Data Science Against Disease

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Does the fact that something can be measured make that something relevant?

or

Maybe both?
The provision of access to clinical trial results that include patient-level data is generating much debate. A growing chorus of transparency advocates is pushing for open access to these data...
Improving Patient Safety through Transparency

Allen Kachalia, M.D., J.D.

Transparency — especially when things go wrong — is increasingly considered necessary to improving the quality of health care. By being candid with both patients and clinicians, health care organizations can promote their leaders’ accountability for safer systems, better engage clinicians in improvement efforts, and engender greater patient trust....

Last year, less than two thirds of staff members reported having a favorable perception of their hospital’s openness in communication, and less than half reported that their hospitals respond to errors in a non-punitive way.
Committee on Strategies for Responsible Sharing of Clinical Trial Data

Session presentations and discussion will inform the development of an interim report that will be released for public comment in January 2014.

The interim report will concisely characterize the landscape of clinical trial data and data sharing activities with respect to the Committee’s tentative findings on:

1) Key elements of and approaches to data sharing activities (to clarify definitions and develop a shared nomenclature)

2) Guiding principles that underpin responsible sharing of clinical trial data.
In Stunning Win For Open Science, Johnson & Johnson Decides To Release Its Clinical Trial Data To Researchers

Matthew Herper, Forbes Staff
I cover science and medicine, and believe this is biology's century.

PHARMA & HEALTHCARE | 1/30/2014 @ 7:09AM | 17,254 views
Disease Knowledge Networks: multi-level mechanistic hypotheses

- Syndrome
- Symptom/Traits
- Cellular Systems/Signaling Pathways
- Proteome/Metabolome
- Genome
- Microbiome
- Envirome
- Internal Mind State
- Interventions

Modified from http://www.phenomics.ucla.edu/phenomics/cognitive_phenomics.htm
Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease
Report from National academy of science, USA, 2011
SHRINE: Enabling Nationally Scalable Multi-Site Disease Studies

Andrew J. McMurry\textsuperscript{1,2,3,4*}, Shawn N. Murphy\textsuperscript{3,5,6}, Douglas MacFadden\textsuperscript{1}, Griffin Weber\textsuperscript{3,7}, William W. Simons\textsuperscript{1}, John Orechia\textsuperscript{8}, Jonathan Bickel\textsuperscript{2,9}, Nich Wattanasin\textsuperscript{5}, Clint Gilbert\textsuperscript{1}, Philip Trevvett\textsuperscript{1}, Susanne Churchill\textsuperscript{3,5}, Isaac S. Kohane\textsuperscript{1,2,3}
Location

• Paris 15th district

Within AP-HP

• HEGP is the most recent acute care hospital within the 38 AP-HP hospitals

• HEGP meets the needs of the 600,000 inhabitants of the Paris south-west
HEGP BDW

Production environment

EHR : Operational Database (ODS)

EHR : Mirrored Database

Biomedical Data Warehouse (BDW)

External Databases

ETL suite (Talend Open Studio)

Evaluation/Research environment

Real time requests

Data Analysis

Data Mining

R

i2b2/tranSMART tools

Business Object

IBM Ilog Rules

EHR/BDW integration
Harvard Medical School to play key coordination role in NIH Undiagnosed Diseases Network

By Raymond MacDougall  Associate Director of Communications, Division of Intramural Research

What’s Wrong With Summer Stiers?
http://www.nytimes.com/2009/02/22/magazine/22Diseases-t.html?_r=3&emc=eta1&

60 Minutes HEALTH & SCIENCE

Hard cases: Investigating rare & tough diseases

NIH Undiagnosed Diseases Program documents two-year pilot as clinic of last resort
Genomic tools prove integral to solving medical mysteries
Cloud computing reduces HIPAA compliance risk in managing genomic data

September 4, 2013

“…a review of data on HIPAA breaches published by the US Department of Health and Human Services (HHS) shows that these concerns are Misplaced.

In fact, by using a cloud-based service with an appropriate security and compliance infrastructure, an organization can significantly reduce its compliance risk…”
HMS Value-added Services Overview

- Biomedical Informatics Capabilities
- Risk-Based Analytics
- Collaboration Design
- Process Design
- Technology Design
- Security and Compliance
Researchers uncover one of the first botnets targeting POS terminals
By Fred Donovan

FDA: We Were Hacked During Government Shutdown
Latest News | Posted: 11 November 2013

Data breaches are significantly underreported, survey of IT pros finds
November 10, 2013 | By Fred Donovan

A disturbing 57 percent of security analysts said that data breaches they investigated or addressed were never disclosed by their companies, according to a blind survey of 200 security professionals...
4 Cyber-security Threats: Data Breach, Theft, Device &/or Infrastructure Attack

Study: Data breaches cost healthcare providers $1.6 billion
Author Name Patrick Ouellette  |  Date February 3, 2014

Wash. Hospital Hit By $1.03 Million Cyberheist
30 APR 13

A New Cyber Concern: Hack Attacks on Medical Devices
The FDA issues guidelines to manufacturers to protect their products

Experts: Cyber Attacks Threaten Hospitals
8.11.2010: By Andy Fell
Experts: Cyber Attacks Threaten Hospitals
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• **Hospitals: 'Soft targets'** "Hospitals are a soft target where a cyber attack can cause a lot of damage quite easily,"

• **'Down for a year'** FBI Special Agent Eric Brelsford described a similar attack on a Chicago-area hospital in 2006 that affected everything from cancer treatments to prescriptions.

