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**EVALUATION OF THE RESULTS OF AN ICU  
DIGITAL CHECKLIST IMPLEMENTATION  
PROJECT IN ESTONIA – MAPPING THE NEEDS FOR  
FURTHER EVALUATION AND DEVELOPMENT**

Master's Thesis

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**INTENSIIVRAVI DIGITAALSE  
KONTROLLNIMEKIRJA RAKENDUSPROJEKTI  
TULEMUSTE HINDAMINE NING TULEVIKU  
HINDAMIS- NING ARENDUSVAJADUSTE  
KAARDISTAMINE**

Magistritöö

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Msc

Tallinn 2018

## **Author's declaration of originality**

I hereby certify that I am the sole author of this thesis. All the used materials, references to the literature and the work of others have been referred to. This thesis has not been presented for examination anywhere else.

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14.05.2018

## **Abstract**

Main focus of this thesis is to evaluate the results of an ICU digital checklist implementation project in Estonia in order to map the needs for further evaluation and development of that digital checklist solution.

The data collection methods include scoping review in order to identify the best practices of digital checklists implementations, features, and their evaluation measures. The secondary data of an ICU digital checklist implementation project which is analysed includes data from the project database, results of the focus group interview, and a survey.

The overview of the project is provided using the items from the CONSORT-EHEALTH checklist. The analysis of the focus group interview is done using pragmatic content analysis, analysis of the questionnaire is done to derive the main findings. The benchmarking of the existing literature is done using directive content analysis and the comparison between evaluation measures and features of the digital checklists from academic literature and practical pilot is made.

The author of this thesis provides suggestions for the evaluation of a digital checklist tool in the next phase of the pilot at NEMC, as well features to be included to the solution based on the user feedback. These suggestions for the evaluation include measuring the clinical effect of the solution, as well having a control group or collecting baseline data to have a state to compare the solution with. The suggested features are IT integration with the hospital system, automatic flow of guidance, and inclusion of the illustrative content in the solution. Proposed features, especially the IT integration require inclusion of the other relevant stakeholders in the development process and the analysis of their perspectives on the problem, as well the solution.

This thesis is written in English and is 61 pages long, including four chapters, and nine figures.

## **Annotatsioon**

Magistritöö eesmärk on hinnata intensiivravi digitaalse kontrollnimekirja rakendamise projekti tulemusi Põhja-Eesti Regionaalhaiglas ning kaardistada vajadused, mis on vaja ellu viia, et tulevikus antud lahendust hinnata, ning kuidas antud lahendust arendada.

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Võrdluse põhjal antakse soovitusel, kuidas järgmises pilootprojekti faasis lahendust hinnata, ning millised funktsioonid lahendusele veel lisama peaks, et lahenduse kasutatavust, kasutajamugavust ning mõju tõsta. Autor soovib mõõta lahenduse kliinilist efekti ning uurimisel vaadata ka kontrollrühma või hinnata tavapraktikat, et oleks võimalus lahendust millegagi võrrelda. Lisaks soovib autor lahendus haigla infosüsteemiga integreerida, lisada automaatne kasutusrežiim ning audio- ning tekstipõhise sisu kõrval ka illustratiivset materjali näidata. Magistritöö toetab uudse digitaalse kontrollnimekirjade lahenduse loomist Eesti ja välismaa haiglatele.

Lõputöö on kirjutatud inglise keeles ning esitatud 61 leheküljel, sisaldab nelja peatükki ning üheksat joonist põhiosas.

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## **Abbreviations**

CA – Cognitive Aid

CERTAIN – The Checklist for Early Recognition and Treatment of Acute Illness and Injury

CRNA – Certified Registered Nurse Anaesthetists

CTICU – Cardiothoracic Intensive Care Unit

ECMO – Extracorporeal Membrane Oxygenation

EHR – Electronic Health Record

ICU – Intensive Care Unit

IT – Information Technology

iABP – Intra-Aortic Balloon Pump

iECS – Electronic Checklist System

LVAD – Left Ventricular Assist Devices

NASA-TLX – National Aeronautics and Space Association Task Load Index

NEMC – North-Estonia Medical Centre

NHS – National Health Services

OR – Operation Room

Pro/cheQ – Procedure-Specific Checklist Tool

RORCC – Robotic-Specific Checklist

RSE – Risk Sensitive Event

SICU – Surgical Intensive Care Unit

SSC – The Surgical Safety Checklist

SCC – The Safe Childbirth Checklist

SURPASS – Surgical Patient Safety System

TURP – Transurethral Resection of the Prostate

VAP – Ventilator Associated Pneumonia

WHO – World Health Organisation



## Introduction

Checklists are simple but potentially effective tools that can improve, support or change operator's cognitive processes by increasing the levels of control necessary for the successful operation of the system and making the outcomes of the operation more predictable and reproducible. Checklists are used in many industries to support decision-making and memory, in aviation, formalized checklist use as a memory and decision aid has shown significant increases in safety, resulting in the substantial reduction of fatalities [14]. There have been several proposals [14,18] to introduce checklists to healthcare. In healthcare, checklists are seen as solutions that can facilitate the integration of guidelines into clinical practice due to their simple and easy-to-use manner. It is believed that the use of checklists in a complex healthcare environment can reduce human error, procedural violations, near mistakes, support medical professionals, increase patient and provider safety, improve care quality and patient outcomes [5,18,32].

Cognuse OÜ and North-Estonia Medical Centre (NEMC) have been developing a digital checklist tool during the past year through a joint venture. The first phase of an ICU digital checklist implementation pilot project is finished and primary results regarding the solution have been collected.

The aim of this master thesis is to evaluate the results of an ICU digital checklist implementation pilot project in Estonia in order to map the needs for further evaluation and development of that digital checklist solution. The comparison of the practical pilot and academic literature regarding the issue is done and suggestions for evaluation and development of the solution are given for the project team.

The author has proposed eight research questions:

- 1) What are the international best practices of digital checklists?
- 2) How have digital checklists been evaluated in international literature?
- 3) What are the relevant types, settings, and features of digital checklists?
- 4) What were the characteristics and features of the NEMC digital checklist tool?
- 5) What was the evaluation approach for the digital checklist pilot?
- 6) What were the initial results of the project?

- 7) What are further evaluation needs and suggested evaluation measures for the NEMC digital checklist pilot?
- 8) What are the further development needs of the NEMC digital checklist pilot?

# **1 BACKGROUND: INTERNATIONAL BEST PRACTICES OF DIGITAL CHECKLISTS IN HEALTHCARE**

World Health Organisation (WHO), responsible party for patient safety, has taken initiative to implement checklists in healthcare at a wider scale. Until now, WHO has developed two checklists for the use in healthcare environments. In 2008, The Surgical Safety Checklist (SSC) was introduced by WHO together with Atul Gawande (MD), American surgeon, who has been a forerunner for checklists implementation and development in healthcare. SSC has now been implemented in many hospitals around the world [18,41] and this has had a strong effect on the research, development, and use of the checklists in healthcare. In 2015, WHO introduced The Safe Childbirth Checklist (SCC). The initiatives to implement SCC have taken place in several locations [3,35]. WHO is not only offering the checklist, but also guidelines to successfully implement checklists supporting the standardised use in healthcare.

Checklists benefit in healthcare has been mostly seen through the increased adherence to guidelines [24]. Positive effect of guidelines adherence on patient outcomes has been widely researched [37], and therefore it is believed that by improving guidelines adherence, checklists have a positive effect on reduction of errors and improve clinical outcomes. Several initiatives of implementation of checklists have shown positive impact on patient outcomes through increased adherence, including reduction in infection rates [5,32], in the rates of death, readmissions [29], and in-patient complications due to surgical procedures [18]. However, not always has the implementation of checklists in healthcare resulted in increased patient safety [41]. The failures in the successful implementation of checklists give space for further research into the effect and usability of checklists in healthcare.

Using checklists in critical situations can be a good support but there are many factors complicating the provision and proper compliance of these low-tech tools in healthcare and hospitals, including rapidly changing patient status, needed team communications, and complex coordination of tasks in a short period of time [25] and even though the use of checklists has increased in the past years, the resistance to using them continues.

The main problem for unsuccessful checklist implementation is the inconsistent implementation of checklists in several fields of medicine (surgery, critical care), despite the

existing evidence of their fundamental role in error management. The inconsistent use has many reasons, main one is the lack of effective and standardised methodologies for checklist design, development, and implementation. The standardised approach of checklists design, development, and implementation could help to overcome this issue. Digital transformation is affecting healthcare, but still most of the checklists used in the hospitals are paper-based and have a static manner [17]. However, the research into the topic of digital checklists is increasing and is presented in this paper in the following paragraphs.

Digitisation of the checklists can be a potential approach to integrate them fully into clinical workflows. Most of the research into digital checklists and transition from paper-based systems to digital, has measured their potential to increase guidelines adherence [24].

### **1.1 Scoping review: international academic literature about digital checklists**

The summary of the used study designs, data sources, dependent variables, checklist types, usage areas, and evaluation measures used is presented in the following paragraphs. The information presented is gathered from the existing international literature accessed via PubMed and Google Scholar databases. There are seventeen articles included in the scoping review, the relevant information is extracted and presented in the table (appendix 1). More thorough overview of the methodology is provided in chapter 2.

#### **1.1.1 Study designs**

The most common study type to evaluate the checklist use was pre-post implementation design (twelve studies) [1-2,6-7,9,11-12,15,27,29,32-33]. In addition, five of the included experimental studies [8,23,30-31,36,40] compare a control condition and the electronic checklist condition, three out of six are randomized assignment of conditions and/or participants [8,31,40].

#### **1.1.2 Data source and dependent variables**

Three of the included studies were simulation-based [8,31,40]. Four of the reviewed studies involved clinical studies that included a record review to assess the effectiveness of the e-checklist intervention [2,12,15,29]. Ten studies used on-site observational methods to collect data [1,6,7,9,19,23,27,33,36] and nine of the studies included participant survey [1,9,11,15,19,31,33,36], one having it as the main research method [11].

### **1.1.3 Measures**

Checklists, by their definition are used to support, improve, or change operator's cognitive processes to increase the levels of operator control that are necessary for the successful operation of the system [14]. This indicates that checklists should increase the adherence and compliance which was seen also by the fact that most of the reviewed studies measured clinicians' or nurses' adherence to guidelines and best practices by complying with the checklist [1-2,7,9,15,19,27,33,36]. As well, in several cases, patient outcomes were evaluated [6,12,15,29], main outcomes indicators were rates of ventilator associated pneumonia (VAP) [12], occurrence of risk sensitive events (RSE) during surgery [6,15], and 30-day readmissions [29]. Participants' general perceptions and satisfaction with the checklist were measured also in several cases [1,8,11,31,33]. In one case, also provider workload, and errors were measured [40], as well the time to e-checklist completion rate in comparison to paper-based [1,8,33,40], and in one case also the duration of the surgery [29]. E-checklist validity [7,23] and reliability [23] and concordance of data between data transmitter and receiver [19] were looked into.

