Archetypes in Electronic Health Records: Making the case and showing the path for domain knowledge governance

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Abstract
Objective: To make the case and show the path for domain knowledge governance in health care.
Background: In the field of open Electronic Health Records (EHRs), *open*EHR as an archetype-based approach is becoming increasingly recognised.
Results: The adoption of an archetypes-based approach – clearly separating knowledge and information – is essential to enable semantic interoperability in health care. To avoid significant overlaps and 'rank growth' during the archetype development, archetype development needs to be coordinated nationwide and beyond and also across the various health professions. Archetypes need to be easily accessible and need to be maintained after creation. Domain knowledge governance comprises all of the above tasks. Essentially, we propose a health-wide umbrella organisation to coordinate the archetype development and to organise domain experts in inter-disciplinary archetype development teams.
Discussion: The dimensions of domain knowledge governance have huge implications for the health industry. The adoption of a set of processes that enable the creation, organisation, dissemination and use of knowledge is required. Collectively this will create the knowledge environment required to effectively foster semantic interoperability between EHR systems.
Conclusion: We conclude that we should no longer be concentrating on the development of standard terminologies alone but we should divert our efforts toward the development of archetypes. The development of terminologies remains crucial as part of this effort.

Objectives:
The aim of this paper is to show what systematic domain knowledge governance is, why it is needed to ensure semantic interoperability in health care, and how it can be achieved using *open*EHR archetypes.

Background:
The aim of *open*EHR is to enable the development of open specifications and software for Electronic Health Record (EHR) systems. It is based on the results of the European Union's GEHR-Project. Following GEHR several projects extended and refined its results (e.g. the Synapses and SynEx projects). All these projects influenced the *open*EHR architecture and the pioneering of a two level modelling approach for EHRs. The first level of this approach 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 models or

represents one clinical or other domain specific concept by constraining instances of the *open*EHR information models to express a valid structure, valid data types, and values.

Design principles of *open*EHR are described in more detail in [Beale et al. 2001], but the key innovation of the *open*EHR architecture is that it separates record keeping concerns from clinical data collection using archetypes [Goodchild et al. 2004], thus enabling patient-centred, longitudinal, comprehensive and prospective EHRs. In other words, with information being defined as statements about specific entities (e.g. "Gina has an atrial septal defect, 1 cm x 3.5 cm") and knowledge being statements which apply to all entities of a class (e.g. "the atrial septum divides the right and left atrial chambers of the human heart") information is strictly separated from knowledge in *open*EHR. Experiences in two field trials supported by the Australian General Practice Computing Group (GPCG) showed that the approach does work [Bird et al. 2003] and it is now the basis of a major trial of data sharing between hospitals and primary care in Australia within the framework of Health*Connect* [Goodchild et al. 2004].

Methods:
To make the case and show the path for domain knowledge governance, we analysed current approaches to EHR system implementation, especially the *open*EHR and archetypes approach. Further, we analysed current standards and standards development environments, as well as Australian and international health care environments.

Results: Making the case
We define *domain knowledge governance* as comprising all tasks related to establishing or influencing formal and informal organizational mechanisms and structures in order to systematically influence the building, dissemination, and maintaining of knowledge within and between domains. Domains can be wide-reaching *sectors* like health care, *areas* like medicine or nursing, or *fields* and *sub-fields* like midwifery or paediatric oncology.

First of all, before examining why archetype development needs to be controlled by domain knowledge governance, we first argue in the following why archetypes are needed in the first place:

- Firstly, we argue in accordance with [Rector 1999] and [Elkin et al. 2003] that a traditional comprehensive terminology is simply too complex, never comprehensive and too difficult to maintain. As the *open*EHR archetype approach does not rely on big standardized terminologies but on micro-vocabularies [Health Level 7 2004], it offers more flexibility during standardisation of clinical concepts and overcomes the shortcomings of terminology-focused approaches. The greater flexibility during standardization processes offered by *open*EHR archetyping is of great value during knowledge harmonization and governance. Furthermore we recently analysed that *open*EHR can support multi-centre research based on routine clinical data [Garde et al. 2005] and thus facilitate the generation of new knowledge through continuous practice evaluation.

