Semantic Interoperability for Health Network

Deliverable 3.1
Initial methodology for developing semantic interoperability resources

[Version 4]
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Document description

Deliverable:	D3.1 Initial methodology for developing semantic interoperability resources
Publishable summary:	This deliverable outlines the initial methodology for developing semantic interoperability resources. After a short introduction of the subject, design principles and requirements are defined with regard to governing the development of models to organize the clinical content of interoperable health records.
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Contact:	Christian.lovis@hcuge.ch
Editors:	Christian Lovis, Dipak Kalra, Pascal Coorevits, Alberto Moreno Conde

Document history

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May 2, 2011	Initial Draft	Dipak Kalra	
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Contents

1   Introduction and objectives

1.1 The SemanticHealthNet Project

Semantic interoperability of clinical data is a vital prerequisite for enabling patient-centred care and advanced clinical and biomedical research. SemanticHealthNet will develop a scalable and sustainable pan-European organisational and governance process to achieve this objective across healthcare systems and institutions. One important aspect is the development of a logical – ontological framework to support interoperability, which is compliant with current terminologies and information models, in particular SNOMED CT, HL7-CDA, EN13606 and openEHR.

According to the work plan, the clinical focus on chronic heart failure and cardiovascular prevention (including all clinical aspects like diagnosis, observables, medication) will drive the semantic resources to be developed. We expect the exemplars in cardiology and public health to be specific enough to permit comprehensive development and validation of these resources, and yet typical enough for wider generalisation of the methodology and its governance. SemanticHealthNet will capture the needs articulated by clinicians and public health experts for evidence-based, patient-centred integrated care in these domains. Existing European consensus in the management of chronic heart failure and cardiovascular prevention will then be integrated in EHR architectures, clinical data structures, terminologies and ontology by leading technical experts.

Clinical and Industrial Advisory Boards will provide links with other domains in which these results can be used beneficially. The involvement of health authorities, clinical professionals, and insurers, ministries of health, vendors, and purchasers will ensure that the project approach and results are realistically adoptable and viable. This work will also build on the SemanticHEALTH[1] and CALLIOPE[2] roadmaps for eHealth interoperability.

A business model to justify strategic investments, including the opportunity costs for key stakeholders such as Standards Development Organisations and industry, will be defined. Links with the epSOS large scale pilot and the eHealth Governance Initiative, will inform the shape of the Virtual Organisation that this Network will establish to sustain semantic interoperability developments and their adoption.

The consortium comprises 17 Partners and more than 40 internationally recognised experts, including from USA and Canada, ensuring a global impact.

Partners

1. Research in Advanced Medical Informatics and Telematics
   (RAMIT) – BE (Admin Coordinator)

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[1] Stroetmann, V. N.; Kalra, D.; et al. (2009) Semantic Interoperability for Better Health and Safer Healthcare: Research and Development Roadmap for Europe: SemanticHEALTH Report. European Commission; Luxembourg: Office for Official Publications of the European Communities
[2] European eHealth Interoperability Roadmap:
http://ec.europa.eu/information_society/activities/health/docs/cip/calliope-roadmap-122010.pdf

2. Imperial College London (Imperial) – UK
3. University of Hull (UHULL) – UK
4. University Hospitals of Geneva (HUG) – CH
5. World Health Organization (WHO) – CH
6. The University of Manchester (UoM) – UK
7. Medical University of Graz (MUG) – AT
8. International Health Terminology Standards Development Organisation (IHTSDO) – DK
9. Institut National de la Santé et la Recherche Médicale (INSERM) – FR
10. Ocean Informatics (Ocean) – UK
11. Health Level 7 International Foundation (HL7 International) – BE
12. EN13606 Association (EN13606) – NL
13. Empirica Gesellschaft für Kommunikations- und Technologieforschung mbH (EMPIRICA) – DE
14. Standing Committee of European Doctors (CPME) – BE
15. European Coordination Committee of the Radiological, Electromedical and Healthcare IT Industry (COCIR) – BE
16. Whittington NHS Trust (WHIT) – UK
17. European Institute for Health Records (EuroRec) – FR (NoE Coordinator)

