D8.4 – Exploratory study for decision aids and citizen driven health science

WP 8 – EEHRXF COMMUNITIES OF PRACTICE: FROM PROOF OF CONCEPT TO LARGESCALE ADOPTION AND INFRASTRUCTURE FOR INNOVATION

12-09-2022

Version 1.0
Status: Final

Grant Agreement nº 951938
Abstract

Deliverable D8.4 reports the results of an exploratory proof-of-concept study around patient decision aids and citizen-driven health science. The objectives of this study were to investigate how EEHRxF can be applied in selected use cases to better serve citizens, and to describe a methodology for incorporating EEHRxF in future use cases. The ISO standard "ISO 27269:2021 Health informatics — International patient summary" was used as a frame of reference for this work. To address this novel area for the use of the patient summary, literature reviews were performed on different topics, namely patient generated health data (PGHD) and patient reported outcome measures (PROM), sensor ontologies for health care, and further emerging areas (artificial intelligence, clinical research, and business analytics). Barriers for using PGHD in the context of the patient summary were identified and categorised according to the Refined eHealth European Interoperability Framework (ReEIF). A tangible use case scenario containing capture and use of PGHD was modelled as an application example using HL7 FHIR. Based on the results of this modelling exercise, we proposed a detailed process to explore new areas, starting by setting up a project team and concluding with a seven-step modelling process.

Further areas such as artificial intelligence, outcomes-based research, clinical research, clinical trial integration and business analytics in the context of the patient summary have been reviewed but have not been modelled in more detail. The results showed that these areas have not been much explored in relation to patient summaries, but the review elicited some specifications of variables, algorithms or methodologies that can be considered for further development of the patient summary.

Key Words: Citizen Driven Health Science; Decision Aids; Interoperability; Patient Empowerment; Patient Generated Health Data
REVISION HISTORY

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<td>0.1</td>
<td>31-12-2021</td>
<td>S. Bonacina, YC Li F. Rugolon, R. Silva, S. Koch</td>
<td>KI</td>
<td>First version of the document</td>
</tr>
<tr>
<td>0.2</td>
<td>30-05-2022</td>
<td>F. Rugolon, R. Silva</td>
<td>KI</td>
<td>Changes Section 2.1.2 and 3.2</td>
</tr>
<tr>
<td>0.3</td>
<td>28-07-2022</td>
<td>S. Bonacina, R. Silva</td>
<td>KI</td>
<td>Added Section 2.1.3 and changes 3.3</td>
</tr>
<tr>
<td>0.4</td>
<td>16-08-2022</td>
<td>S. Bonacina, F. Rugolon, R. Silva, S. Koch</td>
<td>KI</td>
<td>Version for internal review: Revised structure, added Lessons learned, Recommendations, Conclusions and Abstract</td>
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<tr>
<td>0.5</td>
<td>02-09-2022</td>
<td>C. Wray</td>
<td>DOH-IE</td>
<td>Commented version after internal review</td>
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<tr>
<td>1.0</td>
<td>12-09-2022</td>
<td>S. Koch, S. Bonacina</td>
<td>KI</td>
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<tr>
<td>BFO</td>
<td>Basic Formal Ontology</td>
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<tr>
<td>CGM</td>
<td>Continuous Glucose Monitoring</td>
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<tr>
<td>CoP</td>
<td>Community of Practice</td>
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<td>EEHRxF</td>
<td>European Electronic Health Record Exchange Format</td>
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<td>eHDSI</td>
<td>eHealth Digital Service Infrastructure</td>
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<td>EIF</td>
<td>European Interoperability Framework</td>
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<tr>
<td>EPO</td>
<td>Extension Plug-in Ontology</td>
</tr>
<tr>
<td>FASTO</td>
<td>FHIR and SSN-based T1D Ontology</td>
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<td>FHIR</td>
<td>Fast Healthcare Interoperability Resources</td>
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<tr>
<td>GML</td>
<td>Geography Markup Language</td>
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<td>JSON-LD</td>
<td>JavaScript Object Notation – Linked Data</td>
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<td>IoT</td>
<td>Internet of Things</td>
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<tr>
<td>LHR</td>
<td>Linked Health Resource</td>
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<tr>
<td>PGHD</td>
<td>Patient Generated Health Data</td>
</tr>
<tr>
<td>OAE</td>
<td>Ontology for Adverse Effects</td>
</tr>
<tr>
<td>OBOE</td>
<td>Observation Ontology</td>
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<tr>
<td>O&amp;M</td>
<td>Observations and Measurements</td>
</tr>
<tr>
<td>PHR</td>
<td>Personal Health Record</td>
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<tr>
<td>PROMs</td>
<td>Patient Reported Outcome Measures</td>
</tr>
<tr>
<td>PROV-O</td>
<td>PROV Ontology</td>
</tr>
<tr>
<td>QoI</td>
<td>Quality of Information</td>
</tr>
<tr>
<td>QU</td>
<td>Quantity Units</td>
</tr>
<tr>
<td>RDF</td>
<td>Resource Description Framework</td>
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<tr>
<td>RDFa</td>
<td>Resource Description Framework in Attributes</td>
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<tr>
<td>SDM</td>
<td>Shared Decision Making</td>
</tr>
<tr>
<td>SDO</td>
<td>Sensor Data Ontology</td>
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<tr>
<td>SHO</td>
<td>Sensor Hierarchy Ontology</td>
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<tr>
<td>SM</td>
<td>Self-management</td>
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<tr>
<td>SmartBAN</td>
<td>Smart Body Area Network</td>
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<tr>
<td>SOSA</td>
<td>Sensors, Observations, Samples, Actuators</td>
</tr>
<tr>
<td>SSN</td>
<td>Semantic Sensor Network</td>
</tr>
<tr>
<td>SUMO</td>
<td>Suggested Upper Merged Ontology</td>
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<tr>
<td>SWE</td>
<td>Sensor Web Enablement</td>
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<tr>
<td>SWRL</td>
<td>Semantic Web Rule Language</td>
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Scope and Interdependencies

In scope

Deliverable D8.4 is the output of Task 8.3: Exploratory Proof of concept study: from European Electronic Health Record Exchange Format (EEHRxF) to decision aids and citizen driven health science. This exploratory task links EEHRxF to parallel initiatives that are in the process of assessing and integrating new concepts and tools such as for example AI, outcomes-based research, clinical research, clinical trial integration, business analytics, decision aids for patients, and citizen-driven health-science, etc.

The study will result into clear recommendations for incorporating the EEHRxF in selected use cases in these areas, taking technical, legal, procedural, and other barriers into account.

Out of scope

The exploratory study will be limited to defined use cases related to patient generated health data (PGHD) and patient reported outcome measures (PROMs) for self-management and shared decision making. One specific application scenario will be modelled in detail as an example. Use cases not related to patient decision aids and citizen-driven health science will not be analysed.
1 Introduction

The overall vision of X-eHealth is to contribute to a European Union (EU) with integrated health processes in which the health record of every European citizen can be immediately accessed and fully understood by healthcare professionals and citizens in any Member State regardless of the point of care.

An important goal of X-eHealth is to contribute to a Common European Health Data Space, that addresses the challenge of healthcare integration through interoperable and implementable data models, exchange formats and standardised solutions, at cross-border, but also at national, regional, and local levels, between providers themselves and between providers and citizens, taking privacy and cybersecurity regulations into account. Thus, the proposed work is to highlight, contribute and support European eHealth interoperability and the implementation of the EEHRxF through standardisation and harmonisation of health data, providing quality and safety while empowering the patients, professionals, and health institutions.

The key goals of X-eHealth are to:

- Improve healthcare quality and safety for citizens by allowing them to access and manage their electronic health record from any place in the EU
- Contribute to standardisation and harmonisation of eHealth services in the EU by setting European agreements on diverse levels of interoperability
- Contribute to defragmentation of European services
- Facilitate interaction between patients and healthcare providers, to support prevention and citizen empowerment

X-eHealth specific objectives are:

1. To reach a common understanding in the EU on the efforts needed to adopt the commonly defined EEHRxF specifications at different levels and within their national EHR solutions
2. To define, specify and demonstrate the EEHRxF use cases laboratory results, medical imaging and reports, hospital discharge reports and patient summary for those suffering from rare disease and/or comorbidities.
3. To elaborate the roadmap for the above-mentioned use cases for future uptake on the eHealth Digital Service Infrastructure (eHDSI) as well as for the additional usage within Member States on national, regional, or local level
4. To submit the outcomes and recommendations of X-eHealth regarding EEHRxF deployment to the relevant bodies on policy, strategic and operational level (e.g., eHealth Network, National Competence Centres for eHealth, eHDSI operators)
5. To propose a governance framework for the sustainable maintenance, evolution and
distribution of standardisation and interoperability

2 Objectives and principles

Deliverable D8.4 reports on the exploratory work done in relation to novel use cases towards citizens and contributes specifically to the X-eHealth goal to “facilitate interaction between patients and healthcare providers, to support prevention and citizen empowerment”. This is done by performing an exploratory proof of concept study dedicated to patient decision aids and citizen-driven health science. Drawing from these experiences, a methodology for incorporating EEHRxF in future use cases is presented, describing the process of assessing and integrating new concepts and tools rather than providing a proof-of-concept demonstration.

The concrete objectives of this deliverable are to
1. Elicit more detailed requirements for the EEHRxF to better serve citizens
2. Investigate how EEHRxF can be applied in selected use cases and uncover possible barriers
3. Describe a methodology for incorporating EEHRxF in future use cases
4. Disseminate the results of the work

As a frame of reference for this exploratory work the ISO standard "ISO 27269:2021 Health informatics — International patient summary" was used (ISO 27269:2021). According to this standard “An International Patient Summary (IPS) document is an electronic health record extract containing essential healthcare information about a subject of care”. The IPS document is composed of specified, reusable sets of core data items that belong to the IPS Library (Figure 1). The entire IPS dataset is supposed to be “minimal and non-exhaustive; specialty-agnostic and condition-independent; but still clinically relevant” (ISO 27269:2021).
3 Methods

Shared decision making and citizen science have been identified as key issues to be addressed in the EEHRxF. A document analysis of the recommendation (European Commission, 2019), its annex, and the guidelines about the patient summary (eHealth Network, 2016), showed however, that guidance on how to use the specification to facilitate shared decision making is absent (Bonacina et al., 2021). In fact, the Patient Summary does not include any sections devoted to shared decision making, besides the aim to support patient empowerment.

To address this novel area for the use of the Patient Summary, we first performed literature reviews on different topics, namely patient generated health data (PGHD) and patient reported outcome measures (PROM), sensor ontologies for health care, and further emerging areas (Artificial Intelligence, clinical research and business analytics) (section 4). Second, we identified and described barriers for using PGHD and categorised them according to the Refined eHealth European Interoperability Framework (ReEIF) (eHealth Network, 2017) (section 5.1). Third, we provided a concrete use case scenario and modelled it as an application example using HL7 FHIR (section 5.2). The International Patient Summary was used as a reference to guide the modelling. Last, we summarised our lessons learned from this exploratory study (section 6) and provided recommendations on the process of including new use cases (section 7).
4 Literature reviews

An initial literature search including “shared decision making”, “citizen science” and “electronic health record” as search terms. Our results showed that targeted use cases, datasets and associated metadata are needed for the EEHRxF to reliably support and promote citizen science and shared decision-making perspectives (Bonacina et al., 2021 – Appendix 1). It further revealed that patient generated health data (PGHD) and person reported outcome measures (PROMs) are potential resources to share under the EEHRxF to empower citizens to achieve better self-management and facilitate shared decision making between patients and health professionals. Thus, a scoping review was conducted to identify and synthesise existing knowledge on the capture, sharing and utilisation of PGHD and PROMs for self-management (SM) and shared decision making (SDM) (Li, 2021).

4.1 PGHD and PROMs for self-management and shared decision making

A total of 40 articles were reviewed. The most common PGHD and PROMs were classified into three categories, physiological data (n=25), psychometric data (n=22) and lifestyle data (n=15). Glucose value (n=6) and heart rate (n=6) ranked top for physiological data collection. Health literacy ranked top for psychometric data (n=13). Physical activity ranked top for lifestyle data (n=11). Data capture was mostly done through wearable devices (n=13), followed by medical devices (n=8). Personal health records (PHR) were commonly used as software for data entry and management (n=13). Despite the use of technology in many cases, traditional pen and paper questionnaires were still a popular way of collecting PROMs manually (n=8). Most articles described the use of self-monitoring (n=16) for SM while some articles addressed the identification of contextual factors to SM (n=10) Most articles addressed information exchange between healthcare providers and patients (n=9). Some articles mentioned how data facilitated the decision-making process during the medical encounter (n=7).

Figure 2 gives an overview of the analytic framework, adapted from Shapiro et al. (Shapiro et al., 2012) for analysing the PGHD process, that was used in the scoping review (Li, 2021).
The most common data involved in this study were physiological data, psychometric data, and lifestyle data. Physiological data consisted both of quantifiable signs and more subjective, usually disease specific, symptoms. Examples for signs were measurements of glucose, heart rate, body weight, tremor, pain, and blood pressure. Collection of disease specific symptoms included for example, symptoms for asthma, cardiovascular disease, rheumatoid arthritis, gastrointestinal disease, and epilepsy.

Psychometric data included health literacy and disease specific knowledge, measurement of attitude/evaluation to shared decision making, measurement of self-management efficacy and behaviour, quality of life, physical and psychological health status.

Lifestyle data included physical activity, food intake, medication adherence and sleep. Some other, commonly collected data, were social data, ambient data, diary text and medical history.

PGHD was the dominant type of data found in the review by Li (Li, 2021) whereof a majority are captured by sensors. We therefore further searched for sensor ontologies used in health care that could possibly be applied in the context of the Patient Summary.

### 4.2 Sensor ontologies for health care

We first investigated specialty-agnostic and condition-independent ontologies, that could help the integration of any kind of personal sensor data into the EHR. The retrieved ontologies were often high-level ones and sometimes were not specific for healthcare (e.g., SOSA (Janowicz et al., 2019), IoT-Stream (Elsaleh et al., 2020)).

Other ontologies have only been developed on a theoretical level (e.g., LHR (Peng & Goswami, 2019), A Universal Ontology for Sensor Networks Data (Eid et al., 2007), Service-Oriented Ontology for Wireless Sensor Networks (Kim et al., 2008)).
While some of these ontologies have been successfully implemented (e.g., IETF YANG (Jin & Kim, 2018), IoT-Stream (Elsaleh et al., 2020)) in healthcare-related domains, proposing them as a solution did not seem completely satisfying.

A second search for more specific, condition-dependent ontologies retrieved FASTO (El-Sappagh et al., 2019), which is specific for the monitoring of Diabetes type 1, emerged. A solution based on such an ontology cannot be applied to all possible patient conditions, but the level of detail offered by this solution is naturally higher than the condition-agnostic ontologies. In addition, the implementation uses the HL7 FHIR standard, which could allow for a faster implementation of this solution. A solution based on condition-specific ontologies, like FASTO, will need to make use of more than one ontology to be able to monitor many individuals and different conditions.

Table 1: Review of published sensor ontologies

<table>
<thead>
<tr>
<th>Main ontology</th>
<th>Data structure</th>
<th>Building block ontologies</th>
<th>Ontology languages</th>
<th>Messaging standards</th>
<th>Fields of use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sensors, Observations, Samples, Actuators - SOSA (Janowicz et al., 2019)</td>
<td>Observations are conceived as acts or events (Janowicz et al., 2019, section 5.3)</td>
<td>Builds upon Semantic Sensor Network (SSN), introducing alignments to PROV Ontology (PROV-O), Observations and Measurements (O&amp;M), Observation Ontology (OBOE).</td>
<td>Can use Resource Description Framework in Attributes (Rdfa) (section 4.1) or JavaScript Object Notation – Linked Data (JSON-LD) (Janowicz et al., 2019, section 4.2)</td>
<td>Used in more fields than just healthcare.</td>
<td></td>
</tr>
<tr>
<td>Linked Health Resource (LHR) (Peng &amp; Goswami, 2019)</td>
<td>All the resources are represented as Resource Description Framework (RDF)</td>
<td>Some classes are mapped to Fast Healthcare Interoperability Resources (FHIR), SSN, Sensors, Observations, Samples, Actuators (SOSA), Web of Things (WoT) services 1. Description (Peng &amp; Goswami, 2019, section 3.3).</td>
<td>W3C standards, RDF Schema, OWL ontology language</td>
<td>Resources retrieved in a database with SPARQL queries. (SPARQL Protocol and RDF Query Language)</td>
<td>Not implemented</td>
</tr>
<tr>
<td>A Universal Ontology for Sensor Networks</td>
<td>Suggested Upper Merged Ontology (SUMO), composed by:</td>
<td></td>
<td></td>
<td>Unfinished implementation</td>
<td></td>
</tr>
</tbody>
</table>

1 WoT resources are linked mapping objects from the external IoI and WoT vocabulary into the ontology. The mapping extension is described using Resource Description Framework Schema (RDFS) and OWL. The different resources can be classified as environment or health resources into this ontology.
<table>
<thead>
<tr>
<th>Data (Eid et al., 2007)</th>
<th>Sensor Hierarchy Ontology (SHO), Sensor Data Ontology (SDO), Extension Plug-in Ontology (EPO)</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>IETF YANG (Jin &amp; Kim, 2018)</td>
<td>Leaf: for messages containing a single value Container: for messages carrying multiple sensing types of data List: for messages with sequential sensing values List with multiple leaves: for messages with sequential data for multiple sensor outputs. Implementation details are unavailable.</td>
<td>The development of this ontology is ex-novo, not building up on already existing ones.</td>
</tr>
<tr>
<td>IoT-Stream (Elsaleh et al., 2020)</td>
<td>Data is structured as a stream, and events are detected from the stream. For this reason, the observations can be seen as a time series with multiple properties.</td>
<td>For the spatial attributes: W3C Geo, IoT-lite, GeoSPARQL. For the generating source: SOSA, Quantity Units (QU) ontology. For the quality of the stream: Quality of Information (QoI) ontology.</td>
</tr>
</tbody>
</table>
| Service-Oriented Ontology for Wireless Sensor Networks (Kim et al., 2008) | Geography Markup Language (GML), Sensor Web Enablement (SWE), SensorML, Suggested Upper Merged Ontology (SUMO) and OntoSensor ontology | SPARQL queries retrieve RDF graphs. | The retrieved paper is a first attempt to define this ontology. It was published in 2008 and no
4.3 Further concepts: Artificial Intelligence, Clinical Research, Business Analytics

This literature review describes the process of assessing further concepts (outside citizen services) such as for example AI, outcomes-based research, clinical research, clinical trial integration, and business analytics.

