Challenges and Advanced Technology Solutions in Applied Health Informatics
(Case studies from the Bulgarian eHealth National Scientific Program)

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Case studies

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4. Discussion
1. International exchange of ePrescriptions

ePrescription service
1. International exchange of ePrescriptions

[Map showing connections between NCPs in different countries: NCP country A, NCP country B, NCP country C, NCP country D. The map is color-coded to indicate eHDSI and eHealth Digital Service Infrastructure (eHDSI) operational status: Operational, 2021 plan, 2022 plan, 2023 plan, No plan yet.]
1. International exchange of ePrescriptions

eHealth Digital Service Infrastructure (eHDSI):
✓ Provides a common infrastructure for cross-border exchange of ePrescriptions (eP) at EU level.
✓ Establishes a common ePrescription dataset.
✓ Determines use cases and functional requirements.
✓ Establishes National Contact Points (NCP).

Challenges:
❑ eP deployment in a single country.
❑ eP cross-border exchange between multiple EU counties (27) with different Clinical Information Models (CIM) and legislation.

Research Objective:
✓ Propose an approach for cross-border exchange of eP content
✓ Provide uniform representation of the eHDSI basic dataset of eP by means of QR code
1.1 International exchange of ePrescriptions - Methods

Primary Use case for eP cross-border exchange:

Actors:
- Patient
- Dispenser (Dispenser Provider)
- National Contact Points (NCP) in country A (patient’s country)
- National Contact Points (NCP) in country B

Message exchange
- Assumes permanent network availability between pharmacies and NCPs
- Involves large number of bidirectional transformations of eP data between different CIM
- Centralized, NCP- based flow of events
- Allows merely technical interoperability
Business Process Model & Notation (BPMN) diagram (OMG standard) of the primary Use case for cross-border exchange of EPrescriptions

1. Patient identification
2. Patient authorizes eP extract
3. Dispencer extracts Patient’s ePs
4. Patient selects Product
5a. Patient gets Medicinal Product
5b. NCP A saves Dispense report

Centralized, NCP-based flow of events
1.1 International exchange of ePrescriptions-Methods

Inversion of Control:
- The Patient-based centralized control over the ePrescription processing
- The eHDSI basic data set of eP is represented in a CIM-independent XML model
- Represent the eP dataset in QR code technology

Expected benefits:
- QR code storage of eP details is aligned with recently introduced regulations for identification of medicinal products
- Seamless integration of the eP service in pharmacy software
Computer experiments for generating ePrescription content:
- A CIM-independent XML model is developed
- Web application to generate eHDSI “friendly” real-life data for ePrescription
- The ePrescription content is stored in instances of that model
- The XML is compacted in JSON and stored in QR code
1.2 International exchange of ePrescriptions - Results

XML scheme of the eHSDI basic dataset of an ePrescription.

Main sections:
1. Patient identification
2. Health Professional identification
3. Prescription clinical data
4. Prescription data
Note:
1. The ePrescription stores in QR code data for a single Medicinal product.
2. QR code technology provides means for Patient identification.

1a. Patient identification
1b. Patient authorizes eP extract
2. Dispenser serves the product
3a. Patient receives the Product
3b. NCP A saves Dispense report

Patient-based flow of events
1.2 International exchange of ePrescriptions- Results

Inversion of Control reproduces the natural way to handle a prescription, where the Patient has full control over management of prescription data.

