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Can *open*EHR Archetypes Empower Multi-Centre Clinical Research?

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Abstract

*The Electronic Health Record is of utmost importance to enable the provision of high-quality collaborative care; one prominent development is open*EHR. *On the other hand, a systematic approach to support the use of routine data for multi-centre clinical research is becoming increasingly important. One example of this is* the extensible architecture for using routine data for additional purposes (***eardap***) *which features comprehensive terminological support. However, as experiences in various medical fields have shown, the terminology-based approach is limited to specialized fields and it is argued that a comprehensive terminology is simply too complex and too difficult to maintain. As the open*EHR *archetype approach does not rely heavily on big standardized terminologies, it offers more flexibility during standardisation of clinical concepts and overcome the shortcomings of terminology-focused approaches. It is unknown, however, how far the more generic open*EHR *approach can also enable re-use of routinely collected data for clinical research purposes – the use case for which* ***eardap*** *was designed. We therefore explored the feasibility of using the open*EHR *approach to support multi-centre research in comparison to* ***eardap****. Generally speaking, our results show that both* ***eardap*** *and open*EHR *are suitable to enable the use of routine data for multi-centre clinical research. As the open*EHR *approach also ensures open, future-proof Electronic Health Records, we conclude that it is highly desirable that multi-centre clinical trials adopt open*EHR.

Keywords:
Electronic Health Record, Terminology, *open*EHR, Medical Informatics, Clinical Trials

1. Introduction

The Electronic Health Record (EHR) is of utmost importance to provide high-quality collaborative care. EHRs have the potential to offer simultaneous remote access to patient data, increased legibility of the documents, flexible data layout and analysis, integration of information resources, and tailored paper output [1]. In real life, however, a considerable amount of information stored in the records is obsolete, redundant, duplicated, or indecipherable or even contradictory to the extent that it does not benefit the patient at the point of care. To solve this problem, several approaches are currently being explored. Two prominent examples are the Clinical Document Architecture (CDA) [2] which is primarily focussed on documents and document exchange, and the *open*EHR approach ([3], http://www.openEHR.org) which focuses on the semantic interoperability of complete EHRs or EHR extracts and is the basis for the new European standard [4].

On the other hand, a systematic approach to support the use of routine data for clinical research is becoming more important. To support clinical trials in medical fields where the treatment is complex, the severity of the illness high or the incident rates low, collaborative research efforts are vital and information technology support is essential. Such multi-centre clinical trials may even cross national borders. There are powerful data collection, management and Remote Data Entry (RDE) systems for clinical trials ([5], [6]) and even multi-centre clinical trials ([7]). Some of them provide solutions for single terminological aspects like the translation of Case Report Forms (CRFs), for the administration of measurement units and conversion factors. However, there are very few offering a comprehensive terminological support which is useful for conventional trials, desirable in multi-centre trials and absolutely necessary in cooperative groups of multi-centre clinical trials [8]. One example that supports comprehensive terminological support is **eardap** [9].

Still, the terminology-based approach is limited to specialized fields as research in various medical fields has shown [10], [11] and it is argued that a comprehensive terminology is simply too complex and too difficult to maintain [12]. As the *open*EHR archetype approach does not rely on big standardized terminologies but micro-vocabularies [13], it would offer more flexibility during standardisation of clinical concepts and overcome the shortcomings of terminology-focused approaches. Further, *open*EHR provides the basis for future-proof, medico-legally sound EHR systems. While this is not in the focus of **eardap** it might still be valuable for ongoing multi-centre research.

It is unknown, however, how far the more generic *open*EHR approach for Electronic Health Records can also enable the use of routine data for multi-centre research purposes – the use case **eardap** was designed for. We therefore explored the feasibility of the *open*EHR approach to support this and compared its characteristics in detail with **eardap**.

The overall aim of this paper is to answer the research question - to what extent is *open*EHR suitable for multi-centre research environments. We will

- outline essential criteria for collaborative research environments,
- show to what extent these criteria are fulfilled by **eardap** and *open*EHR, and
- highlight differences, advantages and disadvantages between **eardap** and *open*EHR.

2. Material and methods

2.1. openEHR and archetypes

The aim of *open*EHR is to enable the development of open specifications and software for EHR systems. *open*EHR is based on the results of the GEHR-Project of the European Union. GEHR is an acronym for Good European Health Record respectively later Good Electronic Health Record. Following GEHR several projects extended and refined its results (e.g. the Synapses and SynEx projects). All these projects influenced the *open*EHR architecture.
*open*EHR has pioneered a two level modelling approach for EHRs ([3]). An overview of this approach is given in Figure 1. The first level is the reference information model which is pared down to the minimum to support the medico-legal requirements and record management functions. This ensures that clinicians can always send information to another provider and receive information which they can read – thus ensuring data interoperability. The second level involves the *open*EHR archetype methodology – a way of sharing evolving clinical information so that it can be processed by the receiving provider – thus ensuring semantic interoperability. A blood pressure archetype for example represents a description of all the information a clinician might want or has to report about a blood pressure measurement. Basically, one archetype therefore represents one clinical concept.

