IHE SERVICES | Building trust in eHealth interoperability

# eHealth Interoperability in Poland.
# Report on profile recommendations for e-Referral and exchange of medical documentation (P1/Increment 2 & 3)

## Final Report

IHE Services

Edited by:    Karima Bourquard, Director of Interoperability IHE-Europe
              Charles Parisot, Chair of IHE Services
Contract:
Date:         November 27th, 2017
Version:      V 1.5

IHE-Europe – Diamant Building – 80, boulevard A. Ryers, 1030 Brussels Belgium

**Table of Content**

# 1. Introduction

This Report is in  support of eHealth interoperability activities in Poland with special focus on the Project P1 that is conducted by CSIOZ.

The report objectives' are to document:
- Outcomes from the workshop on September 18, 2017and the trainings sessions on September 19, 2017;
- Recommendation on IHE profiles for the use case "e-Referral" (P1/Increment 2);
- Recommendations on IHE profiles for the use case "Exchange of Medical Documentation (EDM) (P1/Increment 3)".

This report concludes the analysis at the high level of the two increments that were initiated and discussed during the workshop of September 18th and 19th, and the teleconferences in the following weeks.
After a review of the outcomes of the workshop and teleconferences, the report presents the recommendations on profiles for the two increments enabling the eReferral and EDM use cases.

A number of notes in this report are in relationships to the orientation of the architecture in which these profiles are deployed. It is not the purpose of this report to analyze this architectural dimension.  Such an analysis should be planned for the future. We recommend proceeding in two steps:
1. Pre-analysis of the architecture design based on the IHE profiles recommended in this report.
2. Refined analysis of the architecture design with the documentation of realization scenarios.

# 2. References

## 2.1.    Presentations at the workshop in Warszawa, September 18 2017

1. Project P1 scope of eReferral Use case
2. Project P1 scope of Electronic Medical Documents
3. Best practices in use of IHE approach for eReferral and Exchange of medical documentation
   a. Introduction on eReferral use cases concepts
   b. Examples of best practices in Europe
   c. Introduction on Electronic Medical Document use cases concepts
   d. Examples of best practices in Europe

## 2.2.  Presentations at the workshop in Warszawa, September 19 2017

Tutorial on IHE profiles:
1. XDS, XCA profiles
2. DSUB and MHD profiles
3. XDW and 360 close loop
4. CT and ATNA
5. XUA, BPPC and APPC profiles

## 2.3.  Other documents

1. Guideline for interoperable XDS Affinity Domains – Metadata for exchange medical documents and images. IHE-Europe, 2017.
2. Examples of possible use of IHE integration profiles for the development of e-health in Poland at the national and the regional level. Final version of the report, CSIOZ, 2017.

# 3. Outcomes of the workshop and trainings

## 3.1.  Presentation of the eReferral use case and related best practices

First, the current use case definition set by the Increment 2 of the Project P1 was presented.  See slides: [CSIOZ Presentations at the workshop on September 18, 2017/Project P1 scope of eReferral Use case].

Second, the key concepts involved in the eReferral use cases defined by various ehealth projects were presented. The purpose was to allow the audience to overcome the inconsistent vocabulary used in Europe to address the scope covered (referral, request, prescription, order, etc.) and the mode of interactions (targeted or flexible). See slides: [IHE Presentations at the workshop on September 18, 2017/Best practices in use of IHE approach for eReferral and Exchange of medical documentation/Introduction on eReferral use cases concepts].

Third, a number of best practices selected across Europe and world-wide in the area of eReferral were presented.  It was noted that the deployment of eReferral in ehealth initiatives are not common, but four interesting examples from:
- Saudi Arabia,
- USA,
- Denmark,
- Veneto Region,

were analyzed and contrasted based on the concepts previously introduced. See slides: [IHE Presentations at the workshop on September 18, 2017/Best practices in use of IHE approach for eReferral and Exchange of medical documentation/Examples of best practices in Europe].

## 3.2. Presentation of the exchange of medical documents use case and related best practices

First, the current EDM use case definition set by the Increment 3 of the Project P1 was presented. See slides: [CSIOZ Presentations at the workshop on September 18, 2017/Project P1 scope of Electronic Medical Documents].

Then the key elements of the exchange of medical document use cases were presented. Such elements include:
- the use of document metadata;
- the types of content for documents and it standardization.

The purpose of this presentation was to explain the better use of clinical documents in the delivery of care. Indeed, the main objective of the EDM use case is to make possible the display and import of the right clinical information to the right Healthcare Professional when he/she has to know the patient care anteriority. See slides [IHE Presentations at the workshop on September 18, 2017/Best practices in use of IHE approach for eReferral and Exchange of medical documentation/ Introduction on Electronic Medical Document use cases concepts].

The final presentation, see slides: [IHE Presentations at the workshop on September 18, 2017/Best practices in use of IHE approach for eReferral and Exchange of medical documentation/Examples of best practices in Europe], was dedicated to the best practices in several countries and their implementation:
- Denmark,
- Finland,
- France,
- Suisse.

This use case is widely deployed in several other countries and has a proven track record.
When it was relevant, the general architecture the EDM implementation was presented in order to show relationship between the national and regional levels.

A list of references to supporting documents was provided for helping implementers to better understand these examples and support implementers in their work.

## 3.3. Lessons learned

### 3.3.1. Common approach from the audience

These lessons were discovered together with the participants and identified as a number of points that should be addressed in the area of the deployment of ehealth interoperability in Poland. On the scope of the two use cases considered by P1 Increment 2&3, the necessity of a better alignment with IHE profiles was raised during the last workshop e.g. the current design of the increments can be improved and being more efficient with profiles as they are using e.g. with more existing features that are not yet implemented in the current design (for example using the folder feature instead of extended XDS metadata attributes). The purpose of this workshop was to identify such points, not to make any decisions on their implementation.

The lessons learnt were used as input for the Section 3.3.2 on the role of Regional ehealth Platforms and the Section 3.3.3 on Comments and Findings in relationship to main issues. These lessons learnt fall in three categories:

**For the regions, P1 and national consistency:**
1. Coordination within the regions for a first step (GPs and hospitals) in health info exchange (e.g. recruit two or three regions with a simple use case using a common set of profiles;
2. Definition of the National-Regional architecture and needs for XDS/XCA, consents, and metadata specification;
3. Robust patient identification policy (beyond the PESEL) - Future: a policy needs to describe process, rules and procedures to allow high quality patient identification including the procedures to identify patient and linkage to pre-existing health information in exceptions cases such as the identifications of newborns, migrants, tourists, citizen status change, unconscious patient, and other cases not supported by PESEL.

