International Patient Summary Standard Based on Archetype Concepts

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***Abstract*—The design and software implementation of a standard for International Patient Summary (IPS) is recently in the focus of several updates of major eHealth standards and technical specifications in European Union countries. The design goal of the final draft version of this European standard is to be implementation independent and to enable semantic interoperability in exchanging clinical data. The paper makes a detailed analysis of the relations of this standard with other European projects. The objective of this paper is to implement the IPS standard making use of archetype concepts and demonstrates the implementation in a fully functional web application for exchange of IPS clinical data. The paper makes a detailed review of the dataset structure and the patterns used to describe the sections in the IPS standard focusing on the Medication summary section. On this basis two archetype models are created correspondingly with EN ISO 13606 and openEHR archetypes. A client-server web application is developed to demonstrate the practical application of the archetype model using openEHR specifications. The discussion of the computer experiments leads to the conclusion that archetype models of the IPS standard can fully satisfy the objectives of this standard for cross- border semantic interoperability. The obtained results correspond to existing sample implementations of the IPS with Message paradigm technologies. These results are novel because for the first time they demonstrate the implementation in a client- server application of the IPS standard designed with archetypes.**

Keywords-semantic interoperability; eHealth; international patient summary; medication summary; archetype concept.

I. INTRODUCTION

Today people, businesses and data resources are globally connected. Every day a lot of people travel around the world or simply move from place to another in the country of their origin. This active way of life of modern people relates to the need of exchanging at least a minimum set of patient data between healthcare professionals. The availability of such data at the right time in case of unscheduled and in scheduled care is essential for providing quality health services. For example, in the outbreak of dangerous virus in one country, a person leaving this country may suddenly fell ill in another country. Then the assignment of proper treatment for this patient requires interoperability of services allowing to obtain among the rest the history of illnesses, allergies and the medications he or she used to take in the country of permanent stay. The requirement for establishing and maintaining a standard International Patient Summary (IPS) becomes imperative in times when huge amounts of people migrate from country, seek employment or better life abroad.

The research work for the development of a standard for an International Patient Summary (IPS) has a long history [1]. It has started with the European Patients – Smart Open Services (epSOS) project having as a main objective to enable a service infrastructure for cross-border interoperability between Electronic Health Records (EHR) systems in Europe [2] [3]. This pilot infrastructure has been planned to allow a citizen from one EU country to receive relevant treatment for unscheduled health need in another country. The outcomes of this project have laid the foundations for sharing and exchanging patient summary and electronic prescription records. Research work has continued in several other EU projects like the Joint Action to support the eHealth Network project (JAseHN [4]) and the obtained results have been implemented in the eHealth Digital Service Infrastructure (eHDSI [5]) or adopted by the eHealth Network (eHN [6] [7]).

The European Commission for Standardization (CEN) in a collaboration with HL7 [8] [9] produced final draft versions correspondingly of a standard (EN 17269 [10]) and a technical specification (FprCEN/TS 17288 [11]) for an IPS. These two documents provide a detailed abstract specification of an IPS model from which concrete models can be derived and implemented. Therefore, the IPS model is described in terms of clinically relevant data set that is "*minimal*", "*specialty-agnostic and condition- independent*".

The objective of this paper is to investigate these newly published documents from the perspective for software implementation of the proposed domain information model and the dataset specifications. For example, it is important to learn how well this IPS model can be expressed with EN ISO 13606 and openEHR [12]., where EN ISO 13606 [13] is the EU approved standard for semantic interoperability. The reason to explore this subject in EN 17269 is that the collaboration of CEN with HL7 has led to a rather unbalanced interpretation of the use cases in terms of software technologies exclusively related to HL7 FHIR [8] and HL7 CDA [14]. Indeed the data set references to ISO 21090 [15]

make this model compatible with the data sets used in information models based on American Standards HL7 v3, HL7 FHIR or an EU standard like EN ISO 13606. On the other side, the IPS draft standard prEN 17269 does not provide guidance for implementing semantic interoperability in the exchange of IPS records. In fact, the draft version of FprCEN/TS 17288 provides just a short informative reference to EN ISO 13606 and openEHR archetypes, while semantic interoperability appears to be out of the scope of this IPS model. Moreover, the evaluation of the IPS model is presented only in terms of the Messages Paradigm of HL7 CDA and HL7 FHIR making use of a specific ART-DECOR template exchange format with Native XML databases (NXD) [16]. Besides, practical experience shows that the support for semantic interoperability of the Messages paradigm is problematic and it is difficult to scale it at national levels [17].

Our approach to evaluate the IPS model is based on designing and implementing the IPS document with archetype concepts satisfying the Archetype Object Models of EN ISO 13606 [18] [19] and openEHR [12]. It is a novel research work because it aims to evaluate newly published draft versions of a standard and the accompanying it technical specification for IPS, where the Archetype paradigm is superficially taken in consideration. Note that the ART-DÉCOR template format is not directly compatible with the Archetype Description Language (ADL) [19] [12]. The above formulated issues are currently poorly explored in the existing literature especially regarding their software implementation. In this paper, we take one of the required sections of the IPS as a case study to validate the application of our approach for introducing semantic interoperability support in the scenarios for managing IPS extracts. The details of our approach are as follows:

- Implement the IPS Medication section in EN 17269 both in terms of EN ISO 13606 Archetype Object Model (AOM)and in terms of the openEHR AOM.
- Explore the compatibility of the obtained EN ISO 13606 Archetype conceptual design with respect to the requirements of an openEHR engine for running openEHR Operational templates.
- Explore the W3C XML Schemas of IPS archetype conceptual models with respect to potential practical implementations of the proposed standard.
- Develop a client- server application for testing the openEHR Operational template on an openEHR engine in a local and cloud environment.
- Propose a methodology for transforming a EN ISO 13606 or openEHR archetype conceptual models into a format that enables the creation of archetype instances compatible with NXD.

This paper is divided into sections as follows. In the following section, we review the genesis of the IPS standard and make an overview of the whole standard. A detailed data analysis for the Medication summary section of this standard is presented in Section III. In Section IV we design the IPS with archetype concepts employing well- structured archetype modeling methodology[20]. In Section V, we present our software implementation details. In Section VI, we summarize the obtained results and on this basis a methodology for implementing the Archetype paradigm with the IPS standard is proposed. Section VII summarizes the research results.

II. BACKGROUND

The development of IPS started as a "Patient Summary" (PS) service designed by the epSOS project (2008-2014) [2] to demonstrate the operation of a service infrastructure for cross- border interoperability between systems maintaining electronic health records in Europe. The clinical rationale that led to the definition of the PS dataset is founded on a normative use case scenario of unplanned care (emergency, accident). In this scenario a health professional of country B (country of treatment) gets access to essential information he needs to provide care or consult a patient from country A (country of origin).