Clinical Modelling Advisory Board

Interoperability of electronic health record systems is a vital prerequisite for enabling patient‑centred care and advanced biomedical research. To support the development of a scalable and sustainable pan‑European organisational and governance process focused on chronic heart failure and cardiovascular prevention, a group of highly recognized clinical experts in the field is working as advisory board:

1. Frans van de Werf, Cardiologist, European Society of Cardiology
2. Stefan Anker, Cardiologist, Heat Failure Association
3. François Mach, Cardiologist, Head Division of Cardiology University hospitals of Geneva
4. Rodney Franklin, Paediatric cardiologist, International Society for Nomenclature of Paediatric and Congenital Heart Disease
5. Karl-Hendrik Lundell, Paediatrician, Clinical lead Swedish eHealth semantics and CONTSYS expert
6. Iain Carpenter, Physician, Royal College of Physician
7. Michael Wilks, General practitioner, EU eHealth user group
8. Jacqueline Bowman-Busato, Executive Director, European Platform for Patients' Organisations, Science and Industry EPPOSI
9. Michèle Thonnet, Ministère du Travail, de l'Emploi et de la Santé, France

Project Plan

Workstream I:

WP1: Patient care exemplar (heart failure)
WP2: Public health exemplar (coronary prevention)
WP3: Stakeholder validation

Workstream II:

WP4: Harmonised resources

WP5: Infostructure and tools

WP6: Industrial engagement

Workstream III:

WP7: Adoption and sustainability

WP8: European Virtual Organisation

WP9: Project management, dissemination, promotion

1.2 Approach and methods of the project

It is of increasing importance for clinical information not just to be communicated between different Electronic Health Record (EHR) systems, but to be richly understood by the receiving system: that the clinical meaning of EHR data imported or queried from elsewhere can be interpreted by computers as well as by humans. The SemanticHEALTH report has defined the ultimate goal, full semantic interoperability, as the ability for received EHR data to be combined seamlessly with local EHR data and processed homogeneously.

Although much of the investment in EHRs has been at national levels, the challenge of semantic interoperability is a global one, not only to support cross-border health care but to support large scale multi-national research and valid international comparisons. However, although multiple initiatives have been provided by different Standards Development Organizations (SDOs), major challenges remain unsolved. In order to enable semantic interoperability, it is necessary to univocally identify the meaning of clinical information in the different systems. Nowadays there are three layers of artefacts to represent the meaning of clinical information:

1. Generic reference models for representing EHR data such as the provided by ISO 13606, openEHR and HL7 RIM.
2. Information models like archetypes and HL7 templates as instantiations of generic reference models, tailored to the needs of structured data acquisition.
3. Clinical terminology systems such as LOINC, ICD and SNOMED-CT, the latter being increasingly based on formal-ontological principles and logic.

For semantic interoperability a linkage (binding) between information models (models of use) and terminologies (models of meaning) is indispensable. This includes both
the fixed elements in an information model and the values, i.e. the variable components. In the final report of SemanticHEALTH it is stated that sharing clinical meaning does not automatically imply identical terms and data structures: different physical or logical EHR representations may have a common meaning, i.e. they may be semantically equivalent. Therefore the goal of semantic interoperability is to be able to recognize and process semantically equivalent information homogeneously, even if instances are heterogeneously represented with great variety by using different combinations of

1. information models;
2. terminologies/ontologies;
3. different encodings within the same (1) or (2) of the same system, e.g. pre- versus post-coordinated expressions in SNOMED CT.

According to the same report, the use of terminologies like SNOMED CT, together with EHR (Electronic Health Record) standards should be embedded into a framework capable of identifying equivalent clinical information even if heterogeneously represented. In order to achieve this goal, SemanticHEALTH recommends that *formal ontologies* should play an important role to univocally represent the meaning of each clinical information item and to map semantically equivalent expressions within and between EHRs, within and between languages, thus supporting semantic interoperability. Formal ontologies consist of logical axioms that convey the meaning of terms for a particular community[3]. The set of logical axioms that define a representational unit (concept, class, represented by a unique preferred name) is named intentional definition. Dependable exchange of clinical data requires that there is only one intentional definition per representational unit. In this way, ontologies are based on the understanding of the members of a community and help to reduce ambiguity in communication[4].

