

Design and implementation of a platform for configuring clinical dynamic safety checklist applications*

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Abstract: In recent years, it has been demonstrated that checklists can improve patient safety significantly. To facilitate the effective use of checklists in daily practice, both the medical community and the informatics community propose to implement checklists in dynamic checklist applications that can be integrated into the clinical workflow and that is specific to the patient context. However, it is difficult to develop such applications because they are tightly intertwined with the content of specific checklists. We propose a platform that enables access to dynamic checklist applications by configuring the infrastructures provided in the platform. Then, the applications can be developed without time-consuming programming work. We define a number of design criteria regarding point of care and clinical processes by analyzing the existing checklist applications and the lessons learned from implementations. Then, by applying rule-based clinical decision support and workflow management technologies, we design technical mechanisms to satisfy the design criteria. A dynamic checklist application platform is designed based on these mechanisms. Finally, we build a platform in various design cycle iterations, driven by multiple clinical cases. By applying the platform, we develop nine comprehensive dynamic checklist applications with 242 dynamic checklists. The results demonstrate both the feasibility and the overall generic nature of the proposed approach. We propose a novel platform for configuring dynamic checklist applications. This platform satisfies the general requirements and can be easily configured to satisfy different scenarios in which safety checklists are used.

Key words: Checklist; Workflow; Clinical decision support; Process management; Patient safety

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1 Introduction

It has been estimated that 50% of hospitalized patients are threatened by preventable medical errors (Baker et al., 2004). This is because medical procedures are still largely based on human memory,

which is error prone (Shillito et al., 2010). Checklist, a cognitive tool to improve short-term memory, which has been used widely in high-risk industries such as aviation and nuclear energy, has been introduced to healthcare in recent years (de Vries et al., 2009; Weiser et al., 2010; Ziewacz et al., 2011; Mullan et al., 2014). Several well-established pilot studies have demonstrated the potential for using safety checklists to standardize care procedures, prevent medical errors, and improve quality of care (Wenzel and Edmond, 2006; Haynes et al., 2009; de Vries

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et al., 2010; Arriaga et al., 2013). Subsequent large-scale clinical studies indicate that the potential can be fully exploited only by implementing these checklists effectively (Borchard et al., 2012; Rydenfält et al., 2014). For example, the traditional checklist forms (i.e., plain paper sheets or rigid web forms passively waiting for action) are not well-received by clinical users (Fourcade et al., 2012; Russ et al., 2015). Thus, researchers in both the healthcare community (de Vries et al., 2009; Hassell et al., 2010; Antnes, 2015; Grigg, 2015) and the clinical informatics community (Avrunin et al., 2012; Nan et al., 2014) suggest using computerized smart applications to facilitate the implementation. With the help of these applications, checklists can be assigned to a specific person at the right time and customized to the specific patient situation. In our study, we call this type of application a dynamic checklist application to emphasize the dynamic nature of both the workflow and the checklist content.

There has been a considerable amount of effort in developing dynamic checklist applications, and various dynamic aspects of the healthcare domain are covered, ranging from helping doctors to gather patient information at the point of care to assigning the proper checklist to the right person at the right time in the care process (Avrunin et al., 2012; Nan et al., 2014; Pageler et al., 2014; Thongprayoon et al., 2014). These dynamic checklist applications have gained higher user acceptance, more frequent use, and better results compared with the same checklists that are implemented in the rigid traditional forms (Idahosa and Kahn, 2012; Garg et al., 2015). However, the success is difficult to repeat or transfer to other researchers, because they have to develop their own dynamic checklist applications from scratch. Therefore, these kinds of effective implementation are currently available only in a few hospitals with strong research informatics and development backgrounds.

It would be possible for more healthcare organizations to benefit from dynamic checklist applications if there were a platform that allows them 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 study, we aim to design and validate a platform that allows hospitals to create their own dynamic checklist applications efficiently by configuring software components. To reach the goal, two research questions need to be answered: (1) Which features should dynamic checklist applications provide in general? (2) Which 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 the configuration mechanisms. The platform has been validated against a number of clinical use cases in a Dutch hospital.

2 Methods

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

2.1 Design criteria

A number of safety checklist applications, in both paper and digitalized forms, 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.

2.1.1 Facilitating adapting checklists at the point of care

All of the safety checklists, ranging from the early anesthesia machine checklist (Liu et al., 2010), the central line checklist (Amarasingham et al., 2007), 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 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 (Fourcade et al., 2012). However, making a checklist that is more specific and targeted to each patient is believed to be the key to solving the problem (Thongprayoon et al., 2014). 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; (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 a perception of lack of direct benefit to clinical users should also be counted as a barrier to implementation (Grigg, 2015). 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 proposed 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 benefit evidence related to the checkable items.