**PubMed/Medline - Definition of Search Strategy**

The first step for exploring literature is defining a search strategy. As the Patient Summary is a data structure extracted from medical record (for example, Electronic Health Records, computerised medical records), for exchanging health information, search strings were defined considering the common terms applied for medical records (Figure 3).
Then, the following terms, "medical records systems, computerised"[MeSH Terms] OR "electronic health records"[MeSH Terms] OR computerised medical records[Text Word] were better explored in MeSH vocabulary, and the term “Health Information Exchange” (a “child” of those concepts) considered as a part of the search string. The topics of “decision aids for patients”, and “citizen-driven health-science” were explored in advanced and are presented in section 4.1 of the present document. As for AI, outcomes-based research, clinical research, clinical trial integration, business analytics, the MeSH vocabulary has been explored to find the adequate concept term. Terms “clinical research” and “outcomes-based research” are specialisations of the concepts of “Biomedical research”, and the latter is a specialisation of “Research” concepts. Consequently, “Research” and “Biomedical research” terms will be in the search strings. Then, as for “clinical trial integration”, a wider concept expressed by the term “clinical trial as topic” has been applied. Finally, “Artificial Intelligence” is a MeSH term, while “business analytics” has been used as text word.

Two distinct literature databases have been used for the searches (performed in March-April 2022), namely, PubMed/Medline (https://pubmed.ncbi.nlm.nih.gov/) and Web of Science (https://www.webofscience.com/wos/alldb/basic-search), time span: 01 January 2000 - 28 February 2022.
The specific search strings applied to PubMed/Medline and the results are as follows:

- "Business analytics"[All fields] AND "Health Information Exchange"[MeSH] (10 results)
- "Artificial Intelligence"[MeSH] AND "Health Information Exchange"[MeSH] (42 results)
- "Biomedical Research"[MeSH] AND "Health Information Exchange"[MeSH] AND "Humans"[MeSH] (46 results)
- "clinical trials as topic"[MeSH Terms] AND "Health Information Exchange"[MeSH] (7 results)

The specific search strings applied to Web of Science and the results are as follows:

- TS=("clinical trial") OR TS=("clinical trials") AND (TS=("Patient summary")) OR TS=("Health Information Exchange") (289 results)
- TS=("clinical research") AND (TS=("Patient summary")) OR TS=("Health Information Exchange") (34 results)
- TS=("Artificial intelligence") AND (TS=("Patient summary")) OR TS=("Health Information Exchange") (16 results)
- TS=("outcomes-based research") AND (TS=("Patient summary")) OR TS=("Health Information Exchange") (0 results)
- TS=("business analytics") AND (TS=("Patient summary")) OR TS=("Health Information Exchange") (0 results)

**Topic (TS):** Searches title, abstract, author keywords, and Keywords Plus.

**Health Information Exchange:** “Organizational framework for the dissemination of electronic healthcare information or clinical data, across health-related institutions and systems. Its overall purpose is to enhance patient care.” ([https://www.ncbi.nlm.nih.gov/mesh/?term=Health+information+exchange](https://www.ncbi.nlm.nih.gov/mesh/?term=Health+information+exchange))

The obtained results have been processed according to the PRISMA workflow. Figure 4 shows all the steps of the process, indicating why and how many paper have been excluded from the final analysis. The citations have been stored in a Zotero file, and the analysis has been conducted in two phases. In the first phase (Figure 4a), FR author assessed the papers that met criteria of inclusion about English language, available abstract, topic connected to health information exchange or patient summary, analysing the title and the abstract of the manuscript (Identification, Screening, and Eligibility). In a second phase (Figure 4b), FR and SB authors explored the full text of the manuscript to check their inclusion in the analysis (Included).

All included papers are listed in Table 2 (review papers) and Table 3 (original research papers). Their content has been summarised and the suitability of each paper in relation to Patient Summaries has been analysed. Most papers did not include any content about Patient Summaries or their implementation. Some papers did however include specifications of variables, algorithms or methodologies that can be considered for further development of the Patient Summary.
Figure 4: The steps of the PRISMA workflow. A – Identification, Screening, and Eligibility (by one author, FR); B – Included (by two authors, FR and SB).
Table 2: Review papers included into the analysis

<table>
<thead>
<tr>
<th>#</th>
<th>Title</th>
<th>Summary of the content</th>
<th>Suitability for current research</th>
<th>Citation as (Author, et al., Publication Year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Key components of knowledge transfer and exchange in health services research: Findings from a systematic scoping review.</td>
<td>The concept of knowledge transfer and exchange (KTE) has been defined and investigated. The given definition is “an interactive interchange of knowledge between research users and researcher producers”.</td>
<td>This paper does not include contents about patient summary or its implementation.</td>
<td>(Prihodova L, et al., 2019)</td>
</tr>
<tr>
<td>2</td>
<td>Health information exchanges (HIE) -- Unfulfilled promise as a data source for clinical research.</td>
<td>A different HIE definition has been presented, as “an organisation that oversees and governs the exchange of health-related information among organisations according to nationally recognised standards”, Health Information Technology for Economic and Clinical Health (HITECH) Act, 2009, USA.</td>
<td>This paper does not include contents about patient summary or its implementation.</td>
<td>(Parker C, et al., 2016)</td>
</tr>
<tr>
<td>3</td>
<td>Heart Failure Management Innovation Enabled by Electronic Health Records</td>
<td>It is a review of &quot;Electronic Health Record features that support Congestive heart failure (CHF) care by improving adherence to evidence-based guidelines, supporting efficient care coordination, and facilitating patient engagement&quot;.</td>
<td>The specific case of CHF was considered. Specific implementation guidelines were not provided, though significant variables for the management of CHF were specified.</td>
<td>(Kao DP, et al., 2020)</td>
</tr>
<tr>
<td>4</td>
<td>Patients' support for health information exchange: a literature review and classification of key factors</td>
<td>The research investigates key factors that affect patients’ willingness to support Health information exchanges (HIE), defined as (*). Among the identified factors, you find type of health information, identity of recipients, and patient preferences regarding consent and features.</td>
<td>This paper does not include contents about patient summary or its implementation.</td>
<td>(Esmaeilzadeh P, et al., 2017)</td>
</tr>
</tbody>
</table>
### Table 3: Original research papers included into the analysis

<table>
<thead>
<tr>
<th>#</th>
<th>Title</th>
<th>Summary of the content</th>
<th>Suitability for current research</th>
<th>Citation as (Author, et al., Publication Year)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The impact of data entry structures on perceptions of individuals with chronic mental disorders and physical diseases towards health information sharing</td>
<td>The study examined the influence of structured and unstructured data entry format on perceptions of individuals suffering from mental and physical illnesses on personal health information (PHI) sharing. Individuals suffering from physical illnesses and mental disorders favour highly structured data entry interfaces for data sharing. Individuals with a physical illness favour higher levels of structure mainly due to information quality dimensions.</td>
<td>This paper does not include contents about patient summary or its implementation.</td>
<td>(Esmaeilzadeh P, et al., 2020b)</td>
</tr>
<tr>
<td>2</td>
<td>The effects of data entry structure on patients' perceptions of information quality in Health Information Exchange (HIE)</td>
<td>The study investigated “factors that contribute to or harm patients’ perceptions of data collection and information sharing efforts in order to reinforce information quality.” “Data entry format and features should match the expectations and preferences of patients to be able to collect complete, accurate, and reliable health information”</td>
<td>This paper does not include contents about patient summary or its implementation.</td>
<td>(Esmaeilzadeh P, et al., 2020a)</td>
</tr>
<tr>
<td>3</td>
<td>Automated Transformation of openEHR Data Instances to OWL</td>
<td>The research proposes and assesses a method for automated transformation of openEHR instance data into web ontology language (OWL) individuals. The assessment has been performed on a data sample of 229 patients.</td>
<td>This paper does not include contents about patient summary or its implementation.</td>
<td>(Haarbrandt B, et al., 2016)</td>
</tr>
<tr>
<td>4</td>
<td>Applying Blockchain Technology for Health Information Exchange</td>
<td>The authors &quot;have implemented a private blockchain for Health Information Exchange</td>
<td>This paper does not include contents about patient summary or its implementation.</td>
<td>(Zhuang Y, et al., 2018)</td>
</tr>
<tr>
<td>and Persistent Monitoring for Clinical Trials</td>
<td>[according to HITECH Act, 2009, USA] and persistent monitoring of clinical trials”. In that way, &quot;the FDA could receive raw data from different healthcare providers in real time without barriers or data corruption”. The exploitation of the developed proof of concept to a real system shall face the following issue, “Competing healthcare providers may have concerns about showing their data to others and storing all data in a centralised database.”</td>
<td>summary or its implementation. While the development of the proof of concept is interesting, in the case of a patient summary building a central database is not the target.</td>
<td></td>
<td></td>
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<tr>
<td>---</td>
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<td>---</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Processing Diabetes Mellitus Composite Events in MAGPIE</td>
<td>“The goal of this paper is to report on a programmable expert Personal Health Systems (PHS) for Diabetes mellitus management with the aim of minimising the risk of developing the health complications related with this disease.” “In the presented agent based PHS (main component is the MAGPIE agent platform) the doctors can personalize for each patient monitoring rules that can be defined in a graphical way.” “Furthermore, to achieve better scalability, the computations for monitoring the patients are distributed among their devices rather than being performed in a centralised server.”</td>
<td>This paper does not include contents about patient summary or its implementation. While the development of the programmable expert Personal Health Systems is interesting, an application for the patient summary could be define if “processing algorithms” will also be exchanged among parties.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Common data elements for secondary use of electronic health record data for clinical trial execution and serious adverse event reporting</td>
<td>“Case report forms for 23 clinical trials in differing disease areas, namely Cardiovascular, Diabetes, Infectious, Neuroscience, Oncology, Psychiatric, Respiratory, were analysed.” “The analysis identified 133 unique data elements. Fifty elements were congruent with a published data inventory for patient recruitment and 83 new elements were identified for clinical trial execution, including adverse event reporting.”</td>
<td>This paper does not include contents about patient summary or its implementation. However, the process of identifying common data elements in heterogeneous Electronic Health Record systems can be mirrored for a future</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Building a Semantic Interoperability Framework for Care and Research in Fibromuscular Dysplasia</td>
<td>The research presents the initial phases of the construction of a framework for accessing and comparing heterogeneous and distributed data with a semantics, about Fibromuscular dysplasia (a heterogeneous group of rare vascular diseases). The construction is based on a two steps process: 1 - e-registry: Defining a standardised set of Core Data elements, 2 - Alignment process for Specific Data Elements.</td>
<td>This paper does not include contents about patient summary or its implementation. However, it could be useful for learning how to align concepts expressed differently in different law context (e.g., USA and Europe). This paper might be helpful for the research in D8.2 of the project.</td>
<td>(Jaulent MC, et al., 2015)</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>8</td>
<td>High Performance Computing on Flat FHIR Files Created with the New SMART/HL7 Bulk Data Access Standard.</td>
<td>&quot;Healthcare organisation may want to frequently upload patients’ data from an electronic medical record system to a research data warehouse. To date, the most widely used FHIR API, SMART on FHIR, is targeted at retrieving data on a single patient at a time. Using this API for population data exports, requires thousands or even millions of queries.&quot; &quot;The project aims at creating a Bulk Data Access method that can be used for large scale sharing from any healthcare system with FHIR implemented as interoperability layer.&quot; “The FHIR Bulk Data API may improve population health analysis.”</td>
<td>This paper does not include contents about patient summary or its implementation. However, it provides technical insights on the implementation of a specific API, for concurrently querying data from a huge number of patients.</td>
<td>(Liu D, et al., 2020)</td>
</tr>
<tr>
<td>#</td>
<td>Using ontologies to improve semantic interoperability in health data</td>
<td>&quot;Ontologies are a set of concepts and categories in a subject area or domain that shows their properties and the relations between them.&quot; They are used in health care for (1) modelling the semantics of medical concepts and (2) to facilitate exchange of medical data between disparate systems.&quot; Then, &quot;diverse range of ontologies has been developed to semantically represent health care concepts&quot;. In this study, 1 - A classification of semantic interoperability issues is presented. It includes the categories such &quot;Meaning&quot;, &quot;Granularity&quot;, &quot;Temporal&quot;, and &quot;Structural&quot;, and 2 - An extended toolkit that supports rapid building of ontologies related to chronic disease management is described.</td>
<td>This paper does not include contents about patient summary or its implementation. However, it provides a method for building ontology, including defining concepts.</td>
<td>(Liyanage H, et al., 2015)</td>
</tr>
<tr>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
<td>---</td>
</tr>
<tr>
<td>10</td>
<td>Uncovering Hospitalists' Information Needs from Outside Healthcare Facilities in the Context of Health Information Exchange Using Association Rule Learning</td>
<td>In the study, the authors &quot;uncovered the relationship between health problems and the most critical information requested, from outside health care facilities, in an urban tertiary care hospital in Florida with no HIE functionality, and in planning stages for implementation.&quot; &quot;The objective was to uncover associations between the health problems of the patient and the type of clinical information requested from outside health care facilities.&quot; &quot;Association rule learning (ARL) algorithms were applied to discover strong associations between the health problems (antecedent) and OI outside information, OI) requested (consequent).</td>
<td>This paper does not include contents about patient summary or its implementation.</td>
<td>(Martinez DA, et al., 2015)</td>
</tr>
<tr>
<td>11</td>
<td>An Architecture for the Integration of Clinical Data from a PEHR in a Regional Research Platform.</td>
<td>A regional personal cross-enterprise electronic health record (PEHR) and a regional research platform (RRP) based on information from the PEHR and their integration is the aim of the INFOPAT (INFORMATION technology for PATient oriented health care in the Rhine-Neckar metropolitan region) project. RRP scenario is for cross-sectorial quality assessment and improvement for colorectal cancer based on a quality indicator (QI) approach including patients’ perspectives. Architecture of PEHR and RRP have been integrated applying interfaces based on Integrating the Healthcare Enterprise (IHE) - Cross Enterprise Document Sharing (XDS) profiles. For getting semantic interoperability the responses are transferred in the form of HL7 CDA L2 documents.</td>
<td>This paper does not include contents about patient summary or its implementation. However, it is an interesting case of health information exchange. Unfortunately, the description of the implementation is not so detailed.</td>
<td>(Schreiweis B, et al., 2016)</td>
</tr>
<tr>
<td>12</td>
<td>SMART-on-FHIR implemented over i2b2</td>
<td>The authors have developed an interface that provides patient data from Informatics for Integrating Biology and the Bedside (i2b2) repositories in HL7 Fast Healthcare Interoperability Resources (FHIR) format on a per-patient basis. The source code is freely available online as open source. The source code is freely available online as open source.</td>
<td>This paper does not include contents about patient summary or its implementation. However, it is an interesting case on translating data into a different format. Then, after some years, as FHIR resources have been updated, the source code should be revised.</td>
<td>(Wagholikar KB, et al., 2017)</td>
</tr>
</tbody>
</table>
5 PGHD use cases

From the scoping review (Li, 2021) two overarching use cases were identified: self-management (SM) and shared decision making (SDM). Patient generated health data (PGHD) was found as the dominant type of data being collected for both use cases. Within SM, PGHD was primarily used for self-monitoring, but also to identify contextual factors, to quantify measurements, and to help setting goals for lifestyle changes, but also to adjust treatments. For SDM, the main usage consisted of PGHD exchange between healthcare providers and patients, and to facilitate conversation during the medical encounter. Li (Li, 2021) categorised the different use cases belonging to either SM or SDM and labelled them accordingly as shown in Table 4.