- Secondly, it is inline with current standards developments. Much standards development work is continuing internationally with considerable Australian input to enable effective electronic communication as required for widespread EHR adoption. In particular the European standard, EN-ISO 13606-1 Electronic Health Record Communication, originally a 4 part standard is now being enhanced to become a 5 part standard by adopting the *open*EHR two level modelling approach. This is arguably the single most important standard requiring international consensus as it defines the fundamental EHR infrastructure requirements.

- Thirdly, openEHR and archetypes empower the domain expert and deal with the ever-changing and growing health environment by separating information and knowledge. Not only

is health care big, it is open-ended in three ways:

- *in breadth*, because new information is always being discovered or becoming relevant
- *in depth*, because finer-grained detail is always being discovered or becoming relevant
- *in complexity*, because new relationships are always being discovered or becoming relevant

In this context, the adoption of archetypes facilitates EHR systems to accommodate changing medical and health service delivery practices over time. This represents an innovation in knowledge engineering as it facilitates knowledge domain experts (clinicians) to electronically document content models such as blood pressure, an ECG result or discharge summary, describe clinical workflow processes such as a patient's assessment, incorporate clinical or best practice guidelines or a knowledge domain ontology. This is achieved by separating knowledge from runtime information and design time models that collectively make up an information system. This way, archetypes are the building blocks of the health knowledge environment. Adoption of the EN-ISO 13606-1 standard [Iso/Cen 1999] ensures an EHR system is able to manage this. Current clinical information systems directly incorporate clinical knowledge concepts within the software and databases making these systems very costly to maintain and constantly changing knowledge will eventually make such systems obsolete.

- Fourthly, archetypes are clinically meaningful. Archetypes are agreed models of clinical or other domain specific concepts and need to adopt a standard set of terms for each archetype. These terms can come from any number of terminologies. Archetypes specify groups of data that are discreet, highly related and clinically meaningful. They enable information to be specified in a far more complex form than is possible in message structures, they can evolve over time yet remain standardised.

Now, accepting (or not) that archetypes are indeed the build blocks of EHRs, we now argue why domain knowledge governance is needed to ensure semantic operability. One main idea of the archetype approach is to empower domain experts to create and change the knowledge inherent in archetypes, thus controlling the way 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. The *open*EHR Archetype Editor was built as a tool to support the domain experts' development of archetypes by providing them with an easy-to-use graphical user interface making the abstract *open*EHR archetype model tangible. As a consequence, health professionals can and need to take charge of managing their domain knowledge. However, this has to be systematically organised – through domain knowledge governance for the following reasons:

- Firstly, there will be significant concept overlaps between the health care domains, and after all what domains do we need to differentiate for the archetype purpose in the first place? For example, it may be that a nursing archetype for an oral assessment for example is equally applicable to knowledge domains other than nursing? Or that various nursing fields have different needs? Essentially, domain experts need to be coordinated and 'rank growth' of archetypes avoided.
- Secondly, some archetypes need to be standardised as they are relevant for and need to be semantically interoperable between the various health areas and specialist fields and also between various organisations. It has to be defined what these archetypes are and who is responsible for them.

- Thirdly, archetypes need to be easily accessible (e.g. on an internet server) and easily locatable, i.e. organised in a way that a certain archetype can be retrieved with high recall and precision from all archetypes.
- Fourthly, archetypes have to be evidence-based. Knowledge in archetypes needs to be based on evidence or best practice although it can include 'tacit' knowledge acquired by experts and agreed to by consensus.
- Fifthly, archetypes need to be maintained and systematically updated when knowledge changes.
- Sixthly, while the Archetype Editor is quite intuitive, domain experts must have a basic understanding of archetypes and *open*EHR's logical building blocks of an EHR (folders, compositions, sections, entries, clusters, elements, and data values) to build useful archetypes, adequate training has to be provided.
- Finally, and more theoretically, it is argued by [Kumar et al. 2004] and [Pisanelli and Gangemi 2004] that the adoption of an ontological framework facilitates the building of better and more interoperable information systems. It facilitates unambiguous communication of complex and detailed concepts. A domain ontology catalogues various aspects known to exist within the domain of interest from a specific point of view to suit a defined purpose. An ontological domain knowledge model shows how key concepts relate to one another and is usually based on a philosophical or theoretical foundation. The term 'ontology' in the field of health concept representation describes the representation of concepts and the reality they attempt to describe. For example terminologies, classifications, knowledge bases, nomenclatures etc are all examples of attempts to represent an ontology [Standards Australia 2004].

