A Domain-specific Modelling Language for Clinical Pathways in the Realm of Multi-perspective Hospital Modelling

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A DOMAIN-SPECIFIC MODELLING LANGUAGE FOR CLINICAL PATHWAYS IN THE REALM OF MULTI-PERSPECTIVE HOSPITAL MODELLING

Complete Research

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Abstract

To increase the quality and decrease costs of medical care provision, hospitals apply clinical pathways (CPs) to ‘model’ and manage their processes. Conceptual models of CPs should foster communication between hospital stakeholders, serve as an instrument for quality assurance and optimisation of resource usage, and a foundation for the (re-)design of hospitals’ action and information system (IS). However, existing approaches to CPs’ modelling suffer from simplifications and a low level of domain-specific semantics. In addition, they focus mainly on processes and neglect other aspects relevant to a comprehensive management of hospitals. We argue that to realise the potential benefits of CPs, a comprehensive modelling method accounting for peculiarities of hospitals’ action system and IS is required. The core of such a method should be a Domain-Specific Modelling Language for CPs presented in this paper.

Keywords: Modelling Clinical Pathways, Multi-Perspective Hospital Modelling, DSML

1 Introduction and Motivation

The healthcare sector is one of the most challenging and complex fields to manage today (Drucker, 2002; Wickramasinghe et al., 2014). The sustainability of the healthcare sector in most industrialised countries is challenged by demographic changes, medical and technological advances, well-informed patients and, in consequence, an increased demand for high-quality medical care, which leads to significantly rising health care expenditures (Adeyemi, Demir, and Chaussalet, 2013, p. 117; Nagel, 2013). This, together with the introduced health care reforms (e.g., reimbursement based on a diagnosis-related groups system (DRG) (Busse et al., 2011; Hsiao et al., 1986)), demands hospitals to (re-)design their medical care provision in order to deliver the medical care of high quality and, at the same time, reduce resulting costs by ensuring the efficient and effective usage of resources (Adeyemi, Demir, and Chaussalet, 2013, p. 117). Therefore,
a paradigm shift from the function-oriented to process-oriented delivery of medical care took place (Vos et al., 2011, p. 1). Against this background, hospitals turn their attention to their clinical processes and possibilities to optimise them using clinical pathways (CPs) (Rotter et al., 2010, p. 3). Indeed, until today more than 80% of hospitals have introduced CPs to address different challenges related to the medical care provision (Rotter et al., 2010, p. 3; Kinsman et al., 2010, p. 1).

1.1 Clinical Pathways and their Representation

CPs describe in detail, for each day of treatment and taking into account all involved actors coming from different professions (e.g., physicians with different medical specialisations, nursery staff, social workers), the suggested sequencing and timing of diagnostic and treatment measures to be performed on a patient with given symptoms or diagnosis (Coffey et al., 1992, p. 45). Thus, a CP may be seen as a method to manage medical care of “a well-defined group of patients during a well-defined period of time” (de Bleser et al., 2006, p. 562) that contributes to improving the quality of care processes, reducing risks, increasing the efficiency of the resource usage, and increasing the patient satisfaction by (de Bleser et al., 2006, p. 562; Schipps and Schippits, 2013, p. 62): (1) explicitly defining the goals and key elements of care based on Evidence-Based Medical (EBM) guidelines, best practices and patient expectations, (2) facilitating communication between all stakeholders, (3) coordinating roles and defining a sequence of activities undertaken by multi-disciplinary care teams, patients and their relatives, (4) documenting, monitoring and evaluating treatment variances, (5) providing information on the necessary resources and outcomes of the care process. If for given symptoms or diagnosis a CP is available, approx. 80% of patients receive medical care according to it, while remaining ones feature clinical characteristics requiring different treatment (Langdale, 2013, p. 3; Küttner and Roeder, 2007, p. 23).

CPs are usually distributed in the form of unstructured textual description of guidelines, table-based schedules, a combination of two previous ones (Heise et al., 2010, p. 211), or computer-interpretable guidelines (CIGs) to facilitate their usage in computer-based clinical workflows (e.g., Mulyar, Aalst, and Peleg, 2007; Peleg, 2013; Peleg et al., 2003). The available representations of CPs, although targeted at human users, proved to be not as easy to understand and interpret for all involved actors. Therefore, the attention was turned towards conceptual modelling of CPs in order to address shortcomings of previous approaches and to provide a well-structured semantically rich graphical representation of CPs on the type level (e.g., Burwitz, Schlieter, and Esswein, 2013; Heise et al., 2010; Heß, 2013; Lenz et al., 2007). Furthermore, conceptual models of CPs could serve as a foundation for a model-driven (re-)design of hospitals’ action and IS (Krogstie, 2012), e.g., to provide a better IT support of prespecified, repetitive as well as knowledge-intensive medical processes by a process-aware Hospital Information System (HIS, Reichert and Weber, 2012, pp. 9-20; Winter et al., 2011, pp. 33-36). In order to support the development and use of such conceptual models however, a modelling language providing adequate concepts is required.

