

A Legal Framework to Enable Sharing of Clinical Decision Support Knowledge and Services across Institutional Boundaries

Tonya Hongsermeier, MD, MBA

Lana Tsurikova, MSc, MA

Other Co-Authors:

Saverio Maviglia, MD MS, Dan Bogaty, Roberto A. Rocha, MD PhD

Howard Goldberg, MD Seth Meltzer, BA, Blackford Middleton, MD, MPH, MSc

October 24, 2011



Agenda

- The Clinical Decision Support Consortium (CDSC):
Why a legal framework?
- Main challenges
- Key CDSC agreements for CDS knowledge and services sharing
- Lessons learned
- Questions and answers

Clinical Decision Support Consortium

CDSC Goal:

Sharing of best practices and services for Knowledge Management (KM) and CDS at scale – across multiple care settings and EHR platforms

CDSC Objectives:

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

AHRQ contract HHSA290200810010

<http://www.partners.org/cird/cdsc/>



NEXTGEN
HEALTHCARE



UMDNJ
UNIVERSITY OF MEDICINE &
DENTISTRY OF NEW JERSEY



DUODECIM
Medical Publications Ltd.



SIEMENS



KAISER PERMANENTE



WVP
HEALTH AUTHORITY

PHILIPS



Legal Barriers Encountered

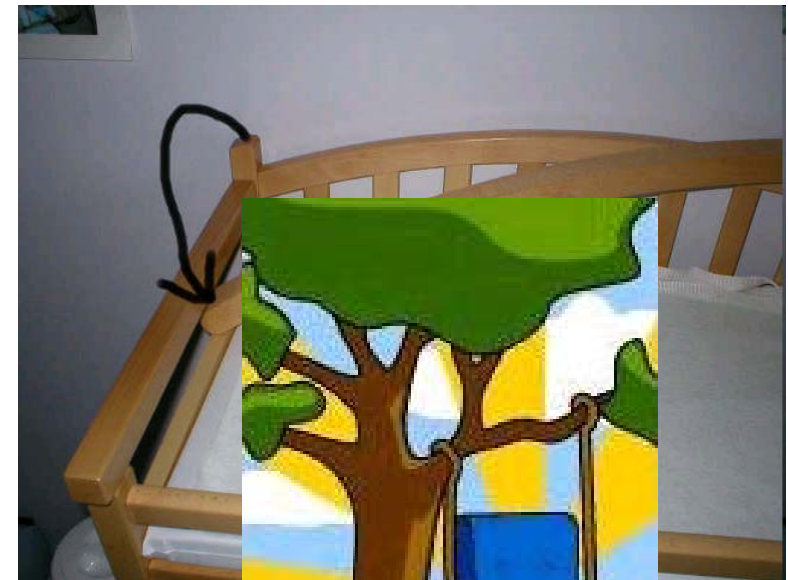
- Intellectual Property
 - If I contribute, will someone else sell it?
- Fear of Liability
 - If I contribute, am I liable for how it is used?
- Unclear accountability
 - Who is responsible for what when we consume a CDS service?
 - What happens when contributed content becomes outdated?
- HIPAA and data security
 - When we “remember” how a CDS service interprets patient data from an outside institution, what’s the legal framework?

Intellectual Property Approach

- Leveraged Creative Commons IP agreements for sharing <http://creativecommons.org/>
- Content contributors accountable for respecting their 3rd party agreements
- Content contributors retain authorship, users may make derivative works with appropriate attribution
- CDSC KM Portal artifacts may not be sold in native or derivative form

CDS Liability Points of Failure

- CDS manufacturing defect
 - Content is inaccurate
 - Software does not perform as designed
- CDS implementation defect
 - Customer implementation of software results in defective functioning
- CDS user error
 - Software performs as designed, customer has implemented correctly, however user does not utilize correctly



Miller, Hurwitz and Colleagues on Liability

- “there can be no duty of care between the author of a document ... and its myriad potential readers...
- CDS software “does not replace the judgment or the functions of a physician; instead, it augments the physician’s existing knowledge by providing further information”
- “even if the software provides an erroneous diagnosis, the doctor subsequently acting on the information possesses specialized knowledge of the patient... and is therefore in the best position to evaluate and reject faulty or inappropriate advice”

Miller RA, Gardner RM. Recommendations for responsible monitoring and regulation of clinical software systems. JAMIA. 1997 4(6): 442-457.

