Material on Website

- http://www.smi.stanford.edu/projects/sage/tutorial06/SAGEWorkbench.zip or obtain CD or copy from flash drives
- Unzip SAGEWorkbench to C:\
- Run Workbench from 'startImmunization.bat'
- Apelon DTS plugin user/password: *sageuser/sageuser*
- Documentation folder
  - US Immunization source documents
  - SW Tu Medinfo paper
  - Hrabak/Campbell draft paper on Immunization vocabulary

Modeling Clinical Guidelines using the SAGE Protégé Guideline Workbench

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Introductions

- Who are we?
- Who are you?
  - Training and experience:
    - Clinical understanding
    - Computer science background
  - Interest
    - Seeing an example of using Protégé to develop applications
    - Employing Protégé to create decision support technology supporting guidelines

Learning Objectives

1. Appreciate the challenges in formulating guidelines into executable algorithms
2. Understand the standardization challenges to creation of interoperable guideline decision support
3. Describe the basic procedures of SAGE guideline model formulation
4. Understand the features and function of Protégé environment contributions to SAGE
5. Enumerate the plug-in developments and feature enhancements to Protégé developed for the SAGE guideline workbench
6. Participate in the development and testing of an immunization guideline using Protégé

Overview

- **Overview of guidelines and challenges to decision support development**

SAGE guideline modeling process:

- Introduction: Modeling the immunization guideline
- Creating the implementation scenarios and assembling decision logic
- Developing concept inventory: employing standard vocabulary
- Specifying information queries
- SAGE guideline model and workbench
- Encoding immunization guideline
- Validating the development
- Demonstration: SAGE at work

What are Guidelines?

- Guideline(n): a cord or rope to aid passage over a difficult point (Merriam-Webster)
- Systematic statements of evidence-based policy rules or principles to assist clinicians and patients make decisions on healthcare alternatives
- Characteristics
  - May be developed by government agencies at any level, institutions, professional societies, governing boards, or by convening expert panels.
  - May be in narrative, outline, flowchart or tabular forms
  - Need to be formalized to provide computerized clinical decision support at point of care

Why Study Guidelines?

President's Information Technology Advisory Committee
"Transforming Health Care through Information Technology" (2001)

Findings:

- The U.S. lacks a broadly disseminated and accepted national vision for information technology in health care
- The introduction of integrated decision-support systems that can proactively foster best practices and reduce errors requires enhanced information-technology methods and tools

Recommendations:

- …
- Develop guidelines based on evidences and best practices
- Implement guidelines so that they are usable effectively at the point of care, including embedded decision support that is continually updated as new evidence accumulates

Clinical Decision Support: Comments on a long History

- 1970-80s: Basic studies in expert systems and reminder technology convinced many of CDSS importance
- 1990s:
  - Developing importance of ontologies in scalable systems design
  - Development of SNOMED and Read as reference terminologies for clinical care systems
  - Appearance of practice guidelines as authoritative reference for standard of care

Clinical Decision Support: Comments on a long History

Musen, M. A. (1999). Scalable Software Architectures for Decision Support. *Methods of Information in Medicine* **38**: 229-238.:

CDSS = domain ontology + problem solving method and

- 1…pert systems and r…ed many of CDSS im…
- 1990s:
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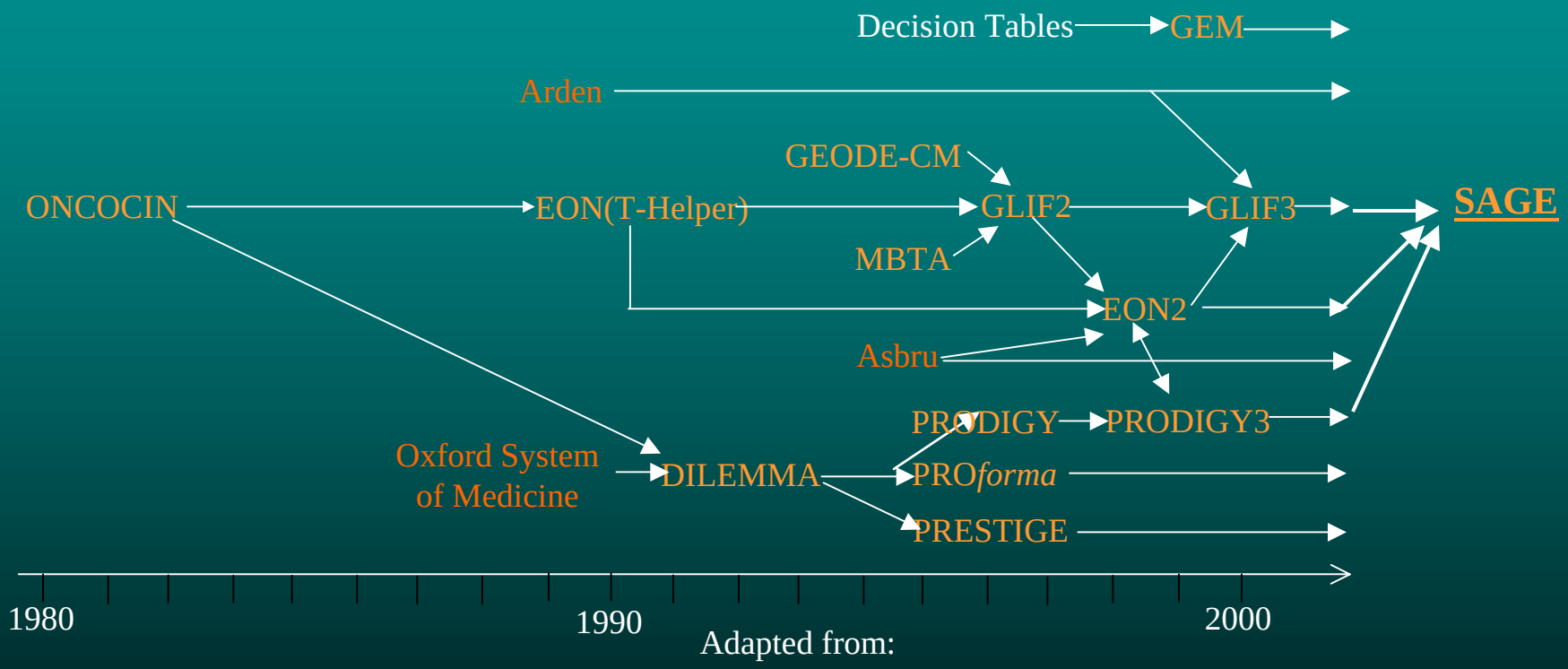
(Partial) Guideline Model Chronology



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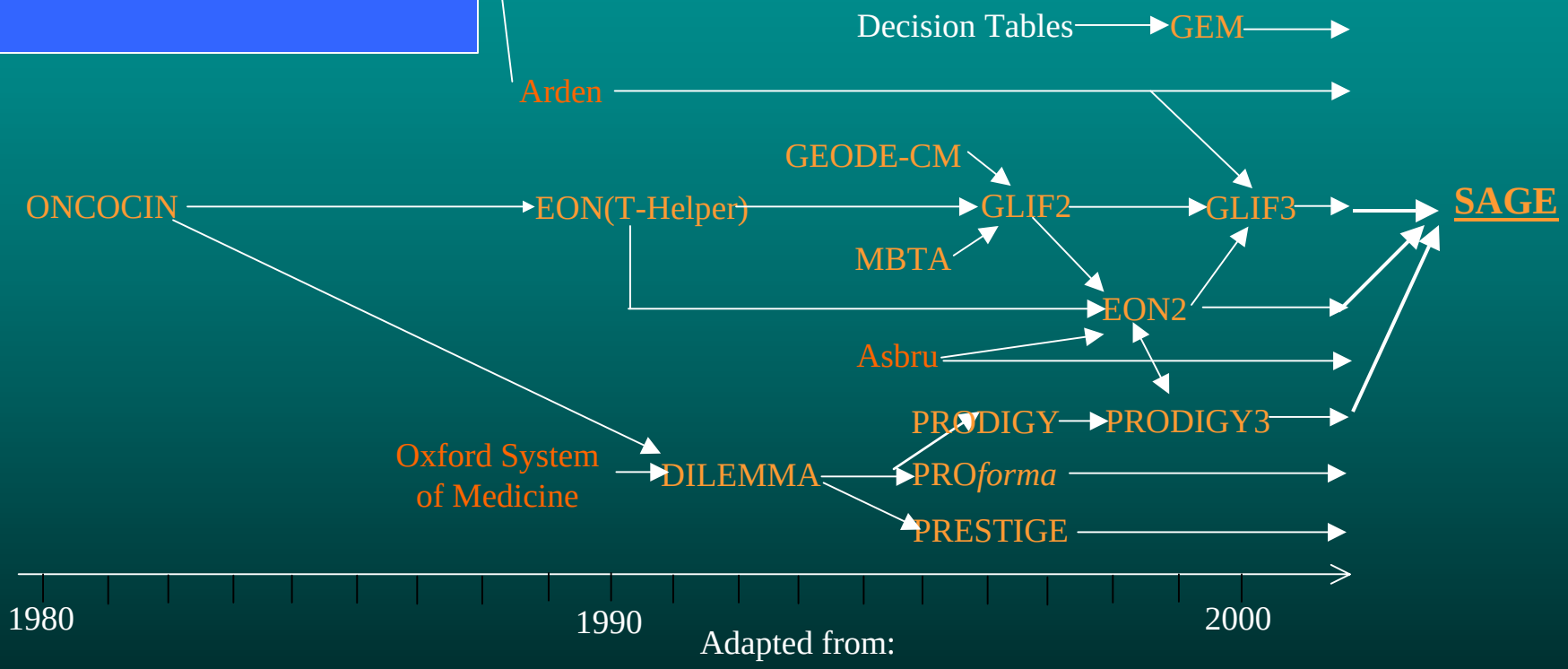
Oriented to single rules; ANSI standard; curly braces problems



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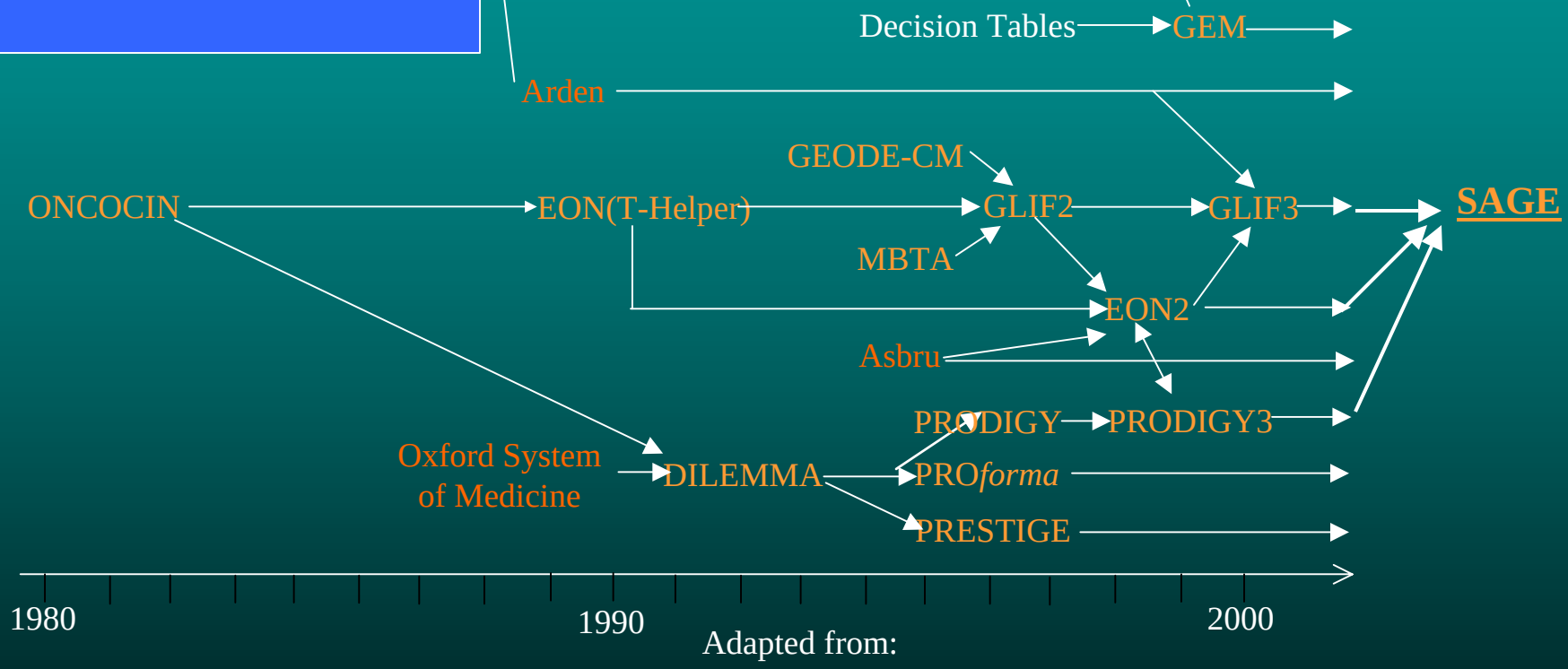
Oriented to standardized mark-up publication; evolving



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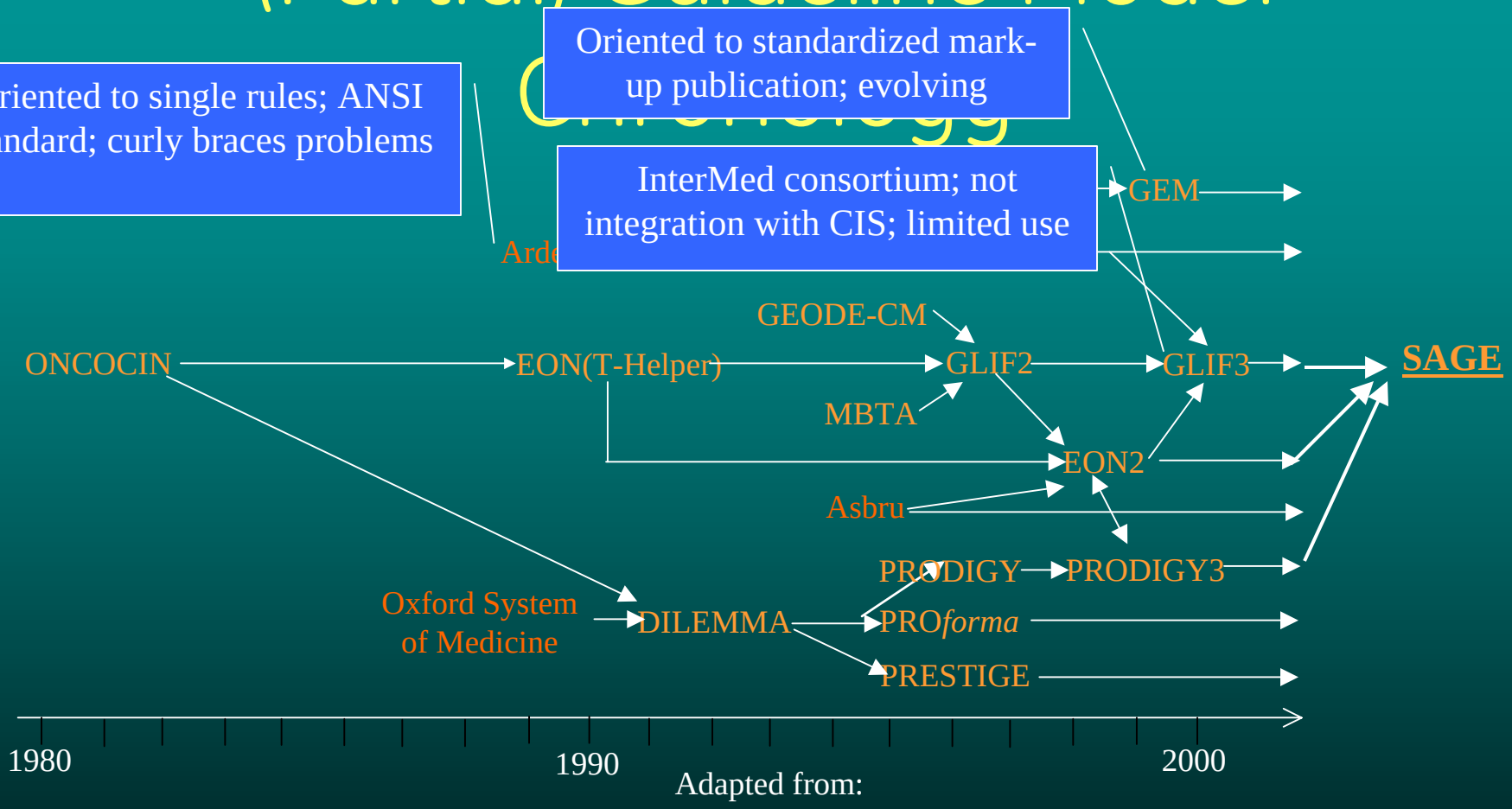

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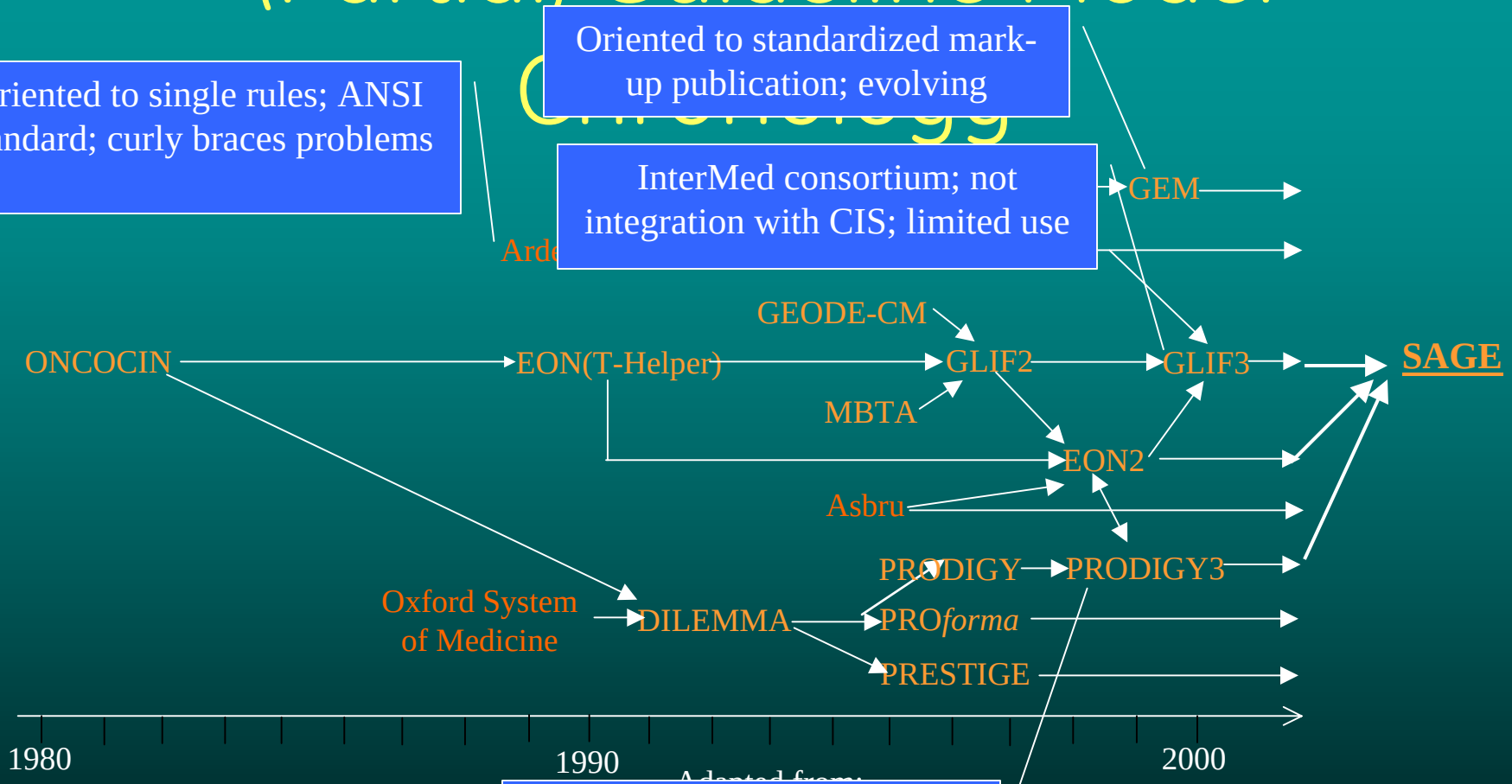

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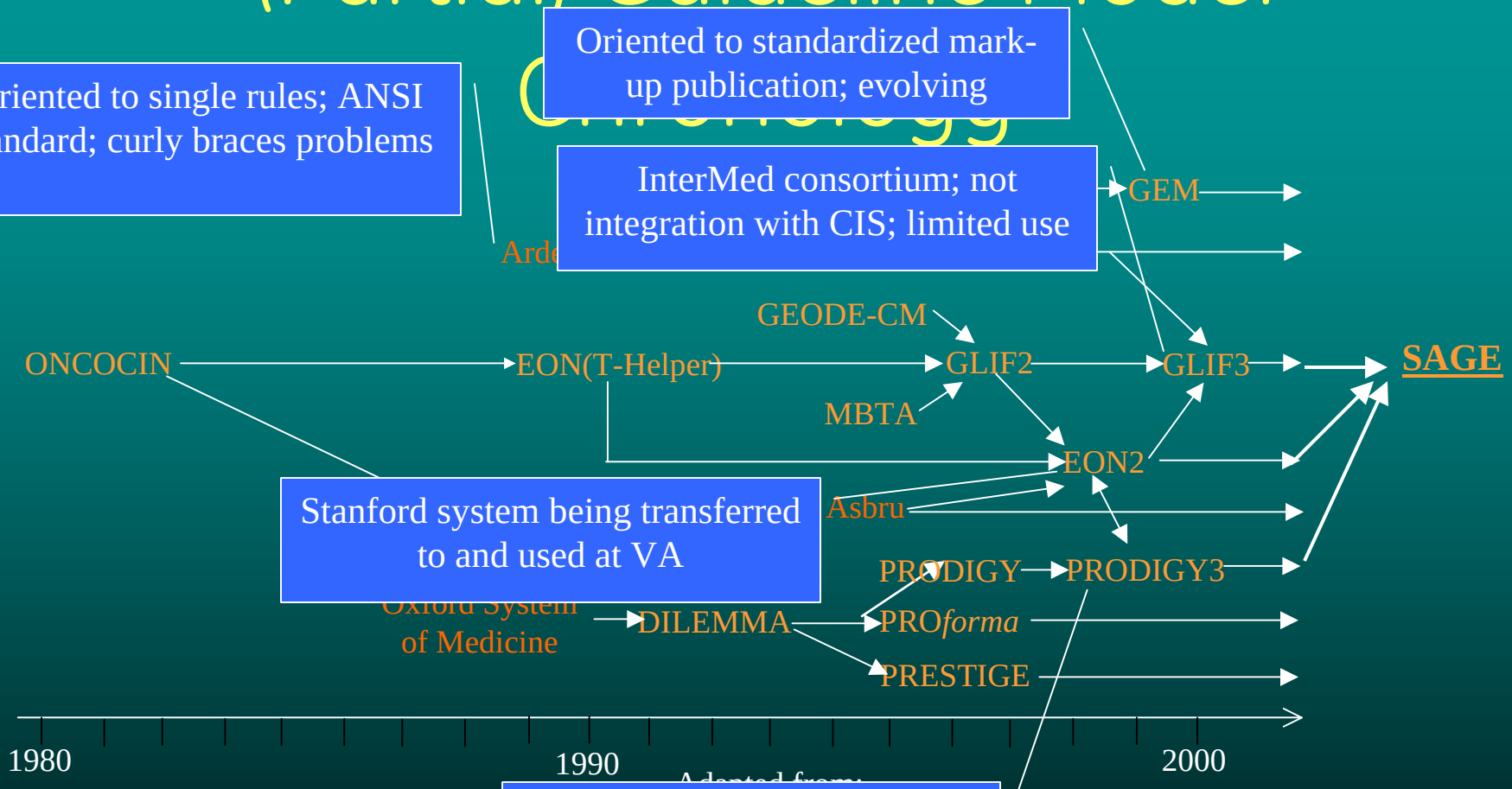

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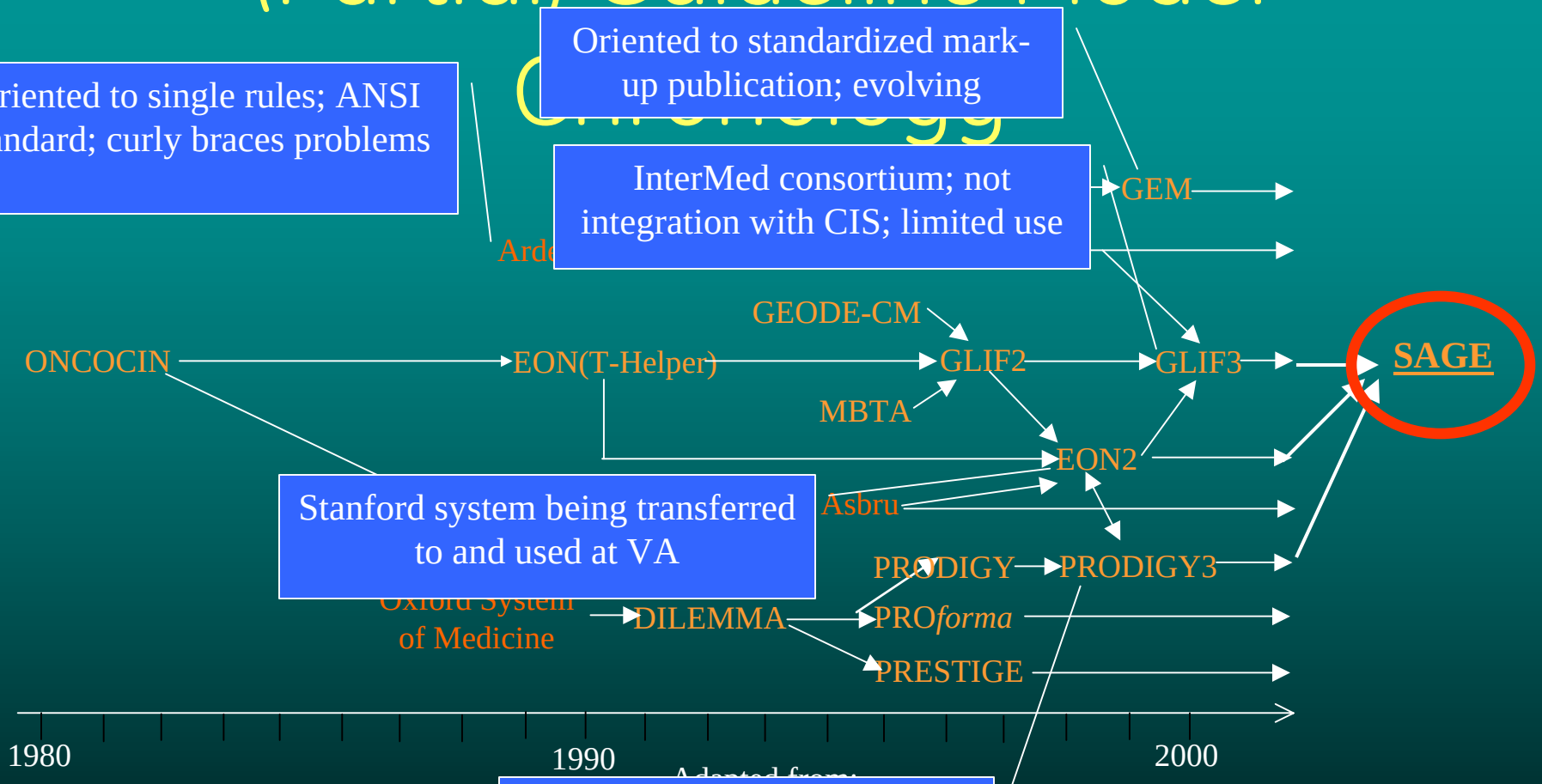

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Requirements of CDSS

- Automated within clinical workflow
- Provision of guidance for care (not diagnoses)
- Timely delivery at point of decision making
- Computer-based decision support; linked with computer patient data base
- Easily encoded and maintained knowledge bases

Guideline Decision Support Prerequisites

1) Identifying an opportunity for clinical process improvement
2) Recognizing an authoritative body of recommendations based upon outcomes research (or reputable best practice model)
3) Maintaining a data base of reliable and useful clinical data
4) Having the tools at hand to organize the knowledge into computable form
5) Obtaining support and involvement of the clinical community
6) Assuring use of vendor tools for implementing within clinical record software

SAGE Project Overview

- Collaborative research and development project to develop a standards-based technology to enable encoding and dissemination of guidelines in executable format.
- Infrastructure will employ informatics standards including Protégé open source workbench, HL7 RIM, SNOMED CT and LOINC, and deployment technology to support encoding and dissemination of guidelines across vendor platforms and throughout the spectrum of care
- Guideline deployment technology will present guideline content to clinicians through active, patient-specific recommendations surfaced through functions of the local clinical information system, and integrated into the care workflow

SAGE is partially supported under a grant from the U.S. Department of Commerce, National Institute of Standards and Technology, Advanced Technology Program, Cooperative Agreement Number 70NANB1H3049.

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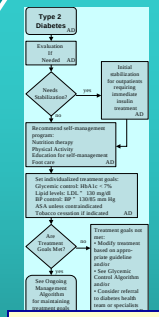
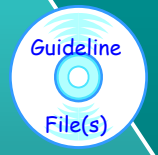
SAGE Infrastructure: Guideline Encoding



Guideline Workbench

SAGE Guideline Model



Patient Data Model
(Virtual Medical Record)

Care Workflow Model

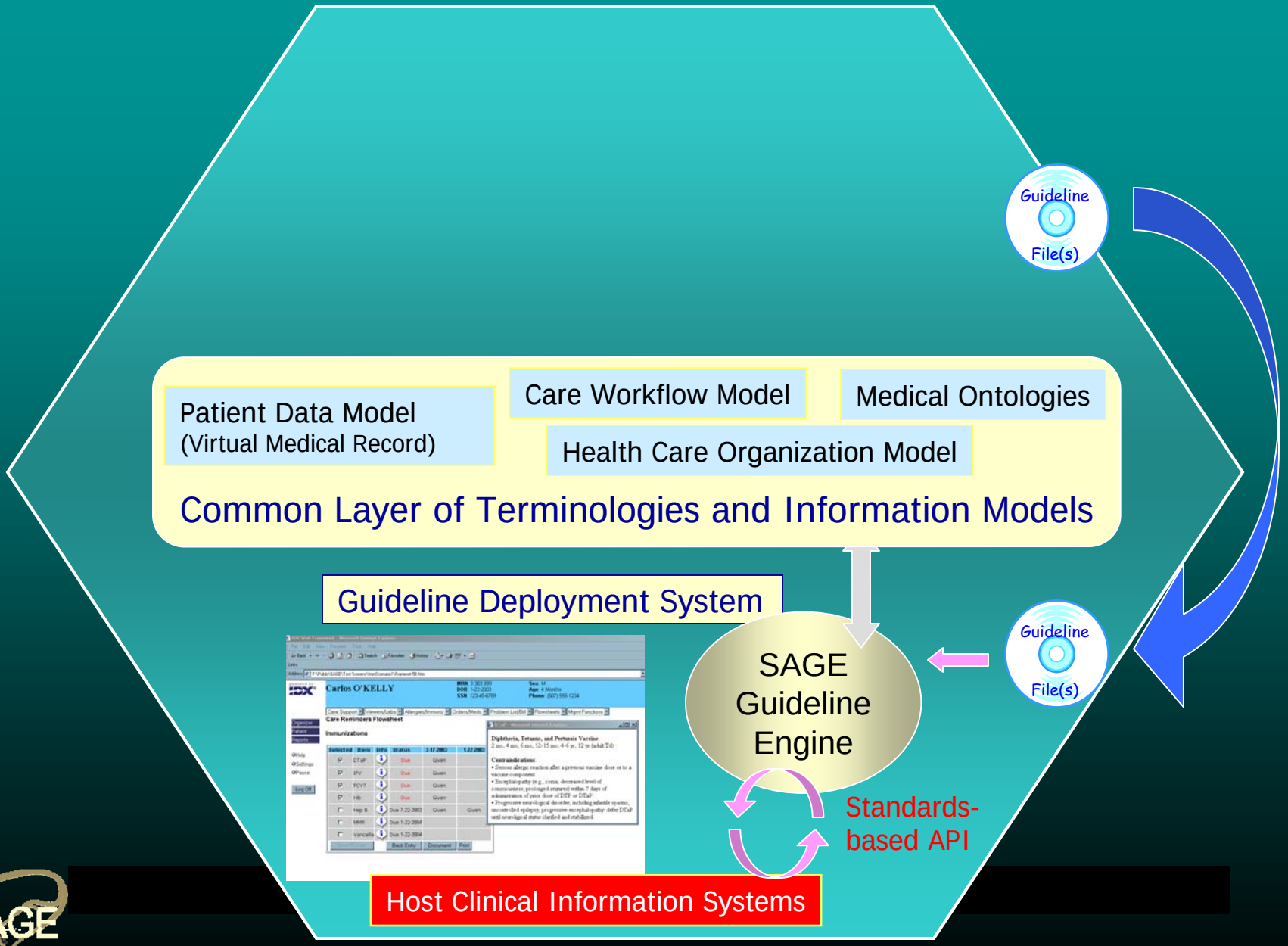
Medical Ontologies

Health Care Organization Model

Common Layer of Terminologies and Information Models

SAGE

SAGE Infrastructure: Guideline Execution



Use of Protégé for Guideline Modeling

- Protégé a good rapid prototyping tool
  - For developing guideline ontologies
  - For encoding instances of guidelines
- Protégé an extensible knowledge-engineering platform
  - Plugin architecture allows SAGE-specific extensions
  - API allows decision-support application to access knowledge base

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SAGE Guideline Encoding Process

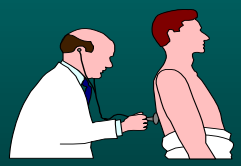
1. Assemble Source Guidelines

3. Formalize Guideline Logic

5. Formalize Vocabulary Inventory

4. Define Guideline Concepts

6. Specify Information Queries



2. Envision Clinical Scenarios

Guideline Installation and Execution

7. Encode Guideline Knowledgebase

SAGE

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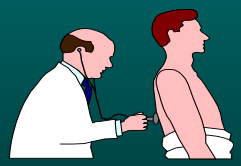

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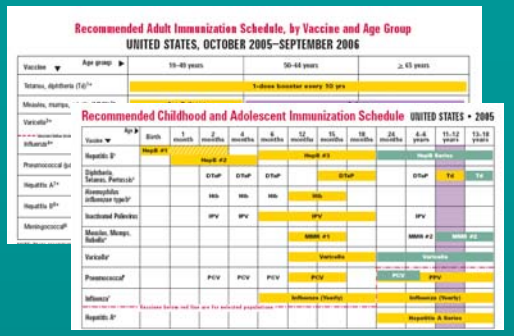
Source Guideline: CDC Immunizations



- US Center for Disease Control(CDC): Advisory Committee on Immunization Practices issues vaccination schedules (handout)
- Birth-death guideline for all vaccinations advised for US healthcare
- 75 complex decision rules
- 172 source clinical concepts
- 1200 criteria in run-time logic

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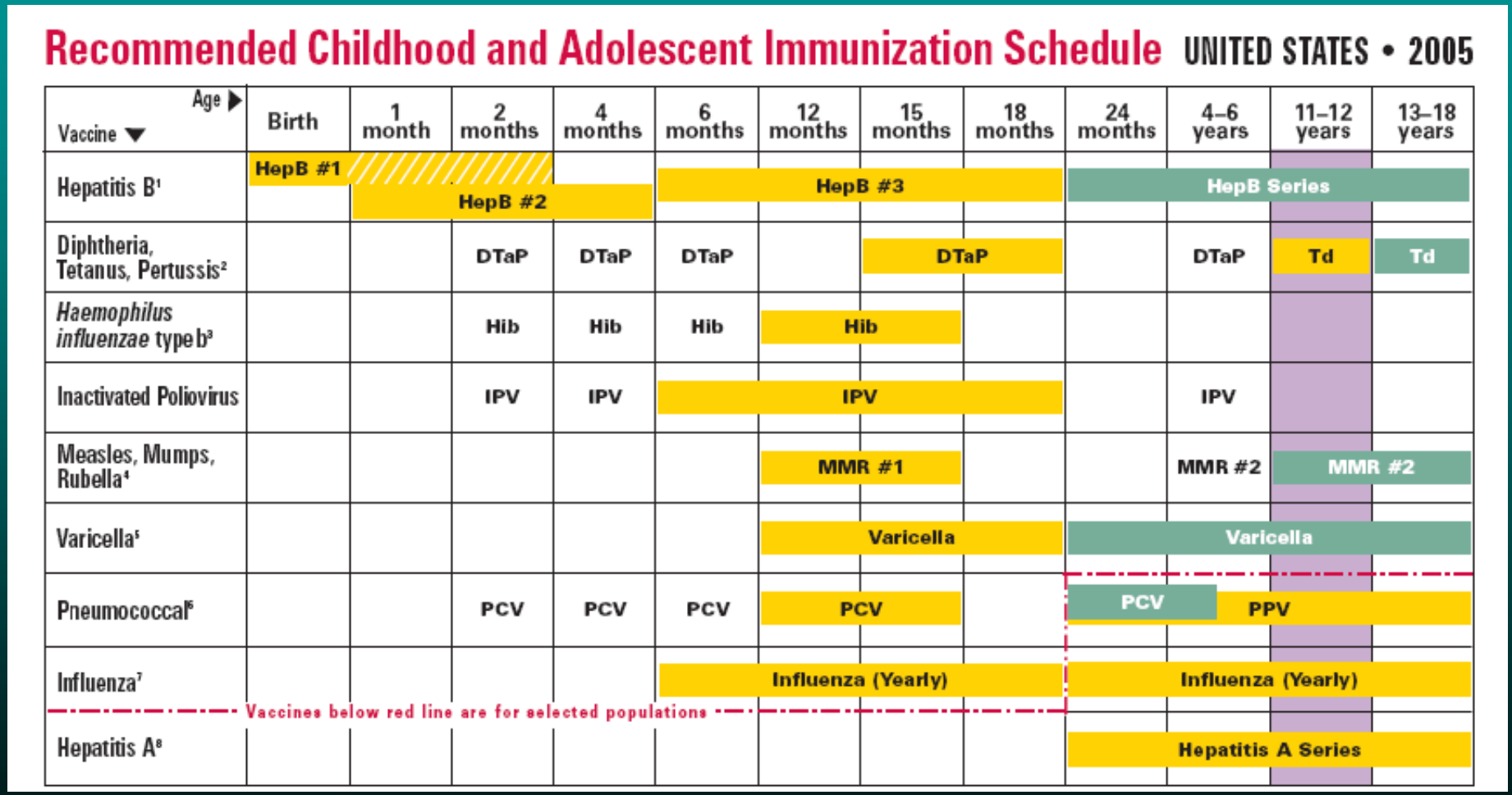
Pediatric Immunization Sub-guideline Schedule



Recommended Childhood and Adolescent Immunization Schedule UNITED STATES • 2005

Vaccine \ Age	Birth	1 month	2 months	4 months	6 months	12 months	15 months	18 months	24 months	4–6 years	11–12 years	13–18 years
Hepatitis B[1]	HepB #1	HepB #2			HepB #3				HepB Series			
Diphtheria, Tetanus, Pertussis[2]			DTaP	DTaP	DTaP		DTaP			DTaP	Td	Td
Haemophilus influenzae type b[3]			Hib	Hib	Hib	Hib						
Inactivated Poliovirus			IPV	IPV	IPV					IPV		
Measles, Mumps, Rubella[4]						MMR #1				MMR #2	MMR #2	
Varicella[5]						Varicella			Varicella			
Pneumococcal[6]			PCV	PCV	PCV	PCV			PCV		PPV	
Influenza[7]					Influenza (Yearly)				Influenza (Yearly)			
Vaccines below red line are for selected populations												
Hepatitis A[8]									Hepatitis A Series			

