



openEHR Architecture
Architecture Overview

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1. Ocean Informatics Australia

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Amendment Record

Issue	Details	Raiser	Completed
RELEASE 1.0.1			
1.1	<p>CR-000200. Correct package names in RM diagram.</p> <p>CR-000130: Correct security details in LOCATABLE and ARCHE-TYPED classes.</p> <p>CR-000203: Release 1.0 explanatory text improvements. Improved path explanation. Slight re-ordering of main headings.</p> <p>Added configuration management and versioning material from Common IM.</p> <p>Added section on ontological landscape.</p> <p>Added section on aims.</p> <p>Added section on systems architectures.</p> <p>Added section on security.</p> <p>Added section on system integration.</p> <p>Added section on terminology.</p>	<p>D Lloyd T Beale</p> <p>T Beale, G Grieve, T Shannon, T Beale</p>	12 Sep 2006
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1	Introduction	7
1.1	Purpose.....	7
1.2	Status	7
1.3	Peer review	7
2	Overview	9
2.1	The openEHR Specification Project	9
3	Aims of the openEHR Architecture	11
3.1	Overview	11
3.2	Clinical Aims	12
3.3	Deployment Environments	13
4	Design Principles	15
4.1	Ontological Separation	15
4.2	Separation of Responsibilities	18
4.3	Separation of Viewpoints	18
5	openEHR Package Structure	21
5.1	Overview	21
5.2	Reference Model (RM)	22
5.2.1	Package Overview	22
5.3	Archetype Model (AM)	24
5.4	Service Model (SM).....	25
6	Design of the openEHR EHR.....	27
6.1	The EHR System	27
6.2	Top-level Information Structures	27
6.3	The EHR	28
6.4	Entries and “clinical statements”	29
6.5	Managing Interventions	32
6.6	Time in the EHR	34
6.7	Language.....	34
7	Security and Confidentiality	37
7.1	Requirements	37
7.2	Threats to Security and Privacy	38
7.3	Solutions Provided by openEHR	39
7.3.1	Overview.....	39
7.3.2	Security Policy	39
7.3.3	Integrity.....	41
7.3.4	Anonymity	43
7.4	Access Control	43
8	Versioning	45
8.1	Overview	45
8.2	The Configuration Management Paradigm.....	45
8.2.1	Organisation of the Repository	46
8.2.2	Change Management	46
8.3	Managing Change in Time.....	47
8.3.1	General Model of a Change-controlled Repository.....	48
8.4	The “Virtual Version Tree”	49

9	Identification	51
9.1	General Scheme.....	51
9.2	Levels of Identification.....	51
10	Archetypes and Templates	53
10.1	Overview	53
10.2	Archetype Formalisms and Models.....	54
10.2.1	Overview	54
10.2.2	Design-time Relationships between Archetypes.....	54
10.3	Relationship of Archetypes and Templates to Data	55
10.4	Archetype-enabling of Reference Model Data.....	55
10.5	Archetypes, Templates and Paths	56
10.6	Archetypes and Templates at Runtime	56
10.6.1	Overview	56
10.6.2	Deploying Archetypes and Templates.....	57
10.6.3	Validation during Data Capture.....	58
10.6.4	Querying.....	59
10.7	The openEHR Archetypes.....	60
11	Paths and Locators	61
11.1	Overview	61
11.2	Paths	61
11.2.1	Basic Syntax.....	61
11.2.2	Predicate Expressions.....	62
11.2.3	Paths within Top-level Structures.....	63
11.2.4	Runtime Paths and Uniqueness	63
11.3	EHR URIs.....	65
11.3.1	Locating Top-Level Structures	66
12	Terminology in openEHR.....	69
12.1	Overview	69
12.2	Terminology to Support the Reference Model	69
12.3	Archetype Internal Terminology	69
12.4	Binding to External Terminologies	71
12.5	Querying using External Terminologies.....	72
13	Deployment.....	75
13.1	5-tier System Architecture.....	75
14	Integrating openEHR with other Systems.....	77
14.1	Overview	77
14.2	Integration Archetypes	77
14.3	Data Conversion Architecture	78
15	Relationship to Standards	79
16	Implementation Technology Specifications	81
16.1	Overview	81
A	References.....	83

1 Introduction

1.1 Purpose

This document provides an overview of the *openEHR* architecture in terms of a model overview, key global semantics, deployment and integration architectures, relationship to published standards, and finally the approach to building Implementation Technology Specifications (ITSs). Semantics specific to each information, archetype and service model are described in the relevant model.

The intended audience includes:

- Standards bodies producing health informatics standards
- Software development groups using *openEHR*
- Academic groups using *openEHR*
- The open source healthcare community

This document is the key technical overview of *openEHR*, and should be read before all other technical documents.

1.2 Status

This document is under development, and is published as a proposal for input to standards processes and implementation works.

This document is available at <http://svn.openehr.org/specification/TAGS/Release-1.0/publishing/architecture/overview.pdf>.

The latest version of this document can be found at <http://svn.openehr.org/specification/TRUNK/publishing/architecture/overview.pdf>.

New versions are announced on openehr-announce@openehr.org.

Blue text indicates sections under active development.

1.3 Peer review

Areas where more analysis or explanation is required are indicated with “to be continued” paragraphs like the following:

To Be Continued: more work required

Reviewers are encouraged to comment on and/or advise on these paragraphs as well as the main content. Please send requests for information to info@openEHR.org. Feedback should preferably be provided on the mailing list openehr-technical@openehr.org, or by private email.

2 Overview

This document provides an overview of the *openEHR* architecture. It commences with a description of the specification project, followed by an overview of the reference model structure and packages. Key global semantics including security, archotyping, identification, version and paths are then described. The relationship to published standards is indicated, and finally, the approach to building Implementation Technology Specifications (ITSs) is outlined.

2.1 The *openEHR* Specification Project

FIGURE 1 illustrates the *openEHR* Specification Project. The project consists of requirements, architectural specifications, implementation technology specifications (ITSs), and conformance specifications. The focus of this document is the architectural and implementation technology specifications (ITSs).

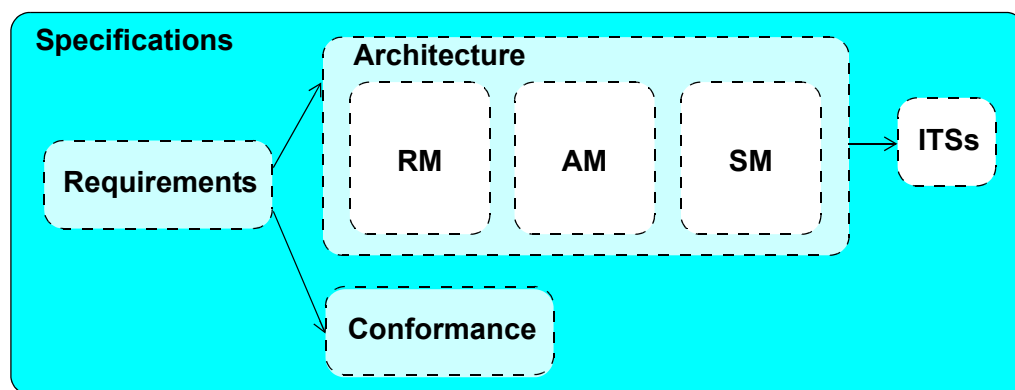


FIGURE 1 *openEHR* Specification project

The architecture specifications consist of the Reference Model (RM), the Service Model (SM) and Archetype Model (AM). The first two correspond to the ISO RM/ODP information and computational viewpoints respectively. The latter formalises the bridge between information models and knowledge resources.

The architecture specifications published by *openEHR* are defined as a set of *abstract* models, using the UML notation and formal textual class specifications. These models remain the primary references for all semantics, regardless of developments in any implementation environment. The *openEHR* Modelling Guide describes the semantics of the models. The presentation style of these abstract specifications is deliberately intended to be clear and semantically close to the ideas being communicated. Conversely, the specifications do not follow idioms or limitations of particular programming languages, schema languages or other formalisms. All such expressions are treated as ITSs, for which explicit mappings generally have to be developed and described (since almost no implementation formalism natively implements complete UML semantics).

There are numerous implementation technologies, ranging from programming languages, serial formalisms such as XML, to database and distributed object interfaces. Each of these has its own limits and strengths. The approach to implementing any of the *openEHR* abstract models in a given implementation technology is to firstly define an “implementation technology specification” (ITS) for the particular technology, then to use it to formally map the abstract models into expressions in that technology.

3 Aims of the *openEHR* Architecture

3.1 Overview

This section provides a brief overview of the requirements underpinning the *openEHR* architecture. The *openEHR* architecture embodies 15 years of research from numerous projects and standards from around the world. It has been designed based on requirements captured over many years.

Because the architecture is highly generic, and particularly due to being archetype-driven, it satisfies many requirements outside the original concept of the “clinical EHR”. For example, the same reference architecture can be used for veterinary health or even “care” of public infrastructure or listed buildings. This is due to the fact that the reference model embodies only concepts relating to “service and administrative events relating to a subject of care”; it is in archetypes and templates that specifics of the kinds of care events and subjects of care are defined. In another dimension, although one of the requirements for the *openEHR* EHR was a “patient-centric, longitudinal, shared care EHR”, it is not limited to this, and can be used in purely episodic, specialist situations, e.g. as a radiology department record system. Requirements for various flavours of “health care record” can be categorised according to the two dimensions, scope, and kind of subject, as shown in FIGURE 2.

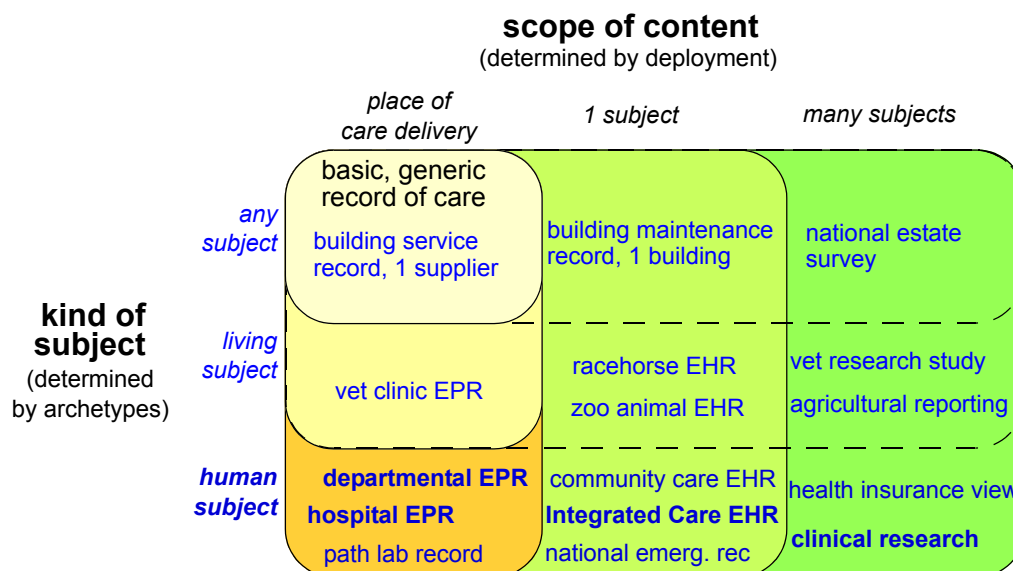


FIGURE 2 Structure of Requirements met by *openEHR*

In this figure, each bubble represents a set of requirements, being a superset of all requirements of bubbles contained within it. Requirements for a generic record of care for any kind of subject in a local deployment are represented by the top left bubble. The subsequent addition of requirements corresponding to living subjects and then human subjects is represented by the bubbles down the left side of the diagram. The requirements represented by the largest bubble on the left hand side correspond to “local health records for human care”, such as radiology records, hospital EPRs and so on. Additional sets of requirements represented by wider bubbles going across the diagram correspond to extending the scope of the content of the care record first to a whole subject (resulting in a patient-centric, longitudinal health record) and then to populations or cohorts of subjects, as done in population health and research. From the (human) healthcare point of view, the important requirements groups extend all the way to the bottom row of the diagram.

Going down the diagram, requirements corresponding to increasing specificity of subject of care (from “any” to “human”) are mostly implemented in *openEHR* by the use of archetypes. Going across the diagram, the requirements corresponding to increasing scope of record content (from episodic to population) are mainly expressed in different deployments, generally going from standalone to a shared interoperable form. One of the key aspirations for EHRs today is the “integrated care record” sought by many health authorities today¹, which provides an informational framework for integrated shared care.

As a result of the approach taken by *openEHR*, components and applications built to satisfy the requirements of an integrated shared care record can also be deployed as (for example) an episodic radiology record system.

Some of the key requirements developed during the evolution of GEHR to *openEHR* are listed in the following sections, corresponding to some of the major requirements groups of FIGURE 2.

Generic Care Record Requirements

The *openEHR* requirements include the following, corresponding to a basic, generic record of care:

- prioritisation of the patient / carer interaction (over e.g. research use of the record);
- suitable for all care settings (primary, acute etc.);
- medico-legal faithfulness, traceability, audit-trailing;
- technology & data format independence;
- highly maintainable and flexible software;
- support for clinical data structures: lists, tables, time-series, including point and interval events.

Health Care Record (EPR)

The following requirements addressed in *openEHR* correspond to a local health record, or EPR:

- support for all aspects of pathology data, including normal ranges, alternative systems of units etc.;
- supports all natural languages, as well as translations between languages in the record;
- integrates with any/multiple terminologies.

Shared Care EHR

The following requirements addressed in *openEHR* correspond to an integrated shared care EHR:

- support for patient privacy, including anonymous EHRs;
- facilitate sharing of EHRs via interoperability at data and knowledge levels;
- compatibility with CEN 13606, Corbamed, and messaging systems;
- support semi-automated and automated distributed workflows.

3.2 Clinical Aims

From a more specifically clinical care perspective (rather than a record-keeping perspective), the following requirements have been identified during the development of *openEHR*:

1. The Integrated Care EHR is described in ISO/TR 20514 (2005)

- The need for a patient-centric, lifelong electronic health record that entails a holistic view of patient needs as opposed to niche problem-solving and decision-support techniques for limited diagnostic purposes;
- Integration of different views of the patient (GP, emergency and acute care, pathology, radiology, computerised patient-order entry, etc.) with the vast body of available knowledge resources (terminologies, clinical guidelines and computerised libraries);
- Clinical decision-support to improve patient safety and reduced costs through repeated medical investigations;
- Access to standards-based computing applications.

The Integrated Care EHR holds great promise: to generalise and make widely available the benefits of computerisation that have been demonstrated individually and in isolated settings. These can be summarised as:

- Reducing adverse events arising from medication errors such as interactions, duplications or inappropriate treatments and the flow-on costs associated with these;
- Improving the timely access to critical information and reduced clinician time searching for information;
- Reducing the incidence of patients being overlooked in the healthcare system due to information not being communicated;
- Reducing the duplication of investigations and other tests and procedures due to results not being available in the local computing environment;
- Improved prevention and early detection, based on predictive risk factor analysis, which is possible with quality EHR data;
- Improved decision making through decision support tools with access to the patient's whole EHR;
- Improving access to and computation of evidence based guidelines;
- Increasing targeted health initiatives known to be effective, based on patient criteria; and
- Reduced hospitalisations and readmissions.

One comprehensive statement of EHR requirements covering many of the above is the ISO Technical Report 18308¹ for which an *openEHR* profile has been created². The requirements summarised above are described in more detail in the *openEHR* EHR Information Model document.

3.3 Deployment Environments

Ultimately any software and information architecture only provides utility when deployed. The architecture of *openEHR* is designed to support the construction of a number of types of system. One of the most important, the integrated shared care health record is illustrated in FIGURE 3.

In this form, the *openEHR* services are added to the existing IT infrastructure to provide a shared, secure health record for patients that are seen by any number of health providers in their community context. *openEHR*-enabled systems can also be used to provide EMR/EPR functionality at provider locations. Overall, a number of important categories of system can be implemented using *openEHR* including the following:

-
1. see <http://www.openehr.org/downloads/ISOEHRRequirements.zip>
 2. see http://svn.openehr.org/specification/TRUNK/publishing/requirements/iso18308_conformance.pdf

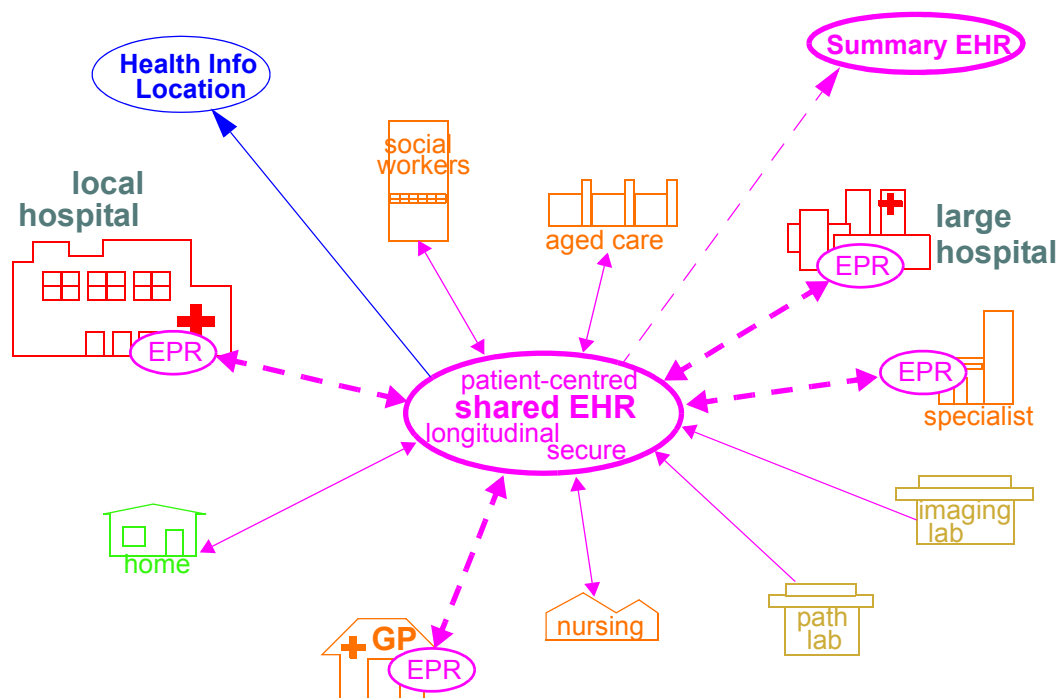


FIGURE 3 Community Shared-care Context

- shared-care community or regional health service EHRs;
- summary EHRs at a national, state, province or similar level;
- small desktop GP systems;
- hospital EMRs;
- consolidated and summary EHRs in federation environments;
- legacy data purification and validation gateways;
- web-based secure EHR systems for mobile patients.

4 Design Principles

The *openEHR* approach to modelling information, services and domain knowledge is based on a number of design principles, described below. The application of these principles lead to a separation of the models of the *openEHR* architecture, and consequently, a high level of componentisation. This leads to better maintainability, extensibility, and flexible deployment.

4.1 Ontological Separation

The most basic kind of distinction in any system of models is ontological, i.e. in the levels of abstraction of description of the real world. All models carry some kind of semantic content, but not all semantics are the same, or even of the same category. For example, some part of the SNOMED-CT¹ terminology describes types of bacterial infection, sites in the body, and symptoms. An *information* model might specify a logical type Quantity. A *content* model might define the model of information collected in an ante-natal examination by a physician. These types of “information” are qualitatively different, and need to be developed and maintained separately within the overall model eco-system. FIGURE 4 illustrates these distinctions, and indicates what parts are built directly into software and databases.

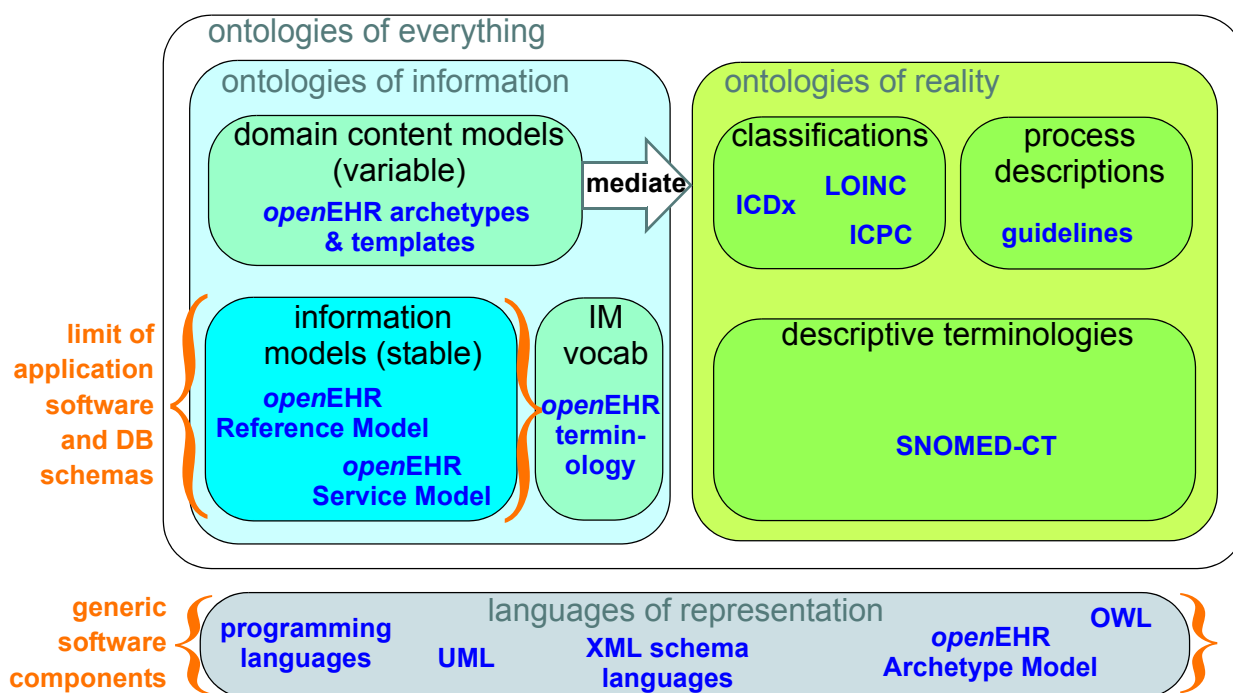


FIGURE 4 The Ontological Landscape

This figure shows a primary separation between “ontologies of information” i.e. models of information content, and “ontologies of reality” i.e. descriptions and classifications of real phenomena. These two categories have to be separated because the type of authors, the representation and the purposes are completely different. In health informatics, this separation already exists by and large, due to the development of terminologies and classifications.

1. See <http://www.snomed.org>

A secondary ontological separation within the information side is shown between information models and domain content models. The former category corresponds to semantics that are *invariant* across the domain (e.g. basic data types like coded terms, data structures like lists, identifiers), while the latter corresponds to *variable* domain level content descriptions - descriptions of information structures such as “microbiology result” rather than descriptions of actual phenomena in the real world (such as infection by a microbe). This separation is not generally well understood, and historically, a great deal of domain-level semantics has been hard-wired into the software and databases, leading to relatively unmaintainable systems.

By clearly separating the three categories - information models, domain content models, and terminologies - the *openEHR* architecture enables each to have a well-defined, limited scope and clear interfaces. This limits the dependence of each on the other, leading to more maintainable and adaptable systems.

Two-level Modelling and Archetypes

One of the key paradigms on which *openEHR* is based is known as “two-level” modelling, described in [2]. Under the two-level approach, a stable reference information model constitutes the first level of modelling, while formal definitions of clinical content in the form of archetypes and templates constitute the second. *Only the first level* (the Reference Model) *is implemented in software*, significantly reducing the dependency of deployed systems and data on variable content definitions. The only other parts of the model universe implemented in software are highly stable languages/models of representation (shown at the bottom of FIGURE 4). As a consequence, systems have the possibility of being far smaller and more maintainable than single-level systems. They are also inherently self-adapting, since they are built to consume archetypes and templates as they are developed into the future.

Archetypes and templates also act as a well-defined semantic gateway to terminologies, classifications and computerised clinical guidelines. The alternative in the past has been to try to make systems function solely with a combination of hard-wired software and terminology. This approach is flawed, since terminologies don’t contain definitions of domain content (e.g. “microbiology result”), but rather facts about the real world (e.g. kinds of microbes and the effects of infection in humans).

The use of archotyping in *openEHR* engenders new relationships between information and models, as shown in FIGURE 5.

