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MASTER'S THESIS

MediCheck - A Domain-Specific Modeling Solution for Medical Checklists

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UTRECHT UNIVERSITY

Abstract

Faculty of Science
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Master of Science

MediCheck - A Domain-Specific Modeling Solution for Medical Checklists

by Patrizia Gieske

Context: The contribution of medical checklists to effectively improve patient safety and quality of patient care has been consistently proven throughout the last decades. However, problems regarding their integration into local workflows and their applicability to the given context and case, rooted in the current checklist design and modeling approaches, result in low compliance rates and an overall slow adaptation of checklists in the healthcare domain.
Objective: The aim of this study is to improve the design of medical checklists by designing a domain-specific modeling solution that improves the integration of medical checklists into clinical workflows and enhances their applicability to the context and case.
Methods: This work is based on the DSR approach, combined with the DSML Engineering Method. Based on a thorough domain analysis through literature studies and expert interviews, we developed the abstract syntax, concrete syntax, and semantics of our DSML specification. Through continuous evaluations with domain experts, we incorporated their feedback and made improvements accordingly. We created a simulated implementation of the language specification, called MediCheck for the validation of the the DSM solution. We conducted four scenario-based qualitative simulations with four prospective end-users. We further discussed MediCheck against the specified requirements and conducted a comparative analysis with existing encoding approaches.
Conclusion: Our DSM solution facilitates the life cycle management of medical checklists, customizations on a type- and instance-level, and is comprehensible by medical checklist end-users. We show that MediCheck has the potential to effectively improve the integration of medical checklists into clinical workflows and to enhance their applicability to the context and case.

Acknowledgements

This research project concludes my very exciting and challenging journey of completing my masters abroad and in a very relevant and promising field. Throughout the last two years, the Business Informatics program has pushed me to new limits, challenged me to go beyond what is expected, and showed me that you can achieve anything you aim for with a dash of ambition, curiosity, and discipline, combined with a strong network of smart and supportive people. I had the opportunity to become part of an amazing international group from all over the world and I am very thankful for all the connections and especially the friendships that arose from that. Besides many valuable life lessons, I have gained a tremendous amount of knowledge and skills from a number of different disciplines and I am very proud of the resulting outcome that is my final project.

First of all, I want to thank my first supervisor Hajo Reijers for introducing me to the world of checklists. I have always been drawn to using lists for organizing myself, my thoughts, and my work, but have not seen the opportunities and benefits checklists offer in fields such as healthcare. Your contribution to and impressive presence in academia has led me to approach you as my supervisor and I am very happy with that decision. I have learned a lot about time management, keeping the bigger picture in mind, and prioritizing tasks. I appreciate the great balance between your professional and guiding input and advice while giving me room for my own thoughts and ideas.

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Above all, I consider myself very fortunate for both my family and my friends that are unfailingly supportive and believe in me no matter what. From the reliable supply of coffee to moral support from all around the world, Costa Rica, Germany, the US, Indonesia, right around the corner, or stuck with me in one apartment for months of quarantine, I always feel your love and support and want to thank you for that.

And last but not least, thank you Nick for mastering this chapter together. Thanks to all the brainstorming and feedback sessions we are now both experts in SaaS continuity certification frameworks and medical checklists. Your devil's advocate services and emotional roller coaster companionship has been very special and I always knew we were in it together.

Contents

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List of Abbreviations

HRO	High-Reliability Organizations
SSC	Surgical Safety Checklist
WHO	World Health Organization
CDSS	Clinical decision support system
WfMS	Workflow management systems
MDD	Model-driven development
DSM	Domain-specific modeling
DSML	Domain-specific language
DSML4MC	Domain-specific language for medical checklists
MRQ	Main research question
SQ	Sub-research questions
MC-DSML	DSML for MediCheck
HIS	Hospital management systems
CMIO	Chief Medical Information Officers
CNIO	Chief Nursing Information Officers
IT	information technology
GPML	General purpose modeling language
DSR	Design Science Research
IS	Information System
UML	Unified Modeling Language
CPOE	Computerized provider order entry
HFMA	Healthcare Financial Management Association
PDCA	Plan-do-checked-act
DO	Design objectives
BPMN	Business Process Modeling and Notation
PEoU	Perceived Ease of Use
Cprh	Comprehension
PU	Perceived Usefulness
ItU	Intention to Use
IQR	Inter quartile range

1 Introduction

The vast amount of knowledge and skills acquired during the last century has spawned tremendous discoveries and advances in medicine [1]. At the same time, healthcare has become exceedingly complex, specialized, and interdisciplinary, inadvertently introducing potentially devastating risks [2]. Despite the complexity, medical procedures are still largely based on human memory [3]. Given its natural limitations, reliance on memory has been proven to be a major cause for errors of omission and adverse events [2]. In fact, recent evidence suggests that untoward medical injuries resulting from unsafe care are likely to be one of the ten leading causes of disability and death worldwide [4], [5]. Nonetheless, research consistently indicates that more than half of the deaths and major complications caused by medical errors can be prevented through the use of comprehensive and systematic approaches to patient safety [6], [7].

In so-called High-Reliability Organizations (HROs), organizations that routinely perform hazardous and complex operations with an exceptionally low failure rate, checklists have long been the cornerstone of safety management [8]. Checklists are typically seen as "*a list of action items or criteria arranged in a systematic manner, allowing the user to record the presence/absence of the individual items listed to ensure that all are considered or completed*" [9, p. 231]. They have the potential to standardize what, when, how, and by whom interventions are performed and thus, provide an effective approach for sharing knowledge, coordinating multidisciplinary teams, and ensuring accurate task completion [2], [10]. In this work, we understand medical checklists as a type of checklist that conceptualizes activities or criteria of a specific clinical procedure. With the Surgical Safety Checklist (SSC) that was developed in 2008 by the World Health Organization (WHO) as one of the most popular examples today [11], medical checklists have proven to effectively enhance the quality of care and patient safety [12].

However, compared to other HROs, the introduction of checklists in healthcare has been slow [8]. Unlike industries such as aviation or engineering, formal oversights, frequent mandatory training and practice, and federal regulations that firmly enforce the use of checklists, are not yet part of the checklist culture in healthcare [13], [14]. Above all, a major contributing factor is the unpredictability of the human physiology, which makes the design and implementation of standardized medical checklists inherently more difficult [9], [15]. Thus, a checklist solution in the medical field will likely look different from other HROs, since the complexity that impedes standardization and predictability will always require a level of efficiency and adaptability [15].

1.1 Problem Statement

Despite the proven benefits of medical checklists, their completion and compliance rates have been reported lower than expected [16]. The main factors contributing to these problems, presented below, are primarily rooted in the current design and modeling approaches of medical checklists [17].

I. The content and the design of medical checklists do not account for a number of context factors that impact their applicability to specific cases and situations [17]–[19]. Medical checklists are commonly developed on a national, regional, or organizational level by a designated

group of representatives for prospective checklist users and managers and their content and design subsequently implemented as a standard [19]. Therefore, context factors that are not accounted for include, inter alia, time-pressured emergencies, rapid turn-over cases, and the variability in the patient population [20]. For example, on a type-level, the SSC is well suited for surgeries performed on adults but unsuitable for children in pediatric surgery [18]. On an instance-level, patient-specific concerns, such as preexisting medical conditions, and unforeseen changes during the checklist application, such as newly available information about a patient's diagnostic status, may further require deviating from the standardized content [2]. Moreover, the standardized format does not account for organizational needs nor the diversity of backgrounds and personal preferences that are common in healthcare settings [21]. Although modifications are recommended both in the academic literature [22] and on some of the standardized medical checklists [23], current modeling approaches do not support customizations that ensure the checklists' applicability.

II. Hard-coded medical checklists are often poorly integrated into clinical workflows and do not support all life cycle phases [24]. Computerized medical checklists are commonly encoded directly in the source code of software systems [25]. This hard-coded approach tightly couples the checklist specifications, i.e., the checklist models, to their execution [26]. As a result, integrating computerized checklists into existing information and workflow management systems is difficult [25]. However, due to the lack of workflow integration, the use of medical checklists often causes interruptions and imposes ancillary workload for healthcare practitioners [27]. Moreover, hard-coded modeling solutions do not support the entire life cycle of medical checklists. The life cycle refers to all phases involved in their creation and management, namely (i) their conception, (ii) determination of the content and design, (iii) testing and validation, (iv) training and implementation, and (v) ongoing evaluation, revision, and updates [28]. Any changes to existing workflows or newly available evidence that affect the content of a checklist are arduous to realize because it takes time to understand and modify the encoded checklist specification [26]. Consequently, extending, maintaining, and reusing medical checklists is inherently difficult.

III. The lack of end-user inclusion in contemporary modeling approaches affects their acceptance and willingness to use medical checklists [29]. Typically, programmers translate the checklist models created by the development committee into executable programming languages [19]. By implication, a fundamental understanding of the modeling language and associated domain jargon is needed to create and maintain medical checklists. This means, end-users of medical checklists with a background in medicine are not able to understand the current encoding approaches of medical checklists, nor the encoded knowledge in the form of software source code [19]. This language barrier between medical checklist end-users and programming experts imposes not only communication costs but is also prone to translation errors [8]. Above all, the involvement of end-users in the development and maintenance of medical checklists is of vital importance as it fosters a sense of ownership and contributes to ensuring the relevance and practicality of medical checklists [30].

To summarize, the main problems contributing to low completion and compliance rates with medical checklists are rooted in the standardized and static nature and the lack of end-user involvement in the current modeling approaches of medical checklists. As a result, medical checklists are often poorly integrated into clinical workflows and not universally applicable to patients or cases.

> **Problem Statement:** Currently, no modeling approach for medical checklists offers full support for checklist end-users allowing them to model, maintain, and customize medical checklists based on their domain knowledge. Additionally, the static nature of the current checklist modeling approaches does not foster dynamically adapting medical checklists to the patients or context they are used in. Thus, medical checklists are often poorly integrated into local workflows and not universally applicable to their respective target population and context.

1.2 Research Aim

Medical checklists are commonly derived from clinical guidelines and clinical pathways [31] for which encoding approaches have already been studied and practiced for decades [32], [33]. Clinical decision support systems (CDSSs) and workflow management systems (WfMSs) have been developed, respectively, that facilitate the use of domain-specific modeling languages by providing a combination of knowledge acquisition tools and execution engines [19]. Therefore, end-users are enabled to encode their domain knowledge in executable, maintainable, and shareable formats. Ideally, those software engineering techniques and tools should be exploited, and their principles applied to the medical checklist domain.

When looking at software engineering approaches, a distinction can be made between code-driven and model-driven development (MDD) [34]. Code-driven development refers to either directly specifying a system's functionalities in code, or first creating models for the design of a system that are subsequently interpreted by developers for producing executable source code [26] (see Figure 1.1). This approach is currently dominating the practice of computerized medical checklists. Typically, models are kept completely separate from the code and, owing to high maintenance costs, are no longer updated, or even discarded once the coding is done.

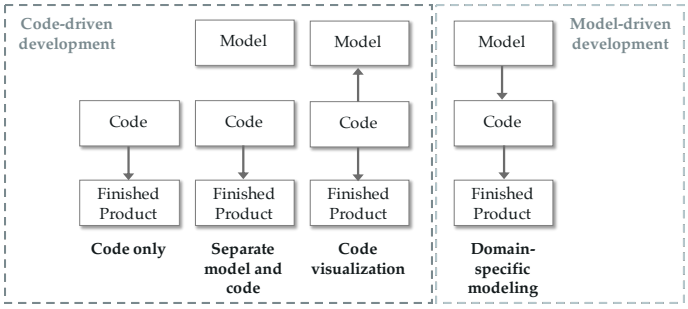


FIGURE 1.1: Aligning code and models in software development, adapted from [26].

By contrast, MDD is characterized by using models as the primary construct in the development process, i.e., by having source models rather than source code [35]. In that way, the level of abstraction is raised beyond programming, and implementation details can be hidden. In a similar manner to compilers used in pure coding approaches, MDD uses automated transformations to generate code from the previously created models, which is subsequently compiled for execution. Domain-specific modeling (DSM) goes one step further by specifying the solution in a domain-specific modeling language (DSML) that directly uses concepts and rules from and tailored to a

specific problem domain [36]. The high level of abstraction requires less specification work, as changes based on domain concepts are easier and faster to make, and changed applications can be generated automatically [26]. As a result, domain experts and end-users can be involved in the development process more directly, as already known domain concepts of the DSML are easily understood. Thus, a DSML aims at bridging the language gap between the domain specialists and software developers [37]. By implication, an MDD approach based on a DSML is suitable in the domain of medical checklists for ensuring that checklist end-users understand the encoding approach, representation formats are integrable with existing systems, and customizing, maintaining, and reusing checklists is be supported.

Against this background, we aim to develop a DSM solution for medical checklists that makes medical checklists more appropriate to their target population and context and improves their integration into clinical workflows. Therefore, our DSM solution, called MediCheck, aims at supporting the modeling, maintenance, and customization of medical checklists on a type- and instance-level while providing a DSML for medical checklists (DSML4MC) that can be understood by medical checklist end-users. Accordingly, the goal statement reads as follows:

> **Goal Statement:** The aim of this research is to
> - *improve* the design and management of medical checklists
> - *by* designing a domain-specific modeling solution for medical checklists
> - *that* facilitates their creation, maintenance, and customization, and is comprehensible by medical practitioners
> - *in order to* enhance the applicability and the workflow integration of medical checklists.

1.3 Research Questions

This research project is guided by our main research question (MRQ) which we derived from the aim of this study and further specified into six sub-research questions (SQs).

MRQ: ***How can an effective domain-specific modeling solution for medical checklists be designed that improves the applicability and workflow integration of medical checklists?***

The main research question of this study addresses the lack of an effective modeling approach for medical checklists that is understandable by checklist end-users. This practical problem is addressed by following the Design Science Research (DSR) approach [38] to create and validate a new DSM solution for medical checklists.

SQ1: ***What concepts and characteristics does a medical checklist encompass?***

A prerequisite for specifying a DSM solution is the identification of domain-specific concepts and how they work together [26]. Therefore, based on a multivocal literature review of the state-of-the-art and state-of-the-practice, relevant concepts of medical checklists and their relationships are identified. The outcome of SQ1 is a characterization of medical checklists.

SQ2: ***Which aspects of existing encoding approaches for similar clinical resources can be adapted for modeling medical checklists?***

SQ2 aims at identifying aspects that can be adapted from encoding approaches for similar resources, such as clinical guidelines and clinical pathways. Based on a second literature review, similarities and differences between related clinical resources and medical checklists are delineated, followed by an investigation of their respective representation formats. The outcome of SQ2 is used as input for the specification of design requirements for MediCheck.

SQ3: ***What phases and activities does the life cycle management of medical checklists entail?***

SQ3 aims at identifying relevant phases and activities that are part of the management life cycle of medical checklists based on a review of contemporary literature. The outcome of SQ3 offers insights into what managerial activities should be supported by the DSM solution.

SQ4: ***Which requirements should a domain-specific modeling solution for medical checklists fulfill to realize expected benefits?***

To answer SQ4, design requirements are engineered based on eight exploratory interviews with domain experts and the preceding literature studies. The requirements are used to guide the development of our DSML4MC and to provide a basis for the validation of MediCheck.

SQ5: ***Is the created language specification complete and comprehensible by prospective users?***

Guided by the answers to SQ4, our DSML4MC is specified. It comprises of the abstract syntax, the concrete syntax, and semantics [26]. By answering SQ5, insights into the overall quality of the language specification are acquired. Therefore, its completeness and comprehension are evaluated via different evaluation methods [39] and identified improvement aspects are incrementally implemented during the development.

SQ6: ***Is the developed domain-specific modeling solution for medical checklists effective?***

MediCheck is considered effective if it fulfills its outlined objectives of improving the life cycle management of medical checklists, allows customizations on a type- and instance-level, is comprehensible by prospective end-users, and is intended to be used in practice [40]. To validate our DSM solution, a proof of concept in the form of an implementation simulation is provided to four prospective end-users and their perceptions elicited through a mixed methods approach [41].

To summarize, by answering SQ1-SQ3, we provide an overview of the medical checklist domain and elicit relevant knowledge for the construction of our DSM solution. SQ4 yields a set of design requirements for MediCheck. The evaluation of the language specification's completeness and comprehension needed to answer SQ5 provides a first assessment of its overall quality. Finally, to answer SQ6 we determine whether MediCheck is effective, and thus, can address the MRQ.

1.4 Research Context and Outline

An overview of the predominant aspects of this study's research context is presented in Figure 1.2. It reflects both the current state-of-the-art and the state-of-the-practice that is prevalent in various countries, including the Netherlands, Germany, Belgium, and the United States. Although regional differences in the degree of digitization of hospital information systems (HISs) can be observed, the context presented here portrays elements all countries have in common.

The main stakeholders of medical checklists and their respective relationships are shown on the left hand side of Figure 1.2. Medical practitioners, such as nurses and doctors, are the end-users of medical checklists. The management of checklists is delegated to various functions, including administrative managers, Chief Medical Information Officers (CMIOs), and Chief Nursing Information Officers (CNIOs). CMIOs and CNIOs are individuals that bridge between medical and IT departments at a health care organization [42]. Typically, they have a medical background, yet they may also be technology professionals who have been trained in health informatics. The development committee of medical checklists commonly consists of representatives of the different stakeholders. Finally, software providers that offer information technology (IT) solutions for healthcare organizations, represent the stakeholders that implement the checklist models.

As shown on the right-hand side of Figure 1.2, the concepts, the structure, and the behavioral elements of a medical checklist are specified in their respective checklist models [43]. This specification can be encoded using either a domain-specific or a general-purpose modeling language (GPML). It should be noted that there is currently no distinct research community focusing primarily on checklists, as there is, for instance, on business process management research. Instead, isolated studies about checklists can be found by researchers in their respective domain, such as aviation [44], policing [45], human systems integration [28], and medicine [9], [24].

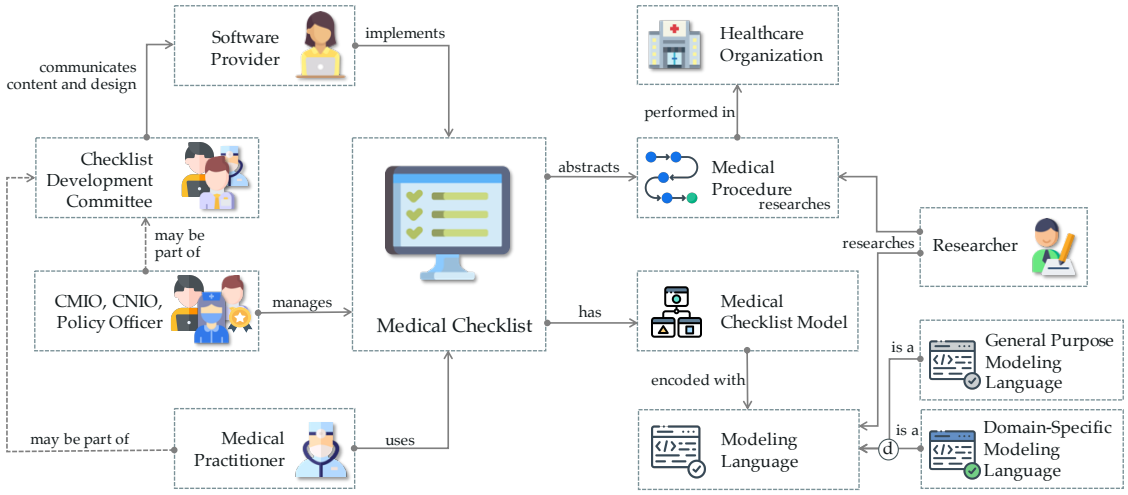


FIGURE 1.2: Illustration of the context of medical checklists focused on in this research study.

During this research, various decisions impacting the scope of this project were made. With the aim to minimize temporal and regional boundaries, we included a wide range of published material and interviewed stakeholders from various countries and different organizations. Furthermore, we refrained from focusing on a specific type of medical checklist, such as diagnostic or procedural

checklists. The primary target stakeholders of this study are the end-users and individuals that are responsible for maintaining medical checklists. Limitations to the type of stakeholders that participated in this research are mainly due to the lack of responses or their limited time resources. For instance, the input from language development experts and software providers for HIS could not be acquired and should be subject to future work.

Finally, this project is based on the principles of domain-specific modeling [26]. As illustrated in Figure 1.3, a DSM solution requires the specification of a DSML, a code generator, and a domain framework to generate the target tool. Since this domain-specific modeling approach for medical checklists is applied for the first time, this research study functions as a demonstration of whether a DSM approach is feasible in the medical checklist domain. Therefore, the scope of this research project is focused on the specification of the DSML for MediCheck (MC-DSML). From here on, we use MC-DSML to refer to our instance of a DSML4MC, while MediCheck refers to the target modeling solution that is based on the MC-DSML.

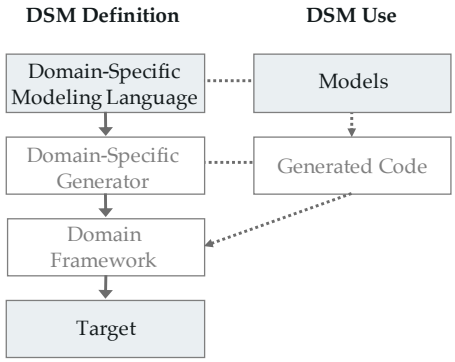


FIGURE 1.3: Definition and use of our DSM solution, adapted from [26]. The elements focused on in this research project are highlighted.

The remainder of this research report is structured as follows. First, the research approach and the research methods are introduced in Section 2. In Section 3, we provide an overview of the problem domain analysis. In Section 4, we present the design of our MC-DSML. The results of its validation are illustrated in Section 5, followed by the discussion of our results, limitations and threats to validity, and suggestions for future work in Section 6. Finally, we conclude our research in Section 7. An overview and the corresponding research questions can be found in Figure 1.4.

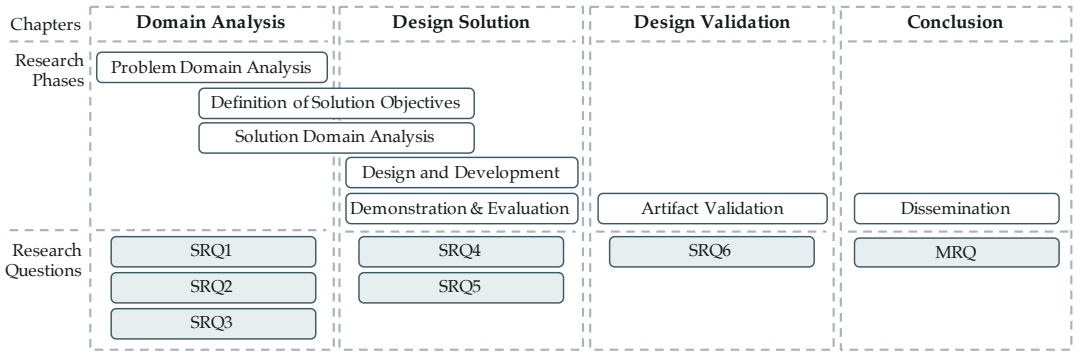


FIGURE 1.4: Scaffolding of the research questions and this thesis report.

2 Research Approach

In this section, we present the research approach followed and the research methods used within this study. Because DSMLs are statements about relationships among constructs, they can be considered models [39]. Therefore, this research project is based on the Design Science Research paradigm, which is characterized by creating meaningful artifacts, such as models, for improving a specific problem domain [38].

To ensure sound and rigorous research, we adhere to the well-respected framework proposed by Hevner and Chatterjee [38]. The application of the DSR framework to this study is illustrated in Figure 2.1. It provides details about the three cycles that are iteratively conducted and further frames the discussed research problem with regard to its environmental context and the underlying knowledge base. The *relevance cycle* initiates the DSR from the application context, which provides requirements and acceptance criteria for the design validation. The *rigour cycle* provides the foundation for mapping our MC-DSML adequately to the real world. Therefore, it draws from a vast knowledge base of scientific theories and methods, as well as the state-of-the-practice and experiences. The *design cycle* iterates numerous times between the construction of the MC-DSML, its evaluation, and subsequent feedback until a satisfactory design is achieved. Our MC-DSML is validated by presenting its implementation simulation, MediCheck, to prospective end-users.

As secondary sources of good practice, we follow Peffers et al. [46] for insights into the process of DSR. In addition, for the development of the DSML specification, we follow the DSML Engineering Method by Frank [36]. This method has already been successfully applied in a number of DSML projects [47]–[49]. The illustration of the interconnection between the approaches can be found in Appendix A.1.

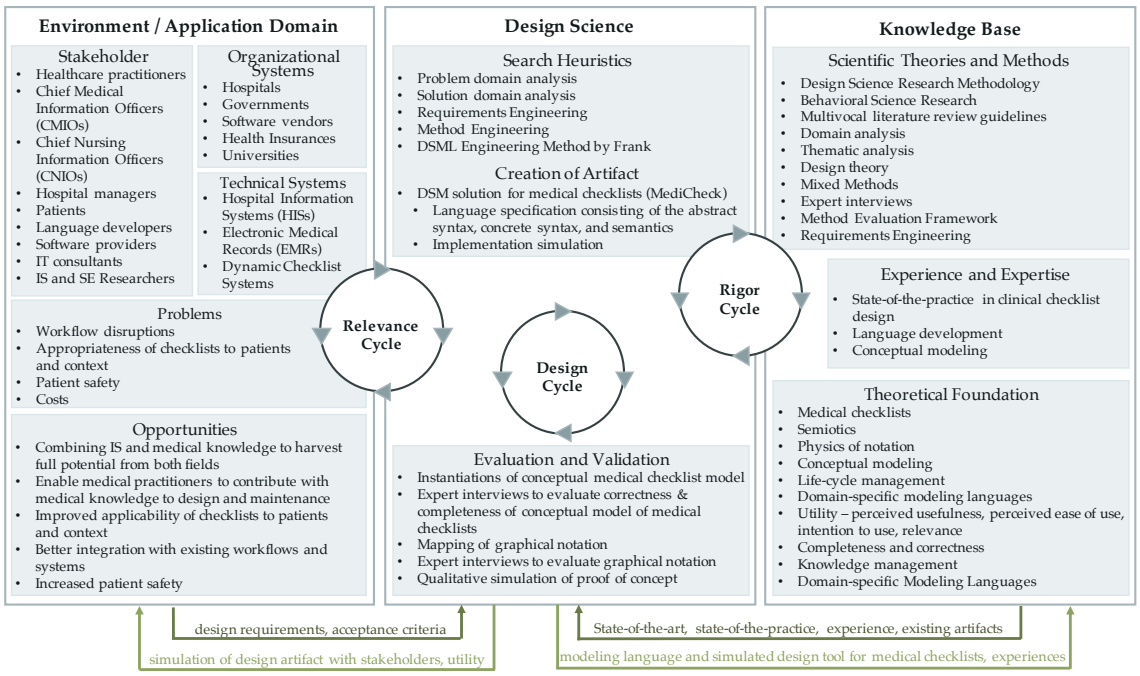


FIGURE 2.1: The DSR framework of this research project, adapted from [38].

2.1 Research Phases and Activities

A success factor, emphasized in both the DSR approach and the DSML Engineering Method, is the continuous involvement of target stakeholders in all phases of the research project. Regardless of the potential benefits or technical advancements, if an information system (IS) is not used in practice, its benefits cannot be realized [40]. Thus, user acceptance has become an important aspect in the field of information science. Particularly for the development of a new DSML, the involvement of domain experts through cyclic feedback is pivotal [50]. Therefore, we closely collaborated with medical practitioners that work with or are responsible for the management of medical checklists, healthcare consultants, and IS experts.

The research process followed for this study is depicted in Figure 2.2, by means of a Process-Deliverable Diagram (PDD) [51] that shows the research activities on the left, and the resulting deliverables on the right side. Activities in which stakeholders were involved are denoted with an asterisk. The main research contributions of this study are indicated with green borders on the deliverable side. Tools that were used are represented with orange boxes. We used the data analysis software *Nvivo*[1] for the qualitative data analysis, *Omnigraffle*[2] as a visualization tool for our graphical notation, and the commercial prototyping tool *Justinmind*[3] for the creation of the proof of concept. Furthermore, various quality checks were conducted before moving on to the next activities. These quality checks are represented through branches, denoted by rhombuses.

Initial Problem Investigation: An initial problem investigation of checklists applied in healthcare settings, laid the foundation for this research project. Accordingly, we derived the research goal and specified the research questions. We further derived the research process from the above-discussed research approach.

Problem Domain Analysis: For creating a universal understanding of the problem domain, this phase was focused on the characterization and abstraction of medical checklists. Therefore, SQ1-SQ3 were guiding the investigation of medical checklist characteristics, similar clinical resources and their respective encoding approaches, and life cycle management activities. This investigation was based on three literature studies.