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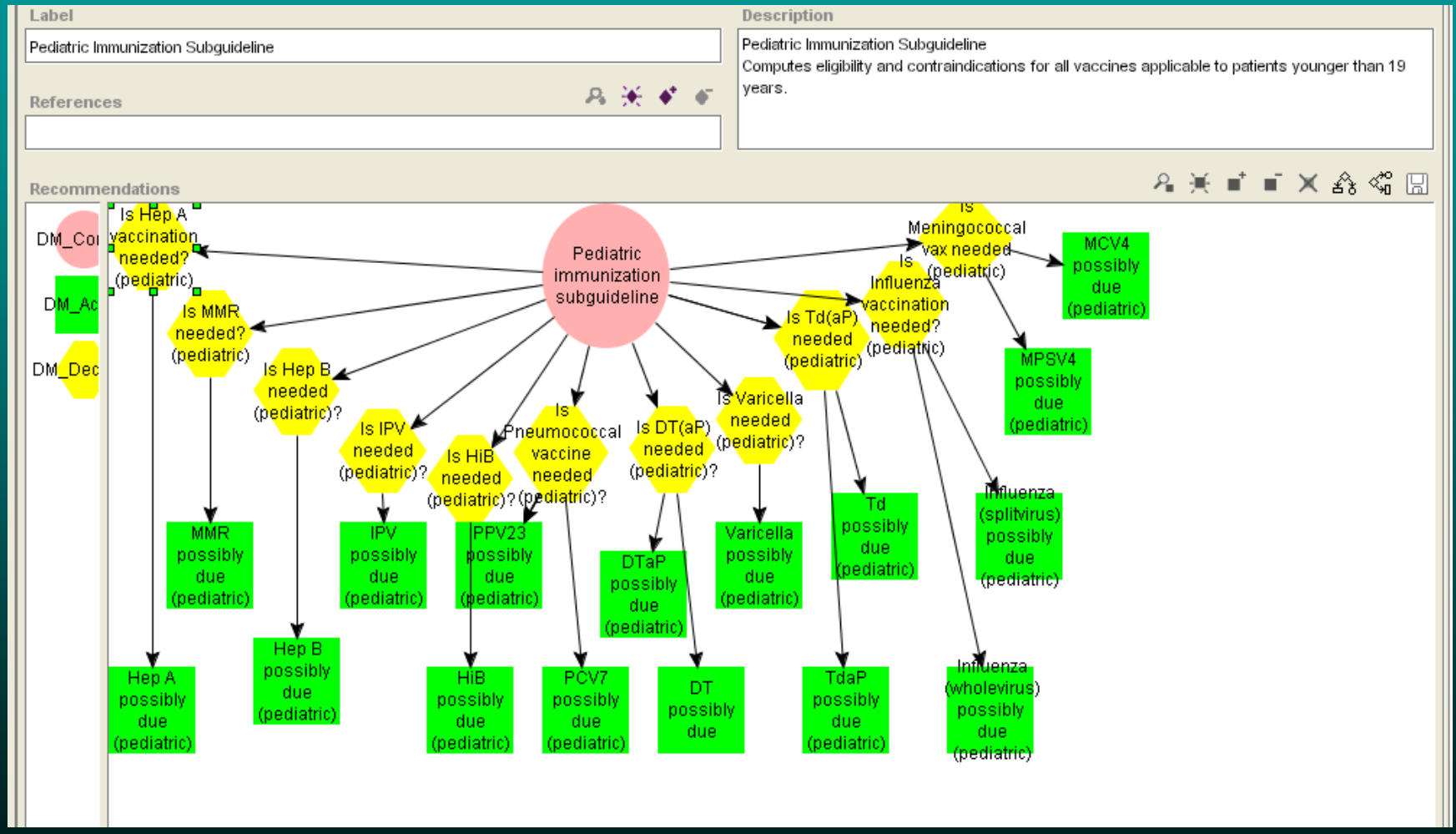
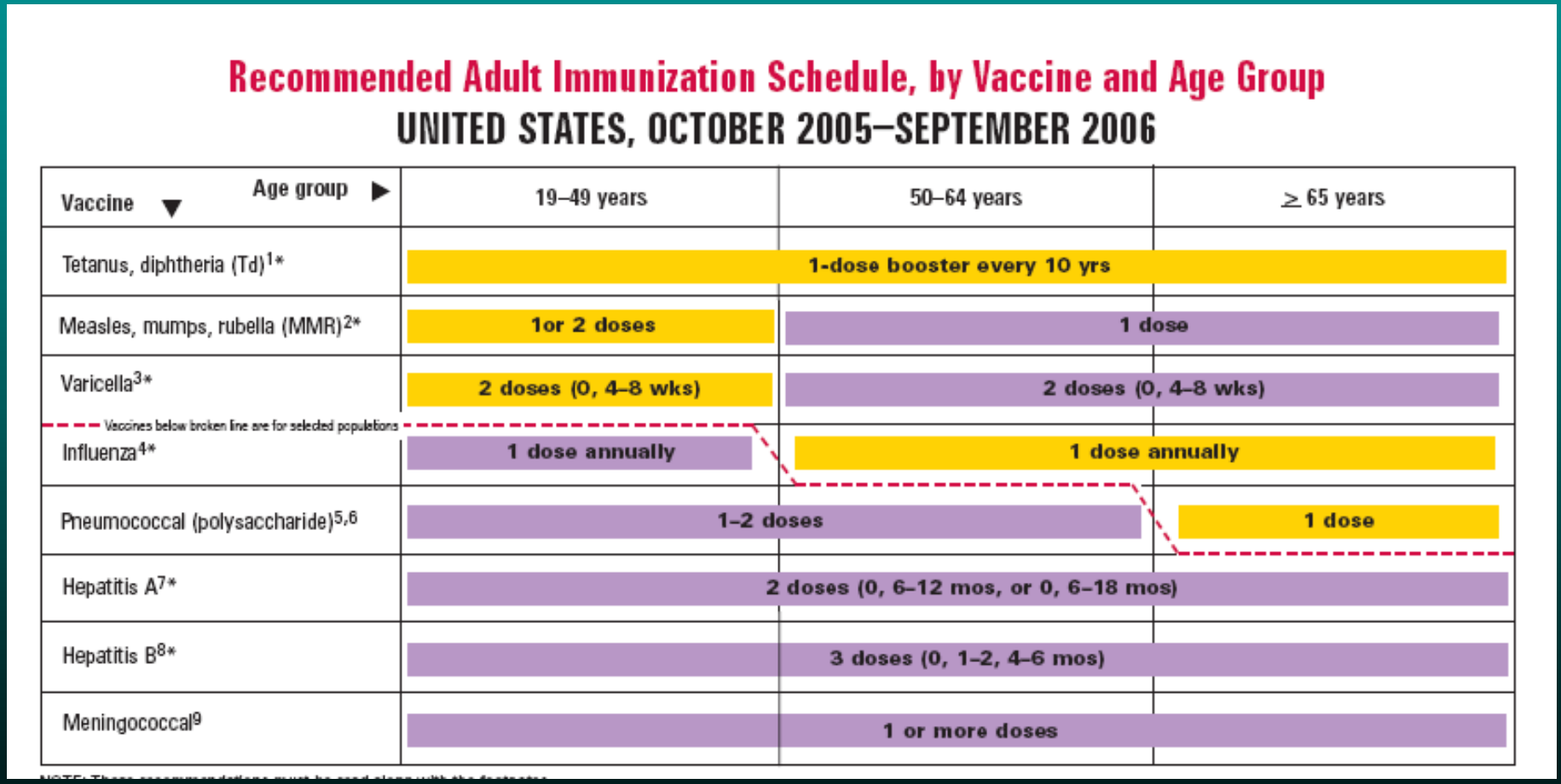
SAGE Pediatric Sub-guideline



Adult Immunization Sub-guideline Schedule



Recommended Adult Immunization Schedule, by Vaccine and Age Group

UNITED STATES, OCTOBER 2005–SEPTEMBER 2006

Vaccine ▼ / Age group ▶	19–49 years	50–64 years	≥ 65 years
Tetanus, diphtheria (Td)[1]*	1-dose booster every 10 yrs		
Measles, mumps, rubella (MMR)[2]*	1or 2 doses	1 dose	
Varicella[3]*	2 doses (0, 4–8 wks)	2 doses (0, 4–8 wks)	
Vaccines below broken line are for selected populations			
Influenza[4]*	1 dose annually	1 dose annually	
Pneumococcal (polysaccharide)[5,6]	1–2 doses		1 dose
Hepatitis A[7]*	2 doses (0, 6–12 mos, or 0, 6–18 mos)		
Hepatitis B[8]*	3 doses (0, 1–2, 4–6 mos)		
Meningococcal[9]	1 or more doses		

NOTE: These recommendations must be read along with the footnotes.

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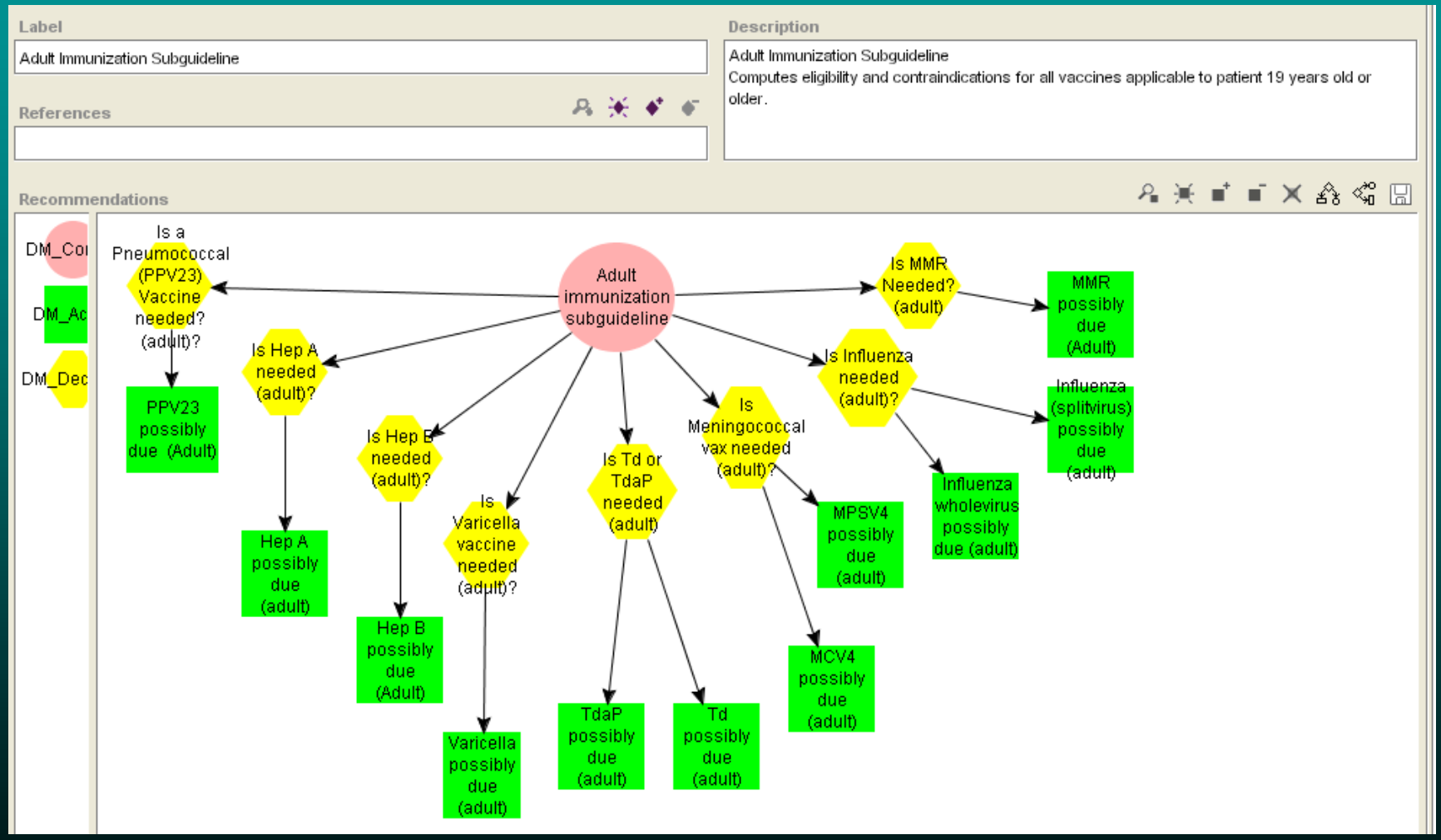
SAGE Adult Sub-guideline



Guideline Focus

- For this discussion we will employ US adult pneumococcal guideline as focus of authoritative source

Use Case: US Adult Pneumococcal Guideline

TABLE 2. Recommendations for the use of pneumococcal vaccine

Groups for which vaccination is recommended	Strength of recommendation*	Revaccination†
Immunocompetent persons§		
Persons aged ≥65 years	A	Second dose of vaccine if patient received vaccine ≥5 years previously and were aged <65 years at the time of vaccination.
Persons aged 2–64 years with chronic cardiovascular disease,¶ chronic pulmonary disease,** or diabetes mellitus	A	Not recommended.
Persons aged 2–64 years with alcoholism, chronic liver disease,†† or cerebrospinal fluid leaks	B	Not recommended.
Persons aged 2–64 years with functional or anatomic asplenia§§	A	If patient is aged >10 years: single revaccination ≥5 years after previous dose. If patient is aged ≤10 years: consider revaccination 3 years after previous dose.
Persons aged 2–64 years living in special environments or social settings¶¶	C	Not recommended.
Immunocompromised persons§		
Immunocompromised persons aged ≥2 years, including those with HIV infection, leukemia, lymphoma, Hodgkins disease, multiple myeloma, generalized malignancy, chronic renal failure, or nephrotic syndrome; those receiving immunosuppressive chemotherapy (including corticosteroids); and those who have received an organ or bone marrow transplant.	C	Single revaccination if ≥5 years have elapsed since receipt of first dose. If patient is aged ≤10 years: consider revaccination 3 years after previous dose.

Overview

- Overview of guidelines and challenges to decision support development

SAGE guideline modeling process: Introduction

- Introduction: Modeling the immunization guideline
- **Creating the implementation scenarios and assembling decision logic**
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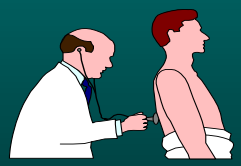

2. Envision Clinical Scenarios

Guideline Installation and Execution

7. Encode Guideline Knowledgebase

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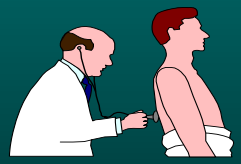

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Creating the Guideline Scenarios

- Guidelines must be reflected against patterns of care and clinical work plans to identify opportunities for productive intervention
- Should be integrated within an efficient work model, not controlling or distorting work activities
- Should provide guidance to the individual who is best suited to intervene when intervention is appropriate and timely

Creating Guideline Scenarios

- Generally multi-faceted interventions which reinforce each other across the enterprise are more effective
- Physicians are not always the best targets for effective intervention
- The recipient community should be educated in the nature and rationale for the guideline; acceptance should be obtained; CDSS should only support the process identified as ideal
- Implementation scenarios will be specific to the organization, the clinical workflow and the capabilities of the information system

Primary Care Visit Scenario

- Check-in process
- Nurse interaction
- Physician visit
- Variable check-out process

Primary Care Visit Scenario

- Check-in process
  - Patient arrives at primary care office requesting care.
  - The patient is checked in to clinic
- Nurse interaction
  - Patient is called for preparation by the nurse.
  - The nurse logs onto the clinic information system and selects the patient record.
  - Vitals are taken and entered into the CIS
- Physician visit
  - Physician assesses patient and makes recommendations/orders
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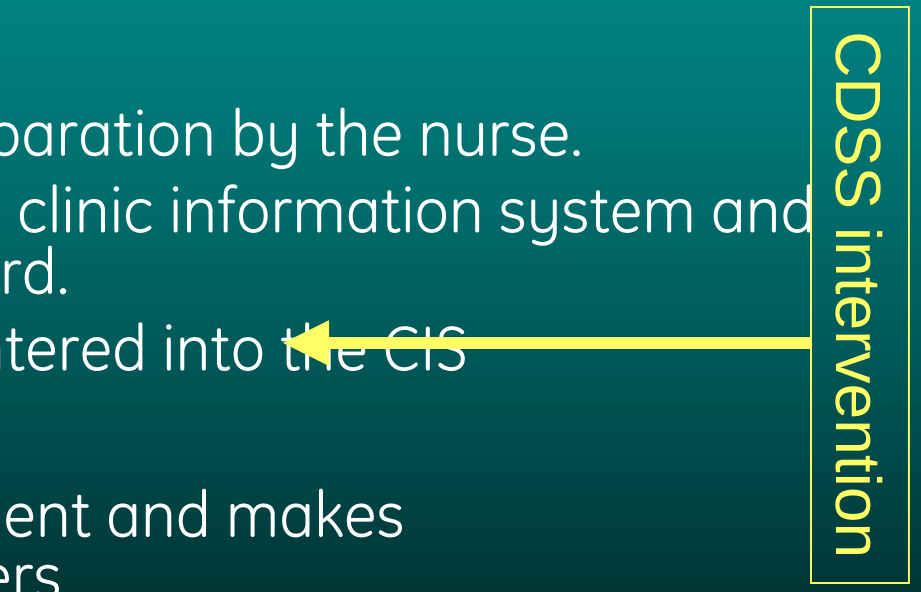

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Primary Care Visit Scenario

- CDSS is triggered
- Review of patient's record for indication/contraindication:
  - –vaccination history
  - –problem list
  - –procedure history
- Physician notified of due, but contraindicated vaccines
- Nurse informed of eligibility and
- Vaccination information sheets are printed for the patient or parent to read.
- The nurse is prompted to obtain and document consent and verify that the patient does not have an inter-current illness that would prevent vaccination today.

CDSS intervention

Primary Care Visit Scenario

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SAGE

Primary Care Visit Scenario

- Clinical record assessed for any known deferral reasons and those vaccines are removed from the list of those to be administered.
- Automated care orders are placed in the system for the vaccines which the patient is to receive.
- The nurse charts against these care orders as she administers the vaccines to the patient, updating the master record.

CDSS intervention

Primary Care Visit Scenario

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Implementation Scenarios

- Focus upon a clinical opportunity
- Have a specified trigger (initiating information event)
- Are constructed with understanding of capabilities of CDSS and CIS; aware of available digital clinical data
- Include plans for decision support, recording of data required for good care, and monitoring of CDSS function

Population Management Scenario

- Every Sunday at midnight, a batch program starts within the clinical information system for a rural health clinic.
- The program checks each patient record within the practice and reviews the vaccination history and all record data pertinent to indications and contraindications for vaccinations.
- It identifies all patients who have come due for vaccines and issues a report for the clinic manager who coordinates the scheduling for patients who need immunization.

Neonatal Birth Scenario (Admission to Nursery)

- A baby is admitted to the nursery in a local hospital following birth in the L&D suite. The admission event is tracked by SAGE which checks for eligibility against the child's and mother's clinical records.
- SAGE recommends orders for Hepatitis B vaccine and Hepatitis immune globulin as appropriate.
- Orders for follow-up serologic testing at nine months of age are issued when exposure status is positive or uncertain.
- When mother's serologic status for Hep B is unknown, SAGE issues orders for maternal testing and tracks results until obtained.

Alternative Scenarios?

- All patients seeking service in the emergency department or urgent care facility have reminders issued for vaccines
- All patients being discharged from hospital have vaccine requirements reviewed and alerts issued
- The home health visitor has automated alerts generated for her scheduled list of patients who are due for vaccination
- The long term care facility is issued automated orders verifying eligibility for overdue vaccinations

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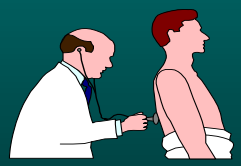

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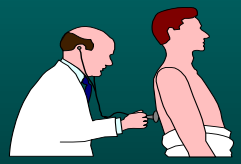
Guideline Installation and Execution



2. Envision Clinical Scenarios

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Use Case: US Adult Pneumococcal Guideline

TABLE 2. Recommendations for the use of pneumococcal vaccine

Groups for which vaccination is recommended	Strength of recommendation*	Revaccination†
Immunocompetent persons§		
Persons aged ≥65 years	A	Second dose of vaccine if patient received vaccine ≥5 years previously and were aged <65 years at the time of vaccination.
Persons aged 2–64 years with chronic cardiovascular disease,¶ chronic pulmonary disease,** or diabetes mellitus	A	Not recommended.
Persons aged 2–64 years with alcoholism, chronic liver disease,†† or cerebrospinal fluid leaks	B	Not recommended.
Persons aged 2–64 years with functional or anatomic asplenia§§	A	If patient is aged >10 years: single revaccination ≥5 years after previous dose. If patient is aged ≤10 years: consider revaccination 3 years after previous dose.
Persons aged 2–64 years living in special environments or social settings¶¶	C	Not recommended.
Immunocompromised persons§		
Immunocompromised persons aged ≥2 years, including those with HIV infection, leukemia, lymphoma, Hodgkins disease, multiple myeloma, generalized malignancy, chronic renal failure, or nephrotic syndrome; those receiving immunosuppressive chemotherapy (including corticosteroids); and those who have received an organ or bone marrow transplant.	C	Single revaccination if ≥5 years have elapsed since receipt of first dose. If patient is aged ≤10 years: consider revaccination 3 years after previous dose.

Decision Logic Inventory

Recommendation set: Adult Pneumococcal polysaccharide vaccine (PPV23)

Contraindication ::= Anaphylaxis reaction to pneumococcal vaccine

Deferral ::= Moderate of severe current illness

Indication::=

- Chronic cardiac disease or
- Chronic pulmonary disease excluding asthma or
- Diabetes mellitus or
- CSF leak or
- Hemodialysis patient or
- Health care worker or
- *Emergency response personnel* or
- Terminal complement component deficiencies or
- Chronic liver disease or
- Chronic alcoholism
- Cochlear implants
- Native American
- American Indian
- *Pregnancy*
- HIV+
- Congenital hypoplasia of spleen
- Splenic atrophy
- Splenectomy
- Chronic renal failure
- Institutionalzed
- Sickle cell disease
- Nephrotic syndrome
- Solid organ transplant
- Long term steroid therapy (12 glucocorticoid doses last six months)
- Antimetabolite therapy
- Chronic transfusion patient (more than 3 transfusions last 6 months)
- Immunodeficiency due to chemotherapy)
- Functional asplenia
- Multiple myeloma
- Generalized malignancy
- Bone marrow transplant recipient
- Congenital immunodeficiency
- Chemotherapy with alkylating agents within last 3 months
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A recommendation set is organized around one subset of guideline recommendations that can be implemented in a single work plan

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A recommendation set is organized around one subset of guideline recommendations that can be implemented in a single work plan

Requires review and integration of all decision elements: contraindications, deferrals, appropriate timing

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Decision Logic Inventory: Which Vaccine to Administer?

Rule 1: Adult First Dose PPV23

IF NO CONTRAINDICATION
AND
NO REASON FOR DEFERRAL
AND
NUMBER OF PPV23 VACCINE DOSES = 0
AND
INDICATION FOR PNEUMOCOCCAL VACCINE OR (AGE >= 65 YEARS)
THEN
ADVISE ADMINISTRATION OF PPV23 VACCINE

Rule 2: Adult Second dose PPV23

IF NO CONTRAINDICATION
AND
NO REASON FOR DEFERRAL
AND
NUMBER OF PPV23 VACCINE DOSES = 1
AND
((SUBGROUP INDICATIONS FOR REVACCINATION))
OR
((AGE > 65 YEARS) AND (PPV23 VACCINE DOSE GIVEN < AGE 65 YEARS)))
AND
PPV23 ADMINISTERED >= 5 YEARS PREVIOUSLY
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SAGE

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Specifies all clinical details required for complete deployment

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Overview

- Overview of guidelines and challenges to decision support development

SAGE guideline modeling process:

- Introduction: Modeling the immunization guideline
- Creating the implementation scenarios and assembling decision logic
- **Developing concept inventory: employing standard vocabulary**
- Specifying information queries
- SAGE guideline model and workbench
- Encoding immunization guideline
- Validating the development
- Demonstration: SAGE at work

SAGE Guideline Encoding Process

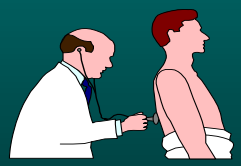
1. Assemble Source Guidelines

3. Formalize Guideline Logic

5. Formalize Vocabulary Inventory

4. Define Guideline Concepts

6. Specify Information Queries



2. Envision Clinical Scenarios

Guideline Installation and Execution

7. Encode Guideline Knowledgebase

SAGE

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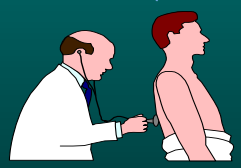

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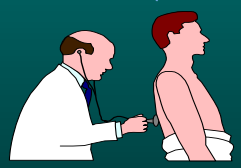

2. Envision Clinical Scenarios

Guideline Installation and Execution

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Reviewing Concept Inventory: Binding to standard vocabulary

- Concepts present in the guideline may require clinical discussion and definition
- Once clarified and matched into information model requirements, meaning must be reviewed against the appropriate vocabulary domain (SNOMED CT, LOINC) to assure that the meaning in the guideline corresponds to the meaning to be retrieved from the patient record

Clarifying Concept Definition…

- What is a chronic cardiovascular disease?
- Functional or anatomic asplenia?
- Who is an immunocompromised person?

Persons aged 2–64 years with chronic cardiovascular disease,¶ chronic pulmonary disease,** or diabetes mellitus	A	Not recommended.
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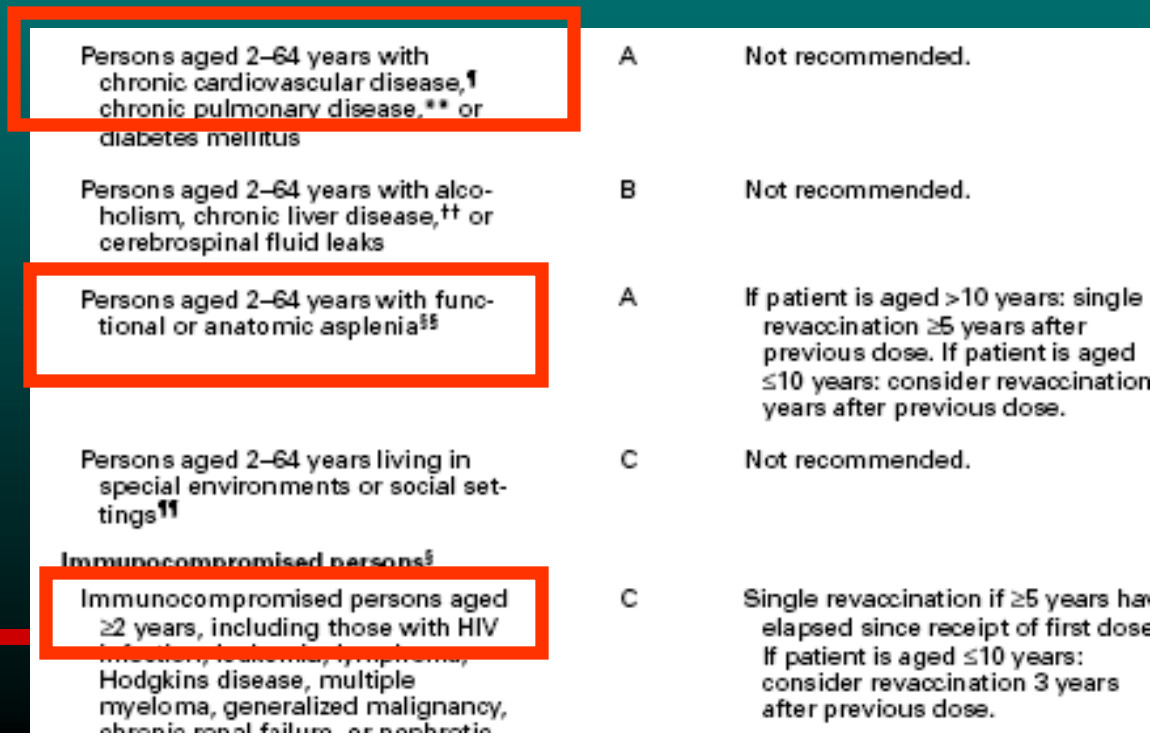

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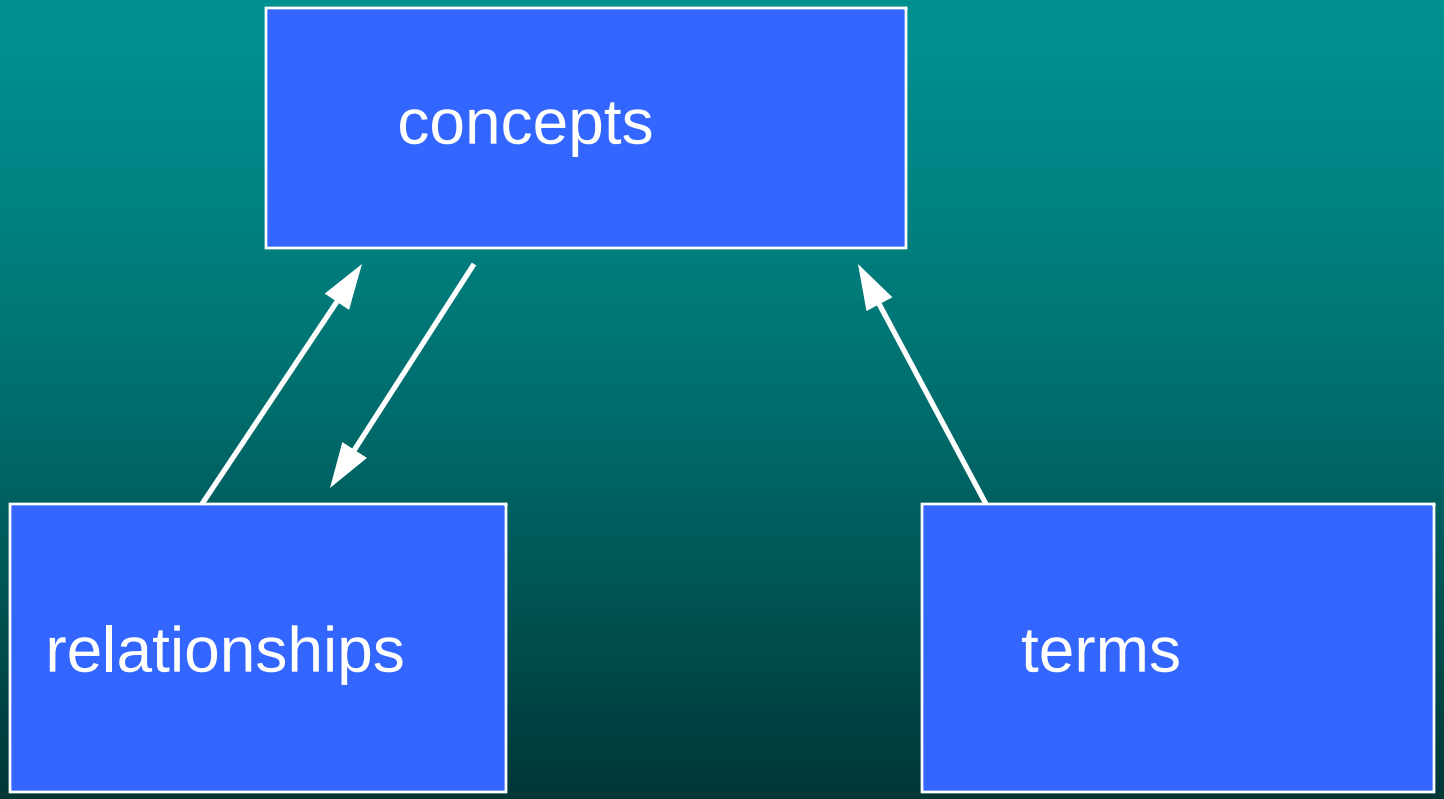
SNOMED CT ®

- Under development by the College of American Pathologists since the 1960's
- Provides a disambiguated, polyhierarchical representation of over 350,000 medical concepts, with approximately 1 million descriptions
- Under licensing agreement with the NLM
- Crossmaps to other commonly-used terminologies are built in
- Presently the most complete formal medical ontology in existence

Why do we need SNOMED CT?

- Synonyms
  - By assigning a unique numeric code to each medical concept, SNOMED CT formalizes clinical terminology.
- Subsumption
  - By representing the complete set of relationships among medical concepts, SNOMED CT automates classification logic.
- Ambiguity
  - By assigning different codes to homonyms, SNOMED CT disambiguates medical language.

SNOMED CT Structure



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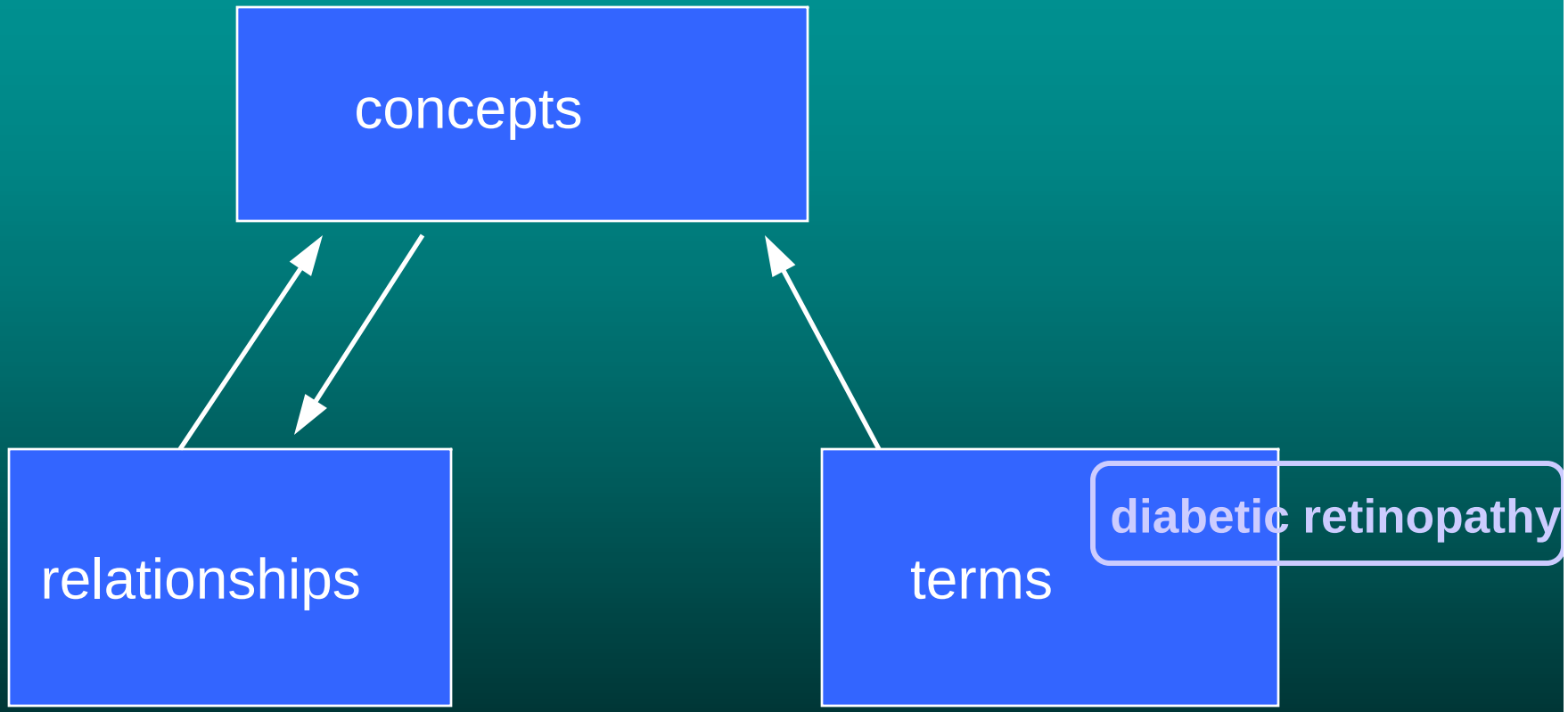

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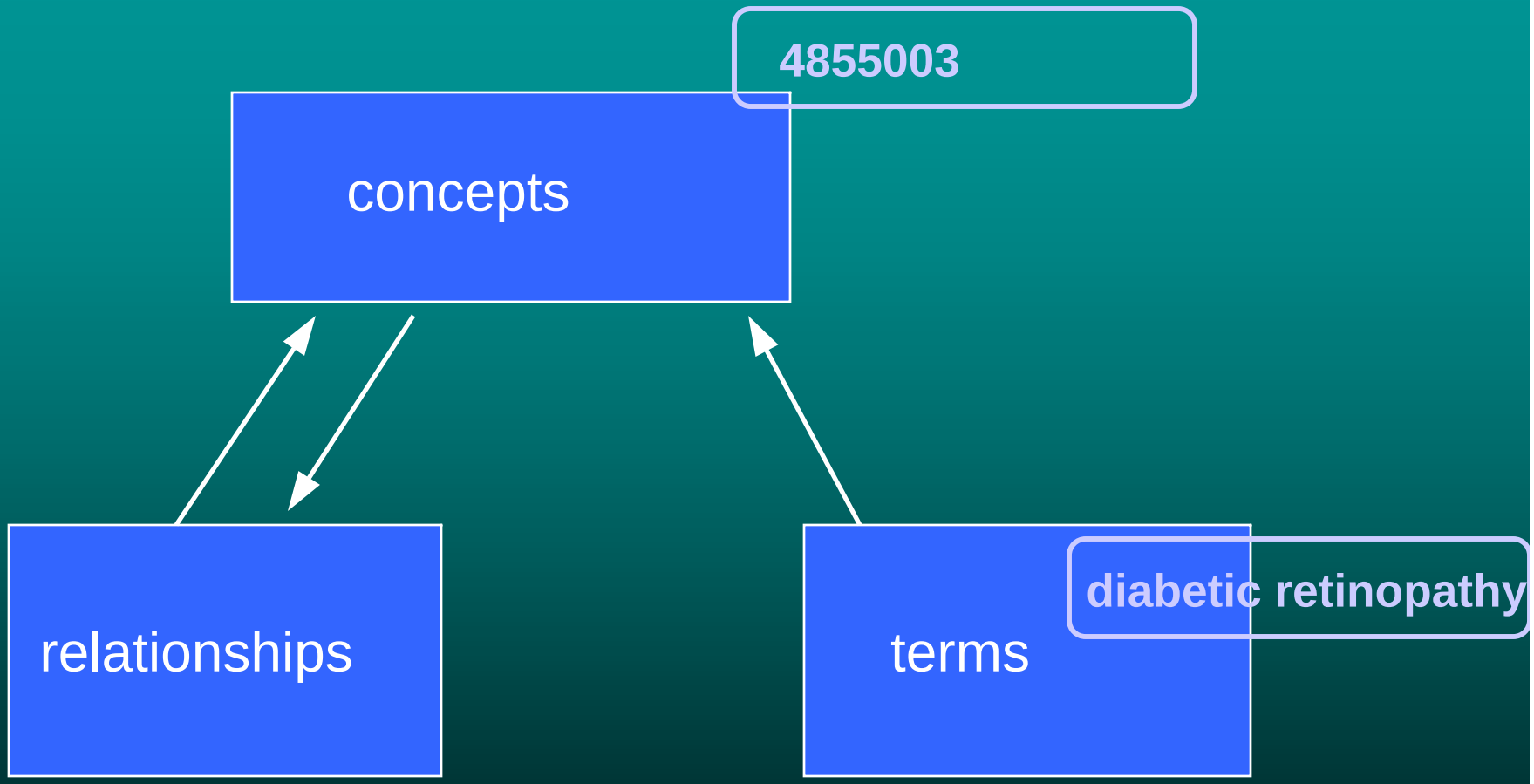