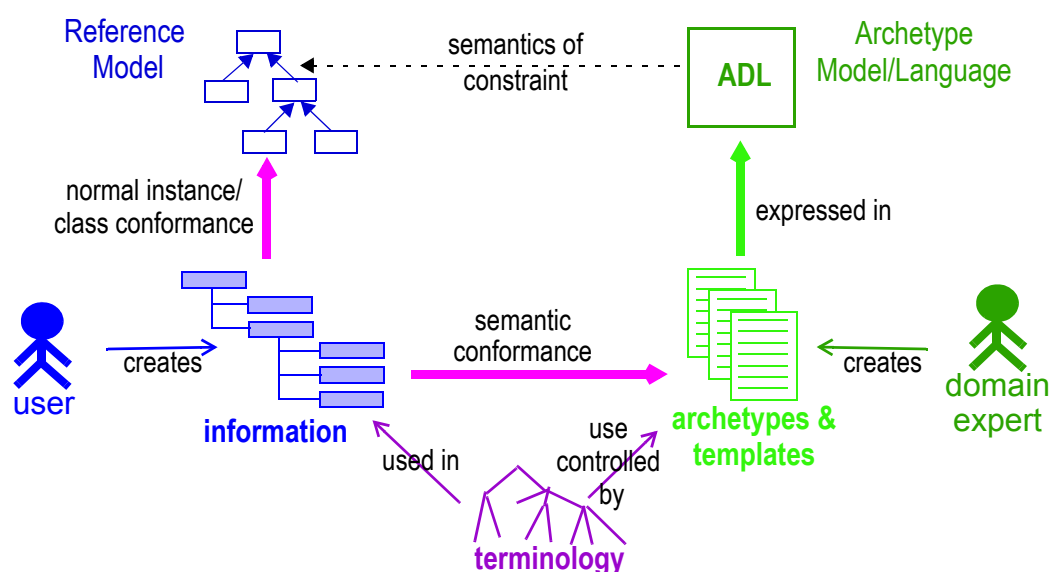


FIGURE 5 Archetype Meta-architecture

In this figure, “data” as we know it in normal information systems (shown on the bottom left) conforms in the usual way to an object model (top left). Systems engineered in the “classic” way (i.e. all domain semantics are encoded somewhere in the software or database) are limited to this kind of architecture. With the use of two-level modelling, runtime data now conform semantically to archetypes as well as concretely to the reference model. All archetypes are expressed in a generic Archetype Definition Language (ADL).

The details of how archetypes and templates work in *openEHR* are described in Archetypes and Templates on page 53.

Consequences for Software Engineering

Two-level modelling significantly changes the dynamics of the systems development process. In the usual IT-intensive process, requirements are gathered via *ad hoc* discussions with users (typically via the well-known “use case” methodology), designs and models built from the requirements, implementation proceeds from the design, followed by testing and deployment and ultimately the maintenance part of the lifecycle. This is usually characterised by ongoing high costs of implementation change and/or a widening gap between system capabilities and the requirements at any moment. The approach also suffers from the fact that *ad hoc* conversations with systems users nearly always fails to reveal underlying content and workflow. Under the two-level paradigm, the core part of the system is based on the reference and archetype models (includes generic logic for storage, querying, caching etc.), both of which are extremely stable, while domain semantics are mostly delegated to domain specialists who work building archetypes (reusable), templates (local use) and terminology (general use). The process is illustrated in FIGURE 6. Within this process, IT developers concentrate on generic components such as data management and interoperability, while groups of domain experts work outside the software development process, generating definitions that are used by systems at runtime.

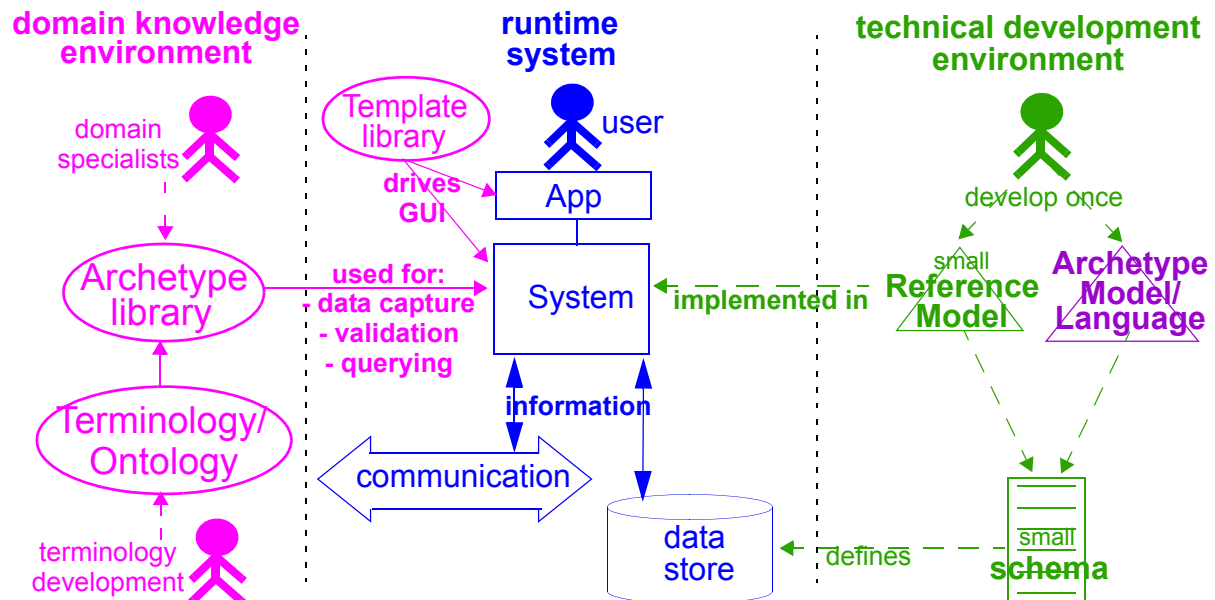


FIGURE 6 Two-level Software Engineering

Clearly applications cannot always be totally generic (although many data capture and viewing applications are); decision support, administrative, scheduling and many other applications still require custom engineering. However, all such applications can now rely on an archetype- and template-driven computing platform. A key result of this approach is that archetypes now constitute a technology-independent, single-source expression of domain semantics, used to drive database schemas,

software logic, GUI screen definitions, message schemas and all other technical expressions of the semantics.

4.2 Separation of Responsibilities

A second key design paradigm used in *openEHR* is that of separation of responsibilities within the computing environment. Complex domains are only tractable if the functionality is first partitioned into broad areas of interest, i.e. into a “system of systems” [5]. This principle has been understood in computer science for a long time under the rubrics “low coupling”, “encapsulation” and “componentisation”, and has resulted in highly successful frameworks and standards, including the OMG’s CORBA specifications and the explosion of object-oriented languages, libraries and frameworks. Each area of functionality forms a focal point for a set of models formally describing that area, which, taken together usually correspond to a distinct information system or service.

FIGURE 7 illustrates a notional health information environment containing numerous services, each denoted by a bubble. Typical connections are indicated by lines, and bubbles closer to the centre correspond to services closer to the core needs of clinical care delivery, such as the EHR, terminology, demographics/identification and medical reference data. Of the services shown on the diagram, *openEHR* currently provides specifications only for the more central ones, including EHR and Demographics.

Since there are standards available for some aspects of many services, such as terminology, image formats, messages, EHR Extracts, service-based interoperation, and numerous standards for details such as date/time formats and string encoding, the *openEHR* specifications often act as a mechanism to integrate existing standards.

4.3 Separation of Viewpoints

The third computing paradigm used in *openEHR* is a natural consequence of the separation of responsibilities, namely the *separation of viewpoints*. When responsibilities are divided up among distinct components, it becomes necessary to define a) the information that each processes, and b) how they will communicate. These two aspects of models constitute the two central “viewpoints” of the ISO RM/ODP model [3], marked in bold in the following:

Enterprise: concerned with the business activities, i.e. purpose, scope and policies of the specified system.

Information: concerned with the semantics of information that needs to be stored and processed in the system.

Computational: concerned with the description of the system as a set of objects that interact at interfaces - enabling system distribution.

Engineering: concerned with the mechanisms supporting system distribution.

Technological: concerned with the detail of the components from which the distributed system is constructed.

The *openEHR* specifications accordingly include an information viewpoint - the *openEHR* Reference Model - and a computational viewpoint - the *openEHR* Service Model. The Engineering viewpoint corresponds to the Implementation Technology Specification (ITS) models of *openEHR* (see Implementation Technology Specifications on page 81), while the Technological viewpoint corresponds to the technologies and components used in an actual deployment. An important aspect of the division into viewpoints is that there is generally not a 1:1 relationship between model specifications in each



viewpoint. For example, there might be a concept of “health mandate” (a CEN ENV13940 Continuity of Care concept) in the enterprise viewpoint. In the information viewpoint, this might have become a model containing many classes. In the computational viewpoint, the information structures defined in the information viewpoint are likely to recur in multiple services, and there may or may not be a “health mandate” service. The granularity of services defined in the computational viewpoint corresponds most strongly to divisions of function in an enterprise or region, while the granularity of components in the information view points corresponds to the granularity of mental concepts in the problem space, the latter almost always being more fine-grained.

5 openEHR Package Structure

5.1 Overview

FIGURE 8 illustrates the overall package structure of the *openEHR* formal specifications. Three major packages are defined: *rm*, *am* and *sm*. All packages defining detailed models appear inside one of these outer packages, which may also be thought of as namespaces. They are conceptually defined within the *org.openehr* namespace, which can be represented in UML as further packages. In some implementation technologies (e.g. Java), the *org.openehr* namespace may actually be used within program texts.

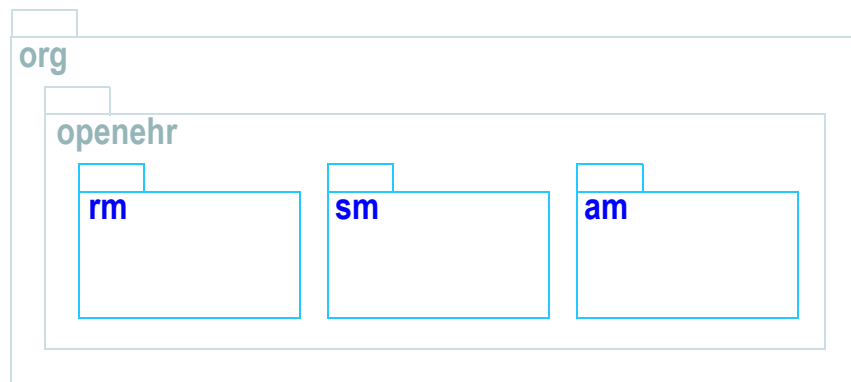


FIGURE 8 Global Package Structure of *openEHR*

One of the important design aims of *openEHR* is to provide a coherent, consistent and re-usable type system for scientific and health computing. Accordingly, a “common type platform” is defined in the lower part of the RM, providing identifiers, data types, data structures and various common design patterns that can be re-used ubiquitously in the upper layers of the RM, and equally in the AM and SM packages. FIGURE 9 illustrates the relationships between the outer packages and their main constituents. The common platform is shown at the bottom.

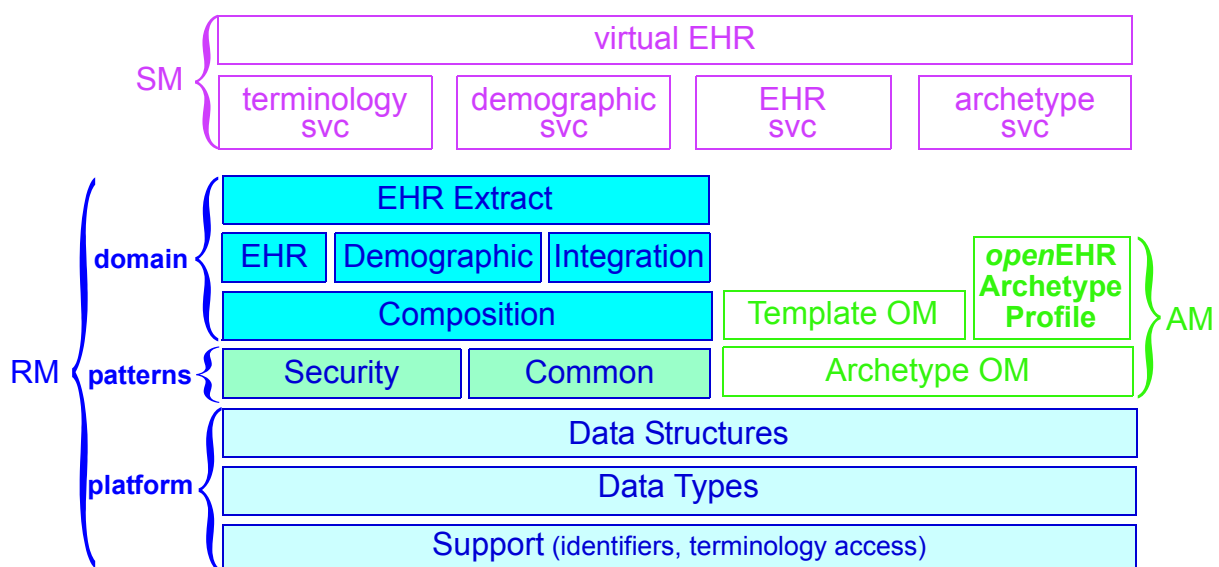


FIGURE 9 Computing Platform view of packages

5.2 Reference Model (RM)

Each package defines a local context for definition of classes. FIGURE 10 illustrates the RM package structure. An informal division into “domain”, “patterns” and “platform” is shown. The packages in the latter group are generic, and are used by all *openEHR* models, in all the outer packages. Together, they provide identification, access to knowledge resources, data types and structures, versioning semantics, and support for archotyping. The packages in the former group define the semantics of enterprise level health information types, including the EHR and demographics.

Each outer package in FIGURE 10 corresponds to one *openEHR* specification document¹, documenting an “information model” (IM). The package structure will normally be replicated in all ITS expressions, e.g. XML schema, programming languages like Java, C# and Eiffel, and interoperability definitions like WSDL, IDL and .Net.

5.2.1 Package Overview

The following sub-sections provide a brief overview of the RM packages.

Support Information Model

This package describes the most basic concepts, required by all other packages, and is comprised of the Definitions, Identification, Terminology and Measurement packages. The semantics defined in these packages allow all other models to use identifiers and to have access to knowledge services like terminology and other reference data. The support package includes the special package *assumed_types*, describing what basic types are assumed by *openEHR* in external type systems; this package is a guide for integrating *openEHR* models proper into the type systems of implementation technologies.

Data Types Information Model

A set of clearly defined data types underlies all other models, and provides a number of general and clinically specific types required for all kinds of health information. The following categories of data types are defined in the data types reference model.

Text: plain text, coded text, paragraphs.

Quantities: any ordered type including ordinal values (used for representing symbolic ordered values such as “+”, “++”, “+++”), measured quantities with values and units, and so on.

Date/times: date, time, date-time types, and partial date/time types.

Encapsulated data: multimedia, parsable content.

Basic types: boolean, state variable.

Data Structures Information Model

In most *openEHR* information models, generic data structures are used for expressing content whose particular structure will be defined by archetypes. The generic structures are as follows.

Single: single items, used to contain any single value, such as a height or weight.

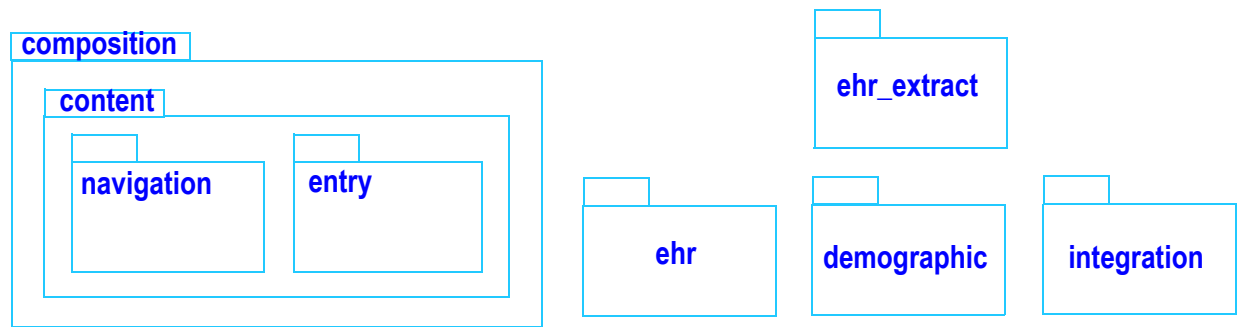
List: linear lists of named items, such as many pathology test results.

Table: tabular data, including unlimited and limited length tables with named and ordered columns, and potentially named rows.

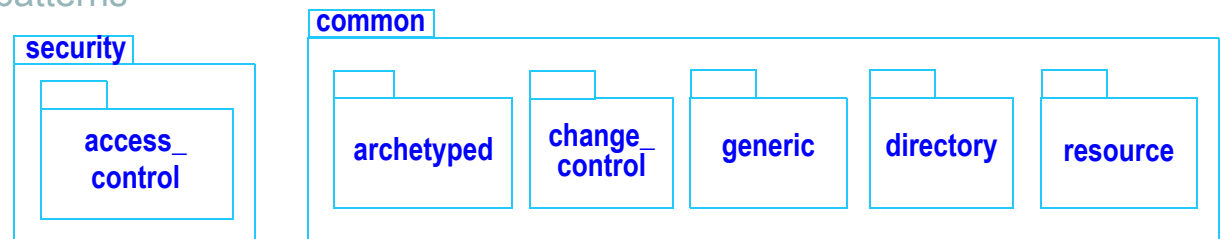
Tree: tree-shaped data, which may be conceptually a list of lists, or other deep structure.

1. with the exception of the EHR and Composition packages, which are both described in the EHR Reference Model document.

domain



patterns



platform

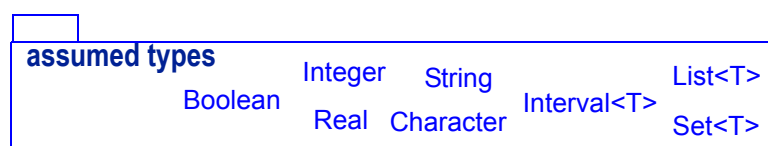
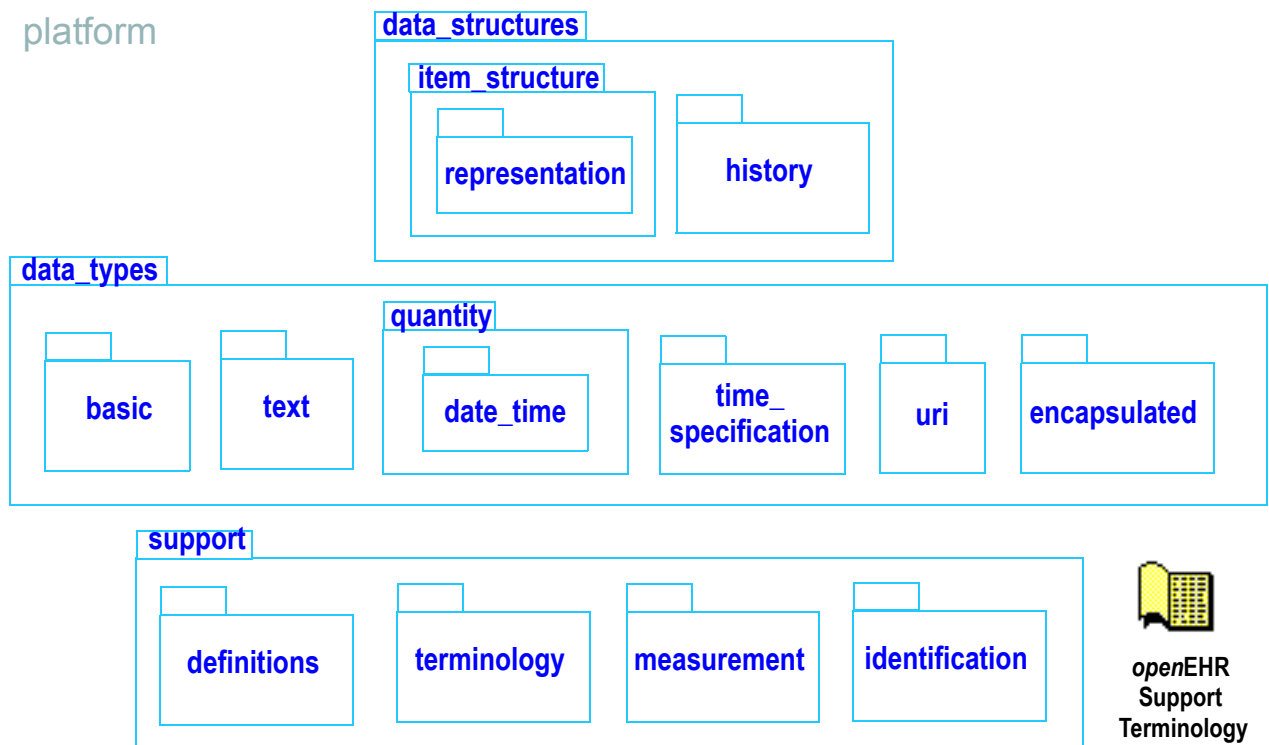


FIGURE 10 Structure of org.openehr.rm package

History: time-series structures, where each time-point can be an entire data structure of any complexity, described by one of the above structure types. Point and interval samples are supported.

Common Information Model

Several concepts recur in higher level packages. The classes `LOCATABLE` and `ARCHETYPED` provide the link between information and archetype models. The classes `ATTESTATION` and `PARTICIPATION` are generic domain concepts that appear in various reference models. The `change_control` package defines a formal model of change management and versioning which applies to any service that needs to be able to supply previous states of its information, in particular the demographic and EHR services. The key semantics of versioning in *openEHR* are described in section 8 on page 45.

Security Information Model

The Security Information Model defines the semantics of access control and privacy setting for information in the EHR.

EHR Information Model

The EHR IM defines the containment and context semantics of the concepts `EHR`, `COMPOSITION`, `SECTION`, and `ENTRY`. These classes are the major coarse-grained components of the EHR, and correspond directly to the classes of the same names in CEN EN13606:2005 and fairly closely to the “levels” of the same names in the HL7 Clinical Document Architecture (CDA) release 2.0.

EHR Extract Information Model

The EHR Extract IM defines how an EHR extract is built from `COMPOSITIONs`, demographic, and access control information from the EHR. A number of Extract variations are supported, including “full *openEHR*”, a simplified form for integration with CEN EN13606, and an *openEHR/openEHR* synchronisation Extract.

Integration Information Model

The Integration model defines the class `GENERIC_ENTRY`, a subtype of `ENTRY` used to represent free-form legacy or external data as a tree. This Entry type has its own archetypes, known as “integration archetypes”, which can be used in concert with clinical archetypes as the basis for a tool-based data integration system. See section 14 on page 77 for more details.

Demographics Information Model

The demographic model defines generic concepts of `PARTY`, `ROLE` and related details such as contact addresses. The archetype model defines the semantics of constraint on `PARTYs`, allowing archetypes for any type of person, organisation, role and role relationship to be described. This approach provides a flexible way of including the arbitrary demographic attributes allowed in the OMG HDTF PIDS standard.

Workflow Information Model (future)

Workflow is the dynamic side of clinical care, and consists of models to describe the semantics of processes, such as recalls, as well as any care process resulting from execution of guidelines.

5.3 Archetype Model (AM)

The *openEHR* `am` package contains the models necessary to describe the semantics of archetypes and templates, and their use within *openEHR*. These include ADL, the Archetype Definition Language (expressed in the form of a syntax specification), the `archetype` and `template` packages, defining the object-oriented semantics of archetypes and templates, and the `openehr_profile` package,

which defines a profile of the generic archetype model defined in the `archetype` package, for use in *openEHR* (and other health computing endeavours). The internal structure of the `am` package is shown in FIGURE 11.

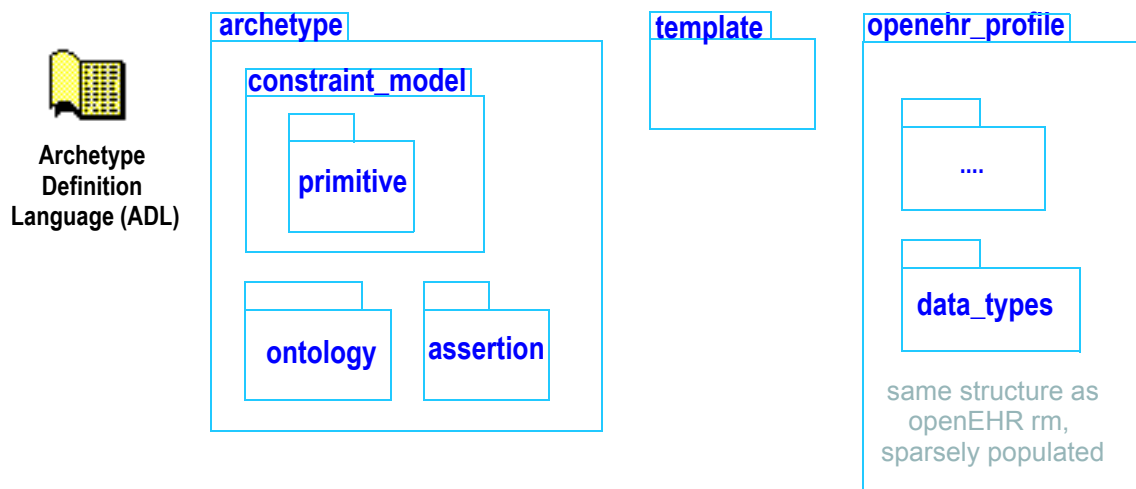


FIGURE 11 Structure of the `org.openehr.am` package

5.4 Service Model (SM)

The *openEHR* service model includes definitions of basic services in the health information environment, centred around the EHR. It is illustrated in FIGURE 12. The set of services actually included will undoubtedly evolve over time, so this diagram should not be seen as definitive.

Virtual EHR API

The virtual EHR API defines the fine-grained interface to EHR data, at the level of Compositions and below. It allows an application to create new EHR information, and to request parts of an existing EHR and modify them. This API enables fine-grained archetype-mediated data manipulation. Changes to the EHR are committed via the EHR service.