In summary, for these reasons, we need to develop a framework to manage archetypes, identify archetypes that need to be standardised. We need to establish and train multidisciplinary teams for archetype development and coordination. This domain knowledge governance will ensure that archetypes meet the information needs of the various areas, minimises redundancy and enables semantic interoperability.

Showing the Path:
Figure 1 shows the regions of standardisation for archetypes and the scope of archetypes. Archetypes can be standardised for different regions and their scope can reach from sub-field or field (e.g. paediatric oncology), and area (e.g. medicine) to the sector (health), and can also be relevant beyond health for other sectors. Not always (or in fact probably only for a few archetypes) is it desirable to strive for worldwide standardisation and worldwide scope. Rather, many archetypes will only be relevant for one field or one area – but this has to be ascertained on the various domain levels. In other cases it will make sense to specialise a health-care-wide and nation-wide standardised archetype to suit a specific field or a specific health service provider. By using archetypes this can be done without endangering semantic interoperability.
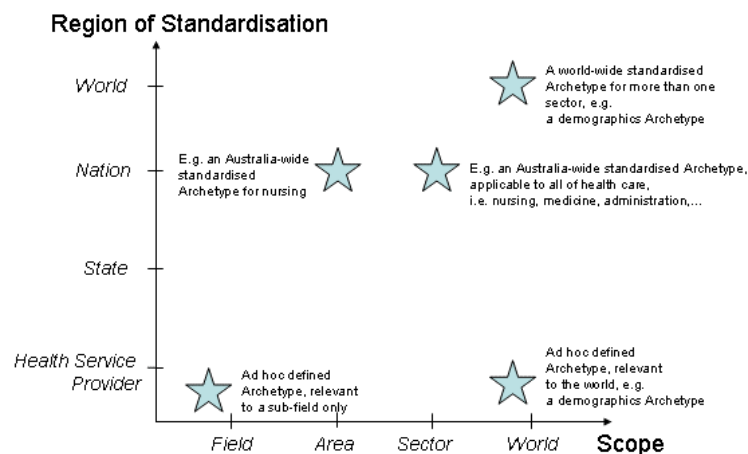
Figure 1: Region of standardisation and scope of archetypes.

Figure 2 presents an overview of a top-down-approach to domain knowledge governance in health. Essentially an approach is needed that ensures that archetypes will be compatible, comprehensive, and not overlapping inconsistently. We propose an umbrella organisation that coordinates the governance for health as a whole. This organisation will have the task to identify archetypes that are to be used by different areas in health (e.g. medicine and nursing), so that these conflicts can be resolved. Then on the next level, medicine has to ensure that archetype work in different specialist fields (e.g. by medical colleges) is compatible, while nursing and possibly other areas have to do the same for their area. However, this will constantly be interwoven with the effort to broaden the region of standardisation.
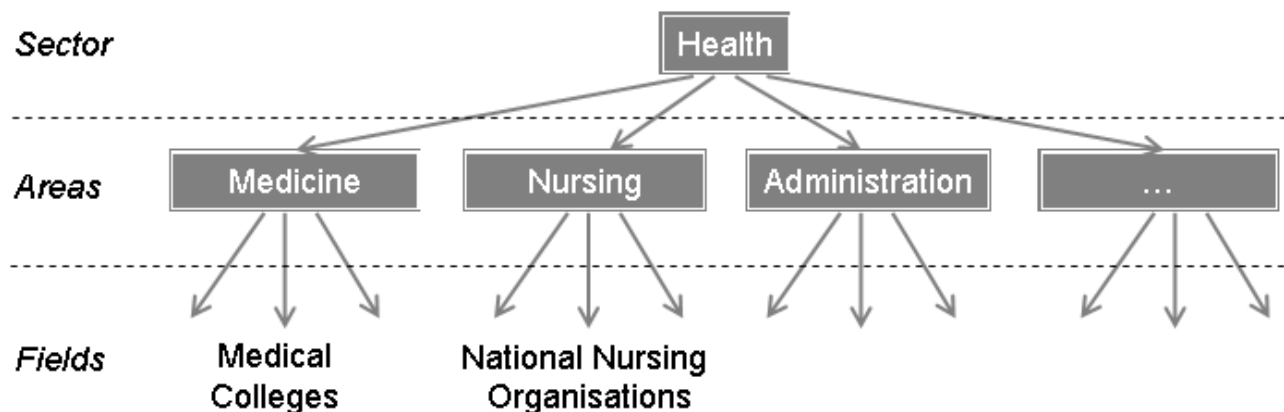

