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LEVERAGING COUNTRYWIDE EHRs TO FACILITATE AN INTEGRATED RESEARCH FRAMEWORK

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Abstract

Collaboration between clinical care and medical research is essential to meet demands for improvements in health care. However, silos of efforts exist as information systems currently utilised lack of integration and interoperability. Initiatives around the world are striving to navigate technical, content-related and legislative challenges of integrated research networks. We propose an Integrated Research Framework incorporating existing consensus to facilitate maintenance of cancer registries on regional, national and international level.

Keywords – Electronic Health Record, Secondary Use, Data Analyses, Standardization

1. Introduction

Countries around the world recognised the electronic health record's (EHR) capability to interface the routine collection of clinical data as means to enhance patient safety, efficiency and quality of health care services [2]. Moreover, the integration of clinical care and clinical research is affirmed as indispensable to facilitate rapid innovation transfer and personalised medicine [8].

Information technology has been utilised by medical research institutions to accomplish data management activities for several years. However, most of the systems employed comprise of various software products which are not interoperable [12]. Moreover, these systems store redundant data in varying formats and standards, thus further impeding interoperability. Consequently, instead of assisting comprehensive collaboration of research activities demanded for improvements in health care, silos of efforts are generated due to the lack of integration and interoperability across information systems.

The vast amount of benefits resulting from the harmonisation between EHRs and electronic data capture (EDC) for scientific purposes is set out in detail by the eClinicial Forum/PhRMA and the EDC/eSource Taskforce [10] and acknowledged for EU practice [11]. In addition, collaborative efforts are concentrated on specifying user interoperability requirements and EHR functionality required to support objectives and processes of clinical research [6][3], thus advancing the issue of interoperability as regards EHRs and electronic data capture. Furthermore, a clinical research domain analysis model is being developed to account for semantic foundations which are incorporated by HL7 and CDISC [1]. Only a few pilot projects successfully demonstrated the integration of an EHR and electronic data capture, yet suffering from limitations impeding extensive reuse. In [4],

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focus is set on shared remote data entry for routine treatment and clinical research at the point of care, however, not featuring retrieval of health data across institutional boundaries afterwards. With [5], cross-institutional queries are supported, though neither incorporating standardised EHR architectures nor communication frameworks, thus inhibiting broad collaboration and curtailing semantic interoperability of yielded health data.

The aim of this work was to utilise existing expertise and technology described above as means to develop a standard-based, *Integrated Research Framework*. Moreover, a medical research scenario in context of maintaining cancer registries on regional, national and international level was designed to assess technical, content-related and legislative feasibility of the research framework.

2. Background

In course of the Austrian EHR project, namely ELGA, evaluation of possible architectural frameworks has taken place in compliance with the requirements stated in the feasibility study conducted by IBM. As a result, the Cross Enterprise Document Sharing (XDS) Integration Profile, related to Integrating the Healthcare Enterprise (IHE) IT Infrastructure Technical Framework, was selected to facilitate cross-institutional sharing, storage and retrieval of medical documents. IHE adopts the approach of incorporating existing international standards regarding content, structure and format of medical documents. Moreover, accounting for semantic interoperability, the concept of Affinity-Domains is introduced which serves the need to commonly agree on particular standards for clinical document exchange.

The issue of mandatory reporting cancer cases by health care providers to the Austrian National Cancer Registry (ANCR) is addressed by the Krebsstatistikgesetz 1969 and Krebsstatistikverordnung 1978. Therefore, periodic reporting of cancer cases is obligatory for 270 health care providers responsible for diagnosis and treatment of cancer, resulting in an average of 78.000 cancer report forms submitted annually to the ANCR.

Reporting on national level is accomplished by utilising a standardised case report form. Moreover, few federal states (i.e. Carinthia, Tyrol) established specialised regional cancer registries, thus requiring detailed, specifically refined reports to be collected and processed. Reporting is currently facilitated in a paper-based manner demanding health care providers to submit the same information on multiple forms of various formats to meet numerous cancer program requirements. Hence, cancer registries suffer from underreporting, lack of representativeness and timeliness as well as inconsistency of yielded health data.

Analysis is performed in order to develop guidance on planning and evaluation of cancer prevention, screening, diagnosis and treatment. Indeed, individual patient data is obtained for the sake of conducting disease surveillance, case investigation, case management and care coordination. Furthermore, yielded data is aggregated to perform population health surveillance, detect public health threats and monitor population's health status.

3. Method

This work proposes an *Integrated Research Framework* based upon international health information standards in context of an existing countrywide EHR architecture. In fact, existing implementations of the XDS profile are extended by additional Integration Profiles which have been speci-

fied primarily by the IHE Quality, Research and Public Health [7] domain in order to achieve seamless integration of clinical care and clinical research.

