Sharable, Computer-Interpretable Clinical Guidelines

An Emerging Core Technology for Future Health Care Systems

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Quality challenges in health care

- reduce errors
- conduct “best practice” medicine

while

- devoting less time!
- spending less money!
How do we improve quality?

- Alerts & reminders
- Measurements & feedback
- Practice guidelines
  - beyond alerts to multi-step care processes
  - focus may be screening, diagnosis, workup, referral, or management
    - consensus-based vs. evidence-based
    - embody “best practices”
  - aim to reduce variation
  - basis for wide range of applications
Some applications of guidelines

- Education & reference
- Risk assessment
- Referral criteria
- Appropriateness determination
- Consultation

- Problem-based encounter forms & info assembly
- Workflow management
- Clinical trials
- Care plans/UR/UM
History of the field

- Long interest dating from early ‘70s
  - dissemination via print → CDROM → Web

- New surge of activity
  - professional societies
  - government agencies
  - managed-care organizations & health plans
  - individual institutions
A Common Feature in Clinical Journals and Textbooks
Guideline Dissemination

- Conventional publication in journals and textbooks
- Mailing of monographs or guideline summaries to clinicians
- Compilations of guidelines for reference
- Online resources
  - National and international
    - see www.guidelines.gov
  - Locally supported
About the National Guideline Clearinghouse™ (NGC)

The National Guideline Clearinghouse™ (NGC) is a comprehensive database of evidence-based clinical practice guidelines and related documents produced by the Agency for Health Care Policy and Research (AHCPR), in partnership with the American Medical Association (AMA) and the American Association of Health Plans (AAHP).

The NGC mission is to provide physicians, nurses, and other health professionals, health care providers, health plans, integrated delivery systems, purchasers and others an accessible mechanism for obtaining objective, detailed information on clinical practice guidelines and to further their dissemination, implementation and use.

Key components of NGC include:

- Structured abstracts (summaries) about the guideline and its development;
- A utility for comparing attributes of two or more guidelines in a side-by-side comparison;
- Syntheses of guidelines covering similar topics, highlighting areas of similarity and difference;
- Links to full-text guidelines, where available, and/or ordering information for print copies;
- An electronic forum for exchanging information on clinical practice guidelines, their development, implementation and use;
- Annotated bibliographies on guideline development methodology, implementation, and use.

Content Overview

Disclaimer

Please read the NGC disclaimer statement.

Technical Information
Yet little impact to date

- Dissemination in read-only form
- Provenance, evidence base not always clear or trusted
- Too general or too specific
- Not adaptable or flexible, too “cookbook”
- Not integrated with point of care or into workflow
What is needed

- High quality guidelines from trusted sources
- Standard computer-based representation, sharability
- Means for adaptation to local setting
- Flexibility of decision/choice model
- Integration with clinical applications
The InterMed Collaboratory

- Decision Systems Group, Brigham & Women’s Hospital, Harvard
- Stanford Medical Informatics (SMI)
- Department of Medical Informatics, Columbia
- Centre for Medical Education, McGill University
- American College of Physicians – American Society of Internal Medicine
Toward GL sharing & integration into applications

- GuideLine Interchange Format (GLIF)
  - developed by InterMed project of Columbia, Harvard, Stanford
  - v 2.0 JAMIA, 1998
- Imported/exported by authoring tools
- Applications can interpret GLIF-encoded guidelines or convert them to app-specific representations
Elements of a GLIF GL

- Flowchart representing temporal sequence of clinical steps
  - Action steps – clinical actions to be performed
  - Conditional steps – decision criteria for conditional flowchart traversal
  - Branch & synchronization steps – simultaneous pathways
Elements of a GLIF GL, cont’d

- Other elements
  - Eligibility criteria (for GL or step)
  - Patient data items needed
  - Supporting or documentary resources (text, citations, URLs, DBs)
Object Hierarchy

Guideline Model

- Guideline
  - Action
    - Conditional
  - Step
- Action Spec
- Criterion
  - Boolean
  - K of N
- Patient Data
- Supplemental Material
  - Local
  - WWW
Flu vaccine guideline

Get age and occupation

Health-care worker or Age>65?

