Clinical Registries in a Rapidly Evolving Healthcare System

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Overview

• Active use of performance comparisons from registries improves quality
• Why your registry output should conform to the Porter framework
• Reasons why your hospital should participate in every applicable registry
• Why your hospital should have a registry of all its registries
• What your hospital is going to ask of you
Context

• Orszag slide showing cost inflation moderating
• Massachusetts cost slide showing commercial insurance costs moderating
Current Data Sources

• Administrative (claims)
  o Readily available, cheap
  o Structured data, increasingly granular with ICD-10
  o Longer-term and non-clinical (e.g., cost) data
  o Many providers distrust claims data for accountability applications

• EHR
  o Initial expense
  o Data are collected routinely as part of patient care (increased structure = increased burden)
  o Much of the data unstructured, lacks standardized definitions

• Clinical Registries (Local/Regional/National)
  o Highly structured data, standardized definitions, designed by clinicians
  o Trained data managers, but data collection burden and cost
  o Often limited to specific populations (disease, procedure), short-term
Registry functions

• Performance measurement & improvement
  o Clinical outcomes, PROMs, costs
  o Adherence to guidelines, evidence based care
• Public reporting
• Shared decision-making based on objective risk estimates
• Health policy
• Population health management
• Clinical research
• FDA post-market surveillance
Registry based performance comparisons improve healthcare

• Sweden

Routine feedback reports

- Audited
- Individual provider results
- Measures of uncertainty
- Odds ratios, O/E’s, risk-adjusted rates
- Your results over time
- Comparison to “Like programs” and to STS overall
- Graphical and tabular reporting
- Star ratings with numerical “drill-down”

NQF-endorsed composite scores

Society of Thoracic Surgeons National Database
Rise of consumerism in healthcare

What Is Value in Health Care?
Michael E. Porter, Ph.D.  NEJM 2010

Source: ichom.org
Leg pain is a symptom caused by spinal stenosis and it is quickly, dramatically, and sustainably relieved for most of our patients.
If I was a payer, and I wanted to actually improve quality, what would I pay for?

• HEDIS served a purpose, but time to move on . . .

• Limitations:
  o Focused on primary care (only 8% of care by cost, 20% by volume)
  o Sorts patients by payer, but improvement occurs at the practice
    • If performance on every patient is measured, performance improves for all, independent of payer or plan (HMO, PPO, etc.)
  o At upper levels of performance, most variation is measure error
  o Hard to use the data for improvement

• Evolution from HEDIS to ECQM
  o Use of EHR based clinical registries; denominator = everyone
  o Practice performance comparisons on all patients using national standard metrics
Partners Publicly Reports performance on all primary care practice metrics

Internal EHR based registries
- All patients included (denominator 10 x HEDIS)
- Data is correct (and auditable)
- Data can be used for improvement
  - Registry is tied to CDS

| Current Partners Healthcare Registries (Internal) |
|-----------------|-----------------|
| Registry        | Status          |
| Asthma Registry (pediatric) | Live           |
| Chronic opioid registry | Live           |
| Depression      | Live            |
| Chronic kidney disease | Live          |
| colon cancer prevention | Live         |
| HIV             | Live            |
| Adult Wellness Registry (Prevention) | Live            |
| ADHD            | In build        |
| Buprenorphine Registry and Smart Form | In build        |
| Pediatric Prevention Registry | Live           |
| Diabetes        | Live            |
| Anesthesia      | Live            |
| CVD             | Live            |
| HTN             | Live            |

http://qualityandsafety.partners.org/Prevention-And-Chronic-Care/Default.aspx
Example: Better Hypertension Measure Definition

**Denominator:**
All primary care patients with hypertension as defined by one of the following:
- Active condition on EHR problem list in past year
- At lease one relevant encounter diagnosis with provider in past 12 months
- At least one relevant billing diagnosis in the past 12 months

**Numerator:**
- If age < 60, goal = ≤140/90*
- If age > 60, goal = ≤150/90*
- DBP ≤70
- Pt is on 3 or more anti-hypertensive medications
- *Use better of last BP or the average of last 3 BPs over 18 mos.

**Data Sources:** Clinical data plus claims
If I was a payer, what would I pay for?

1. Include everyone you treat
2. Pay to install registry infrastructure (including PROMs collection)
3. Participate on every registry that applies to a service you provide
   - EHR based registries for primary care
   - EHR based specialty measures
   - Regional/National registries for procedure outcomes
4. Show evidence that you review the data and respond to poor performance
5. Show evidence that you report performance to fiduciary

Payment policies are:
- Not about the beneficiary – about the patient
- Not punitive: focused on improvement
- Avoid the public reporting debate
Professional Obligation to build, maintain, and use registries

Professionalism is the basis of medicine's contract with society. It demands placing the interests of patients above those of the physician, setting and maintaining standards of competence and integrity, and providing expert advice to society on matters of health. Essential to this contract is public trust in physicians. Due to an explosion of technology, changing market forces, problems in health care delivery . . . As a result, physicians find it increasingly difficult to meet their responsibilities.

