The *open*EHR Archetype System

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The *open*EHR foundation

is an independent, non-profit community, facilitating the creation and sharing of health records by consumers and clinicians via open-source, standards-based implementations.

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Amendment Record

Issue	Details	Who	Completed
0.3.1	Updated diagram; added notes on dissemination network.	S Heard	20 Dec 2003
0.3	Initial Writing	T Beale	29 Nov 2003

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1 Introduction

1.1 Purpose

This document provides a description of the *open*EHR Archetype System, a network of archetype authoring, quality assurance and propagation to archetype-enabled information systems.

1.2 Overview

The Archetype "System" is a global system consisting of two parts: the first is collaborative archetype development, review and publishing; and the second is online propagation of published, approved archetypes to runtime systems. In the first "network", the key features are collaborative development, testing and review by domain experts, enabled by a managed archetype document lifecycle; this network functions like an open source network of developers using version control repositories to share and maintain their deliverables. The second network functions more like the DNS in that it is a high-speed, caching, runtime access mechanism for systems to obtain published archetypes. Archetypes migrate from the development network to the dissemination network via a quality assurance process which is undertaken by recognised expert bodies (e.g. national institute of classification, international college of oncologists) and overseen by recognised standards organisations.

2 Archetype design principles

Defining the information complexes required for interoperability is a complex task. There is a clear opportunity to solve many of the issues of health care computing, but if this is not taken up generally then little will be achieved. The approach taken in the *open*EHR architecture is described in this document and is a straight forward attempt to make these as generic and widely useful as possible. There are a number of developments that make this possible and worthwhile.

First, it is possible to express the archetypes - which must always be a constraint on an underlying information or data model - in terms of a ‘harmonised’ information model. The harmonised information model is a somewhat abstract expression of the common features of a number of key EHR information models in development. The has been possible through the efforts of those working in EHR standards development and, in particular, to the substantial harmonisation of the *open*EHR reference model, the HL7 Clinical Document Architecture and CEN ENV13606.

> **Design principle 1:** Archetypes are expressed as constraints on a ‘generic’ EHR information model which shares the features of the major models being developed in this domain.

Second, there is a growing interest in making the many decision support tools that have been shown to deliver real benefits for patients and providers in specific implementations available in a generic form. This requires a view of the EHR which is generic and generalisable. The *open*EHR approach, and archetypes in particular, offer this possibility. Infact, archetypes provide the means of expressing any information requirements in terms of the harmonised information model. This is of interest to national data collections as well as applications which need to run queries on EHRs.

> **Design principle 2:** The archetypes allow a generic interface to the EHR to be developed, with specific queries being based on the ‘archetypes’ used to validate data during data entry or aquisition.

Finally, the ability to share information across language barriers is critical in a number of countries - Belgium and Canada being two examples. The archetype methodology has removed all language primacy to achieve international utility and acceptance. The methodology has also removed primacy of any particular terminology. The aim of this approach is quite straight forward; a person in a small country without access to any information resources should be able to build and express an archetype. If this is taken up internationally then language translations must be able to be added post hoc. When a terminology is deemed to be applicable in the archetype, bindings should be able to be added at any time.

> **Design principle 3:** There is no language or terminology primacy in archetypes: that is to say, archetypes should be able to be developed without access to terminology and in any language - with the ability to add translations and terminology links at any time.

This rather liberal approach which underpins the design of new archetypes has to be balanced with a means of ensuring interoperability is achieved through the sharing of these concepts. As people travel and software is available globally, this sharing of information in a form that can be automatically processed should be achieved, to the extent required, internationally. Such a requirement demands a thoroughly designed system to ensure that this is the case.

> **Design principle 4:** The system for developing archetypes should enable international sharing of personal health information (i.e. electronic health records),

> and the sharing of software which offers significant improvements in patient care, safety or population health.

It is clear that the laudible aim of international agreement on the concepts we need to share to enable interoperable health care systems will not actually be achieved - it would require too much time spent agreeing such matters. A further barrier is the pace of change in health care, and increasing diversity of care paradigms. But, there are features of the archetype system that we should try and achieve. These are:

- the system should allow local adaption to meet local needs while preserving the more general concepts that are required for generally available software and automatic processing;
- the system should allow evolution of health care concepts over time, with increasing (or even decreasing) agreement about what should be shared locally, nationally and internationally; and
- the system should enable the tools and processes required for standardisation and propogation of standardised concepts.