EHR Service Model

The EHR service model defines the coarse-grained interface to electronic health record service. The level of granularity is *openEHR* Contributions and Compositions, i.e. a version-control / change-set interface.

Part of the model defines the semantics of server-side querying, i.e. queries which cause large amounts of data to be processed, generally returning small aggregated answers, such as averages, or sets of ids of patients matching a particular criterion.

Archetype Service Model

The archetype service model defines the interface to online repositories of archetypes, and can be used both by GUI applications designed for human browsing as well as access by other software services such as the EHR.

Terminology Interface Model

The terminology interface service provides the means for all other services to access any terminology available in the health information environment, including basic classification vocabularies such as ICDx and ICPC, as well as more advanced ontology-based terminologies. Following the concept of division of responsibilities in a system-of-systems context, the terminology interface abstracts the dif-

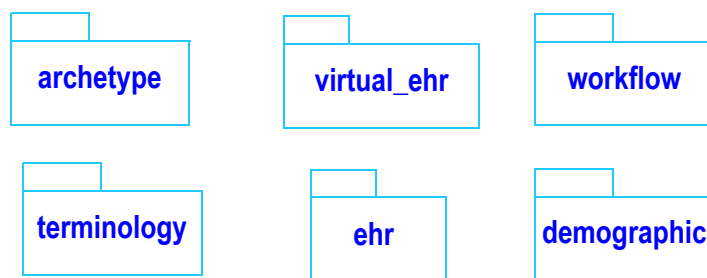


FIGURE 12 Structure of the org.openehr.sm package

ferent underlying architectures of each terminology, allowing other services in the environment to access terms in a standard way. The terminology service is thus the gateway to all ontology- and terminology-based knowledge services in the environment, which along with services for accessing guidelines, drug data and other “reference data” enables inferencing and decision support to be carried out in the environment.

6 Design of the *openEHR* EHR

6.1 The EHR System

In informational terms, a minimal EHR system based on *openEHR* consists of an EHR repository, an archetype repository, terminology (if available), and demographic/identity information, as shown in FIGURE 13.

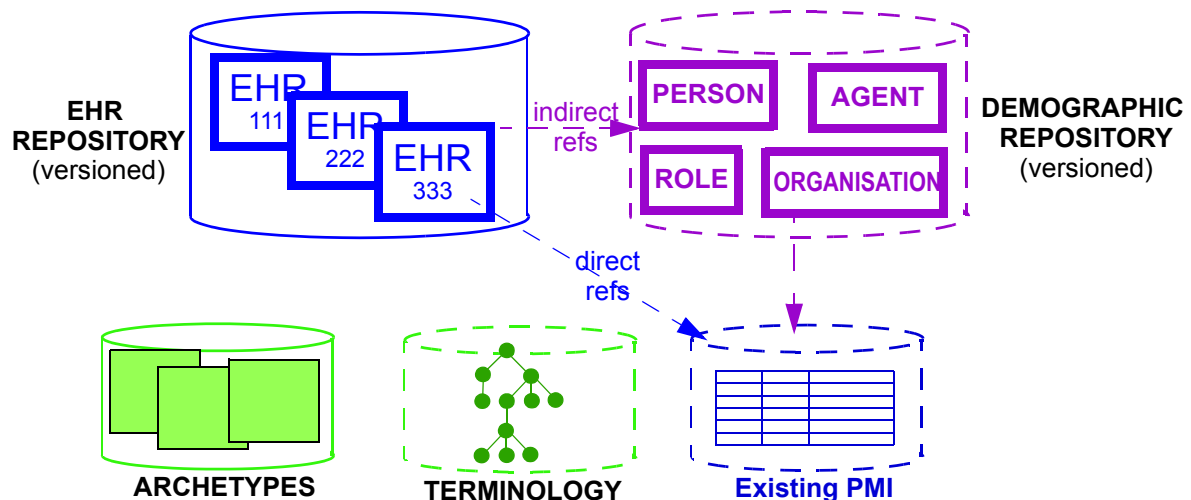


FIGURE 13 Minimal *openEHR* EHR System

The latter may be in the form of an existing PMI (patient master index) or other directory, or it may be in the form of an *openEHR* demographic repository. An *openEHR* demographic repository can act as a front end to an existing PMI or in its own right. Either way it performs two functions: standardisation of demographic information structures and versioning. EHRs contain references to entities in whichever demographic repository is available, and can be configured to include no demographic or identifying data themselves. One of the basic principles of *openEHR* is the complete separation of EHR and demographic information, such that an EHR taken in isolation contains little or no clue as to the identity of the patient it belongs to. The security benefits are described below. In more complete EHR systems, numerous other services (particularly security-related) would normally be deployed, as shown in FIGURE 7.

6.2 Top-level Information Structures

As has been shown, the *openEHR* information models define information at varying levels of granularity. Fine-grained structures defined in the Support and Data types are used in the Data Structures and Common models; these are used in turn in the EHR, EHR Extract, Demographic and other “top-level” models. These latter models define the “top-level structures” of *openEHR*, i.e. content structures that can sensibly stand alone, and may be considered the equivalent of separate documents in a document-oriented system. In *openEHR* information systems, it is generally the top-level structures that are of direct interest to users. The major top-level structures include the following:

Composition - the committal unit of the EHR (see type `COMPOSITION` in EHR IM);

EHR Acces - the EHR-wide access control object (see type `EHR_ACCESS` in EHR IM);

EHR Status - the status summary of the EHR (see type `EHR_STATUS` in EHR IM);

Folder hierarchy - act as directory structures in EHR, Demographic services (see type `FOLDER` in Common IM);

Party - various subtypes including Actor, Role, etc. representing a demographic entity with identity and contact details (see type `PARTY` and subtypes in Demographic IM);

EHR Extract - the transmission unit between EHR systems, containing a serialisation of EHR, demographic and other content (see type `EHR_EXTRACT` in EHR Extract IM).

All persistent *openEHR* EHR, demographic and related content is found within top-level information structures. Most of these are visible in the following figures.

6.3 The EHR

The *openEHR* EHR is structured according to a relatively simple model. A central EHR object identified by an EHR id specifies references to a number of types of structured, versioned information, plus a list of Contribution objects that act as audits for changes made to the EHR. The high-level structure of the *openEHR* EHR is shown in FIGURE 14.

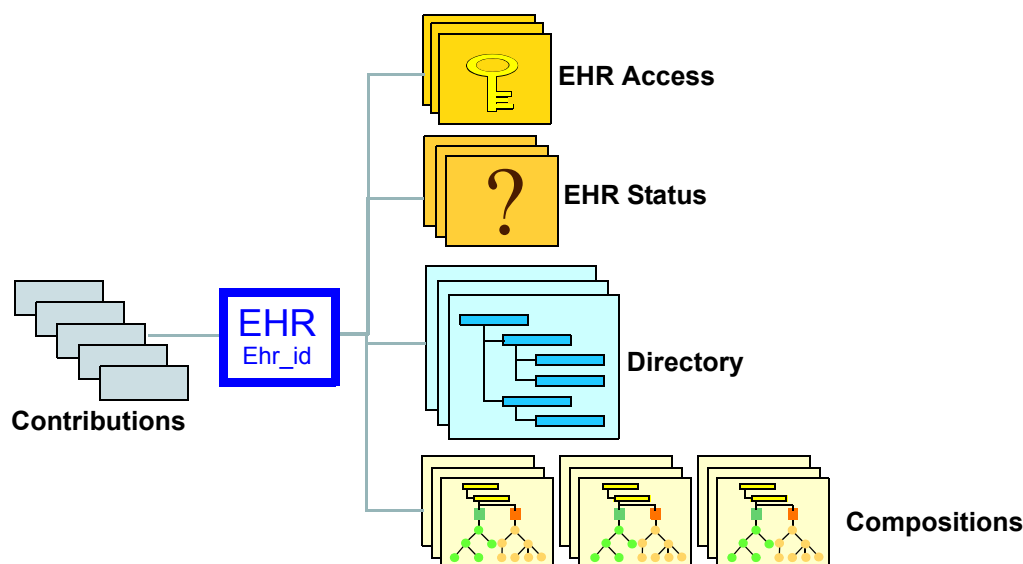


FIGURE 14 High-level Structure of the *openEHR* EHR

In this figure, the parts of the EHR are as follows:

- *EHR*: the root object, identified by a globally unique EHR identifier;
- *EHR_access* (versioned): an object containing access control settings for the record;
- *EHR_status* (versioned): an object containing various status and control information, optionally including the identifier of the subject (i.e. patient) currently associated with the record;
- *Directory* (versioned): an optional hierarchical structure of Folders that can be used to logically organise Compositions;
- *Compositions* (versioned): the containers of all clinical and administrative content of the record;

- **Contributions:** the change-set records for every change made to the health record; each Contribution references a set of one or more Versions of any of the versioned items in the record that were committed together by a user to an EHR system.

The internal structure of the Composition along with the Directory object correspond closely to the levels in internationally agreed models of health information such as the CEN EN13606 and HL7 CDA standards.

The logical structure of a typical Composition is shown in more detail in FIGURE 15. In this figure, the various hierarchical levels from Composition to the data types are shown in a typical arrangement. The 21 data types provide for all types of data needed for clinical and administrative recording.

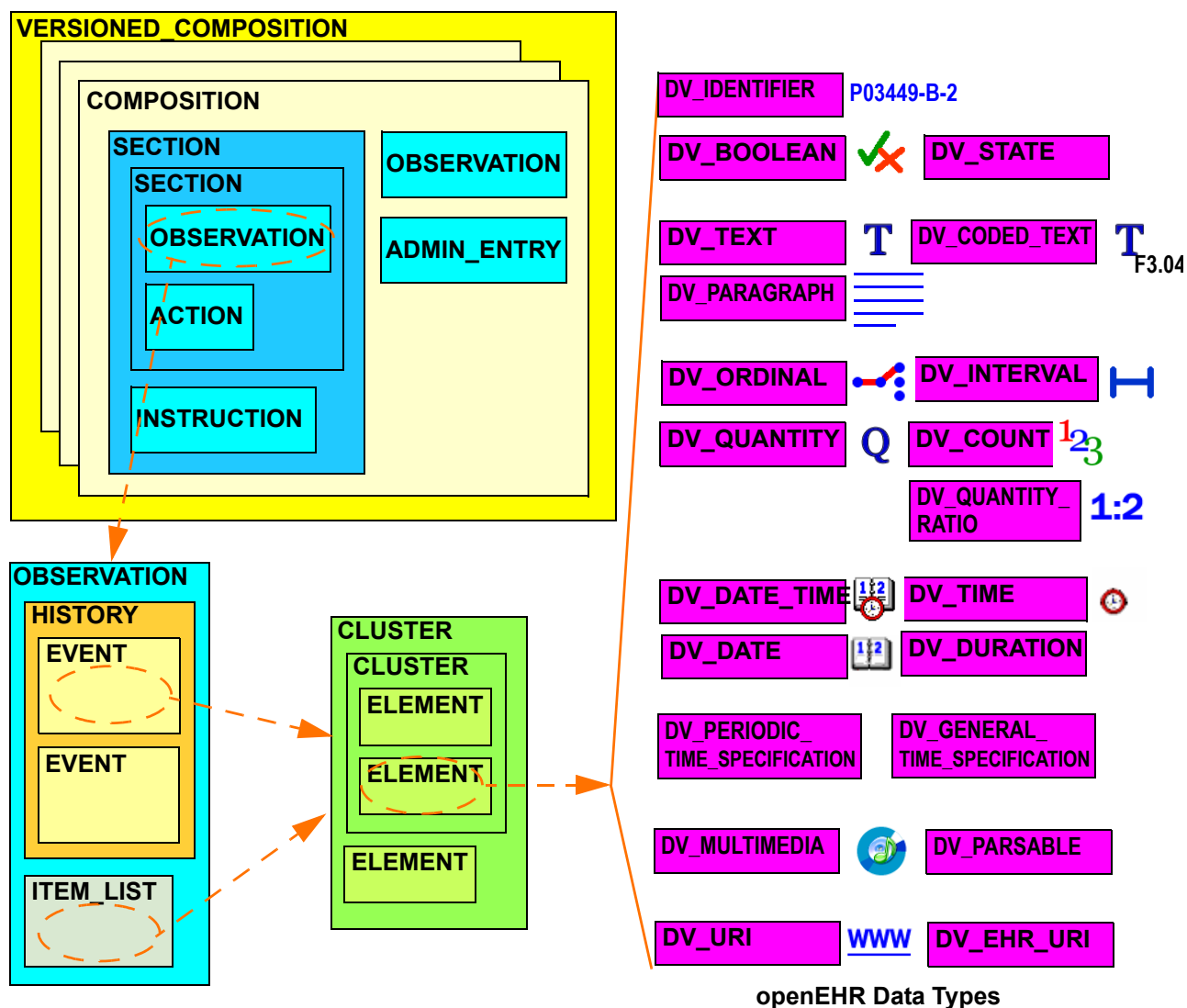


FIGURE 15 Elements of an openEHR Composition

6.4 Entries and “clinical statements”

Entry Subtypes

All clinical information created in the openEHR EHR is ultimately expressed in “Entries”. An Entry is logically a single ‘clinical statement’, and may be a single short narrative phrase, but may also contain a significant amount of data, e.g. an entire microbiology result, a psychiatric examination note, a

complex medication order. In terms of actual content, the Entry classes are the most important in the *openEHR* EHR Information Model, since they define the semantics of all the ‘hard’ information in the record. They are intended to be archetyped, and in fact, archetypes for Entries and sub-parts of Entries make up the vast majority of archetypes defined for the EHR.

The *openEHR* ENTRY classes are shown in FIGURE 16. There are five concrete subtypes: ADMIN_ENTRY, OBSERVATION, EVALUATION, INSTRUCTION and ACTION, of which the latter four are kinds of CARE_ENTRY.

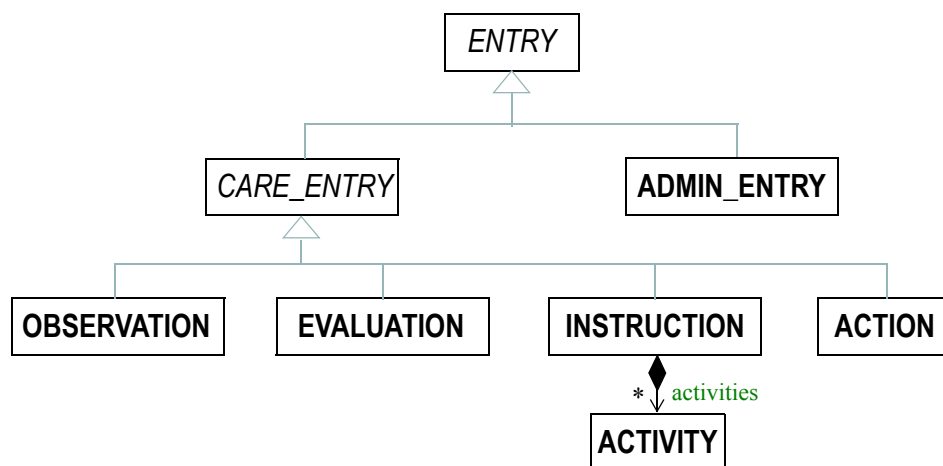


FIGURE 16 The *openEHR* Entry model (in EHR IM)

The choice of these types is based on the clinical problem-solving process shown in FIGURE 17.

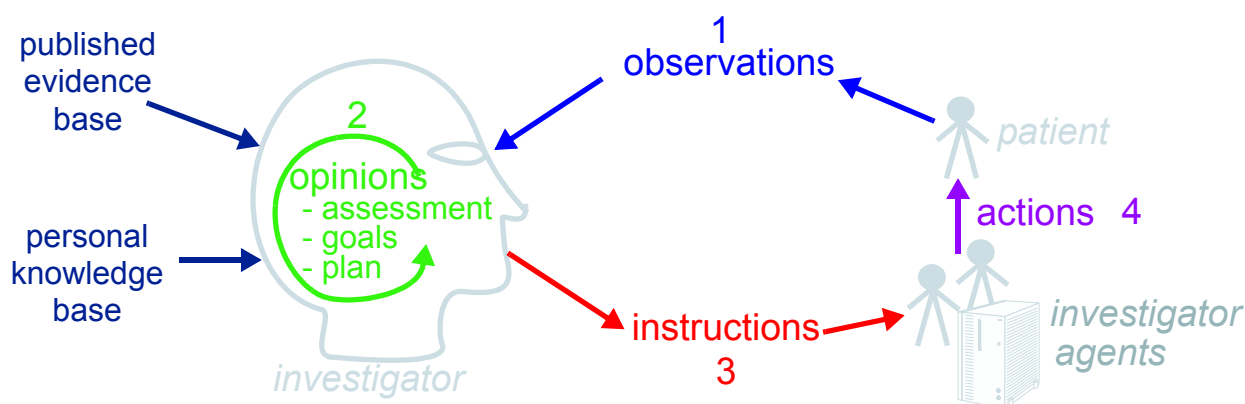


FIGURE 17 Relationship of information types to the investigation process

This figure shows the cycle of information creation due to an iterative, problem solving process typical not just of clinical medicine but of science in general. The “system” as a whole is made up of two parts: the “patient system” and the “clinical investigator system”. The latter consists of health carers, and may include the patient (at points in time when the patient performs observational or therapeutic activities), and is responsible for understanding the state of the patient system and delivering care to it. A problem is solved by making observations, forming opinions (hypotheses), and prescribing actions (instructions) for next steps, which may be further investigation, or may be interventions designed to resolve the problem, and finally, executing the instructions (actions).

This process model is a synthesis of Lawrence Weed’s “problem-oriented” method of EHR recording, and later related efforts, including the model of Rector, Nowlan & Kay¹, and the “hypothetico-deduc-

tive” model of reasoning¹. However hypothesis-making and testing is not the only successful process used by clinical professionals - evidence shows that many (particularly those older and more experienced) rely on pattern recognition and direct retrieval of plans used previously with similar patients or prototype models. The investigator process model used in *openEHR* is compatible with both cognitive approaches, since it does not say how opinions are formed, nor imply any specific number or size of iterations to bring the process to a conclusion, nor even require all steps to be present while iterating (e.g. GPs often prescribe without making a firm diagnosis). Consequently, the *openEHR* Entry model does not impose a process model, it only provides the possible types of information that might occur.

Ontology of Entry Types

In the clinical world practitioners do not think in terms of only five kinds of data corresponding to the subtypes of Entry described above. There are many subtypes of each of these types, of which some are shown in the ontology of FIGURE 18.

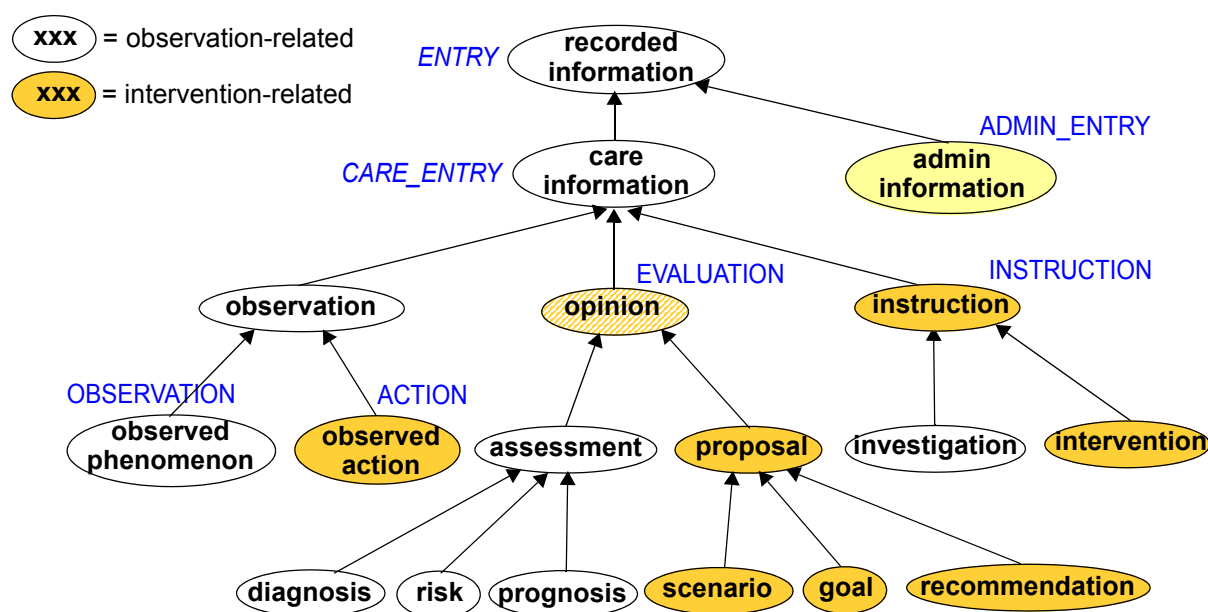


FIGURE 18 Ontology of Recorded Information

The key top-level categories are ‘care information’ and ‘administrative information’. The former encompasses all statements that might be recorded at any point during the care process, and consists of the major sub-categories on which the Entry model is based, namely ‘observation’, ‘opinion’, ‘instruction’, and ‘action’ (a kind of observation) which themselves correspond to the past, present and future in time. The administrative information category covers information which is not generated by the care process proper, but relates to organising it, such as appointments and admissions. This information is not about care, but about the logistics of care delivery.

Regardless of the diversity, each of the leaf-level categories shown in this figure is ultimately a sub-category of one of the types from the process model, and hence, of the subtypes of the *openEHR* Entry model.

1. Rector AL, Nowlan WA, Kay S. *Foundations for an Electronic Medical Record*. Methods of Information in Medicine 30: 179-86, 1991

1. See e.g. Elstein AS, Shulman LS, Sprafka SA. *Medical problem solving: an analysis of clinical reasoning*. Cambridge, MA: Harvard University Press, 1978.

Correct representation of the categories from the ontology is enabled by using archetypes designed to express the information of interest (say a risk assessment) in terms of a particular Entry subtype (in this case, Evaluation). In a system where Entries are thus modelled, there will be no danger of incorrectly identifying the various kinds of Entries, as long as the Entry subtype, time, and certainty/negation are taken into account. Note that even if the ontology of FIGURE 18 is not correct (undoubtedly it isn't), archetypes will be constructed to account for each improved idea of what such categories should really be.

Clinical Statement Status and Negation

A well-known problem in clinical information recording is the assignment of “status” to recorded items. Kinds of status include variants like “actual value of P” (P stands for some phenomenon), “family history of P”, “risk of P”, “fear of P”, as well as negation of any of these, i.e. “not/no P”, “no history of P” etc. A proper analysis of these so called statuses shows that they are not “statuses” at all, but different categories of information as per the ontology of FIGURE 18. In general, negations are handled by using “exclusion” archetypes for the appropriate Entry type. For example, “no allergies” can be modelled using an Evaluation archetype that describes which allergies are excluded for this patient. Another set of statement types that can be confused in systems that do not properly model information categories concern interventions, e.g. “hip replacement (5 years ago)”, “hip replacement (recommended)”, “hip replacement (ordered for next tuesday 10 am)”.

All of these statement types map directly to one of the *openEHR* Entry types in an unambiguous fashion, ensuring that querying of the EHR does not match incorrect data, such as a statement about fear or risk, when the query was for an observation of the phenomenon in question.

Further details on the *openEHR* model clinical information are given in the EHR IM document, Entry Section.

6.5 Managing Interventions

A key part of the investigation process shown in FIGURE 17, and indeed healthcare in general, is intervention. Specifying and managing interventions (whether the simplest prescriptions or complex surgery and therapy) is a hard problem for information systems because it is in “future time” (meaning that intervention activities have to be expressed using branching/looping time specifications, not the simple linear time of observations), unexpected events can change things (e.g. patient reaction to drugs), and the status of a given intervention can be hard to track, particularly in distributed systems. However, from the health professional's point of view, almost nothing is more basic than wanting to find out: what medications is this patient on, since when, and what is the progress?

The *openEHR* approach to these challenges is to use the Entry type `INSTRUCTION`, its subpart `ACTIVITY` to specify interventions in the future, and the Entry subtype `ACTION` to record what has actually happened. A number of important features are provided in this model, including:

- a single, flexible way of modelling all interventions, whether they be single drug medication orders or complex hospital-based therapies;
- a way of knowing the state of any intervention, in terms of the states in a standard state machine, shown in FIGURE 19; this allows a patient's EHR to be queried in a standard way so as to return “all active medications”, “all suspended interventions” etc.;
- a way of mapping particular care process flow steps to the standard state machine states, enabling health professionals to define and view interventions in terms they understand;
- support for automated workflow, without requiring it.

