Material on Website

- <u>http://www.smi.stanford.edu/projects/sage/tutorial06/S</u> <u>AGEWorkbench.zip</u> 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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¹University of Nebraska Medical Center, Omaha, NE; ²GE Healthcare Integrated IT Solutions, Seattle, WA; ³Apelon, Inc., Ridgefield, CT ; ⁴Mayo Clinic, Rochester, MN; ⁵Stanford University, Stanford, CA



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 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 <u>ontologies</u> 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

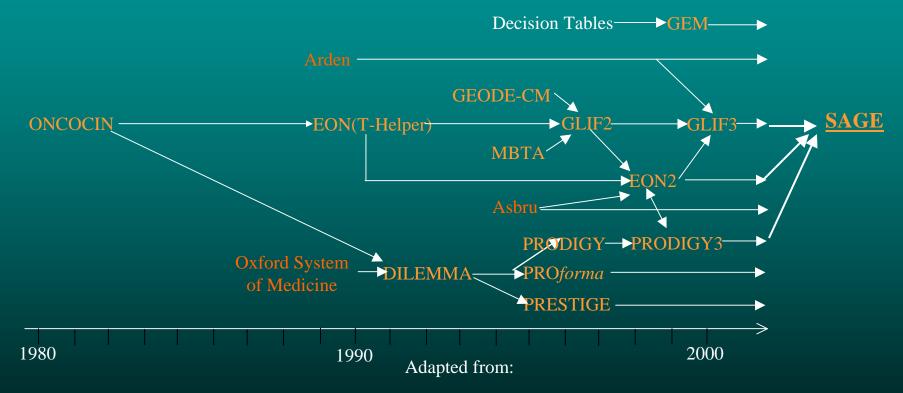
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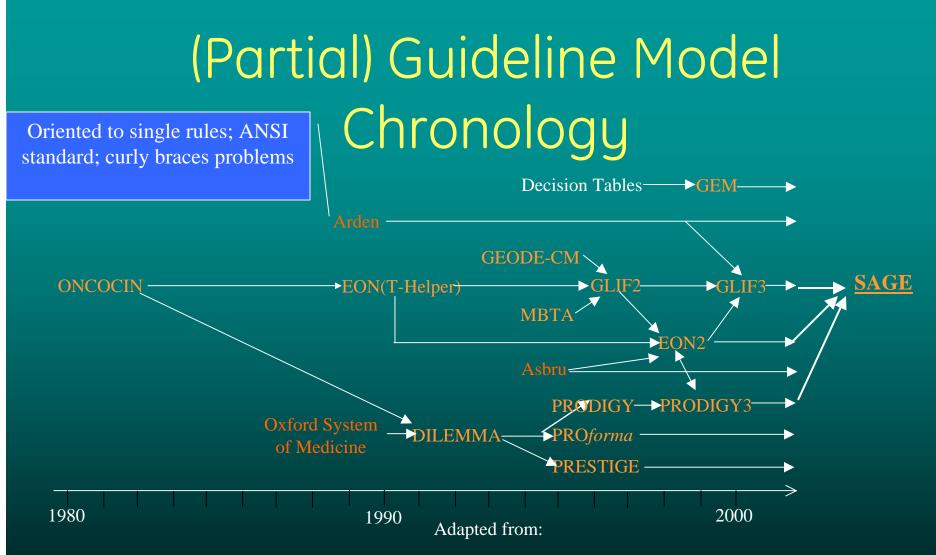


(Partial) Guideline Model Chronology



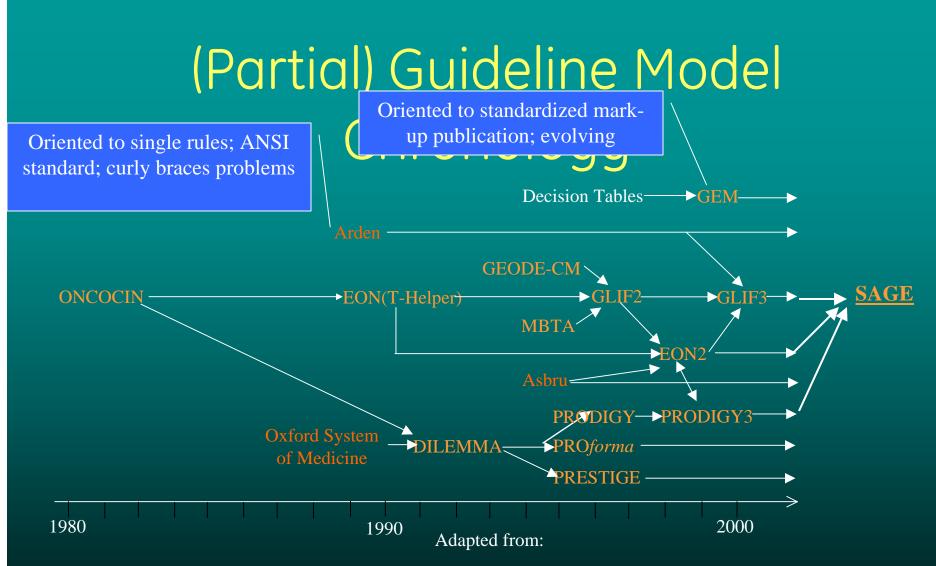
P. L. Elkin, M. Peleg, R. Lacson, E. Bernstam, S. Tu, A. Boxwala, R. Greenes, & E. H. Shortliffe. Toward Standardization of Electronic Guidelines. *MD Computing* 17(6):39-44, 2000





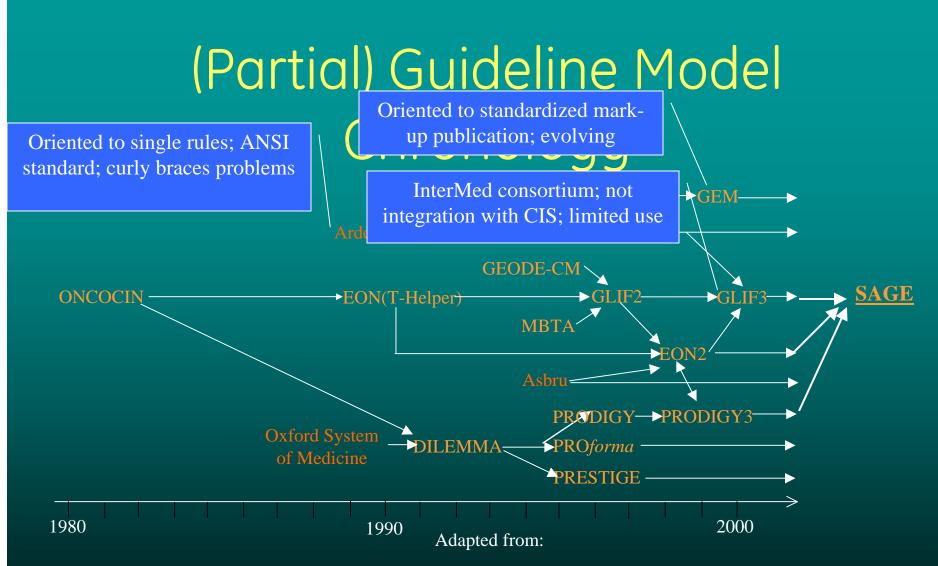
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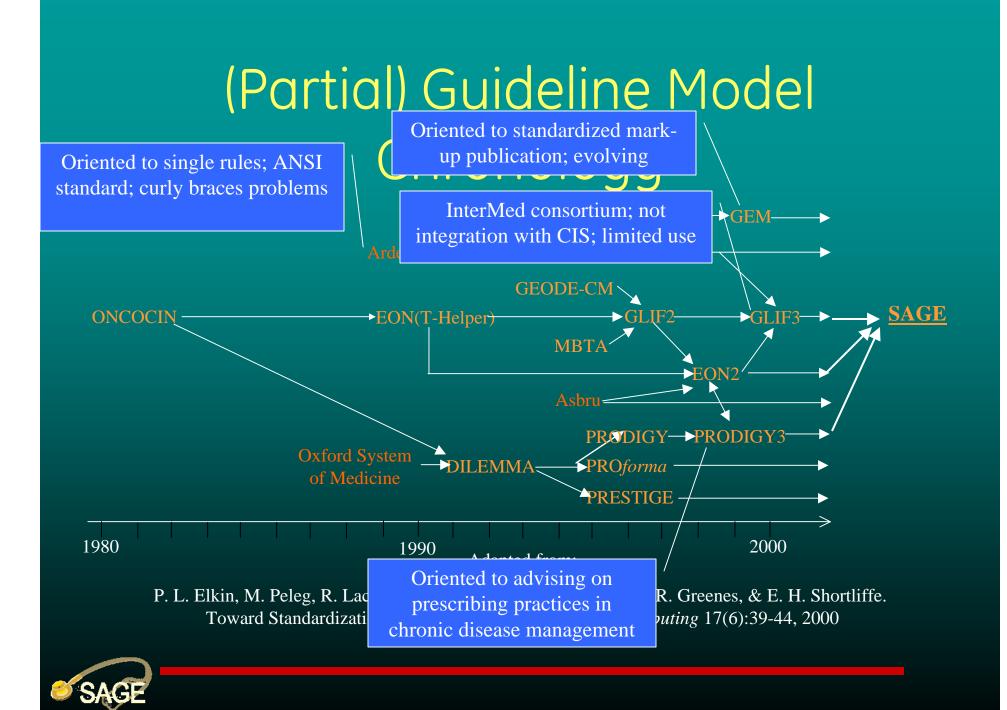
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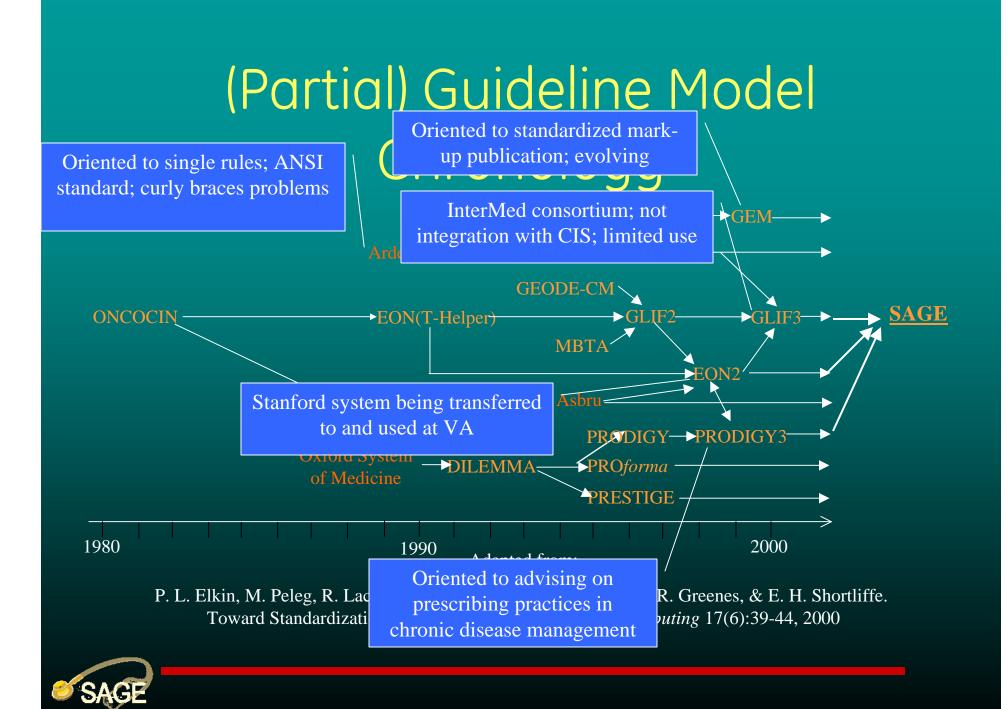


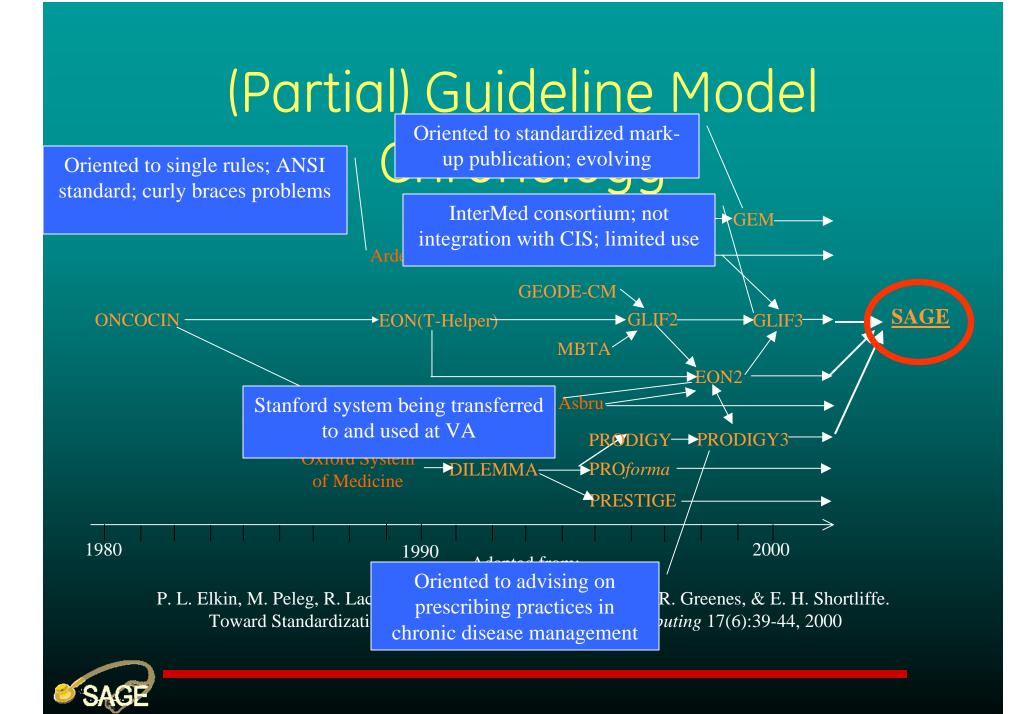


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Requirements of CDSS

- 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



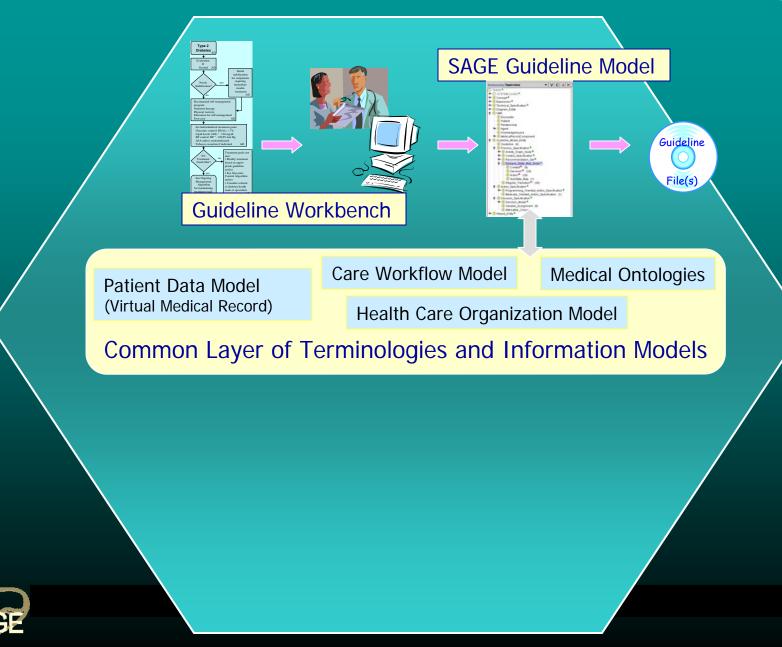
SAGE Project Overview

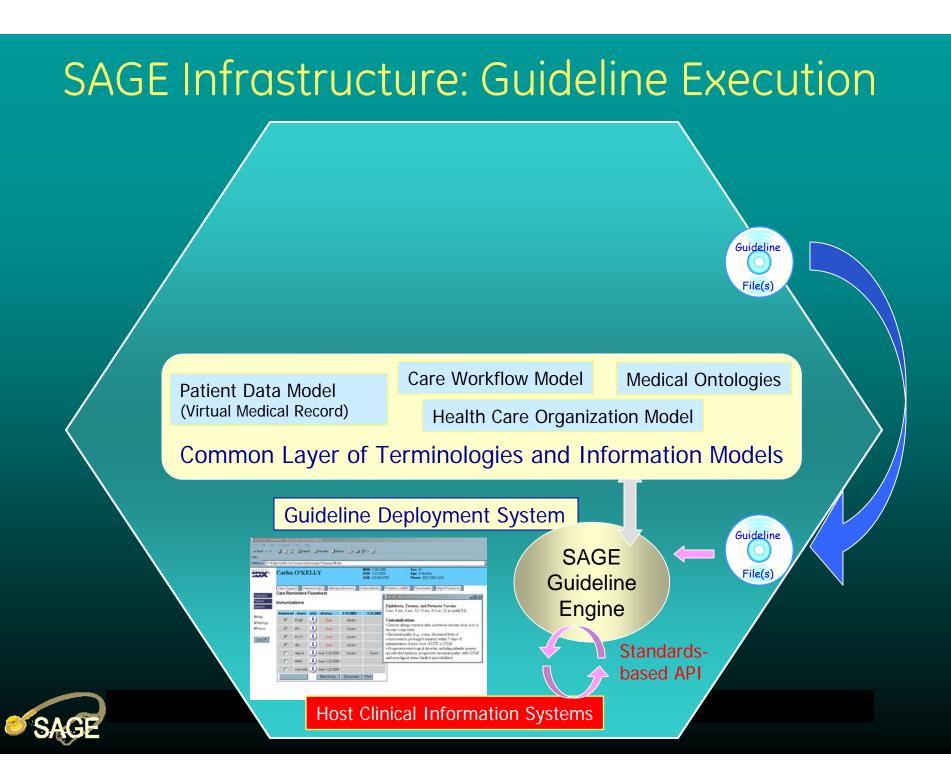
- Collaborative research and development project to develop a **standards-based** technology to enable encoding and dissemination of guidelines in executable format.
- Infrastructure will employ informatics standards including Protégé open source workbench, HL7 RIM, SNOMED CT and LOINC, and deployment 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.



