



The GEHR Object Model Technical Requirements

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1 INTRODUCTION

1.1 Purpose

This document interprets the requirements described in various publications of the Good European Health Record (AIM 2014) project and from other [reference documents](#), into a succinct technical form, directly useful to software developers and planners. This work is now called the Good Electronic Health Record (GEHR) to reflect the interest in the architecture in many parts of the world. It is intended that this document become and be maintained as the definitive list of precise technical requirements for the GEHR concept of electronic health records.

1.2 Audience

The intended users of these requirements include:

Developers of GEHR principles and the GEHR Object Model (GOM): as the proximate set of requirements driving GOM evolution so as to unambiguously fulfil the original (lengthy) requirements.

Developers of GEHR-compliant software and systems: as a primary reference document, which, with the GEHR Architecture, drives software development.

Compliance testers (e.g. standards bodies): as the reference for developing test data and scenarios for testing compliance of GOM implementations.

1.3 Traceability

In the interests of traceability, particular requirements are marked outside the main text in the manner of “example” to the right of this paragraph. These indicators are intended to be used in the formal class model texts to provide traceability back to these requirements. Generally, part of the paragraph immediately to the left will be italicised, indicating phrases to be taken as a definitive statement for the corresponding requirement tag. **RK example**

Three kinds of requirements are distinguished, identified by the leading “RK”, “RS” or “RA” in the requirement marker, as follows:

RK:

kernel requirement - a requirement which must be met by the GEHR Object Model (and therefore any GEHR-compliant kernel or application based on the model);

RS:

system requirement - a requirement which can only reasonably be met by the information system of which GEHR applications and databases might be found. Security requirements are typically included in this category;

RA:

application requirement - any requirement which the GOM should not aim to satisfy.

While this document is primarily about “RK”, i.e. GOM requirements, system and application requirements are included to show the extent of other requirements which have been considered, and deemed *not* appropriate for the GOM itself.

1.4 Status

This document is under construction. Known omissions or questions are indicated in the text with paragraphs like the following:

To Be Determined: indicating not yet resolved

To Be Continued: indicating more work required

Reviewers are particularly encouraged to comment on and/or advise on these paragraphs as well as the main content.

This document is the now the second version released for review. As with all releases, when the review process completes the version will be upgraded as a decimal revision number. Integer number revisions (i.e. version 1.1 -> 2.1) are reserved for major changes to the way the requirements are written. At some point in time, major revisions should be synchronised with the version numbering of the GEHR object model, however, further requirements development and software trials are needed before this becomes meaningful.

Please send requests for information to info@gehr.org and review comments to review@gehr.org.

1.5 Structure of this Document

The remainder of the document can be understood in essentially three logical sections, as follows:

Original GEHR Project Requirements: in section 2, a summary is given of the requirements developed in the original GEHR project (AIM Project 2014), as published in March 1995.

Clinical Requirements: section 3 provides the core clinical requirements of the record, i.e. the requirements for an EHR to be used in a clinical care context.

Other Requirements: sections section 4 to section 6 describe requirements on the record to satisfy requirements for sharing, conversion, education, decision support and so on.

Critical Attributes: section 7 describes attributes of EHRs to do with performance, reliability, robustness, portability and so on.

Software Development: section 8 discusses requirements specific to the development of software systems.

Evolution: section 9 discusses requirements relating to future directions of EHR models, software and records.

Under the requirements sections, a final subsection provides relevant scenarios which are illustrative of real-world situations.

To Be Determined: Currently, the scenarios are informal; in the future, they will be formalised according to a standard way of documenting scenarios.

2 SUMMARY OF ORIGINAL GEHR PROJECT REQUIREMENTS

The requirements determined during the Good European Health Record project were as follows (adapted largely from Deliverable 19):

Clinical comprehensiveness: this area relates to the use of the health record in the clinical context, in particular:

- see: Del19-3.2.1

 - clinical information is *complex*; compromises in the way the health record works should be in favour of *availability* and *usability* for the clinician recording a patient contact
- see: Del19-3.2.1

 - *growth* and *innovation* in medical, clinical and general sciences, as well as public health and the cultural place of health care must be accommodated
- see: Del19-3.2.2

 - the record is important as a *patient history* device
- see: Del19-3.2.3

 - the record promotes *clinical competence* on the part of the care-giver: delivering care, organisation & planning, education, training, learning, QA; it also encourages the moral and ethical aspects of clinical care;
- see: Del19-3.2.4

 - the record has a multitude of possible uses
- see: Del19-3.2.4

 - the record has a multitude of possible users
- see: Del19-3.2.7-
Expressiveness; also
precision and
uncertainty Del19-
3.2.5, 3.2.6

 - the model is powerful enough to *represent diverse information*, including structured text, measurements, multi-media data, coded terms & classification, and unstructured information

Comment: Many of these requirements relate to the semantic sophistication of the information structures in the record.

Sharing: it should be possible to *transmit health record extracts from one health care facility to another* in such a way that the software at the receiver's end can interpret and integrate them into any existing record for the same patient. This must accommodate the fact of different hardware and software in use at either end, different language communities (GEHR has provided for EC languages so far), and different legislation governing information in various states. This is the primary technical requirement of Del19, described in [Del19-3.5.4], [Del19-6], and [Del19-7].

Comment: Essentially, this takes the ownership of the health record away from any single practitioner or facility, by allowing it to travel to other places, for a multitude of reasons, including: the patient relocating, access to specialists not locally available, and mobile clinicians needing access to the record from different locations.

It also takes "ownership" of the record format and structure away from any one software vendor and makes it open to all vendors without favour.

This class of requirements places constraints about the form of information transmitted between computer systems and applications.

see: Del19-3.2.8

Ethical & medico-legal: the information in the record must be faithfully recorded as intended by the clinician; it must be proof against tampering or erasure of earlier additions (which may be relevant in legal cases), without hindering the ability to update it and alter genuine mistakes.

Accountability requires that audit trails of clinicians doing the recording must be included in the record

Rights of access, amendment, and movement of the record must also be provided for, ensuring that the only readers/modifiers are those personnel who a) reasonably need to see the content for clinical purposes, and b) have the patient's informed consent

see: Del19-3.3

Comment: This class of requirements places constraints both on the management of records transmitted between computer systems and on the management of records at a health care facility (HCF) (i.e. regardless of whether it is transmitted or not).

Computation: there are various computational requirements, including: the GEHR definition must be self-consistent, formal, and implementable; it should be possible to determine whether a given software implementation does in fact comply with the model (since otherwise there is no guarantee that either security or transmission requirements will be met).

see: Del19-App.A-1

Comment: This class of requirements requires the information model of the record to be computable and implementable.

Education: computerised health records should be viewed as a rich source for analysis, study, self-learning by students, medical educators and researchers. The user interface should be easy for learners. While this use of the record is outside of the immediate clinical needs of care giving for a particular patient, it is potentially an important generator of clinical and statistical knowledge for society as a whole .

see: Del19-3.2.10,
Del19-3.4

Comment: Educational requirements relate to the *sophistication of applications* and computerised educational facilities; they will probably also have a minor bearing on the semantic sophistication of the record.

Clinical analysis: GEHR touched upon the analytic usefulness of the record, mainly in the educational context; it has since been realised that sophisticated analyses of health records would be desirable during the care-giving process, particularly supporting decision support applications.

see: Del19-3.4

Comment: Analytic requirements relate to the semantic sophistication of the information in the record, in particular for querying.

Open standard: any prescription for a health record architecture should be freely available, and not owned by corporate interests. This ensures that a) implementors wishing to use it may do so freely, and b) that the evolution of the standard continues to reflect the best interests of clinical practice, rather than the economic imperatives of a particular company. For these reasons, all GEHR deliverables are in the public domain. This requirement was not stated explicitly in [Del19] but was the common viewpoint of all parties who took part in the GEHR process.

Comment: This class of requirements places constraints on the ownership and evolution of the standard.

3 CLINICAL REQUIREMENTS

3.1 Modelling

see: Del19-App A2, A3 From a systems engineering perspective, a number of requirements of the modelling formalism used for the GOM were identified during the Good European Health Record project. These are summarised below.

3.1.1 Machine-verifiability

RK formalism:verifiable Only formalisms whose models can be computer verified, i.e. parsed and checked for syntax and semantics, are acceptable. This is a pragmatic requirement: models developed in formalisms for which there are no available tools cannot practically be verified, given the likely size of the model, and the continual need for reverification as the model evolves.

3.1.2 Semantic Power

RK formalism:semantic The model formalism requires a certain amount of power in order to be useful. Two ways of judging “how much?” are:

- It must be at least as powerful as any construct required by modelling of clinical data. This is only easy to quantify in retrospect, of course, but with the advantage of the Good European Health Record project, the following basic constructs were required:
 - single and multiple inheritance (for classification and facility inheritance)
 - association (for references) and aggregation (for composition)
 - basic types such as STRING, INTEGER, BOOLEAN etc
 - container types such as ARRAY, LIST, TABLE
 - ability to construct new types
 - ability to express logical constraints
- It can be argued that it must be at least as powerful as the principal communication formats, since otherwise there would be no way to express constructs which are commonly used in a particular format. Example: since multiple inheritance is available and commonly used in the CORBA and ODMG-93 specifications, it should be available in the modelling formalism.

3.1.3 Clarity

RK formalism:clarity Models expressed in the formalism should contain only logical constructs; use of qualifiers such as `static` and `virtual` as used in C++ for example would be undesirable, since they connote unintended implementation semantics.

3.1.4 Non Format-prescriptive

RK formalism:format The language of the GOM should not be a transmission or storage format language, for two reasons: (a) GEHR is not trying to prescribe particular formats, and (b) most transmission formats are deficient in some way for modelling, since they are

oriented more toward protocol and interface description. In particular none provide support for assertions.

3.2 Medico-legal

3.2.1 Faithful recording

Deliverable 19 states: information must be recorded the way it was intended with no loss of accuracy due to use of computer rather than paper. see: [Del19-3.2.7-Faithfulness]

A satisfactory middle ground between an absolutely verbatim recording and an unacceptably distant representation of a clinician's input, is defined as follows: RK legal:faithful

- Given that clinicians using paper "make notes" and don't generally record patient interviews verbatim for later transcription, it is reasonable that the GOM define structures corresponding to the level of abstraction of such notes, i.e. the clinician's choice of salient information, rather than a linguistically perfect representation of interviews, etc.

As far as is known by clinicians involved in the Good European Health Record Project and related projects, clinicians who do dictate notes for later typing up are still usually using the dictation as a source for note-taking, rather than verbatim transcription.

- Translation of coded terms is acceptable and expected, providing there is a means for code expansions to be included in transmitted extracts, to accommodate receivers without access to termsets.
- Translations of items for internationalisation purposes, e.g. date formats is acceptable.
- The clinician always has recourse to plain text (in the default language of clinical practice at the health facility), if structured forms are too restrictive. Plain text should minimally have the original language recorded with it.
- The author may selectively turn off the display of some items at a detail level (e.g. the cuff size used when measuring a blood pressure with a sphygmomanometer). The display state of such items should be remembered in transmitted extracts, so as to allow the reader at the receiver HCF to see the information in the way the author originally intended. The reader should not be prevented from redisplaying it in total form, however, nor from using locally defined display filtering. RK legal:faithful-orig-disp

Del19 indicates that alternatives to the keyboard must be allowed for. The corresponding requirement is that the record must be able to accept information generated by other kinds of devices, i.e., multimedia information in general. This is dealt with as a functional requirement in section 3.4.5. see: [Del19-3.2.11-conclusions]

3.2.2 Accountability

All modifications to the record must be audit-trailed. In this case "modifications" is interpreted as meaning that transactions (see section 3.4.2 on page 26 for definition of "transaction") are always audit-trailed, and provision exists for different authors of items within a transaction to be audit trailed where desired. An "audit trail" is: RK legal:audit

see: [Del19-3.2.7-
Author]

- Author identification.
- Date/time stamp indicating when modification committed to record.
- Reason for change.

3.2.3 Identification

Unambiguous and *sufficient* identification of the record, its subparts, and associated information structures is required both for use at an HCF, and for transmission of extracts. Identification is unambiguous if there can be no confusion of the identity of information objects; it is sufficient if it contains the minimum elements to satisfy legal and clinical requirements.