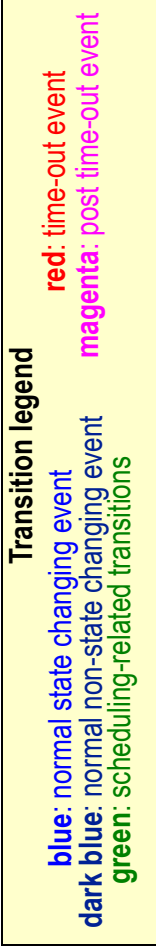
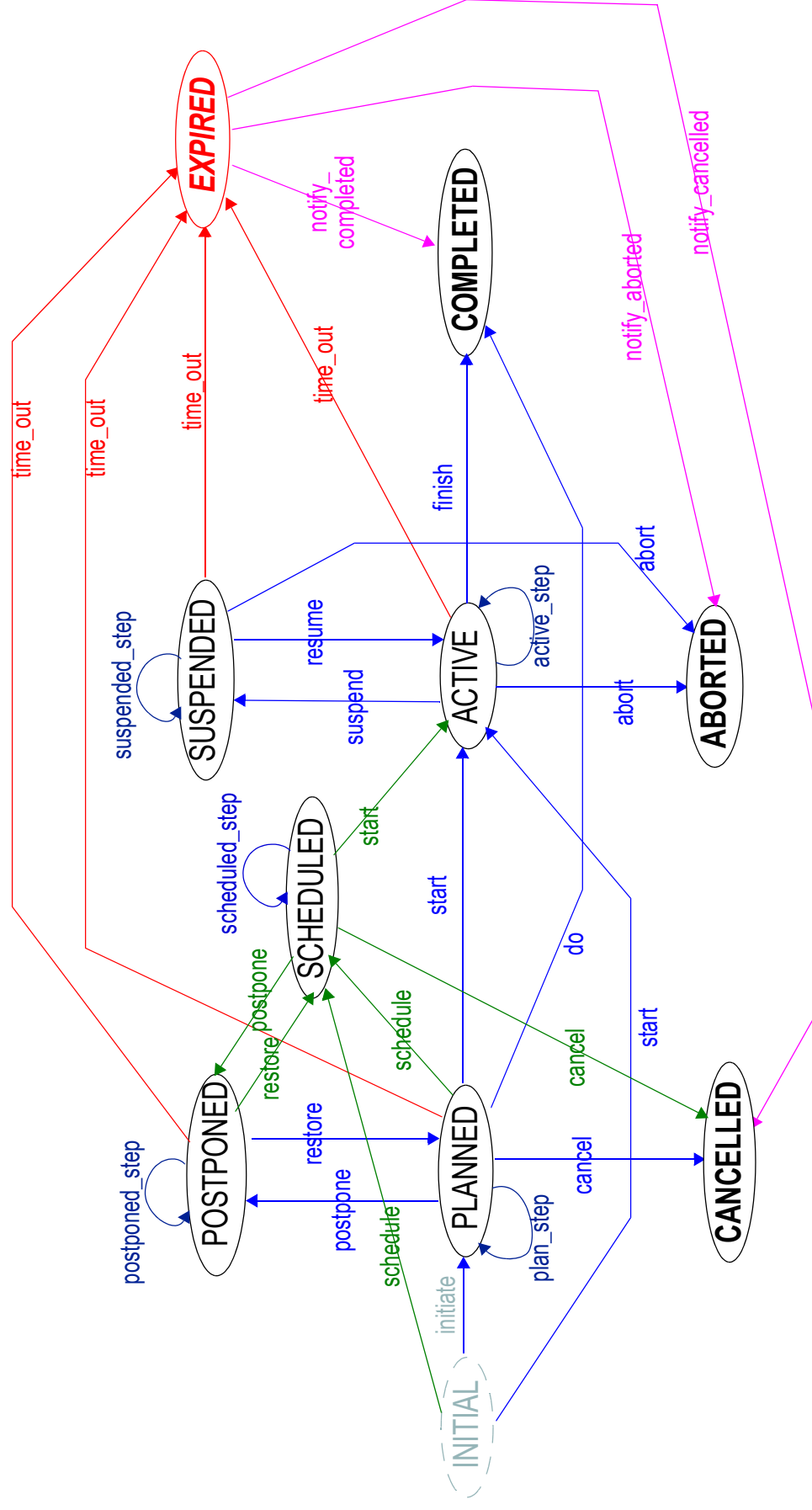


FIGURE 19 openEHR standard Instruction State Machine

Coupled with the comprehensive versioning capabilities of *openEHR*, the Instruction/Action design allows clinical users of the record to define and manage interventions for the patient in a distributed environment.

6.6 Time in the EHR

Time is well-known as a challenging modelling problem in health information. In *openEHR*, times that are a by-product of the investigation process (e.g. time of sampling or collection; time of measurement, time of a healthcare business event, time of data committal) described above are concretely modelled, while other times specific to particular content (e.g. date of onset, date of resolution) are modelled using archotyping of generic data attributes. The following figure shows a typical relationship of times with respect to the observation process, and the corresponding attributes within the *openEHR* reference model. Note that under different scenarios, such as GP consultation, radiology reporting and others, the temporal relationships may be quite different than those shown in the figure. Time is described in detail in the EHR Information Model document.

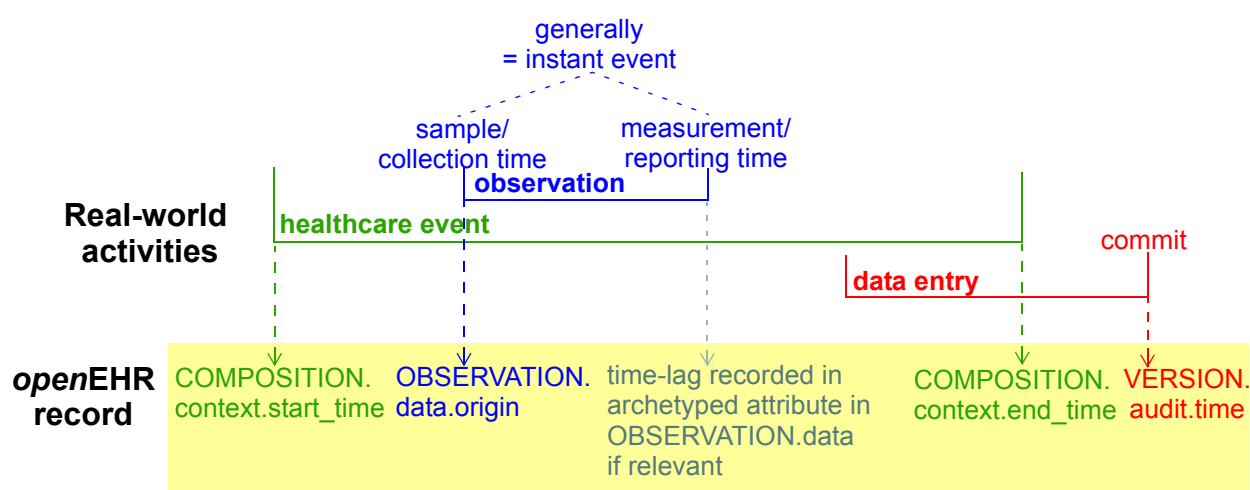


FIGURE 20 Time in the EHR

6.7 Language

In some situations, there may be more than one language used in the EHR. This may be due to patients being treated across borders (common among the Scandinavian countries, between Brazil and northern neighbours), or due to patients being treated while travelling, or due to multiple languages simply being used in the home environment.

Language is handled as follows in the *openEHR* EHR. The default language for the whole EHR is determined from the operating system locale. It may be included in the EHR_status object if desired.

Language is then mandatorily indicated in two places in the EHR data, namely in Compositions and Entries (i.e. Observations, etc), in a *language* attribute. This allows both Compositions of different languages in the EHR, and Entries of different languages in the same Composition. Additionally, within Entries, text and coded text items may optionally have language recorded if it is different from the language of the enclosing Entry, or where these types are used within other non-Entry structures that don't indicate language.

The use of these features is mostly likely to occur due to translation, although in some cases a truly multi-lingual environment might exist within the clinical encounter context. In the former case, some

parts of an EHR, e.g. particular Compositions will be translated before or after a clinical encounter to as to make the information available in the primary language of the EHR. The act of translation (like any other interaction with the EHR) will cause changes to the record, in the form of new Versions. New translations can conveniently be recorded as branch versions, attached to the version of which they are a translation. This is not mandatory, but provides a convenient way to store translations so that they don't appear to replace the original content.

7 Security and Confidentiality

7.1 Requirements

Privacy, Confidentiality and Consent

Privacy (the right to limit who sees the personal data) and confidentiality (the obligation of others to respect the privacy of disclosed data) are primary concerns of many consumers with respect to e-Health systems. A widely accepted principle is that information provided (either directly or due to observation or testing of specimens etc.) in confidence by a patient to health professionals during an episode of care should only be passed on or otherwise become available to other parties if the patient agrees; put more simply: *data sharing must be controlled by patient consent*. A more complex sub-requirement for some patients is allowing differential access to *parts* of their health record, for example, relatively open access rights to most of the health record, but limited access to sexual or mental health items. The interrelatedness of health information can make this difficult. For example the medication list will often give away sensitive conditions even if the diagnosis is hidden, yet is needed for any safe treatment, and many health professionals would see the unavailability of current medications (and allergies) information as highly problematic for giving even basic care.

Requirements of Healthcare Providers

On the other hand, clinical professionals delivering care want fast access to relevant data, and to be sure that what they see on the screen is a faithful representation of what has been said about the patient. Emergency access to health records is sometimes needed by carers otherwise unrelated to the normal care of a patient; such accesses can only be consented to in a general way, since the specific providers involved will not usually be known.

Researchers in healthcare generally want access to the data of large numbers of patients in order to evaluate current care and improve it, or for educational purposes. Both of these latter needs ultimately are patient and societal priorities also. Providing effective care and supporting ongoing medical research therefore have to function in a system that implements the concept of patient consent.

Specifying Access Control

In theory, it should be easy for the patient or some clinical professional to specify who can see the patient record. In some cases it is can be done by direct identification, e.g. the patient might nominate their long-term GP by provider id. Some exclusions could potentially be made this way as well, for example a previous doctor with whom the patient has a problematic personal relationship.

However it soon becomes difficult to identify provider parties individually when the patient moves into parts of the healthcare system where there are many staff, and/or where there is no previously established relationship. The advent of e-prescribing and e-pharmacy will bring even larger numbers of health and allied health workers into the e-Health matrix, making the problem of individual identification of who should see the patient's data infeasible. Further, there is a large and growing category of "very mobile" people (the military, entertainers, NGO workers, international business and tourism professionals, athletes....) who cannot predict even in which country they may require care. As a consequence, the need for some access control to be specified in terms of categories or role types appears inescapable.

The Problem of Roles

One of the difficult challenges to implementing access control to health information is that of defining "roles", i.e. the status of users of the record at the time when right of access is being determined. In principle, roles ought to be knowable in advance. For example, the labels "nurse", "GP" and "psychi-

atrist” can be relatively easily assigned to individuals. However, the kinds of labels that are of more importance are those that differentiate among (for example) personal carers (e.g. primary GP), other care delivery staff (e.g. nurses, aged carers) and support staff (e.g. pathologists, radiographers). In a patient care delivery-oriented view of the world, the professional level of a health care professional is probably less important than his or her relationship to the current care process for the patient.

It will not always be clear which individuals fall into any of these categories at any time, or how such terms are even defined in different sites and jurisdictions. Realistically, the evaluation of a role category such as “care deliverer” into particular identities such as those of nurses on the ward on a particular day must be done in each care delivery environment, not in the EHR. Access decisions for information in the EHR therefore will have some dependence on provider site knowledge of which staff are actively involved in the care process of a given patient.

Role-based access control is further complicated by the common fact of temporary replacements due to illness or holiday and role changes due to staff shortages. Further, if a physician employing a medical secretary requires her to access and update sensitive parts (relating to his own treatment of the patient) of the record, access at the highest level is effectively given to someone not medically trained or related directly to the patient’s care, even if only for 10 minutes. Any role-based system therefore has to take into account the messy reality of clinical care in the real world rather than being based solely on theoretical principles.

Usability

Usability of security and privacy mechanisms is a key requirement of a health record architecture. Some very elegant solutions to fine-grained access control designed by security experts would be simply unusable in practice because they would take too long for patients and doctors to learn, or are too time-consuming to actually use on the screen; they could also be too complex to safely implement in software.

The following sections describe support in *openEHR* for the main security and privacy requirements of EHRs.

7.2 Threats to Security and Privacy

Any model of how security and privacy are supported in the health record must be based on some notion of assumed threats. Without going into great detail, security threats assumed by *openEHR* include the following (here “inappropriate” means anything that is not or would not be consented to by the patient):

- human error in patient identification, leading to incorrect association of health data of one patient with another. Mis-identification of patients can cause personal data for one patient to go into the record of another patient (leading to privacy violations and possibly clinical errors), or into a new record rather than the existing one for the same patient (leading to two or more clinically incomplete records);
- inappropriate access by health professionals or others in the physical care delivery environment (including e.g. any worker in a hospital) not involved in the current care of the patient;
- inappropriate access by other persons known to the patient, e.g. a by family member;
- inappropriate access of health data by corporate or other organisations e.g. for purposes of insurance discrimination;
- malicious theft of or access to health data (e.g. of a celebrity or politician) for profit or other personal motives;

- generic threats to data integrity and availability, such as viruses, worms, denial of service attacks etc.;
- failures in software (due to bugs, incorrect configuration, interoperability failures etc.) causing corruption to data, or incorrect display or computation, resulting in clinical errors.

A key principle with respect to the design of mechanisms supporting security, confidentiality and integrity has to be kept in mind: the likelihood of any given mode of targeted inappropriate access is proportional to the perceived value of the information and inversely proportional to the cost of access. To paraphrase Ross Anderson's BMA paper¹ on health data security, for a given access, the perpetrator will try to find the simplest, cheapest and quickest method, which is more likely to be bribery or burglary than James Bond-inspired technology. *openEHR* makes use of this principle by providing some relatively simple mechanisms that are cheap to implement but can make misuse quite difficult, without compromising availability.

7.3 Solutions Provided by *openEHR*

7.3.1 Overview

Many of the concrete mechanisms relating to security and privacy are found in system deployments rather than in models such as *openEHR*, particularly the implementation of authentication, access control, and encryption. The *openEHR* specifications and core component implementations do not explicitly define many concrete mechanisms since there is great variability in the requirements of different sites - secure LAN deployments many require minimal security inside, whereas web-accessible health record servers are likely to have quite different requirements. What *openEHR* does is to support some of the key requirements in a flexible enough way that deployments with substantially different requirements and configurations can nevertheless implement the basic principles in a standard way.

FIGURE 21 illustrates the main security measures directly specified by the *openEHR* architecture. These include EHR/demographic separation and an EHR-wide access control object. At the level of versioned objects, commit audits (mandatory), digital signatures and hashes are available. The following subsections describe these features in more detail.

7.3.2 Security Policy

In and of itself, the *openEHR* EHR imposes only a minimal security policy profile which could be regarded as necessary, but generally not sufficient for a deployed system (i.e. other aspects would still need to be implemented in layers whose semantics are not defined in *openEHR*). The following policy principles are embodied in *openEHR*.

General

Indelibility: health record information cannot be deleted; logical deletion is achieved by marking the data in such a way as to make it appear deleted (implemented in version control).

Audit trailing: All changes made to the EHR including content objects as well as the EHR status and access control objects are audit-trailed with user identity, time-stamp, reason, optionally digital signature and relevant version information; one exception is where the modifier is the

1. see e.g. Ross Anderson - "Security in Clinical Information Systems" available at <http://www.cl.cam.ac.uk/users/rja14/policy11/policy11.html>.

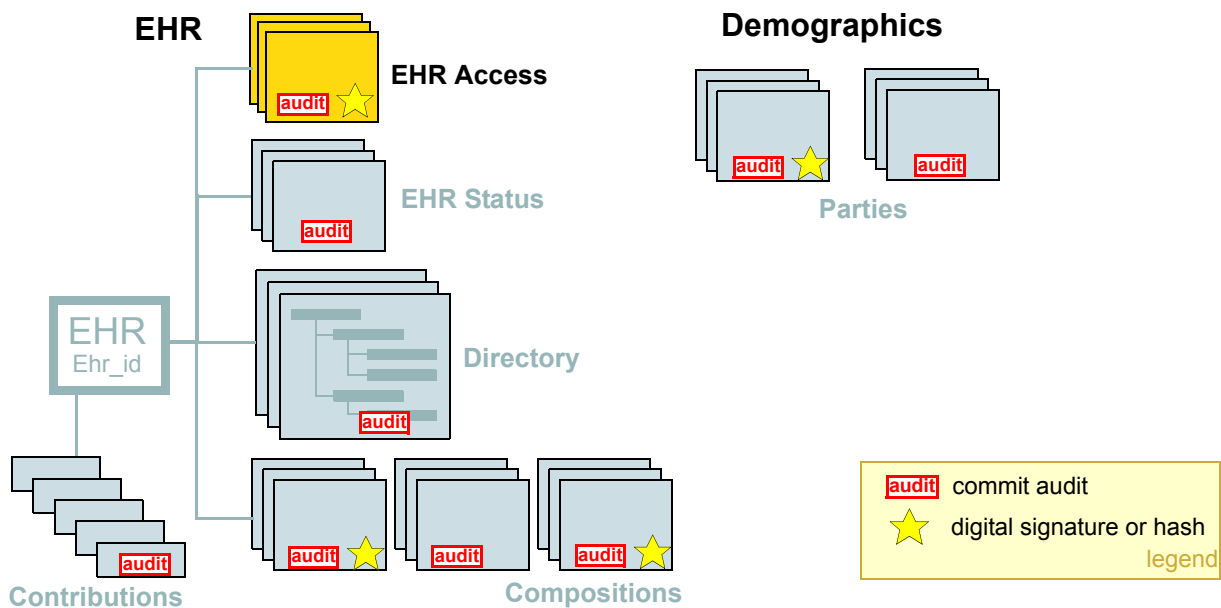


FIGURE 21 Security Features of the *openEHR* EHR

patient, in which case, a symbolic identifier can be used (known as `PARTY_SELF` in *openEHR*; see next point).

Anonymity: the content of the health record is separate from identifying demographic information. This can be configured such that theft of the EHR provides no direct clue to the identity of the owning patient (indirect clues are of course harder to control). Stealing an identified EHR involves theft of data from two servers, or even theft of two physical computers, depending on deployment configuration.

Access Control

Access list: the overriding principle of access control must be “relevance” both in terms of user identity (who is delivering care to the patient) and time (during the current episode of care, and for some reasonable, limited time afterward). An access control list can be defined for the EHR, indicating both identified individuals and categories, the latter of which might be role types, or particular staff groups.

Access control of access settings: a *gate-keeper* controls access to the EHR access control settings. The gate-keeper is established at the time of EHR creation as being one of the identities known in the EHR, usually the patient for mentally competent adults, otherwise a parent, legal guardian, advocate or other responsible person. The gate-keeper determines who can make changes to the access control list. All changes to the list are audit-trailed as for normal data (achieved due to normal versioning).

Privacy: patients can mark Compositions in the EHR as having one of a number of levels of privacy. The definition of the privacy levels is not hard-wired in the *openEHR* models but rather is defined by standards or agreements within jurisdictions of use.

Usability: The general mentality of access control setting is one of “sensible defaults” that work for most of the information in the EHR, most of the time. The defaults for the EHR can be set by the patient, defining access control behaviour for the majority of access decisions. Exceptions to the default policy are then added. This approach minimises the need to think about the security of every item in the EHR individually.

Other security policy principles that should be implemented in even a minimal EHR deployment but are not directly specified by *openEHR* include the following.

Access logging: read accesses by application users to EHR data should be logged in the EHR system. Currently *openEHR* does not specify models of such logs, but might do so in the future. Studies have shown that making users aware of the fact of access logging is an effective deterrent to inappropriate access (especially where other controls are not implemented). There are some proponents of the argument that even read-access logs should be made part of the content of the EHR proper; currently *openEHR* does not support this approach.

Record demerging: when data for a patient is found to be in another patient's EHR, the access logs for that EHR should be used to determine who has accessed that data, primarily to determine if subsequent clinical thinking (e.g. diagnoses, medication decisions) have been made based on wrong information.

Record merging: when more than one EHR is discovered for the same patient, and have to be merged into a single record, the access control lists have to be re-evaluated and merged by the patient and potentially relevant carers.

Time-limitation of access: mechanisms should be implemented that limit the time during which given health professionals can see the patient record. Usually, the outer limits are defined by the interval of the episode of care in an institution plus some further time to cover follow-up or outpatient care. Episode start and end are recorded in *openEHR* as instances of the `ADMIN_ENTRY` class, containing admission and discharge details.

Non-repudiation: if digital signing of changes to the record is made mandatory, non-repudiation of content can be supported by an *openEHR* system. The digital signing of communications (EHR Extracts) is also supported in *openEHR*; coupled with logging of communication of Extracts, this can be used to guarantee non-repudiation of information passed between systems (cf. information passed between back-end and front-end applications of the same system).

Certification: a mechanism should be provided to allow a level of trust to be formally associated with user signing keys.

A key feature of the policy is that it must scale to distributed environments in which health record information is maintained at multiple provider sites visited by the patient.

As Anderson points out in the BMA study, policy elements are also needed for guarding against users gaining access to massive numbers of EHRs, and inferencing attacks. Currently these are outside the scope of *openEHR*, and realistically, of most EHR implementations of any kind today.

The following sections describe how *openEHR* supports the first list of policy objectives.

7.3.3 Integrity

Versioning

The most basic security-related feature of *openEHR* is its support for data integrity. This is mainly provided by the versioning model, specified in the `change_control` package in the Common Information Model, and in the Extract Information Model. Change-set based versioning of all information in the EHR and demographic services constitutes a basic integrity measure for information, since no content is ever physically modified, only new versions are created. All logical changes and deletions as well as additions are therefore physically implemented as new Versions rather than changes to existing information items. Clearly the integrity of the information will depend on the quality of the

implementation; however, the simplest possible implementations (1 Version = 1 copy) can provide very good safety due to being write-once systems.

The use of change-sets, known as Contributions in *openEHR*, provides a further unit of integrity corresponding to all items modified, created or deleted in a single unit of work by a user.

The *openEHR* versioning model defines audit records for all changed items, which can be basic audits and/or any number of additional digitally signed attestations (e.g. by senior staff). This means that every write access of any kind to any part of an *openEHR* record is logged with the user identification, time, reason, and potentially other meta-data. Versioning is described in detail in section 8 on page 45.

Digital Signature

The possibility exists within an *openEHR* EHR to digitally sign each Version in a Versioned object (i.e. for each Version of any logical item, such as medications list, encounter note etc.). The signature is created as a private-key encryption (e.g. RSA-1) of a hash (e.g. MD5) of a canonical representation (such as in schema-based XML) of the Version being committed. A likely candidate for defining the signature and digest strings in *openEHR* is the openPGP message format (IETF RFC2440¹), due to being an open specification and self-describing. The use of RFC2440 for the format does not imply the use of the PGP distributed certificate infrastructure, or indeed any certification infrastructure; *openEHR* is agnostic on this point. If no public key or equivalent infrastructure is available, the encryption step might be omitted, resulting in a digest only of the content. The signature is stored within the Version object, allowing it to be conveniently carried within EHR Extracts. The process is shown in FIGURE 22.

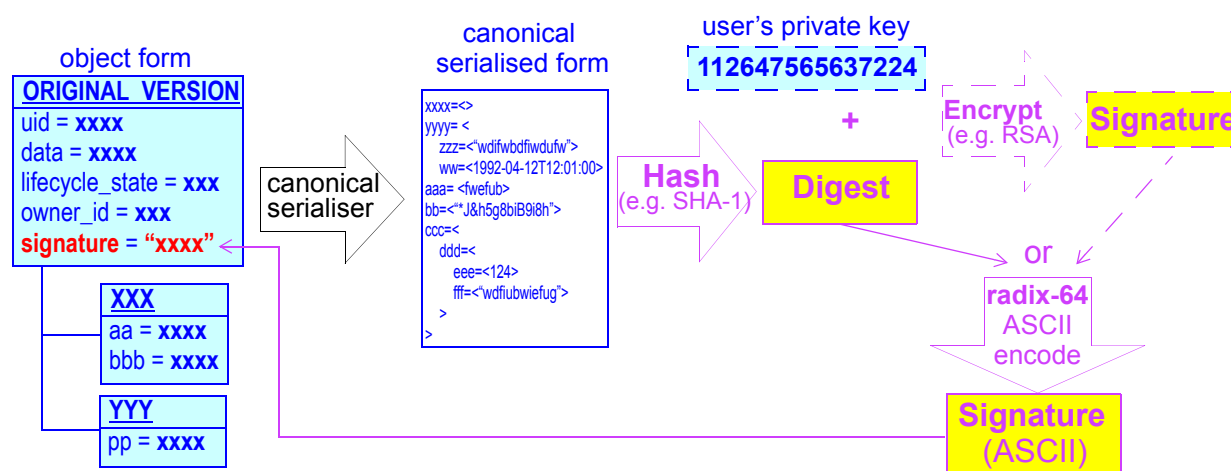


FIGURE 22 Version Signature

The signing of data in a versioning system acts as an integrity check (the digest performs this function), an authentication measure (the signature performs this function), and also a non-repudiation measure. To guard against hacking of the versioned persistence layer itself, signatures can be forwarded to a trusted notarisation service. A fully secure system based on digital signing also requires certificated public keys, which may or may not be available in any given environment.

One of the benefits of digitally signing relatively small pieces of the EHR (single Versions) rather than the whole EHR or large sections of it is that the integrity of items is more immune to localised repository corruptions.