> **Design principle 5:** The archetype system should support local adaptation, general evolution of concepts and the process of increasing standardisation.

2.1 Detailed points

Using archetypes effectively to enable sematic interoperability requires a number of formal processes to be instituted. These processes must deal with the archetype lifecycle and in particular:

- Authoring a new version - generating new semantics
- Specialisation - providing further constraint on information already expressed in the archetype
- Revision - adding to the constraint at the same level of specialisation

Consider an archetype designed to record information about a given concept. This archetype is ‘version 1’ when it is first published and may be considered. There are three possible further processes that might be undergone by this archetype: specialisation of this archetype which will generate a new archetype; to revise the archetype (a continuation of the original authoring process) to include extra features but to leave all prior features as they were; and to re-author the archetype changing the features in a way that is no longer compatible with the previous version. These lifecyle steps are considered individually below. It must be recognised that a specialisation could itself be revised, and that re-authoring archetypes will have implications for their specialisations.

2.1.1 Authoring a new archetype or version

Authoring a new archetype or version is required when there is a new concept that needs to be shared. The new concept may replace a concept that has previously been archetyped: if so then the archetype will be published as a new version of the archetype for the redundant concept.

The publication process will determine which features of the concept will be recorded as data, mandatory and optional, and develop the terms required to express the concept. If the archetype is a new version but with substantive overlap then a sample ‘script’ will be written to enable transformation of data stored in the old archetype to be represented in the new archetype.

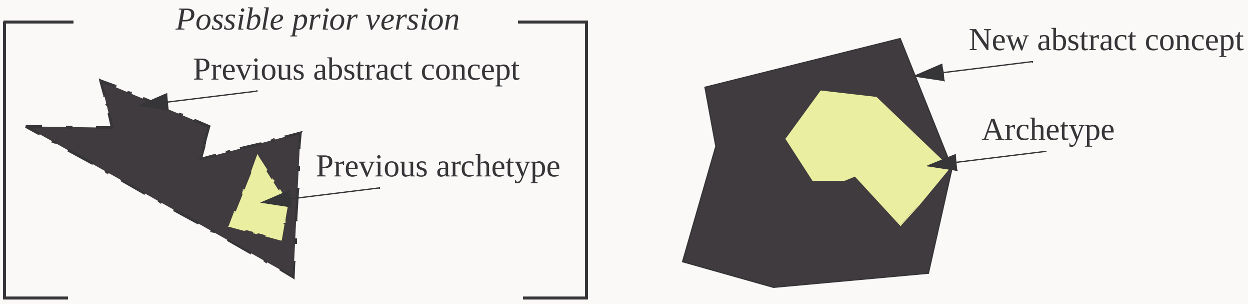

FIGURE 1 Archetype authoring (including new version)

Concepts that are to be archetyped need to be whole, discreet and reuseable as described in FIXME.

2.1.2 Specialisation

Specialisation of archetypes enables further constraining of a parent archetype to allow for use in a more specific situation while maintaining the information linkage with the parent archetype. The purpose is the same as in object oriented programming - to enable the parent and the specialisations to be treated as one when the features of the parent are interogated.

A simple general example to illustrate this is the specialisation of animal to mammal. The concept of animal may be very general with features such as ‘number of legs’ as an integer and diet as a string. The concept of mammal will have number of limbs and diet but might also have new features such as duration of lactation which are specific to mammals. The advantage is that when we seek to know how many limbs an animal has we do not need to know if it is a mammal or not.

In a clinical setting, similar situations arise. Consider the idea of heart rate - a basic measurement of the body. This is usually recorded on the basis of pulse (called a pulse rate) and measured at the wrist - in fact a measure of the mechanical heart rate. Electrical devices measure heart rate through electrical means and are measuring the electrical rate of the heart ventricle - this is usually the mechanical heart rate also - but will differ under some circumstances. If a clinician wants to review the heart rate of a patient over a period of time the pulse rate will be of interest and in many circumstances will be the only record of the heart rate. Specialisation of heart rate to pulse rate is useful for this purpose - they share two features - rate and rhythm. Pulse has a further feature usually called character. Thus a general search for heart rate can return the features of rate and rhythm from electrical and mechanical measurements if required based on a generic approach. Such specialisations are useful in a number of clinical concepts such as:

