Introduction: Clinical Guidelines
Clinical guidelines (GLs) are a powerful method for standardization and uniform improvement of the quality of medical care, while reducing the escalating costs of that care.

Motivation
Most clinical guidelines are in free text and are inaccessible to the physicians who most need them. Even when guidelines exist in an accessible electronic format, physicians rarely have the time and means to decide which guideline best pertains to their patient, and how to apply that guideline to their particular patient. Thus, there is an urgent need to facilitate guideline dissemination and application using automated methods.

The problem
The core of the problem is that expert physicians cannot (and do not need to) program in guideline-specification languages, while programmers and knowledge engineers do not understand the clinical semantics of the guidelines. In addition, free-text representations are useful for search and retrieval of relevant guidelines, while formal representations are essential for creating a machine-comprehensible, executable code.

Our solution - DeGeL
To gradually convert a large mass of clinical guidelines to semantically meaningful representations, we have developed a hybrid, multifaceted representation, an accompanying distributed architecture, the Digital Electronic Guideline Library (DeGeL) and a set of web-based software tools, which gravitate a set of guidelines gracefully from text-based, through structured text (segmented and labeled by The semantic tags of the underlying formal guideline-representation language), to fully formal, machine-comprehensible, executable representations.

Method
Considering the differences between expert physicians and knowledge engineers, we defined different tasks for each one in DeGeL:
- Expert physicians use the web-based tools to index guideline externally (using a set of multimodional indices, such as disorders and therapy types) and to semantically markup the free-text source(s) of the guideline, or to create new guidelines. They markup the text by dragging portions of the text into the appropriate semantic labels of the formal representation language (e.g., entry conditions), possibly editing the text as well, resulting in an XML-based semi-structured text representation.
- Knowledge engineers focus on conversion of the semantically labeled XML elements into machine-comprehensible formal language.

The hybrid-representation model:
The hybrid-representation process in the DeGeL architecture takes input free-text (HTML) guidelines that are uploaded from (a) another Web Site or (b) a Local Source - e.g., a PDF file and indexed, then loaded into a markup editor, in which expert physicians structure the HTML guidelines into XML using semantic roles of the underlying formal language. They can also create a structed guideline de-novo.

Knowledge engineers add executable formal language expressions by filling additional levels in the XML representation.

Figure 1: The hybrid-representation process in the DeGeL architecture.

The Digital Electronic Guideline Library (DeGeL):
- Uses a hybrid (multiple-format) electronic representation of clinical guidelines to cater for different specification skills of the editors and different needs of each guideline-based-care task
- Allows distributed Web-based access for knowledge acquisition, maintenance, retrieval, and application
- Provides tools for distributed performance of:
  - Upload of free-text guidelines/de-novo specification/semantic markup/semantic indexing (Uruz)
  - Search, retrieval, & visualization (Vaydoria)
  - Eligibility & Applicability determination (Dipole)
  - Runtime application (Spock)
  - Quality assessment (QualGuide)
  - Data visualization and exploration (KNAVE)
- Linked to a moderator of time-oriented queries to patient data
- Supports a multiple-group permission model for knowledge access & modification
- Full support using online help-file and user manuals
The DeGel Overall Guideline-Server and Guideline-Services Architecture:

DeGel Procedural Phases:

In DeGel, we consider design time as well as application time scenarios.

- **Design Phase:**
  In this phase, the medical expert can load a free-text guideline into the library (using the Upload module) or create a new guideline by writing directly into the structured fields. The expert can index the guideline by multiple semantic axes, and create various links among guidelines. The medical expert performs semantic markup on the free text guidelines, using the URUZ module and the semantic labels of the guideline ontology. The knowledge engineer converts the semantically marked guideline to the full machine-executable formal language (using more advanced aspects of the URUZ module). In each stage, an expert can search for a guideline (free text, structured text or full formal language) using the hybrid guideline search and retrieval tool (the Vaidurya module).

- **Decision Phase:**
  In this phase, the care provider generates queries to the patient record to determine eligibility (Dipole module). Dipole uses the capability for retrieval of guidelines (Vaidurya module) and automated matching to electronic time-oriented patient records (through the temporal mediator) to determine which patients are eligible for a given guideline and which guidelines are applicable to a given patient.

- **Application Phase:**
  During the application of a guideline, a care provider applies the guideline to the patient medical record (the Spock module). The care provider can visualize and explore the patient data record (the KNAVE module).

- **Quality Assessment Phase:**
  Within this phase, a care provider compares various types of raw data and derived information available in electronic patient records, with prescribed and intended care-provider actions and intended patient outcomes in retrospective view (post application time). Guideline effectiveness can be assessed as well.