1.2 The Need for a Domain-Specific Modelling Language for Clinical Pathways

Enterprise Modelling focuses on the construction and application of conceptual models to describe, analyse, and (re-)design different aspects of an organisation (cf., e.g., Frank, 2014, pp. 2-3; Sandkuhl et al., 2014). The emphasis is placed on the design and analysis of the organisational action system (e.g., business processes, organisational structure, resources) and the information system (IS) (Frank, 2014, p. 2). Conceptual models are built using modelling concepts defined in a modelling language (Siau and Rossi, 2011, p. 251). A modelling language is defined through its syntax and semantics. “The abstract syntax defines rules for constructing syntactically correct models using the language concepts. The concrete syntax defines the symbols used to represent the abstract syntax. Since these symbols are usually graphical, it is also referred to as graphical notation. The semantics of a modelling language defines the (formal) interpretation of modelling concepts.” (Frank, 2011b, pp. 26-27). In order to create conceptual models one may use either a General Purpose Modelling Language (GPML) or a Domain-Specific Modelling...
A DSML is intended to be used in a certain domain of discourse and as such, is based on concepts, which were reconstructed from technical terms used in the respective domain. The benefits of using a DSML instead of a GPML may be summarised as follows (Frank, 2013, pp. 133-134): (1) increased modelling productivity as the domain-level concepts do not have to be reconstructed from semantic primitives of a given GPML, (2) fostering model integrity as the abstract syntax and semantics of a DSML limits the possibility of inappropriate use of language concepts, (3) better communication with prospective users as the modelling concepts correspond with the technical terms users are familiar with.

Although CPs can be conceptualised analogously to business processes, the studies have shown (Burwitz, Schlieter, and Esswein, 2013; Heise et al., 2010; Heß, 2013; Lenz et al., 2007) that the application of widely accepted business process modelling techniques to model CPs does not allow to realise the desired benefits (i.e., fostering communication between hospital stakeholders, serving as an instrument for quality assurance and optimisation of resource usage, and as a foundation for the (re-)design of hospitals’ action system and IS). Thus, several approaches providing basic abstractions required to model CPs were proposed in the field of IS (e.g., Burwitz, Schlieter, and Esswein, 2013; Färber, Jablonski, and Schneider, 2007), medicine (Society for Medical Decision Making, 1992) and medical informatics (e.g., Mulyar, Aalst, and Peleg, 2007; Peleg, 2013). However, although at first glance these languages indeed provide basic domain-specific concepts, the extent of reconstructing the domain-specific terminology with respect to medical care processes, as we show in the paper, seems to be insufficient. In addition, they focus mainly on sequencing of activities neglecting other aspects detailed in CPs and relevant to a comprehensive management of hospitals in general, and medical care in particular.

Although, at first sight, the apparent lack of a higher degree of domain-specific semantics may seem to be beneficial as, on a high level, the simpler a language is, the more likely it is that users are not overburdened by its usage (Frank, 2010). However, such a language does not foster communication and understandability to the same extent as a more comprehensive one (Frank, 2010). One of the most important roles of CPs’ conceptual models is to foster communication between all stakeholders as “communication failures influence the quality of health care and contribute to medical errors and adverse outcomes for patients” (Hewett et al., 2009, p. 1732). Thus, taking into account also other defined benefits of CP modelling, we argue that a corresponding modelling language should provide far richer abstractions reconstructed from the domain-specific professional terminology the prospective users are familiar with.

1.3 Goal and Research Questions

Against this background, our main goal is to develop a semantically rich domain-specific modelling language for clinical pathways (DSML4CPs), which provides modelling concepts reconstructed from the medical terminology. The design of the DSML4CPs is part of a research project aiming at the development of an enterprise modelling method suited for the needs of hospitals, namely a Multi-Perspective Hospital Modelling (MPHM) method (Heß, 2013). The MPHM method is to provide hospitals with an instrument, tailored to their specific needs, which would allow to model not only clinical pathways, but also other elements of hospital’s action system and IS in order to address information needs of all stakeholders. Therefore, the aim is not only to foster communication and increase the transparency of undertaken actions, but also to provide a basis for conducting purposeful model-based analyses taking into account various professional perspectives (Heß, 2013, pp. 372-373), which, on the higher level, can be differentiated into medical, administrative and technical (Heß, 2013, p. 373; Lenz and Reichert, 2007, p. 40; Färber, Jablonski, and Schneider, 2007, p. 77). The method is also to constitute a foundation for (re-)designing the hospital’s action system and IS in order to increase efficiency and/or effectiveness of all hospital’s processes (Heß, 2013, pp. 372-373). Thus, the DSML4CPs builds the core of MPHM method, as it allows to model hospitals’ primary processes (Heß, 2013, p. 371). Further DSMLs are to be developed or extended, each targeted at modelling selected aspects of hospitals, e.g., resource types or the hospitals’ organisational structure.
This paper focuses on the design and development of the DSML4CPs, which constitutes our main contribution. We aim at addressing the following research questions: (1) Which requirements a DSML for CPs should fulfil in order to realise the expected benefits? (2) Which modelling concepts should be specified and at which level of details in order to fulfil the identified requirements, and in consequence, how the language specification should look like? To answer these questions we present the identified requirements as well as the abstract and exemplary concrete syntax of the proposed DSML.

