Harmonizing and extending standards from a domain-specific and bottom-up approach: an example from development through use in clinical applications

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ABSTRACT

Objective Currently, the processes for harmonizing and extending standards by leveraging the knowledge within local documentation artifacts are not well described. We describe a collaborative project to develop common information models, terminology bindings, and term definitions based on nursing documentation systems, and carry the findings through to the adoption in standards development organizations (SDOs) and technical implementations in clinical applications.

Materials and Methods Nursing flowsheet documents from six large organizations were analyzed to generate a common information model and terminologies that fully expressed documentation across all systems, and were sufficient for evidence-based decision support, reporting, and analysis.

Results Significant gaps in existing standards were identified. The models and terminologies were submitted to and incorporated by SDOs, are published, implemented, and now serving as a foundation for an eMeasure.

Discussion There are few examples in the literature of success working through the standards development process from a bottom-up perspective. Subsequently, standards do not yet fully address the need for detailed clinical data that enables, for example, decision support as well as a range of reporting and analytic requirements. Recommendations from this project include transparent processes within SDOs, registries that make models and associated terminologies freely available, and coordinated governance processes.

Conclusion We demonstrated the feasibility of using documentation artifacts in a bottom-up approach to develop common models and sets of terms that are complete from the perspective of clinical implementation. Importantly, we demonstrated a process by which a community of practice can contribute to closing gaps in existing standards using SDO processes.

Key words: standards, harmonization, LOINC, SNOMED CT, HL7

INTRODUCTION

The development and publication of standard logical information models bound to standard terminology systems is recognized as foundational for interoperable health records and the achievement of national goals of better care, improved population health, and cost reduction.1,2 Standards development organizations (SDOs) are actively working together to develop standards that achieve technical, structural, and semantic interoperability for the exchange of healthcare data. The Health Level 7 (HL7) (http://www.hl7.org) organization specifically focuses on the development of models that support cross-platform sharing of healthcare data without loss of meaning (semantic interoperability). Other organizations, including the Regenstrief Institute and the International Health Terminology Standard Development Organization (IHTSDO) (http://www.ihtsdo.org/snomed-ct/) are external to HL7, but work to maintain terminologies that encode content expressed within HL7 standard information models. The Regenstrief Institute maintains and distributes the Logical Observations Identifiers Names and Codes (LOINC®) terminology system used for requesting and reporting tests and observations. The IHTSDO maintains and distributes SNOMED CT®, a clinical terminology system that describes clinical findings, symptoms, body structures, diagnoses, and treatments used in patient care. Jointly, the use of HL7 information models, encoded with LOINC and SNOMED CT terminologies, provides a standardized approach to achieving semantic interoperability when communicating health information across disparate systems. However, gaps in
the current standards exist, some related to challenges engaging those who can bring detailed and specific domain knowledge forward.

**BACKGROUND AND SIGNIFICANCE**

Many of the technical challenges to interoperable communication across distributed systems have been solved, although the challenge of achieving semantic interoperability persists. One particularly useful operational definition of semantic interoperability is “the ability to import utterances from another computer without prior negotiation, and have your decision support, data queries and business rules continue to work reliably against these utterances.”3 Abstract models that describe the information content required to support a particular domain are cornerstones of contemporary efforts to achieve semantic interoperability. Such unambiguous models can inform a wide variety of technical implementations, including electronic health records (EHRs), electronic messages, and data repositories.1,3

While the SDOs have been diligently working on developing and publishing standard information models and coded content, developers of commercial clinical information systems have proceeded with product developments that meet rapidly expanding market demands. The current reality is the majority of clinical information systems are not based on standards enabling semantic interoperability; rather, they are based on highly variable user preferences for content and both explicit and implicit models of clinical domains. Importantly though, clinical information systems such as EHRs do often reflect requirements for content that is standardized at the local level, and end users are commonly involved in local implementations of EHRs. Although vendors may not enforce common models within and across products, end users are often keenly aware of and typically driven by common goals such as decision support, quality measure analysis and improvement, reporting, and research. Thus, local implementations have rich potential to provide a bottom-up approach to extending and/or expanding interoperability standards.