Throughout life sciences, ontology resources have increasingly being developed in the last years, and more and more experience in ontology theory and engineering has been accumulated in the (bio-) medical informatics community. OWL, the Web Ontology Language, supported by the Protégé editor and several description logics reasoners has been established as a de facto standard in biomedical ontology research and practice. It represents a compromise between expressiveness and computing power, thus encompassing known limitations in either aspect.

1.3   Scope of this document

This document defines design principles to govern the development of models to organize the clinical content of interoperable health records.

The principles are needed to

1.   leverage the usage of evolutive and sustainable processes;
2.   facilitate the production of appropriate clinical models;
3.   improve adoption of a methodology leading to sharable and interoperable models;
4.   improve standardisation of electronic health records, across professions, disciplines and specialities;
5.   properly reflects good practice;
6.   promote homogenisation of practices while supporting specific requirements in an interoperable framework;
7.   support the growth of high quality, accurate, trustworthy and useful documentation about the health, healthcare and welfare of individuals.

One of the challenges in the process of designing proper models resides in the changes required or produced by the transition between paper-based and computerized records. To some extent, the principles take into account this point in order to facilitate this transition.

Each record content standard that conforms to these principles will contain one or more models that define the information structure and permitted content for a specified area of

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3   Bishr Y, Pundt H, Kuhn W, Radwan M. Probing the concept of information communities - a first step toward semantic interoperability. Interoperating Geographic Information Systems. 1999;495:203215.
4   Hakimpour F, Geppert A. Global Schema Generation Using Formal Ontologies. In: Proceedings of the 21st International Conference on Conceptual Modeling. ER '02. London, UK; 2002. p. 307-321.

documentation. These record content models need to be expressed formally and unambiguously to ensure consistency of implementation and use across the many systems that will adopt these models to direct the capture, storage, display, analysis and communication of EHRs.

It is important to consider that there are two pillars:

1. the expression of semantic elements, that *convey* meanings at the most atomic level;
2. the record content models that *organize* the semantic elements, thus creating a clinical context.

The design principles have been developed specifically to direct the development and publication of record content models for electronic health records, but they are also largely applicable to the development of structured health records on paper, especially as methodological to facilitate and prepare the transition between paper and electronic health records. They are intended to be relevant to the representation of clinical and social care and wellness information within health records. Further work is advised to validate their applicability to dedicated specialized records or records of complementary therapists or personal health records for example.

1.4 Audience of this document

This document is intended to be used by three main audiences:

1. Provide a global framework to those responsible for the <u>development</u> of record content models, such as clinical professional bodies and clinical guideline developers;
2. it will provide useful insights to those who <u>review</u> or <u>utilise</u> published record content standards, health professional or patient education, and research or health service management purposes;
3. it will be an important source for systems <u>implementations</u>;
4. finally, it will be a useful help for the clinicians involved in using the models, to <u>understand</u> the process behind these models and avoid the "black box" syndrome.

The individual record content models that conform to these principles are expected to be relevant to a much wider range of stakeholders. Such a model will not only carry semantic, but also an organization of this semantic which can be compared to a *<u>context</u>*.

1.5 Background of this document

Some principles developed in this document have been initially elaborated as part of the Clinical Documentation and Generic Records (CDGR) Standards Project, led by the Royal College of Physicians and sponsored by the UK Department of Health, approved by the Academy of Medical Royal Colleges in April 2008 and referenced in national regulatory and professional documents and policies across the NHS.

2   What are the challenges

One of the most important challenges is that at one point in time, for a specific condition such as chronic heart failure, there are different needs.

So, for example, the physical examinations and the symptomatic picture for a cardiologist, and internist, a nurse in cardiac intermediate care, a nurse in intensive care, a home care nurse are different. These needs have common elements, some of them common to all actors, some common to some of them only. Some elements will be specific to only one actor.

