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Interoperability Architecture for a Paediatric Oncology European Reference Network

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Abstract. With the Directive 2011/24/EU on patients' rights in cross-border healthcare and the related delegated decisions, the European Commission defined a legal framework on how healthcare shall be organised by European Union (EU) member states (MS) where patients can move beyond the borders of their home country. Among other aspects, Article 12 of the directive is concerned with supporting MS with the development of so called European Reference Networks (ERN), dedicated to the treatment of "patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare". In the "European Expert Paediatric Oncology Reference Network for Diagnostics and Treatment" (ExPO-r-Net) project, the establishment of such an ERN in the domain of Paediatric Oncology is currently piloted. The present paper describes the high level use cases, the main requirements and a corresponding interoperability architecture capable to serve as the necessary IT platform to facilitate cross-border health data exchange.

Keywords. Integrating the Healthcare Enterprise (IHE), Secondary Use, Standardisation, Cloud Computing, Rare Diseases, Virtual Tumour Boards, Pseudonymisation

1. Introduction

Rare Diseases (RD) are illnesses which affect less than 5 in 10.000 persons. Due to the low number of cases, pooling resources and expertise from different centres is of particular concern for RD.

With the Directive 2011/24/EU on patients' rights in cross-border healthcare [1] and the related delegated decisions [2], the European Commission (EC) defined a legal framework on how healthcare shall be organised by Member States (MS) of the European Union (EU) for patients moving beyond the borders of their home country. Among other aspects, Article 12 of the above directive is concerned with the support of MS in developing so called European Reference Networks (ERN). ERNs are dedicated to the treatment of "patients with a medical condition requiring a particular concentration of expertise in medical domains where expertise is rare" [1]. In the "European Expert Paediatric Oncology Reference Network for Diagnostics and Treatment" (ExPO-r-Net) project, the establishment of such an ERN in the domain of Paediatric Oncology (PO) is

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currently piloted. The present paper describes the high level use cases, core requirements, the technological state of the art and a corresponding interoperability architecture. This architecture foresees capabilities and services needed by ERNs in general and by the ExPO-r-Net in particular, so as to accomplish their mission, including cross-border health data exchange.

2. Methods

The conception of the interoperability architecture for the ERN started with a detailed analysis of the objectives of the EC regulatory framework followed by a comprehensive literature search on the status quo of relevant IT solutions. The literature search was done utilising the Web of Science[2] and Science Direct[3] databases using combinations of the following keywords: European Reference Networks, Interoperability, Integrating the Healthcare Enterprise, IHE, epSOS, open NCP, Virtual Tumour Board, IT Infrastructure. Next, non-functional as well as functional requirements were derived from unstructured interviews of different experts representing the ExPO-r-Net community. Unstructured interviews and therefore open and no predefined questions were used because of the differences between the members of the ExPO-r-Net community. Subsequently, more detailed capabilities were defined and the extracted requirements adjusted accordingly to the use cases of the ExPO-r-Net community. The whole process of requirements analysis was performed accordingly to well-known standards in requirements engineering [3]. The evolving solution concept was presented to the ExPO-r-Net executive committee several times and refined accordingly based in the received feedback. This process lead to the following results:

1. technological state of the art
2. high level (most relevant) use cases
3. core requirements and finally the
4. solution architecture

which was verified concerning feasibility and the degree to which the requirements were met. Key results from these steps are presented in the following.

3. Results

3.1. State of the Art in Cross Border Health Data Exchange

A literature search for papers related to the topic “European Reference Networks” did yield only a few relevant hits, none of which dealt with IT infrastructure aspects in particular (beyond mentioning that such a dedicated IT infrastructure is needed). One paper proposed a minimum dataset definition for rare diseases, which may serve as a starting point in the definition of the data elements in the registries, supposed to be associated with each ERN [4].

As a consequence, we extended our search to publications that were concerned with cross-border healthcare data exchange in general, omitting the context of ERNs. This led

[2] http://apps.webofknowledge.com

[3] http://www.sciencedirect.com

to the following categories of solution approaches beyond those already discovered in [5]:

- ABCD-4-E - Secondary use of Healthcare data for research - IHE-based concepts that deal with a Secondary Use Approach as designed and piloted in ENCCA [5]
- Cross-border exchange of medical images for continuity of care in proton beam therapy [6]. In this paper, the cross border requirement was managed by IHE's Cross Community Access (XCA) profile.

3.2. High level Use Cases of the ExPO-r-Net

The requirements of the EC on ERNs and in particular the needs of the ExPO-r-Net community lead to the following high level use cases:

3.2.1. Survivorship Passport

The Survivorship Passport (SP) is a document intended to provide survivors in Paediatric Oncology with all essential information needed for optimal long-term care. For each child and adolescent cured of cancer an online tool shall provide instant access to his/her medical history. A self-generating document shall contain all details of the survivor's disease and treatment. Within the ExPO-r-Net project the SP shall be made available accordingly to Article 12 of the Directive 2011/24/EU on patients' rights in cross-border healthcare.