SAGE Infrastructure: Guideline Encoding





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



Overview

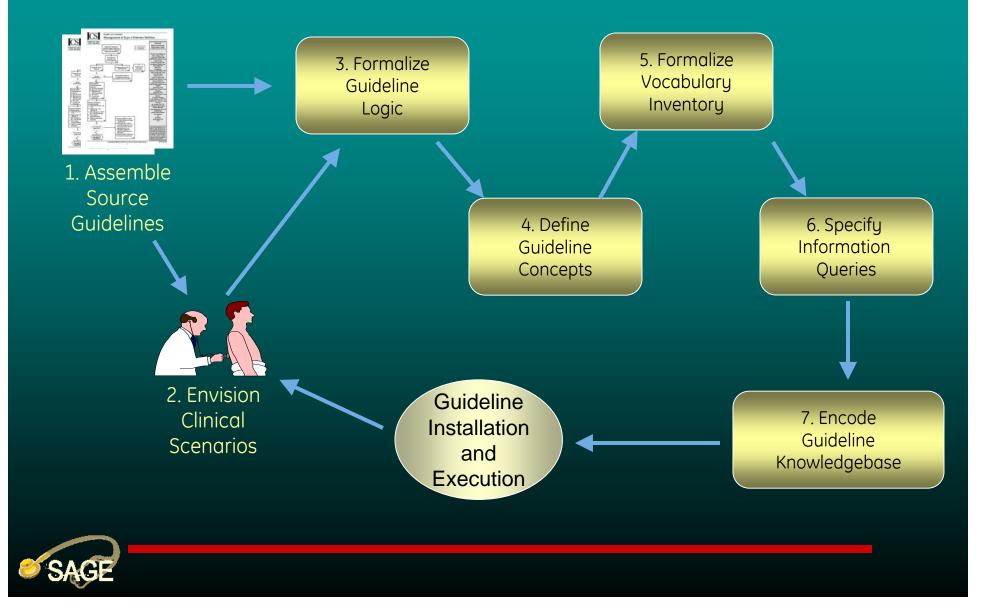
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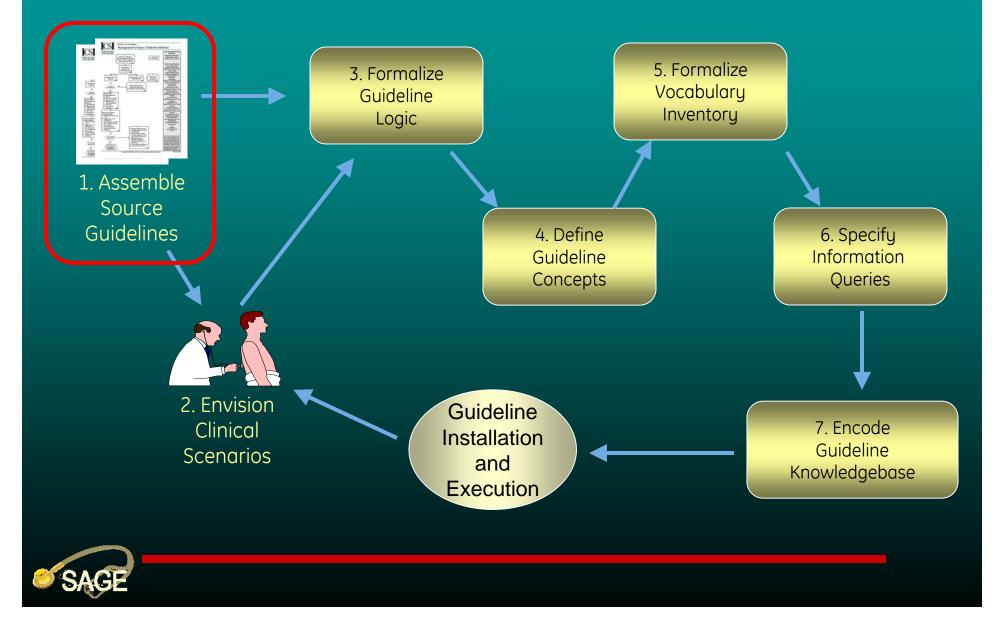
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SAGE Guideline Encoding Process



SAGE Guideline Encoding Process



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



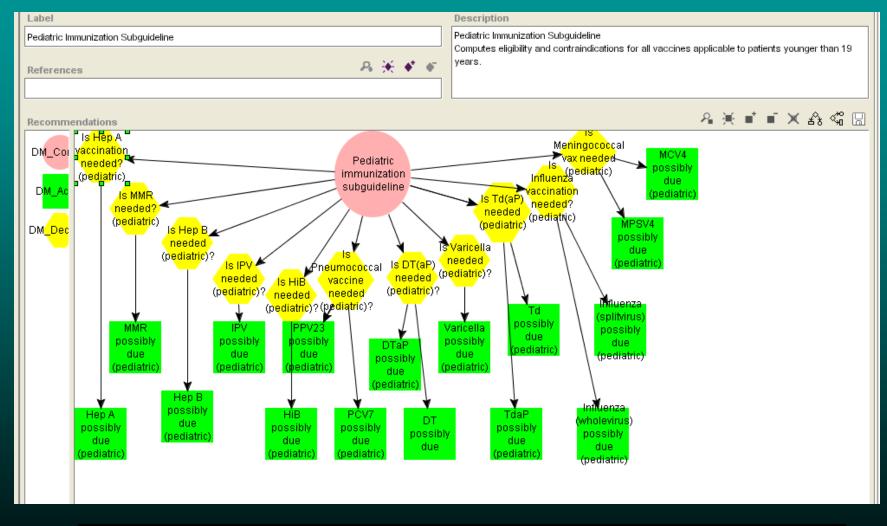
Pediatric Immunization Sub-guideline Schedule

Recommended Childhood and Adolescent Immunization Schedule UNITED STATES • 2005

Age ► Vaccine ▼	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	НерВ #2		HepB #3			HepB Series					
Diphtheria, Tetanus, Pertussis²			DTaP	DTaP	DTaP		DT	aP		DTaP	Td	Td
Haemophilus influenzae type b³			Hib	Hib	Hib	н	ib					
Inactivated Poliovirus			IPV	IPV		IP	v			IPV		
Measles, Mumps, Rubella⁴						MM	R #1			MMR #2	MM	R #2
Varicella ^s							Varicella			Vari	cella	
Pneumococcal ^s			PCV	PCV	PCV	P	cv		PCV	PI	PV	
Influenza ⁷						Influenza	a (Yearly)			Influenza	(Yearly)	
Hepatitis A®	Vaccines be	low red line	are tor sel	ected popul	ations					Hepatitis	A Series	



SAGE Pediatric Sub-guideline





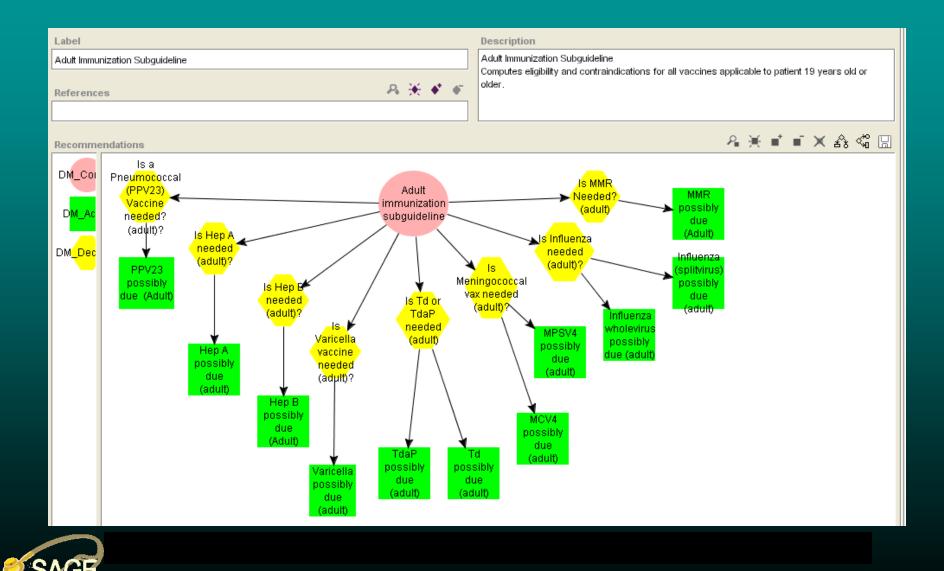
Adult Immunization Sub-guideline Schedule

Recommended Adult Immunization Schedule, by Vaccine and Age Group UNITED STATES, OCTOBER 2005–SEPTEMBER 2006

Vaccine 🔻 Age group 🕨	19–49 years	50–64 years	\geq 65 years				
Tetanus, diphtheria (Td) ¹ *	1-dose booster every 10 yrs						
Measles, mumps, rubella (MMR) ^{2*}	1or 2 doses	1 d	050				
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 a	annually				
Pneumococcal (polysaccharide) ^{5,6}	1–2 de	oses	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					



SAGE Adult Sub-guideline



Guideline Focus

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



MMWR

TABLE 2. Recommendations for the use of pneumococcal vaccine

Groups for which vaccination is recommended	Strength of recommendation*	Revaccination [†]
Immunocompetent persons [§]		
Persons aged 265 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 alco- holism, chronic liver disease, ⁺⁺ or cerebrospinal fluid leaks	В	Not recommended.
Persons aged 2–64 years with func- tional 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 set- tings¶	с	Not recommended.
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Use Case: US Adult Pneumococcal Guideline



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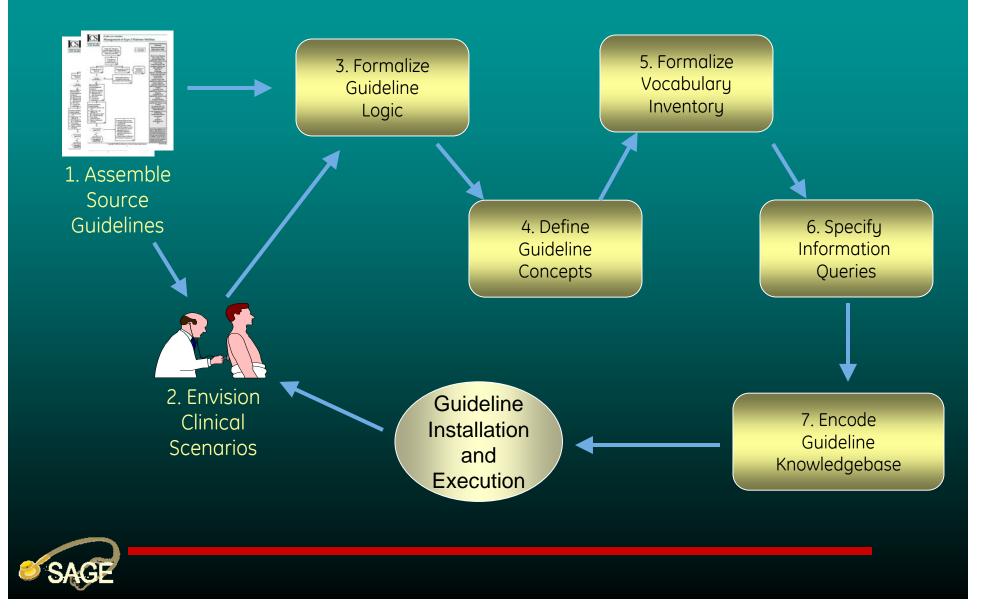
• Overview of guidelines and challenges to decision support development

SAGE guideline modeling process: Introduction

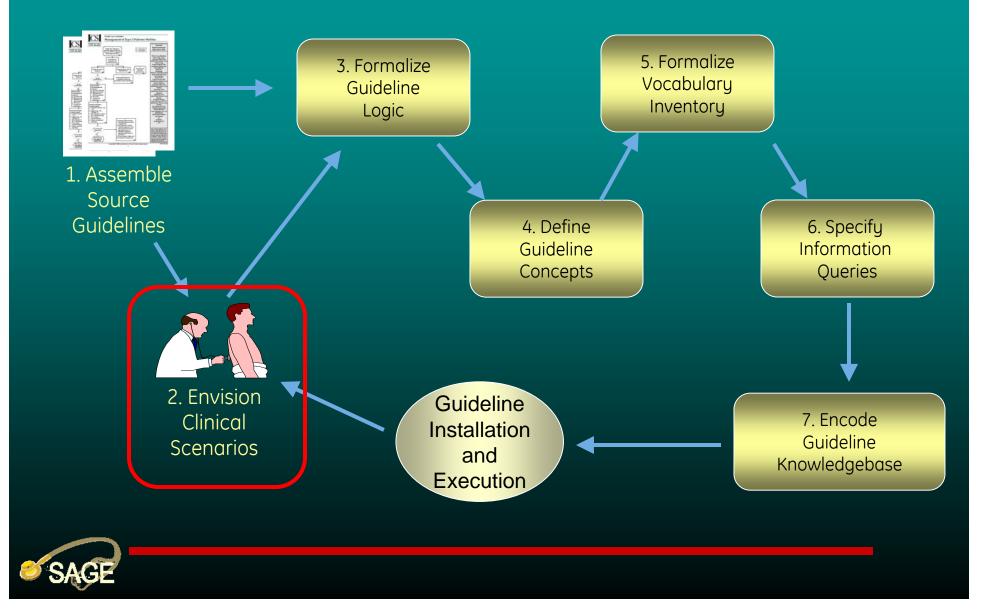
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SAGE Guideline Encoding Process



SAGE Guideline Encoding Process



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



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



- 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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• 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

• CDSS is triggered

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• 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.

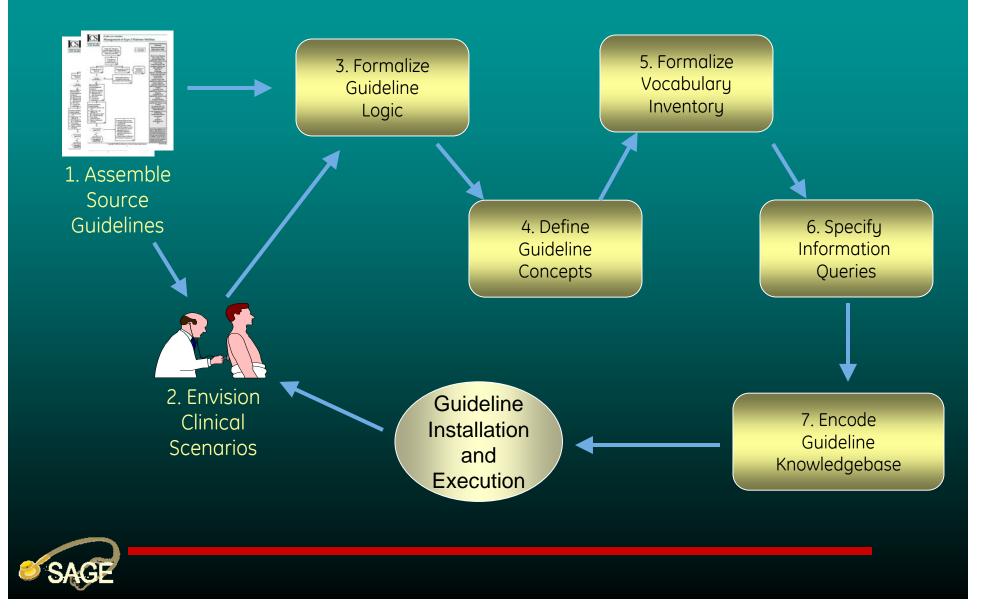
•When mother's serologic status for Hep B is unknown, SAGE issues orders for maternal testing and tracks results until obtained.