Design Solution: Guided by SQ4, we conducted eight expert interviews to elicit design requirements for MediCheck. Three of the experts further provided insights into the requirement priorities. Subsequently, we specified the abstract syntax which defines the structure and grammatical rules of our MC-DSML in the form of meta-models [36]. The abstract syntax's quality was evaluated through four interviews with domain experts. Next, we created the concrete syntax in the form of a graphical notation, which constitutes the visual formalism of our MC-DSML. Through five interviews with domain experts and creating exemplary checklist models, the graphical notation was evaluated regarding its completeness and comprehension. In addition, we discussed the notation regarding its cognitive effectiveness [52]. Thus, guided by SQ5, we assessed the overall quality of our MC-DSML. Finally, a simulated implementation of MediCheck was created. It serves as a proof of concept that we used to validate our MC-DSML design.

[1] https://www.qsrinternational.com/nvivo-qualitative-data-analysis-software/home
[2] https://www.omnigroup.com/omnigraffle/
[3] https://www.justinmind.com

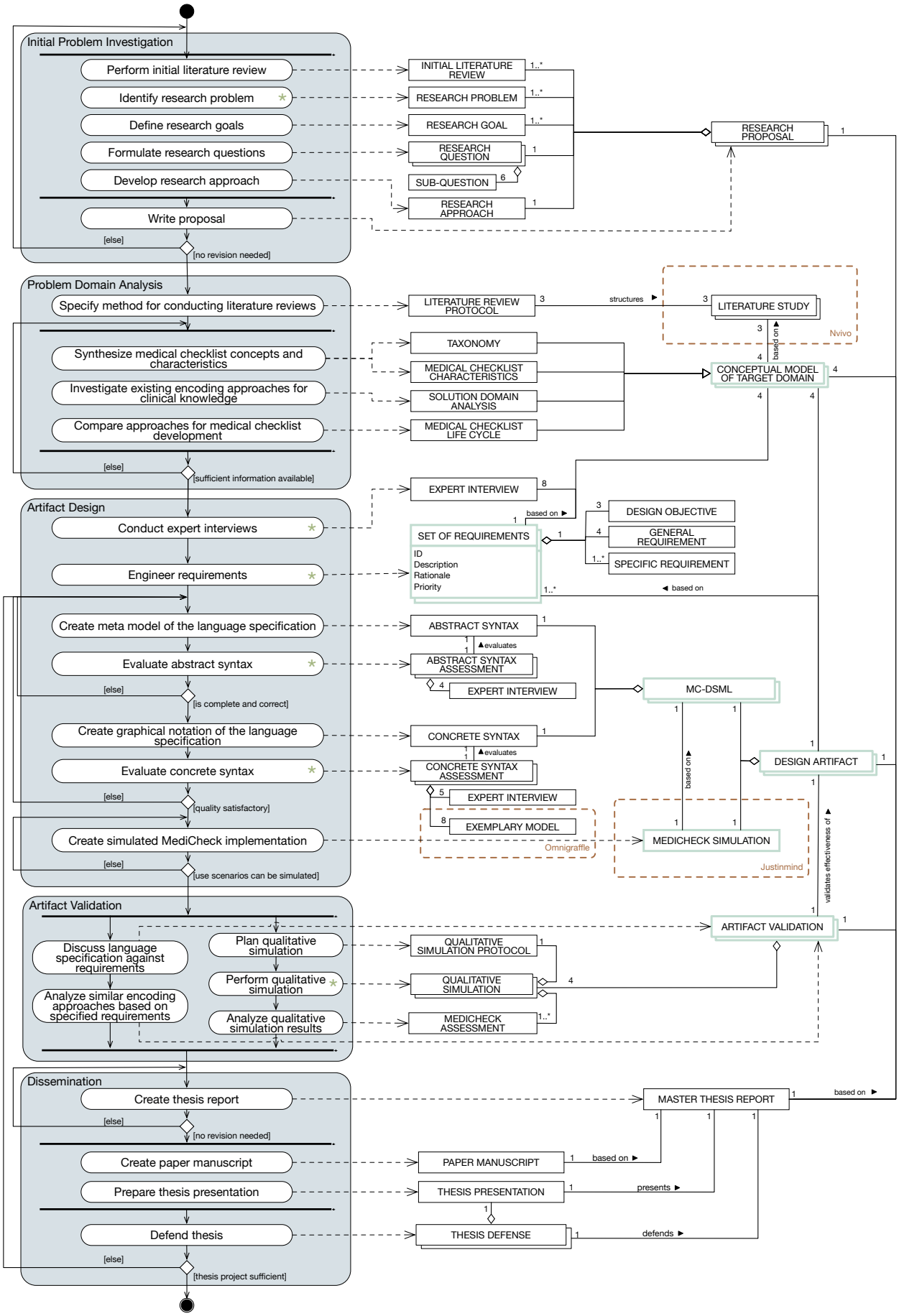


FIGURE 2.2: Process Deliverable Diagram of the research process followed in this study.

Design Validation: For the validation of our MC-DSML we conducted four qualitative simulations with prospective end-users (see Section 2.4). Therefore, we applied a scenario-based mixed methods approach to elicit the participants' feedback regarding the perceived ease of use, comprehension, perceived usefulness, and intention to use [40]. Furthermore, we discussed the final design of our DSM solution against the specified requirements and performed a comparative analysis with existing encoding approaches.

Dissemination: Finally, based on the input from all previous research activities, we can answer the MRQ of this research project. To conclude this research project, we communicate the problem and importance of the topic, the designed DSM solution, its relevance and novelty, and its effectiveness to fellow researchers and medical practitioners in the form of this thesis report and an additional paper manuscript.

We provide the overview of the research methods used for answering the SQs and MRQ of this study in Table 2.1 and a detailed description in the following sections.

TABLE 2.1: Research methods utilized to answer the SQs of this study.

Research Method	SQ1	SQ2	SQ3	SQ4	SQ5	SQ6
Multivocal Literature Study	✓					
Literature Study		✓	✓			
Expert Interviews				✓	✓	
Qualitative Simulation						✓

2.2 Literature Study

As the basis for the DSM design, the problem domain analysis is primarily focused on the construction of the knowledge base. Therefore, we chose a literature review as the main research method for this phase. The review can be divided into three parts: (i) the current state-of-the-art and state-of-the-practice of medical checklists, (ii) encoding approaches for similar clinical resources, and (iii) medical checklist life cycle phases and activities. A tailored approach for each literature study was developed to account for the differences regarding their purpose and their goal. To reduce the possibility of researcher bias, we created literature study protocols for each topic, that specify the methods and techniques, as well as relevant quality criteria [53], [54]. The protocols were piloted and required adjustments made accordingly (see Appendix A.3). For all three studies, we coded the retrieved information in NVivo and methodologically examined it based on the thematic analysis technique [55]. This technique is suitable for "*systematically identifying, organizing, and offering insights into patterns of meaning (themes) across a data set*" [55, p. 57]. The results were inherently validated by the applied analysis method. For instance, we continuously rearranged, aggregated, and refined identified themes through the comparisons of information assigned to each theme. The three literature reviews are described in more detail in the following three sections.

2.2.1 Literature Study of Medical Checklists

The need for the first literature study emerges from the relative paucity of characterizations specific to medical checklists. A systematic literature review conducted by Reijers et al. [11] aimed at conceptualizing checklists and analyzing their contemporary problems but did not focus on a specific application domain such as healthcare. A conceptual model of dynamic medical checklists from a software engineering perspective is proposed by Nan et al. [19], yet with the main focus on the dynamic characteristics of checklists. Therefore, the goal of this literature study is to establish universal concepts and characteristics specific to medical checklists.

For a practical field, such as medical checklists, an overview of both scientific research and non-scientific contributions, so-called grey literature, is important to gain insights into the daily practice and is consistently emphasized in the in healthcare community [56]–[58]. Therefore, we conducted a multivocal literature study, which is characterized by including practice documents, such as medical checklists, and other non-published or not peer-reviewed sources, in addition to academic literature [59]. We followed established guidelines for conducting multivocal literature reviews [53], to minimize researcher bias and ensure that only credible sources are used.

Due to the focus on checklists in the healthcare domain, we utilized PubMed as the primary search engine. Google Scholar and Google Search were used for retrieving additional documents. We identified an initial set of candidate articles by querying various search strings on PubMed. An incipient decision about whether to include a source in the literature study was made based on inclusion and exclusion criteria, as well as an assessment of additional quality criteria. Details about the search strings and criteria can be found in Appendix A.3. We further complemented the initial set of resources through the snowballing procedure [60]. For informative sources, i.e., papers that provide detailed information about the characteristics of medical checklists that are potentially applicable to more than a single checklist, we traced cited references (backward snowballing) and screened papers citing these works (forward snowballing). The final set of resources comprises 91 papers and articles, as well as 45 medical checklists.

For the thematic analysis of the sources, a predominantly inductive approach to data coding and analysis was used. In this bottom-up approach, we derived codes and themes from the content of the data to create a collection of concepts that is close to the content of the sources. The output of the thematic analysis of this literature study is a detailed conceptualization of medical checklists, presented in Section 3.3.

2.2.2 Literature Study of Encoding Approaches for similar Clinical Resources

We conducted a second literature study with the aim of identifying similar clinical resources and their respective encoding approaches. We followed a semi-systematic literature review, that is characterized by (i) studying topics that are investigated by various groups of researchers within diverse disciplines, and (ii) its goal to identify and understand potentially relevant research that may have implications for the studied topic [61]. Despite the scarcity of encoding approaches for medical checklists in executable formats, other domains, such as clinical guidelines and pathways, offer established representation formats and modeling tools that can be exploited [32], [33].

To focus on resources in the medical domain, we used PubMed as our primary search engine and numerous search strings to identify the initial set of candidate papers. The above-described

snowballing technique was applied to identify additional sources, and the retrieved sources judged for inclusion or exclusion (for search strings and inclusion criteria see Appendix A.7).

After thoroughly studying the final set of 59 academic papers, we derived a taxonomy of medical checklists that presents similarities and differences between clinical resources. We further analyzed eleven papers that describe an encoding approach for medical knowledge in detail, with regard to the requirements specified for our DSM solution. Thus, the output of this literature review served (i) for identifying aspects of existing encoding approaches for similar clinical resources (ii) for a comparative analysis of MediCheck.

2.2.3 Literature Study of Medical Checklist Life Cycle

Finally, to establish an understanding of the management activities and phases inherent to the medical checklist life cycle, we investigated approaches used and described for developing and maintaining medical checklists. Since the development of checklists in the healthcare domain requires unique considerations (see Section 3.6), a full systematic literature review to identify all empirical evidence from various disciplines is considered unsuitable [53]. Moreover, the limited access to practical, i.e., non-academic literature about development and management approaches makes a multivocal literature study inapplicable. Instead, we chose to conduct an integrative literature review, characterized by the aim of critically assessing and synthesizing the literature on a specific topic in a way that potentially enables new theoretical models in an emerging field [61].

For identifying relevant sources, we applied the forward and backward snowballing procedure [60]. The paper by De Los Santos et al. [30] served as the starting point of the search process, as it proposes a comprehensive approach for designing, implementing, using, and maintaining checklists in medical settings. Possible reasons for exclusion of additional papers were, inter alia, insufficient information about the development activities, strategies that cannot be applied to more than one checklist, or approaches that are not evidence-based. Out of 72 identified sources, we thoroughly analyzed ten papers that provide general development guidelines for medical checklists and nine papers that describe specific development projects.

Similar to the previous literature study, we applied the thematic analysis method to identify management activities and phases, yet with a predominantly inductive approach. The output of this literature study is a theoretical model of the medical checklist management life cycle, derived from evidence-based development approaches.

2.3 Expert Interviews

Eliciting experts' opinions using interviews, is a fruitful research method for the problem investigation, the evaluation, as well as the validation of design artifacts [62]. Therefore, we conducted various semi-structured interviews that are characterized by prepared questioning based on identified themes. The semi-structured nature helps the conversation to be steered towards the topics and issues of interest [63], while allowing to ask follow-up questions [64]. Various guidelines for conducting expert interviews were consulted [65]–[67] and protocols that outline the major topics and exemplary prompts created and piloted for all interviews.

Due to limited access to medical practitioners, we followed a combination of convenience sampling and referral sampling for the selection of the domain experts. The former refers to selecting research participants based on their proximity and willingness to participate, while the latter describes asking participants for recommendations of acquaintances who might qualify for participation [68]. Although this sampling method limits the generalizability of our results, the focus of the expert interviews to understand the subject matter and to gain qualitative insights justifies the chosen method. Furthermore, proficiency in English or German was a selection criterion for all three interviews. Additional criteria specific to each interview are presented in Table 2.2, while the overview of all research participants, their respective backgrounds, and the length of each interview can be found in Appendix A.1.

A research information sheet and an informed consent form were sent to the participants prior to the interview to inform them about the research purpose, the structure of the interview, and the confidentiality of the discussed information (see Appendix A.5). All interviews were conducted via a video or audio call. Due to the differences in the interviews' aim, content, and contribution, we outline their approaches separately in the following sections.

TABLE 2.2: Overview of the expert interviews conducted in this research study, RP = number of research participants, SE = software engineering.

ID	Objective/Aim	Selection criteria	RP	Duration
I-1	Problem investigation, requirements elicitation	Work experience of min. 6 months w.r.t. medical checklists	8	300 min
I-2	Abstract syntax evaluation	Experience in conceptual modeling or work experience of min. 6 months w.r.t. medical checklists	4	140 min
I-3	Concrete syntax evaluation	Medical background, no experience in SE	5	120 min

2.3.1 Interview I-1 - Problem Investigation and Requirements Elicitation

To acquire insights into the practice of medical checklists, eight exploratory interviews with domain experts were conducted. The interviews' aim was to investigate contemporary problems and respective needs as a basis for deriving design objectives and requirements for our DSM solution. Therefore, our aim was to include domain experts with diverse backgrounds that have at least six months of practical experience with medical checklists. As a result, we interviewed three physicians, one nurse, one policy officer, one healthcare consultant, and two medical students from different healthcare organizations and different countries. After describing the aim and context of the research study, the interviewees were asked to describe their educational background, organizational role, and relation to medical checklists. We investigated contemporary representation formats of medical checklists, their main objectives, integration into local HISs, how the documents are created, updated and maintained, and who is responsible for these activities. Then, we discussed current problems with medical checklists, and what is needed to overcome these issues.

The interviews were transcribed and translated if needed. We applied the thematic analysis method to identify the major problems and needs with regard to contemporary medical checklists, and subsequently engineered a list of design requirements for our DSM solution. This list was

sent to four of the interviewees that volunteered to provide further input for the requirements prioritization. According to the MoSCoW prioritization technique [69], we asked the participants to indicate whether a requirement must be included (M), should be included but is not critical (S), could be included (C), or is not relevant at this point (W). Three participants returned the lists, and their feedback was taken into account for determining the final set of requirements.

2.3.2 Interview I-2 - Evaluation of Abstract Syntax

As part of the evaluation of the language specification's overall quality, we acquired feedback from four domain experts about the abstract syntax and semantics. With the main selection criteria of having a solid domain understanding and potentially experience in conceptual modeling, we interviewed two medical students, one physician, and a consultant for IS integration. We presented the created meta-models and discussed (i) whether the models are missing relevant concepts or relationships, and (ii) to what degree the meta-models contain the minimum number of elements and relationships. Proposed changes to the meta-models were made directly during the interview so that the expert could confirm their correctness. As a result, we were able to assess the overall quality of the abstract syntax with regard to its completeness and simplicity.

2.3.3 Interview I-3 - Evaluation of Concrete Syntax

After the evaluation of the abstract syntax of our language specification, we created the graphical notation that constitutes the concrete syntax. For its evaluation we aimed to interview practitioners with a medical background and without any training or experience in software engineering, to ensure that the graphical notation is comprehensible by prospective end-users of medical checklists. Therefore, we conducted five interviews with two nurses and three medical students. Each notational element was presented, and its meaning and function explained. Then, we discussed (i) whether all relevant elements are provided, (ii) whether the elements are understood, (iii) whether they correspond to their respective semantic construct, (iv) and whether any changes or improvements are suggested. Consequently, we were able to assess the overall quality of the concrete syntax with respect to their completeness and comprehension.

2.4 Qualitative Simulation

For justifying that MediCheck fulfills its outlined objectives, we created an implementation simulation of our developed language specification. Moreover, we prepared two realistic scenarios for the use of MediCheck, covering the conception, creation of the content and design, modifications, customizations, and the maintenance of a medical checklist. For a detailed description of the scenarios, we refer to Appendix A.5. The scenario-based implementation simulation was presented to four prospective medical checklist end-users. With the goal to gather insights into the effectiveness of MediCheck, we applied a pluralistic approach of combining both qualitative and quantitative methods. This mixed methods approach was followed to ensure a greater diversity of divergent views and to take advantage of the strengths of both quantitative and qualitative methods [41]. We refer to the combination of the applied research methods as **qualitative simulation**. The overview of the components can be found in Figure 2.3 and is elaborated on hereafter.

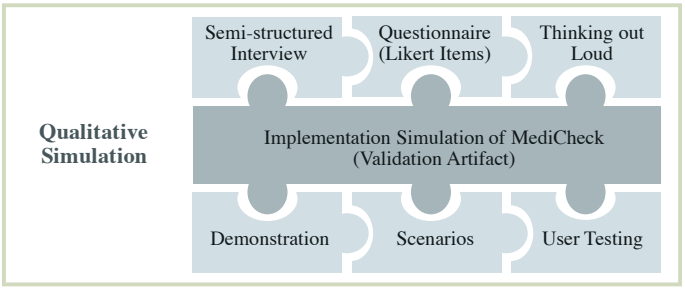


FIGURE 2.3: Components of the qualitative simulation used to validate MediCheck.

Similar to the previous expert interviews, convenience sampling was applied for the selection of the research participants for the qualitative simulation. In addition, the following selection criteria were applied: proficiency in either English or German and at least six months of practical experience in using medical checklists or experience in the creation or the management of medical checklists. The four qualitative simulations were conducted through an online video platform while giving the participant remote access to our computer. The qualitative simulations were started with an explanation of the study's purpose, followed by a semi-structured interview comprising of questions about the participant's background, their relationship and attitude towards medical checklists, and the current situation in their respective organization. Then, MediCheck was introduced, and the participants instructed to conceptually create a medical checklist. By giving them control over the modeling tool, also referred to as user testing, we allowed potentially unexpected interactions that give us valuable insights into the use of the tool [70]. However, since this form of validation requires thorough testing of the implementation simulation and is further susceptible to errors, we demonstrated the subsequent activities ourselves. Although a demonstration limits the degree of potential discovery, it strengthens the reliability of the validation by having full control over the scenarios. Both the checklist development and maintenance scenario were followed by a questionnaire to assess four variables, namely perceived ease of use, perceived usefulness, intention to use, and comprehension. The four variables are measured using a number of statements in the form of Likert items. We split the questionnaire into two parts to avoid fatigue during the case study. The statements used to operationalize the variables were derived from Moody's Method Evaluation Model [40] and the System Usability Scale [71] that are widely used to validate information systems design methods and to assess the usability of different kinds of systems, respectively. The participants were asked to read the items on the questionnaire out loud, and to explain their level of agreement to the given statements. Following this thinking out loud approach [72], we were able to elicit the rationale of their answers and could ask follow up questions. Finally, concluding remarks were exchanged and potential for future improvements discussed in a semi-structured interview fashion. Based on the analysis of the results, we are able to determine the effectiveness of MediCheck and, thus, address the MRQ.

> **Summary Research Approach:** This study is based on the DSR paradigm, which, together with the DSML Engineering Method, guided our research process. Moreover, we utilized three different literature studies, expert interviews, and qualitative simulation as our main research methods for answering our research questions.

3 Domain Analysis

The domain analysis presented in the ensuing sections constitutes the basis for the development of our DSM solution. We first present an overview of characteristics and applications of MDD solutions in the healthcare domain, followed by a definition of medical checklists, and a detailed conceptualization of their characteristics. Then, we provide a delineation of medical checklists and similar clinical resources, based on which we specify aspects of existing encoding approaches that can be adapted for medical checklists. Finally, we present the synthesis of the medical checklist management life cycle.

3.1 Domain-specific Modeling

The development of HISs has been characterized by an evolutionary design of functional modules in the field of laboratory, communication, and administrative systems [73]. As a consequence, the heterogeneous network of HIS applications of different designs and developers is reacting slowly to new requirements that are implicated by changes of the care landscape. In addition, the system design based on traditional modeling languages, such as the widely used Unified Modeling Language (UML), is stored in the specification file, which is programmed and compiled into modeling tools [26]. This hard-coded part defines what kind of models can be made and how they can be processed. As a consequence, the modeling language that is fixed in the code can only be modified by tool providers or software engineers.

By contrast, in DSM solutions, domain-specific concepts and rules prospective users are familiar with are used, and the model of the modeling language (the meta-model) is stored as data in the tool [26]. Therefore, the language specification can be accessed easily by people other than traditional programmers. This does not only avoid costly and time-consuming modifications to the language that hinder the development process but also improves the communication and participation of various stakeholders in the development and maintenance process [73].

The narrow focus of DSM solutions that makes it easier to provide support for specification work, automate otherwise manual programming work, prevent incorrect and poor designs, and provide support for modelers in following approved design guidelines and in reusing available specifications has been taken advantage of for similar problem domains in healthcare settings [26]. Care plan modeling applications [74], open platforms for integrated medical processes [73], autonomic and cognitive monitoring systems to manage patients' health based on wearable devices [75], and multi-paradigm modeling and holistic simulation of healthcare systems [76] have been developed based on the MDD paradigm in recent years. Given the current challenges with medical checklist modeling approaches, the benefits of domain-specific MDD to align different systems and processes and to better fitting the needs of modeling languages and stakeholder needs make a model-driven DSM solution particularly suitable for the medical checklist domain. As a prerequisite for the creation of a DSM solution, a good understanding of the problem domain is needed. Therefore, we provide an overview of the medical checklist domain in the ensuing sections.

3.2 Definition of Medical Checklists

A clear definition of medical checklists is essential in order to be able to analyze its distinct characteristics. However, a universal definition of medical checklists is absent in the current literature [2], [77]. Simply adopting a generic definition for checklists is deemed inappropriate due to the unique characteristics of the healthcare domain. Therefore, we provide a definition that reflects the distinct properties of medical checklists found in practice and described in academic research.

Checklists that are applied in healthcare are most commonly understood as cognitive aids that guide users by helping them to remember or perform tasks, with the goal of reducing errors and omissions [10], [77], [78]. This understanding is in line with the recent proposition by Reijers et al., that checklists are a type of informational artifact that "*encapsulates, abstracts, and represents all relevant information about some real world phenomena in a single abstraction*" [11, p. 5775]. By implication, a medical checklist is a type of conceptual model aiming to describe clinical work routines and to guide activities and decisions within those routines. However, many relevant aspects that are unique to medical checklists are not explicated through this characterization. Therefore, we introduce the following definition of medical checklists:

> **Medical Checklist Definition:** A medical checklist is a
> - collection of items that conceptualize activities or criteria of a clinical procedure
> - that need to be considered or completed
> - right before or during the performance of said procedure,
> - allowing the user to record the presence/absence of the individual item listed
> - in order to prevent avoidable errors and to ensure quality patient care.

This definition emphasizes a number of important aspects. First of all, it distinguishes medical checklists from the general checklist definition by narrowing down their focus to clinical procedures. A clinical procedure is understood as "*any practice of a health practitioner that involves a combination of special skills or abilities and may require drugs, devices, or both*" [79, p. 170]. Moreover, each item on the checklist should be discrete and actionable, meaning it should correspond to a concrete behavior, and it should have a clear objective [30]. Furthermore, the timing of medical checklists is specified to right before or during a clinical procedure to ensure that errors can be caught while there is still time to take corrective action [6]. Similar to general checklists, the aim of medical checklists is to ensure that all items are completed or considered, yet with the specific goal to prevent medical errors and to ensure quality patient care. Above all, the required response or behavior to verify, identify, or answer a specific checklist item constitutes a crucial aspect that makes checklists a powerful safety tool [12], [80]. The act of so-called cross-checking of what is being done or in what order is an important assurance, particularly when time is short, the pressure is high, or competing priorities distract [2].

3.3 Characteristics of Medical Checklists

The definition of medical checklists emphasizes their unique aspects compared to general checklists. To distinguish different types of medical checklists, we further analyzed their properties

and characteristics based on a comprehensive multivocal literature review of the state-of-the-art and state-of-the-practice. This characterization builds the foundation for deriving the modeling language concepts, their properties, and relationships between them [26]. We first provide a description of the characteristics relating to the entire checklist (see Figure 3.1), followed by those that relate to the checklist items (see Figure 3.2).

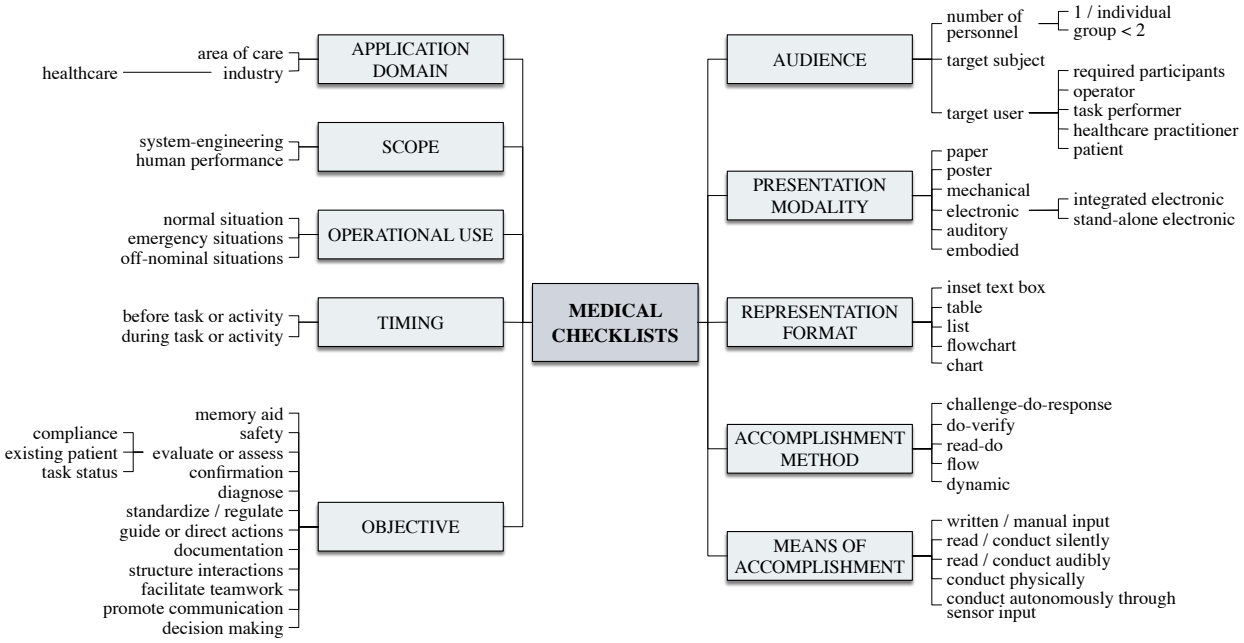


FIGURE 3.1: Properties and characteristics relating to medical checklists.

Application Domain: Medical checklists are a type of checklist that is applied in the healthcare industry. Areas of care medical checklists are currently applied in range from improving neonatal outcomes [80], over general surgical practice [22], to nuclear medicine [30] and prehospital and emergency care [8].

Scope: In general, a distinction can be made between the system engineering, and the human performance approach [14]. A checklist that requires checking all items involved in performing a task or procedure is following the rationale behind the system engineering approach. For instance, a checklist for laparoscopic surgery could include a check for all instruments and steps for setting up the equipment, ensuring that no step or item is missed. To avoid checklists that are too long, the human performance approach suggests only including critical or essential items, ensuring that all items are accounted for that, if failed to check, could lead to an accident. In the medical field, both approaches can be found [28]. For instance, order sets follow the system engineering approach, while safety checklists only include the most essential items (see Section 3.4).

Operational Use: The operational use of checklists in the medical field can be divided into three categories; normal, off-nominal, and emergency situations [28]. A checklist used for a normal operation encompasses routines, how they typically work [11]. A so-called routine checklist usually contains a listing of action items to be performed, but may or may not represent each procedural step in sequential order [14]. Examples of routine checklists are preoperative preparation checklists or timeout checklists such as the SSC [2]. Nevertheless, the SSC prompts the user to anticipate critical events at the same time, which illustrates that a clear distinction is not always

possible [11]. Emergency checklists capture responses to critical events and emergency situations [13]. Through standardizing tasks and processes, the checklist facilitates the organization of different groups and ensures reliable communication [2]. Off-nominal checklists capture workarounds or responses to situations that are not part of the daily routine and not an emergency event [28]. A broken surgical instrument is an example of an off-nominal event. A distinction between the operational use is relevant as it affects design decisions [14]. For instance, off-nominal and emergency checklists must contain each sequential step of a procedure, walking the checklist operator through unfamiliar situations, while requirements for routine checklists are not as strict [81].

