



Semantic Interoperability for Health Network

Deliverable 3.2: Generalized methodology and analysis framework for semantic interoperability resources

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1 Introduction

1.1 Background

SemanticHealthNet (SHN) faces the challenge of improving semantic interoperability of clinical information. It assumes that several standards and proprietary implementations for representing the content of electronic health records (EHRs) will co-exist for a long time.

The approach targets the whole range of health-related information about all medical domains.

SHN has the task to overview all types of resources needed for semantic operability, such as linguistic resources, clinical terminologies, clinical data models and overarching ontologies. As practical exemplars, SHN has set the focus on chronic heart failure and cardiovascular prevention.

SHN addresses on the one hand general purpose resources which serve the whole array of medicine such as : Medical WordNet for linguistic resources; SNOMED-CT, ICD, LOINC, ICPC, ATC, ICF for clinical terminologies; openEHR, EN 13606, and HL7 for representations of electronic health records; candidates for overarching clinical models such as archetypes, templates, DCM, CIMI; and ontologies and concept models such as SNOMED-CT, ContSys, CIOMS, and OBO Foundry Medical Ontologies.

On the other hand, the intention is to develop a structured methodology for sub-disciplines in medicine (e.g. the scientific association of cardiologists, specializing in heart failure) for the construction of domain-specific resources to assure correct representation of a specialized discipline, while preserving semantic interoperability with the resources developed for general purpose and for neighbouring disciplines (including allied health personnel).

The objectives of the methodology are:

- a) To facilitate participation for clinical specialties, such as cardiologists, or specialized groups such as heart failure specialists, in order to ensure clinical pertinence;
- b) To preserve semantic interoperability across clinical specialties; and across specialized fields;
- c) To preserve semantic usability for two major usages: patient-care and population based research.

It was agreed that the chain of resources to be created in semantic interoperable systems should be able to capture the contextual situations in which information is produced, and at the same time be useful for use at three levels:

- optimal medical documentation (registration) for clinical care purposes;
- decision support systems;
- exploitation of the data for research (clinical trials, epidemiological surveys and studies) and public health policy (e.g. construction of quality indicators).

In the first Work Stream of the SHN project, the first two work packages aimed at producing domain-specific clinical models. In WP1, it was foreseen to produce specific clinical models to capture clinical information in a patient summary for heart failure patients, useful for decision support systems based on structured guidelines. In addition, in WP2 8 uses cases were developed in 5 domains (self-

monitoring and personal health records, targeting and deployment of health systems resources, clinical care delivery, co-production of cardiovascular health, and investment in new medicines), from six different perspectives (patients and relatives, care professionals, care provider organisation, commissioner/payer, community, system and service providers) to prepare the representation of cardiovascular risk factors to be used in public health policy for cardiovascular prevention.

In the third work package of the first Work Stream (WP3), the aim is to learn from these two experiments described above and to develop a general methodology for other sub-disciplines to develop, test and validate a chain of domain-specific resources, useful for supporting semantic interoperability within the discipline and across disciplines. This methodology needs to be validated by the stakeholders, in particular the end-users (patients, general practitioners, cardiologists, heart failure specialists, and policy makers in public health).

From the start SHN focussed on the semantic interoperability issues in the exchange of clinical information already represented in clinical models.

These clinical models can be general:

- Representations of clinical records and messages : openEHR, EN 13606 and HL7;
- Summaries of patient records for exchange between systems:
 - EpSos patient Summary
- Domain specific clinical models:
 - e.g. representation of a heart failure patient summary (WP1)
 - representation of cardiovascular risk status, with a smoking and alcohol consumption status (as examined in WP2, and further developed in WP4)

In the fourth work-package, methodologies and tools will be discussed to facilitate communication between these clinical models, either by identifying iso-semantic elements in the different systems either by building meta-models of clinical models or by developing overarching ontologies. The representation of the smoking and alcohol consumption status in the different clinical models will be analysed, to propose solutions for optimal communication between the systems.

This will further contribute to the exploration of the chain of resources needed for assuring semantic interoperability. In later work packages business requirements and business models need to be developed.

1.2 Objectives

WP3 will formulate a general methodology for the consecutive development process of several types of resources, needed to achieve semantic interoperability. In its third deliverable, Work Package WP3 will propose testing criteria for the efficacy of the use of these resources in applications, in terms of semantic interoperability. Finally, WP3 will need to validate the proposed development process with the relevant stakeholders, first with stakeholders relevant to the field of heart failure and cardiovascular prevention, and later with stakeholders of the broad medical field.

For this deliverable WP3.2, we limit ourselves to proposition of a general methodology for the construction of domain-specific clinical models in medicine. In addition, recommendations will be made

for the creation of terminological resources needed for optimal data-entry into these clinical models, and for handling multiple languages.

1.3 Methodology and General Principles

In the first WP4 deliverable (4.1), SHN had outlined the shared logical framework on which the SHN approach is based on. Deliverable WP4.2 provides an overview of the main representational units of the framework and a set of patterns elaborated by following a bottom-up approach for modelling the heart failure summary. There, we stated that many of the patterns provided could be generalised and converted into top-level patterns able to be composed and specialised. Below, we describe the approach and the progress done in the last months concerning the use of patterns for facilitating the modelling of clinical information based on a formal model of meaning.

2 General method to develop clinical models

As part of the SHN work, an investigation was conducted to identify best practice in developing and obtaining consensus on the representation of clinical information in order to support semantic interoperability for EHRs. The specific intention was to understand the user engagement, design methods and quality processes presently being used by leading international experts in clinical information modelling, in order to identify whether there is an emerging consensus in good practice.

The study was undertaken through semi-structured interviews with 20 recognized experts in the field of clinical information modelling. In order to obtain a broad overview of clinical information modelling processes, special effort was made to interview participating experts in regional/national eHealth strategy with an international coverage. Interview experts were from 11 different countries that belong to 3 different continents. This section summarises the recommendations based on their collective experiences. The full report is included in Annex 1.

2.1 Organization of people involved in requirements definition

After the project scope and objectives had been defined, the interviewees reported that those people who participate could usually be classified on three organizational levels. The first level includes the experts who lead the model definition activity. The second is a core team of multidisciplinary experts who work in depth on the detailed clinical and technical needs that the system and clinical information models will need to satisfy. The third level comprises a larger group of experts who validate the proposed definitions. Table 1 details the characteristics of each organizational level.

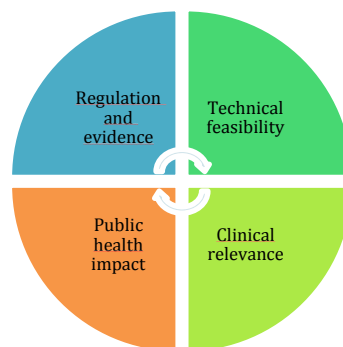
Organizational levels for Clinical Information Modeling Process	
Leading the clinical information modeling team	<p>Who?</p> <ul style="list-style-type: none"> ○ 1 - 3 people with deep understanding of both clinical practice and health informatics ○ Business analysts, clinical information modellers and terminologists <p>Tasks</p> <ul style="list-style-type: none"> ○ Collect functional requirements from the core team and other sources of documentation such as guidelines and paper forms ○ Coordinate the core team and its feedback ○ Applying a methodology to organize and define the requirements ○ Facilitate alignment with the latest clinical evidence <p>Recommendation</p> <ul style="list-style-type: none"> ○ Working experience in clinical settings is desired for clinical information modellers, or experience in the development and deployment of EHR systems for technical experts
Core team of domain experts	<p>Who?</p> <ul style="list-style-type: none"> - Between 1 and 5 clinicians, depending on the complexity of the field and the size of the organization. Up to 10 people on very large projects - Recommended to have representatives from each clinical department and clinical specialty that will use that aspect of the EHR system - People highly committed to the success of the project - Ideally, people already committed in the definition/validation of clinical guidelines <p>Tasks</p> <ul style="list-style-type: none"> - Provide a detailed definition of the EHR documentation required for the clinical domain where they are experts <p>Recommendation</p> <ul style="list-style-type: none"> - Ensure that this group understands correctly the scope of the EHR system and clinical information models to be developed, the modeling methodology being adopted and how this project relates to the systems already in use.
Validation Group of domain experts	<p>Who?</p> <ul style="list-style-type: none"> - Larger representative group for validation purposes - The selection of the group depends on the project scope <p>Tasks</p> <ul style="list-style-type: none"> - This group will verify that the proposed design for the EHR and system will satisfy their current and projected practice needs <p>Recommendation</p> <ul style="list-style-type: none"> - Include also non-clinical actors that will make secondary uses of the data or have expertise in the field. (e.g. managers, health authorities, patient associations, public health experts, researchers, professional medical bodies and system vendors)

Table 1. Organizational levels for Clinical Information Modelling Process

2.2 Current Clinical Information Modelling Process

According to interviewees, CIMP can be described as a continuous improvement cycle: an agile development approach can have substantial benefits because it facilitates rapid and iterative feedback.

The modelling process should start with the scope definition and a prioritization on the basis of medical and nursing, regulatory, management, economic and logistic needs. Next, evidence sources must be identified including current paper and electronic forms, reporting requirements, technical specifications and existing clinical systems. Experts indicated that health providers cannot always be aligned with the very latest clinical evidence, since it takes a while for a sufficient body of evidence to accumulate to justify changing clinical practice, and changing the clinical information structures within EHR systems. Moreover clinical information models and EHR systems should be able to support the documentation of legacy practices for some time, since there is a gradual adoption of clinical evidence. The input sources to model design must therefore combine existing practice with best practice.



The leading experts usually establish the core team and organize meetings to collect the clinical and technical requirements. These meetings were online, face-to-face or workshops depending on the number of experts and their geographic distribution. With the support of the clinical information modeller, the models were defined according to the clinical care processes and the documentation that clinicians create. Some methodologies in use include asking clinicians to critique existing models or EHR systems since this facilitates a common understanding and helps identify new requirements. Other interviewees recommended asking clinicians about a broad range of clinical situations are intended to be covered by the clinical information model as well as identify the most important information to collect, to establish prioritization mechanisms on a detailed definition of the clinical domain.

Based on these requirements, clinical information models were defined and prototype screens designed in order to obtain validation. Usability could be verified using usability testing techniques and interviews. This was best conducted as an iterative process for validation and to detect overlooked requirements. The system was then implemented, ensuring a feedback mechanism. Finally, a governance and maintenance stage ensured that the system could be updated in a consistent way. Figure 1 illustrates the ideal steps for a CIMP.

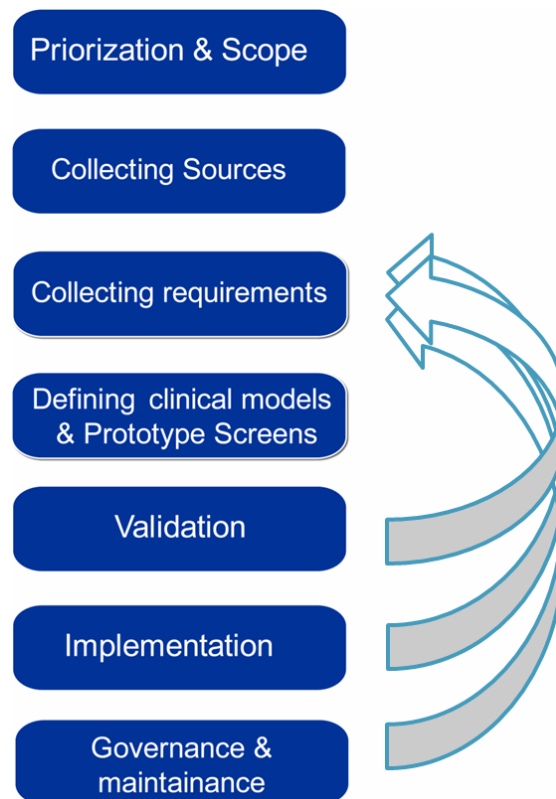


Figure 1: Clinical Information Modelling Process diagram

Some of the most critical barriers to arrive at a clinical consensus arose during the following clinical modelling tasks:

- Determining the level of detail that needs to be documented in the EHR, highlighting differences in clinical practice. This is also called semantic granularity mismatch;
- The level of best practice that should be prescribed was debated through the definition of which data items to make mandatory;
- Determining the useful summary information that would help clinicians to manage chronic diseases over time.

