Evaluating a CDS Hook for FHIR Questionnaires in a SMART on FHIR App and an Existing Dermatological CDS System

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Abstract. Background: To deploy clinical decision support (CDS) systems in routine patient care they have to be certified as a medical device. The European Medical Device Regulation explicitly asks for the use of standards and interoperability in the approval process. Objectives: We extended an existing dermatological CDS system with emerging standards for CDS interoperability, to facilitate a future integration into existing healthcare infrastructure, and approval as a medical device. Methods: The data collection part of a CDS system was extended with the endpoints required by the CDS Hooks specification. FHIR *QuestionnaireResponse* resources trigger a newly defined hook. Results: One hundred and seventeen clinical observations and patient variables needed for the ranking of a disease were mapped to SNOMED CT or LOINC and modeled as FHIR *Questionnaire* which is rendered using LHC LForms in a SMART on FHIR app with the SMART Dev Sandbox. Conclusion: SMART on FHIR in combination with CDS Hooks facilitates the integration of existing CDS systems into EHR systems, potentially improving education and patient care.

Keywords. clinical decision support system, Health Level Seven, FHIR, SMART on FHIR, CDS Hooks

1.   Introduction

In order to use clinical decision support (CDS) systems in routine patient care, they must be certified as a medical device as regulated in the European Medical Devices Regulation (MDR). Beside many other requirements, the MDR explicitly requires the use of standards and interoperability in the approval process. From a medical informatics perspective these regulatory requirements with respect to interoperability and current standards are of great interest. Looking at current publications, the emerging standards for CDS interoperability are the HL7® Fast Healthcare Interoperability Resources (FHIR®) standard [1], the HL7 CDS Hooks standard [2] as well as Substitutable Medical Applications and Reusable Technologies (SMART) on FHIR apps standard [3]. FHIR is a standard to exchange health data in a semantically interoperable way, SMART relies

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on FHIR to develop apps once and run them in any health care system and CDS Hooks is a specification for CDS systems. In [4] Bradshaw et al. present a system based on CDS Hooks and FHIR to identify population health management cohorts. Watkins and Eilbeck implemented CDS Hooks into a FHIR lab report system as a SMART on FHIR app with different response cards for each test [5]. Oosterhoff et al. propose to integrate predictive algorithms into clinical care based on SMART on FHIR and CDS Hooks [6]. CDS Hooks are also evaluated for the Arden Syntax in [7] by De Bruine et al.

DermTrainer is an algorithm for ranking appropriate dermatologic differential diagnoses based on clinical observations and patient variables [8]. Its goal is to collect responses for easy-to-answer atomic elements, collate them to a full virtual dermatologic examination, and provide reasonable feedback based on Bayesian-type search through a knowledge database. The usability of the algorithm was recently evaluated using patient vignettes [9] via a web-based interface[2] (see Figure 1 on the left). While harboring the theoretical potential for clinical application, the tool is currently used in teaching and an educational context. In order to comply with the MDR, various legal and technical requirements would still have to be fulfilled for the tool to be used in routine care.

In order to facilitate a future integration into existing healthcare infrastructure, and a future medical device certification, we propose a generic Hook triggered by entries into a questionnaire and extended the existing dermatological CDS system DermTrainer with standardized interfaces based on the CDS interoperability standards FHIR, CDS Hooks and SMART on FHIR.

2.   Methods

We designed a draft hook for the CDS Hooks specification to be triggered based on questionnaire responses and extended an existing dermatological CDS service to comply with the CDS Hooks specification. The service is triggered by an update in a FHIR *Questionnaire* in an EHR system. When evoked, the service analyzes the FHIR *QuestionnaireResponse* resource and returns fitting dermatological diseases based on the CDS algorithm back to the data enterer as a CDS Hook card.

