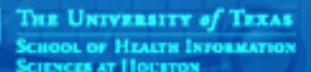
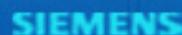
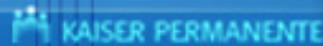


Clinical Decision Support Consortium: Legal Aspects of CDS: IP & Liability

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Agenda



- Legal issues as part of Clinical Decision Support (CDS).
- Knowledge Management (KM) Portal Legal Agreement.
- CDS Services Legal Agreement.
- CDS Consortium (CDSC) contribution to: “Developing a taxonomy/ compendium of CDS-related legal issues”.

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

Goodman KW, Berner ES, Dente MA, Kaplan B, Koppel R, Rucker D, Sands DZ, Winkelstein P; AMIA Board of Directors. Challenges in ethics, safety, best practices, and oversight regarding HIT vendors, their customers, and patients: a report of an AMIA special task force. J Am Med Inform Assoc. 2011 Jan 1;18(1):77-81. Epub 2010 Nov 12.

Koppel R, Kreda D. Health care information technology vendors' "hold harmless" clause: implications for patients and clinicians. JAMA. 2009 Mar 25;301(12):1276-8. No abstract available. PMID: 19318655 [PubMed - indexed for MEDLINE]

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).

Software's Liability

- Software is a product and thus defective software is subject to product liability claims.
- Currently, a plaintiff harmed by a seller's product could recover for injuries if they were caused by manufacturing or design defects.
- Software liability extends to anyone involved in "stream of commerce" (i.e. selling or distributing product).
- Miller RA, 1997. CDSC belongs to Category 2:

Intermediate-risk, patient-specific systems that provide complex, health-related functions that have relatively high clinical risk, but provide easy opportunities for practitioners to ignore or override them.

Miller RA, Gardner RM. Recommendations for responsible monitoring and regulation of clinical software systems. American Medical Informatics Association, Computer-based Patient Record Institute, Medical Library Association, Association of Academic Health Science Libraries, American Health Information Management Association, American Nurses Association. <http://www.ncbi.nlm.nih.gov/pubmed/9391932>> J Am Med Inform Assoc. 1997 Nov-Dec;4(6):442-57.

Physician's Liability

- CDS software does not replace the judgment of a physician.
- Physician may be liable for failing to use CDS software to avert an error, if evidence shows that a reasonable physician would have.
- In some jurisdictions, physicians may be found negligent if they fail to question erroneous advice given by CDS software.
- Question of whether vendor should be held to same standard as physician if negligence of CDS software occurs.

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.

Previous Efforts

- Morningside Initiative

Content Governance Committee (CGC) team reviewed their bylaws and found clear need for a legal foundation for content sharing.

- Institute for Medical Knowledge Implementation (IMKI)

Unwillingness of members to share content, due to:

- complexity of defining the scope.
- complexity of knowledge artifacts.
- the burden of developing and updating published content.

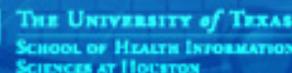
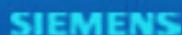
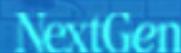
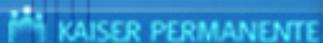
CDSC Legal Documents

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



Portal User Agreement and Portal Publishing Agreement

Tonya Hongsermeier, MD, MBA



KM Portal Legal Agreements

- **Portal User Agreement.** Users are required to accept the agreement on the CDSC KM Portal home page before accessing or downloading content.
- **Portal Publishing Agreement.** Required to be signed by submitting institutions prior to sharing/uploading/publishing content to CDSC KM Portal.

Goal

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

Content Governance Committee

- Formed to develop editorial policies for authorship and sharing of CDS content.
- Came to the conclusion that legal foundation for content sharing was needed to address intellectual property and indemnification concerns.
- Legal agreements must be in place for both content submitters and consumers.
- Portal users would click-through an agreement with each visit.

CGC Editorial Policies

- Submitting members endorse that submitted artifacts are developed in accordance with quality procedures in place for other CDS in production at their own institution.
- Agree to update at least every 3 years or amend the artifact to indicate it is no longer being maintained.
- By publishing to portal, submitter grants license to other CDSC members and portal users to make derivatives of content.
- CDS artifacts are shared freely and should not be resold by anyone accessing portal.