Timing: The timing of the checklist specifies when the checklist is used [82]. The most functional medical checklists are designed to be integrated into local workflow patterns so that minimal disruptions and an efficient workflow can be ensured [83]. The ability to catch errors when they occur is a crucial factor when determining the checklist timing, and frequently referred to as error trapping [84]. For instance, checklists that are conducted right before a procedure is about to start are means to detect errors early in the causation chain and allow taking corrective actions accordingly [8], [84]. Therefore, pause points are defined that refer to trigger moments in a procedure to initiate so-called timeouts, in which the checklist is to be completed [81].

Objective: Essentially, the main objective of medical checklists is to provide a cognitive aid with the goal of improving performance and quality of care [14], and supporting practitioners by freeing mental capacity for the operation itself [8]. Furthermore, a number of different goals to implement a checklist are mentioned in the literature, including to structure interactions [2], facilitate information gathering [85], and evaluating patients, task status, or compliance to best-practices [86], [87]. For more examples, we refer to Figure 3.1.

Audience: We can distinguish between the number and the type of targeted users, as well as the target subject of the checklist. If the target subject is a specific patient population, that population has to be clearly defined, and eligibility criteria determined [2]. It can further be distinguished between who is operating the checklist, who performs the checklist task, and who has to be present when conducting the checklist [88].

Presentation Modality: The presentation modality refers to how the checklist is made available to people. Currently, the majority of medical checklists are paper-based [89], yielding the advantage of being portable and easily reproducible [31], [78]. However, they cannot be automatically updated when items are revised or new items added, nor can they be easily adjusted to the individual patient's or user's needs [11]. Checklists presented in mechanical form provide plastic sliders to be moved over the checklist items to only show non-accomplished ones [28]. Checklists that include tools or other equipment put together into a structured kit are referred to as embodied checklists [28]. Electronic checklists refer to any checklist that is represented digitally. Stand-alone electronic checklists are simple screen-based representations [28], while integrated electronic checklists are able to receive input from sensors or electronic medical records [14]. Thus, they facilitate multi-functional capabilities, such as alerting practitioners [90], performing quick audits, or only allowing to proceed with the checklist if necessary items are completed [30]. Further advantages of electronic checklists over paper-based versions are discussed in [14].

Representation Format: The representation format describes how the content is formatted [85]. For instance, the information can be presented in the form of a list [28] or a table to

guide the user through the checklist items [85]. Flowcharts are a common way of representing actions and decisions in a branched way [91]. They are often used as diagnostic tools, thus, functioning as a decision aid [92].

Accomplishment Method: A distinction can be made between five different methods to perform a checklist. The two basic types are the challenge-do-response and do-verify method [14]. In any system where a human plays a central role in the outcome of a process, establishing redundancy in parallel to the human intervention ensures correct and complete accomplishments. The accomplishment methods vary in the redundancy type they apply, distinguishing between (i) backup redundancy between the initial configuration of the system, machine, or process and the checklist use, and (ii) mutual redundancy, that refers to team members supervising one another while conducting the checklist [30]. For a comprehensive overview of the different accomplishment methods we refer to [14], [28], [81].

Means of Accomplishment: Despite the accomplishment method, medical checklists can be accomplished via different means. A checklist used by a single person may be read or conducted silently [28]. However, checklists used in team settings are typically read aloud so that no matter their place in the hierarchy, all team members can be part of the completion of the checklist [80]. The so-called *call out* serves as a verbal cue to ensure that no items are missed [84]. Other than that, written or manual input can be used to verify the successful completion of checklist items. Similarly, input from sensors or digital data, such as electronic medical record data, can be used to autonomously accomplish an item or an entire checklist [28]. Lastly, embodied checklists involving equipment or tools can be physically conducted by one or multiple users [28].

The four characteristics illustrated in Figure 3.2 and described hereafter relate to the items that conceptualize activities or criteria of a specific clinical procedure, and together compose a medical checklist. A good understanding of the checklist item characteristics is important to provide modeling concepts that can distinguish between the different item types, thus, allowing precisely specified checklist models.

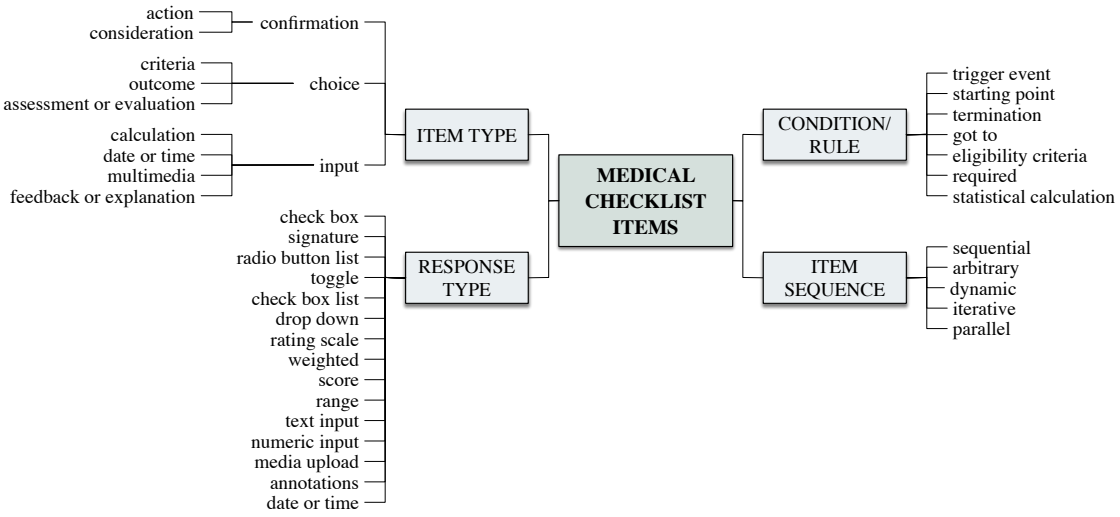


FIGURE 3.2: Properties and characteristics relating to medical checklist items.

Item Type: A distinction can be made between three main item types. First, confirmation

items require a response confirming that a specific goal, activity, or criterion has been accomplished or considered [93]. This can be, for instance, confirming whether potential risks have been discussed with the patient [10]. The second type are choice items that conceptualize multiple criteria or outcomes that are already known upfront. A simple example is a yes/no response. However, more complex options, such as items for rating the severity of pain on a scale, are representative for choice items [94], [95]. Lastly, input items refer to items that require feedback or input from the user. They are typically used when the answer cannot be anticipated upfront [30]. Examples are textual descriptions of symptoms, annotations to images, and provision of numeric values such as the patient's blood pressure [92], [96].

Response Type: The response type refers to different options that an item can be responded to. This can be a simple checkbox or drop-down menu, but also signature fields, rating scales, and radio button lists [97]. In addition, the upload of multimedia elements, such as pictures of a skin abnormality, or audio files are used for subsequently storing it in the patient's electronic medical record, or for sharing the information with other team members [31].

Condition or Rule: Conditions or rules refer to any calculation, comparison, criteria, or rule that may apply to a specific item. For instance, *the average systolic blood pressure in the last five days*, *for each*, or *if, then, else* are common operations that are followed by an action specification such as alerting, making a diagnosis, providing relevant data, or creating a checklist item [98]. Furthermore, delaying or deferring items, go-to items, jump out of checklist items, or checklist terminations are possible rules that may apply to a specific item [28].

Item Sequence: Closely related to conditions and rules, the item sequence refers to the behavioral relationship between the checklist items. It is often determined by conditions or rules such as eligibility criteria or go-to rules. A distinction can be made between sequential items that have to be completed one after the other in a predefined order [2], and arbitrary items that can be completed in any order [28]. Furthermore, dynamic items refer to items that have a conditional relationship with others [2]. Items that need to be conducted at the same time are referred to as parallel items [25]. Lastly, items that must be repeated are referred to as iterative. An example is an item for checking a patient's blood pressure multiple times throughout the day [28].

> **Summary Medical Checklist Characteristics:** Regarding the main properties relating to an entire medical checklist, a distinction can be made between the application domain, scope, operational use, timing, objective, audience, presentation modality, and representation format, as well as the accomplishment method, and means of accomplishment. Relating to the checklist items, different item types, response types, conditions or rules, and behavioral relations between the items can be distinguished.

3.4 Medical Checklist Taxonomy

The shared practical aim of a number of different clinical resources that are directed at improving and standardizing medical care frequently leads to the use of different and often interchangeably used terms [12], [77], [78], [80]. Thus far, the lack of a definition and characterization of medical checklists encumbered a transparent distinction. Therefore, we provide a clear delineation based

on our medical checklist definition (see Section 3.2). The main similarities and differences are discussed below. For a tabular comparison of the clinical resources regarding their function, scope, design and format, and application, we refer to Appendix B.1.

All of the clinical resources represented in Figure 3.3 (indicated in blue) are a type of informational artifact that conceptualizes work routines. For instance, they all abstract relevant information of a clinical flow with the aim to standardize and manage clinical processes and to support clinical decision making. However, those resources considerably differ in terms of their design, scope, and application [80].

With the main goal to foster communication and coordination among stakeholders [99], **clinical process models** formalize and standardize a set of linked activities that together realize medical objectives [88], [100]. Similarly, **clinical pathways** are detailed descriptions in varying formats [101] that manage the medical care of well-defined groups of patients at a defined period of time [102]. Typically, graphical representation formats are used [99], and they may be integrated into clinical decision support systems or clinical workflow management systems [103]. These systems aim at assigning tasks to the right person at the right time [25].

Clinical guidelines describe ideal actions to perform clinical tasks [78], yet with a narrower focus than pathways [101]. They are well suited for broad management topics of general clinical care without one single goal, such as the comprehensive management of pregnancy complications [80]. Correspondingly, **clinical protocols** are locally adapted, institution-specific guidelines [93] that constitute a normative default care plan. Unstructured textual descriptions, time-tasks matrices, and graphical representations, such as flowcharts, are common representation formats for guidelines and protocols [101], [102]. Decision support systems use complex clinical rules defined in the guideline representations that support practitioners in making decisions [25].

A resource that is further well-suited for general management topics are **care bundles** [80]. A care bundle is a collection of evidence-based key interventions and materials that are derived from clinical guidelines [104] and are applied within a clinical pathway [105]. Both clinical pathways and order sets may contain medical checklists [2], [102]. In turn, **medical checklists** are commonly derived from clinical guidelines and clinical pathways [25].

Compared to the previous resources, medical checklists are understood as cognitive aids that focus on a single specific goal and require the verification of whether the items of the checklist have been completed or considered [80]. Unlike broad topics, medical checklists are better suited for more specific topics, such as the management of severe increase in blood pressure. As another type of checklists, **safety checklists** are characterized by only containing essential steps that, if missed, endanger safety [88] and are widely used in HROs [77]. They are further characterized by their timing, as safety checklists must be performed immediately before a procedure is about to start to ensure the detection of errors at an early stage in the causation chain [77]. The SSC is an example of a medical safety checklist. According to Lu et al. [98], the majority of checklists currently used in healthcare are, in fact, safety checklists. On the other side of the spectrum, **order sets** are a type of medical checklist that includes everything a clinician may want to consider ordering for a particular group of patients [2]. Thus, many things on the checklist may not be checked. Lastly, often referred to as a type of checklist [91], **flowcharts** constitute a type of format for representing the checklist content (see Section 3.3) [28], [92].

Generally, different types of medical checklists are commonly distinguished based on their operational use, accomplishment method, or the number of involved personnel. However, there is no universally established categorization of medical checklists, nor a uniform terminology. For instance, checklists describing a set of tasks or criteria with a predetermined order are referred to as both procedural checklist [9] and performance checklist [94].

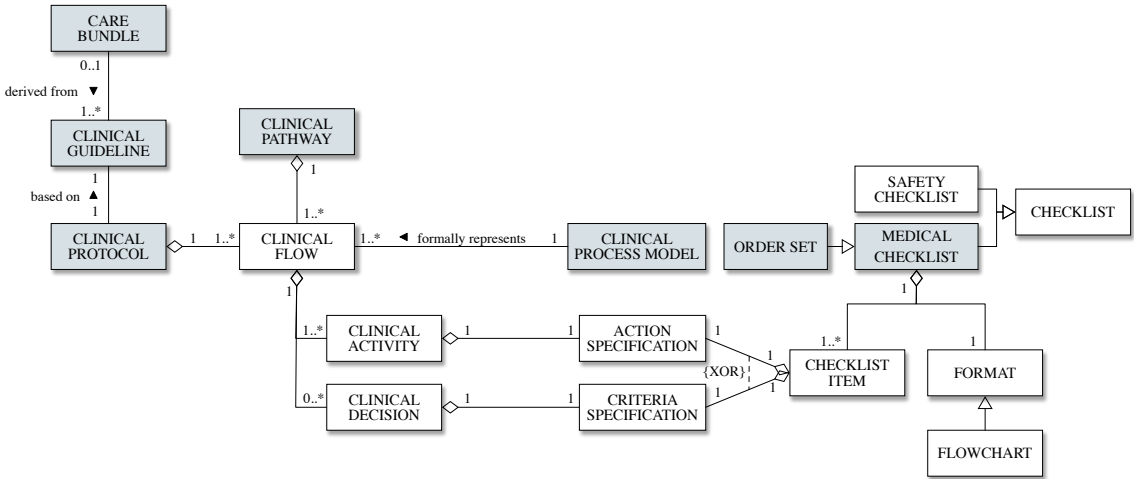


FIGURE 3.3: Delineation of clinical resources - a taxonomy.

> **Summary Medical Checklist Taxonomy:** Medical checklists differ considerably from other clinical resources with regard to their scope, application, and design. Particularly a single specific goal and the aspect of verification are characteristics unique to checklists. However, medical checklists are commonly derived from clinical guidelines or protocols and clinical pathways.

3.5 Encoding Approaches for Similar Clinical Resources

Encoding approaches for executable and shareable formats has been studied for decades in the domain of clinical guidelines and clinical pathways [19]. As a result, decision support and workflow management research already provided solutions in their problem domain that are comprehensible by medical experts, thus, fostering their inclusion in the encoding and management process of the resources, and can be extended, maintained, and reused due to their domain-specific and model-based approaches. Therefore, we analyzed existing encoding approaches for clinical guidelines and clinical pathways to identify aspects that can be adapted for our DSM solution for medical checklists. The results of this analysis are presented hereafter.

In recent years, clinical pathway management systems are increasingly used in hospitals to assign clinical tasks to the right person at the right time [25]. Moreover, computerized provider order entry (CPOE) systems are decision support tools that facilitate the ordering of correct medications and treatments adapted to the specific context [32]. Similarly, clinical decision support systems have been utilized successfully to deliver patient-specific guideline recommendations [3]. Based

on their design purpose and their application domain, the representation formats used in these systems can be divided into two categories. Business process modeling languages focus on complex business processes by specifying activities, roles, resources, and their relationships [102], while guideline modeling languages focus on detailed decision support rules by decomposing guideline tasks [32]. Thus, the two aspects of conceptualizing work routines and guiding decisions inherent to checklists are supported by those systems, respectively.

Within business process modeling languages, checklists have been encoded as a group of activities that should be performed at the right time by the right person [103]. In turn, the clinical pathway behind a checklist is modeled as a process. Activities within a process are performed in different orders, including sequential, branched, and parallel. The concept of gateways is often used to represent the split and merge of several branches [106]. To account for the integration with the process-related aspects, a checklist model should, by implication, support the different types of orders.

In contrast, guideline modeling approaches focus on decision making concerns based on clinical rules [32], [107], [108]. A clinical rule is commonly represented by a group of criteria that, when met, initiate an action. This action can either be a clinical activity, or another clinical rule. Within these formats, medical checklists or single checklist items can be seen as an action specification. Thus, they either specify an activity or a group of criteria.

Although existing modeling languages for clinical pathways and clinical guidelines provide a number of process-related and context- or rule-related aspects a medical checklist representation needs to account for, they currently lack the support of three important aspects. First, they do not support complex calculations, such as *the average of systolic blood pressure in the last 5 days*, which are common primitives for safety checklists [98]. Second, collection operations and statistical calculations, e.g., *all*, or *for each*, are either very difficult for users without programming experience to implement, or are not supported at all. Finally, simple action specifications, such as making diagnoses or sending alerts, are supported, yet providing relevant data or creating checklist items is not [98].

> **Summary Encoding Approaches for Similar Resources:** Existing representation formats for clinical processes and clinical guidelines offer valuable insights into complex process management and control structures, as well as decision support aspects. However, checklist representation formats further need to account for providing collection operations, statistical calculations, and layout-related aspects, such as providing relevant data and creating checklist items based on pertinent context information.

3.6 Medical Checklist Management Life Cycle

To ensure that the DSML4MC supports all phases of the checklist's life cycle, an understanding of its management activities is needed. A a systematic approach for developing checklists in the healthcare domain is fairly new [12], [30]. Available guidance for developing medical checklists is often limited in scope, stated broadly, and does not reflect recent empirical evidence regarding checklist design and use [84]. A development approach from other industries may yield valuable

input for developing medical checklists, yet it cannot be simply adopted for the healthcare industry. For instance, contrary to other HROs, checklists are not yet part of the culture of medicine, nor of the practitioners' training and education [14]. Therefore, the development of medical checklists needs to account for educational material and training interventions [80].

Figure 3.4 illustrates the main life cycle phases we elicited from the academic literature. The life cycle is similar to the plan-do-check-act (PDCA) cycle, a popular cross-industry quality improvement method. The fundamental principle of the PDCA is to repeat the cycle for continuous quality improvement [109] and has been endorsed by the Institute for Healthcare Improvements [110]. In a similar manner, the medical checklist life cycle is of iterative nature, where the cycle is repeated to continuously improve and ensure the checklist's quality. Furthermore, previous phases can be revisited, if changes to the checklist content or design are identified during the testing or training of the checklist. Therefore, the life cycle of a medical checklist only ends if the checklist is retired [28].

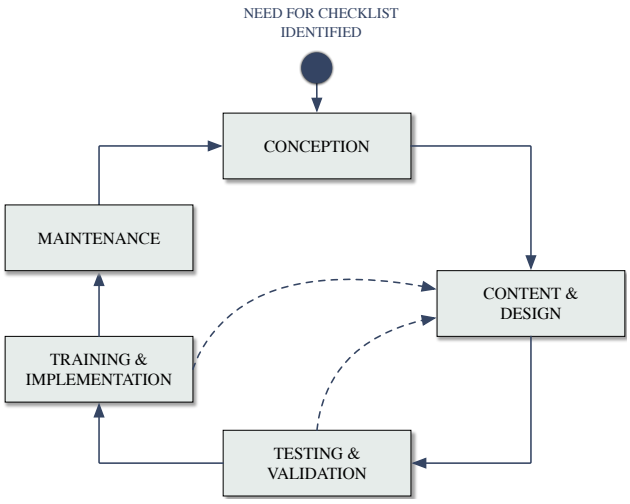


FIGURE 3.4: Medical checklist management life cycle phases.

Hereafter, we provide a description of the activities in each of the phases derived from the analysis of 19 academic papers. The overview of all activities we identified in the literature and the resulting concepts can be found in Appendix B.3.

Conception: The development of a medical checklist is initiated by identifying the need for a new checklist. The first phase of the checklist life cycle comprises of two main tasks, planning and discovery. First, a multidisciplinary development team is assembled, and one person assigned that is responsible for directing and overseeing the checklist development [30]. Furthermore, the purpose of the checklist, its goal, and the target population are specified. In addition, the outcome that the checklist seeks to modify is identified and a specific plan for evaluating the outcome later on determined [80]. A context analysis is performed for discovering relevant input for the checklist content, resulting in a pool of potential checklist items. Finally, the timing of the checklist use within a workflow and potential pause points, the type of checklist, the accomplishment method, and its presentation modality are considered [84]. Note that not every checklist has to be developed from scratch. Existing checklists from other organizations can serve as templates that can be analyzed and modified to fit the target environment and workflow [30].

Content and Design: Based on the input from the conception phase, the content of the checklist and its format and layout are specified [28] and each intervention associated with explicit, concise, and unambiguous behavior [2], [30]. The content of the checklist is then structured by grouping items and determining their sequence. Dependencies between the items are translated into rules, and for each intervention, an appropriate item check type is specified. Furthermore, for each item it should be clear by whom the task is intended to be completed and who will actively run the checklist [80]. Moreover, additional information or supplementary content is specified and operation instructions for the checklist created [111]. Finally, decisions about the font, colors, images, and the presentation format of the checklist are made [97].

Testing and Validation: Following the specification of the content and design, rigorous testing, and validation of the medical checklist follow. The checklist validation is an iterative process that requires several revisions until the checklist design is acceptable for deployment [2]. The checklist can be tested in either a simulated environment or in a real-world clinical setting [80]. Finally, consensus between all development team members and approval from regulatory and leadership bodies is acquired before the checklist is diffused into the clinical settings [84].

Training and Implementation: Education and training interventions should be provided before implementing the checklist to allow the users to practice with the tool before mandating its use [84]. If personnel-related or local problems are detected, the design of the checklist is revised accordingly [14]. The checklist is then disseminated by integrating it into the digital systems.

Maintenance: After the implementation, guidance and reeducation are provided and continuous improvement suggestions and feedback opportunities fostered. That way, the checklist can be kept relevant in a dynamic rather than a static manner and is more likely to become a tool that facilitates and improves patient care [84]. Furthermore, continuous internal audits for evaluating of the checklist's outcome and monitoring of new developments or changes in best practices, research, technologies, or workflows are conducted. The results of periodic reviews are used to determine whether the checklist is still acceptable until the next review, whether it needs to be revised or updated, or if necessary, retired [80].

> **Summary Medical Checklist Domain Analysis:** The benefits of a domain-specific MDD approach makes a DSM solution particularly suitable for the medical checklist domain. Based on a comprehensive domain analysis we defined medical checklists and analyzed their characteristics that provide a basic glossary of domain concepts for the ensuing specification of our modeling language. Moreover, the delineation to other clinical resources allowed us to identify similar resources and to analyze their encoding approaches. Control structures and decision support aspects from guideline and pathway modeling languages provide valuable input for the specification of our modeling language. Finally, the analysis of the medical checklist management life cycle provides insights into phases and activities that need to be supported by our DSM solution. To conclude, the findings from the medical checklist domain analysis provide the foundation for the ensuing MC-DSML development that is described in the following section.

4 Design Solution

In this section, we present the design of our MC-DSML which involves the following three aspects [26]. First, the **abstract syntax** defines the structure and grammatical rules that need to be followed when creating checklist models. It is specified by meta-models that consist of concepts, relationships among the concepts, and the structuring rules. The meta-models that are used to conceptualize the language are, in turn, models themselves. Second, the **concrete syntax** constitutes the visual formalism of checklist models. It is the realization of the abstract syntax and maps the meta-model concepts to their graphical representation. In our case, the concrete syntax is a graphical notation. Third, the **semantics** refer to the meaning of the modeling language. They are defined by textual explanations that map each language concept to the problem domain.

For the MC-DSML development we followed the DSML Engineering Method by Frank [36], which supports the entire process from analyzing requirements to specifying and evaluating a DSML. Furthermore, we involved the following three groups of domain experts via interviews: **Group 1:** included three physicians, two medical students, a nurse, a policy officer, and a healthcare consultant that provided insights into the state-of-the-practice and requirements for MediCheck; **Group 2:** included two medical students, a consultant for IS integration, and a physician that were interviewed for evaluating the abstract syntax; and **Group 3:** included two nurses and three medical students that were interviewed for evaluating the concrete syntax. For the detailed overview of the interviewees and the selection criteria for each group we refer to Appendix A.1 and Section 2.3, respectively. The steps we followed for the MC-DSML development are presented in Figure 4.1. First, we defined the scope, the purpose, and the target audience of MediCheck. Then, we derived design objectives (DOs) and requirements, followed by the prioritization of the latter. Next, we specified and documented the abstract syntax and semantics of the the MC-DSML by reconstructing domain concepts, relationships between the concepts, and corresponding constraints. The documentation of the MC-DSML in the form of meta-models was then evaluated and refined accordingly. Finally, we created the concrete syntax in the form of a graphical notation. The concrete syntax was likewise evaluated and refined with the help of expert interviews, creating exemplary checklist models, and discussing the notation against nine criteria for cognitively effective graphical notations [52]. The results of the development process are presented hereafter.

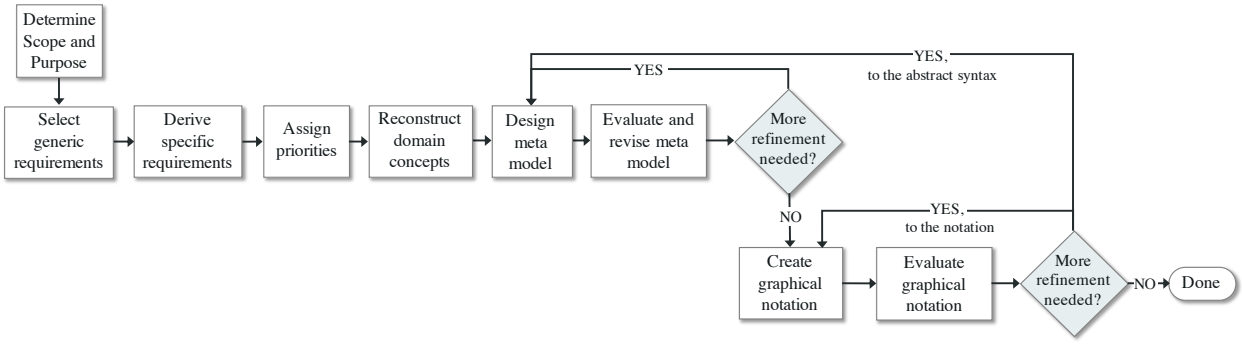


FIGURE 4.1: Development process of our MC-DSML.

4.1 Scope, Purpose, and Target Audience

The main rationale for developing MediCheck is related to the prospect of reducing medical errors to improve patient safety and quality of care. The eight interviews with domain experts during the domain analysis (Group 1) confirmed this observation. According to interviewee I-1G, not using the checklist at all, or only partially filling it in if it does not apply to the patient or situation at hand, is common practice. In fact, not being able to make adjustments to existing checklists that are often too standardized, is one of the major problems mentioned in six out of the eight interviews [I-1B]-[I-1G]. All eight interviewees agreed that the uniqueness of each patient and the variations in context factors and cases require a customizable or dynamically adaptable checklist solution. Yet, changes to existing checklists can currently not be realized by end-users. Interviewee I-1D, a doctor from the Netherlands, described the current situation as follows: "*We can ask either that company [provider of the HIS], or the hospital has a certain department that can make certain alterations. But we know now that it is actually quite difficult to change things, and it is also not always possible*". Moreover, administrative and economic burdens, such as the cost and the time required to keep checklist updated and maintained, impede the effective management of all life cycle phases of a checklist [I-1G]. A doctor from Belgium explained: "*We have to modify it, but the checklist is made by the director who has never set foot in the operating theatre* [...]. *It is actually a long process. That is why we are not always up to date.*" [I-1B]. The comprehensive development of a medical checklist requires a collaborative team approach and particularly the inclusion of end-users in the management of medical checklists is of vital importance [I-1C] to ensure that the checklist is up to date, customized and ultimately effective in ensuring patient safety [77]. Therefore, the following three design objectives guided the development of MediCheck:

> **Design Objectives for MediCheck:**
> DO-1: MediCheck should support all phases of the medical checklist life cycle.
> DO-2: MediCheck should support the customization of medical checklists on both a type- and instance-level.
> DO-3: The MC-DSML should be comprehensible by medical checklist end-users.

The checklist models created with the MC-DSML are tangible and facilitate communication among modelers and model users. In addition, they serve as input for the technical implementation of the checklists within the target system of the DSM solution. Accordingly, the target audience of MediCheck can be divided into the following four groups:

(I) **Software Provider and IS Experts:** providers of HIS who collaborate with the DSML developer to integrate the modeling tool with the existing IT infrastructure and ensure its maintenance. They may further support the development of checklists within MediCheck.

(II) **Managers and IS Experts:** individuals who are responsible for maintaining the medical checklists in practice, including updating them, integrating them into work routines, and assessing and ensuring their effectiveness.

(III) **Medical Checklist Development Committees:** multidisciplinary teams that develop the content and the design of standardized medical checklists.

(IV) **Medical Checklist End-users:** medical practitioners who seek to customize or modify medical checklists, who want to create checklists, or who want to contribute with knowledge and experience to the maintenance and update of the checklists.

