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Guideline-Based Context-Sensitive Decision Modeling for Melanoma Patients

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Abstract. Introduction: The provision of knowledge through clinical practice guidelines and hospital-specific standard operating procedures (SOPs) is ubiquitous in the medical context and in the treatment of melanoma patients. However, these knowledge sources are only available in unstructured text form and without any contextual link to real patient data. The aim of our project is to give a modeled decision support for the next treatment step based on the actual data and position of a patient. **Methods:** First, we identified passages for qualified decision-making necessary at the point of care from the SOP for melanoma. Thereby, the patient-specific contextual reference data at decision points was considered in parallel and represented by FHIR (Fast Healthcare Interoperability Resource) resources. The decision algorithm was then formalized using BPMN modeling with FHIR annotations. Validation was provided by medical experts, dermatooncologists from University Hospital Essen. **Results:** The resulting BPMN model is presented here with the diagnostic procedure of sentinel lymph node excision as the example snippet from the whole algorithm. Each decision point is edited with FHIR resources covering the patient data and preparing the context sensitivity of the model. **Conclusion:** Modeling guideline-based information into a decision algorithm that can be presented at the point of care with contextual reference, may have the potential to support patient-specific clinical decision-making. For patients from a certain status like in the metastatic setting modeling becomes highly tailored to specific patient cases, alternative and individualized treatment options.

Keywords. Clinical Practice Guideline, Clinical Pathway, Clinical Decision-Making, BPMN, Patient-Specific Modeling, Malignant Melanoma

1. Introduction

Clinical practice guidelines (e.g., the national S3 guideline on the diagnosis, treatment, and follow-up of melanoma [1]) and hospital-specific SOPs (e.g., the hospital-specific document *SOP Malignes Melanom*[2] [Malignant Melanoma] of the Department of Dermatology of the University Hospital Essen) generally provide useful knowledge for

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[2] Livingstone E, Zimmer L, Schadendorf D. SOP Malignes Melanom. 2020 Apr. ID: 11365. Unpublished, internal hospital document.

evidence-based care and are used alongside clinical pathways to bring this knowledge into clinical practice. By incorporating all elements of systematic reviews and meta-analyses, S3 guidelines provide the guidelines with the highest evidence base and the highest methodological quality in the medical field [2]. Many guidelines provide treatment recommendations over the entire course of a disease, and SOPs contain the AWMF S3 guideline shortened to the essential treatment steps and provide step-by-step instructions [3] for hospital-specific treatment processes. For this work, we used the document *SOP Malignes Melanom*[2], a shortened version of the *national S3 guideline on the diagnosis, treatment, and follow-up of melanoma* adapted to hospital-specific processes and longer in content than usual SOPs.

To bring evidence-based knowledge into clinical practice, related works map guidelines into FHIR: The EBMonFHIR project extends FHIR to evidence-based medical data and aims to create interoperability for clinical research and clinical care recommendations [4] and the FHIR Clinical Guidelines Implementation Guide (CPG-IG) codifies clinical guidelines to provide evidence-based and best practice recommendations at the point of care [5]. While both works demonstrate how guideline information can be mapped into FHIR and brought to the point of care, they currently do not consider the contextual link between guidelines and SOPs as knowledge sources and the specific patient and physician user. Proper utilization of this knowledge is elaborate and costly as identifying appropriate guideline- or SOP-based information linked to a specific patient context requires a time-consuming search by physicians [6]. Reasons for this are the unstructured information base and missing links of existing modeling and mapping procedures for guidelines to a specific patient or user context from the clinical perspective.