### Table 4: Explanation of the acronyms for use cases (Li 2021)

<table>
<thead>
<tr>
<th>#</th>
<th>Acronym</th>
<th>Meaning of Acronyms</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>SM</td>
<td>self-management</td>
</tr>
<tr>
<td>2</td>
<td>SM1</td>
<td>self-monitoring for physiological changes and lifestyle changes</td>
</tr>
<tr>
<td>3</td>
<td>SM2</td>
<td>setting goals for lifestyle changes</td>
</tr>
<tr>
<td>4</td>
<td>SM3</td>
<td>identifying contextual factors to SM</td>
</tr>
<tr>
<td>5</td>
<td>SM4</td>
<td>quantifiable measurement of the SM capacity</td>
</tr>
<tr>
<td>6</td>
<td>SM5</td>
<td>self-testing/self-screening for disease</td>
</tr>
<tr>
<td>7</td>
<td>SM6</td>
<td>approach to treatment</td>
</tr>
<tr>
<td>8</td>
<td>SMU</td>
<td>unspecified</td>
</tr>
<tr>
<td>9</td>
<td>SDM</td>
<td>shared decision making</td>
</tr>
<tr>
<td>10</td>
<td>SDM1</td>
<td>information exchange</td>
</tr>
<tr>
<td>11</td>
<td>SDM2</td>
<td>option and decision talk</td>
</tr>
<tr>
<td>12</td>
<td>SDM3</td>
<td>identifying contextual factors to SDM</td>
</tr>
<tr>
<td>13</td>
<td>SDM4</td>
<td>quantifiable measurement of the SM capacity</td>
</tr>
<tr>
<td>14</td>
<td>SDM5</td>
<td>validation of PGHD</td>
</tr>
<tr>
<td>15</td>
<td>SDMU</td>
<td>unspecified</td>
</tr>
</tbody>
</table>

The list of specific use cases for SM and SDM (Table 4) was used in the subsequent flow diagram (Figure 5), which illustrates a possible process flow that correlates the SM and SDM use cases along the healthcare continuum of prevention, diagnosis, treatment, and monitoring. Most use cases for SM and SDM could be incorporated in the flow diagram, except for three (SM3, SDM3, and SDM) that apply to the general context of using PGHD in the healthcare setting. Mapping the process flow allowed to identify some steps required for an effective implementation of the use cases, such as data and information analysis, documentation of analysis results, defining the set of PGHD to collect, and defining the hardware and software to be used by the actors involved. Additionally, mapping the process flow permitted the identification of clearly observable implementation barriers related to some steps of the process. For instance, the barrier: “Selecting which PROMs to collect may become burdensome for the clinician”, that can be found in the next section categorised under Care Process.
### Activities involved in using Patient Generated Health Data through the patient journey

<table>
<thead>
<tr>
<th>Prevention</th>
<th>Diagnosis / Treatment</th>
<th>Monitoring</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test-Monitoring for physiological changes and medical changes (EDM)</td>
<td>Test-Monitoring of relevant clinical conditions (EDM)</td>
<td>Self-management of relevant clinical conditions/care plan (EDM)</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Active compliance?</td>
<td>Yes</td>
<td>Schedule appointment with clinician</td>
</tr>
<tr>
<td>No</td>
<td>Yes</td>
<td>Feedback required?</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Information exchange (EDM)</td>
<td>Information exchange (EDM)</td>
<td>Information exchange (EDM)</td>
</tr>
<tr>
<td>Validation of PGHD (EDM)</td>
<td>Validation of PGHD (EDM)</td>
<td>Validation of PGHD (EDM)</td>
</tr>
<tr>
<td>Data and information analysis</td>
<td>Data and information analysis</td>
<td>Data and information analysis</td>
</tr>
<tr>
<td>Documentation of analysis results</td>
<td>Documentation of analysis results</td>
<td>Documentation of analysis results</td>
</tr>
<tr>
<td>Testing patient for specific changes (EDM)</td>
<td>Quantitative measurement of the SSM capacity (SSM)</td>
<td>Quantitative measurement of the SSM capacity (SSM)</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>诃</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>Option and decision task (SSM)</td>
<td>Option and decision task (SSM)</td>
<td>Option and decision task (SSM)</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Defining the SSM capacity</td>
<td>Defining the SSM capacity</td>
<td>Defining the SSM capacity</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td>No</td>
<td>No</td>
<td>No</td>
</tr>
<tr>
<td>Define set of POI and SMM to use</td>
<td>Define approach to treatment (POI)</td>
<td>Define approach to treatment (POI)</td>
</tr>
<tr>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
</tbody>
</table>

### General use cases

- Identifying contributory factors to risk (SSM)
- Identifying contributory factors to SSM (SSM)
- Shared Decision-Making (SSM)

Figure 5: Process flow diagram of PGHD use cases
5.1 Barriers for using PGHD

As mentioned before, the process of mapping the process flow of the use cases, allowed for some early identification of barriers to implement PGHD for citizen science. Even so, the objective was to identify barriers mentioned in published sources to corroborate their relevance and generality. For this purpose, two methods for searching barriers or challenges were combined. First, the snowball method, parting from the work of Li (2021), was used to identify journal articles mentioning barriers or challenges that may affect the implementation of PGHD for citizen science. Second, specific searches were used to corroborate the barriers identified from mapping the process flow of the use cases.

Subsequently, the barriers were categorised based on the Refined eHealth European Interoperability Framework (ReEIF) (eHealth Network, 2017). The ReEIF was chosen over the European Interoperability Framework (EIF) (European Commission, 2017) because of its granularity. The EIF proposes 4 main levels (legal, organisational, semantic, and technical), while the ReEIF splits the organisational and technical layers into two each. Yielding six sublevels: legal and regulatory, policy, care process, information, applications, and IT infrastructure. Lastly, subcategories for each ReEIF layer were used to group the barriers, as it is presented in Erro! A origem da referência não foi encontrada.. A total of 49 barriers or challenges where identified which are presented from section 5.1.1 to 5.1.6.
5.1.1 Legal and regulatory

The Legal and regulatory level involves organisations operating under different legislations, policies and strategies can work together (European Commission, 2017). This might require clear agreements between Member States on how to deal with differences in legal frameworks across borders and within a country or region, including how to create new legislation (eHealth Network, 2017). Barriers at the Legal and regulatory level are shown in Table 5.

<table>
<thead>
<tr>
<th>PRIVACY</th>
<th>Rationale/Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Different interpretations of GDPR requirements for information access within EU state members.</td>
<td>Granularity of Access Control permission differ in each EU state member because of differences in General Data Protection Regulation (GDPR) interpretation and implementation between state members (Vukovic et al., 2022).</td>
</tr>
<tr>
<td>Differences in IT-security architecture may compromise the patient’s data.</td>
<td>Lack of standardisation of IT-security architecture on PRO collection systems (mobile or web-based apps, platforms, etc.) may compromise the patient’s sensible information (Vukovic et al., 2022).</td>
</tr>
<tr>
<td>Lack of established collaboration agreements for secure sharing between organisational stakeholders.</td>
<td>Article 32 in the GDPR requires the controller and the processor of information to implement technical and organisational security measures such as pseudonymisation, anonymisation and encryption of personal data (GDPR, 2016). Therefore, lack of collaboration agreements on the secure sharing interface and processes may compromise the implementation.</td>
</tr>
<tr>
<td>Variability in the levels of security practices between stakeholders creating vulnerability points.</td>
<td>Differences in the implementation of the GDPR between organisations or countries with and without pre-existing laws data privacy laws can affect the variability of data privacy requirements and practices creating vulnerability points (Vukovic et al., 2022).</td>
</tr>
<tr>
<td>Patients may have concerns about their privacy that interferes with them answering PROMs.</td>
<td>Patients may be reluctant to use PROMs if feeling unsure about the purpose and reason to complete a PROM, who will access their responses, and what the data will be used for (Calvert et al., 2019).</td>
</tr>
<tr>
<td>Devices used for remote patient monitoring may face challenges ensuring security from attacks.</td>
<td>There are challenges in ensuring cybersecurity of wearable sensors to be safe from hackers’ access (Abdolkhani et al., 2019). For instance, Glucose Monitoring Devices (GMD) that use Bluetooth technology could be susceptible to interception with the purpose of substituting the glucose measurement and interfering with the insulin dose calculation (Saltzstein, 2020).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>AVAILABILITY</th>
<th>Rationale/Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Disparity of resources available for PGHD collection system implementation.</td>
<td>Disparity of resources may occur between different health entities (clinics, hospitals, etc.) within the same health system in a state member, or between health systems of different</td>
</tr>
</tbody>
</table>

Table 5: Barriers at the Legal and regulatory level
state members. For example, resources necessary for PGHD collection system implementation frequently include technical support, problem solving support, training resources for patients and health team, and device expenses (Tiase et al., 2020).

### 5.1.2 Policy

The Policy level involves the formalisation of contracts and agreements between organisations, including setting the purpose and value of the collaboration (eHealth Network, 2017). Barriers at the Policy level are shown in Table 6.

**Table 6: Barriers at the Policy level**

<table>
<thead>
<tr>
<th>AGREEMENTS</th>
<th>Rationale/Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty or inability to access PGHD collected by the patient due to proprietary software or web-based platforms.</td>
<td>For instance, when patients that require Continuous Glucose Monitoring (CGM) change their device for another brand, healthcare providers find it difficult to access the new data (Abdolkhani et al., 2019).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>CULTURE</th>
<th>Rationale/Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Extremely bureaucratic or authoritarian culture may impede implementation.</td>
<td>Extreme bureaucratic processes are still characteristic of some clinical environments and health systems. These practices can impede timely implementation and compromise innovation (Dixon-Woods et al., 2012).</td>
</tr>
</tbody>
</table>

Implementation of eHealth solutions require de-implementation of ineffective or low-value practices that may be deeply embedded in the work culture. Reducing or stopping the use of a health practice provided by healthcare professionals or systems to patients (de-implementation), is important to mitigate patient harm, improve quality of care and reduce costs (Norton et al., 2017). However, different challenges are involved in improvement initiatives that are deeply related to the organisational culture (Dixon-Woods et al., 2012). For example, Dixon-woods et al. (2012) identified ten challenges for improving quality in healthcare: “convincing people that there is a problem that is relevant to them; convincing them that the solution chosen is the right one; getting data collection and monitoring systems right; excess ambitions and ‘projectness’; organisational cultures, capacities and contexts; tribalism and lack of staff engagement; leadership; incentivising participation and ‘hard edges’; securing sustainability; and risk of unintended consequences.”

### 5.1.3 Care process

Barriers at the Care process level become evident after organisations agreed on working together and the specific care pathways and workflows are analysed and aligned. Furthermore,
it includes the information needed to deliver integrated care (eHealth Network, 2017). Barriers at the Care process level are presented in Table 7.

Table 7: Barriers at the Care process level

<table>
<thead>
<tr>
<th>CARE PROCESSES</th>
<th>Barrier</th>
<th>Rationale/Example</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Misalignment of care processes</td>
<td>Due to the high variety of self-reported questionnaires or data that could be used for a specific case, misalignment of how and which information is recollected is possible (European Commission, 2017).</td>
</tr>
<tr>
<td></td>
<td>Lack of standardised documentation on process modelling.</td>
<td>Process documentation may be different in each organisation. Particularly process modelling that includes the information required during the process and the requirements for data exchange (European Commission, 2017).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>PROM SELECTION</th>
<th>Barrier</th>
<th>Rationale/Example</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Selecting which PROMs to collect</td>
<td>PROMs for different concepts and contexts to be measured exist for the same diseases or conditions. This flexibility might make it harder for the clinician to choose which tool to use for the specific case of the patient (Penedo et al., 2020). For example, collection of PROMs to evaluate Quality of Life (QOL) for thoracic surgery patients may include at least 8 different PRO tools with varied number and categories of items (Singer et al., 2020).</td>
</tr>
<tr>
<td></td>
<td>Patient input is not always considered to ensure correct measurements.</td>
<td>PROMs are not always designed alongside the patient which may compromise the accuracy and purpose of the questionnaire. For instance, if the questionnaire misses to ask a relevant aspect of self-management that is not typically considered by clinicians (Calvert et al., 2019).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DATA CAPTURE OR COLLECTION</th>
<th>Barrier</th>
<th>Rationale/Example</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>“Down time” for data collection.</td>
<td>Increased time during which a sensor, device, or system is out of action (“down time”) may compromise the continuity of the data collection (Yetisen et al., 2018). For example, if the sensor or device disconnects without the patient noticing or the patient decides not to use it for multiple reasons (lack of comfort, disengagement, etc.) (Li, 2021; Tran et al., 2007).</td>
</tr>
<tr>
<td></td>
<td>Properly completing PROMS is labour intensive.</td>
<td>Manually integrating PROMS with PGHD can become a burden to the staff (European Mhealth Hub, n.d.).</td>
</tr>
<tr>
<td></td>
<td>Patients becoming disengaged and declining to participate further in PROM collection.</td>
<td>Patients may become disengaged for multiple reasons including feeling that health professionals are not using the information they just answered (Basch et al., 2018) or because answering multiple questionnaires becomes a burden (Calvert et al., 2019).</td>
</tr>
<tr>
<td>Barrier</td>
<td>Rationale/Example</td>
<td></td>
</tr>
<tr>
<td>--------</td>
<td>------------------</td>
<td></td>
</tr>
<tr>
<td>Training required for the patient to collect PGHD may be time consuming.</td>
<td>The type and complexity of training required for appropriate data collection will depend on different factors such as the patient’s disease or condition, patient’s health literacy, type of sensor or wearable device, data collection process, user interface, etc. (Basch et al., 2018).</td>
<td></td>
</tr>
<tr>
<td>Collection of PGHD may create anxiety for some patients.</td>
<td>For some patient profiles, Self-Management strategies may not improve patient engagement or quality of care (Powell, 2017). A previous evaluation of SM capability may be required.</td>
<td></td>
</tr>
<tr>
<td>Guaranteeing information quality for comparison purposes.</td>
<td>For comparison of values over time the measurement needs to be taken in the same conditions each time (same time of day, before having food, with/without clothes, etc.). If the conditions are not the same or are unknown, the quality of the information could be compromised, making it hard to become clinically useful (Abdolkhani et al., 2019; Lavallee et al., 2020; Calvert et al., 2019).</td>
<td></td>
</tr>
</tbody>
</table>

**ANALYSIS AND DECISION-MAKING**

Refers to the analysis of the data collected from the patient and how it affects or guides clinical decision-making.

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Rationale/Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Difficulty to perform triangulation of data related to the varied and highly specialized applications for PGHD collection.</td>
<td>Triangulation of data from multiple sources could enable more precise clinical assessments, disease monitoring and overall decision making (Li, 2021). However, it requires solutions that connect multiple applications (e.g., a middleware platform). For example, a patient who is monitoring body weight using a smart-scale, activity and exercise tracking using a smart-watch, registration of food intake using a mobile application and answering a PROM through a patient portal. None of the above integrate in a single app automatically, therefore it can become a burden for the patient, in terms of the effort to register data, and for the clinician, in terms of visualisation and analysis of the information.</td>
</tr>
<tr>
<td>Massive amount of data may become a burden to analyse and understand.</td>
<td>Patient who is monitoring physiological, psychometric, and life-style data alongside to multiple PROMs may collect too much data for the clinician to use in clinical decision making (Penedo et al., 2020; Tran et al., 2007). Particularly if the data threshold for treatment adjustments in clinical guidelines depend on laboratory results. For example, A patient with T2D and Hypertension that requires check-up appointments every 6 months and that is using mHealth apps for self-monitoring may have daily data points for: heart rate, blood pressure, glucose, steps taken in a day, minutes of increased physical activity, weight, sleep patterns and diet patterns.</td>
</tr>
<tr>
<td>Lack of commonly accepted standards for analysis and subsequent clinical decision making.</td>
<td>Lack of standardisation makes it difficult to compare outcome data from one study to another (Kneuertz et al., 2020; Penedo et al., 2020; Calvert et al., 2019). This may affect the recognition of quality standards of practice.</td>
</tr>
<tr>
<td>Unknown or unagreed accuracy and precision of data between stakeholders.</td>
<td>Lack of agreed standards between healthcare and solution providers may cause burden (Calvert et al., 2019). For instance, it may repercuss in augmented work burden for clinicians as they may need to validate the precision of the tool used for data collection (Li, 2021; Yetisen et al., 2018).</td>
</tr>
</tbody>
</table>
Lifestyle data is still underutilised in the clinical setting.

Lifestyle data (e.g., physical activity, food intake, calorie burning, sleep data, etc.) is being studied in clinical outcomes research and is still underutilised in the clinical setting (Li, 2021). In a study about diabetes management (Pemue et al., 2019), medication adherence was adopted as one of the outcome measurements of the intervention and other lifestyle parameters were used to guide lifestyle behaviour changes.

PGHD/PROMS defined for follow-up and monitoring will most likely be linked to a certain disease or condition, making it hard to be specialty-agnostic and condition-independent.

Contrary to the purpose of the International Patient Summary, PROM or PGHD recollection is hardly specialty-agnostic or condition-independent. For example, a patient with diabetes mellitus who needs to monitor glucose levels, body weight, blood pressure, diet, activity and answer a PROM for following symptoms.

Patient feeling uncomfortable for the shared decision-making responsibility with the physician.

Patient feels that the responsibility of collecting and managing data is that of the physician (Lavallee et al., 2020).

Lack of international standardisation of PGHD/PROMS in clinical guidelines.

Use of PGHD or PROMS may depend on localised clinical guidelines (Calvert et al., 2019).

Limited evidence on the relation between PRO results and the patient’s individual experience

All information reported by the patient can be considered fundamentally important, while understanding what really matters or affects the individual patient remains a challenge for the health team. For example, patients that undergo long recovery periods in different care settings have complex and varied experiences (Kneuertz et al., 2020).

### 5.1.4 Information

The Information level represents the functional and semantic description of the data model, data elements and their link to terminologies that influence the interoperability between the models (eHealth Network, 2017). Barriers at the Information level are presented in Table 8.

<table>
<thead>
<tr>
<th>SEMANTIC INTEROPERABILITY</th>
<th>Preservation and understanding of the information being exchanged between parties pertaining the meaning of data elements and the relationship between them (European Commission, 2017).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrier</td>
<td>Rationale/Example</td>
</tr>
<tr>
<td>Challenges related to linguistic and cultural differences between Member States.</td>
<td>Translations of self-reported tools or questionnaires need to be validated in the specific context (European Commission, 2017).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SYNTACTIC INTEROPERABILITY</th>
<th>Preservation and understanding of the information being exchanged between parties pertaining the exact format of the information in terms of grammar and format (European Commission, 2017).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrier</td>
<td>Rationale/Example</td>
</tr>
<tr>
<td>Variability of the units being used for the parameters.</td>
<td>The units for some measurements may vary according to the state members (Abdolkhani et al., 2019). For instance, Haemoglobin may be measured as mmol/l or mg/dl depending on the country or the App settings.</td>
</tr>
</tbody>
</table>

### 5.1.5 Applications
The Application level refers to the exchange of information, including how the import and export are handled by the information systems, the communication standards used, and the integration and processing of exchanged information in user-friendly applications (eHealth Network, 2017). Barriers at the Applications level are presented in Table 9.