- condition/problem
    - diagnosis (adds coded data, diagnostic criteria, clinical staging etc)
        - histological diagnosis (adds histological description and staging)
    - accident/injury (adds external cause, insurance, self inflicted)
    - disability (adds functional features)
    - genetic (adds phenotype information)

Specialisation of an archetype must obey certain rules to ensure that their usefulness is maintained. It involves renaming of the archetype (as the specialisation is a new specification) and ‘extension’ of the term identifiers used in the archetype (i.e. the ‘AT’ codes). This renaming and extension means that queries expressed in terms of an archetype and AT codes will return results from all specialisations without necessarily knowing about those specialisations. This is the utility of this approach.

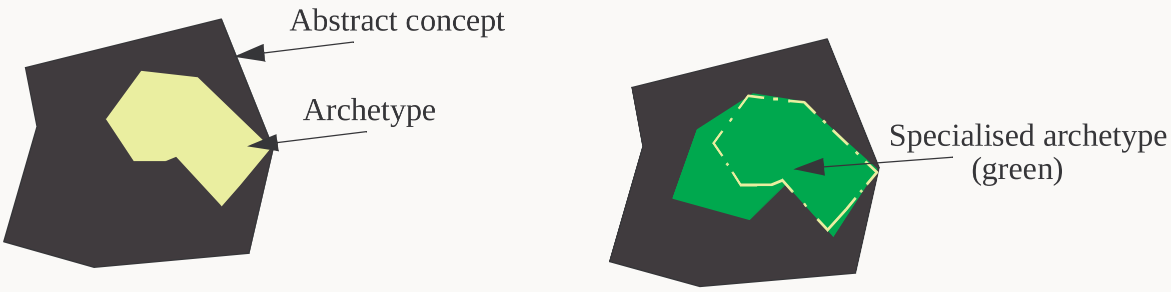

FIGURE 2 Archetype specialisation

The rules governing specialisation are:

1. The data that conforms to a specialised archetype will also conform to a parent archetype. That is to say that, as a minimum, all mandatory data elements in the parent are present in the specialisation.both and the data types are the same or the specialisations

For all terms:

- Terms that are already specialised at the level of the archetype cannot be further specialised without specialising the archetype itself.
- All terms created at a level in the archetype specialisation are themselves specialised at that level.

For terms used as node identifiers:

- A *node-identifying* term can only be specialised according to the cardinality of the node in the parent archetype - if the maximum cardinality is 1 then the term can only be specialised once.
- A complete archetype must be specialised before any *node-identifying* terms within it can be specialised.

For terms used as content:

- Terms used as content do not have cardinality and as such can be specialised multiple times if required.

2.1.3 Revisions

Revisions are of two forms - revisions to the archetype definition and revisions to the ontology. Revisions must be published by the archetype authority in order that the integrity of the knowledge model is preserved and quality control is assured. The different revisions will be considered separately.

2.1.3.1 Revisions to the archetype definition

Archetype definitions can be revised in a manner that further constrains the concept expressed in the archetype. Adding constraints may appear to be ‘extending’ the concept - but it is really extending the constraint model that applies to the concept to achieve greater semantic interoperability or utility.

The rules for revising an archetype are straight forward.

- There can be no specialisation involved
- There is no change to any aspect of the prior archetype
- There are only additional constraints or terms - no removal of any features

- There is general agreement that this is warranted across the user community
- Revisions can only be made and published by a publishing authority - it is not a feature of local adaptation (unlike specialisation)