This can be shown as in the following picture:

Figure 1 - similar but different views for different stakeholders

However, in addition, these needs will change according to context of the patient, such as severity, but also context of the healthcare system, such as availability of home care, social care, or technical means or the legal framework, such as national requirements for public health or billing.
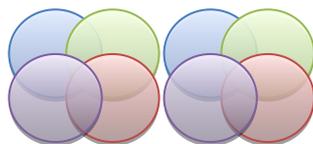
Figure 2 - different contexts lead to different group of views

Finally, these needs will change over time, because medicine changes, because the context changes, etc.
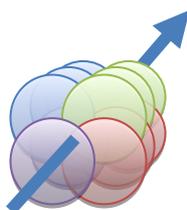
Figure 3 - all these views will then change and evolve during time

Thus, there is a real challenge at finding a solution that can accommodate the plasticity and the evolutive essence of the needs, while keeping interoperability at the two levels: in constant time, for various needs; and across time.

D3.1 Initial methodology for developing semantic interoperability resources

3   Why record content standards are needed

The need for long-term care across all prevention and care providing actors, as well as the increasing need for multi-disciplinary care due to the increasing complexity of care as a very strong and immediate effect: *Good clinical practice is increasingly dependent upon good quality health records*. These are needed to facilitate continuity of care for a specific care provider, but also within and between multi-professional and multi-site teams, to support those professionals to leverage the best available evidence at point of care decisions, helping them to monitor for critical events and trends, and to avoid error. A major aspect is also to provide complete, consistent, pertinent and contextualized information about the past and the present situation of the patient, especially as the information available is increasingly growing and it becomes difficult to find the correct information in time. Consistent and clearly organised records can assist patients in understanding their own health, sharing in healthcare decisions, and engaging with self-care. Health records need to support quality improvement and professional learning, and inform those managing the health service including service planning, commissioning and accounting for resource utilisation. Health records are also needed to underpin population health, post-market surveillance, and clinical research and policy makers.

From an essentially narrative origin, health records are evolving towards more structured forms of documentation. It is well known that templates and forms can encourage more complete clinical consultations, such as by acting as a prompt, as well as more complete data entry. Structured records are therefore ideally suited to representing the steps within a care pathway, to encourage more consistent and evidenced based care. Systematically used structures are also essential to present health record information graphically, as trends or profiles (for example a chart of vital signs or the progress of a child's development). However, one must ensure that the reasons for structured clinical information remains clear, as it can lead to dangerous deviations[5].

As the volume of information within health records grows it is becoming increasingly difficult for healthcare professionals to assess a complete patient history by simply reading (even just recent) past entries. The need to cross-relate personal health information with published knowledge is recognised to be beyond any reasonable expectations of memory alone, and EHR systems will progressively include decision support rules and alerts that check past EHR entries (conditions, allergies, prescriptions, lab values, investigations etc.) for relevant information. For example prescribing systems help prevent serious errors, and require access to comprehensive allergy, diagnosis and present/past medication data, laboratory values, etc. from the EHR in a processable form, cross-mapped to data on drugs, their effects and active ingredients as well excipients and their effects. This kind of analysis not only requires that clinical documentation is structured (within a hierarchy of headings and subheadings) but that the observed findings themselves are computable: clinical expressions are drawn from a standard terminology; units are specified for quantities etc. This requires that record content models specify formally the kinds of value that each fine grained entry may contain (such as a list of possible clinical terms or a value range and

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5   The future state of clinical data capture and documentation: a report from AMIA's 2011 Policy Meeting. Cusack et al. J Am Med Inform Assoc 2012;0:1–7. doi:10.1136/amiajnl-2012-001093

default units). This precision in model specification is important since computers are less able than people to infer meaning from informally expressed information. However not all of clinical information is suited to being highly structured: narrative has a place too and needs to be provided for within models.

Healthcare is divided across multiple locations of care and therefore documented across multiple record systems. As we progressively unite these record systems to form a longitudinal and integrated EHR for each patient, so each clinical application will need to retrieve and analyse information that has been drawn from multiple EHR repositories. In order to do so safely and completely, the information in them needs to be <u>consistently</u> organised. This then requires the models of health record content to be <u>standardised</u> and shared, and incorporated within different EHR products in equivalent ways. Collections (libraries) of this record content specification need to be developed, ideally led by clinical professional bodies but including a wide range of additional relevant stakeholders. These design principles are intended to guide such activities, to ensure they are developed through a uniform and well governed process.