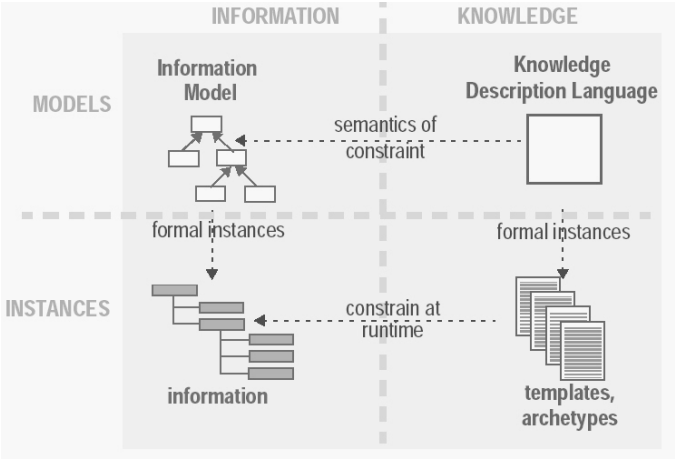

Figure 1: Overview of the openEHR two level modelling approach for EHRs ([3]).

Through the use of freely available archetype tools, e.g. the Archetype Editor, clinical groups are empowered to control the way that EHRs are built up, using designed structures to express the required clinical data and assuring that all necessary constraints on the values of record components are observed. This ensures that all data in an EHR system is valid at two levels, because it conforms both to an information model, and to domain-designed concept definitions. Design principles of *open*EHR are described in more detail in [14], but the key innovation of the *open*EHR architecture is that it separates record keeping concerns from clinical data collection using archetypes [15] and thus enabling **patient-centred, longitudinal, comprehensive** and **prospective** EHRs.

2.2. eardap

eardap as an **e**xtensible **a**rchitecture for using **r**outine **d**ata for **a**dditional **p**urposes was developed to suit the needs of multi-centre clinical research in a multi-hospital environment [9]. It focuses less on generic characteristics which Electronic Health Records must feature. **eardap** can be characterized as terminology-based and component-based architecture. **eardap** consists of 3 main components: core system, terminology management system (TMS) and module generator (***Figure 2***). Main advantage of **eardap** is the comfortable extensibility of any implemented architecture by new items and new research questions. Like *open*EHR **eardap** is concept-oriented. In contrast, however, its architecture is based on object-relational modelling supported by the TMS. The module generator is used each time a new module has to be generated or an existing one has to be adapted. If the underlying terminology has to be changed, the TMS is used: further modules will then be built upon the changed terminology. Once the definition of a terminological system for a trial in the TMS is finished, a consistent, corresponding relational database can be created within short time and without any informatics skills. The process of building forms takes place under strict terminological control. Generated research-specific modules can then be used by the **eardap** core system in the medical centres.

3. Results

Based on our intensive requirements analyses with multi-centre trial environments (e.g. [8], [16]), we developed criteria that are desirable for a multi-centre research environment. These criteria are in harmony with other research (e.g. [5], [6], [17]) and are in the following applied to both **eardap** and *open*EHR. For each criterion a description of how well it is supported by either approach as well as an overall assessment is given (Table 1). Assessments are given using the following scale: ++, +, +–, –, ––. As a baseline, +– is given

if the specification of the respective approach allows the criteria to be fulfilled but is either not yet implemented or the scope of the implementation is outside the approach.

