

Dynamic checklists

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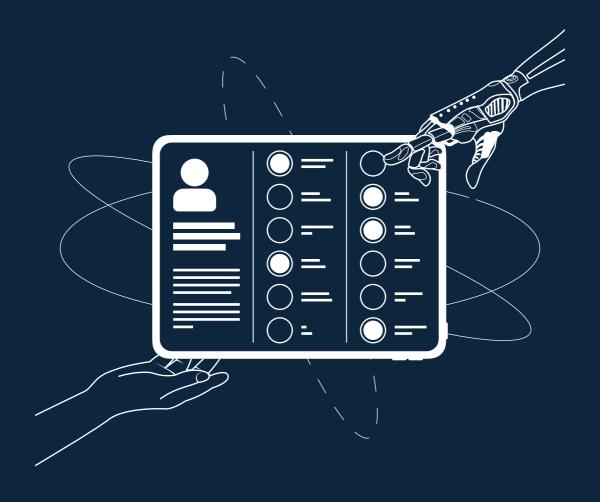
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Dynamic Checklists

Design, Implementation and Clinical Validation



Dynamic Checklists: Design, Implementation and Clinical Validation

Shan Nan

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Dynamic Checklists: Design, Implementation and Clinical Validation

PROEFSCHRIFT

ter verkrijging van de graad van doctor aan de Technische Universiteit Eindhoven, op gezag van de rector magnificus prof.dr.ir. F.P.T. Baaijens, voor een commissie aangewezen door het College voor Promoties, in het openbaar te verdedigen op donderdag 19 november 2020 om 9:30 uur

door

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Het onderzoek of ontwerp dat in dit proefschrift wordt beschreven is uitgevoerd in overeenstemming met de TU/e Gedragscode Wetenschapsbeoefening.

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Acronyms

AMC Academic Medical Center. 19, 41

AMIA American Medical Informatics Association. 7

APIs Application Programming Interfaces. 75

BPMN Business Process Modeling and Notation. 43, 138

CABG Coronary Artery Bypass Graft. 52, 80

CBC Complete Blood Count. 113

CDSS Clinical Decision Support System. 92, 110

CIAKI Contrast-Induced Acute Kidney Injury. 113

CMMN Case Management Model and Notation. 60, 138

CPOE computerized provider order entry. 64, 110

DSC Dynamic Safety Checklist. 31--36

eGFR estimation of Glomerular Filtration Rate. 113, 115

EMR Electronic Medical Record System. 41, 130

FDA US Food and Drug Administration. 17

FHIR Fast Healthcare Interoperability Resources. 139

GLIF GuideLine Interchange Format. 44

Hb Hemoglobin concentration. 113

ICU Intensive Care Unit. 11, 22, 41, 91, 92, 130

xii Acronyms

IOM Institute of Medicine. 2

LSC Local Standard of Care. 92

LVEF Left Ventricular Ejection Fraction. 57, 113

OB Occult Blood, 113

PCI Percutaneous Coronary Intervention. 11, 52, 87, 110, 127

PLAGH People's Liberation Army General Hospital. 53, 87, 118

RBC Red Blood Cell count. 113

SAGE standards-based Shareable Active Guideline Environment. 44

SAR Situational-Action Rules. 42

SURPASS SURgical PAtient Safety System. 6, 41

TNL Task Network Language. 70

VAP Ventilator Acquired Pneumonia. 23

WBC White Blood Cell count. 113

WfMS Workflow Management System. 70

WHO World Health Organization. 6, 15

WHO SSC WHO Surgery Safety Checklist. 111

Chapter 1

Introduction

The unintended harm to patients, which is caused by ignorance and deviation from the best practice due to modern healthcare complexity, becomes a major concern in the medical domain. It is estimated that 44,000 to 98,000 patients in the US died of preventable medical errors in 1998 [1]. A recent report claims that this number had increased to 400,000 in the year of 2014 [2].

In recent years, safety checklists have been developed to respond to the growing number of preventable medical errors [3]. These checklists seek to improve adherence to best practices for error-prone activities in healthcare processes by providing visual or verbal guidance [4]. Although various well-established studies [5, 6] have proven that they can improve the quality of care significantly in experimental environments, they have not yet effectively changed clinical practice [7]. One major reason is the additional workload imposed on the care-givers due to the poor integration into their daily practice and routines [8, 9].

Limited by its rigid form, the content of a checklist is difficult to be adapted to specific patients, and whether or not a checklist is actually used depends entirely on users' willingness due to the lack of active integration with the clinical workflow. These limitations lead to low acceptance and adherence and hinder the wide adoption of checklists. To address these limitations, it is urgently desired for checklists to become patient-specific and context-aware. To this end, clinical decision support systems may be combined with workflow management systems. Using clinical decision support systems and workflow management systems would help reach this goal. However, content-wise, the safety checklist is a combination of clinical workflow knowledge, medical protocols, and safety check activities. None of those above systems can represent or execute the safety checklist knowledge per se. Therefore, there is a need to study a more effective

approach to implement these safety checklists to better integrate with clinical workflow and adapt to patient context.

This introductory chapter presents the context and topic of this thesis. Firstly, we describe the research context by revealing the major problems in patient safety. Next, we briefly introduce the recent research of safety checklists and emerging trends. Then, we discuss the limitations of current safety checklists. These limitations are further detailed by demonstrating a motivating use case. After that, we extract the research goals and research questions of this thesis. Finally, the chapter concludes with an outline of the structure of the remainder of this thesis.

1.1 Safety checklists in healthcare

Safe and reliable healthcare service is not only the requirement of patients, but it is also the pursuit of care-givers. Although the phrase "first do no harm" does not really appear in *Hippocratic Oath*, Florence Nightingale did put the sentence "it may seem a strange principle to enunciate as a first requirement in a hospital that it should do the sick no harm" in her book *Notes on Hospitals* [10].

The reason why Nightingale put "no harm to patients" as a primary goal of a hospital is based on her observation about hospitals in her time. She proved by statistics that clinically related harms killed 10 times more patients than the disease itself [11]. Although hospital conditions have been improved significantly in the past centuries, patient safety is still a major concern of modern healthcare [12].

The Institute of Medicine (IOM) defines patient safety as "freedom from accidental injury" [1]. The US National Patient Safety Foundation has given patient safety a more comprehensive definition, i.e., "the avoidance, prevention and amelioration of adverse outcomes or injuries stemming from the process of healthcare" [13]. Both these definitions take the procedures and consequences into consideration. Unpurposed and avoidable deviations threaten patient safety from the predefined healthcare process from a procedure perspective. For example, it is an error that a doctor gives patient penicillin without considering the patient's allergy history because the doctor's action deviates from the best practice. If the pharmacy and nurse fail to realize the problem and the patient is allergic to penicillin, an adverse event happens. Apparently, in order to keep the patient safe, care-givers should try to prevent errors from happening and control the damage caused by errors.

IOM also defines medical error as "the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim" [1]. Actually, this definition comes from James Reasons definition of error in his book *Human Error* [14]. Building upon Reason's definition, Leape gives another definition, namely "an unintended act - either

of omission or commission - or one that does not achieve its intended outcome" [15]. Leape's definition clarifies that both omission and commission are mistakes. Later, Reason has given the term medical error a more specific definition as "deviations from the process of care, which may or may not cause harm to the patient" [16]. A medical error could cause no damage. We still take the previous penicillin example. If the patient happens to be not allergic to penicillin, then the medical error causes no harm. In the industrial field, Heinrich Law suggests that every 300 mistakes would lead to 29 accidents and one fatal accident [17]. Therefore, it would be reasonable to argue that even if a deviation did not cause any adverse event to a patient, it is still an error that should be avoided.

An adverse event can be defined as "unintended injury to patients caused by medical management - rather than the underlying condition of the patient - that results in measurable disability, prolonged hospitalization or both" [18]. An adverse event could be caused by one or a group of medical errors. However, not all adverse events are caused by medical errors. For example, a doctor prescribes a penicillin test for a patient without penicillin allergy history. Unfortunately, this patient is seriously allergic to this penicillin. This is still an adverse event. However, the doctor is doing the right thing, but the consequence is unintended and unavoidable.

When a medical error could cause an adverse event, for some reason, such an event may not occur. For example, the patient is given penicillin without an allergy test. Fortunately, the patient is not allergic, and the mistake does not cause an adverse event. In this circumstance, the adverse event does not happen only because of fortune. This situation is defined as a near miss. A near miss is "any event that could have had an adverse patient consequence but did not, and was indistinguishable from a full-fledged adverse event in all but outcome" [19]. Not every patient has the same fortune. Therefore, a near miss is also dangerous.

The relationships of these concepts are illustrated in Figure 1.1. From this figure, it is evident that preventing preventable adverse events, especially medical accidents, is the key of patient safety studies. In order to make this happen, researchers should develop approaches to prevent them from leading to adverse events.

Both men and machines make mistakes. In recent years, machines have become more reliable. Human errors are becoming the majority of medical errors [20]. Machine errors are mostly caused by inadequate design, manufacture, use, and maintenance errors by human [14]. Therefore, there is a need to understand what makes humans error-prone in medical processes.

With the development of medicine and medical standards, more and more technical means are used for medical treatment. Medical personnel needs to master increasing

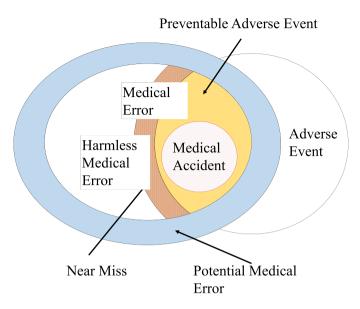


Figure 1.1: Relationship among patient safety related concepts.

amounts of knowledge and data. In order to adapt to such developments, medical processes are also being refined. This development has brought about two problems: complexity and tight-coupling [21].

Modern healthcare is complex, because although there are established clinical pathways to follow, making proper decisions for specific patients still relies on data availability and familiarity of certain knowledge. Even if medical staff understand the procedures and even master the various operations, human error is always difficult to avoid due to the limitations of short-term memory [15, 22].

The healthcare activities are tightly-coupled in the entire process of modern health-care. Patient admission is a complete process from admission to discharge. In this process, various medical activities are carried out in various aspects (such as admission, surgery) by various roles (such as doctors and nurses). These roles and activities are interrelated and interdependent. Moreover, the medical behavior of one role is derived from the diagnosis of another role. In such a process, not only must each participant in the medical activity provide safe medical care within their own duties, but also ensure that the data generated by each participant, the observed precautions, and the opinions provided are adequate [23].

Due to the complexity of the medical process, deviations in any stage of the healthcare process may eventually result in medical errors [24]. The tight coupling of

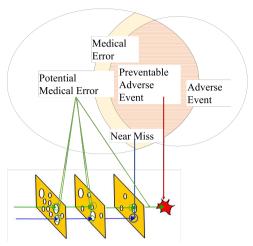


Figure 1.2: The swiss cheese model and medical errors.

activities in the medical process causes errors to be hidden, transmitted, and amplified. Reason proposed the Swiss Cheese Model for error transmission due to coupling in the process (Figure 1.2) [14]. This model's implication is that practitioners have often built layers of defense against security issues to block errors and prevent errors from turning into accidents in mature settings. This practice is called Defense in Depth. However, due to the work's complexity, each defense mechanism layer is like Swiss cheese that has large and small holes. When certain types of errors occur, due to the existence of the coupling relationship between each layer, these vulnerabilities will be penetrated, resulting in an accident.

1.2 Key challenges for implementing safety checklists

Human aspects should be carefully considered in healthcare [20]. No matter what kind of advanced technologies have been applied to healthcare, it is still ultimately human beings making decisions and carrying out patients' treatment. Human beings have short-term memory limitations. This is particularly problematic in dynamic and stressful scenarios, which are omnipresent in modern healthcare. In recent years, the checklist is increasingly used in daily practice as a simple but effective cognitive tool. Several clinical studies indicate that using checklists can reduce mortality by half and co-morbidity by two-thirds in the peri-operative phase. However, these kinds of safety checklists are not yet widely accepted by care-givers due to their static nature. It is yet difficult to fit these checklists in clinical processes and to specific patients.

A checklist is a tool that is often used in everyday life to provide short-term memory

assistance and to avoid forgetting work items. The safety checklist is a cognitive aid that provides memory assistance at key points in the clinic and increases teamwork to avoid negligence and omissions [4]. The safety checklist originated from the anesthesia machine procedure invented by an anesthesiologist [3]. In 1995, when Leape pointed out that information technology is a potential means to avoid medical errors, he also proposed that safety checklists should be encouraged to aid cognition and reduce the memory burden [15].

The safety checklist has received attention to improving patient safety, starting with the Keystone project led by Pronovast et al. in 2006. This project reduced the proportion of infections in ICU patients in Michigan, USA, from the highest in the United States to the lowest in the United States due to central venous catheterization [25]. What made them achieve this was a safety checklist containing five check items. These items include: 1) the operator must wash the hands with soap before surgery; 2) must disinfect the puncture site with an iodine-containing disinfectant; 3) must cover the patient's body with a full-length sterile towel; 4) the doctor must wear sterile Masks, caps, surgical gowns and gloves; 5) Once the cannula is completed, sterile gauze must be wrapped around the cannula. Doctors and nurses collude this content together during intubation, and the operation can only be performed when everyone agrees.

This study inspired the World Health Organization (WHO) to use a safety checklist to control surgical errors worldwide. In 2008, the WHO developed a checklist of pre-operative, intra-operative, and post-operative tasks, which were completed by a team of surgeons, anesthesiologists, and nurses. This checklist's application reduced the mortality of surgery in 8 national hospitals participating in clinical trials from 1.5% to 0.8%, and the incidence of complications decreased from 11% to 7% [5]. Similarly, the SURgical PAtient Safety System (SURPASS) developed by the Amsterdam Medical Center in the Netherlands extends the use of the WHO Safety Checklist to pre-operative preparation and post-operative rehabilitation. SURPASS has achieved similar results in the hospitals in the Netherlands as the WHO Surgery Safety Checklist. After using SURPASS, mortality decreased from 1.5% to 0.8%, and the complication rate decreased from 27.3% to 11.6% [26].

The success of these safety checklists has had a large impact on the medical industry. The WHO surgical safety checklist has been quickly adopted by national health authorities and promoted in the country. In 2010, the Ministry of Health of China issued a "Surgical Safety Checklist" following the WHO Safety checklist, requiring hospitals to follow. In recent years, safety checklists for various medical applications including cardiopulmonary resuscitation [27], interventional [28], intensive care [29] have emerged.

The reason why the form of the safety checklist can help avoid medical errors is precisely that it better meets the requirements mentioned above for patient safety management.

First, the security checklist provides the ability to prevent errors. The safety checklist extracts the key steps specified in the clinical guidelines and clinical pathways by checking the items and requiring them to follow them. Furthermore, it ensures that these key steps are actually implemented by ticking or verbal confirmation.

Second, the security checklist provides the ability to anticipate errors. The design of the safety checklist is highly targeted. Each safety checklist is specifically designed for clinically analyzed errors or serious consequences, and the checklist items are also derived from selected clinical issues. This targeted information effectively helps users find errors in time. In addition, the checklist also encourages its users to discuss potential risks, which further enhances the medical team's foresight of errors and risks.

Finally, the safety checklist provides the ability to control the damage. Some safety checklists are specifically designed to treat errors or adverse reactions and provide measures for these situations.

The safety checklist's success also lies in the fact that it does not mechanically tell the user how he should work step by step in accordance with standardized medical care. On the contrary, this form respects the user's professionalism, encourages the user to make a time-out, and in the atmosphere of a team. The safety checklist is used as a memory aid that helps to confirm that the doctor has paid attention to the most critical data for the patient and that the most necessary operation for the patient was completed without errors. Atul Gawande, the leader of the WHO Surgery Safety Checklist project, argues in his 2009 book The Checklist Manifesto, that safety checklists are a simple form that is easy for users to accept [30].

Both the medical and information science communities believe that the digitization of safety checklists and their close integration with medical information systems is the only way to develop effective safety checklists [6, 28, 31]. Therefore, the information science community has also attached great importance to the safety checklist. At the 2014 annual meeting, American Medical Informatics Association (AMIA) organized a special forum for the digitized safety checklists [32].

Several studies on the digitization of safety checklists have emerged in recent years. Garg et al. [33] proposed a patient discharge safety checklist integrated with the electronic medical record system. The checklist helps the doctor confirm that all discharge preparations have been completed correctly before the patient is discharged from the hospital. This digitized checklist will be automatically displayed on top of the medical record when the doctor writes the medical record, prompting the doctor to

check in time, thus enhancing the degree of integration with the doctor's workflow. Pageler et al. [34] and Thongprayoon et al. [35] reported a computerized security checklist for daily management of ICUs. Both checklists can use data from the electronic medical record system to highlight items in the checklist that require special attention and provide relevant data, thereby reducing doctors' workload when using safety checklists and improving physician compliance with the checklist. The SURPASS Safety Checklist at the Amsterdam Medical Center has also been computerized, using the original paper form checklist as a component of the electronic medical record system to facilitate healthcare professionals' timely use [36].

The digitization of the safety checklist has helped to a certain extent the combination of safety verification work and medical staff's daily work. The data extraction and display relieve their workload in the safety verification work, which improves the compliance of medical actions with the checklist. However, these digitized safety checklists still lack the ability to adapt to medical workflows and adapt to individual patient differences.

These digitized safety checklists still need to rely on the user's consciousness in use, lack the ability to remind the medical staff to use in the workflow actively, and the use of the safety checklist is still relatively independent of the medical workflow. As Gawande introduced, the combination of a safety checklist and the actual medical workflow is crucial. In the book *The Checklist Manifesto*, Gawande reported that his colleague had attached a safety checklist to a metal lid to cover the surgical instrument in order to perform a pre-operative check. In this way, the doctor must uncover the lid before starting the operation, and the check must be completed before the lid is opened. The compliance with the checklist has been significantly improved by combining such a checklist and actual work, and the surgical infection rate has dropped significantly. The current digitized safety checklist is waiting passively for medical personnel to use, making it difficult to avoid forgetting and ignoring. However, how to integrate a digitized safety checklist into a medical workflow remains a problem to be solved.

Another problem with the digitized checklist is how to integrate it with the patient's condition. Patients have different conditions, and the information that needs attention is different from age, gender, condition, and associated diseases. It is difficult to provide a checklist that is suitable for all patients. It is not feasible to develop a checklist for all concerns. The creation of too many checklists can lead to user fatigue, so compliance with the checklist is reduced. Experience in the aviation industry has shown that no more than 10 items can be checked by the user each time, and the length cannot exceed one page of A4 paper. How to provide targeted content as much as possible under the premise of ensuring space is a difficult design issue. In addition, the checklist may need to check a large amount of patient data or consult medical literature during use, which also imposes an additional workload on the medical staff, thereby increasing the

possibility of non-compliance with the checklist. Therefore, it is necessary to provide an efficient method of combining checklist items with patient data and medical knowledge to provide additional help to the checklist users.

1.3 Problem statement

Researchers found that not all studies reproduce the significant efficacy reported initially in the literature during the large-scale implementation and application of the safety checklist. The UK's NHS used the same safety checklist as the Keystone project to replicate their success, but it failed. The use of the safety checklist did not reduce the infection rate of patients with central venous catheterization in the UK ICU [37]. Similarly, the WHO surgical safety checklist was ineffective in several studies [9, 38, 39].

In the application implementation of the safety checklist, there is a widespread lack of user compliance. Also, medical staff often forgets to use the checklists, so that these safety checklists fail to play their due role [6, 8, 40]. Leape commented on this phenomenon in 2014, arguing that these failures stemmed from the failure of the proper implementation of the safety checklist, i.e., the safety checklist was not integrated into the user's workflow [41]. The introduction of a safety checklist also inevitably changes healthcare workers' workflow, and it is difficult for staff to adapt to such changes on time. At the same time, they inevitably increase medical staff's workload, which intensifies the medical staff's resistance. Therefore, how to implement the checklists in clinical practice is the key to their success. In the checklists' implementation, some medical organizations lacked considerations on behavior change and work burden, and forcibly promoted checklists, resulting in clinical users' resistance. Some medical organizations simply understand the checklist as a check while ignoring the transformation of the process and the team's construction so that the use of the checklist is only on paper. These phenomena have led to differences in the effects of the use of the checklist.

In addition, there is currently a lack of methodologies or tools to support the effective implementation of safety checklists [42]. How to effectively design and deploy safety checklists is a major challenge in current safety checklist research [42--44].

We conclude that current safety checklists are "too static" in two respects.

- 1. Checklist support systems are static in terms of the process. Here, the process refers to the collection of checklist-related activities and the order between them. Currently, checklist support systems have a poor division of responsibilities across the people involved. Thus, users may forget or feel unclear about their roles and fail to perform checks appropriately.
- 2. Checklist support systems are static in terms of the context. Here, the context

refers to the data related to the patient (e.g., diagnosis, co-morbidities, laboratory tests, prescription, demographic information, etc.). In the current checklist support systems, items in the checklist are the same for every patient, regardless of whether they may need significantly different concerns. Thus, checklists are excessively long. Based on the aforementioned studies on alert fatigue, it is clear that a lack of prioritization support can drain users' motivation.

As a result, solving the "static" problems is the key to developing a well-accepted checklist support system. Comparing with current checklist support systems, we characterized such a system as a **dynamic checklist** support system, which should be process-oriented and context-aware.

1.4 Research goals and thesis structure

The key hypothesis of this thesis is that a well-designed and effectively-implemented dynamic checklist outperforms a paper-based checklist. We hypothesize that dynamic checklists, which can be adapted to clinical workflow and to specific patient conditions, will improve the adherence and clinical outcome. This thesis concentrates on dynamic checklists' design, the development of support systems for dynamic checklists, and clinical evaluations of their effectiveness.

The thesis is structured as follows:

- 1. The second chapter discusses "what are the necessary features of dynamic checklists". Since the dynamic checklist is still an emerging trend of checklist development, it is yet unclear which features dynamic checklists should have. A mixed approach was applied to answer this research question. A literature review was carried out to identify the success factors and barriers to checklist implementations. Basic functionalities were extracted from the success factors, and the dynamicity requirements were summarized based on the barriers. Referencing to the emerging trends in related research areas, additional considerations were analyzed and summarized as desired dynamic checklist features. By combining these features, a comprehensive functional model was developed.
- 2. The third chapter presents how to make these clinically effective dynamic check-lists shareable between technical platforms and organizations. In order to share dynamic checklists, a technical platform-independent model of dynamic checklists is required. This meta-model captures the generic computerized representation requirements without considering the technical execution. Open technical standards in workflow management and clinical decision support areas were used to validate the feasibility of using the model. The result shows that different

modeling languages and modeling tools can be used interchangeably by using the meta-model.

- 3. The fourth chapter studies how to execute dynamic checklists in computerized systems and implement them in a general way. Based on the functional model, this chapter designed a dynamic checklist execution mechanism. Workflow execution and rule-based reasoning were used to fulfill the process-oriented and patient context-aware requirements, respectively. The results of execution were used to synthesize the content of dynamic checklists. A dynamic checklist platform that is configurable by clinical users has been developed as a general tool for dynamic checklist implementation.
- 4. In chapter five, a case study on an Intensive Care Unit (ICU) round checklist was carried out to evaluate the effectiveness and feasibility of using dynamic checklists for complicated clinical scenarios. An ICU round checklist and supporting system were developed in a Dutch tertiary teaching hospital. A simulation-based clinical trial was designed and organized. The results show that compared with paper-based checklists, the dynamic checklist can improve the adherence to best practice while doing the round, reducing medication errors significantly. The users were satisfied with the dynamic checklist.
- 5. In chapter six, another case study on Percutaneous Coronary Intervention (PCI) pre-operative care was carried out to validate the feasibility of using dynamic checklists for complex clinical processes. A PCI pre-operative checklist set was developed in a Chinese tier-three hospital. The dynamic checklist was based on the hospital's paper-based checklist. Additional clinical rules regarding abnormal value detection and notice for hydration were added. A randomized controlled trial has been developed in a Chinese hospital. The results show that the dynamic checklist significantly improves the hydration rate before the PCI procedure.
- 6. The seventh chapter discusses "what are the success factors and barriers while implementing dynamic checklists". To our best knowledge, this is the first systematic study on dynamic checklists. Summarizing the success factors and barriers for implementing dynamic checklists from our own experience would be beneficial for others working on dynamic checklist related research. The experiences and lessons were summarized out of the two case studies. Future research directions were also synthesized.
- 7. Lastly, the eighth chapter concludes the thesis.

1.5 Publications

Various papers have been published or submitted in the course of studying dynamic checklist design, implementation and clinical validation.

Regarding dynamic checklist design (Chapter 3), 2 papers have been published.

- Shan Nan, Pieter Van Gorp, Xudong Lu, Uzay Kaymak, Hendrikus Korsten, Richard Vdovjak, and Huilong Duan. 'A meta-model for computer executable dynamic clinical safety checklists.' BMC medical informatics and decision making, 2017, 17(1): 170.
- 2. **Shan Nan**, Pieter Van Gorp, Hendrikus HM Korsten, Uzay Kaymak, Richard Vdovjak, Xudong Lu, and Huilong Duan. 'DCCSS: A meta-model for dynamic clinical checklist support systems.' *In Model-Driven Engineering and Software Development (MODELSWARD), 2015 3rd International Conference on, Angers, France*, pp. 272-279. IEEE, 2015.

Regarding dynamic checklist implementation (Chapter 4), 2 papers have been published.

- Shan Nan, Pieter Van Gorp, Xudong Lu, Uzay Kaymak, Hendrikus Korsten, Richard Vdovjak, and Huilong Duan. 'Design and implementation of a platform for configuring clinical dynamic safety checklist applications.' Frontiers of Information Technology & Electronic Engineering 19, no. 7 (2018): 937-946.
- Shan Nan, Pieter Van Gorp, Hendrikus HM Korsten, Richard Vdovjak, Uzay Kaymak, Xudong Lu, and Huilong Duan. 'Tracebook: A dynamic checklist support system.' In Computer-Based Medical Systems (CBMS), 2014 IEEE 27th International Symposium on, New York, USA, pp. 48-51. IEEE, 2014.

Regarding dynamic checklist clinical validation for intensive care (Chapter 5), one paper has been published. Notably, the publication was accompanied by an Editorial in the British Journal of Anaesthesia (see Appendix A).

- A. J. R. De Bie, **Shan Nan**, L. R. E. Vermeulen, P. M. E. Van Gorp, R. A. Bouwman, A. J. G. H. Bindels, and H. H. M. Korsten. 'Intelligent dynamic clinical checklists improved checklist compliance in the intensive care unit.' *BJA: British Journal of Anaesthesia*, 2017, 119(2): 231-238.
- 2. Webster, C. S. "Checklists, cognitive aids, and the future of patient safety." *British Journal of Anaesthesia* 119, no. 2 (2017): 178-181.

Regarding the clinical validation for PCI pre-operative checklist (Chapter 6), one paper has been submitted to the BMJ Quality and Safety journal.

1. Why is a dynamic checklist better than a paper checklist? *submitted to BMJ Quality* and Safety

The dynamic checklist system have been used to configure other dynamic checklists (such as a stroke checklist). The experiences of design, implement and validate dynamic checklists (in Chapter 7) have been published in following papers.

- 1. Jianfei Pang, Haifeng Xu, **Shan Nan**, Shubo Xu, Me Li, and Dongsheng Zhao. 'A Mobile Intelligent Checklist System for Stroke Emergency.' *In 2019 IEEE International Conference on Bioinformatics and Biomedicine (BIBM)*, pp. 1581-1584. IEEE, 2019.
- Shan Nan, Ashley De Bie, Sicui Zhang, Hendrikus Korsten, Xudong Lu, and Huilong Duan. 'Identify Facilitators and Challenges in Computerized Checklist Implementation.' Studies in health technology and informatics 264 (2019): 1737-1738.
- 3. Leixing Lu, **Shan Nan**, Sicui Zhang, Xudong Lu, and Huilong Duan. 'Using openEHR's guideline definition language for representing percutaneous coronary intervention patient safety rules in a dynamic checklist system.' *Studies in health technology and informatics* 264 (2019): 1714-1715.
- 4. Leixing Lu, **Shan Nan**, Sicui Zhang, Xudong Lu, and Huilong Duan. 'Can Existing Guideline Languages Meet the Requirements of Computerized Checklist Systems?' *In 2018 IEEE International Conference on Bioinformatics and Biomedicine (BIBM)*, pp. 1500-1503. IEEE, 2018.

Additionally, the Tracebook platform has also been used to configure other clinical decision support systems, particularly for COVID-19 in 2020.

- Mengyang Li, Heather Leslie, Bin Qi, Shan Nan, Hongshuo Feng, Hailing Cai, and Xudong Lu. 'Development of openEHR template for Coronavirus disease 2019 based on clinical guidelines.' *Journal of Medical Internet Research* 22, no. 6 (2020): e20239
- 2. **Shan Nan**, Tianhua Tang, Hongshuo Feng, Yijie Wang, Xudong Lu, and Huilong Duan. 'A Computer-Interpretable Guideline for COVID-19: Rapid Development and Dissemination.' JMIR Medical Informatics 2020;8(9):e21628

Chapter 2

The approaches of designing, implementing and evaluating checklists: a review

2.1 Introduction

Since the WHO demonstrated that using safety checklists can reduce preventable medical errors in 2007, safety checklists have been implemented in various clinical settings worldwide. However, the results of these implementations are mixed. Although some studies indicated that using checklists is cost-saving and safety improving, some other studies also reported failures due to poor acceptance and adherence. This is not a surprise if we consider that these checklists are still implemented as pieces of paper, whereas modern hospitals are already paperless. Many checklists have already been deployed in information systems. However, they were mostly static and invariably disliked by care-givers. In sharp contrast with these static checklists, some checklists with dynamic features are welcomed by care-givers and lead to better performance. However, it is still difficult for other researchers to reproduce their success as such checklists' desired features are yet unclear. The general user requirements of developing such dynamic checklists have not yet been reported.

Since the dynamic checklist is still a new concept, limited studies are directly related to this concept. However, existing literature has reported how paper-based and computerized checklists were implemented, and their success factors and barriers. Desired functionalities can be deducted from these studies.

While most reviews on safety checklists are about their effectiveness, recently, some researchers have already reviewed checklists from an informatics point of view. Kramer et al. [45] reviewed how digitized checklists are used in healthcare and their benefits. Reijers et al. [46] reviewed checklists and defined the properties of checklists and listed the problems in checklist design and implementation. In their study, they conclude that the problems of the operational use of checklists remain a challenge.

In this chapter, we review how checklists are designed, used, and evaluated. The aims of this review are 1) to identify the success factors and barriers of existing checklist implementations, and 2) to develop a requirements and evaluation model for dynamic checklists.

2.2 Methods

Since the checklist is still an emerging topic, and existing studies focus mainly on evaluating the clinical outcome of using checklists, we perform a systematic qualitative review. Keywords including "safety checklist", "implementation", "medical checklist" were used. Additionally, the reference lists of existing safety checklist publications were considered as supplementary information.

Using the above keywords, we conducted systematic literature research for the period from January 2005 to December 2019 in the PubMed database of the National Library of Medicine, MEDLINE, and in the Web of Science. Totally 1007 publications have been retrieved. After excluding publications whose titles do not cover the required words, the number was reduced to 138. Furthermore, the criteria excluded editorials, letters, case reports, news items, and position statements. As a result, 116 papers were selected for full-text reading, of which 57 finally met our requirements. The key contributions in these papers have been mapped out in a spreadsheet. These contributions include the design approaches, implementation facilitators and barriers, and evaluation indicators.

2.3 Applications of safety checklists

Various checklists have been applied in healthcare to support safety in several medical domains. These applications are reviewed next.

2.3.1 Surgery related checklists

The anesthesia checklist

A serious anesthesia accident can be caused by the improper use of an anesthesia machine. Such machine-related accidents account for 14% of all anesthesia accidents. Among these use cases, 22% are caused by improper inspection before use. To solve this problem, anesthesiologists started using the anesthesia machine safety checklist [47]. This checklist is designed to prevent the anesthesiologist from improperly setting up the machine before the start of anesthesia, thus avoiding a safety hazard to the patient.