Table 9: Barriers at the Applications level

<table>
<thead>
<tr>
<th>DATA INTEGRATION</th>
<th>Process of combining data residing from different sources and providing users with a unified view of them (ISO-OBP, 2020, “data integration”).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrier</td>
<td>Rationale/Example</td>
</tr>
<tr>
<td>Development of PRO collection systems outside the EHR can create barriers to use them at the point of care and to integrate data within the EHR.</td>
<td>If a separate PRO collection system is developed, the integration for visualisation and clinical decision making at the point of care may require additional software development or programming specific to accomplish the integration (Basch et al., 2018).</td>
</tr>
<tr>
<td>Interoperability issues on data export.</td>
<td>Difference in standards of information exchange (Abdolkhani et al., 2019; Basch et al., 2018; Calvert et al., 2019).</td>
</tr>
<tr>
<td>Absence of designated fields within the Clinical Data Architecture (CDA) to record PGHD in the EHR.</td>
<td>CDA is missing fields dedicated to reporting PGHD or agreed formats or documents into which portrayed it (McKinlay et al., 2018).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>DATA EXCHANGE</th>
<th>Storing, accessing, transferring, and archiving of data (ISO-OBP, 2021, “data exchange”).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrier</td>
<td>Rationale/Example</td>
</tr>
<tr>
<td>Different format or granularity of data depending on being directly or indirectly inputted.</td>
<td>Different format for reporting the data between healthcare and solutions providers (Abdolkhani et al., 2019; Calvert et al., 2019). For instance, a health professional may analyse the raw data and input a summary of the clinical findings, including the processed data (temporal averages, min/max values, etc.). On the other hand, the solution provider might store the raw data from the App and summarise it differently.</td>
</tr>
</tbody>
</table>

5.1.6 IT infrastructure

The IT infrastructure level includes all the architecture required to make the healthcare information work including the generic communication, interoperability, and network protocols and standards, storage, backup, and database engines, except for the specifics on data exchange, which are covered in the Applications level mentioned section 5.1.5 (eHealth Network, 2017). Barriers at the IT infrastructure level are presented in Table 10.

Table 10: Barriers at the IT infrastructure level

<table>
<thead>
<tr>
<th>HARDWARE</th>
<th>All or part of the physical components of an information processing system (ISO-OBS, 2011, “hardware”).</th>
</tr>
</thead>
<tbody>
<tr>
<td>Barrier</td>
<td>Rationale/Example</td>
</tr>
<tr>
<td>Lack of precision of physiological data collected from sensors/devices may compromise clinical decision-making.</td>
<td>Different sensors/devices may have inaccurate measurements. For instance, evaluation of several fitness trackers showed inaccurate measurements with error margins up to 25% (Yetisen et al., 2018). Additionally, weight scales that use bioelectrical impedance analysis (BIA) technology have been proven inaccurate when measuring body fat and muscle mass.</td>
</tr>
</tbody>
</table>
### Issues related to regular use of wearable devices that may compromise the quality or continuity of the data collected.

Issues with using wearables for treatment include low biocompatibility, insufficient conformal contact, inefficient battery consumption, and short lifetime (Yetisen et al., 2018).


### Systems that require fully active users to collect the data can become burdensome enough to disengage the patient.

Patient engagement with Self-Management may depend on the type of effort required to collect the information (Li, 2021; Nittas et al., 2019). A study done with Asthma patients that asked them to record their daily symptoms in a diary. Resulted in a low adoption rate due to much burden of manual registration of information (Lau et al., 2015).

### SOFTWARE

All or part of the programs involved in processing or supporting the processing of digital information (ISO-OBS, 2022, “software”).

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Rationale/Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Patient-friendly designs may take years to develop.</td>
<td>Developing patient-friendly dashboards to visualise own information or patient journey linked to the EHR (Basch et al., 2018).</td>
</tr>
<tr>
<td>Integration of PRO questionnaire into EMR/EHR of different organisation often requires re-building.</td>
<td>Even when using the same vendor, the PRO module needs to be adapted to the clinical setting and systems within that organisation (Basch et al., 2018).</td>
</tr>
<tr>
<td>Obstacles related to legacy systems.</td>
<td>Legacy systems are applications and information systems that were developed by organisations to solve domain-specific and local problems (European Commision, 2017). This kind of approach resulted in Information and Communication Technologies (ICT) islands that are difficult to interoperate.</td>
</tr>
</tbody>
</table>

### ACCESSIBILITY

Degree to which a product, service or system can be used by people of a wide range of characteristics to achieve a specific goal and context of use (ISO-OBS, 2022, “accessibility”).

<table>
<thead>
<tr>
<th>Barrier</th>
<th>Rationale/Example</th>
</tr>
</thead>
<tbody>
<tr>
<td>Economic factors leading to unaffordability of sensors/devices or other technological requirements.</td>
<td>Technology or devices required to register PGHD or PROMS may not be affordable for some groups.</td>
</tr>
<tr>
<td>Technologically challenged groups of people may opt-out of self-management strategies.</td>
<td>Older generations (digital immigrants), people with luddite lifestyles or sceptical about the use of their data.</td>
</tr>
<tr>
<td>Small clinics or health programs difficulty to use population-level analytics.</td>
<td>Data sharing with other organisations may be complicated by technical challenges, lack of standardisation of PROs to use (Basch et al., 2018) or lack of representativeness of the population that the clinic or program addresses.</td>
</tr>
<tr>
<td>Limited language translations and validations of PROMs.</td>
<td>PROMs collected as questionnaires and surveys need to be translated and validated locally since the items need to be language and culturally specific (Kim et al., 2018; Schuler et al., 2017; Wang et al., 2020; Zou et al., 2017).</td>
</tr>
</tbody>
</table>

### SYSTEM ARCHITECTURE

Description of the structure and behaviour of a system, its components, functions, and inter-relationships (ISO-OBS, 2014, “system architecture”).

| Barrier | Rationale/Example |
Compromised scalability related to the variety of PRO collection systems available. | Since the apps or platforms available for PROM collection are usually type or questionnaire-specific, the integration of all the collection systems will require an increasingly complex development process. Making it increasingly harder to maintain and improve.

Lack of standardisation in the integration of PGHD collecting systems to EHR/EMR. | Some use middleware platforms to aggregate and assimilate PGHD (e.g., Apple HealthKit) (National eHealth Collaborative, 2013; Tiase et al., 2020).

Lack of necessary in-house skill sets. | If Member States miss to include professionals with interoperability skills in the legal, organisational, semantic, and technical aspects, their interoperability strategies may lack the multi-dimensional awareness required to cooperate with other Member States (European Commission, 2017).

Lack of suitable standards or specifications for the specific domain. | Standards and specifications catalogued in the European Interoperability Cartography (EIC) do not extend to the healthcare domain (European Commission, 2017)

5.2 Scenario example*: Patient suffering from multiple conditions

(*) Please note: This fictive example of a user scenario takes place between Sweden and Spain, but it does not mirror the actual implementation of the IT infrastructure and services in both countries.

Svenna Svensson is a 55-year-old woman from Stockholm, Sweden, that likes to travel in her spare time. During a 6-month trip to Spain, Svenna lost her bag with her medication and smartphone in it. Svenna takes several medications daily and there is little chance of recovering the bag. Svenna is worried because she needs her medication to maintain her quality of life. Her information is as follows:

<table>
<thead>
<tr>
<th>Svenna Svensson</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gatagatan 1234 Apt. 4101, 11534, Stockholm, Sweden</td>
</tr>
<tr>
<td>Person ID: 670530-7656</td>
</tr>
<tr>
<td>Phone: +46 070-893-3234</td>
</tr>
<tr>
<td>Passport No.: 59000002</td>
</tr>
</tbody>
</table>

Svenna was diagnosed one year ago with insomnia, anxiety, and depression as part of a severe Burnout Syndrome. She currently takes Alprazolam 0.75mg and Sertraline 75mg daily, both of which require a medical prescription. Additionally, Svenna has been diagnosed with Diabetes Mellitus type 2 when she was 50 years old, since then she measures her capillary glucose daily and takes Metformin 500mg three times a day. All her medications require a prescription by a certified healthcare professional both in Sweden and in Spain.

Svenna uses a series of Mobile Health Apps to self-manage her health. As part of the Cognitive Behavioural Therapy (CBT) that she follows, she answers monthly a Patient-Reported Outcome Measure (PROM), the Patient Health Questionnaire (PHQ-9) for Depression (Kroenke et al., 2001), containing the questions in Table 11.
Table 11: Questions of PHQ-9 for Depression (Kroenke et al., 2001)

<table>
<thead>
<tr>
<th>Over the last 2 weeks, how often have you been bothered by any of the following problems?</th>
<th>Not at all</th>
<th>Several days</th>
<th>More than half the days</th>
<th>Nearly every day</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Little interest or pleasure in doing things</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>2. Feeling down, depressed, or hopeless</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>3. Trouble falling or staying asleep, or sleeping too much</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>4. Feeling tired or having little energy</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>5. Poor appetite or overeating</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>6. Feeling bad about yourself—or that you are a failure or have let yourself or your family down</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>7. Trouble concentrating on things, such as reading the newspaper or watching television</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>8. Moving or speaking so slowly that other people could have noticed? Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>9. Thoughts that you would be better off dead or of hurting yourself in some way</td>
<td>0</td>
<td>1</td>
<td>2</td>
<td>3</td>
</tr>
</tbody>
</table>

She registers her answers through an App and the results are regularly summarised and sent to her psychiatrist, Gustav Gustavsson. Additionally, Svenna uses a separate App that is linked to her glucometer to register her daily capillary glucose levels, the results are summarised and sent to the diabetes nurse, Virginia Henderson, at the family clinic she is registered in Stockholm.

Due to the potential side effects of dropping her treatment, Svenna decides to go to a health clinic and book an emergency appointment for her prescription medication. She is received by the physician Manuel Rodriguez. His information is the following:

**Name:** Manuel Rodriguez Ruiz  
**Professional ID:** 123456789  
**Specialisation:** General Practitioner  
**Organisation:** Clínica de Salud  
**Address:** Calle del Hospital, 46, 28007 Madrid, Spain  
**Phone:** +34 876 34 69 01

Svenna explains the situation to Manuel. He then asks Svenna for the information of the healthcare professionals in charge to petition a summary of her health record. Manuel calls Virginia Henderson and Gustav Gustavsson and asks for a medical summary where her diagnoses, summary of the Patient Generated Health Data (PGHD) she collected, and prescribed medication is portrayed. Their information is the following:

**Name:** Virginia Henderson  
**Professional ID:** 785357532  
**Specialisation:** Diabetes Nurse
When Manuel receives the information, he integrates it to the Electronic Health Record (EHR) of the clinic and gives Svenna a unique prescription for the medication she requires. Since the branding of the medication available in Spain is different than the ones she took before in Sweden, Manuel wants to follow-up her case within a week of her stay in Spain to ensure that the new medication brand sits well to her. For this purpose, the PROMs and PGHD collected previously through the Apps in her mobile phone are useful. Svenna buys a new phone and continues recording her PGHD through the Web-based Apps. After the follow-up is finished, Manuel sends back his report back to the Psychiatrist and the Diabetes Nurse.

5.2.1 Actors in the scenario

The actors in the scenario are detailed in Table 12.

Table 12: Actor’s role and description

<table>
<thead>
<tr>
<th>Actor</th>
<th>Role</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Svenna Svensson</td>
<td>Patient</td>
<td>The person undergoing medical, surgical or dental care (ISO-OBP, 2009, “patient”). For this scenario, the patient has been diagnosed with diabetes, anxiety, depression, and insomnia and undergoes medical check-ups through her Diabetes Nurse and Psychiatrist.</td>
</tr>
<tr>
<td>Manuel Rodriguez Ruiz</td>
<td>General Practitioner</td>
<td>A General Practitioner in Spain is a healthcare professional with at least 6 years of general medicine training (Universidad Complutense de Madrid, n.d.).</td>
</tr>
<tr>
<td>Gustav Gustavsson</td>
<td>Psychiatrist</td>
<td>A Psychiatrist in Sweden is a General Practitioner specialist in Psychiatry with at least 5 years of specialty training (ST, n.d.).</td>
</tr>
<tr>
<td>Virginia Henderson</td>
<td>Diabetes Nurse</td>
<td>A Diabetes nurse in Sweden is a General Nurse with at least 2 years of specialty training in Diabetes care (Lundqvist, n.d.).</td>
</tr>
</tbody>
</table>

5.2.2 IT systems used in the scenario

The information systems needed for this scenario are:

- **EHR System**: An Electronic Health Record (EHR) is a computer-processable repository of information regarding the health status of a patient (or subject of care) (ISO-OBP, 2009, “EHR”). An EHR System is a system for recording, retrieving information in the EHR (ISO-
OBP, 2009, “EHRS”). An EHR System has a positive effect on patient care by allowing physicians to be better informed, improve the communication with the patient and their family, and improving the workflow of the physicians’ practice (Manca, 2015). By providing different alternatives of visualising information, e.g., graphs, trends, etc., the EHR aids health professionals analyse information and design care plans that can improve patient outcomes (Manca, 2015; Collier, 2015). For this scenario, the EHR System is particularly useful for monitoring Svenna’s medical history evolution (e.g., laboratory results, questionnaire answers, medication effectiveness) and act timely so she can have the best possible health outcomes.

- **Patient Portal**: Patient Portals are used to provide the patient with secure online access to their personal health information (Dendere et al., 2019). Through Patient Portals the patient can access healthcare education, reminders on medication refills or appointment booking, answer self-management questionnaires and other kinds of Patient Reported Outcomes (PRO), book appointments with their physician, and have all their health-related information available (Dendere et al., 2019; Han et al., 2019). In some use cases the Patient Portal can even be linked to home care devices, i.e., blood pressure monitors, to telemonitor a health condition (Milani et al., 2017). This scenario portrays a web-based app that is linked to the Patient Portal to record the information on a PRO questionnaire that can be used by the Diabetes Nurse and the Psychiatrist for clinical decision-making.

- **Personal Health Record (PHR)**: A PHR is defined by ISO/TR 14639-2:2014 as “a representation of information regarding, or relevant to, the health, including wellness, development and welfare of that individual, which may be stand-alone or may integrate health information from multiple sources, and for which the individual, or the representative to whom the individual delegated his or her rights, manages and controls the PHR content and grants permissions for access by, and/or sharing with, other parties.” However, a continuum exists in many countries between the two strict views of the EHR and PHR on the one hand, regarding the entity that has control over the record and the content within it, and tethered PHRs on the other. In the latter case, the patient is given access to the EHR by the care provider without the patient controlling it. This access function is often part of a patient portal. (Tsai CH et al, 2020)

The properties of the IT systems needed are listed in Table 13.

<table>
<thead>
<tr>
<th>System</th>
<th>Functionalities</th>
</tr>
</thead>
<tbody>
<tr>
<td>EHR System</td>
<td>EHR Systems offer a complete solution for health systems and its functionalities are varied and many. Therefore, in this table only the functionalities needed for the scenario will be addressed:</td>
</tr>
<tr>
<td></td>
<td>- <strong>Health information and data</strong>: all medical information required for clinical decision-making (IOM, 2003).</td>
</tr>
<tr>
<td></td>
<td>- <strong>Results management</strong>: management of results of all types, e.g., laboratory, radiology procedures, or biopsy results) (IOM, 2003).</td>
</tr>
</tbody>
</table>
• **Order entry/management**: computerised order entry for products or services. E.g., laboratory tests, radiology studies, medication prescription, or different forms of treatments (IOM, 2003).

• **Administrative processes**: for providing better and more timely service to patients and increasing the efficiency of healthcare organisations (IOM, 2003).
  - **Appointment booking**: provides a general picture of the clinic’s appointments, time-slot availability of specific human resources (e.g., physicians, nurses, counsellors, therapists, etc.) and the opportunity to link the appointment booking through the Patient Portal.

---

**Patient Portal**

Offers the patient the possibility of participating actively in their own care, as the EHR System, a Patient Portal can have multiple functionalities, e.g., FollowMyHealth (FollowMyHealth, n.d.). However, the functionalities that are needed for this scenario are:

- **Appointment booking**: allows the patient to see the available schedule of their GP and send the petition for a given timeslot to the PCC administrative personnel.
- **Report self-management outcomes**: answer standardised self-management questionnaires or other self-reported outcomes tools that can be used as support for clinical decision-making.
- **Notifications**: notifies the patient about approved appointments and pending activities to be completed, e.g., answering a self-management questionnaire before an appointment.

---

**Personal Health Record (PHR)**

The PHR predominantly includes information that is recorded by patients themselves on their own, and not on healthcare provider’s initiative such as self-tracking or monitoring data, own patient notes. The PHR is only used prior to the actual scenario (Figure 7, upper left).

### 5.2.3 Information to be exchanged

A Data Flow Diagram (DFD) and the information to be transferred are summarised in Figure 7. Since the patient reported her data before entering the scenario, a flowchart portraying such data flow was included (upper left).

Figure 7 is divided into three panels and shows 1 – Data Flow before the scenario (regular flow in Sweden); 2 – data to be transferred; 3 – Data flow of the scenario (case in Spain).