### **1.1.4 Checklist area and type**

In the included studies, there were only three areas, where checklists were implemented, critical care [2,7-8,12,23,36,40], surgery [6,9,11,15,27,29,36], and anaesthesiology [1,31]. Since the aim of the thesis was to evaluate checklists used in the process-of-care, studies measuring checklists for radiology/ laboratory and for ambulatory patients, were not included as indicated in the search results. Even though, checklists are believed to provide support and reminders only of the most critical processes and aid memory and attention during the most important steps, it is worth mentioning that none of the studies evaluated checklists at lower levels in the care pathways. There can be several reasons behind the fact, why surgical and critical care departments have implemented checklists at a biggest scale: 1) strong focus on technology development and device use (real-time patient monitors) in both of the departments; 2) relatively frequent occurrence of very critical situations, when professionals have to make quick decisions and work flawlessly in order to provide the best care. The second is probably the main reason, why professionals working in these wards look for support from the checklists. As Gawande wrote in his "Checklist manifesto" that good checklists provide reminders of the critical and important steps and are not trying to fly a plane or perform a procedure [14].

Checklists types varied from daily ward rounds checklists [7-8,12]; decision support checklist tools providing evidence-based practice [2,31,40]; time-out checklists [27], surgical safety checklists [6,9,11,15,29,33], handoff checklists [1,19,36], to resuscitation checklist [23].

### **1.1.5 Effect of digital checklists on adoption rate and adherence to guidelines**

Checklists are seen and used as tools that improve the compliance with best practices and increase adherence to guidelines. Even though paper checklists are used in many hospitals around the world, the adoption and compliance rates are not satisfactory and the goals of increasing the patient safety have not been achieved in many locations [15,33]. Therefore, it is believed that with electronic checklists, checklists could be adopted at a wider scale and the adherence to best practices could be improved.

One of the main usage areas of checklists in healthcare is surgery and checklists have been implemented in many operation rooms (OR) around the world. SSC is implemented in hundreds of hospitals and is believed to decrease complications and to have a positive effect on patient morbidity and mortality [15,18,27,33,41]. In National Health Services (NHS) completion of SSC has been mandatory since February 2010 but there have been issues with checklist compliance and staff engagement, as well continuity of the prevalence of critical events during surgeries and complications which should be avoided with the checklist use. For that reason, Reed et al. [33] implemented an unavoidable pre-recorded audio delivery of the SSC and assessed its effect on the checklist compliance. The researchers evaluated the checklist use during surgeries and measured the completion of checklist items during three types of checklist delivery – standard practice, audio prompt, and full audio delivery. The evaluated outcome measures included occurrence of time-out/sign-out, completion of checklist, as well the staff perceptions which are introduced in the following paragraphs. The study found that during the full audio delivery of the checklist, time outs and sign outs were performed 100% unlike during standard practice, where sign outs were performed 86,8% of the time. Mainthia et al. [27], applied electronic checklist in the OR to increase the compliance of the use of checklist during the pre-incision time out. A standardized time out interactive Electronic Checklist System [iECS] was implemented and the compliance with the checklist was assessed during the twelve-month prospective observational study. It was seen, that iECS had a positive effect on the pre-procedural time outs in the OR, as the compliance was assessed one month prior and one and nine months after the checklist implementation and the observations indicated the surgical staff communication of the core elements of the time out procedure 49.7

$\pm 12.9\%$  of the time and after the implementation at one and nine months  $81.6 \pm 11.4\%$  and  $85.8 \pm 6.8\%$  respectively.

Northshore University Health System implemented the paper-based SSC in 2009, but the compliance was found to be very low with the paper format of the checklist. Due to the fact of low compliance, hospital decided to integrate SSC in electronic health record (EHR) in order to improve the checklist adoption rate [15]. After starting to use the electronic checklist, compliance rate increased from 48% to 92%, the highest increase of compliance among different professionals was seen for nurses, from 55% to 93%. SURgical PATient Safety System (SURPASS) checklist, developed by De Vries et al. [9] to cover the maximum of relevant safety risk events has shown also positive effect on increasing the time between administration of antibiotic prophylaxis and incision during surgical events which is proven to be a positive measure and best practice influencing the surgical site infections (SSI). After implementing the SURPASS checklist, increase from 23,9 minutes to 29,9 minutes of administration of antibiotic prophylaxis was seen which shows the positive effect of digital checklist on adherence to clinical guidelines.

St. Pierre et al. [31] implemented an electronic CA for the management of a severe gynaecological transurethral resection of the prostate (TURP) syndrome under spinal anaesthesia and assessed the guideline adherence and management of the syndrome during a simulation-based study either with a support from an electronic CA, or with management from memory alone. It was seen that teams in the CA group considered evidence-based treatment steps significantly more often than teams of the control group. The findings show the positive effect of an electronic CA and that it can improve implementation of recommended tasks during critical events.

Positive effect of the digital checklists on the adherence to clinical guidelines has been seen also in the ICUs. There have been approaches with positive results increasing the compliance of the performance of needed activities during morning ward rounds with e-checklists. Conroy and colleagues [7], during their twenty-week before-after study, showed the improvement in the compliance with different care components, the largest improvement was seen for pain management (42% increase), followed by glucose management (22% increase) and head-of-bed elevation (19% increase). Moderate improvements were seen for nutrition assessment (7.4% improvement), sedation management (7.5% improvement), and stress ulcer prophylaxis

(3.2% improvement). During the study, concordance between clinicians' responses and audits was evaluated to measure the validity of the checklist. It was seen that concordance between clinician and audit responses was high for most of the care components, indicating that physician responses were reflective of actual care delivery. Another implementation of daily wards checklist for the ICUs [12] showed increased adherence to guidelines, with regard to daily sedation interruption and head-of-bed elevation, as well with improved management of invasive devices, resulting in lower nosocomial infection rates and shorter periods of invasive device exposure. The Checklist for Early Recognition and Treatment of Acute Illness and Injury (CERTAIN) [23] that provides decision-support, charting, and prompting for standardization, has been successfully integrated into clinical workflow for compliance and bedside documentation.

Checklists are used to facilitate communication which is an important factor affecting patient safety and the care quality. Electronic checklists have the potential to be facilitators of critical information exchange and retention. Agarwala et al. [1] found that electronic checklists can affect care quality through reduction of medical errors and adverse events due to poor-quality handoffs by improving the communication quality among team members. Electronic checklist was developed to improve intraoperative handoff process during transfer of care and it worked as a guide to prompt discussion and improve communication. 69 handoffs were observed, in which thirty were performed without and thirty-nine with the checklist. The results from the study indicated that electronic checklists raise the quality of the communication during handoffs, as intraoperative medications were discussed more frequently when the checklist was used. The increase was especially seen for medications and for information exchange about the blood loss, urine output, postoperative planning, and potential areas of concern. The checklist also improved the interpersonal communication within anaesthesia and operative team as a whole. Increase in the satisfaction rates with the quality of communication at the end-of-shift intraoperative transfer of care was seen for all the participant provider groups in the post checklist survey. Research measuring electronic checklist' ability to positively affect communication process among anaesthesia nursing healthcare providers and their information exchange during the patient handoff [31] did find only modest improvement in the information reporting. Electronic anaesthesia information transfer tool was integrated into the workflow to facilitate transfer of care of intubated surgery patients in an ICU for the cardiothoracic service (cardiothoracic intensive care unit (CTICU)) and other surgical services (surgical intensive care unit (SICU)). Among the staff, transfer tool was positively received but the researchers



indicated, that further assessment of the tool is necessary in order to define the potential to decrease adverse communication-related events. Hoskote and colleagues [19] developed another electronic handoff tool to improve handoffs in an adult ICU. The tool was integrated with EMR and was accessible via iPads in the ward. The main goal of the tool was to facilitate the recording of tasks and other information, thereby enhancing communication between providers. After the implementation and analysis of handoffs, this quality improvement intervention was seen to improve the accuracy of handoff without increasing the time required to do so, thus implying an increase in the efficiency of handoff, the study also indicated that the accuracy of the handoffs is far from ideal and needs further development.

All the above-mentioned studies indicate, that digital checklists have the potential to increase the compliance to best practices with increased adoption rate. The positive findings indicate that the use of checklists and CAs in the clinical practice with current medical content could help to close the translational gap between guideline publication and implementation in the acute and surgical patient care by integration of guidelines into the workflow.

#### **1.1.6 Clinical effect of electronic checklists**

Four of the reviewed studies measured primarily the effect of the checklists on patient outcomes [6,12,15,29]. Duclos et al. [12] developed daily-rounds checklist for the ICU which was completed by the certified registered nurse anaesthetists (CRNA) for each patient daily at 07:00. The checklist was accessible via the intranet on computers, smartphones, and tablets and it covered invasive devices (central venous catheter, arterial catheter, peripheral venous line, urinary catheter) and their indications, VAP prevention approaches (head-of-bed elevation, tube cuff pressure control, ventilation pressure < 30 cm H<sub>2</sub>O, daily sedation interruption), physical rehabilitation (enteral feeding, enteral route, transfer from bed to armchair), as well the miscellaneous care (contention, type of mattress, antithrombotic prophylaxis). During their retrospective, before/after study, demographic and clinical data about the patients, as well the information about the types of invasive devices used, were collected. After analysing the data of 3050 patients during the before and after period, electronic checklist use was associated with significant reduction of VAP. The rates of VAP were 21% and 11% in the before and after groups, respectively. Unlike previous researches showing checklist' positive effect on catheter-related and urinary tract infections [5,32], this study found no reduction of central venous catheter-related infection, bacteremia, and catheter-related urinary tract infection rates.

Positive effect of surgical checklist on patient outcomes have been seen through several studies [6,15,29]. Buzink et al. [6] investigating the effect of a digital procedure-specific checklist tool (Pro/cheQ) on the risk sensitive events (RSE) during surgery found a positive correlation of Pro/cheQ and occurrence of RSE. The researchers assessed integrated OR system and the combined effect of the integrated OR system with Pro/cheQ, and their effect on the number and type of equipment- and instrument-related RSE during laparoscopic cholecystectomies. The laptop-based prototype of Pro/cheQ was developed in order to enhance the quality control of structuring and standardizing the preparation of equipment and instruments, time out moments, recording of intraoperative images, debriefing, and filling out the operation report. The responsible person for checking the items was the circulating nurse but completing the Pro/cheQ required the involvement of the whole surgical team. With the use of Pro/cheQ, reduction of RSE was seen, results showed the occurrence of at least one RSE without checklist use in 87% of operations, during the Pro/cheQ use, this decreased to 47%. It is worth mentioning that most of the RSE that occurred were equipment- and instrument-related. Another study looking comparing the occurrence of the risk events [15] during the pre- and post-checklist implementation period, found the reduction of 32%. In the same study, lower rates of thirty-day readmissions and hospital length of stay were also seen but without significant reduction rate. However, one approach of the computerised checklist has shown positive impact of the checklist on thirty-day readmission rates. [29] McCarroll and colleagues assessed the implementation of a robotic-specific checklist (RORCC) with the foundation of the WHO's checklist. After analysing the follow-up data of 89 patients pre-checklist implementation and 121 post-RORCC, the thirty-day readmission rates were twelve and five, respectively. The findings of the research indicate the feasibility and positive outcomes due to implementation of the computerised checklist to the surgery procedures.

Even though not many of the studies have looked into the digital checklists effect on patient outcomes, some of the mentioned studies provide evidence on the improvement in reduction of complications and increase in patient safety through the digital checklist implementations. As mentioned in the background information, many studies have looked into the correlation between guidelines adherence and improvement in clinical outcomes which indicates that by improving the guidelines adherence with digital checklist, patient safety and clinical outcomes are positively affected as well.