Figure 2: Overview of a top-down-approach to domain knowledge governance in health.

An interdisciplinary team needs to be established on sector-level that defines which archetypes need to be developed and delegate this task to the appropriate intra- or interdisciplinary team on area or field level. For this, domain experts must be identified and trained. We need to identify individual ontological knowledge domains, establish who governs which knowledge domain and assess priorities for archetype development. Further, a process for engaging knowledge domain experts, for the development or specialisation of archetypes on area and field level has to be defined. Health-wide archetypes can be specialised for various areas, and likewise a nursing area archetypes (e.g. an oral assessment) can be specialised for a field (e.g. an oncology oral assessment) without endangering semantic interoperability.

Discussion:

It is clear that internationally there is a strong desire to develop and implement health information systems that have semantic interoperability. There is a global trend towards the implementation of EHRs along with the desire to make the best possible use of available technologies to improve patient safety and outcomes, and contain costs. Archetype development requires standards developers to work more closely with domain knowledge experts and means a paradigm shift regarding the methods adopted. Archetype development and management is expected to require the adoption of principles not unlike those used for the development of a classification system or terminology. The dimensions of knowledge generation and its management have huge implications for the health industry. Knowledge management requires the adoption of a set of processes that enable the creation, organisation, sharing, dissemination and use of knowledge. Many archetypes need to be standardised, managed and maintained by the relevant domain knowledge experts. Collectively this will create the knowledge environment required to effectively adopt EHRs.

Once we have professional consensus regarding best practice based on evidence expressed in the form of archetypes, we need to consider how to manage, maintain, update and disseminate archetypes. We already have organisations such as the Cochrane collaboration, an international not-for-profit organisation, providing up-to-date information about the effects of health care. It is desirable to use an existing or establish a new organisation to manage archetype development and dissemination.
We need a formalised process to ensure that standard archetypes are evidence based, reflect current best practice, use the most appropriate terminologies, are updated as required, are easily disseminated and made available to all who need them in a timely manner. It has to be ensured that redundancy is minimised. Organisations such as the Australian Institute of Health and Welfare, DIMDI – the German Institute for Medical Documentation and Information, or the Canadian Institute for Health Information may well be in the best position to do so, but it would require a change to their existing organisational mission and operations. However, there will be a number of archetypes that will reflect specific clinical knowledge domains that can only be managed by the profession that specialises in that area of practice. In medicine the professional colleges are in charge of their specific knowledge domains, while in nursing, the National Nursing Organisations (NNO) group, now consisting of more than 50 nursing organisations could coordinate the development of nursing archetypes. One good example for coordination on field level (here: oncology) is the process adopted in the European WISECARE project where nurse experts agreed on data definitions, data collection and usage to improve nursing care and patient outcomes relevant to various oncology specialisations [Sermeus et al. 2000].

Conclusion:

We conclude that we should no longer be concentrating the development of standard terminologies alone but we should divert our efforts toward the development of archetypes and the establishment of national and international processes to support and govern this development. We acknowledge the continuing need for terminologies for large sets of terms such as anatomy, pathology, and diagnoses. The development and adaptation of these terminologies remains a crucial part of the EHR problem space.

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