This is the peer reviewed version of the following article: [Moreno-Conde A, Jódar-Sánchez F, Kalra D. Requirements for clinical information modelling tools. Int J Med Inform. 2015 Jul;84(7):524-36], which has been published in final form at [doi: 10.1016/j.ijmedinf.2015.03.005].

Requirements for clinical information modelling tools

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Keywords:
Electronic Health Record
Semantic interoperability
Clinical information modelling tools
Archetypes
Detailed Clinical Models
Qualitative research
Delphi study

A B S T R A C T

Objective: This study proposes consensus requirements for clinical information modelling tools that can support modelling tasks in medium/large scale institutions. Rather than iden- tify which functionalities are currently available in existing tools, the study has focused on functionalities that should be covered in order to provide guidance about how to evolve the existing tools.

Methodology: After identifying a set of 56 requirements for clinical information modelling tools based on a literature review and interviews with experts, a classical Delphi study methodology was applied to conduct a two round survey in order to classify them as essen- tial or recommended. Essential requirements are those that must be met by any tool that claims to be suitable for clinical information modelling, and if we one day have a certified tools list, any tool that does not meet essential criteria would be excluded. Recommended requirements are those more advanced requirements that may be met by tools offering a superior product or only needed in certain modelling situations.

Results: According to the answers provided by 57 experts from 14 different countries, we found a high level of agreement to enable the study to identify 20 essential and 21 recom- mended requirements for these tools.

Conclusions: It is expected that this list of identified requirements will guide developers on the inclusion of new basic and advanced functionalities that have strong support by end users. This list could also guide regulators in order to identify requirements that could be demanded of tools adopted within their institutions.

Abbreviations: CIM, clinical information model; CIMP, clinical information modelling processes; CIMT, clinical information modelling tools; CDA, clinical document architecture; DCM, Detailed Clinical Models; EHR, Electronic Health Record; HL7 RIM, HL7 Reference Information Model standard; SDO, Standards Development Organisation.

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1. Introduction

In parallel with the increased acceptance of Electronic Health Record (EHR) systems, there is a recognised need for sharing clinical information to support continuity of care. Limited communication and interoperability capabilities between EHR systems impact negatively on patient safety and healthcare effectiveness, since missing information could affect treatment decisions or require the repeated ordering of tests. In order to move from a silo paradigm to infrastructures where multiple EHR systems are able to transfer patient information, different Standards Development Organisations have defined specifications to determine how EHR information should be structured and communicated. In addition to base standards such as the EN ISO 13606 Reference Model and HL7 Clinical Document Architecture, complementary standards and specifications formalise how clinical information may be structured. The most relevant specifications defined for representing clinical information within EHRs include: ISO EN 13606 archetypes [1], openEHR archetypes [2], HL7 Clinical Document Architecture [3], HL7 Templates, and Detailed Clinical Models (DCM) [4]. In addition, most of the key stakeholders in the EHR interoperability field are working within the Clinical Information Modelling Initiative (CIMI) on the definition of an additional specification for CIMs [5]. Although the specifications identified above are mostly focused on EHR communication, there are experiences of applying some of these specifications for querying [6–8] and clinical decision support [9].

This study applies the concept *clinical information model* (CIM) as a generic term that includes all the above specifications when applied to the structure of EHR related clinical information. CIMs can be used to organise (define) the structure of clinical information for multiple tasks such as exchanging clinical content, querying and analytics over clinical content, decision support over clinical content, entering clinical content, storing clinical content in EHR systems and displaying clinical content [10]. Based on this concept, this study aims to identify the most important requirements that should be met through the tools that are used to define them.

1.1. Clinical information modelling processes

Independently of which standard or specification has been used to represent a CIM, *clinical information modelling processes* (CIMP) normally require the collaboration of a modelling team, clinical domain experts and a technological team. Clinical domain experts will define the set of clinical information that needs to be supported by the EHR system they are focusing on. Experts in information modelling will make sure that the set of clinical concepts identified by the first group are structured to meet the technical needs of the EHR systems. The technological team will be able to develop, test and validate the software components that will manage and record the clinical information according to the defined CIMs. Two studies of the best practices internationally in the human and organisational processes for defining CIMs were previously performed by the authors based either on a systematic review of published experiences [11] and a qualitative analysis of the experiences from a set of 20 international experts [12]. These results are complementary to previous experiences detailing requirements for CIMP [4] and those studies focused on the definition of metrics for CIMs [13].

1.2. Clinical information modelling tools

Clinical information modelling tools (CIMT) are software platforms and applications designed to support the processes associated with the definition of CIMs, the implementation of EHR communications and systems based on CIMs, as well as establishing governance for the multiple CIMs applicable within an infrastructure or domain. As has been explained, different users such as modellers, clinicians and technologists participate in CIMP and therefore multiple tools may be applied for the management of CIM. Our previous research about CIMP highlighted the importance of model authoring tools to promote the adoption of good practices and to facilitate the implementation of EHR interoperable infrastructures [11]. Existing tools applied as part of the CIMP can be classified under five main headings. Fig. 1 depicts the main areas of functional support that CIM tools may provide, and maps the most commonly used tools to those areas that they primarily support. However, it should be noted that the tools may provide some of the other functional areas to a lesser extent.

1.2.1. CIM editors

The definition of CIMs according to a formal specification or standard is not always an easy task since it will require a minimum level of proficiency in the chosen specification. To support the definition of CIMs there are multiple tools that provide the means of representing the clinical information according to a particular specification. Some tools, mostly UML based [14], can define CIMs such as DCM without being restricted to a specific implementation specification. A second group includes tools such as archetype editors [15–17] that enable the definition of CIM according to a single formal specification.

Other tools are more focused on the implementation of CIMs, such as CDA editors [18] that are able to define structures for how clinical documents are modelled for communication between EHR systems according to the HL7 CDA standard. CDA editors are based on the semantics defined within the HL7 Reference Information Model standard [19], which expresses the data content needed in the administrative or clinical domain in a comprehensive and generic way. HL7 RIM defines around 70 different generic classes to represent the explicit representation of the semantic for expressing clinical and administrative content (e.g. Act, Procedure, Observation).

