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Clinical Decision Support Consortium EHR Vendors and Content Vendors

Blackford Middleton, MD, MPH, MSc
Dean Sittig, PhD
Lana Tsurikova, MSc, MA
Adam Wright, PhD

Agenda

1. Study updates (Blackford, 10 min)
2. Demo results (Adam, 10 min)
3. Recommendations summary (Dean, 10 min)
4. Legal and other challenges (Lana, 10 min)
5. Discussion (All, 50 min)

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CDS Consortium Study Updates

Blackford Middleton, MD, MPH, MSc

Introduction

Clinical Decision Support Consortium (CDSC)

- Base Year One and Two: March 2008 – June 2010
- Optional Year One: July 2010 – July 2011
- Agency for HealthCare Research and Quality (AHRQ) Contract #: 290-08-10010
- www.partners.org/cird/cdsc

Participating Organizations:

1. Partners HealthCare
2. Regenstrief Institute
3. Siemens Medical Solutions
4. Veterans Health Administration
5. Kaiser Permanente Center for Health Research
6. University of Texas School of Health IS
7. GE Healthcare
8. NextGen
9. Mayo Clinic
10. MVIPA
11. UMDNJ
12. OHSU

Clinical Decision Support Consortium

CDS consortium

PARTNERS HEALTHCARE

FOUNDED BY BRIGHAM AND WOMEN'S HOSPITAL
AND MASSACHUSETTS GENERAL HOSPITAL

GE

MVP HEALTH AUTHORITY

SIEMENS

NextGen
Healthcare Information Systems, Inc.

UNIVERSITY OF MEDICINE & DENTISTRY OF NEW JERSEY · UMDNJ ·

KAISER PERMANENTE

OREGON HEALTH & SCIENCE UNIVERSITY
OHSU

UCSD

MAYO CLINIC

THE UNIVERSITY of TEXAS
HEALTH SCIENCE CENTER AT HOUSTON

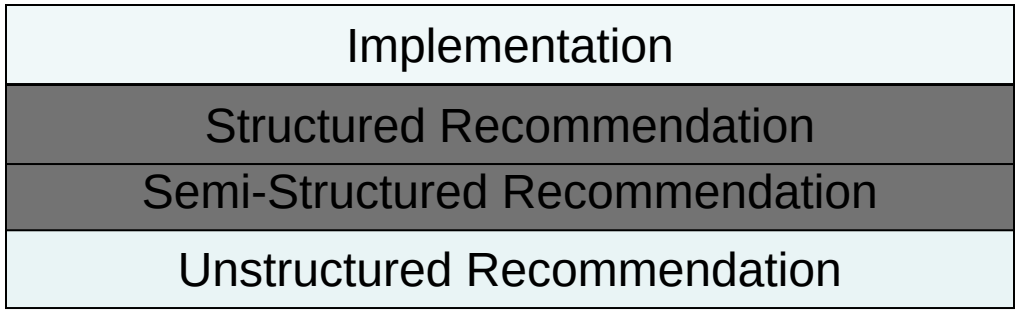
PARTNERS HEALTHCARE · GE · KAISER PERMANENTE · MAYO CLINIC · NextGen · SIEMENS · OREGON HEALTH & SCIENCE UNIVERSITY · THE UNIVERSITY of TEXAS SCHOOL OF HEALTH INFORMATION SCIENCES AT HOUSTON

CDSC Goal and Significance

- **Goal:** To **assess, define, demonstrate**, and **evaluate** best practices for knowledge management and clinical decision support in healthcare information technology at scale – across multiple ambulatory care settings and EHR technology platforms.
- **Significance:** The CDS Consortium will carry out a variety of activities to improve knowledge about decision support, with the ultimate goal of supporting and enabling widespread sharing and adoption of clinical decision support.

1. Knowledge Management Life Cycle		
2. Knowledge Specification	3. Knowledge Portal and Repository	4. CDS Public Services and Content
5. Evaluation Process for each CDS Assessment and Research Area		
6. Dissemination Process for each Assessment and Research Area		

