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UMMS Biomedical Data Assets & D3Health

Jomol Mathew
University of Massachusetts Medical School

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UMMS Biomedical Data Assets & D3Health

Jomol Mathew, Ph.D.
May 15, 2017
Disclosures:

I have no actual or potential conflict of interest in relation to this program/presentation.
University of Massachusetts is Uniquely Positioned to be a Game Changer in Healthcare

- **Pathways to Clinical Integration**
- **Ethnically Diverse Population In Central Mass**
- **World-class Biomedical Research**
- **World-class Health Informatics**
- **Expertise in Digital Health & Sensors**
Patients generate useful data that is not available to health care providers

We will break down barriers to integrate data & make it available for clinical decision making
Our Clinical and Translational Research Data Ecosystem

Vision: Build an Integrative Clinical & Biospecimen Data Ecosystem to:

• Enable data driven research
• Enable translation of research findings to clinical care
• Make a difference in community and global health
Data Lake holds Clinical data from >2.5 Million patients representative of national diversity

- A rich source of data for studying chronic diseases (e.g. cardiovascular, diabetes)
- A useful tool to study genetic diseases (e.g. Cystic Fibrosis, Parkinson’s)
- A mechanism to link biosamples, molecular data & digital health data to clinical data
**D³Health: Integrating Biomedical Big Data, Analytics, & Decision Support**

**Data Collection**
- Smart/Sensor Data
- Hospital EHR Data

**Data Lake**
- Aggregation
- Data Integration

**Predictive Analytics**
- Pattern Recognition
- Artificial Intelligence
- Algorithms

**Decision Support**
- Knowledgebase with Actionable Intervention Points & Generation of Feedback Loops

- **Patient Feedback**
- **Provider Feedback**

**CLINICAL CARE**
- Targeted Clinical Trials
- Intervention Alerts (e.g. Alter Medication)
- More Effective Precision Therapy

**EDUCATION**
- RESEARCH
Data Lake & D3Health will help us study Diseases..... Continuum of care..... Continuous Learning Cycles...

What causes this disease?

What are the treatment options?

How do I compare to other patients?

Is this condition genetically transferable?

What is involved in the study?

What are the Potential Adverse Events for the new study?

What Treatment is Better for Me/My Patient?

Are there sub-classes within this disease?

Why do some patients develop resistance to drugs?

Why does the disease progress faster for some patients?

Why do some patients respond well/poor to specific drugs?

How does this Patient compare to other patients?

What is the best course of treatment?

Why is this condition geneically transferable?

All there clinical trials targeting the specific genetic alterations found in this patient?
Data Ecosystem Components: Volunteer Registry & e-Consenting System

- Enables Researchers to get a list of patients who have consented to be contacted about upcoming studies

Expanding via
- Social media
- Special population resource center
- Direct to patient tools
- Recruiting via EHR once EPIC in place
Data Ecosystem Components: OpenSpecimen for BioBanking

**Single Shop for Biospecimens**
- Consent, collect & barcode
- Create derivatives & keep lineage
- Search & find
- Scan & distribute
- Link to clinical data in Data Lake & facilitate query and request of biospecimens from central biobanks (blood, tumor, microbiome)
Data Ecosystem Components: LabArchives for Collection & Management of Research Data

- Electronic Lab Notebook
- Enables easy access to data between lab members and collaborators
- Supports secure data trail (necessary for commercialization)

- ~ 300 Users are using LabArchives
Data Ecosystem Components: Synergist for Searching & Sharing Research Data

“Amazon” of Research data
- Catalog & Share Experimental Metadata
- Search and Discover Data & Collaborate
- Connect & Gain Insights
- Publish & Submit Data to External Data Banks
Data Ecosystem Components: OnCore Clinical Trials Management System

- A leading CTMS platform at Academic Medical Centers
- Integrates well with EPIC to
  - improve patient safety
  - Improve protocol compliance

- Went live on 10/21/16
- Onboarding complete by 07/01/2017
- EPIC Integration & go-live by 10/01/2017
EHR Primary Concerns:

Comprehensive management of a patient over time

Provide high-quality patient care

Patient safety

Clinical user efficiency and productivity

Research billing compliance (ability to separate clinical and research charges)

CTMS Primary Concerns:

Comprehensive management of a study

Catalogs and tracks all clinical trial processes

Administrative activities e.g., budgeting, approval tracking, study design, randomization

Investigator compliance to administrative requirements

Subject protocol compliance

Direct reporting to sponsors

Overlapping Needs:
- Basic study information
- Patients associated with studies
- Research billing definition for study
ONCORE & EPIC Integration: Empowers Research & Care

• Benefits for Researchers
  • Achieve better recruitment for trials
  • Study Teams can track the subjects
  • Streamline collection of biospecimens

• Benefits for Care Providers
  • See that a patient is on a clinical trial in the banner
  • Get detailed information on the protocol
  • Identify clinical trials for patients

• Benefits for Patients
  • Get access to latest care especially when options are limited
Quantifying Patient Experiences: Patient Reported Outcomes

• Patient Reported Measures
  • Compendium describing PRM use across UMass community to facilitate prioritization of Epic build
  • Domain Examples: QoL, mental health, physical functioning, pain, PTSD, Tobacco/Alcohol/Drug use, etc.
  • Settings: Inpatient, Outpatient, ED
  • Populations: Adults, Pediatrics, Psych

• PRM administration
  • Currently Collected using: REDCap
  • Working with Epic Team to prioritize and build
Honest Broker: Connect Research & Clinical Data

- Enables integrative queries & extraction
- Avoid duplication of data
- Full Traceability & Accountability
- Compliance with HIPAA & regulations
Rules for Diving into the Data Lake:
Data Access Policies and Processes @ UMMS

**Key Policies:**
- **Aggregate or De-identified data:** No IRB approval required
- **Protected Health information (PHI):** IRB approval required
- **BAA & Security clearance required while engaging third-party vendors**

**Who Can Access Data:**
- Research
  - Faculty: Instructor or above
  - Any member of a research team
- Quality & Operations
  - Administrators and staff at UMMHC or UMMS

**How:**

www.umassmed.edu/IT/CDP
37 structured interviewees in Germany, UK, Switzerland, and France indicated strong support for the proposed Electronic Health Records for Clinical Research (EHR4CR). All interviewees reported that using the platform for assessing feasibility would enhance the conduct of clinical trials and the majority also felt it would reduce workloads.
UMMS: DLR Can Help Researchers in Better design of Trials & Identify Cohorts

e.g. Botulinum Toxin for Pelvic Pain in Women With Endometriosis (NCT01553201)

- How does protocol design (exclusion/inclusion) impact recruitment?
- How can other sites selected for a multisite study?

INCLUSION CRITERIA:
- Female gender
- Age between 18 and 50
- History of endometriosis
- Persistent pelvic pain for at least 3 months
- Pelvic floor spasm
- Negative pregnancy test
- Willing to use reliable method of contraception for the month after botulinum toxin injection
- Willing and able to give informed consent
- Willing and able to comply with study requirements

EXCLUSION CRITERIA:
- Women with other causes of chronic pelvic pain including infectious, gastrointestinal, psychological disorders, fibromyalgia and chronic fatigue syndrome based on review of medical history within 1 year of first study visit.
- Untreated severe cervical dysplasia or other gynecologic condition within the past year based on medical record review.
- Significant abnormalities in the physical or laboratory examination including renal and liver function more than twice the normal range
- Hysterectomy and bilateral salpingo-oophorectomy
- Pregnancy
- Lactation
- Allergy to albumen or botulinum toxin
- Presence of antibodies to botulinum toxin or loss of response to previous injections for any indication
- A known neuromuscular junction disorder such as myasthenia gravis or Eaton-Lambert syndrome
- History of urinary or fecal incontinence
- Known pelvic prolapse
UMMS: How to do Feasibility/Recruitment? Use DLR & Aggregate Search Capabilities

INCLUSION CRITERIA:
- Female gender
- Age between 18 and 50
- History of endometriosis

EXCLUSION CRITERIA:
- Fibromyalgia
- Cervical dysplasia
- Renal and liver function

CURRENT

Q2 2017
Integrated Clinical-Genomic Searches
e.g. Female, Asian, NSCLC with EGFR mutations receiving Tarceva
- currently not on other trials
- consented for future contact

www.umassmed.edu/IT/CDP
UMMS: How to do Feasibility/Recruitment? Use DLR & Explore De-identified Data