Publisher Agreement IP Language

- Signed by the institution representative whose members will publish content to KM Portal.
- Publisher grants CDSC the right to free distribution of CDS artifacts.
- CDSC agrees to use best efforts to provide acknowledgement to publisher for any CDS artifacts in Portal.
- End-users may use and modify CDS artifacts solely for their own implementation purposes.
- Warranties that publisher fully owns the artifacts and is liable for respecting any intellectual property agreements between the publisher and any 3rd party content suppliers.

End-user Agreement IP Language

- User must “click-through” with each visit session.
- CDSC grants end-user rights to CDS content for internal patient care, not for commercial benefit.
- Not a transfer of rights of ownership, but end-user shall own derivative works.
- May make modifications and republish as a new version or new artifact, provided there is attribution to original author.

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.

End-user Agreement

Indemnification Language

- CDS content is “AS IS”, and CDSC is not responsible for errors of omission or commission.
- CDSC is not liable for any damages resulting from use of CDS content.
- Access to portal is not a substitute for professional judgment.

Publisher Agreement Indemnification Language

- Publisher agrees to indemnify CDSC against any liability relating to its submissions – aware that portal users must also hold Publishers and CDSC/CGC harmless.
- CDSC does not warrant that portal access will be uninterrupted or make any representations about accuracy of content.

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.

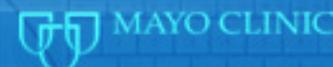
References

1. Miller et al., Legal and Regulatory Issues related to the use of clinical software in health care delivery. From Clinical Decision Support: The Road Ahead by Robert Greenes.
2. Mangalmurti et al., Medical Malpractice Liability in the Age of Electronic Health Records, NEJM Nov 2010.
3. Rubin, Risk and Reward Model: Health IT SAAS Licensing Models, The Licensing Journal, Jan 2010.
4. Waitman LR and Miller RA. Pragmatics of implementing guidelines on the front lines. J Am Med Inform Assoc. 2004 Sep-Oct; 11(5):436-8.

Service Legal Agreement

Lana Tsurikova, MSc, MA

Howard Goldberg, MD



CDS Service Sharing Agreement

- Describes provider's and consumer's responsibilities for integration of the Enterprise Clinical Rules Service (ECRS) and related content.
- Covers sharing, encrypting, reasoning over, and auditing the data/decisions.
- References use of the ECRS service, terminology service(s), and creation of Continuity of Care Document (CCD).

Service Sharing - Technical View

- ECRS is a CDS service shareable to multiple end-users who comply with a set of data standards.
- ECRS accepts data in the form of CCD and provides recommendations back to end-users in the form of an Extensible Stylesheet Language (XML) message.
- ECRS classifies input data into a series of clinical states which form the basis for the CDS calculations.
- ECRS solutions team provides a series of best practices and processes to facilitate consumer's compliance.
- Compliance is ultimately the responsibility of the consumer.

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.

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.
4. The end-user clinician is ultimately responsible for all clinical decisions.
5. 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.

De-Identification.

Sample of the Header Data

```

- <patientRole classCode="PAT">
  <id root="1.3.6.1.4.1.12009.6.1" extension="fake000115" assigningAuthorityName="Regenstrief NHIN
  Home Community ID" />
  - <addr use="H">
    <streetAddressLine>997 OSU BUCKEYE LANE</streetAddressLine>
    <city>BRONX</city>
    <state>NY</state>
    <postalCode>10471</postalCode>
  </addr>
  - <patient>
    - <name>
      <given>SALMA</given>
      <family>FLETCHER</family>
    </name>
    - <administrativeGenderCode code="F" codeSystem="2.16.840.1.113883.5.1" displayName="Female"
      codeSystemName="AdministrativeGender">
      <translation code="F" codeSystem="1.3.6.1.4.1.12009.8.1" displayName="female"
      codeSystemName="SEX" />
    </administrativeGenderCode>
    <birthTime value="19431110" />
    <maritalStatusCode code="M" codeSystem="1.3.6.1.4.1.12009.1.1.8" displayName="M"
      codeSystemName="Wishard Hospital Person MARITAL STATUS codes" />
  </patient>
</patientRole>

```

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.