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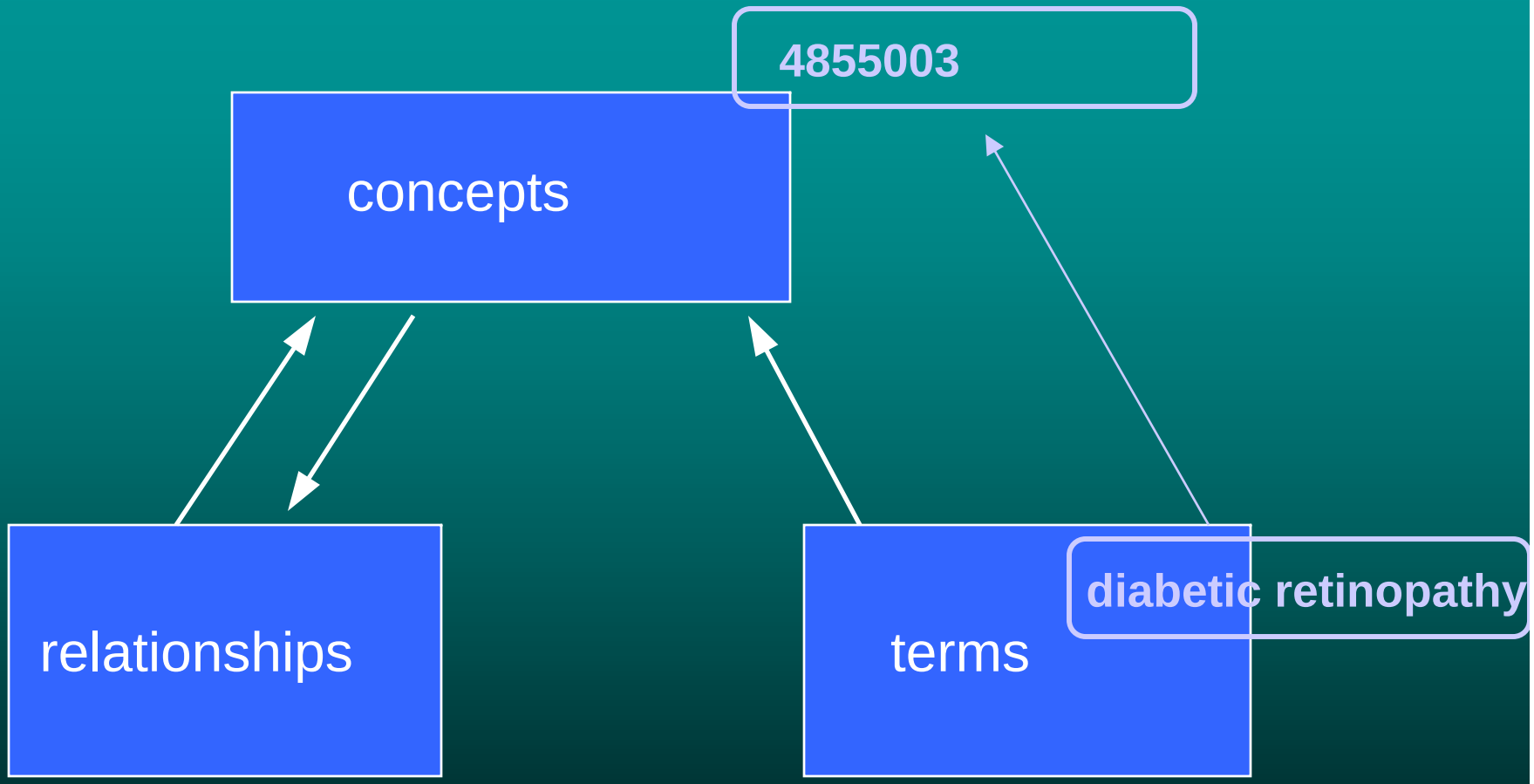

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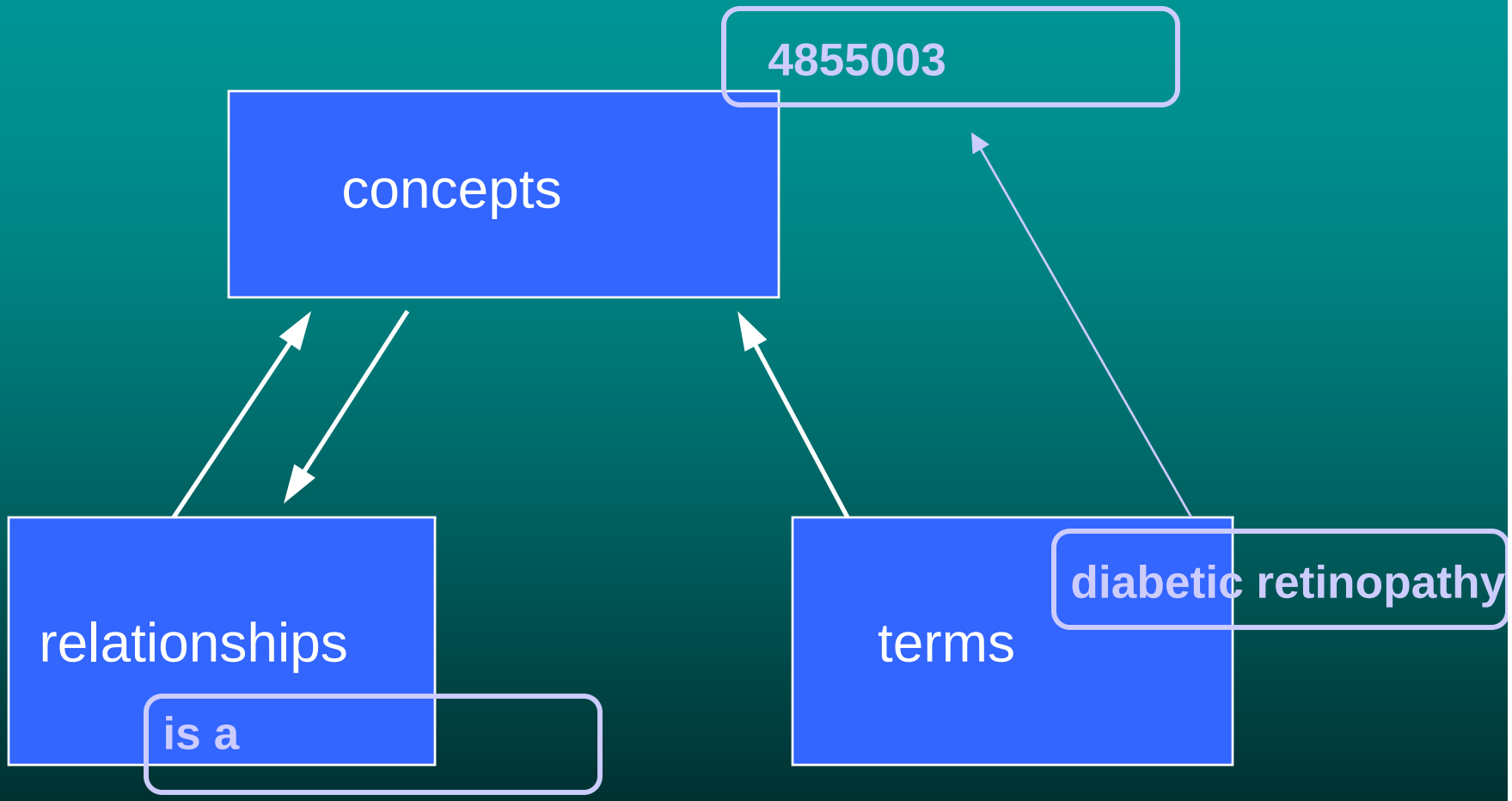

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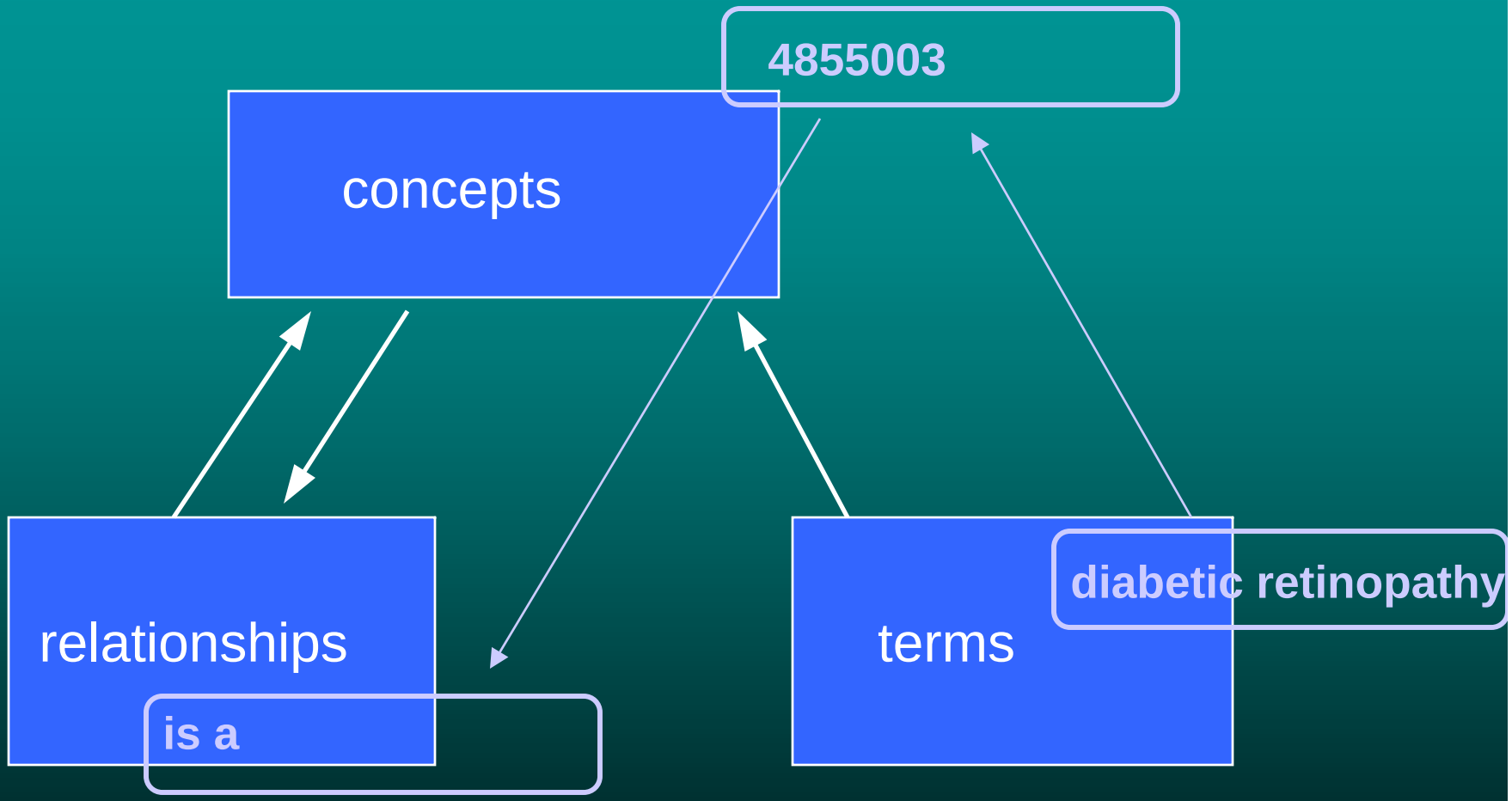

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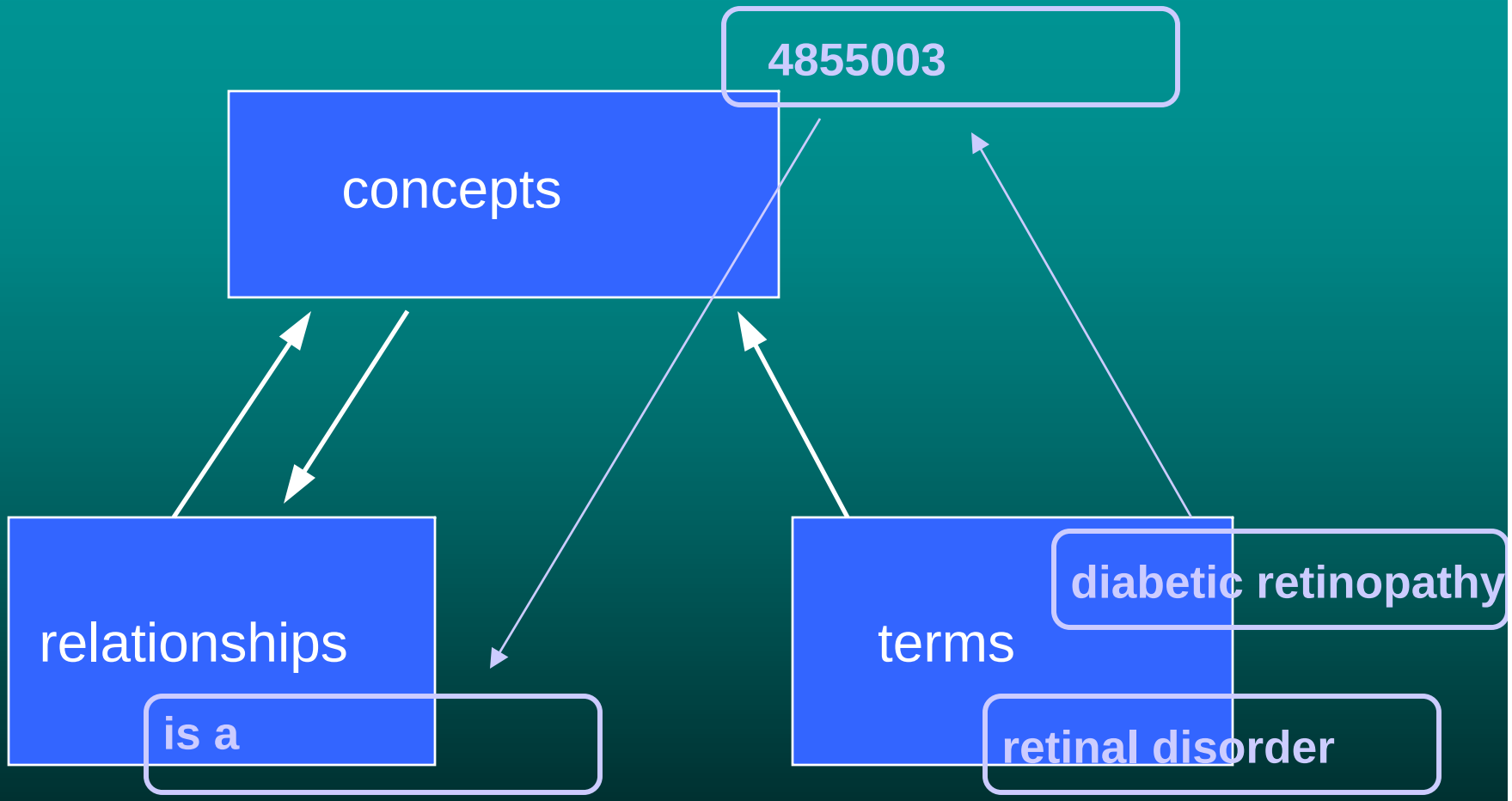

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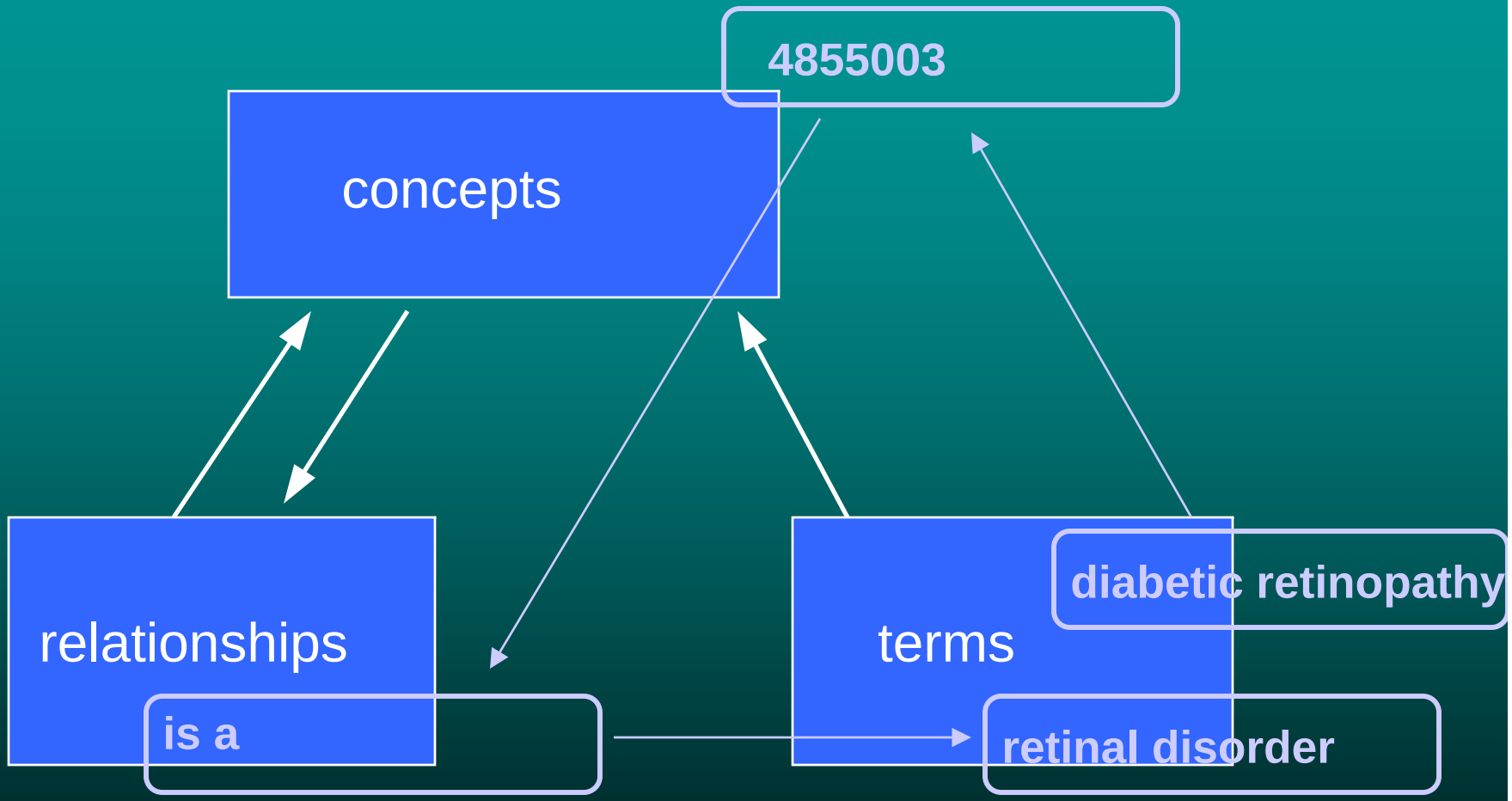

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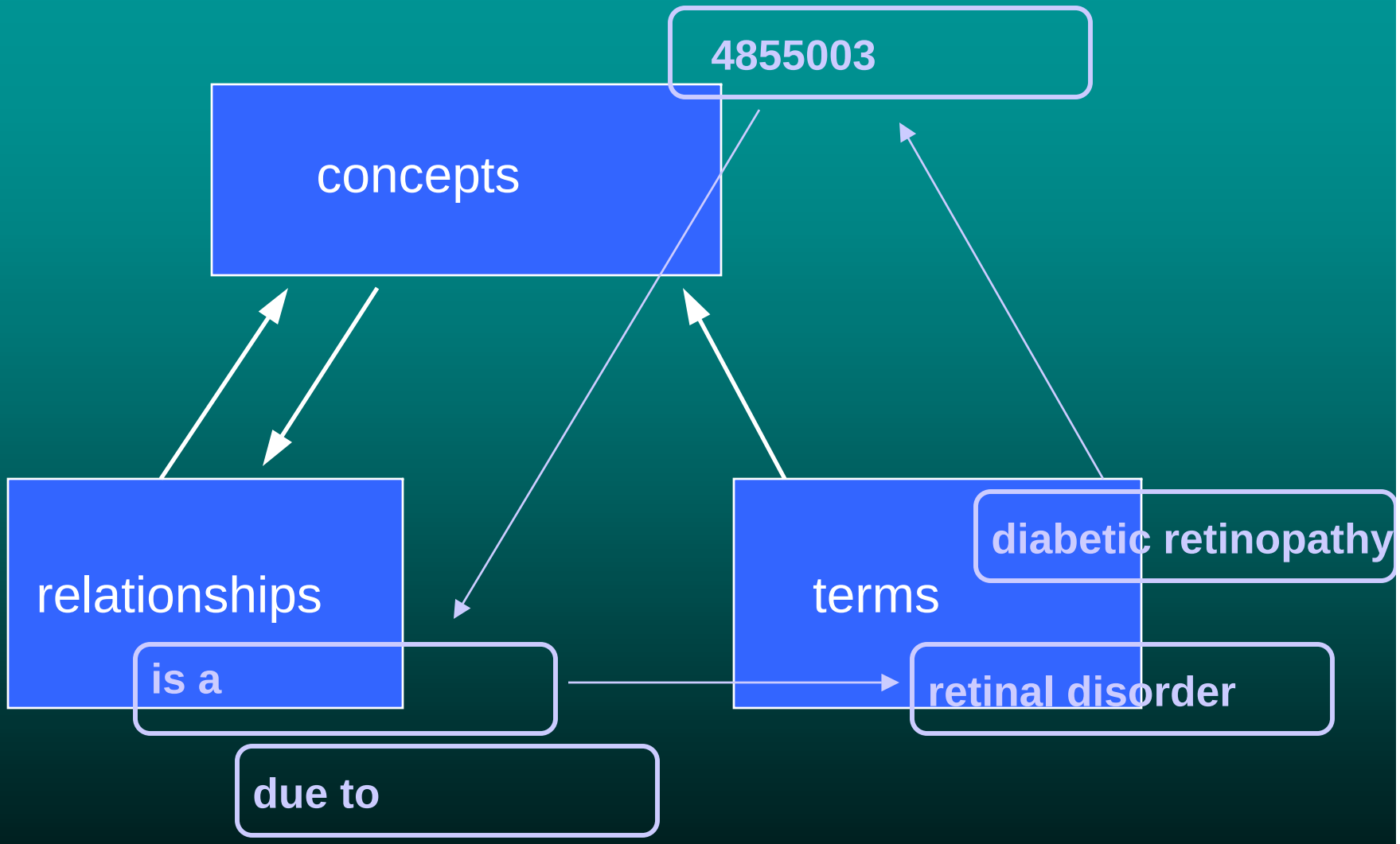

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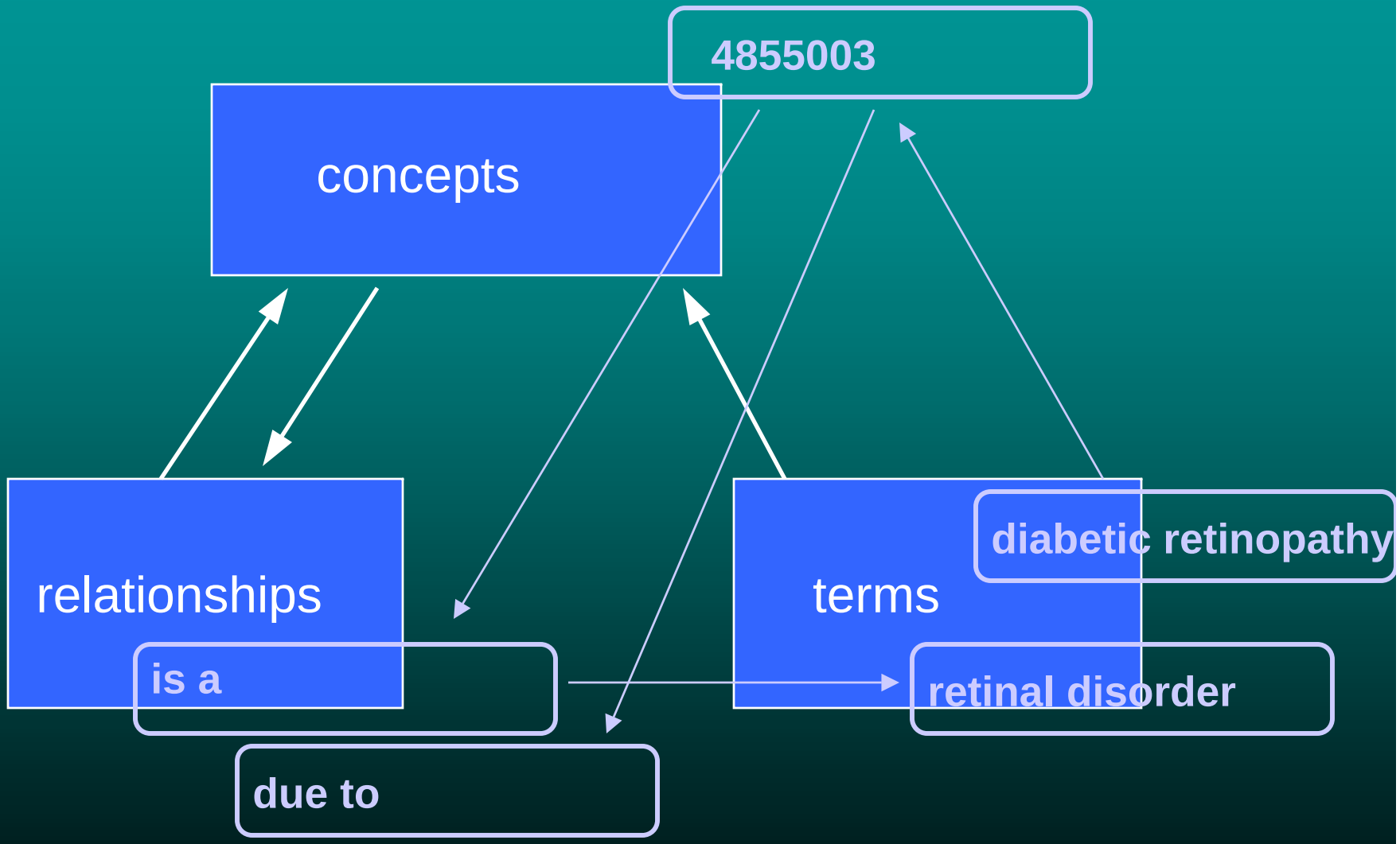

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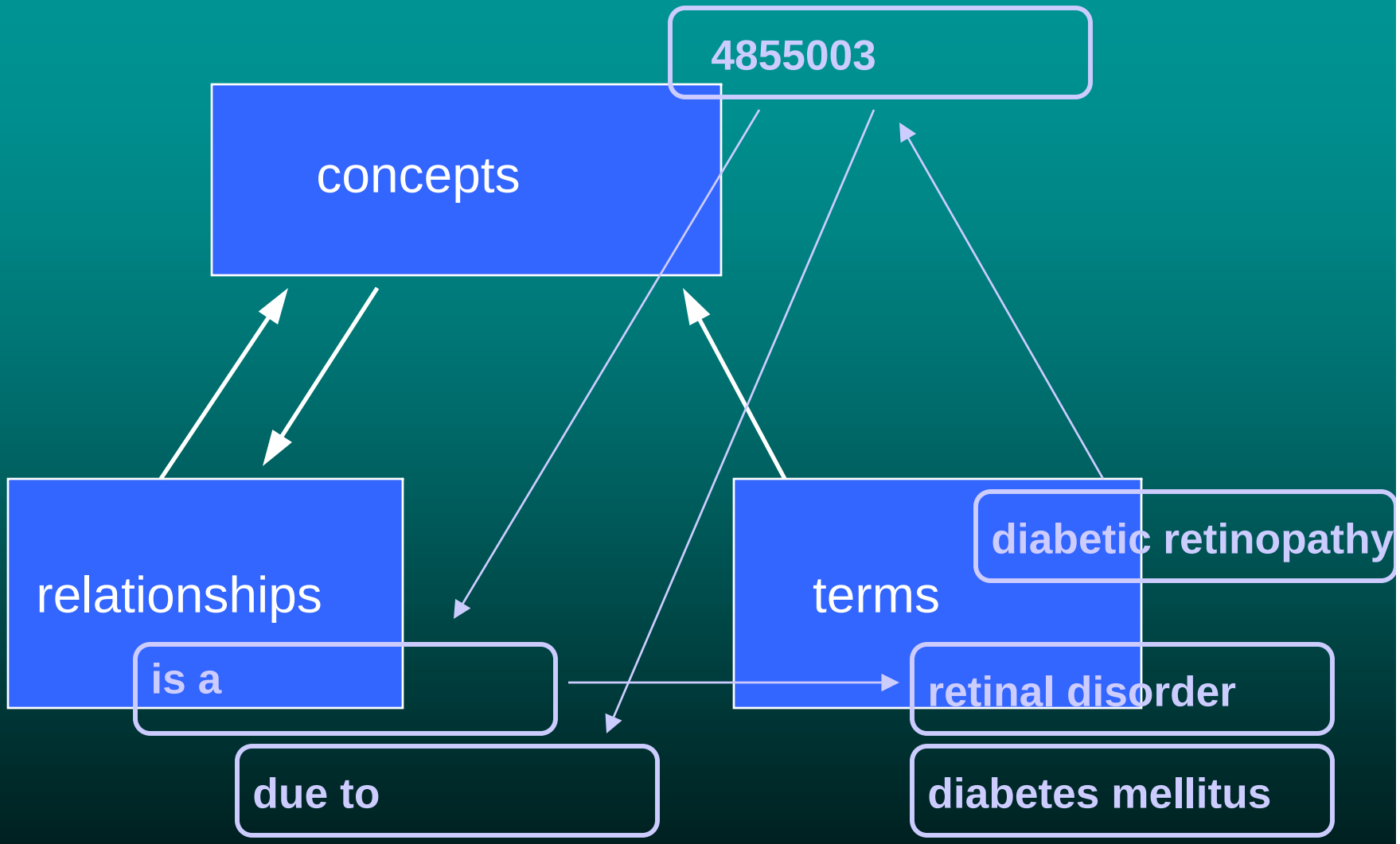

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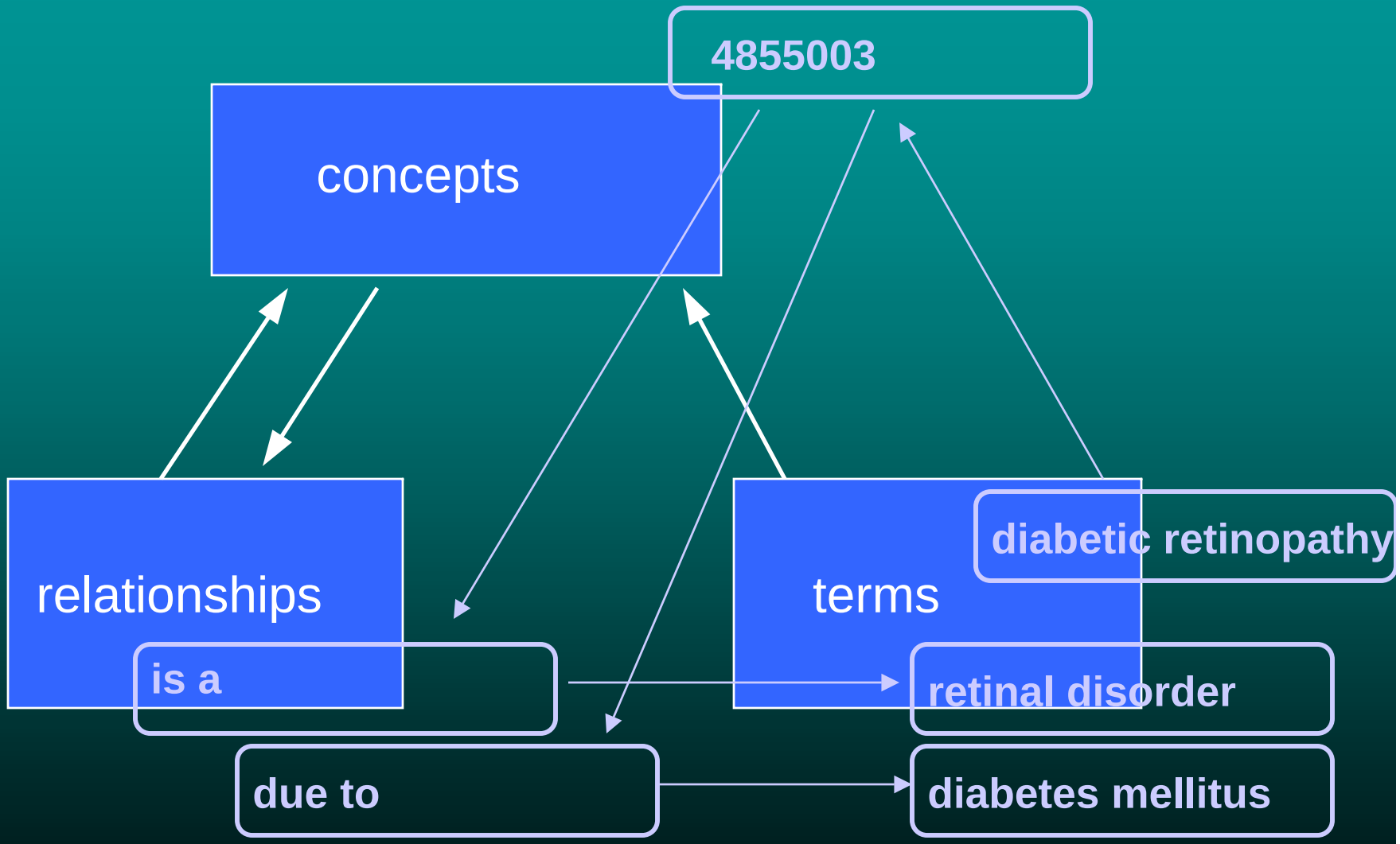
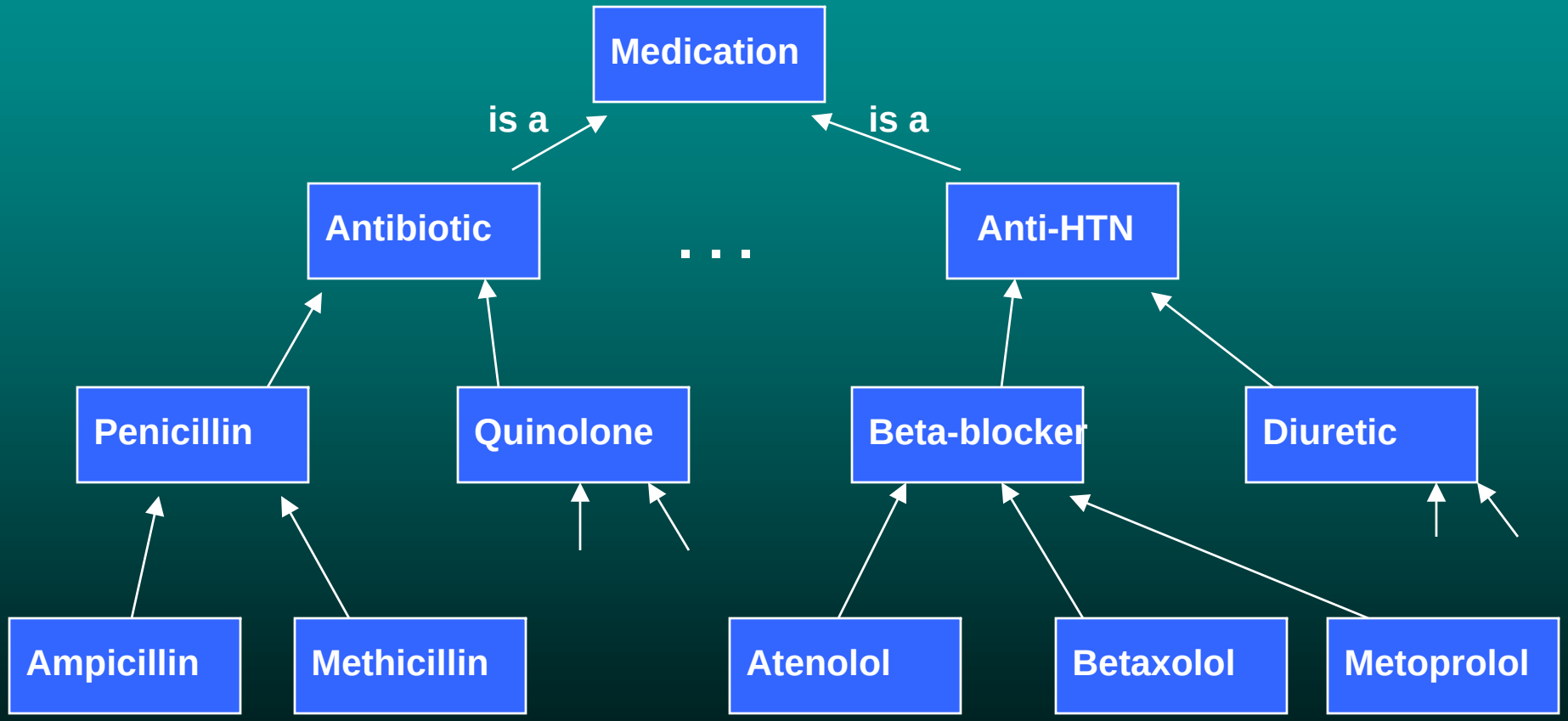


The Inheritance Hierarchy

Concepts are arranged in a tree hierarchy



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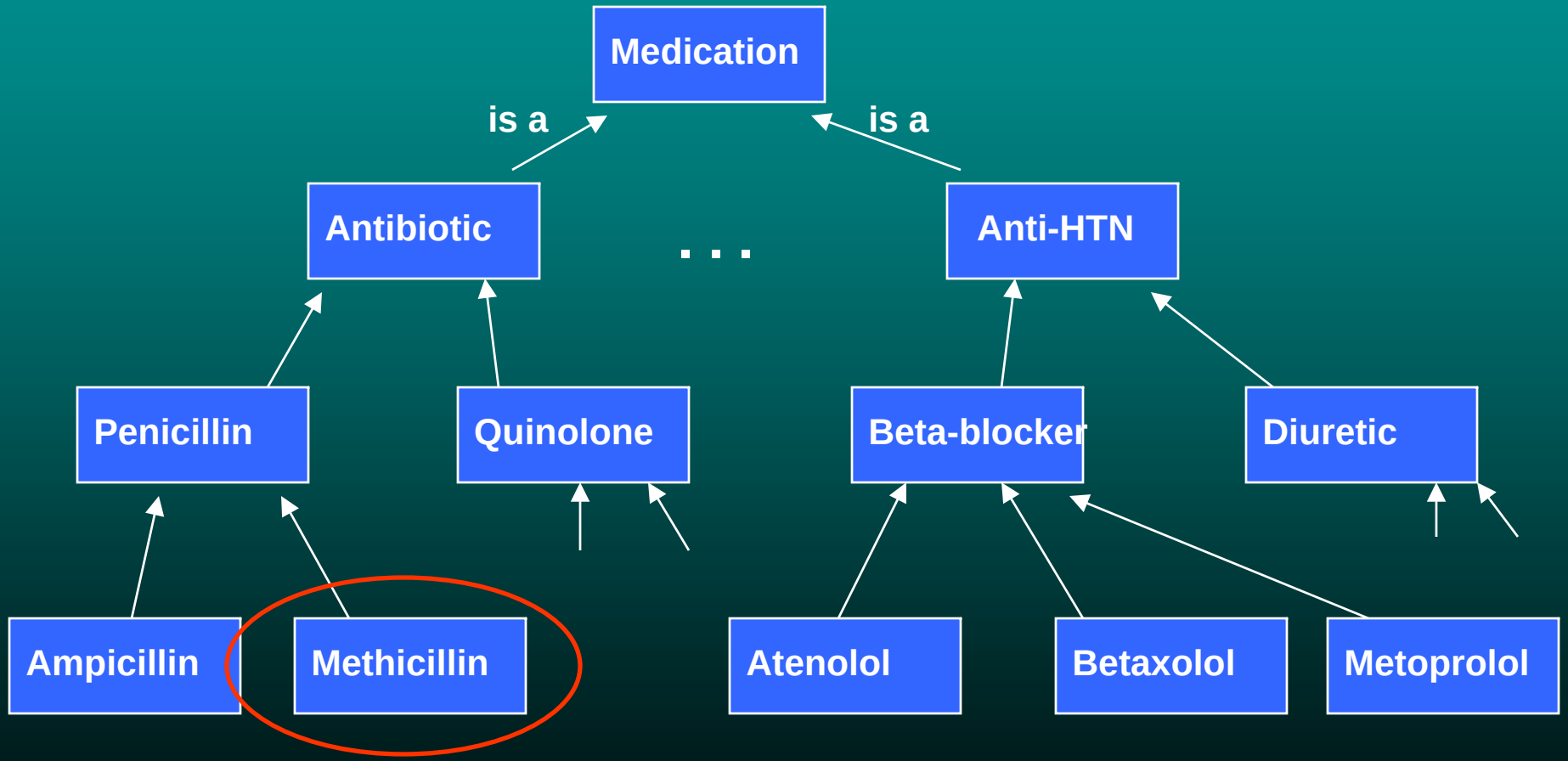

