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

21 December 2005
Hello....

• Robert Abarbanel, MD, PhD
• Jim McClay, MD
• Craig Parker, MD, MS
• Guy Mansfield, PhD
• David Berg
Agenda

1. SAGE mission and goals
2. Technical details
   - Guideline model
   - Execution engine
   - Interfaces
3. Accomplishments
4. 2006 Plan
5. *Azyxxi Collaboration*
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

- Partners in the project are:
  - IDX Systems Inc.
  - Apelon, Inc.
  - Intermountain Healthcare (IHC)
  - Mayo Clinic
  - Stanford Medical Informatics (SMI)
  - University of Nebraska Medical Center (UNMC)

- Funded in part by: NIST Advanced Technology Program

Cooperative Agreement Number 70NANB1H3049

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Sponsored by the Department of Health and Human Services (DHHS), the purpose of the conference was to develop a consensus for a national action agenda to guide the further development of NHII.

Safety and Quality Track Recommendation:

“Create central resources and processes that serve as a library of nationally vetted clinical guidelines and knowledge sources in standardized executable format using a standard guideline authoring tool consistent with the needs of patient safety and quality.”
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.

Type 2 Diabetes Evaluation

If Needed

Needs Stabilization?

- yes
- no

Recommend self-management program:
- Nutrition therapy
- Physical Activity
- Education for self-management
- Foot care

Set individualized treatment goals:
- Glycemic control: HbA1c < 7%
- Lipid levels: LDL < 130 mg/dl
- BP control: BP < 130/85 mm Hg
- ASA unless contraindicated
- Tobacco cessation if indicated

Treatment goals not met:
- Modify treatment based on appropriate guideline and/or
- See Glycemic Control Algorithm and/or
- Consider referral to diabetes health team or specialists

Are Treatment Goals Met?

- yes
- no

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

- Clinical content (criteria, actions)
- Patient status and eligibility
- Decision logic
- Clinical sequencing and workflow
- Guideline goals and intentions
- Guideline evidence and references

Type 2 Diabetes Guideline Flow Diagram, courtesy of Institute for Clinical Systems Improvement (ICSI)
Interoperable Guideline Workbench
A software tool for authoring, editing, encoding, and maintaining guidelines in the format of the Guideline Model

Type 2 Diabetes

Evaluation If Needed

Needs Stabilization?

yes

Initial stabilization for outpatients requiring immediate insulin treatment

no

Recommend self-management program:
- Nutrition therapy
- Physical Activity
- Education for self-management
- Foot care

Set individualized treatment goals:
- Glycemic control: HbA1c < 7%
- Lipid levels: LDL < 130 mg/dl
- BP control: BP < 130/85 mm Hg
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Are Treatment Goals Met?

yes

See Ongoing Management Algorithm for maintaining treatment goals and complication prevention

no

Treatment goals not met:
- Modify treatment based on appropriate guideline and/or
- See Glycemic Control Algorithm and/or
- Consider referral to diabetes health team or specialists

Guideline File(s)

- 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
Specification of Standards

A common “layer” of terminology and information models that mediates guideline encoding and execution.

- Adoption of standard terminologies (e.g., LOINC, SNOMED CT)
- Specification of standard information models (e.g., for patient data).
- Specification of a standard for guideline knowledge representation.
- Employment of a standard expression language for guideline logic.
<table>
<thead>
<tr>
<th>Guideline</th>
<th>Clinical Domain</th>
</tr>
</thead>
<tbody>
<tr>
<td>Immunizations</td>
<td>Routine health maintenance, in both outpatient and inpatient settings.</td>
</tr>
<tr>
<td>Diabetes Management</td>
<td>Chronic disease monitoring and treatment.</td>
</tr>
<tr>
<td></td>
<td>Acute exacerbation of chronic disease.</td>
</tr>
<tr>
<td></td>
<td>Chronic disease as a comorbidity.</td>
</tr>
<tr>
<td>Community Acquired Pneumonia</td>
<td>Emergency room evaluation and diagnosis.</td>
</tr>
<tr>
<td></td>
<td>Outpatient treatment of acute disease.</td>
</tr>
<tr>
<td></td>
<td>Inpatient and ICU treatment of acute disease.</td>
</tr>
<tr>
<td></td>
<td>Follow-up of acute disease.</td>
</tr>
</tbody>
</table>
Sample Activity Graph: Diabetes Primary Care
**Context Nodes** organize and specify the relationship to workflow. They record:
- Who is involved
- Where the session occurs
- What resources are required
  - Clinical
  - Information processing
- What triggers or begins session
SAGE Guideline Representation: Decision Nodes