Hospitals are highly complex socio-technical systems with a high number of different professions and disciplines (e.g., Wickramasinghe et al., 2014; Drucker, 2002, p. 119). Although the aim is to cover the entire field of medicine, taking into account its complexity, a starting point needed to be selected. Therefore, with respect to the medical and societal relevance, the medical field of oncology has been chosen as a current focus of the DSML. “Cancer is a major cause of morbidity and mortality, with approximately 14 million new cases and 8 million cancer-related deaths in 2012” (Forman and Ferlay, 2014, p. 16) and an increase in new cases of cancer of about 75% is prognosed (Stewart and Wild, 2014, p. IX). Comprehensive cancer centers (CCC) – networks of hospitals and/or clinics with a special focus on the treatment of cancer – usually have a portfolio of about 80 or more different multi-disciplinary clinical pathways for diagnostics and therapies of all different entities of cancer. For instance, 43 CCC are certified in the USA by the National Cancer Institute and 13 CCC by German Cancer Aid in Germany. Along with CCC also a considerable number of cancer centers (having a smaller portfolio of CPs than CCC) and organ cancer centers (having a more focussed range of oncological clinical pathways) provide a significant amount of care to patients with cancer. Here “[c]linical pathways should be particularly valuable in reducing both variations in treatment and high cancer treatment costs” (Kreys and Koeller, 2013, p. 1083) and thereby, help to address hospitals’ (and public health’) current challenges. Taking this and the aforementioned numbers on cancer-related cases into account, the relevance of supporting the modelling of corresponding CPs becomes apparent. Although the resulting DSML focuses on the field of oncology, its application is not limited only to oncological CPs, and thus, the potential impact on providing medical care with a high(er) quality in a (more) cost-effective and transparent way, is even higher. However, the application of the proposed DSML in other medical fields requires additional extensions in the future to address specific professional terminology from the targeted medical field.

1.4 Research Approach Followed and Structure of the Paper

This contribution, as well as the overall research project aiming at the design and development of a Multi-Perspective Hospital Modelling method, follows the pro-active research path based on the design oriented research paradigm (Österle et al., 2011). Thus, we follow the scientific principles of abstraction, originality and justification (Österle et al., 2011, p. 9). The resulting IT artefact – DSML4CPs – aims at providing a benefit to hospitals and their stakeholders by contributing to addressing current and preparing for addressing future challenges with respect to modelling and analysing clinical pathways using domain-specific concepts. To ensure its suitability and purposefulness, following the dialogical action research (Mårtensson and Lee, 2004; for a critical discussion of action research, see, e.g., Baskerville, 1999; Mumford, 2001; Avison, Baskerville, and Myers, 2001), domain experts, i.e., medical and management staff, have been involved in all phases of the conducted research.

In order to design the targeted DSML, we follow the method proposed by Frank (2013, 2010), which has already been successfully used in other projects (e.g., Heise, 2013; Strecker et al., 2012). The method provides a macro process model and a corresponding role model that guide a language designer through the development process. The macro process itself consists of 7 steps (Frank, 2013) – (1) clarification of scope and purpose, (2) analysis of general requirements, (3) derivation of specific requirements using a set of scenarios, (4) specification of language (abstract syntax), (5) provision of a graphical notation (concrete syntax) and (6) optional development of a modelling tool. The process ends with the evaluation and iterative refinement of developed artefacts (7). Within this paper, we focus on four main artefacts resulting out of the application of the above approach: identified specific requirements towards a targeted
language, abstract syntax (i.e., meta-model), concrete syntax (i.e., graphical notation) of the proposed language, and its application (i.e., a model based on a use case) that was used for evaluation purposes.

In order to reach the defined goals, the paper is structured as follows. First, after indicating the sources used in the requirements elicitation process, a set of requirements towards the targeted DSML is presented together with short rationale and resulting modelling concepts. The identified requirements are used to discuss and evaluate related work in Sect. 3. The abstract and concrete syntax of the designed DSM4CPs is presented and evaluated in Sect. 4. The paper ends with an outlook on future research activities.