1. IETF RFC 2440 - <http://www.ietf.org/internet-drafts/draft-ietf-openpgp-rfc2440bis-18.txt>

7.3.4 Anonymity

As described above in section 6.1, one of the features of the *openEHR* EHR is a separation of EHR (clinical and administrative) information and demographic information. This mainly relates to references to the patient rather than to provider entities, since the latter are usually publicly known. A special kind of object known as `PARTY_SELF` in *openEHR* is used to refer to the subject in the EHR. The only information contained in a `PARTY_SELF` instance is an optional external reference. The *openEHR* EHR can be configured to provide 3 levels of separation by controlling whether and where this external identifier is actually set in `PARTY_SELF` instances, as follows:

- Nowhere in the EHR (i.e. every `PARTY_SELF` instance is a blank placeholder). This is the most secure approach, and means that the link between the EHR and the patient has to be done outside the EHR, by associating `EHR.ehr_id` and the subject identifier. This approach is more likely for more open environments.
- Once only in the EHR Status object (subject attribute), and nowhere else. This is also relatively secure, if the EHR Status object is protected in some way.
- In every instance of `PARTY_SELF`; this solution is reasonable in a secure environment, and convenient for copying parts of the record around locally.

This simple mechanism provides a basic protection against certain kinds of information theft or hacking if used properly. In the most secure situation, a hacker has to steal not just EHR data but also separate demographic records and an identity cross reference database, both of which can be located on different machines (making burglary harder). The identity cross-reference database would be easy to encrypt or protect by other security mechanisms.

7.4 Access Control

Overview

Access control is completely specified in an *openEHR* EHR in the `EHR_ACCESS` object for the EHR. This object acts as a gateway for all information access, and any access decision must be made based on the policies and rules it contains.

One of the problems with defining the semantics of the EHR Access object is that there is currently no published formal, proven model of access control for shared health information. Various efforts underway include the CEN EN13606 part 4 work, the ISO PMAC (Privilege Management and Access Control) work being done in TC/215 based on the generic security standard ISO/IEC 17799. Undoubtedly experimental and even some limited production health information security implementations exist. In reality however, no large-scale shared EHR deployments exist, and so security solutions to date are still developmental.

The *openEHR* architecture is therefore designed to accommodate alternative models of access control, each defined by a subtype of the class `ACCESS_CONTROL_SETTING` (Security IM). This approach means that a simplistic access control model can be defined and implemented initially, with more sophisticated models being used later. The “scheme” in use at any given time is always indicated in the EHR Access object.

8 Versioning

8.1 Overview

Version control is an integral part of the *openEHR* architecture. An *openEHR* repository for EHR or demographic information is managed as a change-controlled collection of “version containers” (modelled by the `VERSIONED_OBJECT<T>` class in the `common.change_control` package), each containing the versions of a top-level content structure (such as a Composition or Party) as it changes over time. A version-controlled top-level content structure is visualised in FIGURE 23.

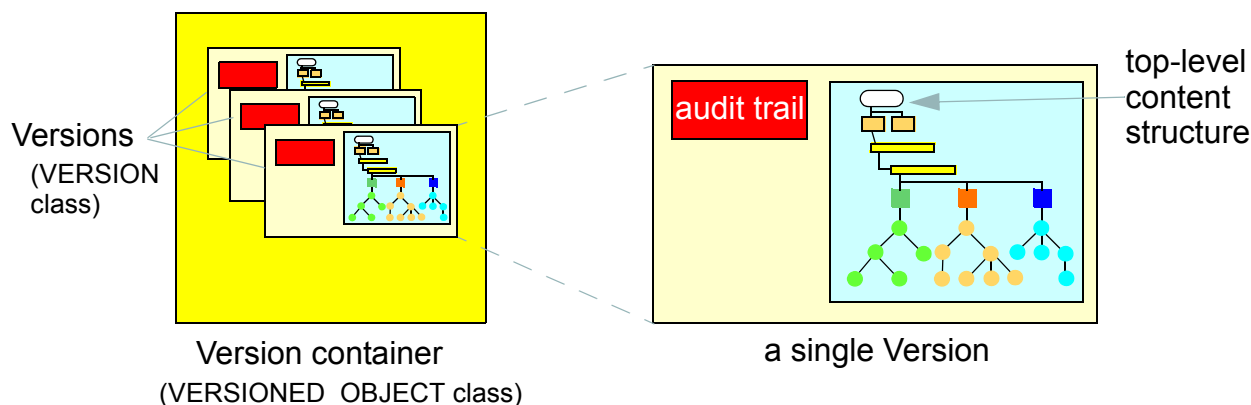


FIGURE 23 Version-control structures

Versioning of single top-level structures is a necessary, but not sufficient requirement for a repository that must provide coherence, traceability, indelibility, rollback, and support for forensic examination of past states of the data. Features supporting “change control” are also required. Under a disciplined change control scheme, changes are not made arbitrarily to single top-level structures, but to the repository itself. Changes take the form of change-sets, called “contributions”, that consist of new or changed versions of the controlled items in the repository. The key feature of a change-set is that it acts like a transaction, and takes the repository from one consistent state to another, whereas arbitrary combinations of changes to single controlled items could easily be inconsistent, and even dangerously wrong where clinical data are concerned.

These concepts are well-known in configuration management (CM), and are used as the basis for most software and other change management systems, including numerous free and commercial products available today. They are a central design feature of *openEHR* architecture. The following sections provide more details

8.2 The Configuration Management Paradigm

The “configuration management” (CM) paradigm is well-known in software engineering, and has its own IEEE standard¹. CM is about managed control of changes to a repository of items (formally called “configuration items” or CIs), and is relevant to any logical repository of distinct information items which changes in time. In health information systems, at least two types of information require such management: electronic health records, and demographic information. In most analyses in the past, the need for change management has been expressed in terms of specific requirements for audit trailing of changes, availability of previous states of the repository and so on. In *openEHR*, the aim is

1. IEEE 828-2005 - standard for Software Configuration Management Plans.

to provide a formal, general-purpose model for change control, and show how it applies to health information.

8.2.1 Organisation of the Repository

The general organisation of a repository of complex information items such as a software repository, or the EHR consists of the following:

- a number of distinct information items, or *configuration items*, each of which is uniquely identified, and may have any amount of internal complexity;
- optionally, a directory system of some kind, in which the configurations items are organised;
- other environmental information which may be relevant to correctly interpreting the primary versioned items, e.g. versions of tools used to create them.

In a software or document repository, the CIs are files arranged in the directories of the file system; in an EHR based on *openEHR*, they are Compositions, the optional Folder structure, Parties in the demographic service and so on. Contributions are made to the repository by users. This general abstraction is visualised in FIGURE 24.

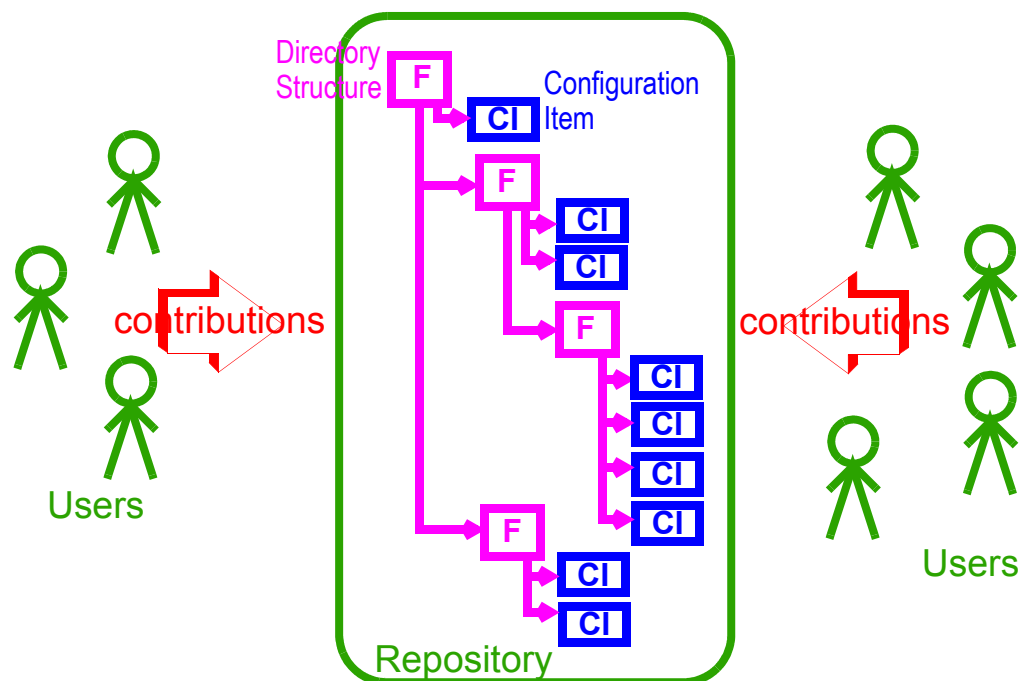


FIGURE 24 General Structure of a Controlled Repository

8.2.2 Change Management

Change doesn't occur to CIs in isolation, but to the repository as a whole. Possible types of change include:

- creation of a new CI;
- removal of a CI;
- modification of a CI;
- creation of, change to or deletion of part of the directory structure;
- moving of a CI to another location in the directory structure.

The goal of configuration management is to ensure the following:

- the repository is always in a valid state;
- any previous state of the repository can be reconstructed;
- all changes are audit-trailed.

8.3 Managing Change in Time

Properly managing changes to the repository requires two mechanisms. The first, *version control*, is used to manage versions of each CI, and of the directory structure if there is one. The second is the concept of the “change-set”, known as a *contribution* in *openEHR*. This is the *set* of changes to individual CIs (and the directory structure) made by a user as part of some logical change. For example, in a document repository, the logical change might be an update to a document that consists of multiple files (CIs). There is one contribution, consisting of changes to the document file CIs, to the repository. In the EHR, a contribution might consist of changes to more than one Composition, and possibly to the organising Folder structure.

A typical sequence of changes to a repository is illustrated below. FIGURE 25 shows the effect of four Contributions (indicated by blue ovals on the left hand side) to a repository containing a number of CIs (the directory tree is not shown for the sake of simplicity). As each Contribution is made, the repository is changed in some way. The first brings into existence a new CI, and modifies three others (changes indicated by the ‘C’ triangles). The second contribution causes the creation of a new CI only. The third causes a creation as well as two changes, while the fourth causes only a change. (Changes to the folder structure are not shown here).

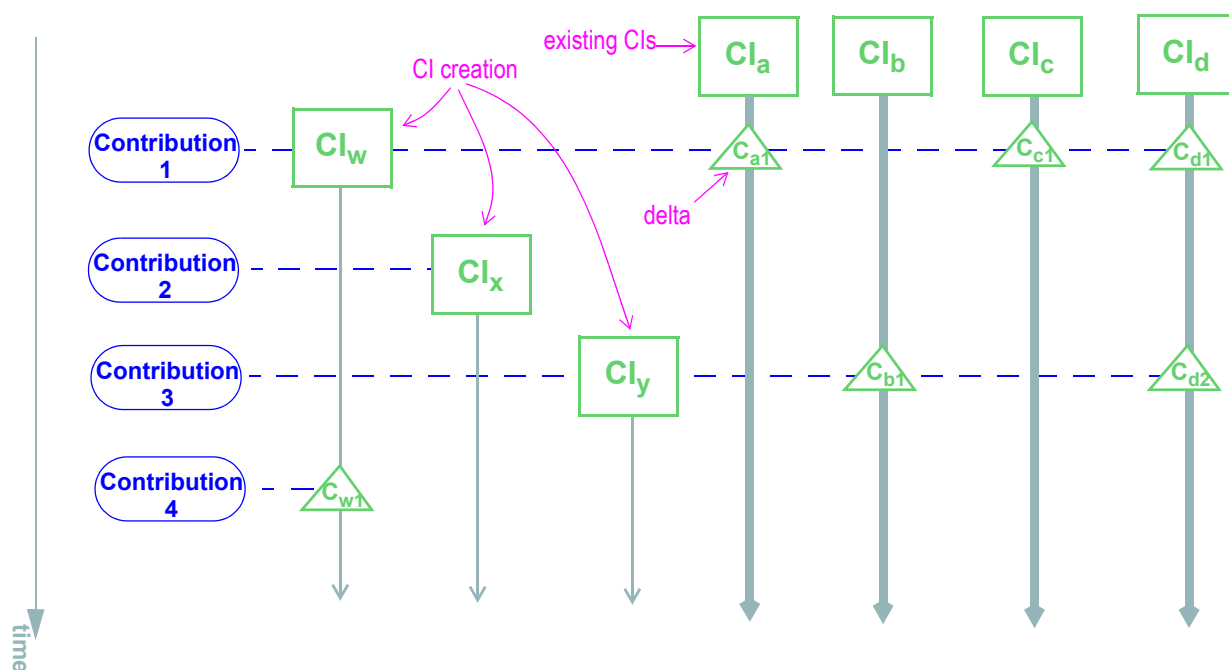


FIGURE 25 Contributions to the Repository (delta form)

One nuance which should be pointed out is that in FIGURE 25, contributions are shown as if they are literally a set of deltas, i.e. exactly the changes which occur to the record. Thus, the first contribution is the set $\{CI_w, C_{a1}, C_{c1}, C_{d1}\}$ and so on. Whether this is literally true depends on the construction of applications. In some situations, some CIs may be updated by the user viewing the current list and entering just the changes - the situation shown in FIGURE 25; in others, the system may provide the current state of these CIs for editing by the user, and submit the updated versions, as shown in FIG-

URE 26. Some applications may do both, depending on which CI is being updated. The internal versioning implementation may or may not generate deltas as a way of efficient storage.

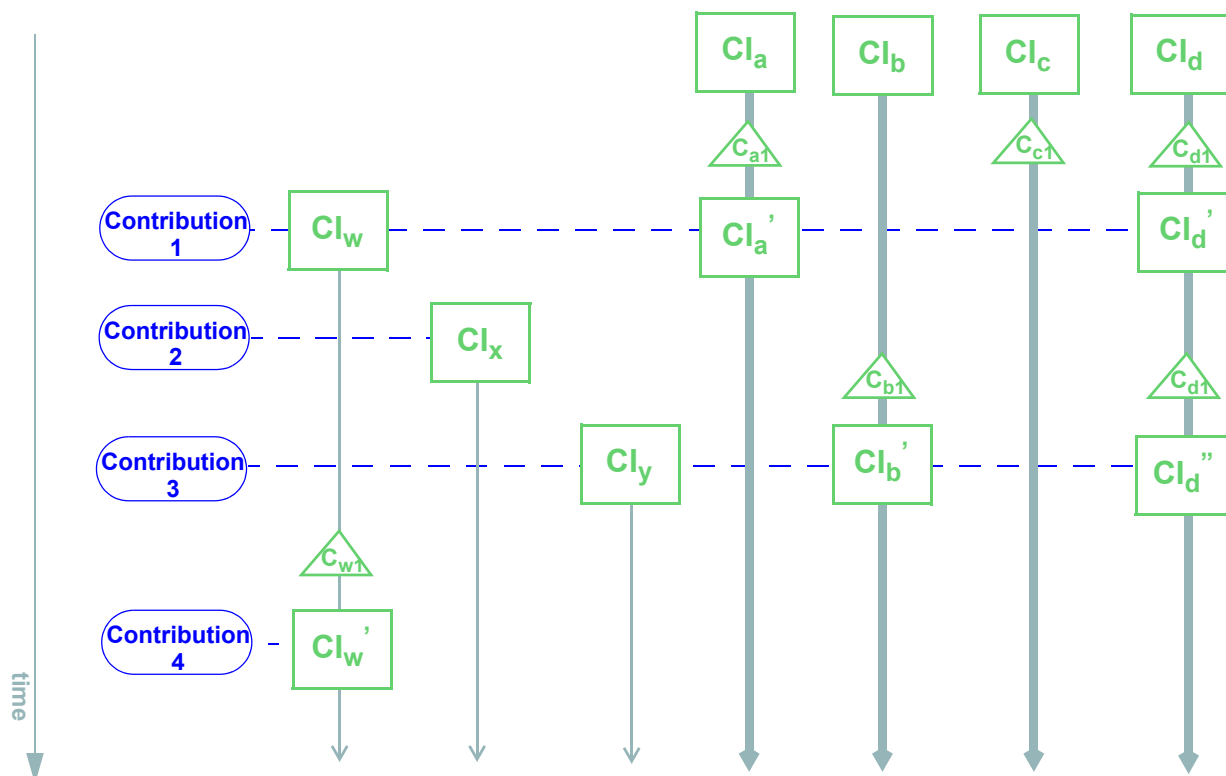


FIGURE 26 Contributions to the Repository (non-delta form)

For the purposes of *openEHR*, a contribution is considered as being the logical set of CIs changed or created at one time, as implied by FIGURE 26.

8.3.1 General Model of a Change-controlled Repository

FIGURE 27 shows an abstract model of a change-controlled repository, which consists of:

- version-controlled configuration items - instances of `VERSIONED_OBJECT<T>`;
- `CONTRIBUTIONS`;
- an optional directory system of folders. If folders are used, the folder structure must also be versioned as a unit.

The actual type of links between the controlled repository and the other entities might vary - in some cases it might be association, in others aggregation; cardinalities might also vary. FIGURE 27 therefore provides a guide to the definition of actual controlled repositories, such as an EHR, rather than a formal specification for them.

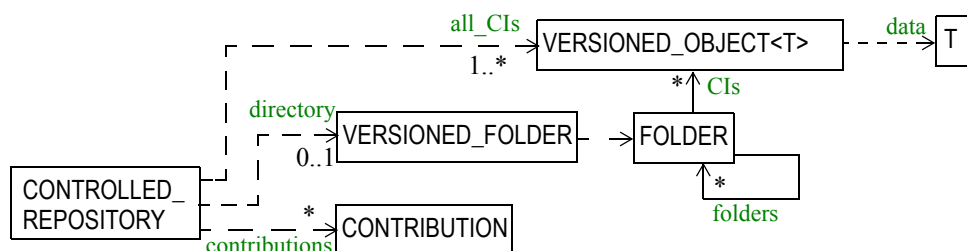


FIGURE 27 Abstract Model of Change-controlled Repository

8.4 The “Virtual Version Tree”

An underlying design concept of the versioning model defined in *openEHR* is known as a “virtual version tree”. The idea is simple in the abstract. Information is committed to a repository (such as an EHR) in lumps, each lump being the “data” of one Version. Each Version has its place within a version tree, which in turn is maintained inside a Versioned object (or “version container”). The virtual version tree concept means that any given Versioned object may have numerous copies in various systems, and that the creation of versions in each is done in such a way that all versions so created are in fact compatible with the “virtual” version tree resulting from the superimposition of the version trees of all copies. This is achieved using simple rules for version identification and is done to facilitate data sharing. Two very common scenarios are served by the virtual version tree concept:

- longitudinal data that stands as a proxy for the state or situation of the patient such as “Medications” or “Problem list” (persistent Compositions in *openEHR*) is created and maintained in one or more care delivery organisations, and shared across a larger number of organisations;
- some EHRs in an EHR server in one location are mirrored into one or more other EHR servers (e.g. at care providers where the relevant patients are also treated); the mirroring process requires asynchronous synchronisation between servers to work seamlessly, regardless of the location, time, or author of any data created.

The versioning scheme used in *openEHR* guarantees that no matter where data are created or copied, there are no inconsistencies due to sharing, and that logical copies are explicitly represented. It therefore provides direct support for shared data in a shared care context.

9 Identification

9.1 General Scheme

The identification scheme described here requires two kinds of “identifier”: identifiers proper and references, or locators. An *identifier* is a unique (within some context) symbol or number given to an object, and usually written into the object, whereas a *reference* is the use of an identifier by an exterior object, to refer to the object containing the identifier in question. This distinction is the same as that between primary and foreign keys in a relational database system.

In the *openEHR* RM, identifiers and references are implemented with two groups of classes defined in the `support.identification` package. Identifiers of various kinds are defined by descendant classes of `OBJECT_ID`, while references are defined by the classes inheriting from `OBJECT_REF`. The distinction is illustrated in FIGURE 28. Here we see two container objects with `OBJECT_ID`s (since `OBJECT_ID` is an abstract type, the actual type will be another `XXX_ID` class), and various `OBJECT_REF`s as references.

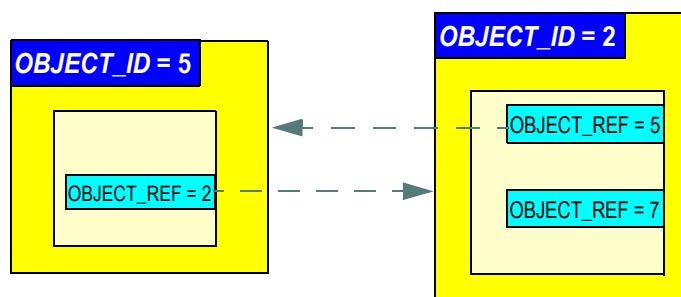


FIGURE 28 XXX_IDs and XXX_REFs

9.2 Levels of Identification

In order to make data items locatable from the outside, identification is supported at 3 levels in *openEHR*, as follows:

- *version containers*: `VERSIONED_OBJECT`s (Common IM) are identified uniquely;
- *top-level content structures*: content structures such as `COMPOSITION`, `EHR_STATUS`, `EHR_ACCESS`, `PARTY` etc. are uniquely identified by the association of the identifier of their containing `VERSIONED_OBJECT` and the identifier of their containing `VERSION` within the container;
- *internal nodes*: nodes within top-level structures are identified using paths.

Three kinds of identification are used respectively. For version containers, meaningless unique identifiers (“uids”) are used. In most cases, the type `HIER_OBJECT_ID` will be used, which contains an instance of a subtype of the `UID` class, i.e. either an ISO OID or a IETF UUID (see <http://www.ietf.org/rfc/rfc4122.txt>; also known as a GUID). In general UUIDs are favoured since they require no central assignment and can be generated on the spot. A versioned container can be then *referenced* with an `OBJECT_REF` containing its identifier.

Versions of top-level structures are identified in a way that is guaranteed to work even in distributed environments where copying, merging and subsequent modification occur. The full identification of a version of a top-level structure is the globally unique tuple consisting of the *uid* of the owning `VERSIONED_OBJECT`, and the two `VERSION` attributes *version_tree_id* and *creating_system_id*. The

version_tree_id is a 1 or 3-part number string, such as “1” or for a branch, “1.2.1”. The *creating_system_id* attribute carries a unique identifier for the system where the content was first created; this may be a GUID, Oid or reverse internet identifier. A typical version identification tuple is as follows:

```
F7C5C7B7-75DB-4b39-9A1E-C0BA9BFDBDEC  -- id of VERSIONED_COMPOSITION
au.gov.health.rdh.ehr1                  -- id of creating system
2                                         -- current version
```

This 3-part tuple is known as a “Version locator” and is defined by the class `OBJECT_VERSION_ID` in the `support.identification` package. A `VERSION` can be *referred to* using a normal `OBJECT_REF` that contains a copy of the version’s `OBJECT_VERSION_ID`. The *openEHR* version identification scheme is described in detail in the `change_control` package section of the Common IM.

The last component of identification is the path, used to refer to an interior node of a top-level structure identified by its Version locator. Paths in *openEHR* follow an Xpath style syntax, with slight abbreviations to shorten paths in the most common cases. Paths are described in detail below.

To refer to an interior data node from outside a top-level structure, a combination of a Version locator and a path is required. This is formalised in the `LOCATABLE_REF` class in the `change_control` package section of the Common IM. A Universal Resource Identifier (URI) form can also be used, defined by the data type `DV_EHR_URI` (Data types IM). This type provides a single string expression in the scheme-space “ehr://” which can be used to refer to an interior data node from anywhere (it can also be used to represent queries; see below). Any `LOCATABLE_REF` can be converted to a `DV_EHR_URI`, although not all `DV_EHR_URI`s are `LOCATABLE_REF`s.

FIGURE 29 summarises how various types of `OBJECT_ID` and `OBJECT_REF` are used to identify objects, and to reference them from the outside, respectively.

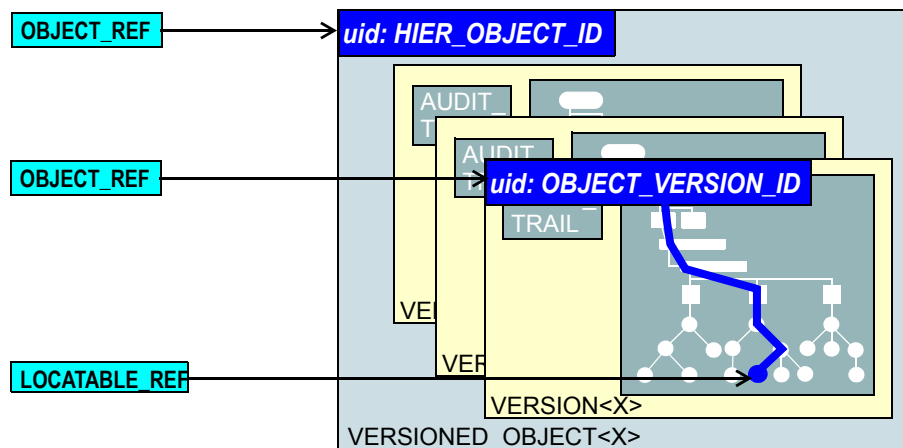


FIGURE 29 How to reference various levels of object

10 Archetypes and Templates

10.1 Overview

Under the two-level modelling approach, the formal definition of information structuring occurs at two levels. The lower level is that of the reference model, a stable object model from which software and data can be built. Concepts in the *openEHR* reference model are invariant, and include things like Composition, Section, Observation, and various data types such as Quantity and Coded text. The upper level consists of domain-level definitions in the form of *archetypes* and *templates*. Concepts defined at this level include things such as “blood pressure measurement”, “SOAP headings”, and “HbA1c Result”.