- Yes
  - Flu-shot
- No
  - Nothing
Conditional step, in GLIF

```
{ name = “High risk determination”; condition = Boolean_criterion 1
  { type = Boolean;
    spec = “HCW OR age>65”;};
  destination = (Action_Step 3);
  otherwise = (Conditional_Step 2);}
```
A GLIF-based GL tool suite

- Tools aimed at providing ability to create, maintain, share, access, and execute clinical GLs
- Distributed framework, with tools designed to work with each other
- GLIF provides the common sharable representation
Server/repository

- Internet-accessible (CORBA-based)
- Classifies and indexes GLs or protocols
- Controls access over a network
GL authoring/browsing
Toxicities

Category: CONSTITUTIONAL SYMPTOMS

Toxicity: Weight gain - veno-occlusive disease (VOD)
- Grade 1: >=2 - <5%
- Grade 2: >=5 - <10%
- Grade 3: >=10% or as ascites
- Grade 4: >=10% or fluid retention resulting in pulmonary failure
- Grade 5: Death related to toxicity

Note: The above criteria are to be used ONLY for weight gain associated with VOD.

Attribution Code
- Unrelated
- Unlikely
- Possible
- Probable
- Definite

Patient Id:          Protocol Id:          Course No.:

Date of Event: (MM/DD/YYYY)
Eligibility determination & patient recruiting
Results - Abbreviated Listing

This is a listing of the 15 clinical trials that your patient may qualify for. Please note that we cannot determine with certainty whether your patient matches all of the eligibility criteria for any trial. The number of criteria matched and number of criteria still unknown are shown next to the name of each trial. The trials are listed in order of probability of match, with the highest probability trials listed first.

Click here for a [FACTS Detailed Listing](http://telmato.bwh.harvard.edu:8000/DEV/FormOut.asp) or click on a Protocol below to view the complete PDQ abstract.

**Key: M - Number of criteria matched, U - Number of criteria still unknown**

<table>
<thead>
<tr>
<th>Clinical Trial Name</th>
<th>M</th>
<th>U</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. <strong>Protocol 12665</strong>: Phase III Study of Prolonged Adjuvant Tamoxifen for Breast Cancer</td>
<td>1</td>
<td>5</td>
</tr>
<tr>
<td>2. <strong>Protocol 10198</strong>: Phase II Pilot Study of PBSC Mobilization with High-Dose Cyclophosphamide/Betoposide or with Cyclophosphamide/Betoposide/Cisplatin Followed by G-CSF or GM-CSF in Cancer Patients Undergoing Transplantation (Summary Last Modified 10/97)</td>
<td>2</td>
<td>7</td>
</tr>
<tr>
<td>3. <strong>Protocol 13151</strong>: Phase II Study of Interleukin-2 in Patients with Hematologic Malignancies or Solid Tumors Who Have Received Autologous Bone Marrow or Peripheral Blood Progenitor Cell Transplantation (Summary Last Modified 06/98)</td>
<td>2</td>
<td>10</td>
</tr>
<tr>
<td>4. <strong>Protocol 12039</strong>: Phase II Study of Neoadjuvant Continuous Weekly Doxorubicin/Cyclophosphamide (AC) for Locally Advanced and Inflammatory Breast Cancer (Summary Last Modified 01/98)</td>
<td>6</td>
<td>11</td>
</tr>
<tr>
<td>5. <strong>Protocol 11793</strong>: Phase II Pilot Study of Stem Cell Mobilization with Paclitaxel/Cyclophosphamide Followed by High-Dose Melphalan/Betoposide with Autologous T-Cell-Depleted CD34+ Peripheral Blood Stem Cell Rescue for Metastatic and High-Risk Breast Cancer (Summary Last Modified 08/98)</td>
<td>5</td>
<td>14</td>
</tr>
<tr>
<td>6. <strong>Protocol 13184</strong>: Phase II Study of High Dose Combination Chemotherapy and Autologous or Syngeneic Peripheral Blood Stem Cell Rescue Followed by Immunotherapy With Interleukin-2 and Sargramostim (GM-CSF) in Patients With Inflammatory Stage IIIB and Responsive Metastatic Stage IV Breast Cancer</td>
<td>5</td>
<td>14</td>
</tr>
</tbody>
</table>
Execution “engine”