By definition [21](p.2) "*An epSOS Patient Summary is a standardized set of basic patient data, which includes the most important clinical facts needed to ensure safe and secure healthcare*". The meaning of the variables included in the proposed PS dataset is described initially in Table 2 of the Guidelines on electronic data exchange (Release 1) [6] adopted by the eHealth Network in 2013. The dataset is split into two groups of data, the *Patient administrative data* group and the *Patient clinical data* group. Both groups distinguish required fields (part of the *Mandatory dataset*) and optional fields (part of the *Extended dataset*) in the PS.

It is noteworthy that from the very beginning the PS document is designed to be compliant to HL7 Common Document Architecture (CDA) Version 2, level 3 [14]. In accordance with this design decision a guide for the implementation of the PS with HL7 technologies has been published [22]. This way the PS document is built by a large number of sections and entry content modules derived from existing HL7 templates and using proprietary encoding. The initial clinical definition of terms in the PS dataset strongly depends on terminology and technical implementations in national infrastructures among European countries. The dataset definition itself lacks a common semantic structure based on standardized data types for information interchange. For example, the proposed translation and transcoding process causes ambiguous identification of a foreign patient. The Guideline on electronic data exchange (Release 2) [7] published in 2016 only partially resolves patient privacy and security issues in the PS dataset design. On the other side this guideline presents a well-structured description of the use case for cross- border PS for unscheduled care and serves as a foundation for the development of the EN 17269 standard of the IPS and its technical specification, FprCEN/TS 17288.

The EN 17269 standard overcomes the major limitations in the implementation of the PS. Its design goal is to be implementation independent; it is all about the IPS data and its logical definition. Unlike the PS, the EN 17269 standard for IPS is underpinned by the System of concepts to support continuity of care (Contsys) EN ISO 13940:2016 [23] and standard data types for information exchange like EN ISO 21090 [15] and HL7 FHIR [8]. For instance, Contsys concepts are used by this standard to interpret the primary use

case of the PS in the epSOS project [5]. Moreover, the technical specification FprCEN/TS 17288 extends the scope of this primary use case to include four scenarios that are combinations of cross- border(international scale) and local (national scale) exchange of PS data with exclusive demands for unscheduled care and scheduled care. References to EN ISO 21090 datatypes support harmonization of the IPS with EN ISO 13606, openEHR, HL7 and FHIR. For example, a Coded element in the IPS standard represents a single concept that provides a reference to a terminology, code system or ontology such as SNOMED-CT [24]. Although the IPS standard employs an abstract data model that is implementation independent such kind of references and Contsys concepts enable semantic interoperability of documents satisfying the requirements of this standard.

An IPS document in cross- border applications must be structured into the following six *Required* sections (Fig. 1) in order to claim full conformance with EN 17269:

- Patient Attributes
- Allergies and Intolerances
- Medication Summary
- Problems
- Provenance
- Cross- Border (conditional)

In national scale scenarios the Cross-border section can be omitted. The three sections with clinical content (Allergies and Intolerances, Medication Summary and Problems) among these six sections are mandatory. In case no information is available for any of these sections, then a dedicated data element in such a section must state the reason for the absence of data. The IPS standard outlines a group of sections that are "required if known", or the so- called group of *Recommended* sections (Immunizations, History of Procedures, Medical Devices and Patient's Address Book). Data in these sections may not be universally available, may not be collected or such data like data in the "Patient's Address Book" section is confidential in some aspect. There is also a group of *Optional* sections (Advance Directives, Functional status, History of Pregnancy, History of Past Illness, Plan of Care, Results, Social History and Vital Signs) that may be omitted in the IPS document without specifying any reason for it. For completeness, the EN 17269 standard allows to include optionally Non-IPS sections in the IPS document as well. The structure and content of such sections is not defined in this standard and it allows to the extend the IPS with condition-specific data.

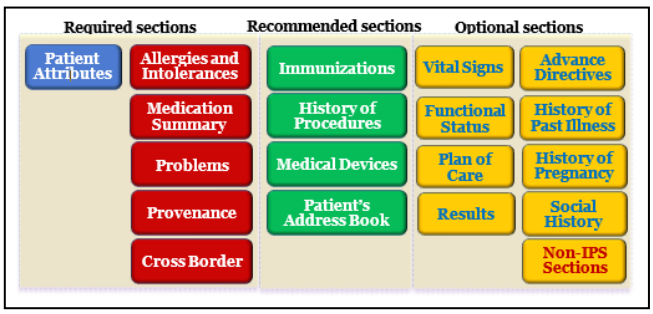

Figure 1. Standard International Patient Summary sections.

Each one of the IPS sections is represented by a hierarchical data structure, where nesting determines the hierarchical level of the data elements. Since the IPS standard is implementation independent the data elements are described in generic form making use of "patterns". Most of these "patterns" correspond to "well- known" data types like Identifier, Coded element, Date- Time and Address. For clarity, the EN ISO 21090 datatypes are referenced to illustrate the expected main characteristics of the data element. Besides, when referring to an EN ISO 21090 datatype it is not assumed that an IPS document implementation must comply with this standard. However, in our opinion compliance of datatypes of the data elements with EN ISO 21090 is a requirement is a necessary condition for ensuring semantic interoperability in cross- border exchange of IPS documents.

Nowadays there exist only two trial implementations of the IPS standard that are reported in the existing literature. Both of them make use of the Message paradigm [17] and implement the IPS standard correspondingly with HL7 FHIR [8] and with HL7 CDA R2 [9]. Both implementation guides share the same design principles and demonstrate the creation of IPS core set of sections as a templated document making use of pre-existing CDA templates and Value sets. An important feature of these sample implementations is the use of terminologies like SNOMED CT [24], ATC [25], LOINC [26] , UCUM [27] for units of measures and EDQM [28] for dose forms and routs of administration.

For example, the HL7 FHIR implementation of a *Medication statement* encodes the *Medication Product Common Name* and *Medication Product code* for the drug SIMVASTATIN in terms of its ATC code C10AA01 (Fig.2).

```
<coding>
        <system value="http://www.whocc.no/atc"/>
        <code   value="C10AA01"/>
        <display value="simvastatin"/>
</coding>
```

Figure 2. Representimg a Coded element in IPS implementations.

The IPS standard does not consider the IPS dataset implementation in the clinical practice. Therefore, these two trial implementations of the IPS serve as a helpful resource for examples about how to interpret the data structure of IPS sections and the "patterns" used to describe the datatypes. The success or the failure of the IPS standard, however, strongly depends on making this standard acceptable for clinical use.

There are several problems that remain to be resolved in order to make the trial implementations useful for the practice. One serious obstacle in this respect is providing user friendly access to terminology services and codes that enable semantic interoperability in cross- border exchange of IPS. Most of these resources are not freely available and identifying the desired code value is time consuming. Some other resources like the set of EN ISO IDMP set of standards [29] are not fully implemented in practice. Although the current IPS standard does not impose obligatory usage of terminology services and

codes, it is self-understood that semantic interoperability is impossible without binding clinical concepts and terms to a coding system. Another major problem that concerns the clinical practice is the management of IPS records. The trial implementations illustrate merely the interpretations of IPS data making use of HL7 related technologies that represent the view of the Message paradigm in Health informatics.

