Finding A Cure: The Case for Regulation and Oversight of Electronic Health Record Systems

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EHR systems

- Record systems
- Clinical alerts and reminders
- Decision aids
- Links to medical literature
- Computerized physician order entry
- Data analysis tools (enable searches)
- Interoperability
Support for EHR systems

- Pres. Bush 10 year initiative for NHIN
- Congressional bills
- State initiatives
- 2008 campaign issue

Benefits of EHR systems

- Reduce errors
- Improve patient safety
- Improve preventive care
- Facilitate communication
- Cost savings
- Improve search capabilities and promote evidence-based medicine and clinical practice guidelines
Risks of EHR systems

- Cost & burden of adopting EHR systems
  - Only 24% of physicians & 5% of hospitals had EHR systems in 2005
- Time investment
- Potential for errors
- Privacy and security concerns

Legal issues

- Will use of decision support be a defense?
- Will EHR system vendors always be sued in medical malpractice cases?
- How will failures of complex EHR systems be proven?
- Faithfully recording all medical interventions can facilitate discovery of truth
- EHR systems will allow for electronic searches of medical records
Federal regulation needed

- Oversight is provided solely by CCHIT, an industry-based organization
  - Testing lasts only 1 day; applicants are given testing scenarios; CCHIT criteria don't address reliability, safety, usability
- Federal regulation should:
  - incentivize EHR system adoption
  - establish quality control

Potential regulatory agencies

- FDA
- CMS
- Newly created agency
Role of government

- Funding to encourage adoption of EHR systems: tax credits, grants, etc.
- Establish EHR system approval and monitoring processes
  - EHR System Oversight Committees (SOCs)
  - Field testing of new products for 6 months
  - Ongoing monitoring

EHR system criteria

- Reliability and safety
- Interoperability
- Audit trails
- Security requirements
- Decision support mechanisms
National research database

- De-identified EHRs sent to national database
- Accessible to researchers who apply to regulatory agency
- Allow for review of millions of files and long-term observational studies
- Fill knowledge gaps and promote evidence-based medicine

Article

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