- Tracks & interprets GLIF-based guideline, as data are obtained
- Used as a core in multiple applications
  - risk assessment
  - consultation
  - clinical trial protocol
  - disease management
  - workflow support
  - educational simulations
Risk assessment

Summary of your responses

Use the back button of your browser to change any of this information

Age: 53
Do you have diabetes?: No
Do you smoke?: Yes
Gender: Female

Please fill in the information below:

<table>
<thead>
<tr>
<th>Metric</th>
<th>Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>HDL Cholesterol</td>
<td>34 mg/dl</td>
</tr>
<tr>
<td>LDL Cholesterol</td>
<td>170 mg/dl</td>
</tr>
<tr>
<td>Total Cholesterol</td>
<td>280 mg/dl</td>
</tr>
<tr>
<td>Blood pressure</td>
<td>140 BP Systolic (mm Hg)</td>
</tr>
</tbody>
</table>

Recommendations

Please keep in mind that if you left an answer blank, we used the average risk for that question to generate these recommendations.

- Based on your answers, your risk for developing heart disease within the next 10 years is 13%. The average risk for a 53 year old woman is 8%. If any member of your family (1st degree relative) developed heart disease before the age of 45 in men, 55 in women, your risk is further increased.
- Your risk is higher than average. We suggest you see your doctor.
- We suggest reviewing all of the following risk factors with your doctor:
  - Smoking
  - Total cholesterol
  - LDL cholesterol
  - HDL cholesterol
  - Blood pressure
- Your risk could be further improved by:
  - Lowering your total cholesterol
  - Lowering your LDL cholesterol
  - Lowering your blood pressure
  - Not Smoking

Heart disease risk
Consultation

Flu vaccine guideline

Recommended reading
- Medline: Influenza vaccine efficacy
- Guideline in XML

Recommended actions
- Obtain patient data regarding contra-indications

Enter patient data
- Hypersensitive to eggs
- History of anaphylactic hypersensitivity to vaccination
- Guillain-Barre syndrome within 6 weeks of a previous vaccine
- Current severe acute illness

Choose: True/False

Recommended actions
- Wait for acute illness to resolve then reapply guideline
Adverse Events

Category: CONSTITUTIONAL SYMPTOMS

Adverse Event: Weight gain - Veno-Occlusive Disease (VOD) for BMT studies if specified in the protocol.

- **Grade 1**: >=2 - <5%
- **Grade 2**: >=5 - <10%
- **Grade 3**: >=10% or as ascites
- **Grade 4**: >=10% or fluid retention resulting in pulmonary failure
- **Grade 5**: death related to toxicity

Note: Also consider Ascites, Edema, Pleural effusion (non-malignant)

**Attribution Code**
- Unrelated
- Unlikely
- Possible
- Probable
- Definite

**Patient Id:**

**Protocol Id:**

**Course No.:**

**Date of Event:** (MM/DD/YYYY)
Guideline-driven clinical encounter

- A possible model for integration into practice
  - tailored information assembly
  - disease management as a primary focus
  - suggestions triggered by data entry
  - workflow facilitated by anticipating user needs
Subjective:

- Patient with Diabetes Mellitus, Headaches, and h/o Depression.
- ROS: No LH, N, V, but complains of polydipsia.
Assessment

- Patient with DM with ☑ excellent ☐ good ☐ fair ☑ poor glucose control
- ☑ Home monitoring suggests need to change medication regimen
- Patient is overdue for the following:
  - ☑ HbA1c
  - ☑ Urine Protein Studies
  - ☑ Dilated Eye Exam
  - ☑ Diabetic-Nurse teaching visit

Accept All

Other

Visit Note

Assessment:
- Patient with DM poor glucose control.
- Home monitoring suggests need to change medication regimen.
- Overdue for: HbA1C, urine protein study or urine microalbumin, dilated eye exam, diabetic-nurse teaching visit
Assessment