At first glance it seems to be straightforward to accomplish mapping of datatypes between Message paradigm technologies and Archetype paradigm technologies because more or less these datatypes derive from EN ISO 21090. However, each one of these two major groups of technologies has their inherent limitations in terms of management of EHR like IPS data [30] [31] [32] [33]. This refers to storage and exchange of IPS data taking in consideration related issues of privacy and confidentiality regulations, language translation of clinical concepts and differences in national legislation as well as availability of tools for executing queries and data visualization. Finally, there should be a convenient way for transforming existing heterogeneous clinical data into a document structure that conforms to the IPS standard. In short, the available IPS implementation guides are too simplified and biased by the advantages and disadvantages of one of the existing paradigms in health informatics for exchange of clinical information.

In the following sections we consider the IPS design from the perspective of the Archetype paradigm. For this purpose, we first analyze the data structure of a required section in the IPS standard. Next, we will implement this section in terms of archetype concepts. Unlike the existing IPS implementation samples we won't just create a computer model of an IPS section. From practical point of view, it is important to investigate and discuss management of instances of the thus created IPS model. Therefore, we build a server- client web application and demonstrate IPS data management of archetype with this application.

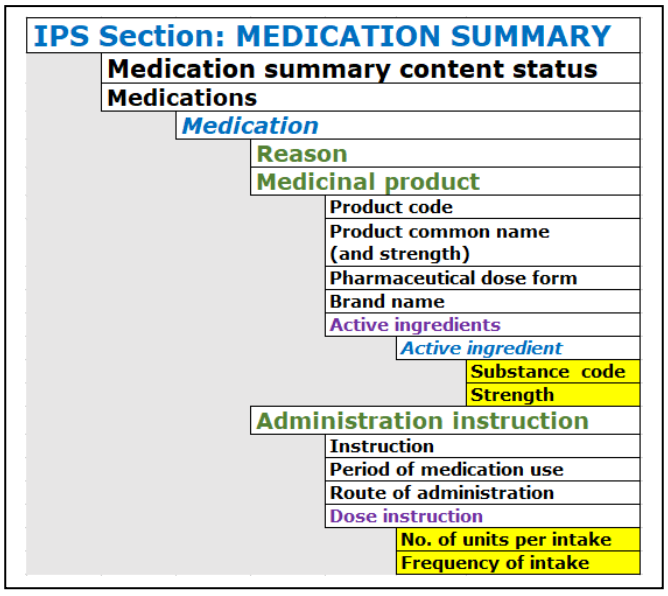

Figure 3. The Medication Sumamry required structure in EN 17269.

III. DESCRIPTION OF THE DATA MODEL

Without loss of generality, we consider the *Medication Summary* section of the IPS standard, which is one of its six *Required* sections (Fig. 3).

The hierarchical data structure and the data types used in this section are described in full details in Tables 15 and 16 of the EN 17269 standard (Fig. 3). The final draft version of this standard describes the same way the rest of the sections of the IPS, where the dataset borrows data types from EN ISO 21090. Therefore, the same approach for can applied for analyzing the remaining sections of the IPS standard. The standard provides detailed description with all the information necessary for building a conceptual model of these sections in terms of archetype concepts.

The "IPS Section: MEDICATION SUMMARY" is closely related to EN ISO IDMP set of standards and it is important part of European eHealth projects like the epSOS project. The IPS standard taking into consideration the limited scope of EN ISO IDMP implementations has relaxed the requirement for using IDMP notations and specifications by introducing high level of abstraction in concept descriptions. This way the IPS standard leaves the option for adopting IDMP notation and specification with *Medication summary* concepts, when they become available.

The dataset of the *Medication summary* section comprises a *Content status* data element and a list of *Medications*. For clarity we keep the same names and order of introducing the data elements of the *Medication Summary* dataset as they are defined in the IPS standard. The *Content status* element is of type denoted in the IPS standard using the pattern *Coded Element*. The semantic meaning of this pattern with reference to *Content status* is a predicate taking for example, values true and false. When the *Content status* is *true*, then the list of *Medications* shall be not empty. Otherwise, the list of *Medications* shall be *empty*.

Each one of the elements of the *Medications* list contains:

- *Reason*
- *Medicinal product*
- *Administration instruction*

The *Reason* element is *Optional* in the *Medications* list. It has the purpose to state, if known or allowed by the patient, the reason for the *Medication* prescription.

The *Medicinal product* and the *Administration instruction* are *Required* datasets of elements that together provide a "*minimal and non- exhaustive*" description of that product. The following elements belong to the *Medicinal product* dataset:

- *Product code*
- *Product common name(and strength)*
- *Pharmaceutical dose form*
- *Brand name*
- *Active ingredients*

The *Product code* element is *Optional*, and its datatype is described with the pattern *Coded element*. The semantics of the product code description in the IPS standard implies a reference to some unique identifier from the EN ISO IDMP set of standards. However, the IPS does not impose such a requirement rather allows for using a more general code from

a terminology like ATC as shown in the sample implementation on Fig. 2.

The *Product common name* (*and strength*) is a *ReqiuredIfKnown* element of type *String*. According to the IPS standard it is used to record in free text a non-proprietary name of the pharmaceutical product eventually including the strength of each ingredient. It should be consistent and associated with the *Product code* value. For example, once the *Product code* is selected from a given terminology classification (ATC) then this determines the *Product common name* ("*simvastatin*") (Fig. 2).

The *Pharmaceutical dose form* is a *Required* element described by a value described by the pattern *Coded element.* This element denotes the physical state of Medication (*Solid*, *Liquid*, *Semi- Liquid* and their variants). The codes for these states are listed in Table A.1 of EN ISO 11239, which is one of the EN ISO IDMP group of standards.

Brand name is an *Optional* element of type *String*. For a given *Product code* there could be multiple titles under which the medication is sold on the market. For example, given the ATC code C10AA01 the *Brand name* could be "*Simvastatin 40 mg Filmtabletten*" or "*Simvastatin 40 mg Tablets*". The standard recommends providing a *Brand name* always when it is justified by the healthcare professional or the medicinal product is of biological origin.

The list of *Active ingredients* is represented by a set of the substances that separately or in combination produce the intended effect of applying the medicinal product. This list is a *Required* element in the Medicinal product dataset. The elements of the list are described in terms of *Substance code* and *Strength*.

Substance code is a *Required* element described by a value described by the pattern *Coded element.* The IPS standard refers to codes in conformance with the EN ISO IDMP set standards and in particular, satisfying the information model for substance codes EN ISO 11238:2018 like the Chemical Abstract Service (CAS) Registry Numbers, European Inventory of Existing Commercial Chemical Substances (EINECS), European Drug Codes (XEVMPD) and Japanese Drug Codes. The sample implementation of IPS by HL7 FHIR stores the *Substance code* in terms of its RxNorm [34] code and respective name (Fig. 4).

```
<coding>
    <system >
        http://www.nlm.nih.gov/research/umls/rxnorm
    </system/>
    <code    value="36567"/>
    <display value="Simvastatin"/>
</coding>
```

Figure 4. Sample representation of Substance code in the IPS standard.

