





"A collaborative project to develop a universal framework for sharing health knowledge in the form of computable clinical practice guidelines"

AMIA 2003 Symposium: Partnerships in Innovation

Session S88

Agenda for Today's Talk

I. SAGE: A Partnership in Innovation

A round-table overview of the vision, objectives, and collaborative approach of the SAGE Project

II. Illustration of SAGE Technology

A walk-through illustration of working SAGE prototypes – from guideline encoding to execution of guideline content via functions of a clinical information system.

III. SAGE: Where are we going from here?

An overview of project futures and implications for delivery of health care

Agenda for Today's Talk

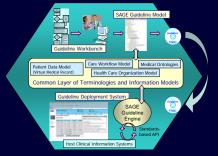
I. SAGE: A Partnership in Innovation A multi-faceted overview of the vision, objectives, and collaborative approach of the SAGE project

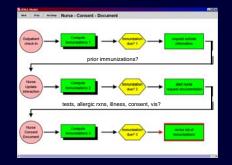
II. Illustration of SAGE Technology

A walk-through illustration of working SAGE prototypes – from guideline encoding to execution of guideline content via functions of a clinical information system

III. SAGE: Looking Forward An overview of project futures and implications for delivery of health care

Overview of the SAGE Infrastructure







A collaborative project to develop a universal framework for encoding and disseminating electronic clinical guidelines*





I. Partnership in Innovation

I. SAGE: A Partnership in Innovation

- Guy Mansfield, PhD (IDX)
 - SAGE vision, project objectives, collaborative approach
- Sidna Scheitel, MD (Mayo Clinic, Rochester)
 - Use case requirements, usability analysis
- Samson Tu, MS (Stanford Medical Informatics)
 - Guideline modeling, guideline representation
- Jim McClay, MD (University of Nebraska Medical Center)
 UNMC, interoperability, guideline context modeling
- Roberto Rocha, MD, PhD (Intermountain Health Care)
 - Standard information models, alignment with standards
- Tony Wieda, PhD (Apelon, Inc.)
 - Integration of controlled medical terminologies





Guy Mansfield, PhD

Director, Health Informatics IDX Systems, Seattle _{Guy_Mansfield@idx.com}

SAGE Project Vision
Key Objectives

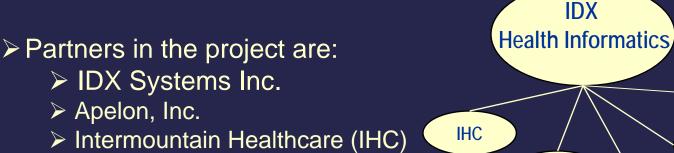
Collaborative Approach

Project Overview

Standards-based Sharable Active Guideline Environment

An R&D consortium to develop the technology infrastructure to enable computable clinical guidelines, that will be shareable and interoperable across multiple clinical information system platforms

Scope: 3 year, \$18 M, multi-site, collaborative project



- Mayo Clinic
- Stanford Medical Informatics (SMI)
- University of Nebraska Medical Center (UNMC)

Funded in part by: NIST Advanced Technology Program

Cooperative Agreement Number 70NANB1H3049

UNMC

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SMI

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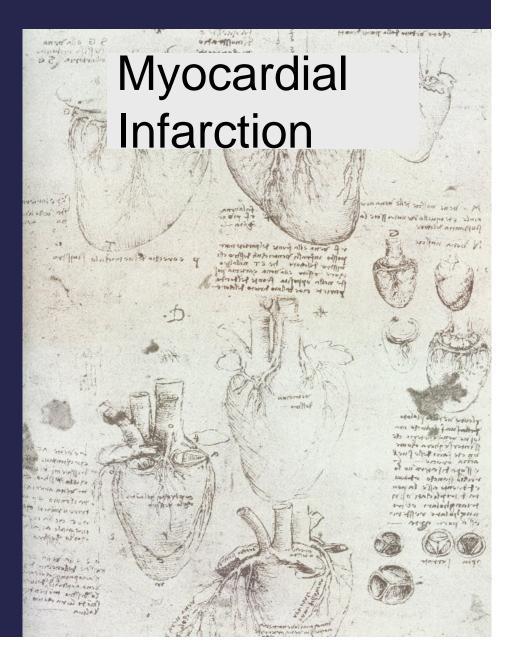
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A knowledge-processing problem

"Current medical practice relies heavily on the unaided mind to recall a great amount of detailed knowledge – a process which, to the detriment of all stakeholders, has repeatedly been shown unreliable"

Crane and Raymond The Permanente Journal Winter 2003 Volume 7 No.1 Kaiser Permanente Institute for Health Policy



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Myocardial Infarction

- Recent JAMA article:
 - Only ~60% of patients are receiving beta blockers post MI.
- This leaves them vulnerable to further cardiac events and sudden death.

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Not just recall:

- Analysis
- Processing
- Application of knowledge to each patient

Myocardial Infarction

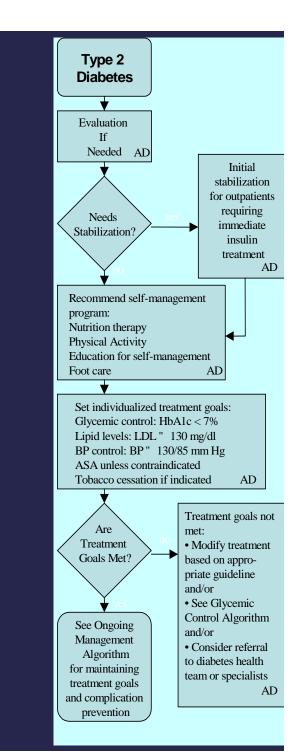
- Recent JAMA article:
 - Only ~60% of patients are receiving beta blockers post MI.
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What if . . . ?

Guideline content became active, offering targeted, relevant guidance at the point of care?

Patients were evaluated against proven guidelines automatically?

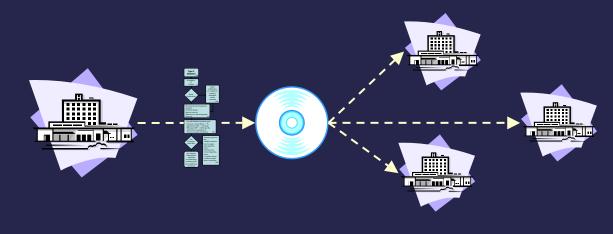
Key data were presented at critical decision points *automatically?*



SAGE Project Goals

The primary goal: Develop a Standards-Based Sharable Active Guideline Environment with which:

- Health experts can author and encode clinical practice guidelines in a standard computable format, and
- Health care organizations throughout the nation can deploy those guidelines easily within any standards-conforming clinical information system.

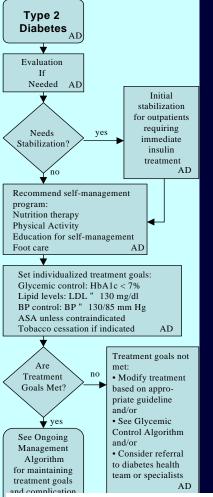


SAGE Main deliverables

- An interoperable guideline model A computable knowledge representation "format" for encoding the content and logic of executable clinical practice guidelines.
- A guideline workbench A software tool for authoring, encoding, and maintaining guidelines in the format of the SAGE guideline model.
- A guideline deployment system Software that "decodes" the content of electronic guidelines and surfaces that content via functions of the local clinical information system.
- Controlled resources -- Specification of a common layer of information models and terminologies to mediate guideline content.