All information conforming to the *openEHR* Reference Model (RM) - i.e. the collection of Information Models (IMs) - is “archetypable”, meaning that the creation and modification of the content, and subsequent querying of data is controllable by archetypes. Archetypes are themselves separate from the data, and are stored in their own repository. The archetype repository at any particular location will usually include archetypes from well-known online archetype libraries. Archetypes are deployed at runtime via templates that specify particular groups of archetypes to use for a particular purpose, often corresponding to a screen form.

Archetypes are themselves instances of an *archetype model*, which defines a language in which to write archetypes; the syntax equivalent of the model is the Archetype Definition Language, ADL. These formalisms are specified in the *openEHR* Archetype Object Model (AOM) and ADL documents respectively. Each archetype is a set of constraints on the reference model, defining a subset of instances that are considered to conform to the subject of the archetype, e.g. “laboratory result”. An archetype can thus be thought of as being similar to a LEGO[®] instruction sheet (e.g. for a tractor) that defines the configuration of LEGO[®] bricks making up a tractor. Archetypes are flexible; one archetype includes many variations, in the same way that a LEGO[®] instruction might include a number of options for the same basic object. Mathematically, an archetype is equivalent to a query in F-logic¹. In terms of scope, archetypes are general-purpose, re-usable, and composable. For data capture and validation purposes, they are usually used at runtime by *templates*.

A template is a specification that defines a tree of one or more archetypes, each constraining instances of various reference model types, such as Composition, Section, Entry subtypes and so on. Thus, while there are likely to be archetypes for such things as “biochemistry results” (an Observation archetype) and “SOAP headings” (a Section archetype), templates are used to put archetypes together to form whole Compositions in the EHR, e.g. for “discharge summary”, “antenatal exam” and so on. Templates correspond closely to screen forms and printed reports, and are generally developed and used locally, while archetypes are usually widely used.

A template is used at runtime to create default data structures and to validate data input, ensuring that all data in the EHR conform to the constraints defined in the archetypes referenced by the template. In particular, it conforms to the *path* structure of the archetypes, as well as their terminological constraints. Which archetypes were used at data creation time is written into the data, in the form of both archetype identifiers at the relevant root nodes, and archetype node identifiers (the [atnnnn] codes), which act as normative node names, and which are in turn the basis for paths. When it comes time to modify the same data, these archetype node identifiers enable applications to retrieve and use the original archetypes, ensuring modifications respect the original constraints.

1. See <http://ftp.cs.sunysb.edu/pub/TechReports/kifer/flogic.pdf>

Archetypes also form the basis of semantic querying. Queries are expressed in a language which is a synthesis of SQL (SELECT/FROM/WHERE) and W3C XPaths, extracted from the archetypes.

10.2 Archetype Formalisms and Models

10.2.1 Overview

In *openEHR*, archetypes are formalised by the Archetype Object Model (AOM). This is an object model of the semantics of archetypes. When an archetype is represented in memory (for example in an archetype-enabled EHR “kernel”), the archetype will exist as instances of the classes of this model. The AOM is thus the definitive statement of the semantics of archetypes.

In serialised form, archetypes can be represented in various ways. The normative, abstract serialisation in *openEHR* is Archetype Definition Language (ADL). This is an abstract language based on Frame Logic queries (also known as F-logic [4]) with the addition of terminology. An ADL archetype is a guaranteed 100% lossless rendering of the semantics of any archetype, and is designed to be a syntactic analogue of the AOM. Nevertheless, other lossless and lossy serialisations are possible and some already exist. For practical purposes, XML-based serialisations are used in some situations. A serialisation purely expressed in dADL, the ADL object serialisation syntax will be available in the future. Various HTML, RTF and other formats are used for screen rendering and human review.

Templates are represented as dADL documents whose object model conforms to the Template Object Model (TOM).

10.2.2 Design-time Relationships between Archetypes

Archetypes are extensible formal constraint definitions of object structures. In common with object model classes, they can be *specialised*, as well as *composed* (i.e. aggregated). Specialised archetypes are created when an archetype is already available for the content that needs to be modelled, but it lacks detail or is too general. For example, the archetype `openEHR-EHR-OBSERVATION.laboratory.v1` contains generic concepts of ‘specimen’, ‘diagnostic service’, a single result of any type, and a two-level result battery for grouped results. This archetype could be (and has been) used to represent nearly any kind of laboratory result data. However, specialisations such as `openEHR-EHR-OBSERVATION.laboratory-glucose.v1` are extremely useful, and can be easily defined based on the predecessor; in this case, the single result node is redefined to be ‘blood glucose’. The formal rule for specialisation is that:

- a specialised archetype can only further narrow existing constraints in the parent (but it may add its own).

This has the effect that the data created with any specialised archetype will always be matched by queries based on the parent archetype - in other words, a query for ‘laboratory’ Observations will correctly retrieve ‘glucose’ Observations as well. This accords with the basic ontological principle of subsumption, which says that instances of a type B are also instances of type A, where type B is related to type A by the semantic relationship ‘IS-A’. Specialised archetypes are indicated by the use of an identifier derived from the parent archetype, with a new sub-element of the semantic part of the identifier, separated by a ‘-’ character.

The second relationship possible between archetypes is composition, allowing large data structures to be flexibly constrained via the hierarchical re-use of smaller archetypes. Composition is defined in terms of ‘slots’ within an archetype. A slot is a point in an archetype structure where, instead of specifying an object type inline, a special *allow_archetype* constraint is used to specify other archetypes constraining that same type, that may be used at that point. For example, the archetype `openEHR-`

EHR-SECTION.vital_signs.v1 defines a heading structure for headings to do with vital signs. It also defines as its *items* attribute value (i.e. what comes under the heading) a number of possible Observations; however, rather than defining these inline, it specifies an archetype slot in the form of constraints on Observation archetypes that are allowed at that point. The simplest kind of constraint is in terms of regular expressions on archetype identifiers. More complex constraints can be stated in terms of paths in other archetypes (for example `exists(/some/path[at0005])`). A slot thus defines a ‘chaining point’ in terms of *possible* archetypes allowed or excluded at that point; limiting this to a single archetype is of course possible. Templates are used to choose which particular archetypes allowed at a slot by an archetype will actually be used in a given circumstance.

10.3 Relationship of Archetypes and Templates to Data

All nodes within the top-level information structures in the *openEHR* RM are “archetypeable”, with certain nodes within those structures being archetype “root points”. Each top-level type is always guaranteed to be an archetype root point. Although it is theoretically possible to use a single archetype for an entire top-level structure, in most cases, particularly for COMPOSITION and PARTY, a hierarchical structure of multiple archetypes will be used, via the slot mechanism described above. This allows for componentisation and reusability of archetypes. When hierarchies of archetypes are used for a top-level structure, there will also be archetype root points in the interior of the structure. For example, within a COMPOSITION, ENTRY instances (i.e. OBSERVATIONS, EVALUATIONS etc.) are almost always root points. SECTION instances are root points if they are the top instance in a Section structure; similarly for FOLDER instances within a directory structure. Other nodes (e.g. interior SECTIONS, ITEM_STRUCTURE instances) might also be archetype root points, depending on how archetypes are applied at runtime to data. FIGURE 30 illustrates the application of archetypes and templates to data.

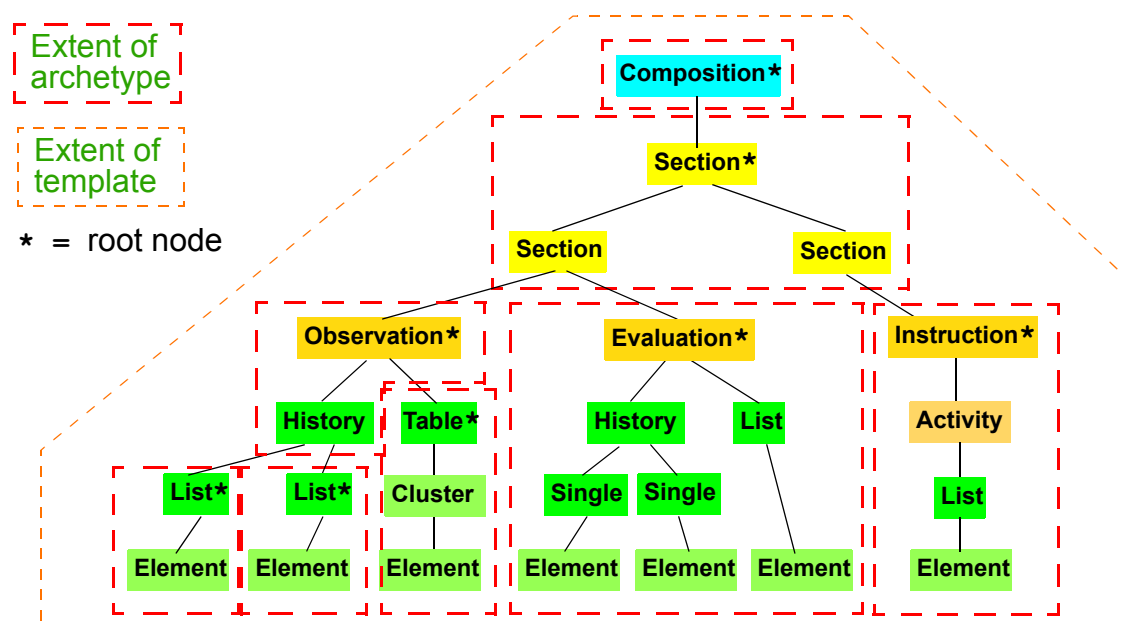


FIGURE 30 How Archetypes apply to Data

10.4 Archetype-enabling of Reference Model Data

Archetype-enabling of Reference Model classes is achieved via inheritance of the class `LOCATABLE` from the package `common.archetyped` (see Common IM). The `LOCATABLE` class includes the

attributes *archetype_node_id* and *archetype_details*. In the data, the former carries an identifier from the archetype. If the node in the data is a root point, it carries the multipart identifier of the generating archetype, and *archetype_details* carries an `ARCHETYPED` object, containing information pertinent to archetype root points. If it is a non-root node, the *archetype_node_id* attribute carries the identifier (known as an “at”, or “archetype term” code) of the archetype interior node that generated the data node, and the *archetype_details* attribute is void.

Sibling nodes in data can carry the same *archetype_node_id* in some cases, since archetypes provide a pattern for data, rather than an exact template. In other words, depending on the archetype design, a single archetype node may be replicated in the data.

In this way, each *archetyped data composition*¹ in *openEHR* data has a generating archetype which defines the particular configuration of instances to create the desired composition. An archetype for “biochemistry results” is an `OBSERVATION` archetype, and constrains the particular arrangement of instances beneath an `OBSERVATION` object; a “problem/SOAP headings” archetype constrains `SECTION` objects forming a SOAP headings structure. In general, an archetyped data composition is any composition of data starting at a root node and continuing to its leaf nodes, at which point lower-level compositions, if they exist, begin. Each of the archetyped areas and its subordinate archetyped areas in FIGURE 30 is an archetyped data composition.

The result of the use of archetypes to create data in the EHR (and other systems) is that the structure of data in any top-level object conforms to the constraints defined in a composition of archetypes chosen by a template, including all optionality, value, and terminology constraints.

10.5 Archetypes, Templates and Paths

The use of *openEHR* archetypes and templates enables paths to be used ubiquitously in the *openEHR* architecture. Paths are extracted from Archetypes and templates, and are constructed from attribute names and archetype node identifiers, in an Xpath-compatible syntax, as shown in

These paths serve to identify any node in a template or archetype, such as the “diastolic blood pressure” `ELEMENT` node, deep within a “blood pressure measurement” archetype. Since archetype node identifiers are embedded into data at runtime, archetype paths can be used to extract data nodes conforming to particular parts of archetypes, providing a very powerful basis for querying. Paths can also be constructed into data, using more complex predicates (still in the Xpath style). Paths in *openEHR* are explained in detail under Paths and Locators on page 61.

10.6 Archetypes and Templates at Runtime

10.6.1 Overview

openEHR archetypes and templates were designed as formal artefacts, so as to be computable at runtime. They perform two key functions. The first is to facilitate data validation at data capture or import time, i.e. to guarantee that data conform to not just the reference model, but also to the archetypes themselves. Data validation with archetypes is mediated by the use of *openEHR* Templates. The second function is as a design basis for queries. Since data are captured based on archetypes, all *openEHR* data are guaranteed to conform to the “semantic paths” that are created by the composition of archetypes within a template. The paths (such as those shown in FIGURE 31 above) are incorpo-

1. Note: care must be taken not to confuse the general term “composition” with the specific use of this word in *openEHR* and CEN EN 13606, defined by the `COMPOSITION` class; the specific use is always indicated by using the term “Composition”.

Node map	Path map
Physical	Logical
/data[at0002]/items[at0019]/items[at0020]/value	/data[structure]/items[Exposure and reaction detail]/items[Date of exposure]/value
/data[at0002]/items[at0019]/items[at0020]	/data[structure]/items[Exposure and reaction detail]/items[Date of exposure]
/data[at0002]/items[at0019]/items[at0021]/value	/data[structure]/items[Exposure and reaction detail]/items[Duration of the exposure]/value
/data[at0002]/items[at0019]/items[at0021]	/data[structure]/items[Exposure and reaction detail]/items[Duration of the exposure]
/data[at0002]/items[at0019]/items[at0015]/value/code	/data[structure]/items[Exposure and reaction detail]/items[Reaction category]/value/code
/data[at0002]/items[at0019]/items[at0015]/value	/data[structure]/items[Exposure and reaction detail]/items[Reaction category]/value
/data[at0002]/items[at0019]/items[at0015]	/data[structure]/items[Exposure and reaction detail]/items[Reaction category]
/data[at0002]/items[at0019]/items[at0023]/value/code	/data[structure]/items[Exposure and reaction detail]/items[Reaction severity]/value/code
/data[at0002]/items[at0019]/items[at0023]/value	/data[structure]/items[Exposure and reaction detail]/items[Reaction severity]/value
/data[at0002]/items[at0019]/items[at0023]	/data[structure]/items[Exposure and reaction detail]/items[Reaction severity]
/data[at0002]/items[at0019]/items[at0032]/value	/data[structure]/items[Exposure and reaction detail]/items[Specific substance]/value
/data[at0002]/items[at0019]/items[at0032]	/data[structure]/items[Exposure and reaction detail]/items[Specific substance]
/data[at0002]/items[at0019]/items[at0028]/value	/data[structure]/items[Exposure and reaction detail]/items[Duration of the reaction]/value
/data[at0002]/items[at0019]/items[at0028]	/data[structure]/items[Exposure and reaction detail]/items[Duration of the reaction]
/data[at0002]/items[at0019]/items[at0027]/value	/data[structure]/items[Exposure and reaction detail]/items[Date of onset of reaction]/value
/data[at0002]/items[at0019]/items[at0027]	/data[structure]/items[Exposure and reaction detail]/items[Date of onset of reaction]
/data[at0002]/items[at0019]/items[at0022]/value	/data[structure]/items[Exposure and reaction detail]/items[Reaction description]/value
/data[at0002]/items[at0019]/items[at0022]	/data[structure]/items[Exposure and reaction detail]/items[Reaction description]
/data[at0002]/items[at0019]/items[at0004]/value/code	/data[structure]/items[Exposure and reaction detail]/items[Probability of causation]/value/code
/data[at0002]/items[at0019]/items[at0004]/value	/data[structure]/items[Exposure and reaction detail]/items[Probability of causation]/value
/data[at0002]/items[at0019]/items[at0004]	/data[structure]/items[Exposure and reaction detail]/items[Probability of causation]
/data[at0002]/items[at0019]/items	/data[structure]/items[Exposure and reaction detail]/items
/data[at0002]/items[at0019]	/data[structure]/items[Exposure and reaction detail]

FIGURE 31 Paths extracted from an archetype

rated within a familiar SQL-style syntax, to form queries that can be evaluated to retrieve items on a semantic basis.

10.6.2 Deploying Archetypes and Templates

Archetypes are mostly designed by clinical or other domain experts, and often require significant study of a subject area, for example, obstetrics. The development process may occur at a national or international level, and requires peer review and testing in real systems. This accords with the semantic value of archetypes, namely as *reusable* models of content. Consequently, from the point of view of any given site of deployment, archetypes are most likely to have been developed elsewhere, and to reside in a recognised, quality assured repository.

Such a repository may contain hundreds or even thousands of archetypes. However, most EHR sites will only require a relatively small number. Clinical experts estimate that 100 archetypes would take care of 80% of routine general practice and acute care, including laboratory, with many of these being specialisations of a much smaller number of key archetypes. However, which 100 archetypes are useful for a given site may well vary based on the kind of health care provided, e.g. diabetic clinic, cancer, orthopedic hospital ward, aged care home. In general, it can be expected that nearly all archetype deployment sites will use only a small percentage of published archetypes. Some sites may also develop a small number of their own archetypes; invariably these will be specialisations of existing archetypes.

While archetypes constitute the main shared and carefully quality-assured design activity in the second layer of *openEHR*'s two-level structure, templates are a more local affair, and are likely to be the point of contact of many system designers with archetypes. A template will typically be designed based on three things:

- what is desired to be in a screen form or report;
- what archetypes are already available;
- local usage of terminology.

Templates will generally be created locally by tools conforming to the *openEHR* Template Object Model.

In the case of GUI applications, the final step in the chain is GUI screen forms. These are created in a multitude of ways and technologies. In some cases, they will be partially or completely generated from templates. Regardless of the details, the connection between a screen form and a template will be established in the tooling environment, so that when the form is requested by a user, the relevant template will be activated, in turn activating the relevant archetypes.

A further technical detail may come into play in many deployment situations: since the archetypes and templates required by the environment will be known in advance, they may well be compiled into a near-runtime form from the sharable *openEHR* form (i.e. ADL, TOM files) in which they are received from a repository or local tool. This form will usually differ from site to site, and both improves performance and ensures that only validated archetypes and templates will actually be accessed by applications. In such systems, runtime form of templates is most likely to incorporate copies of the relevant archetypes.

The deployment of archetypes, templates, and screen forms is shown in FIGURE 32.

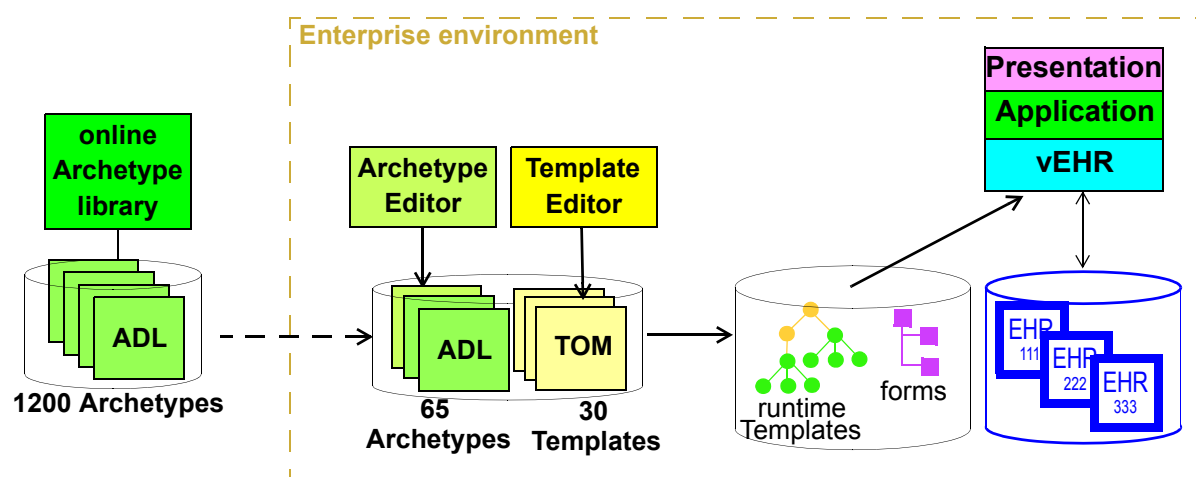


FIGURE 32 Deployment of Archetypes and Templates

10.6.3 Validation during Data Capture

Validation is the primary runtime function of archetypes - it is how “archetype-based” data are created in the first place, and modified thereafter. Archetype-based validation can be used in a GUI application or in a data import service. Although the source of the data (keystrokes or received XML or other messages) is different, the logical process is the same: create archetype-based *openEHR* data according to the input stream.

The process at runtime may vary in some details according to implementations and other aspects of the care setting, but the main thrust will be the same. The archetypes used at a particular site will always be mediated at runtime by *openEHR* templates developed for that site or system; these will usually be linked to screen forms or other formal artefacts that enable the connection between archetypes and the user or application. It will not be uncommon for a template to be constructed partially at runtime, due to user choices of archetypes being made on the screen, although of course the user will not be directly aware of this. Regardless, by the time data are created and validated against the relevant archetypes, the template that does the job will be completely specified.

The actual process of data creation and committal is illustrated in FIGURE 33. The essence of the process is that a “kernel” component performs the task of data creation and validation by maintaining a “template space” and a “data space”. The former contains the template and archetypes retrieved due to a screen form being displayed; the latter contains the data structures (instances of the *openEHR* reference model) that are constructed due to user activity on the screen. When data are finally committed, they are guaranteed to conform to the template/archetype definitions, due to the checks that are made each time the user tries to change the data structure. The committed data contain a “semantic imprint” of the generating archetypes, in the form of archetype node identifiers on every node of the data. This simple inclusion in the data model ensures that all archetypes data are queryable by the use of archetype paths. In XML representations, the archetype node ids are represented as XML attributes (i.e. inside the tag), thus enabling XPaths to be conveniently navigated through the data based on these identifiers (more details on this are in the next section).

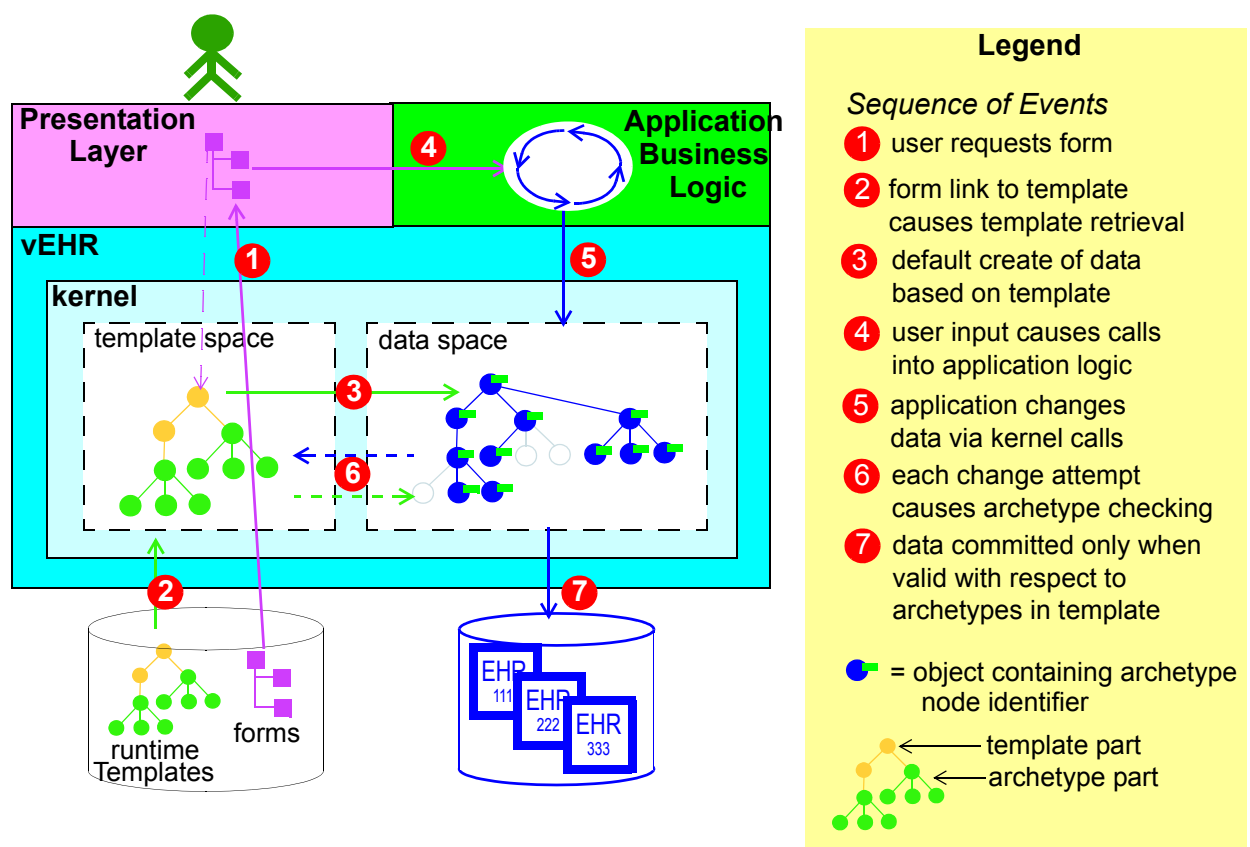


FIGURE 33 Templated Archetypes at Runtime

If data are later modified, they are brought into the kernel along with the relevant template and archetypes, and the embedded node identifiers allow the kernel to continue to perform appropriate checking of changes to the data.