**When should lipid labs be ordered?**

**Decision Nodes** provide support for making choices:
- Specification of alternatives
- Logic used to evaluate choices
- Query data from patient record
- Can change the clinical workflow
**Action Nodes** define activity to be accomplished by clinical information system:
- User interaction and query
- Order sets
- Referrals
- Appointments and scheduling
- Goal setting
- Documentation and recording
- Messaging, print and paging
- Sub-guidelines

---

**Order lipid Labs 24 Months From last labs**

---

**Order lipid Labs now**

---

**Order lipid labs for 6 months from last labs**

---

**Order lipid labs for 3 months from last labs**

---

**Order lipid labs 12 months from last labs**

---

**Order lipid labs 24 months from last labs**

---

**When should lipid labs be ordered?**

---

**Adult Diabetes Patient**
Guideline content will be executed by the SAGE Guideline Engine, interacting with the CIS via standards-based interfaces.
SAGE Guideline
Execution Architecture

- **Encoded Guideline**
- **SAGE Execution Engine**
  - **Event Listener**
  - **Event Notifications**
  - **VMR Service calls**
  - **Action Service calls**
  - **Terminology Server**
  - **Terminology Functions**

- **VMR Services Action Interface**
- **Clinical Information System**
  - **CIS-specific implementation of services**
  - **Standards-based I/F based on web services**

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SAGE Guideline
Execution Architecture

Encoded Guideline

Terminology Functions

SAGE Execution Engine

Event Listener

VMR Service calls

Action Service calls

Event Notifications

VMR Services Action Interface

{ }

Clinical Information System

CIS-specific implementation of services

Standards-based I/F based on web services

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VMR Services Interface

- In the guideline model, patient data concepts are represented using VMR classes
- Queries for patient data are represented using standard VMR-based methods
- Patient data queries are processed via VMR Service web service
- Generic methods are “mapped” to CIS-specific methods
- Data objects returned to SAGE Engine are built from HL7 data types

Example: getObservations [Creat]

**Standards-Based**

- VMR-based query for lab data

**CIS-Specific**

- Local CIS method for: returning Creat lab values

**Observation object(s) returned**

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Implementation Architecture at Mayo

SAGE Engine
- JBoss, EJB Server
- Webservices

http SOAP

CIS Services
- Tomcat, Servlet Engine
- Webservices

NT (IDXSRV01)

Queries & Actions

CTS

DTS Remote (Apelone)

HP Non-Stop ($PMSG)

Carecast
- Tomcat, Servlet Engine

Events

Carecast UI Queries

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Seattle Implementation Architecture

SAGE Engine
  JBoss, EJB Server
  Webservices

CIS Server
  Tomcat, Servlet Engine
  Webservices

DTS Local

HP Non-Stop
  (SPMAD)

Events
  Carecast UI Queries

Carecast
  Tomcat, Servlet Engine

Queries & Actions

http SOAP

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The Virtual Medical record

• Protégé classes “define” services through which SAGE communicates with the CIS

• Attributes of these vMR classes control the ways requests are modeled in the guideline and, thus, the way that calls to the CIS are composed.
SAGE requests Problems

Problem [] getProblems

( CISContext cisContext, String medRecordNum, ProblemFilter problemFilter )
SAGE requests Problems

Problem [] getProblems

(CISContext cisContext, String medRecordNum, ProblemFilter problemFilter)

user, passwd, sessionID
SAGE requests Problems

Problem []

getProblems

(CISContext cisContext, String medRecordNum, ProblemFilter problemFilter)
SAGE requests Problems

Problem [] getProblems

( CISContext cisContext,
  String medRecordNum,
  ProblemFilter problemFilter
)

user, passwd, sessionID

patient

codes
SAGE gets Observations

Observation [] getObservations(
    CISContext cisContext, String medRecordNum, ObservationFilter observationFilter
)
SAGE gets Observations

Observation [] getObservations(
    CISContext cisContext, String medRecordNum,
    ObservationFilter observationFilter
)
The Problem Class

```java
class Problem {
    ConceptValue code;
    TimeInterval effectiveTime;
    String status;
    ConceptValue subject;
    String[] encounterIds;
}
```
ConceptValue

{ String conceptID
  String name
  String extra
  String namespace
  String version
  String type
  boolean subsumption }
A Recommendation Set for Neonatal Immunization orders…

Newborn, inpatient → Compute Immunization Decisions → Hep B dose due? → Order Process
A Recommendation Set for Neonatal immunization orders...