**Specific to P1 (exploration):**
4. EDM alignment with XDS (medical event summary & folder, metadata definitions, queries);
5. eReferral web services definition, and potential alignment with XDS/XDW;
6. Three services (ePrescription, eReferral and EDM) and each with its own transactions and distinct databases. In XDS infrastructure, the eReferral and any other dispensations and reports are considered as medical documents and indexed in a unique registry (see section 3.2.3);
7. Close the loop in eReferral (completion and reference to results provided to requester).

**Additional thoughts:**
8. Synergy between payer information and clinical information exchange for simplifying point of care systems.

### 3.3.2. Role of regional eHealth platforms

In the best practices that were presented, several countries have a consolidated approach considering the national EHR and the regional eHealth platforms. Depending of the internal organization of the country, all are convinced of the benefits to design the architecture based on standards and profiles for a better consistency among the different levels of organizations and flexibility in systems deployment. Various instruments to ensure this consistency have been deployed in several other countries:

- National council, committees on interoperability for the priorisation of the use cases according the national and regional eHealth objectives;
- Communication, support, education and training;
- National interoperability framework supported by the national center of competence;
- Common use of standards, profiles and terminologies for exchanging medical documents;
- Global architecture that include the regional ehealth platforms that ensures autonomy within regions and interoperability with the national levels;
- Some have established a conformity testing strategy to ensure alignment of the regional deployments;

Indeed, in most countries, including Poland, all regions are not at the same level of maturity: the deployment of ehealth in the regions should be performed independently from each other, each one at their own rhythm. Best practices coming from the most advanced regions accelerate implementation in the less advanced regions.

For example, in the case of EDM use cases based on XDS infrastructure, various European countries decided to consolidate the specification of their metadata attributes at the national level and to benefit of the best practices and lessons learnt from other countries or regions.

To do that, a taskforce was created in 2016 with 10 countries (Europe and US). The countries decided to join their force for specifying a metadata guideline that will support new comers or for countries having already metadata specifications to share, to compare, to benefit of the lessons from others and in the future to harmonize the metadata attributes. The first version of this guideline was published in June 2017 (See slides: [IHE Presentations at the workshop on September 18, 2017/Best practices in use of IHE approach for eReferral and Exchange of medical documentation/ Introduction on Electronic Medical Document use cases concepts]) and is available on IHE-Europe website (https://www.ihe-europe.net/news/articles).

This type of initiative can also be created at the national level for supporting the regions in their implementation. The main objective is to communicate and to reach consistency among regions, national and in the future cross border. To be effective, such collaborative work needs to be placed under a national governance so that it delivers its conclusions in a reasonable timeframe and those are approved for implementation and maintained over time.

### 3.3.3. Comments, finding and main issues

**Ensuring national consistency between regions and P1 EDM services to deliver nation-wide access to health information for any patient irrespective of its home and locations of treatment.**

Based on the above lessons, it appears that a number of document repositories managed by a local XDS Registry have emerged in some regions. Others have regional solutions that do not seem to be based on the IHE XDS Profile. The national P1 EDM services that is based on an XDS Registry (pointers to documents) is designed to support XDS Repositories storing documents and located throughout the country. With these variations, Poland is faced with the need to establish some form of national consistency in the sharing and access to medical documents.

It appears that both:
- a top-down approach to introduce such consistency is needed. This should result in the definition of a national overall architecture that supports and integrates regional deployments.
- a bottom-up approach with a targeted set of new regional "pilot" projects that would be architected to realize operational examples of deployments consistent with the P1 national system design and demonstrating that the above national overall architecture is implementable.

Such a national overall architecture should contain a number of elements already specified by P1 as part of the EDM service, specified in such a way that they can be directly used as part of the procurement and deployment of these new pilot projects. Such elements include:
- Polish specification of the XDS Metadata to ensure that all indexed documents in any XDS Registry (P1 EDM or others) are consistent, thus enabling consistent nation-wide queries across multiple document registries and multiple document repositories.
- The specification based on the IHE XCA Profile of cross registry queries with simpler integration and deterministic query results from a clinical point of view
- Define the different modes of integration of regional projects (national architecture), such as being a document repository that relies on the national P1 registry to have its content discoverable and accessible nation-wide (single registry architecture), or being a peer document registry to P1 (multiple registry architecture) that support the federated queries through XCA.[1]
- Identify area where the current patient identification scheme may have gaps, so they are addressed in consistent way, nation-wide. The patient identification approach based on the use of the PESEL should be reviewed to ensure that it has the breadth and robustness to address special cases that other countries have discovered as "blind spots", such a the case of new-born identification before a PESEL is assigned, migrants becoming permanent residents, residents that become citizens and may change PESEL, regular visitors that may change/renew

---

[1] Further detailed analysis and selection of the architecture model is planned for the coming weeks

their country of origin passports/id cards, illegal immigrants that become legal residents, etc. Addressing these potential gaps before the deployment is underway may result in significant risk reduction and cost savings.

- Establishing a consistent approach to patient consents and definitions of the policies implemented in controlling access to health information is critical to avoid the complexities of inconsistent rules across different projects, thus confusing the citizen and making these projects interoperate. Again, the late definition of such policies that span not only the P1 projects but all ehealth projects is a source to clarity and trust for the citizens and cost savings when data flows across the boundaries of these diverse ehealth deployments.

**Analyzing and proposing an alignment of the current design of the P1 Increments 2 and 3 that support the eReferral and EDM use cases is important both in the area of some potential functional gaps and of a better alignment to international standards and profiles. Covering these functional gaps would deliver significant added value to the patients and clinicians. Aligning on international standards and profiles is a long-term cost reduction in the development and deployment (e.g. testing tools) of interoperable health applications and better position the Polish software industry to export their applications.**

Four such functional gaps and standards alignment opportunities where identified during the workshops. They need to be analyzed by CSIOZ in term of impact on the current design of P1 Increment 1, 2 and 3 and weighted against the opportunity they represent. Some may require to be addressed in a transition plan.

