Journal of Health Informatics in Africa

9th Health Informatics in Africa Conference (HELINA 2014)
Peer-reviewed and selected under the responsibility of the Scientific Programme Committee

The European initiative EHR4CR – Lessons learned for EHR implementations in Africa

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Nowadays, more and more clinical data are documented in electronic health records and are thus available in digital form. With the aim of re-using these data for clinical research, a European consortium consisting of 35 partners from academia, clinics, pharmaceutical companies and subcontractors initiated the project "Electronic Health Records for Clinical Research" (EHR4CR). Three different services are envisaged to be supported for the design and implementation of clinical trials using a single platform: Clinical protocol feasibility, Patient identification and recruitment, Clinical trial execution and Serious adverse event reporting. Four different working groups focus on the following areas: Specifications and Business Model development, Technology Platform and Tools including semantic interoperability and data protection/security, Pilot Activities and Reference Site coordination as well as communication, dissemination and project management. It became apparent that one critical issue to reuse clinical data is the availability of structured, standardized data elements at the hospital sites.
African countries that are currently implementing or planning to implement EHRs are strongly advised to make use of medical terminologies and data dictionaries when designing their systems. Medical documentation should be as structured as possible and interfaces be made available in order to reuse clinical data for reporting or research purposes. A common data inventory for medical documentation and health management reporting could be a starting point.

Keywords: Electronic health records, hospital information system, clinical trials, Single source, Secondary Use

1 Introduction

Electronic health records (EHR) are more and more implemented in hospitals and a lot of clinical data are being collected in digital form. It has many advantages to have patient data available in an electronic, structured format: Data are available at the right time to the right people and can be used for treatment planning and follow-up. Furthermore, once collected data can be reused for secondary purposes like quality management reports for the hospital or clinical research [1]. Clinical studies rely on good data and oftentimes these data are collected redundantly during patient visits. This double documentation can be avoided if the EHR systems are prepared to collect data in a structured and reusable form and offer tools to export this data for secondary purposes [2].

The EHR4CR project (http://www.ehr4cr.eu/) was initiated in 2011 to explore the possibilities of reusing data from EHRs for clinical trials and to design a technical platform together with a respective business model [3]. This public-private partnership was enabled by the Innovative Medicine Initiative (IMI) and is funded jointly by the European Union and the European Federation of Pharmaceutical Industries and Associations (EFPIA). It runs for 4 years with a total budget of 16 million Euro and consists of 35 partners (pharmaceutical companies, research institutes, university hospitals, small enterprises). The project objectives are to support the main phases during a clinical trial by (re)using EHR

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 DOI: 10.12856/ JHIA-2014-v2-i2-101

data. The first is 'clinical protocol feasibility' in which the trial is being planned by estimating potential study patients and designing the study protocol. The second is 'patient identification and recruitment' in which the study patients are recruited at the different participating sites. The third is 'clinical trial execution' and 'serious adverse event reporting' in which patient data during the trial is being documented.

The objective of this paper is to present the EHR4CR project and relevant lessons learned. The experiences can be used while designing and implementing EHR systems in African countries or for future similar projects on the African continent.

2 Materials and methods

To achieve the objectives, the project was divided into four thematic groups and a total of eight work packages as depicted in figure 1. It was planned to develop a common EHR4CR platform to connect different, decentralized data provider sites and make their anonymised EHR data available for clinical research.