Currently, the IPS standard allows using "*well- known*" names for ingredients instead of IDMP or other terminology codes, for example, "*paracetamol*".

The *Strength* of the *Active ingredient* is a *Required* element described by a value described by a pattern termed as *Ratio.* When the IPS standard explains this pattern, it makes a reference to the RTO type in the EN ISO 21090 standard having numerator and denominator of type QTY (quantity), where the denominator shall be nonnegative (Fig. 5).

```
<strength>
    <numerator>
        <value  value="40"/>
        <unit   value="mcg"/>
        <system value="http://unitsofmeasure.org"/>
        <code   value="mg"/>
    </numerator>
    <denominator>
        <value  value="1"/>
        <unit   value="tablet"/>
        <system value="http://unitsofmeasure.org"/>
        <code   value="{tablet}"/>
    </denominator>
</strength>
```

Figure 5. Sample representation the Strength of the Active ingredient.

The *Administration instruction* dataset comprises the following data items:

- *Instruction*
- *Period of medication use*
- *Route of administration*
- *Dose instruction*

Instruction is an *Optional* element of type *Text* providing textual information about the procedure to applying the *Medication*. By default, it is used to summarize the content in the remaining three data elements of *Administration instruction.*

Period of medication use is an *Optional* element of type described by the pattern *Period* in the IPS standard. The period is a general concept that could be implemented in terms of start and end dates or in terms of "floating" time for duration ("*5 days*", or "*1 month*").

The *Route of administration* is an *Optional* element described by the pattern *Coded element.* For some reason a description for this element is missing for the *Medication summary* in the IPS standard. However, a clear description for it is provided in the EN ISO 11239 standard, namely, "*path by which the pharmaceutical product is taken or makes contact with the body*". Moreover, Table A.9 in the same standard provides a list with examples for some of the most frequently used *Route of administration* values.

Finally, *Dose Instruction* is a *Required* component of the *Administration instruction* dataset comprising two data elements, *Number of Units per intake* and *Frequency of intake*. Both data elements are *Required* and described correspondingly by patterns *Range or Quantity* and *General Time Specification*. The *Number of Units per intake* is represented by a numeric value and a measurement representation for the unit ("40 mg", "2 tablets"). In a similar way the *Frequency of intake identifies* the number of intakes per a specified period (hour, day, week, month).

This detailed understanding of the data model is an important prerequisite for representing it with archetype concepts in the following section of this paper.

IV. IPS Design with Archetype Concepts

In this section we explore the design of a model of the IPS *Medication Summary* in terms of the Archetype paradigm. Additionally, compare the models of the IPS *Medication Summary* obtained by employing respectively, EN ISO 13606 archetypes and openEHR archetypes in the design process. To achieve this objective, we follow a five- stage methodology for archetype design [20]. It allows us to transform correctly a clinical document like the IPS into an archetype conceptual model after the detailed analysis of its data model in the previous section. Some of the most popular software tools for creating an archetype model are LinkEHR Studio [35], the Template Designer [36] and the Archetype Editor [37]. The Template Designer and Archetype Editor are more specialized and appropriate to employ with the openEHR AOM, while the LinkEHR Studio is more suitable for creating a EN ISO 13606 AOM.

These tools have the potential to bind semantic context to the archetype conceptual model from terminology servers and this way map terms to international standards like LOINC, ATC, SNOMED-CT, RxNorm, and ICD [38]. It allows the IPS conceptual model to deliver meaningful, reliable, semantical clinical information at the point of care. At this stage, however, the IPS standard does not impose requirements to use multilingual international reference terminologies and in our research, we have followed strictly the text of this standard. For clarity, we preserve the names of the concepts, the semantics of the data types employed correspondingly with EN ISO 13606 and openEHR as well as the constraints on occurrences of the data elements the way they are specified in the final draft of the IPS standard.

The design of a clinical document with archetype concepts requires good understanding of the dual- level information model in ISO 13606 and openEHR. This information model comprises a Reference model and Archetype model (Fig. 6).

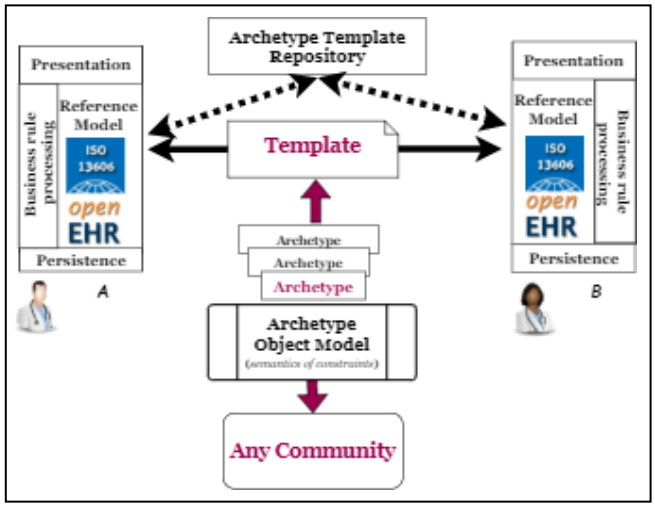

Figure 6. W3C XML Schema of an IPS Section in EN ISO 13606 AOM.

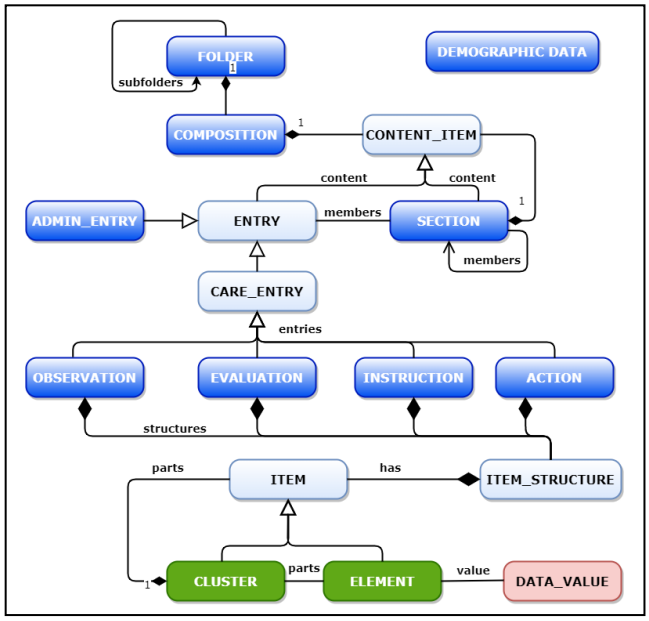

Figure 7. UML class diagram of the openEHR Reference Model.

