipment and other departments were not included in this study. Their input could potentially increase the number of implementation instructions. This protocol omits a distinction between activities for specific medical equipment, as defined in the CMT, and equipment for supporting activities. This distinction could be identified in future studies, as this protocol requires validation based on empirical data.

6 Conclusions and further research

New medical equipment is implemented in ORs in hospitals around the world, yet an integral protocol for the implementation of such equipment does not currently exist. Based on a systematic literature review and an explorative survey that was conducted among surgical support staff, we have composed a protocol for implementation that consists of five factors and related activities. These factors are the establishment of a project plan, organisational preparation, technological preparation, maintenance, and training. In future studies, we will validate this protocol and related activities, using a pilot study of equipment to be introduced in the OR as an explorative case study. With a focus group, we will assess the 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.

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