This requires an open and inclusive discussion, usually collecting additional information about the underlying functional requirements. Such discussions were often reported to result in a common clinical base model that allows for local specializations (variations, profiling) whilst consistency is preserved for the essential information.

The full report of this study, reported here, is given in Annex 1. This manuscript is submitted for publication and become public by the time this deliverable goes public. In Annex 2, a checklist is provided for project leaders of clinical model development project to check conformity of their work to the general methodology.

2.3 Using free text and structured data

Interviewees believed that collecting structured information required more data entry time than free text. Free text has limited computability, and therefore it has limited exploitation. On the other hand free text permitted the collection of unanticipated information, and so a balance between structure and free text was always required. A few interviewees felt strongly that the focus of clinical modeling should be to structure only the information that is expected to be exploited to make decisions or to be included in decision support algorithms, keeping the rest of clinical documentation as free text.

Since many clinicians find it easier to document in free text, a few experts proposed using Natural Language Processing to extract relevant information (e.g. patient problems) for confirmation by clinicians and storage in a structured form. Such tools are becoming integrated within commercial EHR systems.

2.4 Terminologies

Many interviewed experts claimed that clinicians prefer to use locally defined value sets that are well-adapted to their needs rather than applying standard terminologies. In addition, it was common to find EHR systems that incorporated their own terminology, with a need to map these terms onto standard terminologies for subsequent uses and for communication. Since multiple terminologies can cover the same domain subject matter, mapping between multiple terminologies was identified as a major difficulty.

2.5 Sharing information with other locations and domains

There were consistent answers across the questions relating to the sharing of information, and re-use models, between care settings and clinical domains. Interviewees advocated a modular approach to define common core information structures that can be re-used in different domains. Working simultaneously across domains on these core information structures would allow feedback to be gathered from different environments, and result in a good basis for re-use. This core structure should be able to be specialized (extended) to meet the specific needs of each care setting and specialty. It was recommended that the common core structure should be specified in as much detail as possible, as it could be simplified at each local level using templates or masking inapplicable data elements at the application level. For shared model development, widening the set of experts involved in the model design will mean that it takes longer to obtain a consensus. Criteria need to be defined at the outset for determining the basis for signing off a model: when it is likely to achieve sufficient usability and deliver its intended benefits. Interviewees felt that differences in clinical information requirement across locations and specialties were not very great, and that should be possible to arrive at a harmonized design. The most important objectives were to convince the clinicians of the value of adopting generic wording that would be applicable across domains rather than using their own specialist wording for the data elements. They also needed to be encouraged to reuse previously defined models wherever possible, rather than re-inventing from scratch.

2.6 Knowledge evolution at a larger scale

In order to support knowledge evolution at regional, national or international levels there is a need for tools that promote team collaboration on the design of clinical information models and for organizational governance that promotes their acceptance. There are examples of tools [24, 28] able provide a centralized repository with open access to gather design inputs and to facilitate consensus on model definitions. An organizational structure is also required to maintain and update clinical information models. One interviewee suggested that models should be periodically reviewed to check for new evidence, and to monitor whether the models are being correctly applied.

An important problem is that acceptance of the clinical modelling approach is still at an early stage since most existing EHR systems cannot yet directly implement clinical information models represented using the published standards. Even though large scale clinical modelling may reduce costs, there is an initial need for substantial funding for the design and governance of model development, through activities such as education of clinicians, working with health authorities in charge of an IT infrastructure and promoting awareness within eHealth projects.

2.7 A checklist to guide and evaluate model development

The full report detailing these findings is provided in Annex 1. A checklist of key human and organisational processes that are emerging as good practice is provided in Annex 2. This checklist, at this stage a draft for further consultation, may be useful to guide organisations and teams intending to develop clinical models, and may also become incorporated, along with criteria from WP5, into an eventual assessment process for clinical models for quality labelling purposes.

3 Methods to ascertain the perspective of the patient in clinical model development

3.1 Introduction

A successful chronic disease summary must capture and facilitate the use of a wide range of clinical, patient and social information in order to permit high quality, evidence based, patient-centred care. In its current form, we believe there are potential gaps in the heart failure dataset particularly related to capturing a patient's experience of living with heart failure.

The medical model for clinical management of heart failure often concentrates on symptoms such as breathlessness, ankle swelling and assessments of exercise capacity, however, other important patient issues such as reduced quality of life, low mood and depression, reduced functional capacity and fatigue are often under recorded^{1,2}.

We³ describe in this part a number of analyses into aspects specific for patients:

- a review of the Heart Failure dataset;
- a comparison with the InterRAI patient assessment tools;
- findings from direct consultation with patients;
- a review of the scientific literature.

Based on this and experience from previous projects we highlight areas where enhancements could be made to the heart failure summary and describe a series of recommendations for possible future work.

3.2 Method

We invited a small group of patients with experiences of heart failure as well as carers to a meeting held at the Royal College of Physicians. We explored the experience of heart failure from a patient and carer perspective to gain an insight into potential priorities for patients in the management of their condition. This section of the deliverable summarises those results. The full report is provided in Annex 3.

3.3 Results

3.3.1 Literature review

Previous work has been undertaken to try and develop tools to measure health related quality of life in heart failure patients and these include: The Quality of Life in Severe Heart Failure Questionnaire

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- 1 Dunderdale K, Thompson DR, Miles JN V, Beer SF, Furze G. Quality-of-life measurement in chronic heart failure: do we take account of the patient perspective? *Eur J Heart Fail.* 2005 Jun;7(4):572–82.
 - 2 Dekker RL, Lennie TA, Nancy AM, Rayens MK, Chung ML, Wu J, et al. Depressive Symptom Trajectory Predicts One-Year Health-Related Quality of Life in Patients with Heart Failure. *J Card Fail.* 2011;17(9):755–63.
 - 3 This part was prepared in cooperation with Paul Rastall, Iain Carpenter and Jan Hoogewerf, from the Health Informatics Unit, Royal College of Physicians, London

(QLQ-SHF), the Chronic Heart Failure Questionnaire (CHQ) and the Minnesota Living with Heart Failure Questionnaire (MLHFQ)⁴. Many of the tools are derived from expert medical opinion and do not sufficiently take account of patient perspectives. Dunderdale *et al* have carried out work to assess patient perspectives and develop a heart assessment tool⁵⁻⁶ however widespread validation and broad use in clinical practice has not occurred. There is currently no widely used or accepted tool to measure this important area of patient experience.

3.3.2 Consultation with patients

From our review of the scientific literature and our consultation with patients and cares, we were able to derive common themes that patients prioritised, summarised below.

Theme	Details
Symptoms	Fatigue, generally feeling unwell, poor concentration, decreased exercise tolerance, dizziness, breathlessness, oedema, sleep disturbance
Social and physical function	Exercise ability, ability to work, functional ability (related to housework, gardening, shopping, engage in social activity, travel and holidays), requirements for help from others
Mood	Low mood, depression, anxiety, anger, blame, fear
Medication Issues	Understanding of medication/rationale for taking, side effects, compliance issues, shared decision making regarding treatment
Carer Issues	Fears, social support, involvement in patient education
Future plans	Shared decision making regarding treatment, quality of life over quantity for many, tailored care plans, patient and carer involvement, end of life care open discussions
Information	Importance of shared information

We compared our findings with the heart failure dataset and in many cases found that information was not currently recorded or the detail and guidance for capturing data was potentially insufficient. Changes and limitations in social and physical function as well as issues surrounding medication side effects and priorities for future care planning are particular areas where we foresee limitations of the dataset.

3.3.3 Evaluation of InterRAI (Resident Assessment Index) Assessment System

The InterRAI Assessment System is a well-developed international based method for the measurement and assessment of patients' physical, cognitive and social functional capacity and needs, comprising of an integrated suite of instruments that address multiple clinical domains applicable over

4 Dunderdale K, Thompson DR, Miles JN V, Beer SF, Furze G. Quality-of-life measurement in chronic heart failure: do we take account of the patient perspective? *Eur J Heart Fail.* 2005 Jun;7(4):572–82.

5 Dunderdale K, Thompson DR, Beer SF, Furze G, Miles JN V. Development and validation of a patient-centered health-related quality-of-life measure: the chronic heart failure assessment tool. *J Cardiovasc Nurs.* 2008;23(4):364–70.

6 Dunderdale, G. Furze, D. Thompson, S. Beer JM. Health-related quality of life from the perspective of patients with chronic heart failure. *Br J Cardiol.* 2007;14:207–12.

multiple care settings⁷. When assessments are completed over time a person-focused longitudinal record can be established. In addition to the assessment of individual patients the InterRAI system has been extensively used to aggregate data and make comparisons between health providers, between countries as well as informing healthcare planning. We reviewed the individual components to assess their potential suitability for use in a heart failure population. We were able to identify multiple elements of the assessment tools that would capture pertinent information, for example related to mood, psychosocial wellbeing, functional status and social supports. The origins of InterRAI, and its primary area of use, are in the assessment and planning of care for elderly populations in various home and residential care settings. The heart failure population is however heterogeneous with many people living very independently with a wide spectrum of functional ability. The InterRAI assessment tool in its full form is therefore not (yet) suitable for use with this patient group. We conclude that the InterRAI elements provide inspiration and guidance for a future suitable assessment tool but independently they cannot function as a sufficiently broad tool.

3.4 Recommendations

We recommend engagement with patients and patient groups to further explore patient priorities and concerns associated with living with heart failure. Given that this is a European wide project it is important that this engagement process be carried out in multiple member countries. Work then needs to be done to ensure that information related to symptoms, quality of life measures as well as other markers of cognitive, physical and emotional capacity can be adequately captured and recorded in the heart failure summary. It is hoped that this is one way that development of the heart failure dataset may be a driver for enhanced clinical care.

There are several areas of the dataset where we foresee the need for improvement. The current 'Medicine Management by Patient' field should be expanded and enriched. Guiding clinicians to capture more medication related information such as compliance issues, side effects and patient concerns could be achieved by enhancing the descriptor, however we believe that the issues are sufficiently important to warrant specific data fields.

Issues regarding advance care planning should also be more developed, to assure accurate documentation of discussions and decisions of the patient with regard to end-of-life care.

The Heart Failure Care Plan (section 2.4 of the current SHN Heart Failure Summary) is at present an unstructured element of the dataset where information relating to medication issues, patient and carer concerns, future plans and details of plans for information sharing would naturally sit. We propose that providing a formal structure to record information here could benefit clinical care, facilitate greater information sharing with patients as well as enabling data sharing and interoperability between healthcare record systems via a common structure. The Clinical Record Standards developed by the Royal College of Physicians provide a high level structure for the capture of patient focussed data and we propose that a formal exercise to map the current heart failure dataset to the published RCP standards with subsequent recommendations for where additions can be made would be beneficial.

7 Carpenter I, Hirdes J. Identifying and maintaining quality of long term care: An international case study of the interRAI assessment system for the OECD. 2012 p. 1–45.

Many of the priorities and concerns expressed by patients in our consultation are not specific to heart failure and in many cases would be applicable in other chronic diseases. We believe there is a need to formally develop consensus based standards for the recording of patient perspectives on their illness and health. In addition to active involvement in the creation of a chronic disease summary it is important that patients are widely involved in the testing and piloting process.

Our experience with the InterRAI assessment tools has demonstrated the power of an integrated tool to assess, monitor and plan patient care. Whilst we have found that the tools in their current form are not directly applicable to heart failure care we propose that there would be a benefit to developing a tool to accurately assess patient markers of quality of life, social, physical and emotional health over time and in response to management or treatment decisions. We propose a more detailed review of existing assessment tools both disease specific for heart failure and more generally, with specific emphasis on patient perspectives. Given the longstanding experience of InterRAI in this area we propose that this work is presented to the InterRAI group (via Professor Iain Carpenter) for consideration as a potential future work stream or collaboration.