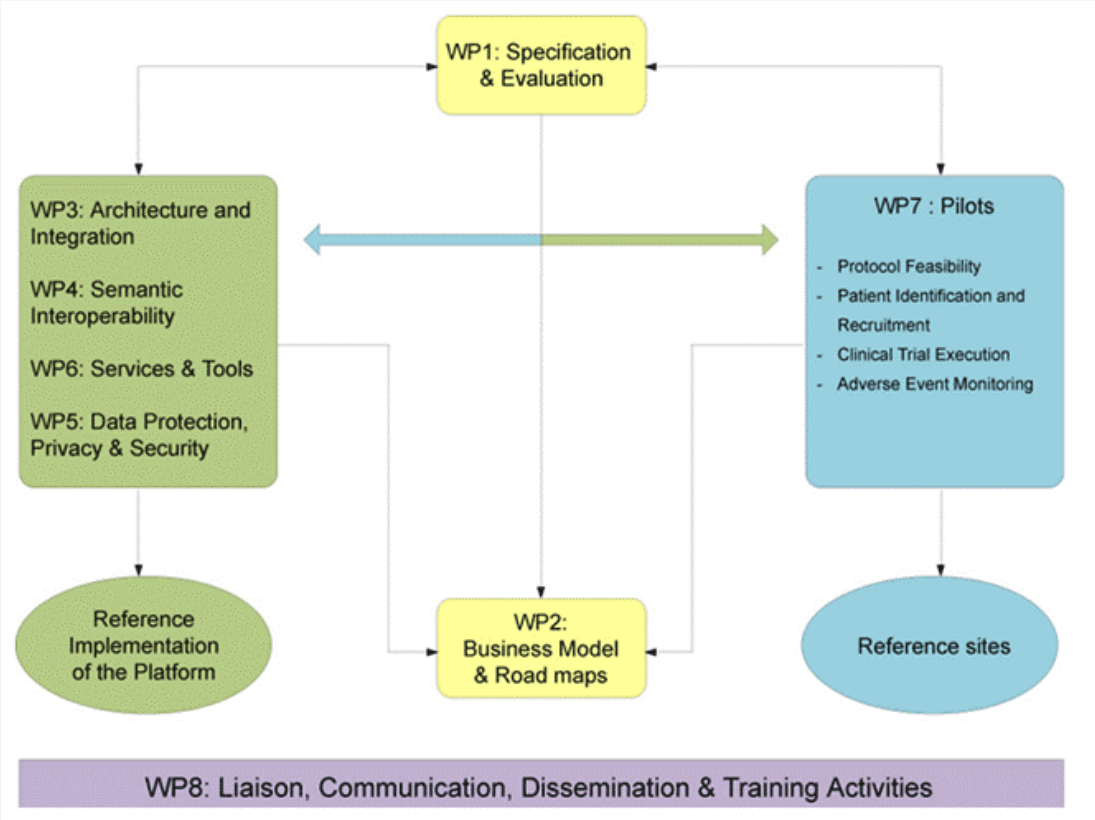


Figure 1. EHR4CR project organization with eight work packages (WP). Work package groups (WPG) consist of one or more WPs and are marked with the same color (e.g. WPG1 with WP1 and WP2).

The first two work packages (WP1 and WP2) focus on collecting requirements and developing the business model. Work packages 3-6 are the core of the project because through them all tools and services of the EHR4CR platform are developed and methods for data privacy across national legislations are established. Work package 7 coordinates the implementation of the different components at the eleven participating data provider sites across five countries and evaluates the piloting of the platform. Finally work package 8 manages the overall project and coordinates dissemination activities.

 DOI: 10.12856/ JHIA-2014-v2-i2-101

3 Results

During the last three years the EHR4CR platform was developed and installed at different European hospitals to query EHR data for research purposes. For the first scenario of protocol feasibility it was demonstrated that data across different EHRs in Europe can be used to obtain numbers about potential study patients faster than on the usual way of sending feasibility questionnaire to potential sites. Through the EHR4CR platform a study feasibility query is distributed to all selected and participating data provider sites. In the local data warehouses the queries are executed and resulting numbers are sent back to the central platform to display aggregated results. Figure 2 and 3 show a sample query and the aggregated results in the central component of the platform.