3.2.2. Virtual Tumour Board

Within the ExPO-r-Net project a Virtual Tumour Board (vTB) in the Paediatric Oncology domain shall be developed based on interoperability concepts, in particular IHE. The VTB shall support sharing of radiology images, radiotherapy treatment plans and support the discussion of cases within online clinical conferences. The purpose of a vTB is to provide expert advice independent of geographical location.

3.2.3. Data Provision to Clinical Research

Provision of data collected for healthcare purposes to clinical research is one of the objectives for ERNs. Whereas professionals always need to be identified directly with personal identifiers, i.e. by their names, for patients, two different types of identification methods need to be provided:

- Healthcare: Personal identifiers (names, social insurance numbers, patient codes, …),
- Clinical research: Pseudonyms, generated and managed by a central pseudonymisation service.

3.2.4. Multimodal communication

Communication is key to facilitate the aim of ERN, i.e. optimised patient treatment, potentially in a multicentre setting. Therefore, a variety of different communication capabilities need to be provided and tailored to the task and group of participants.

- Telephone (for general ad hoc communication)
- Email and instant messaging (for administration collaboration within teams)

- Discussion forums in dedicated groups (for store-and-forward case evaluation)
- Video Conferencing (for vTB clinical conferences)
- Social networking (for teaching and organising events)
- Health data transfer (for preparing vTB and in case of referrals)

Some of the channels need to be sufficiently secured to allow for the communication of sensitive data, e.g. health data.

3.3. Requirements and how they will be met

The non-functional requirements are similar to those already discovered in [5]. **Table 1** gives an overview on the main functional requirements considering ExPO-r-Net, respectively, and how they can be met by the proposed concept.

3.4. ERN solution architecture

The ERN solution architecture was designed to meet the given objectives and requirements, as well as to link healthcare and research.

Figure 1 schematically illustrates the main components. The national contact points (NCPeH) of each country where a participant of the ExPO-r-Net community resides are connected via epSOS and allow the exchange of patient summaries. Documents like the

Table 1. The functional requirements and their fulfilment

		Requirement Description	**Met by …**
Functional requirements in the Healthcare as well as in the Clinical Research Domain	F1	ERN development appropriate to the specifications of the EC	... a development accordingly to Article 12 of the Directive 2011/24/EU on patients' rights in cross-border healthcare
	F2	Utilisation of standards and terminologies for a structured and consistent exchange of data	… the application of IHE and agreed dataset types.
	F3	Cross-patient as well as cross-domain request for documents concerning the ExPO-R-Net high level use cases (3.2)	… the application of epSOS respectively IHE including appropriate adaptations.
	F4	Additional privacy protection in the Clinical Research Domain	… the application of a context-specific pseudonymisation provided by the EUPID-Service [7], separation of metadata and patient data as well as restrictions on the aggregation and output of data.
	F5	Definition and control of transparent policies for secondary use of health data	… a governance policy that restricts registration of documents to previously registered patients. Data manipulation is generally audited.
	F6	Distributed solution approach	… the ERN solution architecture (see 3.4).
	F7	Linking clinical research systems as well as healthcare systems using standardised interfaces	… the application of IHE, epSOS and concepts of ABCD-4-E.
	F8	Respecting data protection regulations	… the security concepts of epSOS and ABCD-4-E [7, 8].

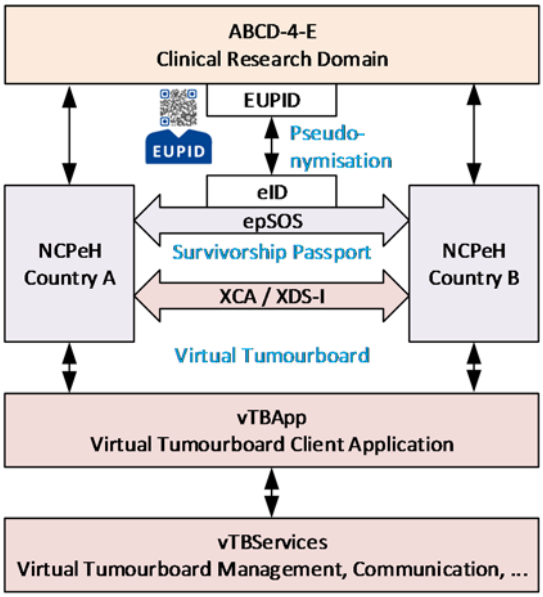

Figure 1. ERN solution architecture.

Survivorship Passport (SP) are stored within one of the national electronic health record systems and transferred to another country on demand. On its way to the recipient, the document is translated by the epSOS terminology services. As the vTB also handles DICOM images, Radiotherapy plans etc. a cross-border communication cannot be facilitated based on epSOS alone. Therefore, additional XCA / XDS-I connectors are used to provide vTB materials also for vTB participants on the remote site. The vTB itself is facilitated by a web-based application (vTBApp) and associated services for the management, the communication etc. of the vTB (vTBServices). The vTBApp implements the workflow defined by the IHE XTB-WD profile [9]. The workflow document and the referenced documents are stored in one of the repositories connected to the NCPeH (Figure 2).