3.2.3.1 Demographics

The aim of the EHCR is not to act as a primary repository of demographic information. Systems will have requirements for demographic information that will require efficiencies not best served by an EHCR. The EHCR model should contain only extracts of relevant entities as are mandated by this requirements. It should always be assumed that an information system, database, or structure outside the EHCR is the source of demographic information, since to do otherwise merges two quite different sets of requirements into the one model.

The extent of demographic information in the EHCR is determined by the following concerns:

- Keying information is available indicating where in a demographic system a full description of the patient and clinicians may be found;
- Sufficient information is available for recipients of transferred EHCRs to identify and contact patient and clinicians implicated in the record;
- Sufficient information is retained for medico-legal investigations, particularly into the past history of treatment of the patient, as described by the record.

People, organisations and their constituent parts must be identified minimally as follows.

RK legal:id-people

Person: all people in the record - clinicians, patients, relatives of the patient, etc require the following identification as a minimum:

- legal name
- any commonly used aliases
- contacts: details and validity for contacting the person, corresponding to their concrete type (clinician, consultant, patient etc). Contacts should include home addresses and phone numbers, fax numbers, electronic addresses, and all alternates which might be required. Each contact item should be marked with date/time validity.

RK legal:id-clinician

Clinician: in addition to the above, clinicians require the following identification:

- profession
- name of registering body
- unique registration identifier at that body

Staff-member: in addition to the above, members of the local HCF staff **RK legal:id-staff** require the following identification:

- position and/or grade;

Record subject (patient): in addition to the above, the subject of the record **RK legal:id-patient** requires the following identification information:

- unique identifiers for the patient in various systems, for example:
 - * in the HCF originating the record;
 - * in the relevant national health care system;
 - * in any health funds the patient is a member of;
- place of birth
- date of birth

Provision should also be made for a multimedia identification item such as a photograph, or such other digital identifications as may be used in the future (e.g. voiceprint).

Organisations: HCFs, laboratories etc must be identified minimally as **RK legal:id-org** follows:

- legal business name;
- any trading names normally used in lieu of the legal name;
- registration or other id, in the case of clinical organisations

For transmitted health record extracts, there are medico-legal and clinical identification requirements. The are discussed in section 3.2.5.

Regarding the unambiguous identification of patients - the classic problem of two "John Smiths" for example - this requirements takes the stance that sufficient data should be recorded so that their records can be differentiated, without stating the precise manner in which this is done. It will be possible for example for any site to require that a patient key of the form <name, place-of-birth, date-of-birth, address> be used to differentiate patients.

It is the responsibility of computer systems to provide a place for all such unforeseen identification information, but not necessarily to be able to disambiguate identities without the intervention of human operators.

3.2.3.2 Association

A further requirement relating to identification is that it is essential that *the association of all items of content with a party be unambiguous*. **RK legal:target** In particular, items of clinical content about a party - the record subject for example - must never be mistakenly associated with another party - e.g. the father of the record subject - during retrieval carried out in application software; the consequences of this type of mistake could be serious clinical errors.

For example, information in a record may relate to the patient (e.g. a blood pressure), a child or relative of the patient (e.g. cord blood sample from a newborn at the time of delivery) or potentially a donor (e.g. HIV status of the donor of a kidney).

3.2.4 Previous Versions

RK legal:non-
erasure

It is required that the state of the record just after committal of a new item be reconstructable if necessary. Such an operation is not likely to be required often, but it is essential that the model provide for it, since both medical and legal “backtracking” procedures may hinge on historical information, including wrong information subsequently corrected.

Particular queries which must be supported include:

RK legal:datum-
history

- For a given datum in the current view (e.g. “Allergy to penicillin”), when was this first added to the record, and by whom?

RK legal:record-
history

- What was the state of the record at a specified prior date? It should be possible to provide a rendering of the record for any previous date in the same fashion as for the current date.
- What is the relation in time of the addition to the record of two specified information items, for example an observational datum, and the record of a surgical procedure?

3.2.5 Record Exchange

There are a number of *clinical or medico-legal* requirements on exchanging records or extracts between health care facilities.

The first set are to do with adequate identification and authorisation, and are distinct from the numerous technical requirements described in section 4.6 on page 49.

RK legal:extract-id

Any part of a record extracted for the purpose of transmission to another HCF requires the following information to be included:

- Identity of the health care professional (HCP) authorising transfer at the sending HCF.
- Identity of sending HCF or department or system, as appropriate.
- Identity of the receiving HCF.

RK legal:merged-
extracts

At the receiving end, the identity of the clinician authorising the merging must be included in the record with the merged extract.

RK legal:sent-
extracts

Further, the parts of a local record sent as extracts to other HCFs must be marked as such, enabling a user of any instance of a patient’s record to ascertain which other HCFs have requested information on that patient from the local HCF.

A second set of requirements for record exchange concerns what *views* of the record can be transmitted. There are two dimensions to this question:

Logical view: what logical subparts are *allowed* to be sent, which may be restated as: what is the minimum unit of exchange? and, what links must be retained in sent extracts? These are dealt with in section 4.6.2 on page 50.

Physical view: what physical parts can be omitted on transmission (of a logical view), and how will the recipient be made aware of omissions? The motivation to omit anything at all is twofold:

- Since it is possible for many or even all logical parts (e.g. transactions, content items) of the record to be connected to each other, unless some links are allowed to be broken on

transmission, a request for any extract, no matter how small, will often result in transmission of the entire record.

A general requirement can be stated that *the sender of a record should be able to optionally follow or break certain kinds of links*. Which types can reasonably be broken will be discussed below. **RK legal:exch-links**

- Multimedia data items can be very large, even if compressed, presenting performance (and sometimes failure) problems for computer systems and networks. Therefore it is reasonable to allow *the sender to optionally ignore certain kinds of bulky data*. Which types can reasonably be omitted will be discussed below. **RK legal:exch-bulky**
- Transactions in a certain date range may be seen as confidential by the patient to one particular clinician. These could not be transferred without explicit consent of the patient.
- Links established in the record for the purpose of connecting events in a process or presenting a problem-oriented view could easily be implicated in a transfer request, and optionally broken by the sender.

A medico-legal and clinical requirement for ensuring views function properly is that *the clinician must be made aware of every omission or substantive transformation in a transmitted record or extract, including broken links, missing bulky data and so on*. The technical software requirements are dealt with in section 4.6.1 and section 4.6.2. **RK legal:exch-aware**

3.3 Security

3.3.1 Overview

Security issues are among the most complex, and most fraught in the domain of health, since health records may contain what patients see as the most sensitive data recorded anywhere about them. Requirements in the area of security fall around the following themes:

Privacy: ensuring that the patient's wishes for their data to be seen only by those to whom they give *consent*.

Accessibility: for the clinical process to occur without unreasonable hindrance, the record must be accessible by a minimum of appropriate clinicians.

Integrity: the informational integrity of the record is of paramount importance, since undetected errors could result in life-threatening clinical mistakes.

This discusses requirements relating to these issues in some detail.

A more detailed background of security issues in EHRs is given in a separate document - "Security of the Electronic Health Record - an architectural approach."

3.3.2 Privacy

Normally electronic health records are held on a system which is inside a secure computing environment, typically protected from outside networks by firewalls.

see: [Del19-3.2.7-
Security, 3.2.8]

Inside this environment, all users are known. At least three sources of security threat can be identified:

Internal: improper use by employees or other staff inside the secure environment.

External: improper use by agents outside the secure environment.

Eavesdropping: improper use to data during legitimate transmission.

The kinds of improper use include:

Viewing: reading of the content of EHRs by unauthorised personnel, which breaking patient confidentiality and compromising consumer privacy requirements.

Appropriation: effectively, the theft of EHRs, e.g. for publicising, blackmail or other criminal purposes.

Tampering: changing the content of the record, e.g. to erase previous data (preventing proper after-the-fact investigations) or to deliberately introduce errors, potentially causing clinical errors.

The intangible nature of electronic records compared to the paper equivalent magnifies security problems, since clandestine access can be carried out electronically.

RS legal:sec-int-
access

Improper access to records by staff or others inside an HCF is an issue of the security of the actual software and hardware systems on which electronic health records reside, as well as the efficacy of personnel security procedures in the offices, buildings and grounds of the HCF. It is difficult to state requirements of the health record itself, beyond requiring the permissions for each part of the record to be clear. We can however require that *adequate authentication (proof of identity) and validation (proof of right of access) procedures are part of any computer system containing electronic health records*. This is normally done via login and password access to the system.

RA legal:sec-int-
approp

Improper appropriation of records by staff (usually by copying) is probably difficult to prevent at a kernel level. This may best be dealt with by requiring that any mechanism by which a record can be copied (including copying to floppy, screen-dumping and printing) is either disabled, or causes a system log entry to be created. The latter, at least, will allow the possibility of tracing all copies of records. Psychological deterrents may in any case be more successful than technical ones, for example, the frequent display of reminder messages letting users know they are being “watched”, and that all their actions are being recorded. This technique is used very successfully at the Harvard hospitals (e.g. Brigham and Womens, Beth Israel) where the level of inappropriate access of clinical information by authorised users is negligible.

RS legal:sec-ext-
approp

The other two types of threat involve, respectively, records being removed improperly from within the secure environment by outsiders, and being copied by eavesdropping during a normal transmission process. Limiting external access places requirements on the security of the computer environment in which a health record system resides. Security is usually implemented in terms of secure local networking procedures and tools such as firewalling. Possible requirements of a health record system include network file system security, intranet security, and internet security.

A further way to combat wrongful appropriation requires that EHRs are rendered illegible to unintended users, e.g. via public key encryption. **RS legal:sec-legible**

3.3.3 Access Control

Access and amendment of the record will be defined using the concept of user stereotypes, for which there will be distinct sets of capabilities enabled.

The following stereotype users of the record are recognised:

RK legal:perm-users

- Patient
- Patient's nominated next of kin
- Doctor responsible for recording particular information
- Doctor involved in care of patient
- Any doctor
- Any HCF staff member
- Any student
- Any person

Capabilities are as follows:

RK legal:perm-caps

- Read only access of transaction headers
- Read only access
- Amendment of an existing transaction (see section 3.4.2 on page 26)
- Addition of a new transaction

A "permission" is defined as: the right of stereotype user X to use capability Y.

While the above specification is straightforward, following typical security models used on computer systems, the issue of exactly what parts, or at what granularity permissions should be defined is more complex. Consider the capability of reading the record. One apparent need is to protect the patient from any familial or social stigma due to a reader of the record discovering entries relating to a stigmatising condition, such as HIV status, which they are not themselves treating and (supposedly) have no need of knowing.

A conflicting point of view says that it is imperative for clinicians to be able to see "all or nothing", since "everything is connected", particularly:

- A general picture of the patient's health requires knowing everything (that is available in the record).
- Drug interactions.
- Known predisposing genetic conditions impact on the validity of health advice.

This requirements document favours the latter view, giving integrity of clinical information priority over perceived security threats. Thus, although there may be strong arguments to say that the whole record is the correct unit for permissions, we will state the requirement that *the transaction is the lowest level unit to which permissions can be applied*, since it is recognised that the transaction will be the smallest unit of transmission (see section 4.6.2 on page 50). **RK legal:perm-gran**

3.3.4 Integrity

RS legal:sec-tamper

Tamper-proofing is also required regardless of whether encryption is in use or not. Consequently, some way of verifying the integrity of the content is needed, e.g. by strong checksumming.

3.4 Clinical Knowledge Representation

see: Del19-3.5.14

The Good European Health Record project reached agreement on the important structural ideas of the *record*, being the outermost container structure, and the *transaction*, being the primary unit of update of the record. Clinical information was identified as being contained inside transactions. An attempt was made to define when transactions could be amended, and when new ones should be added.

These concepts and many of the requirements for internal structure are retained here, with modifications reflecting a better understanding of the practical aspects of the record's use in clinical context.

The sections below summarise the clinical requirements on record structure, beginning with records and transactions, followed by internal transaction structure and content.