1. <u>EDM alignment with XDS (medical event, metadata definitions, queries)</u>
   A. EDM could be better aligned with the XDS Profile with a reduced set of polish extensions for:
      - Metadata specification (specifications need to be extracted from the P1 design documentation, thus making it difficult to access and comply with for system connected to P1),
      - The current specification of the medical event shall be analyzed carefully and the attributes or fields should be split in two parts: in one side, what is relevant as XDS metadata and on the other side what is relevant as a "medical event" document; A proposal to be evaluated would be to make, Medical Events support via a standard XDS means with:
         - Review the P1 requirements and support the medical events attributes as XDS Folder attributes metadata, when possible.
         - If significant number of attributes is missing, it probably means that medical events are a form of patient administrative summary that should be supported by a specific CDA document.

   ⇨ *Such an alignment would reduce the security vulnerability of document registries by exposing much less personal clinical data, would reduce the cost and deployment risks of applications deployed in Poland and be a step in the direction to support a patient summary preparing for the European Cross-border eHDSI.*

2. <u>eReferral web services definition and potential alignment with XDS/XDW</u>

<u>The recommendations introduced below propose a number of transition phases to achieve alignment from the current architecture to future architecture based on standard IHE profiles. Depending of the level of today implementation and/or the current development roadmap, none, some or all steps can be chosen. It depends strongly on the CSIOZ strategy.</u>

B. The eReferral requests documents are not accessible as any other medical documents (EDM service) in the current design. We recommend considering making them part of the medical documentation, thus also published in the EDM Document Registry.

C. Two additional levels of alignments may be considered:
   - o Base the eReferral web services on the XDS transactions plus XDW content to simplify edge systems and increase commonality of interfaces. This would not imply internal data base redesign. This step may be skiped.
   - o Replace the eReferrals Data Base by a standard XDS Registry/Repository with the XDW profile for workflow management. This step is a more important redesign, but is forward looking in reaching sooner the deployment of an XDS infrastructure. It would also add to the static environment of the XDS profile (Document storage), a more dynamic environment with the addition of the XDW profile that allows the management of several types of workflows.

⇨ *Such an alignment would simplify the point of care applications' interfacing to the P1 eReferral services by increasing the commonality the web services already widely used for the exchange of medical documents. In addition, it introduces a much more flexible workflow management infrastructure that is able to support other types of referrals than those currently covered (inter-hospital transfers, clinical conferences, care coordination processes, etc.)*

3. <u>Three services and document access silos</u>
   D. The P1 EDM document registry should index eReferrals requests documents, ePrescriptions documents and Dispensations documents. Because the ePrescription and eReferrals requests documents are recorded when received by a different service (non-XDS based today), in the current design of the P1 we recommend that the P1 system should consider indexing eReferral request documents and eePrescriptions documents and Dispensations documents in the P1 EDM registry (XDS based). This would provide a more cohesive view of all documents shared for a patient. Once the function for Medical Events is clarified (see point A above), it could be useful to consider linking Medical events with eReferrals from a clinical point of view. As discussed above the XDS Folder[2] may

---

[2] In XDS, a document has the option to be assigned a membership in one or more folders. Folders can be used to make a persistent record of a grouping for selected documents that belong together or are in the same category. For example, the documents can be grouped per their relationship to the same medical event, folders grouping documents by the type of care coordination pathway they contribute to, etc. The German Hospitals EleKtronische Fallakte uses this concept to group documents around a care coordination pathway.

   contribute to creating such links not only in an administrative approach, but also in clinical sense for health information sharing.

  E. Current situation is complex for point of care systems with different web services and queries across the three "database in the current P1 design.  Similar point as point B above.

  ⇨ *The proposed functional alignment enables a more cohesive access to all type of document that compose the patient health record.*

4. Close the loop in eReferral functional gap
  F. Referral requesters are not brought in a closed loop with a notification of the referral completion and an easy access (attach reports) to the referral outcome (e.g. report).  This may not be necessary for all types of referrals, but at least for some such as radiology and laboratory requests it is of primary importance for the requester.

  ⇨ *Addressing this gap appears quite important for referral where the requesting physician needs to access the result of the diagnosis service request to continue the treatment of its patient.*

# 4. Profiles recommendations for eReferral use case

## 4.1. Introduction

This section makes recommendations about the profiles of main interest for Polish deployments, and more specifically for the scope of the P1 Increments 2 of the project. P1 Increments 2 deploys a nationwide infrastructure to which the point of care systems connect directly to request referrals or to track the performing of referrals.

The profiles that should be considered in the case of a deployment, where Regions would deploy their own referral infrastructure for classes of referrals not covered by P1 (e.g. care coordination) are addressed as notes, but not fully developed.

Given the findings discussed in section 2.3.3, the recommended profiles strive to offer a consistent approach for eReferral and the Exchange of Medical Documents (e.g. leverage the same XDS Registry for indexing shared documents).

Each profile is presented in a standard form:

| **Name of the profile** |
|---|
| URL to the reference documentation at an overview level.<br>When existing, reference to the slides presented during the workshop of September 19, 2017 (see section 2) |
| Detailed use case and technical Profile Specification: <u>IHE IT Infrastructure Technical Framework Version 13 or later</u><br> ▪ Identification of the section |

| Notes |
| --- |
| |

| Justification: |
| --- |
| • **Deployed projects (level of adoption):**<br>**+ few deployments are known;**<br>**++: some deployments are known;**<br>**+++: many deployments are known; generalization;**<br>• **Related to the use case eReferral or EDM: eReferral or EDM infrastructure**<br>• **Difficulty to implement the profile:**<br>**+: the profile is known, some available expertise, few software and tools are available;**<br>**++: the profile is quite known, available expertise, some software and tools are available;**<br>**+++: the profile is well known, several expertise, several software and tools are available.** |

## 4.2.    Recommended Core Profiles

In the context of the P1 deployment, the objective is clearly to offer a nation-wide support for recording a referral request, allowing any performer to be chosen by the patient.  This is clearly a "flexible type of referral" where the referral can be pick-up by the performer selected by the patient.