### **1.1.7 Usability of and provider perspectives on electronic checklists**

In order to build a digital checklist solution which is to be used in clinical workflows, the user-experience, usability, and general perspective from the user has to be positive. Simulation-based study [40] assessed the physicians' workload, errors, and time of checklist completion of electronic checklist in comparison to paper one. Twenty-one ICU providers participated in the study and completed checklists on the six patients, three electronic and three paper-based checklists. During the electronic checklist completion, reduced workload, measured with National Aeronautics and Space Association Task Load Index (NASA-TLX), was seen, the results for electronic and paper checklist were thirty-nine and fifty respectively. As well, the positive aspect of the electronic checklist was the reduced number of checklist errors, the percentage of unchecked items decreased from 14.9 to 8.8% while using the digital checklist. No difference of completion time was seen. The results from the study indicate that electronic checklists have positive influence on providers workload and errors without negatively influencing the completion rates.

Surveys after digital SSC implementation have shown positive feedback from the providers on the checklists [11,31,33,15]. After the implementation of digital SSC [15], 76% of surgeons, 86% of anaesthesiologists, and 88% of nurses believed the electronic SSC will have a positive impact on patient safety. The study of implementing digital checklist for the management of TURP [31] showed also positive results to the questions regarding the use of electronic CA from the providers and the benefit was seen by all the participant groups (anaesthetic trainees, consultant anaesthetists, and anaesthetic nurses).

During the prospective pilot study conducted by Reed et al. [33], multimedia checklist was developed as an electronic surrogate to the written formatted checklist. The reason for the implementation was to increase attentiveness, participation, and performance of the time out. The baseline survey data, based on the answers of 39 team members, showed that around 82% respondents agreed that a surgical briefing before surgical procedures was important for patient safety and most of the respondents believed that nurses and doctors worked together as a well-coordinated team. After the implementation of the multimedia checklist, the perception of ease of use had increased, as well the clarity of patient identification and procedural laterality. After the multimedia checklist implementation, the higher amount of the respondents believed that the time-out process with digital checklist improved OR safety, but this did not reach

significance. 87,1% of the respondents preferred the multimedia version of the checklist which indicates the positive aspect of digitisation of the SSC.

The results of the scoping review, primarily the evaluation measures and features of the digital checklists, are analysed and compared to the results gathered during an ICU digital checklist project about the developed tool in chapter 4. In the following paragraph, thesis methodology is introduced which is followed by the chapter providing an ICU digital checklist implementation pilot project overview.

## 2 METHODOLOGY

The aim of this master thesis is to evaluate the results of an ICU digital checklist implementation project in Estonia in order to map the needs for further evaluation and development of that digital checklist solution.

The following research questions are answered:

- 1) What are the international best practices of digital checklists?
- 2) How have digital checklists been evaluated in international literature?
- 3) What are the relevant types, settings, and features of digital checklists?
- 4) What were the characteristics and features of the NEMC digital checklist tool?
- 5) What was the evaluation approach for the digital checklist pilot?
- 6) What were the initial results of the project team?
- 7) What are further evaluation needs and suggested evaluation measures for the NEMC digital checklist pilot?
- 8) What are the further development needs of the NEMC digital checklist pilot?

The whole research approach could be described in the following figure:

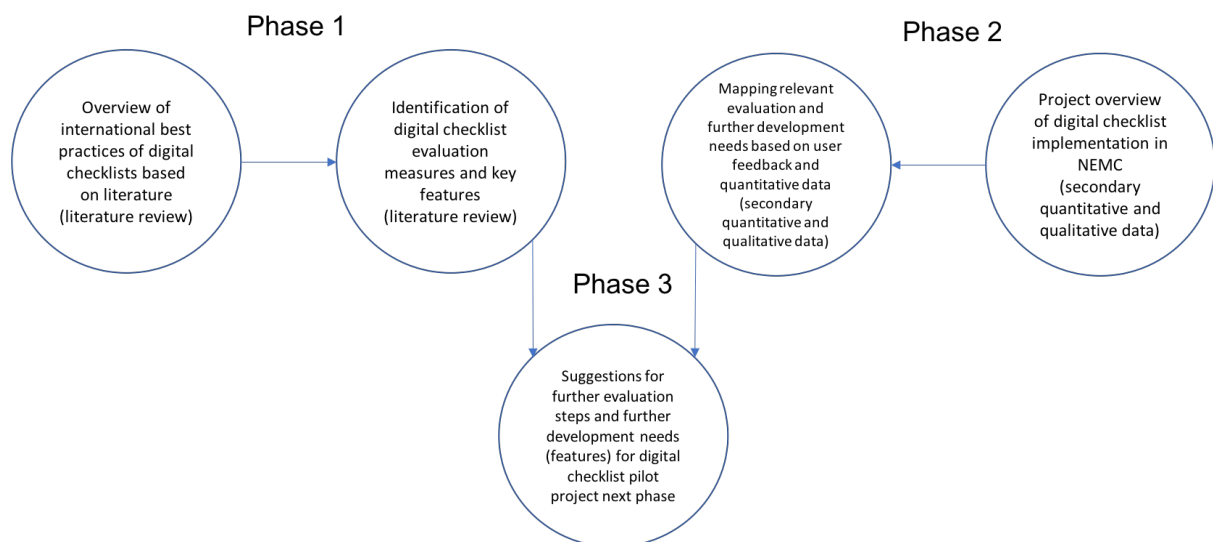


Figure 1. Research approach. Source: author.

The research is done in three phases. After the overview of international best practices of digital checklists' use and implementation, identification of digital checklist evaluation measures and

key features is done. The project overview between Cognuse OÜ and NEMC is presented and relevant evaluation and further development needs are identified. For that, secondary qualitative and quantitative data is used. After these two research phases, comparison of the existing literature and practical pilot is done and based on that, suggestions for further evaluation and further development needs for digital checklist pilot project next phases are given.

## **2.1 Scoping review**

To identify international best practices of digital checklists, how have digital checklists been evaluated in academic literature and what have been the results, what are the relevant types, settings, and features of the digital checklists, the author of this thesis searched two databases (appendix 2, table 1). The scoping review in Med Line was performed using PubMed, as well Google Scholar database was searched. The search strategy included citations from 2008 to 2018. The search was conducted by using simple search terms (free text) which were developed by the author and applied to the two databases according to the construction of the database. The terms were: *digital checklist*; *electronic checklist*; *computerized checklist*. In Google Scholar, term – *hospital* – was added, to limit the search results to hospital settings. The key inclusion criterion was that the study was available in full text and it was in English. The main screening question for the study was that it was about the digital (electronic/ computerized) checklist use in the hospital environment at the point-of-care or during simulation to test the suitability for the hospital environment.

After receiving initial 505 results, the author of this thesis started to apply the inclusion/exclusion criteria (appendix 2, table 2). 467 citations were excluded, making the final list of 38 citations. After removing the duplicates, a total of 33 studies that fit the search criteria were identified. The flow chart of the inclusion and exclusion of articles is stated in the appendix 3 which is based on the study selection reporting by Liberati et al [26]. The author of this thesis found that 16 of the 33 results did not have content sufficient to support the intent to assess digital checklist use in hospital settings facilitating the process of care. Therefore, 16 of the studies were excluded for varying reasons: three papers evaluating checklist as a facilitator to order clinical assessments/lab tests; six papers assessing paper-based checklists and their implementation; one paper assessing checklist in the ambulatory setting at a primary care level; two papers proposing a research plan for checklist implementation and evaluation; two review articles; and two model/solution description papers.

After excluding these sixteen studies, seventeen studies were included in the literature review (appendix 6). The author mapped the studies according to study designs, data sources and dependent variables, evaluation measures, checklist area and type, effect, and usability in order to provide input for assessing the evaluation and further development needs for the NEMC pilot. The scoping review is presented in paragraph 1.2.

## **2.2 Description of the secondary data used**

The obtained qualitative and quantitative data about the pilot project is presented in the following sub-paragraphs.

### **2.2.1 Quantitative data**

The quantitative data concerning the usage of the tool was obtained from the project's database. The author received an anonymous database consisting with usage statistics of the solution.

The following variables were in the database:

- Nurse identifier
- Start time of the procedure
- Duration of the procedure
- End time of the procedure
- Completion of procedure step no 1...50

The database consisted of a total of 398 started procedures. Based on the statistic, author conducted usage level analysis in MS Excel software. The main metrics evaluated were usage and completion rates. The results of these calculations were presented in chapter 2.4.1.

### **2.2.2 Qualitative data**

As qualitative information about the project, the author received two types of data for secondary analysis: a focus group interview recording and a spreadsheet of results of a survey conducted by the project team. The author received also the focus group interview plan and a questionnaire template (appendices 4, 5).

The focus group interview was done to identify the problem-solution fit and needs for further development. There were thirteen people participating in the focus group interview. The

participants were the test users, departmental leaders, quality specialists, and project leaders from both partners side. The author of this thesis participated in the focus group interview as an observer. The survey was sent out to test users after the end of the piloting phase. All of the eight test users provided answers to the survey, which consisted of eleven open- and close-ended questions, and was targeted to identify the desirability of the digital checklist tool and to collect concrete suggestions for further developments.

Both, the focus group interview schedule and the survey template were decided by the project team. This is a limitation to the study, as the current thesis was written after the selection and completion of those data collection activities for the project. The interview schedule and questionnaire were based on the practical project needs. Instead of conducting new interviews or surveys as part of the current thesis, the author decided to use the existing secondary data for analysis. This decision was done based on evaluating the quality of the secondary data, which was found sufficient to fulfil the aim of the current thesis and based on practical considerations regarding efficient time-use of occupied clinical personnel. Furthermore, as the goal of this thesis is to evaluate the further evaluation needs for the project the interview schedule and survey templates were critically assessed as part of the analysis.

### **2.3 Method of analysis**

In order to describe the project between Cognuse OÜ and NEMC, author used the checklist instrument that has been constructed as an extension of the The Consolidated Standards of Reporting Trials (CONSORT) statement [13]. The instrument is called CONSORT-EHEALTH (Consolidated Standards of Reporting Trials of Electronic and Mobile HEalth Applications and onLine TeleHealth) and provides guidance for authors of e-health interventions. CONSORT-EHEALTH is a checklist ensuring that all the relevant information in described in an intervention description. The author of this thesis adapted and used the CONSORT-EHEALTH checklist to provide structured overview of the implementation of an ICU digital checklist tool. As this was the pilot project not an e-health intervention trial, not all the items in the checklist are applicable. A guide proposed by Kelley et al. [22] was used to report the survey results.

Analysis of the questionnaire [4] was done in three phases – exploratory data analysis to identify whether the collected results are enough or more data is needed to be collected. As there were responses from all the eight test-users, the author of this thesis found the amount of



data being sufficient. Data cleaning was also done during this phase. The exploratory phase was followed by the deriving of the main findings. A summary of the findings, as well the relationships, models, interpretations and narratives, are proposed in chapter 3 in this paper. All the collected and analysed data was archived. The results were presented using one-way graphs, which is the most straightforward form of analysis. The method does not provide combinations of answers based on the respondents but provides a summary of the findings.

Focus group interview was transcribed manually. Pragmatic content analysis method was used to analyse the results of the focus group interview. A descriptive analysis of the results is provided in chapter 3 of this thesis [39].