3.4.1 Record Structure

RK clin:record-concept

The concept of "the record" is required to be explicit in the model, both as an outermost container, and in order to associate global semantics such as identity and security. The record contains all transactions, items of context data, and a number of queries facilitating use of the record. The specific requirements are indicated throughout this document.

3.4.2 Transaction Structure

RK clin:trans-concept

The concept of "the transaction" is required in the model. Following from the original Good European Health Record idea, "transaction" is described as: *an interaction between an HCP and the record, to be indelibly preserved once committed*; and as such identified (at least) by the date/time stamp of its addition and the identity of the authorising clinician.

In order to elucidate a more precise definition, we will consider the circumstances under which transactions might be created.

There are two reasons to add information to the record, which have a bearing on the semantics of transactions used to contain them: the need to record temporal event(s) from the outside world and the need to record persistent information. These are distinguished as follows:

RK clin:trans-event

Event: information about temporal events in the real world, whose *validity depends strongly on the point in time at which the information was recorded*.

RK clin:trans-event-chg

Changes to event information in the record must be understood as *corrections*, since the original facts cannot be changed, and are therefore only made if there is an error (omission, extraneous, wrong information).

Examples of event information are found in the following clinical entities:

- contact (between HCP and patient)
- test results
- drug administration
- report
- administrative (e.g. first time visit, hospital admission, death)

Persistent: information which is *remains valid over a period of time until marked otherwise*. This is typically information constructed anew by the clinician, either reflecting chronic conditions, adverse reactions etc in the patient, or his/her own opinions in the form of care plans or summaries. Lists such as active or inactive problem lists, major diagnoses or key events are further examples. **RK clin:trans-persist**

Changes to persistent transactions in the record are understood as *updates*, which may include *corrections* but also new information, and may be made at any time to bring the information up to date with the author's latest thinking. **RK clin:trans-persist-chg**

The current status of persistent transactions must be recorded, and able to be changed by the author of the transaction. Sensible status indications might include: current, closed, obsolete, superseded. **RK clin:trans-persist-sts**

All transactions *must* fall into one of the above two categories - event or persistent. A comprehensive set of examples of both transaction types can be found in Examples of Content Types on page 65.

We can now answer more precisely the question: when is a *new* transaction added to the record? For events, it corresponds to a new care event (progress note, set of test results, nursing observations), while for persistent, it corresponds to a new care-related document (drug chart, problem list, adverse reactions to medication) whose *creation is wholly at the clinician's discretion*. It will be quite common for information in persistent transactions to be partially sourced from event transactions: for example, family history and adverse reactions recorded during a contact may be incorporated into a summary transaction at any time after the original information was recorded. Since persistent transactions would form the basis of a "current picture" of the patient, the creation of such transactions is not an inconsequential clinical action: it effectively upgrades the original information in clinical importance to a level where it becomes permanently visible. **RK clin:trans-add**

It is important to note that the Good European Health Record project distinguished a number of transaction types as part of the model, including contact, report, summary, care plan, nota bene, administrative and trigger. These were largely similar and did not differentiate between event and persistent types.

3.4.3 Internal Transaction Structure

The original GOM proposed in Del. 19 described a simple recursive structure which has never been completely satisfactory, given the diversity of information types to be stored, such as: prescriptions, observations (of varying complexity - BP, audiogram, etc), test results (including reference values), diagnoses, patient histories, triggers and so on.

These requirements attempt to elucidate more clearly these types of information so as to inform an improved version of the GOM. The following subsections discuss

generic structuring of content, and structural refinements specific to various clinical types of information.

3.4.3.1 Generic Structures

As a minimum, the following generic structures should be supported in a model of clinical information:

- RK clin:struct-hier** *Hierarchy*: probably the most ubiquitous structuring mechanism, hierarchy provides a means of grouping, classification (taxonomy), and modelling morphologically hierarchical information such as anatomical concepts (literally hierarchical), and audiology data (information is hierarchical);
- RK clin:struct-table** *Tabular*: as with other scientific disciplines, clinical medicine uses tables to represent many kinds of data, for example pathology results and reference statistical data. Tabular structures (which may be 1-, 2-, or n-dimensional) can be represented hierarchically, but have the extra semantics of a particular row- and column-orientation, ordering of items, and numerous display characteristics. Here a “table” is defined in the sense of a relational database, where columns have names but rows are only identified by the key values of row data. All rows in a table are therefore of identical structure;
- RK clin:struct-matrix** *Matrix*: 2-dimensional tables in which rows and columns have names are denoted “matrix”, in order to differentiate them from tables. Matrices are of fixed dimension once defined, and each cell may be referred to by the logical row/column co-ordinates. Matrices abound in medical text-books, clinical notes and pathology results.
- RK clin:struct-list** *List*: simple lists also abound in clinical information and must be catered for in the record. Lists are again a special case of hierarchy (and also the table), but have implied order.
- RK clin:struct-tim-ser** *Time series*: a kind of list where the item values relate to time-points, which may either be regular in time (e.g. vital sign monitor output in an ICU), or irregular (e.g. an oral glucose tolerance test).
- RK clin:struct-func** *Function*: another list variant whose semantics are $x \rightarrow f(x)$ in 2 dimensions.

Neither the tabular nor the linear form is vertically bounded - rows or items can always be added; they are thus both suitable for recording time-series information.

Clinical Implications

Where medical information which has an inherent structure is represented in the record, it must be structured in such a way as not to render it clinically ambiguous. An example similar to the following (FIGURE 1) was given in the Good European Health Record Deliverable 19.

While this example is somewhat contrived, it illustrates the fact that a hierarchical information arrangement provides not only convenient structure, but *clinical semantics* as well: “it is critical that the two specified locations are associated with their appropriate data subjects: tenderness and mass. It is essential for both tenderness and mass to be clearly identified as being in the abdomen....” (Del 19 4.3.3).

A further example is given in which the weight of the liver of the subject’s deceased father is recorded, showing that disambiguation of human subject is essential in the record, given that facts are often recorded about relatives of subjects in a subject’s

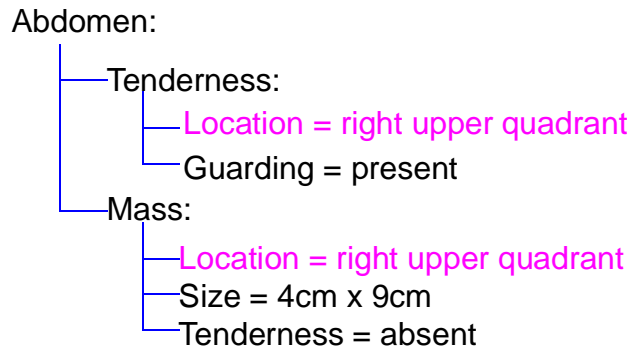


FIGURE 1 Hierarchy expressing physiological morphology

record. Better examples might be the patient’s father’s cholesterol or perhaps the length of the femur of a fetus.

We can in fact generalise from these observations by noting that *the “domain” validity of information expressed in a hierarchical structure (including tables and lists) is dependent upon the integrity of the structure.* As a requirement, we can state a corollary: clinical information cannot necessarily be casually structured according only to the needs of organisation of the information or display; *its underlying semantic structure, if any, must be preserved.* RK clin:struct-sem

3.4.3.2 Context-specific Structure

The difficulty (some would say folly) of definitively describing concrete clinical information structures is well known. Most such attempts are defeated by the sheer diversity of data, and data *types*. The Good European Health Record project recognised this and proposed a generic hierarchical structure, containing sufficient contextual attributes to satisfy all possible clinical needs. Thus, all manner of dates, times, recorders, information providers, comments, certainties and so on is provided on almost every item in a hierarchy. The approach is correct in principle, but in practice makes for overweight, ambiguous data structures in which the semantics of any given exemplar may be unclear.

In order to improve on this situation, we will revisit the requirements for clinical contextual information and structure, using a *knowledge representation* approach suitable for science in general.

Content found within transactions may be characterised *epistemologically* in general as being *propositions* of one kind or another: statements that something is so, for example “systolic blood pressure = 120mmHg”. Propositions may have a hierarchical or tabular structure, for example, the reference data for an oral glucose tolerance test.

Table 1 Example of glucose tolerance test

Time (mins)	Blood sugar (mmol/l)
0	3.5
60	7.9

Table 1 Example of glucose tolerance test

Time (mins)	Blood sugar (mmol/l)
120	4.7

In some cases there is nothing further to say; for example the statement “instrument = sphygmomanometer” in a blood pressure measuring protocol does not require qualification; more often however, clinicians are concerned with the origin of the information and/or its use. Types of information which are generally recognised in epistemology include:

- *a priori* knowledge
- *a posteriori* empirical knowledge
- knowledge of how to do something
- commands

From these we can devise a set of knowledge types for use in clinical medicine, by choosing category names more familiar in science, as follows:

Definitional: stated propositions

Observation: objective empirical observation

Subjective: opinion about something, usually inferred from an observation

Instruction: command (to do something)

When information of each type is created in a clinical information system, various contextual information may be required; the following subsections describe the correspondence between knowledge type and context.

Definitions

RK clin:def

Frequently information simply defines a value or state of something, such as “weight = 85kg”, intended as a goal in a weight-adjustment process. Most non-clinical information used in clinical systems, such as peoples names and addresses is of this type, since it is normally satisfactory to state it as a fact, without requiring further qualification (no-one would ordinarily *observe* that a patient’s address is such-and-such, or even regard it as an *opinion* of the patient - it is just accepted.)

Observation

(Ostensibly) objective information gathered as the result of some *observation* or *recording procedure*, such as:

- Simple measurements e.g. patient’s height, blood pressure.
- Investigation data, e.g. a CT scan.
- Record of surgical procedure.

Such information may take the form of:

- Single values (e.g. height, weight, BP).
- Hierarchy of values (e.g. audiogram).
- Table of values (e.g. time-sequence of <BP, pulse, temperature>).

- Matrix of values (e.g. tendon reflexes on the left and right side of the body).

The defining characteristics of such information are that it was generated by some procedure (no matter how complex or simple), and thus has the following contextual attributes: **RK clin:obs**

Recorder (who) - the person recording the information **RK clin:obs-who**

Protocol (how) - the method, instrumentation, etc of taking the measurements **RK clin:obs-how**

Location (where) - site of observation (patient's home, pathology lab, surgery etc) **RK clin:obs-where**

Time (when) - the date/time of the observation. Time-series observations require timestamps on every item. **RK clin:obs-when**

Reason (why) - purpose of this observation. May not be required in many cases; for test results, this may be a reference to the request for pathology; there may also be a need to include reasons such as discounting a differential diagnosis. **RK clin:obs-why**

In addition, it is normal in science generally, and certainly in medicine to want to record reference values, ranges or other data, to which actual data can be compared. Clinicians typically want to know if an actual datum is "abnormal". *The record should therefore support optional reference values.* Reference information for a given datum will generally be parameterised by a number of variables (e.g. sex, height, geographical and/or genetic origin) and therefore must be preserved during transmission of record extracts. **RK clin:obs-ref**

To Be Determined: Differentiation of laboratory values, target values etc.

Action: clin:obs-ref not added to model

The record thus has to allow the possibility of storing any of this information for an observation (even if it is a simple BP measurement by a nurse), *without necessarily requiring it*, since it is not always clinically significant. Note however, that some of it may be medico-legally significant, even when clinically uninteresting.

Subjective

Subjective information which is the *opinion* of a patient, HCP, or other source, including:

- Patient's statements, impressions etc, as typically listed under a transaction's "subjective" heading in a problem-oriented record.
- Information which is *assumed* as "fact", without any observational procedure having taken place, such as family medical history.
- HCP's diagnoses and differential diagnoses and justification.
- HCP's assessment, summary, conclusions or report information.

Such information is characterised by some level of doubt or fallibility, so the following attributes are important: **RK clin:subj**

Observation attributes (potentially): (see above). **RK clin:subj-who**

Provider (who): the person providing the information may be important in assessing its reliability, especially in the cases of distant relatives, companions, patients themselves who are known to be psychologically

unstable. The provider in the case of diagnoses will (usually) be the clinician.

RK clin:subj-
certainty

Certainty: the likelihood of correctness of the information *in the opinion of the HCP*. This is important both for information generated by the HCP, such as diagnoses; and other providers, such as patients who must be regarded as fallible.