4 Resources to facilitate data entry in clinical models

4.1 Reference terminologies and end-user lexicons in multilingual perspective

In the interface between humans and Information Technology Systems, language is of utmost importance. Patients and physicians express themselves with words and phrases in a specific language, and these need to be entered by the actors or captured by the systems. In that process words and phrases will be transformed into machine-readable concepts.

The medical language is extremely rich and many extensive dictionaries are available.

Traditionally, classification systems from the World Health Organisation (WHO) were used to support data entry on mortality, morbidity, symptoms, reasons for encounter and processes. The International Classification of Diseases (ICD) is used for mortality and morbidity registration, and is a longstanding tool for epidemiological and public health policy research. The International Classification of Primary Care (ICPC) is used in general practice for episode-oriented registration of reasons for encounter, symptoms, prevalent diseases, and processes. The International Classification of Functioning, Disability and Health (ICF) is focussed on the impact of diseases⁸.

Other examples are LOINC for laboratory test results⁹, Anatomical Therapeutic Chemical Classification (ATC) for medicinal products¹⁰.

Historically, the bulk of medical data has been classified with these classifications. It is likely that these systems will continue to be used in the next decade, so mapping to any new reference terminology to be developed for semantic interoperability will be necessary, at least for legacy conversion reasons.

SNOMED-CT evolved as a reference terminology from the American SNOP (Systemized Nomenclature for Pathology) and the British Read-codes. It has incorporated over the years the terms of many classifications systems and even named entity lists. The governance of SNOMED-CT moved to the global level, by the creation of the International Health Terminology Standards Development Organisation ([IHTSDO](http://www.ihtsdo.org/))¹¹. A sophisticated formal ontology layer is under constant development.

SNOMED-CT is now adopted on many e-Health platforms across the world as a single solution for referenced terminology, clinical model and ontology needs. Several mappings between SNOMED-CT and other classifications have been developed¹².

In the US, core sets of SNOMED-CT have been created, in an attempt to shield the users for complexity beyond routine use. In the non-English speaking countries where SNOMED-CT has been adopted,

8 <http://www.who.int/classifications/en/>

9 <http://loinc.org/>

10 http://www.whocc.no/atc_ddd_index/

11 <http://www.ihtsdo.org/>

12 Cardillo E, Eccher C, Serafini L, Tamilin A. Logical Analysis of Mappings between Medical Classification Systems, 311–321. Artificial Intelligence: Methodology, Systems, and Applications. Lecture Notes in Computer Science Volume 5253, 2008, pp 311-321

translations of concept terms from English into the target language (usually on core sets of SNOMED) have been performed.

A more complex approach to terminology has been advocated by Rosenbloom, insisting on the creation of interface terminologies, which start from the language used by the end users¹³.

One of the basics premises of realistic ontology development is to start from words and phrases (utterances) used by patients, physicians and scientists¹⁴.

In recent years, multilingual lexicons based on semantic principles were developed to collect words and phrases and their possible multiple meanings and synonyms. These resources use the ISO standard Lexical Markup Framework (ISO 24613) and its LEMON application and allow also connection to powerful Natural Language Processing applications¹⁵.

There is an ISO standard for the multilingual reference terminologies (managing concepts of machine readable terminology systems): ISO Terminology Markup Framework (ISO 16642). This standard is currently used to manage translations of the Medical Subject Headings (MeSH).

A pilot project was recently performed to use both ISO standards to extract terminology from a guideline on heart failure in Dutch and French and to link the words and phrases and the terms to several nomenclatures and classifications (ICPC, ICD, SNOMED and UMLS)¹⁶.

In the next deliverable of WP3, the importance of terminological preparation for the creation of clinical models and for the creation of domain-specific ontologies will be further explored. It is acknowledged that the participation of computational linguistics will benefit the overall goal to reach semantic interoperability.

13 Rosenbloom ST, Miller RA, Johnson, Elkin PI, Brown SH. Interface terminologies: Facilitating direct entry of clinical data into electronic health record systems. *J Am Med Inform Assoc* 2006;13:277-288.

14 Ceusters W, Buekens F, De Moor G, Waagmeester A. The Distinction between Linguistic and Conceptual Semantics in Medical Terminology and its Implications for NLP-Based Knowledge Acquisition. *Med Inform Med* 1998;37:327-33.

15 <http://babelnet.org/>

16 Cardillo E, Warnier J, Roumier J, Jamouille M, Vander Stichele RH. Using ISO and Semantic Web standards for creating a Multilingual Medical Interface Terminology: A use case for Heart Failure. *Proceedings of the 10th International Conference on Terminology and Artificial Intelligence, Paris, October 28-30, 2013, p27-34.*

4.2 Multilingual management of clinical models

The development of Clinical Models for domain-specific sub-disciplines in medicine is a laborious process, often involving thorough analysis of structured guidelines, which are often issued on the international level, and hence in English, the language of international communication.

However, the models need to be used in everyday life by the citizens of Europe expressing themselves in a variety of languages¹⁷.

Therefore, it is useful to integrate multilingual management of the data categories (or entities), domain values (or value sets), and definitions or scope notes from the inception of the model development process¹⁸. In the field of computer linguistics, the building blocks of models (entities or domain categories) are managed through an open, collaborative web resource, called ISO-CAT¹⁹.

In the EpSOS project, a remarkable effort was made to translate the value lists of their model of a patient summary for cross-border communication of medical record information in Europe²⁰. The approach taken for the EpSOS pivot document is interesting in the fact that it allows cross-terminologies multilingual mapping.

There might be advantages in using semantic web technologies for the multilingual management of clinical models²¹.

These aspects are being communicated to WP4 (development of clinical models) and WP7 (organisation of the governance structure and task list of the Semantic Health Institute and Alliance).

4.3 Lay language terminology to facilitate patient involvement

Patients are important actors in health care. In WP2 of the SHN project, several use cases were chosen, with strong involvement of patients and intense communication between patient and health care workers through IT systems. However, patients experience difficulties in the communication with health professionals because many medical jargon terms are incomprehensible for them and because they might use words and phrases unfamiliar to the medical professionals. Cooperation of the patient in the process of questioning for signs and symptoms is important. Patients are offered the possibility and often request to cooperate in the shaping of medical information in their electronic medical records (EHR). They might even manage their proper electronic patient health record (PHR).

17 http://www.nationsonline.org/oneworld/european_languages.htm

18 Nyulas C, Tudorache T, Tu S, Musen MA. Experiences with Multilingual Modeling in the Development of the International Classification of Traditional Medicine Ontology. <http://ceur-ws.org/Vol-936/paper3.pdf>

¹⁹ <http://www.isocat.org/>

20 <http://www.epsos.eu/technical-background/semantic-issues.html>

21 Breil B, Kenneweg J, Fritz F, Bruland P, Doods D, Trinczek B, Dugas M. Multilingual Medical Data Models in ODM Format: A Novel Form-based Approach to Semantic Interoperability between Routine Healthcare and Clinical Research. *Appl Clin Inform.* 2012 Jul 11;3(3):276-89.

Large parallel corpora exist of medical information in professional and lay language terms, sometimes in multiple languages (e.g. the European Medicines Agency repository of Summaries of Product's Characteristics and User Leaflets)²².

Techniques have been developed to mine such corpora for combined extraction of technical terms and lay equivalents²³, and to create semantically structured definitions from the context²⁴.

Finally, lay language lexicons have been mapped to international Classifications such as the International Classification of Primary Care²⁵.

These techniques facilitate efforts to make the patient a true partner in the quest for semantic interoperability.

22 http://en.wikipedia.org/wiki/Summary_of_Product_Characteristics

23 Elhadad N, Sutaria K. Mining a Lexicon of Technical Terms and Lay Equivalents. Proceedings of the Workshop on BioNLP 2007: Biological, Translational, and Clinical Language Processing. 2007: 49-56.

24 Muresan S, Klavans, J. A Method for Automatically Building and Evaluating Dictionary Resources, 231–234. LREC 2002. Madrid, Spain. May 29-31. Pp.209-217

25 Elena Cardillo: A Lexi- Ontological resource for consumer healthcare : The Italian Consumer Medical Vocabulary. PhD Dissertation at the International Doctorate School in Information and Communication Technologies, DISI - University of Trento, April, 2011. <http://eprints-phd.biblio.unitn.it/570/1/PhD-Thesis-Elena-Cardillo.pdf>.

5 Approach to validation by stakeholders

The proposal of methods to create and maintain domain-specific clinical models and ontologies needs to be reviewed by relevant stakeholders, such as patients, general practitioners, general medical specialists, super-specialists in medical sub-disciplines, developers of structured guidelines, developers of decision supports systems, software vendors, epidemiologists, health policy makers and clinical trial researchers.

The experience of the two use cases in the SHN project, pertaining to cardiology, will be confronted with the proposed general methodology to identify strong points and weak points, and to make a gap analysis of unattended issues. Possible candidates from other scientific societies, who are considering to start a similar process for their sub-discipline will be present at the discussions, to formulate a roadmap for their specific project. Representatives of the organisations, involved in the maintenance of general clinical models, such as HL7, openEHR and EN13606 will be present, to assure compatibility of the newly developed clinical models.

6 Approach to testing

In the proposed general model, an iterative process of development of domain-specific terminologies, clinical models and ontologies is proposed, where the drafts of the resources are brought back to stakeholders and end-users for cycles of comments and refinement. However, at the final stage of the process, there must be a moment of truth, by formal external testing of the results.

There are several levels in the definition of semantic interoperability, and hence, there are also several levels of testing²⁶.

First, there is the quality communication between two different computer systems, without looking at human interface issues and human factors such as interaction between the human entering data and the sending computer, and interaction between receiving computer and reading human.

Second, there is the quality of communication taken the whole chain of interactions, including the interactions of the human entering data and the human receiving data.

As the complexity of the communication increases, other forms of test will be needed.

Communication can be between systems with similar or different reference terminologies, clinical models, or ontologies.

In the SHN project, the starting point is always the actor in health care who is making medical registrations in computer systems for clinical purposes (ex. an English speaking general cardiologists, using HI7 exchanging data with a Portuguese speaking vascular surgeon, using ICD classification for documentation, concerning the need for re-vascularisation procedure in a particular patient).

On the receiving side, functionality can differ from clinical purpose, decision support, epidemiological research, clinical trials, and health policy. In principle, each of these functionalities need to be tested separately.

Once the interaction of the end-user (at the sending or receiving site) is taken into account, aspects of degree of professional specialisation (GP, allied health personnel, specialist, super-specialist) come in to scope. In addition, the end-user (on both sides) can be a lay person (the patient or his/her caregiver). Finally, to add to the complexity, communication can be in different languages.

For testing methods, the methodology of certification can be used, where a list of functionalities is checked for satisfying execution. A more complex testing method is the comparative study of outcomes, while using two different systems. Sophisticated techniques exist for the observation of end-users interacting with computer systems, with analysis of both process and outcome.

²⁶ Dolin RH, Alschuler L. Approaching semantic interoperability in Health Level Seven. *J Am Med Inform Assoc* 2011;18:96-103

7 Summary and conclusions

This deliverable presents a proposal for a general methodology for the clinical model development process, focussed on semantic interoperability. It is based on an extensive interview survey of European clinical model experts and developers. An iterative approach for the development cycle guaranteeing the involvement of relevant stakeholders, and the preliminary definition of requirements is proposed.

In addition, the methods to ascertain the perspective of the patients and care givers were explored. The clinical model for the heart failure summary, proposed in WP1 (and the InterRAI system) was systematically checked for suitability to reflect the patient's and caregiver's perspective.