2 Requirements towards the DSML for Clinical Pathways

As already mentioned, in order to design the targeted DSML, we follow the method proposed by Frank (2013, 2010). In line with the approach followed, in order to identify the specific requirements towards the postulated modelling language (step 3 of the macro process), first the main scenarios, i.e., “stories that illustrate how a perceived [artefact] will satisfy a user’s needs” (Holbrook, 1990, p. 96), should be identified in the close collaboration with the domain experts. Thus, taking into account the selected medical field, it was crucial to involve a number of experienced senior physicians and medical specialists working in different fields of oncology, such as surgical oncology, medical oncology, radio oncology, and pathology. All of them were interviewed – alone and in groups – regarding their expectations towards the usage of CP models, modelling approach and potential initiatives aiming at the (re-)design of hospital’s action system and IS. The knowledge gained during interviews has been extended based on observations of physicians during their daily working routines in different departments. Moreover, further insights have been gained by observing multi-disciplinary case conferences: here physicians from various medical disciplines jointly plan and control each patient’s CP-based individual medical care. Finally, the requirements elicitation process was supported by the analysis of the relevant medical documentation and literature. Further details on the requirements elicitation process and involved actors may be found in Heß et al. (2014).

The above mentioned activities allowed for identification of three main scenarios, showing how CP models could support the caregivers in providing high-quality medical care in a more efficient way. The first scenario points to a CP serving as a reference model for a specific medical problem, a specific group of patients and a specific institution. Thus, it focuses on documenting a CP on the type level, i.e., documenting the medical knowledge in relation to the process flow, economic information, information per process step, and resources to be used (humans, machines, required qualification etc.). The second scenario points to the need to support documentation of the CP-based individual treatment in a HIS (Winter et al., 2011, pp. 33-36). Thus, it focuses on a need to provide support for a CP-based documentation for a specific patient (i.e., on the instance level) encompassing performed medical processes, economic information, provision of documentation structures (e.g., a letter of discharge, clinical/epidemiological cancer registration). Finally, the third scenario focuses on the Process-aware Hospital Information System, where a CP serves as a tool guiding the medical care provision processes (e.g., by suggesting next steps to follow) and allowing to monitor the compliance of CP execution. These scenarios allow to identify the context in which the CP models could be used, and thus, also the scope of information they should encompass. Therefore, together with the literature on the CPs and on their potential role in the medical care, they became a basis for the derivation of specific requirements towards the modelling language, which are presented subsequently in a structured way. First, the requirement is stated. Then, a short rationale and potentially resulting modelling concepts, which should become part of the modelling language, are given.

R1: A DSML for CPs should provide concepts supporting comprehensive modelling of medical processes based on professional terminology. Rationale: As stated by Frank (2013, p. 136), “the concepts of a modelling language should correspond to concepts prospective users are familiar with. That recommends reconstructing existing terminology.” Concepts: Medical Process, Diagnostic Process, Therapeutic Process, various specialisations relevant in the field of oncology.

R2: A DSML for CPs should provide concepts supporting comprehensive modelling of medical decision scenarios including decision alternatives, criteria and their corresponding potential values (Heß,
2013, p. 375). **Rationale:** CPs aim at supporting physicians, patients and their relatives in making medical decisions (de Bleser et al., 2006, p. 562). **Concepts:** Decision scenario, decision criteria.

**R3:** A DSML for CPs should provide concepts for modelling and assigning information on the underlying evidence classification (Heß, 2013, p. 376). **Rationale:** CPs aim at transferring evidence-based Clinical Practice Guidelines (CPGs) (Field and Lohr, 1990, p. 38) into clinical practice. To support decision making, CPs’ processes and decisions should be augmented with information on the underlying level of evidence. **Concepts:** Evidence Classification System, Level of Evidence, Grade of Recommendation.

**R4:** A DSML for CPs should provide basic concepts to model control flow structures. **Rationale:** CPs aim at representing optimal and alternative sequencing as well as repeated or arbitrary sequenced execution of medical processes (Mulyar, Aalst, and Peleg, 2007). **Concepts:** Control flow concepts.

**R5:** A DSML for CPs should allow for specifying one or more goals for each medical process based on both, (evidence based) medical knowledge and patient-specific preferences (Heß, 2013, p. 375). **Rationale:** Explicating and communicating goals and respecting patient-specific preferences fosters transparency and allows to analyse congruency and realisation of goals. **Concepts:** Goal, patient-specific goal.

**R6:** A DSML for CPs should allow for assigning responsibilities to each medical process, differentiating those responsible for performing the medical process, as well as those responsible for its outcome (Heß, 2013, p. 376). **Rationale:** Explicating responsibilities allows to foster communication, optimise sequencing of medical processes and identify contact persons. **Concepts:** Responsibility, or qualifying association to corresponding concepts, e.g., organisational units.

**R7:** A DSML for CPs should allow for representing checklists associated to each medical process. **Rationale:** To provide additional information on the detailed execution of medical processes, checklists are a widely accepted and useful instrument to detail medical processes in CPs (Gawande, 2010; Healey et al., 2011, p. 3; Wolff, Taylor, and McCabe, 2004, pp. 430-431). **Concepts:** Checklist, checklist element.