Communication between care teams, cross disciplines and between care sites, may take place either through direct access to a share record (by sharing a paper file or EHR system) or through specifically created correspondence such as referral letters, discharge summaries, clinic letters and reports. As electronic records mature, communication between professionals will increasingly take place via direct access to records and less via correspondence. Documentation standards within health records needs to consider the future use of the information in support of collaborative care and inter-professional teamwork. For example, this might mean that the description of treatment plan should not only specify why and when a drug is to be used, but include information about how long the treatment is intended for and if there are specific grounds on which a future professional might discontinue it. When developing record content models, this support for continuity of care needs to be considered, recognising that this will be especially challenging, since most record documentation today does not include this kind of information (as it is normally only included in clinical correspondence).

Health record documentation usually arises from clinical encounters between individual patients and clinicians, and occurs as an act of dedicated data entry onto paper forms or clinical applications within electronic systems. However at times information might be entered automatically (e.g. from patient worn devices, or by alerting systems) and only later validated by a responsible clinician. Patients will increasingly themselves enter health information, at times within the same health record that their professionals use, and at other times within independent personal health record systems. Social care agencies might at times access and contribute to health records. All of these kinds of actor might need to view and/or analyse the content of health records. The design of clinical content standards needs to be inclusive of the kinds of information that different actors might need to document or to use, and who therefore need to be consulted during a model's design.

There is an even wider group of persons and organisations that need to use health information: for example for service management and planning, for public health and disease registries, for

research and for education. This ideally means that each model's development should include a process of engagement with multiple stakeholders.

The work of defining record structures must build on established work on the representation and communication of EHRs, now published as International Standards. These standards specify the generic properties of health record information, such as the date and time of the entry, the identity of the author(s), the identity of the patient, the subject of the information (e.g. in family history), how corrections and revisions are to be handled etc. Record content models need not include such properties, but can rely upon these being automatically incorporated when the models are implemented within EHR systems. With regard to EHR systems, several interoperability standards exist:

- Business requirements
  - o ISO 18308 EHR Architecture requirements
  - o HL7 EHR Functional Model
  - o ISO EN 13940 Systems for Continuity of Care
  - o ISO EN 12967-1 HISA Enterprise Viewpoint
- Information models
  - o EHR System reference model openEHR
  - o EHR Interoperability Reference Model ISO/EN 13606-1
  - o HL7 Clinical Document Architecture
  - o Clinical content model representation openEHR ISO/EN 13606-2 archetypes
  - o ISO 21090 Healthcare Datatype
  - o ISO EN 12967-2 HISA Information Viewpoint
- Computational services
  - o EHR Communication Interface Specification ISO/EN 13606-5
  - o ISO EN 12967-3 HISA Computational Viewpoint
  - o HL7 SOA Retrieve, Locate, and Update Service DSTU
- Security
  - o EHR Communication Security ISO/EN 13606-4
  - o ISO 22600 Privilege Management and Access Control
  - o ISO 14265 Classification of Purposes of Use of Personal Health Information
- Clinical knowledge
  - o Terminologies: SNOMED CT, etc…
  - o Clinical data structures: archetypes, etc …

Defining record content standards across the whole of healthcare (to meet the needs of all specialities and professions and of wider stakeholders) is a daunting challenge. It is especially challenging because many areas of record documentation do not yet have any clinical consensus or best practice guidance: this may need to be developed before formalising each model. Experience internationally suggests that this endeavour should prioritise key area in which do already have clinical consensus and for which there is already known to be computational value from having good quality data. The priorities often suggested are the management of chronic conditions, and the support of continuity of care between teams.

