

Protocols & Protocol Systems

HINF1100

Fall 2008

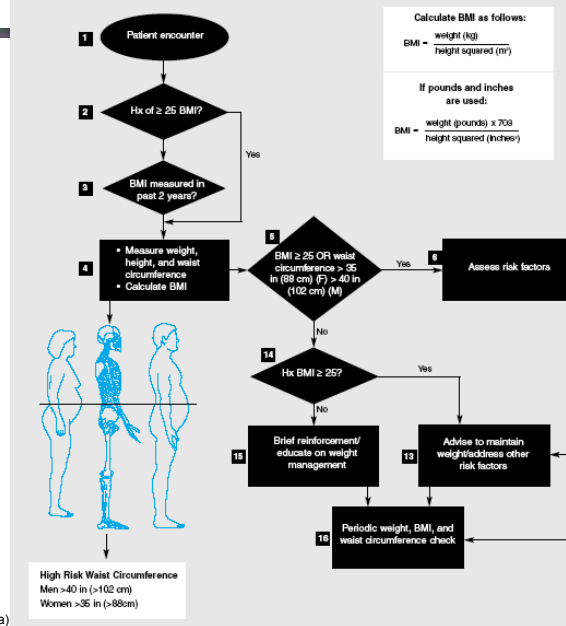
Why Protocols?

- ❖ **Need to standardize healthcare**
 - ❖ Standard clinical decisions
 - ❖ Standard tests
 - ❖ Standard treatments
 - ❖ Standard costs
 - ❖ Standard language to record clinical facts

Protocols: Definition

- ❖ A protocol is a set of instructions. These instructions might describe the procedure to be followed when investigating a particular set of findings in a patient, or the method to be followed in the management of a given disease

(Coiera, 2003)



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Protocols

- ❖ What do they offer?
 - ❖ Advice on the best way to carry out some healthcare task
 - ❖ Advice on what should be done in particular situations
- ❖ What are they based on?
 - ❖ 'Best evidence' derived from clinical studies
 - ❖ Medical knowledge
 - ❖ Clinical data (large quantities of data)
 - ❖ Recommendations by experts

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Uses of Protocols

❖ Protocols ensures that the tasks are carried out uniformly

- ❖ **Diagnosis & Treatment**
 - ❖ Help suggest recommendations based on best evidence
 - ❖ Represent advice on good practice
- ❖ **Research**
 - ❖ When a treatment is assessed, a research protocol determines how to measure the effectiveness of the treatment
- ❖ **Delegation and Demarcation of responsibility**
 - ❖ Give clear instructions to help less trained care providers
 - ❖ Make clear which tasks are to be carried out by different healthcare providers
- ❖ **Education**
 - ❖ Ensure that a minimum standard of knowledge is maintained
- ❖ **Safety-critical or complex situations**
 - ❖ Ensure that errors are reduced by taking prescribed actions
 - ❖ Help to deal with rare conditions by giving clear instructions

Structure of Protocols

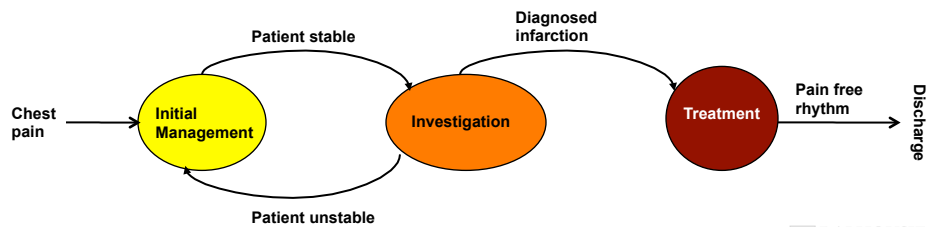
❖ Design consideration

- ❖ **Easy of use**
 - ❖ Can be used in pressure situations
 - ❖ Can be used when time is short
 - ❖ Can we used with basic expertise (not just by specialists !!)
- ❖ **Inclusion and exclusion criteria**
 - ❖ Patient's symptoms, age group, co-morbidities
- ❖ **Link with the patient data**
 - ❖ Connection with the electronic medical record
- ❖ **Decisions represented as a flowchart**