1.2.2. Screen definition tools

Although CIM are defined mainly as an agreed definition for communication purposes, they will be aligned with clinical information collected by clinicians as part of the care process. As a result, there are tools that are able to define the screen layout based on the CIMs. The openEHR template designer is able to define how multiple archetypes will be displayed as final form customised for a clinical scenario [20]. The adoption of tools that link screen definition to CIM allows a team to

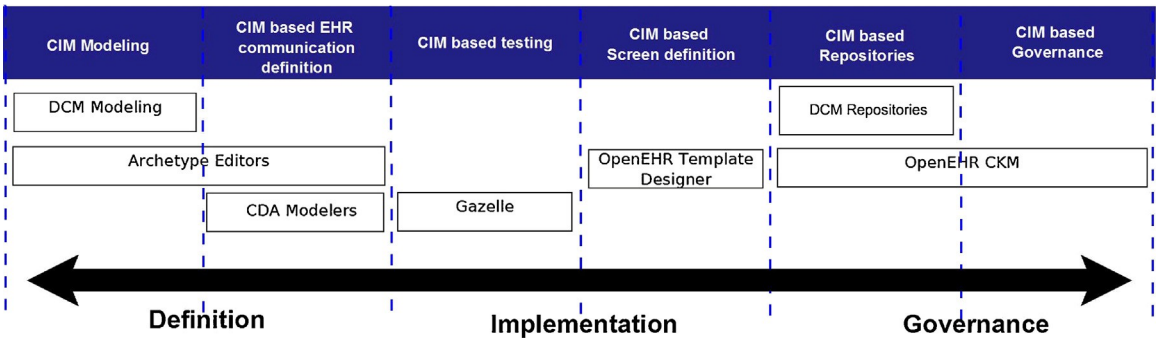

Fig. 1 – Classification of CIM tools.

easily coordinate version management between the information layer and the presentation layer.

1.2.3. *Technological validation and testing tools*

According to the testing tool classification described by the ANTILOPE project [21], some of the tools that verify system or software performance such as test management tools, conformance testers, interoperability validators, simulators/stubs, and test data generators are directly dependent on defined CIMs when they are testing scenarios based on the above specifications. Although most of the available examples of testing tools [22,23] are not integrated with CIM definition tools or repositories, the coordination of the full CIMP from requirements definition to software development and testing will improve if tools improve their integration.

1.2.4. *Knowledge managers and repositories*

Additional tools are applied as repositories that will host a set of CIMs. Large healthcare providers and other health informatics organisations are recommended to use these as an agreed and trusted storage location for CIMs they have chosen to adopt locally [11]. These tools can be useful for people involved in CIMP and IT systems within a technological infrastructure [24]. Multiple national and regional projects such as in Spain [25], Australia [26], Sweden [27], the region of Minas Gerais (Brazil) [28] publish their defined CIMs within repositories, represented according to the modelling specification chosen for their region.

With increased capabilities to support community-based and community-reviewed definitions of CIMs, knowledge manager tools act as an online, collaborative, interactive repository to support editorial, coordination and validation tasks within the group of participants in CIMP. Knowledge manager tools may also support the implementation of a modelling governance process [29].

1.2.5. *Other tools related to clinical knowledge management*

There are additional tools that are involved in the definition and management of clinical knowledge that will be incorporated within health information systems that do not work with CIMs but are closely related to the CIMP. Although this study considers knowledge representation by ontology modelling and terminology building as separate steps to CIMP, multiple CIMTs can benefit from (and complement) ontology or terminology management tools. This may include functionalities that facilitate the integration of CIMP with terminology and ontology management or take advantage of this work to verify if a proposed CIM is semantically well defined.

As an example ontologies can be incorporated within CIM editors in order to guide CIM definition based on the semantics of the concepts that are embedded within each node of the structure or may be applied for validation purposes in order to verify the defined CIM is internally consistent.

Methodologies have also been described for how multi- ple domains and viewpoints interrelate with system design such as the Generic Component Model, to propose how terminology modelling, ontology modelling ought to be included as part of the software engineering process, and where clinical information modelling fits within a multimodel approach for EHR system definition [30]. Such an approach addresses the ontological representation using GCM for interdisciplinary systems [31]. However, it is beyond the scope of this research to examine the fit of CIM within that overall GCM architecture, except for identifying any expert-provided requirements for the inclusion of ontology features within CIMT.

The SemanticHealthNet project is defining an additional semantic layer between ontology and CIM that makes explicit the semantics of the information represented in CIMs, in a way that can be interpreted by computers independently of the degree of granularity in which it has been provided [32]. The formal and unambiguous representation of additional meaningful elements extends the Reference Model semantic capabilities with benefits for mapping across standards and extended query capabilities [33].

On the other hand, terminologies are able to define clinical concepts in an agreed form without specifying all of the semantic relationships between the concepts. In the case of terminology management systems, they can coordinate the management of multiple terms and codes. They are highly relevant in order to be able to bind international and local codes as well as translations to the nodes within CIMs.

1.3. *Objective of the study*

This study sought to identify consensus on the require- ments for clinical information modelling tools in order to be able to support modelling tasks in medium/large scale

institutions. Rather than identify which functionalities are currently available in existing tools the study aimed to identify functionalities that should be provided by good quality tools, in order to provide guidance about how to evolve existing tools.

2. Methodology

This research has been conducted according to the Delphi methodology: a technique designed to obtain the most reliable consensus amongst a group of experts [34]. This is a method for structuring a group communication process to deal with a complex problem. There are multiple variants of Delphi techniques, and this research has been conducted according to the classical Delphi paradigm [35]. This is characterised as an anonymous process that can be achieved by sending the questionnaire either in paper form or online to the identified experts. They can provide their answers without being influenced by the social pressure of a group or differences in status within a group.