Multilayered Framework



Unstructured Recommendation layer

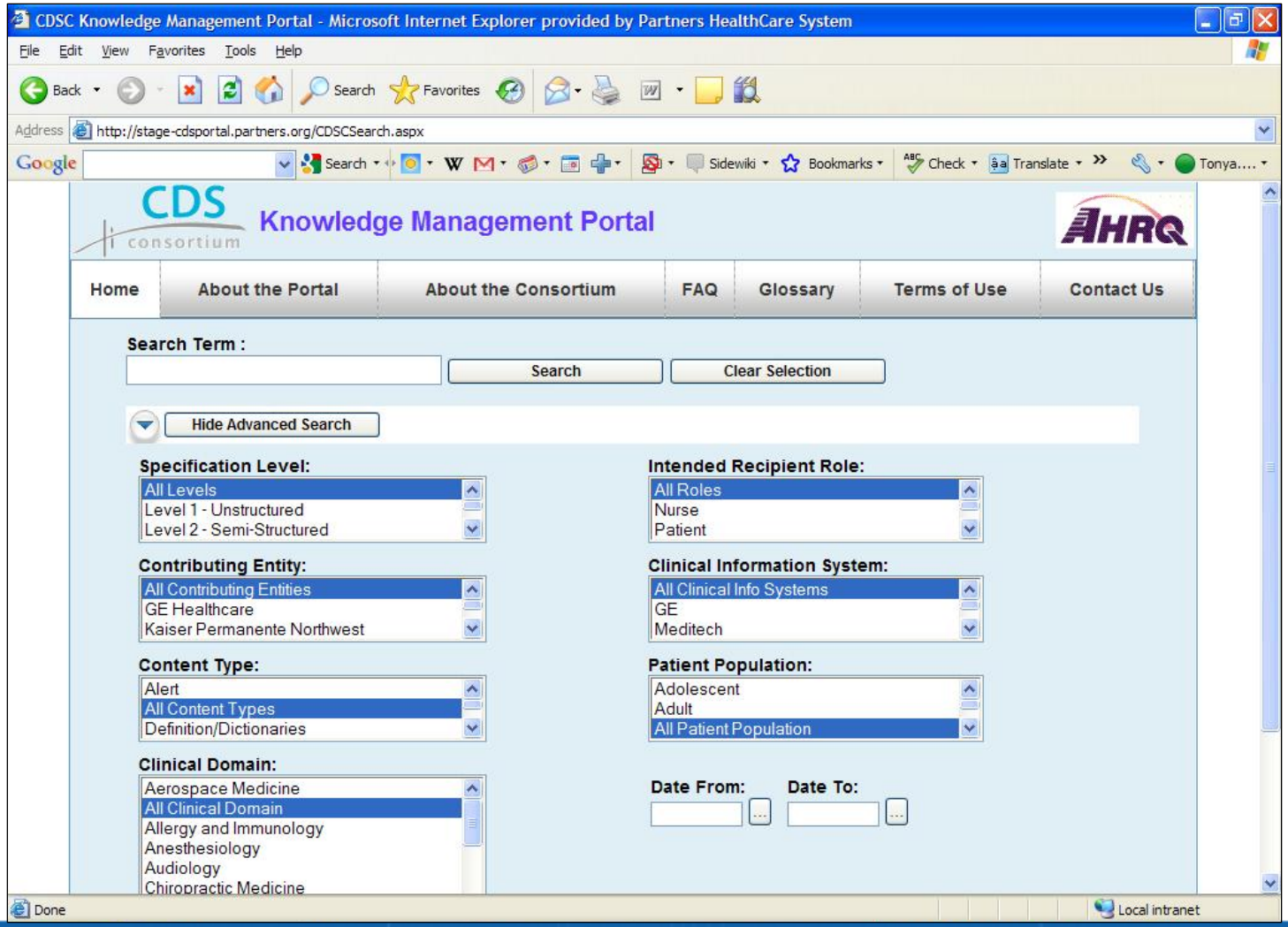
Semi-Structured Recommendation layer

Structured Recommendation layer

Implementation layer

- Knowledge is structured for use within a specific type of CDS tool at a particular clinical site
- Knowledge encoded in a format that can be rapidly integrated into a CDS tool on a specific HIT platform
- E.g., rule could be encoded in Arden Syntax
- A recommendation could have several different artifacts created in this layer, one for each of the different HIT platforms

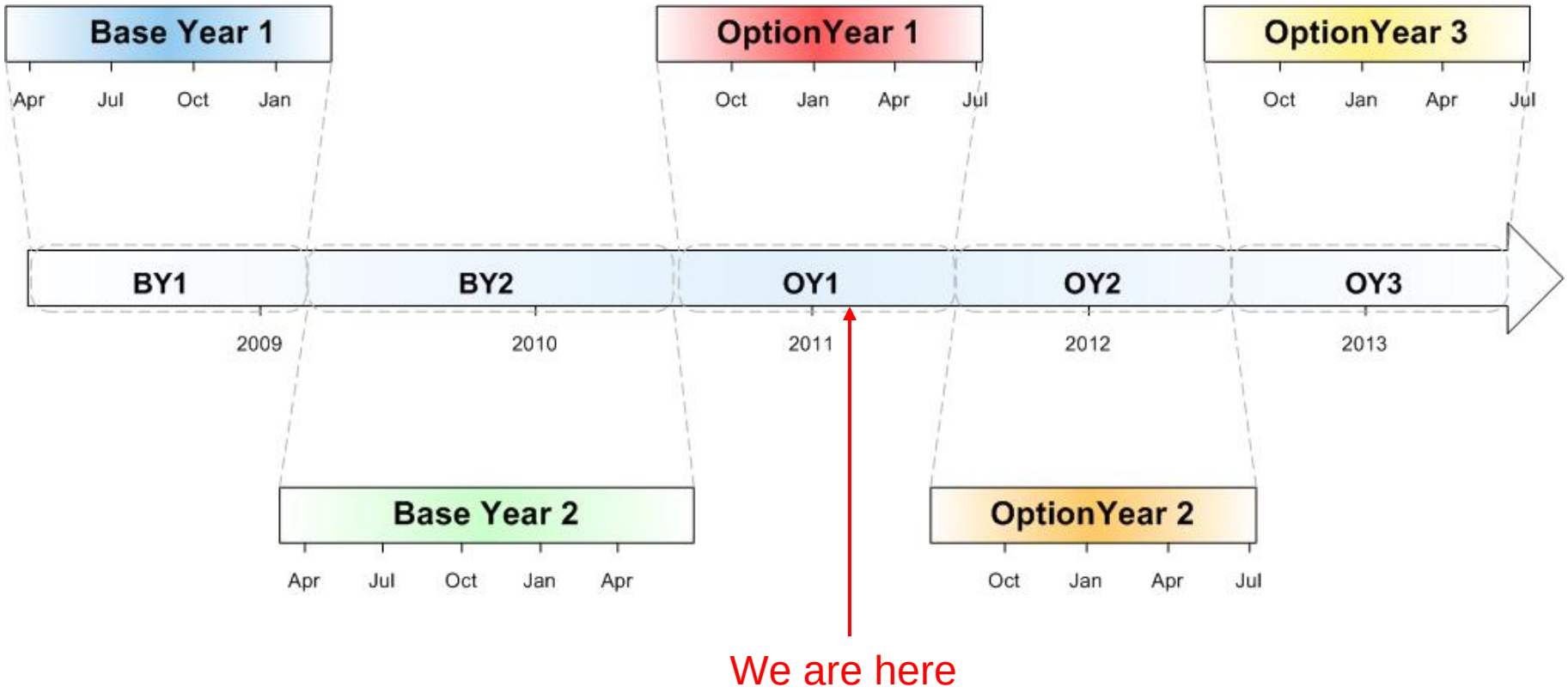
KM Portal: Gateway to Clinical Knowledge



Key Milestones/Accomplishments

- Developed a practical four-layer knowledge representation stack.
- Developed a KM Portal for collating and browsing knowledge artifacts.
- Constructed and tested web-based clinical decision support services, and integrated it into two electronic health record: PHS LMR and RI Wishard Clinics.
- Ran 6 month Pilot.
- Work with NextGen and GE to implement ECRS in their EHRs.
- Devised a novel method for CDS performance assessment.
- Built a robust clinical content governance and editorial process.
- Developed legal agreements to support CDSC work.
- Built a Knowledge Authoring Tool for creating compliant XML representations of knowledge artifacts at Level.
- Disseminated our findings.

Timelines


Base Year 1
Apr Jul Oct Jan
OptionYear 1
Oct Jan Apr Jul
OptionYear 3
Oct Jan Apr Jul
BY1
BY2
OY1
OY2
OY3
2009
2010
2011
2012
2013
Base Year 2
Apr Jul Oct Jan Apr
OptionYear 2
Oct Jan Apr Jul
We are here

Future Directions

- Continue PHS LMR and Regenstrief CareWeb Phase I pilots to Phase 2.
- Implement knowledge sharing and CDS Services Demonstration with 1-3 additional partners (vendors, Beacon HIE, others).
- Port collaborative knowledge engineering tools and rules engine to Open Source technologies.
- Expand breadth of coverage of CDS content, and knowledge artifacts type (Infobuttons, order sets, data display, documentation templates).