Optional attributes include:

RK clin:subj-how

Protocol (how): the method of arriving at the information recorded such as decision support software, discussion with colleagues or reference to a knowledge base.

Instruction

Directions given by someone describing *actions to be taken*, including:

- *Trigger*: direction to perform a clinical action when a specified condition is met. This may be when a certain date/time is reached (“on Thursday 2nd May”) or a condition such as “if temperature > 39.5°C”. The action may be required to be performed periodically, e.g. for BP to be monitored in a hospital situation; or every time the condition occurs. The time period might also be very long, such as for a trigger for a PAP smear recall, which is typically recommended only every 2 years.
- *Procedure*: trigger whose action describes a procedure to be performed (e.g. a surgical operation, wound dressing change, physiotherapy). The condition may be important here, since operations often have to wait until a patient is over a previous or related condition.
- *Request for investigation*: direction for certain tests to be performed. The action might simply be the name of a standard test, or a complete description.
- *Referral*: direction to see another clinician, usually a specialist. The same information as contained in a normal referral letter should be entered into the record.
- *Prescription*: normally understood as a direction for the administration of drug(s) [Del19-3.2.9] but can equally apply to the instruction to perform any treatment or regime involving actions over time.

The information required to specify a prescription may be long and/or complex.

RK clin:inst

In common with the observation type, the following attributes may be required:

RK clin:inst-when

Time (when): when the action should be performed; this may be a single time, or a date/time range with a repetition period (typical for prescription).

RK clin:inst-where

Place (where): place where the action is to be carried out; may indicate a pathology laboratory, or patient’s home, for example.

RK clin:inst-who

Person (who): person who should perform the actions, may be the patient, a nurse, a specialist etc.

RK clin:inst-how

Method (how): method or protocol is likely to be important in all instructions, including prescription and pathology.

RK clin:inst-why

Reason (why) - reason for this instruction. Likely to be a reference to a previous observation or clinical condition.

Further attributes specific to instructions:

- Condition (if)*: the time for carrying out the instruction may be characterised as the condition “current time = time of instruction”. In general, conditions may take other forms, e.g. “as soon as temperature passes 39°C”. **RK** clin:inst-condition
- Action (what)*: the action to be undertaken. The description of an action might be quite complex, as in the case of a major surgical procedure. **RK** clin:inst-what
- Status*: the current status of the action, which might include: intended, executing, overdue, completed, cancelled. **RK** clin:inst-status

3.4.3.3 Organisational Structure and Navigation in Transactions

The organisation of knowledge items within transactions is required. This is done using headings and indenting in the paper record. Headings are not of arbitrary form or importance in clinical practice as they might be in other disciplines: they reflect accepted practice models, and are often standardised by medical schools, national associations and so on. *Consequently, the electronic record must cater both for headings, and for standard models of headings.* **RK** clin:nav-head

Headings not only provide organisation during recording (where to put something) but *navigation* after the fact: they are the key to reading the record. They constitute a fourth kind of knowledge according to the epistemological classification described above.

The defining characteristic of navigational headings is hierarchy, i.e. the headings form a “tree” (may be flat for some clinicians) under which the rest of the information in the record is grouped. **RK** clin:nav-hier

Navigational heading models are usually a function of: **RK** clin:nav-model

- Type of transaction: e.g. care plan headings will be different from contact headings.
- Type of HCF: general practice models are typically different from those used in hospitals; nurses use different headings from those used by physiotherapists.

Given that headings form both the framework within which record content is constructed, and that by which it is read, we can reasonably require that *no content item may be added to the transaction without appearing under at least one organising heading; ensuring no information is hidden from view.* **RK** clin:nav-add

Note that it is not intended to prevent HCPs from entering information without structure: a single heading “Notes” under which everything else is recorded may be acceptable in some contexts, and the record must cater for it.

3.4.4 Structure Adaptation and Evolution

In the above discussion, concrete clinical information structures have been intentionally avoided. Many clinicians accept that it would be impossible to describe all currently known conditions, practices and situations which might lead to information being created in health records, let alone future structures which might arise.

see also: [Del19-3.2.1 final paras], [Del19-3.2.7-Adaptability]

Various factors would seem to guarantee this:

- Mainstream technology changes quickly and can significantly affect procedures and methods (e.g. NMR, ultrasound technology in medicine; telecommunications in telemedicine).
- Clinical norms change. For example, blood pressure was first recorded as phase I and phase IV and later as phase V. Clinicians may wish to record all three. More recently the cuff size has been recorded as well. Clearly it is inappropriate to constrain the recording of the measurement of blood pressure at the architectural level.
- Ongoing medical research (and other research for that matter) is always contributing to better understanding of things, and hence changing the way medicine is done.

Examples: the change in monitoring of diabetes from measuring urine glucose, later blood glucose and more recently glycosylated haemoglobin is an example of different measures. The change from AIDS to HIV status is just as relevant with new ways to classify different diseases.

- The social and cultural environment in which medicine is practised varies from country to country (e.g. US v UK); and procedures often change due to non-clinical factors, e.g. religious/cultural norms, influence of insurance companies, public health care changes and so on.

Consequently, a model which prescriptively proposes information structures for every possible procedure or situation is fundamentally undesirable, for at least two reasons: a) it would compromise widespread and future usability of the model, and b) it would conflate the standardisation of the electronic health record - essentially an information structure - with the standardisation of practice models, protocols, and other clinical concepts - the business of clinical medicine at large.

3.4.4.1 Meta-model Approach

The problem remains then of how concrete clinical structures should be implemented in the model. We have already said that information may be encoded in a generic way, i.e. corresponding to *transactions*, and within these, using generic *epistemological* structures. A way is needed of *configuring* these structures according to the actual concrete structures which turn up in clinical practice.

RK clin:arch

Let us state this requirement in terms of the model. The GOM must include:

Knowledge representation: a model of underlying *content*, describing structures which enable any reasonable knowledge concept to be expressed.

A *meta-model*: i.e. a part of the model whose job it is to describe valid configurations, or *archetypes*, of the underlying information.

RK clin:arch-extent

In order to know how to construct a viable object model, we need to explicitly define where the divide between model and meta-model falls; this determines both how sophisticated the meta-model needs to be, and the limits of the concrete model. Following on from the above discussion, it seems reasonable to *require that the meta-model provide archetypes for*:

- Transaction types, e.g. contact, summary, etc.
- Typical content types e.g. lab-results, prescriptions.

- Navigational headings.

To Be Determined: Extract types may also be required

We can now say that if we accept a GEHR model via which *any* reasonable clinical information can be encoded, it is also accepted that it is not required to be able to represent any given concrete piece of information (e.g. Blood Pressure) in the most optimal way for that item, since the most efficient representation may not be available. This observation is not particularly important clinically, but is a message to developers that the record must favour generic, adaptable structures over purpose-designed ones.

Such an approach corresponds well to the requirement that GEHR not constrain the way medicine is done, but rather to provide a way in which information created under any practice model can be stored.

The two-level approach is illustrated in FIGURE 2. Here we see a record being constructed by an application, whose concrete structures are configured by an Archetype (part of the meta-model).

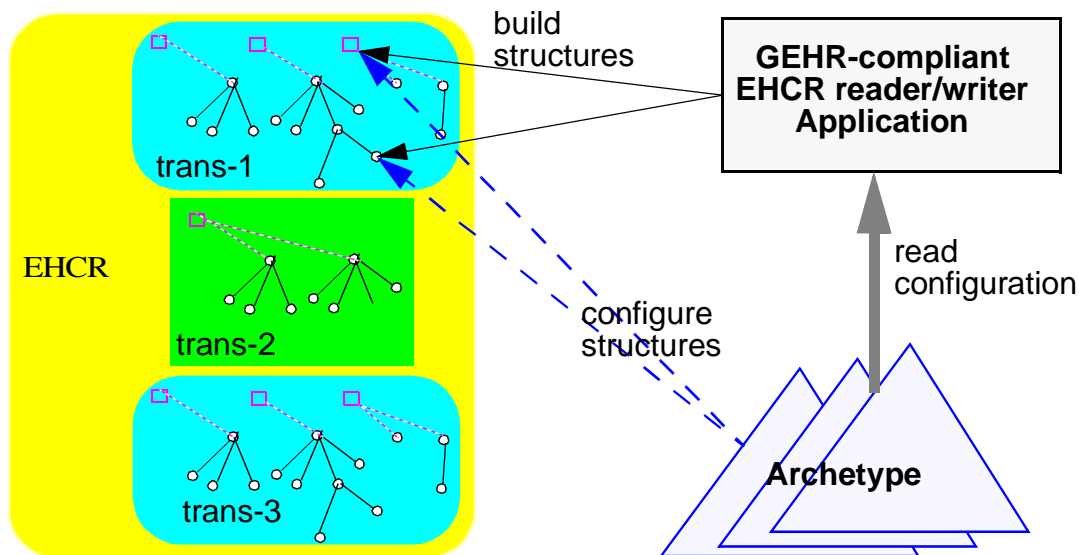


FIGURE 2 Relationships between EHCR, Archetype, and application

There is nothing new in the model/meta-model approach - it is the basis of, for example, SGML and meta-CASE tools in software engineering. It is a standard element in many computer systems.

3.4.5 Data

At the lowest content level of the record we find the data values used to record observation data, instruction items, and subjective information. The following subsections describe the required data types.

3.4.5.1 Text

RK clin:data-text

Text is used in many places in the electronic health record: for textual explanation and notes, as in a paper record, for headings (see above) and for text values of observations, in the same sense that quantities provide numeric values. For the last

two categories, coded terms are likely to be used, or even mandated in some contexts (not mandated by the record however). The following text types are required:

RK clin:data-text-plain

- *Plain text*: items of text of unlimited length must be able to be created in the language in use at the HCF. It should be possible to add emphasis to particular selections within the text, according to some simple scheme whereby different levels of emphasis are rendered in specified fonts, type-faces, colours.

RK clin:data-text-term

- *Term expansions and codes*: from medical/clinical termsets. Expansions of codes must be able to be read as normal text; the corresponding termset code(s) must also be stored, since coding is seen as a significant clinical statement (particularly in the US).

RK clin:data-text-link

- *Hypertext links*: it should be possible to attach a hypertext link to an arbitrary piece of text, in the manner of an HTML link. Links may be internal references to other parts of the same record, or external references (see below).

RK clin:data-nom-arch

Text or term values can be used to represent the finite set of values for an observation type, for example, “blood type” may have associated with it the values “A”, “B”, “AB”, “O”, and so on. They can also be used for values which are often considered to be boolean data, such as “yes”, “no” and “true”, “false”, and such a representation is more desirable than a pure boolean one, since clinical experience shows that value sets for attributes naively thought to be boolean, such as “sex”, often require extra values: “m”, “f”, “indeterminate”, “not provided”. Some LOINC terms have a set of allowable values, and the Australian National Health Data Dictionary has many items with a defined set of values. There is a requirement for nominal item archetypes to have sets of allowable values.

Action: `clin:data-nom-arch` not added to model

RK clin:data-qty

3.4.5.2 Quantities

The following types of quantity data must be supported:

RK clin:data-qty-num

- *Quantities*: to represent any 1-dimensional numeric value, with optional units and precision. Units must be capable of representing any unit combination found in units systems currently in use (mostly the SI system).

RK clin:data-qty-rat

- *Quantity ratios*: for representing dilutions such as “5g per 100ml”, and similar;

RK clin:data-qty-rng

- *Quantity ranges*: for ranges consisting of two quantities with the same units, including indicators for:
 - include/exclude lower, upper
 - range is inside/outside limits

RK clin:data-dt

3.4.5.3 Dates and Times

Dates, times, and timestamps are important in the record, since they are used to define when observations were made, when treatments should take place and so on. They are also crucial in reconstructing chronological sequences of observations, diagnoses and procedures, when the need arises for clinical or medico-legal reasons.

RK clin:data-dt-date-abs

- *Absolute dates*: dates should be represented so that day/month/year can be easily obtained; their validity should not be limited by any near future date, such as dd/mm/2000, or in some systems, dd/mm/2035.