**R8:** A DSML for CPs should account for various perspectives and information needs of hospitals’ stakeholders. **Rationale:** As clinical pathways target improvements of medical care from different perspectives, a corresponding modelling language should account for these by providing concepts allowing to model relevant information, e.g., from the (multi-disciplinary) medical, the organisational, **Concepts:** Concepts and attributes related to/arising from different professional perspectives.

**R9:** A DSML for CPs should allow for allocating medical resource types to medical process types. **Rationale:** CPs aim at optimising resource usage and providing management support. **Concepts:** Medical resource, medical device, drug, aid, as well as their specialisations.

**R10:** A DSML for CPs focussing on oncological CPs should account for supporting dedicated CP-based clinical documentation as well as, based on it, a clinical and epidemiological cancer registry. **Rationale:** To support model-based HIS (re-)design dedicated data structures supporting process type specific documentation should be provided to each process meta type. **Concepts:** Data structures derived, e.g., from a common oncological record format (Klinkhammer-Schalke et al., 2014).

Hospitals realise a number of processes to reach their goals. CPs focus on the main one, i.e., providing the medical care. However, the medical care is supported by or embedded into other processes such as supply management, scheduling and resource allocation, hospital administration and management as well as, e.g., in case of university hospitals, research and teaching (Winter et al., 2011, p. 70). Therefore, it seems reasonable to consider a DSML4CPs as part of an enterprise modelling method that already provides further relevant concepts. With respect to the identified requirements, **R1** to **R6** seem to be the most crucial for the design of a DSML4CP as the concepts they are pointing at are not only indispensable for the realization of the identified scenarios, but also reflect the main constituents of the CP concept (de Bleser et al., 2006, p. 563; Küttner and Roeder, 2007, p. 23; Kinsman et al., 2010).

### 3 Related work and its Evaluation

Related work has been selected based on a literature analysis aiming at identifying modelling languages for CPs developed in the disciplines of Information Systems, medicine, and medical informatics. Both,
GPMLs and DSMLs have been evaluated. The former ones only if at least one publication reporting on its application to model CPs has been found. The approaches differ regarding their extent of the formalisation of the treatment logic, as well as their scope of the presented information. Recently, a number of initiatives aiming at providing formal ontologies for the needs of CPs may be observed (e.g., Hu et al., 2012; Yao and Kumar, 2013). Among them the most comprehensive one – CONFlexFlow (Yao and Kumar, 2013) – is included in the evaluation (see Table 1 for the results).

Table 1. Evaluation results

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Legend: ○ = not fulfilled; • = partly fulfilled; ● = fulfilled

The evaluation was conducted based either on the publicly available language specifications or on relevant publications describing the given approach. Thus, for each requirement each approach was analysed with the aim to identify modelling concepts or structures that address the considered requirement. The evaluation shows that none of the approaches meets all requirements. Furthermore, because of their different intended scopes and purposes, approaches from the IS discipline seem to be semantically richer and support, to a higher extent than approaches from other fields, the identified requirements.

**R1** is only partly or not at all fulfilled. CIG approaches and CP-Mod offer concepts like “clinical state”, “clinical activity”, and “decision” (Peleg, 2013, pp. 747-749; Burwitz, Schlieter, and Esswein, 2013, pp. 57-59). ConFlexFlow offers the concepts “action” and “activity” (Yao and Kumar, 2013, p. 502). MEMO OrgML with extensions (Heise et al., 2010, p. 219) offers as basic abstractions the meta types DiagnosticProcess and TherapeuticProcess and thereby, reconstructs parts of the domain-specific terminology. Modelling complex decision scenarios (**R2**) is covered (at least partly) by all approaches, while **R3** – assigning a level of evidence – is partly covered by most of the approaches emerging from the IS field, but not by the ones coming from medicine/medical informatics. As all of the approaches aim at modelling (medical) processes, all provide more or less comprehensive concepts for modelling control flow structures (**R4**). In turn, **R5** to **R10** originate mainly from an organisational/managerial perspective, which is mostly not in the intended scope of the evaluated approaches.

Therefore, in order to fulfil all identified requirements, there is a need to design a new modelling language for clinical pathways or extend an already existing one with relevant concepts. At first sight, approaches like, e.g., CP-Mod, seem to be good candidates to be extended. However, as already indicated,
the DSML4CPs should be part of or should extend an existing enterprise modelling method in order to allow for a more comprehensive modelling (and in consequence also analysis) of relevant aspects of hospitals as organisations. Among the analysed approaches only BPMN – since being integrated into the ARIS approach –, EPC and MEMO OrgML are part of an existing enterprise modelling method. MEMO OrgML provides a more comprehensive fulfilment of the requirements – esp. with focus on R1 to R6 – than BPMN and EPC. In addition, the MEMO method provides a broader foundation for extending the underlying enterprise modelling method considering both the number of DSMLs being part of it, as well as public availability of all language specifications of MEMO method’s DSMLs. Therefore, MEMO OrgML is selected to be extended towards a DSML4CPs.