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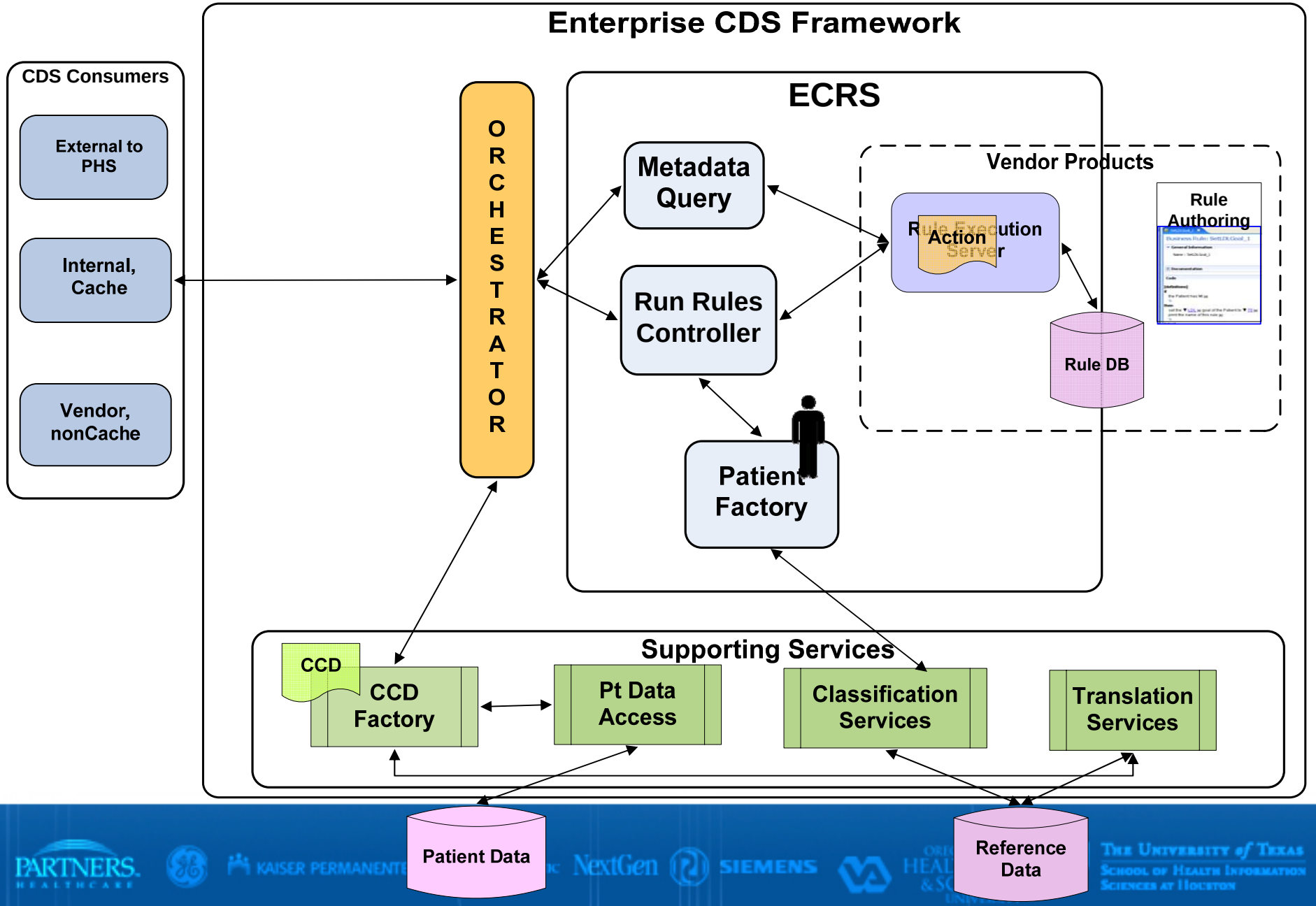
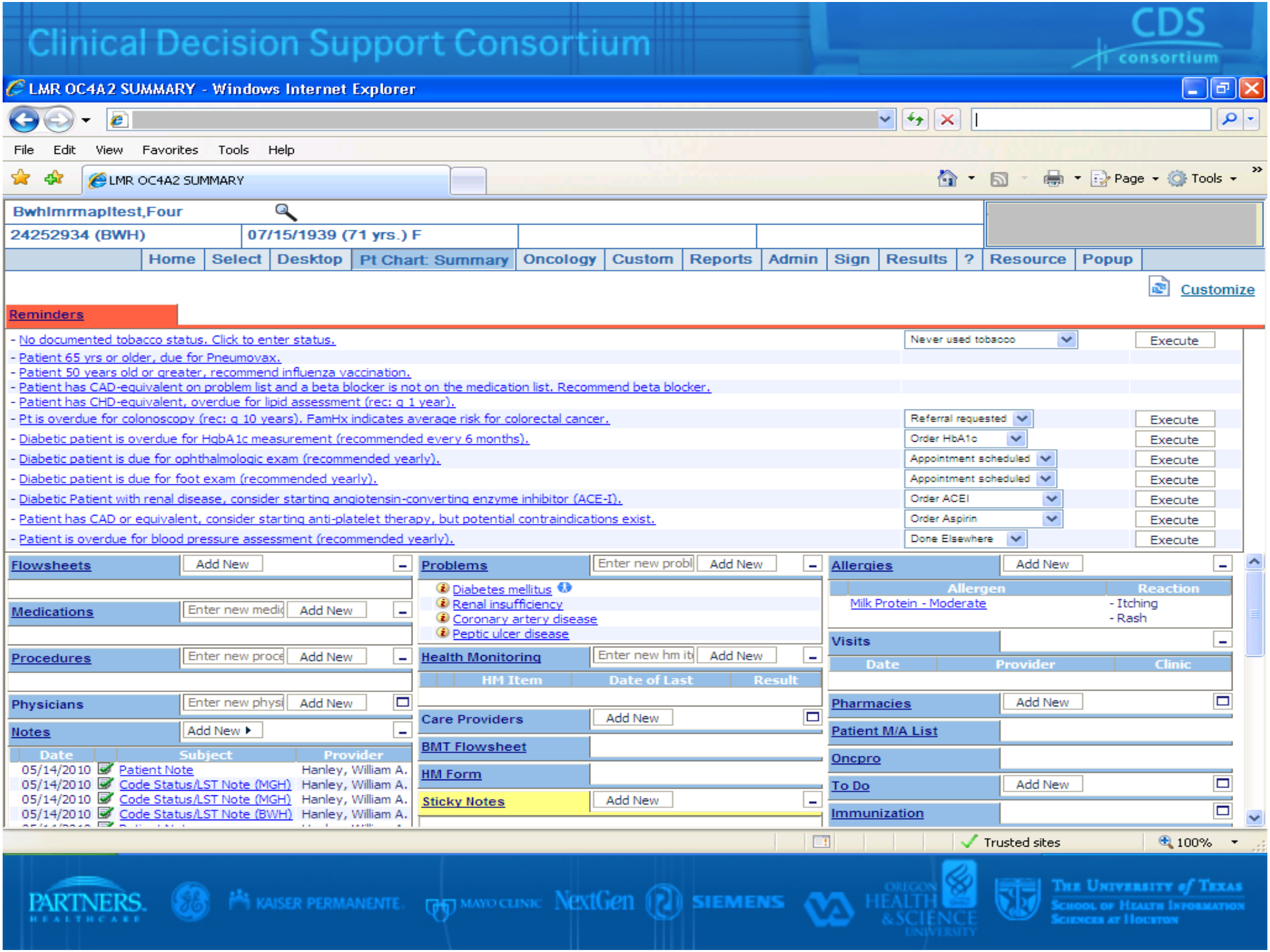
Demo Results