SAGE Interoperable Guideline Model

A standard computable "specification" for representing and encoding the content and logic of clinical practice guidelines



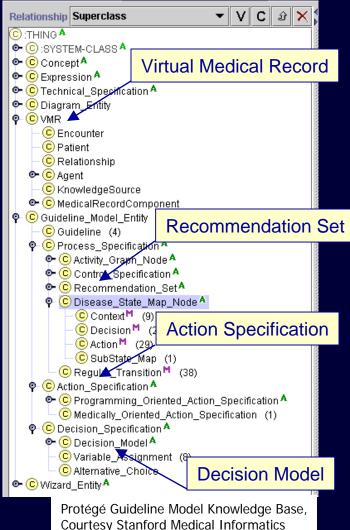
Type 2 Diabetes Guideline Flow Diagram, courtesy of Institute for Clinical Systems Improvement (ICSI)

✓ Clinical content (criteria, actions)✓ Patient status and eligibility

✓ Decision logic

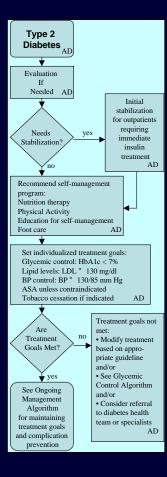
✓ Clinical sequencing and workflow✓ Guideline goals and intentions

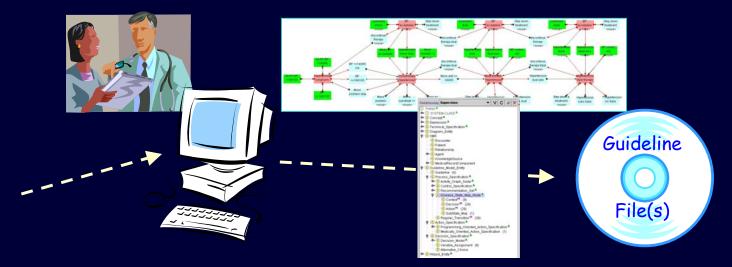
✓ Guideline evidence and references



Interoperable Guideline Workbench

A software tool for authoring, editing, encoding, and maintaining guidelines in the format of the Guideline Model



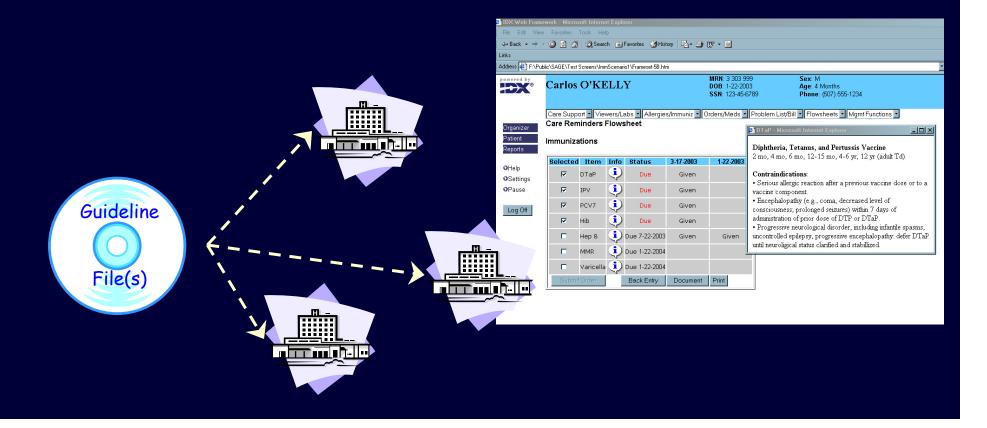


- ✓ Ensure complete *encoding* of guideline knowledge
- ✓ Support access to guideline content model
- ✓ Support access to controlled terminologies
- ✓ Support for visualization of guideline logic

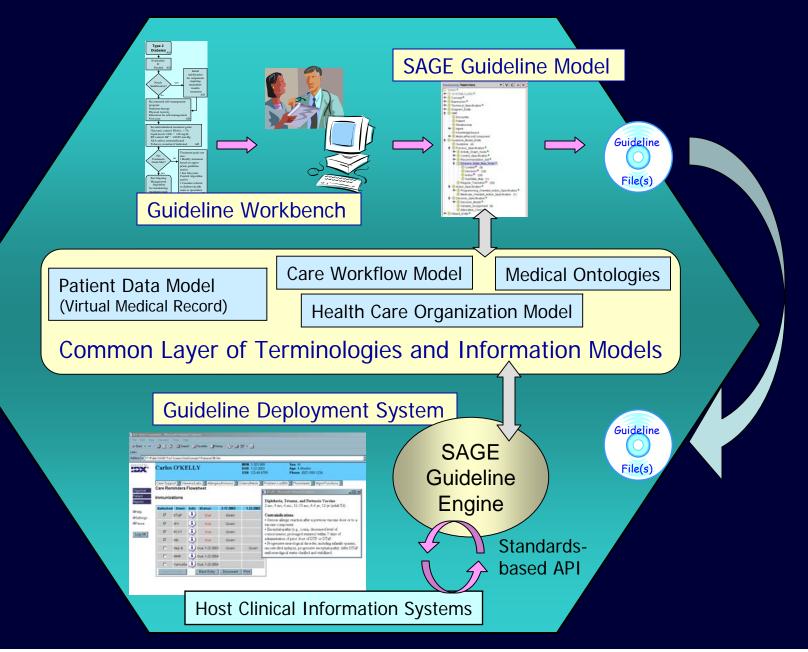
Guideline Deployment System

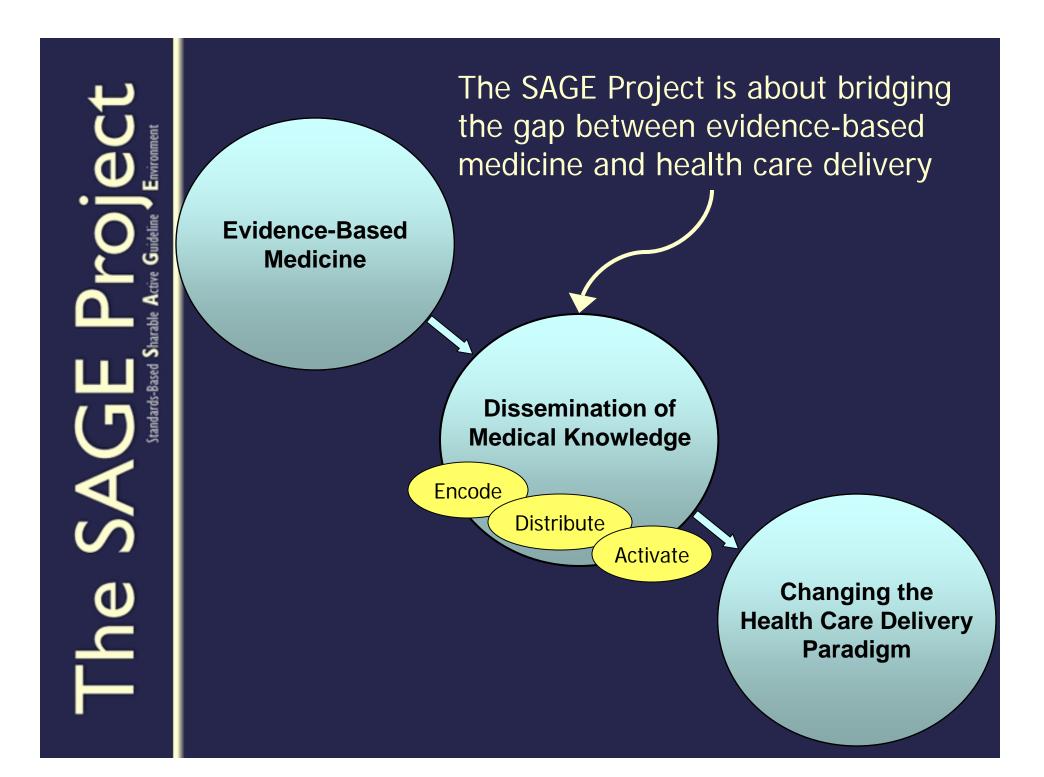
Software that integrates electronic guidelines with the clinical information system to operationalize the guideline for clinicians

- ✓ Administer: Download, import, store
- ✓ Localize: Clinical edits, local constraints
- ✓ Set Up: Mapping to local terminologies and EMR
- ✓ Execute: Activation of guideline via CIS workflow



Overview of the SAGE Infrastructure





Key Problems to Solve:

Functionality

- Represent guideline knowledge in a manner that is both comprehensive and computable.
- > Manage complexity during encoding and deployment.
- Activate guideline content via functions of clinical information systems.

Interoperability

- > Deploy encoded guideline content widely.
- > Semantic interoperability sharing usable knowledge.
- > Install and "map" guideline content at reasonable costs.
- > Execute guideline content in multiple HIS environments.

Approach to Solving Problems:

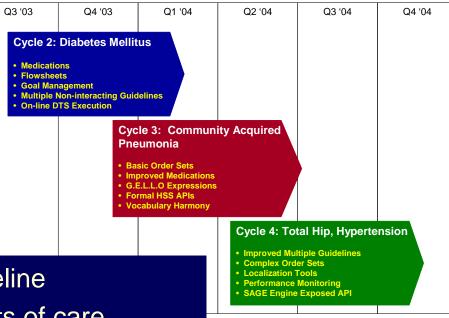
 \succ Build on an invaluable foundation of previous work.