In that context, the suitable IHE profile is the Cross-Enterprise Document Workflow (XDW) Profile (with the WBeR-WD Workflow Definition) and the underlying Cross-Enterprise Document Sharing (XDS) Profiles.  They are presented in the table below.

| XDW |
| --- |
| Profile Overview: http://wiki.ihe.net/index.php/Cross_Enterprise_Workflow<br><br>See slides: [IHE Presentation at the workshop on September 19, 2017/XDW and 360 close loops] |
| Profile  Specification: IHE_IT_Infrastructure_Technical_Framework_Version_13_or_later<br>▪ Vol. 1 - Section 30<br>▪ Vol. 3 - Sections 5.4 |
| Notes: This is a workflow management generic profile that needs to be customized for eReferral (see WBeR-WD Profile).  It operates in conjunction with XDS. |
| Justification:<br>• **Deployed projects (adoption): ++ (eReferral deployments have not been the first priority in Europe)**<br>• **Related to the use case eReferral or EDM: eReferral**<br>• **Difficulty to implement the profile: ++** |

| WBeR-WD |
|---|
| Profile Overview: See Introduction to the supplement below. |
| Profile Specification:<br>https://www.ihe.net/uploadedFiles/Documents/PCC/IHE_PCC_Suppl_XBeR-WD.pdf |
| Notes: This is a workflow definition for Cross-enterprise Basic eReferral Workflow that operates in conjunction with XDW and XDS. |
| Justification:<br>• **Deployed projects (adoption): + (eReferral deployments have often customized WBeR)**<br>• **Related to the use case eReferral or EDM: eReferral**<br>• **Difficulty to implement the profile: ++** |
| |

| XDS |
|---|
| Profile Overview: http://wiki.ihe.net/index.php/Cross-Enterprise_Document_Sharing<br><br>See slides: [IHE Presentation at the workshop on September 19, 2017/XDS,XCA profiles] |
| Profile Specification: IHE IT Infrastructure Technical Framework<br>   ▪ Vol. 1 -<br>       ▪ Section 10,<br>       ▪ Appendix E Cross Profile Considerations,<br>       ▪ Appendix J Content and Format of XDS Documents,<br>       ▪ Appendix K XDS Concepts<br>   ▪ Vol. 2a - Sections 3.18 Registry Stored Query<br>   ▪ Vol. 2b - Sections 3.41 Provide and Register Document Set<br>   ▪ Vol. 2b - Sections 3.42 Register Document Set<br>   ▪ Vol. 2b - Sections 3.43 Retrieve Document Set<br>   ▪ Vol. 2x - Appendix A, B, K, L, M, N, V, W<br>       ▪ Vol. 2x - Appendix A Web Services Definition<br>       ▪ Vol. 2x - Appendix B Definition of a Document<br>       ▪ Vol. 2x - Appendix K XDS Security Environment<br>       ▪ Vol. 2x - Appendix M Using Patient Demographics Query in a Multi-Domain Environment<br>       ▪ Vol. 2x - Appendix N Common Datatypes<br>       ▪ Vol. 2x - Appendix V Web Services for IHE Transactions<br>       ▪ Vol. 2x - Appendix Implementation Materials<br>   ▪ Vol. 3 - Section 4.0 Metadata used in Document Sharing |
| Notes: XDS is used to share among workflow participants an XDW document that records the current state of a workflow per the Workflow Definition (WBeR). |
| Justification:<br>• **Deployed projects (adoption): +++** |

- **Related to the use case eReferral or EDM: eReferral or EDM**
- **Difficulty to implement the profile: +++**

| DSUB |
|---|
| Profile Overview: http://wiki.ihe.net/index.php/Document_Digital_Signature <br><br> See slides: [IHE Presentation at the workshop on September 19, 2017/DSUB and MHD profiles] |
| Profile Specification: IHE IT Infrastructure Technical Framework Version 14 or later <br> ▪ Vol. 1 - Section 26 <br> ▪ Vol. 2b: 3:52 3:53 3:54 |
| Notes: This is a workflow management generic profile that complements XDS and XDW by allowing tonotify entities that are targeted for a referral request or referral completion has been posted. |
| Justification: <br> • **Deployed projects (adoption): ++** <br> • **Related to the use case eReferral or EDM: eReferral or EDM** <br> • **Difficulty to implement the profile: +++** |

Note 1: XDW and WBeR can be also deployed in a federated environment that uses the XCA Profile. In this case that will not be further discussed here, the XCDR Profile is also needed to allow the update of an XDW document managed by a remote XDS Affinity Domain.

Note 2: these profiles XDW and WBeR are recommended to implement after the deployment of the XDS infrastructure. Indeed the XDW and its derivation WBeR runs above XDS infrastructure and provides new features for managing workflow for example in eReferral use cases.

## 4.3. Recommended associated profiles

In the context of the P1 deployment, the patient identification relies on the PESEL identifier that is the unique patient identifier.

However in the case where a patient has no PESEL identifier, an identifier should be given during the care process that ensure consistent demographics data to allow a query for patient and his/her medical data. See also slides: [ Examples of possible use of IHE integration profiles for the development of e-health in Poland at the national and the regional level. Final version of the report, CSIOZ, 2017].

In that context, the suitable IHE profiles are the Patient Demographic Query Profile (PDQ or PDQV3, see below for differences) when used in conjunction with XDS Cross-Enterprise Document sharing.

| PDQ |
| --- |
| Profile Overview: http://wiki.ihe.net/index.php/Patient_Demographics_Query |
| Profile Specification: IHE IT Infrastructure Technical Framework<br>• Vol. 1 - Section 8<br>• Vol. 2 - Sections 3.21, 3.22 |
| Notes: PDQ is based on H7 V2.5.  It is fonctionally equivalent of PDQV3 (See below)<br>Justification:<br>• **Deployed projects (adoption):** +++<br>• **Related to the use case eReferral or EDM: eReferral or EDM**<br>• **Difficulty to implement the profile:** +++ |

| PDQV3 |
| --- |
| Profile Overview:<br>http://wiki.ihe.net/index.php/Patient_Demographics_Query_HL7_v3 |
| Profile Specification: IHE IT Infrastructure Technical Framework<br>• Vol. 1 - Section 8<br>• Vol. 2 - Sections 3.21, 3.22 |
| Notes: PDQV3 is based on H7 V3.  It is functionally equivalent to PDQ (See above)<br>Justification:<br>• **Deployed projects (adoption):** +++<br>• **Related to the use case eReferral or EDM: eReferral or EDM**<br>• **Difficulty to implement the profile:** +++ |

Note 1: These profiles are used inside a community. In the case where a query of Patient demographics is needed cross communities (in a federated architecture), then the Cross-Enterprise Patient Discovery (XCPD) Profile is needed to locate and cache the remote communities where a patient has documents. in the case of Poland, further analysis is needed to understand if there is one community (national community or multiple communities)

Note 2: There may be contexts where the use of the PESEL number is not deployed in a reliable manner (for example, several exceptions such as newborns, migrants, tourists, etc have no PESEL identifiers or some eHealth regional platform, GP or hospitals

15

software are not managing PESEL identifiers but managing local identifiers due to unidentified patients).