Therefore, this work aims to enhance modeling in a way that the clinical context as well as the available data of a specific patient are considered and used automatically in a later step to give context-sensitive decision support. Specifically, we establish the contextual link between information from the SOP document and actual patient data so that the history and medical status can be identified automatically. This data is provided by the "Smart Hospital Information Platform" (SHIP)[3] of the University Medicine Essen, which was set up for research purposes and contains all clinical information transferred into FHIR format. For the SHIP data, the following clinical information systems serve as sources: Hospital Information System (HIS), Radiological Information System (RIS), three Picture Archiving and Communication Systems (PACS), Patient-Recorded Outcomes (PRO), Laboratory Information System (LIS) and Pathology Information System (ISP).

We selected malignant melanoma, the most dangerous and aggressive skin tumor due to its propensity for metastatic spread [8], as the medical model. The presentation of the modeling here focusses on a snippet of the whole algorithm – the pathway for the sentinel lymph node excision (SLNE) diagnostic procedure as sentinel lymph node status is one of the most important prognostic factors in early-stage melanoma [8][9]. SLNE is initially recommended for all patients with any of the following: tumor thickness between 0.75 mm and 1 mm and present risk factors as ulceration, mitotic rate >=1 mitosis and patient age < 40 years, tumor thickness greater than 1 mm and no ulceration present, tumor thickness greater than 1 mm to 4 mm and ulceration present, or tumor thickness greater than 4 mm and ulceration present. Therefore, the indication for or against a SLNE is relevant for a large proportion of melanoma patients.

[3] SHIP: see [7, p. 294]

The whole clinical algorithm contains 53 different decision points, 7 of which are presented in the SLNE section.

2. Methods

To visualize and harmonize the knowledge from the hospital-specific document *SOP Malignes Melanom* as a graphical workflow, we first manually identified the passages necessary for qualified decision-making in the document. For correct identification of medical knowledge, but also for the purpose of iterative inclusion of physician-specific context, the identification step was accompanied and validated by a dermatooncologist of the University Hospital Essen. To ensure that the identified information reflected the level of experience of physicians of all experience levels, but initially of junior physician, the information identification process was initially performed in a very small-step manner in collaboration with a junior physician and checked for medical correctness. The information modules classified as relevant were marked as such directly in the corresponding knowledge source.

For the marked information modules we then additionally identified necessary FHIR (Fast Healthcare Interoperability Resources)[4] resources representing patient data needed for decisions. Thereby the contextual link between the SOP document containing guideline-based knowledge and real patient data was established.

Final modeling was performed with Business Process Model And Notation (BPMN)[5] modeling elements using the open-source modeling tool Camunda Modeler[6]. The modeling was validated by two dermatooncologists of different qualifications (one senior physician, one junior physician); initially iteratively by the junior physician and after the first modeling draft was created by the senior physician. The context reference at decision points was realized via data storage elements. The element names refer to FHIR resources within SHIP.

Figure 1 illustrates the described procedure summarized in graphical form.

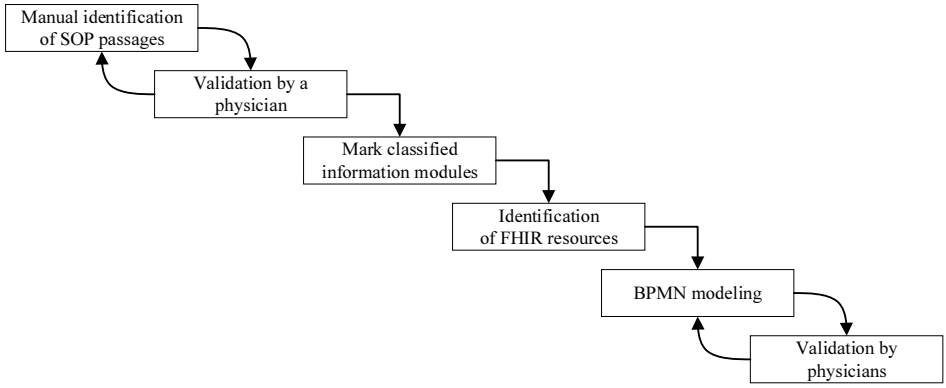


Figure 1. Graphical representation of the procedure

[4] FHIR standard: https://www.hl7.org/fhir/ (18.02.2022)