Structure of Protocols

❖ Break the protocol into a sequence of chunks

- ❖ Each chunk takes care of a specific activity, such as diagnosis, treatment
- ❖ Each chunk has an entry criteria and an exit criteria
 - ❖ Entry criteria: The following patient's data is available
X-Ray, Glucose level etc
 - ❖ Exit criteria: The last step of the task being completed
Patient discharged/referred, drug prescription made, etc

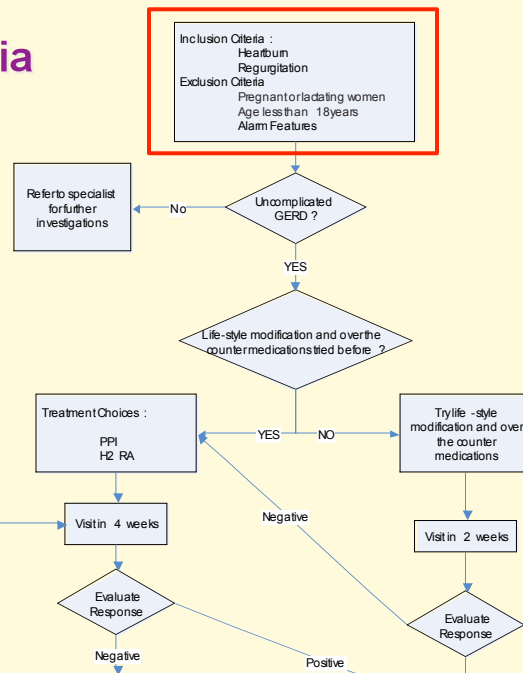


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Inclusion & Exclusion Criteria

Treatment of Gastroesophageal Reflux Disease in Adults



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Types of Protocols

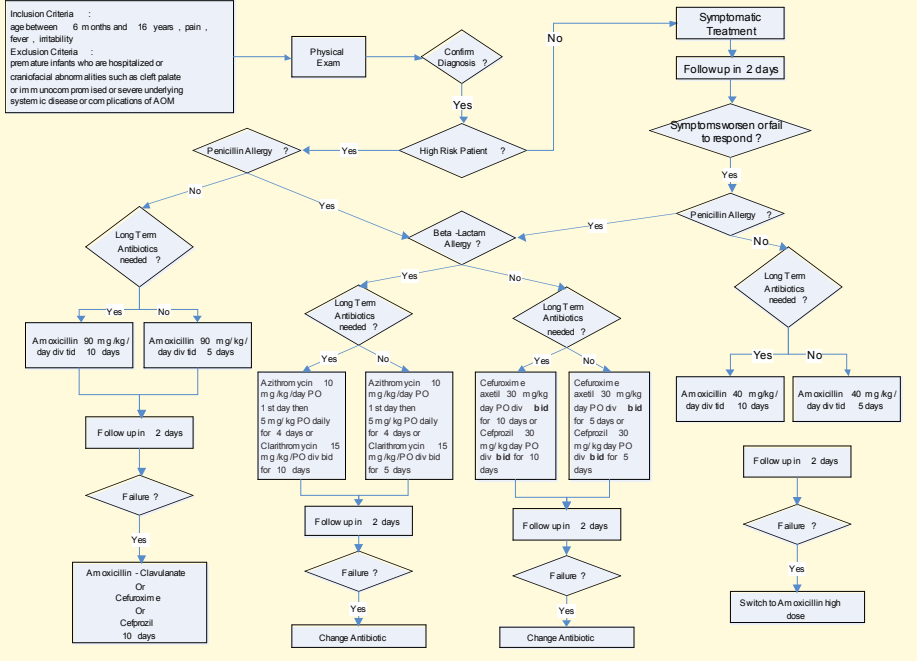
- ❖ **Clinical Practice Guidelines (CPG)**
 - ❖ Standard clinical decisions and practices
 - ❖ Based on medical knowledge
- ❖ **Clinical Pathways (CP)**
 - ❖ Standard way of treating patients in a specific healthcare institution
 - ❖ Based on clinical processes and resources at the healthcare institution

Clinical Practice Guidelines (CPG)

“Systematically developed statements to assist practitioner and patient decisions about appropriate healthcare for specific clinical circumstances.”

