Research Networks as Catalysts for Learning Health Care Systems

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Themes

- How modern research networks have evolved
  - DPM has played a key role
- Why we are struggling to fulfill the promise of big data
- How networks can move us forward
  - Via learning health care systems

Data networks were born of public health necessity

- Vaccine safety research required “large linked data bases”
- 1991 – Vaccine Safety Datalink project initiated
- For a decade, VSD sites sent large patient-level datasets to CDC – “data pooling”
- 2001 – HPHC joined the VSD project
Platt et al advocated distributed data models for multi-site studies

A concerned Congressman requested VSD’s data (2001)

- Dan Burton (R-Indiana)
  - Grandchild with autism
  - Chair of House Government Reform Committee

- Criticisms of VSD Project
  - Independent evaluation not conducted
  - Data not accessible to other researchers
Privacy at Heart of Vaccine Safety Inquiry

Health: A congressman looking into autism might subpoena a database that contains medical records.

By VICKI KEMPER
Times Staff Writer

May 3 2002

WASHINGTON -- An aggressive effort by Rep. Dan Burton (R-Ind.) to investigate whether childhood vaccines can cause autism has set up a political showdown over the medical privacy of 8 million HMO patients, more than 6 million of them Californians.

Scientists said Thursday that the public-private research partnership set up to protect all Americans from deadly diseases and bioterrorist attack could be undermined if Burton subpoenaed the project's huge database.

Rep. Henry A. Waxman (D-Los Angeles) urged Burton in a letter Thursday "to reverse course."

But Burton made no such promise. "While I am not poised to issue a subpoena at this time, I will not foreclose my right to do so at some point if events warrant such action," he said in a response.

Burton's letter criticized the vaccine project's methods. He said he was waiting to see if the "research procedures" to be used in a compromise offered by the Centers for Disease Control and Prevention would be acceptable.
This crisis prompted VSD to adopt one of the first distributed data models.
Distributed data models avert key problems at 3 levels:

- Patients – protect confidentiality
- Researchers – reduce concerns about others re-using data
- Health care system executives – prevent data misuse to cause reputational or competitive harm

Many national research networks have adopted and refined this approach

- HMO Research Network (now the Health Care Systems Research Network), 1994
- Cancer Research Network, 1999
- Cardiovascular Research Network, 2004
- Sentinel, 2008
- Mental Health Research Network, 2010
- PCORnet, 2013
- Addiction Research Network, 2015
Intussusception Risk after Rotavirus Vaccination in U.S. Infants

W. Katherine Yih, Ph.D., M.P.H., Tracy A. Liu, M.D., M.P.H., Martin Kulldorff, Ph.D., David Martin, M.D., M.P.H., Cheryl N. McMahill-Walker, M.S.W., Ph.D., Richard Platt, M.D., Nandini Selvar, Ph.D., M.P.H., Mano Selvan, Ph.D., Grace M. Lee, M.D., M.P.H., and Michael Nguyen, M.D.

BACKGROUND

International post licensure studies have identified an increased risk of intussusception after vaccination with the second-generation rotavirus vaccines RotaTeq (RV5), a pentavalent vaccine and Rotarix (RV1), a monovalent vaccine. We studied this association among infants in the United States.

METHODS

The study included data from infants 5.0 to 36.9 weeks of age who were enrolled in three U.S. health plans that participate in the Mini-Sentinel program sponsored by the Food and Drug Administration. Potential cases of intussusception and vaccine exposure were identified from the Vaccine Adverse Event Reporting System.

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Risk of Intussusception after Monovalent Rotavirus Vaccination

Eric S. Weintraub, M.P.H., James Baggs, Ph.D., Jonathan Duffy, M.D., M.P.H., Claudia Vellozier, M.D., M.P.H., Edward A. Belongia, M.D., Stephanie Irving, M.H.S., Nicola P. Klein, M.D., Ph.D., Jason M. Glanz, Ph.D., Steven J. Jacobsen, M.D., Ph.D., Allison Naleway, Ph.D., Lisa A. Jackson, M.D., M.P.H., and Frank DeStefano, M.D., M.P.H.

BACKGROUND

Although current rotavirus vaccines were not associated with an increased risk of intussusception in large trials before licensure, recent postlicensure data from international settings suggest the possibility of a small increase in risk of intussusception after monovalent rotavirus vaccination. We examined this risk in a population in the United States.

METHODS

Participants were infants between the ages of 4 and 34 weeks who were enrolled in six integrated health care organizations in the Vaccine Safety Datalink (VSD) project.

Why we are struggling to fulfill the promise of big data

- **Vision:**
  - Use rich clinical data to create generalizable knowledge, and apply it in real-life health care

- **Falling short:**
  - Many more people need to be able to access and use the data
  - People internal and external to embedded research groups need to work closely together

Kaiser Permanente Northern California is a rich environment for research

- 4.1 million patients
- 9,000 physicians
- 21 hospitals
- Fully electronic health record
Automated Medicine

A Computerized Health Checkup

By David Pletcher

A computerized health checkup system is being developed at the University of California, San Francisco, to replace the traditional blood test. The system uses automated analyzers to test a variety of blood samples, including cholesterol, glucose, and other substances. The analyzers can process a large number of samples in a short amount of time, making the process more efficient and cost-effective.