[5] BPMN platform: https://www.omg.org/spec/BPMN/2.0/ (18.02.2022)

[6] Camunda Modeler platform: https://camunda.com/de/platform/modeler/ (20.04.2022)

3. Results

Compared with the overall modeling of the entire melanoma treatment, the SLNE section presented as an example in this article represents only a small part of the overall modeling. To quantify the dimension of the overall modeling versus the SLNE excerpt, we compared the number of selected modeling elements utilized in the excerpt to the entire modeling below: The greatest consistency in modeling elements was found in tasks (n=17 of 125; 14%), followed by subprocesses (n=2 of 17; 12%), exclusive gateways (n=13 of 105; 12%), and parallel gateways (n=2 of 40; 5%). This exemplary comparison of selected modeling elements gives an idea of the scope and power of the entire modeled information base *SOP Malignes Melanom*.

The resulting manual extraction of the information modules from the hospital-specific document *SOP Malignes Melanom* is exemplified in Figure 2 using the indication of the diagnostic procedure SLNE.

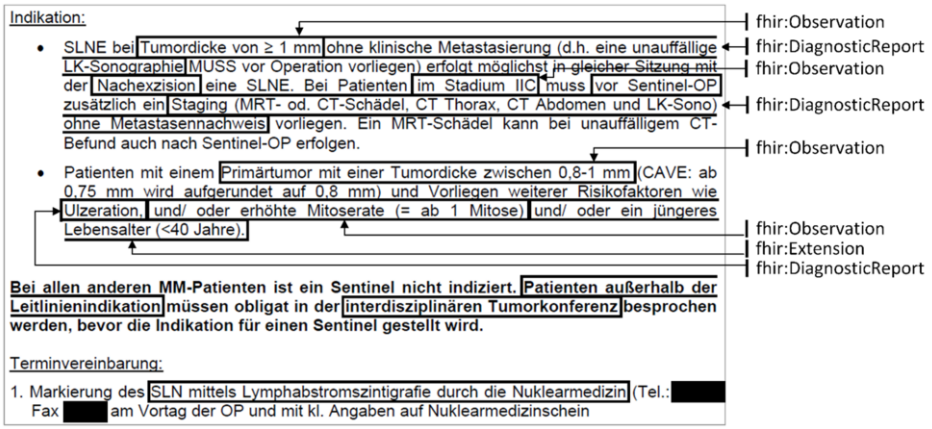
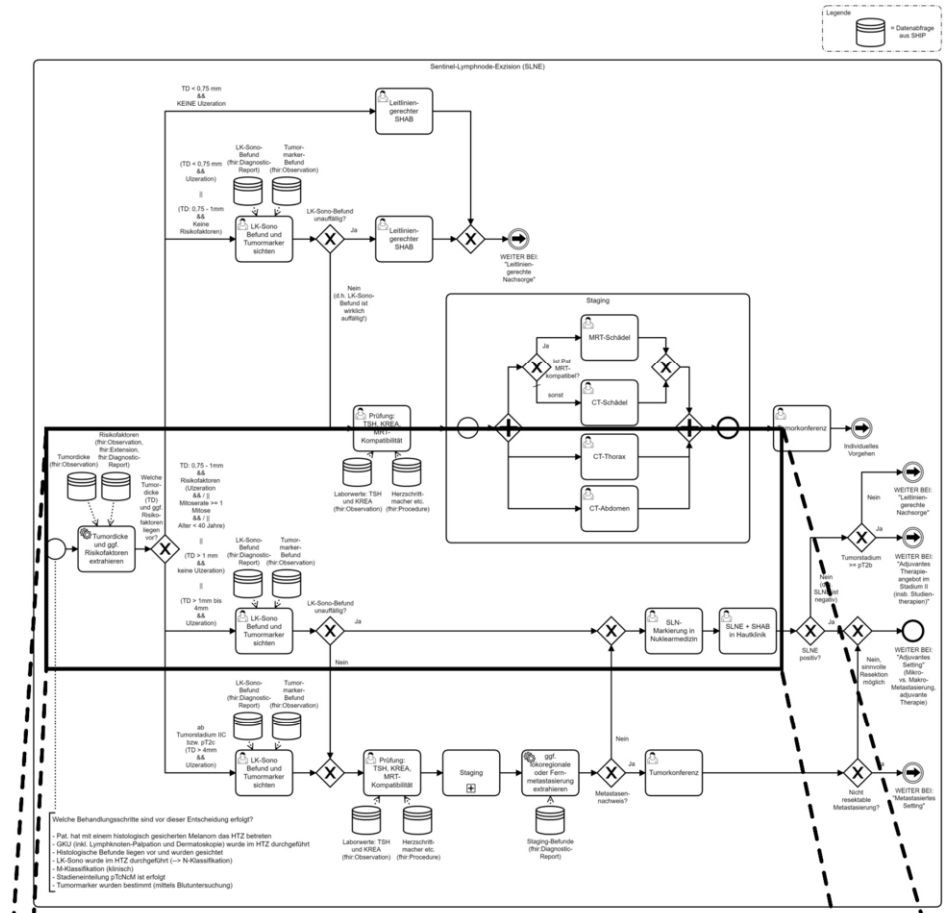
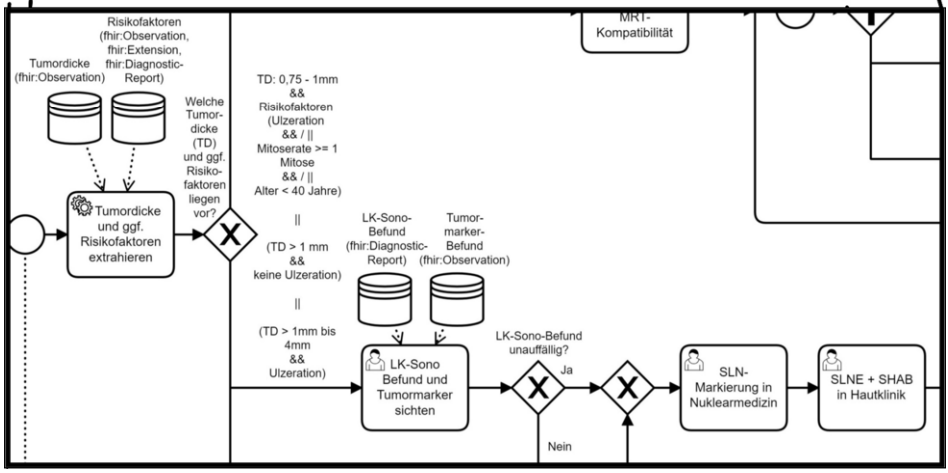


Figure 2. Annotated screenshot of a section of the chapter "Sentinel-Lymphnode-Exzision (SLNE)" from the document *SOP Malignes Melanom*[2] *[Malignant Melanoma]* (see [2], p. 14).

The manual extraction provides the classified content of the information base according to their data relevance. The relevant passages were framed and the corresponding FHIR resource was noted simultaneously in the information base. For example, the patient's tumor thickness [Tumordicke] is stored in the FHIR resource Observation.



(a) Entire section discussing a SLNE investigation.



(b) Main Pathway in which the SLNE is carried out (see User Task "SLNE + SHAB in Hautklinik").

Figure 3. BPMN representation of the SLNE section.