The structured data in nursing flowsheets are a particularly rich source of information for discovering common domain-specific models and content crossing organizations and EHR vendors. In this project, we examined nursing documentation of skin and wound assessments, with a primary emphasis on pressure ulcer documentation. This is a clinical domain of high interest because iatrogenic skin and tissue breakdowns (e.g., pressure ulcers) and the mitigation of risk for skin breakdown are recognized as indicators of quality. The National Quality Forum6 endorsed pressure ulcers as a nursing sensitive outcome measure, and the Centers for Medicare and Medicaid Services view hospital-acquired pressure ulcers as a preventable hospital-acquired condition for which hospitals no longer receive added reimbursement.7 A strong evidence base exists to support the observations, assessments, and interventions recommended for practice to reduce or even eliminate incidences of skin and tissue breakdowns.8–10 Consequently, the authors of this paper speculated that it would be possible to leverage the clinical knowledge embedded in EHRs across local implementations and apply a data-driven approach to the development of standardized models and content.

For over a decade, pressure ulcers have been a clinical model used by nurse informaticists focused on interoperability standards. For example, several participants in the Nursing Terminology Summits held at Vanderbilt University from 1999 to 2008 used pressure ulcers as an exemplar clinical condition for examining and advancing terminology, model, and measurement standards.11–13 While each of these efforts informed standards development efforts, there was little coordination across the initiatives. In 2009, the authors of this paper joined efforts on model and content development relevant to this clinical domain.

In this paper, we report on the process of generating a standardized model and terminology for skin and wound assessment that accommodated variations in documentation across six organizations. The project had three specific aims: 1) to analyze content from six organizations to determine whether local structured documentation could be represented as a common information model; 2) to identify any gaps in LOINC and SNOMED CT terminologies related to the model; and 3) to bring gaps to specific SDOs for inclusion or modifications to their defined standards.

**METHODS**

**Project Management**

Participants in the project included clinical informaticists, a modeler, and a project manager. One participant (S.M.) was supported by her employer to participate in one or more SDOs, a critical factor in the eventual success of this project. Across the six organizations in which the clinical informaticists were employed, there were six different EHRs, including home-grown and commercial systems. The project manager maintained a password-protected wiki that provided access and sharing of stored files by project participants. In addition, toll-free phone calls and web meetings were regularly scheduled. Participants established a group expectation that the output of each meeting was reviewed prior to the next call and if revision of the output was needed based on reviews with others at their “home” organization, files were updated prior to the next call. In this way, a check on the clinical relevance and pragmatics was maintained throughout the project.

**Model Development**

Early on, participants agreed that the final products needed to be comprehensive, precise, and unambiguous for multiple uses of documentation across the six organizations. The modeler brought forward a “starter model,” published using Unified Modeling Language (UML) and based on prior independent work with two of the participating organizations. Because UML models display only attributes, not the enumerated values associated with specific attributes, the starter model was deconstructed from the UML format and divided into three components on three tabs of an Excel® spreadsheet: generalized skin assessment, pressure ulcer risk assessment, and skin alteration/wound assessment. Each participant then entered the terms used within their respective organizations into a single...
A consensus-based approach was used to determine essential content for the models, as well as concept equivalence, synonymy, and common display names recorded across rows in the spreadsheet. A key focus of consensus discussions was whether content was at the level of granularity needed to trigger evidence-based decision support actions and complete with respect to state and national quality and safety reporting requirements. Row-by-row, terms were reviewed by the group until consensus was achieved. When additional discussions were needed, the focus was typically on whether or not the term expressed a concept of assessment, or on the conceptual definitions of terms.

Analysis of Models
As consensus on content was achieved, new UML models were constructed and revised in an iterative manner. Because our goal was to develop models harmonized across healthcare organizations and within and across standards organizations, our models were constructed following recommendations for implementing LOINC and SNOMED CT together. That is, LOINC was considered the “question” and SNOMED CT the “answer,” thus allowing semantic comparisons. Using this approach for constructing the models, the content from the spreadsheets was divided into the notion of questions that became UML attributes and the notion of answers that became the allowable, enumerated values for each attribute. Because LOINC codes are harmonized with HL7 models, we gained an advantage for those bringing forward this domain-specific model to HL7 for balloting as a domain analysis model. However, our primary goal was to identify a common model, so a key focus of the UML model reviews was an analysis of whether the models were complete and accurate for expressing the content of the local nursing documentation systems.