**Computer experiments:**
- Demonstrate practicability of the proposed approach
- Allow significant reduction of message exchanges
- Enable off-line feasibility of eHDSI functional requirements
- Based on QR code representation of ePrescription content
- Allow seamless integration in existing pharmacy software
- Complies with regulations for unique identification of medicinal products
1.3 International exchange of ePrescriptions-

**Summary**

**Advantages:**
- Satisfies the EHDSI functional requirements
- Significantly reduces message exchanges
- Enables off-line operation of the ePrescription service
- Employs XML scheme that is independent of any CIM
- ePrescription cross-border exchange between different CIMs

**Disadvantage**
- Needs support by EU governments and service providers

**Future research work**
- Develop algorithms for secure processing of ePrescription content in QR code
- Improve the process of compiling ePrescription content

*Video presentation in YouTube*

1.3 International exchange of ePrescriptions—Summary

Publications

Evgeniy Krastev, Petko Kovachevachev, Dimitar Tcharaktchiev, Simeon Abanos, Using QR Code for Uniform Representation of Content in Cross-border Exchange of ePrescriptions in the EU, 31th Medical Informatics Europe conference (MIE 2021), May 29 – 31 (2021), Athens, Greece, pp. 684 – 68. DOI:10.3233/SHTI210259,

2. International Patient Summary (IPS) Case study introduction

The International Patient Summary (IPS) has a long story:

- **epSOS**, meaning "Smart Open Services for European Patients"—cross-border pilot projects for Patient Summary and ePrescription exchange
- Joint Action to support the eHealth Network project (**JAsEHN**)
- eHealth Digital Service Infrastructure (**eHDSI**)
International Patient Summary (IPS) for Unscheduled, Cross-border Care

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

FINAL DRAFT
FprEN 17269

TECHNICAL SPECIFICATION
SPÉCIFICATION TECHNIQUE
TECHNISCHE SPEZIFIKATION

July 2019
September 2018
2.1 International Patient Summary (IPS) Case study objectives

- Implement the IPS Medication section in prEN 17269 both in terms of CEN 13606 Archetype Object Model (AOM) and in terms of the openEHR AOM.

- Explore the compatibility of the obtained CEN 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 CEN 13606 or openEHR archetype conceptual models into a format that enables the creation of archetype instances compatible with Native XML Databases (NXD).
2.1 International Patient Summary (IPS) Case study methods

IPS Design with Archetype Concepts

The Archetype Paradigm
(ISO EN 13606:1, ISO EN 13606:2, openEHR)

✓ Based on a dual Information model comprising:
  o A Reference Model (RM) - a generic model for all possible kinds of records
  o Archetype Object Model - specification of constraints to the RM

✓ Makes ‘Plug-and-Play’ semantic interoperability possible

✓ One general health record specification can be implemented only once
IPS Design with Archetype Concepts

18.1 Overview Description for MEDICATION SUMMARY

<table>
<thead>
<tr>
<th>Patient clinical data</th>
<th>Hierarchy:</th>
<th>Conformance</th>
<th>Description</th>
<th>Further Details</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>H1</td>
<td>H2</td>
<td>H3</td>
<td>H4 -- H7</td>
</tr>
<tr>
<td>IPS Section:</td>
<td>MEDICATION SUMMARY (PART 1)</td>
<td>M</td>
<td>Every IPS conformant to IPS must contain this IPS section.</td>
<td>#1</td>
</tr>
<tr>
<td>Synonyms: None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Acronym: None</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Medication Summary content status</td>
<td>C</td>
<td>Coded Element</td>
<td>#2</td>
<td></td>
</tr>
<tr>
<td>List of medication</td>
<td>C</td>
<td>List</td>
<td>#3</td>
<td></td>
</tr>
<tr>
<td>Medication</td>
<td>M</td>
<td>Label Concept</td>
<td>#4</td>
<td></td>
</tr>
</tbody>
</table>
2.2 International Patient Summary (IPS). Case study Results
2.2 International Patient Summary (IPS). Case study Results

Conceptual Design With Archetypes
2.2 International Patient Summary (IPS). Case study Results

Software Implementation
2.2 International Patient Summary (IPS). Case study Results

openEHR engine

✓ data repository with a REST web services API

✓ Document structures defined as Archetypes

✓ Archetypes embedded into openEHR Operational Templates

✓ Provides an Archetype Query Language

✓ Agnostic about what data is stored in its database
2.2 International Patient Summary (IPS). Case study Results

openEHR Frontend Application- prototype
2.3 International Patient Summary (IPS).

