Developing the Capabilities for Device Surveillance through the Medical Device Epidemiology Network

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April 9, 2012
Some Initial Housekeeping

- To minimize feedback, please confirm that the microphone on your telephone is muted.

- To mute your phone, press the mute button or ‘*6’. (To unmute, press ‘*7’ as well.)

- There will be several opportunities for questions and discussion throughout today’s session. Please use the Q&A tab at the top of your screen to submit your questions into the queue at any point and we will call upon you to state your question.

- We will open up the lines for questions from those participating only by phone at the end of each Q&A session.

- Call the Brookings IT Help Desk at 202-797-6193 with technical problems.
FDA Medical Device Epidemiology Network (MDEpiNet) Initiative

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Mary Beth Ritchey, RN, PhD
Benjamin Eloff, PhD
Fred Resnic, MD, MS
Art Sedrakyan, MD, PhD
Outline

- **FDA MDEpiNet Core:**
  - Postmarket context, mission, objectives, strategies: Danica Marinac-Dabic
  - Contracts and Work Streams: Mary Beth Ritchey
  - Public Private Partnership: Benjamin Eloff

- **MDEpiNet Methodology Center**: Fred Resnic
- **MDEpiNet Infrastructure Center**: Art Sedrakyan
- **MDEpiNet Public Private Partnership**: Benjamin Eloff

- **Next steps**: Danica Marinac Dabic
**Enhanced Surveillance**

- 2014-2019: Postmarket infrastructure allows most evaluation via automatic data collection. In rare instances where additional data needed, patient surveys and disease-based registries created.
- 2019-2024: Sentinal Initiative – * Signal Refinement for identified potential public health concerns
  * Initially claims data, will also include electronic healthcare records
- 2024-2029: Postmarket infrastructure allows most evaluation via automatic data collection. In rare instances where additional data needed, patient surveys and disease-based registries created.
- 2029-future: Continue to innovate and utilize novel methodologies and new technologies to better understand performance and clinical outcomes of medical devices in the postmarket. Ongoing evaluation of postmarket landscape used to provide context for benefit-risk balance for newly developed devices.

**De Novo Data Collection**

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**Administrative and Claims Data**

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**Electronic Healthcare Records**

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**Device-Based Registries**

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**International Consortium of Orthopedic Registries**

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**Alternative Data Collection for Registries**

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**Use of EHR and Claims Data**

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**Secondary analysis of previously collected data**

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**Postmarket Infrastructure and Novel Methodologies**

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Devices ≠ Drugs

• **Put what know about drug regulation aside**
  – Drugs and devices, and the way they are used, are very different
    • A minor drug change can alter its properties – not always true for devices
    • Implanted devices may remain in the body for extended time
    • Discontinuing exposure to a device may be difficult/impossible
    • Devices are very susceptible to manufacturing tolerances and mechanical failures
    • Device use is more dependent on the skills of the operator
    • It is very difficult to blind a patient or user to device exposure

  – The laws governing drug regulation (premarket and postmarket processes/requirements) are very different than those for devices.
    • Multiple RCTs are not the norm in the world of devices
    • Device law allows for a broader interpretation of “valid scientific evidence”
    • Many devices can reach market by bench comparison testing to a predicate
http://www.fda.gov/MDEpiNet

The Medical Device Epidemiology Network Initiative (MDEpiNet) is part of the Epidemiology Research Program (ERP) at the FDA’s Center for Devices and Radiological Health (CDRH). The initiative is a collaborative program through which CDRH and external partners share information and resources to enhance our understanding of the safety and effectiveness of medical devices after they are marketed.

By bridging gaps in evidence, developing datasets and creating new methods of conducting robust analytic studies, MDEpiNet aims to develop new ways to study medical devices that improve the understanding of their safety and effectiveness throughout their life cycle.

CDRH is developing MDEpiNet in stages, with the expectation that it will ultimately become a self-sustaining, independent Public-Private Partnership between the FDA and participating partners. By providing more complete and accurate information on device use and performance, MDEpiNet will help the FDA, the medical device industry, medical professionals, and the American public make better, more informed health care decisions.
MDEpiNet Initiative

MISSION

✓ To develop infrastructure and innovative methodological approaches for conducting robust studies to improve medical device safety and effectiveness understanding throughout the device life cycle.
MDEpiNet Initiative

OBJECTIVES

✓ Improve the paradigm of how medical device knowledge is utilized throughout device life cycle

✓ Leverage partner resources and expertise to create a sustainable, robust infrastructure through which stakeholders will continue to gain valuable knowledge about medical devices

✓ Become fully integrated in the systematic evaluation of medical devices and CDRH decision making
MDEpiNet Initiative