Analysis of Gaps between Domain Models and Standards
To analyze gaps between our models and terminology standards, we first mapped concepts to LOINC (Version 2.41) panels and observations (i.e., “questions”), and then used SNOMED CT (Version 2011-01-31) concepts from the domain of Clinical Findings to provide a standard representation of the values (i.e., “answers”) within the context of the models. Experts from LOINC and SNOMED CT were then engaged to ensure the concepts in the model were accurately represented and in the correct structure or hierarchy of the reference terminology. When concepts could not be matched to either LOINC or SNOMED CT, requests were submitted to the terminology standards organizations for additions to the terminology systems using each organization’s standard request process; e.g., the US SNOMED CT® Content Request System (USCRS).

RESULTS
Models and Value Sets
Models
Following analysis, two new UML models were developed and the starter model was enhanced. The final set of three UML models describe the declarative semantics of skin inspection, wound assessment, and pressure ulcer assessment. Each model included the classes, attributes, and the associations between the classes. Figure 1 is an example from the domain model of skin inspection.

Content
Across the three models, 419 unique concepts were initially identified as essential, a two-fold increase over the number of concepts in the starter model (see Table 1). Of note, in addition to the term expansion arising from review of content in the documentation flowsheets, we also identified a need to include content for two specific measures: the Neonatal Skin Risk Assessment Scale and the Braden Q Scale, both used for predicting pediatric pressure ulcer risk. Similar to processes used to express the Braden Pressure Ulcer Risk Scale in LOINC, the developers of the scales were contacted, copyright permission obtained, and the concepts submitted to LOINC for inclusion in the LOINC database. The Neonatal Skin Risk Assessment Scale was released in LOINC version 2.44 and the Braden Q Scale will be included in a future release.

Figure 2 is an example of the domain model of pressure ulcers, and shows the structure of concepts used to fully describe a pressure ulcer. Typically, this structure was described in flowsheets using terms with “drop-down” boxes associating specific attributes with the term in the flowsheet row.

Gaps
Of the 419 concepts in the final models, 294 (70%) could be mapped to SNOMED CT findings, LOINC codes, or LOINC panels (Table 2). One hundred twenty-five new requests were submitted to the SDOs. Of the 320 concepts from the final model mapped to SNOMED CT, 261 (82%) could be mapped as SNOMED CT findings; thus 59 requests were made for an expansion of SNOMED CT. The content area with the most requests was “Skin of” sites, such as “Skin of Ankle.” Of the requests denied or withdrawn (six total), the most common reason was constraints inherent in the terminology.
For example, an assessment of pressure ulcer staging required by many reporting agencies is “suspected deep tissue injury.” SNOMED CT expresses actual observation findings, not suspected injury, or potential diagnoses, so the concept of “suspected deep tissue injury” could not be expressed in SNOMED CT as a finding. After further discussion with the USCRS administrator, the concept was created under the situation with explicit context hierarchy within the US SNOMED CT extension namespace (“Suspected deep tissue injury (situation),” ID 439831000124102). In addition, while modeling our request for concepts, the SNOMED CT content chair identified five additional concepts to complete the underlying semantic model. These were also submitted via the USCRS and approved for inclusion in the US SNOMED CT extension. The concepts in the United States extension will be submitted to the IHTSDO for inclusion in the international version of SNOMED CT.

Of the concepts from the models identified as classes and attributes (i.e., not findings) only 31 of 99 concepts from the model (31%) were mappable to existing LOINC panels and observations.