2.1.2 Facilitating application of checklists in clinical processes

Another important aspect in the implementations is the integration of checklists into clinical processes. Forgetfulness is a major problem when using checklists in healthcare procedures (de Vries et al., 2009). 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.

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 to reflect the actual clinical workflow. Additionally, considering the complexity of some clinical processes, 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.

2.2 Mechanisms available for supporting dynamic checklist applications

In this section, 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 design criteria that were mentioned.

2.2.1 Adapting checklists at the point of care by making checklists related to the patient context

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 stored in hospital information systems, including demographic information, diagnosis, examinations performed, laboratory tests, and prescriptions.

Clinical rules have been well studied in the past few decades by computerized guideline researchers. Test network languages (TNL) were developed to represent the logical relationship between patient context and predefined tasks (Peleg, 2013). Knowledge acquisition and execution mechanisms and tools have been developed accordingly. Typically, a clinical rule can be configured by editing clinical rules in a flowchart format in the knowledge acquisition tool. The 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.

2.2.2 Applying checklists in clinical processes by making checklists process-oriented

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 interoperability between the WfMS and other information systems (Malhotra et al., 2007; Gooch and Roudsari, 2011). In contrast to academically driven clinical decision support systems, WfMSs are industry-driven. Therefore, a reference model was developed as the common basis for developing and deploying such a system. Typically, a workflow engine is at the core of a WfMS, and executes the pre-defined 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.

2.3 Dynamic checklist application platform

In this section, we provide an architectural design for the dynamic checklist application platform and explain how the dynamic checklist application platform is designed and configured.

2.3.1 Architectural design

Since the TNL-based clinical decision support systems and WfMSs can facilitate the implementation of dynamic checklists, we reused their infrastructures in the dynamic checklist application platform architecture. In Fig. 1, we demonstrate the technical architecture of the general dynamic checklist application. In the architecture, we distinguish the

Editor and the Runtime. The Editor facilitates encoding of checklist-related knowledge in a way that Runtime can use it. The Editor includes a workflow editor to model the clinical 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.

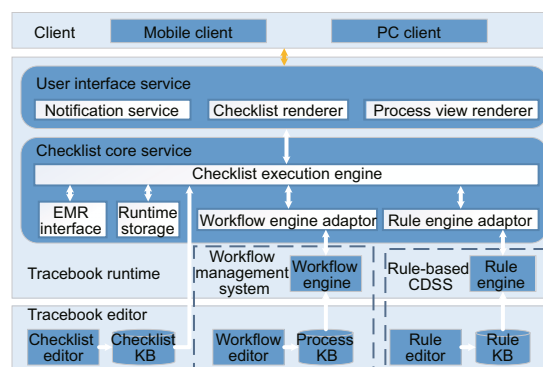


Fig. 1 Technical architecture of the platform

Once the knowledge is acquired by the Editor, the Runtime can execute checklists in clinical settings in a process-oriented and context-aware way. There are four distinct functional components in the Runtime. The workflow engine is used to provide workflow related features, e.g., to disseminate a checklist to a specific role/person or query the state of a checklist (not-handled, open, handled-incomplete, and handled-complete). The rule engine is used to provide patient-context-related features, e.g., create patient-specific checkable items, filter patient data for a specific scenario, and perform automatic checks. The Checklist Core Service makes checklists process-oriented and context-aware by integrating patient data with the workflow engine and the rule engine. The workflow engine adaptor and the rule engine adaptor are used to interface with the engines. The EMR Interface queries data and catches events from the EMR systems. The Checklist Execution Engine coordinates these services to create dynamic checklists. Checked results are stored by the Runtime Storage in a database for further use. Finally, the User Interface Service acts as an interface to the client. Reminders are sent to specific users by the Notification Service. Checklist content and process are rendered here to provide better user experience.

2.3.2 Configuring the platform for dynamic checklist applications

We reuse the knowledge acquisition tools and knowledge base in these systems (dashed rectangles in Fig. 1). The workflow engine adapter and rule engine adapter are designed as plugins. As a result, developers can conveniently interface the platform with various WfMSs and CDSSs by wrapping APIs provided by those systems as plugins.

3 Results

By using the platform, we have configured various dynamic checklist applications for distinct departments and scenarios. In particular, we interfaced the workflow engine adapter with the business management system APIs from BizAgi Express. BizAgi is a popular commercial business process management system used in various industries. For the rule engine, we chose Gaston, which is a GLIF 2.0 based clinical decision support system implemented in our collaborating hospital.