Case study Summary

Novel results- video presentation in YouTube:

✓ Applied the Archetype paradigm in software applications that implement the draft version of the IPS standard.

✓ Proposed a methodology for applying the proposed IPS standard in use cases where semantic interoperability is a requirement.

✓ Provide public access to IPS implementation in archetypes in ISO 13606 and openEHR.

✓ Established difficulties in implementing semantic interoperability with IPS due to the lack of free access to terminology servers.

✓ The obtained archetype conceptual model is ready for reuse in software applications.

✓ Established that it is not possible to convert ISO 13606 archetypes directly into openEHR archetypes.

✓ Relational databases are more suitable for openEHR implementations of the IPS, while ISO 13606 implementations of the IPS are more productive with Native XML databases.
2.3 International Patient Summary (IPS). Case study Summary

✓ The current draft versions of EN 17269 and CEN/TS 17288. **make use exclusively** of HL7, FHIR and HL7 CDA technologies

✓ The analysis of these documents shows that they are built with a **focus on top of the Message paradigm** and provide examples where semantic interoperability is not taken in consideration.

✓ **The obtained results provide evidence that EN 17269 and CEN/TS 17288 can be enabled to provide semantic interoperability**, where the IPS design is based on the Archetype paradigm.

✓ **The obtained results are novel** because the Archetype paradigm is not considered in draft version of the IPS standard EN 17269 and 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

*Video presentation in YouTube*
2.3 International Patient Summary (IPS). Case study Summary

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3. OMOP Common Data Model

European Health Data & Evidence Network (EHDEN):

Objective:
✓ Create an **EU-wide ecosystem** for federated analyses of observational data by mapping to the **OMOP CDM** an excess of 100+ millions of anonymous health records

❑ Supported by a large number of certified **Small-to-Medium-sized Enterprises (SME)**, **OHDSI Software and Tools**, **OMOP Standardized vocabularies** and **Technical infrastructure Services**.

❑ **EHDEN Data Partner**
**National Scientific Program E-Health in Bulgaria**
3. OMOP Common Data Model

Digital health technologies produce huge amounts of data related to patient health collected as part the execution of routine healthcare services under real-world conditions.

Data collected from such sources is collectively known as observational data (OD).

The Observational Medical Outcomes Partnership (OMOP) Common Data Model (CDM) is an open community data standard, designed to standardize the structure and content of observational data and to enable efficient analyses that can produce reliable evidence.

It is a unified database model that allows to integrate various OD sources including EHRs based on this standard.
3. OMOP Common Data Model

- Person
  - Observation_period
  - Visit_occurrence
  - Visit_detail
  - Condition_occurrence
  - Drug_exposure
  - Procedure_occurrence
  - Device_exposure
  - Measurement
  - Note
  - Note_NLP
  - Survey_conduct
  - Observation
  - Specimen
  - Fact_relationship

- Standardized health system data
  - Location
  - Location_history
  - Care_site
  - Provider

- Standardized derived elements
  - Condition_era
  - Drug_era
  - Dose_era

- Results schema
  - Cohort
    - Cohort_definition

- Standardized metadata
  - CDM_source
  - Metadata

- Standardized vocabularies
  - Concept
  - Vocabulary
  - Domain
  - Concept_class
  - Concept_relationship
  - Relationship
  - Concept_synonym
  - Concept_ancestor
  - Source_to_concept_map
  - Drug_strength
The Common Data Model (CDM) defines the structure and content of data to provide significant and reproducible results.

**CDM Design Principles:**
- Suitability for purpose
- Data protection:
- Design of domains
- Rationale for domains
- Standardized Vocabularies
- Reuse of existing vocabularies
- Maintaining source codes
- Technology neutrality
- Scalability
- Backwards compatibility
3. OMOP Common Data Model

- **Suitability for purpose**: The CDM aims to provide data organized in a way optimal for analysis, rather than for the purpose of addressing the operational needs of health care providers or payers.