Adam Wright, PhD

Demonstration of CDS Consortium Services in Partners LMR


Enterprise CDS Framework
CDS Consumers
External to PHS
Internal, Cache
Vendor, nonCache
ORCHESTRATOR
ECRS
Metadata Query
Run Rules Controller
Patient Factory
Vendor Products
Action
Rule Authoring
Rule DB
Supporting Services
CCD
CCD Factory
Pt Data Access
Classification Services
Translation Services
Patient Data
Reference Data

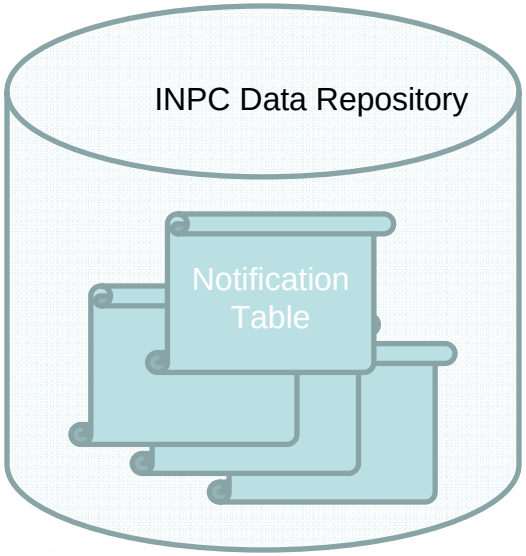

Clinical Decision Support Consortium
CDS consortium
LMR OC4A2 SUMMARY - Windows Internet Explorer
File Edit View Favorites Tools Help
LMR OC4A2 SUMMARY
Page Tools
BwhImrmapItest,Four
24252934 (BWH)
07/15/1939 (71 yrs.) F
Home Select Desktop Pt Chart: Summary Oncology Custom Reports Admin Sign Results ? Resource Popup
Customize
Reminders
- No documented tobacco status. Click to enter status. Never used tobacco Execute
- Patient 65 yrs or older, due for Pneumovax.
- Patient 50 years old or greater, recommend influenza vaccination.
- Patient has CAD-equivalent on problem list and a beta blocker is not on the medication list. Recommend beta blocker.
- Patient has CHD-equivalent, overdue for lipid assessment (rec: q 1 year).
- Pt is overdue for colonoscopy (rec: q 10 years). FamHx indicates average risk for colorectal cancer. Referral requested Execute
- Diabetic patient is overdue for HgbA1c measurement (recommended every 6 months). Order HbA1c Execute
- Diabetic patient is due for ophthalmologic exam (recommended yearly). Appointment scheduled Execute
- Diabetic patient is due for foot exam (recommended yearly). Appointment scheduled Execute
- Diabetic Patient with renal disease, consider starting angiotensin-converting enzyme inhibitor (ACE-I). Order ACEI Execute
- Patient has CAD or equivalent, consider starting anti-platelet therapy, but potential contraindications exist. Order Aspirin Execute
- Patient is overdue for blood pressure assessment (recommended yearly). Done Elsewhere Execute
Flowsheets Add New
Medications Enter new medic Add New
Procedures Enter new proce Add New
Physicians Enter new physi Add New
Notes Add New
Date Subject Provider
05/14/2010 Patient Note Hanley, William A.
05/14/2010 Code Status/LST Note (MGH) Hanley, William A.
05/14/2010 Code Status/LST Note (MGH) Hanley, William A.
05/14/2010 Code Status/LST Note (BWH) Hanley, William A.
Problems Enter new probl Add New
Diabetes mellitus
Renal insufficiency
Coronary artery disease
Peptic ulcer disease
Health Monitoring Enter new hm it Add New
HM Item Date of Last Result
Care Providers Add New
BMT Flowsheet
HM Form
Sticky Notes Add New
Allergies Add New
Allergen Reaction
Milk Protein - Moderate - Itching - Rash
Visits
Date Provider Clinic
Pharmacies Add New
Patient M/A List
Oncpro
To Do Add New
Immunization
Trusted sites 100%
PARTNERS HEALTHCARE
KAISER PERMANENTE
MAYO CLINIC
NextGen
SIEMENS
OREGON HEALTH & SCIENCE UNIVERSITY
The University of Texas School of Health Information Sciences at Houston