In this section, we first chose the most illustrative application, a coronary artery bypass graft (CABG) peri-operative checklist application,

to demonstrate the feasibility of the platform. Then, we show various dynamic checklist applications that we have configured with the platform.

Result 1 It is feasible to configure a model-based dynamic checklist application to such a degree that detailed constraints are considered.

We first modeled the peri-operative care workflow (Fig. 2) 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 (Fig. 3). 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 (Fig. 4).

We implemented each fragment of a checklist as a guideline in Gaston (Fig. 5). For each checkable item in the fragment of the checklist, we implemented it as a task. In each task, we defined the content of the checkable item (including links to patient data) and an explanation of the item if needed.

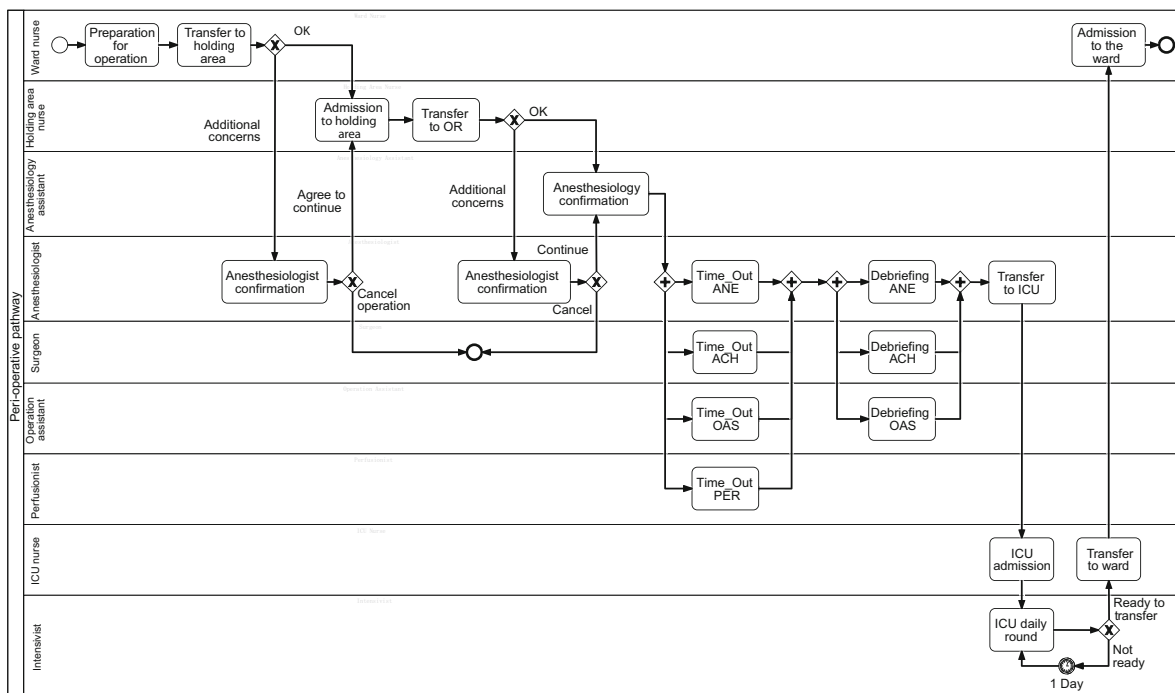


Fig. 2 The coronary artery bypass graft peri-operative pathway

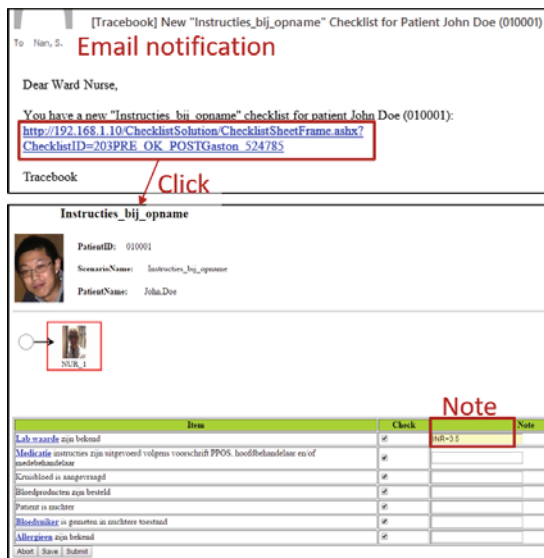


Fig. 3 A notification in the email form

Additionally, decision logic was used to highlight items, provide personalized items, and pre-check items for a double-check. We took the analgesia-related items as an example. The checkable items were 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 was not evaluated either, a pre-checked checklist for double-checking will be provided to the intensivists to confirm it. Otherwise, if the pain score

was less than 4, there will be no checkable item regarding analgesia for this patient, whereas if the pain score was equal to or greater than 4, a warning item mentioning that analgesia should be prescribed was provided.