Figure 3 shows the SLNE subprocess as BPMN modeling. To understand the temporal treatment flow of the modeling, we added the process steps that temporally precede this modeling excerpt (the SLNE) as an annotation to the start state. Depending on the tumor thickness of the patient's primary tumor and the risk factors, SLNE is then performed or not. For a patient with a tumor thickness greater 1.0 mm, no ulceration and inconspicuous lymph node sonography findings (see first two identified information modules in Figure 2), the BPMN modeling indicates that SLNE will be performed (see User Task "SLNE + SHAB in Hautklinik" in Figure 3). The contextual reference prepared in Figure 2 by sideways annotations, i.e., the links between the knowledge of the information base and the real patient data, was represented in the modeling by data storage elements with the label *[data needed for the next decision-making] (fhir:[FHIR Resource])*. These FHIR resources are employed to generate context-sensitive decision recommendations based on the query data when the modelled algorithm is passed later.

Extraction and modeling of all information modules, including parallel contextual reference to real patient data using FHIR resources, was performed for the complete information base *SOP Malignes Melanom* in the same manner as shown for SLNE.

4. Discussion

In this work, we presented BPMN modeling for evidence-based medicine with integrated contextual reference to real patient data annotated in FHIR. The modeling excerpt presented will be useful for the treatment of roughly 155 patient cases per year of the Department of Dermatology of the University Hospital Essen. These patient cases are divided into approximately 125 patient cases per year with an indication for SLNE, for which this modeling can be utilized, and approximately 30 patient cases who only require a wide margin excision, and for whom the modeling indicates that they do not require a SLNE.

The transfer of the classified information modules to BPMN modeling shows, using the SLNE as an example, that modeling as a decision algorithm has limited value beyond a specific degree of detail. Above this level, modeling becomes in this case highly tailored to specific patient cases and alternative treatment options due to more and more individualized and specific oncological treatment options. In the modeling extract, this is exemplified to patients with tumor thickness less than 0.75 mm and ulceration present, or patients with tumor thickness between 0.75 and 1 mm without risk factors, each with conspicuous lymph node sonography findings (see event "individuelles Vorgehen" [individual approach] in Figure 3). For patients in the metastatic setting, this limited value occurs significantly more frequently. Therefore, we focused on the main treatment performed as defined in the hospital-specific SOP document rather than each optional treatment alternative. To double-check which optional treatment suggestions described in the SOP document, we consulted the S3 guideline.

The contextual reference between the information base and real patient data was established using FHIR resources to provide FHIR-oriented data access at the decision points in the further project. Compared to related projects mapping guidelines to FHIR, this contextual link to real patient has not yet been established (see [4][5]). For data that is so far not described in standard FHIR resources, extensions will be used. In addition,

for FHIR-oriented data access, quality, readiness, and completeness of SHIP data is essential to use it in its entirety. This verification is currently being carried out in a parallel work.

Although the modeling presented may offer advantages such as the accurate representation of information at the point of care, its form needs to be evaluated subsequently. It remains to be investigated whether pure modeling of treatment steps supports physicians in decision-making during melanoma treatment or whether additional – possibly textual – information is needed. The additional information would then also be incorporated into the modeling.

5. Conclusion

By providing physicians with the information needed for the subsequent treatment steps in a clear, standardized, and guideline-compliant way, as well as considering the contextual reference to the individual patient, we intend to make a significant contribution to rapid and patient-specific medical decision-making for melanoma patients in the clinical setting, for which this work represents the first step through its context-sensitive decision modeling.

The modeling presented illustrates a modeling approach to potentially better present contextual guideline information for the treatment of malignant melanoma at the point of care, specifically for the indication for or against a SLNE, and to better embed guideline information into the patient workflow. Using the Guide2Treat[7] software, the information could thus be queried context-sensitively from the modeling in later project phases.