Context

1. Newborn, inpatient
2. Compute Immunization Decisions
3. Hep B dose due?
4. Order Process
A Recommendation Set for Neonatal immunization orders…

Context: Newborn, inpatient
Action: Compute Immunization Decisions → Hep B dose due? → Order Process
A Recommendation Set for Neonatal immunization orders...

Newborn, inpatient → Compute Immunization Decisions → Hep B dose due? → Order Process

Context → Action → Decision
A Recommendation Set for Neonatal immunization orders…

Newborn, inpatient → Compute Immunization Decisions → Hep B dose due? → Order Process

Context → Action → Decision
Newborn, inpatient → Compute Immunization Decisions → Hep B dose due? → Order Process

Decision Map for Immunizations Due → DT due and can be given → DT: Deferred

DT: indicated and can be given → DT: not due or contraindicated
Immunization Decisions: DTaP

- **DTaP Deferred**
- **DTaP Indicated and can be given**
- **DTaP Not due or contraindicated**
How does SAGE process criteria?

- Obtain CIS data (e.g., date of birth)
- Convert Units as required (e.g., lb to grams)
- Use evaluator for expressions
- Compute boolean (true or false)
- Examples:
  - Age < 7 days
  - Counting Previous Vaccinations
  - Mother’s HBsAG status
  - Consent for Immunization
SAGE Execution

- Architecture
- Semantics of the guideline model
- Event driven interpretation
- Evaluation of criteria
- Example of decision making
- SAGE Actions
Decision Logic

Hep B vaccination is due.

Neonate w/ HepB positive mother
We have 3 possibilities.

- Hep B
- Hib
- MMR

- Hep immunization not due or contraindicated
- Hep B deferred
- Hep B immunization due
We have 3 possibilities.
We have 3 possibilities.

- Hep B
- Hib
- MMR

- Hep immunization not due or contraindicated
  - Hep B deferred
  - Hep B immunization due
We have 3 possibilities.

- **Hep B**
- **Hib**
- **MMR**

- Hep immunization not due or contraindicated
- Hep B deferred
- Hep B immunization due
Rule Out: Any 1 of these

- Hep B immunization due
- Contraindication to Hep B vaccination
- age >= 19 years
- corrected patient acutely ill by judgement of care provider
Rule Out: Any 1 of these

- Hep B immunization due

- Contraindiation to Hep B vaccination
- age >= 19 years
- corrected patient acutely ill by judgement of care provider

Anaphylaxis
Rule Out: Any 1 of these

- Hep B immunization due

- Contraindication to Hep B vaccination
- Age ≥ 19 years
- Corrected patient acutely ill by judgement of care provider

Observation today of SNOMED-CT 39104002 = Illness
Rule In, ANY ONE OF:

- Hep B immunization due

- no previous hep B vaccination and age >= 1 months
- 1 previous Hep B dose, 4 weeks after first dose
- 2 Hep B doses already, 8 weeks after last dose, 16 weeks after 1st dose
- Birth dose given with early delivery of 3rd dose
- 1 previous Hep B dose, age >= 1 months, mother Hep B+
- age<7 days, previous hep B vaccination
| Rule In, ANY ONE OF: | | |
|----------------------|------------------|
|                      | Hep B immunization due |

- no previous hep B vaccination and age $\geq 1$ months: 3
- 1 previous Hep B dose, 4 weeks after first dose: 2
- 2 Hep B doses already, 8 weeks after last dose, 16 weeks after 1st dose: 3
- Birth dose given with early delivery of 3rd dose: 4
- 1 previous Hep B dose, age $\geq 1$ months, mother Hep B+: 3
- age $\leq 7$ days, previous hep B vaccination: 3
Rule In, ANY ONE OF:

- Hep B immunization due

All N-ary criteria

- no previous hep B vaccination and age >= 1 months
- 1 previous Hep B dose, 4 weeks after first dose
- 2 Hep B doses already, 8 weeks after last dose, 16 weeks after 1st dose
- Birth dose given with early delivery of 3rd dose
- 1 previous Hep B dose, age >= 1 months, mother Hep B+
- age<7 days, previous hep B vaccination
Rule In, ANY ONE OF:

- Hep B immunization due

All N-ary criteria

- no previous hep B vaccination and age ≥ 24 months 2
- 1 previous Hep B dose, 4 weeks after first dose 3
- 2 Hep B doses already, 8 weeks after last dose or 16 weeks after 1st dose 3
- Birth dose given with early delivery of 3rd dose 4
- 1 previous Hep B dose, age ≥ 1 month, another Hep B+ 3
- age < 7 days, previous hep B vaccination 3

All of these must be true (and)
Guideline content will be executed by the SAGE Guideline Engine, interacting with the CIS via standards-based interfaces.
SAGE Guideline Execution: Neonatal Orders for Immunization

- Detect newborn admission
- Detect updates to newborn’s EMR

Guideline content will be executed by the SAGE Guideline Engine, interacting with the CIS via standards-based interfaces.
SAGE Guideline Execution: Neonatal Orders for Immunization

Guideline content will be executed by the SAGE Guideline Engine, interacting with the CIS via standards-based interfaces.

