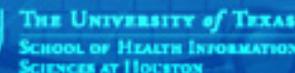
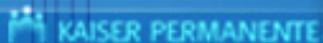


Clinical Decision Support Consortium Technical Expert Panel

Blackford Middleton, MD, MPH, MSc

February 2 - 3, 2011



Agenda

- Status Update (15 min)
 - Progress and Accomplishments
 - Challenges
 - Clinical Decision Support Consortium (CDSC) Findings and Lessons Learned
 - Next Steps
 - Questions for the Technical Expert Panel (TEP)
- Discussion (5 min)

ACCOMPLISHMENTS

Task 1. Program Management

- Prepared Option Year Two (OY2) project ideas.
- Prepared first draft of OY2 project plan.
- Prepared preliminary budget plan for OY2.



ACCOMPLISHMENTS

Task 2. Implementation

Subtask 2.1 Demonstration of CDS service at two organizations

- Completed the demonstration in Longitudinal Medical Record (LMR) and submitted completion letter to Agency of Healthcare Research and Quality (AHRQ).
- Knowledge Management (KM) team moved to production the updated rules required for content integration with Regenstrief Institute (RI).
- Reviewed with RI how to use eRoom to look at the rules and how to test whether rules gave the expected output given the input.
- Service Sharing Agreement (V2) was sent to RI on 1/4/2011.
- RI Demo team:
 - Started calling the Enterprise Clinical Rules Service (ECRS) with some test patient Continuity of Care Documents (CCDs).
 - Continued work on obtaining a certificate from a trusted certificate authority before they can go live.

ACCOMPLISHMENTS

Task 2. Implementation

Subtask 2.2 Other implementation projects

- Knowledge Translation and Specification (KTS) team:
 - Made changes to the knowledge representation schema to support the new requirements.
 - Started the enhancing work on the authoring tool.
 - Presented a the KTS editing tool for Content Governance Committee (CGC) and Key User(s).
 - Created mappings between the semi-structured schema, level 2 (L2) and Guideline Elements Model (GEM) and created an Extensible Stylesheet Language (XSL) script to convert GEM guidelines into CDSC L2 recommendations.
 - Completed research on order sets specifications and defined the requirements for modeling order sets in the structured recommendations.
 - Started research on the infobutton schema.

ACCOMPLISHMENTS

Task 2. Implementation

Subtask 2.2 Other implementation projects (cont.)

- CGC updated the policy to allow submission by non-consortium members.
- Mid-Valley Independent Physicians Association (MVIPA), KP (Kaiser Permanente), Partners Healthcare System (PHS), and the Department of Veterans Affairs (VA) have submitted outpatient, health maintenance and/or chronic disease rules and reminders to the eRoom for the rule prioritization effort.
- CDS Dashboards team prepared draft of report specification and submitted to Research Management Team (RMT) for review.

ACCOMPLISHMENTS

Task 3. Evaluation

Subtask 3.1 Evaluation Plan EVA 3.1 (ongoing activities)

Evaluation team:

- Conducted preliminary reviews of four data sources: dashboard utilization, reminder performance, ECRS performance and CCD factory performance. Data was adequate in each case.
- Continued to act in a consulting role to other teams regarding their evaluation plans.

Subtask 3.3 Conduct evaluation activities as specified in the final Evaluation Plan

- Knowledge Management Lifecycle Assessment (KMLA) team:
 - Completed CDS Content Vendor report.
 - Completed PHS site visit.

ACCOMPLISHMENTS

Task 3. Evaluation

Subtask 3.3 Conduct evaluation activities as specified in the final Evaluation Plan

- KM Portal team:
 - Completed Initial Summary of eRoom evaluation.
 - Received 100% of responses from Portal User Assessment tool.
- CDS Services team created evaluation database and loaded data.
- CDS Demonstration team:
 - Began extracting and analyzing the PHS trial data, in many cases re-using data and methods from the CDS Dashboards.
 - Early data suggests that the services are working well and that performance on the associated quality measures is good.
- CDS Dashboards team worked on the site assessment for the Dashboard Development Guide.

