Starting a Successful Career in QCOR:
The Role of Health IT in Effective Cardiovascular Care Delivery and Research

November 3, 2012

Frederic S. Resnic, MD MSc
Chairman, Department of Cardiovascular Medicine
Co-Director, Comparative Effectiveness Research Institute
Lahey Clinic Medical Center
Tufts University School of Medicine
Health IT Impacts QCOR....

Everywhere

The End
Health IT Impacts QCOR...

• **Patient Care:**
  • Clinical Records (EHR)
  • Imaging – storage, distribution (PACS)
  • Clinical Decision Support (CDS)
  • Prescribing, communication, scheduling, billing

• **Population Health Management:**
  • Quality metrics – adherence, benchmarking
  • Levels: Physician, Practice, Hospital, System, Region
  • Measuring resource utilization, patient satisfaction

• **Health Outcomes Research:**
  • Outcomes measurement and associations
  • Comparative Effectiveness (CER, CEA)
  • Surveillance: Syndromic, Medication, Device Safety
Health IT Impacts QCOR...

• **Patient Care:**
  • Clinical Records (EHR)
  • Imaging – storage, distribution (PACS)
  • Clinical Decision Support (CDS)
  • Prescribing, communication, scheduling, billing

• **Population Health Management:**
  • Quality metrics – adherence, benchmarking
  • Levels: Physician, Practice, Hospital, System, Region
  • Measuring resource utilization, patient satisfaction

• **Health Outcomes Research:**
  • Outcomes measurement and associations
  • Comparative Effectiveness (CER, CEA)
  • Surveillance: Syndromic, Medication, Device Safety
Clinical Decision Support Tools

Study Design:

• Randomized interns to receive automated CDS messages regarding VTE prophylaxis for all hospitalized patients at increased risk for DVT or PE.

• Measured proportion of patients treated with prophylaxis as well as clinical events.

• Over 2,500 patients between 200-2005 included.
Clinical Decision Support Tools

Table 2. Prophylactic Measures against Venous Thromboembolism.

<table>
<thead>
<tr>
<th>Measure</th>
<th>Intervention Group (N=1255)</th>
<th>Control Group (N=1251)</th>
<th>P Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mechanical</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compression stockings</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumatic boots</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pharmacologic</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Unfractionated heparin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Warfarin</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Enoxaparin</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Δ = 41%

Kucher N et al.  NEJM 2005
Clinical Decision Support Tools

A recent meta-analysis of studies of CDS tools for control of BP demonstrated only a marginal trend toward improved BP control with CDS as compared with traditional clinical management.

Association of Public Reporting for Percutaneous Coronary Intervention With Utilization and Outcomes Among Medicare Beneficiaries
Population Health Studies:
Reducing CV Readmissions

The U.S. spends substantially more on healthcare per capita, and as a percent of GDP than other developed nations.

Note (1): $US PPP = purchasing power parity.

Led by Dr. William Weintraub, Christiana Care Health System (DE) was awarded a CMS contract to improve quality and reduce the cost of care following revascularization for CAD - The **Bridges** Program.

### BRIDGING THE DIVIDE – ENROLLMENT AND EVALUATION

- **The Population:** Patients with acute myocardial infarction with PCI, CABG
- **Primary outcomes measures:**
  - **Health:** LDL cholesterol below 70 mg/dl, BP below 140/90
  - **Healthcare:** Reduction in readmissions to the hospital and ED visits
  - **Costs:** Reduction in 1 year costs after the initial hospitalization

*Source: Weintraub W. et al. Presented to ACC Informatics Committee October 2012*
Population Health Studies: Reducing CV Readmissions

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.

Figure 2: GEE Modeled Learning Curve from 107,000 Deployments of Novel VCD

Source: Resnic FS et al. JACC Interventions Jan 2012
Registries for Methodology Development: Device Learning Curve

.... And provides insights into training/learning differences with specific devices as well as “steady-state” performance and safety.

Source: Sarma A., Normand SL and Resnic FS: Preliminary Analysis
Health IT Impacts QCOR…

- **Patient Care:**
  - Clinical Records (EHR)
  - Imaging – storage, distribution (PACS)
  - Clinical Decision Support (CDS)
  - Prescribing, communication, scheduling, billing

- **Population Health Management:**
  - Quality metrics – adherence, benchmarking
  - Levels: Physician, Practice, Hospital, System, Region
  - Measuring resource utilization, patient satisfaction

- **Health Outcomes Research:**
  - Outcomes measurement and associations
  - Comparative Effectiveness (CER, CEA)
  - Surveillance: Syndromic, Medication, Device Safety
Basic Truth: No Medical Device is Perfectly Safe

Doctors Rethink Widespread U

In Data for Heart Devices, Parts Are a Blind Spot

Experts say there is a dearth of information about the performance of the wires that connect defibrillators to the heart.