To provide the data of the ERN ExPO-r-Net also for clinical research a platform for secondary use of healthcare data in clinical research developed in the ENCCA project [10] [5] is connected to the NCPeH of each country so a simple transfer of documents to ABCD-4-E is possible. In the course of transferring data to ABCD-4-E the patient identifier (eID) is exchanged with an EUPID-based pseudonym [7] that is associated to eID. The generated pseudonym is used for data registration. Before a registration can be done, a data clearance step is required. All information contained in the data giving a hint on the patient's identity will be removed prior to the registration and patient consent will be required.

4. Discussion

Some elements of the presented IT infrastructure and tools have already been conceived in the context of the **E**uropean **N**etwork for **C**ancer Research in **C**hildren and **A**dolescents (ENCCA) project [10]. Based on the tight link between research and

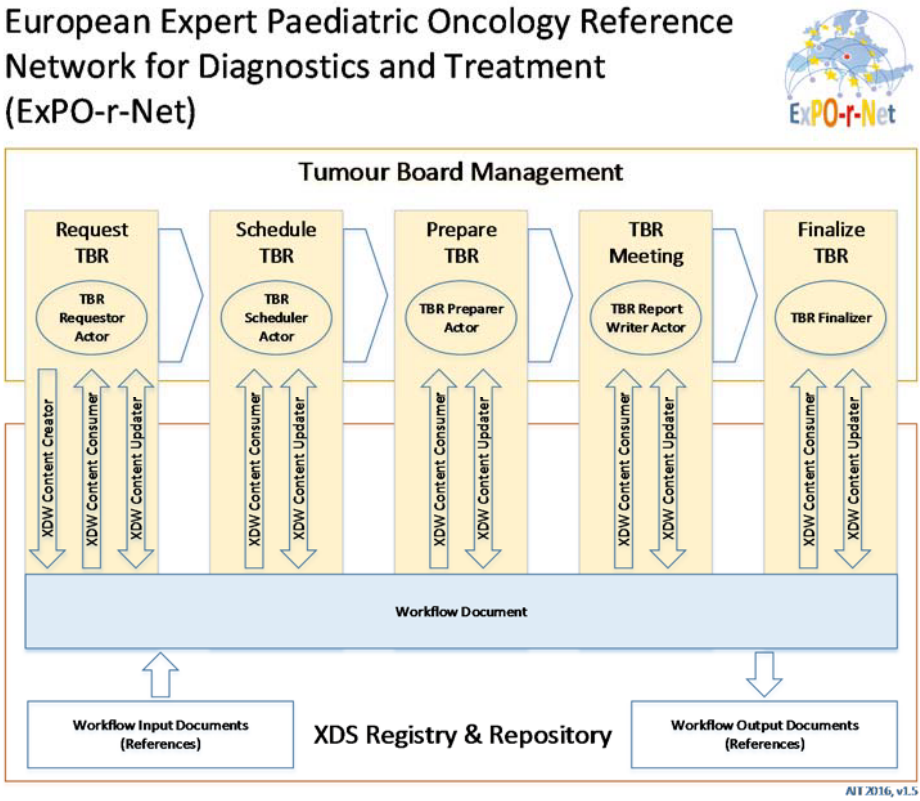

Figure 2. The vTBApp workflow and associated actors and transactions

healthcare in the PO community, some of the concepts and developments of this so called Advanced Biomedical Collaboration Domain for Europe (ABCD-4-E, [5]) were evaluated for their relevance and usefulness for the PO-ERN as well. In this respect, we did not have to start from scratch, but could draw on previously gained expertise related to PO network interoperability concepts (IHE) and tools like the EUPID pseudonymisation service [7] and the Survivorship Passport [11] as well as on a previously developed solution for cross border ion beam radiotherapy [6].

The present approach utilises well established, industry supported and standards-based technologies for the main building blocks of the IT infrastructure.

A still ongoing debate refers to the necessity to link the different ERNs - which are supposed to be established in the next couple of years – with each other. There is the general notion that some resources and – in particular – IT tools could be useful for some if not all ERNs, probably with some customisation. In addition, the need for cooperation between ERNs may arise from the expectation that a significant number of patients may come into contact with more than one ERN. This may be the case, for example, for the PO ERN and a potential ERN for rare cancers in adults. Furthermore, physicians and researchers in larger centres of expertise may also be associated with more than one ERN in their professional activities. Finally, all ERNs will share some regulatory and governance aspects on the national as well as the European level. All those aspects require to foresee ways to link ERNs and, as a consequence, the corresponding IT

infrastructures. Here, an IHE based interoperability solution can undoubtedly provide a versatile solution by means of the Cross Community Access concept [12].

Acknowledgement

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