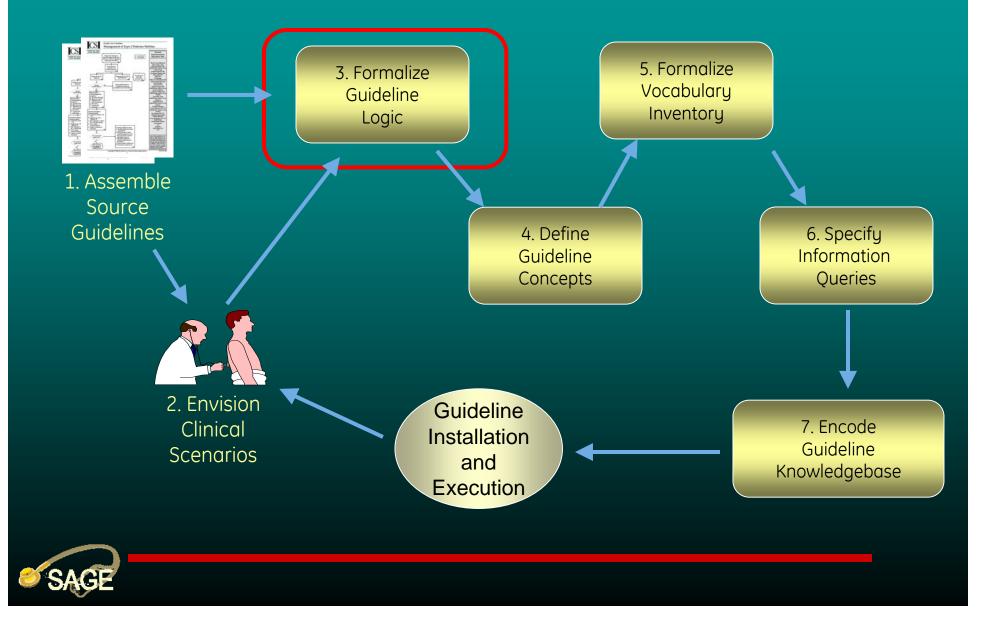


Alternative Scenarios?

- 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







MMWR

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Use Case: US Adult Pneumococcal Guideline



12

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 Nursing home resident



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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



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 THEN ADVISE ADMINISTRATION OF PPV23 VACCINE



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ADVISE ADMINISTRATION OF PPV23 VACCINE

Specifies all clinical details required for complete deployment



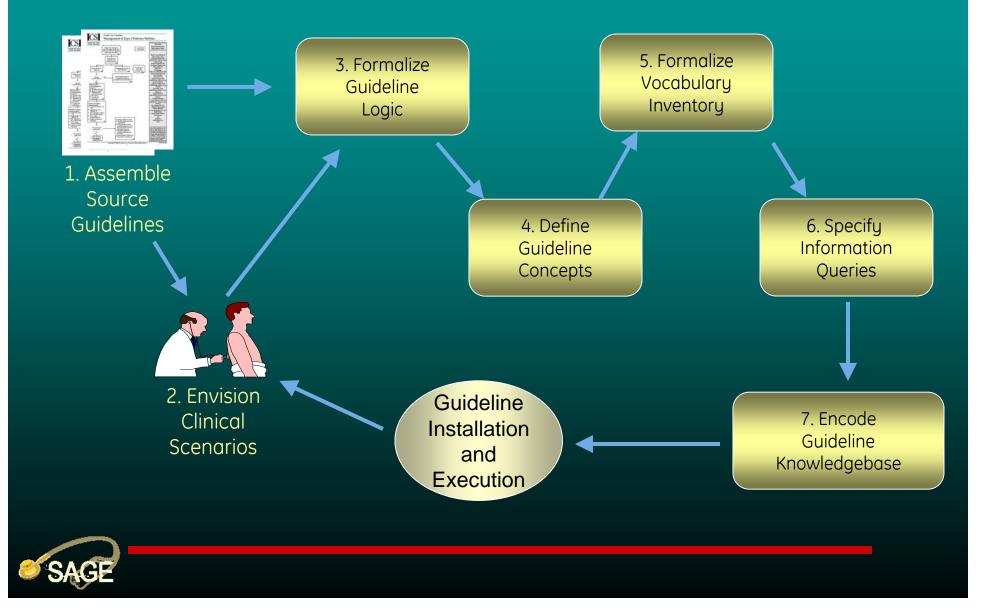


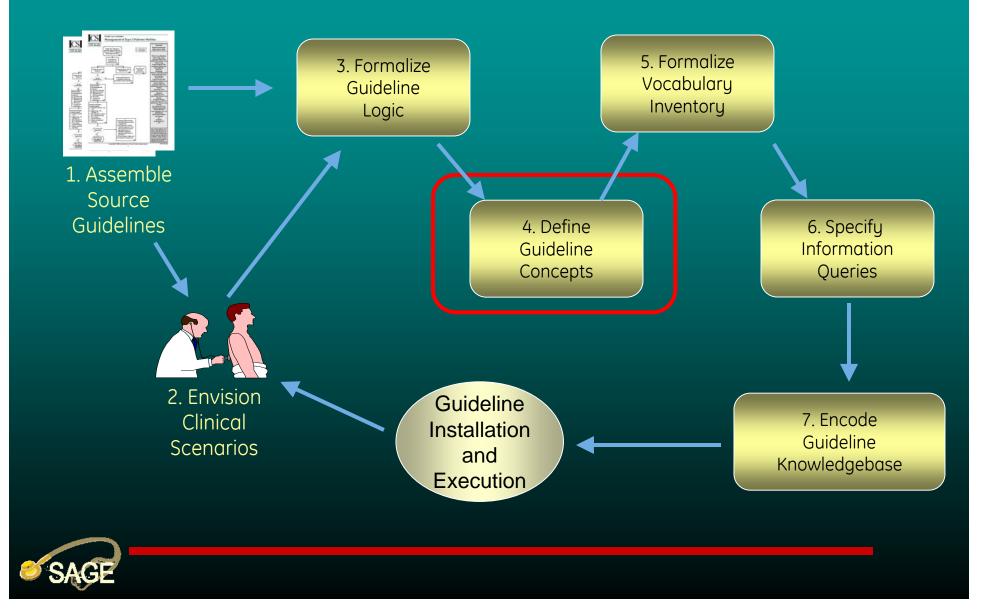
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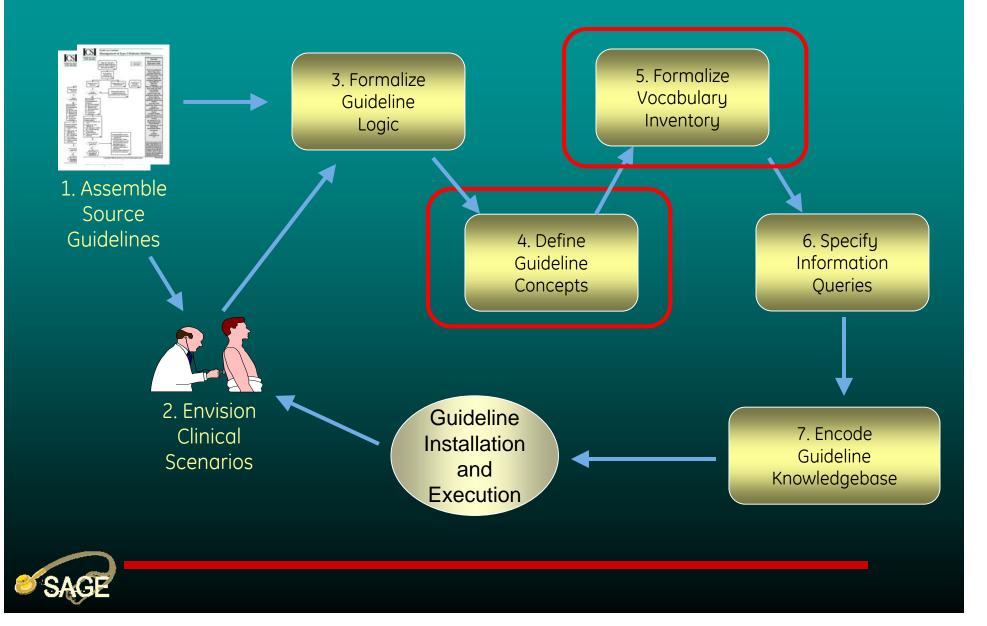
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Reviewing Concept Inventory: Binding to standard vocabulary

- 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



- 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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Persons aged 2–64 years with func- tional 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 years after previous dose.
Persons aged 2–64 years living in special environments or social set- tings¶	с	Not recommended.
Immunocompromised persons [§]		
Immunocompromised persons aged ≥2 years, including those with HIV infection, leukemia, lymphoma, Hodgkins disease, multiple myeloma, generalized malignancy, observice served failure, or perspectio	с	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.



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

L	Persons aged 2–64 years with chronic cardiovascular disease,¶ chronic pulmonary disease,** or	A	Not recommended.	
	diabetes mellitus			
	Persons aged 2–64 years with alco- holism, chronic liver disease, ⁺⁺ or cerebrospinal fluid leaks	в	Not recommended.	
	Persons aged 2–64 years with func- tional 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	
			years after previous dose.	
	Persons aged 2–64 years living in special environments or social set- tings¶	с	Not recommended.	
	Immunocompromised persons [§]			
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	Hodgkins disease, multiple myeloma, generalized malignancy, shrapis range failure, or perspectio			

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



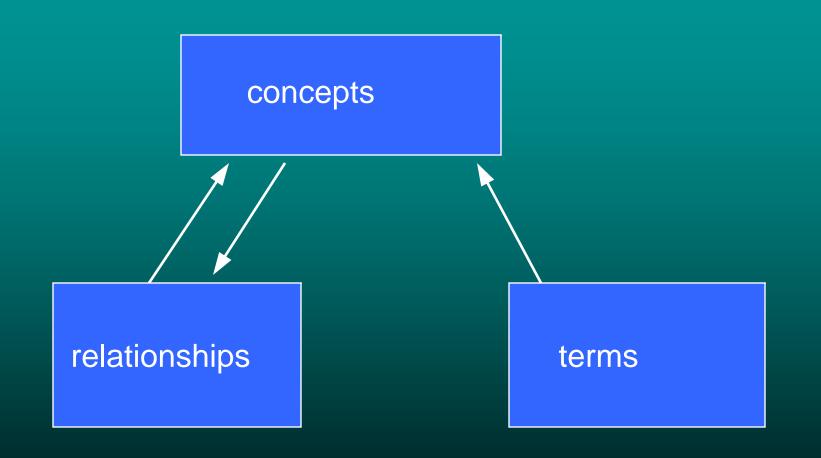
Why do we need SNOMED CT?

• Synonyms

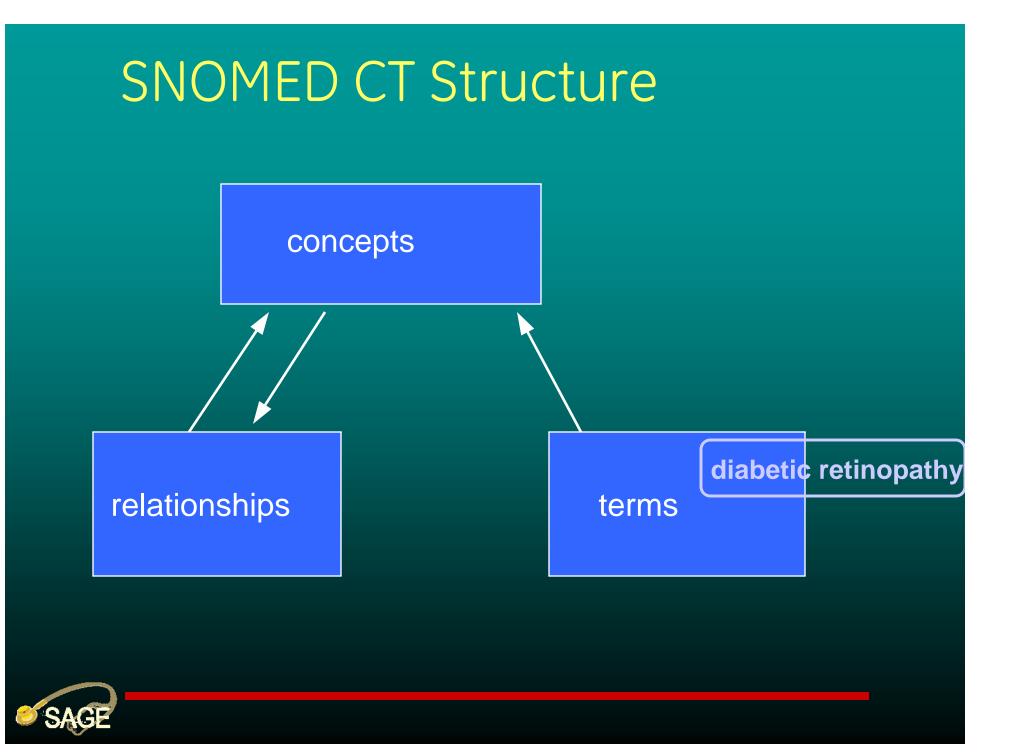
- By assigning a unique numeric code to each medical concept, SNOMED CT formalizes clinical terminology.
- Subsumption
 - By representing the complete set of relationships among medical concepts, SNOMED CT automates classification logic.
- Ambiguity
 - By assigning different codes to homonyms, SNOMED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



