Transforming Healthcare Delivery Through Cardiovascular Registries

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Disclosure Slide

- Receive research support from:
  - AHA GWTG Data Analytic Center
  - ACC NCDR Data Analytic Center
  - STS Data Analytic Center
  - AHRQ
  - NHLBI
  - Eli Lilly
  - Janssen Pharmaceuticals
Why Transformation is Needed

“It takes an average of 17 yrs for 14% of original research findings to lead to changes in care that benefit patients”


Peterson et al, JAMA 2006;295:1863-1912
Hospital Link Between Overall Guidelines Adherence and Mortality

Peterson et al, JAMA 2006;295:1863-1912

Every 10% ↑ in guidelines adherence → 10% ↓ in mortality (OR=0.90, 95% CI: 0.84-0.97)
“Missed opportunities? Quality concerns? Not just our private little secret anymore

EDITORIAL
Simple Treatments, Ignored
Published: September 8, 2012

A new federal health analysis has found that 36 million adults in the United States have high blood pressure that is not being controlled even though 32 million of them get regular medical care and 30 million of them have health insurance.

Related
More on Health Care »

This is not primarily a case of poor, uninsured people unable to get the care they need. It is shocking evidence of how our complicated, dysfunctional health care system can’t deliver recommended care to many patients who could benefit, because their doctors are asleep at the switch. As a result...
"A growing revolution is transforming the everyday practice of medicine. Owing more to laptops than lab coats, this is an information revolution that will change forever the way doctors make decisions."

Millenson ML Univ of Chicago Press 1997
Transformation of Data Collection

Data Collection

Chart review → Registry → EMR

Content

Procedure → Condition → Population/Prevention

Setting

Hospital → Clinic → Community

Who’s the Consumer of the Data?

Doctor → “Healthcare Team” → Team + Patient
CV Provider Led Clinical Registries

- **Society of Thoracic Surgery: 900+ centers**
  - Coronary artery bypass surgery
  - Valve surgery
  - Congenital heart surgery
  - Thoracic surgery
  - TAVR (shared with NCDR)

- **National Cardiovascular Data Registry: 1600+ Hospitals**
  - Cath/Percutaneous coronary intervention
  - Implantable cardiac defibrillators (ICD)
  - Acute coronary syndromes (shared with GWTG)
  - Carotid stenting
  - IC3: Ambulatory CV disease

- **AHA-Get With The Guideline Program: 1500+ hospitals**
  - Heart failure
  - Stroke
  - ADVANCE: Ambulatory module
Role of Registries in Evidence Development and Dissemination

Concept

Clinical Evidence

Guidelines

Performance Indicators

Measurement + Feedback

Outcomes

Clinical Registries

QI Initiatives

Adapted from Califf RM, Peterson ED et al. JACC 2002;40:1895-901
Roles for Clinical Registries

Epidemiology

- Define disease + treatment patterns in community setting
  - Disease presentation
  - Risk factors
  - Genetic, biomarkers
  - Treatment (trends)
  - Patient outcomes
Clinical Registries as Engines for Discovery!

- In-hospital Registry
  - Claims Data
  - Longitudinal Outcomes
  - Device/Drug Information

- Cross sectional studies
- Longitudinal studies
- Translational Discovery
- Comparative Effectiveness
Creating Longitudinal Clinical-Claims Hybrids
The Future Paradigm:
Transform Medicine from Curative to Preemptive

Predictive ↔ Personalized ↔ Preemptive
Roles for Clinical Registries
Safety and Comparative Effectiveness:

- Support Post market Safety evaluation:
  - Off-label uses and outcomes
  - Identify rare side-effects
  - Track late treatment outcomes (beyond trials)
  - Drug-drug and drug-device interactions

- Comparative Effectiveness Research
  - Compare outcomes
  - Compare resource use
One device, VasoSeal, demonstrated a high risk of any vascular complication compared to manual compression controls (OR = 2.38 [1.47-3.85; p = 0.0004]). This resulted in VasoSeal being taken off the market.
NCDR-STS: PCI vs CABG
Comparative Effectiveness Study