A medical research scenario related to the process of cancer registration is developed as a means to illustrate a use case for information exchange involving five vendor EHR systems. Considering an *Integrated Research Framework*, potential Integration Profiles have been identified, examined and interfaced to establish semi-automated acquisition of clinical information from a set of dispersed health information systems. Moreover, patient-level queries are supported to accomplish retrieval of fine-grained information assets. Subsequently, the proposed framework, incorporating prevalent EHR content (ICD-10, SNOMED-CT), structure (HL7 Clinical Document Architecture) and format (XML) standards, is evaluated in compliance with the medical research scenario.

A systematic literature review is conducted to identify, select and align major requirements of maintaining cancer registries on regional, national and international level. Subsequently, a classification is introduced to organise related prerequisites as follows: *Criteria Expression, Identification of Patients meeting the Criteria, Reporting of Data, Data Review and Feedback, Data Analysis and Communication of Results*.

4. Results

A story line was created in compliance with the requirement definition, thus imposing a more realistic feel to the scenario. Furthermore, an *Integrated Research Framework* was developed based upon identified IHE Integration Profiles, therefore facilitating evaluation of the depicted scenario. As a result, the proposed *Integrated Research Framework* (*IRF*) was assessed as feasible.

Figure 1 illustrates the process of cancer registration and involved actors as well as transactions by means of the *IRF*.

IHE Integration Profiles identified to suffice the complex requirements as imposed by the medical research scenario are utilised as follows to establish the *IRF*:

1. *Retrieve Form for Data Capture – RFD*
   RFD features methods to yield medical data from a health care provider's local EHR to suffice the requirements as defined by an external system. Hence, the *IRF* provides functions for retrieval, display, completion and submission of data capture forms, as depicted by *Figure 1* in steps 1-3. Furthermore, automated pre-population of form fields is facilitated to alleviate data entry at user interface level. The same functionality is used to share results of data analysis between high quality cancer registries on international level. Prior to storing received data at the registry's site, routine quality control measures are established by the *IRF* in step 4 in terms of validating data at field-entry level in line with the syntactical validation of case report forms. Finally, step 5 outlines the Retrieve Clarifications transaction tailored for the purpose of processing clarification, correction and verification queries to resolve possible data conflicts and discrepancies. Additionally, this transaction enables backtracking of relevant health information concerning cancer patients who have been registered solely on the basis of a death certificate.

2. *Clinical Research Document – CRD*
   The CRD profile encompasses a general agreement on format and structural elements of data utilised in course of the RFD infrastructure. In general, all IHE profiles incorporate the HL7

CDA for structuring clinical content. In fact, the CRD profile imposes specifically refined constraints on existing CDA templates (i.e. Archetypes) in order to engender reuse for research purposes. Therefore, employment of the CRD profile as a content profile for the *IRF* facilitates achievement of real semantic interoperability of exchanged clinical content.

3. *Query Existing Data – QED*
   The QED profile is accommodated in the *IRF* as a mechanism supporting dynamic queries on patient-level health data stored in EHRs across multiple institutions to accomplish focused assessment of disease conditions. In accordance to *Figure 1*, step 6, these patient-level queries establish follow-up of cancer patients pertaining to an update of current treatment, procedure results and stage of tumour progression. Consequently, the *IRF* assures timeliness and accuracy of cancer data. Indeed, the QED profile focuses on pooling of data from highly structured CDA templates. This profile in conjunction with the RFD and CRD profiles is pivotal to raise the *IRF's* capabilities of fostering a variety of secondary use scenarios like for instance public health reporting, adverse event reporting and clinical trials.

5. Discussion

As depicted in course of the medical research scenario, the spectrum of clinical settings involved in cancer prevention, screening, diagnosis and treatment is connected by means of the *Integrated Research Framework*. Hence, population-based cancer research is facilitated and supplemental data items are collected in order to assist specialised cancer registries in meeting their objectives pertaining to disease-related scientific research. However, feasibility of the presented scenario is based on the assumption that template-compliant (i.e. archetype) EHR data is available countrywide. Currently, HL7 CDA level 1 is being adopted in the course of ELGA.

Data acquisition takes place by means of automated extraction of relevant health data from multiple health care providers and complemental data entry through dedicated user interfaces. Moreover patient-level queries are supported, thereby allowing regional and national cancer registries to meet their objectives of effective, accurate and complete registration. We incorporate standardised coding schemes for description of tumour topography (ICD-10), morphology (ICD-O-3) and progression (TNM), therefore improving data quality and enabling inter-registry comparison. Furthermore, registry specific edits in line with robust mechanisms for correction have been deployed in the *Integrated Research Framework* to enable clarification, correction and verification of possible data conflicts and discrepancies within submitted case report forms. In addition, plausibility checks are performed accommodating field-level constraints, intra-record as well as inter-record consistency validation. However, the issue of anonymisation is not addressed within the scenario's scope, since it strongly depends on the legal context. Though, de-identification would likely be performed within step 2, before submitting or after receiving health information.

Quality of cancer registries strongly relies on completeness of gathered data. Hence, the *Integrated Research Framework* features methods to yield death certificates indicating the presence of cancer. Finally, follow-up of cancer patients pertaining to an update of current treatment, procedure results and stage of tumour progression is facilitated, thereby assuring timeliness of cancer data.