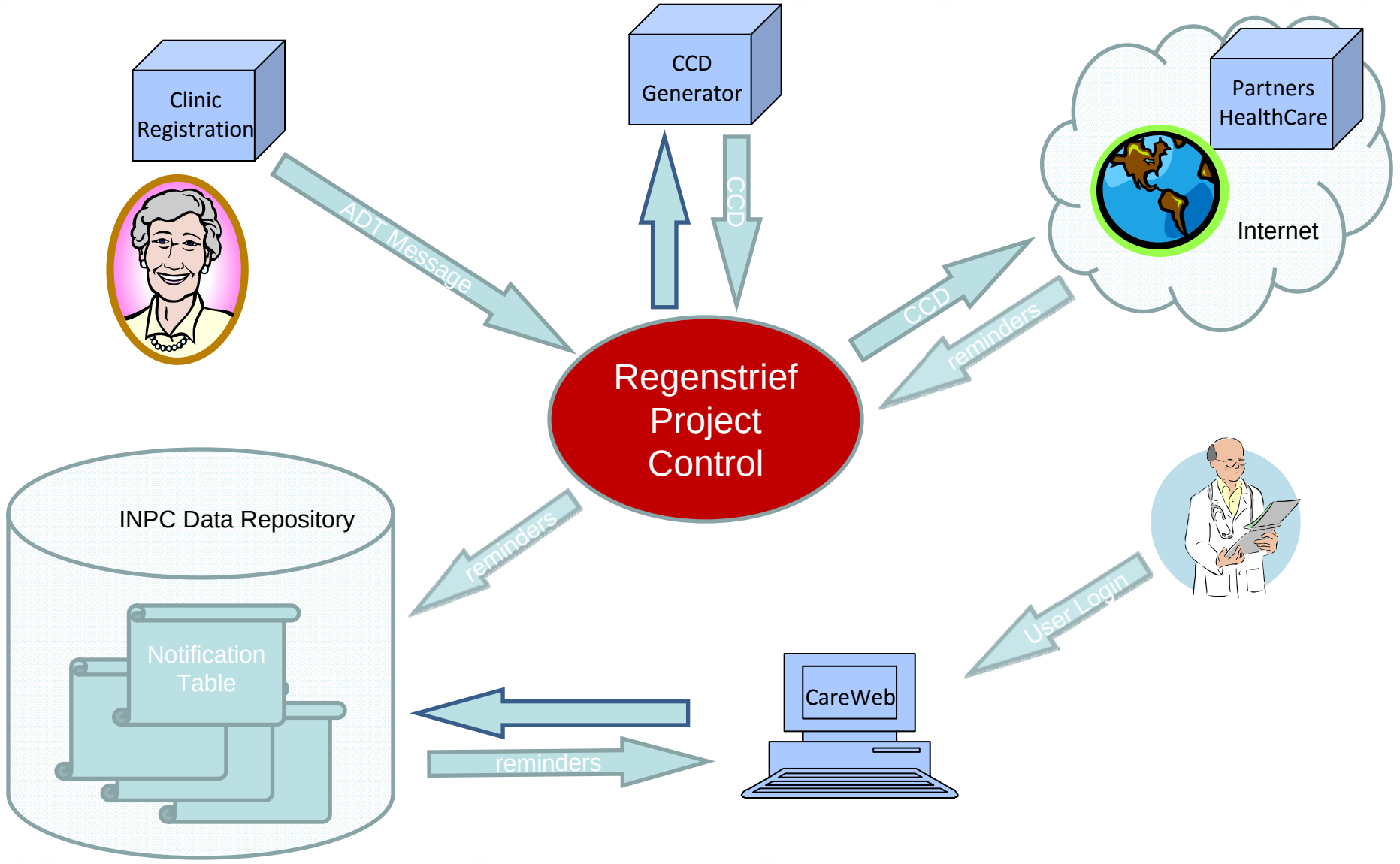
CDSC Performance Data for LMR

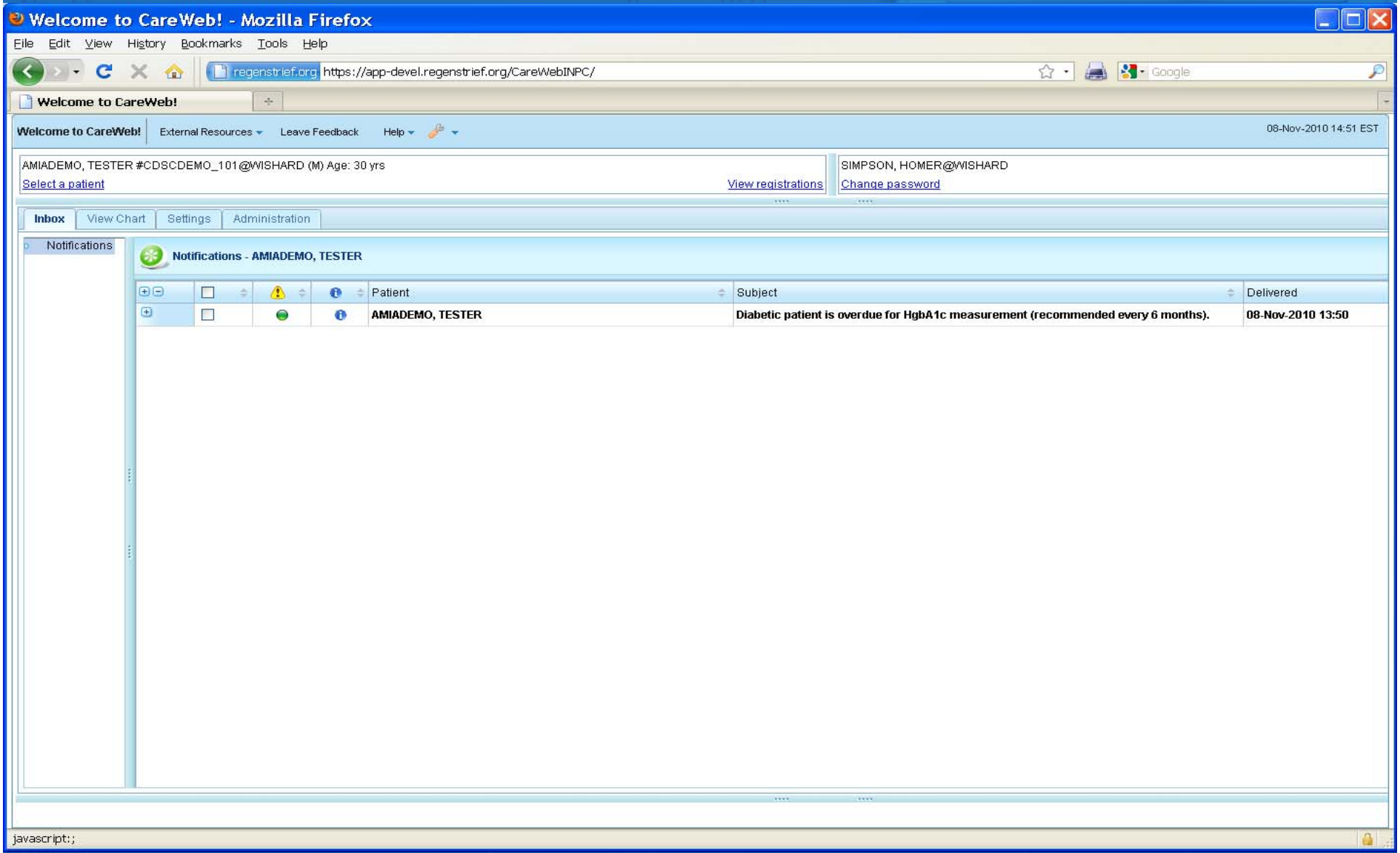
Services Stats (10/27/10 - 11/09/10)				
	All Days (14)		**Weekdays Only (10)**	
Total calls:	**49,160**		**47,297**	
Total Successful calls:	**43,964**	**89 %**	**42,280**	**89%**
Average calls per day:	3,511		4,730	
Average performance:	2.845		2.853	
Total failure calls:	**5,196**	**11 %**	**5,047**	**11%**
CCDFactory timeouts:	2,967	6.04 %	2,840	6%
CCDFactory SOAP failures:	1,939	3.94 %	1,893	4%
Classification services timeouts:	289	0.59 %	283	0.6%
Other failures:	1	0 %	1	0%