The checklist mimics the pre-flight checklist used by pilots in the aviation industry. The anesthesia checklist contains 14 items and requires the anesthesiologist to traverse these items one by one when using the machine to avoid missing any step. It takes an average of 8.9 minutes to complete such verification.

This checklist was recommended by the US Food and Drug Administration (FDA) in 1986 [48]. In the early 1990s, this checklist was also widely adopted in Europe. However, clinical studies have shown that using this safety checklist has no significant difference in the ability to detect problems compared to the anesthesiologist's own pre-anesthesia preparation. This may be because the safety checklist design is too cumbersome and time-consuming, resulting in low compliance and poor completion [49]. For this reason, the British Association of Anesthesiologists and other institutions have been working to shorten the checklist's length until recently [50].

WHO surgical safety checklist and its various implementations

In response to the global surgical safety issues, the WHO organized the Safe Surgery Saves Lives campaign in 2007 to organize experts to explore solutions to improve surgical safety [51]. In the end, the WHO chose the method of the checklist. The checklist consists of the three key surgical phases: before the start of anesthesia, before the incision, and before the patient leaves the operating room.

Before the start of anesthesia, the anesthesiologist and the nurse need to check the following items: the patient's identity, the surgical site, the anesthesia machine, the preparation of the medication, allergy history, dyspnea, excessive blood loss, and if surgery plans have been discussed. Only when these items are all checked can the patient's anesthesia begin.

Before the start of the operation, all the people involved in the operation (surgeon, surgery assistant, anesthesiologist and nurse) need to be together to confirm that the identity and role of the team have been clearly defined, the patient identity, the

surgical content, and the surgical site are correct. Antibiotics must have been given prophylactically, and each role needs to discuss their risk to the surgery. Surgery can only be started after this preparation.

Before the patient leaves the operating room, the nurse needs to verbally confirm to all the surgical participants: the name of the operation, the surgical instrument, the gauze, the checklist of the needle, the label of the collected specimen, whether the intraoperative equipment has a problem, and the full surgical team needs to confirm any special precautions.

A multi-center trial conducted by the WHO in six countries worldwide shows that through this verification, the patient's perioperative mortality rate has dropped from 1.5% to 0.8%, and the complication rate has also dropped significantly [5].

With this clear success, the WHO Surgical Safety Checklist has been introduced by WHO member states. However, when the medical organizations subsequently used the safety checklist, they encountered similar results to the central venous catheterization checklist: the surgical safety checklist's clinical application was not always successful, and different results were obtained in different clinical trials. Fourcade et al. [8] shows that only half of the doctors complete the safety checklist in French hospitals, while the rest of the doctors failed to check due to forgetfulness and repeat with other work, lack of time, etc. Even if the checklist is completed, there is no guarantee that these doctors will actually use the checklist or just tick the paper. Clinical studies have shown that the method of deployment of a surgical safety checklist is the likely cause of this difference. For example, in a hospital with poor teamwork, the use of safety checklists is not as effective as that of well-coordinated hospitals; a clear deployment process is in place, and hospitals responsible for the use of safety checklists are better than unplanned and not engaged hospitals [9].

Currently, research on deploying and customizing the WHO Surgical Safety Checklist is encouraged by the WHO. In recent years, the WHO Safe Birth Checklist [52], the Percutaneous Coronary Intervention Therapeutic Safety Checklist [28], and other safety checklists based on the WHO Surgical Safety Checklist have emerged. This safety checklist covering a particular process fragment has become the main form of the safety checklist.

Surgical crisis checklists

In addition to the safety checklist for planned and predictable processes, the medical community has explored how to use safety checklists in unexpected situations. Ziewacz et al. [53] developed a targeted safety checklist for possible anomalies in the surgery. A

significant number of the research teams in this checklist are from the research team of the WHO Safety Safety Checklist. This checklist consists of a total of 13 checklists.

The first checklist is the first step for all crises. Before starting the rescue, ensure that the rescue request has been sent to external parties, and someone is leading the rescue work. Then, according to the 12 dangerous situations such as respiratory arrest, cardiac arrest, major bleeding, and hypoxemia that may be encountered in the operating room, the steps of coping with the aviation industry's safety checklist to mitigate the risk are formulated. For example, for cardiac arrest, the checklist requires treatment in the following order: 1) seeking rescue team help, 2) cardiopulmonary resuscitation, 3) injection of epinephrine and 4) reassessing the patient's pulse and heart rate after 2 minutes. While giving the steps, the checklist also shows the possible reasons for the sudden cardiac arrest, prompting the doctor to consider solving the corresponding problem.

For more complex decision-making processes, this checklist system is displayed on paper in the form of a flow chart. The checklist uses a read-do mode when it is used, prompting the user to execute them one by one in order. Because the incidence of these crisis situations is very low and it is difficult to conduct a clinical evaluation of the checklist in a real environment, the research team designed a clinical evaluation test using a simulator commonly used in the aviation industry. The research team artificially designed a set of clinically likely crisis scenarios, then placed them in a real operating room, simulated the scenarios in a real-world-like manner, and observed the difference in performance between the health care provider when using the checklist and not using the checklist. The test results show that the use of this checklist can reduce the proportion of non-standard operations in the event of a crisis from 24% to 4% [54].

The SURPASS checklist

Based on the WHO surgical safety checklist, the Academic Medical Center (AMC) further extended the verification process to the recovery room and perioperative ward outside the operating room to develop a perioperative safety checklist system [6]. For local anesthesia surgery, an anesthesiologist is not required to participate, and the verification process employs a branch condition to deal with this situation.

The checklist includes operating room preparation, transporting the patient to the surgical preparation area, before the start of surgery, before transporting from the operating room to the recovery room or ICU, before returning from the recovery room or ICU to the ward, before discharge, etc. At each of these points, depending on the characteristics of the work, it is further broken down into a safety checklist used

by one or more clinical roles. Among them, the operating room preparation safety checklist was completed by the surgical assistant one day before the operation. The pre-operative preparation was assigned to the ward doctor, ward nurse, surgeon and anesthesiologist. These four roles independently completed their checklists. If local anesthesia is scheduled and no anesthesiologist is required to attend, there is no need to complete an anesthesiologist's checklist.

One of the nurse checklist items is that the checklist for the ward doctor has been completed. The checklist before the start of surgery is equivalent to the pre-anesthesia and pre-incision checklists of the WHO surgical safety checklist. Still, the surgeons and anesthesiologists have confirmed that their respective pre-operative preparation lists have been correctly completed. The post-operative checklist is equivalent to the post-operative checklist of the WHO surgical safety checklist. The difference is that SURPASS assigns this checklist to the surgeon and the anesthesiologist. The checklist will be sent back to the ward or ICU, depended on the patient's destination. Before the patient is discharged from the hospital, the ward doctor and the ward nurse need to complete their pre-discharge checklist. Similar to pre-operative preparation, the nurse needs to check that the doctor's checklist has been completed correctly.

Throughout the perioperative process, SURPASS uses a total of 17 checklist for verification of different roles. Multi-center trials involving 12 medical institutions in the Netherlands have shown that SURPASS can reduce perioperative patient mortality by half and complication rates by one-third [26]. This is consistent with the results achieved by the WHO Surgical Safety Checklist. However, considering that WHO's research also includes developed industrial countries and developing countries with varying medical levels, and SURPASS is purely based on developed countries with higher medical standards, it can be considered that SURPASS improves upon the WHO Surgical Safety Checklist.

While using SURPASS, the researchers also reported some problems. The completion rate and compliance rate were also lower than expected. Only 66% of the surgeons always used the safety checklist, and others often forgot to check because of the busywork. Since SURPASS covers a procedure from surgical preparation to discharge, it includes a complete perioperative procedure for the surgical assistant, ward doctor, ward nurse, anesthesiologist, operating room, and operating room nurse. This process involves a large number of people and a long duration, which led to SURPASS encountering a unique logistics problem in the implementation. Participants in the process could not get the patient's checklist in time, so the list could not be verified. For example, the ward nurse needs to check whether the ward doctor's safety checklist has been correctly completed before surgery, and they can only perform this check if they get the checklist of ward doctors [55].

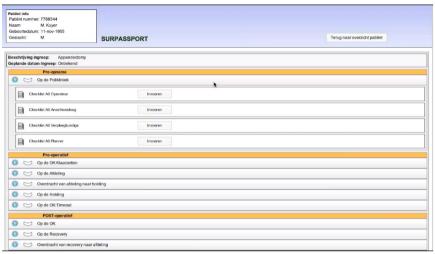


Figure 2.1: Amsterdam Academic Medical Center SURPASS checklist

Computerized implementation of the SURPASS checklist

Due to the inconvenience caused by the paper delivery process, SURPASS researchers began to digitize SURPASS in 2009, making it easy to access and consult at all stages of the treatment process (Figure 2.1) [36].

The system runs a health checklist at a specific point in the medical activity and checks it. Other participants in the process can learn from the checklist the process's progress, including which tasks have been completed and which tasks are to be completed. As a computerized implementation of the SURPASS safety checklist, the checklist assists the implementation of the medical process to a certain extent, avoiding the inconvenience of using and transmitting the paper checklist. However, the checklist system still lacks initiative in implementing the process; that is, it is completely dependent on the user's initiative and lacks the ability to remind and prompt. When the user forgets to check, the corresponding checklist will be skipped. The implementation of the process is also completely dependent on the user's drive and lacks the constraints of a standardized workflow. For example, the checklist can not be used to prevent the user from completing the post-operative check and then supplementing the pre-operative check. This creates a difference between the completion rate of the checklist and the checklist's compliance, which affects the effectiveness of the use of the checklist. On the other hand, unlike the computerized checklist above, the contents of each checklist in the SURPASS digitized checklist lacks the ability to integrate with patient data in electronic medical records.

2.3.2 Intensive care related checklists

The central line checklist

Infections caused by central venous catheterization are a major challenge for the ICU [56]. Central venous catheterization is a kind of puncture in the patient's inferior vena cava or subclavian vein, providing rapid venous access for patients, which is convenient for rapid fluid replacement and medication. It is an indispensable means to save the lives of critically ill patients. However, due to the high incidence of disease and low resistance in ICU inpatients, this invasive procedure is also an important cause of nosocomial infection in ICU patients. Because of the central vein through the heart, infections caused by central venous catheterization are particularly dangerous. How to avoid infection has always been a challenge for ICU doctors. In 2001, Pronovost et al. [25] proposed safety checks on key steps in central venous catheterization, organizing nurses to supervise doctors' performance, and avoiding missing key aspects of the operation.

Through the use of this checklist, the ICU infection rate in Michigan has dropped from the highest level in all states in the United States to the lowest level. This research was published in the authoritative medical journal New England Medicine and received worldwide attention. Many countries, including the UK and Canada, have tried to implement this checklist nationwide to replicate Michigan's success. However, the Marching Michigan initiative launched by the UK has failed. After a year of clinical trials, there was no significant difference in this safety checklist's effectiveness before and after use in UK hospitals. There was no significant benefit to ICU infection in UK hospitals [57]. The researchers attributed this to the fact that the checklist was not properly implemented in hospitals in the UK [37]. In Michigan, the checklist is shared and used by ICU doctors and nurses. If the doctor does not perform the central venous cannula in accordance with the steps required on the checklist, the nurse can request termination of the operation on the spot. In the UK, nurses do not have such rights. Therefore, there is no quarantee that the checklist will be used correctly.

ICU daily round checklists

Patients admitted to the ICU often have complex and unstable physiological conditions and complicated treatment options. Patients even often lose the ability to eat autonomously, and they need to be supplemented by artificial means such as nasal feeding. To combat pain, it is necessary to treat them with analgesia and sedation. Because of their metabolism and medication, patients often do not have normal bowel movements. Due to their inability to move, patients may develop blood clots and pressure sores. These problems must be handled correctly in order to create conditions

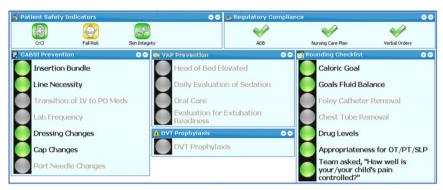


Figure 2.2: Stanford University Lucile Packard Children's Hospital ICU checklist

for the patient to recover. In order to solve these problems, J.L. Vincent of the University of Leuven Medical School in Belgium proposed a safety checklist containing nutrition, sedation, analgesia, thrombosis, bed elevation, pressure ulcer formation, and blood glucose control. It is abbreviated as the FAST HUG checklist [29].

The checklist asks the person in charge of the rounds to verify that each area's key issues have been taken into account. That is, the nutrition provided to the patient is sufficient; the medical staff has performed correct sedation, analgesia assessment and treatment; the medical staff has taken preventive measures for thrombosis; the bed elevation angle has been adjusted to between 30 and 45 degrees; pressure ulcer prevention medicine is given; the patient's blood glucose is controlled to the correct range. There is no necessary order for addressing these items. Users can make their own decisions according to the actual situation. This safety checklist has received the attention and active adoption of the intensive care field since its release. Since then, other research teams have also proposed revisions such as FAST HUGS, FAST HUGS BID, etc. [58]. Clinical trials have shown that using the FAST HUG series of lists helps reduce the incidence of Van dropped from 1.93% to 0.73% [59].

Computerized daily round checklists

The central venous catheterization checklist manages and intervenes in infections during central line insertion. However, prolonged line time still increases the risk of infection. Stanford University Affiliated Lucile Packard Children's Hospital developed a computerized checklist in the form of a dashboard (Figure 2.2) to help control the line time [34].

The checklist is displayed in the form of a dashboard on the intensive care unit's

electronic medical record system interface. Each item in the checklist requires an intensive care unit doctor to check manually. This checklist's advantage is that it can highlight the check items that the doctor needs to focus on according to the patient's condition in the electronic medical record, thus avoiding the doctor's neglect. By using this dynamic checklist, the hospital's central venous catheter infection rate decreased from 2.6% to 0.7%, and compliance with clinical guidelines best practices has improved significantly. This checklist's shortcoming is that it lacks intuitiveness about the item's content and is not tailored to the patient's specific situation. Doctors need more cumbersome operations to click into each verification item to discover possible problems in the verification. This increases the risk that doctors ignore certain key information in the verification.

According to statistics, in every 1000 patients, 149.7 of them will have severe errors, and 80.5 cases will have adverse reactions, and 45% of these adverse reactions can be avoided. In contrast, only 56% of patients received treatment according to best practices in clinical guidelines. In order to solve such problems, the Mayo Clinic in the United States developed and applied an ICU daily management checklist (Figure 2.3) [35] integrated with its ICU electronic medical record interface.

According to the human body's anatomy, the checklist distinguishes 24 problems that need to be checked daily by the ICU into six categories. A total of 12 items to be checked in the checklist can be automatically checked by the computer system based on the electronic medical record data. By using this dynamic checklist, the probability of daily errors in the ICU has dropped by 37.5%, and at the same time, the workload of doctors in the rounds has been significantly reduced. The checklist is designed to reduce doctors' workload in the verification work, so the checklist provides an automatic check function. However, the checklist still has room for improvement in reducing the workload: first, the checklist lacks the ability to display data related to verification, which leads doctors to need still to review data and analyze and judge in electronic medical records during verification. On the one hand, the content of the check items in the checklist lacks adaptability to specific patients, while on the other hand it is difficult for doctors to discover the safety problems directly.

2.3.3 Other safety checklists

Hospital discharge checklist

The discharge is the last key step in the patient's hospital stay. Especially in the United States, the discharge process involves not only communication and education with patients and their families but also communication and discussion with rehabilitation



Figure 2.3: Mayo Clinic ICU checklist

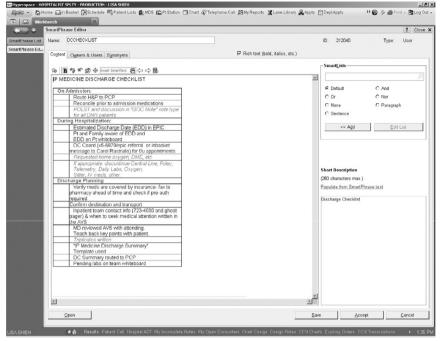


Figure 2.4: Stanford University Medical Center discharge checklist

agencies and family doctors. At this stage, medical staff is prone to omissions. To avoid such omissions, the Stanford University Medical Center developed a computerized safety checklist for pre-discharge verification in 2013 (Figure 2.4), which permits the ward doctors to check related tasks when writing a medical record [33].

Items that do not match the current patient's actual situation are identified by gray fonts, prompting the doctor not to pay attention to these items. In this way, the usage rate of the checklist has increased from 21.9% when using the paper checklist to 81.4%, and the degree of recognition of the doctor's integration with the workflow has increased from 4.8% to 64.6%, while the overall satisfaction increased from 25.5% to 96.3%. However, the checklist still has room for further improvement in terms of the combination of medical business processes and the ease of use of the safety checklist. Compared to the paper checklist, the computerized checklist allows doctors to switch back and forth between the computer system and paper without having to interrupt the doctor's workflow during discharge. However, the checklist is still passively dependent on the user to open the checklist and check, lacking an active reminder mechanism and integration with key clinical work tasks.

On the other hand, the checklist filters out the content that does not require doctors'

attention by judging the patient's data, but there is no further accurate description of what the doctor needs to pay attention to for the current patient. The doctor still needs to rely on his own memory or return to the electronic medical record, partially looking for patient data. This inconvenience may cause the doctor to overlook essential data or lead to misjudgment due to memory errors.

2.4 Review findings

2.4.1 Characteristics of selected publications

Among the selected publications, 14 publications have mentioned the design issues [4, 6, 28, 29, 31, 41, 44, 45, 60--65]. Two of them are summarized design experience from well-known checklists [4, 6]. Three of them are opinions from domain experts [31, 41, 44], while the remaining nine are about design, implementation and evaluation of new checklists [28, 29, 45, 60--65].

36 publications have addressed implementation [3, 7--9, 23, 31, 33--35, 38, 39, 41, 43, 44, 52, 55, 66--85]. Eight publications reported computerized implementation of checklists [34, 35, 80--85].

24 articles reported evaluation related work [7--9, 23, 33--35, 38, 39, 52, 55, 67-74, 76, 79, 81, 83, 84]. Five articles evaluated computerized checklists [34, 35, 81, 83, 84]. Currently most checklists are still implemented in paper format, which does not fit in the clinical workflow.

2.4.2 Design of checklists

The safety checklists are either used for procedures (e.g., surgery, central line insertion, international procedure, trauma resuscitation, etc.) or routine care (e.g., ICU daily round, ICU lines management, discharge, etc.). Most of them are designed for standardizing routine clinical activities. There is currently only one checklist that focuses on improving performance in crisis situations.

Some checklists are designed to **prevent** errors from happening (such as the anesthesia checklist, the central line insertion checklist, and the surgical crisis checklist). Other checklists are designed to **detect** potential omissions and help to **correct** them (such as the WHO SSC and the SURPASS checklist). The checklists that target error prevention are normally designed in a read-do fashion, whereas the checklists that aim to detect and correct potential omissions are designed in a do-confirm fashion.

The checklists' complexity varies from a single page of checklist with fixed items

used by one role to a series of checklists serving for a unified purpose used by a group of care-givers. One page of a checklist can be used by only one role or a group of care-givers with different roles. For example, the anesthesia checklist is only used by an anesthesiologist, whereas the WHO SSC should be used by an anesthesiologist, a surgeon, and a nurse as a team. The order of items in one checklist can be random, sequential, or based on some algorithms. The ICU round checklist items can be organized in a random order, although the initial "FAST HUGS" can help the users remember it. The items in the anesthesia checklist and the central line insertion checklist are designed in sequential order. In the WHO SSC and the SURPASS checklist, some items are optional or conditional based on the actual situation of a patient. Therefore, there are some algorithms designed to control the items.

2.4.3 Implementation problems and possible solutions

Implementation is a major concern in the field of safety checklists. Implementation problems have been reported in the literature. In the meantime, possible solutions have been proposed for these problems. We summarized the problems and possible solutions in Table 2.1.

In response to the challenges in checklist design and implementation, several suggestions have been given. First, the research and application of safety checklists must be properly supported from hospital organization level. This includes: identifying the person responsible for the implementation of the safety checklist project, introducing the reward mechanism used in the checklist, making regulations to facilitate developing and using checklists [9, 43, 87, 88]. In the meantime, potential users of checklists must be well-motivated and well-trained [9, 42, 89].

It is very important to improve the process used surrounding the checklist, including: to achieve a tight integration of the safety checklist with existing medical processes [6, 8, 40]; to avoid requiring a safe checklist without safety issues; to reduce the burden on medical staff [90, 91]; improve the design of the checklist to make it accurate and concise [6, 8, 89, 92]; localize and refine the checklist design to cover specific safety issues [8, 9, 42, 92]; improve the coverage of the health checklist for medical procedures, such as covering the complete process from admission to discharge [6, 93].

2.4.4 Evaluation approaches

The most common study design to evaluate the impact of checklists is a before-after study. Controlled clinical trials have also been used for checklist evaluation. However, they are mostly used in simulation-based studies.

Table 2.1: Checklist implementation barriers versus possible solutions.

Reported Problems	Possible solutions
Checklist not sensitive to context or case [71]	Design and develop "smart" checklists [31, 82]
Non-compliance due to lack of knowledge [8, 57]	Redanduncy and double-check [41], provide insight into the evidence [5, 9]
Checklist fatigue [31, 44]	Only provide most relevant items [31, 44]
Insufficient information while performing the check [39, 86]	Integrate with EMR systems [28, 31, 41]
Poor integration with existing process [75]	Integrate with clinical process [31, 52]
Difficult to read status/receive feedback from checklist [55]	Make link to patient data and outcomes [31, 55]
Duplication of tasks in existing process [8, 52, 75]	Optimizing the checklist use [44]
Difficulty to deal with exceptions [77]	N/A
No time to check [8, 71]	Motivate users [8, 42]
Selection of wrong parts/paths [5]	N/A

44 indicators have been extracted from the selected literature. These indicators are split into five categories, which are the clinical outcome, service quality, teamwork, process, and financial.

Clinical outcomes are the most frequently used indicators. Mortality has been used for various surgery checklist evaluations. Co-morbidity has also been widely used to evaluate the outcome. Commonly used co-morbidities are surgical-site infection, any infection, unplanned reoperation, hemorrhage, hematoma, unconsciousness more than 24 hours, mechanical ventilation more than 48 hours, wound dehiscence, other complication, and accidental puncture or laceration. Other adverse events have also been used, such as readmission, emergency department visits after discharge, stay in ICU, and intra-hospital transfer.

Teamwork is the second most frequently used indicator for checklist evaluation. These indicators include teamwork efficiency, failure/success communication, perception of patient information, perception of safety aspects, numbers of team members at bedsides, teamwork performance, team feeling, identification of team members, understanding of daily goals, perception of roles and responsibilities, instances of error prevention, missing information prevention, and "near-miss" event prevention.

Process indicators are also frequently used. They include accuracy in the operation procedure, critical step timing, loss of critical information, technical error, potential equipment problems, compliance with guidelines, compliance with the checklist, and overall user acceptance.

Length of stay is a financial indicator that is used in many studies. However, other financial indicators, such as per-patient variable cost and per-patient total cost are not frequently reported.

Lastly, patient's view on the service quality is sometimes used as a service indicator.

2.5 A framework for dynamic checklist design and implementation

Using information technology to make checklists smarter is considered a viable approach to increase acceptance and effectiveness [6, 31, 89]. These kinds of checklists are defined as dynamic checklists in this thesis, as they can dynamically fit the patient context and healthcare workflow. In this section, we define the functional model of such dynamic checklists from previous reviews.

2.5.1 The functional model

This section presents a functional model of the Dynamic Safety Checklist (DSC) based on the foregoing analysis. The model describes the DSC's function from the diagnosis process perspective, specific medical scenarios, and integration capabilities with the information system.

The DSC should have the following functional properties (**FP**):

FP 1 The DSC standardizes the diagnostic process.

The DSC must have the function of standardizing the diagnosis and treatment process, that is, intervening in the decision-making and behavior of the medical staff in the form of a checklist at the key points in the diagnosis and treatment process to ensure that it is carried out according to the best clinical practice, clinical pathways, and medical procedures.

FP 1.1 The DSC should express the tasks in the treatment process, the order in which tasks are performed, and the role of the task performer.

The DSC must clearly express the clinical work tasks that must be completed by the relevant medical staff in the medical treatment process, clarify the dependencies or priorities between different tasks, and clarify which role each task should be performed.

FP 1.2 The DSC should have the ability to be driven by the process.

The DSC must be able to be driven by a pre-defined, standardized process that intervenes in the behavior of health care providers based on the progress of medical activities.

FP 2 The DSC proactively prompts the relevant personnel to check at the correct time in the medical process.

The DSC should be targeted and proactive, able to distribute checklist tasks at key points in the process's pre-defined, and alert and notify relevant personnel.

FP 2.1 The DSC should have the ability to generate a checklist at pre-defined stage in the process.

The DSC should have the ability to generate a corresponding safety checklist at a predefined key point in the medical treatment process.

FP 2.2 The DSC should have the ability to distribute lists to pre-defined roles.

The DSC should have the ability to distribute the generated checklist to the appropriate role based on the definition of the verification role in the process. **FP 2.3** The DSC should provide reminders and tips for emails, instant messaging (IM), and more.

The DSC should have the ability to alert the user while distributing the checklist task proactively. This alert can be implemented as email, instant message, text message, pager, etc.

FP 2.4 The DSC should provide a worklist for its users to track the status of checklists.

The DSC should provide each user with a checklist of pending checklists. When it is not convenient to check after receiving the notice, users can still check which check tasks have not been completed by checking the checklist.

FP 3 The DSC should adapt to dynamic changes in the process.

The medical process will make dynamic changes based on the patient's actual condition, and the dynamic checklist must have the ability to adapt to these change.

FP 3.1 The DSC should provide a checklist of relevant medical activities based on changes in the treatment process and patient status.

The DSC adapts to the patient's different conditions and intelligently according to the medical knowledge selection process, and its contents are closely related to the actual medical activity.

FP 4 The DSC should provide assistance for anomalies in the process.

The DSC should support unexpected, unpredictable abnormal conditions in the treatment process and provide a corresponding safety checklist for these conditions.

FP 4.1 The DSC should have data-driven capabilities that are triggered by exception data to generate a checklist.

The DSC should have the ability to monitor patient data actively, automatically analyze the patient's abnormal conditions that require intervention based on the data to respond to such abnormalities by providing a corresponding checklist quickly.

FP 5 The DSC should record the verification process and results of the process to increase transparency.

The DSC should have the ability to assist medical team members in communicating in the execution of medical procedures, thereby increasing the medical process's transparency.

FP 5.1 The DSC should record the verification results.

The DSC should record the results of ongoing treatment to allow staff members involved in subsequent treatment steps to understand the previous patient status and medical work status.

FP 5.2 The DSC should record the remarks generated during the verification.

The DSC should allow the medical staff to make notes. By means of these notes, the follow-up participants are aware that the previous checklist verification is a medical staff concern.

FP 5.3 The DSC should record the verification process.

The DSC should document all verification activities and sequences in the treatment process for team members and managers to understand the medical process's progress and possible verification problems.

The functionalities regarding the checklists' context perspective (**FC**) should be included in the DSC as follows:

FC 1 The DSC should provide the steps and key information related to the current medical scenario.

The DSC must provide operational steps, verification steps, and key information relevant to the medical scenario's appropriate safety issues.

FC 1.1 The DSC should provide standardized steps.

The DSC must provide a series of standardized operating steps. These steps can be represented by a checklist or by a flowchart.

FC 1.2 The DSC should provide personalized steps.

Based on standardization, the DSC should also reflect the actual condition of specific patients. The operation steps are customized according to the specific patient's physiological condition.

FC 1.3 The DSC should provide auxiliary information for the steps.

The DSC should provide information related to the completion of this step while providing key steps. This information includes patient data that requires healthcare professionals' attention and clinical knowledge required by the medical staff.

FC 1.4 The DSC should provide the basis for the occurrence of checklists.

The DSC should provide an explanation for critical item's occurrence to increasing the user's understanding.

FC 2 The DSC should provide an automated verification mechanism to ease the workload of the verifier.

The DSC should provide an automated verification mechanism that automatically completes certain checks based on patient data, reducing medical staff verification work burden.

FC 2.1 The DSC should be able to perform automatic checks based on patient data.

The DSC should have the ability to analyze patient data. Based on the patient data analysis, it determines whether the work specified in the verification project has been completed.

FC 2.2 The DSC should mark out the automatically checked items.

Since the algorithm automatically checks some items, the clinical users need to know which items have been automatically checked.

FC 3 The DSC should provide assistive decisions to help users calculate and make judgments based on data.

The DSC should have appropriate decision support capabilities, use patient data to analyze and reason based on best practice knowledge, and obtain a best practice-based treatment plan.

FC 3.1 The DSC should automate the calculation of critical health status indicators.

The DSC should provide the patient's key indicators' calculation ability and automatically calculate the indicators that require complex calculation formulas or evaluation scale calculations to reduce users' burden. For example, the APACHE-II score in the ICU is calculated, and the eGFR describing the renal function is calculated.

FC 3.2 The DSC should annotate key data.

The DSC should provide an annotation function for abnormal data, especially critical values so that users can pay attention to these abnormalities.

FC 3.3 The DSC should automatically detect anomalies in the diagnosis and treatment activities.

The DSC should provide an analysis of the patient's abnormalities and use the data to determine the patient's condition. For example, the combination of hemoglobin and fecal occult blood can point to the abnormality of gastrointestinal bleeding in patients.

FC 3.4 The DSC should automatically judge whether the treatment is in line with best practices.

The DSC should provide the ability to analyze the diagnosis and treatment's behavior.

FC 4 The content of the checklist item is personalized.

The DSC must provide the ability to personalize items and only provide verification items related to the current patient in his/her current condition.

FC 4.1 The DSC should determine, based on the patient's condition, which item should appear and which should not appear.

The DSC must make a judgment based on the patient's data, filter the safety checklist items, and display only those items that need to be verified.

FC 4.2 The DSC should adapt the contents of items based on the patient's condition.

The DSC must be customized according to the patient's specific conditions so that users can read and understand.

FC 4.3 The DSC must highlight items according to the patient's condition.

The DSC must provide highlights according to the patient's specific conditions, and the information that needs to be focused on in the item should be highlighted.

FC 5 The DSC should provide a review mechanism to review key content.

The DSC should provide a review mechanism for key items to ensure that they are completed correctly.

FC 5.1 The DSC should support computerized configuration redundancy, with critical items being reviewed by the computer.

The DSC should support the use of rules to determine whether the user's ticking of relevant items is consistent with their actual medical treatment. If there is any inconsistency, the checklist's submission should be rejected or authorized by the superior.

FC 5.2 The DSC should support process redundancy and proactively prompts follow-up personnel to review.

The DSC should support the follow-up personnel or superior medical personnel to check the checklist and its associated patient data to verify the medical process.

The DSC should also have the ability to integrate with information systems (Functionalities related to Information systems, **FI**):

Table 2.2: Non-functional requirements of dynamic checklists.

ID	Requirement
RN 1	Integration with hospital IT system
RN 2	Reusing existing IT infrastructure and knowledge base
RN 3	Share checklists among organizations
RN 4	Enable clinical users to create and manage checklists

- **FI 1** The DSC should be integrated with clinical information systems such as EMR to directly use the data in the information system to prevent users from repeatedly entering data.
- **FI 2** The DSC should be compatible with clinical decision support, reuse existing digital medication rules, and medical guidelines to avoid duplication of development and repeated verification by users in different systems.

2.5.2 The non-functional requirements

As a software product, the dynamic checklist should obey the quality standards of general software products, and specifically the ISO 25010 standard. Besides the functional requirements that we detailed above, non-functional requirements are analyzed as well. Alongside the general requirements of reliability, efficiency, and maintainability, special concerns should be given to usability and portability (see Table 2.2).

