EHE Clinical Decision Support System

Commercial Description

Version 5.1

1 Introduction

Electronic Healthcare Exchange (EHE) is a line of products fulfilling a variety of eHealth system needs, ranging from fundamental ones like infrastructure, security, and integration, over exchange and management of clinical documents and discrete medical information, to advanced functionalities like clinical decision support. Solutions made of different EHE products, alone or through integration with the existing infrastructure, support a wide range of processes in a healthcare system.

The EHE Clinical Decision Support System is a generic system for managing, storing, and retrieving clinical and healthcare information required when making decisions about the type and the way of providing healthcare to patients. It is based on the HL7 FHIR standard [1]and the HL7 CDS Hooks specification [8]. The product combines clinical knowledge with clinical information from the patients' health records and based on this, provides health professionals with the information necessary to choose the most effective and efficient personalized health care for patients.

The EHE Clinical Decision Support System aids healthcare professionals in making the correct diagnosis and providing successful and efficient medical treatment, and prevention by providing information on:

- recommended diagnostic procedures in order to efficiently and accurately determine the patient's health condition
- recommended therapeutic procedures, medications and other medical procedures for treatment of certain identified health conditions
- screening and prevention programs in which the patient should be included, and for the purpose of preventing potential health conditions.

The specified clinical information and recommendations (clinical knowledge) and the rules and conditions for selecting the necessary clinical knowledge are stored in clinical knowledge databases which are accessed through application interfaces based on the HL7 CDS Hooks specification [2].

The EHE Clinical Decision Support System includes the following:

- clinical knowledge database
- clinical decision support system management application
- evaluation and execution of clinical knowledge artifacts module
- client component for displaying clinical knowledge
- clinical knowledge data analytics.

1.1 Clinical Knowledge Database

The clinical knowledge database is a data bank within the Clinical Decision Support System that enables the storage of clinical knowledge databases and associated clinical knowledge artifacts, groups of clinical knowledge elements and clinical knowledge elements, and libraries of functions for evaluating and

executing clinical knowledge elements in accordance with the specification of the Clinical Reasoning module of the standard HL7 FHIR.

According to the given specification, clinical knowledge databases consist of clinical knowledge artifacts, groups of clinical knowledge elements, clinical knowledge elements, clinical activities and conditions for their selection. A clinical knowledge artifact is the highest level of clinical knowledge and consists of a set of clinical information necessary for the diagnosis and treatment of certain patient conditions or the prevention of these conditions. An example of a clinical knowledge artifact in the case of the Clinical Protocols service is a health problem (diagnosis). Clinical knowledge artifact consists of groups of elements and elements of clinical knowledge. Groups of knowledge elements are used to group clinical knowledge within the artifact and to define additional rules and detailing conditions. An example of a group of elements of clinical knowledge is, for example, the differentiation of patients by age group within the Clinical Protocol for the purpose of different treatment of patients depending on age. The element of clinical knowledge is a set of information and clinical activities that are recommended to the healthcare professional as an aid in the prevention, diagnosis and treatment of health problems and patients' conditions.

The conditions for the selection of artifacts, and then groups of elements, and finally the elements of clinical knowledge, define the applicability of a certain artifact or element based on medical and administrative data about a patient. The component enables the definition of evaluation rules for the selection of artifacts and elements of clinical knowledge based on the Clinical Quality Language [9].

1.2 Clinical Decision Support Management Application (CDS Management)

The Clinical Decision Support Management Application enables the management of services, clinical knowledge databases and associated clinical knowledge using a graphical user interface.

Service Management

The Service Management component of the Clinical Decision Support System enables system administrators to register and manage clinical decision support service data:

- registration of clinical decision support service
- service data management in clinical decision-making
- deactivation of the clinical decision support service.