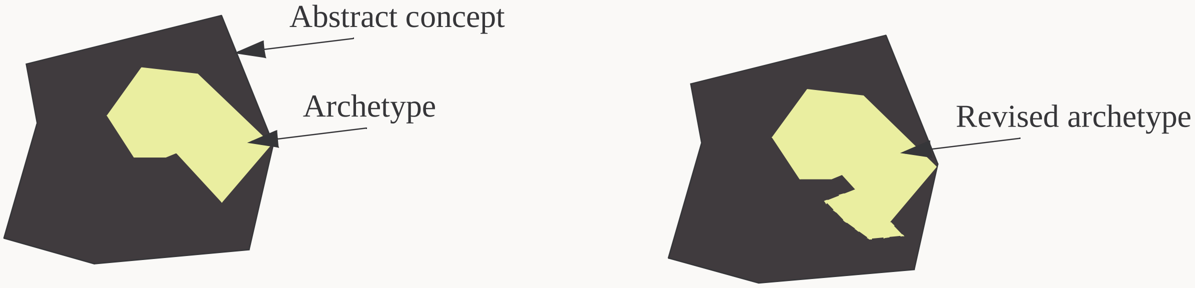

FIGURE 3 Archetype Revision

2.1.3.2 Revisions to the ontology

Revisions to the ontology allow for addition of languages and terminologies to the model. FIXME - need more on this.

Adding a language - quality control

Adding a terminology - quality control

Altering the text or description associated with a term - if this is the primary language then the archetype will need to be reviewed by all language custodians.

2.1.4 Updating of the reference model

FIXME - we need to think about this - all archetypes will need to be validated against the new reference model.

3 Template design principles

Templates describe what is possible at the time of data collection. Templates are expressed in terms of archetypes - they do not add meaning to the data.

> **Design principle 6:** Templates do not add to or in any way alter the semantics as expressed in the underlying archetypes.

Templates, like archetypes, are documents and can be shared. Their use is to express the data collection requirements for specific clinical situations - many will be situation specific and some will express the requirements of individual users. From this we can deduce that just a few archetypes may lead to a plethora of templates.

As templates only express information in terms of archetypes re-authoring (or versioning) of an archetype is the only manner that templates may develop errors.

> **Design principle 7:** Templates must relate to specific versions of archetypes.

Templates express constraints through aggregation and through further constraining specific archetypes. They may describe:

- Which archetypes must be used (i.e. are mandatory)
- Which archetypes may be used (i.e. are optional)
- Which optional nodes of the archetypes are not utilised
- Which optional nodes of the archetypes are mandatory
- Which ‘fillers’ for a slot are optional
- Which ‘fillers’ for a slot are mandatory
- Which language (or languages) are available to the user
- Which terminology (or terminologies) are available to the user at each node
- Which optional values of any element are available
- Which optional value of any element is the default value

> **Design principle 8:** There is a defined set of constraints that can be expressed in a template - all relate to archetypes.

Because templates do not describe the semantics of the data, their use does not have to be recorded in the EHR - but it may be if required. The recording of a template is not part of the reference model information and should itself be archetyped so that the recording meets clinical needs.

> **Design principle 9:** The use of a template does not have to be recorded in the EHR.

4 The Archetype System

The Archetype System consists of two “networks” of communication: one ‘authoring’ or development network which operates among human authors of archetypes, and one ‘Dissemination’ network which provides inter-system communication of archetypes for runtime use. Archetypes are created or edited within the first environment, which includes limited local authoring of specialisations, and migrate into the second via a quality assurance process, as shown in FIGURE 4.