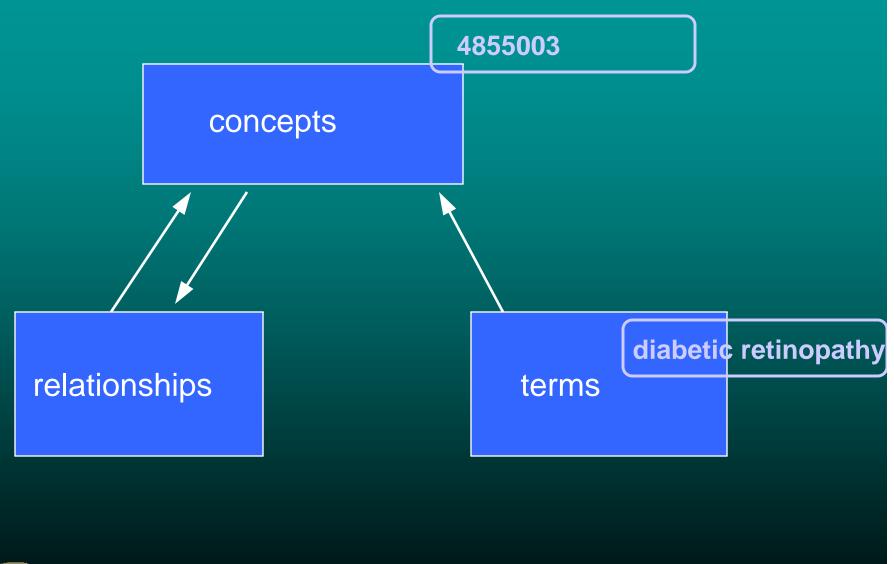
SNOMED CT Structure





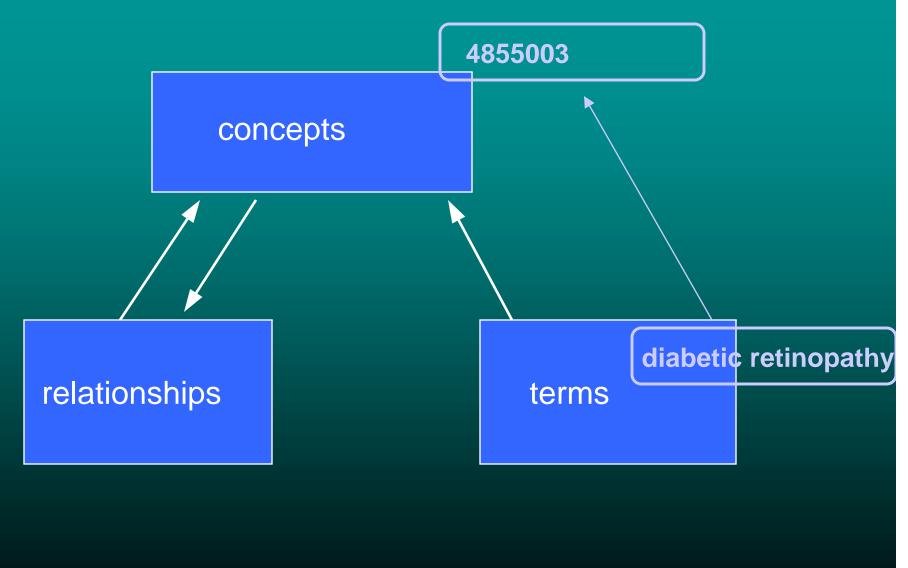


SNOMED CT Structure

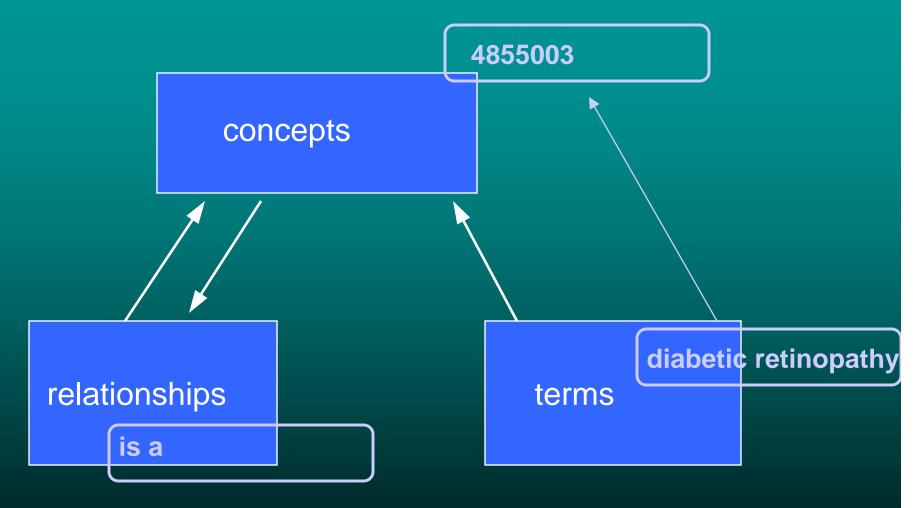




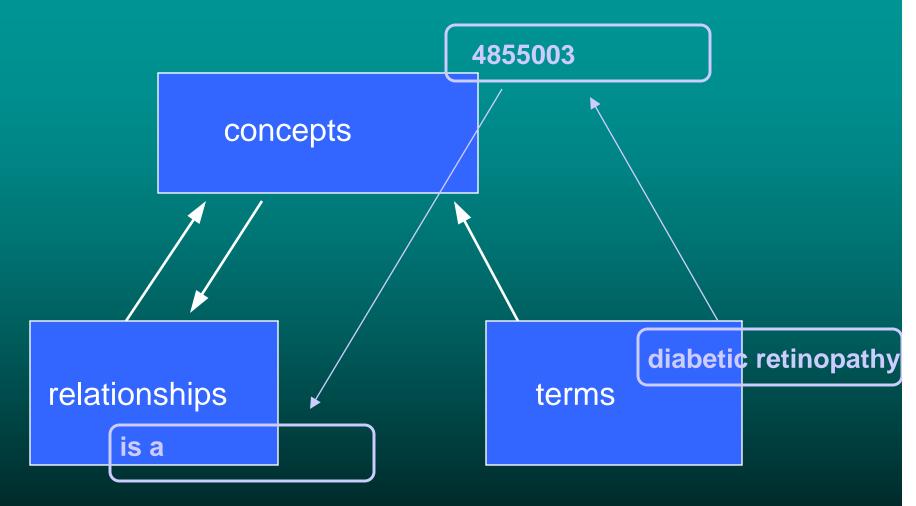
SNOMED CT Structure



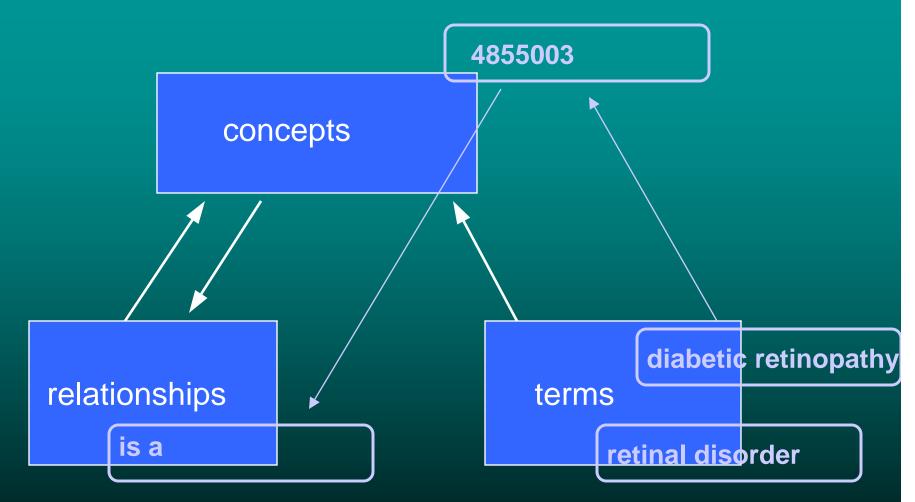




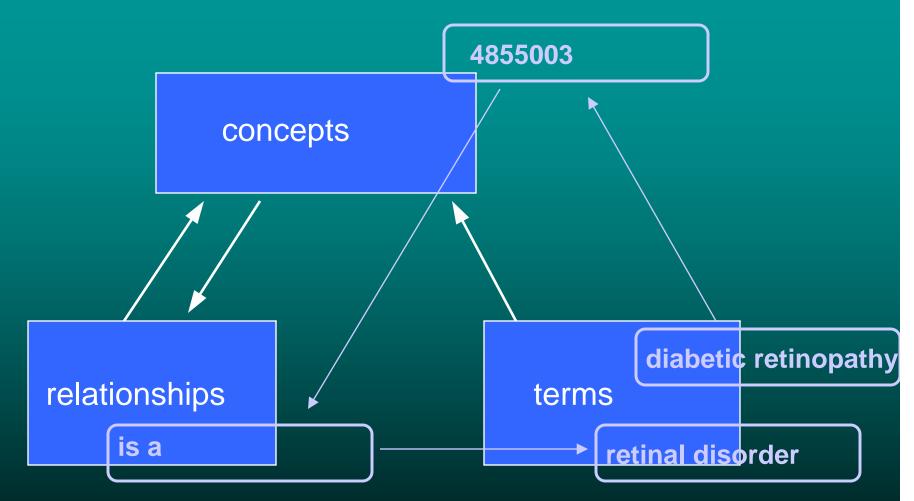




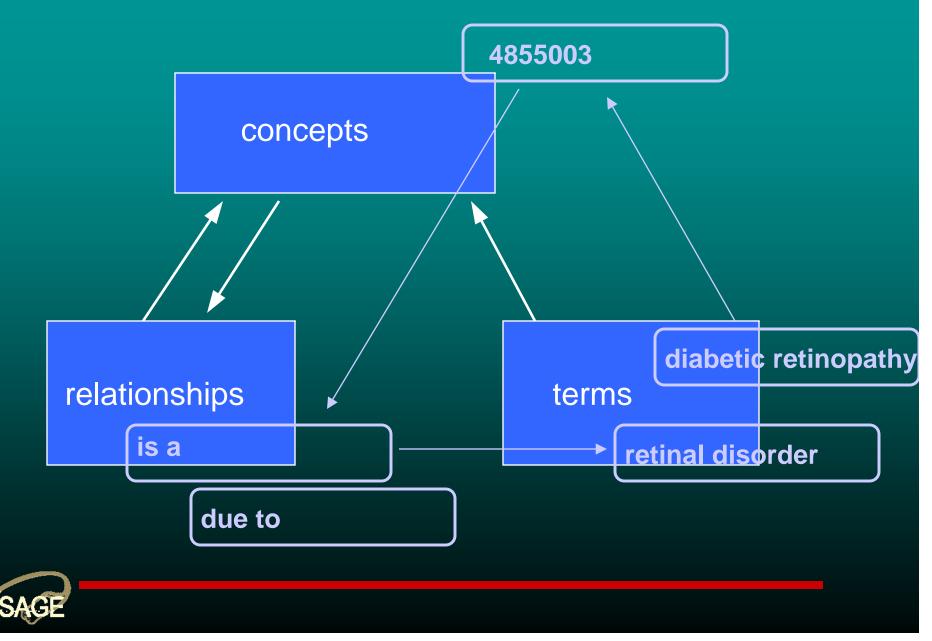


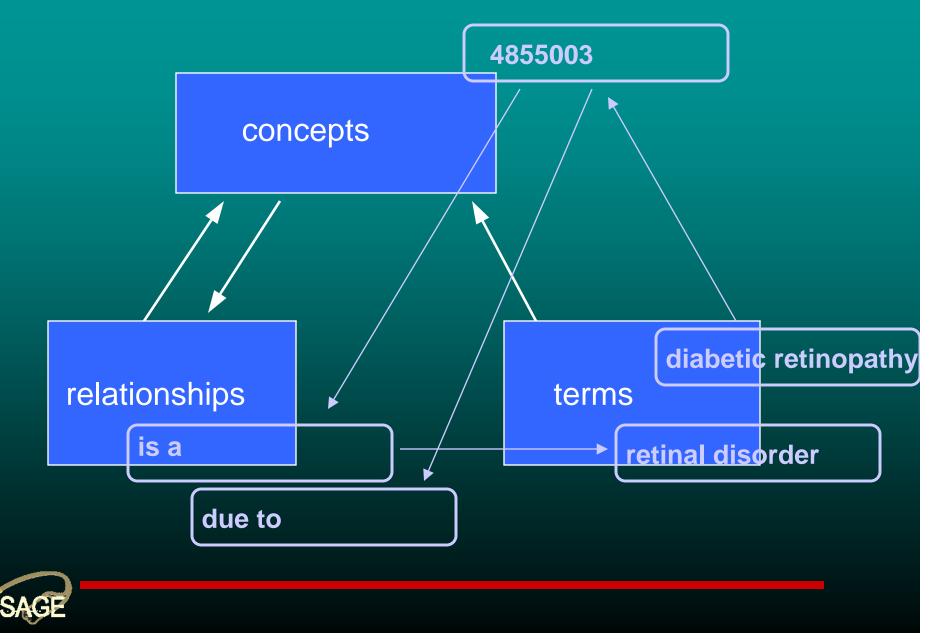


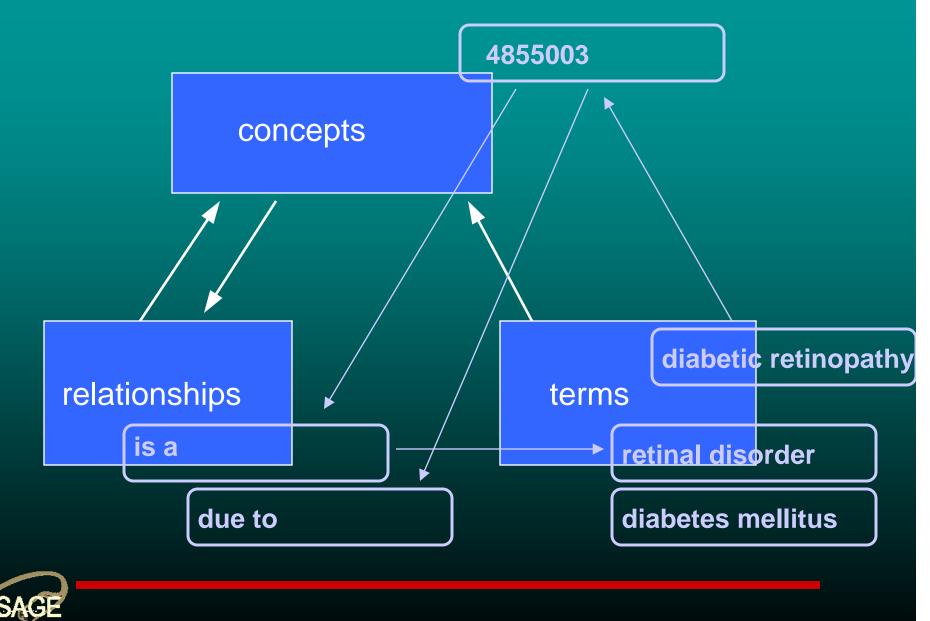


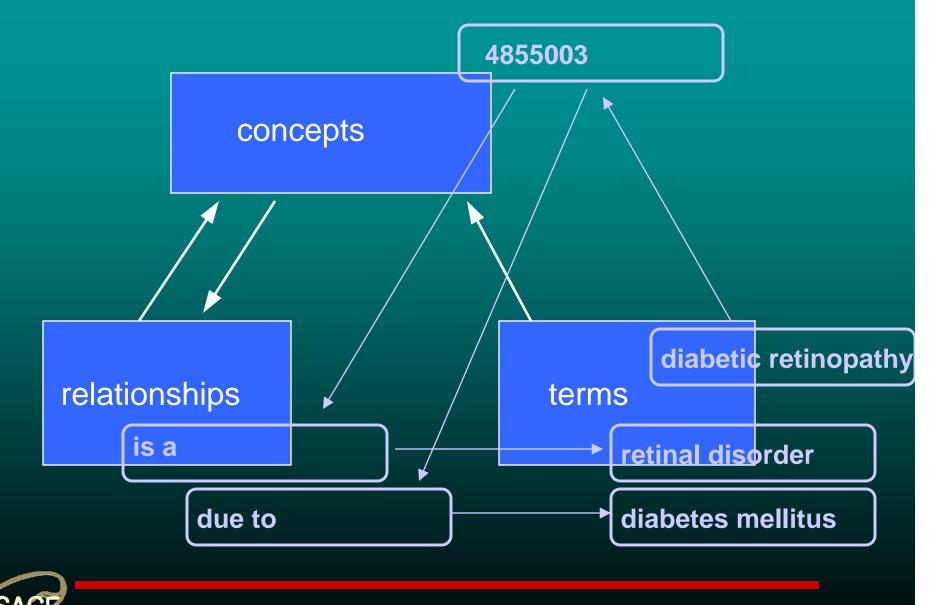


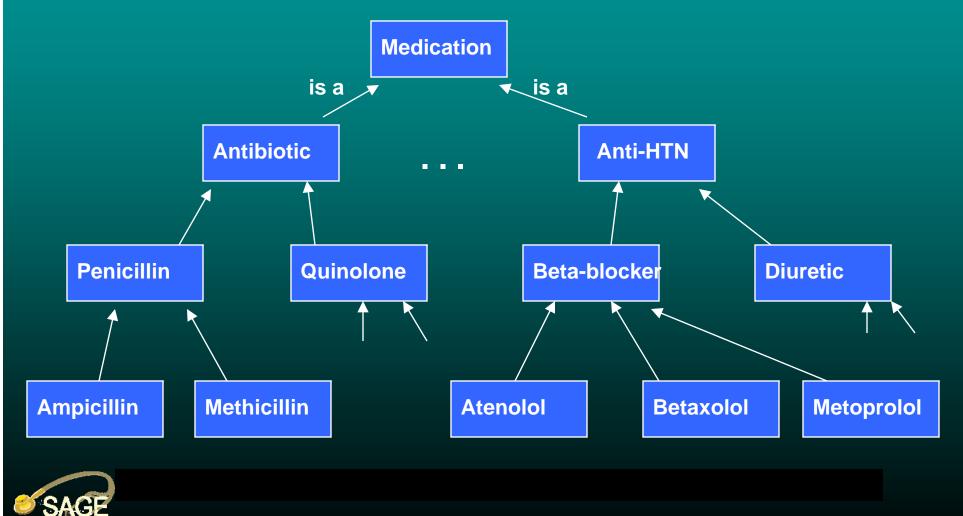


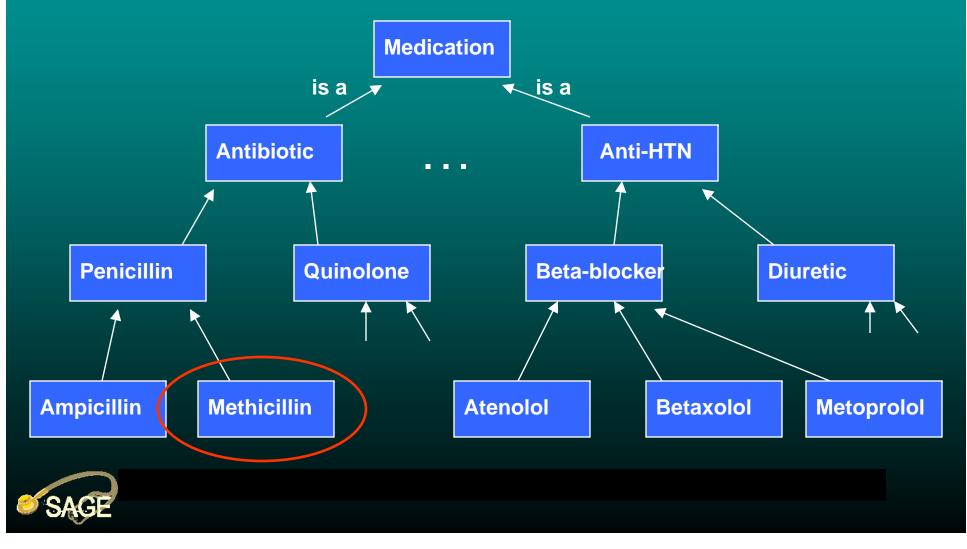


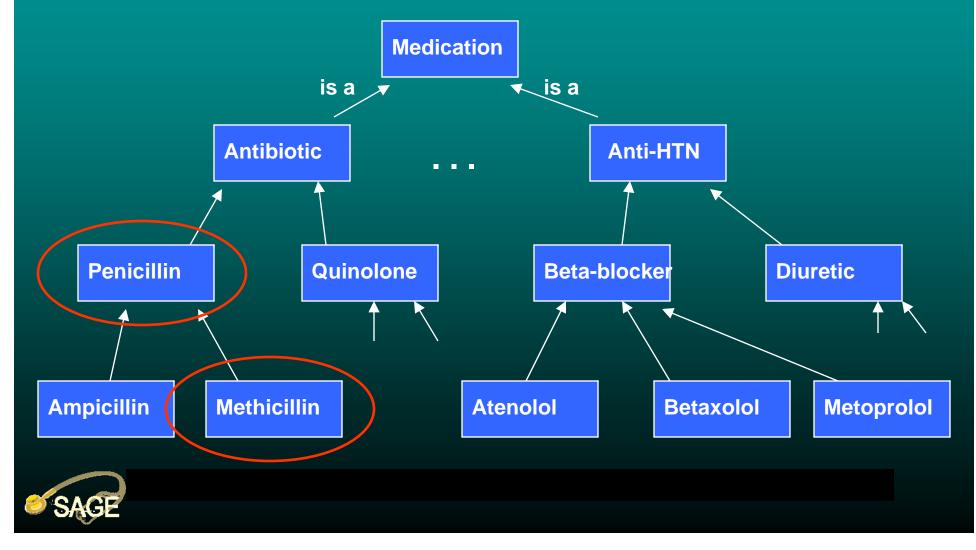


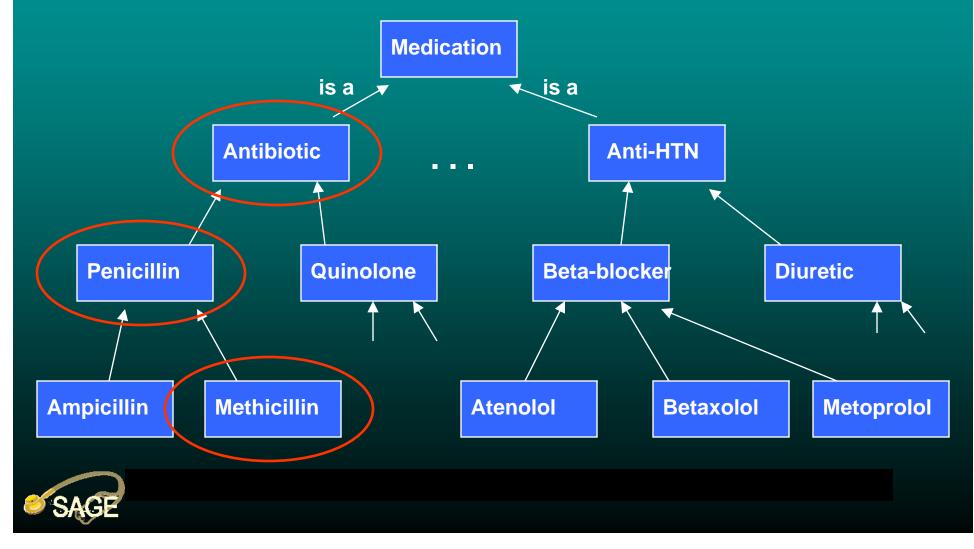


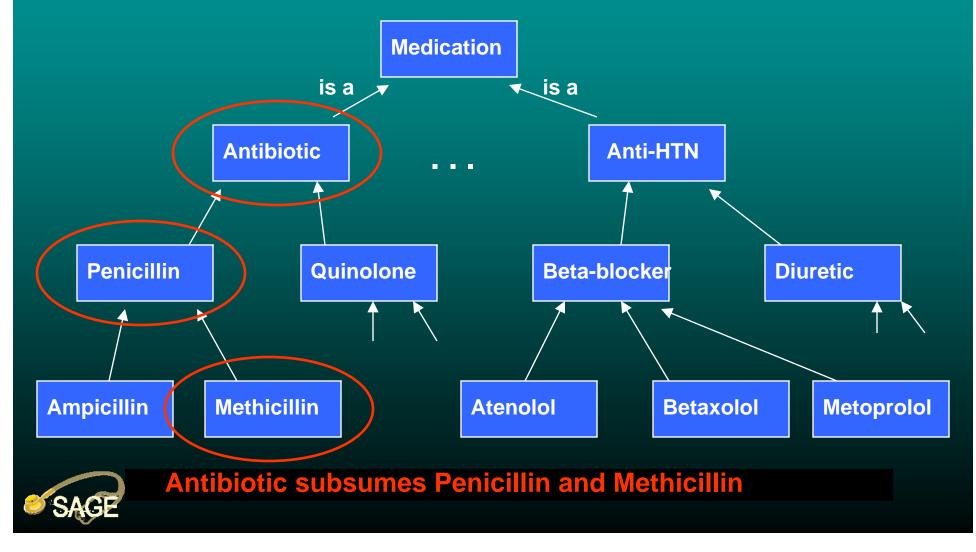


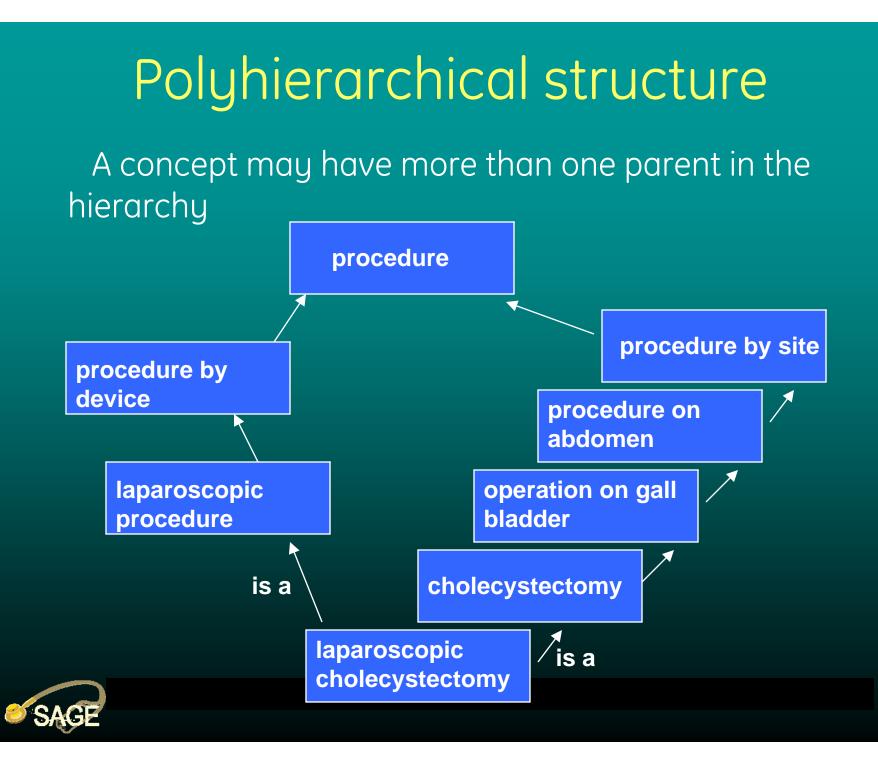


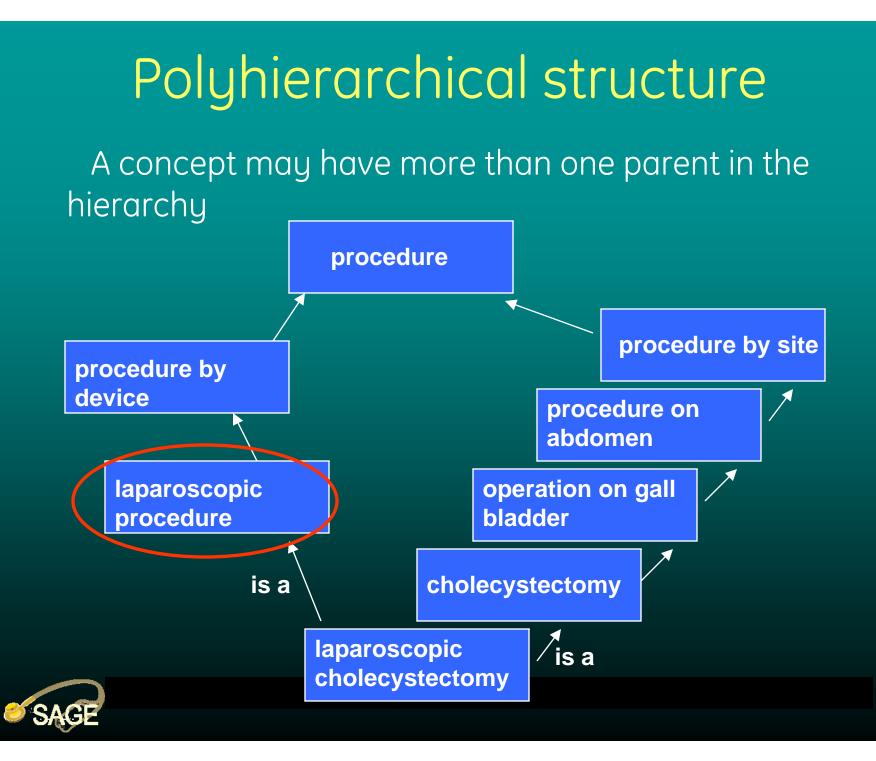


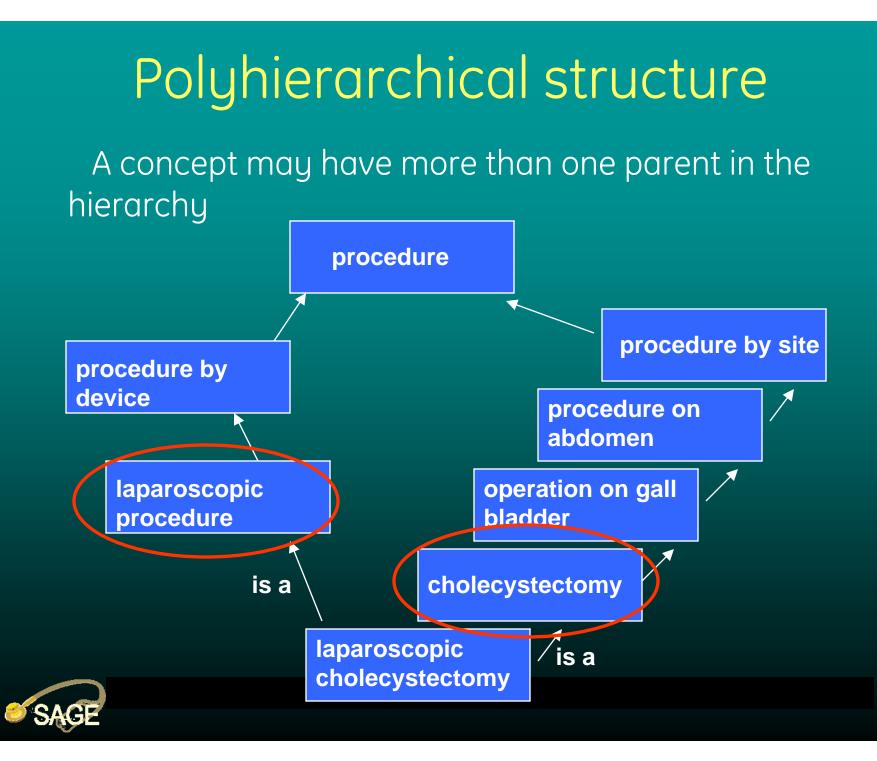












Suprarenal Artery Embolus 297143008

or

Occlusion of Artery Associated Morphology Embolus Finding Site Suprarenal Artery



Suprarenal Artery Embolus 297143008

Pre-Coordinated

or

Occlusion of Artery Associated Morphology Embolus Finding Site

Suprarenal Artery



Suprarenal Artery Embolus 297143008

Pre-Coordinated

or

Occlusion of Artery Associated Morphology Embolus Finding Site

Suprarenal Artery

2929001 116676008

55584005

363698007

89500000



Suprarenal Artery Embolus 297143008

Pre-Coordinated

Post-Coordinated

Occlusion of Artery2929001Associated Morphology116676008Embolus55584005Finding Site363698007

Suprarenal Artery

89500000



or

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...

Α.

B

A.

C.

C.