Subgroups
- Age ≥75
- Age <75
- Male
- Female
- BMI ≤25
- BMI 26-30
- BMI >30
- White
- African American
- Other
- Diabetes: Insulin
- Diabetes: No Insulin
- No Diabetes
- Chronic Lung Disease
- No Chronic Lung Disease
- Peripheral Arterial Disease
- No Peripheral Arterial Disease
- Prior Myocardial Infarction
- No Prior Myocardial Infarction
- Glomerular Filtration Rate ≤30
- Glomerular Filtration Rate 31-60
- Glomerular Filtration Rate >60
- Number of Diseased Vessels = 2
- Number of Diseased Vessels = 3
- Ejection Fraction <30
- Ejection Fraction 30-<60
- Ejection Fraction ≥60
- High Risk
- Low Risk
- Propensity Score, Quintile 1
- Propensity Score, Quintile 2
- Propensity Score, Quintile 3
- Propensity Score, Quintile 4
- Propensity Score, Quintile 5
- Overall

Adjusted RR (95% CI)
0.78 (0.74-0.80)
0.77 (0.73-0.81)
0.81 (0.77-0.84)
0.76 (0.71-0.81)
0.76 (0.71-0.80)
0.81 (0.76-0.86)
0.80 (0.75-0.85)
0.79 (0.76-0.82)
0.69 (0.60-0.78)
0.93 (0.77-1.17)
0.72 (0.66-0.78)
0.78 (0.73-0.83)
0.81 (0.77-0.85)
0.73 (0.70-0.77)
0.76 (0.74-0.78)
0.78 (0.74-0.81)
0.74 (0.72-0.76)
0.80 (0.77-0.84)
0.74 (0.72-0.77)
0.80 (0.72-0.90)
0.80 (0.75-0.86)
0.72 (0.68-0.76)
0.82 (0.77-0.87)
0.75 (0.72-0.79)
0.70 (0.61-0.81)
0.73 (0.68-0.78)
0.82 (0.78-0.86)
0.75 (0.67-0.85)
0.66 (0.55-0.78)
0.81 (0.72-0.90)
0.81 (0.75-0.87)
0.83 (0.78-0.88)
0.75 (0.71-0.79)
0.70 (0.65-0.77)
0.78 (0.75-0.81)
A registry research network can support clinical trials

- Recruit registry sites as clinical trial participants
- Existing registry data + additional data specific for trial
- Built-in post-trial surveillance
- Efficient trials
Registry-trial Hybrid: Efficient patient enrollment and data collection: Safe PCI in Women Trial

Randomization

- Demographics
- Medical Hx
- Procedural data

Auto-populate

Unique pages for trial

Analytic Database

ORACLE
Using Data to Transform our Care Practice Models

‘Learning methods to promote the rapid and complete uptake of clinical research findings into routine practice, leading to improved the quality of health care and outcomes.’

1 First Block: Translation from concept into first human studies
2 Second Block: Translation from clinical trials into practice
The Tools of Transformation

- Systematic Data Collection
- Performance feedback
- Education
- IT (monitors, reminders, decision-support)
- Incentive strategies (financial, behavioral)
- Policy change
Provider-led feedback and QI can improve CV care!
- NRMI, CRUSADE
- AHA GWTG
- ACC-NCDR
- STS

Means to Achieve better care
- Motivated advocates
- Timely, valued feedback
- Simple tools
- Collaborative Teams
Improving In-Patient Guidelines Adherence with Measurement, Feedback and QI

Composite Adherence Rates

Q1 '02
Q1 '03
Q2 '04
Q3 '05
Q4 '06

Reaching the Pinnacle of Perfection
Discharge Medications STEMI vs. NSTEMI

* P2Y12's may overlap

ACTION Registry-GWTG DATA: July 1, 2010 – June 30, 2011
Evolving View of Quality CV Care: Importance of a Longitudinal Perspective