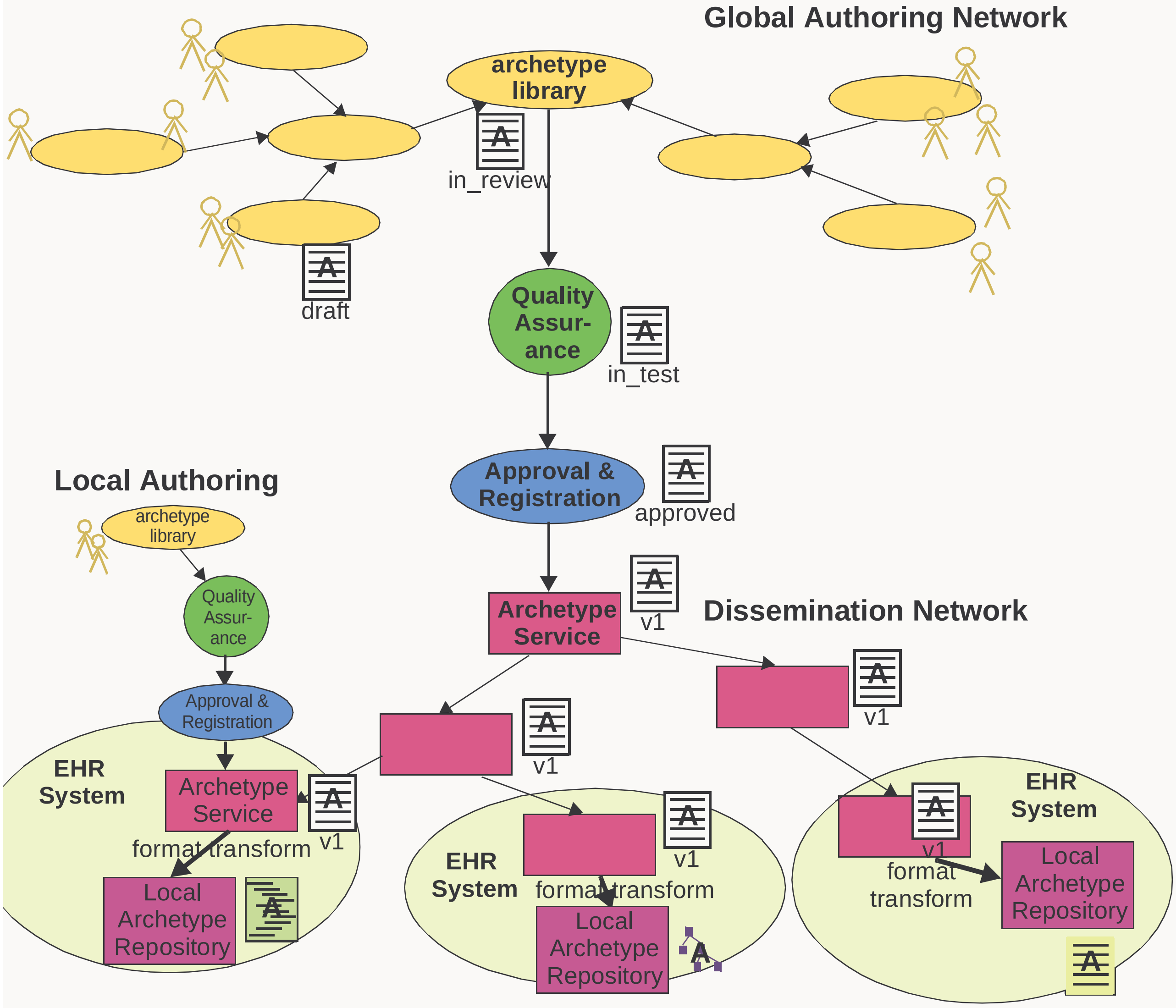

FIGURE 4 The Archetype System

This quality assurance and change control process is described fully in the *open*EHR Change Control Process documentation (FIXME - Tom - what is this called?).

Templates may be propagated using the Archetype system as required by users but there is no control over authoring of templates as this is not deemed to be appropriate or of any benefit. Naming of templates does not need to be controlled and hence an OID must be used for specific templates which are propogated through the dissemination network.

4.1 The Authoring Network

The Authoring network takes place within the *open*EHR document and change control environment - the archetypes exist as stand alone documents and each alteration leads to a defined change set. The library provides a knowledge framework within which the archetypes are identified and classified, based on the semantic web and using OWL. This knowledge framework provides firm links to the underlying reference model classes that have been archetyped, the relation between archetypes in terms of revisions, specialisations and versions and documents the discussion about each archetype change requests etc.

Each archetype has a ‘custodian’ who monitors the discussion and pulls together the views on what revisions are required. This person also moderates the discussion list relating to that archetype. The custodian maintains a document lifecycle in human readable form in addition to the document management system.

The library maintains a set of metadata regarding each archetype, some of which is duplicated in the ‘description’ part of the archetype itself.

4.2 The Dissemination Network

publish/subscribe relationship; flooding algorithm of servers

A publishing server has three calls:

Add_new_archetype

- Id
- Notes

Add_new_specialised_archetype

- Id
- Notes
- Predecessor

Add_new_archetype_version

- Id
- parent Id
- Notes

Obsolete_archetype

- Id
- Notes

Update_archetype -- revisions only - updated ontology etc

- Id
- Notes

4.3 Local Archetype Repositories

5 The Development Lifecycle

5.1 The Authoring Lifecycle

- initial creation
- information testing & debugging

6 Archetype Identification

Archetypes can be identified with various kinds of identifiers. We propose only two here: the ISO Oid and a multi-axial meaningful identifier. The syntax described in this paper is not dependent on the particular form of the identifier. Identifiers are declared in the heading section of the archetype, e.g.

```
archetype openehr-ehr-observation.haematology.v1
```