4 Domain-Specific Modelling Language for Clinical Pathways

4.1 Modelling Guidelines Followed

In general, several means of defining a modelling language exist, however the one frequently used and followed also in case of MEMO, is by specifying a meta model, i.e., a model of models (Eriksson, Henderson-Sellers, and Gerfalk, 2013, p. 2099). A meta model defines the abstract syntax and semantics of a given language together with additional constraints (Frank, 2011d, p. 3). Thus, a model (defined on the M1 level) is specified by a modelling language, which in turn is specified by a meta model (M2 level). Thus, a model is an instance of a meta model, which in turn is an instance of a meta meta model (M3 level) (Frank, 2011d, p. 3). The constraints can be formulated using, e.g., Object Constraint Language (OCL) (Rumbaugh, Jacobson, and Booch, 2005, pp. 490-492; Warmer and Kleppe, 2003, 1999).

Defining a meta model requires making a number of modelling decisions, e.g., should a concept be part of language specification (meta type, M2 level) or part of language application (type, M1 level)? In addition, the decisions regarding attributes and their types as well as relations between concepts and their cardinalities needed to be made. To support making design decisions and to ensure the required quality of the developed meta model, the guidelines proposed by Frank (2011c, 2013) were applied. Thus, each potential modelling concept was evaluated using a set of criteria and rules (Frank, 2011c). For instance, to decide whether a concept should become part of a DSML the fulfilment of two criteria: noteworthy level of invariant semantics and relevance was checked, whereas to check the suitability of a concept as a meta type the criteria: noteworthy semantic difference between types and intuitiveness of an instance of the concept as a type were applied. In turn, in order to check whether the term could be represented as a type: "instance" as an abstraction and invariant and unique instance identity, were considered. If the application of the above guidelines did not lead to the desired effect, the classification of a concept as a local type (Frank, 2011c), application of intrinsic features and language level types were considered. Intrinsic features – marked by the literal “i” in white colour on a black background – “can be instantiated only from the instances of their instances”, i.e., a meta type or meta attribute can be instantiated only on M0 but not on the M1 level (Frank, 2011c, p. 104). Language level types – visualised with a black name of the concept on a grey background – allow for specifying concepts that represent instances already on the type level (M1) and cannot be instantiated on the instance level (M0) anymore (Frank, 2011d, pp. 23-24). This is required in rare cases, when instances should be accounted for in models on the type level.

4.2 Language Specification: Abstract Syntax

As we extend the MEMO OrgML, the meta model excerpts shown in Figures 1 and 2 are created using the MEMO method’s common Meta Modelling Language (MML) (Frank, 2011d) to foster the DSML’s integration into MEMO method’s language architecture (Frank, 2014, pp. 947-950). Figure 1 shows the meta model excerpt specifying concepts for modelling medical process types (R1). Starting point are the concepts AnyProcess and ControlFlowSubprocess of the MEMO OrgML (Frank, 2011a, p. 56). Out of the latter the abstract concept MedicalProcess is specialised. It serves as a common abstraction over the
concepts DiagnosticProcess and TherapeuticProcess that represent two basic types of medical processes distinguished in the medical domain. The concepts DiagnosticProcess and TherapeuticProcess serve as abstraction over specialised diagnostic and therapeutic process types, respectively, e.g., the abstract concept DiagnosticImaging and its specialisations allowing to distinguish procedures with/out radiation being used, or the concepts SurgicalTherapy and RadioTherapy. The latter one includes an enumeration attribute to detail the type of radiotherapy. To each RadioTherapy process type one TreatmentProtocol
needs to be defined. On the type level one or more StandardFraction, i.e., the number of radiotherapy sessions including the single dose, has to be defined, e.g., based on an underlying CPG. As this information cannot be instantiated on the instance level, it is specified as a language level type. The constraint C01 ensures that in case of accelerated fractioning, i.e., a number of fractions with increasing single doses over time, at least two different fractions need to be specified. However, as each patient might receive different fractioning, the intrinsic concept PatientSpecificFraction has been introduced. The constraint C02 applies the same rule to PatientSpecificFraction as C01 to StandardFraction. Based on the patient-specific execution of RadioTherapy, the applied overallDose can be derived on the instance level.

The concept TumourResponseEvaluation serves to model periodically performed evaluation of the tumour’s response to the treatment. Two different classifications – WHO (for the origins see World Health Organisation, 1979, pp. 22-27; Miller et al., 1981) and RECIST (Response Evaluation Criteria In Solid Tumors, Eisenhauer et al., 2009; Nishino et al., 2010) – can be applied. Both distinguish four categories of tumour’s response: complete remission, partial response, stable disease, and progressive disease. Each TumourResponseEvaluation can use exactly one of the two mentioned frameworks, which is allowed to produce exactly one EvaluationResult on the instance level. The definition of the applied criteria differs with respect to partial response and stable disease regarding the percentage of tumour response. Therefore, the common abstraction TumourEvaluationFramework – as an abstract concept – has been conceptualised that allows to be specialised into the language level types WHO-Evaluation and RECIST-Evaluation. The constraint C03 ensures that only exactly one evaluation result can be ‘true’.