2.6 Chapter summary

This chapter analyzes the safety checklist's connotation, systematically reviews the development history of the safety checklist, and reveals the key elements of safety checklists and key development trends. A safety checklist is a memory aid in the form of a checklist that accurately describes and guides the key activities and decisions that should be made in the workflow. As the safety checklist develops, its ability to cover medical processes is also growing, from simple processes to complex processes. With the WHO Safety Checklist's introduction, the safety checklist for dealing with complex, highly coupled processes has become the safety checklist development direction.

This chapter summarizes the functions and limitations that are currently available in the safety checklist through the analysis of the various elements in the design and use of safety checklists. These limitations need to be addressed by enabling the safety checklist to adapt to dynamic medical procedures and to adapt to the patient's individualized situation. Based on the functions that the safety checklist already has and

the functions that should be added, this chapter presents a functional model of desired DCS properties.

Chapter 3

A meta-model for authoring and execution of dynamic checklists

3.1 Introduction

Chapter 2 proposed a framework for the design, implementation, and evaluation of dynamic checklists. While designing and evaluating dynamic checklists, it is necessary to represent them in a computer understandable way so that knowledge can be captured and executed. Currently, most studies represent dynamic checklists in a hard-coded way; and these representations are tightly coupled with specific information systems (typically Electronic Medical Record Systems). Although a hard-code approach is rather straightforward, we argue that it has several limitations. Firstly, clinical experts and users do not understand the encoding approach or the encoded knowledge in the form of software source code. However, clinical experts' involvement is critical for the success of the checklist. This approach introduces unnecessary communication costs and potential communication errors between clinicians and IT specialists. Secondly, the definition of these dynamic checklists is tightly coupled with their execution. This makes the definition (i.e., model) difficult to be extended, maintained and reused.

In recent years, guideline-based clinical decision support and workflow management

¹Shan Nan, Pieter Van Gorp, Hendrikus HM Korsten, Uzay Kaymak, Richard Vdovjak, Xudong Lu, and Huilong Duan. 'DCCSS: A meta-model for dynamic clinical checklist support systems.' In Model-Driven Engineering and Software Development (MODELSWARD), 2015 3rd International Conference on, Angers, France, pp. 272-279. IEEE, 2015.

²Shan Nan, Pieter Van Gorp, Xudong Lu, Uzay Kaymak, Hendrikus Korsten, Richard Vdovjak, and Huilong Duan. 'A meta-model for computer executable dynamic clinical safety checklists.' BMC medical informatics and decision making, 2017, 17(1): 170.

research has already provided solutions in their own problem domain for similar problems. The hard-coded approach can not take advantage of these solutions. This is undesirable, especially since encoding clinical knowledge in executable and shareable formats has been studied and practiced for decades [94, 95]. For example, clinical guideline modeling languages and workflow modeling languages have been developed for and/or applied to encode clinical guidelines and clinical pathways. Knowledge acquisition tools and execution engines have also been developed to facilitate the use of these modeling languages. These languages and tools enable clinical users to encode guidelines and pathways and share the encoded knowledge among hospitals.

It would be ideal if dynamic checklists can take advantage of such modeling languages, tools and encoded knowledge. Prior research considering checklists as a modeling construct in clinical workflow modeling have already contributed partial efforts in this direction. Fäber et al. [96] have demonstrated the meaningful use of parallel tasks for the modeling of checklist-supported workflows. However, it was not yet investigated how to deal, for example, with dynamicity in checklist forms, e.g., to allow them to represent clinical algorithms. Heß et al. [97] have proposed a clinical pathway domain-specific modeling language, which considers the checklist as a supportive concept in medical processes. In their research, a checklist is further decomposed into patient-specific checklist elements. However, it was not revealed how the modelers could define in which context a patient-specific element should be used. Further study is needed to fully answer this research question by developing a conceptual model describing dynamic checklists' complete structural and functional requirements.

Considering that dynamic checklists have the function of managing healthcare processes, personalizing checklist items, and extracting data out of the patient record, it is likely that one single existing modeling language can not fully support representing the dynamic checklists. Instead, multiple languages may be used in combination. In this case, it becomes a challenge to integrate multiple modeling languages to represent dynamic checklists.

In this chapter, we answer these research questions by contributing a meta-model formalizing the modeling requirements and emphasizing the interoperability between modeling languages. With this meta-model, the clinical users choose and use their familiar modeling languages and editors. The execution of the model can also take advantage of using the implemented execution engines. As a result, the notion of a dynamic checklist can be better adapted and more widely used. Furthermore, we have the ambition to enable researchers and vendors to share their dynamic checklist models

worldwide to reuse, validate, and compare models developed by others. In such a way, the implementation of dynamic checklists can be accelerated.

3.2 Development of a meta-model for dynamic checklists

Referring to to [98], we developed a four-step approach to derive our dynamic checklist meta-model. Firstly, a problem domain analysis was performed to clarify what makes dynamic checklists dynamic. Then, we investigated existing modeling approaches to take advantage of mature tools. Finally, we developed the meta-model by eliciting dynamic checklist-related concepts and determining class hierarchies and properties.

3.2.1 Problem domain analysis: scope of dynamic checklists

Efforts on developing and implementing dynamic checklists have been increasingly reported in recent years. The AMC rolled out its SURPASS Digital in 2011 [36], which is the computerized version of their well-known SURPASS checklist [6]. SURPASS Digital aims to streamline better the process of using SURPASS checklists for each patient and ease the use for care-givers. In order to streamline the process, SURPASS Digital uses a web-based user interface integrated with their EMR. Once a patient is selected in the EMR, a care-giver can get an overview of the status and results of all the checklists and/or pick up a checklist to work with. The integration is supported in the back-end by an information integration platform specific to AMC to retrieve patient registries and other information from the EMR. In the front-end, programs like JavaScript are used to improve the interaction and validate the checking logic.

While SURPASS Digital mainly focuses on streamlining the process, other research on encouraging using checklists in specific scenarios is increasingly reported. For example, a computerized discharge checklist is reported by Stanford University Medical Center [33]. In their system, the paper discharge checklist is implemented as an Electronic Medical Record System (EMR) specific keyword. Once a user types the keyword ".dcchecklist", the system automatically inserts a predefined checklist template into the patient's EMR chart. In addition to this, many researchers are now focusing on making a checklist adaptive to specific patients. Two dynamic checklists for the ICU are reported by the Mayo Clinic [35] and the Lucile Packard Children's Hospital at Stanford [34], respectively. Both of them are integrated with the EMR and some of their content is derived from or calculated by clinical rules. For example, for a patient who has been placed with a central line for multiple days, there will be a red item added in the checklist warning the intensivist to evaluate the necessity of keeping these lines placed.

Our research team has also reported the efforts to develop a comprehensive dynamic

checklist support system named Tracebook [99]. It covers both streaming the process and personalizing the checklists. Tracebook is designed to be a checklist execution platform for dynamic checklists, which are process-oriented and patient context-aware. In Tracebook, each checklist is associated with a clinical activity. The order of these activities is defined in a clinical pathway. Moreover, the persons who are supposed to perform the checks in the checklist are also predefined in the clinical pathway by assigning each task a potential owner's role. In each checklist, a checkable item can be defined either as a static text string or as the result of a clinical rule. For example, an item like "Blood samples for cross-typing have been taken" should be applied to every patient without change. Therefore, it is implemented as a static string. However, some patients may have their specific concerns, which should be reflected in the checklist. For example, the surgeon should be aware of the patient's renal insufficiency. This item is implemented as a clinical rule like "IF Renal Insufficiency is true THEN add an item 'Renal insufficiency noticed'". As a result, these items are only present for those who have renal insufficiency.

From the aforementioned checklist implementations, a dynamic checklist should have two main features. Firstly, a dynamic checklist should be process-oriented. SURPASS Digital enables its users to get an overview of the status of the whole checking process. Tracebook even goes further. It disseminates checklists to the right users automatically according to predefined clinical pathways. These process-oriented features help clinical users perform the check at the most proper time. Secondly, a dynamic checklist should be patient context-aware. That is, each checklist should be customized in a patient-specific fashion so that care-givers are able to focus on each patient. Additionally, patient data and supporting materials are provided to the users together with the checklist. In such a way, users can identify the problems that a dynamic checklist item points out.

These features were broken down into the following modeling requirements.

- **Requirement R1** The dynamic checklist model should support clinical workflow which can be in sequential, parallel or conditional orders.
- **Requirement R2** The dynamic checklist model should support domain-specific activities. A domain-specific activity can be associated with safety guard activities that indicate potential safety problems.
- **Requirement R3** The dynamic checklist model should support both simple Situational-Action Rules (SAR) and nested rules, where one rule can serve as the action.
- **Requirement R4** The dynamic checklist model should support expressing the content of safety checklists in such a way that they are associated with relevant clinical activities and specific to every patient when necessary.

Requirement R5 The dynamic checklist model should support providing auxiliary information that can improve user's efficiency, thereby facilitating the easy adoption of safety checklists.

3.2.2 Solution domain investigation: support in existing modeling approaches and tools

Various languages have been developed for modeling healthcare-related processes during the last decades, especially guidelines. They can be divided into two categories by their design purpose and application domain [100]. One category is the business process modeling language, which focuses on describing activities, roles, resources, and relationships in complex business processes. The other category is the guideline modeling language, which focuses on decomposing guideline tasks and clinical logic inside.

For clinical process-related modeling approaches, both domain-specific modeling languages and extensions to general-purpose languages have been studied. Burwitz et al. [101] proposed a domain-specific modeling language for modeling clinical pathways.

The approaches of using general-purpose modeling languages are focused on Business Process Modeling and Notation (BPMN) [102]. BPMN is a standard that offers the most expressive and understandable language at the time of writing this manuscript. The standard also prescribes an interchange format that enables the combination of modeling software and runtime execution software from different industry vendors [102]. The BPMN language was designed to be comprehensible by both IT specialists and professionals. Various other authors treat BPMN as a cost-efficient, rational, standardized, intuitive and flexible instrument for modeling healthcare processes [103]. Besides being expressive and understandable, BPMN is also easy to be extended. BPMN can be extended in two ways [102]. Firstly, the standard BPMN elements can be extended with additional attributes that can be supported in specific modeling tools and executed by a customized execution engine. Additionally, non-standard elements or artifacts for domain-specific purposes can be added to the standard BPMN as extensions. Concrete BPMN implementations already show the feasibility of extending the standard BPMN. For example, jBPM¹ developers have extended a standard BPMN element, user task, with on-entry and on-exit actions to represent actions before and/or after the execution of a user task [104].

Scheuerlein et al. [103] showed the feasibility of using BPMN to model clinical pathways. Müller et al. [105] developed an extension to BPMN so that shared tasks,

¹See http://www.jbpm.org/.

which are very common in healthcare processes, can be expressed in the extended BPMN. Hashemian et al. [95] showed the theoretical feasibility of mapping clinical pathways to BPMN. Braun et al. [106] proposed a BPMN extension named BPMN4CP dedicated to representing the clinical pathway in BPMN.

The representation of clinical algorithms is supported in various guideline modeling languages [107]. These languages are all designed to represent clinical algorithms as groups of decision logic. Among these languages, Arden, standards-based Shareable Active Guideline Environment (SAGE) and GuideLine Interchange Format (GLIF) share similar ontologies and therefore have comparable semantics [108]. Especially, GLIF has been designed to be shareable between organizations [94]. Particularly, de Clercq et al. [109] have developed the Gaston framework, which proposes a domain ontology plus a problem-solving ontology using GLIF's primitives. A pharmacy decision support system has been developed and widely used together with its pharmacy rules across the Netherlands [110]. The mapping between GLIF and other clinical guideline languages is also possible and well studied [111].

In recent years, industry rule languages have been increasingly applied to the clinical domain. For example, Drools was reported in the literature [112, 113]. These languages benefit significantly from open source communities and are developing rapidly.

While studying these modeling languages, model editors, as well as execution engines, have been developed accordingly. These tools have been developed for noncomputer experts and enable domain experts to formalize and encode their thoughts directly (see the editing interface of BizAgi in Figure 3.1 and Gaston Editor in Figure 3.2). In order to make the encoded knowledge executable for clinical applications, execution engines are also developed. We have practiced with these modeling approaches to build a CABG dynamic checklist set in our prior work [99]. Considering our goal of making reusable and shareable checklists, reusing standards or widely-accepted models is preferred.

3.2.3 Definition of the meta-model

Based on the aforementioned modeling requirements and learning from the aforementioned modeling languages, we categorized dynamic checklist related concepts into three groups: process-related concepts, context-related concepts, and concepts describing the format and content of checklists. A meta-model as depicted in Figure 3.3 was then defined.

Clinical activity is at the center of all the process-related concepts. Each clinical related task or group of tasks performed in a specific scenario is considered as a

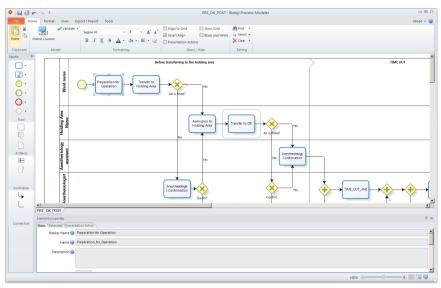


Figure 3.1: User interface of the BizAgi workflow editor while editing a CABG peri-operative care pathway.

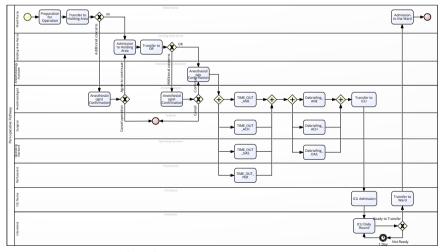


Figure 3.2: User interface of the Gaston Editor while editing a set ICU daily round rules.

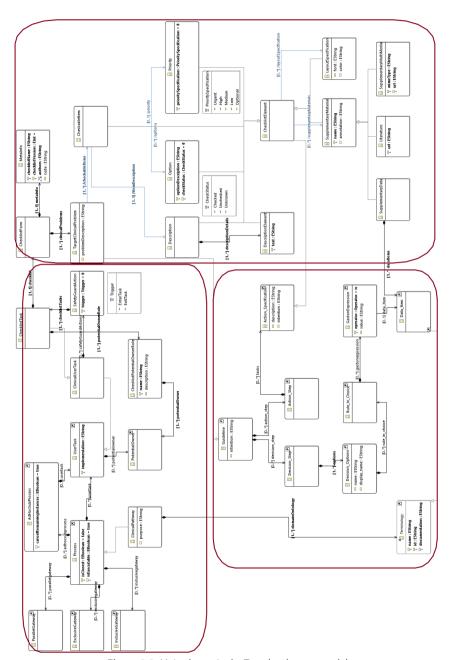


Figure 3.3: Main classes in the Tracebook meta-model.

clinical activity. Each clinical activity has one or several **potential owner(s)**, who is(are) responsible for performing this activity. A potential owner has a role indicating his/her specialization. Clinical task is a kind of atomic clinical activity, meaning that this activity can not be decomposed into more detailed activities. These clinical tasks are organized in a **clinical pathway**, which is a predefined specification of which tasks will be executed in which order. Specifically, the care flow is used to define such orders. These orders include sequential order, parallel order, conditional order and ad-hoc order. Each of these types is described by a specific flow pattern, i.e, sequential flow, parallel flow, conditional flow and ad-hoc flow. Clinical activities are always carried out in high pressure and heavy workload situations where errors or potential problems tend to happen. In order to prevent these **potential problems**, safety guards are needed to protect the activity. A safety quard activity is triggered by a trigger event, which indicates that something happens while performing the clinical activity. For example, an activity may be supposed to be completed, but it might not proceed due to some reason in actual practice. In such a condition, the safety guard is triggered, and a safety quard activity will be performed to quarantee the patient's safety. A safety quard activity is still a clinical activity. So, a safety guard activity is also related to other safety guard activities. However, different from other kinds of clinical activities, the safety guard activity specifies the strategy to protect safety. The strategy is specified in the form of an algorithm, which we describe in the next paragraph.

A **clinical algorithm** is a specification of how to perform a task. An algorithm has one or more **contexts** describing its initial input situations. For example, **patient data** is a kind of context describing the status of a patient. In contrast to context, an algorithm has one or more **actions** indicating what to do if the given context materializes. The detail of the expected action is described in an **action specification**. This is a general structure of a clinical algorithm. However, the link between the context and the action is not specified. This link can, for example, be a heuristic algorithm program, a Bayesian Network model, or a clinical **rule**. In a clinical rule, **expressions** are used to describe the logical relation between conditions and actions.

The checklist is used as a reminder to critical steps in a clinical activity. The action of performing a checklist (**checklist task**) is a safety guard activity defined in the process-related concepts. A **checklist form** is used as the container of the content of the checklist task. **Meta-info**, including title, author, version, etc. is then used to modify the checklist form's maintenance information. Each checklist form is designed for several **target clinical problems**. A target clinical problem can be solved by some **safety algorithms** in the format of a group of **checkable items**. In each checkable item, there must be a **description** of the specification of the task. **Option**s are normally needed as indicators of whether the task has been completed or not. However, in some cases,

e.g., emergency situations, a checklist is used purely for guidance when there is no time or necessity to mark out the options. **Priority** is an optional attribute of a checkable item. A checkable item can be ranked up or marked with highlight according to the **layout specification** if it has a high priority. Lastly, **supplementary materials** can be applied when needed. The supplementary material can be either **supplementary data** facilitating that users understand the current patient situation or **literature**, facilitating that users find useful information from the medical literature.

3.2.4 Mapping of the meta-model to mature modeling languages

We mapped the process-related dynamic checklist concepts to the concepts in the BPMN modeling language. The clinical process's basic ideas can be well-supported by BPMN with the exact BPMN concepts without extension. A clinical pathway related to several checklists can be considered equivalent to a **process** in BPMN. It is a container of the description of the control flow. A care flow is such a control flow. Specifically, each category of care flow has its own map in BPMN. The sequential flow means that two tasks have to be executed one by one. This can be described by using a **sequence flow** in BPMN, which is an arrow that connects two tasks. The parallel flow can be represented by adding a **parallel gateway** in BPMN. The parallel gateway can represent that several tasks (and their succeeding tasks) are executed simultaneously. The conditional flow enables selecting different tasks according to the specific condition. This can be represented with **exclusive gateway** and **inclusive gateway** in BPMN based on convergence criteria. Ad-hoc flow represents a batch of tasks which do not have a predefined execution order. This feature is supported by **ad-hoc subprocess** in BPMN.

To represent specific safety checklist concepts, some items in BPMN need to be extended. We derived the **clinical user task** from the **user task** in BPMN. However, different from the user task, **safety guard activities** are required in order to prevent potential problems that affect patient safety. A **safety guard activity** (e.g. using a checklist) is activated by a **trigger**. For example, at the time when a clinical user task is completed, a checklist should be given to some clinical practitioners to make sure the task has been done properly. These concepts are not supported in the BPMN standard. Fortunately, these requirements are partly supported in BPMN based modeling tools and execution engines, e.g., jBPM and BizAgi. BizAgi provides a feature enabling executing extra tasks at the time of entering and exiting a task. Specific to a checklist, the activity of performing a safety checklist is a kind of **clinical user task**, that is protected by one or more safety guard(s). In this way, a checklist is integrated into the clinical process represented in BPMN. The mapping relationships are summarized in Table 3.1.

We mapped the rule-related concepts to the concepts in Gaston and Drools. A clinical

Table 3.1: Mapping clinical process concepts.

Checklist concept	BPMN concept	Explanation
Clinical Pathway Care Flow	Process Sequence Flow, Gateways, Ad-hoc Subprocess	A clinical pathway is a kind of process. A care flow specifies how two or more clinical tasks are connected.
Sequential Flow Parallel Flow Conditional Flow	Sequence Flow Parallel Gateway Exclusive Gateway, Inclusive Gate-	Two tasks are executed sequentially. Two tasks are executed simultaneously. The succeeding task can only be executed if some conditions are met.
Ad-hoc Flow Clinical Activity	way Ad-hoc Subprocess Task	Tasks are executed without a specific order. A clinical activity is a clinically-oriented task.
Clinical Task Potential Owner Role	User Task Potential Owner Resource Role	A clinical task is a clinical-oriented user task. A potential owner is an expected owner of a clinical task. A role is the clinical role of a potential owner. A potential owner may have one or more roles.
Safety Guard Activity	User Task	Safetyguardactivityisaclinicaltaskdedicatedtopreventingpotentialmedicalerrors.
Potential Problem Trigger	N/A N/A	Potential problem describes what possibly might go wrong while performing a clinical task. A trigger is a description of when a safety guard activity should be
		executed.

algorithm is usually adopted from clinical guidelines describing the best practice. In Gaston, the concept is presented as clinical quideline, whereas in Drools, which is a general purposed rule language, the concept can be mapped to a rule file. An algorithm can be further broken down into several rules. Gaston's guideline concept has a nested mechanism in which a guideline can be decomposed into several subquidelines, and a sub-quideline is also a quideline. In Drools, each rule file contains several rules. The algorithm describes the decision logic in response to some specific patient conditions. The decision logic is usually represented in Gaston's flow chart form, including decision step and action step. These two Gaston concepts map to decision and action, respectively. Similarly, Drools has conditional element and action element to map with these concepts. Patient context is the patient data item used for specifying under which condition a decision should be made. Both data item in Gaston and fact in Drools can be mapped to this concept. An action specification specifies what to do in an action. Gaston has a dedicated element action specification for this. In Drools, a property name value in action can be used. The full mapping relationships are summarized in Table 3.2.

3.2.5 Checklist modeling

As illustrated in Figure 3.4, we use the process modeling tool to build the process model and import it into the dynamic checklist editor in XPDL format. Then we create checklists and related rules, and finally associate the rules with activities in the process.

3.2.6 Model execution

To validate our methodology, we developed a prototype dynamic checklist decision support system, Tracebook, for executing dynamic checklist models [99]. In accordance with the meta-model, Tracebook has three main components for model execution and a UI component for the interaction with users (see Figure 3.5). The workflow engine is designed to support the clinical pathway. In this part, we interfaced with BizAgi Express business management system's APIs². The rule engine is used to support clinical rules. In this part, we interfaced with Gaston and Drools, respectively. We implemented the checklist engine to deal with the interoperability between the workflow engine and rule engine based on our checklist model. The checklist engine also sends checklists to the UI renderer in XML format. The UI renderer uses XSLT to interpret the XML into HTML 5 format and show them to users as checklists.

²See http://wiki.bizagi.com/.

		Table 3.2: Mapping medical rules.	ıles.
Checklist concept	Gaston concept	Drools concept	Explanation
Clinical Algorithm	Nested Guideline	Rule File	A clinical algorithm is usually adopted from clinical
Rule	Guideline	Rule	guadelines describing the best practice. A clinical algorithm is usually adopted from clinical quidelines describing the best practice.
Context	Data Item	Fact	Patient context is the patient data item used for
			specifying under which condition a decision should be made.
Decision	Decision Step	Conditional Element	Decision is a step in an algorithm describing which
Action	Action Step	Action Element	branch to choose under a certain context. Action is a step describing the inference result once
			a decision is made.
Expression	Gaston Expression	ConditionalElement	Expression is used for expressing the criteria for a
		Eval.expression	decision.
Action Specification	Action Specification	Action Element.value	An action specification specifies what to do in an
			action step.

This system has been implemented in both Catharina Hospital and PLA General Hospital, interfacing with these hospitals' hospital EMR systems. Considering different IT infrastructures, these two implementations chose the Gaston rule engine and Drools rule engine. As requested by clinical users, the user interface was adapted and fine-tuned in each hospital accordingly.

Case studies 3.3

After having developed the meta-model, we validated its feasibility by two case studies. The meta-model was mapped to specific modeling languages according to the requirements of hospitals.

Case selection 3.3.1

In order to validate the meta-model, two checklists were implemented in our study. One is a Coronary Artery Bypass Graft (CABG) peri-operative checklist in a Dutch hospital, Catharina Hospital. The other is a PCI peri-operative checklist in a Chinese hospital, i.e., People's Liberation Army General Hospital (PLAGH).

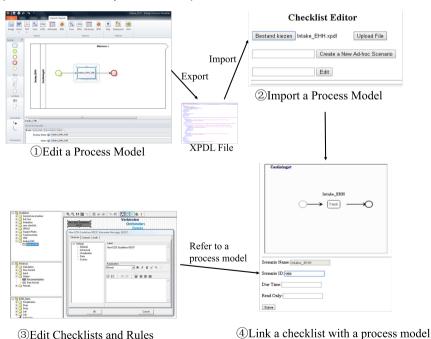


Figure 3.4: Steps of editing a dynamic checklist.

(3) Edit Checklists and Rules

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<task-repository>
   <task-template task-name="LVEF abnormal" task-id="s01|p02|t01" type="default">
       <description>
                LVEF=<span style="color:{$param2}">{$param1}</span>,confirmed and considered.
        </description>
        <mandatory>false</mandatory>
        <result>nochecked</result>
        <explanation></explanation>
       <note></note>
        <task-params>
            <param name="LVEF value" anchor="$param1" />
            <param name="LVEF color" anchor="$param2" />
        </task-params>
    </task-template>
</task-repository>
```

Figure 3.5: System architecture of the prototype system based on the meta-model.

These checklists are designed for the peri-operative phase and involve a comprehensive process requiring collaboration among various clinical roles. Additionally, various clinical rules are applied in the peri-operative process to check if proper treatments are given. These features made these two checklists suitable as our case study objects.

These two hospitals have different IT infrastructures and preferences. In Catharina Hospital, the rule-based clinical decision support system, Gaston, has been used over a decade. Both medical workers and IT staff in the hospital had a strong will to reuse the system and clinical rules in it. Thus, Gaston was implemented to edit and execute clinical rules. However, Gaston is not available in the Chinese hospital. Therefore, we chose Drools, which is a powerful and widely used open-source rule engine. Considering the availability of tool support and the requirement of communicating with medical staff, we chose BPMN to represent both of these cases' clinical processes.

3.3.2 The peri-operative checklist in the Dutch hospital

In order to make the use case process-oriented, we first modeled the peri-operative care workflow (as described in Figure 3.6) in BizAgi Process Modeler. As for this checklist, each checklist sheet is given after practitioners finish some work in the clinical process. Here we use catch message event as a connection between outside clinical processes and checklist's own process. Each checklist is associated with a task in the BPMN model. Every task is assigned to a specific role. Swim lanes are used for specifying the roles that should be assigned to each checklist sheet. The list of persons who belong to this role is edited and managed by Tracebook. The checklist also includes the contact information of these persons. In this way, the workflow engine can distribute a checklist to the

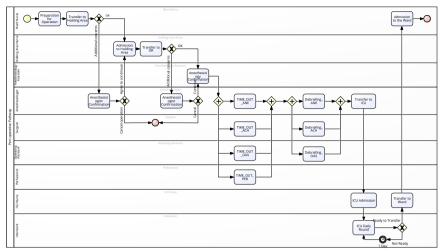


Figure 3.6: A CABG peri-operative pathway model.

concerned persons and further remind them. An execution log can be mapped with this model in the runtime, so that Tracebook can provide an overview of who did what. Parallel gateway is used to split and join parallel tasks, and exclusive gateway is used to branch and synchronize conditional flows. However, the branching condition should be considered here, but the detail of logic is a part of the task layer. Messages are used for the message exchange between the checklist process and the outside process.

We use Gaston editor as the knowledge acquisition tool for checklist task knowledge. The user interface and an example of a rule is included in Figure 3.7. Each fragment of a checklist is implemented as a guideline in Gaston (as described in Figure 3.2). Each checkable item in the fragment of a checklist is implemented as a task. In each task, we define the content of the checkable item (including link to patient data) and explanation of the item if needed. Additionally, the decision logic is used to highlight items, provide personalized items and pre-check items for double-checking.

A post-operative intensive care checklist is given as an example showing how we model a checklist in the clinical pathway. The example can be found in Figure 3.8. In Gaston, the basic clinical rules can be decomposed into decision step and recommendations. These primitives are organized in the form of flowcharts. The flowchart is edited in Gaston editor. Decision step primitives are used for representing conditional choices and expressions in conditions are used for the criteria. Logical and temporal expressions, together with clinical data can be represented within decision step primitives. The expressions are edited in the Gaston environment, as shown in Figure 3.9. The data items are created as described in Figure 3.10.

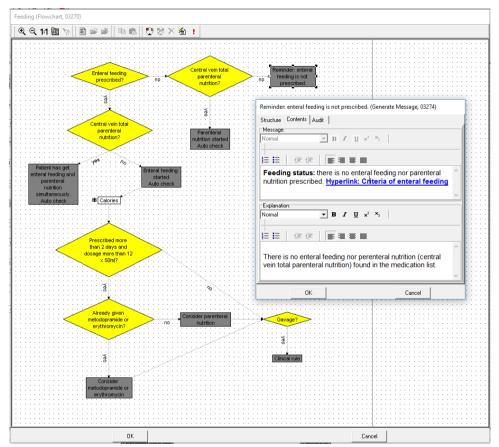


Figure 3.7: An item related to feeding in the ICU daily round checklist.

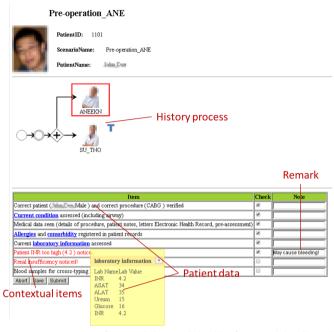


Figure 3.8: An overview of an ICU daily round checklist form model (collapsed).

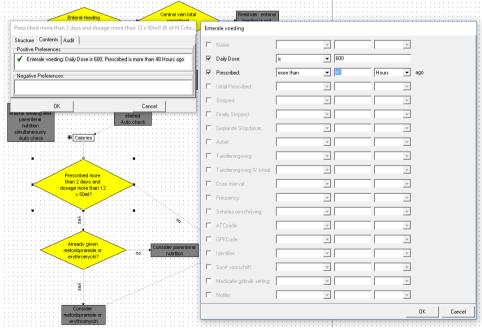


Figure 3.9: Decision logic of providing which check item to a specific patient.

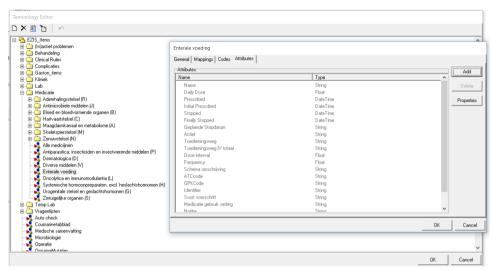


Figure 3.10: Terminology used in the rules.

For the system development, we interfaced with BizAgi Express business management system's APIs and Gaston. We implemented the checklist engine to deal with the interoperability between the workflow engine and rule engine based on our checklist model. The checklist engine also sends checklists to the UI renderer in XML format. The UI renderer uses XSLT to interpret the XML into HTML 5 format and show them to users as checklists.

3.3.3 The PCI checklist in the Chinese hospital

In the Chinese hospital, we implemented the process model also in BPMN. (see Figure 3.11) Unlike the first case, we used another approach to implement clinical rules and checklists' content. In Drools, rules are presented in the form of "WHEN condition THEN action". These rules are edited in a plain-text editor. Checkable items are produced and modified in the action clauses in these rules. We take the Left Ventricular Ejection Fraction (LVEF) as an example. Based on the meta-model, the item is defined in the form illustrated in Figure 3.12. Then, this item is associated with a clinical rule defined as in Figure 3.13. When the patient's LVEF is less than 50, the rule will be fired, and a patient-specific item alerting the doctor will be generated. Specifically, the abnormal LVEF value is marked with the red color so that the doctors can find it at their first glance.

This model is also executed by our Tracebook system in the Chinese hospital. A fragment of pre-operative checklist in the system can be found in Figure 3.14. The check items in gray are automatically checked by the system, according to predefined clinical

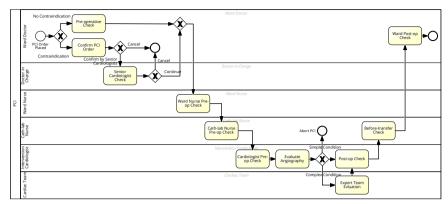


Figure 3.11: The PCI peri-operative care pathway.