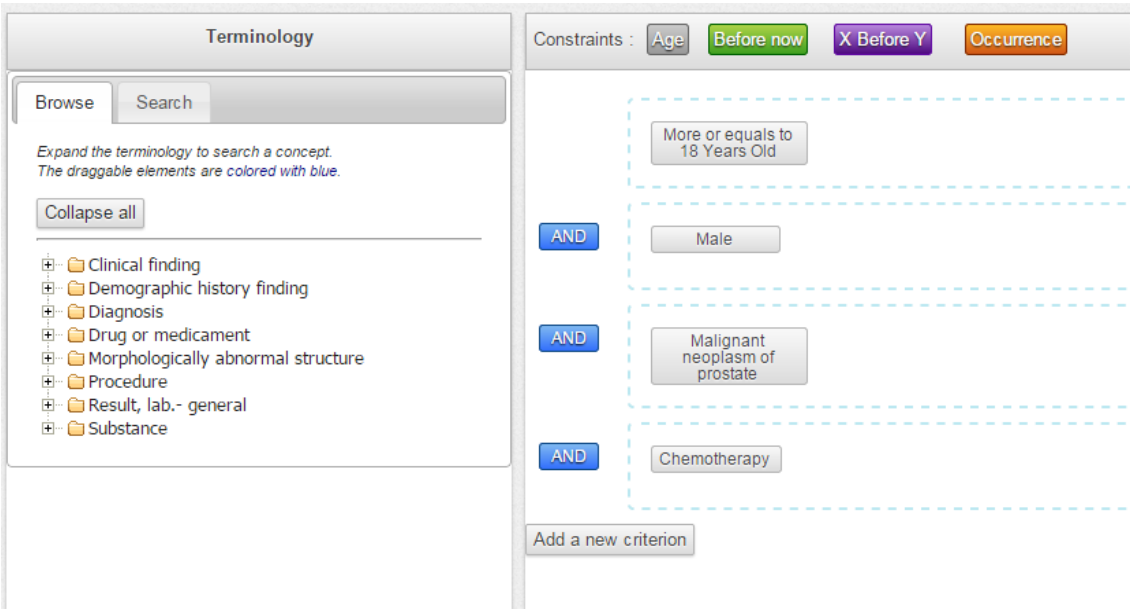
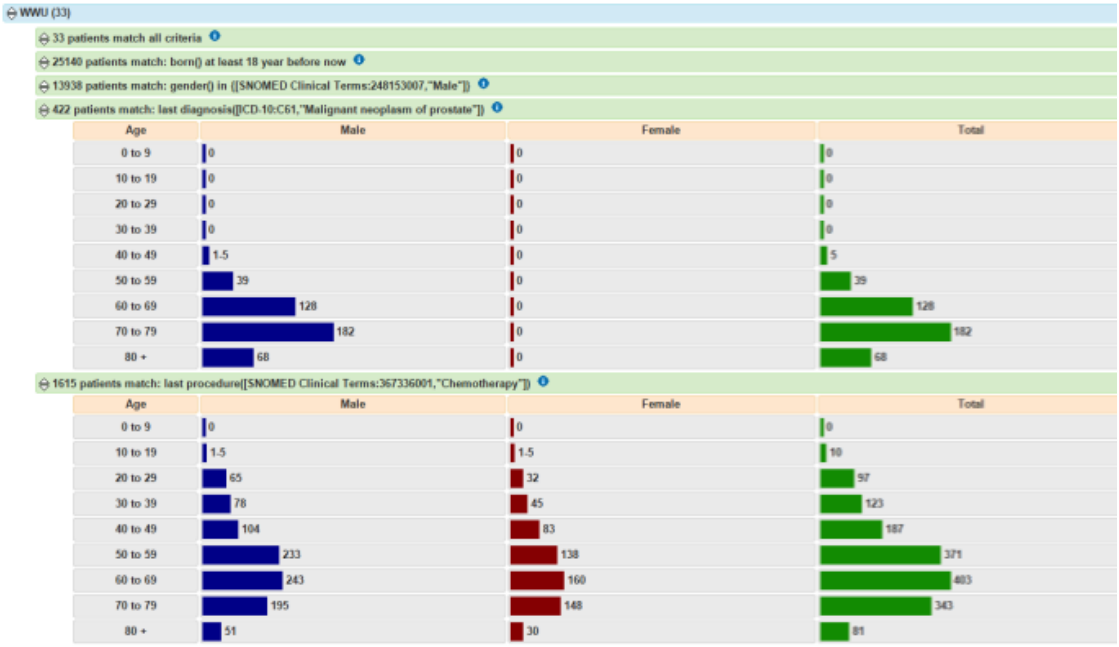


Figure 2. This shows the drag & drop query builder with the available terminology to choose from on the right side; in the example we searched for male patients older than 18 years with prostate cancer who had a chemotherapy.