- \succ Requirements analysis employing clinical use cases.
- Usability testing of clinician / guideline interface.
- \succ Organization into cross-partner work teams.
- \succ Alignment with national health information standards.
- Iterative prototyping / development cycles

SAGE Synchronization Cycles:

SAGE Iterative Development

Cycle Scope and Objectives for Cycles 2 through 4



- 1. Start with "generic" text-based guideline
- 2. Define scenarios for specific contexts of care
- 3. Perform usability analysis and UML modeling
- 4. Specify guideline content at computable level (Decision logic, information models, terminology use)
- 5. Encode scenario content into SAGE guideline model
- 6. Specify required actions of the CIS
- 7. Update execution engine / API technology
- 8. Install and bind guideline to test CIS
- 9. Test execution of guideline contents via CIS

Key Technical Considerations:

Interoperability

- > Deployment across heterogeneous CIS platforms.
- \succ Reasonable costs to install and use guidelines.

Standards-Based Encoding

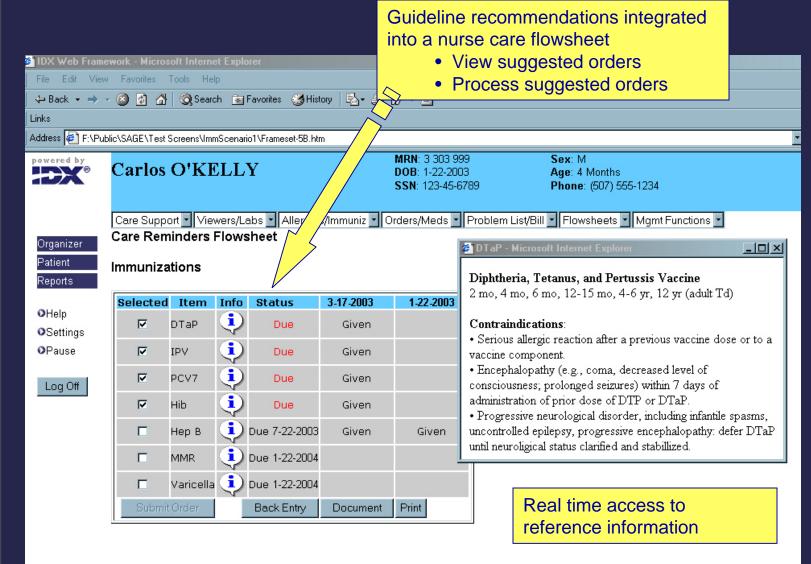
- Employ standard terminologies and information models.
- Collaboration with leading SDOs (e.g., HL7).
- > Alignment with national health information standards.

Active Deployment of Guideline Content

- > Active use of patient EMR data by clinical decision support.
- Patient-specific recommendations.
- > Integrate recommendations with care workflow.



"Activating Guideline Content"



IDX Systems Corporation - Proprietary and Confidential

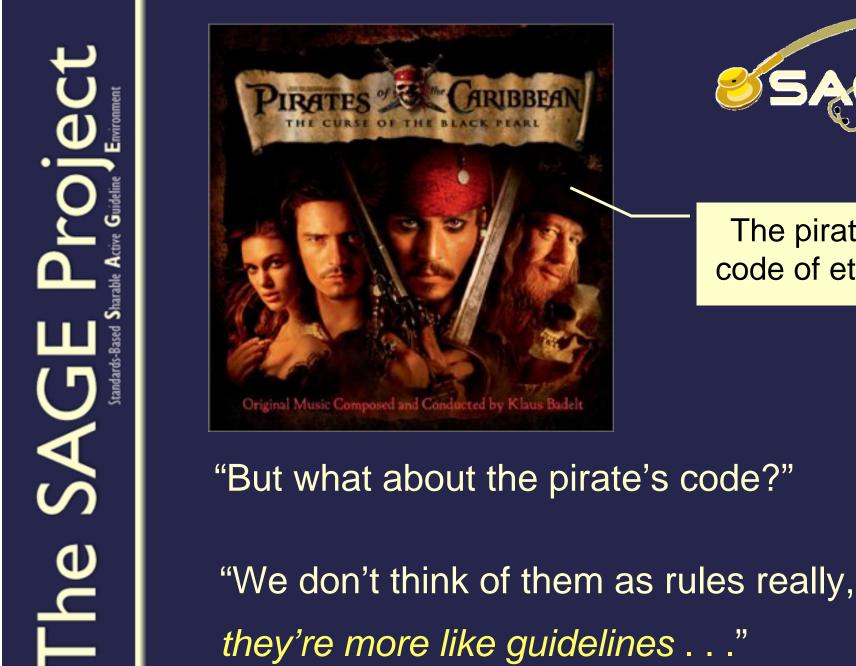




The pirate's code of ethics



The pirate's code of ethics



The pirate's code of ethics





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Mayo Medical School Scheitel.sidna@mayo.edu

Use Case Requirements

Problem Focus: Understanding the requirements integrating active guideline recommendations into the care workflow – via functions of the clinical information system

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Selecting Exemplar Guidelines

Exemplar Guideline	Clinical Domain
Diabetes Management (DBM)	Chronic disease monitoring and treatment. Acute exacerbation of chronic disease. Chronic disease as a comorbidity.
Immunizations (IMM)	Routine health maintenance, in both outpatient and inpatient settings.
Community Acquired Pneumonia (CAP)	Emergency room evaluation and diagnosis. Outpatient treatment of acute disease. Inpatient and ICU treatment of acute disease. Follow-up of acute disease.
Total Joint Replacement (TJR)	Surgical guideline. Comprehensive pre-op workup, inpatient plan of care, and post-op outpatient management.

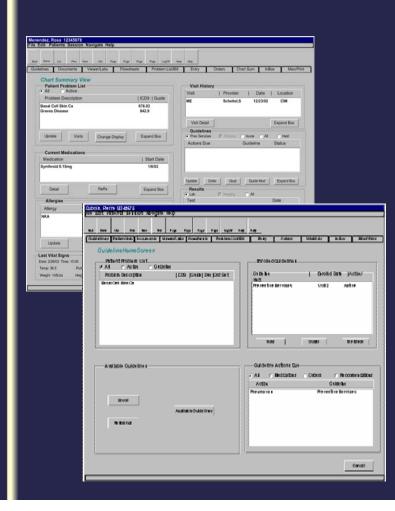
Guideline Use Cases

- Clinical Scenarios where clinician workflow is documented
- Guideline use case examples for immunization
 - Neonatal, uncomplicated
 - Routine pediatric, uncomplicated
 - Pediatric with unknown/uncertain immunization history
 - Pediatric with known, out-of-date immunization history
 - Pediatric with permanent contraindications
 - Adult with transitory contraindications
 - Adult with risk factors
 - Population-based patient survey

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System Prototyping

 Using low fidelity (cheap and quick tools) to develop prototypes (VISIO, Dreamweaver)



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Mayo Usability Lab

- Observers behind one way mirror
 - -2-5 per session
 - Notes taken during testing
 - Debriefing by lab facilitator after each session.
- Participants
 - nurses (LPN, RN)
 - physicians (primary care, specialists)
- Scenarios with EMR screens



Mayo Usability Lab

Prototypes tested by physicians



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Guidelines are Seamlessly Integrated

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Initial Usability Lab Findings

Guideline alert reminders

- Desire to be information dense
- Configurable presentations (pop-up, in-box)
- Ability to target to specific clinician role.
- Meaningful, don't alert if recommendation is pending or ordered.
- Don't want multiple pop-up alerts for each guideline
- Ability to respond to alert with minimal amount of clicks