Population at Risk
- 1° Prevention (no known CAD)
- 2° Prevention (CAD no prior AMI)
- 2° Prevention (CAD with prior AMI) Advanced Care Planning

Staying Healthy

Acute Phase

Post Acute/Rehabilitation Phase

2° Prevention

Assessment of Preferences

Focus on:
- Quality of Life
- Functional Status
- 2° Prevention Strategies
- Rehabilitation
- Advanced care planning

Post AMI Trajectory 1 (T1)
Relatively healthy adult

Focus on:
- Quality of Life
- Functional Status
- 2° Prevention Strategies
- rehabilitation
- Advanced care planning

Post AMI Trajectory 2 (T2)
Adult with multiple co-morbidities

Focus on:
- Quality of Life
- Functional Status
- 2° Prevention Strategies
- Advanced Care Planning
- Advanced Directives
- Palliative Care/Symptom Control

Episode begins – onset of symptoms

Living w/ Illness/Disability (T1)
Coping w/ End of Life (T2)

Episode ends – 1 year post AMI

PHASE 1

PHASE 2

PHASE 3

PHASE 4

Duke Clinical Research Institute
From Thought Leadership to Clinical Practice
Registries and Long-term Medication Adherence: TRANSLATE-ACS

Medication Use at Discharge, 90 days, and 1 year

- Clopidogrel
- ACEI/ARB
- Statin
- Beta-blocker

- At discharge
- 90 days
- 1 year

Fosbol E et al AHA 2012 Abstract
Implementation Science: ‘Digging Deeper’
Lessons from Basic Research

- **High Throughput Screening:**
  - Allows rapid screening of a high number of chemicals to find active compounds.

- **Genome-wide Association (GWAS):**
  - In-depth characterization of genes to identify those that are associated with the trait of interest.

- **Biological Systems Perturbation:**
  - An experimental disruption of a system done to understand its properties.
New Era Implementation Science

Methods and Nomenclature

- **High Throughput Site Screening:**
  - National Clinical Registries
  - allows rapid screening of centers to find those few who are outstanding!

- **Qualitative/Quantitative Drilldowns**
  - In-depth characterization of hospital processes associated with better outcomes

- **Systems Intervention**
  - Natural: policy/payment experiments
  - Induced: Cluster randomized intervention
Using Variation to Advantage

AHA GWTG Study of HF Readmissions

- Characterize variation in heart failure (HF) readmissions
- Identify modifiable MD, hospital and system factors associated with HF readmission

Kociol R 2011 ACC
Goal
To reduce 30 day, all-cause, risk standardized readmission rates for patients discharged with cardiac conditions by 20% by Dec 2012

H2H Registrants

<table>
<thead>
<tr>
<th>Year</th>
<th>Individuals</th>
<th>Facilities</th>
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<tbody>
<tr>
<td>2010</td>
<td>1500</td>
<td>940</td>
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<tr>
<td>2011</td>
<td>2300</td>
<td>1350</td>
</tr>
<tr>
<td>2012</td>
<td>2704</td>
<td>1513</td>
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</table>
Using Registries to Support Diagnosis, Prognosis, + Decision Support

Duke DB Risk for CAD

GRACE ACS Score


JAMA 2004;291:2727–33 (49).
Using IT to Stimulate Patient Centric Decision Support

\[ \eta = \beta_0 + \beta_1 x_{T1} + \ldots + \beta_n x_{Tn} \]

\[ \eta_i = \beta_{i0} + \beta_{i1} x_{T1} + \ldots + \beta_{in} x_{Tn} \]

\[ \pi_i = \left\{ \begin{array}{ll}
\pi_i & i = 1 \\
\pi_i - \sum_{j=1}^{i-1} \pi_j & i = 2, \ldots, s \text{ where } \pi_i = \Phi^{-1} \\
1 - \sum_{j=1}^{i-1} \pi_j & i = s+1
\end{array} \right. \]

Bedside Decision Support Tool

Feedback of Projected Outcomes

Outcomes (Survival, Function, Symptoms, Return to Work)