- *Absolute times*: time must be stored in such a way that time-zone and local time adjustments are included, since the record may travel electronically to different time zones. “Fine” seconds, i.e. fractional seconds should also be available. **RK** clin:data-dt-time-abs
- *Durations*: elapsed time, required for e.g. maximum duration of a prescription = “30 days”, duration of audio signals in an audiogram = “10 ms”. **RK** clin:data-dt-duration
- *Timestamps*: a timestamp is an absolute date + absolute time combination, and is required in many places, e.g. date/time of recorded observation. **RK** clin:data-dt-timestamp
- *Ranges*: of dates, times and timestamps, in the same manner as above. Ranges are required for defining the valid period in which certain activities can be done, were done, etc. **RK** clin:data-dt-range
- *Occurrences*: a time concept consisting of the following parts: **RK** clin:data-dt-occurrences
 - first occurrence
 - most recent occurrence
 - periodic? If so; period
 - average frequency of occurrence (= period if periodic)

This type is required in order to record an event which occurs or should occur many times, Examples include history of asthma attacks, abuse, and administration of medication.

3.4.5.4 Multimedia **RK** clin:data-mm

A number of multimedia types must be supported, without being restricted to formats known currently. Support is required for:

- *Digital images*: as produced by various kinds of diagnostic equipment such as ultrasound and NMR in standard formats such as DICOM. **RK** clin:data-mm-image
- *Digitised and computer constructed drawings*: widely used to indicate complaints during a contact, surgical procedures and so on. It may be desirable to support some of the standard sketch templates available in medical textbooks. It is likely that drawings will be seen as clinically “primary material”. i.e. an effective *replacement* for words in some cases, which is generally not the case for other kinds of digital image. For this reason, implementations should consider using space-efficient representation so that drawings can be treated as a mandatory part of the record for transmission. **RK** clin:data-mm-drawing

To Be Determined: The Good European Health Record proposed a standard set of drawings derived from research of clinicians’ practice. These may be acceptable as is with a standard ‘helper application’ for viewing them.

- *Audiovisual (motion)*: data characterised by motion images, and or sound, e.g. echocardiogram, cardiac angiogram, laryngeal stroboscopy, video recording of a psychiatric examination, audio recording of part of a speech therapy session. **RK** clin:data-mm-av

Multimedia data should be able to be incorporated into the record even if the record management software doesn’t understand it; in all cases, *the name of a tool or format which can be used to understand the object should be recorded with it.* **RK** clin:data-mm-format

RK clin:data-mm-size *Size should also be recorded with multimedia data, to enable software to provide choices to users for including/excluding multi-media data from storage and transmission.*

3.4.5.5 References

References to things not inside the record proper must be supported, as follows:

RK clin:data-ref-phys

- *Physical “data”*: occasionally a reference to a physical sample, specimen or other object will be needed. An Xray film may be kept at another site or by the patient at home. A specimen for testing may be labelled anonymously and the reference kept in the record.

RK clin:data-ref-ext

- *External “data”*: the record may need to refer to objects outside its own structure and storage mechanism, such as large multimedia files, information in other databases, arbitrary files and so on. This will be particularly true when GEHR records are used in an environment containing legacy data (in files) or databases.

RK clin:data-ref-std *A standard way of representing all external electronic references should be used, and given its ubiquity and wide tool support, the URL scheme used on the internet should be considered. This is an extensible scheme which follows the construction “resource-type:locator”, and can be made to incorporate clinical resource types as necessary.*

3.5 Higher-level Clinical Concepts

3.5.1 Processes

RK clin:process A process-oriented view is useful for clinical, administrative and financial reasons. A typical process includes a series of causally linked events, such as:

- A subjective datum, such as “I have a sore throat”, and an observation such as “severely inflamed throat”, both provided in an initial consultation.
- A diagnosis, such as “streptococcal infection of the throat”.
- A prescription such as a course of oral penicillin.
- After the course of medication, a further subjective datum and observation indicating patient wellness.

In a hospital, there may be even more detail, since prescribing would often involve entering an order within the hospital orders system, and administration may be done by a nurse rather than the patient, as would typically occur in a primary care situation. In some circumstances, it may be desirable to record the fact of the intended prescription, the actual order, and the drug or therapy administration events in the health record. For basic medications and therapies (e.g. pain relief), the treating clinician(s) may not care about such micro-process of order management, as long as they are executed without error. However if a problem of some kind occurs, the trail of detailed information provides proof for determining procedural or other failure, and may even be needed as legal evidence.

In more complex medication processes, such as anti-coagulation, the physician will most likely require that the process be recorded in detail, so as to know the status, and to be able to make further decisions, which may modify the course of the process.

A generic model of such processes should allow the following concepts to be represented in the record:

- *Grouping* of multiple information items such as observations, prescriptions, orders and resulting observations, under a single process, identified by name. **RK** clin:process-group
- Identification of the *goal* of the process, its *proposed actions*, its *actual actions*, its *actual results*, and potentially some measure of *variance* between the goal and results.
- The ability to represent the *causal relationships* between items grouped in a process, for example, an observation leading to a prescription. **RK** clin:process-rel
- The ability to allow prescriptions and *orders to be cancelled or superseded* by new ones. **RK** clin:process-cansup
- The ability to know what the *current state of a process* is, for example, based on a comparison with today's date, it should be possible to know that a particular process is in the middle of a course of medication. **RK** clin:process-status

There are obvious financial justifications for representing processes in the record. Not only may the events in a hospital EHR be the basis of billing, they may also be used to determine high-cost areas in which procedural efficiency improvements may be desired.

Finally, the "micro-histories" of events represented by processes in time in populations of EHRs are a potential data source for the evidence-based medicine approach.

The above arguments appear to point to hospital EHRs which contain a large amount of process-related data, which might intrude upon the purely clinical view of a patient's progress. A balancing requirement should thus be stated, that, *regardless of the amount of process-related information added to the EHR, the ability of the clinicians to efficiently see only clinically-relevant data must not be compromised.* **RK** clin:process-clinview

3.5.2 Episodes

"Episode" can be a problematic term in clinical medicine, since different people and professions have slightly different definitions, for example "administrative episode of care" (for billing purposes) versus "clinical episode of care" (for constructing a clinical history). Despite this, a common aspect of "episode" is time.

Rather than state a specific definition, we will require that a flexible concept of episode can be represented in the EHR. It is characterised as a collection of transactions or other data items in the record which satisfy some combination of criteria such as: **RK** clin:episode

- A transaction committal date/time time range
- A particular authorising physician(s)
- A particular health care facility(s)
- Name(s) containing certain terms or patterns

With this approach, an administrative episode of care can be specified, for example, as "the set of transactions in the record between 01/Jun/1998 and 24/Dec/1998, for which the health care facility is the Mayo Clinic". A clinical episode of care might

not specify the health care facility, but would probably specify the clinical problem, e.g. by filtering on information containing the term "diabetes mellitus".

3.5.3 Problems

To Be Determined: A "problem" could be defined as a clinically detected underlying health problem of the patient, such as "diabetes mellitus" or "Atrial Septal Defect". The concept may be useful in the record to thread together all transactions or lower-level items relevant to the problem. This may be a large number of items in a chronic condition.

To Be Determined: It may be that care plan persistent transactions will do this job

To Be Determined: Is there a relationship between this idea of problem, and Weed's "problem" in the Problem/SOAP framework?

To Be Determined: Which class of EHR user is interested in problem threads?

3.5.4 Issues

To Be Determined: An "Issue" could be defined as a problem as perceived by the patient, e.g. "fatigue", "shortness of breath". Is there a need to be able to thread together items under issue headings, as for problems?

To Be Determined: Which class of EHR user is interested in issues?

3.6 Interrogation of the Record

3.6.1 Queries

To Be Continued: Applications should have access to instant queries developed by clinicians - such as "last Chest Xray" or the "last 10 blood pressures".

3.6.2 Views

To Be Continued: Flow charts in intensive care or diabetic followup are examples of views of the record which should be generated quickly by applications.

3.7 Scenarios

The following scenarios relate to the events in the process that occurs during the life of an EHR during clinical use.

3.7.1 Basic

3.7.1.1 New Patient

When a new patient presents to a Health Care Facility (HCF) there will be three possibilities:

- The patient has no record.
- The patient has a record at another site.
- The patient has a hand-held record.

To Be Determined: It is possible that the patient has attended previously but prevention of duplicate entries will not be dealt with here.

A new record is generated at this HCF and an identity transaction built to ensure the patient can be identified in future. Consent for the different uses the HCF makes of the patient record is requested and recorded.

If the patient has a record elsewhere, consent will be requested for the transfer of an extract of the EHCR at the other HCF. These might, for example, include all persistent transactions (latest versions only) and a subset of event transactions (perhaps the last year) and all reports including discharge summaries.

If the patient has a hand held record then this may be used as the source of the information and used as the record for the clinical contact if the patient is moving on. A local record may be produced by copying the identity transaction and recording the transactions made by the local clinician only.

The local clinician will usually record an event transaction and some persistent information such as major adverse reactions to medication or other allergies.

To Be Continued:

3.7.1.2 Birth

A birth is a special case because the child will usually not have any identifying information for a period of time. It is usual to keep a newborn's record within the mother's record for some period of time. This is an example of when the data subject needs to be distinguished from the patient.

Transactions relating to the child can be transferred to its own record when it is created.

An archetype transaction model for the birth event may be warranted to ensure standardisation of birth information for population health and medicolegal reasons.

To Be Continued:

3.7.1.3 Death

An archetype transaction for death may be warranted to ensure standardisation of death information for population health and medicolegal reasons.

To Be Continued:

3.7.1.4 Revalidation of Information

In a primary care context, clinicians will often revisit information stored earlier in the health record. For example, lifestyle information (recorded in a persistent transaction), such as history of smoking and exercise need to be reviewed every so often. The result of the review will include items of information:

- For which there is no change. For example, the patient still smokes around 40 cigarettes a day.

- Which do change, for example the patient smokes only 5 cigarettes a day, or the patient no longer smokes.

The record must accurately record both cases. Clearly in the second case a new value will be recorded, along with its context information, including date/time, making it obvious when the information was recorded. However, it must also be clear in the first case that the clinician has reviewed information which does not need to change in such a way that the fact of review appears in the record at the correct date/time.

3.7.2 Hospital

3.7.2.1 Admission

Admission to hospital may involve the same scenarios as the New Patient scenario above. Further, information may be required that strictly determines which transactions relate to a specific admission episode or some other episode of care for billing or organisational reasons.

Special clinical and administrative admission event transactions are likely to be used at this time to standardise information recording.

Note: the GEHR architecture is specifically for the electronic health record and is not seen as the basis for all information that will be stored about a patient when they are at a health care facility and this applies particularly when they are in hospital.

To Be Continued:

3.7.2.2 Contact

The contact record or 'progress note' are the most common entries in the paper health care record and this is likely to remain the case with the EHCR. Archetypes for different contact records are likely to be developed both at the GEHR level (e.g SOAP or Drug administration) and locally. These will be event transactions and populated with a few organisers that may or may not be required by the locally used archetype.

The architecture limits the scope of information collected in event transactions requiring that information that is of persistent relevance to be copied to persistent transactions at some point. An example might be that a child has a family history of asthma and her mother is ill at the moment. Clearly both are important aspects of the child's family history at present but only the family history of asthma is likely to be of ongoing relevance.

To Be Continued:

3.7.2.3 Surgical Procedures

The record of a minor procedure may be part of a larger contact record or a transaction on its own in the case of an operation. In the latter case an archetype will usually be used - perhaps developed by the College of Surgeons or adapted to local requirements. This will largely be observation information with some subjective data from the clinician.

To Be Continued:

3.7.2.4 Intensive Care

Intensive care is a specific example of continuous recording by different health professionals within one EHCR and potentially within one transaction.

To Be Continued:

3.7.2.5 Out Patients

Out patients' records are a special instance of event recordings and amendments to persistent information. These will be very similar to records kept in other settings although in hospital they may need to be linked to an episode of care. A report may be written and specifically sent to another clinician or a copy of the event transaction sent as an extract.

To Be Continued:

3.7.3 Problem-Oriented Medicine

Lawrence Weed's problem-oriented approach to clinical notes has greatly improved the organisation of clinical information.