Through an iterative process experts are able to revise their opinion based on the controlled feedback provided in the second or successive questionnaire.

2.1. Sample of experts

Starting from the set of experts participating in the SemanticHealthNet project [36] a snowballing methodology was applied to obtain a representative sample of experts with international coverage of tools developers and advanced users in the clinical information modelling field. Each person contacted was requested to suggest additional experts. In addition the survey was distributed through the mailing lists of relevant organisations such as openEHR and HL7 as well as other more generic health informatics forums like the Linkedin groups of the Journal of American Medical Informatics Association and the European Federation of Medical Informatics.

2.2. First round

The first round of the study was conducted between 10th November 2013 and 5th of December 2013. A total of 81 experts were invited by an e-mail detailing the aims of the study and its methodology. The questionnaire was developed based on the published information available in the literature about the above tools, and using results obtained in previous interviews conducted as part of a survey of 20 international recognised experts about how they implemented CIMPs, the current limitations and needs [12].

The first round of this study was focused on classifying and prioritising requirements according to the experts answers. The questionnaire included a request for some personal information to determine if the answers were influenced depending on respondent background. A total of 53 requirements for CIM tools (CIMT) were organised under the following sections:

- Tool objectives.
- Reference Model, formal syntax and technical implementations.
- Semantic requirements.
- Terminology binding.
- Repository capabilities.
- Clinical information modelling process.
- Guiding clinicians in the development process.
- Governance and quality criteria.

Fig. 2 – Example of first round question.

In order to be able to rate responses, all requirements were measured using a 5 point Likert Scale except for two open questions that had the possibility for multiple responses.

The Likert scale allows one to determine if respondents either: 1 – strongly disagree; 2 – disagree; 3 – neither agree nor disagree; 4 – agree or 5 – strongly agree. Fig. 2 gives an example question. The survey was conducted through a Google questionnaire tool with a total of 59 questions that required around 30 min to be completed [37]. Before distributing the online questionnaire a group of five experts were consulted to review the questions and to test the tool (i.e. to pilot the instrument). Their opinions and recommendations were focused mostly in rephrasing some of the questions.

2.3. Classification of requirements

The methodology included thresholds for respondents to prioritise each proposed requirements as essential, recommended or optional. This made it possible to identify the subset of most relevant requirements. The collected answers were classified, after collecting first round results, according to the following rules:

- *Essential requirements:* requirements that must be met by any tool that claims to be for clinical information modelling, and if we one day have a certified tools list, any tool that does not meet the essential criteria will be excluded. Requirements were considered to be essential when they obtained more than 70% of global agreement (4 or 5 point answers) and also had more than 50% of respondents asserting strong agreement. These requirements are identified as the most basic capabilities that should be fulfilled by all future CIMTs.
- *Recommended requirements:* requirements that may be met by tool developers offering a superior product designed to make the work of the modeller easier and may lead to better/more robust models (e.g. a freeware version meeting only essential requirements, and a paid-for one also meeting recommended ones), or the recommended requirements may only be needed in certain modelling situations, by specialised tools. Requirements were considered to be recommended when they obtained more than 70% of global agreement (4 or 5 point answers). These requirements were

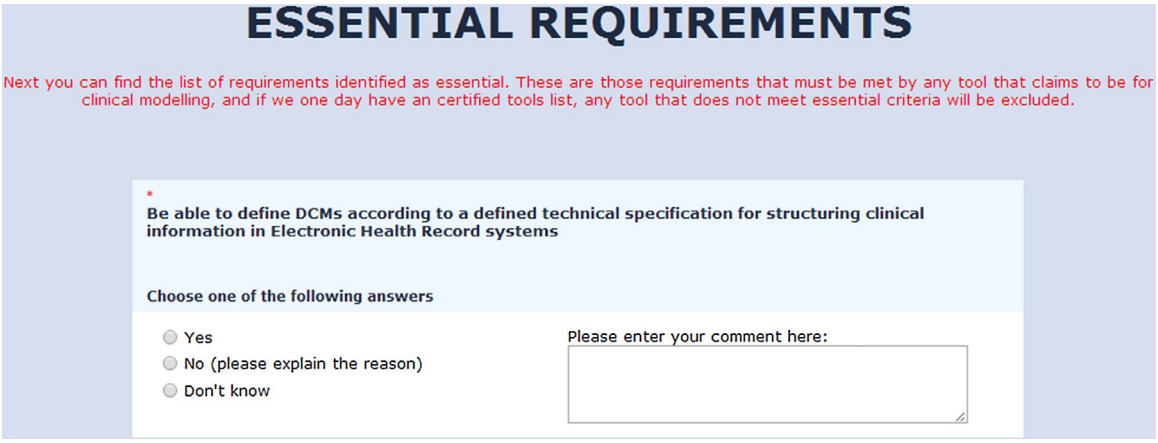

Fig. 3 – Example of essential requirement questions.

identified as recommended capabilities, based on the level of agreement, should be fulfilled by CIMTs but have a lower level of criticality.

- *Optional requirements:* Requirements with a level of global agreement between 50% and 70% (4 or 5 point answers). These requirements did not obtain the minimum level of consensus to be recommended and it will be the decision of tool developers to incorporate them in case that they are suitable for their specific usage scenario.
- *Not recommended requirements:* Requirements with less than 50% agreement (4 or 5 point answers) were considered as not recommended.

2.4. Final round

The final round of the study was conducted between 21th December 2013 and 5th of February 2014. This round aimed to validate the classification of requirements made. In this round a second online questionnaire was developed with the Limesurvey survey tool [38]. This questionnaire asked experts if they agree with the proposed classification of requirements defined according to the first round results. The questionnaire asked experts if they agreed with those requirements which were identified as essential (Fig. 3) and recommended (Fig. 4) in the first round. If experts disagreed with any requirement, they were encouraged to explain why the requirement should not be covered.