- Patient with DM with ☐ excellent ☐ good
- ☑ Home monitoring suggests need to check
- Patient is overdue for the following:
  - ☑ HbA1c
  - ☑ Urine Protein Studies
  - ☑ Dilated Eye Exam
  - ☑ Diabetic-Nurse teaching visit

Accept All Other

Initial stabilization

Needs stabilization?

yes

AD

Initial stabilization

AD

Recommend self-management program:
A. Nutrition therapy
B. Physical activity
C. Education for self-management
D. Foot care

Set individualized treatment goals:
A. Glycemic control - HbA1c ≤ 7%
B. Lipid levels - LDL ≤ 130 mg/dl
C. Blood pressure control - BP ≤ 130/85 mm Hg
D. ASA unless contraindicated
E. Tobacco cessation if indicated

AD

Are treatment goals met?

no

AD

See Ongoing Management Algorithm for maintaining treatment goals and complication prevention

no

Treatment goals not met:
A. Modify treatment based on appropriate guideline and/or
B. See Glycemic Control Algorithm and/or
C. Refer to diabetes health team or specialists

yes

AD
Plan

- Adjust Diabetes Medication
  - Increase Metformin to 500 mg TID
  - Begin Insulin
- Begin Home Monitoring
- Obtain:
  - Serum HbA1C
  - Urine Microalbumin
- Other
- Refer to:
  - Ophthalmology
  - Diabetes-Nurse Educator

Other

Visit Note

Plan:


2. **General:** Return to clinic in 3 months time.
Hypotheses (yet untested)

- Approach will provide positive effect on:
  - structured record keeping
  - adoption of best practices
  - physician attitudes
  - workflow
GLIF 3

GLIF 2, as published in 1998:
- underspecified, yet has spawned a number of implementations & extensions

GLIF 3 created as a draft model for a proposed standard approach
- focus of an international workshop in Boston, March, 2000
Framework

In GLIF 3 we approach the issue of sharing at three different levels:

A. Author/viewer
   - human able to navigate, edit, use

B. Abstract machine representation
   - correctness, completeness of representation able to be proved

C. Integration into application environments
   - linkage to clinical information systems & EMR
Rationale for tri-level framework

- Enables standardization requirements for each level to be considered separately
- Fosters ability to reconcile various formalisms that address different levels
  - e.g., prior GLIF work was focused on level A, Arden syntax aimed primarily at Levels B, C
- Combined focus facilitates use at all levels
GL Workshop
Boston, MA, March 3-4, 2000

- Brought together multiple stakeholders concerned with the development, dissemination, & use of clinical practice guidelines (GLs)
  - To identify the collective needs & purposes of GLs & for sharing of them -- the functional requirements
  - To develop a robust representation model
  - To establish a process to foster sharing
Sponsors

- US Army
- NLM
- CDC
- AHRQ
Stakeholders represented

- Government
- Professional specialty organizations
- Insurers
- Health care provider organizations
- Academic medical informatics
- Industry -- content, systems, tools providers, consultants/integrators
International Scope

Representation from

- UK  - Brazil
- Netherlands  - India
- Italy  - France
- Taiwan  - Japan
- Canada  - USA
Breakout groups

- A. Functional requirements
- B. Representation models
- C. Special needs of clinical trials
- D. Infrastructure & tools
- E. Organization & process
Some meeting outcomes

- Establishment of 5 on-going task forces
- Production of white papers
- Presentations
  - AMIA, HIMSS, professional specialty organizations, other forums
- A Web site for exchange
  - http://www.glif.org
- Decision to form consortium to
Summary & current status

- GLs have many potential roles
- Goal of GL representation for sharability
- Have demonstrated use of GLIF as basis for a suite of tools to support above
- Development beginning to converge on:
  - standards
  - infrastructure & tools
Where do we go from here: An agenda

1. Promote adoption of a GL representation standard
2. Develop internet resource for access to:
   - specifications, tools, well-coded GLs, discussion & information exchange
3. Support projects to:
   - demonstrate feasibility of sharing & reuse
   - explore ways to integrate GLs into