As a part of the registration and management of clinical decision support services, the following functions are enabled:

- management of basic service data

defining the clinical knowledge database that is used to implement the clinical decision support service; the service can use an internal clinical knowledge

database (a database stored in the clinical knowledge database of the clinical decision support system) or an external clinical knowledge database (the prerequisite for using external clinical knowledge databases is that they have implemented access to the database data in accordance with the CDS Hooks specification)

Clinical Knowledge Database Management

The function of managing internal clinical knowledge databases enables specialists in the field of clinical knowledge to create clinical knowledge databases and associated artifacts, groups of elements and elements of clinical knowledge in the clinical knowledge database of the clinical decision support system using a graphical user interface.

The function of managing internal clinical knowledge databases includes the following:

- creating a new database
- creating a new version of the database and restoration of basic data
- logical deletion (deactivation of the clinical knowledge database).

As a part of creating a new clinical knowledge base or a new version of the clinical knowledge base, the following functions for managing clinical knowledge artifacts are enabled:

- creating a new artefact of clinical knowledge in a database
- renewing clinical knowledge artefact data in the database
- deleting clinical knowledge artifacts from the database.

As a part of creating a new artifact or creating a new version of a clinical knowledge artifact, the following functions are enabled:

- managing the conditions for selecting an artifact
- basic artifact data managing
- managing groups of clinical knowledge elements
- clinical knowledge elements managing.

As a part of managing the rules for the selection of clinical knowledge artifacts, the following functions are enabled:

- selecting CQL library with rule definitions for selecting artifacts
- modifying the CQL library with definitions of rules for artifact selection
- selecting the rules for calculating conditions for picking artifacts from the CQL library
- modifying rules for calculating the conditions for selecting an artifact from the CQL library.

As a part of managing of groups of elements of clinical knowledge, the following functions are enabled:

- managing the conditions for selecting a group of clinical knowledge
- managing the basic data of the clinical knowledge group
- managing subgroups of elements of clinical knowledge
- managing elements of clinical knowledge.

As a part of managing conditions for selecting a group of clinical knowledge elements, the same functions are enabled as in the management of conditions for the selection of clinical knowledge artifacts.

As a part of managing subgroups of elements of clinical knowledge, the same functions are enabled as in the management of groups of elements of clinical knowledge.

As a part of managing elements of clinical knowledge, the following functions are enabled:

- adding a new element of clinical knowledge to a group/subgroup of elements of clinical knowledge or an artifact of clinical knowledge
- modifying clinical knowledge data in a group/subgroup of clinical knowledge elements or a clinical knowledge artifact
- deleting a clinical knowledge element from a group of clinical knowledge elements or a clinical knowledge artifact.

As a part of adding a new element or changing the data of an existing element of clinical knowledge, the following functions are enabled:

- managing the conditions for selecting an element of clinical knowledge
- managing the basic data of the element of clinical knowledge
- managing the actions of the element of clinical knowledge.

As a part of managing conditions for the selection of clinical knowledge elements, the same functions are enabled as in the management of conditions for the selection of clinical knowledge artifacts.

As a part of managing the actions of the element of clinical knowledge, the following functions are enabled:

- adding a new action to the element of clinical knowledge
- changing the data of the existing action of the element of clinical knowledge
- deleting an action from elements of clinical knowledge.

As a part of adding a new action to the element of clinical knowledge or changing the data of an existing action in the element of clinical knowledge, the following functions are enabled:

- managing the conditions for selecting an action
- action data management.

As a part of managing the conditions for the selection of actions of elements of clinical knowledge, the same functions are enabled as in the management of rules for the selection of artifacts of clinical knowledge.

In addition to managing clinical knowledge bases, it is also possible to manage CQL libraries that contain CQL definitions that are used in clinical knowledge bases to select artifacts, groups of elements and elements of clinical knowledge, and actions of clinical knowledge elements:

- adding a new CQL library
- creating a new version of the CQL library
- logical deletion (deactivation) of the CQL library.

As a part of adding a new library and creating a new version of the library, it is possible to define basic information about libraries, such as the name, purpose and related libraries, and input CQL definitions and functions via a text editor or via import from a CQL file.