10.6.4 Querying

The second major computational function of archetypes is to support querying. As described above, and in the next section, the paths extracted from archetypes are the basis for queries into the data. Queries are defined in SAQL (Structured Archetype Query Language), which is essentially a synthesis of SQL and XPath style paths extracted from archetypes. The following is an example SAQL query meaning “Get the BMI values which are more than 30 kg/m² for a specific patient”:

```
SELECT o/[at0000]/data[at0001]/events[at0002]/data[at0003]/item[0004]/value
```

```
FROM EHR [uid=@ehrUid]
  CONTAINS COMPOSITION c [openEHR-EHR-COMPOSITION.report.v1]
  CONTAINS OBSERVATION o[openEHR-EHR-OBSERVATION.body_mass_index.v1]
WHERE o/[at0000]/data[at0001]/events[at0002]/data[at0003]/item[0004]/value > 30
```

10.7 The *openEHR* Archetypes

A set of heavily reviewed archetypes is available on the *openEHR* website at <http://svn.openehr.org/knowledge/archetypes/dev/index.html>. This collection is being added to all the time, and includes archetypes developed for specific countries or other “realms” as well as globally applicable ones.

11 Paths and Locators

11.1 Overview

The *openEHR* architecture includes a path mechanism that enables any node within a top level structure to be specified from the top of the structure using a “semantic” (i.e. archetype-based) X-path compatible path. The availability of such paths radically changes the available querying possibilities with health information, and is one of the major distinguishing features of *openEHR*.

Technically, the combination of a path and a Version identifier such as `OBJECT_VERSION_ID` forms a “globally qualified node reference” which can be expressed using `LOCATABLE_REF`. It can also be expressed in portable URI form as a `DV_EHR_URI`, known as a “globally qualified node locator”. Either representation enables any *openEHR* data node to be referred to from anywhere. This section describes the syntax and semantics of paths, and of the URI form of reference. In the following, the term “archetype path” means a path extracted from an archetype, while “runtime path” means one that identifies an item in data. They are no different formally, and this terminology is only used to indicate where they are used.

11.2 Paths

11.2.1 Basic Syntax

Paths in *openEHR* are defined in an Xpath¹-compatible syntax which is a superset of the path syntax described in the Archetype Definition Language (ADL). The syntax is designed to be easily mappable to Xpath expressions, for use with *openEHR*-based XML.

The runtime path syntax used in locator expressions follows the general pattern of a path consisting of segments each consisting of an attribute name², and separated by the slash (‘/’) character, i.e.:

```
attribute_name / attribute_name / ... / attribute_name
```

Paths select the object which is the value of the final attribute name in the path, when going from some starting point in the tree and following attribute names given in the path. The starting point is indicated by the initial part of the path, and can be specified in two ways:

relative path: path starts with an attribute name, and the starting point is the current point in the tree (given by some previous operation or knowledge);

absolute path: path starts with a ‘/’; the starting point is the top of the structure.

In addition, the “//” notation from Xpath can be used to define a path pattern:

path pattern: path starts with or contains a the symbol ‘//’ and is taken to be a pattern which can match any number of path segments in the data; the pattern is matched if an actual path can be found anywhere in the structure for which part of the path matches the path section before the ‘//’ symbol, and a later section matches the section appearing after the ‘//’.

1. See W3C Xpath 1.0 specification, 1999. Available at <http://www.w3.org/TR/xpath>.

2. In all *openEHR* documentation, the term “attribute” is used in the object-oriented sense of “property of an object”, not in the XML sense of named values appearing within a tag. The syntax described here should not be considered to necessarily have a literal mapping to XML instance, but rather to have a logical mapping to object-oriented data structures.

11.2.2 Predicate Expressions

Paths specified solely with attribute names are limited in two ways. Firstly, they can only locate objects in structures in where there are no containers, such as lists or sets. However, in any realistic data, including most *openEHR* data, list, set and hash structures are common. Additional syntax is needed to match a particular object from among the siblings referred to by a container attribute. This takes the form of a predicate expression enclosed in brackets ('[]') after the relevant attribute in a segment, i.e.:

```
attribute_name [predicate expression]
```

The general form of a path then resembles the following:

```
attribute_name / attribute_name [predicate expression] / ...
```

Here, predicate expressions are used optionally on those attributes defined in the reference model to be of a container type (i.e. having a cardinality of > 1). If a predicate expression is not used on a container attribute, the whole container is selected.

The second limitation of basic paths is that they cannot locate objects based on other conditions, such as the object having a child node with a particular value. To address this, predicate expressions can be used to select an object on the basis of other conditions relative to the object, by including boolean expressions including paths, operators, values and parentheses.

The syntax of predicate expressions used in *openEHR* is a subset of the Xpath syntax for predicates with a small number of short-cuts. The general form of a predicate statement is a boolean-returning expression consisting of paths, values, operators and parentheses. In the current release of *openEHR*, it is expected that only very simple expressions will be used. The simplest such expression is to identify an object by its *archetype_node_id* value, which will be an 'at' code from an archetype; in other words, just to use the ADL archetype path against the runtime data. A typical archetype-derived path is the following (applied to an Observation instance):

```
/data/events[at0003]/data/items[at0025]/value/magnitude
```

This path refers to the magnitude of a 1-minute Apgar total in an Observation containing a full Apgar result structure. In this path, the [atNNNN] predicates correspond to [@archetype_node_id = "atNNNN"] in standard Xpath, however, the shorthand form is used in *openEHR* as it is the only kind of predicate used in archetype paths. In *openEHR* paths identifying runtime data, archetype code predicates are also commonly used, and the same short-cut is allowed. However, runtime path predicates can also include other expressions (including the orthodox Xpath equivalent expression for the archetype node id short-cut), typically based on the value of some other attribute such as *ELEMENT.name* or *EVENT.time*. Combinations of the *archetype_node_id* and other such values are likely to be commonly used in querying, such as the following path fragment (applied to an OBSERVATION instance):

```
/data/events[at0007 AND time >= "24-06-2005 09:30:00"]
```

This path would choose Events in Observation.data whose *archetype_node_id* meaning is "summary event" (at0007 in some archetype) and which occurred at or after the given time. The following example would choose an Evaluation containing a diagnosis (at0002.1) of "other bacterial intestinal infections" (ICD10 code A04):

```
/data/items[at0002.1  
  AND value/defining_code/terminology_id/value = "ICD10AM"  
  AND value/defining_code/code_string = "A04"]
```

11.2.3 Paths within Top-level Structures

Paths within top-level structures strictly adhere to attribute and function names in the relevant parts of the reference model. Predicate expressions are needed to distinguish multiple siblings in various points in paths into these structures, but particularly at archetype “chaining” points. A chaining point is where one archetype takes over from another as illustrated in FIGURE 30. Chaining points in Compositions occur between the Composition and a Section structure, potentially between a Section structure and other sub-Section structures (constrained by a different Section archetype), and between either Compositions or Section structures, and Entries. Chaining might also occur inside an Entry, if archotyping is used on lower level structures such as `Item_lists` etc. Most chaining points correspond to container types such as `List<T>` etc., e.g. `COMPOSITION.content` is defined to be a `List<CONTENT_ITEM>`, meaning that in real data, the content of a Composition could be a List of Section structures. To distinguish between such sibling structures, predicate expressions are used, based on the *archetype_id*. At the root point of an archetype in data (e.g. top of a Section structure), the *archetype_id* carries the identifier of the archetype used to create that structure, in the same manner as any interior point in an archetyped structure has an *archetype_node_id* attribute carrying archetype *node_id* values. The chaining point between Sections and Entries works in the same manner, and since multiple Entries can occur under a single Section, *archetype_id* predicates are also used to distinguish them. The same shorthand is used for *archetype_id* predicate expressions as for *archetype_node_ids*, i.e. instead of using `[@archetype_id = "xxxxx"]`, `[xxxx]` can be used instead.

The following paths are examples of referring to items within a Composition:

```
/content[openEHR-EHR-SECTION.vital_signs.v1]/
  items[openEHR-EHR-OBSERVATION.heart_rate-pulse.v1]/data/
    events[at0003 and time='2006-01-25T08:42:20']/data/items[at0004]
/content[openEHR-EHR-SECTION.vital_signs.v1]/
  items[openEHR-EHR-OBSERVATION.blood_pressure.v1]/data/
    events[at0006 and time='2006-01-25T08:42:20']/data/items[at0004]
/content[openEHR-EHR-SECTION.vital_signs.v1]/
  items[openEHR-EHR-OBSERVATION.blood_pressure.v1]/data/
    events[at0006 and time='2006-01-25T08:42:20']/data/items[at0005]
```

Paths within the other top level types follow the same general approach, i.e. are created by following the required attributes down the hierarchy.

11.2.4 Runtime Paths and Uniqueness

Archetype paths are not guaranteed to uniquely identify items in data, due to the fact that one archetype node may correspond to multiple instances in the data. However it is often necessary to be able to construct a unique path to an item in real data. This can be done by using attributes other than *archetype_node_id* in path predicates. Consider as an example the following OBSERVATION archetype:

```
OBSERVATION[at0000] matches { -- blood pressure measurement
  data matches {
    HISTORY matches {
      events {1..*} matches {
        EVENT[at0001] {0..1} matches {-- any event
          name matches {DV_TEXT matches {...}}
          data matches {
            ITEM_LIST matches { -- systemic arterial BP
              count matches {2..*}
              items matches {
                ELEMENT[at1100] matches {-- systolic BP
                  name matches {DV_TEXT matches {...}}
                  value matches {magnitude matches {...}}
```



```

    }
    ELEMENT[at1200] matches {-- diastolic BP
      name matches {DV_TEXT matches {...}}
      value matches {magnitude matches {...}}
    }
  }
}
}
}
}
}
}

```

The following path extracted from the archetype refers to the systolic blood pressure magnitude:

```
/data/events[at0001]/data/items[at1100]/value/magnitude
```

The codes [atnnnn] at each node of the archetype become the *archetype_node_ids* found in each node in the data.

Now consider an OBSERVATION instance (expressed here in dADL format), in which a history of two blood pressures has been recorded using this archetype:

```

<
  -- OBSERVATION - blood pressure measurement
  archetype_node_id = <[openEHR-EHR-OBSERVATION.bp_meas.v2]>
  name = <value = <"BP measurement">>
  data = <
    -- HISTORY
    origin = <2005-12-03T09:22:00>
    events = <
      -- List <EVENT>
      [1] = <
        -- EVENT
        archetype_node_id = <[at0001]>
        name = <value = <"sitting">>
        time = <2005-12-03T09:22:00>
        data = <
          -- ITEM_LIST
          items = <
            -- List<ELEMENT>
            [1] = <
              name = <value = <"systolic">>
              archetype_node_id = <[at1100]>
              value = <magnitude = <120.0> ...>
            >
            [2] = <....
              name = <value = <"diastolic">>
              archetype_node_id = <[at1200]>
              value = <magnitude = <80.0> ...>
            >
          >
        >
      >
    >
  >
  [2] = <
    -- EVENT
    archetype_node_id = <[at0001]>
    name = <value = <"standing">>
    time = <2005-12-03T09:27:00>
    data = <
      -- ITEM_LIST
      items = <
        -- List<ELEMENT>
        [1] = <
          name = <value = <"systolic">>
          archetype_node_id = <[at1100]>
          value = <magnitude = <105.0> ...>
        >
        [2] = <
          name = <value = <"diastolic">>
          archetype_node_id = <[at1200]>
          value = <magnitude = <70.0> ...>
        >
      >
    >
  >

```



```

>
>
>
>
>

```

[Note: in the above example, name values are shown as if they were all `DV_TEXTS`, whereas in reality in *openEHR* they more likely to be `DV_CODED_TEXT` instances; either is allowed by the archetype. This has been done to reduce the size of the example, and makes no difference to the paths shown below].

The archetype path mentioned above matches both systolic pressures in the recording. In many querying situations, this may be exactly what is desired. However, to uniquely match each of the systolic pressure nodes, paths need to be created that are based not only on the *archetype_node_id* but also on another attribute. In the case above, the *name* attribute provides uniqueness. Guaranteed unique paths to the systolic and diastolic pressures of the each event (sitting and standing measurements) are available using the following expressions (identical in Xpath)¹:

```

/data/events[1]/data/items[1]/value/magnitude
/data/events[1]/data/items[2]/value/magnitude
/data/events[2]/data/items[1]/value/magnitude
/data/events[2]/data/items[2]/value/magnitude

```

More expressive unique paths based on archetype paths are also possible, as follows:

```

/data/events[at0001 and
  name/value='sitting']/data/items[at1100]/value/magnitude
/data/events[at0001 and
  name/value='sitting']/data/items[at1200]/value/magnitude
/data/events[at0001 and
  name/value='standing']/data/items[at1100]/value/magnitude
/data/events[at0001 and
  name/value='standing']/data/items[at1200]/value/magnitude

```

Each of these paths has an Xpath equivalent of the following form:

```

/data/events[@archetype_node_id='at0001' and name/value='standing']
  /data/items[@archetype_node_id='at1200']
  /value/magnitude

```

As a general rule, one or more other attribute values in the runtime data will uniquely identify any node in *openEHR* data. To make construction of unique paths easier, the value of the *name* attribute (inherited from the `LOCATABLE` class), is *required* to be unique with respect to the name values of sibling nodes. This has two consequences as follows:

- a guaranteed unique path can always be constructed to any data item in *openEHR* data using a combination of *archetype_node_id* and *name* values (as shown in the example paths above);
- the *name* value may be systematically defined to be a copy of one or more other attribute values. For example, in an `EVENT` object, name could clearly be a string copy of the *time* attribute.

11.3 EHR URIs

To create a reference to a node in an EHR in the form of a URI (uniform resource identifier), two elements are needed: the path *within* a top-level structure, and a reference *to* a top-level structure. These are combined to form a URI in an “ehr” scheme-space, obeying the following syntax:

1. the notation `attr[1]` is a Xpath shorthand for `attr[position() = 1]`

`ehr://top_level_structure_locator/path_inside_top_level_structure`

Under this scheme, any object in any *openEHR* EHR is addressable via a URI. The *openEHR* data type `DV_EHR_URI` is designed to carry URIs of this form, enabling URIs to be constructed for use within `LINKS` and elsewhere in the *openEHR* EHR. (URIs of course are only one method of addressing or querying data in the EHR. Other querying syntaxes and functional interfaces will be developed and used over time.)

11.3.1 Locating Top-Level Structures

The first part of an EHR URI needs to identify a top-level structure. As described above, a Version locator can be used to do this. However, this is not the only way: various logical queries can also be used, e.g. “get the latest version from a given Versioned object matching...”. For reasons of efficiency, the top-level structure locator part of the URI is also likely to include the EHR id, and possibly the EHR system id, even though neither of these are strictly needed for identification. Thus, the first part of an EHR URI might include the following:

- EHR id;
- EHR system id, depending on whether the EHR id is globally unique or not;
- Either:
 - version time, i.e. time baseline for retrieving versions, defaults to “now”;
 - identifier of particular Version container object, typically its *uid*;
- Or:
 - a Version identifier, i.e. {Version container object Uid; *version_tree_id*; *creating_system_id*}

For a number of reasons there is currently no standard syntax for encapsulating these parameters. Firstly, there is an issue to do with how EHRs will be identified in *openEHR* systems. Identifiers may be required to conform to local health jurisdiction requirements, or may not. If EHR identifiers are globally unique, or even nationally unique, then in theory the EHR system identifier can be dispensed with. However in a practical sense the identifier of the EHR system can only be dispensed with if there is a health information location service operating in the environment that can perform EHR id - > EHR system id mappings, in much the same way as the internet DNS converts logical domain names to IP addresses.

Another issue is whether it can be assumed that the version time baseline has already been established in some earlier call or service invocation, and that no version time information is needed.

Various syntax possibilities include:

- an Xpath-style syntax; this does not seem desirable as it implies hierarchical data containment structures that don’t exist and is likely to be confused with the path part of the URI;
- a web-services inspired functional syntax;
- a database-inspired query syntax.

Currently, a fairly typical URI query style of syntax is used, as shown in the following examples.

- This path matches a `VERSIONED_COMPOSITION`:

`ehr://rdh.health.gov.au?ehr=1234567&versioned_composition=87284370-2D4B-4e3d-A3F3-F303D2F4F34B`

- The following path matches the most recent `VERSION<COMPOSITION>` from a specified `VERSIONED_COMPOSITION`:

```
ehr://rdh.health.gov.au?ehr=1234567&versioned_composition=0892BF98-910D-4df9-BF7E-F10D72C1C81A&latest_version
```

- The following path matches a COMPOSITION within VERSION 2 of a VERSIONED_COMPOSITION:

```
ehr://rdh.health.gov.au?ehr=1234567&version={F7C5C7B7-75DB-4b39-9A1E-C0BA9BFDBDEC::au.gov.health.rdh::2}&data
```

In these paths, the following pseudo-identifiers are used:

- `versioned_composition`: to indicate an instance of VERSIONED_COMPOSITION;
- `version_tree_id`: the version identifier of the VERSION within the tree structure of the owning VERSIONED_OBJECT;
- `latest_version`: a pseudo-identifier used to indicate a VERSION instance being the result of the call VERSIONED_COMPOSITION.*latest_version*;

Implementors and users of the current release of *openEHR* are encouraged to experiment and/or propose improved solutions to the locator requirement described in this section.

12 Terminology in *openEHR*

12.1 Overview

openEHR archetypes provide a powerful way to define the meaning of clinical and related data, and to connect, or “bind”, data to recognised terminologies such as LOINC, ICDx, ICPC, SNOMED-CT and the many other terminologies and vocabularies used in healthcare. Terminology is used in *openEHR* in the following ways:

- The values of coded attributes in the reference model are defined by an “*openEHR*” terminology.
- Each archetype contains its own internal terminology, defining the meaning of each element.
- Bindings to external terminologies can be included in an archetype, allowing direct mappings to terms, or mappings to queries that return specific value sets.
- Querying the EHR using external terminologies is supported by archetype bindings.

The following sections describe these features.

12.2 Terminology to Support the Reference Model

openEHR has its own small terminology and code sets, which are used to provide the value sets of a number of attributes in the reference model. Code sets are used to express well-known internationally standardised lists of codes where the codes themselves have meaningful values e.g. the ISO 3166 country codes (“au”, “cn”, “pl” etc). Six such code sets are used by various attributes the reference model, each of type `CODE_PHRASE` (the *openEHR* type used to represent a term code).

For other coded attributes, such as `PARTICIPATION.function` in the reference model, the *openEHR* terminology takes the more orthodox route in terminology design, and defines value sets in groups using meaningless codes and rubrics. These attributes are always of type `DV_CODED_TEXT`; the code itself is contained within the *defining_code* attribute.

The *openEHR* terminology is described in the *openEHR* Terminology document¹, with computable expressions available at the *openEHR* terminology page².

12.3 Archetype Internal Terminology

Archetypes contain their own local terminology (found in the ‘ontology’ section of an archetype). The use of internal term sets is appropriate when there is no structure to the terms (ie no relationships) and when synonyms are not important. Thus, the use is limited to small flat lists of terms. The advantages of the terms being internal to the archetype, apart from computational efficiency mentioned above, are:

- Queries can be based on archetypes alone and do not require interacting with a terminology server;
- Translation of the terms is made within an explicit thematic context (since every archetype is about a specific topic) and is therefore far more likely to be accurate;

1. <http://svn.openehr.org/specification/TRUNK/publishing/architecture/terminology.pdf>

2. <http://svn.openehr.org/specification/TRUNK/publishing/architecture/computable/terminology/terminology.html>

- Many terms required in archetypes are not available even in very large terminologies;
- People can share data based on archetypes even if they do not share terminologies.

It is clear, however, that many archetypes require a connection to external terminologies to provide the full benefits of automatic processing; this is described in the next section.

The internal terminology takes the form of a set of {code, text, description} semantic definitions for each node of the archetype structure. Each such term is identified by an “at” (archetype term) code, e.g. [at0012]. Each code defined locally in an archetype is used for one of two purposes:

- either to semantically identify the data nodes of the archetype (i.e. to “name” the data), or
- to provide value-sets for leaf attributes.

For example, the local codes in an “Apgar result”¹ archetype could contain terms for “1 minute event” and “2 minute event”. These codes are associated with the reference model nodes within the ‘definition’ part of the archetype. In the Apgar example, the two codes (say [at0003] and [at0026]) will be mapped to nodes of reference model type EVENT (rm.data_structures.history package), as shown in FIGURE 34. It is this mapping that is the basis for archetype paths: an archetype path is simply the alternating pattern of reference model attribute names and node codes.

```
OBSERVATION[at0000] matches {                                -- Apgar score
  data matches {
    HISTORY[at0002] matches {                                -- history
      events cardinality matches {1..*; unordered} matches {
        POINT_EVENT[at0003] occurrences matches {0..1} matches {-- 1 minute
          offset matches { |PT1M| }
          data matches {
            ITEM_LIST[at0001] matches {-- structure
              items cardinality matches {0..1; ordered} matches {
                ELEMENT[at0005] occurrences matches {0..1} matches {-- Heart
                  value matches {
                    ORDINAL matches {
                      value matches {
                        0|[local::at0006], -- No heart beat
                        1|[local::at0007], -- Less than 100 bpm
                        2|[local::at0008] -- Greater than 100 bpm
                      }
                    }
                  }
                }
              }
            }
          }
        }
      }
    }
  }
  ...
}
POINT_EVENT[at0026] occurrences matches {0..1} matches {-- 2 minute
  offset matches { |PT2M| }
  data matches {
    use_node ITEM_LIST /data[at0002]/events[at0003]/data[at0001]
  }
}
...
```

FIGURE 34 Apgar archetype definition (extract)

The second use of local codes is as values. In FIGURE 34, the ELEMENT node identified by code [at0005] has as its value constraint an ORDINAL type whose values can be 0, 1, or 2. Each of these

1. Apgar is a basic measure of health of a newborn, taken 2 or 3 times after delivery, in the form of a 0-10 score.

values is coded by the codes [at0006], [at0007], and [at0008]. An extract of the archetype ontology showing these terms is shown in FIGURE 35.

```
ontology
  primary_language = <"en">
  languages_available = <"en", "en-us">
  terminologies_available = <"LNC205", ...>
  term_definitions = <
    ["en"] = <
      items = <
        ["at0000"] = <
          description = <"Clinical score derived from assessment of
            breathing, colour, muscle tone, heart rate and reflex
            response usually taken at 1, 5 and 10 minutes after birth">
          text = <"Apgar score">
        >
        ["at0003"] = <
          description = <"Apgar score at one minute">
          text = <"1 minute">
        >
        ["at0006"] = <
          description = <"No heart beat is present (palpation at base of
            umbilical cord)">
          text = <"No heart beat">
        >
        ["at0007"] = <
          description = <"Heart rate of less than 100 beats per minute">
          text = <"Less than 100 beats per minute">
        >
        ["at0008"] = <
          description = <"Heart rate of greater than or equal to 100
            beats per minute">
          text = <"Greater than 100 beats per minute">
        >
        ["at0026"] = <
          description = <"Apgar score 2 minutes after birth">
          text = <"2 minute">
        >
      >
    >
  >
  term_binding = <
    ["LNC205"] = <
      items = <
        ["/data[at0002]/events[at0003]/data/items[at0025]" =
          <[LNC205::9272-6]> -- 1 minute total
        ["/data[at0002]/events[at0026]/data/items[at0025]" =
          <[LNC205::9271-8]> -- 2 minute total
      >
    >
  >
```

FIGURE 35 Apgar archetype ontology section (extract)

12.4 Binding to External Terminologies

Binding External Terminology Codes to Archetype Codes

The first kind of binding is the ability within an archetype to map an internal code to a code from an external terminology. The bindings are grouped on the basis of external terminology, allowing any given internal code in an archetype to be bound to codes in multiple terminologies. Usually, coverage provided by external terminologies is incomplete, and the mappings may be approximate, so care

must be taken in creating the mappings in the first place. In the example shown in FIGURE 35, two paths are shown respectively as being bound to LOINC codes for 1-minute and 2-minute Apgar total. In this example, the whole path is bound, meaning that the mapping only holds between [at0025] and [LNC205::9272-6] when [at0025] occurs in the first path; when it occurs in the second path, the mapping is to a different LOINC code. This is how so-called “pre-coordinated” codes from external terminologies can be mapped to an *openEHR* archetype concept.

Bindings can also be made between atomic internal codes and external codes, in which case the meaning is that the mapping always holds, no matter how many times the internal code is used within the archetype.

Binding Terminology Value-sets to Archetypes

An important requirement with respect to terminology is that of specifying value sets for attributes defined in archetypes. Sometimes value sets are defined locally within the archetype, because the terms are not available in published terminologies, and in any case may be too hard to define therein, due to the lack of encapsulation. The terms “no effort”, “moderate effort” and “crying” for example are recognised values for the “breathing” attribute of an Apgar result¹. In the context of Apgar / breathing, the meanings are clear; clearly however a term with this rubric within a terminology like SNOMED-CT would need to be pre-coordinated. More importantly, there seems to be little business value in mapping a SNOMED term for “no effort”, since a query for items containing “no effort” is unlikely to be useful in a clinical context.