To support this common method of organising clinical information, it must be possible to create a contact event transaction with a hierarchy of organisers with "Problem" headings at the top level, and sub-organisers "subjective", "objective", "assessment" and "plan".

Further, it should be possible to reference problems listed in event transactions to in persistent transactions.

To Be Continued:

4 EXCHANGE AND SHARING

The following subsections discuss the requirements of the architecture for ensuring that EHCRs can be exchanged between GEHR-compliant implementations.

4.1 Overview

Two modes of health record *communication* are possible:

Exchange: the movement of records out of one computing environment and into another.

see: Del19-3.2.7-
Sharing

Sharing: for reading and writing of the same records by different software applications, but within the same computing environment.

Successful communication of the record as a stream of bytes, bits, or other “atoms” relies on a common agreement, *for a given communication medium*, on the form of *representation*, in terms of:

- Basic data types (INTEGER, REAL, BOOLEAN, STRING, DATE, BIT etc).
- Container types (ARRAY, LIST etc).
- Other generic (template) types.
- Internal references.
- External references.

Complex data types are constructed from basic types, and so once the rules are established for basic types, they will automatically be taken care of. This approach defines the basis for a logical protocol, and is used in, for example, the Remote Procedure Call (RPC) protocol found on Unix and Windows platforms.

With a logical protocol in place, records can be exchanged or shared using any of the following media:

Files: in the same way as a word-processor document. May be used for both storage and exchange (e.g. as an email attachment).

Databases: where the reader application reads data representing the record from the database, previously written by a writer application (may be itself). Databases are normally oriented towards sharing rather than exchange (although this is technically possible, and sometimes used), since their main purpose is persistence.

Networks: information is transferred between computers via mechanisms such as:

Distributed object systems: where information is transferred between applications using an agreed object protocol, such as DCOM or CORBA.

Messaging systems: where information is transferred between applications using an agreed message protocol.

The following sections describe the requirements for correct communication over such media.

4.2 Media Formats and Protocols

While the aim of the model is to describe a required information structure, independent of communications media formats, there must still be expressions of the model in various formats, to allow software systems to be developed. Technically there are two possibilities for doing this:

- Provide a *mapping*, i.e. a definitive expression of the model in each protocol. Each such expression can be regarded as a formal mapping of the primary model, and may be depended on by software using the corresponding media. Note that such definitions must change in time, following the evolution of the primary model.
- Provide a *binding*, i.e. a set of rules or heuristics for converting between the formalism of the primary model and that used for each medium. This is normally a prerequisite for the above method, although “hand-coded” mappings can be formulated without recourse to a definitive binding. Advantages of this method: it only has to be done once (assuming the definitions of the model and medium formalisms don’t themselves change); it is likely to already exist (e.g. OMG language bindings for IDL, Microsoft language bindings for DCOM).

In practice both methods are used. The second is typical for object systems: CORBA systems rely on bindings between a programming language and IDL, the language of CORBA; object database systems assume a binding between the application language and (something like) ODMG-93 (and potentially SQL3, if it ever sees the light of day...). For relational and messaging systems, definitive mappings may be more useful.

An essential requirement for any medium- or protocol-specific expression of the GOM is that it supports *bi-directional translation without loss of meaning*. In other words, records encoded in the protocol format must be 100% reconstructable to their original form.

4.3 Media-specific Requirements

Which descriptions must the GEHR architecture minimally provide, and what media must a minimally GEHR-compliant implementation support? To answer the first question, we can be guided by pragmatic considerations: the network and database protocols mentioned above are widely used and must be taken into account if GEHR is to be relevant for today’s software developers and users.

A complete GEHR description should include mappings or bindings of the GOM in open system network protocols with high industry support, currently OMG CORBA, and Microsoft DCOM.

Database protocol definitions are less important in the sense that they are not primarily used to engineer open systems communication; nevertheless, the GEHR architecture should attempt to provide standard mappings in ODMG-93 and SQL.

The question of which media an application *must* support is easily answered when we consider the requirement for *vendor-independence of EHCRs* - the guarantee that the records created by one GEHR-compliant implementation can be read by

any other implementation used by the same HCF, or in use at another HCF. *The implication is that all GEHR implementations must support at least one media protocol: a GEHR-nominated “standard exchange format”.* Since this must be by necessity a “lowest common denominator” format, it should be a *file* format description. The GEHR Exchange (file) Format (GEF) concept proposed by the Good European Health Record project is ideal for this purpose.

These requirements are elaborated upon in the following subsections.

4.3.1 File Exchange

RK exch:GEF-support

As mentioned above, a GEF definition must be provided as part of the GEHR architecture, and must be supported by software implementations for minimal compliance. GEF would have a role similar to the Microsoft RTF format which has become a defacto standard for communicating word processed documents between different vendor tools.

see: the Kona proposal

There may also be reasons to argue for a previously published format, such as encrypted SGML, however, security is likely to be an issue since SGML is a directly human-readable textual format.

4.3.2 Network Protocols

RK exch:IDL-std

CORBA

Since there already exists a CORBA binding for the current language of the GOM - Eiffel - the CORBA definition of the GOM is relatively simple to produce. The rules of the binding are applied to the GOM in order to create an IDL definition which is then directly usable by CORBA implementations.

RK exch:DCOM-std

DCOM

The problem of creating a COM IDL description of the GOM is technically similar to creating a CORBA IDL description, although no official Eiffel/COM binding exists.

Clinical Protocols

RK exch:msg-std

Expressions of the GOM are required for the clinical protocols HL7 and EDIFACT. Since these two contain a significant amount of clinical detail and are message-oriented, it is likely that a definitive mapping will be required. This must show how GEHR structures will be encoded in HL7 etc, and how any HL7 structure will be encoded by a GEHR system.

4.3.3 Databases

Object Databases

RK exch:odb-std

The current standard for object databases is the ODMG-93v2 standard. The SQL3 proposal in its current form appears to be a good (in some ways better) offering, and can be used as soon as it is published.

Relational Databases

RK exch:rdb-std

There is not yet a published standard for relational storage of object information. It would be reasonable to use an arbitrary mapping from the GOM to relational database tables, as long as it is published in the same manner as the GEF, allowing software vendors targeting relational databases to write GEHR-compliant software.

Note that there is technically no reason preventing the adoption of GEF and RDB mappings from industry vendors as standards, rather than specification by a standards body; this may even be preferable if it brings a more solid guarantee of computability and usability.

4.4 Boundary of the Model

There is a further requirement on the primary expression of the model, relating to the formalisms of different media: the model must explicitly define all *types* (in the sense of data or programming language types) not defined natively by a given formalism. This requirement is in fact quite profound, as will become clear in the following.

Basic Types

If, for example, the target formalism is “relational table definition language”, the types `STRING`, `DATE`, `MONEY`, `INTEGER` will be implicitly understood and the GOM could reasonably use these types as its base types. If on the other hand a formalism lacking `MONEY` and `DATE` was used, but these types were still required in the model, they would have to be explicitly defined. The same argument exists for any target formalism, with a differing set of base types and containers being natively understood. The question is: how far must the GOM model go in declaring basic types?

To answer this, we must look at the language of the GOM. The example of Eiffel will be used in the following discussion; the details will be slightly different for other formalisms.

As a pure object language, Eiffel does not use “native” types in the sense of the C languages - there is no difference between `INTEGER` and `MOTOR_CAR` (although compilers do detect basic types and optimise them). The basic types of Eiffel are defined to be those from the `BASE` library, of which the interface was standardised by the Eiffel Library Kernel Standard 1995 (ELKS95), by the Non-profit Consortium for Eiffel (NICE). These types are:

- `CHARACTER`
- `STRING`
- `INTEGER`
- `REAL`
- `DOUBLE`
- `BOOLEAN`
- `ARRAY[G]`
- `POINTER`
- `BITn`

These types can be *assumed* in the GOM, since mappings will normally be available between them and formats. Other types which can reasonably be assumed are those commonly found in exchange formalisms to which the GOM is likely to be mapped, such as `IDL`:

- `LIST[G]` (implied order, non-unique membership)

- SET[G] (no order, unique membership)

Examples of types often used in software development, but which would have to be explicitly declared in the GOM:

- DATE, TIME, DATE_TIME etc
- MONEY

Generic (parameterised) Types

Generic types such as the following would also have to be explicitly defined in the GOM, since they do not fall under the category of “basic” container types such as List<T>, Bag<T> etc commonly recognised by representation formats.

- TABLE[G,H]
- HASH_TABLE[G,H]
- RANGE[G]

RK model:limits

The conclusion is: *any type or container construct not known in target communications formats should therefore have an explicit definition in the GOM*, regardless of whether such types might normally be available in the model formalism.

4.5 Applications

From the software developer point of view, any piece of software which purports to read and write GEHR records via a medium, will assume that the record data is represented in the standard format for that medium. For instance, an application writing records to a Sybase database will assume that the record data is stored in tables accessible via SQL2; an application writing to the O2 object database will assume the ODMG-93 object format. The same goes for applications reading and writing records via an interface such as DCOM or CORBA - they will use the standard IDL description for reading and writing objects.

In general, to construct an application capable of representing GEHR-compliant records on a medium, one of the following must be true:

- (Some part of) the application is written in the same language as the GOM, in which case it can immediately take advantage of the published mappings or bindings for the language of the GOM and various communications formats;
- The application is completely written in another language, and contains or has access to the mapping (not just binding) of the GOM for each communication format it uses;
- The application is written in another language, contains an object model (i.e. classes or the equivalent) which is itself a certified mapping of the GOM, and also contains or has access to bindings for each communication format it uses.

Previously stated requirements guarantee that the GOM and its mappings and/or bindings will be sufficient to support this.

4.6 Integrity

Some way of ensuring the *integrity* of both transmitted records, and records at the receiver's end into which transmitted extracts will be merged, is required. There are a number of aspects to integrity:

- Transmission of certain types of content, such as internal and external references, bulky data.
- The *granularity of the record* from the viewpoint of transmission, or, put another way, what is the smallest unit of transmission?
- The *virtual record* concept and uniqueness of identifiers of transmitted parts. see: Del19-3.5.4

These are discussed in the following subsections.

4.6.1 Translation over Transmission

The Good European Health Record requirements state that the exchange of records or parts thereof must occur such that: see: [Del19-7.7.1, 7.2]

- Patient identity for the extract is clear.
- The version of the GOM assumed at each site is taken into account.
- Received extracts are “intact”.

Further details do not appear to have been stated in the Good European Health Record deliverables, but widely accepted requirements for integrity over transmission include:

- Coded terms are sent in such a way that receivers with no access to the term set can see the “expansion” of the code in the same way as at the source; however, the receiver should also be able to know what code was specified at the source, since coding is commonly considered a clinically significant exercise. RK exch:code-translat
- **NB:** the Good European Health Record specification required that local termsets be transmitted with record extracts, but there appears to be no need for this, since from the point of view of a receiver, a sender's local termset is no different from any other termset unavailable to the receiver. see: e.g. Del19-7.2.2
- References to information outside the GEHR system at a site (e.g. to records in a local relational database) should either: RK exch:ext-ref-translat
 - Be preserved on transmission, in order to act as a reference at the sending HCF, should the receiver require the referred-to information.
 - Or the information referred to should be extracted and transmitted as in the record as e.g. a plain-text item, along with the source reference. Such automatically included information should be marked as such, since it is an exception to the rule that content is only added to the record intentionally by the clinician.

In both cases, the identifier of the sending facility must be included, as a qualifier to external references.

RK exch:bulky-transl

- Bulky data may be optionally transmitted; if it is not, either a global reference (such as a URL) or an external reference (as above) to it should be transmitted.
- Internationalisation-related translations should take place. See section 7.2 on page 58.

4.6.2 Minimum Unit of Exchange

RK comm:min-unit

Since for reasons of clinical clarity it was agreed during the Good European Health Record project to make the transaction the basic unit of addition to the record, representing an interaction between a carer and the record, it is reasonable to require that *no smaller unit than a transaction be transmitted to another site*. We can justify this by realising that while the transaction forms the container within which a clinician organises information, no general statement can be made about its sub-structure in terms of compartments: it would be very easy for example to construct a transaction whose components referenced each other, and which should therefore travel together to be meaningful. Furthermore, if the transaction defines the boundaries of the clinician's "palette" on which to paint a story, transmitting anything less than the whole could easily constitute a serious misrepresentation, from the point of view of the receiver.