4.2 Design Requirements

Based on the domain analysis and a set of generic requirements that apply to every DSML (see requirements R1-R4) we engineered a comprehensive list of 59 design requirements. We organized the requirements into thematically similar groups and, with the help of the domain experts, assigned each requirement a priority level. For this, we followed the MoSCoW prioritization technique [69]. Accordingly, requirements that must be included are denoted with *M*, those that should be included with *S*, nice to have requirements that could be included are denoted with *C*, and those that will not be included with *W*. The complete list of requirements, including their sources and rationale, can be found in Appendix C, while the must-have requirements are summarized in Table 4.1 and described below.

First and foremost, the requirements are directed at realizing the DOs of MediCheck. To foster the inclusion of end-users, requirement R1 specifies that the MC-DSML should correspond to the concepts prospective users are familiar with. Relating to the support of all life cycle phases, the requirements R5.2-R5.5 refer to the conception of medical checklists while R6-R7.7 detail the requirements specific to the required content and design specification. Once a checklist is created, it is important to ensure that its content is up to date and that elements can be deleted or added if needed [I-1E]. Thus, the MediCheck should further support the maintenance of medical checklists (see requirements R8-R8.8).

The definition of eligibility criteria and goals that allow the customization of what items are presented to the checklist user depending on the clinical context are specified in requirement R10. The relevance of this requirement becomes evident by the illustration of interviewee I-1D, who described the current lack of customization possibilities as follows: "*What is not in the checklist but a shame if you have a fertile woman, you should ask if she is pregnant because we use radiology. That is an example of something that is not customized, and there is no backup. It depends on the treating physician or assistant, whether they remember to ask the woman if they are pregnant or not*". Therefore, both customizations on a type-level, i.e., for a group of people that have common attributes such as their gender, and customizations for a specific patient or user on an instance-level can be realized.

Finally, the requirements R11-R11.2 specify the definition of rules that determine the item sequence. Together with R12.2, which specifies the need to define the timing of a checklist in correspondence to the respective clinical path, these requirements relate to integrating the checklists into clinical workflows. Asking the right question at the right time [I-1F] and supporting the availability of different parts of the checklist at different times during the procedure [I-1H], were reported as important aspects in the domain analysis interviews. Moreover, accounting for changes in the workflow or the patient status is mentioned in the academic literature [112]. Guided by the specified requirements, we developed the abstract and concrete syntax of the MC-DSML, which are presented in the following sections.

TABLE 4.1: Overview of the Must-have requirements for MediCheck.

ID	Description
R1	The concepts, relationships, and notational elements of the MC-DSML should correspond to concepts prospective users are familiar with.
R5.2	The MC-DSML should allow specifying a checklist ID, the checklist name, date of creating, version date, checklist type, contact person, and the development committee.
R5.4	The MC-DSML should allow specifying the target population of the medical checklist.
R5.5	The MC-DSML should allow specifying the checklist timing.
R6	The MC-DSML should provide concepts for modeling different checklist item types and corresponding response options.
R6.1	The MC-DSML should allow the modeling of different item types, including at least check items, choice items, and input items.
R6.1.1	The MC-DSML should allow specifying a description, a response option type, check labels, a unique ID, and one or more objectives for each item.
R7	The MC-DSML should support the comprehensive modeling of the checklist content and design.
R7.1	The MC-DSML should allow modeling different container types to group checklist content, including sections that can contain items, and header/footers.
R7.2	A section should be allowed to contain further sub-sections.
R7.4	The MC-DSML should allow the modeling of roles that can be associated with an entire checklist, a checklist section, and specific checklist items.
R7.4.1	The MC-DSML should allow specifying whether a role is operating the checklist, executing the associated task, or should be present during checklist execution.
R7.6	The MC-DSML should allow specifying one or multiple roles associated with an entire checklist, a checklist section, or a checklist item.
R7.7	The MC-DSML should allow specifying whether an item is required.
R8	MediCheck should support the maintenance of medical checklists.
R8.3	MediCheck should allow deleting elements.
R8.4	MediCheck should allow adding elements.
R8.5	MediCheck should allow modifying or changing elements.
R8.8	MediCheck should allow changing the order of checklist items.
R10	MediCheck should allow the definition of eligibility criteria and one or more goals.
R11	The MC-DSML should support the specification of clinical rules that determine the sequence of items and action specifications.
R11.1	The MC-DSML should provide concepts for specifying the relation between items.
R11.2	The MC-DSML should support sequential, unordered, conditional, and parallel item flows.
R12.2	The timing of the checklist or of a specific item should be connected to the corresponding workflow or clinical path.

4.3 Abstract Syntax of the MC-DSML

The specification of the MC-DSML's abstract syntax is directed towards the reconstruction of concepts in the medical checklist domain. Thus, the preceding domain analysis provided a basic glossary of key terms with corresponding descriptions as a foundation for deriving the MC-DSML. We selected the widely used UML [113] for documenting the concepts, relationships, and constraints of the MC-DSML in the form of meta-models.

In order to account for different views, aspects, and levels of detail, we constructed four meta-models with different foci. First, the context-related view of the MC-DSML (see Appendix D.1) specifies concepts and rules that determine *what* is presented to the checklist user. We specified those concepts closely to existing guideline modeling languages for CDSS, since they offer valuable insights into decision making concerns and clinical rules [32]. *Where* and *when* the checklist is shown to the user, determined by the clinical workflow, is specified in the process-related view (see Appendix D.2). For that reason, we specified the concepts closely to clinical workflow modeling languages [102]. The layout-related view defines concepts that specify *how* the checklist is shown to the user (see Appendix D.3). For instance, in emergency situations, the most critical items should be presented on top of the list or by being highlighted [25]. The layout view can be seen as the intermediary between the process- and context-related views for presenting relevant content to the right person at the right time. Finally, the integrated view consolidates the different meta-models at the language level with shared or linked modeling constructs (see Figure 4.3). Before describing the integrated view in more detail in Section 4.3.2, we present the core concepts of the MC-DSML in the following section.

4.3.1 Core Meta-Model of the MC-DSML

The core concepts and relationships of the MC-DSML are presented in Figure 4.2.

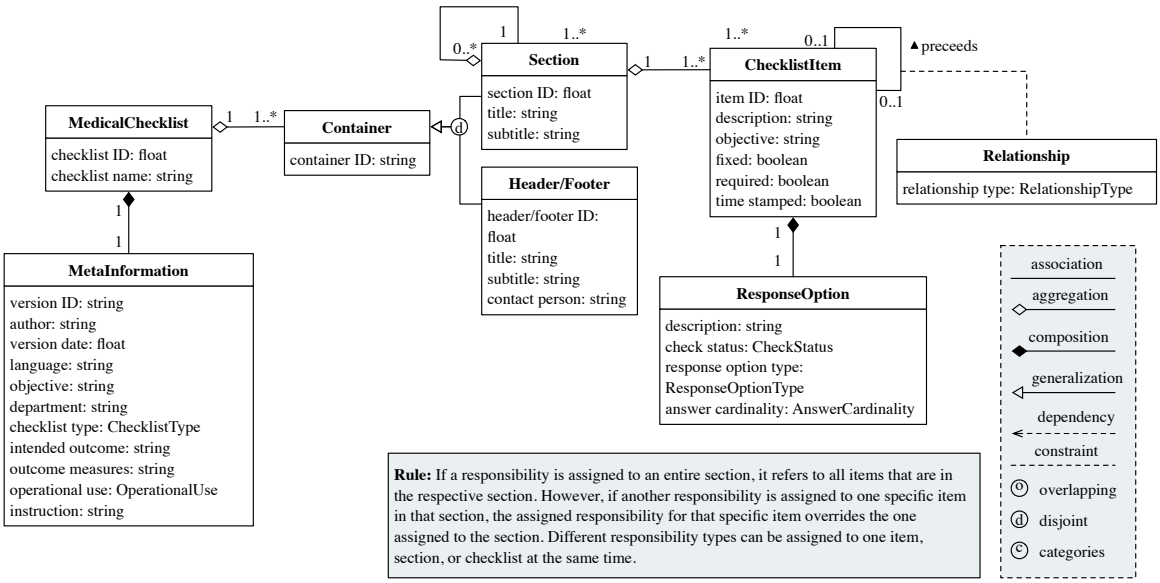


FIGURE 4.2: Core concepts of the MC-DSML.

In the MC-DSML, a **MedicalChecklist** consists of one or multiple **Container**s that group together various elements. A container can either be a **Header/Footer** or a **Section**. Unlike a header/footer, that typically contains the checklist's title, subtitle, images, the contact person, or the version date, a section groups one or multiple **ChecklistItem**s. A section further may contain any number of sub-sections. Each checklist item contains one **ResponseOption**. Both items and response options can be of different types. For instance, we distinguish between confirmation items, choice items, and input items, while response options can be simple checkboxes, drop-down lists, or input fields. A detailed overview of the different types and possible answer cardinalities

is provided in Appendix D.1.3 as part of the layout-related view. Moreover, an item can proceed either one or no other checklist item while preceding either one or no other item. The flow between the checklist items is determined by the **Relationship** between them. Each relationship has a relationship type that specifies whether the flow is a sequential, parallel, unordered, or conditional flow. Lastly, information about the checklist conception, such as its objectives, intended outcomes, and the checklist's author, are specified in the **MetaInformation** that is part of the medical checklist.

4.3.2 Integrated Meta-Model of the MC-DSML

The integrated meta-model of the MC-DSML presented in Figure 4.3 represents the modeling constructs that combine the context-related view (green), layout-related view (yellow), and process-related view (blue). Opposed to integrating the models when generating code, which requires copying the same kind of information to multiple places, the chosen method makes changes to the specification at one level available to other levels, without additional transformations [26]. Thus, design reuse and model refactoring are supported.

Starting with the layout-related concepts, each medical checklist has a **LayoutSpecification** that determines visual representation aspects, such as the font type, font size, visual breaks, or the background color. Thus, the layout can be tailored to the checklist's environmental conditions, such as darkened procedure suites, settings with changing light conditions, or surroundings with a high noise level, and be adapted to users that may require a bigger font size to ensure readability [8]. Similarly, the **Format** of the checklist determines whether the checklist content is presented as a flowchart, a table, or a list. Different sections of the checklist can have a different format to ensure that information is conveyed effectively, depending on factors such as the level of expertise of the process performer or the current process execution state [88]. In addition, both sections and header/footers can contain **EmbeddedField**s. Embedded fields can be multimedia content, such as images, audio, or video material, shapes that help the user navigate through the checklist or text strings. Text strings can be used for providing instructions or guidance, or additional information that supports the checklist use. Similarly to embedded information on the checklist, a specific item can contain **SupplementaryMaterial** that provides additional, yet optionally accessible information to the user. It can be underlying evidence, instructions or support tools, hyperlinks to external resources, or additional literature associated with the specific checklist item. Finally, a **Note** represents an empty field that allows the checklist user to record any additional information or annotations they wish to save [88]. A note can be attached to a section, a specific item, or an entire checklist.

Who operates the checklist, who executes the associated task, or who should be present during the checklist completion, is specified by assigning one or more **Responsibility**s to the entire checklist, a section, or a specific item. A distinction is made between **Role**s and **Actor**s. A role refers to an organizational character a person is assigned to, e.g., a nurse or a surgeon [80]. Contrary, an actor represents a specific personal resource, an individual independent of their role (e.g., Dr. Smith) [82]. Each of these concepts may have a responsibility related to the checklist, such as the **ChecklistOperator** or **TaskExecutor**.

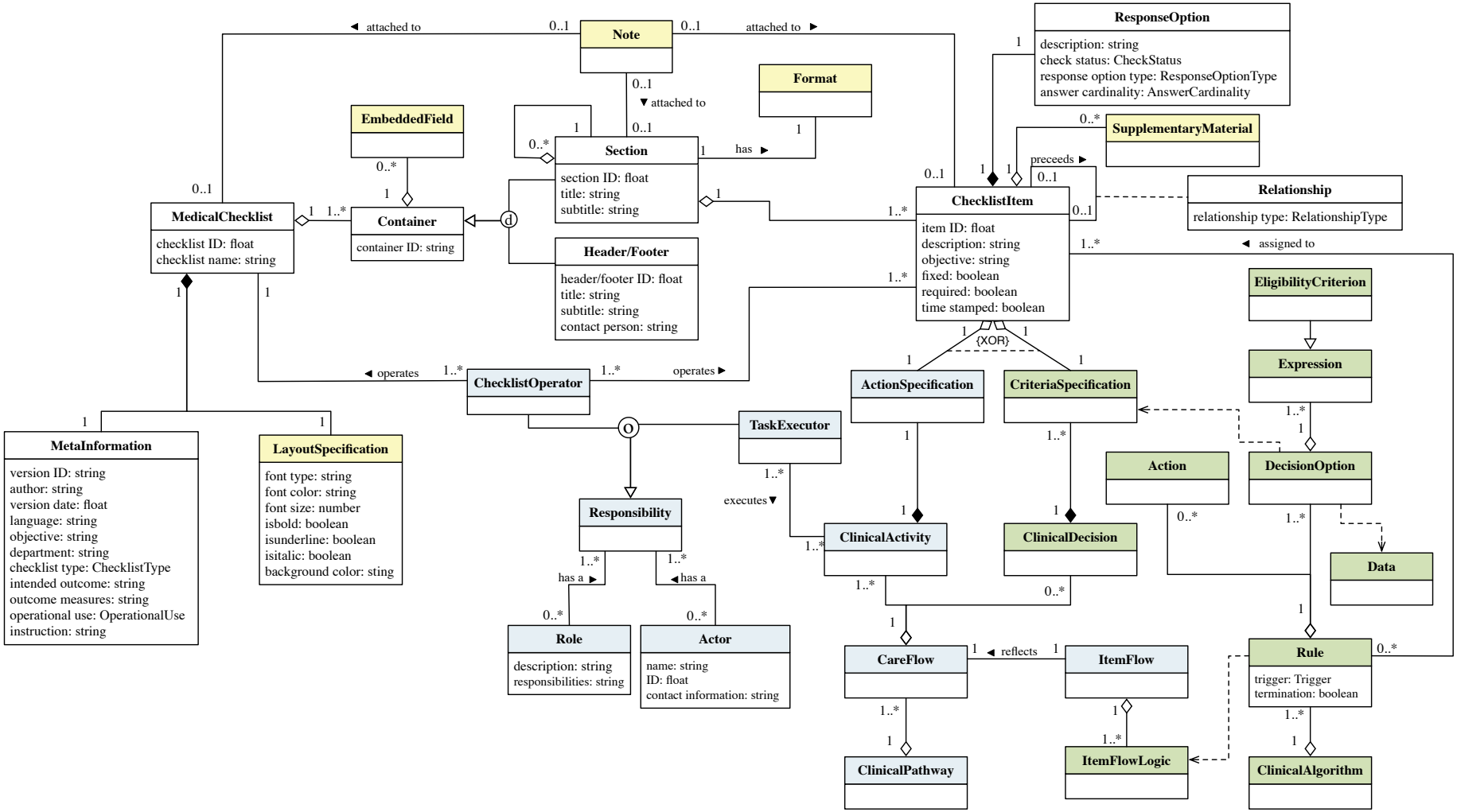


FIGURE 4.3: Integrated meta-model of the MC-DSML.

Moreover, a checklist item either contains an **ActionSpecification** or a **CriteriaSpecification**, that can be found in the process- and context-related views, respectively. Each specification is part of a **ClinicalActivity** or **ClinicalDecision**, which, in turn, are part of a **CareFlow**. A care flow represents a clinical process that is part of a **ClinicalPathway**. By implication, the action specification and criteria specification of a checklist item correspond to the clinical activities and decisions of clinical pathways [48]. Thus, allowing the integration of the medical checklist with clinical pathways. The relationship between the checklist items, specified in the **ItemFlow**, reflects the care flow of a clinical pathway accordingly. The item flow is determined by its **ItemFlowLogic**, which, in turn, depends on a **Rule**. A rule is part of a **ClinicalAlgorithm** that reflects a collection of clinical decision steps. A rule determines the choice among competing, mutually exclusive alternatives, represented by a **DecisionOption** [32]. The alternatives are usually a group of criteria that, when met, initiate an **Action**. An action can either trigger a clinical activity or another rule. Decision options further depend on available **Data**, such as patient data, context information, or data about the user of the checklist. For example, patient data from an electronic medical record (EMR) can be used to identify the patient's gender, and thus, determine whether a specific item is displayed based on the respective rule. A rule can be, for instance, a statistical calculation, such as *in the last five days* [98], or be determined by an **Expression**. Eligibility criteria are an example of such an expression. It can be specified that a certain item is only shown if the patient is a fertile woman, i.e., if the patient is *female AND between 11-55 years old* [I-1D].

> **Abstract Syntax of the MC-DSML:** The abstract syntax of the MC-DSML defines the concepts, relationships, and structuring rules that constrain the checklist model elements and their combinations to respect the domain rules. It combines the process-, context-, and layout-related views that together allow specifying comprehensive models of medical checklists to determine what, where, when, and how content is presented to the user.

4.4 Concrete Syntax of the MC-DSML

We designed a graphical notation that constitutes the concrete syntax of the MC-DSML [114] congruently with the abstract syntax. We chose a graphical over a textual notation to take advantage of its conciseness and precision in conveying information that is superior to textual languages [52]. Moreover, information that is represented visually is more likely to be remembered [115], also referred to as the picture superiority effect [52]. This is particularly useful in the domain of medical checklists since the understanding and memory of the underlying principle and information of a checklist is what guides a practitioner in everyday clinical practice [I-4A].

The graphical elements of the notation are presented in Figure 4.4. To take advantage of existing notations, prospective users may already be familiar with, various modeling languages for business process modeling and guideline modeling were consulted. Whenever possible, notational elements for the MC-DSML were reused or derived from well-known modeling languages, including Business Process Management and Notation (BPMN), Flowcharts, Archimate, and PDDs.

We distinguish between three different item types: confirmation items, choice items, and input items. Confirmation items represent a goal, task, action, or consideration that needs to be confirmed. Thus, we adopted a shape commonly used for representing activities and tasks. Similarly, for choice items that represent criteria with different options to choose from, a decision-like shape is used. For the input item that represents qualitative user feedback we chose a field-like shape, according to suggestions from domain experts [I-3A, I-3B]. For a section, an element similar to a grouping in BPMN and Archimate is utilized, while the start and end elements are adopted from PDDs. The flow between the items can be represented with an item flow arrow, while conditional item flows can be represented through branches using either a rule-branch or eligibility-branch. Moreover, symbols representing item properties, such as fixed, time-stamped, and required, as well as other artifacts associated with checklists, are represented through icons. A detailed description of each notational element of the MC-DSML and their respective sources can be found in Appendix D.3.

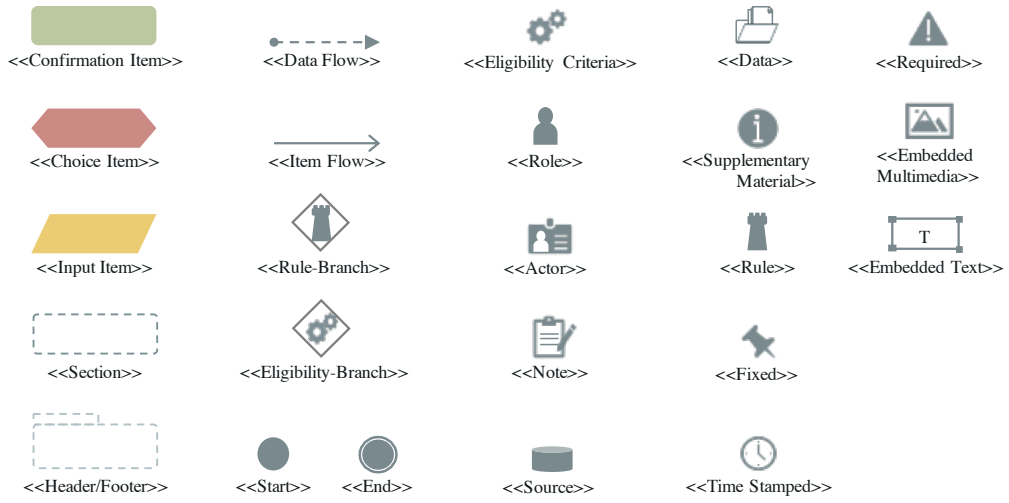


FIGURE 4.4: The main elements of the graphical notation of the MC-DSML.

> **Concrete Syntax of the MC-DSML:** The graphical notation, together with its documentation, constitutes the concrete syntax of the MC-DSML and provides a visual representation of the main concepts of the abstract syntax of the MC-DSML. Together with its detailed description, it provides semantic and syntactic elements for modeling medical checklists.

The language specification of the MC-DSML presented in the preceding sections reflects the final version after acquiring and incorporating feedback from nine domain experts. In the ensuing sections, we illustrate the main design considerations and quality evaluation aspects from the expert interviews and provide an exemplary application of the graphical notation.

4.5 Evaluation of the Overall Quality of the MC-DSML

To determine the overall quality of the MC-DSML, we evaluated both the abstract and the concrete syntax with the help of four expert interviews (Group 2) regarding their completeness and simplicity of the abstract syntax and the completeness, comprehension, and cognitive effectiveness of the concrete syntax. Completeness is defined as the degree to which the MC-DSML contains all necessary elements and relationships between the elements, while simplicity assesses the degree to which the MC-DSML contains the minimal number of elements and relations between them [116]. Regarding the comprehension of the concrete syntax we assess the degree to which the notation can be comprehended by the experts [116]. Lastly, cognitive effectiveness is evaluated by discussing the nine principles of cognitively effective graphical notations provided by Moody [52]. The results and exemplary changes that resulted from the expert feedback are presented below.

4.5.1 Evaluation of the Abstract Syntax

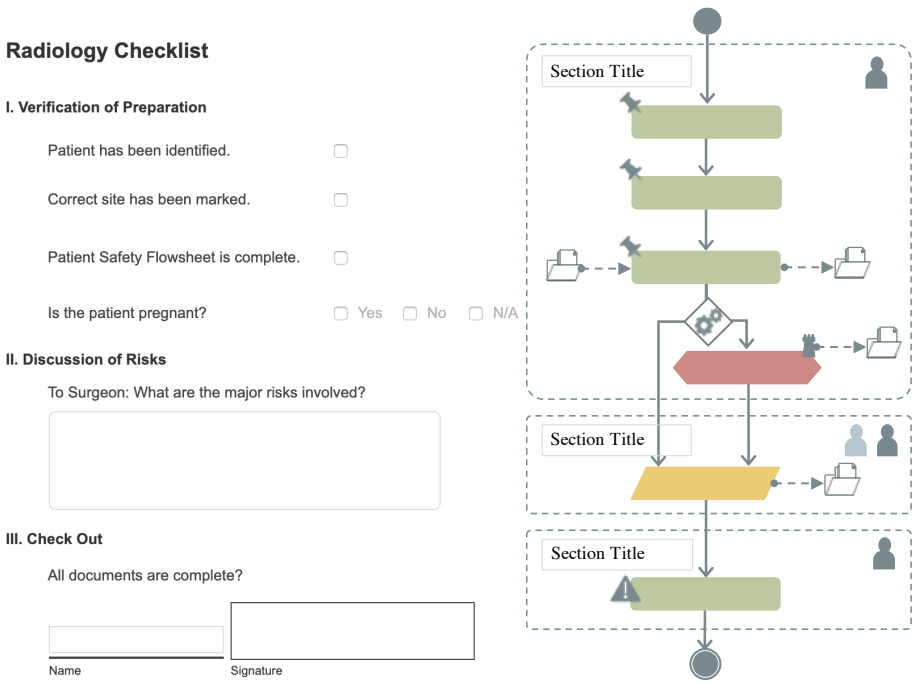
Through the demonstration and discussion of the abstract syntax with four domain experts, we identified missing or redundant concepts and directly adjusted them during the interview so that the expert could confirm the changed version. For example, interviewee I-2B suggested to differentiate between actors and roles that can be assigned to a checklist or a specific item, as opposed to solely roles. This adjustment was confirmed in the ensuing interviews with the rationale of being able to assign the treating doctor for specific patients. Interviewee I-2A further proposed to establish a relationship not only between a note and an item but also between a note and a section or an entire checklist. That way, additional note-taking that is not related to a specific item can be supported. Moreover, we discussed the option to allow the completion of an item by entering a note [I-2B]. For instance, if an item confirming that the patient has been shaved prior to their surgery cannot be verified because the patient wishes to shave themselves, annotating that circumstance should allow the user to carry on with the checklist. However, this requirement exceeded the scope of this research project and was noted in a list of requirements for future developments (see Appendix E.2). To keep the meta-models at an adequate level of detail, we removed some of the relationships from the models and specified them as separate rules, as suggested by interviewee I-2C. For instance, supplementary material can be provided for a specific item, a section, or a checklist. For detailed documentation of the design decisions regarding the abstract syntax we refer to Appendix D.2.

Overall, the research participants expressed that the provision of different views facilitates the understanding and decreases the level of complexity. Regarding the completeness of the abstract syntax we consciously refrained from presenting all details of the MC-DSML in the meta-models to cope with its complexity. By implication, not all properties of each concept and not all possible relationships are represented. However, all experts confirmed that no crucial domain concepts are missing. Moreover, within the last two interviews, no concepts were identified that noticeably exceeded the minimal number of elements. Therefore, we can conclude that the abstract syntax performs well with regard to its simplicity.

4.5.2 Evaluation of the Concrete Syntax

After ensuring that the abstract syntax contains all relevant domain concepts, we developed the graphical notation of the MC-DSML. The notational elements were shown to three medical students and two nurses to evaluate their comprehension and completeness (Group 3). We discussed with the domain experts whether any notational elements were missing, whether each element reflects its meaning, and whether they are distinctive. Various changes to the initial draft of the notation were made according to the experts' feedback. For instance, different color shades were introduced to represent the different responsibilities an actor or a role can hold [I-3B] (see Appendix D.3). Furthermore, the symbol representing an actor, which was initially adopted from the business actor in Archimate, was changed to a badge-like icon. According to interviewee I-3A, the difference between the role and the actor is clearer that way, because "*the badge indicates more that it is a specific instance, an individual rather than some kind of person*". For detailed documentation of the design decisions regarding our graphical notation, we refer to Appendix D.4.

To illustrate the notation, we further created exemplary models of existing checklists. It should be noted that paper-based medical checklists, without any additional documentation, provide limited input for the comprehensive modeling of checklists with the MC-DSML. For instance, information about rules that determine the item sequence or supplementary material is not available in paper formats. However, since the aim of the MC-DSML is to generate digital checklists from the created models, the examples solely served for testing whether the most basic elements can be represented using the notation. Therefore, we modeled seven checklists that we found in the literature and one based on a description from interviewee I-2B. A representation of the latter, together with its corresponding checklist model, can be found in Figure 4.5.



(A) Example checklist (B) Example checklist model

FIGURE 4.5: Exemplary application of the MC-DSML graphical notation.

Finally, we discuss our notation regarding the nine criteria for cognitively effective graphical notations proposed by Moody [52]. Cognitive effectiveness in this context refers to the "*speed, ease, and accuracy with which a representation can be processed by a human mind*" [52, p. 757]. The first principle, **semiotic clarity**, refers to minimizing symbol redundancy, symbol overload, and symbol excess. Through the expert interviews, we made sure that each symbol only represents one semantic concept, while a semantic concept is not represented by two different symbols. The visual distance between two symbols, defined by the number of visual variables the symbols differ in (e.g., color, or shape), is referred to as **perceptual discriminability**. While visual distance compares the symbols pair-wise, **visual expressiveness** refers to using the full range of capacities of visual variables within the entire vocabulary. All interviewees expressed that the symbols are clearly distinguishable. While partially competing with visual expressiveness, **graphic economy** refers to only using a limited number of notational elements. We purposefully develop a graphical representation limited to concern-specific symbols for the construction of checklist models by medical checklist end-users [117]. The development of further graphical symbols is subject to future work. **Complexity management** refers to utilizing mechanisms to deal with complexity. We make use of groupings, i.e., sections and header/footer to provide semantic concepts for modularization. **Semantic transparency** refers to using visual representations that clearly suggest their respective meaning [118]. We discussed and ensured this principle during our interviews by adjusting symbols that did not yet reflect their intended meaning. **Dual coding** refers to using textual annotations in addition to the graphical representation. Based on the feedback from the domain experts we provide an annotation in our language definition, yet it is not attached to the symbols when modeling to avoid visually overloaded models. Furthermore, **cognitive integration** refers to supporting the integration of information from different diagrams. It is not applicable in our case yet. However, in future projects, symbols for representing the system's architecture or its stakeholders could be added. Finally, **cognitive fit** refers to different visual dialects for different tasks or audiences. With the aim to provide a language that is easily understood by medical practitioners, while providing enough comprehensiveness and technicality for the envisioned software implementation, we derived the symbols from well-known graphical notations such as BPMN, flowcharts, and Archimate, whenever possible.

> **Evaluation of the MC-DSML:** The evaluation of the MC-DSML provides a first indication of the MC-DSML's strength in its completeness while maintaining simplicity. Domain experts further confirmed a good level of comprehension. All experts confirmed the relevance of the research problem and saw potential in the MC-DSML to improve the current checklist modeling approaches.