- **Data protection**: All data that might jeopardize the identity and protection of patients, such as names, precise birthdays etc. are limited. Exceptions are possible when the research expressly requires more detailed information, such as precise birth dates for the study of infants.

- **Design of domains**: The domains are modeled in a person-centric relational data model, where for each record the identity of the person and a date is captured as a minimum. Here, a relational data model is one where the data is represented as a collection of tables linked by primary and foreign keys.

- **Rationale for domains**: Domains are identified and separately defined in an entity-relationship model if they have an analysis use case (conditions, for example) and the domain has specific attributes that are not otherwise applicable. All other data can be preserved as an observation in the observation table in an entity-attribute-value structure.
3. OMOP Common Data Model

• **Standardized Vocabularies**: To standardize the content of those records, the CDM relies on the Standardized Vocabularies containing all necessary and appropriate corresponding standard healthcare concepts.

• **Reuse of existing vocabularies**: If possible, these concepts are leveraged from national or industry standardization or vocabulary definition organizations or initiatives, such as the National Library of Medicine, the Department of Veterans’ Affairs, the Center of Disease Control and Prevention, etc.

• **Maintaining source codes**: Even though all codes are mapped to the Standardized Vocabularies, the model also stores the original source code to ensure no information is lost.

• **Technology neutrality**: The CDM does not require a specific technology. It can be realized in any relational database, such as Oracle, SQL Server etc., or as SAS analytical datasets.

• **Scalability**: The CDM is optimized for data processing and computational analysis to accommodate data sources that vary in size, including databases with up to hundreds of millions of persons and billions of clinical observations.
3. OMOP Common Data Model

Backwards compatibility: All changes from previous CDMs are clearly delineated in the github repository

✓ The CDM is considered a “person-centric” model, meaning that all clinical Event tables are linked to the PERSON table. Together with the date or start date this allows for a longitudinal view on all healthcare-relevant Events by person. The exceptions from this rule are the standardized health system data tables, which are linked directly to Events of the various domains.

✓ Schemas, or database users in some systems, allow for separation between read-only and read-write tables. The clinical Event and vocabulary tables are in the “CDM” schema and are considered read-only to the end user or analytic tool. Tables that need to be manipulated by web-based tools or end users are stored in the “Results” schema.

✓ The CDM is platform-independent. Data types are defined generically using ANSI SQL data types (VARCHAR, INTEGER, FLOAT, DATE, DATETIME, CLOB). Precision is provided only for VARCHAR. The CDM does not prescribe the date and datetime format.

✓ CDM provides standardized DDL SQL for creating schemas according CDM model for most RDBMs like PostgreSQL, Oracle, MSSQL, BigQuery, Amazon Redshift and other.
3. OMOP Common Data Model

CDM General conventions:
- General Conventions of the Model
- General Conventions of Schemas
- General Conventions of Data Tables
3.1 OMOP Common Data Model Methods

A. Preparing the CDM database

B. Creating the required database users;

C. Creating the OMOP CDM tables with the Common Data Model/MSSQL DDL scripts;

D. Importing the standard OMOP standarizied vocabularies from [http://athena.ohdsi.org](http://athena.ohdsi.org)

- All the OHDSI sources are available at [http://github.org/OHDSI](http://github.org/OHDSI).
3.1 OMOP Common Data Model Methods

ETL - Extract Transform Load

In order to get from the native/raw data to the OMOP Common Data Model (CDM) we have to create an extract, transform, and load (ETL) process with these steps:

1. Design the ETL
2. Create the Code Mappings
3. Implement the ETL
4. Quality Control
3.1 OMOP Common Data Model Methods

ETL - Extract Transform Load

1. To initiate an ETL process on a database we need to understand source data, including the tables, fields, and content. The White Rabbit software from OHDSI to perform a scan of the source data. The scan generates a report used as a reference when designing the ETL. With the White Rabbit scan in hand, we have a clear picture of the source data. We also know the full specification of the CDM.