Persons aged 2–64 years with chronic cardiovascular disease,¶ chronic pulmonary disease,** or diabetes mellitus

Persons aged 2–64 years with alcoholism, chronic liver disease,⁺⁺ or cerebrospinal fluid leaks

Fersons aged 2–64 years with functional or anatomic asplenia⁵⁵

Persons aged 2–64 years living in special environments or social settings¹¹

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. Not recommended.

Not recommended.

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.

Not recommended.

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.



"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"

- Congenital asplenia
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Clinical Definition ------ SNOMED CT Concept

- 93030006
- 93292008
- 234319005 (Procedure)
- 82893001
- 127040003 (Hemoglobin S disease)



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



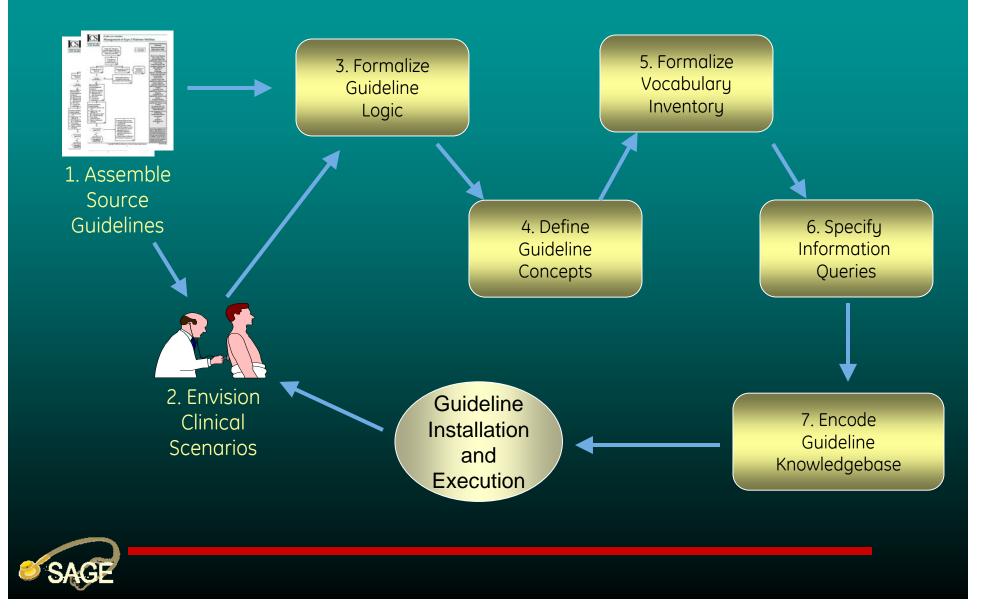
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SAGE guideline modeling process:

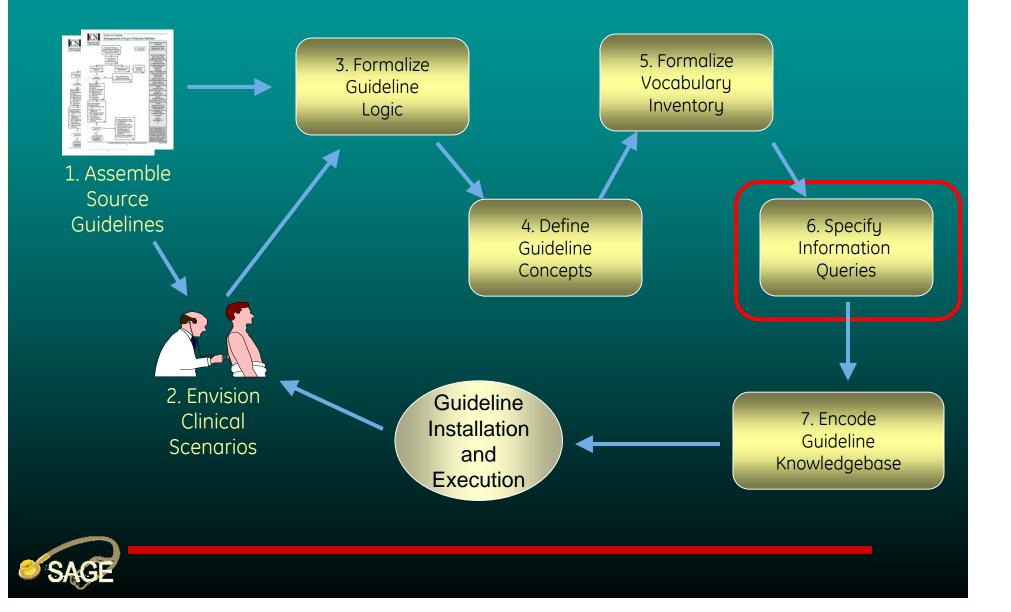
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SAGE Guideline Encoding Process



SAGE Guideline Encoding Process



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



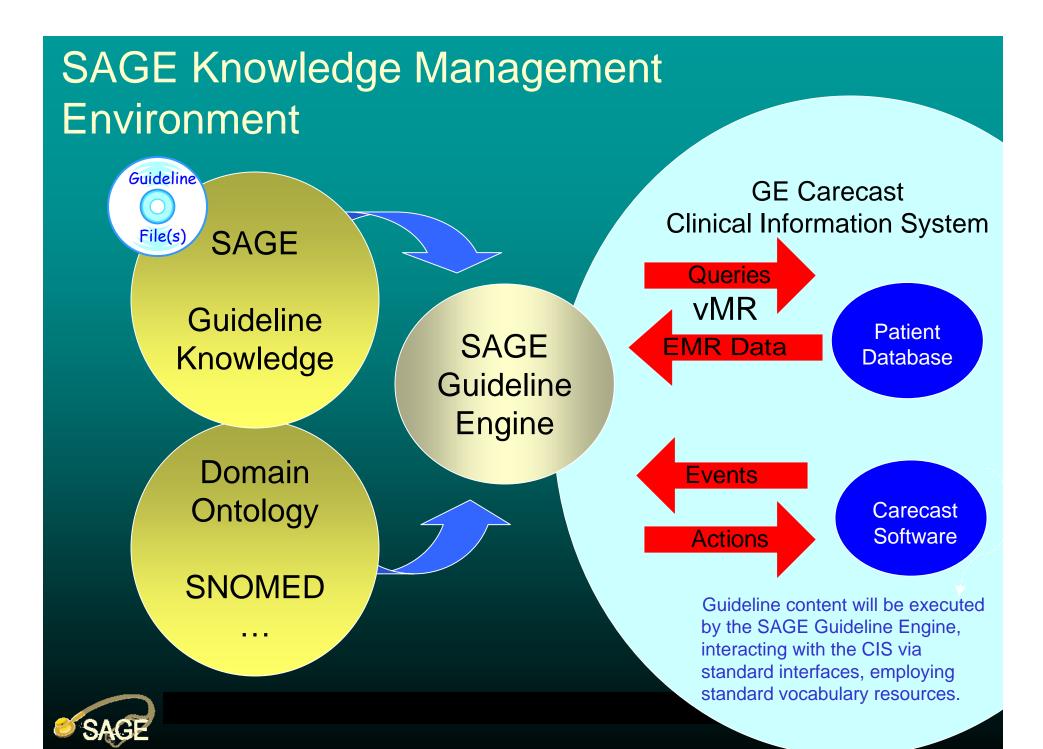
Possible Representations of a patient's Diabetes Mellitus • Entry on Problem List – Diabetes Mellitus type II Observation Lab Value of Fasting Glucose > 125 mg/dL or - Lab value for two-hour 75-g oral glucose tolerance test > 200 mg/dL • Entry in Diagnoses & Procedures list – Diabetes Mellitus type II