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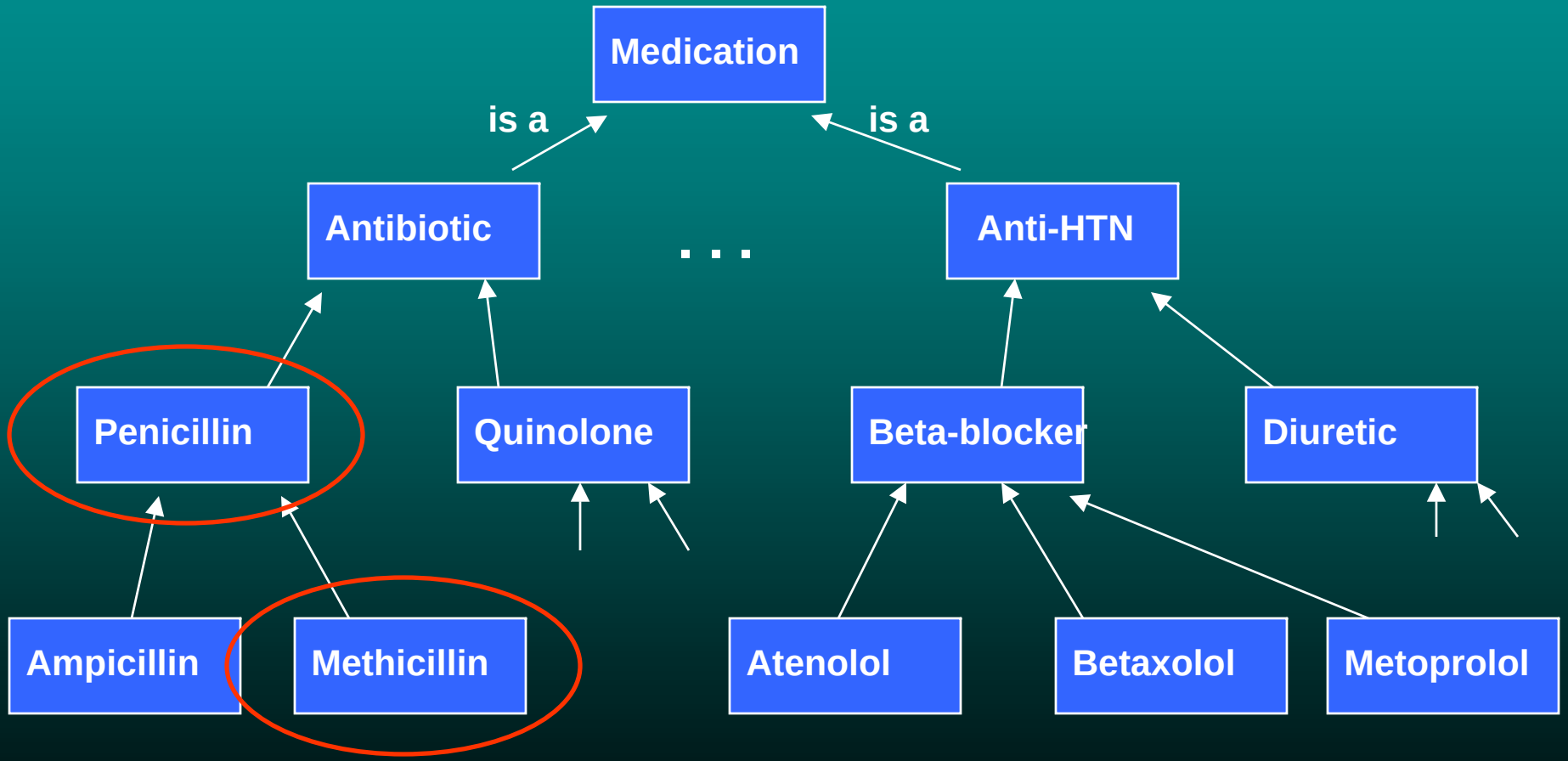

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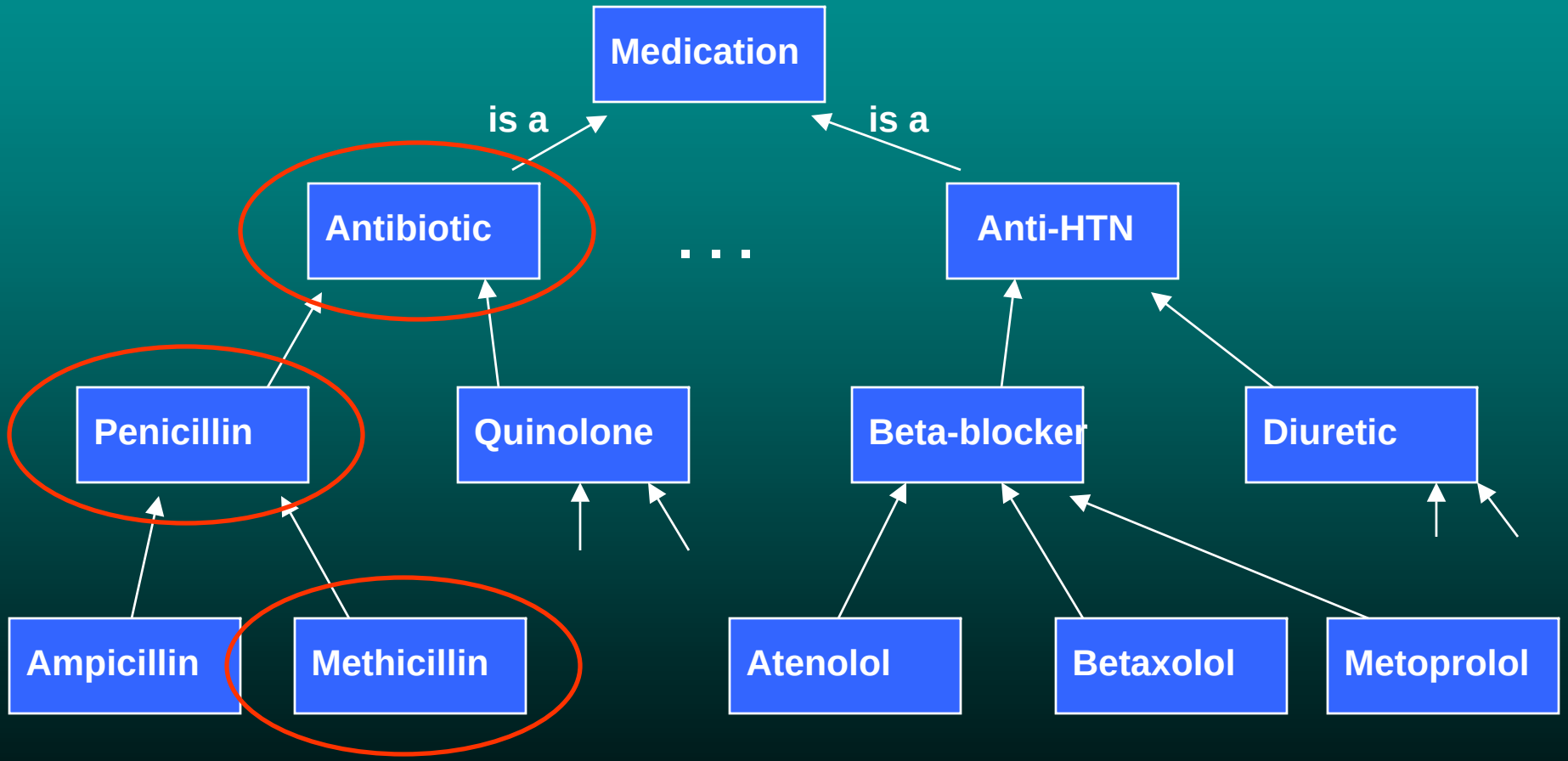

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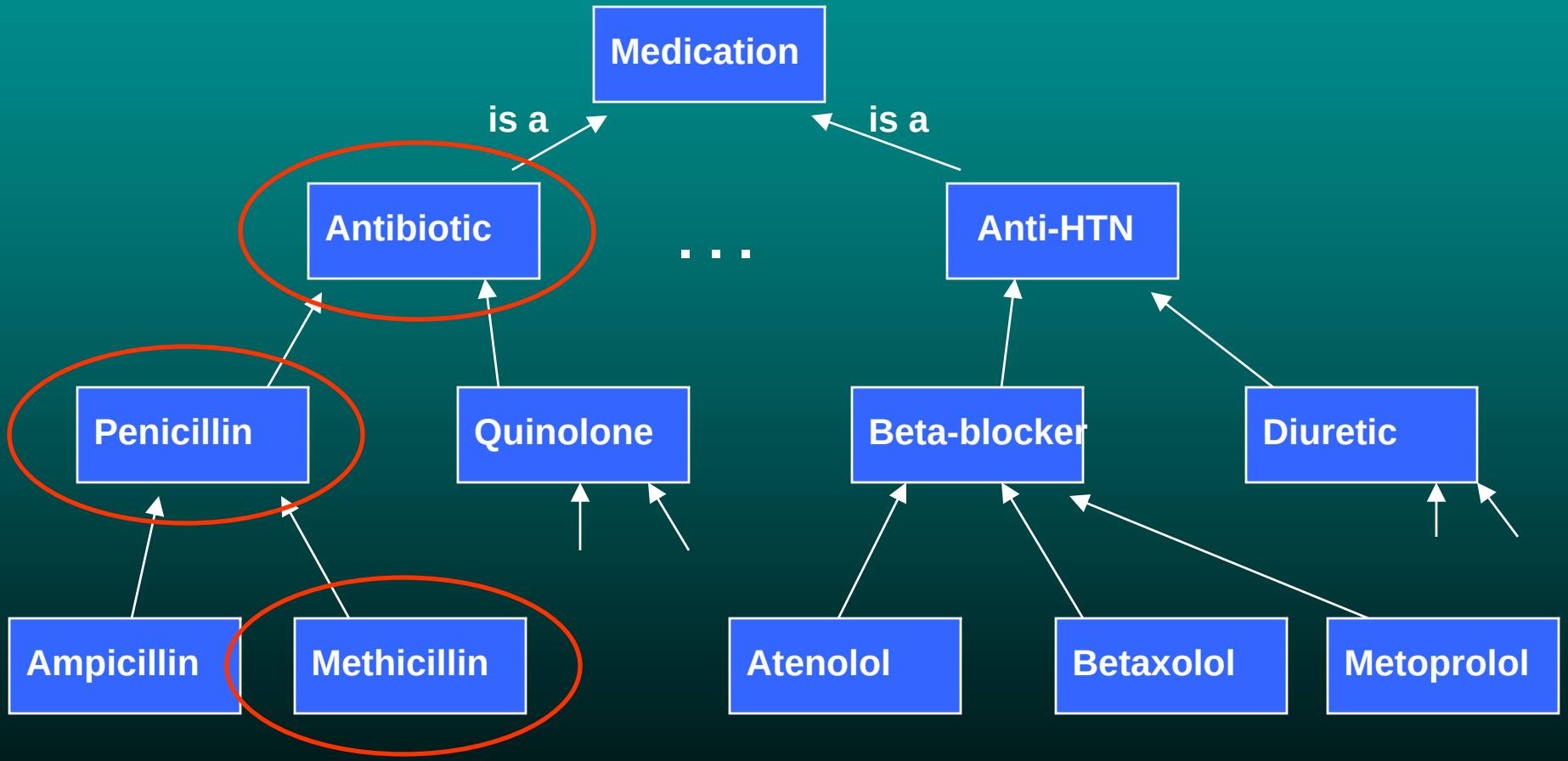

Antibiotic subsumes Penicillin and Methicillin

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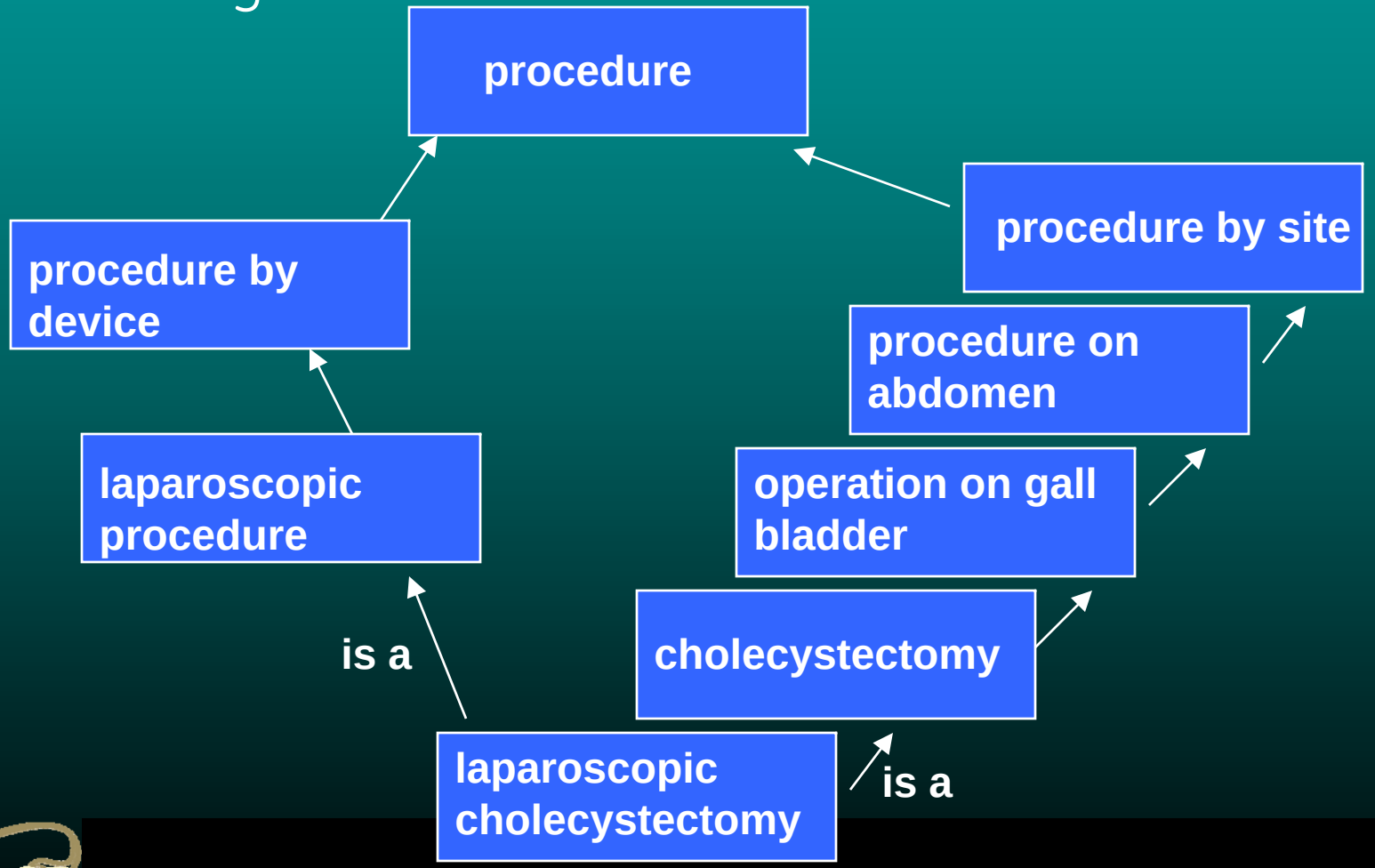
Polyhierarchical structure

A concept may have more than one parent in the hierarchy



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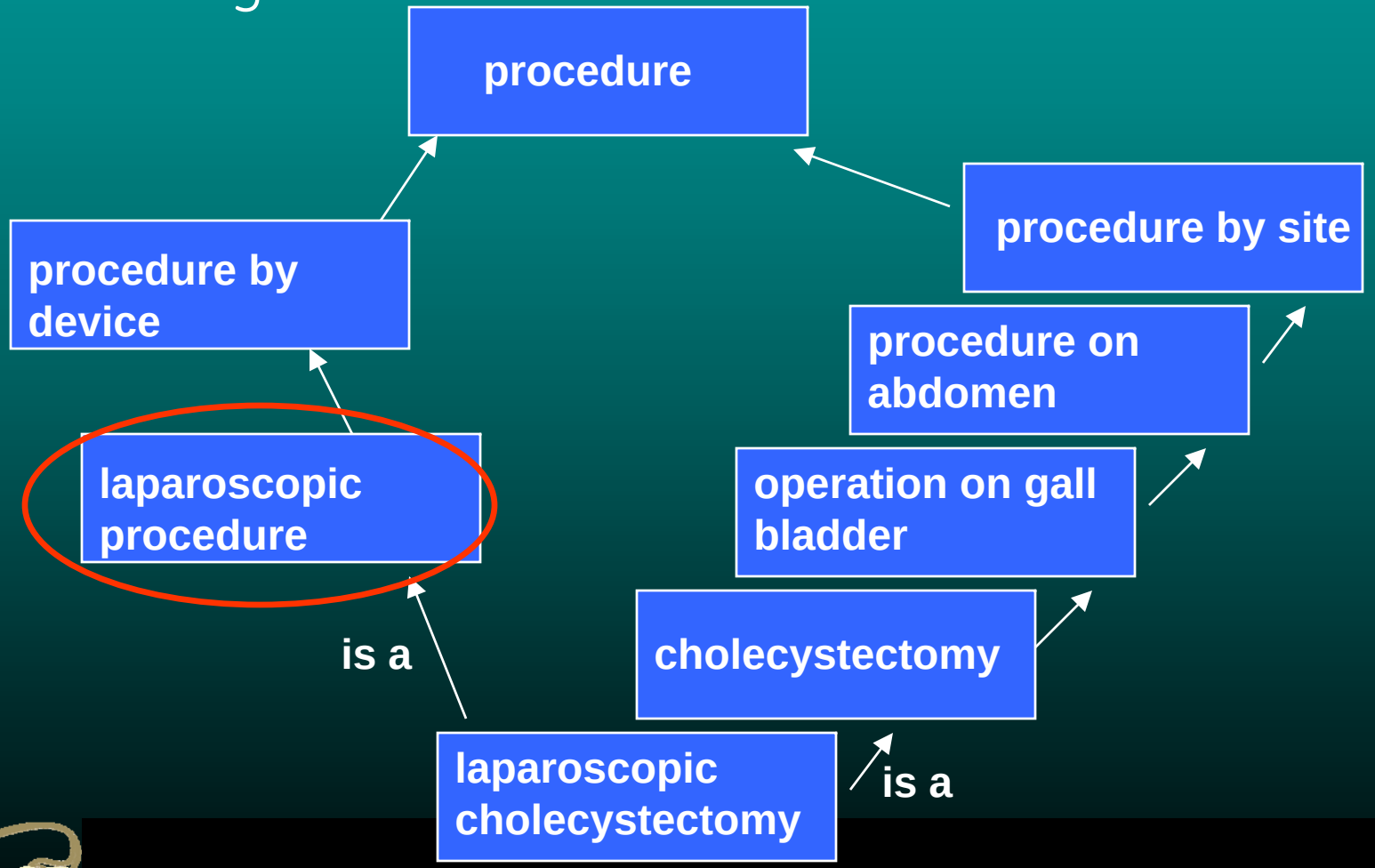

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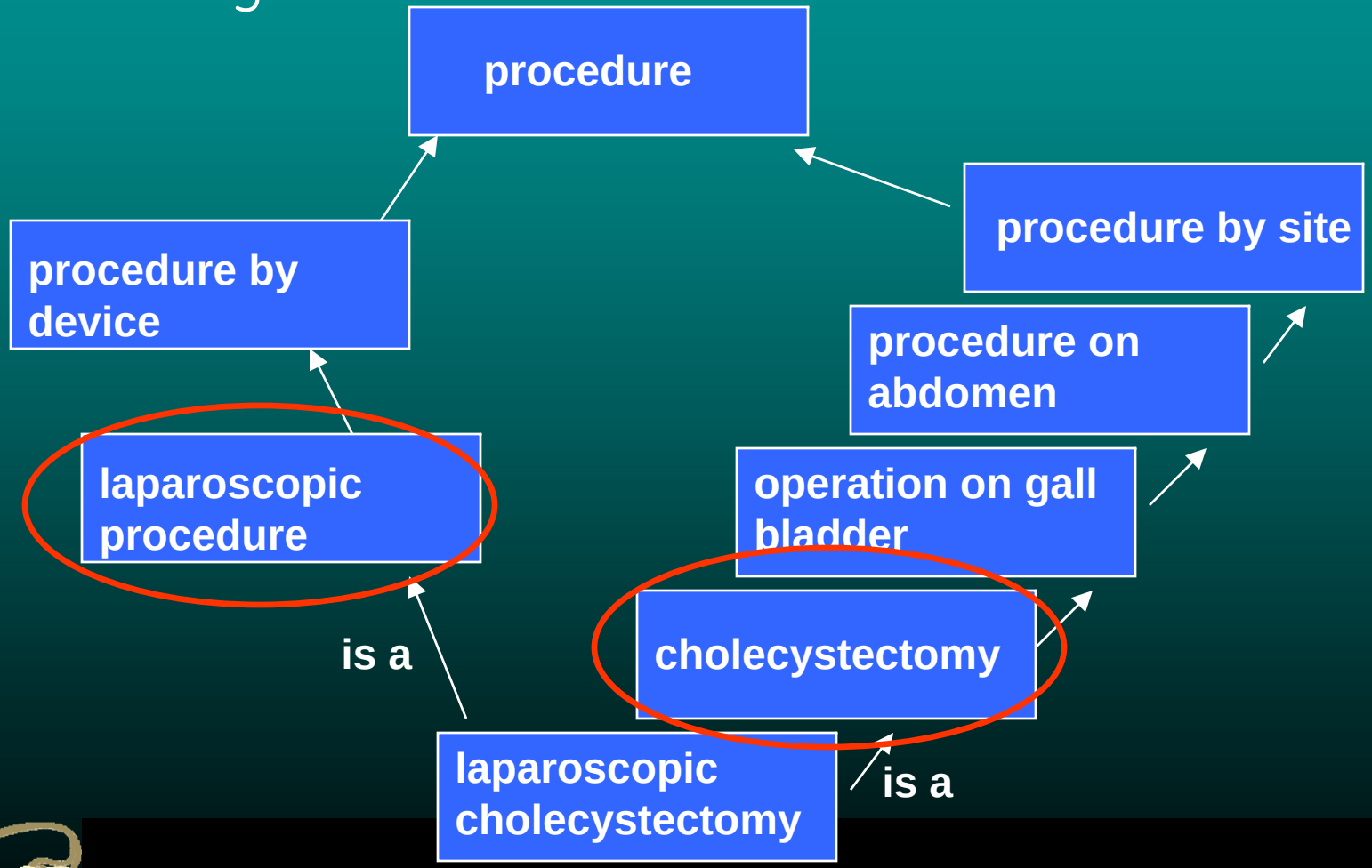

Pre- and Post-Coordination

Suprarenal Artery Embolus
297143008

or

Occlusion of Artery	2929001
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Vocabulary Formalization: Overview

- Once a concept from the guideline is clear and has an understandable meaning, it is compared against SNOMED-CT or other vocabulary concepts in the assigned domain:
  - Is it pre-coordinated?
  - Is the SNOMED definition and all children consistent with the scope of guideline meaning?
  - Can it be defined within standard vocabularies or is it outside the scope of standards and require an extension?

Example…

Persons aged 2–64 years with chronic cardiovascular disease,[¶] chronic pulmonary disease,[**] or diabetes mellitus	A	Not recommended.
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“Functional or anatomic asplenia”

- **Clinical Definition**
  - Congenital asplenia
  - Congenital hypoplasia of spleen
  - Splenectomy
  - Splenic atrophy
  - Sickle cell disease
- **SNOMED CT Concept**
  - 93030006
  - 93292008
  - 234319005 (Procedure)
  - 82893001
  - 127040003 (Hemoglobin S disease)

“Functional or anatomic asplenia”

- **Clinical Definition**
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→

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CDSS Vocabulary Services

Effective use of SNOMED vocabulary by the CDSS requires that these functions (at a minimum) be supported by the query/vocabulary management software:

1) Query for an instance of concept
2) Query for … a concept or any of its children
3) Query for … a set of concepts defined as a Boolean construction of SNOMED concepts
4) Query for … an concept defined as an extension to SNOMED-CT

Vocabulary Services: Vendor Requirements for Immunizations

Vocabulary Service	Frequency
I: Concept identification	17%
II: Aggregation and concept subsumption	81.1%
III a&b: Boolean definition without negation	4.6%
IIIb: Boolean definition including negation	1.5%
IV: Post-coordination and extensions	6.1%

Draft paper included as reference on CD

Overview

- Overview of guidelines and challenges to decision support development

SAGE guideline modeling process:

- Introduction: Modeling the immunization guideline
- Creating the implementation scenarios and assembling decision logic
- Developing concept inventory: employing standard vocabulary
- **Specifying information queries**
- SAGE guideline model and workbench
- Encoding immunization guideline
- Validating the development
- Demonstration: SAGE at work

SAGE Guideline Encoding Process

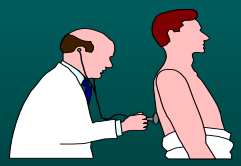
1. Assemble Source Guidelines

3. Formalize Guideline Logic

5. Formalize Vocabulary Inventory

4. Define Guideline Concepts

6. Specify Information Queries



2. Envision Clinical Scenarios

Guideline Installation and Execution

7. Encode Guideline Knowledgebase

SAGE

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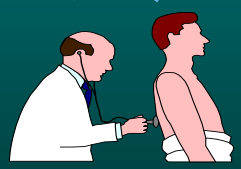

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SAGE

Why do we need to specify information queries?

- The CDSS must obtain patient data from the CIS to perform logic
- Every CIS represents patient data differently
  - Object-oriented vs Relational
  - Variation in patient data components

Example

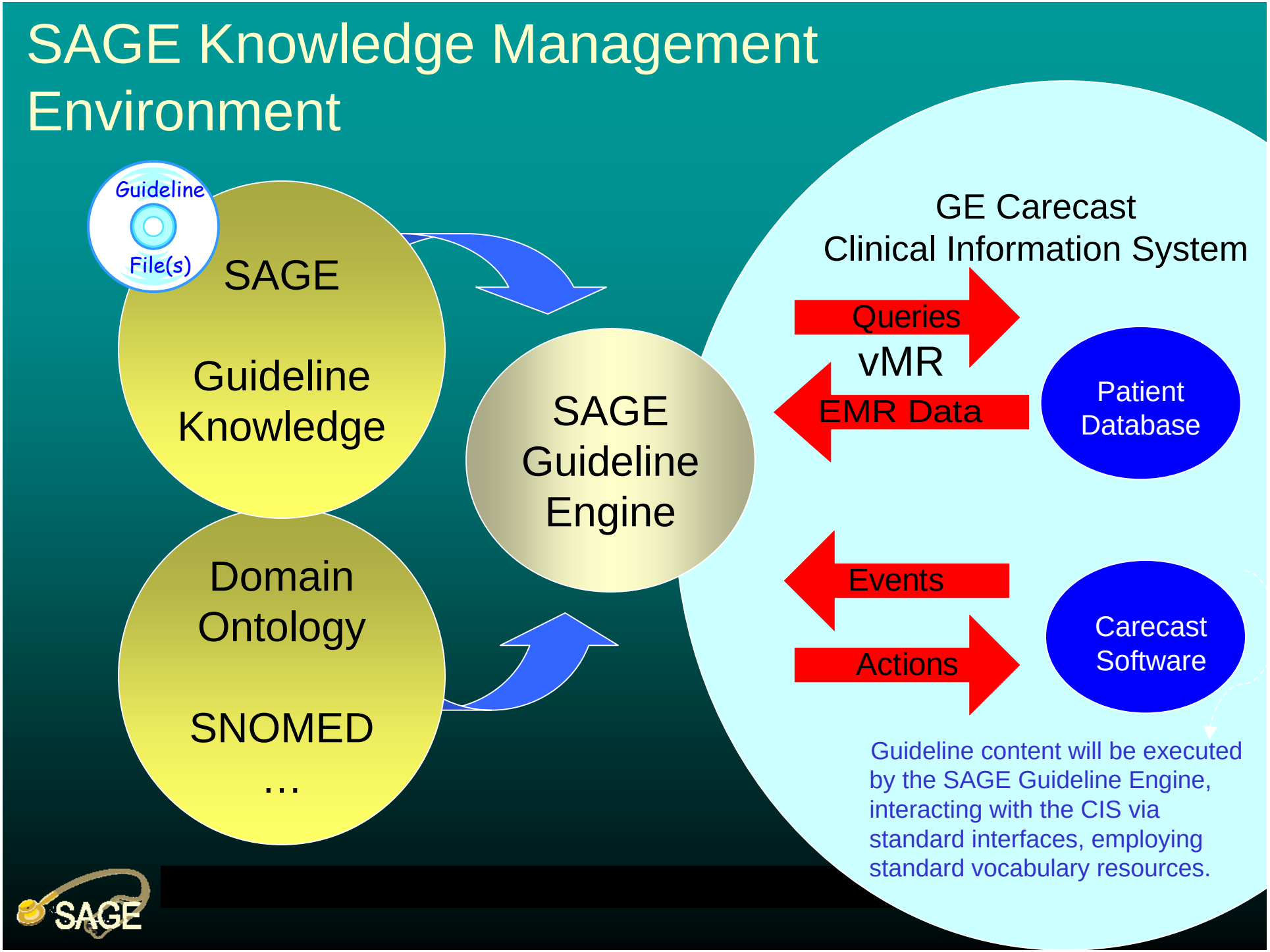
Possible Representations of a patient's Diabetes Mellitus

- Entry on Problem List
  - Diabetes Mellitus type II
- Observation
  - Lab Value of Fasting Glucose > 125 mg/dL or
  - Lab value for two-hour 75-g oral glucose tolerance test > 200 mg/dL
- Entry in Diagnoses & Procedures list
  - Diabetes Mellitus type II

Information Model and Use of Vocabulary

- Interoperable decision support must be able to interact correctly with any vendor information model
- Since we cannot tell CIS vendors how to structure their systems, the SAGE approach to interoperability is to use a standard information model and then have each vendor build their own translation from the standard to their system

SAGE Knowledge Management Environment



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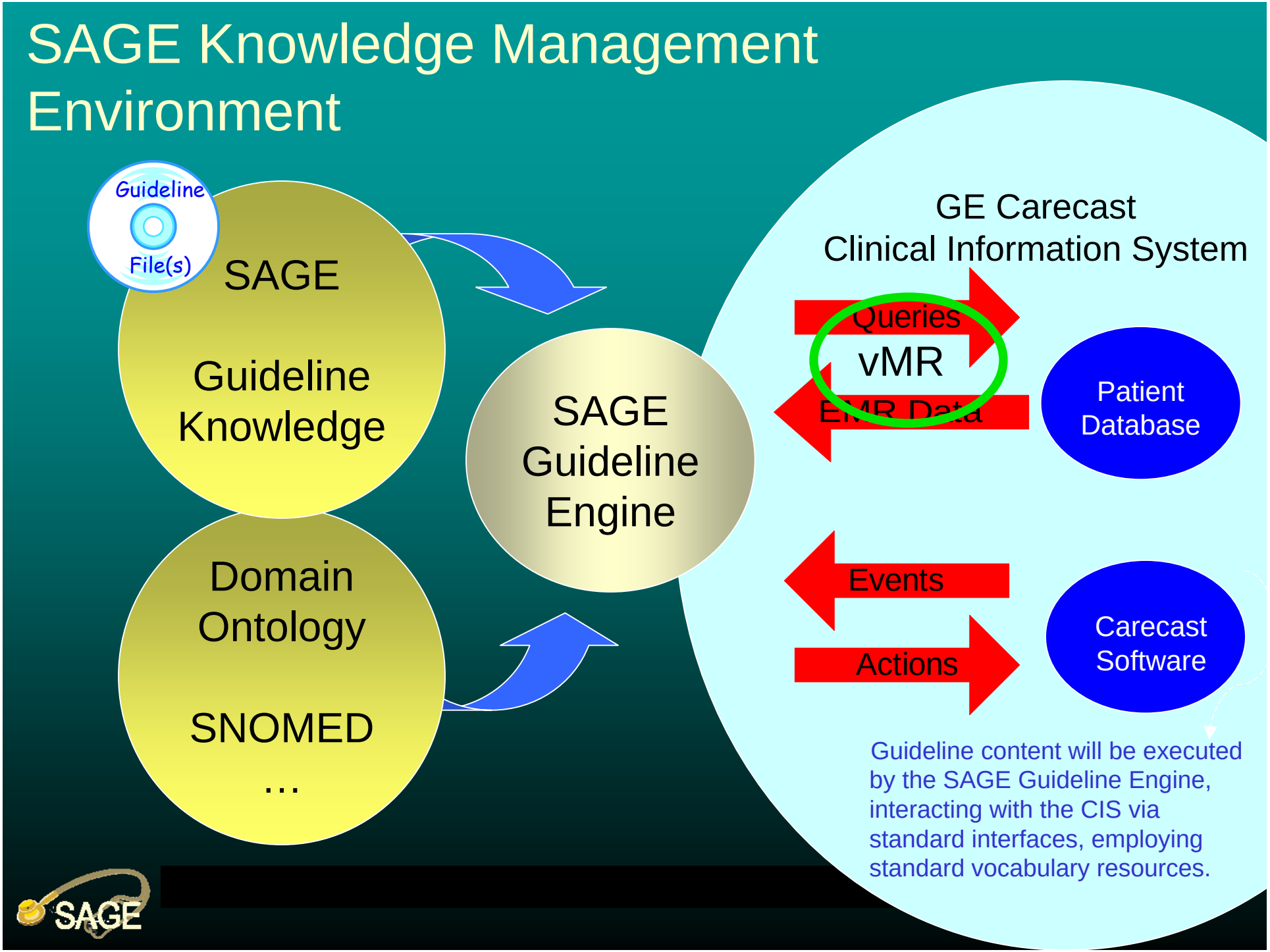

HL7 RIM and Knowledge Modeling

- HL7 – A Standards Development Organization dedicated to definition of interoperability standards for electronic healthcare information
- HL7 RIM (Reference Information Model) v3 specifies the "grammar" of HL7 messages, including data type definitions
- The HL7 RIM v3 is the basis for the SAGE idealized information model
- Developed in dialogue with the Clinical Decision Support Technical Committee of HL7, this model is termed the vMR (virtual medical record)

Virtual Medical Record Objects (SAGE idealized information model)

- Substance administration
- Referral
- Procedure
- Problem
- Order (non-medication)
- Medication order
- Observation
- Goal
- Encounter
- Appointment
- Adverse reaction
- Agent
- Alert

Binding Information Queries to the vMR

- Effective linking of the decision support logic to the clinical record depends upon:
  - Information model
  - Vocabulary (ontology) employed
  - Pragmatics of recording by those who use the CIS

Interaction of vMR and Vocabulary

- "Family history of colon cancer"
  - Observation: code = 275937001|"family history of colon cancer"
  - Observation: code = 363406005|"colon cancer", subject = 303071001|"family member"
- "Elevated blood sugar"
  - Observation: code = 166892002|"random blood sugar raised"
  - Observation: code = 2339-0|"Blood glucose", value = 250mg/dl

Interaction of vMR and Vocabulary

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- "Elevated blood sugar"
  - O
    su
  - O
    2

The "context free" assumption within SNOMED states that the concept assertion always implies:

1) Involves the patient
2) Current state
3) Assertion is present

SAGE

Pragmatics of Clinician Use

- Is encounter data reliably recorded? When is it available?
- Does nursing staff record vital signs and I&O real-time?
- Who places orders in the system? When are they recorded?
- When do lab results cross the interface and appear in the CIS?
- Do the physicians use the problem list?
- Are procedures recorded as they are billed?