Liability Approach

- Legal language created a mutual circle of indemnification for CDSC as the host of CDSC KM Portal, Content Contributors, and Content Users
- Ensure the effort is regarded as a research and not commercial enterprise
 - CDSC services is “beta test version for research purposes only and not available for commercial distribution”
- CDSC services’ consumer posts a disclaimer with the alert message
- CDS as a service presented additional challenges that required we clarify accountability

Accountability

- CDSC services provider is accountable for ensuring the rules and terminologies in the service are accurate, valid, and current
- CDSC Services consumers are accountable for
 - Ensuring integration/insertion is accurate
 - Ensuring our rules can reason over their data accurately (semantics using standard terminologies)
 - Notifying CDSC if anything changes re: integration and semantics that might compromise CDS accuracy

Patient Data Management

- CDSC rules service reasons over de-identified patient data in the form of a CCD
- CDSC only uses patient data as necessary and must “maintain appropriate administrative, physical, technical and procedural safeguards to protect the confidentiality of electronic information”
- In compliance with legal and IRB requirements, CDSC retains 7 year of encrypted data



CDSC Agreements

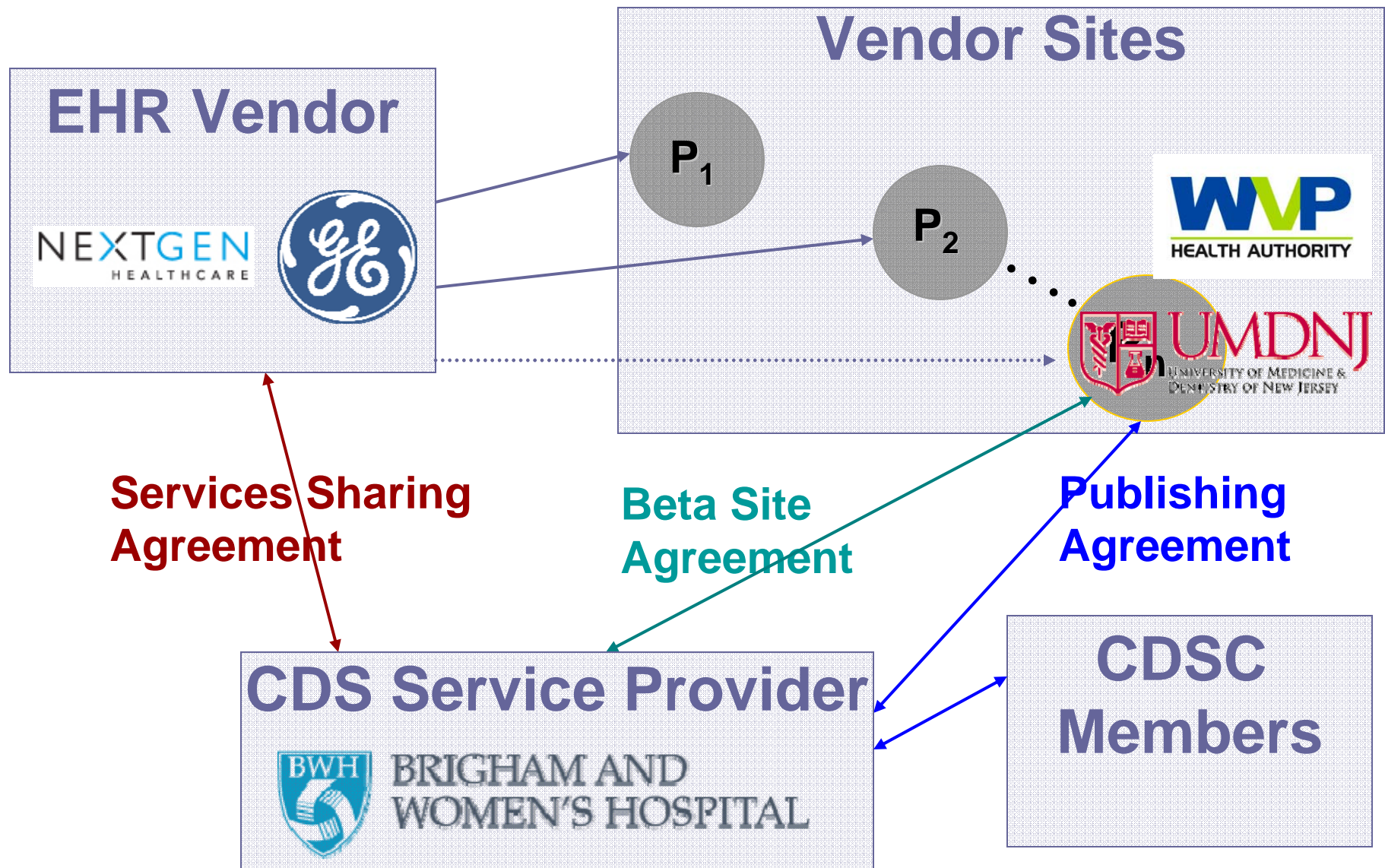
1. Publishing Agreement
2. Portal User Agreement
3. Service Sharing Agreement
4. Beta Site Agreement