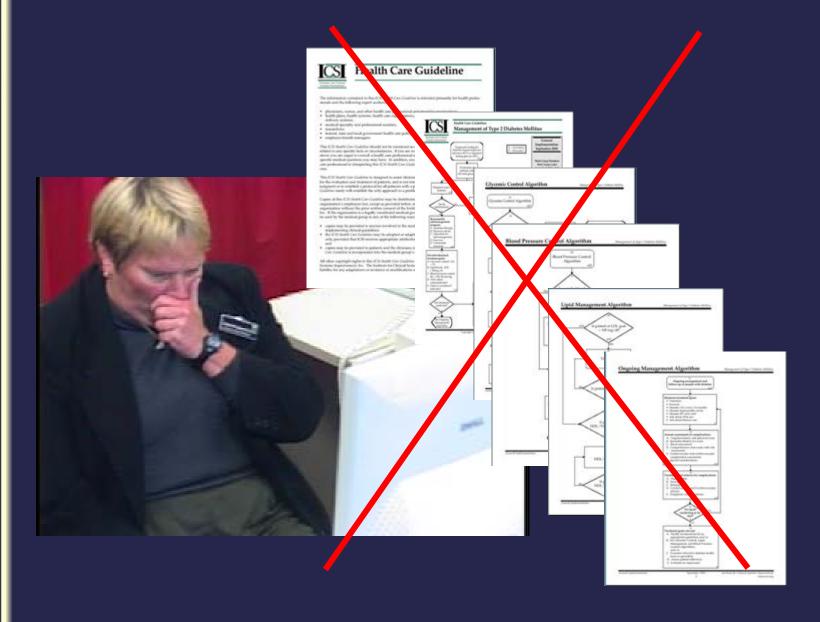
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Rationale For Recommendations



Rationale For Recommendations

- Liked pull not push presentation
- Like succinct summaries
- Present at appropriate time in workflow
- If full guideline referenced desired bookmark

Guideline Recommendation

Guideline Flowsheet

Guideline Reference Box

 Guideline: Diabetes Mellitus

 Recommendation: Alb/Creat Ratio-Urine

 Guideline Reference

 Recommended annually in patients < 70</td>

 At the discretion of the provider on patients > 70

 If a positive test (>30mg/gm) the test should be repeated twice in the next 3 months

 Laboratory Reference

 Factors that can influence this test are blood in the urine, heavy exercise, fever, congestive heart failure, uncontrolled diabetes, severe hypertension, UTI and vaginal fluid contamination

Guideline References

Cancel

General Findings

Enrollment

- What is it and when is someone "enrolled" ?
 - Prev Services at birth or first contact
 - Chronic Diagnosis of disease
 - Diagnostic, Acute Illness– No answer yet
- Miscellaneous Embedded Tools
 - Calculators with pre-filled data elements
 eg. Goal setting LDL Cholesterol
 - Level of care eg. Community Acquired Pneumonia
 - Establishment of diagnosis Disease criterion

General Findings

- Use of Order Sets
 - Critical for efficient use of guidelines and CIS

- Diagnostic, Acute Illness guidelines are problematic
 - When is enrollment done?
 - Workflow issues



SAGE Project

Samson W. Tu, Ravi Shankar, Mark A Musen (PI) Stanford Medical Informatics Stanford University School of Medicine

Problem Focus: Solving the challenge of comprehensive, interoperable, and computable representation and encoding of guideline content

Stanford Medical Informatics

- History of guideline modeling and execution projects
 - ONCOCIN, T-Helper, InterMed, PRODIGY, EON, ATHENA
- Protégé national resource
 - Robust and extensible knowledgeengineering environment
 - Basis for SAGE guideline workbench

Guideline Modeling Goal

• Create a guideline model that

- Is sufficient to encode guideline knowledge needed to provide situation-specific decision support
- Uses standardized components that allow interoperability with the standard services of vendor clinical information systems.
- Includes organizational knowledge to capture workflow information and resources needed to provide decision-support in enterprise setting

Guideline Modeling Overview

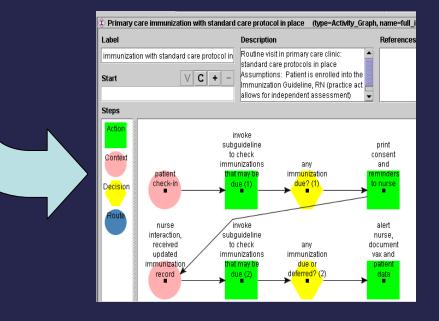
• Scenario-driven modeling

 Clinical scenario: Patient arrives for visit with primary physician. At check-in, SAGE checks for immunizations that are due and prints consents and information sheets. Nurse then reviews any other shots received, updates the record, and records immunizations given that day in CareCast

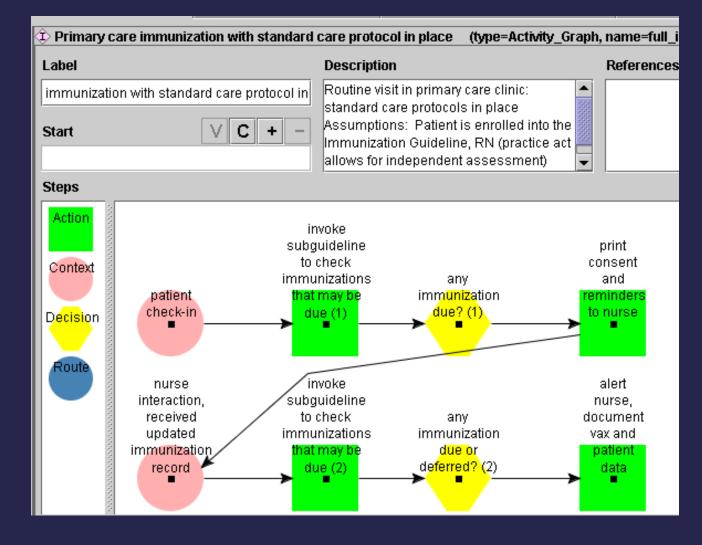
Guideline Modeling Overview

• Scenario-driven modeling

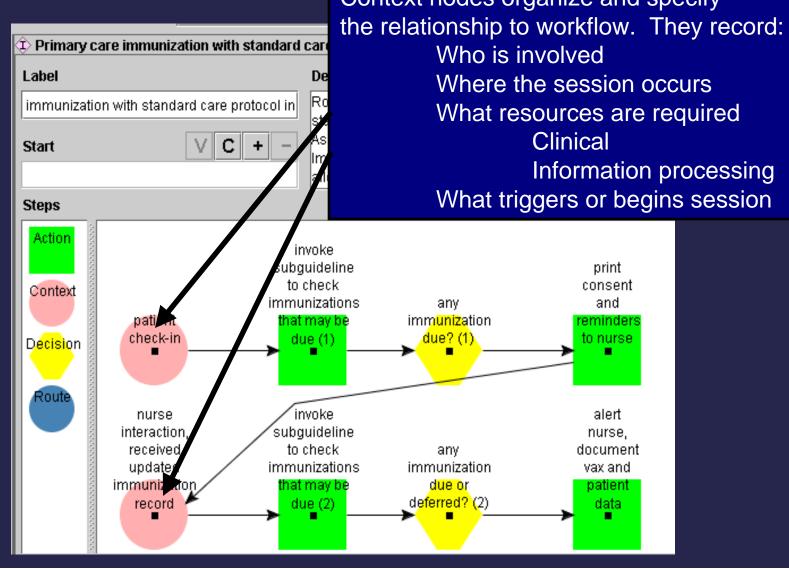
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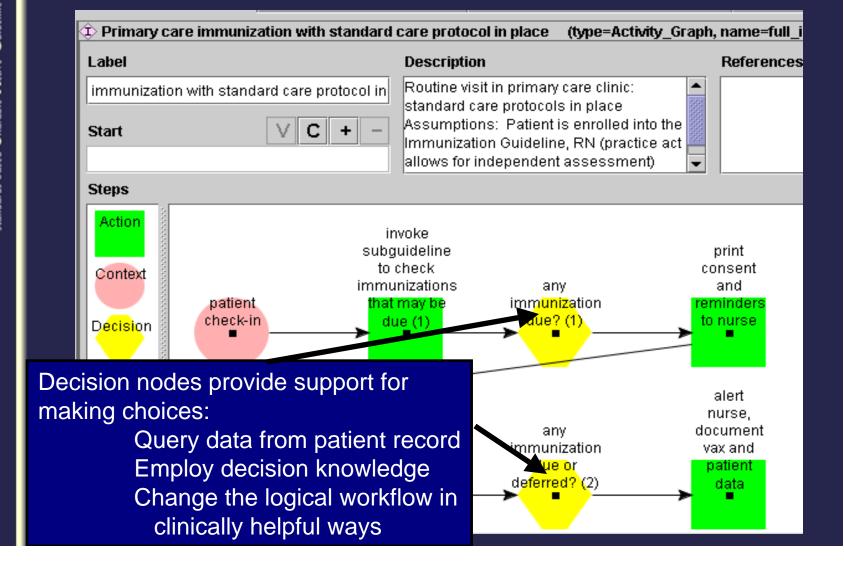
Top-Level Workflow-Aware Process