Binding Information Queries to the vMR

- The knowledge engineer must consider each of these three layers when creating decision support functionality
- For interoperability, the most common (or all) use cases must be supported
- At the time of localization of shared knowledge, the knowledge base must be examined for differences of interpretation of information model and patterns of data use in the local system

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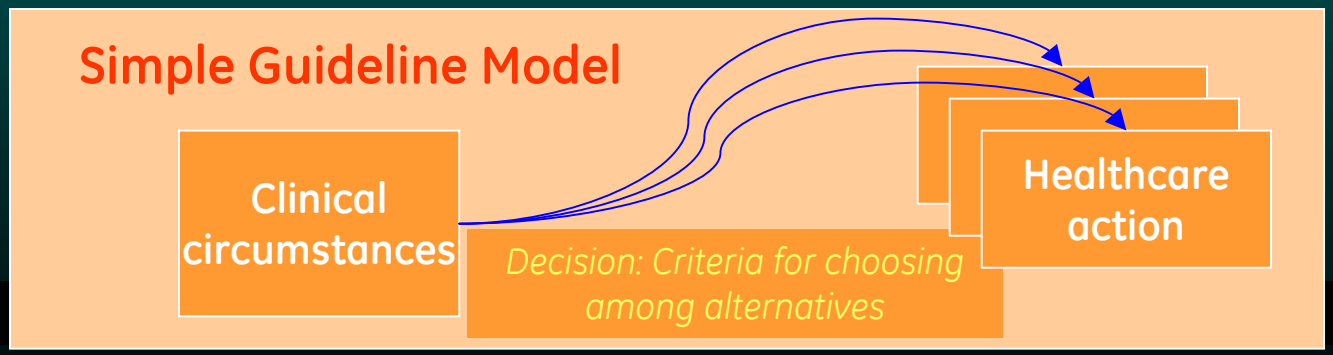
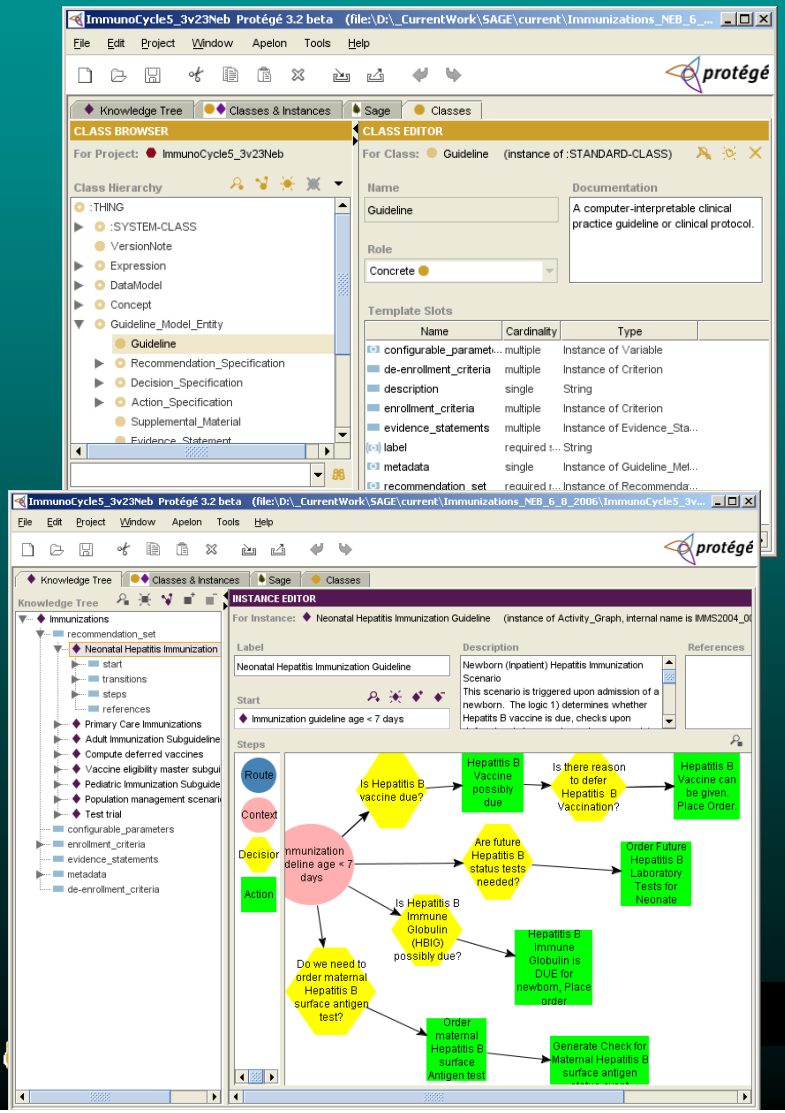
Model-Based Approach to Encoding Guidelines

- Model: a simplified abstraction of a system (guideline), aimed at understanding and/or explaining aspects of interest
- Guideline: "...systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Field, 1990)

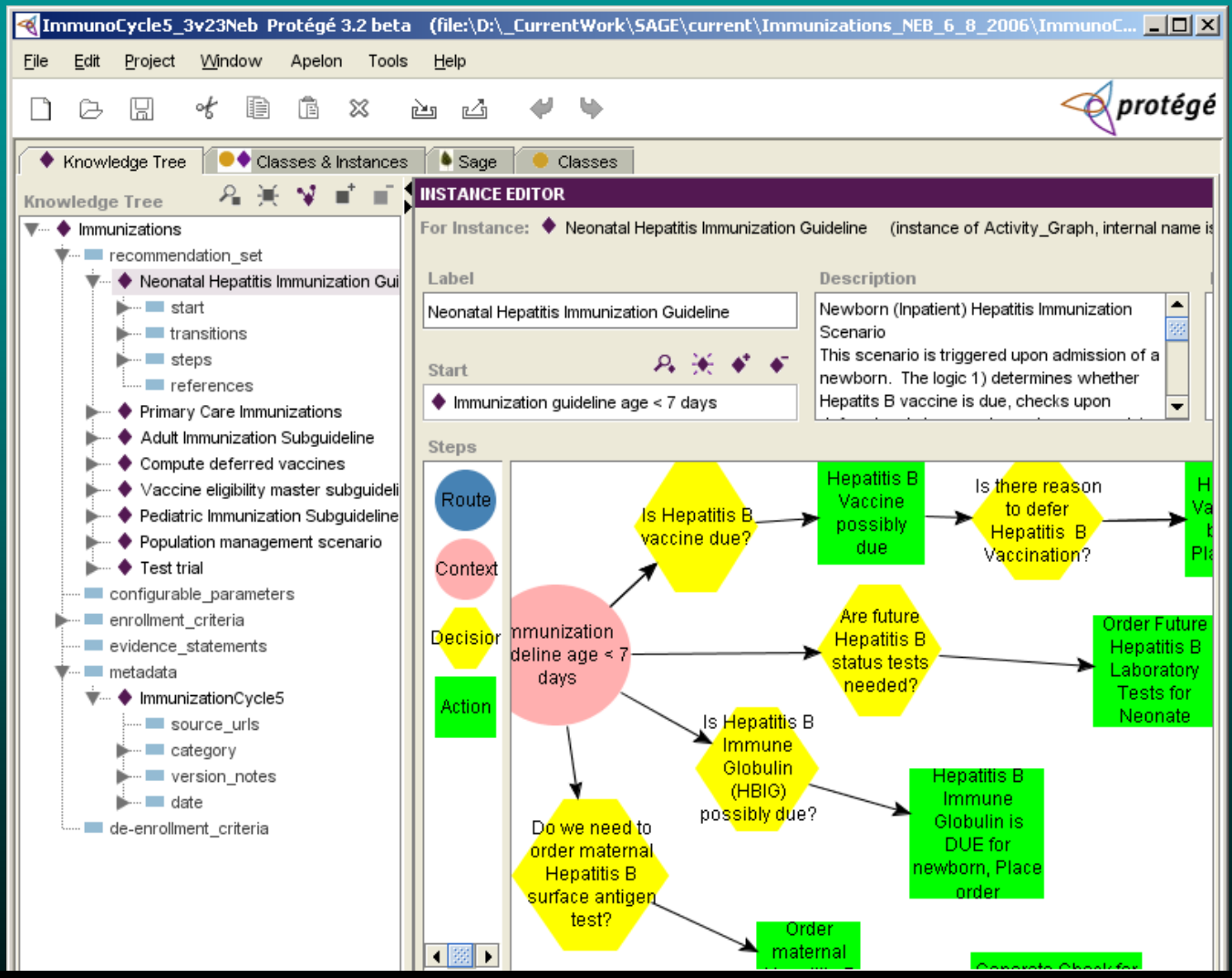


SAGE Guideline Model and Modeling Environment



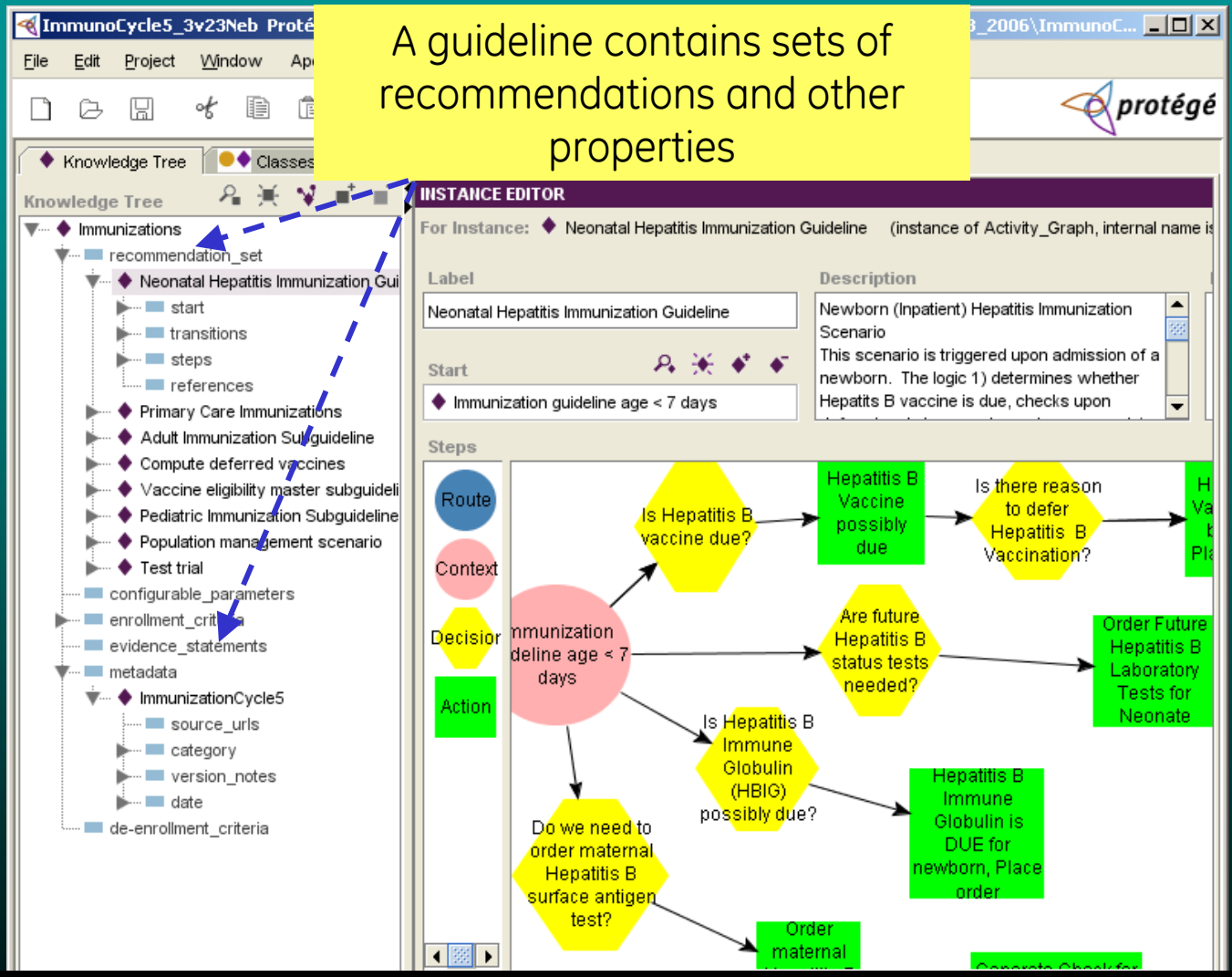
- Guideline model represented as a collection of classes and relationships among them
- Encoding a guideline (e.g. immunization guideline) means creating instances of these classes
- Use of graph widget to specify guideline recommendations as directed graphs

Structure of a SAGE Guideline



Structure of a SAGE Guideline

A guideline contains sets of recommendations and other properties



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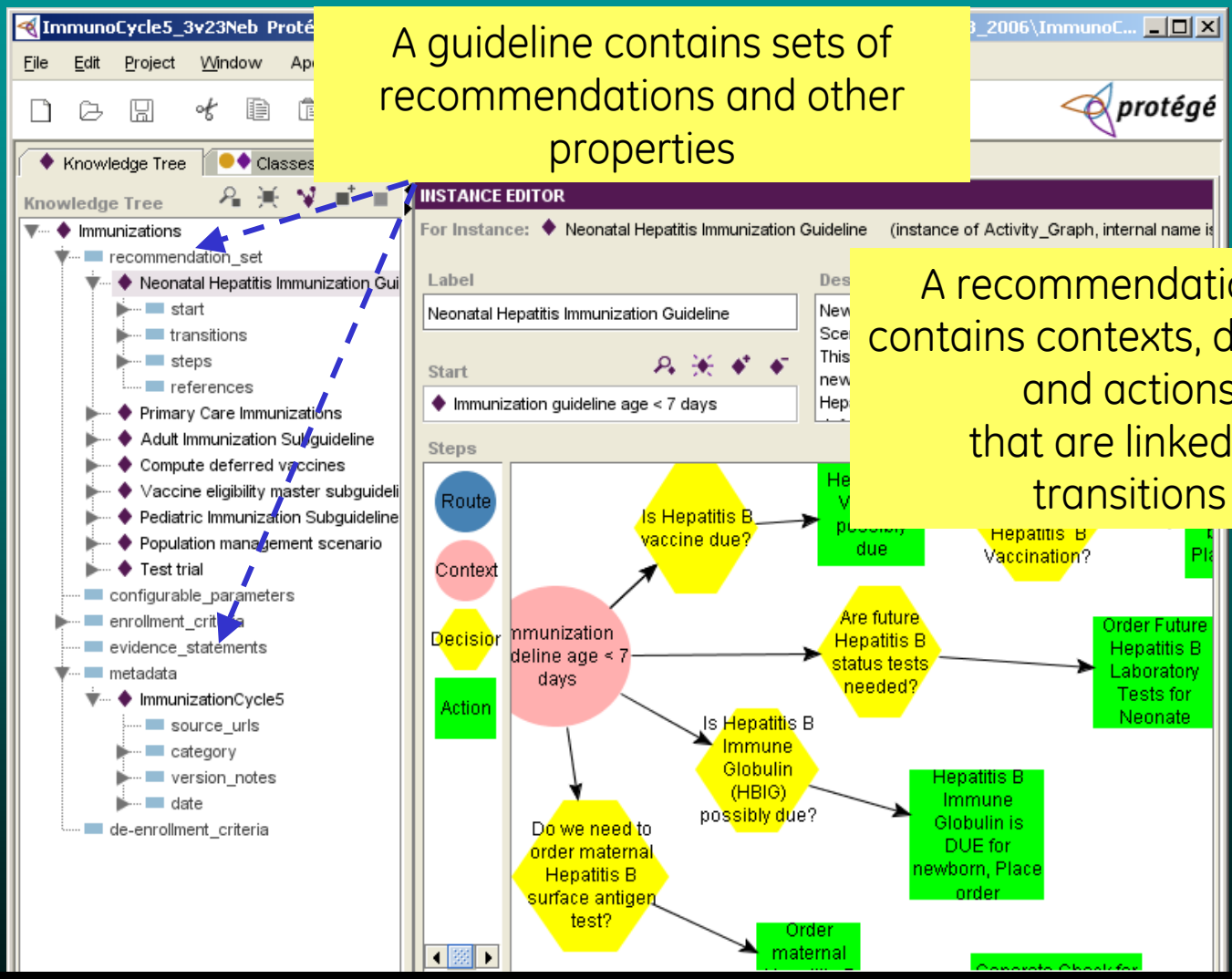
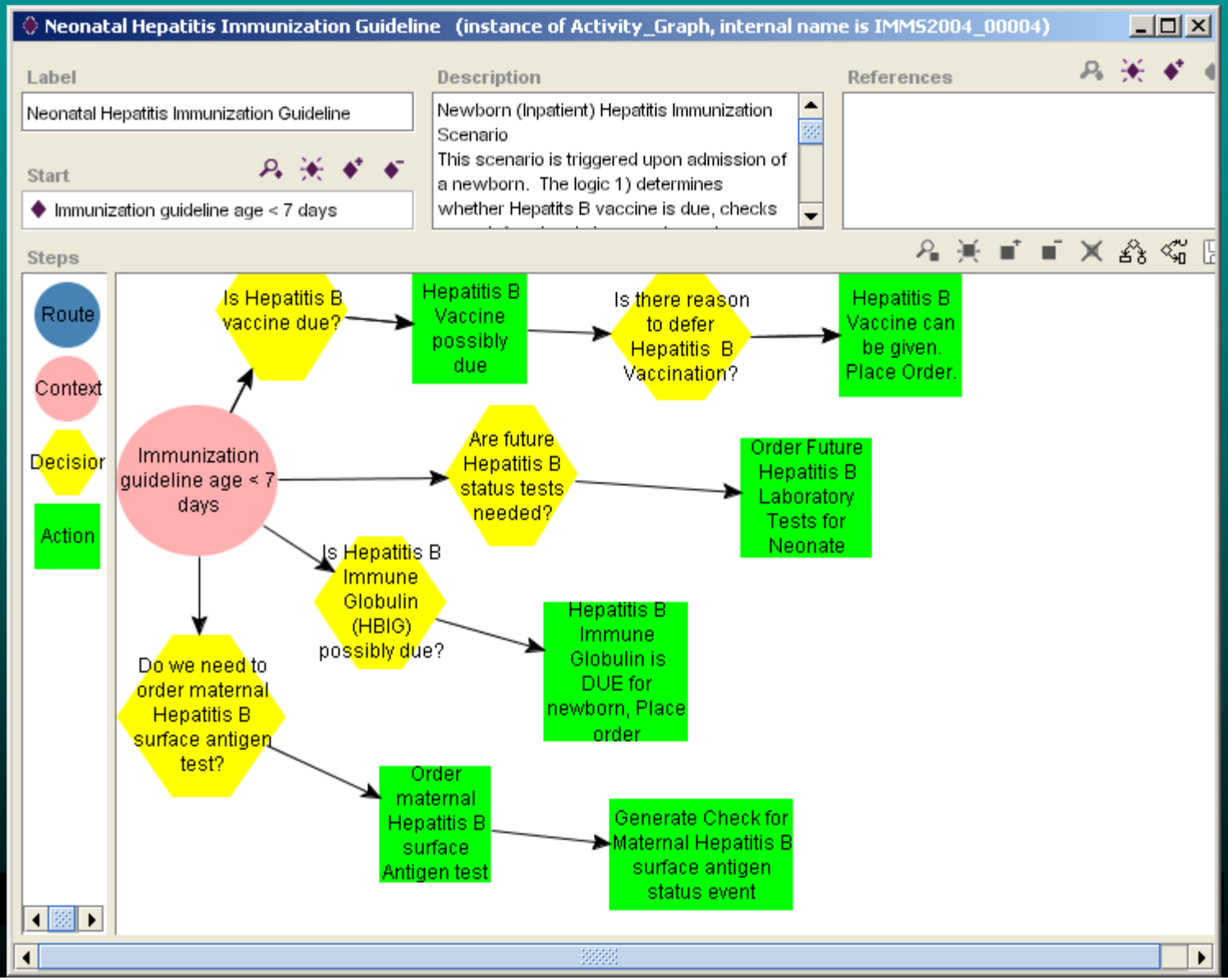


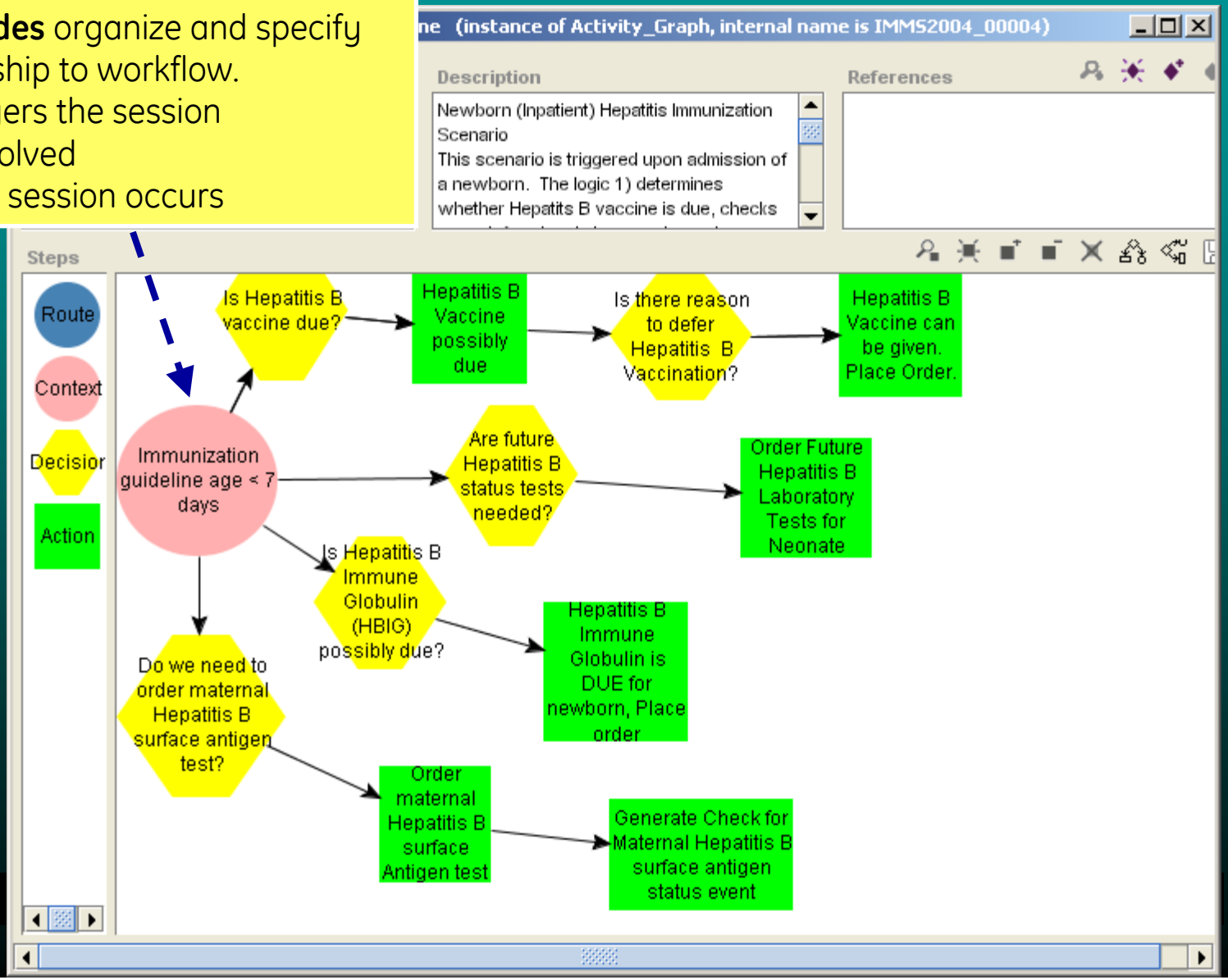
A Guideline Recommendation: Basic Components



A Guideline Recommendation: Basic Components

Context Nodes organize and specify the relationship to workflow.

- What triggers the session
- Who is involved
- Where the session occurs



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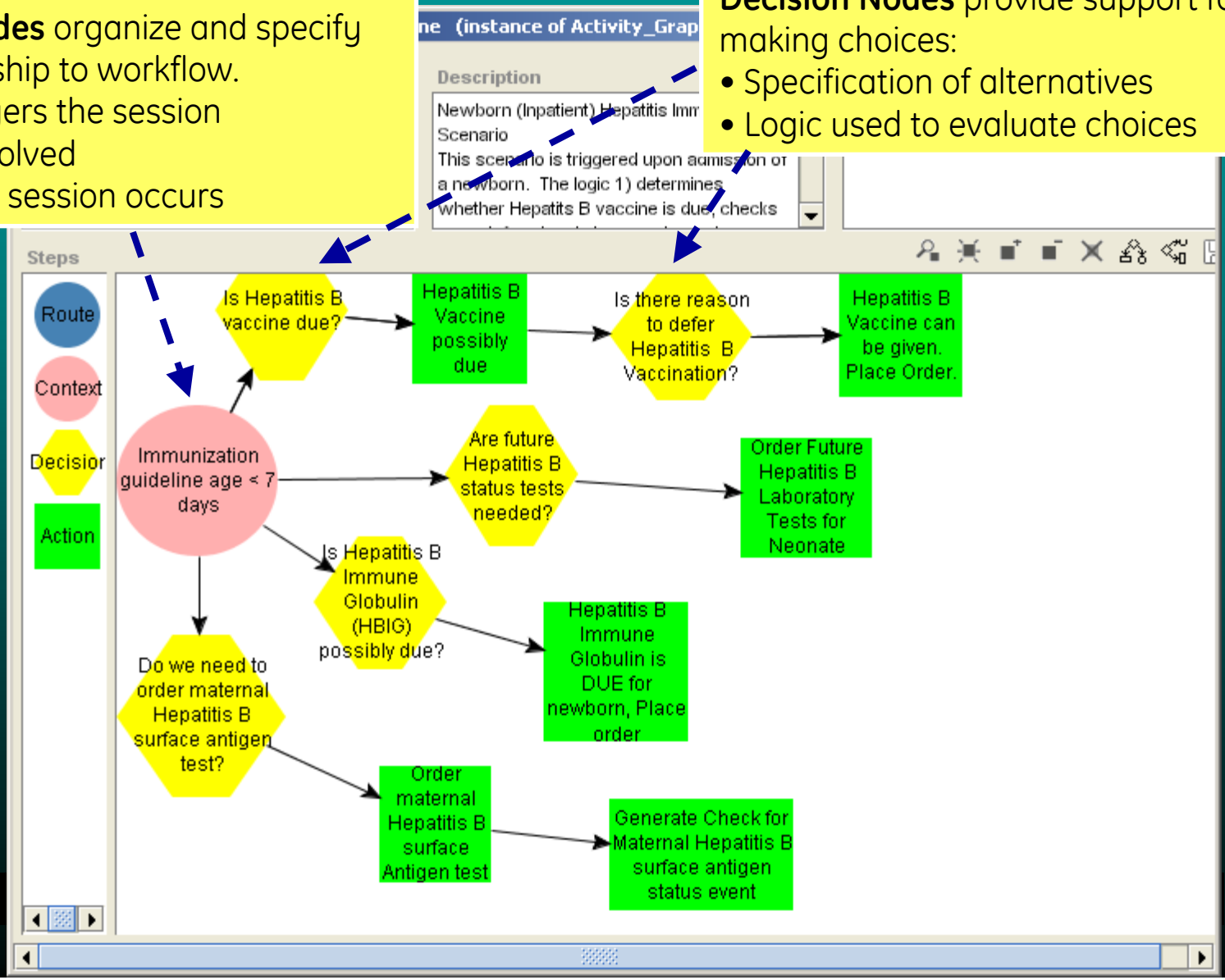
- Specification of alternatives
- Logic used to evaluate choices



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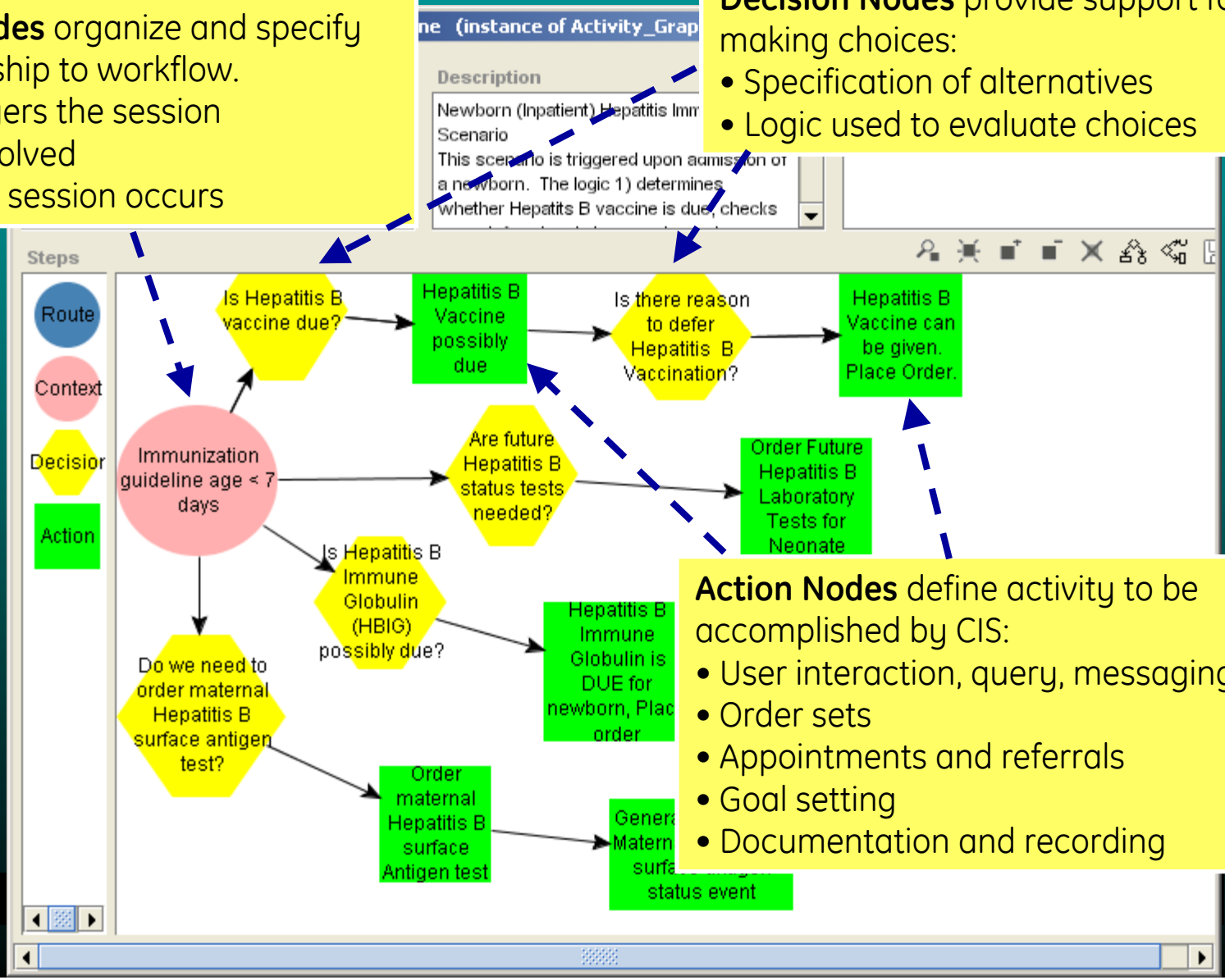
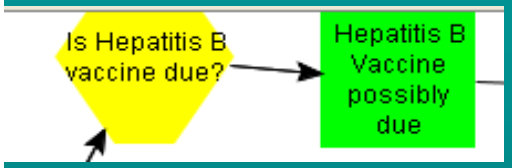
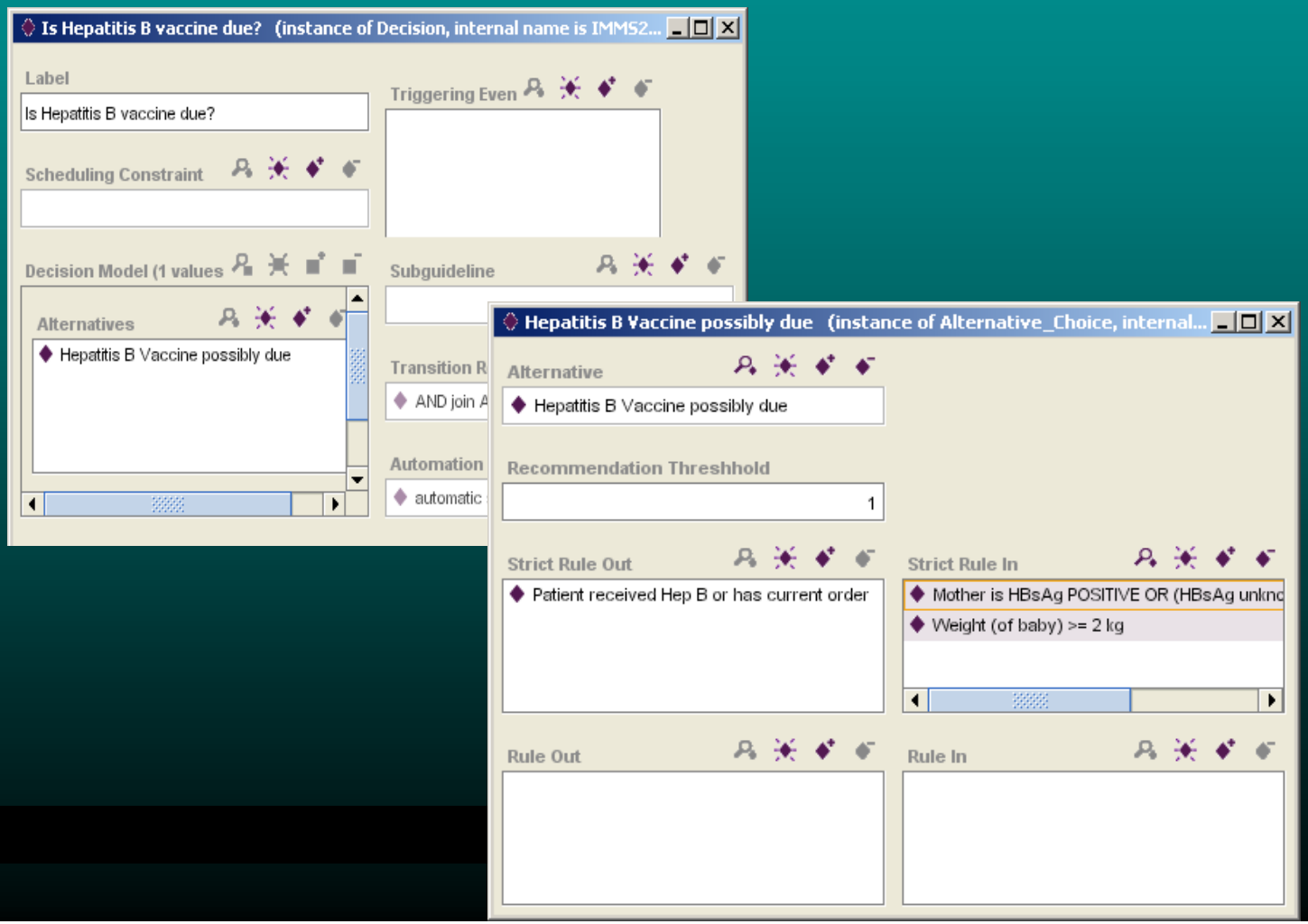


Action Nodes define activity to be accomplished by CIS:
- User interaction, query, messaging
- Order sets
- Appointments and referrals
- Goal setting
- Documentation and recording

SAGE

A Decision Node contains reasons for choosing each alternative





SAGE

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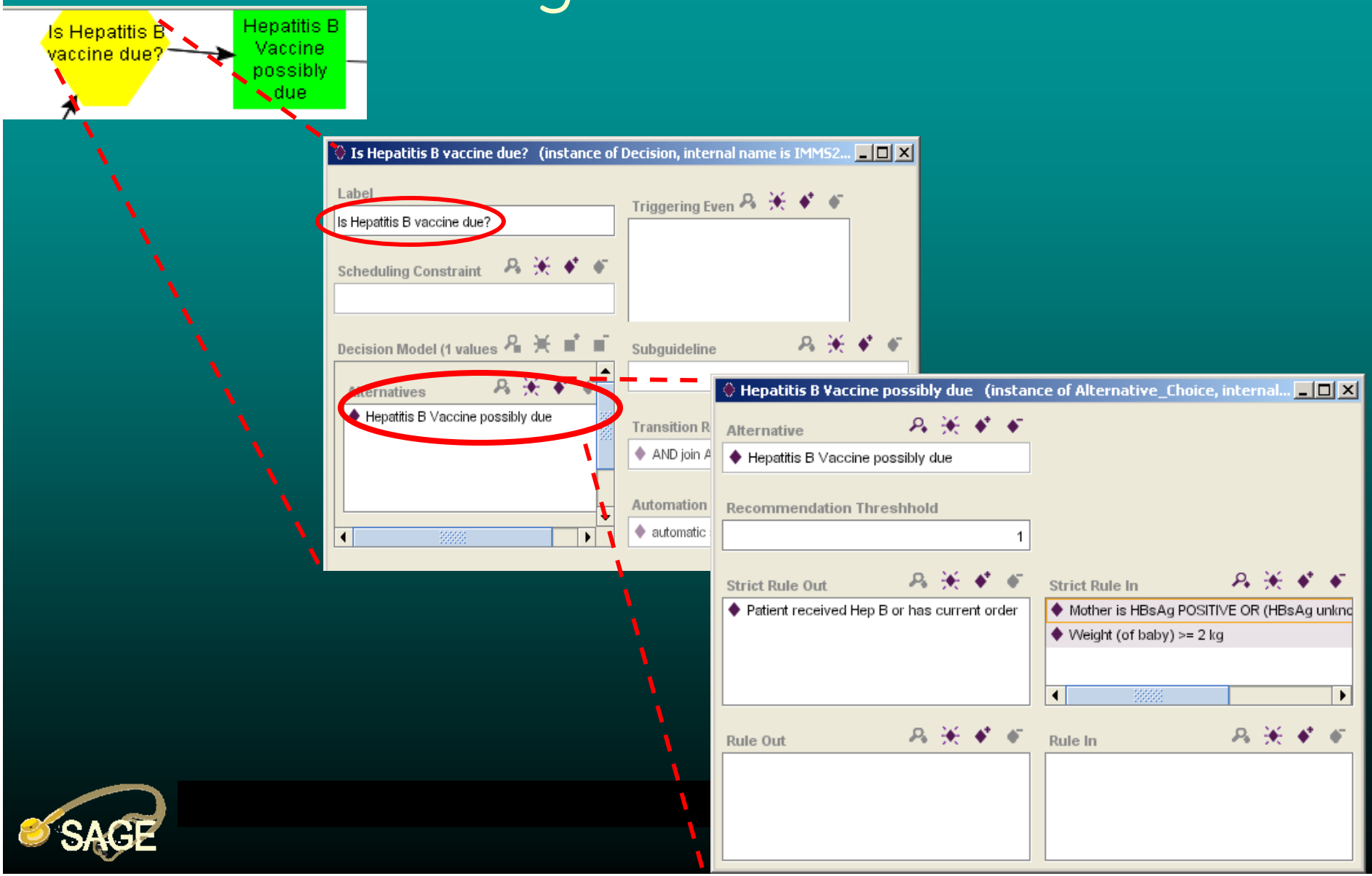

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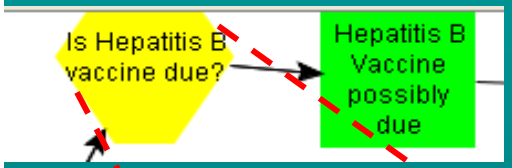


Rule-in and rule-out criteria determines whether an alternative is recommended

Is Hepatitis B vaccine due? (instance of Decision, internal name is IMMS2...

Label
Is Hepatitis B vaccine due?

Triggering Even

Scheduling Constraint

Decision Model (1 values

Subguideline

Alternatives
Hepatitis B Vaccine possibly due

Transition R
AND join A

Automation
automatic

Hepatitis B Vaccine possibly due (instance of Alternative_Choice, internal...