Four Types of Agreements

1	Publishing Agreement	Required to be signed by submitting institutions prior to sharing/uploading /publishing content to KM Portal
2	Portal User Agreement	Required for anybody who would like to access and/or download KM Portal content. This is a “click-through” agreement on the CDSC KM Portal home page
3	Service Sharing Agreement	Required for any EHR or Content vendor that integrates Enterprise Clinical Rules Service (ECRS) services. Describes provider’s and consumer’s responsibilities for integration of the ECRS and related content
4	Beta Site Agreement	Required for any vendor customer site what will utilize ECRS services. Include text around confidentiality, compliance with Privacy and Security Laws, disclaimers, infringement and indemnification

Stakeholders and Agreements



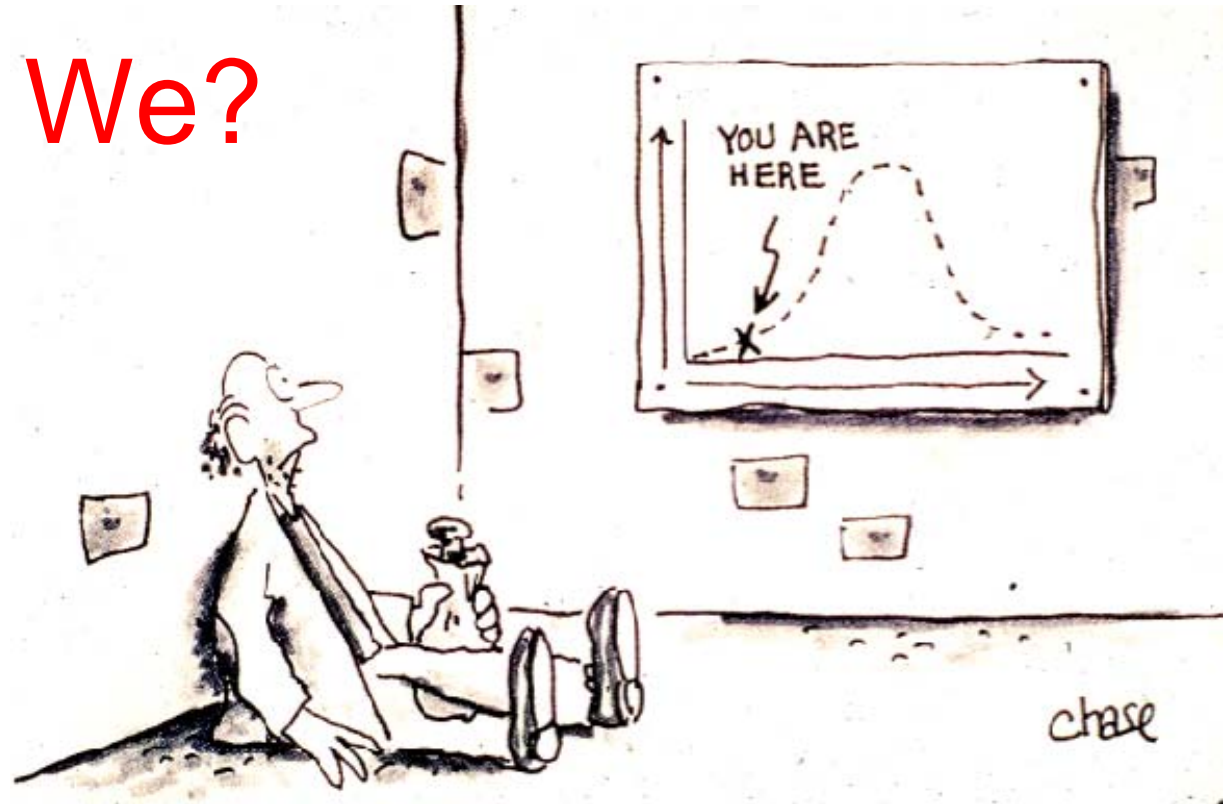
Barriers

- Complexity and diversity of the legal concerns: building agreements that accommodate all concerns is time consuming
- Signing entities: identifying people who have the authority to sign legal agreements
- Liability concerns persist

Lessons Learned

- Make initial cost and time estimates and then **triple** them
- Plan on significant time to identify and educate lawyers
- Clarify stakeholder roles and the many possible permutations early on
- Make sure you have full support bilaterally
- Expect ongoing investment of time and legal resources in further modifications of signed agreements
- The possibility of future regulation will further impact the complexity in creating sound legal arrangements for knowledge and data sharing

Where Are We?



Thank you!

Tonya Hongsermeier, MD, MBA
thongsermeier@partners.org
www.partners.org/cird/cdsc/

Lana Tsurikova, MA, MSc
rtsurikova@partners.org
www.partners.org/cird/cdsc/

Discussion/Q&A