All services are locally deployed and tested in separate Docker containers. The existing PHP backend of the DermTrainer algorithm was extended to be used as a CDS service to evaluate the system. HL7 FHIR Release 4 was used to model the FHIR resources. The SMART Dev Sandbox[3] with the FHIR R4 Server was used to persist the created FHIR resources and sample data. LHC LForms v30[4] was used to generate functional web-forms from FHIR *Questionnaire* resources. The SMART on FHIR JavaScript Library v2.5.0[5] was used to enable the needed SMART API functionality and enable basic FHIR CRUD operations. The static HTML pages were served with a basic web server. LOINC and SNOMED CT were used to code all clinical observations and patient variables needed for the ranking of a disease. All FHIR resources were validated with the HL7 FHIR validator.

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[2] https://www.dermtrainer.com

[3] https://github.com/smart-on-fhir/smart-dev-sandbox

[4] https://github.com/lhncbc/lforms

[5] https://github.com/smart-on-fhir/client-js

3. Results

A draft version for a hook triggered whenever a user is in the progress of answering a questionnaire was submitted to the CDS Hooks specification. To comply with the CDS Hooks API specification, a general endpoint to retrieve available services as well as the endpoint that implements the CDS Hook for FHIR *QuestionnaireResponse* resources were added to the CDS system. The *QuestionnaireResponse* fields are internally mapped to the existing CDS algorithm query fields and the internal response of the CDS system is converted into a CDS Hook information card as required by the CDS Hooks specification. As seen in Figure 1 on the left, the original CDS system is accessed via a web-based form. To improve usability, the one hundred and seventeen items were grouped into different tabs and various icons were added to add visual cues of the disease features and to better represent their meanings. This existing structure of the form was used as a blueprint to model a FHIR *Questionnaire* resource. We used additional extensions from the FHIR structured data capture implementation guide (i.e. US realm implementation guides) to map the internal logic and grouping of the form (i.e. enabledWhen, groups, repeats etc.). To further increase the interoperability of the created form, for all fields relevant for the ranking of a disease, LOINC and SNOMED CT codes were searched. SNOMED CT and LOINC codes are in addition factors to facilitate a future quality assurance. Since no official german translation of SNOMED CT exists, own translations were made by a board certified dermatologist (author PT). For some combined fields the code for the more general concept had to be selected. The finished FHIR *Questionnaire* resource was validated and uploaded to a FHIR server. Except for the missing official German translations, all FHIR resources were successfully validated. Due to resource constraints, no interobserver agreement study on code selection was conducted with additional physicians, which could be helpful to improve usability and avoid human interaction problems in the future.
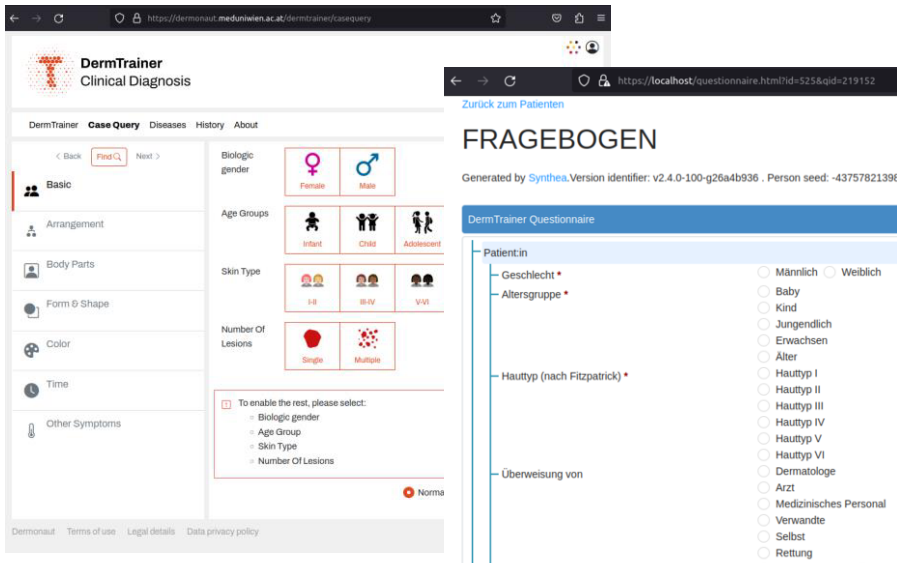

Figure 1: The original DermTrainer questionnaire web-form on the left compared to the automatically generated web-form based on the FHIR *Questionnaire* resource on the right.