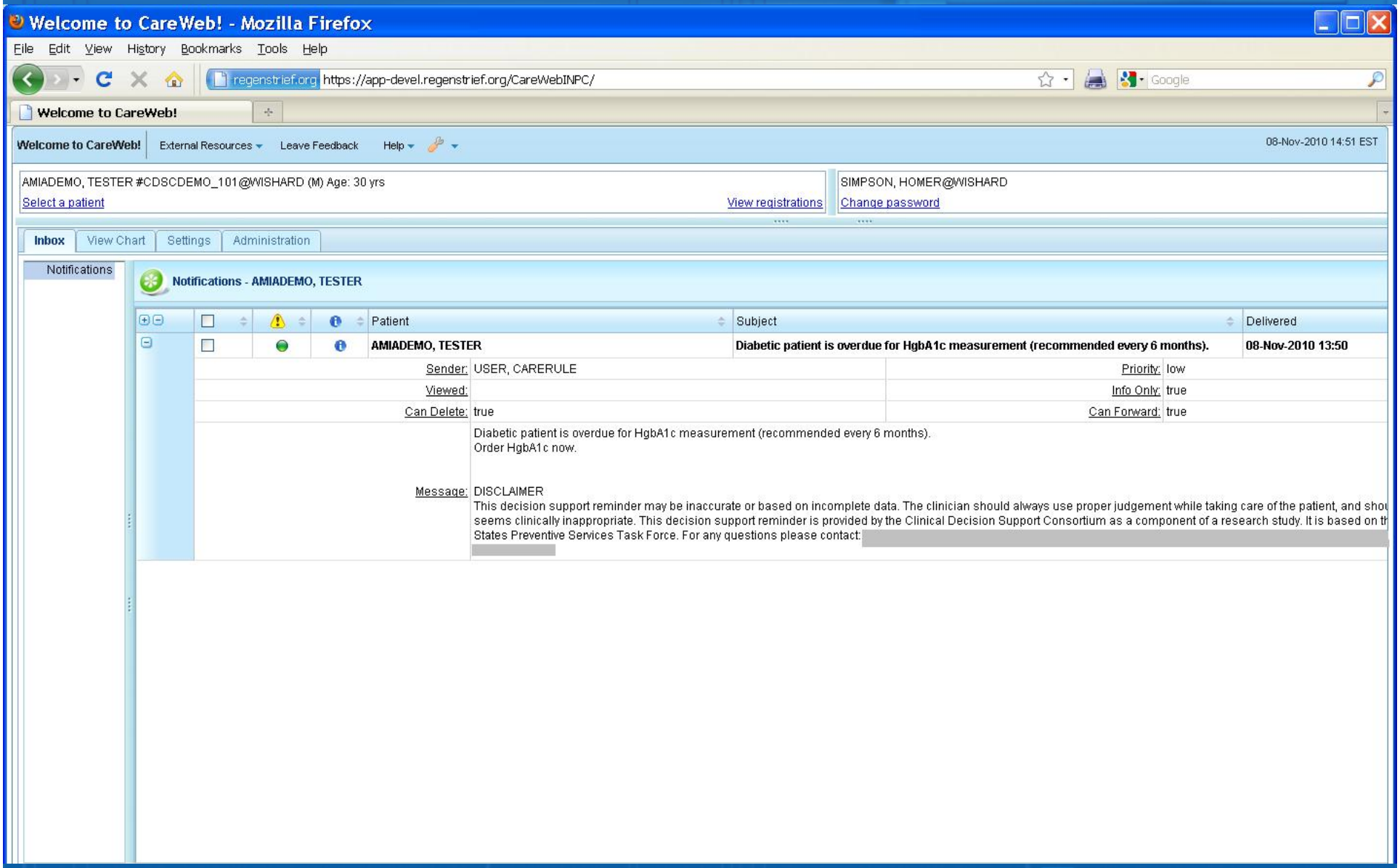
Statistics provided are raw data only. No analysis is provided, including comparison with previous data, and data are not 'cleaned' to remove test or duplicate instances or other anomalies. This update shows two sets of figures; since by far most patients are seen in the outpatient clinics during the week, we did a second run that excludes weekends.*Please bring any questions or concerns to a member of the CDS Services team and include us in any discussion around the implications of these data.*

Demonstration of CDS Consortium Services in Regenstrief CareWeb EMR


Clinic Registration
CCD Generator
Partners HealthCare
Internet
ADT Message
CCD
CCD
reminders
Regenstrief Project Control
reminders
INPC Data Repository
Notification Table


Clinic Registration
CCD Generator
Partners HealthCare
Internet
ADT Message
CCD
CCD
reminders
Regenstrief Project Control
INPC Data Repository
Notification Table
reminders
User Login
CareWeb
reminders