2.5. Checking for variability of results

In order to evaluate differences in responses to an item on the survey after two rounds, the *Wilcoxon* signed-rank test was applied [39]. This test is commonly used in this situation, and was applied here to check that there was no difference between the ranks of the responses of the experts from the two rounds [40]. The test provides the sum of each of the positive and negative ranks of the differences between any consecutive rounds of Delphi survey responses (e.g. ratings) with a Z statistic and its asymptotic p-value. This makes it possible to evaluate how each person is influenced in the final round based on the classification made from the whole set of experts consulted. A p-value threshold of 0.05 was used to determine the comparison between the two round answers.

Table 1 – Assignment of values to questionnaire answers for Wilcoxon test.

Round	Answer	Assigned value
First round	1	0
	2	0
	3	1
	4	2
	5	2
Final round: essential requirements	No	0
	Don't know	1
	Yes	2
Final round: recommended requirements	I don't agree	0
	I don't know	1
	I agree	2
	This requirement should be essential	2

Given that questions in the first round had five possible answers and in the final round there were three possible answers for essential requirements and four for recommended requirements, a variable was created in order to being able to map answers provided to each round in a harmonised framework that could be analysed. This variable had the following values to express: disagreement (0 point), don't know (1 point) and agreement (2 points). According to this assignation, positive variations will represent increasing the level of agreement (e.g. one expert changing from disagreement to don't know or agreement). The negative variations are the opposite variations. The analysis included all the questions that have closed answers, Table 1 details how value assignation was applied for each question from the possible answers contained in the first round or final questionnaire.

3. Results

3.1. First round results

Of the 81 experts directly invited to participate, 57 experts (63%) participated in the first round questionnaire. Only five

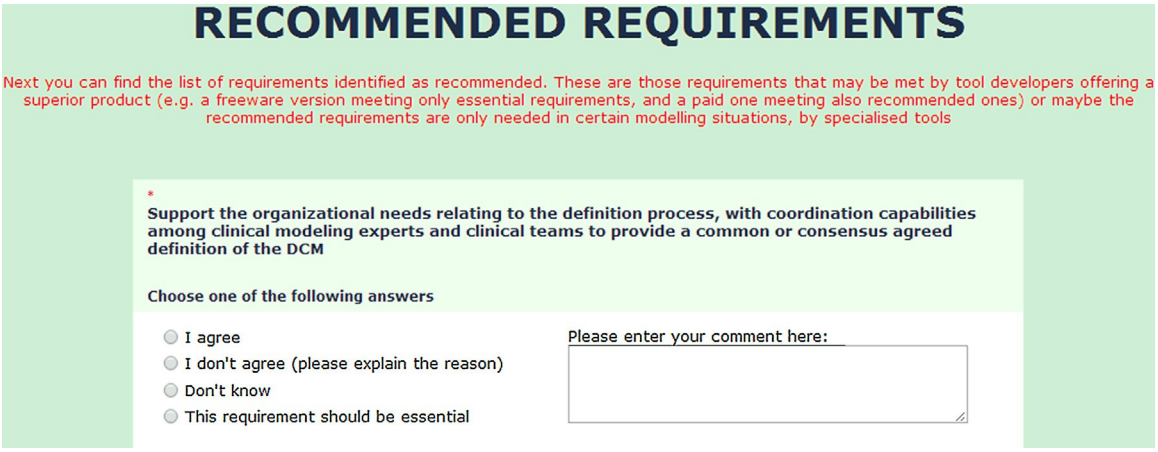

Fig. 4 – Example of recommended requirement questions.

people joined the study through the publicly available information in the specialised mailing lists and online groups.

This study only sought to include experts who had a minimum level of experience with CIMTs, either as end users or developers. Three respondents who declared not being familiar to CIMT were therefore excluded from the study. The question about expert background provided for multiple answers because participants could be identified with both developer and end-user roles. Nine participants identified as end-users with basic modelling skills were considered to have the minimum level of understanding of the field based on their declared familiarity with multiple CIMT, and their length of experience in health informatics. Next are detailed the participant skills (Fig. 5), how they are involved in multiple organisations (Fig. 6) and their experience with existing tools (Fig. 7).

Most of the experts included in the study are active in more than one organisation, with a high proportion of involvement of academia, industry and Standards Development Organisations (SDOs). This was helpful as it was intended to obtain international coverage aiming to collect answers from multiple backgrounds. Table 2 details the distribution of experts between countries.

Table 2 – Distribution of experts between countries.

Continent	Number of experts	Countries
Europe	41	Spain, Austria, Slovenia, France, Netherlands, UK, Norway, Denmark, Germany, Italy, Sweden and Ireland
America	7	US and Brazil
Oceania	3	Australia
Africa	1	Kenya

Table 3 – Classification of requirements from first round questionnaire results.

Requirements classification	
Essential	22
Recommended	21
Optional	13
Not recommended	0

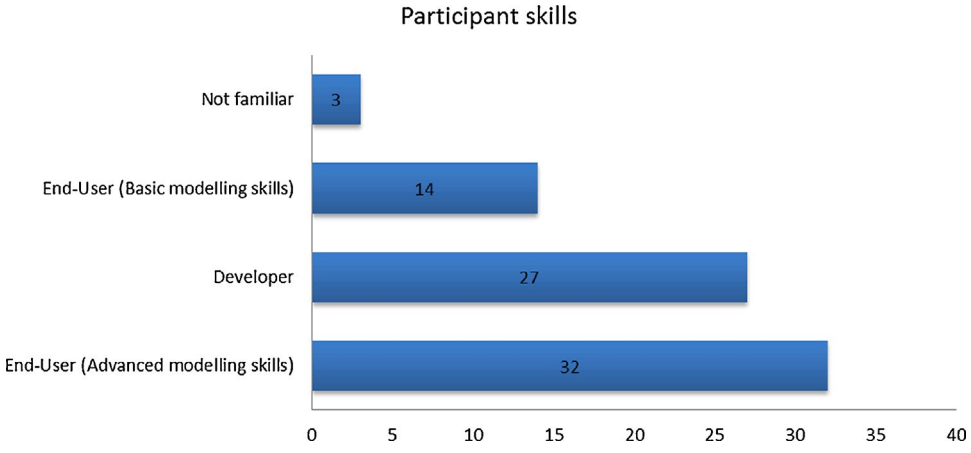

Fig. 5 – Participant skills.