CDSC Usage Summary Statistics to Date

CDSC Portal Stats					
Current Published Assets	December, 2010		Since February, 2010		Most Viewed Content
	Unique IP Addresses	Number of Visits	Unique IP Addresses	Number of Visits	
35	55	40	351	558	CDSC-Hypertension-L4-PHS-2010-L4EXP-2.0-090221fe800231a6.pdf

CDS Services Statistics 10/27/10 - 11/09/10	
Total calls:	49,160
Average calls per day:	3,511
Average performance:*	2,845

*Average performance equals the average successful calls per day.

Statistics provided are raw data only. No analysis is provided, including comparison with previous data.

CDS Dashboards Total Usage Summary Statistics to 1/10/2011	
Provider View:	164 times by 85 unique people 56 people used it once 12 people used it twice 8 people used it three times 9 people used it four or more times
Designer View:	5 times by 3 unique people 2 people used it once 1 person used it three times

ACCOMPLISHMENTS

Task 4. Meeting with Technical Expert Panel

Subtask 4.1 In-Person TEP Meeting

RMT prepared TEP in – person meeting materials.

Task 5. Dissemination

Subtask 5.3 Carry out dissemination activities as described in final Dissemination Plan

- CDSC and RAND/Brigham and Women’s Hospital (BWH) Advanced CDS (ACDS) project team work together to add the ACDS artifacts to the CDSC KM Portal.
- KTS team received the reviewers’ comment for the manuscript on the multilayer model submitted to Journal of the American Medical Informatics Association (JAMIA) in May.
- The complete CDSC program was successfully demonstrated at the American Medical Informatics Association (AMIA) Annual Symposium in Washington, DC.

Challenges



CHALLENGES

Task 2. Implementation

Subtask 2.1 Demonstration of CDS Service at two organizations.

- Open legal issues around Service Agreement are being worked on by PHS and RI and their respective legal counsels.
- The RI CareWeb is undergoing major improvement work that is beyond the scope of this CDSC project; however it impacts this CDSC project.
- ECRS is undergoing major updates and version change.
- RI has to obtain a digital certificate from an official third-party certificate granting authority. They are currently testing with a self-signed certificate.
- PHS and RI initially interpreted the CCD standard differently.
- Open legal issues around Portal Agreement for the ACDS and Structured Clinical Recommendations (SCR) artifacts to be published to the CDSC KM Portal.

CHALLENGES

Task 3. Evaluation

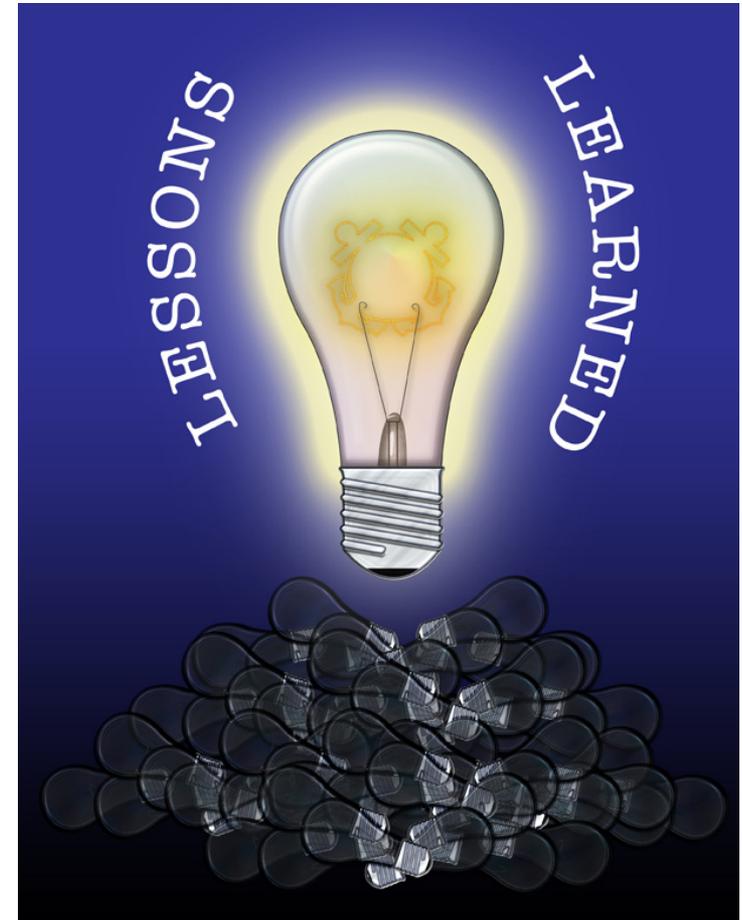
Subtask 3.1 and 3.2 Evaluation Plan

Evaluation team has a rich variety of data sources available, and is determining how to correlate and integrate all of the data sources to maximize our learning.