SAGE Context Model: Workflow Specification and Sharing Context nodes organize and specify



SAGE Decision Model: Clinical Decision Making

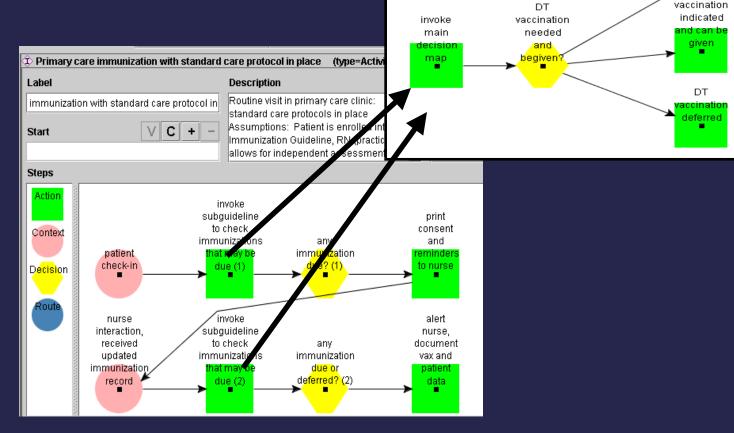


SAGE Action Model: Creating Interventions for Favorable Outcomes Image: Primary care immunization with standard care protocol in place. (type=Activity Graph, name=full i Description Label References Routine visit in primary care clinic: immunization with standard care protocol in standard care protocols in place Assumptions: Patient is enrolled into the Start Immunization Guideline, RN (practice act allows for independent assessment) Steps Action invoke subquideline print consent Action nodes define activity to be and anv accomplished by clinical information system: om<mark>uniz</mark>ation eminders due? (1) to nurse User interaction and query Order sets Referrals alert Appointments and scheduling nurse, document anv Goal setting าmunization vax and due or patient Documentation and recording eferred? (2) data. Messaging, print and paging Sub-guidelines

Sub-guidelines

Can be thought of as reusable subsets of guideline logic (much like subroutines) for repeated use within

a recommendation set



DT vaccination

co<mark>ntraindicat</mark>ed

SAGE Guideline Workbench

Protégé-2000 as foundation

- Extensible with custom plug-ins (e.g. Apelon terminology service plug-in)
- Knowledge-acquisition (KA) GUI generated from guideline ontology
- Kwiz: Protégé application to improve KA process
 - Chunk work into discrete steps
 - Create alternative views
 - Reuse components from guideline knowledge repository
 - Improved navigation and search



James McClay, MS, MD

Assistant Professor University of Nebraska Medical Center jmcclay@unmc.edu

- Guideline Context Specification

Problem Focus: Specifying the guideline modeling and encoding requirements for interoperable active deployment of guideline recommendations via actions of the clinical information system he

SAGE Enhances Memory

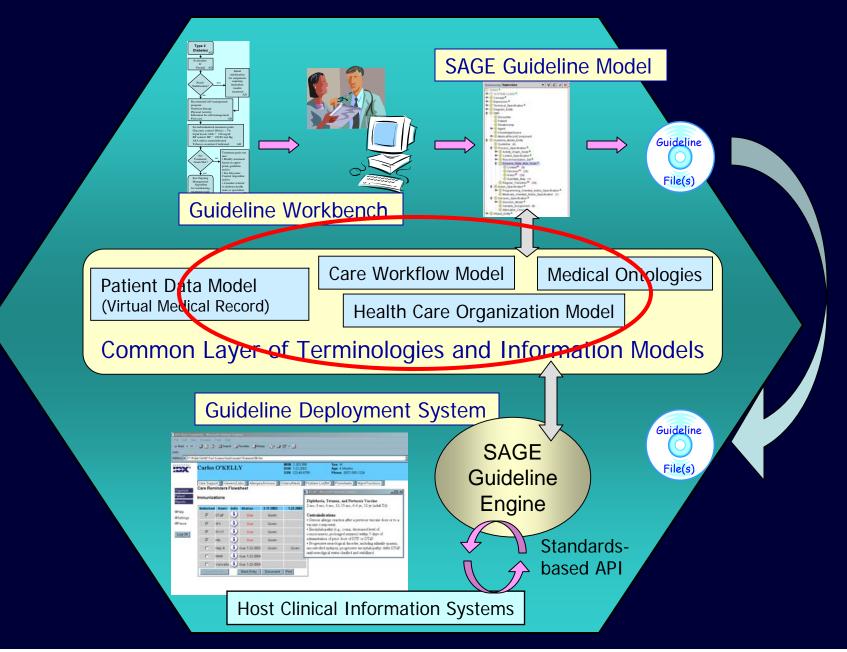
Sage herb "can boost memory"

Centuries-old theories that the herb sage can improve memory appear to be borne out by modern research.

BBC News Published: 2003/08/28 23:15:38 GMT



Overview of the SAGE Infrastructure



Interoperability

- In common terms, interoperability is "plugand-play" functionality, in this case – for clinical knowledge and decision support
- Requires that the software employs the same terminology, models knowledge using the same constructs, and is applied only in comparable clinical environments
- Allows different institutions to share software and knowledge bases
- Required if we want to achieve economies of scale in clinical decision support

SAGE: Transactional and Semantic Interoperability

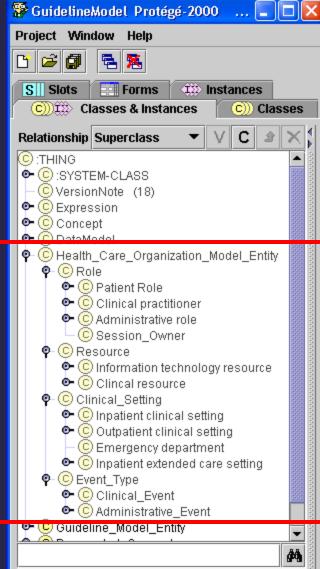
- Create all SAGE sharable guideline data strictly adhering to SNOMED CT, LOINC, RxNorm standards requirements
- Explicitly model guideline context and workflow assumptions for translation to local settings
- Vendor-specific process translates SAGE data sets to their local terminologies and information models
- Create a virtual medical record (vMR) model in dialogue with standards developers including HL7 RIM and College of American Pathologists
- A guideline execution engine employs the SAGE data, supplementing their clinical information system, and delivering the guideline decision support during ordering sessions

Interoperability: Computer systems freely sharing data and programs for a common purpose

- 1) Functional: physical link
- 2) Transactional: sharing data
- 3) Semantic: sharing data meaning
- 4) Procedural: sharing executable process
- 5) Ergonomic: software employed within a shared work plan

- 1) OSI layers 1-2: physical connectivity
- 2) OSI 3-6: transport and messaging
- 3) OSI layer 7: data content standards
- 4) OSI 7: software and knowledgebased standards
- 5) OSI 7+: workflow coalition and others

Standardizing The Clinical Context



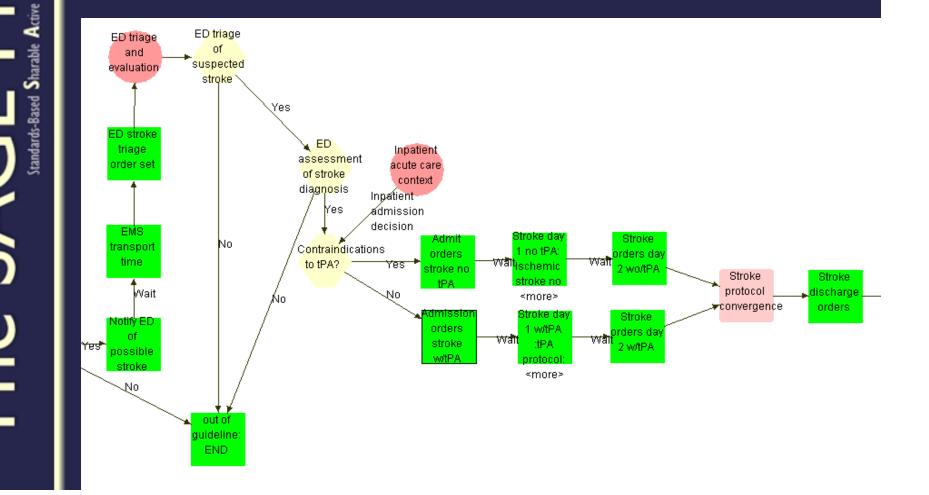
- Organizational Model
 - Roles
 - Resources
 - Settings
 - Events