The proposed *Integrated Research Framework* enables clinicians and researchers to gain access to the results of analysis and original data as means to stimulate coordinated efforts in tackling the cancer burden. Finally, evidence-based findings of comprehensive analysis may be shared among

various cancer registries on international level to realise even greater potentials in respect to public health services and monitoring.

Summing up, the *Integrated Research Framework* improves completeness, timeliness and accuracy of cancer case reporting compared with existing manual systems. Comprehensive collaboration between multidisciplinary teams is engendered, therefore advancing rapid innovation transfer. However, public policies providing the legal framework for processing health data in context of clinical research are lacking far behind. Following other countries like the USA [9], a legal framework for the secondary use of EHRs is going to be established in Austria.

Substantial future tasks to establish integrated research networks on national and international level address further development of comprehensive IT concepts, measures to engender acceptance for utilising the EHR as a valuable source in medical research as well as continuing efforts on standardisation and bridging of both content and structure related health information standards.

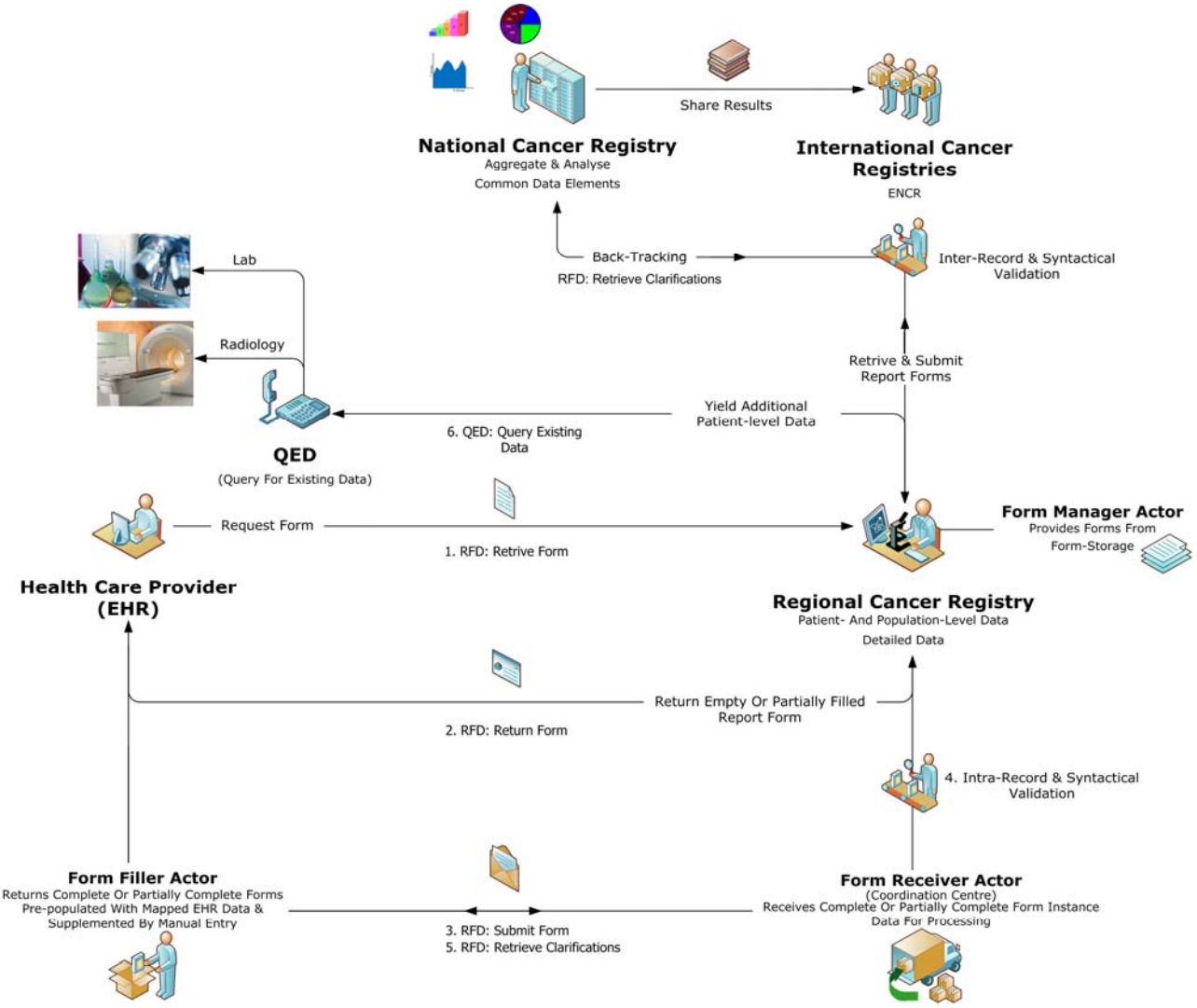

Figure 1: Illustration depicting the process of registering cancer cases by means of the Integrated Research Framework

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