(Field and Lohr, 1990)

Diagnosis and Treatment of Acute Otitis Media (AOM) in Children



Clinical Practice Guidelines

- ❖ **CPG recommends but not restricts!**
- ❖ **CPG aims**
 - ❖ Encourage best-practices
 - ❖ Standardize clinical practices
 - ❖ Eliminate variations in practice
 - ❖ Accountability of practice
 - ❖ Eliminate errors (due to lack of knowledge)
 - ❖ Optimize resources
- ❖ **CPG are effective if**
 - ❖ Available at the point-of-care
 - ❖ Patient-specific advice at key clinical decision-making points

Clinical Practice Guideline: Conversion Issue

❖ Operational limitations of CPG:

- ❖ The guidelines are too long.
- ❖ Impractical to use at point of care.
- ❖ Not readily available or accessible.
- ❖ Not always current.
- ❖ Informal language --> Different interpretations

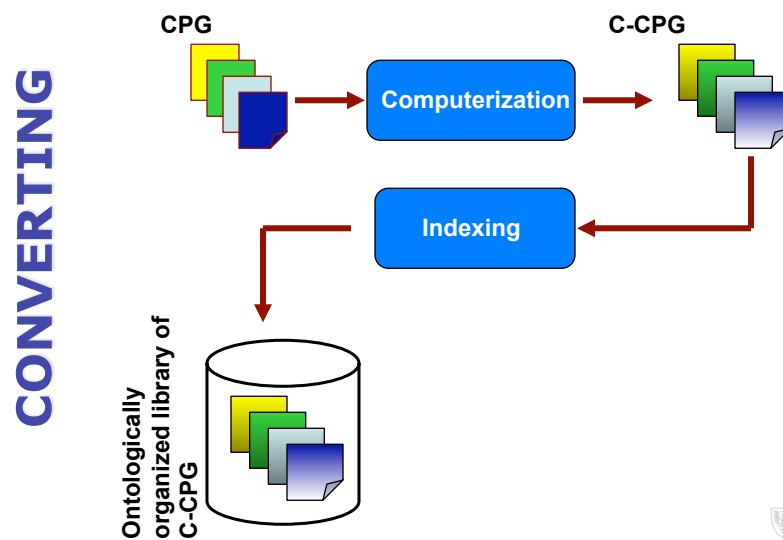
Knowledge
Management
Solution

Converting Paper-based CPG to computerized CPG

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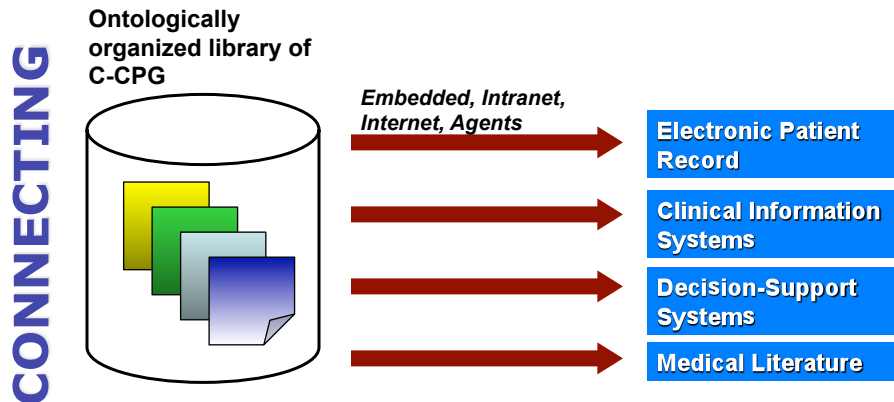
Clinical Practice Guidelines: A KM Framework for Converting and Connecting



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Clinical Practice Guidelines: A KM Framework for Converting and Connecting



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Clinical Pathways (CP)

