Strategic and Policy Implications of Unintended Consequences of HIT and HIE

Meryl Bloomrosen, AMIA
Julie J. McGowan, Regenstrief Institute and Indiana University
Doug Peddicord, Washington Health Strategies Group
Dean Sittig, University of Texas Houston
Justin Starren, Northwestern University Feinberg School of Medicine

AMIA Annual Symposium
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Participants

• **Meryl Bloomrosen**, AMIA, moderator
• **Julie McGowan**, Regenstrief Institute and Indiana University
• **Doug Peddicord**, Washington Health Strategies Group
• **Dean Sittig**, University of Texas Houston
• **Justin Starren**, Northwestern University Feinberg School of Medicine
Session Format

• Welcome, Introductions, Goals and Objectives, and Setting the Stage - Meryl

• Panelist Remarks
  • Overview of UCs and Strategic and Policy Considerations - Justin
  • Current Legislative and Policy Landscape - Doug
  • Exchanging Health Information (HIE) - Julie
  • Electronic Health Records (EHRs) and the Need for Comprehensive Monitoring and Evaluation - Dean

• Question and Answer Session With Audience - All
  • Why are strategic and policy considerations of UCs an ongoing critical priority?
  • What programs are working and how do we know?
  • What are the consequences of doing nothing?
  • What are possible action items and next steps?
Session Goals and Objectives

• Discuss potential unintended consequences of HIT- and HIE-related policy, guidance, and regulatory, legal, or legislative efforts

• Explore strategic and policy related implications of unintended consequences of HIT and HIE

• Identify where national policy development and other actions could help prevent UCs from occurring or mitigate the impact if they did

• Leverage AMIA’s ongoing work on “Anticipating and Addressing Unintended Consequences of HIT and Policy”
Setting the Stage

- Continued unprecedented national attention on exchange of health information (HIE) and health information technology (HIT).
- Many factors can potentially and negatively affect adoption or use of HIT and/or (HIE).
- Unintended consequences (UC) are outcomes of actions that are not originally intended in a particular situation.
- Some events may be sudden and obvious in nature (e.g., a natural or man-made disaster).
- Other events might unfold more slowly and almost silently over a period of time, causing a slow-motion unfolding of events that may not be obvious until the process has played out.
• Events may not stem from a single activity, but rather occur as a result of cascading events – a set of plausible but structurally different circumstances that come together to create UCs with more widespread, strategic, and/or systematic implications.

• Some UCs can be anticipated, addressed or mitigated by those individuals or organizations experiencing the consequences.

• Other UCs are likely to have serious negative impacts unless action is taken at a national or strategic level to help identify and then prevent or mitigate them.
Unintended Consequences

Justin Starren
Northwestern University
Feinberg School of Medicine
UCs of Health Policy and Programs

- Often some time has to pass before the full scope and impact of UCs are revealed.
- Over time new programs come to operate in different environments that originally envisioned.
- Political realities often deter policy modifications and refinements to correct UCs.

Source:
Unintended Consequences of Health Policy Programs and Policies: Workshop Summary (2001) Institute of Medicine (IOM)
http://www.nap.edu/openbook.php?record_id=10192&page=18
Anticipating and Addressing the Unintended Consequences of Health Information Technology (HIT) and Policy:

Meeting Co-Chairs

Nancy M. Lorenzi, PhD, MS, MA, FACMI
Professor of Biomedical Informatics, Vanderbilt University School of Medicine and Clinical Professor of Nursing at the Vanderbilt University School of Nursing

Justin Starren, MD, PhD, FACMI
Director, Biomedical Informatics Research Center and Associate Medical Director for Informatics, Marshfield Clinic
Not a new idea...

**Quite often, good things have hurtful consequences**

- Aristotle, 384-322 B.C.

[Everyone is] led by an **invisible hand** to promote an end which was no part of his intention.

- Adam Smith, *Wealth of Nations*, 1776

The best laid schemes o' Mice an' Men, Gang aft agley

—Robert Burns, *To a Mouse*, 1785

**The Unanticipated Consequences of Purposive Social Action.**

Describing Consequences: Desirability

• Is the outcome positive, negative or mixed (good for some, bad for others)
Describing Consequences: Direct vs. Indirect

• Does the input cause the consequence directly or is there a chain of events?
Describing Consequences: Anticipatability

Can such events be anticipated?

Focus of ONC and AHRQ tools development.

Focus of Hazard Model efforts

Predictable: Experts may Predict
Anticipate with effort
Total Surprise
Describing Consequences

Inputs
- Technology
- Human and Cognitive
- Organizational
- Fiscal
- Policy and Regulation

HIT

Outputs
- Type of Consequence
- Care Process
- Social/Legal
- Fiscal
- Technology

Stakeholder (Those Affected)
- Patient
- Provider
- Organization
- Vendor
- Payer
- Government
The Legislative, Political and Policy Environment

Doug Peddicord, President
Washington Health Strategies Group
The Current Environment

With Congress and the legislative process at a complete impasse, expect the future funding environment to be extremely challenging, with the threat of a shutdown over FY 12 appropriations and a potential 4% cut in discretionary spending for FY 13, with a 2% reduction in Medicare hospital and physician payments, a 7.8% reduction in NIH and other agency funding.