Complications (Death, Recurrent MI, Stroke, Disability)

Costs (Direct & Indirect)

\( e^{PRISM} \) Demo

Medical Decision Making

Medical Therapy

Percutaneous Revascularization

Surgical Revascularization

High Risk \( \rightarrow \) ICD for SCD

High Risk for SCD

Patients at Risk for CAD

Risk Factor Modification ± Medical Therapy

Observation

Patients Diagnosed with CAD
## Worldwide Burden of CV Disease

<table>
<thead>
<tr>
<th>Year</th>
<th>Disease</th>
<th>Rank</th>
<th>Disease</th>
<th>Rank</th>
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<tbody>
<tr>
<td>1990</td>
<td>Lower Respiratory Infection</td>
<td>1</td>
<td>Ischemic heart disease</td>
<td>1</td>
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<tr>
<td></td>
<td>Diarrheal Disease</td>
<td>2</td>
<td>Depression</td>
<td>2</td>
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<tr>
<td></td>
<td>Perinatal</td>
<td>3</td>
<td>Road Traffic Accidents</td>
<td>3</td>
</tr>
<tr>
<td></td>
<td>Depression</td>
<td>4</td>
<td>Cerebrovascular</td>
<td>4</td>
</tr>
<tr>
<td></td>
<td>Ischemic Heart Disease</td>
<td>5</td>
<td>COPD</td>
<td>5</td>
</tr>
<tr>
<td></td>
<td>Cerebrovascular</td>
<td>6</td>
<td>Lower Respiratory Infection</td>
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<tr>
<td></td>
<td>Tuberculosis</td>
<td>7</td>
<td>Tuberculosis</td>
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</tr>
<tr>
<td></td>
<td>Measles</td>
<td>8</td>
<td>War</td>
<td>8</td>
</tr>
<tr>
<td></td>
<td>Road Traffic Accidents</td>
<td>9</td>
<td>Diarrhoeal Disease</td>
<td>9</td>
</tr>
<tr>
<td></td>
<td>Congenital Diseases</td>
<td>10</td>
<td>HIV</td>
<td>10</td>
</tr>
<tr>
<td></td>
<td>Malaria</td>
<td>11</td>
<td>Perinatal Disease</td>
<td>11</td>
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<tr>
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<td>COPD</td>
<td>12</td>
<td>Violence</td>
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<td></td>
<td>Falls</td>
<td>13</td>
<td>Congenital</td>
<td>13</td>
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<tr>
<td></td>
<td>Iron-deficiency anemia</td>
<td>14</td>
<td>Self-inflicted injury</td>
<td>14</td>
</tr>
<tr>
<td></td>
<td>Protein calorie malnutrition</td>
<td>15</td>
<td>Bronchial and Lung Cancer</td>
<td>15</td>
</tr>
</tbody>
</table>

www.dcp2.org
34 Clusters (Public Hospitals) including 1,150 consecutive patients with ACS

Concealed Randomization

Multifaceted Quality Improvement Intervention (n= 17 clusters and 602 patients)

Routine Practice (n= 17 clusters and 548 patients)

**Primary Endpoint:** Adherence to all eligible evidence-based therapies during the first 24 hours

**Secondary Endpoints:** Adherence to all eligible evidence-based therapies during the first 24 hours and at discharge, composite EBM score, major cv events

Results

Adherence to all evidence-based therapies in the first 24 hours

OR$_{PA}$ = 2.64 (1.28–5.45) ICC = 0.32

Adherence to all evidence-based therapies in the first 24 hours without statins

OR$_{PA}$ = 2.63 (1.27–5.42) ICC = 0.32

$\text{p} = 0.01$

Registries: Conclusion
(or just the start!)

- Registries will continue to play a transformational role in CV care
- CV Registries can:
  - Promote scientific discoveries
  - Support RCTS
  - Identify gaps in care quality
  - Support quality improvement
- Ultimately leading to better patient care and outcomes around the nation and around the globe!
“Be a yardstick of quality. Some people aren't used to an environment where excellence is expected.”