Without loss of generality we shortly describe the Reference Model of openEHR because in the following section we will present a web application making use of this model. It is displayed in Fig. 7, where for clarity the diagram is simplified by omitting some classes like LOCATABLE and PATHABLE, corresponding to RECORD_COMPONENT in EN ISO 13606. The classes displayed with dark background are concrete classes and the rest are abstract classes. Once a patient creates an EHR or IPS document in particular, this patient is associated with a unique UID identifier. All references to openEHR patient data are made by means of this UID. Committed changes of the document are considered as a contribution and such contributions are represented by a new instance of class COMPOSITION. All contributions are identified by a version number related to the UID of the EHR. This way a FOLDER instance serves as a container for a versioned structure of COMPOSITION instances (contributions for a given EHR). The COMPOSITION instances contain all the information in the clinical document which is the IPS in our case. The base definition of class COMPOSITION needs to be enriched in each given case of EHR with semantic constraints specific to this case. This happens by creating an archetype of type COMPOSITION in the Archetype Object Model. Further on, archetypes of COMPOSITION type are organized in Templates that facilitate reusability of archetypes. It is noteworthy that the latest edition EN ISO 13606-2:2019 has introduced templates as part of its archetype object model as well. A Template allows to dynamically update the semantic structure of the clinical document by adding slots for splitting the COMPOSITION archetype into multiple SECTIONs, which can be further on structured into archetypes, representing semantic constraints determined by the clinical practice as OBSERVATION, EVALUATION, INSTRUCTION and ACTION. The data ITEMs are in the leaves in this tree

structure, where concrete data ELEMENTs may exist standalone or organized in CLUSTER groups (list or tree). The data types assigned to each ELEMENT derive from class the abstract class DATA_VALUE. The openEHR datatypes derive from EN ISO 13606.

All of these allow us to make the conclusion that the IPS can be designed according to the dual- level information model in EN ISO 13606 and openEHR. This model allows not only to reproduce the structural constraints in the IPS document. It enables semantic interoperability, flexibility and reuse of the archetype concepts. Instead of using predefined XML schemas (templates) in HL7 CDA and HL7 FHIR the dual- level information model allows to develop custom archetype concepts that accommodate the specific needs in the clinical practice. A great advantage in using the Archetype paradigm is the introduction of a common information model for validation the template instances in EN ISO 13606 and openEHR.

The IPS standard represents this clinical document as a tree hierarchical of sections, where each section is composed of datasets that can be designed as clusters (lists or trees) of data elements. The IPS *Medication Summary* data model is a typical example of this kind. A Mind map of this data model designed with archetype concepts from EN ISO 13606 allows to visualize the structure of the conceptual model as a single archetype (Fig. 8). This model maps exactly the hierarchical structural constraints of the IPS Medication summary as described in the IPS standard to semantically correct structures within the archetype model.

At the highest level we observe the CONTENT_STATUS (*Content status)* and the LIST_OF_MEDICATION (*Medications)*, where each element MEDICATION of this list is a tree structure of REASON (*Reason)*, MEDICINAL_PRODUCT (*Medicinal product)* and ADMINISTRATION_INSTRUCTION (*Administration instruction).* For comparison purposes, the names of the respective data elements in the IPS are placed in brackets. All the occurrences, cardinalities and data types of the elements in the leaves of this hierarchical structure are assigned in accordance with the semantic interpretation of the patterns in the IPS standard. These settings are denoted on Fig. 9, where the archetype models correspondingly, in EN ISO 13606 (left side) and openEHR (right side), are displayed.

In technical terms, the creation of an archetype model with openEHR first requires to design with the Archetype Editor an archetype a type COMPOSITION archetype (representing the whole IPS) with slots for SECTION archetypes for each of the sections of the IPS, create the SECTION archetypes themselves (representing each of the sections of the IPS) as well as specialized ENTRY archetypes (representing the CONTENT_ITEM in each one of the IPS sections) like OBSERVATION, EVALUATION, INSTRUCTION or ACTION. For example, the contents of the *Medication Summary* section have been created as an INSTRUCTION specialization of the ENTRY archetype because medication orders or multi- drug courses in the clinical practice instructions are considered as instructions. Next, a template can be created with the Template Designer, where all the above archetypes get assembled into a single archetype model of the IPS. Once the constraints of the Reference model are satisfied this template to be exported as Operational template to a openEHR platform for managing instances of the thus created archetype model. The procedure is similar in the case of creating a EN ISO 13606 archetype model with LinkEHR Studio.

The conceptual design of the IPS section of the archetype models can be explored in W3C XML Schema format as well. This approach to investigate the IPS conceptual model is a novelty in the existing literature because a W3C XML Schema Definition Language (XSD) model of the IPS is not presented in the proposed prEN 17269 standard. At the same time, its practical implementation implies the use of web services, where the XSD model specification is important. This model is suitable for implementations in NXD, where XQuery can serve as a good replacement for the absence of an Archetype Query Language in the AOM of EN ISO 13606. For comparison, the XSD model of openEHR concepts includes a lot of metadata payload. Real- life IPS applications process large numbers of openEHR XSD model instances.

Finally, we note that in the existing literature there is evidence that openEHR archetypes can be transformed to EN ISO 13606 archetypes making use of the common ISO 21090 data set [39] The mapping from EN ISO 13606 to openEHR is not explored so far. As a side result, we have established that it is not possible to convert EN ISO 13606 archetypes directly into openEHR archetypes.

The reason is that the concrete class ENTRY from the Reference model of EN ISO 13606 is mapped to the abstract class ENTRY in the Reference model of openEHR. Therefore, we can export a EN ISO 13606 archetype into a valid openEHR Operational template. However, it is not possible to create instances of that template. In openEHR there are concrete specializations of class ENTRY like OBSERVATION, EVALUATION, INSTRUCTION and ACTION. Hence, it is very difficult to map a concrete ENTRY class in EN ISO 13606 to some of these specializations of the openEHR class ENTRY.

Once the openEHR archetype model is built the conceptual model can be exported to valid openEHR Operational template. Thus, in contrast to the existing implementation guides of the IPS, which merely publish XML schemas adapted to the IPS standard, we demonstrate the obtained archetype model in action. In the following section we show results of execution and testing the obtained openEHR conceptual model in a client- server application making use of an openEHR engine for processing instances of the Operational template for the *Medication Summary* section. Without loss of generality the whole IPS can be designed with archetype concepts in the above described way.

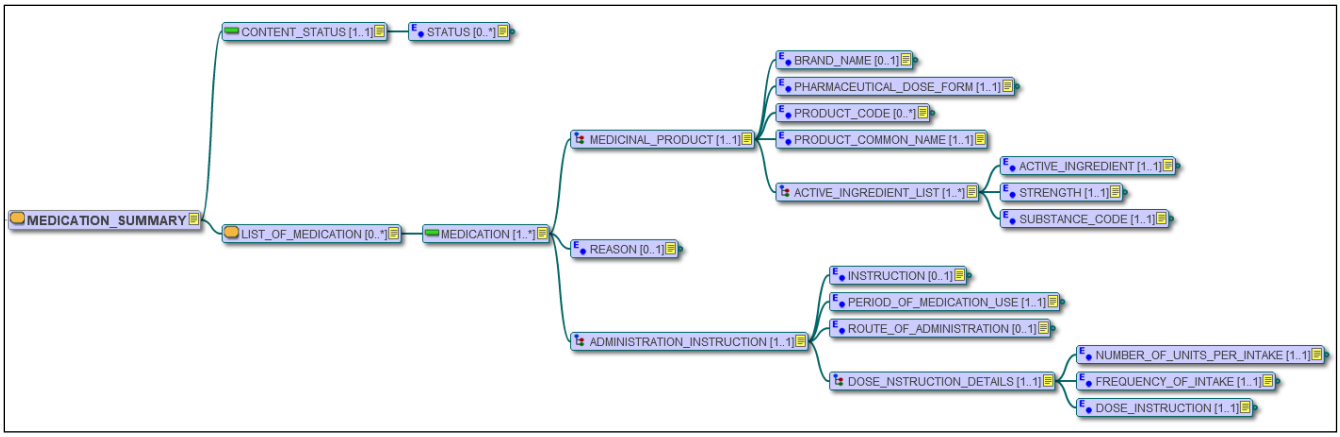

Figure 8. Mind map design of the IPS Medication Summary Section in EN 17269:2018 with a EN ISO 13606 archetype.

