From Guidelines to Implementation: Who Determines Best Practice and How Does It Get Adopted?

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Definitions

- **Guideline (GL)** – a recommended process for addressing a problem or task
- **Clinical practice guideline (CPG)** - best practice for a particular clinical problem
  - Can be screening, workup, treatment, management, ...
  - CPGs tend to be normative
- **Protocol** – specific procedure for a problem or task
  - Prescriptive process
  - May be in the form of a worksheet, e.g., for dialysis
  - Clinical trials as a specific example (after randomization)
Why guidelines

- Capture procedural knowledge
  - What to do in a given setting
    - …not usually addressed: what NOT to do
  - How to do it
    - Optimal method or approach
  - When to do it
    - Conditions under which it is appropriate and timing
  - Sequence/process flow
    - Order in which actions and decisions should occur
Formats

• narrative text
• decision tables
• flowcharts/algorithms
• graphs
• diagrams
• lists
• critical pathways
• if–then–else statements
• ...
RECOMMENDATIONS FOR THE USE OF INFLUENZA VACCINE

Influenza vaccine is strongly recommended for any person aged ≥6 months who -- because of age or underlying medical condition -- is at increased risk for complications of influenza. In addition, health-care workers and other individuals (including household members) in close contact with persons in high-risk groups should be vaccinated to decrease the risk of transmitting influenza to persons at high risk. Influenza vaccine also can be administered to any person aged ≥6 months to reduce the chance of becoming infected with influenza.

Target Groups for Vaccination

Groups at Increased Risk for Complications

Vaccination is recommended for the following groups of persons who are at increased risk for complications from influenza or who have a higher prevalence of chronic medical conditions that place them at risk for influenza-related complications:

- persons aged ≥50 years;
- residents of nursing homes and other chronic-care facilities that house persons of any age who have chronic medical conditions;
- adults and children who have chronic disorders of the pulmonary or cardiovascular systems, including asthma;
- children and teenagers (aged 6 months to 18 years) who are receiving long-term aspirin therapy and therefore might be at risk for developing Reye syndrome after influenza infection; and
- women who will be in the second or third trimester of pregnancy.
A Common Feature in Clinical Journals and Textbooks example from the 1970s
Computer-Interpretable GLs (CIGs)

• An unambiguous rendering that can be executed by a computer
  • usually as a flow chart of the steps and sequences
  • can be as a decision table or other formalism
Value of CIGs

• Direct benefit to care
• Task of translation can highlight deficiencies and lead to helpful revisions
• Decision-table methods can verify completeness and to detect inconsistencies and redundancies.
• Can include additional material
  • such as images, videos, sounds, simulations, and links to bibliographic databases.
• Given patient data, can automatically select the next step
Guidelines as a core methodology for ... 

- modeling of clinical knowledge
- reference or education
- simulations & training
- driving decision support
- Consultation
- process monitoring

- care plans and critical paths
- monitoring and predicting resource requirements
- conduct of clinical protocols clinical trials
- workflow support
The Guideline Interchange Format (GLIF)


- An example of a CIG modeling approach
  - 4 step types
    - Decision
    - Action
    - Branch, synchronization
    - State
  - Other elements
    - Criteria
    - Patient data
    - Supplemental material
Flu vaccine guideline

Asymptomatic → Get age and occupation

Health-care worker or Age≥65?

Yes → Give Flu shot

No → Do Nothing
{ name = “High risk determination”; 
  condition = Boolean_criterion 1 
    { type = Boolean; 
      spec = “HCW OR age>65”;};
  destination = (Action_Step 3);
  otherwise = (Conditional_Step 2);}

Guideline authoring - action

Flu_Guideline v1.0.0.0

edit Options Authoring Access

risk for complications of influenza?

months old

False

Age < 9 years old

False

Age < 12 years old

False

Adult dose

Administer one split 0.50 mL Vaccination IM from
September through March, preferably between October 1
and November 15.