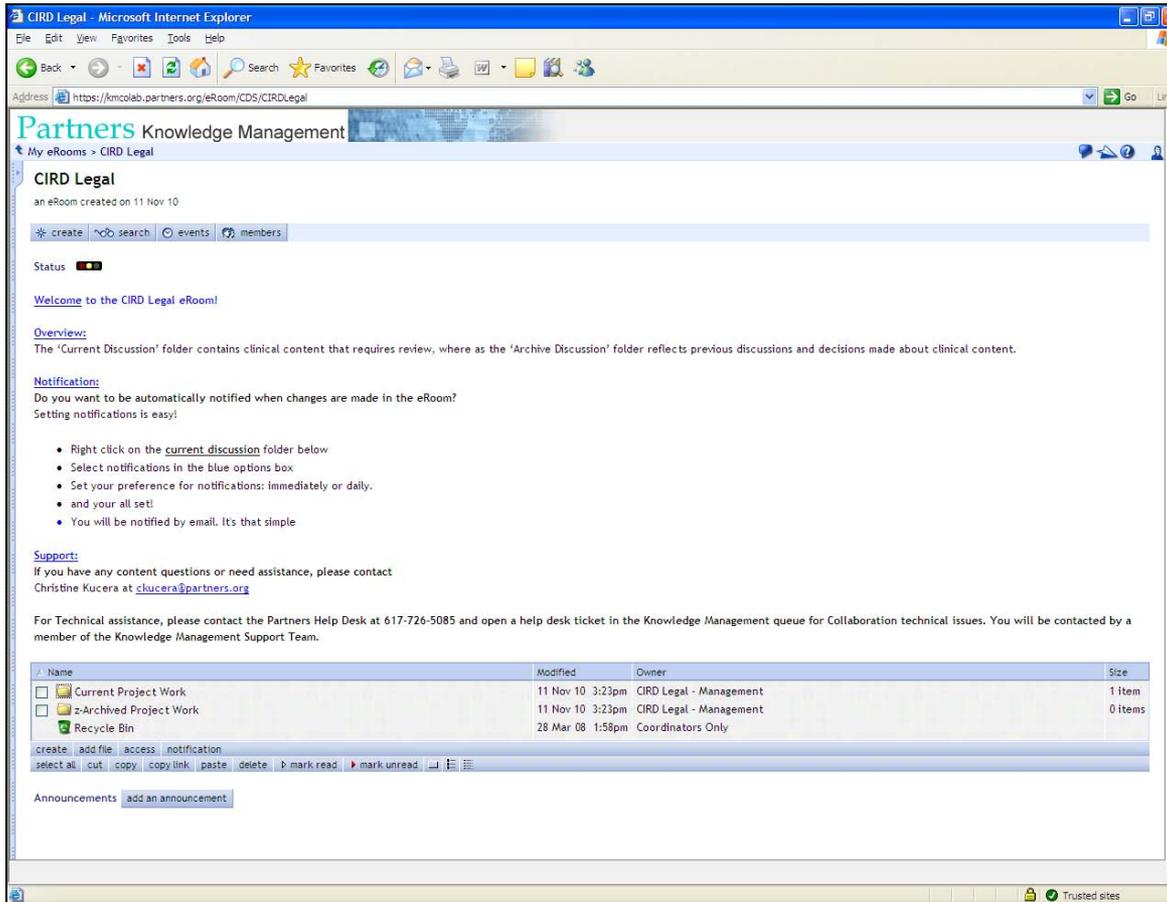
Barriers

1. **Signing entities:** Brigham and Women's Hospital (BWH)? PHS? RI? Wishard Clinic? *There seems to be a misconception that the RI is a licensed medical provider of some type, we are not. We do not practice medicine. Because of this nuance, many of the provisions of the draft agreement are inapplicable.*
2. **Previous agreements:** Confusion with KM Portal agreement. *If the RI had not previously been involved in and not had existing contracts with PHS/BWH that already govern much of this relationship, then the legal agreement proposed would make sense.*
3. **Indemnification:** *PHS/BWH provide services and therefore are viewed as a vendor by RI.*
4. **Privacy and HIPAA:** *Descriptions of the HIPAA limited data sets are absent. One goal of this agreement was to incorporate those terms into the same document.*
5. **Data storage:** per IRB requirements PHS has to store all research related data for 7 years. RI asked for 72 hours.
6. **IP:** *IP and publication rights are governed by the subcontract for this work.*