A corollary of the above requirement becomes clear when we remember that exchange (transmission) is only one form of communication; there is also sharing *in situ*, as occurs for example within a client/server database system. Communication in such systems occurs at the point of reading, and of committal of records. Consider what might happen if a writer application committed part of a transaction: a reader application in the same system (somewhere else in the same hospital perhaps) accessing the same record might assume a partial transaction was complete. Thus we must also *require that the transaction is the minimum unit of reading and modification*.

Unfortunately, defining a minimum unit of transmission so simply is not the end of the story, but it is fundamental to meeting many other requirements. What happens if a transaction containing links to other transactions is sent? Is it sufficient to state requirements for the integrity of such links (exch:ext-ref-translat on page 49), or are there circumstances requiring the transmission of linked transactions?

To Be Continued: This area requires testing during implementation.

4.6.3 Clinically Acceptable Partial Record Views

At times a clinician may need to send bits and pieces from different transactions to another site: perhaps the last 4 HbA1cs, the last blood pressure, the last creatinine and a paragraph from the report sent by a clinician. Today this would be done in a letter but within a GEHR record this can be a new transaction created in the record thus preserving automatic processing at the other end. This raises one problem - the blood pressures are now potentially in the original record twice. Major diagnoses will be entered in patient summaries as well as in the encounter record.

RK query:duplicate records

As each transaction is unique and must be available for transmission, the kernel will be required to recognise when information is duplicated. Clearly, the first example of a duplicated blood pressure reading is of a different order than an entry

of ‘diabetes’ as a diagnosis in an encounter record or an entry in the patient summary.

Action: query duplicate records is not in the model

4.6.4 Merging and The Virtual Record

The notional collection of all physical records for a particular patient held in various places forms what is often known as the *virtual record* or single logical record of care. Whilst no need has been identified in GEHR for the physical assembly of virtual records, partial assemblies will occur anyway, due to exchange of extracts: any health facility may wind up with the record for a particular patient containing transactions sourced from any number of other facilities, as well as itself.

The issue here is the integrity of such assemblies: they must appear “normal” in the same way as a “home-grown” record. Since it is already accepted that there may be unresolved (but known) references in exchanged transactions, the problems reduce to:

- Can transactions have a unique identifier based on the core attributes they possess - date/time committed, EHCR source and responsible clinician. As the EHCR source is a single repository this can easily be controlled and can become a requirement of any system. It will require unique identification of each EHCR source perhaps through a GEHR license. **RK** exch:record-order
- Sensible ordering of the transactions. We can guarantee a sensible order by requiring that received transactions are date/time stamped. (See clin:trans-concept);
- Discarding duplicate transactions (due to repeated requests or having sent transactions to that source in the past, for example): guaranteed by date/time stamping + sending HCF’s identifier. **RK** exch:uniqueness

This requirement is not met in other proposed architectures. It is challenging, but portability of the record is a fundamental GEHR requirement. Consider catering for the scenario of a record moving back and forward between different HCFs, parts of it on a smart card or other medium and additions and corrections being made at any or all HCFs. This requirement states that all transactions of a single patient at vari- **RK** exch: medico-legal

ous HCFs must constitute a single logical record of care which can be merged in future and remain medico-legally acceptable.

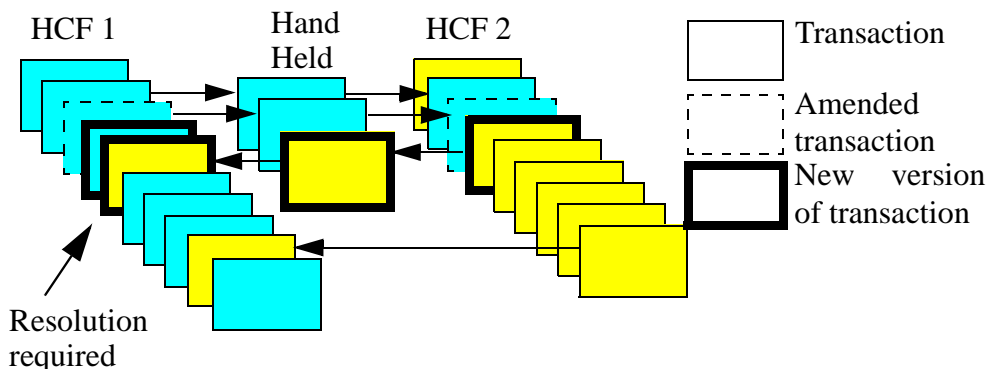


FIGURE 3 Merging Transactions

Action: `exch: medico-legal` is not in the model. This may mean adding features to `EHCR_EXTRACT` to cope with what was done with some transactions when merging occurred. If an amendment of a transaction occurred at another HCF in error, and the transaction has been correctly amended locally - the date-time stamp of the local record may mean that the received transaction is taken as the latest version. The choice which preserves the single logical record is to recreate the local revision explaining why - thus ensuring accountability for doing so.

4.7 Import and Export

The previous section dealt with EHCRs being shared or transmitted between GEHR systems. The problem of receiving and transmitting health record information to non-GEHR systems remains. Broadly speaking, there are two kinds of non-GEHR system: legacy systems (e.g. hospital databases) where the intention is eventual replacement by (or upgrading with) a GEHR-compliant system, and specialist systems using published clinical protocols. Legacy systems are discussed in the next section; clinical protocol systems are described below.

There are a number of clinical protocols in wide use in various parts of the world, mainly for communicating pathology orders and results. HL7 and EDIFACT are common in the US and Europe, respectively. The purpose of these protocols is generally to transmit detailed messages indicating exact nature of pathology orders, results, and observations; numerous rules ensure that relevant patient, provider and billing or rebate details are included in messages. Some such protocols also contain generic communications semantics (e.g. ACK, NAK etc). HL7 supports also real-time messaging as might be used for biosignals in a hospital ICU.

A defining characteristic of protocols such as HL7 and EDIFACT is that they *directly encode concrete clinical concepts*, whereas the GEHR approach is one of

generic information structures, with particular instances being built using a meta-model approach.

Communication between a GEHR system and an HL7 2.3 system (say) therefore requires a mapping between HL7 messages and both the GEHR concrete- and meta-models. For example, the order for and filling of a Liver Function Test corresponds to a number of HL7 messages. There will be some correspondence between the HL7 message structures, and GEHR concrete structures (transactions, hierarchy of propositional items), and also between the HL7 content and the GEHR meta-model description of a liver test request and results.

What are the requirements of the GEHR architecture and systems built using it in order to effect correct communication in the manner described above? We can state a negative requirement first: since the aim is not GEHR/GEHR system communication, there is no need to be able to export a GEHR record in a non-GEHR format without information loss.

In general terms, the aim is for GEHR systems to be able to correctly participate in protocol exchanges with non-GEHR systems, not to be able to faithfully represent GEHR records in non-GEHR protocols. The extent of such exchanges is as follows:

- GEHR systems should be able to understand all those messages which might be reasonably directed towards them. There may however be messages in the protocol intended only for like systems, which a mapping to GEHR could ignore.
- GEHR systems should be able to formulate correct responses. There is however no need for *all* semantics of the GEHR model to be encodable as a response in the target protocol.

In summary, it is a requirement that messages be clinically faithful to the intention *as described in the protocol definition*. This is achieved by an unambiguous mapping between those *parts of the protocol* and the *parts of the GEHR model* relevant to communications between systems of the respective types. RK nonGEHR:map
ping

4.8 Scenarios

4.8.1 Pathology Information

Pathology information usually resides on a specialised computer system within a hospital or laboratory. Results are usually viewed in the format used by the pathology system. The GEHR approach would separate the pathology information system from the record. Thus a result would be received from the laboratory via a message which would be entered into a transaction by either:

- Manually, by a clinician
- Or via automatic conversion software

Where the pathology system uses a recognised protocol such as HL7, automated converters can be used to perform this task, requiring only the authorisation of the clinician.

It is possible that the result could come via a GEHR extract but a clinician would still need to authorise its addition to the record. This separation is medicolegally important ensuring that the boundary of the record is explicit.

To Be Continued:

5 AUTOMATED PROCESSING

5.1 Introduction

We have already dealt with the need to generate views of the record to support clinical practice. The requirements for support go beyond queries to the automatic processing of the record. While there will be much debate about when third parties should have access to aggregated information, patients are keen (and rightly so) that their clinicians have access to decision support that has been demonstrated to aid clinical care. Further, clinicians and patients will benefit with audit and monitoring of performance which is aided by automatic processing. The ethical issues raised by this are covered in detail in DEL9 of the Good European Health Record project. Terms used in the record will need to 'know' their original term sets. Ideally in the future, terms will be independent of any particular classification system and will be classified later for a particular purpose relevant to that setting. This is the approach of UMLS and more recently is the approach taken by Read.

5.2 Decision Support

The GEHR architecture enables decision support systems (DSSs) to operate on records about which the software knows very little. Requirements for decision support include the following:

- That sufficient raw data be entered into the record to satisfy the needs of a DSS, for example required algorithm parameters.
- That where terms occur in the record, they are in a form in which a DSS can effectively use them. To be most effective, concept identifiers are required, ensuring that slight linguistic or presentation variations (plurals, differences in case, etc) are collapsed onto the one concept.
- Formal expressions of clinical guidelines in the form of rules may need to be stored in the record, since both the rule itself and the parameters (e.g. target blood counts) will usually be patient specific. For this purpose, it is likely that a mapping can be developed between the Arden syntax and the prescription knowledge type described earlier, enabling generic decision software to be written for many systems using the same kernel.

see: [Arden Ref
required;
Columbia
Presbyterian Medical
Center, NY]

To Be Continued: further research is required on application of standard queries such as MIQUEST and the Arden Syntax.

5.2.1 Scenarios

To Be Continued:

5.3 Population Medicine

Population medicine involves monitoring groups of people. This may be aimed at improving the performance of a HCF or determining the health needs of a larger group. Such efforts require standardisation of data that will grow over time and GEHR proposes that this is achieved through use of archetypes.

RK query:aggreg
data

In a similar manner as for decision support, it should be possible to develop queries that trawl record stores for aggregated and anonymous data. This sort of functionality is important within a health care facility for audit and regionally for monitoring outcomes and clinical approaches. It is widely viewed as a benefit of electronic health records by clinicians and health care managers but is of concern to patients and their advocates.

Clear and well documented controls are required to stop access to the GEHR kernel directly, full logging of access is also required. Access to the data persistence mechanism also require control.

Examples of these requirements will need to be developed and an appropriate mechanism for implementing the queries developed.

To Be Continued: Examples of population based queries across GEHR record stores need to be developed and then tested.

Action: Query:aggreg data is not in the model

5.3.1 Statistical Analysis

RK query:stats

It is possible that the sort of data required by the HCF or by a collection of HCFs will be a statistical analysis of the data in the record. To preserve confidentiality, this analysis could be done on the data directly. This may require statistical functions to be part of the kernel. This may also be required for decision support.

To Be Determined: The statistical functions required in the kernel.

Action: query stats not in model

5.3.2 Scenarios

Queries to request lists of patients that have a certain condition or are using a certain medication can then be queried for specific measurements or other parameters. Terms sets and classification will be required and the GOM contains ample constructs to allow this process to be carried out.

6 EDUCATION

Health care records are used by students and teachers. A mechanism for students to enter records will be required.

6.1 Student Use of the Record

The Good European Health Record project determined that students should be able to write in the records - this is current practice and it is reasonable to expect students to take on responsibility in this area before they qualify. There was an expectation that students records would be of a different fundamental kind. It is clear that versioning already allows updating of errors and all that is important is that student records should appear different in some way than qualified professional's records.

It is probably not acceptable for student records to remain in the record without being accepted by a clinician. Two possible mechanisms are available:

- The application to hold the student transaction 'in limbo' until it is accepted by a clinician. This seems problematic.
- The Kernel to recognise a student entry and treat it like any other, but **RK** `rm:stud-trans` insist on an 'overwriting' by a clinician before it is accepted for processing or transfer.