Alternative
Hepatitis B Vaccine possibly due

Recommendation Threshhold
1

Strict Rule Out
Patient received Hep B or has current order

Strict Rule In
Mother is HBsAg POSITIVE OR (HBsAg unkno
Weight (of baby) >= 2 kg

Rule Out

Rule In

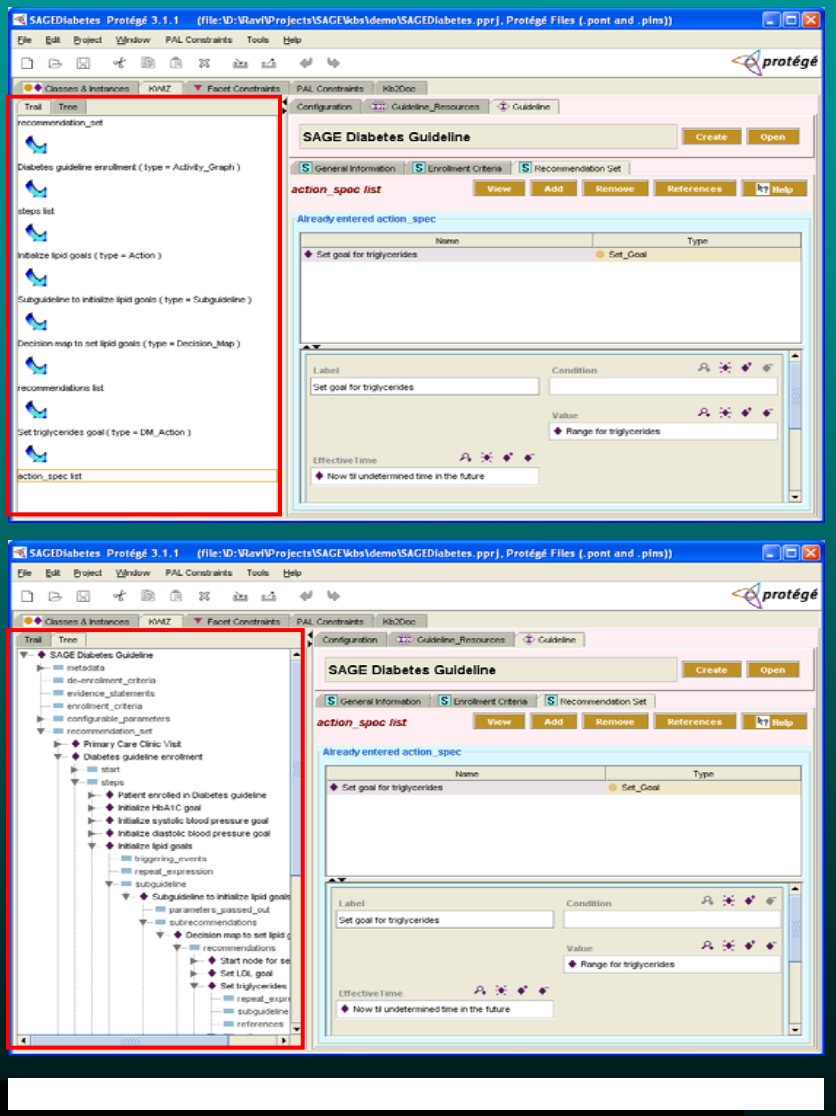
SAGE

Features of SAGE Protégé Workbench

- Alternative instance form: KWIZ tab
- Generation of XML/HTML: kb2doc tab
- Constraint checking: FacetConstraint tab & PALConstraint tab
- Case-based testing: SAGE tab
- Terminology server: Apelon terminology plugin

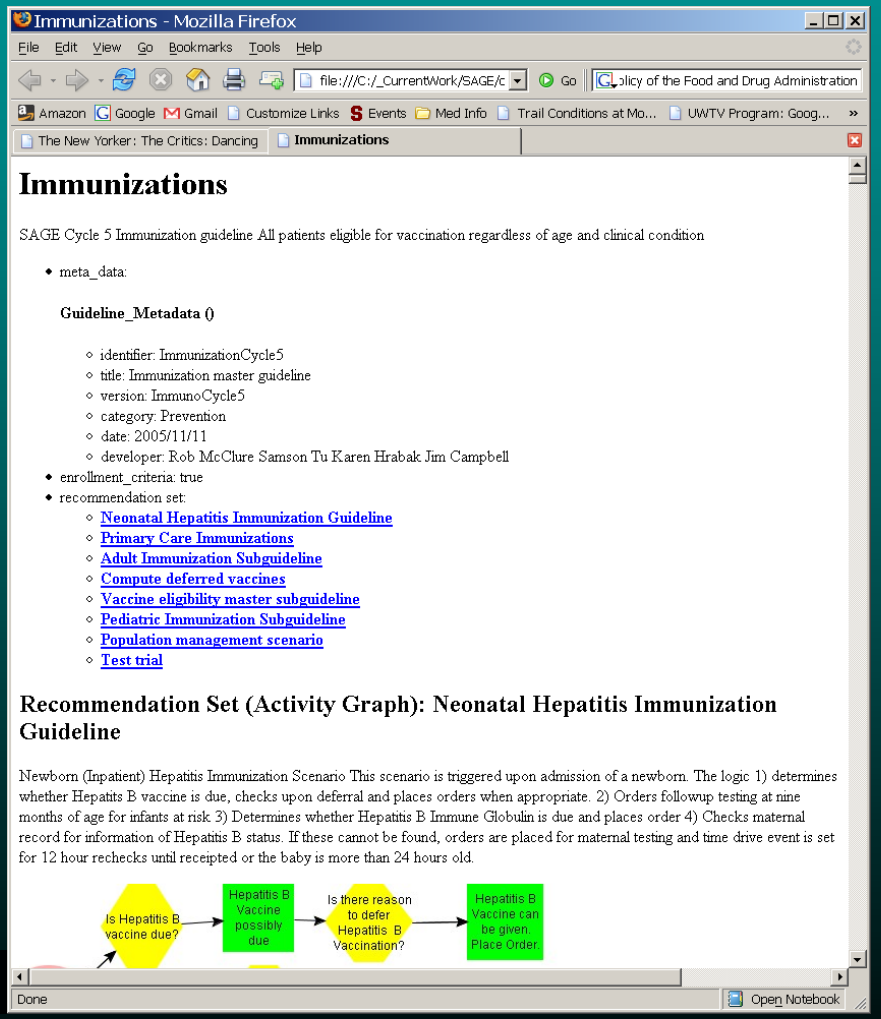
Kwiz

- Alternative navigation
- Enhanced Search
- Re-use of instances from other projects



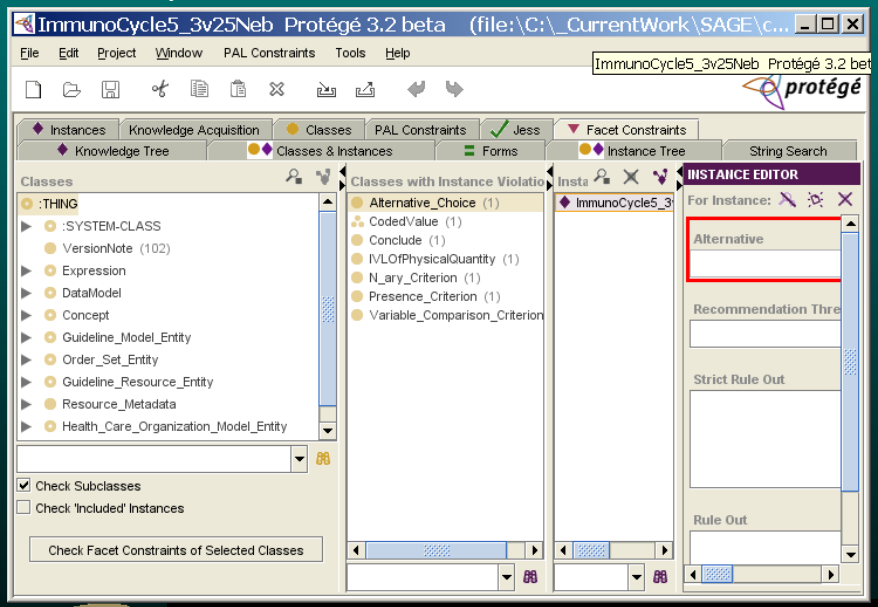
XML/HTML Guideline View

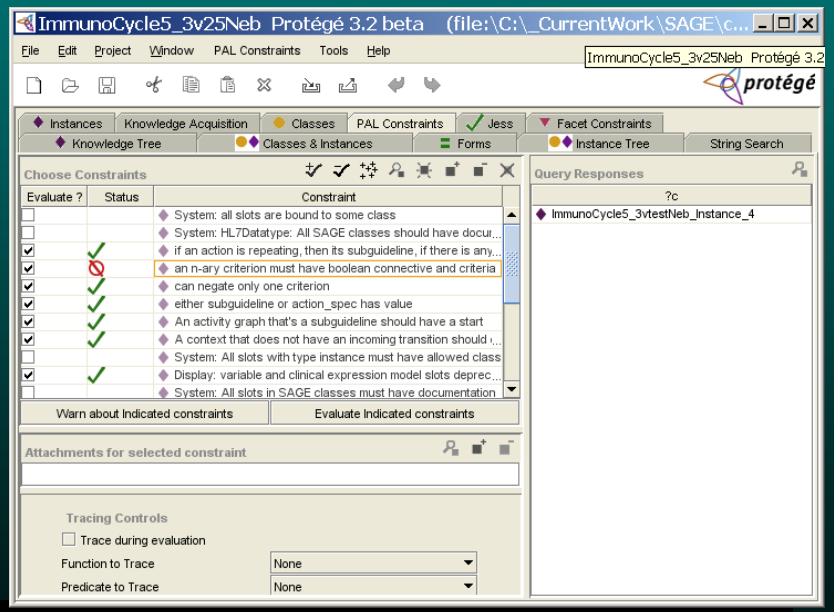
- Uses a separate Protégé knowledge base to specify how XML should be generated from instances
- Uses XSLT to transform XML to HTML



Constraint Checking: PAL and Facet Constraint Tabs

- PALConstraint tab: Learning curve
  FacetConstraint tab: Problems with performance





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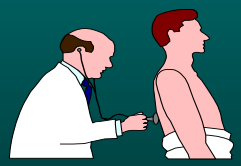

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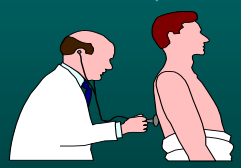

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Demo of Encoding Exercise: Adult Pneumoccocal Vaccine

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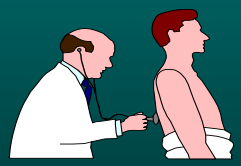

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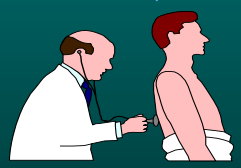

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Validating the Encoding

- Validation of decision logic
- Internal review by modeler team
- Validation of run-time environment
  - Simulated cases
  - Copies of live data records
- Quality assurance plan
- Evaluation and feedback

Validating the Decision Logic

- Guideline workflow logic is often more complicated than can be embodied in simple rules
- As the complexity of the scenarios increases, probability of errors rises geometrically
- CDSS environment should consider workbench for testing important to overall activity
- Internal consistency checking of bindings and data constraints should be integrated within the CDSS workbench

Dynamic tests:

Demonstration

SAGE TAB

Patient: Yura Sage

- 36 year old Caucasian male
- Allergies: Penicillin
- Problems: Hypertension, rheumatoid arthritis, nasal allergies, chronic bronchitis, history of splenectomy
- Medications: Cytoxan 50mg (alkylating agent), Celebrex 200mg
- Vaccinations:
  - 1 dose Pneumococcal (PPV23)vaccine (last dose 2000)
  - 2 doses Diphtheria containing vaccine
  - 1 dose Hepatitis B vaccine

Validating the Run-Time Environment

- Data bases within clinical systems in-use frequently have variable content and may reflect different patterns of usage between sites
- Demonstration cases are valuable for testing but execution against live (parallel) data often exposes:
  - Need for different pragmatics or expanded decision logic
  - Failure of model to handle missing or incomplete data

Validating the Run-Time Environment

in-use
nd may
between sites
for testing
data often

For example:
1) Adult patients in US often transfer physicians
2) Immunization history is frequently not recorded in adults
3) Should model make simplifying assumptions regarding primary immunization for Dt?

- Need for different pragmatics or expanded decision logic
- Failure of model to handle missing or incomplete data

Localization and Binding to Vendor CIS

- Interoperable model (such as SAGE) assumes compliance with all information and vocabulary standards
- Implementing this model in a system with parochial terminology requires:
  - Review of scenario assumptions for local applicability
  - Exhaustive mapping to local data tables (code sets must be supported)

Quality Assurance Safety Monitoring

- Guideline interventions should generally be tracked and recorded on a patient-by-patient basis
- Consider that one or more implementation scenarios should always address monitoring of success and safety events
- Modeling team should review for safety sentinel events, these should be considered as part of implementation plan

Possible Compliance / Safety Monitoring Scenarios

- Report of non-compliance events issued with summary statistics by site and provider
- Babies leaving hospital without record of Hepatitis B vaccination
- Hospitalization of elderly for pneumonia with no history of pneumococcal or influenza vaccinations and clinic visit within past year
- Elderly discharged from hospital in flu season without vaccination

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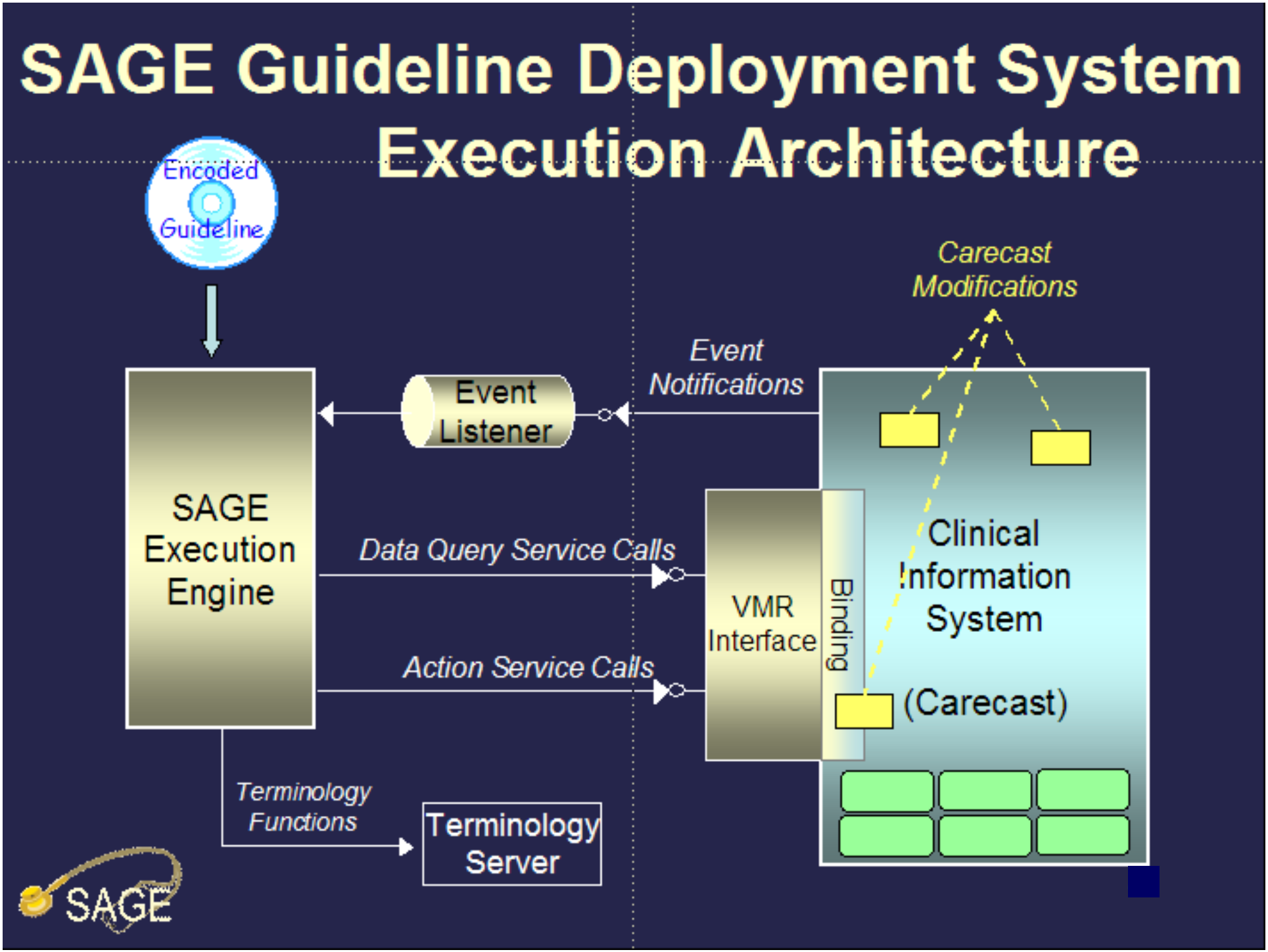
SAGE Guideline Deployment System Execution Architecture



SAGE in Action!
Primary Care Visit Scenario
Patient: Yura Sage

- 36 year old Caucasian male
- Allergies: Penicillins
- Problems: Hypertension, rheumatoid arthritis, nasal allergies, chronic bronchitis, **history of splenectomy**
- Medications: Cytoxan 50mg (**alkylating agent**), Celebrex 200mg
- Vaccinations:
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Primary Care Visit Scenario

- Patient checks into clinic
- Clinician accesses the patient record, triggering CDSS (SAGE)
  - Event sent from web page
- CIS queries problem list, procedure history and vaccination history to evaluate vaccinations due or due but contraindicated
- In Carecast, Inbox messages sent:
  - 'Vaccines due/ due but contraindicated'
  - Inquire about illness and obtain immunization consent
  - Generate vaccine information sheets (VIS)
- In Carecast, clinician documents consent and verifies absence of severe illness (SAGE queries in CIS)
- SAGE checks for any vaccine deferral reasons
- Carecast Inbox message sent:
  - Order session: orders present for due vaccines

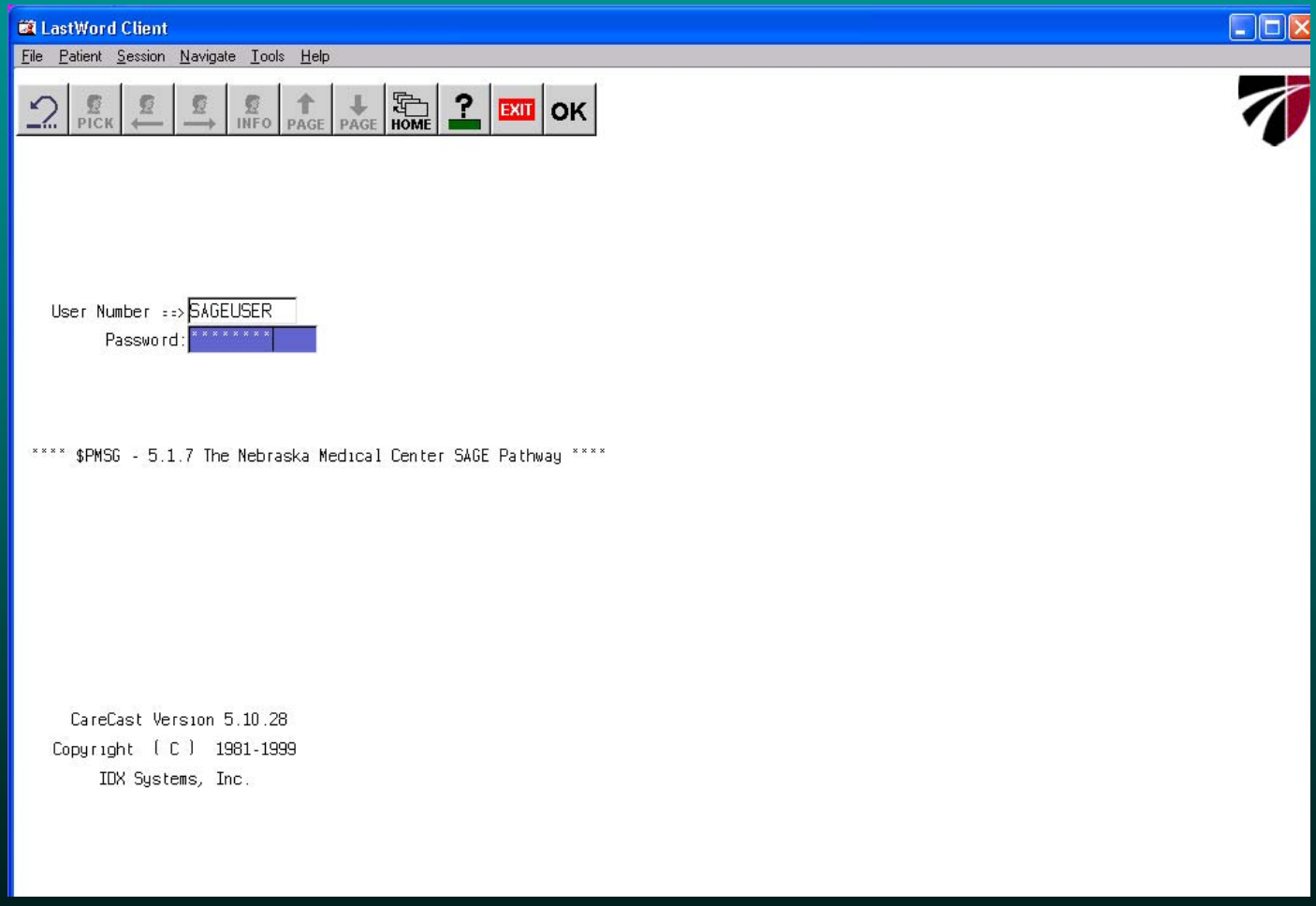
Questions?

