Functional requirements for a representation for sharable guidelines

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Recent trends in health care delivery have led to an increased emphasis on the development of guidelines for prevention, diagnostic work-up, treatment, and patient-management processes. Such guidelines are motivated by concerns about marked variations in clinical practice and are designed to help to provide a common standard of care both within a health care organization and among different organizations. For better integration of guidelines into the clinical workflow, they are increasingly being disseminated and implemented using computer-based systems. The range of possible applications for computer-based guidelines is very broad, including use for disease management, encounter workflow facilitation, reminders/alerts, design and conduct of clinical trials, care plan/critical path support, appropriateness determination, risk assessment, demand management, education and training, and reference.

Computer-based approaches to representation of guidelines are being developed by various groups [1-7]. Critical to sharing of the knowledge in these guidelines across institutional, national, and medical domain boundaries would be adoption of a common format for representing them. In order to be widely usable and acceptable, such a common representation for guidelines must provide several functional capabilities. The representation must account for requirements for (a) human communication, (b) validation of logical consistency and completeness (not correctness), and (c) incorporation into institutional information system environments. We hereby propose a set of functional requirements for a sharable guideline representation language and briefly provide their underlying rationale:

1. Support for different types of guidelines. Guidelines may be classified [8] along a variety of axes such as: (a) stage of the care process, e.g., screening, diagnostic workup, and treatment; (b) the medical domain; (c) the intended application, such as in disease management, critical paths/care plans, clinical trial conduct, and appropriateness determination. Different types of guidelines may entail representations of fundamentally different concepts. For example, an appropriateness criterion that evaluates relative suitability of two diagnostic tests would represent a decision making process. A clinical trial protocol, on the other hand, represents a prescriptive patient management plan that contains concepts such as treatment visit and adverse event. The guideline representation format must be flexible to accommodate these needs.
2. Different modes of use. Encoded guidelines can potentially be used in different modes. Users

may read or browse guidelines as educational and reference resources. Guidelines could be used interactively for patient-specific decision support and workflow support. Quality assurance applications would use guidelines as benchmarks of quality care, perhaps in a batch-processing mode. The knowledge in guidelines must be represented in a format that is independent of the expected mode of use. The representation must enable the variety of uses by structuring the knowledge in a way that will support its retrieval for all those likely uses.

3. Adaptation of guidelines for local use. Due to variations in health care settings, guidelines developed by national organizations, medical specialty organizations, or under other broad aegis often need to be modified before practitioners find them suitable for local use. Reasons for adaptation of guidelines include variations among settings due to the type of institution (e.g., hospital vs. office), location (e.g., urban vs. rural), differential availability of equipment and medications, dissimilarity of patient population (e.g., as reflected in prevalence of the disease), and local policies and workflow patterns. A common representation format must provide the ability to adapt knowledge contained in guidelines, and track and document modifications to the guideline.
4. Integration with institutional systems. For integrating guidelines into the clinical workflow, references to patient data and clinical actions in guidelines will need to be mapped to their instantiations or implementations in heterogeneous clinical information systems environments. This requirement implies the use of standard vocabularies and standard reference data models by the guideline representation format, which mapping tools can utilize to achieve the integration.
5. Revision tracking. Guidelines are often revised in response to changing medical knowledge. The representation format must keep track of and document revisions to the guideline. Among other reasons, revision tracking is important for incorporating new versions of externally developed guidelines into institutional use.
6. Managing complexity. Guidelines and their logic may get fairly complex. The representation format must deal with this complexity by abstracting details into high-level concepts. The management of complexity in representation is important during authoring and viewing of guideline.

The InterMed project, a collaboration among medical informatics groups at Stanford, Harvard, McGill, and Columbia universities, supported by the National Library of Medicine, developed a representation for sharable clinical guidelines. The initial version of the representation, known as the Guideline Interchange Format (GLIF), was published in 1998. A follow-on project, funded by both the NLM and the US Army, brings together investigators at Harvard, Stanford, Columbia, and McGill, with guideline developers from the American College of Physicians-American Society of Internal Medicine, to further define guideline representation requirements so as to facilitate authoring, sharing, and integration into applications. The requirements stated above are a result of our experience with the development and use of GLIF, and form the basis for refinements being made to the GLIF specification.

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