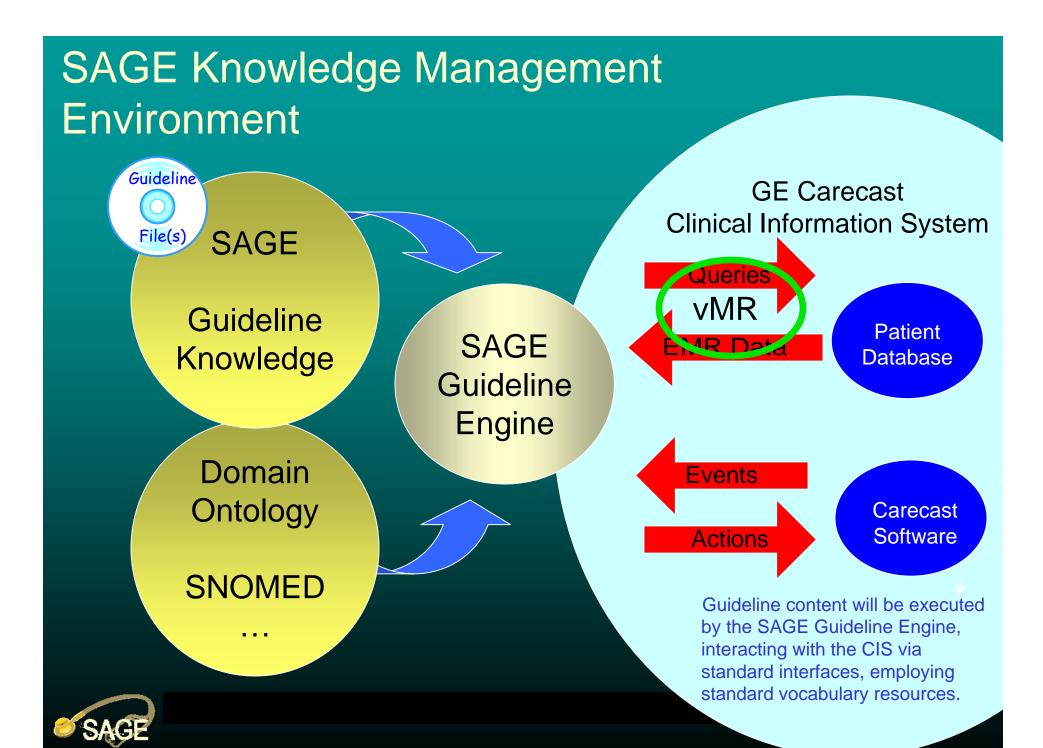


Information Model and Use of Vocabulary

- Interoperable decision support must be able to interact correctly with <u>any</u> 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







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

- "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"
 - O The "context free" assumption within SNOMED states that
 st the concept assertion always implies:
 - 1) Involves the patient
 - 2) Current state
 - 3) Assertion is present



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





 Overview of guidelines and challenges to decision support development

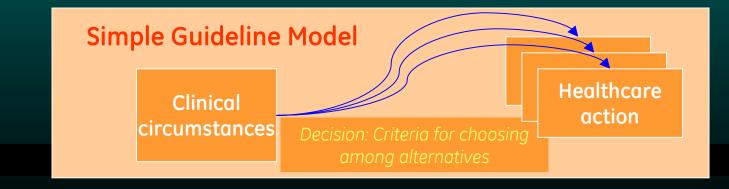
SAGE guideline modeling process:

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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)



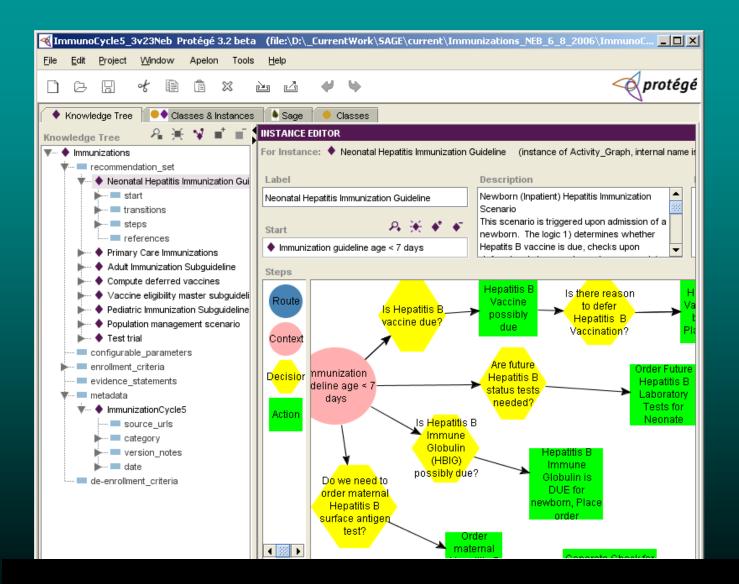


SAGE Guideline Model and Modeling Environment

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SYSTEM-CLASS		Guideline	A computer-interpretable practice guideline or clin	
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O Decision_Specifica		description	single String	
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	INSTANCE EDITOR	s Hepatitis immunization Guideline Descrip	(instance of Activity_Graph, internal name is	IMMS2004_01
Neonatal Hepatitis Immunization start	Neonatal Hepatitis Immuniza		rn (Inpatient) Hepatitis Immunization	tererences
transitions		Scenario		
steps	Start	newbor	n. The logic 1) determines whether	
Primary Care Immunizations	Immunization guideline a	ge < 7 days Hepatits	B vaccine is due, checks upon	
 Adult Immunization Subguideline Compute deferred vaccines 	Steps			₽_
▶ ♦ Vaccine eligibility master subgui	Route	Hepati	IS LICIC ICOSUII	epatitis B scine can
 Pediatric Immunization Subguide Population management scenario 		Is Hepatitis B poss vaccine due? du	Hepatitis B	e given.
▶ ♦ Test trial	Context		Pla	ce Order.
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	👗	(HBIG) possibly due?	Immune	
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	Hepatitis E		newborn, Place	
	surface antig test?	Order		
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		Hepatitis B surface	Maternal Hepatitis B	
		Antigen test	surface antigen	
	•			•

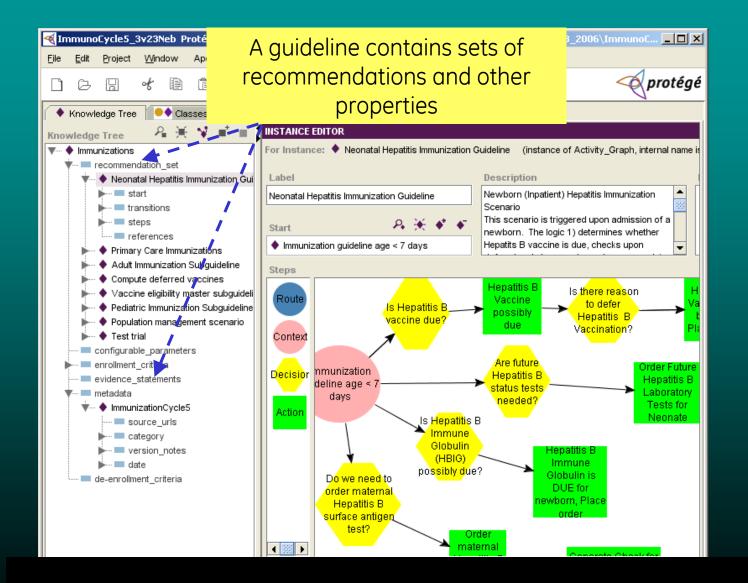
- Guideline model represented as a collection of classes and relationships among them
- Encoding a guideline (e.g. immunization guideline) means creating instances of these classes
- Use of graph widget to specify guideline recommendations as directed graphs

Structure of a SAGE Guideline



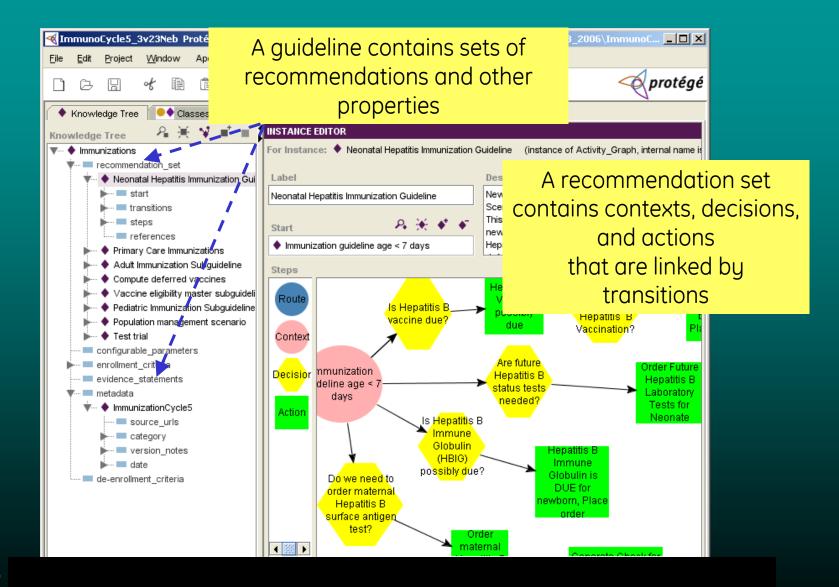


Structure of a SAGE Guideline

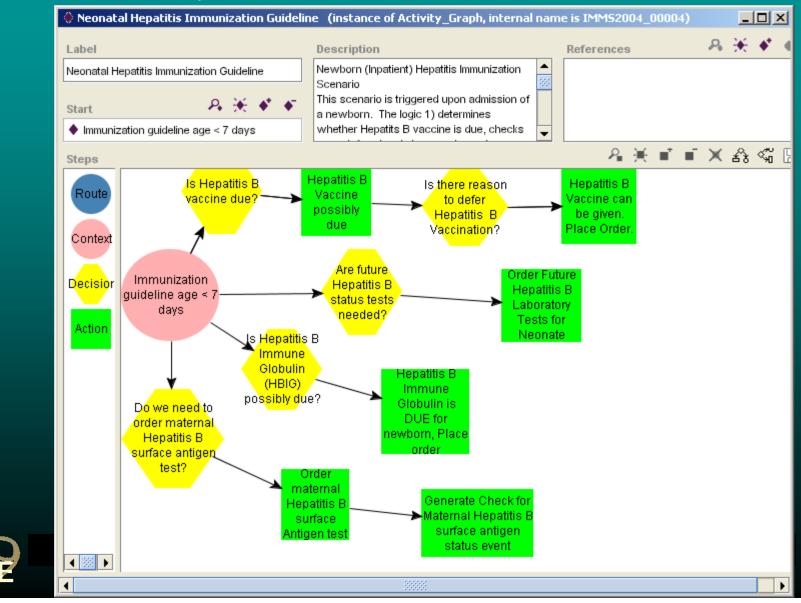


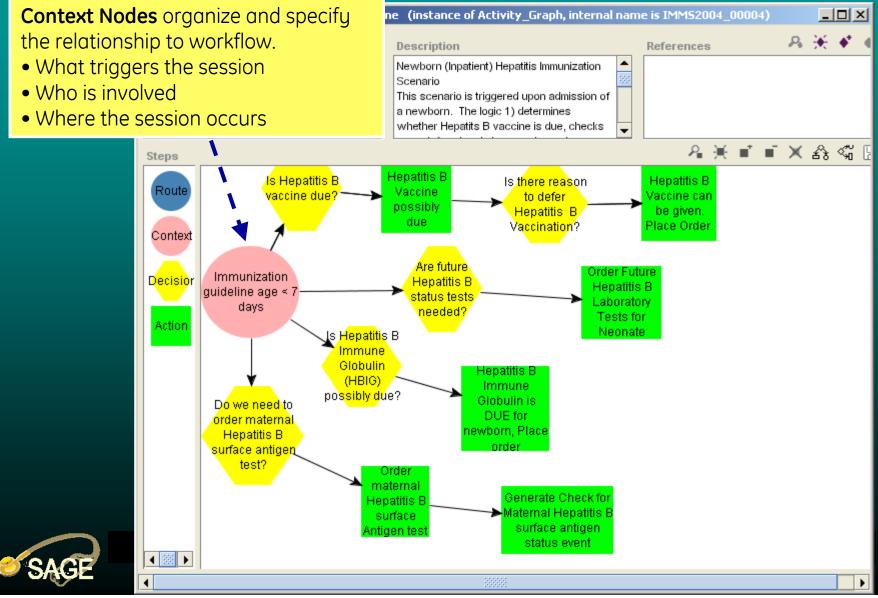


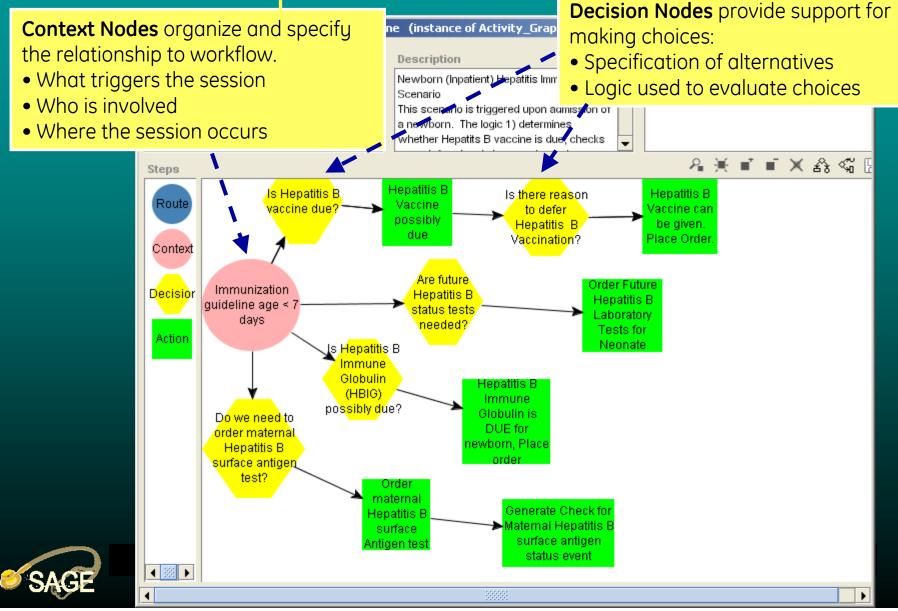
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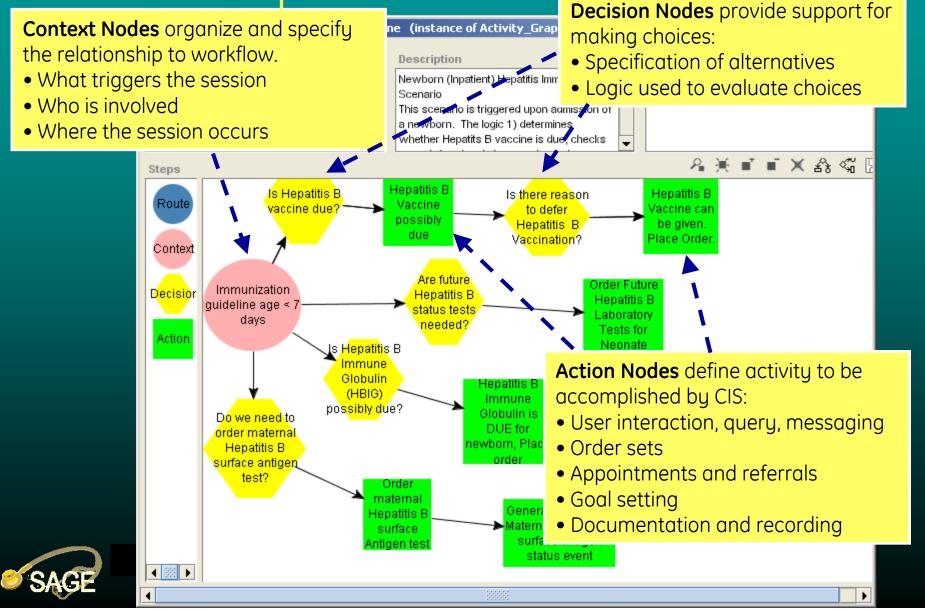