• **Identity theft** Medical information is also a rich target for thieves.

• **Waves of time attacks** …By day 16, the nation's hospitals would be in chaos… "If a doctor can get to it, I guarantee a bad guy can,"…

• **Undermines confidence** A security breach can cause a company to fold…"Trust is key in healthcare, and anything that could break that trust is a
People Power!
DATA HARMONIZATION FOR PATIENT-CENTERED CLINICAL RESEARCH

An Institute of Medicine Workshop sponsored by the Patient-Centered Outcomes Research Institute

Meeting goals
1. Inform the work of the Patient Centered Outcomes Research Institute’s (PCORI) National Patient-Centered Clinical Research Network (NCRN) awardees and coordinating center in working toward inter-network data harmonization.
2. Reflect on past efforts and current state of the art approaches to help identify barriers and challenges, share best practices, and identify options for progress in the area of data harmonization.
3. Identify strategic priorities for accelerating data interoperability between PCORI NCRN awardees and existing national data sharing activities.
Mission
The Patient-Centered Outcomes Research Institute (PCORI) helps people make informed healthcare decisions, and improves healthcare delivery and outcomes, by producing and promoting high integrity, evidence-based information that comes from research guided by patients, caregivers and the broader healthcare community.

**PCORI Board Approves $114 Million for Patient-Centered Outcomes Research**

**PCORI Awards $9 Million Contract to Harvard Group to Coordinate National Patient-Centered Clinical Research Network**

**PCORI to Invest $17 Million to Answer Long-Standing Questions About Disparities in Asthma Burden and Care**

**PCORI Awards $88.6 Million in Funding for Comparative Effectiveness Research Projects**
Patient Powered Research Network

- **240,000+ Patients**
- **2000+ Diseases**
- **Top 10 Communities**
  - Fibromyalgia
  - Multiple Sclerosis
  - Major Depressive Disorder
  - Diabetes Type 2
  - Generalized Anxiety Disorder
  - Chronic Fatigue Syndrome
  - Epilepsy
  - Parkinson’s Disease
  - Rheumatoid Arthritis

- **16 mm structured data points**
  - 400,000 symptom reports
  - 350,000 condition PRO scores
  - 150,000 side effect reports
  - 110,000 treatment stop reports
  - 100,000 quality of life scores

- **3 mm free text fields**
  - 2 mm forum conversations
  - 750,000 journal stories
  - 320,000 private messages
  - 90,000 peer-peer comments

- **35 peer-reviewed papers**
  - Networking ‘dose effect’
  - Off-label effectiveness data
  - Data sharing preferences
  - Burden of chronic illness
  - Risk / benefit tolerance
  - Subgroup stratification
  - Refute clinical trial finding

- **Safety monitoring platform**
- **Patient-generated taxonomy**
Challenges in Hypothesis Testing:
From “Big Data” to narrow questions

Total Population → Sampled Population → On Treatment → Reporting Treatment → Reporting Treatment X → Switched Treatment X

Harder questions to answer

The highest priority group we aim to understand
Digital Disease Detection for Hard to Reach Populations, Behaviors and Outcomes

John Brownstein, PhD
@johnbrownstein
Associate Professor
Computational Epidemiology Group, Harvard Medical School
Canadian University Press Annual Conference – Victoria BC

North America's only student press cooperative since 1938.

#NASH74
NASH Plenary Motions
@PlenaryMotion

Motion that nobody else on this bus puke. #nash74
15 Jan 12

Emma Godmere
@godmere

@CUPnash Attention CUPpies: shutting gala down because too many people are sick. Please let us know if you're ill.
#NASH74
15 Jan 12
Number of foodborne illnesses reported each year in the US

By the Centers for Disease Control and

10,000
Number of days from outbreak start to outbreak discovery

- In 1996: 167 days
- In 2010: 20 days

Overall Association

All Medical Products

Twitter AEs via MedWatcher Social vs. FDA AE Reporting System

- General disorders
- Nervous system
- Psychiatric
- Gastrointestinal
  - Skin
  - Injury
  - Vascular
  - Cardiac
- Musculoskeletal
- Immune system
- Respiratory
- Investigations
- Reproductive
  - Infections
  - Ear
  - Metabolism
  - Eye
  - Liver
  - Pregnancy
  - Urinary
  - Blood
Themes:
- Globalization and Partnerships
- Prevention-Based Controls
- Supply Chain Accountability
- Business Process Improvements
- Food Safety Modernization Act
FDA Information Management and Office of Information Management
Strategic Plan Version 1.1 FY2012 – FY2016

September 2012
Innovation at FDA - Innovation 2.0: A cloud-based approach to Innovation in End-stage Renal Disease

Expert Innovators on Innovation Pathway 2.0

http://www.youtube.com/watch?v=txd0P9LUWa0

HHS Secretary Sebelius on FDA’s Innovation Pathway:

http://www.youtube.com/watch?v=OEdmrSaiv00
Last but not least, Physician Leadership

http://www.asco.org/institute-quality/cancerlinq
Peace and Thank you!