1.3 Clinical Knowledge Artifact Evaluation and Execution Component (CDS Execution Engine)

This component enables the evaluation and execution of clinical knowledge artifacts stored in the clinical knowledge database of the clinical decision support system. In case the clinical decision support service uses an external clinical knowledge base, the component forwards the query to the external clinical knowledge base for evaluation and execution.

The component enables the following services:

- clinical decision support request
- access to all available clinical decision support services
- information about the acceptance or rejection of a clinical decision support service recommendation.

The request for support in clinical decision-making service enables sending of requests to individual services of the system for support in clinical decision-making. After receiving the request, the component evaluates the rules for selecting artifacts and elements of clinical knowledge, executes the artifact and elements of clinical knowledge, and in response returns cards with information and recommended actions to the user in the form of CDS Cards.

To be able to evaluate the rules for the selection of artifacts and elements of clinical knowledge, and to be able to execute the corresponding elements of clinical knowledge, the system must have access to administrative and medical data. These data can be sent to the system via a support service request (CDS Hooks Service Request) or the system can retrieve such data from the patient's electronic health record, i.e. registers of patients, healthcare institutions, healthcare professionals, etc. For the clinical decision support system to be able to retrieve the data from the patient's electronic health record or various registers, these systems must have an implemented data access interface based on the HL7 FHIR specification.

The retrieval of all available clinical decision support services enables the retrieval of all clinical decision support services provided by the system in accordance with the Discovery service parameters of the CDS Hooks specification.

The information on the acceptance or rejection of the recommendation of the clinical decision support service enables the users of the Clinical Decision Support System to send information about the acceptance or rejection of individual recommendations obtained based on the previously sent request for the clinical decision support service. For each recommendation (card), users can send information on whether the recommendation was accepted or not, and if not, what is the reason for not accepting the recommendation. The system saves this data together with the data on the request for the clinical decision support service and the data on the response to the request. This data can be used for analysis and improvement of clinical knowledge bases

1.4 Client component for displaying clinical knowledge (CDS Client)

Client component for displaying clinical knowledge is web-based GUI component based on microfrontend architecture that can be integrated in any web based end user application to enable access to clinical decision support services and related clinical knowledge

1.5 Clinical knowledge data analytics (CDS Analytics)

Clinical knowledge data analytics enables collecting of data related to usage and applicability of clinical knowledge artefacts in real life environment. Analysis of this data may be used to improve clinical knowledge artefacts, remove artefacts that are not applicable or to create new artifacts.

2 Technical Aspect

Access to Clinical Decision Support System services (search for services, use of services and retrieval of recommendations, sending data on acceptance of recommendations) is supported by application interfaces based on the CDS Hooks specification [2].

The structure of clinical knowledge bases and applications for managing clinical knowledge bases conforms to the specification of the Clinical Reasoning module of the HL7 FHIR standard.

In accordance with the specification of the Clinical Reasoning module of the HL7 FHIR standard, the PlanDefinition FHIR resource is used to define clinical knowledge bases, clinical knowledge artifacts, and groups of clinical knowledge artifacts, while the ActivityDefinition FHIR resource is used to define actions related to the execution of clinical knowledge elements.

To define the rules for evaluating the applicability of clinical artifacts and groups of clinical knowledge elements and evaluating and executing the clinical knowledge elements, CQL functions are used, which are stored in CQL function libraries using the Library FHIR resource.

3 Interdependencies

The EHE Clinical Decision Support depends on the following products and components:

- EHE FHIR Repository [2] – it is also possible to use other providers' data repository compliant with the FHIR R4 standard
- EHE Terminology Services [3] – it is also possible to use other providers' terminology repository and terminology service compliant with the FHIR R4 standard and the IHE SVCM integration profile [10][11]
- EHE Infrastructure [4]
- EHE Health Entities Register [5] – it is also possible to use other providers' healthcare data repository that complies with the FHIR R4 standard and the IHE mCSD integration profile [12]
- EHE Person and Patient Register [6] – it is also possible to use other providers' person and patient data repository compliant with the FHIR R4 standard and the integration profiles IHE PIXm [13], IHE PDQm [14] and IHE PMIR [15]
- EHE Medical Records Database [7] – It is also possible to use other providers' medical data repository compliant with the FHIR R4 standard. The internal structure used to store medical data does not have to be compliant with the FHIR R4 standard, but it is important that the interface for accessing and managing data in the repository is compliant with that standard.