- ❖ *“schedules of medical and nursing procedures, including diagnostic tests, medications, and consultations designed to effect an efficient, coordinated program of treatment.”* (National Library of Medicine)
- ❖ *“a document that describes a process within health and social care... [Clinical pathways] embed guidelines, protocols and locally agreed, evidence based, patient centered best practice into everyday use for the patient.”* (UK Commission for Health Improvement)
- ❖ *“[The clinical pathway] forms all or part of the clinical record, documents the care given and facilitates the evaluation of outcomes for continuous quality improvement.”* (National Pathway Association)

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Exemplar CP

Task Driven

Acute Coronary Syndrome Pathway

Eligibility
Patients presenting with chest pain at rest for greater than 15 minutes or suspected acute MI

First name _____
Last name _____
DOB _____
CHI No _____
Attach Patient Label

Date _____
Time of admission _____
Time of onset of symptoms _____

Immediate Actions		Before admission	Withheld or not done (reason)
Aspirin 300mg chewed <input type="checkbox"/>	Time _____	<input type="checkbox"/>	<input type="checkbox"/>
Oxygen 8l/min <input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Pulse oximetry <input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
12 lead ECG <input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
ECG mentor <input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Blood pressure <input type="checkbox"/>	Value _____	<input type="checkbox"/>	<input type="checkbox"/>
IV cannula <input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Diamorphine 2.5 to 5mg IV <input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Cyclizine 50mg IV <input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>
Estimated weight (kg) <input type="checkbox"/>	Value _____	<input type="checkbox"/>	<input type="checkbox"/>

Yes to any No to all

ST Elevation > 1 mm in two or more limb leads?

ST Elevation > 2 mm in two or more adjacent chest leads?

New left bundle branch block?

Pre-existing LBBB or LBBB of uncertain duration associated with corresponding symptoms

ECG signs of posterior myocardial infarction?

Branch to ACS ST Elevation Pathway

Sign Off

Pathway completed

Date _____

Content authorised by _____

Name _____

Signature _____

Branch to ACS Non ST Elevation Pathway

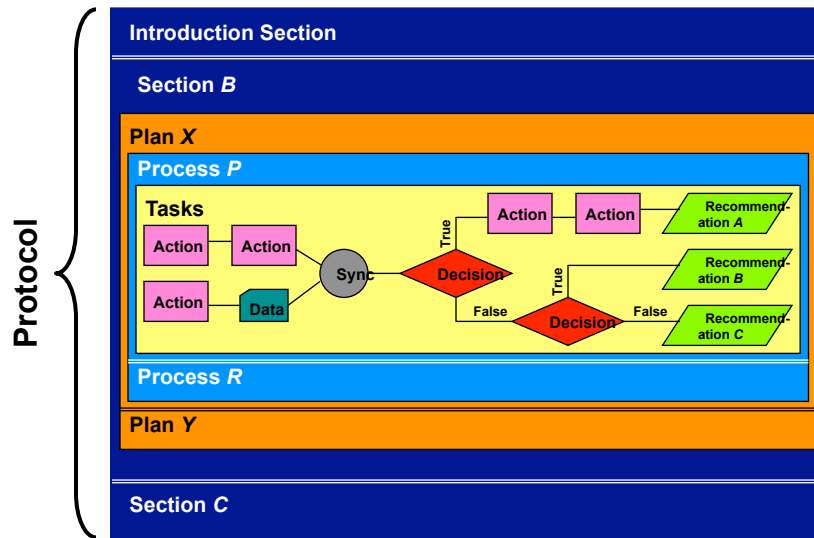
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Characteristics of Clinical Pathways

❖ Salient characteristics of clinical pathways:

- ❖ Statement of the goals of the care process
 - ❖ Based on evidence, best practice, and patient expectations
- ❖ Points of communication and collaboration between care providers
- ❖ Description of the key elements in the care process
- ❖ Sequence of the care activities
- ❖ Documentation of the care activities and patient observations
- ❖ Recording of variances and outcomes;
- ❖ Identification of the appropriate resources.