 DOI: 10.12856/JHIA-2014-v2-i2-102

Figure 3. The results show aggregated numbers of all queried data provider sites which can also be displayed in a detailed view showing the resulting numbers for each single criterion (as seen here for site "WWU").

The second scenario for patient identification and recruitment is based on the same principle. Queries with the inclusion and exclusion criteria of the study protocol are distributed to the participating hospital sites. Query execution is done locally in specific data warehouses and results are only available for the local principal investigator so that he/she can decide to get in contact with the patient for recruitment. Only aggregated numbers of the finally recruited patients per site are sent back to the central platform to the respective EFPIA company.
Extensive work has been done to make EHR data available at the sites. A prerequisite was the development of methods to adhere to the different legislations regarding data privacy. Furthermore we analysed EHR data and data elements typically needed in clinical trials and created a data inventory of the most commonly needed elements [4]. Those data elements became part of the EHR4CR core terminology to which all sites mapped their EHR data in the specific data warehouses. Through this common terminology (based on standard medical terminologies wherever possible) we were able to formulate one query and execute it at eleven different sites with different data being available in different languages. This decentralized approach proved to be feasible.

3.1 Main lesson learned

During the analysis of data elements being available in the EHRs of the different sites it became apparent that a key issue was format and quality of the data. Not all data elements were available in the EHRs and of the available ones only some have been documented in a structured format, mainly diagnosis codes and demographic data. The bigger part of clinical data from the medical history was often only available in free text. In addition, very few data were tagged with common medical terminologies like SNOMED codes. The data quality was very diverse across the different sites.
Furthermore a common data exchange language had to be created to transfer data to the platform. Extensive mapping work had to be done during ETL (extract, transform, load) processes to make the data elements queryable using the common EHR4CR vocabulary.
However, it has been possible to reuse commonly available, structured EHR data across different sites using a single platform for the purpose of clinical research.

4 Discussion

To answer the question which of these experiences can be used while designing and implementing EHR systems in African countries we would like to focus on the above described issue of data quality and interoperability. Based on the experiences from the EHR4CR project our strongest recommendation is to ensure structured medical documentation based on standard medical terminologies when EHR systems are designed or implemented. Oftentimes EHR systems have grown over many years with no or little thought on data structures and dictionaries or their data collection is based on different objectives and thus results in very diverse data quality [5]. Results of the previously mentioned review by Häyrinen et al. on EHRs can be confirmed [1]. However, we can see that it is possible to reuse EHR data.
In a setting like in most African countries where EHRs are currently on the upsurge [6] we would like to encourage all healthcare providers and policy makers to take the chance and implement systems through which structured documentation and easy data exports are possible. Even further, trial management functionalities and supporting modules for all of the above mentioned scenarios should be included to facilitate clinical research in an efficient way for African countries. As a bonus, well-structured systems might also encourage health professionals who are not familiar in using electronic systems for their documentation. Knowledge about clinical terminologies and standards like SNOMED and HL7 or self-defined data dictionaries needs to be acquired and used for any system that is being installed. Metadata should be standardized to ensure integration on regional/national levels or as seen in the EHR4CR project even between countries. An inventory of data elements commonly used for medical documentation and reporting issues, as just presented for clinical trials, could be a starting point to harmonize data collection.

 DOI: 10.12856/ JHIA-2014-v2-i2-101

Acknowledgements

We acknowledge all consortium partners of the EHR4CR project.

Statement on conflicts of interest

There is no conflict of interest.

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 DOI: 10.12856/JHIA-2014-v2-i2-102