Some linguistic methodologies were discussed to facilitate end-user data entry that will be instrumental to the performance of semantic interoperability. Lexical enduser terminologies and conceptual reference terminologies were discussed, together with their standards, from a multilingual perspective. Suggestions were made for the multilingual management of clinical models and value sets. Also, methods to integrate linguistic aspect of lay language terminology into the concept of semantic interoperability were discussed.

Finally, approaches to validation and testing were outlined and planned for the next phase of the SHN Project.

8 Annex 1: General methodology for the clinical model development process

Note

This Annex is intended for academic publication. It is therefore included here for internal project use only, and is not to be cited or distributed outside the SHN Consortium. The public version of this deliverable will instead include a reference to the publication.

An International survey of development practice for EHR clinical information models

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BACKGROUND

Despite substantial and growing experience in the development of Electronic Health Record (EHR) systems, further research is still required to maximize the benefit from the full potential of EHR systems. EHR semantic interoperability is recognized as one such area. Despite increasing adoption, we still lack consensus among clinicians, EHR systems vendors, health authorities and researchers on how best to structure clinical information consistently.

This study aims to provide requirements for Clinical Information Models in general, as semantic structures that are able to organize EHR information based on the definition of constraints over a specific Reference Model. In this field, Standards Development Organizations and other relevant institutions have defined standards and specifications to represent the emerging consensus on EHR information structures and terms, although with some overlap between them, such as ISO EN 13606 archetypes[1], openEHR archetypes[2], HL7 Clinical Document Architecture[3] and HL7 Templates, and Detailed Clinical Models[4]. Further, the Clinical Information Modeling Initiative is currently working in collaboration with most of the key stakeholders in the EHR semantic interoperability field on the definition of an additional specification for structuring EHR information[5].

Motivation

Although the above has listed many EHR specifications, each of which can represent a model that has been agreed by relevant stakeholders, there is a need for complementary research on best practice methodologies for the clinical information modeling process (CIMP). This is a process that covers the definition of clinical information models based on the participation of relevant domain experts.

New methodologies should define how relevant stakeholders should develop and agree on appropriate structures for clinical information so that these meet the needs of the many users who will create or use the information shaped by them. Different initiatives working in the semantic interoperability field have claimed that additional research is required (i) to establish good modeling governance practices, (ii) to assure the quality of clinical information models, (iii) to scale up the resource development process, and (iv) to support education about implementation and use[6, 7] [ENREF 7](#). This paper focuses only on the first three of these items, since it will be necessary to obtain results from research of these areas to later improve the associated educational content.

Although there are examples of the adoption clinical information modeling processes in some organizations [8-11] these processes have been described as dependent on each specific scenario and technology applied. There are additional proposals about organizational structures for supporting CIMP defined from a theoretical perspective [12]. As a consequence, there is a need for complementary research to identify additional issues regarding CIMP that have not been well described yet based on real experience. These issues include highlighting barriers to agreeing a definition for clinical information structures as well as proposing mechanisms to overcome them. Moreover, clinical modeling work performed by large EHR vendors is not usually published since they are more focused on the dissemination of their products rather than the clinical information requirements and their modeling process. This research aims to be able to advance knowledge about consensus practice in CIMP, through qualitative research methods.

Quality metrics recommended for clinical information models [13] cover the following dimensions (i) Scope and purpose, (ii) stakeholder involvement, (iii) management and maintenance (iv) information about the metadata (v) rigor of development (vi) compliance to standard, (vii) clarity and presentation, and (viii) general methodology. Based on the metrics proposed clinical information models can be compared and evaluated in a systematic and objective manner.

OBJECTIVE

This research seeks to identify best practice in developing and obtaining consensus on the representation of clinical information in order to support semantic interoperability for EHRs. The specific intention was to understand the user engagement, design methods and quality processes presently being used by leading international experts in clinical information modeling, in order to identify if there is an emerging consensus in good practice.

MATERIALS AND METHODS

The study was undertaken through semi-structured interviews with 20 recognized experts in the field of clinical information modeling. The interview length was 1 hour and these were conducted either by face-to-face or teleconference meeting. These interviews were transcribed and analyzed according to inductive Content Analysis methodology[14]. This methodology is recommended in cases where previous published material is either fragmented or lacking. In the case of clinical information modeling processes, the large number of specifications recommended to adopt this bottom-up methodology for content coding.

1. Questionnaire development

Based on a preliminary literature review, the three seminal papers related to quality criteria and quality approaches for clinical information modeling were examined in depth to extract the key topics that should be covered by the questionnaire[15-17]. These topics were verified through a second literature review to identify any additional points.

Special effort was made in order to express the interview questions using a language easily understood by experts, who were expected to come from varied professional backgrounds (i.e. avoiding standards jargon). The questions were open, to invite diverse interviewee responses. The questions were reviewed by two independent experts, resulting in some rephrasing and re-ordering. These two experts were then formally interviewed in order to test the openness of the questions and to evaluate if the questionnaire flow required modifications.

2. Sampling

Experts were selected as those known to have participated in defining clinical functional requirements and specifying the information contained in large scale EHR systems with the objective of being able to compare and contrast international approaches to clinical modeling. They were selected either because they have published multiple papers on the topic or by direct recommendation by a previously identified expert (snowballing), also ensuring broad international coverage. In order to be able to include a broader picture about the definition of EHR clinical information models, inclusion was not limited to those with expertise in the set EHR standards with published literature. This survey applied the snowballing process to include experts from EHR vendors with a strong experience in this field based on proprietary solutions. Thirty one experts were contacted to be interviewed between May 2012 and March 2013. Two experts refused due to agenda problem, 8 didn't answer and one felt that his background was not suited for the interview. Details about the interviewed experts are given in Table I.

Interviewed experts details

Countries of residence	UK, Netherlands, Sweden, Norway, Australia, Brazil, Spain, USA, New Zealand, Austria and Switzerland
National/regional eHealth strategy committees and regional projects	12 experts participate in the eHealth strategy of Norway, New Zealand, Sweden, Australia, Austria, UK, region of Andalusia, region of Geneva in Switzerland and region of Minas Gerais in Brazil
Experience on functional requirements and modeling clinical information for EHR systems	Average 14.8 years of experience (SD=6.3)
Number of papers authored by the experts indexed in PUBMED	Average 17.6 papers (SD=19.2)
SDO and other key initiatives in the semantic interoperability field	11 experts participating in ISO, CEN HL7, openEHR[18], CIMI[5] and EN13606 Association[19]
Member of other National Health Informatics Associations	13 experts
Large healthcare providers	5 experts
EHR vendors	2 experts from top EHR vendors (more than \$300 million income) 7 experts from Small and Medium Enterprises acting as EHR vendors
Academia	13 experts
Graduated with medical degree	14 experts
Graduated with technical degree	8 experts

Table I. Personal profiles of the interviewed experts

3. Content analysis

Content analysis was conducted using inductive category development in the coding stage. This is the recommended strategy for studies where the existing literature is limited or heterogeneous, to avoid creating preconceived categories[14]. As recommended by Hsieh & Shannon (2005), to increase the reliability and validity of the results[20] a set of 8 interview transcripts were reviewed by a second researcher to verify that the final categories and conclusions were correctly developed. This process was made with Nvivo software for qualitative data analysis[21]. Table II outlines the areas covered by the interview questionnaire

1. Barriers to reach consensus on the definition of the EHR functional requirements	6. Mechanisms to ensure quality of models
2. Organization of people involved in requirements definition	7. Preventing medical errors
3. Fulfilling of the requirements by the definitive systems	8. Using free text and structured data
4. Current clinical information modeling process	9. Terminologies
5. Improving the clinical information modeling process	10. Sharing information with other locations and domains
	11. Knowledge evolution at a larger scale

Table II. Areas covered in the interview

RESULTS

1. Barriers to reach consensus on the definition of EHR functional requirements

The most common barrier identified was the difficulty in obtaining a common understanding of the consequences of specifying a clinical modeling requirement. Respondents often indicated that clinicians did not usually understand why it is essential to define clinical information models, and how these would influence the functionalities that their EHR system would subsequently provide. When clinical groups within the same organization have different ways of working, each group usually preferred to modify a proposed clinical information model to fit their practice rather than examine the evidence to determine a consensus best practice. Unless there is an experienced health informatics expert leading the CIMP, it was common to find communication barriers between clinicians and computer scientists. Some of the most critical barriers to arrive at a clinical consensus arose during the following clinical modeling tasks:

- *Determining the level of detail* that needs to be documented in the EHR, highlighting differences in clinical practice. This is also called semantic granularity mismatch.
- *The level of best practice* that should be prescribed was debated through the definition of which data items to make mandatory.
- *Determining the useful summary information* that would help clinicians to manage chronic diseases over time.

Organizational barriers related to missing (overlooking, omitting) the participation of some professional specialties that would use the system, and to having enthusiastic experts who forget to include additional stakeholders in the project team.

It was also reported that another consequence of personal dependence (if projects have only one expert representing a medical specialty) is that it is common to get an emotional attachment to the final models and systems because the expert has invested a lot of personal time as an addition to their daily job.

Business reasons can be another barrier to obtain consensus on the granularity of information, since the models could result in system modifications or generate indicators that measure clinical performance, with a high impact for suppliers or clinical departments (e.g. on reimbursements, resource allocation).

Finally, when the system is implemented, any further major changes to the clinical information models did not always follow the same level of governance. Interviewed experts recommended that changes in the modeling requirement should require the experts to also consider the impact on the EHR system as a whole.

How to overcome these barriers:

In order to overcome the barriers described above, interviewed experts identified it as critical to recognize and value the contribution that others had made to the existing system, and to focus particularly on those aspects that will have a business impact on clinical work, and to understand (recognize) the contribution that people had previously made to the legacy system. It is recommended that experts with experience in defining requirements and clinical modeling facilitate this process. They can apply methodological approaches, communicate the benefits of interoperability modeling and the importance of high quality clinical information models. If conflicts are identified, such an expert can facilitate agreement through helping to prioritise the interoperability business drivers. This requires an open and inclusive discussion, usually collecting additional information about the underlying functional requirements. Such discussions were often reported to result in a common clinical base model that allows for local specializations (variations, profiling) whilst consistency is preserved for the essential information. At other times it was found necessary to wait and review the definition once additional information about the interoperability requirements had been collected.

2. Organization of people involved in requirements definition

After the project scope and objectives had been defined, the interviewees reported that those people who participate could usually be classified on three organizational levels. The first level includes the experts who lead the model definition activity. The second is a core team of multidisciplinary experts who work in depth on the detailed clinical and technical needs that the system and clinical information models will need to satisfy. The third level comprises a larger group of experts who validate the proposed definitions. Table III details the characteristics of each organizational level.

Organizational levels for Clinical Information Modeling Process	
Leading the clinical information modeling team	<p>Who?</p> <ul style="list-style-type: none"> - 1 - 3 people with deep understanding of both clinical practice and health informatics - Business analysts, clinical information modelers and terminologists <p>Tasks</p> <ul style="list-style-type: none"> - Collect functional requirements from the core team and other sources of documentation such as guidelines and paper forms - Coordinate the core team and its feedback - Applying a methodology to organize and define the requirements - Facilitate alignment with the latest clinical evidence <p>Recommendation</p> <ul style="list-style-type: none"> - Working experience in clinical settings is desired for clinical information modellers, or experience in the development and deployment of EHR systems for technical experts
Core team of domain experts	<p>Who?</p> <ul style="list-style-type: none"> - Between 1 and 5 clinicians, depending on the complexity of the field and the size of the organization. Up to 10 people on very large projects - Recommended to have representatives from each clinical department and clinical specialty that will use that aspect of the EHR system

	<ul style="list-style-type: none"> - People highly committed to the success of the project <p>Tasks</p> <ul style="list-style-type: none"> - Provide a detailed definition of the EHR documentation required for the clinical domain where they are experts <p>Recommendation</p> <ul style="list-style-type: none"> - Ensure that this group understands correctly the scope of the EHR system and clinical information models to be developed, the modeling methodology being adopted and how this project relates to the systems already in use.
<p>Validation Group of domain experts</p>	<p>Who?</p> <ul style="list-style-type: none"> - Larger representative group for validation purposes - The selection of the group depends on the project scope <p>Tasks</p> <ul style="list-style-type: none"> - This group will verify that the proposed design for the EHR and system will satisfy their current and projected practice needs <p>Recommendation</p> <ul style="list-style-type: none"> - Include also non-clinical actors that will make secondary uses of the data or have expertise in the field. (e.g. managers, health authorities, patient associations, public health experts, researchers, professional medical bodies and system vendors)

Table III. Organizational levels for Clinical Information Modeling Process

3. Fulfillment of the requirements by the definitive systems

Most interviewees claimed that their systems in general fulfilled their requirements. They recognized the benefits from iterative development and early involvement of end users with prototype validation. Conveying the importance of the consistency of clinical information, and the impact of the models on system usability and functionality, as well as management of expectations, were all considered key success factors. Their experience also indicated that the systems become more mature over time, and would increasingly fulfill the modeling requirements as a continuous improvement cycle. Questionnaires and on screen feedback buttons were cited as useful feedback mechanisms.