The strategy for development of the evaluation metrics and features to be developed in the next phase of the development included a broad preliminary evaluation approach (based on scoping review) as a benchmark and comparing it to the evaluation metrics used in the pilot experience [21]. A directed content analysis technique is used for describing a phenomenon which benefits from further description. Directed content analysis is guided by structured process, using prior research for identifying key variables for evaluation of digital checklists and data from the pilot of the digital checklists to draw suggestions, how should the digital checklist solution be evaluated in the further phases of the pilots, as well, what features should be added to the solution. In order to compare international literature and the practical pilot, the metrics used for evaluation of digital checklists are identified from the academic literature, as well from the pilot results.

As a result, the author suggests the features to be included into the solution in the future, as well suitable evaluation measures and data collection methods, that would provide relevant information and feedback for the project team about the solution and to help making decisions about adjustments to the solution.

### **3 DIGITAL CHECKLIST TOOL IMPLEMENTATION AT NORTH-ESTONIA MEDICAL CENTRE**

The overview of an ICU digital checklist implementation project is provided using the items from CONSORT-EHEALTH checklist.

#### **3.1 Background and objectives**

The ICU project between Cognuse OÜ and NEMC started in March 2017 and finished by the end of February 2018. During this period, digital checklist tool was developed, and the author of this thesis was an active participant in the process.

The tool included seven nursing guidelines that were converted into checklist mode to be actionable and usable in the clinical workflows. Seven different procedural guidelines were chosen from the 400 total nursing guidelines that currently exist at NEMC. The procedures included aspirations (both with open and closed system), mouth hygiene, tracheostomy, blood transfusion, taking care of the deceased, and ECMO set up procedure.

During the project, guidelines were split into procedural steps and the inclusion and exclusion of certain tasks from the guidelines to the checklist application was discussed with departmental chief nurse and quality leader. Several iterations of the checklists were performed with the project's nursing specialists.

The objectives of the development of the digital checklist tool were:

- 1) to bring distant guidelines closer to the clinical staff;
- 2) to convert clinical guidelines to checklist format, making them usable and actionable during clinical work;
- 3) to standardise nursing procedures through active usage of procedural checklists during clinical work;
- 4) to improve patient outcomes through reduction of medical errors and complications.

#### **3.2 Methods**

The methods of the solution implementation are described in the following sub-paragraphs. The overview of project design, participants, intervention, and outcomes is provided.

### **3.2.1 Project design**

After setting up the initial set of procedures, three sets of preliminary try-outs were performed in the department in real practice. Preliminary try-outs were done in April, May, June. After each of the testing, certain changes in the procedural checklists were done to adjust the application seamlessly into the workflow without conflicting with users' understandings of successful performance of the procedure.

From the end of July, test device with three Bluetooth headsets stayed at NEMC and eight nurses participating in the project, were testing the solution. The glitches fixes during the project were done on 28.10.2017 and 29.12.2017 – 04.01.2018.

### **3.2.2 Participants**

During the test period from the end of July 2017 to the end of February, checklist application was used in the 2<sup>nd</sup> cardiac ICU of NEMC by eight nurses at two different experience levels – beginners and experienced nurses. Both groups included four nurses. All the nurses working in the ward were eligible to be part of the ICU project, the departmental leader chose the participants randomly.

The procedures were done randomly on patients who required the intervention that was possible to be supported by the tool. The users could choose when to use the tool. There was no data captured about the control state (procedures done without the tool), neither of the baseline.

### **3.2.3 Intervention – solution overview**

During the project, novel digital checklist tool was developed. The tool ran on the iOS operation system. After opening the application, user had to insert initials. The existing procedures were presented on the application's home page and the procedure was launched after clicking on it.

The user-experience while doing the procedure was entirely hands-free, meaning that the user had to wear a headset and after hearing a guidance step, user had to provide an audio command to guide the application. Users could guide the solution with six different audio commands,

which, even though the solution and the guidance the nurses received was in Estonian, were in English. The commands were: “yes”, “no”, “next”, “back”, “repeat”, “stop”.

The usage flow:

- 1) user puts on the headset and launches the digital checklist tool from the smartphone;
- 2) user inserts initials;
- 3) user clicks on the procedure name;
- 4) procedural checklist starts;
- 5) the application plays either a question or a task as a checklist item;
- 6) user has to provide an answer (audio command) to move on in the procedural checklist;
- 7) by providing the answer ‘*next*’, user confirms the implementation of the checklist item;
- 8) after finishing the procedure, application provides information about the duration of the procedure;
- 9) after finishing the procedure, user quits the application.

### **3.2.4 Outcomes of the ICU project**

The usage data of the application was collected to the database. Collected data included started and finished procedures, duration of the procedure, and performed steps. As the users had to insert initials after opening the application, it was possible to connect users to the usage data. After the testing period, focus group interview was conducted and a survey was sent out to test users.

The measures that were evaluated with quantitative data were compliance with checklist, completion of checklist, and usage rate. The measures that were evaluated with qualitative data included occurrence of errors, occurrence of risk-sensitive events, and user satisfaction. Participation was evaluated with both qualitative and quantitative measures. However, also feedback and interest for future developments of the users were collected via focus group interview and survey. No correlation between measures about patient outcomes or any other clinically relevant information and the solution could be evaluated due to not systematic implementation of the solution in the ward.

Focus group interview was held in January 2018, to get perspectives of different stakeholders on medical errors, guidelines adherence and management, checklists, and the tested solution. The participants in the interview were the project leaders of the joint venture between Cognuse

and North Estonia Medical Centre, Andres Mellik (Cognuse, CEO) and Indrek Rätsep (chief intensivist, North Estonia Medical Centre, cardiac intensive care unit) Andra-Maris Post (departmental chief nurse, cardiac intensive care unit), Piret Sillaots (departmental quality leader, cardiac intensive care unit), Kersti Naelapää (hospital quality specialist, North Estonia Medical Centre) and eight nurses who participated in the project as test users (four experienced and four beginners). The interview lasted for two hours.

At the end of the testing period, survey to eight test users was sent out. The survey was used to collect users' perspectives on developed solution and development interests. All the test users provided answers to the survey. The survey consisted of eleven questions in total and it was anonymous. However, the nurses had to provide their working experience in the survey. The evaluation of the pilot results was done in March 2018, after the end of the pilot by the author of this thesis. The results of the pilot are presented in the following paragraphs.

### **3.3 Quantitative data results**

During the pilot project (excluding the dates of the glitches fixes, 28.10 and 29.12 – 04.01), seven of the included procedures were started in total 398 times and completed 274 times. However, the results do not indicate that this amount of the procedures were performed using the tool as it was a pilot phase and users were sometimes looking through the application while not performing a procedure.

The completion rate of procedures was 69%. There can be several reasons behind the relatively low completion rate, including technical issues or patient-specific problems. Since the solution was designed and developed as the nurses had to confirm each and every step in the protocol, adherence to the checklist was 100%.

### **3.4 Qualitative data results**

In the following paragraphs, results of the focus group interview and the survey are presented.

#### **3.4.1 Medical errors as part of the clinical practice and guidelines as measures to decrease the amount of errors**

The first part of the focus group interview was held on medical errors. The current workflow regarding guidelines is as follows:

- 1) when starting clinical work, mandatory guidelines have to be read through and signed;

- 2) guidelines are accessible via the Intranet when needed;
- 3) when guidelines are renewed nurses get the notification to the e-mail and have to read through the guidelines and sign them.

The quality department is renewing the guidelines in every two-three years and after the renewal, whole personnel has to go through the guidelines, sign them and after this ensure, that based on the changes in the guidelines, adjustments in the working practices are made. However, nurses brought out that existing guidelines are not accordance with the real situation and do not reflect the workflows in the right manner. The quality manager explained the problem and said that at the moment, all the guidelines are the same for all the wards and minor differences in the procedures between the wards exist and cannot be reflected in the guidelines. Department specific guidelines exist only for certain procedures that are done only in the certain wards. It was emphasised, that NEMC has all together 400 nursing activities that should have guidelines but at the moment, procedural guidance exists for 120 nursing activities.

The problems regarding guidelines were discussed. The main problems regarding low guidelines consumption and adherence during practical work were stated as:

- 1) guidelines are in the paper folders and it takes time to find the right ones/the ones that are needed;
- 2) guidelines are also accessible via the Intranet, but the usage of the Intranet is low among the staff in the cardiac ICU;
- 3) guidelines are not a part of the clinical workflow due to lack of policies;
- 4) guidelines are not actionable – they are lengthy and have lots of irrelevant and impractical information for the use at the work processes.

The guidelines creation process is done in order to standardize care processes and decrease the amount of occurrence of errors. Most common errors during the last quarter of 2017 at NEMC were:

- 1) self-harm activities: 15 times;
- 2) medication errors: 3 times;
- 3) documentation errors during pre-analytic phase: 2 times.

The questions about medical errors, as well the guidelines and their integration into the solution were included also to the questionnaire. Nurses believed that the solution could prevent different kinds of mistakes and errors occurring during clinical work:

- 1) mistakes made while setting the table (5 times);
- 2) mistakes made during rarely occurring procedures (7 times);
- 3) mistakes made during everyday procedures (3 times);
- 4) medication errors (3 times);
- 5) mistakes made while assembling devices (3);
- 6) mistakes made during taking analyses (2 times).

One nurse, with working experience of 25 years, added a comment to this question, *‘The solution supports while something in the best practice has changed and it is not memorised yet.’*

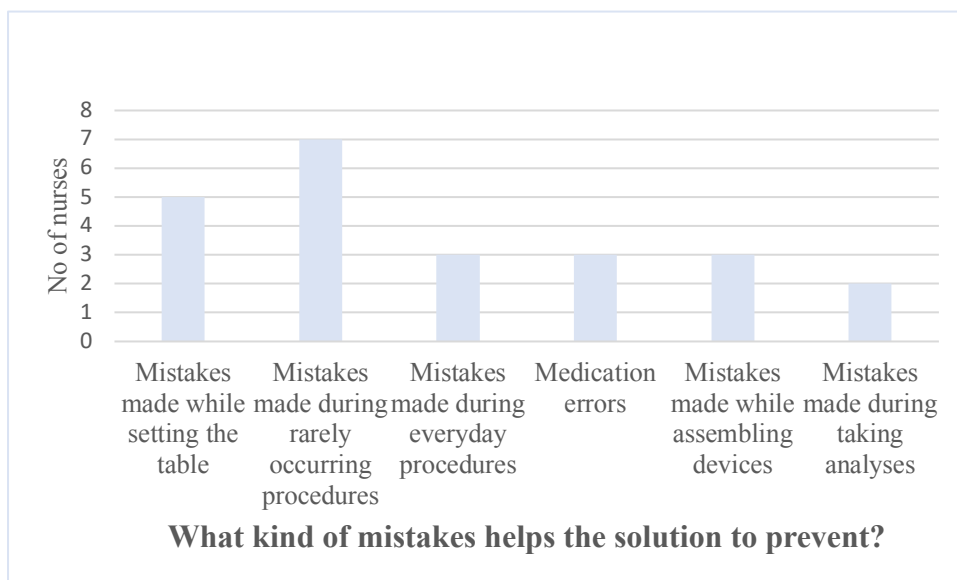


Figure 2. Areas, where the solution brings value

### 3.4.2 Feedback on the solution

The feedback on the developed and tested solution was obtained through the focus group interview and the survey.