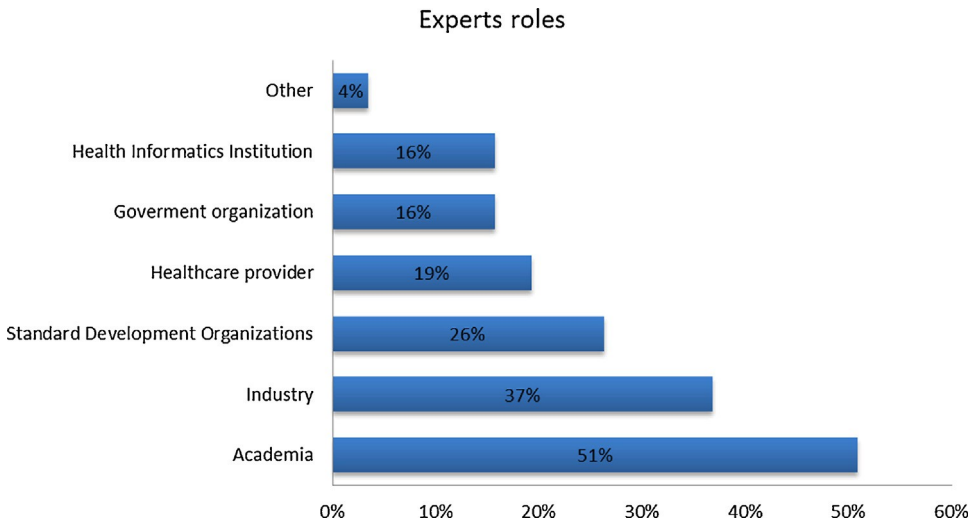

Fig. 6 – Experts involvement in organisations.

According to the previously defined classification of requirements, the first round results resulted in the distribution as detailed in Table 3.

3.2. Final round results

All the experts who answered the first questionnaire were invited to participate in the final round by email. A total of 38 experts (67%) participated in the final round to ver- ify that they agreed with the classification of requirements made in the first round. Table 4 details the results obtained in the final round for essential and recommended require- ments.

To be approved as essential or recommended each requirement had to obtain over 70% agreement in the final round. Although first round showed a balance between those who declared to be developers (51%) and those who declared being only end-users (49%), in the final round developers were by 13% more participative than end users. The distribution between agreements and disagreements was similar in both groups of experts in the first and final round surveys.

Table 4 – Classification of requirements from final round questionnaire results.

Type of requirements	Total	Approved	Rejected
Essential	22	20	2
Recommended	21	21	0

3.2.1. Essential requirements

In general the level of agreement was very high and only one essential requirement R21 did not obtain the minimum of 70% of agreement. It was also identified that R18 (about enabling the formal definition of clinical content by domain experts without the need for technical understanding) had a 21% disagreement. Given that 73% of respondents agreed to support this requirement the authors agreed to include this requirement as essential. The authors understand that in addressing the comments from those who disagreed with this requirement, this statement could be approved only after making clear that "no technical understanding" means having no previous knowledge about CIM specifications but still there could still be a need for support by a health informatician during the CIMP.

An open question determined the importance of the ability to import and export CIMs in multiple formats (R5). The results indicated that it is essential for CIMT to support XML and ADL representations. In contrast, an OWL representation (R22) obtained 63% of agreement. This was below the threshold but close enough to be considered an optional requirement,

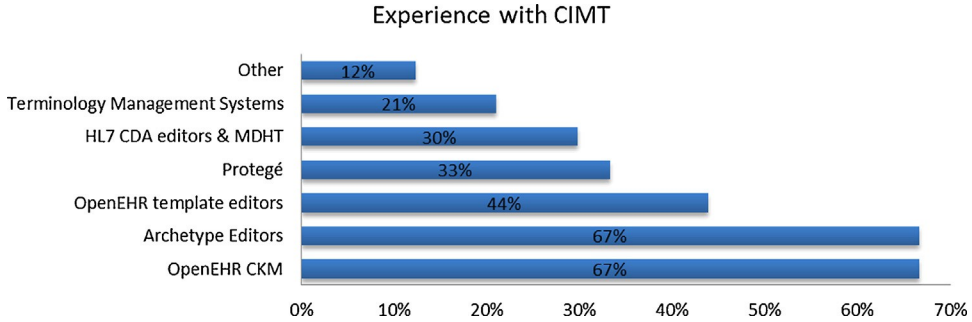

Fig. 7 – Experts experience with CIMT.

Table 5 – Classification of requirements for clinical information modelling tools. E, Essential; R, Recommended; O Optional.