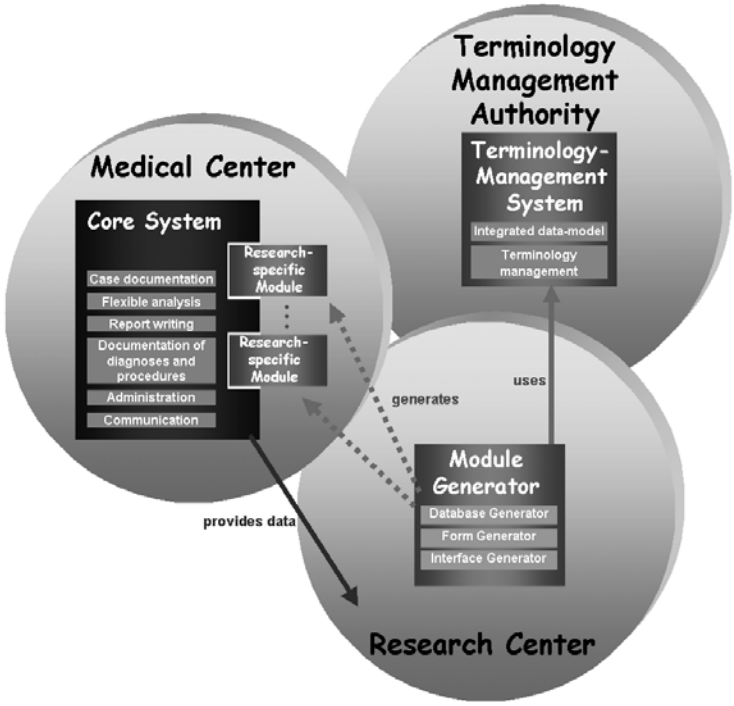

Figure 2: Overview of the eardap architecture in a typical eardap environment.

4. Discussion

Generally speaking, our results show that both **eardap** and *open*EHR are suitable to enable the use of routine data for multi-centre medical research. **eardap** excels in providing highly integrated tools for convenient analysis and report writing – exclusively based on the terminology provided and therefore usable for all scenarios. Further, mechanisms for high data quality are supported by **eardap** through its warning and error integrity constraints. *open*EHR excels in enabling a more flexible standardisation process and making internationalisation and localisation feasible through concept-oriented multi-language support and specialisation of archetypes. Further *open*EHR enables data and semantic interoperability via its generic information model, archetypes and EHR extracts.

Our experiences in paediatric oncology in Germany have shown the applicability of the **eardap** architecture for national research [9]. The functions of our core system – including additionally chemotherapy decision support based on the system – were in routine use in several hospitals all over Germany [16]. With **eardap** special emphasis has to be laid on interfaces to local hospital information systems and data security.

The *open*EHR approach is currently being trialed in Australia in the framework of Health*Connect* (http://www.healthconnect.gov.au), the Australian initiative for a national health information network and used in further projects [18]. First results are promising.

In this paper we have considered **eardap** and *open*EHR solely in the context of how well they support clinical research based on routine clinical data; the primary purpose of *open*EHR – laying the foundation for sound Electronic Health Records - of course is slightly different. Our criteria do not intend to generally assess approaches to Electronic Health Records.

Independent of the approach used, the degree of reuse of routine data for multi-centre research is highly dependant on the quality of the terminology used. Our experiences confirm that terminology harmonization, maintenance and general governance are key factors for

success in this area and a challenging task in a multi-centre project. The greater flexibility during standardization processes offered by the *open*EHR archetyping is of great value here.

Table 1: Overview of all criteria and how well they are supported by eardap and openEHR.

Criteria	**eardap**		***open*EHR**	
Usable for basic data set documentation	Yes.	++	Yes.	++
Data validation/integrity constraints	Sophisticated model for warning and error integrity constraints, intra- and inter-contextual.	++	Error integrity constraints can easily be applied in one archetype (one context). Warning constraints or inter-contextual constraints are indirectly supported by templates and invariants.	+
Support for multiple trial terminologies[1]	Yes, inbuilt.	++	Not inherently supported by *open*EHR. Achievable through specialized archetypes and external control which archetypes are to be applied.	–
Support for evolving terminologies	Yes, possible via new or adapted research-specific module based on terminology server and created by **eardap** module generator.	++	Yes, as *open*EHR features a standard information model. For incompatible changes a new version of the archetype and adequate update routines are needed.	++
Automatic form generation	Yes, via Form Building Component.	++	In the future, via templates, GUI-Generator.	+–
Specialisation of concepts allowed	Indirectly via specialized data in research-specific module.	+	Yes (basic feature of archetypes).	++
Supports rapid cross-patient analysis	Integrated (standard and flexible analysis based on terminology).	++	Possible to implement even retrospectively based on archetypes, but not integrated.	+–
Supports report writing	Integrated (based on terminology and templates).	++	Possible to implement, but not integrated.	+–
Provides data basis for decision support modules	Yes, but have to know database schema.	+	Yes, based on archetypes.	++
Export/Import of Data	Possible via HL7 or own protocols. Context has to be established.	+	Possible via *open*EHR EHR Extracts based on archetypes. Context is guaranteed.	++
Degree of standardization needed	Flexible through common terminology (e.g. basic data set) that is extendable by research-specific terminologies.	+	Even more flexible through specialisation and because only commonly used archetypes have to be standardized.	++
Degree of governance needed	Only essential to agree on basic data set by all parties. Further items can be standardised.	+	Only essential to agree on standardized archetypes that are used by all parties, more flexible.	++
Possibility for internationalisation (international trials)	Not easily achievable.	––	Yes, possible via context-based translation of archetypes.	++

While HL7 primarily defines messages between applications and HL7 CDA is a generic model for the communication of clinical documents, and in this is similar to openEHR Transactions, openEHR's focus is the EHR as a whole. The Clinical Data Interchange Standards Consortium Operational Data Model (CDISC ODM) as a format for clinical trial

[1] Various trial terminologies extending the basic terminology and are applied based on patient characteristics like diagnosis.

data exchange could support data exchange between openEHR and non-openEHR clinical trial systems.