```
<?xml version="1.0" encoding="UTF-8" standalone="yes"?>
<task-repository>
   <task-template task-name="LVEF abnormal" task-id="s01|p02|t01" type="default">
        <description>
                LVEF=<span style="color:{$param2}">{$param1}</span>,confirmed and considered.
        </description>
        <mandatory>false</mandatory>
        <result>nochecked</result>
        <explanation></explanation>
        <note></note>
        <task-params>
            <param name="LVEF value" anchor="$param1" />
            <param name="LVEF color" anchor="$param2" />
        </task-params>
    </task-template>
</task-repository>
```

Figure 3.12: Example of a predefined checklist item.

```
rule "Check LVEF-Low"
  lock-on-active true
  salience 0
  when
     $p : Patient(lvef < 50 && lvef> 0)

     $builder : ChecklistBuilder()
     $t : TaskFactory()
  then
     $t.addParam("LVEF value", $p.getLvef() + "%");
     $t.addParam("LVEF color", "#ff0000");
     $builder.addTask($t.getTaskInstance("s01|p02|t01"));
end
```

Figure 3.13: Example of a clinical rule related to a checklist item.

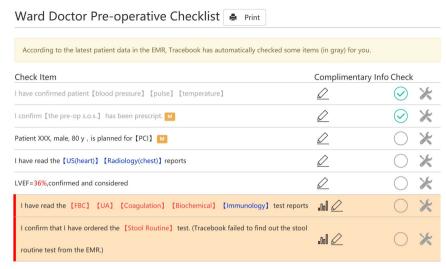


Figure 3.14: Screen shot of a fragment of checklist used in the Chinese hospital.

rules. The items ending with a mark "M" are items of high priority. Data items in the checklist items are linked to patient data in the EMR. Items in red color indicate that abnormalities are found in these items. In the given example, the patient's LVEF is 36, which is less than 50. Therefore, an item alerting the situation is provided.

3.4 Discussion

3.4.1 Experiences gained in the two implementations

While implementing these two cases, we found that there are several advantages of using our meta-model. The model-driven approach significantly reduced the workload of developing checklist support systems. In both the Dutch hospital and the Chinese hospital, checklists' contents have been updated continuously without changing the source code of the Tracebook system. This shortens the iteration loop of developing dynamic checklists in hospitals. The meta-model enables its developers to choose mature modeling languages, tools and execution engines. By doing so, clinical workers, informaticists and hospital IT staff all benefit. Indeed, in our case study, our clinical participants could fully understand care pathways in BPMN and clinical algorithms in Gaston. The IT infrastructure in hospitals can be reused to speed up development and implementation.

Both Gaston and Drools are used in our implementations. While modeling clinical rules for dynamic checklists, these two languages, together with their related tools, have

their own advantages and disadvantages. Gaston represents clinical rules in a flowchart fashion, which is easy for clinical experts to understand. Clinical rules in Drools are organized as groups of SARs, which are easy to maintain by informaticists. However, both of these two languages can fully capture the algorithms provided by clinical experts. When it comes to the tool support, Gaston has a user-friendly rule editing tool, which enables trained clinicians to edit rules by themselves. Such nice tools are as yet lacking for Drools. Therefore, informaticists have to write the rule by themselves and confirm them with clinical experts.

3.4.2 Shareability and reusability enabled by the meta-model

Both our cases use BPMN as the language for expressing clinical processes. Previous research shows the feasibility of mapping BPMN to other executable languages such as BPEL and Petri-net [114, 115]. Thus, our model should be able to use with other languages. Our ongoing work is to implement Case Management Model and Notation (CMMN) in another case study.

Though this work is an extension to BPMN and GLIF, with our proposed conceptual model, it is also possible to apply the methodology to other business modeling languages (even descriptive languages, e.g., CMMN [116]) which have the concept of task. Moreover, the conceptual model also serves as a guideline of using the built-in rule module and UI designer in commercially available business modeling tools e.g., BizAgi, jBPM and Activiti.

3.4.3 The necessity of using more than one modeling language

In our case studies, we use more than one modeling language to implement dynamic checklists. In the Chinese hospital case, it is clear that it is impractical to use Drools to represent the care processes. However, in the Dutch hospital case, both BPMN and GLIF are used. Both of them are wide-spread modeling languages in industry and healthcare. These two languages share lots of similarities in their syntax and modeling constructs. Moreover, both of these two languages have been used to represent clinical processes. In addition to the process, rules are supported in both languages as well. However, both processes and rules are supported at different levels by these two languages.

Comparing with BPMN, GLIF does not support user, role, event, etc. The ability to represent workflow concepts of GLIF and BPMN has been studied thoroughly by Peleg et al. As a conclusion, though it is possible to model clinical processes with GLIF, extra constructs are needed or have to be added in the runtime [117].

Regarding rules, BPMN has defined a limited interface and leaves the implementation to the vendors. Therefore, the content of rules is not defined in the BPMN model [118]. This is exactly the strength of GLIF, in which rich constructs and expressions can be used to represent rules, especially clinical rules.

From the analysis mentioned above, it is clear that by solely using BPMN or GLIF, the whole idea of the checklist can be supported only to some extent, but not completely. In order to explicate every concept that is needed for a checklist, these two languages should be combined and integrated.

3.4.4 The strengths and short-comings of extending existing modeling languages

Both BPMN and GLIF have good visualization supported by various applications. Drools has become a popular rule language in the industry in recent years. The first strength of these languages is the widely-available modeling tools and execution engines. Existing models in their support systems that are already running in the hospital can be easily adapted and reused. Secondly, domain users are already familiar with these languages so that the adoption cost is lower than newly-developed languages. It might be argued that there is a short-coming in that our approach is difficult due to the complexity of learning and using two languages instead of a single unified language. Note, however that usually clinical processes and specific checklists are different concerns by different roles in a hospital. The management board is usually the main stakeholder of standardizing the clinical process so that the care processes carried out in their hospital is standardized and controllable. Regarding a checklist, it is the concern of a specific department where the checklist related activities are carried out. As a result, actually, two groups of people are working on one set of checklists. These two groups of people can work with their familiar language and integrate their work together as a whole at the very end. Only limited and affordable marginal efforts need to be taken.

3.4.5 Limitations

In clinical settings, some people may work together as a group for some scenarios but with their own duty in parallel. In the proposed meta-model, we consider this group of people a composed role that includes all the actors involved. However, this concept is not well represented in the execution phase. This is because workflow execution engines have only one actor for every task. One way to solve this problem is to duplicate those tasks to different actors. However, this is against the idea that people should physically work together for those tasks.

The layout of the checklist influences the acceptance of checklist implementation a lot. Different tasks may have different priorities and be marked with different colors. However, the layout problem is not yet considered in our meta-model. This is because we think that we should split the content of knowledge and leave the representation to the end users. In this way, it is more flexible to be applied and distributed within different organizations.

One potential advantage of this work is that it gives a platform-independent model that can be applied to multiple modeling languages and execution engines by the model transformation. Hospitals always have their own legacy clinical decision support system in real clinical settings, which often contains a rule engine. In this case, they want to have an easy way to reuse the checklist knowledge. Model transformation provides this mechanism. Since our process layer and scenario layer reuse concepts from basic business process modeling languages, all workflow modeling languages, and most task network languages work fine. For the task layer, which is mostly for logic expression, all task network languages and rule languages are applicable.

Another potential advantage is that international standards are used for representing checklist knowledge. That is to say, knowledge sharing between different facilities will be easy if they also follow standards in their information systems, which is a trend in system implementation in hospitals.

3.5 Chapter summary

The checklist is a widely used technique to help improve medical quality and reduce avoidable errors. Clinical researches show the great power of checklists. However, due to the static nature of paper-based checklists and simple digital checklists, checklists' adherence still has significant room for improvement. One way to improve adherence is to make checklists more dynamic and seamlessly integrated in the workflow and make them more context-aware. Checklist modeling is the first step of making such dynamic checklists.

This chapter proposed a framework that reuses existing modeling languages and tools to model dynamic checklists. We analyzed the modeling requirements for checklists and proposed a three-layer framework of checklist modeling. For each layer, based on the requirements, we analyzed and selected concepts from existing formal languages and reused these concepts and their relationships in our model. We also used BPMN and Gaston to validate our meta-model by modeling and implementing the CABG peri-operative checklist into a dynamic checklist that can integrate into the hospital EMR system.

Chapter 4

A dynamic checklist system platform

4.1 Introduction

In chapter 3, we have developed a meta-model of dynamic checklists so that checklist knowledge is no longer intertwined with software source code. In order to create and execute such models, there is a need for a platform that allows users to create their own dynamic checklist applications by configuring software components according to the requirements of a specific checklist and the scenario. However, developing such a platform is difficult. Such a platform has to fulfill the general requirements drawn from various dynamic checklist applications, which may differ significantly in their purpose, format, function, and layout. Moreover, the platform would need to allow healthcare organizations to develop applications by configuring software components, rather than programming directly. Some mechanisms need to be investigated and applied.

In this chapter, we aim to design and validate a platform that allows hospitals to create their own dynamic checklist applications efficiently by configuring software components. In order to reach the goal, two research questions need to be answered: (1) Which features should dynamic checklist applications provide in general? (2) Which

¹Shan Nan, Pieter Van Gorp, Hendrikus HM Korsten, Richard Vdovjak, Uzay Kaymak, Xudong Lu, and Huilong Duan. 'Tracebook: A dynamic checklist support system.' In Computer-Based Medical Systems (CBMS), 2014 IEEE 27th International Symposium on, New York, USA, pp. 48-51. IEEE, 2014.

²Shan Nan, Pieter Van Gorp, Xudong Lu*, Uzay Kaymak, Hendrikus Korsten, Richard Vdovjak, and Huilong Duan. 'Design and implementation of a platform for configuring clinical dynamic safety checklist applications.' Frontiers of Information Technology & Electronic Engineering 19, no. 7 (2018): 937-946.

mechanisms can support the realization of the above-mentioned features through configuration? We therefore propose an architecture for the platform that supports general requirements and configuration mechanisms. The platform has been validated in a number of clinical use cases in a Dutch hospital.

4.2 Related work

In existing clinical practice and studies, some techniques have been applied to support the execution of checklist related knowledge. For example, clinical pathway management systems have been accepted and applied by hospitals in recent years, and these systems can distribute treatment tasks to predefined people at specific points in time according to predefined processes [119--121]. Systems in the class of computerized provider order entry (CPOE) apply medication rules including patient age, gender, and kidney function to assist doctors in judging the rational of their medical orders [122, 123]. Clinical guidance-based decision support systems can apply complex clinical guidelines with multiple nested rules to help doctors make the best diagnosis decisions for patients based on clinical guidelines [124, 125]. In this section, we analyze information systems architecture and the execution mechanism to serve as the basis for our study.

4.2.1 Workflow execution

One key issue in the implementation of the safety checklist is how to integrate the safety checklist into the medical process, so that users can use the checklist correctly when needed. Therefore, it is necessary to design a mechanism for reminding and prompting to inform relevant personnel to check relevant items in time. This reminder mechanism needs to remind the right role at the right time based on the progress of the medical process.

In the application practice of the safety checklist, if the checklist is not used normally, the most common reason is forgetting [6]. Due to the busy medical work, medical staff are busy with the medical work itself and forget to stop for safety checks. Furthermore, by the time they think of it they have missed the opportunity to conduct a safety check. At the same time, this forgetting will affect the implementation of the safety verification process. For example, in pre-operative preparation, if the ward doctor forgets the safety check, the safety checklist will remain in his hand all the time, and the subsequent nurses will not be able to check the work because they cannot get the checklist. Therefore, based on the medical workflow description, a computerized execution technique must be provided to achieve process control and active task distribution and provide reminders and prompts to the user.

This implementation technique should have the ability to create targeted instances of the process model based on the specific conditions of each patient, enabling independent management of each patient's safety checklist and enabling personalization of the treatment process. In the execution of the process, the execution technique should have the routing capability of the task according to the order and conditions defined in the model, combined with the patient's data and the choice of the medical staff, that is, automatically select the process execution branch path that adapts to the actual situation of the patient. In order to provide targeted reminders and prompts, the ability to assign tasks based on the availability of resources (i.e., users and roles) must also be considered in the execution of the process. For the management of the process execution, it is also necessary to be able to obtain active work lists to be checked to facilitate the verification of the ongoing verification tasks and obtain the verification work execution records to facilitate the monitoring of progress.

Workflow management technology can meet the above process execution requirements. Workflow management technology is a technology that defines, executes, and manages business processes through computerized methods, and coordinates the interaction between tasks and personnel in the process [126]. The core of workflow technology focuses on separating the process organization in the business from the specific work and driving the computer system to run in an orderly manner through the business process. This technology has been widely used in the industrial field and has become an important technical basis for assisting collaborative work within and between enterprises. In recent years, workflow management technology has been clinically applied [120]. A typical case is the implementation of the auxiliary clinical pathway [127] and the implementation of clinical guidelines in the medical process [128, 129].

The Workflow Management Coalition introduced a workflow reference model (Figure 4.1 adopted from [130]) in 1995. This reference model has become the basic reference and basis for subsequent workflow technology research and system developments.

In this model, the Workflow Enactment Service is the core component of workflow execution. The component creates, manages, and manages process models through one or more distributed workflow engines to create, manage, and execute process instances. The Process Definition Tool is a tool for creating and managing process models. The workflow model created by the process definition tool is exported to a certain format (such as XPDL, BPEL, BPMN, etc. mentioned in Chapter 3) and parsed and executed by the workflow engine. In the execution of the workflow, a Work List with execution is generated. The user and the external program operate the task list through a Worklist Handler. The User Interface is the interface that the workflow management system interacts with. In addition to direct user interaction, workflow technology allows

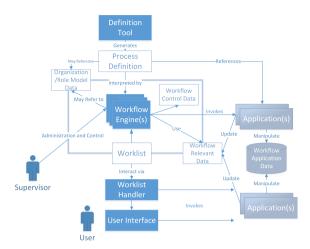


Figure 4.1: Workflow reference model.

interoperability with processes in other software or information systems. The workflow engine, worklist processor, and user can all call external information systems. These information systems can also change the execution of the workflow by changing the relevant data of the workflow execution through the corresponding interface.

The existing workflow management systems and workflow engines can meet the technical requirements of the implementation of dynamic checklist processes. However, within our clinical setting, we need to further develop the interface specification of the workflow management system according to the workflow reference model and design a set of workflows in the dynamic checklist system.

4.2.2 Clinical guideline decision support

Even if the right evidence-based medical knowledge is provided to the right user at the right time, it is still difficult for users to understand this knowledge and use it effectively in patients with busy clinical work and stress [131]. In addition, the checklist will prompt during use and ask the user to check repeatedly whether the clinical task has been completed. In the past, the user had to repeatedly search for the corresponding data in each module of the electronic medical record and read through the data to find out whether there is an abnormal situation. Such work is time-consuming and laborious, and there may be omissions and errors in the completion of the work.

Rule-based clinical guidelines decision support research provides a reference for solving this problem [122, 132]. The researchers shaped the clinical guidelines into the rules of diagnosis (if the conditions of judgment were met). These treatment rules are

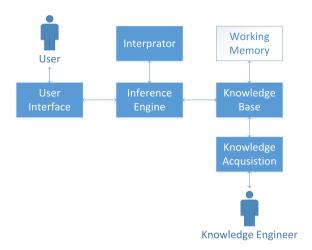


Figure 4.2: Reference model of a rule-based clinical decision support system.

enforced where an application guide is needed. When the patient's condition meets the rule's conditions, the computer system performs the corresponding action. These actions include giving reminders, automatically generating medical orders, and more. Such inference forms can also be nested to achieve complex reasoning. Such nested rules are usually expressed in the form of a flowchart, which is convenient for the user to edit and read [94]. In fact, rules expressed in the form of flowcharts are still parsed into several nested production rules when executed. Therefore, such a rule-based clinical decision system has a unified reference model (e.g. Figure 4.2) [133].

Knowledge Engineers use the Knowledge Acquisition Subsystem to formally express knowledge, abstract it into rules, and store it in the Knowledge Base. The Inference Engine combines the rules in the knowledge base with the patient data in the Working Memory to infer the corresponding results and display them via the user interface. When necessary, these clinical decision support tools also record the triggered rules, the conditions that trigger the rules, and the order in which the rules are executed, and provide such information to the user using the Explanation Facility.

Unlike workflow execution technology, clinical decision support technologies lack the constraints and coordination of organizations such as workflow management alliances. Their technologies and products lack specifications and are difficult to invoke in a uniform form. In response to this problem, De Clercq proposed in an OpenClinical seminar the standardization of clinical decision support systems (including both operations and data) such that they become more convenient to be called by other systems [134].

Rule-based execution can present an abstract description to each patient for the

patient's individualized situation. In this way, checklists can also provide verification for rare but serious clinical problems. That is, an execution platform can ensure that only relevant verification items are provided for patients with potential risks. With this approach, the checklist can be further personalized, and the medical staff can be less subject to interference from extraneous information. Rule-based clinical decision support can further provide data screening capabilities for the checklist. In this way, the filtered data related to the project can be provided at the time of checking the checklist, thereby reducing the workload of the medical staff. However, how to organize these rules, when to enforce them, which rules to enforce, how to organize the results of rule execution into a safety checklist, and its items still need elaboration.

4.3 Platform design and development

A variety of checklists have already been published and applied to clinical practice with the help of support systems in paper form or digitized form. The paper form checklists are difficult to integrate into the healthcare process, although they are easy to design and develop. Digitized checklists are integrated with healthcare information systems so that they are more convenient to use. However, to design and develop digitized checklists costs more. In the following section, we analyzed these materials as a foundation and applied these materials as the basis for our research.

4.3.1 Software architecture and design

Design criteria analysis

A number of safety checklist applications, in both paper and digitized form, have been deployed and implemented in past years. In these implementations, various features facilitating their adoption had been developed and tested. Lessons were learned from these implementations. Considerations for both the point of care and the whole care process were raised in the studies.

All of the safety checklists, ranging from the early anesthesia machine checklist [135], the central line checklist [136] to the newly developed SURPASS checklist, focus on solving specific safety problems at a certain point of care. These checklists are implemented at a specific point in the care and are presented in the form of a list of items to be checked. Clinical users claim that checking the form is time-consuming and duplicates their existing work [8]. However, making a checklist that is more specific and targeted to each patient is believed to be the key to solving the problem [35]. Several strategies can be deduced by analyzing these studies: 1) a dynamic checklist should

have the ability to prioritize items which should receive more (or less) consideration; 2) a dynamic checklist should have the ability to add/remove items specific to the patient; and 3) a dynamic checklist should be able to perform an automatic check for some items whose results can be deduced by patient data and execution logs.

In addition to reducing workload, some researchers believe that the perception of lack of direct benefit to clinical users should also be counted as a barrier to implementation [31]. If clinical users do not see the direct benefits, e.g., improving their work efficiency or preventing mistakes from happening, they are not enthusiastic about using these checklists. Therefore, some clinical researchers propose to provide patient data that relates to the check items at the point of care. A dynamic checklist should ensure that the users have access to the most relevant patient data details and the benefits evidence related to the checkable items.

Another important aspect emphasized in the implementations that have been reported is the integration of checklists into clinical processes. Forgetfulness is a major problem when using checklists in healthcare procedures [6]. Therefore, a notification and reminder mechanism should be provided to inform the users to perform timely checks. Furthermore, the reminder should be specific to a certain (group of) persons at an optimal time. Otherwise, it will very likely be ignored. Therefore, a dynamic checklist should have the ability to distribute a specific checklist to a specific role/person at the proper time based on a predefined model.

In order to achieve the aforementioned goals, a dynamic checklist should be adaptive to the actual clinical workflow. Depending on the complexity of the clinical processes and support for branching processes, synchronization is required in order to reflect the actual clinical workflow. Additionally, considering some clinical processes' complexity, certain clinical workers are not likely to have a global view of the whole care process or the participants involved. Thus, a dynamic checklist should have picture logging enabled for every participant so that participants can recognize each other.

In the next subsection, we design a dynamic checklist application platform to meet the criteria. During the design process, the hospital information system infrastructure was checked against the design criteria to test the feasibility of meeting the mentioned design criteria.

Mechanisms for supporting dynamic checklist applications

In this subsection, we design a dynamic checklist application platform to meet the criteria. During the design process, the hospital information system infrastructure was checked against the design criteria to test the feasibility of meeting the mentioned design criteria.

The requirements of arranging the order of each item, adding/removing items for specific patients, performing automatic checks, and providing filtered, related information can be fulfilled by clinical rules considering the patient-context and specific actions. The patient context can be collected from patient data which is stored in hospital information systems, including demographic information, diagnosis, examinations performed and laboratory tests, prescriptions, and so on.

Clinical rules are executed by a guideline execution engine. The guideline execution engine is typically responsible for collecting information from outside the information system and inferencing with the information in an embedded rule engine. By using the knowledge acquisition tool and interfacing with the guideline execution engine, we can configure each item in a patient-context-aware checklist.

For the requirement of integrating safety checklists with the processes, there needs to be a mechanism that could represent, execute, and monitor the processes and also interact with other applications. Workflow management is such a technology dedicated to solving this problem. In recent years, it was also used in the healthcare domain as the backbone for clinical pathway management systems and other workflow-related systems.

A Workflow Management System (WfMS) provides users with the ability to model, execute, and monitor the control flow of clinical processes and enables interoperation between the WfMS and other information systems [137, 138]. In contrast to academically driven clinical decision support systems, WfMSs are industry-driven. Therefore, a reference model was developed as a common basis for developing and deploying such a system. Typically, a workflow engine is at the core of a WfMS, and executes the predefined model created by the modeling tools. During execution, the workflow engine creates a worklist handled by the worklist handler. The worklist handler can invoke outside applications as defined.

4.3.2 The dynamic checklist application platform architecture

In Chapter 3, we introduced our dynamic checklist meta-model can be mapped to the Task Network Language (TNL) and Workflow Modeling Language. Therefore, it is possible to reuse the infrastructures of TNL-based clinical decision support systems and workflow management systems. In Figure 4.3 we demonstrate the technical architecture [130] of the general dynamic checklist application. In the architecture, we distinguish the Editor and the Runtime. The Editor facilitates the encoding of checklist-related knowledge in a way that Runtime can use it. The Editor includes a workflow editor to model the clinical

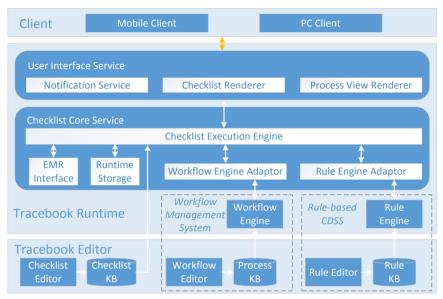


Figure 4.3: Architecture.

workflow, a rule editor to create clinical rules, and a checklist editor to edit the linkage between the clinical workflow and rules. The encoded knowledge is stored in three knowledge bases accordingly.

The system architecture can be divided into two parts: **Tracebook Editor** and **Tracebook Runtime**. The dynamic checklist editor is used to edit the model of the dynamic checklist for the execution of the checklist execution environment. The editor contains three components: **Workflow Editor**, **Rule Editor** and **Checklist Editor**, which are responsible for the editor. How the diagnosis process, medical logic, and dynamic checklist relate to the editing of the three parts of the medical process and medical logic. The three forms of knowledge are stored in the corresponding database.

The **Tracebook Runtime** is used to combine and execute instances of the dynamic checklist model in conjunction with patient data. The dynamic checklist execution environment consists of four main functional modules: **Workflow Engine**, **Rule Engine**, **Checklist Core Service** And **User Interface Service**. The workflow execution engine is used to provide workflow-related services, including the distribution of checklist and query checklist execution status (unverified, verified, verified, etc.) in the process. The rules engine is used to provide individual functions related to patient personalization, including creating patient-specific checklist items, customizing item content, screening and labeling data for attention, and performing automated checks. The Checklist Core Service is responsible for integrating and scheduling the workflow execution engine

and rules engine, in conjunction with the execution of the process, invoking the rules engine execution rules to generate a personalized dynamic checklist of patients.

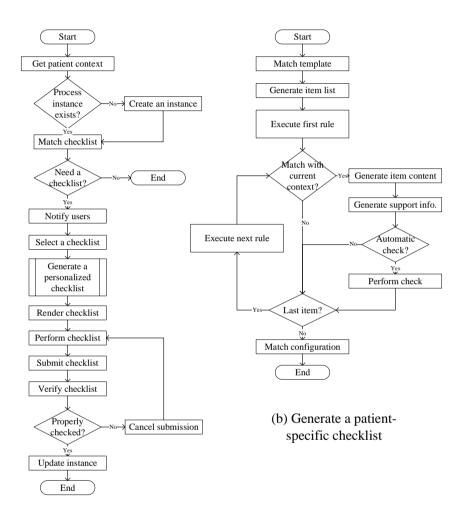
Since we aim to take advantage of the existing infrastructure of existing clinical decision support systems and workflow management systems, it would be ideal if we could directly interface to their rule engines and workflow execution engines. In order to do so, the checklist core service provides **Workflow Engine Adaptor** and **Rule Engine Adaptor** to interface with the engines. In such a way, the dynamic checklist core service can be independent of a specific engine. **EMR Interface** is used to obtain data in the EMR for the reasoning of rules and triggering of certain events in the process. **Runtime Storage** is used to persist the execution of the stored safety checklist. **Checklist Execution Engine** is the core function of the dynamic checklist core service. This module is responsible for implementing the above dynamic checklist generation method. The user interaction service visualizes the dynamic checklist generated by the checklist execution engine, and renders them into flow charts, checklist forms, and provides a reminder and prompt service.

4.3.3 Generating dynamic checklists

Correlation mechanism of workflow and rules

To dynamically generate a checklist, it is necessary to match a checklist to a specific activity in the process instance. Based on the analysis of workflow integration of clinical information systems, there are three possible situations: 1) directly interoperate with the workflow sub-system when the informations system has a workflow management component; 2) listening to the message sent by the information systems as a trigger condition; 3) using database triggers or monitor database events to trigger corresponding tasks [138]. In this subsection, we use workflow management technology and rule-based clinical decision support technology to design a dynamic checklist generation mechanism (as illustrated in Figure 4.4).

The key steps are explained as follows. Patient context information, including patient data and process data, is collected as the basis to generate a checklist. These data include the patient ID, the treatment plan being performed for the patient, and the progress of the patient's process. After obtaining the context information, it can be used to determine whether there is already an instance of the process being executed. When the corresponding process information does not exist, a new process instance is created for the patient. Otherwise the current scenario is matched with a scenario in the process model. This match is based on the currently active task list tasks in the process and related medical events in the patient data. For example, if there is a pre-operative



(a) Execution process on the dynamic checklist

Figure 4.4: The process of generating a dynamic checklist item.

verification task in the work list and it is detected that a surgical order has been issued for the patient, the task is activated.

When the task requires checklist assistance, the corresponding user is alerted to check and generate a personalized checklist for it. The process is shown in the right half of the Figure 4.4. The first step is to match a checklist template according to the activity. In the verification process, each checklist is assigned to a predefined role (such as a doctor, nurse, anesthesiologist, etc.) whose actions correspond to a set of predefined rules. Executing these rules generates a set of safety checklists. According to the parsing of the rules, a set of rules lists is generated, and the rules in the rule list are executed one by one. The rules are executed based on the acquired patient context information. When the patient context does not match the conditions in the rule, there will be no related items. When there is a match, a corresponding item and explanation are generated. When there is a corresponding auto-verification rule for the item, an automatic verification rule is executed, the check status of the item is changed, and an automatic check is performed for the item. When all the rules corresponding to the item are executed, the layout information will be set.

In order to achieve a better display effect, the method separates the content and display. This separation causes the output of the checklist to automatically change as the content of the checklist changes under the constraints of the checklist style. The contents of the checklist are expressed in the form of templates. The template contains all the clinical issues that need to be considered in the checklist to meet the complete and comprehensive requirements of the checklist. The treatment of clinical problems in the template uses the rule that the clinical problem is considered when the patient meets certain conditions, and the specific clinical problem corresponds to a specific safety checklist. Further, the items of the safety checklist may also include links to patient data, medical documents, etc., and the information is also obtained by screening the data in the medical records by executing rules. The style of the checklist is expressed in the form of a style file. This style file specifies what the page information in the checklist template should represent and the layout of the elements. The content and style are combined with a rendering tool and ultimately presented to the user.

After that, the user can perform the checklist and submit the results of the verification. After the user submits the checklist, the corresponding verification rule will be triggered to verify the consistency of the verification result with the actual patient status. When an inconsistency is found, the checklist submitted by the user is rejected and asked to reconfirm the problem found. Only when the checklist is correctly completed and submitted, the status of the process can be updated.

Integrating with Workflow Engines

The workflow engine is here to parse and execute the process model described in Chapter 3. The order in which tasks are executed is defined in the process model. These sequences include order, parallel order, and selection order. The workflow engine distributes and monitors tasks according to a predefined sequence. In the process model, each task is assigned to a predefined role, and the distribution of tasks is based on these predefined roles. In addition, with additional auxiliary information such as schedules, the workflow engine can more accurately distribute characters to a specific executor. In addition to tasks, elements such as events that interact with external systems are defined in the workflow model. The workflow engine can synchronize with other system workflows based on predefined send or receive events. The workflow engine not only provides the execution function of the process but also provides the supervision function of the process. The tasks performed at each step, the executor of the task, and the completion status are all recorded by the workflow engine. In the future, it will be further utilized.

In the current research of workflow technology, a large number of workflow engine research results and products have emerged. These workflow engines can be categorized according to the workflow models they support in the background. Such workflow models include Petri net, YAWL, BPEL, and BPMN. Through the comparison in Chapter 3, BPMN is most suitable for medical applications in these workflow models. Therefore, in this study, the BPMN-based workflow engine is selected in this study.

This study analyzes the Application Programming Interfaces (APIs) provided by common workflow engine products such as BizAgi, JBPM, and Activiti, summarizes and abstracts them, classifies them into three different types of interfaces, and wraps each interface with a unified interface. The details of these APIs are shown in the Table 4.1. Using this relationship, workflow engine adapters can be developed for a variety of different workflow engines, transforming their proprietary interfaces into the interfaces listed in the table, and providing them to the dynamic checklist core services in a unified form. An interface module in the checklist core service has been designed for this purpose. This module calls workflow engine adapter by RESTful web services. In such a way, the checklist core service and workflow engine adapter are loosely coupled. Following the API specification, new workflow engine adapters can be developed by other parties.

Table 4.1: Application programming interfaces of typical workflow management systems.

Туре	API	Description
Co-ordinating organizational	CreateInstance(processID, patientID) SetEvent(caseID, eventID)	Creating process instance base on patient ID. Trigger an event in the workflow model by an external event.
WORLIOW AND HIS WORLIOW	GetClosedTasks(caseID)	Acquire complete task list in a workflow instance.
	GetPendingTasks(caseID)	Acquire on-going task list in a workflow instance.
	SetTaskFinishSignal(caseID, taskID)	Set the statues of a task as completed.
Co-ordinating organizational workflow with resources in HIS.	AssignTask(caseID, taskID, userID)	Assign a task to a user.
	OstTool/potionation	
Co-ordinating orgainzational workflow with clinical rules.	GetTask(patientID, taskID)	Provide rule-based recommendations based on specific patient ID and rule ID.

Integrating with Rule Engines

The rules engine deals with the rule model described in Chapter 3. It parses the rule base formed by the knowledge engineer's editor and enforces these rules through dynamic binding to patient data. Specifically, each entry in the checklist can be the result of a rule. During the execution process, by judging the condition, only the corresponding entry of the checklist will appear when the condition is met. In addition, the specific content in the entry can be expressed in the form of an expression. For example, in the entry, the patient's name, abnormal value and other indicators can be directly displayed, so that the medical staff can find possible abnormalities more quickly in use. In addition to this, rules are also used to filter auxiliary information. For example, if the checklist item prompts the doctor to confirm that the patient has an abnormality in a certain test indicator, then the predefined rule here will filter out all abnormal test indicators of the patient and ignore the normal indicators, thereby reducing the workload of the medical staff and avoiding An error caused by omission. It should be noted that the anomaly indicators here can be specified and modified by the rule maker (usually a medical expert). Although some indicators have not reached the abnormal range of medical definition, they have clinical significance for patients with specific conditions, and can also be recognized as abnormal values by rules. When the rule engine performs these operations, it is completed by the caller of the rule engine providing the identification number of the specified rule and related data.

The use of the rules engine is very common both in the industrial and medical fields. Especially in clinical practice, many hospitals have begun to use a variety of rule-based clinical decision support systems. Under this premise, this approach provides the flexibility of rule engine selection. The system here encapsulates the existing rules engine so that it provides the same interface. Since the rules engine is called in a single way, only the interface of the form FireRules(ruleIDs[]) is defined here to implement the call to the rules engine. In this way, the dynamic checklist system can select the appropriate rules engine according to its specific needs in different hospitals without having to modify other parts of the system for this purpose.

Generating a checklist

The checklist model is defined in Chapter 3. In this subsection, we describe how a checklist is generated by the platform.

Generating the checklist content

The dynamic checklist is an organic combination of processes and rules. In order to achieve the purpose of integration, the engine scheduler is designed here. The engine

scheduler executes the rules at the appropriate time points of the process execution according to the relationship between the predefined process links and the rules, and can further update the process according to the results of the rule execution.

According to the workflow engine function described above, the scheduler needs to implement an interface with the workflow engine to create a workflow instance, query completed tasks, query work lists, and set task status. In addition, one needs an interface to listen for changes in the state of the workflow engine.

Due to the rules engine's interchangeability in the design, the system fully considers this factor when designing the rules engine interface. So there is only one interface to the rules engine. The interface takes the unique identifier of the rule and the unique identifier of the patient as input. The unique identifier of the rule is used to specify the set of rules that need to be used, while the patient unique identifier is used to query the clinical data for reasoning. The specific query work is completed by the data acquisition module.

According to the preset configuration, the scheduler schedules the workflow engine and the rules engine during execution. Specifically, when the workflow engine activates a new task, the scheduler receives a notification and looks up the rules that need to be invoked in the configuration based on the task name in the notification. After the scheduler invokes the rules engine, it will generate a checklist according to the task type or directly return the inference result to the scheduler. After the checklist is submitted, the dispatch engine invokes an interface with the workflow engine to notify the workflow engine that the checklist has been verified, allowing the workflow engine to continue executing the task.

Through the call to the workflow engine, the overall process execution status related to the checklist, including the execution history can be known; the individualized checklist for the current patient can be obtained by calling the rule engine. However, this information is only scattered and needs to be assembled by the checklist content generation module to generate a real checklist.

The checklist generation module is called after the user issues a request to the checklist system. This can happen either when the user wants to get and check a new checklist or when the user gets a completed checklist. In the first case, the checklist content generation module invokes the workflow engine and the rules engine to dynamically generate the checklist; in the latter case, the checklist content generation module searches the database of the dynamic checklist system for the storage record of the checklist and restructures that into a one-page read-only checklist. The snippet generated by this module is shown in Figure 4.5.