APPROACHES

✓ Systematically evaluate evidence of risks and benefits associated with medical devices
✓ Collaborate with external parties with relevant expertise to determine evidence gaps, study questions, methodologies and best practices
✓ Develop and test innovative methodological approaches for medical device research and regulatory science
✓ Disseminate the findings to all stakeholders
MDEpiNet Conceptual Framework

Translate the results for regulatory decision making and dissemination for patients, clinicians

CDRH Epidemiology Program

MDEpiNet Partners

Combined Evidence

Systematic appraisal of all available evidence

New real world studies to fill the gaps/ Research consortium development
Methodology Work Stream

MDEpiNet Methodology Center: Harvard University
Evidence Synthesis

- Obtain safety and effectiveness estimates, develop and apply modeling techniques, translate results
Compare adverse events between groups, accounting for important device, operator, and patient characteristics.
Existing Gaps

- Identify gaps in existing data sources and develop sustainable infrastructure and methods for addressing gaps to better evaluate medical devices
Infrastructure Work Stream

MDEpiNet Science and Infrastructure Center:
Cornell Weill Medical College
ICOR

- International Consortium of Orthopedic Registries
- Classification and harmonization with UDI
- Demonstration projects: bearing surface, femoral head size, fixed vs. mobile knees, pediatric joints
UDI Work Stream

Incorporated within Methodology Center and Science and Infrastructure Center
UDI

- Identify challenges and opportunities with UDI; demonstrate capabilities for use within EHR and registries
  - Roadmap of potential hurdles and best practices
  - 2 EHR cardiovascular demonstration projects
  - 3 orthopedic registry demonstration projects
The MDEpiNET Methodology Center

Co-Principal Investigators:

Sharon-Lise Normand, PhD
Harvard Medical School & Harvard School of Public Health

Frederic S. Resnic, MD MSc
Brigham and Women’s Hospital & Harvard Medical School

Harvard Medical School
Brigham & Women’s Hospital
Harvard School of Public Health
No Medical Device is Perfectly Safe

Remedy Is Elusive as Metallic Hips Fail at a Fast Rate

Doctors Rethink Widespread Use of Heart Stents
Key Differences in Safety Monitoring

**Medications:**
- Exposure: NDI uniform documentation; available in claims records
- Outcomes: general clinical conditions, rare diagnoses
- Often suitable for population based surveillance

**Devices:**
- Exposure: No existent uniform identification. Initial UDI efforts underway; ? claims requirement for UDI.
- Variable documentation of implant procedure
- Multiple failure modes of interest
- Learning curve; procedural quality
Learning Curve with Novel Device

An evaluation of 107,000 consecutive new VCD deployments in the national NCDR CathPCI dataset demonstrates a clear learning curve in the use of these devices.

Clinical Success Rate vs. Institutional Experience

Clinical Success Rate vs. Average Operator Experience

Average VCD Use per Physician
(Hospitals >2,400 VCD Impants per year)

Source: Resnic FS et al. JACC Interventions Jan 2012
Methodology Center Project Goals

1. Developing evidence-based regulatory science
   – Novel approaches for combining information
   – Identification of methodological gaps
   – Comparative effectiveness and safety studies

2. Implementation of a Unique Device Identifier Demonstration Project
   – Development of an end-to-end (purchaser to point of consumption) UDI tracking system
   – Utilize electronic health records and clinical registries to assess the continued safety and effectiveness of medical devices after they have reached the marketplace
Investigators

• **Statisticians:**
  – Sharon-Lise Normand (HMS & HSPH)
  – Laura Hatfield (HMS)

• **Epidemiologists:**
  – Miguel Hernan (HSPH)
  – Sebastian Schneeweiss (HMS & HSPH)

• **Clinicians:**
  – Frederic Resnic (Brigham & HMS)
  – Joe Drozda (Mercy Healthcare System)
Developing Evidence-Based Regulatory Science and Surveillance

**Combining Information**

- Selection of Medical Device Area & Data Sources
- Protocol Development of Evidence Abstraction
  - From published literature
  - From virtual data bases
- Development of Methodology to Combine Information
  - New measures of evidence
  - Comparison groups
- Proof of Concept: apply to selected devices

**Existing Resources for Evaluation of Medical Devices**

- Identification of Classes of Medical Devices and Data Sources
  - diagnostic, therapeutic, aesthetic, combination
- Evaluation of Gaps in Analytical Approaches
- Identification of Databases & Development of New Methodology
- Proof of Concept: apply to selected devices
Going Forward

• **Tools**: statistical methodologies to use retrospectively and prospectively data (1) to infer cause and effect and (2) validity of assumptions to infer cause and effect

• **Collaborators**: network of multidisciplinary investigators interested in assessing devices

• **Data Sources**: virtual warehouse of post-approval surveillance information
Using the MA state-wide PCI device dataset, we explored the cumulative post-procedure myocardial infarction rate for new drug eluting stent as compared with propensity matched control DES.