Centers for Disease Control

http://www.cdc.gov/
Workflow integration

- For chronic disease, in particular, patient state evolves over time
  - Can represent as a state model with transitions
  - Patient may stay in same state for weeks or years
- This can be used to predict the starting point for a patient encounter
  - What data needed to review
  - What new data to collect
  - What likely to be done
- Can improve efficiency as it provides advice

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 □ fair □ poor
- □ Home monitoring suggests need to change
- Patient is overdue for the following:
  □ HbA1c
  □ Urine Protein Studies
  □ Dilated Eye Exam
  □ Diabetic-Nurse teaching visit

Other

Visit Note

Assessment:

- Patient with DM poor glucose control
- Home monitoring suggests need to change
- Overdue for: HbA1C, urine protein, diabetic-nurse teaching visit

Initial stabilization

Needs stabilization?

yes

Initial stabilization

no

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

Are treatment goals met?

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

See Ongoing Management Algorithm for maintaining treatment goals and complication prevention
Plan

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

Other

Visit Note


2. **General:** Return to clinic in 3 months time.
Where GLs come from

- Clinical trials, technology assessments, evidence-based practice studies, comparative effectiveness research
- Literature review, meta-analysis, critical appraisal
- Organize into a timeline, sequence, decision points
  - Based on considerations of urgency, cost-effectiveness, risk minimization, etc.
    - Can be helped by formal decision analysis
  - Not a systematic process, arbitrary, may require consensus development
The GL implementation gap

- GLs typically not developed with an awareness of implementation requirements
- Cause of much frustration over the years
Examples of variation - 1


- terms defined inadequately
  - e.g., “left ventricular systolic dysfunction”),

- criteria for decisions unclear
  - e..g., “continued symptoms”)

- patient states described inadequately
  - e.g., “drug intolerance”

- modifiers vague
  - e.g., “frequently,” “recurring”

- recommendations vague
  - e.g., “when needed”
Examples of variation - 2


- Modeling experiment where task was to convert 4 guidelines from narrative to flowchart, by 2 encoders
  - Breast-mass workup protocol
  - Breast-cancer treatment protocol
  - Cholesterol screening and management
  - Influenza-vaccine recommendations
- Found significant variation in
  - order in which data elements are collected
  - level of detail represented
  - use of atomic or composite sentences in criteria
  - specification of data elements
  - omissions due to human error
NGC Search Results

Your search criteria:

**Keyword:** colon cancer screening

Your search found 59 related guidelines, which are listed below by relevance. Use the "Limit Search" button to sort by publication date.

To view a guideline summary, click on a title below.

<table>
<thead>
<tr>
<th>Limit Search</th>
<th>Select All</th>
<th>Add to My Collection</th>
<th>Next 20</th>
</tr>
</thead>
</table>

Items 1 to 20

**Title**

- **Adult preventive health care: cancer screening.** University of Michigan Health System - Academic Institution. 2004 May. 12 pages. NGC:003785

- **Preventive health recommendations for adults with mental retardation.** Massachusetts Department of Mental Retardation - State/Local Government Agency [U.S.] University of Massachusetts Medical School’s Center for Developmental Disabilities Evaluation and Research - Academic Institution. 2003 Sep 19. 2 pages. [NGC Update Pending] NGC:003209
Markup/Analysis of GLs

• Guideline Elements Model (GEM)
  • Elements of various types
• GL quality assessment criteria (COGS)
• Guideline Implementability Appraisal (GLIA)

Logical Analysis with Highlighters

• UTI Recommendation 3
  If an infant or young child 2 months to 2 years of age with unexplained fever is assessed as being sufficiently ill to warrant immediate antimicrobial therapy, a urine specimen should be obtained by SPA or bladder catheterization; the diagnosis of UTI cannot be established by a culture of urine collected in a bag. (Strength of evidence: good) Urine obtained by SPA or urethral catheterization is unlikely to be contaminated...