To support understandability and applicability of the DSML in different medical contexts, concepts should be related to one or more contexts they are relevant to. Concepts relevant particularly to the field of oncology are marked by a circle in the upper right corner of the concepts’ visualisation. Concepts without a circle are relevant for the medical field in general. Concepts being part of the MEMO OrgML have been marked by a quadratic icon to indicate their origin. This allows for identifying the extent of domain-specific extensions, and thereby the contribution of this paper.

The process types have been identified and conceptualised based on single and group interviews with experts as well as an extensive literature analysis, and with respect to R10, partly derived from the common oncologic record set1 (Arbeitsgemeinschaft Deutscher Tumorzentren, 2008; Klinkhammer-Schalke et al., 2014). This set names, e.g., the medical processes “medical oncology”, “radiotherapy”, “surgical therapy”, and data structures relevant to clinical cancer registry (CCR) and epidemiological cancer registry (ECR).

Fig. 2 shows the DSML’s meta model excerpt specifying additional concepts addressing requirements R3, R5, R6, R7, and R9. Concepts addressing R2 can be found in Heß, Schlieter, and Täger (2012, pp. 281-285). Due to space limitation, not only some concepts instead of listed attributes feature “...”, but also concepts addressing R10 cannot be presented here. Instead the reader is referred to the specification of the common oncologic record set (Klinkhammer-Schalke et al., 2014), which allowed for a detailed specification of data structures addressing R10. A discussion on selected concepts follows.

The language level types EvidenceClassificationSystem, LevelOfEvidence, and GradeOfRecommendation address R3. Due to the existence of numerous, varying evidence classification systems (Atkins et al., 2004) one or more LevelOfEvidence (LoE) originating from different sources can be assigned to any MedicalProcess – in contrast to, e.g., the specification provided by Burwitz, Schlieter, and Esswein (2013, p. 1333). Each LoE is supported by one GradeOfRecommendation.

According to the definition of CP, responsibilities for performing medical processes and for their results to be differentiated. It is assumed that at least one organisational unit (OrganisationalUnit) (Frank, 2011a) takes responsibility for one or more MedicalProcesses (R6).

A variable number of Checklists can be associated to any number of MedicalProcesses (R7). Each Checklist contains one to many ChecklistElements on the type level (M1). The intrinsic attributes is-

1 It specifies a set of paper documents (Arbeitsgemeinschaft Deutscher Tumorzentren, 2008) and an XML schema, both allowing for submitting patient- and case-specific information on the cancer disease to local or regional CCR as well as to regional and/or national ECR. The record set distinguishes between data relating to diagnosis, course, surgical therapy, radiotherapy, systemic therapy, closing data, and autopsy data, and includes different data items as specified by Klinkhammer-Schalke et al. (2014).
Completed and finallyNotExecuted allow to state at runtime, i.e., during the pathway-execution within a HIS, that the check/task has been completed or finally not executed in order to allow deriving the execution/completion status of the checklist. In case it is not executed within an instantiated MedicalProcess (M0 level), a JustificationStatement needs to be provided (see constraints C01 and C02 respectively). Furthermore, a Checklist may have to be extended with any number of PatientSpecificChecklistElements on the instance level, e.g., because of additional patient-specific characteristics. Here, the same applies regarding the evaluation of the checklist’s complete execution.

Allocation of medical resource types (R9) is possible due to the integration of an extension of MEMO OrgML providing the concept MedicalResource (Heß, 2014, pp. 91-93; Heß, Burwitz, and Schlieter, 2014, pp. 743-745), which for now is further specialised into the concepts MedicalProduct, Drug, and Aid. As the DSML4CPs is in fact extending the already existing MEMO OrgML with domain-specific concepts, it is also fully integrated with all other DSMLs being part of the MEMO method. This allows for reusing existing concepts from other DSMLs as well (e.g., from MetricM (Strecker et al., 2012)) and, whenever necessary, to design further domain-specific extensions to address additional requirements.

### 4.3 Language Specification: Concrete Syntax

Figure 3 shows the application of the DSML4CPs based on the example of the CP Diagnostics and therapeutic strategy for Soft Tissue Sarcoma (Schütte et al., 2007). This case has been modelled together with the West German Sarcoma Centre to evaluate the developed DSML using MEMO’s modelling tool MEMOCenterNG (Gulden and Frank, 2010) with a prototypical extension allowing to create models applying the DSML4CPs. Soft Tissue Sarcoma (STS) can be considered as a rare malignant tumour disease (1.5% of all malignant tumour diseases) with an incidence of 6 per 100,000 per year (Goldblum, Folpe, and Weiss, 2014, p. 1). The excerpt shows the situation starting with the tumour staging\(^2\) resulting

\(^2\) For detailed information on the staging of STS see Goldblum, Folpe, and Weiss (2014, pp. 3-9) and for more details on modelling the corresponding decision see Heß, Schlieter, and Täger (2012, pp. 285-286).