5 Design Validation

In this section, we present the results from the validation of our DSM solution. To assess whether MediCheck is effective, we created an implementation simulation of the MC-DSML as a proof of concept and utilized it to demonstrate MediCheck to four prospective users. A presentation of the simulated tool can be found here: MediCheck Demonstration. The MC-DSML is considered effective if it fulfills its outlined objectives (DO-1-DO-3) and prospective users express their intention to use it. Therefore, we conducted four qualitative simulations to assess the perceived ease of use (PEoU), comprehension (Cprh), perceived usefulness (PU), and intention to use (ItU). PEoU measures the degree to which a person believes that using the MC-DSML would be free of effort [40], while Cprh measures the degree to which the MC-DSML as the underlying checklist model is understood by the expert [116]. PU measures the degree to which a person believes that the MC-DSML will achieve its intended objectives and ItU the extend to which the expert intends to use the MC-DSML [40]. Moreover, we assessed the degree to which the DSM solution fulfills the specified requirements as they are derived from the design objectives. Lastly, to validate the relevance of our DSM solution, we performed a comparative analysis of existing artifacts for encoding medical knowledge in clinical resources based on our must-have requirements.

5.1 Qualitative Simulation Results

We conducted four qualitative simulations with medical practitioners, specialized in neurology, primary care for elderly patients, internal medicine, and radiology, that constitute prospective end-users of MediCheck. Based on two scenarios that included the conception, creation of the content and design, modifications, customizations, and the maintenance of a medical checklist, we demonstrated the use of the modeling language for developing executable medical checklists. With the help of a post-task questionnaire, we measured PEoU, Cprh, and ItU with four items each. Since the perceived usefulness of the MC-DSML is the most important variable in our study, we measured it using ten items. The participants were asked to think out loud while filling in the questionnaires. That way, additional insights into the expert's perception was gained. Moreover, two dichotomous items asked whether there is a similar tool for the creation and maintenance of medical checklists, respectively, providing an indication of the relevance of the tool. Finally, we asked various open-ended questions to elicit further feedback.

5.1.1 Post-task Questionnaire Results

All items of the post-task questionnaire were answered by all four research participants. For the analysis and the presentation of the questionnaire results, we inverted the scores of the negatively formulated items. Furthermore, we assigned an integer to each category of the Likert scale, consecutively increasing with each choice (fully disagree = 1, fully agree = 5). Due to the small sample size and number of items per variable, we treat the data as ordinal. We assessed the validity of the empirical indicators by performing inter-item correlation analysis. Item Q4 (PU) had a low convergent validity with < .3. The item aimed at measuring to what degree the participant believes

the tool would make it easier for them to develop a medical checklist compared to now. However, the participants' current lack of involvement in creating new checklists may have impacted the validity of this item and was therefore removed from all further analyses.

The results of the questionnaire for each measured variable are presented with a diverging stacked bar chart in Figure 5.1. We interpret full and partial disagreement as well as neutral responses as negative responses, while partial and full agreement is interpreted as positive. The visualization shows that overall more than 50% of the responses were positive. In particular, 97% of all items that measured PU were agreed to, with 64% fully and 33% partially agreed.

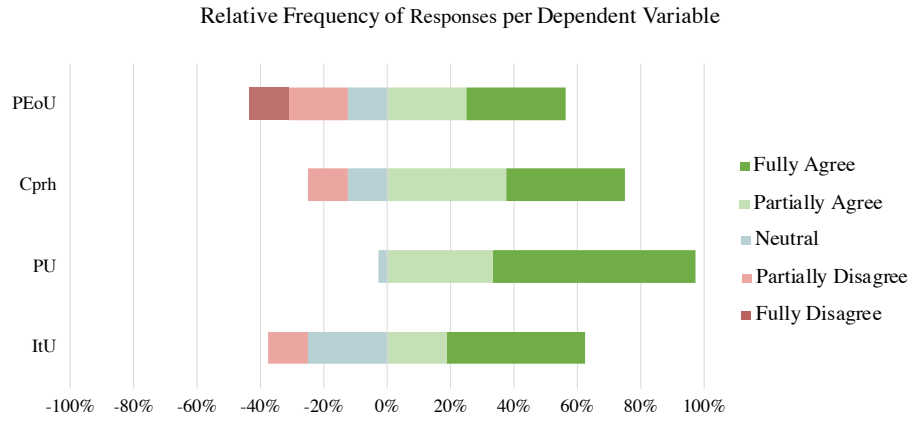


FIGURE 5.1: Questionnaire results for each variable.

To get an indication of the center and dispersion of the results, we calculated the median and the interquartile range (IQR) for each variable (see Table 5.1). The results confirm that PU has the highest median compared to the other variables while showing the smallest IQR. By implication, the variability between the responses is the lowest for PU. Moreover, the results show that all variables are predominantly agreed with. However, the IQR for PEoU indicates that the responses are spread out over a larger range of the Likert scale compared to the other variables.

TABLE 5.1: Descriptive statistics of the post-task questionnaires by variable.

Variable	No. of Items	Median	Likert Scale	Interquartile Range
PEoU	16	4	Partially agree	3
Cprh	16	4	Partially agree	1.25
PU	35	5	Fully agree	1
ItU	16	4	Partially agree	2

For a better understanding of each variable we investigated the results of their respective operational statements. All analyzed items are depicted in Figure 5.2. They are organized by the variables on the vertical axis, and by the relative frequency of responses on the horizontal axis. Since the number of responses per item equals four, each response is represented by 25% on the horizontal axis.

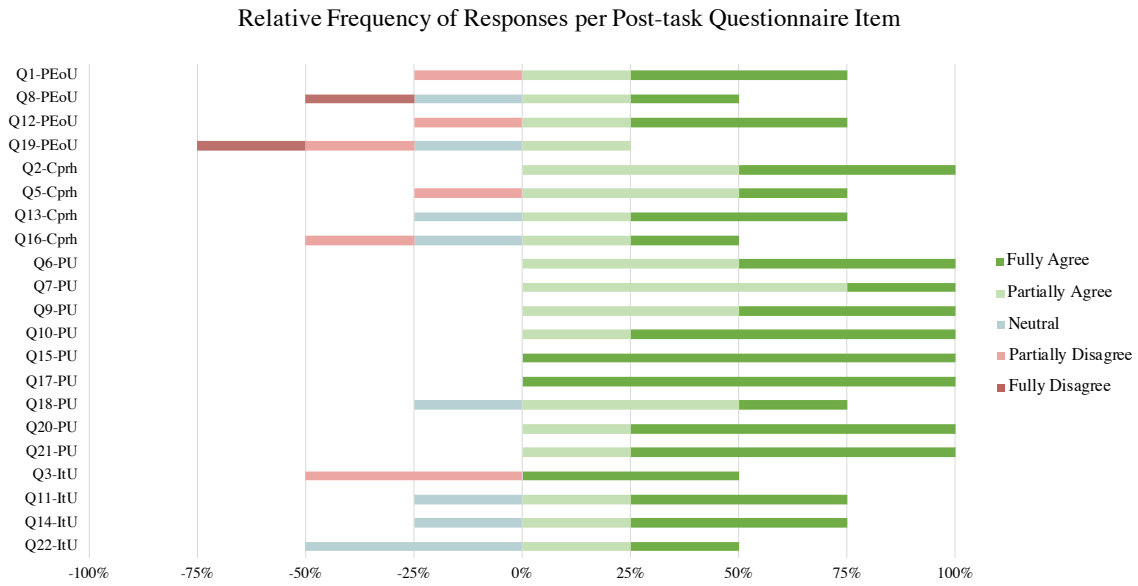


FIGURE 5.2: Diverging stacked bar chart for post-task questionnaire results.

5.1.1.1 Perceived Ease of Use

PEoU was assessed with four items. The participants overall partially agreed with the statements, indicated by the median of 4. Participant I-4C expressed: "*as a young physician myself who grew up using computers, I think that was phenomenal*". However, the IQR of 3 shows that the variability between the responses is high. Especially item Q8 and Q19 indicate that the perceived ease of use can be improved. These items assessed whether the participant believes that help from an expert would be needed to develop and maintain medical checklists with MediCheck, respectively.

The need for a certain level of computer affinity was given as a rationale for three out of the five negative responses. Therefore, participant I-4B argued that the intricacy that makes the tool very useful for users that are experienced with computers, may negatively affect the ease of use for less experienced users. Under the assumption that the tool is aimed at being applied across a wide range of users, providing additional support for accommodating less experienced practitioners was therefore suggested [I-4C]. Moreover, participant I-4D mentioned that creating comprehensive checklists with MediCheck may require a substantial investment of time, yet they further argued that "*once you have created it, it can save a lot of time*".

5.1.1.2 Comprehension

The comprehension of MediCheck was measured with four items that assessed the degree to which the participants understood how the actions performed with MediCheck are related to the underlying checklist model. The median of 4 indicates a high level of comprehension, while the variability between the responses is relatively low with 1.25.

However, some difficulties of comprehension were detected. For instance, how setting eligibility criteria for a specific item is affecting the item flow was not fully understood after the first scenario by one participant [I-4B]. Similarly, understanding the relationship between the items

without seeing the checklist model was described as challenging [I-4C]. However, once the checklist model is displayed it is described as "*pretty intuitive to understand*" [I-4C]. A

5.1.1.3 Perceived Usefulness

For measuring the perceived usefulness, nine items (excluding item Q4) assessed whether using MediCheck for the creation and maintenance would (i) facilitate the applicability of medical checklists to the context and the patient, (ii) improve the integration of medical checklists into the daily workflow, (iii) facilitate sharing and (iv) updating medical checklists, and (v) make it easier to adjust existing checklists. Overall, the PU of MediCheck was rated very high, as indicated by the median of 5. Moreover, the low IQR of 1 shows a small variability between the responses.

All respondents agreed that the tool has the ability to improve keeping checklists up to date and to reuse existing checklists. Furthermore, all participants fully agreed with both item Q15 and Q17, which assessed whether the expert believes that the tool would help to make adjustments to an existing checklist and to make them more applicable to the context and patient, respectively. The perceived improvement of integrating checklists into daily workflows was explained by the interactivity of the tool. Participant I-4C argued that for building a checklist with MediCheck it required the user to think about how to integrate it with their workforce and their clinical approach.

In turn, the aspect of interactivity was also mentioned as a concern since it may impose an administrative burden on the developers of the checklists [I-4A]. The participant emphasized that it is crucial to keep the administrative efforts as low as possible. Finally, next to all the positive responses, the only neutral response was to item Q18 which assessed whether MediCheck would improve the integration of medical checklists into clinical workflows. This response was reasoned with the current lack of clarity within the system on the technical integration of the checklists with other information systems [I-4A].

5.1.1.4 Intention to Use

ItU was measured with four items that assessed whether the participant would use MediCheck in practice. Two of the participants fully and partially agreed with all four statements, indicating their intention to use MediCheck. The overall intention to use MediCheck is indicated by the median of 4 while the IQR of 2 shows a moderate variability between the responses.

The negative responses are reflected by participant I-4D who stated that the need to create new checklists is currently not given in their outpatient clinic. In addition, participant I-4A claimed that their responses depended on *whether* they intend to create new checklists in the first place.

Before presenting the discussion of MediCheck against its requirements and its comparative analysis with modeling languages for similar clinical resources, additional feedback gained during the qualitative simulations is presented in the ensuing section.

5.1.2 Additional Feedback

Through the dichotomous items on the questionnaire and the discussion before and after performing the two scenarios in MediCheck, we were able to additionally identify the following aspects.

Relevance: During the initial discussion about the current situation, all four participants confirmed the research problem and the need for improving the maintenance of medical checklists. All

participants further proclaimed that no similar tool for the development nor for the maintenance of medical checklists is currently available in their organization or based on their experience. The overall feedback regarding MediCheck's relevance can be summarized by the following statement: "*This work is meaningful, there is definitely a use for it*" [I-4B].

Understanding and Acceptance: By providing a legend for the graphical notation within MediCheck the comprehension of the modeling language may be improved [I-4C]. Additionally, presenting the checklist model next to the created checklist by default was suggested by three of the experts [I-4A-I-4C]. That way, the logic behind the checklist, and the relationship between the items become transparent. This ties together with the concern expressed by participant I-4B, that the successful implementation of a medical checklist requires the practitioners' trust in its reliability and validity. Thus, the more transparent the checklist model is to the doctor, the better they can assess its quality. Moreover, the aspect of formally approving a created checklist becomes a crucial aspect. Distinguishing between validated standardized checklists, and self-made checklists is therefore important.

Checklist Reuse: Another aspect of consideration is how to ensure an efficient reuse of checklists modeled with the MC-DSML [I-4B]. To ensure that existing checklists, parts of checklists, or specific items can be easily identified, a modular approach was suggested that would allow users to find useful reusable content based on, for example, specified keywords.

Revision and Maintenance: MediCheck allows setting reminders for revising a checklist. To further support committees or managers in the maintenance of medical checklists, distinguishing between types of revisions was suggested [I-4C]. For instance, it could be distinguished between whether the revision aims at reviewing evidence, the user-interface or system-related aspects, or evaluating outcome measures and correct deployment of the checklist.

5.2 Discussion Against Requirements

To further assess to what degree MediCheck achieves its objectives, we discuss it against the specified design requirements. As illustrated in Figure 5.3, all must-have requirements (21/21) and 30/35 should-have requirements are fulfilled, while 4/35 are partially fulfilled.

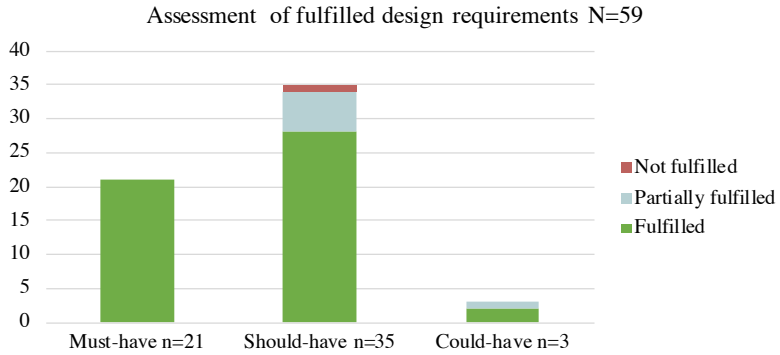


FIGURE 5.3: Assessment of design requirements, N=59.

The partial fulfillment mainly results from the limited scope of this research project. For instance, requirement R8.2 specified that the MC-DSML should be integrable with guidelines and protocols

so that changes and updates in the underlying evidence can be communicated to the checklist creator or updated automatically. However, the automatic update is not yet defined in the MC-DSML. In addition, R13.6 specified that the MC-DSML should be integrable with local HIS so that checklist users have a unique login and specific medication policies can be considered. This requirement is realized in part with an association between MediCheck and other information systems in the abstract syntax, but the technical specifics are not yet defined. The only requirement that is not fulfilled by our DSM design is R7.3. It describes that a concrete behavior associated with each checklist item should be specified. In the current design of MediCheck a textual description of the behavior can be assigned to a checklist item as supplementary information. Although these textual specifications provide guidance for the checklist users, they do not support automated observations of the task performance that allow the detection of deviations from the specified behavior. Detecting incorrect or omitted task completions not only enables root cause analyses but also enables immediate alerts that can prompt the checklist user to correct their actions. Therefore, we deem this requirement as not sufficiently fulfilled but stress its relevance for future development iterations. Overall, 90% in total and 100% of the must-have requirements are fulfilled by our DSM solution. Therefore, we can conclude that MediCheck successfully achieves its specified design requirements.

5.3 Comparative Analysis

Finally, based on our must-have requirements, we compared MediCheck with competing artifacts for encoding medical knowledge in clinical resources. Owing to their close relationship, we focused on modeling languages for medical checklists, clinical guidelines, and clinical processes. We selected approaches that are commonly referred to in the literature and for which extensive documentation could be found. The results of the analysis can be found in Table 5.2.

TABLE 5.2: Evaluation of encoding approaches for clinical knowledge based on our must-have requirements.

Type	Approach	R1	R5.2	R5.4	R5.4	R6	R6.1	R6.1.1	R7	R7.1	R7.2	R7.4	R7.4.1	R7.6	R7.7	R8	R8.3	R8.4	R8.5	R8.8	R10	R11	R11.1	R11.2	R12.2
Checklist	Tracebook [19]	◐	●	●	●	◐	○	◐	●	◐	●	●	●	◐	●	○	○	○	○	○	●	●	●	●	●
	Digital Checklist System [89]	○	●	◐	◐	◐	◐	◐	●	●	●	○	○	○	●	○	○	○	○	○	◐	◐	◐	○	○
	DoT-U2 [119]	○	◐	●	○	◐	◐	◐	◐	○	◐	○	○	○	○	○	○	○	○	○	○	○	○	○	○
	SmartChecklist[120]	○	◐	○	●	◐	◐	◐	○	○	○	◐	○	○	●	○	○	○	○	○	○	◐	◐	●	●
	dpAid [121]	○	◐	◐	○	○	○	○	●	◐	◐	○	○	○	○	○	○	○	○	○	○	○	◐	◐	◐
Process	CONFlexFlow[122]	◐	○	○	○	○	○	◐	○	○	◐	●	○	○	◐	○	○	○	○	○	●	○	◐	●	●
	DSML4CP [48]	●	○	◐	●	○	○	○	○	○	◐	●	○	●	●	○	○	○	○	○	◐	◐	●	●	●
	BPMN4CP[106]	●	○	◐	○	○	○	○	○	○	○	●	◐	◐	○	○	◐	◐	◐	○	○	●	◐	●	◐
	Clinical Process Model [103]	○	○	●	●	◐	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	○	◐	○	●
Guideline	GLIF3 [32]	◐	○	●	○	○	○	○	○	○	○	○	○	○	●	◐	○	○	○	○	◐	●	◐	●	●
	Asbru [123]	○	○	◐	○	◐	○	○	○	○	○	◐	○	○	◐	○	○	○	○	○	◐	●	●	●	○

Legend: ○= Not fulfilled; ◐= Partly fulfilled; ●= Fulfilled

The closest encoding approach to ours is the dynamic checklist support system Tracebook [112]. Tracebook provides a general modeling framework that reuses existing modeling languages. It combines BPMN for modeling the process part of the system, GLIF for modeling each checklist as a guideline, and a checklist engine for the interoperability between the respective workflow and rule engine. However, the system focuses on safety checklists and does not aim at including medical practitioners in the creation and maintenance of the checklists. In fact, maintenance activities (see R8-R8.8) are not supported in Tracebook. Another dynamic checklist system is SmartChecklist [120]. It uses a specific modeling language (Little-JIL) for modeling clinical processes to support task assignments and complex ordering of tasks, yet does not consider the checklist layout, groupings of checklists, or maintenance activities. Both the DSML4CP [48] and the Clinical Process Model [103] model checklists as a concept as part of a clinical path, yet do not support the specification of different item types or response options, maintenance activities, or rules that determine the item sequence. Overall, the analysis demonstrates that only a few approaches support the comprehensive modeling of different item types and response option types, while none of the existing modeling approaches provides full support for the maintenance of medical checklists. Particularly for checklist systems, none of the existing approaches provide a modeling language directed at medical practitioners. Thus, the results of the comparative analysis confirm the experts' assertion that there is currently no modeling approach that fulfills all requirements and, thus, emphasizes the relevance of our DSM solution.

5.4 Summary of the Validation Results

All experts confirmed the usefulness of our DSM solution, while none of the participants reported a similar tool for either the creation, or the maintenance of medical checklists in the current practice. The experts further agreed that MediCheck would improve the workflow integration of checklists, their customization on a type- and instance-level, and their applicability to the context and case. Moreover, creating medical checklists, making adaptations, sharing them, and keeping them updated is seen to be supported by MediCheck. The experts further ascertained their comprehension of how the underlying checklist model is related to the tool and, overall, expressed their intention to use MediCheck in practice. Lastly, the comparative analysis with existing encoding approaches confirmed the relevance of our DSM solution, while the discussion against the specified requirements further confirmed the fulfillment of its objectives.

> **Validation Results:** MediCheck is considered effective, as its validation confirmed that it (i) supports all phases of the medical checklist management life cycle, (ii) facilitates customization, (iii) is comprehensible by prospective end-users, and (iv) domain experts expressed their intention to use it.

6 Discussion

In this section, we provide a discussion of our research results. Therefore, our research aim and prospective goal, the DOs of MediCheck and its components, and the variables and utilized methods to evaluate and validate our design are illustrated in Figure 6.1. The visualization represents the scaffolding of this research study and explicates the relations between the elements. In the following sections, we provide a discussion of the implications that can be drawn from our results and relate them to the literature review findings. Furthermore, we discuss the limitations and threats to validity and suggest opportunities for future work before concluding the research in Section 7.

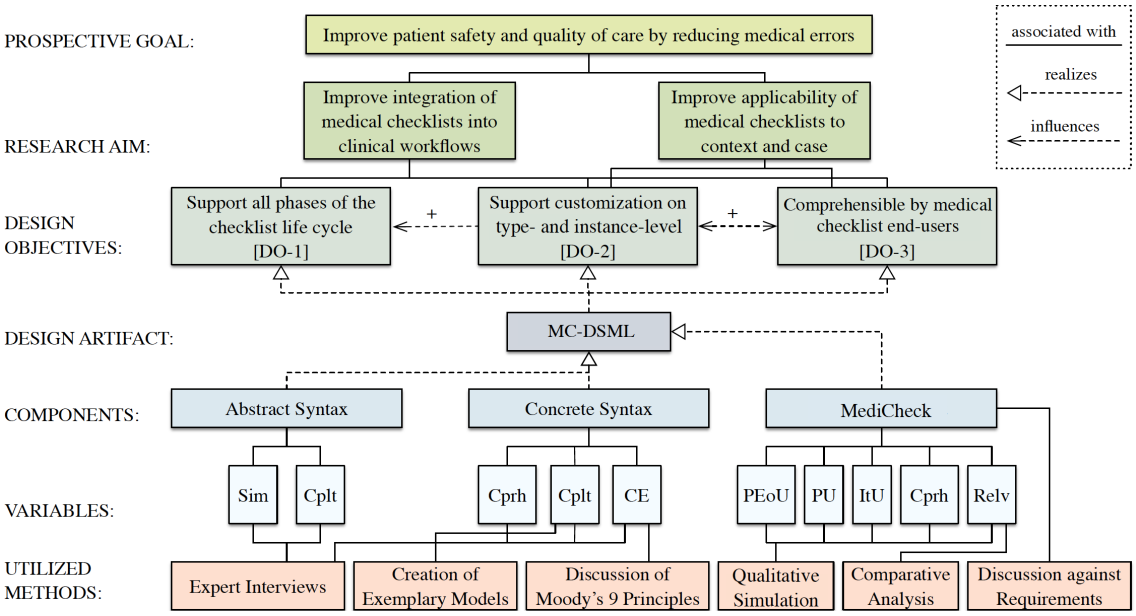


FIGURE 6.1: Overview of the research goal and aim, design objectives, components of the design artifact, analyzed variables, and utilized methods.

6.1 Implications

Implication 1: A DSM solution for medical checklists requires a collaborative approach. Our DSM solution for medical checklists provides a promising tool for both the comprehensive development of checklists and their subsequent maintenance. However, the intricacy of the modeling tool requires a collaborative approach [I-4C]. Through our qualitative simulation we found that the support from an (IS) expert is perceived as being needed, particularly with respect to medical practitioners that have little experience with computers. Moreover, since the training of medical practitioners typically does not involve conceptual thinking and quality improvement strategies I-4C, the relevance of continuous quality improvement may not be seen by the checklist end-users. Consequently, both end-users and individuals that are more familiar with IS and quality management, such as CMIOs, should collaborate throughout the entire checklist management life cycle. Moreover, allowing end-user to submit new checklists or proposing changes to

an existing standardized checklist to the responsible committee or role was suggested for encouraging the practitioners' inclusion [I-4B, I-4C]. Likewise, the collaboration between individuals that understand the broad context, available evidence and importance of the topic, individuals who actually perform the task, and those responsible for the technical implementation is recognized and consistently emphasized in the literature [2]. The lack of a designated role for the management and maintenance of checklists, as well as the communication barrier between the medical and the IT domain, currently avert the direct engagement of medical practitioners in the maintenance of the tools [I-4C]. MediCheck provides a tool that fosters the collaborative development and maintenance of medical checklists by allowing end-users to directly participate in maintaining and updating medical checklists through bridging the communication gap between the modeling and the domain language.

Implication 2: A checklist alone may not effectively change medical practice.

According to Reason's theory of the *cumulative act effect* [124], safety in complex environments relies on multiple system defenses, including the organizational structure, training of the professionals, and the quality of equipment and technology. Thus, a system approach is needed that includes the support from political and financial systems, hospital administration, and medical practitioners to build strong defenses against human errors and diminishing their effects [14]. In addition, regular feedback and training and aligning the checklist with organizational structures and local procedures is needed to ensure adherence to and the relevance of medical checklists [97], [125]. Within our interviews with various domain experts we further learned that a modeling approach for medical checklists needs to ensure that the checklist improves patient safety by providing support for the practitioners without imposing additional administrative burden for the end-users [I-1B, I-1C, I-4C]. Therefore, a DSM solution for medical checklists needs to provide support beyond modeling the core checklist concepts. It should further allow to offer training material, enable analyses of collected data to develop quality improvement strategies, be integrated with existing CDSS and WfMs to ensure the workflow integration and adaptivity of medical checklists to different context factors, and end-user acceptance.

Implication 3: No one size fits all solution.

Within this research we identified a number of external factors that are affecting the creation, use, and management of medical checklists and need to be considered for the application of a modeling tool in practice. Therefore, we illustrate a checklist orbit in Figure 6.2, that we derived from our findings in both the literature and our expert interviews. It is divided into three levels, (i) the macro-level that contains political, economic, and social factors, (ii) the meso-level that contains technical structures and organizational groups, and (iii) the micro-level that contains individuals and their intentions.

Factors impacting medical checklists on the macro-level are, inter alia, compensation strategies, healthcare regulations for quality and safety, and legal frameworks. For example, an important objective for checklists in the US is for practitioners to document their activities, including precise time stamps to provide protection against possible liability claims [I-4C]. Thus, depending on the region, providing specific functionalities may need to be considered, such as automatically time-stamping each checklist item when completed.

On the meso-level, impacting factors are the degree of digitization, collaborations between healthcare organizations, and cross-institutional associations. In Germany, for example, EMRs are not universally stored in electronic formats [I-1A, I-4 1E]. Therefore, the benefits of MediCheck of integrating checklists with local IS cannot be fully realized.

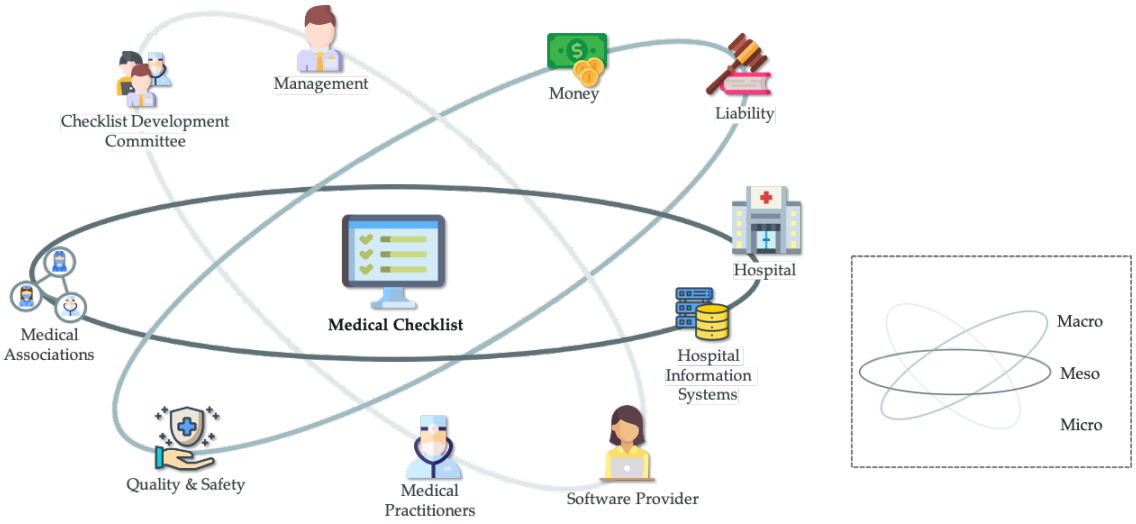


FIGURE 6.2: Medical checklist orbit.

On the micro-level, the interests and intentions of hospital management, checklist development committees, software providers, and the attitude of medical practitioners affect the success of medical checklist modeling solutions [I-4B].