Four of the respondents had tested the solution six to ten times, three nurses more than ten times and one had not kept track on this. Higher usage rate was seen for the beginner-nurses.

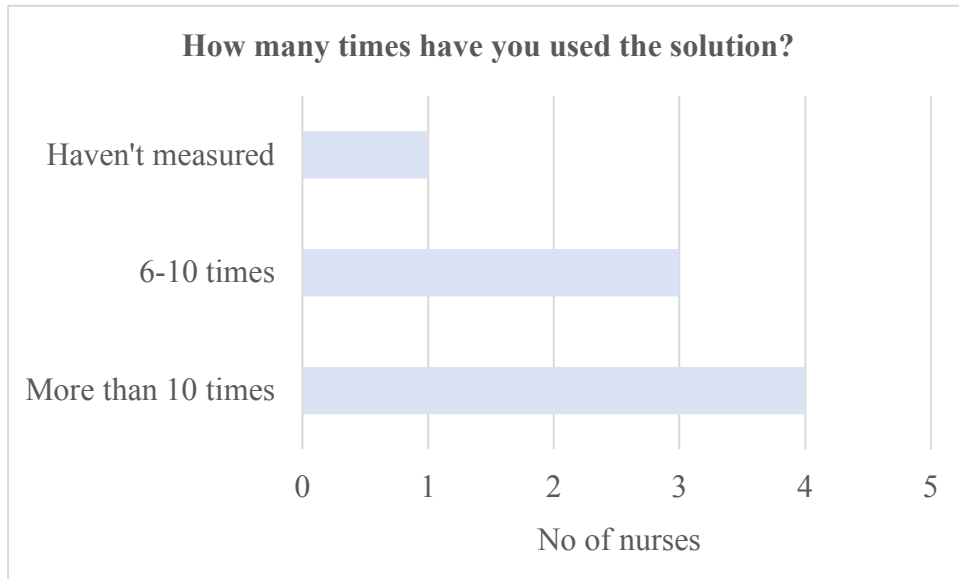


Figure 3. Self-reported usage rate of the solution

One of the nurses had tested all seven procedural checklists on the application, three had tested six procedural checklists, one had tested five procedural checklists, two had done four procedures with the support of the solution, and one nurse had tested only one procedural checklist. The lowest usage rate was for the blood transfusion procedure which happens rarely when compared to other procedures that were included in the solution.

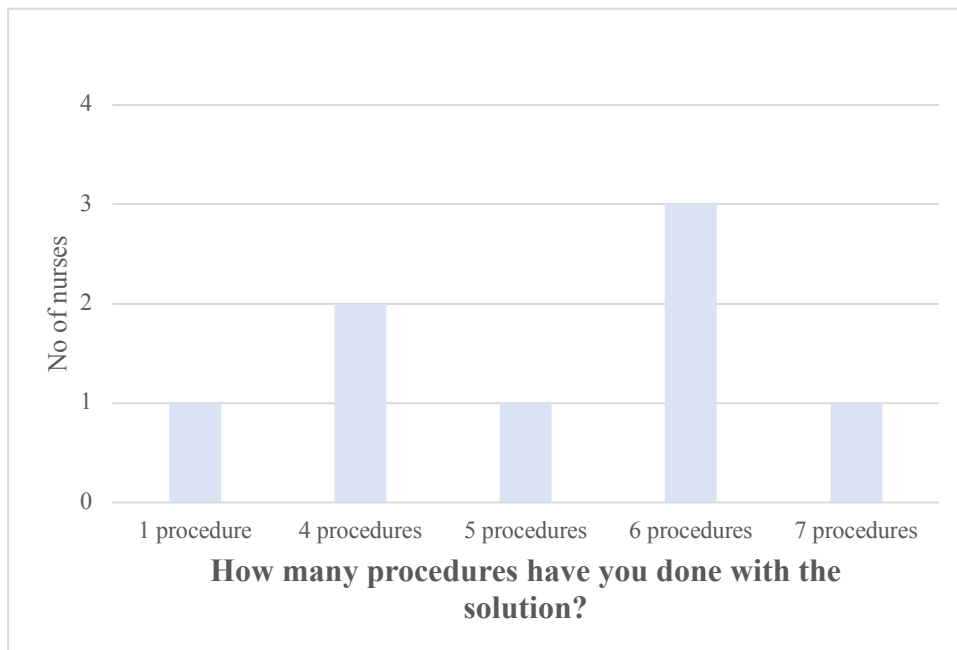


Figure 4. Self-reported usage rate of different procedures



The nurses saw the developed solution as a good tool for easily accessing existing and introducing new guidelines. The nurses provided positive feedback on the possibility to rather search for a needed guideline from the smartphone and go quickly through it than to log in the Intranet and waste time. Having the guidelines both in written and audio manner was also perceived positively, as with audio support it is possible to use the guidelines at the process-of-care.

The positive aspects of the solution, that were brought out, were:

- 1) the solution is easily accessible and the use during clinical procedures does not violate with hygiene measures;
- 2) useful reminder about how to do the procedures in real-time;
- 3) possibility to go through the guidelines before doing the procedure;
- 4) possibility to analyse the existing guidelines – to see differences between real situations and what is in the guidelines and to improve the quality of the existing guidelines.

*‘The solution is very good but I believe that this is not meant for critical care nurses. Some of the included procedures take place 20 times a day. I know them by heart!’*

The nurses who participated in the pilot believed that the solution is a good support for young nurses while doing the procedures. Majority of the respondents believed also that the solution is supporting them while doing the procedures. Only one nurse answered, that she does not get any support from the tool. One experienced nurse, after answering ‘yes’, added, ‘*The solution supports me while recalling and checking the built-in skills,*’ and the other nurse, with twenty years of working experience, commented ‘*With the solution I won’t forget anything to the equipment closet.*’

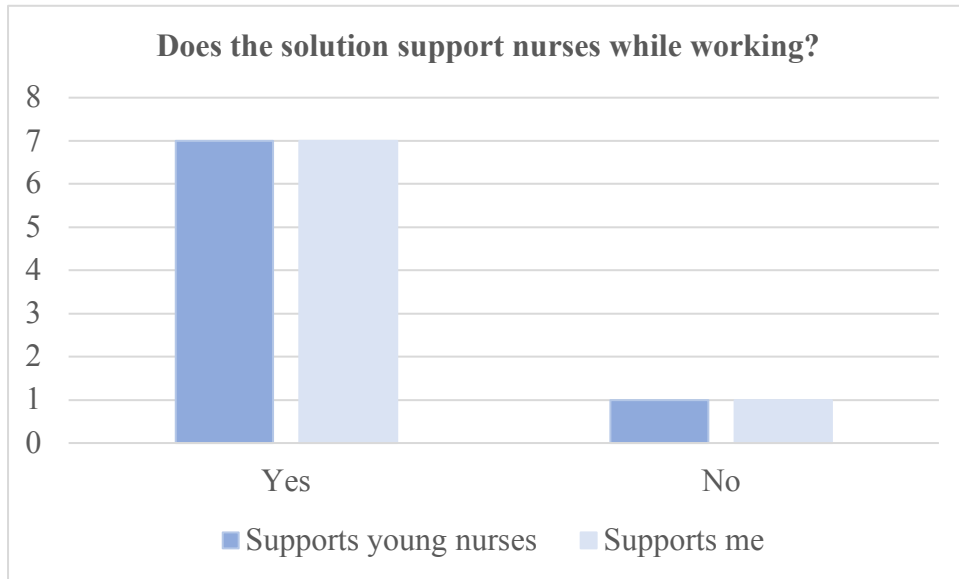


Figure 5. Value of the solution for nurses

The nurses brought out several positive aspects about the solution:

- 1) it is a good reminder (2 times);
- 2) it is easy to use (2 times);
- 3) patient orientation (1 time);
- 4) correctness (1 time);
- 5) right order of steps (2 times);
- 6) I did not forget anything (1 time).

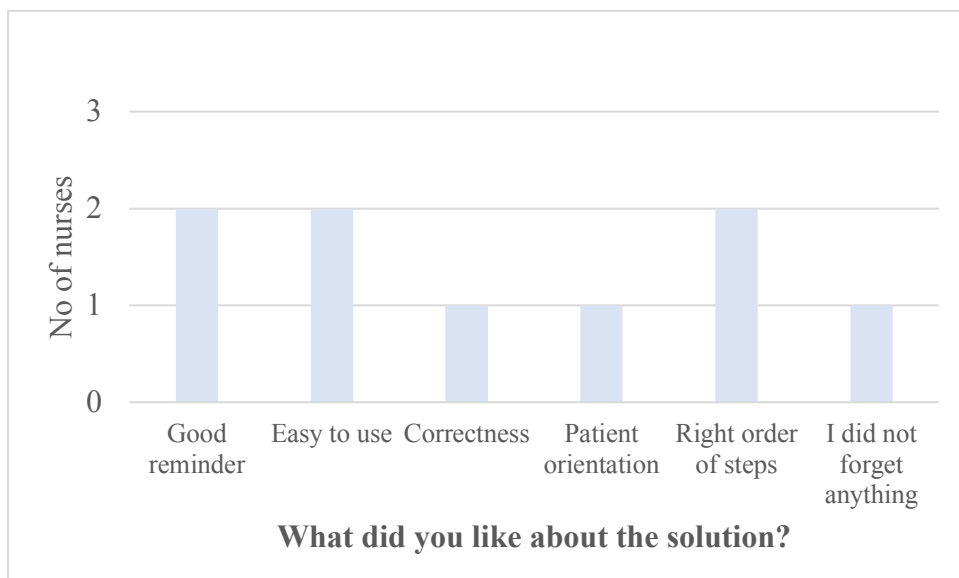


Figure 6. Positive aspects about the solution

The question about recommending the solution to a colleague, received 10 (very likely) as a response (3 times); 9 as a response (2 times); 8 as a response (2 times); and 4 as a response (1 time). Respondents who are very likely, to recommend the solution (answers 9 or 10), are seen as Promoters, respondents answering a number in the range of 0-6, are seen as Detractors. Based on the answers, Net Promoter Score was calculated, by Subtracting the percentage of Detractors from the percentage of Promoters. Net Promoter Score for the solution was 50 [20].

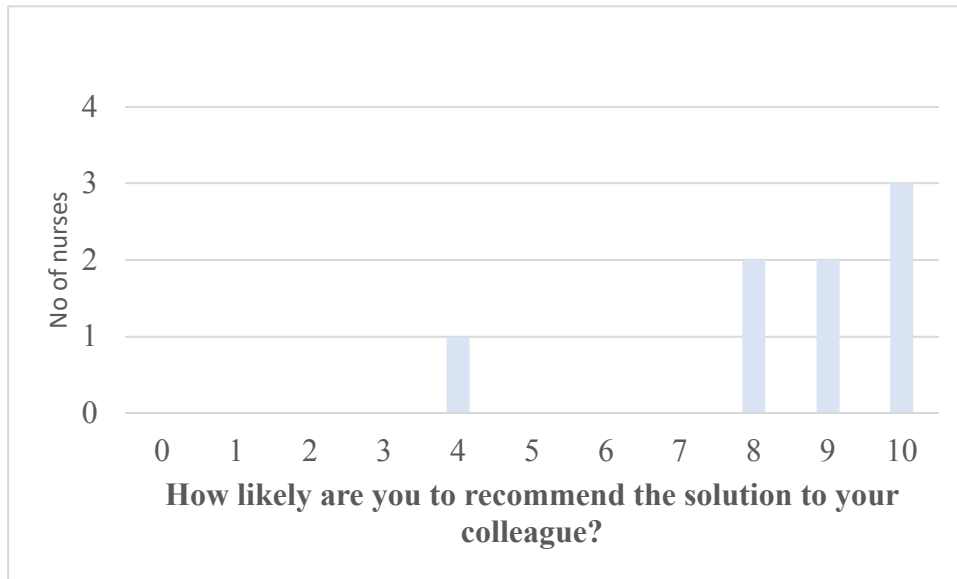


Figure 7. No of nurses willing to recommend the solution to the colleague

### 3.4.3 Proposed future developments by the users

Nurses brought out several aspects that could be improved and what affected the adoption and testing period:

- 1) technical issues;
- 2) extra time that required to put on the headset;
- 3) need to confirm each of the step.