2. With Usagi from OHDSI tools we perform manual process of creating a code mappings with standard source codes to Vocabulary concepts.

3. Once the design and code mappings are completed, the ETL process is implemented with ETL-CDM Builder. As result, we have CDM relevant database populated with the data from the source database.

For the extract, transform, load process, quality control is iterative. The typical pattern is to Write logic > Implement logic > Test logic > Fix.
3.2 OMOP Common Data Model Results

The most convenient and precise approach to perform observational study against CDM database is to use ATLAS free, publicly available, web-based tool developed by OHDSI that facilitates the design and execution of analyses on standardized, patient level, observational data in the CDM form.
ATLAS is deployed as a web application in combination with the OHDSI Web API and is hosted on Apache Tomcat and could be deployed and started as Docker container or cloud service.

- **Data Sources** - provides the capability review descriptive, standardized reporting for each of the configured data sources.
- **Vocabulary Search** - provides the ability to search and explore the OMOP standardized vocabulary.
- **Concept Sets** provides the ability to create collections of logical expressions that can be used to identify a set of concepts to be used throughout your standardized analyses.
- **Cohort Definitions** - ability to construct a set of persons who satisfy one or more criteria for a duration of time.
3.2 OMOP Common Data Model Results

- **Characterizations** - an analytic capability that allows you to look at one or more cohorts and to summarize characteristics about those patient populations.

- **Cohort Pathways** - Cohort pathways is an analytic tool that allows you to look at the sequence of clinical events that occur within one or more populations.

- **Incidence Rates** - a tool that allows you to estimate the incidence of outcomes within target populations of interest.

- **Profiles** - tool that allows exploring of an individual patients longitudinal observational data to summarize what is going on within a given individual.

- **Population Level Estimation** - a capability that allows to define a population level effect estimation study using a comparative cohort design whereby comparisons between one or more target and comparator cohorts can be explored for a series of outcomes.
3.2 OMOP Common Data Model Results

- **Patient Level Prediction** - allows to apply machine learning algorithms to conduct patient level prediction analyses whereby you can predict an outcome within any given target exposures.

- **Jobs** - used to explore the state of processes that are running through the WebAPI.