Taking blood pressure on a 1970s-era monitor.
Division of Research, Kaiser Permanente Northern California

- 50+ faculty-level researchers; 600 people
- Portfolio
  - ½ -- Epidemiology, externally funded
  - ¼ -- Clinical effectiveness, externally funded
  - ¼ -- Delivery science, internally funded
- Volume
  - 350 ongoing projects
  - 350 publications a year (NEJM, JAMA, Annals)

Thinking / believing

Create clinical knowledge (Effectiveness research)

Knowing

Create operational knowledge (Delivery science)

Doing
Barriers to giving outsiders broader access to clinical data
Perspective of a health care system stakeholder

Risks
• Executives – reputational and proprietary issues
• Researchers – competitive threats
• Patients – confidentiality

Costs
• Financial
• Opportunity

Benefits
• Executives – ?
• Researchers – scientific collaboration, credit, funding
• Clinicians – ?
• Patients – ?

Vendors of “big data” technologies don’t offer what health care systems need

<table>
<thead>
<tr>
<th>We have . . .</th>
<th>We need . . .</th>
<th>They offer . . .</th>
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<tbody>
<tr>
<td>Raw material – demographics, ICD-10s, vitals, labs</td>
<td>Machine tools – usable variables, e.g. “severe congenital heart disease”</td>
<td>Analytics and predictive models – the easy part</td>
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Thanks to Jason Jones, VP, KP Info Mgmt for Care Trans
Research networks can be catalysts for learning health care systems

- Multi-way sharing of knowledge, methods, tools
- Distributed data models limit risks
- Examples of three types:
  - Facilitated case identification
  - Clinical decision support
  - Patients-like-me tools

Facilitated case identification: MDPHnet and Electronic Support for Public Health (ESP)

Software and architecture to extract, analyze, and transmit electronic health information from providers to public health

- Scans codes in electronic medical record data for patients with conditions of public health interest
- Generates secure electronic reports for the state health department
- Designed to be compatible with any EMR system

Mike Klompas
Electronic Support for Public Health (ESP)

Practice EMR's → ESP Server → Health Department

- diagnoses
- lab results
- meds
- vital signs
- demographics

electronic case reports or aggregate summaries

*JAMIA* 2009;16:18-24
*Am J Pub Health* 2012;102:S325–S332

Current Modules

- Notifiable diseases
- Influenza-like illness
- Vaccine adverse events
- Chronic diseases
Clinical decision support: Risk Stratification Tool (RISTRA)
David Vinson, Uli Chettipally, Mary Reed, et al

- Physicians often want to estimate the risk of an adverse outcome for specific diagnoses
- Prediction scores are cumbersome to calculate by hand
- Risk Stratification Tool draws data from Epic and the user, creates a risk score – in real time

In pulmonary embolism, accurate risk assessment can lead to better outcomes

- Clot in blood vessels to lungs
- Can cause death, but risk varies widely
- Patients are often hospitalized
- Low-risk patients can be identified by risk scores and managed as outpatients
Risk stratification tool was tested in a clustered non-randomized controlled trial

- Intervention (10 EDs)—education, ongoing promotion, gift cards x 3
- Control (11 EDs) – without full intervention
- Outcomes
  - Outpatient management = Discharge home or to short-term outpatient observation
  - Safety: 5-day PE-related returns, 30-day all-cause mortality, admission to hospital from outpatient observation
- Difference-in-difference design over 8 months
Outpatient management of PE increased.

\[ \% \text{ of pts with outpatient management} \]

Pre Post

Intervention Control

\[ \% \text{ of pts with outpatient management} \]

\[ \text{and safety outcomes were equivalent} \]
Patients-like-me-tools: Cancer Prognostic Tool

Problem:
- Many patients with cancer are sicker than those enrolled in published trials
- Patients (and their doctors) want to know the outcomes of patients who look like them

Informatics solution:
- Develop a tool to rapidly identify patients similar to a patient of interest, and show their outcomes

With the Cancer Prognostic Tool,* the oncologist can:

- Rapidly select cancer patients with a specific diagnosis
- Select patients based on cancer stage, age, sex, and comorbidity score
- Select those who had specific treatments
- Generate survival curves

* In prototype
Cancer Prognostic Tool development draws together multiple stakeholders

- Physicians
- Researchers – cancer, biostatistics, health care delivery
- Informatics specialists – data architects, user workflow experts
- Physician education specialists
- Patients
What will health care look like in 10 years?

Informatics (Big Data) > Genomics

- Clinical decision support
- Telemedicine
- Personalized care

Research can miss being translated to practice

A problem of interest

Assemble relevant data

Analyze data

Interpret results

Journals

Improve practices?

Decision to study

Friedman C IOM 2015
Tools developed and shared via research networks can close this gap

A problem of interest

Tools for data management and analysis

Assemble relevant data

Analyze data

Interpret results

Tools to tailor messages

Deliver messages to decision makers

Take action to change practice

Tools to measure practice change

Decision to Study

Summary

- Research networks have potential to transform health care
- To fulfill this promise, we need to focus more on the needs of clinicians and patients
- We can develop tools that integrate the needs of multiple stakeholders