A data-flow diagram (DFD) is a way for representing a flow of data through a process or a system. The DFD provides information about the inputs and outputs of each entity and the process itself. In Figure 7, panels 1 and 3 are DFDs.

In panel 1 (Figure 7), the Patient is recording the data about the Capillary Blood Glucose (by a glucometer) and the answers to the PHQ-9 questionnaire. The data collected by the glucometer are automatically stored in the Personal Health Record (a database, according to the DFD notation), the answers of the PHQ-9 questionnaire are automatically stored in the Patient Portal (a database, according to the DFD notation). The two mentioned databases are feeding the Electronic Health Record of the Patient (a database, according to the DFD notation). The
Electronic Health Record of the Patient is accessed by the Psychiatrist (interested in the answers to the PHQ-9 questionnaire) and by the Diabetic Nurse (interested in the glucometer recordings) for future steps of patient care.

Panel 2 (Figure 7) presents the data to be transferred. They are as follows: Patient Information, Diagnoses, Medication Information, PHQ-9 items, Diabetes Nurse, Psychiatrist, and General Practitioner. All of them include specific attributes, as listed in the Panel 2 (Figure 7).

Panel 3 (Figure 7) presents the situation at the receiving country, i.e., Spain, where the Swedish patient stayed when in need of care. At the General practitioner in Spain, the DFD starts with some checks (blocks 1 and 2), about the identity of the patient and the ones of the healthcare professionals involved. After that, a patient summary is requested by the General Practitioner in Spain (block 3), and the patient summary is prepared (block 4), involving Diabetes Nurse and Psychiatrist. When the patient summary is received by the General Practitioner in Spain, she can prescribe medications (block 5), book a follow-up appointment with the patient (block 6), document the care that the patient receives in Spain (block 7), and summarising the care received (block 8). In addition, the patient is notified about the follow-up appointment with the General Practitioner in Spain.
Figure 7: Use Case Scenario’s data flow.
5.2.4 Conceptual data modelling

Considering the DFD, the classes shown in Figure 8 were defined as basic requirements for the scenario.

![UML Class Diagram of the Use Case Scenario](image.png)

Figure 8: UML Class Diagram of the Use Case Scenario
The Unified Modelling Language (UML) is a standard graphical notation to describe and design software systems, based on object-oriented modelling, and other systems that can be represented as object-oriented. In object-oriented modelling, an object is an instance of a class. In turn, a class represents the abstraction of all objects sharing the same characteristics. Example of a class is the “Person” class for representing all persons with their characteristics, such as first name, last name, birth date and so on. Another common concept in object-oriented modelling is the sub-class (specialisation). A sub-class inherits all the characteristics and properties of a class, and in addition it has its own properties. For example, “Patient” class is a sub-class of “Person”, and current diseases are the properties of the sub-class. All the other properties, such as first name, last name, birth date and so on, are inherited. Figure 8 shows the UML Class diagram of a data structure to represent a Patient (sub-class of a Person class), with specific medical condition and medications (Conditions and Medication classes), collecting data in form of a questionnaire and from a personal device, i.e., a glucometer (InstanceOfQuestionnaire and GlucometerRecordings classes). Doctor and Nurse classes, both sub-classes of Person class, represent the healthcare professionals taking care of the patient (Patient class). For example, the doctor prescribes medications (a segment between the classes Doctor and Medication indicates that), and the nurse assesses the recording from the glucometer. On the right side of Figure 8 there are classes that work as preliminary data for the model, for example coded medical terminology (SNOMED_CT, ATC_DDD classes). A class can also be defined to represent a specific type of data, for example the Address class.

In the diagram (Figure 8), each class is a square composed by three compartments. The top one presents the name, the middle one shows the specific properties of a class, and the third (bottom) one if for the operations (not specified in this model.)

5.2.5 From conceptual model to HL7 FHIR implementation

5.2.5.1 Required level of interoperability

Since the EHR System and the Patient Portal are connected and used to support the processes and services offered to the patients at a national and European Union (EU) level, all levels of interoperability should be considered (technical, semantic, organisational, and legal) (European Commission, 2017). This translates, at a practical level, to offering available, easy, identifiable, accessible, and user-focused services. One of these services, described in this scenario, is smooth and timely medical summary sharing that includes the information of an active participation intervention through a Patient Portal.

5.2.5.2 Required classes and attributes of the information

The HL7 FHIR Resources (Resourcelist - FHIR v4.0.1, n.d.) structure, elements and data types were used as reference to complement the classes and attributes presented in Figure 8. Compared to the UML Class Diagram, Table 14 contains additional data elements that are mandatory for the related FHIR Resource instantiation without being necessarily suitable for the conceptual modelling (marked with an asterisk at the beginning). Additionally, notice that some FHIR Resource Types need to be instantiated more than once because more than one actor holds
that type of information (e.g., practitioner and practitioner role), in those cases, the information instantiation column only gives one of the examples.

Table 14: Required classes, attributes and FHIR Resources with Information Instantiation examples

<table>
<thead>
<tr>
<th>Attributes with description</th>
<th>Information Instantiation</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Class: Person</strong></td>
<td></td>
</tr>
<tr>
<td>Contains the relevant personal and demographic information of a person.</td>
<td>FHIR Resource: Person (FHIR, n.d., “Person”).</td>
</tr>
<tr>
<td>firstName: string</td>
<td>Svenna</td>
</tr>
<tr>
<td>Person’s first name.</td>
<td></td>
</tr>
<tr>
<td>lastName: string</td>
<td>Svensson</td>
</tr>
<tr>
<td>Person’s last name.</td>
<td></td>
</tr>
<tr>
<td>personNumber: Identifier</td>
<td>670530-7656</td>
</tr>
<tr>
<td>Unique identifier of the person.</td>
<td></td>
</tr>
<tr>
<td>passportNumber: Identifier</td>
<td>59000002</td>
</tr>
<tr>
<td>Patient’s passport number.</td>
<td></td>
</tr>
<tr>
<td>dateOfBirth: date</td>
<td>30 May 1967</td>
</tr>
<tr>
<td>Patient’s birth date.</td>
<td></td>
</tr>
<tr>
<td>gender: code</td>
<td>Female</td>
</tr>
<tr>
<td>Person’s administrative gender as corresponding to official personal documentation.</td>
<td></td>
</tr>
<tr>
<td>address: Address</td>
<td>Gatagatan 1234 Apt. 4101, 11534, Stockholm, Sweden</td>
</tr>
<tr>
<td>Patient’s address.</td>
<td></td>
</tr>
<tr>
<td>phoneNumber: ContactPoint</td>
<td>+46 070-893-3234</td>
</tr>
<tr>
<td>Patient’s contact number.</td>
<td></td>
</tr>
<tr>
<td><strong>Class: Patient</strong></td>
<td></td>
</tr>
<tr>
<td>patientCode: Identifier</td>
<td>19203948757</td>
</tr>
<tr>
<td>Unique identifier of the patient within the system.</td>
<td></td>
</tr>
<tr>
<td>*language: CodeableConcept</td>
<td>eng</td>
</tr>
<tr>
<td>UNIR code for the language of the document. Recommended attribute on the IPS.</td>
<td>es</td>
</tr>
<tr>
<td>sv</td>
<td>Swedish</td>
</tr>
<tr>
<td>*target: Reference</td>
<td>URL of applicable resource.</td>
</tr>
<tr>
<td>The resource to which this actual person is associated.</td>
<td></td>
</tr>
<tr>
<td><strong>Class: Organisation</strong></td>
<td></td>
</tr>
<tr>
<td>name: string</td>
<td>Clínica de Salud</td>
</tr>
<tr>
<td>Organisation’s name.</td>
<td></td>
</tr>
<tr>
<td>identifier: Identifier</td>
<td>SEC18293746</td>
</tr>
<tr>
<td>Organisation’s unique identifier.</td>
<td></td>
</tr>
<tr>
<td>type: CodeableConcept</td>
<td>prov</td>
</tr>
<tr>
<td>HL7 code for type of organisation.</td>
<td></td>
</tr>
<tr>
<td>address: Address</td>
<td>Calle del Hospital, 46, 28007 Madrid, Spain</td>
</tr>
<tr>
<td>Organisation’s address.</td>
<td></td>
</tr>
<tr>
<td>phone: ContactPoint</td>
<td>+34 876 34 69 01</td>
</tr>
<tr>
<td>Organisation’s contact number.</td>
<td></td>
</tr>
<tr>
<td><strong>Class: Doctor</strong></td>
<td></td>
</tr>
<tr>
<td>Information about the person with a formal responsibility related to healthcare or related services.</td>
<td></td>
</tr>
</tbody>
</table>

Cooperative and Supportive Action – [https://www.x-ehealth.eu/](https://www.x-ehealth.eu/)

<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>regNumber</td>
<td>Identifier</td>
</tr>
<tr>
<td>specialisation</td>
<td>CodeableConcept</td>
</tr>
<tr>
<td></td>
<td>SNOMED CT code for the practitioner’s specialty.</td>
</tr>
</tbody>
</table>

**Class: Nurse**

Information about the person with a formal responsibility related to healthcare or related services.


<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>regNumber</td>
<td>Identifier</td>
</tr>
<tr>
<td>specialisation</td>
<td>CodeableConcept</td>
</tr>
<tr>
<td></td>
<td>SNOMED CT code for the practitioner’s specialty.</td>
</tr>
</tbody>
</table>

**Class: Appointment**

Contains the elements required to book an appointment for health services.


<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>identifier</td>
<td>Identifier</td>
</tr>
<tr>
<td>status</td>
<td>Code</td>
</tr>
<tr>
<td>appointmentType</td>
<td>Code</td>
</tr>
<tr>
<td></td>
<td>Coded reason for the appointment, includes checkup, follow up, emergency, etc.</td>
</tr>
<tr>
<td>specialty</td>
<td>CodeableConcept</td>
</tr>
<tr>
<td></td>
<td>SNOMED CT code representing the clinical specialty of the practitioner.</td>
</tr>
<tr>
<td>startDateTime</td>
<td>DateTime</td>
</tr>
<tr>
<td>endDateTime</td>
<td>DateTime</td>
</tr>
</tbody>
</table>

**Class: Questionnaire**

Contains the elements required to document a questionnaire answered by the patient.


<table>
<thead>
<tr>
<th>Field</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>createdDateTime</td>
<td>DateTime</td>
</tr>
<tr>
<td>concept</td>
<td>CodableConcept</td>
</tr>
<tr>
<td></td>
<td>SNOMED CT code for the questionnaire.</td>
</tr>
<tr>
<td>status</td>
<td>code</td>
</tr>
<tr>
<td></td>
<td>Status of the publication of the questionnaire.</td>
</tr>
<tr>
<td>question1</td>
<td>string</td>
</tr>
<tr>
<td>question2</td>
<td>string</td>
</tr>
<tr>
<td>question3</td>
<td>string</td>
</tr>
<tr>
<td>question4</td>
<td>string</td>
</tr>
<tr>
<td>question5</td>
<td>string</td>
</tr>
<tr>
<td></td>
<td>First item of the questionnaire.</td>
</tr>
<tr>
<td></td>
<td>Second item of the questionnaire.</td>
</tr>
<tr>
<td></td>
<td>Third item of the questionnaire.</td>
</tr>
<tr>
<td></td>
<td>Fourth item of the questionnaire.</td>
</tr>
<tr>
<td></td>
<td>Fifth item of the questionnaire.</td>
</tr>
</tbody>
</table>
### Questionnaire Items

**Question 6:** Feeling bad about yourself—or that you are a failure or have let yourself or your family down.

**Question 7:** Trouble concentrating on things, such as reading the newspaper or watching television.

**Question 8:** Moving or speaking so slowly that other people could have noticed? Or the opposite—being so fidgety or restless that you have been moving around a lot more than usual.

**Question 9:** Thoughts that you would be better off dead or of hurting yourself in some way.

---

**Answer 1:** Integer for possible answers that apply to all questions:
- 0 - Not at all
- 1 - Several days
- 2 - More than half the days
- 3 - Nearly every day

**Answer 2:** 1

**Answer 3:** 0

**Answer 4:** 2

**Answer 5:** 1

**Answer 6:** 2

**Answer 7:** 3

**Answer 8:** 0

**Answer 9:** 1

**Total Score:** 11

**Interpretation:** Moderate depression

---

**Class: CurrentMedication**

The documentation of current medications, including supplements and homeopathic remedies, is fundamental on aiding the discovery of a new diagnosis or explanation of current symptoms.


**Created DateTime:** 20/03/2022 18:34:05

**Drug:** ATC_DDD

ATC code for medications, including supplements and homeopathic remedies.

**Drug:** N06AB06 | Sertraline

**StartDate:** 20/05/2021
### Condition
Summary of patient’s conditions as determined by healthcare professionals.

**FHIR Resource:** Condition (FHIR, n.d., “Condition”).

| CreatedDateTime: Date/Time | 20/03/2022 16:34:05 |
| Description: CodeableConcept | 35489007 | Depressive disorder (disorder) |
| StartDate: Date | 20/03/2022 |
| EndDate: Date | NA |
| DiagnosedDate: Date | 20/03/2022 |

### GlucometerRecordings
Summary of capillary blood glucose recordings in mg/dL taken with a glucometer.


| CreatedDateTime: Date/Time | 20/03/2022 17:34:05 |
| DailyPrePraAv: integer | 117 mg/dL |
| WeeklyPrePraAv: integer | 107 mg/dL |
| MonthlyPrePraAv: integer | 109 mg/dL |
| DailyPostPraAv: integer | 108 mg/dL |
| WeeklyPostPraAv: integer | 109 mg/dL |
| MonthlyPostPraAv: integer | 107 mg/dL |

### PROMsummary
Summary of capillary blood glucose recordings in mg/dL taken with a glucometer.


| CreatedDateTime: Date/Time | 20/03/2022 13:34:05 |
| FirstAnsweredTotalScore | 17 |
| FirstAnsweredInterpretation | Moderately severe |
| LastSixAnsweredTotalScore | 14 |
5.2.5.3 Standards and dictionaries for the implementation

In this scenario the main data transfer standard used is HL7 FHIR, which includes its resources, elements, and data types. Following the recommendation for the standardisation of information and interoperability (Benson & Grieve, 2016), standardised terminologies, value sets and code systems were used as much as possible. Within the elements and datatypes of HL7 FHIR, a wide variety of internal codes and value sets are defined thoroughly; these include all the attributes with data types defined as “Code” or “CodeableConcept” presented in Table 14 (e.g., specialisation, medication name, etc.). External terminologies that could be used are described in Table 15.

Table 15: External terminologies used for the Use Case Scenario

<table>
<thead>
<tr>
<th>Terminology</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>Systematised Nomenclature of Medicine -- Clinical Terms (SNOMED CT)</td>
<td>SNOMED CT “…is the most comprehensive, multilingual, clinical healthcare terminology… It enables the consistent representation of clinical content in clinical information systems, health data and analytics platforms, and interoperability solutions.” (SNOMED, n.d.)</td>
</tr>
<tr>
<td>Anatomical Therapeutic Chemical (ATC) Classification System</td>
<td>“The ATC Classification System is a classification of active ingredients of drugs according to the organ or system on which they act and their therapeutic, pharmacological and chemical properties.” (National Library of Medicine, n.d.)</td>
</tr>
<tr>
<td>International Classification of Diseases (ICD)</td>
<td>“…ICD has been the basis for comparable statistics on causes of mortality and morbidity between places and over time. Originating in the 19th century, the latest version of the ICD, ICD-11, was adopted by the 72nd World Health Assembly in 2019 and came into effect on 1st January 2022.” (ICD, n.d.)</td>
</tr>
<tr>
<td>Logical Observation Identifiers Names and Codes (LOINC)</td>
<td>“LOINC is a common language (set of identifiers, names, and codes) for identifying health measurements, observations, and documents.” (LOINC, n.d.)</td>
</tr>
<tr>
<td>Nomenclature for Properties and Units (NPU)</td>
<td>“The NPU terminology is a coding system and terminology for identification and communication of examination results from clinical laboratories in the health area.” (NPU, n.d.)</td>
</tr>
</tbody>
</table>

5.2.6 Logical data modelling with HL7 FHIR resources
ClinFHIR Graph Builder 2 (ClinFHIR GB2, n.d.) was used for the logical data modelling step of the use case scenario building. ClinFHIR GB2 was preferred because of its capability for visualising the data and resources required to model a scenario, its compatibility with HL7 FHIR latest version, and the ability to create views according to the healthcare professional’s profile.

The use case scenario modelling project was created and uploaded to ClinFHIR GB2 server and can be accessed via this link: [http://gb2.clinfhir.com#cfsb1658224034226](http://gb2.clinfhir.com#cfsb1658224034226) or by searching for “Use case PHGD v1.0.6” in the GB2 Library. Four different views were defined in accordance with each healthcare professional profile and a global view: Diabetes Nurse (DN) (Figure 9), Psychiatrist (PS) (Figure 10), General Practitioner (GP) (Figure 11) a Global view (Figure 12). The HL7 FHIR Resource types and names for this instantiation are detailed in Table 16. A total of 31 resources were used to model the scenario.