```
| Schedulation | decomposition | decompositio
```

Figure 4.5: A fragment of a checklist in XML format.

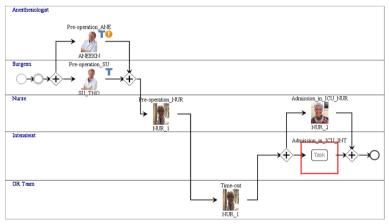


Figure 4.6: Process view.

Generating user Interface

The interaction between the dynamic checklist and the user has three meanings: providing the user with process execution information, providing the user with a checklist and providing reminders for them.

The rendering of the process information is done by matching the process description information provided in the BPMN with the execution record of the dynamic checklist. BPMN not only contains the execution information of the process, but also contains the layout of the process. Based on this typesetting information, an execution record is obtained from the workflow engine, matching the executive, and rendering the process view in the page. The rendering effect is shown in Figure 4.6.

Once the content of the checklist is generated, it needs to be rendered in order to generate a user interface that the user can understand and manipulate. The interface

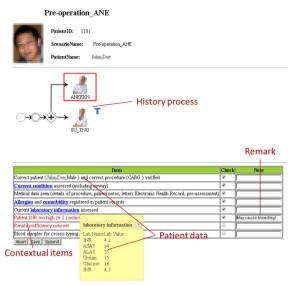


Figure 4.7: A page of checklist.

rendering module will match the results produced by the checklist content production module with the corresponding style templates in the configuration file. The matching style template will convert the content into HTML5 format, and the template comes with additional styles and manipulation tools such as style cascading tables and JavaScript. With JavaScript, you can also choose different styles of interface for devices of different resolutions and platforms to meet the requirements of checklist style flexibility. The rendering effect is shown in Figure 4.7.

The dynamic checklist system also provides a variety of reminders and reminders to prompt users to check. These reminder mechanisms include emails, text messages, and more. The example of Figure 4.8 describes an example of using an email to notify an anesthesiologist. When the process is executed to the appropriate link, the mail is sent to the relevant role. At the same time of reminding and prompting, the user is also provided with a list of checklists to be checked so that they can use the checklist to re-find the checklists to be checked if it is inconvenient to check immediately.

4.4 Results

By using the platform, we have configured various dynamic checklist applications for distinct departments and scenarios. In this section, we first chose the most illustrative application, a CABG peri-operative checklist application, to demonstrate the feasibility of

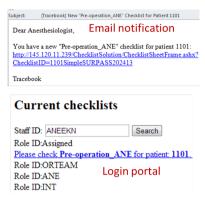


Figure 4.8: Notification.

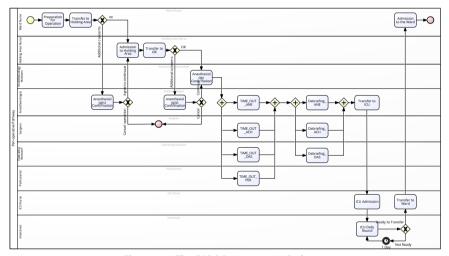


Figure 4.9: The CABG Peri-operative Pathway.

the platform. Then, we show various dynamic checklist applications we have configured with the platform.

4.4.1 Result one: it is feasible to configure a model-based dynamic checklist application to such a degree that it takes into account detailed constraints

We first modeled the peri-operative care workflow (as described in Figure 4.9) with BizAgi. Each task was assigned to a specific role.

When the operation is planned, the application starts a new CABG peri-operative

checklist process instance. Based on the predefined workflow model, it sends a notification to the corresponding person (see Figure 4.10). The application detects an abnormal situation and therefore goes to the branch where the anesthesiologist should have an additional checklist. In every step of the check, the picture log of the responsive person is automatically extended. As a result, everyone in the care path can find a picture log of who did what and the details (see Figure 4.11).



Figure 4.10: A notification in the email form.

We implement each fragment of a checklist as a guideline in Gaston (see Figure 4.12). For each checkable item in the fragment of the checklist, we implement it as a task. In each task, we define the content of the checkable item (including links to patient data) and an explanation of the item if needed. Additionally, the decision logic is used to highlight items, provide personalized items, and pre-check items for a double-check.

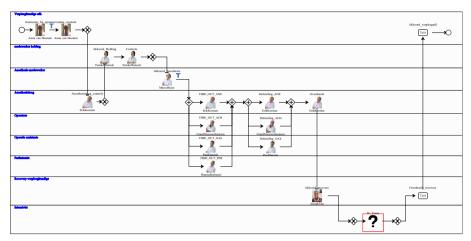


Figure 4.11: Peri-operative Care Use Case Implementation.

We take the analgesia-related items as an example. The checkable items are provided based on whether the patient was prescribed with analgesia and based on the patient's pain score. If analgesia was not prescribed, the patient's pain score should be checked. If the pain score is not evaluated either, a pre-checked checklist for double-checking will be provided to the intensivists to confirm that. Otherwise, if the pain score is less than 4, there will be no checkable item regarding analgesia for this patient, whereas if the pain score is equal to or greater than 4, a warning item mentioning that analgesia should be prescribed is provided.

The content of the ICU round checklist is in Figure 4.13. Checkable items are grouped by their target clinical problems. In such a way, the analgesia-related checkable items are fully personalized based on the patient's context.

4.4.2 Result two: the dynamic checklist application platform is generic to implement

The generic nature of the dynamic checklist application platform has been validated through the implementation and testing of various checklists, all of which have quite different natures. Furthermore, the validation consisted of letting different individuals engineer the configuration models. Up to now, a team of three engineers has implemented and tested eight dynamic checklist sets, including 242 dynamic checklists. These checklists include a bariatric surgery checklist set, a resuscitation checklist set, a breast cancer checklist set, etc., by various researchers in our collaborating hospital. These engineers are master or bachelor students who major in industrial engineering

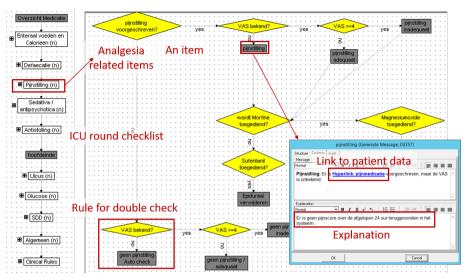


Figure 4.12: Implementation of the ICU round checklist.

and have no programming experience. The full list of these checklists can be found in Table 4.2. Most of these checklists have been validated against retrospective patient data. The ICU round checklist has been implemented in the ICU and evaluated by a simulation-based experiment, which is reported elsewhere [139].

The results show that the dynamic checklist application platform fits the requirements arising from the different types of checklists used in different clinical scenarios by different clinical roles. These checklists are developed for various scenarios, from routine jobs such as the daily rounds in the ICU to emergency jobs like resuscitation. The configuration models were based on various sources, ranging from observational studies in a Dutch hospital to Chinese clinical pathway publications. These results prove the generic nature of the proposed dynamic checklist application platform.

4.5 Discussion

The research aims to provide a platform by which developers can easily configure dynamic checklist applications for various purposes and scenarios. We formulated two aspects of our efforts while developing the platform. The first is our aim to make the platform general so that it can be used for various application scenarios. In order to do so, we conducted a literature review to understand what the design criteria were for designing dynamic checklist applications. The other aspect is to make the platform configurable. Once the platform is deployed in a clinical setting, knowledge engineers

Table 4.2: Dynamic checklist applications developed with the platform.

Name	Number of	Description
	cneck- lists	
Peri-operative checklist set	17	Used for peri-operative care for general surgery by ward doctors, nurses, anesthesiologists, and surgeons. These checklists are based on published SURPASS checklists and localized to the target hospital. Developed by an engineer under the supervision of a
:		surgery nurse practitioner.
Unstable angina care pathway checklist set	_	A set of checklists supporting the standardized diagnosis and treatment of unstable angina based on the localized unstable angina care pathway. These checklists are
		developed primarily based on observational study and interviews with cardiologists,
		nurses, and nurse practitioners. Developed by a master student under the supervision
		of two surgery nurse practitioners.
ICU daily round checklist	_	A daily round checklist in ICU with the purpose of providing essential concerns to
		the patient and gathering patient information related to the concerns. This checklist
		is based on the hospital-localized version of the FAST HUGS checklist and combined
		with clinical rules proposed by intensivists. Developed by two engineers and two
		intensivists. Tested in a simulation-based environment.
Antibiotic checklist	-	Checking the correctness of antibiotic prescriptions and raising concerns based on
		antibiotic protocols used in the hospital. This checklist is developed from protocols
		for antibiotic choices for specific diseases and dosage adjustment for specific kinds of
		patients. Developed by an intensivist.

Table 4.3: Dynamic checklist applications developed with the platform (continued).

Name Number Pescription of check- lists Resuscitation protocol checklist of A checklist for the standardized steps in advanced life support. It helps participants know each other, count the rounds, and list critical steps based on rounds. These checklists are developed based on a hospital-localized version of an advanced life support protocol. Developed by two engineers and an internist. Bariatric surgery checklist set Lung cancer surgery checklist set Seast cancer diagnosis and treat- ment pathway checklist set 15 Resuscitation protocol checklist Loved for the longitudinal care process for bariatric surgery ranging from pre-operative care to follow-up after 5 years. These checklists are developed from clinical guidelines and refined with surgeons. Developed by a bachelor student under the supervision of a gastric surgery clinical pathway published by the Ministry of Health of the People's Republic of China. Developed by a Master's student under the supervision of a surgeon. Breast cancer diagnosis and treat- ment pathway checklist set 172 A set of peri-operative checklists for lung cancer surgery based on the lung cancer surgery based on the People's Republic of China. Developed by a Master's student under the supervision of a surgeon. diagnosis, second opinion, hormone therapy, chemotherapy chebulking surgery, and their combinations. These checklists are developed based on guidelines, observational studies, and interviews with all stakeholders involved in the process. Developed by a post-master researcher.			
of check-lists suscitation protocol checklist 6 iatric surgery checklist set 23 ig cancer surgery checklist set 15 ing cancer diagnosis and treat-172 int pathway checklist set 172	Name	Number	Description
iatric surgery checklist set 23 ig cancer surgery checklist set 15 ig cancer fliagnosis and treat-172 int pathway checklist set		of check- lists	
iatric surgery checklist set 23 ng cancer surgery checklist set 15 nst cancer diagnosis and treat- 172 nt pathway checklist set	Resuscitation protocol checklist	6	A checklist for the standardized steps in advanced life support. It helps participants
et 23 ist set 15	set		know each other, count the rounds, and list critical steps based on rounds. These
et 23 ist set 15 d treat- 172			checklists are developed based on a hospital-localized version of an advanced life support protocol. Developed by two engineers and an internist.
ist set 15 d treat- 172	Bariatric surgery checklist set	23	Used for the longitudinal care process for bariatric surgery ranging from pre-operative
ist set 15			care to follow-up after 5 years. These checklists are developed from clinical guidelines
ist set 15			and refined with surgeons. Developed by a bachelor student under the supervision of
ist set 15			a gastric surgeon.
d treat- 172	Lung cancer surgery checklist set	15	A set of peri-operative checklists for lung cancer surgery based on the lung cancer
d treat- 172			surgery clinical pathway published by the Ministry of Health of the People's Republic
d treat- 172			of China. Developed by a Master's student under the supervision of a surgeon.
	Breast cancer diagnosis and treat-	172	A group of checklists for the comprehensive process of breast cancer from screening, to
diagnosis, second opinion, hormone therapy, chemotherapy, debulking surgery, and their combinations. These checklists are developed based on guidelines, observationa studies, and interviews with all stakeholders involved in the process. Developed by a post-master researcher.	ment pathway checklist set		diagnosis and treatment. The process is divided into 12 processes including screening,
their combinations. These checklists are developed based on guidelines, observationa studies, and interviews with all stakeholders involved in the process. Developed by a post-master researcher.			diagnosis, second opinion, hormone therapy, chemotherapy, debulking surgery, and
studies, and interviews with all stakeholders involved in the process. Developed by a post-master researcher.			their combinations. These checklists are developed based on guidelines, observational
post-master researcher.			studies, and interviews with all stakeholders involved in the process. Developed by a
			post-master researcher.

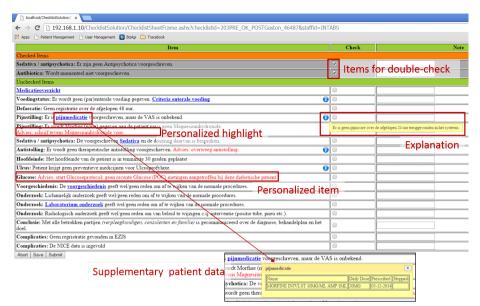


Figure 4.13: ICU Daily Round Checklist

and trained clinical experts who have little knowledge of programming could configure various applications by themselves. This is particularly helpful considering the growing demand for dynamic checklists. To meet this requirement, we made the platform model-based, such that everything else besides the models constitutes infrastructure that developers can reuse. Additionally, the workflow engine and rule engine used in the platform can also be reused from existing hospital information systems. This would not only reduce the cost of software development and training but also enables reuse of clinical pathways and clinical rules that have already been modeled in existing systems.

By using this platform, dynamic checklist applications have been developed and tested in both a Dutch hospital and a Chinese hospital. An ICU round checklist has been tested in Catharina Hospital in Eindhoven, the Netherlands [139]. Intensivists have used the checklist checking patients' general condition and medication usage in the morning round. A simulation-based experiment reveals this application increases adherence to best practice guidelines from 73.6% to 100%, and reduces inappropriate prescription from 80% to 3.6%. Users of the application reported high acceptance (4.13 out of 5). In China, a PCI peri-operative checklist has been implemented in PLAGH [140]. Cardiologists have used this application on a daily basis. Users' feedback shows it can help improve their work efficiency and discover patient abnormalities more effectively.

4.5.1 Advantages of the dynamic generative approach

How to integrate medical logic applications into the diagnosis and treatment workflow is a long-standing problem in the field of medical informatics. Due to the difficulty of this integration, many powerful and well-designed clinical decision support systems have failed to play their due role in the clinic. Previous studies of clinical decision support systems have attempted to solve this problem by relying solely on the improvement of the expression of medical logic, that is, using a more comprehensive knowledge representation mechanism to express business processes and logic processes together. This method has a long development cycle and a narrow application. The method proposed in this chapter separates the concerns in the process, disassembles the diagnosis process into business processes and logic processes, and uses different systems to express and execute them so that the corresponding medical logic can focus on its own purpose.

4.5.2 Comparison between developing a new system and reusing existing systems

The design approach presented in this chapter allows both the invocation of existing information systems and the development of a complete system. In the two case studies in Europe and Asia, these two methods were practiced according to the actual needs. Integrating other systems has the advantage of cost, efficiency and reliability for the hospital information department to develop on its own. Independent development is suitable for information system manufacturers to develop products.

4.5.3 Granularity and flexibility of the modeling style

Sitting et al. [141] presented 10 challenges in the research and application of clinical decision support systems. Among them, how to integrate reminders into the workflow of the diagnosis and treatment has always been a problem in the implementation of CDSS. To this end, researchers have added event mechanisms for the Guide Modeling Language, or adapted the information system to invoke CDSS, or use database triggers actively. However, these methods add to the complexity of the CDSS and do not tell the CDSS workflow information. The method proposed in this chapter also has implications for this issue.

This study also has certain limitations. The medical process is flexible and changeable. As the patient develops the disease, the diagnosis and treatment process will often be adjusted accordingly, such as additional examinations and consultations. These

emergencies are expressed using the currently used procedural process model, which is cumbersome and difficult to maintain. Therefore, the method used in this study is currently applicable to processes where the process is relatively fixed and there is not much variation. For such flexible and versatile processes, the academic community has adopted descriptive methods such as Case Handling. Correspondingly, the industry has also developed equivalent expression languages and corresponding support tools. As these studies deepen and mature, this problem can be solved by replacing the workflow engine in this study.

4.5.4 Opportunities for improving communication / messaging

Limitations concerning usability are identified in our research. We have currently implemented email as a reminder mechanism in the hospital because of our limited access to the hospital IT infrastructure. However, in daily practice, clinicians are too busy with their work, and email may not be the most efficient notification method. However, we argue that our architecture supports general messaging APIs and so we can shift to other reminder methods very easily once we have access to more IT resources.

4.6 Chapter Summary

In this chapter, we discuss the scalability issues of state-of-the-art dynamic checklist applications and present a novel solution that overcomes those issues via configurable models. Although checklists have already shown their unique power in promoting patient safety by providing users with a clear view of critical tasks and helping with multidisciplinary communication, overly rigid implementations have still hindered the effective and systematic use of these promising checklists. While dynamic checklist applications have been emerging, the cost of developing dedicated applications is too high when handling checklists for more than a handful of clinical domains. We have demonstrated that the use of a model-based approach does not lead to compromises regarding the dynamics or level of detail. We have also demonstrated that a model-based approach enabled us to keep the infrastructure stable while expanding the number of models on top of it. In particular, we have covered one case in depth to demonstrate the support for detail while we discussed eight other comprehensive checklist sets as proof of the generic nature of the system. In conclusion, both the feasibility and the overall generic nature of the platform were demonstrated.

Subsequent chapters will focus on using the platform to validate various applications in larger-scale clinical studies. Such studies no longer focus on the feasibility and generic nature of the platform but rather on the quality of specific configuration models.

Additionally, technical foundations will be strengthened to enable safe and reliable dynamic checklist applications across hospital boundaries. In order to improve the usability of the applications configured by the platform, in our future work, we will evaluate the pros and cons of aligning the messaging schedule with working schedules. We are working on building dynamic checklist models step by step, so we do not yet claim that the system framework overcomes the barriers to checklist adoption for all domains today. However, we are working on the sharing of dynamic checklist models, such that they can be used as online supplements to enriched medical publications. This requires separating the checklist configuration models from the underlying infrastructure.

Chapter 5

An ICU round dynamic checklist to prevent errors

5.1 Introduction

As described in Chapter 1, two kinds of checklists exist: read-do and do-confirm. In Chapter 2 and Chapter 3, we demonstrate how these two types of checklists are implemented in a dynamic checklist format and evaluated in clinical trials.

This chapter reports the development, implementation, and evaluation of a dynamic checklist for the ICU daily round. During this daily round, the intensivists need to review the condition and medical history of each patient. Various sources of information are studied for each patient, such as medical history, co-morbidities, clinical observations, laboratory test results, radiology reports, microbiology results, and respiratory parameters. Although intensivists are well-trained and familiar with the procedures, human errors still occur due to the complexity of the patients and information overload.

The FAST HUG checklist and its mnemonics are widely used in ICU to support the daily round. The checklist provides a short-term memory aid for intensivists during the rounds. Intensivists read the checklist and go through each item to make sure no critical issue of the patient is missed. The checklist is usually implemented in paper format and

¹ A. J. R. De Bie, Shan Nan, L. R. E. Vermeulen, P. M. E. Van Gorp, R. A. Bouwman, A. J. G. H. Bindels, and H. H. M. Korsten. 'Intelligent dynamic clinical checklists improved checklist compliance in the intensive care unit.' BJA: British Journal of Anaesthesia, 2017, 119(2): 231-238.

 $^{^2}$ The above publication was accompanied by an Editorial in the British Journal of Anaesthesia, see Appendix A.

available at the bedside of each patient. However, this checklist is not well accepted and applied because contextual information, which makes it easier to complete the checklist, is not provided, and inclusion or exclusion of items based on the characteristics of a particular patient or caregiver is not possible.

In this chapter, we use the modeling techniques reported in Chapter 3 and the execution platform reported in Chapter 4 to create a dynamic checklist for ICU round and validated the effectiveness by a clinical experiment.

5.2 Dynamic checklist design and development

5.2.1 Modeling the content of the dynamic checklist

Background

The combination of stress, fatigue, and complex critically ill patients makes medical errors relatively common in the ICU setting [142]. One study reported an average of 149.7 serious errors and 80.5 adverse events per 1000 patient days in the ICU of a university hospital. Of these adverse events, 45% were estimated to be preventable. Although multiple guidelines and/or protocols have been published on "best practice" in the ICU, these have not been optimally used, as there is often a discrepancy between published guidelines and clinical practice. Another study showed that only 56% of ICU patients received care that was recognized as compliant with the best practice eligible for them. Therefore, there is a need to implement an intervention to standardize the process of care in the ICU settings [143].

Rounds at the bedside are important and part of routine clinical care. A number of studies have indicated that daily rounds at the bedside by intensivists may result in better outcomes.

Sources of medical knowledge

The current Local Standard of Care (LSC) during an ICU ward round is a paper checklist that is available at the bedside to be used at the care-giver's convenience. This paper checklist is based on the FAST HUG mnemonic [29, 58], and since its introduction to the ICU, intensivists have optimized this checklist by adding extra items (Figure 5.1).

For more than a decade, the Catharina Hospital Eindhoven has also been using the Clinical Decision Support System (CDSS) Gaston to improve guideline compliance regarding medication. This CDSS is connected to the EHR and checks predetermined pharmacological clinical rules for the ICU. If these clinical rules are violated, the CDSS

		ziekenhuis
		Department IC – Checklist IC rounds
		Department to - Checklist to rounds
		Date:/
	Add Patient sticker	
F	Enteral feeding possible?	
	Calories sufficient?	
	Recent defecation?	
Α	Suitable pain relief?	
_	Can / Should dose be adjusted	` ,
S	Sedatives and / or antipsycho	•
_	Adjust dose? (RASS or CAM	
D T	Pressure Ulcer present? Prop	
•	Indication for therapeutic antic Reason for bridging?	oagulant?
	Adequate thrombosis prophyla	axis?
н	Headboard is at least 30 degre	
	Indication for protective ventila	
U	Ulcer prophylaxis?	
G	Glucose protocol?	
S	SDD protocol? (selective intes	stinal decontamination)
Line	e	
	ace?	
S	ince?	
	biotics	
	nce? eason? (Cultivate?)	
	eason? (Cultivate?)	
	top date?	
	r history	
		ns to deviate from the normal procedures?
	sical examination	om the physical examination that require policy change?
	pratory examination	on the physical examination that require policy change:
	re there laboratory results that re	equire a change of policy?
	ological examination	
		ation results a change of policy or intervention (position
	be, pneumatic, etc.)?	
	orking diagnosis?	
	oal formulated?	
		parties (nurses, consultants, family)?
	plications	
	cored in EHR? ICE data completed?	
11	ion data completed:	

Figure 5.1: Paper-based FAST HUG checklist.

produces alerts. An example of such a violation could be a patient in the ICU receiving non-steroidal anti-inflammatory drugs without gastric protection. Once a day, after the ICU ward rounds, a list of all the alerts is generated and evaluated by a hospital pharmacist, who then contacts the physician on duty by telephone to discuss the recommendations [144, 145]. This physician decides whether a recommendation should lead to an intervention or not.

The following pharmacological clinical rules are checked using Gaston:

- The system checks if methotrexate and folic acid are administered; If so, it will
 provide a checkable item to check if the dosage is correct and if folic acid is
 co-administered.
- The system checks if nefrotoxic medication is administered in case of kidney dysfunction; If so, it will provide a checkable item to check whether medication is nefrotoxic or if the dosage needs to be changed.
- The system checks if laxatives are started simultaneously with the administered opiates; If not, it will provide a checkable item to start laxatives provided there are no contraindications.
- The system checks if aminoglycosides are administered; If so, it will provide a checkable item to check if aminoglycosides levels are monitored and if the dosage is correct.
- The system checks if there is a hyper- or hypokalium and if so it checks if there is any medication responsible for it. If so, it will provide a checkable item to check potassium levels and medication.
- The system checks if there is a hyper- or hyponatrium and if so it checks if there is any medication responsible for it. If so, it will provide a checkable item to check natrium levels and medication.
- The system checks if there is a hyper- or hypocalcemia and if so it checks if there is any medication responsible for it. If so, it will provide a checkable item to check calcium levels and change medication.
- The system checks if the patient receives NSAIDs and whether stress ulcer profylaxis
 is started. If not so, it will provide a checkable item to start stress ulcer prophylaxis
 and to check whether NSAID administration can be discontinued.
- The system checks if the patient with heart failure gets medication that is contraindicated. If so, it will provide a checkable item to check if this medication is necessary and to evaluate if it can be stopped.
- The system checks if the INR is greater than 6. If so, it will provide a checkable item to suggest to start Vitamin K.

- The system checks if lithium is prescribed and if blood levels of lithium are known and acceptable. If so, it will provide a checkable item to suggest checking the blood levels of lithium or if the dosage needs to be modified.
- The system checks if digoxin is prescribed and if blood levels of digoxin are known and acceptable. If so, it will provide a checkable item to suggest checking the blood levels of digoxin or if the dosage of digoxin needs to be modified.
- The system checks if clozapine is prescribed for the patient and if blood levels
 of clozapine are known and acceptable. If so, it will provide a checkable item to
 suggest checking the blood levels of clozapine or if the dosage of clozapine needs
 to be modified.
- The system checks if phenytoin is prescribed for the patient and if blood levels
 of phenytoin are known and acceptable. If so, it will provide a checkable item
 to suggest checking the blood levels of phenytoin or if the dosage of phenytoin
 needs to be modified.
- The system checks if enteral feeding and levothyroxine are given at the same time. If so, it will provide a checkable item to suggest skip one bolus of enteral feeding or pause enteral feeding for half an hour if given continuously.
- The system checks if dalteparin dosage > 5000IE/day if the patient is > 80kg. If not so, it will provide a checkable item to start daltaparin 5000IE/day.
- The system checks if the patient gets daltaparin and whether the INR is two consecutive times > 2.2. If so, it will provide a checkable item to suggest pausing the dalteparin.
- The system checks if the patient gets amiodaron 1200mg/24hr >3 days. If so, it
 will provide a checkable item to suggest to correct the dosage to 600mg/24hr or
 start oral amiodaron.
- The system checks if vancomycin is prescribed for the patient and if blood levels
 of vancomycin are known and acceptable. If so, it will provide a checkable item to
 suggest checking the blood levels of vancomycin or if the dosage of vancomycin
 needs to be modified.
- The system checks if amikacin is prescribed for the patient and if blood levels
 of amikacin are known and acceptable. If so, it will provide a checkable item to
 suggest checking the blood levels of amikacin or if the dosage of amikacin needs
 to be modified.
- The system checks if selective oral decontamination is prescribed for patient admitted on the IC > 48 hours. If not so, it will provide a checkable item to suggest starting selective oral decontamination.

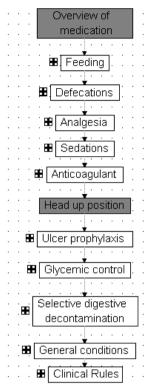


Figure 5.2: ICU Round Checklist.

- The system checks if the patient has an enteral tube and if the prescribed medication is eligible to be given through the enteral tube. If not so, it will provide a checkable item to suggest to change the ineligible medication to medication that can be given intravenously or via the enteral tube.
- The system checks if a venous or arterial line is in situ > 7 days. If so, it will provide
 a checkable item to consider change the line or evaluate if the line is still needed.

Checklist items design

According to the paper checklist and medication rules, the dynamic ICU round checklist is broken down into 12 clinical problems, i.e., medication overview, feeding, defecation, analgesia, sedation, anti-coagulation, head-up position, ulcer prophylaxis, glycemic control, selective digestive decontamination, general conditions, and alerts from other information systems (Figure 5.2).

Each clinical problem is represented as a flowchart (as shown in Figure 5.3). Gaston's

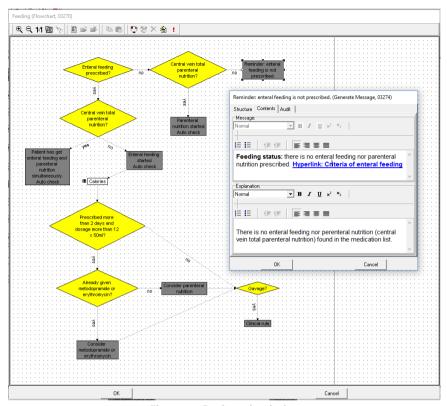


Figure 5.3: Feeding related rules.

flowchart allows nesting mechanisms so that complex flowcharts can be expressed in several sub flowcharts.

Here we take feeding as an example to illustrate the structure of a rule. The rule first uses a decision primitive to determine if enteral feeding or parenteral feeding is prescribed. If not, the doctor is informed that the appropriate method should be given and the doctor is required to confirm. If parenteral nutrition is detected, a reminder for confirming parenteral feeding is given and automatically checked by the intensivist. The rule also calculates whether sufficient calories are given. When the intake amount is insufficient, it will remind the intensivist of how many calories should be given in the checkable item. Further, the rule also checks the duration of the use of enteral feeding. If the nutritious need can not be reached by enteral feeding for more than two days, the intensivist is advised to consider switching to parenteral feeding.

Each checkable item contains "Description", "Explanation", and "Option". This information is expressed in XML format. Among them, "Description" and "Explanation"

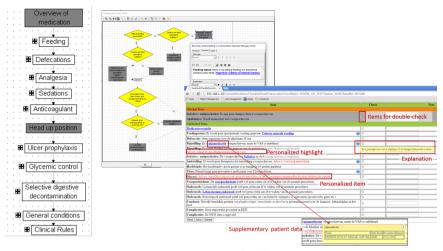


Figure 5.4: Design a checklist item.

support the expression of HTML format, which improves the readability of the item. By using the HTML format, critical information can be highlighted, providing links to relevant literature knowledge and patient data. An example is shown in Figure 5.4.

5.2.2 System implementation

The intervention was based on the use of Tracebook that generates a dedicated checklist for each individual patient. To do this, the systems of Tracebook and Gaston both use a rule engine containing a model of algorithms, comparable with a decision tree, with general clinical rules and pharmacological rules that are both specifically applicable to the ICU. First, Gaston gathers the relevant information about the patient from different medical information systems, such as patient monitors, the EHR, the pharmaceutical prescription system, and others. Then Gaston and Tracebook run the rule engines containing the clinical and pharmaceutical rules with their algorithms, and Tracebook determines which rules are relevant for a specific patient in a specific context and should become a checkable item for that particular patient. Some of these items can be checked automatically, depending on the available information, the algorithm of the rules, and whether the professionals' local consensus decided that a rule may be checked automatically. This last condition also implies that professionals can decide that some rules should not be checked automatically.

The model for Tracebook for the ICU ward round is based on the combination of our local paper checklist, which is also available during the control group, and the pharmacological rules that are specifically applicable for our ICU and generated by Gaston.

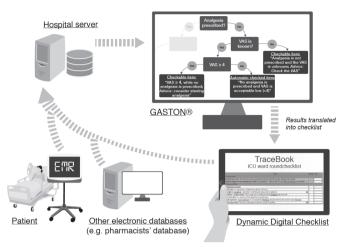


Figure 5.5: A schematic overview of how Tracebook is composed.

Figure 5.5 provides a schematic overview of how a dynamic checklist is composed, showing a small part of the algorithm for prescribing analgesia based on the pain rating scale because this comprehensively illustrates how the clinical rules work and how they generate checkable or automatically checkable items in Tracebook. Figure 5.5 also demonstrates a part of Tracebook where Tracebook can highlight text for extra attention and provide the user with data from the EHR and guidelines on request.

The whole system was designed to create or modify the rules in the model easily. No rules were adjusted, added, or removed during the simulation procedure. The number of items and critical items that were relevant and needed to be checked per scenario is described in Table 1. In addition, Table 1 shows the number of these relevant checkable items that can be checked automatically by Tracebook.