If there is a need to perform cross-referencing of local identifiers with the PESEL number, then the IHE Patient Identification Cross-referencing profiles PIX and PIXV3 (see below for differences) may be applicable.

| PIX |
| --- |
| Profile Overview: http://wiki.ihe.net/index.php/Patient_Identifier_Cross-Referencing |
| IHE IT Infrastructure Technical Framework Version 1 or later<br>  ▪ Vol. 1 - Section 5<br>  ▪ Vol. 2 - Sections 3.8, 3.9, 3.10 |
| Notes: PIX is based on H7 V2.  It is functionally equivalent to PIXV3 (See above) |
| Justification:<br>  • **Deployed projects (adoption): +++**<br>  • **Related to the use case eReferral or EDM: eReferral or EDM**<br>  • **Difficulties to implement the profile: +++** |

| PIXV3 |
| --- |
| Profile Overview: http://wiki.ihe.net/index.php/Patient_Identifier_Cross-Reference_HL7_v3 |
| HE IT Infrastructure Technical Framework Supplement PIX-PDQ HL7v3 Rev2-1 TI 2010-08-10<br>See also:<br>IHE IT Infrastructure Technical Framework<br>  ▪ Vol. 1 - Section 5<br>  ▪ Vol. 2 - Sections 3.8, 3.9, 3.10 |
| Notes: PIXV3 is based on H7 V3.  It is functionally equivalent to PIX (See above) |
| Justification:<br>  • **Deployed projects (adoption): +++**<br>  • **Related to the use case eReferral or EDM: eReferral or EDM**<br>  • **Difficulty to implement the profile: +++** |

Note: The deployment of applications on mobile devices (phones and tablets) is a critical extension to any national of regional ehealth infrastructure in facilitating the engagement of patients and flexibility of health professional delivery of care in the primary sector.  IHE has developed a number of profiles that plug into an XDS and XCA

based infrastructure including the associated patient identification: MHD (XDS on FHIR option) and PDQm profiles.

| MHD |
| --- |
| Profile Overview:<br>http://wiki.ihe.net/index.php/Mobile_access_to_Health_Documents_(MHD)<br>See slides: [IHE Presentation at the workshop on September 19, 2017/DSUB and MHD profiles] |
| Profile Specification: MHD Supplement |
| Notes: MHD is in trial implementation status as it is based on HL7 FHIR (STU3) which is not yet issued as a standard. |
| Justification:<br>• **Deployed projects (adoption): +**<br>• **Related to the use case eReferral or EDM: eReferral or EDM**<br>• **Difficulty to implement the profile: ++** |

| PDQm |
| --- |
| Profile Overview:<br>http://wiki.ihe.net/index.php/Patient_Demographics_Query_for_Mobile_(PDQm) |
| ITI Technical Framework<br>PDQm supplement<br>Examples and FHIR Profile specification |
| Notes: PDQm is in trial implementation status as it is based on HL7 FHIR (STU3) which is not yet issued as a standard. |
| Justification:<br>• **Deployed projects (adoption): +**<br>• **Related to the use case eReferral or EDM: eReferral or EDM**<br>• **Difficulty to implement the profile: ++** |

## 4.3.1. Security and privacy

In the context of the P1 deployment, the security and privacy of shared patient identified health information needs to be ensured. In such an environment, a number of technical measures have to be addressed such as managing current time to avoid replay attacks, ensuring that exchanges made over the internet used an encrypted channel, that peer communicating systems mutually authenticate each other, recording security events audit trail for forensic analysis, authenticating the user and its security traits, when accessing health information to provide input to access controls, and taking into account the patient privacy consent permissions.

In that context, the suitable IHE profiles are the Consistent Time (CT), Audit trail and node Authentication (ATNA), Cross-Enterprise User Assertions (XUA) and either the Basic Patient Privacy Consent (BPPC) or the Advanced Patient privacy Consent (APPC). A further detailed analysis, including requirements from Polish implementation of GDPR, should be made in order to select the suitable profile in the Polish context.

Note. Several countries (e.g. US eHealth Exchange, Italy, Saudi Arabia) started with the basic patient consent because it is easier to explain to Healthcare Professionals and Patients how to use it in their daily journeys.

| CT |
|---|
| Profile Overview: http://wiki.ihe.net/index.php/Consistent_Time<br><br>See slides: [IHE Presentation at the workshop on September 19, 2017/CT and ATNA] |
| Profile Specification: IHE IT Infrastructure Technical Framework<br>  ▪  Vol. 1 - Section 7<br>  ▪  Vol. 2a - Sections 3.1 |
| Notes: None |
| Justification:<br>  •  **Deployed projects (adoption): +++**<br>  •  **Related to the use case eReferral or EDM: eReferral or EDM**<br>  •  **Difficulty to implement the profile: +++** |

| ATNA |
|---|
| Profile Overview:<br>http://wiki.ihe.net/index.php/Audit_Trail_and_Node_Authentication<br><br>See slides: [IHE Presentation at the workshop on September 19, 2017/CT and ATNA] |
| Profile Specification: IHE IT Infrastructure Technical Framework<br>  ▪  Vol. 1 - Section 9<br>  ▪  Vol. 2a - Sections 3.19,<br>  ▪  Vol. 2a - Sections 3.20 |
| Notes: None |