For many other kinds of attributes however, terminologies are an appropriate source of values. Often such attributes define kinds of real world phenomena, such as kinds of disease and blood groups, rather than qualities of a phenomenon such as “no effort”, or “blue”. For these attributes a different kind of connection to external terminology is required. This is achieved in a similar way as for single code bindings: an internal code is defined, in this case an “ac” code (“ac” = archetype constraint), and this is bound to queries to one or more external terminologies, whose result would be a (possibly structured) value set from that terminology. The logical scheme is illustrated in FIGURE 36, where the attribute value to be coded is “blood group phenotype”.

Currently there is no standard for such queries. This does not affect archetypes directly, since they simply hold an *identifier* for a query; the query itself is defined within a “terminology query server”. The result of this query is a list of blood group phenotypes, which might appear as shown at the bottom of FIGURE 36.

12.5 Querying using External Terminologies

Querying through EHR data is frequently cited to be the major utility of terminology with respect to health information. With the mappings defined in archetypes, a number of approaches are possible, however the semantics of the intended query need to be understood first. Consider a query for “adenocarcinoma” on a patient record. SNOMED-CT includes 63 terms beginning with “adenocarcinoma” (and 171 terms which include the word as a secondary part of the phrase), some as children of a common parent. Nevertheless, the terms do not *all* have a single common parent; a choice has to be made of which terms correspond to the intent of the query. If it is to find any previous diagnosis of “adenocarcinoma”, then at least the terms of the form “adenocarcinoma of lung” [snomed-ct::254626006], “... of liver” have to be included. These are within the “clinical finding” hierarchy, so the use of these latter terms should ensure that matches are not made with other uses of the same terms in the record,

1. See Apgar archetype - <http://svn.openehr.org/knowledge/archetypes/dev/html/en/openEHR-EHR-OBSERVATION.apgar.v1.html>

Archetype

```

definition
....
ELEMENT[at0004] matches { -- blood phenotype
  1 value matches {
    CODE_TEXT matches {[ac0002]} 2
  }
}
ontology
  constraint_definitions = <
    ["en"] = <
      ...
      ["ac0002"] = <
        text = <"a blood phenotype">
      >
    >
  >
  constraint_bindings = <
    ["snomed-ct"] = <
      ...
      ["ac0002"] = <http://tqs.openEHR.org/2938495>
    >
  >

```

- 1 = the attribute requiring a value-set
- 2 = the archetype-local id for the constraint
- 3 = the archetype-local definition of the constraint (= what to put on the screen if no codes available)
- 4 = binding to a query identifier in an online terminology query server

Children of ABO group phenotype (4)	Children of Blood group B (4)
<input type="checkbox"/> Blood group A	<input checked="" type="checkbox"/> Blood group B Rh(D) negative
<input type="checkbox"/> Blood group AB	<input type="checkbox"/> Blood group B Rh(D) positive
<input checked="" type="checkbox"/> Blood group B	<input type="checkbox"/> Blood group B variant
<input type="checkbox"/> Blood group O	<input type="checkbox"/> Blood group B>h<

What might appear on the screen

FIGURE 36 Archetype Constraint Binding

e.g. “fear of adenocarcinoma” or “minimal risk of adenocarcinoma”. Such correct matching is completely dependent upon the correct use of SNOMED-CT terms in the first place by the software application and/or user creating the data. It is easy to imagine an application that saves data (including openEHR data) in the form of two name/value pairs: {“principal diagnosis”, [snomed-ct::35917007] (“adenocarcinoma”)} and {“site”, “lung”}. Querying using “adenocarcinoma of lung” [snomed-ct::254626006] will fail, even though this is exactly the meaning of the data. The data are not wrong as such, but the lesson is clear: coding of data and code use in queries must be governed by common models, otherwise there is no hope of reliably processing the data.

Under the openEHR approach, path-based querying can be used to specify (for example):

“EVALUATIONS based on a problem-diagnosis-histological_staging archetype” with a value at the path /data/items[at0002.1.1]/value/code (histological diagnosis) equal-to-or-subsumed-by “clinical finding” and equal-to-or-subsumed-by “adenocarcinoma”.

The assumption here is that the value at this path was *originally* restricted by the archetype from which the path is taken, to conforming to the relation {is-a “clinical finding” and is-a “abnormal morphological mass”}. Any finding of adenocarcinoma of the lung is then forced to be from the resulting subsumption hierarchy; other “adenocarcinoma” terms cannot be wrongly used in this position.

However, even if the archetype had not restricted the value in this way, the same query which searched for any “adenocarcinoma” term at the same path could reasonably be used to locate “previous diagnoses of adenocarcinoma”, since this is the only use of the archetype. In a similar way, archetype path-based querying can be used to distinguish the other potential ambiguities described in section 6.4 on page 29.

13 Deployment

13.1 5-tier System Architecture

Previous sections have described the software architecture of the *openEHR* specifications. Here we describe how the package architecture can be applied to building real systems. The general architectural approach in any *openEHR* system can be considered as 5 layers (i.e. a “5-tier” architecture). The tiers are as follows.

1. **persistence:** data storage and retrieval.
2. **back-end services:** including EHR, demographics, terminology, archetypes, security, record location, and so on. In this layer, the separation of the different services is transparent, and each service has a coarse-grained service interface.
3. **virtual EHR:** this tier is the middleware, and consists of a coherent set of APIs to the various back-end services providing access to the relevant services, thereby allowing user access to the EHR; including EHR, demographics, security, terminology, and archetype services. It also contains an archetype- and template-enabled kernel, the component responsible for creating and processing archetype-enabled data. In this tier, the separation of back-end services is hidden, only the functionality is exposed. Other virtual clients are possible, consisting of APIs for other combinations of back-end services.
4. **application logic:** this tier consists of whatever logic is specific to an application, which might be a user application, or another service such as a query engine.
5. **presentation layer:** this layer consists of the graphical interface of the application, where applicable.

The same tiers can be used in large deployments, as shown in FIGURE 37, or simply as layers in single-machine applications.

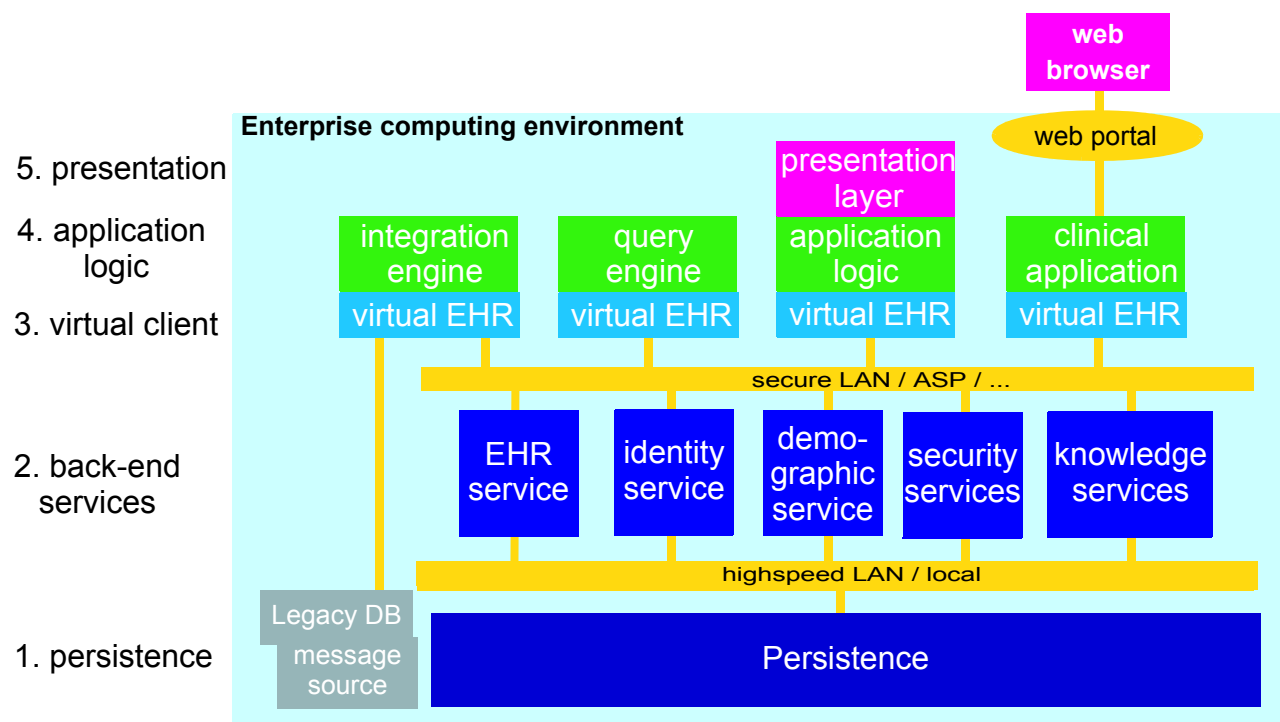


FIGURE 37 Basic Enterprise EHR System Architecture

FIGURE 38 illustrates an approximate mapping of major parts of the *openEHR* software architecture to the 5-tier scheme. Clearly where parts of the architecture are used will depend on various implementation choices; the mapping shown is therefore not definitive. Nevertheless, the principal use of parts of the architecture is likely to be similar in most systems, as follows:

- RM and AM: mainly used to construct an archetype- and template-processing kernel;
- RM `common.change_control` package: provides the logic for versioning in versioned services such as the EHR and demographics;
- SM: various service model packages define the exposed interfaces of major services;
- SM `virtual_ehr` package defines the API of the virtual EHR component;
- archetypes: archetypes might be assumed directly in some applications, e.g. a specialist peri-natal package might be partly based on a family of archetypes for this specialisation;
- templates: both archetypes and templates will be used in the presentation layer of applications. Some will base the GUI code on them, while others will have either tool-generate code, or dynamically generate forms based on particular templates and archetypes.

In the future, an abstract persistence API and optimised persistence models (transformations of the existing RM models) are likely to be published by *openEHR* in order to help with the implementation of databases.

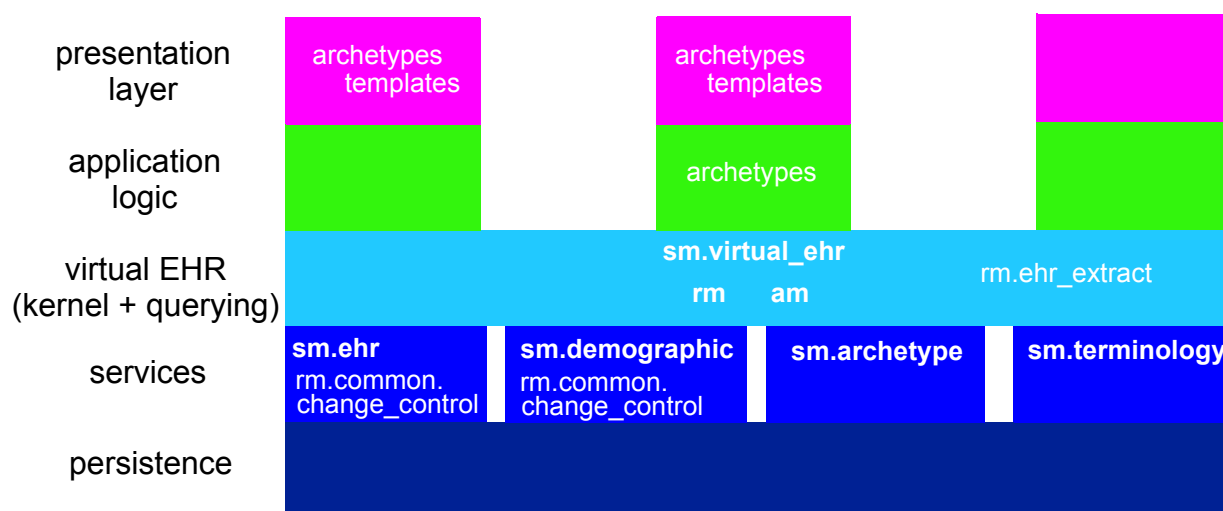


FIGURE 38 Mapping of software architecture to deployment architecture

14 Integrating *openEHR* with other Systems

14.1 Overview

Getting data in and out of the EHR is one of the most basic requirements *openEHR* aims to satisfy. In “greenfield” (new build) situations, and for data being created by GUI applications via the *openEHR* EHR APIs, there is no issue, since native *openEHR* structures and semantics are being used. In almost all other situations, existing data sources and sinks have to be accounted for. In general, external or ‘legacy’ data (here the term is used for convenience, and does not imply anything about the age or quality of the systems in question) have different syntactic and semantic formats than *openEHR* data, and seamless conversion requires addressing both levels.

Existing data sources and sinks include relational databases, HL7v2 messages, HL7 CDA documents and are likely to include CEN EN13606 data. HL7v2 messages are probably one of the most common sources of pathology messages in many countries; EDIFACT messages are another. More recently, HL7v2 messages have been designed for referrals and even discharge summaries. Not all legacy systems are standardised; most hospital and GP products have their own private models of data and terminology usage.

The primary need with respect to legacy data is to be able to convert data from multiple mutually incompatible sources into a single, standardised patient-centric EHR for each patient, that can then be longitudinally viewed and queried. This is what enables GP and specialist notes, diagnoses and plans to be integrated with laboratory results from multiple sources, patient notes, administrative data and so on, to provide a coherent record of the patient journey.

In technical terms, a number of types of incompatibility have to be dealt with. There is no guarantee of correspondence of scope of incoming transactions and target *openEHR* structures - an incoming document for example might correspond to a number of clinical archetypes. Structure will not usually correspond, with legacy data (particularly messages) usually having flatter structures than those defined in target archetypes. Terminology use is extremely variable in existing systems and messages, and also has to be dealt with. Data types will also not correspond directly, so that for example, a mapping between an incoming string “110/80 mmHg” and the target *openEHR* form of two DV_QUANTITY objects each with their own value and units has to be made.

14.2 Integration Archetypes

The foundation of a key approach to the integration problem is the use of two kinds of archetypes. So far in this document “archetypes” has meant “designed” archetypes, generally clinical, demographic or administrative. The common factors for all such archetypes are:

- they are based on the main part of the reference model, particularly the Entry subtypes OBSERVATION, EVALUATION, INSTRUCTION and ACTION;
- they are consciously designed from scratch by groups of domain specialists, and integrated into the existing library of *openEHR* archetypes;
- there is one archetype per identifiable health “concept”, such as an observation type, person type etc.

A second category of archetypes is “integration” archetypes. These are characterised as follows:

- they are based on the same high-level types (COMPOSITION, SECTION etc), but use the Entry subtype GENERIC_ENTRY (see EHR Information Model);

- they are designed to mimic the structure of legacy or existing data or messages; the design effort therefore is completely different, and is more likely to be done by IT or other technical staff who are familiar with the structures of the incoming data;
- there is one integration archetype per message type or identifiable source data that makes sense as a transaction to the EHR.

In the data integration environment, “designed” archetypes always define the target structures, coding and other semantics of data, while “integration” archetypes provide the means mapping of external data into the *openEHR* environment.

14.3 Data Conversion Architecture

The integration archetype-based strategy for importing data into an *openEHR* system, shown in FIGURE 39, consists of two steps.

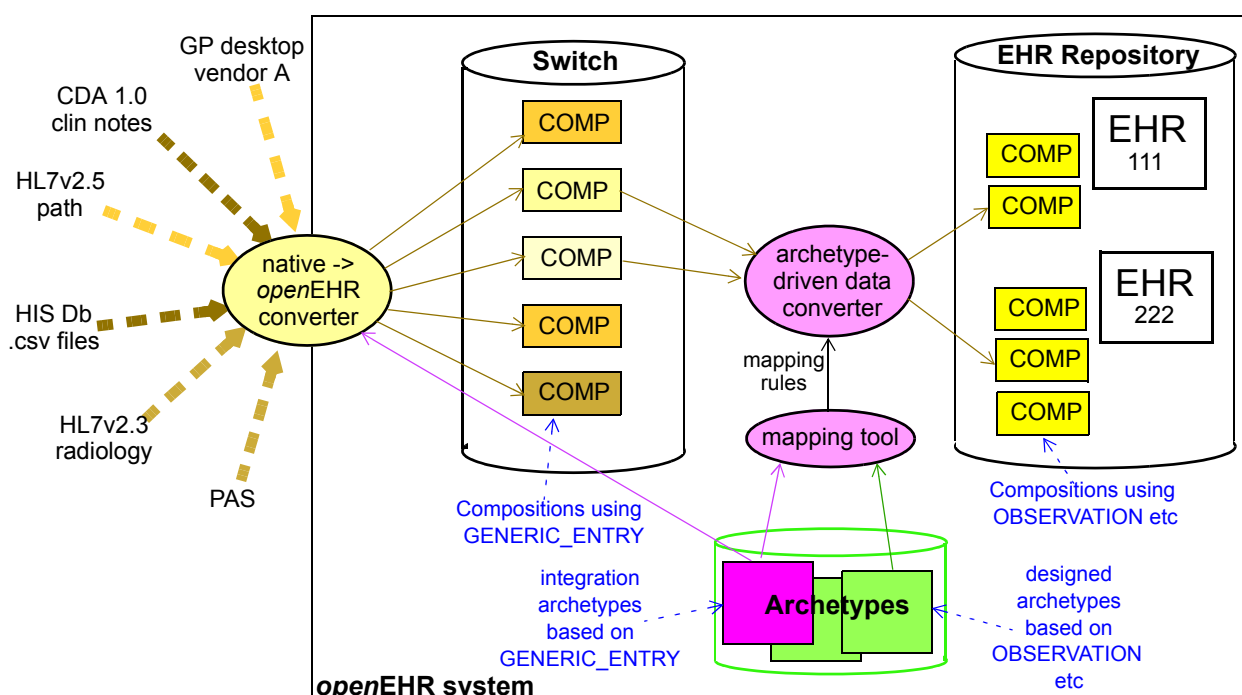


FIGURE 39 Data Integration using *openEHR*

Firstly, data are converted from their original syntactic format into *openEHR* COMPOSITION/SECTION/GENERIC_ENTRY structures, shown in the *openEHR* integration switch. Most of the data will appear in the GENERIC_ENTRY part, controlled by an integration archetype designed to mimic the incoming structure (such as an HL7v2 lab message) as closely as possible; FEEDER_AUDIT structures are used to contain integration meta-data. The result of this step is data that are expressed in the *openEHR* type system (i.e. as instances of the *openEHR* reference model), and are immediately amenable to processing with normal *openEHR* software.

In the second step, semantic transformation is effected, by the use of mappings between integration and designed archetypes. Such mappings are created by archetype authors using tools. The mapping rules are the key to defining structural transformations, use of terminological codes, and other changes. Serious challenges of course remain in the business of integrating heterogeneous systems; some of these are dealt with in the Common IM document sections on Feeder systems.

15 Relationship to Standards

The *openEHR* specifications make use of available standards where relevant, and as far as possible in a compatible way. However, for the many standards have never been validated in their published form (i.e. the form published is not tested in implementations, and may contain errors), *openEHR* makes adjustments so as to ensure quality and coherence of the *openEHR* models. In general, “using” a standard in *openEHR* may mean defining a set of classes which map it into the *openEHR* type system, or wrap it or express it in some other compatible way, allowing developers to build completely coherent *openEHR* systems, while retaining compliance or compatibility with standards. The standards relevant to *openEHR* fall into a number of categories as follows.

Standards by which *openEHR* can be evaluated

These standards define high-level requirements or compliance criteria which can be used to provide a means of normative comparison of *openEHR* with other related specifications or systems:

- **ISO/TR 20514.** Health informatics — Electronic health record — Definition, scope, and context. ISO TC 215/WG 1.
- **ISO/TS 18308.** Technical Specification for Requirements for an EHR Architecture. ISO TC 215/WG1.

Standards which have influenced the design of *openEHR* specifications

The following standards have influenced the design of the *openEHR* specifications:

- **OMG HDTF Standards** - general design
- **CEN EN 13606:2006:** Electronic Health Record Communication
- **CEN HISA 12967-3:** Health Informatics Service Architecture - Computational viewpoint

Standards which have influenced the design of *openEHR* archetypes

The following standards are mainly domain-level models of clinical practice or concepts, and are being used to design *openEHR* archetypes and templates.

- **CEN HISA 12967-2:** Health Informatics Service Architecture - Information viewpoint
- **CEN ENV 13940:** Continuity of Care.

Standards which are used “inside” *openEHR*

The following standards are used or referenced at a fine-grained level in *openEHR*:

- **ISO 8601:** Syntax for expressing dates and times (used in *openEHR* Quantity package)
- **ISO 11404:** General Purpose Data types (mapped to in *openEHR* `assumed_types` package in Support Information Model)
- **HL7 UCUM:** Unified Coding for Units of Measure (used by *openEHR* Quantity data type)
- **HL7v3 GTS:** General Timing Specification syntax (used by *openEHR* Time specification data types).
- some HL7v3 domain vocabularies are mapped to the *openEHR* terminology.
- **IETF RFC 2440** - openPGP.

Standards which require a conversion gateway

The following standards are in use and require data conversion for use with *openEHR*:

- **CEN EN 13606:2005:** Electronic Health Record Communication - near-direct conversion possible, as *openEHR* and CEN EN 13606 are actively maintained to be compatible.

- **HL7v3 CDA:** Clinical Document Architecture (CDA) release 2.0 - fairly close conversion may be possible.
- **HL7v3 messages.** Quality of conversion currently unknown due to flux in HL7v3 messaging specifications and diversity of message schemas.
- **HL7v2 messages.** Importing of HL7v2 message data is technically not difficult, and is already used in some *openEHR* systems. Export from *openEHR* may also be possible.

Generic Technology Standards

The following standards are used or referenced in *openEHR*:

- ISO RM/ODP
- OMG UML 2.0
- W3C XML schema 1.0
- W3C Xpath 1.0

16 Implementation Technology Specifications

16.1 Overview

ITSs are created by the application of transformation rules from the “full-strength” semantics of the abstract models to equivalents in a particular technology. Transformation rules usually include mappings of:

- names of classes and attributes;
- property and function signature mapping;
- mapping of basic types e.g. strings, numerics;
- how to handle multiple inheritance;
- how to handle generic (template) types;
- how to handle covariant and contravariant redefinition semantics;
- the choice of mapping properties with signature $xxxx:T$ (i.e. properties with no arguments) to stored attributes ($xxxx:T$) or functions ($xxxx():T$);
- how to express pre-conditions, post-conditions and class invariants;
- mappings between assumed types such as `List<>`, `Set<>` and inbuilt types.

ITSs are being developed for a number of major implementation technologies, as summarised below. Implementors should always look for an ITS for the technology in question before proceeding. If none exists, it will need to be defined. A methodology to do this is being developed.

FIGURE 40 illustrates the implementation technology specification space. Each specification documents the mapping from the standard object-oriented semantics used in the *openEHR* abstract models, and also provides an expression of each of the abstract models in the ITS formalism.

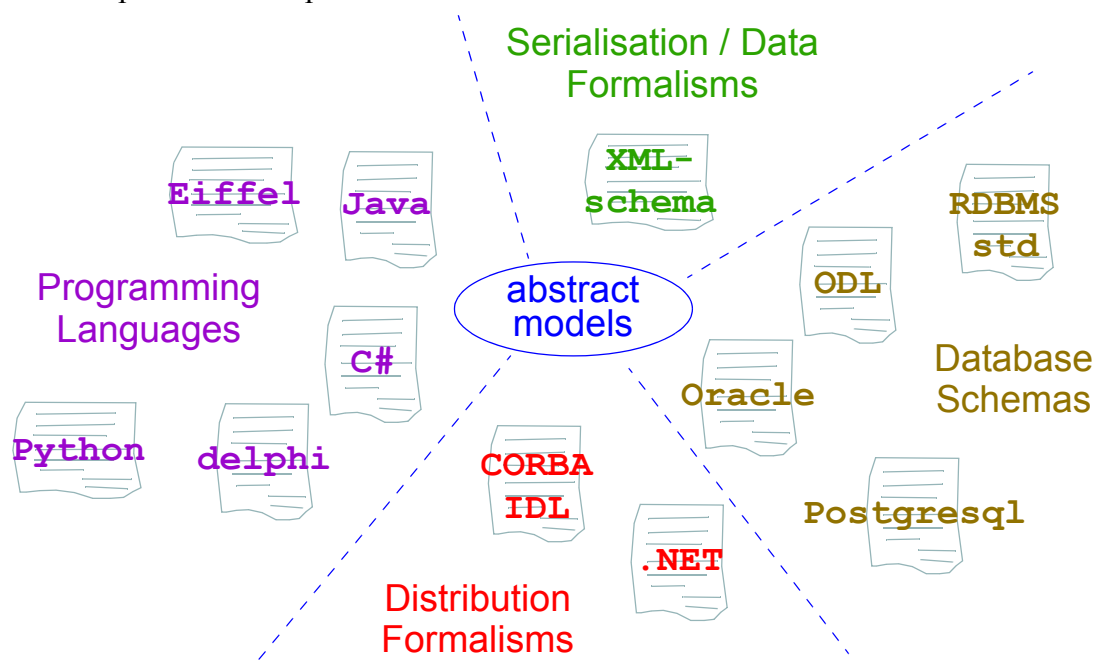


FIGURE 40 Implementation Technologies

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