A Decision Node contains reasons for choosing each alternative

Is Hepatitis B

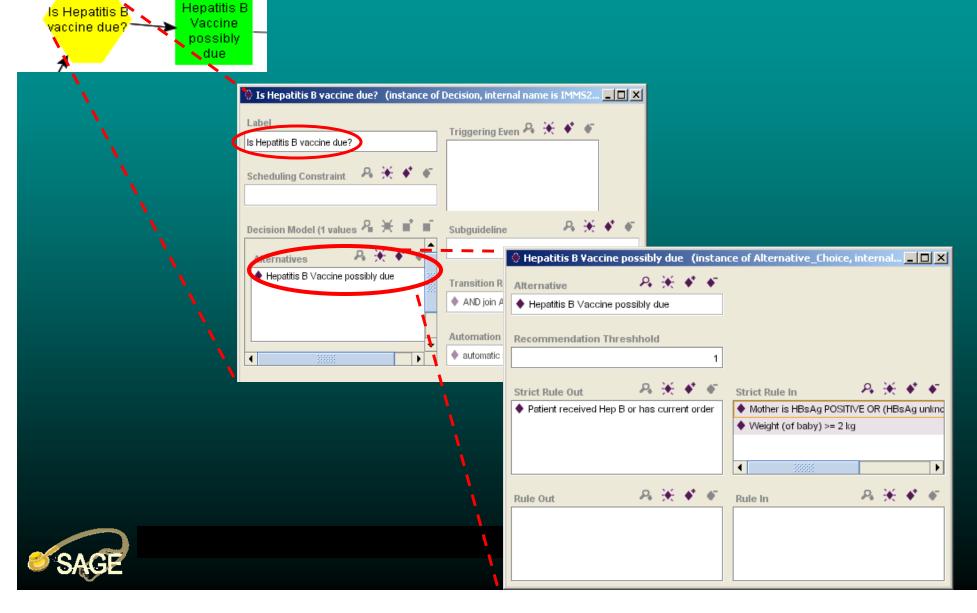
/accine due'

Vaccine

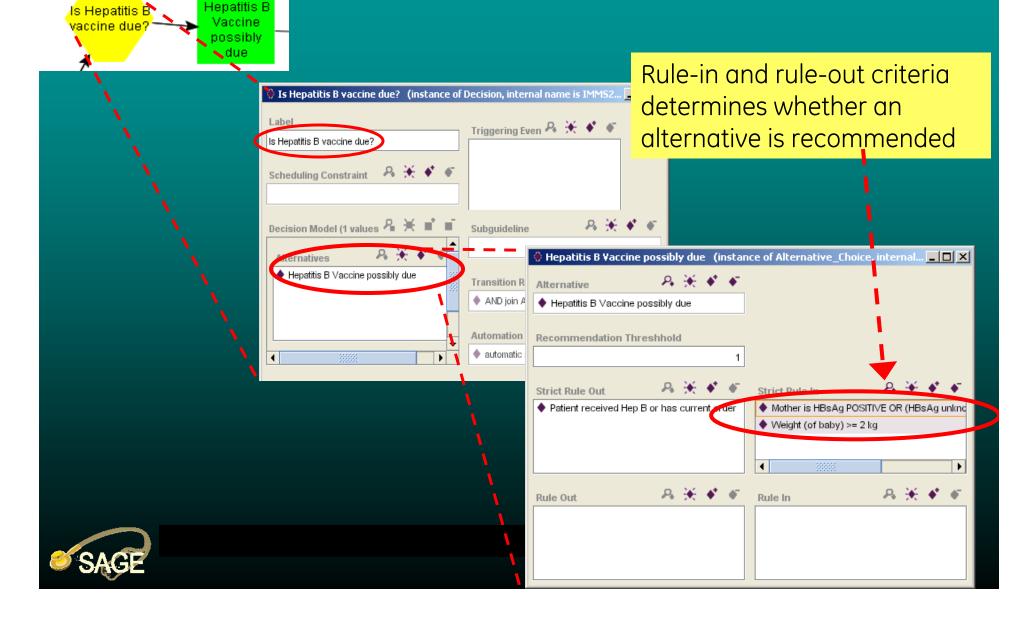
possibly due

Is Hepatitis B vaccine due? (instance of l	Decision, interi	nal name is IMM52				
Label Is Hepatitis B vaccine due?		en 🖧 🔆 🗲 🖝				
Scheduling Constraint 🤌 🔆 🗲						
Decision Model (1 values 🔏 💥 💣 🖬	Subguideline	<u> А Ж</u>	• •			
Alternatives 🔒 🔆 🔹 🗖		🔶 Hepatitis B Vaco	ine possibly o	due (instan	ce of Alternative_Ch	oice, internal 💶 🔼
♦ Hepatitis B Vaccine possibly due	Transition R	Alternative		€ ♦ ₹		
	AND join A	Hepatitis B Vacci	ne possibly due	,		
↓	Automation	Recommendation	Threshhold			
	♦ automatic			1		
		Strict Rule Out	- A 3	e 🔹 🖝	Strict Rule In	A ★ ★ ★
		Patient received I	Hep B or has cu	irrent order		OSITIVE OR (HBsAg unkno
					♦ Weight (of baby) >	= 2 kg
		Rule Out	8.3	÷ • •	Rule In	B 🔆 🗲 🐔
		Rule Out			Kule III	

A Decision Node contains reasons for <u>ch</u>oosing each alternative



A Decision Node contains reasons for <u>ch</u>oosing each alternative



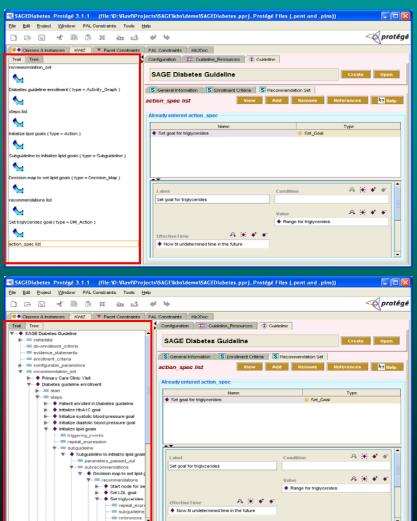
Features of SAGE Protégé Workbench

- 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





- 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

Immunizations - Mozilla Firefox	×
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J Amazon <u>G</u> Google 🎦 Gmail 📋 Customize Links 💲 Events 🗀 Med Info 📋 Trail Conditions at Mo 📄 UWTV Program: Goog	»
The New Yorker: The Critics: Dancing 📄 Immunizations	×

Immunizations

SAGE Cycle 5 Immunization guideline All patients eligible for vaccination regardless of age and clinical condition

• meta data:

Guideline Metadata ()

- ♦ identifier: ImmunizationCycle⁴
- title: Immunization master guideline
- o version: ImmunoCycle5
- category Prevention
- date: 2005/11/11
- o developer: Rob McClure Samson Tu Karen Hrabak Jim Campbell
- enrollment criteria: true recommendation set:

 - Neonatal Hepatitis Immunization Guideline Primary Care Immunizations
 - Adult Immunization Subguideline
 - Compute deferred vaccines
 - Vaccine eligibility master sub
 - Pediatric Immunization Subs
 - Population management scenari
 - Test trial

Recommendation Set (Activity Graph): Neonatal Hepatitis Immunization Guideline

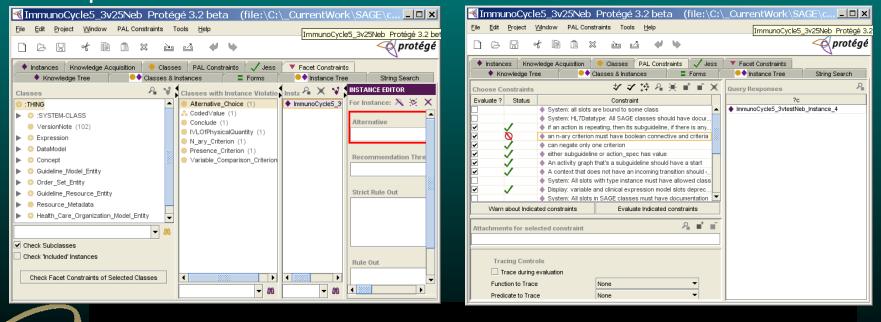
Newborn (Inpatient) Hepatitis Immunization Scenario This scenario is triggered upon admission of a newborn. The logic 1) determines whether Hepatits B vaccine is due, checks upon deferral and places orders when appropriate. 2) Orders followup testing at nine months of age for infants at risk 3) Determines whether Hepatitis B Immune Globulin is due and places order 4) Checks maternal record for information of Hepatitis B status. If these cannot be found, orders are placed for maternal testing and time drive event is set for 12 hour rechecks until receipted or the baby is more than 24 hours old.





Constraint Checking: PAL and Facet Constraint Tabs

 PALConstraint tab: Learning curve FacetConstraint tab: Problems with performance





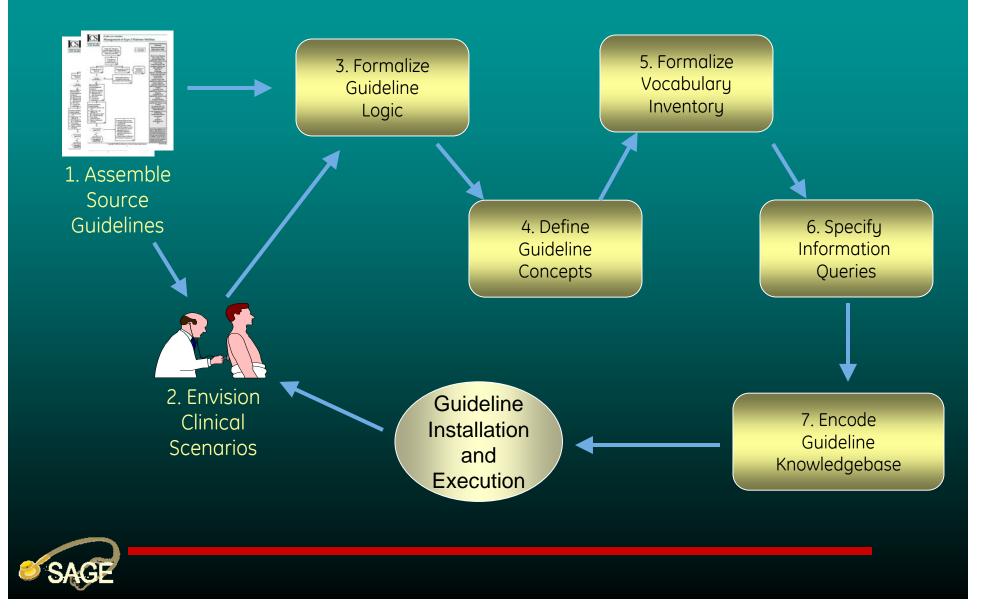
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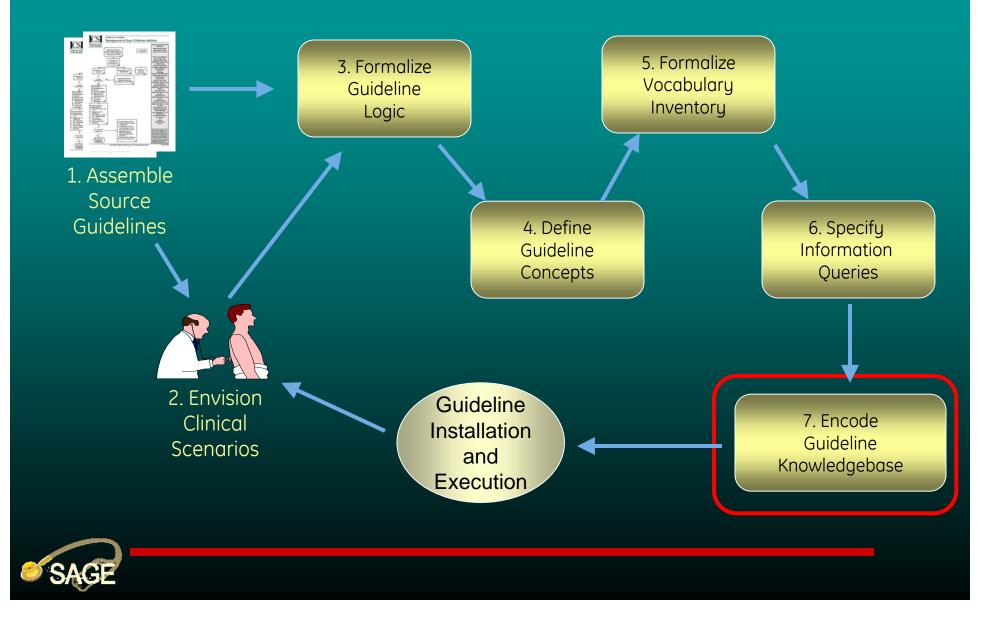
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SAGE Guideline Encoding Process



SAGE Guideline Encoding Process



Demo of Encoding Exercise: Adult Pneumoccocal Vaccine





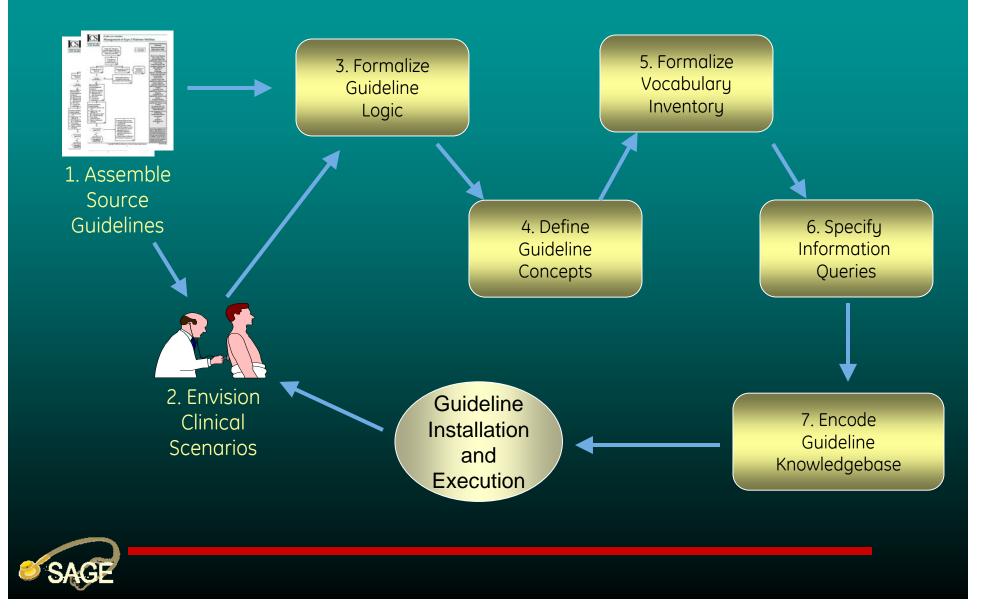
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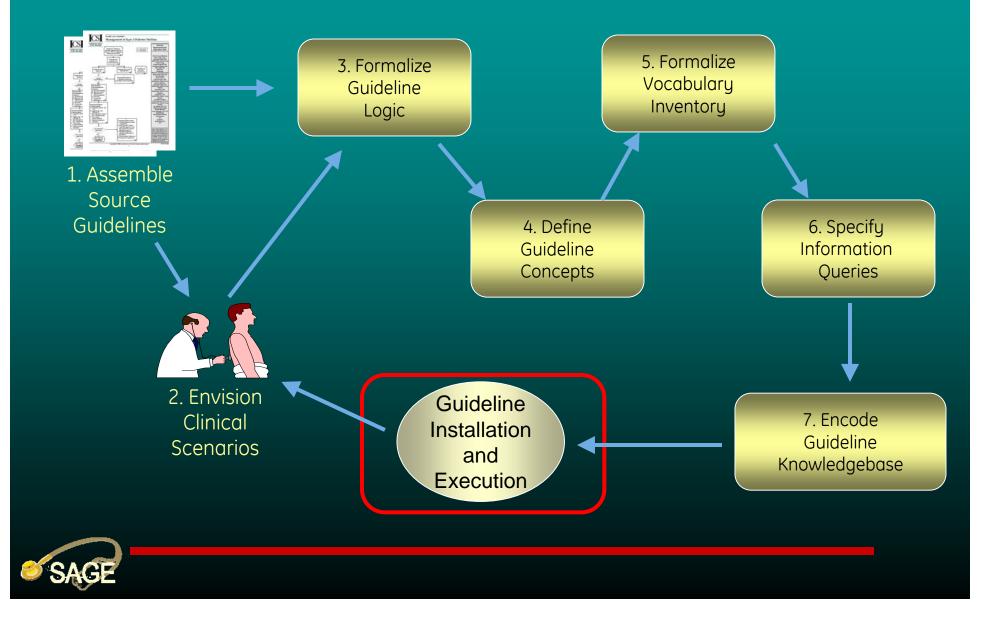
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SAGE Guideline Encoding Process