Protocol Abstraction



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Points of Departures from a Protocol

- ❖ **Departure from a protocol is known as VARIANCE**
 - ❖ **Patient condition**
 - ❖ Patient has co-morbidities (multiple diseases)
 - ❖ Patient is not responding to the treatment
 - ❖ **Treatment variation**
 - ❖ To change the state of the patient in response to unforeseen events
 - ❖ **Resource constraints**
 - ❖ Resource is not available at a given time

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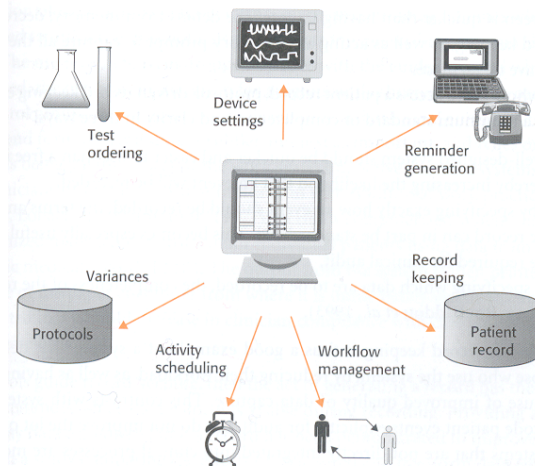


How to Interpret Variances

- ❖ **Signal to care team to reassess the application of the protocol on patient**
 - ❖ Maybe more individualized care is needed
- ❖ **Recurrent variances suggest that the protocol is sub-optimal**
 - ❖ Resources are not available
 - ❖ Evidence is out-dated
 - ❖ Patients are not responding as expected

Active Protocols Systems

- ❖ **Active protocol systems are built in clinical information systems.**



Protocol based systems

- ❖ **Semi-automated record keeping and data entry**
 - ❖ Protocol guides the healthcare provider to collect specific patient data
 - ❖ Protocols help to capture complete data
 - ❖ Protocol helps to capture data with respect to specific actions, tasks & processes
- ❖ **Recommendations**
 - ❖ Protocols provide evidence based recommendations to the patient's conditions
- ❖ **Alerts & Reminders**
 - ❖ Protocols can help detect critical/unusual situations
- ❖ **Activity scheduling & Workflow management**

Computational Protocols: Primitives

The primitives are used to construct the specific steps of a protocol.

- ❖ **Actions**
 - ❖ A clinical or administrative task that a protocol recommends to be performed (or avoided)
- ❖ **Decisions**
 - ❖ The determination of an option when multiple options are available.
Eg. Selection of a laboratory test when multiple tests are available
- ❖ **Patient status**
 - ❖ The condition of the patient based on the actions and the decisions performed on the patient
- ❖ **Execution state**
 - ❖ Record of the completion of a task (such as action or decision)

Computational Protocols: Logical Connections

The different steps in a protocol are connected by logical connectors using a process model that comprises

❖ Scheduling Constraints

- ❖ The order in which the primitives can be executed.
- ❖ The execution may be either a linear or a parallel sequence
- ❖ Use a flowchart or state transitions to show the order of primitives

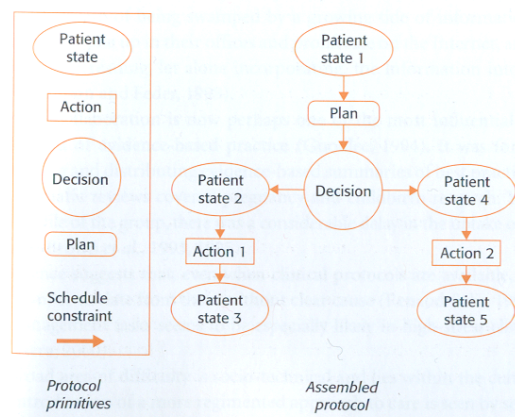
❖ Plans or Nesting of Guidelines

- ❖ The Hierarchical relationship between guidelines.
- ❖ Nesting enables multiple levels of abstraction in the protocol representation

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Assembling a Computational Protocols



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Protocol Languages and Representations

❖ Protocols need to be computerized

- ❖ Needs a rich language to capture the care tasks and how to achieve these tasks
- ❖ Need to be specified in considerable detail
- ❖ Needs to capture medical knowledge
 - ❖ Knowledge about cardiac surgery
 - Tests, procedures, therapy, tools, etc.
 - Rules that capture relationships between the above elements