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Figure 2. Meta model excerpt: Additional concepts associated to the concept MedicalProcess
in either a low-grade sarcoma (upper branch) or a high-grade sarcoma (lower branch) being diagnosed. Patients with a low-grade sarcoma usually undergo a primary resection and, based on the pathological result, either proceed with a treatment-free follow-up or, depending on the resectability, either undergo a second resection, or undergo a radiotherapy. As high-grade sarcoma are not primarily resectable, a neoadjuvant, i.e., pre-surgical, therapeutic modality needs to be selected aiming at maximally reducing the tumour’s gross volume in order to reach a state that potentially allows for a later resection. Possible therapies are: chemotherapy and radiotherapy (solely or in sequence); isolated limb perfusion; and regional hyperthermia in combination with chemotherapy. As conducting a radiotherapy requires the definition of a TreatmentProtocol, the corresponding representation on the type level is given – its association to the process type is indicated by a dashed line –, including some reference values for a conventionally
fractioned radiotherapy. Subsequent to the neoadjuvant therapy, the tumour response is evaluated according to the WHO or RECIST criteria as well as its resectability, indicating either a resection or the definition of an individual treatment plan for the patient. Please note, that prior and subsequent elements of the CP are omitted for the sake of clarity and in-/outgoing control flow of the omitted concepts is coloured in grey.

The concrete syntax shown has been designed together with the domain experts and a professional graphics designer in order to ensure its intuitiveness. Corresponding guidelines provided by, e.g., Moody (2009) have been considered in the design process (for more details see Heß et al., 2014).

4.4 Preliminary Evaluation of Resulting Artefact

Following the iterative and dialogical design research process, the domain experts have been involved in the requirements elicitation, language specification and exemplary language application phases. Thus, a number of experienced senior physicians and medical specialists, from the fields of surgical oncology, medical oncology, radio oncology, and pathology, working at the West German Sarcoma Centre, were periodically interviewed. Their feedback on the partial artefacts was considered for the needs of their iterative refinement, both when it comes to the modelling concepts as well as the graphical notation. Although the core concepts for modelling medical processes have been identified rather easily, the identification of corresponding attributes was not trivial. Attributes allow to represent more detailed information on the process types. Therefore, specific information needs that should be accounted for in CP models (on the type and the instance level), with respect to the identified scenarios, needed to be identified for each concept specified in the meta model. As, aside from the DSML's expressiveness, the graphical representation is a key success factor of the understandability of process models (e.g., Figl, Mendling, and Strembeck, 2013; Reijers and Mendling, 2011), special emphasis was put on the iterative evaluation and refinement of the concrete syntax. A first draft of notation was designed and presented to the domain experts from West German Sarcoma Centre, which led to numerous refinements of the draft by a professional graphics designer in order to increase the congruency of the notation with domain-specific graphical artefacts present in the physicians’ workaday life in order to achieve a more intuitive graphical representation of modelling concepts. The results provided by the graphics designer again have been evaluated by the domain experts and were refined until no more changes were requested.

In the final phase of the language design, during the conducted interviews, the domain experts have confirmed that the proposed language is able to raise transparency and foster communication between all involved parties and that it might contribute to future initiatives in re-designing hospitals’ action and IS.

Finally, evaluation of the DSML4CPs against the identified requirements confirmed their fulfillment.

5 Conclusions and Outlook on Future Research

In order to realise the potential benefits of application of CPs in hospitals, a modelling language suited to the characteristics of CPs, their potential applications as well as peculiarities of hospitals and their action system and information system should be available. In this paper, we have shown the design and exemplary application of the DSML4CPs, which reconstructs the professional terminology from the medical domain with a special focus on oncology. The DSML is integral part of the targeted MPHM.

Our next research activities encompass further development of the designed DSML towards other fields of medicine as well as continuative evaluation of the DSML regarding its intuitiveness and the domain coverage (Frank, 2013, p. 154). The evaluation will be, e.g., based on the application scenarios and laboratory/field experiments with domain experts and/or prospective users, as they are familiar with the linguistic concepts being reconstructed in the DSML (Frank, 2013, p. 154). Kahraman and Bilgen (2013, pp. 4-7) propose a set of criteria to evaluate domain-specific programming languages that might be used – adjusted to the needs of a DSML – to evaluate DSMLs: functionality, usability, expressiveness, and productivity as well as maintainability, extensibility, reusability and integrability. Furthermore, other DSMLs that are to be part of the Multi-Perspective Hospital Modelling method are to be designed.
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