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Navin Sewberath Misser

HU University of Applied Sciences Utrecht, The Netherlands University Medical Centre Utrecht, The Netherlands,
Navin.SewberathMisser@hu.nl

Joris Jaspers

University Medical Center Utrecht, J.Jaspers@umcutrecht.nl

Bas van Zaane

University Medical Center Utrecht, B.vanZaane@umcutrecht.nl

Hein Gooszen

Radboud University Medical Center Nijmegen, Hein.Gooszen67@gmail.com

Johan Versendaal

HU University of applied sciences, johan.versendaal@hu.nl

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Transforming operating rooms: factors for successful implementations of new medical equipment

NAVIN SEWBERATH MISSER, JORIS JASPERS, BAS VAN ZAANE,
HEIN GOOSZEN & JOHAN VERSENDAAL

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 surgical supportive 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; integration of medical equipment in processes, systems and organization; knowledge and skill development and effective communication during the implementation process.

Keywords: • Implementation • Operating Room • Operating Theatre • Medical Technology • Medical Equipment • Training • Healthcare transformation • Technological innovation • Scrub nurse • Circulating nurse • Process integration •

CORRESPONDENCE ADDRESS: Navin Sewberath Misser Bsc. Msc., Ph.D.-candidate and Programme coordinator Industrial Engineering and Management programme, HU University of applied sciences, Institute for Engineering and Design, Padualaan 99, 3584CH Utrecht, The Netherlands, email: Navin.SewberathMisser@hu.nl. Joris Jaspers Ph.D., Associate Professor Labour Saving Devices, University Medical Center Utrecht, Heidelberglaan 100, 3584CX Utrecht, The Netherlands, email: J.Jaspers@umcutrecht.nl. B. van Zaane MD Ph.D., Anesthesiologist, University Medical Center Utrecht, Heidelberglaan 100, 3584CX Utrecht, The Netherlands, email: B.vanZaane@umcutrecht.nl. Prof. Dr. Hein Gooszen, emeritus Professor of surgery, Radboud University Medical Center Nijmegen, Geert Grooteplein Zuid 10, 6525 GA Nijmegen, The Netherlands, email: Hein.Gooszen67@gmail.com. Prof. Dr. Johan Versendaal, Professor Digital Smart Services, HU University of applied sciences, 3584CH Utrecht, The Netherlands, email: Johan.Versendaal@hu.nl.

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, Massey, & Gillespie, 2015; Sheikhzadeh, Gore, Zuckerman, & Nordin, 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. These policies address 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 Dutch Health and Youth Care Inspectorate 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, Fanelli, Price, & Richardson, 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 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.

2.1 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.

2.2 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.

Table 1: Variables related to questions in survey

Variable	Question	Type of response
1. Implementation	Q14: Which steps are currently undertaken in the implementation process for new medical equipment?	Multiple responses
	Q16: Which aspects are important when implementing new medical equipment successfully?	Open question
	Q20a: Which aspects of the implementation process are currently going well?	Open question
	Q20b: Which aspects of the implementation process provide room for improvement?	Open question
	Q22: It is clear how new medical equipment are being implemented.	Likert scale (1-5)
Variable	Question	Type of response
2. 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
3. Readiness	Q18: How should the readiness for the use of the new medical equipment be assessed?	Multiple responses
4. 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)

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

2.3 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.

3 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.

3.1 Respondent information

Out of the 90 respondents, 8 were male and 84 female. 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.

Table 2: Focus areas of the respondents (Results)

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 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.

Table 2: Impact of implementations (Results)

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

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 some kind of training related to the implementation of medical equipment.

3.2 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.

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

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%

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.

3.3 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.

Table 4: Training features (Results)

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%

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 organizing and facilitating trainings.

3.4 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.

3.5 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 4.

Table 4: Results on presence implementation protocol and implementation of the CMT

	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%

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.

4 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, Lango, & Yavuz, 2004; Pennington & DeRienzo, 2010; Pluyter, Rutkowski, & Jakimowicz, 2014). 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 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, Carlson, & Deckers, 2014; Frasier et al., 2017; Marvik, Lango, & Yavuz, 2004; Pennington & DeRienzo, 2010; Saleem et al., 2015).

5 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.

6 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; integration in processes, systems and organization; knowledge and skill development and effective communication during the implementation process.

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