Functional Requirements For A Standard Representation Of Clinical Guidelines

Abstract

Clinical guidelines are potential tools for standardizing care in order to improve its quality and cost effectiveness. For guidelines to be delivered to the point of care through decision-support systems, they must be represented in a computer-interpretable format that enables machine inference. Because creating guidelines in this format is difficult, sharing the guideline specification across different institutions is vital. Many research groups have been working individually on developing modeling methods and computer-interpretable representations for clinical guidelines. Naturally, most of these efforts have been guided by local, application-specific considerations.

An invitational workshop addressing these issues was held in Boston on March 3-4, 2000. The workshop was hosted by InterMed, a collaboration of researchers at Stanford, Harvard, Columbia, and McGill, as well as by the American College of Physicians-American Society of Internal Medicine. The meeting was attended by stakeholders from academia in 8 different countries, government agencies, professional organizations, users, providers, and industry. All stakeholders recognized the need for a standard sharable computer-interpretable guideline representation. One focus of the workshop was to address and further define functional requirements for such a standard representation of clinical guidelines. A task force initiated at the workshop continued to address these requirements after the meeting. The proposed requirements encompass the entire life cycle of a computer-interpretable guideline: (1) authoring; (2) encoding; (3) reliability studies; (4) dissemination; (5) local adaptation and implementation; (6) testing; (7) use and maintenance; and (8) performance analysis.

- Functional requirements for a sharable computer-interpretable guideline representation
  - Expressiveness (authoring)
    - Ability to express different guidelines and clinical trial protocols
    - Ability to express different guideline knowledge components: recommendations, definitions, and algorithms
    - Ability to express different guideline tasks, including decision making, alert sending, goal setting, specifying work to be performed, and data interpretation
  - Human comprehension (authoring, use)
    - Support guideline visualization
    - Support readability
    - Manage complexity
    - Support different views of the guideline (different users such as patient or MD; different settings, such as in-patient or out-patient)
  - Accessing patient data
    - Representing patient data (authoring)
    - Mapping guideline variables into the local electronic patient record (localization)
    - Support for using vocabularies and reference information models (authoring, encoding)
    - Support for expressing data abstractions (*e.g.*, pharmacological agent) (authoring, encoding)
    - Handling semantic matches and range checks (encoding, use)
  - Structuring guideline output
    - Enabling multiple views of guideline output (localization, use)
    - Enabling better workflow integration (localization, use)
  - Handling negative recommendations and contraindications
    - Expressing negative recommendations (authoring, encoding)
    - Expressing course of action if negative recommendations are not followed (authoring, encoding)
    - Supporting an interactive mode that gives the negative recommendations only if it is necessary (the non-recommended option was considered by the user) (authoring, encoding)
  - Representing patient preferences (authoring, encoding)
  - Representing costs and qualities of services (authoring, encoding, localization)
  - Expressive decision model
    - Automatic and non-automatic decisions (authoring, encoding)

- Utility theory, patient preferences, cost-effectiveness, Bayesian model, sensitivity analysis (authoring, encoding, localization)

- Representing adverse conditions (authoring, encoding)
- Handling uncertainties in data (missing and incomplete data)
  - Three-valued criterion semantics (True, False, Unknown) (authoring, encoding)
  - Probabilistic criteria (authoring)
  - Uncertainties of temporal characteristics of patient data (*e.g.*, when a measurement was taken) (authoring, encoding, use)
  - Providing recommendations despite uncertainty in data (authoring, encoding, use)
- Linking the guideline to support material (authoring)
- Present clear statements of evidence and recommendations
  - Strength of evidence (authoring, use)
  - Strength of recommendations (authoring, use)
  - Magnitude of anticipated benefits to following a recommendation (authoring, use)
- Expressing what cannot be changed in the guideline representation during local adaptation (authoring, localization)
- Representing goals (authoring, use, analysis)
- Documenting use-cases of guidelines: who uses them and in what settings/situations (authoring, encoding, use, analysis)
- Ensuring reliability and safety
  - Ensuring reliability and safety within a guideline, among several guidelines that apply to a patient (simulation, testing)
  - Verification and/or validation capabilities (simulation, testing)
  - Documenting test cases that were run (authoring, simulation, testing)
- Ease of transporting representation format among collaborators (text format, preferably, XML) (dissemination)
- Possibility of sharing standard representations that are devoid of visualization and site-specific details (dissemination)
- Coupling guidelines to workflow: resource allocation (authoring, encoding, use, analysis)
- Ability to link to vendor applications: interface to information systems data and functions (localization and implementation)
- Support different usage modes
  - Interactive vs. batch (usage)
  - Enable different possible user-interfaces (usage)
- Maintenance
  - Version control: dates, names of updating person, guideline-author, encoder, version number, etc.
  - Change management: documentation changes in a structural way (authoring)
  - Methods for documenting changes only, without specifying the full new version (authoring)
  - Document problems in a structured way (use, analysis)
- Support analysis of user compliance with the guideline (available patient data, actions taken, decision options chosen, goals reached, adverse conditions and contraindications) (usage, analysis)
- Handle legal issues: disclaimers (authoring)