The DeGel framework supports those four phases using specific tools in each phase:

- **Design Time**
  - Design phase
    - Upload/upload guideline
    - URUZ markup guidelines
    - Classify/classify guidelines
  - Decision phase
    - Vaidurya (OL search & retrieval)
  - Application phase
    - Spock (Asbru runtime application)
    - KNAVE (patient data acquisition)
    - Vaidurya (OL search & retrieval)
  - Quality Assessment phase
    - QualiGuide

*General DeGel framework tools: Asbru, builder, Help manual, Permissions and Authentication*

Requirements for a Formal Guideline Representation Language:

Our research over the past decade has demonstrated that automating guideline-based care requires the use of an underlying expressive, machine-comprehensible formal language that enables specification of (1) multiple types of actions (e.g., sequential, parallel, periodic) and temporal constraints and (2) explicit clinical-process and patient-outcome goals—the process and outcome intentions of the guideline. Thus, care providers might modify the guideline during application time, while still preserving the spirit of the guideline with respect to the care provider's actions and the patient's state.

In the Asbru project, we had designed such an expressive, intention-oriented language, Asbru.

**WHY Asbru?**
- An expressive, time-oriented specification language for care provider actions
  - Sequential plans
  - Parallel plans
  - Periodic plans
  - Task-specific annotations:
    - Conditions (entry, completion, abort, etc.)
    - Intentions (process, outcome)
    - Preferences (Global & local utility considerations such as maximization of length of stay)
  - Effects (expected changes due to the application of the guideline)
- Supports quality assessment through explicit annotation by multiple types of time-oriented process and outcome intentions expressed as temporal patterns to be achieved or avoided
Uruz - Classifier and Axis builder tools:

Figure 4: The Uruz Web-based text-to-semi-structured (XML) guideline markup user interface. The expert physician highlights in one window a portion of the text (source text, in this case) and drops it into a window labeled by an ontology semantic role. Text can then be modified. Tables and figures can be dragged similarly.

Classifier

The current selected indexing axis type and its respective axis tree used to classify the guideline.

The particular indices under which the specific guideline is classified.

Guideline's Classification Page

Figure 5: With the Plan-Body Wizard, the user can decompose the current guideline into sub-sections or sections. Thus, a hierarchy of plans creates a representation of the control structure of the guideline and inter-relationships among guidelines.

Plan-Body Wizard

This wizard enables the user to define the type and relevant attributes of each plan.

Axis Builder

Selection of an axis to modify

The ontology tree of the selected axis

Available operations that can be performed on an axis ontology node

Figure 6: With the Classifier, the expert indexes the guideline along one or more paths in one or more external (indexing) semantic axes trees, which are mostly used for retrieval (see Figure 8). Currently the semantic-indexing axes include Anatomical sites, Diagnostic classes, Body systems and disorder types, Therapy types, Signs & symptoms, and Laboratory tests.

Figure 7: The Axis builder is a tool for building and modifying the multi-axis structure of the Clinical guidelines library classification indices. It was developed for constructing and maintaining single ontology hierarchies such as the semantic axes.
Vaidurya - The hybrid guideline search, retrieval, and guideline Browsing tool

Query interface

This tree represents the node that was chosen at the list box. Used for the external index-based search.

The external search query

The internal search query

The tree represents the internal ontology of a requested marked up guideline. Terms can be searched within specific nodes.

Results view

The user is offered different kinds of predefined views.

Flag to control the semantic labeling of the retrieved guidelines.

Each node represents a semantic index. The guidelines are the leaves and are clustered by the relevant semantic indices.

Query description

Print a pre-defined view of the guideline

The search results view shows the results of a guideline search. Selecting a node from the semantic index tree shows the retrieved guidelines that belong to the node or to its descendants. The columns are those which were chosen in the ontology tree.

DeGel Help Manual

Figure 11: The DeGel Help manual accompanies users during their work in DeGel, while using all of DeGel's different tools.

DeGel Permissions Model

Figure 12: The Permissions model controls which user-type (e.g. expert searcher) can access or modify which aspect of the guideline knowledge base. Expert groups are organized by medical specialty.

Future Work

1. Support Multi-ontology in U-LIR (e.g. GEM, GLIF).
2. Support of 1:Many relationship between the GL source and its semi-structured representation(s).
3. Develop the Semi-Structured to Formal language conversion tool for ASBRU.
4. Three level Query Interface:
   1. Basic: Free text search
   2. Semi: Using few ontology-encyclopedic and content elements and limited semantic indices
   3. Full: Advanced: all ontology elements and semantic indices.
5. Analysis of the results by clustering, shows the statistics of the results for each semantic index.
6. Show all the semantic indices under which each specific guideline was indexed.
7. Query expansion based on the UMLS.
8. Query interface using natural language analysis.
10. Completing and integrating the Spock - Asbru hybrid runtime application tool.
11. Integrating the DeGel eligibility determination tool.
12. Completing and integrating the quality-assessment tools.
13. Verification of a guideline's process specification (syntactic verification) and validation of the guideline's prescribed actions versus its goals (semantic validation).
14. Definitive evaluation of all tools.

Summary

We have demonstrated the feasibility of a distributed hybrid guideline digital library. The library supports upload specification storage, search, retrieval, and browsing of clinical GLs and their use by advanced decision-support tools. Preliminary results are encouraging. More definite evaluations are underway.

About The DeGel Research Group

The DeGel research group is part of the Medical Informatics Research Center, in the Department of Information Systems Engineering, at Ben-Gurion University of the Negev.

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