6.1 Multi-axial Archetype Identifier

A meaningful multi-axial identifier has a different purpose from the OID-based id: it encodes the partitioning of the archetype concept space in the identifier. Each identifier instance denotes a single archetype within a versioned 2-dimensional space, with the dimensions being:

- reference model entity, i.e. target of archetype
- domain concept

As with any multi-axial identifier, the underlying principle of an archetype id is that all parts of the id must be able to be considered immutable. This means that no variable characteristic of an archetype (e.g. accrediting authority, which might change due to later accreditation by another authority, or may be multiple) can be included in its identifier.

The inclusion of versioning and lifecycle state to the identifier have the effect of defining a 4-dimensional space. The syntax of an Archetype id is as follows:

archetype_id: qualified_model_entity '.' domain_concept '.' version_id ['.' lifecycle_state]

qualified_model_entity: model_originator '-' model_name '-' model_entity_name

domain_concept: concept_name { '-' specialisation }*

version_id: 'v' NUMBER

model_originator: NAME

The name of the authority issuing the underlying reference model to which this archetype applies e.g. openEHR, HL7, CEN etc.

model_name: NAME

The name of the model as labelled by the model_originator e.g. ehr, demographics, CDA etc.

model_entity_name: NAME

The name of the class in the model (model_name) to which this archetype applies.

domain_concept: NAME

A unique string that describes the concept expressed in the archetype e.g. weight

specialisation: NAME

A string which describes this specialisation e.g. 'birth' as a specialisation of 'weight' to describe birth-weight

NUMBER: [0-9]*

NAME: [a-z][a-z0-9()/%$#&]*

The field meanings are as follows:

model_originator: id of organisation originating the model on which this archetype is based;

model_name: name of the model on which this archetype is based;

model_entity_name: entity type in the model;

domain_concept: the domain concept name, including any specialisations;

version_id: numeric version identifier;

lifecycle_state: state of this archetype in its lifecycle

Examples of archetype identifiers include:

```
openehr-ehr-organiser.physical_examination.v2.draft
openehr-ehr-organiser.physical_examination-prenatal.v1
hl7-rim-act.progress_note.v1.in_test
```

A basic rule for the multi-axial archetype identifier is that it changes as soon as anything is done to the archetype which makes data created using the previous form invalid with respect to the changed form. For this reason, version is included in the identifier (see discussion below).

6.2 ISO Oid

ISO Oids can be used to unambiguously identify archetypes within storage systems, online repositories etc., regardless of where the archetype sits in the concept space. In order that archetypes can be authored at any place and time without access to OIDs, the OID is optional at all times until publication. The OID can have been issued at any point in the publication lifecycle, but must be unique in the authority's database.

Local specialisations do not require OIDs.

7 Quality Assurance

7.1 Technical Validation

7.2 Semantic Validation

8 Registration

9 Archetype Propagation

9.1 Authoritative Servers

9.2 Digital Signing

9.3 Archetype Service Interface

9.4 Archetype Repositories

Archetypes and Templates in the local environment:

- converted from shared format to local computable format
- only those archetypes used in a given EHR or other server

9.5 Archetype Indexes

Archetype index maps of data built from archetypes:

- hierarchical indexes containing only those branches of archetypes actually chosen a) by templating and b) due to further runtime choices
-

10 Creation of New Archetypes

10.1 Semantic Rules

To Be Determined: Note: see rules described in original archetype paper and in ADL manual.

10.1.1 Specialisation

Basic Rule:

- Specialised archetype must not create data that is not a valid instance of parent archetype

Consequence:

- narrowed constraints ok

10.1.2 Revision

Basic Rule:

- Data created by precursor of revised archetype must be compatible with revised version
- Data created by revised version must be valid w.r.t. precursor

Consequence:

- wider constraints ok

10.1.3 New Versions

Basic Rule:

- new archetype may be neither clean superset or subset; may be incompatible
- must supply a conversion argorithm for existing data (equivalent to a viewing algorithm for existing data)

10.2 Local Authoring

10.3 Managing Conflicts

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END OF DOCUMENT