V. SOFTWARE IMPLEMENTATION

The software implementation of the IPS conceptual models in a client server application has been developed with the objective to evaluate the applicability of the Archetype paradigm in implementing the proposed IPS standard. For this purpose, the openEHR Operational template of the *Medication Summary* section has been installed and run on both a local CaboLabs openEHR platform [36] and a cloud-based Code4Health platform [40]. Here we present results from a local installation of an openEHR server.

Initially, the Operational template for the *Medication Summary* section is uploaded on the openEHR server and an EHR UID is created for a given patient. On Fig. 10 there are two patients registered with their UIDs. The different versions of updates of the IPS for the second patient in the list are displayed as his Contributions on the same figure.

These Contributions are created and managed by a client web application. This web application employs the RESTful API published by the openEHR server to manage instances of the Operational template that actually are XML documents validated with respect to the information model of openEHR.

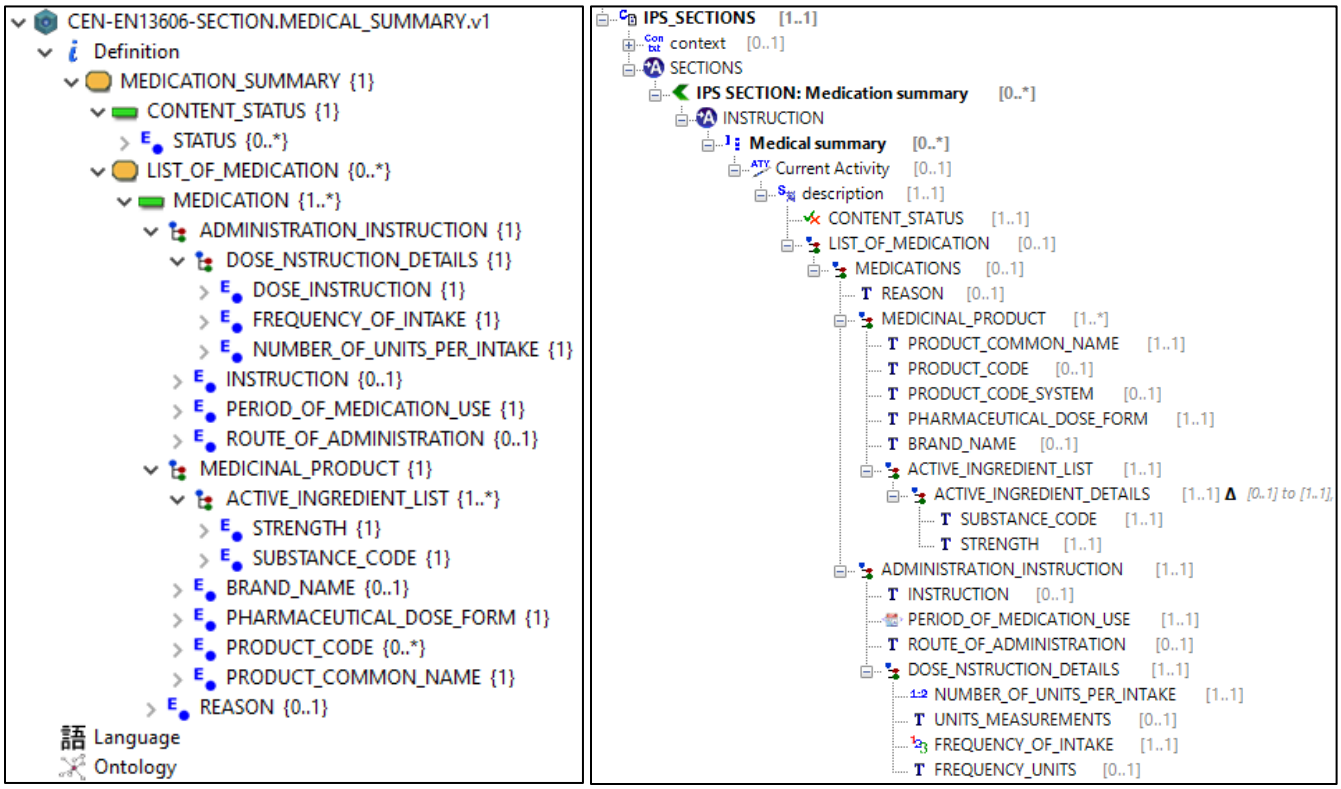

Figure 9. IPS Medication Summary design as a EN ISO 13606 archetype (left side) and as a template of openEHR archetypes (right side).

#	UID	Date
1	bb2dea41-e1dc-415b-95ea-7693d5c14c20	2020-02-29 12:09:31
2	d76df9d8-3013-43ac-9dbd-0c446c4a67d8	2020-02-29 16:09:50

Contributions for EHR

#	UID	Date
1	e87044b6-d2ce-4528-8473-db3e8aa5401c	2020-02-29 16:10:12
2	14a0ba7b-e591-4158-b2d1-38e53e10cc5b	2020-02-29 19:17:03
3	6a76d4be-e034-4080-b8f7-12cd04587aee	2020-02-29 19:41:42

Figure 10. Registered EHR UIDs and versioned Contributions.

The client application at this stage operates in two modes, "writer" (update, add or delete content) and "reader" (read only content). Snapshots of the client application are shown in Fig. 12 and Fig.13.

The graphical user interface of the client is custom designed in PHP. The combo box on the right upper side allows to load an existing contribution or create blank form by the patient, whose EHR UID is displayed below the title of the form. The combo box on the left upper side allows to select an existing Medication in the Medication summary section and display details for it in the fields of the form. Currently, for the registered patient we demonstrate in Fig. 12 and Fig.13 the contents of two Medication. One of them is the same drug, SIMVASTATIN, used in the sample implementation guide for the IPS produced by HL7 FHIR. With this we want to demonstrate that the conceptual model implemented with archetype concepts can handle the same use cases of the IPS as those included in the existing in the literature. For example, the input on Fig. 13 for *Product code* (PRODUCT_CODE on Fig. 9, right side) and *System* the (PRODUCT_CODE on Fig. 9, right side) match completely those input in the sample HL7 FHIR template. Besides, the data elements holding these input values are part of the archetype model and respectively, they are effectively exchanged and managed in the communication between the client and the openEHR server. Note that the input for PRODUCT_CODE is required in the IPS standard. However, this way we show that the obtained archetype model can be extended to serve bindings with terminology specifications and notations. For clarity, we have extended the model by adding input identifying the measures for units and frequency when recording *Dose instructions*. Moreover, we have used data published in EN ISO 11239 to populate with standard coded terms the combo boxes for *Pharmaceutical dose form* and *Route of administration*. Additionally, the Medication summary form provides default values, where possible and a calendar wizard for input of dates. The objective in the client form design has been to enhance the user experience in dealing with IPS.