5. Conclusion

It can be concluded that *open*EHR can support multi-centre research based on routine clinical data about as well as **eardap**. As, in addition, *open*EHR inherently offers valuable features of Electronic Health Records, we recommend that multi-centre clinical trials adopt the *open*EHR approach for their research activities. For higher efficiency and data quality, some of the features **eardap** excels in could be applied in addition to the *open*EHR methodology.

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7. References

[1] Powsner SM, Wyatt JC, and Wright P. Opportunities for and challenges of computerisation. *Lancet* 1998; 352(9140):1617-22.
[2] Dolin RH, Alschuler L, Beebe C, Biron PV, Boyer SL, Essin D, Kimber E, Lincoln T, and Mattison JE. The HL7 Clinical Document Architecture. *J Am Med Inform Assoc* 2001; 8(6):552-69.
[3] Beale T. Archetypes: Constraint-based Domain Models for Future-proof Information Systems OOPSLA 2002 workshop on behavioural semantics., 2002.
[4] CEN/TC 251. EHRCOM prEN 13606-1. Health informatics — Electronic health record communication — Part 1: Reference model. 2004.
[5] Duftschmid G, Gall W, Eigenbauer E, and Dorda W. Management of data from clinical trials using the ArchiMed system. *Med Inform Internet Med* 2002; 27(2):85-98.
[6] Kuchinke W, Eich HP, and Ohmann C. Software for Remote Data Entry and Clinical Trials: Review of Commercial Solutions and Trends 46. annual meeting of Deutsche Gesellschaft für Medizinische Informatik, Biometrie und Epidemiologie (gmds), Urban & Fischer, Cologne, 2001. 205-6.
[7] Abdellatif M and Reda DJ. A Paradox-based data collection and management system for multi-center randomized clinical trials. *Comput Methods Programs Biomed* 2004; 73(2):145-64.
[8] Merzweiler A, Weber R, Garde S, Haux R, and Knaup-Gregori P. TERMTrial - Terminology-based documentation systems for cooperative clinical trials. *Comput Methods Programs Biomed* 2005; to appear
[9] Knaup P, Garde S, Merzweiler A, Graf N, Weber R, and Haux R. Towards shared patient records: An Architecture for Using Routine Data for Nationwide Research. *EuroMISE 2004: EFMI Symposium on Electronic Health Record, Health Registers and Telemedicine. Prague, 12.-15.4.2004.* 2004;
[10] Brown PJ. Coming to terms with datasets for diabetes care. *Diabetes Nutr Metab* 2000; 13(4):215-9.
[11] Cimino JJ. Terminology tools: state of the art and practical lessons. *Methods Inf Med* 2001; 40(4):298-306.
[12] Rector AL. Terminology and concept representation languages: where are we? *Artif Intell Med* 1999; 15(1):1-4.
[13] Health Level 7. HL7 EHR System Functional Model: A Major Development Towards Consensus on Electronic Health Record System Functionality - A White Paper. 2004.
[14] Beale T, Goodchild A, and Heard S. EHR Design Principles. *open*EHR Foundation; 2001.
[15] Goodchild A, Gibson K, Anderson L, and Bird L. The Brisbane Southside HealthConnect Trial: Preliminary Results Health Informatics Conference (HIC), Brisbane, 2004.
[16] Garde S, Baumgarten B, Basu O, Graf N, Haux R, Herold R, Kutscha U, Schilling F, Selle B, Spiess C, Wetter T, and Knaup P. A meta-model of chemotherapy planning in the multi-hospital/multi-trial-center-environment of pediatric oncology. *Methods Inf Med* 2004; 43(2):171-83.
[17] Silva JS, Ball MJ, Chute CG, Douglas JV, Langlotz CP, C. NJ, and Scherlis WL. *Cancer Informatics - Essential Technologies for Clinical Trials*. New York: Springer, 2002.
[18] Bird L, Goodchild A, and Tun Z. Experiences with a Two-Level Modelling Approach to Electronic Health Records. *Journal of Research and Practice in Information Technology* 2003; 35(2)

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