Protocol Representation Languages

❖ Arden syntax

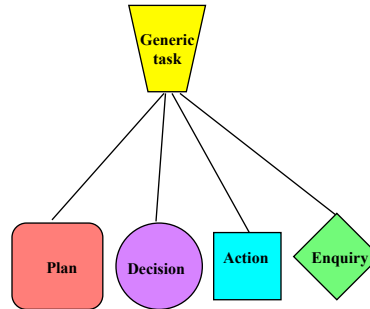
- ❖ All actions in the protocol are represented as situation-action rules known as Medical Logic Modules (MLM)

```
//maintenance:
  //title: Messages based on Physical Activity Level of Patient;;
  //filename: Exercise;;
  //version: 1.00;;
  //institution: Dalhousie University;;
  //author: Name1;;
  //specialist:Name2;;
  //date: 2006-2-14;;
  //validation: testing;;
// library:
  //purpose: Get message tags for patients about their level of
  //physical activity;;
  //explanation: When a patient indicates her/his level of physical
  //activity in one week, it affects the personalised messages;;
  //Keywords: Regular Exercise, Physical Inactivity, CVD;;
// knowledge:
  //type: data-driven;;
  //data;;
  //evoke: data entered from the DCT;;
  logic:
    if Exercise=five or more times per week then conclude
      false;
    elseif Exercise=no regular exercise and Gender=Female and
      Readiness to change=no present interest in making any
      lifestyle change then conclude true;
    endif;
  action:
    write "<Exercise motivation> and <Exercise Female> and
    <Exercise Stagel> and <Exercise Link2>";
//end:
```

Protocols representation languages

❖ Proforma

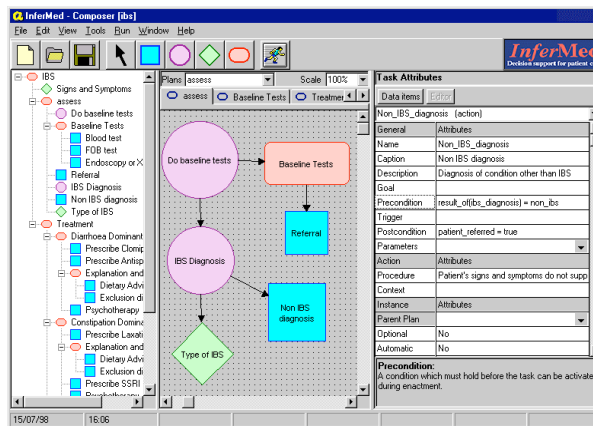
- ❖ Captures the logical and procedural aspects of a protocol as 'TASKS'
 - ❖ Plans are the basic building blocks of a guideline and may contain any number of tasks of any type, including other plans.
 - ❖ Decisions are taken at points where options are presented, e.g. whether to treat a patient or carry out further investigations.
 - ❖ Actions are typically clinical procedures (such as the administration of an injection) which need to be carried out.
 - ❖ Enquiries are typically requests for further information or data, required before the guideline can proceed.



Protocol Representation Languages

❖ Proforma

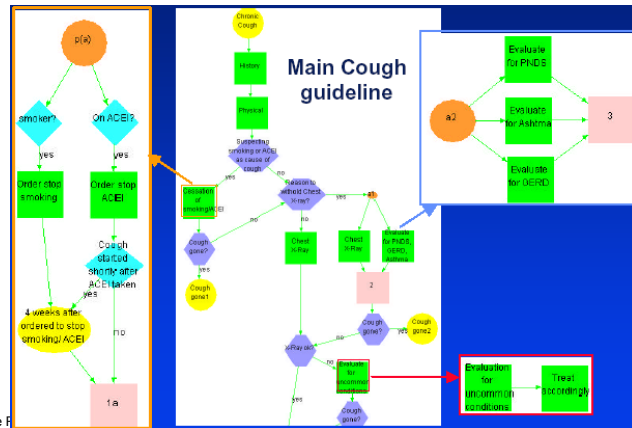
- ❖ A tool to computerize protocols



Protocol Representation Languages

❖ GLIF (Guideline Interchange Format)

- ❖ Object oriented protocol specification model.
- ❖ Based on ARDEN syntax.
- ❖ Medical data model is based on HL7 Reference Information Model (RIM)



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