The buttons in the bottom of the form allow adding a new *Medication* to the list of *Medications* in the IPS as well as new *Active ingredient* to a *Medication*. The web application is fully functional and demonstrates that contents of the IPS can be exchanged employing an information model designed with archetype concepts. Further on IPS exchange can be extended to take place between openEHR servers serving as access points and this way enable true cross- border exchange of IPS data. As far as we know this sample web application is the first operational sample implementation of the IPS standard.

VI. DISCUSSION

In this paper, we have evaluated the applicability of the Archetype paradigm in software applications that implement the draft version of the IPS standard. Although the Archetype paradigm is not in the focus of this standard, we have demonstrated that it can be successfully employed in software applications.

The practical experience in producing the here reported results allow us to propose a methodology for applying the proposed IPS standard in use cases where semantic interoperability is a requirement (Fig. 11).

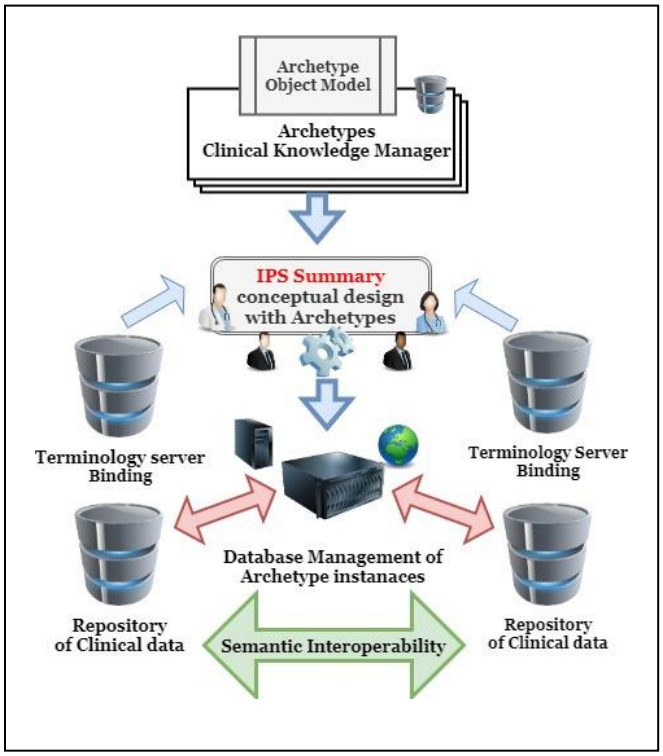

Figure 11. Methodology for semantic interoperability of the IPS.

The first stage in this methodology is to create a correct conceptual model of the IPS document. The archetypes in this model serve as "*plug-and-play*" building blocks for semantic interoperability that can be imported from a repository known a Clinical Knowledge Manager. At this stage we just note to the important requirement for binding of the archetype model to terminology servers for specifications and notations. Therefore, it would be useful by the next version of the IPS standard to obtain well organized and structured public access not only to the promised standard set of SNOMED-CT code set, but also access to other registers for international codes, specifications and terms mentioned in this standard. The obtained archetype conceptual model is ready for reuse in software applications. Clients select an archetype conceptual

model and manage instances of that model in terms of semantic interoperability. Unlike the Messaging Paradigm the implementation of the Archetype paradigm with the proposed IPS standard makes possible all data, information and knowledge in each system to be available in a uniform and standard way.

VII. Conclusion and Future Work

This paper investigates the design and software implementation of the International Patient Summary according to the final draft versions of EN 17269 and FprCEN/TS 17288. These versions make use exclusively of HL7 FHIR and HL7 CDA technologies with the purpose to develop a single, common specification of the minimal and non- exhaustive set of clinical data that can be used by all clinicians for cross- border, unscheduled care of a patient.

In this paper we have presented a detailed analysis of the dataset of the IPS standard with a focus on the IPS Medication summary section. The design objectives of this standard are to make it implementation- independent. It attempts to harmonize requirements among the existing standards and specifications. However, our analysis of the genesis of IPS standard and existing sample implementation guides shows that it is biased by the Message paradigm information model and data set. Therefore, in this paper, we explore how the objectives of this standard can be achieved by applying the Archetype paradigm approach. Especially because the Archetype paradigm is implemented by the EN ISO 13606 standard which is the leading standard for health information exchange approved in the European Union. In the literature it is recognized that reusability and semantic interoperability of clinical data like the IPS sections are delivered essentially in terms of Archetype concepts. Since the IPS sections in EN 17269 have quite a similar structure then the here obtained results can be extended and design the whole IPS in terms of EN ISO 13606 and openEHR archetype concepts. Both archetype models support binding to semantic context provided by terminology servers like SNOMED-CT.

We have established that the EN ISO 13606 AOM cannot be used to create instances compatible with the openEHR AOM. It is an important conclusion because the compatibility of transformation from EN ISO 13606 to openEHR has not been confirmed in the existing literature. The numerical experiments demonstrate that both archetype models can be exported in W3C Schema definitions, where the XSD of openEHR AOM contains considerably larger payload of metadata. Therefore, it is preferable to manage instances of openEHR archetype models by means of operational templates on native openEHR platforms or relational databases with API support for publishing web services.

It is noteworthy that the current versions of the IPS standard and its technical specification do not consider an XSD model of the IPS. At the same time, practical implementations of this standard rely on web services where the specification of the XSD models is important. We have demonstrated this approach in a client server application with real medicinal data and terminology codes, where the same operational template of the IPS section can run both on a local and on a cloud-based openEHR engine. Implementation details are reported in related research work [41] [42] Accordingly, instances of EN ISO 13606 archetypes can be managed in NXD as it is demonstrated in the use cases of FprCEN/TS 17288 with HL7 concepts.

In our future work, we first plan to explore the feasibility of executing an EN ISO 13606 archetype model of the IPS on a NXD. At the same time, we will try to improve the user interface experience for managing the IPS in client applications. In addition, we plan to create a complete Archetype model of all the sections in the IPS standard. Finally, we will continue work directed on exchanging bulk data between servers that provide support for EN ISO 13606 or openEHR.

In summary, the obtained results are presented in a uniform methodology for implementing the IPS in terms of the Archetype paradigm. These results are novel because the Archetype paradigm is not considered in the final draft version of the IPS standard and implementation guides in the existing literature. They serve to extend the practical experience in cross-border sharing of clinical data represented in terms of semantic interoperability of archetype concepts.