Welcome to CareWeb! - Mozilla Firefox
File Edit View History Bookmarks Tools Help
regenstrief.org https://app-devel.regenstrief.org/CareWebINPC/
Google
Welcome to CareWeb!
Welcome to CareWeb! External Resources Leave Feedback Help
08-Nov-2010 14:51 EST
AMIADEMO, TESTER #CDSCDEMO_101@WISHARD (M) Age: 30 yrs
Select a patient
View registrations
SIMPSON, HOMER@WISHARD
Change password
Inbox View Chart Settings Administration
Notifications
Notifications - AMIADEMO, TESTER
Patient
Subject
Delivered
AMIADEMO, TESTER
Diabetic patient is overdue for HgbA1c measurement (recommended every 6 months).
08-Nov-2010 13:50
javascript:;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Google
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08-Nov-2010 14:51 EST
AMIADEMO, TESTER #CDSCDEMO_101@WISHARD (M) Age: 30 yrs
Select a patient
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Change password
Inbox View Chart Settings Administration
Notifications
Notifications - AMIADEMO, TESTER
Patient
Subject
Delivered
AMIADEMO, TESTER
Diabetic patient is overdue for HgbA1c measurement (recommended every 6 months).
08-Nov-2010 13:50
Sender: USER, CARERULE
Priority: low
Viewed:
Info Only: true
Can Delete: true
Can Forward: true
Diabetic patient is overdue for HgbA1c measurement (recommended every 6 months).
Order HgbA1c now.
Message: DISCLAIMER
This decision support reminder may be inaccurate or based on incomplete data. The clinician should always use proper judgement while taking care of the patient, and shou
seems clinically inappropriate. This decision support reminder is provided by the Clinical Decision Support Consortium as a component of a research study. It is based on th
States Preventive Services Task Force. For any questions please contact:

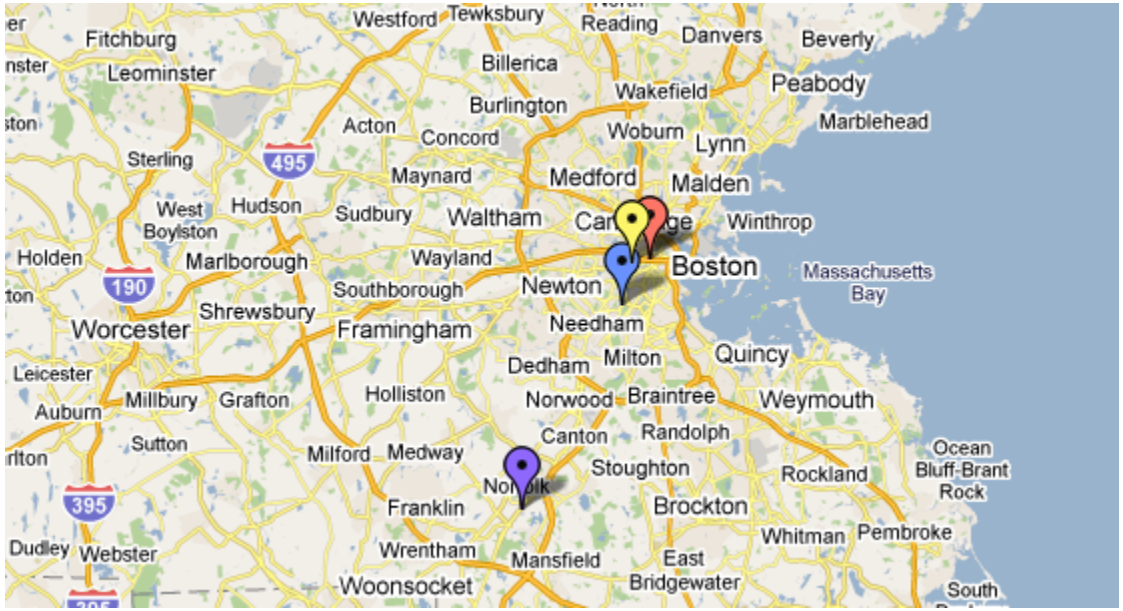
Trial Results

Rule Firings

Rule	Description	Firings
265	Pt with DM, overdue for HbA1c	10,121
266	Pt with DM, almost due for HbA1c	2,820
267	Order A1c Now (Recent poor diabetes control)	2,318
268	Pt with DM, overdue for eye exam	31,105
269	Pt with DM, overdue for foot exam	43,183
270	Proteinuria screening	17,648
271	Start ACE-I or ARB in DM pt (ACE)	2,487
272	Start ACE-I or ARB in DM pt (ARB)	720
273	Start Anti-Platelet Therapy (contraindications)	619
274	Start Anti-Platelet Therapy (no contraindications)	4,555
275	Assess BP	43,878
	Total	**159,454**

Clinics

Description	Firings
BWH Foxborough Primary Care	47,422
Brigham Primary Physicians at Faulkner	45,190
MGH Back Bay	37,522
B&W PCA of Brookline	28,602



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Recommendations Summary

Dean Sittig, PhD

Accomplishments to Date

- Conducted a broad ethnographic study of clinical decision support and knowledge management in clinical practice, and developed best practices recommendations.
- Authored recommendations regarding decision support to a variety of audiences
  - Certification Commission for Health Information Technology
  - Healthcare Information Technology Standards Committee
  - Clinical practice guideline developers
  - Health IT vendors

Comparison of Clinical KM Capabilities

- Commercially-available and leading internally-developed electronic health records.
- Qualitative research program focused on the barriers and facilitators to successful adoption and use of various features of advanced, state-of-the-art EHRs within large, academic, teaching facilities with long-standing EHR research and development programs.
- Sought to assess whether the current generation of commercially-available EHRs are capable of providing the clinical knowledge management features, functions, tools, and techniques required to deliver and maintain the CDS interventions required to support the recently defined “meaningful use” criteria.
- Developed and fielded a 17-question survey about the vendor’s EHR, CDS-related system tools and capabilities that each vendor provides, and clinical content.
- Majority of the systems were capable of performing almost all of the key knowledge management functions we identified
- The transformation of the healthcare enterprise is achievable using commercially-available, state-of-the-art EHRs.

Partners Site Visit to Study the Service-Oriented Architecture

Background

- PHS Site Visit: December 1-3, 2010
- POET Research Team: Joan Ash, Dean Sittig, Vishnu Mohan
- 20 interviewees from different teams: ECRS, KM, Meds, CDSC, LMR, Infrastructure and CCD team.
- Eight dimension socio-technical model.
- Findings and lessons learned based on general questions.
- Lessons learned by CDSC project should be heeded by anyone with a desire to conduct a similar project in the future.

Example Set of Question

Background

- First, we'd like to learn a little about you. Could you give us a few words about your background?
- I know you have work beyond CDSC work--could you please describe your general role here?