**Table 16: HL7 FHIR Resources required**

<table>
<thead>
<tr>
<th>Resource Instances</th>
<th>Resource Type</th>
<th>Resource name</th>
<th>DN</th>
<th>PS</th>
<th>GP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Patient</td>
<td>Svenna Svennson</td>
<td>X</td>
<td>X</td>
<td>X</td>
</tr>
<tr>
<td>5</td>
<td>Organization</td>
<td>Diabetesgatan Huslakarmottagning</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Teva Sweden AB</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Stockholms Psykiatri</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pfizer</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Clinica de Salud</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>3</td>
<td>Practitioner</td>
<td>Virginia Henderson</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Gustav Gustavsson</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Manuel Rodriguez Ruiz</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>3</td>
<td>PractitionerRole</td>
<td>Diabetes Nurse</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Psychiatrist</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td></td>
<td></td>
<td>General Practitioner</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>2</td>
<td>MedicationStatement</td>
<td>Diabetes Medication List</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Psychiatry Medication List</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Medication</td>
<td>Metformin</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Alprazolam</td>
<td></td>
<td>X</td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Sertraline</td>
<td></td>
<td></td>
<td>X</td>
</tr>
<tr>
<td>1</td>
<td>Device</td>
<td>Glucometer</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>DeviceUseStatement</td>
<td>Blood glucose monitoring by patient</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Condition</td>
<td>Diabetes Diagnosis</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Insomnia</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Severe depression</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Anxiety</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Observation</td>
<td>Glucometer recordings</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Questionnaire</td>
<td>PHQ-9 for Depression</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>QuestionnaireResponse</td>
<td>PHQ-9 initial response</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>PHQ-9 last response</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>ClinicalImpression</td>
<td>Summary of PHQ-9 responses</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>1</td>
<td>Encounter</td>
<td>Emergency visit</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td>2</td>
<td>Composition</td>
<td>Summary from Diabetes Nurse</td>
<td>X</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>Summary from Psychiatrist</td>
<td></td>
<td>X</td>
<td></td>
</tr>
</tbody>
</table>
The use case scenario uses two types of PGHD: a PROM questionnaire (PHQ-9 for Depression) and data generated from glucose monitoring. A series of resources were used to summarise the data from the glucometer recordings. On one side resources to register the device and its specific use were Device and DeviceUseStatement, on the other side, an Observation resource summarises the measurements per se (Figure 9). It should be observed that one of the advantages of using ClinFHIR is that the resources can be graphed, showing the relationships between resources. Therefore, it can be easier to observe what references need to be made between them. For instance, following from the Glucometer recording Observation resource it can be observed that both the subject and the performer is the patient.

Figure 9: Diabetes Nurse View
The other PGHD type used, the PHQ-9 questionnaire, was modelled using a Questionnaire, QuestionnaireResponse, and ClinicalImpression by the psychiatrist for the interpretation of the results (Figure 10).

![Figure 10: Psychiatrist View](image1)

![Figure 11: General Practitioner View](image2)
Figure 12: Global View
5.2.7 Instantiation of the resources

After the data has been modelled in ClinFHIR, the JSONs created per FHIR resource can be instantiated into the HAPI FHIR server (HAPI FHIR, n.d.). This can allow to test data exchange between the server and the system being developed. For this case scenario, only one FHIR resource was instantiated in HAPI FHIR: the Questionnaire resource. This was done to insert an appropriate URL reference in the QuestionnaireResponse resources. The instantiation can be accessed in: https://hapi.fhir.org/baseR4/Questionnaire/6843309/_history/1. A glimpse of the JSON file structure can be seen in Figure 13, were the benefits of using standardised terminologies can be observed. For instance, in this case the LOINC codes for each question-and-answer value set of the questionnaire were used to allow for semantic and syntactic interoperability.

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  "id": "6843309",
  "meta": {
    "versionId": "1",
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    "source": "#1Da011Eapoxu7ML"
  },
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  "version": "2002",
  "title": "Patient Health Questionnaire (PHQ-9) for Depression",
  "derivedFrom": [ "https://www.phqscreeners.com/" ],
  "status": "active",
  "experimental": false,
  "publisher": "Pfizer, Inc",
  "description": "The PHQ-9 is a validated, 9-question tool to assess the degree of depression present in an individual: the last question is not scored, but is useful functionally to help the clinician assess the impact of the patient's symptoms on his or her life.",
  "copyright": "Copyright © Pfizer Inc. All rights reserved. Developed by Drs. Robert L. Spitzer, Janet B.W. Williams, Kurt Kroenke and colleagues, with an educational grant from Pfizer Inc. No permission required to reproduce, translate, display or distribute.",
  "code": [ {
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    }
  ]
}
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Figure 13: Questionnaire resource JSON instantiated in HAPI FHIR
6 Lessons learned

This study aimed to explore new areas where Patient Summaries could be included for data exchange. We found literature reviews as a start useful to map the respective area, here more specifically defining and implementing a project that involves PGHD which has no designated fields in the Patient Summary yet. Per definition, the Patient Summary aims to be condition-agnostic. Depending on the chosen use case, more detailed modelling of condition-specific information might however be needed. PGHD/PROMs defined for follow-up and monitoring will most likely be linked to a certain condition. Handling of continuous monitoring data requires decisions how to aggregate them in a Patient Summary as massive amounts of data may become a burden to analyse and understand.

Regarding the data modelling process for the exploratory use case scenario using ClinFHIR GB2, some lessons learned are worth mentioning. First, ClinFHIR GB2 facilitates data modelling by providing a graphical user interface (GUI) that can graph the relationship between the FHIR resources used for the use case scenario. Additionally, ClinFHIR GB2’s capability to suggest potential references between resources may allow to construct more comprehensive data modelling scenarios. Second, even the most thorough terminologies are lacking some categories of data elements. For instance, even if SNOMED CT is the most comprehensive terminology for clinical terms, it misses coded questionnaires items for both questions and answers value sets. Hence, using only one terminology could be insufficient. In use cases involving PGHD, it is recommended to choose a PROM that has been codified in a standardised terminology to allow for data exchange and avoid creating stand-alone data elements. Such a PROM has preferably been validated in as much countries as possible worldwide, especially if the scenario may require international data exchange. Still, language translation and validation of PROMs is very limited in general. In cross-border healthcare translation becomes an issue and relying on the description field of a terminology might not necessarily convey the clinical meaning correctly.

7 Recommendations

The recommendations concluded from the deliverable are related to the process of including the Patient Summary in new use cases or areas. We propose the following steps:

1. Perform a stakeholder analysis and set up a multidisciplinary team of stakeholders that are involved in the use case. This multidisciplinary team should be composed of healthcare professionals (domain experts), knowledge engineers (to express knowledge in different ways), computer scientists and programmers (for the implementation), medical informaticians (for data modelling and to bridge the experts together), and decision makers (at least at local level). Involve them in the definition of the scenario and data model from the beginning of the project.
2. Explore a new area by doing a literature review and set up a list of possible use cases
3. Create a process flow diagram that can guide you to map your own process within the area
4. Review the barriers in section 5.1 and score them in terms of probability of occurrence and impact related to your own use case. The following barriers might apply to most use cases:
   - Assess coherence of applicable legislation before adoption and throughout the implementation (European Commission, 2017).
   - Undergo a “Digital check” to ensure that the legislation requirements suit the digital world and barriers to digital exchange have been identified (European Commission, 2017).
   - Identify the extent to which different state-members’ information security laws and regulations may apply to the data collection, storage, or exchange.
   - Recognise the stakeholders involved in the implementation process and involve them in the definition of the scenario and data model from the beginning of the project. Perform a risk analysis in your multi-disciplinary stakeholder team to identify and address barriers related to work culture and organisational agreements in a timely manner.
   - Evaluate if the use of proprietary software can be avoided to capture data or identify what needs to be adapted to facilitate data exchange, monitoring, or analysis.
   - Invest time in knowing, with as much detail as possible, the steps involved during the care processes involved in the implementation, as well as the risks and potential barriers to encounter along the way.
   - Ensure agreements on reference data in the form of taxonomies, ontologies, controlled vocabularies, code lists, reusable data structures or models and thesauri (European Commission, 2017).
   - Undergo a revision of how the data collected will be incorporated into the EMR or EHR of the stakeholders that could be involved.
   - Use formal technical specifications when creating the system documentation.

5. Model the data required for a representative use case scenario of the implementation using the seven-step approach illustrated in Figure 14 and followed as an example in section 5.2.

Start with a textual description of your Use Case Scenario (Scenario). Then define prerequisites involving actors, Information Technologies (IT) systems and the properties of the IT systems involved. Scenario prerequisites definitions ease the definition of the information to be transferred, and furthermore, set the basis for the conceptual data modelling using a UML Class Diagram. Afterwards, analyse the Scenario further analysed in terms of the required level of interoperability, classes and attributes for the information, and the standards and terminologies needed for the implementation. Using the Scenario analysis, you may proceed with the logical data modelling using for example Health Level Seven (HL7) Fast Healthcare Interoperability Resources (FHIR) Resources.
8 Conclusions

This exploratory study described the process of assessing and integrating new concepts using the example of patient-generated health data as a proxy for the area of patient decision aids and citizen-driven health science. We gave an overview of different barriers that are relevant in this context and presented the results of modelling one specific use case scenario. Based on the results of this modelling exercise, we proposed a detailed process to explore new areas, starting by setting up a project team and concluding with a seven-step modelling process.

Further areas such as artificial intelligence outcomes-based research, clinical research, clinical trial integration and business analytics in the context of the patient summary have been reviewed but not been modelled in more detail. The results showed that these areas have not been much explored in relation to Patient Summaries, but the review elicited some specifications of variables, algorithms or methodologies that can be considered for further development of the Patient Summary.
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Appendices

Appendix 1 – Paper presented at MIE2021, published in *Stud Health Technol Inform*

Appendix 2 – Workshop slides presented at MIE2022

Appendix 3 – J:son code from the use case example
Can the European EHR Exchange Format Support Shared Decision Making and Citizen-Driven Health Science?

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Abstract. The European Commission published in 2019 the Recommendation on the European Electronic Health Record exchange format (EHRxF) to support citizens and healthcare providers in securely accessing and sharing Electronic Health Records (EHRs). The European EHRxF is expected to contribute to the digital transformation of health and care in the digital single market empowering citizens and building a healthier society. This paper presents areas of work that need to be resolved for the European EHRxF to advance shared decision-making for patients and citizen-centered science.

Keywords. Interoperability, shared decision making, citizen science, citizen empowerment, person centered care, digital Health Policy

1. Introduction

The European EHRxF recommendation \cite{1} presents the list of principles and guidelines for the creation and adoption of specifications that support citizens and health care providers in securely accessing and sharing Electronic Health Records (EHRs). At the same time, the recommendation connects the European EHRxF to key European initiatives for the advancement of the digital health infrastructure across the Union \cite{2}.

The recommendation recognizes the right of citizens to access and securely share their health data across borders, and describes significant benefits including quality of care for citizens, health care costs reduction, significant time savings and modernization of health systems. Noting that more than two million Europeans sought health care in another member state \cite{3}, the European Council conclusions in 2017 emphasized the need of member states to make their EHR systems interoperable, enabling citizens to have better control of their data \cite{4} and become active agents of their own health journey.

With wide adoption of the European EHRxF, the level of interoperability will improve and information will be processed in a consistent manner across health systems, respecting the General Data Protection Regulation and using secure electronic identification and authentication means (eIDAS) supported by the EU cybersecurity framework and building upon the eHealth Digital Services Infrastructure (eHDSI) and

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forthcoming myHealth@EU programmes. With the European EHRxF advancing the quality of data, large health data repositories will enable the use of new technologies such as big data analytics and artificial intelligence to fuel new scientific discoveries, support shared decision making, and provide effective decision aids to patients.

The recommendation presents a set of principles, a set of common technical specifications and a process to further the elaboration of the European EHRxF [1]. The suggested mechanisms include frameworks for security and trust at the national level using the tools created in eHDSI and create incentives of the use of interoperable EHRs in national digital health networks. To develop the basis for a uniform interoperable data-sharing format framework, the intergovernmental eHealth cooperation action “X-eHealth” was established in September 2020 [5]. X-eHealth aims to foster the uptake of the European EHRxF on regional, national and European level by extending the already in place Patient Summary and ePrescription services. This will be done by defining functional and technical requirements for the newly added use cases considered of highest priority: Laboratory Results, Medical Imaging and Reports, Hospital Discharge Reports and patient summaries for Rare and Undiagnosed Diseases.

This paper presents initial results of an exploratory study that is part of X-eHealth, aiming to explore the degree to which and under what conditions these priority specifications for the European EHRxF can be used to support shared decision making and citizen science. Shared decision making is defined as “collaborative process of reaching a decision” [6] and refers to the decisions that patients make about alternative health treatments and procedures, guided by healthcare professionals [7]. Citizen Science is defined as “the general public engagement in scientific research activities when citizens actively contribute to science either with their intellectual effort or surrounding knowledge or with their tools and resources”, by Socientize Consortium [8]. This definition relates closely to the use of the European EHRxF for citizen science. European Commission considers “Citizen science” a significant domain [9], and results from proposed initiatives about “state of Citizen Science in Europe” [10] and “COVID-19-related mobile apps” [11] have been published as reports, by the Joint Research Centre (JRC), the European Commission’s science and knowledge service. The next sections present our methodology, results, discussion and conclusions on the next steps to be taken so that the European EHRxF is fit for shared decision making and citizen science.

2. Methodology

Starting point for this exploratory study was document analysis of the European EHRxF recommendation document and its annex [1]. Preliminary literature search investigated whether shared decision making and citizen science were part of studies about Electronic Health Records and their summaries. Relevant papers about the topic were analyzed. Further, Health Level 7 (HL7) International work on accelerators [12], which aims at developing global health data interoperability adopting HL7 Fast Healthcare Interoperability Resources (FHIR) standard, was analyzed, and material from the FHIR connectathon in 2021 was reviewed to elicit trends in standardization. Three different literature searches in PubMed/Medline were done using the following search strings: 1 - ("citizen science"[MeSH] OR "citizen science"[Text word]) AND "Electronic Health Records"[MeSH]; 2 - "Decision Making, Shared"[MeSH] AND "Electronic Health Records"[MeSH]; 3 - ("Patient Generated Health Data" [Text word] OR "Patient Generated Health Data"[MeSH]) AND “Electronic Health Record”[MeSH].
3. Results

Shared decision making and Citizen Science have been identified as key issues to be addressed in the European EHRxF. From the document analysis of the recommendation, its annex, and the guidelines about the patient summary [13], guidance on how to use the specification to facilitate shared decision making was absent. In fact, the Patient summary does not include any sections devoted to shared decision making, besides the aim to support patient empowerment. From the literature search about “shared decision making” and “Electronic Health Record”, five items have been identified. Results show that “clinician notes shared with the patients” [14] and “pattern of decision making discourse” [15] have to be taken into account for developing an enriched European EHRxF. The literature search about “Citizen Science” and “Electronic Health Record” gave no results (zero item). A more targeted search using “Patient Generated Health Data” and “Electronic Health Record” as search terms resulted in 24 hits. Some studies [16,17] reported about the adaptation of standards for integration of data from wearables into EHRs, in particular HL7 Common Document Architecture (CDA). Other studies point out the limited capacity of EHRs for direct patient input [18], insufficient integration of mental health apps with EHRs [19], and EHRs being inferior at storing patient contextual data such as patients' needs, values, goals, and preferences relevant to their care [20]. This limited support for direct patient engagement was confirmed in the recent FHIR connectathon, in the Patient Empowerment track.

As for HL7 accelerators [12], the “Argonaut Project” aims at developing FHIR-based API and Core Data Services specifications to speed up the sharing of data. These APIs have been largely adopted by health systems in the US and inspired developments in Canada, Australia, and the Nordics. Results from that project can be considered in implementing the modelling of datasets about shared decision making and citizen science (https://argonautwiki.hl7.org/Main_Page). Then, "The CARIN Alliance" project aims at enhancing the ability for consumers and their authorized caregivers to get, use, and share their digital health information. However, it seems the project is focusing on the US context as the concept of “Consumer-Directed Exchange” defined by HIPAA legislation needs to be satisfied (https://www.hl7.org/carin/). Finally, the "Da Vinci project" is for defining a holistic view, including payers and providers to benefit patient-centred care, again focusing in the US (https://www.hl7.org/about/davinci/). These developments can inform similar activities aiming at including public and private payers in technical solutions adopting the European EHRxF.

The recent online HL7 FHIR Connectathon attracted more than 600 people (FCAT26 - https://confluence.hl7.org/display/FHIR/2021-01+Connectathon+26) and was an opportunity to validate several scenarios and proof of concept applications related to shared decision making, many of which associated with accelerators. Among them, Patient Empowerment and International Patient Summary (IPS) where quite well attended. Patient empowerment concerned use cases where patients requested changes to their health record. IPS introduced the notion of IPS on demand. The track Findable Accessible Interoperable Reusable (FAIR) was most relevant to our study in the direction of supporting citizen science. The FAIR track and HL7 Fairness for FHIR project (FHIR4FAIR Implementation Guide) supported by the European funded FAIR4Health (www.fair4health.eu) project explored metadata for health data sets and developed links to the Bricks activity by the US National Institute of Health (https://brics.cit.nih.gov). That work would be most relevant in the generation of high-quality health data sets appropriately targeted for citizen science.
4. Discussion

Our results show that targeted use cases, datasets and associated metadata are needed for the European EHRxF to reliably support and promote citizen science and shared decision making perspectives. At present, literature searches involving “Citizen Science” and “Electronic Health Record” (as terms from MeSH vocabulary) did not give results, and we used “Patient Generated Health Data” as a sub-group to achieve more targeted results. The fact that Electronic Health Record frequently refers to data vetted by health professionals may explain this outcome. As an exploratory study, concepts included in the definition of “Citizen Science” should be used to further refine search strings for more extensively reviewing the area, complementing the knowledge gained from the different projects and connectathons, to also survey the feasibility of European EHRxF not only for information exchange, but also for analysis of longitudinal data. For future research, we suggest the following next steps to improve the suitability of the European EHRxF for citizen empowerment and further use of data:

1. Conduct in-depth literature review to elicit more detailed requirements for the European EHRxF to better serve citizen
2. Verify these requirements in a series of dedicated multi-stakeholder workshops with engagement of the industry including the civil society, startup cycles, researchers, policy makers, and standards development organizations.
3. Inform, educate and support the community about European EHRxF specifications and their support decision aids, shared decision-making, and citizen science focusing on metadata used in high-quality data sets.
4. Improve and refine the European EHRxF specifications to advance interoperability, quality, usability of the health data.