In the meantime, health policy is being driven (and made) in the agencies (where HIT is favored) with varied and unpredictable results.
Multiple New Policies, Regulations, Initiatives, and Programs

- State Health Information (State HIE) Exchange Cooperative Agreement Program
- Beacon Evidence and Innovation Network (BEIN)
- State-based health insurance exchanges implementation
- MU incentives implementation
- Meaningful Use of Electronic Health Records Final Rule
- Stage 2 + Meaningful Use Objectives
- Nationwide Health Information Network Exchange
- Virtual Lifetime Electronic Record (VLER)
- Blue Button Initiative
- Standards and Certification Criteria for Electronic Health Records
- ANPRM Metadata Standards
- HITECH Breach Notification Interim Final Rule
- Accounting of Disclosures
- Electronic Prescriptions for Controlled Substances
- ANPRM Common Rule
- FDA Proposed Guidance of Mobile Medical apps
- ONC’s Query Health initiative
- PNC’s Data Segmentation initiative
- ICD-10 implementation
• **DHHS Text4Health Task Force** issues recommendations for HHS’ role in encouraging and/or developing **health text messaging and mobile health programs**.

• In October 2011 **NIST** issues draft guidance on Technical Evaluation, Testing and Validation of the **Usability of Electronic Health Records** (NISTIR 7804) for public comment.

• **DHHS (September 2011)** plans to create a **database of health care claims information to facilitate comparative-effectiveness research**.

• **CLIA Program and HIPAA Privacy Rule; Patients’ Access to Lab Test Reports**- CMS issues a proposed regulation that a laboratory to provide access to completed test reports.

• **ONC’s e-Consent Project** addresses "whether and when" providers can share patients' data and to figure out how best to share electronic health data between patients and providers.

• **ONC’s Million Hearts Challenge** invites innovators and developers to create applications that activates and empowers patients to take charge of their cardiovascular disease.

• **SAMHSA** provides up to $13.2 million in new grants to support **the adoption of health IT in organizations serving people with mental and substance use disorders**.
Exchanging Health Information (HIE)

Julie McGowan
Regenstrief Institute and Indiana University
A Word about Unintended Consequences and Unanticipated Consequences of HIE

- Unintended Consequences are caused by the implementation of HIE.
- Unanticipated Consequences happen during the process to affect its implementation, functionality, and sustainability.
  - SRDs, RHIOs, Beacons
Past Policy with Negative Impact on HIE

- **Stark Statute – Early 2000**
  - Telemedicine
  - Antitrust, Referrals, Fair Market Value

- **HIPAA II (HITECH)**
  - Self-pay Provision for Information Exclusion
  - Secondary Use / Cost of data capture
Health Information Exchange and It’s Unintended Consequences

What is HIE?

- EHR is an Application
- HIE is a Capability Linking EHR Data
- A Focus on HIE UCs:
  - Technological
  - Organizational
  - Personal / Patient
Technological UCs

• The Vendor Promises
  • The EHR-based HIE
  • Telemedicine Deja-Vu

• The Linking of Disparate Systems
  • Data to Data Mismatch
  • Patient Mismatch
Organizational UCs

• Lack of Sustainability
  • Loss of Access
  • Loss of Small PC Offices

• Legal Issues
  • Attorneys Know Best
  • Crossing State Lines
    • Telemedicine Revisited
Personal / Patient UCs

- Provider Disagreements
- Impact of HIPAA Decisions across Institutions
- Public Health Mandates
- What is Real Meaningful Use in an HIE Environment?
Policy Implications for HIE UCs

Two Major Policy Recommendations:

1. UIs to Mitigate Patient Matching Issues

2. Federal Preemption of State Laws that Restrict Access to Patient Data for Care Purposes
Strategic Policy Recommendations for Mitigating Unintended Consequences of Electronic Health Records

Dean F. Sittig
A comprehensive EHR monitoring framework: 5 essential components

1. **Reporting EHR-related hazards and adverse events** – both voluntary and trigger-based

2. **Enhanced EHR certification program** - high-quality software development practices are used, all features meet minimum usability standards & all reported hazards remediated

3. **Self-assessment tools** to address the 8 dimensions of safe and effective EHR use

4. Random, unannounced, **on-site inspections of EHRs** as implemented and used

5. **Investigation of serious EHR-related adverse events** by a nationally recognized, independent, outside group.

Sittig & Classen. JAMA 2010 Feb 3;303(5):450-1; Classen & Bates. NEJM 2011 Sep 1;365(9):855-8
What is needed to create the EHR monitoring framework?

- Development of comprehensive, socio-technical EHR hazard **reporting framework** (AHRQ – common format)
- Development & validation of **triggers** for EHR hazards
- Agreement on & Endorsement of EHR **usability standards** (NIST)
- Development & validation of **EHR assessment tools**
- Definition of EHR-related errors that should be investigated

Open Discussion

• What are other potential UCS and relevant policy considerations?
• Why are strategic and policy considerations of UCs an ongoing critical priority?
• What programs are working and how do we know?
• What are the consequences of doing nothing?
• What are possible action items and next steps?
Selected Resources

- The Joint Commission Safely implementing health information and converging technologies
  http://www.jointcommission.org/assets/1/18/SEA_42.PDF


  http://www.nap.edu/openbook.php?isbn=0309057930

- Unintended Consequences of Health Policy Programs and Policies: Workshop Summary (2001) Institute of Medicine (IOM)
  http://www.nap.edu/openbook.php?record_id=10192&page=18

- National Strategic Plan for Public Health Preparedness and Response


- The Rhetoric of Reaction: Perversity, Futility, Jeopardy Albert O. Hirschman


Thank You!

Contact

Meryl Bloomrosen
Vice President for Public Policy and Government Relations
AMIA
4720 Montgomery Avenue, Suite 500
Bethesda, MD 20814
301.657.1291
meryl@amia.org