5.3 Clinical study design

5.3.1 Scenario development

We created six patient scenarios based on data of patients that had been admitted to the ICU and deliberately implemented some flaws (see Table 5.1 and Table 5.2). The patients were virtually admitted in the EHR-test environment (CS-EZIS test, Chipsoft BV, Amsterdam).

Based on the international guidelines, the current paper checklist and local expert

Table 5.1.1	aticiit	Dasic	condit	.10113.		
Scenario	1	2	3	4	5	6
Gender	F	М	М	М	F	F
Age	62	66	61	74	68	42
APACHE-II	19	26	18	11	32	26
Mechanical ventilation	Υ	Υ	Υ	Ν	Ν	Υ
Sedation	Υ	Υ	Υ	Ν	Ν	Υ
CVL	Υ	Υ	Υ	Υ	Υ	Υ

Table 5.1: Patient basic conditions

opinion, the highest achievable score for each scenario was established containing all the items that should be checked by the participant during each ward round. Medical issues requiring a direct intervention were called critical items. The scenarios with their corresponding highest achievable score were reviewed and approved by two intensivists of the research team, who could not participate in the trial.

5.3.2 Study participants

Clinicians were eligible to participate if they had ward round experience in the ICU for at least one month between January 2013 and November 2014. Participants could be intensivists, nurse practitioners of the ICU, residents or final year medical students following an ICU internship. Eligible participants were invited to participate and participation was voluntary. Participants gave verbal and written consent to use the collected data for publication.

5.3.3 Simulation procedure

Participants were randomly assigned into two groups for a cross-over design. Group one performed scenarios one to three by the local standard of care, followed by a tutorial about the Tracebook and then they completed scenarios four to six with the Tracebook available. Group two performed scenarios four to six by the local standard of care, followed by the same tutorial and then accomplishing scenarios one to three with the Tracebook available.

As in daily routine, the principal investigator presented to each participant the clinical history of each simulated scenario, including medical history, physical examination, diagnostic tests and the conclusion with the plan for the day. After presenting, the participant had the opportunity to agree with the proposed plan or adjust it as he preferred. During this time the participant could choose to use the paper checklist or the Tracebook, depending on which one was available in the scenario. The scenario only

Table 5.2: Patient disease features.

ICU days Items Critical Automated	3	8	4	8	4	2
Critical	14	11	6	2	13	11
ltems	31	30	29	23	59	27
ICU days	-	3	2	-	æ	-
Features	Pneumonia and sepsis.	Out of hospital cardiac arrest, after therapeutic hypothermia.	CABG and MVA, complicated by cardiac stunning.	CABG and atrial valve replacement, uncomplicated.	High output stoma with hypokalemia after chemotherapy.	Subarachnoid bleeding, complicated by status epilepticus.

ended when the participant declared that he finished the scenario. After all scenarios the participant completed a survey, containing questions on usability, training and support, behavior change, usefulness and user satisfaction on a 5-point Likert scale (with 1 totally disagree, 2 disagree, 3 neutral, 4 agree, and 5 totally agree). Participants were also asked to rate their satisfaction of the Tracebook on a scale from one to five, where a higher score indicates better satisfaction.

5.3.4 Data collection and analyses

All scenarios were observed by one observer and recorded on video. The observer was sitting out of sight of the participants and noted which items were checked. Items could be checked vocally or in writing and interventions were documented. The principal investigator reviewed all video records to double-check which items had been checked.

The primary outcomes were the satisfaction rate of the Tracebook and the percentages of checked items and unchecked critical items during the scenarios. The secondary outcomes were the required time from the end of case presentation until the end of the scenario and the percentage of scenarios needing a phone call by the pharmacist based on violated pharmacological clinical rules.

Statistical analyses were performed with SPSS version 21 (IBM Corp. Armonk, NY, USA). The distribution of continuous variables was assessed with Kolmogorov-Smirnov tests. The chi-square test and independent-samples t-test were used if data was parametric, while the Mann-Whitney U test was used for non-parametric data. A two-sided p-value less than 0.05 was considered statistically significant.

5.4 Study results

5.4.1 Participants and scenarios

Twenty clinicians consented to participate in this study: three intensivists, fifteen residents, one nurse practitioner and one final year medical student. The difference of experience in weeks between group one (median = 20, interquartile range (IQ) = 16 to 52) and group two (median = 54, IQ = 16 to 200) was not significant (p = 0.23). In total, the participants completed 116 scenarios. Two participants could not fulfill all six scenarios due to work-related issues and performed four scenarios. In one participant the Tracebook was forgotten, and therefore this simulated scenario was counted as a ward round performed with the local standard of care.

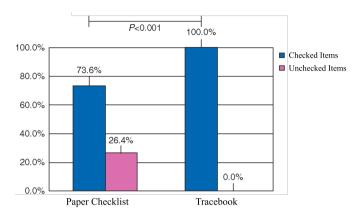


Figure 5.6: Median percentages of checked items overall.

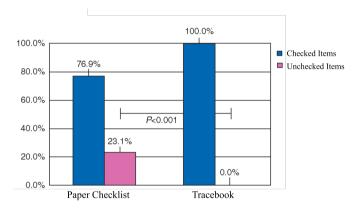


Figure 5.7: Median percentages of unchecked critical items.

5.4.2 Outcomes

Figure 5.6 and Figure 5.7 illustrate the comparison of the scenarios performed by paper-based checklist with the scenarios accomplished with Tracebook, showing an increase of the median percentage of checked items from, respectively, 73.6% (IQ = 64.5-79.3) to 100% (IQ=100.0-100.0) (p<0.001 with z=-7.74), while a decrease was observed of the median percentage of unchecked critical items from, respectively, 23.1% (IQ = 9.0-40.0) to 0.0% (IQ = 0.0-0.0) (p<0.001 with z = 9.61).

Based on CDSS alerts after the ward round, the pharmacist had to call after 80.0% of the scenarios performed by the local standard of care, compared to 3.6% (p<0.001) in the scenarios with the Tracebook available (Figure 5.8).

The time from the end of case presentation until the end of the scenario was lower

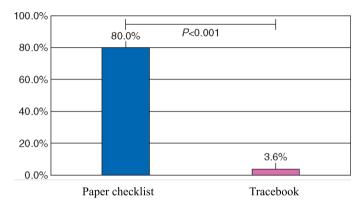


Figure 5.8: Median percentage of scenarios requiring a pharmacist's call after the scenario.

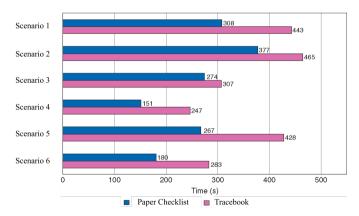


Figure 5.9: The median time (in seconds) between the end of scenario presentation until the end of the scenario for each of the six scenarios.

for the scenarios performed by paper-based checklist compared to scenarios completed with the Tracebook (264 seconds (SD:135) versus 364 seconds (SD 125)(p¡0.001, 95% confidence interval, -150 to -51). In two of the scenarios there was no significant difference perceived (Figure 5.9).

The mean satisfaction score of the Tracebook was 4.13 out of 5 (95% confidence interval of 3.91 to 4.34). All participants agreed with the statement that there is a potential for intelligent Tracebooks in medical care.

5.5 Discussion

In this prospective simulation-based study we observed that the compliance to the best practice during ICU ward rounds improved if a dynamic checklist (Tracebook) was used. The percentage of checked items and unchecked critical items improved. This leads to a significant reduction of phone calls by the pharmacist after the ward rounds. Although the time to complete the scenarios with Tracebook was higher in four out of the six scenarios, the satisfaction score was high.

To compare our results with the results of other studies is difficult since the intelligent Tracebook is a new sophisticated form of the checklist. Therefore, research on this kind of checklist is not available, while research on digital checklists overall is limited. Considering only the scenarios with a paper checklist, we found a similar percentage of checked items as in other studies.

Thongprayoon et al. [35] showed that if a digital checklist was used during ICU ward rounds, the percentage of unchecked items decreased from 14.9% to 8.8%. In our study, an even larger reduction was established, which may be explained by the dynamic design of the Tracebook with features like items being checked automatically and providing valuable information to complete the checklist easier. However, this comparison between both studies should be considered with care, as the content of both checklists differs.

Our observation of a significantly longer time needed to complete ward rounds with dynamic checklists is consistent with the results of other studies, of which only one study showed no difference of time [35, 146, 147]. However, the extra time required was never more than 3 miniutes. Besides, this longer duration can be explained by the increased number of detected errors that were resolved. In the long run, this will probably prevent complications and errors, which commonly require more time of care-givers. This hypothesis is supported by the fact that the use of Tracebook significantly reduced the number of CDSS alerts, which would have required the hospital pharmacist to recommend interventions after the ward rounds.

The detected high satisfaction score of Tracebook is supported by studies reporting improved checklist usefulness, workload and integration in workflow if a digital instead of the paper checklist was used. However, evidence on differences of user satisfaction rates between both forms of checklists is lacking [33, 35].

Based on the results of this study, we consider that the intelligent Tracebook can achieve a high satisfaction rate of checklists by care-givers and could therefore challenge the practical downsides of current static checklists that may be responsible for low checklist compliance. This is important since there seems to be a direct relationship between the compliance of checklists and reduction in adverse events [148].

A likely explanation for the high satisfaction rate of Tracebook could be the direct sense of benefit by the user, since Tracebook acts as a cognitive aid and helps the user to complete the checklist. This ensures that Tracebook becomes a helpful tool for clinicians, instead of being a mandatory, workload increasing goal with only beneficial effects outside of the users' scope.

Another advantage of Tracebooks, designed by the Tracebook system, is that the clinical rules can easily be updated or modified overcoming the concern of current static checklists being too slow to adapt to improvements in medical practice.

The most important limitation of our study is inherent to the simulation-based study design. Although the testing environment was an actual room of the ICU with a mannequin and EMR available, common distractions on an ICU were missing because the lack of real patient, nursing staff or family available for the participant to gather information from. A mannequin was used since the added value of a real patient is doubtful, because, in our opinion, a constant performance as a realistic intensive care patient is difficult and could provide too much variation in performance or distract the participants from the interventions that needed to be investigated.

Furthermore, all scenarios were new for the participants, while normally the physicians are more or less aware of the patient's conditions before starting their ward rounds. Moreover, all the scenarios were presented, as objectively as possible, by the same principal investigator, who was involved in the development of the Tracebook. These impacts on the participants' performance have not been evaluated during our study and it is possible that participants tried to please the investigator while completing the surveys. Nonetheless, in highly reliable organizations, that use checklists simulation is indispensable for testing and revising checklists. Simulation is therefore also accepted in medicine as a method for evaluating the effectiveness of new clinical tools. Tracebook is also a novel computer-based tool and the impact of these features on the results of this study remains unclear. As two final possibly limitations, our findings only evaluate the compliance during one ICU ward round of one patient and only the satisfaction

score of Tracebook, not the local standard of care. Therefore, no conclusions can be drawn on the long term compliance and satisfaction, nor on the comparison of the satisfaction score of Tracebook with the use of paper checklists.

More research is needed in a real-world clinical setting over a longer period of time to investigate the long term compliance and satisfaction rate of the Tracebook. In addition, it would be interesting to evaluate how different Tracebooks in clinical pathways for different types of medical staff can improve the traceability of medical processes, accountability of medical staff and safety of medical care.

5.6 Chapter summary

This chapter describes the design and constructs of dynamic checklist (Tracebook) for intensivists who are burdened with heavy workload. The medical procedures required for ward rounds are expressed in the form of a safety checklist, combined with patient data, a patient-specific safety checklist is constructed, and a dynamic checklist system is configured.

The checklist was clinically evaluated based on a simulated patient-based clinical trial protocol in the ICU ward of a Dutch regional hospital. The results of the assessment show that compared to the paper checklist, the dynamic checklist can significantly improve the doctor's compliance with clinical best practices during the ICU rounds, significantly reducing the doctor's medication errors, and the doctor's acceptance of the dynamic checklist is high, thus proving the effectiveness of the method.

Chapter 6

A Percutaneous Coronary Intervention (PCI) pre-operative dynamic checklist to detect and correct errors

6.1 Introduction

There are two types of checklists, the read-do checklist the do-confirm checklist. While the read-do checklist requires its users to read through the items and strictly follow them, the do-confirm checklist is designed for its users to verify if the defined activities have already been completed [30]. In Chapter 5, we have reported a read-do checklist for preventing medical errors. In this chapter, we report a do-confirm dynamic checklist for detecting and correcting errors.

Medical error is the third leading cause of death in recent decades [2]. It causes 575000 adverse events [149], and leads to 180000-400000 death in the US each year [150]. Among these errors, 78% are due to lack of information or knowledge and forgetfulness and therefore be considered as avoidable [151]. Efforts such as pay-for-performance and clinical pathways have been implemented to prevent medical errors for many years [152, 153]. Information technology has also been used in the form of

¹ Shan Nan, Qiang Xu, Sicui Zhang, Yuqi Liu, Yudai Chen, Hendrikus Korsten, Ashley De Bie, Xudong Lu, and Huilong Duan. 'Why is a dynamic checklist better than a paper checklist?' submitted to BMJ Quality and Safety

CDSS and CPOE [123, 154]. Despite all these efforts, medical errors are far from being eliminated [155].

It is impractical to stop humans from making mistakes or violating policies. Instead, the processes and technologies must be designed and implemented properly to fit the real-world need of caregivers [15]. Many high-risk clinical processes (e.g., operations) have introduced an extra step, which is called a time-out, for error detection and correction [38]. The time-out is a moment before starting a procedure that requires caregivers to review the available data, what has been done, and what are critical decisions or procedures before starting the case. By doing so, omission and commission errors can be detected and managed so that adverse consequences can be prevented or mitigated [156].

During the time-out procedure, a checklist is considered to be an essential tool for helping to remind the important tasks and promote communication [5]. Computerized checklists are developed and implemented in order to reduce the workload by providing automation and integration with the EMR to the workflow [31, 32]. Comparing with the paper checklist, the computerized checklist performs better in terms of acceptance and adherence [34, 139].

Despite the fact that the use of a checklist is associated with a positive impact, it is argued that the role of the checklist in the improvement is overrated [42, 44]. Strict management, additional training, and learning effect during the checklist implementation might contribute to the improvement as well and perhaps even more significantly. Moreover, it is unclear which factors make a computerized checklist perform better than a paper checklist. Furthermore, the optimal design for a computerized checklist is unknown.

In this chapter, we sought to understand how a computerized checklist can contribute to the improvement of adherence to the best practices in daily care. Using a system that we have already validated in a read-do scenario in the ICU [139], we now examine how it performs during the daily practice of PCI during the pre-operative check in a do-confirm fashion. Firstly, we aim to understand if a dynamic computerized checklist performs better than a paper-based checklist in daily practice. Secondly, we sought to understand how a dynamic checklist interacts with its users. We hope that the features associated with the effective use of our checklist can help to improve the design of future checklists.

6.2 Dynamic checklist design and development

6.2.1 The PCI process and peri-operative checklist

An interventional procedure is more or less similar to procedures used in general surgery. Therefore, peri-operative checklists have also been developed for interventional procedures like PCIs. Particularly, in this case, the PCI peri-operative checklist (see Figure 6.1) was designed with reference to WHO Surgery Safety Checklist (WHO SSC). This checklist can be divided into four sections, which are (1) pre-operative ward check by the doctor, (2) pre-operative ward check by the nurse and (3) pre-operative cath-lab check by the cardiologist and (4) post-operative cath-lab nurse check by the nurse.

Among these four sections, the pre-operative preparation phase is the most errorprone, since various laboratory tests and examinations need to be confirmed and pre-operative medications need to be administrated.

6.2.2 Definition of the content of the PCI pre-operative checklist

The pre-operative part of the paper-based PCI checklist has 13 items. The structure of this part is illustrated in Figure 6.2. Three items (right name, gender, and age; informed consent form signed; known allergy) are directly adopted from the WHO Surgical Safety Checklist. Two items (procedure deposit; letter of authorization signed) are designed to assist the cardiologists to note financial and legal affairs. The remaining eight checkable items are specific for the PCI specific pre-operative preparations.

In summary:

- Correct name, gender, and age
- Informed consent signed
- Known allergy registered
- Procedure deposit has been payed
- Letter of Authorization signed
- Pre-operation considerations discussed
- Cardiac US report has been read
- Chest X-ray report has been read
- Complete blood count is noted
- Blood chemistry is noted
- Coagulation tests are noted
- Serology test are noted
- Pre-operative hydration with saline has been given, according to the kidney function

Intravenous Procedure Safety Checklist

Date:

Name:	Gender:	М□	F□	Age:	ID:	Dept.:
Planned procedure name	2:					
Ward Cardiologist Prepar	ation Signa	ature	:			
Right name, gender, and	age: Y□ N	lo		Procedu	re deposit:	Y□ N□
Informed consent form s	N□	Letter of	Authorizati	ion signed∶ Y□ N□		
Pre-op discussion ☐ Heart	US□ Ches	t X-ra	y□	Complet	e blood cou	int□ Blood chemistry □
						erology test□
Known allergy: Y□ N□		Pre-op sa	aline hydrat	ion∶ Y□ N□		
Ward Nurse Preparation	Signature:					
Aspirin and clopidogrel to	aken: Y□ ľ	V□		Sober: \	Y□ N□	
22G trocar prepared in le	ft arm: Y	⊐ N□	Pre-op e	ducation: `	Y□ N□	
Skin preparation: Y□ N□			Valuable properly		and dentures stored	
Intravenous Procedure C	enter Prep	aratio	on OR	Num OT N	um Signatu	re:
Right name, gender, and	age: Y□ N	lo		Pre-op vi	isit∶ Y□ N□	
Right procedure: Y□ N□				Anesthes	sia∶ Local□	Basal□ General□
Devices and dressing ster	ilized∶ Y□	N□		Instrume	nts and dev	vices ready: Y□ N□
High value consumables	nd on	ie-	Confirm	allergy: Y⊏	1 N □	
time use: Y□ N□						
Actual Procedure Name:	Signature	e:				
Right name, gender, and	age: Y□N	lo		Right pro	cedure: Y	□N□
High value consumables	used∶ Y□ I	N□		High valu	ie consuma	bles destroyed∶ Y□ N□
Puncture site: Radial A	(L/R) Fen	noral	Α	Sheath:	Unremove	d□ Removed□ Stitched □
(L/R) Ulnar A (L/R) S	V (L/	/R)	Back to v	vard with o	ccluder (stapler) 🗆	
Femoral V (L/R) Extern	al jugular \	/ (L/	R)			
Unremoved devices: Tra	acheal intu	batio	n□	Patient b	ack to: Wa	ard□ CCU□ OR□
Bladder catheter Arteri			th 🗆	Outpatie	nt□ Others	
Stent□ Pace maker□ Coc	uder□ Filte	er□				
Others Planted stents: RCA ()	1CV () I	AD (1	Honorin	during tha	araaadura'
LM () OM () (L/R)				ACT:	during the p	procedure.
() Totally () stents	Renai A (,) Oti	iers	ACT.		
Transfer ready: Y \(\text{N} \)						
Trocar fixed CVL fixed	Eluid upol	hetru	ctad 🗆	Clothes	Dationt roce	ord Defibrator
Temporary pace maker						JIGO DETIDI ALEI O
Concerns after procedure					_ 0	
Signature of ward nurse:						
- 0						

Figure 6.1: The PCI checklist developed by the Chinese People's Liberation Army General Hospital (originally in Chinese).

Each of the eight PCI specific items has its own purpose. The pre-operation consideration item is designed to ensure patients' diagnosis, symptoms, and medications have considered by the cardiologists. A Cardiac Ultrasound report is mandatory before the PCI procedure that takes place. The LVEF needs to be reviewed in order to evaluate the heart function. The chest X-ray report is mandatory to evaluate the heart and lung function. A Complete Blood Count (CBC) needs to be reviewed to evaluate multiple hematologic factors that may influence the procedure. The Red Blood Cell count (RBC) and the Hemoglobin concentration (Hb), together with Occult Blood (OB) are evaluated to assess the risk of developing hemorrhage shock per- and postoperatively. The White Blood Cell count (WBC) and body temperature are reviewed to see if the patient has an active infection. Blood chemistry is reviewed to understand the patient's general situation. Among these indicators, potassium level is one of the most important, since it may affect heart rhythm during and after the procedure. Both low- and high potassium values may be dangerous. Coagulation tests need to be reviewed before the procedure to understand if the patient has a risk of developing hemorrhage. When one or more of these situations occur, the patient should be evaluated carefully and the procedure should be postponed.

Along with the coagulation test, the use of anti-coagulation medication is also noted. Aspirin and clopidogrel should be administrated as a loading dose before the procedure. Otherwise, the new stent may be occluded by thrombosis. Pre-operative saline hydration is considered particularly important for the PCI procedure since the use of contrast during the procedure is associated with Contrast-Induced Acute Kidney Injury (CIAKI). CIAKI happens in 30% of elderly patients with kidney insufficiency. It is a significant concern of the interventional cardiologists since it prolongs the length of stay in the hospital and negatively impacts the progression afterward [157]. CIAKI is mostly preventable if at least 500 mL of saline is given 12 hours before the procedure. However, this is frequently forgotten in daily practice. Patient's kidney function is evaluated by the estimation of Glomerular Filtration Rate (eGFR), calculated from creatinine levels. If the patient has severe kidney insufficiency, he or she needs at least pre-hydration of 500 mL saline before the procedure.

All this knowledge, obtained from the paper-based checklist and/or provided by the cardiologists, have been used as the knowledge base for the dynamic checklist.

Complex relations exist between the pre-operative tasks. We extracted these relations based on interviews with doctors, following the above category of 20 critical indicators and 7 suggested or compulsory preparations orders. With the help of the

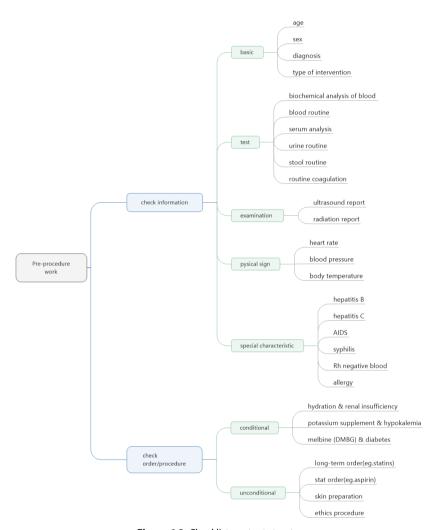


Figure 6.2: Checklist content structure.

doctors, we created a total of 636 rules involving attributes like name, value, time, dosage, to specify the creation of each item in the PCI checklist. For example, to determine whether and how the item about hydration and renal insufficiency needs to be presented, the system will refer to age, weight, sex, and the most recent value of creatinine with the general equation for eGFR. For patients with an eGFR less than 75 but more than 59, a slight renal insufficiency is present, and the system will generate the abnormal value and the recommendation for a hydration order (if there is no order yet). But if the eGFR is lower than 59, indicating serious renal insufficiency, the corresponding item will be a strong order for pre-hydration will be given (if there is no order yet). Based on these rules and EMR data of the specific patient, a digital checklist is generated according to best practices, which is consistent with the conventional paper checklist, but more detailed and dynamic in its behavior (e.g., tailored to the specific actual clinical situation of the patient).

The clinical rules are represented in Drools rule language [158]. Specifically, each clinical problem is mapped to a set of rules. Each rule is in a situation-action style like "WHEN...THEN...". Figure 6.3 represents a rule for judging and dealing with heart failure. The part of WHEN matches the patient data. When LVEF < 50, the patient is judged to be in heart failure, and the operation in THEN is performed. In THEN, the patient's LVEF value is marked in red, inserted into the HTML code corresponding to the item, and the checkable item is added to the final output checklist.

Figure 6.3: A rule in Drools format.

6.2.3 System development and implementation

The system was configured using the framework described in Chapter 4. A dedicated pre-operative patient management function was developed for the hospital to produce a list of patients undergoing a PCI procedure the next day. For the pre-operative check, the dynamic checklist currently provides the following functions. 1) EMR data extraction: extract patient diagnosis, examination reports, laboratory test reports, medication



Figure 6.4: The patient management page.

orders, and surgical application from the hospital EMR. 2) Detecting abnormal patient data: the abnormal value and the critical value were detected from the examinations and laboratory tests. 3) Analyzing abnormalities: analyzing whether the abnormalities are relative or absolute contraindications for the procedure according to the clinical rules. 4) Producing patient-specific suggestions: based on the above data, abnormalities and analysis results, generating a personalized dynamic checklist. Abnormal data that may affect the procedure are highlighted. Critical checkable items are double-checked by clinical rules when a checklist is submitted. 5) Checklist archiving: once the checklist is validated and submitted, the checklist is saved for future review by follow-up nurses and cardiologists. In the meantime, a hard-copy is produced to meet the hospital policy requirements. These functions are explained in detail below.

A patient management page was designed to help cardiologists in which patients are planned to have a PCI procedure the next day (illustrated in Figure 6.4). This page automatically shows the patients list who will have a PCI order the next day, based on the operation plan in the EMR. The patients are grouped by their cardiologists in charge, which means a cardiologist can only see his or her patients by default. Once the cardiologist selects a patient, the patient's basic information is provided. The cardiologist clicks the "Go to Check" button to perform a checklist.

An example of the dynamic checklist is illustrated in Figure 6.5. The dynamic checklist is designed to detect, present and highlight abnormal values. Hypokalemia, renal insufficiency, uncontrolled hypertension, and infection can be detected and highlighted with the clinical rules. Important items are set to be mandatory checked. Critical items are double-checked by clinical rules, even when the cardiologists have already confirmed them. If the double-check results are inconsistencies with the cardiologists'

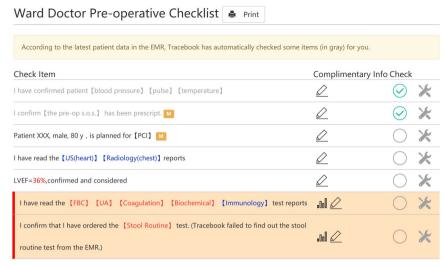


Figure 6.5: Example of a checklist.

confirmation, the checklist is not allowed to be submitted. The cardiologist will have to confirm that if the items were properly checked.

Since the reporting of the current medical activities in the hospital are not completely paperless, it is still necessary to read the paper checklist. Therefore, the system provides a print function to meet the requirement of the hospital (Figure 6.6). Any abnormality is printed on the paper checklist as well.

LIDV4			Chine	se PLA	Genera	1 H	ospital				
HBV			PCI safety checklist								
							Procedure date				
Name: XXX	Sex:M F □	Age: 57	ID:	Y168	86385		Department:Ward 1 of Cardiovascular Department				
Procedure na	me: Coronary Ar	teriography									
Doctors Prepara	tions						Signature: XXX				
The name, sex	and age are cor	rect:	Y	•	N		Deposit has been payed: Y 🗷 N 🗆				
The informed	consent has been	n signed:	Y	•	N		The authorization has been signed: $_{\Upsilon}$ $_{\blacksquare}$ $_{\parallel}$ $_{\parallel}$				
Preprocedure	discussion 🗹						blood routine examination €				
B-mode ultra	sound report 🗹						blood biochemistry 🗹 coagulopathy testing 🗹				
Chest radiog	raphy 🗹						Serology ♥				
Allergy:Alle	ergic to Penicill	in	Y	•	N		Preprocedure hydration: γ $\!$				

Figure 6.6: Printed checklist.

6.3 Clinical study design

A clinical trial to evaluate the effectiveness of a computerized checklist versus a paper-based checklist has been performed in the Cardiology department of the PLAGH in Being from May 2017 to April 2018.

6.3.1 Study settings and participants

PLAGH is a 6000-bed teaching hospital in the capital of China, and the cardiology department is the local center for interventional coronary procedures. The cardiology department has 6 wards. Elective PCI patients are diagnosed in the outpatient department and then admitted at random to ward 1 and ward 2, based on the availability of beds. In each ward, there is one director in charge, 5 senior cardiologists, and approximately 10 junior cardiologists. Since 2012, the junior cardiologists have been using a paper-based checklist to support their pre-operative preparation. The hospital is using an electronic medical record system and a computerized provider order entry system for over 20 years.

All the junior cardiologists in both wards, being 8 junior cardiologists in ward 1 and 10 junior cardiologists in ward 2, were enrolled in this study. All of them are first-year and second-year residents. They were allocated in these two wards randomly after they passed the department qualification examination.

6.3.2 Study procedure

Inherited from the underlying mechanism, both patients and junior cardiologists were allocated to the two wards randomly. Patients' severity illness was similar in the two groups. The sample size was estimated through the estimation of improvement of hydration from the baseline level to 100%. The estimated sample size was 364. One ward has 100 PCI procedures in each month on average. Considering the culture of not going to the hospital during the Chinese Spring Festival holidays, we added an extra month. Therefore, the experimental time was set to 5 months. A one-month implementation phase was set out. Data in the implementation month were not used. To make the comparison equal, baseline data of 5 months were also collected. Eventually, we collected patient data from April 2017 to August 2017 as the baseline data and the data from November 2017 to March 2018 as the experimental data. The scheme of the study is explained as Figure 6.7.

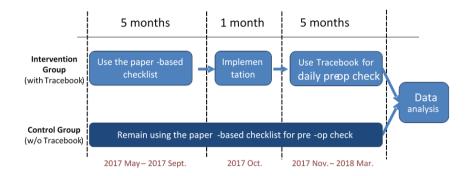


Figure 6.7: Study design.

6.3.3 Measures and analysis

Experimental data were collected through multiple approaches. Patients' condition and clinical outcomes were collected from the EMR system database. Dynamic checklist results were obtained from the database in Tracebook that stores the submitted checklists and relevant patient data. At the end of the study, a questionnaire was sent to the participants who used Tracebook. The questionnaire was deliberately designed to conform to our previous study.

The primary outcome is the hydration rate, which is calculated by actual hydrated patients divided by the number of patients who need hydration. Patients who needed hydration were selected by the algorithm that yielded an eGFR less than 60. Proper hydration is defined as patients who were hydrated with at least 500 mL saline 24 hours before the procedure. The results were reviewed by a senior cardiologist. Secondary outcomes included performance variation per month and users' acceptance.

Statistical analyses were carried out by SPSS 14. Continuous parameters were tested using the student t-test.

6.4 Results

6.4.1 Features of patients

Totally 1918 patients were enrolled in the study. Among them, 466 patients have been admitted to ward 1 between May 2017 and September 2017, 487 patients have been admitted to ward 2 between during the same period. Between November 2017 and March 2018, 519 patients have been admitted to ward 1, and 446 patients have been admitted to ward 2. Patients' age, gender ratio, eGFR, abnormal renal function rate,

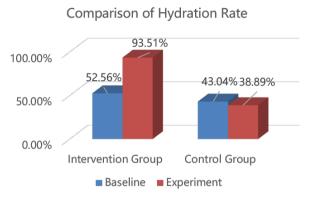


Figure 6.8: Hydration rate in different groups.

potassium, systolic blood pressure, and diastolic blood pressure were compared and no significant differences existed between these four groups (P<0.05). The patient features are detailed in Table 6.1.

6.4.2 Primary outcome: improvement of hydration rate

The improvement of the hydration rate is illustrated in Figure 6.8.

As illustrated in Figure 6.8, in the baseline phase, the hydration rate in the intervention group (52.56%) was slightly higher than in the control group (43.04%). However, the difference is not significant (P=0.232). Therefore, we can conclude that junior cardiologists in these two wards perform equally without the dynamic checklist.

The randomized controlled trial shows the hydration rate in the intervention group (93.51%) is significantly higher than the control group (38.89%, P<0.00001). A beforeafter comparison indicates the same results. In the intervention phase, the hydration rate in the intervention group has increased significantly from 52.56% to 93.51% (P=0.00016). Whereas in the control group, the hydration rate dropped from 43.04% to 38.89%. However, the drop is not significant (P=0.323).

Users' satisfaction of the dynamic checklist is illustrated in Figure 6.9.

A questionnaire was sent to all the 11 participants who used Tracebook via a survey applet in WeChat and collected anonymously. 9 valid questionnaires were finally collected. The average acceptance is 4.61 out of 5. The users were highly satisfied with Tracebook.

Table 6.1: Patient features.

Features	Group 1 in baseline	Group 2 in baseline	Group 1 in baseline Group 2 in baseline Group 1 in experiment Group 2 in experiment	Group 2 in experiment
Age(SD)	61.8(10.9)	(0.0(10.0)	62.0(10.4)	60.1(9.6)
Male%	72.2%	73.0%	74.2%	71.6%
eGFR(SD)	86.3(31.8)	88.7(29.3)	88.1(28.6)	92.0(29.5)
(eGFR<60)%	16.7%	16.2%	15.6%	12.3%
SBP(SD)	130(15)	130(20)	129(16)	129(19)

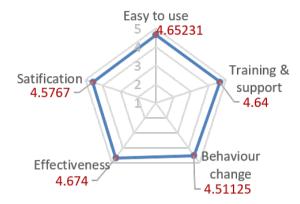


Figure 6.9: User acceptance of the dynamic checklist.