Using 38 clinical variables in propensity match a total of 81.5% of 18,277 new stents were analyzed.

Adapted from: Resnic F et al. JAMA November 2010
Using pooled data from three high volume centers, DELTA performed a propensity matched analysis of 859 Fidelis lead implants versus traditional leads. By 25 months of analysis (dashed line) 3% of Fidelis leads had fractured (red line) whereas only 0.1% (1 of 859) alternative ICD leads had fractured.
Unique Device Identifier Demonstration Project

- Dr. Joe Drozda (PI)
- **Site:** Mercy Health System
  - 34 acute care hospitals
  - 2 heart hospitals, outpatient care facilities
  - Over 1200 integrated physicians
  - Skilled nursing and long-term residential care facilities, clinics, and other health-related services
  - One of the nation’s “Most Wired” health care organizations in the U.S. (Hospitals and Health Networks)

- **Professional Society Advisors:** ACC and SCA&I

- Implement a *coronary artery stent* UDI-based surveillance system in the EHR in a multi-hospital system
- Identify obstacles to implementation of the UDI Roadmap & to characterize the effectiveness of interventions to overcome them;
- Assess the validity and utility of data obtained from the EHR and incorporated UDIs for purposes of post-market surveillance
34 ACUTE CARE HOSPITALS
4,396 LICENSED BEDS
36,917 CO-WORKERS
185 PHYSICIAN PRACTICE LOCATIONS
4,659 MEDICAL STAFF MEMBERS
1,235 INTEGRATED PHYSICIANS
$4.05 OPERATING REVENUE (Billions USD)
Define most clinically relevant attributes

Device Manufacturers

GS1

Item Master (GTIN & attribute)

GTIN

GTIN attributes

GHX Data Cleansing as needed

FDA

UDI Taskforce

ACC

Device Manufacturers

Facilitate/negotiate GTIN & attribute adoption

Define most clinically relevant attributes

HTG

Mayo

Geisinger

Kaiser

Intermountain

ROI

Integration Hub

Data Warehouse (GTIN longitudinal clinical data)

Data Marts

Comparative Effectiveness Research

Spend Analysis

Contracting

Procurement

Logistics

Cardiology

Billing

Business Objects/Cognos

Bravo

Lawson

Tecsys

Camtrons Apollo/Epic

Epic

Safety Surveillance

Data

Alerts & Reports

DHX

ACC NCDR

FDA

Drozda J. and Mercy Healthcare

Conceptual Design
**PRIME**
Chickasaw Nation Industries (CNI)

**SUB to CNI**
Harvard Medical School:
Normand (PI)
Dr. Hatfield

**SUB to HMS**
Brigham & Women’s Hospital:
Dr. Resnic (PI)
Dr. Schneeweiss

**SUB to HMS**
Harvard School of Public Health:
Dr. Hernan

**SUB to HMS**
Sisters of Mercy Hospital System
Dr. Drozda (PI)

**FDA**
Statistical/Epidemiological Group:
- Develop novel approaches to enhance post market evaluation of medical devices
- Evaluate existing resources for evaluation of medical devices
- Conduct patient centered outcomes research

**Unique Device Identifier (UDI) Group:**
- Implement a coronary artery stent UDI-based surveillance system in the EHR in a multi-hospital system
- Identify obstacles to implementation of the UDI Roadmap & to characterize the effectiveness of interventions to overcome them;
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The MDEpiNET Science and Infrastructure Center

Principal Investigator:

Art Sedrakyan, MD, PhD
Associate Professor
Weill Cornell Medical College
Director of Comparative Effectiveness Research Program

Co-investigator:

Elizabeth Paxton, MA
Director of Surgical Outcomes and Analysis
Kaiser Permanente
Science and Infrastructure Center