The LHC FHIR Tools were used to generate a web-based questionnaire from the FHIR *Questionnaires* resource as seen in Figure 1 on the right. This is a generic representation of the resource and we did not extend the FHIR *Questionnaires* to incorporate for example the individual icons for the fields. The basic form logic and groupings are supported out of the box in the LHC FHIR tools. The LHC FHIR tools also allows data entry resulting in a FHIR *QuestionnaireResponse* resource. We successfully validated the *QuestionnaireResponse*.

To test the practicability of our approach we created a SMART on FHIR app using the SMART on FHIR JavaScript Library in combination with proprietary JavaScript in static HTML pages. The app allows to authenticate the user based on the SMART on FHIR standard, to retrieve the FHIR *Questionnaire*, to render the FHIR *Questionnaire* using the LHC FHIR tools, to store *QuestionnaireResponse* resources on the FHIR server as well as to load and pre-fill the forms with existing *QuestionnaireResponse* resources from the FHIR server.

The entry point for the SMART on FHIR app is the *launch_smart.html* where the server url, the client id, the redirect url (i.e. patient.html) as well as the authorization scopes (e.g. patient/patient.read, patient/Questionnaire.cruds, patient/QuestionnaireResponse.cruds) are defined and the SMART patient browser is loaded. Once a patient is selected in the SMART patient browser the user is redirected to the *patient.html* page showing all available questionnaires and already documented questionnaires for the specified patient on the FHIR server. Once a questionnaire or a questionnaire response is selected the *questionnaire.html* with the rendered empty or pre-filled questionnaire is presented. After each 'click' on the form the CDS Hook is triggered with the current *QuestionnaireResponse and* the results from the cards are displayed as a notification in the top right corner. Once the questionnaire is submitted and basic form validation is satisfied the *QuestionnaireResponse* is stored on the FHIR server.

4.   Discussion

The main focus of this study are the technical aspects involved with using CDS Hooks. Many other standards for CDS systems exist, have been used as medical devices and are viable alternatives to the approach presented here. For a future integration into an existing healthcare infrastructure this is only one of many aspects to be approved as a medical device. Aspects not covered include beside other things quality and risk management, quality assurance, usability testing, system evaluation to just name a few.

Currently the CDS Hooks specification only defines six official hooks to trigger a CDS service (e.g. patient_view, appointment-book, encounter-discharge, encounter-start, order-select, order-sign.). For our use case we specified and implemented an additional hook called *questionnaire-inprogress* which is to be invoked whenever a user is in the process of answering a questionnaire. FHIR *QuestionnaireResponse* resources communicate data originating from forms in medical history examinations or full clinical records where the exact phrasing of the question is important. This is in contrast to FHIR *Observation* where the meaning of the answer is the main focus and should be mainly used for actual observations like lab measurements or vital signs. We think *QuestionnaireResponse* resources are an important input for future CDS systems and this kind of hook is needed as part of the CDS Hook specification. We did propose to include

our Hook via a pull request in the official CDS Hook GitHub repository and cross-posted it to Zulip.

The adaptation to the CDS service to comply with the CDS Hooks specification was minimal and straightforward. The most challenging part was mapping the existing fields to SNOMED CT and LOINC. We did not implement the authentication of trusted CDS clients and do not filter depending on the id of the FHIR *Questionnaire* to support different questionnaires yet. On the client side we tried to keep the SMART on FHIR app as simple as possible by only using the JavaScript dependencies mentioned earlier and vanilla JavaScript served via four static HTML pages. Including all the rendering of the forms the most complicated HTML page has only some 260 lines of code. The SMART Dev Sandbox significantly facilitated the development.

FHIR, SMART on FHIR and CDS Hooks are promising standards to facilitate the integration of CDS systems into EHR systems. Major EHR vendors already support SMART on FHIR in their products, making it easier for cutting edge research to be deployed and integrated into routine care. CDS Hooks and FHIR resources allow the specification of clear API endpoints and API content. The presented approach using questionnaires is sufficiently general to be also applied in settings other than dermatology. Only time will tell whether the specification is also suitable for more complex CDS use cases.

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