SAGE Guideline Encoding Process



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

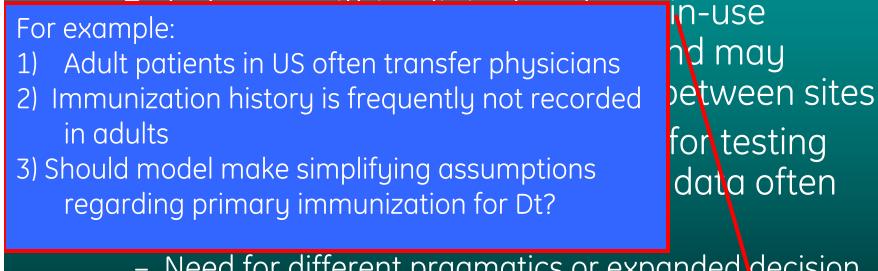


Validating the Run-Time Environment

- 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



- 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



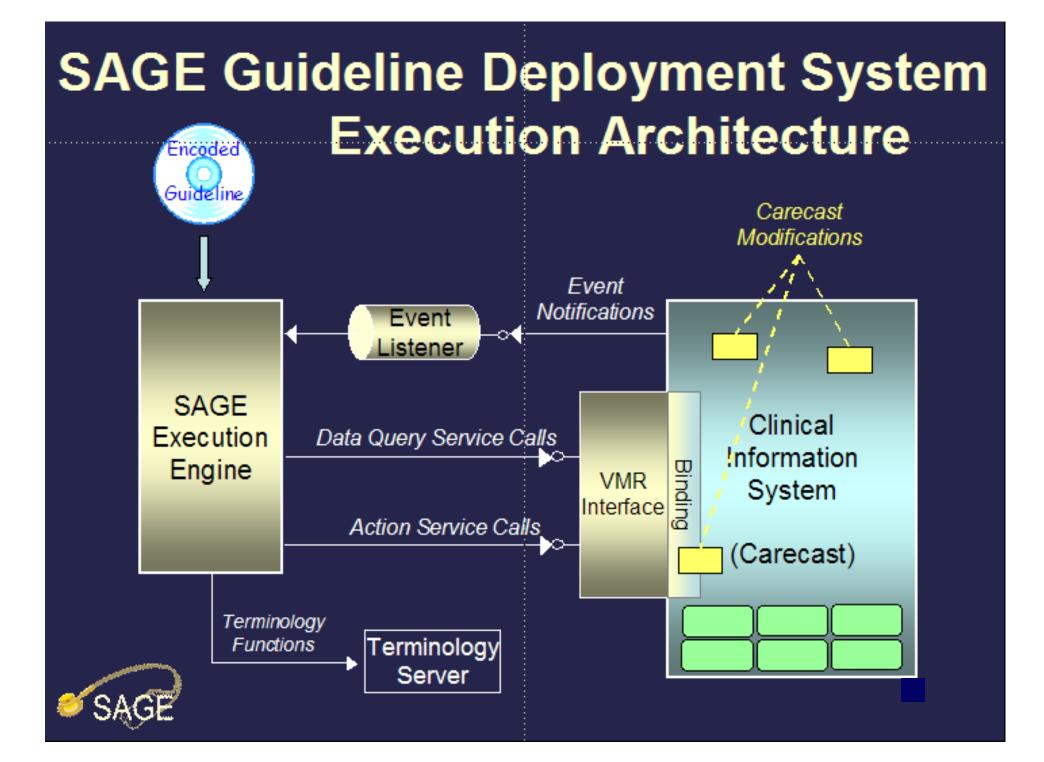


 Overview of guidelines and challenges to decision support development

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 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:
 - 1 dose Pneumococcal (PPV23)vaccine
 - 2 doses Diphtheria containing vaccine
 - 1 dose Hepatitis B vaccine



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...





Carecast / SAGE interactions



CIS (CareCast) Logon

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Patient: Yura Sage

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Problem List and Current Orders

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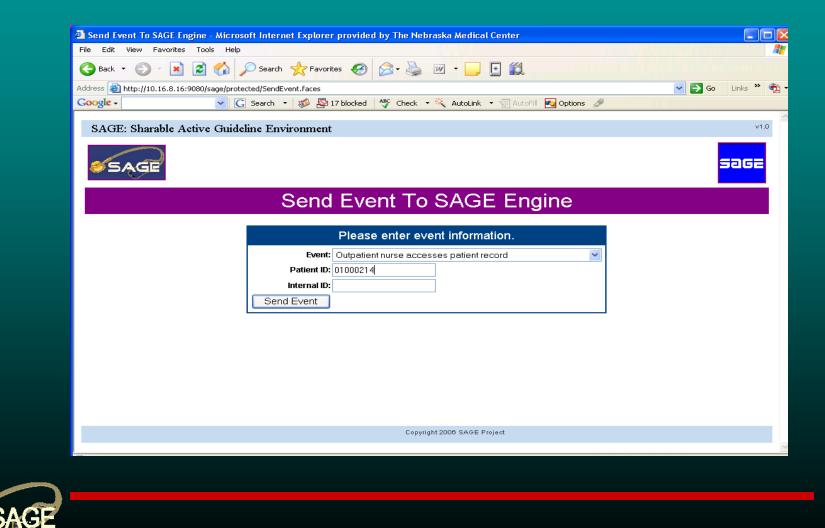


Problem List and Current Orders

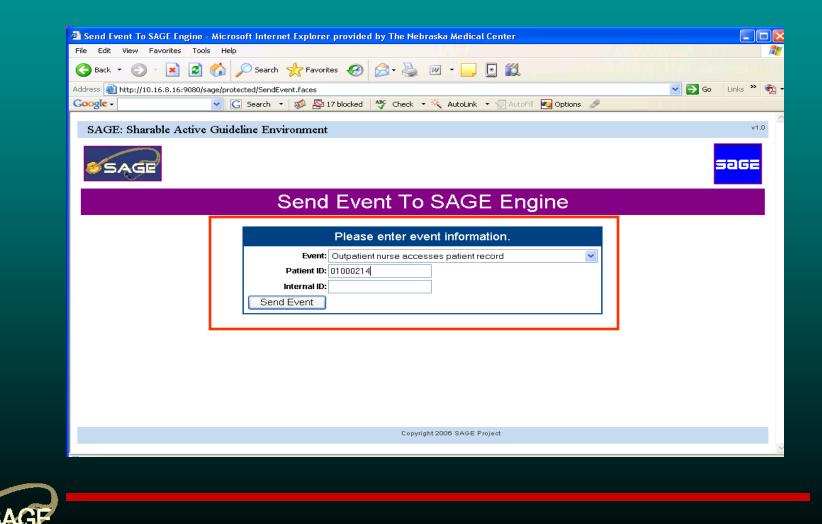
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SAGE Triggering Event



SAGE Triggering Event



Inbox Messages

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SAGE

Inbox Messages

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SAGE

Query for Consent and Illness

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Generate Vaccine Information

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Generate Vaccine Information

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Sage Reports Log: Due and Due but Contraindicated Vaccines

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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	 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 			
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Provider Queries to Resolve

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SAGE

Is Serious Illness Present?

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SGPRS	
Sage: Is a serious illness present in this patient that renders immunization inadvisab Absent (qualifier value) Present (qualifier value) 	Flowcharts

Has Consent Been Given?

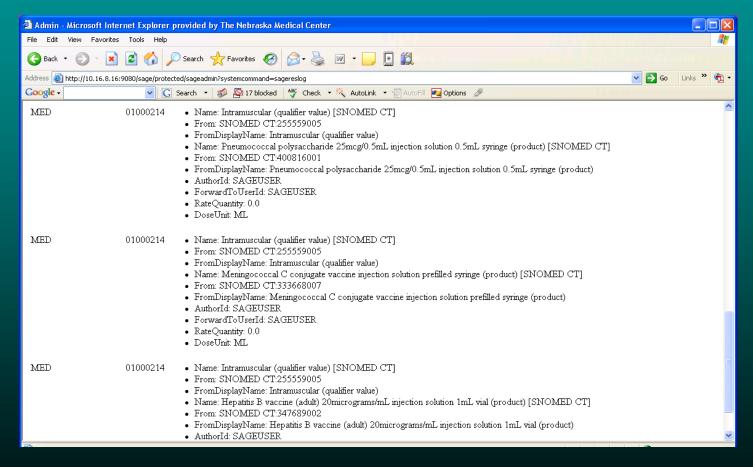
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SAGE Log: 'Place Orders for Due Vaccines'

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2006-07-16 21:13:30,473 II		criterion 00219ms: PCV7 vaccine is DUE result=false pid=01000214 gid=4
2006-07-16 21:13:30,473 II	NFO [STDOUT]	action sp: Order Pneumococcal 7-valent Conjugate Vaccine pid=01000214 gid=4
2006-07-16 21:13:30,723 II	NFO ISTDOUTI	criterion 00250ms: Influenza wholevirus vaccine is DUE result=false pid=01000214 gid=4
2006-07-16 21:13:30,723 II	NFO ISTDOUTI	action sp: Order Influenza wholevirus Vaccine pid=01000214 gid=4
2006-07-16 21:13:31,019 II	NFO [STDOUT]	criterion 00296ms: Pneumococcal (PPV23) is DUE result=true pid=01000214 gid=4
2006-07-16 21:13:31,019 II	NFO [STDOUT]	action sp: Order Pneumococcal 23-valent polysaccharide Vaccine pid=01000214 gid=4
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2006-07-16 21:13:31,926 H		action sp: Order Varicella Vaccine pid=01000214 gid=4
2006-07-16 21:13:32,113 II		criterion 00187ms: MCV4 vaccine is DUE result=true pid=01000214 gid=4
2006-07-16 21:13:32,113 II		action sp: Order Meningococcal (MCV4) Vaccine pid=01000214 gid=4
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2006-07-16 21:13:32,488 II		action sp: Order IdaP Vaccine pid=01000214 gid=4
2006-07-16 21:13:32,676 II		criterion 00188ms: Influenza splitvirus vaccine is DUE result=false pid=01000214 gid=4
2006-07-16 21:13:32,676 II		action sp: Order Influenza splitvirus Vaccine pid=01000214 gid=4
2006-07-16 21:13:32,910 II		evaluate: 1141420412910 >= 19.0YEAR
2006-07-16 21:13:32,910 H		criterion 00234ms: AGE >= 19 YEAR result=true pid=01000214 gid=4
2006-07-16 21:13:33,098 II		criterion 00188ms: Hepatitis B vacine is DUE result=true pid=01000214 gid=4
2006-07-16 21:13:33,098 H		evaluate: true AND true
2006-07-16 21:13:33,098 II		criterion 00422ms: Hep B vaccine is due and age $>=$ 19 years result=true pid=01000214 gid=4
2006-07-16 21:13:33,098 II		action sp: Order Hep B vaccine (adult) pid=01000214 gid=4
2006-07-16 21:13:33,348 II		action 04282ms: Place Orders for Due Vaccines
2006-07-16 21:13:36,582 II		adorant STATE RESOLUTION pid=01000214
2000 01 10 21.10.00,002 11		
		Copyright 2006 SAGE Project



SAGE Reports Log: Med Orders





Inbox Message: 1 Order Session

🛱 01000214 SA	SE, Yura - M						
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<u> </u>		ne 2 ⊠∎ ok					7
▼ Pt. Info & Misc.	▼ Orders ▼ Notes	▼ Procedures 🔹 ▼ L	ab 🔹 🔻 Ancillary	▼ Nursing	▼ Meds	✓ Summary	▼ Flowcharts
Desktop				Patient List D	Directory		
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MRN	Patient Name	Other Information		List Name		Туре	Owner
01000217	SAGE,Geriatricmale	outor monnauon		Hotlist 🧡		11100	lo inition
01000224	SAGE, Jaundice baby	S 01IN-C Campbe	II. James R	SAGECAP		GRP	Sage
01000214	SAGE,Yura			SAGEdiabet	tes	GRP	Sage
01000199	SAGE Neonate	S 02IN-A Campbe	II, James R	SAGEimmur	nization	GRP	Sage
01000222	SAGE,One year old			SAGEtest		GRP	Sage
01000216	SAGE, Pedi8yearold A			TemporaryL	.ist	PERS	User, Sage
				Select InBox Messa InBox Messa	-	It Make Freq	Move/Remove
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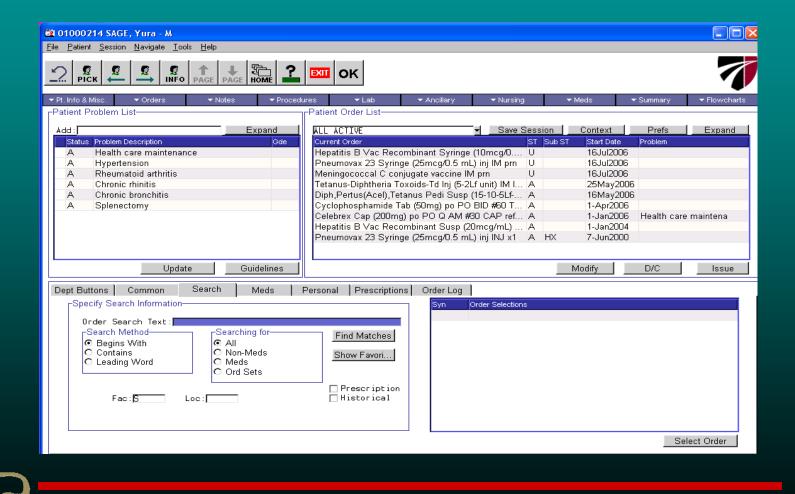


Inbox Message: 1 Order Session

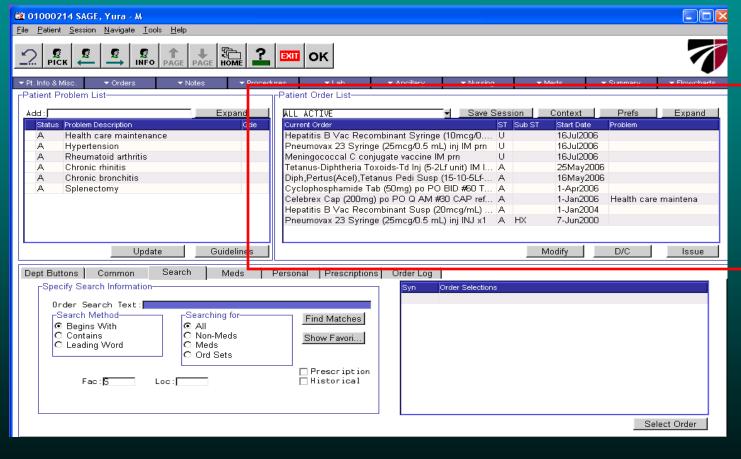
🛍 01000214 SAGE, Yura - M	
Eile Patient Session Navigate Iools Help	7
▼Pt. Info & Misc. ▼Orders ▼Notes ▼Procedures ▼Lab ▼Ancil	ary ▼Nursing ▼Meds ▼Summary ▼Flowcharts
Desktop	Patient List Directory
Current Patient List: GRP: SAGE immunizatio Sage	Freq O Folders O Avail
MRN Patient Name Other Information	List Name Type Owner
01000217 SAGE,Geriatricmale	Hotlist 🤎
01000224 SAGE, Jaundice baby S 01IN-C Campbell, James R	SAGECAP GRP Sage
01000214 SAGE,Yura	SAGEdiabetes GRP Sage
01000199 SAGE,Neonate S 02IN-A Campbell, James R	SAGEimmunization GRP Sage
01000222 SAGE,One year old	SAGEtest GRP Sage
01000216 SAGE,Pedi8yearold A	TemporaryList PERS User, Sage
	Select Make Default Make Freq Move/Remove
	O All Mine O Patient O
	Notifications
	I SAGE
	LYou have saved order sessions 1
Select Remove Add Active Find Temp List Print List Refre	esta
Command Central	
Active MRN: 01000214 Global Name Lookup	Create Resolve Refresh Sage



3 Un-issued Orders to Resolve



3 Un-issued Orders to Resolve





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

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TYPE	PATIENT		^
Observation	• Nar • Froi • Froi • Stat	m: SNOMED CT.31874001 me: Hepatitis B vaccine is due [SAGE] m: SAGE:C116 mDisplayName: Hepatitis B vaccine is due teName: IMMS2004_00271 ionType: Conclude	μų.
Observation	 Froi Froi Nan Froi Froi Froi Stat 	me: Contraindicated (qualifier value) [SNOMED CT] m: SNOMED CT:410536001 mDisplayName: Contraindicated (qualifier value) me: MMR vaccine is due [SAGE] m: SAGE:C115 mDisplayName: MMR vaccine is due teName: ImmunoCycle5_3v4Neb_Instance_40023 ionType: Conclude	
Observation	• Nar • Froi • Froi • Stat	m: SNOMED CT:31874001 me: PPV23 vaccine is due [SAGE] m: SAGE:C122 mDisplayName: PPV23 vaccine is due teName: IMMS2004_00192 ionType: Conclude	
Observation	• Nan • From	m: SNOMED CT:31874001 me: MCV4 vaccine is due [SAGE] m: SAGE:C127 mDisplayName: MCV4 vaccine is due	>



Sage Reports Log: Due and Due but Contraindicated Vaccines

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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	 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	 subject: Generate Hep B education material message: \par http://www.cdc.gov/nip/publications/VIS/vis-hep-b.j subject: Generate Pneumococcal (PPV23) education material message: \par http://www.cdc.gov/nip/publication subject: Generate Meningococcal (MCV4) education material message: \par http://www.cdc.gov/nip/publication SubjectStr: Sage Mesg. AddresseeStr: Session_Owner 	ns/VIS/vis-ppv.pd:		
Display	 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: Ingui e about illness message: \par SubjectStr: Sage Mesg. AddresseeStr: Primary care physician 	licated		