| XUA |
| --- |
| Profile Overview: http://wiki.ihe.net/index.php/Cross-Enterprise_User_Assertion_(XUA)<br><br>See slides: [Presentation at the workshop on September 19, 2017/XUA, BPPC and APCC profiles] |
| Profile Specification: IHE IT Infrastructure Technical Framework<ul><li>Vol. 1 - Section 13 - Cross-Enterprise User Assertion</li><li>Vol. 2b - Sections 3.40 - Provide X User Assertion</li><li>Vol. 2b - Section 3.42 - Additional section to add to ALL ATNA audit messages when the transaction includes XUA Assertion</li></ul> |
| Notes: None |
| Justification:<ul><li>**Deployed projects (adoption):** +++</li><li>**Related to the use case eReferral or EDM: eReferral or EDM**</li><li>**Difficulty to implement the profile:** ++</li></ul> |

| BPPC |
| --- |
| Profile Overview: http://wiki.ihe.net/index.php/Basic_Patient_Privacy_Consents<br>See slides: [IHE Presentation at the workshop on September 19, 2017/XUA, BPPC and APPC profiles] |
| Profile Specification: IHE IT Infrastructure Technical Framework<ul><li>Vol. 1 - Section 19</li><li>Vol. 3 - Sections 5.1</li></ul> |
| Notes: The profile overview and the Slides discuss the Consent capabilities supported by BPPC versus those supported by APPC. |
| Justification:<ul><li>**Deployed projects (adoption):** ++</li><li>**Related to the use case eReferral or EDM: eReferral or EDM**</li><li>**Difficulty to implement the profile:** ++</li></ul> |

| APPC |
| --- |
| Profile Overview:<br>http://wiki.ihe.net/index.php/Advanced_Patient_Privacy_Consents<br><br>See slides: [IHE Presentation at the workshop on September 19, 2017/XUA, BPPC and APPC profiles] |
| Profile Specification: IHE IT Infrastructure Technical Framework |

- ▪ [APPC Supplement](#)

Notes: The profile overview and the Slides discuss the Consent capabilities supported by BPPC versus those supported by APPC.

Justification:
- **Deployed projects (adoption): +**
- **Related to the use case eReferral or EDM: eReferral or EDM**
- **Difficulty to implement the profile: +**

# 5. Profiles recommendations for EDM use case

## 5.1. Introduction

This section provides recommendations about the profiles of main interest for Polish deployments, and more specifically for the scope of the P1 Increment 3 (EDM) of the project.

The purposes of the EDM use case in Poland is to ensure coordination of medical care from a GP or Hospital stand point by providing clinical documents and to support the establishment of the care plan of the patient.

The P1 project designed an architecture based on an XDS infrastructure supported by other infrastructure services such as national patient directory (that delivers the PESEL identifier), health care professionals directory and security infrastructure (X509 certificates for system authentication.

In the following sections, the standards and profiles that are recommended are described.

## 5.2. Recommended core profiles

The suitable IHE profile is the Cross-Enterprise Document Sharing (XDS) Profiles. This profile is already used by P1 Increment 3 for the exchange of medical documents.

EDM is based on exchanging clinical documents. Specifications of these documents in standards way are also the key challenges for a successful deployment. Poland specific clinical documents can also be exchanged as defined in the Polish National Implementation guide for HL7 CDA. In the future, alignment of the Polish laboratory report specifications to XD-LAB, radiology reports and other clinical documents can be considered.

These profiles are presented in the table below.

| XDS |
|---|
| Profile Overview: http://wiki.ihe.net/index.php/Cross-Enterprise_Document_Sharing<br>See Slides [IHE Presentation at the workshop on September 19, 2017/XDS, XCA profiles] |

| |
|---|
| Profile Specification: IHE IT Infrastructure Technical Framework<br>    ▪ Vol. 1 -<br>        ▪ Section 10,<br>        ▪ Appendix E Cross Profile Considerations,<br>        ▪ Appendix J Content and Format of XDS Documents,<br>        ▪ Appendix K XDS Concepts<br>    ▪ Vol. 2a - Sections 3.18 Registry Stored Query<br>    ▪ Vol. 2b - Sections 3.41 Provide and Register Document Set<br>    ▪ Vol. 2b - Sections 3.42 Register Document Set<br>    ▪ Vol. 2b - Sections 3.43 Retrieve Document Set<br>    ▪ Vol. 2x - Appendix A, B, K, L, M, N, V, W<br>        ▪ Vol. 2x - Appendix A Web Services Definition<br>        ▪ Vol. 2x - Appendix B Definition of a Document<br>        ▪ Vol. 2x - Appendix K XDS Security Environment<br>        ▪ Vol. 2x - Appendix M Using Patient Demographics Query in a Multi-Domain Environment<br>        ▪ Vol. 2x - Appendix N Common Datatypes<br>        ▪ Vol. 2x - Appendix V Web Services for IHE Transactions<br>        ▪ Vol. 2x - Appendix Implementation Materials<br>    ▪ Vol. 3 - Section 4.0 Metadata used in Document Sharing |
| Notes: XDS is used to share a variety of clinical documents. |
| Justification:<br>    • **Deployed projects (adoption): +++**<br>    • **Related to the use case eReferral or EDM: eReferral or EDM**<br>    • **Difficulty to implement the profile: +++** |

As XDS is content agnostics, the specification of document content based on standardized data structures (e.g. HL7 CDA or DICOM) using terminologies that can be either international standards or Polish standards is critical to semantic interoperability. IHE Profiles include only a small number of terminology value sets for the concept that have widely adopted internationally agreed terminologies. The specification and management of all other terminology value sets is a critical element that is not discussed in this report, but that is an indispensable companion to the IHE Profiles and Polish Implementation Guides for medical document content listed below.

| XDS-I |
|---|
| Profile Overview: http://wiki.ihe.net/index.php/Cross-enterprise_Document_Sharing_for_Imaging |
| Profile Specification: IHE Radiology Technical Framework:<br>    ▪ Vol. 1 - Section 18 (XDS-I.b Profile) |
| Notes: XDS-I is used to share a variety of imaging reports and all types of image content specified by DICOM. |