By BARRY MEIER
Published: October 16, 2007

Medtronic’s decision to stop selling a widely used part for implanted heart devices underscores the dearth of safety monitoring of such medical devices.
Device Adverse Event Reporting Today

- Primary responsibility of healthcare facilities to report medical device failures and complications to manufacturers. Must report all related deaths.
  - FDA receives >300,000 reports per year
  - GAO estimates <0.5% events reported

- Major Failures of Adverse Reporting Today:
  - No “denominator” information
  - Lack of (implemented) unique device identification
  - Poor quality reports; not interpretable
  - Influenced by media reports, publicity as much as by clinical and safety concerns
Key Differences Between Drugs and Medical Devices

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

**Devices:**
- Exposure: No uniform identification; ? claims requirement for UDI.
- Variable documentation of implant procedure
- Multiple failure modes of interest
- Learning curve; procedural quality
- Rapid Iteration / Life Cycle

Resnic FS
Automated Safety Surveillance Systems
Idealized Safety Monitoring System

Monitoring System

- Continuously updated
- Array of statistical analytic options
- Monitor multiple analyses simultaneously
- Flexible Alert notification
- Generic structure
- Widely accessible – feedback to source sites

Distributed Data Ownership

Expectation and Risk Adjustment

Reports

Alerts

Safety Analyst
Welcome to DELTA

Data Extraction and Longitudinal Time Analysis System

Engineered to support dynamic safety monitoring in healthcare utilizing various statistical methods.

Supported by grant R01-LM08142 from the National Library of Medicine.

Developed by Coping Systems, Inc.
Delta Version V3.0.1.19a

Links

Frederic S. Resnic, MD, MSc, FACC
Michael Matheny, MD, MS, MPH
Lucila Ohno-Machado, MD, PhD
Coping Systems, Inc.
DELTA2 Documentation Wiki

BRIGHAM AND WOMEN’S HOSPITAL
Specializing in care for a lifetime
Data Sources: Clinical Registries for Surveillance and Outcomes Research

- **Single Center Voluntary**
  - Duke Database
  - Brigham
  - Many others
- **Multi-Center Voluntary**
  - Northern New England
  - ICD Consortium
- **National Voluntary**
  - NCDR: PCI, ICD
  - CAS
- **Regional Mandatory**
  - MA PCI
  - NY PCI
- **Universal Mandatory**
  - InterMACS
  - TVT

Cost vs. Reliability:
- **Lower Cost, Lower Reliability**
- **Higher Cost, Data Reliability**
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.

Those 25 months of delayed recognition led to 70,000 patients in the U.S. receiving the defective ICD lead AFTER we should have known that they were dangerous. 70,000 people is....
DELTA Automated Surveillance: Prospective Surveillance Network Pilot

Resnic FS and Robbins S. Preliminary Results
Ongoing DELTA Surveillance Projects

• VA Healthcare System – Catheter safety during complex coronary stenting procedure

• ACC-NCDR Pilots: Vascular Closure Devices and Thrombectomy Devices

• Kaiser-Permamente: Artificial Hip implant safety
Health IT Impacts QCOR…

- **Patient Care:**
  - Clinical Records (EHR)
  - Imaging – storage, distribution (PACS)
  - Clinical Decision Support (CDS)
  - Prescribing, communication, scheduling, billing

- **Population Health Management:**
  - Quality metrics – adherence, benchmarking
  - Levels:  Physician, Practice, Hospital, System, Region
  - Measuring resource utilization, patient satisfaction

- **Health Outcomes Research:**
  - Outcomes measurement and associations
  - Comparative Effectiveness (CER, CEA)
  - Surveillance:  Syndromic, Medication, Device Safety
Device Registries: Today

- Claims Data
- EHR
- EHR
- EHR
- EHR
- Data Abstract
- Data Abstract

Device Registry

Safety Monitoring System

Resnic FS. MDEpiNet 2012 Annual Meeting
Device Registries: 2020

Claims Data
UDI
OMOP

UDI
Quality Reporting Standards
Data Abstract

EHR

UDI
OMOP

EHR

Sentinel MDEpiNet

Personal EHR

Safety Monitoring System

Meaningful Use Requirements (Stage 2+)
Standardization of EHR Platforms
Standardized data exchange formats (OMOP)

Health Info Exchanges

Resnic FS.  MDEpiNet 2012 Annual Meeting
Thank You!!