Req. Number	Type	Description
R1	E	Be able to define clinical information models according to a defined technical specification for structuring clinical information in EHR systems
R2	E	Support the semantic interoperability of EHR systems
R3	E	Ensure consistency of information collected by enabling the definition of clinical information models generic enough to be compatible in multiple scenarios through specialisation mechanisms for the additional constraints of each local scenario
R4	E	Definition and validation of the clinical information models according to a formal syntax
R5	E	Import and export clinical information models according to the following formal syntaxes: XML and ADL
R6	E	Represent data types according an accepted data type standard (e.g. ISO 21090 standard or a subset of this)
R7	E	Support for version management, tracking changes and past history for each clinical information model
R8	E	Provide an automatic parser for the defined clinical information model
R9	E	Tools will verify that clinical information model and their instances are semantically and syntactically consistent
R10	E	The tool allows the author to create term bindings by connecting with Terminology Servers using (e.g. using CTS2) or another suitable terminology server communication specification
R11	E	Should include an intuitive graphical user interface for navigating large taxonomies
R12	E	Allows the user to assign one or multiple terminology/ontology concept to each node of the clinical information model structure
R13	E	Should include mechanisms that enable users and find a clinical information models in the repository by searching on any of its structured information properties
R14	E	Should export its clinical information model in at least one format that conforms to a published international standard or specification
R15	E	The repository and its services shall maintain a complete and audited version history for all of its clinical information models
R16	E	Should allow collaborative authoring of clinical information models according to the established roles. As well as recording experts and organisation participating in this process
R17	E	Should provide mechanisms to support multiple language translations of an clinical information model
R18	E	Should enable the formal definition of clinical content by domain experts without the need for technical understanding
R19	E	Should ensure the definition of purpose, appropriate description of usage, and precise mention of clinical information model domain
R20	E	Generate documentation for clinician review as MindMaps and Prototype Screens
R21	O	Facilitate the implementation of EHR systems that meet clinical requirements
R22	O	Import and export clinical information models according to Web Ontology Language (OWL)
R23	R	Support the organisational needs relating to the definition process, with coordination capabilities among clinical information modelling experts and clinical teams to provide a common or consensus agreed definition of the clinical information model
R24	R	Support the implementation of governance mechanisms to allow the establishment of an agreed editorial policy, process and quality criteria
R25	R	Promote the clinician adoption with a simplified and guided view well understood by them that guide their participation in the modelling process
R26	R	Define semantic and syntactic patterns in the form of constraints to on the selected Reference Model
R27	R	Provide an automatic testing environment for systems using the defined clinical information model
R28	R	Should allow the definition and import of Semantic patterns
R29	R	Should include visualisation components for viewing complex term relationships
R30	R	Should facilitate the use of the clinical information model to transform/map from existing data
R31	R	Should allow to define transformations of the clinical information models to/from other specifications
R32	R	A repository service should provide a notification service to experts and systems about clinical information model updates, additions and backwards compatibility
R33	R	Where more than one format is supported, requester user or system will be able to nominate the preferred retrieval format
R34	R	Requesters of obsolete versions of an clinical information model shall be provided with a notification that an update (or updates) exist and be able to nominate the version(s) to be returned
R35	R	Allows to subscribe to clinical information model and terminology repositories from national/international regulatory bodies to ensure that is contained version of the clinical knowledge is updated
R36	R	Provide mechanisms for backward compatibility
R37	R	Should provide mechanisms to assign the following roles to experts participating in the clinical information modelling process and document this information in the final clinical information model produced: editor, author and reviewer
R38	R	Should provide mechanisms for document sharing, discussion and wiki with 2.0 capabilities to support the collaborative development
R39	R	Should provide the means to define the clinical and usage scope of the clinical information model in a structured and coded format, in order to be able to check for possible scope overlap with other clinical information model
R40	R	Should implement clinician understandable mechanisms for a guided process for local specialisation and validation purposes

Table 5 – (*Continued*)

Req. Number	Type	Description
R41	R	Should be able to create prototype screens for domain expert validation of the defined clinical information model auto-generates example GUIs to test the creation of example instances
R42	R	User friendly interface for clinicians including drag and drop capabilities to be able to manage multiple clinical information models easily
R43	R	Editorial role can examine changes, and accept or reject changes
R44	O	Should be easily adapted to using alternative types of (or new versions of) a Reference Model
R45	O	Import/select the Reference Model that will lead underpin the definition
R46	O	Should be able to compare 2 clinical information models covering a similar clinical domain and highlight differences
R47	O	Should allow to rank similar clinical information models
R48	O	Tools should suggest clinical information modellers with candidate terminology/ontology terms based on their semantic underlying model.
R49	O	Should request the items to be included in the generic definition of clinical information models according to the maximal data set approach
R50	O	Should provide mechanisms for prioritising data items to be included in local implementations based on minimal data set approach and multiple user needs
R51	O	Should integrate or link to educational material to teach clinicians how to participate either in core and validation domain expert group
R52	O	Should allow to assign or edit the GUI presentation capabilities for local purposes, making possible that clinician/administrator edit the local presentation
R53	O	Tools for ongoing monitoring level of use and acceptance of clinical information models
R54	O	Provide mechanisms for generalisation capabilities
R55	O	Ensure conformance to any relevant licenses or restrictions for use of a clinical information model, and provide appropriate means for potential users of it to be informed of these
R56	O	Should include checkbox to verify that the resultant clinical information model quality has been developed according to the quality metrics defined by editorial role

and is a candidate to be included in the recommended group in future.

3.2.2. *Recommended requirements*

For some of those identified as recommended requirements, a few respondents claimed that they should be promoted to the essential level, but the number of respondents claiming this promotion was in each case less than those who agreed with the proposed classification. As a consequence, it was determined that none of those proposed as recommended requirements had obtained the minimum level of consensus to be promoted to essential.

The exhaustive list of requirements included in this study is presented in Table 5 indicating if they were classified after the final round either as Essential (E), Recommended (R) or Optional (O).

3.2.3. *Checking Variability of responses*

According to the Wilcoxon signed-rank test only two requirements had a result below the previously defined minimum threshold. This test was applied to check the variability of responses of those 37 experts who participated in both rounds of the study (one expert was excluded because he didn't provide enough information to perform this test). Firstly, it was confirmed that R21 should not be approved as essential since this requirement obtained a result ($p = 0.012$) below the threshold and was not appropriated to be approved as essential. As a result it was determined that it was not essential that CIMT should facilitate the implementation of EHR systems. Based on the high level of agreement (68.5%) in the second round, it was determined that it could be considered as an optional requirement which is a candidate to be included in the recommended group in the future. Secondly, R32 was the only requirement that obtained a result below the threshold ($p = 0.033$) within the Wilcoxon test due improved perception in the second round questionnaire. Although 24% of respondents had an improved perception (positive rank in second round), the number of people claiming the requirement as recommended was so much higher (78%) than those claiming to promote the requirement to essential (13%).