- Remind nurse to check immunization HX
- Remind nurse to check contraindications
- Remind nurse to obtain consent
- Create recommended (pending) immunization orders in CIS
- Notify physician of new pending orders

Local Clinical Information System

Queries

EMR Data

Patient Record

Execution System

Order Entry

Actions

Events
Neonate w/ HepB positive mother

Not So Simple

1. **Triggering event:** SAGE engine detects newborn admission.
2. **“Automatic enrollment”:** SAGE enrolls new patient.
3. **Context node:** Obtain and check patient age.
4. **Decision node:** Compute vaccinations that are due.
   a. **Evaluate** MMR and HepB.
   b. Query child’s record re: # of past immunizations.
   c. Mother’s HBsAG status (CEM)
5. **CEM-based query:** Has consent been obtained?
6. **CEM-based query:** Obtain child’s weight.
7. **Concept Expression:** e.g., “progressive encephalopathy”
8. **SAGE-initiated action:** Non-active orders sent to CIS.
9. **SAGE-initiated action:** Inbox.
Concept Expressions

- DTaP should be deferred if following presence criterion evaluates to true
Progressive Encephalopathy is encoded as
Boolean using SNOMED-CT codes

Progressive Encephalopathy

or

and

or

Progressive neurologic finding
12321232

Developmental delay
248290002

Encephalopathy
81308009

Tuberous sclerosis syndrome
7199000

Lenox-Gastaut syndrome
234418006
Guideline Execution:

SAGE listens for and detects context-specific events

[Diagram showing a step in a guideline with options for Primary care clinic check-in, Clinical Context, Precondition, Automation Mode, Transition Restriction, and Subguideline]
Guideline Execution:

SAGE executes encoded decision logic
Guideline Execution:

SAGE executes encoded decision logic

SAGE will query the patient EMR as necessary, and evaluate all decision criteria.
SAGE communicates actions to the CIS

Guideline Execution:

- HBA1C out of goal, due now, order
  - Order HbA1c
  - Inform PCP HbA1c is out of goal and due
SAGE guideline execution has generated patient-specific notifications to care providers.
### Subject: If HbA1C is out of goal range, notify physician via inbox.

**Message:** This patient’s HbA1C is out of goal range.
SAGE guideline execution has caused 7 pending orders to be created in the CIS.
SAGE guideline execution can populate a patient-specific clinical care “flowsheet” with guideline recommendations, goals, and reference information.
SAGE guideline execution can support display of guideline rationale, accompanied by patient-specific clinical logic.
Accomplishments

We have:

- Shown that clinical guidelines can be encoded in a standards-based, sharable, computable format.
- Demonstrated the capability to represent complex guideline content and logic for both acute and chronic care domains.
- Used standard information models and terminologies to support interoperable transfer of medical knowledge.
- Addressed interoperability goals via:
  - A standards-based guideline model
  - A VMR-based interface to CIS
  - Standard web services to access EMR data
  - Standards based access to terminology services
Partial 2006 Plan

- Interoperability
  - Demonstrate interoperable transfer of medical knowledge
  - Tools to support deployment (mapping, binding, …)

- Standards
  - Tune vmr to emerging standards
  - Order Set Standard at HL7

- Demonstrations
  - Complete all three exemplars
  - ONCHIT and NIST
  - HIMSS
  - Surveillance study (Diabetes and Immunization)

- Final documentation
  - Reference CIS
  - Visible KB
  - Several publications
Azyxxi Collaboration

- **Demonstrate** interoperability: SAGE Engine runs w/ Azyxxi
- **Audience**: NIST, ONCHIT?, others?
- **Time line**: feasibility by 15 Feb, complete by 15 June
- **Guideline**: TBD
- **Steps**: agreement, plan schedule and efforts, interface experiments, plan CIS side user experience, toy example, “real” possibly new guideline, plan for, announce, and execute demonstration