The modeling created based on an unstructured information source, which was presented as an example using the SLNE subprocess, shows the current state of modeling initially represents only the preliminary work for a clinical decision support system (CDSS). In a further step, we will integrate this model into everyday clinical practice. Thereby, we are aware that precautions, such as criteria for qualification as a medical device or as medical device software, must be taken in the general application of CDSS in clinical routine; however, we will work retrospectively as part of this research. We will investigate whether the modeling developed in theory needs to be modified for its use in everyday practice and at which points in the modeling there are deviations between theory and clinical practice. The next steps are to simulate the approximately 2,000 data sets from SHIP and verify the modeling against those data sets.

[7] Guide2Treat software: https://ieee-dataport.org/documents/guide2treat-software (23.02.2022)

Declarations

Ethical vote: Ethik-Kommission der Medizinischen Fakultät der Universität Duisburg-Essen, Prof. Dr. U. Schara-Schmidt, 21-10391-BO, 02.12.2021

Conflict of Interest: The authors declare, that there is no conflict of interest.

Author contributions:
CB, BB: conception of the work, data aquisition and interpretation;
CB, GL: study design, data analysis and interpretation;
GL, EL, DS: monitoring and validation of the information identification process and the BPMN modeling;
CB: writing the manuscript;
BB, EL: substantial revising of the manuscript.
All authors approved the manuscript in the submitted version and take responsibility for the scientific integrity of the work.

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References

[1] Leitlinienprogramm Onkologie (Deutsche Krebsgesellschaft, Deutsche Krebshilfe, AWMF). Diagnostik, Therapie und Nachsorge des Melanoms. Langversion 3.3. 2020 Jul. AWMF Registernummer: 032/024OL. http://www.leitlinienprogramm-onkologie.de/leitlinien/melanom/ http://www.leitlinienprogramm-onkologie.de/leitlinien/melanom/ (accessed February 15, 2022).
[2] AWMF Leitlinien. Available at: https://www.awmf.org/leitlinien.html (accessed 25 February 2022).
[3] Lödel S, Ostgathe C, Heckel M, et al. Standard Operating Procedures (SOPs) for Palliative Care in German Comprehensive Cancer Centers - an evaluation of the implementation status. BMC palliative care. 2020 May; 19(1): 62. doi: 10.1186/s12904-020-00565-6.
[4] EBMonFHIR. HL7 Confluence Page. https://confluence.hl7.org/display/CDS/EBMonFHIR (accessed May 04, 2022).
[5] FHIR Clinical Guidelines. http://hl7.org/fhir/uv/cpg/ (accessed May 04, 2022).
[6] Becker M, Kasper S, Böckmann B, Jöckel KH, Virchow I. Natural language processing of German clinical colorectal cancer notes for guideline-based treatment evaluation. Int J Med Inform. 2019 Jul; 127:141-146. doi: 10.1016/j.ijmedinf.2019.04.022.
[7] Tewes R. Mutige Zukunft der Personalentwicklung im Gesundheitswesen. Innovative Personalentwicklung im In- und Ausland. Springer, Berlin, Heidelberg. 2021 Nov; 285-335. doi: 10.1007/978-3-662-62977-2.
[8] Gershenwald JE, Scolyer RA, Hess KR, Sondak VK, Long GV, Ross MI, Lazar AJ, Faries MB, Kirkwood JM, McArthur GA, Haydu LE, Eggermont AMM, Flaherty KT, Balch CM, Thompson JF; for members of the American Joint Committee on Cancer Melanoma Expert Panel and the International Melanoma Database and Discovery Platform. Melanoma staging: Evidence-based changes in the American Joint Committee on Cancer eighth edition cancer staging manual. CA Cancer J Clin. 2017 Nov; 67(6):472-492. doi: 10.3322/caac.21409.
[9] Mays MP, Martin RC, Burton A, Ginter B, Edwards MJ, Reintgen DS, Ross MI, Urist MM, Stromberg AJ, McMasters KM, Scoggins CR. Should all patients with melanoma between 1 and 2 mm Breslow thickness undergo sentinel lymph node biopsy? Cancer. 2010 Mar 15; 116(6):1535-44. doi: 10.1002/cncr.24895.