The Project

- Would you please give us a very brief history of the CDSC project from your perspective?
- Would you now please tell us more about your role on the CDSC project?
- How does your role fit into the bigger picture of the CDSC project?
- In your estimation, what are the most interesting aspects of the project?
- A complex project like this one takes a lot of collaboration. Can you tell me about your collaborators?
- What the collaboration process like for this project?
- How did it go?
- I understand the ECRS was disabled at times--what happened?
- Probe: When there were problems, what was the response?
- Probe: How is monitoring done and what were some of the issues related to it?
- Probe: What would you consider an acceptable response time for the system and what is acceptable downtime?
- Given that there were bumps along the way, what measures have been taken to prevent future problems?

The Future

- Since there will likely be another 2.5 years of funding for CDSC, what are your hopes about the future of this project?
- What might you like to add that we haven't covered?

Findings and Lessons Learned

1. **New roles for special essential people**
   - Members of SOA management team, who put together agreement for services.
   - The knowledge engineers, especially who work with medication terminology.
   - Project managers, who can promote collaboration across teams, are key for maintaining this collaboration.
2. **Collaboration across teams**
   - People are autonomous
   - Teams flying in tight formation
   - Unique management
   - Huge coordination effort including external vendors
   - Communication training and support team in place

Findings and Lessons Learned (cont.)

3. **Content and knowledge management**
   - Idea of library type for management process for clinical knowledge.
   - Challenges in managing CDS related to resolving clinical rules, terminology, and definition conflicts.
   - Legal issues, knowledge authoring tools.
4. **User / computer interaction**
   - System's response time and how important response time is.
   - Problem with alerts generated using SOA interfering with the workflow intended by the interface design.
   - Create shadow rules in the LMR can help keep track of the alert state, i.e., that they have given that alert about this patient to someone and it should not be repeated for a specified time period.
   - SOA is "stateless." This issue must be addressed and the problem solved before the service can be rolled out nationwide.

Findings and Lessons Learned (cont.)

5. **Measurement and metrics**
   - System and end-user measurement and monitoring services, or system performance characterization, e.g. LMR metrics track.
   - Important to measure on a regular basis.
   - The metrics must be in place so one can narrow down the problem.
6. **Internal governance policies, procedures and organizational culture**
   - Balance between the EHR research and production efforts.
   - Decisions must be made about handling violations of agreements.
   - Hard to set up a service level agreement and get it to work.
7. **Hardware / software, technical issues**
   - If the hardware does not work, the CDS that is embedded in the EHR cannot possibly work.
8. **External regulations and pressures**
   - AHRQ requirements and rules that are included in the contract often take more time to deal with than expected.
   - Sharing CDS involves difficult legal issues.

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Legal and Other Challenges

Lana Tsurikova, MSc, MA

History

- 14 years ago, Miller et al. first published on legal liability for injuries resulting from software in health care.
- To date, no American courts have clarified how vendors, institutions, or clinicians might be liable to patients for harm resulting from software.
- If there is suboptimal design of an Electronic Health Records (EHR) that leads to error, who is at fault…those in control of system architecture or the end user?

Contracts between developers and providers organizations include provisions to protect the developer from liability.

Miller RA, et al. Recommendations for responsible monitoring and regulation of clinical software systems JAMIA 1997.

Goodman KW, et al, Challenges in ethics, safety, best practices, and oversight regarding HIT vendors, their customers, and patients: a report of an AMIA special task force. JAMIA 2011

Koppel R, et al. Health care information technology vendors' "hold harmless" clause: implications for patients and clinicians. JAMA 2009.

Not so Simple…

- Thus there is a great need to meet requirements of data security, confidentiality, and control over data.
- The Health Information Technology for Economic and Clinical Health (HITECH) Act expanded scope of the Health Insurance Portability and Accountability Act (HIPAA) privacy and security rules to include "business associates" of covered entities.

  Any Health (Information Technology) IT solution must be HIPAA compliant.

- In the past vendor owned the software, customer owned the content…but now it is much more complicated (cross-licenses, etc).

Liability Points of Failure

- CDS manufacturing defect
  - Software does not perform as designed
  - i.e. alerts fail to notify due to bug in software or service
- CDS implementation defect
  - Customer implementation of software results in defective functioning
  - i.e. alerts fail to fire because customer has failed to update or accurately represent the knowledge in the system
- CDS user error
  - Software performs as designed, customer has implemented correctly, however user does not utilize correctly
  - i.e. user ignores alert, turns off alerts, fails to notice alert
  - Blurred distinctions here because users typically blame CDS manufacturer or implementation team for creating unusable CDS.

CDSC Legal Documents

- Portal User Agreement
- Portal Publishing Agreement
- Service Sharing Agreement

- To support sharing of knowledge and artifacts for CDS across Consortium sites.
- To collect CDS artifacts in various formats, ranging from unstructured human readable guidelines to machine executable code.

Indemnification

- CDS software cannot provide accurate advice 100% of the time (imperfect context awareness, heuristics).
- CDS software cannot be viewed as medical device; healthcare provider is expected to exercise independent medical judgment regarding CDS advice before treating a patient.
- CGC members make no warranty of accuracy of content, and take no responsibility for harm.

Ongoing Challenges

- Potential content-sharers continue to be wary of liability, difficult to identify who can sign on behalf of the institutions.
- Concerns remain how to untangle CDS from 3rd party content.
- Potential content-sharers also may still regard their CDS as potentially valuable IP, source of market advantage.

1. Responsibilities of Service Provider

1. Assure the most recent clinical guidelines and the best practice logic is utilized by the services
2. Assure that the ECRS produces a correct recommendation for any given set of data.
3. Provide timely notice to all consumers if definitions, classifications, or practice logic used by the ECRS changes.

2. Responsibilities of Service Consumers

1. Ensure that local institutional definitions are aligned with the classifications used by the ECRS, and remain aligned if local terminologies change.
2. Create CCDs in a manner that accurately represents patient data using the format and terminologies prescribed by the ECRS.
3. Conduct end-to-end testing, ensuring that the desired outputs are produced by a given set of inputs.

3. Responsibilities of CDS User

1. The end-user clinician is ultimately responsible for all clinical decisions.
2. For randomized controlled trial (RCT) (s):
   - End-user institution tested the CDS for appropriateness.
   - Clinicians are appropriately consented and aware that the CDS is only an aid.

Example Provisions: CDSC and Regenstrief Institute (RI)

1. Quality assurance and thorough testing performed by Partners HealthCare System (PHS) and RI.
2. Institutional Review Board (IRB) of both PHS and RI.
3. Informed consent for participating clinics and providers.
4. Every participating physicians must review and interpret provided CDS. In each and every case, it is up to the physician to act or not act on the CDS advisory.
5. Indication on the CDS message of the source of this CDS advisory.

Discussion/Q&A