Based on workflow management coalition specifications

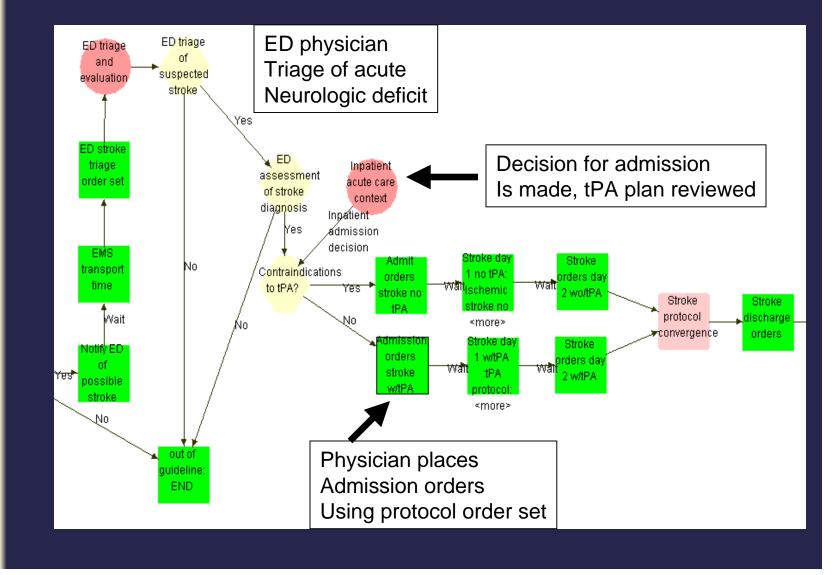
Organizing Workflow Around Problemindexed Session-based Order Sets

- Order sessions are defined by points in the care process when decision making or change in care plan occur
- Goal setting and outcomes documentation integrated with charting
- Integrated problem list management
- Order sets and subsets:
 - Navigation within large list (2-3,000) of order sets by diagnosis or procedure
 - Co-morbidity order sets for managing complex patients
 - Identification of "units of work" as nested sets for editorial maintenance

How will it work? 1) Specify the clinical scenario for support 2) Model the decisions and actions for specific guideline clinical scenarios



How will it work? 3) Link the model to an 'ideal enterprise' workflow and supporting software tools



D C

UNMC Goal: Expanding Institutional Memory

- Content development for CPOE too expensive for one institution
- Integration of nursing care plans and institutional workflow into guideline model
- Clinical context specification



Roberto A. Rocha, MD, PhD

Senior Medical Informaticist, Intermountain Health Care Assistant Professor, University of Utah roberto.rocha@ihc.com

- Alignment with standards organizations

Problem Focus: Designing and specifying the standardsbased information models required to mediate the encoding and deployment of guideline content

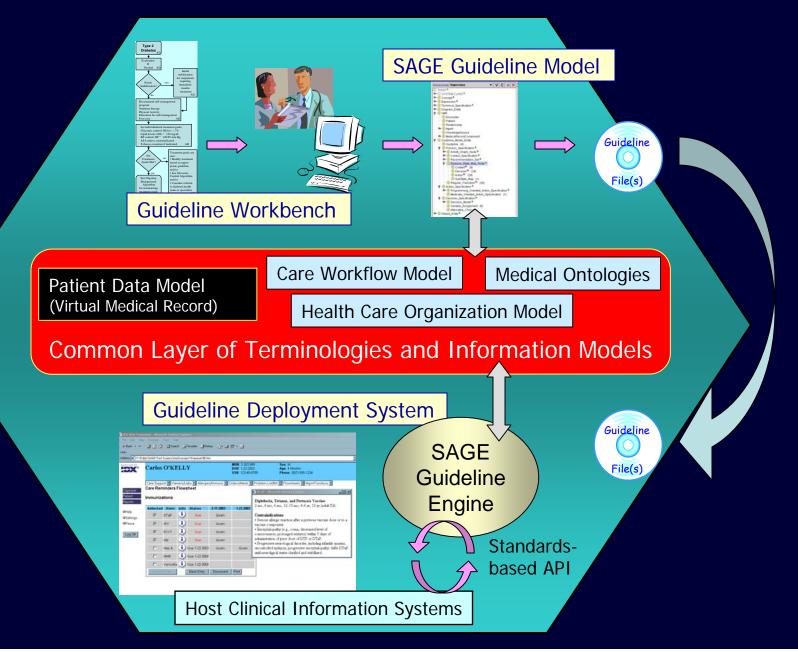


Information models

 Interoperability with: –EMR

- Virtual Medical Record (VMR)
- -Hosting CIS
 - Host System Services (HSS)

Overview of the SAGE Infrastructure



Assumption

Sharable, executable guidelines...
 All patient data referenced in a guideline <u>MUST</u> be defined by a base information model which is coupled to standard terminologies

 VMR is a standard layer that enables interoperability between different systems (models)

Adapted from Harold Solbrig

P P

SAGE VMR

- Set of broad classes of clinical information → generic information model
 - Classes that a decision support system would need to read and write data to/from an electronic patient record
 - Model designed to be implementation independent, but with sufficient expressiveness to allow guideline execution

SAGE VMR Strategy

- Identify classes and sets of attributes from standard reference models
 - Classes from artifacts of the HL7
 Reference Information Model (RIM)
 - Attributes needed for decision support are selected
 - Use more general RIM artifacts if no specific ones are available
 - Data models from other systems
- Keep the VMR as simple as is practical

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Reconcile with RIM

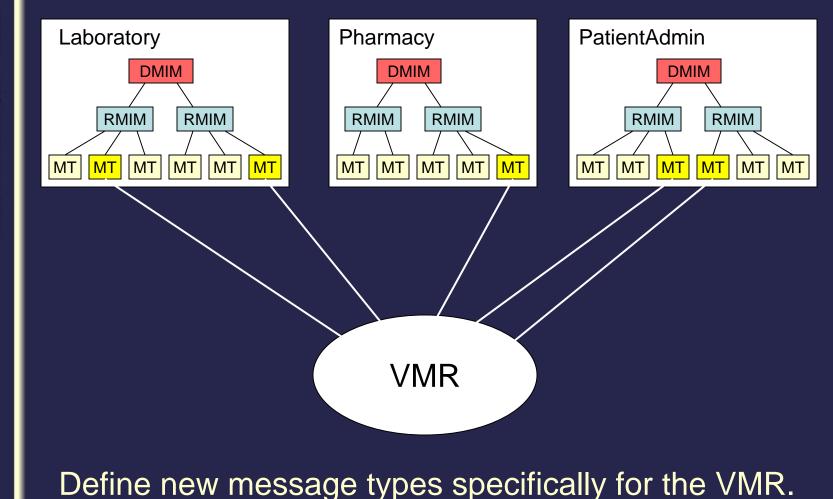
- Three approaches:
 - 1. Use existing v3 messages
 - 2. Create VMR specific v3 messages based on existing DMIMS/RMIMs
 - 3. Create VMR DMIM

Proposed Approach

• #2 - VMR specific messages based on existing DMIMs/RMIMs

- Define guideline information needs in terms of existing, higher-level v3 artifacts.
 - Estimate ³⁄₄ already exist
- Propose Message Types based on VMR needs (focused scope)
 - Create all of the HMDs and MTs

VMR Specific Messages



VMR Specific Messages

• Pros:

- Leverage existing higher-level models
- Leverage efforts of other TCs and SIGs
- Messages tailored to VMR needs
- Con:
 - Dependent on other TCs and SIGs

VMR: Current SAGE Plans

- Iteratively:
 - Create implementation (4 guidelines)
 - Refine model based on gathered experience (supporting documentation)
 - Reconcile with existing/new R/DMIMs
- Open collaboration with interested parties
 - Formalize within HL7 (SIGs and TCs)

Detailed Clinical Models

- Created by restricting aspects of the VMR classes
 - Representation of concepts from clinical guidelines
 - Common model of information that implementers will map to their local data representations
- "Clinical Expression Models" (CEMs)