There is also a difficult balance to be struck, when defining models, between completeness and utility. If models are incomplete, such as when important aspects of a clinical encounter cannot be documented because the relevant models - and therefore the EHR systems - do not cater for that need, then users will face the awkward choice of leaving key facts undocumented or placing the information in an unintended part of the record: in either way this causes poor data quality and introduces clinical risk. On the other hand, if models are overly complex, the resulting data entry forms will become time consuming to complete and users will, as experience has shown, take shortcuts such as avoiding the documentation of what they consider to be extraneous and less relevant items of information. This also hampers data quality. Models therefore need to prioritise precise structures for information items that every good professional should record in a given situation, and leave provision for additional details in less prescriptively structured parts of a model, for example in free text. This approach will also ease implementation, end user training and adoption in making the transition easier.

Well defined models are also mandatory in order to avoid redundant or useless data acquisition, for example at helping pre-filling with existing values or at allowing the dynamic remodelling required by contextual granularity. Thus, such models help at defining what is pertinent and at which granularity for each context of a single element.

Work on developing record content models and standards need to be relevant to the communities intending to use it. Since many clinical specialities collaborate on standards of practice internationally, for example using validated approaches of European Societies, many vendors of EHR systems are global companies, and much clinical and population health research is multi-national, it will be helpful to align efforts on model development with parallel efforts in other countries. In particular, there is now a momentum to foster such collaborations at a European level.

The migration towards more structured records will inevitably require changes in professional practice, and therefore requires acceptance amongst professionals. To achieve this acceptance, record standards much reflect clinical practice, be evidence based, developed through consensus and professionally endorsed. Models should be published along with the evidence that has informed their design (not just published evidence, but experience from the use of existing systems and data sets, and consultation processes during the model's design) and meaningful use. Ideally standards should also include clear guidance on when the model is intended to be used, such as its clinical purpose and target patient population, why it is of value for this information to be structured, the anticipated benefits. Finally, all context information, such as who defined the

model and the source of knowledge, experience and evidence behind it. Ideally, there should also be the list of organisations endorsing the model.

Healthcare, medical knowledge and our experience of good quality documentation are all evolving, and models will inevitably be subject to change. Standards should include information on the currency of the evidence that was used, and indicate a likely period after which each model should be reviewed.

As the library of model standards grows, mechanisms will be needed to formalise the editorial review and formal endorsement (certification) of each standard, to publish and maintain the overall collection, to manage copyright and licensing of use, to notify standards users of new publications and updates, and to provide a feedback mechanism so that problems can be quickly identified and rectified, and so that experience of use can inform future revisions of each standard.

Effective implementation of standardised, structured, patient focused records requires strongly led culture change, embraced by all professionals and other health service staff. They are essential prerequisites for safe, high quality care and for the safe, efficient and effective migration from paper to electronic patient records. They will also enable innovative development of services that cross traditional boundaries, and when patients and citizens themselves are given access to the record, empower them to take more responsibility for their own care.

4 Design principles for record content models standards

This section specifies the principles and processes that should be followed when developing a record content model intended for publication as a standard.

The principles are based on a set of governing principles that drive the management of the content models.

4.1 Governing principles

It is important that a set of governing principles is outlined. Examples of such governing principles could be e.g. "trustworthiness", "sustainability", "traceability", "readability", etc... A big task within the project will be to define in detail these governing principles. Once these have been defined, the conformance of record content models against those principles can be assessed. The outcome of this process will be part of the next WP3 deliverable.

4.2 Governing requirements

4.2.1 Governance process

A governance body is required to oversee the development of record content models standards. This body must be established with an agreed and inclusive representation across relevant stakeholders including at minimum clinical professional bodies, patient representative groups, social care organisations, health service senior management, and representatives from the EHR systems industry, academic research and public health.

This body is organized in three levels

There is a "Convergence board", in charge of insuring a global coherence and interoperability between all models.

There are "Domain boards", for each domain to be addressed. These boards ensure the coherence and the interoperability within one domain, such as cardiology.

Finally, there are "Working groups" for each model or group of models within one domain.

4.2.2 Scoping each record content model standard

Each record content model standard must specify its scope clearly and unambiguously.

The scope must be determined on the basis of a clear understanding of the requirement for this particular standard and a certainty that a near equivalent model does not already exist and which could be adapted.

The scope must specify precisely the kind of clinical information the documentation of which it models.

The scope must include the kinds of clinical situation in which this information is intended to be collected, including the kinds of profession, discipline, speciality and patient group if any of these categories are not universal.