**Lahey Clinic**
Susan Robbins
Usha Govindarajulu, PhD

**Vanderbilt University VAMC**
Michael Matheny, MD MSc MPH

**Harvard Medical School**
Sharon-Lise Normand, PhD
Robert Yeh, MD MPH
Aartik Sarma, MS IV MSc

**FDA CDRH**
Thomas Gross, MD MPH
Danica Marinac-Dabic, MD PhD
Nilsa Loyo-Berrios, PhD

**USCD**
Lucila Ohno-Machado, MD PhD

**Coping Systems, Inc.**
Richard Cope

For more information contact: frederic.resnic@lahey.org
DELTA Automated Surveillance: Retrospective Cohort Registry Analysis

Propensity matching selected as primary analysis as a strategy to reduce treatment selection bias based on ability to communicate to public and policy makers.

Table 2. Distribution of Clinical Covariates in Patients Receiving Taxus Express2 or Alternative Drug-Eluting Stents

<table>
<thead>
<tr>
<th>Covariate</th>
<th>Total Study Population</th>
<th>Propensity Matched</th>
<th>Unmatched Patientsa</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Taxus Express2 (n = 18,277)</td>
<td>Alternative (n = 28,327)</td>
<td>Standard Difference</td>
</tr>
<tr>
<td>Age, mean (SD), y</td>
<td>64.6 (12.2)</td>
<td>64.8 (12.5)</td>
<td>1.50</td>
</tr>
<tr>
<td>Women</td>
<td>31.0</td>
<td>30.1</td>
<td>2.00</td>
</tr>
<tr>
<td>History of diabetes</td>
<td>30.6</td>
<td>30.2</td>
<td>0.90</td>
</tr>
<tr>
<td>History of MI</td>
<td>27.8</td>
<td>29.3</td>
<td>3.30</td>
</tr>
<tr>
<td>Current smoker</td>
<td>21.6</td>
<td>20.4</td>
<td>2.90</td>
</tr>
<tr>
<td>History of renal insufficiency</td>
<td>5.26</td>
<td>6.25</td>
<td>4.30</td>
</tr>
<tr>
<td>History of PAD</td>
<td>13.5</td>
<td>13.7</td>
<td>0.60</td>
</tr>
<tr>
<td>Ejection fraction &lt;30%</td>
<td>41.9</td>
<td>43.8</td>
<td>3.80</td>
</tr>
<tr>
<td>Emergent procedure</td>
<td>16.2</td>
<td>15.1</td>
<td>3.00</td>
</tr>
<tr>
<td>Acute MI on presentation</td>
<td>36.3</td>
<td>35.3</td>
<td>2.10</td>
</tr>
<tr>
<td>Left main vessel disease &gt;50%</td>
<td>5.91</td>
<td>6.27</td>
<td>1.50</td>
</tr>
<tr>
<td>Vein graft lesion</td>
<td>5.08</td>
<td>6.20</td>
<td>4.90</td>
</tr>
<tr>
<td>Glycoprotein IIb/IIIa antagonist</td>
<td>29.3</td>
<td>34.5</td>
<td>11.10</td>
</tr>
<tr>
<td>Final stent diameter, mean (SD), mm</td>
<td>3.15 (0.52)</td>
<td>3.22 (0.49)</td>
<td>13.90</td>
</tr>
<tr>
<td>Maximum lesion length, mean (SD), mm</td>
<td>17.8 (9.9)</td>
<td>17.1 (9.7)</td>
<td>7.10</td>
</tr>
</tbody>
</table>

Adapted from: Resnic F et al. JAMA November 2010
Cryptosporidiosis Outbreak
Utah 2008

Source: Staes K. Woods Hole Symposium 2010
Notifiable Condition Reporting
National Electronic Disease Surveillance System

- Open source base system used by 16 states, Java based system

- Slow adoptions, from inception in 2001 to 2008, only 38 states and DC were fully integrated.