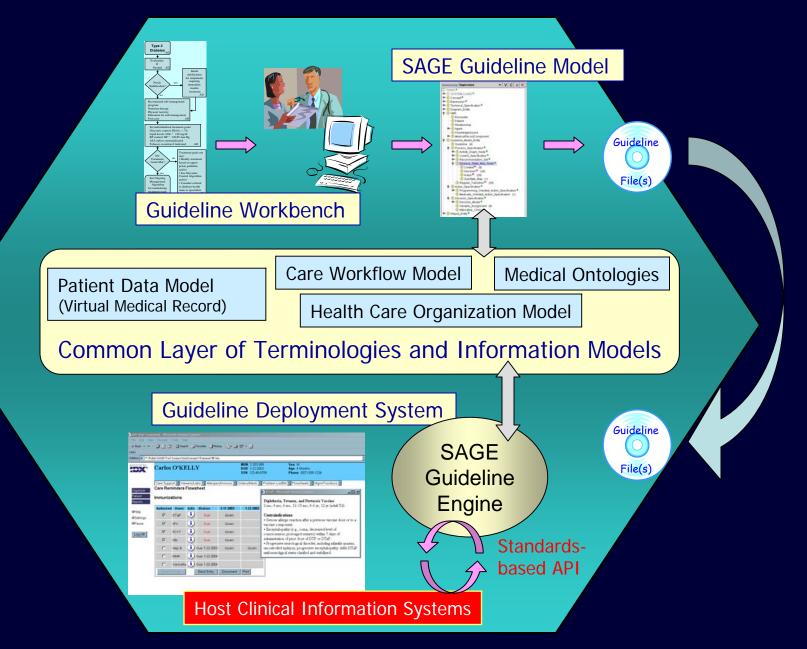
CEM Example

<cem vmrClass="Observation"> <restrict> <field>code.code</field> <value>271649006</field> <!--"Systolic Blood Pressure"--> </restrict> <restrict> <field>code.codeSystemName</field> <value>SNOMED-CT</value> </restrict> <restrict> <field>value.unit</field> <value>mmHg</value> </restrict> </cem>

CEM: Current SAGE Plans

- Iteratively:
 - Create necessary CEMs for each implementation (4 guidelines)
- Close collaboration with HL7's VMR and Template projects
 - Propose a method for creating and sharing detailed clinical models

Overview of the SAGE Infrastructure



Host System Services

• Services provided by a clinical information system ("host") to a guideline execution environment

 These services complement and interoperate with those provided by the guideline execution environment

Identified HSS

- Order an action or a service
- Route a message
- Schedule an event
- Collect data from a person

- Access (retrieval) of clinical data
- Store clinical data
- Create relationships to patient
- CIS event publishing

HSS Scope

How far do HSSs go?

e.g. For an Alert Service do we:
specify a level of priority?
specify a delivery time range?
specify a delivery modality?
specify message formatting?

e.g. put the text "critical" in bold.

Mapping to "guideline-defined activities"

HSS: Current SAGE Plans

- Iteratively:
 - Define services for next guideline implementations
 - EHR initiative
 - Implement the APIs
- Open collaboration with interested parties
 - Formalize service definitions within HL7 (SIGs and TCs)
 - Provide reference implementations?



Tony Weida, PhD

- Director, Emerging Applications
- Apelon, Inc.
- weida@apelon.com

✤ Integration of standard medical terminologies

Problem Focus: Specifying and automating the integration of controlled medical terminologies in guideline modeling and guideline deployment

Apelon

- Products
 - Terminology Development Environment
 - Distributed Terminology System
 - Concept Based Indexing and Retrieval
 - TermWorks Web Services
- Services
 - Terminology development, integration and applications

Terminology-powered Guidelines

- Make guidelines easier to
 - Author
 - Explain and understand
 - Publish and retrieve
 - Customize
 - Localize
 - Execute

Apelon's SAGE Contributions

- Modeling
 - Terminology plug-in
 - Guideline registry
 - Concept expressions
- Execution
 - Terminology server
 - CTS specification
- Further directions ...



Terminology services

 <u>– Browse, search and inspect concepts</u>

- Standards: SNOMED, LOINC
- Emerging terminologies: NDF-RT
- Extensions proposed by SAGE
- Map selected concepts to Protégé slots

Terminology services

 <u>– Browse, search and inspect concepts</u>

- Standards: SNOMED, LOINC
- Emerging terminologies: NDF-RT
- Extensions proposed by SAGE
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Protégé

Terminology services

Browse, search and inspect concepts
Standards: SNOMED, LOINC
Emerging terminologies: NDF-RT
Extensions proposed by SAGE

- Map selected concepts to Protégé slots



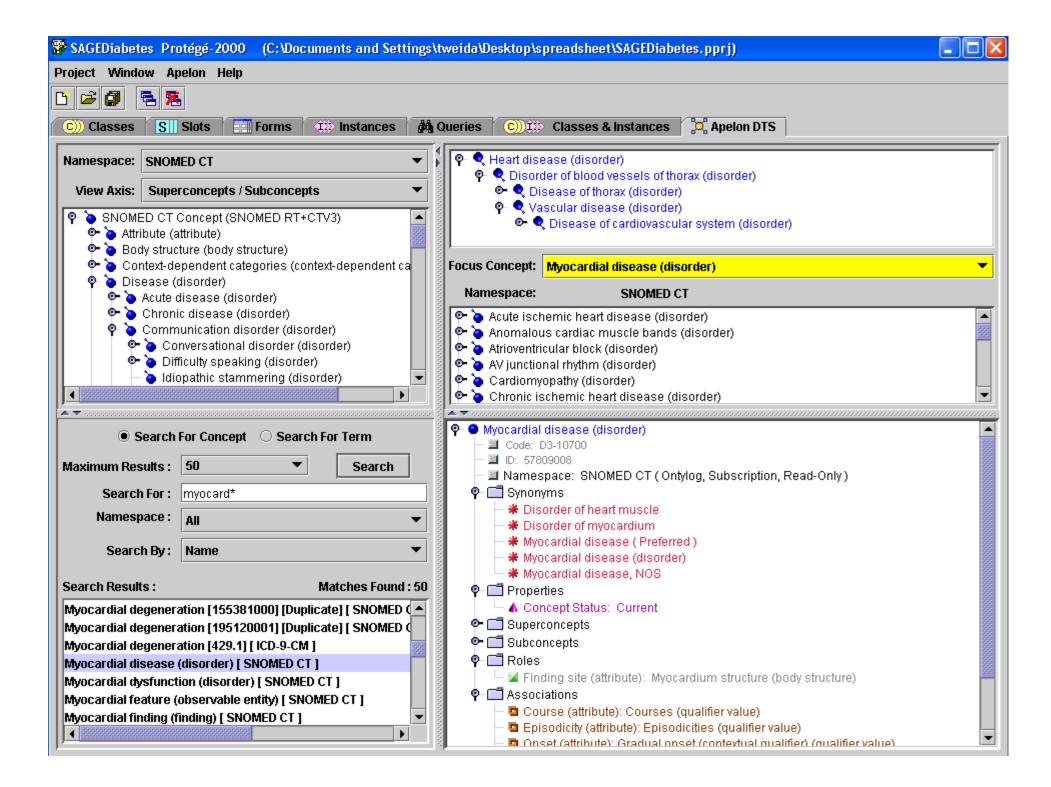
 Terminology services – Browse, search and inspect concepts • Standards: SNOMED, LOINC Emerging terminologies: NDF-RT Extensions proposed by SAGE Map selected concepts to Protégé slots DTS Protégé **DTS Server** plug-in