6.4.3 Secondary outcomes

Errors captured and corrected by the dynamic checklist are illustrated in Figure 6.10.

By analyzing the hydration prescription time, 36 patients out of 72 patients who have hydration orders were prescribed during the use of the dynamic checklist. If we deduct these 36 patients, the hydration rate will fall to 46.75%, which is not significantly different from the baseline phase and the control group in the intervention phase (p-value is 0.118 and 0.501, respectively).

The hydration rate variation in both these two wards does not show any trend in these five months. After the implementation of the dynamic checklist, the hydration rate suddenly increased from 52.56% to 88.46%, whereas the hydration rate in the control group remains the same. In the following 5 months, they stayed more or less the same (Figure 6.11).

In the intervention group, 3 of the 8 junior cardiologists made 77.8% of the errors and this did not change over time(see Table 6.2).

CIAKI cases were counted from EMR. In the baseline period, there were 6 cases in the intervention group and 3 cases in the control group. In the experimental period, there was 4 case in the intervention group and 3 case in the control group. However, the decrease in the intervention group is not significant due to the small sample size.

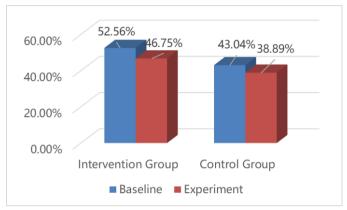


Figure 6.10

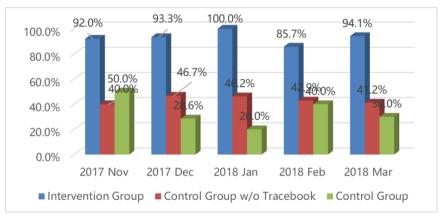


Figure 6.11

Table 6.2: Errors per cardiologist.

Num.	Patient	Completion Rate	Average Com-	Median	Errors	Error
	Count		pletion Time (s)	Completion	Number	Rate
				Time (s)		
1	76	84.2%(46.3%)	95.0(12.3)	36	14	18.4%
2	51	98.7%(28.8%)	98.7(13.2)	45	7	13.7%
3	44	99.9%(10.0%)	75.5(11.3)	21.5	4	9.1%
4	81	99.5%(15.2%)	55.0(7.8)	28	4	4.9%
5	128	46.3%(20.5%)	20.5(4.9)	14	0	0.0%
6	97	99.9%(9.2%)	70.3(12.9)	35	7	7.2%
7	26	72.3%(51.7%)	36.9(4.8)	32	0	0.0%
8	17	99.3%(14.5%)	47.6(7.3)	28	0	0.0%

6.5 Discussion

6.5.1 Does the idea of dynamic checklist work in daily practice?

In this randomized controlled trial in daily practice, we observed that the dynamic checklist indeed improved the adherence to the best practice and keeping high acceptance. These results are in line with the results of our previous study and other simulation-based studies [35, 139]. The acceptance is even higher in this study, as compared with our prior work [139]. This can be explained by the fact that for the daily ICU round checklist more time was needed. Our pre-operative PCI checklist actually decreased the duration of the pre-operative preparation. Cardiologists reported that before using the dynamic checklist, they spend around 5 minutes to collect and analyze patient data from "everywhere" in the EMR system. Our dynamic checklist reduced their workload on data retrieval and analyzed substantially.

6.5.2 Why does the dynamic checklist perform better than the paper checklist?

In this study, we observed that the same checklist, implemented in different ways, achieves different results. While the paper-based checklist was treated as paperwork and had limited effect, the dynamic checklist was highly accepted and effective.

The acceptance is high in daily practice based on our questionnaire survey. The result is similar to what we have gained in our previous study. The high acceptance can be explained by 1) the core clinical value that the dynamic checklist presents, and 2) the extra value (such as generating the patient list, collecting most relevant patient data, highlight critical value, etc.) it offers. The dynamic checklist can help cardiologists to detect their omissions before they become errors. Many cardiologists reported this during our study. On top of this, the dynamic checklist helps cardiologists to extract, calculate, filter, and review important clinical information. Therefore, it saves cardiologists' time, improves efficiency while detecting and correcting errors and thus improving safety.

A change of clinical practice does not happen automatically. No matter how good a checklist is designed, an active implementation is always required [159]. Despite perhaps nobody likes to be forced to do something or redundancy, it is suggested by the error theories that forcing and redundancy are really needed for us human beings to make things correct [15]. A safety checklist needs certain kinds of forcing and redundancy [41]. For example, in the WHO SSC, the time-out forces the whole operation team to stop, and some important items seem to be redundant in pre-incision, time-out, and sign-out [4].

However, forcing and redundancy must be implemented nicely, comfortably, and yet mandatory for the users so that they can accept and follow [160]. Independent from the patient context and care process, it is difficult to implement proper forcing and redundancy for paper-based checklists without troubling their users [8, 161].

Nevertheless, by using the dynamic checklist, accountability is improved by added the director's evaluation step [9].

6.5.3 Who benefits from using the dynamic checklist?

In our previous study, we explained the reason for high acceptance, but we have no indication by what mechanism(s) adherence to best practice was improved. The checklist is not an isolated intervention. While implementing a checklist, besides a checklist itself, organizing, motivating, workflow improving, teaching, training, learning, supervising, administrating, and team-building all inevitably affect the outcome. Then it becomes an interesting question that, given all these factors, to what extent the checklist contributes to the overall improvement of outcomes?

In this study, we showed that the dynamic checklist prevented the omissions and provide intervention suggestions to the cardiologists. If we leave out the omissions captured by Tracebook, the performance of the cardiologists returns to the lower baseline level of the paper checklist.

There is an interesting finding in our study that there are roughly three types of junior cardiologists. One type is the one that rarely makes mistakes. However, they do not finish all the check items, and they complete their checks very quickly. They have the heaviest workload, lowest checklist completion rate, and the shortest check time. But astonishingly, they also have the lowest error rate. Another extreme are the cardiologists with the highest error rate. Their completion rate is high, but it various a lot. They have the longest checking time. Meanwhile, their workload is not heavy. The other cardiologists have a median behavior, average error rate, average completion rate, and time needed for completion. It appears that the first group of cardiologists know exactly what has been to be done and what should be done by heart. So, they quickly finish their jobs without making mistakes. The dynamic checklist is like a reference to them. The second group appears not knowing their patients well. They are not aware of their patients need for pre-hydration nor what their condition is. The real asset of the dynamic checklist is that it makes these three types of cardiologists equally good and effective. Therefore, they all benefit from the dynamic checklist, but the forgetfulness, perhaps less experienced caregivers benefit most.

There is no trend in the improvement of performance during the four months.

Omissions per month do not change. It suggests that checklists should always be used since there seems to be no learning effect. We also studied the correlation between omissions and individual cardiologists. A few of them make the most mistakes. Additionally, there is no learning effect observed in this study.

Personalities and burnout may affect care-givers' performance. It appears those care-givers who are error-prone benefits more from using the dynamic checklist. We would argue it is important for everyone to use the dynamic checklist since it improves patient safety consistently.

6.5.4 Why did our dynamic checklist fail to improve the adherence to 100%?

The dynamic checklist is designed to check all the patients. To ensure consistency, forcing and double-check mechanism are employed. It would be reasonable to assume the adherence to best practice is 100%. However, the experimental results show it is not yet 100%. It would be important to check the reason. 4 patients who were detected with kidney function insufficiency but were not pre-hydrated after using Tracebook. We have checked their medical record and checklist logs. We found that all the 4 patients had normal eGFR values when the cardiologists were reviewing the Lab-results. However, their lab-results were updated after the submission of their checklists. Unfortunately, the new Lab-results indicated that hydrations were actually required.

This result shows that one checklist cannot fully protect patients. More checklists in the pre-operative period are required and that always the most recent tests should be observed. Extra clinical rules may be needed that compares the date and time of newer Lab results with the date and time of the latest performed dynamic checklist.

6.5.5 What are the success factors of the dynamic checklist implementation?

There are three factors making the dynamic checklist implementation successful. Firstly, the dynamic checklist brings its users an additional benefit, aggregating and combining data together, motivating the users to use the checklist and do not consider it to be extra work. Secondly, the workflow control, which already exists in the checklist process, prevent the cardiologists from skipping the steps in the workflow. Lastly, but perhaps most importantly, the forcing mechanism that double-checks the most important items provided by the dynamic checklist. This is the ultimate factor that makes the checklist effective.

6.5.6 Limitations of this study

There are several limitations in this study. This study uses the pre-hydration rate as the primary outcome. However, hard endpoints such as acute kidney injury were only considered as a secondary outcome. This is due to the relatively small sample size. This study is carried out in a top-level teaching hospital. Although the monthly admission rate is high, 800 patients are still not enough to observe endpoints like kidney failure due to pre-hydration omissions.

Different from the previous two simulation-based studies [35, 139], this study did not involve a cross-over in the study design. Cardiologists in ward 2 have never used the dynamic checklist during the experiment. It is difficult to perform a cross-over study in daily practice, especially when people already recognize the value of the intervention. However, we would argue that cross-over is not really necessary in our study. Cross-over is used to eliminate the possible bias between the two groups. In our study protocol, baseline data are analyzed and showed that the cardiologists in the two wards performed the same.

In our study, we can only detect omissions in the control group with Tracebook in the study phase. Omissions in other groups were not detected and calculated. In the intervention group in the experimental phase, the time of performing a checklist is recorded by our system automatically and reliably. However, when using the paper checklist, it is not possible to know at what time the cardiologists performed the checklist. Arrange resources to look over the shoulders of cardiologists might possibly provide such data. However, it is impractical to do so in daily practice. Moreover, it may cause a Hawthorne Effect and evolve bias [162].

Our dynamic checklists are well-accepted by junior cardiologists. However, it is reported that senior doctors tend to be more resistant to use paper checklists [163]. In this study, we did not investigate the attitude of senior doctors to dynamic checklists. Further studies on this topic is required.

6.6 Chapter summary

In conclusion, we report that a dynamic checklist improves patient safety during a PCI. The dynamic checklist performs better than a paper checklist because it motivates cardiologists to use it by giving additional information. Gathering and presenting information together, that fits in the workflow, assuring that the important checks have been performed, motivates the users as well. The pre-hydration rate improvement is caused by forcing care-givers to give the hydration order when needed while performing the checklist. To our best knowledge, this is the first study of how precisely

a checklist improves outcomes. The results also indicate that a few people make the majority of mistakes. The performance without a checklist has not improved during the implementation. This suggests that the persistent use of a checklist is necessary. The study also analyzed why adherence is not 100%. We found that performing one checklist at a specific moment during the workflow may not be enough and repeated checks are necessary.

Chapter 7

What makes an effective dynamic checklist implementation: a comparison of two case studies

7.1 Introduction

A safety checklist is a promising tool for improving patient safety as it can reduce the likelihood of human error to occur in daily practice. However, many checklist studies failed to achieve their initial goals due to the poor implementation and lacking compliance of checklists. A potential cause for this might be that current paper and even computerized checklists are still mostly static pages and do not fit within

¹Shan Nan, Ashley De Bie, Sicui Zhang, Hendrikus Korsten, Xudong Lu, and Huilong Duan. 'Identify Facilitators and Challenges in Computerized Checklist Implementation.' Studies in health technology and informatics 264 (2019): 1737-1738.

²Leixing Lu, Shan Nan, Sicui Zhang, Xudong Lu, and Huilong Duan. 'Can Existing Guideline Languages Meet the Requirements of Computerized Checklist Systems?.' In 2018 IEEE International Conference on Bioinformatics and Biomedicine (BIBM), pp. 1500-1503. IEEE, 2018.

³Leixing Lu, Shan Nan, Sicui Zhang, Xudong Lu, and Huilong Duan. 'Using openEHR's guideline definition language for representing percutaneous coronary intervention patient safety rules in a dynamic checklist system.' Studies in health technology and informatics 264 (2019): 1714-1715.

⁴Jianfei Pang, Haifeng Xu, Shan Nan, Shubo Xu, Me Li, and Dongsheng Zhao. 'A Mobile Intelligent Checklist System for Stroke Emergency.' In 2019 IEEE International Conference on Bioinformatics and Biomedicine (BIBM), pp. 1581-1584. IEEE, 2019.

clinical workflows nor the patients' context. Therefore, computerized dynamic checklist implementations might be the solution to overcome the barriers of the current checklist while its effectiveness remains.

A few studies on implementing such computerized checklists have been reported in the literature. For example, Garg et al. proposed a patient discharge checklist integrated with the hospital EMR. Pageler et al. [34] and Thongprayoon et al. [35] reported efforts on computerized checklists for the ICU. By analyzing patient data in the EMR, they were able to highlight critical items in the checklist that were relevant for specific patients. These studies showed that process-oriented and context-aware computerized checklists were more effective than static checklists even though the dynamic properties were limited.

Despite these encouraging outcomes and urgent need, there have been only a limited number of such types of checklists reported in the literature until now. This is unexpected, especially considering the notion of a safety checklist has already been proposed for ten years. There are several possible barriers that might explain this issue, like hampering development and local implementation. In previous studies, researchers have defined the functionalities of such checklists [99], proposed knowledge representation mechanism and software framework for developing relevant computerized systems. However, it remains unclear what the success factors and challenges are in the implementation phase of this new kind of checklists.

Due to the limited amount of implementation reports, it is yet not possible to summarize these elements based on available literature. Therefore, the aim of this paper was to describe the success factors and challenges for the implementation phase of computerized checklist systems since this research team implemented this in two countries for two different clinical scenarios in past years.

7.2 Comparing the two case studies

While developing the computerized checklists in these two studies, we followed a proof-by-demonstration approach[4]. With this approach, the development was divided into several iterations. In each iteration, we demonstrated the latest software to the clinical users, interviewed them while demonstrating, analyzed users' comments, and applied validated comments to the next version of the software that would be discussed in the next iteration. After several iterations, the software was stable and brought to daily use.

In the Dutch case, two engineers and one intensivist had worked on developing checklist items and related clinical rules for half a year based on the local protocols. Another large part of the clinical rules was derived from the CDSS knowledge base.

In the Chinese case, three engineers and two cardiologists have been working on

the computerized checklist in two years. The related clinical rules were based on their existing paper-based checklist and narrative clinical guidelines.

Users' comments were collected and analyzed afterward. Those comments on what they like about computerized checklists were categorized as facilitators. Those comments on what may hinder the acceptance were considered a challenge. Additionally, engineers' own developing experiences were also summarized into these two categories.

7.3 Results

These two case studies achieve comparable results. They are listed in the Table 7.1.

Both studies indicate that a dynamic checklist has better performance on improving the adherence to best practice comparing with paper-based checklists. In the PCI checklist, the reported compilation rate is 100% since it is mandatory to complete this checklist before the procedure. However, the clinicians may tick the boxes without really considering the content. The real complication rate was not checked due to the limitation of clinical resources. Clinicians in both cases reported high satisfaction with the use of dynamic checklists. The PCI checklist has a higher score comparing with the ICU round checklist. One possible reason is while designing the user interface of the PCI checklist. We had more discussions with several cardiologists with different levels of experience. That means the end-users are involved in the design of the dynamic checklist and their requirements are collected and fulfilled.

Regarding the implementation, while sharing some similarities, these two cases have some differences. They are compared in Table 7.2.

Both hospitals already had experiences with paper-based checklists. Therefore clinicians already had initial feelings and expectations of computerized checklists. However, in the PCI checklist case, using a paper-based checklist was mandatory even before dynamic checklist implementation. It encourages clinicians to look for a more convenient and helpful way of using a checklist. Since the two case studies were carried out in two countries, there are significant medical cultural differences. Compared with the western medical culture in the Netherlands, which puts emphasis on equality and open discussion, the Chinese medical culture has a clear hierarchy. We observed that clinicians stick to their supervisors' orders tightly and fear to argue with their supervisors. On one hand, the hierarchy accelerates the implementation of dynamic checklists. Once the deputy director of the department agreed to start the use of a dynamic checklist, every cardiologist started to use it on the next day. On the other hand, the dynamic checklist makes medical processes more transparent. Now junior cardiologists have

Table 7.1: Comparison of outcomes in two case studies.

Outcome	ICU Round Checklist	PCI Checklist
Adherence to best practice	Increase from 20.0% to 96.4%	Increase from 52.6% to 84.2%
Compilation rate	Increase from 73.6% to 100%	Not compared
User acceptance	4.2	4.6

Table 7.2: Comparision of implementations in two case studies.

	ICU Round Checklist	PCI Checklist
Checklist Usage	Optional	Mandatory
Medical Culture	Equality, open	Hierarchy, protective, blaming
IT Infrastructure	EMR and CDSS	EMR
Knowledge Sources	International guidelines, local	Local protocols adapted from international guide-
	CDSS knowledge base	lines
Resource Invested	One engineer and one intensivist,	One engineer and one intensivist, One engineer and two cardiologists, 18 months
	six months	

to communicate with their supervisors once the dynamic checklist detects unsolved clinical problems. However, there was one problem while using the checklist, which was caused by the hierarchy and blaming culture in the PCI checklist case. Chinese cardiologists sometimes tended to tick all the boxes to prevent blame from their supervisors. Therefore, a validation function was added to the Chinese implementation.

The IT infrastructures in the two cases were different. The Dutch hospital in the ICU case already has a mature CDSS, which is not the case in the Chinese hospital in the PCI case. Both the CDSS and the pharmacy rules in the CDSS were reused in the ICU round checklist design and implementation. It has saved significant time and human resources for checklist design, system development, and user training. Lacking of such CDSS was a part of the reason why the PCI case implementation took more time.

7.4 Discussion

Several success factors and challenges of implementing a dynamic checklist are summarized from the comparison in the previous section.

7.4.1 Facilicators of dynamic checklist implementation

Well-established local standard of care

An established local standard of care facilitates the implementation of computerized checklists. The local standard of care includes existing guidelines, pathways, safety checklists, CDSSs, and other approaches that aimed to improve the guality of care.

Both of these two test cases benefited a lot from the existing checklists and local protocols. Since they were already using paper-based checklists for years, they were more likely to accept the dynamic checklist that was based on their familiar paper-based checklist but more specific to patients and scenarios. This knowledge was already accepted and followed at the department level. This would make checklist items more acceptable and reasonable to clinicians. In addition, structured local guidelines and clearly defined pathways are essential for implementing the process-oriented and context-aware computerized checklists.

Dynamicity of computerized checklists

The notion of safety checklist has already been proposed in the medical domain for a decade. However, clinicians still refuse to use paper-based checklists due to their static nature that does not fit in their dynamic and demanding daily workflow. They are always

the same for patients with various diseases, treatments, and medical backgrounds. This inconsistency leads to the idea that checklists are more like an administrative burden instead of a safety method.

In that light, a computerized checklist that can be adapted to each specific patient makes much more sense to clinicians. During the interviews, clinicians mentioned that they like the dynamic properties as it saves time to complete the checklists and it is able to detect more patient-specific problems that are worth noticing.

Adaptive to clinicians' requirements

Clinicians are well-trained and highly-experienced experts in their specialism. Based on their own knowledge and experience, they already have their own thoughts on how to improve the quality of care. If a computerized checklist support system adapts to their requirements, we hypothesize that they would be more include to use checklists in daily practice.

In both of the studies, during our implementations, clinicians were also mentioning new potential clinical rules showing their interest in this important feature of computerized checklists. Especially in the Dutch case, a visualized knowledge acquisition tool is used to build clinical rules. Intensivists implemented and updated the clinical rules all by himself.

Additional values provided by computerized checklists

In the literature, it is frequently mentioned that the use of checklists is time-consuming. With only ticking boxes and no direct benefits from this, it is a time-consuming burden. If well implemented, dynamic checklists are really able to help clinicians and use the checklists as a cognitive aid, resulting in better acceptance and compliance to the checklist as well as better patient care. A detailed comparison of the acceptance for these two cases can be found in Appendix B.

The digital checklist's additional value is also their capability to extract and display relevant patient data, automate data analysis, and present appropriate literature or local protocols.

Existing hospital information systems

In our practice, we found that the use of data from the existing hospital information systems and their components saves a significant amount of time and cost and therefore

increases the chance of a successful implementation.

One example is the CDSS used in the Dutch hospital. The clinical rules in the system have been developed and tested for decades. Intensivists have all agreed on them and are familiar with these rules. Reusing these rules saves not only time for the development phase, but also makes checklist items more convincible to the intensivists. Additionally, we also benefited from the software architecture of the CDSS. The CDSS has already been integrated with the hospital EMR. So we do not have to do data integration work with EMR again. This also saves time. In the Chinese case, they did not have such knowledge and systems at that moment. This resulted in a development phase of two years since a significant amount of time had to be spent on developing CDSS components and data integration.

7.4.2 Barriers of dynamic checklist implementation

Users' perception and medical culture

Checklists could help to deliver more transparent healthcare, that people could use to see who did what at what time and why making the process more transparent. However, in our study, some caregivers showed concerns. Some clinicians worry about patients and their families, who may lack medical knowledge and might misinterpret the medical record . Since these systems make their work more traceable and themselves more accountable, some clinicians tick all boxes without considering the content in order to avoid trouble.

Some inappropriately implemented CDSS have caused alert fatigue and cookbook medicine in the past. Because of this, some clinicians have a negative impression even before they are trying to use the computerized checklist. It is not easy to convince these people.

Flexibility of healthcare

Healthcare processes are highly flexible. It is yet difficult for computerized checklists to cover every path of the healthcare process. When some situation happens, it may not be covered by a checklist or a checklist may no longer be valid for that case.

In our PCI peri-operative checklist, there is a situation that the pre-operative check cannot be completed on the day before the procedure due to a lack of lab test results. In this case, specific items should be done the next morning. However, this is not supported by our current technology.

Knowledge acquisition

Knowledge acquisition is a classic problem for knowledge-based information systems. The computerized checklist is not an exception. The cost of knowledge acquisition is high. Knowledge engineers and clinical experts have difficulties understanding each other. The knowledge provided by experts may not reflect the specific problem in a specific department. It always takes several iterations to finalize a clinical rule.

The problem is even more complex for computerized checklists because there is a lack of tools for analyzing safety problems. Without a tool helping analyzing clinical problems, even clinical experts may not clearly know which items should be designed in a checklist.

Hospital information system integration

Integrating decision support with hospital information systems is becoming more and more difficult because data safety and privacy issues are becoming increasingly important.

There is no standard interface to acquire patient data from different EMRs developed by different vendors. Even when patient data can be acquired, the data model is not shared. The mapping between each data model is extremely time-consuming. It is therefore very difficult to share computerized checklists among organizations.

Another challenge is to push the output of the checklist back to the EMR. Clinicians always like to see all the information, including the checklist, in one system. In that case, the EMR system is the best option. However, EMR and their vendors are mostly not open for computerized checklist developers to interact with their EMR. Therefore, currently, computerized checklists are still on additional webpages within the EMR.

Based on the summarized success factors and challenges, this section discusses suggestions for future computerized checklist implementations and possible research directions.

7.4.3 Suggestions for future checklist implementation

Make use of existing IT infrastructure

The lesson we learned from our own experience is to make use of existing IT infrastructure as much as possible. This would save a great amount of time and thereby human cost. Additionally, the system would be more robust and easier to be accepted by both the hospital IT department and clinicians. Specifically, any kind of knowledge-based system,

like CDSS, clinical pathway management systems, rules in EMRs should be considered whenever it is possible.

Emphasize additional value for users

It is crucial for the acceptance of the computerized checklist by clinicians that they fit in their daily workflow, provide a direct benefit and save time. Without this direct feeling of benefits, the implementation will probably fail to achieve acceptable compliance rates over the long term. A checklist that is not used, will also not help.

Provide right-level of redundant and forcing function

Redundant and forcing functions might not be liked by clinicians directly. However, it could be the key that might lead to a successful implementation of computerized checklists.

Making crucial elements in the safety checklist mandatory may guarantee the redundancy mechanism to function. Failure to comply with medical regulations is an important cause of safety problems. Moreover, failure to comply with the safety checklist is the main reason for the poor performance of the paper checklist application. Therefore, engineers could have a role to ensure compliance of health care personnel with the safety checklist by facilitating the use of the checklist system. Among them, taking mandatory means is one of the solutions. However, considering the differences between patients and medical procedures, not all verification must be done and mandatory crucial elements must be specified by the responsible medical teams. For fatal entries, you can not simply assume that the user will follow and set up a double-check mechanism. It is up to the person or computer to ensure that the necessary safety work has been properly completed.

Process redundancy and configuration redundancy are effective means for detecting errors and improving safety in the medical industry and other high-reliability industries. The computerized checklist can provide both process redundancy and configuration redundancy. Computerized checklists can provide the same problem or the same set of questions in different places in the medical process to make sure the problem is noticed. It is also possible to ask two clinical roles to check the same problem repeatedly to minimize the possibility of neglect.

Respect users' expectations and concerns

In the design of the dynamic checklist, it must be clarified that the medical staff is still the key. It is the medical staff in charge of the care process, doing the clinical activity, and making the final decision. An information system can warn the medical staff when it detects medical staff's potential errors and finally advice the medical staff to make decisions.

When the decision of the health care provider does not match the best practices in the computerized checklist, the computerized checklist can still motivate the health care provider to fill in the cause or give the decision to the superior health care provider as appropriate and to get a better understanding why and when certain protocols are not followed. One very important factor is therefore to involve the local clinicians in both the development and implementation phase.

7.4.4 Directions for future checklist research

Support flexible care processes

For scenarios with high flexibility requirements, it is necessary to introduce new expressions and study the corresponding implementation methods. For the standardization needs, the way to express the general process with workflow modeling language such as BPMN should not be abandoned. But for fine-grained, medical processes that are driven by patient data and medical events, data-driven process representation is needed. The case handling method represented by CMMN is the possible direction. Unlike BPMN, CMMN's focus is not on the order of activities in the process, but on the causal relationship between activities. That is, what kind of results an activity will lead to, and what causes an activity to occur. This approach has advantages in expressing complex processes that involve much knowledge. At the same time as the research of this thesis, the combination of BPMN, CMMN and rules expression, flexible modeling of complex and flexible workflows has begun to attract the attention of researchers in the field of workflow management, and there is already clinical research. This approach helps to increase the flexibility of the medical process further, thereby further facilitating the distribution of safety lists to the right users at a more precise time, increasing the acceptance and effectiveness of the safety checklist.

Improve checklist knowledge acquisition

For the editing problem of the computerized checklist, the unified expression model of the computerized checklist should be further studied, and the diagnosis process, medical logic, checklist content style and the interaction relationship between them should be expressed in a unified form. The third chapter of this thesis has proposed a meta-model of the computerized checklist, which expresses the relationship between concepts and concepts related to the computerized checklist, and provides a basis for the execution of a computerized checklist. However, this study has not yet covered the expression model of the computerized checklist; that is, the way in which the concepts and relationships in the computerized checklist are visualized. Using a graphical and user-friendly knowledge acquisition tool could greatly reduce the workload of checklist modeling. Schuerlein et al. [103] invented a process modeling tool based on the BPMN language, which is shaped like a puzzle. The modeler spells out the graphics for the medical staff to understand and modify at any time. This approach provides insight into the development of visualization tools.

In recent years, the development of medical artificial intelligence has provided a research basis for the detection of mutations in medical activities and the analysis of the correlation between mutation and adverse reactions. Huang et al. proposed a method for detecting behavioral variation from the records of patient medical activities using the cluster analysis method; Yan et al. [164] proposed a method of comparing the medical activity record with the clinical path model to detect the diagnosis and treatment activities that do not follow the clinical path. These methods of detecting mutations in medical treatments offer the possibility of offline detection or online detection of abnormal behavior in medical activities.