Justification:
- **Deployed projects (adoption): +++**
- **Related to the use case eReferral or EDM: eReferral or EDM**
- **Difficulty to implement the profile: +++**

| **XD-lab** |
|---|
| Profile Overview: http://wiki.ihe.net/index.php/Sharing_Laboratory_Reports |
| IHE Laboratory Technical Framework:<br>▪ Vol. 1 - XD-LAB profile overview<br>▪ Vol. 3 - Content<br>▪ Vol. 4 - LOINC subset |
| Notes: XD-lab is used to share a variety of reports from a variety of laboratory specialties. |
| Justification:<br>• **Deployed projects (adoption): +++**<br>• **Related to the use case eReferral or EDM: eReferral or EDM**<br>• **Difficulty to implement the profile: +++** |

| **Polish National Implementation of HL7 CDA** |
|---|
| Profile Overview: http://wiki.ihe.net/index.php/Sharing_Laboratory_Reports |
| *For more information, see:*<br>***Polish version:*** https://www.csioz.gov.pl/HL7POL/pl-cda-html-pl-PL/<br>***English version:*** https://www.csioz.gov.pl/HL7ENG/pl-cda-html-en-US/ |
| Notes: CSIOZ engaged in collaboration with HL7 Poland, the specification of national refinements for clinical documents based on the CDAr2 format that is the most common standard used today in different countries. |
| Justification:<br>• **Deployed projects (adoption): +**<br>• **Related to the use case eReferral or EDM: eReferral or EDM**<br>• **Difficulty to implement the profile: ++** |

Note 1: "Alignment" of the CDA document headers with XDS metadata should be considered. In the future, this alignment should also be done with the DICOM document header.

There are Integrated workbenches that support the specification or the test of the standardized documents content (Art Décor and Gazelle Objectschecker) that can be used in the Polish context. These workbenches are today well deployed in many countries and facilitate the specification tasks and the maintenance of the deliverables.

It facilities also the testing due to the high integration between the two environments (specifications and testing)

Note: CDA header and XDS metadata are together structured and use coding systems to describe the structures or the values (CDA level 2 or level 3). Therefore terminologies shall be chosen carefully by defining set of codes related to each use cases embedded in the EDM use cases. The terminologies that are currently analyzed or used are LOINC, SNOMED/CT, ICD 10, etc.

Note: The exchange of medical documents can be also deployed in a federated environment that uses the XCA Profile (in addition to the XDS profile).  In the case of imaging information sharing, the XCA-I profile is also needed for cross-community access to images.  These profiles should be considered for P1 to interoperate with the ehealth infrastructure of regions.

Further architectural analysis should be done in the context of Poland.

| XCA |
|---|
| Profile Overview: http://wiki.ihe.net/index.php/Cross-Community_Access <br> See slides: [IHE Presentation at the workshop on September 19, 2017/XDS, XCA profiles] |
| Profile Specification: IHE IT Infrastructure Technical Framework <br>   ▪ Vol. 1 - Section 18 – Cross Community Access <br>   ▪ Vol. 2b - Section 3.38  - Cross Community Access Gateway Query <br>   ▪ Vol. 2b - Section 3.39  - Cross Community Access Gateway Retrieve <br>   ▪ |
| Notes: None |
| Justification: <br> • **Deployed projects (adoption): ++** <br> • **Related to the use case eReferral or EDM: eReferral or EDM** <br> • **Difficulty to implement the profile: ++** |

| XCA-I |
|---|
| Profile Overview: http://wiki.ihe.net/index.php/Cross-Community_Access |
| Profile Specification: IHE Radiology Technical Framework: <br>   ▪ Vol. 1 - Section 29 – Cross-Community Access for Imaging (XCA-I) <br>   ▪ Vol. 3 - Section 4.69 - Retrieve Imaging Document Set [RAD-69] <br>   ▪ Vol. 3 – Section 4.75 -  Cross Gateway Retrieve Imaging Document Set [RAD-75] |
| Notes: None |

Justification:
- **Deployed projects (adoption): +**
- **Related to the use case eReferral or EDM: eReferral or EDM**
- **Difficulty to implement the profile: ++**

## 5.3. Recommended associated profiles

### 5.3.1. Patient identification

To complete the set of core profiles, profiles regarding the patient identification shall be considered (see section 4.3. Considerations are developed in section 3.

### 5.3.2. Security and privacy

The recommended associated profiles are the same as defined for eReferral use case (see section 4.3.1).

Note: In addition, if the Polish policies allow or require that clinical documents exchanged are signed to ensure a strong non-repudiation, the IHE DSG profile may be used. In the context of Poland, this profile can be deployed when individual certificate for signature is in place (in the future).

| DSG |
|---|
| Profile Overview: http://wiki.ihe.net/index.php/Document_Digital_Signature |
| Profile Specification:  IHE IT Infrastructure Technical Framework<br>▪ Vol. 1 - Section 37<br>▪ Vol. 3 - Sections 5.5 |
| Notes: The DSG Profile offers different signature options.  These will need to be analyzed based on the requirements of the polish ehealth exchange policies |

# 6. Annexes

## 6.1.    Terminology

**Business case:** high-level description of a domain that illustrates the business need for the use of health information technology (HIT) in an organization including the cost-effectiveness analysis of HIT and interoperability solutions use. The target audience is decision makers (Definition from "Use cases driven approach"; IHE International, JAHIMA, 2017).

**Interoperability use case:** description of a specific use of HIT that includes depiction of both humans (business actors) and systems (technical actors), scope, workflows of tasks performed by healthcare professionals and associated data flows. It should be written in natural language. May include several scenarios. One or more use cases are derived from one business case. The target audience is the Healthcare Professionals and citizens/patients. (Definition from "Use cases driven approach"; JAHIMA, 2017).

**IHE Profile:** An IHE profile specifies a set of functions that, once deployed by applications, enable the exchange or sharing of health data, to achieve a specific interoperability use case. An IHE profile is built based on recognized standards that are combined to meet one or more use cases or needs expressed by Information System healthcare users. The interoperability technical frameworks that specify these profiles are available at http://www.IHE.net

**Realization scenario:** description of human activities (business actors), systems (technical actors) roles (i.e., IHE actors) and transactions related to a set of technical use cases that support the interoperability infrastructure for use cases (implementable infrastructure). The audience is Project Managers, System Architects, Implementers. (Definition from "Use cases driven approach"; IHE International, JAHIMA,2017).

**Service:** In order to facilitate the understanding, a set of profiles are gathered in a service. (Definition from "Use cases driven approach"; IHE International. JAHIMA,2017).