- **Configuration** - to review the configured data sources that have been in the source configuration section.
Entity relationship diagram of the Source database taken from the Bulgaria Diabetes Register (DIAB2018)
<table>
<thead>
<tr>
<th>Source Table</th>
<th>English Name</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>AmbLists</td>
<td>AmbLists</td>
<td>Outpatient records generated during a visit to GP or Specialist of Ambulatory Care, coded in ICD9.</td>
</tr>
<tr>
<td>Diagnoses</td>
<td>Diagnoses</td>
<td>Diagnoses set in Outpatient record</td>
</tr>
<tr>
<td>Doctors</td>
<td>Doctors</td>
<td>Doctors data</td>
</tr>
<tr>
<td>HospitalizationLists</td>
<td>Hospitalization Lists</td>
<td>List with hospitalization directions related to an outpatient record</td>
</tr>
<tr>
<td>HospitalNapravlenie</td>
<td>HospitalNapravlenie</td>
<td>Direction for hospitalization</td>
</tr>
<tr>
<td>MDdirections</td>
<td>MDdirections</td>
<td>Direction for medical examination by Specialist in Ambulatory care</td>
</tr>
<tr>
<td>Patients</td>
<td>Patients</td>
<td>Patient description data</td>
</tr>
<tr>
<td>PrimaryVisit</td>
<td>PrimaryVisit</td>
<td>Initial visit to a Specialist in Ambulatory Care</td>
</tr>
<tr>
<td>Procedures</td>
<td>Procedures</td>
<td>Procedures assigned in Outpatient record</td>
</tr>
<tr>
<td>Profilact</td>
<td>Profilact</td>
<td>Describes a visit for Disease prevention</td>
</tr>
<tr>
<td>RecipeBooks</td>
<td>RecipeBooks</td>
<td>Recipe Books of Patient</td>
</tr>
<tr>
<td>Recipies</td>
<td>Recipies</td>
<td>Recipes for reimbursable medicinal products. These are stored in the patient’s Recipe Book</td>
</tr>
<tr>
<td>Reimbursables</td>
<td>Reimbursables</td>
<td>Reimbursable medicinal products</td>
</tr>
<tr>
<td>SecondaryVisit</td>
<td>SecondaryVisit</td>
<td>Secondary visit to a Specialist in Ambulatory Care</td>
</tr>
<tr>
<td>SIMPConsults</td>
<td>SIMPConsults</td>
<td>Specialized Medical care</td>
</tr>
<tr>
<td>VSDSIMPConsults</td>
<td>VSDSIMPConsults</td>
<td>Highly Specialized Medical care</td>
</tr>
<tr>
<td>BloodPressure</td>
<td>BloodPressure</td>
<td>Blood pressure values measured in mmHg extracted from natural language text description of patient status and examination data</td>
</tr>
<tr>
<td>BloodSugar</td>
<td>BloodSugar</td>
<td>Blood sugar profile first value measured in mmol/l extracted from natural text description of patient status and examination data</td>
</tr>
<tr>
<td>BMldata</td>
<td>BMldata</td>
<td>Body Mass Index data extracted from natural language text description of patient status and examination data. Table includes also Height and Weight measurements in sm and kg, when Height and Weight data are found in the text</td>
</tr>
<tr>
<td>HbAc1Data</td>
<td>HbAc1Data</td>
<td>Contains values of HbAc1 extracted from natural language text description of patient status and examination data measured in mmol/mol</td>
</tr>
<tr>
<td>DiabetTimeData</td>
<td>DiabetTimeData</td>
<td>Contains the number of years before the illness diabetes has been established for the first time, extracted from natural language text description of patient status and examination data</td>
</tr>
<tr>
<td>TrigData</td>
<td>TrigData</td>
<td>Contains values of triglycerides extracted from natural language text description of patient status and examination data and measured in mmol/L</td>
</tr>
</tbody>
</table>
3.2 OMOP Common Data Model
Results

In Bulgaria outpatient records are produced by the General Practitioners (GPs) and the Specialists from Ambulatory Care for every contact with the patient.

- Outpatient records from patients with diabetes are maintained by the Bulgarian Diabetes Register. These records represent a true example of OD that can be produce valuable evidence for improving the treatment and management the healthcare services for such patients. The outpatient records are semi-structured files with predefined XML schema.

- The source XML documents included more than 1,600,000 pseudo anonymized outpatient records. The most important indicators in the records like Age, Gender, Location, Diagnoses are stored in explicit tags.

- The Case history is presented as free text in the Anamnesis. Additionally, these records include in native text information about the Patient status described the patient state, symptoms, syndromes, patients’ height and weight, body mass index (BMI), blood pressure and other clinical concepts.

- The values of clinical tests and lab data are enumerated also as free text in a separate section of the XML document. A special section is dedicated to the prescribed treatment.
3.2 OMOP Common Data Model Results

Source data from DIAB2018 to CDM v. 5.3.0 database mapping using White Rabbit

Database features:

Common data models (CDMs) offer a standardized approach for data persistence and exchange. This is especially useful when nowadays clinical data is distributed among heterogeneous sharing systems. Besides, OHDSI provides software tools in support on each stage of the ETL and ensure quality control. Therefore, data CDM possesses all the features of a reliable source for a broad range of statistical analyses.

This case study presents initial results of a research work done with the objective to transfer outpatient records from the Bulgarian Diabetes register into the OMOP CDM. One of the major challenges has been the extraction of clinical data from native text as well as the use of international OMOP concepts to annotate data recorded in a Bulgarian context.
3.3 OMOP Common Data Model Summary

Publications:


Acknowledgment

This research is supported by the National Scientific Program eHealth in Bulgaria
Thanks for your attention!

Questions?

Comments?