The coordination of semantics across LOINC and SNOMED CT is illustrated in the wound tunneling and undermining panel that resulted from this effort (Table 3). The panel, observations, and coding system were all new requests to LOINC and SNOMED CT, with the coordination between the two SDOs managed by a member of this team (S.M.). Details of the “Wound Tunnel and Undermining Panel” (LOINC ID 72299-1) can be viewed via the online LOINC browser at search.loinc.org.

Adoption and Use

Following completion of this work, colleagues from the Veterans Health Administration and Kaiser-Permanente led an effort to successfully shepherd the models through the HL7 Balloting process. The final models are published on the Federal Health Information Model (FHIMs) website http://www.fhims.org/press_ulcer.html.

ONC Challenge Grant

The Office of the National Coordinator (ONC) for Health Information Technology sponsored Challenge Grants to encourage the use of information exchange standards. The 2012–2013 ONC Challenge Grant was “Mobilizing Data for Pressure Ulcer Prevention Challenge” (http://www.health2con.com/devchallenge/mobilizing-data-for-pressure-ulcer-prevention-challenge/). The models described in this paper, as well as the SNOMED CT and LOINC terminologies, were required for all applications to that challenge. Three cash prizes totaling $80,000 were awarded to the developers who successfully implemented the models.
NQF eMeasure
Pressure ulcers are a condition targeted for meeting goals of Meaningful Use Stage 3, which requires exchanging clinical structured data in a manner both accurate and complete to improve patient care in a cost-efficient way. The HL7 balloted models we described provide the foundation for an NQF eMeasure, under development as a way to express NQF endorsed quality measures (personal communication, Warren).

Discussion
This project demonstrates the feasibility and indeed the value of developing and extending standards based on a
“bottom-up” or data driven approach to models and code sets. The project was informative to the SDOs and demonstrated the value of using existing documentation artifacts in standards development. We identified gaps in existing standards published by LOINC and SNOMED CT, and the gaps are being addressed through the established processes at each of these SDOs. The process we applied for addressing gaps in standards that require detailed and specific domain knowledge can be replicated by others to address gaps in standards.

There are a number of unresolved issues uncovered by this project. First, the success of this project was due to the active involvement of clinical informaticists with close ties to nursing documentation systems. SDOs are built upon largely volunteer efforts; however, few organizations support clinician involvement in such efforts. Our success in going the full circle from development to standards to implementation was enabled because one member of the team (S.M.) was supported by her employer for standards development work throughout the life-span of this project. In addition, a dedicated project manager and modeler, resources not typically available without support from a specific organization, were essential to the project. Second, there is a need for a common accessible repository for storing and maintaining the models and resulting data sets bound to terminology. While the models are currently posted on the FHIMs website, the terminology bindings to the models are not reported there. We expect others will want to add to the models and value sets, but we have not yet identified a good process for maintenance of the models or a way to publish updates. Third, coordination within and across the SDOs was challenging. There are no “roadmaps” for the bottom-up type effort we describe. It was not at all clear what to monitor and when to become actively engaged with each SDO process. Furthermore, at the time of this project, there was not a shared governance process across LOINC and SNOMED CT organizations, and recommendations were at times conflicting. Finally, one cannot assume that vendors or even developers of open source software will adopt standards, or that standards will be consistently implemented — even when those standards address domains under the umbrella of meaningful use criteria. Without adopting the use of open standards, and testing conformance with those standards, it will remain difficult to break down barriers to interoperability.

**Limitations**

Several limitations of the project are recognized. First, we focused on a well-defined area of nursing care with a strong evidence base for the practice. In addition, both quality reporting and financial incentives motivate the inclusion of relevant content in local EMR implementations. It may be more difficult to identify common data and derive a common model for a clinical domain with less of an evidence base — even when those standards address domains under the umbrella of meaningful use criteria. Without adopting the use of open standards, and testing conformance with those standards, it will remain difficult to break down barriers to interoperability.