Unsuccessful modeling initiatives had either changed in scope during the process or were influenced by a set of factors that included poor understanding of requirements, organizational changes or greater pressure to meet a deadline than fulfill the requirements.

4. Current Clinical Information Modeling Process

According to interviewees, CIMP can be described as a continuous improvement cycle: an agile development approach can have substantial benefits because it facilitates rapid and iterative feedback.

The modeling process should start with the scope definition and a prioritization on the basis of management, economic, logistic, regulatory, medical and nursing needs. Next, evidence sources must be identified including current paper and electronic forms, reporting requirements, technical specifications and existing clinical systems. Experts indicated that health providers cannot always be aligned with the very latest clinical evidence, since it takes a while for a sufficient body of evidence to

accumulate to justify changing clinical practice, and changing the clinical information structures within EHR systems. Moreover clinical information models and EHR systems should be able to support the documentation of legacy practices for some time, since there is a gradual adoption of clinical evidence. The input sources to model design must therefore combine existing practice with best practice.

The leading experts usually establish the core team and organize meetings to collect the clinical and technical requirements. These meetings were online, face-to-face or workshops depending on the number of experts and their geographic distribution. With the support of the clinical information modeler, the models were defined according to the clinical care processes and the documentation that clinicians create. Some methodologies in use include asking clinicians to critique existing models or EHR systems since this facilitates a common understanding and helps identify new requirements. Other interviewees recommended asking clinicians about the most important information to collect, to establish prioritization mechanisms and apply a Socratic questionnaire [22] method and knowledge elicitation techniques[23] to obtain a detailed definition of the clinical domain.

Based on these requirements, clinical information models were defined and prototype screens designed in order to obtain validation. Usability could be verified using usability testing techniques and interviews. This was best conducted as an iterative process for validation and to detect overlooked requirements. The system was then implemented, ensuring a feedback mechanism. Finally, a governance and maintenance stage ensured that the system could be updated in a consistent way. Figure 1 illustrates the ideal steps for a CIMP.

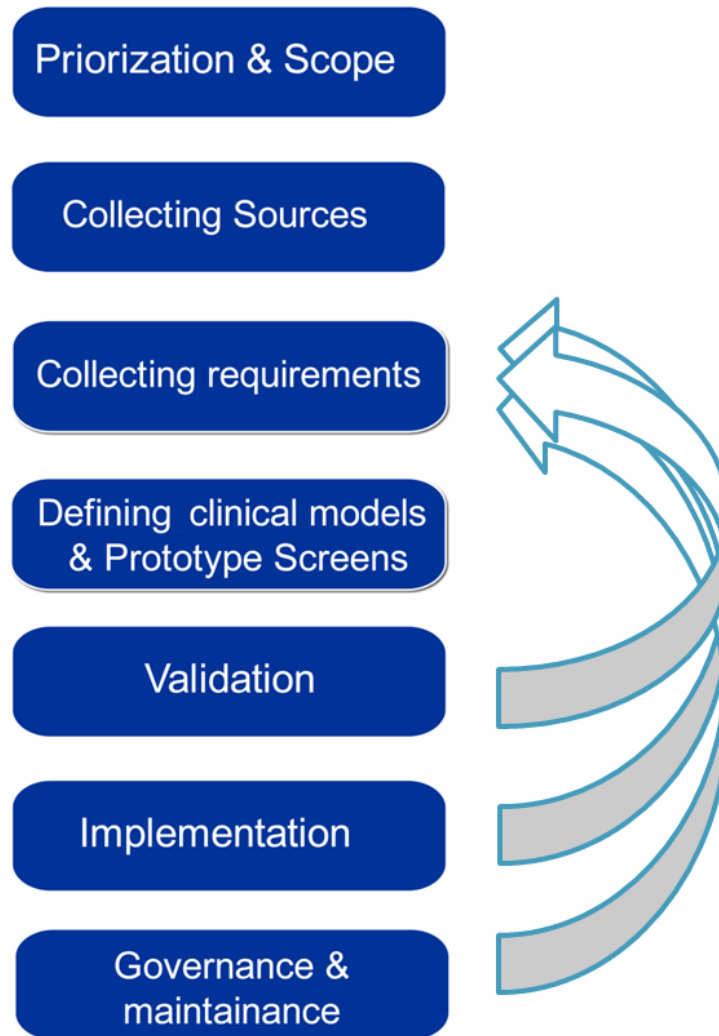


Figure 1: Clinical Information Modeling Process diagram

5. Improving the Clinical Information Modeling Process

Interviewees highlighted the need for additional research to improve tools for creating the clinical information models and ideally having a drag and drop tool that would create a user-interface based on them. They also recommended to define a formal development process for capturing requirements and model clinical information. Many highlighted the need for professional bodies to participate in the definition of policies, good practice for documentation and healthcare professional education. They also expressed a need to improve the interrelationship between structural and semantic health informatics standards.

Further work was felt to be needed on how to handle situations (including legacy data migration) when it is not possible to retain backwards compatibility when developing a new clinical model.

6. Mechanisms to ensure quality of models

Factors helping to determine if models are of good quality include the previous adoption of the models by other systems or other communities, a clinical model certification process, confirming the level of consensus that was achieved, specifying which stakeholders had participated in the design and validation process, and making sure that clinical information models were not simply reused after any change to their scope without an evaluation of the consequences and a further iteration of the validation process.

A second kind of assessment suggested was to incorporate technological validation for syntactic and semantic correctness (against predefined modeling rules) and for consistency. Currently there are tools as the openEHR Clinical Knowledge Manager[24] and Intermountain Healthcare[25] that verify if clinical information models satisfy technical specifications and perform other automatic checking. It will be also be necessary, as modeling efforts scale up globally, to have tools that are able to verify if there are semantic overlaps and inconsistencies across multiple clinical information models. A tool for clinical modeling with semantic validation capabilities could increase the quality and consistency of multiple clinical information models. These capabilities can be found in already existing tools like Protegé [ENREF 18](#)[26].

A third kind of quality assessment is monitoring how well the data that are collected according to the models can then be used e.g. for clinical audit and outcomes assessment.

7. Preventing medical errors

It was recognized to be difficult to design clinical information models that might reduce medical errors without a detailed understanding of how errors arise. A detailed requirements analysis might indicate if particular data items should be mandatory to collect. Interviewees indicated that the way a model is implemented, in particular the user interface, might have a greater impact on the prevention of errors than the design of the model itself. It is recognized that checklists can help prevent error[27], and some models may be designed to represent checklist items. Supportive functions for data entry, as well as algorithms and decision support, can be implemented to avoid collecting invalid values and thereby reduce errors.

8. Using free text and structured data

Interviewees believed that collecting structured information required more data entry time than free text. Free text has limited computability, and therefore it has limited exploitation. On the other hand free text permitted the collection of unanticipated information, and so a balance between structure and free text was always required. A few interviewees felt strongly that the focus of clinical modeling should be to structure only the information that is expected to be exploited to make deci-

sions or to be included in decision support algorithms, keeping the rest of clinical documentation as free text.

Since many clinicians find it easier to document in free text, a few experts proposed using Natural Language Processing to extract relevant information (e.g. patient problems) for confirmation by clinicians and storage in a structured form. Such tools are becoming integrated within commercial EHR systems.

9. Terminologies

Since multiple terminologies can cover the same domain subject matter, mapping between multiple terminologies was identified as a major difficulty. It was found helpful to have clarification on the application of terminologies, for example as provided by the Meaningful Use program specifying which terminologies and vocabularies are applied for each purpose.

Interviewees also reported difficulties in using the updating mechanisms provided by international terminologies, and that terminology development organizations need to provide more support and explanation about the introduction of new terms and changes to hierarchies. It was noted that there are still few rules for post-coordination, which is something that clinicians found very difficult. Given these difficulties it was felt beneficial to involve the support of terminology experts in clinical modeling activities.

Many interviewed experts claimed that clinicians prefer to use locally defined value sets that are well-adapted to their needs rather than applying standard terminologies. In addition, it was common to find EHR systems that incorporated their own terminology, with a need to map these terms onto standard terminologies for subsequent uses and for communication.

10. Sharing information with other locations and domains

There were consistent answers across the questions relating to the sharing of information, and re-use models, between care settings and clinical domains. Interviewees advocated a modular approach to define common core information structures that can be re-used in different domains. Working simultaneously across domains on these core information structures would allow feedback to be gathered from different environments, and result in a good basis for re-use. This core structure should be able to be specialized (extended) to meet the specific needs of each care setting and specialty. It was recommended that the common core structure should be specified in as much detail as possible, as it could be simplified at each local level using templates or masking inapplicable data elements at the application level.

For shared model development, widening the set of experts involved in the model design will mean that it takes longer to obtain a consensus. Criteria need to be defined at the outset for determining the basis for signing off a model: when it is likely to achieve sufficient usability and deliver its intended benefits. Interviewees felt that differences in clinical information requirement across locations and specialties were not very great, and that should be possible to arrive at a harmonized design. The most important objectives were to convince the clinicians of the value of adopting generic wording that would be applicable across domains rather than using their own specialist wording for the data elements. They also needed to be encouraged to reuse previously defined models wherever possible, rather than re-inventing from scratch.

11. Knowledge evolution at a larger scale

In order to support knowledge evolution at regional, national or international levels there is a need for tools that promote team collaboration on the design of clinical information models and for organizational governance that promotes their acceptance. There are examples of tools[24, 28] able provide a centralized repository with open access to gather design inputs and to facilitate consensus on model definitions. An organizational structure is also required to maintain and update clinical information models. One interviewee suggested that models should be periodically reviewed to check for new evidence, and to monitor if the models are being correctly applied.

An important problem is that acceptance of the clinical modeling approach is still at an early stage since most existing EHR systems cannot yet directly implement clinical information models represented using the published standards. Even though large scale clinical modeling may reduce costs, there is an initial need for substantial funding for the design and governance of model development, through activities such as education of clinicians, working with health authorities in charge of an IT infrastructure and promoting awareness within eHealth projects.