Discussion…

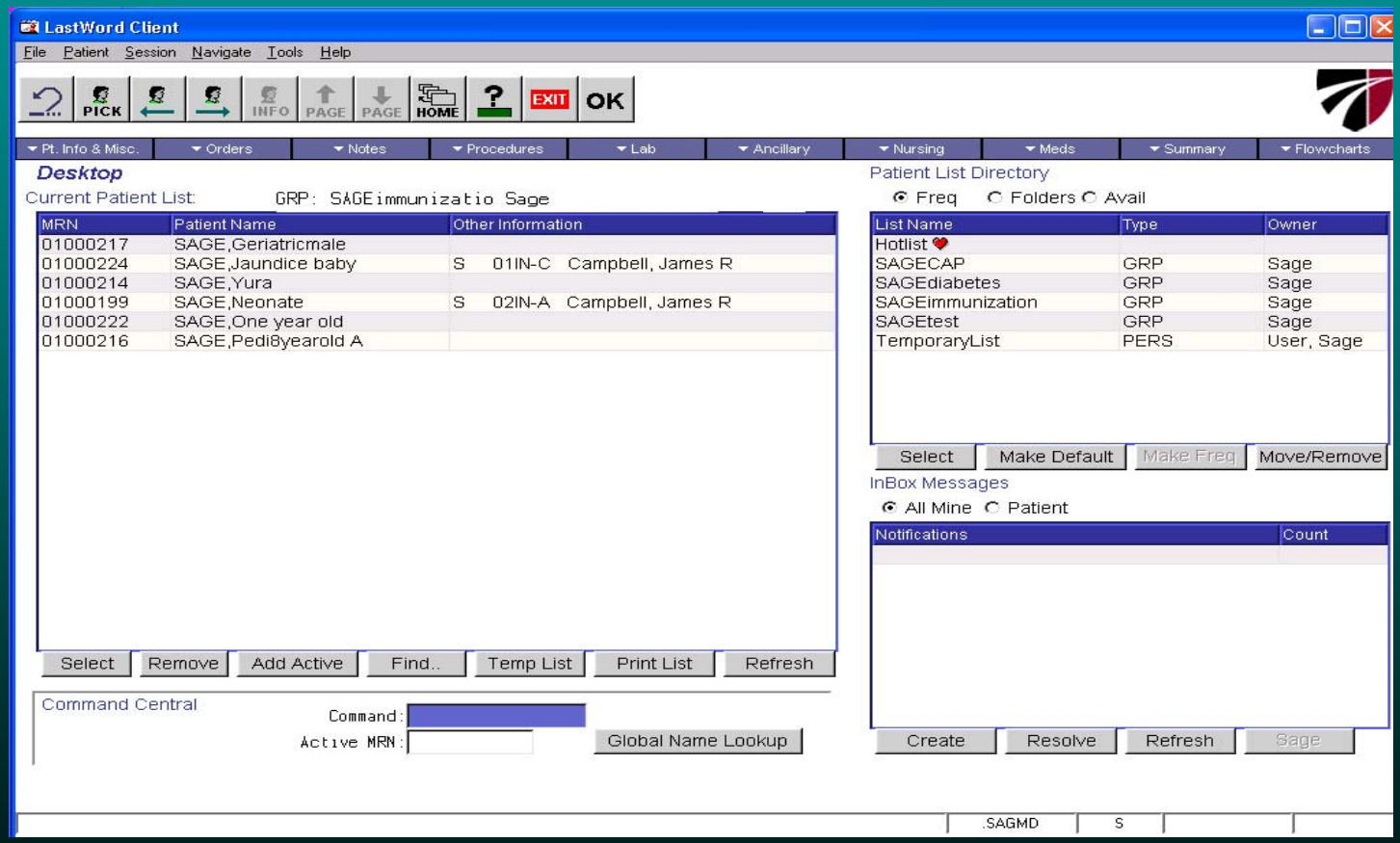
SAGE

Carecast / SAGE interactions

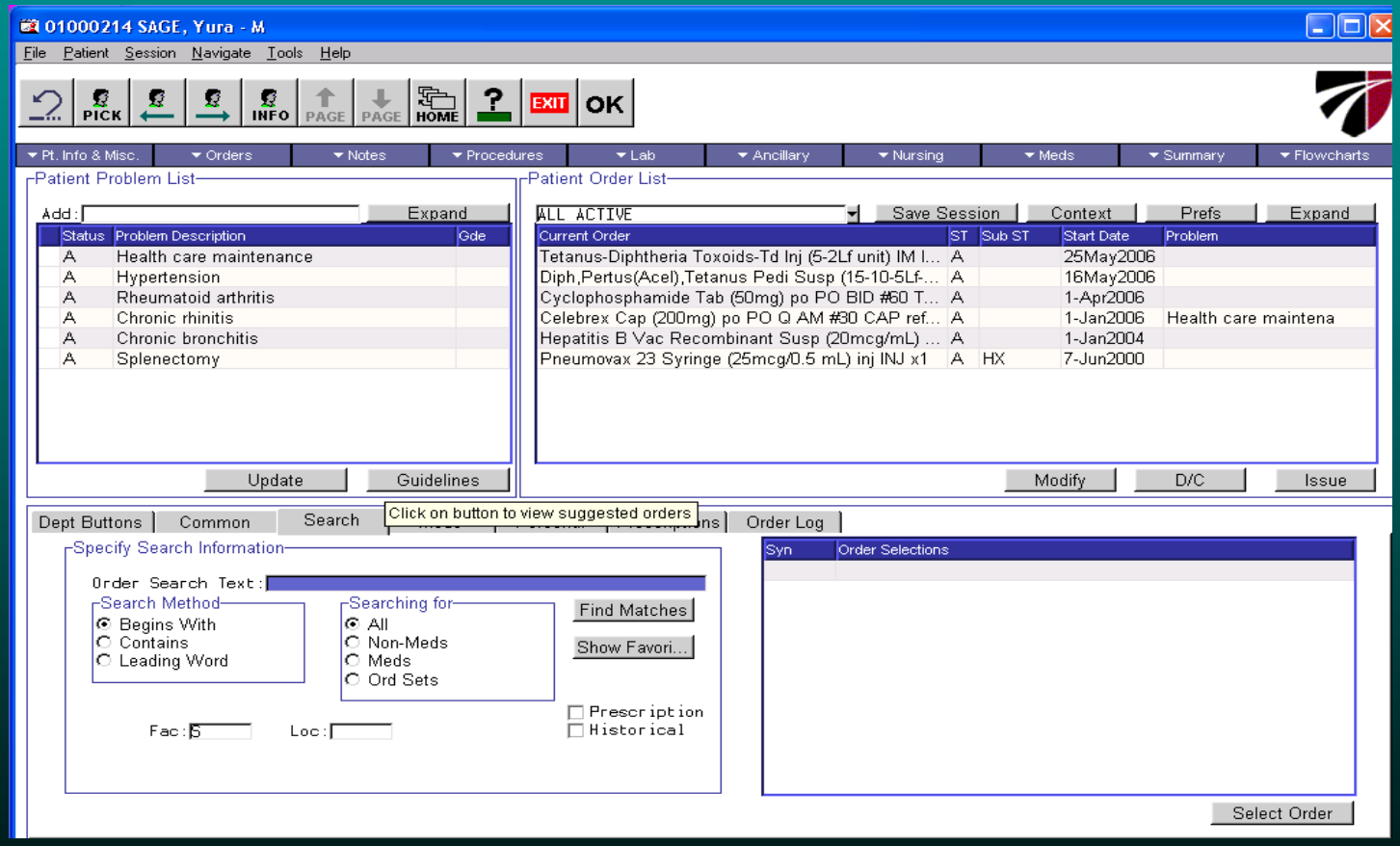
CIS (CareCast) Logon



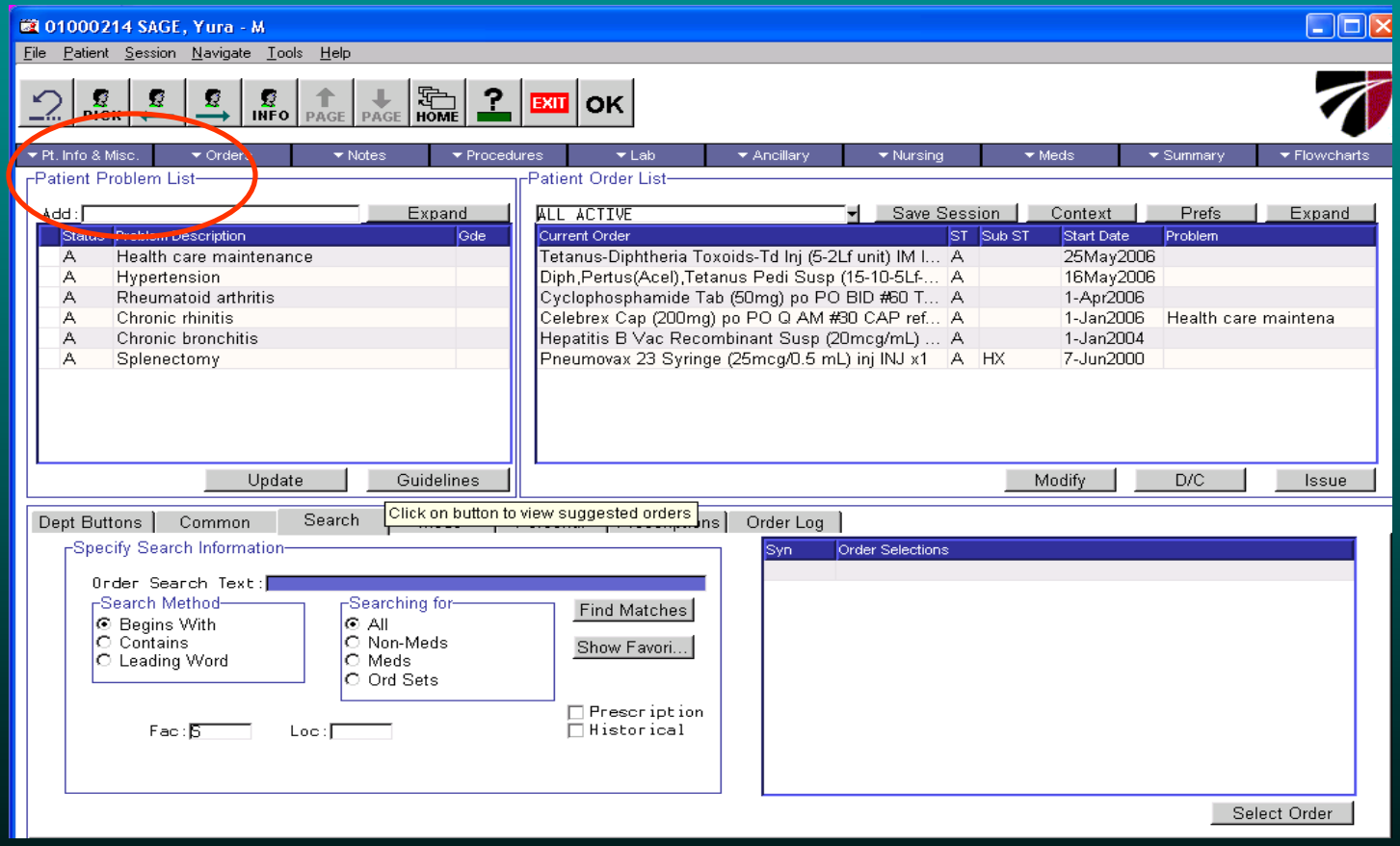
Patient: Yura Sage



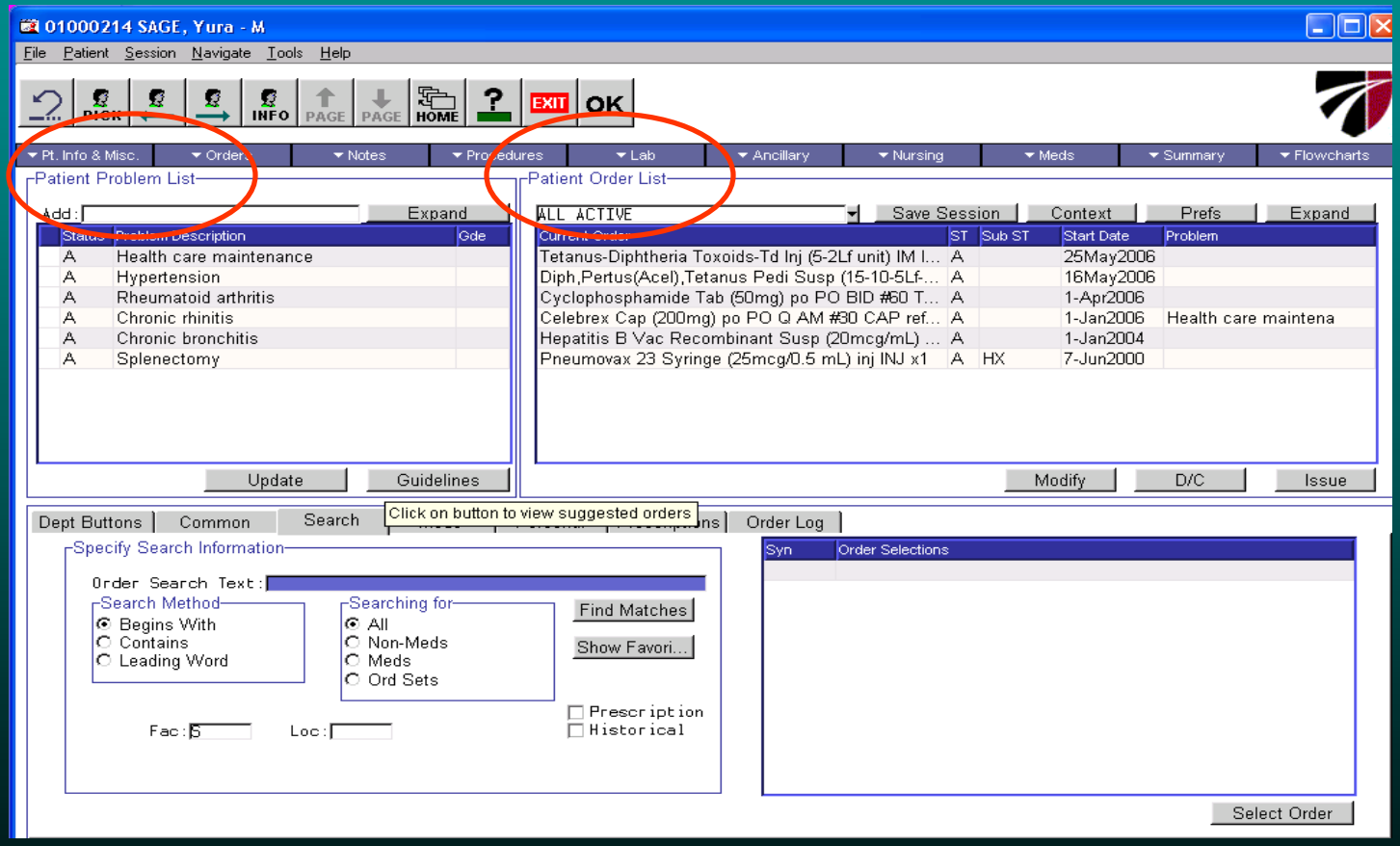
Problem List and Current Orders



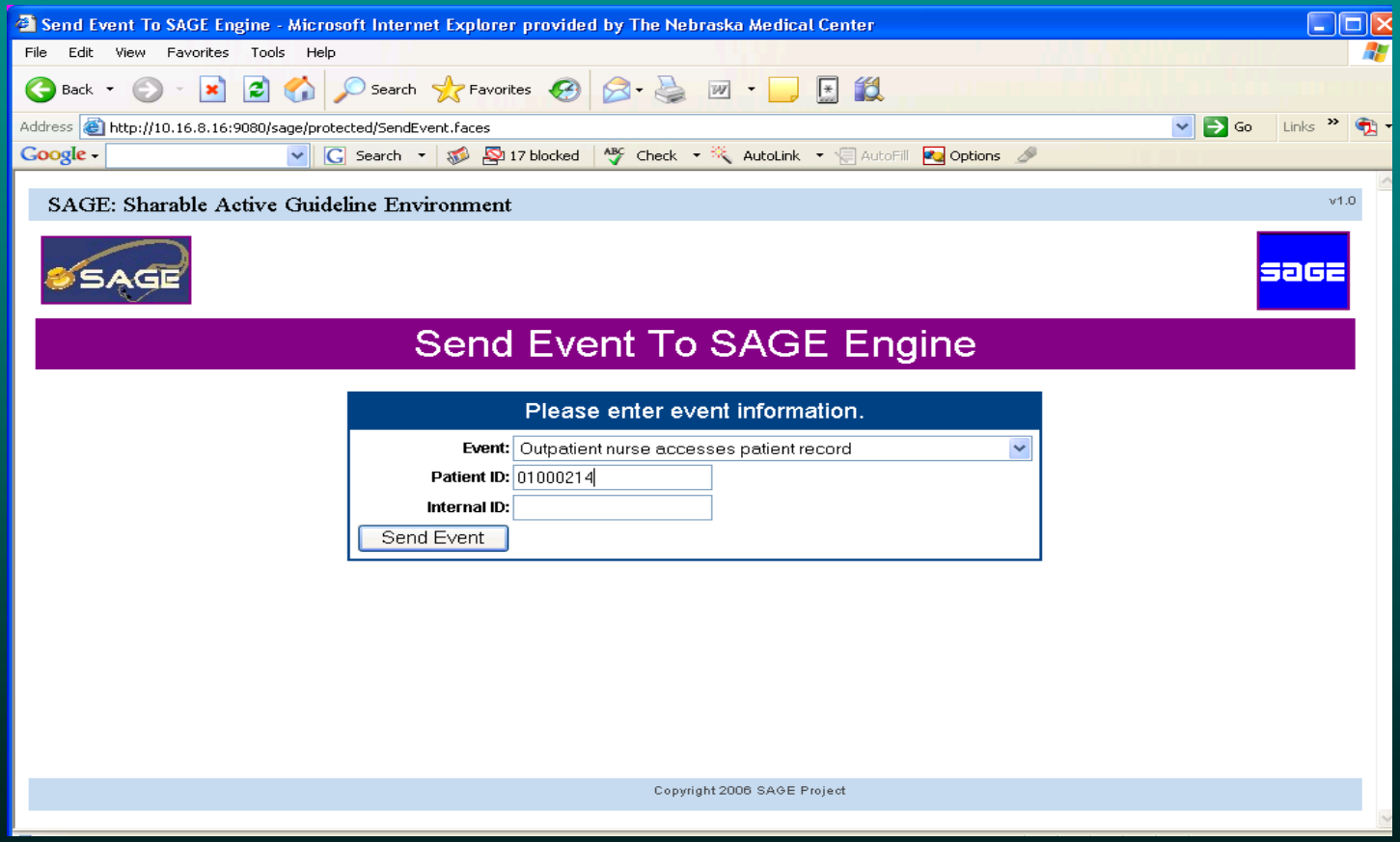
Problem List and Current Orders



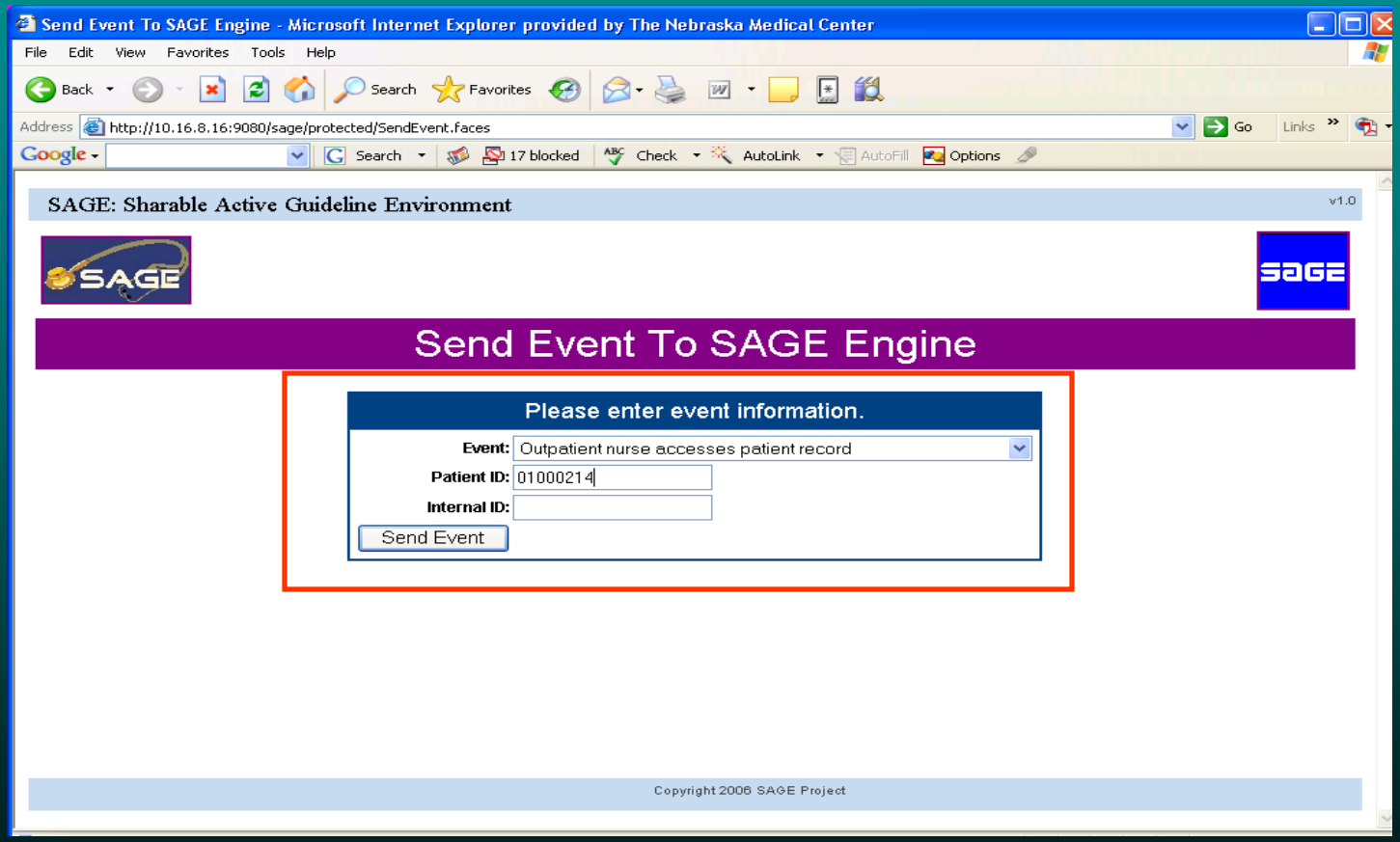
Problem List and Current Orders



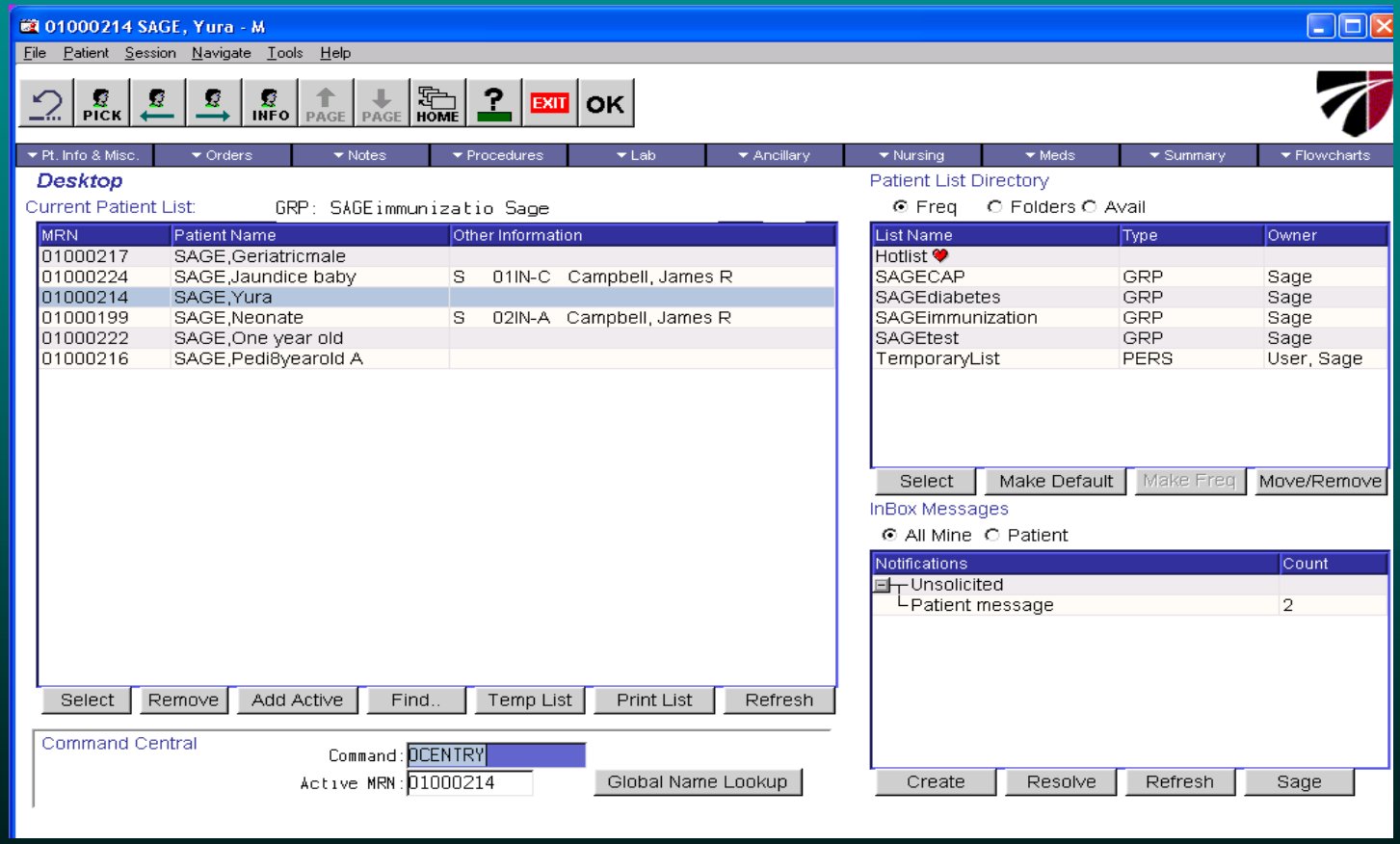
SAGE Triggering Event



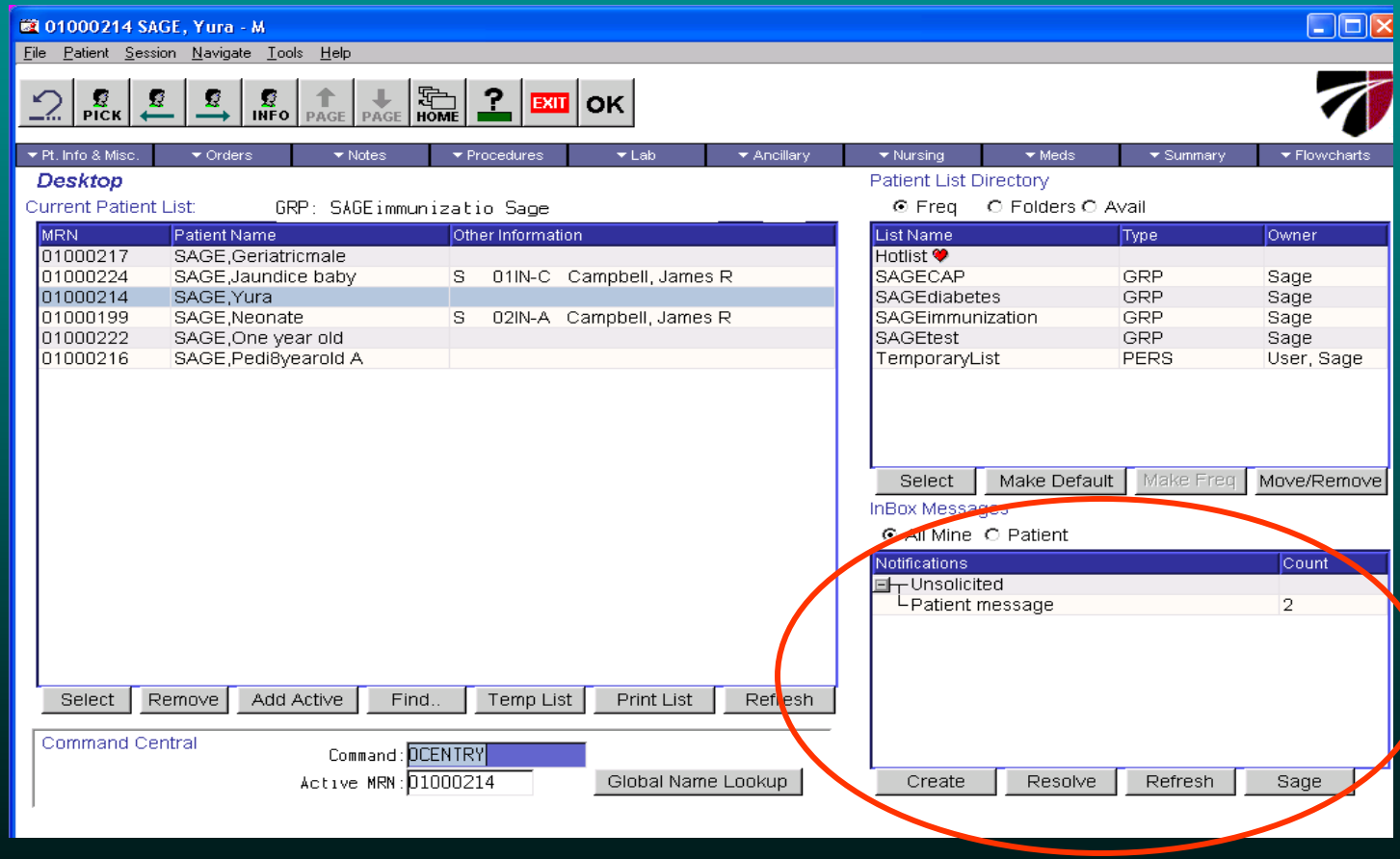
SAGE Triggering Event



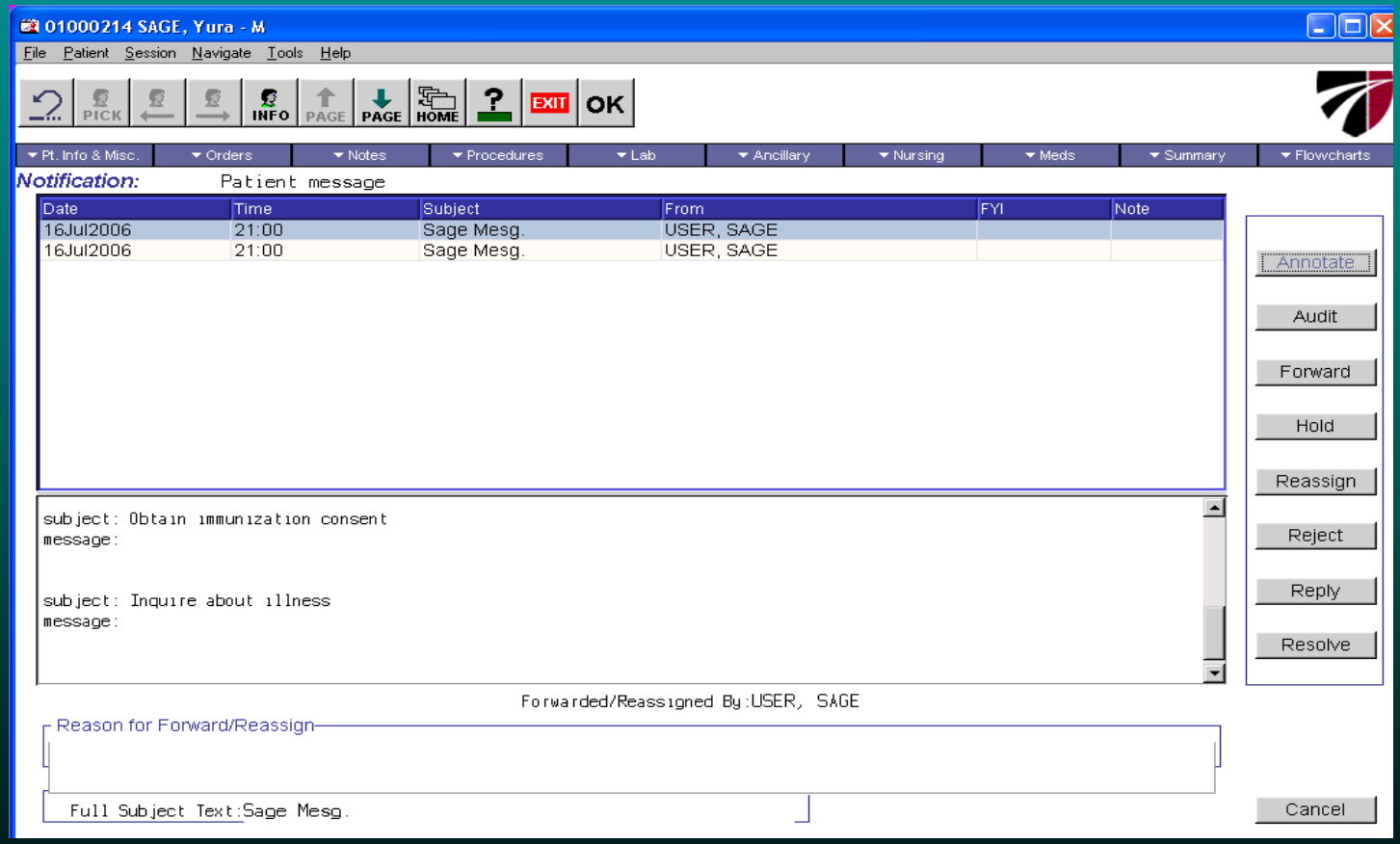
Inbox Messages



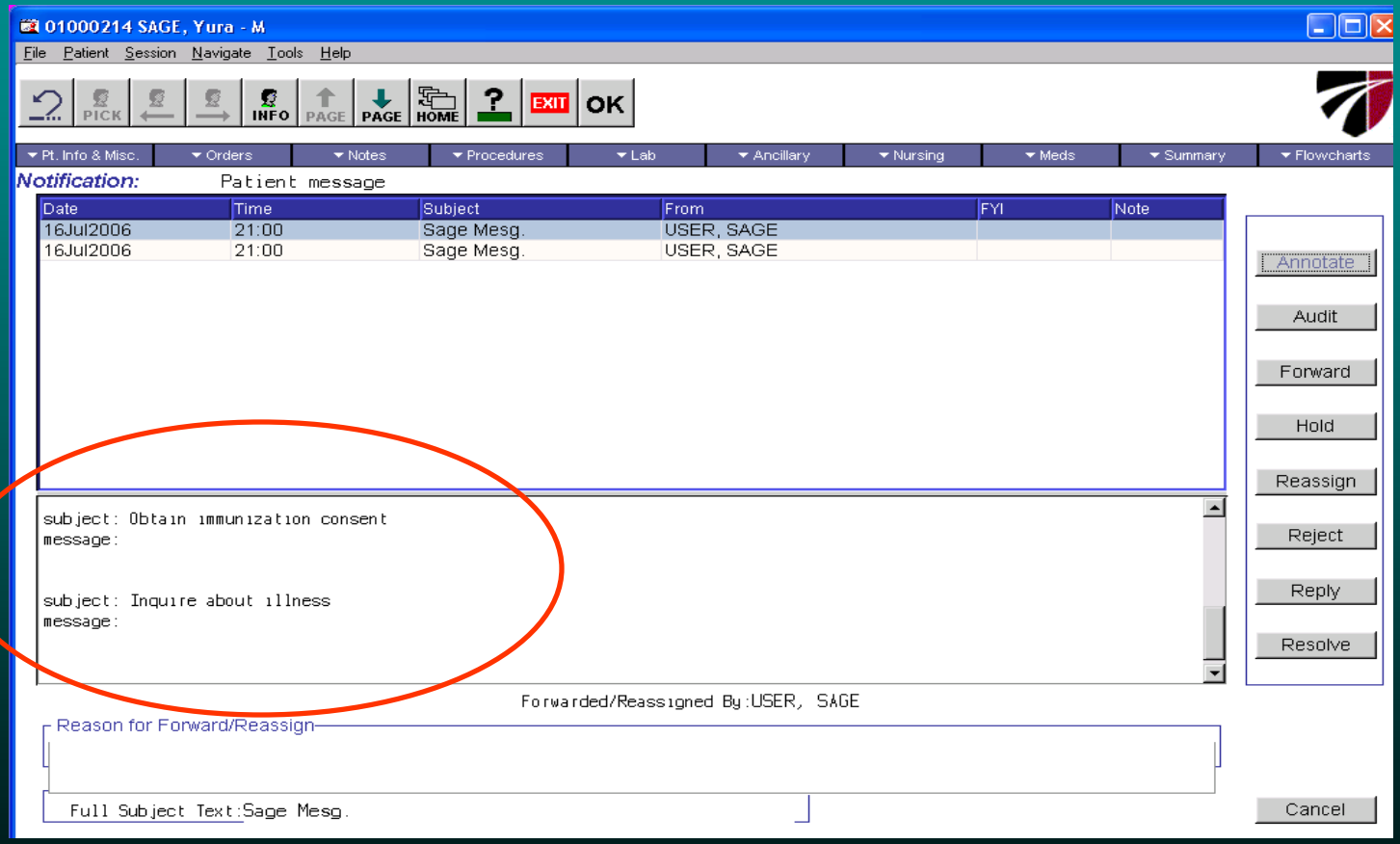
Inbox Messages



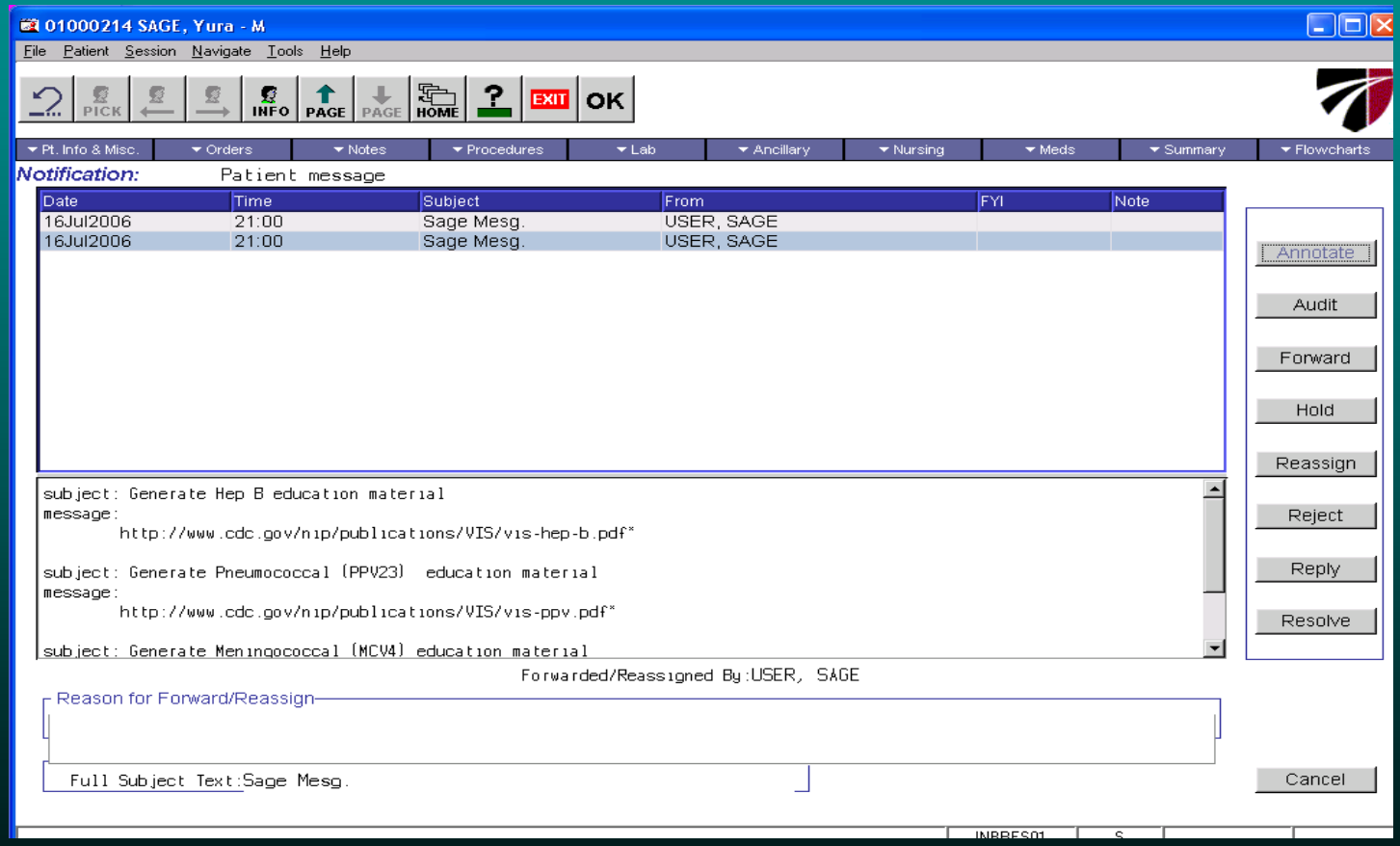
Query for Consent and Illness



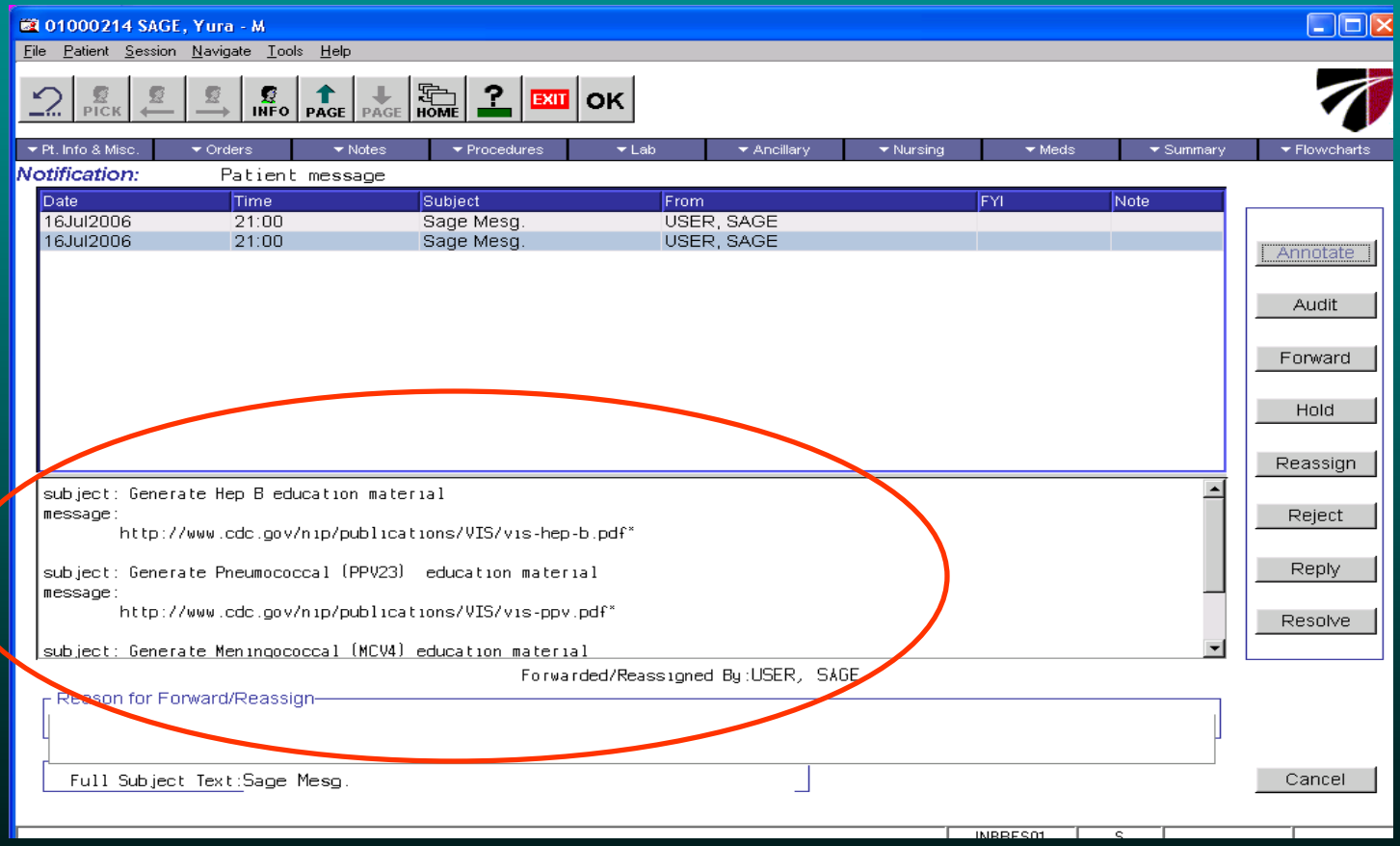
Query for Consent and Illness



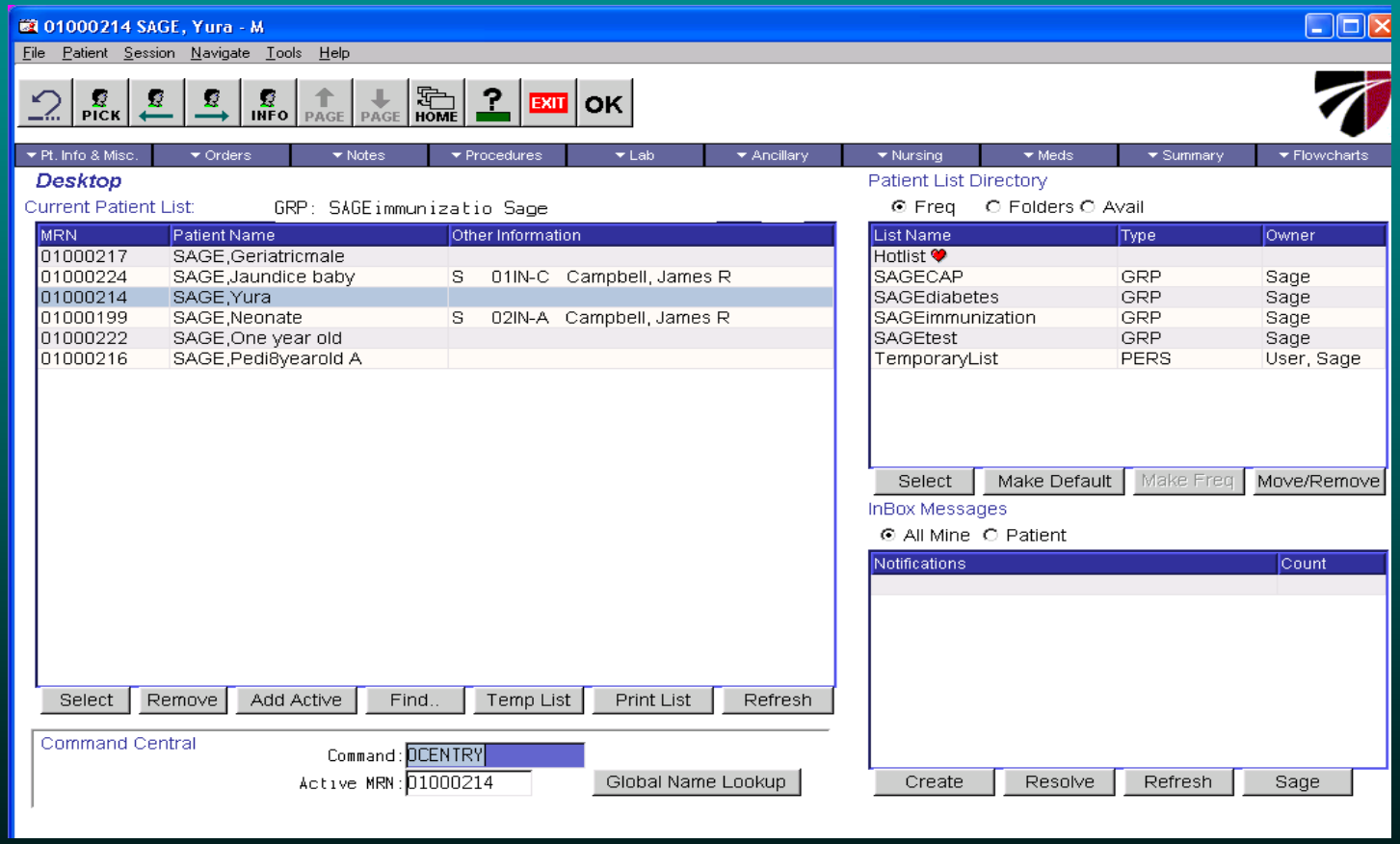
Generate Vaccine Information



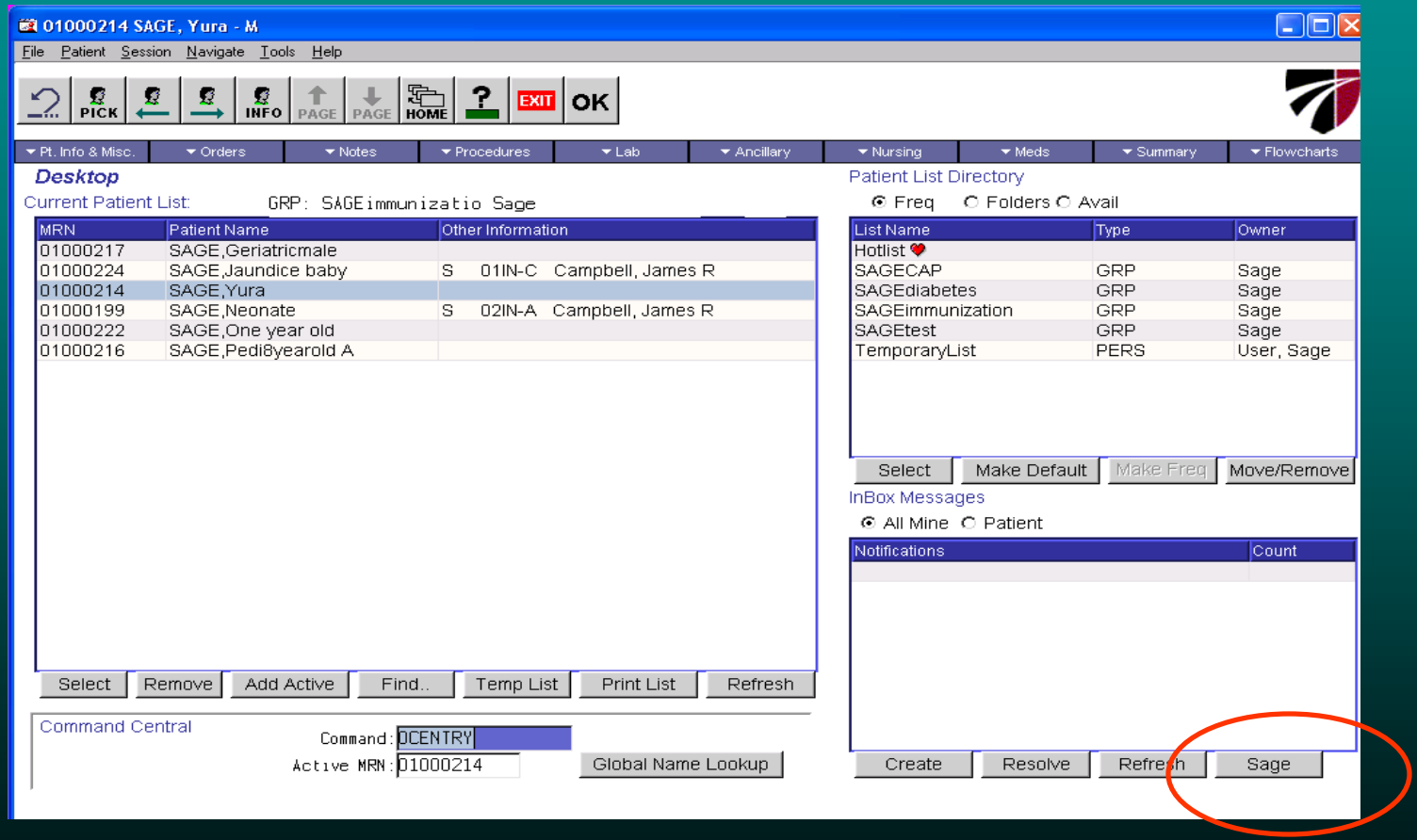
Generate Vaccine Information



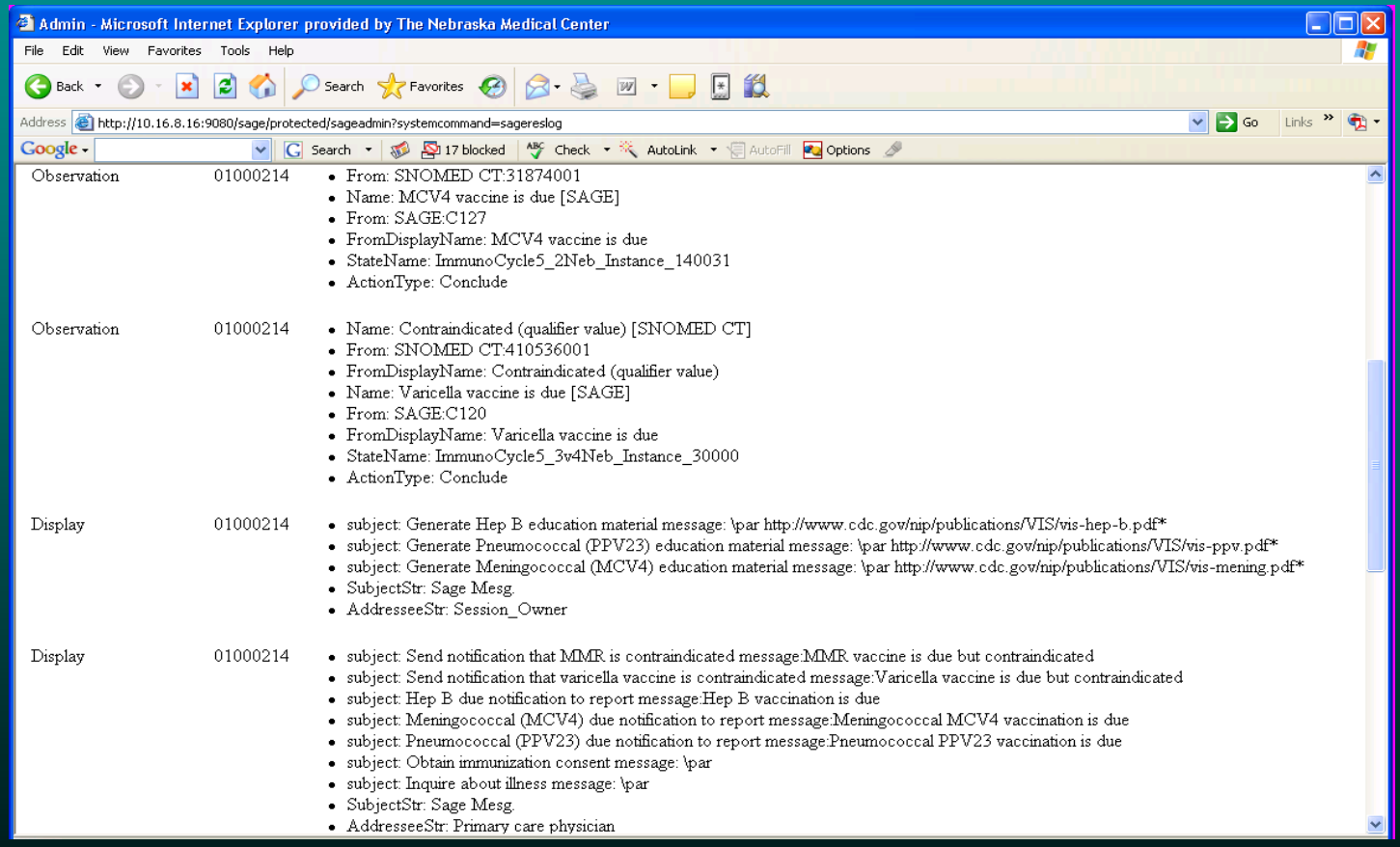
SAGE Button Active



SAGE Button Active

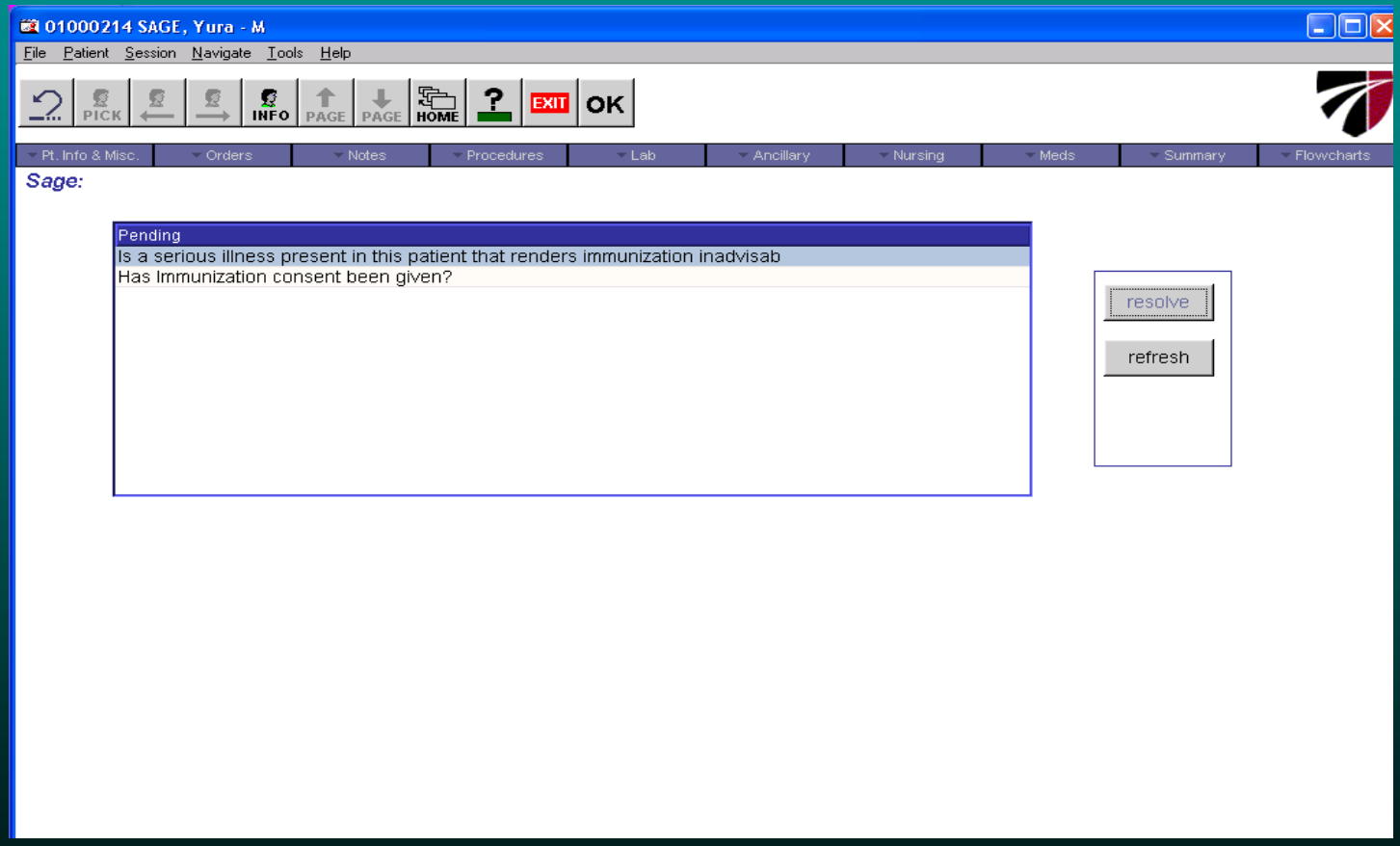


Sage Reports Log: Due and Due but Contraindicated Vaccines

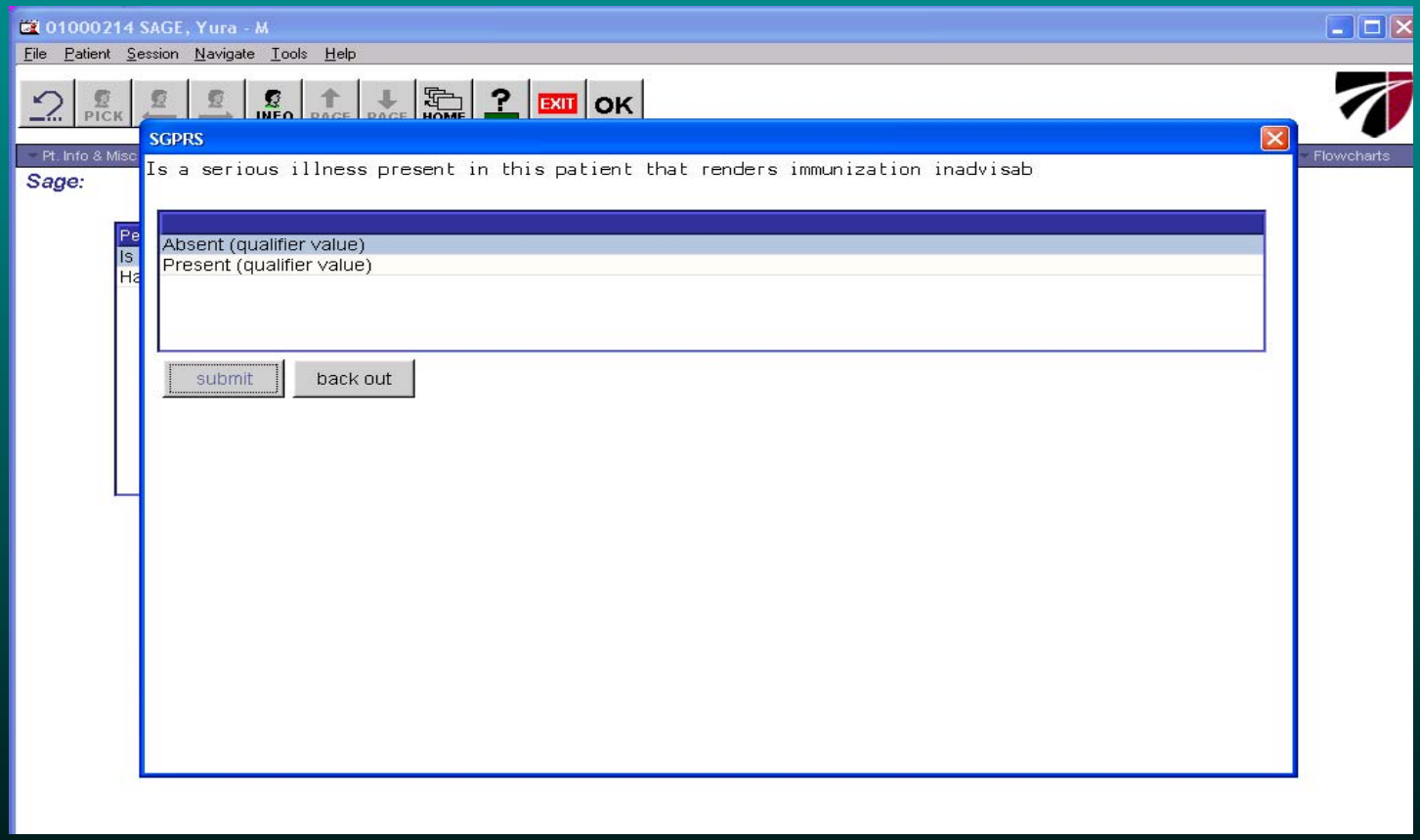


Observation	01000214	• From: SNOMED CT:31874001 • Name: MCV4 vaccine is due [SAGE] • From: SAGE:C127 • FromDisplayName: MCV4 vaccine is due • StateName: ImmunoCycle5_2Neb_Instance_140031 • ActionType: Conclude
Observation	01000214	• Name: Contraindicated (qualifier value) [SNOMED CT] • From: SNOMED CT:410536001 • FromDisplayName: Contraindicated (qualifier value) • Name: Varicella vaccine is due [SAGE] • From: SAGE:C120 • FromDisplayName: Varicella vaccine is due • StateName: ImmunoCycle5_3v4Neb_Instance_30000 • ActionType: Conclude
Display	01000214	• subject: Generate Hep B education material message: \par http://www.cdc.gov/nip/publications/VIS/vis-hep-b.pdf* • subject: Generate Pneumococcal (PPV23) education material message: \par http://www.cdc.gov/nip/publications/VIS/vis-ppv.pdf* • subject: Generate Meningococcal (MCV4) education material message: \par http://www.cdc.gov/nip/publications/VIS/vis-mening.pdf* • SubjectStr: Sage Mesg. • AddresseeStr: Session_Owner
Display	01000214	• subject: Send notification that MMR is contraindicated message:MMR vaccine is due but contraindicated • subject: Send notification that varicella vaccine is contraindicated message:Varicella vaccine is due but contraindicated • subject: Hep B due notification to report message:Hep B vaccination is due • subject: Meningococcal (MCV4) due notification to report message:Meningococcal MCV4 vaccination is due • subject: Pneumococcal (PPV23) due notification to report message:Pneumococcal PPV23 vaccination is due • subject: Obtain immunization consent message: \par • subject: Inquire about illness message: \par • SubjectStr: Sage Mesg. • AddresseeStr: Primary care physician