### Table 3: Coordinating LOINC and SNOMED CT semantics for wound tunneling and undermining class

<table>
<thead>
<tr>
<th>Panel/observation/value</th>
<th>Long name</th>
<th>Fully specified name</th>
<th>Code</th>
<th>Coding system</th>
</tr>
</thead>
<tbody>
<tr>
<td>Panel</td>
<td>Wound tunneling and undermining panel</td>
<td>Wound tunneling &amp; undermining panel::Pt:Wound::</td>
<td>72299-1</td>
<td>LOINC</td>
</tr>
<tr>
<td>Observation</td>
<td>Tunneling of wound</td>
<td>Tunneling:Find:Pt:Wound:Ord::</td>
<td>72298-3</td>
<td>LOINC</td>
</tr>
<tr>
<td>Value</td>
<td>Present</td>
<td>Present (qualifier value)</td>
<td>52101004</td>
<td>SNOMED CT</td>
</tr>
<tr>
<td>Value</td>
<td>Absent</td>
<td>Absent (qualifier value)</td>
<td>2667000</td>
<td>SNOMED CT</td>
</tr>
<tr>
<td>Observation</td>
<td>Tunneling clock position of wound</td>
<td>Tunneling clock position:Find:Pt:Wound:Nom::</td>
<td>72296-7</td>
<td>LOINC</td>
</tr>
<tr>
<td>Value</td>
<td>Present</td>
<td>Present (qualifier value)</td>
<td>52101004</td>
<td>SNOMED CT</td>
</tr>
<tr>
<td>Value</td>
<td>Absent</td>
<td>Absent (qualifier value)</td>
<td>2667000</td>
<td>SNOMED CT</td>
</tr>
<tr>
<td>Observation</td>
<td>Undermining of wound</td>
<td>Undermining:Find:Pt:Wound:Ord::</td>
<td>72295-9</td>
<td>LOINC</td>
</tr>
<tr>
<td>Value</td>
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<td>Present (qualifier value)</td>
<td>52101004</td>
<td>SNOMED CT</td>
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<td>Value</td>
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<td>SNOMED CT</td>
</tr>
<tr>
<td>Observation</td>
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<td>Undermining clock position:Find:Pt:Wound:Nom::</td>
<td>72294-2</td>
<td>LOINC</td>
</tr>
</tbody>
</table>

RESEARCH AND APPLICATIONS
Recommendations
The experience and results of this project led to several recommendations. First, the processes for engaging clinical informaticists and domain experts needs to be streamlined within and across the SDOs in order to decrease the burden of participation for those who are motivated to collaborate with SDOS in extending existing standards. In addition, a process for addressing gaps and coordinating within and across SDOS needs to be defined. There is a current collaboration agreement between SNOMED CT and LOINC for lab observations, but this process should be extended to clinical observations to attain complete observation interoperability. There needs to be some sort of registry that facilitates consumption of the models and terminology bindings, not only by human reviewers but also at the application programming interface level. There are some registry efforts underway including the Value Set Authority Center provided by the National Library of Medicine in collaboration with ONC and Centers for Medicare and Medicaid Services and the FHIMs repository. However, the Value Set Authority Center currently only supports value sets aligned with meaningful use and does not encompass the broad array of value sets that are going to be needed within clinical models. The FHIMs website currently houses the federal information models (including the three models developed from this project) but is not recognized as a formal repository for standardized models and does provide services for consumption. Finally, there is a need for governance processes that are coordinated across SDOS and registries and is transparent to the multiple stakeholders for whom standard provide value.

CONCLUSION
Realizing the full potential of HIT to deliver improvements to healthcare requires interoperability across systems. Effective standards development requires collaboration, and interoperability requires standards that are adopted. We demonstrated the feasibility of using a collaborative and bottom-up approach to developing common models and sets of terms that are complete from the bottom-up perspective of clinical implementations and use. Importantly, we demonstrated a process by which a community of practice can contribute to SDOS.

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CONTRIBUTORS
M.R.H., L.H.L., H.M., M.H., P.C.D., and S.A.M. all contributed to the conception, design, and acquisition and contribution of data as well as drafting and revising the manuscript.

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COMPETING INTERESTS
The authors have no competing interests to declare. The contributions are solely the responsibility of the authors and do not necessarily represent the official views of the University of Michigan, Intermountain Healthcare, the US Department of Veteran’s Affairs, Harvard Medical School, or 3M Health Information Systems.

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