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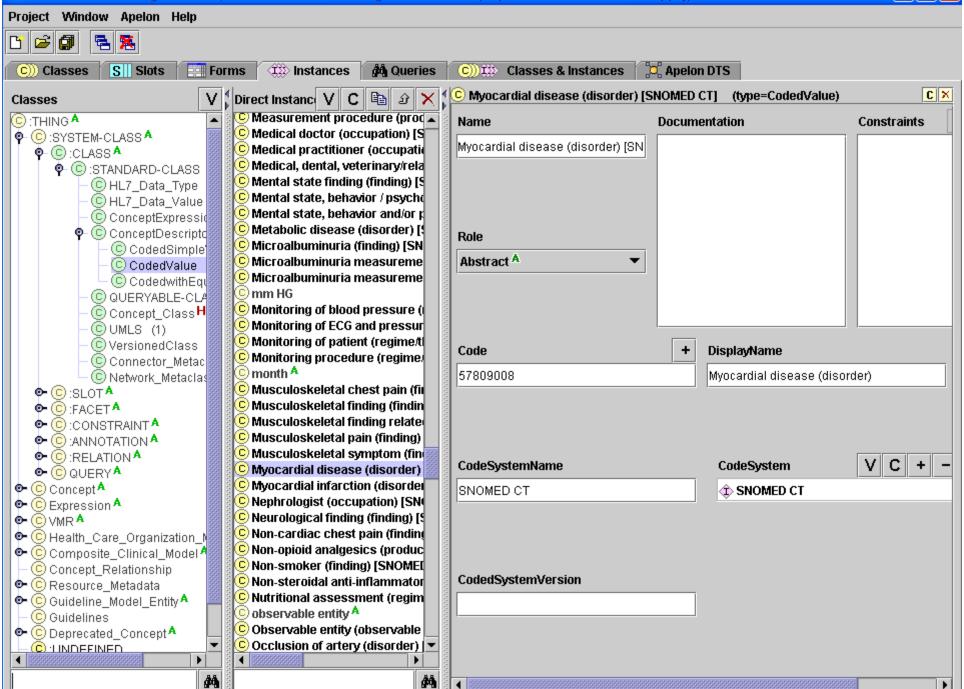
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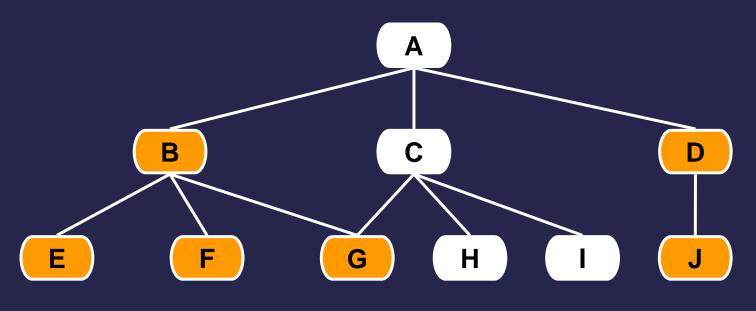




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Concept Expressions

- Arbitrary subsets of taxonomies
 Defined with logical operators
- Novel taxonomic interpretation



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Expression Editor

🗑 Modify Concept Expression						
Concept: Customized Heart Disease [Local Namespace]						
Concept Expression						
AND Heart disease (disorder) [SNOMED CT]						
P ¬ NOT						
Sudden cardiac death (disorder) [SNOMED CT]						
Infectious disease of heart (disorder) [SNOMED CT]						
	_					
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Apply Close						

Guideline Registry

Goals

- Collaborative development
- Sharing and reuse
- Lifecycle management
- Standards-based
- Terminological metadata



Registry Architecture



Registry Architecture

Guideline Registry Client

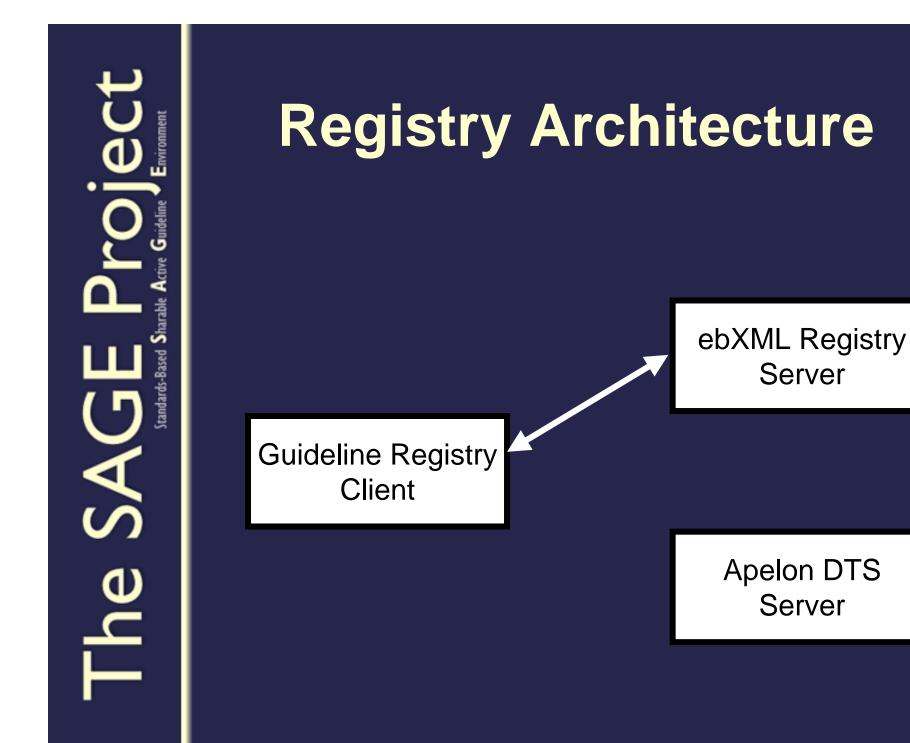
Registry Architecture

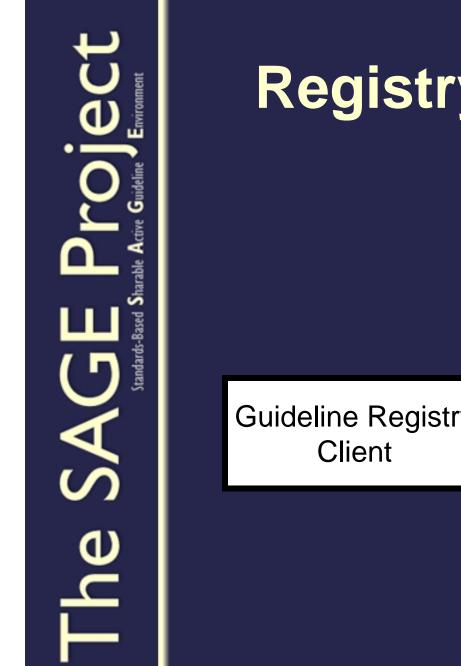
Guideline Registry Client ebXML Registry Server Ð

Registry Architecture

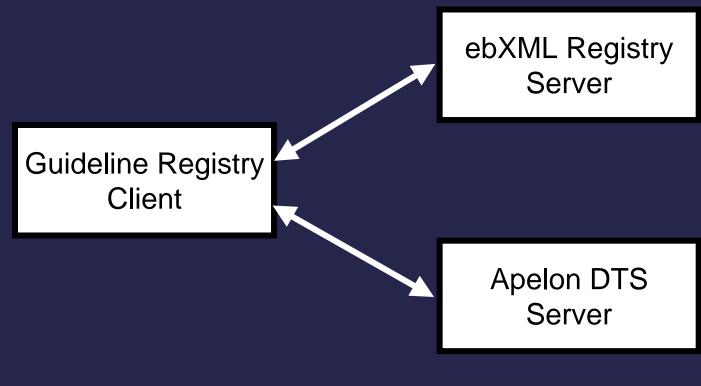
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> Apelon DTS Server



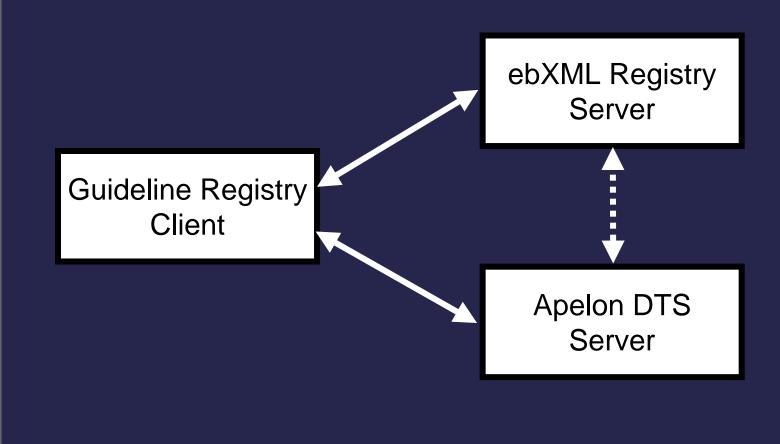


Registry Architecture





Registry Architecture



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Guideline Registry Client

🇁 Apelon Guideline Registry Browser - Robert Anthony Weida 🛛 📃 🗖 🔀								
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Runtime Services

- Hosted DTS Server
- CTS specification

Further Apelon Directions

- Modeling
 - Terminology extensions
 - Concept expressions
 - Local concept classification with reference to standard terminologies
 - -CEMs
- Execution
 - Concept expression support
 - CTS interface prototype