*‘The solution could never work as a must-be. It should be the aid and support for nurses but not something that has to be followed 24/7. It might make nurses also stupid, while using this kind of support, nurses do not have to think anymore while doing the procedures.’*

Potential guidelines that can be added to the solution:

- 1) hand-off checklist for transferring patients from ICU to the OR and vice versa;
- 2) checklist for leaving and coming to work;

- 3) blood transfusion;
- 4) tracheostomy;
- 5) ECMO procedures.

*‘A serious problem that our ward is facing these days, is that the nurses finishing the shift forget to fill in the drawers with needed equipment. It would be very good, if the checklist could give reminders about the needed actions when finishing the shift. Also, checklist could support while taking over the shift, checking the medications, etc.’*

The questions about further developments, as well guidelines to-be-added to the solution were included also into the questionnaire. For the question regarding the future developments of the solution, 8 of the respondents would like to see pictures integrated into the solution; 7 would like to have Estonian speech recognition, and 3 would like to have a possibility to create checklists themselves.

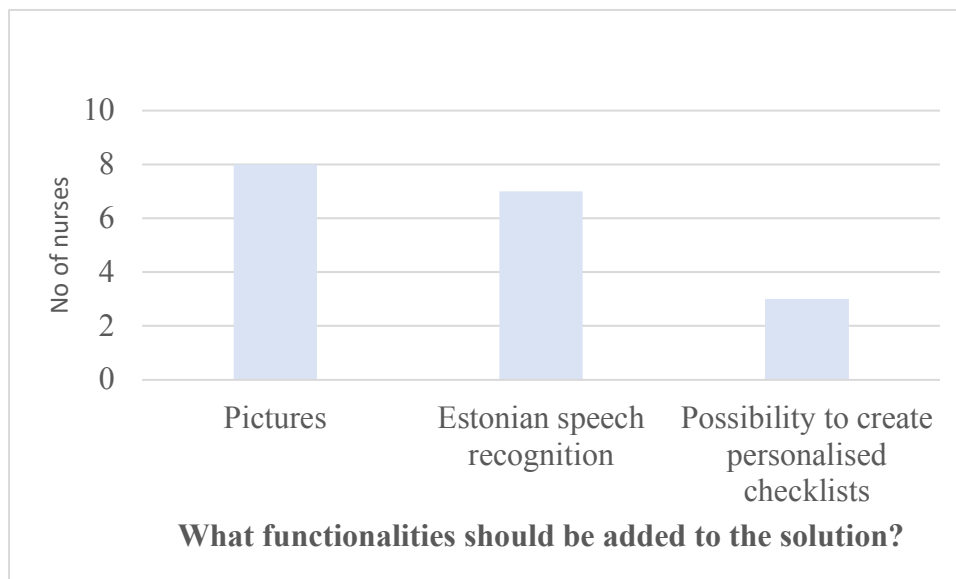


Figure 8. Functionalities to be added to the solution

Responses to the question, which aimed to identify the procedural guidelines that should be added to the solution at first, three of the respondents brought out guidelines for setting sterile tables, procedural guidelines for pleural drain insertion, and a central venous insertion were mentioned one time, and also one of the respondents wanted to add the guidelines that need to be done quickly, she added as a comment *‘These guidelines would be easily accessible from*

*the smartphone because there's no time to go look into the papers.* Four of the respondents did not know, what kind of procedural guidelines should be added to the solution.

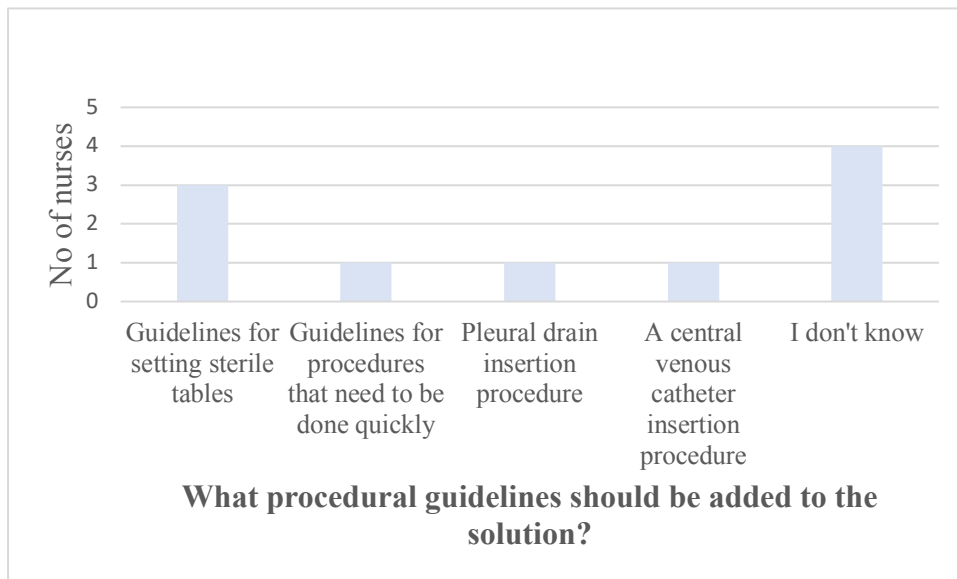


Figure 9. Procedural guidelines to be added to the solution

The first phase of the pilot project is followed by the second phase. For the second phase of an ICU digital checklist implementation project the author of this thesis provides suggestions of the evaluation measures to be included in the analysis, as well the features to be added to the solution. The author of this thesis provides the comparison of digital checklists best practice literature and practical pilot in the following chapter, based on what the suggestions are made.

## 4 SELECTING EVALUATION MEASURES AND SUGGESTING DEVELOPMENT NEEDS

In this chapter, the author provides comparison of evaluation measures and data collection methods used in the academic literature and in an ICU digital checklist implementation project. As well, comparison between the features of the solutions is provided. The author provides suggestions for the project team, what evaluation measures to include in the following phase of the pilot, as well, what features to include into the solution.

### 4.1 Evaluation measures and data collection methods

In the following table, evaluation measures and data collection methods from academic research are extracted and compared to the evaluation measures and methods used during the pilot. The academic literature is analysed using qualitative content analysis to identify, code, and categorise the evaluation measures used for the digital checklists evaluation. The evaluation measures about the pilot are extracted from the project database, as well relevant measures identified from the survey questions and focus group plan.

Table 1. Evaluation measures used for evaluating digital checklists. Source: author.

Evaluation measure	Used in pilot?	Data collection method identified via scoping review	Data collection method used during the pilot
1) Rates of VAP		EMR record review	
2) Number of days free of invasive devices		EMR record review	
3) Number of consults		EMR record review	
4) Provider workload		NASA-TLX instrument	
5) Occurrence of errors	X	Observational audits	Focus group interview
6) Completion time	X	Observational audits	Built-in data collection of the application
7) Compliance with checklist/adherence to guidelines	X	Observational audits	Built-in data collection of the application
8) Completion of checklist	X	Observational audits	Built-in data collection of the application

9) Occurrence of risk sensitive events	X	Observational audits	Focus group interview
10) User satisfaction	X	Survey	Focus group interview and survey
11) Usage rate	X	Observational audits	Built-in data collection of the application /survey
12) Thirty-day readmissions		EMR record review	
13) Reliability (inter-observer agreement of checklists items [23])		EMR record review and observational audits	
14) Validity (do the answers provided in the checklist reflect the actual situation [23])		EMR record review and observational audits	
15) Attendee participation	X	Survey	Survey
16) Data concordance		EMR record review and observational audits	
17) Right timing of the event		Observational audits	

Based on the literature analysis, there are many different measures that can be used for evaluating digital checklists. The author cannot say that the list proposed is complete, however all the evaluation measures that were identified through scoping review (paragraph 1.1) are presented in the table above. During the pilot at NEMC, ten different evaluation measures were used. Five of the measures were evaluated based on the data from the database and five were evaluated based on the qualitative data from the focus group interview and survey. The measures included occurrence of errors, occurrence of risk-sensitive events, completion time, compliance with checklist, completion of checklist, user satisfaction, usage rate, attendee participation.

The most common data collection method for evaluation measures of digital checklists based on literature is observational audit, meaning the on-site observations of digital checklist use. During the pilot at NEMC, no observations were done which is definitely a negative aspect of the evaluation approach. During the pilot, many measures were evaluated subjectively based on the feedback from the participants. The subjectively evaluated measures included among others also the occurrence of errors, occurrence of risk sensitive effects, and usage of the solution. In the academic literature, all these measures have been evaluated using observational

audits. The author of this thesis suggests to definitely include observational audits into the evaluation plan for further phases of the pilot.

As checklists increase guidelines adherence [37], it was also being targeted by the developed digital checklist solution. However, the solution design required the user to confirm each of the steps and as users had to confirm all the steps to move on within the application, the adherence was found to be 100%. Scoping review revealed that usually, adherence is evaluated through observational audits. The author of this thesis suggests using observational audits for data collection method while evaluating adherence, as this would give concrete results and understanding regarding the issue.

The clinical effect of the solution was not the primary interest of the first phase of the pilot. Therefore, no patient data was analysed to identify the benefits of the solution on patient outcomes. In the literature, EMR record review is used to identify the effect of digital checklists on patient outcomes, checklist reliability, and validity. During the pilot, no review of the medical record was done. The author of this thesis suggests including the record review for the next phases of the pilot, as it raises the credibility of the effect of the solution on the patient outcomes. However, as it was the first phase of the solution testing and the usage in the ward was not systematic, record review at this point would have not provided any relevant information. The effect of the solution was evaluated based on the data from the focus group interview, as well from the data obtained from the survey. As the effect of the solution is evaluated in the academic literature with data collected from record reviews or by observational audits, the subjective evaluation of the effect evaluation is not sufficient, and the effect of the solution is not validated with the existing data. The potential clinical effect of the piloted solution has to be re-evaluated in the further phases of the pilot.

The majority of the evaluation measures used for the pilot were usage related. The usage data was collected by the application itself and subjectively assessed by the test users during the questionnaire. In the existing literature, the metrics about the usage are evaluated mostly through observational audits. The built-in method provides more realistic/instant feedback of the actual usage and adoption of the solution and provides relevant information for the authors of the solution. However, usage should be definitely evaluated using observational audits as well, to provide more information about the practical use of the solution in clinical workflows.