Action: `rem:stud-trans` not in model

7 CRITICAL ATTRIBUTES

7.1 Availability and Usability

see: [Del19-3.2.1, 3.2.7] Availability and usability of the record should be oriented toward care-giving (clinical contact between patient and carer(s)) as the first priority; compromise may be needed for other uses of the record. This translates to two requirements:

- Availability of electronic health records in a computing infrastructure - a *requirement of the record storage and access systems*, and of the searching and query ability of user applications.
- Usability of the record, once retrieved, on the screen. This is *primarily a requirement on the design of GUI applications*, but does require that the underlying information structures be sufficiently flexible as not to hinder sophisticated visual software design.

7.2 Internationalisation

Requirements for internationalisation in the health record deserve some emphasis, since one of the principal *raisons d'être* of GEHR is the validity of the record when transmitted to other locations, including the EU states.

Translation related requirements include:

- Original language recorded for textual items.
- Translation of terms over transmission (already covered).
- Translations of tracts of text can be added to the record. It may be clinically important for a patient who is moving into a new language community to have text (summaries, plans etc) in his/her record completely translated. For the record to be of any use in the new location, these translations must be added to the record.

RK internat:text-trans

However, for medico-legal reasons, it must not obscure the original texts. Translations should therefore be made available using a concept such as *alternative language views*.

RK internat:lang-views

Exactly where and when translation occurs in the record is worth considering. If the transaction is the minimum unit of transmission, it is sensible for all terms in a transaction to be translated to the target language: translating only some terms would result in an arbitrarily bilingual (and after further transmissions, trilingual, etc) document. *The transaction should therefore be the unit of translation*; original language information can be recorded at that level.

RK internat:trans-unit

This is not the whole story however. The electronic record must support both the need to represent extended pieces of text (as in a paper record), and expansions of coded terms. It is clear that coded terms will be used to represent names and values of things ("diabetes mellitus", "thorax, upper", and so on); clinicians have also identified the likely need to embed such terms within a larger free text item (e.g. for a summary), resulting in text which reads normally, but is actually a construction of term expansions and joining words. When it comes to translation for transmission purposes, it is clear that extended pieces of text should remain in the same language throughout to ensure readability. Since extended text is unlikely to be automatically

RK internat:mixed-text

translated (or even automatically *translatable* - reliably - for years to come), terms embedded in such text items should not be automatically translated either.

Further requirements include:

- Multiple unit systems. In general, the SI system is used in medicine, as in science, however, imperial systems are in wide public use in the US and UK, and should be catered for. There are also certain measurements which are habitually recorded in archaic unit systems: feet/inches for person's height, degrees Fahrenheit for temperature, inches for floppy discs, nautical miles (even "purely metric countries" have exceptions: e.g. the French *mille marin* or *nautique*) etc. The record must therefore cater for the concept of unit systems. RK internat:unitsys
- Date/time locale. *The correctness of date/time interpretations in the record is of paramount importance*, since the time of symptoms, observations, treatments etc can all be highly significant in the clinical sense. The *locale* concept commonly used in operating systems should be used by applications to ensure the correct reading and writing of dates. The requirements for the GOM are to: RK internat:dt
 - state clearly its model of date/time, so that visual reformatting can be reliably programmed in software.

NB: there is nothing to stop a clinician entering a date as text, which can create the usual problem experienced between countries using US-style dates, and those using the British style - what does "6/5/96" mean? This is no different from the same problem with paper records, and as always, it is ultimately the responsibility of the clinicians involved to determine the intended meaning. However: users of record software might reasonably expect that since dates are translated correctly for their locale, this would apply everywhere in the record, including in plain text. Some allowance may have to be made for such errors - perhaps in the form of usage guidelines.

7.3 Localisation

7.3.1 National and Local HCF Standards

There is a requirement that many aspects of the EHCR will be determined at a national, regional and local level, as well as within different professional groups. To preserve meaning a hierarchy of constraints will need to be determined. The levels of the hierarchy may include:

- Concrete constraints of the architecture
- International standards for EHCR
- National standards for EHCR
- Standards for professional groups
- Regional standards
- Local standards (HCF)

The two mechanisms for standardisation in the GEHR architecture are termsets and archetypes.

7.3.1.1 Termsets

There are a plethora of termsets used in health care around the world. The content termsets, such as ICD-10, SNOMED and Read have been in use for some time. The labelling termsets like LOINC are new and are less likely to be duplicated. The greatest effort at present to draw these efforts together is the Unified Medical Language project.

The GEHR architecture is open to all termsets but if processing of records created at another source is to be possible, some standardisation of terms will be required.

To Be Determined: Constraints on use of termsets that will benefit patients.

7.3.1.2 Archetypes

Archetypes have become a requirement of the EHCR to enable development of the record over time, and the need to meet differing requirements in different settings. To enable successful transfer of the record a hierarchy of archetypes is proposed. This hierarchy could be many levels, as many as are required, but if maintained as a strict hierarchy the possibility of automatic processing will be maintained.

An example of a hierarchy might be in an item of drug ordering. Clearly this might be a prescription or an entry in a drug chart. This is an instructional data item and in any setting it will have a core set of sub-items (e.g. drug name; dose; formulation; route). An archetype can then be established (e.g. by ISO) for such an item from which all related archetypes can be developed. Archetypes can then be developed for prescriptions, Australian prescriptions, Hospital prescriptions, private prescriptions, specialist prescriptions, general practitioner prescriptions as required.

RK clin:item model

This requirement allows processing of all information in all records to be done at the level of the GEHR archetype, and national processing of an item to be done at the level of the national archetype. GEHR items must know the archetype or model on which they are based.

Action: clin item model is not in model

7.3.2 National Model Extensions

7.3.2.1 Security

The GEHR security issues are addressed in a separate document, “The GEHR Object Model: Security Issues”, which refers to security issues related to the kernel in particular. There are multiple complex requirements for security at national and local levels and these will remain the responsibility of the system and application.

7.3.2.2 Legal Requirements

Archetypes will enable specific data items to be required at the time of data collection, thus enabling local legal regulations to be met. More complex local requirements will have to be met by the system and applications.

8 SOFTWARE DEVELOPMENT

8.1 Introduction

From the point of view of software developers, implementability issues are of the utmost importance. The following requirements are identified:

- Applications should be implementable in different languages, databases, & exchange mechanisms (which is dealt with by section 4.5 on page 48).
- The object model should be extensible by software developers (according to certain rules).

Further requirements relating to the evolution of the GOM in time, and continuing validity of records and software are described in section 9.

8.2 GEHR-Compliance of Software

Software will be deemed GEHR-compliant on a given target medium if it complies with all the requirements in this document which are relevant to the medium. What does this mean practically? In terms of testing, a proposed implementation must be able to: RK software:compliance

- Correctly process test records containing structures embodying the content and structure requirements.
- Persistence:
 - Correctly read and write records in GEF.
 - If developed as a *product*: correctly read and write test records on the relevant media using at least one of *the published formats* for those media. Custom formats will only be accepted if a) the vendor can prove that the format is a valid mapping of the model, and b) the mapping is available in the public domain, for the use of other developers.
 - If developed for *in-house use*: correctly accept and transmit records from an external source, in a standard representation. This may simply be reading and writing records expressed in GEF.
- Transmission:
 - It must be able to correctly exchange and merge test records with a certified test application over the relevant medium, both within and outside the same locale (in order to test termset code and other translations).

Further requirements may be added in the final definition of “GEHR-compliance”.

8.3 Legacy Systems

The Good European Health Record project specified various requirements for (non-GEHR) legacy systems:

see: Del19-7.2.2

- Records coming from a legacy system into a GEHR-compliant system would have to be converted to legal GEHR information structures, i.e. transactions, and within that, legal content structures. Minimally this might be a textual rendering of all information into the simplest legal GEHR structures.
- Wherever persons are identified within the legacy record, valid GEHR structures for people would have to be constructed.
- Coded terms must be converted to the appropriate GEHR-compliant structures.

Generally speaking, the validity of the record must not be compromised by allowing the rules for creating legal GEHR information structures to be relaxed because the source data comes from a legacy system. Otherwise, the quality of “GEHR-compliant” records everywhere would diminish, eventually preventing software implementations from correctly processing them, and reducing the likelihood of error-free transmission.

An allowance which *can* safely be made for legacy data entering a GEHR record system is that it need not necessarily be encoded in the most powerful information structures possible; where necessary, large amounts of content can be encoded as text, and written to a GEHR text data object. Providing such objects are legal (that is, the requisite context attributes exist; any other rules embodied in the GOM are observed), the record will be a valid structure, and correct representation on data and transmission media will be guaranteed.

Such “simple” GEHR records may of course be quite opaque to powerful system functions such as statistical analysis, reporting and so on due to their structuring.

9 EVOLUTION

9.1 Introduction

As with any standard whose use is widespread, changes have far-reaching consequences. Consider the impact of new IP network standards, the introduction of a new version of SQL, or the effect of making obsolete the PC ISA-bus.

GEHR is no different. Two areas of concern can be identified: the fate of GEHR records, and the fate of GEHR-compliant software and systems.

As a starting point, we can restate the requirement that every GEHR-compliant implementation must be capable of exporting its records in GEF.

These are discussed below.

9.2 Backwards Compatibility of Software

Any GEHR-compliant implementation should be able to read EHCRs in the GEF format, regardless of the vintage of the standard implemented by the writer. This is essentially the same requirement met by word processors capable of processing documents written by earlier versions of the same tool. **RK** evol:sw-back-comp

9.3 Backwards Compatibility of the Record

Conversely, software built on a previous version of the GEHR standard must be capable of correctly processing GEF records created by a newer version to cater for the likely situation (particularly in hospitals) where GEHR software from multiple vendors may coexist. In this case, “correctly processing” means reading and writing of all structures common to both vintages of the standard. This requirement offers some protection to software developers (the introduction of a new piece of software in a mixed environment won’t instantly make older software obsolete), as well as to users. **RK** evol:sw-fwd-comp

In order to facilitate meeting these requirements, the effects of changes to the standard should be determined before implementing them.

9.4 Ownership of the Standard

While it may not be technically appropriate to state requirements about the ownership of a standard (or proposal), the issue of ownership is important for a proposal such as GEHR, given its primarily clinical aims. At least two reasons can be stated as to why the proposal and any resulting standard should remain in the public domain:

- The usefulness of the standard is related directly to the ubiquity of its use, as with any standard dealing with electronic communications or data sharing. If its use is restricted by non-development due to private ownership, or prohibitively expensive single-vendor software, its availability and therefore clinical value is greatly diminished.

- There would be a clear (and quite normal) conflict of interest between clinical integrity and commercial profitability, if the standard and its implementations were in private hands.

An obvious parallel is the well-known incompatibility of legacy word processor software with documents created by (slightly) newer versions of the software, a situation clearly in the commercial interests of the vendor (users must upgrade to read documents written by newer versions of the tool), but can create enormous difficulties for users. A typical scenario is that of a service company (e.g. a translation bureau) newly equipped with the most recent software version, being unable to process previous version documents (e.g. user manuals) of a client company, while guaranteeing original formatting.

If the word processor format were in the public domain, it could be controlled in the interest of users, avoiding legacy document and software incompatibility problems; furthermore, competing vendors could provide alternative offerings based on the same format.

Appendix A Examples of Content Types

Content Type	Provider	Subject	Temporal Event Content	Persistent Content
Subjective	Patient	Patient	Symptoms Presenting complaint History of presenting complaint Reason for encounter Review of systems Social History Medical, Surgical, Psychiatric, Obstetric history	Adverse reactions Education Family history
		Patient relative	Family history	Family history
	Clinician	Patient	Assessment Diagnosis Differential diagnosis Interpretation	Past history Problem list Active Inactive
Phenomena	Patient	Patient	Self monitoring	
		Patient relative	Family history?	Risk factors
	Clinician	Patient	Signs Physical examination Investigation Test results Procedure Drug administration Treatment	Risk factors
Instructional	Clinician	Patient	Plan Referral Acute Prescription Treatment plan Education	Care plan Other care Repeat prescription Ongoing treatment Treatment not to be given (sensitivities)

Patient	Clinician	Restrictions Preferences	Treatment not to be given
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