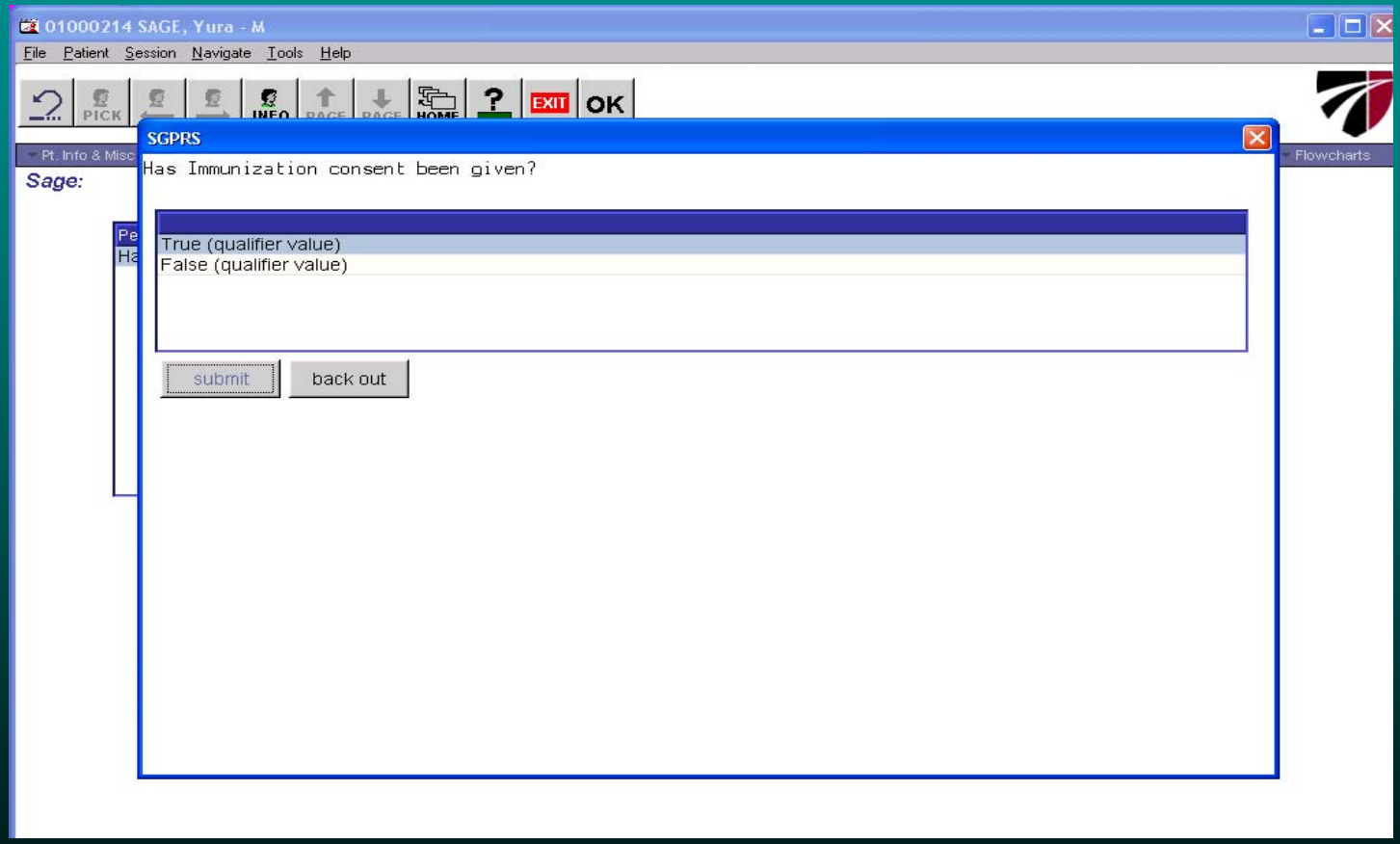
Provider Queries to Resolve



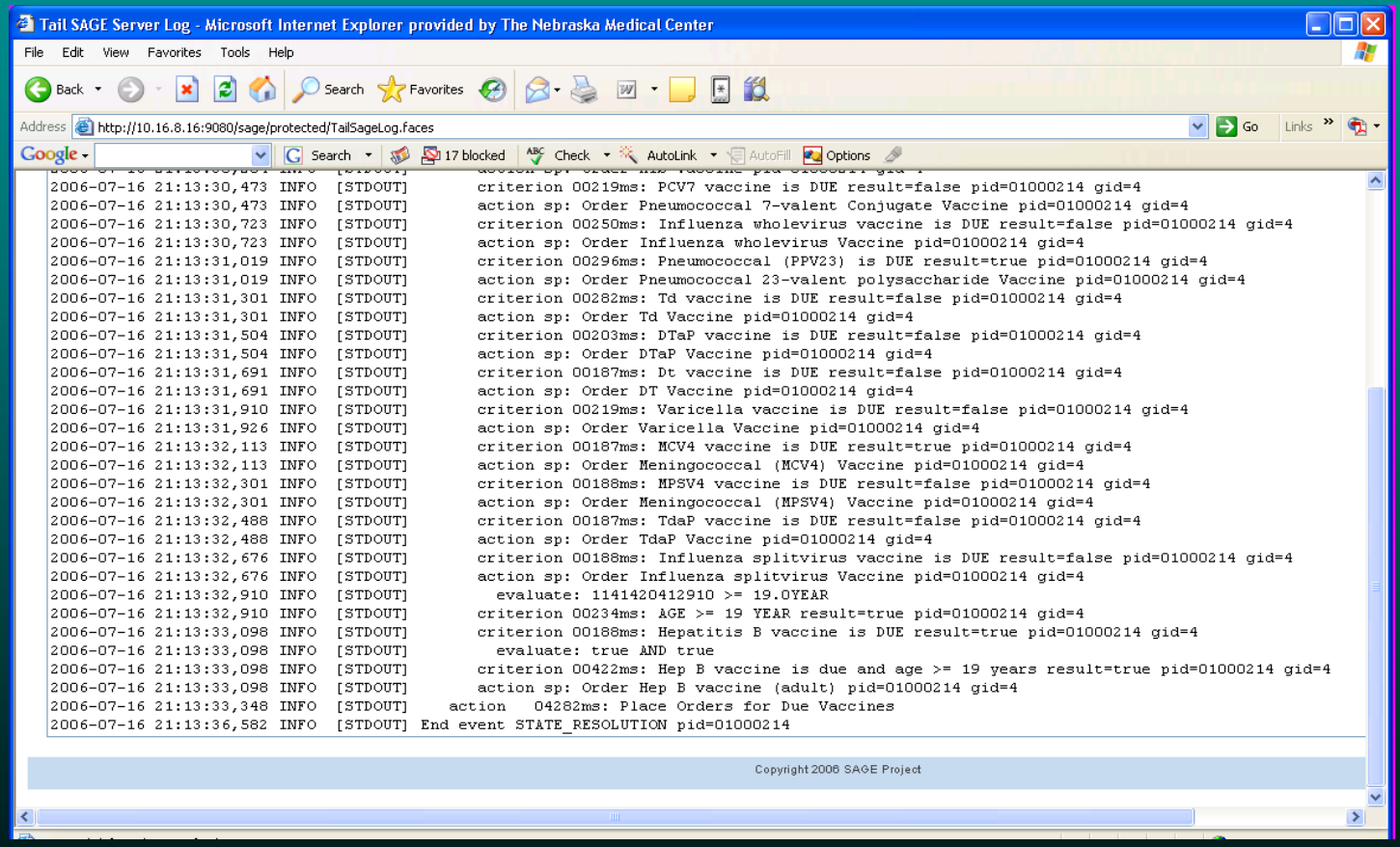
Is Serious Illness Present?



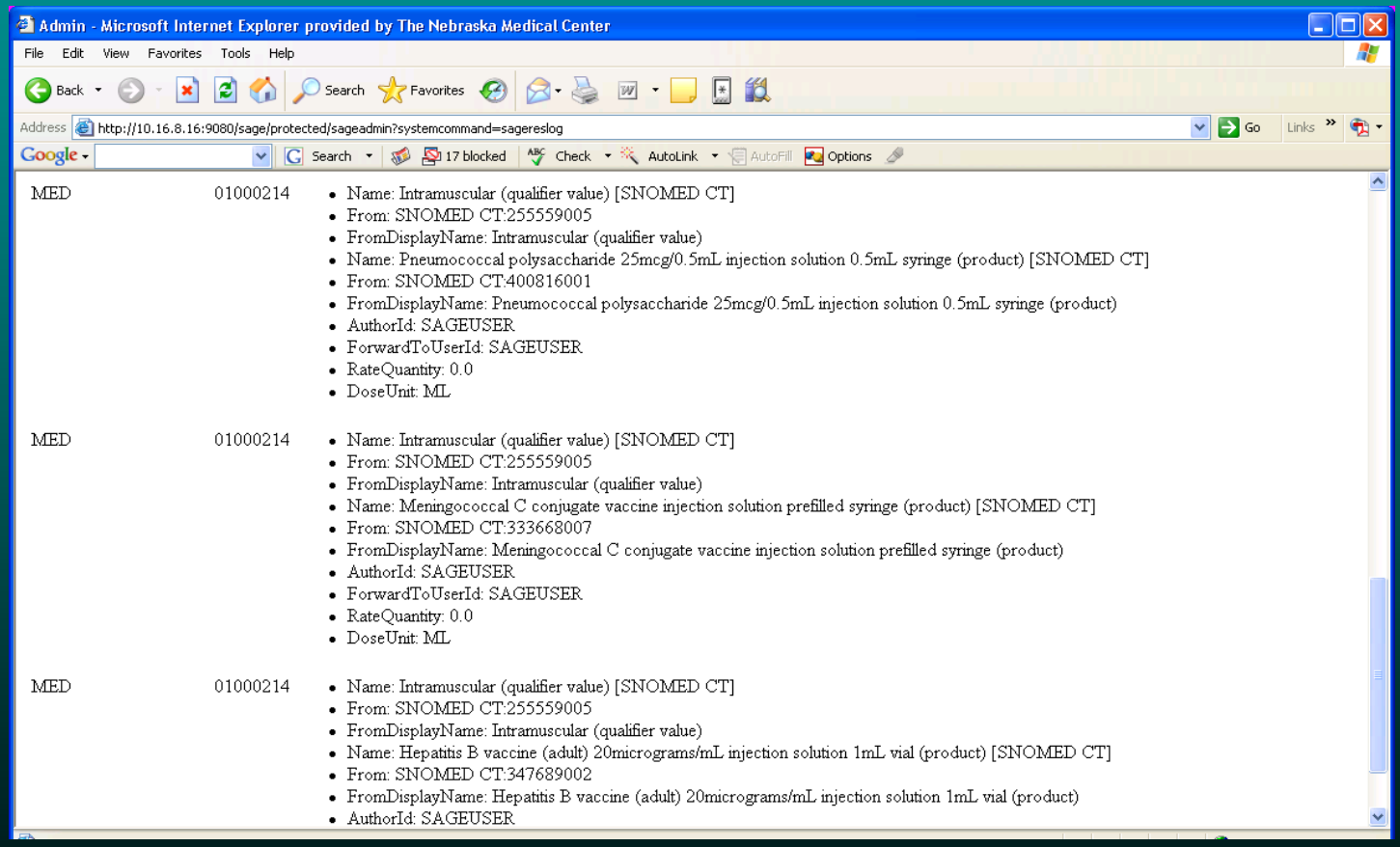
Has Consent Been Given?



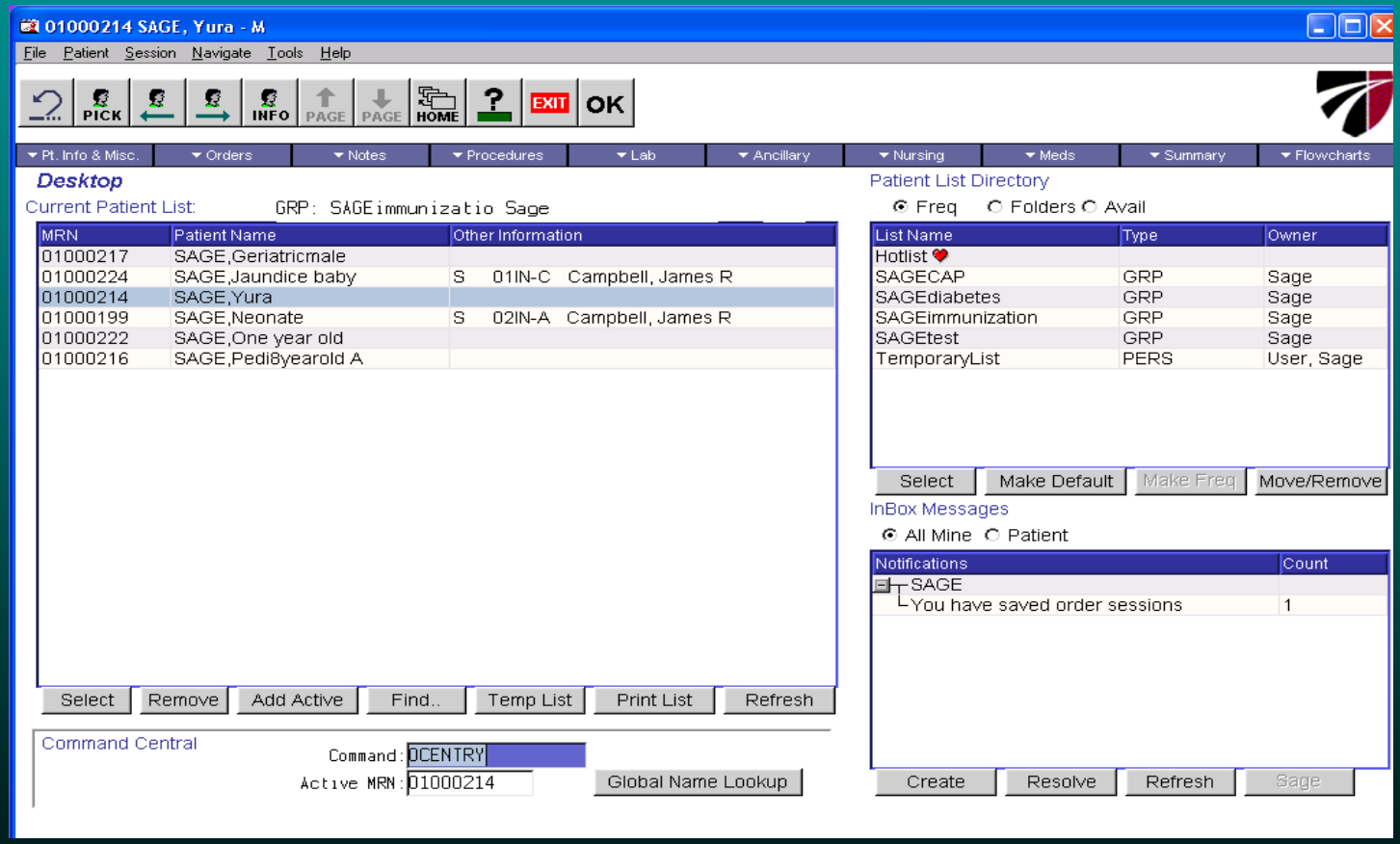
SAGE Log: 'Place Orders for Due Vaccines'



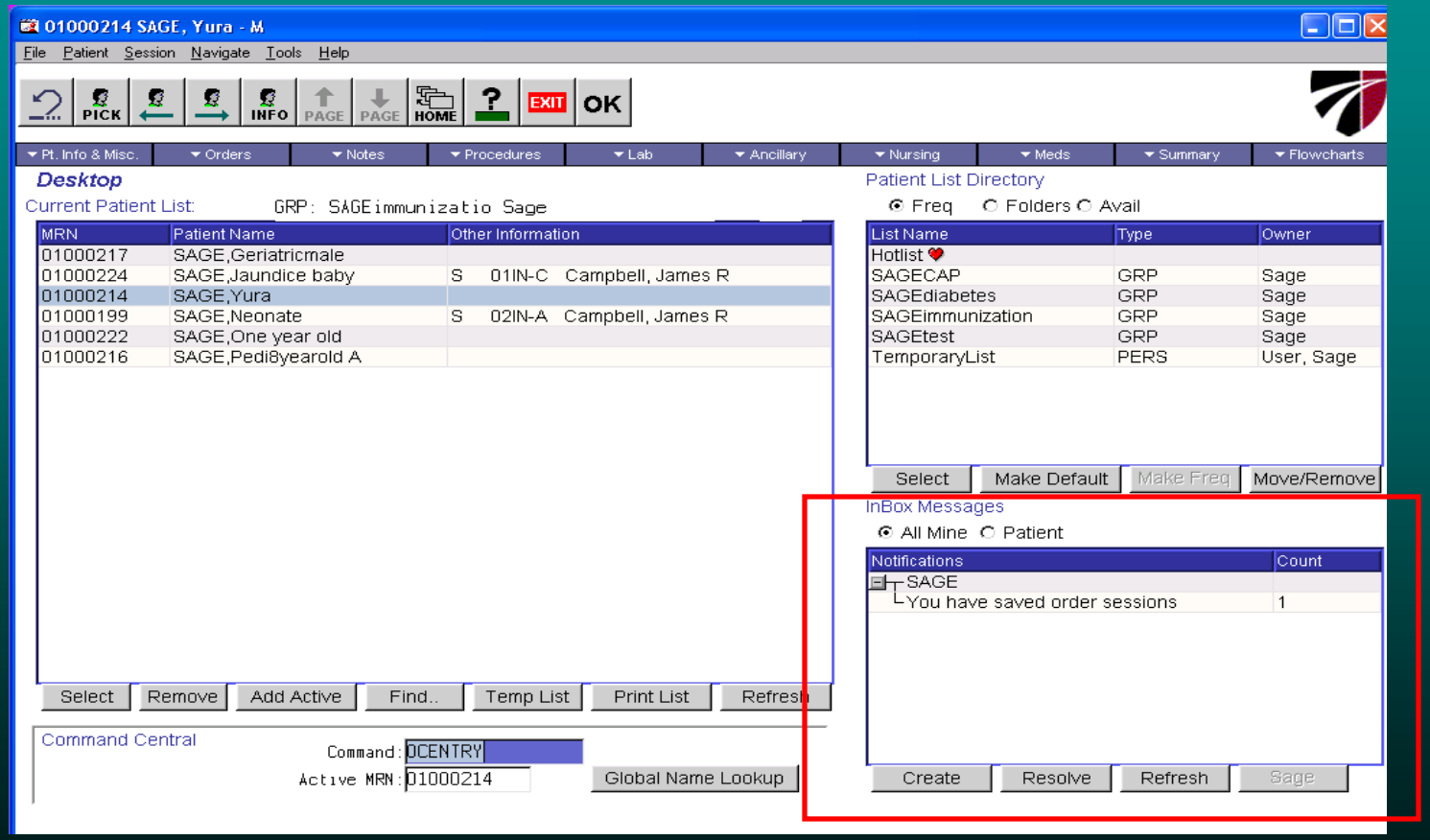
SAGE Reports Log: Med Orders



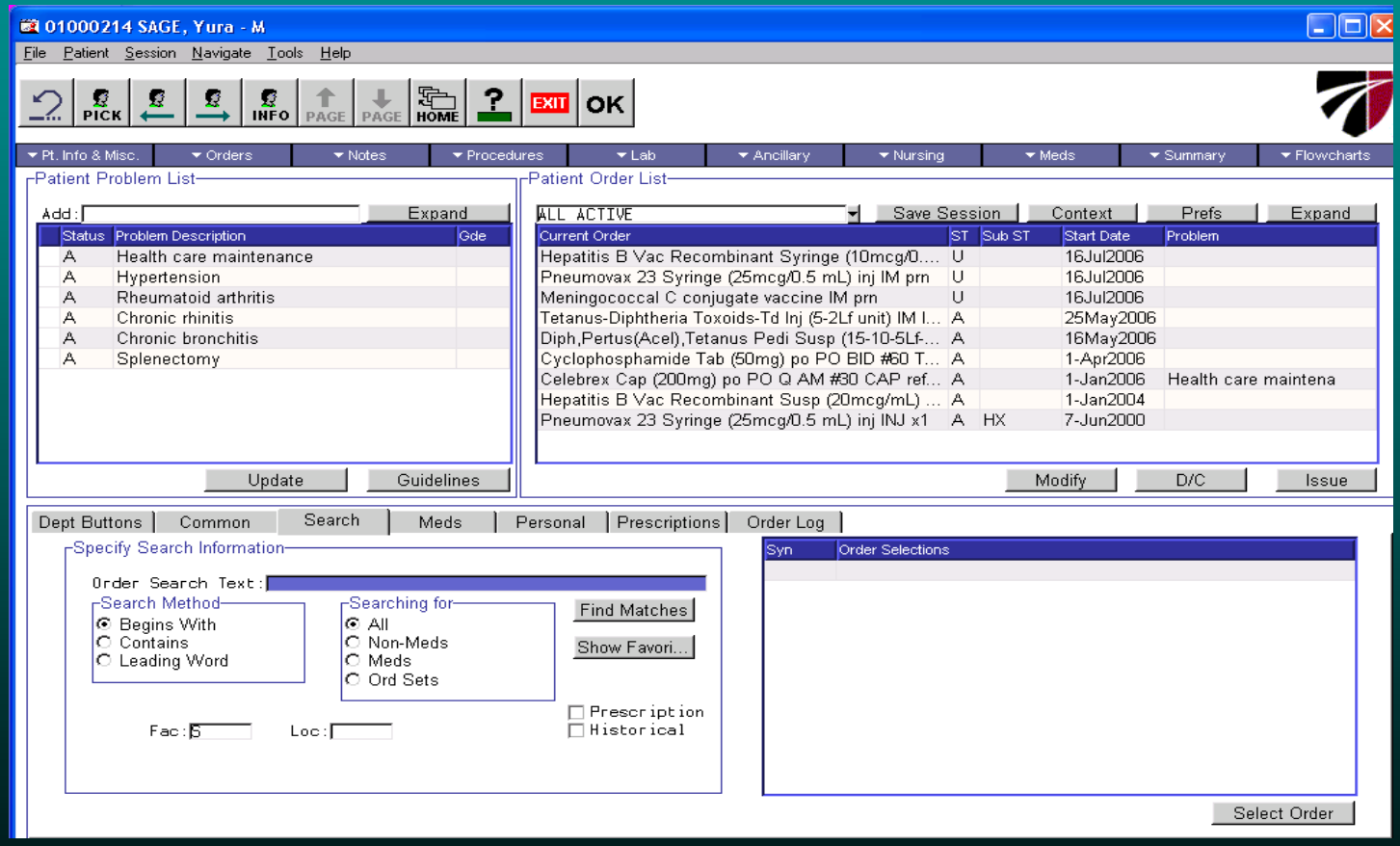
Inbox Message: 1 Order Session



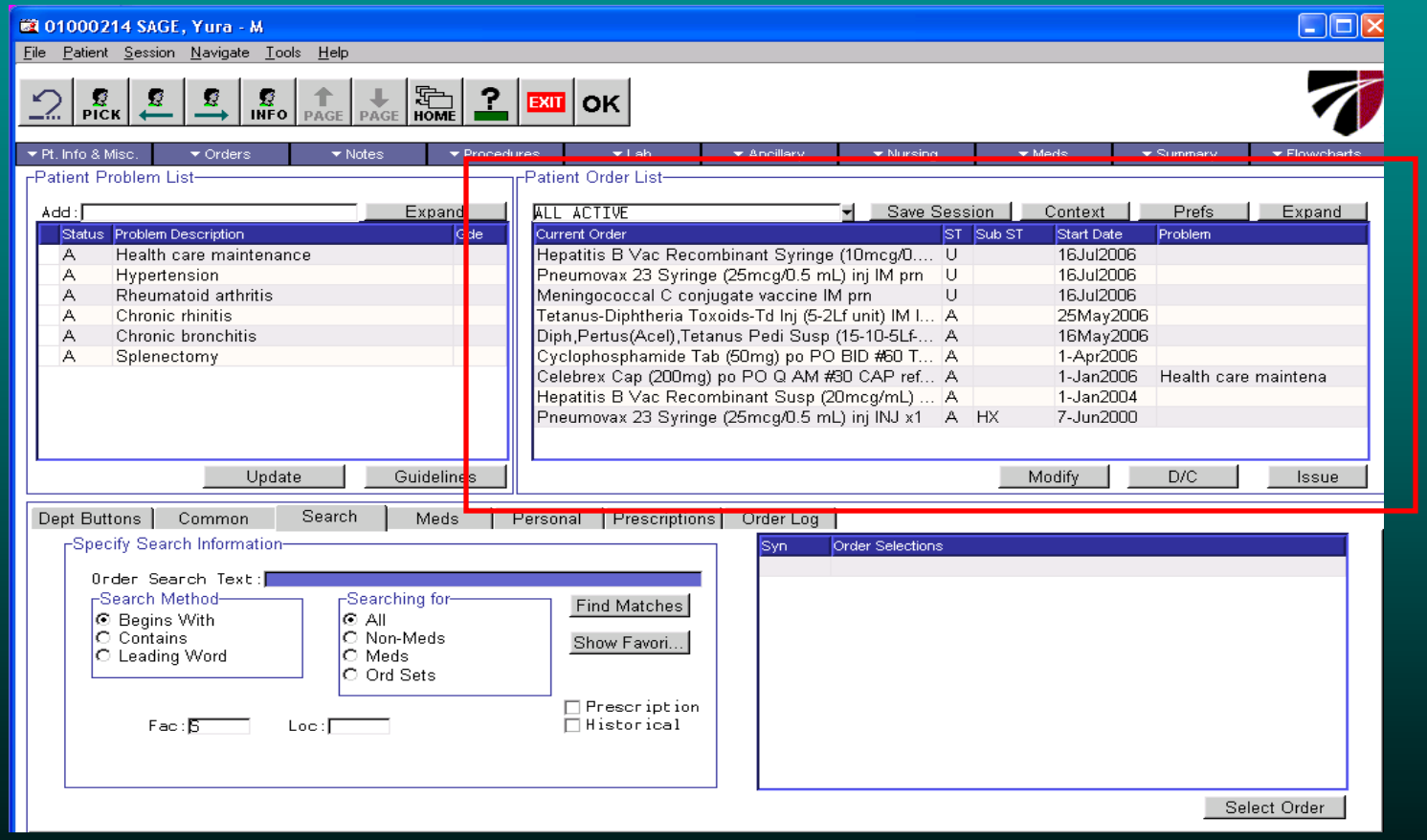
Inbox Message: 1 Order Session



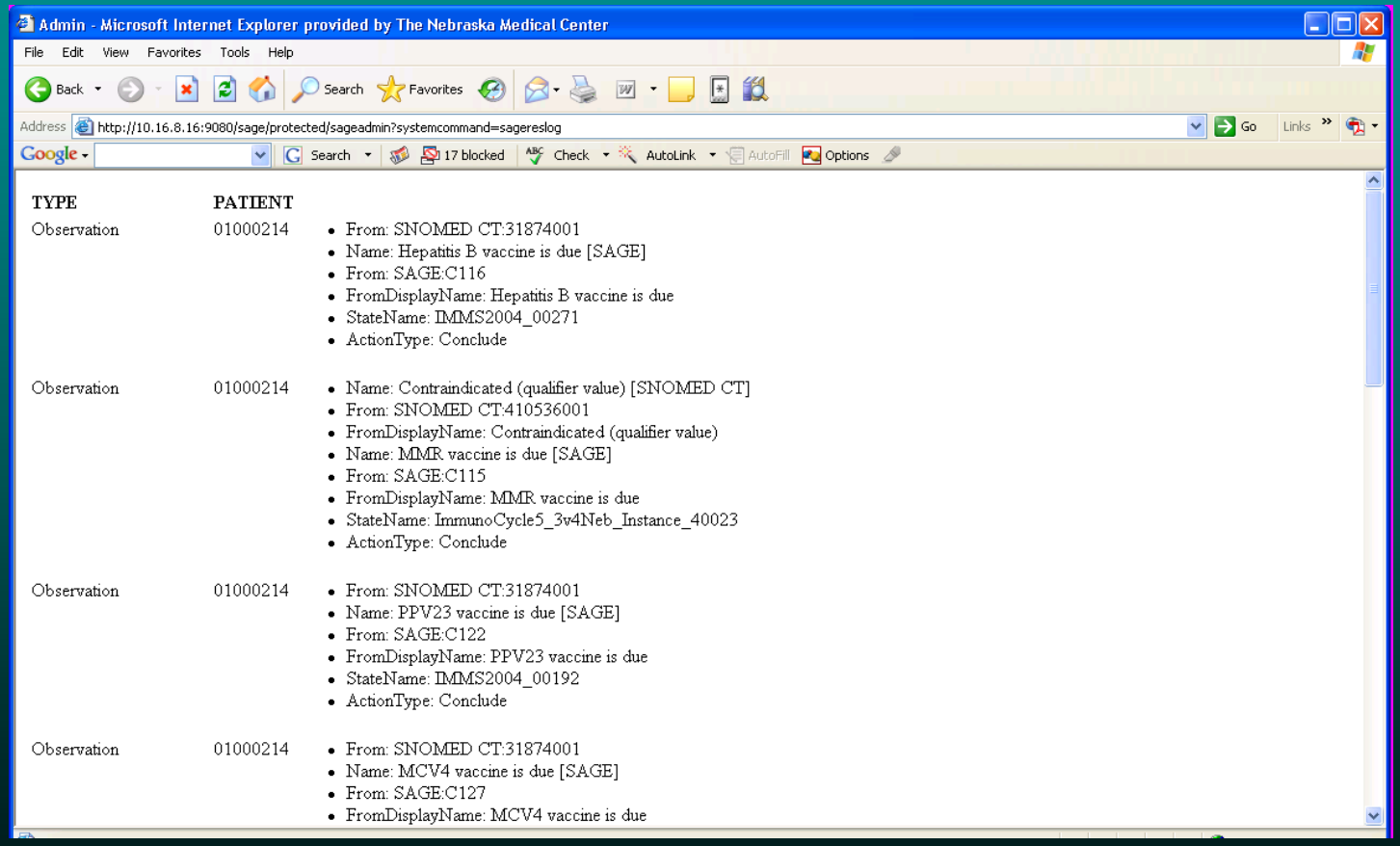
3 Un-issued Orders to Resolve



3 Un-issued Orders to Resolve

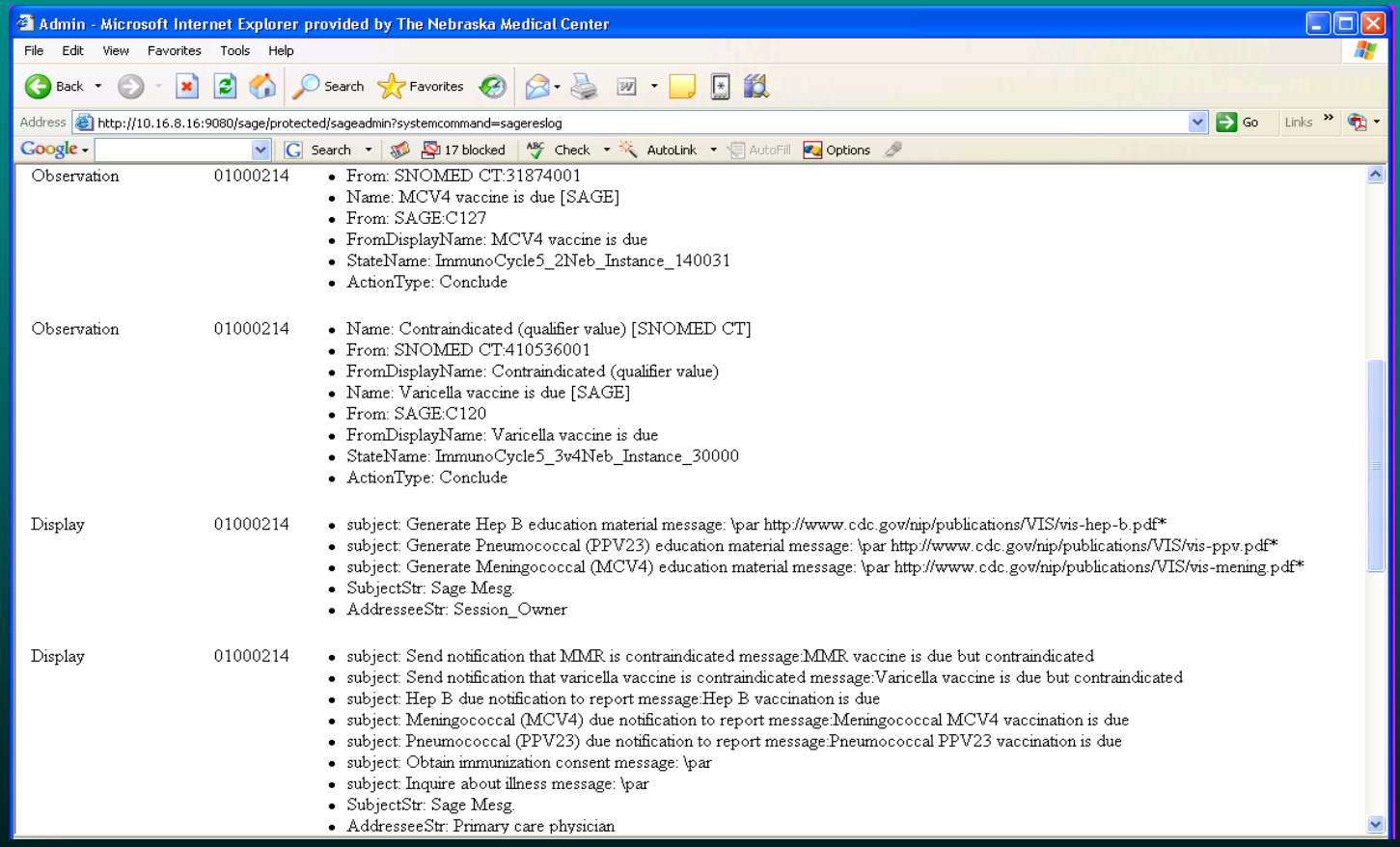


Sage Reports Log: 'Due' and 'Due but Contraindicated' Vaccines



TYPE	PATIENT	
Observation	01000214	• From: SNOMED CT:31874001 • Name: Hepatitis B vaccine is due [SAGE] • From: SAGE:C116 • FromDisplayName: Hepatitis B vaccine is due • StateName: IMMS2004_00271 • ActionType: Conclude
Observation	01000214	• Name: Contraindicated (qualifier value) [SNOMED CT] • From: SNOMED CT:410536001 • FromDisplayName: Contraindicated (qualifier value) • Name: MMR vaccine is due [SAGE] • From: SAGE:C115 • FromDisplayName: MMR vaccine is due • StateName: ImmunoCycle5_3w4Neb_Instance_40023 • ActionType: Conclude
Observation	01000214	• From: SNOMED CT:31874001 • Name: PPV23 vaccine is due [SAGE] • From: SAGE:C122 • FromDisplayName: PPV23 vaccine is due • StateName: IMMS2004_00192 • ActionType: Conclude
Observation	01000214	• From: SNOMED CT:31874001 • Name: MCV4 vaccine is due [SAGE] • From: SAGE:C127 • FromDisplayName: MCV4 vaccine is due

Sage Reports Log: Due and Due but Contraindicated Vaccines



Observation	01000214	• From: SNOMED CT:31874001 • Name: MCV4 vaccine is due [SAGE] • From: SAGE:C127 • FromDisplayName: MCV4 vaccine is due • StateName: ImmunoCycle5_2Neb_Instance_140031 • ActionType: Conclude
Observation	01000214	• Name: Contraindicated (qualifier value) [SNOMED CT] • From: SNOMED CT:410536001 • FromDisplayName: Contraindicated (qualifier value) • Name: Varicella vaccine is due [SAGE] • From: SAGE:C120 • FromDisplayName: Varicella vaccine is due • StateName: ImmunoCycle5_3v4Neb_Instance_30000 • ActionType: Conclude
Display	01000214	• subject: Generate Hep B education material message: \par http://www.cdc.gov/nip/publications/VIS/vis-hep-b.pdf* • subject: Generate Pneumococcal (PPV23) education material message: \par http://www.cdc.gov/nip/publications/VIS/vis-ppv.pdf* • subject: Generate Meningococcal (MCV4) education material message: \par http://www.cdc.gov/nip/publications/VIS/vis-mening.pdf* • SubjectStr: Sage Mesg. • AddresseeStr: Session_Owner
Display	01000214	• subject: Send notification that MMR is contraindicated message:MMR vaccine is due but contraindicated • subject: Send notification that varicella vaccine is contraindicated message:Varicella vaccine is due but contraindicated • subject: Hep B due notification to report message:Hep B vaccination is due • subject: Meningococcal (MCV4) due notification to report message:Meningococcal MCV4 vaccination is due • subject: Pneumococcal (PPV23) due notification to report message:Pneumococcal PPV23 vaccination is due • subject: Obtain immunization consent message: \par • subject: Inquire about illness message: \par • SubjectStr: Sage Mesg. • AddresseeStr: Primary care physician