In this phase of the pilot, no control group was being evaluated. As well, no baseline data was collected. As described in paragraph 1.1.1, several studies about digital checklists have compared checklist use to no checklist use either in the simulation-basis or in the clinical practice and collected data with observational audits. The author suggests including a control group or at least define the baseline of the variables that the solution is targeted to change. Practically, it can be done by observing certain amount of procedures done with and without the solution or identifying the baseline data from the hospital database about the errors occurring while certain procedures or patient complication and/or infection rates. Including this step into the analysis of the solution effect provides the team a state to compare the solution with.

The qualitative data about the project was obtained via a questionnaire and a focus group interview. The focus group interview was primarily composed based on the objective of the project to identify the problem-solution fit and the questionnaire included questions primarily targeted to evaluate the desirability of the solution. The team was successful in getting the responses from all the test users to the survey. However, the focus group sample size was thirteen, which is relatively high. As well, the project team could include other relevant stakeholders from the hospital side (IT, board) to the focus group interview to facilitate the implementation process, which indicates that more interviews would be required. The author of this thesis assessed the templates of the data collection measures (appendices 4-5) critically and suggests the project team to:

- 1) include less questions with optional answers in the questionnaire;
- 2) use an existing questionnaire/focus group interview template;
- 3) include less participants in the focus group interview and have a more homogenous group, if possible, conduct more interviews with different stakeholders.

#### **4.2 Features/functionalities to be added to the solution**

In the following table, functionalities and features of the digital checklists solutions from academic research are compared to the features and functionalities of the tested prototype. The academic literature is analysed using qualitative content analysis to identify and categorise the functionalities of digital checklists. The suggestions for the new features and functionalities to be added to the solution are given based on the academic literature and secondary analysis of the feedback provided to the tested solution.

Table 2. Features/functionalities to be added to the digital checklist tool. Source: author.

Feature/functionality	Existing literature	Used in pilot?	Need for inclusion in the solution in the future
Audio-based delivery	[33]	X	
Automatic flow of guidance	No existing literature		X Suggestion proposed based on the user feedback. Users perceived the continuous commanding of the solution negatively. Adding this feature would improve the user-experience.
Procedural checklist	[23]	X	
Speech recognition (English)	No existing literature	X	
Speech recognition (Estonian)	No existing literature		X Suggestion proposed based on the user feedback. Adding this feature would improve the user-experience.
Illustrative content (pictures, videos)	[11,27]		X Suggestion proposed based on the user feedback. Adding this feature would improve the user-experience. There were two studies in the scoping review that had included illustrative content to the solution.
Decision support	[2,31,40]		
IT integration	[1-2,7,12,31,36,40]		X Suggestion proposed based on the existing literature. The author of this thesis believes that for wider adoption of the solution, IT integration is inevitable. However, users of the solution did not request the IT integration.
Different types of checklists	[1,7-8,12,19,23,36]		X Suggestion proposed in combination of user feedback obtained from focus group interview and existing literature.

The prototype that was tested (solution overview is provided in paragraph 3.2.3) in the clinical setting was functionally primitive and the main feature of the solution was being assessed – possibility to include digital checklist solution into the clinical workflow. In the prototyped solution, there were three functionalities included. The functionalities included audio-based delivery, support for procedural checklist, and English speech recognition. The piloted solution had 100% audio delivery. The users had to confirm each of the steps which ensured 100%

guidelines adherence. The author of this thesis could identify only one similar approach of audio-based checklist use from the academic literature [20]. The audio delivery meant also guiding the solution with audio commands. However, the users did not like giving voice commands and confirming each of the steps, which poses a need for future developments to re-design the solution and enable automatic flow of the steps. The author of this thesis suggests including automatic flow to increase user-experience. The illustrative content has been used in the literature to facilitate the delivery process of the checklists [11,27]. The users requested also for the inclusion of the pictures so the author of this thesis suggests to include illustrative content to the digital checklist tool to provide enhanced visual provision of the checklist, among the audio-delivery.

Most of the electronic checklists that were covered in the literature review, are integrated into the EHR or to the anaesthesia system and can be accessed from there via desktop or iPad [1-2,7,12,31,36,40]. The developed tool did not have IT integration with EHR in this phase of the project. The existing literature provides evidence, that IT integration is very important to increase the adoption rate of digital checklist solution and therefore influence the care quality. Having an audit trail with confirmation of procedure completion using the tool would increase the value for the hospital about the solution. Therefore, the author suggests the project team to integrate the solution with EHR.

The project team collected a lot of information via survey and focus group interview (overview provided in paragraph 3.4) regarding the future development interests and needs from the users. The users would like to see very straight-forward adaptations to the existing solution (pictures, Estonian speech recognition, personalised checklists) and among procedural audio-based checklists, the users would like to see a more classic checklists that are not used only for procedural support. As the piloted approach is entirely novel and that there is a lack of evidence of the audio-based delivery of the checklist, the author of this thesis suggests to definitely include more traditional types of checklists (presented on one screen) which have been researched more specifically and have already provided positive results on patient outcomes [6,12,15,29]. The included procedures and protocols were chosen by the hospital partner and included evidence-based practice guidelines for the procedures. As there is a lot of existing evidence from the literature [1,19,36], that the handoffs checklist has shown positive impact on clinical work and need for inclusion was also provided during the focus group interview, the handoff checklist should be added to the solution.

The literature revealed that the processes where digital checklists are currently the most used, are time outs and sign outs during surgery; patient handoffs from one department to the other; daily rounds, resuscitation, and general evidence-based practice checklists in critical care to support guidelines adherence. The digital solutions target nurses, intensivists, and anaesthesiologists. The piloted solution was only tested by the nurses and only nursing protocols were included there. As there is a lot of literature of the checklist usage among doctors, the development team should include also the procedures done by doctors and other professionals into the solution in the following phases to achieve broader adoption. However, the author of this thesis suggests not doing it in the next phase and to work on the adoption among nurses.

### **4.3 Limitations**

The main limitation of the study is that the focus group interview schedule and the survey template were decided by the project team and the current thesis was written after the selection and completion of those data collection activities for the project. The interview schedule and questionnaire were based on the practical project needs. The author of this thesis decided not to conduct new interviews or surveys and use the information as secondary data for analysis. This decision is supported by the primary goal of this thesis which was to evaluate the further evaluation needs for the project the interview schedule and survey templates were critically assessed as part of the analysis.

Another limitation of the current thesis is the novelty of the solution being studied. Very few checklists, that have been implemented in the hospitals, have audio-delivery. As this was the main feature of the piloted solution, a lot of feature suggestions from the users came regarding this feature. The author of this thesis can provide suggestions based on the users' needs identified from the feedback and scoping review results, however there is a lack of common parts between academic literature and an ICU digital checklist implementation pilot project.

## **Conclusion**

This thesis work is a contribution to the development of a novel digital checklist tool. The thesis is relevant for hospitals and their quality managers, as well for the healthcare payers and/or regulatory bodies that are looking for ways to increase care quality or are already thinking about improving their hospital's or healthcare system's quality through the checklist implementation. This thesis is relevant also for the developers of the solution in order to adapt the solution based on users' need and to have a clear understanding, what measures should be evaluated while assessing the solution in the next phase of the pilot.

The author of this thesis identified relevant measures for digital checklists evaluation via scoping review. By looking at the qualitative and quantitative data about the pilot, the author identified the measures that were evaluated by the project team. The author compared the academic literature and practical ICU digital checklist implementation project and gave suggestions for the project team about the future evaluation measures and features to be included in the solution based on identified best practices. The author of this thesis suggests measuring the variables providing information about the clinical effect of the solution. This data can be captured with observational audits or by analysing the EHR. As well, it is definitely necessary to include baseline and/or control group to the evaluations, which would provide a state to compare the solution with and provide information about the benefits that the solution has.

The author identified the features and functionalities of digital checklists. As the survey and focus group interview were strongly focused on evaluating the future steps regarding the solution, users had proposed several functionalities and features to be added to the solution. Based on the best practices, IT integration, as well inclusion of illustrative content and wider set of checklists content, as well the traditional checklists shown on one screen are the proposed development areas by the author of this thesis. The project team should also add automatic regime of guidance and Estonian speech recognition to the solution based on the requests from the users. However, the solution is novel and there is a lack of evidence of certain proposed functionalities.

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## APPENDICES

### Appendix 1 – Full text articles included in the scoping review

Reference no	Article	Study design and method	Data source	Effect measure	Specialty area	Checklist type and function	Study findings on checklist benefit
12	Implementation of an electronic checklist in the ICU: Association with improved outcomes	Pre-post e-checklist use	Record review of rate of VAP and number of days free of invasive devices	1)Rates of VAP; 2)Number of days free of invasive devices before and after implementation of the electronic checklist	Critical care	Daily-rounds checklist	Increases in ICU-free days (OR = 1.05; 95% CI = 1.04–1.07) and mechanical ventilation-free days (OR = 1.03; 95% CI = 1.01–1.04); an electronic checklist was associated with positive effects on patient outcomes, especially on VAP
2	Effect of daily use of electronic checklist on physical rehabilitation consultations in critically ill patients	Pre-post e-checklist use	EMR review of patient demographics, outcomes, checklist use, and physical therapy consults	Effect of the use of an electronic checklist on occupational therapy/physical therapy (OT–PT) consults in critically ill patients	Critical care	Evidence-based practice checklist and decision-support tool	Increased number of OT/PT consults
40	The Effect of an Electronic Checklist on Critical Care Provider Workload, Errors, and Performance	Randomized controlled comparison of paper checklist to e-checklist use during simulation	Simulation on 6 ICU patients	ICU provider workload, errors, and time to checklist completion (electronic checklist vs paper checklist)	Critical care	Evidence-based practice checklist with decision-support tool	Reduced provider workload and errors without any measurable difference in the amount of time required for checklist completion
27	Novel use of electronic whiteboard in the operating room increases surgical team compliance with pre-precision safety practices	Pre-post e-checklist use	Direct observational analyses of preprocedural time outs	Surgical team compliance with the pre-incision time out	Surgery	Interactive electronic checklist system (accessible from electronic whiteboard); time-out checklist	Increase in time out procedural compliance

33	Does a novel method of delivering the safe surgical checklist improve compliance? A closed loop audit.	Pre-post delivery of SSC with digital-checklist	Direct observational analyses; staff feedback via survey	Compliance and staff engagement with the checklist; occurrence of time-out/sign-out, completion of checklist, and presence, and engagement of staff during checklist administration. Staff feedback on the process was also sought	Surgery	WHO Surgical Safety Checklist (SSC); time-out checklist	Improved rate in checklist completion
11	Enhancing surgical safety using digital multimedia technology	Pre-post checklist use	e-Survey among staff participants	Perceptions of the staff participants	Surgery	SSC incorporated with digital and video multimedia; time-out checklist	Improved clarity of patient identification ( $P < .05$ ) and operative laterality ( $P < .05$ ) with the digital method. About 87% of the respondents preferred the digital version to the standard time-out (75% anaesthesia, 89% surgeons, 93% nursing). Although the duration of time-outs increased (49 and 79 seconds for standard and digital time-outs, respectively, $P > .001$ ), there was significant improvement in performance of key safety elements.
6	Risk-sensitive events during laparoscopic cholecystectomy: the influence of the integrated operating room and a preoperative checklist tool	Pre-post checklist use	e-Direct observational analyses of 45 laparoscopic surgeries	Occurrence of risk sensitive events (RSE)	Surgery	Integrated OR system and Pro/cheQ, a digital checklist tool	Pro/cheQ tool supported the optimal workflow in a natural way and raised the general safety awareness amongst all members of the surgical team
1	An Electronic Checklist Improves Transfer and Retention of Critical Information at	Pre-post checklist use	e-Direct observations; survey among department members	Retention of critical patient information; checklist usage and clinician satisfaction	Anaesthesiology	Handoff checklist	Significant improvements in the frequency of information relay occurred with checklist use