If a standard is to include more than one record content model, then the differential purposes for each must be specified.

The scope may also reference other published models and indicate how adopters can differentiate the use of this standard from those others.

The scope may be supplemented by usage guidance that further elaborates the clinical contexts of intended use, seemingly similar situations in which it is not intended to be used, and deliberate limitations of the scope.

This scope must be ratified (or pre-agreed) with the governance body before detailed modelling work is undertaken.

4.3 Evidence and input gathering (Working groups)

A list of stakeholder groups whose inputs will be invited to the development of the proposed standard must be proposed and ratified (or pre-agreed) with the governance body before detailed modelling work is undertaken. This list should propose which stakeholders will take lead responsibility for the design, which will be consulted to provide significant input and which will be kept informed.

A contact list for each stakeholder must be compiled, co-ordinated through the governance body if appropriate.

A core project team must be established from amongst those invited stakeholders who can furnish a relevant expert, or a representative with relevant knowledge of the domain. At minimum, experts from the health professional groups most likely to author health record entries within the scope of this standard should be included.

Each of the responsible and consultative stakeholder groups should be invited to propose inputs to the design of the record content model. These inputs may include any of the following:

- accepted knowledge (for example as published in textbooks);
- the results of published scientific studies;
- authoritative guidelines or care pathways;
- policies and guidance developed by professional bodies, the health service or recognised national or international fora;
- formalised examples of existing accepted practice, for example templates and forms used in paper records and screen captures and data models from existing clinical applications and EHR systems;
- reporting and audit data sets that are in widespread use;
- requirements that have been obtained through direct consultation with potential users, including patient representatives
- legal / billing requirements in various countries.

Additional inputs may be received from non-health service stakeholders, such as research communities for whom particular data items might have importance, and industry who may wish to highlight constraints or other considerations to be taken into account during model

development. Such constraints should not end up at modifying the models, but should be represented in a manageable way in the models.

Key organizations stakeholders who are not in a position to provide inputs should be asked to confirm this in writing.

Any concerns raised by consulted stakeholders about the intended scope, possible overlap with other content standards, or use cases that they believe need to be included or omitted, should be resolved before proceeding with model design. Escalation to the governance body may be considered.

A consultative process may be established through which a wider and more informal set of inputs and initial feedback can be obtained from stakeholders. This might, for example, be undertaken through conference presentations, dedicated workshops or an online collaboration space.

4.4   Data item selection (codebook)

The process of model development should commence by extracting relevant data items that are explicitly stated or implied within each of the inputs received.

For each data item, the sources advocating its inclusion should be documented, and whether the item is required as good practice to be collected on every occasion (mandatory), or at the discretion by the author (optional). In particular, it should be noted if collecting a particular data item is a necessary part of conforming to a particular policy or guideline.

Recommended or prescribed values for each data item specified within these input sources must be noted, including any obligations to use particular terminology or classification systems.

Conflicts and inconsistencies between the recommendations from different sources of evidence should be resolved by consensus within the project team, referring back to the sources of evidence as necessary. A hierarchy of evidence approach, in which some forms of evidence rank more highly than others, may be required and should be documented if used.

From an initial candidate list of data items from across the input sources, a short list of mandatory data items and a long list of optional ones should be compiled.

Data items that are already recognised properties of all health record entries (such as the date and time of the entry, the identity of the author, the identity of the patient) should be excluded. (This list of generic properties will be published separately).

For each data item, an extensive set of information will be required, ranging from the type up to the list of rules applying to this data item.

The project team should aim to compile as complete a list of data items as is needed to satisfy the scope, but not such an exhaustive list that it likely to prove unnecessarily cumbersome to use in practice, or so full of options that the resulting content model might be used inconsistently by different kinds of user.

Each standard should aim to produce one clinical content model that can be shared by all professions and specialties, even if not all will use or fill all elements of that content model. In cases where significant differences need to be catered for, a standard may include a generic

content model plus one or more specialty or professional profiles. A content model profile must still conform to the generic model, although it may add supplementary data items. The scope and usage of each profile must be clearly differentiated.