Subtask 3.3 Conduct Evaluation Activities

- KMLA team was wondering if developers tell the truth during interview during PHS site visit.
- New CareWeb application that contains the SOA-based CDS is still in testing phase.
- The PHS LMR is experiencing performance issues, and the LMR team has disabled the CDS Services, so data is not currently being collected. The LMR team plans to re-enable the services by mid-January.

CDSC Findings, Lessons, and Questions



CDSC Findings and Lessons Learned

- KM discovered there is a significant amount of preparation work that the external CDSC members must do prior to integrating with the CDSC content. It is critical that KM be included in the discussions with the CDSC members early on to get this work started.
- Evaluation team discovered that data from the CDS Dashboards can be reused for the demonstration analysis.
- The legal road for a general service to provide CDS by an external entity (not just access to the rules) has not been paved previously. The legal agreement between PHS and RI therefore has been challenging. Liability and indemnification remain issues, especially in the wake of the recent AMIA workshops and papers denouncing “hold harmless clauses” in software and service contracts.
- Demonstration team has found that legal issues can be time consuming and require considerable attention. They can rival technical issues in complexity.
- KMLA team has found that the modified rapid assessment process works for clinical knowledge vendors. Clinical knowledge vendors are much better prepared, in terms of informatics skills and knowledge than we had anticipated.

Next Steps



NEXT STEPS

Task 1. Program Management

Subtask 1.5 *Submit monthly reports to AHRQ (ongoing)*

Subtask 1.6 *Submitted monthly meeting agenda to AHRQ (ongoing)*

Subtask 1.7 *Submitted conference call summary and action items one week after conference call (ongoing)*

NEXT STEPS

Task 2. Implementation

Subtask 2.1 Demonstration of CDS service at two organizations

- Complete the Service Sharing Agreement negotiations with RI and get it signed by all parties.
- Continue discussing the legal considerations related to adding ACDS artifacts on the CDSC KM Portal.
- Test ECRS2 with LMR.
- Complete integration testing with RI and ECRS2.
- Move ECRS2 into production (target date: January 31, 2011).
- RI demonstration team will continue testing and configuration of the various components.
- RI will finish informal testing and begin formal testing.

NEXT STEPS

Task 2. Implementation

Subtask 2.2 Other implementation projects

- CDS Services team will create technical documents for consuming site.
- KTS team:
 - Will continue work on schema refinements to accommodate new requirements and continue the work on the editing tool. will conduct interdocument linking and automated assistance for field entry.
 - Will define an XSL transformation to render a structured guideline in an order set format.
 - Will develop draft specifications for order sets within the structured recommendation (level 3 (L3)) schema.
 - Will develop a draft model for representing order sets within the structured guideline schema (L3).

NEXT STEPS

Task 2. Implementation

Subtask 2.2 Other implementation projects (cont.)

- Dashboard team
 - Review PHS documentation of CDS Dashboards, work on Definitions and document how to define our measures.
 - Site Readiness Assessment: complete research and review of the types of questions that should be addressed when implementing a dashboard into different Electronic Health Records (EHRs).
- CGS Team:
 - Review of policies regarding rule templates, and assess how much effort will be required to normalize the list of all institutions' outpatient, health maintenance and/or chronic disease rules.
 - Confirm attendees for the face-to-face meeting on March 4-5, 2011.

NEXT STEPS

Task 3. Evaluation

Subtask 3.3 Conduct evaluation activities as specified in the final Evaluation Plan

- KMLA team:
 - Wait for transcripts to be returned to start analysis of PHS visit.
 - Work on scheduling RI site visit.
- KM Portal team:
 - Complete data analysis and Initial Summary/eRoom Evaluation.
 - Continue with data collection, analysis and evaluation for KM Portal.
- CDS Services team will continue data collection and analysis.
- CDS Demonstration team:
 - Continue demonstration and evaluation of preliminary data.
 - Finish analyzing data and write a report.
- CDS Dashboards team will prepare detailed Analysis Plan and will develop usage evaluation tools.