Fundamental Principles

- Principle of primacy of patient welfare, patient autonomy, (empower them to make informed decisions about their treatment), and social justice.

A Set of Professional Responsibilities

- Commitment to professional competence. Physicians must be committed to lifelong learning and be responsible for maintaining the medical knowledge and clinical and team skills necessary for the provision of quality care. The profession must strive to see that all of its members are competent and must ensure that appropriate mechanisms are available for physicians to accomplish this goal.

- Commitment to honesty with patients. Physicians must ensure that patients are completely and honestly informed before the patient has consented to treatment and after treatment has occurred.

- Commitment to patient confidentiality.

- Commitment to maintaining appropriate relations with patients.

- Commitment to improving quality of care. Physicians must be dedicated to continuous improvement in the quality of health care. This commitment entails not only maintaining clinical competence but also working collaboratively with other professionals to reduce medical error, increase patient safety, minimize overuse of health care resources, and optimize the outcomes of care. Physicians must actively participate in the development of better measures of quality of care and the application of quality measures to assess routinely the performance of all individuals, institutions, and systems responsible for health care delivery.

Physicians, both individually and through their professional associations, must take responsibility for assisting in the creation and implementation of mechanisms designed to encourage continuous improvement in the quality of care.

- Commitment to a just distribution of finite resources.

- Commitment to scientific knowledge. Much of medicine's contract with society is based on the integrity and appropriate use of scientific knowledge and technology. Physicians have a duty to uphold scientific standards, to promote research, and to create new knowledge and ensure its appropriate use.

- Commitment to maintaining trust by managing conflicts of interest.

- Commitment to professional responsibilities. As members of a profession, physicians are expected to work collaboratively to improve patient care, be respectful of one another, and participate in the processes of self-regulation, including remediation and discipline of members who have failed to meet professional standards. The profession should also define and organize the educational and standard-setting process for current and future
Tug boats, negligence, and registries

• 1932: T.J. Hooper tugboats did not have reliable radio on board during a storm when two barges were lost. Plaintiff sued Hooper stating that it was negligent not to equip the tugboats with reliable radios. Four other tugs on the same route avoided losses because of reliable radios.
  
  o If new effective technology is widely used and accepted, then it is negligent not to utilize it.

• 1944: the tug Carroll was sent to remove a barge from a Pier in NY Harbor resulting in sinking of the barge Anna C. The United States, lessee of the Anna C, sued Carroll Towing Co. for negligence.

• The case resulted in the famous decision by the second circuit judge Learned Hand that defined negligence algebraically
  
  o If (Adoption Burden < Cost of Injury × Probability of occurrence), then accused has not met the standard of care.
Each hospital must develop, implement, and maintain an effective, ongoing, hospital-wide, data-driven QAPI Program.

The hospital’s governing body oversees the program and ensures it reflects the complexity of the hospital’s organization and services.

The program includes indicators related to improved outcomes and the prevention and reduction of medical errors.

Priorities are selected for quality improvement and patient safety efforts, and all improvement actions are periodically evaluated.

The program is maintained and available for review by CMS.

* CMS Conditions of Participation § 482.21
What should your hospital’s registry of registries report?

• What process and outcomes comparisons are reported?
• Periodicity of performance comparisons?
• above, equal to, or below benchmark on each comparison?
• Improved since the last reporting period?
• performance issues of concern to hospital management?
Summary of the case for registries in management & policy

• Active use of performance comparisons from registries improves quality
  o It is the right thing to do for our patients

• Does your registry output conform to the Porter framework?
  o It should, otherwise it is not including all the measures that matter

• Does your hospital participate in every applicable registry?
  o It is a abdication of professional obligation not to
  o It should be required by all payers (and satisfy MIPS/MACRA)
  o It may be negligent not to

• Does your hospital have a registry of all your registries?
  o It is a violation of Joint Commission QAPI rules not to
  o Your senior executives and board need to know
• Now the bad news
Challenge as a provider: variation, complexity, expense

Sample of 11 surgical specialty society registries in use at MGH:

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Range (per registry)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Size</td>
<td>30 to &gt;2,500 cases per year</td>
</tr>
<tr>
<td>Number of variables abstracted per case</td>
<td>125 – 900</td>
</tr>
<tr>
<td>Variable definitions</td>
<td>Often varies by registry, even for the same risk factor or condition</td>
</tr>
<tr>
<td>Abstraction time per case</td>
<td>15 minutes - 4 hours</td>
</tr>
<tr>
<td>RN FTEs per year</td>
<td>0.5 -10 FTEs</td>
</tr>
<tr>
<td>Staffing costs per year</td>
<td>$32k - $500k</td>
</tr>
<tr>
<td>Vendor costs per year</td>
<td>$5k - $700k</td>
</tr>
<tr>
<td>Data submission method</td>
<td>- Home grown product; - ‘Certified’ registry vendor; - Mandated registry vendor/software</td>
</tr>
</tbody>
</table>

- Multiple input clinical FTEs
- Multiple input tools, registry vendors, & contracts
- Minimal automation of data extraction
- Multiple database administrators
We need a better way

<table>
<thead>
<tr>
<th>Registry</th>
<th>FTEs</th>
<th>Patients / year</th>
</tr>
</thead>
<tbody>
<tr>
<td>ACS-NSQIP</td>
<td>1.5 FTE registered nurse, 0.125 data analyst, 0.05 manager</td>
<td>1,800</td>
</tr>
<tr>
<td>ACS-NSQIP Peds</td>
<td>0.5 FTE data collector, 0.125 data analyst, 0.05 manager</td>
<td>900</td>
</tr>
<tr>
<td>MBSA-QIP</td>
<td>0.5 FTE registered nurse, 0.125 data analyst, 0.05 manager</td>
<td>460</td>
</tr>
<tr>
<td>ACS-NTDB and ACS-TQIP</td>
<td>3.5 FTE staff responsible for data abstraction, data entry,</td>
<td>2,500</td>
</tr>
<tr>
<td></td>
<td>data validation, research support and performance improvement,</td>
<td></td>
</tr>
<tr>
<td></td>
<td>0.3 manager</td>
<td></td>
</tr>
<tr>
<td>Burn Registry</td>
<td>0.5 FTE data abstractor, 0.15 manager</td>
<td>400</td>
</tr>
<tr>
<td>Emergency Surgery Registry</td>
<td>0.5 FTE data abstractor</td>
<td>2,000</td>
</tr>
<tr>
<td>SRTR</td>
<td>7.0 – 10.0 FTE registered nurses, 1.5 manager and general</td>
<td>750</td>
</tr>
<tr>
<td></td>
<td>auditing support.</td>
<td></td>
</tr>
<tr>
<td>STS-Cardiac</td>
<td>3 FTEs registered nurses, 0.5 PSC</td>
<td>1,300</td>
</tr>
<tr>
<td>STS-Thoracic</td>
<td>1 FTE registered nurse and manager</td>
<td>1,000</td>
</tr>
<tr>
<td>CeSQIP</td>
<td>0.5 FTE, 0.125 data analyst, 0.05 manager</td>
<td>700</td>
</tr>
<tr>
<td>Intermacs</td>
<td>3 part time research coordinators, 1 part time research</td>
<td>30</td>
</tr>
</tbody>
</table>
What your hospital is going to ask of you

- Any actual application of the data requires compromise – can’t let the perfect be the enemy of the very good. The team at Mass-DAC had to add variables to account for some rare outlier events. We should expect this.

- One registry vendor contract (for the whole hospital)

- Reduced/shared costs in FTEs
What our kids should expect

• National, comprehensive, risk adjusted organization level comparisons, consistently reviewed by the organizations fiduciary, for most standard care processes that directly impacts health and any procedure with greater than moderate risk.
The Importance of Data Accuracy—External Audit

- Initial review: missing, inconsistent, out-of-range data
- Verification against hospital and governmental data sources
- External audit 10% of sites
- 96-97% accurate coding on ~100,000 data elements audited annually

“There were 96,259 total variables abstracted, and there were 92,991 variables that matched resulting in an overall agreement rate of 96.60%. This overall performance rate reflects a high level of accuracy in data collection and evidence that the data contained in the ACSD is valid.”

2013 audit

Shahian et al, Heart, 2013
Use of Real-World Evidence to Support Regulatory Decision-Making for Medical Devices

Guidance for Industry and Food and Drug Administration Staff

- Expanded indications for use
- Post-market Surveillance
- Post approval Surveillance
- Supplementary Data (new issues)
- Objective Performance Criteria (OPC)
- Performance goals (PG)

“FDA’s national surveillance strategy emphasizes the importance of medical device registries. ...’FDA envisions continuing to help facilitate the creation of registries.’ National Cardiovascular Data Registry, will play a key role in this process.”