Lastly, while the reuse and sharing of checklist models is encouraged in the literature [19], the multitude of external factors across the different layers is not taken into account. For instance, depending on the prevalent compensation structures or competitiveness between healthcare organizations, sharing created checklist models may be disadvantageous [I-4B, I-4C]. Therefore, a DSM solution for medical checklists may require customizations depending on the type of organization or region it is applied to. However, these organization- or region-specific requirements can be realized in MediCheck due to the extendable nature of its language specification.

Implication 4: The practitioners' attitude towards checklists matters.

A prevalent aspect in the culture of physicians is their resistance to change, mandated procedures, and standardizations that undermine their professional sovereignty [I-4B, I-4D], [2]. Research has shown that this negative attitude affects the successful implementation of checklists in practice [126]. Likewise, during this research project, it became apparent that the negative attitude of doctors towards checklists in general may have affected the perceived usefulness of the tool. For example, one of the research participants indicated a skeptical attitude towards checklists while having the lowest scores for both perceived usefulness and intention to use [I-4A]. However, the participant explained that administrative burdens needed to be minimized, the rationale behind the checklists and their items transparent, and the flexibility to deviate from defined checklist content if deemed inapplicable given. Those arguments align with the recommendations in the literature to warrant medical practitioners the freedom to use their own judgment, and to give them a sense of

control over their work [12]. Consequently, to counter potentially negative attitudes towards medical checklists, MediCheck (i) provides transparent checklist models behind the displayed checklist items allowing the user to understand the logic behind the checklists [I-4B], (ii) supports the automated completion of items through integration with existing information systems to decrease the administrative burden for practitioners [I-4A], and (iii) facilitates the end-users involvement in the creation, maintenance, and customization of checklists by providing a language prospective end-users are familiar with.

6.2 Limitations and Threats to Validity

To consider the results of this research in light of its limitations, we provide a discussion of the main threats to the validity below. First, construct validity denotes threats to the design of the research methods that do not measure what they are intended to measure, while internal validity refers to external factors that may have affected the dependent variables [127]. External validity further concerns the generalizability of the results. Finally, reliability denotes to what extend the results are independent of the researcher.

Construct Validity: We followed an established and widely used design science research framework complemented with a successfully used method for engineering DSMLs. Moreover, established methods for the literature study and interview conduct were followed. Furthermore, we determined the variables to measure the effectiveness of MediCheck based on the widely used Theoretical Model for Validating Information Systems Design by Moody [40]. We further created the items, i.e., the operational statements according to [40] and the System Usability Scale [71] and piloted each protocol used for the interviews, literature studies, and the qualitative simulation prior to the conduct. Although we attempted to involve different stakeholder groups of our DSL solution, we did not successfully include software providers or IS experts in our design validation. Due to the exploratory nature of this research project and the focus on the comprehension and acceptance by medical checklist end-users, we ascertain their lack of input during the validation limited impact on the construct validity of our research. Finally, we gathered insights from multiple sources, i.e., applied triangulation, to ensure that our results do not rely on just one source [41].

Internal Validity: The main threat to internal validity is the use of an implementation simulation and the lack of knowledge regarding the technical requirements for integrating MediCheck with existing IT systems. Thus, the proof of concept that was demonstrated to the experts is based on the assumption that the integration-related factors are, in fact, realizable. Moreover, for the experts included in this research, we applied broad selection criteria. We deem this acceptable due to the lack of empirical arguments for individuals being more or less qualified for our study since no specific education or distinct roles exist that are responsible for medical checklist management. The experts' attitude towards checklists and the limited time available for the qualitative simulation may have affected the participants' responses. However, for a first investigation of whether a DSM solution is feasible in the medical checklist domain, the potential impact of these factors is not expected to endanger the internal validity of this study.

External Validity: Although the number of participants per country, specialty, and organizational role is limited, we were able to investigate across a wide range of organizational, regional, and professional boundaries (see Appendix A.1). Therefore, our findings from the domain analysis and the derived requirements can be generalized to the medical checklist domain with limited regional or organizational boundaries. Regarding the validation results of MediCheck, due to the small number of qualitative simulations, rather than attempting to generalize over the findings based on inferential statistics, we treat each participant as a case to gain in-depth insights from. Thus, the qualitative simulation results cannot be generalized across countries or organizations as definite, but rather function as an indication for the feasibility of a DSM solution in the medical checklist domain in general. Lastly, our findings relate to a domain-specific solution for checklists in the medical domain. By implication, they cannot be generalized to checklist modeling approaches in other HROs.

Reliability: Through thorough documentation of our research and design procedures, we established a rigorous and reliable design research process. To limit researcher bias, we made use of protocols for the literature studies, expert interviews, and qualitative simulation and utilized post-task questionnaires. To further strengthen the qualitative simulation's reliability, we mainly demonstrated the simulated implementation of the MC-DSML to the experts. However, since a demonstration limits the insights into possible interactions between the expert and the system we could learn from, we let the experts perform the conception of a checklist themselves. Therefore, we thoroughly tested the prototype with fellow master students to ensure its reliable functionality.

6.2.1 Future Work

The findings of our study suggest that the MediCheck is effective in achieving its outlined objectives, and domain experts expressed their intention to use it. Thus, we demonstrated the feasibility of a DSM approach in the medical checklist domain. Therefore, further research into the quality of the language specification, particularly the graphical notation, should be conducted, and software providers consulted for further insights. Subsequently, the first version of the DSM solution can be defined by building a generator to translate the medical checklist models into code and a domain framework to realize the implementation of MediCheck (see Figure 1.3) and tested in practice. However, due to the limited number of qualitative simulations, we cannot generalize our validation results across different healthcare organizations, regional boundaries, and medical departments. Thus, an investigation of factors impacting the effectiveness of MediCheck from multiple viewpoints should be conducted as well. Moreover, our MC-DSML conceptually supports the use of collected data to elicit new insights into diseases or the effectiveness of procedures and to share these insights among organizations. Especially the current Corona pandemic illustrates how what is learned about the virus and applied treatment strategies can be used to update and improve guidelines and checklists while sharing these insights with other organizations [I-4C]. Therefore, an investigation into the context factors and data needed for MediCheck should be conducted to determine *what* data is relevant and *how* and *where* the data can be collected and classified. Finally, by creating instructions for how to apply the MC-DSML, for instance, through the creation of a process model, the MC-DSML can be developed into a method for modeling medical checklists.

7 Conclusion

The ability of medical checklists to effectively improve patient safety and quality of patient care has been consistently proven throughout the last decades [9], [128], [129]. However, problems regarding their integration into local workflows and their applicability to the given context and case, rooted in the current checklist design and modeling approaches, result in low compliance rates and an overall slow adaptation of checklists in the healthcare domain [8], [14]. Therefore, the aim of this study was to improve the design of medical checklists by designing a DSM solution for medical checklists that facilitates the creation, maintenance, and customization of checklists and is comprehensible by prospective end-users. The research was organized around our MRQ and six SQs, which we answer below.

SQ1: ***What concepts and characteristics does a medical checklist encompass?***

Medical checklists are collections of items that conceptualize essential activities and criteria of clinical procedures with the aim to ensure that all items are completed or considered. We identified and described fourteen characteristics relating to checklists and their respective items.

SQ2: ***Which aspects of existing encoding approaches for similar clinical resources can be adapted for modeling medical checklists?***

As medical checklists are commonly derived from clinical guidelines and clinical pathways, the following aspects can be adapted from their respective modeling approaches: (i) conceptualizations of work routines to determine when and where checklist content is presented, (ii), assigning tasks and responsibilities to organizational roles, and (iii) rules consisting of criteria that, if fulfilled trigger actions or additional rules to determine clinical decisions.

SQ3: ***What phases and activities does the life cycle management of medical checklists entail?***

The phases inherent to every checklist life cycle are their conception, specification of their content and design, testing and validation, training and implementation, and maintenance. The life cycle is similar to the PDCA cycle, emphasizing continuous quality improvement.

SQ4: ***Which requirements should a domain-specific modeling solution for medical checklists fulfill to realize expected benefits?***

We specified a comprehensive list of 59 design requirements. Most importantly, the DSM solution should provide concepts prospective users are familiar with, support all phases of the medical checklist life cycle, and the customization of checklists on a type- and instance-level.

SQ5: ***Is the created language specification complete and comprehensible by prospective users?***

The evaluation of the MC-DSML's overall quality indicates its strength in its completeness, while primary stakeholders confirmed a good level of comprehension. However, it should be noted that our MC-DSML constitutes a proof of concept rather than a mature design solution.

SQ6: ***Is the developed domain-specific modeling solution for medical checklists effective?***

The validation of MediCheck through its scenario-based demonstration in four qualitative simulations shows that MediCheck fulfills its outlined objectives while being intended to be used in practice. Therefore, we consider our DSM solution effective.

MRQ:

How can an effective domain-specific modeling solution for medical checklists be designed that improves the applicability and workflow integration of medical checklists?

Following the DSR approach combined with the DSML Engineering Method by Frank [36], we developed an effective DSM solution. Through a comprehensive analysis of the medical checklist domain, we elicited relevant domain concepts, relationships, and requirements. Subsequently, we designed the abstract syntax, concrete syntax, and the semantics of the language specification. Through continuous evaluations with domain experts, we incorporated feedback about the MC-DSML's quality and made improvements accordingly. A simulated implementation of the MC-DSML was then created and validated in four qualitative simulations.

The outcome of this research study has both scientific as well as societal contributions. The **scientific contributions** include (i) a definition for medical checklists that reflects their distinct characteristics, (ii) an overview of both the management life cycle phases and characteristics of medical checklists derived from contemporary literature, (iii) a taxonomy of clinical resources distinguishing medical checklists from similar artifacts, (iv) a comprehensive list of design requirements for MediCheck derived from the literature and domain experts, (v) a DSML for medical checklists, consisting of meta-models that specify the abstract syntax, semantics, and the concrete syntax in the form of a graphical notation, (vi) insights into the usefulness, additional requirements, and potential future directions for MediCheck derived from the qualitative simulation, and (vii) a visualization of external impact factors on medical checklists.

Furthermore the **societal contributions** include that we built a DSM solution for medical checklists that is based on source-models rather than source code. Therefore, we contribute to bridging the gap between the end-users of medical checklists and information system experts by offering a unified nomenclature that concisely expresses the abstractions of medical checklists. In addition, we created awareness of the research problem and the usefulness of medical checklists.

To summarize, we have shown that the design of our DSM solution has the potential to effectively improve the integration of medical checklists into clinical workflows and to enhance their applicability to the context and case. Consequently, we have shown that our domain-specific, model-driven approach is feasible in the domain of medical checklists.

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A Research Approach and Methods

A.1 Intersection of DSRM and DSMLEM

Figure A.1 demonstrates the intersection between the DSR process proposed by [46] and the DSML engineering method by [114] and illustrates the approach we followed in our research design.

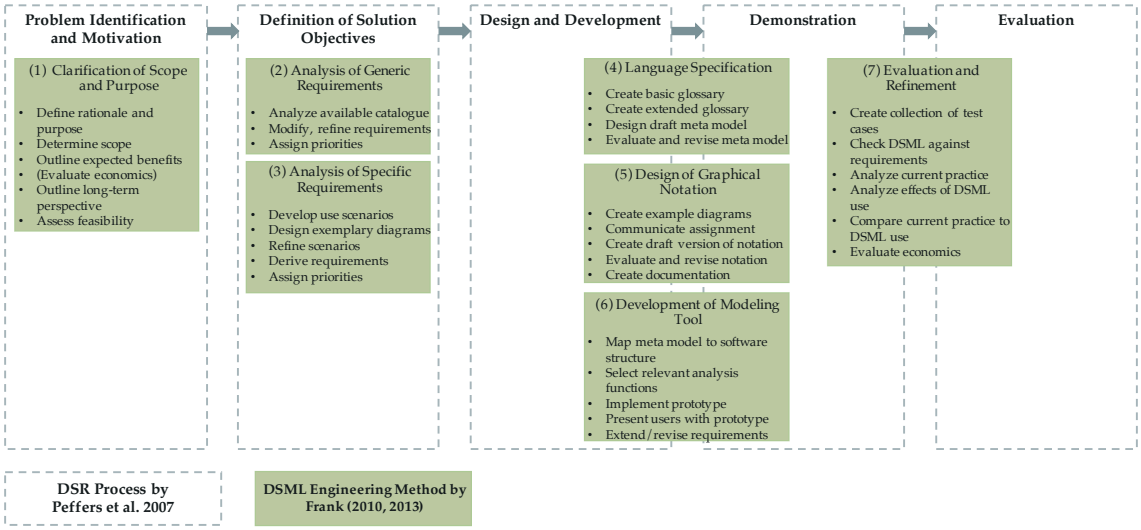

FIGURE A.1: The DSR process proposed by [46] combined with the DSMLEM by Frank [36], [114]

A.2 Overview of Research Participants

In this section we present an overview of the research participants in our study. Table A.1 presents the domain experts from our first interview to analyze contemporary problems and elicit design Table A.2 provides an overview of the experts that provided feedback to our abstract syntax, while the experts that provided feedback to our concrete syntax are presented in Table A.3. Finally, the research participants in our qualitative simulation are presented in Table A.4.

TABLE A.1: Research participants in problem investigation and requirements elicitation interviews.

ID	Current job title	Organization	Country	Length
I-1A	Medical Student	University, hospital	Germany	54 min
I-1B	Resident in orthopedic surgery	Hospital	Belgium, Canada, Luxembourg	56 min
I-1C	Anesthesiologist and Pain Specialist	Hospital	Netherlands	21 min
I-1D	Medical Student	University, hospital, nursing home	Netherlands, Belgium	49 min
I-1E	Nurse	Hospital	Germany	44 min
I-1F	Policy Officer and Advisor for safety and quality	Hospital	Netherlands	30 min
I-1G	Healthcare Consultant with medical background	Company providing business intelligence solutions for healthcare organizations	Netherlands	56 min
I-1H	Dermatologist, Mohs Surgeon	Outpatient clinic	Netherlands	32 min

TABLE A.2: Research participants in expert opinion interview to evaluate the abstract syntax of the MC-DSML.

ID	Current job title	Organization	Country	Length
I-2A	Consultant for IS integration	Consultancy	Netherlands	28 min
I-2B	Medical Student	University	Netherlands	42 min
I-2C	Primary Care Physician	General Practice	Netherlands	35 min
I-2D	Medical Student	University	Germany	37 min

TABLE A.3: Research participants in expert opinion interview to evaluate the concrete syntax of the MC-DSML.

ID	Current job title	Organization	Country	Length
I-3A	Medical Student	University	Germany	20 min
I-3B	Medical Student	University	Netherlands	26 min
I-3C	Nurse	Hospital	Netherlands	35 min
I-3D	Medical Student	University	Netherlands	21 min
I-3E	Pediatric Nurse	Hospital	Belgium	33 min

TABLE A.4: Research participants in the qualitative simulation.

ID	Current job title	Organization	Country	Duration
I-4A	Neurologist, member of Federation of Medical Specialists and supervisory board of a hospital	Hospital	Netherlands	57 min
I-4B	Physician, ER, primary care for elderly patients	Hospital	Netherlands	80 min
I-4C	Physician Internal Medicine	Hospital	United States	78 min
I-4D	Radiologist	Outpatient clinic	Germany	56 min

A.3 Literature Study Material

In this section we provide addition material regarding our research methods. Table A.5, A.6, and A.7 present the literature protocols for the three literature studies of medical checklist characteristics, encoding approaches for similar clinical resources, and the life cycle of medical checklists, respectively. Table A.8 provides an overview of the quality criteria that guided the selection of sources within the multivocal literature study.

TABLE A.5: Literature study protocol 1 - medical checklist literature study.

Phases	Steps	Medical checklist conceptualization
Preparation	Purpose	Provide understanding about clinical checklists by mapping field of clinical checklist design research and practice
	Goal	Identify components (concepts and relationships), support conceptualization of medical checklists
	Type of review	Different types of studies, studied by various type of researchers within different disciplines, inclusion of documents used in practice, such as checklists, non-academic manuals, or guidelines → multivocal literature review
Design	Search terms	*"allfields: checklist AND design", "allfields: checklist AND development", "allfields: elements AND checklist", "allfields: checklist AND ontology", "allfields: checklist AND concept", "allfields: checklist AND component", "allfields: checklist AND vocabulary", "allfields: checklist AND model", "allfields: checklist AND properties"*
	Search strategy	Backward snowballing and forward snowballing
	Databases	PubMed, Google Scholar (for retrieval), Google Search, Healthcare Professionals
	Inclusion & exclusion criteria	language: English, Dutch publication year: 1995-2020 checklist documents, manuals, academic articles accessible with UU account
	Quality criteria	Authority of the producer; methodology; objectivity, date, position w.r.t. related sources, novelty, impact, outlet type
Conduct	Selection approach	Initial set based on key words → top 100 hits → read title and abstract → candidate set → read thoroughly → identify additional articles through forward and backward snowballing
	Pilot test	✓
	Revision	✓
	Decide on final sample	Stopping criteria: effort bounded (top 100 query hits per search term), theoretical saturation
Analysis	Coding	NVivo, Thematic Analysis
	Means of abstraction	Concept map (medical checklist conceptualization), taxonomy

TABLE A.6: Literature study protocol 2 - encoding approaches for similar clinical resources

Phases	Steps	Artifacts for encoding clinical knowledge
Preparation	Purpose	Combine perspectives and insights from different fields of research to create new conceptual model for encoding clinical checklists
	Goal	Identify potentially relevant research traditions that have implications for encoding medical knowledge, assess existing artifacts critically
	Type of review	Critically reviewing emerging topic → semi-systematic literature review
Design	Search terms	*"allfields: clinical AND knowledge", "allfields: encoding AND clinical AND knowledge", "allfields: modeling AND techniques", "allfields: executable AND model", "allfields: guideline AND modeling", "allfields: clinical AND path AND modeling", "allfields: checklist AND modeling"*
	Search strategy	Backward snowballing and forward snowballing
	Databases	PubMed, Google Scholar (for retrieval)
	Inclusion & exclusion criteria	language: English publication year: 1995-2020 academic articles accessible with UU account
	Quality criteria	Authority of the producer; methodology; objectivity, date, position w.r.t. related sources, novelty, impact, outlet type
Conduct	Selection approach	Initial set based on key words → top 100 hits → read title and abstract → candidate set → read thoroughly → identify additional articles through forward and backward snowballing
	Pilot test	✓
	Revision	✓
	Decide on final sample	Stopping criteria: effort bounded (top 100 query hits per search term), theoretical saturation
Analysis	Coding	NVivo, Thematic Analysis, critically analyze
	Means of abstraction	Map field of research

TABLE A.7: Literature study protocol 3 - life-cycle management of medical checklists

Phases	Steps	Life-cycle management of medical checklists
Preparation	Purpose	Provide overview of life-cycle management activities of medical checklists
	Goal	Identify phases and activities of life-cycle management for medical checklists
	Type of review	Differently conceptualized and recently emerging topic → semi-systematic literature review
Design	Search terms	Starting point for snowballing technique: de los Santos et al. [30]
	Search strategy	Backward snowballing and forward snowballing
	Databases	WorldCat catalogue and Google Scholar for retrieval
	Inclusion & exclusion criteria	language: English describes life-cycle or development activities of medical checklist(s) academic article accessible with UU account
	Quality criteria	Authority of the producer; methodology; objectivity, date, position w.r.t. related sources, novelty, impact, outlet type
Conduct	Selection approach	Identify potentially relevant article by scanning title and abstract (if available) → focus on literature review and findings section to identify relevant articles → final selection
	Pilot test	✓
	Revision	✓
	Decide on final sample	Stopping criteria: theoretical saturation
Analysis	Coding	NVivo, Thematic Analysis
	Means of abstraction	Map field of research

TABLE A.8: Additional quality assessment criteria, adapted from Garousi et al. [53]

Criteria	**Questions**
Authority of producer	Is the publishing organization reputable? Is an individual author associated with a reputable organization? Has the author published other work in the field? Does the author have expertise in the area?
Methodology	Does the source have a clearly stated aim? Does the source have a stated methodology Is the source supported by authoritative, contemporary references? Are any limits clearly stated? Does the work cover a specific question? Does the work refer to a particular population or case?
Objectivity	Does the work seem to be balanced in presentation? Are the statements in the source as objective as possible? Are the conclusions supported by data?
Date	Does the source have a clearly stated date?
Linkage of related sources	Have key related grey literature or formal sources been linked or discussed?
Novelty	Does the source enrich or add something unique to the research? Does the source strengthen or refute current position?
Outlet type	1^{st} tier grey literature - high credibility (books, magazines, theses) 2^{nd} tier grey literature - moderate credibility (annual reports, presentations, videos, wiki articles) 3^{rd} tier grey literature - low credibility (blog, email, tweet)

A.4 Expert Interview Material

In this section we present our Interview Consent Form, an exemplary information sheet, and the interview protocol for the exploratory interview in Figure A.4, A.2 and A.3, and A.6, respectively.

Interview Consent Form

Research Project Title: MediCheck – A Domain-Specific Modeling Solution for Medical Checklists

Research Investigator: Patrizia Gieske; supervised by Prof. Dr. Ir. Hajo Reijers

Contact information: p.m.gieske@uu.nl; h.a.reijers@uu.nl

Research Participant:

Date and Place of the Interview:

Dear *XY*,

Thank you for agreeing to be interviewed as part of the above research project for my master's thesis. This consent form ensures that you understand the purpose of your involvement and that you agree to the conditions of your participation.

1. I agree to participate in a research project conducted by Patrizia Gieske from Utrecht University, the Netherlands.
2. I have received sufficient information about this research project and understand my role in it. The purpose of my participation as an interviewee in this project and the future processing of my personal data has been explained to me and is clear.
3. My participation as an interviewee in this project is completely voluntary. There is no explicit or implicit coercion whatsoever to participate.
4. Participation involves being interviewed by a master student from Utrecht University. The interview will last approximately 60 minutes. I allow the researcher to take notes during the interview.
5. I also may allow the recoding of the interview and subsequent dialogue by audio/video tape. It is clear to me that in case I do not want the interview and dialogue to be taped I have the right to deny the request or to withdraw from participation.
6. I have the right not to answer questions at any time. I have the right to withdraw from the interview at any time, without giving a reason and ask that the data collected prior to the withdrawal will be deleted.

FIGURE A.2: Exemplary informed consent form Part 1

Utrecht University

7. I have been given the explicit guarantee that my data will be processed in full compliance with the University Utrecht's Personal Data Processing Policy.
8. I understand that I am free to contact any of the people involved in the research to seek further clarification and information at any time.
9. I have carefully read and fully understood the points and statements of this form. All my questions were answered to my satisfaction, and I voluntarily agree to participate in this study.
10. I obtained a copy of this consent form co-signed by the interviewer.

_____	_____
Place, Date	Participant's Signature
_____	_____
Place, Date	Researcher's Signature

FIGURE A.3: Exemplary informed consent form Part 2

Utrecht University

Information Sheet – Research Interview

Research Project Title: MediCheck – A Domain-Specific Modeling Solution for Medical Checklists

For research conducted by Patrizia Gieske, supervised by Prof. Dr. Ir. Hajo Reijers at Utrecht University. Contact information: p.m.gieske@uu.nl; h.a.reijers@uu.nl

Thank you for agreeing to be interviewed as part of the above stated research project for my master's thesis. The purpose of this research is to investigate how healthcare practitioners and medical checklist managers can be supported in creating, maintaining, and updating medical checklists.

A literature review of scientific sources revealed common properties and characteristics of medical checklists and their development, use, and management practices. This interview is intended to gather insights from the practical perspective on medical checklists and to understand how healthcare practitioners can be supported in designing, sharing, and maintaining medical checklists. The interview is planned not to take longer than 45 minutes.

All data gathered will be treated strictly confidentially and anonymously. You are free to end the interview at any given time, without any reason.

Within 10 days after the interview you will be provided with the interview documentation to review and provide feedback regarding the characterization of the interview. If you have any objections or detect any misinterpretations, you have the right to request changes and/or withdraw parts or the entire interview within 14 days after the day of receiving the interview documentation.

Please read and sign the accompanying consent form to ensure that you understand the purpose of your involvement and that you agree to the conditions of your participation.

If further information is needed or if you have any other questions, please do not hesitate to contact any of the people involved in this research stated above.

Kind regards,

Patrizia Gieske

FIGURE A.4: Research information sheet

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Problem Investigation Interview Protocol

1. **Introduction**
   - Thank you for the participation
   - Is the consent form available? Are there any objections or concerns?
   - Introduction of interviewer and the research project
     - Research problem
     - Aim
     - Definition of medical checklists
   - Goal and structure of this interview
   - How the interviewee can contribute
   - Questions?
2. **Interviewee's Background**
   - Educational background
   - Practical experience
   - Current role
   - 'Relation' to medical checklists (user, manager)
3. **Current Situation**
   - Hospital Information System
     - Digital/paper-based/posters
     - Patient medical record
     - Hand-held devices/stationary computers?
   - What kind of checklists are used?
     - Standardized or 'self-made'
     - Procedural, decision aid, task list, etc.
     - Format (flow chart, list, etc.)
   - Are checklists integrated into HIS?
   - Checklist creation
     - Who designed the checklists? Who should be the one?
     - Checklist team (size), checklist content (sources), etc.
     - How did they get introduced?
     - Who signalizes the need for a checklist?
     - Do you have the authority to design your own checklist?
   - Maintenance
     - Who is responsible for the maintenance (e.g. updates or changes)?
     - How often do they get updated?
     - How do you initiate or realize any modifications?
   - Modifications and changes
     - What happens if checklist not applicable?
     - What happens if something should change?
     - Can you modify them? Or update them? Change font or color?

FIGURE A.5: Interview Protocol for Interview 1 - Part 1.

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4. **Personal Experience with Checklists**
   - Experience in creating or updating checklists, got involved in the design or maintenance
   - Have you ever experienced a situation in which you wanted to add something or change a certain checklist?
   - Did you get training in using them? Or creating checklists?
5. **Current Problems**
   - What are the main challenges?
   - Are there situations where you would like to have a checklist, but none exists?
   - Any issues with applicability in all situations?
6. **Possible Solutions**
   - Do you have any ideas what would improve the current situation?
   - Do you think it would be useful or beneficial to create your own? Why? Why not?
   - Do you think it would improve your ability to perform your work more effectively/safely if you were able to design or modify checklists?
   - Customization needed for each patient? Or one general – adjustable for each patient?
   - Print or digital?
   - How much time/effort can be allocated?
   - Shareable?
   - How important are different design options? (Different check types, etc.)
   - How should it be integrated into existing systems? Paper format or digital? Displayed on tablet/computer or integrated with HMS?
7. **Conclusion**
   - Summarize
   - Is there anything you would like to add?
   - I will send documentation within the next 10 days
   - Thank you (informative, for the time)

FIGURE A.6: Interview Protocol for Interview 1 - Part 2.

A.5 Qualitative Simulation Material

Within the qualitative simulations we simulated two scenarios, (i) the development of a new checklist, and (ii) the modification and customization of an existing checklist. A video demonstration of the steps can be found here: MediCheck Demonstration. Table A.9 provides an overview of what variable is measured with which item on the questionnaire.

Scenario I: The life cycle of medical checklists was presented and the creation of a new checklist started with its conception. The expert was asked whether they have a checklist in mind they want to create. If that was the case, they created the checklist based on their own information. If not, we provided some guidelines: the checklist is intended for the admission of children under 18 years to the Emergency Room, to make sure that all important questions are asked and relevant data collected. We then granted the participant access to our computer so that they were able to operate the simulation. First, general information about the checklist, including the checklist ID, the checklist name, date of creation, checklist type, etc. were determined by filling in designated fields. Then, the purpose and the outcome had to be described and outcome measures defined, followed by the specification of the target audience. Since the checklist was intended for children under the age of 18, eligibility criteria for the checklist were specified. Next, the operational use and target procedure were defined and the checklist timing determined. For the latter, the phase in the workflow that was displayed had to be selected, and the participant had to determine whether the checklist has to be performed before or during this activity. Then, the participant had to search the database for a guideline for admitting patients to the ER and select the one specific to children. That way, the guideline was linked to checklist. Finally, the context of the checklist regarding the light level and changes in light were specified and the checklist saved. An overview of the input information was then presented and the participant either confirmed that data, or could go back to make changes. When the information was confirmed, a new entry in the database was shown.

After this step, we took over the control and demonstrated how to design the checklist. The following steps were demonstrated:

1. Create a header, a footer, and a section and determine the title and the subtitle of the checklist. The contact person and date of creation was automatically filled in the footer from the preceding conception.
2. Create a choice item with radio button list options, determine item description and option labels, add an option, show the checklist model.
3. Add a choice item with scores, determine item description, add score category, change score label, add an option for the user to insert a note, assign attribute so that the item is fixed, show checklist model.
4. Create input item with text input, determine item description, specify a role and the role's responsibility, assign attribute that the item is required, show checklist model.
5. Create decision item with toggle yes/no, determine item description, determine source of the item - choose guideline from repository, show checklist model.
6. Create a rule for the previous item that *if* data from the patient file is available, *then* check the item aromatically, *else* display item, show checklist model.