These steps should be taken with the initiative from the scientific community reaching out to the relevant stakeholders and the accelerated digitalization makes it urgent.

This preliminary research especially focuses on prospective exchange formats and implementable artifacts such as HL7 FHIR resources. To overcome the limitation to the level of information and data models, and reach context-sensitive level, aspects and perspectives of multiple domain such as patients’ personal, social, occupational and environmental context and individual perspectives will be addressed (step 2 in the above list), including knowledge and skills issues and eHealth literacy. For enabling knowledge-based decision support, multiple knowledge spaces, their formalization and mapping based on domain, as well as, specific ontologies will be considered (steps 3 and 4 in the above list). In addition, standards such as ISO 23903 “Health informatics — Interoperability and integration reference architecture — Model and framework” and previous literature on the topic, for instance [21], will be carefully examined.

5. Conclusions

For the European EHRxF to be successfully deployed in the areas of shared decision making and citizen science, it has to be known and be recognized by stakeholders including the civil society, academia, policy makers, and the industry. Tools need to be made available that incorporate the format in relevant applications. Guidance on the process of integrating the European EHRxF in technical solutions need to be developed and validated. Semantic, language and accessibility aspects need to be elaborated on. Besides connecting to the start-up cycles, connection to research networks, and
facilitating communities of practice can help advance adoption and quality of the information shared in the European EHRxF.

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Barriers on implementation of Patient Reported Outcomes and Patient Generated Health Data

MIE2022 Workshop: Evaluating the Prospects of implementing EHRxF in European Digital Health Ecosystem: Barriers and Facilitators

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2 - Introduction
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References
1 - Definitions

- **Citizen Science** is defined as “the general public engagement in scientific research activities when citizens actively contribute to science either with their intellectual effort or surrounding knowledge or with their tools and resources”, by Socientize Consortium [1].

- **Shared decision making** is defined as “collaborative process of reaching a decision” [2] and refers to the decisions that patients make about alternative health treatments and procedures, guided by healthcare professionals [3].

- **Patient Generated Health Data**: "Health-related data created, recorded, or gathered by patients, family members, or caregivers, to help address a health concern. Distinct from data generated in clinical settings and through encounters with providers.” [4]

- **Patient Reported Outcome Measures**: "Assessment of the quality and effectiveness of health care as measured and directly reported by the patient." [5]
2 - Introduction

The European Electronic Health Record Exchange Format (EHRxF) aims to serve as a driver for advancing technical interoperability and improving health data quality in the European digital health ecosystem [6].

For the European EHRxF to be successfully deployed in the areas of shared decision making and citizen science:

- it has to be known and be recognized by stakeholders including the civil society, academia, policy makers, and the industry [7];
- tools need to be made available that incorporate the format in relevant applications [7].
3 - Aim of the study

Presenting initial results about barriers to the implementation of Patient Reported Outcomes and Patient Generated Health Data for self-management and shared decision making.

The starting point was a literature review study aimed at investigating capture, sharing and utilization of patient generated health data and patient reported outcome measures [8].
4 - Methodology

Mapping
• Mapping the use cases identified in the scoping review [5]

Additional searches
• Snowballing literature searches
• Intentional literature searches, e.g., with keywords “challenges”, “limitations” or “difficulties”

Analysis
• Thematic categorization of barriers
5 - Results
Categorization of barriers

- Some categories overlap
  - E.g.: “procedural” and “organisational”
- Difficulty to define clear limits between one and another category
  - E.g.: “security” and “software”
5 - Results

Example of Barrier: Technical - Software

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**Barrier**

PRO collection systems developed outside the EMR/EHR can create integration barriers at the point of care. [9]

**Rationale/Example**

If a separate PRO collection system is developed, the integration for visualization and clinical decision making at the point of care may require additional software development or programming specific to accomplish the integration.
5 - Results
Example of Barrier: Legal - Accessibility

**Barrier**
Small clinics or health programs difficulty to use population-level analytics.[9]

**Rationale/Example**
Data sharing with other organizations may be complicated by technical challenges, lack of standardization of PROs to use or lack of representativeness of the population that the clinic or program addresses.
5 - Results
Example of Barrier: Procedural – Capture or Collection

Barrier
Collection of PGHD may create anxiety for some patients [10].

Rationale/Example
For some patients, Self-Management (SM) strategies may not improve patient engagement or quality of care [10]. A previous evaluation of SM capability may be required.
Barriers on implementation of PROs and PGHD

**Technical**
- Hardware
- Software
- Interoperability
- System integration

**Legal/Political**
- Privacy
- Security
- Accountability

**Procedural**
- Data Modelling
- Capture or collection
- Reporting and sharing
- Analysis and Decision-Making

**Organisational**
- Business model
- Culture
- Resources

**Barrier**
Disparity of resources available for PGHD collection system implementation.

**Rationale/Example**
Disparity of resources may occur between different health entities (clinics, hospitals, etc.) within the same health system in a state member, or between health systems of different state members.

Resources necessary for PGHD collection system implementation frequently include technical support, problem solving support, training resources for patients and health team, and device expenses [11].
6 – Final remarks

- From the study, 45 barriers about the implementation of Patient Reported Outcomes and Patient Generated Health Data have been identified.
- To overcome the barriers:
  - Ensure that the process of collecting and sharing information is not burdensome for the patient. Otherwise, they will not comply with the process.
  - Ensure that the process of analysis and decision-making is not burdensome for the healthcare professional. (For example, if it requires the manual analysis of a huge amount of information it would be hard for the physician to find patterns from which to reach conclusions)
- The complete study will be published as scientific publications.
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Many thanks for your attendance!

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"definition": "Describes the details of the manufacturer of the medication product. This is not intended to represent the distributor of a medication product.",
"fshLine": "* manufacturer = Reference(cfsb1658224663590)"
],
"cfsb1658224483188": [
{
"path": "manufacturer",
"node": {
"id": "cfsb1658224663590",
"type": "Organization",
"display": "Pfizer",
"text": "Manufacturer of Sertraline and Alprazolam being administered by the patient.",
"x": 506,
"y": -727,
"fixed": true
},
"definition": "Describes the details of the manufacturer of the medication product. This is not intended to represent the distributor of a medication product.",
"fshLine": "* manufacturer = Reference(cfsb1658224663590)"
}
],
"cfsb1658226742345": [
{
"path": "recorder",
"node": {
"id": "cfsb165822403422416",
"type": "Practitioner",
"display": "Gustav Gustavsson",
"text": "Psychiatrist in Sweden.",
"x": 718,
"y": -285,
"fixed": true
},
"definition": "Individual who recorded the record and takes responsibility for its content.",
"fshLine": "* recorder = Reference(cfsb165822403422416)"
},
{
"path": "subject",
"node": {
"id": "cfsb16582240342243",
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario.",
"x": -164,
"y": -293,
"fixed": true
}
]
"definition": "Indicates the patient or group who the condition record is associated with."
"fshLine": "* subject = Reference(cfsb16582240342243)"
]}
"cfsb165822403422411": [
{"path": "recorder",
"node": {
"id": "cfsb16582240342242",
"type": "Practitioner",
"display": "Virginia Henderson",
"text": "Diabetes Nurse at Diabeteseagan Huslakarmottagning",
"x": -800,
"y": -416,
"fixed": true
},
"definition": "Individual who recorded the record and takes responsibility for its content."
"fshLine": "* recorder = Reference(cfsb16582240342242)"
]}
"cfsb16582240342248": [
{"path": "patient",
"node": {
"id": "cfsb16582240342243",
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario."
"x": -164,
"y": -293,
"fixed": true
},
"definition": "Patient information, If the device is affixed to a person."
"fshLine": "* patient = Reference(cfsb16582240342243)"
],
{"path": "owner",
"node": {
"id": "cfsb16582240342240",
"type": "Organization",
"display": "Diabeteseagan Huslakarmottagning",
"text": "Diabetes clinic in Sweden."
"x": -648,
"y": -659,
"fixed": true
},
"definition": "An organization that is responsible for the provision and ongoing maintenance of the device."
"fshLine": "* owner = Reference(cfsb16582240342240)"
]}
"cfsb16582240342249": [
{"path": "source",
"node": {
"id": "cfsb16582240342242",
"type": "Device",
"display": "Glucose Monitor",
"text": "Device that sends readings to the pharmacy."
"x": -293,
"fixed": true
},
"definition": "The device that sends readings to the pharmacy."
"fshLine": "* source = Reference(cfsb16582240342242)"
]}
"cfsb16582240342250": [
{"path": "encounter",
"node": {
"id": "cfsb16582240342251",
"type": "Encounter",
"display": "Diabetesgatan Huslakarmottagning",
"text": "Encounter for diabetes care."
"x": 788,
"y": -861,
"fixed": true
},
"definition": "Encounter for diabetes care."
"fshLine": "* encounter = Reference(cfsb16582240342251)"
]}
"cfsb16582240342251": [
{"path": "condition",
"node": {
"id": "cfsb16582240342252",
"type": "Condition",
"display": "Diabetes",
"text": "Condition recorded during the encounter."
"x": 788,
"y": -861,
"fixed": true
},
"definition": "Condition recorded during the encounter."
"fshLine": "* condition = Reference(cfsb16582240342252)"
]}
"cfsb16582240342252": [
{"path": "relatedArtifact",
"node": {
"id": "cfsb16582240342253",
"type": "RelatedArtifact",
"display": "Diabetes Nursing Notes",
"text": "Notes related to diabetes care."
"x": 788,
"y": -861,
"fixed": true
},
"definition": "Notes related to diabetes care."
"fshLine": "* relatedArtifact = Reference(cfsb16582240342253)"
]}
"cfsb16582240342253": [
{"path": "observation",
"node": {
"id": "cfsb16582240342254",
"type": "Observation",
"display": "Blood Sugar Levels",
"text": "Observation recorded during the encounter."
"x": -293,
"y": -293,
"fixed": true
},
"definition": "Observation recorded during the encounter."
"fshLine": "* observation = Reference(cfsb16582240342254)"
]}
"cfsb16582240342254": [
{"path": "resource",
"node": {
"id": "cfsb16582240342255",
"type": "Resource",
"display": "Diabetesgatan Huslakarmottagning",
"text": "Resource associated with the encounter."
"x": -293,
"y": -293,
"fixed": true
},
"definition": "Resource associated with the encounter."
"fshLine": "* resource = Reference(cfsb16582240342255)"
]}
"cfsb16582240342255": [
{"path": "relatedArtifact",
"node": {
"id": "cfsb16582240342256",
"type": "RelatedArtifact",
"display": "Diabetes Nursing Notes",
"text": "Notes related to diabetes care."
"x": -293,
"y": -293,
"fixed": true
},
"definition": "Notes related to diabetes care."
"fshLine": "* relatedArtifact = Reference(cfsb16582240342256)"
]}
"cfsb16582240342256": [
{"path": "activity",
"node": {
"id": "cfsb16582240342257",
"type": "Activity",
"display": "Diabetesgatan Huslakarmottagning",
"text": "Activity associated with the encounter."
"x": -293,
"y": -293,
"fixed": true
},
"definition": "Activity associated with the encounter."
"fshLine": "* activity = Reference(cfsb16582240342257)"
]}
"cfsb16582240342257": [
{"path": "resource",
"node": {
"id": "cfsb16582240342258",
"type": "Resource",
"display": "Diabetesgatan Huslakarmottagning",
"text": "Resource associated with the activity."
"x": -293,
"y": -293,
"fixed": true
},
"definition": "Resource associated with the activity."
"fshLine": "* resource = Reference(cfsb16582240342258)"
]}
"cfsb16582240342258": [
{"path": "relatedArtifact",
"node": {
"id": "cfsb16582240342259",
"type": "RelatedArtifact",
"display": "Diabetes Nursing Notes",
"text": "Notes related to diabetes care."
"x": -293,
"y": -293,
"fixed": true
},
"definition": "Notes related to diabetes care."
"fshLine": "* relatedArtifact = Reference(cfsb16582240342259)"
]}
"cfsb16582240342259": [
{"path": "activity",
"node": {
"id": "cfsb16582240342260",
"type": "Activity",
"display": "Diabetesgatan Huslakarmottagning",
"text": "Activity associated with the resource."
"x": -293,
"y": -293,
"fixed": true
},
"definition": "Activity associated with the resource."
"fshLine": "* activity = Reference(cfsb16582240342260)"
]}
"cfsb16582240342260": [
{"path": "resource",
"node": {
"id": "cfsb16582240342261",
"type": "Resource",
"display": "Diabetesgatan Huslakarmottagning",
"text": "Resource associated with the activity."
"x": -293,
"y": -293,
"fixed": true
},
"definition": "Resource associated with the activity."
"fshLine": "* resource = Reference(cfsb16582240342261)"
]}
"cfsb16582240342261": [
{"path": "relatedArtifact",
"node": {
"id": "cfsb16582240342262",
"type": "RelatedArtifact",
"display": "Diabetes Nursing Notes",
"text": "Notes related to diabetes care."
"x": -293,
"y": -293,
"type": "Practitioner",
"display": "Virginia Henderson",
"text": "Diabetes Nurse at Diabetessgatan Huslakarmottagning",
"x": -800,
"y": -416,
"fixed": true
},
"definition": "Who reported the device was being used by the patient.",
"fshLine": "* source = Reference(cfsb16582240342242)"
},
{ "path": "subject",
"node": {
"id": "cfsb16582240342243",
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario.",
"x": -164,
"y": -293,
"fixed": true
},
"definition": "The patient who used the device.",
"fshLine": "* subject = Reference(cfsb16582240342243)"
},
{ "path": "reasonReference",
"node": {
"id": "cfsb165822403422411",
"type": "Condition",
"links": [
{
"path": "subject",
"node": {
"id": "cfsb1657278108849",
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario.",
"x": -527,
"y": -393,
"fixed": true
},
"definition": "Indicates the patient or group who the condition record is associated with.",
"fshLine": "* subject = Reference(cfsb1657278108849)"
}
],
"display": "Diabetes Diagnosis",
"text": "Diabetes Diagnosis of Svenna Svennson.",
"x": -476,
"y": -384,
"fixed": true
},
"definition": "Indicates another resource whose existence justifies this DeviceUseStatement.",
"fshLine": "* reasonReference = Reference(cfsb165822403422411)"
},
{ "path": "device",
"node": {
"id": "cfsb16582240342248",
"type": "Device",
"x": -476,
"y": -384,
"fixed": true
},
"definition": "Indicates the device used in the scenario.",
"fshLine": "* device = Reference(cfsb16582240342248)"
}
"links": [
  {
    "path": "patient",
    "node": {
      "id": "cfsb1657278108849",
      "type": "Patient",
      "display": "Svenna Svennson",
      "text": "Patient of the scenario.",
      "x": -527,
      "y": -393,
      "fixed": true
    },
    "definition": "Patient information, If the device is affixed to a person.",
    "fshLine": "* patient = Reference(cfsb1657278108849)"
  },
  {
    "path": "Glucometer",
    "text": "Capillary blood glucometer used by patient.",
    "x": -384,
    "y": -642,
    "fixed": true
  },
  {
    "path": "performer",
    "node": {
      "id": "cfsb16582240342243",
      "type": "Patient",
      "display": "Svenna Svennson",
      "text": "Patient of the scenario.",
      "x": -164,
      "y": -293,
      "fixed": true
    },
    "definition": "Who was responsible for asserting the observed value as \"true\".",
    "fshLine": "* performer = Reference(cfsb16582240342243)"
  },
  {
    "path": "subject",
    "node": {
      "id": "cfsb16582240342243",
      "type": "Patient",
      "display": "Svenna Svennson",
      "text": "Patient of the scenario.",
      "x": -164,
      "y": -293,
      "fixed": true
    },
    "comment": "One would expect this element to be a cardinality of 1..1. The only circumstance in which the subject can be missing is when the observation is made by a device that does not know the patient. In this case, the observation SHALL be matched to a patient through some context/channel matching technique, and at this point, the observation should be updated.",
    "definition": "The patient, or group of patients, location, or device this
observation is about and into whose record the observation is placed. If
the actual focus of the observation is different from the subject (or a
sample of, part, or region of the subject), the `focus` element or the
`code` itself specifies the actual focus of the observation.