01. Barriers to reach consensus on the definition of the EHR functional requirements	
<ul style="list-style-type: none"> - Changes in requirement definitions - Different perspectives for clinical modeling - Commercial, economic and administrative issues - Organizational issues 	<ul style="list-style-type: none"> - Scope Definition issues - Lack of proper tooling - Lack of understanding - Lack of clinical consensus before requirement definition
02. Organization of the people involved in requirements definition can be classified in	
<ul style="list-style-type: none"> - Leading clinical modeling team - Core team of domain experts 	<ul style="list-style-type: none"> - Validation team - Prioritizing committee
03. Fulfilling of the requirements by the definitive systems	

- Continuous improvement & iterations	- Methods for evaluation success development
04. Steps of the Clinical Information Modeling Process	
- Agile deployment plus continuous improvement cycles	- Collecting requirements from health and IT professionals
- Feedback & Iterations	- Defining clinical information models and Prototype
- Prioritization & Scope definition	- Validation stage
- Collecting sources of information	- Implementation stage
	- Governance and maintenance
05. Recommendations for improving the Clinical Information Modeling Process	
- Improve tools	- Professional bodies participation
- Define formal clinical modeling process	- Improve semantic definitions and applications of standards
- Additional resources to cope with iterative cycles	
06 Recommended mechanisms to ensure quality of the models	
- Tools with syntactical and semantic validation	- Quality principles for each step of clinical modeling methodology
- Increase the clinician's perception of usefulness of information	- Check EHR functional requirements and related standards
07. Recommendations for preventing Medical Errors	
- Analyze how data is collected	- Education for participants on requirement definition processes
- Strong work on requirement definition	
- Ensure that usability & Graphical User Interface has been well designed	
08. Using Free Text and structured data	
- Structured information characteristics	- Recommendations for Free text
- Recommendations for structured data	- Supportive NLP functionalities
- Free text characteristics	
09. Terminologies	
- Terminology servers	- Reducing lack of guidance
- Tools for terminology management	- Clinician and Terminology experts involvement
- Adding termset to clinical information models	- Determine sensible length of value list
	- Mapping to international terminologies
10. Sharing information with other locations and domains	
- Common reference & specialization	- Involve clinicians from other locations
- Convince clinicians for generic wording	- Focus on increase quality of care rather than reuse models
- Gradual harmonization	

11. Knowledge evolution at larger scale	
- Clinicians education about knowledge definition	- Organizational structures
- Required economical resources	- Acceptance is the most important factor
- Collaborative Tools are beneficial	- Clinical Engagement
	- Monitor local eHealth projects

Table IV. Summary of key findings

DISCUSSION

a) Establish good modeling governance practices,

Based on the qualitative content analysis of 20 experienced EHR experts, this research has identified common practices and needs for clinical information modeling processes in large EHR infrastructures. Results show that the modeling processes adopted, even through different EHR standards and specifications, could be harmonized.

The research results can be useful to provide a wider spectrum of clinical modeling processes and the proposed steps and roles can help to palliate the lack of common nomenclature in this area. For instance different experts applied many different terms for the person leading clinical modeling process. (e.g. medical informatician, information analyst, clinical modeler and expert in methodology). This contributes to increase barriers related with different perspectives for clinical modeling and lack of understanding.

These results indicate that it is possible to define a common CIMP able to be applied with the multiple EHR specifications. Results obtained from experts experienced in heterogeneous EHR communication technologies were consistent between them, making it possible to identify common recommendations to improve the establishment of good modeling governance practices. The information provided can contribute to define a generic CIMP.

b) Assure the quality of clinical models

It was confirmed that interviewed experts have directly identified most of the 8 dimensions recommended by Ahn et al. (2012). Interviews experts recommended defining a formal CIMP able to check each step of the process and the items identified are aligned with Ahn's quality metrics. In addition, some of the metrics defined by Ahn regarding compliance to standards, clarity and presentation, and general methodologies for reference model related capabilities were not directly identified in our results. Since most of these items are related to syntactical and semantic checking, they should preferably be supported by next generation of clinical information modeling tools to facilitate the work done by clinical information modelers. Finally, as another mechanism that will complement the

Ahn recommendations, interviewed experts recommended monitoring how well EHR data are collected according to the models.

c) Scaling up the resource development process

Existing collaborative tools allow the participation of relevant stakeholders but it is recommended that this be complemented by a regulatory endorsement, as well as a practical strategy for eHealth semantic interoperability. Monitoring and collaborating with other eHealth projects within a region/nation (but with a reduced or local scope) should enable promotion of a gradual harmonization of clinical information models within a region. Existing recommendations to define clinical information models as maximum data sets [8] can incorporate data items required by localised eHealth projects (centered on a hospital or city) into a regional or national governance process. Local eHealth projects will have more project resources including budgets, but could use their limited resources by working with regional/national recommendations for clinical information modeling and then applying prioritization mechanisms to select the most relevant information that they will require locally for their final screen forms and to share within the regional infrastructure. Even though a clinical modeling approach will result in reduced costs, there is an initial need for substantial funding for monitoring and coordinating the eHealth semantic interoperability strategy.

On the other hand, the involvement of professional bodies needs to be promoted and this will make it easier to obtain wider clinician participation in the CIMP. New functionalities should be incorporated to these modeling tools: interviewed experts suggested improving tool capabilities for creating clinical information models and user-interfaces as a mechanism for accelerating the CIMP. Moreover, they can be combined with new functionalities that will guide the participation of different actors in the CIMP.

d) Limitations of the study

Although the sample selection of experts was made in an intent to obtain international coverage and a large experience of clinical information modeling and processes across multiple institutions using different EHR technologies, it was difficult to ensure representation across the full spectrum of clinical modeling expertise and processes, and so some approaches may have been missed. Despite such limitations, the results obtained are proposed as useful to guide the development and test of a formal CIMP.

CONCLUSION

This research has provided an overall description of the CIMP based on the experiences obtained with the definition and implementation EHR systems in 13 countries. This process includes multiple stages and multiple actors, which are coordinated to provide an inclusive collection of requirements and data items from multiple sites and domains. Research has identified a set of consistent barriers such as personal dependences and emotional attachment, as well as recommended mechanisms to overcome them making possible to obtain an inclusive CIMP where participants have a clear understanding of their role and duties. Based on these results, the research proposes how quality metrics for clinical information models can be incorporated in modeling tools. Based on the experience from large scale infrastructures for clinical knowledge definition the need is highlighted for monitoring and guiding projects with local scope.

The information obtained through this qualitative research process have identified new requirements for the CIMP and modeling tools, as well as will be applied to propose a formal process for clinical information modeling. This work is being taken forward within the SemanticHealthNet Network of Excellence on Semantic Interoperability, a project funded by the EC within the 7th Framework Programme[29].

- Research confirms the need for the existing quality metrics and propose to include those related with reference model capabilities as new functionalities for clinical information modeling tools
- Research identifies recommendations for supporting knowledge evolution at large scale making based on coordination with local projects and increased participation of professional health bodies.

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Summary Table of Representative Quotations

1. Barriers to reach consensus on the definition of the EHR functional requirements

Member of International clinical modeling initiative:

- “if we can’t come to an agreement we tend to leave it and park it for a little while and the intent is to revisit those when we have more info about requirements. We then try to design it so that the things we have ‘parked’ can be brought in later as a revision.”

Member of Health Informatics organization:

- “first step to overcoming those problems is to diagnose them, so to recognize when what you’re dealing with is a financial investment issue and when what you’re dealing with is an emotional

investment issue.”

2. Organisation of the people involved in requirements definition

Member of large EHR provider:

- “In general there are a small number of people who understand the whole picture (of our product) and then they work to make sure the teams stay coordinated. It’s a big enough product so there is no single person that knows everything.”

Member of Health Informatics association

- “What the modeller does is facilitate that conversation, but the decisions and the trade offs around what you do, specifically locally, what you share, what the mapping maintains locally. How you synchronize those different perspectives are all issues that the modeller can’t determine but the modeller can facilitate those discussions and it’s really important that that is done in the context of value of benefits and costs rather than in an ideological way.”

3. Fulfilling of the requirements by the definitive systems

Member of national healthcare provider:

- “My systems were highly successful, and the reason was partly due to working with the top experts with most of the requirements already defined, a result of tonnes of prior work of many years.”

Member of Health Informatics association

- “What you’re doing is making things better you’re not getting to a point where the job is finished and you can move one. There is a need for continuous improvement and continuous refinement”

4. Current clinical information modeling process

Member of national healthcare provider

- “You start with what you find in the field, you bring a structure into that, identify the common elements, and then you design those elements. Then you test how they work on the screen and you get the expertise from others.”

Member of health informatics association

- “we applied a rapid prototype environment. That help to improve the perception of the people involved. The people involved in the clinical modelling, we could quite quick show them example screens that reflected their modelling ideas.”

5. Improving the clinical information modeling process

Expert clinical modeler

- “There should probably be a more formal way of capturing and documenting their requirements”

Member of large healthcare provider

- “better tools for creating the models and having a drag and drop tool that would create a user-interface based on the model content. Basically what you would be doing is using the models for the screen content and then as you put things on the screen you are able to change the visual attributes and change the data entry field and be able to create the field traversal order for items on a screen – it would be nice to have a tool that supported that visual creation of a screen.”

Member of large healthcare provider

- “I think that if we can collaborate to gather requirements online rather than working in isolation with the experts we could make the process quicker.”

6. Mechanism to ensure quality of the models

Member of large healthcare provider

- “In an ideal world it would be nice to have all that information within a modelling tool – one could think of like Protégé – so that you have some automatic checking of semantic interoperability and consistency between the different models.”

Member of health informatics association

- “check that not only the data is being collected as expected but to actually use it, to come to some, to interesting conclusions because if the data’s being used than the data quality will be sustained”

7. Preventing Medical Errors

Member of health informatics association

- “there are a number of places within clinical practice where by using a mechanism like the pre-flight check-list the airlines employ is a good way of making sure that people don't make mistakes”

Member of health informatics association

- “look where the errors are made, which has been the kind of clinical mistakes that the result is an error, can you workout from those where could an information system make a difference. Once you know that can you workout how to design a clinical data that would remind the clinician for good practice to prevent errors.”

Member of large IT provider

- “probably the most important is actually very good visual design ... a number of medical errors in medical software are related to poor usability”

8. Using Free Text

Member of large healthcare provider

- ‘don’t collect any data that you don’t know how to use’... leave it as free-text unless you know that this going to be used in algorithms”

Member of large IT provider

- “In the early days everything was free text, then we moved pretty aggressively towards making everything structured, and now we are coming back to free text but we are using natural language parsing tools to pull the right important structures out of the free text and have the physician confirm it.”

9. Terminologies

Member of national healthcare provider

- “You don’t have to put a terminology binding to each and every data element and if you get the data items right in terms of semantics then you can add these things as required along the way as well.”

Member of large healthcare provider

- “Fortunately, in the US, the terminologies are now, are beginning to get stabilized because of meaningful use... So that settles a lot of the old debates that forces us to have many different vocabularies and now it’s a little bit less complicated, but it is still hard.”

Expert clinical modeler

- “The big problem is just lack of pre-coordinated terms. In SNOMED to bind to our data sets. So there are still quite a few rules in post-coor there are still things we can’t bind to using post-coordination. But post-coordination is very difficult for clinicians to understand.”

10. Sharing information with other locations

Expert clinical modeler

- “can we please make the wording generic. In that there is a battle sometimes. They have a particular way of doing, and that is how they want the system to be rather than thinking they are building a system that other might use.”

Member of large IT provider

- “You know we have found very little that is different enough across either practice locations or specialities to warrant those differences. So we really have very few, reflect very few differences, so the clinical content is somewhat different.”

Member of health informatics association

- “I think that is better to have two models of diagnosis, which different groups use and each use them completely rather than having a supermodel of diagnosis which everyone uses in different ways.”

11. Supporting knowledge evolution at large scale

Member of health informatics association

- “we have to get organisations like professional bodies or specialist groups at European level like the European Society of Cardiology. They ‘ve got to have a working party who would help develop models and work with maybe not the vendors directly but with prototyping groups that can develop screens that look like the models”

Member of large healthcare provider

- “I have no doubt that all technical mechanisms are in place, but I don’t think that the problem is there...we need to find a methodology, a language, a process, that we can explain, teach, “sell” to clinicians at a LARGE scale.”