7. Create confirmation item with checkbox, determine item description, set rule that this item is terminating the checklist, show checklist model.
8. Save the checklist.
9. Upload logo for your organization and embed in header.
10. Change font type and font size.
11. change background color.
12. Save - shows final checklist -confirm.
13. Determine whether (i) the checklist is approved by the hospital administration, (ii) the checklist will be mandatory, (ii) the checklist should be published in MediCheck, (iv) a reminder for revision should be set - if yes, set date. Save.

After this scenario, the first part of the questionnaire (see Figure A.7 was shown to the participant. The participant was asked to read the statements out loud and to indicate their level of agreement and their rational.

Scenario II: After discussing the first scenario, we presented the second scenario. The following steps were conducted:

1. Show the checklist and provide explanation of context.
2. Show the checklist model.
3. Click *edit* and add a 4th item to the first section. Create a choice item with a checkbox list, determine the item description and response option labels, add third response option. Add eligibility criteria for the item with *gender* and *female*. Create a rule that *if YES*, *display note* - specify note, *if No go to item 5*, *if N/A go to to item 5*. Show checklist model.
4. Change and item from the second section. Select item from the item bank, change the role and determine their responsibility.
5. Add a new section, create confirmation item with signature, determine item description, set attribute that this item is mandatory, add a role, specify the role and their responsibility. Show checklist model.
6. Save and view final version

After this scenario, the second part of the questionnaire (see Figure A.8 was shown to the participant. The participant was again asked to read the statements out loud and to indicate their level of agreement and their rational. Finally, an open discussion about what the tool can improve, what it cannot improve, what could be changed to make the tool better, and any open concerns were discussed.

	CHECKLIST DEVELOPMENT	Fully agree	Partially agree	Neutral	Partially disagree	Fully disagree
1.	I find it easy to create a new checklist with this tool.	☐	☐	☐	☐	☐
2.	I understand how the underlying checklist model relates to what I can do with the tool.	☐	☐	☐	☐	☐
3.	I would use this tool in practice to create a new checklist.	☐	☐	☐	☐	☐
4.	Compared to now, using this tool would make it easier for me to develop a medical checklist.	☐	☐	☐	☐	☐
5.	It is clear to me how changes made with the tool affect the underlying checklist model.	☐	☐	☐	☐	☐
6.	I believe this tool would help to design checklists that are more applicable to the context and the patients.	☐	☐	☐	☐	☐
7.	I believe creating checklists with this tool would improve the integration of checklists into the daily workflow.	☐	☐	☐	☐	☐
8.	I think I would need support from an expert to create a checklist with this tool.	☐	☐	☐	☐	☐
9.	I believe this tool would facilitate the sharing of medical checklists.	☐	☐	☐	☐	☐
10.	I believe this tool would help to keep checklists up to date.	☐	☐	☐	☐	☐
11.	I would prefer using a different tool to create a new checklist.	☐	☐	☐	☐	☐
12.	Is there anything similar in your organization that helps you create medical checklists?	☐ Yes	☐ No			

FIGURE A.7: Template of the post-task questionnaire of the qualitative simulation for the checklist conception and creation of the content and design

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	CHECKLIST MAINTENANCE	Fully agree	Partially agree	Neutral	Partially disagree	Fully disagree
1.	I find it easy to modify an existing checklist with this tool.	☐	☐	☐	☐	☐
2.	I understand how the underlying checklist model relates to the changes I make with the tool.	☐	☐	☐	☐	☐
3.	I would use this tool in practice to adjust an existing checklist to my needs.	☐	☐	☐	☐	☐
4.	Compared to now, using this tool would make it easier for me to make adjustments to a medical checklist.	☐	☐	☐	☐	☐
5.	It is clear to me how changes made with the tool affect the underlying checklist model.	☐	☐	☐	☐	☐
6.	I believe this tool would help to make checklists more applicable to the context and the patients.	☐	☐	☐	☐	☐
7.	I believe using this tool would improve the integration of checklists into the daily workflow.	☐	☐	☐	☐	☐
8.	I think I would need support from an expert to make adjustments to an existing checklist with this tool.	☐	☐	☐	☐	☐
9.	I believe using this tool would make it easier to share medical checklists.	☐	☐	☐	☐	☐
10.	I believe this tool would help to keep checklists up to date.	☐	☐	☐	☐	☐
11.	I would prefer using a different tool to modify an existing checklist.	☐	☐	☐	☐	☐
12.	Is there anything similar in your organization that helps you create medical checklists?	☐ Yes	☐ No			

FIGURE A.8: Template of the post-task questionnaire of the qualitative simulation for the checklist maintenance and customization

TABLE A.9: Variables measured with each questionnaire item.

ID	Variable	Statement
		Scenario I - Checklist Development
Q1	Perceived Ease of Use	I find it easy to create a new checklist with this tool.
Q2	Comprehension	I understand how the underlying checklist model relates to what I can do with the tool.
Q3	Intention to Use	I would use this tool in practice to create a new checklist.
Q4	Perceived Usefulness	Compared to now, using this tool would make it easier for me to develop a medical checklist.
Q5	Comprehension	It is clear to me how changes made with the tool affect the underlying checklist model.
Q6	Perceived Usefulness	I believe this tool would help to design checklists that are more applicable to the context and the patients.
Q7	Perceived Usefulness	I believe creating checklists with this tool would improve the integration of checklists into the daily workflow.
Q8	Perceived Ease of Use	I think I would need support from an expert to create a checklist with this tool.
Q9	Perceived Usefulness	I believe this tool would facilitate the sharing of medical checklists.
Q10	Perceived Usefulness	I believe this tool would help to keep checklists up to date.
Q11	Intention to Use	I would prefer using a different tool to create a new checklist.
		Scenario II - Checklist Maintenance
Q12	Perceived Ease of Use	I find it easy to modify an existing checklist with this tool.
Q13	Comprehension	I understand how the underlying checklist model relates to the changes I make with the tool.
Q14	Intention to Use	I would use this tool in practice to adjust an existing checklist to my needs.

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Table A.9 – *Continued from previous page*

ID	Variable	Statement
Q15	Perceived Usefulness	Compared to now, using this tool would make it easier for me to make adjustments to a medical checklist.
Q16	Comprehension	It is clear to me how changes made with the tool affect the underlying checklist model.
Q17	Perceived Usefulness	I believe this tool would help to make checklists more applicable to the context and the patients.
Q18	Perceived Usefulness	I believe using this tool would improve the integration of checklists into the daily workflow.
Q19	Perceived Ease of Use	I think I would need support from an expert to make adjustments to an existing checklist with this tool.
Q20	Perceived Usefulness	I believe using this tool would make it easier to share medical checklists.
Q21	Perceived Usefulness	I believe this tool would help to keep checklists up to date.
Q22	Intention to Use	I would prefer using a different tool to modify an existing checklist.

End of Table A.9

B Domain Analysis - Additional Material

B.1 Comparison of Clinical Resources

TABLE B.1: Comparison of Clinical Resources

Concept	Function	Scope	Design and Format	Application
Checklist	Standardizes tasks that must be completed or considered [93], aids memory	Lists suggested sequence of actions and criteria related to a specific procedure [9], allows recording of presence or absence of each individual item [12], system-engineering or human-performance approach; focused on a single specific goal [80]	Systematically developed, list of action items or criteria, paper-based, screen-based, auditory prompts	Clear pause point defined indicating when to use the checklist [1], right before, during, or right after performing a task or procedure [78], require response or behavior (verification) [80]
Medical Checklist	Standardizes **clinical** tasks that must be completed or considered [101], aids memory	Lists suggested sequence of actions and criteria related to a **specific clinical procedure** [78]; allows recording of presence or absence of each individual item [12], system-engineering or human-performance approach; focused on a single specific goal [80]	Systematically developed, list of action items or criteria, paper-based, screen-based, auditory prompts	Used in medical setting, clear pause point defined indicating when to use the checklist [1], right before, during, or right after performing a task or procedure [78], require response or behavior (verification) [80]

Continuation on next page

Continuation of Table B.1

Concept	Function	Scope	Design and Format	Application
Safety Checklist	Standardizes tasks that must be completed or considered [101], aids memory	Lists suggested sequence of **essential** actions and criteria related to a **specific procedure** [78]; allows recording of presence or absence of each individual item [12], human-performance approach; focused on a single specific goal [80]	Systematically developed, list of **essential** action items or criteria, paper-based, screen-based, auditory prompts	Used in safety critical settings, clear pause point defined indicating when to use the checklist [1], **right before** performing a task or procedure [77], require response or behavior (verification) [80]
Clinical Pathway	Standardize, model, manage, and optimize clinical processes [48], supports clinical decision making [2], defines goals and key elements of care for specific symptoms or diagnosis [48]	Manages medical care of well-defined group of patients at defined period of time [48], may contain medical checklists [2], [48], may contain multiple components [101]; encompass medical requirements, coordination of roles, activities, and sequence of activities [103]; system-engineering approach	Detailed descriptions in varying format [101], can be unstructured textual descriptions, graphical representations, computer-interpretable [48], time-task matrix [101]	Utilized for recording retrospective and prospective analysis and identification of appropriate resources [101], to support clinical workflows [48]

Continuation on next page

Continuation of Table B.1

Concept	Function	Scope	Design and Format	Application
Clinical Guideline	Standardize care [32], provide benchmark of what evidence-based best practice should be [12], contains detailed care process that should be invoked in providing optimal care for patients [31], [32]	Describe ideal actions to perform a clinical task [78], summarize complex set of procedures, less detailed than procedures [78], narrower focus than pathways [101], broad management topic of general clinical care [80], system-engineering approach	Often lengthy, textual document [78], emerging encoding approaches enabling integration into patient care process in computerized format [32]	Directive for recommendations of care [12]
Clinical Protocol	**Locally adapted, institution specific** guideline [93], normative default care plan [101]; parameters and rules about how to proceed in certain situations [12]	Describe ideal actions to perform a clinical task [78], summarize complex set of procedures, less detailed than procedures [78], narrower focus than pathways [101], broad management topic of general clinical care [80], system-engineering approach	Often lengthy, textual document [78], emerging encoding approaches enabling integration into patient care process in computerized format [32], [130]	Directive for recommendations of care [12]

Continuation on next page

Continuation of Table B.1

Concept	Function	Scope	Design and Format	Application
Clinical Process Model	Standardization and formalization of clinical processes that reflects hospital policy [88], fosters understanding, communication, and coordination among stakeholders [99]	clinical processes that describe a set of linked activities that together realize medical objectives [100], contains at least activities, events/states, and control flow logic [99], system-engineering approach	Formal or semi-formal representation of clinical processes [100], usually graphical representation [99]	May be integrated in clinical decision support systems [103]
Care Bundle	Independent, evidence-based key interventions that, when implemented together in an all-or-none fashion, result in significantly improved outcomes [105]	Collection of independent key interventions and materials for general management topics, derived from clinical guidelines [104]; may contain checklists [80], targeted to particular morbidity, comprehensive, system-engineering approach [105]	Collection of different key intervention formats [105]	general management topics [80], application of number of interventions within care pathway [105]
Order Set	Type of checklist to ensure everything that may be ordered for a patient is considered [2]	Include everything a clinician may want to consider ordering for a particular group of patients, many things may not be checked [2], system-engineering approach	Pre-printed instructions, allows item check [2]	Instructions to be considered when ordering clinical services or medications for patients [2]

Continuation on next page

Continuation of Table B.1

Concept	Function	Scope	Design and Format	Application
Flow Chart	Guiding complex decision making	contains all possible activities, information, systems, and decisions to choose from [131]; human-performance approach	Simple design, including type of people and activity, patient-, information-, material-, clinical decision-making flow [131]; particular path containing multiple options to choose from [2], paper, poster, or digital formats	For decision making and diagnoses, often in team settings

End of Table B.1

B.2 Comparison of Medical Checklist Development Methods

TABLE B.2: Life Cycle Comparison

Phase	Activities	[132][93]	[80]	[133][97]	[28]	[30]	[94]	[111][84]	[12]	[134][10]	[92]	[96]	[135][15]	[14]	[2]
Conception	Get permission and support		✓					✓							
	Assemble development team	✓ ✓	✓		✓	✓		✓	✓					✓	✓
	Assign person to direct and oversee							✓						✓	
	Collect information	✓ ✓		✓	✓	✓	✓		✓	✓	✓		✓	✓	✓
	Specify purpose, outcome and goals	✓	✓		✓		✓		✓						✓
	Specify outcome measures		✓				✓		✓				✓		
	Identify and analyze existing systems	✓			✓				✓						
	Identify and analyze clinical concern	✓	✓	✓	✓	✓	✓	✓	✓	✓			✓	✓	✓
	Analyze process an related tasks		✓				✓		✓					✓	✓
	Assemble list of potential items	✓ ✓	✓	✓			✓	✓	✓	✓		✓ ✓	✓	✓	✓
	Define set of inputs and outputs									✓					
	Specify setting, context, and timing		✓					✓	✓						
	Determine checklist type										✓				
	Define target population	✓			✓				✓					✓	✓
	Determine how it will be used				✓										

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Table B.2 – *Continued from previous page*

Phase	Activities	[132]	[93]	[80]	[133]	[97]	[28]	[30]	[94]	[111]	[84]	[12]	[134]	[10]	[92]	[96]	[135]	[15]	[14]	[2]
	Determine presentation modality						✓								✓					
Design	Define content, level of detail, and length			✓	✓		✓	✓	✓	✓	✓			✓				✓	✓	✓
	Associate items with behavior							✓												✓
	Select item checks and rules	✓		✓								✓								
	Refine the language							✓			✓	✓								✓
	Specify layout and format		✓	✓	✓	✓	✓		✓		✓	✓			✓			✓	✓	✓
	Group items and determine sequence	✓				✓		✓				✓		✓					✓	
	Assign who performs tasks and who runs the checklist			✓																
	Create instructions for use	✓								✓										
	Possible modifications	✓	✓	✓	✓		✓	✓		✓	✓	✓	✓			✓	✓	✓	✓	✓
Validation	Review content, format, and design and achieve consensus							✓		✓		✓	✓		✓	✓		✓	✓	✓
	Pilot in simulation			✓			✓	✓			✓	✓	✓			✓				✓
	Pilot in real-world setting	✓	✓	✓		✓	✓				✓		✓					✓	✓	✓
	Gather feedback		✓	✓			✓				✓				✓	✓	✓		✓	✓
	Analyze metrics	✓		✓	✓	✓	✓	✓	✓		✓		✓			✓			✓	✓

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Table B.2 – *Continued from previous page*

Phase	Activities	[132][93]	[80]	[133][97]	[28]	[30]	[94]	[111][84]	[12]	[134][10]	[92]	[96]	[135][15]	[14]	[2]
Training & Implementation	Create implementation instructions							✓						✓	
	Education and training		✓		✓	✓		✓	✓				✓	✓	
	Gather feedback		✓			✓								✓	
	Disseminate checklist	✓	✓	✓					✓				✓	✓	
	Integrate into policy	✓						✓					✓		
	Publish							✓				✓			
Maintenance	Monitor and analyze outcome		✓		✓	✓		✓				✓			
	Gather feedback and suggestions				✓				✓			✓			
	Review content		✓			✓		✓	✓	✓				✓	✓
	Initiate modifications				✓	✓			✓			✓		✓	✓
	Retire				✓										

End of Table B.2

B.3 Resulting Concepts of Each Life Cycle Phase

TABLE B.3: Resulting concepts of each life cycle phase

Life cycle phase	Resulting concepts
Conception	Permission and support, development team and person in charge, setting, operational use, target procedure or situation, checklist type, purpose, goal, outcome, outcome measures and evaluation plan, target population, presentation modality, accomplishment method, list of potential items, set of inputs and outputs, context, and timing.
Content and Design	Checklist content, representation format, item check type, item sequence, rules and conditions, starting point and termination, layout.
Testing and Validation	Validated checklist, consensus, approval.
Training and Implementation	Implementation instructions, education and training interventions, published checklist.
Maintenance	Continuous outcome measurements, feedback, guidance, and communication, revision of content, initiation of updates, possible retirement.

C Design Requirements

C.1 High-Level Requirements

TABLE C.1: High-level requirements for MediCheck including their rationale and level of priority - must have (M), should have (S), could have (C), won't have (W)

ID	Description	Rationale	Source	Prior.
R1	The concepts, relationships, and notational elements of the MC-DSML should correspond to concepts prospective users are familiar with.	The more users are familiar with the concepts and their representation, the easier it will be for them to understand and use them properly.	[114]	M
R2	Rules for defining the semantics of a modeling language should be clearly guiding prospective users with the construction of appropriate models.	Only if semantics of modeling concepts is precisely defined, conceptual models can be unambiguous.	[114]	S
R3	There should be a clear mapping of the language concepts to the concepts of relevant target representations	A crucial case for the requirement is the software development. The semantics of the language is characterized by a few subtle peculiarities, such as the notion of class or specialization or generalization, and should provide clear mapping to the target representation of the software system.	[114]	S

Continued on next page

Table C.1 – *Continued from previous page*

ID	Description	Rationale	Source	Prior.
R4	MediCheck should allow building models at different levels of detail.	Typically, users have different demands for the level of abstraction and detail provided by a model and should therefore not be burdened with too much detail, while others should be enabled to focus on a higher degree of detail.	[114]	S
R5	The MC-DSML should provide concepts for the specification of the medical checklist conception.	The purpose, the title, the development team and responsible person, setting, timing, checklist type, and the target population should be specified. That way, all information is available to all stakeholders and can be easily traced and adjusted in the future.	[2], [12], [80] [2], [12], [80]	S
R6	The MC-DSML should provide concepts for modeling different checklist item types and corresponding response options.	Distinguishing between different item types allows customizing the checklist, collecting relevant information, and thus, minimizing the clinicians' workload. For instance, if possible response options are known upfront, a choice item can be specified, whereas an input item is suitable when the responses are not known beforehand. Moreover, different response options support specifying whether multiple or only a single response is possible, or whether an item needs to be marked as checked or a signature given to confirm its completion.	[I-1D], [I-1E], [I-1G]	M

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Table C.1 – *Continued from previous page*

ID	Description	Rationale	Source	Prior.
R7	MediCheck should support the comprehensive modeling of the checklist content and design.	The central part of the DSML are the core concepts of medical checklists. Those include checklist items, sections, answer types, artifacts such as actors, roles, and rules, flows, branches, attributes, and embedded elements. The specification of whether the layout is for instance, a table, a flowchart, or a combination should be enabled. Furthermore, embedding multimedia, shapes or text fields to provide additional information and adjustments to the font, e.g., the size or contrast are important, in order to accommodate different settings and users that may require bigger fonts. It should also support highlighting items when they are seen as important. This can either be done by visually highlighting them, or by assigning priorities	[I-1A]-[I-1H], [8], [12], [14], [19], [28], [30], [80], [82], [85], [88], [89], [136]	M
R8	MediCheck should support the maintenance of medical checklists.	To keep the checklist up-to-date and ensure its relevance, reminders for revision should be specified and sources or underlying evidence assigned to the checklist or specific checklist items. That way, automated updates or alerts when content changes are possible. In addition, by specifying intended outcomes and outcome measures, the success of the checklist and potential improvements can be determined and communicated.	[I-1A]-[I-1H]	M
R9	The MC-DSML should provide concepts for specifying implementation instructions and training material.	To support the training and implementation of medical checklists, providing s and training material supports the clinician in understanding how to use the checklist and the objective and purpose of using it, and facilitates the implementation of the tool in a standardized way.	[13], [28], [30], [88]	S

Continued on next page

Table C.1 – *Continued from previous page*

ID	Description	Rationale	Source	Prior.
R10	The MC-DSML should allow the definition of eligibility criteria and one or more goals for each checklist.	Based on (evidence-based) medical knowledge and patient-specific or physician-specific preferences, the checklist can be customized to accommodate preferences on a type- and instance-level.	[I-1B]-[I-1D], [I-1F], [I-1H], [13], [30], [78], [88], [102]	M
R11	The MC-DSML should support the specification of clinical rules that determine the sequence of items and action specifications.	Rules for determining the sequence of the checklist items should allow specifying the starting point, the termination, and the order the items are to be completed in. In addition, conditional relations or statistical calculations associated with specific checklist items or an entire checklist allow further determining action specifications such as sending alerts or notifications, and automatically checking items.	[I-1B]-[I-1E], [I-1G], [I-1H] [19], [98]	S
R12	The MC-DSML should provide concepts for representing clinical resources the checklist or checklist items are associated with.	Associating the checklist with other clinical resources such as clinical guidelines, pathways, workflows, drugs, medical devices, and aids can interconnect the checklist with its context and enable the automated collection or transmission of data as well as support the clinician to conduct the checklist. It further allows specifying the checklist timing according to local workflows.	[I-1A]-[I-1H], [102]	S

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Table C.1 – *Continued from previous page*

ID	Description	Rationale	Source	Prior.
R13	MediCheck should allow the integration with other information systems.	The checklist specification should be integrable with other clinical resources such as clinical decision support system, and the hospital management system. Moreover the integration with electronic medical records is important to be able to link patient specific information to the checklist and adapt the checklist accordingly. In addition, data collected through the checklist execution can be documented and linked to both management analysis programs and patient records. Links to external sources such as https://www.mdcalc.com are possible that way and support the clinician in making evidence-based and best-practice decisions.	[I-1A]-[I-1H], [19], [43]	S
R14	MediCheck should support sharing medical checklists and checklist items.	MediCheck should allow checklists and checklist items to be shared within and between organizations to facilitate the reuse of resources and sharing of evidence-based and best practice data. Therefore, a repository for checklists and an item bank that stores checklist items should be available.	[I-1A], [I-1B], [I-1D]-[I-1H] [89]	S

End of Table C.1

C.2 Specific Requirements

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TABLE C.2: Specific requirements for MediCheck

ID	Description	Prior.
R1	The concepts, relationships, and notational elements of the MC-DSML should correspond to concepts prospective users are familiar with.	M
R2	Rules for defining the semantics of a modeling language should be clearly guiding prospective users with the construction of appropriate models.	S
R3	There should be a clear mapping of the language concepts to the concepts of relevant target representations	S
R4	The MC-DSML should support building models at different levels of detail.	S
R5	The MC-DSML should provide concepts for the specification of the medical checklist conception.	S
R5.1	The MC-DSML should allow the specification of the purpose, the outcome, and outcome measures, as well as the operational use and the target procedure of the checklist.	S
R5.2	The MC-DSML should allow the specification of a unique checklist ID, the checklist name, date of creating, version date, checklist type, contact person (who is responsible for the checklist), and the development team.	M
R5.3	The MC-DSML should allow the specification of the setting of the checklist use, including at least the light levels and changes in light.	C
R5.4	The MC-DSML should allow the specification of the target population of the medical checklist.	M
R5.5	The MC-DSML should allow the specification of the checklist timing.	M
R6	The MC-DSML should provide concepts for modeling different checklist item types and corresponding response options.	M
R6.1	The MC-DSML should allow the modeling of different item types, including at least check items, choice items, and input items.	M
R6.1.1	For each item, the MC-DSML should allow specifying an item description, an item response option type, check labels, a unique ID, and one or more objectives of a specific item.	M
R7	MediCheck should support the comprehensive modeling of the checklist content and design.	M

Continued on next page

Table C.2 – *Continued from previous page*

ID	Description	Prior.
R7.1	The MC-DSML should allow the modeling of different container types to group the checklist content, including sections that can contain items, and header/footer containers that can not contain items.	M
R7.2	A section should be allowed to contain further sub-sections.	M
R7.3	The MC-DSML should allow the specification of a concrete behavior associated with each checklist item.	S
R7.4	The MC-DSML should allow the modeling of organizational roles that can be associated with an entire checklist, a checklist section, and specific checklist items.	M
R7.4.1	The MC-DSML should allow the specification of whether an organizational role is operating the checklist, executing the associated task, or should be present during checklist execution.	M
R7.5	The MC-DSML should allow the modeling of individual actors that can be associated with an entire checklist, a checklist section, and specific checklist items.	S
R7.5.1	The MC-DSML should allow the specification of whether an actor is operating the checklist, executing the associated task, should be present during checklist execution, or is the contact person for that checklist.	S
R7.6	The MC-DSML should allow the specification of one or multiple roles and/or actors associated to an entire checklist, a checklist section, or a checklist item.	M
R7.7	The MC-DSML should allow the specification of whether an item is required to be completed or checked.	M
R7.8	The MC-DSML should allow the specification of whether an item is fixed, meaning that this item cannot be changed or deleted by another user.	S
R7.9	The MC-DSML should allow the specification of whether an item is time stamped, meaning that the time the item is completed is registered/documented.	C
R7.10	The MC-DSML should allow the specification of whether an item is seen as important by a specific user, so that the user can highlight that item.	C
R7.11	The MC-DSML should allow the modeling of notes that represent an empty input field for checklist users to add additional information, associated with both a specific checklist item and an entire checklist.	S

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Table C.2 – *Continued from previous page*

ID	Description	Prior.
R7.12	The MC-DSML should allow the association of information on the underlying level of evidence with both the checklist and each checklist item.	S
R7.13	The MC-DSML should allow the provision of multimedia content such as images, video, or audio material, hyperlinks to other websites or sources, or textual descriptions, on the checklist, to provide additional support for the user of the checklist.	S
R7.14	The MC-DSML should allow the specification of different layout options.	S
R7.14.1	The MC-DSML should allow the determination of whether the layout of the checklist should be in the form of a table, a list, a flowchart, or a combination.	S
R7.14.2	The MC-DSML should allow the specification of the size, the color, and the alignment of text, as well as the background color of sections.	S
R7.14.3	The MC-DSML should support highlighting specific checklist items for both a checklist in general, or for a specific patient, so that a user can indicate that this item is seen as important.	S
R8	MediCheck should support the maintenance of medical checklists.	M
R8.1	The MC-DSML should allow the specification of the underlying level of evidence of both the checklist and each checklist item.	S
R8.2	MediCheck should be integrable with guidelines or protocols, so that changes and updates in the underlying evidence can be communicated to the checklist creator or automatically updated.	S
R8.3	MediCheck should allow the deletion of elements.	M
R8.4	MediCheck should allow the addition of elements.	M
R8.5	MediCheck should allow the modification of or changes to elements.	M
R8.6	MediCheck should support setting reminders for checklist revision.	S
R8.7	MediCheck should allow the collection of data, so that determined variables (outcome measures) can be communicated with relevant stakeholders.	S
R8.8	MediCheck should allow changes the order of checklist items.	M
R9	The MC-DSML should provide concepts for specifying implementation instructions and training material.	S
R10	The MC-DSML should allow the definition of eligibility criteria and one or more goals for each checklist.	M

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Table C.2 – *Continued from previous page*

ID	Description	Prior.
R10.1	The MC-DSML should allow the modeling of eligibility criteria that can be associated with both the entire checklist and specific checklist items or sections of the checklist.	M
R10.2	The MC-DSML should allow the specification of one or more goals based on both medical knowledge and patient specific preferences.	S
R11	The MC-DSML should support the specification of clinical rules that determine the sequence of items and action specifications.	M
R11.1	The MC-DSML should provide a concept for specifying the relation between items to determine the item sequence.	M
R11.2	The MC-DSML should allow the modeling sequential, arbitrary, and conditional item sequences.	M
R11.4	The MC-DSML should allow the modeling of rules that represent conditions or statistical calculations associated with specific checklist items or an entire checklist.	S
R11.4.1	The MC-DSML should allow the specification of rules for determining the sequence of the checklist items. Those include at least the specification of the *starting point* of the checklist, the *termination*, *if-then-else*, for *all*, and for *each*.	S
R12	The MC-DSML should provide concepts for representing clinical resources the checklist or checklist items are associated with.	S
R12.1	MediCheck should allow the specification of a unique pause point along the continuum of a patient's care for each section of the checklist.	S
R12.2	The timing of the entire checklist or a specific item should be connected to the corresponding workflow or clinical path	M
R13	MediCheck should allow the integration with other information systems.	S
R13.1	The MC-DSML should allow the provision of hyperlinks to websites or empirical evidence	S
R13.2	The MC-DSML should allow the specification of data, e.g. patient data or documents, that can be associated to both the entire checklists or a specific checklist item.	S
R13.3	The MC-DSML should allow the specification of the source of underlying evidence, relevant input data, or of the output data.	S

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Table C.2 – *Continued from previous page*

ID	Description	Prior.
R13.4	The MC-DSML should allow the specification of the direction of the information flow associated to a source, data, an entire checklist, or a checklist item.	S
R13.5	MediCheck should be integrable with Electronic Medical Records (EMR), so that patient-specific information can be used as both input to the checklist and output from the checklist and stored in the EMR of that patient.	S
R13.6	MediCheck should be integrable with the local hospital management system - hospital staff has a unique log-in and hospital specific policies and medication can be considered.	S
R14	MediCheck should allow the sharing of medical checklists and checklist items.	S
R14.1	MediCheck should allow the storage of a checklist in a repository.	S
R14.2	MediCheck should allow the creation of an item bank.	S
R14.3	The MC-DSML should allow the user to specify whether the checklist can be accessed by other users.	S
R14.4	The MC-DSML should allow the user to specify whether the checklist can be modified by other users.	S

End of Table C.2

D MC-DSML Specification

D.1 Abstract Syntax and Design Considerations

Below we provide the context-related abstract syntax and map the language concepts to the concepts of relevant target representations. Note that we solely provide a mapping for the concepts that were not covered in the integrated abstract syntax in Section 4.3.