REGISTRY-BASED PROSPECTIVE, ACTIVE SURVEILLANCE OF MEDICAL-DEVICE SAFETY

FREDERIC S. RESNIC, M.D., ARJU MAJITHIA, M.D., DANICA MARINAC-DABIC, M.D., PH.D., SUSAN ROBINS, B.S., HENRY SAMMAGANDA, M.D., KATHLEEN HEWIT, M.S.N., ANGELO PONIRIASKIS, PH.D., NILISA LOYOS-BERICIO, PH.D., ISSAM MOUSSA, M.D., JOSEPH DROZDA, M.D., SHARON-LISE NORMAND, PH.D., AND MICHAEL E. MATHENY, M.D., M.P.H.

ABSTRACT

The process of assuring the safety of medical devices is constrained by reliance on voluntary reporting of adverse events. We evaluated a strategy of prospective, active surveillance of a national clinical registry to monitor the safety of an implantable vascular-closure device that had a suspected association with increased adverse events after percutaneous coronary intervention (PCI).

METHODS

We used an integrated clinical-data surveillance system to conduct a prospective, propensity-matched analysis of the safety of the Mynx vascular-closure device, as compared with alternative approved vascular-closure devices, with data from the CarotidCI Registry of the National Cardiovascular Data Registry. The primary outcome was any vascular complication, which was a composite of access-site bleeding, access-site hematoma, retroperitoneal bleeding, or any vascular complication requiring intervention. Secondary safety endpoints were access-site bleeding requiring treatment and postprocedural blood transfusion.

RESULTS

We analyzed data from 73,124 patients who had received Mynx devices after PCI procedures with femoral access from January 1, 2011, to September 30, 2013. The
Registries on FHIR

Registries on FHIR is a PCPI project launched in collaboration with the Duke Clinical Research Institute and the Medical Device Epidemiology Network (MDEpiNet), an FDA public-private partnership.

Registries on FHIR aims to demonstrate the value of adoption of common clinical data elements in registries to improve interoperability. Health Level Seven® International (HL7®) Fast Healthcare Interoperability Resources (FHIR®) is a standard that if adopted in registries, EHRs and related systems will improve interoperability in health care.

By drafting and testing in registries a common clinical data set based on existing standards including the ONC 2015 Common Clinical Dataset, we aim to show a measurable reduction in registry data acquisition burden and improvements in registry data quality.

Expected deliverables:

- An implementation guide based on HL7 FHIR that contains a common clinical data standard set for registries, tested in multiple registries
- A publication with the results of an effort to measure the cost/effort to apply the standards, as well as benefits e.g., reduced registry burden of participation, improved data quality
The Joint Commission’s Survey Analysis for Evaluating Risk (SAFER™) Matrix™

<table>
<thead>
<tr>
<th>Likelihood to Harm a Patient/Staff/Visitor</th>
<th>Scope</th>
</tr>
</thead>
<tbody>
<tr>
<td>HIGH</td>
<td>Immediate Threat to Life (a threat that represents immediate risk or may potentially have serious adverse effects on the health of the patient, resident, or individual served)</td>
</tr>
<tr>
<td>MODERATE</td>
<td>LIMITED</td>
</tr>
<tr>
<td>LOW</td>
<td>PATTERN</td>
</tr>
<tr>
<td></td>
<td>WIDESPREAD</td>
</tr>
</tbody>
</table>

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## Search CABG Data by Hospital

<table>
<thead>
<tr>
<th>Hospital</th>
<th>Year</th>
<th>State</th>
<th>Overall Composite Score*</th>
<th>Absence of Operative Mortality</th>
<th>Absence of Major Morbidity</th>
<th>Use of Internal Mammary Artery</th>
<th>Receipt of Required Perioperative Medications</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abbott Northwestern Hospital</td>
<td>July 2016 - June 2017</td>
<td>- Any -</td>
<td>🌟🌟</td>
<td>🌟🌟</td>
<td>🌟🌟</td>
<td>🌟🌟</td>
<td>🌟🌟🌟🌟🌟🌟🌟🌟</td>
</tr>
<tr>
<td>Abington Memorial Hospital</td>
<td></td>
<td></td>
<td>🌟🌟</td>
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<td>🌟🌟</td>
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<tr>
<td>Adena Health System</td>
<td></td>
<td></td>
<td>🌟🌟</td>
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<td>🌟🌟</td>
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<tr>
<td>Adventist Health Glendale</td>
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<td></td>
<td>🌟🌟</td>
<td>🌟🌟</td>
<td>🌟🌟</td>
<td>🌟🌟</td>
<td>🌟🌟🌟🌟🌟🌟🌟🌟</td>
</tr>
</tbody>
</table>
Registries to support providers

• Resist temptation to be financially punitive
• Market principles – quick, cheap, dramatic
  o Improve population-level performance (public health benefit)
  o New services are expensive to train, deploy, and replace (cost benefit)
  o Reward instead of punishment (satisfaction)
  o Increased sustainability
  o Risk adjustment not ready