- (2008) : Last 12 States still need to achieve compliance with one or more of the three NEDSS criteria; an integrated data repository (IDR), electronic lab-result (ELR) messaging, and Web based accessibility.
  - Alaska, Minnesota, Mississippi: IDR and Web support
  - Arizona, Arkansas, Iowa, Kansas, New Hampshire, Wyoming: ELR
  - California, Connecticut, Utah: All three
# Notifiable Condition Reporting

National Electronic Disease Surveillance System

## Table 1. Characteristics of operational and implemented NEDSS modules/components for data that are being sent to CDC: No. (%)

<table>
<thead>
<tr>
<th></th>
<th>COTS*</th>
<th>State-developed</th>
<th>CDC-developed</th>
<th>State hybrid**</th>
<th>N/A</th>
<th>Total States</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Communicable Disease</td>
<td>12 (24)</td>
<td>15 (30)</td>
<td>15 (30)</td>
<td>8 (16)</td>
<td>0 (0)</td>
<td>50</td>
</tr>
<tr>
<td>HIV Surveillance</td>
<td>4 (8)</td>
<td>1 (2)</td>
<td>32 (65)</td>
<td>8 (16)</td>
<td>4 (8)</td>
<td>49</td>
</tr>
<tr>
<td>STD Surveillance</td>
<td>7 (14)</td>
<td>11 (22)</td>
<td>20 (41)</td>
<td>9 (18)</td>
<td>2 (4)</td>
<td>49</td>
</tr>
<tr>
<td>Lead Surveillance</td>
<td>1 (2)</td>
<td>15 (35)</td>
<td>14 (33)</td>
<td>5 (12)</td>
<td>8 (19)</td>
<td>43</td>
</tr>
<tr>
<td>Vectorborne/Zoonotic Disease Surveillance</td>
<td>10 (21)</td>
<td>12 (26)</td>
<td>14 (30)</td>
<td>11 (23)</td>
<td>0 (0)</td>
<td>47</td>
</tr>
<tr>
<td>Animal Disease Surveillance</td>
<td>8 (18)</td>
<td>12 (27)</td>
<td>9 (20)</td>
<td>6 (13)</td>
<td>10 (22)</td>
<td>45</td>
</tr>
<tr>
<td>Environmental Disease Surveillance</td>
<td>2 (5)</td>
<td>12 (30)</td>
<td>2 (5)</td>
<td>6 (15)</td>
<td>18 (45)</td>
<td>40</td>
</tr>
<tr>
<td>Poisoning Surveillance</td>
<td>2 (5)</td>
<td>12 (30)</td>
<td>3 (8)</td>
<td>4 (10)</td>
<td>19 (48)</td>
<td>40</td>
</tr>
<tr>
<td>Cancer Surveillance</td>
<td>9 (21)</td>
<td>8 (19)</td>
<td>8 (19)</td>
<td>6 (14)</td>
<td>12 (28)</td>
<td>43</td>
</tr>
<tr>
<td>Injury Surveillance</td>
<td>3 (8)</td>
<td>6 (16)</td>
<td>3 (8)</td>
<td>1 (3)</td>
<td>25 (66)</td>
<td>38</td>
</tr>
<tr>
<td>Occupational Disease Surveillance</td>
<td>0 (0)</td>
<td>7 (18)</td>
<td>4 (11)</td>
<td>3 (8)</td>
<td>24 (63)</td>
<td>38</td>
</tr>
<tr>
<td>Other Chronic Disease Surveillance</td>
<td>2 (5)</td>
<td>6 (16)</td>
<td>1 (3)</td>
<td>3 (8)</td>
<td>25 (68)</td>
<td>37</td>
</tr>
</tbody>
</table>

* COTS: Commercial-off-the-shelf

**State hybrid: systems that are combinations of State and COTS systems or State and CDC developed systems

---

Council of State and Territorial Epidemiologists: 2010 NEDSS Assessment
Outbreak Statistics

- 1,902 confirmed cases
- Median age: 9 years (range: <1–101 years)
- 8% hospitalized (97 / 1,144)
- No reported deaths
- Morbidity, lost time from work, swimming pools closed
Electronic Laboratory Reporting
Meaningful Use Criteria

- Messaging Standard: HL7 2.5.1
- Message Vocabulary: LOINC version 2.27
- Capability to submit electronic data on reportable lab results (as required by state or local law) to public health agencies and actual submission in accordance with applicable law and practice.
- Measure: perform at least one test of certified EHR technology capacity to provide electronic submission of reportable lab results to public health agencies and follow-up submission[s] if the test [is] successful
- Stage 2 Measure: Successful ongoing submission of reports from EHR to public health agencies for entire reporting period
- Final rule: just hospitals have to do final submission (not providers)
- Legally, both provider and hospital required to report