Member of large healthcare provider

- “the key thing is to connect to each and every project which is going to benefit from this and also to be in control of the future projects requirements and at least be aware of what is going to happen in the next run”

9 Annex 2: Checklist for clinical model development

Checklist for clinical information modeling process (CIMP)	
Understanding	
-	Has the scope (domain coverage, purpose) of the Clinical Information Models been shared and understood by all user stakeholders and additional relevant experts? (it is recommended to reduce the chances for lack of common understanding between participants)
-	There were communicated the exploitation benefits? (why formalizing these clinical models will deliver value to nominated stakeholder groups: it is recommended to explain benefits for end users to increase acceptance, and to document these intended benefits for future verification)
Teams	
-	Has a multidisciplinary team participated in the modeling process? (it is recommended to include at minimum doctors and nurses, but often other user groups and those who will access/analyse the data)
-	Has more than one expert per field participated in the modeling process? (it is recommended to have more than one expert from the same field to avoid personal dependences)
-	Have experts from more than one location participated in the modeling process experts? (it is recommended to have more than one expert from the same field to avoid personal dependences, even if the eventual models are only to be implemented and used in one care location)
-	All professional specialties and medical fields who will use the Clinical Information Models were consulted before the models were finalised? (it is recommended to have more than one expert from the same field to avoid personal dependences)
Sources of knowledge	
-	Have existing published sources of clinical knowledge been consulted (e.g. pre-existing clinical information models, interoperability standards, national or international data sets). (it is recommended to use technical examples defined through a review process and standard based)
-	Has the CIMP examined or developed the clinical examples in form of scenarios or EHR screens to help communicate and gain consensus on the design of the models? (it is recommended to provide additional inputs to clinicians to ensure a good understanding of the implications of the model features, and to reduce dependency on the understanding of a small number of experts)
-	Have the clinical models been examined for their level of agreement with relevant regional, national or local guidelines? Optional -This will allow to measure the level of clinical validity
Validation	
-	Has a methodology been applied for CIM validation? (e.g. discussion at a multi-stakeholder workshop, testing against the recording previous patient data, etc) (it is recommended to validate with a larger group of clinical experts than those who

<p>participated in the CIM design)</p> <ul style="list-style-type: none"> - Did the CIMP have more than one iteration process to allow clinical review the models? (it is recommended to establish an iterative process that helps to tune the Clinical Information Models)
Clinical Information models
<ul style="list-style-type: none"> - Have the final clinical information models been approved by consensus? (it is recommended to establish an iterative process that helps to tune the CIM) - Can the clinical models be shared with other clinical domains? (it is recommended to define models able to be applied in multiple domains to the best extent possible, to maximize consistency of clinical documentation) - Has provision been made in each of the defined sections to record free text comments, unless it has been agreed that this is not appropriate? (it is recommended to allow recording free text comments associated to most relevant concepts) - Each entry is mapped to international terminology? (it is recommended to have each Clinical Information Model concept mapped to international terminology) - Has the mapping to terminology been made by an expert in that terminology? (it is recommended to ensure that clinical information models have not wrong maps to terminologies) - - In order to allow a broad range of clinical situations are intended to be covered by the model, does the model provide for all of the different kinds of clinical information that may need to be documented? (it is recommended to identify and model all concepts required by relevant stakeholders in an inclusive process) - Has been specified which are the priorities to those items included in the CIM? (it is recommended to identify those concepts that won't be included in the final system because either budget or usability constrains) - Have been specified the mandatory items (it is recommended to identify level of quality of care recording agreed by experts)
Knowledge Evolution & Governance
<ul style="list-style-type: none"> - It is clear how and when the defined models will be updated? (it is recommended to define how the process will update the models) - Have the eHealth projects that will adopt these models been specified? (it is recommended to identify which projects and systems will use the models, at least initially)

10 Annex 3: Involvement of patients in the clinical model development process

Patient Perspectives in Heart Failure

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Overview

The evolution and greater implementation of electronic health records provides us with unprecedented opportunities to change how we deliver healthcare, share information, carry out research and most importantly to finally create a truly patient centred health record. To achieve these aims we need to be capturing and storing information in ways that allow it to be safely and easily shared between people, health organisations, IT systems and patients. Key to this is the concept of semantic interoperability, the ability to share data with no loss of its context or meaning.

In line with this aim the Health Informatics Unit at the Royal College of Physicians (London) recently published a body of work entitled 'Standards for the clinical structure and content of patient records'⁽¹⁾. This is the culmination of many years of work and provides detailed headings and subheadings for the structure of admission, referral, handover, outpatient and discharge documents. These standards are the result of extensive consultation and are based on the consensus opinion of over 50 professional organisations covering the full spectrum of clinical and social care disciplines. Crucially, there was also significant input from patients and patient groups at all stages of the process. The published record standards provide a basis for recording clinical, social and patient centred information. The Academy of Medical Royal Colleges signed them off as fit for purpose for the whole medical profession in April 2013 and implementation has begun at sites across the UK. Adopting this common structure for health records facilitates the safe and accurate transfer of data and enables interoperability between IT systems, databases and health record systems.

The Health Informatics Unit at the RCP is committed to the development of patient focussed clinical records and this paper describes a review of the SemanticHealthNet data set with specific attention paid to the inclusion and recording of patient perspectives. The Health Informatics Unit comprises expertise in the process and methodology for developing clinical record standards as well as longstanding involvement with the development of clinical assessment tools as part of the InterRAI project group.

We describe a review of the Heart Failure dataset, comparison with the InterRAI patient assessment tools, findings from patient consultation and a review of the scientific literature. Based on this and experience from previous projects we highlight areas where enhancements could be made to the heart failure summary and describe a series of recommendations for possible future work.

SemanticHealthNet

The SemanticHealthNet project has developed a detailed template for a data set for the shared care of heart failure⁽²⁾. The management of heart failure is increasingly complex, involving many investigations and potential therapeutic interventions. Additionally management involves multi-disciplinary teams encompassing both primary and secondary care as well as allied health professional groups. Provision of a shared health record is essential to allow these professionals to best manage patient care. The use of an agreed data set along with appropriate IT systems provides the opportunity to employ decision support tools, automatically provide prompts to monitor or review and helps to avoid repeated unnecessary investigations and tests.

The heart failure dataset proposed comprehensively records the clinical, laboratory and investigation results required to monitor and manage the medical aspects of the disease. However, a key feature of shared health records is that they should be patient focused and allow patient involvement and we believe that the current dataset doesn't give sufficient detail and priority in this respect.

The medical model for clinical management of heart failure concentrates on symptoms such as breathlessness, ankle swelling and assessments of exercise capacity amongst others. These are characteristics where quantification is possible, therapy is available to attempt to modify the symptom and outcome can be recorded. For many patients these are also key markers of their disease and a way for them to measure the success of their treatment. There are, however, other important issues that heart failure patients may or may not readily report including perceived reduced quality of life, low mood and depression, reduced functional capacity and fatigue^(3,4). Anecdotal evidence from clinical experience and views expressed during previous patient engagement supports our belief that patient priorities and concerns are often at odds with the clinical view and are commonly not captured or given the same value during current clinical care.

Exploring patient perspectives in heart failure

Literature

We conducted a light touch review of the literature concerning symptoms and patient experience for patients with heart failure.

Symptoms reported by patients with heart failure vary dependent on the population, disease severity and also how the information is collected. It is reported that providing patients with a list of symptoms yields a more comprehensive report of symptoms experienced compared with asking them to report from memory⁽⁵⁾. Where patients select from a checklist the top five reported symptoms have been found to be shortness of breath, decreased exercise tolerance, orthopnoea, fatigue and dizziness/light-headedness⁽⁵⁾. Fear and anxiety are also common features in people with heart failure as well as guilt, particularly where people have not been able to comply with a recommended fluid restriction or drug regimen. Where men had experienced of a relative or partner with heart failure they reported significantly more anxiety and fear related to coping with their own illness and possible deterioration. A further study reports shortness of breath and fatigue as the most common symp-

toms experienced but found that the most burdensome problem was difficulty sleeping⁽⁶⁾. Based on these findings Zambroski et al advocate a symptom based approach to heart failure management with the target of increased quality of life. It is well described in the medical literature that depression is common amongst heart failure patients and is associated with a greater number of other symptoms and a decrease in overall quality of life⁽⁴⁾.

Information and education is key to allowing patients to understand their health problems and rationale for treatment. A small study found that all but one of their cohort (who was medically trained) profoundly lacked understanding of heart failure⁽⁷⁾ and this contributed significantly to experience of anxiety, depression and anger. Information also allows informed future care planning and shared decision making, all particularly important when dealing with a chronic disease. Patients with heart failure are however a heterogeneous group with varying symptoms, experience, expectations and wishes for future care. It is therefore important that structures exist to allow discussions about these issues, capture of the information and care planning. Patients' priorities for care will be highly individualised however a common theme reported is that the majority of heart failure patients attach more weight to quality of life over longevity⁽⁸⁾.

Heart failure rarely exists in isolation and commonly sits alongside other vascular related disorders of the brain, kidneys and peripheries as well as diseases and conditions associated with ageing such as dementia and cognitive decline. These are of relevance in both the assessment and management of heart failure patients and it is therefore vital that adequate information is collected in the dataset to enable this. For some people with heart failure their disease course will be progressive and ultimately lead to death and it is therefore important that details of the symptoms and priorities for care at this stage in life are captured⁽⁹⁾.

Focus group

We invited a small group of patients with experiences of heart failure as well as carers to a meeting held at the Royal College of Physicians. 3 patients and 1 carer were able to attend. Our aim was to discuss the experience of heart failure from a patient and carer perspective and gain an insight into potential priorities for patients in the management of their condition. Detailed notes were taken, reviewed and summarised into the following themes:

Symptoms

The group members explained that they found this very difficult both personally and when asked by clinicians, often because the symptoms experienced were vague or they were not sure if they were attributable to their heart condition. They all agreed that fatigue was a common problem and they found this difficult to quantify or adequately explain it to other people. They also highlighted poor concentration and general feelings of weakness or feeling unwell. One patient described significant misunderstanding of which previous symptoms had been due to his heart attack and which related to heart failure and indeed what the two terms meant.

Breathlessness and oedema are commonly given a lot of attention medically. Whilst the patients were aware of these they were not currently troubled by them personally but highlighted that they were always asked about these symptoms in medical consultations. (It is worth noting that our patient group may not have been representative of the full spectrum of patient with heart failure).

Medication

Patients reported variable understanding of medications they had been prescribed and highlighted variable clinical attitudes to shared decision making regarding treatment. Positive feedback for specialist nurses and cardiac rehabilitation services was expressed. One patient felt very strongly that his doctor was very focussed on applying clinical guidelines and taking steps that may make him live longer but less interested in discussing his possible side effects or compliance issues. Special attention was focussed on beta-blockers with two members of the group feeling very strongly that side effects from the medication had had a significant impact on the quality of their lives. One patient detailed how taking a beta-blocker had dramatically reduced his energy levels, lowered his mood and led to cold extremities that further limited certain recreational activities he had previously enjoyed. This patient reported limited sympathy from his doctor and described having to be very persistent in driving the agenda to reduce and ultimately try an alternative medication. Other medications and side effects were also mentioned with regards to amiodarone and diuretics. Members of the group felt that decisions about their treatment often couldn't be taken by their GP and that they often had to wait extended periods of time to see the hospital clinicians before any changes could be made. They described a lack of faith in primary care and a perceived lack of information sharing between the hospital and the GP.

Mood, social and physical function

The group members were happy to discuss issues related to mood and depression. Two of the male patients were particularly concerned by both the actual and assumed limitations placed on their lives. They detailed concerns about low feelings of self-worth because they couldn't be as active as before and also guilt that they felt they looked well and people wouldn't understand why their functional ability was diminished. One of the patients had heart failure secondary to a cardiomyopathy and was only in his mid-40's. He highlighted particular issues with having to give up his very active professional job, feelings of guilt that he could not financially support his family and concerns that he was curtailing his partner's life experiences because of his illness. He also felt that being much younger than many people with heart failure many of the resources available were not suitable for him and that many of his expectations were different to many older heart failure patients. He pointed to a generalised approach to treatment at times where clinicians were used to dealing with a more sedentary, older population. One patient described an altered sense of self-worth and feelings of fear regarding future deterioration in his health. Interestingly fear was largely centred on future limitations of functional ability rather than physical symptoms. Death was something that group described an awareness of but not any specific anxiety or fear over. Several members of the group agreed that they were reluctant to discuss their mood/concerns/fears as they were worried they could be labelled as depressed or may be given anti-depressant medication. There was consensus that mood

and potential depression was not something they had been routinely asked about. Physical function was a key priority for the group members and they listed examples ranging from being able to help with household chores, mow the lawn, go shopping through to being able to go on holidays and seeing family. One patient was particularly concerned about being judged by others if he could not be as active as they expected and a fear that people would think he was making his symptoms up. There was universal agreement in the group that arenas for social interaction with fellow patients were very beneficial and cardiac rehabilitation programmes were highly praised as well as independent support groups.