	Intraoperative Handoff of Care						
8	Intelligent dynamic clinical checklists improved checklist compliance in the intensive care unit	Randomized controlled comparison of local standard of care to dynamic clinical checklist use during simulation	Video recordings of the procedures during simulations; survey among participants	Caregiver satisfaction score and the percentages of checked items overall and of critical items requiring a direct intervention	Critical care	Daily-rounds checklist	Increases compliance with best practice by reducing the percentage of unchecked items during ICU ward rounds
7	Testing the implementation of an electronic process-of-care checklist for use during morning medical rounds in a tertiary intensive care unit: a prospective before–after study	Pre-post e-checklist use	Direct observations	Compliance rate; e-checklist validity	Critical care	Daily-rounds checklist	Compliance with each care component improved significantly over time; the largest improvement was for pain management (42% increase; adjusted odds ratio = 23, p < 0.001), followed by glucose management (22% increase, p < 0.001) and head-of-bed elevation (19% increase, p < 0.001), both with odds ratios greater than 10.
29	Development and implementation results of an interactive computerized surgical checklist for robotic-assisted gynecologic surgery	Pre-post e-checklist use	Record review of patients undergoing GYN procedures	Thirty-day readmissions; duration of the surgery	Surgery	Robotic-specific checklist (RORCC)	Thirty-day readmissions pre-checklist and post-checklist were 12 and 5, respectively, which is a significant (p = 0.02) reduction. The duration of surgery was not significantly affected
15	Increasing compliance with the World Health Organization Surgical Safety Checklist—A regional health system's experience	Pre-post e-checklist use	OR observer selected cases; electronic audit; survey among participants	Compliance rate; perioperative risk events, such as consent issues, incorrect counts, wrong site, and wrong procedure were	Surgery	Computerised SSC	Compliance increased from 48% (n = 167) to 92% (n = 1,037; P < .001) after the SSC was integrated into the electronic health record. Hospital-wide indicators including length of stay and 30-day readmissions were lower. In a survey to assess the OR personnel's

				compared before and after the electronic SSC rollout.			perceptions of the new checklist, 76% of surgeons, 86% of anaesthesiologists, and 88% of nurses believed the electronic SSC will have a positive impact on patient safety.
23	Reliability and Validity of the Checklist for Early Recognition and Treatment of Acute Illness and Injury as a Charting Tool in the Medical Intensive Care Unit	Experimental study: standard practice vs checklist use	Direct observations, EMR record review	Reliability and validity	Critical care	Resuscitation Checklist for early recognition and treatment of acute illness and injury	Inter-observer agreement was very good ( $\kappa = 0.79$ ) in this study and agreement between CERTAIN and the EMR was good ( $\kappa = 0.5$ ). CERTAIN charting was completed in real-time that was 121 (92–150) min before completion of EMR charting.
36	An electronic handoff tool to facilitate transfer of care from anesthesia to nursing in intensive care units	Experimental study: standard practice vs checklist use	Observing handovers; survey among users	Information reporting and attendee participation	Surgery/Critical care	Handoff checklist	Modest improvement in information reporting on part of the anaesthesia provider, as well as team discussions regarding the current hemodynamic status of the patient.
19	Improving the Quality of Handoffs in Patient Care Between Critical Care Providers in the Intensive Care Unit	Pre-post e-checklist use	Direct observations of handoffs; survey	Concordance between data transmitted by the outgoing team and data received by the incoming team	Critical care	Handoff checklist	Increase in the level of agreement for tasks and other important data points handed off without an increase in the time required to complete the handoff.
31	Does an electronic cognitive aid have an effect on the management of severe gynaecological TURP syndrome? A prospective, randomized simulation study	Randomized controlled comparison of standard practice to dynamic clinical checklist use during simulation	Direct observations of simulation; survey	Adherence to guidelines; clinical relevance and participant perception of the usefulness of the cognitive aid	Anesthesiology	Cognitive aid checklist	The cognitive aid improved the implementation of evidence-based practices in a simulated intraoperative scenario
9	The SURgical PATient Safety System (SURPASS)	Pre-post e-checklist use	Direct observations;	Timing of antibiotic prophylaxis	Surgery	Surgical safety checklist	3.9 minutes before implementation of SURPASS to 29.9 minutes after

	checklist optimizes timing of antibiotic prophylaxis.		survey among participants				implementation ( $p = 0.047$ ). In procedures where the checklist was used, the interval increased to 32.9 minutes ( $p = 0.004$ )  (1) The SURgical PATient Safety System (SURPASS) checklist optimizes timing of antibiotic prophylaxis.
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## Appendix 2 - Search strategy

**Table 1. Database search results**

Database	Search words	Citations retrieved
Pubmed	“Electronic checklist”	(23)10
	“Digital checklist”	(104)7
Google Scholar	“Electronic checklist” AND “hospital”	(378)28 (duplicates: 5)

(Note: (no.) - citations retrieved after search;

no - citations retrieved after second screening)

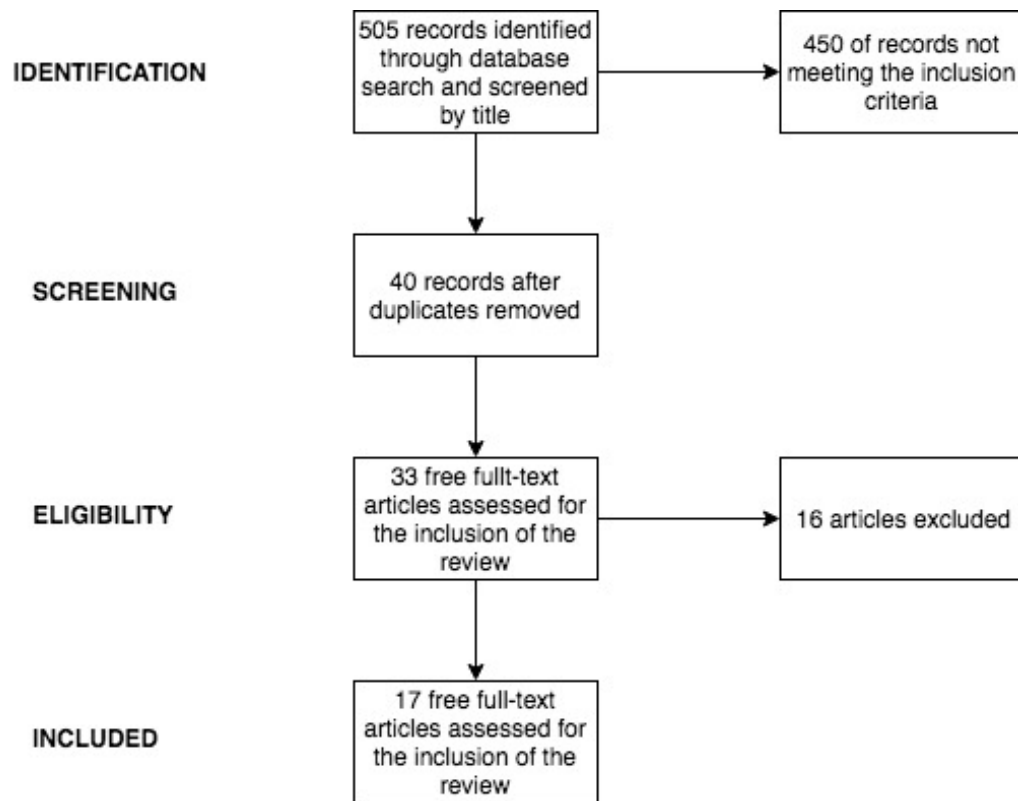
**Table 2. Inclusion and exclusion criteria**

<b>Screening questions</b>	Is the citation about the digital (electronic/computerised) checklist use in the hospital environment at the point-of-care or during simulation to test the suitability for the hospital environment?
<b>Types of studies</b>	Only original research articles with free full text will be included
<b>Inclusion/ exclusion of languages</b>	Literature in any language with at least the abstract was in English will be included into the first screening process. For the second screening process only the citations fully in English will be included.
<b>Timeline</b>	2008-2017

Source: author

### Appendix 3 – FLOW Diagram for study selection of the articles

The PRISMA Statement consists of a four-phase flow diagram with the aim of improving the reporting of study selection (Liberati et al.2009)



Source: author.



## **Appendix 4 – Questionnaire for focus group interview**

### 1) Medical errors

- a. How often have you faced medical mistakes?
- b. What leads to medical mistakes? What are the influencing factors?
- c. Should clinical staff report and talk about medical errors?
- d. How much do people talk about medical errors?
- e. What do you feel when you have done a mistake?
- f. During what kind of procedures do the mistakes occur?

### 2) Guidelines introduction/ usage in daily practice

- a. How are the guidelines used during training?
- b. How are new guidelines introduced?
- c. How often do you read the guidelines/ search help from guidelines? When? Why?

### 3) Checklists in daily practice

- a. How much are checklists used in your ward? (paper-based/ electronic)
- b. During what procedures do you think about the order step-by-step?
- c. In what kind of situations, would you like to have a checklist by your side?
- d. What are the potential benefits that checklist can have for daily practice?

### 4) Feedback on the solution and discussion on further developments

- a. What is the feedback and general recommendations?
- b. What kind of guidelines/ checklists should be included?
- c. What kind of effect has the solution today? What kind of effect could it potentially have in the future?
- d. What functionalities should be added to the solution?

## Appendix 5 – Questionnaire for test users

- 1) How many years have you worked as a nurse?
- 2) How many times have you tried using the solution?
  - a. I have seen the solution only when others are using it
  - b. 1-2
  - c. 6-10
  - d. More than 10 times
  - e. *Other*
- 3) How many different procedures have you done with the solution?
  - a. 1
  - b. 2
  - c. 3
  - d. 4
  - e. 5
  - f. 6
  - g. 7 (all the procedures that are currently included)
- 4) Does the solution support young nurses while learning/ doing procedures?
  - a. Yes
  - b. No
- 5) Does the solution support you while doing procedures?
  - a. Yes
  - b. No
- 6) What did you like about the solution? What you did not like?
  - a. *Short answer text*
- 7) What kind of errors and deviations can be avoided with the solution?
  - a. Medication errors
  - b. Mistakes made while setting the table
  - c. Mistakes made during rarely occurring procedures
  - d. Mistakes made during everyday procedures
  - e. Mistakes made while assembling devices
  - f. Mistakes made during taking analysis
  - g. *Other*
- 8) Should all the hospitals' nursing guidelines be included in the solution? Why?
  - a. *Short answer text*

- 9) What functionalities should be added to the solution?
- a. Picture
  - b. Estonian speech recognition
  - c. Possibility to create personalized checklists
  - d. *Other*
- 10) What procedural guidelines should be added to the solution at first?
- a. *Short answer text*
- 11) How likely are you to recommend the solution to your friend/ colleague on a scale 1-10?
- a. 1 (not at all)
  - b. ...
  - c. 10 (very likely)