NEXT STEPS

Task 4. Meeting with Technical Expert Panel

Subtask 4.2 TEP In-person meeting

- Principal Investigator (PI) and Research Program Manager (RPM) will attend TEP in person meeting on February 2-3, 2011.
- RMT will submit meeting materials for the TEP meeting.
- Legal Aspects of CDS: IP & Liability
 - CDSC Knowledge Sharing Agreement – Tonya Hongsermeier.
 - CDSC Services Agreement – Lana Tsurikova.

NEXT STEPS

Task 5. Dissemination

Subtask 5.3 Carry out dissemination activities as described in final Dissemination Plan

Recommendations team will continue work on paper described:

- Health Information Technology (IT) Policy Recommendations.
- Quality Measure Developers Recommendations.
- Clinician Professional Organizations Recommendations.
- Clinical Guideline Developers Recommendations.
- Health IT Electronic Medical Records (EMR) and Knowledge Vendor Recommendations.

Other dissemination activities

- KM team will update the level 4 (L4) artifacts on the portal to reflect the rule changes that were recently moved to production.
- Demonstrations team will continue data analysis and write report.
- Evaluation team will support teams preparing publications.

NEXT STEPS

Task 6. Option Year One (OY1) Report

Subtask 6.1 Submit draft OY1 report to AHRQ Project Officer (PO)

- CDSC teams document lessons learned in monthly reports for inclusion in draft and final OY1 report.
- CDSC teams prepare evaluation reports for inclusion in draft and final OY1 report.

Subtask 6.2 Submit final OY1 report to AHRQ PO

Final OY1 report summarizes all CDSC activities, evaluation findings and lessons learned.

NEXT STEPS

Task 7. Coordination with Other AHRQ Contractors

Subtask 7.1 Coordinate with designated contractors (ongoing)

Coordinate with designated National Research Council (NRC) Domain 2 contractor for the “Support for AHRQ’s CDS Demonstration Projects” task order and other relevant AHRQ contractors with regard to disseminating contract findings and required recommendations, submitting materials for meetings or teleconferences with the TEP, and other relevant contract deliverables.

NEXT STEPS

Task 8. Ensuring High-Quality/508 Compliant Deliverables

Subtask 8.1 Develop and implement quality assurance procedures to ensure all deliverables to AHRQ are reviewed for quality control, professional writing, and copy editing (ongoing)

Subtask 8.2 Ensure 508-compliance of deliverables (ongoing)

Task 9. Compliance with the Paperwork Reduction Act

Subtask 9.1 Submit Office of Management and Budget (OMB) clearance package to AHRQ PO (if applicable)

- Develop information collection request.
- Publish a 60-day federal register notice.

Potential OY2 Plans

- Carry on Phase 2 of services implementation at PHS and RI.
- Start Phase 1 of services implementation with 1 or 2 EHR vendors.
- Refinement and generalization of the knowledge stack.
- Enhancements to the editing tool, including style sheets.
- Support and maintenance of the portal.
- Develop an approach to open the KM Portal environment to wider community of publishers, reviewers, etc.
- Refine and evaluate the CDS indicators and measures model.
- Develop editorial policies and prioritization metrics for clinical content and maintaining content in the three existing disease areas.
- Develop recommendations for the audiences specified in the contract.
- Development of new content area for CDSC services (budget permitting).

More to come!

Questions to TEP



1. What are the legal issues and liability if decision support for only part of a domain is implemented, for example for only some of the important drug-drug interactions?
2. To what extent should CDS content and systems be regulated by the Food and Drug Administration (FDA) or other government agencies?
3. Who is liable for CDS content errors or omissions? For example, if a physician orders an overdose of a drug because the default dose in the hospital's EHR is incorrect, who is liable? What if the default dose came preloaded in the EHR? Or if it's from a commercial content vendor?
4. Can the government create a safe harbor for certain CDS types (e.g. as long as your Drug-Drug Interactions (DDI) content includes at least X, you won't be liable for omissions)?

Questions to TEP (cont.)



5. In what ways might CDS interact with malpractice? Does CDS contribute to establishing the standard of care for a particular disease?
6. What should we do about logs of alerts? Do logs that show an alert was overridden increase or decrease exposure to malpractice loss?
7. Are there any specific court cases where a CDS publisher, EHR vendor or hospital was sued for errors or omissions in CDS content?

Discussion

Thank You!