D.1.1 Context-related View

The context-related view specifies what is shown on the checklist (see Figure D.1). A **MedicalChecklist** is part of **MediCheck**. MediCheck represents the target application of the DSM solution. It is linked to **InformationSystem**s such as external **Websites**, **HIS**, **DrugRepository**s, or **LiteratureDataBase**. By linking MediCheck to other IS, we enable the integration of various systems. For instance, the drug repository of a hospital contains a data base of all drugs and medications and their respective information. Therefore, depending on the context of the checklist and patient-specific data, the most suitable medication can be suggested by the MediCheck. In addition, medication that is taken by a patient can be saved, and a warning displayed if an action taken by a doctor may impose risks (e.g., contraindications). Furthermore, a medical checklist can be linked to a **ClinicalResource** such as a **ClinicalGuideline**, **ClinicalPathway**, or a **CareBundle**. That way additional information can be provided to the checklist user. In addition, if the clinical resource is linked as underlying evidence for a checklist or a specific item, the checklist creator can be notified when the clinical resource is updated, or automatic updates realized. Similarly, the association between MediCheck and a **Source**, which in turn contains **Data**, ensures that any updates to the data are communicated to the checklist system. Data can be **PatientData**, **UserData**, or **ContextInformation**. In future projects, specifying the source of each data type further allows the use of data collected via medical appliances such as thermometers, or speech input.

D.1.2 Process-related View

In the process-related view of the abstract syntax (see Figure D.2) we further define the type of **Responsibility** an actor or a role can have. A role can either be an **Attendant**, **ChecklistOperator**, or **TaskExecutor**, while an actor can further be a **ContactPerson** (see Rule 2). Both a role and an actor can have more than one responsibilities. For instance, an actor can be the contact person for a checklist, but also be the task executor for a specific item. Moreover, multiple roles or actors can be assigned to an item. For instance, in the SSC, the surgeon, the anesthetist, and the nurse should be present to discuss specific items. Moreover, different types of **ItemFlow**s are defined. An item flow can either be a **ParallelFlow**, **UnorderedFlow**, **SequentialFlow**, or **ConditionalFlow**. The types of flow are explained in Section 3.3 and reflect the sequence of the corresponding **CareFlow**.

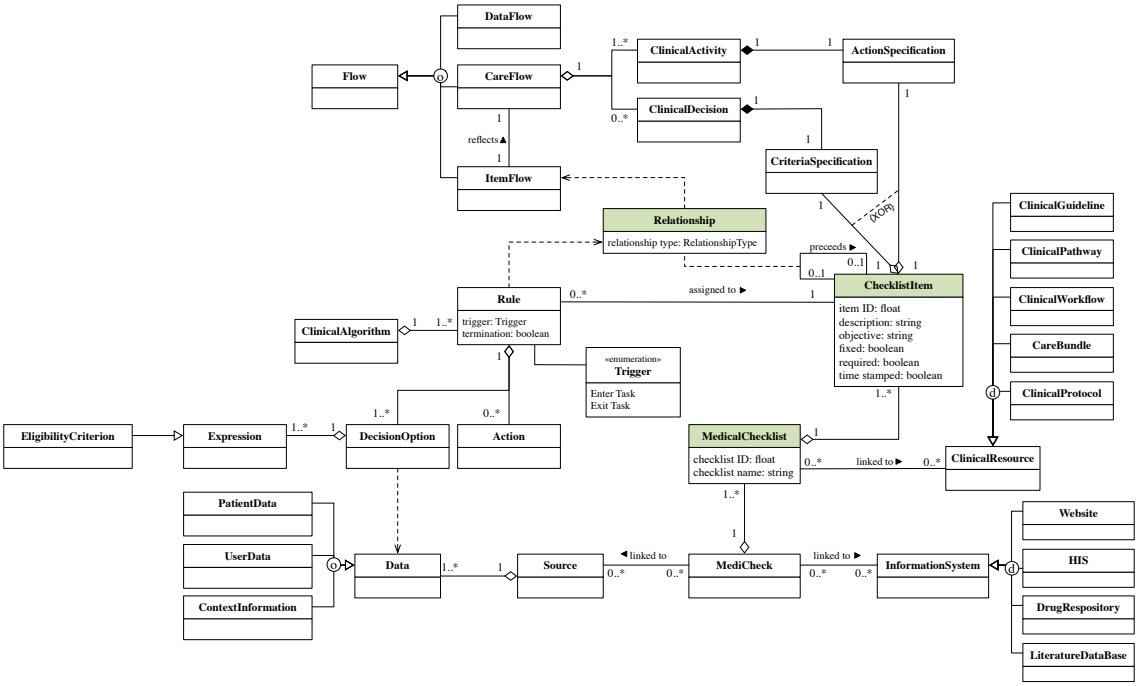

FIGURE D.1: Context-related view of the abstract syntax.

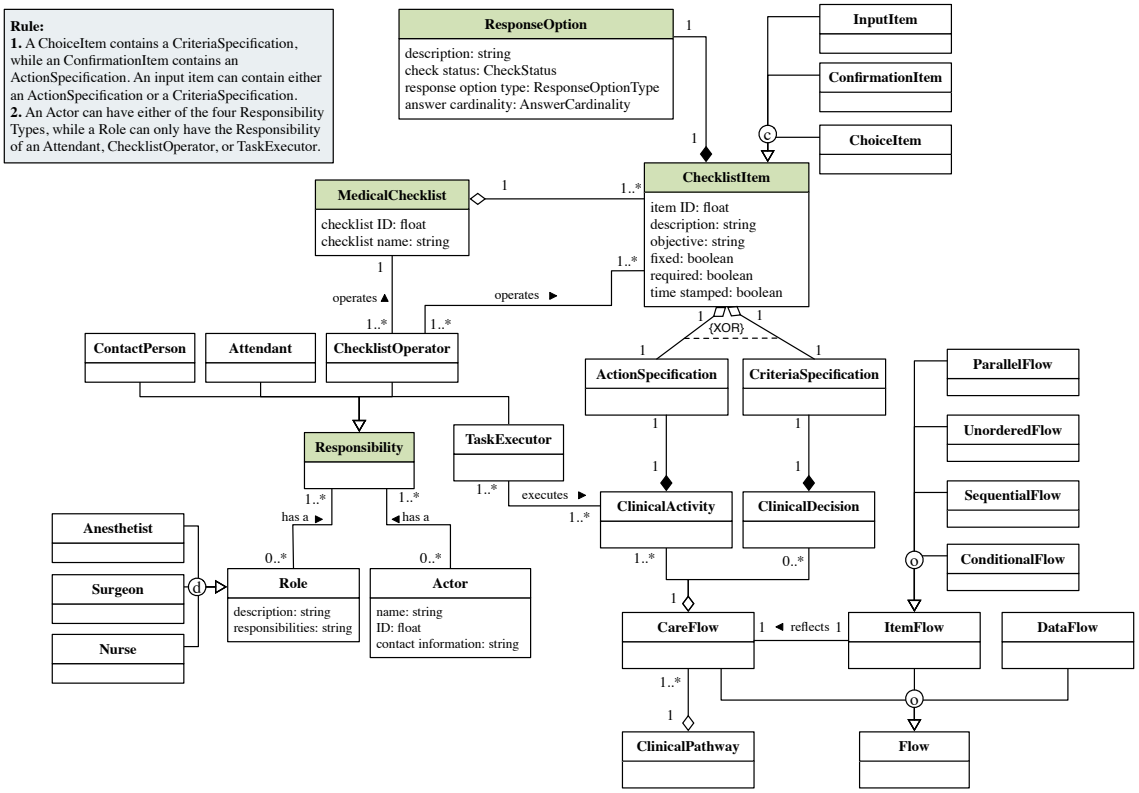

FIGURE D.2: Process-related view of the abstract syntax.

D.1.3 Layout-related View

Finally, the layout-related view specifies how information is displayed on the checklist (see Figure D.3). The meta information of a medical checklist contains a specification of the **ChecklistAudience**, **ChecklistTiming**, and **UnderlyingEvidence**. The checklist audience specifies the number and type of target user. For instance, the checklist could be targeting a single medical practitioner, a group of practitioners, but also patients. Furthermore, a **Container**, irrespective of whether is is a **Section** or a **Header/Footer**, can contain **EmbeddedField**s. An embedded field can be **EmbeddedText**, **EmbeddedMultimedia**, or an **EmbeddedShape**. For instance, an explanation to a specific item or section can be embedded with a text string. A common example of an embedded image is the organization's logo. Moreover, each section has a Format of either the type **Table**, **List**, or **FlowChart**. The layout-view further specifies the **RepsonseOptionTypes** that distinguish the type of response options that a checklist item can have. Table D.1 specified the rules of which item type can have which response option type and **AnswerCardinality**. The latter specifies whether one or multiple reponses to a single item are possible. Lastly, various types of **SupplementaryMaterial** can be distinguished, that can be part of a checklist item. For example, **UnderlyingEvidence** can be part of a specific item that provides information of the evidence for the item. It further allows the update of the item if the underlying evidence is updated. In addition, **SupplementaryData**, **Instruction**s, **Hyperlink**s, or **Literature** can be part of an item that provides further information for the checklist user.

TABLE D.1: Item types, response option types, and answer cardinalities in the MC-DSML.

Item Type	Response Option Type	Answer Cardinality	
		Multiple Choice	Single Choice
ConfirmationItem	CheckBox	✓	
	Signature	✓	
ChoiceItem	Toggle	✓	
	RadioButtonList	✓	✓
	CheckBoxList	✓	✓
	DropDown	✓	
	Score	✓	
InputItem	TextInput	✓	
	NumberInput	✓	
	MultimediaUpload	✓	✓
	MultimediaAnnotation	✓	✓
	TimeDate	✓	

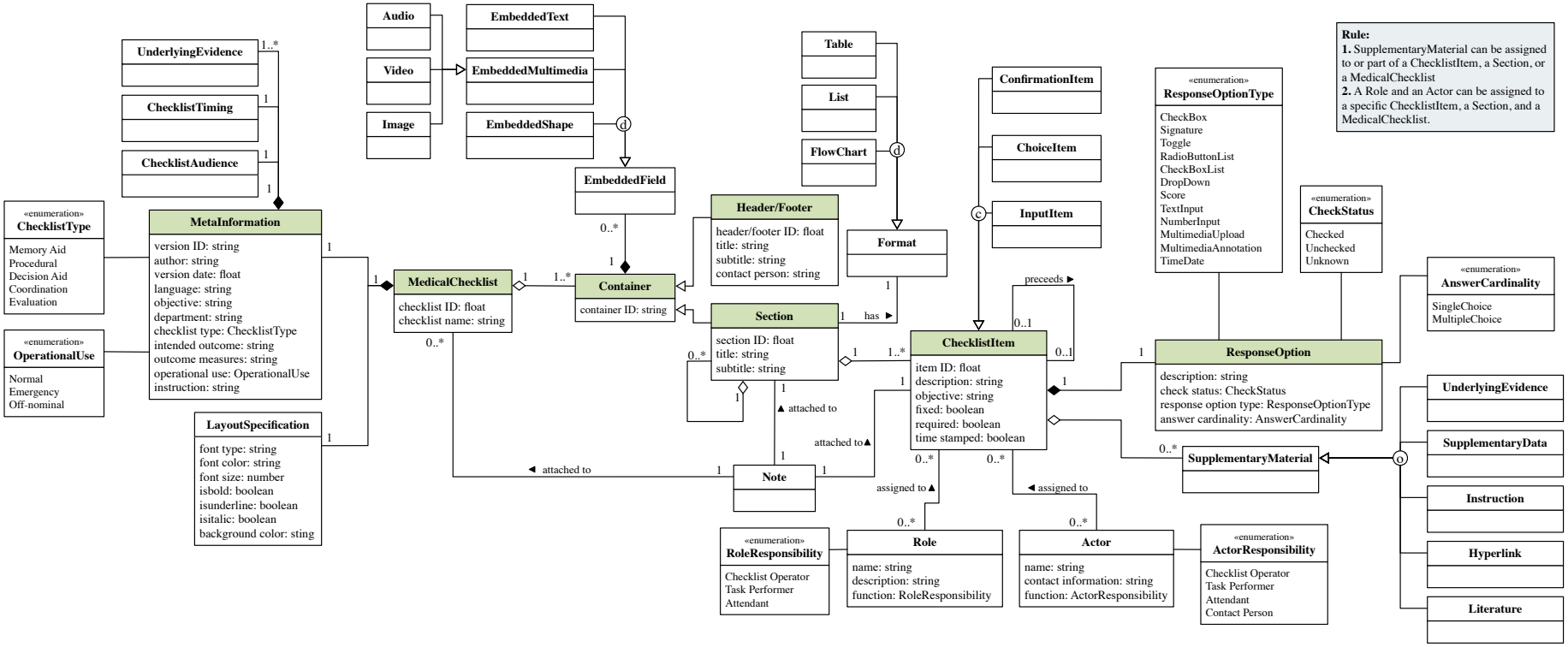

FIGURE D.3: Layout-related view of the abstract syntax.

D.2 Design Considerations Abstract Syntax

In this section we present the main design considerations for our abstract syntax.

Attributes modeled as concepts: The initial version of the abstract syntax contained many concepts that are, in fact, attributes of other concepts. Therefore, thy UML syntax rules were reviewed and the model adapted accordingly.

Structure, Format, and Content: Concepts specifying the structure, the format, and the content of the checklist were initially placed throughout the models. I-2A suggested to group them thematically, which we did accordingly.

Creating different views: Due to the complexity of the abstract syntax and the difficulties for I-2A to comprehend the demonstration of the meta-model, we decided to model different views that distinguish between the process, context, and layout view. We further created a meta-model with the core concepts of the language to emphasize the central concepts of the language specification.

Creating an integrated meta-model: To make sure that changes to one meta-model do not need to be copied to the other views, we created an integrated meta-model.

Naming of the concepts: First, the Container concepts was labeled as Sections, while a Section was specified as a BodySection. However, due to the feedback from I-2B we made adjustments accordingly.

Adding actors: Since the specification of individuals was mentioned by I-2B as being preferable, we added actors as a concept. That way, an individual can be modeled as the contact person of a specific checklist.

Changes to notes: I-2A argued that it would be beneficial if notes cannot just be provided to specific items, but also a section, or an entire checklist. Furthermore, the annotation of notes should be able to allow users to proceed with the checklist if a required item cannot be verified.

Omission of relationships: Owing the complexity of the abstract syntax, some relationships were specified with the help of rules, according to the feedback from I-2C.

D.3 Concrete Syntax and Design Considerations

TABLE D.2: Concrete Syntax of DSL4MC

Type	Name	Notational Element	Definition	Source	Inspired by
Item Type	Confirmation Item		A check item represents a task, an action, a consideration, or a goal that has to be accomplished or considered and its accomplishment confirmed with, for example, a check box or a signature. This can be for instance the confirmation that a patient has been admitted, or that potential risks have been discussed.	[10], [92], [93], [97], [137]	BPMN (task/subtask), Archimate (business process), Flowchart (process)
	Choice Item		Choice items represent items (often criteria) that provide the user with multiple options to choose from. These items are used when the outcome is already known upfront. The simplest version is a yes/no choice, but more options are possible. It can further be distinguished between multiple choice and single choice items, differentiating between being able to check multiple options for one item, or solely one. The chosen option can further be used to determine either the next item, or to derive at a certain conclusion (e.g. diagnosis).	[10], [31], [86], [87], [90], [92], [94]–[96], [137]–[139]	Flowchart (decision), BPMN (gateway)

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Continuation of Table D.2

Type	Name	Notational Element	Definition	Source	Inspired by
	Input Item		The input item requires the user to provide feedback or input in the form of for example text, numeric values, uploads of images, audio, or video, or annotations to embedded multimedia. Input items are typically used when the answer cannot be anticipated.	[10], [30], [90], [92], [96], [137]	
Events	Start		The start event indicates where a checklist is started. It can be connected with the item flow element to a single checklist item or a section.		PDD
	End		The end event indicates where a checklist ends. It can be connected with the item flow element from a single checklist item or a section.		PDD
Grouping	Section		The section is a way to logically or functionally group items. This can be for example a common role or actor performing the tasks or operating the checklist, or a temporal grouping indicating the completion of the items at a certain point in time.	[28]	BPMN (group), Archimate (grouping)

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Continuation of Table D.2

Type	Name	Notational Element	Definition	Source	Inspired by
	Header/Footer	 <<Header/Footer>>	The header/footer is a way of grouping information such as the title and subtitle of the checklist, the organization's logo, the contact information, and version date of the checklist. Contrary to the section, no items can be placed in the header/footer.	[14], [28], [30], [85], [136]	BPMN (group), Archimate (grouping)
Artifacts	Role	 <<Role>>	A role represents the organizational character or function a person is assigned to. This can be for example a nurse, a surgeon, or an anesthetist. One or multiple roles can be assigned to items, sections, and the entire checklist. Furthermore, it can be distinguished between the operator of a checklist (dark), the performer of the associated task (light), or an attending role that should be present during the checklist execution (white).	[28]	BPMN (group), Archimate (grouping)

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Continuation of Table D.2

Type	Name	Notational Element	Definition	Source	Inspired by
	Actor	 <<Actor>>	An actor represents a specific personal resource, an individual independent of their role. This can be for example Dr. Brown or Mr. Smith. Like a role, an actor can be assigned to items, sections, and the entire checklist. For actors, it can be distinguished between the operator of the checklist (dark), the performer of the associated task (light), whether that actor should be present during the checklist execution (white), and the contact person for the checklist (green).	[12], [28], [82], [88], [92], [140]	Expert interviews
	Supplementary Material	 <<Supplementary Material>>	Supplementary material represents any information or material that provides additional information for the checklist user. This can be the item's or checklist's purpose, instructions, or background information to support the checklist user. Examples are instructions in textual form, provision of documents, hyperlinks to other resources or websites, or any other kind of data or multimedia.	[28], [30], [85], [94], [140]	Expert interviews

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Continuation of Table D.2

Type	Name	Notational Element	Definition	Source	Inspired by
	Source	 <<Source>>	A source represents the origin or storage of data. This can either be the underlying evidence for the checklist or the checklist item, such as a specific guideline or empirical study, or the source for relevant data in order to complete or answer a specific checklist item.	[8], [12], [86], [96], [134]	Flowchart (database)
	Note	 <<Note>>	A note represents an empty input field, providing the user with the possibility to provide additional information. This information is then saved in the respective EMR of the patient. A note can be associated with the entire checklist, a section, or a specific checklist item.	[28], [94], [I-1A-I-1E], [I-1G], [I-1H]	Expert interviews
	Data	 <<Data>>	Data represents information that is either input to or output of the checklist or the checklist item (indicated through information flow arrows). Incoming data are for instance consumed data and documents that are needed to perform the associated task or confirm the checklist item, whereas outgoing data are data or documents that are produced during the associated task or completion of the checklist item. For example, for an item such as 'Patient Safety Flowchart is complete', the Patient Safety Flowchart is both input and output data.	[10], [88], [141]	Expert interviews

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Continuation of Table D.2

Type	Name	Notational Element	Definition	Source	Inspired by
	Timing	 <<Timing>>	Timing represents the trigger event or the point in a workflow or clinical path where the checklist, a section, or a specific checklist item is to be completed.	[82]–[84], [140]	Expert interviews
	Rule	 <<Rule>>	A rule represents any calculations, comparisons, or rules that initiate actions, checklist, or checklist item use. For instance, 'the average systolic blood pressure in the last five days', 'all levels should be between 3.5 mmol/L and 5.5 mmol/L', 'for each', or 'if, then, else' are common operations that are followed by an action specification such as alerting, making a diagnosis, providing relevant data, or creating a checklist item. Furthermore, delaying or deferring items, go to items, jump out of checklist items, or checklist terminations are possible to be represented with a rule.	[28], [98],[I-1B-I-1E], [I-1G], [I-1H]	Expert interviews
	Eligibility Criteria	 <<Eligibility Criteria>>	Eligibility criteria represent criteria that need to be fulfilled in order for the item to be applicable to either the context, the patient, or the user of the checklist. This can be for instance, the age, gender, or a specific diagnosis of a patient, the kind of procedure, or the type of user (e.g. intern or attending).	[I-1C]	Expert interviews

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Continuation of Table D.2

Type	Name	Notational Element	Definition	Source	Inspired by
Attributes	Time Stamp	 <<Time Stamped>>	A time stamp represents that the time when an item is completed is registered/recorded. It can be associated with each checklist item.	[85]	BPMN (timer)
	Required	 <<Required>>	This element can be associated with a checklist item. It represents the fact that the item has to be performed or confirmed before the checklist can be completed.	[96], [I-1D], [I-1G]	Expert interviews
	Fixed	 <<Fixed>>	This element can be associated with an entire checklist, a section, or a specific item. It indicates that the associated element or group of elements cannot be changed or removed by other checklist users. For example, this is relevant for standardized checklists or checklist items that have to be completed by each doctor or for each patient.	Added according to interviewee's feedback	Expert interviews
Flow	Data Flow	 <<Data Flow>>	The data flow represents the flow of data or information and indicates its direction. For instance, weather data is incoming or outgoing data can be indicated using the data flow. The circle at the arrow tail is attached to the origin of the data or information that flows, whereas the arrow tip is pointing toward the destination.	[10], [88], [141]	BPMN (message flow)

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Continuation of Table D.2

Type	Name	Notational Element	Definition	Source	Inspired by
	Item Flow		The item flow represents the sequence of the items of a checklist. If items need to be completed in a predefined order (sequentially, branched, or parallel), the items are connected with an arrow, indicating that they have to be followed in that sequence. Unordered items, items that can be completed arbitrarily, i.e. completed in any order, are represented without transitions.	[2], [12], [28], [85], [92], [134], [137]	BPMN, PDD
	Rule Branch		A rule branch represents a condition or rule that determines the next action or item. For example, different options of a choice item can lead to different paths that are followed. If an item asking whether the patient has coughed during the last days is answered with yes, it may result in the termination of a treatment, whereas a negative response, no, may lead to continuing the treatment, and thus, the checklist. Furthermore, rule-branches can be used for items that need to be repeated (i.e. iterative items), in order to indicate how often the repetition has to be performed. For instance, checking a patient's blood pressure can be a task that has to be performed multiple times during the time of the checklist completion.	[I-1C]	Expert interviews

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Continuation of Table D.2

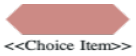
Type	Name	Notational Element	Definition	Source	Inspired by
	Eligibility Branch		An eligibility-branch represents a condition or rule that determines a certain patient or user population for which certain actions or items are applicable. For example, an item that is only applicable to fertile women (e.g. asking whether the patient is pregnant) would only be shown if the patient is a fertile female individual.	[28], [98]	Expert interviews
	Synchronizatio		A synchronization bar allows the forking of multiple concurrent activities. Items are modeled in parallel, connected with a synchronization bar, and can later on be joint again by using the same synchronization bar.	[25]	PDD
Embedded	Embedded Text		Embedded text represents any text that is provided on a checklist in addition to items. This can be for instance the checklist title, a section title, additional information or the date.	[22], [28], [30], [31], [94], [136]	Expert interviews)
	Embedded Multimedia		Embedded multimedia represents images, audio, or video material that is provided next to checklist items on a checklist. For instance, this could be the organization's logo or video material supporting or instructing the checklist use.	[12], [14], [82]	Expert interviews

End of Table D.2

D.4 Design Considerations Concrete Syntax

Below we provide an overview of the main design considerations and changes regarding the graphical notation.

TABLE D.3: Concrete Syntax of DSL4MC

Name	Original Element	Final Element	Explanation
Required			Differentiating between required and not required items by using different lines, therefore introducing two different elements for each item type, did not seem to be intuitive [I-C3]. Thus, suggested to introduce a separate element that can be attached to items that are required.
Actor			"The difference between the role and the actor is clearer that way. The batch indicates more that it is a specific instance, an individual, rather than some kind of person" [I-C3]
Confirmation Item			The initial checkmark limited the symbol to representing checkboxes, instead of further including signature. Moreover, the item description could not be placed within the symbol.
Decision Item			The initial symbol limited it to representing drop-down lists, instead of representing all possible response option types. Moreover, the item description could not be placed within the symbol.
Input Item			Text and numeric item into one, difference will be determined with attributes

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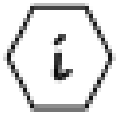
Continuation of Table D.3

Name	Original Element	Final Element	Explanation
Role			Distinguish between operator, present, and task executor
Actor			Distinguish between operator, present, task executor, and contact person.
Note			The note symbol was not recognized as such [I-3A], and therefore replaced by the BPMN symbol for messages.
Note		 <<Note>>	The message symbol did not represent the meaning of a note properly and was therefore replaced by a note icon, as suggested by I-3B
Data Flow		 <<Data Flow>>	Separate element for data and flow for more flexibility.
Data			Changes to the data symbol that was adopted from BMPN were made according to the feedback of I-3B. Various meaning could be attributed to this symbol, thus, a folder was suggested.
Data		 <<Data>>	The folder was again attributed various meanings by I-3C. Therefore, we changed it to a combination of the previous two version.
Information		 <<Supplementary Material>>	Change name into Supplementary Material [I-C1]

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Continuation of Table D.3

Name	Original Element	Final Element	Explanation
Supplementary Material		omitted	Can be combined with information
Embedded Text			Can be combined with additional information
Critical Aspects	Can multiple roles or actors be assigned to the same item or section? [I-3D] Yes, can be represented like this: 		
	Description of “Note” might be misleading. Consider changing into “empty note field”, or “empty text field for notes” [I-3E]		

End of Table D.3

E MediCheck Validation - Additional Material

E.1 Discussion of MediCheck Against Design Requirements

Note, we did not include requirements that solely provide a high-level specification for grouping a set of more specific requirements. Therefore, R5, R6, R7, R8, R10, R11, R13, and R14 are not included in this analysis.

TABLE E.1: Overview of the high-level requirements for MediCheck.

ID	Priority	Fulfilled
R1	M	✓
R2	S	✓
R3	S	✓
R4	S	✓
R5.1	S	✓
R5.2	M	✓
R5.3	C	✓
R5.4	M	✓
R5.5	M	✓
R6.1	M	✓
R6.1.1	M	✓
R7.1	M	✓
R7.2	M	✓
R7.3	S	X
R7.4	M	✓
R7.4.1	M	✓
R7.5	S	✓
R7.5.1	S	✓
R7.6	M	✓
R7.7	M	✓

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Table E.1 – *Continued from previous page*

ID	Priority	Fulfilled
R7.8	S	✓
R7.9	C	✓
R7.10	C	(✓)
R7.11	S	✓
R7.12	S	✓
R7.13	S	✓
R7.14	S	✓
R7.14.1	S	✓
R7.14.2	S	✓
R7.14.3	S	✓
R8.1	S	✓
R8.2	S	(✓)
R8.3	M	✓
R8.4	M	✓
R8.5	M	✓
R8.6	S	✓
R8.7	S	(✓)
R8.8	M	✓
R9	S	✓
R10.1	M	(✓)
R10.2	S	✓
R11.1	M	✓
R11.2	M	(✓)
R11.3	S	✓
R11.4	S	✓
R11.4.1	S	✓
R12	S	✓
R12.1	S	✓
R12.2	M	✓

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Table E.1 – *Continued from previous page*

ID	Priority	Fulfilled
R13.1	S	✓
R13.2	S	✓
R13.3	S	✓
R13.4	S	✓
R13.5	S	(✓)
R13.6	S	(✓)
R14.1	S	✓
R14.2	S	✓
R14.3	S	✓
R14.4	S	✓

End of Table E.1

E.2 Additional Requirements for Future Development

AR-1: MediCheck should allow the storage of the information that is provided in a note in the EMR of a specific patient and to store it in the checklist system, so that the notes can be analyzed for checklist improvements.

AR-2: MediCheck should allow the specification of whether providing information in a note qualifies as completing/confirming a checklist item.

AR-3: The MC-DSML should allow the user to distinguish between different types of reviews, including reviewing the user interface, the content, the underlying evidence, the outcome, and adherence to the checklist.

AR-4: MediCheck should support linking the personal calendar with MediCheck so that scheduled reviews can be automatically saved in personal calendars.

AR-5: MediCheck should support requesting reviews or propose changes to the responsible checklist contact person.

AR-6: MediCheck should support showing the corresponding checklist model at all times next to checklist.