Table 6 displays the results from the analysis of variability of answers. Data is presented indicating the number of people and their percentage as *n* (%) that either reduced the level of agreement (negative), increased their level of agreement (positive) or kept the same answer (draw). The *p* value was calculated through the Wilcoxon signed-rank test and the threshold for this variable was ($p = 0.05$).

4. Discussion

This is the first study that has analysed requirements for CIMT based on the opinion of a representative sample of experts. The sample of participant experts in the study includes members from industry, academia, SDOs and the most relevant health informatics organisations with an international coverage. The study tried to be open to collect answers from any experts from the field and the snowballing invitation process resulted in a far more effective process than dissemination through specialised forums.

Experts were advised that agreed requirements should be fulfilled by tools in a reasonable time for adjustment (e.g. 2 years time). This was effectively addressed through their responses, obtaining consensus on more basic capabilities that are common in tools but at the same time promoting the adoption of functionalities that still need to increase adoption such as requesting that tools should connect with terminology servers according to formal specifications. The

Table 6 – Non-parametric analysis results.

Req. Number	Negative rank	Positive rank	Draw rank	*p*
R1	1 (2.7)	8 (21.6)	28 (75.7)	0.075
R2	4 (10.8)	3 (8.1)	30 (81.1)	0.792
R3	2 (5.4)	4 (10.8)	31 (83.8)	0.330
R4	1 (2.7)	3 (8.1)	33 (89.2)	0.317
R6	4 (10.8)	2 (5.4)	31 (83.8)	0.330
R7	3 (8.1)	2 (5.4)	32 (86.5)	0.655
R8	4 (10.8)	4 (10.8)	29 (78.4)	0.557
R9	5 (13.5)	2 (5.4)	30 (81.1)	0.340
R10	3 (8.1)	0 (0.0)	34 (91.9)	0.083
R11	8 (21.6)	6 (16.2)	23 (62.2)	0.628
R12	3 (8.1)	2 (5.4)	32 (86.5)	0.783
R13	5 (13.5)	1 (2.7)	31 (83.8)	0.084
R14	1 (2.7)	2 (5.4)	34 (91.9)	0.564
R15	1 (2.7)	3 (8.1)	33 (89.2)	0.317
R16	4 (10.8)	3 (8.1)	30 (81.1)	0.603
R17	2 (5.4)	4 (10.8)	31 (83.8)	0.915
R18	5 (13.5)	4 (10.8)	28 (75.7)	0.902
R19	2 (5.4)	6 (16.2)	29 (78.4)	0.473
R21	10 (27.0)	2 (5.4)	25 (67.6)	0.012
R23	9 (24.3)	5 (13.5)	23 (62.2)	0.175
R24	5 (13.5)	4 (10.8)	28 (75.7)	0.623
R25	8 (21.6)	2 (5.4)	27 (73.0)	0.103
R26	7 (18.9)	3 (8.1)	27 (73.0)	0.166
R27	11 (29.7)	5 (13.5)	21 (56.8)	0.236
R28	6 (16.2)	5 (13.5)	26 (70.3)	0.963
R29	4 (10.8)	6 (16.2)	27 (73.0)	0.222
R30	6 (16.2)	9 (24.3)	22 (59.5)	0.854
R31	4 (10.8)	7 (18.9)	26 (70.3)	0.285
R32	2 (5.4)	9 (24.3)	26 (70.3)	0.033
R33	3 (8.1)	8 (21.6)	26 (70.3)	0.088
R34	4 (10.8)	8 (21.6)	25 (67.6)	0.153
R35	2 (5.4)	8 (21.6)	27 (73.0)	0.124
R36	6 (16.2)	6 (16.2)	25 (67.6)	0.614
R37	3 (8.1)	3 (8.1)	31 (83.8)	0.999
R38	2 (5.4)	8 (21.6)	27 (73.0)	0.052
R39	6 (16.2)	6 (16.2)	25 (67.6)	0.796
R40	7 (18.9)	7 (18.9)	23 (62.2)	0.816
R41	3 (8.1)	3 (8.1)	31 (83.8)	0.739
R42	5 (13.5)	5 (13.5)	27 (73.0)	0.791
R43	2 (5.4)	4 (10.8)	31 (83.8)	0.414

authors designed the research method to ensure the confidentiality of respondents' identities and of their current involvement in the field, which should have minimised the "halo effect" commonly associated with Delphi studies [41], allowing respondents to be honest in supporting or disagreeing with the statements proposed in the questionnaire.

Given that both groups, developers and end-users, had similar distributions of agreement and disagreement, it could be inferred that technical limitations for satisfying the requirements are reasonable. Given that many of the existing tools will need to be modified to satisfy even the proposed essential requirements, this study appears to have overcome any potential difficulties associated with obtaining consensus amongst users that have existing products in the field.

4.1. Classification of requirements

According to the high level of acceptance provided in the first round of the study, the definition of a threshold to determine the classification of requirements and obtain agreement needed to be highly sensitive. Although the initial 70% threshold level requiring a strong level of agreement might appear restrictive, the results obtained in the final round confirmed that experts agreed with the final classification.

4.2. Essential requirements

These are the requirements that must be met by any tool that claims to be for clinical information modelling. They effectively cover the full spectrum of the CIMPs including definition, version management and, repository capabilities. These tools should be adapted for use by modelling experts and by clinicians with a simplified view, such as a mind map and prototype screens that allow clinician engagement without the need for technical (information modelling) understanding. On the technical capabilities, experts agreed on the need to include standard data types, connect with terminology servers, verify syntactic and semantics. The essential specifications for importing CIMs were XML and ADL.

Although this publication does not include a detailed evaluation about how existing tools satisfy the set of requirements agreed in this study, the authors would like to highlight

that some of the requirements identified as essential are not adopted by any existing tools or representative initiatives. An example requirement that is presently unsupported by most of the tools is the definition of CIMs in an XML format, since some of the CIM specifications with wide acceptance use other formats such as ADL(R5). This requirement reflects a desire among tool developers and experts for making it possible to define constrains over the RM in XML format, which is not currently supported by CIMI, openEHR or EN ISO13606.