Shiffman et al
http://gem.med.yale.edu
GLIA Criteria

- **Decidability** – precisely under what circumstances to do something
- **Executability** – exactly what to do under the defined circumstances
- **Effect on process of care** – the degree to which the recommendation impacts the workflow
- **Presentation and formatting** – the degree to which the recommendation is recognizable and succinct
- **Measurable outcomes** – the degree to which the GL identifies markers or endpoints to track the effects of the recommendation
Standardization status

- GEM as an HL7 and ASTM standard since 2001
- Arden Syntax HL7 standard since mid-1990s for single-step Medical Logic Modules (MLMs)
- Clinical Guidelines Special Interest Group formed in HL7 in 2001
  - Part of Clinical Decision Support Technical Committee
  - Also includes Arden Syntax SIG
  - Aim to decide standard for guideline implementation
    - Ran into opposition from developers of competing GL models
    - Deemed better to focus on components of GLs and not GL models
  - CGSIG in 2008 absorbed into CDSTC
Approach

- Work has focused on key infrastructure components:
  - **vPR**: an object-oriented virtual patient record subset for decision support
  - **GELLO**: object-oriented guideline expression language
  - **vocabulary** management tools
  - Process/workflow representation model
    - Least well developed
  - Evolution of Arden Syntax
Differences between GLs and CDS

• **GLs**
  - Focus on particular settings/problems (entry points)
  - Recommend actions
  - Identify anticipated results
  - Cycle repeats as timeline unfolds

• **CDS**
  - Focus on single events/points in care
  - Recommend actions
    - May relate to points on GL
    - May seek to move to a GL
  - Alerts for inappropriate actions
  - Other forms of CDS - infobuttons, structured forms, order sets, calculations, predictive models, etc.
From CIGs to CDS

- Guidelines often not seen as being implemented directly
- Rather, they are mapped onto process and workflow of the organization or practice
  - decomposed into actionable CDS components
    - Order entry, alerts, reminders, scheduled events
    - Ideally delivered as independent web “services”
- explored in SAGE project (IDX, Mayo, Intermountain, Stanford, U of Nebraska, Apelon)
  http://sage.wherever.org/model/components.html
- most recently being explored in the GLIDES (GuideLINES Into DECision Support) collaboration (Shiffman, AHRQ support)
  - Goal of transparent, systematic, and replicable processes for transforming guideline knowledge into computer-mediated decision support
CIGs and clinical decision support (CDS)

The usual evidence-to-GL-to-CIG-to-CDS lifecycle
Ways to improve the process

• Document sources of GL and choices made
• Directly author GLs in CIG authoring tool
• Precisely specify
  • eligibility criteria, data elements, decision criteria, timeline, and actions
• Identify actionable (implementable) components and workflow settings for them
• Create shared repositories
• Coordinate development with standardization process
  • to fill gaps in the standards
The Morningside Initiative as an example

A joint project of:

- American Medical Informatics Association
- Arizona State University
- DoD Tri-Care Management Activity, Military Health System
- Henry Ford Health System
- Intermountain Health
- Kaiser Permanente
- Partners Healthcare
- Veterans Healthcare Administration
Goal to stimulate sharing by

- Concentrating on organizational, technical, and content issues that have impeded sharing in the past
- Demonstrating effectiveness
  - In terms of content and knowledge resources and secondary adoption
- Focusing on “executable” knowledge for CDS
  - Already implemented, evaluated, effective
  - Initially diabetes
- Aim of providing a forum for vetting and disseminating best practices
- Aim of scaling up to broader national (perhaps international) ongoing process
Current role of specialty societies

- Promote data standards and studies to add to evidence base
- Develop materials to add to knowledge base
  - Offer CME, web, and other resources
  - Operate primarily at (2) and to a lesser extent at (3) in this process
  - Very slow cycle
    - blunt instruments
    - have “less than optimal” impact on actual practice

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(1) EPC/CER libraries, literature
(2) CPGs
(3) CIGs
(4) Parts to be implemented
Potential role of specialty societies and “meta-society”

- Take leadership of this process
- Go directly from (1) to (3)
- Identify “best practices” via collective authority
- Establish active process of determining (4)
- Drive standards and tool development based on needs coming out of this process

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Toward a library of implementable best practices

• Can we create a national process for this?
• How organize?
  • By specialty
  • By problem
• What tools needed
• How decide on problems to address
• How disseminate and promote