To implement the EHE Clinical Decision Support System, it is necessary to provide the operating system Ubuntu Linux.

The components of the EHE Clinical Decision Support System can be installed on physical servers, virtual machines or in containers.

4 Free and Open Source Software

This product uses free and open source software (FOSS) components with the following licenses:

- Apache Software License 2.0 [16]
- MIT License [17]
- Eclipse Distribution License [18]
- Eclipse Public License [19]
- Creative Commons CC0 [20]
- BSD License (2 clause and 3 clause) [21]
- Bouncy Castle License [22]

- Common Development and Distribution License [23]
- GNU Library General Public License [24]
- Mozilla Public License (MPL) [25]
- Elastic license v2 [26]

5 Version

The current product version is 5.1.

6 Reference

[1] HL7 FHIR - a standard that describes data formats and elements and an application programming interface for the exchange of electronic health records. It was created by Health Level Seven of the International Health Standards Organization. The specification is available at https://www.hl7.org/fhir/.

[2] EHE FHIR Repository – standard Ericsson Nikola Tesla's product which enables data management and storage based on the HL7 FHIR standard.

[3] EHE Terminology Services - standard Ericsson Nikola Tesla's product which enables the use of terminologies, terminological operations, and management of terminologies (code lists, concept groups, concept maps) based on the HL7 standard, the FHIR standard and the IHE SVCM integration profile.

[4] EHE Infrastructure – standard Ericsson Nikola Tesla product which implements the functions necessary for the operation, internal communication, and monitoring of the solution components.

[5] EHE Health Entities Register - standard Ericsson Nikola Tesla's product which enables the management and storage of data on health care providers (health care workers, health care facilities and health care facilities) based on the HL7 FHIR standard and the IHE mCSD integration profile.

[6] EHE Person and Patient Register - standard Ericsson Nikola Tesla's product which enables the management and storage of data about people and patients based on the HL7 FHIR standard and the integration profiles IHE PDQm, IHE PIXm and IHE PMIR.

[7] EHE Medical Records Database – standard Ericsson Nikola Tesla's product which enables the management and storage of health and clinical data in accordance with the HL7 FHIR standard and the IHE QEDm integration profile.

[8] CDS Hooks – interface specification for Clinical Decision Support Systems access – specification available at https://cds-hooks.hl7.org.

[9] HL7 standard: Clinical Quality Language – specification available at https://cql.hl7.org.

[10] IHE (Integrating the Healthcare Enterprise) – This is a joint initiative of healthcare professionals and industry with the aim of improving the way in which information systems and applications in healthcare exchange information by defining integration profiles that determine standards to solve common integration tasks in healthcare (https://ihe.net).

[11] IHE SVCM (Sharing Valuesets, Codes and Maps) – profile defines a lightweight interface through which healthcare systems may retrieve centrally managed uniform nomenclature and mappings between code systems based on the HL7 FHIR specification – specification available at https://profiles.ihe.net/ITI/SVCM/.

[12] IHE mCSD (Mobile Care Services Discovery) – profile supports provider and care services discovery usecases using FHIR – specification available at https://profiles.ihe.net/ITI/mCSD/.

[13] IHE PIXm (Patient Identifier Cross-Reference for Mobile) – profile defines a lightweight RESTful interface to a Patient Identifier Cross-reference Manager, leveraging technologies readily available to mobile applications and lightweight browser based applications – specification available at https://profiles.ihe.net/ITI/PIXm/index.html.

[14] IHE PDQm (Patient Demographics Query for Mobile) – profile defines a lightweight RESTful interface to a patient demographics supplier – specification available at https://profiles.ihe.net/ITI/PDQm/.

[15] IHE PMIR (Patient Master Identity Registry) – profile provides a RESTful patient identity management – specification available at https://profiles.ihe.net/ITI/PMIR/.

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