- Developing Conceptual Frameworks for Device evaluation

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<tr>
<th>Idea</th>
<th>Development</th>
<th>2b Exploration</th>
<th>3 Assessment</th>
<th>4 Long-term study</th>
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</thead>
<tbody>
<tr>
<td>Purpose</td>
<td>Proof of concept</td>
<td>Learning</td>
<td>Assessment</td>
<td>Surveillance</td>
</tr>
<tr>
<td>Number and types of patients</td>
<td>Single digit; highly selected</td>
<td>Few; selected</td>
<td>Many; may expand to mixed; broadening indication</td>
<td>Many; expanded indications (well defined)</td>
</tr>
<tr>
<td>Number and types of surgeons</td>
<td>Very few; innovators</td>
<td>Few; innovators and some early adopters</td>
<td>Many; innovators, early adopters, early majority</td>
<td>Many; early majority</td>
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<tr>
<td>Output</td>
<td>Description</td>
<td>Description</td>
<td>Measurement; comparison</td>
<td>Comparison; complete information for non-RCT participants</td>
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<td>Intervention</td>
<td>Evolving; procedure inception</td>
<td>Evolving; procedure development</td>
<td>Evolving; procedure refinement</td>
<td>Stable</td>
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<td>Method</td>
<td>Structured case reports</td>
<td>Prospective develop studies</td>
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<tr>
<td>Outcomes</td>
<td>Proof of concept; technical achievement; disasters; dramatic successes</td>
<td>Mainly safety; technical procedural success</td>
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<tr>
<td>Ethical approval</td>
<td>Sometimes</td>
<td>Yes</td>
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<td>Examples</td>
<td>NOTES video</td>
<td>Tissue engineered</td>
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Sedrakyan et al. A framework for evidence evaluation in implantable device studies. Med Care 2010
Registry: a key infrastructure

• ‘A patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by a particular disease, condition, or exposure, and that serves one or more predetermined scientific, clinical, or policy purposes’ *AHRQ handbook*

• Critical discussion issues:
  – Hypothesis driven?
  – Comprehensive, all inclusive, mandatory
    • National or nationally representative?
Building UDI based device registries: Various models of Implementation

Supply chain

Hospital IT

OR / Cath-lab

UDI entry

Hospital EHRs

Hospital IT

Device Registries

Hospital IT

Implant Clinical Classification

Art Sedrakyan, Md, PhD
The ICOR: Mission and Goals

- Contract Awarded to Cornell-Kaiser
- To advance the research and improve evidence for the safety and effectiveness of orthopedic devices and procedures
  - Harmonize the data among US based and international orthopedic registries
  - Implement a distributed data analysis system and conduct studies to monitor the safety and effectiveness of orthopedic devices
- First study: bearing surface
American Joint Replacement Registry
Australian Orthopaedic Assoc. Registry
Austrian Arthroplasty Register
California Joint Replacement Registry
Canadian Joint Replacement Registry
Central England Joint Registry
Hip and Knee Registry of the Netherlands
Hospital for Special Surgery
Italian Register of Orthopaedic Implants
Kaiser Permanente
Massachusetts General Hospital
Mayo Clinic
New England Baptist Hospital Registry
New Zealand Joint Register
Norwegian Arthroplasty Register
OrthoCarolina
Portuguese Arthroplasty Register
Rush University Med. Ctr. Joint Registry
Slovakian Arthroplasty Register
ScFCOT THA Registry
Swedish Hip and Knee Registers
Scottish Arthroplasty Project
UMass FORCE Registry
Virginia State Registry
Western Slope Study Group

>3,000,000 Patients Worldwide
Why Public-Private Partnerships?

- FDA and stakeholders have limited resources, time & expertise
- Leverage resources and expertise among stakeholders to minimize costs (time and money)
- Open new lines of communication among partners
- Create “value added” for all stakeholders: optimizing economies of scale . . . advancing public health mission
FDA

Enhance Regulatory Decision-Making

Scientific Research

PARTNERING FOR THE PUBLIC HEALTH

Improve Healthcare

Expedit Medical Product Development

GOVERNMENT/ ACADEMIA

PATIENTS/ SOCIETIES/ PAYERS

INDUSTRY
Who are our Partners?

Other Federal Agencies ("public-public" partnerships)
Academia
Public & Patient Advocates
Professional Societies
Industry
3rd Party Payers & Hospitals

So long as . . . The Partnership is:

- Science Driven & Rigorous
- Fair & Inclusive
- Compliant with Federal law, regulation & policy
- Priority to the agency and stakeholders
Alignment of Missions

Alignment of Missions & Goals -- relatively easy
Alignment of cultures is not so easy

- Different timelines
- Different concepts of time
- Different internal processes
- Different decision points
- Different vocabularies

Difficulty is in the details!
Keys to Successful Collaborations

- Collaboration and Stakeholder involvement...early
- Shared risks and benefits
- Develop infrastructure (e.g. registries/databases) that may serve many needs
- Collaboratively identify and address gaps in knowledge
- Leverage resources, expertise, best practices, and know how
- Communicate outcomes/findings: timely, inform future efforts
- Translate findings into medical product development, labeling, and guidelines for public health benefit
Next Steps

- May 14-17, 2012 – Series of FDA Public meetings (FR Notices going out next week) focusing on:
  - National postmarket surveillance system for devices
  - MDEpiNet
  - Registries
- RFA – opportunity
- Public Private Partnership development
Roundtable Discussion and Questions

View this and past Active Medical Product Surveillance webinars at:
http://www.brookings.edu/health/Projects/surveillance/roundtables.aspx