Acknowledgment

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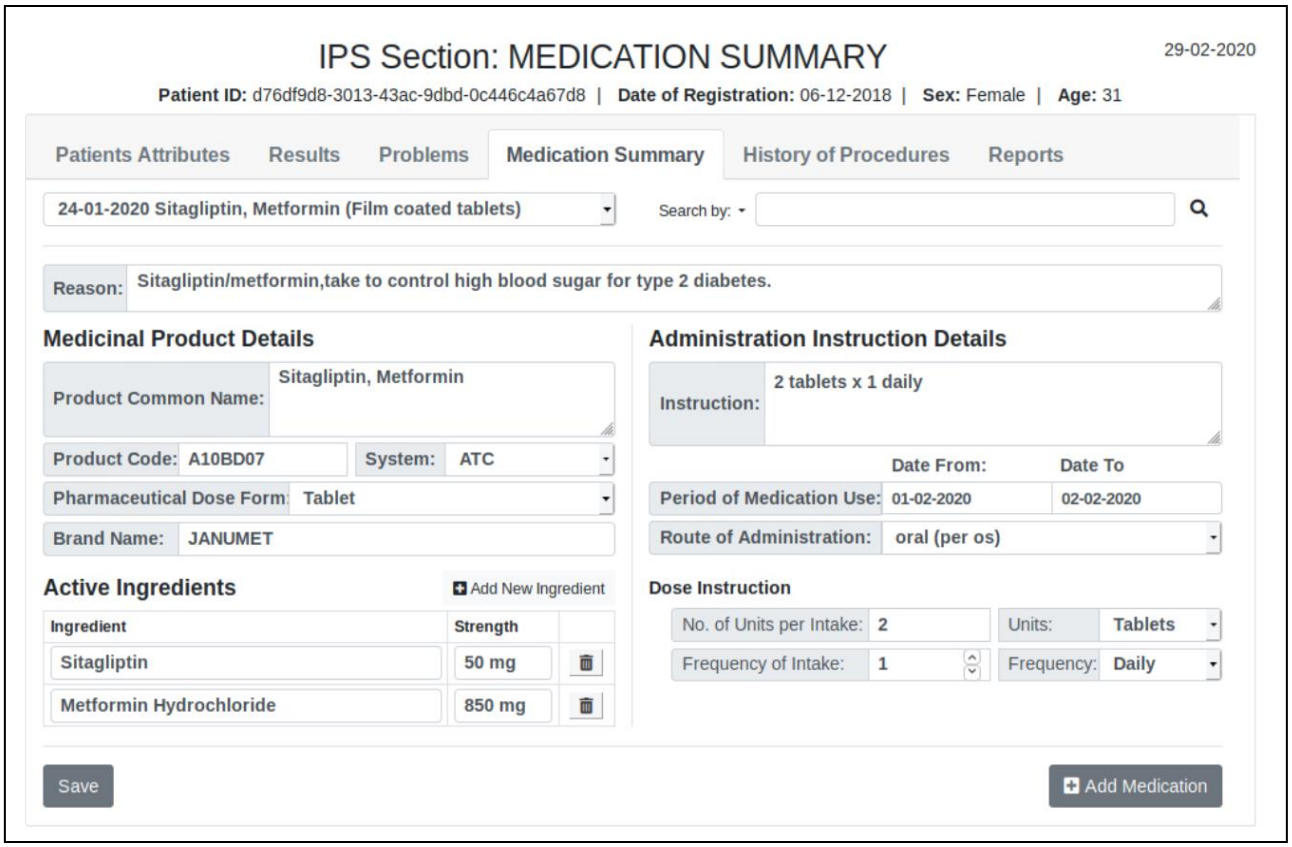

Figure 12. Snapshot of a client application adding a Medication to an openEHR archetype instance of the IPS Medication Summary Section.

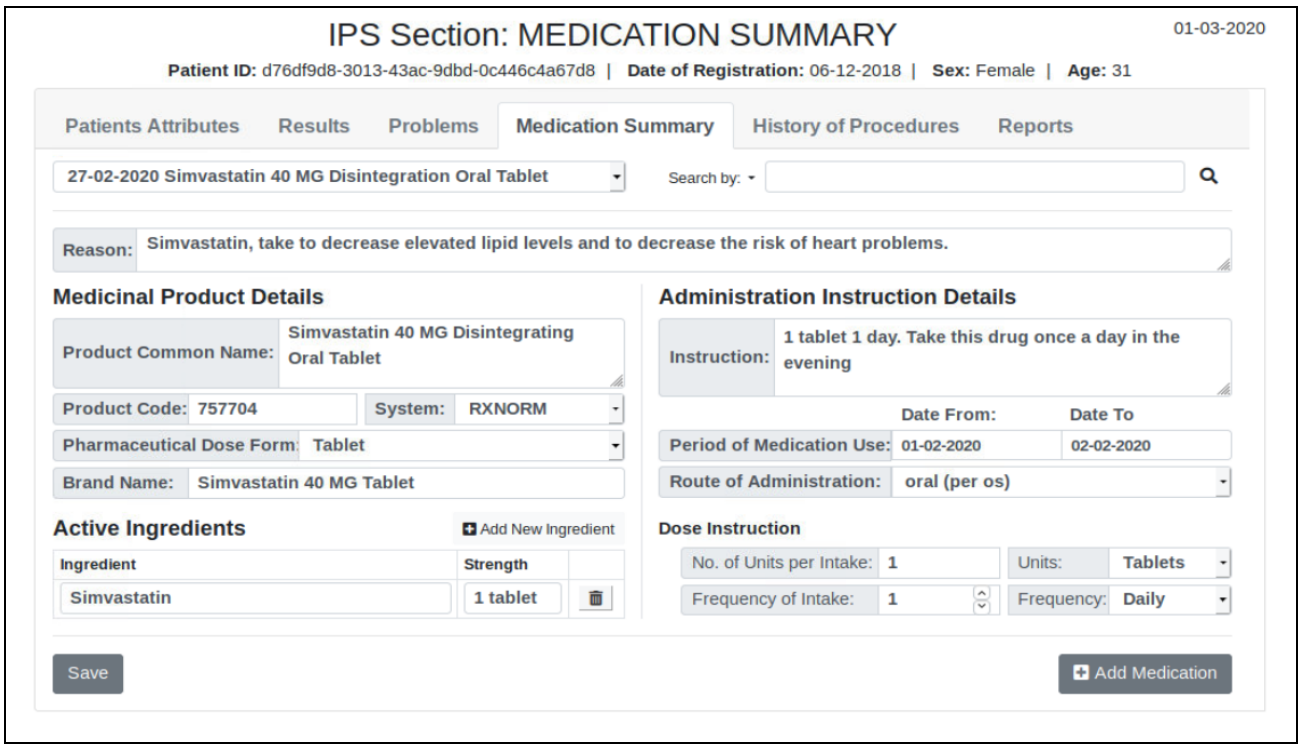

Figure 13. Snapshot of a client application updating an existing Medication in an openEHR archetype instance of the IPS Medication Summary Section.