How We Addressed Barriers

1. **Signing entities:** BWH and RI.
2. **Previous agreements:** Acknowledged all previous agreements, but devoted significant time to educate RI lawyer on the difference between KM Portal and Services.
3. **Indemnification** is the key component of the agreement and should be included in the text of this agreement in some form. PHS/BWH is not a vendor and CDSC is a research study.
4. **Privacy and HIPAA:** We defined required data set and included it in the Exhibit E.
5. **Data storage:** Addressed by IRB rules. Wrote 3 years into the Agreement with explicit language that this duration may increase up to 7 years if needed for research purposes.
6. **IP:** RI's lawyer is ok with BWH disclaiming any non-infringement reps and warranties.

CIRD Legal eRoom



CIRD Legal
an eRoom created on 11 Nov 10

create search events members

Status **ON**

Welcome to the CIRD Legal eRoom!

Overview:
The 'Current Discussion' folder contains clinical content that requires review, where as the 'Archive Discussion' folder reflects previous discussions and decisions made about clinical content.

Notification:
Do you want to be automatically notified when changes are made in the eRoom?
Setting notifications is easy!

- Right click on the current discussion folder below
- Select notifications in the blue options box
- Set your preference for notifications: immediately or daily.
- and your all set
- You will be notified by email. It's that simple

Support:
If you have any content questions or need assistance, please contact
Christine Kucera at ckucera@partners.org

For Technical assistance, please contact the Partners Help Desk at 617-726-5085 and open a help desk ticket in the Knowledge Management queue for Collaboration technical issues. You will be contacted by a member of the Knowledge Management Support Team.

Name	Modified	Owner	Size
Current Project Work	11 Nov 10 3:23pm	CIRD Legal - Management	1 Item
z-Archived Project Work	11 Nov 10 3:23pm	CIRD Legal - Management	0 Items
Recycle Bin	28 Mar 08 1:58pm	Coordinators Only	

create add file access notification
select all cut copy copy link paste delete mark read mark unread

Announcements [add an announcement](#)

CIRD Legal eRoom Groups:

- CIRD Legal - CDSC Reps
RI – observer
- CIRD Legal - CDSC Reps
PHS – observer
- CIRD Legal - CDSC Reps
Authorized
- CIRD Legal - Management

Thought from PHS Lawyer

- RI, Agency for Healthcare Research and Quality (AHRQ) and a lot of others who are thinking about CDS software seem to fail to appreciate its inherent limitation. In its March 2010 report on the CDS efforts at BWH and Yale, the AHRQ lists the following as its first "lesson learned": "Guidelines should be specific, unambiguous, and clear". With some limited exceptions, I don't see how they can be.
- If it were possible to write code that could generate in any given situation a "specific, unambiguous, and clear" guidance to the clinician, we could try to treat CDS software the same way we treat medical devices. The risks of being wrong (designing bad code, or code that works badly -- analogous to the design defect/ manufacturing defect we see with devices) could be assessed in a meaningful way. That risk, to the extent not mitigated, could be apportioned between the contracting parties in the usual, commercial way.

Thought from PHS Lawyer (cont.)

- The reason we insist on all of the disclaimers and limits on liability is because we know CDS software cannot be written in a way that will generate the "right" patient care answer every time. We tell the users to take the CDS software advice for what it is -- advice -- and then exercise their own independent, professional medical judgment and make the decision.
- Since we can't write code (yet) that we know will be right almost every time, CDS software vendors need to push the liability risk back to the healthcare provider. Diagnosis and treatment is still about professional judgment. But people don't want to hear that. They want to believe that CDS software can quickly come to the point where it delivers „the answer“, and they expect the vendor to stand behind that answer.
- That disconnect between reality and expectations accounts for a good portion of the time and effort devoted to working out the terms of the agreements, especially around the issues of indemnification, warranties, and representations.

Question for the Technical Expert Panel

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. Are there any specific court cases where a CDS publisher, EHR vendor or hospital was sued for errors or omissions in CDS content?

Discussion/Q&A