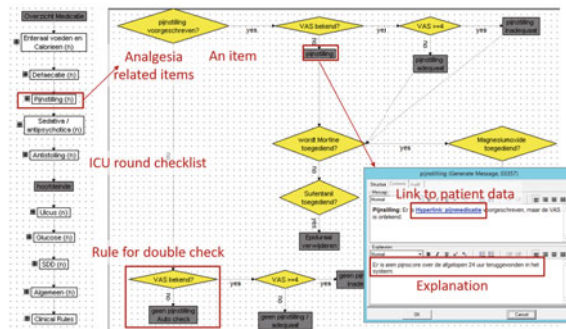


Fig. 5 Implementation of the ICU round checklist

The content of the ICU round checklist is in Fig. 6. 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.

Result 2 The dynamic checklist application platform is generic to implement.

The generic nature of the dynamic checklist application platform has been validated through implementation and testing of various checklists, all of which have quite different natures. Furthermore, the validation consisted of letting different

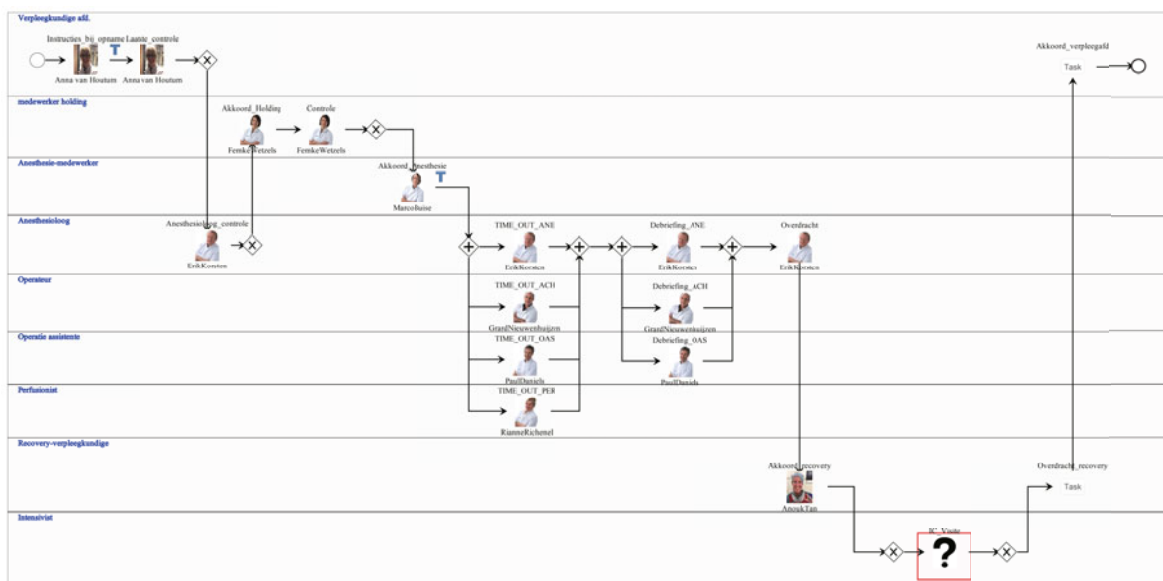


Fig. 4 Peri-operative care use case implementation

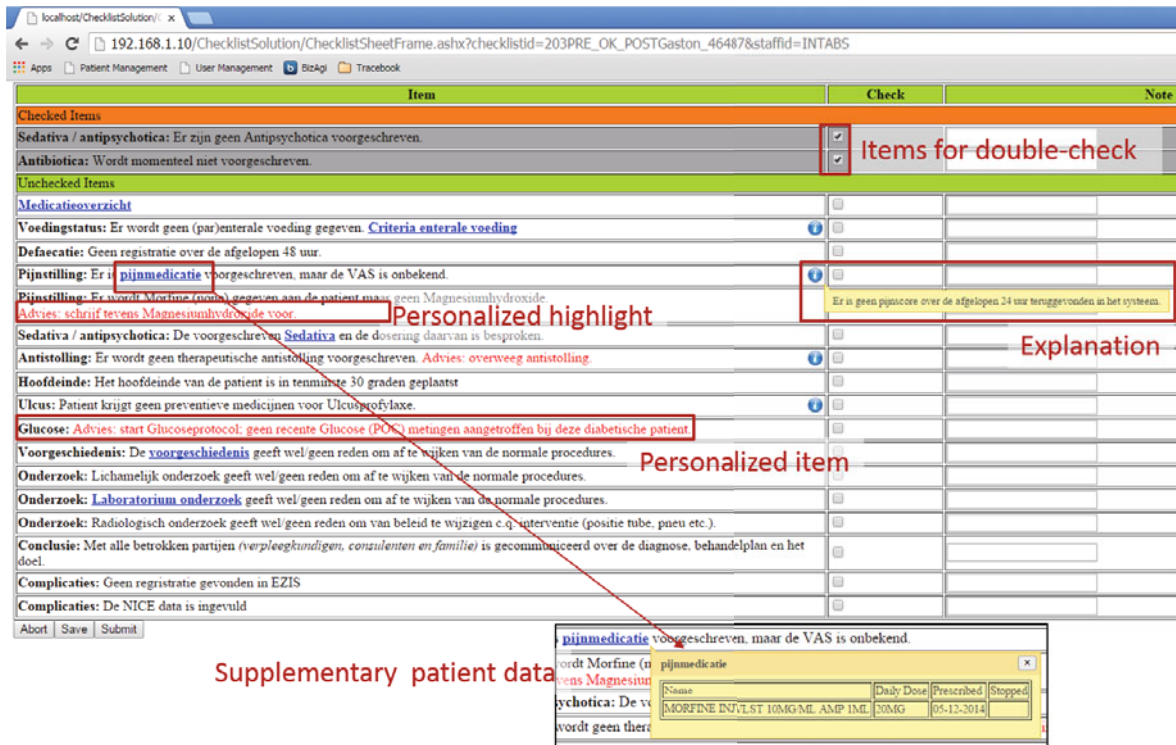


Fig. 6 ICU daily round checklist

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, and a breast cancer checklist set by various researchers in our collaborating hospital. The full list of these checklists can be found in Table 1. 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 was reported elsewhere (de Bie et al., 2017).

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 were developed for various scenarios from routine jobs such as the daily rounds in the ICU to emergency jobs like resuscitation. The configuration models are 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 Discussion

The goal of the research is to provide a platform, by which developers can easily configure dynamic checklist applications for various purposes and scenarios. We formulated two aspects in 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. 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 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 the infrastructure that developers can reuse. Additionally, the workflow engine and rule engine used in the platform can be reused from existing hospital information systems. This would not only reduce the cost of software development and train-

Table 1 Dynamic checklist applications developed with the platform

Name	Number of checklists	Description
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	7	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	1	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	1	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.
Resuscitation protocol checklist set	6	A checklist for the standardized steps in advanced life support. Helps participants to know each other, to count the rounds, and to 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	23	Used for the longitudinal care process for bariatric surgery ranging from pre-operative care to follow-up after five years. These checklists are developed from clinical guidelines and refined with surgeons. Developed by a bachelor student under the supervision of a gastric surgeon.