"fshLine": "* subject = Reference(cfsb16582240342243)"
},

"path": "device",
"node": {
  "id": "cfsb16582240342248",
  "type": "Device",
  "links": [
    {
      "path": "patient",
      "node": {
        "id": "cfsb1657278108849",
        "type": "Patient",
        "display": "Svenna Svennson",
        "text": "Patient of the scenario.",
        "x": -527,
        "y": -393,
        "fixed": true
      },
      "definition": "Patient information, If the device is affixed to a
person."
    }
  ],
  "display": "Glucometer",
  "text": "Capillary blood glucometer used by patient.",
  "x": -384,
  "y": -642,
  "fixed": true
},
"comment": "Note that this is not meant to represent a device involved in
the transmission of the result, e.g., a gateway. Such devices may be
documented using the Provenance resource where relevant.",
"definition": "The device used to generate the observation data.",
"fshLine": "* device = Reference(cfsb16582240342248)"
],
"cfsb16582240342242": [
  {
    "path": "author",
    "fshLine": "* author = Reference(cfsb16582240342242)",
    "node": {
      "id": "cfsb16582240342242",
      "type": "Practitioner",
      "display": "Virginia Henderson",
      "text": "Diabetes Nurse at Diabetessgatan Huslakarmottagning",
      "x": -769,
      "y": -466,
      "fixed": true
    }
  }
],
"cfsb16582240342245": [
  {
    "path": "section.entry",
    "fshLine": "* section.entry = Reference(cfsb16582240342245)",
    "node": {
      "id": "cfsb16582240342245",
      "type": "MedicationStatement",
      "text": "Medication for diabetes patient.",
      "x": -115,
      "y": -357,
      "fixed": true
    }
  }
]
"links": [
    {
      "path": "subject",
      "node": {
        "id": "cfsb1657278108849",
        "type": "Patient",
        "display": "Svenna Svennson",
        "text": "Patient of the scenario.",
        "x": -527,
        "y": -393,
        "fixed": true
      },
      "definition": "The person, animal or group who is/was taking the medication.",
      "fshLine": "* subject = Reference(cfsb1657278108849)"
    }
  ],
  "display": "Diabetes Medication List",
  "x": -818,
  "y": -263,
  "fixed": true,
  "text": "Medication list from the Diabetes Nurse."
}]
},
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario.",
"x": -527,
"y": -393,
"fixed": true
},
"definition": "Indicates the patient or group who the condition record is associated with.",
"fshLine": "* subject = Reference(cfsb1657278108849)"
],
"display": "Diabetes Diagnosis",
"text": "Diabetes Diagnosis of Svenna Svennson.",
"x": -431,
"y": -346,
"fixed": true
},
{
"path": "section[2].entry",
"fshLine": "* section[2].entry = Reference(cfsb165822403422413)",
"node": {
"id": "cfsb165822403422413",
"type": "Observation",
"links": [
{"path": "subject",
"node": {
"id": "cfsb1657278108849",
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario.",
"x": -527,
"y": -393,
"fixed": true
},
"definition": "The patient, or group of patients, location, or device this observation is about and into whose record the observation is placed. If the actual focus of the observation is different from the subject (or a sample of, part, or region of the subject), the `focus` element or the `code` itself specifies the actual focus of the observation.",
"fshLine": "* subject = Reference(cfsb1657278108849)"
],
"display": "Glucometer recordings",
"text": "Glucometer recordings by Svenna Svennson.",
"x": -32,
"y": -580,
"fixed": true
},
{
"path": "subject",
"fshLine": "* subject = Reference(cfsb16582240342243)",
"node": {
"id": "cfsb16582240342243",
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario.",
"x": -527,
"y": -393,
"fixed": true
}
"x": 5,
"y": -329,
"fixed": true
]
},
"cfsb165822403422422": [
{
"path": "questionnaire",
"fshLine": "* questionnaire = Reference(cfsb1658224034224219)",
"node": {
"id": "cfsb1658224034224219",
"type": "Questionnaire",
"display": "PHQ-9 for Depression",
"text": "Patient Health Questionnaire 9 (PHQ-9) for Depression.",
"x": 827,
"y": -20,
"fixed": true
}
},
{
"path": "subject",
"node": {
"id": "cfsb16582240342243",
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario.",
"x": -164,
"y": -293,
"fixed": true
}
},
"comment": "If the Questionnaire declared a subjectType, the resource pointed to by this element must be an instance of one of the listed types.",
"definition": "The subject of the questionnaire response. This could be a patient, organization, practitioner, device, etc. This is who/what the answers apply to, but is not necessarily the source of information.",
"fshLine": "* subject = Reference(cfsb16582240342243)"
},
{
"path": "source",
"node": {
"id": "cfsb16582240342243",
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario.",
"x": -164,
"y": -293,
"fixed": true
}
},
"comment": "If not specified, no inference can be made about who provided the data.",
"definition": "The person who answered the questions about the subject.",
"fshLine": "* source = Reference(cfsb16582240342243)"
},
{
"path": "author",
"node": {
"id": "cfsb165822403422416",
"type": "Practitioner",
"display": "Gustav Gustavsson",
"fshLine": "Gustav Gustavsson"
}
"text": "Psychiatrist in Sweden."
"x": 718,
"y": -285,
"fixed": true
}
"comment": "Mapping a subject's answers to multiple choice options and determining what to put in the textual answer is a matter of interpretation. Authoring by device would indicate that some portion of the questionnaire had been auto-populated."
"definition": "Person who received the answers to the questions in the QuestionnaireResponse and recorded them in the system."
"fshLine": "* author = Reference(cfsb165822403422416)" ]
"cfsb165822403422425": [
{
"path": "questionnaire",
"fshLine": "* questionnaire = Reference(cfsb165822403422419)",
"node": {
"id": "cfsb165822403422419",
"type": "Questionnaire",
"display": "PHQ-9 for Depression",
"text": "Patient Health Questionnaire 9 (PHQ-9) for Depression."
"x": 827,
"y": -20,
"fixed": true
}
},
{
"path": "subject",
"node": {
"id": "cfsb16582240342243",
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario."
"x": -164,
"y": -293,
"fixed": true
}
},
"comment": "If the Questionnaire declared a subjectType, the resource pointed to by this element must be an instance of one of the listed types."
"definition": "The subject of the questionnaire response. This could be a patient, organization, practitioner, device, etc. This is who/what the answers apply to, but is not necessarily the source of information."
"fshLine": "* subject = Reference(cfsb16582240342243)"
},
{
"path": "source",
"node": {
"id": "cfsb16582240342243",
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario."
"x": -164,
"y": -293,
"fixed": true
}
},
"comment": "If not specified, no inference can be made about who provided the data."
"definition": "The person who answered the questions about the subject."
}
Mapping a subject's answers to multiple choice options and determining what to put in the textual answer is a matter of interpretation. Authoring by device would indicate that some portion of the questionnaire had been auto-populated.

The patient or group of individuals assessed as part of this record.

Information supporting the clinical impression.
"x": 47,
"y": 21,
"fixed": true
],
"definition": "Information supporting the clinical impression.",
"fshLine": "* supportingInfo[1] = Reference(cfsb165822403422425)"
},
{
"path": "problem",
"node": {
"id": "cfsb1658226760615",
"type": "Condition",
"links": [
{
"path": "subject",
"node": {
"id": "cfsb16582240342243",
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario.",
"x": -164,
"y": -293,
"fixed": true
},
"definition": "Indicates the patient or group who the condition record is associated with.",
"fshLine": "* subject = Reference(cfsb16582240342243)"
}
],
"display": "Severe depression",
"text": "Severe depression Diagnosis of Svenna Svennson.",
"x": 239,
"y": -503,
"fixed": true
},
"comment": "e.g. The patient is a pregnant, has congestive heart failure, has an Adenocarcinoma, and is allergic to penicillin.",
"definition": "A list of the relevant problems/conditions for a patient.",
"fshLine": "* problem = Reference(cfsb1658226760615)"
},
{
"path": "problem",
"node": {
"id": "cfsb1658226742345",
"type": "Condition",
"links": [
{
"path": "subject",
"node": {
"id": "cfsb16582240342243",
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario.",
"x": -164,
"y": -293,
"fixed": true
}
},
"definition": "Indicates the patient or group who the condition record is associated with.",
"fshLine": "* subject = Reference(cfsb16582240342243)"
}
"display": "Insomnia Diagnosis of Svenna Svennson."
},
"comment": "e.g. The patient is a pregnant, has congestive heart failure, has an Adenocarcinoma, and is allergic to penicillin.",
"definition": "A list of the relevant problems/conditions for a patient."
"fshLine": "* problem[1] = Reference(cfsb1658226742345)"
},

{ "path": "problem",
"node": {
  "id": "cfsb1658301405829",
  "type": "Condition",
  "links": [
  {
    "path": "subject",
    "node": {
      "id": "cfsb16582240342243",
      "type": "Patient",
      "display": "Svenna Svennson",
      "text": "Patient of the scenario.",
      "x": -164,
      "y": -293,
      "fixed": true
    },
    "definition": "Indicates the patient or group who the condition record is associated with."
  }
  ],
  "display": "Anxiety",
  "text": "Anxiety Diagnosis of Svenna Svennson."
  
  "x": 271,
  "y": -348,
  "fixed": true
},
"comment": "e.g. The patient is a pregnant, has congestive heart failure, has an Adenocarcinoma, and is allergic to penicillin.",
"definition": "A list of the relevant problems/conditions for a patient."
"fshLine": "* problem[2] = Reference(cfsb1658301405829)"
}
],
"cfsb1658227482561": [
  { "path": "author",
  "fshLine": "* author = Reference(cfsb165822403422416)",
  "node": {
    "id": "cfsb165822403422416",
    "type": "Practitioner",
    "display": "Gustav Gustavsson",
    "text": "Psychiatrist in Sweden."
  },
  "x": 729,
  "y": -156,
  "fixed": true
}
"path": "section.entry",
"fshLine": "* section.entry = Reference(cfsb1658226467995)",
"node": {
  "id": "cfsb1658226467995",
  "type": "MedicationStatement",
  "links": [
    {
      "path": "subject",
      "node": {
        "id": "cfsb16582240342243",
        "type": "Patient",
        "display": "Svenna Svennson",
        "text": "Patient of the scenario.",
        "x": -133,
        "y": -251,
        "fixed": true
      },
      "definition": "The person, animal or group who is/was taking the medication.",
      "fshLine": "* subject = Reference(cfsb16582240342243)"
    }
  ],
  "display": "Psychiatry Medication List",
  "text": "Medication list from psychiatrist",
  "x": 209,
  "y": -556,
  "fixed": true
},

"path": "section[1].entry",
"fshLine": "* section[1].entry = Reference(cfsb1658226742345)",
"node": {
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  "type": "Condition",
  "links": [
    {
      "path": "subject",
      "node": {
        "id": "cfsb16582240342243",
        "type": "Patient",
        "display": "Svenna Svennson",
        "text": "Patient of the scenario.",
        "x": -133,
        "y": -251,
        "fixed": true
      },
      "definition": "Indicates the patient or group who the condition record is associated with.",
      "fshLine": "* subject = Reference(cfsb16582240342243)"
    }
  ],
  "x": 137,
  "y": -433,
  "fixed": true,
  "display": "Insomnia",
  "text": "Insomnia Diagnosis of Svenna Svennson."
},

"path": "section[1].entry"
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"fshLine": "* section[1].entry = Reference(cfsb1658226760615)",
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  "type": "Condition",
  "links": [
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      "node": {
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        "type": "Patient",
        "display": "Svenna Svennson",
        "text": "Patient of the scenario.",
        "x": -133,
        "y": -251,
        "fixed": true
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      "definition": "Indicates the patient or group who the condition record is associated with.",
      "fshLine": "* subject = Reference(cfsb16582240342243)"
    }
  ],
  "display": "Severe depression",
  "text": "Severe depression Diagnosis of Svenna Svennson.",
  "x": 299,
  "y": -423,
  "fixed": true
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  "fshLine": "* section[1].entry = Reference(cfsb1658301405829)",
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    "type": "Condition",
    "links": [
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        "node": {
          "id": "cfsb16582240342243",
          "type": "Patient",
          "display": "Svenna Svennson",
          "text": "Patient of the scenario.",
          "x": -133,
          "y": -251,
          "fixed": true
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        "definition": "Indicates the patient or group who the condition record is associated with.",
        "fshLine": "* subject = Reference(cfsb16582240342243)"
      }
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    "display": "Anxiety",
    "text": "Anxiety Diagnosis of Svenna Svennson.",
    "x": 425,
    "y": -347,
    "fixed": true
  }
},
{
  "path": "section[2].entry",
  "fshLine": "* section[2].entry = Reference(cfsb1658239280178)",
  "node": {
    "id": "cfsb1658239280178",
    "type": "Condition",
    "links": [
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        "path": "subject",
        "node": {
          "id": "cfsb1658239280178",
          "type": "Patient",
          "display": "Svenna Svennson",
          "text": "Patient of the scenario.",
          "x": -133,
          "y": -251,
          "fixed": true
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        "fshLine": "* subject = Reference(cfsb1658239280178)"
      }
    ],
    "display": "Depression",
    "text": "Depression Diagnosis of Svenna Svennson.",
    "x": 335,
    "y": -347,
    "fixed": true
  }
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"node": {
  "id": "cfsb1658239280178",
  "type": "ClinicalImpression",
  "links": [
    {
      "path": "subject",
      "node": {
        "id": "cfsb16582240342243",
        "type": "Patient",
        "display": "Svenna Svennson",
        "text": "Patient of the scenario.",
        "x": -133,
        "y": -251,
        "fixed": true
      },
      "definition": "The patient or group of individuals assessed as part of this record.",
      "fshLine": "* subject = Reference(cfsb16582240342243)"
    }
  ],
  "display": "Summary of PHQ-9 responses",
  "text": "Clinical impression about disease progression.",
  "x": 133,
  "y": -92,
  "fixed": true
}
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"node": {
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  "fshLine": "* section[2].entry = Reference(cfsb16582240342242)",
  "node": {
    "id": "cfsb16582240342242",
    "type": "QuestionnaireResponse",
    "display": "PHQ-9 initial response",
    "text": "Patient response of a PHQ-9 for Depression questionnaire instance at the beginning of the Episode of Care.",
    "x": 199,
    "y": -197,
    "fixed": true
  }
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"node": {
  "path": "section[2].entry",
  "fshLine": "* section[2].entry = Reference(cfsb16582240342245)",
  "node": {
    "id": "cfsb16582240342245",
    "type": "QuestionnaireResponse",
    "display": "PHQ-9 last response",
    "text": "Last response of a PHQ-9 for Depression questionnaire instance recorded by patient.",
    "x": 116,
    "y": 87,
    "fixed": true
  }
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"cfsb1658302654068": [
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    "fshLine": "* subject = Reference(cfsb16582240342243)",
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      "type": "Patient",
      "display": "Svenna Svennson",
      "text": "Patient of the scenario.",
      "x": -133,
      "y": -251,
      "fixed": true
    }
  }
]
"id": "cfsb16582240342243",
"type": "Patient",
"display": "Svenna Svennson",
"text": "Patient of the scenario.",
"x": -164,
"y": -293,
"fixed": true
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"path": "serviceProvider",
"fshLine": "* ServiceProvider = Reference(cfsb1658304205801)",
"node": {
"id": "cfsb1658304205801",
"type": "Organization",
"display": "Clínica de Salud",
"x": -121,
"y": 491,
"fixed": true
}
},
{
"path": "participant.individual",
"fshLine": "* participant.individual = Reference(cfsb165822403422416)",
"node": {
"id": "cfsb165822403422416",
"type": "Practitioner",
"display": "Gustav Gustavsson",
"text": "Psychiatrist in Sweden.",
"x": 718,
"y": -285,
"fixed": true
}
},
{
"path": "participant[1].individual",
"fshLine": "* participant[1].individual = Reference(cfsb16582240342242)",
"node": {
"id": "cfsb16582240342242",
"type": "Practitioner",
"display": "Virginia Henderson",
"text": "Diabetes Nurse at Diabetesgatan Huslakarmottagning",
"x": -800,
"y": -416,
"fixed": true
}
},
{
"path": "participant[2].individual",
"fshLine": "* participant[2].individual = Reference(cfsb1658304244176)",
"node": {
"id": "cfsb1658304244176",
"type": "Practitioner",
"display": "Manuel Rodriguez Ruiz",
"x": -132,
"y": 268,
"fixed": true
}
},
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"path": "diagnosis.condition",
21
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  "type": "Condition",
  "links": [
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      "path": "subject",
      "node": {
        "id": "cfsb16582240342243",
        "type": "Patient",
        "display": "Svenna Svennson",
        "text": "Patient of the scenario.",
        "x": -164,
        "y": -293,
        "fixed": true
      },
      "definition": "Indicates the patient or group who the condition record is associated with."
    }],
  "display": "Severe depression",
  "text": "Severe depression Diagnosis of Svenna Svennson.",
  "x": 239,
  "y": -503,
  "fixed": true
},

"path": "diagnosis[1].condition",
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  "type": "Condition",
  "links": [
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        "id": "cfsb16582240342243",
        "type": "Patient",
        "display": "Svenna Svennson",
        "text": "Patient of the scenario.",
        "x": -164,
        "y": -293,
        "fixed": true
      },
      "definition": "Indicates the patient or group who the condition record is associated with."
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  "display": "Anxiety",
  "text": "Anxiety Diagnosis of Svenna Svennson.",
  "x": 271,
  "y": -348,
  "fixed": true
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"path": "diagnosis[2].condition",
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"node": {
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  "type": "Condition",
  "links": [
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      "node": {
        "id": "cfsb16582240342243",
        "type": "Patient",
        "display": "Svenna Svennson",
        "text": "Patient of the scenario.",
        "x": -164,
        "y": -293,
        "fixed": true
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      "fshLine": "* subject = Reference(cfsb16582240342243)"
    }
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  "x": 252,
  "y": -430,
  "fixed": true,
  "display": "Insomnia",
  "text": "Insomnia Diagnosis of Svenna Svennson."
},

{ "path": "diagnosis[3].condition",
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    "type": "Condition",
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        "path": "subject",
        "node": {
          "id": "cfsb1657278108849",
          "type": "Patient",
          "display": "Svenna Svennson",
          "text": "Patient of the scenario.",
          "x": -527,
          "y": -393,
          "fixed": true
        },
        "definition": "Indicates the patient or group who the condition record is associated with.",
        "fshLine": "* subject = Reference(cfsb1657278108849)"
      }
    ],
    "display": "Diabetes Diagnosis",
    "text": "Diabetes Diagnosis of Svenna Svennson.",
    "x": -476,
    "y": -384,
    "fixed": true
  }
}