Sharing checklist among organizations

For the problem of sharing computerized checklists between different hospitals, the current Fast Healthcare Interoperability Resources (FHIR) and openEHR provide a way to express clinical data in a standardized way. On the basis of this, researching a general data model suitable for intelligent checklist knowledge expression will help to improve the sharing ability of computerized checklist knowledge.

7.5 Chapter summary

The computerized checklist can help the implementation of safety checklists in a process-oriented and patient context-aware way so that it better fits the medical

practices. However, due to the lack of experiences, it remains unclear what are the success factors and challenges while implementing a computerized checklist in hospitals. To help accelerate the widespread adoption of computerized checklists, this chapter summarizes the success factors and challenges of computerized checklist implementation from our experiences. Two successfully implemented checklists have been analyzed.

Chapter 8

Conclusions

8.1 Summary of research findings

Medical errors are a major threat to patient safety. The current error management method lacks consideration of human factors and lacks systematic management of errors, so it is difficult to control medical errors effectively. The use of safety checklists is a new type of medical error management method that fully considers the causes of errors and control methods. However, the effectiveness of these checklists depends on their design and implementation. Paper or naive computerization does not adequately support human factors and increases the workload of users. Also, the lack of a checklist deployment mechanism leads to forgetting, non-execution, and non-compliance in the use of the checklist. It is necessary to develop a new type of safety checklist to support the above factors. In this thesis, we have explored, developed and evaluated a novel dynamic type of checklist that promises to overcome these difficulties. Our main research findings are as follows.

- We have systematically reviewed the clinical development and application of safety checklists. The forms, contents and characteristics of various safety checklists were analyzed. By analyzing the benefits and obstacles factors in the clinical application of safety checklists, the dynamic checklist concept was proposed, and a functional model of dynamic checklists was proposed.
- 2. We have studied a hierarchical intelligent knowledge representation method. The dynamic checklist knowledge is decomposed into three classes, which are clinical process, clinical rules, and checklist contents. Based on this approach, dedicated dynamic checklists are successfully developed for several clinical scenarios, thus proving this expression method's feasibility and versatility.

- 3. We have studied a dynamic generation method for dynamic checklists that integrates workflow management techniques and rule-based reasoning techniques. Based on the hierarchical expression of dynamic checklist knowledge, the workflow process is executed by a Workflow Execution Engine, a Rule Engine executes the rules, and the dynamic checklist engine matches the generated process context and patient state context. Based on this method, a dynamic checklist system is designed dynamically. The feasibility of the method and system is proved by the successful construction of dynamic checklists for several practical clinical scenarios.
- 4. We designed and built a dynamic checklist for intensivists who have heavy workloads and need to pay attention in the daily round. A dynamic checklist was developed based on the original paper-checklist and clinical rules. A simulation-based clinical trial has been carried out to evaluate the effectiveness of the dynamic checklist. The result shows that the dynamic checklist can significantly improve the intensivists' compliance with clinical best practices and significantly reduce medication errors while having high acceptance.
- 5. We designed and constructed a pre-operative dynamic checklist for Percutaneous Coronary Intervention (PCI) pre-operative preparation. The dynamic checklist was based on the hospital's paper-based checklist. Additional clinical rules regarding abnormal value detection and notice for hydration were added. A randomized controlled trial has been developed in a Chinese hospital. The results show that the dynamic checklist significantly improves the hydration rate before the PCI procedure.
- 6. We discussed the experience and lessons learned in the intensive care ward round dynamic checklist and perioperative dynamic checklist research, summarizing the dynamic checklist design and the general method of system development and implementation in the dynamic checklist building process.

8.2 Limitations and future work

With the further development of medical care, patient safety issues will be increasingly closely watched by the medical industry and the public. The constantly updated clinical guidelines and clinical pathways have further provided an improved basis for high-quality care. The application and promotion of new technologies, including artificial intelligence technology, further improve diagnostic accuracy. However, for the foreseeable future, the main body of medical activities is still human, and technology remains an aid in human medical activities. Whether or not the correct method can be used accurately still determines the key issues of patient safety. As noted by

Reason et. al [14], any technique, including automation, does not eliminate errors. They can only change the form of errors and change the time and location of errors. Safety verification and safety checklists will play an increasingly important role in an increasingly procedural, intelligent future medical environment. As far as this thesis's work is concerned, the following topics require further exploration and research.

- 1. This thesis proposes the dynamic checklists' concept and evaluates dynamic checklists' effectiveness for two typical clinical application scenarios of intensive care ward and perioperative management. However, for the new knowledge form and medical intervention method of dynamic checklists, there is still a lack of large-scale, multi-center clinical research similar to the WHO surgical safety checklist or the SURPASS perioperative checklist. Organizing such a transnational, multi-center study is an important follow-up of this research.
- 2. We currently have a single source of knowledge for building safety and dynamic checklists, relying entirely on clinical guidance and expert experience. However, abstracting such knowledge is very difficult. Data sources such as clinical data and adverse reaction reporting records can be used as an important basis for safety checklist development. With the development of big data technology in recent years, the analysis and mining research of these data sources, the discovery of the relationship between adverse events and medical behaviors, and the intervention of medical behaviors that cause adverse reactions are promising directions of dynamic checklist research.
- 3. Standardization and personalization are two aspects that complement each other in medical practice. Diagnosis and treatment activities must conform to the norms and fully reflect the individualized differences of patients. How to express the standardization of medical knowledge while ensuring medical care's personalization and avoiding "cookbook medicine" is still an important challenge for clinical decision support research. Combining workflow modeling and case handling methods to study the flexible modeling of medical processes, combining standardization and personalization, would be a breakthrough in dynamic checklist research.
- 4. Usefulness and usability are the two major factors that ensure those information systems are used correctly and reasonably. The research in this thesis has fully revealed the usefulness of the dynamic checklist system. However, how to engage the busy medical staff appropriately at the right time to prompt them to comply with the safety checklist is still a problem to be studied. An ergonomic perspective will be needed to design optimal interaction approaches of dynamic checklists and people.

Appendix A

The editorial accompanied with the ICU checklist clinical validation

Checklists, cognitive aids, and the future of patient safety

C. S. Webster

Accompanying editorial in British journal of anaesthesia 2017; 119: 178-81

On Wednesday, October 30, 1935, an evaluation flight of the Boeing Model 299 was undertaken at Wright Field, northeast of Dayton, OH, USA. The Model 299 was the most technologically sophisticated aircraft of its time and was nicknamed the Flying Fortress because of the extent of its armaments. Major Ployer P. Hill was the pilot, and it was his first flight in the new aircraft. The aircraft appeared to ascend normally, but suddenly stalled, turned on one wing, and crashed, killing two of the aircraft's five crew, including Major Hill. The investigation into the crash discovered that Major Hill had omitted a crucial step during the preflight preparation; he forgot to release a catch, which on the ground locked the aircraft's control flaps. Once in the air, this mistake rendered the aircraft uncontrollable. The crash investigators knew that there was probably no one better qualified to fly the new aircraft than Major Hill—his co-pilot was also highly qualified—yet despite this, the fatal error was still made. The investigators concluded that given the experience of the pilots, further training would not be an effective response to prevent such an event from happening again; a response that is very different from that which often occurs in health care when a mistake is made.² Some commentators initially believed that this meant the new aircraft was simply too complicated to fly reliably. A new approach was needed, and it took the form of a simple list of crucial tasks that must be completed before the aircraft could leave the ground. The first aviation checklist had been devised. With the checklist in use, despite the aircraft's sophistication, the Model 299 (and later versions of it) performed safely for many years.

Around 70 yr later, the crash of the Model 299 and creation of the aviation checklist were the inspiration for the development of the now celebrated World Health Organization (WHO) Surgical Safety Checklist.¹ The technical issues for surgical safety were similar to those in aviation; highly qualified and skilled clinicians working in the high-technology environment of the operating room needed to ensure that certain crucial steps were not omitted during a procedure. The WHO Surgical Safety Checklist was therefore designed to improve team communication and consistency of care by prompting checking and communication at crucial points. In a large-scale multinational study of 7688 patients reported in 2009, use of the WHO Surgical Safety Checklist was shown to reduce the overall rate of postoperative complications by 36%.³ In the succeeding years, there have been a flurry of safety checklist studies, which have included the emergence of a better understanding of the limitations of the use of checklists in surgery and health care.⁴⁻⁷

One substantial limitation of applying aviation-type checklists in health care is the fact that although aircraft are complicated, patients undergoing health care are complex.^{2,8,9} The challenge of patient variability should not be underestimated. Unlike many high-technology endeavours where a great deal of standardization is possible, health care clearly must contend with the subtle physical variations and abnormal anatomies and pathologies that exist in individuals; differences that are often unknown and unknowable before the procedure has begun. This represents a different situation from that with a machine, such as an aircraft, where its exact structure and function is known and where these details are documented. Checklist design for aircraft, where the vast majority of eventualities can be anticipated, is therefore a relatively simpler task than attempting to adopt the same approach in health care.

However, despite such limitations, systematic reviews of the use of safety checklists in the operating room demonstrate their substantial benefits in terms of improving patient outcomes, but only when teams engage with the checklist process and when compliance with checklist items is high.^{10–15} One study found no improvements in postoperative survival rates when checklists were not completed or when completed only in part, but showed significant survival benefits when checklists were fully completed.¹⁶ Checklist design is not a trivial process. The checklist should be short; its design must be based on the best clinical knowledge, and it must not be influenced by managerial concerns regarding the medico-legal protection of the organization.^{1,17,19} A formal process for the introduction of a safety checklist is typically needed so that clinicians know how the checklist should be used.^{4,7} Engagement by key team personnel is also important to establish a safety culture that encourages and maintains compliance with the checklist for every patient.^{5,18}

The article by De Bie and colleagues²⁰ in this issue of the British Journal of Anaesthesia describes an in situ simulation study of a new electronic dynamic clinical checklist (DCC), which contains two significant innovations with the potential to solve a number of important problems in the successful use of checklists in health care and to advance patient safety more widely.^{21, 22} These innovations are as follows: (1) meaningful sharing and integration of information between multiple hospital systems; and (2) automatic preparation of a personalized electronic checklist of items relevant to the care of each individual patient. The DCC system achieves this by using a set of algorithms to select checklist items relevant to each patient in the intensive care unit based on information accessed from the patient's electronic health record, the hospital's treatment protocols, and

pharmaceutical databases. The algorithms can also automatically check certain items when the system has access to the relevant information, hence reducing the checklist burden on the clinician. Comparing the use of their hospital's standard paper-based checklist with the new DCC during 116 in situ simulations demonstrated an increase in completion rate of checklist items from 74 to 100%. Participants rated their satisfaction with the DCC highly and agreed that the approach had potential in medical care. In addition, follow-up by the pharmacist after the simulated ward round, as prompted by alerts from the hospital's clinical decision support system, reduced dramatically from 80% to only 3.6% with use of the DCC. The use of simulation is becoming more common for the purposes of evaluating new safety interventions and in making inferences about team behaviour in the clinical setting.²³ Given the evidence that compliance with checklists is an essential part of their effectiveness in improving patient outcomes, we might therefore expect the DCC to have substantial potential to improve clinical care in the intensive care unit, and I look forward to these clinical studies.

Many hospital systems and devices currently have some facility for sharing certain information with other devices, but few have achieved the kind of meaningful, safety-orientated integration that is reported here with the DCC. One potential risk of the success of the WHO Surgical Safety Checklist is that the use of checklists has now become so widely mandated throughout health care that poorer quality checklists may be introduced into use, and checklists may be introduced into practice areas where they are less effective; both outcomes are likely to lead to disengagement by clinicians. 9,24,25,26 In contrast, allowing the algorithms of the DCC to access all relevant data when generating checklist items for individual patients means that the resulting personalized checklist is immediately relevant to the patient's care. Unlike a paper-based or static checklist, non-relevant or generic checklist items need not appear on the DCC. From a psychological perspective, the salience of any message or signal is determined by its informational content or informativeness, hence messages that contain misinformation or false alarms tend quickly to be ignored.²⁷ Therefore, a checklist with few or no generic items would be expected to be more salient for the user. As the authors state, in this sense the DCC is a true cognitive aid, in that it supports and assists the clinician in getting his or her job done, rather than potentially being viewed as a mandatory requirement, of variable relevance, that might add further burden to their existing workload. The DCC is therefore likely to engage clinicians better and to encourage

them to check every item, as occurs during every flight with an aviation checklist. Further research considering what happens to clinicians' work patterns when the DCC is used in the clinical setting and whether it has indeed become integrated into their workflow will be interesting, particularly given that conversion of other formerly physical records into electronic formats (e.g. radiographs and patient notes) has often had unanticipated consequences.²²

I was interested that the feature which allows certain checklist items to be completed automatically by the DCC could be overridden by clinicians, if they preferred to complete such a check themselves. The tailoring of the set of algorithms of such a dynamic checklist system is clearly important for many reasons; in order to adjust sensitivity to the kinds of events that clinicians want to monitor, to update the checklist items when clinical knowledge changes, and to customize the checks for particular patient populations or clinician preferences. If systems such as the DCC become more widespread, I expect that additional work will be done to fine-tune the algorithms that generate the checklists. This work could determine what kinds of information the checklist algorithms need to access to make the best checklists, and what the optimal hierarchy or prioritization of checklist items might be to produce a checklist that tells you all you need to know but isn't too long. Electronic systems, such as the DCC, make it easy to update such features, because like all software, updates can propagate out from a central location to all devices in the network, and there will be no physical copies of the old version of the checklist to remove from use.

The DCC represents an example of a system where electronic clinical information has been meaningfully synthesized from various hospital systems, and non-relevant information has been filtered out. I believe such an approach will have many applications in the improvement of the quality and safety of patient care in the near future, particularly if we are indeed at the dawn of medicine's computer age.^{21,22,25}

One pressing area of need for such an approach is that of alarm management in operating rooms and intensive care units, and this is an area where health care could again benefit from the techniques used in aviation. The functional integration possible in many clinical devices is currently limited and hampered by various different proprietary formats and standards. The practical consequence of this is that many devices, from drug infusion pumps to patient monitors, generate their own stream of alerts and alarms independently of each other, without any co-ordination or prioritization, leading to a cacophony of auditory alerts where important alarms can be lost amongst trivial ones. This leads to alarm fatigue, where alarms may be

ignored or switched off. A recent study of this problem reported from a single hospital, with 77 intensive care beds, recorded the occurrence of an astonishing 2558760 unique physiological alarms during intensive care in a single month.²⁸ In aviation, the alarm fatigue problem is managed by engineers and pilots working co-operatively to agree upon exactly what needs to be alerted to the pilot from all aircraft systems and what does not. Agreed alarms are then placed hierarchy. with manv events beina reported only as 'cautions' or 'advisories' on a screen, but without any auditory alert. Pilots would not tolerate the alarm chaos that clinicians currently face. Even an event as apparently serious as an engine failure in a multi-engine aircraft will not result in a top-level alarm with an auditory alert, but only a caution. This is because such an event does not require immediate pilot intervention owing to the automatic systems on modern aircraft.²² The manufacturers of components for aircraft cockpits must meet very specific compatibility standards, but at present this is not the case in health care. Although checklists, either dynamic or otherwise, are a successful approach to align and increase the consistency of key procedural aspects of patient care, such alignment needs to extend beyond procedures to include the equipment used in clinical environments. 29

We know that paper checklists, when well designed, properly introduced, and complied with, can substantially reduce the burden of postoperative complications. The electronic DCC reported in this issue of the British Journal of Anaesthesia represents an important development beyond paper or static checklists, in that the checklist is automatically tailored to each patient by drawing on various sources of patient data. The results of a simulation study in the intensive care unit are encouraging, including excellent checklist compliance. The next step will be clinical trials of the DCC in order to determine whether the excellent compliance rates seen in the simulator translate into improvements in the safety and quality of patient care. The information filtering and prioritization features of a dynamic checklist also seem highly suitable for solving other difficult problems in health care, such as the alarm management problem.

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Appendix B

Questionnaires and results of two clinical studies

User acceptance of the ICU round checklist and the PCI pre-operative checklist.

Abbreviations: N.A. = not applicable; DCC = dynamic clinical checklist.

		1	2	3	4	5	
	Question/score	Totally	Disagree	Neutral	Agree	Totally	ICU/
		disagree				agree	PCI
	Usability:						
		_	=	Ξ	36.36%	63.64%	DOL
U1	Overall, I am satisfied with how easy it				(n=4)	<u>(n=7)</u>	<u>PCI</u>
01	is to use DCC.	=	<u>5%</u>	=	60%	<u>35%</u>	ICII
			<u>(n=1)</u>		(n=12)	<u>(n=7)</u>	<u>ICU</u>
		=	=	=	36.36%	63.63%	PCI
U2	It was simple to use DCC.				<u>(n=4)</u>	<u>(n=7)</u>	101
02	it was simple to use DCC.	=	<u>5%</u>	=	<u>55%</u>	<u>40%</u>	ICU
			<u>(n=1)</u>		<u>(n=11)</u>	<u>(n=8)</u>	100
		=	=	=	18.18%	81.82%	PCI
U3	I was able to complete the tasks and				(n=2)	<u>(n=9)</u>	<u>1 01</u>
	scenarios quickly using DCC.	_	=	<u>20%</u>	<u>65%</u>	<u>15%</u>	ICU
				<u>(n=4)</u>	(n=13)	(n=3)	
		=	=	=	<u>27.27%</u>	<u>72.73%</u>	PCI
U4	I was able to efficiently complete the				(n=3)	(n=8)	
	tasks and scenarios using DCC.	=	=	<u>15%</u>	<u>70%</u>	<u>15%</u>	ICU
				(n=3)	(n=14)	(n=3)	
		=	=	=	27.27%	72.73%	PCI
U5	I felt comfortable using DCC.				(n=3)	(n=8)	
		=	10%	<u>5%</u>	60%	<u>25%</u>	<u>ICU</u>
			<u>(n=2)</u>	<u>(n=1)</u>	(n=12)	(n=5)	
		=	Ξ	Ξ	27.27%	72.73%	<u>PCI</u>
U6	I quickly understood on how to interact				(n=3)	(n=8)	
	with DCC.	=	=	=	45%	<u>55%</u>	<u>ICU</u>
					(n=9)	(n=11)	
	It was a service was developed the items	=	=	=	27.27%	72.73%	<u>PCI</u>
U7	It was easy to understand the items provided by DCC.				(n=3)	(n=8)	
	provided by DOC.	=	=	=	65% (n=13)	35% (n=7)	<u>ICU</u>
					(N=13) 27.27%	<u>(n=7)</u> 72.73%	
	It was easy to find the information I	=	=	=	<u>27.27%</u> (n=3)	<u>/2./3%</u> (n=8)	<u>PCI</u>
U8	needed.	_	_	20%	55%	25%	
	nocucu.	Ξ	=	(n=4)	(n=11)	(n=5)	<u>ICU</u>
				<u>(11–4)</u>	<u>(11= 1 1)</u>	<u>(11=5)</u>	

		1	2	3	4	5	
	Question/score	Totally	Disagree	Neutral	Agree	Totally	ICU/
		disagree				agree	PCI
		=	=	9.09%	27.27%	63.64%	PCI
U9	The interface of DCC was pleasant.			(n=1)	(n=3)	(n=7)	<u>FGI</u>
00		=	10%	<u>15%</u>	55%	20%	ICU
			<u>(n=2)</u>	(n=3)	<u>(n=11)</u>	(n=4)	100
		=	=	=	36.36%	63.64%	PCI
U10	I liked using the interface of DCC.				<u>(n=4)</u>	<u>(n=7)</u>	<u></u>
		=	<u>5%</u>	<u>25%</u>	50%	20%	ICU
			<u>(n=1)</u>	(n=5)	(n=10)	<u>(n=4)</u>	
		=	=	=	27.27%	72.73%	PCI
U11	I could effectively complete the tasks				<u>(n=3)</u>	(n=8)	
	and scenarios using DCC.	=	=	=	<u>80%</u>	20%	ICU
					<u>(n=16)</u>	(n=4)	
	Whenever I made a mistake using	=	=	18.18%	27.27%	54.55%	PCI
U12	DCC, I could recover easily and quickly. (N=19)			(n=2)	(n=3)	(n=6)	
		=	=	45%	40%	10%	ICU
				(n=9)	(n=8)	(n=2)	
		=	=	9.09%	36.36%	54.55%	PCI
U13	The lay-out of information on the		2001	(n=1)	(n=4)	(n=6)	
	screens was clear.	=	20%	20%	55%	<u>5%</u>	<u>ICU</u>
	Training & Support:		<u>(n=4)</u>	<u>(n=4)</u>	<u>(n=11)</u>	<u>(n=1)</u>	
	Training & Support.						
		=	=	9.09%	27.27%	63.64%	PCI
T1	Training in the use of DCC was sufficient.			(n=1)	(n=3)	(n=7)	
	SUTTICIENT.	=	=	<u>15%</u>	60%	25%	<u>ICU</u>
				(n=3)	(n=12)	(n=5)	
	It was easy to get acquainted using	=	=	=	27.27%	72.73% (n=8)	<u>PCI</u>
T2	, , , ,			F0/	(n=3)		
	DCC. The manual of DCC was clear.	=	=	<u>5%</u>	60%	35% (p. 7)	<u>ICU</u>
				(n=1) 9.09%	(n=12) 18.18%	(n=7) 72.73%	
	It was easy to find guideline-related	=	=	9.09% (n=1)	18.18% (n=2)	<u>/2./3%</u> (n=8)	<u>PCI</u>
Т3	information in DCC.	_	_	25%	50%	25%	
	Information in DCC.	=	=	(n=5)	(n=10)	(n=5)	<u>ICU</u>
				<u>(II=5)</u>	<u>(II= IU)</u>	<u>(II=3)</u>	

	Question/score	1 Totally disagree	2 Disagree	3 Neutral	4 Agree	5 Totally agree	ICU/ PCI
	Behavior change				E 4 E E 0 /	45 450/	
B1	Working with DCC has changed my	=	=	=	54.55% (n=6)	45.45% (n=5)	<u>PCI</u>
	way of quering patient data.	=	10% (n=2)	<u>55%</u> (n=11)	35% (n=7)	=	<u>ICU</u>
B2	Working with DCC makes me more	Ξ	=	=	54.55% (n=6)	45.45% (n=5)	<u>PCI</u>
DZ.	aware on how to use patient data.	=	10% (n=2)	30% (n=6)	<u>55%</u> (n=11)	<u>5%</u> (n=1)	<u>ICU</u>
В3	Working with DCC has limited the	Ξ	=	=	36.36% (n=4)	63.64% (n=7)	<u>PCI</u>
	amount of entered patient data.	=	25% (n=5)	45% (n=9)	15% (n=3)	15% (n=3)	<u>ICU</u>
B4	By using the ICU checklist I think I will	Ξ	=	=	27.27% (n=3)	72.73% (n=8)	<u>PCI</u>
	get less feedback from the nurses.	<u>5%</u> (n=1)	Ξ	20% (n=4)	45% (n=9)	30% (n=6)	<u>ICU</u>
B5	I prefer feedback before my actions	=	9.09% (n=1)	18.18% (n=2)	18.18% (n=2)	54.55% (n=6)	<u>PCI</u>
В	rather than reminders afterwards.	=	=	<u>5%</u> (n=1)	65% (n=13)	30% (n=6)	<u>ICU</u>
B6	I am prepared to encode patient	9.09% (n=1)	=	=	36.36 (n=4)	54.55% (n=6)	<u>PCI</u>
	information (e.g. allergy) in DCC.	Ξ.	=	10% (n=2)	70% (n=14)	20% (n=4)	<u>ICU</u>
В7	By using DCC, I don't spend more time	Ξ	=	9.09% (n=1)	18.18% (n=2)	72.73% (n=8)	<u>PCI</u>
	on pre-operative check.	Ξ	=	20% (n=4)	<u>55%</u> (n=11)	25% (n=5)	<u>ICU</u>
В8	The ward team becomes more	=	=	0.09% (n=1)	18.18% (n=1)	81.82% (n=9)	<u>PCI</u>
	structured when DCC is used.	<u>=</u>	<u>5%</u> (n=1)	<u>5%</u> (n=1)	50% (n=10)	35% (n=7)	<u>ICU</u>

		1	2	3	4	5	
	Question/score	Totally	Disagree	Neutral	Agree	Totally	ICU/
		disagree				agree	PCI
	Usefulness:						
		=	=	=	<u>27.27%</u>	<u>72.73%</u>	PCI
Us1	I support the use of decision support				(n=3)	<u>(n=8)</u>	<u> </u>
	systems in my ward.	=	=	<u>5%</u>	<u>60%</u>	<u>35%</u>	ICU
				<u>(n=1)</u>	(n=12)	<u>(n=7)</u>	100
		=	=	=	<u>27.27%</u>	<u>72.73%</u>	PCI
Us2	I like to see DCC-like systems				(n=3)	<u>(n=8)</u>	
	implemented in other departments.	Ξ	<u>5%</u>	<u>40%</u>	<u>35%</u>	20%	ICU
			<u>(n=1)</u>	<u>(n=8)</u>	<u>(n=7)</u>	<u>(n=4)</u>	
	DCC is usable as a training and	=	=	Ξ	27.27%	72.73%	<u>PCI</u>
Us3	guidance tool. The patient will benefit				(n=3)	(n=8)	
	from DCC.	Ξ	=	Ξ	<u>70%</u>	30%	<u>ICU</u>
					(n=14)	(n=6)	
	I think that the 1011 was allowed as a soldier.	=	=	=	18.18%	81.82%	<u>PCI</u>
Us4	I think that the ICU ward round checklist			F0/	(n=2)	(n=9)	
	of DCC can prevent medical errors.	=	=	<u>5%</u>	<u>50%</u>	<u>45%</u> (n=9)	<u>ICU</u>
				<u>(n=1)</u>	(n=10) 18.18%	81.82%	
	I think DCC can improve the quality of	=	=	=	(n=2)	(n=9)	<u>PCI</u>
Us5	care on the hospital wards.	_	_	_	80%	20%	
	oard on the Hospital Wards.	_	_	-	(n=16)	(n=4)	<u>ICU</u>
		<u>=</u>	<u>=</u>	18.18%	27.27%	54.55%	
Us6	If the DCC is not available I have the feeling of forgetting items.	_	_	(n=2)	(n=3)	(n=6)	<u>PCI</u>
080		=	10%	<u>45%</u>	<u>35%</u>	<u>10%</u>	ICIJ
			(n=2)	<u>(n=9)</u>	<u>(n=7)</u>	<u>(n=2)</u>	<u>ICU</u>

		1	2	3	4	5	
	Question/score	Totally disagree	Disagree	Neutral	Agree	Totally agree	ICU/ PCI.
	Behavior change						
	DCC generates the right amount of	=	<u>=</u>	9.09%	36.36%	54.55%	PCI
G1	checkable items for the pre-operative		100/	(n=1)	(n=4)	(n=6)	<u> </u>
	checklist.	=	<u>10%</u>	<u>15%</u>	<u>65%</u>	<u>10%</u>	ICU
	CHECKISI.		(n=2)	(n=3)	(n=13)	(n=2)	100
		=	=	=	36.36%	63.64%	PCI
G2	Overall, I think DCC is a useful tool.				<u>(n=4)</u>	(n=7)	<u> </u>
	Overall, I think DCC is a useful tool.	=	Ξ.	=	<u>80%</u>	<u>20%</u>	1011
					<u>(n=16)</u>	<u>(n=4)</u>	<u>ICU</u>
	It is convenient that DCC can	=	=	Ξ	27.27%	72.73%	PCI
G3	automatically check items based on				(n=3)	(n=8)	<u>FCI</u>
	•	<u>=</u>	<u>15%</u>	<u>5%</u>	<u>60%</u>	<u>20%</u>	1011
	medical rules.		(n=3)	<u>(n=1)</u>	<u>(n=12)</u>	<u>(n=4)</u>	<u>ICU</u>
		=	=	=	36.36%	63.64%	PCI
G4	DCC generates correct checkable items				<u>(n=4)</u>	(n=7)	101
	for most patients.	=	=	<u>5%</u>	<u>65%</u>	<u>30%</u>	ICII
				<u>(n=1)</u>	<u>(n=13)</u>	<u>(n=6)</u>	<u>ICU</u>
		=	=	=	27.27%	72.73%	PCI
G5	Overall, I am satisfied with DCC.				<u>(n=3)</u>	<u>(n=8)</u>	<u>FUI</u>
	Overall, I am satisfied with DOC.	=	=	<u>5%</u>	<u>65%</u>	<u>30%</u>	1011
				<u>(n=1)</u>	(n=13)	<u>(n=6)</u>	<u>ICU</u>
G6	I rate the ICU ward round checklist of 4.55 out of 5						<u>PCI</u>
	DCC with a (1 to 5):		4	1.13 out of 5			<u>ICU</u>

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Summary

Dynamic Checklists: Design, Implementation and Clinical Validation

Preventable medical errors are major concerns in modern healthcare. They are caused by caregivers' ignorance and deviation from the best practice due to the complexity of medical procedures and the reliance on human memory. To overcome these problems, the checklist, a cognitive assistance tool, has been introduced from high-reliable industries to healthcare in recent years. Several clinical studies indicate that properly designed and implemented checklists can improve the adherence to best practice and reduce adverse events.

Unfortunately, numerous subsequent studies have failed to reproduce this success. This failure can be attributed to the low completion rate and low compliance rate of checklists due to inappropriate implementation. This should be no surprise if one considers that these checklists are still implemented as paper forms or static computerized forms, which are independent of clinical workflow and patient conditions. It is believed that developing dynamic checklists, which can be adapted to clinical workflow and to specific to patient conditions, could improve the adherence and clinical outcome, compared with static checklists. This thesis concentrates on the design of dynamic checklist, the development of support systems for dynamic checklists, and clinical evaluations of their effectiveness.

The first research question is "what are the necessary features of dynamic checklists". Since the dynamic checklist is still a newly proposed trend of checklist development, it is yet unclear which features dynamic checklists should have. A mixed approach was applied to answer this research question. A literature review was carried out to identify the success factors and barriers of checklist implementations. Basic functionalities were

extracted from the success factors and requirements regarding the dynamicity were summarized out of the barriers. Referencing to the emerging trends in related research areas, additional considerations were analyzed and summarized as desired dynamic checklist features. By combining these features, a comprehensive functional model was developed.

The second research question is how to make these dynamic checklists shareable between technical platforms and organizations. In order to share dynamic checklists, a technical platform-independent model of dynamic checklists is required. This metamodel should capture the generic computerized representation requirements without considering the technical execution. A three-tier model was developed to this end. Open technical standards from workflow management and clinical decision support areas were used to validate the feasibility of using the meta-model. The result shows that by using the meta-model, different modeling languages and modeling tools can be used interchangeably.

The third research question is how to execute dynamic checklists in computerized systems and implement them in a general way. To address this question, we designed a checklist execution mechanism that is based on our functional meta-model. Workflow execution and rule-based reasoning were used to fulfill the process-oriented and patient context-aware requirements, respectively. The results of execution were used to synthesize the content of dynamic checklists. A dynamic checklist platform that is configurable by clinical users has been developed as a general tool for dynamic checklist implementation.

The fourth research question is whether dynamic checklists are better than static checklists in terms of acceptance, adherence, and clinical outcomes. Using our dynamic checklist platform, two case studies were carried out in two hospitals in the Netherlands and China. These two studies pertained to different clinical scenarios, medical cultures, and hospital information system infrastructures.

A case study on ICU round checklists was carried out to evaluate the effectiveness and feasibility of using dynamic checklists for complicated clinical scenarios. An ICU round checklist and supporting system were developed in a Dutch tertiary teaching hospital. A simulation-based clinical trial was designed and organized. The results show that compared with paper-based checklists; the dynamic checklist can improve the adherence to best practice while doing the round, reducing medication errors significantly. The users were satisfied with the dynamic checklist.

Another case study on PCI pre-operative care was carried out to validate the feasibility of using dynamic checklists for complex clinical processes. A PCI pre-operative checklist was developed in a Chinese tier-three hospital. A randomized clinical trial was carried

out to validate the effectiveness of dynamic checklists. Pre-operative hydration rate was significantly improved by this dynamic checklist.

The final research question of this thesis is "what are the success factors and barriers while implementing dynamic checklists". To our best knowledge, this is the first systematic study on dynamic checklists. Summarizing the success factors and barriers while implementing dynamic checklists from our own experience could be beneficial for others working on dynamic checklist related research. The experiences and lessons were summarized out of the two case studies. Future research directions were also synthesized.

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Curriculum Vitae

Shan Nan was born on 1st of March, 1986 in Xi'an, China. After finishing his BSc in 2008 at Northwestern Polytechnical University in China, he continued his Master and Doctoral study of Medical Informatics at Zhejiang University in China. From 2012 he started a joint PhD project supported by the Brain Bridge Program at Eindhoven University of Technology in the Netherlands of which the results are presented in this dissertation. Since 2020 he is employed at Hainan University, China.

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