Lung cancer surgery checklist set	15	A set of peri-operative checklists for lung cancer surgery based on the lung cancer surgery clinical pathway published by the Ministry of Health of the People's Republic of China. Developed by a master student under the supervision of a surgeon.
Breast cancer diagnosis and treatment pathway checklist set	172	A group of checklists for the comprehensive process of breast cancer from screening to diagnosis and treatment. The process is divided into 12 processes including screening, diagnosis, second opinion, hormone therapy, chemo therapy, debulking 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.

ing, but also enable reuse of clinical pathways and clinical rules that have already been modeled in existing systems.

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 (de Bie et al., 2017). Intensivists use the checklist to check patients' general condition and medication usage in the morning round. A simulation-based experiment revealed that this application increases adherence to best practice guideline from 73.6% to 100%, and reduces inap-

propriate prescription from 80% to 3.6%. Users of the application reported high acceptance (4.13 out of 5). In China, a percutaneous coronary intervention (PCI) peri-operative checklist has been implemented in People's Liberation Army General Hospital (Nan et al., 2017). Cardiologists use this application on a daily basis. Users' feedback shows that it can help improve their work efficiency and discover patient abnormalities more effectively.

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 infras-

structure. 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, so we can shift to other reminder methods very easily once we have access to more IT resources.

5 Conclusions

In this study, 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. In this study, we have demonstrated that the use of a model-based approach does not lead to compromises regarding the dynamics or level of details. We have also demonstrated that a model-based approach enables 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 details 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.

Future work will focus on using the platform to validate various applications in larger-scale clinical studies. Such studies would 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. 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 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.

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