**Technical use case:** explanation of a specific set of transaction between systems (IHE actors) supported by a profile. For each profile, a set of variance or implementation are included (Options). One or more technical use cases (described for example in IHE Volumes 1-4 of the technical frameworks) may be used in the realization scenario. The audience is Systems Architects, Implementers. (Definition from "Use cases driven approach"; IHE International, JAHIMA, 2017).

## 6.2.    Acronyms
- APPC          Advanced Patient Privacy Consents
- ATNA          Audit Trail and Node Authentication
- BPPC          Basic Patient Privacy Consents
- CMPD          Community Medication Prescription and  Dispense
- CT             Consistent Time

- DIS        Pharmacy Dispense (Content Profile)
- HMW        Hospital Medication Workflow
- IS        Interoperability Specifications
- PADV        Pharmacy Pharmaceutical Advice (Content Profile)
- PDQ        Patient Demographics Query (PDQ)
- PIX        Patient Identifier Cross-Referencing
- PRE        Pharmacy Prescription (Content Profile)
- XCA        Cross- Community Access for Imaging
- XCPD        Cross Community Patient Discovery
- XDS.b        Cross-Enterprise Document Sharing
- XDW        Cross  Enterprise Document Workflow
- XUA        Cross-Enterprise User Assertion
- XBeR-WD        Cross Enterprise Basic eReferral Workflow Definition Profile

## 6.3. Elements of discussion about P1 adoption of the above recommendations

This annex records a number of points raised during the workshop about the approach to interoperability that has been designed in the current implementation of P1 Increments 1, 2 and 3, considered both individually and together.  These elements are also important input for defining transition steps from the current P1 design to future alignment with an IHE based architecture that is not described in the present report.

 These findings are elements of discussions and they rely on the high-level of understanding of the P1 applications design based on the parts of the documentation that was translated and provided to IHE Services. These remarks and comments are provided as inputs towards a more complete analysis that should assess their validity and relevance.  These elements relate only to the way point of care delivery systems would interoperate with the P1 System and other related systems.  In no way, these should be considered definite conclusions.

The recommendations made in this report could be implemented in Poland using a mix of strategies that includes the P1 architecture and future architecture for new projects as described below.
New projects would need to be provided with a precise national Polish interoperability specifications that aligns with an agreed architecture that not only include central systems such as P1 and the point of care systems that could connect directly to central systems for some services and to regional systems if they exist in their region.

Focusing on the P1 system evolution, a number of approaches could be considered:

A. When the P1 service has been designed with an IHE profile at its core, e.g. the EDM service with XDS, the first analysis detected only relatively minor adjustments. They should be addressed to ensure that the Polish extensions do not introduce non-compatibilities at the level of the generic IHE profile.   Such

adjustments are often small and gain to be made at the earliest opportunity. Further detailed analysis will provide the needed list of adjustments.

B. When the service has been designed as a Polish extension to an IHE profile (e.g. medical events with XDS) and it appears that an alternative approach (e.g. create a Medical Event Document that is grouped/linked with other medical documents through an existing means such as an XDS Folder[3]). Such a change may appear important, but because it is likely to reuse the existing XDS Registry function with possibly an extension for the support of XDS folders, it may be considered as an overall system simplification and would gain to be implemented as early as possible.

C. When redesign of a current P1 service, such as to move the eReferral service to a document sharing environment with XDS and the recording of the state of a referral workflow using an XDW document, a careful evaluation is needed. From this evaluation, two typical strategies may be considered:
   a) If the timeframe is not a constraint, perform the redesign of this part of P1 before opening the eReferral service;
   b) If the timeframe is a constraint as expressed by P1 project, limit the adaptation to the external transactions (web services) to make them as aligned as possible with the XDS+XDW transactions so that the interfacing of point of care systems is as "standard" as possible, although the inner structure of the P1 implementation remains minimally impacted. This could be pictured as "placing an XDS+XDW proxy" in front of the current P1 eReferral service. This proxy would parse the XDS+XDW based transactions, extract the information and update the existing P1 database. The XDW documents would not be stored in any other XDS Repository/Registry.

The b) approach (if evaluated as feasible) may reduce changes in P1 without negatively impacting the point of care systems. However, it creates complexity in the P1 design, but allows to consider a migration and to realize the simplification of sharing the same XDS Registry/Repository platform as a second step (use the a) approach) within P1.

.

D. Some services in P1 operating at the national level have been architected as stand-alone central services, but they may have to be considered in conjunction with other systems, such as regional ehealth platforms. Such national architectures need to be analyzed and rules established well before these systems are implemented and interconnected. This is critical to enable the planning and deployment of such systems on independent timelines, while preserving their ability to interconnect without being redesigned.

---

[3] A folder references multiple documents and each document can be referenced in several folders. Folders can be used for multiple purposes such as administrative documents, for care coordination documents for specific diseases (diabetes, COPD), etc.

To achieve the above distribution of systems, A number of issues need to be addressed and the corresponding alignment evaluated for implementation on P1. Examples are:

a) the definition of a nation-wide specification of XDS metadata. It seems that this should be done at the earliest opportunity;

b) if it is found important to allow the deployment of XDS Registries at the regional level, then the specification of inter registry integration (between those and the P1 XDS Registry) should be specified by leveraging the XCA and XCPD Profiles. An analysis of regional needs should help determine if this is urgent or not;

c) introducing an IHE profile for services such a patient demographics query (PDQ) and at the same time address potential gaps in patient identification. This may be urgent if PESEL identifiers change in the course of the life of a person in Poland (e.g. changing from a resident to a citizen, care of illegal immigrants, etc.);

d) making the health information exchange policies more consistent across services and defining a consent policy that applies with minimal adaptation across all current services. Evaluate if the implementation of such consents would be simplified with the adoption of either the BPPC or APPC Profiles. These are topics that take some time to reach a national consensus and should be started as early as possible, planned to be deployed as a future evolution. It is important to note that the implementation of consents based on BPPC is much simpler (See slides [IHE presentation at the workshop on September 19, 2017/ XUA, BPPC and APPC profiles]);

e) The support of APPC is more complex as it implies that the all access control points (central or regional) become XACML enabled and have access to all attributes that can be included in the XACML statements. This is a choice driven by the choice made at the level of the national consent policies, including requirements from Polish implementation of GDPR.