Comorbidities

Concomitant Medications

Labs
Leveraging EHR Data for Outcomes and Comparative Effectiveness Research in Oncology

Frank J. Manion, MS, Marcelline R. Harris, PhD, RN, Ayse G. Buyuktur, MPH, MS, Patricia M. Clark, PhD, RN, Lawrence C. An, MD, and David A. Hanauer, MD, MS

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PHARMA COEPIDEMIOLOGY AND DRUG SAFETY 2013; 22: 413–422
Published online 24 February 2013 in Wiley Online Library (wileyonlinelibrary.com) DOI: 10.1002/pds.3413

ORIGINAL REPORT

Comparative effectiveness research using electronic health records: impacts of oral antidiabetic drugs on the development of chronic kidney disease

Andrew L. Masica, Edward Ewen, Yahya A. Daoud, Dunlei Cheng, Nora Franceschini, Rustam E. Kudyakov, James R. Bowen, Emily S. Brouwer, Dennis Wallace, Neil S. Fleming and Suzanne L. West
EHR Data Can help in Risk Prediction Studies

Identifying primary care patients at risk for future diabetes and cardiovascular disease using electronic health records

Marie-France Hivert, Richard W Grant, Peter Shrader and James B Meigs

Predicting Hospital-Acquired Infections by Scoring System with Simple Parameters

Ying-Jui Chang, Min-Li Yeh, Yu-Chuan Li, Chien-Yeh Hsu, Chao-Cheng Lin, Meng-Shiuan Hsu, Wen-Ta Chiu

Published: August 24, 2011 • https://doi.org/10.1371/journal.pone.0023137
EHR Data along with Biospecimens and Genomic data can aid in Pharmacogenomics studies

**Pharmacogenomics**
(doi:10.2217/pgs.11.164)

**Research Article**

*Predicting warfarin dosage in European–Americans and African–Americans using DNA samples linked to an electronic health record*

Andrea H Ramirez, Yaping Shi, Jonathan S Schildcrout, Jessica T Delaney, Hua Xu, Matthew T Oetjens, Rebecca L Zuvich, Melissa A Basford, Erica Bowton, Min Jiang, Peter Speltz, Raquel Zink, James Cowan, Jill M Pulley, Marylyn D Ritchie, Daniel R Masys, Dan M Roden, Dana C Crawford & Joshua C Denny*
Validating drug repurposing signals using electronic health records: a case study of metformin associated with reduced cancer mortality

Hua Xu¹, Melinda C Aldrich²,³, Qingxia Chen⁴,⁵, Hongfang Liu⁶, Neeraja B Peterson⁷, Qi Dai⁸, Mia Levy⁵,⁷, Anushi Shah⁵, Xue Han⁴, Xiaoyang Ruan⁶, Min Jiang¹, Ying Li⁸, Jamii St Julien², Jeremy Warner⁵,⁷, Carol Friedman⁸, Dan M Roden⁷,⁹, Joshua C Denny⁵,⁷
Secondary Use of EHR Timestamp data: Validation and Application for Workflow Optimization

Michelle R. Hribar, PhD,² Sarah Read-Brown,¹ Leah Reznick, MD,¹ Lorinna Lombardi, MD,¹ Mansi Parikh, MD,¹ Thomas R. Yackel, MD, MPH, MS,² and Michael F. Chiang, MD, MA¹,²

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UMMS: Researchers can Obtain Detailed PHI/PII Data from DLR

HIPAA Waiver/Authorization + Investigator Study Plan/DCF + Clinical Data Request Form

IRB Documents

Required to Obtain PHI/PII Data for Research Purposes

Must be Consistent!

If you are requesting identifiable data (PHI/PII) from the DLR, you must do so under:

• A HIPAA Waiver and/or HIPAA Authorization
• Other appropriate documentation

www.umassmed.edu/IT/CDP

Study DataMart

Fully Automated Process By Dec 2017

SAS, R, ...
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• Advisory Committee (K. Luzuriaga, C. Kiefe, S. Corvera, M. Koziel, N. Hafer, G. Wolf)
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• Clinical Trial Management Steering Group (M. Koziel & J Mathew Chairs)
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