4.5 Validation

A draft clinical content model and standard must be externally validated by at least one of the following methods:

- referral to a peer review group external the project team, comprising relevant stakeholders;
- detailed presentation to a large and representative group of relevant stakeholders, for example at a conference or workshop;
- online review, provide that this has been well publicised and enough time given for feedback to accumulate;
- prototyping within an EHR system, possibly by practice data entry using fictitious cases;
- prototyping on paper, either with direct data entry or by mapping samples of existing records.

Proxy validation may be acceptable if the model is a faithful representation of a content specification that has already been validated e.g. a widely accepted and used paper form.

The process for refining the content model in the light of feedback must be documented, and if changes that conflict with original input recommendations are made then these must be clearly justified.

4.6 Publication

A published record content standard must define:

- its scope, including its relationship to other published standards where relevant;
- additional guidance on its use including clinical scenarios, population groups, user groups, and exclusions of use;
- the stakeholder groups that have been consulted during the model's development;
- a list of the source inputs that have been reviewed;
- the formal clinical content model or models;
- a summary of the validations undertaken;
- a discussion of any limitations or known areas of incomplete or sub-optimal modelling, outstanding challenges needing further work;
- recommendations for review of the model: the recommended time interval, key stakeholders who should be involved and any aspects of the model that should be given special consideration.

The standard must identify the project lead organisation, the date and time of publication.

The standard document and any accompanying artefacts (such as the model in a computable form) must be formally identified and version tracked.

4.7 Certification

The governance body must establish a process for receiving and quality reviewing draft record content standards and of certifying them once accepted.

The quality review must verify that the model's development process has conformed to these design principles, that the model corresponds to its intended scope, and that the extent of the validation is appropriate.

The quality review must confirm if there are any special usage restrictions or licensing requirements relating to intellectual property within the model, and ensure that these are clearly specified.

The review must also confirm the date on which a review of the standard should be initiated.

With regard to the quality labelling and certification aspect, several "actors" can be identified such as "certification bodies", "accreditation bodies" and "conformity assessment bodies", each with a distinct role.

The certification (and quality labelling) body is the organisation that will manage the whole process. Ideally, certification bodies should be accredited by an accreditation body.

The task of accreditation bodies is to "certify" the "certification bodies". The accreditation bodies verify the conformance against ISO standards with regard to quality labelling and certification activities.

Conformance assessment bodies are organisation which will be testing and evaluating the content models.

Below a number of relevant ISO/IEC standards have been outlined:

- ISO/IEC 17000:2004 Conformity assessment – Vocabulary and general principles
- ISO/IEC 17011:2005 Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies
- ISO/IEC 17020:2000 General criteria for the operation of various types of body performing inspection
- ISO/IEC 17021:2011 Conformity assessment -- Requirements for bodies providing audit and certification of management systems
- ISO/IEC 17025:2005 Conformity assessment – General requirements for the competence of testing and calibration laboratories
- ISO/IEC Guide 28:2004 Conformity assessment – Guidance on a third-party certification system for products
- ISO/IEC Guide 65:1996 General requirements for body operation product certification systems
- ISO/IEC Guide 67:2004 Conformity assessment – Fundamentals of product certification

When setting up the quality labeling and certification activities within SemanticHealthNet the actors above will need to be identified.

4.8 Distribution and maintenance

The governance body must establish a process whereby certified standards are published within appropriately accessible and well managed repository or repositories.

The governance body must establish a process for receiving feedback or issues relating to the adoption and use of the standards it publish.

The governance body should maintain an inventory of bodies and countries that have endorsed the use of particular content standards, and seek to obtain feedback on their adoption into products and on their use.

The governance body must establish a process for rectifying errors and inconsistencies within and between content standards within a reasonable time frame, and for notifying adopting communities about such errors and updates.

The procedure for reviewing standards and possibly updating record content models needs to take into account the desirability or otherwise of backwards compatibility, in particular with regard to maintaining the usability of legacy EHR data that conforms to the previous version.

The process of reviewing standards must consider if and when any particular standard should be deprecated rather than revised, and in such cases for nominating an appropriate successor.

5   Bibliography

The following information sources have been consulted during the development of these design principles.

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