Carers

The patients in the group expressed significant concern that their health and functional limitations had an impact on their partners. We had one partner/carer at the meeting and she explained that she had found it difficult to understand both the medical and emotional impact of heart failure. She explained that she had initially been very fearful of her husband deteriorating/suffering and had tried to be protective by making him rest, stopping him lifting or doing work around the house. She became worried if he was away from home or left alone and therefore tended to ensure he always had company. She also described a feeling of limited involvement in his healthcare interactions and limited information provided for partners. She had not attended any cardiac rehab education sessions with her husband and was unaware as to whether this was an option.

Future care

All patients expressed clear opinions that they would prioritise quality of life over quantity in the future. (It is worth noting that the patients were all medically stable with well controlled symptoms). They felt they would want clear explanations regarding the rationale for future treatment with the opportunity to evaluate possible benefits and side effects before deciding. Whilst they were aware of potential future deterioration they had not had specific thoughts about end of life care or planning. They acknowledged that individual wishes were likely to be very different and felt that such plans would need to be tailored individually, taking into account patient and family/carer opinions.

Key themes

Based on personal experience, evidence from the literature and findings from the focus group we drew together what we believe are key themes related to the patient experience of heart failure and its treatment. Subsequently we examined the proposed heart failure dataset to assess whether we feel it adequately captures the information items and themes identified.

Symptoms	Heart Failure Dataset
Fatigue	Placeholder included
Generally feeling unwell	Not included
Poor concentration	Not included
Decreased exercise tolerance	Recommended use of NYHA assessment
Dizziness	Placeholder included
Breathlessness	Placeholder included with guidance on quantification
Oedema	Placeholder for ankle swelling included
Sleep disturbance	Not included
Social and physical function	Heart Failure Dataset
Exercise ability	Lifestyle section includes placeholders for Exercise and Quality of life score. Social circumstances includes information on social network
Ability to work	
Functional ability to:	
Do housework	
Gardening	
Shopping	
Engage in social activity	
Travel/holidays	
Requirements for help from others	

Mood	Heart Failure Dataset
Low mood	Mood assessment (HADS score or simple enquiry) is included as a placeholder
Depression	
Anxiety	
Anger	
Blame	
Fear	

Medication Issues	Heart Failure Dataset
Understanding of medication/rationale for taking	Not included
Side effects	Not included
Compliance issues	Medicine management by patient (rate as poor, moderate, good)
Shared decision making regarding treatment	Not included

Carer Issues	Heart Failure Dataset
Fears	Not included
Social support	Reference to social network under social circumstances section
Involvement in patient education	Not included

Future plans	Heart Failure Dataset
Shared decision making regarding treatment	The heart failure care plan (section 2.4) provides a place holder and describes a plan to address and control symptoms, apply treatments known to improve prognosis and docu-
Quality over quantity for many	

Tailored care plans	ment medication. Also reference to detailing an advance care directive where relevant.
Patient and carer involvement	
End of life care open discussions	This is in unstructured narrative section at present.

Information	Heart Failure Dataset
Importance of shared information	Not explicitly included however crossover with heart failure care plan exists.

Discussion

Our investigation and engagement has not been exhaustive however we do feel that it is sufficient to allow us to identify some potential gaps within the heart failure dataset as it currently exists. It is important to note that many of the issues we have identified are well known and have been published previously. It is therefore likely that current clinical practice takes account of many of these areas (although this is not universal judging by our patient engagement). It is however important that the heart failure dataset is sufficiently detailed to capture current practice as well as new areas that potentially capture best practice. In this way the development of interoperable electronic health records can facilitate improvements in health care delivery.

Symptoms are clearly a key way for clinicians to assess disease activity, are of paramount importance to patient experience and provide a target for delivery of therapy and measuring its effect. Our work has shown a mismatch between the symptoms prioritised medically and by patients as well as highlighting that patient response is markedly different when they are given a list to select from versus being asked an open question about symptoms. The NYHA scale is widely used and is referenced in the current dataset however it has previously been shown to be unresponsive to change, has significant interobserver variability and represents the perspective of the clinician rather than the patient⁽³⁾.

Within our patient focus group concerns regarding physical function were their top priority. Physical function is in many cases closely linked with symptoms and breathlessness, fatigue or depression may clearly be the cause of physical limitation however for patients we believe it is often more tangible for them to quantify and discuss what they can and can't do functionally rather than trying to quantify a symptom. Low mood and depression are long recognised features of heart failure and the recommended Hospital Anxiety and Depression score is used elsewhere in medical clinical practice.

With knowledge of patient concerns and priorities the challenge is to then how to incorporate this into clinical care and recording. Clinician and patient education, written information and providing patients with prompts or checklists before clinic visits are all potential ways of enhancing the patient experience. However it is not our intention or remit to comment on current or future clinical prac-

tice. Instead, we restrict our scope to look at ways that this information can be captured and recorded, assuming that clinical consensus exists.

Many previous attempts have been made to develop assessment tools or questionnaires that capture relevant patient information. We have reviewed three disease specific questionnaires used in heart failure: The Quality of Life in Severe Heart Failure Questionnaire (QLQ-SHF), the Chronic Heart Failure Questionnaire (CHQ) and the Minnesota Living with Heart Failure Questionnaire (MLHFQ). Use of these is currently variable and uptake has often been in the research domain of clinical trials rather than everyday practice.

A common criticism of the instruments has been that they do not measure components of quality of life that are important to patients, with many derived from an expert medical viewpoint⁽³⁾. A review by Leidy et al found 41 instruments used in the assessment of heart failure quality of life⁽¹⁰⁾. They concluded that no single tool dominated the field, many were focused on a specific domain and three quarters were used in conjunction with clinical trials to test the effectiveness of new treatments. Quality of life is a personal perception and a gap exists for the formulation of a quality of life tool based on patient values and perceptions.

Steps have been taken to develop patient centred tools to measure quality of life in heart failure patients. Dunderdale et al conducted a series of patient interviews, with results very similar to our own, finding that the topic of changes in physical ability was the most described.⁽¹¹⁾ Their work has continued with attempts to develop the Chronic Heart Failure Assessment Tool (CHAT)⁽¹²⁾. This, however, has not been widely validated or applied in broader clinical practice.

The InterRAI Assessment System is a well developed international based method for the measurement and assessment of patients' physical, cognitive and social functional capacity and needs⁽¹³⁾. There has been a long history of using individual assessment scales to measure single domains and examples include the Mini Mental State Examination (MMSE) and the Geriatric Depression Scale (GDS). However, the strength of the InterRAI system is that it incorporates an integrated suite of instruments that address multiple clinical domains that are applicable over multiple care settings. Where individual assessment scales will often have duplicated data items this is not the case where a suite of assessments can be derived from a central, single data collection. When assessments are completed over time a person-focused longitudinal record can be established. In addition to the assessment of individual patients the InterRAI system has been extensively used to aggregate data and make comparisons between health providers, between countries as well as informing healthcare planning.

Professor Iain Carpenter has a long history of involvement in the development of the InterRAI assessment system and so we reviewed the individual components to assess their potential suitability for use in a heart failure population. We identified multiple elements of the assessment that would have direct applicability, including:

- Mood
 - Self reported mood questions
- Psychosocial wellbeing
 - Loneliness
 - Change in social activities in the last 90 days
 - Major life stressors in the last 90 days
- Functional status
 - Activity level
 - Distance walked self
 - Distance wheeled self
 - Physical function improvement potential
 - Change in ADL status as compared to 90 days ago
- Social supports
 - Informal helpers
 - Hours of informal care and active monitoring in the last 3 days

The origins of InterRAI, and its primary area of use, are in the assessment and planning of care for elderly populations in various home and residential care settings. As previously discussed heart failure patients are heterogeneous and whilst some will be in formalised care environments many will be living independently with a wide spectrum of functional ability. The InterRAI assessment tool in its full form is therefore not suitable for use with this patient group. We conclude that the elements extracted above provide inspiration and guidance for a future suitable assessment tool but independently they cannot function as a sufficiently broad tool.

With regards to medication issues we do not believe that the current dataset element of 'Medicine Management by Patient' is sufficient to capture the breadth and detail of patients' issues with medications. We propose this be enhanced to cover patient understanding, a record of side effects experienced and issues with compliance.

The themes of carer issues, future plans and information shared conceptually fit within the 'Heart Failure care plan' element of the dataset. At present the structure and recommended content for this element is unspecified. We propose that formalising a structure here has benefits in guiding clinical care and correctly capturing information for use in chronic care management.

Recommendations/Further work:

A successful chronic disease summary must capture and facilitate the use of a wide range of clinical, patient and social information in order to permit high quality, evidence based, patient centred care. In its current form we believe there are potential gaps in the heart failure dataset particularly related to capturing a patients experience of living with heart failure.

We recommend engagement with patients and patient groups to further explore patient priorities and concerns associated with living with heart failure. Given that this is a European wide project it is important that this engagement process be carried out in multiple member countries. Work then needs to be done to ensure that information related to symptoms, quality of life measures as well as other markers of cognitive, physical and emotional capacity can be adequately captured and recorded in the heart failure summary. It is hoped that this is one way that development of the heart failure dataset may be a driver for enhanced clinical care.

There are several areas of the dataset where we foresee the need for improvement. The current 'Medicine Management by Patient' field should be expanded and enriched. Guiding clinicians to capture more medication related information such as compliance issues, side effects and patient concerns could be achieved by enhancing the descriptor, however we believe that the issues are sufficiently important to warrant specific data fields. During the process of development of the Clinical Documentation and Generic Record Standards (CDGRS) at the RCP we have incorporated headings that record 'Information given', 'Patient and carer concerns' as well as specific headings related to medications and we believe they may be suitable for incorporation into the current dataset.

The Heart Failure Care Plan (section 2.4) is at present an unstructured element of the dataset where information relating to medication issues, patient and carer concerns, future plans and details of plans for information sharing would naturally sit. We propose that providing a formal structure to record information here could benefit clinical care, facilitate greater information sharing with patients as well as enabling data sharing and interoperability between healthcare record systems via a common structure. The Clinical Record Standards developed by the Royal College of Physicians provide a high level structure for the capture of patient focussed data and we propose that a formal exercise to map the current heart failure dataset to the published RCP standards with subsequent recommendations for where additions can be made would be beneficial.

In addition to involvement in the creation of a chronic disease summary it is important that patients are widely involved in the testing and piloting of the clinical use of the dataset with facilities to gain and learn from their feedback.

Many of the priorities and concerns expressed by patients in our consultation are not specific to heart failure and in many cases would be applicable in other chronic diseases. We believe there is a need to formally develop consensus based standards for the recording of patient perspectives on their illness and health.

Our work with the InterRAI assessment tools has demonstrated the power of an integrated tool to assess, monitor and plan patient care. Whilst we have found that the tools in their current form are not directly applicable to heart failure care we propose that there would be a benefit to developing a tool to accurately assess patient markers of quality of life, social, physical and emotional health over time and in response to management or treatment decisions.

We propose a more detailed review of existing assessment tools both disease specific for heart failure and more generally. We specifically advocate in depth patient engagement in this process. Given the longstanding experience of InterRAI in this area we propose that this work is presented to the InterRAI group (via Professor Iain Carpenter) for consideration as a potential future work stream or future collaboration.

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