It is important to note that although most of the effort in CIM tools development has traditionally been focused only on technical developers as users, our results suggest that tools should also take into account the participation of clinical experts, providing them with mind-maps and screen forms for validation, and enable their participation in the formal definition of clinical content without the need for technical understanding (R18, R20). Today most CIM Editors are designed and expected to be used by software developers. It is recommended that tools allow collaborative development of CIMs based on multiple (collaborating) user roles (R16).

4.3. Recommended requirements

These requirements involved included additional capabilities mostly linked with design governance, the modelling process (workflow) itself, model adoption and implementation. In addition, advanced functionalities were identified such as the definition and import of semantic patterns as guidance for clinical information modelling and the ability to map information models to multiple specifications.

4.4. Optional requirements

Those identified as optional requirements include more complex semantics such as being able to work with multiple reference models, suggest candidate terminology/ontology concepts, identify semantic overlaps and rank similarities between models as well as support generalisation capabilities rank. In addition to the increased difficulties associated with the development of tools with increased semantics, it was recognised that tools could satisfy user needs being compliant with just one specification.

Requirements based on CIMP such as specific steps for identifying items according to the maximal data set approach, prioritising them and including a checkbox to verify metrics did not obtain the minimum level of agreement to be considered recommended. The lack of available published material at the time of this survey about best practices in clinical information modelling could impact on obtaining consensus on these requirements.

The first round results showed that all the requirements included in each category had a high level of relevance, obtaining at least 60% of acceptance for all of them. Given that some requirements were derived from previously implemented systems and suggestion made by previously interviewed experts, it could be inferred that they were perceived as requirements that could be successfully implemented and were desirable to be included in any tool.

4.5. Limitations of the study

Although the sample of experts was representative by including highly active experts from leading health informatics communities, the selection of experts is one the most critical issues in Delphi studies [42]. We recognise there may be potential future users of CIMT who were not identified as they are not connected with the field at present. For example, patients are not presently engaged in the design of most EHR systems, but will increasingly access EHR data and contribute to their provider held EHR. Their views on the shape of clinical information structures and terminology will become increasingly important.

The tool functions that were reflected in the initial list of candidate requirements were drawn from the existing literature, which has largely been authored by those active in the field already and therefore has the risk of having reinforced at least some of the functions that are already largely perceived as relevant.

There are multiple (usually independent) tools that currently support different parts of the CIMP life cycle, and this research did not seek to distinguish which kinds of tool will be required to satisfy each requirement. In future, any organisation that intends to develop CIMP may be able to choose from a range of tools the one that will best satisfy their requirements. This may be a single tool (e.g. a CIM editor integrated with a repository in the cloud) or multiple tools that work together as an ecosystem for clinical information modelling.

For both kinds of limitation, the diversity of survey respondents from different backgrounds, countries and initiatives offers some mitigation. It is in practice very difficult to engage completely novice individuals in apprising the need for tools in such a niche area of health informatics as this. A more broad survey of potential future CIM developers would have needed an extensive educational process before their views could have been obtained. This might in the future be considered.

Although the authors tried to collect answers at an international level including dissemination of the questionnaire within organisations not based on Europe such as AMIA, HL7 and openEHR, most of respondents were based in Euro- pean countries. Dissemination within mailing lists from non-European organisations such as IMIA could have provided a wider representation from multiple continents.

5. Conclusion

This research helps to provide a better understanding about the basic and advanced functionalities that should be covered by CIMT, independently of the capabilities of existing tools. The results successfully identified a set of relevant and implementable requirements for CIMT. Based on a Delphi study methodology, requirements were classified and prioritised according to the opinion provided by a representative sample of experts in health informatics and clinical information modelling. It is expected that this list of requirements will guide developers on the implementation of new basic and advanced functionalities that have strong support from users. They could also guide regulators in order to identify

Summary points

What was already known on the topic:

- Clinical information modelling processes require the collaboration clinical and technical teams in order to define, implement, test and update clinical information models for EHR communication.
- As a consequence of the multiple standards applicable for EHR communication, existing tools for clinical information modelling processes have a large variety of functionalities that result from a lack of consensus about requirements that should be covered.

What this study added to our knowledge:

- This study successfully identified a set of relevant and implementable requirements for clinical information modelling tools that should be fulfilled by tools in a reasonable time for adjustment (e.g. 2 years time)
- This study classified and prioritised requirements in order to guide developers about basic and advanced functionalities according to the level of consensus from a representative sample of experts in the field.

requirements that could be demanded of tools adopted within their institution. The defined functionalities were proposed to overcome identified barriers of the CIMPs expecting to improve the quality of those processes.

Over the following months, this work will continue with the definition of a self-assessment evaluation questionnaire and a test plan for CIMT that will be used to measure the functionalities already covered in existing tools.

6. Funding

This research has been partly funded by the Platform for Innovation in Medical Technologies and Health (Plataforma ITEMAS in Spanish), code PT13/0006/0036 and by the European Union's Seventh Framework Programme (FP7) SemanticHealthNet Network of Excellence under grant agreement n° 288408.

7. Author contributions

A.M.-C. and D.K. determined the expert selection and designed the study and questionnaire. A.M.-C. set up online questionnaires, collected and evaluated results. F.J.-S. assessed about methodological process and questionnaire design, reviewed the statistical analysis and performed the statistical Wilcoxon test evaluation. A.M.-C. led the drafting of the manuscript with the revision and edition of D.K. F.J.-S. supported the definition of discussion and conclusion based on the obtained results. All authors approved the final manuscript.

8. Competing interests

None of the authors have any competing interests to declare.

Acknowledgments

Authors thank experts who participated in this research for participating in questionnaires based on their experience about CIMTs.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.ijmedinf.2015.03.005.

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